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GUEST EDITORIAL

Is puberty delaying treatment 'experimental treatment'?

In 2019 five clinicians working at the Gender Identity Development Service (GIDS) at the Tavistock and Portman NHS Foundation Trust in London in the United Kingdom (UK) resigned (The Times, 2019), and one of the governors of the Trust also resigned (The Guardian, 2019b). Among other reasons, they adduced that puberty 'blockers'[1] are prescribed experimentally to gender diverse youth, without sufficiently robust evidence around efficacy and safety, and without sufficiently robust diagnosis.

One issue that has emerged from these disputes is that there seems to be lack of clarity around whether or not clinicians, patients, families, and policy-makers should consider puberty delaying intervention as experimental, and, if so, in what ways. This concern has also been raised in the academic literature (Biggs, 2019; Henegan & Jefferson, 2019).

In this editorial we unpack and analyze the claim that prescribing puberty delaying medications is experimental and we show that provision of puberty delaying medications to adolescents with gender dysphoria is not experimental, or at least not any more experimental than standard pediatric practice when there are no licensed[2] treatment options for a pediatric patient population.

We will analyze three issues in particular: 1) Does the fact that the drugs used for inducing and maintaining puberty delay are prescribed 'off label' make the use experimental?; 2) does the fact that the drugs do not have market authorization for puberty delay in gender diverse children make the use experimental?; and 3) does the fact that there are no randomized controlled trials of puberty delay in gender diverse children make the use experimental?

We should note at the outset that the question concerning whether the use of a pharmaceutical product is experimental is different from the question concerning whether it is ethically provided. A drug could be used experimentally and yet it could be clinically indicated and ethically provided. The UK courts have, for instance accepted that a completely novel, experimental use of a drug can be in the best interest of a patient, even if the only evidence for possible efficacy is from small animal studies (Simms v An NHS Trust, 2002).

The treatment of gender diverse children involves a range of interventions and our analysis here is restricted to puberty delaying pharmaceutical products and in particular gonadotropine releasing hormone analogs (GnRHa).

Who is prescribed puberty delaying treatment?

Puberty delaying hormones are typically only prescribed to adolescents who suffer strong and persistent gender dysphoria (Hembree et al., 2017). The treatment is not normally prescribed either to young children, or to those who identify as simply gender diverse, and is even less likely to be prescribed to those who might just be perceived as gender diverse by others.

Gender dysphoria is defined as distress caused by the discrepancy between a person's gender identity and a person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics) (WPATH, 2011).

Not all children who have non-congruent gender expression also suffer dysphoria and there is significant variability in gender expression, both in cisgender children and transgender children (Gülgöz et al., 2019). Many cisgender children express behaviors that are perceived as gender non-congruent in the culture of belonging. These are not the children who would typically be treated medically.

Since the mid 1990s, puberty delaying medications have been prescribed to some *adolescents* (not prepubertal children) with severe and persistent gender dysphoria, in cases in which such distress was aggravated by pubertal development.

The Royal College of Psychiatrists (RCP), in 1998, recommended delaying puberty in *young adolescents* who experienced strong and persistent "cross-sex identification" and distress around the physical body that intensifies with the onset of puberty. The RCP added:

> In order for adolescents and those with parental responsibility to make properly informed decisions, it is recommended that they have experience of themselves in the post-pubertal state of their biological sex. Where, for clinical reasons, it is thought to be in the patient's interest to intervene before this, this must be managed within a specialist service with paediatric endocrinological advice and more than one psychiatric opinion[3]. (Royal College of Psychiatrists, 1998)

The Harry Benjamin International Gender Dysphoria Association's Standards of Care for Gender Identity Disorders (now the World Professional Association for Transgender Health (WPATH) similarly stated in 2001 that:

> Adolescents may be eligible for puberty-delaying hormones as soon as pubertal changes have begun. In order for the adolescent and his or her parents to make an informed decision about pubertal delay, it is recommended that the adolescent experience the onset of puberty in his or her biologic sex […]. In order to provide puberty delaying hormones to an adolescent, the following criteria must be met:
>
> 1. through *childhood the adolescent has demonstrated an intense pattern of cross-sex and cross-gender identity and aversion to expected gender role behaviors;*
> 2. *sex and gender* discomfort *has significantly increased with the onset of puberty*
> 3. *the* family *consents and participates in the therapy* (Harry Benjamin Standards of Care, 2001, p. 10).

These older recommendations have fed into more recent international guidance.

Advice has evolved; however, these guidelines have historical importance: they show that puberty blockers are not 'novel' treatment. They were recommended by prominent bodies of medical opinion in the UK and internationally over two decades ago, and have thus been part of standard medical treatment for many years. Interestingly, the Royal College of Psychiatrists expected situations in which blockers might be in a patient's best interests even before they had experienced life in the post-pubertal state.

The guidelines currently recognized as most authoritative are the WPATH Standards of Care (2011) and the US Endocrine Society guidelines (2017) (Hembree et al., 2017).

Claims that 'transgender children' have their puberty blocked (Reed, 2018) are thus in some ways misleading. They might lead readers to think that puberty delaying hormones are routinely prescribed to young children who are gender diverse. Instead, endocrine treatment is unlikely to be prescribed to anyone unless they have experienced gender dysphoria, and clinically significant distress after the onset of puberty. The clinical consensus is that only adolescents who suffer from severe gender dysphoria, and whose dysphoria persists or is aggravated by pubertal development, should be prescribed puberty delaying hormones. Moreover, puberty is not 'suppressed'; the intervention is temporary and thus puberty is being delayed, rather than suppressed.

The problems of off label use

The medications that are most commonly used to delay puberty in adolescents with gender dysphoria are gonadotropine releasing hormone analogs (GnRHa). There are a number of different GnRHas on the market in the UK with market authorisations for the treatment of prostate cancer, uterine fibroids, endometriosis, and as part of the ovulation induction regime used in the context of assisted reproduction (BNF, 2019). In pediatrics one product (Triptorelin) is licensed in the UK for the treatment of central precocious puberty and the unlicensed use for adolescent endometriosis is mentioned in the BNF for Children for several of the marketed GnRHa (BNF, 2019). No GnRHa has market authorization for puberty suppression in gender diverse children in the UK.

The GnRH analogs act on the pituitary gland and they suppress the endogenous production of sex hormones temporarily. There is little doubt that GnRHa administration is effective as a puberty delaying treatment: it does temporarily suspend pubertal development during the time of administration. When the medication is withdrawn, puberty is thought to restart as normal (but see discussion of possible long-term side-effects below).

GnRHa has been used in the treatment of gender dysphoria since the mid 1990s, and their efficacy in delaying puberty in adolescents is documented by numerous studies and scientific publications (Cohen-Kettenis, Schagen et al., 2011; Cohen-Kettenis, Steensma et al., 2011; De Vries & Cohen-Kettenis, 2012; Coleman et al., 2012; Desforges et al., 1991; Costa et al., 2015; Delemarre-van de Waal & Cohen-Kettenis, 2006; Kreukels & Cohen-Kettenis, 2011; De Vries et al., 2011, 2014; Edwards-Leeper & Spack, 2012; Hembree et al., 2009; Hembree, 2013; Hewitt et al., 2012; Khatchadourian et al., 2014; Nakatsuka, 2012; Shumer & Spack, 2013; Spack, 2013; Vrouenraets et al., 2015, 2016; Wylie et al., 2016).

Thus the puberty delaying efficacy of GnRHa in adolescents with severe gender dysphoria is well evidenced and not experimental.

However, GnRHa is not expressly licensed by the EMA (European Medicine Agency) or the MHRA (Medicines and Healthcare products Regulatory Agency) for the treatment of gender dysphoria in adolescents (Fisher et al., 2014) and this is one of the reasons why it has been argued that GnRHa is provided experimentally (The Times, 2019).

The use of a drug for an indication that is different from the one for which the drug is licensed, usually referred to as 'off label use' or 'off label prescription' is common in many areas of medicine, but we will focus here on pediatrics. Off label prescription is both common and necessary in pediatrics, because many drugs have only been tested on adults as part of the development process leading to licensing and are therefore only licensed for use in an adult population (Balan et al., 2018; Cuzzolin et al., 2003; Magalhães et al., 2015). Off-label prescribing in pediatrics is endorsed in general by the Royal College of Pediatrics and Child Health (RCPCH), and even for a sensitive area such as pediatric psychiatry by the British Association for Psychopharmacology (Sharma et al., 2016) which states that:

> Health-care professionals have a responsibility to prescribe the most effective and safe treatments for their patients. For children and adolescents, this may

> mean choosing an off-label medication in preference to a licensed one, a non-pharmacological treatment or no treatment at all. The purpose of off-label use is to benefit the individual patient. Practitioners use their professional judgment to determine these uses. As such, the term off-label does not imply an improper, illegal, contraindicated or investigational use. (p. 420)

The EU and the USA have put in place schemes in order to incentivise the pharmaceutical industry to do more pediatric research on new molecular entities in order to enable licensing for pediatric use, but these schemes do not apply to old, already licensed products (Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for pediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004; Penkov et al., 2017). GnRHa were first licensed in the 1980s when there was no requirement for, or incentives to conduct pediatric research for licensing purposes (Conn & Crowley, 1994). It would be possible for a pharmaceutical firm to apply for the licensing of their GnRHa for puberty delay in adolescents with gender dysphoria, but there is very little incentive for the firm to do so. Having a licensed product would not necessarily lead to increased sales, even if it was the only licensed product on the market. If the product is already the market leader for the new licensed indication there would be little extra sales, and if it is not the market leader doctors could still go on prescribing the unlicensed competitor products off label.

It is not primarily the lack of research that prevents the licensing of GnRHa for puberty delay in adolescents with gender dysphoria. It is likely that GnRHa could be licensed based on already existing research, but no one has an incentive to use the necessary resources to submit a license application. If we look at the licensing of GnRHa for puberty suppression in children with central precocious puberty that use has been licensed in Europe and the US based on relatively short open-label studies with small groups of patients (MHRA), because it is impossible and unethical to perform a Randomized Controlled Trial (RCT) for this indication. The same would apply to puberty delay in adolescents (see below). It is worth noting that GnRHa is only licensed for this indication because there are so few patients with central precocious puberty that the condition is classified as an orphan condition (IPSEN), which provides specific financial incentives in terms of market exclusivity for the first firm obtaining a license. The mere fact that a drug is used 'off label' therefore does not show that it is used experimentally. The first time it is prescribed off label, especially if it is for a different condition than that for which it is licensed the prescription may be said to be experimental (but, as noted earlier, that would not necessarily mean that the use is unethical). However, as the knowledge about the effects and side-effects of the treatment builds up over time and is documented in the academic literature, the use becomes less and less experimental and may eventually become routine and standard, especially if the knowledge is generated through well designed follow up studies and not just as an accumulation of unsystematic clinical experience.

Why not a randomized controlled trial?

One of the claims found in the recent literature is that the use of GnRHa for puberty delay is experimental because it has not been tested in a randomized controlled trial (RCT) (NHS, 2019). In a typical two-armed RCT patients are allocated by randomization to either a treatment arm where they receive the new treatment or a control arm where they do not receive the new treatment, but may receive a placebo if it is necessary to maintain blinding. Both arms receive whatever else is part of standard treatment, e.g. counseling etc.

These types of trials are normally taken as providing the highest level of scientific and medical evidence that can be derived from a single study (Elamin & Montori, 2012; Evans, 2003), and are, in cases where they are possible, usually a requirement for the licensing of a pharmaceutical product. In the case of puberty delay with GnRHa it is, however, practically impossible to conduct a RCT, and it might be unethical to try to do it. There are two main practical problems that preclude conducting a RCT.

First, patients who approach clinics for help because of distress caused by the first signs of puberty will be unlikely to accept to be a part of a RCT. Medications are needed within a relatively short period of time, at pain of treatment being less effective or ineffective. Recruitment would thus be hard if not impossible.

Second, the ideal RCT is either double blind, i.e. neither researchers nor participants know who gets the active drug, or it assesses outcomes using blinded observers when treatment allocation cannot be hidden from participants. Blinding is necessary in order to reduce bias in outcome assessments. But, a RCT of puberty delay could not maintain blinding. Because GnRHa are effective in delaying puberty it would soon become evident to participants, researchers and outcome assessors who was in the active treatment arm and who was not. This breakdown of blinding would mean that there would be potential bias in the outcome assessments, both in relation to biological and psychological outcomes. It would also mean that participants allocated to the non-treatment arm of the study would be likely to either withdraw from the study at a much higher rate than in the treatment arm introducing potential bias, and/or be more likely not to adhere to the trial but seek puberty delaying treatment outside of the trial thereby adding a confounder. It is also not clear that a RCT would provide answers to the questions that are

still outstanding in relation to puberty delay with GnRHa in the relevant group of patients. We already know that the treatment is effective in delaying puberty and that puberty restarts when GnRHa is withdrawn. The questions that still need answering are about the medium- and long-term effects of puberty delay. We can divide these in two categories, that is questions about 1) negative side-effects, e.g., in relation to bone density or other long term biological risks, and; 2) effects on gender dysphoria and gender transition.

We will discuss both types of questions in separate sections below, but in this section on the putative need for RCTs it is important to note two things. First, that both types of questions require long-term follow up that extends well into adulthood and much longer than in a typical RCT. Second, that in those patients who eventually continue transition with cross sex hormones[4] and in some cases surgery or other gender affirming medical interventions, the effects of puberty delay will become entangled with the effects of later treatments and will become difficult to assess because of confounding. The absence of RCT evidence, which could in reality not be obtained, does not make the prescription of GnRHa for puberty delay in adolescents with gender dysphoria experimental.

GnRHa have unknown long term side effects

Another worry around GnRHa relates not perhaps to prescription off label but to the potential unknown side effects in the medium and long term. In this interpretation prescribing a drug is 'experimental' as long as there is uncertainty about it medium and long term side effects. But, the fact a drug or medical intervention have unknown side effects does not entail that prescribing the drug or performing the intervention can be described as experimental in any meaningful way. This can be shown in two different ways. The first follows from the current drug development pathway. A new drug will go through a series of trials in humans before being licensed. However, even the pivotal Phase 3 randomized clinical trials that may involve hundreds or thousands of patients and which are the basis for licensing are not powered to detect even moderately rare side effects (Sonal & Loke, 2012; Wahab et al., 2013). It is not uncommon for a drug to be marketed and then later withdrawn from the market because serious side effects are discovered. This shows that at the point of marketing there are still significant remaining uncertainties about the side effects of a drug, but we would not say that a doctor who prescribed a recently marketed drug for its registered indication was prescribing 'experimental treatment'. Furthermore, the follow up period in the pivotal Phase 3 trials is usually not long enough to detect late, long term side effects even if they are not rare. But, that again does not entail that prescribing drugs that have not been on the market for many years allowing for the detection of late side effect is 'experimental'.

Second, we are rarely in a position where we can predict an individual's response to a particular drug with absolute certainty. Most drugs have side effects, and most have some rare but serious ones, but our inability to predict whether this particular patient will experience a serious side effect does not make the prescription 'experimental'. If it did all prescription, even of Aspirin would be experimental. What drives clinical decisions is the risk/benefit ratio using a probabilistic calculation, which includes elements such an assessment of the risks of the condition if left untreated, the expected benefits of the intervention, the expected risks, the potential more remote risks, their likelihood. From this a conclusion is drawn concerning whether the intervention is overall clinically appropriate. However, in response to the concerns around the medium and long term side effects of GnRHa, we will briefly summarize the current understanding of its long-term effects and then discuss the general problems in researching possible side-effects of GnRHa treatment of transgender adolescents.

Broadly the concerns can be divided in the following categories:

1. Effects on bone density (risk of osteoporosis later in life);
2. Effects on reproductive capability;
3. Increased odds of later medical transition.

1. Effects on bone density and risk of osteoporosis

A major concern is the impact of GnRHa on bone development. Administration of GnRHa slows the pubertal growth spurt. This can represent an advantage for natal males, as it reduces their likely final height and makes it more likely for them to achieve an ultimate height within the normal female range. However, the question is whether reduction of the rate of growth has any effects on bone formation and metabolism and whether these effects persist after the end of the treatment (Haraldsen et al., 2007). GnRHa inhibits the production of endogenous sex hormones and thereby impacts negatively on the formation of bone mass, by delaying the increase in bone mass during the pubertal growth spurt. There is some evidence from follow up studies that adolescents treated with GnRHa and later cross sex hormones may not reach the same peak bone mass as they would have reached if untreated (Klink et al., 2015) and this issue has been identified as one of the priority issues for further research (Olson-Kennedy et al., 2016). The findings are difficult to interpret, since the available evidence on bone density and mass in transgender persons receiving gender-affirming hormonal treatment as adults is ambiguous (Wiepjes et al., 2019).

If it can be substantiated in larger studies that peak bone mass is affected by GnRHa treatment it will obviously become an important consideration in the general risk/benefit calculation prior to offering this treatment.

2. Effects on reproductive and sexual capability

Additional concerns regarding puberty delaying treatment relates to its effects on reproductive capability (De Sutter, 2005; De Sutter, 2009).

There are two most likely scenarios. In one, the adolescent proceeds with the transition to the other gender, and eventually in adulthood receives full genital surgery. In these cases, natural conception is not possible. However, it might still be possible to have genetically related children with assisted reproduction technologies. In this scenario, one concern is that the use of blockers in early puberty might prevent the extraction and storage of sperm (for males assigned at birth) and of ova (for females assigned at birth). However, the suppression of spermatogenesis in natal males is temporary and can be restored by interrupting treatment. A male assigned at birth whose puberty has been suppressed before spermatogenesis has occurred could decide to stop treatment long enough for spermatogenesis to start if they wish to collect and store sperm for reproductive purposes (this of course would mean that they would have to accept the masculinizing effects of endogenous testosterone on the body during this period). They can then continue with treatment for transition to female gender.

Collection of ova in natal females is less problematic. The treatment has little impact on the already formed ova. They may be collected and stored at the time of oophorectomy (Cheng et al., 2019; De Sutter, 2005). The other possible scenario is one in which the person does not need or requests genital surgery. A person with a penis and functioning testes and a vagina and functioning ovaries and womb can in principle reproduce naturally. There are in fact reports of trans men who have conceived naturally and have given birth (The Guardian, 2019a; Obedin-Maliver & Makadon, 2016). What impact cross sex hormones and the previous provision of GnRHa have on fertility in this scenario is unknown.

3. Increased odds of later medical transition

There is also a worry that delaying puberty may lead to increased odds of later medical transition, i.e., that a larger proportion of adolescents treated with GnRHa choose to transition than would have chosen to transition if their puberty had not been delayed. The problem here is due to the fact that GnRHa has multiple purposes: on the one hand, it has a therapeutic purpose (reduce distress and prevent or reduce the need for future surgeries, making transition easier); on the other hand, it has a diagnostic purpose (in delaying puberty, the adolescent is given time to elaborate their gender identity without the distress of the fast developing body). Because gender identity might fluctuate in puberty and after puberty (Wallien & Cohen-Kettenis, 2008), it is difficult to conceptually differentiate the diagnostic aims from the therapeutic aims. If we had clear early indicators of persistence, clinicians could in principle limit provision of GnRHa only to prospective persisters, thus reducing the risk of offering the treatment to adolescents who will not apply for gender affirming treatment later on. But it is not clear that GnRHa only benefits those who will transition. If a child is anxious or distressed at the development of sex characteristics, it may be difficult for them to explore their gender identity, due to the anguish that the developing body causes. They might benefit from puberty delay regardless of whether they choose to transition at a later stage. This seems coherent with earlier clinical recommendations. GnRHa prescription has since the late 1990s also been considered as a diagnostic intervention: by giving time to the adolescent without the distress of the changing body, GnRHa may facilitate the exploration of gender identity (Cohen-Kettenis & Van Goozen, 1998). Hypothetically, one could argue that the prescription of drugs may crystallize in the significant others or others at large the idea that the adolescent is transgender, when in actual fact they are not. The social expectations might result in psychological pressure for the adolescent to continue on the path to transition. However, this would be a problem not with GnRHa per se, but with the expectations that significant others form or might form around an adolescent's gender identity development. To deny beneficial treatment because others might form unrealistic expectations around the patient would be ethically problematic: medical treatment is to serve the interests of the patient, not of others. However, there is no evidence that GnRHa induces people to cross genders. There is for example no evidence in those treated for precocious puberty that they are more likely than others to identify as transgender. Whereas there is a clear correlation between being on GnRHa and later medical transition, the cause of the later medical transition is unlikely to be GnRHa provision in itself. GnRHa is only provided after puberty has commenced, and to those adolescents who have strong and persistent dysphoria: only a minority of those who continue to experience strong dysphoria and cross gender identification after the onset of puberty revert to the original birth gender, regardless of GnRHa provision (Steensma et al., 2013). Another related potential risk is that GnRHa provision (but also social transition) might alter the cognitive representation of self, that is, might induce a person to internalize the idea of one self as transgender. However, developmental psychology shows that many factors contribute to shape the cognitive representation of ourselves and our gender (our names, the way parents interact with us since birth, the attitudes of our environment of belonging, prenatal exposure to

hormones and so on (Gross, 2015, pp. 609–619), and it is difficult, if not impossible, to assess the impact that one individual factor might have.

General problems in researching possible side-effects

The health care journey of gender diverse youth does not begin or end with GnRHa treatment. Before GnRHa treatment is initiated there will usually be long, exploratory diagnostic process. Before, during and after GnRHa treatment there will be counseling and potentially other psychological interventions. And after GnRHa treatment has ended those who go on to transition will have cross-sex hormones and perhaps gender affirming surgery. And, the health care journey is just one part of the complex social journey that gender diverse youth have to navigate on the way to becoming adults. For those who go on to transition the long term effects will be determined by the totality of all of the medical and psychological interventions they have received. And, in addition by their response to the supportive or less supportive social environment in which they have grown up. This entails that even large, well conducted follow-up studies may not be able to provide definitive answers to questions about the biological, psychological and social long term effects of GnRHa treatment seen in isolation. Even if long term follow up shows a particular set of effects of the 'whole package' of interventions, it will be close to impossible to disentangle the specific effects of GnRHa treatment. This is the case even for seemingly hard biological outcomes like peak bone mineral density. This may be influenced by GnRHa treatment, but also by dose and duration of cross sex hormone treatment, by surgery and reconvalescence, by level of physical activity etcetera.

This means that it is unlikely that in this area of care we can achieve the sort of evidence-base that can lead to whole-ranging clinical guidance applicable to all patients in all contexts. It is therefore important that, while furthering understanding and collating additional evidence around gender identity development and GnRHa, clinicians retain sufficient discretion to use current evidence and current international guidelines as guidance for clinical practice, while also remaining flexible and sensitive to the particular needs of individual patients and to the specific circumstances in which they live.

Conclusions

Puberty delaying medications are currently provided off label to adolescents affected by gender dysphoria and this particular use cannot be investigated by a RCT. We have shown that this does not mean they are experimental drugs or are provided experimentally. Whether or not these (or even approved drugs) are ethically prescribed depends on whether they are likely to serve the patient's health interests based on the evidence available at the time of prescription.

The published literature provides insight into the likely benefits of GnRHa. In summary, they reduce the patient's dysphoria (Cohen-Kettenis & Pfäfflin, 2003, p. 171; Kreukels & Cohen-Kettenis, 2011, p. 467), reduce the invasiveness of future surgery (for example, mastectomy in trans men; treatment for facial and body hair, thyroid chondroplasty to improve appearance and cricothyroid approximation to raise the pitch of the voice in trans women) (Cohen-Kettenis & Pfäfflin, 2003, p. 171); GnRHa is correlated with improved psychosocial adaptation (Cohen-Kettenis & Pfäfflin, 2003, p. 171; Kreukels & Cohen-Kettenis, 2011, p. 467) and reduced suicidal ideation and attempts. Hembree noted increased suicidal ideation where blockers were not given (Hembree, 2011; see further, Imbimbo et al., 2009; Kreukels & Cohen-Kettenis, 2011; Murad et al., 2010; Spack, 2008).

In light of the collected and published evidence, it seems that the international clinical community has found a sensible point of balance: GnRHa can be prescribed to adolescents who experience strong and distressing dysphoria. GnRHa is not usually recommended for prepubertal children, when there is still significant uncertainty around the future gender identity development trajectory. The reaction to pubertal development will be part of the clinical assessment. In this way, most likely GnRHa will only be given to those who most likely will choose to continue to transition, but should the patient change their mind, then no permanent changes will have been effected (whereas, should an untreated person transition, permanent changes of pubertal development will only be partially reversible surgically). Parents, clinicians and significant others should continue to be open to the idea that the gender identity development of an adolescent might fluctuate even after puberty and therefore that the provision of gender affirming medical treatment is a separate decision from the earlier provision of puberty delaying treatment.

Notes

1. The popular name for these medications is 'blockers'. Another popular name is 'puberty suppressant' medications. Because these medications do not suppress puberty, but delay its onset, we use 'puberty delaying' medications/puberty 'delay' in this paper.
2. In the literature 'licensed', 'registered', or 'with market authorisation' is used interchangeably to denote the situation where the relevant national or international pharmaceutical regulatory body has formally approved a pharmaceutical product for marketing / use in a specific population or for a specific indication.
3. Royal College of Psychiatrists, Gender identity disorders in children and adolescents, guidance for management,

Council Report CR63, January 1998, p.5 available at http://www.spitjudms.ro/_files/protocoale_terapeutice/psihiatrie/tulburari%20de%20identitate%20sexuala%20la%20copil%20si%20adolescent.pdf

4. In this article we use the terms 'transition' and 'cross sex' hormones, in line with common usage. However, it must be noted that some people never fully embrace the gender assigned to them at birth, and for them medical treatment is best described as 'affirmative', and cross sex hormones would be best described as gender affirming hormonal treatment.

Declaration of interest

No potential conflict of interest was reported by the authors.

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Investigando en *clave Trans:* Recomendaciones para investigar con población Trans

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RESUMEN

La investigación y producción académica relacionadas con diversas temáticas que involucran a personas con experiencias de vida trans han experimentado un incremento significativo en las últimas décadas. No obstante, en el abordaje de la población Trans en los procesos investigativos se pueden evidenciar algunas tensiones entre investigadores y participantes. Estas tensiones se manifiestan particularmente en los objetivos planteados y los resultados obtenidos, a menudo influenciados por el contexto heterocisnormativo en el cual operan los investigadores o investigadoras. En ese sentido, es esencial iniciar un diálogo académico y científico que aborde la cuestión de cómo llevar a cabo investigaciones desde una perspectiva transgénero, lo que en este artículo se denomina *investigar en clave trans*, es decir, centrada en la acción sin daño, la sensibilidad y la responsabilidad social en el abordaje investigativo de personas Trans. El objetivo de este artículo es ofrecer recomendaciones sobre el desarrollo de investigaciones *en clave trans*, con el fin de evitar posibles faltas éticas en el desarrollo de proyectos de investigación. En total, se presentan once recomendaciones que se dividen en tres etapas específicas del proceso de investigación: el acercamiento a los participantes, el trabajo de campo y el análisis de la información.

Palabras Clave
persona trans, investigación, recomendaciones, psicología, salud

ABSTRACT

Research and academic production related to various topics that involve people with transgender life experiences have experienced a significant increase in recent decades. However, in the approach to the Trans population in research processes, some tensions between researchers and participants can be evident. These tensions are particularly manifested in the objectives set and the results obtained, often influenced by the heterocisnormative context in which the researchers operate. In this sense, it is essential to initiate an academic and scientific dialogue that addresses the question of how to carry out research from a transgender perspective, what in this article is called research in a trans key, that is, focused on action without harm, Sensitivity and social responsibility in the investigative approach to Trans people. The objective of this article is to offer recommendations on the development of trans research, in order to avoid possible ethical misconduct in the development of research projects. In total, eleven recommendations are presented that are divided into three specific stages of the research process: outreach to participants, field work and information analysis.

Keywords
trans people, research, recommendations, psychology, health

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Researching in *Trans Key*: Recommendations for Research with Trans people

Introducción

En la actualidad, se observa un crecimiento sostenido en la valoración positiva de las investigaciones sociales que incorporan la participación activa de la comunidad y la población transgénero en el proceso de investigación y la formulación de políticas públicas. En esta línea, una tendencia investigativa actual se destaca claramente: la necesidad de llevar a cabo investigaciones *desde, con y para* las personas transgénero, es decir, basadas en las experiencias, realidades y perspectivas de esta población, realizadas en colaboración con ellas y dirigidas a su beneficio. Esta forma de investigación participativa se complementa con un aumento significativo del interés científico y académico en la inclusión de personas transgénero en estudios. Esta tendencia se refleja en un notable incremento en la producción académica y en la cantidad de trabajos de grado dedicados a este tema en los últimos diez años.

Durante muchos años, las investigaciones relacionadas con personas transgénero fueron llevadas a cabo, generalmente, por investigadores cisgénero y heteronormativos, sin la participación activa de las propias personas trans (Suess, 2014). Este enfoque ha resultado en un sesgo significativo en el acercamiento y análisis de la información, en gran parte basado en prejuicios hacia las diversas identidades de género. Además, se ha observado que los estudios centrados en la población trans tienden a girar en torno a temas como la identidad de género (Rigueiral & Seidmann, 2019), el VIH (Meléndez Sáez et al., 2016), la vulneración de derechos y sus repercusiones (Cochran et al., 2002), discriminación (Levitt & Ippolito, 2014), entre otros, y a menudo concluyen con la patologización de las identidades transgénero.

Estos estudios, junto con muchos otros, abordan a las personas transgénero desde una perspectiva que se basa en prejuicios y estereotipos sociales cisheteronomativo. Esto tiene impactos significativos en la población trans en varios aspectos: primero, la reproducción del discurso científico desde una perspectiva binaria de género lleva a que la identidad transgénero se vea como una patología, perpetuando así la discriminación y exclusión social hacia las identidades de género diversas. Segundo, esto afecta la salud mental de las personas trans debido a la discriminación social basada en identidades y expresiones de género no binarias. Tercero, crea barreras en el acceso a los derechos humanos debido a la exclusión basada en la identidad de género. Cuarto, genera desconfianza en la comunidad trans hacia el ámbito científico y académico, debido a

múltiples investigaciones en las que han sido instrumentalizadas en detrimento de su bienestar (Pérez-Arizabaleta y Moncayo, 2023). En consecuencia, el discurso científico, al utilizar clasificaciones basadas en el binarismo de género, contribuye a la exclusión social de las personas trans (Moncayo y Pérez, 2022).

A esta problemática se suma la lógica patologizante que proviene de las disciplinas médicas y psicológicas, lo que obstaculiza la realización de investigaciones contextualizadas y dirigidas a satisfacer las necesidades de la población trans. Según Dellacasa (2017), esta lógica patologizante representa una manifestación de la biopolítica frente a la sexualidad, los cuerpos y la subjetividad. En este contexto, se vuelve imperativo iniciar diálogos académicos y científicos sobre cuestiones éticas, la acción sin daño y la responsabilidad social en la investigación con personas trans. Además, es esencial continuar y fortalecer los diálogos que cuestionan la patologización de las identidades de género disidentes del sistema binario de género y sus implicaciones en la vida de las personas trans.

En lo que respecta a la literatura académica que proporciona datos importantes para llevar a cabo investigaciones con poblaciones vulnerables y de difícil acceso, se consultaron fuentes relevantes, entre las cuales se incluyen (Lambert y Wiebel, 1990; Adams et al., 2017). Además, algunas de estas fuentes también abordan enfoques relacionados con personas transgénero, como se evidencia en los trabajos de (Sentamanas, 2014; Platero y Ortega, 2017; Cárdenas et al., 2021; Pérez-Arizabaleta y Moncayo, 2023). Esta literatura no solo identifica las consideraciones fundamentales, sino que también propone estrategias específicas para el acercamiento y el desarrollo del trabajo de campo con personas trans. Estos antecedentes se han incorporado de manera integral en el desarrollo del presente artículo.

Considerando lo expuesto anteriormente y basándonos en la experiencia investigativa, en este artículo se presentan y reflexionan sobre una serie de recomendaciones para llevar a cabo investigaciones con personas trans. En otras palabras, se reconoce la importancia de establecer una colaboración cercana con esta población, lo que fue denominado como *investigación en clave trans*. Por lo tanto, el objetivo de este artículo es reflexionar sobre el desarrollo de investigaciones desde esta perspectiva, con el propósito de promover la dignidad y el bienestar de la comunidad trans.

Método

Contextualización de las experiencias investigativas

Las reflexiones y recomendaciones, presentadas en este artículo, son el fruto de cinco años de investigación en los campos de la salud y la psicología, realizada en colaboración con personas trans. Durante este periodo, se desarrollaron dos proyectos de investigación que abarcaron desde la fase inicial de formulación del proyecto hasta la presentación de los resultados.

Participantes

Estas investigaciones se realizaron en Colombia en colaboración con una organización de base comunitaria ubicada en la ciudad de Cali. Contó con la activa participación de diversas mujeres transgénero y lideresas de Medellín, así como de municipios cercanos a Cali.

Aspectos éticos

Para enriquecer la reflexión propuesta en este artículo, se realizó una revisión exhaustiva de antecedentes relevantes. Se consultó el trabajo realizado por Cárdenas et al. (2021), quienes ofrecieron recomendaciones para la investigación con la comunidad transgénero en Chile. Además, se exploró la literatura transfeminista que proporcionaba detalles metodológicos sobre investigaciones con personas trans, incluyendo los trabajos de Sentamanas (2014), Garaizabal (2014) y Platero y Ortega (2017).

Igualmente, fueron considerados los marcos normativos al elaborar las recomendaciones propuestas para preservar la integridad en el proceso de investigación con personas trans. Estos incluyen la Ley colombiana 1090 del 2006, que regula el ejercicio de la profesión de Psicología y establece el Código Deontológico y Bioético. También, se consideraron las pautas proporcionadas por la Resolución 8430 de 1993 de Colombia, la cual establece las normas científicas, técnicas y administrativas para la investigación en salud.

Procedimientos

Las recomendaciones que se presentan a continuación surgieron de la interacción constante con personas trans en diversos espacios, como reuniones, encuentros informales, grupos focales, entrevistas y la aplicación de cuestionarios. Este diálogo continuo y colaborativo con la comunidad trans fue fundamental para desarrollar estas recomendaciones. La colaboración con la población trans se caracterizó por tener enfoque participativo y un diálogo horizontal a lo largo de todo el proceso. Esta experiencia investigativa proporcionó una valiosa oportunidad para comprender en profundidad los contextos y realidades de las personas transgénero, así como las complejas dinámicas de investigación en cada una de sus fases.

Resultados

Investigar en clave Trans: Recomendaciones para la investigación

A partir del trabajo realizado, fue posible llegar a once recomendaciones clave para llevar a cabo una investigación desde una perspectiva centrada en las realidades, contextos y experiencia de vida trans. Lo que se denomina *investigación en clave Trans* implica resaltar la importancia de que el investigador o investigadora se sumerja en las realidades trans y aborde cada fase de la investigación teniendo en cuenta esta perspectiva, en lugar de hacerlo desde la lente cisheteronormativa. Esto conlleva un proceso de deconstrucción a nivel personal, profesional y académico por parte del investigador, dado que generalmente ha crecido y socializado desde dinámicas tradicionales y dicotómicas del binarismo de género.

Las recomendaciones se han estructurado jerárquicamente en una pirámide, en la cual la base representa las acciones éticas fundamentales para el inicio de una investigación efectiva con un impacto positivo en la comunidad trans. Conforme se avanza en la pirámide, las recomendaciones se vuelven más específicas y complejas, culminando en la fase final de la investigación que involucra el análisis y la presentación de resultados. Es crucial destacar que las recomendaciones en la cima de la pirámide no serían factibles sin haber transitado previamente por las etapas inferiores de manera gradual (Ver figura 1).

En el primer nivel de la pirámide, se encuentra una recomendación relacionada con la formulación de la idea y el proyecto de investigación. Del nivel dos al nivel seis,

las recomendaciones se centran en el proceso de acercamiento a la población, ya sea a través de organizaciones de base comunitaria o mediante la estrategia de bola de nieve. El nivel siete resume los niveles anteriores y prepara el terreno para la recomendación del nivel ocho, que consolida el trabajo *con, desde y para* la población trans. Los niveles nueve y diez ofrecen pautas específicas para el trabajo de campo, y finalmente, el nivel once presenta una recomendación crucial para la fase de análisis y presentación de resultados, marcando el cierre de la investigación.

Figura 1.

Pirámide jerárquica de las recomendaciones

Nota: autoría propia, 2023.

1. El beneficio de la investigación debe favorecer a la población participante y no solamente al investigador o la institución financiadora

Antes de definir y consolidar el problema de investigación, es fundamental reflexionar sobre la necesidad y el grado en que los resultados de la investigación contribuirán a la resolución de problemáticas. Como ha señalado Barley (2012), en el ámbito de la investigación académica, es común encontrar investigadores que, impulsados por sus intereses personales, se enfocan en investigar aspectos que no generan ningún beneficio tangible para la sociedad. En el caso de las personas transgénero, históricamente ha ocurrido que las investigaciones se han centrado más en enriquecer indicadores internacionales y las bibliotecas académicas que en abordar y solucionar las necesidades reales de esta comunidad.

En el contexto de investigaciones centradas en personas trans, aunque existe un marco ético que exige que el equipo de investigación proponga beneficios para esta población, persisten desafíos para lograr resultados investigativos que realmente beneficien o tengan un impacto positivo en sus vidas. Se identificó que las acciones con un impacto positivo en las personas transgénero se pueden agrupar en dos enfoques principales. El primero se orienta hacia el impacto en políticas públicas, lo que implica exponer y defender soluciones a las necesidades particulares de esta comunidad en espacios políticos y académicos. El segundo enfoque se dirige al impacto en la población general, logrado a través de la participación ciudadana y la creación de contenido divulgativo, como folletos, cartillas y videos, ya que, por medio de esta materia existe mayor posibilidad de hacer llegar a esta población los resultados de las investigaciones. Es relevante señalar que un gran porcentaje de personas transgénero no tiene acceso a bibliotecas ni bases de datos académicas, debido a las barreras que enfrentan en su educación básica y superior (Platero, 2013; Carvajal, 2018; Romero, 2019).

Es importante resaltar que, para lograr un mayor impacto, la socialización de los resultados de la investigación debe contar con la colaboración de líderes y líderesas trans. En este sentido, trabajar en estrecha colaboración con organizaciones de base comunitaria trans cobra vital importancia, ya que estas entidades poseen un conocimiento más contextualizado tanto de las necesidades de la comunidad como de las estrategias efectivas para lograr un impacto positivo.

2. No instrumentalizar a los y las participantes

Relacionado con la recomendación anterior, en investigaciones con personas trans es lamentablemente común encontrar proyectos en los que estas personas son instrumentalizadas únicamente para obtener resultados (Pérez-Arizabaleta y Moncayo, 2022). Esto significa que los y las participantes se convierten en simples herramientas para alcanzar los objetivos de investigación, lo que tiene graves repercusiones. En primer lugar, esta instrumentalización conlleva a la realización de acciones perjudiciales durante el trabajo de campo, ya que los investigadores suelen actuar con premura y enfocarse únicamente en la obtención de datos, lo que puede afectar la sensibilidad y paciencia necesarias en los momentos de recolección de información. En segundo lugar, al desconocer las realidades de las personas trans, el análisis de los resultados tiende a sesgarse debido a la perspectiva cisgénero de los investigadores. Esto perjudica a la población trans, ya que sus dinámicas, realidades y experiencias de vida son frecuentemente juzgadas a través del prisma del binarismo de género. Un ejemplo de esta instrumentalización se evidencia en proyectos que buscan la participación de mujeres trans para recopilar datos relacionados con el VIH. En varias ocasiones, se han denunciado prácticas en las que se realizan pruebas rápidas de VIH en entornos de trabajo sexual, es decir, en lugares donde las condiciones laborales, más que la identidad de género, aumentan la vulnerabilidad de las personas a este virus (Moncayo, Pérez-Arizabaleta, Reyes y Orejuela, 2022).

3. No abordar a las personas trans desde una mirada patologizadora

Concebir a la población trans desde una perspectiva patologizadora y abordarla en consecuencia refuerza el estigma asociado a los estereotipos sociales relacionados con las identidades de género no binarias. Cuando los investigadores se acercan a las personas transgénero con esta mentalidad, pueden surgir varios problemas. En primer lugar, durante la interacción, es probable que expresen prejuicios, lo que genera violencia y, de manera más grave aún, viola el derecho a la identidad y expresión de género. En segundo lugar, pueden surgir acciones perjudiciales en el proceso de contacto directo con la población, como en entrevistas o grupos focales. En tercer lugar, existe el riesgo de

perpetuar mitos o conceptos erróneos relacionados con la sexualidad e identidad de género transgénero a través del discurso académico, a través de la voz de los investigadores (Platero, 2014).

Un ejemplo de este enfoque erróneo es cuando los investigadores asumen sin cuestionamiento que la identidad de género transgénero se debe a un trastorno mental o cuando etiquetan a las personas transgénero, especialmente a las mujeres trans, como "población clave". Por lo tanto, esta recomendación enfatiza la necesidad de cuestionar y desafiar el binarismo de género antes de acercarse a la población trans. Esto permitiría cumplir con la primera recomendación, que se relaciona con buscar un impacto positivo en la población a través de la investigación, y al mismo tiempo abordaría los tres problemas mencionados en esta recomendación.

4. Reconocer la singularidad de los contextos y experiencias de vida Trans

La falta de reconocimiento de las dinámicas del binarismo de género en los análisis de investigación impone un “castigo” a las personas trans al no ajustarse a las narrativas hegemónicas. Por lo tanto, se recomienda reconocer que el binarismo de género es una estructura que perpetúa y genera desigualdades sociales y, en consecuencia, abrirse a la posibilidad de comprender las realidades y experiencias de las personas trans a través de sus discursos, practicando la escucha activa y la sensibilidad, sin emitir juicios.

La omisión de las singularidades de las realidades y experiencias de vida de las personas trans conduce a sesgos en la investigación. Por ejemplo, si los instrumentos de estudio, como cuestionarios, entrevistas o grupos focales, se construyen exclusivamente basados en la lectura de la literatura teórica, es probable que las preguntas o temas de discusión giren en torno a las realidades cisgénero, es decir, las propias del investigador, lo que impediría captar las dinámicas diferenciales que experimentan las personas trans.

Es igualmente esencial reconocer que la población trans tienen realidades distintas a las de las personas lesbianas, gais y bisexuales (LGB). Por lo general, los estudios y políticas públicas tienden a no desagregar los análisis por cada grupo poblacional, lo que invisibiliza las realidades y contextos de las personas trans. Por esta razón, se recomienda encarecidamente abordar y analizar los resultados de manera desagregada para cada grupo poblacional.

5. Utilizar lenguaje inclusivo

El desconocimiento por parte de los investigadores del uso adecuado del lenguaje inclusivo y de los conceptos relacionados con la sexualidad, como género, sexo, expresión de género, identidad de género y orientación sexual, puede dar lugar a acciones perjudiciales. A pesar de que las personas trans son conscientes de la resistencia estructural que enfrentan las personas cisgénero-binarias en relación con la diversidad de la sexualidad, y específicamente, en lo que respecta a las identidades transgénero, y a pesar de que realizan pedagogía en los espacios en los que son incorrectamente nombradas, es responsabilidad del equipo de investigación tener un conocimiento sólido sobre estos términos y utilizarlos de manera adecuada.

Para la población trans, el lenguaje desempeña un papel crucial como instrumento de reivindicación. A medida que han sido objeto de juicios a través del lenguaje, también lo utilizan como herramienta para reafirmar su identidad. Por ejemplo, referirse a una mujer transgénero en términos masculinos o a un hombre transgénero en términos femeninos refleja la falta de reconocimiento de su identidad de género. Por lo tanto, la recomendación es nombrar a las personas trans participantes de la investigación de acuerdo con la identidad de género que sienten y expresan.

6. Fomentar un diálogo horizontal

El saber académico ha prevalecido durante muchos años como el conocimiento dominante. Sin embargo, en el trabajo con comunidades, particularmente en las ciencias sociales, se ha cuestionado esta supremacía. Cuando se trata de trabajar con población trans, la imposición del saber académico sobre el saber popular puede generar obstáculos para establecer conexiones significativas con la población. Por lo tanto, es esencial que el discurso académico no asuma una posición jerárquica vertical ni ejerza poder sobre el conocimiento de los y las participantes. En otras palabras, el saber académico no debe imponerse sobre el saber de las personas trans, ya que un enfoque de diálogo vertical limita la comprensión al privilegiar el conocimiento académico, invalidando y sesgando las experiencias compartidas por las personas trans en los diversos procesos de recopilación de datos.

Establecer un diálogo horizontal implica un intercambio de conocimientos en ambas direcciones, desde el académico al popular y viceversa, en el que se reconozcan y valoren por igual los saberes de ambas partes. Este enfoque puede plantear desafíos tanto para el investigador como para los preconceptos sobre las realidades de la comunidad trans, pero es fundamental para construir relaciones respetuosas y enriquecedoras que promuevan una comprensión más profunda de las experiencias de vida trans.

7. Construir confianza: un camino desafiante con resultados valiosos.

La construcción de la confianza es un aspecto fundamental, ya que las personas trans han experimentado en muchas ocasiones que la ciencia y la academia solo buscan obtener resultados de investigación en beneficio propio, con un impacto limitado o nulo en la población. Esta desconfianza hacia la academia se basa en varias razones, que incluyen la falta de resultados positivos tras la participación en investigaciones, la sensación de ser instrumentalizadas por el sector académico e institucional, y experiencias de violencia en "nombre de la ciencia".

Para construir la confianza, es crucial que los investigadores se involucren activamente en espacios trans donde se expongan y discutan las realidades de esta población. Además, se deben crear espacios de colaboración donde se puedan explorar posibles soluciones y estrategias para abordar la vulneración de derechos de las personas trans. Los investigadores deben demostrar un compromiso genuino por mejorar las condiciones de vida de esta comunidad y proponer estrategias para influir en los espacios que históricamente han ignorado sus voces. La confianza también implica transparencia en el proceso de investigación, informando a los participantes sobre los posibles riesgos, cómo enfrentarlos y los beneficios potenciales de su participación. Establecer esta confianza requiere tiempo, sensibilidad y un sincero interés en contribuir al bienestar de las personas transgénero.

8. Trabajar de manera conjunta (academia – personas Trans): pensar la problemática juntos (as)

El trabajo de manera conjunta es el producto o fruto de la recomendación anterior. Por lo tanto, la confianza se materializa por medio de la construcción de trabajos

colaborativos, en donde el equipo académico, de acuerdo a las necesidades de las personas trans (las cuales se conocen por medio de reuniones), consolida proyectos de investigación y busca fuentes de financiación, en donde se incluyen a las personas trans como co-investigadoras de los mismos.

Se espera que, tras establecer confianza, el trabajo de manera conjunta esté presente en todas las acciones. En el caso de un proyecto, comenzando con la identificación del problema de investigación, donde la participación de las personas trans es esencial debido a que su conocimiento es fundamental para comprender las necesidades reales de la población y fomentar su colaboración. Una vez que se ha definido la problemática, se discute cómo el proyecto puede tener un impacto positivo en las personas transgénero. Esto puede implicar la implementación de intervenciones o la producción de materiales de divulgación accesibles (como folletos, videos, etc.).

Sumado a lo anterior, los instrumentos de recolección de datos y los análisis de los resultados deben ser construidos en medio de la dialogicidad de ambos saberes (el académico de los investigadores y el popular de las personas trans). Este trabajo a dos voces permite minimizar la influencia de sesgos de los investigadores. Esta dinámica ejerce un control en doble vía que pretende la objetividad en la medida en que las personas trans mitigan los sesgos de la academia (la inclinación a lo teórico) y la academia mitiga los sesgos de las personas trans (que parten del conocimiento práctico y vivencial). Cabe destacar que el ejercicio escritural del trabajo en conjunto, escritura de proyectos y de informes, es desarrollada por el equipo académico en medio de las reuniones y espacios de diálogo.

9. Evitar las preguntas que puedan generar acción con daño

Es importante evitar preguntas que pueden generar acción con daño. Como investigadores académicos cisgénero, es posible que genere preguntas o que aplique instrumentos que no han sido revisados por personas trans. En este sentido, estos instrumentos pueden tener preguntas descontextualizadas, cuestión que llevaría a una acción con daño. Por ejemplo, preguntar sobre la ideación o intentos de suicidio en investigaciones sobre salud mental; o indagar por la dinámica familiar asumiendo que esta institución social les ha servido de apoyo, cuando la realidad plantea dinámicas de

exclusión familiar a la que se enfrentan las personas trans, en mayor proporción, las mujeres. Por lo tanto, la construcción de instrumentos de investigación debe ser un proceso colaborativo y ético que involucre la participación activa de personas trans en todas las etapas del proyecto. Esto garantiza que las preguntas y los instrumentos sean culturalmente sensibles, contextualmente apropiados y respetuosos de las experiencias de la población trans, evitando así cualquier acción con daño.

10. El trabajo de campo: Una labor compartida y colaborativa.

a- Moderar y acompañar: un trabajo colectivo entre personas trans y academia.

Se recomienda que, para la convocatoria de participantes y la moderación de espacios grupales, estos sean liderados por personas trans, lo que facilita una mayor cercanía y accesibilidad para las personas involucradas en la investigación. Esta estrategia aumenta las posibilidades de que las personas trans se sientan invitadas y motivadas a participar en el estudio. Además, en función del contexto y la situación, es recomendable que la moderación de actividades grupales se realice de manera alternada entre líderes trans y académicos. La alternancia en la moderación permite una mayor contextualización de las intervenciones, lo que aumenta la eficacia de los espacios de investigación. Al involucrar tanto a líderes trans como a académicos en la moderación y el acompañamiento de las actividades, se minimizan las intervenciones descontextualizadas y se garantiza que las dinámicas sean culturalmente sensibles y respetuosas de las experiencias de las personas trans.

Con relación al trabajo de campo, es importante tener en cuenta las siguientes consideraciones prácticas: Primero, utilizar cualquier tipo de espacio para la aplicación de instrumentos puede generar situaciones incomodas a los y las participantes; por ejemplo, realizar un encuentro en un espacio donde los baños estén delimitados bajo el binarismo de género, esto generara incomodidad al o la participante. Para contrarrestar esto, se recomienda que los sitios en los cuales se realicen los encuentros para entrevistas, grupos focales, aplicación de cuestionarios, etc., sean espacios en donde los y las participantes se sientan seguros (as). Esto suele lograrse en las sedes de las organizaciones de base comunitaria. Este punto es coherente con lo que plantean Mertens y McLaughlen (2004) y Eckhardt y Anastas (2007) sobre la adaptabilidad a los participantes que debe

tener quien realiza una investigación y no al revés, ya que es necesario brindarles todo tipo de facilidades. Segundo, las personas suelen ser bastante anecdóticas. En este sentido se recomienda estimar el tiempo de las entrevistas y grupos focales y, además, contar con destrezas para recoger el discurso del o la participante y volverlo a orientar al tema de la investigación ya que, por lo anecdóticas, suelen ampliar tanto el tema de la entrevista como el tiempo de la misma. Tercero, debido a las condiciones laborales en las cuales se inscriben, mayoritariamente, la población Trans (en especial las mujeres) es usual que los y las participantes expongan dificultades de orden económico para participar de los espacios del trabajo de campo. Para contrarrestar esta dificultad, se recomienda ofrecer un reconocimiento económico por el tiempo invertido, ya que se tiene consciencia que durante el tiempo del trabajo de campo él o la participante está dejando de generar ingresos para suplir sus necesidades diarias.

b- La estructura del instrumento, la escucha activa y la empatía

Durante la aplicación de instrumentos, es posible que las personas trans narren, de manera anecdótica, sucesos dolorosos de la vida. Por ejemplo, situaciones de acoso en el hogar, escuela y otros espacios, así como abuso sexual, entre otros. Esta narración de anécdotas puede generar que los y las participantes rememoren situaciones dolorosas que no han sido elaboradas emocionalmente y/o que se continúan presentando en la actualidad y, por lo tanto, que se fragilicen emocionalmente. Ante situaciones como estas, se recomienda que quien se encuentre aplicando los instrumentos (entrevistas, encuestas, grupos focales, entre otras), ofrezca una escucha activa, comprensiva y respetuosa y, ante todo, que ofrezca empatía respecto a lo que él o la participante le comparte sobre su vida. De ser necesario, se recomienda detener la aplicación del instrumento y tomarse el tiempo suficiente para que él o la participante retome la calma.

Relacionado con este punto, en la construcción del instrumento, se recomienda no finalizar con preguntas que pueden generar repercusiones a nivel emocional. De ser necesarias estas preguntas, podrían realizarse después de unas iniciales y previo a las finales. El objetivo de esto es, iniciar con preguntas algo "superficiales" o con la indagación de los aspectos sociodemográficos para generar confianza y, de igual manera, no finalizar con preguntas sensibles para que él o la participante no se marche del espacio del trabajo de campo con desaliento o desanimo a causa de este. Cabe resaltar que, en lo

posible, ningún participante debe finalizar la realización del instrumento deseando no haber querido participar del mismo.

c- La reivindicación del nombre versus la confidencialidad

Este punto se relaciona con la confidencialidad que demanda el consentimiento informado. Se ha encontrado, en el marco de los trabajos de campo que muchas personas trans solicitan ser nombradas en los resultados de los proyectos de investigación por medio del nombre actual. Esto da cuenta de un acto reivindicativo en donde muchos de los y las participantes no negocian la opción de no ser nombrados o reconocidos por fuera de la identidad sentida. En este contexto, el consentimiento informado proporciona un espacio donde la persona tiene la capacidad de decidir si desea que se utilice su nombre en los resultados de la investigación o no. Esta práctica adicional también contribuye a reconocer a los participantes como sujetos activos con capacidad de decisión en el proceso de investigación.

d- Reconocimiento económico por la participación

Se compensará económicamente por el tiempo que invierten en la participación y se asumirá el costo que les genere el transporte para asistir a los encuentros. Este reconocimiento económico ha sido una solicitud de líderes y lideresas, pues reconocen las condiciones en las cuales viven una amplia cantidad de personas trans, en donde el sustento económico se basa en actividades de generación de ingresos que realizan diariamente. En este sentido, se reconoce que el tiempo que inviertan en la participación sería un tiempo no productivo para ellos y ellas y, por lo tanto, debe ser compensado. Este tipo de dinámica de recompensas económicas es usual en investigaciones con madres cabezas de familia, las cuales tienen dinámicas similares, de generación de ingresos, a las mencionadas de las personas trans.

11. Análisis de resultados: lo importante de desagregar las informaciones

En el análisis de resultados, se aconseja desagregar los resultados, especialmente en investigaciones que involucren múltiples grupos poblacionales, como personas LGBTI. Se debe presentar y analizar los hallazgos por separado para cada grupo antes de realizar un análisis global. Esto se debe a las notables diferencias en las realidades, contextos y experiencias de vida entre lesbianas, gais, bisexuales y personas trans.

Además, cuando se analicen los resultados relacionados con personas trans, es crucial evitar la homogeneización de la población, ya que se ha observado que los hombres trans y las mujeres trans experimentan las dificultades de manera diferente. Esto se debe en parte a que la sociedad tiende a tener una mayor aceptación de la expresión de género de los hombres trans en comparación con las mujeres trans. Por lo tanto, comparar las experiencias de hombres y mujeres trans sin reconocer estas diferencias podría poner en riesgo la salud mental de los participantes y sesgar los resultados.

Discusión

Las once recomendaciones presentadas se alinean con enfoques de investigación participativos (Denzin y Lincoln, 2012), lo que no limita su aplicabilidad a otros tipos de investigaciones con personas trans. Por el contrario, se sugiere que, independientemente del enfoque de su investigación, ya sea básica, aplicada o participativa se tengan en cuenta estas recomendaciones. *Investigar en clave trans* representa un enfoque respetuoso, sensible y responsable para la investigación con personas transgénero, y, por lo tanto, estas recomendaciones son coherentes con las discusiones bioéticas establecidas en las pautas de investigación en psicología y medicina (ver Tabla 1).

La posición respetuosa y sensible propuesta a través de estas recomendaciones está en línea con las investigaciones llevadas a cabo por y para personas trans (Platero, 2013; 2014; Galofre y Missé, 2015; Platero y Ortega, 2017), así como con las realizadas por investigadores cisgénero que han optado por alejarse de la connotación patologizadora y los prejuicios que a menudo se asocian con las personas trans. Como un punto crucial para construir esta perspectiva de investigación, Garaizabal (2014) sugiere que los investigadores cisgénero deben sumergirse en el campo de las identidades de género trans, conocerlo antes de llevar a cabo trabajos de campo, y desarrollar sensibilidad hacia este tema. Así las cosas, tener en cuenta las recomendaciones expuestas en el momento de investigar con personas trans puede evitar acciones con daño.

Tabla 1

Relación entre las recomendaciones y el marco ético de la psicología y de la medicina

Recomendación	Psicología	Medicina
1	**Artículo 2.** La investigación debe contribuir a mejorar el desarrollo de la psicología y el bienestar humano. La investigación debe ser desarrollada respetando la dignidad y el bienestar de las personas que participan en ella. **Artículo 55.** Abstenerse de aceptar presiones o condiciones que limiten la objetividad del estudio.	**Artículo 4 del título I.** La investigación en salud debe contribuir al desarrollo de: a) conocimiento de procesos biológicos y psicológicos; b) conocimiento de las causas de las enfermedades, la práctica médica y la estructura social; 3) la prevención y control de problemas de salud; c) conocimiento y evaluación de efectos nocivos ambientales en salud; d) técnicas y métodos para la prestación de servicios de salud; e) la producción de insumos para la salud. **Artículo 17 del título II.** La investigación con comunidades se admite sólo cuando el beneficio esperado sea asegurado y cuando se determine en poca la escala los riesgos.
2		
3	**Artículo 50.** Toda investigación científica debe basarse en principios éticos de respeto y dignidad. Se debe salvaguardar el bienestar y los derechos de las personas participantes de la investigación.	**Artículo 5 del título II.** Se debe garantizar a las personas participantes del estudio los criterios de respeto a la dignidad, la protección de los derechos y bienestar.
4	**Artículo 49.** Responsabilidad, de los profesionales de psicología, de los temas de estudio, las metodologías, los materiales, de los resultados, análisis, conclusiones y divulgación de las investigaciones realizadas. **Artículo 51.** Evitar el recurso de la información incompleto o encubierto, salvo que 1) el problema por investigar sea de importancia; 2) no haya otra forma de investigarse si no es con dicha información y 3) los y las participantes sean informados, al terminar la investigación, sobre las variables usadas y objetivos de investigación.	Artículo 5 del título II
5	Artículo 50	Artículo 5 del título II
6	Artículo 50	Artículo 5 del título II
7	Artículos 50 y 51	**Artículo 9 del título II.** Considerar como riesgo de la investigación la probabilidad que el participante sufra un daño como consecuencia inmediata o tardía de la investigación. **Artículo 10 del título II.** Identificar los riesgos a los cuales estarán expuestos los participantes. **Artículo 11 del título II.** Categorías de riesgos. **Artículo 12 del título II.** Se debe suspender la investigación cuando se advierta algún riesgo o daño en la salud del participante. **Artículo 13 del título II.** Proporcionar atención al participante que sufra algún daño.
8	Artículo 51	**Artículo 6 del título II.** La investigación con seres humanos debe garantizar: a) la seguridad de los beneficios y la exposición clara de los riesgos; b) el consentimiento informado por escrito del participante o de su representante legal; c) un equipo profesional con conocimiento y experiencia para garantizar la integridad de los participantes; d) la

		autorización del representante legal de la institución donde se realice la investigación. **Artículo 18 del título II.** En la investigación con comunidades se debe obtener la aprobación de las autoridades en salud y civiles de la comunidad a estudiar. Además de contar con el consentimiento informado de los participantes. **Artículo 19 del título II.** En caso que algún individuo de la comunidad no tenga capacidad de comprender las implicaciones de participar en el estudio, el comité de ética de la entidad a la cual pertenece el investigador o donde se realizará la investigación podrá usar un consentimiento firmado por una persona confiable con autoridad moral sobre la comunidad.
9	Artículo 50	**Artículo 9 del título II** **Artículo 21 del título II.** En la investigación con comunidades se deben ofrecer medidas de protección a los individuos.
10	Artículos 50, 51 y 55	Artículo 9 y 10 del título II
11	**Artículo 52.** Firma del consentimiento informado del representante legal en los casos de participantes menores de edad y personas incapacitadas.	Artículo 8 del título II. Proteger la privacidad del participante de la investigación, identificándolo solo cuando los resultados lo requieran y este lo autorice.

Fuente: Elaboración propia, 2023, tomando información de la Ley 1090 de 2006 y la Resolución 8430 de 1993.

Consideraciones finales

El incremento de estudios sobre personas trans y otras poblaciones de difícil acceso ha generado preocupación en investigadores interesados en trascender lógicas patologizantes y dominantes que, desde un punto de vista humano y ético, le apuestan a minimizar acciones con daño en el momento de la investigación. Este es el caso de estudios como el de Cárdenas et al., (2021) en Chile y de Fielding-Miller et al., (2022) en Estados Unidos, que desde la ciencia y academia ofrecen beneficios a la población participante. Es decir, que los investigadores y fuentes de financiación se interesen en aportar posibles soluciones a problemáticas y necesidades. Esto se identifica como la principal recomendación a quien esté interesado a realizar estudios con personas trans.

Trascender la posición cisheteronormativa basada en prejuicios, es la apuesta que se propone. De acuerdo a Barrientos y Radi (2021) esta posición genera sesgos y, por lo tanto, acciones con daño e investigaciones descontextualizada a las realidades sociales por enfocarse a las necesidades académicas.

En este sentido, a manera de consideraciones finales es posible esbozar que las recomendaciones expuestas representan una invitación a los investigadores e investigadoras de diferentes disciplinas para el abordaje ético y humano con, desde y para

las personas trans. Lo ético radica en la apuesta por mitigar posibles daños que puedan ser causados a la población trans participante de proyectos de investigación. Para esto se reconoce que el trabajo con la comunidad trans requiere abordajes y reflexiones diferenciales debido a que sus experiencias y realidades de vida son particulares, por causa del estigma y discriminación del resto de las personas.

De igual manera se destaca la necesidad de incrementar líneas de investigación de largo aliento, más que procesos de investigación cortos. Esto permitiría dar continuidad a las investigaciones y con ello generar impacto en la población. Lo anterior permitiría afianzar la relación entre la academia y sociedad civil en la construcción de conocimiento y la generación de soluciones a problemáticas y/o necesidades sociales.

El fortalecimiento de los puntos anteriores contribuirá a consolidar posiciones teóricas, ontológicas y metodológicas sólidas para investigaciones en este ámbito. Esto es particularmente importante dada la conciencia de los desafíos y limitaciones que enfrentan las investigaciones en este campo, debido a los movimientos anti-género que cuestionan las identidades de género trans. Se reconocen las posibles limitaciones que pueden surgir, como los obstáculos políticos en contextos latinoamericanos que puedan generar tensiones en apoyo a investigaciones que buscan promover la dignidad y el bienestar de las personas trans. Por lo tanto, se sugiere no pasar por alto las recomendaciones expuestas para abordar estos desafíos de manera contextualizada, sensible y respetuosa.

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“Demons and Imps”: Misinformation and Religious Pseudoscience in State Anti-Transgender Laws

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ABSTRACT: In a hearing before the Florida House of Representatives, Rep. Webster Barnaby addressed transgender witnesses as “demons and imps who come and parade before us and pretend that you are part of this world.” Barnaby’s remarkably candid statement is an outlier because it reveals that religion—rather than sound science—underlies the new wave of anti-transgender laws that have been adopted by at least 20 states since 2021, with the vast majority enacted in 2023. In legislatures, courts, and agency hearings, proponents of anti-trans measures – in contrast to Barnaby – frame their arguments in scientific terms, contending that biology and medicine dictate exceptionalist treatment of transgender people.

In this Article, we make three contributions. First, we debunk these purported scientific claims, showing (with full citations to the scientific literature) that the core arguments for anti-trans laws rest on misinformation (defined as false information that could, with due diligence, be determined to be false) and religious pseudoscience (defined as statements that use scientific vocabulary but rest on religious tenets and defy sound science). We closely examine key state legal documents, including legislation, attorney general opinions, and administrative agency documents. Our analysis shows that the core and repeated “scientific” arguments in these documents defy sound science and rest, instead, on religious principles about the binary nature of sex and gender and the corruption of secular society.

Second, we show that the “playbook” of misinformation and pseudoscience that has long fueled anti-LGBTQIA+ and anti-abortion laws is now being deployed by conservative religious organizations to promote and defend anti-trans laws. Not all religious organizations oppose transgender and

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queer rights, and not all opposition to transgender rights is based in religion. Still, close-knit conservative Catholic and evangelical Protestant groups have been on the front lines of efforts to promote and defend anti-trans laws. Leaked documents and emails show how medical and legal groups united by religion collaborated to create purported "scientific" documents and identify purported "experts" to push anti-trans measures.

Third, we address the limitations of litigation in combatting anti-trans laws. Transgender plaintiffs challenging healthcare bans won decisive victories at the trial level, with federal and state courts in six jurisdictions forcefully rejecting the misinformation and purported "experts" put forward by the states. In the summer of 2023, however, subsequent decisions in federal appellate courts and state supreme courts overturned these decisions, with the higher courts giving credence to states' pseudoscientific claims and sharply narrowing constitutional protections for transgender youth and their families. These decisions explicitly connected transgender rights to abortion rights and adopted the Dobbs approach of limiting constitutional protections based on nineteenth-century social conditions.

Litigation remains ongoing, and recent court decisions have addressed only preliminary injunctions based on limited factual records, so the plaintiffs may yet prevail in some cases. Even in the best case, however, litigation takes years—with harm accruing to transgender people in the meantime— and is vulnerable to gaming by states that are doubling down, enacting new anti-trans laws even as existing ones are struck down.

We conclude that litigation is a welcome but limited remedy and that additional legal and policy measures are worth exploring. These include the enactment of express protections for LGBTQIA+ people by Congress and federal agencies. More speculatively, we consider procedural protections that could be adopted at the state level as well as possibilities for private action by researchers and nonprofit organizations. Although there are no easy answers, this Article outlines a range of possible approaches, some of which would make it more difficult for states to target queer people and others of which would tackle the broader problem of misinformation and religious pseudoscience enacted into law. We also explore potential challenges under the Establishment Clause, which could prompt courts, legislatures, executives, and popular movements to reject pretextual secular claims when—as here—the underlying motivation and asserted "facts" are religious in nature and amount to the state adoption of religious doctrine.

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I. INTRODUCTION

In a hearing before the Florida House of Representatives, Rep. Webster Barnaby addressed transgender witnesses:

> "You are mutants living among us on Planet Earth, Planet Earth, where God created men, male and women, female! … [T]he Lord rebuke you Satan and all of your demons and imps that come parade before us. That's right, I called you demons and imps who come and parade before us and pretend that you are part of this world."[1]

1. *Facility Requirements Based on Sex: Hearing on H.B. 1521 Before the H. Reg. Reform & Econ. Dev. Subcomm.*, 2023 Leg., 54th Sess. (Fla. Apr. 10, 2023) (statement of Rep. Webster Barnaby, Member, H. Commerce Comm., at 2:30:35 to 2:34:10), https://www.myfloridahouse.gov/VideoPlayer.aspx?eventID=8804 [https://perma.cc/5T6P-ZCPQ]. Barnaby apologized later in the hearing. *See* Kiara Alfonseca, *Florida Republican Apologizes for Anti-transgender 'Demons' and 'Mutants' Comments*, ABC NEWS (April 11, 2023, 1:53 PM), https://abcnews.go.com/US/florida-republican-

Barnaby's remarkably candid statement is an outlier in legislative debates that typically invoke facially secular and scientific arguments. Barbaby later apologized, but his outburst reveals an important truth: that religion—rather than sound science—underlies the new wave of anti-transgender laws that have been adopted by at least 20 states since 2021. In legislatures, courts, and agency hearings, proponents of anti-trans measures – in contrast to Barnaby – frame their arguments in scientific terms, contending that biology and medicine dictate exceptionalist treatment of transgender people.

In the past three years, an unprecedented wave of state legislation and executive action has targeted LGBTQIA+ (or, collectively, "queer") people in the United States, with special virulence aimed at transgender, nonbinary, and gender-nonconforming (collectively, "transgender" or "trans") people. At least 20 states have now deployed legislative, judicial, and executive power to marginalize and endanger the lives of trans people. See Table 1.

These anti-trans legal actions attack medical and social support for trans people—particularly, but not exclusively, trans children and teens. Health care prohibitions ("health care bans") impose criminal and civil penalties on medical providers and parents who provide standard gender-affirming care to trans youth, which has been used successfully for decades and carries the approval of every major U.S. medical association. See Table 2. Bathroom bans, sports bans, and "don't say gay or trans" laws make schools an unsafe place to be trans, while forcible outing laws prevent supportive school personnel from facilitating social transition.

Anti-trans laws illustrate a larger problem: the troubling prevalence of misinformation and religious pseudoscience in state legislation and executive actions. By "misinformation," we mean claims (e.g., that gender-affirming health care poses enormous medical risks) that are unsupported by sound science and that could, with due diligence, be detected as false by state actors. State legislators can and do incorporate false findings of fact into bills. State executives can and do rely on misinformation and pseudoscience in attorneys general opinions and executive agency actions. We use the term "religious pseudoscience" to refer to the subset of misinformation that rests on religious beliefs and not sound science but is couched in seemingly scientific terms (e.g., that biology establishes that sex and gender are binary and immutable).

Some people assume that the culture wars only play out through social and legacy media and can safely be ignored. But, in this Article, we explore how

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apologizes-anti-transgender-demons-mutants-comments/story?id=98500770 [https://perma.cc/3AC6-BYKX].

legal actors have relied upon, cited, and written anti-trans misinformation and religious pseudoscience into law while rejecting sound science.[2]

This is not a new strategy: the same "playbook" of misinformation and pseudoscience has long fueled anti-LGBTQIA+ and anti-abortion laws.[3] Today, as in the twentieth century, anti-trans legal measures are fueled by conservative religious organizations, some of which frame their religious agendas in seemingly scientific terms in order to appeal to a broader audience. See Parts II and III. Legal organizations include Americans Defending Freedom and Liberty Counsel; medical organizations include the American College of Pediatricians (misleadingly named to evoke the authoritative American Academy of Pediatrics) and the Catholic Medical Association. Although the strategy of cloaking religion in scientific garb is a familiar one, it is important to document and call out the current, ongoing use of misinformation and religious pseudoscience by these institutional actors.

To focus our analysis, we provide a detailed examination of health care bans, which multiplied exponentially in 2023, to show how religious organizations successfully promoted and defended these laws with misinformation and religious pseudoscience. First, we show anti-trans laws are promoted by an organized set of right-wing Christian religious groups, some of which conceal their religious affiliations. Second, we demonstrate that the purported scientific experts and evidence offered in support of these laws rely on disinformation and religious pseudoscience, not scientific evidence. Anti-trans organizations and state actors frame their legal arguments in secular terms, as they must if they are to avoid Establishment Clause challenges. But the substance of their enactments—and, in some cases, the literal language of the laws—incorporates religious, rather than scientific, commitments.

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2. We define sound science as the body of data, conclusions, and recommendations supported by rigorous, peer-reviewed research and clinical practice guidelines. Throughout this Article, we offer extensive citations to such materials as evidence for our own claims about sound science. See Tables 2 and 4 for an overview.

3. Indeed, current assaults on trans dignity are part of a broader attack on identity and bodily autonomy. It is no coincidence that many of the same states have simultaneously passed other anti-LGBTQIA+ measures and restrictive abortion laws, taking advantage of the Supreme Court's 2022 decision in *Dobbs v. Jackson Women's Health*, 597 U.S. 215 (2022). Indeed, the anti-abortion agenda is often portrayed as linked to anti-LGBTQIA+ laws: In Nebraska, anti-abortion and anti-trans laws were enacted in a single bill, and the original text of a Tennessee anti-trans law specifically targeted Planned Parenthood, finding that the organization is "responsible for killing tens of thousands of unborn children." *See* L.B. 574, 2023 Leg., 180th Sess. (Neb. 2023); S.B. 1, 2023 Leg., 113th Sess., at 68-33-101 (l) (Tenn. 2023) (as introduced on Nov. 9, 2022). Statements by 2024 Presidential candidates suggest that, if elected, a Republican administration would limit health care for trans youth *and* extend those attacks to health care for trans adults. Alex Roarty, *It's Trans Adults, Too: GOP Candidates Now Back Trans Medical Restrictions for all Ages*, MIAMI HERALD (July 14, 2023, 5:21 PM), https://www.miamiherald.com/news/politics-government/article277322158.html.

To reveal the religious pseudoscience and misinformation at work in the law, this Article examines these purported scientific claims, showing (with full citations to the scientific literature) that the core arguments for anti-trans laws rest on and religious pseudoscience. We undertake a close examination of key state legal documents (including legislation), attorney general opinions, and administrative agency documents. Our analysis shows that the core and repeated "scientific" arguments in these documents defy sound science and rest, instead, on religious principles about the binary nature of sex and gender and the corruption of secular society.

We also show that the "playbook" of misinformation and pseudoscience that has long fueled anti-LGBTQIA+ and anti-abortion laws is now being deployed by conservative religious organizations to promote and defend anti-trans laws. Close-knit conservative Catholic and evangelical Protestant groups have been on the front lines of efforts to promote and defend anti-trans laws. Leaked documents and emails show how medical and legal groups united by religion collaborated to create purported "scientific" documents and identify purported "experts" to push anti-trans measures.

Notably, the religious tenets we identify are not part of every religion but are instead drawn from conservative strains of Catholicism and fundamental Protestant teachings. Indeed, some religious traditions within and outside Christianity support transgender and LGBTQIA+ people. Thus, we do not claim that there is any necessary opposition between religion and LGBTQIA+ equality but, rather, that a narrow but politically potent strand of conservative Christianity has been weaponized to adopt legal measures targeting queer people.

It is common, of course, for religious and secular motivations to overlap, and such overlap is constitutionally permissible provided that there are genuine secular reasons for lawmaking.[4] Laws prohibiting murder, for example, serve both religious ends and genuine secular purposes. Further, not every legal actor who supports anti-trans measures is necessarily acting in bad faith. Some legal authorities may be naïve consumers of anti-trans pseudoscience. Still, we show that legal actors could, with ordinary due diligence, take note of the actual medical evidence on gender-affirming care, as well as the public endorsements of such care by every relevant major medical organization.

Consistent with our findings, we show that trial courts have so far shown exceptional capacity to distinguish real science from misinformation. As of

4. Lemon v. Kurtzman, 403 U.S. 602 (1971) (permitting the government to assist religion only if (1) the primary purpose of the assistance is secular, (2) the assistance must neither promote nor inhibit religion, and (3) there is no excessive entanglement between church and state); *see also* McGowan v. Maryland, 366 U.S. 420 (1961) (upholding Sunday "blue laws" because they served a secular purpose as well as a religious one).

July 2023, federal courts in six jurisdictions have temporarily or permanently enjoined health care bans (although a recent Sixth Circuit decision has reversed two of these decisions). A state court in Texas preliminarily enjoined enforcement of a governor's order directing child abuse investigations of parents who consent to gender-affirming care. See Table 3. Because the law treats preliminary injunctions as extraordinary remedies to be granted only when plaintiffs show a substantive likelihood of success on the merits plus irreparable harm, these injunctions are notable.[5] For example, in *Brandt v. Rutledge*, a federal court permanently enjoined Arkansas's 2021 health care ban holding that the ban violated the Equal Protection Clause (because it discriminates on the basis of sex), the Due Process Clause (because it infringes parental rights to make health care decisions), and the First Amendment (because it penalizes physician speech). The court's lengthy opinion correctly and carefully describes the actual science of gender-affirming care and repeatedly criticizes the state's purported "expert" witnesses and the religious pseudoscience they offered to the court.[6]

As of this writing, however, the litigation landscape is unsettled and appears to be reversing the early victories for transgender plaintiffs. In the summer of 2023, state supreme courts and federal appellate courts have blocked lower court decisions enjoining healthcare bans. These decisions have given credence to misinformation and religious pseudoscience and have sharply narrowed constitutional protections for transgender people and their families. Drawing explicitly on the *Dobbs* decision, the Eleventh Circuit in August vacated the trial court's preliminary injunction against Alabama's criminal ban on gender-affirming healthcare for youth The court adopted a skeptical view of parental rights to control their transgender children's health care, finding that the right to enable a gender transition was not "deeply rooted" in our nation's history and tradition and was not anticipated as of 1868 when the Fourteenth Amendment was adopted.[7] The Eleventh Circuit also rejected the trial court's interpretations of constitutional and statutory protections against sex discrimination as extending to transgender people.[8] Following the Eleventh Circuit decision, the district court judge who had preliminarily enjoined Georgia's ban stayed the injunction in September 2023 to accord with the circuit court's views.[9]

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5. *See, e.g.*, L. W. by & through Williams v. Skrmetti, 73 F.4th 408, 414–15 (6th Cir. 2023) (setting forth the standards for preliminary injunctions).

6. Brandt v. Rutledge, No. 4:21CV00450 JM, 2023 WL 4073727, at *27–30 (E.D. Ark. Jun. 20, 2023).

7. Eknes-Tucker v. Governor of Ala., 80 F.4th 1205, 1219–21 (11th Cir. 2023) (vacating preliminary injunction granted by trial court).

8. *Id.* at 1226–27.

9. Koe v. Carlson, No. 1:23-cv-02904, BL (N.D. Georgia September 5, 2023), ECF No. 119,

In two broadly similar decisions in the Sixth Circuit in July, the court invalidated the trial courts' preliminary injunction against Tennessee's and Kentucky's ban on gender-affirming care for youth.[10] The court of appeals gave credence to the state's claim (which we debunk below) that the lack of FDA approval for medications used in gender transitions are experimental and adopted a narrow view of the Equal Protection Clause's protections for transgender people.[11] The Texas Supreme Court overturned a trial court's preliminary injunction in an August 2023 decision that permitted the state's ban on gender-affirming care for minors to take effect.[12]

Many of these decisions are preliminary, and litigation challenging healthcare bans is ongoing in at least ten states.[13] What is clear is that litigation is a slow and uncertain remedy when states adopt laws based on misinformation and religious pseudoscience.

The lack of safeguards in state legislatures and executive agencies thus signals a bigger problem for democracy: state legislators have seemingly concluded that the political advantage of stoking the culture wars outweighs their duties to inquire into facts and to ensure that public laws reflect secular purposes that align with constitutional guarantees of basic rights.

Even if struck down, healthcare bans take time and, in the interim, deny necessary medical care and create painful uncertainty for transgender people.[14] These laws also generate fear among medical providers. In several states, hospitals have voluntarily ended or limited gender-affirming care in response to pressure by legislators, even with injunctions in effect.[15] In Tennessee, the state attorney general demanded—and Vanderbilt University provided—the medical records of transgender patients at the university's clinic, stoking fear of

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https://www.bloomberglaw.com/public/desktop/document/KoeetalvNoggleetalDocketNo123cv02904NDGaJun292023CourtDocket/4?doc_id=X52V560Q7LV81J91G4EGL2S74B6 [https://perma.cc/YQG7-ZV2Q].

10. *See* L. W. by & through Williams v. Skrmetti, 73 F.4th 408 (6th Cir. 2023); Doe v. Thornbury, 75 F.4th 655 (6th Cir. 2023).

11. *Skrmetti*, 73 F.4th at 415–21.

12. Texas v. Loe, No. 23-0697 (Tex. Aug. 31, 2023), https://www.txcourts.gov/supreme/orders-opinions/2023/august/august-31-2023/ [https://perma.cc/R6UF-2T5N] (denying plaintiff-appellees motion for emergency relief).

13. Morgan Watkins, *Can States' Bans on Transgender Care Hold up in Court? We Break Down Arguments*, NPR (Jul. 28, 2023, 8:55 AM), https://www.npr.org/2023/07/28/1190673042/trans-health-care-bans-gender-affirming-federal-supreme-court-kids-lawsuits [https://perma.cc/CC4M-5544].

14. In Florida, for example, a 2022 Medicaid ban on gender-affirming care left thousands of teen and adult patients without access to care until June 2023, when a federal judge enjoined the ban permanently as unconstitutional. Gary Fineout, *Federal Judge Knocks Down Florida's Medicaid Ban on Gender-Affirming treatment*, POLITICO (Jun. 21, 2023, 9:23 AM), https://www.politico.com/news/2023/06/21/florida-gender-affirming-ban-00103067 [https://perma.cc/4RWF-2D6F].

15. *See infra* Part IV.

targeted persecution.[16] Furthermore, in a dynamic reminiscent of resistance to racial integration after *Brown v. Board of Education*, some states are doubling down on anti-trans measures in the wake of court decisions. Florida has been particularly active in enacting a number of separate measures designed to block or limit gender-affirming care, some adopted shortly after adverse court rulings on earlier measures. The multiplication of laws means that challengers must continually file new cases or attempt to amend outstanding cases to encompass new measures.[17]

This dynamic legal landscape requires urgent attention: research shows that political and legal attacks on transgender people spur violence against them and burden their mental health.[18] In a recent survey by researchers at Boston University, trans youth commented, *inter alia*, that "[t] hey are actively discriminating against us and taking our safe spaces, coping mechanisms, and ways of living happily from us. They are trying to kill us and make us fade away as if we never existed."[19]

This Article proceeds in four parts. In Part II, we link current anti-trans efforts to the history of persecution of LGBTQIA+ people in the United States. Taking the long view, attacks on trans people reflect longstanding animus by conservative political and religious authorities toward queer people. In Part III, we analyze key legal sources to show how misinformation and pseudoscience have been incorporated into the laws banning gender-affirming healthcare. We also highlight that some courts, when presented with sound information, have been able to detect and reject misinformation and religious pseudoscience.

In Part IV, we show that the current wave of anti-trans laws did not arise from grassroots concern but from a coordinated strategy by conservative religious organizations, legislators, and purported anti-trans experts. Here, we make "grassroots" organizations distinct from "religious groups" in that much of anti-trans rhetoric is created within an institutional, organized fashion. While there are certainly individuals who are responsible for the dissemination of pseudoscience, we are interested in how a small handful of right-wing religious groups funds litigation, provides purported experts for testimony, and promulgates reams of anti-trans pseudoscience—while often hiding their religious affiliations and mission. In Part V, we conclude by analyzing the

16. Anisha Kohli, *Vanderbilt's Decision to Turn Over Trans Patient Records to the State Sparks Backlash*, *Time* (June 23, 2023, 10:17 AM), https://time.com/6289609/vanderbilt-transgender-records-patients-backlash/ [https://perma.cc/V52Q-VQ4R].

17. See *infra* Part IV.

18. Timothy Wang & Sean Cahill, *Antitransgender Political Backlash Threatens Health and Access to Care*, 108 AM. J. PUB. HEALTH 609 (2018).

19. Andrew Thurston, *How Will Anti-Trans Laws Impact Transgender and Gender-Diverse Youth Mental Health*, B.U. BRINK (March 24, 2023), https://www.bu.edu/articles/2023/how-will-anti-trans-laws-impact-transgender-and-gender-diverse-youth-mental-health/ [https://perma.cc/3RCH-QB52].

limitations of litigation and court-ordered remedies in this context and by exploring legal and policy measures that could protect LGBTQIA+ rights and, more broadly, ensure that lawmakers act on correct information rather than misinformation and pseudoscience.

II. CONSERVATIVE RELIGIOUS ORGANIZATIONS AND TWENTIETH-CENTURY ANTI-LGBTQIA+ LAWS

The current situation is not new. It marks a new chapter in the long and shameful history of legal attacks on queer people, including now-unconstitutional prohibitions on sexual intimacy and the denial of marriage equality. Proponents of these historical measures also offered secular justifications for their passage, but then, as now, religion has often played a major role in garnering political support and structuring the law. In this Part, we offer a brief history of this messaging strategy by examining the work of some of its major exponents – actors who resurfaced in the current wave of anti-trans legal measures. We also propose that by cloaking religious argumentation in a veneer of scientific legitimacy, the right seeks to attract support for its anti-LGBTQIA+ message from a moderate mainstream that might otherwise be more skeptical of such bigotry.

Though attacks on the trans community—from state and national politicians, conservative activists, and individuals who target trans people for brutal acts of violence—have dramatically intensified in recent years,[20] hostility to the rights of LGBTQIA+ Americans more broadly is nothing new. Since at least the early 1980s, right-wing Christian groups have pushed back against attempts by queer activists to secure greater social acceptance and legal protections.[21] Even as LGBTQIA+ Americans secured some important

20. *See*, *e.g.*, Maggie Astor, *Transgender Americans Feel Under Siege as Political Vitriol Rises*, N.Y. TIMES (Dec. 10, 2022), https://www.nytimes.com/2022/12/10/us/politics/anti-transgender-lgbtq-threats-attacks.html ("Over the past couple of years, it has become routine for conservatives to liken transgender people and their allies to pedophiles, and to equate discussion of gender identity with 'grooming' children for sexual abuse—part of an intensifying push, reminiscent of campaigns against gay rights dating back to the 1970s, to turn increasing visibility of transgender Americans into a political wedge"); Madeleine Carlisle, *Anti-Trans Violence and Rhetoric Reached Record Highs Across America in 2021*, TIME (Dec. 30, 2021, 7:06 AM), https://time.com/6131444/2021-anti-trans-violence/ [https://perma.cc/3PFS-A9F6] (describing 2021 as the "deadliest year for transgender and gender non-conforming people in the U.S. on record" and noting that the Human Rights Campaign has documented at least 50 murders of trans and gender non-conforming people in 2021 alone); *An Epidemic of Violence 2022*, HUM. RTS. CAMPAIGN, https://reports.hrc.org/an-epidemic-of-violence-2022 [https://perma.cc/NH2D-K7KA] (last visited July 20, 2023) (reporting that in 2022, 145 anti-transgender bills were introduced across 34 states, and 17 were enacted across 13 states).

21. DIDI HERMAN, THE ANTIGAY AGENDA: ORTHODOX VISION AND THE CHRISTIAN RIGHT 61 (1997).

victories in the judicial[22] and legislative realms,[23] the Christian right and their allies sought to frustrate and roll back those gains, promulgating narratives designed to stoke fear, animosity, and disgust against the queer community. Present-day slurs against LGBTQIA+ people as "groomers," for example, harken back to earlier efforts to tar gay people as pedophiles and a moral threat to youth.[24]

A key feature of anti-queer messaging has historically been its use of ostensibly secular, "scientific" language. "Scientific" evidence is used to paint queer people as a threat to themselves and others (particularly children) and to justify the suppression—via conversion therapy—of queer self-expression. Institutions and individuals alike weaponize pseudoscientific messaging against queer Americans.

One noteworthy proponent of this pseudoscientific strategy is Paul Cameron, a psychologist and former instructor at the University of Nebraska who, in 1982, founded the "Institute for the Scientific Study of Sexuality" (later the Family Research Institute) to bolster the religious right's anti-LGBT claims with "scientific research."[25]

Cameron is notable for his influence. Over a decades-long career, Cameron has repeatedly held himself out as an expert on gay and lesbian issues. During the AIDS crisis in the 1980s, he published a series of pamphlets claiming, among other things, that gay people were more violent, and tended to molest,

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22. *See* Romer v. Evans, 517 U.S. 620 (1996) (ban on anti-discrimination protections for gays and lesbians violates 14th Amendment's Equal Protection Clause); Lawrence v. Texas, 539 U.S. 558 (2003) (anti-sodomy law violates the 14th Amendment's Due Process Clause); United States v. Windsor, 570 U.S. 744 (2013) (Defense of Marriage Act's definition of "marriage" as a "legal union between one man and one woman" deprives same-sex couples of equal protection guaranteed by the 5th Amendment); Obergefell v. Hodges, 576 U.S. 644 (2015) (14th Amendment requires states to issue marriage licenses to same-sex couples); Bostock v. Clayton County, 140 S. Ct. 1731 (2020) (Title VII of the Civil Rights Act of 1964 prohibits employers from firing employees simply because they are gay or transgender).

23. Three especially significant victories at the federal level have been the 2009 Matthew Shepard and James Byrd, Jr. Hate Crimes Prevention Act, which created a new category of sexual-orientation and gender-identity-based federal hate crimes; the 2010 repeal of "Don't Ask, Don't Tell," a law that forbade gay and lesbian military servicemembers from disclosing their sexual orientation on pain of discharge; and 2022's "Respect for Marriage Act," which formally recognized same-sex couples for purposes of federal law. *See* Division E—Matthew Shepard and James Byrd, Jr. Hate Crimes Prevention Act, Pub. L. No. 111-84, 123 Stat. 2835 (2009); Don't Ask, Don't Tell Repeal Act, Pub. L. No. 111-321, 124 Stat. 3515 (2010); Respect For Marriage Act, Pub. L. No. 117-228, 136 Stat. 2305 (2022).

24. Gillian Frank, *"The Civil Rights of Parents": Race and Conservative Politics in Anita Bryant's Campaign Against Gay Rights in 1970s Florida*, 22 J. HISTORY SEXUALITY 126 (2013).

25. Anthony Niedwiecki, *Save Our Children: Overcoming the Narrative that Gays and Lesbians are Harmful to Children*, 21 DUKE J. GENDER L. & POL'Y 125, 155 (2013); *Family Research Institute (FRI)*, LIBRARY OF CONGRESS WEB ARCHIVE, https://www.loc.gov/item/lcwaN0006619/ [https://perma.cc/HD64-5TR3] (last visited Mar. 7, 2023).

rape, and murder children at higher rates, than the general population.[26] In subsequent years, he has—using his Family Research Institute as a vehicle—repeatedly published studies in pay-to-publish journals making similar claims.[27] In 1984, Cameron was retained as an expert witness by the state of Texas in a legal challenge to its anti-sodomy laws.[28] Eight years later, the Attorney General of Colorado hired him to act as an expert witness in defense of the state's Amendment Two, which banned all judicial, executive, and legislative action designed to protect queer people from discrimination.[29] The Supreme Court later invalidated that amendment in *Romer v. Evans*.[30] In 2007, Cameron testified before the Colorado State Senate that gays and lesbians—according to his own studies—were more likely to drive drunk and molest children than heterosexuals.[31]

Cameron's work was roundly discredited, with one researcher in his field saying she is "amazed that he is able to continue to be published."[32] His work was condemned by the American Sociological Association,[33] rebuked by the Nebraska Psychological Association,[34] and Cameron himself was expelled by the American Psychological Association.[35] Nevertheless, Cameron's work has been highly influential in the religious right's campaign against LGBTQIA+ equality, including in legal venues. His work was cited by the anti-gay Family Research Council in Congressional testimony against the 1994 Employment Non-Discrimination Act,[36] which died in committee. His work was also cited

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26. Niedwiecki, *supra* note 25, at 155–56 (noting that Cameron has asserted that gay people are responsible for one-third of all child molestations and ten to twenty times more likely than heterosexuals to molest children).

27. Michael Kranish, *Beliefs Drive Research Agenda of New Think Tanks: Study on Gay Adoption Disputed by Specialists*, THE BOSTON GLOBE (Jul. 31, 2005), https://plus.lexis.com/api/permalink/f71d9382-5d09-4bac-9416-e4a36a4b9972/?context=1530671 [https://perma.cc/Y5W8-628N].

28. Niedwiecki, *supra* note 25, at 157.

29. *Id.*

30. 517 U.S. 620 (1996).

31. *Paul Cameron*, SO. POVERTY L. CTR., https://www.splcenter.org/fighting-hate/extremist-files/individual/paul-cameron [https://perma.cc/7AHD-AC6C] (last visited Mar. 9, 2023).

32. Kranish, *supra* note 27 (quoting Dr. Ellen C. Perrin, author of a 2002 report that led the American Academy of Pediatrics to conclude that there was no meaningful difference between children raised by same-sex vs. heterosexual couples).

33. AM. SOCIO. ASS'N, Resolution of the Am. Socio. Ass'n Condemning Paul Cameron (Aug. 1985), https://digital.library.unt.edu/ark:/67531/metadc786184/m1/1/ [https://perma.cc/54K7-3ZQE] ("[Cameron] has consistently misinterpreted and misrepresented sociological research on sexuality, homosexuality, and lesbianism").

34. Kranish, *supra* note 27 (quoting a statement from the Nebraska Psychological Association saying that it "formally dissociates itself from the representations and interpretations of scientific literature offered by Dr. Paul Cameron.").

35. Letter from Max Seigel, Pres. of the Am. Psych. Ass'n, to Paul Cameron (Dec. 2, 1983) (on file with LGB Psychology) (expelling Cameron for ethics violations).

36. *Employment Non-Discrimination Act: Hearing on S. 2238 Before the S. Comm. on Labor and Human Resources*, 103d Cong., S. Hrg. 103-703, at 92 (1994) (statement of Robert H. Knight, Director of Cultural Affairs, Family Research Council) (quoting a Cameron study of "6,400 obituaries in

by dissenters when the Massachusetts Supreme Judicial Court held that gays and lesbians had the right to marry in the state[37] and by the Eleventh Circuit in a 2004 decision upholding Florida's adoption ban for same-sex couples.[38]

Though Cameron and his Family Research Institute have been recognized as among the most prominent producers of pseudoscientific research for the Christian right,[39] they are far from the only religious actors to weaponize "science" in furtherance of an anti-queer agenda. Several major nonprofit organizations with explicitly Christian missions have in recent years pursued the same strategy. For instance, the Witherspoon Institute—a Princeton, New Jersey-based nonprofit that organizes programming on what "the ancient and Judeo-Christian traditions can teach us about contemporary biomedical ethics, sexual morality, marriage and family"[40]—was a driving force behind the so-called "New Family Structures Survey,"[41] a 2012 study led by University of Texas sociologist Mark Regnerus that purported to show that children raised in same-sex households fared worse than those raised by heterosexual parents.[42] The release of the study, which contradicted a wide body of sociological research and was severely criticized for methodological errors,[43] was cited by amici in *United States v. Windsor*[44] (a challenge to the constitutionality of the

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homosexual publications" which asserted that "homosexuals typically have far shorter life spans than the general population.").

37. Goodridge v. Dep't. of Public Health, 798 N.E.2d 941, 999 n.26 (Mass. 2003) (Cordy, J., dissenting) (citing Cameron's research for the proposition that "children raised by homosexuals disproportionately experience emotional disturbance and sexual victimization").

38. Lofton v. Sec'y of Dep't. of Children and Family Servs., 358 F.3d 804, 825 n.25 (11th Cir. 2004). The adoption ban was invalidated on state constitutional grounds in 2010. *See* Fla. Dep't. of Children and Families v. Adoption of X.X.G., 45 So. 3d 79 (Fla. Dist. Ct. App. 2010).

39. HERMAN, *supra* note 21, at 77.

40. *For High School Students*, THE WITHERSPOON INSTITUTE, https://winst.org/for-high-school-students/ [https://perma.cc/Y8FN-74PS] (last visited Mar. 11, 2023).

41. Mark Regnerus, *How Different are the Adult Children of Parents Who Have Same-Sex Relationships? Findings from the New Family Structures Survey*, 41 SOC. SCI. RSCH. 752, 755 (2012). A subsequent internal investigation conducted at Social Science Research found serious errors in the peer review process that led to the publication of Regnerus's study—including that three of the six peer reviewers were on the record opposing same-sex marriage. *See* Tom Bartlett, *Controversial Gay Parenting Study is Severely Flawed, Journal's Audit Finds*, CHRONICLE HIGHER EDUC. (Jul. 26, 2012), https://www.chronicle.com/blogs/percolator/controversial-gay-parenting-study-is-severely-flawed-journals-audit-finds [https://perma.cc/VJ5A-4S48].

42. Sofia Resnick, *Conservative Group Tries to Sway SCOTUS on Gay Marriage with Flawed Study*, SALON (Mar. 11, 2013, 10:10 PM), https://www.salon.com/2013/03/11/conservative_group_tries_to_sway_scotus_on_gay_marriage_with_flawed_study_partner/ [https://perma.cc/A756-EA2T]; *see also* DeBoer v. Snyder, 973 F. Supp. 2d 757, 766 (E.D. Mich. 2014) (finding that the New Family Structures Survey was "hastily concocted at the behest of a third-party funder, which . . . 'was confident that the traditional understanding of marriage will be vindicated by this study.'").

43. *See*, *e.g.*, Brief for Am. Socio. Ass'n as Amicus Curiae Supporting Respondents, Hollingsworth v. Perry, 570 U.S. 693 (2013) (No. 12-144), 2013 WL 4737188, at *16–20 (outlining flaws in Regnerus study, including that it did not specifically study children born or adopted into same-sex families, but children whose parents at any time engaged in a "same-sex romantic relationship").

44. 570 U.S. 744 (2013).

Defense of Marriage Act) and *Hollingsworth v. Perry*[45] (which challenged California's Proposition 8 banning gay marriage).[46]

Another such organization is the American College of Pediatricians (a.k.a. AC Peds), which formed as a breakaway group from the American Academy of Pediatrics after the latter released a statement in 2002 stating that gay parents posed no risk to adopted children.[47] Despite its secular-sounding name, AC Peds (which has been classified by the Southern Poverty Law Center as a hate group)[48] has been described by its own founder, Joseph Zanga, as an organization with Judeo-Christian values that opposes abortion and same-sex adoption.[49] AC Peds is active in litigation around the country against LGBTQIA+ equality and reproductive rights, often as an amicus[50] and sometimes as a named party.[51] For example, since 2019, AC Peds has been included in sixteen amicus briefs, five of which are included before the Supreme Court.[52] Currently, AC Peds is named plaintiff in *Alliance for Hippocratic Medicine v. FDA*, an ongoing lawsuit to reverse FDA approval of mifepristone, an abortion medication. Co-plaintiffs include the Alliance for Hippocratic Medicine and the Christian Medical and Dental Association.[53]

Furthermore, AC Peds published pseudoscientific resources for policymakers— on issues ranging from reproductive to gender-affirming

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45. 570 U.S. 693 (2013).

46. *See* Resnick, *supra* note 42.

47. Jack Turban, *The American College of Pediatricians Is an Anti-LGBT Group*, PSYC. TODAY (May 8, 2017), https://www.psychologytoday.com/us/blog/political-minds/201705/the-american-college-pediatricians-is-anti-lgbt-group [https://perma.cc/BH35-ABNG].

48. *American College of Pediatricians*, SO. POVERTY L. CTR., https://www.splcenter.org/fighting-hate/extremist-files/group/american-college-pediatricians [https://perma.cc/ZD23-N94X] (last visited Mar. 12, 2023) (describing AC Peds as a "fringe anti-LGBTQ hate group that masquerades as the premier U.S. association of pediatricians to push anti-LGBTQ junk science, primarily via far-right conservative media and filing amicus briefs.").

49. Bill Fancher & Jody Brown, *Pro-Life Pediatric Group Stands Contrary to Established American Academy of Pediatrics*, CATHOLIC EXCHANGE (Jul. 30, 2003), https://catholicexchange.com/pro-life-pediatric-group-stands-contrary-to-established-american-academy-of-pediatrics/ [https://perma.cc/2Z3W-ZTHU].

50. The many cases in which AC Peds has acted as an amicus include Bostic v. Schaefer, 760 F.3d 352 (4th Cir. 2014) (challenge to Virginia's same-sex marriage ban), State ex rel. Kutil v. Blake, 679 S.E.2d 310 (W.Va. 2009) (challenge to denial of foster placement with a same-sex couple), Massachusetts v. U.S. Dep't. of Health and Human Servs., 682 F.3d 1 (1st Cir. 2012) (challenge to Defense of Marriage Act's denial of federal benefits to same-sex married couples), and Gainesville Woman Care, LLC v. State, 210 So. 3d 1243 (Fla. 2017) (challenge to Florida's 24-hour waiting period for people seeking abortions).

51. *See* Am. Coll. of Pediatricians v. Becerra, No. 1:21-cv-195, 2022 WL 17084365 (E.D. Tenn. Nov. 18, 2022) (challenge to HHS rule interpreting "discrimination on the basis of sex" to encompass discrimination on the basis of gender identity).

52. *Amicus Briefs*, AM. COLL. OF PEDIATRICIANS, https://acpeds.org/positions/amicus-briefs [https://perma.cc/C3LN-CAXR] (last visited Oct. 16, 2023).

53. Emergency Motion for a Stay Pending Appeal, Alliance for Hippocratic Medicine v. Food & Drug Admin. No. 23-10362, 2023 WL 2913725 (5th Cir. April 12, 2023).

care.[54] Their earlier work challenged the American Psychological Association's assertion of the immutability of homosexual attraction among youth as "biased and scientifically unfounded" and a position that "puts youth at risk."[55] To do so, they argue that the APA's factsheets were "generated by political pressure."[56] Several of the medical sources cited deliberately misused the statements of physicians to support their claims.[57] This statement was used in support of their letter to 14,800 school superintendents endorsing reparative therapy, also known as conversion therapy.[58]

AC Peds repeatedly characterizes queer identity as mutable, political, and harmful to children. Gender-affirming treatment, it contends, turns "children into hormone- and surgery-dependent experimentees"[59] and constitutes "the experimental abuse of our children."[60] Instead, they argue that "[s]ex is a dimorphic, innate trait defined in relation to an organism's biological role in reproduction."[61] The growing support of gender-affirming care, they argue, "requires a dangerous dismissal of both science and medical ethics."[62] Based on these views, AC Peds has pursued a sustained campaign promoting the supposed benefits of conversion therapy for queer youth.[63]

The campaign—as well as the researchers involved—has been condemned by, for example, a researcher, who was the director of the National Institutes of Health, who accused AC Peds of distorting their work.[64] Despite these

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54. *For Policymakers*, AM. COLL. OF PEDIATRICIANS, https://acpeds.org/policy-makers [https://perma.cc/L2VH-SFRG] (last visited Oct. 16, 2023); *Position Statements*, AM. COLL. OF PEDIATRICIANS, https://acpeds.org/positions/position-statements [https://perma.cc/SC9T-UA9F] (last visited Oct. 16, 2023).

55. *Perspectives in Medicine*, AM. COLL. OF PEDIATRICIANS, https://acpeds.org/positions/perspectives-in-medicine [https://perma.cc/6WQN-B63H] (last visited Oct. 16, 2023); Dale O'Leary et al., *A Response to the APA's "Factsheet,"* https://ACPeds.org/assets/imported/Response_to_the_APA_Factsheet.pdf [https://perma.cc/6RQS-4Y6C] (last visited Oct. 16, 2023).

56. *See* O'Leary et al., *supra* note 55, at 3 (arguing that homosexuality is a political question).

57. *See* SO. POVERTY L. CTR., *supra* note 48.

58. *Id.*

59. Monique Robles, *Observations in a Gender Diversity Clinic,* 44 ETHICS & MED. 1, 3 (2019).

60. *Id.* at 3–4.

61. Michael Artigues & Michelle Cretella, *Sex is a Biological Trait of Medical Significance*, AM. COLL. OF PEDIATRICIANS., https://acpeds.org/position-statements/sex-is-a-biological-trait-of-medical-significance [https://perma.cc/3M33-JWJ9] (last visited Oct. 16, 2023). Importantly, this "statement" follows the structure of traditional scientific knowledge production (*i.e.,* providing an abstract and introduction) but is not published on a journal.

62. *Id.*

63. *See, e.g.*, *Facts About Youth*, AM. COLL. OF PEDIATRICIANS, http://factsaboutyouth.com/ [https://perma.cc/8HNS-ZHTL] (last visited Mar. 12, 2023).

64. *Statement from NIH Director Francis S. Collins, M.D., Ph.D., in Response to the American College of Pediatricians*, NAT'L INSTITUTES OF HEALTH, (Apr. 15, 2010), https://web.archive.org/web/20110727115017/http:/www.nih.gov/about/director/04152010_statement_ACP.htm [https://perma.cc/ZPQ3-3NJS]; Nick Pinto, *University of Minnesota Professor's Research Hijacked*, CITY PAGES (May 26, 2010), https://web.archive.org/web/20100601201941/http://www.citypages.com/

statements, AC Peds continues to be referenced in the media and put forward as a source of expertise for policymakers. The AC Peds website trumpets mentions by news outlets, principally Christian and Catholic publications, as well as right-wing sites like The Daily Caller and the Daily Wire.[65] The group has also received exposure in more mainstream news outlets and in state legislatures. To take just a few examples, AC Peds official Michelle Cretella appeared on "Tucker Carlson Tonight" to claim that because "[s]ex is hard-wired from before birth" gender-affirming care is "child abuse").[66] Another AC Peds official, Quentin Van Meter, was hired by the Ohio Department of Health to serve as an expert witness in a civil rights lawsuit against the state for refusing to change the sex on birth certificates of four transgender people[67] and provided testimony to the Alabama state legislature in favor of banning gender-affirming healthcare for children).[68]

AC Peds, The Witherspoon Institute, Mark Regnerus, the Family Research Institute, and Paul Cameron are just a few exponents of the pseudoscientific messaging that the religious right has weaponized against queer Americans for decades.[69] Though a full accounting of the histories and strategies of the various right-wing actors to have pursued this strategy would be beyond the scope of this paper, these examples vividly illustrate a broader and well-

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2010-05-26/news/university-of-minnesota-professor-s-research-hijacked/ [https://perma.cc/N38G-VNFX].

65. *In the media*, AM. COLL. OF PEDIATRICIANS, https://acpeds.org/in-the-media [https://perma.cc/L82H-YX9F] (last visited Nov. 12, 2023).

66. Brennan Suen, *Tucker Carlson Teams with Hate Group to Spread Junk Science About Transgender Kids*, MEDIA MATTERS (July 25, 2017, 2:48 PM), https://www.mediamatters.org/tucker-carlson/tucker-carlson-teams-hate-group-spread-junk-science-about-transgender-kids [https://perma.cc/A232-66Y2].

67. Jake Zuckerman, *Conversion Therapy is a Discredited Practice. Ohio Hired its Advocate as an Expert Witness*, OHIO CAPITAL J. (Feb. 5, 2020, 1:00 AM), https://ohiocapitaljournal.com/2020/02/05/conversion-therapy-is-a-discredited-practice-ohio-hired-its-advocate-as-an-expert-witness/ [https://perma.cc/RDU8-TDNA].

68. *See* SO. POVERTY L. CTR., *supra* note 48. *See also* Cheryl Wetzstein, *Pediatricians Have a New Mission: Fight "Homophobia,"* WASH. TIMES. (June 24, 2013), https://www.washingtontimes.com/news/2013/jun/24/pediatricians-set-new-policy-on-sexual-minorities/ [https://perma.cc/HP9F-BCH6] (quoting then-AC Peds president Den Trumbull's endorsement of reparative therapy for LGBTQ teens); Kayla Gogarty, *Extreme anti-LGBTQ Groups Family Research Council and American College of Pediatricians Were on Capitol Hill Fighting the Equality Act*, MEDIA MATTERS (March 21, 2019, 12:15 PM), https://www.mediamatters.org/family-research-council/extreme-anti-lgbtq-groups-family-research-council-and-american-college (reporting on a 2019 address to members of Congress in which Cretella argued the alleged dangers of the Federal Equality Act); Chad Dorsett, *Rep. Ginny Ehrhart Announces Vulnerable Child Protection Act*, SKY 96.3 (Oct. 31, 2019), https://sky963.com/rep-ginny-ehrhart-announces-vulnerable-child-protection-act/ [https://perma.cc/H6AQ-6WYE] (reporting on a 2019 press release from Georgia state Rep. Ginny Ehrhart quoting AC Peds president Quentin Van Meter, who stated that children need to be protected from "medical experimentation based on wishful social theory").

69. *See*, e.g., HERMAN, *supra* note 21, at 73.

documented discourse.[70] On issues including adoption, conversion therapy, and LGBTQIA+ "criminality," conservative Christian organizations have long sought to cast what are, at bottom, religious views about sexual morality, family structure, and abortion in a deceptively secular, "scientific" light.

What explains this messaging strategy? Nathaniel Klemp offers a persuasive answer in his article *Beyond God-Talk*,[71] which analyzes the political practices of another right-wing religious group that has deployed scientific language against the queer community: Focus on the Family ("Focus"). Explaining that Focus—like AC Peds and Witherspoon—has purported to back up its arguments against gay marriage with objective sociological research, Klemp argues that such rhetoric is designed to appeal to a broader democratic coalition than the Christian conservative movement would otherwise command.[72] By concealing its religious views behind supposedly scientific data, in other words, the Christian right aims to give its message the appearance of moderation, attracting those likely to be alienated by more overtly theological arguments.[73] Klemp's view finds support in the work of the philosopher Sven Ove Hansson, who has described religious movements' use of pseudoscience as a strategic adaptation to "modern societies where science is perceived as having more authority than what religion has."[74]

As the citation record of Cameron, The Witherspoon Institute, and others indicates, arguments that sound scientific—that on their face appear to be backed up by studies, figures, credentialed "experts"—can find a receptive audience in certain quarters of the judiciary, and among policymakers who lack the training necessary to evaluate them critically.[75] Though moderate on their

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70. For more extensive accounts of the anti-LGBT religious right's embrace of pseudoscience, see, e.g., HERMAN, *supra* note 21; ANTONY ALUMKAL, PARANOID SCIENCE: THE CHRISTIAN RIGHT'S WAR ON REALITY (2017); Gabby Bess, *Uncovering the Christian Think Tanks Behind the Bogus Studies on Gay Parenting*, VICE (Feb. 16, 2017, 10:45 AM), https://www.vice.com/en/article/3k8qmw/uncovering-the-christian-think-tanks-behind-the-bogus-studies-on-gay-parenting [https://perma.cc/96F5-CMPR].

71. Nathaniel J. Klemp, *Beyond God-Talk: Understanding the Christian Right from the Ground Up*, 39 POLITY 522 (2007).

72. *Id.* at 532–33.

73. *Id.* at 533.

74. Sven Ove Hansson, *Religion and Pseudoscience, in* ENCYCLOPEDIA OF SCIENCES AND RELIGIONS 1993 (Anne Runehov & Lluis Oviedo eds., 2013).

75. There is a disturbing parallel—a full accounting of which would be beyond the scope of this paper, but is a fruitful subject for further research—between the use of pseudoscientific rhetoric to support attacks on the trans community and the use of pseudoscience to prop up narratives of racial inferiority. For some helpful overviews of the history of the latter phenomenon, often referred to as "scientific racism," see, e.g., William H. Tucker, *The Ideology of Racism: Misusing Science to Justify Racial Discrimination*, U.N. CHRONICLE, https://www.un.org/en/chronicle/article/ideology-racism-misusing-science-justify-racial-discrimination [https://perma.cc/9QB8-ZN4Z] (last visited Oct. 7, 2023); Rutledge M. Dennis, *Social Darwinism, Scientific Racism, and the Metaphysics of Race*, 64(3) J. NEGRO EDUCATION 243 (1995); John P. Jackson, Jr. & Nadine M. Weidman, *The Origins of Scientific Racism*, 50 J. OF BLACKS IN HIGHER ED. 66 (Winter 2005/2006). Comparing the two strands of rhetoric

face, such arguments have a long and pernicious history in anti-LGBTQIA+ activism. They have propped up decades of religiously-motivated attacks on the rights of queer people to marry, raise children, and live openly as their authentic selves.

Calling attention to the harms perpetuated by these actors is not meant to ignore the history of harm perpetuated by scientific and medical organizations against LGBTQ+ people. Medicine, in particular, has historically been complicit in the pathologization of queerness and labeling queer people as deviant.[76] It was not until 1973 that the American Psychological Association removed homosexuality from its list of mental disorders.[77]

With time, however, science and medicine evolved and corrected not only the pathologization of queerness but also began to affirmatively support gender-affirming care. Anti-queer actors co-opt this evolution to argue that these changes are not due to advancements in medicine, but instead, to social and political pressure.[78] In 2022, Florida's health care agency, for example, attacked the credibility of the American Psychological Association, questioning"[w]hether the APA has shifted its terminology and criteria for gender identity issues due to emerging clinical data or cultural changes is another question."[79] This strategy continues in legal arguments today. For example, in one recent case, the attorneys general of fifteen states argued in an amicus brief that the evolution in the consensus on gender-affirming care is motivated by "politics, not science or the best interests of young people."[80] In another ongoing case, the state of Florida argued that "medical history is littered with . . . prominent physicians getting [medical science] wrong, often with disastrous consequences."[81]

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powerfully illuminates the extent to which the invocation of objective, "scientific" authority can be used to justify the mistreatment of disfavored groups and maintain social hierarchies.

76. Emily Ward, *Pride is a State of Mind: The History of the Pathologisation of Queerness*, BRITISH ONLINE ARCHIVES (June 27, 2021), https://microform.digital/boa/posts/category/articles/415/pride-is-a-state-of-mind-the-history-of-the-pathologisation-of-queerness [https://perma.cc/LV5R-7CLZ].

77. Allison Turner, *#FlashbackFriday – Today in 1973, the APA Removed Homosexuality from List of Mental Illnesses*, HUM. RTS. CAMPAIGN (Dec. 15, 2017), https://www.hrc.org/news/flashback friday-today-in-1973-the-apa-removed-homosexuality-from-list-of-me [https://perma.cc/7EM3-T35L].

78. DIV. OF FLA. MEDICAID, GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS ON THE TREATMENT OF GENDER DYSPHORIA 6 (June 2, 2022), https://ahca.myflorida.com/content/download/4869/file/AHCA_GAPMS_June_2022_Report.pdf [https://perma.cc/ZJV4-JSMW].

79. *Id.* at 5–6.

80. Brief of the States of Ark. at 15, Alaska et al. as Amici Curiae Supporting Defendants-Appellants, Eknes-Tucker v. Governor of Ala., 80 F.4th 1205 (11th Cir. 2023) (No. 22-11707).

81. Redacted Defendants' Response in Opposition to Motion for Preliminary Injunction and Incorporated Memorandum of Law at 14, Dekker v. Marstiller, No. 4:22-cv-00325-RH-MAF (N.D. Fla. Oct. 3, 2022), ECF No. 49.

III. MISINFORMATION AND RELIGIOUS PSEUDOSCIENCE WRITTEN INTO HEALTHCARE BANS

State actors who support health care bans frame their actions in secular terms and invoke purported scientific evidence, as they must if they are to avoid an obvious Establishment Clause problem. (To see the point, imagine the reception a state attorney general would receive if she argued, in federal court, that an anti-transgender law was enacted to enforce the will of God as dictated by the writings of the Vatican.)

But a closer examination shows that these purportedly secular and scientific arguments stand at odds with the actual scientific evidence. In this Part, we examine key legal documents, including the text of legislation, briefs, and administrative reports, and show that the core arguments used by state actors to justify these measures are actually grounded in misinformation and religious pseudoscience.

Although healthcare bans differ in their targets (youth or youth and adults), penalties (criminal and civil liability for medical providers and parents, as well as custody determinations), and form of enactment (legislative and executive actions), all have been deployed to deny gender-affirming care to trans people. As of 2023, an estimated 156,500 trans youth live in 32 states that have restricted or considered bans on access to gender-affirming care.[82] Trans residents in these jurisdictions are left with just two choices: move or seek medication illegally.

We concentrate on healthcare bans because they illustrate clearly how state actors rely on misinformation and religious pseudoscience. We identify four sets of core and recurring arguments, which are repeated in most healthcare bans across jurisdictions. We show that these core arguments are not only unsupported by science but also map closely onto four religious tenets associated with conservative Christian beliefs:

- First, that sex and gender are binary and immutable;
- Second, that (accordingly) trans people are confused or deluded;
- Third, that secular authority, including science and medicine, is untrustworthy; and,
- Fourth, that secular society affirmatively pushes "gender ideology" on youth via social media and schools.

As noted above, these tenets are not part of every religion but rather are drawn from conservative strains of Catholicism and fundamental Protestant teachings. To illustrate the religious foundations of purported secular and

82. Elana Redfield et al., *Prohibiting Gender-Affirming Medical Care for Youth*, UCLA SCH. L. WILLIAMS INSTITUTE (March 2023), https://williamsinstitute.law.ucla.edu/publications/bans-trans-youth-health-care/ [https://perma.cc/8YVB-QUFF].

scientific claims, we draw on materials from the Vatican and from conservative evangelical organizations. While the Vatican's views are authoritative for Catholics worldwide, there is no central authority for conservative Protestants. Instead, we draw on materials from Liberty University and the Southern Baptist Convention to illustrate conservative Protestant views. Both are well-known evangelical Christian organizations with a history of taking conservative political positions on political matters, especially cultural matters.[83]

This Part begins with a brief overview of gender-affirming care and its scientific evidence base. We then examine the four tenets and show how misinformation and pseudoscience have been used to cast these as "scientific" or "common sense" claims. We conclude this Part by briefly describing how major court decisions have correctly rejected this misinformation and called out the religious pseudoscience and the experts promoting it.

Throughout this Part, we aim to briefly document the misinformation and pseudoscience that appears in statutes, briefs filed by state actors, and administrative agency filings. Our discussion of the scientific evidence is brief because the actual science of gender-affirming care has been deeply documented in the scientific literature and because we (and other researchers) have extensively debunked many of these arguments, with full scientific citations, in other work, which readers can consult.[84]

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83. Liberty University was founded in 1971 by Jerry Falwell, one of the leaders of the political Christian Right in the 1980s. *About Liberty*, LIBERTY UNIV., https://www.liberty.edu/about/ [https://perma.cc/6KUE-3HNY] (last visited Dec. 4, 2023); *History of Liberty*, LIBERTY UNIV., https://www.liberty.edu/about/history-of-liberty/ [https://perma.cc/86MX-WSJZ] (last visited Dec. 4, 2023). The university hosts conferences that feature right-wing speakers and views. *See, e.g.*, Logan Smith, *Sold-out Freedom Center Conference Brings in Top Conservative Influencers to Weigh in on Christians' role in Public Arena*, LIBERTY NEWS (Nov. 16, 2021) https://www.liberty.edu/news/2021/11/16/sold-out-freedom-center-conference-brings-in-top-conservative-influencers-to-weigh-in-on-christians-role-in-the-public-arena/ [https://perma.cc/8459-RKYF] (describing a "Freedom Uncensored" event that "brought in conservative influencers" to "weigh in on social issues, politics, Marxism, and a multitude of other concerns facing Christians and the Church." The Southern Baptist Convent is a body of more than 50,000 "like-minded local churches cooperating together to reach the world with the Good News of Jesus Christ." *About the SBC*, SO. BAPTIST CONVENT, https://www.sbc.net/about/ [https://perma.cc/N7P4-DBT2] (last visited Dec. 4, 2023). Their statement of faith includes the view that marriage is a lifelong covenant between a man and a woman and that wives must respect their husbands and serve as "helpers" by raising children. *Baptist Faith & Message 2000*, SO. BAPTIST CONVENT, https://bfm.sbc.net/bfm2000/#xviii [https://perma.cc/4HZ3-NNE8] (last visited Dec. 4, 2023). Their statement also treats "homosexuality" as a form of "sexual immorality" that must be opposed, along with adultery and pornography. *Id.* at Article XV. The SBC also announces an explicitly political mission: "Every Christian should seek to bring industry, government, and society as a whole under the sway of the principles of righteousness, truth, and brotherly love." *Id.*

84. *See* Susan D. Boulware, et al., *Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims*, YALE SCH. MED. (April 28, 2022), https://medicine.yale.edu/lgbtqi/research/gender-affirming-care/biased-science/ [https://perma.cc/AA9J-NYMU] (hereinafter, "Boulware et al. (2022)"); Meredithe McNamara, et al., *A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria*, YALE SCH. MED. (July 8, 2022), https://medicine.yale.edu/lgbtqi/research/gender-affirming-care/florida-medicaid/

A. The sound science of gender-affirming care

Gender-affirming care is evidence-based medical treatment recommended by every relevant major medical organization and supported by at least 17 sound studies. See Tables 2 and 4. The purpose of gender-affirming care is to treat gender dysphoria, a condition recognized by psychiatric authorities as the distress caused by the discordance between one's gender identity and the sex assigned at birth. [85] Put another way, individuals who live in a manner that is physically and socially incongruent with their gender identity can experience clinically significant psychological distress. Left untreated, gender dysphoria can lead to depressed mood, suicidal ideation, and disordered eating, among other negative effects.[86]

The leading guidelines for the medical treatment of transgender children and adolescents are published by the World Professional Association for Transgender Health (WPATH) and by the Endocrine Society.[87] See Table 2. Both sets of guidelines are based on reviews of the best available science conducted by panels of experts and independent, outside review.

In the early phases of treatment, gender-affirming care begins with social transition. When adolescence begins, physicians may prescribe puberty-pausing medications that delay the onset of distressing physical changes that

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[https://perma.cc/T433-BTT6] (hereinafter, "McNamara et al. (2022)"); Meredithe McNamara et al., *Protecting Transgender Health and Challenging Science Denialism in Policy*, 387 NEW ENG. J. MED. 1919 (2022); Christina Lepore et al., *Scientific Misinformation Is Criminalizing the Standard of Care for Transgender Youth*, 176 JAMA PEDIATRICS 965 (2022); Meredithe McNamara et al., *Scientific Misinformation and Gender Affirming Care: Tools for Providers on the Front Lines*, 71 J. ADOLESCENT HEALTH 251 (2022); Katherine L. Kraschel et al., *Legislation restricting gender-affirming care for transgender youth: Politics eclipse healthcare*, 3 CELL REPS. MED. 1 (2022); Nicholas Meade et al., *Understanding and Addressing Disinformation in Gender-Affirming Health Care Bans*, TRANSGENDER HEALTH (2023).

85. *What is Gender Dysphoria?*, AM. PSYCHIATRIC ASS'N., https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-gender-dysphoria [https://perma.cc/PE48-WTVE] (last visited July 20, 2023); AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (5th ed. 2013).

86. *See* Sorbara, et al., *Mental Heath and Timing of Gender-Affirming Care*, 146 PEDIATRICS (2020); Jody Herman et al, *Suicide Thoughts and Attempts Among Transgender Adults*, UCLA SCH. L. WILLIAMS INSTITUTE (Sept. 2019), https://williamsinstitute.law.ucla.edu/publications/suicidality-transgender-adults/ [https://perma.cc/8669-4Y4A]; Jennifer S. Coelho, et al., *Eating Disorder Diagnoses and Symptom Presentation in Transgender Youth: A Scoping Review*, 21 CURRENT PSYCHIATRY REP. 107 (2019); Rebecca C. Kamody et al., *Disordered Eating Among Trans-Masculine Youth: Considerations Through a Developmental Lens*, 7 LGBT HEALTH 170 (2020); Isabelle Legroux & Bernard Cortet, *Factors Influencing Bone Loss in Anorexia Nervosa: Assessment and Therapeutic Options*, 5 RMD OPEN 1 (2019).

87. *See* E. Coleman, et al., *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8,* 23 INT'L J. OF TRANSGENDER HEALTH S1 (2022), https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644 [https://perma.cc/4Y53-EHDV] (hereinafter, "WPATH (2022))"; Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. CLINICAL ENDOCRINOLOGY METABOLISM 3869 (2017) (hereinafter, "Endocrine Society (2017)").

occur in puberty (e.g., facial hair in those assigned male at birth or breast development in those assigned female at birth). Using such a medication allows the young person to receive supportive psychological care, understand their identities, and clarify their care goals. Older adolescents and adults with gender dysphoria may be prescribed cross-sex hormones, with the goal of enabling physical development that is concordant with gender identity. At each stage, medical providers obtain the informed consent of patients and (in the case of youth) their parents. And at each stage, care is provided only when gender dysphoria is well documented, and treatment is medically appropriate. Gender-affirming surgeries typically are performed only on adults.

The scientific evidence shows that gender-affirming medical care is effective. At least 17 solid studies show that puberty blockers and hormones benefit patients with gender dysphoria, with benefits including improved well-being and psychosocial functioning and reduced suicidality. See Table 4. For these reasons, the American Medical Association, the American Academy of Pediatrics, the American Psychological Association, and the American Academy of Child and Adolescent Psychiatry, among many other national and state medical authorities, have endorsed gender-affirming care.[88]

B. Misinformation and religious pseudoscience regarding gender-affirming care: four core claims

However, despite the scientific evidence and medical consensus, anti-trans legislation typically repeats a number of seemingly scientific claims about gender dysphoria and gender-affirming care. In other work, we and others have extensively debunked this misinformation.[89] Here, we show how four of these repeated claims – that sex and gender are binary and immutable; that trans people are confused or deluded; that secular authorities such as mainstream science and medicine are untrustworthy; and that society pushes "gender ideology" on youth via social media and schools – not only contradict sound scientific evidence but also map onto tenets of religious belief.

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88. *See* Table 2; *see also* Alyson Sulaski Wyckoff, *AAP Continues to Support Care of Transgender Youth as More States Push Restrictions*, AM. ACAD. OF PEDIATRICS, (January 6, 2022), https://publications.aap.org/aapnews/news/19021/AAP-continues-to-support-care-of-transgender [https://perma.cc/N84T-JMWD]; *Criminalizing Gender Affirmative Care with Minors*, AM. PSYCH. ASS'N, https://www.apa.org/pi/lgbt/gender-affirmative-care (last visited July 20, 2023); AM. ACAD. OF CHILD & ADOLESCENT PSYCHIATRY, *AACAP Statement Opposing Actions in Texas Threatening the Health, Mental Health and Well-Being of Transgender and Gender Diverse Youth and Their Families* (March 1, 2022), https://www.aacap.org/AACAP/zLatest_News/AACAP_Statement_Opposing_Actions_in_Texas.aspx [https://perma.cc/3PFN-RMZK]; Amy Lynn Sorrel, *TMA Supports Evidence-Based Gender-Affirming Care in Lawsuit*, TEXAS MED. ASS'N (March 14, 2022), https://www.texmed.org/TexasMedicineDetail.aspx?id=59040 [https://perma.cc/GX7S-9EVN].

89. *See supra* note 84.

We draw on statutes and legal briefs in Arkansas, Alabama, and Florida, along with a key administrative agency decision in Florida and an attorney general's opinion in Texas. We focus on these jurisdictions because, as the early initiators of healthcare bans in 2021 and 2022, they have produced the most extensive legal record to date. For each claim, we also draw on federal district court decisions in these jurisdictions to illustrate how trial courts, when provided with evidence by both sides, have consistently been able to distinguish real science from pseudoscience and, accordingly, have temporarily or permanently blocked such bans.

1. Sex and gender are binary and immutable

State health care bans often assert that biological sex is fixed and natural and that transgender identity is subjective and fleeting. The Alabama ban's statutory findings state, for example, that "[t]he sex of a person is the biological state of being female or male, based on sex organs, chromosomes, and endogenous hormone profiles, and is genetically encoded into a person at the moment of conception, and it cannot be changed."[90]

The Arkansas ban's statutory language emphasizes that "biological sex" is defined by "naturally occurring" hormones and does not take into account "an individual's psychological, chosen, or subjective experience of gender."[91] By contrast, the Alabama ban's findings imply that gender (if it departs from biological sex) may be imaginary: "The cause of the individual's *impression* of discordance between sex and identity is unknown, and the diagnosis is based exclusively on the individual's self-report of *feelings and beliefs*."[92]

Indeed, Tennessee's 2023 statute defines transgender identity and gender dysphoria in frankly skeptical terms, prohibiting medical treatment:

- Enabling a minor to identify with, or live as, a *purported identity inconsistent with the minor's sex*; or

90. ALA. CODE § 26-26-2 (2023).

91. 2021 Arks. Act 626.

92. S.B. 184, 2022 Reg. Sess., § (3)(3) (Ala. 2022) (emphasis added); *see also* Letter from Ken Paxton, Tex. Att'y Gen., to Honorable Matt Krause, Chair, House Comm. On Gen. Investigating, at 1, 4 (Feb. 18, 2022), https://texasattorneygeneral.gov/sites/default/files/global/KP-0401.pdf [https://perma.cc/LMB4-P77C] (referring to medical treatments that "transition individuals with gender dysphoria to their *desired* gender"; and stating that "it is particularly unethical to radically intervene in the *normal physical development of a child* to 'affirm' a 'gender identity' *that is at odds with bodily sex*") (italics added); Redacted Defendants' Response in Opposition to Motion for Preliminary Injunction and Incorporated Memorandum of Law at 3, Dekker v. Marstiller, No. 4:22-cv-00325-RH-MAF (N.D. Fla. Oct. 3, 2022), ECF No. 49 (stating that "[n]o laboratory tests, imaging, biopsies, or other objective tests exist to diagnose someone with gender dysphoria. No biological markers establish gender dysphoria as an immutable condition. Gender identity and, by extension, gender dysphoria are psychological constructs.").

- Treating *purported discomfort or distress* from a discordance between the minor's sex and asserted identity.[93]

As a matter of logic, the laws' insistence on a sex binary and its biological immutability is odd because it is irrelevant to the evidence on gender-affirming care. (Both the binary and its immutability are also overstated as a matter of science.)[94] As noted above, gender-affirming medical treatment aims to address gender dysphoria, which arises from a difference between gender identity and sex assigned at birth. Nothing in the scientific literature denies the existence of physical sex characteristics or the influence of biology of physical development. Indeed, gender-affirming care at and after puberty is designed to alter physical characteristics to align with gender identity.

Curiously, then, the assertion of an immutable binary is thus not doing any logical work in the case against gender-affirming care; rather, it is signaling an allegiance to the religious idea that God created man and woman and assigned them gender roles that accord with their physical sex. For example, the Florida statutory health care ban defines sex as "either male or female based on the organization of the human body of such person for a specific reproductive role."[95] This maps neatly onto the AC Peds statement that "[h]uman sexuality is binary by design with the obvious purpose being the reproduction and flourishing of our species" and that gender "is a sociological and psychological concept; not an objective biological one."[96]

The AC Peds statements, in turn, seems to reflect Catholic teaching. According to a Vatican document, "[I]t is from [their] sex that the human person receives the characteristics which, on the biological, psychological and spiritual levels, make that person a man or a woman, and thereby largely condition his or her progress towards maturity and insertion into society."[97]

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93. S.B. 1 § (a)(1), 2023 Leg., 113th Sess., at 68-33-101 (l) (Tenn. 2023) (emphasis added).

94. This is a large literature. For a recent review in a peer-reviewed journal, see Riska Ristori, et al., *Brain Sex Differences Related to Gender Identity Development: Genes or Hormones?* 21 INT'L J. MOL. SCI. 21123 (2020). For a sample of relevant studies documenting brain structures that align with gender identity, see, e.g., Florian Kurth, et al., *Brain Sex in Transgender Women Is Shifted towards Gender Identity*, 11 J. CLIN. MED. 1582 (2022); Milton Diamond, *Transsexuality Among Twins: Identity Concordance, Transition, Rearing, and Orientation*, 14 INT'L J. TRANS. 24 (2013); J.N. Zhou, et al., *A Sex Difference in the Human Brain and its Relation to Transsexuality*, 378 NATURE 68 (1995); Frank P. Kruijver, et al., *Male-to-female Transsexuals Have Female Neuron Numbers in a Limbic Nucleus*, 85 J CLIN ENDOCRINOL METAB. 2034 (2000); and Eileen Luders, et al., *Regional Gray Matter Variation in Male-to-female Transsexualism*. 36 NEUROIMAGE 893 (2009).

95. S.B. 254, 2023 Leg., 54th Sess. (Fla 2023).

96. AC PEDS, GENDER IDEOLOGY HARMS CHILDREN (2017), https://acpeds.org/assets/imported/9.14.17-Gender-Ideology-Harms-Children_updated-MC.pdf [https://perma.cc/RZW8-DE4A] (emphasis added).

97. CONGREGATION FOR CATH. EDU., "MALE AND FEMALE HE CREATED THEM": TOWARDS A PATH OF DIALOGUE ON THE QUESTION OF GENDER THEORY IN EDUCATION (2019), http://www.educatio.va/content/dam/cec/Documenti/19_0997_INGLESE.pdf (internal quotation marks omitted), *citing* CONGREGATION FOR THE DOCTRINE OF THE FAITH, PERSONA HUMANA, DECLARATION ON CERTAIN QUESTIONS CONCERNING SEXUAL ETHICS 1 (Dec. 29, 1975).

Some of the ADF's purported experts use words much like these when they are addressing religious audiences: Patrick Lappert, for instance, told a Catholic publication that

> Transgenderism and the whole gender ideology business are inhuman, because they separate our souls from our bodies. They propose the essence of who we are has nothing to do with our body, contrary to revealed truth and to the revelation of Jesus Christ in his Incarnation. So this is not a small theological question. This is at the heart of our path to salvation.[98]

Lappert also referred to gender affirmation surgery as "an intentional mutilation."[99]

Indeed, the court in *Dekker v. Weida* detected just this kind of subtext. The court notes:

> An unspoken suggestion running just below the surface in some of the proceedings that led to adoption of the rule and statute at issue—and just below the surface in the testimony of some of the defense experts and [state of Florida] consultants—is that transgender identity is not real, that it is made up... And so, for example, one of the defendants' experts, Dr. Paul Hruz, joined an amicus brief in another proceeding asserting transgender individuals have only a "false belief" in their gender identity—that they are maintaining a "charade" or "delusion."[100]

Healthcare bans often also rely on assertions that transgender identity is malleable and fleeting. In *Dekker*, for example, the state of Florida claimed that, "[b]roadly speaking, most of those with gender dysphoria revert to their birth sex."[101] The Arkansas ban's legislative findings assert that "[f]or the small percentage of children who are gender nonconforming or experience distress at identifying with their biological sex, studies consistently demonstrate that the majority come to identify with their biological sex in adolescence or adulthood, thereby rendering most physiological interventions unnecessary."[102] Similar statements appear in state statutes and other state legal filings.[103]

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98. Gina Christian, *Transgender Interventions Pose Serious Medical Consequences for Minors, Says Surgeon*, THE TABLET (April 17, 2023), https://thetablet.org/transgender-interventions-pose-serious-medical-consequences-for-minors-says-surgeon/ [https://perma.cc/M5B4-4DQ6].

99. Remote Videotaped Videoconference Deposition Testimony of: Patrick Lappert, M.D. at 60, Kadel v. Folwell, No. 1:19-cv-00272-LCB-LPA (M.D.N.C. Sep. 30, 2022), ECF No. 209-3.

100. Dekker v. Weida, No. 4:22cv325-RH-MAF, 2023 WL 4102243 at *2 (N.D. Fla. June 21, 2023).

101. Redacted Defendants' Response in Opposition to Motion for Preliminary Injunction and Incorporated Memorandum of Law at 27, Dekker v. Marstiller, No. 4:22-cv-00325-RH-MAF (N.D. Fla. Oct. 3, 2022), ECF No. 49.

102. H.B. 1570, 93rd Gen. Ass., Reg. Sess (Ark. 2021).

103. *See* Defendants' Response in Opposition to Plaintiff's Motion for Preliminary Injunction at 17, Eknes-Tucker v. Ivey, No. 2:22-cv-0184-LCB-SRW (M.D. Ala. May, 2 2022), ECF No. 74 ("If not given medical interventions to transition—and that is an important if—most children with [gender dysphoria] will grow up to identify as gay or lesbian and will not suffer from [gender dysphoria] as adults.").

This so-called "desistance" claim is potentially relevant to gender-affirming care for the reason that the Arkansas ban states. If it were the case that transgender people usually cease being transgender after a short period, one could argue that it would be prudent to hold off on major physical changes. One might oppose such an argument on the grounds of personal autonomy, but we need not delve further into the details, because the states' claims are simply untrue. Repeated state assertions about the fleeting nature of trans identity are based on a misleading presentation of outdated studies.

Studies demonstrate that both prepubertal children and adolescents can express a transgender identity and experience gender dysphoria. Several older studies of prepubertal children used expansive criteria for gender nonconformity or gender incongruity (rather than stricter, modern criteria for gender dysphoria). Using these broad categories, the early studies often included, for instance, "tomboy" girls or "feminine" boys (who would not today be considered to have gender dysphoria). It is true that several of these studies found that the majority of prepubertal children did not identify as transgender in adolescence; many were gay or lesbian. However, even this older literature found that transgender *adolescents* continued to be trans and to experience gender dysphoria into adulthood. Thus, even these studies would suggest that gender-affirming care is sound because medical treatment begins only in adolescence, when gender identity has solidified.

More recent studies using the narrower, modern category of gender dysphoria suggest that even young transgender children continue to be transgender into adolescence and beyond.[104] 94% of prepubertal transgender children who socially transitioned continued to identify as trans after five years.[105] This study, importantly, studied prepubertal children who had chosen to make a full social transition (rather than, as in earlier studies, children observed to have gender nonconforming behaviors).

Given the nonexistent scientific foundations for "desistance" claims, why do state actors continue to repeat them? One explanation is that these statements, once again, signal a theological rather than scientific message. Biology, on this view, is immutable and God's design, while human perceptions of discordant gender identity are untrue and unverifiable and at odds with God's plan. According to the Vatican:

> [T]he propositions of gender theory converge in the concept of 'queer', which refers to dimensions of sexuality that are *extremely fluid, flexible, and as it were, nomadic*. This culminates in the assertion of the *complete emancipation of the individual from any*

104. Kristina R. Olson et al., *Gender Identity Five Years After Social Transition*, PEDIATRICS (preprint, May 2022).

105. *Id.*

> *a priori given sexual definition* and the disappearance of classifications seen as overly rigid.[106]

Patrick Lappert, the ADF repeat witness, made a similar connection in an interview, stating that "changing a person's sex is a lie and also a moral violation for a physician."[107]

Along similar lines, Liberty University, a well-known evangelical Christian college founded by Jerry Falwell, [108] includes "denial of birth sex by self-identification with a different gender" as one of a list of "sinful acts" that also includes "participation in devil worship, practice of the occult, astrology, fortune-telling, sorcery, or witchcraft."[109] The Southern Baptist Convention, a Protestant evangelical sect that in 2023 voted to ban female pastors, also resolved that "the differences between men and women are complementary, determined at conception, immutable, rooted in God's design, and most clearly revealed in bodily differences (Genesis 1:28; Psalm 100:3), not in self-defined and ultimately false notions of 'gender identity.'"[110]

Trial courts have, to date, decisively rejected the states' efforts to cast sex as binary, immutable, and determinative of gender. In *Dekker*, plaintiffs challenged Florida regulations and a later-enacted statute that imposed a blanket denial of Medicaid coverage for gender-affirming care for people of all ages on the grounds (according to the state) that such care is "experimental."[111] The *Dekker* trial court opinion offers a scathing rejection of the state's use of misinformation and religious pseudoscience. Leading with the heading, "Gender identity is real," the court's decision calls out "the elephant in the room:" "[A] n unspoken suggestion running just below the surface in

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106. *See* CONGREGATION FOR CATH. EDU., *supra* note 97.

107. Lisa Bourne, *Plastic Surgeon: Sex-Change Operation "Utterly Unacceptable" and a Form of "Child Abuse,"* LIFESITE (Sept. 9, 2019, 6:42 PM), at https://www.lifesitenews.com/news/plastic-surgeon-sex-change-operation-utterly-unacceptable-and-a-form-of-child-abuse/ [https://perma.cc/M3T9-C3QK].

108. The school's mission statement says that "Liberty University is a distinctively Christian academic community," and states that Liberty University will "[e]ncourage a commitment to the Christian life, one of personal integrity, sensitivity to the needs of others, social responsibility and active communication of the Christian faith, and, as it is lived out, a life that leads people to Jesus Christ as the Lord of the universe and their own personal Savior." *Educational Philosophy & Mission Statement*, LIBERTY UNIV., https://www.liberty.edu/about/purpose-and-mission-statement/ [https://perma.cc/3AME-ZU9U] (last visited June 20, 2023).

109. *Doctrinal Position*, LIBERTY UNIV., https://www.liberty.edu/about/doctrinal-statement/ [https://perma.cc/7EEG-XPBG] (last visited July 20, 2023); see also *Baptist Faith & Message 2000*, SO. BAPTIST CONVENTION, https://bfm.sbc.net/bfm2000/ [https://perma.cc/SW4M-D7XE] (last visited July 20, 2023) ("Man is the special creation of God, made in His own image. He created them male and female as the crowning work of His creation. The gift of gender is thus part of the goodness of God's creation.").

110. *On Opposing "Gender Transitions,"* SO. BAPTIST CONVENTION, https://www.sbc.net/resource-library/resolutions/on-opposing-gender-transitions/ [https://perma.cc/FKW7-2Y49] (last visited July 20, 2023) (emphasis added).

111. Dekker v. Weida, No. 4:22CV325-RH-MAF, 2023 WL 4102243 (N.D. Fla. June 21, 2023).

[administrative proceedings and at the trial] is that transgender identity is not real, that it is made up.[112]

The *Dekker* opinion goes on to call out the deliberate discrimination animating the state's actions:

> [T]he State's disapproval of transgender status...was a substantial motivating factor in enactment of the challenged rule and statute. Discouraging individuals from pursuing their gender identities, when different from their natal sex, was also a substantial motivating factor.[113]

The opinion characterizes the "laundry list of purported [scientific] justifications for the statute and rules" as "largely pretextual"[114] and found that the process leading to the adoption of the Medicaid ban was tainted by anti-trans bias. Florida's Medicaid agency retained purported "experts" known for their opposition to gender-affirming care, and "[t]he [administrative process] was, from the outset, a biased effort to justify a predetermined outcome, not a fair analysis of the evidence."[115] Even the agency's hearing on the proposed rule was not conducted in good faith: the "well-choreographed public hearing" was "an effort not to gather facts but to support the predetermined outcome."[116]

2. Trans people are confused or deluded

State documents enacting or defending health care bans often state or imply that transgender people are mentally ill, confused, and unable to identify their own gender or consent to gender-affirming care. State statutes and legal briefs commonly offer three related types of "confusion" narratives.

The first line of argument is that transgender people are mentally ill. As the state of Alabama wrote:

> Many, if not most, gender dysphoric children also suffer from "significant comorbid mental health disorders, have

112. *Id.* at *2. The court went on: "Any proponent of the challenged rule and statute should put up or shut up: do you acknowledge that there are individuals with actual gender identities opposite their natal sex, or do you not? Dog whistles ought not be tolerated." *Id.* The court repeated many of these criticisms in *Doe v. Ladapo*, granting a preliminary injunction against a statutory health care ban and an administrative health ban adopted by the state's Board of Medicine. The judge had already engaged in full fact-finding in a substantively related case challenging Florida's administrative ban on Medicaid coverage for gender-affirming care and, thus, had the benefit of an extensive factual record. *See* Doe v. Ladapo, No. 4:23cv114-RH-MAF, 2023 WL 3833848 (N.D. Fla. June 6, 2023) (citing trial record in *Dekker v. Weida*, 2023 WL 4102243). The parties in Doe stipulated to the use of the factual record in *Dekker*.

113. *Dekker*, 2023 WL 4102243, at *14.

114. *Id.*

115. *Id.* at *4.

116. *Id.*

> neurocognitive difficulties such as ADHD or autism[,] or have a history of trauma."[117]

The implication is that trans children do not actually have gender dysphoria but rather some underlying mental illness that is misdiagnosed. The state of Florida made the asserted causal connection plain, writing that "[f]or those with gender dysphoria, regardless of age, there was a greater likelihood of comorbidities--some other affliction--being the root cause of distress and even suicide."[118] The Arkansas statute, similarly, includes in its findings of fact that "individuals struggling with distress at identifying with their biological sex often have already experienced psychopathology, which indicates these individuals should be encouraged to seek mental health services to address comorbidities and underlying causes of their distress before undertaking any hormonal or surgical intervention."[119]The scientific evidence shows that these claims are misleading. Studies do show that trans people, including youth, have higher rates of anxiety, depression, and other conditions than cisgender people. But it is facile to conclude, as the states do, that these conditions must, therefore, *cause* gender dysphoria.

Indeed, the scientific evidence strongly suggests that the direction of causation runs the other way. It is well-established that being transgender leads to mental health concerns because of the social stress and discrimination of being transgender in a society that is strongly oriented to cisgender identity. [120] Transgender individuals experience a great deal of discrimination, hostility, and physical violence.[121] Accumulation of existential fear and threatening experiences can manifest as physical and mental conditions. Thus, one would expect—and studies confirm—that transgender people, on average, have worse physical and mental health than cisgender people.

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117. Defendants' Response in Opposition to Plaintiff's Motion for Preliminary Injunction at 16, Eknes-Tucker v. Ivey, No. 2:22-cv-0184-LCB-SRW (M.D. Ala. May, 2 2022), ECF No. 74.

118. Redacted Defendants' Response in Opposition to Motion for Preliminary Injunction and Incorporated Memorandum of Law at 5, Dekker v. Marstiller, No. 4:22-cv-00325-RH-MAF (N.D. Fla. Oct. 3, 2022), ECF No. 49. *See also* Defendants' Motion for Summary Judgment and Memorandum of Law at 18, Dekker v. Marstiller, No. 4:22-cv-00325-RH-MAF (N.D. Fla. Oct. 3, 2022), ECF No. 49 ("those with gender dysphoria likely have mental health comorbidities—anxiety disorders, ADHD, autism spectrum disorder, OCD, for example...As such, it remains unclear whether hormone therapies and surgeries will resolve underlying mental-health concerns.") (internal citations omitted).

119. 2021 Arks. Act 626 § 2(4).

120. Rylan J. Testa, et al., *Development of the Gender Minority Stress and Resilience Measure*, 2 PSYCH. SEXUAL ORIENTATION & GENDER DIVERSITY 65 (2015); Rylan J. Testa et al., *Suicidal Ideation in Transgender People: Gender Minority Stress and Interpersonal Theory Factors*, 126 J. ABNORMAL PSYCH. 125 (2017); Alexandria M. Delozier et al., *Health Disparities in Transgender and Gender Expansive Adolescents: A Topical Review from a Minority Stress Framework*, 45 J. PEDIATRIC PSYCH. 842 (2020); Jessica Hunter, et al., *Gender Minority Stress in Trans and Gender Diverse Adolescents and Young People*, 26 CLINICAL CHILD PSYCH. & PSYCHIATRY 1182 (2021).

121. *See, e.g.*, Rebecca L. Stotzer, *Violence Against Transgender People: A Review of United States Data*, 14 AGGRESSION & VIOLENT BEHAVIOR 170 (2009).

Further, the co-occurrence of psychological distress among people gender dysphoria does not support healthcare bans. Medical providers are aware, and the WPATH and Endocrine Society clinical practice guidelines recognize, that there is a higher prevalence of anxiety, depression and post-traumatic stress disorder among transgender youth than among cisgender youth. In response, the guidelines include a careful psychological assessment as part of the process for determining whether medical treatment for gender dysphoria is appropriate.[122]

A second type of "confusion" narrative claims that trans people are incompetent to consent to informed consent. The Texas Attorney General, for example, states that "[c]hildren and adolescents are promised relief and asked to 'consent' to life-altering, irreversible treatment—and to do so in the midst of reported psychological distress, when they cannot weigh long-term risks the way adults do."[123]

But this claim is misleading and fatally flawed. The statement that "children" are asked to consent is false: under the law of every state, minors cannot generally consent to medical treatment and parental consent is required. Thus, gender-affirming care proceeds only if parental consent is obtained, the WPATH and Endocrine Society guidelines set out extensive informed-consent procedures that require extended conversations among parents, child, and medical providers. It is true that youth assent, in addition to parental consent, is required, and experts have established that youth can make complex medical decisions. Further, the literature specifically demonstrates that transgender youth with co-occurring mental health conditions can competently participate in decision-making.[124]

A third variant of the "confusion" narrative asserts that youth with gender dysphoria should not be offered medical treatment but instead should only receive psychotherapy.[125] This position is likely a veiled nod to so-called

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122. Endocrine Society (2017), *supra* note 87.

123. Letter from Ken Paxton, Tex. Att'y Gen., to Honorable Matt Krause, Chair, House Comm. On Gen. Investigating at 4 (Feb. 18, 2022), https://texasattorneygeneral.gov/sites/default/files/global/KP-0401.pdf [https://perma.cc/LMB4-P77C].

124. Lieke J. Vrouenraets et al., *Assessing Medical Decision-Making Competence in Transgender Youth*, 148 PEDIATRICS 1 (2021); Beth A. Clark & Alice Virani, *"This Wasn't a Split-Second Decision": An Empirical Ethical Analysis of Transgender Youth Capacity, Rights, and Authority to Consent to Hormone Therapy*, 18 J. BIOETHICAL INQUIRY 151-64 (2021); Megan S. O'Brien, *Critical Issues for Psychiatric Medication Shared Decision Making with Youth and Families*, 92 FAMILIES IN SOCIETY 310 (2011); Mary Ann McCabe, *Involving Children and Adolescents in Medical Decision Making: Developmental and Clinical Considerations*, 21 J. PEDIATRIC PSYCHOLOGY 505-16 (1996).

125. For example, the Florida Medicaid Division Report asks, "[S]hould conventional behavioral health services be utilized without proposing treatments that pose irreversible effects [i.e., drug therapies]? Would that approach not provide additional time to address underlying issues before introducing therapies that pose permanent effects (i.e., the watchful waiting approach)?" DIV.OF FLA. MEDICAID, *supra* note 78. The report misuses the term "watchful waiting" to describe the denial of medical care to adolescents with gender dysphoria, and the report miscites its own purported expert

"gender exploratory therapy," also known as conversion therapy, which seeks to persuade trans people to identity with their biological sex.[126] But the Florida administrative agency document that asserts this proposition offers no solid evidence for denying gender-affirming care.[127] (Indeed, conversion therapy has been shown to be extremely harmful, has been denounced by every major medical association, and is banned in many states.)[128] The states of Arkansas and Florida unsuccessfully repeated the psychotherapy-only position in litigation.[129]

Although the "confusion" narrative thus has no scientific support, it does resonate with Catholic theology. The Vatican underscores that identity should be based solely on one's biological sex and that "the fictitious construct known as 'gender neuter' or 'third gender'...obscur[es] the fact that a person's [biological] sex is a structural determinant of male or female identity."[130] Catholic teaching holds that the sex binary is the foundation of human identity, family, and society.[131] Thus, transgenderism is at best confusion and at worst a rejection of God's design.[132]

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report. *Id.* at 20. The Cantor document discusses "watchful waiting" meaning the denial of social transition to prepubertal children, not the denial of medical treatment to adolescents. JAMES M. CANTOR, REP. SUBMITTED TO THE FLA. AGENCY FOR HEALTHCARE ADMIN. 10-11 (2022).

126. See the anonymous report on the AC Peds website. Anonymous, *Psychotherapeutic and Behavioral Approaches to Treating Gender Dysphoria*, AM. COLL. OF PEDIATRICIANS, https://acpeds.org/blog/psychotherapeutic-and-behavioral-approaches-to-treating-gender-dysphoria [https://perma.cc/L8KA-CHM2] (last visited July 20, 2023).

127. *See* McNamara, et al. (2022), *supra* note 84, at 27–28.

128. *See, e.g.*, Jack L. Turban et al., *Association Between Recalled Exposure to Gender Identity Conversion Efforts and Psychological Distress and Suicide Attempts Among Transgender Adults*, 77 JAMA PSYCHIATRY 68 (2020); Jack Drescher & Kenneth J. Zucker, *Position Statement on Therapies Focused on Attempts to Change Sexual Orientation (Reparative or Conversion Therapies)*, 157 AM. J. PSYCHIATRY 10, 1719 (2000); *The AACAP Policy on "Conversion Therapies,"* AM. ACADEMY OF CHILD & ADOLESCENT PSYCHIATRY, (Feb. 2018), https://www.aacap.org/AACAP/Policy_Statements/2018/Conversion_Therapy.aspx [https://perma.cc/94MJ-VRKK]; Hilary Daniel & Renee Butkus, *Lesbian, Gay, Bisexual, and Transgender Health Disparities: Executive Summary of a Policy Position Paper From the American College of Physicians*, 163 ANNALS INTERNAL MED. 135 (2015); AM. ACADEMY OF PEDIATRICS, COMMITTEE ON ADOLESCENCE, *Homosexuality and Adolescence*, 92 Pediatrics 4, 631 (1993); *Advisory Committee on LGBTQ Issues*, AM. MED. ASS'N, https://www.ama-assn.org/member-groups-sections/advisory-committee-lgbtq-issues [https://perma.cc/BQ23-A86Q] (last visited July 20, 2023).

129. *See* Brandt v. Rutledge, No. 4:21CV00450 JM, 2023 WL 4073727, at *3 (E.D. Ark. June 20, 2023) (finding that "efforts to change an individual's gender identity can harm individuals by increasing feelings of shame and creating an expectation that change is possible when it is not, which can increase a sense of failure") and *7 ("Psychotherapy can be important for individuals with gender dysphoria to address and alleviate other conditions such as depression and anxiety, but it does not alleviate the underlying distress due to the incongruence between a person's gender identity and birth-assigned sex. There are no psychotherapeutic interventions that have been demonstrated to be effective at alleviating the gender dysphoria itself.") (internal citations omitted).

130. CONGREGATION FOR CATH. EDU., *supra* note 97, at 13.

131. *Id.* at 19 ("The denial of this duality not only erases the vision of human beings as the fruit of an act of creation but creates the idea of the human person as a sort of abstraction who chooses for himself what his nature is to be....But if there is no pre-ordained duality of man and woman in creation,

"Confusion" is frequently invoked by AC Peds, with the group's webpage headed "Gender Confusion and Transgender Identity."[133] The AC Peds position statement on gender dysphoria recites that "[a] person's belief that he is something or someone he is not is, at best, a sign of confused thinking; at worst, it is a delusion."[134]

Family Life, a conservative Protestant organization, also treats transgender identity as mistaken. Addressing the hypothetical story of Bryce, a transgender boy, the site advises, "we need to remember that God made them to be a man or a woman, with a male body or a female body, and so how they feel about themselves is not what God wants for them. Bryce is a girl, because God made her that way."[135]

"Confusion" morphs into sin in the Southern Baptist Convention's 2023 resolution, which opposes "gender transition" as "a futile quest to change one's sex and as a direct assault on God's created order" and "call[s] on any members of the Southern Baptist Convention who are performing or actively supporting 'gender transition' interventions to immediately *repent* and refrain."[136]

One Florida House member made his religious views quite clear, calling transgender witnesses at a hearing "mutants" and "demons." The federal court decisions in *Dekker* and *Doe v. Ladapo* took note of the exchange in finding that the state's health care bans were animated by discriminatory intent: "There has long been, and still is, substantial bigotry directed at transgender individuals. Common experience confirms this, as does a Florida legislator's remarkable reference to transgender witnesses at a committee hearing as 'mutants' and 'demons.'"[137]

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then neither is the family any longer a reality established by creation. Likewise, the child has lost the place he had occupied hitherto and the dignity pertaining to him.").

132. *Id.* at 18 ("The Holy Scripture reveals the wisdom of the Creator's design, which "has assigned as a task to man his body, his masculinity and femininity; and that in masculinity and femininity he, in a way, assigned to him as a task his humanity, the dignity of the person, and also the clear sign of the interpersonal communion in which man fulfils himself through the authentic gift of himself.").

133. *Gender Confusion and Transgender Identity*, AM. COLL. OF PEDIATRICIANS, https://ACPeds.org/topics/sexuality-issues-of-youth/gender-confusion-and-transgender-identity [https://perma.cc/WV9J-UPD7] (last visited July 20, 2023).

134. *Gender Dysphoria in Children*, AM. COLL. OF PEDIATRICIANS, https://ACPeds.org/position-statements/gender-dysphoria-in-children [https://perma.cc/U6KC-M866] (last visited July 20, 2023).

135. *Talking to Your Kids About Transgender Issues*, FAM. LIFE, https://www.familylife.com/articles/topics/parenting/foundations/spiritual-development/talking-to-your-kids-about-transgender-issues/ [https://perma.cc/PK23-8THR] (last visited July 20, 2023).

136. *On Opposing "Gender Transitions,"* SO. BAPTIST CONVENTION, https://www.sbc.net/resource-library/resolutions/on-opposing-gender-transitions/ [https://perma.cc/FKW7-2Y49] (emphasis added) (last visited July 20, 2023).

137. Dekker v. Weida, No. 4:22CV325-RH-MAF, 2023 WL 4102243, at *16 (N.D. Fla. June 21, 2023); Doe v. Ladapo, No. 4:23cv114-RH-MAF, 2023 WL 3833848, at *13 (N.D. Fla. June 6, 2023).

3. Secular authority, including science and medicine, is untrustworthy

As noted above, every major medical association has endorsed gender-affirming care, and care is provided according to longstanding (and updated) guidelines from WPATH and the Endocrine Society. See Table 2. In an effort to counter these facts, state health care bans often claim that the mainstream medical community is untrustworthy. These assertions—which, as a shorthand, we call the "victimization claim"—characterize doctors as predators, fueled by political ideology and a disregard for children's well-being, who push impressionable youth into damaging medical procedures.

For example, the Alabama ban includes in its findings that "[s]ome in the medical community are aggressively pushing for interventions on minors that medically alter the child's hormonal balance and remove healthy external and internal sex organs."[138] The state of Florida attacks Plaintiffs' experts' characterization of WPATH as a "preeminent medical organization," instead characterizing it as "an advocacy organization where non-medical experts can work on the standards"[139] and "an 'echo-chamber' that can't 'claim to speak for the medical profession.'"[140]

In litigation, the state of Alabama described gender-affirming care as "unproven, sterilizing, and permanently scarring medical interventions pushed by ideological interest groups"[141] and charged that "the American Medical Association and the American Academy of Pediatrics continue to follow the popular zeitgeist when it comes to unproven gender-affirming interventions."[142] The state of Florida went a step further, casting gender-affirming care as analogous to past discredited therapies including eugenics, lobotomies, opioids, and cigarettes:[143] "[M]edical history is littered with such groups and prominent physicians getting things wrong, often with disastrous consequences."[144]

The Texas Attorney General discusses the widespread harms of opioids as "an epidemic caused largely by pharmaceutical companies and medical

138. S.B. 184, 2022 Reg. Sess., § (2)(6) (Ala. 2022).

139. Defendants' Motion for Summary Judgment and Memorandum of Law at 4, Dekker v. Marstiller, No. 4:22-cv-00325-RH-MAF (N.D. Fla. Oct. 3, 2022), ECF No. 120.

140. *Id.* at 20 (internal quotations omitted).

141. Defendants' Response in Opposition to Plaintiff's Motion for Preliminary Injunction at 7–8, Eknes-Tucker v. Ivey, No. 2:22-cv-0184-LCB-SRW (M.D. Ala. May, 2 2022), ECF No. 74.

142. *Id.* at 58.

143. Redacted Defendants' Response in Opposition to Motion for Preliminary Injunction and Incorporated Memorandum of Law at 7–8, Dekker v. Marstiller, No. 4:22-cv-00325-RH-MAF (N.D. Fla. Oct. 3, 2022), ECF No. 49.

144. *Id.* at 14.

professionals"[145] to draw comparisons to gender-affirming care. An amicus brief filed by fifteen states in Alabama referred to "the rush by some practitioners to supply these vulnerable young people with life-altering drugs and surgical treatment."[146] The states' assertions are backed up only by anecdotal evidence, however.[147] Litigating states typically offer testimony by so-called "detransitioners"—people who received gender-affirming care and subsequently reverted back to living as the gender they were assigned at birth.[148] These testimonials present disturbing accounts of doctors and complicit parents rushing the affiants into treatment, making outlandish promises, and providing inadequate information about risks and benefits.[149]

The state legal documents also marshal a grab bag of other sources for the victimization claim: opinion pieces;[150] policy positions by medical organizations that (the states contend) demonstrate the political motives underlying gender-affirming care;[151] letters to the editors of scientific journals, including by doctors linked to right-wing medical organizations;[152] articles

145. Letter from Ken Paxton, Tex. Att'y Gen., to Honorable Matt Krause, Chair, House Comm. On Gen. Investigating at 4 (Feb. 18, 2022), https://texasattorneygeneral.gov/sites/default/files/global/KP-0401.pdf [https://perma.cc/LMB4-P77C].

146. Brief of Arkansas, et al. as Amici Curiae Supporting Defendants at *1, Eknes-Tucker v. Ivey, No. 2:22-cv-0184-LCB 2022 WL 19983530 (M.D. Ala. May 2, 2022) (hereinafter "Fifteen States Amicus").

147. In support of their claim that youth are being rushed into treatment, the fifteen states cite two *Washington Post* opinion pieces, one by Edwards-Leeper and Anderson and another by a detransitioner; interviews with Anderson and WPATH President Marci Bowers published on the Substack of political commentator Bari Weiss; an *Economist* article reporting and opining on these interviews; and a quote from a former psychotherapist with the UK Gender Identity Development Service – included in an article on the website *Medscape* – who left her job because she felt that young people were being rushed into treatment. *See* Fifteen States Amicus, at 10 n.5; 8; 11 n.12; 13 n.17.

148. As the *New York Times* recently documented, a small group of activists have come to wield outsize influence in legal and legislative fights over access to gender-affirming care across the country, becoming "fixtures" at hearings and rallies to voice their support for care bans. *See* Maggie Astor, *How a Few Stories of Regret Fuel the Push to Restrict Gender Transition Care*, N.Y. TIMES (May 16, 2023), https://www.nytimes.com/2023/05/16/us/politics/transgender-care-detransitioners.html.

149. *See*, *e.g.*, Defendants' Response in Opposition to Plaintiffs' Motion for Preliminary Injunction at 54, Eknes-Tucker v. Ivey, No. 2:22-cv-184-LCB (M.D. Ala. May 2, 2022), ECF No. 74 (quoting affidavit of Carol Freitas); Redacted Defendants' Response in Opposition to Motion for Preliminary Injunction and Incorporated Memorandum of Law at 8, Dekker v. Marstiller, No. 4:22-cv-00325-RH-MAF (N.D. Fla. Oct. 3, 2022), ECF No. 49 (quoting affidavit of Chloe Cole); Defendants' Combined Brief in Opposition to Plaintiffs' Motion for Preliminary Injunction; and Reply in Support of Defendants' Motion to Dismiss at 19, Brandt v. Rutledge, No. 4:21-cv-00450-JM (E.D. Ark. Jul. 9, 2021) (henceforth "Brandt Brief in Opposition to PI"), ECF No. 44 (citing detransitioner Laura Perry's affidavit to assert that Perry's gender dysphoria resulted from sexual abuse and from her mother wishing she was a boy).

150. *See, e.g.*, Fifteen States Amicus, *supra* note 146, at 5 n.12.

151. *Id.* at 7–12.

152. *See*, e.g., Brandt Brief in Opposition to PI, at 27-28 n.89-93. One of the letters Arkansas cites in its brief is from Andre Van Mol, Co-Chair of the American College of Pediatricians' (AC Peds) Committee on Adolescent Sexuality. *See About the Author, Andre Van Mol*, PUBLIC DISCOURSE: J. WITHERSPOON INST., https://www.thepublicdiscourse.com/author/andre-van-mol/ [https://perma.cc/A6AJ-TYJ5] (last visited May 27, 2023). AC Peds has been classified by the Southern Poverty Law Center as a hate group. SO. POVERTY L. CTR., *supra* note 48.

about the history of forced sterilization against minority populations;[153] and TikTok videos of a surgeon talking about hormone treatments and surgery.[154]

Trial courts have, to date, roundly rejected the victimization claim. In *Dekker*, for example, the District Court concluded: "[I]t is fanciful to believe that all the many medical associations who have endorsed gender-affirming care, or who have spoken out or joined an amicus brief supporting the plaintiffs in this litigation, have so readily sold their patients down the river."[155]

In *Brandt*, the District Court noted that:

> The State argues that many doctors do not require mental health counseling before treatment and will let children get hormone therapy and permanently altering surgeries upon demand. The evidence at trial did not support the State's argument. The State's experts admitted that they have had no contact with any Arkansas doctors or information about how doctors in Arkansas treat minors with gender dysphoria.[156]

The state's purported expert, sociologist Mark Regnerus, claimed that the medical community's support for gender-affirming care is grounded in "ideology rather than science," but the court rejected that claim, finding that Regnerus "did not offer any support for his conclusion, and the Court finds that there is no evidence to support this assertion."[157]

In Florida, a federal district judge refused to credit the state's account of avaricious and ideological doctors pushing care on children: "The overwhelming majority of doctors are dedicated professionals whose first goal is the safe and effective treatment of their patients. There is no reason to believe the doctors who adopted these standards were motivated by anything else."[158] In Kentucky, the district court explicitly rejected the state's claim that gender-affirming care is suspect because it is a huge "money maker" for providers. Noting that the cited authority was a video of one doctor making a claim about surgery (not drug treatment), the court concluded that the state "offers no evidence" that Kentucky doctors prescribe gender-affirming drugs "for financial gain as opposed to patients' well-being."[159]

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153. Letter from Ken Paxton, Tex. Att'y Gen., to Honorable Matt Krause, Chair, House Comm. On Gen. Investigating at 3 n.4 (Feb. 18, 2022), https://texasattorneygeneral.gov/sites/default/files/global/KP-0401.pdf [https://perma.cc/LMB4-P77C].

154. *See* Fifteen States Amicus, *supra* note 146, at 7 n.24.

155. Dekker v. Weida, No. 4:22CV325-RH-MAF, 2023 WL 4102243, at *17 (N.D. Fla. June 21, 2023).

156. Brandt v. Rutledge, No. 4:21CV00450 JM, 2023 WL 4073727, at *35 (E.D. Ark. June 20, 2023).

157. *Id.* at *28.

158. *Dekker*, 2023 WL 4102243, at *17.

159. Doe 1 v. Thornbury, No. 3:23-cv-230-DJH, 2023 WL 4230481, at *9 (W.D. Ky. June 28, 2023).

Trial courts have also taken a skeptical view of detransitioner testimony. In Arkansas, the court noted that "[r]egret over a medical procedure is not unique to gender-affirming medical care and is common in medicine."[160] Evaluating the testimony of the two witnesses offered by the state, the court found the "anecdote[es]" to be "irrelevant to the issues to be decided," because the witnesses were not treated in Arkansas, transitioned as adults, "detransitioned as a result of a religious experience and ... continued to struggle with living consistently with their birth-assigned sex after deciding to detransition."[161]

Once again, the victimization claim, as it appears in state legal documents, is framed in secular terms but sounds in a religious register. It maps onto an argument, often made by evangelical activists, that Christian communities are under threat from sinful cultural forces pressuring them to abandon the tenets of their faith. This sort of persecution narrative has long held sway in American evangelical life.[162] Professor Elizabeth Castelli has noted, for example, that the Christian right increasingly "mobilize[d] the language of religious persecution to shut down political debate and critique," characterizing any dissent as "an example of antireligious bigotry."[163]

For example, *Decision* magazine ("The Evangelical Voice for Today") writes that "[t] he brokenness of the world explains why sinners will often deny the distinctions between male and female.... Christians guided by Scripture recognize that controversies and confusions over sex, marriage and other issues are part of what it means to live in a fallen world."[164] Echoing these views, Patrick Lappert, one of the ADF's repeat witnesses, made a presentation (to a religious audience) titled "Transgender Surgery & Christian Anthropology," casting gender-affirming care as a challenge to the Biblical notion that men and women are created in the image of God.[165] In the presentation, Lappert claims

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160. *Brandt*, 2023 WL 4073727, at *20.

161. *Id.* at *21. *See also* Boe v. Marshall, at 12–13 (opinion granting preliminary injunction) (recounting that the detransitioner witness completed hormone therapy as an adult and in Georgia not Alabama).

162. Writing in *The Atlantic* in 2014, Professor Alan Noble of Oklahoma Baptist University argued that the tension between evangelical values and American public policy and cultural mores—on issues like contraception, abortion, and same-sex marriage—had caused many believers to "see victimhood as part of their identity," and to imagine their way of life as under existential threat. Alan Noble, *The Evangelical Persecution Complex*, THE ATLANTIC (Aug. 4, 2014), https://www.theatlantic.com/national/archive/2014/08/the-evangelical-persecution-complex/375506/ [https://perma.cc/JJ3F-U9D5].

163. Elizabeth A. Castelli, *Persecution Complexes: Identity Politics and the "War on Christians,"* 18 DIFFERENCES 152, 154 (2007).

164. R. Albert Mohler, Jr., *The Transgender Challenge: An Evangelical Response*, DECISION (Jan. 1, 2017), https://decisionmagazine.com/transgender-challenge-evangelical-response-2/ [https://perma.cc/XSZ2-VNQR].

165. *See* Ex. 15 of Plaintiffs' Memorandum of Law in Support of Motion to Exclude Expert Testimony of Dr. Patrick W. Lappert at 4, Kadel v. Folwell, No. 1:19-cv-00272-LCB-LPA (M.D.N.C. Feb. 2, 2022), ECF No. 209-16 ("'Male and Female He created them' has been replaced by a confusion

the accessibility of gender-affirming interventions represents the "grooming [of] a generation," following an anti-religious view of human behavior that views "man as merely a particularly complicated animal."[166] Similarly, the Southern Baptist Convention in 2023 condemned "corporate medical services that promote harmful and often irreversible 'gender transition' experiments on vulnerable minors and young adults, exploiting them for the sake of profit."[167]

4. Society pushes "gender ideology" on youth via social media and schools

The fourth repeated claim, which we call the "social contagion" claim, is that transgender people have been recruited or hoodwinked by social media and peers. In Alabama, for example, the state asserted that "'the majority of new patients with sex-gender discordance are not males with a long, stable history of gender dysphoria since early childhood—as they were for decades—but instead adolescent females with no documented long-term history of gender dysphoria.' Some researchers have labeled the phenomenon Rapid Onset Gender Dysphoria."[168] The brief goes on to claim that the majority of cases of gender dysphoria "appear to occur within clusters of peers and in association with increased social media use."[169]

More colorfully, the state of Florida offered the testimony of parent Katie Caterbury, who claims that doctors went behind her back to treat her "once healthy and happy daughter" with testosterone injections after the Gay-Straight Alliance at her child's school "convinced [him]…that [he] was my son."[170]

The states' cited source for their social contagion claims is a 2018 study by Lisa Littman, which claimed that social contagion, and specifically social media, had prompted a large increase in the number of transgender adolescents, many of them assigned female gender at birth. Littman termed this condition "rapid-onset gender dysphoria."[171]

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of exceptional cases"); 14 (gender-affirming care is an expression of the secular belief that humans can "modify the person in any way that 'choice' demands").

166. *Id.* at 17, 22-24. A full recording of Dr. Lappert's presentation is available at https://vimeo.com/256410102.

167. SO. BAPTIST CONVENTION, *supra* note 110.

168. Defendants' Response in Opposition to Plaintiff's Motion for Preliminary Injunction at 14, Eknes-Tucker v. Ivey, No. 2:22-cv-0184-LCB-SRW (M.D. Ala. May, 2 2022), ECF No. 74 (citation omitted).

169. *Id.*

170. Redacted Defendants' Response in Opposition to Motion for Preliminary Injunction and Incorporated Memorandum of Law at 9, Dekker v. Marstiller, No. 4:22-cv-00325-RH-MAF (N.D. Fla. Oct. 3, 2022), ECF No. 49.

171. Lisa Littman, *Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria*, 16 PLOS ONE 1 (2018). Note that in a later correction, Littman softened this to a hypothesis requiring further research. *See* Lisa Littman, *Correction: Parent reports of*

The Littman hypothesis has, however, been discredited due to biases in the initial study, failures by other researchers to confirm the "rapid-onset" hypothesis, and contrary empirical evidence.[172] Among other issues, the study relied on parent reports rather than clinical observation and recruited parents from anti-trans websites. The journal of publication required an extensive correction of the original study, and the American Psychological Association and a coalition of other psychological societies issued a statement supporting the elimination of "rapid onset" as a clinical and diagnostic category, "given the lack of rigorous empirical support for its existence."[173] Recent research has failed to detect rapid onset dysphoria, further discrediting the social contagion hypothesis.[174]

The lack of scientific foundation for the social contagion claim does not sap its power as a religious proposition. As noted above, conservative Christians have long asserted that secular society is undermining Godly values and practices. Along similar lines, the Vatican posits that secular educational curricula "reflect an anthropology opposed to faith and to right reason"[175] and decries the "ideology" of "gender theory," which "leads to educational programmes [sic] and legislative enactments that promote a personal identity and emotional intimacy radically separated from the biological difference between male and female."[176]

A Liberty University event, for example, urged attendees to fight "against the transgender indoctrination of children."[177] In 2023, the Southern Baptist Convention passed a resolution "oppos[ing] gender transitions," asserting that "cultural change, the promotion of gender ideology, and social pressures [are leading] unprecedented numbers of adolescents and young adults are experiencing identity or body-related distress or asserting an identity at odds with their birth sex."[178]

Echoing these views, "gender ideology" is a favorite target of the expert witnesses called by states defending their health care bans. An amicus brief filed in one of ADF's cases by AC Peds members Quentin van Meter and

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adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria, 19 PLOS ONE 1 (2019).

172. Boulware et al. (2022), *supra* note 84; McNamara et al. (2022), *supra* note 84.

173. *CAAPS Position Statement on Rapid Onset Gender Dysphoria (ROGD),* COAL. FOR THE ADVANCEMENT & APPLICATION OF PSYCH. SCI., (Jul. 26, 2021), https://www.caaps.co/rogd-statement [https://perma.cc/4J3P-CDS6].

174. Greta R. Bauer et al., *Do Clinical Data from Transgender Adolescents Support the Phenomenon of "Rapid-Onset Gender Dysphoria"?*, 243 PEDIATRICS 224, 224 (2022).

175. CONGREGATION FOR CATH. EDU, *supra* note 97, at 3 (internal quotation marks omitted).

176. *Id.*

177. Christian Fields, *Standing for Freedom Summit calls for Christians to impact culture*, LIBERTY NEWS (Nov. 5, 2022), https://www.liberty.edu/news/2022/11/05/standing-for-freedom-summit-calls-for-christians-to-impact-culture/ [https://perma.cc/3DWH-BN95].

178. *On Opposing "Gender Transitions," supra* note 110, at 1–2.

Andre van Mol (along with Miriam Grossman of Do No Harm) claims that "some number of gender-dysphoric children who would naturally come to peacefully accept their sex are prevented from doing so when gender affirming policies are imposed upon them by adults in their orbit who have bought into *gender identity ideology*."[179]

Nevertheless, trial courts have consistently given little or no weight to the states' claims about rapid-onset gender dysphoria. In *Brandt*, the court credited the plaintiff's expert and concluded that "If any adolescents are seeking care at gender clinics because of social influence, they would not meet the criteria of gender dysphoria or be considered for gender-affirming medical treatment unless they had a longstanding incongruent gender identity and clinically significant distress."[180]

IV. How Religious Organizations Deploy Misinformation and Pseudoscience to Promote Anti-Trans Legal Measures

In this Part, we show that the current wave of anti-trans legal measures was manufactured by religious organizations pursuing precisely the two-pronged strategy that Klemp's work (described in Part II) identifies. The evidence in this part establishes that conservative religious organizations—often disguising their religious origins and agendas—have been key proponents of GAC bans and other anti-LGBTQIA measures. Their use of misinformation and pseudoscience, which we documented in Part III, is familiar and quite deliberate.

In the late twentieth and early twenty-first centuries, anti-LGBTQIA+ measures suffered major political and judicial defeats. Many states repealed their anti-sodomy laws, and in *Lawrence v. Texas*, the Supreme Court struck down such laws nationwide.[181] By the early 2010s, a number of states had acted to permit same-sex marriage, and in *Obergefell v. Hodges*, the Supreme Court mandated marriage equality nationwide.[182]

In the wake of these defeats, conservative Protestant and Catholic religious groups continued to whittle away at *Roe v. Wade* and (successfully) set the stage for the eventual overruling of *Roe*.[183] By the late 2010s, these organizations came up with a new target for energizing and unifying their

179. Brief of Dr. Miriam Grossman et. al, as Amici Curiae Supporting Defendant-Appellant at 21, Adams v. School Board of St. John's County, 57 F.4th 79 (11th Cir. 2022) (No. 18-13592) (emphasis added).

180. Brandt v. Rutledge, No. 4:21CV00450 JM, 2023 WL 4073727, at *4 (E.D. Ark. June 20, 2023).

181. 539 U.S. 558 (2003).

182. 576 U.S. 644 (2015).

183. *Dobbs*, 597 U.S. ___.

members and asserting political power: anti-trans measures.[184] These measures reflect a coordinated campaign by conservative religious-affiliated organizations rather than grassroots opposition to transgender rights.

Beginning in the late 2010s, right-wing Christian organizations began to marshal support for attacks on transgender people. One explicitly religious organization, the pro-life Family Policy Alliance, hosted a "boot camp" aimed at training state officials to promote and defend anti-trans legislation. According to an investigation by the publication *Insider*, the "Statesmen Academy" launched in 2016 to provide "pro-family legislators" with training necessary for "Christ-centered public service." Alumni of the program included state legislators who went on to sponsor anti-trans health care and sports bans.[185] One alum reported that "[t]he Statesmen Academy was finally a place of Biblical training that I have been yearning for."[186] At the same time, religious legal organizations like the Alliance Defending Freedom (ADF) and Liberty Counsel pivoted from opposing same-sex marriage to attacking transgender rights,[187] and medical professionals formed organizations to provide cover for these measures using pseudoscience.[188]

The political, legal, and medical activists promoting anti-trans laws follow a two-pronged strategy. One prong is explicitly religious: some groups state outright that their goal is to use the law to implement right-wing Christian doctrine, which (in their view) denies the existence of transgender people. These groups often speak to their own members using explicitly religious appeals. Liberty Counsel, for example, states that it is "a Christian ministry that proclaims, advocates, supports, advances, and defends the good news that God in the person of Jesus Christ paid the penalty for our sins and offers forgiveness and eternal life to all who accept him as Lord and Savior. Every ministry and project of Liberty Counsel centers around and is based upon this good news, which is also referred to as the gospel."[189] ADF is more circumspect but

184. Adam Nagourney & Jeremy W. Peters, *How a Campaign Against Transgender Rights Mobilized Conservatives*, N.Y. TIMES (April 16, 2023), https://www.nytimes.com/2023/04/16/us/politics/transgender-conservative-campaign.html.

185. Sarah Posner, *The Christian Nationalist Boot Camp Pushing Anti-trans Laws Across America*, INSIDER (Sept. 21, 2022 9:13 AM), https://www.insider.com/christian-nationalist-trans-statesmen-academy-alabama-ohio-missouri-laws-2022-8 [https://perma.cc/4B45-Q7SW].

186. *Statesmen Academy About*, FAM. POL'Y FOUND., https://familypolicyalliance.com/statesmen-academy/about/ [https://perma.cc/T6Q8-Q6CU] (last visited December 3, 2023) (quoting Minnesota state senator Mark Johnson: "I've been learning politics over the past year in the school of hard knocks. The Statesmen Academy was finally a place of Biblical training that I have been yearning for. Thank you so much for all you did and are doing in Christ's name.").

187. Nagourney & Peters, *supra* note 184.

188. Dell Cameron & Dhruv Mehrotra, *An Anti-Trans Doctor Group Leaked 10,000 Confidential Files*, WIRED (May 20, 2023, 3:53 PM), https://www.wired.com/story/american-college-pediatricians-google-drive-leak/.

189. *About Liberty Counsel*, LIBERTY COUNS., https://lc.org/about [https://perma.cc/2TRK-5CKK] (last visited July 20, 2023).

characterizes itself as "the world's largest legal organization committed to protecting religious freedom, free speech, the sanctity of life, parental rights, and God's design for marriage and family."[190] Based on their anti-LGBTQIA+ views, Liberty Counsel, ADF, and AC Peds are all designated hate groups by the Southern Poverty Law Center.[191]

The second prong targets a wider audience, including legal authorities: here, the arguments take secular form, with proponents making arguments couched in scientific language and "common sense." For example, AC Peds, introduced in Part II, is a small organization dedicated to pro-life and anti-LGBTQIA+ views and does not publicly state its religious orientation. However, a trove of leaked emails showed that the group attempted to "target Christian M.D.s," and the group's leaders are also members of the Catholic Medical Association ("CMA"), whose members pledge not to support medical treatment for gender dysphoria and to reject "policies that condition all persons with gender dysphoria to accept as normal a life of chemical and surgical impersonation of the opposite sex."[192] The CMA has joined AC Peds in lawsuits filed by the ADF to challenge civil-rights protections for transgender people.[193]

This two-pronged strategy is effective politically, as Klemp predicted, because it appeals to both believers and non-believers. From a legal perspective, the key advantage of this strategy is that it permits defenders both to promote these laws as religious measures to religious and political audiences *and* to defend these laws as entirely secular. Notably, not all right-wing anti-trans groups are religious in origin, but they often have close ties to religious groups.[194] For example, "Do No Harm," founded in 2022 by Stanley Goldfarb,

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190. *Who We Are*, ALLIANCE DEFENDING FREEDOM, https://adflegal.org/about-us/who-we-are [https://perma.cc/L2L3-GJLD] (last visited November 22, 2023).

191. *Liberty Counsel*, SO. POVERTY L. CENTER, https://www.splcenter.org/fighting-hate/extremist-files/group/liberty-counsel [https://perma.cc/J4JN-PDDR] (last visited July 20, 2023); *Alliance Defending Freedom*, SO. POVERTY L. CENTER, https://www.splcenter.org/fighting-hate/extremist-files/group/alliance-defending-freedom [https://perma.cc/8YAD-AZAZ] (last visited Nov. 22, 2023); *American College of Pediatricians*, SO. POVERTY L. CENTER, https://www.splcenter.org/fighting-hate/extremist-files/group/american-college-pediatricians [https://perma.cc/7PX8-LFRK] (last visited Nov. 22, 2023).

192. Madison Pauly, *Inside the Secret Working Group That Helped Push Anti-Trans Laws Across the Country*, MOTHER JONES (Mar. 8, 2023), https://www.motherjones.com/politics/2023/03/anti-trans-transgender-health-care-ban-legislation-bill-minors-children-lgbtq/ [https://perma.cc/FL6N-RNSC]; CATH. MED. ASS'N, *Resolution 8-13* (2017), https://www.cathmed.org/programs-resources/health-care-policy/resolutions/familysexual-education/ [https://perma.cc/BWZ6-QWY8] (last visited July 20, 2023).

193. CATH. MED. ASS'N, *Catholic Medical Association Joins Alliance Defending Freedom in Lawsuit Challenging Biden Transgender Mandate* (Aug. 26, 2021), https://www.cathmed.org/resources/catholic-medical-association-joins-alliance-defending-freedom-in-lawsuit-challenging-biden-transgender-mandate/ [https://perma.cc/9PLU-W4A3].

194. For another example, see Heron Greenesmith, *A Room of Their Own*, POL. RSCH. ASSOCS. (July 14, 2020), https://politicalresearch.org/2020/07/14/room-their-own [https://perma.cc/BWP6-33MT] (stating anti-trans group Women's Liberation Front received funding from the ADF).

aims to "protect healthcare from a radical, divisive, and discriminatory ideology." Their initial projects targeted diversity initiatives in medicine, and the group has since become a major political force in anti-trans health care bans, providing model bills adopted by Montana and other states. Miriam Grossman, a senior fellow of "Do No Harm," who identified herself as a psychiatric consultant with AC Peds,[195] has co-authored amicus briefs and commentaries with AC Peds members and worked with AC Peds members and Catholic Medical Association members to assist the state of Florida in defending its Medicaid ban on gender-affirming care.[196]

In the following, we provide examples of the organizations and purported experts whose publications and testimony have furnished pseudoscience in support of anti-trans legal measures. We also show that both the organizations and their experts have deep ties to religious groups and have stated (at least privately) that their anti-trans views are grounded in religious belief.

A. A closer look at the American College of Pediatricians

AC Peds, introduced in Part II, has in recent years become a major player in the push to restrict access to gender-affirming care, deploying the same pseudoscientific playbook it previously used to advocate against abortion and same-sex equality. In this Subpart, we scrutinize AC Peds's public messaging strategy on gender-affirming care, and its behind-the-scenes collaboration with Christian legal actors to promote anti-trans measures.

The mission statement on the AC Peds website is bland: "Enabling all children to reach their optimal physical and emotional health and well-being." Both the name and mission of the organization are misleading, however. A non-expert might mistake the group for the American Academy of Pediatrics ("AAP"), which is a pediatric professional organization in the United States, with nearly 70,000 members.[197] The AAP was founded in 1930 and sponsors a

195. Trumbull et al., *Puberty is Not a Disorder*, 135 PEDIATRICS (2015).

196. *About Us*, DO NO HARM, https://donoharmmedicine.org/about/ [https://perma.cc/U6XL-UTG2] (last visited July 20, 2023) (listing Dr. Miriam Grossman as a senior fellow). For involvement in anti-trans legislation, see Jeff McMillan & Kimberlee Kruesi, *Meet the Influential New Player on Transgender Health Bills*, AP NEWS (May 20, 2023, 6:08 PM) https://apnews.com/article/transgender-bills-lobbying-do-no-harm-94f56059d24608d724eb78fefecf4e09 [https://perma.cc/KHP4-PSRQ]; Jeff McMillan, Kavish Harjai & Kimbelee Kruesi, *Many Transgender Health Bills Came from a Handful of Far-right Interest Groups, AP Finds*, AP NEWS (MAY 20, 2023, 9:24 AM) https://apnews.com/article/transgender-health-model-legislation-5cc4a7cb4ab69150f670d06fd0f361ab [https://perma.cc/QQ2E-R2AM]. *See also* Brief for Dr. Miriam Grossman et al. as Amici Curiae Supporting Petitioners, Doe v. Boyertown Area School District, 139 S. Ct. 2636 (2019) (No. 18-658) (amicus brief in locker room case); Plaintiffs' Notice of Filing Trial Exhibits, Exhibit 307, Email from Miriam Grossman 7/10/2022, Dekker v. Weida, No. 4:22CV325-RH-MAF, ECF No. 183-9 (emails among Grossman, van Meter, van Mol, and Florida officials after Grossman's participation in administrative agency rulemaking hearing).

197. *About the AAP*, AM. ACADEMY OF PEDIATRICS, https://www.aap.org/en/about-the-aap/ [https://perma.cc/89CJ-F6EB] (last visited July 20, 2023).

host of scientific enterprises. It publishes *Pediatrics*, a leading peer-reviewed medical journal, holds conferences for members, and commissions scientific literature reviews that support standards of care for various medical conditions, including the treatment of youth with gender dysphoria.[198]

By contrast, AC Peds was founded in 2002 and apparently has approximately 700 members.[199] The group's website consists primarily of policy statements and other materials opposing abortion, gender-affirming care, and marriage equality and promoting conversion therapy to combat "unwanted homosexual attraction among youth."[200] The group does not publish a journal.

The public face of AC Peds, as reflected on its website, is primarily secular, although there are allusions to conservative Christian beliefs. For example, the site's list of topics includes the statements that "[e]very human life is precious and worthy of protection from conception to natural death," which is an allusion to the group's opposition to abortion and death-with-dignity laws. The site also asserts that "[a] family, formed and nurtured within the secure environment of a loving marriage between a man and a woman, is the optimal childrearing setting,"[201] flagging the group's opposition to LGBTQIA+ identity, relationships, and marriage.

The AC Peds website content under the heading "Gender Confusion and Transgender Identity" states that medical treatments for gender dysphoria are based on "an unscientific gender ideology."[202] The group's position statement on gender dysphoria does not mention religion explicitly but again contains dog whistles. For instance, the statement recites that "The debate over how to treat children with [gender dysphoria] is primarily an ethical dispute," that "[m]edicine does not occur in a moral vacuum" and that transgender children are "impersonat[ing] the opposite sex."[203]

The pseudoscientific appearance of the AC Peds website is deliberate. An investigation by *Mother Jones* based on AC Peds internal documents found that

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198. *Pediatrics* is published by the AAP. *See Publications*, AM. ACADEMY OF PEDIATRICS, https://publications.aap.org/pediatrics [https://perma.cc/C63Z-9YJX] (last visited July 20, 2023). AAP clinical practice guidelines and policy statements address a range of topics in pediatric medicine, including the treatment of ADD/ADHD, bronchiolitis, Type 2 diabetes, HIV prevention, breast feeding, and sleep-related infant deaths. *See Pediatric Clinical Practice Guidelines & Policies*, AM. ACADEMY OF PEDIATRICS, https://publications.aap.org/aapbooks/book/738/Pediatric-Clinical-Practice-Guidelines-amp?_ga=2.109796741.1095773555.1686942662-134273173.1686942662 [https://perma.cc/EW42-5EMG] (last visited July 20, 2023).

199. Cameron & Mehrotra, *supra* note 188.

200. *Topics*, AM. COLL. OF PEDIATRICIANS, https://ACPeds.org/topics [https://perma.cc/2HVQ-SRFE] (last visited July 20, 2023); *Psychotherapy for Unwanted Homosexual Attraction Among Youth*, AM. COLL. OF PEDIATRICIANS, https://ACPeds.org/position-statements/psychotherapy-for-unwanted-homosexual-attraction-among-youth [https://perma.cc/QBF4-ETD3] (last visited July 20, 2023).

201. *Topics*, AM. COLL. OF PEDIATRICIANS, https://ACPeds.org/topics [https://perma.cc/2HVQ-SRFE] (last visited July 20, 2023).

202. AM. COLL. OF PEDIATRICIANS, *supra* note 133.

203. AM. COLL. OF PEDIATRICIANS, *supra* note 134.

"[a]ccording to an agenda for the spring 2018 board meeting, an ADF attorney had recently told AC Peds (sic) that 'it was best that [AC Peds] was not religiously affiliated in order to provide maximum benefit for our message.'"[204]

Although the AC Peds website presents the group's position statements as based on scientific evidence, a trove of leaked documents shows that they were crafted with a purpose: to support the ADF and Liberty Counsel in challenging civil rights protections for transgender individuals. In 2023, *Wired* obtained access to 10,000 documents left on a public Google drive (and later removed), and other journalists and organizations examined them. These documents showed that the ADF and AC Peds began collaborating in 2014 "to shore up anti-trans policy efforts and legal arguments with bespoke research."[205] An investigation by *Mother Jones* also documented the collaboration among AC Peds, ADF, and state legislators in South Dakota, Utah, Florida, and Alabama.[206]

B. The Alliance Defending Freedom's stable of "expert" witnesses

"Most of the State's expert witnesses...were unqualified to offer relevant expert testimony and offered unreliable testimony. Their opinions regarding gender-affirming medical care for adolescents with gender dysphoria are grounded in ideology rather than science....

It is clear from listening to the testimony that Professor Mark Regnerus, Dr. Paul Hruz, and Dr. Lappert were testifying more from a religious doctrinal standpoint rather than that required of experts by Daubert."[207]

AC Peds and Catholic Medical Association members have repeatedly testified as purported experts, often in cases brought by ADF, to support health care bans and other anti-trans measures.[208] These purported experts typically

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204. Madison Pauly & Emma Rindlisbacher, *A Massive Leak Spotlights the Extremism of an Anti-Trans Medical Group*, MOTHER JONES (May 17, 2023), https://www.motherjones.com/politics/2023/05/anti-trans-american-college-pediatrics-leak-michelle-cretella-abortion/ [https://perma.cc/FK4E-A7Z5].

205. R.G. Cravens, *Documents Reveal ADF Requested Anti-Trans Research from American College of Pediatricians*, SO. POVERTY L. CENTER (June 5, 2023), https://www.splcenter.org/hatewatch/2023/06/05/documents-reveal-adf-requested-anti-trans-research-american-college-pediatricians [https://perma.cc/5N39-XY3Y].

206. Madison Pauly, *Inside the Secret Working Group That Helped Push Anti-Trans Laws Across the Country*, MOTHER JONES (March 8, 2023), https://www.motherjones.com/politics/2023/03/anti-trans-transgender-health-care-ban-legislation-bill-minors-children-lgbtq/ [https://perma.cc/MD26-TCSX].

207. Brandt v. Rutledge, No. 4:21CV00450 JM, 2023 WL 4073727, at *29-30 (E.D. Ark. June 20, 2023).

208. David Cary Hart, *Alliance Defending Freedom Developed Stable of Anti-LGBT "Expert" Witnesses*, SO. POVERTY L. CENTER (Dec. 13, 2017), https://www.splcenter.org/hatewatch/2017/12/13/alliance-defending-freedom-developed-stable-anti-lgbt-expert-witnesses [https://perma.cc/5NJ3-

present only secular arguments in such contexts: they are careful to present their case in scientific language, with citations to (seemingly) scientific publications. But in other contexts, these individuals make it clear that their anti-trans views are grounded primarily in religion, and the courts have called out the ideological and religious basis for their opinions, as in the quotes from *Brandt* above.[209] This Subpart highlights several of the most prominent witnesses who have testified in defense of care restrictions and other anti-trans policies, the religious bases of their views, and the persistent rejection of their testimony by federal courts.

Some of the most frequent repeat witnesses include AC Peds past president Quentin van Meter, AC Peds official and Catholic Medical Association member Paul Hruz, Catholic Medical Association member Patrick Lappert, and sociologist Mark Regnerus, whose earlier work opposed marriage equality. All were recruited to become expert witnesses in a 2017 ADF conference that asked for volunteers to oppose transgender rights and inclusion.[210] The testimony of all four has been viewed skeptically by multiple courts and excluded under *Daubert* in some instances.

Van Meter's proffered expert testimony was excluded entirely in a divorce case,[211] and he has advocated conversion therapy. In one deposition, van Meter

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GZMM] (discussing Paul Hruz, an AC Peds member); Aviva Stahl, *Four Controversial Doctors Helping Republicans Attack Trans Healthcare*, THE GUARDIAN (June 9, 2023, 3:00 PM) https://www.theguardian.com/society/2023/jun/09/doctor-republican-trans-gender-affirming-minor-healthcare-lgbtq-rights [https://perma.cc/X5WJ-4GJD] (discussing Lappert, van Meter, Hruz, and Laidlaw).

209. Alejandra Caraballo provides additional examples of purported anti-trans experts with limited qualifications, some of whose testimony has been disqualified in court. *See* Alejandra Caraballo, *The Anti-Transgender Medical Expert Industry*, 50 J. L. MED ETHICS. 687, 689 (2022) (discussing Stephen B. Levine, Paul McHugh, and Michael Laidlaw).

210. *See* Brandt v. Rutledge, No. 4:21CV00450 JM, 2023 WL 4073727, at *29 (E.D. Ark. June 20, 2023) ("Like Professor Mark Regnerus and Dr. Paul Hruz, Dr. Lappert was recruited by the Alliance Defending Freedom ("ADF") at a seminar held in Arizona. The meeting was held to gather witnesses trained in various fields that would be willing to testify in favor of laws passed that limit transgender care. The ADF . . . is not a scientific organization, but a Christian-based legal advocacy group."). *See also* Deps. of Lappert, and Hruz in *Brandt*, 2023 WL 4073727 and Kadel v. Folwell, No. 1:19CV272, 2022 WL 2106270 (M.D. N.C. June 10, 2022). Both Hruz and Lappert belong to the Catholic Medical Association, which adopted a resolution stating that the organization "and its members reject all policies that condition all persons with gender dysphoria to accept as normal a life of chemical and surgical impersonation of the opposite sex." CATH. MED. ASS'N, *Resolution 8-13*, https://www.cathmed.org/programs-resources/health-care-policy/resolutions/familysexual-education/ [https://perma.cc/Q5K3-X2B7] (last visited June 20, 2023*). See also* Molly Redden, *Inside the Cottage Industry of 'Experts' Paid to Defend Anti-Trans Laws*, HUFFPOST (Sept. 15, 2023, 5:45 AM), https://www.huffpost.com/entry/paid-experts-defending-anti-trans-law_n_65021a7ee4b01df7c3b6d513 [https://perma.cc/72HS-Y2PD] (explaining how Van Meter has been recruited to appear in cases regarding gender affirming care).

211. *See* Stephen Caruso, *A Texas judge ruled that this doctor was not an expert. A Pennsylvanian Republican invited him to testify on trans health care*, PENN. CAP.-STAR (Sept. 15, 2020, 7:24 AM), https://www.penncapital-star.com/government-politics/a-texas-judge-ruled-this-doctor-was-not-an-expert-a-pennsylvania-republican-invited-him-to-testify-on-trans-health-care/

stated that his opposition to gender-affirming care and his medical practice are "impossible to separate" from his "religious faith."[212] The Fourth Circuit opinion in *Grimm v. Gloucester County School Board* noted that van Meter is an outlier in disagreeing with conventional standards of care for gender dysphoria and in treating "transgender youth by encouraging them to live in accordance with their sex assigned at birth." The court observed that "one can always find a doctor who disagrees with mainstream medical professional organizations on a particular issue."[213]

Paul Hruz is an endocrinologist and another frequent ADF witness.[214] In *Kadel v. Folwell*, the judge excluded much of his testimony, noting that Hruz is not a psychiatrist, psychologist, or mental healthcare professional [and] has never diagnosed a patient with gender dysphoria, treated gender dysphoria, treated a transgender patient, conducted any original research about gender dysphoria diagnosis or its causes, or published any scientific, peer-reviewed literature on gender dysphoria."[215]

In the Florida case that struck down a Medicaid ban, the court castigated the state for offering Hruz as an "expert" witness. The court called out Hruz for asserting that "transgender individuals have only a 'false belief' in their gender identity—that they are maintaining a 'charade' or 'delusion.'"[216] The opinion also recounted that at trial, "Hruz fended and parried questions and generally testified as a deeply biased advocate, not as an expert sharing relevant evidence-based information and opinions.[217]

Similarly, the court in *Brandt* made a scathing critique of the pseudoscience offered by the State, writing that "[m]ost of the State's expert witnesses" (including Regnerus, Lappert, and Hruz) "were unqualified to offer relevant expert testimony and offered unreliable testimony. Their opinions regarding gender-affirming medical care for adolescents with gender dysphoria

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[https://perma.cc/77AJ-WJMG] (reporting that van Meter was disqualified as an expert in a Texas divorce case, now sealed).

212. *See* Plaintiffs' Memorandum of Law in Support of Motion to Exclude Expert Testimony of Dr. Quentin Van Meter at 27, Dekker v. Weida, No. 4:22CV325-RH-MAF (N.D. Fla. Apr. 7, 2023), 2023 WL 3723964, ECF No. 144.

213. Grimm v. Gloucester Cnty. Sch. Bd., 972 F.3d 586, 596 n.3 (4th Cir. 2020), *as amended* (Aug. 28, 2020).

214. *Fellows of the National Catholic Bioethics Center*, NAT. CATH. BIOETHICS CENTER, https://www.ncbcenter.org/our-fellows [https://perma.cc/E6PL-5QCW] (last visited July 20, 2023).

215. Kadel v. Folwell, No. 1:19CV272, 2022 WL 2106270, at *9 (M.D.N.C. June 10, 2022), *order corrected and superseded*, 620 F. Supp. 3d 339 (M.D.N.C. 2022). The judge also referred to evidence that Hruz once "told a fellow doctor that he had 'a significant problem with the entire issue' and 'whole idea of transgender.'" *Id.*

216. Dekker v. Weida, No. 4:22CV325-RH-MAF, 2023 WL 4102243, at *2 (N.D. Fla. June 21, 2023).

217. *Id.* at *2 n.8.

are grounded in ideology rather than science."[218] The *Brandt* court also called out the role of ADF in recruiting Regnerus, Hruz, and Lappert:

> The ADF is not a scientific organization, but a Christian-based legal advocacy group...While there is nothing nefarious about an organization recruiting witnesses to testify for their cause, it is clear from listening to the testimony that [Regnerus, Hruz, and Lappert] were testifying more from a religious doctrinal standpoint rather than that required of experts by *Daubert*.[219]

And in *L.W. v. Skrmetti*, the district court that granted a preliminary injunction against Tennessee's health care ban treated Hruz's testimony as "minimally persuasive," given that he has never diagnosed or treated a minor with gender dysphoria.[220]

The testimony of a third frequent ADF expert, Patrick Lappert, was disqualified as an expert in a recent federal court decision in North Carolina. [221] Lappert, a retired plastic surgeon, opined on matters outside his scope of practice and has not provided hormonal treatments to any transgender patients.[222] During one deposition, Lappert said that being transgender requires "delusional thinking" and that gender-affirming care is a "form of mutilation."[223] In an interview with a Catholic newspaper, Lappert said that "[t]ransgenderism and the whole gender ideology business are inhuman, because they separate our souls from our bodies." He continued, "[w]e have to protect our children from this great evil that's been unleashed into their lives."[224]

In *Brandt*, the court noted that Lappert "has no training or professional experience in mental health or gender dysphoria and has never provided gender-affirming surgery. He acknowledges that he is not an expert in the

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218. Brandt v. Rutledge, No. 4:21CV00450 JM, 2023 WL 4073727, at *20 (E.D. Ark. June 20, 2023).

219. *Id.* at *29.

220. L.W. by & through Williams v. Skrmetti, No. 3:23-CV-00376, 2023 WL 4232308, at *20 (M.D. Tenn. June 28, 2023), *rev'd and remanded*, 83 F.4th 460 (6th Cir. 2023).

221. Kadel v. Folwell, No. 1:19CV272, 2022 WL 2106270, at *13 (M.D.N.C. June 10, 2022), *order corrected and superseded*, 620 F. Supp. 3d 339 (M.D.N.C. 2022). The judge ruled that Lappert was not qualified to "render opinions about the diagnosis of gender dysphoria, its possible causes, the efficacy of the DSM, the efficacy of puberty blocking medication or hormone treatments, the appropriate standard of informed consent for mental health professionals or endocrinologists, or any opinion on the non-surgical treatments." Lappert was also disqualified from opining on "the efficacy of randomized clinical trials, cohort studies, or other longitudinal, epidemiological, or statistical studies of gender dysphoria." *Id.*

222. *See* Stahl, *supra* note 208.

223. *Id.*

224. Gina Christian, *Transgender Interventions Pose Serious Medical Consequences for Minors, Says Surgeon*, THE TABLET (April 17, 2023), https://thetablet.org/transgender-interventions-pose-serious-medical-consequences-for-minors-says-surgeon/ [https://perma.cc/GY7U-CYM7].

treatment of gender dysphoria." The court concluded that Lappert "does not meet the requirements under *Daubert* to give opinions relevant to this case."[225]

In *Dekker*, the court also discounted Lappert's and Hruz's testimony (as well as statements by state employees and consultants) for "dog whistles" signaling the view that transgender identity is invalid: Lappert, the court noted, had "said in a radio interview that gender-affirming care is a 'lie,' a 'moral violation, a 'huge evil,' and 'diabolical.'"[226]

Mark Regnerus, another frequent ADF witness, has also had his testimony discredited in court. In *Brandt*, the district court gave "no weight" to his testimony, noting that "Professor Regnerus, a sociologist whose work has focused on sexual relationship behavior and religion, has no training or experience related to the fields of medicine or mental health care, or the treatment of gender dysphoria."[227] Indeed, writes the judge, Regnerus, a sociologist, "has no training or experience related to the fields of medicine or mental health care, or the treatment of gender dysphoria."[228] In a footnote, the court pointed out that Regnerus's past testimony opposing marriage equality had several times been questioned by courts and other experts.[229]

Despite the repeated negative treatment of their testimony by courts, many of the same purported experts have been centrally involved in health care bans enacted via administrative action. In June 2022, the state of Florida produced a lengthy report, full of misinformation,[230] which expressly included portions written by van Meter and Lappert.[231] Discovery in a lawsuit subsequently revealed that the state had paid substantial sums to van Meter, Lappert, and AC Peds member Andre van Mol for their role in the administrative process. (Lappert was also paid more later for testifying in a court case challenging the Medicaid ban.)[232]

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225. Brandt v. Rutledge, No. 4:21CV00450 JM, 2023 WL 4073727, at *29 (E.D. Ark. June 20, 2023).

226. Dekker v. Weida, No. 4:22CV325-RH-MAF, 2023 WL 4102243, at *2 (N.D. Fla. June 21, 2023).

227. *Brandt*, 2023 WL 4073727, at *28 (E.D. Ark. June 20, 2023) ("The Court does not credit the testimony of Professor Regnerus and gives it no weight because the Court finds that he lacks the qualifications to offer his opinions and failed to support them.").

228. *Id.*

229. *Id.* at *28 n.11.

230. *See* McNamara et. al (2022), *supra* note 84.

231. FLA. AGENCY FOR HEALTH CARE ADMIN. (AHCA), DIV. OF FLA. MEDICAID, AGENCY FOR HEALTH CARE ADMIN., GENERALLY ACCEPTED PRO. MED. STANDARDS DETERMINATION ON THE TREATMENT OF GENDER DYSPHORIA 3 (June 2022), https://www.ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Report.pdf [https://perma.cc/U9MQ-7FRJ].

232. Dara Kam, *Florida Runs up Tab in Medicaid Transgender Case*, WINK NEWS (Jan. 24, 2023), https://winknews.com/2023/01/24/florida-runs-up-tab-in-medicaid-transgender-case/ [https://perma.cc/F5UA-W8HZ].

V. THE LIMITS OF LITIGATION: THE NEED FOR NEW LEGAL SOLUTIONS TO COMBAT ANTI-LGBTQIA+ LEGISLATION AND STATES' RELIANCE ON MISINFORMATION AND PSEUDOSCIENCE

The current status of litigation over healthcare bans is unsettled. On the hopeful side, six federal district courts (and one state trial court) in red states have so far been able and willing to block—at least temporarily, and sometimes permanently—legislation based on scientific misinformation and religious pseudoscience.[233] Adversarial litigation and the *Daubert* standard have, so far, held up at the trial level despite organized efforts by religious groups and their allies to target the LGBTQIA+ community.

These initial victories, however, have been overshadowed by appellate rulings in the Sixth and Eleventh Circuits, which narrowed the scope of constitutional protections for parents and for transgender people.[234] The content of these opinions is primarily legal, not factual, as one would expect for an appellate court. But by lowering the standard of review to rational basis from heightened or intermediate scrutiny, both courts have signaled their willingness to uphold health care bans based on even flimsy evidence by the state. And both courts seemed ready to embrace misinformation put forward by the states, despite the repudiation of those claims by the trial courts.

The appellate opinions also signal sympathy for the states by using hostile language and familiar dog whistles for anti-trans views. In the Eleventh Circuit, a transgender girl, plaintiff Allison Poe, is unnamed and instead described as "a biological male who identifies as a female."[235] That appeals court also repeated the testimony of the state's witnesses, without noting that the District Court gave the testimony "very little weight."[236] And the court cited the declarations of witnesses like van Meter without acknowledging challenges to their expertise in this and other cases.[237] In the Sixth Circuit, the court terms the health care bans a "vexing and novel topic of medical debate"[238] and bats away the fact that more than 20 major medical societies support gender-affirming care.[239]

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233. See Brandt (Arkansas), Eknes-Tucker (Alabama), Dekker and Doe v. Ladapo (both Florida), Koe v. Noggle (Georgia), Skrmetti (Tennessee), and Doe v. Thornbury (Kentucky). For the Texas trial decision, see PFLAG v. Abbott.

234. *See* Eknes-Tucker v. Governor of Alabama, 80 F.4th 1205, (11th Cir. 2023); L. W. by & through Williams v. Skrmetti, 73 F.4th 408, 415 (6th Cir. 2023).

235. Eknes-Tucker v. Governor of Alabama, 80 F.4th 1205, 1215 (11th Cir. 2023).

236. Eknes-Tucker v. Marshall, 603 F. Supp. 3d 1131, 1142–42 (M.D. Ala. 2022).

237. *See supra* notes 212-14 and accompanying text.

238. L. W. by & through Williams v. Skrmetti, 73 F.4th 408, 415 (6th Cir. 2023).

239. *Id.* at 416. ("At all events, the medical and regulatory authorities are not of one mind about using hormone therapy to treat gender dysphoria. Else, the FDA would by now have approved the use of these drugs for these purposes. That has not happened, however, giving us considerable pause about constitutionalizing an answer they have not given or, best we can tell, even finally studied."). The FDA

Procedurally, all of the appellate decisions so far are preliminary decisions because they address only preliminary injunctions granted by trial courts. Substantively, the legal pronouncements in these decisions will shape trial proceedings, because trial judges in these circuits can no longer rely on constitutional protections for parents and for transgender people to gain heightened or intermediate scrutiny. Several lines of argument remain open to plaintiffs, however. These include the argument that bans on gender-affirming care fail to meet even a rational basis test: indeed, the district court in *Dekker v. Weida* held just that, in a decision that has not yet undergone appellate review.[240]

With litigation ongoing in more than ten states, there are likely to be further victories and defeats. The Seventh Circuit has signaled a more open view on transgender rights (in a bathroom ban case),[241] and there may be a sufficient circuit split brewing to invite Supreme Court review.

Regardless of the outcomes in these cases, there is a deeper problem for American democracy here, because litigation —even in the best scenarios—is an imperfect check on the use of misinformation by legislatures and state executives. Litigation takes time and resources, and even injunctions do not necessarily counteract the full effects of anti-LGBTQIA+ laws, for several reasons.

First, delay imposes real human costs. Anti-trans health care bans have denied necessary medical care to and created painful uncertainty for transgender people. In Florida, for example, a 2022 Medicaid ban on gender-affirming care (which was not preliminarily enjoined) left thousands of teen and adult patients without access to care until June 2023, when a federal judge enjoined the ban permanently as unconstitutional.[242]

Second, state lawmakers have managed to deploy political pressure outside formal legal channels with harmful effect. Trans patients can be turned away when medical providers decide that the political climate and legal uncertainty make it too risky to provide care. In Texas, one of the state's largest gender clinics shut down in 2021 after pressure from the governor's office; the clinic remained closed to new patients even after a state court in 2022 preliminarily

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"lack of approval" argument described in *Skrmetti* is frank misinformation, as we have documented and as the District Court in *Dekker* recognized. *See* Boulware, et al. (2022), *supra* note 84, at 23–24; Dekker v. Weida, No. 4:22CV325-RH-MAF, 2023 WL 4102243, at *14 (N.D. Fla. June 21, 2023).

240. *Dekker*, 2023 WL 4102243 at *14 (N.D. Fla. June 21, 2023) ("The State of Florida's decision to ban payment for GnRH agonists and cross-sex hormones for transgender individuals is not rationally related to a legitimate state interest.").

241. *See* A.C. by M.C. v. Metro. Sch. Dist. of Martinsville, 75 F.4th 760 (7th Cir. 2023).

242. Dekker v. Weida, No. 4:22CV325-RH-MAF, 2023 WL 4102243, at *5 (N.D. Fla. June 21, 2023).

enjoined the state's 2022 health care ban.[243] In Arkansas, the state's only gender clinic refused to see any new patients during the two years of litigation, leaving large numbers of trans youth without access to care in their home states. This was despite a preliminary injunction blocking Arkansas's 2021 health care ban: the University of Arkansas gender clinic explained to patients' families that "the change was due to concern that [the Arkansas health care ban] might go into effect in the near future and disrupt patients' care."[244]

Third, preliminary injunctions may not offer effective legal protections to nonparties. In Florida, for example, the judge in *Doe v. Ladapo* limited the preliminary injunction to named plaintiffs.[245] While nonparties could invoke the court's decision in pursuing their own care, the state could force patients to take formal legal action on their own—something that is costly and difficult for most patients.

Fourth, litigation is also a slow and partial remedy when states enact multiple health care bans that must be challenged separately. In Florida, for example, a federal judge has, as of July 2023, temporarily enjoined a state health care ban and permanently enjoined a Medicaid ban.[246] Thus, the status of gender-affirming care in that state will be settled only after the second case proceeds to trial and final decision.

Fifth, the impact of piece-by-piece litigation is especially limited when states react to adverse court decisions by pursuing new routes to deny gender-affirming care. In Florida, the legislation enacting a health care ban for youth also contained a number of new attacks on gender-affirming care. Although a federal court preliminarily enjoined the health care ban in early June 2023, other provisions of the law remain in effect, including rules that require adult patients seeking gender-affirming care to be treated by physicians in person. These requirements effectively limit access for patients who would otherwise be treated by nurse practitioners or by telehealth.[247] In late June 2023, the state's medical boards continued to draft "informed consent" documents and

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243. Abbott v. Doe, No. 03-22-00107-CV, 2022 WL 710093 (Tex. App. Mar. 9, 2022) (preliminarily enjoining efforts by the state to initiate child abuse investigations of parents who consent to gender-affirming care); *see also* Azeen Ghorayshi, *Texas Youth Gender Clinic Closed Last Year Under Political Pressure*, N.Y. TIMES (March 8, 2022), https://www.nytimes.com/2022/03/08/health/texas-transgender-clinic-genecis-abbott.html (describing the political pressures leading to the closure of GENECIS).

244. Brandt v. Rutledge, No. 4:21CV00450 JM, 2023 WL 4073727, at *9 (E.D. Ark. June 20, 2023).

245. Doe v. Ladapo, No. 4:23CV114-RH-MAF, 2023 WL 3833848, at *17 (N.D. Fla. June 6, 2023).

246. *See* Ladapo, 2023 WL 3833848; Dekker v. Weida, 2023 WL 4102243.

247. Committee Substitute for Senate Bill No. 654, ch. 2023-90, §5 (2023), http://laws.flrules.org/2023/90 [https://perma.cc/UB5V-MB7T].

enacted administrative rules that permitted physicians to renew existing prescriptions in the meantime only if dosage did not change.[248]

These dynamics are reminiscent of states' efforts to circumvent other civil rights protections. Before the decision in *Dobbs*, states spent decades devising experimental anti-abortion laws, pushing the constitutional limits established by courts.[249] Similarly, Southern states after *Brown v. Board of Education* attempted to circumvent racial integration mandates in numerous ways.[250]

In light of these limitations, federal and state policy makers and private actors should consider new measures to combat anti-LGBTQIA+ legislation and the use of misinformation and pseudoscience in legal measures. Below are four broad avenues worth exploring. While we do not fully analyze each one, we offer preliminary observations on advantages and disadvantages.

First, federal legislation and regulations could enact protections for LGBTQIA+ people that would pre-empt state attempts to target them. The proposed Equality Act, for example, would include express protections for sexual orientation and gender identity in employment, housing, health care, and public accommodations.[251] Even without legislation, regulations could adopt stronger protections based on existing laws, including Title IX and the Affordable Care Act; the Education Department and the Department of Health and Human Services have both proposed regulations that would protect transgender students and patients.[252]

Second, states might adopt procedural rules to weed out misinformation and pseudoscience in legislation. While it is unlikely that the same politicians who vote for anti-LGBTQIA+ laws would willingly limit their own discretion, it is worth exploring whether states could establish fact-checking bodies that would opine publicly on the factual foundations of legislation. These bodies

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248. *Agenda*, *Rule No. 64B8ER23-3*, FLA. DEPT. OF HEALTH, BOARD OF MEDICINE AND FLA. BDS. OF MED. & OSTEOPATHIC MED. 1, (June 23, 2023), https://ww10.doh.state.fl.us/pub/medicine/Agenda_Info/Public_Information/Agendas/2023/June/06232023_JRL_Agenda.pdf.

249. *See, e.g.*, Planned Parenthood v. Casey, 506 U.S. 833, 833 (1992) (upholding some Pennsylvania abortion restrictions).

250. *See* Sonya Ramsey, *The Troubled History of American Education After the* Brown *Decision*, THE AMERICAN HISTORIAN, https://www.oah.org/tah/february-3/the-troubled-history-of-american-education-after-the-brown-decision/ [https://perma.cc/7YAM-EDLS] (last visited July 20, 2023).

251. *See* H.R.5, 117th Cong. (as passed by House, Feb. 25, 2021).

252. U.S. DEP'T OF HEATH & HUM. SERVS., *HHS Issues Proposed Rule to Advance Non-discrimination in Health and Human Service Programs for LGBTQI+ Community* (July 11, 2023), https://www.hhs.gov/about/news/2023/07/11/hhs-issues-proposed-rule-advance-non-discrimination-health-human-service-programs-lgbtqi-community.html [https://perma.cc/6KH8-YQ6T]; *see also HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy*, U.S. DEP'T OF HEATH & HUM. SERVS. (March 2, 2022), https://www.hhs.gov/sites/default/files/hhs-ocr-notice-and-guidance-gender-affirming-care.pdf [https://perma.cc/PVE9-KR22], *stayed by* Texas v. EEOC, et. al., 633 F.Supp.3d 824 (N.D. Tex. 2022); *FACT SHEET: U.S. Department of Education's Proposed Change to its Title IX Regulations on Students' Eligibility for Athletic Teams*, U.S. DEP'T OF EDUC., (April 6, 2023), https://www.ed.gov/news/press-releases/fact-sheet-us-department-educations-proposed-change-its-title-ix-regulations-students-eligibility-athletic-teams[https://perma.cc/SUC8-XLTM].

might have preclusive power or merely an advisory status, but mandated, standard, public reports could put pressure on state legal actors to conform their actions to the facts. By analogy, the Congress and Treasury produce authoritative revenue estimates for tax legislation in order to establish how much legislation will cost; the existence of different estimators serving different branches of government (the legislative and the executive) produces a useful separation-of-powers constraint. The impact of these analyses is amplified by procedural budget rules which limit revenue losses due to tax cuts. In addition, bodies such as the Government Accountability Office (GAO) and Inspectors General Offices at the federal level, and Legislative Auditors' Offices at the state level could still provide models for independent oversight of lawmakers' activities.[253] The Congressional Research Service (CRS) also has an excellent track record of providing impartial and expert research.

All these institutions are limited, of course. Nominally independent agencies can become politicized, and separation-of-powers checks atrophy when the legislature and executive are held by the same party. Nevertheless, institutions like the Joint Committee on Taxation, CRS, and the GAO have retained a high degree of professionalism and impartiality.

Third, given the slim political chances that states will restrain their own use of misinformation and pseudoscience, there is a potential role for private actors, including medical organizations, to adopt systematic review processes that can publicly call out the use of falsehoods in legal action. Early efforts of this variety are underway: the American Academy of Pediatrics, the American Medical Association, and a large number of other mainstream medical organizations have been active in filing amicus briefs and publicly calling out the scientific claims made in defense of health care bans.[254] Individual doctors and groups of researchers have also published materials that debunk the misuse of science in health care bans.[255] The National Institutes of Science and Medicine have not yet used their considerable academic authority to weigh in on anti-trans legislation, but they could do so. The National Institutes are well-known for commissioning experts to summarize scientific research.

Another route might create alliances between mainstream scientific and medical organizations and pro-trans figures from a variety of religious faiths. Already, anti-trans initiatives in various states have met with pushback from

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253. *See generally*, *What GAO Does*, U.S. GOVT. ACCOUNTABILITY OFF., https://www.gao.gov/about/what-gao-does [https://perma.cc/N3NX-UZR2] (last visited Oct. 6, 2023); *Our History*, LA. LEGIS. AUDITOR, https://lla.la.gov/about/our-history [https://perma.cc/PX7V-CRBW] (last visited Oct. 6, 2023); *Statutory Authority*, MINN. LEGISLATURE OFF. OF THE LEGIS. AUDITOR, https://www.auditor.leg.state.mn.us/statu.htm [https://perma.cc/PF54-8GPP] (last visited Oct. 6, 2023); U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF THE INSPECTOR GEN., *Statement of Organization, Functions, and Delegation of Authority*, 83 Fed. Reg. 55553, 55553-56 (Nov. 6, 2018).

254. *See* Table 2.

255. *See* Table 4.

coalitions of progressive faith leaders who have emphasized that their religions teach them to accept others and celebrate human differences.[256] Indeed, the first named plaintiff in the challenge to Alabama's healthcare ban is a minister, Paul Eknes-Tucker. By collaborating with LGBTQIA+-affirming faith coalitions, private scientific and medical actors could avoid ceding the moral authority of religious argumentation to the religious right, instead contesting faith-based anti-trans arguments on their own terms.

Finally, the continuing prevalence of religious pseudoscience should motivate scrutiny of anti-LGBTQIA+ legislation under the Establishment Clause.[257] It would be patently unconstitutional for legislation to provide expressly that citizens must abide by God's dictates to live in accordance with their God-given genitals at birth.[258] But, as we have documented, the proponents of anti-trans laws are savvy enough to avoid this mistake: they instead cloak the religious motivations for these laws in the guise of science and put forward only secular-seeming justifications in court. Thus, under the canonical rule of *Lemon*, the defenders of these laws are resting on the proposition that the laws serve permissible secular ends.[259] At some point, however, a plaintiff may assert, and a court may be willing to entertain, the claim that these rationales are pretextual, based on the kind of evidence we provide here.

In *Webster v. Reproductive Health Services*, the Supreme Court upheld a Missouri statute regulating abortion, finding that the law promoted a number of reasonable state purposes, including protecting potential human life.[260] Writing in dissent (in part), Justice Stevens argued that there was "no secular purpose" for the legislative declarations that "life begins at conception and that conception occurs at fertilization." That proposition, Stevens argued, reflected

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256. *See*, e.g., Ariana Eunjung Cha, *'Our State is at War with our Family': Clergy with Trans Kids Fight Back*, The WASH. POST (Feb. 28, 2023, 2:18 PM), https://www.washingtonpost.com/health/2023/02/28/missouri-transgender-bills/ [https://perma.cc/P794-WY7W]; WIS. FAITH VOICES FOR JUSTICE, *Faith Leaders Support for Transgender Equality*, WISPOLITICS (Oct. 4, 2023), https://www.wispolitics.com/2023/wisconsin-faith-voices-for-justice-faith-leaders-support-for-transgender-equality/ [https://perma.cc/F5U8-PFV4].

257. Here, a critical distinction is between (a) laws that cover the entire populace and are explicitly justified by religious belief, and (b) laws that authorize an exemption from some law based on religious belief. The former violates the Establishment Clause, while the latter may (depending on the facts) be permissible or even mandated under the Free Exercise Clause.

258. *See, e.g.*, Stone v. Graham, 449 U.S. 39, 42 (1980) (discussing display of Ten Commandments in classrooms); Wallace v. Jaffree, 472 U.S. 38, 38 (1985) (striking down a moment of silence in schools based on legislative history showing religious motivation); Edwards v. Aguillard, 482 U.S. 577, 577 (1987) (striking down a ban on the teaching of evolution).

259. In *Kennedy v. Bremerton School District*, the Court took a dismissive view of *Lemon* in the context of prayer by a school football coach. But that case involves whether a public institution (there, a school) may prohibit an individual's religious activity—it did not consider whether the state itself may, through its laws, enact religious precepts without any secular foundation. *See* Kennedy v. Bremerton School District, 597 U.S. ____ (2022).

260. 492 U.S. 490, 495 (1989).

a "theological position" and not a scientific one and, thus, should make that portion of the preamble "invalid under the Establishment Clause."[261] Importantly, Stevens noted that his conclusions about the Establishment Clause were informed by "the fact that the intensely divisive character of much of the national debate over the abortion issue reflects the deeply held religious convictions of many participants in the debate."[262]

Stevens's 1989 analysis, while not binding precedent, would apply forcefully to present anti-LGBTQIA+ legislation. As we have shown, religious organizations and theological commitments are driving these laws. Although defenders of health care bans, for instance, frame their arguments in secular and scientific terms, their commitments—as we have shown—are fundamentally theological and not scientific.[263]

In the wake of *Dobbs*, Establishment Clause arguments about abortion laws have re-entered legal discourse. Religious groups have challenged abortion restrictions in Florida and Missouri, for example, on the grounds that the laws elevate one set of religious beliefs at the expense of other religious beliefs.[264] In Missouri, for example, legislators made numerous statements suggesting that a restrictive abortion law was motivated by religious belief.[265]

At the moment, legal challenges to anti-LGBTQIA+ laws have prevailed on other grounds. As we have seen, judges have enjoined the health care bans on equal protection, due process, and free speech grounds, and there is a risk that a Supreme Court hostile to Establishment Clause claims might ultimately rule against a challenge made on this basis. Still, the Establishment Clause could provide additional constitutional weight, and appropriately so, since these measures, as we have detailed, originate in religious commitments and not scientific fact.

Further, as many constitutional scholars have urged, the Constitution should inform not only litigation but also Congressional and Executive deliberations and popular political movements.[266] Legislators and agency officials can and should point out the Establishment Clause problem inherent in

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261. *Webster*, 492 U.S. at 566–68.

262. *Id.* at 571.

263. *See generally* Linda Greenhouse, *Let's Not Forget the Establishment Clause*, N.Y. TIMES (May 23, 2019), https://www.nytimes.com/2019/05/23/opinion/abortion-supreme-court-religion.html.

264. *See* Complaint at 2, Generation to Generation, Inc. v. DeSantis, No. 2022 CA 000980, 2022 WL 23882392 (Fla. Cir. Ct. June 16, 2022) (arguing that Florida's abortion ban violates the state constitution's Establishment Clause). The case was later dismissed for inadequate pleading.

265. *See* Complaint at 7, Blackmon v. Missouri, No. 2322-CC00120 (Mo. Cir. Ct. Jan. 19, 2023) (giving examples of legislators' statements, including "as a Catholic I do believe life begins at conception and that is built into our legislative findings.").

266. *See* Ernest A. Young, *Constitutionalism Outside the Courts*, *in* OXFORD HANDBOOK ON THE U.S. CONST. 846, 861 (Mark Graber et al. eds., 2015); LARRY KRAMER, THE PEOPLE THEMSELVES 8 (2004); Mark V. Tushnet, *The Constitution Outside the Courts: A Preliminary Inquiry*, 26 VAL. U. L. REV. 437, 439 (1992).

adopting religious views into law. They can use their pulpit and their power not only to challenge misinformation but also to point out and criticize the religious content of anti-trans lawmaking.

Misinformation and religious pseudoscience pose a growing threat to the integrity of the legal system, and they threaten not only the lives of LGBTQ people but those of others as well. Abortion bans based on misinformation are now a fact of life across red America, and there are early signals that misinformation will be deployed to challenge constitutional rights to contraception and marriage equality. We need new institutions that can unmask misinformation and the religious and unscientific foundations of these attacks on fundamental rights.

APPENDIX

Table 1. An overview of U.S. state anti-trans legal measures.*

Type of legal restriction	**Number of states**	**Targets**
Health care bans	22[267]	Medical care for transgender people with gender dysphoria
Bathroom bans	24[268]	Use of bathrooms aligned with gender identity (rather than sex assigned at birth)
Sports bans	9[269]	Participation in school sports aligned with gender identity (rather than sex assigned at birth)
"Don't Say Gay" laws	14[270]	Curriculum mentions of LGBTQIA+ people and issues
Drag bans	2[271]	Drag performances

* Note that the table includes only state-level legislation and executive action. It does not include local actions (e.g., bathroom bans adopted by

267. *Map: Attacks on Gender Affirming Care by State*, HUM. RTS. CAMPAIGN, https://www.hrc.org/resources/attacks-on-gender-affirming-care-by-state-map [https://perma.cc/B2R6-CE2L] (last visited June 22, 2023).

268. *Bans on Transgender Youth Participation in Sports*, MOVEMENT ADVANCEMENT PROJECT, https://www.lgbtmap.org/equality-maps/youth/sports_participation_bans [https://perma.cc/65B8-KYYK] (last visited June 22, 2023).

269. *Bans on Transgender People Using Bathrooms and Facilities According to their Gender Identity*, MOVEMENT ADVANCEMENT PROJECT, https://www.lgbtmap.org/equality-maps/nondiscrimination/bathroom_bans [https://perma.cc/N2FC-VMK6] (last visited July 20, 2023).

270. *LGBTQ Curricular Laws,* MOVEMENT ADVANCEMENT PROJECT, https://www.lgbtmap.org/equality-maps/curricular_laws [https://perma.cc/4LP7-5CBB] (last visited July 20, 2023).

271. *Restrictions on Drag Performances*, MOVEMENT ADVANCEMENT PROJECT, https://www.lgbtmap.org/equality-maps/criminaljustice/drag_restrictions [https://perma.cc/5EBK-PZBJ] (last visited July 20, 2023).

schools or school boards) or aggressive interpretations of existing laws (e.g., attempts to regulate drag performances as “adult” entertainment).

Table 2. Clinical practice guidelines for gender-affirming healthcare

Medical Claim	**Endorsed by the Following Medical Assocs.**
Authoritative guidelines for medical treatment of gender dysphoria based on comprehensive reviews of scientific evidence.	World Professional Association for Transgender Health (WPATH) Standards of Care (2022);[272] Endocrine Society Clinical Practice Guidelines (2017)[273]
Treatment for gender dysphoria after the onset of adolescence may include, when medically appropriate, puberty suppression and cross-sex hormones.	World Professional Association for Transgender Health (WPATH) Standards of Care (2022);[274] Endocrine Society Clinical Practice Guidelines (2017);[275] American Academy of Pediatrics (2018);[276] American Psychological Association Guidelines for Psychological Practice with Transgender and Gender Nonconforming People (2015);[277] American Academy of Child and Adolescent Psychiatry (2011);[278] American Medical Association, American College of Obstetricians and Gynecologists, and 18 additional medical societies (2022)[279]

272. WORLD PRO. ASS'N FOR TRANSGENDER HEALTH, *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People*, 23 INT. J. OF TRANSGENDER HEALTH S1 (2022), https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644.

273. Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. CLINICAL ENDOCRINOLOGY METABOLISM 3869 (2017).

274. WORLD PRO. ASS'N FOR TRANSGENDER HEALTH, *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People*, 23 INT. J. OF TRANSGENDER HEALTH S1 (2022), https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644.

275. *See* Hembree et al., *supra* note 273.

276. Jason Rafferty et. al, *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142 PEDIATRICS 1 (2018).

277. AM. PSYCH. ASS'N, *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*, 70 AM. PSYCHOLOGIST 832 (2015).

278. Stewart L. Adelson, *Practice Parameter on Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and Adolescents*, 51 J. AM. ACAD. CHILD & ADOLESCENT PSYCHIATRY 957 (2012).

279. Brief for American Academy of Pediatrics and Additional National and State Medical and Mental Health Organizations as Amici Curiae Supporting Plaintiffs, Eknes-Tucker v. Ivey, No. 2:22-cv-0184-LCB-SRW, 2022 WL 19983530 (M.D. Ala. May 3, 2022) (later redesignated *Eknes-Tucker v. Abbott*).

Care should be individualized following a thorough psychosocial assessment and consultation with a multi-disciplinary medical team.	All.
Care should be individualized following a thorough psychosocial assessment and consultation with a multi-disciplinary medical team.	All.

Table 3. Judicial injunctions against state bans on gender-affirming medical care

State	**Parties**	**Terms of ban**	**Judicial ruling**	**Date**	**Level of judicial challenge**
Alabama	Boe v. Marshall[280]	SB 184 Statute imposing felony penalties if treatment provided to a minor	Preliminary injunction	2022	Federal
Arkansas	Brandt v. Rutledge[281]	HB 1570 Statute imposing loss of licensure on medical providers treating minors	Preliminary injunction followed by permanent injunction	2021, 2023	Federal
Florida	Dekker v. Weida[282]	Fla. Admin. Code R. 59G-1.050(7)	Permanent injunction	2023	Federal

280. Formerly Eknes-Tucker v. Marshall, 603 F. Supp. 3d 1131, 1139 (M.D. Ala. 2022) (granting preliminary injunction), *vacated sub nom*. Eknes-Tucker v. Governor of Alabama, 80 F.4th 1205 (11th Cir. 2023).

281. Brandt v. Rutledge, 551 F.Supp.3d 882 (E.D. Ark. 2021).

282. Dekker v. Weida, No. 4:22CV325-RH-MAF, 2023 WL 4102243 (N.D. Fla. June 21, 2023).

		State agency denial of Medicaid coverage for all ages			
	Dekker v. Weida[283]	CSSB 254 State statute	Permanent injunction	2023	Federal
	Doe v. Ladapo[284]	Fla. Admin. Code R.64B8-0.019(1)(b); Fla. Admin. Code R. 64B15-14.014(1)(b) State Board of Medicine penalties on physicians providing care to minors	Preliminary injunction	2023	Federal
	Doe v. Ladapo[285]	CSSB 254 State statute	Preliminary injunction	2023	Federal
Indiana	K.C. v. Medical Licensing Board of Indiana[286]	SEA 480 Statute	Preliminary injunction	2023	Federal

283. *Id.*
284. Doe v. Ladapo, No. 4:23CV114-RH-MAF, 2023 WL 3833848 (N.D. Fla. June 6, 2023).
285. *Id.*
286. K.C. v. Med. Licensing Bd. of Ind., No. 1:23-cv-00595-JPH-KMB, 2023 WL 4054086 (S.D. Ind. June 16, 2023).

Kentucky	Doe v. Thornbury[287]	SB 150 Statute imposing loss of licensure and per se malpractice liability	Preliminary injunction granted by District Court but stayed pending appeal to the Sixth Circuit	2023	Federal
Tennessee	L.W. v. Skrmetti[288]	SB 1[289] Statute imposing loss of licensure and civil fines for treatment of minors	Preliminary injunction granted by District Court but stayed pending appeal to the Sixth Circuit	2023	Federal
Texas	PFLAG v. Abbott[290]	Feb. 22. 2022 Letter from Gov. Greg Abbott to Jaime Masters, Commissioner of TX Dep't of Family and Protective Servs.; Texas AG Opinion KP-0401 State	Preliminary injunction	2022	State

287. Doe 1 v. Thornbury, No. 3:23-cv-230-DJH, 2023 WL 4230481 (W.D. Ky. June 28, 2023).
288. L.W. v Skrmetti, No. 3:23-cv-00376, 2023 WL 4232308 (M.D. Tenn. June 28, 2023).
289. S.B. 1, 2023 Leg., 113th Sess. (Tenn. 2023).
290. The Texas court has issued three preliminary injunctions against the state of Texas. For the most recent preliminary injunction (which recounts the procedural history), see PFLAG v. Abbott, No. D-1-GN-22-002569, 2022 WL 4549009 (Tex. Dist. Sept. 16, 2022) (order granting temporary injunction).

		executive directive ordering (pursuant to AG Opinion) investigation by TX Department of Family and Protective Services into parents consenting to treatment of minors			

Table 4: Original, peer-reviewed research studies demonstrating the benefits of gender-affirming care (GAC) for transgender youth (in chronological order)

Study	**Outcomes**
De Vries, et al. (2011)[291]	Behavioral and emotional problems and depressive symptoms decreased; general functioning improved; feelings of anxiety and anger did not change; gender dysphoria and body satisfaction did not change; all participants progressed to cross-sex hormone treatment.
De Vries, et al. (2014)[292]	Gender dysphoria and psychological functioning improved. Well-being was similar to or better than cisgender age-matched controls.
Costa, et al. (2015)[293]	Adolescents with gender dysphoria who received puberty suppression had significantly better psychosocial functioning after 1 year of puberty suppression than with just

291. Annalou L.C. deVries et al., *Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study*, 8 J. SEX. MED. 2276 (2011).

292. Annalou L.C. deVries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 PEDIATRICS 696 (2014).

293. Rosalia Costa et al., *Psychological Support, Puberty Suppression, and Psychosocial Functioning in Adolescents with Gender Dysphoria*, 12 J. SEX. MED. 2206 (2014).

	psychotherapy.
Allen, et al. (2019)[294]	Improvement in general well-being and decreased suicidality.
Kaltiala, et al. (2020)[295]	Decreased need for psychiatric treatment of depression, anxiety, suicidality and self-harm.
van der Miesen, et al. (2020) [296]	Transgender adolescents receiving puberty suppression had fewer emotional and behavioral problems than newly referred patients and had similar or fewer problems than their same-age cisgender peers.
Achille, et al. (2020).[297]	Mean depression scores and suicidal ideation decreased, quality of life scores improved over time.
de Lara, et al (2020)[298]	At baseline, trans adolescents had worse measures of mental health than the cisgender control adolescents. The transgender adolescents in the study who received gender affirming hormones had statistically significant improvements in anxiety and depression.
Kuper, et al. (2020)[299]	Large improvement in body dissatisfaction, small to moderate improvement in depression and anxiety
Sorbara, et al. (2020)[300]	Late pubertal stage and older age at onset of GAC were found to be associated with worse mental health among youth, with outcomes including greater depression, self-harm,

294. Luke R. Allen et al., *Well-Being and Suicidality Among Transgender Youth After Gender-Affirming Hormones*, 7 CLINICAL PRAC. PEDIATRIC PSYCH. 302 (2019).

295. Riittakerttu Kaltiala et al., *Adolescent Development and Psychosocial Functioning After Starting Cross-Sex Hormones for Gender Dysphoria*, 74 J. NORDIC PSYCHIATRY 1 (2020).

296. Anna I.R. van der Miesen et al., *Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared With Cisgender General Population Peers*, 66 J. ADOLESCENT HEALTH 699 (2020).

297. Christal Achille et al., *Longitudinal Impact of Gender-Affirming Endocrine Intervention on the Mental Health and Well-Being of Transgender Youths: Preliminary Results*, 2020 J. INT'L PEDIATRIC ENDOCRINOLOGY 1 (2020).

298. Diego López de Lara et al., *Evaluación psicosocial en adolescents transgénero* [Psychosocial assessment in transgender adolescents], 93 ANALES DE PEDIATRÍA 41 (2020) (Sp.).

299. Laura E. Kuper et al., *Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy*, 145 PEDIATRICS 1 (2020).

300. Julia C. Sorbara et al., *Mental Health and Timing of Gender-Affirming Care*, 146 PEDIATRICS 1 (2020).

	suicide and suicide attempts, and psychoactive medication.
Turban, et al. (2020)[301]	Access to pubertal suppression was associated with a lower odds of lifetime suicidal ideation.
Carmichael, et al. (2021)[302]	Overall patient experience of changes on puberty blockers was positive, based on qualitative interviews.
Grannis, et al. (2021)[303]	Those receiving testosterone had lower scores in generalized anxiety, social anxiety, depression, and body image dissatisfaction compared to those not receiving hormones.
Green, et al. (2021)[304]	Access to gender-affirming hormones was associated with lower odds of recent depression and suicide attempts compared to those who desired but did not access gender-affirming hormones.
Turban, et al. (2022)[305]	Accessing GAC was associated with lower odds of past-year suicidal ideation and past year severe psychological distress. Access to GAC during adolescence was associated with a lower odds of these same adverse mental health outcomes when compared to those not accessing gender-affirming hormones until adulthood.
Tordoff, et al. (2022)[306]	Lower odds of depression and suicidality GAC, when compared to those who did not.
Chen, et al. (2023)[307]	Appearance congruence, positive affect, and

301. Jack L. Turban et al., *Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation*, 145 PEDIATRICS 1 (2020).

302. Polly Carmichael et al., *Short-Term Outcomes of Pubertal Suppression in a Selected Cohort of 12 to 15 Year Old Young People with Persistent Gender Dysphoria in the UK*, 16 PLOS ONE 1 (2021).

303. Connor Grannis et al., *Testosterone Treatment, Internalizing Symptoms, and Body Image Dissatisfaction in Transgender Boys*, 132 PSYCHONEUROENDOCRINOLOGY 1 (2021).

304. Amy E. Green et al., *Association of Gender-Affirming Hormone Therapy with Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth*, 70 J. ADOLESCENT HEALTH 643 (2022).

305. Jack L. Turban et al., *Access to Gender-Affirming Hormones During Adolescence and Mental Health Outcomes Among Transgender Adults*, 17 PLOS ONE 1 (2022).

306. Diana M. Tordoff et al., *Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care*, 5 JAMA NETWORK OPEN 1 (2022).

	life satisfaction increased, and depression and anxiety symptoms decreased. Appearance congruence correlated positively with increases in positive affect and life satisfaction and decreases in depression and anxiety symptoms.

307. Diane Chen et al., *Psychosocial Functioning in Transgender Adolescent After 2 Years of Hormones*, 388 NEW ENG. J. MED. 240 (2023).

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Incongruencia de género en niñas, niños y adolescentes: intervenciones transafirmativas en Hospital las Higueras Talcahuano

Gender incongruity in girls, boys and adolescents: transaffirmative intervention at Las Higueras Hospital, Talcahuano.

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Resumen:

Introducción: incongruencia de género (IG) en niñas, niños y adolescentes (NNA), es un tema que se ha ido visibilizando cada vez más y es definida como una marcada discordancia entre la identidad de género y el sexo asignado al nacer. El objetivo es realizar una revisión de la evidencia en relación a la IG en NNA, las intervenciones recomendadas basadas en evidencia y finalmente dar a conocer la experiencia local en el Hospital las Higueras de Talcahuano. **Métodos:** se realizó una búsqueda en PUBMED artículos en inglés y español, desde 2011 a 2019. De los artículos encontrados, se revisó además la bibliografía de ellos, sumando a la revisión las publicaciones que fueran pertinentes. En la revisión práctica se realizó una sistematización de las intervenciones que se llevan a cabo a nivel endocrinológico y en salud mental. **Resultados:** los resultados indican que la prevalencia ha ido en aumento, al igual que la prevalencia hombre trans. Existen indicadores específicos para poder diferenciar la desistencia o persistencia de la IG. Las condiciones asociadas tales como ansiedad, depresión, ideación y conducta suicidas son generadas por el estrés de minorías y la intervención más apropiada es la afirmativa. Existe alta varianza de género en personas de condición trastorno de espectro autista (TEA), siendo mayor en las niñas que en los niños. Desde marzo 2019 Hospital las Higueras de Talcahuano inicia intervención transafirmativa con IG en NNA. **Conclusiones:** es necesario visibilizar el tema y despatologizarlo para que las(os) NNA tengan mayor acceso a apoyo transafirmativo.

Palabras clave: incongruencia de género; transgénero; niñas(os); adolescentes; intervenciones transafirmativas,

Abstract:

Introduction: Gender incongruity (GI) in boys, girls, and adolescents (BGA), is becoming an ever more visible issue. It is defined as a marked misalignment between gender identity and the sex assigned at birth. **Objective**: to make a review of evidence regarding GI in BGA, the recommended evidence-based interventions and, ultimately, to show the local experience at Las Higueras Hospital in Talcahuano. **Methods**: A search of articles written in English and Spanish between 2011 and 2019 was performed in PUBMED and, from the articles found, their biblographies were also revised, adding the pertinent publications to the revision process. In the practical revision, a systematization of the interventions performed at an endocrinological level and in mental health, was also made. **Results**: the results indicate that prevalence has been increasing, as has male trans prevalence. There are specific indicators to differentiate GI desistance or persistance. The associated conditions such as anxiety, depression, suicidal ideation and conduct, are generated by the stress minorities suffer and the most appropriate intervention is the affirmative one. There is a high gender variance in people within the autism spectrum disorder (ASD), which is higher in girls than in boys. In 2019, Las Higueras Hospital in Talcahuano started with a trans-afirmative intervention with GI in BGA. **Conclusions**: It is necessary to make GI visible and depathologize it so that BGA have greater access to trans-affirmative support.

Keywords: Gender incongruity; Transgender; Boys/Girls; Adolescents, Trans-affirmative interventions.

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Introduccion

En los países occidentales, un creciente número de adolescentes transgénero están buscando acompañamiento – acogida en clínicas especializadas en niñas, niños y adolescentes (NNA) que presentan incongruencia de género (IG) (Kaltiala-Heino *et al*., 2018). Además, durante la última década ha habido un importante aumento del interés por parte de la comunidad y los profesionales de la salud en temas relacionados con la población transgénero. Por su parte, los cuerpos legislativos han comenzado a evaluar los derechos de estas personas (Turban *et al*., 2018).

En Chile, a nivel salud se da a conocer la vía clínica para la adecuación corporal en personas con incongruencia de género (MINSAL, 2010), en donde se exponen las intervenciones de salud mental, hormonales y quirúrgicas en el manejo de personas transgénero mayores de 18 años. Al siguiente año se instruye a los establecimientos de la red asistencial con la circular 34 (MINSAL, 2011) respecto de la atención de personas trans en relación con la identificación de la persona o nombre social, registro en ficha clínica y hospitalización. En 2012 se da a conocer la circular 21 (MINSAL, 2012) que rige a la fecha y que reitera y profundiza instrucciones sobre la atención de personas trans en la red asistencial en aquellas que son de competencia en la atención ambulatorial abierta, atención primaria y de especialidades. A nivel educacional, se da a conocer la circular 0768 (MINEDUC, 2017), la cual está dirigida a todos los establecimientos educacionales del país y se enfoca en los derechos de NNA en el ámbito de la educación, particularmente en el uso del nombre social, uniforme adecuado a su identidad de género y uso de baños. A nivel legislativo, en diciembre de 2018 se publicó la ley de identidad de género 21120 (Congreso Nacional de Chile, 2018) que reconoce y da protección al derecho a la identidad de género, lo que ha permitido avanzar en visibilizar los derechos de las personas transgénero, ha incentivado la creación de programas de salud especializados en IG para NNA (Turban *et al*., 2018) y ha generado una derivación más expedita a estos centros de mayor especialización.

Definiciones

El género desde siempre había sido considerado binario, es decir como solamente femenino o masculino y se ha relacionado al sexo al nacer y a la orientación sexual, es decir una mujer de nacimiento debía ser de género femenino y, además al momento de su madurez sexual sentirse atraída a un hombre y por el contrario un hombre de nacimiento debía ser masculino y sentirse atraído hacia una mujer. Es necesario destacar que estos tres aspectos son diferentes entre sí y no necesariamente se van a relacionar linealmente, es decir una mujer de nacimiento se puede identificar con el género masculino y sentirse atraída sexualmente hacia una mujer. El género no es binario, ya que existen personas que se identifican con otros géneros distintos de lo femenino o masculino tales como el **género** fluído, agénero y género no binario.

Tabla 1: Definiciones

Sexo: condición biológica de la persona (cromosómica, hormonal, gonadal y genital).
Identidad de género: alude al autoconcepto respecto a cómo la persona siente internamente su género.
Rol de género: características consideradas como masculinas o femeninas por una cultura en particular.
Expresión de género: presentación individual de su propia identidad de género (ropa, peinados, actividades, etc.).
Orientación sexual: se refiere a quién resulta sexualmente atractivo para la persona; alude a la elección de pareja del individuo.
Incongruencia de género: discordancia entre la vivencia que la persona tiene respecto de su género y el sexo asignado al nacer.
Transgénero: la persona que vivencia una IG. Término que se utiliza indistintamente a incongruencia de género.
Cisgénero: persona cuya identidad de género es concordante con su sexo asignado al nacer. Vivencia su género como congruente.
Disforia de género: disconfort o distress al conectarse con su IG.
Condiciones asociadas: sintomatología que puede o no acompañar la IG tales como ansiedad, depresión, autoagresiones y suicidalidad.
Hombre transgénero: persona asignada a sexo femenino al nacer y que se vive hombre.
Mujer transgénero: persona asignada a sexo masculino al nacer y que se vive como mujer.

Para el propósito de esta revisión bibliográfica y el quehacer profesional en Hospital las Higueras de Talcahuano (HLH) utilizaremos la clasificación diagnóstica CIE-11 (Organización Mundial de la Salud, 2018) y los términos incongruencia de género y/o transgénero para referirnos a esta población infanto juvenil.

El objetivo de este trabajo es por una parte realizar una revisión teórica de la literatura existente en relación a la IG en NNA y además dar a conocer la realidad local en relación al tema y las intervenciones transafirmativas que se realizan por parte de los profesionales del equipo trans pediátrico en HLH.

Metodologia

El presente trabajo corresponde a una revisión teórica y práctica. En la revisión teórica se realizó una búsqueda en PUBMED, utilizando los siguientes términos: *gender incongruency in child, affirmative intervention in child and youth, autism and gender, transgender child*

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and youth, gender no conforming, minority stress model, desist and persist in children. Se buscaron artículos en inglés y español, desde 2010 a 2020. De los artículos encontrados, se revisó además la bibliografía de ellos, sumando a la revisión las publicaciones que fueran pertinentes.

En la revisión práctica se realizó una sistematización de las intervenciones que se llevan a cabo a nivel endocrinológico y en salud mental, en donde cada profesional y autor aportó desde su área respectiva.

Resultados

Etiología

Se considera que la IG tiene orígenes multifactoriales, genéticos, biológicos, psicológicos y sociales. En el pasado el área de mayor interés fue psicológica y hoy el interés se ha movilizado hacia la etiología de carácter biológico (Turban *et al*., 2018).

Los estudios sobre la heredabilidad de la IG han reportado que los factores genéticos pueden contribuir en el desarrollo del género (Shumer *et al*., 2016).

Los estudios sobre el origen biológico han mostrado que las hormonas sexuales prenatales no sólo determinan el desarrollo de genitales externos e internos, sino también actúan en la diferenciación sexual del cerebro (Martinerie *et al*., 2018). En esta área se hace mención a la teoría neurobiológica, que se centra en el periodo de la embriogénesis y refiere que la diferenciación genital ocurre mucho antes que la sexual en el cerebro, por lo que no hay una sincronización de estos procesos y pueden no requerir similares niveles de impregnación hormonal, por lo tanto es posible que en relación a niveles variables de secreción hormonal en aquellos dos órganos, los genitales se desarrollen hacia el fenotipo mujer, mientras que el cerebro se diferencie hacia el fenotipo masculino o al contrario (Martinerie *et al*., 2018).

Los factores psicológicos que se han estudiado son el rol de las características de los padres en el desarrollo de la IG, tales como las expectativas, preferencias por el sexo de sus hijas(os) y la ausencia del padre; sin embargo, no hay investigaciones concluyentes al respecto (Shumer *et al*., 2016; Martinerie *et al*., 2018; Turban *et al*., 2018).

Prevalencia

Ha sido difícil el establecimiento de la verdadera prevalencia de la IG a causa de los cambios en la terminología y el estigma asociado a la autoidentificación (Turban *et al*., 2018).

En un metaanálisis de estudios de prevalencia en IG, se encontró que ha aumentado en los últimos cincuenta años llegando a 4,6 en 100000 individuos, en donde 6,8/ 100000 es para mujeres transgénero y 2,6/100000 para hombres transgénero (Arcelus *et al*., 2015). En 2017, en un estudio (Eisenberg *et al*., 2017) con un gran número de jóvenes de escuelas de Minnesota (N: 81885) se publicó una prevalencia de 2,7% de jóvenes transgénero, con un 3,6% de hombres transgénero y 1,7% de mujeres transgénero.

En Alemania, en 2017 (Becker *et al*., 2017), se encuestó a 940 adolescentes hombres y mujeres de diez a dieciséis años y se les preguntó cuál era su experiencia actual de género (masculina o femenina) y su expresión de género y los resultados revelaron que el 4,1% de los adolescentes eran género no binario y el 3,0% no conformes con su género. En general se ha observado un incremento en la prevalencia debido a la despatologización y desestigmatización de la IG (Martinerie *et al*., 2018). Y en los adolescentes ha habido una inversión reciente en la proporción que antes favorecía a las mujeres transgénero, hoy es mayor la proporción de hombres transgénero (Littman, 2019).

En Chile existe un desconocimiento de la prevalencia de personas trans, lo que influye notablemente en las políticas públicas nacionales. La única estimación sobre diversidad sexual la ha entregado la Encuesta de Caracterización Socioeconómica Nacional CASEN (Ministerio de Desarrollo Social, 2015) y los resultados indicaron que la población que se reconoce como heterosexual es el 98, 51%, la que indica ser homosexual o lesbiana 1,04%, bisexual 0, 37%, otra 0,02%, estimándose que dentro de esta última categoría se encontraría la población transgénero. En esta misma encuesta frente a la pregunta "en cuanto a su género usted se identifica como", el 3,1% de la población mayor de 18 años se identificó como transfemenina y el 2,3% como transmasculino. En E.E.U.U estudios realizados estiman que 0,5% de la población se podría definir como transgénero y al hacer una extrapolación de las cifras norteamericanas a la población chilena del ultimo censo se estimaría que en Chile habrían más de 80000 personas transgénero y cada año existirían cerca de 30 nuevas personas transgénero que podrían demandar asistencia sanitaria (Zapata *et al.,* 2019).

Desarrollo de identidad de género

Tres teorías psicológicas clásicas han elaborado explicaciones para el desarrollo de la identidad de género: la teoría psicoanalítica, la teoría del aprendizaje social y la cognitivo evolutiva, sin embargo, las tres teorías son dificilmente comparables ya que tienen planteamientos distintos (Freixas, 2012). En la teoría psicoanalítica la socialización del rol sexual se produce al superar el complejo de edipo, en la teoría del aprendizaje social los roles de género se aprenden inicialmente por observación y luego por imitación, en donde los adultos desempeñan un papel básico reforzando

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diferencialmente las conductas que les parecen apropiadas a lo femenino o masculino (Freixas, 2012), pero se ha visto que las(os) niñas(os) una vez que desarrollan su identidad de género pueden entrar en conflicto con la socialización externa (Gülgöz *et al.,* 2019). La teoría cognitivo evolutiva desarrollada por Kohlberg (Kohlberg *et al.,* 1967) plantea que existen estructuras centrales activas que determinan la evolución de la identidad sexual y de género y que se fundamenta en el desarrollo cognitivo del mundo social, en donde un aspecto importante es el juicio de autoclasificación que realiza la (el) niña(o) como niña o niño. Plantea tres etapas en el desarrollo, relacionadas con las etapas del desarrollo cognitivo preoperacional, operacional concreto y operacional formal: Etapa 1: adquisición de la identidad de género, surge a partir del juicio de la realidad física de que mujeres y hombres son diferentes. Etapa 2: Constancia e irreversibilidad de género, en donde se adquiere la comprensión de que el género no se puede cambiar con el tiempo y que a pesar de cambios en aspectos externos sigue estable. Etapa 3: capacidad para relativizar y criticar los contenidos sociales asignados a los roles de género.

Los teoricos del desarrollo del género actuales explican su desarrollo desde una combinación de influencias de factores biológicos (como el sexo asignado y exposición a hormonas prenatales), cognición de género y la socialización cultural e interpersonal que experimentan las niñas y niños (Gülgöz *et al.,* 2019).

En entrevistas a madres, padres y cuidadores de jóvenes transgénero, éstos percibían las primeras señales alrededor de los cuatro años y medio, mientras las mismas niñas(os) se describían como diferentes, alrededor de los seis años (Murchison, 2016).

En un estudio norteamericano (Olson *et al*., 2015) se evaluó en niñas(os) de cinco a doce años la cognición de género (preferencia de género, identidad de género y preferencias explícitas de género) y los resultados mostraron que las niñas(os) transgénero no se confunden en relación a su identidad de género, piensan de acuerdo a ella y no de acuerdo a su sexo al nacer y además lo hacen desde muy pequeñas(os).

En Chile se realizó un estudio a gran escala (Organizando Trans Diversidades, 2017), mediante una encuesta online (encuesta T), en donde participaron 315 personas trans que fueron encuestadas(os) por diversos temas y entre ellos el desarrollo y específicamente a qué edad percibían que no se adecuaban al género impuesto, destacándo que la mayoría (41,3%) lo reconoce entre los 0 y 5 años, un 39,4% lo sitúa entre los 6 y 11 años. Un 42,5% de las(os) entrevistados declara haber reconocido su identidad de género entre los 12 y 18 años de edad, mientras que un 36,2% lo hizo entre los 19 y 25 años de edad. Estos datos nos muestran que la mayoría se autoclasifica con un género distinto desde la primera infancia tal como fue comentado anteriormente en las etapas del desarrollo del género. También nos muestran lamentablemente el extenso tiempo que puede pasar una(o) NNA en Chile hasta que finalmente sea apoyado en su identidad y tomar contacto con un equipo de salud especializado, lo que puede conllevar dificultades de salud mental y retrasar sus intervenciones transafirmativas.

Incongruencia de género y tareas del desarrollo adolescente

Las tareas del desarrollo se refieren a los hitos normativos del desarrollo que deben alcanzarse durante una etapa del desarrollo determinada, surgen de las interacciones entre el desarrollo físico, aspectos individuales y las expectativas de la sociedad. La finalización favorable de las tareas del desarrollo de una etapa dada es un requisito previo para el éxito en las etapas posteriores. Las tareas del desarrollo de la adolescencia fueron formuladas por primera vez por Havighurst (Kaltiala-Heino *et al.*, 2018) y comprenden aceptar el cuerpo, adoptar un rol social masculino o femenino, lograr la independencia emocional de los padres, desarrollar relaciones cercanas con los mismos géneros y opuestos, prepararse para una ocupación, prepararse para la vida familiar y la pareja, establecer un valor personal o un sistema ético y lograr un comportamiento socialmente responsable.

De todos estos aspectos, la relación con el propio cuerpo y la adquisición de un rol social de género no necesariamente binario, son desafíos de las(os) adolescentes que presentan IG (Kaltiala-Heino *et al.*, 2018). Otra posible área de conflicto sería la relación cercana con pares, ya que muchas(os) de estas(os) jóvenes sufren acoso, hostigamiento o han pasado por periodos de aislamiento en la infancia y adolescencia (Kaltiala-Heino *et al.*, 2018), por lo que desarrollar relaciones de cercanía puede ser difícil para adolescentes con IG. Con respecto a la sexualidad como uno de aquellos desafíos, se podría esperar que las(os) jóvenes transgénero presenten un desarrollo sexual tardío, debido a que es el cuerpo sexual la fuente de angustia (Kaltiala-Heino *et al.*, 2018).

Condiciones asociadas

Las personas transgénero en general tienen más riesgo de experimentar síntomas depresivos, intentos suicidas, agresión física y psicológica (Zapata *et al.,* 2019) y presentar ansiedad, abuso de sustancias, virus de inmunodeficiencia humana (VIH) y dificultades de acceso a la salud (Barrientos *et al.,* 2019). Específicamente las(os) NNA transgénero muestran altas tasas de trastornos internalizantes como ansiedad y depresión (Martinerie *et al*., 2018), conductas de autolesión y suicidio (Shumer *et al*., 2016; Martinerie *et al*., 2018).

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En Chile, la encuesta T (Organizando Trans Diversidades, 2017) informó que un 56% de las(os) encuestadas(os) declaró haber intentado suicidarse, siendo entre los 11 y 15 años las edades en que más se cometen los primeros intentos de suicidio (46%) y en menor medida entre los 16 y los 18 años (26%). Una explicación de la presencia de estas condiciones asociadas es la hipótesis del estrés de las minorías (Jaggi *et al*., 2018; Turban *et al*., 2018). Las personas transgénero o no conformes con su género están expuestas a niveles más altos de discriminación, estigmatización y violencia (Jaggi *et al*., 2018). El modelo de estrés de minorías se basa en la premisa de que las experiencias de estigmatización toman la forma de un llamado estrés de minoría específico que a su vez afecta el estado de salud de las personas. Los factores estresantes se dividen en distales y proximales, en donde los distales son causados por una fuente externa y los proximales se refieren a pensamientos y procesos internos subjetivos de la misma persona transgénero (Jaggi *et al*., 2018).

Trastorno de espectro autista (TEA) e incongruencia de género

En población transgénero existe una alta prevalencia de trastorno de espectro autista (Cooper *et al.*, 2018; Strang *et al.*, 2018; Turban *et al.*, 2018; Mahfouda *et al.*, 2019; Warrier *et al.*, 2020), que se estima es entre el 4,8% y el 26% (Warrier *et al.*, 2020) debido a que las personas TEA presentan altas tasas de género no conforme, siendo esto mayor en mujeres que en hombres. Las personas TEA tienen menos probabilidad de tener una sensación de afiliación a cualquier grupo de género debido a la diferencia en la cognición social y el no compartir los roles sociales (Cooper *et al.*, 2018). Las(os) NNA género diverso y TEA son un grupo especialmente vulnerable a presentar dificultades de salud mental, particularmente del tipo internalizante (ansiedad, depresion, quejas somáticas y dificultades del pensamiento) y baja calidad de vida (Mahfouda *et al.*, 2019). También se ha planteado una hipótesis biológica a esta alta prevalencia, la cual tiene relación con la teoría del cerebro masculino extremo (Cooper *et al.*, 2018) y que explicaría las características de las mujeres TEA, pero no la de los hombres de esa misma condición.

En un estudio de más de 1400 adolescentes y adultos TEA, el 6,5% de las(os) adolescentes y 11,4% de adultos reportó desear ser del otro sexo, comparado con 3% de adolescentes y 5% de adultos controles (Van der Miesen *et al*., 2018). Se realizó seguimiento (Strang *et al*., 2018) a 22 adolescentes TEA por cerca de dos años, la mayoría de los adolescentes reportó ser género no conforme desde muy pequeño y además un tercio de los participantes dijo que otras personas habían cuestionado su diversidad de género porque eran TEA, diciéndoles que era una obsesión más que una experiencia real.

Respecto de la orientación sexual y TEA, en un gran estudio sueco (Rudolph *et al*., 2018) de 47000 adultos con rasgos TEA, se encontró que estas personas tenían más probabilidades que sus compañeros de describirse a sí mismos como bisexuales o como no conformes con las etiquetas de lo heterosexual, homosexual o bisexual.

Incongruencia de género y familia

El apoyo familiar es la principal herramienta para mantener la salud mental de las(os) NNA con IG. En un estudio (Olson *et al*., 2016) cuya muestra fueron 73 niñas y niños de entre tres y doce años que hicieron el tránsito social (cambio de nombre y apariencia) y que además eran apoyados en sus identidades por sus familias, los resultados mostraron que estas niñas y niños tenían niveles normativos de depresión y niveles de ansiedad sólo un poco más altos que la media; además de tener sintomatología internalizante notablemente más baja que los que han mostrado otros estudios con niñas y niños con IG que no han hecho el tránsito social. En Chile, la encuesta T (Organizando Trans Diversidades, 2017) informó que al interior de las familias la violencia más recurrente es el cuestionamiento de la identidad con un 97%, mientras que el ignorar corresponde a un 42% y la agresión verbal a un 36%. Respecto de quiénes cuestionan la identidad, un 39% señala que es su madre y un 29% que es su padre. Al comparar los datos nacionales con una de las mayores encuestas realizadas en EEUU (James *et al.,* 2016), en donde participaron 27715 personas trans, realizada en línea y de forma anónima, observamos que la mayoría de las(os) participantes (60%) respondieron que sus familias apoyaron su identidad trans, el 18% dijeron que no los apoyaron y el 22% dijo que sus familias no los apoyaron ni tampoco se negaron a hacerlo. Los que tuvieron el apoyo de sus familias directas tenían menos probabilidades de registrar una variedad de experiencias negativas relacionadas con la estabilidad económica y de la salud como estar sin hogar, intentar suicidarse o un malestar psicológico grave. Los datos nos muestran que el apoyo del núcleo familiar directo es muy relevante para una persona trans y específicamente para las(os) NNA, ya que aún son dependientes económica, psicológica y afectivamente. Nos queda mucho por hacer como país en garantizar un mayor apoyo familiar a las identidades trans.

Persistencia y desistencia

Las familias de NNA habitualmente preguntan a los profesionales, si es que la IG persistirá o desistirá más adelante en el tiempo. Autores como Temple Newhook (Steensma & Cohen-Kettenis, 2018) reportan la desistencia de la IG en un 80%, sin embargo, Steensma (Steensma & Cohen-Kettenis, 2018) afirma que estos datos estarían basados en estudios con problemas metodológicos respecto de los conceptos de IG y basados también en la comparación de estudios con muestras distintas.

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En las niñas y niños la intensidad de la incongruencia parece ser un predictor de la persistencia (Steensma *et al*., 2013) y el rango de edad de diez a trece parece ser crucial para la persistencia o desistencia (Steensma *et al*., 2011) ya que en este periodo comienzan a emerger las características sexuales secundarias del sexo no deseado, aumentando la disforia o la angustia frente a los cambios corporales, surgiendo así como un indicador de persistencia en su identidad de género (Shumer *et al*., 2016).

Otros aspectos importantes a observar en las niñas y niños que persisten en su IG es la insistencia, persistencia y consistencia en su identidad de género y las declaraciones de las niñas(os) respecto de su identidad de género (Yo soy un niño) v/s su expresión de género (me gustaría ser un niño). (Murchison, 2016).

Hoy en día muchas madres y padres en foros online describen que sus hijas(os) han tenido un inicio rápido de identificarse como transgénero, al igual que el grupo de pares a quienes sus hijas(os) frecuentan y antes de revelarlo a su familia pasan bastante tiempo en uso de internet y redes sociales. Este nuevo grupo de inicio rápido (rapid onset of gender dysphoria ROGD) ha sido estudiado (Littman, 2019) en forma descriptiva por medio de 256 reportes de madres y padres, quienes informaron que sus hijas(os) en su mayoría eran mujeres asignadas al nacer (82%), con una edad promedio de 15,2 años al momento que se identificaron como transgénero y el 41% había expresado una orientación sexual no heterosexual antes de identificarse como transgénero. Un 86,7% de los padres informó que junto al inicio rápido de la incongruencia de género también observaron que sus hijas(os) tuvieron un aumento en el uso de redes sociales e internet y pertenecieron a un grupo de amigas(os) en el que uno o varias(os) también se identificaron como transgénero.

Al hacer un análisis de esta investigación es necesario decir que si bien es cierto muchas(os) NNA se identifican como transgénero en la adolescencia, tal como lo de muestra la encuesta T, en donde un 15,6% se da cuenta que no se adecua al género impuesto entre los 12 a 18 años. Otras(os) NNA perciben desde pequeñas(os) que no se adecúan a su género, pero aún no toman contacto con un concepto que las(os) identifique, por lo que muchas(os) se identifican durante mucho tiempo como homosexual, lesbiana o bisexual hasta que finalmente por medio de redes sociales e internet toman contacto con el concepto transgénero y se identifican con él, es así que las madres y padres de la investigación de Littman reportan que un 54,2% pedían consejo para saber si eran o no transgénero. Muchas(os) NNA recurren a internet y redes sociales para conocerse e identificarse a través de otras(os).

Una limitación que muestra la investigación de Litman es que obtiene información desde las madres y padres, quienes a veces niegan o no quieren reconocer las primeras manifestaciones de incongruencia de género en la infancia de sus hijas(os), es así como un 76,5% de los padres consideraron que sus hijas(os) estaban equivocadas(os) en su creencia de ser transgénero. Es importante saber que muchas(os) NNA pueden iniciar rápidamente la identificación transgénero, pero hay que tomar con cautela esta información y se require más investigación al respecto.

Intervenciones transafirmativas

Las intervenciones se basan en el modelo afirmativo, el cual considera que todos los resultados de la identidad de género son igualmente válidos y deseables y permite a las niñas(os) que expresen su deseo de transición social, hacerlo después de un asesoramiento cuidadoso (Turban *et al*., 2018).

Las intervenciones médicas se clasifican en reversibles, parcialmente reversibles e irreversibles. Dentro de las reversibles se encuentra el bloqueo puberal y es la primera intervención que se puede realizar desde el estadio 2 de Tanner usando análogos de la hormona liberadora de gonadotropina. Luego alrededor de los catorce o dieciséis años las(os) adolescentes pueden optar a la siguiente intervención que es la terapia hormonal cruzada con estrógenos o testosterona (Hembree *et al.*, 2017). A la edad legal para la adultez las(os) usuarias(os) pueden someterse a intervenciones quirúrgicas como se encuentra sugerido en la vía clinica (MINSAL, 2010).

Intervenciones transafirmativas con NNA y sus familias en Hospital las Higueras de Talcahuano (HLH)

Desde el mes de abril de 2019, en el HLH y con un equipo multidisciplinario, se formalizó la atención a NNA transgénero, en donde el enfoque de trabajo se basa en el modelo de intervención transafirmativo. Con el objetivo de despatologizar la intervención de NNA, el ingreso al programa se realiza desde endocrinología (ver figura 1), luego se realiza interconsulta a psiquiatría y finalmente a psicología. El objetivo antes mencionado va en directa relación con las necesidades sentidas por la comunidad trans de despatologización - buen trato y diálogo - participación social, las cuales fueron determinadas en una investigación cualitativa en la mesa trans compuesta por personas de la comunidad trans, del Servicio de Salud Talcahuano y del Hospital Las Higueras de Talcahuano (Valenzuela *et al.,* 2020).

A la fecha el equipo atiende 19 usuarias(os), las(os) cuales son atendidas(os) en salud mental infanto juvenil hasta los 18 años y en endocrinología infantil hasta los 15 años, luego de esa edad son derivadas(os) a la continuación de sus intervenciones con el equipo adulto. Del total de usuarias(os) atendidas(os), 18 son hombres trans (89,4%) y 2 son mujeres trans (10,5%), siendo estos datos locales coincidentes con el aumento de la prevalencia del hombre trans que

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se ha venido señalando en distintas publicaciones internacionales (Zucker, 2017; Litman, 2019). Del total de usuarias(os), 2 son TEA – trans (10,5%), porcentaje que se ajusta a la prevalencia observada internacionalmente (Warrier *et al.,* 2020) y de ellas(os) 1 es mujer TEA – trans (5,2%) y 1 hombre TEA – trans (5,2%). Respecto de los grupos etáreos, el mayor grupo de usuarias(os) es el adolescente (94,7%) y en menor medida el grupo preadolescente (5,2%). Dentro de la adolescencia el 42,1% corresponde a adolescents de 16 años, luego el 21,0% corresponde a adolescents de 18 años y 15,7% corresponde a adolescents de 15 años.

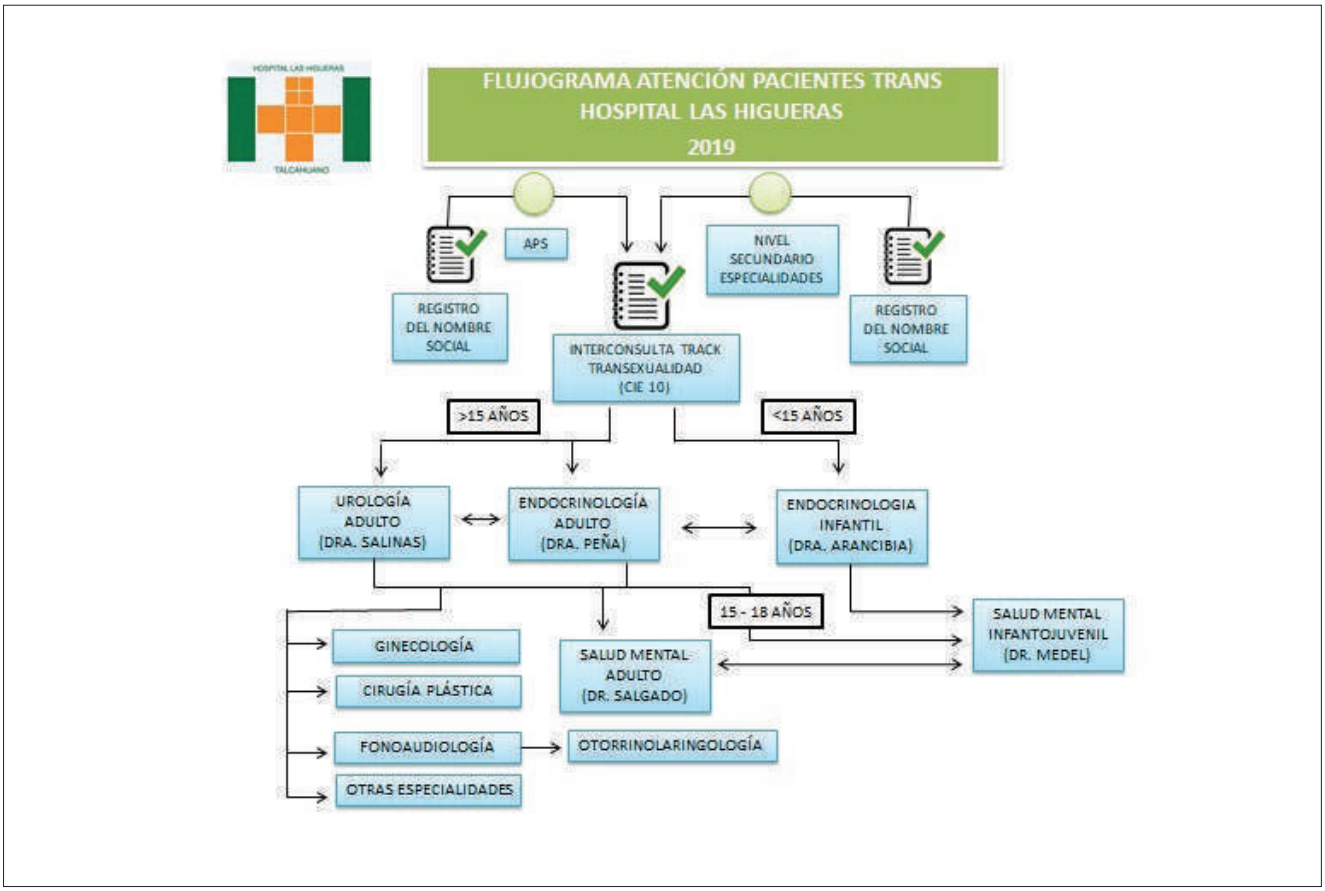

Figura 1: Flujograma de atención a usuarias(os) transgénero en Hospital las Higueras.

Intervenciones en endocrinología:

Etapa prepuberal: se debe realizar evaluación diferencial con variaciones del desarrollo sexual y vigilancia activa frente a la aparición de los primeros signos de pubertad (estadio 2 de Tanner) (Devoto *et al*., 2016). La aparición de botón mamario en niñas regularmente ocurre entre los ocho y doce años y el crecimiento testicular mayor a 4 cc en niños generalmente es entre los nueve y los trece años. La transición social es una intervención que se puede realizar en esta etapa y es completamente reversible asociada con disminución de depresión y ansiedad en niñas(os) prepúberes transgénero (Scherer, 2016).

Etapa puberal: Al pesquisar estadio 2 de Tanner se indica frenación del eje hipotálamo hipófisis gónada para evitar progresión de pubertad. Antes de iniciar este tratamiento se debe cumplir con los siguientes criterios de elegibilidad para uso de análogo del GnRH (Hembree *et al.*, 2017):

1. Cumplir con criterios de IG

2. Estadio 2 de Tanner

3. Ausencia de alteraciones psiquiátricas

4. Estar en algún tratamiento que no contraindique la readecuación corporal

5. Evaluación psicológica y apoyo social adecuado, comprensión realista de resultados esperados, conocimiento de riesgos y beneficios de esta terapia reversible (Devoto *et al.,* 2016).

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A la edad de dieciséis años (Hembree *et al.*, 2017) se recomienda iniciar la terapia hormonal cruzada para inducir pubertad acorde a su identidad de género.

Criterios de elegibilidad para uso de terapia hormonal cruzada (Hembree *et al.*, 2017):

1. Persistencia de IG

2. Que las condiciones asociadas psicológicas, médicas o sociales estén abordadas y resueltas.

3. Adolescente con capacidad mental suficiente (dieciséis años) para entender las consecuencias, riesgos y beneficios de esta terapia parcialmente irreversible, además de dar su asentimiento y consentimiento informado.

Actividades en endocrinología

A continuación, se detallan las actividades que se realizan en esta área con NNA y sus familias:

Tabla 2: Actividades Endocrinología

Anamnesis, examen físico.
Discusión de las metas deseadas y posibles del tratamiento con los padres y/o cuidadores y las(os) NNA.
Discusión de efectos adversos con las madres, padres y/o cuidadores de NNA.
Derivación para consejería en fertilidad.
Evaluación de riesgos.
Interconsulta a otras especialidades en caso de detección de riesgos específicos.
Solicitud de exámenes de laboratorio e imágenes.
Consentimiento y asentimiento informado para padres y NNA.
Inicio de supresión puberal.
Inicio de inducción puberal
Seguimiento.
Reunión clínica para estudio de casos.

Intervenciones en salud mental:

Se realizan en primera instancia dos entrevistas de evaluación con psiquiatra infanto juvenil. Mediante estas entrevistas se establece la presencia de IG, condiciones asociadas y se descarta trastorno psiquiátrico. Se realiza derivación a psicóloga y luego que la psicóloga realiza dos sesiones de evaluación, se analiza caso a caso y se realiza informe por parte de psiquiatra que confirma la IG y sugiere iniciar intervención con endocrinóloga y de salud mental.

Actividades en salud mental

Tabla 3*:* Actividades Salud Mental

Coordinación en colegios
Educación en colegios en el tema Trans
Intervención mensual grupal con familia
Intervención grupal con los NNA
Visitas domiciliarias
Acompañamiento y asesoramiento en aspectos legales en relación al cambio de nombre social en ficha, registral en Tribunales de Familia o registro civil de acuerdo a la edad, circular 0768 MINEDUC y derivación de caso a OPD en caso de vulneración de derechos.
Reunión clínica

Discusion y conclusiones

La IG en NNA se ha ido visibilizando cada vez más, debido de la despatologización en las clasificaciones diagnósticas, a cambios progresivos en la sociedad al ir entendiendo el género como un concepto no binario, al desarrollo de cuerpos legislativos que reconocen y protegen la identidad de género y al esfuerzo diario que realizan las organizaciones que apoyan a la población LGBTQ+.

Este trabajo al visibilizar la IG, creemos que va en la dirección de aportar en disminuir el estrés de minorías, el estigma y la discriminación, que de acuerdo a la literatura genera sintomatología ansiosa, depresiva, bajo autoconcepto y suicidalidad.

Todos los ambientes y contextos donde se desenvuelven y desarrollan las(os) NNA con IG juegan un rol determinante en disminuir la estigmatización y/o patologización de la condición, es así como las instituciones educativas y también las de salud, deben crear conciencia de esta realidad y adecuar su funcionamiento para disminuir el surgimiento de sintomatología disfórica.

Respecto de la prevalencia, en el equipo trans pediátrico también nos hemos ido encontrando con un mayor número de usuarios NNA hombres transgénero (89,5%) que ingresan al programa en búsqueda de intervenciones, por que lo advertimos una disminución de la prevalencia de mujeres transgénero adolescentes, lo que coincide con la literatura internacional revisada y que por lo demás requiere futuras investigaciones para ir comprendiendo estos cambios.

Por su parte la familia realiza un gran aporte en la reducción de síntomas al respaldar y apoyar en el cambio social a NNA, por lo que los esfuerzos de los profesionales también deben estar encaminados a conseguir el apoyo necesario desde los padres, madres

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y cuidadores. Respecto de las intervenciones a nivel familiar otorgadas por el equipo Higueras, se ha valorado bastante el grupo para familias, ya que allí pueden compartir experiencias con otras familias que se encuentran en el mismo proceso.

Con las(os) adolescentes, se ha valorado la intervención grupal debido al espacio que brinda el grupo de compartir experiencias con otras(os) que se encuentran en una misma situación, no sentirse sola(o) y ayudar en tareas del desarrollo adolescente.

Otra población que es necesario conocer y apoyar son las(os) NNA TEA con IG, que por lo demás están en un mayor riesgo de desarrollar condiciones asociadas por pertenecer a dos grupos de minorías.

La creación de un equipo especializado en la atención precoz e integral de NNA con IG en el Hospital las Higueras, es una experiencia pionera en la región del Bío Bío, pero quedan muchos desafíos futuros en relación a la temática, como la formación de más equipos especializados en intervención trans pediátrico a nivel país, la creación de una red en el tema a nivel infanto juvenil, establecer mayor conección con educación y con las organizaciones de la comunidad. Esperamos ir acercándonos a estos desafíos en pro del bienestar de las(os) NNA con IG.

Contribuciones y reconocimientos:

No existe conflicto de intereses de participación como activistas de organizaciones LGBTIQ+, tampoco el trabajo recibió financiamiento.

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American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

POLICY STATEMENT

Off-Label Use of Drugs in Children

Policy Statement–Reaffirmed with Reference & Data Updates

This policy statement has been reaffirmed with reference and data updates. New or updated references or datapoints are indicated in bold typeface. No other changes have been made to the text or content of the policy.

The AAP would like to acknowledge Jennifer Foster, MD, MPH, for these updates.

COMMITTEE ON DRUGS

KEY WORDS
off-label drug use, pharmaceuticals, pediatrics, infants, children, adolescents, prescribing

ABBREVIATIONS
BPCA—Best Pharmaceuticals for Children Act
FDA—US Food and Drug Administration
PREA—Pediatric Research Equity Act

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abstract

FREE

The passage of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act has collectively resulted in an improvement in rational prescribing for children, including more than **800** labeling changes. However, off-label drug use remains an important public health issue for infants, children, and adolescents, because an overwhelming number of drugs still have no information in the labeling for use in pediatrics. The purpose of off-label use is to benefit the individual patient. Practitioners use their professional judgment to determine these uses. As such, the term "off-label" does not imply an improper, illegal, contraindicated, or investigational use. Therapeutic decision-making must always rely on the best available evidence and the importance of the benefit for the individual patient. *Pediatrics* 2014;133:563–567

INTRODUCTION

The purpose of this statement is to further define and discuss the status of off-label use of medications in children. Since publication of the 2002 statement from the American Academy of Pediatrics on the off-label use of drugs,[1] the number of drugs approved by the US Food and Drug Administration (FDA) with pediatric indications or expanded labeling that informs drug use in pediatric patients (eg, pharmacokinetic/pharmacodynamic data, safety data) has substantially increased. The passage of the Best Pharmaceuticals for Children Act[2] (BPCA) and the Pediatric Research Equity Act[3] (PREA) has resulted in more than **800** pediatric labeling changes. However, despite this success and advances in both basic science and clinical trials in pediatrics, off-label drug use remains a common and important issue for children and adolescents. Moreover, off-label use of drugs presents an even larger and more complex issue in preterm and full-term neonates, infants and in children younger than 2 years,[4] and children with chronic and/or rare diseases.[5,6]

DEFINING OFF-LABEL USE

The term "off-label" use refers to use of a drug that is not included in the package insert (approved labeling) for that drug. The purpose of off-label use is to benefit an individual patient. It is important to note that the term "off-label" does not imply an improper, illegal, contraindicated, or investigational use. To approve a drug for sale and marketing within the United States, the FDA requires substantial

evidence for efficacy and safety, usually in the form of 2 well-controlled trials. Subsequent requests by a sponsor to add a new indication to drug labeling must also be accompanied by additional evidence in support of that indication. If the FDA finds that such evidence supports approval, the new indication is added to the product labeling. If the evidence is deemed insufficient or if the sponsor chooses not to submit evidence, the indication is not added.

According to the Code of Federal Regulations,[7] a sponsor is the entity that holds an investigational new drug application and that both takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. A sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. A person other than an individual who uses 1 or more of his or her own employees to conduct an investigation that he or she has initiated is considered to be a sponsor, not a sponsor-investigator. In this case, the employees are investigators. Sponsor-investigators both initiate and conduct an investigation and direct the administration or dispensing of the investigational drug. The requirements applicable to a sponsor-investigator include both those applicable to an investigator and a sponsor. It is important to note that sponsors are not allowed to promote or even speak to off-label use. If a physician speaks on behalf of a sponsor, the same rule applies. It is acceptable to use drugs off label and to publish results related to off-label use, but it is not acceptable to receive remuneration from the sponsor for these uses.

The absence of labeling for a specific age group or for a specific disorder does not necessarily mean that the drug's use is improper for that age or disorder. Rather, it only means that the evidence required by law to allow inclusion in the label has not been approved by the FDA. Additionally, in no way does a lack of labeling signify that therapy is unsupported by clinical experience or data in children. Instead, it specifically means that evidence for drug efficacy and safety in the pediatric population has not been submitted to FDA for review or has not met the regulatory standards of "substantial evidence" for FDA approval. In contrast to the absence of pediatric-specific information on some medications, other drug labels contain statements such as "the safety and efficacy in pediatric patients have not been established," and explicit evidence-based warnings and contraindications are included on the label where indicated. Understanding the distinction between the lack of FDA approval for a particular use or dosing regimen in the former case versus explicit warnings or contraindications against use in the latter is essential for the pediatric practitioner. In addition, when considering best practices for therapeutic decision-making, it is essential to understand that the FDA does not regulate the use of drugs as they pertain to the practice of medicine.[8]

THE ROLE OF THE FDA

The FDA is the federal government agency charged with oversight responsibility for the manufacturing, labeling, advertisement, and safety of therapeutic drugs and biological products. The Food, Drug, and Cosmetic Act[9] requires that "substantial evidence," resulting from "adequate and well-controlled investigations" demonstrating that a new drug "will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling," be submitted to and reviewed and approved by the FDA before the drug is marketed in interstate commerce. For drugs and biological agents (eg, vaccines, antibodies), proof of effectiveness consists of "adequate and well-controlled studies" as defined for new drugs in the Code of Federal Regulations.[10] Biological agents are approved under the Public Health Service Act.[11] Given these requirements as well as the rapid pace of medical discovery, it is not surprising that labeling does not reflect all possible uses of an agent. Off-label use of drugs in children is not overseen by the FDA, because the FDA does not regulate the prescription practices of individual practitioners.

The FDA maintains a system for postmarketing drug surveillance, compiling and analyzing information about the incidence and severity of adverse events reported by practitioners, sponsors, hospitals, and other health care facilities. It is important to note that this postmarket surveillance system is passive and that the total number of adverse event reports in pediatrics relative to adults is small. To address this issue, the BPCA provides for a systematized review of adverse event reports in pediatric patients through the FDA Pediatric Advisory Committee. When the FDA notes an apparent association between use of a drug and an adverse event, the FDA may choose from several actions: to request further focused study of the drug, to add a contraindication or warning to the drug labeling, to issue a warning about use of the drug, or to seek voluntary or compulsory removal of the drug from the market. Therefore, although the FDA does not regulate the practice of medicine, practitioners should be aware of new information brought forward by the FDA, because it can serve as a valuable resource for information regarding the potential or proven adverse effects of drugs (see www.fda.gov).

THERAPEUTIC DECISION-MAKING

Therapeutic decision-making should always be guided by the best available evidence and the importance of the benefit for the individual patient. Practitioners are in agreement regarding the importance of practicing evidence-based medicine. However, for the pediatric population, gold standard clinical trials are often not available, so practitioners must rely on either less definitive information, such as expert opinion for the age group that they are treating, or use evidence from a different population to guide practice. There are now many resources available to help assess the quality of evidence-based medicine, including but not restricted to articles in peer-reviewed journals, American Academy of Pediatrics practice guidelines and policy statements, consensus statements, and handbooks and databases (ie, Cochrane, Lexicomp, and Harriet Lane). At times, there may be little or no published information to guide therapy. This situation is especially true when treating rare diseases or sparse populations such as neonates. In such situations, the practicing physician can play an important role in adding to therapeutic information by publishing his or her experience with off-label uses of drugs. These reports can serve as the basis of more formal efficacy and safety studies and can serve as a therapeutic decision-making resource for other physicians. The practicing physician also has a responsibility to report adverse events to the FDA through the Medwatch program (www.fda.gov/Safety/MedWatch).

In most situations, off-label use of medications is neither experimentation nor research. The administration of an approved drug for a use that is not approved by the FDA is not considered research and does not warrant special consent or review if it is deemed to be in the individual patient's best interest.[8]

In general, if existing evidence supports the use of a drug for a specific indication in a particular patient, the usual informed-consent conversations should be conducted, including anticipated risks, benefits, and alternatives. If the off-label use is based on sound medical evidence, no additional informed consent beyond that routinely used in therapeutic decision-making is needed.[12,13] However, if the off-label use is experimental, then the patient (or parent) should be informed of its experimental status.[14] It would be prudent for pediatricians to know and abide by the appropriate informed consent laws in their respective states. In addition, particular risk-benefit ratios presented by the unproven therapies must be carefully considered and disclosed, and standard of care practices should be reviewed. When use of a drug is truly investigational, drug use should be performed in conjunction with a well-designed clinical trial whenever possible. This is especially true when the physician proposes to treat a group of patients rather than a single individual. Patients and/or their legal guardians should be specifically informed that the proposed therapy is investigational, and their consent to proceed despite the risks of investigational therapy should be carefully documented. Whether institutional review, consultation, or written consent are required for a given intervention depends on the degree of risk or departure from standard practices and the extent to which research, rather than individual patient care, is involved.

Practitioners may be concerned that the off-label use of an approved drug may invite a variety of legal actions. To conform to accepted professional standards, the off-label use of a drug should be done in good faith, in the best interest of the patient, and without fraudulent intent. A practitioner may be accountable for the negligent use of any drug in a civil action, regardless of whether the FDA has approved the use of that drug. Labeling is not intended to preclude the practitioner from using his or her best medical judgment in the interest of patients or to impose liability for off-label use. Indeed, the practice of medicine will more than likely require a practitioner to use drugs off label to provide the most appropriate treatment of a patient. However, because the use of drugs in an off-label capacity can increase the liability risk for a practitioner should an adverse event or poor outcome ensue, it is essential that practitioners document the decision-making process to use a drug off label in the patient's medical record.

FEDERAL LEGISLATION TO INCREASE DRUG TESTING IN CHILDREN

The BPCA and the PREA are 2 complementary federal laws that have substantially increased clinical evaluation and labeling of drugs in children both by the pharmaceutical industry and through government-sponsored trials.[10] The PREA mandates that almost all new drugs and certain approved drugs must be studied in children for approved uses of the product if there is potential for use of that drug in children and that the application for new drug approval include the results of adequate pediatric studies unless the studies are deferred or waived by the FDA. The BPCA allows sponsors to qualify for an additional 6 months of market exclusivity if the sponsor completes and submits pediatric studies to the FDA, as outlined in an FDA-issued written request. A written request may include off-label as well as approved uses of a drug. In addition, the BPCA authorizes the National Institutes of Health, in conjunction with the FDA

and physicians from clinical disciplines, to work together to assign priority for testing of specific drugs in children. The National Institutes of Health, acting through the Eunice Kennedy Shriver National Institute of Child Health and Human Development, then solicits proposals for pediatric drug testing concordant with the drug prioritization recommendations and funds clinical studies that are judged meritorious by external review. The ratification of these 2 laws has been considered a significant success, because there have been more than **600** pediatriclabeling changes. Also as a result of these laws, increased prospective pediatric drug testing has occurred via industry-sponsored studies, investigator-initiated studies, and consortia, such as the National Institute of Child Health and Human Development–funded Pediatric Trials Network. The net result has been an expansion of both pediatric labeling information and the knowledge base from which practitioners can draw to make informed therapeutic decisions.[15,16]

In 2012, Congress passed the Food and Drug Administration Safety and Innovation Act,[17] reauthorizing and strengthening the BPCA and PREA. The legislation aims to ensure that pediatric evaluations under PREA are conducted earlier in the drug development process to improve the quality of and accountability for completion of such studies and to advance the neonatal drug studies under the BPCA and PREA. The legislation also makes both the BPCA and PREA permanent law.

CONCLUSIONS

Off-label drug use remains an important public health issue, especially for infants, young children, and children with rare diseases. Evidence, not label indication, remains the gold standard from which practitioners should draw when making therapeutic decisions for their patients. The PREA and BPCA have been extremely successful and represent an essential first step in expanding this evidence as a means of achieving the ultimate goal that any and all drugs used to treat children will have age-appropriate evidence sufficient to provide information for labeling. However, labeling with pediatric information still exists in less than 50% of products,[18] such that much work remains to be done to ensure the best possible practice for therapeutic decision-making in pediatrics.

RECOMMENDATIONS

1. The practitioner who prescribes a drug is responsible for deciding which drug and dosing regimen the patient will receive and for what purpose.
   a. This decision should be made on the basis of the information contained in the drug's labeling (when available) or other data available to the prescriber.
   b. The use of a drug, whether off or on label, should be based on sound scientific evidence, expert medical judgment, or published literature whenever possible.
   c. Off-label use is neither incorrect nor investigational if based on sound scientific evidence, expert medical judgment, or published literature.
2. Pediatricians should continue to advocate for necessary incentives and requirements to promote the study of drugs in children.
3. Physician researchers are encouraged to continue the rational and critical study of drugs in children through conducting and/or collaborating in well-designed pediatric drug studies, including national consortium studies.
4. Journals should be encouraged to publish the results of all well-designed investigations, including negative studies.
5. Institutions and payers should not use labeling status as the sole criterion that determines the availability on formulary or reimbursement status for medications in children. Similarly, less expensive therapeutic alternatives considered appropriate for adults should not automatically be considered appropriate first-line treatment in children. Finally, off-label uses of drugs should be considered when addressing various drug-related concerns, such as drug shortages.

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Poststerilization Regret: Findings From the United States Collaborative Review of Sterilization

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***Objective*: To evaluate the cumulative probability of regret after tubal sterilization, and to identify risk factors for regret that are identifiable before sterilization.**

***Methods*: We used a prospective, multicenter cohort study to evaluate the cumulative probability of regret within 14 years after tubal sterilization. Participants included 11,232 women aged 18–44 years who had tubal sterilizations between 1978 and 1987. Actuarial life tables and Cox proportional hazards models were used to identify those groups at greatest risk of experiencing regret.**

***Results*: The cumulative probability of expressing regret during a follow-up interview within 14 years after tubal sterilization was 20.3% for women aged 30 or younger at the time of sterilization and 5.9% for women over age 30 at sterilization (adjusted relative risk [RR] 1.9; 95% confidence interval [CI] 1.6, 2.3). For the former group, the cumulative probability of regret was similar for women sterilized during the postpartum period (after cesarean, 20.3%, 95% CI 14.5, 26.0; after vaginal delivery, 23.7%, 95% CI 17.6, 29.8) and for women sterilized within 1 year after the birth of their youngest child (22.3%, 95% CI 16.4, 28.2). For women aged 30 or younger at sterilization, the cumulative probability of regret decreased as time since the birth of the youngest child increased (2–3 years, 16.2%, 95% CI 11.4, 21.0; 4–7 years, 11.3%, 95% CI 7.8, 14.8; 8 or more years, 8.3%, 95% CI 5.1, 11.4) and was lowest among women who had no previous births (6.3%, 95% CI 3.1, 9.4).**

***Conclusion*: Although most women expressed no regret after tubal sterilization, women 30 years of age and younger at the time of sterilization had an increased probability of expressing regret during follow-up interviews within 14 years after the procedure. (Obstet Gynecol 1999;93:889–95.)**

In the United States, tubal sterilization is the most commonly used form of contraception among women.[1]

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More than 600,000 women choose this procedure each year,[2] and approximately 10 million American women have been sterilized.[3] Although tubal sterilization is considered a permanent form of contraception, many women may regret their decision during the ensuing years.[4] Regret is defined as "distress over a desire unfulfilled or an action performed or not performed" (*Webster's New Riverside University Dictionary*. Boston: Houghton Mifflin, 1988). The human and economic consequences of regret regarding tubal sterilization may be substantial. The impact of curtailed reproductive potential ranges from the intangible costs of reduced quality of life[5] to an increase in the use of expensive procedures with limited success, including reanastomosis and assisted reproductive technologies.

We used data from the largest and longest prospective study of women undergoing tubal sterilization in United States medical centers to identify subgroups who have the highest cumulative probability of regret during the 14 years after tubal sterilization and the strongest risk factors for regret identifiable before sterilization. A preliminary analysis of interim data from this cohort examined the risk of experiencing regret during the first 5 years after tubal sterilization.[6] Information on regret within 14 years might help clinicians and women considering sterilization to reduce the prevalence of poststerilization regret and its consequences.

Table 1. Characteristics of the Study Population

Characteristic	%	(Total n = 11,232)
Age at sterilization (y)		
18–30	50.2	5640
>30	49.8	5592
Race*		
White	53.8	6047
Black	34.0	3816
Other	12.2	1368
Married at time of sterilization*		
No	32.0	3592
Yes	68.0	7637
History of abortion*		
No	77.5	7805
Yes	22.5	2265
Reason for tubal sterilization*		
Medical	3.8	288
Contraceptive	96.2	7272
Time between sterilization and birth of youngest child*		
Postpartum		
After vaginal delivery	11.4	1276
After cesarean	4.6	519
Interval†		
15 d–1 y	25.6	2875
2 y–3 y	13.2	1481
4 y–7 y	15.1	1694
≥8 y	24.7	2770
No previous births	5.4	610

* Sample size is decreased because of missing data.

† Time was coded as follows: 15 d–1 y = 15 d–364 d; 2 y–3 y = 365 d–1094 d; 4 y–7 y = 1095 d–2554 d; ≥8 y = 2555 d or more. Interval group includes 222 women who had tubal sterilization immediately after abortion.

Methods

The methods for the Collaborative Review of Sterilization, a prospective multicenter study, have been described.[6–8] Participating medical centers were located in Baltimore, Maryland; Buffalo, New York; Chapel Hill, North Carolina; Honolulu, Hawaii; Houston, Texas; Memphis, Tennessee; Sacramento, California; St. Louis, Missouri; and San Francisco, California. The study was approved by the institutional review board at each center.

Women were enrolled from 1978 to 1987 and were eligible for inclusion in this analysis if they were 18–44 years of age at the time of sterilization; underwent sterilization during the postpartum period in conjunction with cesarean or vaginal delivery; underwent interval sterilization, ie, while not recently pregnant or immediately after elective abortion; completed at least one-follow interview; and answered the question used to measure poststerilization regret. The question that was asked at each follow-up interview was: "Do you still think tubal sterilization as a permanent method of birth control was a good choice for you?" Possible answers were 'yes,' 'no,' or 'don't know.' Only one woman chose 'don't know' as her response. A total of 11,232 women met these criteria.

At the time of enrollment, trained interviewers used standardized questionnaires to evaluate clinical and demographic characteristics that may have influenced the probability of regret. Because our primary focus was on the occurrence (as opposed to persistence) of regret after tubal sterilization, women who answered 'no' to the aforementioned question at any time during follow-up were defined as having regret. Among women who experienced regret, we used an open-ended question to evaluate the most important reason for it. The occurrence of regret was evaluated at each of the intended follow-up interviews, which occurred yearly for the first 5 years. Women enrolled between 1978 and 1983 had one final follow-up interview between 8 and 14 years after sterilization. We considered the participants at risk for poststerilization regret until the interview date when regret was acknowledged, or, for those who never reported regret, until the date of the last interview. Women who had major health events after

Table 2. Probability of Reporting Poststerilization Regret by Selected Characteristics

Characteristic	Years after sterilization procedure*		
	3	7	14
Overall	3.9 (3.5, 4.2)	7.5 (7.0, 8.1)	12.7 (11.2, 14.3)
Age at sterilization (y)			
18–30	5.1 (4.5, 5.7)	10.5 (9.5, 11.4)	20.3 (17.1, 23.4)
>30	2.6 (2.2, 3.1)	4.8 (4.2, 5.4)	5.9 (5.0, 6.8)
Race			
White	3.5 (3.0, 4.0)	6.0 (5.3, 6.7)	7.4 (6.3, 8.5)
Black	4.3 (3.7, 5.0)	10.2 (8.9, 11.4)	21.7 (17.3, 26.1)
Other	4.3 (3.2, 5.4)	7.9 (6.3, 9.5)	16.0 (10.9, 21.0)
Married at time of sterilization			
No	4.5 (3.8, 5.2)	9.4 (8.2, 10.6)	20.4 (15.7, 25.1)
Yes	3.6 (3.2, 4.0)	6.8 (6.1, 7.4)	10.2 (8.8, 11.6)
History of abortion			
No	3.6 (3.1, 3.9)	7.1 (6.5, 7.7)	12.1 (10.4, 13.9)
Yes	5.0 (4.1, 5.8)	9.1 (7.8, 10.4)	14.9 (11.5, 18.3)
Reason for tubal sterilization			
Medical	4.6 (2.0, 7.1)	6.6 (3.4, 9.8)	7.5 (3.9, 11.1)
Contraceptive	4.6 (4.1, 5.0)	8.1 (7.4, 8.8)	13.7 (11.9, 15.4)
Time between sterilization and birth of youngest child			
Postpartum			
After vaginal delivery	5.6 (4.3, 6.9)	10.2 (8.4, 12.0)	17.8 (13.8, 21.9)
After cesarean	8.8 (6.3, 11.4)	14.0 (10.7, 17.3)	16.1 (12.1, 20.1)
Interval†			
15 d–1 y	3.3 (2.6, 4.0)	8.8 (7.3, 10.0)	17.6 (13.2, 22.0)
2 y–3 y	4.5 (3.4, 5.7)	8.2 (6.6, 9.9)	12.6 (9.3, 15.9)
4 y–7 y	3.4 (2.5, 4.3)	7.0 (5.5, 8.4)	9.5 (7.1, 11.8)
≥8 y	2.8 (2.2, 3.4)	4.7 (3.8, 5.5)	5.1 (4.1, 6.1)
No previous births	3.0 (1.6, 4.4)	5.1 (3.2, 7.0)	5.7 (3.5, 8.0)

* Cumulative probability per 100 procedures (95% confidence interval).
† Time was coded as per Table 1.

tubal sterilization (including hysterectomy, pregnancy, tubal anastomosis, repeat tubal sterilization, or death) were considered at risk for poststerilization regret only until the occurrence of the event because follow-up was discontinued at that time.

We evaluated several characteristics present at the time of sterilization that might have increased the probability of experiencing regret. These included age, race, marital status, history of abortion, reason for sterilization, and time between sterilization and birth of the youngest child. We did not consider the number of living children as a potential risk factor because of incomplete data for those women who had postpartum procedures. Because the number of women who had sterilization after abortion was small (n = 222) and because their cumulative probability of regret was similar to that of women having interval sterilization, they were included in the interval group for all analyses.

We used actuarial life tables, the Kaplan-Meier method for evaluating the proportionality assumption, and unadjusted hazards ratios to examine whether the 3-, 7-, and 14-year cumulative probabilities of regret were increased in any subgroups of participants. To estimate the likelihood of experiencing poststerilization regret, we preferred the life-table approach over the crude-incidence approach because the former adjusts these estimates for the substantial loss to follow-up that is essentially unavoidable in a study of such duration. Cumulative probability is the corresponding frequency measure used to describe the results of life-table analyses at specific time intervals. Previous reports showed that young age at tubal sterilization was the strongest predictor of poststerilization regret,[6,9,10] so we also performed age-stratified analyses to identify subgroups of young women at highest risk. All variables that were significant predictors of regret in unadjusted analyses were included in a multivariate Cox proportional hazards model to identify independent risk factors. Maximum-likelihood ratio χ^2 tests were used to evaluate whether age at sterilization was a significant effect modifier. We also analyzed the reason for regret according to age at sterilization among women who experienced poststerilization regret.

Table 3. Cumulative Probability of Regret by Age at Tubal Sterilization and Years After Sterilization*

Characteristic	Age at tubal sterilization					
	18–30 y			>30 y		
	Years after sterilization			Years after sterilization		
	3	7	14	3	7	14
Race						
White	5.1 (4.2, 5.9)	8.7 (7.4, 9.9)	11.2 (8.8, 13.6)	2.4 (1.9, 2.9)	4.2 (3.4, 4.9)	4.8 (3.9, 5.7)
Black	5.1 (4.1, 6.0)	12.7 (11.0, 14.5)	29.5 (23.2, 35.8)	3.1 (2.1, 4.0)	6.0 (4.6, 7.5)	7.5 (5.6, 9.4)
Other	5.7 (3.8, 7.6)	10.5 (7.9, 13.1)	22.6 (16.1, 29.2)	3.0 (1.8, 4.3)	5.7 (3.9, 7.5)	10.1 (4.1, 16.1)
Married at time of sterilization						
No	6.1 (5.0, 7.2)	13.0 (11.1, 14.9)	31.0 (23.3, 38.7)	2.5 (1.7, 3.2)	5.0 (3.7, 6.3)	6.4 (4.5, 8.3)
Yes	4.6 (3.9, 5.3)	9.2 (8.1, 10.3)	15.6 (12.7, 18.5)	2.7 (2.7, 3.2)	4.7 (4.0, 5.5)	5.8 (4.8, 6.8)
History of abortion						
No	4.6 (3.9, 5.3)	9.8 (8.7, 10.9)	20.1 (16.4, 23.9)	2.6 (2.1, 3.1)	4.7 (4.0, 5.4)	5.5 (4.6, 6.3)
Yes	6.7 (5.3, 8.0)	12.4 (10.3, 14.4)	20.7 (14.8, 26.5)	2.8 (1.8, 3.8)	5.1 (3.7, 6.6)	7.9 (5.1, 10.7)
Reason for sterilization						
Medical	6.5 (1.8, 11.1)	10.5 (4.2, 16.8)	10.5 (4.2, 16.8)	3.2 (0.4, 6.0)	4.1 (0.9, 7.4)	5.5 (1.3, 9.7)
Contraceptive	6.1 (5.3, 6.9)	10.9 (9.8, 12.1)	21.4 (18.4, 24.8)	3.0 (2.4, 3.6)	5.3 (4.5, 6.1)	6.4 (5.4, 7.4)
Time between sterilization and birth of youngest child						
Postpartum						
After vaginal delivery	6.3 (4.5, 8.1)	11.9 (9.3, 14.5)	23.7 (17.6, 29.8)	4.7 (2.8, 6.5)	8.0 (5.5, 10.5)	8.7 (6.1, 11.4)
After cesarean	10.3 (6.8, 13.7)	17.8 (13.8, 22.5)	20.3 (14.5, 26.0)	6.3 (2.7, 9.9)	7.7 (3.7, 11.8)	9.5 (4.2, 14.7)
Interval†						
15 d–1 y	4.1 (3.2, 4.9)	10.6 (8.9, 12.3)	22.3 (16.4, 28.2)	1.3 (0.4, 2.1)	3.9 (2.1, 5.7)	5.2 (2.7, 7.8)
2 y–3 y	5.4 (3.9, 6.9)	10.1 (7.8, 12.4)	16.2 (11.4, 21.0)	3.0 (1.4, 4.5)	4.9 (2.7, 7.1)	5.8 (3.0, 8.5)
4 y–7 y	4.7 (3.2, 6.2)	9.1 (6.6, 11.5)	11.3 (7.8, 14.8)	2.3 (1.3, 3.3)	5.2 (3.5, 7.0)	7.9 (4.7, 11.0)
≥8 y	4.9 (2.7, 7.0)	8.3 (5.1, 11.4)	8.3 (5.1, 11.4)	2.5 (1.8, 3.1)	4.1 (3.2, 5.0)	4.6 (3.6, 5.7)
No previous births	4.7 (2.0, 7.4)	6.3 (3.1, 9.4)	6.3 (3.1, 9.4)	1.8 (0.4, 3.2)	4.3 (2.0, 6.6)	5.4 (2.2, 8.5)

* Data represent cumulative probability per 100 procedures (95% confidence interval).
† Time was coded as per Table 1.

Results

Consideration of demographic and reproductive characteristics showed that the study population was racially diverse and that the majority of participants were married, underwent interval laparoscopic sterilization procedures, and had elected tubal sterilization for contraceptive rather than medical reasons (Table 1). Half of the participants were 30 years or younger at the time of sterilization. The mean follow-up time was 6.5 years. Among the women eligible for interview at 1, 3, 5, and 8–14 years after sterilization, 93.2%, 84.1%, 75.2%, and 57.1%, respectively were interviewed. Women who were 30 years or younger, nonwhite, or married were significantly more likely to be lost to follow-up at 8–14 years than women without these characteristics (data not shown).

During follow-up interviews, 744 women reported having regret within the 14-year study period, and the cumulative probability of regret 14 years after sterilization was 12.7% (Table 2). The cumulative probability of regret increased steadily over the follow-up period. The highest cumulative probabilities of regret at 3 and 7 years were in women whose sterilization procedures were done postpartum (after cesarean, 8.8% and 14.0%, respectively; after vaginal delivery, 5.6% and 10.2%, respectively) or in those who were younger than 30 at the time of sterilization (5.1% and 10.5%, respectively). Among women who had interval procedures, we observed that poststerilization regret at 14 years varied markedly according to the time between sterilization and birth of the youngest child. The overall cumulative probability of regret for the interval group was 10.0%. Similar regret at 14 years was reported by women who had sterilization immediately after abortion (cumulative probability of 10.6% after first-trimester abortion). The cumulative probability of regret at 14 years was higher among women whose sterilizations were done within 1 year of birth of their youngest child (17.6%) or during the postpartum period (16.1–17.8%). The long-term cumulative probability of regret during the 14 years after sterilization was also higher among women who were 30 years or younger (20.3%), black (21.7%), or unmarried (20.4%) at sterilization.

Compared with older women, women aged 30 years

Table 4. Rate Ratios of Regret After Tubal Sterilization According to Characteristics at Sterilization*

Characteristic	Unadjusted rate ratio	95% Confidence interval	Adjusted rate ratio	95% Confidence interval
Age (y)				
18–30	2.3	2.0, 2.7	1.9	1.6, 2.3
>30	Referent			
Race				
Nonwhite	1.7	1.5, 2.0	1.3	1.1, 1.5
White	Referent			
Married at time of sterilization				
No	1.4	1.2, 1.6	1.3	1.1, 1.6
Yes	Referent			
History of abortion				
No	Referent			
Yes	1.3	1.1, 1.5	1.2	1.0,† 1.4
Reason for sterilization				
Contraceptive	1.4	0.65, 2.2		
Medical	Referent			
Time between sterilization and birth of youngest child				
Postpartum				
After vaginal delivery	2.5	2.0, 3.1	1.6	1.2, 2.1
After cesarean	3.0	2.3, 4.1	2.0	1.5, 2.8
Interval§				
15 d–1 y	1.8	1.5, 2.3	1.3	1.0,‡ 1.7
2 y–3 y	1.8	1.4, 2.3	1.4	1.1, 1.8
4 y–7 y	1.5	1.1, 1.9	1.2	0.9, 1.6
≥8 y or no previous birth	Referent			

* Each variable was adjusted simultaneously for all variables that were significant in unadjusted analyses and for cohort of entry (1979, 1980, 1982, 1985, 1986, 1987).
† Lower confidence limit = 0.997.
‡ Lower confidence limit = 1.02.
§ Time was coded as per Table 1.

or younger at sterilization had a higher cumulative probability of regret regardless of subgroup and over all time intervals considered (Table 3). Among women 30 years or younger at sterilization, those who were unmarried (31.0%) or black (29.5%) had the highest cumulative probabilities of regret during the 14 years after sterilization. Among women who were young at sterilization, similarly high cumulative probabilities of regret at 14 years were seen in women who were sterilized during the postpartum period (after cesarean, 20.3%, 95% confidence interval [CI] 14.5, 26.0; after vaginal delivery, 23.7%, 95% CI 17.6, 29.8) or within 1 year of birth of their youngest child (22.3%, 95% CI 16.4, 28.2). As the time since birth of the youngest child increased, the cumulative probability of regret at 14 years decreased (2–3 years, 16.2%, 95% CI 11.4, 21.0; 4–7 years, 11.3%, 95% CI 7.8, 14.8; 8 or more years, 8.3%, 95% CI 5.1, 11.4). The probability was lowest among women who had no previous births (6.3%, 95% CI 3.1, 9.4).

In adjusted analyses using the proportional hazards model, probabilities of regret were significantly increased in women who were 30 years and younger, who had sterilization during the postpartum period or within 3 years of birth of the youngest child, who were non-white, or were unmarried (Table 4). Reasons for regret differed by the age at tubal sterilization (Table 5). Among women aged 30 years or younger, the most commonly reported reason for regret was the desire to have more children (33.1%). Women over age 30 were most apt to report subsequent gynecologic or menstrual changes (28.8%) as their primary reasons for regret. Further analyses showed that among women who experienced poststerilization regret, nearly half (48%) of those aged 30 years or younger at the time of sterilization and nearly one third (30%) of those over age 30 at sterilization requested information about sterilization reversal (data not shown).

Discussion

The cumulative probability of expressing regret during follow-up interviews within 14 years after tubal sterilization was 20% for women who were aged 30 years or younger when sterilized. Young women sterilized within 1 year after the birth of their youngest child were just as likely to experience regret at some point as were women sterilized during the immediate postpartum period. Poststerilization regret decreased as the time since the birth of the youngest child increased. A large number of women who experienced poststerilization

Table 5. Reported Reasons for Poststerilization Regret by Age at Tubal Sterilization

Reason for regret	18–30 y (n = 490*)	>30 y (n = 226*)
Subsequent gynecologic or menstrual problems	19.6 (96)	28.8 (65)
Other complication after sterilization	4.5 (22)	6.2 (14)
Divorce or remarriage	23.9 (117)	8.0 (18)
Death of child	0.8 (4)	0.9 (2)
Decision made without adequate consideration†	4.1 (20)	5.8 (13)
Desire for more children	33.1 (162)	26.1 (59)
Loss of sexuality	1.2 (6)	2.7 (6)
Other	12.9 (63)	21.7 (49)

Data are presented as % (n).
* Data were available for 716 of 744 women who reported regret.
† Includes "too young," "emotionally unstable," or "husband's idea."

regret requested information about sterilization reversal.

Rather than plateauing after short-term follow-up (3 years), the cumulative probability of poststerilization regret increased during the intermediate (7-year) and long-term (14-year) follow-up periods, especially for women who were 30 years old or younger when sterilized. Long-term regret 10 or more years after sterilization ranged from 5% to 21% in two previous cross-sectional studies done in Puerto Rico[9] and Sweden.[11] Our report used a prospective cohort study to describe the long-term cumulative probability of regret among women living in geographically diverse areas of the United States. Although few previous reports have described the long-term probability of poststerilization regret, a number of investigators have identified risk factors for poststerilization regret in general. The one predictor identified by all of these studies, and confirmed by our findings, was young age at the time of sterilization.[4,6,9,11–17] Preliminary reports from the Collaborative Review of Sterilization study also identified postpartum, as opposed to interval, timing of tubal sterilization as an important predictor of regret.[6,12] However, our analysis of data from the completed study found that sterilizations performed within 1 year of childbirth had just as high a risk of regret within 14 years as those done postpartum.

The increased probability of regret within 14 years after tubal sterilization among women who were young at sterilization was usually attributed to changes in the desired family size. Older women specified menstrual or other gynecologic problems occurring after tubal sterilization as the common reasons for regret. However, evidence to date does not support a biologic explanation for any association between tubal sterilization and subsequent menstrual or other gynecologic disorders.[18–21] Women who were sterilized at older ages may have believed that normal changes attributable to aging were instead abnormal consequences of sterilization.

Potential limitations may have influenced our findings. Because regret is an attitudinal measure for which there is no standardized definition,[10] the use of self-report to assess the occurrence of regret in our study, as in previous studies, may have led to some misclassifications. Although the selective attrition of women who were young or nonwhite may have caused us to underestimate the long-term cumulative probability of regret in our cohort, the preferential loss of married women should have had the opposite effect. We also assumed that our findings were not selectively biased by loss to follow-up, for the following reasons: 1) It is unlikely that it would have been easier to reach by telephone those who regretted rather than those who did not regret their decisions; and 2) only 2% of all participants contacted for follow-up actually refused further participation (data not shown). Another limitation of our study may have been the lack of information about additional risk factors that may influence the risk of regret, such as satisfaction with presterilization counseling and identification of the person who had the greatest influence on the woman's sterilization decision.[9,13,22]

A number of women who had poststerilization regret ultimately requested information about sterilization reversal, which is associated with high costs and limited success. Among sterilized women who participated in the 1982 National Survey of Family Growth, 11% reported that they would reverse their sterilization if it were safe to do so.[4] In our cohort, one of five women aged 30 years or younger at sterilization regretted their decisions at some point afterward. Our findings cannot be directly extrapolated to the entire United States because our cohort was not specifically selected to represent the entire population of women undergoing sterilization in this country (eg, our cohort included a higher percentage of black women than in the U.S. population of women who undergo tubal sterilization).

Although most women had no regret after tubal sterilization, our findings suggested strongly that a surprisingly high percentage of women sterilized at a young age in the United States will regret their decision at some point. Regret after tubal sterilization cannot be considered in isolation. Some young women who contemplate sterilization but choose a form of temporary contraception may regret not having been sterilized, either because of unintended pregnancy or side effects of temporary methods. Ideally, presterilization counseling can be used to highlight those groups of women who are most likely to experience poststerilization regret and to reassure those who do choose tubal sterilization that most sterilized women do not regret their decisions.

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FACTORES ASOCIADOS AL ARREPENTIMIENTO DESPUÉS DE LA REALIZACIÓN DE ESTERILIZACIÓN QUIRÚRGICA EN MUJERES QUE ASISTEN A CONSULTA EN EL INSTITUTO DE SALUD DE BUCARAMANGA (ISABU) Y LA CLÍNICA GIRÓN.

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TABLAS, FORMATOS Y ANEXOS

Resumen

Introducción: La tasa de arrepentimiento de la esterilización quirúrgica a nivel mundial se encuentra alrededor del 14,3% y es casi 4 veces mayor en las mujeres jóvenes. En Colombia, la esterilización quirúrgica femenina es el método anticonceptivo más usado (34,9%) según la Encuesta de Salud y demografía **Objetivo:** Conocer los factores asociados al arrepentimiento autoinformado después de la esterilización quirúrgica en mujeres usuarias de servicio de salud de primer nivel.

Metodología: Estudio de corte transversal realizado en 512 participantes con antecedente de esterilización quirúrgica mayor a un año. Se evaluaron variables sociodemográficas, consejería en planificación familiar, factores asociados a la realización de esterilización quirúrgica y presencia o no de arrepentimiento. Los datos se tabularon en Microsoft Excel y fueron analizados con STATA 14.0. Se realizó análisis por regresión logística para proponer un modelo multivariado. **Resultados:** 512 mujeres entre 18-50 años participaron entre julio de 2018 y marzo de 2020. La frecuencia de arrepentimiento fue del 12,5%, algunas de las variables asociadas a este fueron la edad actual y al momento de la cirugía, tener pareja estable y haber sido influenciada por alguien para realizarse la cirugía ($p<0,05$). En el modelo propuesto haber sido influenciada por el médico para la realización de la cirugía y tener 44 años o más se comportan como factores protectores. El desconocimiento de la irreversibilidad de la cirugía se comporta como un factor de riesgo para el arrepentimiento.

Conclusión: En este estudio se encontraron factores protectores y de riesgo que pueden usarse como herramientas claves al momento de brindar la asesoría en planificación familiar.

Palabras clave: esterilización quirúrgica, arrepentimiento, factores de riesgo, consejería, cirugía de recanalización

Abstract

Introduction : The regret rate for surgical sterilization worldwide is around 14.3% and is almost 4 times higher in young women. In Colombia, female surgical sterilization is the most used contraceptive method (34.9%) according to the Health and Demographic Survey.

Objective : To know the factors associated with self-reported regret after surgical sterilization in women users of first-level health services.

Methodology : cross-sectional study carried out in 512 participants with a history of surgical sterilization greater than one year. Sociodemographic variables, family planning counseling, factors associated with the performance of surgical sterilization and the presence or absence of regret were evaluated. The data were tabulated in Microsoft Excel and analyzed with STATA 14.0. Logistic regression analysis was performed to propose a multivariate model.

Results: 512 women between 18-50 years old participated between July 2018 and March 2020. Frequency of regret of 12.5%. Variables such as current age and age at time of surgery, having a stable partner and having been influenced by someone to perform the surgery were found to be associated with regret ($p < 0.05$). In the proposed model, having been influenced by the doctor to perform the surgery and being 44 years of age or older behaves as a protective factor. The ignorance of the irreversibility of the surgery behaves as a risk factor for regret.

Conclusion: In this study, protective and risk factors were found that can be used as key tools when providing counseling in family planning.

Key words: Tubal sterilization, regret, risk factor, Quality of care, reversal surgery

Introducción

La esterilización quirúrgica femenina es un método anticonceptivo permanente que consiste en bloquear las trompas de Falopio a fin de obstruir el transporte de los óvulos maduros desde los ovarios al útero, con el fin de evitar la fertilización. Más de 600,000 mujeres en Estados Unidos eligen este procedimiento cada año(1), es el método más común entre las parejas casadas, para el caso de Colombia, según datos de la Encuesta Nacional de Demografía y Salud (ENDS) 2015 esté es el método de mayor prevalencia con un 34,9%(2).

Siendo este el método de mayor elección en la población colombiana, es importante mencionar las complicaciones asociadas al mismo, entre las que se encuentra el arrepentimiento posterior a su realización. Es difícil cuantificar la incidencia de este evento por una variedad de razones metodológicas, incluidas definiciones inconsistentes y cuestionamientos parciales (3). Basados en datos del "U.S. Collaborative Review of Sterilization" (CREST), estudio de cohorte prospectiva con seguimiento por 14 años a mujeres sometidas a esterilización quirúrgica, la probabilidad acumulativa de solicitar información de reversión fue de un 14,3%, siendo casi 4 veces mayor en las mujeres jóvenes entre 18 a 24 años(4). Según la Organización Mundial de la Salud (OMS) en la quinta edición de los criterios de elegibilidad en planificación familiar del 2015, hasta el 20% de las mujeres jóvenes pueden llegar a presentar arrepentimiento(5). En Colombia, basados en reportes del ENDS de 2015, se estima un 15,9 % de arrepentimiento en las mujeres que se han realizado una esterilización quirúrgica, relativamente mayor entre las mujeres jóvenes de 30 a 34 años: 22,4%. Según ENDS 2015 los principales motivos de arrepentimiento reportados entre las mujeres esterilizadas quirúrgicamente en Colombia son los siguientes: el deseo de otro hijo (75,9%) y el compañero desea otro hijo (14,7%)(2). Si bien en el país se dispone de datos estadísticos generales sobre esta problemática, a la fecha de hoy no hay estudios que valoren a profundidad los factores que puedan estar relacionados con esta situación.

Entre los factores asociados al arrepentimiento después de la esterilización quirúrgica se encuentra una consejería deficiente. Los datos del estudio de Jadhav

publicado en el 2018, evidencian resultados alarmantes sobre la calidad de la consejería previa a la esterilización quirúrgica en nuestro país, pues se encontró que solo el 27% de las mujeres que acudían a consejería en planificación familiar obtuvo información completa sobre el carácter permanente del procedimiento, los efectos adversos potenciales y sobre otros métodos de planificación familiar(6).
Basados en estos datos y teniendo en cuenta que el ISABU y la clínica Girón son instituciones donde diariamente se realizan procedimientos de esterilización quirúrgica femenina, se realizó esta investigación, con el objetivo de identificar los factores asociados al arrepentimiento posterior a la realización de esterilización quirúrgica en usuarias que asisten a estas instituciones de salud. Entre los factores evaluados se encuentran la edad materna, estrato socioeconómico, estado civil, número de hijos, nivel educativo, historia obstétrica, tiempo entre el nacimiento del último hijo y la esterilización y calidad de la consejería previa al procedimiento (1,3,4). Para tal fin se realizaron encuestas a la población femenina que asistió a las instituciones ya mencionadas para la realización de citología o a consulta ginecológica y que referían la esterilización quirúrgica como método de planificación, de lo que se infiere que no todas estas esterilizaciones fueron realizadas en las instituciones donde se evaluó la población. Se espera que derivado de los datos obtenidos en este estudio se tomen acciones con miras a mejorar la calidad en la consejería de planificación familiar y se tenga especial cuidado al momento de asesorar pacientes en las que se detecte algún factor relacionado con un probable arrepentimiento en el futuro.

1. Planteamiento del problema

La esterilización quirúrgica femenina es un método anticonceptivo permanente que consiste en bloquear las trompas de Falopio con el fin de obstruir el transporte de los óvulos maduros desde los ovarios al útero, generando una barrera para la fertilización. Más de 600.000 mujeres en Estados Unidos eligen este procedimiento cada año(1). Para el caso de Colombia según datos de la ENDS 2015, esté es el método de mayor prevalencia con un 34,9%(2).

La esterilización quirúrgica femenina debe considerarse como un método de anticoncepción permanente, pues las opciones para lograr un embarazo después de un procedimiento de esterilización, que incluyen la cirugía de reversión y la fertilización in vitro, son costosas, conllevan riesgos y no siempre son exitosas(7). Por otro lado, los métodos reversibles a largo plazo, como los dispositivos intrauterinos y los implantes subdérmicos, tienen una eficacia comparable e incluso ligeramente mayor que la esterilización femenina, lo cual implica que deben ser incluidos en la consejería de planificación familiar en mujeres con paridad satisfecha. Así mismo, en comparación con la esterilización masculina, la mayoría de los métodos de esterilización femenina son menos efectivos, más costosos y con mayores riesgos asociados(1).

Uno de los factores que ha sido previamente documentado y que se considera primordial para la toma de decisión exitosa por parte de la paciente es la consejería. En nuestro medio la solicitud de ligadura de trompas como método de planificación familiar ha ido en aumento, en especial por parte de mujeres jóvenes e incluso sin hijos. A pesar de tratarse de un elemento fundamental previo a la realización del procedimiento y para la toma de decisiones en planificación familiar, la consejería se ha visto seriamente afectada, ya que por las características del sistema de salud nacional cada vez se da menos tiempo para realizarla, situación que conlleva la mayoría de veces a realizar asesorías incompletas e incluso inadecuadas. Así mismo los datos demuestran que el momento en el que se realizan la mayoría de las esterilizaciones quirúrgicas es en el postparto inmediato, siendo mayor en pacientes cuyo parto fue por cesárea, en quienes por lo general no se ha realizado una asesoría previa al procedimiento (2,6,8).

Dentro de las principales complicaciones o consecuencias tanto a corto como mediano y largo plazo, se encuentran los sentimientos de arrepentimiento posterior a la realización de la esterilización quirúrgica. La tasa de arrepentimiento a nivel mundial se encuentra alrededor del 14,3%, y es casi 4 veces mayor en las mujeres

jóvenes entre 18 a 24 años(4); de acuerdo con datos de la OMS hasta el 20% de las mujeres jóvenes pueden llegar a presentar arrepentimiento(8).
A nivel nacional, el arrepentimiento en mujeres que se han realizado una cirugía de esterilización oscila en un 15,9%, sentimiento que es relativamente mayor (22,4%) entre las mujeres entre 30 a 34 años, al evaluarlo por zonas de procedencia se hace más frecuente en las mujeres que viven en zona rural con un 18% contrastado con la zona urbana 15,4%(2).

Son muchos los estudios que han descrito los factores asociados al arrepentimiento de esterilización quirúrgica femenina, el más fuertemente asociado es la edad de la mujer y especialmente se ha encontrado que si el procedimiento se realiza a una edad menor de 30 años el riesgo relativo es de 3,5 (I.C 2,8-4,4). En relación al momento de realización del procedimiento, el arrepentimiento es mayor si el procedimiento es simultáneo con algún evento obstétrico y, por último, los cambios en la estructura familiar como cambio de pareja o perdida de un hijo (3,4).

Guías internacionales respaldan la esterilización quirúrgica como método anticonceptivo en mujeres bien informadas. La sociedad de obstetricia y ginecología de Canadá (SOGC) recomienda que una mujer no coaccionada y bien informada no debe tener restricción por edad o paridad para que obtenga la esterilización(9). De manera similar, las pautas del Colegio Estadounidense de Obstetras y Ginecólogos establecen: "En una mujer bien informada, la edad y la paridad no deberían ser una barrera a la esterilización "(10). El Royal College of Obstetricians and Gynecologists igualmente recomienda no restringir la esterilización en función de la edad y la paridad, y sugiere "atención especial" al momento de brindar consejería a estas pacientes(11). La OMS recomienda no colocar barreras por edad y realizar en pacientes una mayor educación y orientación dado que tienen las mayores tasas de arrepentimiento(12). Además, varios estudios han mostrado que mujeres sometidas a la esterilización quirúrgica no tienen claro el carácter permanente que implica esta intervención, es por esto que asociaciones internacionales hacen énfasis en la gran

importancia en la consejería en planificación familiar y del consentimiento informado (1,6).

Reconociendo la relevancia del tema y ante el hecho de desconocer a profundidad los factores relacionados con el arrepentimiento de la esterilización quirúrgica en nuestro medio, partiendo de que en Colombia solo se dispone de datos estadísticos que no permiten caracterizar los factores relacionados con el arrepentimiento, se desarrolló la presente investigación, con el fin de dar a conocer datos epidemiológicos locales y factores asociados al arrepentimiento posterior a la esterilización quirúrgica femenina en nuestro medio.

Es pertinente tener esta información para fortalecer la educación de la paciente previa a la decisión sobre un método de planificación y para identificar aquellas pacientes que tienen un mayor riesgo de presentar arrepentimiento después de la esterilización, ofreciéndoles siempre una opción ideal y segura. Cabe resaltar que no es la intención de este estudio aumentar las barreras para el acceso a la planificación definitiva, sino por el contrario fortalecer el proceso de consejería para realizar una adecuada selección de método según las características de cada paciente.

Conociendo el problema y teniendo en cuenta que el ISABU y la clínica Girón son instituciones donde diariamente se atienden pacientes en edad reproductiva que consultan a los programas de citología o a consulta externa de ginecología y algunas dentro de sus antecedentes podrán referir la esterilización quirúrgica como método de planificación, se plantea abordar a estas pacientes para responder la pregunta de investigación ¿cuáles son los factores asociados al arrepentimiento después de la realización de esterilización quirúrgica en mujeres que asisten a consulta en el ISABU y la clínica Girón?

2. Justificación

El arrepentimiento posterior a la realización de la esterilización quirúrgica se encuentra asociado a factores como edad menor de 30 años, pérdida de un hijo, pareja inestable y asesoría deficiente entre otros (3,4,14). En Colombia a la fecha no hay estudios en los que se evalúen los factores asociados a este fenómeno, siendo esta la principal razón que motivó la realización de esta investigación.
Los datos disponibles a nivel nacional sobre la consejería previa al procedimiento revelan cifras que evidencian una calidad deficiente de la misma, es una necesidad tanto para pacientes como ginecólogos el mejorar la información brindada en estos procesos(6). Es pertinente tener esta información porque de los datos obtenidos y de su puesta en conocimiento con los colegas, se derivará una mejor educación a la paciente previa a la decisión sobre un método de planificación y adicionalmente se conocerán características que pueden llevar a las pacientes a tener un mayor riesgo de presentar arrepentimiento después de la esterilización, sobre las cuales se pueden tomar medidas de mejoramiento.

Este trabajo es el primero en realizar una caracterización del arrepentimiento de esterilización quirúrgica en mujeres de la región. Se constituye entonces en un aporte importante tanto en el contexto académico por la generación de nuevo conocimiento y la formación de talento humano, así como para las instituciones donde se llevó a cabo el mismo ya que sirve de fuente de obtención de datos que a futuro se constituirán en el material de apoyo para la toma de decisiones administrativas y clínicas.

3. Marco teórico

3.1. Esterilización quirúrgica femenina

La esterilización quirúrgica femenina es un método anticonceptivo permanente que interrumpe quirúrgicamente la permeabilidad de las trompas de Falopio con el fin de obstruir el transporte de los óvulos maduros desde los ovarios al útero, para así evitar la fertilización(10). La esterilización femenina es el método anticonceptivo más comúnmente usado en todo el mundo, utilizado por el 19 % de todas las mujeres entre 15 a 49 años. La prevalencia de la esterilización femenina es más alta en Asia (23,4 %) y América Latina y el Caribe (26%), y es baja en África (1,7 %) y Europa (3,8 %)(13).

En Colombia según datos de la ENDS 2015, también es el método anticonceptivo de elección entre las mujeres en algún tipo de unión, en ellas la prevalencia es del 34,9%; se evidencian diferencias según factores sociales, por ejemplo, las pacientes con menor nivel educativo tienen mayor prevalencia siendo 44,6% en mujeres con nivel educativo de primaria. El porcentaje de mujeres esterilizadas antes de los 25 años sigue en aumento. Según datos de 2015 un 22,6% de las mujeres esterilizadas se encontraban en este rango de edad en comparación con un 20% en el 2010. Alrededor del 80% de las mujeres esterilizadas se operan antes de los 35 años. Los otros métodos anticonceptivos usados según ENDS 2015 son la inyección con un 14,2%, la píldora en un 7% de mujeres y los métodos reversibles de largo plazo como el DIU en un 4,7% y los implantes en un 5,4% (2).

Se consideran candidatas ideales para este procedimiento las mujeres que tienen paridad satisfecha y que han recibido información clara y suficiente sobre la técnica, complicaciones y sobre todo, la irreversibilidad del método(1). Al tratarse de un procedimiento quirúrgico se requiere una adecuada valoración preoperatoria que debe incluir, una buena anamnesis, examen ginecológico completo, evaluación de riesgo quirúrgico y anestésico y finalmente el diligenciamiento de un consentimiento informado(14).

Clasificación

Según momento de la realización: La esterilización quirúrgica femenina puede realizarse en cualquier momento de la vida. La elección y el momento de la

esterilización dependen de la preferencia de la paciente, la evaluación médica de riesgos y el acceso a los servicios de atención sanitaria. El momento del procedimiento influye tanto en el abordaje quirúrgico como en el método de oclusión tubárica. En Estados Unidos, más de la mitad de todas las oclusiones tubáricas se realizan en el período posparto temprano(10).

Esterilización quirúrgica posparto: Se realiza en el momento del parto por cesárea o después de un parto vaginal y no debe prolongar la estancia hospitalaria de la paciente. Después del parto vaginal el abordaje de elección es la minilaparotomía, la cual se realiza antes del inicio de la involución uterina significativa a través de una pequeña incisión infraumbilical. Por lo general, se realiza con anestesia regional o general(10).
La esterilización posparto requiere asesoramiento y consentimiento informado antes del trabajo de parto y el parto. Idealmente, se debe obtener el consentimiento durante la atención prenatal, cuando el paciente puede tomar la decisión sin estar sometida a estrés y tiene el tiempo suficiente para considerar las implicaciones de dicha elección, es importante brindar información acerca de los riesgos y beneficios del procedimiento y considerar métodos alternativos de anticoncepción(10).

Esterilización quirúrgica postaborto: La esterilización postaborto puede realizarse inmediatamente después de un aborto espontáneo o inducido sin complicaciones, sin aumento del riesgo de falla y complicaciones en comparación con un procedimiento de intervalo. Después de un aborto en el primer trimestre o un aborto en el segundo trimestre, la oclusión tubárica mediante laparoscopia o minilaparotomía es aceptable. Con cualquiera de los enfoques, se puede usar un único anestésico para el aborto y la oclusión de las trompas(10).

Esterilización quirúrgica en periodo de intervalo: Se refiere a la esterilización quirúrgica que se relaciona en un periodo separado del embarazo. Antes de su realización se requiere una prueba de embarazo negativa o el uso adecuado de un método anticonceptivo eficaz antes del procedimiento. Al igual que en las dos

anteriores se requiere de la firma del consentimiento informado posterior a la consejería(10).

Según la vía de abordaje:

Minilaparotomía: Se puede llevar a cabo aprovechando una cicatriz abdominal de cesárea o durante la cirugía electiva abdominal. Se han descrito varias técnicas para su realización. En Colombia, basados en experiencia clínica, la minilaparotomia es la vía de abordaje más usada y las técnicas quirúrgicas que predominan son la técnica Pomeroy y la de Parkland (2).

- **Técnica de Pomeroy:** fue introducida en 1929, y es la técnica más común y ampliamente utilizada por su simplicidad y efectividad. Consiste en sujetar la parte ístmica de la trompa con una pinza atraumática, ligar el asa con sutura absorbible y realizar la escisión. La parte ístmica media de la trompa se eleva y se forma un asa en el punto medio. La trompa se liga atando una o dos suturas de absorción rápida alrededor del asa. Pomeroy originalmente describió el uso de suturas crómicas. Se corta la porción media del asa con cuidado de dejar suficiente espacio entre las suturas, para evitar que los extremos cortados se salgan de la sutura. Ambos extremos tubáricos se separan después de la reabsorción de la sutura y se forma el tejido fibrótico intermedio (17,18).

- **Técnica modificada de Pomeroy (Pritchard):** la sección avascular del mesosalpinx se sutura con material absorbible, evitando los vasos sanguíneos. El hilo se ata alrededor de la parte proximal y distal del lazo del tubo, posteriormente se extirpa este segmento(15).

- **Técnica de Parkland:** Se crea una abertura en una porción avascular del mesosalpinx. Luego se pasan dos puntos con sutura absorbible a través de la abertura, uno para ligar el extremo proximal de la trompa y el otro para ligar el extremo distal. Los extremos pueden ligarse doblemente para asegurar la

hemostasia. Un segmento de 2 cm se corta entre las suturas. A diferencia de la técnica de Pomeroy, el método de Parkland logra la separación anatómica inmediata de los extremos cortados de la trompa de Falopio (17,18).

- **Fimbriectomía de Kroener:** la parte distal de la ampolla se divide entre dos ligaduras de sutura de material no absorbible y luego se corta el infundíbulo del tubo con las fimbrias. Esta técnica es obsoleta debido a una alta tasa de fallas, presumiblemente relacionada con el riesgo de lúmenes tubáricos residuales (15).

- **Técnica de Irving**: descrita en 1924, es un método destinado a reducir el riesgo de fracaso de la esterilización llevada a cabo en la cesárea. La trompa uterina se corta entre dos ligaduras de sutura a unos 3 a 4 cm del útero. El extremo proximal se entierra en un pequeño túnel hecho con tijeras en el miometrio superficial de la pared uterina posterior o anterior. El extremo distal se coloca entre las hojas del ligamento ancho. El ligamento ancho se cierra con material de sutura absorbible. Cuando el procedimiento se realiza en el período puerperal, los extremos proximales enterrados de los tubos se comprimen durante el proceso de involución uterina y finalmente se obliteran. En tales circunstancias, este método tiene una tasa de falla muy baja de menos de 0,1%. El procedimiento de Irving no se recomienda para la esterilización por intervalo (16).

- **Técnica de Uchida:** reportado por primera vez en 1946, se inicia con la inyección de una solución diluida de adrenalina en solución salina fisiológica entre las hojas del mesosalpinx, justo debajo de la trompa uterina, lo que hace que el tubo muscular se separe de la serosa. La serosa hinchada que recubre el tubo se corta con una tijera, dejando al descubierto la capa muscular del tubo que luego se agarra, se eleva y se divide. La parte proximal del tubo se despoja de su serosa en una longitud de 3-4 cm. Después de la ligadura de su extremo más proximal con material no absorbible, se extirpan

3 cm de esa parte del tubo. El extremo de corte proximal se entierra automáticamente en el mesosalpinx. El mismo material no absorbible se usa para suturar el extremo del corte distal del tubo, que se deja fuera del mesosalpinx. La técnica de Uchida es más compleja que los otros procedimientos (16).

Las dos últimas técnicas descritas, requieren una disección y un tiempo quirúrgico más extensos, están asociadas a un mayor riesgo de hemorragia y no se usan comúnmente. Su uso es factible al momento de la cesárea, pero es más difícil de lograr a través de una incisión de minilaparotomía. Estas técnicas fueron desarrolladas para minimizar el riesgo de formación de fístula tuboperitoneal y embarazo después de la ligadura de trompas, que puede ocurrir en hasta 1 por ciento de las mujeres después de una salpingectomía parcial, se cree que estas técnicas son más efectivas que las técnicas de Pomeroy o de Parkland, pero no se han comparado directamente. En la práctica clínica estas técnicas se han reservado para pacientes con antecedentes de esterilizaciones quirúrgicas fallidas. Sin embargo, no hay datos que permitan comparar la eficacia entre estas técnicas y los métodos tradicionales utilizados para la esterilización posparto(17).

Laparoscopia: Esta vía se prefiere para la esterilización por intervalos sobre la laparotomía y la minilaparotomía, dada la recuperación más rápida(15). Sin embargo, en Colombia sigue siendo superada por la minilaparotomia. La ventaja sobre la vía transcervical es que permite una exploración de la cavidad abdominal, comparada con la minilaparotomia tiene a su favor menor morbilidad asociada, menor tiempo de ingreso y recuperación más rápida.

- **Electrocoagulación monopolar:** Requiere electrocoagulación del istmo tubárico seguido de escisión tubárica y recoagulación de los bordes cortados, su efectividad implica la destrucción de al menos 3 cm de la trompa (necrosis isquémica hasta 3/4 de la longitud total). Está asociada a complicaciones como quemaduras o lesiones intestinales (11,18).

Fue la primera técnica usada pero después del reporte de 11 casos de muertes por quemaduras , y de 100 casos de lesiones térmicas intestinales, en un estudio americano publicado en 1981, se recomendó su uso con precaución y el cambio a electrocoagulación bipolar(14).

- **Electrocoagulación bipolar:** Consiste en aplicación de corriente a través de una pinza con 2 electrodos**,** la corriente pasa selectivamente a través del tejido agarrado entre las mandíbulas de las pinzas, por lo que la quemadura se limita al tejido dentro de las mandíbulas, lo que reduce la tasa de complicaciones. La corriente debe aplicarse a lo largo de 3 cm de la zona ístmica de la trompa. Esta técnica presenta una menor tasa de complicaciones, sin embargo, se ha reportado mayor tasa de fallas comparada con la electrocoagulación monopolar (11,16,17).

- **Clip de Filshie:** dispositivo compuesto de titanio y silicona, en forma de boca de cocodrilo, debe aplicarse con una pinza especial, abrazando la trompa y cerrándolo con la pinza. La trompa queda aplastada y ocluida y solo 4 mm de la trompa son afectados lo que permite una mayor efectividad en el caso de realizarse procedimientos de recanalización(14).

- **Anillo de Yoon:** a base de goma de silicona impregnada con sulfato de bario. Los dos anillos se pueden cargar en el aplicador al mismo tiempo, empujando el anillo sobre un asa hecha en la trompa de forma bilateral para inducir gradualmente la esclerosis tubárica, es un método poco usado en la actualidad (16,17).

Histeroscopia: Desde la disponibilidad de la histeroscopia, se han introducido nuevos métodos mecánicos que pueden llevarse a cabo de forma ambulatoria con anestesia local o sin ella. Estos métodos ocluyen las trompas al estimular el crecimiento del tejido fibrótico(16). Se trata de una vía de abordaje mínimamente invasiva que elimina la necesidad de hospitalización, se asocia a menor dolor y

permite una recuperación más rápida. Es la vía de elección en mujeres obesas o con múltiples cirugías previas. Para un adecuado abordaje histeroscópico se requiere acceder a los ostium tubáricos, inserción de un dispositivo efectivo que ocluya la trompa y que este dispositivo no migre (14).

- **Essure:** El sistema es un método transcervical, no incisional de esterilización permanente, fue aprobado en 2001 por la Oficina de Salud Europea y en 2002 por la Administración de Alimentos y Medicamentos. Contiene una aleación de níquel-acero, por lo tanto, no está indicado en pacientes con alergia al níquel conocida o potencial. La colocación puede realizarse en un entorno ambulatorio, aunque la técnica anestésica utilizada con más frecuencia es un bloqueo paracervical con o sin sedación oral o intravenosa. La recuperación demora generalmente menos de 24 horas. Se debe usar método adicional durante los primeros 3 meses y se requiere confirmación mediante histerosalpingografía (11,18).

3.1.1. Efectividad:

La Revisión Colaborativa de Esterilización (CREST) de los EE. UU, es un estudio observacional prospectivo y multicéntrico, realizado en el año 2000, en el que se incluyeron 10,685 mujeres; concluyó que, aunque la esterilización por laparoscopia o minilapatoromía es un método altamente efectivo de la anticoncepción, el riesgo de fracaso es sustancialmente más alto que el reportado previamente. El análisis de los datos de CREST encontró una tasa de falla acumulada al año de 5,5 por 1000 pacientes, a los 5 años de 13 por 1000 pacientes y a los 10 años de 18,5 por 1000 pacientes para los métodos de esterilización quirúrgica femenina (incluyendo laparoscopia y laparotomía)(18) .

Según la técnica empleada se encontró una mayor tasa de falla con la técnica de electrocoagulación bipolar y anillos de Yoon (18).

En cuanto a los métodos histeroscópicos la tasa de embarazos comunicados a los 5 años fue del 0,25% (14).

3.1.2. Consejería

La consejería en planificación familiar es un proceso continuo en el cual se brinda información completa y acertada acerca de los métodos de planificación a la paciente para ayudarla en la toma de la mejor decisión. Mejorar la calidad del asesoramiento anticonceptivo es una estrategia para prevenir embarazos no deseados. Los enfoques para mejorar las experiencias de la consejería en anticoncepción de las mujeres incluyen trabajar para desarrollar una relación estrecha y de confianza con las pacientes y utilizar un enfoque de toma de decisiones compartido que se centre en obtener y responder a las preferencias de la paciente (19).

El impacto del asesoramiento se ve claramente en los estudios que han encontrado que la elección de un nuevo método anticonceptivo por parte de las mujeres depende de si los proveedores mencionan o recomiendan métodos específicos. Existen estudios acerca de la calidad de la consejería en los que se han utilizado entrevistas cualitativas tanto de pacientes como de proveedores para evaluar sus experiencias de consejería anticonceptiva. Estos han evidenciado que las mujeres a menudo informan estar insatisfechas con su experiencia de asesoramiento, incluida la sensación de que no pueden hablar de sus inquietudes y de que reciben información insuficiente sobre sus opciones. Los estudios cuantitativos que investigan esta cuestión también han encontrado que muchas mujeres expresan insatisfacción sobre el enfoque centrado en el paciente y la idoneidad del asesoramiento(19).

Según la OMS el proceso de consejería para la esterilización quirúrgica debe cubrir 7 puntos, los cuales deben ser explicados claramente a la paciente para poder proceder con la firma del consentimiento informado (5):

- Los anticonceptivos reversibles de acción prolongada son una opción que está disponible.
- La esterilización femenina es un procedimiento quirúrgico.

- Los riesgos y beneficios del procedimiento deben explicarse de forma que la paciente pueda entender
- Si el procedimiento es exitoso, este va a evitar que la paciente pueda tener otro hijo
- El procedimiento se considera permanente y probablemente no pueda ser revertido
- La paciente puede rechazar el procedimiento en cualquier momento antes de que tenga lugar (sin perder los derechos a otros servicios médicos, de salud, otros servicios o beneficios).
- El procedimiento no protege contra infecciones de transmisión sexual, incluido el VIH.

Es deber de los ginecoobstetras el cumplimiento de estos puntos y el conocimiento de las leyes que regulan la esterilización quirúrgica en el país, deben garantizar que las pacientes comprendan los riesgos y beneficios de la esterilización, que la esterilización debe considerarse permanente y la tasa de falla del procedimiento. Siempre debe darse información amplia sobre los métodos anticonceptivos reversibles de acción prolongada, y plantearlos como opciones, especialmente en mujeres jóvenes, sin pareja estable o que no tienen hijos. Dentro del proceso de consejería debe incluirse además información sobre la vasectomía y se debe informar a las pacientes que es un método de planificación más eficaz y con menores riesgos que la esterilización femenina.

Es importante en la consejería detectar los factores de riesgo relacionados con un posterior arrepentimiento y hacer consiente a la paciente de la presencia de los mismos; entre estos destacan la edad joven y las dificultades de pareja u otros factores estresantes (1,22). Una vez se hayan explicado todos estos aspectos, la decisión del método de planificación dependerá únicamente de la paciente y debe respetarse su preferencia.

El objetivo de la consejería es adoptar un enfoque en el cual la determinación del método de planificación se basa en una decisión en conjunto del paciente y el

médico. Debe evitarse una posición paternalista, en la cual el médico anula los deseos y la autonomía del paciente para “protegerla” de las consecuencias de su decisión. Cuando los pacientes consideran una decisión irreversible como la esterilización, no es raro que un médico sienta un “impulso protector” para ayudar al paciente a evitar que se presente arrepentimiento postesterilización (1). Este “impulso protector” se presenta con mayor frecuencia cuando la que solicita la esterilización es una mujer joven, nulípara, con inestabilidad emocional o factores estresantes en su vida. En estas situaciones, como en todos los servicios de esterilización, es importante plantear los métodos de largo plazo como opciones igualmente efectivas y reversibles (1).

Aunque no es posible eliminar todo riesgo de remordimiento, negar la esterilización a quienes lo solicitan tiene el costo de limitar la capacidad de las mujeres para expresar plenamente su autonomía con respecto a la decisión de ser o no madre. Eliminando el riesgo de arrepentimiento al limitar la autonomía del paciente en general es considerado por los bioeticistas como algo peor que permitir que un paciente tome una decisión posiblemente errónea. Es imposible eliminar el arrepentimiento, ya que el solo hecho de tratarse de un ser humano totalmente autónomo con capacidad de decisión conlleva el riesgo de un arrepentimiento posterior (1).

3.1.3. Panorama en Colombia

Al ser el método de elección en un 34,9% de mujeres se considera que la esterilización quirúrgica femenina es el método de mayor prevalencia en Colombia; se evidencian diferencias según factores sociales, por ejemplo, las pacientes con menor nivel educativo tienen mayor prevalencia con un 44,6% en mujeres estudios de primaria. El porcentaje de mujeres esterilizadas antes de los 25 años sigue en aumento, según datos de 2015 un 22,6% de las mujeres esterilizadas se encontraban en este rango de edad en comparación con un 20% en el 2010. Alrededor del 80% de las mujeres esterilizadas se operan antes de los 35 años (2).

El 76% de las mujeres que son esterilizadas lo hacen a través de recursos públicos y solo un 24% mediante entidades privadas (6).

Con respecto al arrepentimiento, el porcentaje total de mujeres que refirieron estar arrepentidas de la realización de la esterilización quirúrgica es del 15,9% y es relativamente mayor en las mujeres de 30 a 34 años (22,4%). Por regiones se encontró una tasa mayor de 20% en La Guajira, Atlántico, Norte de Santander, Santander, Meta, Arauca y Vichada. Los principales motivos de arrepentimiento que fueron reportados son el deseo de otra hija/o en un 75,9% de los casos y que el compañero sentimental desea otro hijo/a en un 14,7% (2).

A pesar de los grandes avances en planificación familiar que ha tenido Colombia, aun es notoria la necesidad de mejorar el nivel de información y educación para la planificación familiar y otros aspectos de la salud sexual y reproductiva (20). El estudio de Jadhav y cols. publicado en el 2018 evaluó la calidad de la consejería y el consentimiento informado en países de Asia y América latina mediante 3 indicadores: información acerca del carácter permanente del procedimiento, información sobre efectos adversos potenciales y por último información sobre otros métodos de planificación familiar. Los resultados para Colombia indican que el 88% de las mujeres fueron informadas acerca del carácter permanente del procedimiento, solo un 43% recibieron información de los efectos adversos y un 48% información acerca de otros métodos de planificación familiar. Adicionalmente se encontró que un 6% de mujeres referían no haber recibido información sobre ninguno de los tres aspectos, 32% solo sobre un indicador, 32% sobre dos indicadores y solo un 27% de mujeres recibieron información completa y detallada sobre los tres aspectos evaluados. Varios factores influyeron en la calidad de la información brindada a las pacientes, se encontró una mejor calidad en la consejería en el sector privado y en mujeres con mayor nivel educativo (6).

3.1.4. Legislación

La ley 1412 de 2010 autoriza el acceso gratuito a los métodos anticonceptivos permanentes a la población colombiana para fomentar la paternidad y maternidad

responsable, ya sea vasectomía o ligadura de trompas. En el artículo cinco se hace referencia a la responsabilidad del médico de informar a la paciente las implicaciones, riesgos, beneficios y educar acerca de otros métodos anticonceptivos, antes de firmar el consentimiento informado. En el artículo siete se prohíbe la práctica de la esterilización quirúrgica en menores de edad. Esta prohibición es acorde con la Constitución porque permite proteger el consentimiento futuro del menor y adicionalmente, no lo priva de su facultad de decidir el número de hijos que quiere tener (21).

Posteriormente, en la sentencia C-131 de 2014 se exponen las causales de anticoncepción quirúrgica en menores de edad, siendo la primera aquellos adolescentes en los que se presente riesgo inminente de muerte por embarazo, siempre y cuando este riesgo este certificado por un médico, el menor dé su consentimiento y el procedimiento este autorizado por un juez. La segunda causal es la discapacidad profunda o severa, la cual debe estar certificada por un médico, ambos padres deben solicitar el procedimiento ante un juez y este debe dar su autorización (22).

3.2. Arrepentimiento

El termino arrepentimiento, de forma literal, parece ser un concepto relativamente simple; generalmente, significa sentir tristeza por lo que ha sucedido antes, más comúnmente alguna decisión o acción que se haya tomado o algún evento que haya ocurrido. Sin embargo, en el uso real, el concepto de arrepentimiento resulta ser bastante complejo, especialmente cuando se trata de decidir qué es lo que realmente puede tomarse como arrepentimiento y qué es lo que no cuenta como tal, o en términos más precisos, cuáles son realmente los indicadores del arrepentimiento. Partiendo de esta premisa se han identificado tres formas de medir la intensidad de arrepentimiento postesterilización: primero, pesar o arrepentimiento autoinformado; segundo, solicitud de información sobre la reversión de la esterilización; y tercero, realización de cirugía de reversión o fertilización in vitro (4).

El arrepentimiento se considera la complicación más común de la esterilización tubárica; aunque la mayoría de las mujeres que eligen la esterilización no se arrepienten del procedimiento, es necesaria una adecuada consejería para disminuir el riesgo de su presentación. El estudio CREST, una cohorte prospectiva que siguió por 14 años a pacientes que eligieron la esterilización quirúrgica como método de planificación encontró una tasa global de arrepentimiento del 14,3%, y esta era casi cuatro veces mayor en las mujeres jóvenes entre 18 a 24 años. Adicionalmente de ese porcentaje de pacientes, solo el 1% de estas mujeres lograron obtener procedimientos de reversión (1,4).

Existen indicadores con fuerte asociación al arrepentimiento, muchos de estos son parte de las circunstancias individuales de la paciente. Dentro de los factores que se han visto relacionados con el arrepentimiento posterior a la esterilización quirúrgica se encuentran: (10)

- Edad joven en el momento de la esterilización (edad <30 años): La edad es el factor de riesgo más fuerte relacionado con el arrepentimiento postesterilización, ya sea en mujeres que solicitan información sobre reversión del procedimiento o en aquellas que obtienen dicha reversión. Este es un factor de riesgo independiente del número de hijos o el estado civil (4,25).

  La edad joven ha sido una variable que se ha relacionado consistentemente con el arrepentimiento, en un estudio Divers reportó que las mujeres que presentan arrepentimiento, son en promedio nueve años menores que las que no lo presentan (23).

  Las mujeres entre 18 a 24 años en el momento de la esterilización tienen casi cuatro veces más riesgo de presentar arrepentimiento, comparadas con aquellas mujeres que son esterilizadas después de los 30 años (1).

  En el estudio CREST se encontró una probabilidad de arrepentimiento a los 14 años de seguimiento de un 12,7%, entre las mujeres menores de 30 años

el riesgo aumentó a un 20,3% comparado con un riesgo de 5.9% en las mayores de 30. Adicionalmente la probabilidad de solicitar información sobre los procedimientos de reversión a los 14 años fue de un 40,4% en las mujeres esterilizadas entre los 18 y 24 años , siendo casi cuatro veces más que en las mujeres mayores de 30 años al momento de realizarse la esterilización quirúrgica (4).

Cuanto antes se lleve a cabo la esterilización, mayor será el período restante de vida fértil y mayores serán las posibilidades de cambios en el estado civil o la pérdida de un hijo, todo lo cual puede llevar a un cambio en el tamaño de familia deseado (24).

- Mujeres afrodescendientes: En un estudio transversal realizado en el 2015, la mitad de las mujeres afrodescendientes que eran jóvenes y estaban solteras en el momento de la esterilización quirúrgica refirieron presentar arrepentimiento (25).
- Decisión tomada en el postparto inmediato: múltiples estudios demuestran un mayor número de arrepentimientos cuando la paciente se encuentra en el puerperio inmediato, en relación con el periodo de intervalo. Las mujeres que solicitan la esterilización en relación a un evento obstétrico (parto, cesárea o aborto) tienen mayor riesgo de estar insatisfechas con su decisión (3).

Respecto a este punto varios estamentos se han pronunciado, la Federación Internacional de Ginecología y Obstetricia (FIGO) en el 2015 se pronunció en contra de la esterilización quirúrgica ligada a parto o cesárea cuando esta no ha sido discutida con la paciente durante los controles prenatales, en etapas tempranas del embarazo. El consentimiento para la esterilización no debería solicitarse cuando la mujer esta vulnerable como es en el caso de una cesárea de emergencia o en trabajo de parto. También se resalta que la esterilización como prevención de futuros embarazos no puede justificarse éticamente cuando se está ante una emergencia obstétrica. Incluso si un

futuro embarazo pone en riesgo la vida o salud de la mujer , ella no se embarazara inmediatamente y por lo tanto se puede dar la consejería adecuada antes de tomar esta decisión (26).

- Nivel socioeconómico: las mujeres con menor nivel socioeconómico y cultural tienen mayor tendencia al arrepentimiento (3).
- Otros: relación de pareja inestable al momento de tomar la decisión de realizarse la esterilización quirúrgica, información errónea sobre el procedimiento, falta de información / apoyo para métodos anticonceptivos alternativos, decisión tomada bajo presión del cónyuge o debido a indicaciones médicas (3,4,14).

4. Estado del arte:

4.1. Esterilización quirúrgica femenina

El bloqueo de las trompas de Falopio como método de esterilización femenina se documentó por primera vez en 1827. A principios del siglo XX hasta bien entrados los años 60 en los EE. UU. y hasta los años 70 en Suecia, este método se practicó por razones sociales o ante enfermedades (16).

La esterilización se realizó por vía abdominal utilizando diferentes técnicas. En ese entonces se consideraba como una intervención mayor que podría conducir a todo tipo de complicaciones quirúrgicas y anestésicas. Desde mediados de la década de 1960 en adelante, a medida que se disponía de técnicas endoscópicas, la esterilización femenina voluntaria a menudo era el primer método anticonceptivo ofrecido a las parejas que consideraban completa a su familias (16).

La edición de 1946 del libro de obstetricia y ginecología de Munro Kerr ni siquiera mencionó la esterilización. Un poco más de cinco páginas están dedicadas a este tema en la segunda edición de Principios de ginecología de Jeffcoate que se publicó en 1962. En el párrafo introductorio, el autor compara la esterilización con una “destrucción de la función reproductiva. En 1965 en Bélgica, una mujer podía

solicitar la esterilización electiva solo sí tenía 35 años de edad o más y tenía al menos cuatro hijos, dos de ellos de cada sexo (16).

La esterilización quirúrgica ha estado marcada por múltiples diferencias y en algunos casos injusticias. Durante la década de 1970, en Estados Unidos los ginecoobstetras usaron la directriz de que la edad de una mujer multiplicada por su paridad debería ser igual a 120 antes de que la esterilización fuera apropiada. Esto presentó una barrera a la esterilización para algunas mujeres, especialmente para las mujeres blancas de clase media. Por el contrario, muchas mujeres de bajos ingresos y mujeres de color en los hospitales públicos fueron sometidas a programas estatales y federales destinados a limitar su fertilidad. Entre 1909 y 1979 los médicos realizaron más de 60.000 esterilizaciones forzadas en programas organizados por el gobierno. En 1976 el Departamento de Salud, Educación y Bienestar de EE. UU. desarrolló normas de protección para las esterilizaciones para evitar procedimientos coercitivos o no consensuales (1).

4.2. Esterilización quirúrgica femenina en Colombia

Colombia que para la época de los 60 era uno de los países más conservadores y religiosos de América Latina, se convirtió en la primera nación de Suramérica en promover la disponibilidad generalizada de métodos de planificación familiar (20).

Desde la década de 1960, Colombia ha tenido un progreso constante en la reducción de la fertilidad con programas de planificación familiar bien administrados. La esterilización es el método de planificación familiar más común en Colombia y ha crecido en popularidad en las últimas tres décadas (2). Con ese crecimiento ha disminuido el uso de métodos temporales tradicionalmente proporcionados por las farmacias del sector privado, y el sector público ahora representa la mayor parte de la prestación de servicios de planificación familiar (6).

En 1969, Colombia tenía un programa activo de planificación familiar que se expandía rápidamente en todo el país, a través de las clínicas Profamilia y las instalaciones del Ministerio de Salud, con una variedad de métodos que incluían la

píldora, el DIU y los métodos de barrera. La esterilización quirúrgica femenina se incluyó en estos programas desde 1972 (20).

4.3. Arrepentimiento

Conforme se vio el aumento en la prevalencia de esterilización quirúrgica también se empezó a notar un aumento en el número de mujeres que reportaban arrepentimiento después de la realización del procedimiento, son varios los estudios que han investigado el tema, a continuación, se mencionan en orden cronológico los de mayor relevancia, cabe resaltar que la mayoría de bibliografía es de países latinoamericanos, siendo el de mayor aporte Brasil.

Grubb y col. en 1985 basados en datos de CREST con 5.022 pacientes reportaron que el 2% presentó arrepentimiento un año después de la esterilización quirúrgica y el 2,7% de pacientes presentó arrepentimiento dos años después del procedimiento. Las características más fuertemente asociadas fueron edad menor de 30 años y esterilización al momento de una cesárea (27).

Wilcox y col. En 1991 publicaron los datos de seguimiento de CREST a cinco años en los que se encontró que el 6,2% de las pacientes habían solicitado información sobre la reversión, de las cuales solo un 0,2% habían obtenido la cirugía de reversión (28).

Platz y col. En 1992 en Suecia reportaron una frecuencia de arrepentimiento del 5,2%, el arrepentimiento entre los 5 a 11 años después de la cirugía, se redujo con el incremento de la edad, encontrando un 14,9% en las mujeres de 25 a 29 años, 7,2% en mujeres de 30-34 años y un 3,8% en mujeres mayores de 35 años. No se encontraron diferencias significativas en el arrepentimiento postparto o postaborto. El deseo de un hijo con una nueva pareja fue un factor significativo como causa de arrepentimiento (29).

Hardy y col. En 1996 en Brasil, realizaron un estudio de casos y controles comparando 216 mujeres que solicitaron reversión con mujeres que no lo hicieron, el riesgo relativo de solicitar una cirugía de reversión para las mujeres que fueron esterilizadas antes de los 25 años fue 18 veces mayor que en las mujeres mayores

de 29 años, los factores de riesgo reportados en este estudio fueron la edad joven, menor información sobre el procedimiento (OR 3,71 IC 2,03-7,25), y poco conocimiento sobre métodos anticonceptivos antes de la esterilización (OR 1,69 IC:0,82-3,63) (30).

Melo y col. En 2005, en Brasil realizaron un estudio de casos y controles para investigar la asociación entre los cambios en la estructura familiar y la solicitud de recanalización tubárica, encontrando como factores asociados la muerte de un hijo, compañeros sin hijos previos a la unión actual y cambio de pareja después de la esterilización quirúrgica (31).

Hillis y col. En el 2000, utilizando los datos del estudio completo de CREST, encontraron una probabilidad acumulada de arrepentimiento autoinformado del 12,7% a los 14 años de seguimiento, en las mujeres de 18 a 24 años esta probabilidad aumentaba a un 40,4%, es decir tenían 4 veces más riesgo de presentar arrepentimiento (4).

Sefa y col. En el 2005, en población de Estambul, realizaron un estudio evaluando la relación entre el arrepentimiento posterior a la esterilización y la depresión según la escala de Beck, encontrando mayores puntajes en esta escala en las mujeres jóvenes que se encontraron insatisfechas con el procedimiento (32).

Curtis y col. En el 2006 publicaron un metaanálisis que incluyó 19 estudios observacionales evaluando el riesgo de arrepentimiento y la edad joven. En este metaanálisis se evidencia que entre más joven es la mujer en el momento de la esterilización, es más probable que presente arrepentimiento. Las mujeres sometidas a esterilización a la edad de 30 años o menos tienen aproximadamente el doble de probabilidades que las mayores de 30 de expresar su arrepentimiento; también tienen entre 3,5 y 18 veces más probabilidades de solicitar información sobre cómo revertir el procedimiento y 8 veces más probabilidades de experimentar una reversión o un procedimiento de fertilización in vitro (33).

Arlete y col. En el 2006 en Brasil encontraron que el 91% de las ligaduras realizadas estuvieron relacionadas con un evento obstétrico, siendo la mayoría a cesáreas y entre estas mujeres un 14,6% presentaron arrepentimiento (34).

Moseman y col. En el 2006 publicaron un estudio describiendo los factores

asociados al arrepentimiento posterior a la esterilización quirúrgica en mujeres de una población militar, encontrando que la edad menor de 25 años, esterilización debido a presión del compañero, pobres relaciones maritales en el momento de la esterilización y un nuevo matrimonio fueron factores altamente predictivos de arrepentimiento. Adicionalmente las mujeres que solicitaron la reversión reportaron una baja calidad en la consejería y poco énfasis en el carácter permanente de la esterilización y la alternativa de la vasectomía (24).

Ludermir y col. En el 2009 en Brasil encontraron que las mujeres con una probabilidad mas alta de presentar arrepentimeinto era aquellas de menor edad, cuya decisión no habia sido autónoma, esterilización realizada dentro de los 45 días postparto, muerte de un hijo, compañero sin hjos, cambio de compañero y las que adquirieron informacion acerca de metodos anticonceptivos después del procedimiento (3).

Singh y col. En el 2012 en India, encontraron que el 66% de las mujeres elige la esterilización quirúrgica como método de planificación. Aplicaron una encuesta a 30.999 mujeres reportando 5% de mujeres arrepentidas entre los 15-49 años, otros factores relacionados fueron el solo tener hijos de un mismo sexo y pérdida de un hijo (35).

Bouffetal y col. En el 2014 en Africa realizaron un estudio retrospectivo en el que encontraron que el 48% de las mujeres se habían arrepentido de realizar la ligadura de trompas. El tiempo dedicado a las explicaciones fue muy corto en todos los casos, tres cuartas partes de las mujeres desconocían las complicaciones de la ligadura de trompas. El arrepentimiento se debió al factor religioso (23%), dolor pélvico (11,5%), deseo de otros niños (9,6%) o conocimiento de otros anticonceptivos (3,9%). Este estudio tuvo un tamaño de muestra pequeño lo cual trae limitaciones (36).

Becner y col. En el 2015 en Eslovenia, encontraron que el 1,3% de las mujeres sometidas a esterilización quirúrgica presentaban arrepentimiento, adicionalmente estas mujeres tenían puntajes más altos en la escala de depresión (37).

Shreffler y col. En el 2016 en Estados Unidos, evaluaron la asociación entre los motivos para la esterilización, el arrepentimiento y los síntomas depresivos,

encontrando que el 28% de las mujeres que se han sometido a esterilización quirúrgica reportan arrepentimiento, los factores más asociados con el arrepentimiento fueron el tiempo desde la esterilización lo cual estaba relacionado con cambio de pareja y tener una razón diferente a no querer más hijos al momento de realizarse el procedimiento, entre estas se encuentran problemas de salud y presión de otras personas. Se encontró también una relación entre síntomas depresivos y arrepentimiento (38).

Mas recientemente, en el 2020, Bansal y colaboradores, realizaron un estudio transversal para explorar la tendencia del arrepentimiento por esterilización en la India de 1992 a 2015 e identificar los factores asociados al mismo, prestando especial atención a la calidad de la consejería. Se encontró el doble de posibilidad de arrepentimiento en las mujeres que reportaron mala calidad de la consejeria, las pacientes que recibieron buena consejeria presentaron 26% menos riesgo de experimentar arrepentimiento (ORa 0,74, IC: 0,71- 0,77). Las pacientes que recibieron consejeria no tan buena y mala presentaron 1,33 y 2,39 veces mas riesgo de arrepentimiento respectivamente. (ORa1,33, IC: 1,22 1,46 y ORa 2,39, IC: 1,96 2,91)(39).

Tambien en el 2020 Pal y col. En India, realizaron un estudio transversal utilizando datos de la cuarta encuesta nacional de salud familiar (2015-2016) , se encontró una frecuencia de arrepentimiento del 7%. Los factores asociados significativamente con el arrepentimiento por esterilización fueron años desde la esterilización, experiencia de pérdida de un hijo, regiones de residencia y calidad de los servicios. Las mujeres que tenían hijos varones eran menos propensas a manifestar arrepentimiento por esterilización que las mujeres que solo tenían hijas (aOR: 1,3). Las mujeres que habían sufrido la pérdida de un hijo tenían mayores probabilidades de informar de arrepentimiento por esterilización en áreas rurales (aOR:1,2) así como en áreas urbanas (aOR: 1,3) en comparación a aquellos que no experimentaron ninguna pérdida de hijos (40).

5. Objetivo general

Conocer los factores asociados al arrepentimiento autoinformado después de la esterilización quirúrgica en pacientes del Hospital Local del Norte, puestos de salud del ISABU y clínica Girón.

5.1. Objetivos específicos

1. Describir los factores sociodemográficos asociados al arrepentimiento autoinformado posterior a un procedimiento de esterilización quirúrgica como método de planificación.
2. Determinar la prevalencia de arrepentimiento autoinformado posterior a la realización de esterilización quirúrgica en mujeres que acuden al Hospital Local del Norte y Clínica Girón.
3. Evaluar la percepción de las pacientes sobre la consejería realizada en planificación familiar previa a la realización de la esterilización quirúrgica.

6. Metodología

6.1. Pregunta de investigación: ¿Cuáles son los factores asociados al arrepentimiento autoinformado de la realización de esterilización quirúrgica en mujeres del HLN, puesto de salud ISABU y Clínica Girón?

6.2. Diseño: Estudio observacional analítico de corte transversal

6.3. Población: Las usuarias de esterilización quirúrgica como método de planificación familiar que asistieron al servicio de consulta externa de ginecología y al programa de Promoción y Prevención (PYP) para toma de citología del Instituto de Salud de Bucaramanga (ISABU-Hospital Local del Norte y puesto de salud pertenecientes a la red) y la clínica Girón.

6.4. Tamaño de la muestra: Para efectos de la estimación de tamaño de muestra se tomó como referente el estudio de casos y controles de Ludermir y colaboradores (2009), donde se evaluaron los factores de riesgo de

arrepentimiento para ligadura de trompas en mujeres brasileñas. Para ello, se tuvieron en cuenta las variables sociodemográficas que se han descrito como factores de riesgo de tipo sociodemográfico. Para todos los casos se consideró un nivel de confianza del 95% y una potencia del 80%. Las estimaciones muestrales obtenidas en el programa Epidat 4.2 se resumen a continuación:

Variable	**Proporción casos expuestos**	**Proporción controles expuestos**	**OR**	**n calculado**
Edad <25 años	74,4%	29%	7,1	36
Ligadura >45 días desde el parto	66,4%	54,3%	1,7	512
Cambio de pareja	86,0%	13,8%	38,6	14
Compañero con 1 o + hijos	76,4%	64,9%	1,8	490

El cálculo de tamaño de muestra estimado fue de 512. Adicional a esto, se incluyeron de manera anticipada a 50 mujeres (10% del tamaño de muestra) para la ejecución de la prueba piloto del estudio.

6.5. Tipo de muestreo: La recolección se realizó mediante muestreo secuencial entre septiembre de 2018 a marzo de 2020. La prueba piloto se llevó acabo entre julio y septiembre de 2018.

6.6. Criterios de inclusión:

- Mujeres entre los 18 y 50 años que refieran la esterilización quirúrgica como método de planificación familiar, la cual haya sido realizada hace más de 1 año, y estén de acuerdo con el diligenciamiento de la encuesta.
- Mujeres zonificadas en ISABU y clínica Girón.

6.7. Criterios de exclusión:

- Mujeres con limitaciones cognitivas que impidan la comprensión del formato de recolección de información.
- Pacientes que no diligencien el consentimiento informado y por tanto no acepten participar en el estudio.
- Pacientes que refieran que el contenido de la encuesta toca puntos susceptibles para ellas.

6.8. Técnica: Previa firma de consentimiento informado se aplicó una encuesta en la cual se indagaron datos sociodemográficos, motivos por los que eligió el método de planificación, presencia o no de arrepentimiento, así como factores asociados y la calidad de la consejería en planificación familiar. Ver anexo 1

7. Procedimiento

El presente estudio tuvo como objetivo evaluar los factores asociados al arrepentimiento posterior a la realización de esterilización quirúrgica en usuarias de la consulta externa de ginecología y del programa de citologías de las IPS asociadas a la red ISABU y la clínica Girón. Se decidió tomar esta población porque en la consulta ginecológica y en el programa de promoción y prevención de toma de citologías el método de planificación hace parte de la entrevista general, la población no se limitó a pacientes de consulta ginecológica para evitar un sesgo de selección al restringir la población únicamente a mujeres enfermas. De esta población se incluyeron únicamente las mujeres que refirieron la ligadura de trompas como método de planificación.

Se realizó una prueba piloto con 50 participantes entre julio a septiembre de 2018 para identificar factores tales como el tiempo promedio de duración de la encuesta y la presencia de elementos en el instrumento que podían dificultar su realización, posterior al análisis de estos datos no se requirieron ajustes. Para garantizar la

confidencialidad cada encuesta se codificó usando un número de identificación desde el momento en que la paciente firmó el consentimiento informado.
Las participantes fueron invitadas a hacer parte del proyecto al terminar la consulta ginecológica o la citología, por la residente que estaba rotando por ginecología o la enfermera que realizó la citología. El personal encargado de la aplicación de encuestas recibió capacitación respecto al tema y los objetivos de la investigación.

La investigadora o un miembro del grupo de encuestadores (residentes del programa de ginecoobstetricia UNAB, enfermeras de programa de citologías), explicó a cada participante el objetivo principal del proyecto, el tipo de preguntas que se le realizarían, haciendo especial énfasis en aquellas que podían tocar puntos susceptibles para ellas: indagar por la vida en pareja, pérdida de un hijo, deseo de nuevo embarazo e imposibilidad de lograrlo, siempre que fue necesario se brindó la orientación pertinente y se aclararon dudas a las participantes que así lo solicitaron. Las participantes firmaron un consentimiento informado en el que se les indicó que este estudio fue avalado por la Universidad Autónoma de Bucaramanga y que las personas encargadas de la realización de la encuesta, estaban en la capacidad de brindar la información necesaria en caso de ser solicitada. La encuesta aplicada estuvo constituida de nueve preguntas sociodemográficas, nueve preguntas relacionadas con el momento en que tomó la decisión de realizarse la esterilización quirúrgica y finalmente ocho preguntas para evaluar la presencia o no de arrepentimiento, para un total de 26 preguntas.
Para verificar el proceso de recolección de datos, la información obtenida se digitó en una hoja de Excel por duplicado y de forma independiente por 2 personas del equipo de trabajo. Los datos fueron analizados con el programa estadístico STATA 14,0.

8. Plan de análisis de datos

Para el análisis univariado las variables cualitativas se expresaron en frecuencia absoluta y porcentaje. Las variables cuantitativas se resumen como media y

desviación estándar o mediana y rango intercuartílico conforme a la normalidad (la condición de normalidad evaluada con test de Shapiro wilk). Para el análisis bivariado entre las variables dependientes y el arrepentimiento, se aplicó el test exacto de Fisher o prueba de Chi2 y se presenta el valor de p.

Finalmente, se realizó un modelo multivariado mediante regresión logística a fin de proponer un modelo predictivo de las variables explicatorias y el arrepentimiento. Se incluyeron todas aquellas variables que en el análisis bivariado mostraran un valor de p menor o igual a 0,2. Para ello, se utilizó la estrategia de remoción progresiva de variables paso a paso. En el modelo final se incluyeron las variables con un valor de p ≤0,05. Todos los análisis se realizaron con el paquete estadístico STATA 14,0.

9. Tabla de operacionalización de variables

Variable	**Definición conceptual**	**Definición operativa**	**Naturaleza**	**Escala**
Edad	Tiempo transcurrido desde el nacimiento.	Años cumplidos desde la fecha de nacimiento	Cuantitativa	Continua
Edad al momento de la esterilización quirúrgica	Tiempo transcurrido desde el nacimiento.	Años de la paciente al momento de la realización de la esterilización quirúrgica	Cuantitativa	Continua
Estado civil	Condición de una persona en relación con su filiación o matrimonio.	La referida por la paciente en la encuesta	Cualitativa	Nominal (soltera, unión libre, casada)

Nivel educativo	Conjunto de cursos que en calidad de estudiante una persona alcanza	Estudio parcial o completo	Cualitativa	Ordinal (primaria incompleta, completa, bachiller, universitario)
Número de embarazos	Número de embarazos que ha acumulado una mujer a lo largo de su vida	Según la información de la participante	Cuantitativa	Discreta
Número de partos vaginales	Número de partos que ha tenido en su vida	Según la información de la participante	Cuantitativa	Discreta
Número de cesáreas	Número de cesáreas que ha tenido en su vida	Según la información de la participante	Cuantitativa	Discreta
Número de abortos	Número de abortos que ha tenido en su vida	Según la información de la participante	Cuantitativa	Discreta
Tiempo entre nacimiento de ultimo hijo y la esterilización quirúrgica.	Periodo de tiempo	Transcesárea, hasta 45 días postparto, más de 45 días postparto	Cuantitativa	Continua
Sexo de los hijos	Condición orgánica, masculina o femenina	Niño o niña	Cualitativa	Nominal

Estrato socioeconómico	Clasificación en estratos de los inmuebles residenciales que deben recibir servicios públicos	Lo reportado por la encuestada	Cualitativa	ordinal
Arrepentimiento	Acción o efecto de arrepentirse	Arrepentirse de la cirugía	Cualitativa	Nominal
Formación nueva pareja	Unión de hecho entre dos personas de sexo opuesto	El compañero actual es diferente al que tuvo cuando se realizo la esterilización quirúrgica	Cualitativa	Nominal
Influencia de otra persona	Ejercer determinado control sobre la decisión de otra persona	Lo referido en la encuesta	Cualitativa	Nominal
Muerte de un hijo	Muerte de un hijo de la paciente o su compañero tiempo después de la realización del procedimiento	Lo referido en la encuesta	Cualitativa	Nominal
Compañero sin hijos previos a la unión actual	Pareja nueva que no tiene hijos de una antigua unión	Si el compañero no tenía hijos de una unión	Cualitativa	Nominal

		diferente a la actual.		
Año en el que se realizó la esterilización quirúrgica	Momento en e tiempo en el que la paciente fue intervenida	Lo referido en la encuesta	Cuantitativa	Discreta
Consejería de planificación	Se incluyeron datos sobre irreversibilidad del procedimiento, otros métodos anticonceptivos	Lo referido en la encuesta	Cualitativa	Nominal

10. Disposiciones éticas

Esta investigación se considera de riesgo mínimo de acuerdo con los principios establecidos en la Declaración de Helsinki, las Pautas CIOMS y en la Resolución 008430 de octubre 4 de 1993. El estudio se desarrolló con base en:

- Principio de no maleficencia: por ser un estudio observacional, no se realizaron intervenciones a las pacientes y no estuvieron expuestas a ningún daño.
- Principio de autonomía: no se coaccionó a las pacientes al momento de responder la encuesta.
- Principio de justicia: No hubo exposición a situaciones de riesgo para las participantes
- Principio de beneficencia: con los resultados obtenidos se podrán realizar acciones de mejora que beneficiarán a mediano plazo a pacientes que soliciten el procedimiento de esterilización quirúrgica.

Este tipo de estudio se ha realizado previamente en humanos sin generar daños en ellos, sin embargo, se tocaron puntos sensibles en la vida de una mujer como es el deseo de tener un nuevo hijo y no tener la posibilidad de lograrlo o la muerte de un

hijo, por este motivo en el consentimiento informado se enfatizó que si el diligenciamiento de la encuesta le causaba malestar podía decidir no continuar con la misma.

11. Resultados esperados

RESULTADO/PRODUCTO ESPERADO	INDICADOR	BENEFICIARIO
Conocer la prevalencia y factores sociodemográficos asociados al arrepentimiento autoinformado en población consultante al HLN, puestos de salud del ISABU y la clínica Girón	Prevalencias arrepentimiento	Profesionales en salud.
Nuevo conocimiento acerca de un método de planificación familiar y datos que indiquen necesidad de fortalecer consejería.	Motivos de arrepentimiento	Profesionales en salud.
Artículo derivado del estudio que se someterá ante una revista indexada a nivel nacional.	Factores asociados al arrepentimiento posterior a la esterilización quirúrgica, presentado como escrito promocional de cuarto año el cual está en proceso de someterse a revista indexada.	Universidad, grupo de investigación y contexto académico
Presentación de tesis de grado para obtener el título de Especialista en	Presentación de tesis de grado para obtener el título de	Residente de Ginecología & Obstetricia de la

Ginecología & Obstetricia en la Universidad Autónoma de Bucaramanga.	especialista en Ginecología & Obstetricia	Universidad Autónoma de Bucaramanga
Presentación de los resultados en un evento académico.	Presentación de poster en el XIII Encuentro de Semilleros de Investigación 2019 y el XIV Encuentro de Semilleros de Investigación 2020.	Comunidades académicas y clínicas

12. Impactos esperados

IMPACTO ESPERADO	PLAZO (AÑOS) DESPUES DE FINALIZADO EL PROYECTO	INDICADOR VERIFICABLE	SUPUESTOS
SOCIAL	Mediano	Calidad de la atención clínica.	Conocimiento sobre el tema que mejore la práctica clínica y la consejería.
SOCIAL	Mediano	Pacientes	Mejor información antes de ofrecer un procedimiento definitivo

13. Resultados

13.1. Análisis univariado

Se encuestaron 512 mujeres en edad reproductiva (18-50 años) que refirieron la esterilización quirúrgica como método de planificación familiar en las consultas de ginecología en el Hospital Local del Norte y puestos de salud de la red ISABU y en

el programa de toma de citología en el Hospital de Girón. La información se recogió en el periodo comprendido entre julio de 2018 y marzo de 2020.

La mediana de edad de las participantes fue de 38 años (RIC 33-44). Más de la mitad de éstas eran bachilleres (55,1%). En cuanto al estrato socioeconómico el 59,4% pertenecían al estrato uno y solo un 8% se encontraban en estratos tres y cuatro. La unión libre fue el estado civil reportado por la mayoría de las encuestadas (60,5%) y respecto a la ocupación más de la mitad de las participantes refirieron dedicarse al hogar (63,8%). El 98% de las participantes de este estudio pertenecían al régimen subsidiado. El lugar de procedencia más común fue Bucaramanga (38,5%) seguido por Girón (31,8%) y respecto a la residencia, la mayoría vivían en Girón al momento de la entrevista (71,9%) (Ver tabla 1).

Tabla 1. Características sociodemográficas de las participantes del estudio

Variable	**n (%)**	**IC95%**
Edad (años cumplidos)	38* (33-44) **	22-50♣
Nivel educativo		
Básica Primaria	193(37,8)	33,5-42,1
Bachillerato	282(55,1)	50,7-59,4
Técnico	22(4,3)	2,7-6,4
Posgrado	6(1,2)	0,4-2,5
Ninguno	9(1,8)	0,8-3,3
Estrato socioeconómico		
1	304(59,4)	55,0-63,7
2	166(32,4)	28,4-36,7
3	49(7,8)	7,2-12,4
4	2(0,4)	0,05-1,4
Estado civil		
Soltera	50(9,8)	7,3-12,7
Casada	129(25,2)	21,5-29,2
Unión Libre	310(60,5)	56,2-64,8
Divorciada	20(4,1)	2,4-6,0
Viuda	3(0,6)	0,1-1,7
Ocupación		
Estudiante	4(0,8)	0,2-2,0
Hogar	324(63,2)	58,9-67,5
Empleada	84(16,4)	13,3-19,9
Trabajadora independiente	90(17,6)	14,4-21,2

Desempleada	10(1,9)	0,9-3,6
Afiliación a seguridad social		
Régimen Contributivo	7(1,4)	0,6-2,8
Régimen Subsidiado	504(98,4)	96,9-99,3
Vinculado	1(0,2)	0,0-1,1
EPS a la que se encuentra adscrita		
Coosalud	188(36,7)	32,5-41,1
Asmetsalud	23(4,5)	2,9-6,7
NuevaEPS	81(15,9)	12,7-19,3
Medimas	58(11,3)	8,7-14,4
Comparta	108(21,1)	17,6-24,9
Saludvida	51(9,9)	7,5-12,9
Famisanar	2(0,4)	0,05-1,4
Saludtotal	1(0,2)	0,0-1,1
Procedencia		
Bucaramanga	197(38,5)	34,2-42,8
Girón	163(31,8)	27,8-36,1
Floridablanca	4(0,8)	0,2-2,0
Otros municipios de Santander	104(20,3)	16,9-24,1
Municipios de Bolivar	30(5,8)	4,0-8,3
Municipios de Cesar	3(0,6)	0,1-1,7
Municipios Norte de S	11(2,1)	1,1-3,8
Lugar de residencia		
Bucaramanga	86(16,8)	13,7-20,3
Girón	364(71,9)	67,0-75,0
Floridablanca	3(0,6)	0,1-1,7
Otros municipios de Santander	22(4,3)	2,7-6,4
Municipios de Bolívar	37(7,2)	5,1-9,8

*Mediana **Rango intercuartílico ♣Valor mínimo y máximo

La mitad de las participantes del estudio tenían entre tres y cuatro gestaciones (50,1%), el 31,6% refirió no haber tenido ningún parto vaginal y el 42,5% no haber tenido ninguna cesárea, en cuanto a los abortos la mayoría negó tenerlos (77,3%) y un 19% refirió al menos un aborto, solo 1,4% de las pacientes tenían antecedente de embarazo ectópico y el 2,9% de hijos nacidos muertos (Tabla 2).

Tabla 2. Características ginecobstétricas de las participantes

Característica	**n(%)**	**IC95%**
Fórmula obstétrica		
Gestaciones		
1 a 2	181(35,3)	31,2-39,7
3 a 4	257(50,1)	45,8-54,6
5 a 6	56(10,9)	8,3-14,0
7 o más	18(3,5)	2,1-5,5
Partos		
0	162(31,6)	27,6-35,9
1	58(11,3)	8,7-14,4
2	127(24,8)	21,1-28,8
3	81(15,8)	12,8-19,3
4	43(8,4)	6,1-11,1
5 o más	41(8,0)	5,8-10,7
Cesáreas		
0	218(42,5)	38,3-47,0
1	108(21,1)	17,6-24,9
2	132(25,8)	22,0-29,8
3	45(8,8)	6,5-11,6
4	9(1,7)	0,8-3,3
Abortos		
0	396(77,3)	73,5-80,9
1	98(19,1)	15,8-22,8
2	13(2,7)	1,4-4,3
3	4(0,8)	0,2-2,0
4	1(0,2)	0,0-1,1
Embarazos ectópicos		
0	505(98,6)	97,2-99,4
1	7(1,4)	0,6-2,8
Numero de nacidos vivos		
1	23(4,5)	2,9-6,7
2	198(38,7)	34,4-43,0
3	170(33,2)	29,1-37,5
4	71(13,8)	11,0-17,2
5 o más	50(9,7)	7,3-12,7
Número de nacidos muertos		
0	494(96,5)	94,5-97,9
1	15(2,9)	1,6-4,8
2-3	3(0,6)	0,1-1,7

Con respecto a las estrategias de planificación usadas por las participantes antes de la esterilización quirúrgica, se observó que la mayoría habían planificado con píldoras (41,8%) y un 3,7% experimentaron dos o más métodos (Tabla 3).
Las participantes tenían una edad comprendida entre los 20 y 46 años al momento de la cirugía, siendo la mediana de la edad de realización de la cirugía los 30 años. Más de la mitad de las pacientes se sometieron a la esterilización en el momento de una cesárea (53,1%) y el 41,2% lo hicieron más de 45 días después del parto. El 92,9% de las participantes tenían una pareja estable cuando decidieron esterilizarse y el 95,7% reportaron haber tenido un hijo sano, sin requerimiento de hospitalización (Tabla 4).

Al interrogar a las participantes sobre el motivo de esterilización, se encontró que la razón principal era que al momento ya tenían el número de hijos que deseaban (84,6%), seguida de ésta razón, las mujeres manifestaron que fue la indicación médica lo que las llevó a tomar la decisión (5,7%); en un menor porcentaje por la combinación de varios factores (influencia de la pareja, problemas con la pareja, influencia de tercera persona). En cuanto a sentirse influenciadas en su decisión la mayoría lo negó (84,8%), solo un 15,4% refirió sentirse influenciada. Al indagar sobre la persona que influenció en la toma de decisión el 68,3% indicó que fue el médico, 15,2% mencionaron a la pareja y un 20,2% a otra persona.
La mayoría de las pacientes fueron informadas sobre la irreversibilidad de la cirugía (93,1%), las complicaciones que podrían derivarse de esta (83%) y los otros métodos de planificación a su disposición (83,6%).
Respecto a los hallazgos en relación al arrepentimiento, se encontró que el 12,5% de las participantes expresaron haber sentido arrepentimiento posterior a la realización de la esterilización quirúrgica, de éstas un 78,1% confirmaron persistencia del mismo. En cuanto al tiempo en que presentaron el arrepentimiento, el 32,8% refirió presentarlo a los cinco años de la cirugía, seguido por un 26,6% en el primer año y un 21,8% en los 2 años posteriores. Solo el 26,6% de las participantes arrepentidas accedieron a consulta médica con la intención de una

recanalización tubárica y ninguna de ellas hasta el momento de la encuesta había accedido a la cirugía (Tabla 5).

Los motivos del arrepentimiento encontrados fueron la formación de una familia con una nueva pareja en el 26,6% de las participantes, deseo de otro hijo en el 14%, la presencia de hijos de un solo sexo en el 10,7% y complicaciones posteriores a la cirugía en el 9,2%. En menor medida las participantes refirieron deseo de otro hijo por la pareja (4,7%) y la combinación de los motivos anteriormente mencionados.

Tabla 3. Estrategias de planificación familiar descritas por las participantes

Método	**n(%)**	**IC95%**
Inyección	53(10,3)	7,9-13,3
Pastillas	214(41,8)	37,5-46,2
DIU	82(16,0)	12,9-19,5
Preservativo	11(2,1)	1,1-3,8
Barras	11(2,1)	1,1-3,8
Ninguno	122(23,8)	20,2-27,8
2 métodos	11(2,1)	1,1-3,8
Más de 2 métodos	8(1,6)	0,7-3,1

Tabla 4. Aspectos relacionados con la decisión de esterilización quirúrgica

Variable	**n (%)**	**IC95%**
Edad a la realización de la cirugía	30* (25-34)**	20-41♣
Momento de la cirugía		
Durante la cesárea	272(53,1)	48,7-57,5
Más de 45 días posparto	211(41,2)	36,9-45,6
Durante los primeros 45 días posparto	29(5,7)	3,8-8,0
Pareja estable		
Sí	476(92,9)	90,4-95,0
No	35(6,8)	4,8-9,4
No reporta	1(0,2)	0,0-1,1
Salud del hijo		
Sano	292(95,7)	92,8-97,7
Hospitalizado	13(4,2)	2,3-7,2
Motivo por el que se realizó la cirugía		
Tenía los hijos que deseaba	433(84,6)	81,1-87,6
Problemas de pareja	12(2,3)	1,2-4,1

Problemas de salud-indicación médica	29(5,7)	3,8-8,0
Consejo de tercera persona	4(0,8)	0,2-2,0
Más de dos razones antes señaladas	34(6,6)	4,6-9,2
Influenciada por una tercera persona		
Si	79(15,4)	12,4-18,9
No	433(84,6)	81,1-87,6
Influenciada por la pareja		
Si	12(15,2)	8,1-25,0
No	67(84,8)	75,0-91,9
Influenciada por el médico		
Si	54(68,3)	56,9-78,4
No	25(31,6)	21,6-43,1
Influenciada por otra persona		
Si	16(20,2)	12,0-30,8
No	63(79,8)	69,2-88,0
Informada sobre la irreversibilidad de la cirugía		
Sí	477(93,1)	90,6-95,2
Informada sobre las complicaciones de la cirugía		
Sí	425(83,0)	79,5-86,2
Informada sobre otros métodos de planificación		
Sí	428(83,6)	80,1-86,7

*Mediana **Rango intercuartílico ♣Valor mínimo y máximo

Tabla 5. Hallazgos relacionados con el arrepentimiento

Hallazgo	**n (%)**	**IC95%**
Arrepentimiento de la esterilización		
Si	64(12,5)	9,8-15,7
No	448(87,5)	84,3-90,2
Tiempo al arrepentimiento post-esterilización		
Un año	17(26,6)	16,3-39,1
Dos años	14(21,8)	12,5-34,0
3-5 años	12(18,7)	10,1-30,5
Más de 5 años	21(32,8)	21,6-45,7
Persistencia del arrepentimiento		
Si	50(78,1)	66,0-87,5
Consulta médica por el arrepentimiento (intención de recanalización tubárica)		
Si	17(26,6)	16,3-39,1
Motivos de arrepentimiento		
Formación de familia con una nueva pareja	17(26,6)	16,3-39,1
Tiene hijos de un solo sexo	7(10,7)	4,5-21,2

Muerte o desaparición de un hijo	2(3,1)	0,4-10,8
Complicaciones después de la cirugía	6(9,2)	3,5-19,3
Deseo de otro hijo	9(14,0)	6,6-25,0
La pareja desea otro hijo	3(4,7)	1,0-13,1
Otra	3(4,7)	1,0-13,1
Formación nueva familia, deseo de nuevo hijo por participante y pareja	4(6,2)	1,7-15,2
Hijos de un solo sexo, deseo de nuevo hijo por participante y pareja	2(3,1)	0,4-10,8
Formación nueva familia, deseo de nuevo hijo por participante	3(4,7)	1,0-13,1
Hijos de un solo sexo, deseo de nuevo hijo por participante	1(1,6)	0,0-8,4
deseo de nuevo hijo por participante y pareja	3(4,7)	1,0-13,1
Hijos de un solo sexo y pareja desea otro hijo	2(3,1)	0,4-10,8
Formación de nueva familia e hijos de un solo sexo	2(3,1)	0,4-10,8

13.2. Análisis bivariado

Se encontraron asociaciones entre el arrepentimiento después de la esterilización quirúrgica y algunas de las variables sociodemográficas incluidas en el estudio. Se puede afirmar que la edad actual entre 33 a 43 años (12,9% Vs 87,1%, p: 0,001) , la edad al momento de la cirugía entre los 26 a 30 años (9,3% Vs 90,7%, p<0,0001), tener una pareja estable (11,3% Vs 88,7%, p: 0,003), estar influenciada para realizarse la cirugía por el médico (13% Vs 87%, p: 0,002) o por una tercera persona (56,3% Vs 43,7%, p<0,0001), recibir información sobre la irreversibilidad de la cirugía (31,4% Vs 68,6%, p< 0,0001) y las complicaciones asociadas a la misma (10,4% Vs 89,6%, p: 0,001) se asocian con el arrepentimiento posterior a la esterilización. Llamó la atención que el momento de la cirugía (durante la cesárea, en el postparto o mas de 45 días postparto) no tuvo una asociación significativa con el arrepentimiento (Tabla 6).

Tabla 6. Análisis bivariado entre el arrepentimiento de la esterilización quirúrgica y variables sociodemográficas y clínicas

Variable	Arrepentimiento		Valor de p
	Sí	No	
Edad			
22-32 años	24(20,0)	96(80,0)	0,001*
33-43 años	33(12,9)	222(87,1)	
44-50 años	7(5,1)	130(94,9)	
Nivel educativo			
Ninguno-Básica Primaria	17(8,4)	185(91,6)	
Bachillerato	42(14,9)	240(85,1)	0,055
Técnico-Universitario	5(17,9)	23(82,4)	
Estrato socioeconómico			
1-2	61(13,0)	409(87,0)	
3-4	3(7,1)	39(92,9)	0,339
Estado civil			
Soltera/viuda/separada	12(16,4)	61(83,5)	
Casada/unión libre	52(11,8)	387(88,2)	0,272
Ocupación			
Hogar/desempleada	37(11,1)	297(88,9)	
Empleada /Trabajadora independiente	25(14,4)	149(85,6)	0,054
Estudiante	2(50)	2(50)	
Afiliación a seguridad social			
Régimen subsidiado	61(12,1)	443(87,9)	
Régimen contributivo	2(28,6)	5(71,4)	0,031*
Vinculado	0(0)	1(100)	
Gestaciones			
1-2	28(15,5)	153(84,5)	0,240
3-5	34(11,5)	262(88,5)	
6 o más	2(5,7)	33(94,3)	
Partos			
Ninguno	21(12,9)	141(87,1)	0,444
1-3	36(13,5)	230(86,5)	
4 o más	7(8,3)	77(91,7)	
Cesáreas			
Ninguna	25(11,5)	193(88,5)	0,829
1-2	32(13,3)	208(86,7)	
3-4	7(13,0)	47(87,0)	

Mortinatos			
No	62(12,5)	432(87,5)	1,00
Si	2(11,1)	16(88,9)	
Edad al momento de la cirugía			
20-25 años	38(24,1)	120(75,9)	
26-30 años	14(9,3)	137(90,7)	<0,0001*
≥31 años	12(5,9)	191(94,1)	
Planificación previa			
No	19(15,6)	103(84,4)	0,240
Si	45(11,5)	345(88,5)	
Pareja estable			
Sí	54(11,3)	423(88,7)	
No	10(28,6)	25(71,4)	0,003*
Momento de la cirugía			
Durante la cesárea	32(11,8)	240(88,2)	
Más de 45 días posparto	2(6,9)	27(93,1)	0,529
Durante los primeros 45 días posparto	30(14,2)	181(85,8)	
Influenciada para realizarse la cirugía			
Sí	18(22,8)	61(77,2)	0,003*
No	46(10,6)	387(89,4)	
Influenciada por médico			
Si	7(13)	47(87,0)	0,002*
No	11(44,0)	14(56,0)	
Influenciada por pareja			
Si	2(16,7)	10(83,3)	0,724
No	16(23,9)	51(76,1)	
Influenciada por otra persona			
Si	9(56,3)	7(43,7)	<
No	9(14,3)	54(85,7)	0,0001*
Información sobre irreversibilidad			
Si	11(31,4)	24(68,6)	<
No	53(11,1)	424(88,9)	0,0001*
Información sobre complicaciones			
Si	44(10,4)	381(89,6)	0,001*
No	20(22,9)	67(77,1)	
Información sobre otros métodos de planificación			
Si	50(11,7)	379(88,3)	0,189
No	14(16,9)	69(83,1)	

13.3. Análisis multivariado

Para realizar el análisis multivariado fueron incluidas aquellas variables que en el análisis bivariado presentaron valores de p menores o iguales a 0,2. Estas variables fueron las siguientes: edad, seguridad social, nivel educativo, edad al momento de la cirugía, tener pareja estable, haber estado influenciada para realizarse la cirugía, (por el médico o por otra persona), estar informada sobre la irreversibilidad de la cirugía, sobre las complicaciones y sobre los métodos de planificación familiar, tener hijos vivos, tener hijo y tener hija.

Se probaron varios modelos encontrando que no conocer de la irreversibilidad de la cirugía aumenta 6,46 veces la posibilidad de presentar arrepentimiento (OR: 6,46, IC95%: 1,13-36,97, p: 0,036); por el contrario, tener 44 años o más al momento de diligenciar la encuesta (OR: 0,07, IC95%: 0,09-0,60, p: 0,015) y haber sido influenciada para realizarse la cirugía por el médico (OR: 0,16, IC95%: 0,04-0,57, p: 0,005) se comportan como factores protectores. Llama la atención que no se pudo demostrar asociación entre la edad al momento de la cirugía y el arrepentimiento (Tabla 7).

Tabla 7. Modelo multivariado

Variable	OR	Valor de p	Intervalo de confianza 95%
Edad (44 años o más)	0,07	0,015	0,09-0,60
Haber sido influenciada para realizarse la cirugía por el médico	0,16	0,005	0,04-0,57
No conocer de la irreversibilidad de la cirugía	6,46	0,036	1,13-36,97

14. Discusión

Son pocos los estudios que hasta la fecha han indagado respecto al fenómeno del arrepentimiento posterior a esterilización quirúrgica. En Colombia solo se cuenta con los datos estadísticos aportados por la encuesta nacional de demografía y salud (ENDS) pero no hay información acerca de los factores que se asocian al mismo.

En este estudio, se pudo encontrar una prevalencia de arrepentimiento autoinformado del 12,5% en las mujeres que asistieron a la red ISABU y la clínica Girón, algo menor que la reportada en ENDS para el año 2015 (15,9%)(2).

Es bien sabido que la decisión de esterilización quirúrgica debe sustentarse en información solida, la cual debe ser proporcionada a la paciente por el médico que realiza la asesoría. Respecto a este ítem, con la información recolectada en el estudio, podemos afirmar que la asesoría brindada a las pacientes es suficiente y contiene al menos los 3 aspectos básicos a tratar (irreversibilidad, disponibilidad de otros métodos y complicaciones). Específicamente la información escasa y el desconocimiento acerca de la irreversibilidad del procedimiento actuaron como un factor de riesgo para el arrepentimiento.

Como se mencionó anteriormente el estudio más fuerte metodológicamente respecto al tema de arrepentimiento es el “U.S. Collaborative Review of Sterilization” (CREST), estudio de cohorte prospectiva con seguimiento a 14 años en mujeres sometidas a esterilización quirúrgica. Los resultados de este arrojaron que la probabilidad acumulativa de solicitar información de reversión fue de un 14,3%, siendo casi 4 veces mayor en las mujeres jóvenes entre 18 a 24 años (4). Los datos de nuestro estudio son concordantes con los hallazgos del CREST, ya que se evidenció que el arrepentimiento en pacientes entre 22 y 32 años fue del 20%, entre 33 y 43 años del 12,9% y de 44 a 50 años de un 5,1%, evidenciandose un valor de p de 0,001, lo cual aporta significacncia estadística a dichos datos.

Respecto a la edad al momento de la realización de la cirugía, se encontró que las pacientes menores de 25 años presentaron mayor tasa de arrepentimiento (24,1%) comparadas con las pacientes entre 26 y 30 años (9,3%) y mayores de 31 años (5,9%). Estos hallazgos son similares a los reportados por Moseman en 2006, donde también son mencionados como factores asociados la presión del compañero y la baja calidad de la consejería. Hallazgos también reportados en nuestro estudio (24).

Un dato llamativo del estudio fue no encontrar relación entre el momento de la cirugía y el arrepentimiento, basados en estudios como el de Ludermir y col, en el 2009 en Brasil, se esperaba encontrar una mayor prevalencia de arrepentimiento en aquellas participantes sometidas a esterilización dentro de los primeros 45 días postparto, sin embargo si hubo correlación entre otros hallazgos como fueron la relacion entre el cambio de compañero y estar influenciadas en la decisión con la presencia de arrepentimiento posterior (3).

A pesar de tratarse de un estudio de corte transversal, se encontraron asociaciones fuertes entre ciertos factores y la posibilidad de arrepentimiento. Es así como el hecho de haber sido influenciada por el médico para la realización de la cirugía actúa como un factor protector, disminuyendo 6,25 veces la posibilidad de arrepentimiento, esto va muy ligado al hallazgo de una adecuada asesoría en la mayoría de las pacientes que se sometieron a la esterilización. Esta relación sustenta claramente la recomendación mencionada al principio de este manuscrito: la mujer que decide realizarse la esterilización quirúrgica debe estar bien informada acerca de su decisión (9,10, 11), y el médico en este caso es el mejor educador siempre teniendo claro que este papel no debe sobrepasar los límites para evitar adoptar una posición paternalista.

Un hallazgo tan especifico como éste (la influencia del médico) no había sido descrito previamente en la literatura como un factor protector lo cual es un aporte importante del actual estudio y suscita nuevas dudas como por ejemplo saber en qué momento el médico influenció más a la paciente (control prenatal, consulta de planificación o incluso en una sala de partos o servicio de urgencias). Se podría pensar que esta influencia quizá es más fuerte cuando se realiza a lo largo de los controles prenatales, incluso en presencia de la pareja, sin embargo en el estudio actual no se indago en qué momento se presentó dicha influencia, sería interesante poder demostrar si hay o no diferencias en dar esta asesoría en consulta externa (CPN) o en un servicio de urgencias para así contar con herramientas que apoyen

o no la realización de esterilización quirúrgica en el posparto inmediato sin haber sido solicitada anteriormente.

De igual manera tener 44 años o más (al momento de participar en el presente estudio) disminuye 14,28 veces el riesgo de arrepentimiento. Respecto a este factor podemos inferir que la cercanía al final de la vida reproductiva reduce en gran medida el deseo de paridad y por lo tanto la posibilidad de arrepentimiento frente a la esterilización quirúrgica. Por otra parte, se encontró que una asesoría inadecuada, manifestada por la ausencia de información clara sobre la irreversibilidad del procedimiento quirúrgico, actúa como un factor de riesgo para el arrepentimiento, aumentando 6,46 veces la posibilidad de presentarlo. Datos que ya habían sido mencionados por Hardy y col, en 1996 en Brasil, con un estudio de casos y controles en el que compararon 216 mujeres que solicitaron reversión con mujeres que no lo hicieron, encontrando 3,7 veces más riesgo de arrepentimiento entre las pacientes que habían recibido menor información sobre el procedimiento (OR 3,71 IC 2,03-7,25), y 1,69 veces más riesgo en aquellas con poco conocimiento sobre otros métodos anticonceptivos antes de la esterilización (OR 1,69 IC:0,82-3,63) (30). Respecto a la consejería, el estudio de Mooseman encontró que las mujeres que solicitaron la reversión reportaron una baja calidad en la consejería y poco énfasis en el carácter permanente de la esterilización y la alternativa de la vasectomía (24). Más recientemente, en el estudio de Bansal, realizado en India en el 2020 se encontró el doble de posibilidad de arrepentimiento en las mujeres que reportaron mala calidad de la consejería. Se demostró que las pacientes que recibieron buena consejería presentaron 26% menos riesgo de experimentar arrepentimiento (OR 0,74 IC95% 0,71- 0,77); las pacientes que recibieron consejería no tan buena y mala presentaron 1,33 y 2,39 veces más riesgo de arrepentimiento respectivamente (39).

Como parte de los objetivos del estudio se quiso evaluar la relación entre el tiempo de presentación de arrepentimiento y los motivos asociados, se hizo el análisis en el subgrupo de pacientes arrepentidas encontrando que el motivo más prevalente

en las pacientes con arrepentimiento temprano (un año posterior a la cirugía) fueron las complicaciones quirúrgicas, después de dos años de la cirugía lo más frecuente fue la formación de nueva familia con otra pareja al igual que en el grupo de entre tres y cinco años. En el grupo de arrepentimiento tardío (más de cinco años de la cirugía) el principal motivo fue el deseo de tener otro hijo por parte de la participante sumado a la formación de una nueva familia con otra pareja.

Como se ha señalado anteriormente, la medición del arrepentimiento posterior a la esterilización presenta muchos desafíos, por ejemplo, existe incertidumbre acerca de la intensidad del arrepentimiento posesterilización. La presente investigación se enfocó en indagar los factores asociados al arrepentimiento autoinformado, sin embargo, existen diferentes formas de medir el arrepentimiento, las cuales a su vez podrían darnos una idea de la intensidad de dicho sentimiento. Basados en esto y con los hallazgos de este estudio podemos ver que el arrepentimiento autoinformado estuvo presente en el 12,5% de las participantes, la intención de recanalización tubárica, una forma más intensa de arrepentimiento fue del 3,3% en la población evaluada, se debe tener en cuenta que al ser este un procedimiento no incluido dentro de los servicios de salud en Colombia este porcentaje podría estar sesgado, finalmente la última forma de medir el arrepentimiento serían aquellas pacientes que accedieron a la cirugía de recanalización, forma de arrepentimiento que no estuvo presente en la población en mención, pero al igual que la anterior categoría esto se ve muy influenciado por los costos derivados de dicho procedimiento. En resumen, del total de pacientes con arrepentimiento autoinformado (12,5%), solo el 26% accedieron a consulta médica con la intención de una recanalización tubárica y ninguna de ellas hasta el momento de la encuesta había accedido a la cirugía de recanalización, poniendo en evidencia la gran dificultad que implica para las pacientes arrepentidas el tomar acciones que puedan remediar su situación. Estos datos son comparables a los de Wilcox y colaboradores que evidenciaron en el seguimiento de CREST a 5 años que el 6,2% de las pacientes habían solicitado información sobre la reversión y solo un 0,2% habían obtenido la cirugía de reversión (28).

El estudio actual muestra que el arrepentimiento posterior a la esterilización quirúrgica es un fenómeno que continúa presentándose en un porcentaje no despreciable y se seguirá presentando ya que es inherente a la condición humana la posibilidad de arrepentirse de sus decisiones o acciones a lo largo del tiempo. Aunque no fue uno de los objetivos del presente estudio es importante conocer las consecuencias que puede traer este sentimiento a las mujeres, como las descritas por Sefa y cols en el 2005, en población de Estambul, donde demostraron mayores puntajes en la escala de Beck para evaluar depresión en las mujeres jóvenes que se encontraron insatisfechas con el procedimiento de esterilización (32). Del mismo modo Becner y cols en 2015 en Eslovenia, encontraron que el 1,3% de las mujeres sometidas a esterilización quirúrgica presentaban arrepentimiento, adicionalmente estas mujeres tenían puntajes más altos en la escala de depresión (37). Shreffler y cols en el 2016 también encontraron una relación entre síntomas depresivos y arrepentimiento (38). El actual estudio podría dar pie a la realización de investigaciones futuras en lo que respecta a las consecuencias del arrepentimiento en la salud y calidad de vida de las mujeres y sus familias.

14.1. Fortalezas y limitaciones

Dentro de las fortalezas del estudio resalta el hecho de haber indagado el tiempo de presentación del arrepentimiento y si este sentimiento persistía en la actualidad. Esto lo diferencia de estudios previos en los que la pregunta para evaluar el arrepentimiento era si se había sentido arrepentida en algún punto de esta decisión o en estudios mas grandes como el CREST la pregunta ¿piensas que la esterilización quirúrgica como método permanente de planificación fue una buena opción para ti? fue usada para evaluar las pacientes. Como se puede ver en estos estudios se realizó abordaje mas general del tema, además el estudio actual indagó por la calidad de la consejería, con hallazgos relevantes a nivel de este aspecto, siendo esta una variable omitida en CREST (4). En la presente investigación se indagó sobre la persistencia de arrepentimiento, evidenciando que, del total de las pacientes arrepentidas, el 78,1% tenían persistencia de ese sentimiento, mientras

que el 21,9% restante había experimentado el arrepentimiento de manera pasajera. Además, como ya se mencionó es el primero en su tipo realizado en la región nororiental de Colombia y por tanto aporta nuevo conocimiento respecto al arrepentimiento de la esterilización quirúrgica en la mujer.

Dentro de las limitaciones se encuentran que, al tratarse de un estudio transversal, la información suministrada pudiera ser susceptible a sesgos de información por parte de las participantes en aspectos como la recordación de éstas respecto a las condiciones en las cuales se tomó la decisión de realizarse la esterilización quirúrgica, por lo que sugiere apropiar los resultados con cautela. Así mismo, la muestra procede de dos centros clínicos en donde se atiende población en su mayoría de estratos 1 y 2, por lo tanto, al realizar la generalización de estos hallazgos debe tenerse en cuenta estos aspectos.

15. Conclusiones

El arrepentimiento posterior a la esterilización quirúrgica es una complicación poco estudiada e indagada por los médicos en general. En este estudio se encontraron factores protectores y de riesgo que pueden usarse como herramientas claves al momento de brindar la asesoría en planificación familiar. De esta manera se puede influir positivamente en la toma de la decisión mas adecuada para la paciente y su familia.

Los resultados obtenidos en la presente investigación mostraron que un 12,5% de las participantes expresaron haber sentido arrepentimiento posterior a la realización de la esterilización quirúrgica. Los factores de riesgo identificados fueron la consejería deficiente, especialmente la no información sobre la irreversibilidad del procedimiento y los factores protectores fueron la influencia del médico en la toma de la decisión y la edad de 44 años o más (al momento de participar en el estudio).

Con los resultados de este estudio se confirma la necesidad de reforzar la consejería y educación de la paciente en los métodos de planificación familiar,

siendo de mayor importancia dejar claridad en el carácter permanente de la esterilización quirúrgica. Con esto no se piensa motivar la conducta paternalista de algunos médicos que niegan la esterilización a pacientes basados en la posibilidad de arrepentimiento futuro al ser estas pacientes jóvenes o sin hijos, sino por el contrario mejorar la atención brindada a este tipo de pacientes y de esta manera poder garantizar sus derechos sexuales y reproductivos.

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Anexo 1 . Instrumento

Formato de captación de datos de estudio de investigación médica: "Factores asociados al arrepentimiento después de la realización de esterilización quirúrgica en mujeres que asisten a consulta en el instituto de salud de Bucaramanga (ISABU) y la clínica Girón

Consecutivo			

Muchas gracias por participar en el estudio, los datos de la siguiente encuesta van a ser anónimos y será aplicada con el objetivo de conocer la prevalencia y factores asociados al arrepentimiento después de la realización de esterilización quirúrgica femenina.

Lectura y firma del consentimiento informado: Si ____ No _____

Para facilitar su comprensión a continuación hacemos las siguientes definiciones:

El término esterilización quirúrgica femenina hace referencia a: cirugía para no tener hijos, operación para no tener familia, pomeroy, ligadura de trompas.

El término arrepentimiento se refiere a: sentimientos de culpa o no satisfacción en relación a una decisión.

A. DATOS SOCIODEMOGRÁFICOS	
1. Procedencia	
2. Residencia	
3. Edad:	_____ años
4. Seguridad social	Contributivo (__) Subsidiado (__) Vinculado (__) Otro (___) Nombre de EPS o EPS-S _____
5. Estado civil	Soltera (__) Casada (__) Unión libre (__) Divorciada (__) Separada (__) Viuda (__)
6. Nivel académico Elija el nivel y escriba el último año cursado y aprobado	Ninguno ____ Primaria ____ Bachillerato ___ Técnico o tecnólogo ___ Universitario ____ Posgrado___
7. Ocupación	Estudiante ____ Hogar _____ Empleada _____ Independiente___ Desempleada _____
8. Estrato socioeconómico	0(__)1 (__) 2(__) 3(__) 4(__) 5(__) 6(__)

9. Fórmula obstétrica ¿Cuantos de los siguientes ha tenido?	Embarazos ___ Partos vaginales ___ Cesáreas___ Abortos___ Embarazo Ectópico___ Hijos nacidos vivos__ Hijos nacidos muertos ___

B. Respecto al momento en que se realizó la esterilización quirúrgica responda:	
1. ¿Qué edad tenía?	_____ **años**
2. ¿En qué año se realizó el procedimiento?	_____
3. ¿Usó algún método de planificación antes?	Pastillas ___ Inyección ___ DIU ___ Preservativo ___ Barras ___ Ninguno ___
4. ¿Tenía una pareja estable?	Si (____) No (___)
5. ¿En qué momento se realizó la cirugía? Teniendo en cuenta la finalización de su último embarazo (Incluye aborto, hijo vivo o muerto):	Durante la cesárea _____ Dentro de los primeros 45 días _____ Después de 45 días _____
6. Sí se realizó la esterilización quirúrgica en el postparto responda sobre el estado de salud del hijo que tuvo en ese momento	Fue un niño sano ____ Requirió hospitalización ____ Falleció ____
7. ¿Por qué decidió realizarse la cirugía?	Problemas de pareja ___ Tenía los hijos que deseaba ___ Problemas de salud o por indicación médica ____ Por consejo de una tercera persona __ Otro cuál _____
8. ¿Se sintió influenciada por alguien para realizarse la esterilización quirúrgica?	Si (____) No (___) ¿Por quién? Compañero sentimental o pareja _____ Por el médico ____ Otra persona ____
9. Recibió la siguiente información por parte del personal de la salud antes de la realización de la cirugía	a. Le hablaron sobre la irreversibilidad del método SI ____ NO ___ b. Le hablaron sobre las complicaciones y riesgo asociados SI ____ NO ___ c. Le describieron otros métodos de planificación SI ____ NO ___

	C.ACTUALMENTE	
1.	**¿Cuantos hijos vivos tiene?**	Ninguno (_) 1 (_) 2 (_) 3 (__) 4 (_) Más de 4___
2.	**Sexo de los hijos (Escriba el número)**	Niños _____ Niñas_____
3.	**¿En algún momento se ha arrepentido de haberse realizado la esterilización quirúrgica?**	Sí (___) No (___)
4.	**¿Cuál o cuáles son los motivos de su arrepentimiento? Puede marcar uno o más motivos.**	- Formación de una nueva pareja ___ -Porque tiene hijos de un solo sexo ___ -Muerte o desaparición de un hijo ___ -Complicaciones después de la cirugía ___ - Deseo de otro hijo ___ - Mi pareja desea otro hijo ___ - Otra. Cuál:_____ _____
5.	**¿Cuánto tiempo después de realizarse la cirugía experimentó arrepentimiento?**	-Un año ____ -Dos años ___ -3-5 años ___ -Más de 5 años ___
6.	**En estos momentos, ¿Todavía se encuentra arrepentida de su decisión?**	-Si ____ -No ____
7.	**¿Ha consultado para buscar información acerca de revertir la cirugía y así poder tener otro hijo?**	Sí (___) No (___)
8.	**¿Se realizó la cirugía de recanalización tubárica (unir las trompas para tener hijos nuevamente) o se sometió a fertilización in vitro?**	Sí (___) No (___)

¡Gracias!

ANEXO 2.

Consentimiento informado: Factores asociados al arrepentimiento después de la realización de esterilización quirúrgica en mujeres que asisten a consulta en el instituto de salud de Bucaramanga (ISABU) y la clínica Girón

Código Investigación: _____

Usted ha sido invitada a participar del estudio "**Factores asociados al arrepentimiento después de la realización de esterilización quirúrgica en mujeres que asisten a consulta en el instituto de salud de Bucaramanga (ISABU) y la clínica Girón" .**

El objetivo es conocer sí se presenta arrepentimiento después de la realización de cirugía para no tener hijos (pomeroy o ligadura de trompas) y los factores que se relacionan. La recolección de los datos, se hará mediante la realización de una encuesta diligenciada por usted con la posibilidad de resolver las dudas por parte de la persona que le ha dado este documento. Se realizará de manera *voluntaria, privada, anónima, confidencial y sólo con fines investigativos.*

Los resultados de esta encuesta serán socializados manteniendo en reserva sus datos personales de tal forma que no sea posible identificarla. Las preguntas dentro de la encuesta incluyen temas como relación de pareja, pérdida de un hijo, abortos, sentimientos de arrepentimiento, teniendo en cuenta esto, informamos que, si usted cree que estos temas la van a incomodar puede abstenerse de participar.

Los datos recolectados se utilizarán en este proyecto investigativo y en futuras publicaciones sobre el estudio del arrepentimiento después de la cirugía para no tener hijos. Con su participación colaborará en la investigación sobre arrepentimiento después de la cirugía de no tener hijos y con los datos obtenidos se podrá mejorar la educación previa a la realización del procedimiento.

Si usted requiere mayor información acerca del estudio, siéntase en total libertad de preguntar al investigador que le ha suministrado este documento. Recuerde que

puede retirarse del estudio en cualquier momento que lo decida. La no participación en el mismo no interferirá en la atención usual que usted ha venido recibiendo de parte de la institución.

Esperamos que sus respuestas sean lo más *sinceras* posibles para garantizar la credibilidad de los resultados.

Si tiene dudas puede comunicarse con los Investigadores Principales: Marianelly Conde Angarita: mconde2@unab.edu.co, al celular 3164966008, Amanda Mantilla: amantilla12@unab.edu.co , Margarita Navarro: mnavarro53@unab.edu.co

Datos del participante:

Nombre:			
No. Documento		**De:**	
Fecha (día/mes/año)		**Dirección:**	
Teléfono:		**Celular:**	
Firma:			

Firma del testigo Nº 1

_____ Documento de identidad _____

Firma del testigo Nº2

_____ Documento de identidad _____

Firma del investigador

_____ Documento de identidad _____

Bucaramanga, ___ de _____ de 2.0__

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Decision regret up to 6 years after sleeve gastrectomy

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Abstract

Background Sleeve gastrectomy (SG) is one of the most popular types of weight loss surgery today but is neither risk-free nor universally effective. We previously demonstrated that 5% of Roux-en-Y gastric bypass (RYGB) patients and up to 20% of gastric banding patients report overall regret 4 years after surgery. This study explores patients' attitudes toward their decision to have SG and decision regret rates up to 6 years postoperatively.

Methods We surveyed 185 patients who were at least 6 months post-SG (response rate 30%). We used a modified version of the Decision Regret Scale developed by Brehaut et al. We converted responses to a 0–100 scale so that higher scores (> 50) reflect greater regret. We characterized patients who expressed having overall decision regret (score > 50) vs. those who did not (≤ 50). Demographic and preoperative clinical information was extracted from the online medical records.

Results Of 185 SG patients, only 13 (7%) reported regret scores > 50 (i.e. high decision regret). Mean time from SG to survey completion was 41 months (range 6–76 months). Unadjusted comparisons between the two groups revealed that patients with high regret scores had lower mean weight loss (32.1% vs. 48.9% EBMIL), and reported less improvement in quality-of-life (QoL), such as physical health (46.2% vs. 93.5% "somewhat" or "significantly" improved). The two groups were similar in short-term complications, but those reporting overall regret were more likely to report GI complaints such as bloating (61.5% vs. 30.4%). Finally, patients with regret scores > 50 were more likely to be further out from SG (median time since surgery 61.8 vs. 41.1 months).

Conclusion In our study, very few patients reported regret (7%) up to 6 years postoperatively, in line with prior reports after RYGB. Those with regret reported poorer QoL.

Keywords Sleeve gastrectomy · Bariatric surgery · Decision regret · Quality of life · Weight loss

Obesity is a major, growing health problem in the United States (US) and worldwide. Obesity is an independent risk factor for numerous diseases and a substantial cause of morbidity and mortality [1–3]. Fortunately, obesity is preventable and treatable, and bariatric or weight loss surgery (WLS) is the most effective treatment approach for severe obesity [4–6]. One of the most common and popular WLS procedures in the US is laparoscopic sleeve gastrectomy (SG), which accounts for the majority of all WLS performed today. However, SG is invasive and restrictive [7], and comes with its own risks and complications.

Our group previously reported patients' reports of decision regret after Roux-en-Y gastric bypass (RYBG) and gastric banding (GB) [8]. Very few studies, however, have evaluated patient satisfaction and overall regret with regard to the decision to undergo SG [9]. Many factors may lead patients to regret their decision. Although not very common, SG has been associated with both early (deep venous thrombosis/pulmonary thromboembolism, portal vein thrombosis, leak, etc.) [10, 11] and long-term complications, such as nutrient deficiency and gastroesophageal reflux (GERD) [12, 13]. In addition, weight regain [14, 15] and patients' often very different expectations pre-operatively can affect overall satisfaction and regret. Findings also suggest persistent cognitive restraint of food intake may affect their

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long-term experience [16]. Finally, evidence is mixed in terms of whether some patients might develop high-risk alcohol intake behaviors following SG [17–19].

The present study investigates patient-reported perspectives regarding the decision to have SG. In the present study, we explore patients' attitudes toward their decision to have SG among 185 patients that underwent this type of WLS up to 6 years postoperatively.

Materials and methods

Study sample, recruitment, and data collection

We report on this study according to the STROBE 2021 guidelines. We surveyed patients who underwent SG at one academic WLS center in Boston, MA, between January 1, 2016, and December 31, 2021. Patients were identified through the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) registry at Beth Israel Deaconess Medical Center (BIDMC). As an MBSAQIP-accredited center, every metabolic and bariatric procedure (open, laparoscopic, robotic, etc.) performed for the treatment of metabolic or obesity-related diseases at BIDMC is entered into the MBSAQIP Registry. We included only patients that had undergone laparoscopic SG (Current Procedural Terminology-CPT code 43775). All patients were 18 years of age or older at the time of surgery. Patients that had undergone any other type of bariatric procedure (e.g., RYGB, placement of adjustable band, duodenal switch, etc.), as well as revision surgeries were excluded from our study. From a total of 994 eligible patients identified through the MBSAQIP registry, two-thirds (662 patients) were randomly selected for this study. The remaining one-third (332 patients) were selected for a competing study. The decision to only recruit patients to participate in one study or the other was made to maximize response rate, minimize survey fatigue, and achieve optimal utilization of funds available for this study. This randomization process was conducted using a computer-generated random number sequence, where each eligible patient had an equal probability of being selected for inclusion in this study. Eligible, randomly selected patients were mailed a survey packet including the informed consent language, the survey, and a pre-stamped envelope for returning the completed material. Patients who did not return a completed survey within 30 days and did not decline participation were subsequently contacted and given the opportunity to complete the survey via telephone. We attempted to call each patient at least twice. The survey was mailed to the participants in May of 2022. The telephone surveys were conducted between May and July of 2022. Via our survey, we elicited patients' demographics (race, ethnicity, education, marital and work status at the time of the survey), weight, self-reported health status and behaviors at the time of the survey, and quality-of-life (QoL), as well as their perspectives on their WLS. We extracted additional demographics (sex, age), weight, and clinical information at the time of WLS, including comorbidities, from the respondents' medical records. The study was approved by the institutional review board at BIDMC (Protocol #2022P000099).

Measures

Decision regret

In our study, respondents were asked to reflect on their decision to undergo SG. We used a modified version of the Decision Regret Scale developed by Brehaut et al. [20], which had been originally developed to explore decision-making around hormone replacement therapy. The Brehaut scale has been previously shown to be internally consistent and to validate well to correlate strongly with decision satisfaction, decisional conflict, and overall rated QoL [21]. This modified scale had been previously administered by our group (CCW, AF, DJ) to assess decision regret in patients that had undergone RYBG or gastric band and was shown to correlate with change in QoL and weight loss among gastric band patients [8]. Participants were asked how often they thought about whether or not they had made the right decision (often, sometimes, rarely, never). Participants were then asked five items that are used to capture overall decision regret: (1) given their experience of surgery, whether they thought they had made the right decision (definitely yes, probably yes, probably no, definitely no), (2) how much they regretted the choice they made (very much, somewhat, a little, or not at all); (3) if they had to do it over again, how likely they would make the same decision (very likely, somewhat likely, not very likely, or not at all likely); (4) how much had their decision caused negative effects for them (a lot, some, a little, or not at all); (5) how wise they thought their decision had been (very wise, somewhat wise, not very wise, or not wise at all). Items 3 and 5 were reversed coded, and for five items, responses were converted to a 0–100 scale so that higher scores reflect greater regret with the decision they made; these scores were then summed and averaged such that a score of 50 reflected a neutral position and a score greater than 50 reflected greater overall or net decision regret—i.e., those who on average had more responses that indicated regret on the individual items than not.

Demographic and clinical information

We asked about respondents' demographic information, including race (White/Black or African American/Native Hawaiian or Pacific Islander/American Indian or Alaska Native/Asian/more than one race/other), ethnicity (Hispanic

or Latino/not Hispanic or Latino), education (did not complete high school/high school graduate or General Educational Development (GED)/some college—less than a Bachelor's degree/college graduate/professional or graduate degree), and marital status (single, never married/married or partnered, living together/separated or divorced/widowed).

In addition, information about patients' age, sex, weight, height, body mass index (BMI), and comorbidities at the time of their SG were extracted from medical records. Respondents' BMIs at the time of the survey were calculated based on patients' self-reported weight during the interview and measured height from the clinical record.

Health behaviors

We asked participants to reflect on their health behaviors at the time of the survey. Specifically, we asked them to describe their level of physical activity (inactive/low activity/active/very active) and their eating habits (not at all healthy/not very healthy/healthy/very healthy). We also asked them to describe their status regarding smoking (every day/some days/not at all). Lastly, we included the Audit-C questions—How often did you have a drink containing alcohol in the past year? (never/monthly or less/2–4 times a month/2–3 times a week/4 or more times a week), How many drinks containing alcohol did you have on a typical day when you were drinking in the past year? (1 or 2 drinks/3 or 4/5 or 6/7 to 9/10 or more), How often did you have six or more drinks on one occasion in the past year? (never/once/2–5 times/6 or more times)—to elicit participants' alcohol use.

Health status, QoL, postoperative complications

We asked participants to reflect on their current health status, eating habits, and level of physical activity. To assess participants' QoL, we asked participants how seven key QoL domains related to obesity may have changed after surgery (significantly improved, somewhat improved, no change, somewhat worsened, significantly worsened). These domains include physical and emotional health, self-esteem, body image, sexual life, work-life/performance at work, and social life [22]. In addition, we asked patients to report any short- (hemorrhage, leak, wound infection, etc.) or long-term (abdominal pain, nausea/vomiting, bloating, etc.) postoperative complications.

Data analysis

We performed descriptive statistics to characterize the survey respondents. We report continuous variables as means and standard deviations and categorical variables as counts and percentages. Time from surgery to survey completion and decision regret scores are reported as median and quartiles 1 and 3 as this best represents the distribution of these data. We stratified respondents as low decision regret (score ≤ 50) and high decision regret (score > 50) and compared baseline demographics and patient-reported surgical outcomes, complications, and QoL using Pearson's chi-squared tests for categorical variables, and t-tests and Wilcoxon rank sum tests for normally and non-normally distributed data, respectively. In post-hoc analysis at the suggestion of an external reviewer, we dichotomized decision regret as no regret (score $= 0$) and any regret (score > 0). Results of these analyses are presented in the supplement. All analyses were performed using R version 4.2.2 (R Development Core Team, 2022; Vienna, Austria).

Results

Sample characteristics

Of the 662 patients who were selected to participate in this study, 34 could not be contacted due to lack of updated contact information, and 5 had passed away. Of the remaining 623, 22 actively declined participation, and 310 were unreachable; 185 completed the survey, 68 by mail and 117 by phone, representing a response rate of 30%. Supplement Table 1 presents the demographics and comorbidities of the non-respondents. Compared to respondents, non-respondents were slightly younger (43 [standard deviation (SD) 11.3] vs 45.3 [SD 11.3], $p = 0.02$) and were less likely to have baseline GERD (35% vs 46%, $p = 0.01$) and renal insufficiency (3.2% vs. 7%, $p = 0.05$) (Supplement Table 1).

Table 1 presents respondents' demographic and clinical characteristics at the time of surgery as well as participant educational, marital, and employment status at the time of the survey. The majority of participants were White and female. The mean age was 45.3 years. The mean weight preoperatively was 275.4 lbs with a mean BMI of 44.8 kg/m^2. Hypertension, obstructive sleep apnea, and GERD were the most common baseline comorbidities overall. A majority of respondents described an active life and healthy eating habits at the time of the survey (Table 2).

Decision regret after sleeve gastrectomy

Table 3 presents the patient's perspective on their decision to undergo SG. A quarter (25.4%) reported thinking about whether or not they made the right decision often (Table 3). Among the respondents, up to one-third reported experiencing negative effects after the gastrectomy. In contrast, more than 90% of the patients responded that they "definitely" or "probably" made the right decision, and 80% did not regret this decision "at all." Consistently, the

Table 1 Respondent characteristics overall and stratified by decision regret scores

	Overall $n=185$	Low decision regret[a] $n=172$	High decision regret[a] $n=13$	p value
At time of surgery				
Age, years, mean (SD)	45.3 (11.3)	44.9 (11.4)	50.4 (8.7)	0.09
Sex, female, *n* (%)	144 (77.8)	131 (76.2)	13 (100)	0.10
Race, *n* (%)				0.98
White	109 (58.9)	101 (58.7)	8 (61.5)	
Black or African American	60 (32.4)	56 (32.6)	4 (30.8)	
Asian/more than one race/other or unknown	16 (8.6)	15 (8.1)	1 (0.5)	
Ethnicity, non-Hispanic, *n* (%)[b]				0.75
Hispanic or Latino	38 (20.5)	36 (20.9)	2 (15.4)	
Non-Hispanic or Latino	143 (77.3)	132 (76.7)	11 (84.6)	
BMI at SG, kg/m^2, mean (SD)	44.8 (6.6)	44.9 (6.5)	44.5 (8.7)	0.85
Comorbidities, *n* (%)				
Hypertension	102 (55.1)	94 (54.7)	8 (61.5)	0.85
Obstructive sleep apnea	88 (47.6)	81 (47.1)	7 (53.8)	0.86
GERD	85 (45.9)	81 (47.1)	4 (30.8)	0.40
Depression/anxiety disorder/other mental health disorders	81 (43.8)	73 (42.4)	8 (61.5)	0.29
Hyperlipidemia	75 (40.5)	68 (39.5)	7 (53.8)	0.47
Osteoarthritis	63 (34.1)	56 (32.6)	7 (53.8)	> 0.99
Chronic pulmonary disease	55 (29.7)	51 (29.7)	4 (30.8)	> 0.99
Congestive heart failure/peripheral vascular disease/cerebrovascular disease/myocardial infarction	36 (19.5)	32 (18.6)	4 (30.8)	0.48
Diabetes				0.79
Yes, no complication	39 (21.1)	36 (20.9)	3 (23.1)	
Yes, with complications	6 (3.2)	6 (3.5)	0 (0.0)	
Chronic back pain	35 (18.9)	33 (19.2)	2 (15.4)	> 0.99
Venous stasis	25 (13.5)	24 (14.0)	1 (7.7)	0.83
Liver disease	14 (7.6)	13 (7.6)	1 (7.7)	> 0.99
History of malignancy/leukemia/lymphoma	14 (7.6)	14 (8.1)	0 (0.0)	0.60
Renal insufficiency	13 (7.0)	12 (7.0)	1 (7.7)	> 0.99
Rheumatologic disease	9 (4.9)	7 (4.1)	2 (15.4)	0.25
Peptic ulcer disease	7 (3.8)	7 (4.1)	0 (0.0)	> 0.99
Immunosuppressive therapy	6 (3.2)	4 (2.3)	2 (15.4)	0.08
HIV/AIDS	2 (1.1)	2 (1.2)	0 (0.0)	> 0.99
At time of interview/survey				
Time from surgery to survey, months, median ($q1$–$q3$)	42.2 (27.3–58.0)	41.1 (23.4–56.9)	61.8 (42.6–69.5)	0.01
Highest education, *n* (%)[b]				0.77
High school diploma, GED, or less	26 (14.1)	23 (13.4)	3 (23.1)	
Some college	56 (30.3)	52 (30.2)	4 (30.8)	
4-Year college diploma or more	101 (54.6)	95 (55.2)	6 (46.2)	
Current marital status[b]				0.55
Single, never married	50 (27.0)	48 (27.9)	2 (15.4)	
Married/partnered, living together	102 (55.1)	95 (55.2)	7 (53.8)	
Separated/divorced	29 (15.7)	25 (14.5)	4 (30.8)	
Widowed	2 (1.1)	2 (1.2)	0 (0.0)	
Current work status[b]				0.01
Part-time (< 30 h/week)	21 (11.4)	16 (9.3)	5 (38.5)	
Full-time (≥ 30 h/week)	127 (68.6)	120 (69.8)	7 (53.8)	
Not working	34 (18.4)	33 (19.2)	1 (7.7)	

Age, BMI, sex, and comorbidities at the time of surgery were extracted from the MBSAQIP database and the patients' online medical records. Data regarding race, ethnicity, education, and marital and work status are patient-reported and were collected at the time of the survey/interview

BMI body mass index, *SG* sleeve gastrectomy, *GED* general educational development, *GERD* gastroesophageal reflux disease, *HIV* human immunodeficiency virus, *AIDS* acquired immunodeficiency syndrome

[a]High regret scores: regret scores > 50, low regret scores: regret scores ≤ 50

Table 1 (continued)

[b]Percentages do not add up to 100 due to missing data. Four participants did not report their ethnicity. Two participants did not report their highest education. Two participants did not report their marital status. Three participants did not report their work status

Table 2 Health behaviors of respondents at the time of the survey overall and stratified by decision regret scores

	Overall $n=185$	Low decision regret[a] $n=172$	High decision regret[a] $n=13$	p value
On average, how would you describe your level of physical activity?[b]				0.008
Inactive	13 (7.0)	10 (5.8)	3 (23.1)	
Low activity	65 (35.1)	57 (33.1)	8 (61.5)	
Active	70 (37.8)	69 (40.1)	1 (7.7)	
Very active	34 (18.4)	33 (19.2)	1 (7.7)	
On average, how would you describe your eating habits?[b]				< 0.001
Not at all healthy	5 (2.7)	4 (2.3)	1 (7.7)	
Not very healthy	30 (16.2)	22 (12.8)	8 (61.5)	
Healthy	128 (69.2)	126 (73.3)	2 (15.4)	
Very healthy	15 (8.1)	15 (8.7)	0 (0)	
Current smoking status[b]				0.76
Every day	5 (2.7)	5 (2.9)	0 (0)	
Some days	2 (1.1)	2 (1.2)	0 (0)	
Not at all	176 (95.1)	163 (94.8)	13 (100)	
Audit-C score,[b] *median* ($q1$–$q3$)	1 (0–2)	1 (0–2)	1 (1–2.2)	0.64
Misuse, *n* (%)	19 (10.3)	19 (11.0)	0 (0)	

Data regarding health behaviors are patient-reported and were collected at the time of the survey/interview

[a]High regret scores: regret scores > 50, low regret scores: regret scores ≤ 50

[b]Percentages do not add up to 100 due to missing data. Three participants did not complete level of physical activity question. Seven participants did not complete eating habits question. Two participants did not complete smoking status question. Five participants did not complete the Audit-C questionnaire

majority of respondents reported that they would be "very likely" to make the same decision over again and thought of their decision as wise.

The median overall regret score was 0 (IQR 0, 17.5) and a mean regret score 13.4 (SD 19.9). The distribution of decision regret scores is presented in Fig. 1. Overall, only 13 patients (7%) across the 6 years scored more than 50 on the decision regret scale indicating net overall regret (they responded more negatively than neutral on more than half of the items comprising the regret score); Tables 1 and 2 present unadjusted differences between having high (net) overall decision regret vs lower regret across participant characteristics.

Compared to patients reporting a decision regret score of less than 50, those reporting a higher regret score were more likely to be further out from SG. Among patients expressing low regret (regret score ≤ 50), the median time was 41.1 months (IQR 23.4, 56.9), whereas among patients with high decision regret (regret score > 50), the median time since surgery was 61.8 months (IQR 42.6, 69.5).

Surgical outcomes and complications and decision regret

The mean weight was 217.5 lbs postoperatively; participants lost a mean of 20.4% of total body weight (Table 2). The mean change in BMI was − 9.3 (Excess BMI Loss = 47.8%). Table 4 presents patients' self-reported surgical outcomes and complications. Patients who reported high regret had a lower mean change in BMI than those who reported low regret. Almost half of all patients reported experiencing late complications from their surgery, most commonly bloating, nausea/vomiting, constipation, and GERD.

Patient-reported health status at the time of the survey, the QoL-related outcomes, and gastrointestinal (GI) side-effects complications on patients' everyday lives are summarized in Table 5. Overall, the majority of patients reported improved physical and emotional health, self-esteem, and body image with greater overall improvement in QoL being associated with lower decision regret. The majority of patients also

Table 3 Respondent perspective on decision to undergo sleeve gastrectomy (SG)

	Overall *n* (%)
How often do you think about whether or not you made the right decision? Do you think about it…[a]	
Often	47 (25.4)
Sometimes	40 (21.6)
Rarely	29 (15.7)
Never	69 (37.3)
Five items included in decision regret score	
1. Given your experience and what you now know about surgery, would you say you made the right decision?	
Definitely yes	138 (74.6)
Probably yes	35 (18.9)
Probably no	10 (5.4)
Definitely no	1 (0.5)
Missing	1 (0.5)
2. How much would you say you regret the choice you made? Would you say you regret it…	
Very much	3 (1.6)
Somewhat	10 (5.4)
A little	25 (13.5)
Not at all	147 (9.5)
3. If you had to do it over again, how likely would you be to make the same decision? Would you say…	
Very likely	152 (82.2)
Somewhat likely	20 (10.8)
Not very likely	7 (3.8)
Not at all likely	4 (2.2)
Missing	2 (1.1)
4. How much has your decision to have weight loss surgery caused negative effects for you?	
A lot	3 (1.6)
Some	18 (9.7)
A little	40 (21.6)
Not at all	124 (7.0)
5. How wise do you think your decision has been?	
Very wise	145 (78.4)
Somewhat wise	36 (19.5)
Not very wise	4 (2.2)
Not wise at all	0 (0.0)
Decision regret score, median ($q1$–$q3$)	0 (0.0–17.5)

SG sleeve gastrectomy

[a]Not included in decision regret score

reported no impact of their GI side effects on aspects of their everyday life, including eating and drinking or working.

Post-hoc analysis

Of respondents, 88 (47.6%) had decision regret scores above 0 indicating that they gave less than the most positive responses to at least one of the 5 items that comprised the decision regret score. Post-hoc analyses comparing respondent characteristics and post-surgical outcomes between those with a score of 0 (most positive response to all 5 items) and those with scores above 0 are presented in Supplemental Tables 2, 3, 4 and 5.

Discussion

In our study of 185 patients who underwent SG, approximately 7% expressed net overall regret up to 6 years after surgery. The majority of patients reported improvement in the key QoL of physical and emotional health, including self-esteem and body image, and sexual, work, and social function. More than 30% reported experiencing negative

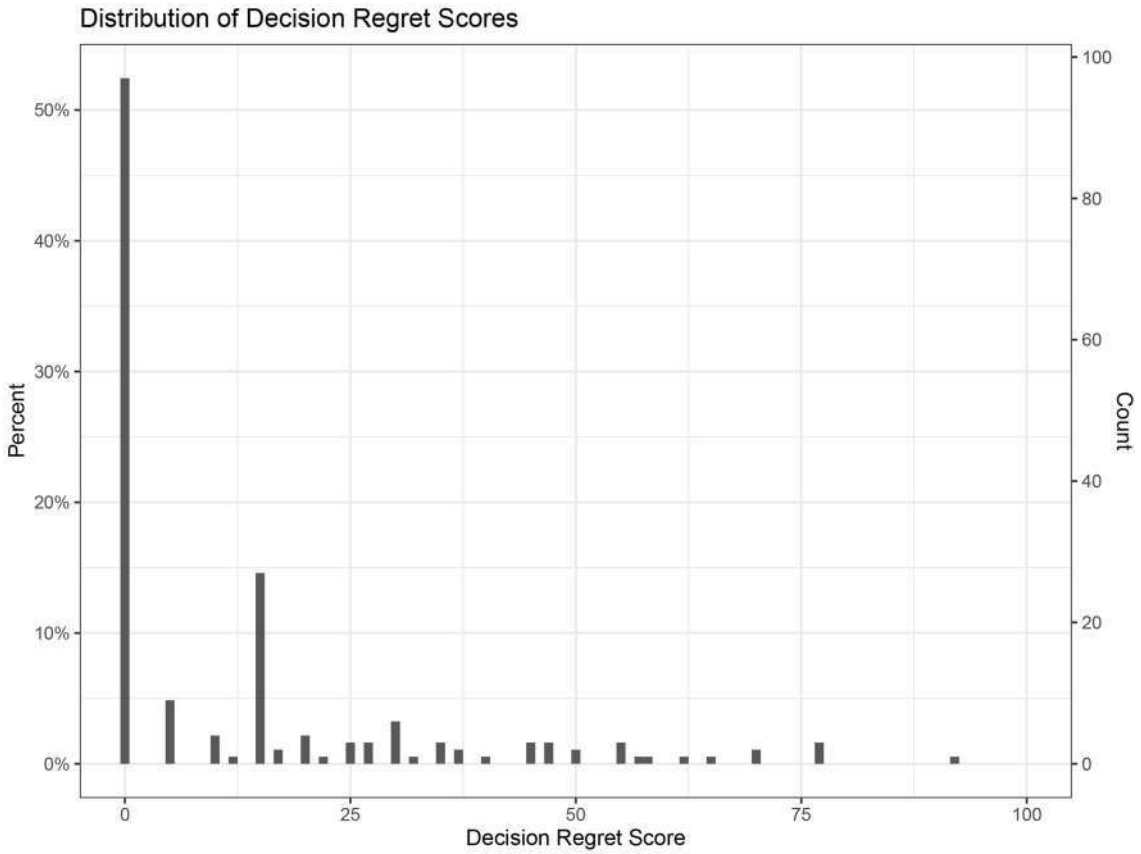

Fig. 1 Distribution of decision regret scores

short- or long-term GI effects after the SG. Patients with higher (net) regret scores (> 50) were more likely to be further out from SG, to have smaller improvements in weight loss and QoL, and to report some GI side effects although the latter findings were not statistically significant.

Turrentine et al. [23] reported high satisfaction in as much as 99% of all 155 RYGB patients that participated in their study. Our group has also previously explored decision regret in patients following RYGB and GB [8]. In our earlier study, no more than 5% of 205 patients who underwent RYGB expressed net decision regret at any time point in the up to 4 years of follow-up. In contrast, up to 20% of 188 patients who underwent gastric band scored greater than 50 on the overall decision regret scale. In another study, Bartosiak et al. explored decision regret among 104 SG patients up to 5 years after surgery, with 7% of respondents reporting high decision regret [9]. Our findings of low prevalence of overall regret with SG is consistent with earlier related research on RYGB and SG.

Our results are also in accordance with earlier studies suggesting a correlation between greater improvement in QoL and greater satisfaction with decisions to undergo bariatric surgery. Turrentine's [23] and our earlier study on RYBG and SG [8] showed an association between the level of improvement in QoL scores and overall satisfaction after WLS. In contrast, Arman et al. [13] followed up with 65 SG patients for up to 11 years post-operatively and reported that 83% of the patients were "pleased" or "extremely pleased" with their surgery in the long term, despite developing complications such as GERD. More recently, Bartosiak et al. [24] studied the effects of significant postoperative complications on 90 patients' decision regret after laparoscopic SG which found that patients who experienced postoperative complications did not report higher regret compared to patients with an uneventful postoperative recovery. Furthermore, a different study exploring the impact of gastric leaks after SG also concluded that despite the morbidity associated with them, satisfaction rates were similar between patients who experienced this type of complication and patients who didn't [25]. Our findings suggest a higher percentage of those with net overall regret also reported GI complications, although these associations did not reach significance. Given that many substantive complications are uncommon and most studies are small and underpowered to detect small but clinically meaningful differences in the complication between those with greater vs. lesser regret, the lack of definitive findings

Table 4 Respondent-reported surgical outcomes and complications overall, and stratified by high vs. low regret scores

	Overall $n=185$	Low decision regret[a] $n=172$	High decision regret[a] $n=13$	p value
ΔBMI, mean (SD)[b]	9.3 (6.0)	9.5 (6.0)	5.7 (4.3)	0.03
%EBMIL, mean (SD)[b]	47.8 (26.2)	48.9 (26.3)	32.1 (20.0)	
%TBWL, mean (SD)[b]	20.4 (11.6)	20.9 (11.6)	13.2 (9.2)	
Postoperative complications (patient-reported)				
Gastrointestinal bleeding	2 (1.1)	2 (1.2)	0 (0)	> 0.99
Blood clot	1 (0.5)	1 (0.6)	0 (0)	> 0.99
Wound infection	4 (2.2)	4 (2.3)	0 (0)	> 0.99
Other complications or side effects	39 (21.1)	36 (20.9)	3 (23.1)	> 0.99
Hospitalization(s) or ED visit(s) associated with weight loss surgery, n(%)	26 (14.1)	25 (14.6)	1 (7.7)	0.78
Additional surgery associated with weight loss surgery, n(%)	2 (1.1)	2 (1.2)	0 (0)	> 0.99
Are you currently experiencing any of the following problems?				
Nausea and vomiting	30 (16.4)	25 (14.7)	5 (38.5)	0.07
Abdominal pain	27 (14.8)	24 (14.1)	3 (25.0)	0.55
Diarrhea	18 (9.9)	16 (9.4)	2 (16.7)	0.75
Bloating/gassiness	60 (32.6)	52 (30.4)	8 (61.5)	0.05
Other stomach, intestinal, or bowel problems	36 (20.0)	29 (17.4)	7 (53.8)	0.005

ΔBMI change of body mass index, *EBMIL* excess body mass index loss, *%TBWL* excess body mass index loss, *ED* emergency department

[a]High regret scores: regret scores > 50, Low regret scores: regret scores ≤ 50

[b]Three participants missing BMI at survey

between post-complications and decision regret should be interpreted with caution.

Previous research has also identified a temporal association with weight regain and decision regret [26]. In our study, patients with low regret scores had greater mean reductions in BMI than those with high regret scores. A review by Parretti et al. [27] concluded that bariatric patients may benefit from longer, high-quality, multidisciplinary follow-up care because of their complex care needs. However, they also found that attendance to follow-up care can be quite low due to both patient- and healthcare-provider-related factors and that low attendance is associated with poorer outcomes and more difficulty adhering to lifestyle and dietary advice. These findings might help explain our results suggesting that patients with higher regret scores (> 50) were more likely to be further from SG. Future studies will need to identify more effective interventions to mitigate this recidivism.

Limitations

Our findings should be interpreted in the context of the study's limitations. First, response bias may have influenced the findings due to the self-report nature of much of our data collection. While we tried to mitigate this by ensuring confidentiality, participants may still be influenced by social desirability, particularly regarding sensitive topics such as regret. Another limitation pertains to the challenges inherent in measuring decision regret, which is complex and subjective and influenced by many factors, including individual perceptions, expectations, and life circumstances. Our focus on those with a decision score of over 50 is also a subjective decision and reflects our interest in understanding what proportion expressed a net response that exceeded an average neutral response on included items. Our reliance on self-reported measures of regret may not capture this emotion's full complexity and nuances. For those interested and at the request of an external reviewer, we also reported on patients who reported score above zero (or perfectly optimal responses) which were not originally pre-specified and should be interpreted with care given the risk of multiple testing and false discovery. As with many patient surveys, our response rate was lower than ideal, and coupled with the small sample from a single institution, our results may not be generalizable. Prior evidence suggests those at the extremes of healthcare (the most satisfied and the most dissatisfied) are more likely to participate in such surveys [28, 29]. Our small sample size precludes our examining correlates of decision regret in a robust and definitive way as we are unable to adjust for multiple confounders in a multivariable model. We are also underpowered to detect even fairly large differences across factors, and risk false discovery where statistically significant findings may have emerged via chance alone. Finally, our observational study design can only suggest associations and cannot prove causality.

Table 5 Respondent-reported responses to QoL-related questions in the overall sample and stratified by high vs. low decision regret scores

	Overall $n=185$	Low decision regret[a] $n=172$	High decision regret[a] $n=13$	p value
General health status				
In general, would you say your health is…				0.031
Excellent	29 (15.7)	28 (16.3)	1 (7.7)	
Very good	54 (29.2)	53 (30.8)	1 (7.7)	
Good	77 (41.6)	71 (41.3)	6 (46.2)	
Fair	21 (11.4)	17 (9.9)	4 (30.8)	
Poor	3 (1.6)	2 (1.2)	1 (7.7)	
Missing	1 (0.5)	1 (0.6)	0 (0)	
Change in overall health and QoL				
Your overall physical health has…				< 0.001
Significantly improved	108 (58.4)	108 (62.8)	0 (0.0)	
Somewhat improved	57 (30.8)	51 (29.7)	6 (46.2)	
No change	10 (5.4)	8 (4.7)	2 (15.4)	
Somewhat worsened	7 (3.8)	2 (1.2)	5 (38.5)	
Significantly worsened	1 (0.5)	1 (0.6)	0 (0.0)	
Missing	2 (1.1)	2 (1.2)	0 (0)	
Your overall emotional health has				< 0.001
Significantly improved	84 (45.4)	84 (48.8)	0 (0.0)	
Somewhat improved	55 (29.7)	51 (29.7)	4 (30.8)	
No change	31 (16.8)	24 (14.0)	7 (53.8)	
Somewhat worsened	11 (5.9)	9 (5.2)	2 (15.4)	
Significantly worsened	0 (0.0)	0 (0.0)	0 (0.0)	
Missing	4 (2.2)	4 (2.3)	0 (0)	
Your self-esteem has…				< 0.001
Significantly improved	87 (47.0)	87 (50.6)	0 (0.0)	
Somewhat improved	54 (29.2)	51 (29.7)	3 (23.1)	
No change	33 (17.8)	24 (14.0)	9 (69.2)	
Somewhat worsened	8 (4.3)	7 (4.1)	1 (7.7)	
Significantly worsened	1 (0.5)	1 (0.6)	0 (0.0)	
Missing	2 (1.1)	2 (1.2)	0 (0)	
Your body image has…				< 0.001
Significantly improved	69 (37.3)	69 (40.1)	0 (0.0)	
Somewhat improved	74 (40.0)	69 (40.1)	5 (38.5)	
No change	33 (17.8)	28 (16.3)	5 (38.5)	
Somewhat worsened	5 (2.7)	3 (1.7)	2 (15.4)	
Significantly worsened	1 (0.5)	0 (0)	1 (7.7)	
Missing	3 (1.6)	3 (1.7)	0 (0)	
Your sexual life has				< 0.001
Significantly improved	36 (19.5)	36 (20.9)	0 (0.0)	
Somewhat improved	42 (22.7)	41 (23.8)	1 (7.7)	
No change	86 (46.5)	78 (45.3)	8 (61.5)	
Somewhat worsened	7 (3.8)	5 (2.9)	2 (15.4)	
Significantly worsened	2 (1.1)	0 (0.0)	2 (15.4)	
Missing	12 (6.5)	7 (7.0)	0 (0)	
Your work life/performance has				< 0.001
Significantly improved	55 (29.7)	55 (32.0)	0 (0.0)	
Somewhat improved	35 (18.9)	34 (19.8)	1 (7.7)	
No change	82 (45.9)	72 (41.9)	10 (76.9)	
Somewhat worsened	2 (1.1)	1 (0.6)	1 (7.7)	

Table 5 (continued)

	Overall $n=185$	Low decision regret[a] $n=172$	High decision regret[a] $n=13$	p value
Significantly worsened	1 (0.6)	0 (0.0)	1 (7.7)	
Missing	10 (5.4)	10 (5.8)	0 (0)	
Your social life has				0.001
Significantly improved	50 (27.0)	50 (29.6)	0 (0.0)	
Somewhat improved	44 (23.8)	44 (26.0)	0 (0.0)	
No change	85 (45.9)	73 (43.2)	12 (92.3)	
Somewhat worsened	3 (1.6)	2 (1.2)	1 (7.7)	
Significantly worsened	0 (0.0)	0 (0.0)	0 (0.0)	
Missing	3 (1.6)	3 (1.7)	0 (0)	
Impact of GI side-effects				
In the past 2 weeks, how much have your stomach, intestinal, or bowel problems affected the following:				
Your general emotional well-being…				0.001
A lot	7 (3.8)	4 (2.3)	3 (23.1)	
Some	16 (8.6)	14 (8.1)	2 (15.4)	
A little	19 (10.3)	17 (9.9)	2 (15.4)	
Not at all	141 (76.2)	135 (78.5)	6 (46.2)	
Missing	2 (1.1)	2 (1.2)	0 (0)	
Being irritable, tense, or frustrated…				0.05
A lot	7 (3.8)	5 (2.9)	2 (15.4)	
Some	12 (6.5)	10 (5.8)	2 (15.4)	
A little	22 (11.9)	20 (11.6)	2 (15.4)	
Not at all	142 (76.8)	135 (78.5)	7 (53.8)	
Missing	2 (1.1)	2 (1.2)	0 (0)	
Your ability to study or do work…				0.16
A lot	4 (2.2)	3 (1.7)	1 (7.7)	
Some	6 (3.2)	6 (3.5)	0 (0.0)	
A little	10 (5.4)	8 (4.7)	2 (15.4)	
Not at all	163 (88.1)	153 (89.0)	10 (76.9)	
Missing	2 (1.1)	2 (1.2)	0 (0)	
Your ability to enjoy your work or study…				0.15
A lot	3 (1.6)	2 (1.2)	1 (7.7)	
Some	4 (2.2)	4 (2.3)	0 (0.0)	
A little	12 (6.5)	10 (5.8)	2 (15.4)	
Not at all	162 (87.6)	152 (88.4)	10 (76.9)	
Missing	4 (2.2)	4 (2.3)	0 (0)	
Your ability to eat and drink…				0.05
A lot	18 (9.7)	15 (8.7)	3 (23.1)	
Some	15 (8.1)	12 (7.0)	3 (23.1)	
A little	26 (14.1)	24 (14.0)	2 (15.4)	
Not at all	123 (66.5)	118 (68.6)	5 (38.5)	
Missing	3 (1.6)	3 (1.7)	0 (0)	
Your enjoyment of eating and drinking…				0.09
A lot	16 (8.6)	13 (7.6)	3 (23.1)	
Some	20 (10.8)	18 (10.5)	2 (15.4)	
A little	23 (12.4)	20 (11.6)	3 (23.1)	
Not at all	124 (67.0)	119 (69.2)	5 (38.5)	
Missing	2 (1.1)	2 (1.2)	0 (0)	
Your ability to do things you usually do for fun (such as going out, doing hobbies, playing sports, etc.)…				0.76

Table 5 (continued)

	Overall $n=185$	Low decision regret[a] $n=172$	High decision regret[a] $n=13$	p value
A lot	3 (1.6)	3 (1.7)	0 (0.0)	
Some	7 (3.8)	6 (3.5)	1 (7.7)	
A little	8 (4.3)	7 (4.1)	1 (7.7)	
Not at all	164 (88.6)	153 (89.0)	11 (84.6)	
Missing	3 (1.6)	3 (1.7)	0 (0)	
Your ability to enjoy the things you usually do for fun above…				0.69
A lot	3 (1.6)	3 (1.7)	0 (0.0)	
Some	6 (3.2)	5 (2.9)	1 (7.7)	
A little	8 (4.3)	7 (4.1)	1 (7.7)	
Not at all	165 (89.2)	154 (89.5)	11 (84.6)	
Missing	3 (1.6)	3 (1.7)	0 (0)	
Wondered whether you will always have these stomach issues…				0.18
A lot	14 (7.6)	11 (6.4)	3 (23.1)	
Some	19 (10.3)	18 (10.5)	1 (7.7)	
A little	26 (14.1)	24 (14.0)	2 (15.4)	
Not at all	124 (67.0)	117 (68.0)	7 (53.8)	
Missing	2 (1.1)	2 (1.2)	0 (0)	
Thought these stomach problems may be due to a very serious illness (such as cancer or heart problem, etc.)…				0.14
A lot	4 (2.2)	3 (1.7)	1 (7.7)	
Some	3 (1.6)	3 (1.7)	0 (0.0)	
A little	9 (4.9)	7 (4.1)	2 (15.4)	
Not at all	166 (89.7)	156 (90.7)	10 (76.9)	
Missing	3 (1.6)	3 (1.7)	0 (0)	

QoL quality-of-life, *GI* gastrointestinal

[a]High regret scores: regret scores > 50, Low regret scores: regret scores ≤ 50

Given these limitations, the findings should be interpreted as exploratory and should be confirmed by larger future studies. In particular, we caution against over-interpreting isolated results or the overemphasis on p-values but rather results should be interpreted based on the consistency of results within the study and relative to prior work.

Conclusions

In summary, our study suggests relatively few patients report net overall regret after undergoing sleeve gastrectomy with those with worse weight loss and QOL improvements more likely to report regret. While further research is necessary, our study suggests the need for more patient-centered research related to WLS and the importance of understanding the patient's perspective in evaluating the postoperative course and outcome.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00464-023-10364-8.

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Declarations

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Ethical approval The study was approved by the IRB at BIDMC.

Informed consent Informed consent was obtained from all individual participants included in the study.

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GINECOMASTIA. CARACTERÍSTICAS CLÍNICAS Y TRATAMIENTO EN LA PUBERTAD

GYNECOMASTY. CLINICAL CHARACTERISTICS AND TREATMENT IN PUBERTY

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RESUMEN:

La ginecomastia es la enfermedad que se caracteriza por el aumento no tumoral de tejido glandular mamario en el varón. Puede aparecer desde la etapa neonatal hasta en el adulto mayor. Esta afección tiene características específicas y responde a diversas causas. El grado de ginecomastia es variable y abarca desde la presencia de un botón subareolar hasta el

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desarrollo de una mama con características similares a la de una mujer en la edad adulta. Es causa frecuente de consulta médica durante la niñez y más frecuente en la pubertad. El diagnóstico se realiza por lo general mediante examen físico de la región anterior del tórax a nivel de las mamilas. La ginecomastia puberal puede coincidir con múltiples afecciones y, además de ser una afección física, puede ocasionar trastornos psicológicos en los adolescentes que la presentan; es por este motivo que se debe tener especial cuidado del paciente durante el período puberal.

PALABRAS CLAVE: ginecomastia, adolescente, testosterona, mastectomía

ABSTRACT

Gynecomastia is the disease characterized by the non-tumorous increase in mammary glandular tissue in men. It can appear from the neonatal stage to the elderly. This condition has specific characteristics and responds to various causes. The degree of gynecomastia is variable and ranges from the presence of a subareolar button to the development of a breast with characteristics similar to those of an adult woman. It is a frequent cause of medical consultation during childhood and more frequent in puberty. Diagnosis is usually made by physical examination of the anterior region of the chest at the level of the nipples. Pubertal gynecomastia can coincide with multiple conditions and besides being a physical condition, it can cause psychological disorders in adolescents who present it; it is for this reason that special care of the patient must be taken during the pubertal period.

KEY WORDS: gynecomastia, teen, testosterone, mastectomy

INTRODUCCIÓN

La ginecomastia es una afección de origen benigno que consiste en la proliferación del tejido glandular mamario en el varón y depósito excesivo de tejido adiposo, puede ser

unilateral o bilateral, concéntrica o no al pezón y la areola. La ginecomastia puberal es un motivo muy frecuente de atención en consultas médicas de pacientes adolescentes. Puede desencadenar trastornos psicológicos y emocionales en la pubertad que requieren tratamiento (Araujo Herrera, 2014).

La enfermedad es más frecuente en pacientes masculinos entre los 13 y 14 años de edad, la padecen alrededor de 50% de los púberes. Se ha demostrado en diferentes investigaciones realizadas al respecto que en un 95% de los casos involuciona espontáneamente sin tratamiento. El límite fisiológico de evolución considerado en la ginecomastia es de 24 meses o hasta que el paciente cumple la edad de 17 años (Hayes Dorado, 2013).

En esta enfermedad histológicamente existe una proliferación ductal en un estroma de tejido fibroso. Con el tiempo el tejido tiende a ser más denso y fibrótico, pero benigno. El tratamiento varía en dependencia de la edad del paciente y el grado de la misma, de modo que requiere observación y seguimiento médico. Si bien involuciona espontáneamente en algunos casos, en otros requiere tratamiento medicamentoso y/o quirúrgico (Barros& Sampaio, 2012).

DESARROLLO

La etiología de la ginecomastia es multifactorial. Entre los principales factores se citan el hipogonadismo, donde existe la disminución o ausencia en la producción de testosterona que ocasiona incremento de hormona luteinizante (LH) y se eleva la secreción de estradiol por las células de Leydig (Jiménez Almaguer et al, 2020).

En la hiperprolactinemia, en la cual la prolactina estimula directamente el crecimiento de la mama masculina, causa hipogonadismo secundario y altera la relación andrógeno/estrógeno, ya que la cantidad de receptores androgénicos disminuyen y, por consiguiente, aumentan los receptores de estrógenos. Puede estar determinada por

desbalances estrógeno/testosterona que ocurren en pacientes que consumen medicamentos como Espironolactona, Cimetidina, Omeprazol, Ketoconazol e Imatinib (Barros & Sampaio, 2012).

También esta enfermedad puede aparecer por la exposición de los pacientes a químicos con cierta actividad agonista estrogénica como son las radiaciones, pesticidas, contaminantes ambientales, combustibles, hidrocarburos aromáticos policíclicos, entre otros; así como en enfermedades que cursan con malnutrición, en las cuales existe una disminución en la degradación de estrógenos. Existen otras causas pero menos frecuentes (Barros & Sampaio, 2012).

En relación con el tamaño o extensión de la ginecomastia, Hung Huang y colaboradores (2016) citan la clasificación que las divide en cuatro grados:

- Grado I: Cuando existe aumento del diámetro y protrusión leve limitada a la región areolar.
- Grado II: Hipertrofia moderada con el complejo areola-pezón sobre el pliegue inframamario.
- Grado III: Existe mayor hipertrofia mamaria, ptosis glandular y complejo areola-pezón a la misma altura o hasta 1 cm bajo el pliegue inframamario.
- Grado IV: Mayor hipertrofia mamaria, con redundancia severa de la piel, ptosis severa y complejo areola-pezón más de 1cm bajo el pliegue inframamario.

El tratamiento de la ginecomastia puberal varía en dependencia de la edad del paciente y el grado de la misma, en algunos pacientes se indica observación y seguimiento médico conservador por un período entre 3-6 meses, pues por lo general esta suele involucionar espontáneamente (Barrantes Rodríguez, 2016).

Si se trata de un adolecente con sobrepeso u obeso, se debe indicar una dieta baja en calorías y carbohidratos y ejercicios físicos como primera línea de tratamiento, ya que el volumen de la mama puede estar muy aumentado por la proliferación de tejido graso en

estos pacientes; además, debe suspenderse cualquier droga o medicamentos que pudieran ser la causa de ginecomastia (Nuñez et al., 2010).

Unido al tratamiento médico es importante explicar al paciente y su familia que esta es una enfermedad que no genera consecuencias en relación a la virilidad o fertilidad del varón y que se trata de una afección de etiología benigna en la cual no existe la posibilidad de malignización (Ruiz et al., 2013).

Es preciso orientar muy bien, tener en cuenta y tratar los trastornos emocionales que pueden estar presentes como sentimientos de inferioridad, baja autoestima, miedo y ansiedad en los pacientes jóvenes. Algunos casos requieren tratamiento medicamentoso con andrógenos como Testosterona, terapia sustitutiva en los hipogonadismos de corta evolución pero no se han obtenido resultados satisfactorios. Una minoría de pacientes requerirá de tratamiento quirúrgico (Palmieri et al., 2021).

Están descritas diferentes técnicas quirúrgicas las cuales dependen del grado de la ginecomastia, de la distribución de grasa y parénquima de la mama. Entre las técnicas quirúrgicas están la exéresis quirúrgica simple, la cual se indica en pacientes con aumento de la mama debido a hipertrofia glandular; también, la liposucción simple, que se debe aplicar a los casos en los que predomine el tejido graso (Bailey et al., 2016).

Se pueden combinar la exéresis quirúrgica con la liposucción en los pacientes con hipertrofia glandular limitada al área retro o periareolar, y que el resto del aumento mamario se deba a tejido graso. En los pacientes que tengan un exceso cutáneo puede que se requiera trasladar el complejo areola-pezón y en ellos se realizará la exéresis quirúrgica más resección cutánea (Oroz et al., 2005).

Por lo general, los resultados en pacientes operados de ginecomastia son satisfactorios desde el punto de vista quirúrgico, estético y psicológico pero pueden aparecer

complicaciones tales como hematomas, seromas, necrosis, defectos estéticos no esperados o iatrogénicos tales como depresiones de la areola, malposiciones, cicatrices hipertróficas o ensanchadas, las que son más frecuentes en pacientes obesos con abundante tejido graso a nivel de las mamas o en aquellos que se les practique una liposucción o exceresis excesiva y quede gran cantidad de piel redundante (Calderon et al., 2010).

CONCLUSIONES

La ginecomastia puberal es una enfermedad benigna que puede desaparecer espontáneamente en la mayoría de los pacientes, solo la minoría necesita tratamientos tanto medicamentosos como quirúrgicos; también genera alteraciones estéticas, las cuales pueden afectar la esfera psicológica en pacientes púberes, por lo que requiere atención médica especializada. En la actualidad los resultados son favorables.

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ORIGINAL RESEARCH

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Factors associated with decision regret after bariatric surgery

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Summary

It is assumed that the individuals who undergo bariatric surgery will experience significant improvements in their health and overall well-being. However, it is yet to be examined whether these individuals may also experience subsequent decision regret. The level of regret regarding the choice to undergo bariatric surgery was assessed 1 year after bariatric surgery using the Decision Regret Scale (DRS). Associations of regret with patient characteristics, complications, weight loss and quality of life (BODY-Q) were investigated using linear regression analyses. In total, 115 patients completed the DRS (92% underwent Roux-en-Y gastric bypass Roux-en-Y gastric bypass and 8% underwent sleeve gastrectomy (SG)). Two out of 115 patients indicated absolute regret about their decision to undergo bariatric surgery because of insufficient weight loss and complications. The median decision regret score was zero (range 0–80). Most patients experienced no decision regret (50.4%), followed by mild regret (34.8%) and moderate to strong regret (14.8%). Higher levels of regret were associated with having osteo-articular disorders, gastro-oesophageal reflux disease or a history of psychiatric disorders at baseline. Patients with mild regret demonstrated significantly more weight loss and better psychological function. Major surgical complications were not associated with increased decision regret. Only two out of 115 patients (1.7%) indicated absolute regret about their decision to undergo bariatric surgery, and 15% reported moderate-to-strong regret according to the results of the DRS. These findings should be considered when providing pre-operative counselling and could assist patients in their decision-making process.

KEYWORDS
bariatric surgery, Decision Regret Scale, quality of life, Roux-en-Y gastric bypass, sleeve gastrectomy

What is already known about this subject

- Bariatric surgery is an effective method for improving overall health and well-being; however, negative outcomes may also occur.
- Negative outcomes after bariatric surgery might be associated with decision regret.
- Regret occurs when an individual reflects on a decision and wishes that the outcome had been different.

What this study adds

- This is the first study to quantitively assess the prevalence of decision regret after bariatric surgery using the Decision Regret Scale (DRS).

- Only two out of 115 patients (1.7%) indicated absolute regret about their decision to undergo bariatric surgery, and 15% reported moderate-to-strong regret according to the results of the DRS.

1 | INTRODUCTION

The prevalence of obesity has reached alarmingly high levels worldwide, affecting approximately one-third of the global population.[1] This has resulted in a significant increase in the number of bariatric procedures over the years.[2,3] Bariatric surgery is an effective method for achieving significant weight loss and improving overall health and well-being.[4] However, positive results are not guaranteed for every individual. Studies have shown that a small proportion of individuals may experience negative outcomes after bariatric surgery including suboptimal weight loss, surgical complications or decreased quality of life (QoL).[5,6] In addition, the expected results of bariatric surgery might be overestimated by patients, leading to frustration and dissatisfaction.[7–9] As a result, individuals may experience decision regret after bariatric surgery.

Regret can be defined as a negative emotional state that occurs when an individual reflects on a decision and wishes that the outcome had been different.[10,11] In other fields of surgery, post-operative regret has been shown to negatively impact post-operative outcomes.[12,13] In these studies, a higher level of decision regret was associated with several patient and surgery-related factors. These include, among others, surgical complications, decreased QoL (psychological health and body image), depression and anxiety.[12–15] While the concept of regret has been studied in various disciplines of decision-making to undergo surgery,[13] it has yet to be investigated in the context of bariatric surgery.

Given the potential negative impact of regret on the overall well-being of individuals who have undergone bariatric surgery, it is important to investigate this issue further. Data on regret can aid individuals with a desire to undergo bariatric surgery in their decision-making process. Furthermore, the identification of factors associated with decision regret in bariatric surgery could assist healthcare providers in providing adequate post-operative care to prevent negative outcomes. This study aims to examine the incidence of decision regret after bariatric surgery, as well as to identify the factors that may contribute to decision regret in this population. Based on the potential benefit of weight loss after bariatric surgery, it was hypothesized that only a minority of individuals will experience regret regarding their decision to undergo bariatric surgery. Moreover, an association with decreased QoL and a higher level of regret was anticipated.

2 | MATERIALS AND METHODS

2.1 | Participants

Patients were prospectively included from 2020 to 2021 at the OLVG Hospital in Amsterdam, the Netherlands. Inclusion criteria consisted of patients aged between 18 and 65 years who were diagnosed with morbid obesity (body mass index (BMI) >40 kg/m^2 or BMI >35 kg/m^2 with a comorbid medical condition) based on the International Federation for the Study of Obesity criteria and were approved by a multi-disciplinary team of surgeons, internal medicine physicians, dieticians, physical therapists and psychologists for either an elective primary Roux-en-Y gastric bypass (RYGB) or sleeve gastrectomy (SG).[16] Exclusion criteria were patients who previously had bariatric surgery and patients unable to understand the Dutch language. Data were collected using Castor EDC, a secure web-based application.[17] The National and Institutional Medical Ethical Review Committee approved the protocol of this study.

2.2 | Outcomes

The primary outcome was the level of decision regret 1 year after bariatric surgery assessed using the Decision Regret Scale (DRS). Secondary outcomes included potential factors that were associated with the level of regret. These included baseline characteristics (age, gender, pre-operative BMI, diabetes mellitus type 2 (DM2), hypertension, dyslipidemia, osteoarticular disorders, gastroesophageal reflux disease (GERD) and history of psychiatric illness) and post-operative factors such as type of surgery, major surgical complications, weight loss (defined as percentage total weight loss [%TWL]) and QoL scores (BODY-Q). Surgical complications were assessed by searching the electronic patient file for peri-operative complications or readmissions for every individual patient. A major surgical complication was defined as any event related to bariatric surgery requiring endoscopic, radiological or surgical intervention, or leading to severely disabling consequences (Clavien–Dindo classification IIIb or higher). Data on pre- and post-operative weights, comorbidities and (history of) psychiatric illness were supplemented from the electronic patient file of the Dutch Obesity Clinic (Nederlandse Obesitas Kliniek (NOK)). The Dutch Obesity Clinic provides a comprehensive pre- and post-operative, multi-disciplinary, care program with regular assessments by physicians, dieticians and psychologists, and physiotherapists specialized in obesity treatment. People living with obesity were informed about the risks and benefits of bariatric surgery during six preparatory pre-operative group sessions at the Dutch Obesity Clinic.

2.2.1 | Decision Regret Scale

The level of regret experienced by individuals who have undergone bariatric surgery was assessed using the DRS.[18] This scale has been developed to measure the level of regret in healthcare decision-making and was validated in patients undergoing different surgical and non-surgical treatments. It makes use of a five-point Likert scale, with 1 indicating "strongly agree" and 5 indicating "strongly disagree." Mean scores were transformed by subtracting 1 and multiplying by

25 for each item, resulting in a sum score ranging from 0 to 100, as was recommended by the developers of the scale.[18] A higher score indicates a greater degree of regret. The DRS was administered 1 year after bariatric surgery. One additional item was administered besides this scale, asking patients whether they regret their previous decision to have undergone bariatric surgery (answered with a "yes" or "no").

2.2.2 | Quality of life

QoL was assessed using the Dutch version of the BODY-Q questionnaire, namely the OBESI-Q.[19] This questionnaire has been psychometrically validated in people living with obesity undergoing weight loss treatment and was selected as the most suitable measurement instrument to assess QoL after bariatric surgery.[20] For this study, six independently functioning domains of QoL were assessed including body image, physical function, social function, psychological function, sexual function and eating behaviour. These domains consist of 5 to 11 items, utilizing a four-point Likert scale. The responses were added up to a sum score per domain, which was then converted to a Rasch score, ranging from 0 to 100. Higher scores are indicative of better QoL for that specific domain. The OBESI-Q was sent by email before- and at 6 and 12 months after bariatric surgery. The results were stored in the electronic patient file of the Dutch obesity clinic.

2.3 | Statistical analyses

Data analyses were performed using IBM SPSS Statistics 28. Continuous variables with normal distribution were presented as mean (standard deviation (SD)); non-normal variables were presented as median (lower range value—upper range value). Comparisons of two groups for a continuous variable were performed using an independent samples Student's *t*-test (for normally distributed variables) or Mann–Whitney *U* test (for non-normally distributed variables). Differences between dichotomous variables were analysed using a chi-square test. Linear regression analyses were used to assess the association of regret (continuous) with baseline characteristics and major complications. Patients were categorized into three groups according to the results of the decisional regret score: no regret (score of 0), mild regret (score between 1 and 25) and moderate to strong regret (score between 26 and 100). This method of categorization for the DRS is most frequently used in literature.[14] The associations of %TWL and QoL scores with regret (categorical) were assessed using linear regression analyses. A *p*-value less than 0.05 was considered to indicate statistical significance.

3 | RESULTS

A total of 240 patients were asked to participate in the present study. Of those, 115 (48.1%) patients completed the DRS 1 year after bariatric surgery. Among the patients, 107 (92.2%) underwent RYGB and nine (7.8%) underwent SG. An overview of baseline characteristics is provided in Table 1. Patients who did not complete the DRS 1 year after bariatric surgery ($n = 125$) were younger (40.2 vs. 44.2 years old; $p = 0.01$) compared with patients who completed the questionnaire but did not differ in other variables.

3.1 | Decisional Regret Scale

The scores of the DRS followed a right-skewed distribution. The median score on the DRS was 0 (range 0–80) and the mean score was 11.3. Most patients reported no decision regret (50.4%; a score of 0) regarding their decision to undergo bariatric surgery. Of the remaining patients, 34.8% reported mild regret (score between 1 and 25) and 14.8% reported moderate to strong regret (score between 26 and 100). Table 2 presents an outline of patient factors before and after bariatric surgery categorized by regret group.

3.2 | Absolute decision regret (answer option yes/no)

Two patients (1.7%) reported absolute decision regret regarding their previous decision to have undergone bariatric surgery. The first

TABLE 1 Baseline characteristics.

	Total cohort
Total number of patients, *n*	115
Age at operation, years (SD)	44.2 (±11.3)
Gender, female, %	81.0%
Weight before surgery, kg (SD)	122.4 (±18.9)
BMI before surgery, kg/m^2 (SD)	41.9 (±4.7)
Operation	
Roux-en-Y gastric bypass, *n*	107 (92.2%)
Sleeve gastrectomy, *n*	9 (7.8%)
Comorbidities	
Having any comorbidity, *n*	91 (78.4%)
Diabetes mellitus type 2, *n*	62 (15.5%)
Hypertension, *n*	36 (31%)
Dyslipidemia, *n*	14 (12.1%)
Obstructive sleep apnea, *n*	71 (61.2%)
Osteoarticular disorder, *n*	23 (19.8%)
Gastroesophageal reflux disease, *n*	12 (10.3%)
History of psychiatric illness	
History of any psychiatric illness, *n*	29 (25.0%)
Depression, *n*	15 (12.9%)
Binge eating disorder, *n*	5 (4.3%)
Post-traumatic stress disorder, *n*	4 (3.4%)
Other, *n*	5 (4.3%)

Abbreviations: BMI: body mass index, kg: kilogram, SD: standard deviation.

TABLE 2 Factors associated with decision regret.

	Missing, %	No regret	Mild regret	Strong regret[a]	*p*-value[b]
Number of patients, *n* (%)		58 (50%)	40 (35%)	17 (15%)	
Age, years (SD)	0	45.3 (±10.9)	44.1 (±11.7)	41.4 (±10.4)	0.409
Gender, female, %	0	81%	75%	94%	0.244
BMI before surgery, kg/m^2 (SD)	0	42.0 (±5.0)	41.7 (±4.0)	41.5 (±5.0)	0.889
Operation	0				0.256
RYGB, *n*		54 (93%)	35 (88%)	17 (100%)	
SG, *n*		4 (7%)	5 (13%)	0 (0%)	
Comorbidities	0				
Having any comorbidity, *n*		45 (78%)	31 (78%)	14 (82%)	0.906
Diabetes mellitus type 2, *n*		9 (16%)	4 (10%)	0 (0%)	0.196
Hypertension, *n*		20 (48%)	12 (30%)	4 (24%)	0.676
Dyslipidemia, *n*		10 (17%)	3 (8%)	1 (6%)	0.242
OSAS, *n*		37 (64%)	24 (60%)	9 (53%)	0.716
Osteoarticular disorder, *n*		11 (19%)	5 (13%)	7 (41%)	0.045
GERD, *n*		4 (7%)	4 (10%)	4 (24%)	0.142
History of any psychiatric illness, *n* (%)	0	14 (24%)	5 (13%)	10 (59%)	0.001
BMI 12 months after surgery, kg/m^2 (SD)	22.6	28.4 (±4.9)	26.9 (±4.7)	28.4 (±5.8)	0.397
%TWL 12 months after surgery, % (SD)	22.6	32.1 (±8.0)	36.2 (±8.2)	35.2 (±9.0)	0.124
Major complications	0	4 (7%)	1 (3%)	2 (12%)	0.382

[a]Moderate to strong regret.
[b]Difference calculated with ANOVA or chi-square.
Abbreviations: %TWL: percentage total weight loss, Age, age at operation; BMI, body mass index; GERD, gastro-oesophageal reflux disease; kg, kilogram; OSAS, obstructive sleep apnea syndrome; RYGB, Roux-en-Y gastric bypass; SD, standard deviation; SG, sleeve gastrectomy.
Note: Major complications: less than 12 months after surgery.

patient (a 52-year-old female) indicated absolute regret because of insufficient weight loss. She had a weight and BMI of 91.9 kg and 36.8 kg/m^2 before bariatric surgery and 70.2 kg and 28.1 kg/m^2 12 months after bariatric surgery, with a TWL of 23.5%. The other patient (a 49-year-old female) expressed regret because of a surgical complication, namely a stenosis of the gastro-jejunal junction that was treated with surgical revision of the gastro-jejunal anastomosis. She continued to experience pain and encountered difficulty in maintaining a healthy weight because of excessive weight loss after revisional surgery and expressed the feeling that her complaints were not taken seriously.

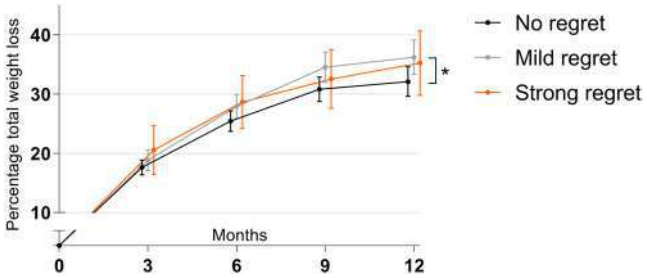

FIGURE 1 Difference in percentage total weight loss for patients with (A) no regret, (B) mild regret and (C) moderate to strong regret, 12 months after bariatric surgery. "*": indication of a statistically significant difference, vertical lines: 95% confidence interval, no regret: Decision Regret Scale (DRS) score zero, mild regret: DRS score 0–24 and moderate to strong regret: DRS score 25–100.

3.3 | Factors associated with decision regret

A higher level of decision regret 1 year after bariatric surgery was associated with having osteoarticular disorders (beta 7.6; 95% CI 0.1–15.2; $p = 0.048$), GERD (beta 11.4; 95% CI 1.6–21.2; $p = 0.023$) and (a history of) psychiatric illness (beta 7.2; 95% CI 0.2–14.2; $p = 0.043$) before bariatric surgery (adjusted R-squared 0.118).

Clinical weight data of patients who completed the DRS at 12 months after bariatric surgery was available for 89 to 95 out of 115 patients (77%–83%) at 3, 6, 9 and 12 months after bariatric surgery. The progression of %TWL over time for patients with no regret, mild regret, or moderate to strong regret is provided in Figure 1. Patients with no regret ($n = 43$) demonstrated significantly lower % TWL at 12 months after bariatric surgery (beta −3.8%; $p = 0.03$) compared with patients with mild and moderate to strong regret ($n = 46$).

Major complications were observed in seven out of 115 (6.1%) patients after bariatric surgery. These included internal leakage requiring surgery in two, stenosis requiring surgery in two, cholelithiasis and diaphragmatic herniation requiring surgery, cicatricial herniation

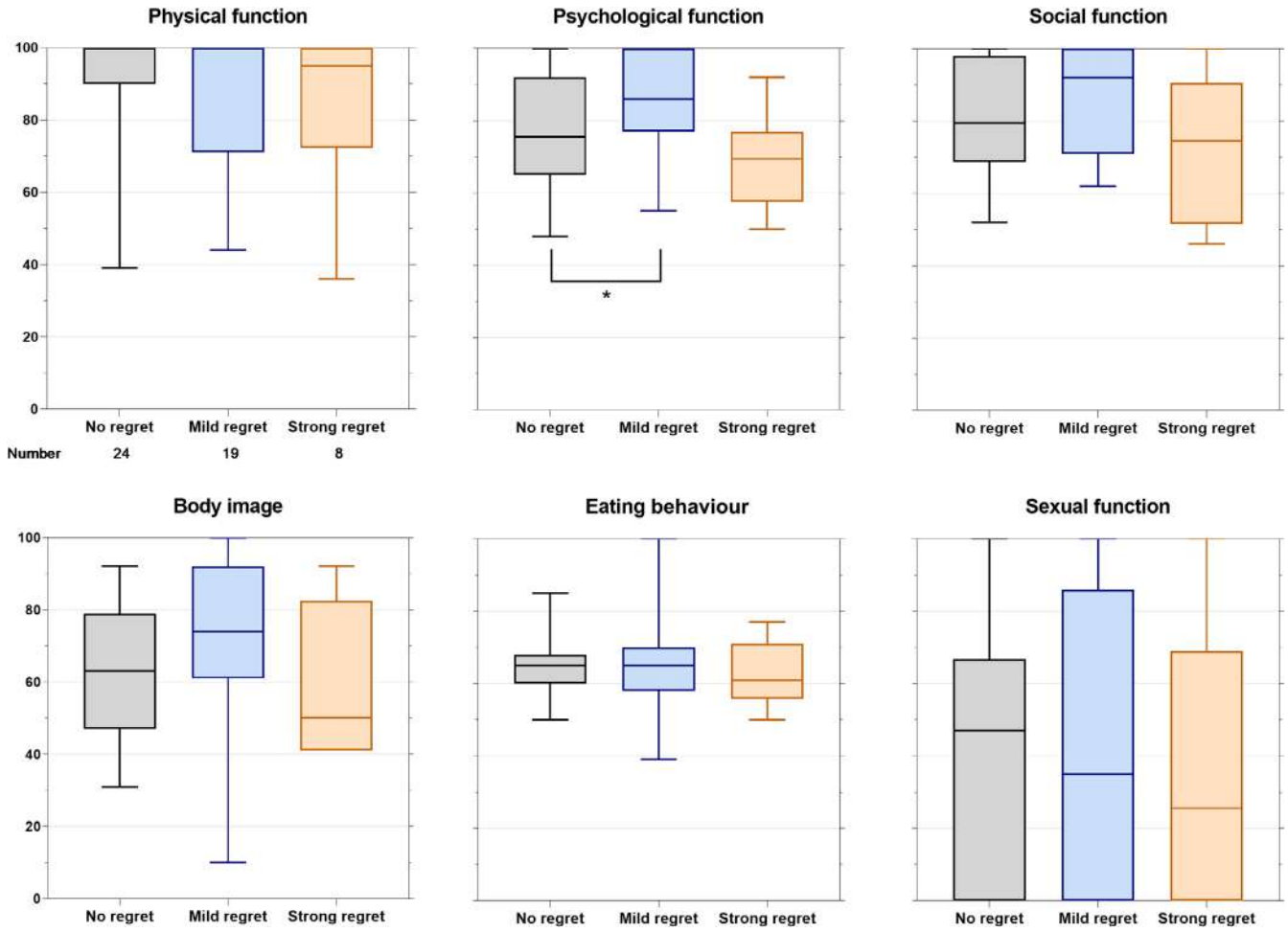

FIGURE 2 Difference in quality of life scores for patients with (A) no regret, (B) mild regret and (C) moderate to strong regret, 12 months after bariatric surgery. Boxplots indicating median, quartiles and range, "*": indication of a statistically significant difference, no regret: Decision Regret Scale (DRS) score zero, mild regret: DRS score 0–24 and moderate to strong regret: DRS score 25–100.

requiring surgery, and vitamin B1 deficiency resulting in disabling neurological complaints.

There was no significant difference in the Decision Regret score between patients with a major complication compared with no complication ($p = 0.683$). One out of these seven patients with a major complication answered yes to the additional question: "Do you regret your previous decision to undergo bariatric surgery?"

Post-operative QoL scores were available for 51 out of 115 patients (44.3%). Differences in QoL scores at 12 months after bariatric surgery between patients with no regret, mild regret and moderate to strong regret are provided in Figure 2. Patients with mild regret demonstrated significantly higher psychological function scores compared with patients with no regret (beta 9.2; $p = 0.048$), indicating better psychological function/mental health.

4 | DISCUSSION

This study assessed the level of regret patients' experience 1 year after bariatric surgery regarding the decision to undergo bariatric surgery. Among all patients, only two (1.7%) reported absolute regret regarding their previous decision to undergo bariatric surgery because of a surgical compilation and insufficient weight loss. According to the DRS, most patients experienced no decision regret (50.4%), followed by mild regret (34.8%) and moderate to strong regret (14.8%). A higher level of decision regret was associated with having osteoarticular disorders, gastroesophageal reflux disease or (a history of) psychiatric illness before bariatric surgery.

A high percentage of patients experienced no or only mild regret (85.2%) after bariatric surgery. Despite the right-skewed distribution of the decisional regret score, studies often report on the mean score. In a systematic review by Becerra Pérez et al. (2016), the mean decisional regret score was 16.5 out of 100 in 44 studies measuring regret after various surgical and non-surgical healthcare decisions.[14] This score is notably higher than the mean score of 11.3 (SD 17.0) observed in our data, suggesting that patients who have undergone bariatric surgery do not often regret their decision compared with other healthcare decisions. In a systematic review by Wilson et al (2017) focusing on regret in surgical decision-making, the prevalence of regret was generally higher among oncologic procedures compared

with non-oncologic procedures.[13] However, the definition of regret and no regret varied considerably across the included studies. In addition, various measurement tools were used to assess regret, with the DRS being the most frequently employed (31.5%). The absence of a standardized definition for decision regret makes interpretation and comparison of these results difficult. This can be partially attributed to the lack of an established cut-off score for the DRS.

The findings of previous studies suggest that the level of regret after surgery may be influenced by the decision-making process leading up to the surgery. Specifically, research has shown that patient regret is more likely to occur when the decision to undergo surgery is primarily driven by the surgeon rather than the patient.[13] Bariatric surgery, in contrast to other surgical procedures, is typically a patient-driven procedure, with the type of surgery (such as RYGB or SG) being decided upon through a shared decision-making process between the patient and the surgeon, unless there is a medical indication for one procedure over the other. As such, it may be expected that the level of post-operative regret would be lower for bariatric surgery compared with other surgical procedures.

Patients with (a history of) psychiatric disorders, osteoarticular disorders or GERD before bariatric surgery were more likely to express feelings of regret 12 months after bariatric surgery. These associations may be explained by unrealistic expectations among patients with osteoarticular or psychiatric disorders. Heuts et al. have concluded in a systematic review of knee and hip joint pain that bariatric surgery is likely to have a beneficial effect on joint pain.[21] Yet, weight loss associated with bariatric surgery solely alleviates symptoms by reducing joint stress, and joint pain may persist even after massive weight loss.[22] Regarding psychological function, individuals with obesity may mistakenly attribute part of their psychological complaints to their weight, and weight loss may not necessarily resolve the underlying psychological issue.[23] However, it should be noted that the justifications for these associations with decision regret are only speculative. The association of more decision regret in patients with GERD before bariatric surgery was unexpected.

Contrary to expectations, mild regret was associated with significantly higher psychological function and more %TWL. Validation studies of the DRS have demonstrated the opposite, an association of regret with a bad outcome that is perceived as the result of a bad decision.[18] Despite our efforts to explore all possible explanations for the observed results, we were unable to provide a clear explanation for these findings. It should be noted that these results were limited by the small sample size as the groups for these analyses consisted of only 8, 19 and 24 patients for QoL and 13, 33 and 43 patients for %TWL, increasing the likelihood of random error and limiting the generalizability of these results. Therefore, these findings were not considered clinically relevant and should be interpreted with caution.

The positive finding that only two out of 115 patients indicated to regret undergoing bariatric surgery supports the argument that bariatric surgery is a well-established and effective treatment option for obesity, also from the patient's perspective. Although previous research has suggested that the fear of surgical complications is a major barrier to bariatric surgery,[24] our study found no significant association between experiencing a major surgical complication and increased post-operative regret. This finding suggests that patients seldom regret their previous decision to undergo bariatric surgery, even in the case of major surgical complications (except for one patient). These data may prove useful for people living with obesity who are uncertain whether bariatric surgery is the appropriate choice, as it could help inform their decision-making process. It is important for healthcare providers to accurately inform patients about the potential benefits and risks of the procedure, including realistic expectations for weight loss and changes in psychosocial and physical outcomes. By providing this information, healthcare providers can help patients make informed decisions regarding their choice to undergo bariatric surgery and may also help to reduce the potential for post-operative regret.

The major strength of this study is that is it first to investigate decision regret in individuals who have undergone bariatric surgery using a reliable and validated measure, the DRS.[18] Furthermore, the level of decision regret was compared with QoL scores, which were assessed using the BODY-Q, a widely recognized and reliable measurement instrument for QoL in bariatric surgery.[20,25] A number of potential limitations should be considered. First, the sample size of 115 patients is relatively small, and 52% of the patients did not complete the DRS. The participants who did not complete the DRS were significantly younger and may have experienced different outcomes, which may have biased our results. Thus, this sample may not be representative of the larger population of individuals who undergo bariatric surgery. In addition, QoL scores were available for only 44% of the included patients. Second, most patients in the current study underwent RYGB, and only nine patients underwent SG. As such, the results may not be generalizable to patients who have undergone SG or other types of bariatric surgery. Third, the DRS was only administered at 12 months following bariatric surgery. It is unclear whether decision regret may change over a longer period of time.

It should be noted that this is the first study to investigate the level of regret in bariatric surgery using the DRS. Therefore, it is recommended to conduct further research to confirm these findings. Future studies should aim to include larger sample sizes and assess decision regret at various post-operative time points in patients who have undergone different types of bariatric surgical procedures.

5 | CONCLUSION

Only two out of 115 patients indicated absolute regret about their decision to undergo bariatric surgery, and 15% reported moderate to strong regret according to the results of the DRS. This study identified several factors associated with decision regret, but the validity of these associations should be confirmed by future research. Overall, these findings should be considered when providing pre-operative counselling and could assist patients in their decision-making process.

CONFLICT OF INTEREST STATEMENT

The authors declare no competing interest.

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ORIGINAL ARTICLE

Gender affirmation surgeries in transgender women: Aesthetic, sexual, and urinary results of an initial series of vaginoplasties☆

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KEYWORDS
Transsexual;
Transgender;
Gender dysphoria;
Reconstruction genital reassignment;
Vaginoplasty

Abstract
Introduction and objectives: Gender dysphoria is associated with mental health comorbidity, such as depression and suicide. ''Gender affirming surgeries'' improve sexuality and psychosocial well-being. The goal of vaginoplasty is for the genitalia to resemble in form and function to a biological vagina with a depth of at least 11 cm and a sensitive clitoris. In addition, the urethra must be shortened and allow voiding in a sitting position. Our objective is to describe the aesthetic, sexual and urinary results.
Patients and method: Retrospective study of all patients undergoing feminizing genitoplasty, at Hospital Sótero del Río between 2018 and 2019, that met WPATH requirements. Vaginal dimensions, neo-clitoral sensitivity, aesthetic and sexual satisfaction of the neovagina, questionnaires Female Sexual Function Index (FSFI) and the Female Genital Self-Image Scale (FGSIS), IPSS-QoL, uroflowmetry and post-void residue were evaluated.
Results: 10 women who underwent feminizing genitoplasty were identified. The neovaginal depth average was 14.2 cm. There was no rectal injury or reoperation. There was 100% of Neoclitoris sensitivity and 88% satisfaction with the neovaginal width.

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The FGSIS averaged 25.4 points and the FSFI averaged 16 points. The IPSS was 6.7 points, the average Qmax was 22 ml/s and post-void residual volume average was 22 ml. There was no neomeatal stenosis.
Conclusions: Feminizing Genitoplasty is a complex, demanding and not completely standardized surgery. However, it is a relatively safe procedure that achieves adequate aesthetic, sexual and urinary results.

PALABRAS CLAVE
Transexual;
Transgénero;
Disforia de género;
Reconstrucción reasignación genital;
Vaginoplastía

Cirugías de afirmación de género en mujeres trans: resultados estéticos, sexuales y urinarios de una serie inicial de vaginoplastias

Resumen
Introducción y objetivos: La disforia de género se asocia a elevada comorbilidad de salud mental, como depresión y suicidio. Las «cirugías de afirmación de género» mejoran la sexualidad y el bienestar psicosocial. El objetivo de la vaginoplastia es que los genitales se asemejen en forma y función a una vagina con una profundidad de al menos 11 cm y un clítoris sensible. Además, la uretra debe acortarse y permitir la micción en posición sentada. Nuestro objetivo es describir los resultados estéticos, sexuales y urinarios.
Pacientes y método: Estudio retrospectivo de todas las pacientes operadas de genitoplastia feminizante en el Hospital Sótero del Río entre 2018 y 2019 que cumplían requisitos de WPATH. Se evaluaron dimensiones vaginales, sensibilidad del neoclítoris, conformidad estética y sexual de la neovagina, cuestionarios Índice de Función Sexual Femenina (FSFI) y la Escala de Autoimagen Genital Femenina (FGSIS), IPSS-QoL, uroflujometría y residuo posmiccional.
Resultados: Se identificaron 10 mujeres operadas de genioplastia feminizante. La profundidad promedio neovaginal fue de 14,2 cm. No hubo lesión rectal ni reoperación. Hubo 100% de sensibilidad del neoclítoris y 88% de conformidad con el ancho neovaginal. La FGSIS promedió 25,4 puntos y el FSFI promedió 16 puntos. El IPSS fue de 6,7 puntos, el Qmax promedio fue de 22 ml/s y el residuo posmiccional promedio fue de 22 ml. No hubo estenosis del neomeato.
Conclusiones: La genitoplastia feminizante es una cirugía compleja, exigente y no completamente estandarizada. Sin embargo, es un procedimiento relativamente seguro que logra adecuados resultados estéticos, sexuales y urinarios.

Introduction

Transgender people are characterized by having a gender identity different from their biological (anatomical) sex. Some related terms[1–4] are defined in Appendix B Annex 1.

Transgender prevalence is difficult to establish. In the United States and Europe, figures of 0.6% of the population are described[5,6]. The incidence has increased in recent years[7], mainly attributable to greater visibility and social acceptance.

Acceptance of transgender status varies across cultures, but is generally accompanied by stigma, discrimination, exclusion and violence. Gender dysphoria is also associated with high mental health comorbidity. Transsexual individuals, in relation to the general population, present higher rates of depression, anxiety, suicide, substance abuse and alcoholism[8]. In one publication[9], the prevalence of suicidal ideation in trans population was 48% versus 3.7% in the general population; suicide attempts were reported in 24% of trans population versus 1.5% in the general population. Similar figures are described in a review,[10] where suicidal ideation averaged 47% and suicide attempts, 27%. As described by Virupaksha et al.[11], mistreatment and derogatory labeling in the health care system are factors that affect these figures.

This is why the process of transition or counseling by a multidisciplinary specialty team has consistently and systematically shown improvement of the mental health and general wellbeing of this population[12]. This is variable for each person and may include psychological support, hormone therapy and surgery, among others.

About half of trans men (male identity born in a female body) population and one third of trans women (female identity born in a male body) population seek one or more surgical interventions to achieve an appearance more in line with their gender identity[13].

This broad group of procedures are referred to as ''gender affirming surgeries'' (formerly called sex reassignment surgeries). Among the alternatives requested by trans women are facial feminization surgeries, voice modification surgeries, breast augmentation, orchiectomy as a stand-alone procedure, and feminizing vaginoplasty or genitoplasty.

The most common care protocol globally used has been proposed by the World Professional Association for Transgender Health (WPATH)[12]. It encourages multidisciplinary team care and emphasizes on the importance of having surgical professionals trained in specific reconstructive techniques to maximize outcomes and decrease complications.

The WPATH recommends some requirements for access to surgery, such as age of majority, two referral letters from qualified mental health professionals specifying the diagnosis of persistent gender dysphoria, capacity to make decisions and, in case of mental health concerns, the letters must afform that these are being managed. In the case of simple gonadectomy (hysterectomy and oophorectomy or orchiectomy), at least 12 months of hormone

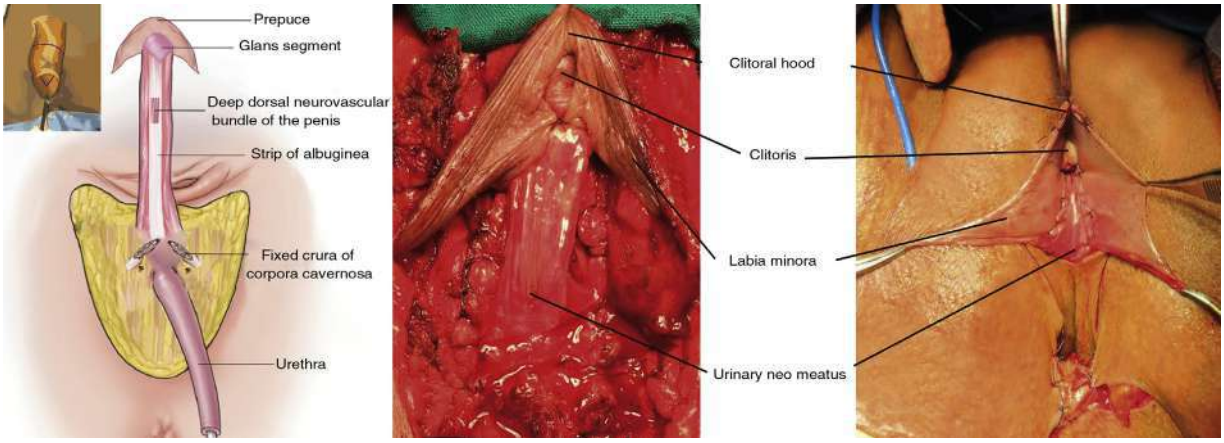

Figure 1 Formation of neoclitoris with hood, labia minora, mucosal introitus (with preserved segment of the dorsal urethra) and spatulated urethral neomeatus. Before and after exteriorization through sagittal incision in the penile flap.

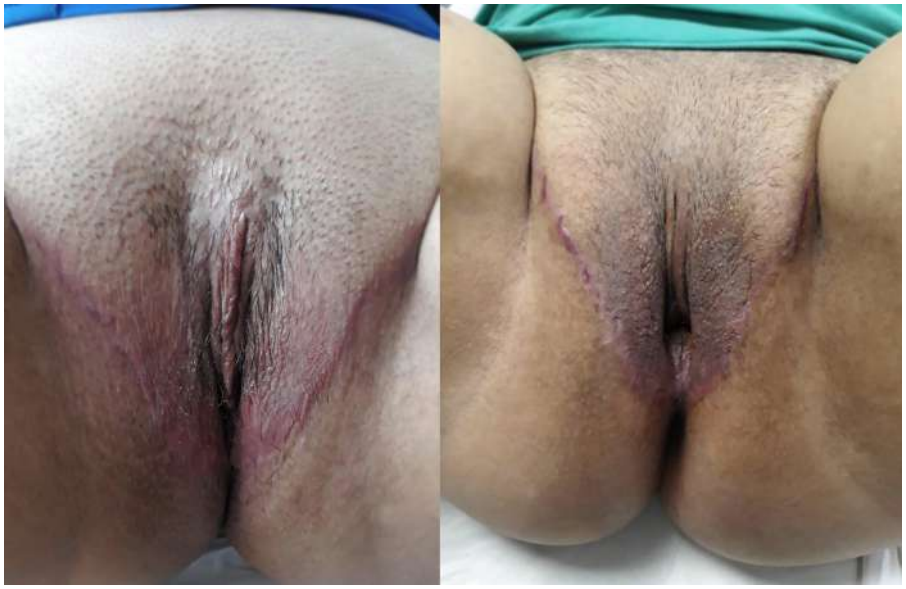

Figure 2 Feminizing genitoplasty: results at 2 and 4 months of follow-up.

therapy is recommended. For genitoplasty, both feminizing and masculinizing, it is further recommended to have the real-life experience, with at least 12 months living in a gender role that is congruent with their manifested gender identity.

The goal of vaginoplasty is to create a vagina that resembles in form and function to a biologically developed hair-free vagina, with a cavity of at least 11 cm deep and 3 cm wide, a sensitive clitoris and the presence of labia minora and labia majora. In addition, the urethra should be shortened in a way that the direction of the urinary stream is downward in the sitting position. This gender affirmation surgery is increasingly recognized, not as a cosmetic procedure, but as a therapeutic intervention and a medical-surgical necessity. The importance and benefits of this surgery are documented, including improvements in terms of sexuality and psychosocial well-being[13,15].

There are different techniques for performing vaginoplasty. The following are the most relevant[14–17]:

- *Simple penile inversion*, which includes penile degloving, closure of the edge of the skin tube, and invagination into the neovaginal cavity.
- *Penile inversion with graft*, the free scrotal graft is the most commonly used to lengthen the skin cylinder that will cover the neovagina.
- *Penile skin with perineoscrotal flap technique*, based on the creation of an inferior vascularized flap to enlarge the penile skin tube opened ventrally in the midline to increase depth and width.
- *Bowel segment technique* using ileum, sigmoid or colon.

The penile inversion technique with scrotal free graft is the most widely used at a global level[14,15].

In this series we have used the penile skin flap with perineoscrotal flap technique, with several original modifications described by Dr. Guillermo MacMillan. It consists of the creation of a cavity between the rectum and the prostate/bladder, partial resection of the urethra, removal of both testicles, corpora spongiosum and corpora cavernosa to avoid occlusion of the neovagina after engorgement. Part of the glans is kept for the formation of the neoclitoris and a strip of albuginea is kept attached to the neurovascular bundle to preserve the sensitivity and vascularization of the neoclitoris and part of the prepuce for the labia minora (Figs. 1 and 2). The inverted penile skin in addition to a perineoscrotal flap are used

for the inner lining of the neovaginal cavity. Preoperative removal of genital hair is recommended to avoid complications.

Although vaginoplasty is being performed with more frequency worldwide, few studies focus on patient perception or patient reported outcome measures (PROMs) in relation to sexual, urinary and cosmetic outcomes. The present report aims to describe the cosmetic, sexual and urinary outcomes of the first trans women undergoing vaginoplasty at the Sótero del Río Public University Hospital in Santiago, Chile.

Materials and methods

Retrospective descriptive study of all transsexual female patients submitted consecutively to feminizing genitoplasty at the Sótero del Río Public University Hospital, in Santiago, Chile, between 2018 and 2019, who met WPATH requirements.

After approval by the ethics committee, medical records were reviewed by extracting data on epidemiology, education level, comorbidities, body mass index, suicidal ideation, smoking habits, time on hormone therapy, and previous surgeries. The collected data regarding surgery were operative time, intraoperative complications, estimated blood loss and vaginal size achieved.

In the postoperative follow-up, urinary, sexual and general well-being aspects were periodically evaluated. Physical examination, recorded adherence to dilation schedule, vaginal size, sensitivity of the neoclitoris, surgery regret, compliance with cosmetic and sexual function of the neovagina were evaluated using the Female Sexual Function Index (FSFI) and Female Genital Self-Image Scale (FGSIS) questionnaires (described in Appendix B Annex 2). Additionally, new questions were asked: On a scale from 0 to 10, Are you happy after surgery? How satisfied are you with the aesthetic outcome of surgery?, Would you recommend this surgery?, Would you go through it again?, Do you regret it?, and Has it affected (improved or worsened) your quality of life? The urinary aspect was evaluated with IPSS/AUA-QoL urinary symptom score, voiding frequency recording, questions aimed at detecting alterations in voiding stream, free uroflowmetry and ultrasound measurement of postvoid residual.

Results

Ten trans women who consecutively underwent feminizing genitoplasty were identified. Their general characteristics are described in Table 1. The mean follow-up was 5.2 months, ranging from 1.6 to 9 months.

Mean operative time was 6.4 h (range 5–7) and estimated blood loss was 530 ml. The only intraoperative complication was injury of the membranous urethra, which was immediately repaired with monocryl 4.0 without further complications. There was no rectal injury or reoperation in any patient.

The mean neovaginal depth was 14.2 cm at surgery completion and 13.7 cm at follow-up (Table 2). One patient abandoned dilations due to vaginal discomfort/pain, presenting neovaginal stenosis with 5 cm depth that she decided not to treat as it did not affect her; the rest of the patients had a mean vaginal depth of 14.6 cm.

Surveys were responded by 9 patients (90%). One patient could not be reached.

We found 100% neoclitoris sensitivity, 88% satisfaction with neovaginal width (3.7 cm mean) and 66% satisfaction with depth (13.7 cm mean). Responses to each question are presented in Table 3.

The FGSIS scored a mean of 25.4 points and the FSFI scored a mean of 16 points (range 2–28.9) (Table 4).

Urinary assessment is presented in Table 5: AUA/IPSS questionnaire score was 6.7 points or mild urinary symptoms, maximum flow was 22 ml/s and postvoid residual was 22 ml (all mean values). There were no cases of stenosis in the neomeatus.

Table 1 General characteristics of the study group.

General characteristics	Number (%)
Total patients	10
Mean age in years/range	30/20–42
Time of hormone therapy in years/range	3/1–8
Tobacco use	5 (50)
Marijuana use	2 (20)
Regular alcohol use	6 (60)
Mean body mass index/range	24,9/19–28
Overweight or BMI > 25	6 (60)
[0.1-2]*Medical comorbidities.*	
HIV positive	4 (40)
Depression	5 (50)
OSAHS with BIPAP use.	1 (10)
Suicidal ideation	2 (20)
Suicide attempt.	2
[0,1-2]*History of related surgeries.*	
Total patients with previous surgeries.	4 (40)
Circumcision	2 (20)
Orchiectomy	1 (10)
Breast implants	2 (20)
No previous surgeries.	6 (60)
[0.1-2]*Education*	
University studies	3 (30)
Technical studies	6 (60)
Middle school	1 (10)

Table 2 Neovaginal size at the end of surgery and at completion of follow-up.

Neovaginal size	Mean centimeters (range)
[0,1-2]*Intraoperative*	
Vaginal diameter	3,2 (2,8–3,5)
Vaginal depth.	14,25 (13–15)
[0.1-2]*Postoperative with mean follow-up 5.2 months (1.6-9)*	
Vaginal diameter	3,47 (3,4–3,5)
Vaginal depth.	13,7 (5–16)

Discussion

The satisfaction of patients who undergo vaginoplasty depends, in part, on neovaginal depth, sensitivity of the neoclitoris and cosmesis regarding their expectations. Several studies consider that an ideal neovagina should be have least 10 cm deep and 3–4 cm in diameter[5,15,16]. However, Franco et al.[18] noted that some trans women had other expectations and desired a deeper neovagina than the vagina of cisgender women, which is 8–10 cm. It is important to note that trans women do not experience physiological vaginal elongation during sexual arousal.

Other international series report a mean neovaginal depth of 11 cm (range 10–14 cm) and diameter of 3–4 cm.[19] Buncamper[20], in the report including 100 patients, encounters a mean intraoperative depth of 13.8 ± 1.4 cm and of 11.5 ± 2.5 cm at one year, and the meta-analysis by Dreher et al.[21], which included 1,684 patients, reports a mean depth of 12.5 cm (range 6.3–14.4 cm).

Table 3 Results to original questions assessing sensitivity, sexual function and perceived impact on quality of life. FGSIS and FSFI results.

Original questions from research team	Result/number (%)
Do you have neoclitoral sensitivity?	Yes/9 (100)
Have you had penetrative sexual activity?	Yes/5 (55)
Are you satisfied with sexual activity?	Yes/5 (55)
Is your partner satisfied with sexual activity?	Yes/5 (55)
Are you satisfied with your own lubrication?	Yes/8 (88)
Have you had pain with sexual activity or dilations?	Yes/6 (66)
Are you satisfied with the width of the neovagina?	Yes/8 (88)
Are you satisfied with the depth of the neovagina?	Yes/6 (66)
Would you recommend this surgery?	Yes/9 (100)
Would you have this surgery again?	Yes/9 (100)
Do you regret having this surgery?	Yes/0
Perception measured on a scale of 0 to 10 (maximum)	Mean (range)
On a scale from 0 to 10, where 0 is much worse, 5 is the same and 10 is much better, what was the impact of this surgery on your quality of life?	9 (5–10)
On a scale from 0 to 10, where 0 is very unhappy, 5 is neutral and 10 is very happy, what was the impact of this surgery on your *happiness*?	9 (6–10)
On a scale from 0 to 10, where 0 is very unhappy, 5 is neutral and 10 is very satisfied, how would you rate your compliance with genital aesthetics after this surgery?	8,8 (6–10)
Female Sexual Function Index (FSFI)	16,5 (2–28)
Female Genital Self-Image Scale (FGSIS)	25,4 (21–27)

Table 4 Female Genital Self-Image Scale (FGSIS). Detail of mean score per question.

Affirmations	Score
I feel positively about my genitals.	3,78
I am satisfied with the appearance of my genitals.	3,375
I would feel comfortable letting a sexual partner look at my genitals.	3,5
I think my genitals smell fine.	3,125
I think my genitals work the way they are supposed to work.	3,62
I am comfortable letting a health care provider examine my genitals.	4
I am not embarrassed about my genitals.	3,87

It's a 4-point response scale: from ''strongly disagree'' (1 point) to ''strongly agree'' (4 points). Higher scores indicate a more positive genital self-image.

Table 5 Results of the urinary function assessment.

Tool or description	Score
AUA/IPSS	6,7
Quality of Life AUA	0,7
Uroflowmetry and PVR measurement	Mean (range)
Maximum flow in ml/s	22 (15–27)
Postvoid residual volume in ml	22 (0–70)
Original questions regarding urine stream	Number of patients
Worsening of micturition	1
De novo urgency	2
Daytime/nighttime voiding frequency (times)	5/1
Spraying of the stream	2
Tenesmus	1
Hesitancy	0
Stress urinary incontinence	1
Urge urinary incontinence	1
Mixed urinary incontinence	1
Enuresis	1
Lower urinary tract infection	1
Stenosis of urethral neomeatus	0

Our results report slightly larger dimensions than the international series, with a mean depth of 13.7 cm; excluding the patient who abandoned dilations, the depth was 14.6 cm. We attribute these good results to careful and thorough intraoperative neovaginal cavity dissection, the use of vaginal gauze packing in the early postoperative period, and strict dilation schedules. Despite these favorable objective results, satisfaction with depth and diameter reached a 66.6% and 88%, respectively. In face of the same objective result, such as a neovaginal diameter of 34 mm, certain patients were satisfied, and others were dissatisfied.

Regarding neoclitoral sensitivity, Amend's series[19] reports it as excellent in 18 patients (78%), good in 5 (19%) and unsatisfactory in one patient, and the meta-analysis by Dreher et al.[21] shows presence of clitoral sensitivity in 70% of patients. In our cohort, 100% of the patients reported clitoral sensitivity, demonstrating the effectiveness of the technique of careful preservation of the dorsal neurovascular bundle of the penis with a strip of albuginea to create the clitoris and labia minora from the glans and prepuce, preserving aesthetic appearance and adequate function.

In relation to satisfaction with aesthetic and functional results of the neovagina, Buncamper et al.[14] report data obtained from 49 patients who underwent vaginoplasty through the ''penile skin inversion'' approach. They used the FSFI and SQSV questionnaires. The score was 8 out of a maximum of 10 for aesthetic outcomes and 56% were found to be sexually dysfunctional according to the FSFI. In some cases, this was because they were sexually inactive or due to lubrication issues and discomfort. Bizic et al.[16] reported sexual satisfaction in 79% of patients after vaginoplasty, further concluding that a patient can be sexually satisfied despite being categorized as sexually dysfunctional according to the questionnaires. Massie et al.[22] reported that, despite a considerable prevalence of complications and reoperations, 94% of patients declared ''feeling positively about their genitals'' and ''would do this operation

again''; they further conclude that the main predictors of dissatisfaction were large intravaginal or external scarring, prolonged pain, loss of sensation, and presence of hematoma or bleeding. A 2019 review by Scahrdein et al.[5] determined similar predictors of dissatisfaction.

All our patients report a relevant ''improvement in quality of life'', ''happiness with surgery'' and ''aesthetic conformity'' with a score of 9 out of 10. Although the mean FSFI score is low (16.5), the results of the sexually active patients are close to the normal range, and in addition, this subgroup reports high personal and partner satisfaction with vaginal sexual function.

Urinary tract function following vaginoplasty has not been described in detail; most studies show small case series, without preoperative and postoperative comparison and/or without clear postoperative results. Kuhn et al.[23] described that, following vaginoplasty, there is an increased risk of developing voiding disorders, mainly stress urinary incontinence and overactive bladder, compared to age-matched control groups. Goddard et al.[24] report that, out of a total of 197 patients with a mean follow-up of 56 (8-351) days, urethral stenosis was present in 18.3%, and 6% complained of spraying of urine. Rossi-Neto et al.[25] evaluated the results of 332 cases, reporting 40% (132 cases) of meatal stenosis, which required repair in a second surgery, and 4% (14 cases) presented transient urinary incontinence. Melloni et al.[26] evaluated the presence of LUTS pre- and post-feminizing genitoplasty in 30 cases; the predominant LUTS were increased frequency, weak urine stream, urge incontinence and nocturia. Combaz and Kuhn[27] reported one third of postoperative voiding complications, including overactive bladder, stress incontinence, decreased urine stream and meatal stenosis.

In our post-genitoplasty report, the urinary symptoms found in the IPSS were mild, without affecting quality of life. All patients had nonobstructive flow and complete bladder emptying. There were no cases of meatal stenosis or repairs.

There are no assessment tools validated in the trans population. This obliges us to use instruments which have been designed for other population groups, thus limiting the validity of the results.

Conclusion

Trans people constitute a population that is becoming increasingly visible in healthcare centers, and gender affirmation surgery is being progressively demanded due to its positive impact on quality of life and on many health areas.

Feminizing genitoplasty is a complex, demanding and not entirely standardized surgery. However, it is a relatively safe procedure that achieves adequate aesthetic, sexual and urinary results.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

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Appendix A. Supplementary data

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Gender Regrets: Banning Abortion and Gender-Affirming Care

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GENDER REGRETS: BANNING ABORTION AND GENDER-AFFIRMING CARE

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INTRODUCTION

In the spring of 2023, the *New York Times* published a piece entitled "How a Few Stories of Regret Fuel the Push to Restrict Gender Transition Care."[1] It features Chloe Cole, who lived as a transgender boy for several years but now identifies as a cisgender woman. Cole has become a poster child for the idea that gender-affirming care ("GAC") for minors may lead to later regret and should therefore be restricted by the state. Cole, who has been travelling the country as part of a conservative lawmaking effort to ban GAC, received a standing ovation after Florida Governor Ron DeSantis told her story in his State of the State address.[2] Cole and a few others

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[1] Maggie Astor, *How a Few Stories of Regret Fuel the Push to Restrict Gender Transition Care*, N.Y. TIMES (May 16, 2023), https://www.nytimes.com/2023/05/16/us/politics/transgender-care-detransitioners.html [https://perma.cc/8H64-B5TE].

[2] Cole helped organize a "Detransition Awareness Day" rally in Sacramento, but only about forty people participated. *Id.*

have been invited by conservative politicians and lawmakers in several states to testify about the perils of providing GAC to children and youth.[3]

These politicians and lawmakers have generated a national moral panic about transgender children and youth that has resulted, as of early 2024, in restrictions or bans on GAC for minors in twenty-three states.[4] Three core beliefs drive this moral panic. First, many children and youth who identify as transgender are only following a social-media amplified fad, a "social contagion."[5] Second, gender dysphoria is the result of childhood trauma and should therefore be treated via psychological therapy only.[6] Third, cisgender children and adults are a preferable social outcome (over transgender children and adults).[7] Based on these three convictions, gender-

[3] A Wyoming bill to ban transition care for minors was named "Chloe's Law." *Id. See also* Jesse Singal, *When Children Say They're Trans,* THE ATLANTIC, (July-Aug. 2018), https://www.theatlantic.com/magazine/archive/2018/07/when-a-child-says-shes-trans/561749/ [https://perma.cc/7D2Z-URWT] (highlighting people who have come to regret their gender-affirming care); Rikki Schlott, *'I Literally Lost Organs:' Why Detransition Teens Regret Changing Genders*, N.Y. POST, (June 19, 2022, 10:50 AM), https://nypost.com/2022/06/18/detransitioned-teens-explain-why-they-regret-changing-genders/ [https://perma.cc/P3XL-VR3Z] ("[T]he politicization of the issue was shutting down proper clinical rigor. That meant quite vulnerable kids were in danger of being put on a medical path for treatment that they may well regret."). As a director at the Heritage Foundation has professed, "We are glad to work with individuals who are willing to stand up to the corrosive effects of gender ideology, especially when it is being pushed on children." Astor, *supra* note 1.

[4] *See infra* note 30 (citing statutes); Nikolas Lanum, *Detransitioner Slams Clinics, Media for Politicizing 'Gender Affirming Care': 'They do Everything for Profit*,*'* FOX NEWS, (Apr. 8, 2023, 3:54 PM), https://www.foxnews.com/media/detransitioner-clinics-media-politicizing-gender-affirming-care-everything-for-profit [https://perma.cc/7AMZ-GTAA] (discussing Walt Heyer, an outspoken anti-transgender rights advocate, attributing transgender identification to "social contagion," social media outlets such as TikTok, and adverse childhood experiences that are potentially traumatic). *See also* Hannah Grossman, *'Tomboy' Who Regretted Gender Transition Breaks Down Crying Describing Difficulty of Breast Removal Surgery*, FOX NEWS, (Dec. 4, 2023, 5:00 AM), https://www.foxnews.com/media/detransitioner-breaks-down-describing-difficulty-breast-removal-surgery-something-wrong-me [https://perma.cc/Y3J7-E22F] (telling the story of an individual who had previously identified as transgender man but now identifies as a ciswoman, who "broke down" twice during the interview: "The first time, she discussed a point in her teenage years when her father left the family. She was devastated, and around that same time she began to experience gender dysphoric symptoms. During the second time, Teran described the challenging experience with complications from her breast removal surgery – a double mastectomy.").

[5] Lanum, *supra* note 4.

[6] *Id.*

[7] *See also* Noa Ben-Asher, *Transforming Legal Sex*, 102 N.C. L. REV. 335, 392 (2024) ("The underlying rationale of the current voluminous laws and policies against transgender children and youth . . . is that transgender children and adults are *not* desirable social outcomes.") [hereinafter Ben-Asher, *Transforming Legal Sex*]; Deborah L. Brake, *Title IX's Trans Panic*, 29 WM. & MARY J. RACE, GENDER & SOC. JUST. 41, 43 (2022) ("The new

affirming care for minors is presented as harmful, ideological, unnecessary, and likely to lead to future regret. The Supreme Court recently granted an emergency stay of a Ninth Circuit preliminary injunction against Idaho's GAC ban for minors.[8] In his concurrence, Justice Gorsuch echoed these sentiments when he quoted extensively from Idaho's application for stay, including language as to how the law seeks to block "surgeries that sterilize or mutilate a child's genitals," and protect children from "lasting harm and irreversible damage."[9]

The role of regret in the movement to ban GAC parallels the role of regret in the ongoing conservative campaign to ban abortion. In *Dobbs v. Jackson Women's Health Organization*, the Supreme Court held that pregnant people have no constitutional right to terminate an unwanted pregnancy.[10] The decision overturned *Roe v. Wade*[11] and *Planned Parenthood v. Casey*.[12] In the years between *Roe* (1973) and *Dobbs* (2022), advocates, politicians, and lawmakers repeatedly promoted the idea that pregnant people may come to regret the decision to end a pregnancy, and that laws should protect them from that decision.[13]

This Article analyzes the use of "regret" in the campaigns to ban GAC and abortion. It identifies two overlapping threads. First, both campaigns against medical care point to protection of patients from future regret as a legitimate state interest justifying restrictions on providing medical care. Second, both rely on concerns about regret to redefine the legal meaning of "informed consent" and make it easier for potential future plaintiffs to prevail in civil suits against providers of medical care. In doing so, both treat the emotion of regret as a distinct injury that may give rise to a range of legal rights and liabilities. The Article reveals a strategic conservative legal movement that has used "regret" as a disciplinary tool to promote

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trans-exclusion bills that have recently swept through state legislatures overtly draw on the legacy and logic of Title IX to press a right-wing gender agenda, in sport and beyond. The result is a perfect storm for ushering in a new gender panic now playing out in sports."); Farhad Manjoo, *America Is Being Consumed by a Moral Panic over Trans People*, N.Y. TIMES (Sept. 1, 2022), https://www.nytimes.com/2022/09/01/opinion/america-is-being-consumed-by-a-moral-panic-over-trans-people.html. [https://perma.cc/8MGM-L7C5].

[8] Labrador v. Poe, 2024 WL 1625724 (Apr. 15, 2024) (granting stay "except as to the provision to the plaintiffs of the treatments they sought").

[9] *Id.* (Gorsuch, J., concurring).

[10] 142 S. Ct. 2228 (2022).

[11] 410 U.S. 113 (1973).

[12] 505 U.S. 833 (1992).

[13] *See*, *e.g.*, Gonzales v. Carhart, 550 U.S. 124, 159–60 (2007) (upholding the constitutionality of the Partial Birth Abortion Ban Act of 2003, and reflecting that "It is self-evident that a mother who comes to regret her choice to abort must struggle with grief more anguished and sorrow more profound when she learns, only after the event, what she once did not know: that she allowed a doctor to pierce the skull and vacuum the fast-developing brain of her unborn child, a child assuming the human form.").

"traditional family values," especially those of natalism and "biological" sex difference.[14]

The rise of anti-abortion legislation and restrictions on GAC are not isolated occurrences. These policies are closely linked within conservative political movements, legislative agendas, and court rulings.[15] A manifestation of this interconnection is found in the Eleventh Circuit's decision in *Eknes-Tucker v. Governor of Alabama* where transgender teens, their parents, and healthcare providers challenged Alabama's ban on GAC for minors.[16] In assessing whether parents have a Due Process right to consent to medical treatment of minors, the court turned to *Dobbs*: "To determine whether a right at issue is one of the substantive rights guaranteed by the Due Process Clause, courts must look to whether the right is deeply rooted in [our] history and tradition and essential to our Nation's scheme of ordered liberty."[17] The Eleventh Circuit concluded—as the Supreme Court did vis-à-vis abortion in *Dobbs*—that "the use of these medications in general—let alone for children—almost certainly is not 'deeply rooted' in our nation's history and tradition."[18] Accordingly, "[n]either the record nor any binding authority establishes that the 'right to treat [one's] children with transitioning medications subject to medically accepted standards' is a fundamental right protected by the Constitution."[19] The Sixth Circuit (relying on *Dobbs*) similarly rejected the parental Due Process right to consent to medical care of transgender minors.[20] This

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[14] For an analysis of the resistance of conservative lawmakers and courts to the concept of "sex assigned at birth" and the promotion of "biological sex," see Jessica Clarke, *Sex Assigned at Birth*, 122 COLUMB. L. REV. 1821 (2022). For an analysis of the backlash against the concept of "gender identity" in law and broader culture, see Ben-Asher, *Transforming Legal Sex*, *supra* note 7. For an analysis of the shifting classifications of sex in official state documents, see Ido Katri*, Transitions in Sex Reclassification Law*, 70 UCLA L. REV. 636 (2023).

[15] For example, Nebraska recently passed, in combined legislation "relating to public health and welfare," prohibitions on abortion ("Preborn Child Protection Act") and GAC for minors ("Let Them Grow Act"). Legis. B. 574, 108th Leg., 1st Sess. (Neb. 2023).

[16] Eknes-Tucker v. Governor of Ala., 80 F.4th 1205, 1210 (11th Cir. 2023). *See* Alabama's Vulnerable Child Compassion and Protection Act for its ban. Ala. Code § 26-26-4(a) ("no person shall engage in or cause" the prescription or administration of puberty blocking medication or cross-sex hormone treatment to a minor "for the purpose of attempting to alter the appearance of or affirm the minor's perception of his or her gender or sex, if that appearance or perception is inconsistent with the minor's sex.").

[17] *Eknes-Tucker*, 80 F.4th at 1220 (internal quotation marks omitted) (quoting *Dobbs*, 597 U.S. 215, 237–38 (2022)).

[18] *Id.*

[19] *Id*. at 1226 (applying rational basis review and concluding the district court erroneously reviewed the statute with heightened scrutiny and that the Parent Plaintiffs' likelihood of success does not justify a preliminary injunction).

[20] L.W. *ex rel.* Williams v. Skrmetti, 83 F.4th 460, 473 (6th Cir.) ("This country does not have a 'deeply rooted' tradition of preventing governments from regulating the medical profession in general or certain treatments in particular, whether for adults or their children."), *cert. dismissed in part sub nom.* Doe v. Kentucky, 144 S. Ct. 389 (2023).

interpretation of "ordered liberty" undermines the rights of pregnant people to bodily autonomy and of parents to support a minor's gender identity.

A few words on terminology. First, regret can be a vague concept subject to a variety of definitions. We define it simply as the backward-looking preference that "things should have been otherwise."[21] Regret can also be understood by contrast to its inverse, "affirmation."[22] To affirm a decision or event "is to prefer on balance that [the past] should have the features it actually had."[23] Second, although conservative media, politicians, and lawmakers often refer to individuals who decide to discontinue GAC as "detransitioners," this Article refers to them as those who decided to desist gender-affirming care.

The Article proceeds in three main parts. Part I explores the role of regret in state laws that restrict or ban access to GAC for minors, and the judicial treatment of those laws. Part II considers state abortion restrictions and bans, and the judicial treatment of those laws. Part III analyzes how the concept of regret is used by conservative thinktanks, politicians, and lawmakers to promote "traditional family values," especially involving natalism, traditional gender norms, and "biological" sexual difference. This Part also considers two other choices—the choice to have children and the choice to be childless. It contrasts regret narratives in these two contexts with those in the GAC and abortion contexts to reveal the work that regret is doing for anti-GAC and anti-abortion movements.

I. BANNING GENDER-AFFIRMING CARE

It is unusual for individuals to regret GAC. Available data from medical experts reveals two key findings. First, the phenomenon of desisting GAC among transgender teen and youth is infrequent.[24] Second, when it occurs, it often involves

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[21] R. JAY WALLACE, THE VIEW FROM HERE: ON AFFIRMATION, ATTACHMENT, AND THE LIMITS OF REGRET 6 (2013). We focus almost exclusively on what philosophers call "agent-regret," meaning regret about decisions and actions over which the regretter had control. *See* Bernard Williams, *Moral Luck*, MORAL LUCK PHILOSOPHICAL PAPERS 1973–1980 20, 27 (1981). This definition excludes a broad range of regret feelings that may relate general to the state of the world or past events that the regretter wishes did not occur but had no control over. *Id.*

[22] WALLACE, *supra* note 21, at 5.

[23] *Id*.

[24] *See* Marci L. Bowers, Opinion, *What Decades of Providing Trans Health Care Have Taught Me*, N.Y. TIMES (April 1, 2023), https://www.nytimes.com/2023/04/01/opinion/trans-healthcare-law.html [https://perma.cc/7ULU-7NZ4]; Jen Christensen, *Transgender and Nonbinary Patients Have No Regrets About Top Surgery, Small Study Finds*, CNN (Aug. 9, 2023, 3:48 PM), https://www.cnn.com/2023/08/09/health/top-surgery-no-regrets-transgender-nonbinarystudy/index.html [https://perma.cc/4VQW-BCH9] (discussing Lauren Bruce, Alexander N. Khouri, Andrew Bolze, Maria Ibarra, Blair Richards, Shokoufeh Khalatbari, Gaines Blasdel, Jennifer B. Hamill, Jessica J. Hsu, Edwin G. Wilkins, Shane D. Morrison and Megan Lane); *Long-Term Regret and Satisfaction with Decision Following Gender-Affirming Mastectomy*, JAMA SURGERY, Oct. 2023, at 1070–77 ("Of the

a range of complicated factors that cannot be easily reduced to regret.[25] According to Dr. Marci Bowers, a gynecologic and reconstructive surgeon and the president of the World Professional Association for Transgender Health ("WPATH"), there is a consensus among experts that gender-affirming care, including hormones and surgeries "improves the well-being of transgender people," and that "regret — a decision to either stop treatment or express unhappiness about one's decision to transition socially, medically or surgically — became even less common as surgical quality and social support improved."[26] A 2021 study reveals that "fewer than 1 percent of those who have received gender-affirming surgery say they regret their decision to do so, a much lower rate than has been reported for more common medical interventions like plastic surgery and orthopedic care."[27]

Conservative politicians and lawmakers have questioned the credibility of these studies, positing that they rely too heavily on self-reports without attention to those

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participants, 139 – nearly 60% – answered the survey accurately and returned it to the researchers. Their median Satisfaction With Decision Scale score was 5 on a 5-point scale, indicating the highest possible level of satisfaction. The median Decision Regret Scale score was 0 on a 100-point scale, meaning not a single patient regretted their choice to have the surgery."); Lindsey Tanner, *How Common Is Transgender Treatment Regret, Detransitioning?*, AP NEWS (Mar. 5, 2023, 6:55 AM), https://apnews.com/article/transgender-treatment-regret-detransition-371e927ec6e7a24cd9c77b5371c6ba2b [https://perma.cc/R8X4-PJWH] ("Some studies suggest that rates of regret have declined over the years as patient selection and treatment methods have improved. In a review of 27 studies involving almost 8,000 teens and adults who had transgender surgeries, mostly in Europe, the U.S and Canada, 1% on average expressed regret."); K.R. MacKinnon, F. Ashley, H. Kia, J.S.H. Lam, Y. Krakowsky & L.E. Ross, *Preventing Transition "Regret": An Institutional Ethnography of Gender-Affirming Medical Care Assessment Practices in Canada*, SOC. SCI. & MED., Oct. 2021, at 1, 7–8 ("[D]issatisfaction with surgical results, transition regret, and detransition are all conceptually and materially discrete outcomes"—"regret is an 'exceedingly rare' outcome . . . [and] evidence suggests that many people who detransition do so only temporarily and their trans identities often persist even whilst discontinuing gender transition (or their gender identities may shift dynamically).").

[25] *See* Bowers, *supra* note 24.

[26] *Id.*

[27] *Id.* Bowers also mentions a separate survey of over 27,000 adults that found that those who stop gender-affirming care do so for a range of factors (family pressure, financial reasons, loss of access to care, etc.), and "not because they had been misdiagnosed or their gender identities had changed." *Id. See also* Kristina R. Olson, Lily Durwood, Rachel Horton, Natalie M. Gallagher & Aaron Devor*, Gender Identity 5 Years After Social Transition,* PEDIATRICS, Aug. 2022, at 1, 3–6 (tracking the gender identities of youth—317 in total—an average of five years after their initial social transitions). The Olson et al. study found that "most youth identified as binary transgender youth (94%), including 1.3% who retransitioned to another identity before returning to their binary transgender identity. A total of 2.5% of youth identified as cisgender and 3.5% as nonbinary." *Id.* The researchers also found that a later cisgender identification was more common amongst those whose initial social transition was before the age of six, and that in those cases the retransition often occurred before the age of ten. *Id.*

who may choose not to report regret.[28] These politicians and lawmakers have cited instead anecdotal regret stories to justify restrictions on access to care. This Part begins by investigating those restrictions, showing how they rest on prevention of future regret. Next, it considers how these laws expand potential tort liability of medical health professionals who provide gender affirming care.

A. Preventing Future Regret: A State Interest in Restricting GAC

In 2023, state legislatures introduced 185 bills aiming to restrict transgender healthcare access, with many imposing stringent guidelines or outright bans on GAC for minors.[29] As of January of 2024, twenty-three states have enacted laws or policies limiting youth access to GAC.[30] Regret is a central theme in a national legislative campaign to ban GAC for minors. Advocates for the Missouri Save Adolescents from Experimentation ("SAFE") Act, for instance, cited regret testimonies from individuals like Chloe Cole, who had desisted GAC.[31]

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[28] *See*, *e.g.*, Pamela Paul, *As Kids, They Thought They Were Trans. They No Longer Do*, N.Y. TIMES (Feb. 2, 2024), https://www.nytimes.com/2024/02/02/opinion/transgender-children-gender-dysphoria.html [https://perma.cc/CH8M-QXBQ].

[29] *See Tracking the Rise of Anti-Trans Bills in the U.S.*, TRANS LEGISLATION TRACKER, https://translegislation.com/learn [https://perma.cc/2RKW-22MP] (last visited Feb. 27, 2024).

[30] *See*, *e.g.*, S.B. 184, 2022 Leg., Reg. Sess. (Ala. 2022); H.B. 1570, 2022 Leg., Reg. Sess. (Ark. 2021); S.B. 1238, 2022 Leg., Reg. Sess. (Ariz. 2022); S.B. 254, 2022 Leg., Reg. Sess. (Fla. 2022) (temporarily blocked in part); S.B. 140, 2022 Leg., Reg. Sess. (Ga. 2023) (in effect) (stating that the following "irreversible procedures or therapies" shall not be performed in a licensed institution "on a minor for the treatment of gender dysphoria": "Sex reassignment surgeries, or any other surgical procedures, that are performed for the purpose of altering primary or secondary sexual characteristics"); S.B. 14, 2022 Leg., Reg. Sess. (Tex. 2022) (prohibiting physicians and healthcare providers from providing gender-affirming care to youth, including puberty blockers, hormone therapy, and surgeries); S.B. 49, 102nd Gen. Assemb., Reg. Sess. (Mo. 2023) ("[N]o health care provider shall perform gender transition surgeries on any minor. . . . no health care provider shall prescribe or administer cross-sex hormones or puberty-blocking drugs to a minor for a gender transition . . . ."); H.B. 1570, 2021 Leg., Reg. Sess. (Ark. 2021). For a tracker of these bans, see Lindsey Dawson & Jennifer Kates, *Policy Tracker: Youth Access to Gender Affirming Care and State Policy Restrictions* KFF, (Jan. 31, 2024), https://www.kff.org/other/dashboard/gender-affirming-care-policy-tracker/ [https://perma.cc/X856-C794].

[31] Jill Carter, *Senator Jill Carter's Capitol Report #4*, MO. SEN., https://www.senate.mo.gov/Media/NewsDetails/755 [https://perma.cc/6Z6T-Q87P] ("I presented Senate Bill 164, the Save Adolescents from Experimentation (S.A.F.E.) Act, to the Senate Emerging Issues Committee on Feb. 14. . . . Senate Bill 164 would prevent children from being subjected to hormone therapy or life-altering sex change surgical procedures before the age of 18. My colleagues and I held a press conference with 18-year-old Chloe Cole and 21-year-old Luka Hein . . . . Chloe and Luka's stories are incredibly moving. As minors, Chloe and Luka both endured double mastectomy surgeries and hormone treatment. [They] both regretted these decisions, detransitioned and are still suffering from the harm these surgeries and hormones caused.").

Interestingly, Georgia's legislature acknowledges the absence of comprehensive studies tracking the long-term satisfaction or regret among those who underwent gender-related medical care as children.[32] Nonetheless, it cites rising anecdotal evidence of regret and permanent physical harm associated with such treatments to support a ban on GAC for minors.[33]

Pointing to the lack of evidence, several courts have rejected arguments justifying bans on regret-prevention grounds. For example, in *Koe v. Noggle*, a district court in Georgia imposed a preliminary injunction blocking legislation that had relied on the risk of future regret as an incentive to ban GAC.[34] The court reasoned that the state demonstrated "little in the way of reliable evidence of desistance or regret in those who would qualify for hormone therapy pursuant to the applicable standard of care."[35] Another court blocked an Arkansas ban on GAC for minors after lawmakers cited "detransitioner" testimony that Christian spiritual awakening sparked their regret.[36] The court found the ban likely unconstitutional and dismissed the state's reliance on the risk of future regret as baseless speculation.[37] A federal district court in Florida also dismissed reliance on regret in

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[32] S.B. 140, 157th Gen. Assemb., Reg. Sess. (Ga. 2023) (banning performing any procedures on a minor, including surgeries and hormone replacement therapy). The bill states: "No large-scale studies have tracked people who received gender-related medical care as children to determine how many remained satisfied with their treatment as they aged and how many eventually regretted transitioning." *Id.* § 1(5).

[33] *Id.* ("[T]he General Assembly is aware of statistics showing a rising number of such individuals who, as adults, have regretted undergoing such treatment and the permanent physical harm it caused . . . .").

[34] Koe v. Noggle, No. 1:23-CV-2904-SEG, 2023 WL 5339281 (N.D. Ga. Aug. 20, 2023). This case was decided one day prior to the Eleventh Circuit's judgment in *Eknes-Tucker v. Governor of Alabama*, 80 F.4th 1205 (11th Cir. 2023), which allowed Alabama's ban to go into effect.

[35] Koe, 2023 WL 5339281, at *20 (the court added that "when gender-affirming care involving hormone therapy is provided in accordance with the WPATH standards of care, rates of regret are low.").

[36] Arkansas Code § 20-9-1502 provides that "physician or other healthcare professional shall not provide gender transition procedures to any individual under eighteen (18) years of age." *See also* Tess Vrbin, *Federal Judge Strikes Down Arkansas Ban of Gender-Affirming Health Care for Transgender Youth*, ARK. ADVOCATE (June 20, 2023, 7:46 AM), https://arkansasadvocate.com/2023/06/20/judge-strikes-down-arkansas-ban-on-gender-affirming-health-care-for-transgender-youth/ [https://perma.cc/Y8AG-CCXS].

[37] *See* Brandt v. Rutledge, No. 4:21CV00450 JM, 2023 WL 4073727, at *36–*38 (E.D. Ark. June 20, 2023) (issuing permanent injunction was warranted because the act violated equal protection, parents' rights to substantive due process, and the First Amendment). *See id.* at *34 (internal citations omitted) ("The State argues that minors with gender dysphoria will desist with age. They contend that there is a significant risk of harm to a minor who elects to undergo gender hormone therapy or surgery because they will eventually identify with their sex assigned at birth and regret the treatment they sought as a minor . . . To the contrary, the evidence proved that there is broad consensus in the field that once adolescents reach the early stages of puberty and experience gender dysphoria, it is very unlikely they

laws that prohibit Medicaid payment for GAC.[38] These courts did not reject the premise that preventing regret might be a legitimate state interest. Instead, all three focused on the state's failure to establish adequate evidence of the potential for regret. And, as discussed in the introduction, as of this writing the Supreme Court, in Labrador, and two circuit courts, the Eleventh, in *Ecknes-Tuckner*, and the Sixth, in *Skrmetti*, have allowed GAC bans to go into effect.[39]

Among other areas of alleged concern, regret about future infertility is frequently raised in support of GAC bans. In Tennessee's ban on GAC for minors,[40] the ban at issue in *Skrmetti*,[41] the legislature warned that GAC "can lead to the minor becoming irreversibly sterile, having increased risk of disease and illness, or suffering adverse and sometimes fatal psychological consequences."[42] The Alabama Vulnerable Child Compassion and Protection Act ("V-Cap"), at issue in *Eknes-Tucker*, states a similar concern: "minors, and often their parents, are unable to

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will subsequently identify as cisgender or desist. The testimony confirmed that for most people gender identity is stable over their lifetime.").

[38] *See* Dekker v. Weida, No. 4:22CV325-RH-MAF, 2023 WL 4102243, at *18 (N.D. Fla. June 21, 2023) (holding that rule and statute were subject to intermediate scrutiny and motivated by discriminatory purposes in violation of the Equal Protection Clause; that risks attendant to using blockers and cross-sex hormones were not rational bases for enacting rule and statute); Doe v. Ladapo, No. 4:23CV114-RH-MAF, 2023 WL 3833848, at *14 (N.D. Fla. June 6, 2023) ("Fluidity is common prior to puberty but not thereafter. Regret is rare; indeed, the defendants have offered no evidence of any Florida resident who regrets being treated with GnRH agonists or cross-sex hormones.").

[39] *See supra* notes 8–9, 16–20 and accompanying text; Labrador v. Poe, 2024 WL 1625724 (Apr. 15, 2024) (granting stay "except as to the provision to the plaintiffs of the treatments they sought"); L.W. *ex rel.* Williams v. Skrmetti, 83 F.4th 460, 491 (6th Cir.) (holding that challenges to GAC bans in Kentucky and Tennessee likely would not succeed; transgender individuals were not a suspect class, rational basis review applied; and factor related to harm largely favored states opposing preliminary injunction.), *cert. dismissed in part sub nom.* Doe v. Kentucky, 144 S. Ct. 389 (2023); Eknes-Tucker v. Governor of Ala., 80 F.4th 1205, 1231 (11th Cir. 2023) (similarly staying a district court preliminary injunction and allowing Alabama's Vulnerable Child Compassion and Protection Act). Neither of these decisions engage directly with questions of regret.

[40] TENN. CODE § 68-33-101.

[41] L.W. *ex rel.* Williams v. Skrmetti, 83 F.4th 460, 468 (6th Cir.), *cert. dismissed in part sub nom* (holding that plaintiff's due process and equal protection challenge likely would not succeed; transgender individuals were not a suspect class, and factor related to harm largely favored states opposing preliminary injunction). Doe v. Kentucky, 144 S. Ct. 389 (2023); *but see* Doe v. Ladapo, No. 4:23CV114-RH-MAF, 2023 WL 3833848, at *12–*13) (N.D. Fla. June 6, 2023) ("There are legitimate concerns about fertility and sexuality that a child entering puberty is not well-equipped to evaluate and for which parents may be less-than-perfect decisionmakers. . . . There is a risk that a child later confronted with the bias that is part of our world will come to believe it would have been better to try to pass as cisgender. Risks attend many kinds of medical treatment, perhaps most . . .That there are risks of the kind presented here is not a rational basis for denying patients the option to choose this treatment.").

[42] *Id.* § 68-33-101(b).

comprehend and fully appreciate the risk and life implications, including permanent sterility, that result from the use of puberty blockers, cross-sex hormones, and surgical procedures."[43] Clinics treating transgender youth are, however, well-aware of the fertility risks involved in GAC, and conversations about fertility effects are a regular part of GAC for minors and adults.[44]

Conservative lawmakers in Congress have also cited potential future regret as a justification for proposed bans or restrictions on GAC for minors. On May 18, 2023, Senator J.D. Vance announced his intent to introduce legislation that would criminalize providing GAC to minors as a federal Class C felony, punishable by ten to twenty-five years in prison. The *Protect Children's Innocence Act* would block taxpayer funding for GAC procedures, ban coverage of the treatments from Affordable Care Act insurance plans, stop universities from providing instruction on GAC, and deem noncitizens who have performed GAC on a minor ineligible to receive visas or admittance to the United States. Vance declared, "With this legislation, we have an opportunity to save countless young Americans from a lifetime of suffering and regret."[45] Republican Congresswoman Marjorie Taylor Greene proposed a similar bill that "will make it illegal to perform any gender-affirming care on minors. This includes puberty blockers, hormone therapy, and sex-change surgeries."[46] As Greene explained, "Children who are not allowed to drive,

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[43] S.B. 184, 2022 Leg., Reg. Sess. (Ala. 2022).

[44] *See*, *e.g.*, Joshua Sterling & Maurice M. Garcia, *Fertility Preservation Options for Transgender Individuals*, 9 TRANSLATIONAL ANDROLOGY & UROLOGY S215, S215 (2020) ("Options for transwomen at any point in their transition range from simply providing a semen sample to be used with assistive reproductive techniques to experimental techniques involving testicular cryopreservation followed by *in vitro* initiation of spermatogenesis. Transmen before and after starting hormone therapy can pursue any assistive reproductive techniques available for ciswomen."); Jensen Reckhow, Hakan Kula & Samir Babayev, *Fertility Preservation Options for Transgender and Nonbinary Individuals*, 14 THERAPEUTIC ADVANCES IN ENDOCRINOLOGY & METABOLISM 1, 1 (2023) ("The methods available for fertility preservation depend on the patient's pubertal status and utilization of gender-affirming therapies, and counseling and delivery of these services are complex and require a multidisciplinary approach. . . . Fertility preservation is an active and exciting area of scientific discovery and offers a wealth of opportunities to improve the care of transgender and nonbinary individuals."). *See also* Beth A. Clark, *Narratives of Regret: Resisting Cisnormative and Bionormative Biases in Fertility and Family Creation Counseling for Transgender Youth*, 14 INT'L J. OF FEMINIST APPROACHES TO BIOETHICS 157, 158 (2021) (identifying "bionormativity," or the preference for parentage via genetics and gestation, as a concerning bias in transgender care). For additional discussion of fertility and GAC, see *infra* Part III.B.1 (arguing that one function of GAC bans is to promote natalism and traditional gender roles).

[45] Sabrina Eaton, *JD Vance Proposes Federal Ban on Gender Transition Care for Minors*, CLEVELAND NEWS (July 18, 2023, 1:15 PM), https://www.cleveland.com/news/2023/07/jd-vance-proposes-federal-ban-on-gender-transition-care-for-minors.html [https://perma.cc/GY4A-2VVH].

[46] *Congresswoman Marjorie Taylor Greene's Protect Children's Innocence Act Included in RSC Budget* (June 14, 2023), https://greene.house.gov/news/documentsingle.aspx?DocumentID=469 [https://perma.cc/5MQH-XKEM].

vote, or see an R-rated movie should not be allowed to make life-altering decisions that will forever alter their precious bodies."[47]

B. GAC Regret as Actionable Injury

Many of the GAC-restricting laws create future tort liability for GAC providers in the event that patients report regret about receiving medical care. These laws extend statutes of limitations for torts claims (sometimes for decades), recognize emotional harm as actionable in-and-of-itself, eliminate consent as a possible defense for physicians, or establish future negligence per-se claims against physicians based on statutory violations. For example, on March 2, 2023, several Republican senators introduced a bill that provides that a practitioner "who performs a gender-transition procedure on an individual who is less than 18 years of age shall . . . be liable to the individual if injured (including any physical, *psychological*, *emotional*, or physiological harms) by such procedure, related treatment, or the aftereffects of the procedure or treatment."[48] Furthermore,

> An individual covered by subsection (a) who receives a gender-transition procedure from a medical practitioner . . . may, not later than the day that is *30 years after the date* on which the individual turns 18 years of age, bring a civil action against such medical practitioner in a court of competent jurisdiction for—(1) declaratory or injunctive relief; (2) compensatory damages; (3) punitive damages; and (4) attorney's fees and costs.[49]

Senator Tom Cotton cited the risk of future regret as justification for this expansion of potential tort liability. He explained, "radical doctors in the United States perform dangerous, experimental, and even sterilizing gender-transition procedures on young kids, who cannot even provide informed consent. Our bill allows *children who grow up to regret these procedures to sue for damages*. Any doctor who performs these irresponsible procedures on kids should pay."[50]

Another example is Louisiana's ban, which went into effect in July 2023. This law provides that "a person who has been harmed as a result of [GAC] *with or without consent*, shall have a cause of action for damages in a court of competent jurisdiction."[51] It also clarifies that "Consent shall not operate as defense to a

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[47] *Id.*

[48] The Protecting Minor from Medical Malpractice Act of 2023, H.R. 1276, 118th Cong. (2023) (emphasis added).

[49] *Id.* (emphasis added).

[50] *Rubio, Cotton, Colleagues Introduce Legislation to Protect Minors from "Gender Reassignment" Surgery*, MARCO RUBIO U.S. SENATOR FOR FLORIDA (June 23, 2022), https://www.rubio.senate.gov/rubio-cotton-colleagues-introduce-legislation-to-protect-minors-from-gender-reassignment-surgery/ [https://perma.cc/K8T3-BBGC] (emphasis added).

[51] H.B. 648, 2023 Reg. Sess. (La. 2023) (emphasis added) (adding, "If a court finds that a person is entitled judgment pursuant to this Section, the court shall award damages,

petitioner's claim that is filed pursuant to this Section,"[52] establishes a long statute of limitations,[53] and recognizes a broad range of injuries for which damages would be available.[54] Other state legislatures have adopted similar strategies. Arkansas's SAFE Act provides that "a person may assert an actual or threatened violation of this subchapter as a claim or a defense in a judicial or administrative proceeding and obtain compensatory damages, injunctive relief, declaratory relief, or any other appropriate relief."[55] Those under eighteen may "bring an action throughout their minority . . . and may bring an action in their own name upon reaching majority at any time from that point until twenty years after reaching the age of majority."[56] The statute does not mention *any injury* that a plaintiff is required to show to recover from a medical provider. Real or alleged regret would seem to be enough to trigger liability even decades after medical treatment.[57] Indiana's GAC statute similarly establishes a private right of action for teens or their parents to "assert an actual or threatened violation of this chapter as a claim or defense in a judicial or administrative proceeding and may seek to obtain compensatory damages, injunctive relief, declaratory relief, or any other appropriate relief."[58] And

attorney fees, and all costs of the proceeding against the defendant for violation of this Part."). *Id.* at §1098.5.D(1). The law of informed consent "is intended to ensure that patients are not just the objects of medical practice but also free and willing participants." Pamela Laufer-Ukeles, *Reproductive Choices and Informed Consent: Fetal Interests, Women's Identity, and Relational Autonomy*, 37 AM. J.L. & MED 567, 577 (2011). Medical malpractice claims raising issues of informed consent can sound in either battery or negligence claims. *Id*. at 575–78 (describing the evolution and permutations of informed consent doctrine).

[52] H.B. 648, 2023 Reg. Sess. §1098.5.E (La. 2023).

[53] *Id.* §1098.5.B ("The cause of action for damages shall be commenced before the later of either of the following: (1) The lapse of a twelve-year liberative prescription once the minor reaches the age of majority. (2) Within three years from the time the person discovered or reasonably should have discovered that the injury or damages were caused by the violation.").

[54] *Id.* §1098.5.D(2) ("Damages awarded by the court pursuant to this Section may include but is not to be limited to damages for infertility or sterility that is suffered by the minor as a result of the acts prohibited by this Part.").

[55] ARK. CODE § 20-9-1504(b); *but see* Brandt v. Rutledge, No. 4:21CV00450 JM, 2023 WL 4073727, at *36–*38 (E.D. Ark. June 20, 2023) (holding that a permanent injunction was warranted because the act discriminated based on sex and violated equal protection, violated parents' rights to substantive due process and the First Amendment).

[56] ARK. CODE § 20-9-1504(c)(2).

[57] In addition, a private plaintiff under this statute is not required to exhaust available administrative remedies and is entitled to recover "reasonable attorneys' fees." *Id.* § 20-9-1504(d)–(e).

[58] IND. CODE § 25-1-22-16. The statute extends the time to sue for ten years after minority. *Id*. § 25-1-22-17 ("If an individual was less than eighteen (18) years of age when the cause of action for a violation of this chapter accrued, when the individual is eighteen (18) years of age or older, the individual may bring a cause of action at any time until the individual reaches twenty-eight (28) years of age."). The law does not require plaintiff to demonstrate an injury or exhaust administrative remedies. *Id.* § 25-1-22-18. A preliminary

Nebraska's ban provides that "an individual that received [GAC] while they were younger than nineteen years of age, or the parent or guardian of such individual, may bring a civil action for appropriate relief against the healthcare practitioner who performed the gender altering procedure."[59] This ban also does not clarify what damages would qualify for a successful lawsuit.[60]

Overall, these laws replace existing medical standards of care, establishing new standards for care of gender dysphoria (in minors) that strongly deter any provision of care at all.[61] The combination of new statutory presumptions of negligence or battery, broad definitions of injury (including emotional and psychological harm), long statutes of limitations, and the absence of a consent defense means that medical professionals who violate these laws can potentially be liable for battery or negligence *per se* or both.[62] These laws have already had a chilling effect on

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injunction against this law was issued in *K. C. v. Individual Members of Med. Licensing Bd. of Indiana*, No. 1:23-CV-00595-JPH-KMB, 2023 WL 4054086 (S.D. Ind. June 16, 2023) (holding that plaintiffs were likely to succeed on merits of equal protection claim, physicians were likely to succeed on First Amendment claim, plaintiffs demonstrated irreparable harm in absence of preliminary injunction; and balance of harms favored issuance of preliminary injunction.).

[59] Legis. B. 574, 108th Leg., 1st Sess. § 20 (Neb. 2023) (adding that "[a]ppropriate relief under this Section includes actual damages and reasonable attorney's fees [and the action shall] be brought within two years after discovery of damages.").

[60] *See also* S.B. 538, 19th Gen. Assemb., 2023 Sess. (Iowa 2023) ("[A]n action under this Section may be commenced, and relief may be granted, in a judicial proceeding without regard to whether the person commencing the action has sought or exhausted available administrative remedies."); S.B. 150, 2023 Leg., Reg. Sess. (Ky. 2023) ("Any civil action to recover damages for injury suffered as a result of [providing GAC] may be commenced before the later of: (a) The date on which the person reaches the age of thirty years; or (b) Within three years from the time the person discovered or reasonably should have discovered that the injury or damages were caused by the violation . . . .").

[61] *See generally* WPATH, THE WORLD PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH: STANDARDS OF CARE FOR THE HEALTH OF TRANSEXUAL, TRANSGENDER, AND GENDER NONCONFORMING PEOPLE (7th ed. 2012), https://www.wpath.org/publications/soc [https://perma.cc/69ZH-5GCZ] (outlining contemporary medical treatment standards). In medical malpractice actions, "[t]he applicable standard of care is that employed by the medical profession generally and not what one individual doctor thought was advisable and would have done under the circumstances." McNabb v. Landis, 479 S.E.2d 194, 196 (Ga. Ct. App. 1996). *See* Mayo v. McClung, 64 S.E.2d 330 (Ga. Ct. App. 1951) (the standard of care is "not a question of what one individual doctor thought was advisable."); Slack v. Moorhead, 262 S.E.2d 186, 188 (Ga. Ct. App. 1979) (the standard of care is "not what a particular doctor would do in the circumstances"); 15 GA. JUR. § 36:37 (2024).

[62] The doctrine of negligence *per se* allows a plaintiff to prove the duty and breach elements of a negligence claim by simply showing that the defendant committed or omitted a specific act that is prohibited or required by law. *See*, *e.g.*, Jacobs v. Great S. Shopping Ctr., LLC, 2024-Ohio-1180. Not all violations of a statute or ordinance will constitute negligence *per se*, however. Courts will consider factors such as whether the injured person

medical providers who can no longer support their young patients without threat of significant tort liability.[63]

II. BANNING ABORTION

Data suggests that abortion regret rates are quite low. A 2020 study tracking people from the time of an abortion over five years found that the vast majority of abortion recipients affirmed their choice.[64] Nevertheless, anti-abortion advocates have repeatedly and successfully sought to give regret legal and political meaning. This Part turns to that effort, tracing abortion regret narratives from *Roe v. Wade* (1973) to *Dobbs v. Jackson Women's Health Org.* (2022) and beyond, underscoring stark parallels in legal rhetoric and strategy between anti-abortion and anti-GAC campaigns.

A. Preventing Future Regret: A State Interest in Restricting Abortion

Adopting a core argument of the post-*Roe* anti-abortion movement, the Supreme Court in *Gonzales v. Carhart* (2007) recognized preventing potential future regret as a legitimate state interest justifying abortion regulation.[65] In *Carhart*, the Court upheld the constitutionality of a federal law banning intact dilation and extraction ("D&E"), a form of late term abortion. In the majority opinion, Justice Kennedy justified the decision in part on the ground that the ban protected those who

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falls within the class of persons the statute was intended to protect, and whether the harm complained of was the harm the statute was intended to guard against. A plaintiff must also demonstrate a causal connection between the negligence per se and the injury. Mercy Hous. Ga. III, L.P. v. Kaapa, 888 S.E.2d 346 (Ga. Ct. App. 2023).

[63] *See*, *e.g.*, Jim Salter & Geoff Mulvihill, *Some Providers Are Dropping Gender-Affirming Care for Kids Even in Cases Where It's Legal*, AP NEWS (Sept. 23, 2023), https://apnews.com/article/genderaffirming-care-providers-treatment-parents-liability-45012ee33f078eeea7871e622a5eee1d [https://perma.cc/HG3T-NHBY].

[64] Corinne H. Rocca, Goleen Samari, Diana G. Foster, Heather Gould & Katrina Kimport, *Emotions and Decision Rightness over Five Years Following an Abortion: An Examination of Decision Difficulty and Abortion Stigma*, 248 SOCIAL SCI. & MED. 1, 4 (2020) (finding that while about half of the participants found that it was difficult to choose an abortion only about six percent had negative feelings about the abortion five years later). These researchers found that one week after an abortion seventeen percent of study participants felt mostly negative emotions about the abortion (including some combination of sadness, anger, guilt, and regret), but less than three percent felt it was the wrong decision. *Id*. at 3, 6.

[65] Gonzales v. Carhart, 550 U.S. 124 (2007) (upholding the constitutionality of the Partial Birth Abortion Ban Act of 2003). For a history of the regret narrative in the anti-abortion movement, see J. SHOSHANNA EHRLICH & ALESHA E. DOAN, ABORTION REGRET: THE NEW ATTACK ON REPRODUCTIVE FREEDOM (2019) (tracing the narrative back to the nineteenth century anti-abortion movement and citing the role of "Crisis Pregnancy Centers," religious quasi-medical pregnancy-related service providers, in entrenching the narrative in the modern anti-abortion movement).

might later come to regret the decision to end a pregnancy. Justice Kennedy offered two interrelated arguments about the potential for abortion regret. The first relates to the abortion itself:

> [R]espect for human life finds an ultimate expression in the bond of love the mother has for her child. The Act recognizes this reality as well. Whether to have an abortion requires a difficult and painful moral decision. While we find no reliable data to measure the phenomenon, it seems unexceptionable to conclude some women come to regret their choice to abort the infant life they once created and sustained. Severe depression and loss of esteem can follow.[66]

To support this statement, Justice Kennedy relied on an amicus brief, submitted by Sandra Cano, the named plaintiff in *Doe v. Bolton*, the companion case to *Roe v. Wade*. Although Cano never received an abortion, she lamented her role in *Roe*, claiming that she was pressured to pursue an abortion that she did not want and that she was manipulated into serving as the named plaintiff in the case.[67] Cano, joining with 180 women "injured by abortion," argued that abortion has serious psychological consequences and that those signing on to the brief experienced "depression, suicidal thoughts, flashbacks, alcohol and/or drug use, promiscuity, guilt, and secrecy. Each of them made the 'choice' to abort their baby, and they have regretted their 'choices.'"[68] Cano estimated that around one in ten women receiving abortions experience some or all these negative psychological consequences.[69]

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[66] *Id.* at 159 (citations omitted).

[67] *See generally* Affidavit of Sandra Cano, Cano v. Bolton, 2005 WL 3881370 (N.D. Ga. 2005) (No. 13676).

[68] Brief of Sandra Cano et al. as Amicus Curiae Supporting Petition, Gonzales v. Carhart, 550 U.S. 124, at 22–24 (2007).

[69] *Id.* at 25. Norma McCorvey, who was Jane Roe in *Roe v. Wade*, also became an anti-abortion activist and filed a lawsuit seeking to reopen the case on the ground that many women, years after their abortions, were finally reckoning with the psychological harm that they caused. *See* Jeannie Suk, *The Trajectory of Trauma: Bodies and Minds of Abortion Discourse*, 110 COLUM. L. REV. 1193, 1231–32 (2010) (describing this history). These legal efforts by Cano and McCorvey were part of a broader shift in the anti-abortion movement to situate abortion restrictions as protective of women. *See* Reva B. Siegel, *The Right's Reasons: Constitutional Conflict and the Spread of Woman-Protective Antiabortion Argument*, 57 DUKE L.J. 1641, 1688 (2008) (tracing this history, focusing in particular on anti-abortion legislation in South Dakota in 2006 and 2008 that relied on an investigation of post-abortion regret and trauma). *See also* Khiara M. Bridges, *Capturing the Judiciary:* Carhart *and the Undue Burden Standard*, 67 WASH. & LEE L. REV. 915, 930 (2010) (observing that "the Court's citation to the 'self-evident' fact that a woman will suffer more if she learns that her abortus resembled a child reveals that, also a part of this metaphysics, is the belief that the more the woman approximates motherhood, the more damage the procedure inflicts on her. Conversely, the less the object of the procedure approximates a child, the less the woman approximates motherhood, and as a result, the less the damage that is inflicted by the abortion.").

Justice Kennedy's second use of regret was more narrowly related to the subject of *Carhart*, the intact D&E procedure. He explained,

> It is self-evident that a mother who comes to regret her choice to abort must struggle with grief more anguished and sorrow more profound when she learns, only after the event, what she once did not know: that she allowed a doctor to pierce the skull and vacuum the fast-developing brain of her unborn child, a child assuming the human form.[70]

He posited that "[i]n a decision so fraught with emotional consequence some doctors may prefer not to disclose details of the means that will be used, confining themselves to the required statement of risks the procedure entails."[71] Justice Kennedy concluded that many pregnant people will not understand the nature of the procedure at the time it is performed and expressed concern that they will later be disturbed by it.[72] Under *Carhart*, the potential for future regret justifies narrowing the range of procedures available for late term abortions.[73]

Carhart broadened what the Court had previously considered legitimate state interest in regulating abortion. While *Casey* and *Roe* identified state interest in

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[70] *Carhart*, 550 U.S. at 159–60.

[71] *Id.* at 159.

[72] Although *Casey* did not speak overtly of regret, the plurality decision foreshadows this rationale. *See* Planned Parenthood v. Casey, 505 U.S. 833, 1002 (1992). In *Casey*, the court upheld a Pennsylvania law mandating disclosure, among other things, of the gestational age of the embryo or fetus. The plurality concluded that "women considering an abortion would deem the impact on the fetus relevant, if not dispositive of the decision." *Id.* at 882. To the plurality then, the disclosure "ensure[d] that a woman apprehend the full consequences of her decision, . . . further[ing] a legitimate purpose of reducing the risk that a woman may elect an abortion, only to discover later, with devastating psychological consequences, that her decision was not fully informed." *Id*. For critiques of this use of regret, focusing on its misogyny and paternalism, see Susan Frelich Appleton, *Reproduction and Regret*, 23 YALE J.L. & FEMINISM 255, 268 (2011) (arguing that this view of regret relies on gender stereotypes about women as "ignorant, naïve, and unable to elicit pertinent information from health care providers, as well as emotionally fragile if not psychologically unfit" (internal quotation marks omitted)). Justice Ginsburg also makes this same argument in her dissent to *Carhart*. *See* Carhart, 550 U.S. at 183–85 (Ginsburg, J., dissenting).

[73] For other scholarly critiques of the use of regret in *Carhart*, *see*, *e.g.*, Siegel, *supra* note 69, at 1688; Rebecca Dresser, *From Double Standard to Double Bind: Informed Choice in Abortion Law*, 76 GEO. WASH. L. REV. 1559 (2008); Maya Manian, *The Irrational Woman: Informed Consent and Abortion Decision-Making*, 16 DUKE J. GENDER L. & POL'Y 223 (2009); Chris Guthrie, Carhart*, Constitutional Rights, and the Psychology of Regret*, 81 S. CAL. L. REV 877 (2008) (arguing that *Carhart* misunderstands the fundamental nature of regret and its role in human decision-making); Jody Lyneé Madeira, *Aborted Emotions: Regret, Relationality, and Regulation*, 21 MICH. J. GENDER & L. 1 (2014).

protecting maternal health, including mental health,[74] and "potential life," *Carhart* introduced considerations related to "the integrity and ethics of the medical profession" and the "ethical and moral concerns" of society.[75] Justice Kennedy justified invocation of both by reference to regret that those who choose abortion may experience. Regret, in *Carhart*, demonstrates the grave moral risk associated with abortion generally and intact D&E in particular.[76] *Carhart*'s logic intertwines concerns over future regret with concerns over the immorality of abortion. In *Dobbs*, the Supreme Court did not expressly invoke regret.[77] Chief Justice Roberts' concurrence, however, relied heavily on *Carhart*. Roberts cited the three-page passage of *Carhart* in which the regret argument is laid out. He observed that *Carhart* expanded the legitimate grounds for state regulation of abortion to include a "broader array of interests, such as . . . maintaining societal ethics, and preserving the integrity of the medical profession."[78] The majority also repeated a similar list of legitimate state interests, citing *Carhart*.[79]

Since *Dobbs*, the risk of future regret has continued to play a meaningful role in shaping anti-abortion laws and policies. For instance, following Florida's 2023

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[74] In *Roe*, the Supreme Court cited to mental health concerns as a reason to prohibit outright abortion bans, reasoning that "Maternity, or additional offspring, may force upon the woman a distressful life and future. Psychological harm may be imminent." Roe v. Wade, 410 U.S. 113, 153 (1973). *See* Suk, *supra* note 69, at 1214–23 (describing this reasoning as a precursor to *Carhart* because, although it reaches it the opposite result, it establishes precedent for the idea that "women's psychological trauma is a distinct danger in which the state is interested").

[75] *Carhart*, 550 U.S. at 157–58.

[76] *Id.* at 160 ("The State's interest in respect for life is advanced by the dialogue that better informs the political and legal systems, the medical profession, expectant mothers, and society as a whole of the consequences that follow from a decision to elect a late-term abortion.").

[77] *See generally* Dobbs v. Jackson Women's Health Org., 597 U.S. 215 (2022). A number of amicus briefs relied heavily on regret arguments, including numerous anecdotes from individuals expressing regret about their own abortions. Brief for Advancing American Freedom, Inc. et. al. as Amici Curiae Supporting Petitioners, Dobbs v. Jackson Women's Health Org., 597 U.S. 215 (No. 19-1392) at *20–21; Brief for Priests for Life as Amicus Curiae Supporting Petitioners, Dobbs v. Jackson Women's Health Org., 597 U.S. 215 (2022) (No. 19-1392) at *11–12; Brief for 375 Women Injured by Second and Third Trimester Late Term Abortions and Abortion Recovery Leaders as Amici Curiae Supporting Petitioners, Dobbs v. Jackson Women's Health Org., 597 U.S. 215 (2022) (No. 19-1392) at *14–15.

[78] Dobbs v. Jackson Women's Health Org., 597 U.S. 215, 350–52 (2022) (Roberts, C.J. concurring) (citing *Gonzales v. Carhart*, 550 U.S. 124, 157–60 (2007)); *see supra* notes 66–76 (analyzing and quoting from this three-page passage of Carhart).

[79] Although the majority rejects Chief Justice Roberts's preferred disposition of the case, they seem to agree with his assessment of the legitimate state interests at stake. *Dobbs*, 550 U.S. at 301 (citing *Carhart*, 550 U.S. at 157–58, which includes the discussion of legitimate state interests). The majority neither discusses regret nor cites directly to the passage of *Carhart* discussing regret but given that the regret narrative was fundamental to *Carhart*'s conclusions regarding what qualified as legitimate state interests, the majority's reliance on *Carhart* is meaningful.

passage of a law criminalizing abortion after fifteen weeks, the state posted the following passage on its website:

> "The bill that the Governor is signing will save babies. This bill will save mothers and fathers from the lifetime of pain that I have suffered, and for that I am so grateful," said Pro-Life Advocate Heather Grall Barwick. "I made a mistake [to get an abortion] at 21 years old that I cannot change but I can let others learn from my mistake. I choose to share my story for my 6-year-old daughter and my 19 nieces and nephews. I chose to speak up for the women who say abortion does not cause mental distress and the women in their 70s who had abortions who just now are able to testify on the regret they have held for 40 years."[80]

Barwick implies that statements from women who claim not to regret their abortions should not be taken seriously.[81] Instead, these women are not yet willing or able to speak of their regret.[82] Here, the State of Florida identifies the desire to protect pregnant people from potential regret as a key function of a legislation that limits abortion in the state.

The risk of future regret is a key component of informed consent laws that anti-abortion advocates have promoted over several decades. At the time *Carhart* was decided, twenty-three states had already passed laws containing abortion-unique informed consent requirements.[83] These requirements serve at least two roles in the

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[80] *What They Are Saying: Governor Ron DeSantis Signs Bill to Protect the Lives of Florida's Most Vulnerable*, RON DESANTIS (Apr. 14, 2022), https://www.flgov.com/2022/04/14/what-they-are-saying-governor-ron-desantis-signs-bill-to-protect-the-lives-of-florid as-most-vulnerable/ [https://perma.cc/659Q-MVAM] (quoting a pro-life advocate in support of Florida's fifteen-week abortion ban).

[81] *Id.*

[82] *See* Suk, *supra* note 69, at 1232 (recounting a very similar story from other anti-abortion activists); *see infra* note 153 and accompanying text (elaborating on the rhetorical use of this phenomenon).

[83] Rachel Benson Gold & Elizabeth Nash, *State Abortion Counseling Policies and the Fundamental Principles of Informed Consent,* GUTTMACHER INST. (Nov. 8, 2007), https://www.guttmacher.org/gpr/2007/11/state-abortion-counseling-policies-and-fundamental-principles-informed-consent [https://perma.cc/WE9Q-8LYS]. Legal scholars have criticized these laws on a number of grounds, including as a form of "abortion exceptionalism," special legal treatment for abortion by contrast to other types of medical care. Manian, *supra* note 73, at 227 (describing the divergence of informed consent law in the abortion context). Legal Scholar Ian Vandewalker has referred to this type of disclosure law as "biased counseling," "placing requirements on providers and patients that are more demanding than for another medical procedure [in order to] discourage women from choosing to terminate their pregnancies." Ian Vanderwalker, *Abortion and Informed Consent: How Biased Counseling Laws Mandate Violations of Medical Ethics*, 19 MICH. J. OF GENDER & L. 1, 13 (2012). *See also id.* (identifying a range of laws including those that require specific statements, often false or misleading, on a broader range of topics from

anti-abortion movement. First, they seek to dissuade those seeking abortions from going through with them.[84] Second, they have long served as part of a broader incrementalist strategy to undermine the right to an abortion.[85] Many informed consent laws were modeled on the Pennsylvania statute that the Supreme Court upheld in *Casey*, which included abortion-specific informed consent requirements such as a twenty-four-hour waiting period.[86] These laws included features such as waiting periods,[87] mandatory descriptions of all common abortion procedures (not just the procedure sought), descriptions of fetal development throughout pregnancy, and either a requirement to provide an ultrasound or to direct the pregnant person to where they might get an ultrasound.[88]

A common feature of anti-abortion informed consent laws is the mandate to disclose the risk of psychological harm.[89] Psychological harm is a stand in for

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including the mental health risks of abortion to fetal pain). For another example of malpractice-related abortion exceptionalism, see *K.P. v. LeBlanc*, 729 F.3d 427, 442–43 (5th Cir. 2013) (upholding a Louisiana law excluding abortion providers from a state malpractice insurance fund).

[84] *See* Katarzyna Kordas, *A Hurdle Too High: The Unconstitutionality of Mandatory Ultrasounds Under* Casey*'s Undue Burden Standard*, 23 CARDOZO J. GENDER & L. 367, 371–74 (2017) (exploring the purposes behind mandatory ultrasound laws).

[85] Danielle Lang, *Truthful but Misleading? The Precarious Balance of Autonomy and State Interests in* Casey *and Second-Generation Doctor-Patient Regulation*, 16 U. PA. J. CONST. L. 1353, 1376–83 (2014); Kathryn A. Eidmann, Acuna *and the Abortion Right: Constraints on Informed Consent Litigation*, 20 COLUM. J. GENDER & L. 262, 271–74 (2011).

[86] Planned Parenthood v. Casey, 505 U.S. 833, 1002 (1992). *Casey* established the undue burden test that governed review of abortion restrictions until the case was overturned by *Dobbs* in 2022. Manian, *supra* note 73, at 247–49 (characterizing *Casey* as a deviation from earlier Supreme Court precedent that was far more skeptical of abortion-specific informed consent mandates).

[87] A waiting period is the duration of time after the patient has received mandated disclosures and before the procedure can be performed. Many states require that the initial disclosure be given in person, meaning that the waiting period necessitates a second visit to the doctor. *Counseling and Waiting Periods for Abortion*, GUTTMACHER INST. (Aug. 30, 2023), https://www.guttmacher.org/state-policy/explore/counseling-and-waiting-periods-abortion [https://perma.cc/8GVP-ZWWJ] [hereinafter GUTTMACHER INST., *Counseling and Waiting Periods for Abortion*].

[88] *State Policy on Informed Consent for Abortion*, GUTTMACHER INST. (2007), https://www.guttmacher.org/sites/default/files/graphics/gpr1004/gpr100406t1.pdf [https://perma.cc/37CN-DHLZ] [hereinafter GUTTMACHER INST., *State Policy*]; Nadia N. Sawicki, *Tort Law Implications of Compelled Physician Speech*, 97 IND. L.J. 939, 942–47 (2022) (summarizing these laws and explaining how they are different from traditional common law informed consent doctrine).

[89] Katherine Shaw & Alex Stein, *Abortion, Informed Consent, and Regulatory Spillover*, 92 IND. L.J. 1, 11 (2016). *See also* GUTTMACHER INST., *State Policy*, *supra* note 88.

regret.[90] Laws mandating disclosure often force the spread of what many have characterized as misinformation about the nature of the psychological risks.[91] Others have pointed out that these disclosure requirements could cause actual regret by increasing abortion recipient perceptions of abortion stigma.[92] Together, *Casey* and *Carhart* enabled state legislatures to rely on risks of coercion and psychological trauma to constrain abortion access.[93] Preventing abortion regret is a legislative interest prevalent in informed consent laws, and courts have regularly upheld them.[94]

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[90] Alesha Doan, Carolina Costa Candal & Steven Sylvester, *"We Are the Visible Proof": Legitimizing Abortion Regret Misinformation Through Activists' Experiential Knowledge*, 40 LAW & POL'Y 33, 33 (2017) (describing how these laws "conceptualize [regret] as a form of posttraumatic stress disorder").

[91] *Id*. at 35–37 (tracking the use of regret misinformation in state abortion disclosure laws).

[92] Appleton, *supra* note 72, at 316–17 (identifying a variety of ways in which public policy might generate regret of adoption and abortion decisions); *see* Rocca et al., *supra* note 64 (finding that regret increases with perception of abortion stigma).

[93] In *Carhar*t, Justice Ginsburg, dissenting, proposed that any true concern regarding consent should be addressed not by banning the procedure but by mandating additional disclosures to patients. *See* Suk, *supra* note 69, at 1236–37 (positing that this remedy was unsatisfying to Justice Kennedy because the risk of trauma was too high to be bearable). Since *Carhart*, six more states have passed such laws and many states have added additional requirements to laws already on the books. GUTTMACHER INST., *Counseling and Waiting Periods for Abortion*, *supra* note 87.

[94] *See*, *e.g.*, Bristol Reg'l Women's Ctr., P.C. v. Slatery, 7 F.4th 478, 481 (6th Cir. 2021), *abrogated by* Dobbs v. Jackson Women's Health Org., 597 U.S. 215 (2022) (finding a rational basis for the law grounded in Tennessee's interest in "protecting the life of the unborn" and ensuring that a "woman's consent is informed and deliberate") (internal quotation marks omitted). Tennessee defended the law explicitly on regret grounds, relying in the District Court on expert testimony about rates about post-abortion regret, but the District Court, which found the law unconstitutional, found the evidence not credible and determined that it instead established the low incidence of post-abortion regret. *See id.* at 517–20 (Moore, J., dissenting) (concluding that "there is no evidence whatsoever that a waiting period improves decisional certainty or causes a woman not to have an abortion that she would have regretted"). When Indiana passed a similar law in 1995, with an eighteen-hour waiting period, concern about regret featured heavily in the legislative debate. A Woman's Choice-E. Side Women's Clinic v. Newman, 305 F.3d 684, 701–02 (7th Cir. 2002) (Coffee, J., concurring) (describing the legislative hearing).

B. Abortion Regret as Actionable Injury

1. Tort Liability

Shortly after *Roe*, anti-abortion activists began using medical malpractice litigation strategically, seeking to dissuade abortion providers by increasing liability costs.[95] State legislatures have also taken up this strategy, passing strategic liability laws that create causes of action for recipients of abortions.[96] In some states, these laws are directly tied to informed consent, creating strict liability for doctors who violate statutory mandates.[97] Strategic abortion liability laws deviate from traditional medical malpractice standards, making it easier to prevail in lawsuits against medical practitioners.[98] Even in states without an express civil liability provision, the informed consent provisions may themselves create an implied right of action.[99]

Without identifying regret expressly, many of these strategic liability laws allow abortion recipients to seek recovery based on emotional injuries. *Carhart's* equation of regret and psychological harm makes mention of regret unnecessary.[100] Justice

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[95] *See* Eidmann, *supra* note 85, at 267; Kathy Seward Northern, *Procreative Torts: Enhancing the Common-Law Protection for Reproductive Autonomy*, 1998 U. ILL. L. REV. 489, 494–96 (describing this history). Legal scholars dispute whether these laws expose doctors to more liability or narrower potential liability. *Compare id*. at 540–45 (arguing that many of these right to know statutes have the effect of insulating doctors from common law liability standards by creating exclusive causes of action based on violation of the statutes) *with* Sawicki, *supra* note 88 (arguing that these statutes relax liability standards and make it easier to sue abortion providers for malpractice related to informed consent).

[96] *See* Sawicki, *supra* note 88, at 941–55 (citing and discussing numerous examples).

[97] *See*, *e.g.*, Wis. Stat. § 253.10(6); *see also* Karlin v. Foust, 188 F.3d 446, 446 (7th Cir. 1999) (reading the Wisconsin law to establish strict liability where a physician omits any of the required disclosures).

[98] *See generally* Sawicki, *supra* note 88 (arguing that these statutes relax liability standards and make it easier to sue abortion providers for malpractice related to informed consent); *but see* Northern, *supra* note 95, at 540–45 (arguing that many of these right to know statutes have the effect of insulating doctors from common law liability standards by creating exclusive causes of action based on violation of the statutes).

[99] *See* Shaw & Stein, *supra* note 89, at 4 n.16 (explaining that violation of informed consent is a tort in every jurisdiction, that health and safety statutes typically create duties toward their beneficiaries, and that patients receiving abortions are typically the designated beneficiaries of informed consent laws).

[100] Commenting on *Carhart*, Jeannie Suk Gersen reflected that what was then the "newly prominent legal discourse of abortion regret" did not, as some critics had argued, come out of nowhere. Instead, "the reasoning continues a . . . feminist discourse of trauma around women's bodies and sexuality." Suk, *supra* note 69, at 1197; *see also* Noa Ben-Asher, *Trauma-Centered Social Justice*, 95 TUL. L. REV. 95 (2020) [hereinafter Ben-Asher, *Trauma-Centered Social Justice*]. Reading *Carhart* closely, Suk Gersen viewed the psychological harm described as "more elaborate than regret." Suk, *supra* note 69, at 1234. Arguably, what it is more elaborate than run-of-the-mill regret, that is relatively easily processed. Guthrie, *supra* note 73 (explaining how *Carhart* misunderstands the way in which

Kennedy emphasized how the later revealed information about the nature of the procedure could change the abortion recipient's understanding of the event, rendering it psychologically harmful and generating regret after the fact.[101] Other kinds of revelations, for instance religious conversions, could have the same result.

In the anti-abortion movement, regret and psychological harm have become synonymous. Consider some examples. In 1993, South Dakota amended its abortion laws to provide for both civil and criminal liability where an abortion is performed in violation of the informed consent requirements.[102] The provision provided for punitive damages in the amount of $10,000 and treble damages.[103] The Eighth Circuit read the provision to create strict liability and, applying *Casey*'s undue burden test, struck it down on the ground that "[t]he potential civil liability for even good-faith, reasonable mistakes is more than enough to chill the willingness of physicians to perform abortions in South Dakota."[104] This law would have allowed a person experiencing abortion regret to prevail if they could find any violation, however small or unintentional, of South Dakota's informed consent requirements.

A 1997 Louisiana law created even broader liability, establishing a cause of action based on harm to either the mother or the fetus resulting from the abortion.[105] Defenders of the statute argued that the law was necessary to protect women who might experience psychological side-effects from the abortion.[106] The scope of statutory liability was vague, creating the possibility that an abortion recipient might successfully sue even in the absence of physical harm and even where a doctor had complied fully with any relevant standards of care.[107] A District Court found the law unconstitutional, expressing concern about "the removal of the cause of action from the realm of medical malpractice," and observing that the broad catchall provision directly contradicted the states informed consent law, which established compliance

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most people learn from and move on from feelings of regret). Central to the trauma narrative is the implication of *coercion*, that the abortion itself was not the result of free choice. Suk, *supra* note 69, at 1246–49 (tracing this thread in the anti-abortion rhetoric and tracing it to feminist arguments about coercion in sexual relationships). For parallel arguments about the choice to become a mother, *see infra* note 179 and accompanying text.

[101] Suk, *supra* note 69, at 1234. This interpretation of *Carhart* potentially explains why the Justice Kennedy's apparent definition of regret is out of step with that of many philosophers, who emphasize that regret occurs when a person evaluates a past decision using knowledge that was not available to them at the time. *See* Appleton, *supra* note 72, at 267 (pointing out that in *Carhart*, the regret occurs instead when a woman evaluates the decision to get an abortion applying knowledge she has acquired later about the nature of the procedure that would have been available at the time of the decision).

[102] S.D. CODIFIED LAWS § 34-23A-22 (1993).

[103] *See id*. (also providing for fee shifting for successful plaintiffs).

[104] Planned Parenthood, Sioux Falls Clinic v. Miller, 63 F.3d 1452, 1467 (8th Cir. 1995).

[105] LA. STAT. § 9:2800.12 (establishing that compliance with informed consent requirements only reduces but does not eliminate liability).

[106] Okpalobi v. Foster, 981 F. Supp. 977, 983 (E.D. La. 1998), *aff'd*, 190 F.3d 337 (5th Cir. 1999), and *rev'd en banc*, 244 F.3d 405 (5th Cir. 2001).

[107] *Id.* at 983–94.

with disclosure obligations as an affirmative defense to tort suits alleging inadequate warning.[108] Further, the court observed that because the statute included harm to the "unborn child," any abortion would, by definition, give rise to liability.[109] This decision was reversed by the Fifth Circuit, sitting *en banc*, on jurisdictional grounds.[110] The civil liability provision in Louisiana remains on the books.

One final example illustrates how broad civil liability laws make regret an actionable injury. A 2010 Nebraska law established a variety of specific disclosure and informed consent requirements and provided that "failure to comply with [those] requirements shall create a rebuttable presumption that the pregnant woman would not have undergone the recommended abortion had the [disclosure requirements] been complied with by the physician."[111] Criticizing the bill, a federal court observed:

> For the woman who comes to regret having had an abortion, LB 594 provides her with a target to blame—a physician stripped of the usual statutory and common law defenses, and made civilly liable for the most extensive damages, by way of an "informed consent" mandate that is either impossible to satisfy, or so vague that the physician (and a jury) are left to speculate about its meaning. LB 594 also provides the remorseful woman and her lawyer with a very substantial financial incentive to initiate such litigation, whether or not she truly does regret her decision to obtain an abortion—her regret is presumed. Although this presumption is "rebuttable," it is difficult to conceive how any defendant could effectively rebut such as assertion.[112]

As the District Court explains, regret, in this (and similar) legislation, was weaponized against doctors. Regret functionally makes what was a consensual medical procedure nonconsensual *in hindsight*. Applying *Casey*, the court refused to treat regret differently in the abortion context. The court observed that some degree of abortion regret is inevitable "because any major decision will lead to regret in some percentage of cases. The most important choices have consequences, and

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[108] *Id*.

[109] *Id.* at 986.

[110] *See generally* Okpalobi v. Foster, 244 F.3d 405 (5th Cir. 2001).

[111] Planned Parenthood of the Heartland v. Heineman, 724 F. Supp. 2d 1025, 1034 (D. Neb. 2010) (granting a preliminary injunction against the bill after determining it was likely unconstitutional). The disclosures included detailed descriptions of the risks association with the abortion procedure and the gestational age of the child. Under traditional tort principles, a plaintiff bringing an action based on failure to provide informed consent would need to prove that they would not have undergone the procedure if they had been better informed. *See*, *e.g.*, Reynier v. Delta Women's Clinic, Inc., 359 So. 2d 733 (La. Ct. App. 1978) (applying this principle in the abortion context).

[112] *Planned Parenthood of the Heartland*, 724 F. Supp. 2d at 1045 (internal citations omitted).

no matter how well-reasoned and fully deliberated, those decisions can lead to remorse. That is part of the price we pay for our freedom."[113]

Medical malpractice litigation is always a possible outcome of providing medical care, but for the most part, regret—absent physical harm or absent lack of consent—generates no physician liability.[114] A patient who changes their mind after a medical procedure has no recourse. Strategic abortion liability laws bypass this central common law principle, making regret alone actionable.

2. Standing

More recently, the North District of Texas and the Fifth Circuit have recognized regret as a distinct injury that might give rise to Article III standing. Typically, to establish standing to bring an action in federal court, a plaintiff must demonstrate, among other things, "an injury in fact."[115] In *Alliance for Hippocratic Medicine v. FDA*, Judge Matthew Kascmaryk of the Northern District of Texas relied on abortion regret to conclude that an association of doctors had standing to challenge FDA approval of Mifeprestone, a drug approved for early-term abortion.[116] The plaintiffs

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[113] *Id*. at 1045 & n.12 (concluding, parenthetically, "Only Edith Piaf was without regret. Had she been sober, she, too, might have had second-thoughts."). The state consequently entered into a settlement agreement with the plaintiffs, agreeing not to enforce the provisions of the new law. *See generally* Planned Parenthood of the Heartland v. Heineman, Case no. 4:10CV3122 (D. Neb. 2010) (Order and Final Judgement). Nebraska currently enforces an older version of the law, which makes violation of the disclosure requirements "prima facie evidence of professional negligence," but establishes a "rebuttable presumption of full compliance" where the person upon whom an abortion has been performed signed, at the time of the procedure, a written certification that they received all the necessary disclosures. NEB. REV. STAT. § 28-327.04 (the current evidentiary rule); NEB. REV. STAT. § 28-327(7) (requiring the written certification as part of the informed consent process).

[114] Most states apply an objective causation standard in informed consent malpractice claims, requiring that a plaintiff establish that a reasonable person would not have undergone the procedure had they been adequately informed. Explaining the choice of an objective standard over a subjective approach, the D.C. Circuit explained, "[i]n our view, [the subjective approach] of dealing with the issue of causation comes in second-best. It places the physician in jeopardy of the patient's hindsight and bitterness." Canterbury v. Spence, 464 F.2d 772, 790–791 (D.C. Cir. 1972). In the medical malpractice negligence context, regret alone would not form the basis for a cause of action even in jurisdictions recognizing emotional harms, plaintiffs must still establish breach of the duty of care. *Elements of Malpractice or Negligence in General*, AM. L. REP. § 611 (2024); RESTATEMENT (THIRD) OF TORTS: PHYSICAL & EMOTIONAL HARM § 47 cmt. f (AM. L. INST. 2012) (observing that some jurisdictions allow recovery for the emotional harm to the parent flowing from the negligent caused loss of a fetus or newborn).

[115] Lujan v. Defs. of Wildlife, 504 U.S. 555, 560 (1992) (defining injury as the "invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical").

[116] All. for Hippocratic Med. v. FDA, 668 F. Supp. 3d 507, 524 (N.D. Tex. Apr. 7, 2023) (analyzing plaintiffs' standing for a preliminary injunction on FDA's approval of mifepristone and relaxation of regulations).

asserted standing on behalf of member doctors and on behalf of patients. Judge Kascmaryk accepted both, explaining that inadequacies in the FDA approval process meant that doctors could not adequately inform their patients about "potential negative emotional reactions like fear, uncertainty, sadness, regret, and pain."[117] In support of the conclusion that doctors have third-party standing on behalf of patients, Judge Kascmaryk observed, "Women who have aborted a child — especially through chemical abortion drugs that necessitate the woman seeing her aborted child once it passes — often experience shame, regret, anxiety, depression, drug abuse, and suicidal thoughts because of the abortion."[118] Judge Kascmaryk concluded that the plaintiff doctors "— rather than their patients — are most likely the 'least awkward challenger[s]' to Defendants' [FDA] actions."[119] The Fifth Circuit upheld these conclusions on appeal, agreeing that "treating mifepristone patients imposes considerable mental and emotional stress on emergency-room doctors. This is due to the unique nature of chemical abortions, which, according to the plaintiff-doctors, frequently cause 'regret' or 'trauma' for the patients and, by extension, the physicians."[120]

This case—which focuses on regret potentially experienced by those receiving chemical abortions and by the doctors administering them or treating recipients if something goes wrong—recognizes the validity of regret as a distinct injury.[121] Although regret is not the sole injury on which plaintiffs rely,[122] the attention to it is

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[117] *Id.* This is not the first time that regret has come up in the context of an abortion-related standing decision. In several pre-*Dobbs* cases, state defendants unsuccessfully contested the standing of medical associations who were challenging abortion restrictions, arguing that because of the possibility of future abortion decision regret, doctors had a conflict of interest with abortion patients and could not represent them on third-party standing theory. *See* Little Rock Fam. Plan. Servs. v. Rutledge, 398 F. Supp. 3d 330, 372 (E.D. Ark. 2019) (relying on abortion informed consent laws to conclude that the possibility of regret did not create a conflict of interest). *See also* Singleton v. Wulff, 428 U.S. 106, 113 (1976) (finding doctors have third-party standing to challenge abortion restrictions).

[118] *All. for Hippocratic Med.*, 668 F. Supp. 3d at 526 (finding that "women who have *already* obtained abortions may be *more* hindered than women who challenge restrictions on abortion").

[119] *Id.*

[120] All. for Hippocratic Med. v. U.S. Food & Drug Admin., 78 F.4th 210, 232 (5th Cir. 2023), *cert. granted sub nom*. Danco Lab'ys, L.L.C. v. All. Hippocratic Med., No. 23-236, 2023 WL 8605744 (U.S. Dec. 13, 2023), and *cert. granted sub nom.* FDA v. All. Hippocratic Med., No. 23-235, 2023 WL 8605746 (U.S. Dec. 13, 2023), and *cert. denied sub nom.* All. Hippocratic Med. v. FDA, No. 23-395, 2023 WL 8605749 (U.S. Dec. 13, 2023).

[121] Regret does not carry this same legal significance in all contexts. *See generally* Appleton, *supra* note 72 (comparing the legal significance of regret in the abortion context with a variety of other contexts involving reproduction, including adoption, where the regret of the birth mother, even in the face of strong evidence of manipulation by the adoptive parents, was not persuasive in establishing a standard more protective of birth mothers).

[122] *All for Hippocratic Med.*, 668 F. Supp. 3d at 524 (discussing potential physical side effects of mifepristone among other related injuries).

significant. Mere regret has historically not been enough to justify standing,[123] but courts have previously acknowledged the possibility that emotional trauma could be sufficient injury, so long as it is particularized to plaintiffs.[124] The Supreme Court has also been hesitant to accept arguments that standing flows from fear or anxiety of future events, especially where there is not a "real and immediate future threat."[125] Lower courts have frequently relied on tort law to determine whether a particular claim of emotional harm constitutes an injury, tying the federal law of standing to state tort law.[126]

In recognizing regret as an injury, the Northern District of Texas and the Fifth Circuit make two significant moves.[127] First, they implicitly accept the gravity of the regret concern—that regret is a serious harm to be avoided. Second, they further entrench the state's interest in preventing future regret by allowing litigants to use federal courts to vindicate an interest in regret avoidance.

III. GENDER REGRETS AND TRADITIONAL "FAMILY VALUES"

There are striking parallels between the use of regret in the movements to ban GAC and abortion. In both, advocates cite a hypothetical risk of future regret to support bans on medical care. Those seeking GAC or abortions must allegedly be protected from these procedures, the doctors who would perform them, and the parents who support them. This Part explores the ideological threads that tie these two movements together. Section A uses the writings of two conservative leaders—Pat Buchanan and Phyllis Schlafly—to illuminate the values underlying both

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[123] *See*, *e.g.*, Eike v. Allergan, Inc., 850 F.3d 315, 318 (7th Cir. 2017) (rejecting standing in a class action suit against a manufacturer where standing was based on "a regret or disappointment" with the product).

[124] *See* Rachel Bayefsky, *Psychological Harm and Constitutional Standing*, 81 BROOK. L. REV. 1555, 1578 (2016).

[125] *Id.* at 1578–80 (describing this jurisprudence).

[126] *See id.* at 1590–92 (describing this trend); *see supra* notes 124–25 and accompanying text (discussing principles of emotional harm in tort law).

[127] As of this writing, this case has been fully briefed and argued before the Supreme Court, but the Court has yet to issue a decision. In its brief in opposition to certiorari, the Alliance for Hippocratic Medicine repeated these arguments but emphasized the emotional harm to doctors themselves rather than the emotional harm to abortion recipients. FDA v. All. Hippocratic Med., 2023 WL 9643014, at *34–*35 (Nov. 9, 2023) (Respondents' Brief in Opposition); *see also* Transcript of Oral Argument at 62, FDA v. All. for Hippocratic Med., (2024) (No. 23-235, No. 23-236), https://www.supremecourt.gov/oral_arguments/argument_transcripts/2023/22-235_q8l1.pdf [https://perma.cc/7JXT-5ZNP]. Numerous amici repeat the argument. Some to support standing analysis. *See*, *e.g.*, FDA v. All. Hippocratic Med., 2024 WL 948009, at *22 (Feb. 29, 2024) (Brief of Missouri, Idaho, & Kansas in Support of Alliance for Hippocratic Medicine). Some to support the claim, on the merits, that FDA approval of abortion-inducing drugs was flawed because the safety analysis did not adequately consider the harm of potential regret. *See*, *e.g.*, Brief of Amici Curiae Family Policy Alliance and State Family Policy Councils in Support of Respondents, FDA v. All. Hippocratic Med., 2024 WL 945351, at *13–*14 (Feb. 28, 2024).

movements. Section B demonstrates how both movements use regret as a disciplining tool to pursue conservative values, including natalism, traditional gender roles, and the male-female binary. Section C reflects on the use of regret to justify government action, calling for caution.

A. A Fight for the "Soul of America"

In a passionate speech in the summer of 1992 at the Republican National Convention in Houston, Patrick J. Buchanan declared a "cultural war" for the "soul of America."[128] "George Bush is a defender of right-to-life, and a champion of the Judeo-Christian values and beliefs upon which America was founded," he said, following, "Mr. Clinton, however, has a different agenda. At its top is unrestricted abortion on demand."[129] Buchanan warned Republicans:

> The agenda that Clinton & Clinton would impose on America – abortion on demand, a litmus test for the Supreme Court, homosexual rights, discrimination against religious schools, women in combat units – that's change, all right. But it is not the kind of change America needs. It is not the kind of change America wants. And it is not the kind of change we can abide in a nation that we still call God's country.[130]

The "cultural war," declared over three decades ago at the Republican convention that nominated George H.W. Bush, portrayed reproductive freedoms and gay rights as an attack on "God's country" and on "Judeo-Christian values."[131] Four years later, with President Bill Clinton in the White House, the Supreme Court in *Romer v. Evans* held that an amendment to Colorado's Constitution that denied antidiscrimination protections for gays and lesbians violated the Equal Protection Clause.[132] Justice Scalia dissented, with a dramatic exclamation: "The Court has mistaken a *Kulturkampf* [culture war] for a fit of spite."[133] Coloradans, according to

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[128] Patrick Joseph Buchanan, Culture War Speech: Address to the Republican National Convention (Aug. 17, 1992), https://voicesofdemocracy.umd.edu/buchanan-culture-war-speech-speech-text/ [https://perma.cc/Q469-K572] ("It is a cultural war, as critical to the kind of nation we shall be as was the Cold War itself, for this war is for the soul of America. And in that struggle for the soul of America, Clinton & Clinton are on the other side, and George Bush is on our side. And so, to the Buchanan Brigades out there, we have to come home and stand beside George Bush."). *See also* Adam Nagourney, *'Cultural War' of 1992 Moves in from the Fringe*, N.Y. TIMES (Aug. 29, 2012), https://www.nytimes.com/2012/08/30/us/politics/from-the-fringe-in-1992-patrick-j-buchanans-words-now-seem-mainstream.html [https://perma.cc/P7KD-G2D7].

[129] Buchanan, *supra* note 128 (adding, "a militant leader of the homosexual rights movement could rise at that same convention and say: 'Bill Clinton and Al Gore represent the most pro-lesbian and pro-gay ticket in history.' And so they do.").

[130] *Id.*

[131] *Id.*

[132] Romer v. Evans, 517 U.S. 620 (1996).

[133] *Id.* at 636 (Scalia, J. dissenting) (emphasis added).

Justice Scalia, discriminated against gays and lesbians not out of animus but due to a desire to "preserve traditional sexual mores."[134] Justice Scalia resisted an "elite class" that would impose its view that "'animosity' toward homosexuality is evil" on the rest of America.[135]

The GAC regulations examined here—like abortion regulations—often have overt Judeo-Christian grounding. For instance, Oklahoma titled its GAC ban the *Millstone Act*, referring to Matthew 18:6: "but whoever causes one of these little ones who believe in Me to sin, it is better for him that a heavy millstone be hung around his neck, and that he be drowned in the depths of the sea."[136] The Millstone Act is about disciplining sinners. The ban sets up heavy millstones—civil and criminal liability—to be hung on the necks of medical providers and parents who cause "these little ones" to sin by pursuing their gender identity. What is at stake here is not a dispute with medical science or, even, psychological regret. It is conservative Christian morality *defending against* transgender existence.

Phyllis Schlafly was a well-known critic of feminism and what she called the "equality principle." Her advocacy for "traditional family values" foreshadows and sheds light on twenty-first century campaigns to ban abortion and GAC.[137] From the 1960s and on, Schlafly was an influential conservative activist, a national leader and spokesperson of the conservative movement, and an anti-feminist.[138] In a representative piece published in 1994, Schlafly attacked the newly appointed associate justice of the Supreme Court, Ruth Bader Ginsburg (who, for Schlafly, represented feminism itself) for attempting "to induce changes in cultural stereotypes, social mores, and relationships between men and women."[139] Schlafly warned,

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[134] *Id.*

[135] *Id.*

[136] S.B. 129, 2023 Leg., Gen. Sess. (Okla. 2023) (prohibiting gender transition procedures or referral services relating to such procedures to anyone under the age of 26, authorizing the state's attorney general to enforce the act and those found guilty of violating it would be guilty of a felony and subject to license revocation).

[137] Phyllis Schlafly, *How the Feminists Want to Change Our Laws*, 5 STAN. L. & POL'Y REV. 65, 66–67 (1994).

[138] *See*, *e.g.*, Valerie J. Nelson*, 'Don't Call Me Ms. . . . It Means Misery: Phyllis Schlafly, Anti-feminist and Conservative Activist, Dies at 92*, LA TIMES (Sept. 5, 2016, 6:20 PM), https://www.latimes.com/local/obituaries/la-me-phyllis-schlafly-snap-story.html [https://perma.cc/54UV-NJZN].

[139] Schlafly, *supra* note 137, at 66 ("To her and to other feminists, any route to that goal was acceptable: activist judicial re-interpretation of the Fourteenth Amendment to the U.S. Constitution (which she used for her winning Supreme Court cases), or ratification of the then-pending Equal Rights Amendment."). For an analysis of Justice Ruth Bader Ginsburg's approach to sex discrimination, see generally Cary Franklin, *The Anti-Stereotyping Principle in Constitutional Sex Discrimination Law*, 85 N.Y.U. L. REV. 83 (2010); Noa Ben-Asher, *The Two Laws of Sex Stereotyping*, 57 B.C. L. REV. 1187 (2016).

> *Sex Bias*[140] stands today as a textbook on how Ruth Bader Ginsburg and the feminists want to change our laws, our institutions, and our attitudes, in order to conform them to the "equality principle" and convert America into a "gender-neutral" society. It documents the radical and extremist goals of the feminists and how they seek to restructure our laws and society.[141]

As a thought leader for the conservative movement, Schlafly expressed pro-natalist views, most explicitly apparent in opposition to abortion and reproductive rights. She was also concerned with preserving traditional gender norms and was a fierce opponent of same-sex marriage.[142]

Twenty-first century policies and laws involving GAC and abortion echo Schlafly's agenda of traditional family values and a rigid system of binary sexual difference. Schlafly viewed gender equality *in all its manifestations* as an attack on the traditional American family because equality (as she saw it) upsets traditional gender roles of men as breadwinners and women as caregivers.[143] She associated Justice Ginsburg with "the typical 1970s feminist attitude that women's liberation and equality in the workforce required liberation from marriage, that is, easy divorce . . . ."[144] She was hostile to the no-fault divorce reforms that feminists had promoted as a tool to liberate women from oppressive marriages.[145] The primary role of woman, claimed Schlafly, was a homemaker and a mother.[146] Like conservative policymakers and lawmakers today, she underscored the role of women as birth-

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[140] U.S. COMM'N ON C.R., SEX BIAS IN THE U.S. CODE: A REPORT OF THE UNITED STATES COMMISSION ON CIVIL RIGHTS, V (1977).

[141] Schlafly, *supra* note 137, at 66–67.

[142] The Phyllis Schlafly Report, *Feminists Psychoanalyze Themselves Again*, 43 EAGLE FORUM 4 (2009), https://eagleforum.org/psr/2009/nov09/psrnov09.html [https://perma.cc/LRE2-K2XU] ("Attacks on the definition of marriage as the union of one man and one woman come from the gay lobby seeking social recognition of their lifestyle, from the feminist movement that opposes what they call the patriarchy (that supposedly makes women second-class citizens), and also from some libertarians . . . .").

[143] Schlafly, *supra* note 137, at 67 (criticizing Justice Ginsburg for allegedly proposing "that the traditional family concept of husband as breadwinner and wife as homemaker must be eliminated.").

[144] *Id.*

[145] Eliminating no-fault divorce is now part of the Republican Party platform in two states. *See* Kimberly Wehle, *The Coming Attack on an Essential Element of Women's Freedom*, THE ATLANTIC (Sept. 26, 2023), https://www.theatlantic.com/ideas/archive/2023/09/no-fault-divorce-laws-republicans-repeal/675371/ [https://perma.cc/6A27-48BU]; AJ Willingham, *What Is No-Fault Divorce, and Why Do Some Conservatives Want to Get Rid of It?*, CNN (Nov. 27, 2023, 9:49 AM), https://edition.cnn.com/2023/11/27/us/no-fault-divorce-explained-history-wellness-cec/index.html [https://perma.cc/D9AG-VU2X].

[146] *Anniversary:* Roe v. Wade *with Phyllis Schlafly*, WASH. POST (Jan. 18, 2002, 3:00 PM), https://www.washingtonpost.com/wp-srv/liveonline/02/nation/nation_schlafly011802.htm [https://perma.cc/U7TT-EF75] (arguing that invalidating laws that favor wives and mothers ought to be seen as an attack on women).

givers. She characterized *Roe v. Wade* as "the worst decision in the history of the U.S. Supreme Court" because it is "responsible for the killing of millions of unborn babies."[147] And she condemned Ginsburg's claim that "government has an affirmative duty to fund abortions for poor women [and that] anti-abortion laws interfere with a woman's ability 'to participate equally in the economic and social life of the Nation.'"[148]

Schlafly asserted that Ginsburg's positions on traditional gender roles, no-fault divorce, and access to abortion for poor people, "betray her as a radical, doctrinaire feminist, far out of the mainstream . . . [who] shares the chip-on-the-shoulder radical feminist view that American women have endured centuries of oppression and mistreatment from men."[149] Schlafly concludes,

> Feminists are split by a curious dichotomy. Do they really want a totally gender-neutral society in which we are all forced to pretend there is no difference between men and women? . . . Or, on the other hand, do they want special privileges for women, conveniently resting this demand on the theory that such privileges are needed to remedy centuries of discrimination? Does "equality" mean forever playing the role of victim and demanding affirmative action, protection against sexual harassment, and expensive employer and government benefits (such as family leave and daycare) to accommodate women's traditional family responsibilities?[150]

It is evident from Parts I and II of this Article that by 2024, Buchanan and Schlafly's conservative and traditionalist approaches to gender, sexuality, and the family are shaping state laws, policies and jurisprudence. In the twenty-three states that have so far passed laws restricting GAC, and the twenty-five states that have so far restricted or eliminated abortion access, natalism, a male-female sex binary, and traditional gender roles are legislative priorities.

B. Using "Regret" in a Crusade for "Traditional Family Values"

Regret has become an effective tool in a conservative campaign against reproductive justice and LGBTQ rights. Political and legal debates about GAC and abortion typically play out between anecdotal evidence (about individual regret) and statistical evidence (revealing low incidence of regret). In *Carhart*, for example, Justice Kennedy invoked the risk of regret while acknowledging the absence of

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[147] Schlafly also bashed Justice Ginsburg for "clearly believ[ing] that her 'equality principle' demands that taxpayer funding of abortions be written into the U.S. Constitution in order to give women 'equality' in the workplace." *Id.* at 70.

[148] *Id.* at 71.

[149] *Id.*

[150] *Id.* For critique of this conservative approach, see Mary Anne Case, *After Gender the Destruction of Man? The Vatican's Nightmare Vision of the "Gender Agenda" for Law,* 31 PACE L. REV. 802 (2011).

"reliable evidence."[151] Dissenting, Justice Ginsburg critically observed that "the Court invokes an antiabortion shibboleth for which it concededly has no reliable evidence . . . ."[152] Ginsburg objected that "neither the weight of the scientific evidence to date nor the observable reality of [thirty-three] years of legal abortion in the United States comports with the idea that having an abortion is any more dangerous to a woman's long-term mental health than delivering and parenting a child that she did not intend to have."[153]

A similar pattern has emerged in the legislative, political, and public debates over GAC. A small group of former GAC recipients regularly participates in legislative hearings offering testimony about their regret and suffering,[154] while advocates for transgender individuals rely on scientific studies that reveal that incidence of regret is extremely low.[155]

These encounters between individual anecdotes and scientific data raise interesting questions about the task of lawmakers as truth seekers.[156] But legal and political struggles over GAC and abortion are part of a bigger national drama. At stake are traditional values, sexual morality,[157] and the so-called "soul of America."[158] Current bans on GAC and abortion are calculated ideological attempts

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[151] Kennedy cited to a brief recounting the experiences of 180 women describing their experiences with abortion regret. *See supra* notes 67–69 and accompanying text (citing and discussing these briefs); *see also* Doan et al., *supra* note 90 (exploring how anti-abortion advocates have relied on personal stories of regret to establish credibility).

[152] Gonzales v. Carhart, 550 U.S. 124, 183 (2007) (Ginsburg, J., dissenting).

[153] *Id.* at 183 n.7 (internal quotation marks omitted). Anti-abortionists often dismiss such scientific studies, alleging that many individuals do not feel comfortable telling their regret stories. *See supra* notes 80–82 and accompanying text. *See also* Siegel, *supra* note 69, at 1658–59 (citing anti-abortion literature making the argument that most, if not all, women experience regret and guilt but do not have safe spaces to talk about it). Prominent abortion opponent, Vincent Rue, has argued that those who claim not to be suffering from post-abortion trauma are simply repressing their emotions. Eidmann, *supra* note 85, at 276–77 (describing Rue's role in the anti-abortion movement). Rue explains that "The factors of being surprised and overwhelmed by the intensity of the emotional and physical response to the abortion-experience frequently act upon the post-abortive woman to cause her to resort to the defenses of repression and denial." *Id.* at 277 n.50.

[154] *See supra* notes 1–3 and accompanying text (offering examples of this phenomenon).

[155] Supporters of bans criticize the data primarily on the ground that it fails to consider the numbers of people who never report their regret. *See supra* note 28 and accompanying text.

[156] The relationship between science, morality, and democracy has long plagued policymakers. *See generally* Dov Fox, *Subversive Science*, 124 PENN ST. L. REV. 153 (2019) (exploring the legal implications of scientific findings that conflict with widely held ideals); FRANK ACKERMAN & LISA HEINZERLING, PRICELESS: ON KNOWING THE PRICE OF EVERYTHING AND THE VALUE OF NOTHING (2005) (critiquing the use of cost-benefit analysis in policymaking).

[157] *See*, *e.g.*, Ben-Asher, *Transforming Legal Sex*, *supra* note 7.

[158] *See supra* notes 128–31 and accompanying text.

to promote natalism and preserve the male-female binary as a way of defending against a perceived liberal and LGBTQ attack on conservative and Christian values.

1. Natalism, Regretting Children, Regretting Childlessness

Campaigns against abortion and GAC reflect, among other things, cultural anxiety about childbearing, reproduction, and fertility. In *Carhart*, for instance, Justice Kennedy observed that "Respect for human life finds an ultimate expression in the bond of love the mother has for her child."[159] Indeed, natalism is a fundamental feature of all abortion restrictions that force pregnant people to carry unwanted pregnancies.[160] It is also expressed in biased counseling laws that require providers to warn about future fertility consequences of abortion.[161]

Natalism is also predominant in GAC bans, many of which warn that "sterility" is an inevitable consequence of GAC.[162] Despite evidence that fertility of transgender teens and youth can be (and often is) preserved in clinical settings,[163] the risk of infertility is high on the list of justifications for these bans. Arkansas's 2021 statute is representative on this point. It warns that "[i]t is of grave concern to the General Assembly that the medical community is allowing individuals who

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[159] Gonzales v. Carhart, 550 U.S. 124, 159 (2007).

[160] Natalism, sometimes referred to as pro-natalism, is "an attitude or policy favoring or encouraging population growth." *Natalism*, MERRIAM WEBSTER DICTIONARY, https://www.merriam-webster.com/dictionary/natalism [https://perma.cc/5LRX-96MU] (last visited Mar. 7, 2024).

[161] Twenty-three states have laws with specific disclosure requirements related to risks of abortion for future fertility, and three of these states include misleading information in these disclosures. GUTTMACHER INST., *Counseling and Waiting Periods for Abortion*, *supra* note 87.

[162] *See*, *e.g.*, S.B. 184, 2022 Leg., Reg. Sess. (Ala. 2022) ("Introducing cross-sex hormones to children with immature gonads as a direct result of pubertal blockade is expected to cause irreversible sterility. Sterilization is also permanent for those who undergo surgery to remove reproductive organs . . . ."); H.B. 1570, 2022 Leg., Reg. Sess. (Ark. 2021) § 2(8)(A)(vii), (B)(viii) (identifying "irreversible infertility" as a risk of cross-sex hormone therapy); H.B. 71, 2023 Leg., Reg. Sess. (Idaho 2023) § 10(c), (d) (expressing concern that healthcare providers administer puberty-blockers and cross-sex hormones despite "scientific evidence that children who remain on puberty blockers may never recover lost development").

[163] *See*, *e.g.*, T.H.R. Stolk, J.D. Asseler, J.A.F. Huirne, E. van den Boogaard, & N.M. van Mello, *Desire for Children and Fertility Preservation in Transgender and Gender-Diverse People: A Systematic Review*, 87 BEST PRAC. & RSCH. CLINICAL OBSTETRICS & GYNAECOLOGY (2023) (finding that for transmasculine people oocyte retrieval rates parallel those of cis people even with prior testosterone use and recommending semen preservation prior to hormone treatment in transfeminine people); Philip J. Cheng, Alexander W. Pastuszak, Jeremy B. Meyers, Isak A. Goodwin, & James M. Hotaling, *Fertility Concerns of the Transgender Patient*, 8 TRANSLATIONAL ANDROLOGY & UROLOGY, 209 (2019) (describing broad range of fertility preservation options and identifying discrimination, costs, and dearth of facilities as some of the main barriers to fertility preservation). *See also* Clark, *supra* note 44.

experience distress at identifying with their biological sex to be subjects of . . . irreversible, permanently sterilizing genital gender reassignment surgery."[164] These bans and the politics that surround them communicate one central untruth: GAC is necessarily a path to future childlessness and should thus be banned.

A different yet related set of issues illuminates the interaction of regret, natalism, and gender roles. Consider the contrast between individuals who are childless by choice and those who have children and later come to regret it. The former are presumed to live with deep regrets and are often warned: "[D]o not make this decision [childlessness], you will come to regret it."[165] The latter are presumed to affirm parenthood. Their regret stories often lack a platform or an audience. Although studies suggest that those who are childless by choice report similar levels of satisfaction to those who are not, they are often perceived to be less fulfilled.[166]

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[164] S.B. 184, 2022 Leg., Reg. Sess. (Ala. 2022). These statutes universally ignore the possibility of gamete preservation. They also typically inflate the evidence of the risk that puberty blockers and cross-hormone therapies pose to fertility. *See* Stolk et al., *supra* note 163; Cheng et al., *supra* note 163.

[165] ORNA DONATH, REGRETTING MOTHERHOOD: A STUDY 58 (2017) (observing that "regret is used as a threat to push women who do not wish to be mothers into motherhood"); Kate Greasley, *Abortion and Regret*, 38 J. MED. ETHICS 705, 710 (2012) (arguing that this type of reasoning is persuasive when it "derives from the belief that the regret will reflect justification. What is really meant by 'don't go out in the rain, you'll regret it,' is 'you will regret it *because* it is imprudent'"). Brittany Wong, *If You're Afraid You'll Regret Not Having Kids, Read This*, HUFFPOST (Oct. 31, 2023, 5:49 PM), https://www.huffpost.com/entry/unsure-if-you-want-to-have-kids-read-this_l_65402c65e4b0a78a26a470f4 [https://perma.cc/HS46-S997] (quoting a psychotherapist who reports regularly hearing fear of future regret from patients considering the possibility of not having children); Elmo Keep, *I Am So Sick of Being Asked If I Regret Not Having Children*, THE GUARDIAN (Feb. 9, 2021), https://www.theguardian.com/commentisfree/2021/feb/09/i-am-so-sick-of-being-asked-if-i-regret-not-having-children [https://perma.cc/QB7D-56P9]. *See*, *e.g.*, Barton Goldsmith, *Why I Regret Not Having Children*, PSYCH. TODAY (July 28, 2021), https://www.psychologytoday.com/us/blog/emotional-fitness/202107/why-i-regret-not-having-children [https://perma.cc/J8HV-VZQT]; *Child-Free People over 40 Are Sharing Whether or Not They Regret Not Having Kids, and It's Super Insightful*, BUZZFEED (Aug. 30, 2023), https://www.buzzfeed.com/victoriavouloumanos/older-people-who-are-childfree-share-how-life-is-now [https://perma.cc/GL7M-REQQ] ("We do not have kids by choice and certainly don't have regrets. I can tell you firsthand the problem is not that you personally regret the decision; it's dealing with parents . . . ." (quoting a Reddit user)).

[166] *See* Leslie Ashburn-Nardo, *Parenthood as Moral Imperative? Moral Outrage and the Stigmatization of Voluntarily Childfree Women and Men*, 76 SEX ROLES 393, 398 (2017).

Parenting is the presumed preferable path,[167] and motherhood, the "ultimate femininity."[168]

The narrative of regret in the context of childlessness, especially for those assigned female at birth, serves as a disciplining tool, threatening those who deviate from the norm of natalism. Those who choose not to have children often become subjects of "moral outrage."[169] As sociologist Orna Donath observed, "Regretting having behaved otherwise than socially expected wins respect, and thus regret can be utilized to maintain society's values. From this angle, regret becomes hegemony's watchdog, a normalizing mechanism aimed to restore each of us to the good graces of society."[170]

Prospective warnings of anticipated regret are notably absent for a larger group of individuals—those who become mothers.[171] A large percentage of mothers who

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[167] *See* DONATH, *supra* note 165, at 10 ("The American feminist philosopher Diana Tietjens Meyers refers to this as the colonization of our imagination, whereby we absorb the notion that motherhood is the only path to the point that we cannot conceive of other available options, making the only decision that can be imagined appear to have come from a 'pure space.'").

[168] DONATH, *supra* note 165, at 103; Rebecca Harrington, *Childless*, 29 PSYCHOANALYTIC DIALOGUES 35, 48 (2019) (describing how she and her patient both experienced themselves as outsiders for failing to become mothers and observing that "male gender identity does not seem to be nearly as tied to fatherhood as female gender identity is to motherhood");

[169] Ashburn-Nardo, *supra* note 166, at 398 (finding that participants in the study responded to childless by choice adults with "anger, disgust, and disapproval"); *see also* DONATH, *supra* note 165, at 9 (quoting Pope Francis, who claimed, in 2015, that choosing not to have children was "selfish"). Discussing societal denigration of women who remain childless by choice, psychoanalyst Katie Gentile observes that "Women without children, unlike men in the same position, are considered selfish, emotionally unavailable, aggressive, or just sublimating their 'natural' 'maternal instincts' into their jobs, animals ('furbabies'), or other activities that automatically lose their legitimacy when seen in this light." Katie Gentile, *"Dying for a Baby" and Other "Confusions of Tongues": A Discussion of "Childless*,*"* 29 PSYCHOANALYTIC DIALOGUES 51, 54 (2019).

[170] DONATH, *supra* note 165, at 57.

[171] Today over 86% of women in the United States give birth to a child before they are 49. PEW RSCH. CTR., THEY'RE WAITING LONGER, BUT U.S. WOMEN TODAY MORE LIKELY TO HAVE CHILDREN THAN A DECADE AGO 3 (Jan. 18, 2018), https://www.pewresearch.org/social-trends/wp-content/uploads/sites/3/2018/01/Pew-Motherhood-report-FINAL.pdf [https://perma.cc/3GNM-KG8Y]. This suggests that the total percentage of women who become mothers is higher than 86% because the statistic includes only those who have given birth thus excluding those who become mothers via adoption or stepparenting. *Id.* at 2 (noting that about 6% of children in the U.S. live with either an adoptive parent or a stepparent). By contrast, one recent study of Michigan adults found that 21.35% were childless by choice (as opposed to undecided or childless due to infertility issues or life circumstances). Jennifer Watling Neal & Zachary P. Neal, *Prevalence, Age of Decision, and Interpersonal Warmth Judgments of Childfree Adults: Replication and Extensions*, 18 PLOS ONE at 6, 9 (2023) (noting that one shortcoming of the data is that it is a snapshot in time and thus cannot account

participated in a 2023 study claimed to find parenting to be a source of joy and fulfillment.[172] Many reported, however, that mothering is harder, more stressful, and more tiring than expected.[173] Although data is limited, preliminary research suggests that around seven percent of parents regret the choice and would not have children again if they could do things over.[174]

Until recently, however, public dialogue about regretting motherhood was scarce.[175] In a groundbreaking book, *Regretting Motherhood: A Study*, Donath argued that "we fail to recognize the possibility of regretting motherhood."[176] She interviewed mothers who self-identified as regretting having children and found that while they all claimed to love their children, they viewed the decision to have a child

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for the possibility that some people will change their minds, but finding that the percentage of adults identifying as childfree by choice is about the same among those over forty as under); James L. McQuivey, *To Have Kids or Not: Which Decision Do Americans Regret More?*, INST. FOR FAM. STUD. BLOG (June 10, 2021), https://ifstudies.org/blog/to-have-kids-or-not-which-decision-do-americans-regret-more [https://perma.cc/25MX-YTNF] (including statistics from the US Adult Sexual Behaviors and Attitudes study from 2021 finding that 19% of Americans do not have and do not want children and 10% have children and wish they had fewer or none).

[172] Katherine Schaeffer & Carolina Aragão, *Key Facts About Moms in the U.S.*, PEW RSCH. CTR. (May 9, 2023), https://www.pewresearch.org/short-reads/2023/05/09/facts-about-u-s-mothers/ [https://perma.cc/JS7L-TSPW] (reporting survey results finding that 83% of moms say that being a parent is "enjoyable for them most (56%) or all of the time (27%)" and 80% say it is "rewarding most or all of the time").

[173] *Id.* (reporting survey results finding that 66% of mothers say "being a parent is a lot or somewhat harder than they thought it would be," 47% of mothers reporting that being a parent is tiring all or most of the time, and 33% of mothers saying that is stressful all or most of the time).

[174] Konrad Piotroswki, *How Many Parents Regret Having Children and How It Is Linked to Their Personality and Health: Two Studies with National Samples in Poland*, 16 PLOS ONE at 2–3 (2021) (citing data from a 2013 Gallup poll, not distinguishing participants by gender, in which 7% of respondents with children said that if they had it do over again they would have zero children). *See also* Eir Nolsoe, *One in Twelve Parents Say They Regret Having Children*, YOUGOV (June 24, 2021, 2:53 AM), https://yougov.co.uk/society/articles/36590-one-twelve-parents-say-they-regret-having-children [https://perma.cc/9CL5-9E92] (finding, based on a YouGov survey, that 8% of parents expressed regret at the time of the study and another 6% said that they had previously experienced regret but no longer did); Anne Kingston, *'I Regret Having Children': In Pushing the Boundaries of Accepted Maternal Response, Women Are Challenging an Explosive Taboo—and Reframing Motherhood in the Process*, MACLEAN'S, https://macleans.ca/regretful-mothers/ [https://perma.cc/RE9D-R77M] (describing a 1975 poll by advice columnist Ann Landers in which 70% of respondents said they would not have children if they had it to do over again).

[175] *See* Hillary Grill, *What Women Want: A Discussion of "Childless,"* 29 PSYCHOANALYTIC DIALOGUES 59 (2019) (observing that widespread pronatalist assumptions prevent serious inquiry into what individual women actually want, arguing that "[t]he conflation of feminine, woman, and motherhood serve to negate female subjectivity").

[176] DONATH, *supra* note 165, at 48.

as a mistake.[177] For many, it was traumatic.[178] Many women in the study reported experiencing coercion, suggesting that while they consented to have children, they never wanted them.[179] In the years since Donath's study, the topic has received more attention.[180]

One factor explaining the dearth of public dialogue on regretting motherhood is the children themselves. Philosopher R. Jay Wallace argues that many mothers do not have access to what he calls "all-in regret" because they form attachments to their children, so even if they continue to believe that the choice to have a child was the wrong choice, they may nevertheless affirm it.[181] Thus for women who may in fact have preferred not to become mothers, the language of regret is unavailable. This hypothesis is consistent with the findings of Donath's interviews, in which many of the respondents emphasized that they did not regret "the existence of their children in the world," but rather they regretted "becoming their mothers and being responsible for their [children's] lives."[182] This confirms that these mothers were not experiencing "all-in" regret, which by definition, includes comprehensive regret of everything flowing from the initial decision.[183]

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[177] *See id.* at 71–76 (distinguishing between regretting motherhood and regretting the children).

[178] *See id.* at 106–10.

[179] *See id.* at 21–27. *See also* Raymond Shih Ray Ku, *Free Speech & Abortion: The First Amendment Case Against Compelled Motherhood*, 43 CARDOZO L. REV. 2105, 2138 (2022) (characterizing abortion bans as a form of compelled motherhood that force the identity of mother and the expressions of pregnancy onto individuals who would otherwise seek abortions); Katharine Silbaugh, *Family Needs, Family Leave in 2023*, 53 SETON HALL L. REV. 1609, 1610, 1613–18 (2023) (also characterizing post-*Dobbs* abortion restrictions as forced parenthood). On reproductive coercion more generally, see Jessica E. Moulton, Martha Isela Vazquez Corona, Cathy Vaughan, & Meghan A Bohren, *Women's Perceptions and Experiences of Reproductive Coercion and Abuse: A Qualitative Evidence Synthesis*, 16 PLOS ONE (2021); A. Rachel Camp, *Coercing Pregnancy*, 21 WM. & MARY J. WOMEN & L. 275 (2015).

[180] Kingston, *supra* note 174 (identifying a number of recent books and articles on the topic); Valerie Heffernan & Katherine Stone, *International Responses to Regretting Motherhood*, *in* WOMEN'S LIVED EXPERIENCES OF THE GENDER GAP: GENDER INEQUALITIES FROM MULTIPLE GLOBAL PERSPECTIVES 121 (Angela Fitzgerald ed., 2021) (crediting Donath's study with "open[ing] conversation about regret," and concluding based on a study of responses to the book that the conversation is "perceived as a further step toward destabilizing traditional attitudes towards gender roles").

[181] WALLACE, *supra* note 21, at 98. Wallace himself imagines only the possibility that the mistake was to have children too early and not that the mistake was to have children at all. *Id.* at 118–31.

[182] DONATH, *supra* note 165, at 75. For another narrative describing a personal experience with this phenomenon, see Merritt Tierce, *The Abortion I Didn't Have*, N.Y. TIMES (Dec. 2, 2021), https://www.nytimes.com/2021/12/02/magazine/abortion-parent-mother-child.html [https://perma.cc/7WU5-546U].

[183] WALLACE, *supra* note 21, at 98.

Contrasting the data about regretting motherhood with data about those who regret having received GAC (around one percent)[184] and those who regret receiving abortions (under three percent)[185] reveals much about the politics and ideology of regret narratives.[186] Post-2020s abortion and GAC bans hinge on intertwined ideologies of natalism and rigid gender roles, particularly those defining women as mothers and caregivers. Warnings about future regret are also directed at those who choose to remain childfree. Ironically, political and legislative focus bypasses the most common regret: motherhood.

2. The Male-Female Binary

The rise of transgender visibility since the 2000s, and the increasing numbers of transgender and non-binary identifying youth and adults have generated a new dread for conservatives: *sex is mutable*! An increasing number of men in America were assigned female at birth, and an increasing number of women were assigned male at birth. In addition, more young Americans are identifying as non-binary.[187] Younger generations are apparently less bound by traditional convictions about sex as binary and immutable. This new reality has generated anxiety, violence, and a national moral panic, all of which are reflected in legislative campaigns against transgender children and youth.

Conservative *New York Times* opinion columnist Ross Douthat has expressed this moral panic, calling it a *New LGBTQ Culture War*.[188] Douthat reported with alarm that "[c]omparing the Generation Z to the baby boom generation, the percentage of people identifying as transgender, in particular, has risen twentyfold."[189] He warned, "we have been running an experiment on trans-identifying youth without good or certain evidence, *inspired by ideological motive* rather than scientific rigor, in a way that future generations will regard as a grave medical-political scandal."[190] Douthat predicted that liberals will regret this moment

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[184] *See*, *e.g.*, Valeria Bustos, Samyd Bustos, Andres Mascaro, Gabriel Del Corral, Antonio Forte, Pedro Cuidad, Esther Kim, Howard Langstein, & Oscar Manrique, *Regret After Gender-Affirmation Surgery: A Systematic Review and Meta-Analysis of Prevalence*, J. AM. SOC. PLASTIC SURGEONS 1 (2021).

[185] *See supra* note 64 and accompanying text.

[186] Imagine advocating bans on parenting based on these levels of future regret!

[187] Anna Brown, About 5% of Young Adults in the U.S. Say Their Gender Is Different from Their Sex Assigned at Birth, PEW RSCH. CTR. (June 7, 2022), https://www.pewresearch.org/short-reads/2022/06/07/about-5-of-young-adults-in-the-u-s-say-their-gender-is-different-from-their-sex-assigned-at-birth/ [https://perma.cc/722A-9L92].

[188] Ross Douthat, Opinion, *How to Make Sense of the New L.G.B.T.Q. Culture War*, N.Y. TIMES (Apr. 13, 2022), https://www.nytimes.com/2022/04 /13/opinion/transgender-culture-war.html [https://perma.cc/T9TC-57PC] ("Almost twenty-one percent of Generation Z—meaning, for the purposes of the survey, young adults born between 1997 and 2003—identifies as L.G.B.T., as against about 10 percent of the millennial generation, just over 4 percent of my own Generation X and less than 3 percent of baby boomers . . . .").

[189] *Id.*

[190] *Id.* (emphasis added).

in which they supported the trans-identified youth in gender transitions, arguing "if you are a liberal who believes [that there is no evidence to support gender-affirming care for youth] but you don't feel comfortable saying it, *your silence will eventually become your regret*."[191]

This anxiety fuels GAC bans for minors, which are designed to *preserve the male-female binary* (as assigned at birth) and are justified as regret-preventative. The bans contain two features to this end. First, they typically define sex strictly as "biological sex,"[192] while excluding or ignoring *gender identity* as a core characteristic of sex.[193] This is a striking feature that unites these laws. This definition explicitly and intentionally contradicts many current legal rules and most leading sex, medical, psychiatric and pediatric guidelines that view gender identity (an internal sense of being male, female, or non-binary) as a key factor in determining an individual's sex.[194] For instance, the Diagnostic and Statistical Manual of Mental Disorders ("DSM-5") of the American Psychiatric Association ("APA") includes a diagnosis of "gender dysphoria," a condition defined as a "distress that may accompany the incongruence between one's experienced or expressed gender and one's assigned gender."[195]

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[191] *Id.* (emphasis added).

[192] *See*, *e.g.*, S.B. 184, 2022 Leg., Reg. Sess. (Ala. 2022) § 2(1) ("the sex of a person is the biological state of being male or female, based on sex organs, chromosomes, endogenous hormone profiles, and is genetically encoded into a person at the moment of conception, and it cannot be changed"); H.B. 1570, 2022 Leg., Reg. Sess. (Ark. 2021) ("'Biological Sex' means the biological indication of male and female in the context of reproductive potential or capacity, such as sex chromosomes, naturally occurring sex hormones, gonads, and nonambiguous internal and external genitalia present at birth, without regard to an individual's psychological, chosen, or subjective experience of gender.").

[193] This reverses a trend in medical literature and in courts to define sex by reference to gender identity. *See* Ben-Asher, *Transforming Legal Sex*, *supra* note 7 (identifying a backlash against the increasing legal acceptance of the concept of "gender identity").

[194] *See*, *e.g.*, GLAAD, GLAAD MEDIA REFERENCE GUIDE (10th ed. 2016), https://publicwebuploads.uwec.edu/documents/GLAAD_Media_Reference_Guide.pdf [https://perma.cc/N9L3-F52G] ("Gender Identity: A person's internal, deeply held sense of their gender. For transgender people, their own internal gender identity does not match the sex they were assigned at birth. Most people have a gender identity of man or woman (or boy or girl). For some people, their gender identity does not fit neatly into one of those two choices . . . .").

[195] AM. PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 451 (5th ed. 2013); *see also* Jack Turban, *What Is Gender Dysphoria?*, AM. PSYCHIATRIC ASS'N (Aug. 2022), https://www.psychiatry.org/patients-families/gender-dysphoria/what-is-genderdysphoria [https://perma.cc/FP5P-XY5V] (defining dysphoria as "clinically significant distress or impairment in social, occupational, or other important areas of functioning").

Second, bans on gender-affirming care include an exception for provision of care to a child born with intersex conditions, sometimes known as DSD.[196] According to DSM-5, "Disorders of sex development (DSD) refers to a group of medical conditions (e.g., XXY/Klinefelter Syndrome, 45XO/Turner Syndrome, or Androgen Insensitivity Syndrome) in which anatomical, chromosomal, or gonadal sex varies in some way from what would be typically considered male or female."[197] Current exceptions in the GAC bans allow for surgery and hormone treatment when a child is diagnosed with a DSD condition. They allow doctors to assign a child a sex, and for parents to consent to medical procedures that would conform the assignment with the child's body. Despite vast literature on the actual and real regret of intersex individuals who undergo sex assignment surgery as children or infants, current GAC bans allow for such surgeries and medical care to continue.[198] Only an ideology of preserving the male-female binary as it is traditionally understood explains why these bans would *deny* gender affirming care to those who seek it (transgender teens and youth) and *allow* it to be imposed on those who do not (intersex infants and children).

C. The Perils of Using Regret in Political Projects

After *Carhart*, legal scholar Chris Guthrie warned that legislatures might follow *Carhart*'s logic to use presumed future regret to justify constraints on autonomy.[199] Part I, *supra*, suggests that there is good reason to take this warning seriously—legislatures have relied in part on regret to constrain the autonomy of children seeking GAC and their parents. In addition, two phenomena suggest that regret is a permanent fixture in the legal landscape. First, as discussed in Part III.B, *supra*, regret often serves as proxy for traditional morality, and morality plays an

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[196] *See Policy Tracker: Youth Access to Gender Affirming Care and State Policy Restrictions*, KFF (last updated Jan. 31, 2024), https://www.kff.org/other/dashboard/gender-affirming-care-policy-tracker/ [https://perma.cc/5AVM-MKXU] (finding that twenty-three of twenty-three statutes "permit[] Rx and Surgical Care Used in GAC for Other (non-GAC) Medical Purposes"). *See* S.B. 14, 2022 Leg., Reg. Sess. (Tex. 2022).

[197] *Gender Dysphoria Diagnosis*, AM. PSYCHIATRIC ASS'N (Nov. 2017), https://www.psychiatry.org/psychiatrists/diversity/education/transgender-and-gender-non conforming-patients/gender-dysphoria-diagnosis [https://perma.cc/62ER-JQLM] ("Some individuals with such conditions prefer the term 'intersex'").

[198] *See*, *e.g.*, SUZANNE J. KESSLER, LESSONS FROM THE INTERSEXED 4–7 (1998); SHARON PREVES, INTERSEX AND IDENTITY: THE CONTESTED SELF 32–36 (2003); KATRINA KARKAZIS, FIXING SEX: INTERSEX, MEDICAL AUTHORITY, AND LIVED EXPERIENCE 49–62 (2008). *See also* Noa Ben-Asher, *The Necessity of Sex Change: A Struggle for Intersex and Transsex Liberties*, 29 HARV. J.L. & GENDER 51, 55 (2006) (arguing for liberty of intersex infants and children from unnecessary medical intervention, and for a positive liberty of transgender individuals to pursue gender identity and gender affirming care).

[199] Guthrie, *supra* note 73, at 880–81 (observing that "as an analytical matter, if the state is deemed to have a legitimate interest in protecting citizens from experiencing regret associated with the exercise of one right, the state should also have an interest in protecting citizens from experiencing regret associated with the exercise of other rights").

increasingly important role in contemporary courts and legislatures. Second, rapid developments of science and technology open up new realms for self-realization and exploration. More choices. More to regret.

When, if at all, is preventing regret a legitimate state interest? Two interventions may help clarify and streamline policy debates around regret. First, policymakers should not treat regret as a monolith (as did the lawmakers in Parts I and II). Political debates around regret often conflate a variety of emotional states: trauma, disappointment, repentance.[200] As Jeannie Suk Gersen observed, stories of regret are often, in fact, stories of trauma.[201] Whereas regret is an emotional experience—usually defined simply as the preference that something in the past had gone differently—trauma is both an emotional and physical experience.[202] To the extent regret is a stand in for trauma, preventative legislation is a fraught endeavor. Any medical procedure including abortion, childbirth, mastectomy, or rhinoplasty, can cause trauma. But denial of medical treatment can also cause trauma.

Trauma-prevention is, unquestionably, a legitimate state interest, but the difficulty of distinguishing, ex ante, between medical treatment that will cause trauma and that which will not, complicates potential legislation and counsels in favor of caution. Standard medical malpractice law navigates this quagmire through

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[200] In the GAC context, commentators often also conflate regret with the choice to cease care. A recent study of youth that discontinued gender-affirming care offers a more complex understanding of detransition and regret. *See* Annie Pullen Sansfaçon, Ello Gravel, Morgane Gelly, Tommy Planchat, August Paradis & Denise Medico, *A Retrospective Analysis of the Gender Trajectories of Youth Who Have Discontinued a Transition*, INTL. J. OF TRANSGENDER HEALTH (2023). The authors observe that

> The idea of detransition is often conflated with experiences of regret after a gender transition . . . . However, negative transition experiences may only be a subcategory within experiences of detransition . . . . Although regret may accompany a detransition, other feelings can be presenting such positive one or ambivalence and can evolve over time.

Id. The researchers of this study, which included twenty youth participants (most of them assigned female at birth) who discontinued transition ("YDT") concluded that

> YDT undergo diverse gender journeys and changes in various aspects of their experiences . . . . [O]ur study revealed nuances and evolving perspectives in youth, challenging previous research that simplified discontinuation as a single set of factors outcome. This insight encourages providers to critically assess narratives as presented in the media and refine their practice to better support youth, regardless of their gender journey direction.

Id.

[201] *See* Suk, *supra* note 69.

[202] Greasley, *supra* note 165, at 710 (distinguishing between psychological trauma and regret); Ben-Asher, *Trauma-Centered Social Justice*, *supra* note 100 (defining trauma and exploring how it is used in social justice movements); WALLACE, *supra* note 21, at 6 (defining regret).

the doctrine of informed consent—seeking to ensure that patients choose whether or not to receive medical care on the basis of accurate and sufficiently thorough information about risks, including psychological risks, and effectiveness of treatment. In the cases of abortion and GAC—where reported rates of trauma are quite low—potential regret does not provide adequate justification for legislative action.

Alternative versions of regret—regret as disappointment and regret as moral judgment—further undermine the legitimacy of regret as the basis for state action. Stories of regret can often be stories of disappointment. The decision did not generate the desired result. This is particularly true in the context of GAC, where regret can follow from medical care that does not successfully allow a trans person to "pass."[203] In such cases, a person may lament the current state of things, the consequences of seeking care, but might nevertheless not do anything differently if they could make the decision again knowing what they know now. Regret might also be a "retrospective *judgment* about the wrongness of the . . . decision."[204] Anti-abortion advocacy groups highlight, and perhaps encourage, this variation of regret through post-abortion counseling services that emphasize "forgiveness" and "redemption."[205]

These alternative permutations of regret point to a second critical consideration for lawmakers. Drawing on the philosophical literature unpacking the meaning and experience of regret, it may be helpful to understand "regret" in relation to "affirmation," and to contextualize both. Neither regret nor affirmation follow inevitably from a particular decision. Instead, according to philosopher R. Jay Wallace, whether an individual eventually comes to regret or affirm a decision depends, in large part, on the attachments that they form (or fail to form) as a result of that decision.[206] Wallace reasons from this observation that it is necessary to

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[203] *See* Marci L. Bowers, *What Decades of Providing Trans Health Care Have Taught Me*, N.Y. Times (Apr. 1, 2023), https://www.nytimes.com/2023/04/01/opinion/trans-healthcare-law.html [https://perma.cc/7ULU-7NZ4] (disentangling the many different reasons that people who sought GAC might experience some kind of regret).

[204] Greasley, *supra* note 165, at 706.

[205] *See Post Abortive Recovery Services*, FOCUS ON THE FAM. (last visited Feb. 27, 2024), https://www.focusonthefamily.com/get-help/post-abortive-recovery-resources/ [https://perma.cc/57FJ-G3NF]; *see also Post Abortion Support*, LIFE CLINIC: CMTY. RESOURCES (last visited Feb. 27, 2024), https://lifeclinic.org/trauma-services/post-abortion-support/ [https://perma.cc/57FJ-G3NF] (describing emotional effects of abortion including "mild to severe grief, anger, and shame"); *Hope and Healing*, SISTERS OF LIFE, https://sistersoflife.org/healing-after-abortion/ [https://perma.cc/LQ6M-GPWF] (last visited Feb. 27, 2024) (describing the feelings of "deep guilt, shame, pain, anxiety, depression, fear, and feelings of isolation from God and others" that can follow abortion); Greasley, *supra* note 165, at 706 (arguing that what these anti-abortion services are doing is treating all regret as "regret that, once pregnant, she decided to end the life of the fetus" and ignoring the wide variety of other aspects of the abortion that a woman might regret, such as regret that she got pregnant in the first place, or regret that the abortion was necessary).

[206] *See* PAUL J. GRIFFITHS, REGRET: A THEOLOGY 24–27 (2021) (offering a Christian theological account differentiating mistakes).

consider regret independently from the normative desirability of the initial decision.[207]

Legal scholar Kate Greasley draws on this literature to debunk what she calls the "moral justification thesis" in anti-abortion advocacy. The core (false) premise, she explains, is that "postabortion regret renders abortion morally unjustified."[208] Applying Wallace's theory of regret to abortion regrets, she concludes that just as the absence of regret in having a child does not tell us that having the child was the morally desirable choice, the "*presence* of regret in the abortion scenario does not therefore take on justificatory significance simply because, had she kept the pregnancy, she would eventually have to affirm her decision."[209] In other words, the normative assessment of a reproductive choice (was it morally desirable or not?) in hindsight cannot be assessed through the lens of regret or affirmation because those are determined by later attachments (or their absence).

Similarly, a person who receives gender-affirming care and loses (or fails to gain) access to a school, a job, a close relationship with a parent, sibling, partner, or friend, may regret receiving gender-affirming care. In this hypothetical, the regret flows from the *traumatic loss* of (or an inability to form) a desired attachment. Thus, the regret in this hypothetical does *not* indicate that the decision to receive gender-affirming care was normatively or morally undesirable.

Disentangling regret from normative assessment helps illuminate the ways in which regret can be socially and politically constructed.[210] If, as Wallace posits, whether a person come to regret a choice depends on how that choice affects their attachments, then, to understand potential for regret, lawmakers must evaluate what those effects might be. But such analysis is contingent on unpredictable future events. For instance, a study in the 1970s of post-sterilization regret found that one of the populations most likely to regret the decision were those who ultimately separated from their current partners and entered a new relationship in which they desired to "bear children to a new partner."[211] These effects are also subject to manipulation. In the abortion context, laws requiring an ultrasound prior to abortion can hasten regret by causing a pregnant person to develop an attachment to a fetus that they may not otherwise have had.[212] Social influence is also an important factor. For instance, the widespread availability of post-abortion counseling provides

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[207] *See* WALLACE, *supra* note 21, at 6–7.

[208] Greasley, *supra* note 165, at 707–08.

[209] *Id.* at 710.

[210] Appleton, *supra* note 72, at 316–17 (identifying a variety of ways in which public policy might generate regret of adoption and abortion decisions).

[211] Brian Alderman, *Women Who Regret Sterilization*, 2 BRIT. MED. J. 766, 766 (1977).

[212] Appleton, *supra* note 72, at 316–17; *see also* Katrina Kimport, *(Mis)Understanding Abortion Regret*, 35 SYMBOLIC INTERACTION 105, 106 (2012) (identifying "seeing an ultrasound" as one of many experiences that can increase a person's attachment to pregnancy).

individuals with a vocabulary and a framework through which to understand a broad range of complicated feelings that they may have after an abortion.[213]

Policymakers and courts should be skeptical of regret-prevention as a state interest, and instead strive to deconstruct the normativities driving regret in the first place. Removing regret from the conversation forces a more honest reckoning with what is at stake in these decisions—bodily autonomy, religious freedom, and the rights to self-identification and expression.

CONCLUSION

Regret is a fundamental part of the human experience, and it can be generative, even "transformative."[214] In a provocative piece entitled, *My New Vagina Won't Make Me Happy: And It Shouldn't Have To*, transgender activist and public intellectual, Andrea Long Chu, reflected on her own gender dysphoria and transition. She wrote,

> I'm telling you now: I still want this, all of it. I want the tears; I want the pain. Transition doesn't have to make me happy for me to want it. . . . Desire and happiness are independent agents. . . . Nothing, not even surgery, will grant me the mute simplicity of having always been a woman. I will live with this, or I won't. That's fine. The negative passions — grief, self-loathing, shame, regret — are as much a human right as universal health care, or food. There are no good outcomes in transition. There are only people, begging to be taken seriously.[215]

Many states have restricted access to abortion and gender-affirming care, ostensibly to protect individuals from decisions they may later regret. But the well-being of these individuals is not, and never was, the motivation behind this legislation. Rather, these laws are emblematic of a conservative agenda seeking to regress the nation to an era when women and LGBTQ+ people had no rights. Conservative lawmakers cite anecdotal cases of people discontinuing gender-affirming care or regretting abortions to justify denying these medical services

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[213] Greasley, *supra* note 165, at 706–07 (observing that "women who do undergo abortions may be culturally conditioned or required to fit their subsequent reflections into a certain expressive framework, typically packaged in the language of regret"); Kimport, *supra* note 212, at 110–12 (identifying social disapproval of friends and family as an important factor in shaping post-abortion emotional experiences).

[214] BRIAN PRICE, A THEORY OF REGRET 134 (2017) (arguing that "turmoil, anxiety, and disarray are not only devastating . . . but also productive of thought itself, which rarely happens, when it happens, with immediate clarity, ease and indications of self-assurance"); Guthrie, *supra* note 73, at 898–902 (describing the way that regret can function as a learning tool that improves decision-making going forward).

[215] Andrea Long Chu, *My New Vagina Won't Make Me Happy: And It Shouldn't Have To*, NY TIMES (Nov. 24, 2018), https://www.nytimes.com/2018/11/24/opinion/Sunday/vaginoplasty-transgender-medicine.html [https://perma.cc/LD47-6NJQ].

broadly. Yet, available research suggests regret is extremely uncommon for transgender youth receiving gender-affirming care, and the vast majority affirm their decision to have an abortion. The general public should be skeptical of these regret stories. Judges, likewise, should scrutinize regret-prevention rationales and treat them as what they are: foot soldiers in the ongoing battle over the "soul of America."

Canadian Paediatric Society

POSITION STATEMENT

An affirming approach to caring for transgender and gender-diverse youth

Test Your Knowledge

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Abstract

Increasing numbers of youth identify as transgender or gender-diverse (TGD). Many paediatricians and primary care providers (PCPs) will encounter this population in their practice, either for gender-related care or general health needs. This statement is intended as a resource to guide paediatricians and PCPs in implementing an affirming approach to routine health care provision for all youth. Furthermore, it presents information to assist providers in responding to requests for counselling from TGD youth and their families around potential options for medical transition, and in making referrals to specialized services, if desired and relevant. Finally, as demand for gender-affirming care is anticipated to continue to increase, some health care providers (HCPs) may wish to develop the knowledge and skills required to initiate adolescents on hormone-blocking agents and gender-affirming hormones. This document is not intended to be a clinical practice guideline, but will provide foundational information regarding these potential components of gender-affirming care, recognizing that the needs and goals of individual adolescents may or may not include such interventions. Additional resources relevant to developing the expertise required to provide gender-affirming interventions will also be identified.

Keywords: *Adolescent; Gender diverse; Health; Hormones; Paediatrics; Transgender; Youth*

Introduction

Paediatricians and other primary care providers (PCPs) are optimally positioned to support children and youth through the developmental processes that contribute to identity formation. Gender identity, a critical facet of a young person's sense of self, first emerges in early childhood and evolves over the child and adolescent life course[1][2]. Recent studies suggest that an increasing number of youth identify with a gender other than the sex assigned to them at birth, and demand and need for gender-related care within the paediatric health care system is growing[3]-[10]. Paediatricians and PCPs may be the first professionals from whom transgender or gender-diverse (TGD) youth and their families seek support[11]. However, providers often lack knowledge, training, and comfort in how to care for this population[12][13]. This position statement reviews opportunities to provide affirming, supportive, inclusive, and non-judgmental care to youth of all gender identities across the health care system.

Terminology

Being familiar with common and appropriate terms to use when caring for TGD youth can help cultivate an affirming and supportive clinical environment[14] (Table 1).

Table 1. **Key terms relevant to gender-affirming care**

Term	Definition
Assigned sex at birth, AMAB, AFAB	Referring to a person's initial designation as male ("assigned male at birth" – AMAB) or female ("assigned female at birth" – AFAB) at birth, this label is based on the child's genitalia and other visible physical sex characteristics
Cisgender	Individuals whose gender identity aligns with their sex assigned at birth
Gender-affirming care	Care provided to an individual to support their gender identity; this care may be medical, surgical, social, and/or psychological
Gender-affirming hormone therapy (GAHT)	Hormones prescribed to induce the development of secondary sex characteristics associated with an individual's experienced gender: testosterone for those who seek masculine features, and 17β-estradiol for those seeking feminine features
Gender-affirming surgeries	Also called 'transition-related surgeries' or 'gender-confirming surgeries', this term refers to a range of surgical options that individuals may pursue as a component of transitioning

Gender-diverse	A broad term used to describe people with gender expressions or identities that are different from their assigned sex at birth. The term acknowledges and includes the vast diversity of existing gender identities. It replaces terms such as gender-nonconforming, gender-incongruent, and gender-variant, all of which have pathologizing or exclusionary connotations[14]. Not all transgender individuals identify with this term
Gender dysphoria	Refers to the distress that can arise from the incongruence between an individual's experienced gender and their sex assigned at birth. Gender dysphoria is a formal diagnosis in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR)
Gender expression	The way a person portrays gender to others through external means, such as clothing, appearance, or mannerisms; this may or may not reflect gender identity
Gender identity	Also called 'experienced' or 'affirmed' gender, this is an individual's internal, psychological sense of their own gender
Gender incongruence	Refers to a person's marked and persistent experience of an incompatibility between their gender identity and the gender expected of them based on their sex assigned at birth. Gender incongruence is a diagnostic term used in the International Classification of Diseases Eleventh Revision (ICD-11). Use of this term should be limited to diagnostic contexts

Gonadotropin-releasing hormone agonist (GnRHa)	A long-acting pharmacological analogue of naturally produced gonadotropin-releasing hormone that is prescribed to inhibit production of pituitary gonadotropins (LH and FSH), thereby inhibiting gonadal production of sex steroids (i.e., testosterone or estrogen)
Medical transition	The process of undergoing medical treatment to align one's physical experiences with one's gender identity (e.g., by using hormone blockers or gender-affirming hormones)
Non-binary	A gender identity that is neither entirely male nor entirely female
Social transition	The process of expressing one's gender identity outwardly to others through such actions as changing name, pronouns, and/or gender expression (e.g., clothing, hair style)
Transgender	An umbrella term used to describe all individuals with a gender identity that differs from their sex assigned at birth and physical sex characteristics. Not all gender-diverse individuals identify with this term
Transgender female, transfeminine, trans girl, trans female, formerly 'MTF'	These terms describe an individual assigned male at birth but who identifies along the feminine spectrum

Transgender male, transmasculine, trans boy, trans male, formerly ‘FTM’	These terms describe an individual assigned female at birth but who identifies along the masculine spectrum
Two-Spirit	Referring to a person who identifies as having both a masculine and a feminine spirit, this term is used by some Indigenous communities and can encompass cultural, spiritual, sexual and/or gender identity

Note that terminology is sure to evolve with time.

*This table is also available as a downloadable resource.

The development of gender identity

Gender cognition emerges early in life. By 2 years of age, children are often able to identify differences between sexes, and by age 3, most can label their gender with ease[1]. Over the course of the preschool years (ages 3 to 5) children develop an appreciation for gender stability — the notion that gender is stable over the life course[15]. However, preschoolers do not typically recognize gender as an identity, but rather (and primarily) attribute it to external features and appearances[16]. They are highly attuned to gender roles and behaviours, often aligning themselves closely with those of the same gender and expressing preferences for toys or activities that are stereotypically associated with their gender[17]. At this age and stage, displaying gender-atypical behaviour does not necessarily reflect a gender identity that differs from assigned sex[18]. Parents of young children should be encouraged to provide their child with a safe environment for gender exploration that does not make assumptions about future gender identity[19].

By age 6 to 7 years, children begin to appreciate gender as an identity independent of external features. They may start to reduce outward or stereotypical expressions of gender, though they often continue to show affinity for same-gender peers and gender-typed toys and clothing through middle childhood[1][16]. As they move through late childhood and transition into adolescence, a more sophisticated appreciation for gender identity emerges, with pubertal onset being a particularly salient event that may trigger more intensive reflection on the alignment of assigned and experienced gender[20].

Most research on gender identity development has been conducted with cisgender children, using a White, Eurocentric lens. The developmental trajectory of children who do not identify with their sex assigned at birth is an active focus of scientific study, and characterizations of gender identities across cultures and ethnicities are only beginning to be recognized in the dominant literature. Recent research has suggested that some children may recognize a degree of ‘mismatch’ between their gender identity and their assigned sex as early as age 2 to 3 years[2][16]. Similar to their cisgender peers, school-aged TGD children can have a strong

sense of gender identity and a preference for peers of the gender with which they identify, along with the objects and activities they endorse or pursue[1][17][21]. For others, awareness of a difference between assigned and experienced gender may not emerge until puberty or beyond[2][22]-[24]. While current conceptualizations of gender are often categorical (i.e., binary: male versus female and fixed over time), emerging theoretical and empirical studies that employ multidimensional and dynamic constructs of gender may afford more nuanced insights into this domain, throughout the life course[2][25][26].

A snapshot of transgender and gender-diverse youth

A growing number of youth articulate a gender identity that differs from the sex they were assigned at birth. Population-based studies from a number of high-income countries have estimated the proportion of the adolescent population who identify as transgender ranges at between 1% and 4%[27]-[32]. A recent study of school-attending youth that asked about gender identity without using the term "transgender" found that 9.2% of respondents reported a difference between sex assigned at birth and experienced gender[33].

TGD youth are at elevated risk for adverse health outcomes, including depression, anxiety, eating disorders, self-harm, and suicide[34]-[45]. This elevated risk is thought, in part, to be attributable to 'minority stress', defined as the "distinct, chronic stressors minorities experience related to their stigmatized identities, including victimization, prejudice, and discrimination"[46]-[48]. Consistent with this theory, Canadian TGD youth report high levels of exposure to harassment and violence[49][50]. Risk may be mitigated by affirming experiences and environments, such as supportive parents, early social transition for those who express this desire, and inclusive and non-judgmental interactions with the health care system[51]-[59].

Gender dysphoria

The term 'gender dysphoria' is often used descriptively, to characterize the significant distress that can arise when an individual's experienced gender does not align with their sex assigned at birth. Clinically, the DSM-5-TR presents criteria for the diagnosis of gender dysphoria in children (Table 2), and in adolescents and adults (Table 3)[60]. The inclusion of gender dysphoria in the DSM-5-TR is a topic of ongoing debate. Some argue that including the term promotes a binary view of gender and pathologizes gender diversity in a manner that perpetuates stigma. Others assert that its inclusion helps facilitate access to relevant services[60][61]. The recently published World Professional Association for Transgender Health Standards of Care 8 (WPATH SOC-8) advocates that where a diagnosis is required to support access to care, the International Classification of Diseases Eleventh Revision (ICD-11) diagnosis of 'gender incongruence' should be used preferentially, when jurisdictionally feasible. This diagnosis does not require that there be distress associated with gender diversity, and is therefore considered less pathologizing[62][63]. At present, however, the ICD-11 is not widely used in Canada. The utility of diagnosing either gender dysphoria or gender incongruence in young children is particularly contentious, because prepubertal children experiencing gender diversity may not continue to have this experience into adolescence, and medical interventions are not recommended for prepubertal children[2][20][64][65].

When an adolescent voices concerns of gender dysphoria, care should be taken to facilitate timely access to appropriate psychosocial supports and diagnostic assessment. In many jurisdictions, options for gender-affirming medical treatment require a formal diagnosis of gender dysphoria. Younger age and earlier pubertal

stage at time of presentation for medically affirming care have been associated with lower rates of mental health conditions[45][66]. Individuals diagnosed with gender dysphoria should be reassured that this diagnosis does not indicate "pathological" gender identity, but rather, characterizes the distress that arises from their sex assigned at birth not aligning with their identified gender[2][61]. Formal efforts to change a young person's gender identity, sometimes referred to as "conversion" or "reparative" therapy, are harmful and unethical and should not be undertaken[58][61][62].

Table 2. **Diagnostic criteria for gender dysphoria in children**

Diagnostic Criteria

Gender Dysphoria in Children

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months duration, as manifested by at least six of the following (one of which must be Criterion A1):

1. A strong desire to be of the other gender or an insistence that one is other gender (or some alternative gender different from one's assigned gender).
2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.
3. A strong preference for cross-gender roles in make-believe play or fantasy play.
4. A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender.
5. A strong preference for playmates of the other gender.
6. In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities.
7. A strong dislike of one's sexual anatomy.
8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.

B. The condition is associated with clinically significant distress or impairment in social, school, or other important areas of functioning.

Reference 60

Table 3. **Diagnostic criteria for gender dysphoria in adolescents and adults**

Diagnostic Criteria

Gender Dysphoria in Adolescents and Adults

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months duration, as manifested by at least two of the following:

1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics).
2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced and/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).
3. A strong desire for the primary and /or secondary sex characteristics of the other gender.
4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Reference 60

Strategies for providing a gender-affirming health care experience

Inclusive and affirming approaches to engaging youth in health care promote safety for all adolescents, and can be particularly impactful for youth with multiple structurally marginalized identities (e.g., Black or Indigenous adolescents)[67]. Attention must be paid to both the environmental and interpersonal aspects of health care encounters, with particular focus on a welcoming clinical space, the use of affirming language, and adolescent-oriented care (Table 4)[35][59][68]-[82].

Table 4. Strategies for providing a gender-affirming health care experience

Objective	**Strategies**
Craft an affirming space	• Display a clinic mission statement that explicitly articulates a commitment to inclusive care • Have waiting room posters depicting youth with diverse gender expression[69][70] • Ensure all intake forms and questionnaires allow for diverse responses to demographic questions[69][70] • Designate bathrooms as gender-neutral[69][70] • Have all medical staff routinely introduce themselves with their names and pronouns[71]
Employ inclusive language	• Acknowledge diversity through language used in standard intake forms[69][72] • Provide adolescents with the opportunity to articulate the name and pronouns that best resonate with their experiences and identities, and the option of documenting pronouns and preferred name in their health record[69][73]-[75] • Consistently use an adolescent's preferred name and appropriate pronouns[68][69] • Train all staff interacting with youth in inclusive language[76] • Phrase questions in neutral terms during history-taking to avoid assumptions (e.g., "*Who makes up your family?*" rather than "*Do you live with your mother and father?*") • Avoid labelling. Instead, focus on experiences (e.g., "*Are you in a romantic relationship?*" rather than "*Do you have a boy/girlfriend?*")[35][68] • Ask for guidance with language (e.g., "*Is there a way you would like me to refer to your gender?*" rather than "*Do you identify as male, female, or non-binary?*") • Use gender-neutral language during physical exam (e.g., "*upper body*" rather than "*breasts*", or "*genitals*" rather than "*penis/vagina*")[77][78] • If you make a mistake with language, thank the youth for pointing out your error, apologize, and correct yourself

Provide adolescent-oriented care	• Engage youth collaboratively in all aspects of health care • Acknowledge specific intersections between an adolescent's health and life experiences[79][80] • Ensure confidentiality, but also review its limits with adolescents and involved parents or caregivers[35][69] • Spend some allotted time alone with adolescents for every visit, without a parent or caregiver present[81] • Support efforts to strengthen the parent–child relationship whenever possible[59][82]

A respectful, collaborative approach with adolescents positions the health care provider (HCP)'s medical expertise as complementing, rather than superseding, an adolescent's expertise in their own life experience. Foster self-efficacy, promote autonomy, and encourage self-reflection by recognizing—and building on—the adolescent's capacities[83]. An affirming approach should never be directive, but rather, should support the adolescent in identifying and moving along the trajectory that best aligns with their individual goals[30] through facilitated self-exploration and shared decision-making[83]. Starting from a strengths-based stance, asking open-ended questions, and responding to statements with reflections and curiosity are motivational interviewing-informed strategies that can promote collaborative exploration of an individual's motivation and goals. This approach also facilitates assessment of an adolescent's capacity to make treatment decisions. While attending to the adolescent's emerging autonomy, the value of having supportive family members or caregivers engaged in the life of the adolescent should also be emphasized. TGD youth with supportive parents have been shown to have markedly better mental health outcomes, including lower risk of suicide[59][82]. Efforts to strengthen the parent–child relationship should be made whenever possible.

Recognize the psychosocial context

During the one-on-one portion of each visit, consider exploring an adolescent's experiences using the HEEADSSS psychosocial interview tool[84]. A question pertaining to gender identity should be included for all youth, and can be phrased simply: "*How do you describe your gender identity?*" For TGD youth, additional questions exploring how their gender identity may impact or be affected by their experiences across psychosocial domains should be integrated into the HEEADSSS assessment (Table 5). If a concern is identified, further assessment and resources may be needed to ensure a holistic, safe care trajectory.

Table 5. Sample HEEADSSS questions for transgender or gender-diverse youth

Domain	**Question**
Home	• Are your parents or caregivers involved and supportive of your gender identity? • Do those you live with use your appropriate pronouns? • Do you feel safe expressing your gender identity at home?
Education and employment	• Are you able to express your gender safely at school and/or work? • Do you have access to a preferred washroom at school and/or work?
Eating	• Do you ever restrict or increase what you eat to change your body's appearance to better match your gender identity?
Activities	• Do you feel comfortable expressing your gender during after-school activities? • Do you have supportive peers and friends?
Drugs	• If you use substances, is this ever related to feelings about gender?
Sexuality and gender	• Are there particular genders you are attracted to? • If you have a partner, does your partner know about and support your gender identity?

Suicide/depression	• How do you feel about having a gender identity that differs from the sex you were assigned at birth?
Safety	• Are there places where, or people with whom you choose not to share your gender identity? Is this because you have safety concerns?

Clinical components of gender-affirming care

Gender-affirming medical interventions may be an important component of comprehensive care for some TGD adolescents. Open dialogue with an adolescent that emphasizes the diversity of paths that TGD individuals can take is critical to ensuring an individualized approach. Some TGD adolescents may only ever desire social transition, while others may pursue social transition initially and later become interested in medical options, while still others may articulate a clear goal of medical transition from early in adolescence. After completing a comprehensive biopsychosocial assessment, the following options for gender-affirming medical interventions may be considered for adolescents with marked and sustained gender diversity[62].

Hormone blockers

Also referred to as puberty blockers or hormone-suppressing agents, hormone blockers are medications that mitigate the effects of endogenously produced sex steroids. Hormone blockers commonly prescribed in Canada, and key considerations for their use are reviewed in Table 6. Hormone blockers can suppress sex steroid-mediated experiences, such as menses (for AFAB youth) or erections (for AMAB youth), and pause or slow sex steroid-related physical changes that continue into young adulthood. Gonadotropin-releasing hormone agonists (GnRHa) are hormone blockers that, if started before pubertal development is complete, will pause pubertal progression. Hormonal suppression is reversible, and endogenous sex-steroid production and/or effects will resume if hormone blockers are discontinued[62][64][85]-[89].

Initially, the clinical objective of prescribing a hormone blocker is to provide a young person with time to further explore their gender identity without pressure or distress related to ongoing development of secondary sex characteristics, or gendered experiences such as menses or erections[18][23][62][64][85][90]. Should a young person continue to express gender dysphoria over time and eventually wish to pursue other gender-affirming treatments, GnRHa may also prevent the further development of irreversible secondary sex characteristics that can make medical and surgical transition more difficult[18][62][64][85][86]. Additionally, their blocking action may also allow for the use of lower doses of gender-affirming hormones to achieve phenotypic transition goals later on[64][78][91].

TGD adolescents who have sought and received hormonal suppression as a part of a multidisciplinary approach to care report improved mental health and

psychosocial functioning[37][85][92]-[94]. Access to these medications has been associated with lower odds of suicidal ideation over the life course[95]. Treatment with a GnRHa during puberty is associated with a slowing of bone mineral density accrual, which at least partially reverses with the start of gender-affirming hormone therapy or the resumption of endogenous sex-steroid production[86][96]-[101]. The utility of baseline and routine repeat DEXA scans for those on a GnRHa is an area of ongoing research and debate. Concerns voiced by opponents of gender-affirming medical care around the potentially permanent impacts on cognitive function of temporarily blocking sex-steroid exposure during adolescence have not been substantiated to date[102].

Hormone blockers should not be prescribed before the onset of puberty (i.e., Tanner stage 2) for two reasons. First because concentrations of circulating sex steroids in prepubertal children are already low, but also because the onset of puberty is an important experience through which young people may develop clearer understanding of their gender identity[18][20][64][85][86][90]. Initiating hormone blockers in early puberty may have both positive implications for gender-affirming surgical options (e.g., more surgical options for chest wall masculinization) and negative ones (e.g., less scrotal tissue for vaginoplasty) for those who desire such interventions in the future[64][103]. Detailed guidance for the initiation of hormone blockers is available in guidelines from the Endocrine Society[64] and WPATH SOC-8[62].

Although hormone blockers do not permanently impact fertility, speaking with adolescents about the option of fertility preservation before starting a blocker is recommended for several reasons. Fertility preservation cannot always be performed while on a blocker and, once initiated, some youth may be hesitant to discontinue blocker use to facilitate these procedures[64][90][104]. Because fertility preservation may not be conducted (outside of research contexts) for adolescents in early puberty, eliciting their views on fertility may be relevant for timing hormone blocker initiation in some individuals.

Table 6. Commonly used hormone blockers in gender-affirming medical care

Agent	Key considerations
For individuals assigned female at birth (AFAB)	
Gonadotropin-releasing hormone agonist (GnRHa; leuprolide acetate for depot suspension)	• Administered intramuscularly (IM), typically every 4 or 12 weeks • Acts on the hypothalamic–pituitary–gonadal (HPG) axis to inhibit gonadal production of estrogen, and therefore the most effective blocker option • Side-effects may include pain, redness, and irritation, or a sterile abscess at injection site (in approximately 5% of cases), hot flashes during the first few months post-initiation, mood fluctuations (i.e., irritability, low mood) around time of initiation, decreased libido, headaches, or visual changes (including a rare association with idiopathic intracranial hypertension) • May experience a “surge” bleed after the first dose • Can slow rate of linear growth if administered during the pubertal growth spurt • If not taken on schedule, can cause resumption of puberty • Expensive (for some, costs may be covered under provincial/territorial benefits programs, private insurance, or a manufacturer’s compassionate coverage program) • If stopped, endogenous puberty/hormonal effects typically resume within 6 months • Advise weight-bearing exercise and optimizing calcium and vitamin D intake to promote bone health. Consider obtaining a baseline DEXA to assess pre-initiation bone mineral density • ECG is recommended for adolescents undergoing therapy with another medication known to prolong the QT interval or those with family history of QTc abnormalities • Use as monotherapy for an extended (i.e., typically >2 years) period of time may introduce potential risks associated with prolonged lack of exposure to sex steroids

Combined oral contraceptive pill	• Taken by mouth (PO) once daily • When prescribed continuously, may reduce frequency of menstrual bleeds • Does not stop further pubertal development • Can treat dysmenorrhea and act as a contraceptive • Requires daily adherence to be effective • Side effects may include nausea, chest tissue tenderness, spotting, bloating • Increased risk of thromboembolism.Adolescents must be assessed for contraindications • Contains female hormones (estrogens and progestins), which may be source of distress to TGD youth
Depot medroxyprogesterone acetate (DMPA)	• Administered IM, typically every 12 weeks • Can reduce frequency of menstrual bleeds, but this effect is variable. Typically is more effective with longer use • Does not stop further pubertal development • Side effects may include pain, redness, or irritation at injection site, weight gain, decreased libido, mood fluctuations, breakthrough bleeding • Use as monotherapy for an extended (i.e., typically >2 years) period may introduce potential bone health risks • Advise weight-bearing exercise and optimizing calcium and vitamin D intake to promote bone health • Contains female hormones (progestins only), which may be source of distress to TGD youth
Levonorgestrel-containing intrauterine device (LNG-IUD)	• Inserted into the uterus by a trained HCP. Effective for up to 5 years • Can reduce frequency of menstrual bleeds, but this effect is variable • Does not stop further pubertal development • Expense can be prohibitive • Can treat dysmenorrhea and act as a contraceptive • Side effects may include discomfort at time of insertion, breakthrough bleeding, acne • Contains female hormones (progestins only) and may be considered invasive, which may be sources of distress to TGD youth

Progestin-only pill	• Taken by mouth (PO) once daily • Can reduce frequency of menstrual bleeds, but this effect is variable based on progestin type and dose. Typically is more effective with longer use • Does not stop further pubertal development • Some formulations can treat dysmenorrhea and act as a contraceptive • Requires daily adherence to be effective, including strict adherence (i.e., use at the same time each day) for some formulations • Side effects may include spotting, breast tenderness, acne, decreased mood • Contains female hormones, which may be source of distress to TGD youth
For individuals assigned male at birth (AMAB)	
Gonadotropin-releasing hormone agonist (GnRHa; leuprolide acetate for depot suspension)	• Considerations similar to those outlined above for AFAB youth • Acts on the hypothalamic–pituitary–gonadal (HPG) axis to inhibit gonadal production of testosterone, and therefore the most effective blocker option • Youth may experience transient increase in frequency of erections after the first dose • Unlikely to inhibit erections completely, but may reduce frequency and duration
Spironolactone	• Pills taken PO 1 to 2 times daily • Blocks action of testosterone, but mild ongoing exposure can occur, causing some individuals to retain some sexual function • Requires daily adherence to be effective • May slow but will not fully prevent pubertal progression • Requires electrolyte monitoring • Side-effects may include fatigue, mood fluctuations, decreased libido, headache, increased urination • Can cause gynecomastia (an increase in the amount of breast tissue), which may be a desired effect for some individuals

Cyproterone acetate	• Pill taken PO daily or every other day • Acts both centrally and peripherally (progestogenic and anti-androgenic effects). Can be more effective than spironolactone • Requires adherence to be effective • May slow but will not fully prevent pubertal progression • Side-effects may include mood fluctuations (more pronounced than for spironolactone), fatigue, decreased libido, bloating, acne • Prolactin monitoring is required. Cyproterone acetate has been associated with increased risk for hyperprolactinemia, particularly when used alongside estrogen • Has been associated with increased risk of meningioma. Can be associated with hepatotoxicity. Contraindicated for individuals with hepatic dysfunction

BMD Bone mineral density; DEXA Dual-energy X-ray absorptiometry; HCP Health care provider; TGD Transgender or gender-diverse

Gender-affirming hormones

For some adolescents with marked and sustained gender diversity, gender-affirming hormone therapy (GAHT) can be an important care component[62][64]. GAHT is prescribed to promote the development of physical features that are better aligned with an individual's experienced gender[62][64][98][105]. For AFAB individuals wishing to appear more masculine, testosterone esters are prescribed, while for AMAB individuals who desire a more feminine physique, 17β-estradiol is used. Starting doses for hormone medications in adolescents are typically lower than those prescribed in adults, with doses being titrated up over time in a manner intended to simulate pubertal progression in sex-steroid exposure[64][91].

GAHT is considered a partially reversible intervention because hormone administration over time results in both reversible and irreversible changes[62][64]. Irreversible effects of testosterone include voice deepening, clitoral enlargement, body and facial hair growth, and, possibly, androgenetic alopecia. Changes to body composition (e.g., fat redistribution and increased muscle mass), increased libido, acne, mood fluctuations, and menstrual suppression are considered reversible effects of testosterone. Once the serum testosterone level is within the adult masculine range, exogenously administered testosterone will suppress endogenous production of estrogen and, therefore, menses. Reaching this level takes time, and individuals often continue GnRHa or other forms of menstrual suppression while testosterone doses are titrated.

Estradiol will, over time, induce irreversible breast tissue development. Reversible effects of estradiol include skin softening, changes in body composition (e.g., fat redistribution, decreased muscle mass), fewer spontaneous erections, and changes in the quality of body hair. The reversibility of estrogen's effect on testicular

volume remains unclear[106]. Treatment with estrogen alone is not effective for suppressing endogenous testosterone production. Because testosterone interferes with estradiol treatment, individuals typically continue to use hormone blockers for the duration of GAHT unless gonadectomy (the surgical removal of the testes or the ovaries) is pursued[64]. Otherwise, much higher doses of estrogen, with attendant health risks, are required.

Both testosterone and estradiol can permanently decrease fertility to an extent that is not yet fully known. It is essential for prescribers of GAHT to explore adolescents' desires regarding future genetically related offspring and, when indicated, to refer for fertility preservation before initiating therapy[62][64][90][91]. GAHT must never be used as a method of contraception. Engaging all adolescents in conversations about contraception and the types of sexual encounters in which contraception is needed to prevent unwanted pregnancies is a critical component of promoting safe sexual practices.

Prescription of GAHT should only be provided to adolescents with a confirmed diagnosis of gender dysphoria or gender incongruence who demonstrate the capacity to understand and appreciate both the benefits and risks of these medications, given their profound effects[62][64]. Any co-existing psychological, medical, or psychosocial issues that interfere with treatment should be addressed to ensure the adolescent is stable enough to start GAHT[62][64]. When GAHT is initiated appropriately for adolescents who desire this option, it has been associated with improved perceived well-being and mental health, decreased suicidality, and decreased body dissatisfaction[107]-[109]. GAHT is considered safe for adolescents, but it can have associated short- and long-term health risks that are beyond the scope of this statement to review[62][64][91][105][110][111]. HCPs who are considering prescribing gender-affirming hormones must familiarize themselves with these risk profiles and associated recommendations for monitoring, which are described in guidelines from the Endocrine Society[64] and WPATH SOC-8[62]. HCPs who feel they lack the knowledge or skills to prescribe GAHT should ensure timely referral of interested adolescents to colleagues who can offer such care.

Gender-affirming surgery

While gender-affirming surgeries are less commonly performed in the adolescent population, TGD youth may identify surgery as one of their transition goals. Being aware of the most common gender-affirming surgeries, and talking about them with adolescents who express interest, can position paediatric providers to support patient education and reflection on if (or how) such interventions might fit into their future lives[112].

The most frequently sought out gender-affirming surgery among AFAB individuals is chest wall masculinization (bilateral mastectomy with male chest contouring), typically referred to as 'top' or 'upper' surgery[113]. 'Bottom' or 'lower' surgeries are pursued by some TGD individuals. However, these procedures are restricted to individuals 18 years of age and older. They can include surgeries to create a phallus (clitoral release, metoidioplasty, phalloplasty) or hysterectomy with or without bilateral salpingo-oophorectomy for AFAB individuals, and vaginoplasty or orchiectomy in AMAB individuals[62][64]. Processes and age cut-offs for funding gender-affirming surgeries vary by province/territory in Canada.

Recommendations

- Health care providers (HCPs) should adopt an affirming approach to care for all children and youth, including those who are transgender or gender-diverse

(TGD).

- HCPs should develop the knowledge required to counsel TGD children and youth and their families on options for medically affirming care (Table 7). If HCPs feel they are not able to develop adequate knowledge to provide such counselling, they must refer TGD children and youth to relevant resources to support optimal care.
- Increased training on affirming care should be integrated into paediatric and paediatric subspecialty training programs across Canada.
- HCPs with the relevant knowledge and skills must be supported in initiating and maintaining pubertal TGD youth on hormone-blocking agents while awaiting specialized gender care.
- HCPs with the relevant knowledge and skills must be supported in initiating and maintaining pubertal TGD youth on gender-affirming hormone therapy.
- HCPs should advocate for timely access to specialized gender-related care.
- HCPs should advocate for all spaces where children and adolescents spend time to be safe for, and inclusive of, those with a TGD identity, including schools and extracurricular activities.
- Gender-affirming care must be upheld as standard of care for TGD youth

Table 7. **Clinical steps to gender-affirming practice**

1. Ensure a safe, welcoming space	• Learn current, appropriate terminology • If unsure of language, ask patients for guidance • Train all staff to use affirming language for every office encounter • Post images and provide resources that signal a diverse, inclusive culture of care in the waiting room • Implement adolescent-oriented office procedures (e.g., designating some time for confidential care at all visits, flexible scheduling, walk-ins, follow-ups by phone or text)
2. Provide early, proactive family care	• Encourage parents to create a home where gender identity is not assumed, stigmatized, or enforced • Strengthen the parent-child relationship when and however possible • Engage family, extended family, alternate caregivers, and community supports for parents and adolescents • Promote trustful, collaborative therapeutic relationships, with a child's or youth's best interests as the guiding focus
3. Respond to adolescents' needs	• Be open to discuss options and pathways for TGD individuals, OR • Ensure timely referral to colleagues who can offer this care • Be sufficiently familiar with gender-affirming hormone therapy (GAHT) to *either* discuss benefits and risks of each intervention, and monitoring protocols, OR • Ensure timely referral to colleagues who can offer this care • Elicit an individual's fertility goals and discuss fertility preservation to guide timing of hormone blocker initiation, AND • Refer to experts before starting medical treatment, as appropriate • Invite questions and conversations about contraceptive health and sexual encounters where contraception is needed • Be able to discuss how gender-affirming surgeries (though less common for TGD adolescents) might (or might not) fit into future life, OR • Refer to colleagues who can offer this information

4. Support adolescent mental well-being	• Use the HEEADSSS psychosocial interview tool • Reassure that 'gender dysphoria' reflects related distress and a pathway to supportive services, not "pathology" • Use motivational interviewing to assess individual motivation, life goals, capacity to make treatment decisions
5. Optimize health outcomes	• Address co-existing psychological, medical, or psychosocial issues, if present • Be equipped to monitor and provide follow-up care for individuals who start hormone treatment • Be aware of appropriate screening tests (e.g., monitor electrolytes in adolescents prescribed spironolactone to block hormones)

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CANADIAN PAEDIATRIC SOCIETY ADOLESCENT HEALTH COMMITTEE (2021-2022)

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Clinical Research Article

Clinical Research Article

Bone Development in Transgender Adolescents Treated With GnRH Analogues and Subsequent Gender-Affirming Hormones

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Abbreviations: 1CTP, carboxyterminal cross-linked telopeptide of type I collagen; aBMD, areal bone mineral density; ANOVA, analysis of variance; BMAD, bone mineral apparent density; BMD, bone mineral density; CV, coefficient of variation; DXA, dual-energy x-ray absorptiometry; GnRH, gonadotropin-releasing hormone; GnRHa, gonadotropin-releasing hormone analogue; P1NP, N-terminal propeptide of type-1 collagen; PBM, peak bone mass.

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Abstract

Context: Hormonal interventions in adolescents with gender dysphoria may have adverse effects, such as reduced bone mineral accrual.

Objective: To describe bone mass development in adolescents with gender dysphoria treated with gonadotropin-releasing hormone analogues (GnRHa), subsequently combined with gender-affirming hormones.

Design: Observational prospective study.

Subjects: 51 transgirls and 70 transboys receiving GnRHa and 36 transgirls and 42 transboys receiving GnRHa and gender-affirming hormones, subdivided into early- and late-pubertal groups.

Main Outcome Measures: Bone mineral apparent density (BMAD), age- and sex-specific BMAD z-scores, and serum bone markers.

Results: At the start of GnRHa treatment, mean areal bone mineral density (aBMD) and BMAD values were within the normal range in all groups. In transgirls, the mean z-scores were well below the population mean. During 2 years of GnRHa treatment, BMAD stabilized or showed a small decrease, whereas z-scores decreased in all groups. During 3 years of combined administration of GnRHa and gender-affirming hormones, a significant increase of BMAD was found. Z-scores normalized in transboys but remained below zero in transgirls. In transgirls and early pubertal transboys, all bone markers decreased during GnRHa treatment.

Conclusions: BMAD z-scores decreased during GnRHa treatment and increased during gender-affirming hormone treatment. Transboys had normal z-scores at baseline and at the end of the study. However,

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transgirls had relatively low z-scores, both at baseline and after 3 years of estrogen treatment. It is currently unclear whether this results in adverse outcomes, such as increased fracture risk, in transgirls as they grow older.

Key Words: bone mineral density, bone, GnRH analogue, sex steroids, gender dysphoria, transgender, adolescents

Over the last decades, children diagnosed with gender dysphoria have increasingly come to the attention of the psychomedical care system and clinicians recognize their suffering, aggravated by the somatic changes of puberty (1, 2). The development of secondary sex characteristics can be temporarily halted with gonadotropin-releasing hormone analogue (GnRHa) treatment (3). This offers the adolescent the opportunity to explore their wish to pursue gender-affirming treatment, while no longer experiencing the agonizing development of secondary sex characteristics due to endogenous puberty, which are incongruent with gender identity. Birth-assigned girls must be at least in Tanner breast stage 2 with clear palpable mammary tissue, while birth-assigned boys must have reached Tanner stage G2 before initiating treatment with GnRHa (3, 4). If no contraindications exist, sex steroids consistent with the affirmed gender are added to the GnRHa treatment at an age where adolescents can give informed consent to such treatment, usually at approximately 16 years (3). There is much discussion about this age, since 16 years is considered a late age to induce puberty in adolescents.

In young adults, peak bone mass (PBM) is higher in men than in women (5). Sex steroids play an essential role in the establishment of gender differences in bone mass, both through direct effects and indirect effects, for example, via differences in muscle mass and insulin-like growth factor (6). Puberty is an important period in determining adult bone mineral content (6). Together, these findings strengthen the notion that maximizing bone mineral accrual during adolescence may be important in the prevention of osteoporosis and fractures at older age.

One of the primary concerns when using GnRHa in adolescents for a prolonged period of time is the potential decrease in bone mineral density (BMD) (3, 7). The suppression of the endogenous sex steroids to stop pubertal development, as recommended by current guidelines, may potentially interfere with the normal pubertal bone mass increment and reduce PBM. Therefore, assessment of BMD every 1 to 2 years is recommended (3). Three studies in adolescents diagnosed with gender dysphoria receiving GnRHa and gender-affirming hormone treatment reported decreases in areal BMD (aBMD) and bone mineral apparent density (BMAD) z-scores during GnRHa treatment, although not all significant (8-10). Little difference was noted in change of BMAD z-scores between early- and late-pubertal groups as defined by bone age (8). Catch-up of bone mineral accrual during subsequent gender-affirming hormone treatment may be incomplete (8-10). One study investigated bone markers and showed a decrease of carboxyterminal cross-linked telopeptide of type I collagen (1CTP) and N-terminal propeptide of type-1 collagen (P1NP) during GnRHa and during subsequent gender-affirming hormone treatment which was interpreted as evidence of decreased bone turnover (8). All these studies compared data at the start of GnRHa treatment, at the start of gender-affirming hormones and one endpoint, either 12–24 months after the start of gender-affirming hormone therapy or age 22 years. However, this does not provide information on the course of BMD during treatment. Do BMD z-scores continue to decline with prolonged use of GnRHa? How long do BMD z-scores continue to increase during GAH treatment? These questions remain unanswered. Now that increasing numbers of adolescents undergo this treatment, possibly starting at younger ages, there is a clear need for such data. Therefore we set out to describe the course of BMD during 2 years of GnRHa therapy and during 3 years of subsequent gender-affirming hormone treatment in a large group of adolescents diagnosed with gender dysphoria, with measurements at yearly intervals. We also investigated whether the outcome was influenced by the pubertal stage, as defined by Tanner stage, at which GnRHa treatment was started. In addition, we report data from a small subgroup with more prolonged GnRHa treatment.

Methods

Subjects and protocol

Subjects were adolescents fulfilling *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* (*DSM-IV-TR*) criteria for gender identity disorder (the term used at the time) (11) and eligible for treatment according to existing guidelines at that time (4, 12, 13). The design of the study was observational and prospective, and individuals were included from 1998 to 2009. The first phase of treatment consisted of intramuscular injections of GnRHa 3.75 mg (Triptorelin-CR (Ferring Pharmaceuticals, Denmark). The first 2 injections were administered with a 2-week interval followed by injections every 4 weeks to suppress endogenous sex steroid production. To induce female pubertal development in

transgirls, oral estrogens were prescribed in an increasing dosage over a period of 2 years as previously described (4). Male puberty in transboys was induced by administering Sustanon (a mixture of testosterone propionate, -fenylpropionate, -isocaproate and -decanoate) intramuscularly in increasing doses over a period of 2 years (14). In subjects who were 16 years of age or older at the start of pubertal suppression, gender-affirming hormones were started at half the adult dose and increased to the adult dose after 6 months. A dose of 2 mg 17beta-estradiol per day and 125 mg testosterone-esters per 2 weeks was considered an adult dose. From 45 subjects, some data were also included in previous studies by Vlot et al (8) and Klink et al (10), but those studies only reported results at 3 time points: at the start of GnRHa, at the start of gender-affirming hormones, and after 2 years of gender-affirming hormones (8) or age 22 years (10), and they did not describe a detailed course of BMD and bone markers over several years of GnRHa or gender-affirming hormone treatment.

Different effects of treatment might be expected depending on the pubertal stage at baseline. A previous study used a bone age cutoff of 14 and 15 years for transboys and transgirls, respectively, to define early- and late-pubertal groups (8). However, especially for transboys, bone age 14 years signifies the final stages of puberty and near completion of linear growth rather than midpuberty. In the current study, Tanner stage was used to define early- and late-pubertal groups, with the early-pubertal group defined as Tanner stage 2 or 3 at the start of GnRHa treatment, and the late-pubertal group as Tanner stage 4 or 5.

Bone densitometry

Dual-energy x-ray absorptiometry (DXA) was performed before GnRHa administration and then every subsequent year using Hologic QDR 4500 (Hololgic Inc., Waltham, MA, USA). Likewise, at the start of gender-affirming hormone treatment, a DXA scan was performed, with yearly measurements thereafter. Areal BMD (aBMD, g/cm^2) of the lumbar spine, nondominant hip, and whole body, as well as the bone mineral content of the whole body (BMC-WB, g) were measured. To calculate z-scores based on age and sex, the National Health and Nutrition Examination Surveys (NHANES) references values were used. Because changes in aBMD might partly be due to altered growth during treatment, we also studied BMAD (g/cm^3) calculated as described by Ward et al (15). BMAD z-scores were calculated using LMS data from an English reference population (15). To calculate z-scores the reference population of the birth-assigned sex was used. For adolescents older than 17 years no reference values of BMAD are available; therefore, reference values of 17 year-olds were used to calculate the z-score at older ages (15).

Serum bone markers

Markers of bone formation (P1NP, P3NP, and osteocalcin) and of bone resorption (1CTP) were determined in fasting blood samples, drawn before noon on the same days as the DXA scans, and stored at –20 °C.

Osteocalcin was measured by an immunometric assay (Colorimetric, BioSource, Nivelles, Belgium) (lower detection limit of 0.4 nmol/L; inter-assay coefficient of variation (CV) for the whole range <10%). Serum 1CTP, P1NP, and P3NP levels were measured using a radioimmunoassay (Orion Diagnostica, Espoo, Finland). The lower ranges of detection were 1 µg/L for 1CTP, 5 µg/L for P1NP, and 1µg/L for P3NP. The inter-assay CV for the whole range of 1CTP was 7% and for P1NP 8%. The CV for P3NP was 6% at 4.2 µg/L and 8% at 6.2 µg/L.

Statistical analyses

Independent *t* tests were used to ascertain differences between the ages of the transgirls and transboys. To analyze changes in BMAD over time, data were analyzed using a linear mixed model. A full factorial model was chosen as fixed part of the model, ie, a model consisting of time (3 or 4 levels), pubertal stage (early/late), and sex and all possible interactions (ie, three 2-way and one 3-way interactions). An unstructured covariance matrix was used as random part of the model. An advantage of the linear mixed model approach above traditional repeated measurements analysis of variance (ANOVA) is that all acquired data are included in the analyses and no data are lost due to incomplete data sets.

Differences in aBMD during a more prolonged period of GnRHa treatment were calculated using the related samples Wilcoxon Signed Ranked test.

All data on BMAD, and z-scores are presented as estimated marginal means and standard error of the mean. The statistical package was SPSS 22.0 (SPSS Inc., Chicago, IL, USA).

Ethical approval

The study was placed on the International Standard Randomized Controlled Trial Number register and ascribed registration number ISRCTN 81574253 (www.isrctn.com). Approval by the local medical ethical committee was obtained. Informed consent for the study was obtained from all adolescents, and if aged <18 years also from their parents.

Results

A total of 54 transgirls and 73 transboys started treatment according to this protocol. For 51 transgirls and 70 transboys, DXA scans were available at the start of GnRHa administration and these individuals were included in the analyses. There were no significant differences between the ages of the transgirls and the transboys at the start of GnRHa administration (Table 1).

A total of 36 transgirls and 42 transboys received gender-affirming hormone treatment in addition to GnRHa treatment. The transboys were slightly but significantly older at start of gender-affirming hormone treatment than the transgirls (Table 1). The ratio of subjects who were in early and in late puberty was not different in the group evaluated for the effects of gender-affirming hormone treatment compared with the group analyzed during GnRHa treatment alone.

Anthropometric data and data on pubertal development of the subjects at baseline are shown in Table 1. All adolescents had sex characteristics typical of the sex assigned at birth and none had signs of a difference/disorder of sex development. None of the adolescents had a bone fracture during the study.

Changes during 2 years of GnRHa treatment

Bone mineral apparent density. Changes in aBMD and aBMD z-scores are shown in Table 2. BMAD of the lumbar spine did not change during 2 years of GnRHa treatment in the transgirls or the early pubertal transboys ($P = 0.84$, $P = 0.09$, and $P = 0.69$, respectively) (see Fig. 1, Table 2). In the late-pubertal transboys, a small but significant decrease in BMAD of the lumbar spine was found.

BMAD of the femoral neck showed a significant decrease in the late-pubertal transgirls and in both groups of transboys ($P = 0.007$, $P = 0.015$, and $P < 0.001$, respectively) (see Fig. 1, Table 2). The small decrease in the early pubertal transgirls was not significant ($P = 0.31$).

Bone mineral apparent density z-scores. At the start, z-scores of the BMAD at both locations were higher in the transboys than in the transgirls. The BMAD z-score of the lumbar spine significantly decreased in all 4 groups ($P \leq 0.001$) (see Fig. 1, Table 2). The BMAD z-scores of the femoral neck significantly decreased in all groups ($P = 0.006$, $P = 0.002$, and $P < 0.001$) except for the early-pubertal transgirls ($P = 0.25$). Four transgirls had a z-score of the hip below −2 after 2 years of GnRHa treatment and 3 individuals had a z-score of the lumbar spine below −2. Two transboys had a z-score of the hip below −2 whereas none of the transboys had a z-score of the lumbar spine below −2 after 2 years of GnRHa treatment.

Bone mineral density during prolonged GnRHa treatment. Because the average age at the start of GnRHa treatment was more than 14 years, most individuals were not treated with GnRHa for more than 2 years

Table 1. Characteristics at the Start of GnRHa Treatment and at the Start of Gender-Affirming Hormone Treatment

Start GnRHa		Transgirls (n = 51)	Transboys (n = 70)	*P* value
	Age in years, mean ± SD	14.1 ± 1.7	14.5 ± 2.0	n.s.
	Pubertal group: Early/late	15/36	14/56	n.s.
	Height in cm, mean ± SD	169.0 ± 8.9	162.2 ± 8.8	<0.001
	Weight in kg, mean ± SD	57.9 ± 12.9	56.2 ± 14.7	n.s.
	BMI in kg/m^2, mean ± SD	20.1 ± 3.3	21.3 ± 4.2	n.s.
	Serum estradiol in pmol/L, median [IQR]		Early: 113.5 [63.5–129.3] Late: 121 [83.5–231.5]	
	Serum testosterone in nmol/L, median [IQR]	Early: 3.8 [2.15–6.15] Late: 13 [10.3–17.8]		
Start gender-affirming hormones		Transgirls (n = 36)	Transboys (n = 42)	
	Age in years, mean ± SD	16.2 ± 1.2	16.9 ± 1.1	0.005
	Pubertal group: Early/late	10/26	5/37	n.s.
	Duration of GnRHa use before start GAH, years	2.0 ± (0.94)	1.8 ± (1.11)	n.s.
	Height in cm, mean ± SD	176.5 ± 7.3	167.1 ± 7.4	0.005
	Weight in kg, mean ± SD	66.7 ± 11.9	63.5 ± 11.5	n.s.
	BMI in kg/m^2, mean ± SD	21.1 ± 3.2	22.8 ± 4.0	n.s.

Abbreviations: BMI, body mass index; GAH, gender-affirming hormones; GnRHa, gonadotropin-releasing hormone analogue; IQR, interquartile range; n.s., not significant; SD, standard deviation.

Table 2. aBMD and BMAD During 2 Years of GnRHa Treatment

	Transgirls					
	Early Pubertal		Late-Pubertal			
	0 mo	24 mo	0 mo	24 mo	*p*1	*p*2
aBMD_LS g/cm^2	0.73 (0.03)	0.75(0.03)	0.79 (0.02)	0.82 (0.02)	<0.05	<0.05
Z-score	−0.67 (0.26)	−1.26 (0.24)	−0.33 (0.17)	−0.92 (0.17)	<0.05	<0.05
aBMD_hip g/cm^2	0.81 (0.03)	0.86 (0.03)	0.87 (0.02)	0.89 (0.02)	<0.05	n.s.
Z-score	−0.49 (0.24)	−0.93 (0.21)	−0.43 (0.16)	−1.01 (0.15)	<0.05	<0.05
Whole body BMD g/cm^2	0.90 (0.02)	0.92 (0.02)	0.95 (0.01)	0.95 (0.01)	<0.05	n.s.
Z-score	−0.56 (0.24)	−1.51 (0.20)	−0.51 (0.16)	−1.62 (0.15)	<0.05	<0.05
BMAD_LS g/cm^3	0.20 (0.01)	0.20 (0.01)	0.20 (0.01)	0.21 (0.0!)	n.s.	n.s.
Z-score	−0.33 (0.33)	−1.19 (0.34)	−0.65 (0.20)	−1.21 (0.22)	<0.05	<0.05
BMAD_hip g/cm^3	0.28 (0.01)	0.27 (0.01)	0.28 (0.01)	0.26 (0.01)	n.s.	<0.05
Z-score	−0.94 (0.27)	−1.23 (0.35)	−1.01 (0.17)	−1.56 (0.25)	n.s.	<0.05
	Transboys					
	Early-pubertal		Late-pubertal			
	0 mo	24 mo	0 mo	24 mo	*p*1	*p*2
aBMD_LS g/cm^2	0.75 (0.03)	0.80 (0.03)	0.95 (0.01)	0.92 (0.01)	<0.05	<0.05
Z-score	−0.28 (0.27)	−1.04 (0.26)	0.38 (0.14)	−0.71 (0.14)	<0.05	<0.05
aBMD_hip g/cm^2	0.79 (0.03)	0.83 (0.03)	0.93 (0.01)	0.89 (0.02)	<0.05	<0.05
Z-score	0.09 (0.26)	−0.50 (0.24)	0.46 (0.13)	−0.56 (0.13)	<0.05	<0.05
Whole body BMD g/cm^2	0.88 (0.02)	0.92 (0.02)	1.03 (0.01)	1.01 (0.01)	<0.05	<0.05
Z-score	−0.28 (0.27)	−0.82 (0.24)	0.66 (0.13)	−0.40 (0.13)	<0.05	<0.05
BMAD_LS g/cm^3	0.22 (0.01)	0.22 (0.01)	0.25 (0.01)	0.24(0.01)	n.s.	<0.05
Z-score	−0.15 (0.29)	−0.86 (0.30)	0.33 (0.14)	−0.56 (0.17)	<0.05	<0.05
BMAD_hip g/cm^3	0.30 (0.01)	0.28 (0.01)	0.32 (0.01)	0.30 (0.01)	<0.05	<0.05
Z-score	−0.23 (0.25)	−0.94 (0.30)	0.04 (0.12)	−0.54 (0.18)	<0.05	<0.05

aBMD and BMAD during 2 years of GnRHa treatment. Values are presented as estimated marginal means ± standard error. *p1* represents the *P* value between the start and after 2 years of treatment for the early pubertal groups. *p2* represents the *P* value between start and after 2 years of treatment for the late-pubertal groups. For changes per year of treatment see Fig. 1.

Abbreviations: aBMD, areal bone mineral density; BMAD, bone mineral apparent density; BMD, bone mineral density; LS, lumbar spine.

before gender-affirming hormone treatment was started. However, a few younger individuals were treated for up to 4 years. The aBMD values of the lumbar spine and hip in 4 transboys and 11 transgirls remained stable during 3 years of GnRHa treatment. The z-scores on the other hand declined (Table 3).

Serum bone markers. At baseline, there were no significant differences in serum levels of any of the 4 bone markers (P1NP, P3NP, osteocalcin, 1CTP) between the early- and late-pubertal groups of transgirls (Fig. 2). In the transboys, baseline serum levels of all 4 bone markers were significantly higher in those in early puberty compared to those in later puberty.

After 2 years of GnRHa treatment serum levels of all 4 bone markers showed a significant decrease in both groups of transgirls and in early-pubertal transboys, which was most marked during the first year of treatment (Fig. 2). Serum levels of P3NP and 1CTP showed a smaller but significant decrease in late-pubertal transboys whereas serum levels of P1NP and osteocalcin did not change in this group.

Changes during 3 years of gender-affirming hormone treatment

After an average of 1.89 years (± 1.03 year) of GnRHa administration, gender-affirming hormones were added to the treatment. Both early-pubertal groups were on GnRHa for a significantly longer time (2.5 years in transgirls (n = 7) and 4.0 years in transboys (n = 3)) when compared with both late-pubertal groups (1.5 years in transgirls and 1.7 years in transboys) ($P < 0.001$).

Bone mineral apparent density. Changes in aBMD and aBMD z-scores are shown in Table 4. A significant increase in BMAD of the lumbar spine was found in all 4 groups

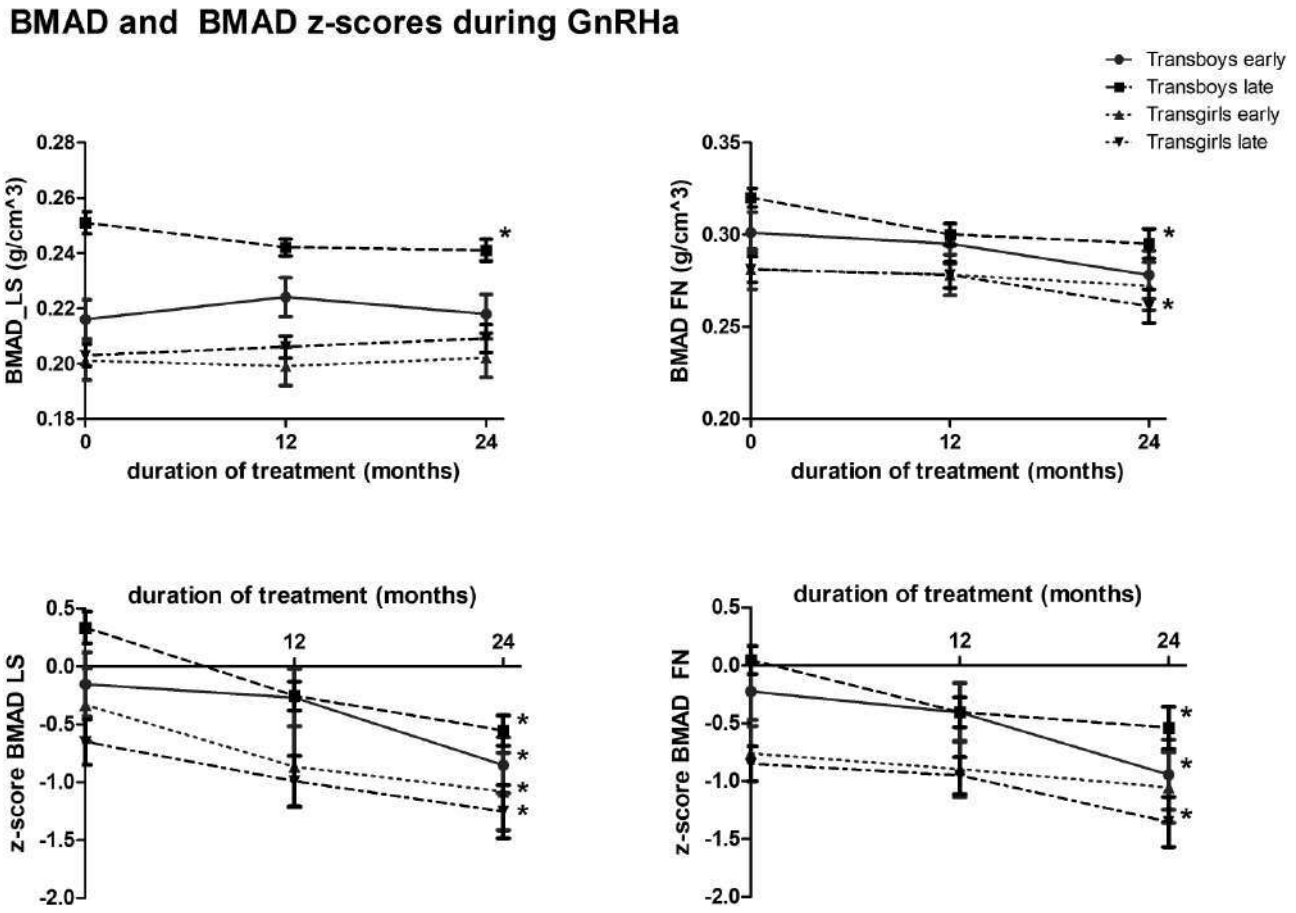

Figure 1. Estimated marginal means and standard error of the mean of BMAD prior to and during 2 years of GnRHa administration in transgirls and transboys. Significant changes during the 2 years of GnRHa administration are indicated by an asterisk. Abbreviations: BMAD: bone mineral apparent density; FM, femoral neck; LS, lumbar spine.

($P < 0.001$) after 3 years of gender-affirming hormone treatment (Fig. 3, Table 4). The BMAD of the femoral neck showed a significant increase in both groups of transgirls and in the early-pubertal transboys ($P < 0.05$). In the late-pubertal transboys the increase was not significant.

Bone mineral apparent density z-scores. The BMAD z-scores of the lumbar spine significantly increased in all 4 groups (Fig. 3, Table 4). Z-scores of the femoral neck showed a significant increase in both groups of transgirls and in the early pubertal transboys. The increase of the z-score in late-pubertal transboys was not significant.

Three transgirls had a z-score of the femoral neck below –2 and 3 individuals had a z-score of the lumbar spine below –2 after 3 years of gender-affirming hormone treatment. None of the transboys had a z-score below –2 after 3 years of gender-affirming hormone treatment.

Serum bone markers. The mean serum levels of the bone markers prior to gender-affirming hormone administration are shown in Fig. 4. Serum levels of P1NP, P3NP, and 1CTP were significantly higher in the early pubertal transgirls than in the late-pubertal transgirls. In the transboys, baseline serum levels of P1NP and P3NP were significantly higher in the early pubertal group compared with the late-pubertal group. Levels of all 4 markers changed little in the late-pubertal transboys, whereas in the early pubertal transboys and late-pubertal transgirls, osteocalcin, P1NP, and P3NP showed a pronounced decrease during the first year of gender-affirming hormone treatment, after which levels stabilized. Remarkably, in the early-pubertal transgirls an initial increase in the P1NP, P3NP, and 1CTP levels was found followed by a decrease. After 3 years of gender-affirming hormone treatment, all 4 bone markers had significantly decreased in both early and late-pubertal transgirls. In transboys, osteocalcin, P1NP, and 1CTP significantly decreased. In both early and late-pubertal transboys, serum levels of P3NP did not significantly change.

Discussion

This study examined the impact of puberty suppression and subsequent addition of gender-affirming hormones

Table 3. aBMD and aBMD Z-Scores During 3 Years of GnRHa Treatment

Sex	Age at Start (Range)	Duration GnRHa(yrs)		Start	12 Months	24 Months	36 Months	*P*
Transgirls	12.6 (12.1-12.8)	3.45 (0.43)	aBMD LS (g/cm^2) mean(± SD) (n = 4)	0.73 (0.9)	.74 (0.10)	0.77 (0.11)	0.77 (0.11)	0.14
			Z-score LS mean (± SD) (n = 4)	−0.43 (1.41)	−0.92 (1.40)	−1.05 (1.31)	−1.15 (1.00)	0.07
			aBMD Hip (g/cm^2) mean (± SD) (n = 4)	0.80 (0.04)	0.82 (0.4)	0.83 (0.05)	0.85 (0.06)	0.07
			Z-score hip mean (± SD) (n = 4)	−0.18 (0.50)	−0.65 (0.34)	−1.08 (0.42)	−1.08 (0.42)	0.007
Transboys	12.7 (11.9-14.0)	3.30 (0.50)	aBMD LS (g/cm^2) mean (± SD) (n)	0.85 (0.13) (11)	0.88 (0.10) (11)	0.90 (0.11) (11)	0.90 (0.9) (11)	0.29
			Z-score LS mean (± SD) (n)	0.42 (1.01) (9)	−0.52 (0.83) (10)	−0.35 (0.96) (11)	−0.53 (0.78) (11)	0.008
			aBMD Hip (g/cm^2) mean (± SD) (n)	0.88 (0.09) (9)	0.88 (0.71) (11)	0.87 (0.08) (11)	0.88 (0.09) (11)	0.95
			Z-score hip mean (± SD) (n)	0.86 (0.71) (8)	0.40 (0.71) (8)	−0.18 (0.67) (9)	−0.30 (0.67) (10)	0.12

Abbreviations: aBMD, areal bone mineral density; LS, lumbar spine; SD, standard deviation.

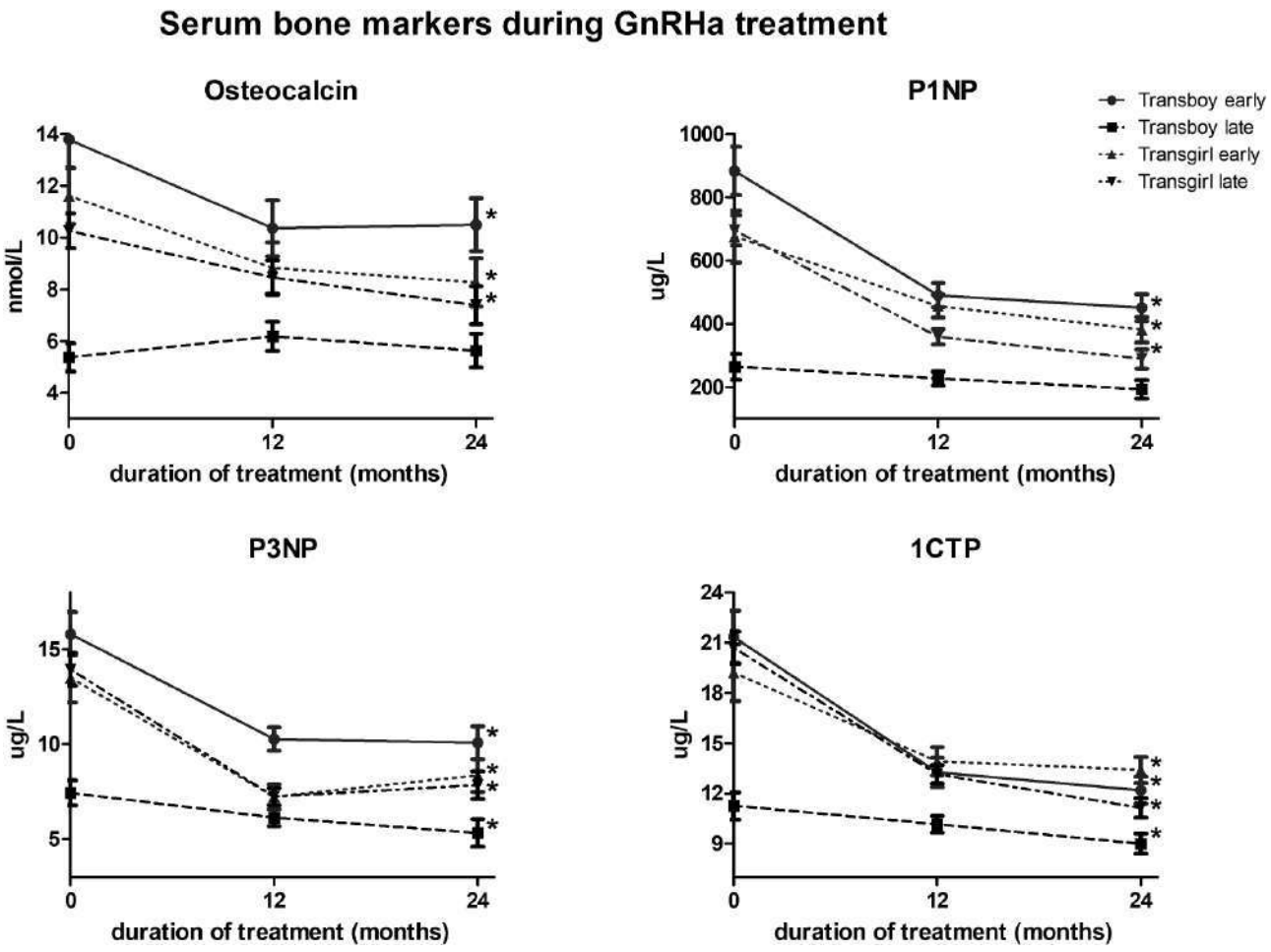

Figure 2. Estimated marginal means and negative standard error of the mean of osteocalcin, P1NP, P3NP, and 1CTP prior to and during 2 years of GnRHa administration in transgirls and transboys. Significant changes during the 2 years of GnRHa administration are indicated by asterisk.

Table 4. aBMD and BMAD During 3 Years of Gender-Affirming Hormone Treatment in Addition to GnRHa Treatment

	Transgirls					
	Early-Pubertal		Late-Pubertal			
	0	36	0	36	*p*1	*p*2
aBMD_LS g/cm^2	0.77 (0.03)	0.95 (0.04)	0.83 (0.02)	0.95 (0.03)	<0.05	<0.05
Z-score	−1.37 (0.30)	−0.82 (0.39)	−0.99 (0.19)	−1.05 (0.25)	<0.05	n.s.
aBMD_hip g/cm^2	0.87 (0.03)	1.02 (0.04)	0.88 (0.02)	0.96 (0.02)	<0.05	<0.05
Z-score	−0.99 (0.23)	−0.09 (0.28)	−0.86 (0.14)	−0.70 (0.18)	<0.05	n.s.
Whole body BMD g/cm^2	0.93 (0.02)	1.06 (0.06)	0.96 (0.01)	0.98 (0.04)	<0.05	n.s.
Z-score	−1.67 (0.23)	−1.22 (0.28)	−1.42 (0.14)	−1.48 (0.18)	<0.05	n.s.
BMAD_LS g/cm^3	0.20 (0.08)	0.24 (0.09)	0.21 (0.05)	0.24 (0.06)	<0.05	<0.05
Z-score	−1.39 (0.36)	−0.49 (0.40)	−1.29 (0.23)	−0.50 (0.25)	<0.05	<0.05
BMAD_hip g/cm^3	0.28 (0.01)	0.31 (0.02)	0.27 (0.01)	0.27 (0.01)	<0.05	<0.05
Z-score	−0.88 (0.23)	−0.35 (0.37)	−1.36 (0.20)	−1.21 (0.24)	<0.05	<0.05
	Transboys					
	Early-pubertal		Late-pubertal			
	0	36	0	36	*p*1	*p*2
aBMD_LS g/cm^2	0.82 (0.04)	1.02 (0.07)	0.90 (0.02)	0.99 (0.02)	<0.05	<0.05
Z-score	−1.30 (0.43)	0.11 (0.58)	−0.68 (0.16)	−0.26 (0.22)	<0.05	<0.05
aBMD_hip g/cm^2	0.83 (0.04)	1.02 (0.06)	0.88 (0.02)	0.96 (0.02)	<0.05	<0.05
Z-score	−0.82 (0.33)	0.59 (0.43)	−0.50 (0.12)	0.12 (0.16)	<0.05	<0.05
Whole body BMD g/cm^2	0.94 (0.03)	1.11 (0.10)	1.02 (0.01)	1.10 (0.03)	n.s.	<0.05
Z-score	−1.06 (0.32)	0.21(0.43)	−0.30 (0.12)	−0.05 (0.16)	<0.05	<0.05
BMAD_LS g/cm^3	0.22(0.01)	0.26 (0.01)	0.24 (0.01)	0.26 (0.01)	<0.05	<0.05
Z-score	−1.01 (0.49)	0.12 (0.51)	−0.61 (0.18)	−0.04 (0.18)	<0.05	<0.05
BMAD_hip g/cm^3	0.28 (0.02)	0.32 (0.02)	0.30 (0.01)	0.32 (0.01)	<0.05	n.s.
Z-score	−0.71 (0.37)	0.01 (0.43)	−0.41 (0.14)	−0.10 (0.16)	<0.05	n.s.

aBMD and BMAD during 3 years of GnRHa plus gender-affirming hormone treatment. Values are presented as estimated marginal means ± standard error. *p1* represents the *P* value between start and after 3 years of treatment for the early-pubertal groups. *p2* represents the *P* value between start and after 3 years of treatment for the late-pubertal groups.

For changes per year of treatment see Fig. 2.

Abbreviations: aBMD, areal bone mineral density; BMAD, bone mineral apparent density; BMD, bone mineral density; LS, lumbar spine.

on bone development in adolescents diagnosed with gender dysphoria. At the start of GnRHa treatment, aBMD and BMAD values were within the normal range. However, transgirls had z-scores well below zero, whereas these were close to zero in transboys. This finding is consistent with previous studies (8, 10, 16-18) and may be explained by differences in lifestyle and exercise intensity between transgirls and transboys. A recent study showed that high-school transgirls have a higher intake of fast-food and are less physically active than transboys (19). In a different cohort of transgender adolescents we found vitamin D levels <50 nmol/L in 74% of transboys and 78% of transgirls starting GnRHa treatment ((9) and unpublished data). However, these findings do not explain why BMD z-scores are lower in transgirls than in transboys. Alternatively, it may be hypothesized that biological factors that act during intrauterine or early development and are involved in the development of gender dysphoria, are also related to bone development programming. For example, a whole-exome sequencing study in transgender individuals found 21 variants in 19 genes associated with estrogen activated pathways of sexually dimorphic brain development (20). These variants in estrogen receptor–activated pathways might also play a role in bone mineral acquisition.

During GnRHa treatment we observed a decline of aBMD and BMAD z-scores in line with previous studies (8-10). In transgirls a decrease of aBMD z-scores was also reported with the use of the anti-androgenic progestin cyproterone acetate (18). In contrast, 1 study showed that in transboys treated with the progestin lynestrenol for an average of 11.6 months aBMD z-scores were stable or increased (18). If these results are confirmed, also with more prolonged treatment duration, the better safety profile with regard to bone health is an important point to discuss with adolescents. In particular, older transboys who have already

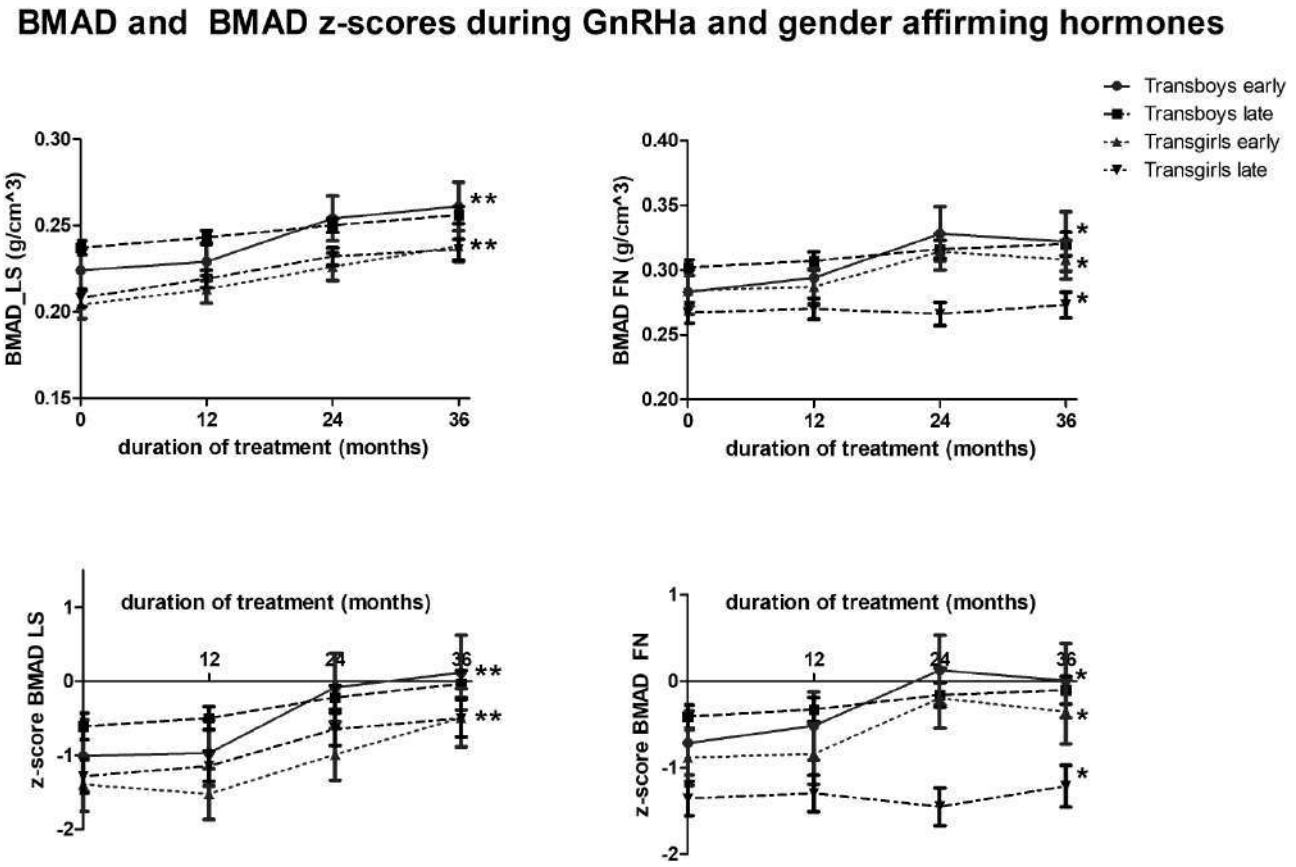

Figure 3. Estimated marginal means and standard error of the mean of BMAD prior to and during 3 years of GnRHa + gender-affirming treatment in transgirls and transboys. Significant changes during the 3 years of GnRHa + gender-affirming treatment are indicated by an asteriks.

completed breast development may prefer lynestrenol to GnRHa treatment.

In most individuals with prolonged (3-4 years) GnRHa treatment, no further decrease in aBMD z-scores was observed in the last year, suggesting that z-scores might stabilize. Data from a larger cohort of adolescents treated with GnRHa for longer periods of time are needed, especially now that adolescents are presenting at younger ages at gender identity clinics and starting treatment at the onset of puberty.

During gender-affirming hormone treatment, a significant increase in the BMAD of the lumbar spine was found in all groups, and of the femoral neck in all but the late-pubertal transboys. In line with previous studies, BMAD z-scores were close to zero in transboys after 3 years of testosterone treatment (8-10). The increase in z-scores was most pronounced in the early pubertal transboys whose z-scores were slightly higher after 3 years of androgen treatment than at the start of GnRHa treatment.

The BMAD z-scores remained well below zero in transgirls in line with previous studies (8, 10). However, BMAD z-scores in early-pubertal transgirls increased more during estrogen treatment and were higher after 36 months than the scores reported by Vlot et al after 24 months (8). This might be due to the extra year of estrogen treatment in the current study, although the z-score of BMAD at the femoral neck no longer seemed to increase between 24 and 36 months. In contrast, the BMAD z-scores of the femoral neck in the late-pubertal transgirls were much lower after 36 months in the current study than previously reported (8). This may be due to the lower z-scores at the start of GnRHa treatment (–1.01 vs –0.44) and at the start of estrogen treatment (–1.36 vs –0.36) in the current study compared with the study by Vlot et al.

An important limitation of this study is the lack of an untreated control group. As discussed above, z-scores in transgirls were already well below 0 at the start of treatment, and these might have further decreased even without treatment, as low BMD was also observed in adult transwomen before the start of any treatment (16, 17).

Another issue is which reference population should be used to calculate BMD or BMAD z-scores. In transgirls who started treatment in early puberty, bone architecture may be more similar to that of cisgender females than to cisgender males. A recent study did not find changes in cortical bone geometry in response to estrogen treatment in adult transwomen, but the authors suggested that this might have been different if they had started treatment during puberty (21).

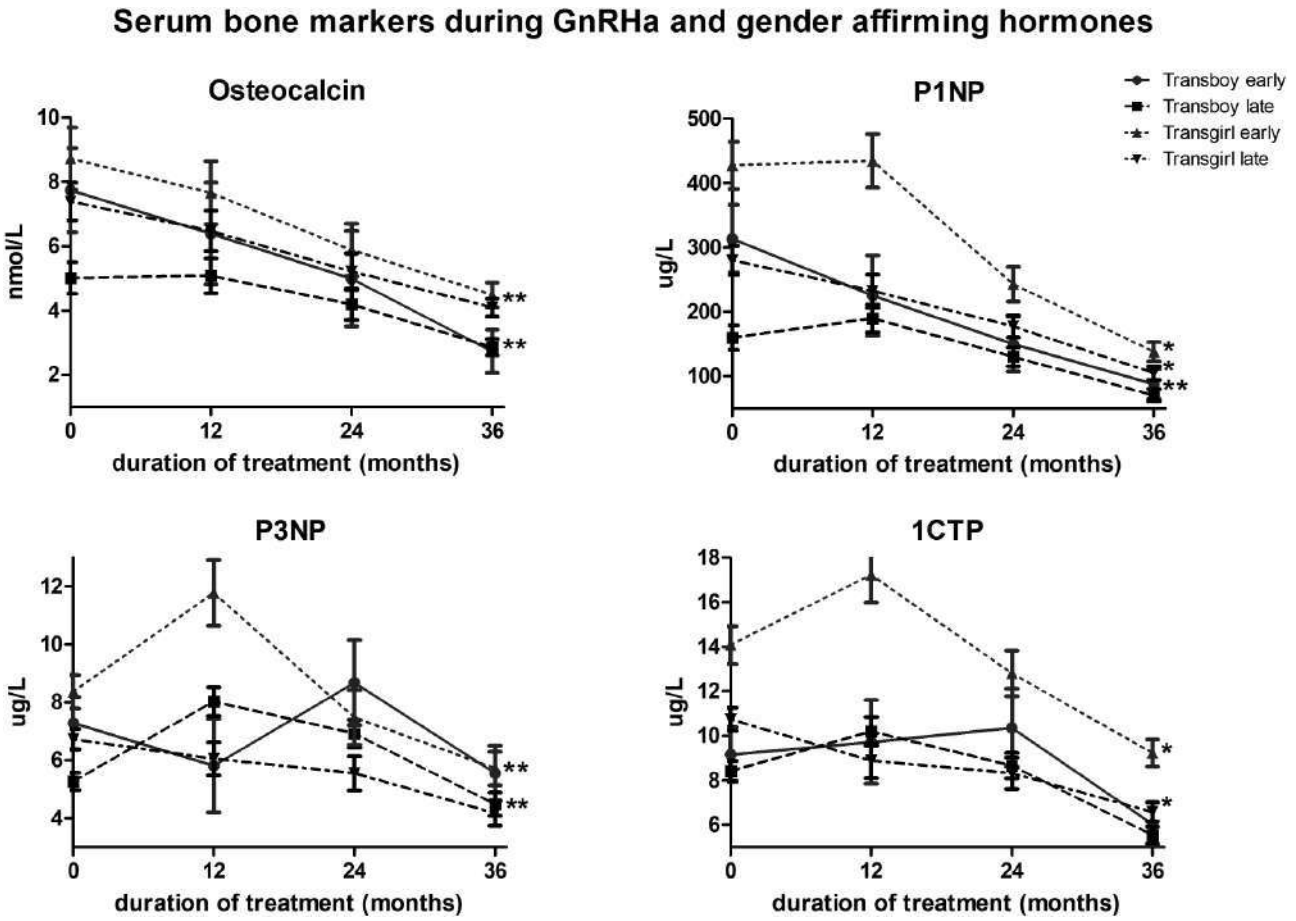

Figure 4. Estimated marginal means and standard error of the mean of osteocalcin, P1NP, P3NP, and 1CTP prior to and during 3 years of GnRHa + gender-affirming treatment in transgirls and transboys. Significant changes during the 3 years of GnRHa + gender-affirming treatment are indicated by an asteriks.

GnRHa are not only used in transgender children, but also in other populations, mainly in children with precocious or early puberty. A recent publication from an international consortium on the use of GnRHa concluded from the available evidence in this group that the treatment was safe with regard to bone mineral density, with attenuated bone mineral accrual reported during treatment but recovery by late adolescence (22). Different findings in children with precocious puberty compared with transgender adolescents may be due to the different timing of GnRHa treatment, the use of gender-affirming hormones, with current estradiol dose possibly insufficient (23), versus endogenous puberty, and due to differences in baseline BMD between the groups.

In transgirls and early-pubertal transboys, all bone markers decreased during the first year of GnRHa treatment while BMD levels remained stable. However, in the late-pubertal transboys bone turnover markers were lower at baseline and did not change. This suggests that the decline of the bone markers during GnRHa treatment may not be due to reduced bone mineral accrual but may rather reflect reduced growth velocity after initiating treatment. The late-pubertal transboys had likely already reached (near) adult height, which could explain the lower and stable levels of bone turnover markers. We previously observed a similar decrease of alkaline phosphatase during GnRHa treatment, but only in those who had not yet completed growth (24). The opposite effect was seen during the first year of treatment with gender-affirming hormones, where bone markers increased in the early pubertal transgirls, who likely had most growth potential. In adults, changes in P1NP were also found to be only weakly correlated to changes in BMD in transwomen and not significantly correlated in transmen (25). A previous study of bone turnover markers in adolescents observed a similar pattern of changes in P1NP and 1CTP to the current study (8). However, changes in osteocalcin were only seen in late-pubertal transboys, possibly due to the small number of subjects in that study with large interindividual differences in the changes of osteocalcin levels (8).

Based on the current study we propose that it is sufficient to perform DXA scans at the start of GnRHa

treatment, every 2 years during GnRHa treatment, at the start of gender-affirming hormone treatment, and then every 2 to 3 years. Adolescents should be counseled on the importance of weight-bearing exercise, an adequate dietary calcium intake, sufficient sunlight exposure to ensure adequate vitamin D levels, or vitamin D supplementation (26). In addition, it is important to ensure an adequate estrogen dose resulting in physiological serum estradiol levels. Routine measurement of bone turnover markers does not seem to be useful for monitoring bone health.

In conclusion, treatment with GnRHa results in a stabilization and maintenance of previously achieved bone mass in the lumbar spine but a small decrease in BMAD of the femoral neck of the nondominant hip. Gender-affirming hormone treatment increases bone accretion and normalizes the age- and sex-specific BMAD z-scores in transboys. Transgirls had lower BMAD z-scores, especially the late-pubertal group, but as z-scores were already lower at baseline, this may be due to other factors than the endocrine treatment, such as lifestyle factors. The consequences of lower BMD for long-term bone health in these individuals remains unclear. Future studies should evaluate peak bone mass in those who started treatment as adolescents and investigate clinically important outcomes such as fracture risk in this population.

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Clinical Trial Information: International Standard Randomized Controlled Trial Number registration no. ISRCTN 81574253 (http://www.controlled-trials.com/isrctn/).

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Data Availability: The datasets generated during and/or analyzed during the current study are not publicly available but are available from the corresponding author on reasonable request.

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Child rights in trans healthcare – a call to action

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EDITORIAL

Child rights in trans healthcare – a call to action

Introduction

Trans healthcare has seen some positive changes over the past two decades, moving from the pathologisation of difference as 'disorder', to approaches that recognize and embrace the diversity, dignity and value of trans lives. In a short time, we have also seen a shift from widespread clinical control and gate-keeping to the growing adoption of affirmative approaches to trans healthcare, which are predicated on respecting trans and gender-diverse peoples' rights to safe and respectful healthcare. Whilst these evolutions are welcome and important, progress is inconsistent and uneven, and subject to legislative and political rollback. Progress is particularly patchy and fragile in healthcare services for trans, gender-diverse, and gender non-conforming children, with children defined here as encompassing all non-adults under the ages of 18 (United Nations, 1989). In multiple countries affirmative healthcare is under attack, with children's trans healthcare services bearing the brunt of attacks on rights-based practice. There are many locations where trans healthcare services for children fail to uphold trans children's rights, with approaches in children's services not keeping up with the improvements that are more widely being seen in adult trans healthcare.

In this editorial we first call attention to the importance of child-rights informed policy and practice in trans healthcare. We outline critical pillars of rights-respecting healthcare for trans, gender-diverse, and gender non-conforming children. We highlight the importance of embedding rights within service delivery, discussing the need for child participation in healthcare design, evaluation and accountability. In the second section of this editorial we articulate and call attention to a sector-wide ethical duty of care to children, building a sector where child rights violations are no longer tolerated. We highlight the responsibilities of all trans healthcare stakeholders and professionals, including those in adult trans healthcare, in ensuring a sector-wide shift to ethical and rights-respecting practice. Trans children in particular require greater allyship from professionals working in trans health, including those in adult healthcare, helping to ensure that as the wider field evolves and improves, children are not left behind.

Child rights in trans healthcare

Ethical approaches to working with or providing services to children have an obligation to recognize and uphold child rights. Child rights are enshrined in international human rights frameworks including the United Nations Convention on the Rights of the Child (UNCRC). The UNCRC protects the rights of children in every country in the world apart from the USA (the sole country to have failed to ratify it). The UNCRC recognizes each child as a rights holder, with rights articulated across 54 articles that cover all aspects of a child's life (United Nations, 1989). The UNCRC rights that are particularly relevant to trans children include the right to identity (article 8), the right to protection from violence and abuse (article 19), the right to life, survival and development (article 6), the right to health (article 24), and the right not to be discriminated against in accessing all other rights (article 2). Child rights may also be explicitly guaranteed in domestic law, as seen to differing degrees in countries including Belgium, Norway, Spain, Iceland, South Africa (Lundy et al., 2013), and more recently in Scotland (United Nations Convention on the Rights of the Child (Incorporation) (Scotland) Bill, 2022).

Within the UNCRC trans, gender-diverse, and gender non-conforming children have a right to equitable healthcare. This right to health must be upheld through addressing entrenched barriers to healthcare equality. This editorial articulates critical pillars that can enable and sustain rights-respecting practice in children's trans healthcare. These pillars are presented in terms of institutional responsibilities for children's rights below, summarized in Box A. These same pillars are revisited in terms of children's healthcare rights at the end of the article in Box B. These pillars of rights-respecting practice are designed to enhance healthcare well-being and justice for all users of children's trans healthcare services, whether or not a given child identifies as trans, and regardless of social and/or medical transition pathways. The centering of children's rights within healthcare services, benefits both trans children and those children who are exploring their identity.

Box A: Institutional responsibilities for children's rights in trans healthcare services.

Rights-based healthcare services and institutions need to:

1. Protect children from anti-trans prejudice, including from healthcare professionals
2. Proactively carry out depathologisation of health services, reforming healthcare policy and practice to undo a long legacy of problematizing trans, gender-diverse, and gender non-conforming children's lives
3. Uphold a commitment to self-determination, repudiating approaches built on conversion, suppression or control of children's identities
4. Respect bodily autonomy
5. Enable children's power and influence in medical decision-making, supporting and enhancing evolving capacity, within approaches based on informed consent, or informed assent.
6. Tackle cisnormativity and transnormativity in trans healthcare, recognizing diverse identities and pathways as equally valid, with an equal right to healthcare
7. Protect children from anti-trans bias in assessments of healthcare evidence or risk, and in medical policy and practice
8. Protect children from abuse, violence, and the harms of gender minority stress, including in schools and at home.
9. Build safe and affirming communities to help protect children from trans-hostile environments, including through healthcare interventions in political, legislative or media discourse and policy.

Protection from prejudice is vital for reducing healthcare inequalities. Anti-trans prejudice, including amongst healthcare staff and healthcare leadership, is a significant driver of healthcare inequalities, with trans people harmed by the impacts of prejudice or ignorance in healthcare (Sundus et al., 2021). Healthcare leaders have a responsibility to recognize healthcare prejudice, including amongst healthcare professionals, taking steps to protect trans, gender-diverse, and gender non-conforming children from prejudice or ignorance. Prejudice can be ingrained at a systemic and institutional level, for example in services where being trans is regarded as a 'bad outcome' (Horton, 2024). Prejudice can be addressed through enhanced training and education, as well as through clear policy commitments to a child's right to trans positive and respectful healthcare provision. Anti-trans prejudice needs to be recognized, with targeted action to protect trans children from its influence across healthcare policy, procurement, management and delivery.

Trans depathologisation is another critical priority to protect children's healthcare rights. Pathologisation is recognized as a driver of healthcare inequalities, influencing healthcare approaches wherein trans identities are devalued and problematized (Horton, 2022a; Pearce, 2018; Suess Schwend et al., 2018). Trans identity is not in itself a form of illness, and a growing body of literature indicates that trans children with access to appropriate care and support do not have higher rates of psychopathology than the general population (Olson et al., 2016). Treating trans identities as a pathology or problem adds to healthcare inequalities, escalating and reproducing shame, perpetuating and reinforcing society prejudice, and justifying clinical coercion and institutional violence (Horton, 2022b, 2024; World Health Organisation, 2020). Healthcare providers and leaders have a responsibility to ensure children's healthcare is depathologised in line with World Health Organization's International Classification of Disease Version 11 (ICD-11), which stipulates the importance of trans healthcare being delivered without treating trans-ness as a pathology or problem (World Health Organisation, 2021). This depathologisation effort needs to be proactive, resourced and comprehensive, recognizing both the legacy of pathologisation in current trans healthcare approaches, and institutional responsibilities to upholding children's right to healthcare that is free from pathologisation (Adams et al., 2017).

Health inequalities are also connected to past and present practices of clinical control over trans people's lives, bodies and identities. Across trans healthcare there is widespread recognition of the importance of **self-determination** and **bodily autonomy** (Allen et al., 2024). These principles are arguably even more important in trans, gender-diverse, and gender non-conforming children's healthcare, recognizing the harms of approaches that seek to convert, deny or suppress children's identities, or healthcare services that operate through coercion and control over children's lives, bodies and healthcare options.

In adult healthcare there has been a significant shift toward services based on informed consent (Cavanaugh et al., 2016). In children's healthcare (outside of trans-specific services), informed consent and informed assent are recognized as vital components of rights-based healthcare (Lansdown et al., 2016; Modi et al., 2014; World Health Organization, 2021). The World Health Organization recognizes the importance of recognizing child decision-making rights in healthcare, with healthcare providers playing an important role in building and enhancing evolving capacity (World Health Organization, 2021). Within trans healthcare services for children, informed consent approaches need to recognize children's right to healthcare decision making considering their evolving capacity (as with e.g. Gillick competency in England and Wales), with healthcare professionals taking steps to support and enhance decision-specific

capacity. Where children are not considered competent, they need to be supported to make decisions with their informed assent. Trans children are particularly vulnerable to coercion, barriers to transition, and denial of healthcare, with healthcare decisions (including decisions made on behalf of a child to prevent access to healthcare, or decisions to keep a child in extended assessment) made by families, healthcare providers or legislators in direct opposition to a child's assent. Approaches based on **informed consent and informed assent** are therefore even more important in trans children's healthcare, recognizing the steep power differentials between parent/carers and adult healthcare gatekeepers and child healthcare service users (Cavanaugh et al., 2016).

Ethical healthcare services need to **tackle cisnormativity** (assuming everyone is or should be cis). This can include avoiding double standards between healthcare offered to trans or cis children, ensuring trans lives are valued as highly as cis lives, and being vigilant to policies or practices that implicitly or explicitly regard transness as a bad outcome (Horton, 2024). Services also need to tackle **transnormativity** (assuming there is one acceptable way to be trans, gender-diverse, or gender non-conforming), avoiding clinical policy or practice that validates a normative description of being trans or enforces a normative route to social or medical transition (Clark, 2021). Cisnormativity and transnormativity can both negatively impact on children's experiences in healthcare services, limiting and constraining possible outcomes in terms of personal identity and treatment pathways.

Ethical services also need to **tackle anti-trans bias.** Conscious and subconscious bias is known to impact on the design, delivery and management of children's trans healthcare services, with double standards in the appraisal of evidence (Giordano & Holm, 2020; Horton, 2024). Clark et al. (2020, p. 176) have highlighted the need to "recognize how anti-trans bias may impact the perceived magnitude of risk regarding gender health-care interventions".

Ethical healthcare services also need to **protect children from abuse**, supporting trans children's safety, mental health, happiness and well-being. Trans, gender-diverse, and gender non-conforming children have a right to healthcare provision that is safe, respectful and supportive, avoiding abusive and intrusive approaches (Horton, 2022b). As part of this, children need to be **protected from the violence and gender minority stress** that they can experience in homes, schools and communities that are non-affirming or unsafe (Veale et al., 2017). Healthcare services must adopt a holistic approach to health and wellbeing, including efforts to ensure schools are trans-positive, safe and affirming, and that trans children have safe and affirming homes (Katz-Wise et al., 2018). Targeted interventions can build parent and carer understanding and support for their child, while also protecting children from harmful 'reparative' or 'conversion' approaches and familial abuse (Riggs & Bartholomaeus, 2018).

As part of the principal of justice for ethical clinical practice, a healthcare provider's duty of care extends beyond the clinic, with responsibilities to **help build safe and affirming communities** for the trans, gender-diverse, and gender non-conforming children under their care (Clark et al., 2020). This responsibility calls for healthcare providers to do more to challenge local, national or global policy and discourse that creates a hostile climate for trans children (Ashley & Domínguez, 2021). Trans children in particular are significantly impacted by the wider political, legislative and media climate, experiencing significant harm in environments where trans people are at risk of violence, persecution and abuse. Healthcare providers and services have a unique opportunity and responsibility to use their positions of trust and authority to advocate for children's safety, especially where medicalised misinformation or a legacy of trans pathologisation is driving harmful and abusive legislation or policy.

Embedding child rights and trans ethics in clinical practice

There are many positive examples of healthcare practitioners recognizing the importance of a rights-based approach to working with trans children, including in primary healthcare (Well BN, 2024), social work (Redcay et al., 2019), pediatrics and education (RCPCH, 2024). Practitioners and institutions without a clear commitment to trans children's rights need to take steps toward this. A commitment to children's rights is a necessary but insufficient component of rights-respecting practice. Rights-respecting approaches need to be built into trans healthcare systems, institutions, policies and practices. Healthcare institutions can undertake child rights focused reviews of existing policy and practice, seeking to understand and reduce areas of potential child rights violations.

Healthcare services must learn from and embed best practices in trans healthcare ethics (Allen et al., 2024; Ashley, 2023). Lessons can also be drawn from existing scholarship on trans research ethics (Adams et al., 2017; Bauer et al., 2019; Vincent, 2018). Wider trans research ethics has highlighted the importance of working in partnership with trans communities (Adams et al., 2017), taking responsibility for the wider impacts of policies or practices on trans communities (Bauer et al., 2019), recognizing decision-maker positionality and power differentials vis-à-vis participants or service users (Bauer et al., 2019), being accountable to trans communities, and centering trans priorities and perspectives (Marshall et al., 2022).

Partnership and accountability is a vital part of children's healthcare rights under UNCRC article 12.

Children have a right to participate in decisions that affect their lives, having their views listened to, and utilized to reform healthcare policy and practice. In healthcare the UNCRC Committee have emphasized children's right to participate in the "*development of health policy and services*" (United Nations, 2009, 98), noting children's views "*should be sought on all aspects of health provision, including what services are needed, (and) how and where they are best provided*" (United Nations, 2009, p. 104). Trans healthcare providers have a duty to take action on the basis of trans, gender-diverse, and gender non-conforming children's perspectives and priorities, ensuring children have power and influence over the design, operation and evaluation of their healthcare services.

Children's trans healthcare services therefore need to center the perspectives and priorities of children and young people, informed by the healthcare outcomes that matter to children (Chong et al., 2021; Sitas et al., 2023). This team of authors from across multiple countries and nations (England, Scotland, Wales, Australia, New Zealand, Canada) is engaged in a new research project focused on understanding the trans healthcare measures that matter most to trans children and young adults. The project is taking place in partnership with existing clinical services, to ensure identified child and youth priorities are embedded into culturally competent service design, delivery and evaluation.

All healthcare service users have an equal right to have their views taken seriously in shaping the design and delivery of their healthcare services. Efforts are needed to ensure children's trans healthcare services are engaged with, respectful to, and accountable to all trans, gender diverse and gender non-conforming children, especially those who are multiply marginalized. Non-binary children are at risk of being disadvantaged in healthcare services, with effort needed to uphold non-binary children's rights (Chew et al., 2020; Clark et al., 2018). Neurodivergent trans children are at particular risk of experiencing healthcare rights violations or barriers to having their views heard and listened to in shaping policy and practice, and healthcare services need to recognize their responsibilities to such children and young people (Glaves & Kolman, 2023). Other groups of trans, gender-diverse, and gender non-conforming children who may be vulnerable to losing out on their rights to participation in the design and evaluation of healthcare services include children with unsupportive parents (Clark et al., 2020; Riggs & Bartholomaeus, 2018), children in care (Winter, 2006), refugee or migrant children, children from marginalized racial, religious or ethnic communities, Indigenous children and children of color, and disabled children (Baril et al., 2020). Healthcare systems and services must significantly enhance their efforts to proactively articulate, champion and protect the rights of all children, especially those facing multiple intersecting axes of oppression.

Younger children are also at risk of being overlooked in the design or evaluation of trans healthcare services. Pre-adolescent trans children are particularly at risk of being medicalised, coerced and controlled by healthcare services that problematize trans childhood (Horton, 2024). When considering the healthcare needs of younger children, healthcare services may benefit from co-operation with supportive parents and carers. Collaboration with parents and carers needs to recognize the risk of parental prejudice or cis/transnormativity, or the potential for parental misunderstanding of trans children's experiences (Riggs & Bartholomaeus, 2018). Action is needed to ensure service collaboration with families is held accountable to younger children's priorities, with proactive action to ensure younger children's views are heard and centered.

A sector-wide duty of care to trans children

Trans children are disproportionately likely to experience rights violations in trans healthcare services for a range of reasons. Rights violations can occur actively by design, through clinical approaches shaped by pathologisation and anti-trans prejudice (Horton, 2024). Rights violations can be sustained passively, in services that incrementally adapt or repeat historic approaches without questioning or addressing the legacy of harmful policy and practice that is particular to trans children's healthcare (Winters, 2022). This can happen for example in services that force trans children through extended and intrusive assessments, without inspecting the history of pathologisation and prejudice that informed past presumptions of clinical necessity. Rights violations can be sustained through subconscious cisnormativity, transnormativity or anti-trans bias (Pearce, 2018). They can also be engineered, through social climates and legislation hostile to trans existence (Abreu et al., 2022). A prejudice-driven rhetoric of child protection or safeguarding can ironically be weaponised to undermine child rights in a sector like trans healthcare, for example where unsupportive parents advocate for child rights violations and conversive practices. Rights violations are also more likely to persist in children's trans healthcare due to power differentials between adults and children. Trans children are disadvantaged compared to trans adults in their ability to mobilize and collectively demand healthcare rights at an institutional, sectoral and national level, especially when already overwhelmed with a fight for rights, dignity and survival at family, school and community level (Amery, 2023; Hawkesworth, 2023).

In a context of historic, contemporary and likely future rights violations, greater efforts are needed to protect and defend the rights of trans children. This responsibility lies particularly with stakeholders in trans healthcare, including and perhaps especially professionals in adult trans healthcare. Healthcare professionals working in trans health need to consider their responsibilities

to trans children, becoming active allies in articulating, establishing and holding the whole sector accountable to an ethical duty of care.

Healthcare professionals working in trans health need to step up, building a sector where child rights violations are no longer passively tolerated. This responsibility cuts across diverse arenas, in healthcare policy and practice, research, media, legislation, academic journals and conferences. In all these spheres healthcare professionals working in trans health, especially in adult services, can do more to call out child rights violations, centering trans children's healthcare rights. Allies can add their voice in challenging pathologising rhetoric and centering the rights of child service users. Allies, particularly those with professional credentials, can make vital interventions in institutional or legislative consultations on trans healthcare policy and practice. Allies can and should do more to highlight and challenge abusive and rights-violating clinical practice.

Positive examples of stakeholders standing up for trans children's healthcare rights can be found. The Welsh Children's Commissioner, Rocío Cifuentes, recently called out the likely child rights violations in the National Health Service's (NHS England) proposed approach to trans children's healthcare. She described the NHS draft service specification as "highly concerning and…contrary to children's human rights" (Children's Commissioner for Wales, 2023, p. 42). She also critiqued proposed NHS restrictions on social transition, and plans to make healthcare access contingent on mandatory research participation, describing these requirements as "highly concerning", at odds with a child's right to "free and informed consent" (Children's Commissioner for Wales, 2023, p. 42).

As healthcare practitioners and researchers, we recognize the significant challenges inherent in a shift to rights-based practice, especially in children's trans healthcare. The forces invested in upholding the status quo are strong, notwithstanding the forces fighting for shifts in an even more regressive and harmful direction. A coalition for child rights must therefore be proactive, coordinated, strategic and assertive in testifying to the necessity of child rights-respecting practice. Progressive clinical stakeholders in children's trans healthcare services will face extensive challenges to enacting reform, and need the support, backing and advocacy of clinical peers, especially those in adult healthcare. They will also need the support, ambition and accountability mechanisms of civil society, of groups working with trans, gender-diverse, and gender non-conforming children, of affirming families, and of children themselves, collectively using whatever power and influence is available to call for and demand healthcare that is respectful of child rights.

Conclusion and recommendations

We are at a critical moment for children's trans healthcare services, with growing barriers and threats to rights-respecting practice. All actors within trans healthcare need to recognize and uphold a duty of care to children, with explicit and proactive commitments to children's rights. In several countries and institutions forces opposed to trans rights are being successful in defending and expanding healthcare rights violations, starting with trans children. Trans-positive stakeholders in civil society, politics, communities, the media, and especially in healthcare services, need to more assertively articulate and defend trans children's rights. This effort needs to be prioritized and resourced within healthcare institutions, with investment in identifying and tackling rights violations, being accountable to children and upholding child rights in service design, delivery and evaluation.

This editorial concludes by revisiting the critical pillars of rights-respecting practice. Earlier in this article (in Box A) rights were presented from a perspective of institutional and professional responsibilities toward trans, gender-diverse, and gender non-conforming children. Here we revisit and restate those same rights from the perspective of rights that are due to and can be claimed by children (Box B). This reframing of rights is vital as rights operate in both directions. Upholding child rights is a

Box B: Children's rights in trans healthcare.

We recognize trans, gender-diverse, and gender non-conforming children's rights to:

1. Safe and respectful healthcare, free from anti-trans prejudice.
2. Healthcare services where trans, gender-diverse, and gender non-conforming lives are welcomed and celebrated, not pathologized or problematized
3. Self-determination, in a healthcare system where trans children's identities are recognized and respected
4. Bodily autonomy, in systems where children are protected from institutionalized control over their bodies.
5. An informed consent (or informed assent) approach to healthcare, where children have supported and evolving power and autonomy over their own healthcare.
6. Healthcare wherein diverse lives and healthcare pathways are recognized and respected
7. Healthcare unaffected by anti-trans bias
8. Safe and affirming homes and schools, where children are not exposed to violence, trauma and gender minority stress.
9. A safe and affirming wider political, legislative and media climate, where trans children can grow up in confidence and security.

responsibility and duty of rights-bearers, in particular those with institutional and professional power and responsibilities (Box A). Rights can also be loudly and confidently demanded by trans, gender-diverse, and gender non-conforming children (Box B). Advocates for children's rights can work both to hold institutions and professionals accountable, and to help children to understand, articulate and demand their rights. Trans-positive stakeholders, whether in civil society, politics, community, and especially those in healthcare services, need to be much more active, coordinated and effective in building a sector and society where trans children's rights are secured.

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Gender Identity 5 Years After Social Transition

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abstract

BACKGROUND AND OBJECTIVES Concerns about early childhood social transitions among transgender youth include that these youth may later change their gender identification (ie, retransition), a process that could be distressing. The current study aimed to provide the first estimate of retransitioning and to report the current gender identities of youth an average of 5 years after their initial social transitions.

METHODS The current study examined the rate of retransition and current gender identities of 317 initially transgender youth (208 transgender girls, 109 transgender boys; = 8.1 years at start of study) participating in a longitudinal study, the Trans Youth Project. Data were reported by youth and their parents through in-person or online visits or via e-mail or phone correspondence.

RESULTS We found that an average of 5 years after their initial social transition, 7.3 of youth had retransitioned at least once. At the end of this period, most youth identified as binary transgender youth (94), including 1.3 who retransitioned to another identity before returning to their binary transgender identity. A total of 2.5 of youth identified as cisgender and 3.5 as nonbinary. Later cisgender identities were more common among youth whose initial social transition occurred before age 6 years; their retransitions often occurred before age 10 years.

CONCLUSIONS These results suggest that retransitions are infrequent. More commonly, transgender youth who socially transitioned at early ages continued to identify that way. Nonetheless, understanding retransitions is crucial for clinicians and families to help make retransitions as smooth as possible for youth.

Increasing numbers of children are socially transitioning to live in line with their gender identity, rather than the gender assumed by their sex at birth, a process that typically involves changing a child s pronouns, first name, hairstyle, and clothing. Some concerns about childhood social transitions have been raised,[1] including that these children may not continue to identify as transgender, rather they might "retransition" (also called a "detransition" or "desistence"), which some suggest could be distressing for youth.[1–3] Research has suggested that ages 10 to 13 years may be particularly key times for retransition and that identity may be more stable after this period for youth who show early gender nonconformity.[3]

Other clinicians argue that early social transitions can be beneficial for some gender-diverse youth.[4–6] Some clinicians and scholars who support early childhood social transitions encourage families to remain open to later retransitions,[7,8] which are seen by some as part of a youth s exploration of their gender.[9]

Unfortunately, very few data about retransitions exist in the scientific literature. We have been able to find limited data on the number of youth

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who socially transition in childhood and then go on to retransition afterward. One paper included 4 youth who socially transitioned; none of them had retransitioned 7 years later.[10] We know of 3 mentions of early-transitioning youth who retransition.[8,9] However, these papers include no mention of how many other youth the same clinical team saw who did not retransition, making it impossible to guess a retransition rate.

In the present paper, we aimed to compute an estimate of retransition among a cohort of more than 300 early-transitioning children. Here, we report the retransition rate an average of 5 years after initial (binary) social transition, as well as how many of these participants are living as binary transgender youth, nonbinary youth, and cisgender youth at the same timepoint.

METHODS

A total of 317 binary socially transitioned transgender children ($_{age}$ = 8.07; SD = 2.36; 208 initially transgender girls, 109 initially transgender boys; see Table 1 for additional demographics) joined this longitudinal study (The Trans Youth Project) between July 2013 and December 2017. For inclusion in The Trans Youth Project, children had to be between 3 and 12 years of age and had to have made a "complete" binary social transition,[10] including changing their pronouns to the binary gender pronouns that differed from those used at their births.

As part of the larger longitudinal study, parents and youth were regularly asked about whether they had begun using puberty blockers and/or gender-affirming hormones. At most visits, they were not asked about whether puberty had begun, though our available data suggests that because these youth had socially transitioned at such early ages, most participants were followed by an endocrinologist well before puberty began. The endocrinologists helped families identify the onset of Tanner 2 (the first stage of puberty) and prescribed puberty blockers within a few months of this time; therefore, the onset of puberty blockers is used as our proxy for the onset of puberty in youth who received blockers. Of the youth in this sample, 37 (11.7) had begun puberty blockers before beginning this study.

This study did not assess whether participants met criteria for the Diagnostic and Statistical Manual of Mental Disorders, Fifth edition, diagnosis of gender dysphoria in children. Many parents in this study did not believe that such diagnoses were either ethical or useful, even if they had been diagnosed, and some children did not experience the required distress criterion after transitioning. Based on data collected at their initial visit, these participants showed signs of gender identification and gender-typed preferences commonly associated with their gender, not their sex assigned at birth.[11] Further, parent report using the Gender Identity Questionnaire for Children[12] indicated that youth showed significant "cross-sex" identification and preferences (when scored based on sex at birth).[12]

Final identity classification for these analyses was based on our most recent interaction with the child and/or their parent before January 1, 2021. Because some families have not participated recently, we also separately report (Table 2) the results of the n = 291 youth with whom the research team had an interaction within the 2 years before that deadline. This additional analysis allows us to assess whether those who retransitioned were more likely to have missed their more recent appointments with our team. Importantly, only 1 of the 26 families with whom we did not meet in the past 2 years has formally dropped out of the study; the others often did not complete participation during these 2 years because of personal circumstances at the time we attempted re-recruitment. We anticipate that many in this group will participate again in the future.

TABLE Participant Demographics = 317)

Demographics	%
Race	
White, non-Hispanic	69
White, Hispanic	9
Black	2
Asian	3
Native American	1
Multiracial	17
Annual household income,	
25 000	3
25 001–50 000	10
50 001–75 000	21
75 001–125 000	31
>125 000	35
Location	
Northeast	15
Midwest/Upper Plains	21
Southeast	15
Mountain West	13
Paci c Northwest	20
Paci c South	16

Based on pronouns at follow-up, participants were classified as binary transgender (pronouns associated with the other binary assigned sex), nonbinary (they/them pronouns or, n = 3, a mix of they/them and binary pronouns), or cisgender (pronouns associated with their assigned sex). We confirmed this classification by reviewing other information available to the research team (eg, child s self-categorization in an interview or survey, e-mail communications with the parents). Only 1 classification was debatable; this participant was classified by pronouns (and in this paper) as nonbinary but could have been

TABLE 2 Participant Information and Current Identity at Last Visit Before January 1, 2021, Overall, for Those With Recent Visits Only, and by Initial Social Transition and Gender

	Total Sample	Recent Sample (With Visits in 2019 or 2020)	Sample Who Initially Socially Transitioned Before Age 6	Sample Who Initially Socially Transitioned at Age 6 or Later	Transgender Girls (At Recruitment)	Transgender Boys (At Recruitment)
Sample size	317	291	124	193	208	109
Assigned male at birth, %	65.6	65.3	73.4	60.6	100	0
Mean age at rst transition, y	6.5	6.4	4.3	7.9	6.2	7.1
Mean age at start of study, y	8.1	8.0	5.9	9.5	7.7	8.7
Average time since start of study, y	3.8	4.1	3.8	3.8	3.9	3.7
Average time since rst transition, y	5.4	5.7	5.4	5.4	5.5	5.3
Current identity, *n* (%)						
Binary transgender	298 (94.0)	276 (94.8)	112 (90.3)	186 (96.4)	194 (93.3)	104 (95.4)
Cisgender	8 (2.5)	6 (2.1)	7 (5.6)	1 (0.5)	7 (3.40)	1 (0.9)
Nonbinary	11 (3.5)	9 (3.1)	5 (4.0)	6 (3.1)	7 (3.40)	4 (3.7)

classified as binary transgender (and not retransitioned).

This study has been approved by the University of Washington and Princeton University institutional review boards.

RESULTS

The overall rate of retransition was 7.3 . An average of 5.37 years (SD = 1.74 years) after their initial binary social transition, most participants were living as binary transgender youth (94.0 ; Table 2). Included in this group were 4 individuals (1.3 of the total sample) who retransitioned twice (to nonbinary then back to binary transgender). Some youth (3.5) were currently living as nonbinary, including one who had retransitioned first to cisgender then to nonbinary. Finally, 2.5 were using pronouns associated with their sex at birth and could be categorized as cisgender at the time of data collection, including one who first retransitioned to live as nonbinary. Similar percentages were observed when examining the 291 youth who were in touch with the research team in the past 2 years (Table 2), when examining only those 280 youth who had not begun puberty blockers at the start of the study (Table 3), or if we examine only the 200 youth who had gone at least 5 years since their initial transition (Table 3).

We observed 1 potential (post hoc) age effect. Youth who initially socially transitioned before age 6 (n = 124), were more likely to be living as cisgender (n = 7; 5.6) than youth who transitioned at age 6 or later (n = 1 of 193; 0.5), Fisher exact test (comparing binary, cisgender, nonbinary; before vs. age 6 years or later), P = .02, although low rates of retransition were seen in both groups. In Table 2, we also report the results separately for children assigned male versus female at birth; this distinction was not significantly associated with later identity, P = .47, Fisher exact test. Finally, for exploratory purposes, in Table 3, we report outcomes separately for several subsets of our participants, including youth who had started puberty blockers, youth who had used puberty blockers and gender-affirming hormones, and youth who are at least 14 years old (the age at which past work[3] has suggested retransitions will be less likely).

DISCUSSION

Five years after an initial binary social transition, 7 of youth had retransitioned at least once. Most youth (94) were living as binary transgender youth at the time of data analysis, including 1.3 who retransitioned initially to cisgender or nonbinary and then retransitioned back to binary trans identities. A small number of youth were living as cisgender youth (2.5) or nonbinary youth (3.5). We observed comparable rates when examining all participants who began the study (n = 317), those who had been in touch with the research team in the last two years (n = 291), those who had gone at least 5 years since initial social transition (n = 200), and

TABLE 3 Participant Information and Current Identity at Last Visit Before January 1, 2021, as a Function of Stages of Medical Transition and/or Age

	Total Sample	Sample of Youth Who Had Not Begun Blockers at Start of the Study	Sample of Youth Who Have Begun Blockers (and Not Gender-Affirming Hormones) at the End of the Study	Sample of Youth Who Have Begun Gender-Affirming Hormones at the End of the study	Sample of Youth 5 y of Age Since Initial Binary Social Transition	Sample of Youth Who Are Currently 14 y of Age
Sample size	317	280	92	98	200	70
Assigned male at birth, %	65.6	69.6	57.6	58.2	69.0	52.9
Mean age at rst transition, y	6.5	6.1	6.6	8.4	6.2	8.9
Mean age at start of study, y	8.1	7.6	8.3	10.2	8.0	10.8
Average time since start of study, y	3.8	3.9	4	4.3	4.5	4.4
Average time since rst transition	5.4	5.5	5.8	6.1	6.4	6.3
Current identity						
Binary transgender	$n = 298$; 94.0%	$n = 263$; 93.9%	$n = 88$; 95.7%	$n = 97$; 99.0%	$n = 190$; 95.0%	$n = 69$; 98.6%
Cisgender	$n = 8$; 2.5%	$n = 8$; 2.9%	$n = 1$; 1.1%	$n = 0$	$n = 4$; 2.0%	$n = 1$; 1.4%
Nonbinary	$n = 11$; 3.5%	$n = 9$; 3.2%	$n = 3$; 3.3%	$n = 1$, 1.0%	$n = 6$; 3.0%	$n = 0$

those who started the study before beginning puberty blockers ($n = 280$). We found no differences as a function of participant sex at birth. We observed slightly higher rates of retransition, and particularly later cisgender identity, among youth who initially socially transitioned before age 6 years. However, even in these youth, retransition rates were very low.

Among those who had begun puberty blockers and/or gender-affirming hormones, only 1 had retransitioned to live as cisgender (and this youth had begun blockers, but not gender-affirming hormones). One likely reason so few retransitions to cisgender occurred among those accessing medical transition is that most retransitioning in this cohort happened at early ages. All but 1 of the 8 cisgender youth had retransitioned by age 9 years (the last retransition was at age 11 years). Some of these youth are still not eligible for blockers because they are still prepubertal; we anticipate that those who identify as cisgender are unlikely to seek blockers or hormones, but that the participants who have not begun puberty and who identify as binary transgender or nonbinary likely will.

Past work has suggested that the ages 10 to 13 years are an especially critical time for retransition.[3] In our sample, many of the youth who retransitioned did so before that time frame, particularly the cisgender youth. In the nonbinary group, however, 6 of 11 retransitioned between ages 10 and 13 years, with the remainder retransitioning before age 10. Importantly, our sample differed from the past work on which this age range was determined in several key ways, including that our participants socially transitioned at earlier ages (perhaps pushing retransitions earlier, too), had undergone complete social transitions including pronouns and names (not just hairstyle and clothing changes as in most cases in previous studies[3]), and are living at a different historic time in a different country. Any, or all, of these may turn out to be key differences related to age of retransition.

Our observed low retransition rate is consistent with a study in which 4 youth who had completely socially transitioned had not retransitioned 7 years later.[10] That finding is in the same ballpark as our study s estimate of 2.5 if we examine the percentage living as cisgender at the end of the study (ie, those "desisting" from gender-diverse outcomes). Together, these papers suggest this outcome is relatively rare in this group.

Our observation that few youth who have begun medical intervention have retransitioned to live as cisgender is consistent with findings in the literature. Several studies reporting on outcomes among transgender youth receiving blockers and gender-affirming hormones have reported relatively low rates of regret or stopping treatment,[13] which are potential indicators of retransition, though stopping treatment can occur for other reasons as well (eg, side

effects), as can regret (eg, experiences of transphobia).

Our key finding, that there was a relatively low rate of retransition about 5 years after initial social transition, may, on the surface, appear contradictory with past clinic-based research on what is sometimes called persistence and desistence[3] of childhood gender dysphoria. Several large studies attempted to recontact adolescents and adults who had previously been evaluated for gender dysphoria in childhood.[14–17] Many of those were formally diagnosed with what was, at the time, called gender identity disorder. Those studies reported that a minority of youth later identified in a way that might indicate a transgender identity by today s definition.

Interpretation of those results, and especially comparison with the present work, is difficult for several reasons. First, in past studies, when asked "are you a boy or a girl?" about 90 of the children supplied answers that aligned with their sex at birth,[18] leading some to question whether the majority of those children were the equivalent of transgender children today or not.[19–21] Second, participants in those studies were children between the 1960s and the 1990s, and many features of society have changed since then, including greater rates of acceptance and acknowledgment of transgender identities. Third, the parents of the youth in the current study support their children s identities, as indicated by their approval of their social transitions, whereas many of the parents of youth in past studies explicitly discouraged gender nonconformity or "cross-gender" identification.[15,22] In addition, it would have been exceedingly rare for youth in those studies to socially transition, especially completely.[1,10] Finally, there were substantial drop-out rates in all of the previous studies,[14,15,17] making the true estimates of persistence or desistence difficult to obtain.[19,21] Because there are so many possible contributors to differences in rates of persistence (in past work) and retransition in the current work, we urge caution about overinterpreting differences, or overconfidence about which contributing factors explain the differences.

There are also some reasons why we might have had such a low retransition rate. First, on average, participants had socially transitioned 1.6 years before joining our study. It is possible that some youth initially try socially transitioning and then change their minds quickly. Such youth would be unlikely to be enrolled in this study because their eligibility period would have been quite short and therefore the odds of finding the study and completing it would have been low. This means the children in our study may have been especially unlikely, compared with all children who transition, to retransition because they had already lived and presumably been fairly content with that initial transition for more than a year. Second, it is possible that families who failed to participate in the past 2 years of our study ($n = 26$) were disproportionately those whose children retransitioned and who were therefore hesitant to participate again. If true, their exclusion could have reduced our retransition rate. We are skeptical of this possibility for a few reasons. First, 4 of these participants did retransition and had told us about that outcome, so it does not appear that hesitancy in telling us was widespread in this group. Second, many of these families continue to be in touch with our research team and only missed participation because of ongoing personal issues (eg, COVID-19, emergency family circumstances). We anticipate that most of these families will be able to participate as we continue to follow these youth. Finally, from the beginning of the study, the research team has been clear in discussing with the families that we are open to any outcome in their youth.

As with past work, the present work has several key limitations. First, this is a volunteer community sample, meaning there could be biases in the kinds of families who sign up to participate. We know, for example, that unlike many samples of transgender youth, this sample of youth have normative levels of depression and only slight elevations in anxiety.[23] The parents of the participants in this study are disproportionately higher income and went to college at higher rates than the general population. We do not know whether these potential biases in the sample reflect biases in the cohort of children who socially transitioned in the mid-2010s in the United States and Canada. Therefore, whether the results generalize to youth without these characteristics is unknown.

Another potential limitation is that we used pronouns as the criterion for retransitions. Not everyone who, for example, uses they/them pronouns identifies as nonbinary and someone might identify as transgender even if they are currently using pronouns associated with their sex at birth. However, examination of other data provided by families suggests that our pronoun-based criteria were largely consistent with classification that would have arisen from other types of information provided to the research team (eg, labels used in an interview). Only 1 of the youth categorized as "retransitioned" might, by some other criteria, not meet that definition. However, because pronouns were the initial

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TRANSGENDER HEALTH

Individual Treatment Progress Predicts Satisfaction With Transition-Related Care for Youth With Gender Dysphoria: A Prospective Clinical Cohort Study

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ABSTRACT

Background: The number of adolescents presenting with gender dysphoria (GD) in healthcare services has increased signi cantly, yet specialized services offering transition-related care (TRC) for trans youth is lacking.

Aim: To investigate satisfaction with TRC, regret, and reasons for (dis)satisfaction with transition-related medical interventions (TRMIs) in trans adolescents who had presented to the Hamburg Gender Identity Service for children and adolescents (Hamburg GIS).

Methods: Data were collected from a clinical cohort sample of 75 adolescents and young adults diagnosed with GD (81% assigned female at birth) aged 11 to 21 years ($M = 17.4$) at baseline and follow-up (on a spectrum of ongoing care, on average 2 years after initial consultation). To determine progress of the youth s medical transitions, an individual treatment progress score (ITPS) was calculated based on number of desired vs received TRMIs.

Outcomes: Main outcome measures were satisfaction with TRC at the time of follow-up, ITPS, social support, reasons for regret and termination of TRC, and (dis)satisfaction with TRMIs.

Results: Participants underwent different stages of TRMIs, such as gender-af rming hormone treatment or surgeries, and showed overall high satisfaction with TRC received at the Hamburg GIS. Regression analysis indicated that a higher ITPS (an advanced transition treatment stage) was predictive of higher satisfaction with TRC. Sex assigned at birth, age, and time since initial consultation at the clinic showed no signi cant effects for satisfaction with TRC, while degree of social support showed a trend. No adolescents regretted undergoing treatment at follow-up. Additional analysis of free-text answers highlighted satisfaction mostly with the physical results of TRMI.

Clinical Implications: Because youth were more satis ed with TRC when their individual transition (ITPS) was more progressed, treatment should start in a timely manner to avoid distress from puberty or long waiting lists.

Strengths and Limitations: This study is one of the rst to report on treatment satisfaction among youth with GD from Europe. The ITPS allowed for a more detailed evaluation of TRMI wishes and experiences in relation to satisfaction with TRC and may close a gap in research on these treatments in adolescent populations. However, all participants were from the same clinic, and strict treatment eligibility criteria may have excluded certain trans adolescents from the study. Low identi cation rates with non-binary identities prevented comparisons between non-binary and binary genders.

Conclusion: The study highlights the role of TRMI and individual treatment or transition progress for youth s overall high satisfaction with TRC received at the Hamburg GIS. **Nieder TO Mayer TK Hinz S et al. Individual Treatment Progress Predicts Satisfaction With Transition-Related Care for Youth With Gender Dysphoria: A Prospective Clinical Cohort Study. J Sex Med 2021;18:632–645.**

Key Words: Transgender; Gender Dysphoria; Individual Treatment Progress; Health Care; Treatment Satisfaction; Gender-Af rming Treatment

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INTRODUCTION

Transgender (or trans) adolescents, like their adult counterparts, experience an incongruence between their sex assigned at birth and their gender identity.[1,2] This experienced incongruence is often accompanied by psychological distress and a persistent strong desire for social and physical gender changes, at which point they can be diagnosed with gender dysphoria (GD), as per the diagnostic and statistical manual of mental disorders.[3]

Trans youth, being underage, cannot legally consent alone to gender-af rming treatments (transition-related medical interventions [TRMI]), resulting in involvement of parents/guardians, who also have limited decision-making authority.[4] This places unique prerequisites on client self-determination and high demands on health care professionals (HCPs) working in specialized services aiming at reducing GD in children and adolescents,[5] as it must be ensured that youth are cognitively and emotionally capable of understanding decisions regarding transition steps.[6] As such, a 4-step framework for pediatric shared decision-making has been suggested to balance the youth s client autonomy and the parents /guardians choices and values[7]; both must work together with HCPs to agree on where the youth s best interests lie.[4] In each step, the HCP weighs treatment options and approaches parents/guardians for decision-making at the point in which there are multiple options or when certain treatments have particular bene ts/burdens. As adolescents mature, modi cations to the framework can be made to include the youth more actively in shared decision-making. Taking such an approach to health-related decisions in childhood and adolescence can help ensure that biomedical ethical principles are respected for trans youth.[7,8]

Thus, treatment decisions are a staggered process that do not always follow certain strict criteria but rather are age-dependent and influenced by the developmental and psychosocial situation.[9,10] Younger children may undergo social transition, highlighted by use of gender-af rming name, pronoun, and clothing.[10] Adolescents undergoing medical transition often start treatment with hormone blockers gonadotropin-releasing hormone agonists (GnRHa) to suppress secondary sex characteristics at the start of puberty to allow more time for identity development,[9,10] which can minimize risks of false decisions and quell worries of treatment regrets from parents and HCPs.[11,12] Treatment with gender-af rming hormones (GAH; estrogen or testosterone) and surgeries (GAS; usually after reaching legal age) can follow.[9,10,13,14] Adolescents and young adults rarely regret or stop TRMIs, provided they ful ll the criteria for a GD diagnosis and their readiness for treatment is suf ciently assessed.[6,15]

Recent research points to gender af rmation being the appropriate care for youth GD, when indicated by a thorough assessment process, as trans adolescents are likely to experience improvements to general mental well-being through social[16] and/or medical transition.[15,17,18] However, with few specialized centers dedicated to transition-related care (TRC) existing in Germany[19] and a steady rise of children and adolescents with GD presenting clinically in recent years,[6,20–22] including more diverse gender presentations, variant gender experiences and non-binary youth,[2,23] the speci c examination of the quality of TRC for youth becomes increasingly relevant.

In the German health system, health insurances largely cover TRMIs, such as hormone treatment and most surgical interventions being relevant to TRC.[24] However, with the exception of hormone treatment, each cost reimbursement is based on an individual case decision by the medical service of the insurance companies.[25] In general, physicians working for the medical services of the insurance companies are not specialized in TRC but decide on reimbursement based on various requirements (eg, to undergo psychotherapy of at least 6 months before starting hormone treatment). However, with regard to the reduction of GD, the effectiveness of these requirements is not evidence-based. To increase the quality of TRC in Germany, an evidence-based guideline for adults was developed by the German Society for Sex Research (Deutsche Gesellschaft für Sexualforschung, DGfS) in collaboration with related professional societies following methodologies proposed by the Association of the Scienti c Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V., AWMF). The treatment recommendations of this guideline are evidence-based, researched, and evaluated systematically. In a structured consensus process, the guideline development group, representative of the target group, and a stakeholder group of trans people in Germany agreed on 100 recommendations.[24] The guideline aims to individualize and deregulate TRC in Germany. Based on empirical and clinical evidence, a procedure is recommended that is tailored to the individual conditions of treatment and encompasses the full range of TRC. However, the guideline is aimed at trans adults, a comparable guideline for children and adolescents is still being developed.[26]

Satisfaction with received health care is often used as an indicator of health care quality and a springboard for identifying potential areas of improvement.[27] The few studies investigating adolescents experiences with TRC from specialized gender clinics or doctors specializing in transgender health care (THC) generally show high levels of satisfaction. Speci cally, receiving care from respectful, af rming HCPs with specialized knowledge on THC and open client-clinician communication were identi ed as key elements for satisfaction,[28,29] as well as the effects of TRMI (GAH).[28,30] These ndings are encouraging, as youth may not seek out or continue treatment relevant to their transitions[31–33] owing to poor treatment experiences. However, long wait times[34] or treatment delays, especially to start GAH treatment,[28–30] as well as low frequency of appointments[34] and lengthy assessment processes[30] or gatekeeping,[29] may lead to decreased satisfaction with TRC. Negative experiences or barriers to TRC are more common among non-binary youth,[31,35,36] as many clinicians approach THC from a binary understanding.

Studies examining treatment regret or effects on mental well-being also hint at further potential factors for satisfaction with TRC in trans adolescents. Age may play a role; in one prospective follow-up study exploring puberty suppression in 70 youth gender clinic clients, younger individuals were more likely to react negatively to long wait times, while older youth started treatment feeling more dissatis ed with their bodies.[15] Studies of (young) trans adults determined social support[37] and being further along in transition[15,37] predicted improved mental well-being after receiving TRMI. Finally, trans individuals may also undergo different pathways of medical procedures based on the sex assigned at birth/gender identity,[10,38,39] therefore having different encounters with TRC. Thus, experiences of slow treatment or transition progress, social support, age, and birth sex may influence experiences of, and satisfaction with, the process of TRC and it s results.

Use of transition measurement tools such as the Individual Treatment Progress Score (ITPS)[37,38] may help to assess and compare individual treatment progress across trans individuals, without assuming a xed end of a medical transition. By dividing the number of received interventions by the number of planned and received interventions for each participant, the ITPS emphasizes the individual approach in TRC. Because of the variability as a coherent part of adolescence in general, this approach appears to be particularly relevant for adolescents with GD.

Longitudinal data on the impact of TRC in youth are lacking.[40] To close a gap in the research on health care for GD received in Germany during adolescence, the present study aims to investigate satisfaction with TRC and the relationships with the individual transition process.

MATERIAL AND METHODS

Study Design

The present study was based on the rst cross-sectional evaluation of a clinical cohort sample from the Hamburg Gender Identity Service for children and adolescents (Hamburg GIS) at the Department of Child and Adolescent Psychiatry, which is part of the Interdisciplinary Transgender Health Care Centre at the University Medical Center Hamburg-Eppendorf (UKE). Participants were assessed individually at 2 time points: at intake/initial consultation (baseline) and at follow-up (at least 6 months after initial consultation and up to 4 years later, with an average of 2 years). At baseline, none of the participants had received TRC. Follow-up refers to a second measurement point in which participants found themselves on a spectrum of care; all had received some form of TRC (including mental health care) and were considered eligible for TRMI. However, while some had not yet undergone any kind of TRMI, others had reached their transition goals or were at a later stage of their transition at the Hamburg GIS.

Adolescents and young adults who had participated in the baseline data collection (between September 2013 and June 2017) and who were considered eligible for further TRMI were invited by the principal investigator (IBH) to participate in the follow-up study. Participation in both studies was voluntary and independent of the care received at the Hamburg GIS, but the follow-up was rewarded with a 20 voucher. Participants who did not respond after 1 month were sent a reminder. Informed consent from the adolescents (and their guardians) was obtained at both time points. Follow-up data collection took place between November 2017 and March 2018 using a similar set of standardized self-report questionnaires as used at baseline. Only the social support scale and satisfaction with TRC scales were added to an adjusted version of the baseline questionnaire at follow-up. The study was approved by the local ethics committee.[17]

The specialized Hamburg GIS provides TRC for children and adolescents questioning their gender or sex, including referral to a specialized pediatric endocrinologist for GAH.[17,19,41] The diagnostic procedures and further treatments are oriented on the 7th version of standards of care, published by the World Professional Association for Transgender Health (WPATH).[10] After a comprehensive diagnostic evaluation over multiple sessions, TRC is currently recommended at the Hamburg GIS if adolescents present the following criteria: (i) maintaining persistent GD over at least 6 months (without strict onset criteria of rst GD presentation) and rst attempts at living in the preferred gender role; (ii) increased distress because of the incongruent body characteristics (after the onset of rst pubertal changes) and a request for TRC; (iii) a mental health assessment revealing the absence of severe mental health problems that may interfere with the diagnostic workup (such as acute suicidality, psychosis, or other severe mental health problems that need to be addressed through psychotherapy rst); (iv) adequate local mental health care (close to home) and social support (via the family or others) during the course of TRMI; and (v) a demonstration of thorough understanding and knowledge about the effects of puberty suppression (via GnRHa), GAH, GAS, and the social impacts of a transition.[10,13,14,42] This entails that in some cases, diagnostics may take longer as treatment referral follows individual developmental pathways instead of strict criteria checklists. For more details regarding the sample, study design, and treatment approaches, refer to Becker-Hebly et al. (2020).[17]

Sample Characteristics

The original study sample consisted of 434 children and adolescents with gender-variant behaviors and/or experiences who presented at the Hamburg GIS. Of these 434 children and adolescents, 230 individuals had to be excluded from the study for various reasons (see Figure 1),[17] resulting in 204 adolescents whose responses in the baseline study were viable and who were then contacted to complete the follow-up survey. The follow-up response rate was 37%, resulting in a nal sample size of 75 adolescents and young adults. Responders did not signi cantly differ in their sociodemographic characteristics from non-responders.[17]

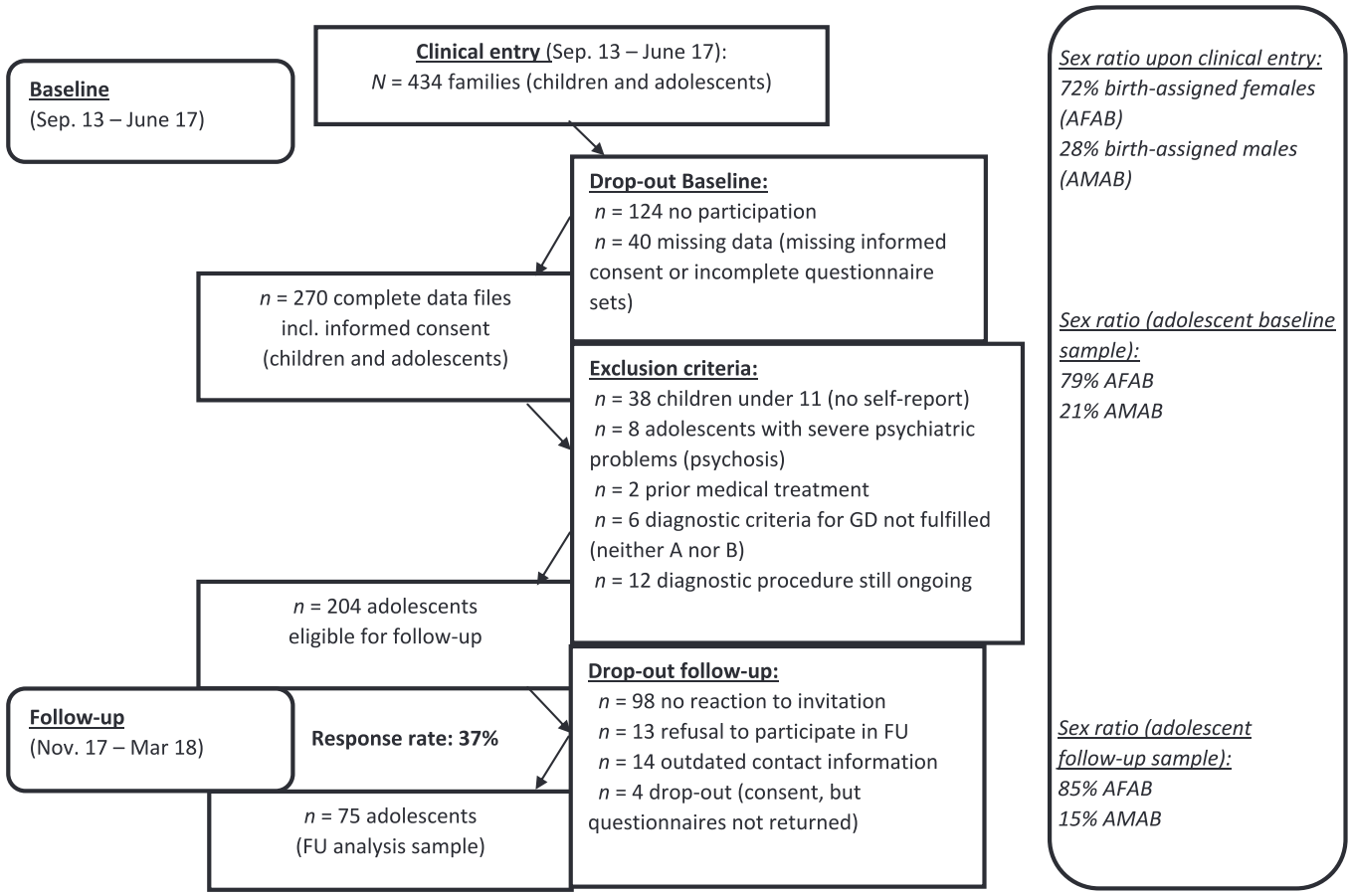

Figure 1. Referrals, participants during baseline and follow-up, and sex ratios.

Within the nal sample, 64 (85%) participants were assigned female sex at birth (AFAB) and 11(15%) were assigned male sex at birth (AMAB). When asked at follow-up, all 11 AMAB participants identi ed as female/trans girl, while 59 AFAB participants identi ed as male/trans boy. The remaining 5 AFAB participants identi ed with non-binary identities at follow-up ("in between, "non-binary, or "other). Their ages ranged from 12 to 21 years ($M = 17.4$, $SD = 1.7$) at the time of follow-up. Youth were in treatment at the Hamburg GIS for a length between seven and 47 months ($M = 21.4$, $SD = 12.2$).

Of the 75 adolescents and young adults at follow-up, 54 participants had already received TRMI. A smaller group of 21 participants had not yet undergone any medical interventions; this group was either still in the diagnostic/psychosocial treatment phase, but assessed as eligible for these interventions, or was receiving mental health support without GnRHa or GAH.

At baseline, 99% of the adolescents had indicated a desire for GAH hormone treatment. At follow-up, 11 youth had received GnRHa and 32 adolescents had received GAH, while the other 32 (43% of sample) had desired GAH but had not yet begun this form of treatment. Furthermore, 91% of the adolescents had indicated a desire for GAS at baseline. At follow-up, 11 adolescents and young adults had received both GAH and (at least 1) GAS, while the other 72 youth (96% of sample) desired GAS but had not received this form of treatment (or additional desired surgeries). Table 1 provides a detailed description of each treatment groups, including sex assigned at birth, age, time since initial consultation and average ITPS scores.

Measures and Operationalization

Sociodemographic and Clinical Data (Diagnosis, TRMI History, Treatment Desires, Reasons for Regret or Termination of TRC, and [Dis]satisfaction with TRMI).

Sociodemographic data (age, sex assigned at birth) and self-report data regarding completed TRMI history, (further) treatment desires, reasons for treatment regrets or termination, and (dis)satisfaction with TRMI were collected with the help of (free-text) survey questions. Data regarding diagnosis and time since initial consultation were added from the adolescents clinical records provided by HCPs working at the Hamburg GIS.

Satisfaction with TRC

Youth s satisfaction with TRC received at the Hamburg GIS was measured using the Client Satisfaction Questionnaire[43] (ZUF-8). The ZUF-8 captures the general satisfaction at the

Table 1. Sample characteristics based on treatment group

Treatment group	*n* (%)	Sex assigned at birth[a] *n* (%)	Age at follow-up (y) M (SD) Range	Treatment length[b] (mo) M (SD) Range	ITPS[c] M (SD) Range
No TRMI	21 (18)	18 (85.7) AFAB 3 (14.3) AMAB	16.7 (1.5) 14.6–20.9	13.9 (6.9) 7–35	.25 (.00) .25–.25
GnRHa	11 (14.7)	8 (72.7) AFAB 3 (27.3) AMAB	16.6 (2.0) 11.9–18.8	12.6 (4.8) 8–23	.52 (.05) .50–.67
GAH	32 (42.7)	28 (87.5) AFAB 4 (12.5) AMAB	17.5 (1.2) 14.6–20.4	23.5 (10.3) 7–47	.75 (.00) .75–.75
GAH + GAS	11 (14.7)	10 (90.9) AFAB 1 (9.1) AMAB	19.2 (1.5) 16.2–21.0	38.0 (11.2) 23–49	.84 (.08) .80–1.0
Total	75 (100)	75 (100)	17.4 (1.7)	21.4 (12.2)	.59 (.23) .25–1.0

[a]AFAB = sex assigned female at birth; AMAB = sex assigned male at birth
[b]Treatment length = time in months since initial consultation at the GIS.
[c]Individual Treatment Progress Score, sum of received treatments divided by sum of received and desired treatments, *M*-values also as percentage.[38]
GAH = gender-af rming hormone treatment; GAS = gender-af rming surgery; TRMI = transition-related medical intervention.

end of a clinical treatment. The questionnaire consists of 8 items rated on a four-point scale (with 4 representing the highest degree of satisfaction).[44] Adding the scores of the 8 questions together, a nal sum score with a range between 8 and 32 can be reached. A cutoff value of 24 was used to classify treatment experiences as (un)satisfactory.[45] Table 2 presents the questionnaire items and corresponding scores.

Individual Treatment Progress

The individual progress with regard to completion of a medical transition with the help of TRMIs was calculated using the ITPS.[38] The ITPS is a metric score with a continuous value between 0% and 100%, calculated for each adolescent based on the number of received treatments divided by the number of received treatments plus treatments still desired (but not yet received) at follow-up. For the participant group without TRMI, the desires for hormonal treatment (GnRHa and GAH) were doubled when calculating the ITPS because both types of hormonal treatment were considered individual steps in the care of adolescents with GD on a spectrum toward a "complete" transition at the Hamburg GIS. For more information on the ITPS, see Koehler et al.[38]

Social Support

The adolescents perceived social support was measured using the short-form version of the Perceived Social Support Questionnaire (F-SozU). The F-SozU consists of 14 items on a ve-point scale that captures the degree of agreement to various aspects of perceived support in one s social environment.[46]

Statistical Analysis

Data on received and desired treatments at both baseline and follow-up were analyzed descriptively. Four treatment groups were created (see Table 1), to which participants were assigned based on their received TRC at follow-up: no TRMI, GnRHa, GAH, and GAH *and* GAS. The treatment groups were also used along with their treatment desires at follow-up to calculate their ITPS[38] as well as to examine treatment satisfaction (global satisfaction based on ZUF-8 scores).[45]

Table 2. ZUF-8 items

1. How would you rate the quality of the care/consultation you received?
Excellent (4)/good (3)/satisfactory (2)/bad (1)
2. Did you receive the type of care/consultation that you wanted?
De nitely not (1)/no, not really (2)/yes, in general (3)/yes, de nitely (4)
3. To what extent did our clinic meet your needs?
Almost all my needs (4)/most of my needs (3)/only a few of my needs (2)/none of my needs (1)
4. Would you recommend our clinic to a friend if s/he requires similar help?
De nitely not (1)/no, I don't think so (2)/yes, I think so (3)/yes, de nitely (4)
5. How satis ed are you with the extent of the help which you received here?
Very unsatis ed (1)/unsatis ed (2)/satis ed (3)/very satis ed (4)
6. Did the care that you received here help you to deal more appropriately with your problems/questions?
Yes, it helped a lot (4)/yes, it helped a bit (3)/no, it did not help (2)/no, it made things worse (1)
7. How satis ed are you overall with the care you received?
Very satis ed (4)/satis ed (3)/unsatis ed (2)/very unsatis ed (1)
8. Would you come to our clinic again if you needed help?
De nitely not (1)/no, I don't think so (2)/yes, I think so (3)/yes, de nitely (4)

Values in brackets refer to the number of points awarded to each answer to calculate nal ZUF-8 score.[44,45]

In the second part of analysis, a multiple linear regression with block-wise factor inclusion was performed to analyze the relationship between treatment-dependent factors (such as time since initial consultation and ITPS), treatment-independent factors (such as age, sex assigned at birth, and social support) and the outcome, satisfaction with TRC. For the analysis of the role of social support on satisfaction with TRC in the multiple linear regression, the total sum score in the F-SozU was calculated for each participant and then divided by the number of completed items. SPSS 22 was used for all analyses.

Finally, free-text answers addressing reasons for termination/suspension of TRC and/or possible treatment regrets, as well as (dis)satisfaction with TRMI, were used to add individual qualitative insights to the quantitative findings.

RESULTS

Individual Treatment Progress Score

The ITPS showed that the sample of adolescents and young adults had completed 59% of their desired TRMIs on average at the time of follow-up, although ITPS values varied between treatment groups. For example, youth who had not yet received any TRMI at follow-up had completed on average only 25% of their treatment, while those who had received GAH and GAS were of course further along in transition, with an average ITPS of 84%. Table 1 describes the ITPS across treatment groups in detail.

Satisfaction with TRC

Based on the scores on the ZUF-8, 75% of all participants indicated that they were overall satisfied with the TRC received at the Hamburg GIS and thus scored higher than the cutoff score of 24.[45] Analysis of the ZUF-8 mean scores also indicated that youth were generally satisfied with the care received ($M = 3.29$ of a possible score of $M = 4.00$). The mean scores further show a tendency of increased satisfaction with TRC with advanced treatment stages. However, the differences in mean scores across groups were not statistically significant ($F[3,71] = 1.76$, $p = .16$). Table 3 shows the ZUF-8 scores for all treatment groups.

Factors Influencing Satisfaction with TRC

The final model 2 of the multiple linear regression, with all factors included, explained approximately 11% of the variance. The ITPS was the only factor with a statistically significant impact on satisfaction with TRC ($P = .012$ in model 2). The factor social support showed a trend towards predicting satisfaction with TRC ($P = .055$). Model 2 had an adjusted $R = 0.114$ and as such, a weak goodness of fit (see Table 4). The Durbin-Watson test for potential autocorrelation had a value of 1.614 and therefore showed a trend of positive correlation. Multicollinearity could be ruled out (variance inflation factor values between 1.043 and 2.516). In a multiple regression with a final sample size of $n = 75$ (valid completed study questionnaires) and 5 predictors, a moderate effect ($f = 0.15$; error = 0.05) with a power of 95% (0.951) could be tested (power analysis using G*Power program; $\delta = 3.33$; critical t-value = 1.67; $df = 68$).

Reasons for Termination of TRC, Regret, and (Dis) Satisfaction with TRMI

Table 5 provides details of the $n = 9$ free-text responses on reasons for termination of TRC or regret. At follow-up, none of the adolescents and young adults in the sample indicated that they regretted transition so far. In total, 13 participants (of which 4 were AMAB) indicated at follow-up that they had either

Table 3. ZUF-8 scores

	ZUF-8 cutoff score[a] 24		ZUF-8 mean scores[b]		ZUF-8 total scores[c]
Treatment group	Dissatisfied n (%)	Satisfied n (%)	M (SD) Range	95% CI	M (SD) Range
No TRMI	9 (12)	12 (16)	3.08 (.63) 1.88–4.00	2.79–3.37	24.67 (5.06) 15–32
GnRHa	3 (4)	8 (11)	3.17 (.85) 1.25*–4.00	2.59–3.74	25.36 (6.83) 10–32
GAH	6 (8)	26 (35)	3.41 (.57) 1.88–4.00	3.21–3.62	27.31 (4.55) 15–32
GAH + GAS	1 (1)	10 (13)	3.49 (.37) 2.75–4.00	3.24–3.74	27.37 (2.95) 22–32
Total	19 (25)	56 (75)	3.29 (.62) 1.25–4.00	3.15–3.44	26.37 (4.98) 10–32

[a]Cutoff Score by Hannöver et al.[45] A score higher than 24 indicates satisfaction with treatment.
[b]ZUF-8 mean score value between 0 and 4.
[c]ZUF-8 total score value between 0 and 32.
GAH = gender-affirming hormone treatment; GAS = gender-affirming surgery; TRMI = transition-related medical intervention.
*One adolescent's treatment satisfaction score of M = 1.25 was an outlier. However, this data point was kept in all following calculations as its removal did not indicate any significant changes in test results.

Table 4. Multiple linear regression (model 2)

	Non-standardized coefficients		Standardized coefficients		
	B	*SE*	*β*	*t*	*p*
(Constants)	3.771	.991		4.141	.000
ITPS[a]	.918	.356	.346	2.582	.012*
Treatment Length [b]	−.007	.009	−.138	−.797	.428
Age	−.043	.058	−.118	−.747	.458
Assigned sex at birth	.211	.198	.121	1.068	.289
Social Support	−.201	.103	−.218	−1.950	.055

[a]Individual Treatment Progress Score.
[b]Time in months since initial consultation at GIS.
* P .05; *adjusted* $R^2 = 0.114$.

suspended or terminated their TRC at the Hamburg GIS. Nine participants did so while in the no-TRMI group, while three individuals did so at the GAH stage. One AFAB individual in the GAH group indicated that treatment was terminated after successful GAH administration; however, this individual had previously indicated desire for mastectomy and potentially other surgical procedures. Only one participant terminated/suspended treatment at the GAS stage. Reasons related to mental health issues were most often listed as a cause for suspension/termination, followed by reasons unrelated to direct treatment experience (eg, long distance to Hamburg). Only one participant (trans boy in the no-TRMI group) indicated poor TRC experience (subjective lack of understanding from HCPs) as cause for treatment termination.

Table 6 provides details of the free-text responses on (dis) satisfaction speci cally with TRMI for the three treatment groups that had received TRMI. The free-text responses of the 21 adolescents and young adults who had not yet undergone TRMI were excluded from analysis as these participants could not yet evaluate medical treatment experiences and/or results. Of the 54 youth who had received TRMI, 38 individuals (33 AFAB and 5 AMAB participants) provided free-text responses. The positive and negative physical effects of TRMI were highlighted by participants as reasons for both treatment satisfaction (eg, praised suppression of primary sex characteristics or surgery results) and dissatisfaction (eg, criticism of GAH side effects or slow physical changes).

DISCUSSION

The present prospective clinical cohort study following up 75 adolescents and young adults with GD aged 12 to 21 years aimed to assess satisfaction with TRC received at the Hamburg GIS, individual treatment progress (ITPS), regret, and reasons for (dis) satisfaction with TRMI. Most youth had desired TRMIs at baseline and had undergone GAH treatment at follow-up, as well as some surgical procedure(s). However, the treatment pathways, including time since initial consultation and number/order of procedures, varied; therefore, the ITPS in the sample also ranged from 25 to 100%. The sample reported overall high satisfaction with TRC. Considering that trans youth are still an underserved population and specialized clinics for GD are rare, not only in Germany,[5,19] participants may have simply been happy to (be able to) receive any TRC at all, thus explaining the determined overall high satisfaction with TRC. More likely, however, is that the high satisfaction rates reflected the high quality of TRC offered, as the results mirror ndings of other studies investigating treatment satisfaction.[28,30,34]

Table 5. Free-text responses of reasons for TRC termination/suspension

Reason	*n* (%)
Mental Health Issues	5 (38)
"I should rst get my depression treated"	
"Clinic stay and therapy pause"	
"I have to go to a clinic, but I'm back at the GIS since summer 2017	
"Personal reasons (psychological), desire for re-admission [to the Hamburg GIS]"	
"Psychological treatment"	
Long Distance to GIS	3 (23)
"Moving away"	
"Distance from Nuremberg to Hamburg too big, too expensive long term"	
"Save the way to Hamburg (from Hannover), appointments when needed"	
Other Reasons	1 (8)
"I did not feel understood"[a]	

[a]Listed as reason by 1 trans boy in the no-TRMI group.
GIS = Gender Identity Service; TRC = transition-related care; TRMI = transition-related medical intervention.

Table 6. Free-text responses of reasons for TRMI (dis)satisfaction

Treatment group	Satis ed with:	*n* (%)	Unsatis ed with:	*n* (%)
Hormone blockers, GnRHa ($n = 14$)	Menstruation suppression	7 (50.0)	Insuf cient menstruation suppression	3 (21.4)
	"lack of period"		"that I have spotting"	
	"living without my period "		"menstruation did not stop"	
	"that I don't have my period anymore"		"menstruation returned"	
	"good suppression"			
	"no period"			
	"end of menstruation"			
	"suppression, especially of menstruation"			
	Breast tissue shrinkage	2 (14.3)	Hot flashes	4 (28.6)
	"chest becoming smaller"		"hot flashes"	
	"breasts getting smaller"		"temperature fluctuations/hot flashes"	
	Improved skin	1 (7.1)	Libido suppression	2 (14.3)
	"less acne"		"decrease in sex drive"	
			"less libido"	
	Libido suppression	1 (7.1)		
	"reduced libido"			
	Other responses	4 (28.6)	Other responses	2 (14.3)
	"the effects"		"mood swings"	
	"everything (especially my beard growth)"		"voice cannot be undone"	
	"no male puberty"			
Gender-af rming hormones ($n = 31$)	Voice change	11 (35.5)	Skin appearance	5 (16.1)
	"voice"		"acne"	
	"voice breaking"		"pimples"	
	"change in voice"		"side effects (such as acne and so on)"	
	"changes in body (voice, and so on.)"			
	Hair growth	7 (22.6)	Mood swings	2 (6.5)
	" , hair, "		"mood swings sometimes"	
	"body hair (especially beard)"		"irritability"	
	"body hair"			
	"hair coverage"			
Treatment group	Satis ed with:	*n* (%)	Unsatis ed with:	*n* (%)
Gender-af rming hormones ($n = 31$)	Other physical changes	8 (25.8)	Too slow/little changes	9 (29.0)
	"breast growth, skin, ,facial features"		"takes a long time, I take hormones as gel for almost 5 months and notice little"	

(continued)

Table 6. Continued

Treatment group	Satis ed with:	*n* (%)	Unsatis ed with:	*n* (%)
	"light breast growth"		"through the low dosage (25 mg) it takes a bit too long"	
	"more weight, small breasts"		"could be more"	
	"face"		"long wait for change"	
	"fat distribution, muscle growth"		"the hormones take effect very slowly"	
	"muscle mass"		"otherwise little effect"	
	"changes, body"		"too little beard growth, change in physique"	
	"body changes"		"too little change to genitals"	
			"too little change"	
	Other responses	17 (54.8)	Other responses	2 (6.5)
	"everything"		"libido, "	
	"the onset of the proper puberty"		" , that the hormones have not completely suppressed my period"	
	"the changes"			
	"the effects"			
	"total treatment"			
	"complete change"			
	"otherwise everything"			
	"Testosterone gel"			
	"Testosterone"			
Gender-af rming surgery ($n = 8$)	Breast reduction	4 (50.0)	Scars	2 (25.0)
	"the flat chest"		"the scars don't heal that well"	
	"the right breast"		"big, thick scars"	
	"mastectomy"			
	"abovementioned operations"			
	Other responses	3 (37.5)	General result	2 (25.0)
	"entire picture"		"Form (a little bit)"	
	"small scars, natural appearance"		"the left a lot of tissue is still inside"	
	"scars, result"			

GnRHa = gonadotropin-releasing hormone agonists; TRMI = transition-related medical intervention.

The study also showed that overall satisfaction with TRC for adolescents in the GnRHa group, although still quite high, was slightly lower than satisfaction with care found in the GAH and GAS groups. While studies show favorable results for GnRHa to treat GD in adolescents,[6,42] another recent study from Germany only reported moderately better scores at follow-up.[17] As satisfaction with psychiatric treatment has been shown to be influenced by intrapersonal factors such as trust in treatment or prior treatment experiences,[47] it is unclear if the satisfaction rates between groups is influenced by expectations based on previous treatment experiences or subjective perception of GnRHa effectiveness, for example.

A higher ITPS (advanced individual medical transition stage or more desired TRMIs) predicted higher satisfaction with care outcomes. This nding, that advanced individual treatment progress proved signi cant for overall satisfation with TRC, mirrors ndings that show many trans individuals do not feel like their transition has fully begun with mental health care/psychotherapy,[48] which was captured in a lower ITPS score/earlier transition stages. Rather, it is at the earliest with GAH and/or GAS, that trans individuals feel like their identi ed gender and feel like they are recognized by others as such[49] and report suf ciently diminished GD.[6,50]

The signi cance of the ITPS emphasizes the importance of integrating individual desires and individual treatment pathways into TRC plans.[10–12,17] Although most adolescents came to their initial consultation with the goal to receive most types of TRMI, some had individual desires for speci c medical interventions. Results showed that satisfaction with TRC was higher when more of these desires were ful lled, even for those still within the treatment process. This result has also been found in non-trans populations: a similar study determined an effect between the implementation of individual desires and expectations of psychiatric clients and their experienced treatment.[51] In general, it is recommended to consider individual treatment desires instead of following criteria-based checklists, if decisions must be made in which several equivalent and ideally evidence-based treatment options are available (so-called equipoise), if decisions on how to deal with life-changing situations are preference-sensitive, and if the consequences of the decision are potentially signi cant for the further life of the person concerned.[52]

In addition, this individualized approach ensures client autonomy, as reflected in pediatric shared decision-making[4,7]; input from adolescents themselves can reduce the gatekeeping function of the HCPs, improving the client and HCP relationship[53] and increasing treatment satisfaction.[29,54] As such, participants further along in their transition (higher ITPS) had more subjective positive experiences of receiving TRC which reflected and respected their treatment desires.

Although previous studies found effects for age on psychiatric treatment satisfaction,[55] for example, or that younger adolescents reacted particularly frustrated to waiting for TRC,[6] no influence of age on satisfaction with TRC was found in this study. This nding is not only relevant as it contradicts previous research, it indicates that younger trans adolescents do not react signi cantly differently to TRC than older youth, demonstrating they may possess (cognitive and emotional) maturity needed for treatment. However, the present sample was relatively old on average. Even though there were no strict age criteria for the start of TRMI, youth received TRMIs at approximately age 16 on average, with the youngest participants being 11.8 years old at the start of GnRHa administration and 14.5 years at the start of GAH.

Similarly, time since initial consultation did not prove signi cant. However, this could be owing to the operationalization; the often long waiting period up until the initial consultation was not incorporated, and many studies show it to be criticized by trans youth.[6,34] Social support only demonstrated a slight trend ($P = .055$), which may be owing to low variance in the sample; most adolescents from the same baseline sample reported high levels of support from family.[41] As adolescents are dependent on guardians for accessing TRC and subsequent decision-making, this factor may be particularly important, and further research is needed.

When it comes to satisfaction with TRMI, the physical effects, particularly as a result of GAH or GAS, seemed to be of paramount importance for adolescents. This is in line with studies showing that medical transition has positive effects on young trans individuals who began transition in adolescence, including decreases in GD and improvements in psychosocial functioning (ie, decrease in depression and anxiety).[6,15,17,42]

Results indicate that adolescents have high expectations and speci c visions for (the outcomes of) TRMI. Youth desire their body to physically reflect their experienced gender identity[23] and, as such, may be disappointed by less than ideal treatment results. Indeed, treatment side effects (such as scarring) or slow progress/lack of physical changes were most often listed as reasons for dissatisfaction with TRMIs, which is in line with other studies revealing that cosmetic outcomes of (surgical) TRMI in adulthood were criticized,[56] including the results of mastectomy.[57] With this in mind, the high satisfaction rates should be weighed against the overall low rate (14.7%) of surgical interventions undergone in the sample.

With respect to prevailing uncertainties when it comes to treatment of trans youth and desires of HCPs to avoid misdiagnoses,[5,11,12] an important nding is that no adolescents and young adults in the present study regretted TRC at the time of follow-up, mirroring other studies that determined no regret of GnRHa administration[6] or GAH and GAS.[15,18,58] It can be assumed that the sample selection (of only adolescents who were considered generally eligible for further TRMI) and value placed on the individual treatment desires played a role in this outcome.

However, a small percentage of youth indicated they had terminated or delayed treatment, among others, because of mental health concerns. Good mental health and psychosocial functioning is an important aspect for consideration with TRC.[6,9,10,13–15,17,19] While many adolescents may have mental health concerns which do not interfere with TRC when they are stable in treatment or on medication, it is in the interest of the adolescents and young adults to receive mental health care rst for issues which may put successful TRC at jeopardy (ie, acute suicidality) followed by — if needed — a medical transition. While this may seem sensible, it does have its drawbacks (eg, a delay in transition because of mental health care in line with increased frustration).[6] Other participants indicated treatment termination

owing to long distance to the Hamburg GIS. This result is not surprising given the poor THC provider situation for trans youth in Germany.[19] For many individuals, a specialized clinic such as the Hamburg GIS is too far away, and they must rely on local (potentially unspecialized) HCPs. It is therefore essential that more clinics provide specialized care for youth with GD, including in rural or suburban areas or offer e-health approaches.

Clinical Implications

HCPs should get bidirectional feedback from adolescents/guardians throughout the TRC process to ensure treatment desires and needs are adequately captured and integrated into TRC. As changes in desires can occur throughout the treatment process,[59] this may also help not to ignore changing transition pathways.

Treatment expectations and what TRMI can accomplish, side effects (eg, acne), cosmetic outcomes (eg, scarring), complications, and so on should be discussed to avoid dissatisfaction with physical outcomes or side effects of TRMI, as much emphasis is placed on these aspects by youth. As also recommended by the WPATH,[10] this can help empower adolescents in making fully informed decisions on what TRMI are right for them. Satisfaction may thereby increase because treatments will best suit transition goals[10] and youth could be mentally prepared for potentially less-than-ideal side effects or outcomes.

Since youth were more satis ed with TRC when their transition was more progressed and effects of puberty were "paused or "reversed, TRC should start in a timely fashion and HCPs should mind the distress that some of the puberty-related changes of the body may cause for adolescents.[3,60]

Mental HCPs can help young people deal with feelings of impatience during the process toward a medical transition (ie, with slow physical changes). In addition, HCPs should expect treatment satisfaction to increase as adolescents and young adults get closer to their individual transition goals; dissatisfaction with TRC in earlier stages should not necessarily be interpreted as a sign that the treatment is wrong or will be regretted.

Limitations and Future Research Directions

Results must be interpreted cautiously as participants came from the same clinic, and there was no randomized control group owing to ethical considerations. The strict internal diagnostic requirements for the selection of the follow-up sample as well as treatment eligibility criteria at the Hamburg GIS for children and adolescents may have led to a biased sample selection; while all study participants had been deemed eligible for further TRMI, individuals presenting with certain gender expressions or experiences (eg, non-binary) may have been excluded from the data collection.

Furthermore, the high level of desired/underwent TRMI may not be representative for the total sample of referred adolescents or all trans youth who do not consult with a specialized service such as the Hamburg GIS. Many adult trans individuals report satisfactory decreases in GD with only social transition,[10,61] with some explicitly refusing TRMI.[62] These individuals would most likely not seek TRC from a specialized service, and thus, their treatment desires are not included in clinical cohort samples.

The low number of adolescents and young adults who participated in the follow-up survey (37%) could indicate that the survey had low priority for those nished transitioning or that only those who experienced positive course of treatment were motivated to participate. In addition, the large number of participants in the GAH group could indicate that youth currently in treatment were worried a lack of participation could have negative consequences for their further treatment and may have even rated treatment more positively than actually experienced. However, this can be considered unlikely, as participants were aware that their HCPs had no access to study data.

The low follow-up participation may have also increased the already disproportionate sex ratio, with only 15% of the participants who were AMAB; however, non-responder analysis determined no signi cant differences in sex assigned at birth between the follow-up group and those who only participated in baseline.[17] This sex ratio also reflects ndings in other studies on prevalence rates of gender-incongruent experiences and behaviors.[2,21,41] Nonetheless, the sex ratio meant analyses of the GAH + GAS group could only explore satisfaction with mastectomy for AFAB participants.

Finally, only 5 participants identi ed with non-binary identities at follow-up. This is particularly relevant, as previous studies show that between 11%[23] and 41%[63] of youth and young adults under the age of 25 years identify with non-binary gender identities, meaning the percentage (7%) of non-binary youth in the current sample is lower than average prevalence rates. However, all non-binary participants in the sample were AFAB, mirroring results of other studies showing non-binary youth[35] and adults[38] more likely to be AFAB. Recent studies showed that non-binary youth are less likely to undergo GAH to reach transition goals[35] and may face barriers regarding access to hormones when they do desire this type of TRMI,[31,35] making it essential to critically examine the lack of non-binary participants in the present study. Nonetheless, the small sample size means additional analyses based on gender binarity would have most likely been severely limited anyway.

In sum, sampling limitations imply that the results cannot be transferable to all other trans populations, particularly non-Western countries or people of color, or youth identifying with non-binary genders, but also to AMAB youth or those undergoing other types of TRMI, such as genital surgeries. Future research should thus explicitly capture the TRC experiences of non-binary and racially diverse adolescents, in particular. Furthermore, while the present study was performed over a period of several years, this early data regarding satisfaction with TRC cannot be extrapolated to assume long-term TRC success as many adolescents continue to grow and

evolve their identities throughout the years. Future research should aim to follow up the developmental pathways of trans youth long term into their adult years.

On a different note, results provide suggestions for improvement in measurement tools to be used with trans adolescents. The ITPS was an interesting measurement tool for capturing individual transition progress in the present adolescent population and future research should consider its application, as existing tools for understanding GD and transition needs have limitations.[40] With regard to measuring satisfaction using the ZUF-8, high satisfaction must be interpreted cautiously as it may simply be caused by a ceiling effect.[45,47] To make a valid assessment of treatment satisfaction, high satisfaction values should be classi ed with the help of further information, such as free-text answers. Furthermore, the ZUF-8 only reflected overall satisfaction with general health care instead of satisfaction with the specialized nature of TRC. Analysis of the free-text responses suggest that future research should also include speci c questionnaires to capture aspects that other studies have shown to be relevant to satisfaction with TRC: wait times, TRMI side effects and outcomes, relationships with HCPs, psychotherapy and assessment requirements, and so on.[6,30,34,57]

CONCLUSION

This study was one of the rst in Germany to assess satisfaction with TRC within a prospective sample of clinically referred trans adolescents and young adults. It builds on the few studies in this[28,30,34] and related areas, such as effects of TRC on adolescent mental well-being.[15,17,42] Overall, satisfaction with TRC was high in this population of trans youth, and no participants regretted treatment, reflecting high quality of care at the Hamburg GIS. Participants focus on physical results of treatment as reason for (dis) satisfaction with TRMI adds to the literature supporting the use of TRMI on adolescent populations. A progressed transition (higher ITPS) signi cantly predicted higher satisfaction with TRC, providing insight into the usefulness of measuring individual treatment progress and incorporating individual desires in TRC in younger populations.

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Original Investigation | Pediatrics

Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care

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Abstract

IMPORTANCE Transgender and nonbinary (TNB) youths are disproportionately burdened by poor mental health outcomes owing to decreased social support and increased stigma and discrimination. Although gender-affirming care is associated with decreased long-term adverse mental health outcomes among these youths, less is known about its association with mental health immediately after initiation of care.

OBJECTIVE To investigate changes in mental health over the first year of receiving gender-affirming care and whether initiation of puberty blockers (PBs) and gender-affirming hormones (GAHs) was associated with changes in depression, anxiety, and suicidality.

DESIGN, SETTING, AND PARTICIPANTS This prospective observational cohort study was conducted at an urban multidisciplinary gender clinic among TNB adolescents and young adults seeking gender-affirming care from August 2017 to June 2018. Data were analyzed from August 2020 through November 2021.

EXPOSURES Time since enrollment and receipt of PBs or GAHs.

MAIN OUTCOMES AND MEASURES Mental health outcomes of interest were assessed via the Patient Health Questionnaire 9-item (PHQ-9) and Generalized Anxiety Disorder 7-item (GAD-7) scales, which were dichotomized into measures of moderate or severe depression and anxiety (ie, scores ≥10), respectively. Any self-report of self-harm or suicidal thoughts over the previous 2 weeks was assessed using PHQ-9 question 9. Generalized estimating equations were used to assess change from baseline in each outcome at 3, 6, and 12 months of follow-up. Bivariate and multivariable logistic models were estimated to examine temporal trends and investigate associations between receipt of PBs or GAHs and each outcome.

RESULTS Among 104 youths aged 13 to 20 years (mean [SD] age, 15.8 [1.6] years) who participated in the study, there were 63 transmasculine individuals (60.6%), 27 transfeminine individuals (26.0%), 10 nonbinary or gender fluid individuals (9.6%), and 4 youths who responded "I don't know" or did not respond to the gender identity question (3.8%). At baseline, 59 individuals (56.7%) had moderate to severe depression, 52 individuals (50.0%) had moderate to severe anxiety, and 45 individuals (43.3%) reported self-harm or suicidal thoughts. By the end of the study, 69 youths (66.3%) had received PBs, GAHs, or both interventions, while 35 youths had not received either intervention (33.7%). After adjustment for temporal trends and potential confounders, we observed 60% lower odds of depression (adjusted odds ratio [aOR], 0.40; 95% CI, 0.17-0.95) and 73% lower odds of suicidality (aOR, 0.27; 95% CI, 0.11-0.65) among youths who had initiated PBs or GAHs compared with youths who had not. There was no association between PBs or GAHs and anxiety (aOR, 1.01; 95% CI, 0.41, 2.51).

(continued)

Key Points

Question Is gender-affirming care for transgender and nonbinary (TNB) youths associated with changes in depression, anxiety, and suicidality?

Findings In this prospective cohort of 104 TNB youths aged 13 to 20 years, receipt of gender-affirming care, including puberty blockers and gender-affirming hormones, was associated with 60% lower odds of moderate or severe depression and 73% lower odds of suicidality over a 12-month follow-up.

Meaning This study found that access to gender-affirming care was associated with mitigation of mental health disparities among TNB youths over 1 year; given this population's high rates of adverse mental health outcomes, these data suggest that access to pharmacological interventions may be associated with improved mental health among TNB youths over a short period.

+ Invited Commentary

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

Abstract (continued)

CONCLUSIONS AND RELEVANCE This study found that gender-affirming medical interventions were associated with lower odds of depression and suicidality over 12 months. These data add to existing evidence suggesting that gender-affirming care may be associated with improved well-being among TNB youths over a short period, which is important given mental health disparities experienced by this population, particularly the high levels of self-harm and suicide.

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Introduction

Transgender and nonbinary (TNB) youths are disproportionately burdened by poor mental health outcomes, including depression, anxiety, and suicidal ideation and attempts.[1-5] These disparities are likely owing to high levels of social rejection, such as a lack of support from parents[6,7] and bullying,[6,8,9] and increased stigma and discrimination experienced by TNB youths. Multidisciplinary care centers have emerged across the country to address the health care needs of TNB youths, which include access to medical gender-affirming interventions, such as puberty blockers (PBs) and gender-affirming hormones (GAHs).[10] These centers coordinate care and help youths and their families address barriers to care, such as lack of insurance coverage[11] and travel times.[12] Gender-affirming care is associated with decreased rates of long-term adverse outcomes among TNB youths. Specifically, PBs, GAHs, and gender-affirming surgeries have all been found to be independently associated with decreased rates of depression, anxiety, and other adverse mental health outcomes.[13-16] Access to these interventions is also associated with a decreased lifetime incidence of suicidal ideation among adults who had access to PBs during adolescence.[17] Conversely, TNB youths who present to care later in adolescence or young adulthood experience more adverse mental health outcomes.[18] Despite this robust evidence base, legislation criminalizing and thus limiting access to gender-affirming medical care for minors is increasing.[19,20]

Less is known about the association of gender-affirming care with mental health outcomes immediately after initiation of care. Several studies published from 2015 to 2020 found that receipt of PBs or GAHs was associated with improved psychological functioning[21] and body satisfaction,[22] as well as decreased depression[23] and suicidality[24] within a 1-year period. Initiation of gender-affirming care may be associated with improved short-term mental health owing to validation of gender identity and clinical staff support. Conversely, prerequisite mental health evaluations, often perceived as pathologizing by TNB youths, and initiation of GAHs may present new stressors that may be associated with exacerbation of mental health symptoms early in care, such as experiences of discrimination associated with more frequent points of engagement in a largely cisnormative health care system (eg, interactions with nonaffirming pharmacists to obtain laboratory tests, syringes, and medications).[25] Given the high risk of suicidality among TNB adolescents, there is a pressing need to better characterize mental health trends for TNB youths early in gender-affirming care. This study aimed to investigate changes in mental health among TNB youths enrolled in an urban multidisciplinary gender clinic over the first 12 months of receiving care. We also sought to investigate whether initiation of PBs or GAHs was associated with depression, anxiety, and suicidality.

Methods

This cohort study received approval from the Seattle Children's Hospital Institutional Review Board. For youths younger than age 18 years, caregiver consent and youth assent was obtained. For youths ages 18 years and older, youth consent alone was obtained. The 12-month assessment was funded via a different mechanism than other survey time points; thus, participants were reconsented for the

12-month survey. The study follows the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.

Study Procedures

We conducted a prospective observational cohort study of TNB youths seeking care at Seattle Children's Gender Clinic, an urban multidisciplinary gender clinic. After a referral is placed or a patient self-refers, new patients, their caregivers, or patients with their caregivers are scheduled for a 1-hour phone intake with a care navigator who is a licensed clinical social worker. Patients are then scheduled for an appointment at the clinic with a medical provider.

All patients who completed the phone intake and in-person appointment between August 2017 and June 2018 were recruited for this study. Participants completed baseline surveys within 24 hours of their first appointment and were invited to complete follow-up surveys at 3, 6, and 12 months. Youth surveys were used to assess most variables in this study; caregiver surveys were used to assess caregiver income. Participation and completion of study surveys had no bearing on prescribing of PBs or GAHs.

Measures

Mental Health Variables

We assessed 3 internalizing mental health outcomes: depression, generalized anxiety, and suicidality. Depression was assessed using the Patient Health Questionnaire 9-item scale (PHQ-9), and anxiety was assessed using the Generalized Anxiety Disorder 7-item scale (GAD-7). We dichotomized PHQ-9 and GAD-7 scores into measures of moderate or severe depression and anxiety (ie, scores $\geq$10).[26,27] Self-harm and suicidal thoughts were assessed using PHQ-9 question 9 (eTable 1 in the Supplement).

Pharmacological Interventions

Participants self-reported if they had ever received GAHs, including estrogen or testosterone, or PBs (eg, gonadotropin-releasing hormone analogues) on each survey. We conducted a medical record review to capture prescription of androgen blockers (eg, spironolactone) and medications for menstrual suppression or contraception (ie, medroxyprogesterone acetate or levonorgestrel-releasing intrauterine device) during the study period.

Covariates

We a priori considered potential confounders hypothesized to be associated with our exposures and outcomes of interest based on theory and prior research. Self-reported gender was ascertained on each survey using a 2-step question that asked participants about their current gender and their sex assigned at birth. If a participant's self-reported gender changed across surveys, we used the gender reported most frequently by a participant (3 individuals identified as transmasculine at baseline and as nonbinary on all follow-up surveys). We collected data on self-reported race and ethnicity (available response options were Arab or Middle Eastern; Asian; Black or African American; Latinx; Native American, American Indian, or Alaskan Native or Native Hawaiian; Pacific Islander; and White), age, caregiver income, and insurance type. Race and ethnicity were assessed as potential covariates owing to known barriers to accessing gender-affirming care among transgender youth who are members of minority racial and ethnic groups. For descriptive statistics, Asian and Pacific Islander groups were combined owing to small population numbers. We included a baseline variable reflecting receipt of ongoing mental health therapy other than for the purpose of a mental health assessment to receive a gender dysphoria diagnosis. We included a self-report variable reflecting whether youths felt their gender identity or expression was a source of tension with their parents or guardians. Substance use included any alcohol, marijuana, or other drug use in the past year. Resilience was measured by the Connor-Davidson Resilience Scale (CD-RISC) 10-item score developed to measure change in an individual's state resilience over time.[28] Resilience scores were

dichotomized into high (ie, ≥median) and low (ie, <median). Prior studies of young adults in the US reported mean CD-RISC scores ranging from 27.2 to 30.1.[29,30]

Statistical Analysis

We used generalized estimating equations to assess change in outcomes from baseline at each follow-up point (eFigure 1 in the Supplement). We used a logit link function to estimate adjusted odds ratio (aOR) for the association between variables and each mental health outcome. We initially estimated bivariate associations between potential confounders and mental health outcomes. Multivariable models included variables that were statistically significant in bivariate models. For all outcomes and models, statistical significance was defined as 95% CIs that did not contain 1.00. Reported *P* values are based on 2-sided Wald test statistics.

Model 1 examined temporal trends in mental health outcomes, with time (ie, baseline, 3, 6, and 12 months) modeled as a categorical variable. Model 2 estimated the association between receipt of PBs or GAHs and mental health outcomes adjusted for temporal trends and potential confounders. Receipt of PBs or GAHs was modeled as a composite binary time-varying exposure that compared mean outcomes between participants who had initiated PBs or GAHs and those who had not across all time points (eTable 2 in the Supplement). All models used an independent working correlation structure and robust standard errors to account for the time-varying exposure variable.

We performed several sensitivity analyses. Because our data were from an observational cohort, we first considered the degree to which they were sensitive to unmeasured confounding. To do this, we calculated the E-value for the association between PBs or GAHs and mental health outcomes in model 2. The E-value is defined as the minimum strength of association that a confounder would need to have with both exposure and outcome to completely explain away their association (eTable 4 in the Supplement).[31] Second, we performed sensitivity analyses on several subsets of youths. We separately examined the association of PBs and GAHs with outcomes of interest, although we a priori did not anticipate being powered to detect statistically significant outcomes owing to our small sample size and the relatively low proportion of youths who accessed PBs. We also conducted sensitivity analyses using the Patient Health Questionnaire 8-item scale (PHQ-8), in which the PHQ-9 question 9 regarding self-harm or suicidal thoughts was removed, given that we analyzed this item as a separate outcome. Lastly, we restricted our analysis to minor youths ages 13 to 17 years because they were subject to different laws and policies related to consent and prerequisite mental health assessments. We used R statistical software version 3.6.2 (R Project for Statistical Computing) to conduct all analyses. Data were analyzed from August 2020 through November 2021.

Results

A total of 169 youths were screened for eligibility during the study period, among whom 161 eligible youths were approached. Nine youths or caregivers declined participation, and 39 youths did not complete consent or assent or did not complete the baseline survey, leaving a sample of 113 youths (70.2% of approached youths). We excluded 9 youths aged younger than 13 years from the analysis because they received different depression and anxiety screeners. Our final sample included 104 youths ages 13 to 20 years (mean [SD] age, 15.8 [1.6] years). Of these individuals, 84 youths (80.8%), 84 youths, and 65 youths (62.5%) completed surveys at 3, 6, and 12 months, respectively.

Our cohort included 63 transmasculine youths (60.6%), 27 transfeminine youths (26.0%), 10 nonbinary or gender fluid youths (9.6%), and 4 youths who responded "I don't know" or did not respond to the gender identity question on all completed questionnaires (3.8%) (**Table 1**). There were 4 Asian or Pacific Islander youths (3.8%), 3 Black or African American youths (2.9%); 9 Latinx youths (8.7%); 6 Native American, American Indian, or Alaskan Native or Native Hawaiian youths (5.8%); 67 White youths (64.4%); and 9 youths who reported more than 1 race or ethnicity (8.7%). Race and ethnicity data were missing for 6 youth (5.8%).

Table 1. Participant Characteristics

Characteristic	Participants, No. (%) (N = 104)
Gender	
Male or transgender male	63 (60.6)
Female or transgender female	27 (26.0)
Nonbinary or gender fluid	10 (9.6)
Don't know or missing	4 (3.8)
Race and ethnicity[a]	
Asian or Pacific Islander	4 (3.8)
Black or African American	3 (2.9)
Latinx	9 (8.7)
Native American, American Indian, or Alaskan Native or Native Hawaiian	6 (5.8)
White	67 (64.4)
More than 1 race or ethnicity chosen	9 (8.7)
Missing	6 (5.8)
Age at baseline, y	
13	8 (7.7)
14	20 (19.2)
15	18 (17.3)
16	22 (21.2)
17	22 (21.2)
18	8 (7.7)
19	5 (4.8)
20	1 (1.0)
Pharmacological intervention	
PBs[b]	19 (18.2)
GAHs[b]	64 (61.5)
Androgen blockers[c]	17 (51.5)
Menstrual suppression or contraception[d]	25 (35.2)
Depression at baseline (using PHQ-9)	
0-4 (minimal)	14 (13.5)
5-9 (mild)	27 (26.0)
10-14 (moderate)	22 (21.2)
15-19 (moderately severe)	11 (10.6)
≥20 (severe)	26 (25.0)
Missing	4 (3.8)
Anxiety at baseline (using GAD-7)	
0-4 (minimal)	20 (19.2)
5-9 (mild)	28 (26.9)
10-14 (moderate)	20 (19.2)
≥15 (severe)	32 (30.8)
Missing	4 (3.8)
Self-harm or suicidal thoughts at baseline	45 (43.2)
Receiving mental health therapy	65 (62.5)
Tension with caregiver about gender identity or expression	36 (34.6)
Any substance use	34 (32.7)
Resilience at baseline (using CD-RISC 10)	
0-10	8 (7.7)
10-20	35 (33.7)
21-30	15 (14.4)
30-40	34 (32.7)
Missing	12 (11.5)

Abbreviations: CD-RISC 10, Connor-Davidson 10-item Resilience Scale; GAD-7, Generalized Anxiety Disorder 7-item scale; GAH, gender-affirming hormone; PB, puberty blocker; PHQ-9 Patient Health Questionnaire 9-item scale.

[a] Available response options for race and ethnicity were Arab or Middle Eastern; Asian or Pacific Islander; Black or African American; Latinx; Native American, American Indian, or Alaskan Native or Native Hawaiian; Pacific Islander; and White. Asian and Pacific Islander groups were combined owing to small population sizes.

[b] Self-reported receipt ever of PBs or GAHs at baseline or through the end of the study period.

[c] Includes androgen blockers received during the study period; percentage is among 33 youths assigned male sex at birth.

[d] Includes pharmacological interventions for menstrual suppression or contraception received during the study period; percentage is among 71 youths assigned female sex at birth.

At baseline, 7 youths had ever received PBs or GAHs (including 1 youth who received PBs, 4 youths who received GAHs, and 2 youths who received both PBs and GAHs). By the end of the study, 69 youths (66.3%) had received PBs or GAHs (including 50 youths who received GAHs only [48.1%], 5 youths who received PBs only [4.8%], and 14 youths who received PBs and GAHs [13.5%]), while 35 youths had not received either PBs or GAHs (33.7%) (eTable 3 in the Supplement). Among 33 participants assigned male sex at birth, 17 individuals (51.5%) had received androgen blockers, and among 71 participants assigned female sex at birth, 25 individuals (35.2%) had received menstrual suppression or contraceptives by the end of the study.

A large proportion of youths reported depressive and anxious symptoms at baseline. Specifically, 59 individuals (56.7%) had baseline PHQ-9 scores of 10 or more, suggesting moderate to severe depression; there were 22 participants (21.2%) scoring in the moderate range, 11 participants (10.6%) in the moderately severe range, and 26 participants (25.0%) in the severe range. Similarly, half of participants had a GAD-7 score suggestive of moderate to severe anxiety at baseline (52 individuals [50.0%]), including 20 participants (19.2%) scored in the moderate range, and 32 participants (30.8%) scored in the severe range. There were 45 youths (43.3%) who reported self-harm or suicidal thoughts in the prior 2 weeks. At baseline, 65 youths (62.5%) were receiving ongoing mental health therapy, 36 youths (34.6%) reported tension with their caregivers about their gender identity or expression, and 34 youths (32.7%) reported any substance use in the prior year. Lastly, we observed a wide range of resilience scores (median [range], 22.5 [1-38], with higher scores equaling more resiliency). There were no statistically significant differences in baseline characteristics by gender.

In bivariate models, substance use was associated with all mental health outcomes (**Table 2**). Youths who reported any substance use were 4-fold as likely to have PHQ-9 scores of moderate to severe depression (aOR, 4.38; 95% CI, 2.10-9.16) and 2-fold as likely to have GAD-7 scores of moderate to severe anxiety (aOR, 2.07; 95% CI, 1.04-4.11) or report thoughts of self-harm or suicide in the prior 2 weeks (aOR, 2.06; 95% CI, 1.08-3.93). High resilience scores (ie, ≥median), compared with low resilience scores (ie, <median), were associated with lower odds of moderate or severe anxiety (aOR, 0.51; 95% CI, 0.26-0.999).

There were no statistically significant temporal trends in the bivariate model or model 1 (Table 2 and **Table 3**). However, among all participants, odds of moderate to severe depression increased at 3 months of follow-up relative to baseline (aOR, 2.12; 95% CI, 0.98-4.60), which was not a significant increase, and returned to baseline levels at months 6 and 12 (**Figure**) prior to adjusting for receipt of PBs or GAHs.

We also examined the association between receipt of PBs or GAHs and mental health outcomes in bivariate and multivariable models (eFigure 2 in the Supplement). After adjusting for temporal trends and potential confounders (**Table 4**), we observed that youths who had initiated PBs or GAHs had 60% lower odds of moderate to severe depression (aOR, 0.40; 95% CI, 0.17-0.95) and 73% lower odds of self-harm or suicidal thoughts (aOR, 0.27; 95% CI, 0.11-0.65) compared with youths who had not yet initiated PBs or GAHs. There was no association between receipt of PBs or GAHs and moderate to severe anxiety (aOR, 1.01; 95% CI, 0.41-2.51). After adjusting for time-varying exposure of PBs or GAHs in model 2 (Table 4), we observed statistically significant increases in moderate to severe depression among youths who had not received PBs or GAHs by 3 months of follow-up (aOR, 3.22; 95% CI, 1.37-7.56). A similar trend was observed for self-harm or suicidal thoughts among youths who had not received PBs or GAHs by 6 months of follow-up (aOR, 2.76; 95% CI, 1.22-6.26). Lastly, we estimated E-values of 2.56 and 3.25 for the association between receiving PGs or GAHs and moderate to severe depression and suicidality, respectively (eTable 4 in the Supplement). Sensitivity analyses obtained comparable results and are presented in eTables 5 through 8 in the Supplement.

Discussion

In this prospective clinical cohort study of TNB youths, we observed high rates of moderate to severe depression and anxiety, as well as suicidal thoughts. Receipt of gender-affirming interventions, specifically PBs or GAHs, was associated with 60% lower odds of moderate to severe depressive symptoms and 73% lower odds of self-harm or suicidal thoughts during the first year of multidisciplinary gender care. Among youths who did not initiate PBs or GAHs, we observed that depressive symptoms and suicidality were 2-fold to 3-fold higher than baseline levels at 3 and 6 months of follow-up, respectively. Our study results suggest that risks of depression and suicidality may be mitigated with receipt of gender-affirming medications in the context of a multidisciplinary care clinic over the relatively short time frame of 1 year.

Our findings are consistent with those of prior studies finding that TNB adolescents are at increased risk of depression, anxiety, and suicidality[1,11,32] and studies finding long-term and short-term improvements in mental health outcomes among TNB individuals who receive gender-affirming medical interventions.[14,21-24,33,34] Surprisingly, we observed no association with anxiety scores. A recent cohort study of TNB youths in Dallas, Texas, found that total anxiety symptoms improved over a longer follow-up of 11 to 18 months; however, similar to our study, the authors did not observe

Table 2. Baseline Factors Associated With Mental Health Outcomes in Bivariate Models

	Moderate or severe depression (PHQ-9 ≥10)[a]		Moderate or severe anxiety (GAD-7 ≥10)[b]		Any self-harm or suicidal thoughts[c]	
Factor	aOR (95% CI)	*P* value	aOR (95% CI)	*P* value	aOR (95% CI)	*P* value
PBs or GAHs	0.67 (0.33-1.34)	.25	0.90 (0.49-1.66)	.74	0.47 (0.26-0.86)	.01
Time, mo						
0 (baseline)	1 [Reference]	NA	1 [Reference]	NA	1 [Reference]	NA
3	1.96 (0.99-3.90)	.05	1.46 (0.71-2.97)	.30	1.00 (0.49-2.06)	.99
6	1.01 (0.46-2.19)	.99	0.77 (0.39-1.52)	.45	1.22 (0.64-2.34)	.54
12	1.42 (0.55-3.66)	.47	0.95 (0.43-2.06)	.89	1.02 (0.41-2.52)	.97
Gender						
Male or transgender male	1 [Reference]	NA	1 [Reference]	NA	1 [Reference]	NA
Female or transgender female	1.07 (0.51-2.24)	.87	3.15 (0.92-10.8)	.07	1.20 (0.55-2.64)	.64
Nonbinary or gender fluid	2.40 (0.84-6.87)	.10	1.35 (0.67-2.72)	.40	2.17 (0.73-6.41)	.16
Race or ethnicity						
White	1 [Reference]	NA	1 [Reference]	NA	1 [Reference]	NA
Member of minority race or ethnic group[d]	1.08 (0.51-2.28)	.84	0.86 (0.45-1.66)	.66	0.92 (0.53-1.61)	.77
Age, y						
13-15	1 [Reference]	NA	1 [Reference]	NA	1 [Reference]	NA
16-17	1.79 (0.82-3.88)	.14	0.63 (0.29-1.39)	.25	0.86 (0.44-1.68)	.66
18-20	0.78 (0.24-2.51)	.68	1.17 (0.43-3.17)	.76	0.79 (0.36-1.74)	.55
Mental health and substance use at baseline						
Moderate or severe depression (PHQ-9 ≥10)	27.2 (13.4-55.4)	<.001	1.91 (0.85-4.29)	.12	1.06 (0.50-2.24)	.88
Moderate or severe anxiety (GAD-7 ≥10)	4.90 (2.27-10.6)	<.001	14.3 (7.31-27.9)	<.001	1.44 (0.76-2.72)	.27
Self-harm or suicidal thoughts	1.32 (0.61-2.85)	.48	1.49 (0.73-3.06)	.28	18.9 (10.4-34.1)	<.001
Receiving mental health therapy	1.46 (0.69-3.08)	.32	0.65 (0.31-1.38)	.26	0.75 (0.36-1.56)	.45
Tension with caregivers about gender identity or expression	1.93 (0.90-4.14)	.09	1.06 (0.52-2.15)	.87	1.55 (0.88-2.74)	.13
Any substance use	4.38 (2.10-9.16)	<.001	2.07 (1.04-4.11)	.04	2.06 (1.08-3.93)	.03
Resilience at baseline (CD-RISC 10 ≥22.5)[e]	0.85 (0.42-1.74)	.67	0.51 (0.26-1.00)	.05	0.74 (0.39-1.44)	.38

Abbreviations: aOR, adjusted odds ratio; CD-RISC 10, Connor-Davidson 10-item Resilience Scale; GAD-7, Generalized Anxiety Disorder 7-item scale; GAH, gender-affirming hormone; NA, not applicable; PB, puberty blocker; PHQ-9, Patient Health Questionnaire 9-item scale.

[a] Bivariate models are adjusted for baseline PHQ-9.

[b] Bivariate models are adjusted for baseline GAD-7.

[c] Bivariate models are adjusted for self-harm or suicidal thoughts reported at baseline.

[d] Owing to small sample sizes, this group includes Asian or Pacific Islander; Black or African American; Latinx; and Native American, American Indian, Alaskan Native, or Native Hawaiian youths and youths who reported more than 1 race or ethnicity.

[e] The median (range) CD-RISC score for the cohort was 22.5 (1-38).

statistically significant improvements in generalized anxiety.[22] This suggests that anxiety symptoms may take longer to improve after the initiation of gender-affirming care. In addition, Olson et al[35] found that prepubertal TNB children who socially transitioned did not have increased rates of depression symptoms but did have increased rates of anxiety symptoms compared with children who were cisgender. Although social transition and access to gender-affirming medical care do not always go hand in hand, it is noteworthy that access to gender-affirming medical care and supported social transition appear to be associated with decreased depression and suicidality more than anxiety symptoms.

Time trends were not significant in our study; however, it is important to note that we observed a transient and nonsignificant worsening in mental health outcomes in the first several months of care among all participants and that these outcomes subsequently returned to baseline by 12 months. This is consistent with findings from a 2020 study[36] in an academic medical center in the northwestern US that observed no change in TNB adolescents' GAD-7 or PHQ-9 scores from intake to first follow-up appointment, which occurred a mean of 4.7 months apart. Given that receipt of PBs or GAHs was associated with protection against depression and suicidality in our study, it could be that delays in receipt of medications is associated with initially exacerbated mental health symptoms that subsequently improve. It is also possible that mental health improvements associated with receiving these interventions may have a delayed onset, given the delay in physical changes after starting GAHs.

Few of our hypothesized confounders were associated with mental health outcomes in this sample, most notably receipt of ongoing mental health therapy and caregiver support; however, this is not surprising given that these variables were colinear with baseline mental health, which we adjusted for in all models. Substance use was the only variable associated with all mental health outcomes. In addition, youths with high baseline resilience scores were half as likely to experience moderate to severe anxiety as those with low scores. This finding suggests that substance use and resilience may be additional modifiable factors that could be addressed through multidisciplinary gender-affirming care. We recommend more granular assessment of substance use and resilience to better understand support needs (for substance use) and effective support strategies (for resilience) for TNB youths in future research.

This study has a number of strengths. This is one of the first studies to quantify a short-term transient increase in depressive symptoms experienced by TNB youths after initiating gender-affirming

Table 3. Temporal Trends in Mental Health Outcomes in Multivariable Model 1[a]

	Moderate or severe depression (PHQ-9 ≥10)		Moderate or severe anxiety (GAD-7 ≥10)		Any self-harm or suicidal thoughts	
Factor	aOR (95% CI)	*P* value	aOR (95% CI)	*P* value	aOR (95% CI)	*P* value
Time, mo						
0 (baseline)	1 [Reference]	NA	1 [Reference]	NA	1 [Reference]	NA
3	2.12 (0.98-4.60)	.06	1.50 (0.71-3.15)	.29	0.99 (0.48-2.06)	.98
6	0.99 (0.42-2.35)	.98	0.78 (0.38-1.59)	.49	1.22 (0.63-2.36)	.56
12	1.27 (0.44-3.67)	.66	0.96 (0.43-2.11)	.91	0.98 (0.39-2.48)	.97
Mental health and substance use at baseline						
Moderate or severe depression (PHQ-9 ≥10)	18.5 (8.44-40.5)	<.001	NA	NA	NA	NA
Moderate or severe anxiety (GAD-7 ≥10)	3.63 (1.83-7.19)	<.001	12.4 (6.25-24.7)	<.001	NA	NA
Self-harm or suicidal thoughts	NA	NA	NA	NA	19.9 (10.9-36.1)	<.001
Any substance use	3.35 (1.56-7.18)	.002	2.21 (1.09-4.49)	.03	2.07 (1.09-3.93)	.03
Resilience at Baseline (CD-RISC 10 ≥22.5)[b]	NA	NA	0.48 (0.24-0.95)	.04	NA	NA

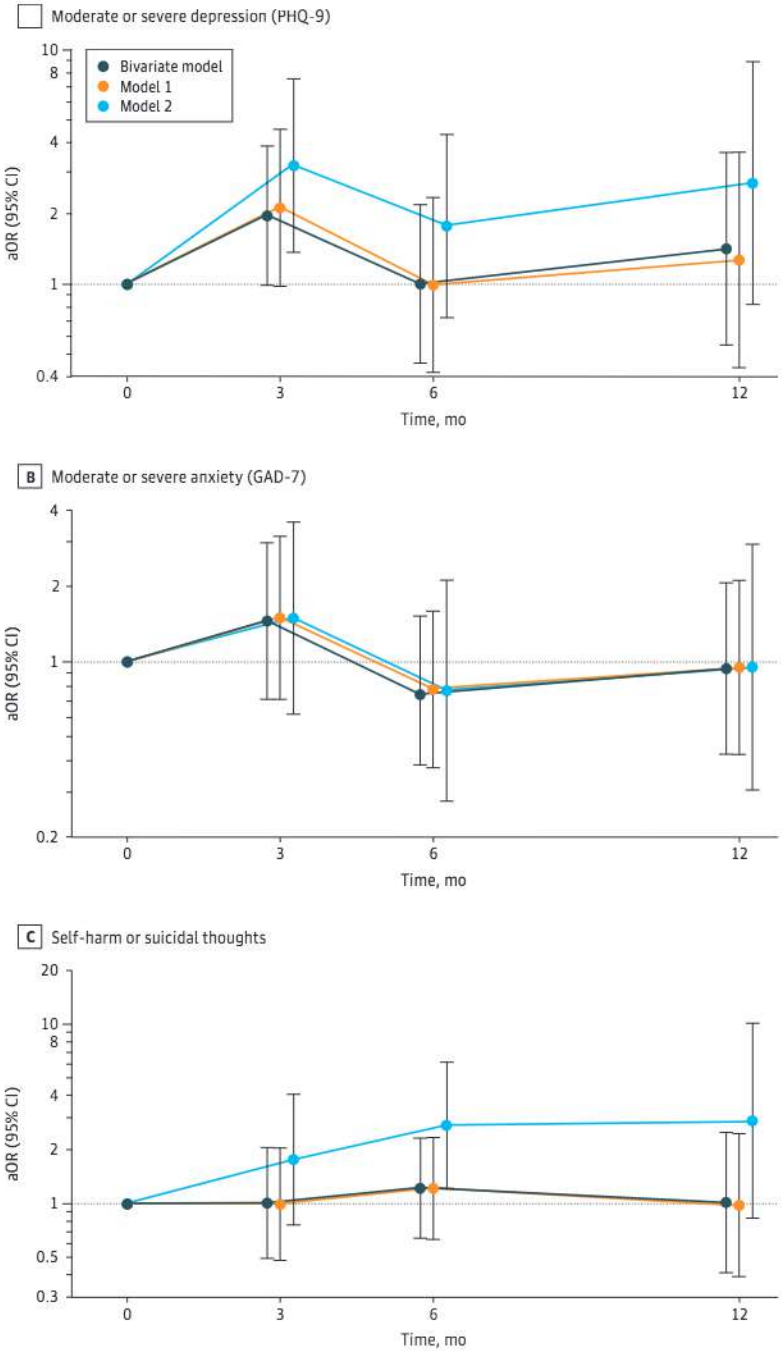
Abbreviations: aOR, adjusted odds ratio; CD-RISC 10, Connor-Davidson 10-item Resilience Scale; GAD-7, Generalized Anxiety Disorder 7-item scale; NA, not applicable; PHQ-9, Patient Health Questionnaire 9-item scale.

[a] Model 1 includes categorical temporal variables (ie, months 3, 6, and 12 relative to baseline) and covariates that were statistically significant in bivariate models (such that 95% CIs did not contain 1.00) (see Table 2). Covariates that were not significant in bivariate models are marked NA.

[b] The median (range) CD-RISC score for the cohort is 22.5 (1-38).

care, a phenomenon observed clinically by some of the authors and described in qualitative research.[37] Although we are unable to make causal statements owing to the observational design of the study, the strength of associations between gender-affirming medications and depression and suicidality, with large aOR values, and sensitivity analyses that suggest that these findings are robust to moderate levels of unmeasured confounding. Specifically, E-values calculated for this study suggest that the observed associations could be explained away only by an unmeasured confounder that was associated with both PBs and GAHs and the outcomes of interest by a risk ratio of 2-fold to 3-fold each, above and beyond the measured confounders, but that weaker confounding could not do so.[31]

Figure. Temporal Trends in Mental Health Outcomes



Outcomes are estimated from bivariate and multivariable generalized estimating equation models. aOR, indicates adjusted odds ratio; GAD-7, Generalized Anxiety Disorder 7-item scale; PHQ-9, Patient Health Questionnaire 9-item scale; whiskers, 95% CIs.

Limitations

Our findings should be interpreted in light of the following limitations. This was a clinical sample of TNB youths, and there was likely selection bias toward youths with supportive caregivers who had resources to access a gender-affirming care clinic. Family support and access to care are associated with protection against poor mental health outcomes, and thus actual rates of depression, anxiety, and suicidality in nonclinical samples of TNB youths may differ. Youths who are unable to access gender-affirming care owing to a lack of family support or resources require particular emphasis in future research and advocacy. Our sample also primarily included White and transmasculine youths, limiting the generalizability of our findings. In addition, the need to reapproach participants for consent and assent for the 12-month survey likely contributed to attrition at this time point. There may also be residual confounding because we were unable to include a variable reflecting receipt of psychotropic medications that could be associated with depression, anxiety, and self-harm and suicidal thought outcomes. Additionally, we used symptom-based measures of depression, anxiety, and suicidality; further studies should include diagnostic evaluations by mental health practitioners to track depression, anxiety, gender dysphoria, suicidal ideation, and suicide attempts during gender care.[2]

Conclusions

Our study provides quantitative evidence that access to PBs or GAHs in a multidisciplinary gender-affirming setting was associated with mental health improvements among TNB youths over a relatively short time frame of 1 year. The associations with the highest aORs were with decreased suicidality, which is important given the mental health disparities experienced by this population, particularly the high levels of self-harm and suicide. Our findings have important policy implications, suggesting that the recent wave of legislation restricting access to gender-affirming care[19] may have significant negative outcomes in the well-being of TNB youths.[20] Beyond the need to address antitransgender legislation, there is an additional need for medical systems and insurance providers to decrease barriers and expand access to gender-affirming care.

Table 4. Association Between GAHs or PBs and Mental Health Outcomes in Multivariable Model 2[a]

	Moderate or severe depression (PHQ-9 ≥10)		Moderate or severe anxiety (GAD-7≥10)		Any self-harm or suicidal thoughts	
Factor	aOR (95% CI)	*P* value	aOR (95% CI)	*P* value	aOR (95% CI)	*P* value
PBs or GAHs	0.40 (0.17-0.95)	.04	1.01 (0.41-2.51)	.98	0.27 (0.11-0.65)	.003
Time, mo						
0 (baseline)	1 [Reference]	NA	1 [Reference]	NA	1 [Reference]	NA
3 mo	3.22 (1.37-7.56)	.007	1.49 (0.62-3.59)	.37	1.77 (0.76-4.13)	.19
6 mo	1.77 (0.72-4.37)	.21	0.77 (0.28-2.11)	.61	2.76 (1.22-6.26)	.02
12 mo	2.71 (0.82-8.95)	.10	0.95 (0.31-2.93)	.93	2.93 (0.83-10.4)	.10
Mental health & substance use at baseline						
Moderate or severe depression (PHQ-9 ≥10)	19.4 (8.64-43.4)	<.001	NA	NA	NA	NA
Moderate or severe anxiety (GAD-7 ≥10)	3.82 (1.87-7.82)	<.001	12.4 (6.25-24.7)	<.001	NA	NA
Self-harm or suicidal thoughts	NA	NA	NA	NA	23.9 (12.9-44.5)	<.001
Any substance use	3.20 (1.49-6.84)	.003	2.21 (1.09-4.50)	.03	2.00 (1.08-3.73)	.03
Resilience at baseline (CD-RISC 10 ≥22.5)[b]	NA	NA	0.48 (0.24-0.95)	.04	NA	NA

Abbreviations: aOR, adjusted odds ratio; CD-RISC 10, Connor-Davidson 10-item Resilience Scale; GAD-7, Generalized Anxiety Disorder 7-item scale; GAH, gender-affirming hormone; NA, not applicable; PB, puberty blocker; PHQ-9, Patient Health Questionnaire 9-item scale.

[a] Model 2 includes a time-varying exposure variable measuring the receipt of PBs or GAHs adjusted for temporal trend (ie, categorical variable for months 3, 6, and 12 relative to baseline) and covariates that were statistically significant in the bivariate models (such that 95% CIs did not contain 1.00) (see Table 2). The unadjusted bivariate associations between PBs or GAHs and mental health outcomes are reported in Table 2. Covariates that were not significant in bivariate models are marked NA.

[b] The median (range) CD-RISC score for the cohort is 22.5 (1-38).

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SUPPLEMENT.

ORIGINAL ARTICLE

Psychosocial Functioning in Transgender Youth after 2 Years of Hormones

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ABSTRACT

BACKGROUND

Limited prospective outcome data exist regarding transgender and nonbinary youth receiving gender-affirming hormones (GAH; testosterone or estradiol).

METHODS

We characterized the longitudinal course of psychosocial functioning during the 2 years after GAH initiation in a prospective cohort of transgender and nonbinary youth in the United States. Participants were enrolled in a four-site prospective, observational study of physical and psychosocial outcomes. Participants completed the Transgender Congruence Scale, the Beck Depression Inventory–II, the Revised Children's Manifest Anxiety Scale (Second Edition), and the Positive Affect and Life Satisfaction measures from the NIH (National Institutes of Health) Toolbox Emotion Battery at baseline and at 6, 12, 18, and 24 months after GAH initiation. We used latent growth curve modeling to examine individual trajectories of appearance congruence, depression, anxiety, positive affect, and life satisfaction over a period of 2 years. We also examined how initial levels of and rates of change in appearance congruence correlated with those of each psychosocial outcome.

RESULTS

A total of 315 transgender and nonbinary participants 12 to 20 years of age (mean [±SD], 16±1.9) were enrolled in the study. A total of 190 participants (60.3%) were transmasculine (i.e., persons designated female at birth who identify along the masculine spectrum), 185 (58.7%) were non-Latinx or non-Latine White, and 25 (7.9%) had received previous pubertal suppression treatment. During the study period, appearance congruence, positive affect, and life satisfaction increased, and depression and anxiety symptoms decreased. Increases in appearance congruence were associated with concurrent increases in positive affect and life satisfaction and decreases in depression and anxiety symptoms. The most common adverse event was suicidal ideation (in 11 participants [3.5%]); death by suicide occurred in 2 participants.

CONCLUSIONS

In this 2-year study involving transgender and nonbinary youth, GAH improved appearance congruence and psychosocial functioning. (Funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development.)

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Transgender and nonbinary youth comprise 2 to 9% of high-school–aged persons in the United States.[1-3] Many transgender and nonbinary youth have gender dysphoria, the persistent distress arising from incongruence between gender identity and external phenotype. Increasingly, transgender and nonbinary youth receive medical care to alleviate gender dysphoria, including gonadotropin-releasing hormone (GnRH) agonists to suppress gender-incongruent puberty and gender-affirming hormones (GAH; testosterone or estradiol) to foster gender-congruent secondary sex characteristics. An important goal of such treatment is to attenuate gender dysphoria by increasing appearance congruence — that is, the degree to which youth experience alignment between their gender and their physical appearance.

The available prospective research indicates that gender-affirming medical care is associated with improvements in psychosocial functioning.[4-9] Previously published studies with modest sample sizes[5,6,9] have examined outcomes for relatively short follow-up periods (approximately 1 year on average),[5,6,9] focused exclusively on outcomes of GnRH agonists,[7,8] or examined outcomes for mixed samples of youth initiating GnRH agonists or GAH,[4,6,9] despite evidence that such cohorts have distinct psychosocial profiles.[10] Evidence has been lacking from longitudinal studies that explore potential mechanisms by which gender-affirming medical care affects gender dysphoria and subsequent well-being.

We characterized the longitudinal course of psychosocial functioning over a period of 2 years after GAH initiation in a prospective cohort of more than 300 transgender and nonbinary young people in the United States. We hypothesized that appearance congruence, positive affect, and life satisfaction would increase and that depression and anxiety symptoms would decrease. We also hypothesized that improvements would be secondary to treatment for gender dysphoria, such that increasing appearance congruence would be associated with concurrent improvements in psychosocial outcomes. We also explored the potential moderating effects of demographic and clinical characteristics, including age, designated sex at birth, racial and ethnic identity, and the initiation of GAH in early as compared with later stages of puberty.

Methods

Study Design and Participant Recruitment

Participants were recruited from gender clinics at the Ann and Robert H. Lurie Children's Hospital of Chicago, UCSF Benioff Children's Hospitals, Boston Children's Hospital, and Children's Hospital Los Angeles from July 2016 through June 2019 for the Trans Youth Care–United States (TYCUS) Study,[11] a prospective, observational study evaluating the physical and psychosocial outcomes of medical treatment for gender dysphoria in two distinct cohorts of transgender and nonbinary youth — those initiating GnRH agonists and those initiating GAH as part of their clinical care. All participating clinics employ a multidisciplinary team that includes medical and mental health providers and that collaboratively determines whether gender dysphoria is present and whether gender-affirming medical care is appropriate. For minors, parental consent is required to initiate medical treatment. Publications by individual study teams provide details on site-specific approaches to care.[12-15]

Study visits occurred at baseline and at 6, 12, 18, and 24 months after treatment initiation. Details on study procedures have been published previously,[11] and the protocol is available with the full text of this article at NEJM.org. The present analyses focus on the GAH cohort; outcomes for the cohort initiating GnRH agonists are being analyzed separately, given differences in baseline functioning between the two cohorts[10] and distinct outcomes of GnRH agonists[8] as compared with GAH treatment.[4] Participants provided written informed consent or assent; parents provided permission for minors to participate. Procedures were approved by the institutional review board at each study site.

The first and second authors analyzed the data and wrote the initial draft of the manuscript. All the authors critically reviewed the manuscript. The authors vouch for the accuracy and completeness of the data and for the fidelity of the study to the protocol. There were no agreements regarding confidentiality of the data among the sponsor (Eunice Kennedy Shriver National Institute of Child Health and Human Development), the authors, and the participating institutions. The sponsor had no role in the design of the study; the collection, analysis, or in-

terpretation of data; the writing of the manuscipt; or the decision to submit the manuscript for publication.

MEASURES

Participants reported age, racial and ethnic identity, gender identity, and designated sex at birth (details are provided in the Supplementary Appendix, available at NEJM.org). A small subgroup had been treated with GnRH agonists in early puberty (Tanner stage 2 or 3) (20 participants) or had a relatively late age at onset of endogenous puberty, such that they began receiving GAH in Tanner stage 3 (at 13 to 15 years of age) even without previous treatment with GnRH agonists (4 participants). These 24 participants comprise a subcohort in that they did not undergo extensive gender-incongruent puberty. Participants with a history of GnRH agonist treatment that was initiated in Tanner stage 4 (5 participants) were not included in this subcohort, because their experience of substantial gender-incongruent puberty is more similar to that of youth initiating GAH in Tanner stage 4 or 5.

With respect to longitudinal outcomes, participants completed the Transgender Congruence Scale,[16] the Beck Depression Inventory–II,[17] the Revised Children's Manifest Anxiety Scale (Second Edition),[18] and the Positive Affect and Life Satisfaction measures from the NIH (National Institutes of Health) Toolbox Emotion Battery[19] at each study visit. Scoring information and sample items from each scale are provided in the Supplementary Appendix. Higher scores on these measures reflect greater appearance congruence, depression, anxiety, positive affect, and life satisfaction, respectively.

STATISTICAL ANALYSIS

Trajectories of psychosocial functioning were examined with the use of repeated-measures multivariate analysis of variance and mixed-effects models. Multivariate analysis of variance provided a preliminary omnibus test for significant within-person change over time. Owing to listwise deletion, 150 participants were excluded from the multivariate analysis of variance (the analysis involved 141 participants). Mixed-effects modeling was therefore selected owing to greater flexibility in accommodating missing data and nonnormal distributions and examining parallel processes. Specifically, we used latent growth curve modeling, which uses a structural equation modeling framework to examine changes in mean scores over time.[20] Repeated measures are treated as indicators of latent factors: an intercept factor (estimates of initial levels) and a slope factor (rate of change). Intercept and slope factors can be regressed on covariates in adjusted models to explore moderation effects. In addition, growth curves for two different outcomes can be combined to examine how intercepts and slopes of those constructs correlate with each other. Data were Winsorized at the 95th percentile to reduce the influence of outliers.

Analyses involving latent growth curve modeling proceeded in three steps. First, we modeled trajectories of appearance congruence and psychosocial outcomes (i.e., effects of time only). Second, we adjusted models to estimate the effects of covariates on baseline scores and rates of change over time. Third, because changes in appearance congruence and psychosocial outcomes occur as parallel, simultaneous processes during GAH treatment, we examined how initial levels and rates of change in appearance congruence correlated with those of each psychosocial outcome. Standardized β levels were used as indicators of effect sizes for longitudinal models using conventional ranges (small, 0.20; medium, 0.50; and large, 0.80). Our conceptual model is shown in Figure S1 in the Supplementary Appendix. All statistical analyses were conducted with the use of SPSS software, version 27, and Mplus software, version 8.8.

RESULTS

ANALYTIC SAMPLE

There were a total of 6114 observations from 315 participants, who were assessed up to five times over a period of 2 years (data were available for 81% of all possible observations). Most participants (238 [75.6%]) completed either four study visits (76 participants) or five visits (162 participants). Tables S1 and S2 show the number of completed visits by time point and data coverage for key variables. The analytic sample for longitudinal models included 291 participants with follow-up data on primary outcome variables (Fig. S2). The analytic sample did not differ substantially from the overall sample with respect to age, designated sex at birth, racial and ethnic

identity, initiation of GAH in early puberty, or baseline scores on psychosocial measures (Table S3).

SAMPLE CHARACTERISTICS

We enrolled 315 eligible participants 12 to 20 years of age (mean [±SD], 16±1.9 years) (Table 1). Most were transmasculine (i.e., persons designated female at birth who identify along the masculine spectrum; 60.3%), designated female at birth (64.8%), and non-Latinx or non-Latine White (58.7%). Transmasculine, non-Latinx or non-Latine White, and multiracial participants were overrepresented and nonbinary and Black participants were underrepresented as compared with the study sample in the Williams Institute Executive Report[21] (Table S4); however, the study sample was representative of transgender and nonbinary youth presenting to pediatric subspecialty gender programs[22] and generalizable to this population. Two participants died by suicide during the study (one after 6 months of follow-up and the other after 12 months of follow-up), and 6 participants withdrew from the study. For these eight participants, data that had been collected before death or study withdrawal were included in the analyses. Data on adverse events are provided in Table 2.

APPEARANCE CONGRUENCE AND PSYCHOSOCIAL OUTCOMES OVER TIME

Table S5 depicts mean scores for appearance congruence, depression, anxiety, positive affect, and life satisfaction at baseline and 24 months. Results for multivariate analysis of variance indicated that there were significant within-participant changes over time for all psychosocial outcomes in hypothesized directions (Wilk's lambda, 0.32; F statistic with 20 and 122 degrees of freedom; 12.86; P<0.001). Specifically, scores for appearance congruence, positive affect, and life satisfaction increased significantly, and scores for depression and anxiety decreased significantly.

Means and variances of the variables for latent growth curve modeling, with estimated baseline levels and change over time for both time-only and adjusted models, are provided in Table 3. Scores for appearance congruence increased (annual increase on a 5-point scale, 0.48 points; 95% confidence interval [CI], 0.42 to 0.54; standardized $\beta=1.47$), as did T scores for positive affect (annual increase on a 100-point scale, 0.80 points; 95% CI, 0.08 to 1.54; $\beta=0.19$) and life satisfaction (annual increase on a 100-point scale, 2.32 points; 95% CI, 1.64 to 3.00; $\beta=0.52$). We observed decreased scores for depression (annual change on a 63-point scale, –1.27 points; 95% CI, –1.98 to –0.57; standardized $\beta=-0.29$) and decreased T scores for anxiety (annual change on a 100-point scale, –1.46 points; 95% CI, –2.13 to –0.79; $\beta=-0.35$) over a period of 2 years of GAH treatment.

Unadjusted models can be interpreted on their original scale. For instance, depression scores range from 0 to 63 (ranges of severity, minimal, 0 to 13; mild, 14 to 19; moderate, 20 to 28; and severe, 29 to 63). The model had an intercept (baseline mean) of 15.46 and estimated slope (change per year) of –1.27. Thus, on average, depression started in the mild range and decreased to the subclinical level by 24 months. Table S6 shows the percentages of youth scoring in the clinical range for depression and anxiety at each time point. Of 27 participants with depression scores in the severe range at baseline, 18 (67%) reported a depression score in the minimal or moderate ranges at 24 months. Similarly, 21 of 33 participants (64%) with depression scores in the moderate range at baseline reported a depression score in the minimal or moderate ranges at 24 months (chi-square statistic with 9 degrees of freedom, 49.85; P<0.001). With respect to anxiety, 47 of 122 participants (38.5%) with baseline scores in the clinical range (T scores, >60) were in the nonclinical range at 24 months (chi-square statistic with 1 degree of freedom, 22.05; P<0.001).

ASSOCIATIONS BETWEEN APPEARANCE CONGRUENCE AND PSYCHOSOCIAL OUTCOMES

Figure 1 depicts parallel processes between appearance congruence and each psychosocial outcome as analyzed by means of latent growth curve modeling. As described above, we used linear latent growth curve modeling to estimate baseline scores (intercepts) and linear rates of change (slopes) of each outcome (see Table 3 for details of each model). In parallel-process models, we examined how the components for latent growth curve modeling for appearance congruence related to those for scores for depression (Fig. 1A) and T scores for anxiety (Fig. 1B), positive affect (Fig. 1C), and life satisfaction

Table 1. Demographic and Clinical Characteristics of the Participants.*

Characteristic	Participants (N=315)
	no. (%)
Gender identity†	
Transmasculine	190 (60.3)
Transfeminine	106 (33.7)
Nonbinary	19 (6.0)
Designated sex at birth	
Female	204 (64.8)
Male	111 (35.2)
Racial and ethnic identity	
Non-Latinx or non-Latine White	185 (58.7)
Latinx or Latine non-White	50 (15.9)
Latinx or Latine White	25 (7.9)
Black	11 (3.5)
Asian or Pacific Islander	10 (3.2)
Multiracial	32 (10.2)
Other	1 (0.3)
Unknown	1 (0.3)
Age at baseline	
12 yr	6 (1.9)
13 yr	23 (7.3)
14 yr	38 (12.1)
15 yr	67 (21.3)
16 yr	55 (17.5)
17 yr	51 (16.2)
18 yr	48 (15.2)
19 yr	15 (4.8)
20 yr	12 (3.8)
Tanner stage at GAH initiation‡	
1	2 (0.6)
2	13 (4.1)
3	9 (2.9)
4	29 (9.2)
5	262 (83.2)
Past use of GnRH agonist	
No	290 (92.1)
Yes	25 (7.9)
Tanner stage at initiation of GnRH agonist	
2	12 (3.8)
3	8 (2.5)
4	5 (1.6)
Not applicable	290 (92.1)
Initiation of GAH in early puberty subcohort§	
No	291 (92.4)
Yes	24 (7.6)

* The table does not include demographic and clinical characteristics for one participant who was accidentally enrolled and did not meet criteria for study eligibility. Percentages may not total 100 because of rounding. GAH denotes gender-affirming hormones, and GnRH gonadotropin-releasing hormone.
† Transmasculine refers to persons designated female at birth who identify along the masculine spectrum. Transfeminine refers to persons designated male at birth who identify along the feminine spectrum.
‡ Three participants began receiving GnRH agonists in either Tanner stage 2 or 3 and subsequently had pubertal regression to Tanner stage 1 or 2 by the time of GAH initiation.
§ This subcohort includes 20 participants who began receiving GnRH agonists at Tanner stage 2 or 3 and 4 participants who had not previously received GnRH agonists but had begun receiving GAH in Tanner stage 3 owing to a relatively late onset of puberty (13 to 15 years of age) and thus did not have physical changes associated with later stages of endogenous puberty. This subcohort does not include 5 participants with a history of initiation of GnRH agonists in Tanner stage 4 and who thus did undergo substantial gender-incongruent puberty.

(Fig. 1D). Higher appearance congruence at baseline was associated with lower baseline scores for depression (r=−0.60) and T scores for anxiety (r=−0.40), and increases in appearance congruence were associated with decreases in scores for depression (r=−0.68) and T scores for anxiety (r=−0.52) over time. In addition, higher appearance congruence at baseline was associated with higher baseline T scores for positive affect (r=0.46) and life satisfaction (r=0.72), and increases in appearance congruence were associated with increases in T scores for positive affect (r=0.74) and life satisfaction (r=0.84) over time.

MODERATING EFFECTS OF DEMOGRAPHIC AND CLINICAL COVARIATES

Table 3 shows the effects of covariates on scores for appearance congruence and depression and T scores for anxiety, positive affect, and life satisfaction. Age was not associated with any outcomes at baseline or over time.

Designated Sex at Birth

Depression and anxiety scores decreased among youth designated female at birth but not among those designated male at birth. Similarly, T scores for life satisfaction increased among youth designated female at birth but not among those designated male at birth (Fig. S3). Designated sex at birth was not associated with any other outcomes at baseline or over time.

Table 2. Adverse Events.

Event	No. of Events in Sample
Any event	15
Death by suicide	2
Suicidal ideation reported during study visit	11
Severe anxiety triggered by study visit	2

Effects of Racial and Ethnic Identity

At baseline, youth of color had higher scores for appearance congruence, lower scores for depression, and higher scores for positive affect than non-Latinx or non-Latine White youth. With respect to change over time, non-Latinx or non-Latine White youth had greater decreases in depression scores than youth of color (Fig. S4). Racial and ethnic identity were not associated with any other outcomes at baseline or over time.

Initiation of GAH in Early Puberty

Youth who had initiated GAH in early puberty had higher scores for appearance congruence, positive affect, and life satisfaction at baseline and lower scores for depression and anxiety at baseline than those who had initiated GAH in later puberty. Tables S7, S8, and S9 provide more information regarding differences between youth initiating GAH in early puberty and those initiating GAH in late puberty. With respect to change over time, youth initiating GAH in later puberty had greater improvements in appearance congruence than those initiating GAH in early puberty (Fig. 2).

DISCUSSION

Understanding the effect of GAH on the psychosocial outcomes of transgender and nonbinary youth would appear crucial, given the documented mental health disparities observed in this population,[10,15,23,24] particularly in the context of increasing politicization of gender-affirming medical care.[25] In our U.S.-based cohort of transgender and nonbinary youth treated with GAH, we found decreases in depression and anxiety symptoms and increases in positive affect and life satisfaction as assessed through validated instruments. Our findings are consistent with those of other longitudinal studies involving transgender and nonbinary youth receiving GAH, which showed reductions in depression[6,9] and anxiety[6] and increases in overall well-being[5] with small-to-moderate effects over a follow-up period of up to 1 year. We replicated these findings in a larger sample of racially and ethnically diverse transgender and nonbinary youth recruited from four geographically distinct regions in the United States and found sustained improvements over a period of 2 years.

Increasing appearance congruence is a primary goal of GAH, and we observed appearance congruence improve over 2 years of treatment. This was a moderate effect, and the strongest effect observed across our outcomes, consistent with the effect seen in research involving other samples, which has noted large effects of GAH on body image and small-to-moderate effects on mental health.[6] Appearance congruence was also associated with each psychosocial outcome assessed at baseline and during the follow-up period, such that increases in appearance congruence were associated with decreases in depression and anxiety symptoms and increases in positive affect and life satisfaction. These findings suggest that appearance congruence is a candidate mechanism by which GAH influences psychosocial functioning.

The importance of appearance congruence for psychosocial well-being is further highlighted by the effect of avoiding gender-incongruent pubertal changes. Youth who had not undergone substantial gender-incongruent puberty had higher scores for appearance congruence, positive affect, and life satisfaction and lower scores for depression and anxiety at baseline than youth who had undergone substantial endogenous puberty. These observations align with other published reports that earlier access to gender-affirming medical care is associated with more positive psychosocial functioning.[10,26] Alternatively, youth who first recognize their gender incongruence in adolescence may represent a distinct subgroup of transgender and nonbinary youth who have more psychosocial complexities than youth recognizing gender incongruence in childhood.[27]

The effects of GAH on some psychosocial outcomes varied on the basis of designated sex

Table 3. Variable Estimates for Individual Latent Growth Curve Models of 2-Year Outcomes.*

Model	Appearance Congruence†	Depression‡	Anxiety§	Positive Affect¶	Life Satisfaction‖
			value (95% confidence interval)		
Unconditional model: time					
Intercept mean	2.99 (2.90 to 3.08)	15.46 (14.27 to 16.70)	59.58 (58.22 to 60.68)	42.93 (41.82 to 44.03)	40.12 (38.99 to 41.26)
Intercept variance	0.35 (0.27 to 0.50)	86.23 (68.13 to 106.85)	17.84 (11.38 to 24.54)	63.50 (46.23 to 81.79)	75.21 (59.76 to 93.98)
Slope mean	0.48 (0.42 to 0.54)	−1.27 (−1.98 to −0.57)	−1.46 (−2.13 to −0.79)	0.80 (0.08 to 1.54)	2.32 (1.64 to 3.00)
Slope variance	0.11 (0.07 to 0.15)	19.44 (12.23 to 27.14)	17.84 (11.38 to 24.54)	17.98 (9.25 to 27.57)	20.33 (14.12 to 27.70)
Conditional model					
Time					
Intercept mean	2.59 (1.91 to 3.27)	20.01 (10.79 to 29.48)	60.82 (53.56 to 67.95)	47.27 (38.93 to 55.81)	38.86 (29.90 to 47.75)
Intercept variance	0.32 (0.25 to 0.42)	80.92 (63.35 to 100.47)	114.74 (91.96 to 138.23)	56.96 (41.19 to 74.75)	71.93 (57.15 to 90.22)
Slope mean	0.51 (0.07 to 0.96)	−0.92 (−3.82 to −0.06)	−1.95 (−3.81 to −0.09)	1.79 (0.14 to 3.43)	4.54 (2.66 to 6.43)
Slope variance	0.10 (0.06 to 0.14)	18.81 (11.71 to 26.34)	18.37 (11.78 to 25.63)	17.97 (9.29 to 27.66)	19.74 (13.61 to 27.06)
Time-invariant effects on intercept					
Baseline age	0.02 (−002 to 0.06)	−0.23 (−0.08 to 0.36)	−0.20 (−0.78 to 0.38)	−0.32 (−0.84 to 0.21)	0.06 (−0.49 to 0.62)
Designated sex at birth**	−0.12 (−0.31 to 0.06)	1.74 (−0.69 to 4.09)	0.05 (−2.37 to 2.49)	−1.26 (−3.53 to 0.91)	−2.36 (−4.89 to 0.18)
Racial and ethnic identity††	0.19 (0.03 to 0.36)	−2.60 (−4.82 to −0.32)	−2.22 (−4.48 to 0.06)	2.30 (0.22 to 4.38)	1.70 (−0.58 to 3.98)
Early gender-affirming care‡‡	0.70 (0.35 to 1.04)	−5.88 (−9.67 to −1.96)	−7.41 (−11.30 to −3.52)	5.34 (1.70 to 8.98)	7.55 (2.82 to 12.28)
Time-invariant effects on slope					
Baseline age	0.00 (−0.03 to 0.03)	−0.04 (−0.18 to 0.10)	−0.02 (−0.15 to 0.12)	−0.03 (−0.15 to 0.10)	−0.09 (−0.22 to 0.05)
Designated sex at birth**	0.03 (−0.09 to 0.15)	1.91 (0.33 to 3.50)	1.56 (0.01 to 3.10)	−0.43 (−2.10 to 1.31)	−1.86 (−3.49 to −0.24)
Racial and ethnic identity††	−0.10 (−0.20 to 0.01)	1.70 (0.23 to 3.15)	0.62 (−0.77 to 1.98)	−1.42 (−2.98 to 0.13)	−1.08 (−2.52 to 0.36)
Early gender-affirming care‡‡	−0.42 (−0.66 to −0.19)	−0.73 (−3.41 to 1.93)	0.04 (−2.53 to 2.59)	−0.78 (−3.56 to 2.06)	−1.08 (−4.01 to 1.86)

* Shown are unstandardized variable estimates with 95% confidence intervals. Slope means indicate change over time, and slope variances indicate heterogeneity within the sample.
† Scores on the Appearance Congruence subscale of the Transgender Congruence Scale range from 1 to 5, with higher scores indicating greater appearance congruence.
‡ Scores on the Beck Depression Inventory–II range from 0 to 63, with scores of 20 to 28 indicating moderate depression and scores of 29 to 63 indicating severe depression.
§ T scores on the Revised Children's Manifest Anxiety Scale (Second Edition) have a mean of 50 and a standard deviation of 10, with scores of 60 or more indicating clinical levels of anxiety.
¶ T scores for the Positive Affect measure from the NIH (National Institutes of Health) Toolbox Emotion Battery have a mean of 50 and a standard deviation of 10, with higher scores indicating greater positive affect.
‖ T scores for the Life Satisfaction measure from the NIH Toolbox Emotion Battery have a mean of 50 and a standard deviation of 10, with higher scores indicating greater life satisfaction.
** Coding for designated sex at birth was as follows: 0=assigned female at birth (reference) and 1=assigned male at birth.
†† Coding for racial and ethnic identity was as follows: 0=non-Latinx or non-Latine White (reference) and 1=other racial and ethnic identities.
‡‡ Coding for early gender-affirming care was as follows: 0=initiated GAH in later puberty (Tanner stage 4 or 5) (reference) and 1=initiated GAH in early puberty (Tanner stage 2 or 3).

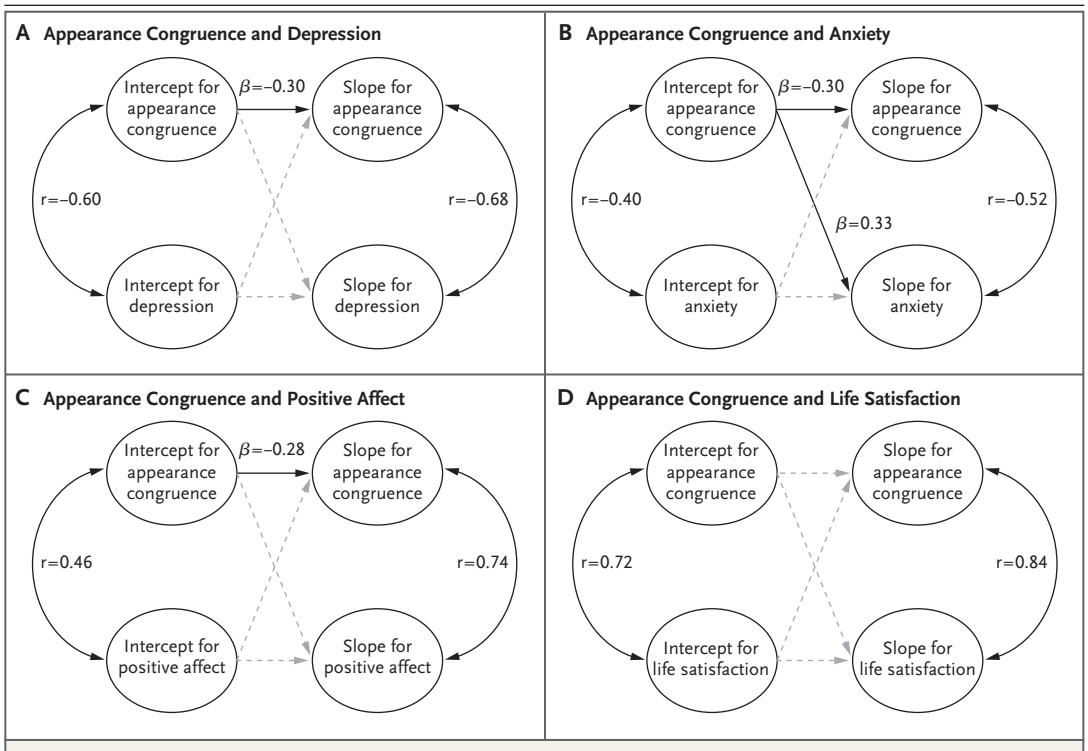

Figure 1. Appearance Congruence and Depression, Anxiety, Positive Affect, and Life Satisfaction.

Parallel-process latent growth curve models are depicted. A linear latent growth curve model was fitted for each outcome, with model-based estimates of baseline scores (intercept) and rates of linear change over time (slope). Parallel-process models can provide tests of how aspects of trajectories relate to each other. Each panel provides estimates for correlations between baseline scores of appearance congruence and each outcome (intercept correlations, arcs displayed on the left side of each panel), correlations between rate of change of appearance congruence and rate of change of each outcome (slope correlations, arcs displayed on the right side of each panel), and effects of baseline scores on slopes (straight lines in the middle of each panel). Solid black lines and arcs indicate significant effects (confidence intervals for variable estimates do not contain 0); nonsignificant effects are shown with dashed gray lines. All models were controlled for age, designated sex at birth, racial and ethnic identity, and early gender-affirming care (not shown for ease of interpretation).

at birth. Depression and anxiety symptoms decreased significantly, and life satisfaction increased significantly, among youth designated female at birth but not among those designated male at birth. Given that some key estrogen-mediated phenotypic changes can take between 2 and 5 years to reach their maximum effect (e.g., breast growth),[28] we speculate that a longer follow-up period may be necessary to see an effect on depression, anxiety, and life satisfaction. Furthermore, changes that are associated with an endogenous testosterone-mediated puberty (e.g., deeper voice) may be more pronounced and observable than those associated with an endogenous estrogen-mediated puberty. Thus, we hypothesize that observed differences in depression, anxiety, and life satisfaction among youth designated female at birth as compared with those designated male at birth may be related to differential experiences of gender minority stress, which could arise from differences in societal acceptance of transfeminine (i.e., persons designated male at birth who identity along the feminine spectrum) as compared with transmasculine persons. Indeed, gender minority stress is consistently associated with more negative mental health outcomes,[29] and research suggests that transfeminine youth may experience more minority stress than transmasculine youth.[30]

Our study has certain limitations. Because participants were recruited from four urban pediatric gender centers, the findings may not be generalizable to youth without access to comprehensive interdisciplinary services or to transgen-

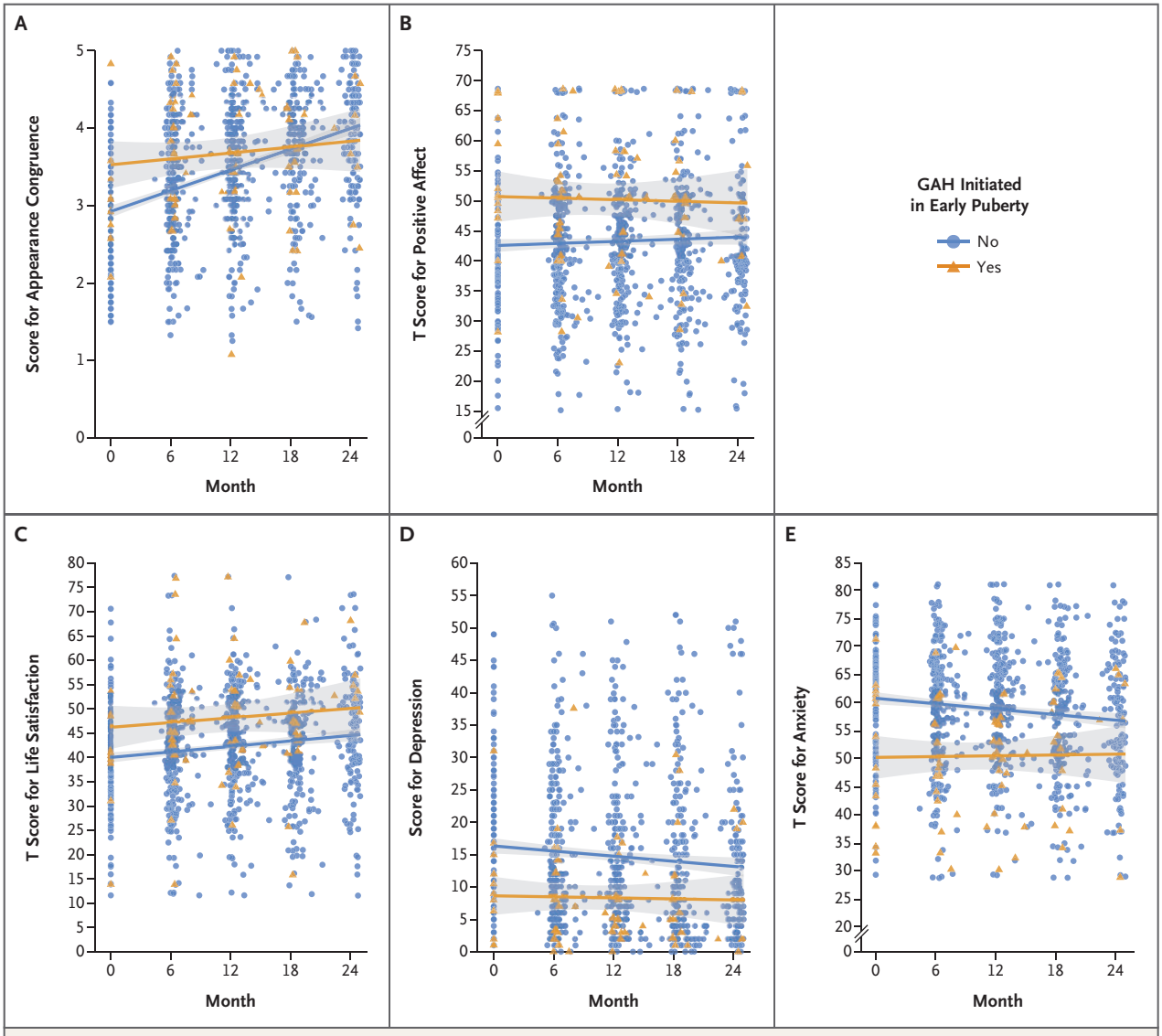

Figure 2. Psychosocial Outcomes during 2 Years of GAH.

Shown are changes in participant-reported measures over a period of 2 years of treatment with gender-affirming hormones (GAH). Scores on the Appearance Congruence subscale of the Transgender Congruence Scale (Panel A) range from 1 to 5, with higher scores indicating greater appearance congruence. T scores for the Positive Affect measure from the NIH (National Institutes of Health) Toolbox Emotion Battery (Panel B) range from 0 to 100, with higher scores indicating greater positive affect. T scores for the Life Satisfaction measure from the NIH Toolbox Emotion Battery (Panel C) range from 0 to 100, with higher scores indicating greater life satisfaction. Scores on the Beck Depression Inventory–II (Panel D) range from 0 to 63, with higher scores indicating greater depression. T scores on the Revised Children's Manifest Anxiety Scale (Second Edition) (Panel D), range from 0 to 100, with higher scores indicating greater anxiety. Individual scores are depicted with orange triangles for youth initiating GAH in early puberty ("Yes") and with blue circles for youth who did not initiate GAH in early puberty ("No"). Lines indicate mean scores for each group, with gray shaded bands for 95% confidence intervals.

der and nonbinary youth who are self-medicating with GAH. In addition, despite improvement across psychosocial outcomes on average, there was substantial variability around the mean trajectory of change. Some participants continued to report high levels of depression and anxiety and low positive affect and life satisfaction, despite the use of GAH. We plan to examine other factors that are known to contribute to psychosocial functioning among transgender and non-

binary youth and may not be affected by GAH, such as parental support,[31,32] in this cohort. Finally, our study lacked a comparison group, which limits our ability to establish causality. However, the large effects in parallel-process models examining associations between improvements in appearance congruence and improvements in psychosocial outcomes provide support for the concept that GAH may affect psychosocial outcomes through increasing gender congruence.

Despite these limitations, our findings showed improvements in psychosocial functioning across 2 years of GAH treatment, which supports the use of GAH as effective treatment for transgender and nonbinary youth. We are now following this cohort to see whether gains in functioning are sustained over a longer follow-up period, and — given substantial variability in outcomes even after controlling for a number of factors — we hope to discover additional predictors of change to identify youth for whom GAH alone is not adequate to address mental health challenges. We intend to initiate further work with this cohort to focus on understanding reasons for discontinuing GAH among the small subgroup of youth who stopped medical treatment. Overall, our results provide evidence that GAH improved appearance congruence and psychosocial functioning in transgender and nonbinary youth.

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APPENDIX

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Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation

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abstract

BACKGROUND AND OBJECTIVES: Gonadotropin-releasing hormone analogues are commonly prescribed to suppress endogenous puberty for transgender adolescents. There are limited data regarding the mental health benefits of this treatment. Our objective for this study was to examine associations between access to pubertal suppression during adolescence and adult mental health outcomes.

METHODS: Using a cross-sectional survey of 20 619 transgender adults aged 18 to 36 years, we examined self-reported history of pubertal suppression during adolescence. Using multivariable logistic regression, we examined associations between access to pubertal suppression and adult mental health outcomes, including multiple measures of suicidality.

RESULTS: Of the sample, 16.9% reported that they ever wanted pubertal suppression as part of their gender-related care. Their mean age was 23.4 years, and 45.2% were assigned male sex at birth. Of them, 2.5% received pubertal suppression. After adjustment for demographic variables and level of family support for gender identity, those who received treatment with pubertal suppression, when compared with those who wanted pubertal suppression but did not receive it, had lower odds of lifetime suicidal ideation (adjusted odds ratio = 0.3; 95% confidence interval = 0.2–0.6).

CONCLUSIONS: This is the first study in which associations between access to pubertal suppression and suicidality are examined. There is a significant inverse association between treatment with pubertal suppression during adolescence and lifetime suicidal ideation among transgender adults who ever wanted this treatment. These results align with past literature, suggesting that pubertal suppression for transgender adolescents who want this treatment is associated with favorable mental health outcomes.

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Dr Turban conceptualized and designed the study, drafted the initial manuscript, and incorporated all revisions and comments; Ms King conducted statistical analyses and reviewed and revised the manuscript for important intellectual content, with a focus on statistical aspects of the manuscript; Dr Carswell assisted in the design of the study and in interpretation of the data analyses and critically reviewed and revised the manuscript for important intellectual content, with a focus on relevant clinical endocrinology; Dr Keuroghlian supervised and contributed to the conceptualization and design of the study and the design of the statistical analyses and reviewed and revised the manuscript for important intellectual content as it relates to mental health considerations for transgender people; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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WHAT'S KNOWN ON THIS SUBJECT: Gonadotropin-releasing hormone analogues are commonly used to suppress endogenous puberty for transgender adolescents. Small studies have revealed that pubertal suppression results in favorable mental health outcomes. No studies to date have examined associations between pubertal suppression and suicidality.

WHAT THIS STUDY ADDS: In this study, using the largest survey of transgender adults to date, we show that access to pubertal suppression during adolescence is associated with lower odds of lifetime suicidal ideation among transgender young adults.

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According to the Centers for Disease Control and Prevention's Youth Risk Behavior Surveillance System, ~1.8% of adolescents in the United States identify as transgender.[1] These youth suffer mental health disparities that include higher rates of internalizing psychopathology (ie, anxiety and depression) and suicidality, theorized to be due to a combination of dysphoria toward their bodies and minority stress.[2–5] In a large study of transgender adults in the United States, 40% endorsed a lifetime suicide attempt.[6]

Over the past 2 decades, protocols have been developed to provide transgender adolescents with gender-affirming medical interventions that align their bodies with their gender identities. Most prominent among these are the Endocrine Society guidelines[7] and the World Professional Association for Transgender Health (WPATH) Standards of Care.[8] Both sets of guidelines recommend that transgender adolescents be offered gonadotropin-releasing hormone analogues (GnRHas), colloquially referred to as "puberty blockers," once they reach Tanner 2 of puberty. These medications are provided as subcutaneous implants or are administered as either 1- or 3-month depot injections. GnRHa therapy effectively halts the production of gonadal sex steroids (testosterone and estrogen) by persistently activating and thereby desensitizing the gonadotropin-releasing hormone receptor, which in turn leads to suppression of luteinizing hormone and follicle-stimulating hormone release from the anterior pituitary gland.[9] This process inhibits endogenous puberty for the duration of GnRHa use. Once further pubertal development is delayed, youth are able to explore gender identities without the pressure of dysphoria associated with gender-incongruent physical development.[10] GnRHa therapy is unique among gender-affirming medical interventions in that the resultant pubertal suppression is fully reversible, with the resumption of endogenous puberty after their discontinuation.[7,8]

Since the publication of the WPATH Standards of Care and the Endocrine Society guidelines, the use of pubertal suppression for transgender youth has become more common in the United States[9] There are limited data, however, regarding the mental health outcomes of pubertal suppression. To date, there have been 2 published studies in which the effects of this treatment on the mental health of transgender youth were examined. In the first study, the authors assessed changes in mental health among 55 Dutch adolescents who received pubertal suppression.[11] This study, which notably lacked a control group, revealed that internalizing psychopathology improved after treatment with pubertal suppression. In the second study, researchers followed a group of 201 adolescents with gender dysphoria and found that those who received pubertal suppression in addition to psychological support (n = 101) had superior global functioning, measured by the Children's Global Assessment Scale, when compared with those who received psychological support alone (n = 100).[12]

In the current study, we use the largest survey of transgender people to date, a community-recruited sample of transgender adults in the United States, to conduct the first-ever investigation into associations between pubertal suppression and suicidality.

Transgender youth present to clinicians with a range of concerns. Some have minimal body dysphoria and do not desire pubertal suppression, whereas others report significant dysphoria around the physical changes related to puberty. Because not all transgender and gender-diverse youth desire medical interventions, we examined only those youth who desired pubertal suppression because these are the young people who would present to care and for whom clinicians would need to decide about whether to initiate pubertal suppression. We specifically examined measures of past-year suicidality, lifetime suicidality, past-month severe psychological distress, past-month binge drinking, and lifetime illicit drug use. We hypothesized that among those who wanted pubertal suppression, those who received it would have superior mental health outcomes when compared with those who wanted but did not receive it.

METHODS

Study Design and Data Source

The 2015 US Transgender Survey (USTS) was conducted over a 1-month period in 2015 by the National Center for Transgender Equality (NCTE). It is, to our knowledge, the largest existing data set of transgender adults and includes data regarding demographics, past gender-affirming medical treatment, family support, and mental health outcomes. Participants were recruited through community outreach in collaboration with >400 lesbian, gay, bisexual, and transgender organizations and were provided with a Web address to complete the survey online. Details regarding outreach efforts are further described in the NCTE report on the survey.[6] The USTS protocol was approved by the University of California, Los Angeles Institutional Review Board. For the purposes of the current study, data were obtained via a data-sharing agreement with the NCTE, and the current protocol was reviewed by The Fenway Institute

Institutional Review Board and determined to not comprise human subjects research.

Study Population

The USTS data set contains responses from 27 715 US transgender adults, with respondents from all 50 states, the District of Columbia, American Samoa, Guam, Puerto Rico, and US military bases overseas. Given that pubertal suppression for transgender youth was not available in the United States until 1998,[4] only participants who were 17 or younger in 1998 would have had health care access to GnRHa for pubertal suppression. We thus restricted the analysis to participants who were 36 or younger at the time of the survey, resulting in a sample of 20 619 participants. Data were further restricted to those who selected "puberty blocking hormones (usually used by youth ages 9–16)" in response to the question "Have you ever wanted any of the health care listed below for your gender identity or gender transition? (Mark all that apply)." Response options for this question were "counseling/therapy," "hormone treatment/HRT," "puberty blocking hormones (usually used by youth ages 9–16)," or "none of the above." This resulted in a sample of 3494 individuals between the ages of 18 and 36 who ever wanted pubertal suppression as part of their gender-affirming medical care.

Exposures

Exposure to pubertal suppression was defined as selecting "puberty blocking hormones (usually used by youth ages 9–16)" in response to the question "Have you ever had any of the health care listed below for your gender identity or gender transition? (Mark all that apply)." Response options for this question were "counseling/therapy," "hormone treatment/HRT," "puberty blocking hormones (usually used by youth ages 9–16)," and "none of the above." Participants who reported having pubertal suppression were also asked, "At what age did you begin taking Puberty Blocking Hormones?" Those who reported beginning treatment after age 17 were excluded to only include participants who likely had pubertal suppression during active endogenous puberty. The vast majority of adolescents would have reached Tanner 5, the final stage of puberty, by age 17.[13,14]

Outcomes

Comparing those who received pubertal suppression with those who did not, we examined past-month severe psychological distress (defined as a score of ≥13 on the Kessler Psychological Distress Scale [K6], a cutoff previously validated among US adults[15]), past-month binge drinking (operationalized as drinking ≥5 standard alcoholic beverages during 1 occasion; the rationale for this threshold when studying alcohol use among transgender people has been discussed previously[16]), lifetime illicit drug use (not including marijuana), past-year suicidal ideation, past-year suicidal ideation with a plan, past-year suicide attempts, past-year suicide attempts resulting in inpatient care, lifetime suicidal ideation, and lifetime suicide attempts.

Control Variables

Demographic variables collected included age, age of social transition, age of initiation of gender-affirming hormone therapy, current gender identity, sex assigned at birth, sexual orientation, race, education level, employment status, relationship status, total household income at the time of data collection in 2015, family support for gender identity, and current hormone treatment.

Statistical Analysis

Data were analyzed by using SPSS software version 25 (IBM SPSS Statistics, IBM Corporation, Armonk, NY). Descriptive statistics were conducted and are presented as frequency (percentage) or mean (SD). Analysis of variance and χ^2 tests were used to assess significance by age, gender identity, sex assigned at birth, race, education level, employment status, relationship status, total household income, family support for gender identity, and current hormone treatment between those who received pubertal suppression and those who did not. We used univariate logistic regression to examine associations between receiving pubertal suppression and each mental health outcome, as well as between age and both ever wanting and receiving pubertal suppression. $P < .05$ defined statistical significance. Multivariable logistic regression models were adjusted for using the demographic variables associated with each outcome at the level of $P \leq .20$. Because all outcomes were associated with level of family support, sexual orientation, education level, employment status, and total household income, all models were adjusted for these variables. Lifetime suicide attempts were associated with gender identity, and this model was therefore additionally adjusted for this variable. Past-month severe psychological distress and past-year suicidal ideation were additionally associated with age, gender identity, and relationship status, and therefore models were adjusted for these variables as well. Race was found to be associated with lifetime suicidal ideation and lifetime suicide attempts; therefore models were therefore additionally adjusted for race.

RESULTS

Of the 20 619 survey respondents 18 to 36 years of age, 3494 (16.9%) reported that they had ever wanted pubertal suppression. Of those who wanted pubertal suppression, only 89 (2.5%) had

received this treatment. The following variables were found to be associated with those who wanted and received pubertal suppression compared with those who wanted pubertal suppression but did not receive it: younger age, age of social transition, age of initiation of hormone therapy, feminine gender identity, male sex assigned at birth, heterosexual sexual orientation, higher total household income, and greater family support of gender identity (Table 1).

In univariate analyses, when comparing those who received pubertal suppression with those who did not, receiving pubertal suppression was associated with decreased odds of past-year suicidal ideation, lifetime suicidal ideation, and past-month severe psychological distress (Table 2). After controlling for demographic variables from Table 1, pubertal suppression was associated with decreased odds of lifetime suicidal ideation. Raw

TABLE 1 Sample Demographics

		Have You Ever Had [Pubertal Suppression] for Your Gender Identity or Gender Transition?			
	All (N = 3494)	Yes (n = 89; 2.5%)	No (n = 3405; 97.5%)	F	P
n (%) n (%) n (%)					
Age	23.4 (5.0)	21.7 (4.7)	23.4 (5.0)	10.3	.001*
Age of social transition	20.0 (5.5)	15.2 (4.5)	20.1 (5.5)	67.5	<.001*
Age began hormone therapy	22.1 (4.5)	15.7 (2.4)	22.5 (4.3)	217.4	<.001*
Gender identity				25.5[a]	<.001*
Woman		23 (25.8)	617 (18.2)		
Man		19 (21.3)	383 (11.3)		
Transgender woman		25 (28.1)	720 (21.3)		
Transgender man		16 (18.0)	795 (23.5)		
Nonbinary or genderqueer		6 (6.7)	866 (25.6)		
Sex assigned at birth				4.4[a]	.04*
Female		39 (43.8)	1874 (55.0)		
Male		50 (56.2)	1531 (45.0)		
Sexual orientation				36.5[a]	<.001*
Heterosexual or straight		27 (30.3)	350 (10.3)		
Asexual		9 (10.1)	437 (12.8)		
Pansexual or queer		36 (40.4)	1784 (52.4)		
Gay or lesbian		12 (13.5)	539 (15.8)		
Not listed		5 (5.6)	295 (8.7)		
Race, n (%)				3.5[a]	.06
Racial minority		28 (31.5)	782 (23.0)		
Not racial minority (white or European American)		61 (68.5)	2623 (77.0)		
Education level				2.9[a]	.41
Less than high school		9 (10.1)	220 (6.5)		
High school graduate or GED		20 (22.5)	683 (20.1)		
Some college or associate degree		39 (43.8)	1729 (50.8)		
Bachelor's degree or higher		21 (23.6)	773 (22.7)		
Employment status				0.6[a]	.45
Employed		51 (79.7)	1976 (75.6)		
Unemployed		13 (20.3)	638 (24.4)		
Relationship status				0.5[a]	.47
Partnered		35 (40.2)	1447 (44.1)		
Unpartnered		52 (59.8)	1834 (55.9)		
Total household income, $				21.9[a]	<.001*
<25 000		21 (26.3)	1153 (38.3)		
25 000–49 999		13 (16.3)	652 (21.7)		
50 000–99 000		14 (17.5)	630 (20.9)		
>100 000		32 (40.0)	574 (19.1)		
Family support for gender identity					
Supportive		71 (81.6)	1551 (55.8)	24.3[a]	<.001*
Neutral		11 (12.6)	573 (20.6)		
Unsupportive		5 (5.7)	658 (23.7)		
Current hormone treatment		87 (97.8)	1617 (96.3)	0.5[a]	.48

Descriptive statistics for transgender adults in the United States who ever wanted pubertal suppression for their gender identity or gender transition when comparing those who received this treatment with those who did not receive this treatment (total N = 3494). Percentages were calculated from the total of nonmissing values.

*Indicates statistical significance.

[a] χ^2.

TABLE 2 Mental Health Outcomes Among Those Who Received Pubertal Suppression

	Univariate Analyses		Multivariable Analyses	
	OR (95% CI)	*P*	aOR (95% CI)	*P*
Suicidality, past 12 mo				
Ideation	0.6 (0.4–0.8)	.006*	0.6 (0.3–1.1)	0.09
Ideation with plan	0.9 (0.5–1.6)	.73		
Ideation with plan and attempt	1.2 (0.6–2.3)	.64		
Attempt resulting in inpatient care	2.8 (0.8–9.4)	.09		
Suicidality, lifetime				
Ideation	0.3 (0.2–0.5)	<.001*	0.3 (0.2–0.6)	0.001*
Attempts	0.7 (0.4–1.0)	.08		
Mental health and substance use				
Past-month severe psychological distress, K6 ≥13	0.5 (0.3–0.8)	.001*	0.8 (0.4–1.4)	0.38
Past-month binge drinking	1.3 (0.8–2.0)	.29		
Lifetime illicit drug use	1.1 (0.7–1.8)	.67		

Univariate and multivariable analyses of mental health outcomes among transgender adults in the United States who ever wanted pubertal suppression when comparing those who received this treatment with those who did not. Multivariable logistic regression models were adjusted for using the demographic variables associated with each outcome at the level of $P \leq .20$. Because all outcomes were associated with family support, sexual orientation, education level, employment status, and total household income, all models were adjusted for these variables. Lifetime suicide attempts were associated with gender identity, and this model was additionally adjusted for this variable. Past-month severe psychological distress and past-year suicidal ideation were additionally associated with age, gender identity, and relationship status, and thus these models were adjusted for these variables as well. Race was found to be associated with lifetime suicidal ideation and lifetime suicide attempts, and thus these models were additionally adjusted for race. Models for psychological distress and past-year suicidal ideation were also adjusted for age, gender identity, and relationship status. aOR, adjusted odds ratio.

[a] Indicates statistical significance.

frequency outcomes are presented in Table 3.

To examine associations between age, ever wanting, and ever receiving pubertal suppression, we divided participants into 2 age groups with the cutoff point at the median, 18 to 22 and 23 to 36, in light of the skewed distribution of age.[17] The younger age group had increased odds both of ever wanting pubertal suppression (odds ratio [OR] = 1.4, $P < .001$, 95% confidence interval [CI]: 1.3–3.5) and of receiving pubertal suppression (OR = 2.1, $P = .001$, 95% CI: 1.4–3.4).

Among those who had ever received pubertal suppression, 60% reported traveling <25 miles for gender-affirming health care, 29% traveled between 25 and 100 miles, and 11% traveled >100 miles.

TABLE 3 Raw Frequencies of Outcome Variables

	Have You Ever Had [Pubertal Suppression] for Your Gender Identity or Gender Transition?	
	Yes (*n* = 89; 2.5%)	No (*n* = 3405; 97.5%)
	n (%)	*n* (%)
Suicidality (past 12 mo)		
Ideation	45 (50.6)	2204 (64.8)
Ideation with plan	25 (55.6)	1281 (58.2)
Ideation with plan and attempt	11 (24.4)	473 (21.5)
Attempt resulting in inpatient care	5 (45.5)	108 (22.8)
Suicidality (lifetime)		
Ideation	67 (75.3)	3062 (90.2)
Attempts	37 (41.6)	1738 (51.2)
Mental health and substance use		
Past-month severe psychological distress (K6 ≥13)	32 (37.2)	1847 (55.1)
Past-month binge drinking	26 (29.2)	825 (24.3)
Lifetime illicit drug use	24 (27.3)	850 (25.3)

Raw frequencies of mental health outcomes among transgender adults in the United States who ever wanted pubertal suppression. Percentages were calculated from the total of nonmissing values.

DISCUSSION

This study is the first in which the association between access to pubertal suppression and measures of suicidality is examined. Treatment with pubertal suppression among those who wanted it was associated with lower odds of lifetime suicidal ideation when compared with those who wanted pubertal suppression but did not receive it. Suicidality is of particular concern for this population because the estimated lifetime prevalence of suicide attempts among transgender people is as high as 40%.[6] Approximately 9 of 10 transgender adults who wanted pubertal suppression but did not receive it endorsed lifetime suicidal ideation in the current study (Table 3). Access to pubertal suppression was associated with male sex assignment at birth, heterosexual sexual orientation, higher total household income, and higher level of family support for gender identity.

Results from this study suggest that the majority of transgender adults in the United States who have wanted pubertal suppression did not receive it. Of surveyed transgender adults in

the current study, 16.9% reported ever desiring pubertal suppression as part of their gender-related care; however, only 2.5% of these respondents indicated they had in fact received this wanted treatment. This was the case even for the youngest survey respondents, who were 18 years old at the time of data collection in 2015. Only 4.7% of 18-year-olds who wanted the treatment reported receiving it.

Although rates both of desiring and of receiving pubertal suppression were higher among younger respondents, results from the current study indicate that still only 29.2% of the youngest participants in the study (ie, those who were 18 years of age in the year 2015) reported ever desiring pubertal suppression as part of gender-related care. No individuals <18 years of age were captured by this data set; future research should investigate the rate of desiring pubertal suppression among younger populations. Some respondents may have simply never been aware of the possibility of puberty suppression while still within the range of developmentally suitable candidates for receiving this treatment, or they may have believed that they were not suitable candidates. This finding may also reflect the diversity of experience among transgender and gender-diverse people, highlighting that not all will want every type of gender-affirming intervention.[7,8] Future research is needed to understand why younger participants reported desiring pubertal suppression at higher rates; we hypothesize that this is likely due in part to recent increased public awareness about and access to gender-affirming interventions.[5]

Access to pubertal suppression was associated with a greater total household income. Without insurance, the annual cost of GnRHa therapy ranges from $4000 to $25 000.[18] Among adolescents treated with pubertal suppression at the Boston Children's Hospital Gender Management Service before 2012, <20% obtained insurance coverage.[19] More recently, insurance coverage for these medications has increased: a study from 2 academic medical centers in 2015 revealed that insurance covered the cost of GnRHa therapy in 72% of cases.[18] This is 1 potential explanation for why younger age was found to be associated with accessing pubertal suppression in the current study (Table 1). It is also plausible that those who receive pubertal suppression experience more improvement in mental health, which in turn may contribute to greater socioeconomic advancement.[20] This study's cross-sectional design limits further interpretation.

Participants who endorsed a heterosexual sexual orientation were more likely to have received pubertal suppression. This is in line with past research revealing that nonheterosexual transgender people are less likely to access gender-affirming surgical interventions.[21] Some clinicians may be biased against administering pubertal suppression to patients whose sexual orientation identities do not align with society's heteronormative assumptions.[21] In the current study, nonbinary and genderqueer respondents were also less likely to have accessed pubertal suppression, suggesting that clinicians may additionally be uncomfortable with delivering this treatment to patients whose gender identities defy more traditional binary categorization. Of note, because research on gender-affirming hormonal interventions for adolescents has been focused on transgender youth with binary gender identities,[11] some clinicians have reservations about prescribing pubertal suppression interventions to nonbinary youth in the event of a potentially prolonged state of low sex-steroid milieu.

Family support was also associated with receiving pubertal suppression among those who wanted this treatment. This finding is unsurprising given that most states require parental consent for adolescents to receive pubertal suppression.[22] Past studies have revealed that family support of gender identity is associated with favorable mental health outcomes.[6] Of note, treatment with pubertal suppression in the current study was associated with lower odds of lifetime suicidal ideation, even after adjustment for family support (Table 2).

We did not detect a difference in the odds of lifetime or past-year suicide attempts or attempts resulting in hospitalization. It is possible that we were underpowered to detect these differences given that suicide attempt items were less frequently endorsed than suicidal ideation items (Table 3). Given this study's retrospective self-report survey design, we were unable to capture information regarding completed suicides, which may have also reduced the number of suicide attempts we were able to account for. Given that suicidal ideation alone is a known predictor of future suicide attempts and deaths from suicide, the current results warrant particular concern.[23]

This study adds to the existing literature[11,12] on the relationship of pubertal suppression to favorable mental health outcomes. The theoretical basis for these improved mental health outcomes is that pubertal suppression prevents irreversible, gender-noncongruent changes that result from endogenous puberty (eg, bone structure, voice changes, breast development, and body hair growth) and that may cause significant distress among transgender youth. Pubertal suppression allows these adolescents more time to decide if they wish to either induce exogenous gender-congruent puberty or allow

endogenous puberty to progress.[7,8] Some have also theorized that gender-affirming medical care may have mental health benefits that are separate from its physical effects because it provides implied affirmation of gender identity from clinicians, which may in turn buffer against minority stress.[24]

Strengths of this study include its large sample size and representation of a broad geographic area of the United States. It is the first study in which associations between pubertal suppression for transgender youth and suicidality are examined. Limitations include the study's cross-sectional design, which does not allow for determination of causation. Longitudinal clinical trials are needed to better understand the efficacy of pubertal suppression. Because the 2015 USTS data do not contain the relevant variables, we were unable to examine associations between access to pubertal suppression and degree of body dysphoria in this study. Notably, past studies have revealed that body image difficulties persist through pubertal suppression and remit only after administration of gender-affirming hormone therapy with estrogen or testosterone.[11] It is also limited by its nonprobability sample design. Future researchers should work toward the collection of population-based survey data that include variables related to gender-affirming medical interventions. Of note, because pubertal suppression for transgender youth is a relatively recent intervention, some participants might not have known that these interventions existed and thus would not have reported ever wanting them. Had these individuals known about pubertal suppression, it is possible that they might have desired it. Because we do not have data on whether individuals who did not desire pubertal suppression would have wanted it had they known about it, we restricted our analysis to those who reported ever desiring pubertal suppression. Reverse causation cannot be ruled out: it is plausible that those without suicidal ideation had better mental health when seeking care and thus were more likely to be considered eligible for pubertal suppression. The Endocrine Society guidelines for pubertal suppression eligibility recommend that other mental health concerns be "reasonably well controlled."[7] Because this study includes only adults who identify as transgender, it does not include outcomes for people who may have initiated pubertal suppression and subsequently no longer identify as transgender. Notably, however, a recent study from the Netherlands of 812 adolescents with gender dysphoria revealed that only 1.9% of adolescents who initiated pubertal suppression discontinued this treatment without proceeding to gender-affirming hormone therapy with estrogen or testosterone.[25]

CONCLUSIONS

Among transgender adults in the United States who have wanted pubertal suppression, access to this treatment is associated with lower odds of lifetime suicidal ideation. This study strengthens recommendations by the Endocrine Society and WPATH for this treatment to be made available for transgender adolescents who want it.

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ABBREVIATIONS

CI: confidence interval
GnRHa: gonadotropin-releasing hormone analogue
K6: Kessler Psychological Distress Scale
NCTE: National Center for Transgender Equality
OR: odds ratio
USTS: US Transgender Survey
WPATH: World Professional Association for Transgender Health

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Sexual Experiences of Young Transgender Persons During and After Gender-Affirmative Treatment

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abstract

OBJECTIVES: Early gender-affirmative treatment (GAT) of adolescents may consist of puberty suppression, use of affirming hormones, and gender-affirmative surgeries. This treatment can potentially influence sexual development. In the current study, we describe sexual and romantic development during and after treatment.

METHODS: The participants were 113 transgender adolescents treated with puberty suppression, affirmative hormones, and affirmative surgery who were assessed as young adults (38 transwomen and 75 transmen; mean age 20.79 years, SD 1.36) during and after their GAT. A questionnaire on sexual experiences, romantic experiences, and subjective sexual experiences was administered and compared to the experiences of a same-aged sample from a Dutch general population study (N = 4020).

RESULTS: One year post surgery, young transgender adults reported a significant increase in experiences with all types of sexual activities: masturbation increased from 56.4% to 81.7%, petting while undressed increased from 57.1% to 78.7%, and sexual intercourse increased from 16.2% to 37.6% post surgery compared to presurgery. Young transmen and transwomen were almost equally experienced. In comparison with the general population, young transgender adults were less experienced with all types of sexual activities.

CONCLUSIONS: Early GAT (including puberty suppression, affirmative hormones, and surgeries) may provide young transgender adults with the opportunity to increase their romantic and sexual experiences.

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Dr Bungener conceptualized and designed the study, collected data, planned and conducted the analyses, drafted the initial manuscript, and reviewed and revised the manuscript; Dr Steensma conceptualized and designed the study, supervised data collection, assisted in conducting the analyses, and reviewed and revised the manuscript; Dr de Vries conceptualized and designed the study, designed the data collection instrument, supervised data collection, assisted with data interpretation, and reviewed and revised the manuscript; Dr Popma assisted with data interpretation and critically reviewed and revised the manuscript for important intellectual content; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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WHAT'S KNOWN ON THIS SUBJECT: Early gender-affirmative treatment of transgender adolescents (including puberty suppression, affirming hormones, affirming surgeries) may start as early as the initiation of puberty. Its potential effect on sexual and romantic development during and after treatment has not been investigated so far.

WHAT THIS STUDY ADDS: During the process of gender-affirmative treatment, many transgender adolescents reach their first sexual milestones. After completing treatment, a large increase in sexual experiences is observed. However, although approaching their same-aged peers from the general Dutch population, they are less experienced.

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In recent decades, there has been a major development in health care for transgender adolescents in various Western countries.[1–6] For this young group, gender-affirmative treatment (GAT) has become available and may consist of puberty suppression with gonadotropin-releasing hormone (GnRH) analogues to prevent the development of secondary sex characteristics and create time for a balanced decision regarding possible use of affirming hormones (testosterone or estrogen) and gender-affirmative surgeries (chest surgery, genital surgery).[7] During all phases of treatment, psychological support is included in the counseling. Support is adapted to the specific needs of the adolescent and includes preparation for the various steps of gender-affirming medical interventions, social transitioning, discussion of sexuality and fertility, and so on.[7] Evaluation studies on GAT with use of GnRH analogues in transgender youth reaching adulthood reveal an improvement in psychological functioning, social functioning, body image, and quality of life and alleviation of gender dysphoria.[8–10] One important area of interest that has not yet been explored is sexual functioning during and after GAT.

Sexual development is a key developmental task for all adolescents[11] and accelerates during puberty with the release of puberty hormones.[12] Sexual milestones are generally obtained in an age-dependent and progressive line of intimacy: at the start of puberty, most youth have not had a kiss, whereas at the end, the majority have some sexual experience.[13,14] Although sexuality might be complex for all adolescents because of its biopsychosocial aspects,[15–17] it might be difficult for transgender youth to explore during their affirmative treatment. Our earlier study on sexual experiences of transgender adolescents revealed that at the time of referral (12–17 years), when no affirming medical interventions had yet been provided, the majority of 137 untreated transgender adolescents fell in love (77%), approximately half of the group engaged in romantic relationships (51%), a somewhat smaller group had some experience petting while undressed (26%), and only a few reported sexual intercourse (5%). Comparisons with cisgender peers from the general population revealed that overall, these rates were lower on all types of sexual activities.[18] In qualitative retrospective research, transgender adults reported that they had skipped sexual stages because of the gender dysphoria that they had experienced and that sexual pleasure was negatively affected by the persistent feelings of incongruence.[19]

Many transgender adolescents view their affirmative surgeries as the final step of GAT and the long awaited transition to bring their bodies into alignment with their experienced gender.[9] One of the main reasons given by untreated transgender adolescents for withholding from sexual activities was being ashamed of their bodies related to gender dysphoria.[18] Affirming masculinizing or feminizing hormones and surgeries are therefore expected to have a positive effect on sexuality. One follow-up study on 22 transgender adolescents after affirming hormone therapy and surgeries (puberty suppression was not given at the time) revealed that 36% had a stable relationship and 71% were satisfied with their sex life, whereas masturbation was not frequent, and some transmen described living without a penis to be difficult.[8]

Quantitative data from adult studies on sexuality after hormones and/or gender-affirming surgery reveal mixed results, with either an increase in sexual satisfaction and activity (eg, more arousal, desire, increase in masturbation), or a decrease (eg, arousal difficulties).[20–31] The authors of a qualitative study in transgender adults describing the subjective experience of sexuality during gender transition reported ambivalent outcomes as well.[32]

Thus far, there has been no investigation of sexual development during and after early affirming medical treatment in transgender adolescents. In the current study, we aim to describe the sexual and romantic experiences of young transgender adults during and after GAT, comparing these experiences with those of general population peers while examining gender differences.

METHODS

Participants and Procedure

The study sample included 113 young adults (38 transwomen [birth-assigned men] and 75 transmen [birth-assigned women]) who had received early GAT consisting of puberty suppression, affirming hormones (estrogen or testosterone), and gender-affirmative surgeries at the Center of Expertise on Gender Dysphoria at the Amsterdam University Centers, Location VUmc (Vrije Universiteit medical center), Amsterdam, the Netherlands, between 2000 and 2016. They were the first group to complete this trajectory of an initial 538 adolescents referred to the Center of Expertise on Gender Dysphoria between 2000 and 2013 who were diagnosed with gender dysphoria[33] (gender identity disorder in the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*) and were considered eligible for treatment. The mean age at referral was 14.69 (SD 2.2, range 10.94–17.74) years. Participants were invited at least 1 year after affirmative surgeries, between 2009 and 2016 (see Table 1), for questionnaires about their sexual and romantic experiences in their current situation (after receiving puberty

TABLE 1 General Characteristics of the Participants

Variable	All Participants (N = 113)	Transwomen[a] (n = 38)	Transmen[a] (n = 75)	Significance, P
Age at assessment, y				
Mean (SD)[b]	20.8 (1.36)	20.9 (1.25)	20.7 (1.42)	.58
Range	18.6–25.4	18.9–24.9	18.6–25.4	n/a
Current living situation, n (%)[c]				
With parents	73 (64.6)	23 (60.5)	50 (66.7)	.52
With romantic partner	4 (3.5)	1 (2.6)	3 (4.0)	.52
With others, eg, student house	20 (17.7)	7 (18.4)	13 (17.3)	.89
Alone	15 (13.3)	7 (18.4)	8 (10.7)	.82
No permanent residence	1 (0.9)	0 (0)	1 (1.3)	n/a
Educational level, n (%)[c]				
High school, basic level	67 (59.3)	23 (60.5)	45 (60)	
High school, advanced level	45 (39.8)	15 (39.5)	30 (40)	.96
Profession, n (%)[c]				
Studying	66 (58.4)	25 (65.8)	41 (54.7)	
Working	34 (30.1)	9 (23.7)	25 (33.3)	.29
Job seeking	8 (7.1)	3 (7.9)	5 (6.7)	.81
Incapacitated	5 (4.4)	1 (2.6)	4 (5.3)	.51
Time since surgery, y				
Mean (SD)[b]	1.57 (0.73)	1.53 (0.59)	1.59 (0.80)	.72
Range	0.46–5.38	0.46–3.09	0.69–5.38	n/a
Surgery				
Vaginoplasty	n/a	38 (100.0)	n/a	n/a
Breast augmentation	n/a	9 (23.7)	n/a	n/a
Mastectomy	n/a	n/a	63 (97.9)	n/a
Metoidioplasty	n/a	n/a	6 (8.7)	n/a
Waiting for metoidioplasty	n/a	n/a	15 (21.7)	n/a
Waiting for phalloplasty	n/a	n/a	20 (29.0)	n/a
Does not want metoidioplasty or phalloplasty	n/a	n/a	29 (42.0)	n/a
Sexual orientation, n (%)[c]				
Attracted to birth-assigned gender	94 (84.7)	35 (92.1)	59 (80.8)	<.05
Attracted to opposite gender	2 (1.8)	0 (0)	2 (2.7)	n/a
Attracted to both	10 (10.8)	0 (0)	10 (13.7)	n/a
Does not know yet	3 (2.7)	1 (2.6)	2 (2.7)	.99
Preferred sexual orientation of partner, n (%)[c]				
Heterosexual	73 (64.6)	33 (86.8)	40 (53.3)	<.05
Gay	5 (4.4)	1 (2.6)	4 (5.3)	.51
No preference	32 (28.3)	4 (10.5)	28 (37.3)	<.05
Does not know yet	3 (2.6)	0 (0)	3 (4.0)	n/a
Duration of longest relationship, mo				
Mean (SD)[b]	15.43 (15.3)	14.6 (17.4)	15.8 (14.4)	.78
Range	1.0–80	1.0–80	1.0–48.0	n/a
No. partners[c]				
No partner	28 (24.8)	14 (36.8)	12 (16.4)	<.05
1 partner	22 (19.8)	8 (21.1)	14 (19.2)	.81
>1 partner	63 (56.8)	16 (42.1)	47 (64.4)	<.05

n/a, not applicable.

[a] Young transgender adults at inclusion, including birth-assigned men (transwomen) and birth-assigned women (transmen).

[b] Differences calculated by T-test.

[c] Differences calculated by Chisquare test.

suppression, cross-sex hormones, and surgery) and retrospectively (the period right before surgery, after receiving puberty suppression and cross-sex hormones). The mean age at the assessment was 20.79 (SD 1.36, range 18.60–25.36) years. Surgery for transwomen consisted of a vaginoplasty and sometimes breast augmentation, and surgery for transmen involved a hysterectomy with an ovariectomy (requested for legal sex change until 2014) and, when necessary, a mastectomy (for most). Some transmen underwent a metaoidioplasty, whereas the majority was either on the waiting list for a phalloplasty or chose not to undergo genital surgery at that point in time. At the closure of inclusion of the current study (2016), 135 transgender individuals had received early GAT since 2000.

For the current study, 22 persons could not be included because of (1) refusal to participate (n = 5), (2) failure to return questionnaires (n = 12), (3) being medically ineligible for surgery (n = 4), and (4) death (n = 1). For comparison with peers from the Dutch population, a data set of the same age, between 18 and 25 years (N = 4020), from a large population study on sexual health in Dutch adolescents (N = 8250, 12–25 years) was used.[34] All participants gave written informed consent. The study was approved by the research ethics committee.

Measures

Sociodemographic Data

Background information was obtained through questionnaires. Birth-assigned gender, age, current living situation, highest educational level completed, current profession or study, sexual orientation, preferred sexual orientation of their partner ("Do you want your partner to have a certain sexual orientation?"), number of partners, duration of longest relationship, time since surgery (years), and type of surgery

TABLE 2 Sexual Experiences of Young Transgender Adults During (Retrospectively Reported) and After (Current) GAT

Sexual Experience	Total Group[a] During and After GAT[b] (N = 138)					Transwomen[a] During and After GAT[b] (n = 38)					Transmen[a] During and After GAT[b] (n = 75)				
	During GAT, n (%)	After GAT, n (%)	Significance,[c] P	Effect Size,[d] pD	Difference 95% CI[e]	During GAT, n (%)	After GAT, n (%)	Significance,[c] P	Effect Size[d]	Difference 95% CI[e]	During GAT, n (%)	After GAT, n (%)	Significance,[c] P	Effect Size[d]	Difference 95% CI[e]
Has been in love	n/a	100 (89.3)	n/a	n/a	n/a	n/a	35 (92.1)	n/a	n/a	n/a	n/a	65 (87.8)	n/a	n/a	n/a
Romantic relationship	n/a	85 (75.9)	n/a	n/a	n/a	n/a	24 (63.2)	n/a	n/a	n/a	n/a	61 (82.4)	n/a	n/a	n/a
French kissing	93 (83.0)	96 (85.7)	.98	n/a	n/a	31 (81.6)	33 (86.6)	.45	n/a	n/a	62 (83.8)	63 (85.1)	.572	n/a	n/a
Masturbation	62 (56.4)	89 (81.7)	<.001	0.28	0.17 to 0.33	12 (31.6)	33 (89.2)	<.05	0.56	0.40 to 0.72	50 (69.4)	56 (77.8)	<.001	0.083	0.02 to 0.15
Petting undressed	64 (57.1)	85 (78.7)	<.001	0.22	0.22 to 0.22	22 (57.9)	32 (84.2)	<.001	0.08	0.08 to 0.08	42 (56.8)	53 (75.7)	.063	−0.06	−0.2 to 0.09
Manual masturbation															
Active[f]	61 (56.0)	77 (71.3)	<.05	0.16	0.09 to 0.23	19 (50.0)	26 (68.4)	<.05	0.18	0.06 to 0.31	42 (59.2)	51 (72.9)	<.05	0.14	0.06 to 0.22
Passive[g]	23 (21.1)	56 (51.9)	<.001	0.31	0.21 to 0.40	6 (15.8)	26 (68.4)	<.001	0.53	0.37 to 0.69	17 (23.9)	30 (42.9)	<.001	0.19	0.10 to 0.28
Sexual intercourse[h]	18 (16.2)	41 (37.6)	<.001	0.21	0.13 to 0.29	5 (13.2)	23 (60.5)	<.05	0.47	0.31 to 0.63	13 (17.8)	18 (25.4)	.063	0.07	0.01 to 0.13
Oral sex															
Active[f]	49 (45.0)	61 (57.0)	<.05	0.13	0.06 to 0.20	17 (44.7)	21 (55.3)	<.001	0.11	0.01 to 0.20	32 (45.1)	40 (58.0)	<.05	0.14	0.05 to 0.24
Passive[g]	19 (17.4)	46 (43.0)	<.001	0.25	0.17 to 0.33	4 (10.5)	20 (52.6)	<.001	0.42	0.26 to 0.58	15 (21.1)	26 (37.7)	<.001	0.16	0.07 to 0.25
Anal sex	12 (10.9)	18 (16.7)	.31	n/a	n/a	8 (21.1)	13 (34.2)	.063	n/a	n/a	4 (5.6)	5 (7.1)	.97	n/a	n/a

CI, confidence interval; n/a, not applicable.

[a] Young transgender adults at inclusion, including birth-assigned men (transwomen) and birth-assigned women (transmen).

[b] Early GAT for adolescents may consist of puberty suppression, use of affirming hormones, and gender-affirmative surgery.

[c] McNemar test.

[d] Effect size of McNemar test, calculated by the difference in proportion.

[e] 95% CI of the difference in proportion.

[f] Manual or oral genital touching of another person.

[g] Receiving genital touching manually or orally.

[h] Sexual intercourse was defined as penile-vaginal penetration.

were all assessed (see Table 1). For the highest level of education completed, individuals were categorized into 2 groups: (1) high school basic level (prevocational and secondary vocational students) and (2) high school advanced level (secondary or preuniversity students). Sexual orientation was assessed in 4 categories based on attraction: attracted to a person of their birth-assigned gender, of the opposite gender, of either gender, or does not know yet.

Sexual Behavior

Sexual behavior was assessed by using a 21-item questionnaire directly derived and adapted from the large Dutch sexual health population study.[34] This enabled comparisons with the general Dutch youth population to be made. The first set of items were related to sexual and romantic relationship experiences: falling in love, romantic relationships, French kissing, solo masturbation, petting while undressed, mutual masturbation active (manual genital touching of another person), mutual masturbation passive (receiving genital touching manually), sexual intercourse (vaginal penetration with a penis), oral sex active (oral genital touching of another person), oral sex passive (receiving oral genital sex), and anal sex (giving or receiving). For each of these behaviors, participants could indicate whether they had ever experienced these behaviors before surgery and/or after surgery (eg, "Did you have experience with sexual intercourse before surgery?" and "Have you had experience with sexual intercourse since surgery?"). The answer options were dichotomous (yes or no experience). If the answer was "yes," age at the time of the first experience was asked.

In addition to the actual experiences with sexual activities, the questionnaire included questions about sexuality-related topics: the importance of love, relationships, and sexuality; the ability to get in touch with someone the individual likes; longest relationship; and negative sexual experiences (eg, "Has anyone ever forced you to do or allow sexual things that you did not want to do?"). Participants who had not engaged in sexual intercourse were asked to specify the reason by choosing from a list of options. Additional domains on sexual functioning were assessed by 4 questions by using a 5-point scale (from "often" to "never"). A few transgender specific answer options and items were added that were not used in the general population study (eg, negative sexual experiences due to being transgender, sexual assertiveness, competence, sexual self-esteem, and self-image).

Analyses

To describe demographic data, descriptive statistics and independent *t* tests were used. To compare mean age at the first sexual experience one-sided *t* tests were used. χ^2 tests and independent *t* tests were conducted to calculate group differences. McNemar tests were used to assess pre-post treatment differences within the same group. Effect sizes were calculated by proportions of differences. To compare with the general population, χ^2 tests were used. Because of the explorative character of this study, a correction factor was not applied so that all possible signals in the data could be seen. To minimize recall bias in the retrospective analyses, the ages provided as the first time of the sexual experience were used to confirm that the behavior was experienced before or after surgery. No irregularities were found.

RESULTS

Sexual Experiences During and After GAT

In Table 2, we show the sexual experiences of the total sample of young transgender adults during and after GAT (puberty suppression by GnRH analogues, followed by affirming hormones and surgeries). One year after affirming surgeries, the young adults reported significant increases in experiences of all types of sexual activities, except for romantic relationships and anal sex, compared to immediately before these surgeries.

TABLE 3 Sexual Experiences of Transgender Young Adults Versus the General Population

Sexual experience	Transgender Young Adults[a] (*N* = 113), *n* (%)	General Population[b] (*N* = 4020), *n* (%)	Significance, χ^2 (df = 1)	*P*
Has been in love	100 (89.3)	3881 (97)	20.1	<.001
Romantic relationship	85 (75.9)	3585 (89.2)	21.5	<.001
French kissing	96 (85.7)	3724 (92.6)	9.3	<.05
Masturbation	89 (81.7)	3507 (87.2)	7.0	<.05
Petting while undressed	85 (78.7)	3705 (92.2)	41.5	<.001
Manual masturbation				
Active[c]	77 (71.3)	3255 (81.0)	11.6	<.001
Passive[d]	56 (51.9)	3237 (80.5)	65.1	<.001
Sexual intercourse[e]	41 (37.6)	3336 (83.0)	160.4	<.001
Oral sex				
Active[c]	61 (57.0)	3138 (78.1)	36.4	<.001
Passive[d]	46 (43.0)	3419 (85.1)	159.5	<.001
Anal sex	18 (16.7)	1067 (26.5)	6.4	<.05

df, degree of freedom.

[a] Young transgender adults at inclusion, including birth-assigned men (transwomen) and birth-assigned women (transmen).

[b] Data from a population study on sexual health in Dutch youth performed at Rutgers University.[32]

[c] Manual or oral genital touching of another person.

[d] Receiving genital touching manually or orally.

[e] Sexual intercourse was defined as penile-vaginal penetration.

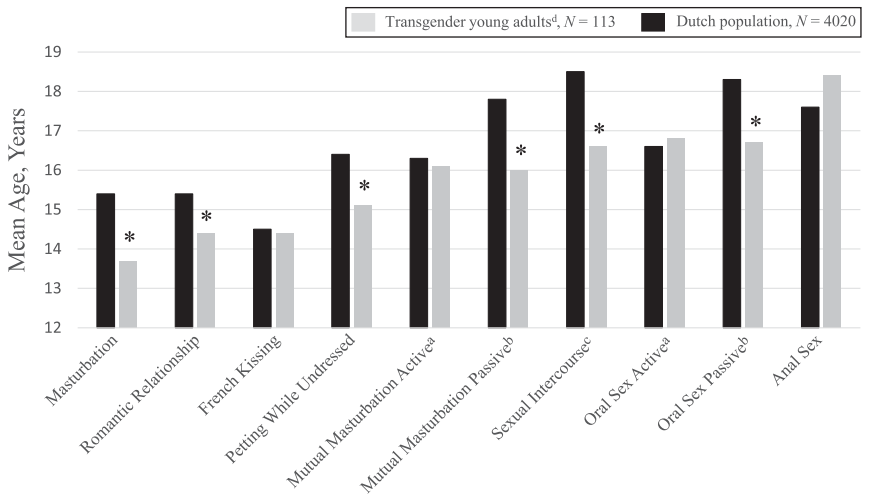

FIGURE 1

Mean age of first time sexual experience of transgender young adults Dutch population. The mean age of transgender young adults and their same-aged peers from the Dutch population when sexual activity was experienced for the first time. The mean age was analyzed for the group that did experience this sexual or romantic activity. [a] Manual or oral genital touching of another person. [b] Receiving genital touching manually or orally. [c] Sexual intercourse was defined as penile-vaginal penetration. [d] Young transgender adults, including birth-assigned men (transwomen) and birth-assigned women (transmen).* Significant difference in mean age between young transgender adults and the Dutch population: $P < .001$.

Transwomen

Compared to presurgery, young transwomen reported significantly more sexual experiences after completing GAT, except for French kissing, oral sex active (giving sex to someone else), and anal sex. The largest increase in percentages was observed in types of sexual behaviors that included the involvement of their own genitals: intercourse (from 13.2% to 60.6%), oral sex passive (receiving oral sex; from 10.5% to 52.6%), manual sex passive (from 15.8% to 68.4%), and masturbation (from 31.6% to 89.2).

Transmen

Compared to presurgery, an increase was observed in most types of sexual activity in transmen, except for French kissing, intercourse, and anal sex. The latter 2, however, were infrequently reported both during and after completing GAT. In the young transmen, the strongest increase was found in types of sexual behavior that included touching their own genitals, such as oral sex passive and manual sex passive.

Gender Differences

Transmen and transwomen were almost equally experienced (Table 2). Presurgery gender differences were observed only for masturbation, with transmen being more experienced than transwomen (31.6% vs 69.4%; $\chi^2_1 = 14.05$; $P < .001$). Post treatment, transwomen reported more experience with sexual intercourse (60.5% vs 25.4%; $\chi^2_1 = 13.05$; $P < .001$) than transmen, whereas transmen reported more experience with romantic relationships (63.2% vs 82.4%; $\chi^2_1 = 4.47$; $P < .05$) than transwomen. Analysis of the mean age at the first experiences with sexual activity revealed no gender differences.

Sexual Development and Experiences Compared With the General Population

Table 3 reveals the posttreatment sexual experiences of young transgender adults compared with their peers from the general Dutch population. The group of young transgender adults was significantly less sexually experienced than their Dutch peers.

Figure 1 reveals the mean age of the transgender young adults and the Dutch population when sexual activity was experienced for the first time. Transgender young adults were significant older than their Dutch peers when first engaging in 6 experiences: masturbation (mean = 15.4 [SD = 3.1] versus mean = 13.7; $t_{68} = 4.54$; $P < .001$), relationships (mean = 15.4 [SD = 2.1] versus mean = 14.4; $t_{85} = 4.3$; $P < .001$), petting while undressed (mean = 16.4 [SD = 2.3] versus mean = 15.1; $t_{80} = 4.96$; $P < .001$), manual sex passive (mean = 17.8 [SD = 2.1] versus mean = 16.0; $t_{47} = 5.79$; $P < .001$), oral sex passive (mean = 18.3 [SD = 2.3] versus mean = 16.7; $t_{38} = 4.3$; $P < .001$), and sexual intercourse (mean = 18.5 [SD = 2.1] versus mean = 16.6; $t_{34} = 5.3$; $P < .001$). For transgender persons, experiences with passive sex (receiving genital sexual touching orally or manually) occur later then experiences with active sex (touching the other person): manual active, mean = 16.3 (SD = 2.6), versus passive, mean = 17.8 (SD = 2.1) ($t_{47} = 57.5$; $P < .001$); oral active, mean = 16.6 (SD = 1.9), versus passive, mean = 18.3 (SD = 2.2) ($t_{38} = 50.5$; $P < .001$).

Sexual Satisfaction, Sexual Competence, and Negative Experiences

Transgender young adults value sex (92.7%; $n = 92$), love (93.7%; $n = 104$), and relationships (94.6%; $n = 105$) as moderate to very important, with no significant gender differences. Young transgender adults report being moderately to very satisfied with the frequency of sex (58.7%; $n = 37$), how good it feels (73.0%; $n = 46$), and their sex life in general (66.7%; $n = 42$). There were no gender differences.

The majority of transgender young adults manage to get in touch with a person to whom they are romantically or sexually attracted (73.9% [$n = 82$]; no gender

differences). For most of the group, the last sexual activity happened within the past month (68.8%; *n* = 44) or year (87.6%; *n* = 56). Sexual competence and assertiveness in the young adult transgender group was high: the percentage answering "often" or "always" was 82.8% for "feeling at ease during sex" (*n* = 40) and 66.6% for "I let the other person know what I like" (*n* = 31).

Of all transgender young adults, 13.6% (*n* = 15) reported negative sexual experiences, with no significant gender difference between transwomen (16.2%; *n* = 6) and transmen (12.3%; *n* = 9). In 20% (*n* = 3) of this group, being transgender was reported as a cause of the negative experience. In the general population, 17% (no number given) of female individuals and 5% (no number given) of male individuals had experienced sexual acts against their will; however, this was in the total group of 12- to 25-year-olds.

DISCUSSION

In the current study, we found that young transgender adults reported a strong increase in sexual experiences after completing early GAT, including puberty suppression, affirming hormones, and surgeries. Although the difference between them and their same-aged peers in experience was attenuated, in comparison with the Dutch population, young transgender adults were still less experienced in all types of sexual activities. Between young transmen and transwomen, hardly any differences in sexual experiences were reported. Almost all valued sex as important, and the majority was satisfied with their sex life. After the surgeries, young transgender adults who started early GAT became far more sexually active. Because sexuality is multifactorial,[15,35,36] multiple factors could play a role.

First, one expected factor is the improvement in overall body image and body satisfaction due to early puberty suppression (no [further] virilization in transwomen and no [further] feminizing in transmen), affirming hormones, and nongenital surgeries, such as a mastectomy.[37] An interesting finding in our study was that the largest increase was seen in passive types of sexual activities. Before gender-affirmative surgeries, the majority of transgender youth touched only their sexual partners' genitals during mutual sexual activity and excluded their own genitals. After affirmative surgeries, more transgender individuals allowed their own genitals to be touched (either orally or manually, both in transmen and transwomen). It should be realized that in our sample, all transwomen had genital surgery, but the majority of transmen still had a vagina. Apparently, this increase in passive types of sexual activities can only be partially explained by the surgical alleviation of genital aversion, a key symptom of gender dysphoria.[19,32] This highlights that body satisfaction is not only confined to the genital area.[37,38]

Second, psychological well-being, a vital factor in the sexual behavior and feelings of transgender people[9] and the general population,[39] improves steadily during early GAT.[9] In addition, the fact that the young transgender adults had started their affirmative treatments early in their lives seemed to lead to more sexual activity compared with transgender adults from previous studies. In our group, 78% had sexual experiences with another person (defined as at least petting while undressed), and 81.7% masturbated, whereas in adult studies, sexual activity (often not defined) ranged from 29% to 91%,[21,24,25,31] and masturbation ranged from not frequent to 89.4%.[8,25,27,31] The increase in sexual activity of our group seems to be even more exponential than that in studies of adults after treatment, in which a variety of outcomes on sexual and romantic activity are found, ranging from an increase in sexual activity to no change or even a decrease.[24–30,34] These findings might suggest that early GAT, including puberty suppression, makes sexual development easier for transgender youth compared with adults. This might be due to the fact that adolescents and adults treated with GnRH analogues are described as having fewer problems passing in their experienced gender,[40,41] which makes it easier to form a romantic relationship or find a sexual partner. Second, in different studies, transgender adolescents have been found to have better psychological functioning than transgender adults,[10,25,31] which may have a positive impact on sexual functioning.[39]

Despite the increase in sexual and romantic activities, transgender youth are still less experienced then their cisgender peers in all types of romantic and sexual activities. This is in line with our former study on transgender adolescents before GAT, who were even less experienced than their same-aged peers.[18] It seems that many transgender youth begin their sex life after having received gender-affirmative hormones and surgeries. Thereafter, their sexual development follows the same progressive linear line from less intimate sex (eg, kissing) to more intimate sex (eg, intercourse, anal sex).[13] One of the reasons for this late involvement in sexual activity could be that, although globally, average levels of acceptance for lesbian, gay, bisexual, transgender, intersex queer/questioning people have increased since 1980,[42] transgender youth are still at risk for bullying[43] and social exclusion.[44,45] This might negatively interfere with finding a romantic or sexual partner and, therefore, with their ability to gain sexual experience. Finally, the participants had just finished the surgical phase of medically transitioning, and future researchers

should learn how their further sexual development evolves and what factors, inhibiting and facilitating, play a role.

Young transwomen and transmen are overall equally experienced in sexual activities. Only transmen reported masturbating more before affirming surgeries (mastectomy and hysterectomy). This could be an effect of testosterone because adult studies reveal an increase in arousal, desire, and masturbation after the beginning of affirming hormones.[22,23]

After gender-affirmative surgeries, transmen had more romantic relationships than transwomen. This might be related to the fact that gender nonconforming birth-assigned boys (transwomen) are more prone to encounter discrimination[44,46] than gender nonconforming birth-assigned girls (transmen). This may also lead to more difficulties in finding a romantic partner during and after GAT. By contrast, transwomen had more sexual intercourse experiences than transmen. This is most likely due to the fact that for the young transmen in our sample, sexual intercourse was not applicable because they were mostly attracted to persons of their birth-assigned gender (women) and none of them had received a phalloplasty yet (only 6 had undergone a metaoidioplasty). Sexual intercourse is thus only possible by using prostheses, and these experiences might not have been reported as intercourse.[32]

The current study had some limitations. First, the data on sexuality during GAT (before surgery) were collected retrospectively. Although we tried to minimize potential recollection bias by conducting an additional analysis on the provided ages of the first experience, we could not prevent the risk of recall bias. Second, sexuality is an individual process, which we assessed quantitatively. For further research, we would like to broaden the scope on sexuality using qualitative methods to learn more about overall subjective experiences and challenges, including topics such as practicing safe sex. Third, further research should be focused on sexuality in transgender young adults who are not sexually active, persons with a nonbinary gender identity with different treatment necessities, and transgender young adults who did not receive GAT. Fourth, future research on sexuality should include the mental health status of young people. Finally, individuals participated in our study only 1 year after surgery. It would be of great interest to conduct a longer-term follow-up study to learn about transgender adults' romantic relationships, sexuality, parenthood, and fertility into middle adulthood.

CONCLUSIONS

This study on the sexual and romantic experiences of young transgender adults during and after early GAT reveals an increase in sexual activity after gender-affirmative surgeries. Young transgender adults seem to follow the same order of sexual experiences, from less intimate to more intimate sexual behavior, as their cisgender peers, only at later ages. After affirmative surgeries, they are less experienced than their same-aged cisgender peers. For health care practitioners working with transgender youth, it is important to address sexuality and romantic relationships with all patients.

ABBREVIATIONS

GAT: gender-affirmative treatment
GnRH: gonadotropin-releasing hormone

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ORIGINAL PAPER

Trajectories of Adolescents Treated with Gonadotropin-Releasing Hormone Analogues for Gender Dysphoria

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bstract

Gonadotropin-releasing hormone analogues (GnRHa) are recommended as initial treatment for adolescents diagnosed with gender dysphoria, providing time to follow gender identity development and consider further treatment wishes without distress caused by unwanted pubertal changes. This has been described as an extended diagnostic phase. However, there are also concerns about the physical, neurocognitive, and psychosocial effects of this treatment. In this retrospective study, we document trajectories after the initiation of GnRHa and explore reasons for extended use and discontinuation of GnRHa. Treatment was considered appropriate in 143 (67%) of the 214 adolescents eligible for GnRHa treatment by virtue of their age/pubertal status, and all started GnRHa (38 transgirls, 105 transboys; median age, 15.0 years [range, 11.1–18.6] and 16.1 years [range, 10.1–17.9]). After a median duration of 0.8 years (0.3–3.8) on GnRHa, 125 (87%) started gender-affirming hormones (GAH). Nine (6%) discontinued GnRHa, five of whom no longer wished gender-affirming treatment. Thirteen had used GnRHa for longer than required by protocol for reasons other than logistics and regularly met with a mental health professional during this time, supporting the use of GnRHa treatment as an extended diagnostic phase. In conclusion, the vast majority who started GnRHa proceeded to GAH, possibly due to eligibility criteria that select those highly likely to pursue further gender-affirming treatment. Due to the observational character of the study, it is not possible to say if GnRHa treatment itself influenced the outcome. Few individuals discontinued GnRHa, and only 3.5% no longer wished gender-affirming treatment.

Keywords Gender dysphoria · Transgender · Gonadotropin-releasing hormone analogues · Hormone treatment · Gender identity

Introduction

Increasing numbers of young people diagnosed with gender dysphoria are seen by pediatric endocrinologists. Gender dysphoria is the persistent feeling of incongruence between gender identity (sense of being a man, woman, or other) and the sex assigned at birth. The diagnosis gender dysphoria can be made if the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) criteria are met (American Psychiatric Association, 2013). The prevalence of gender dysphoria among Dutch adolescents aged 12–18 years was recently estimated to be 1 in 6300 based on numbers of adolescents seeking medical treatment, with a ratio of transboys (assigned female at birth) to transgirls (assigned male at birth) of 1.9:1 (Wiepjes et al., 2018). Genetic, hormonal, psychological, and social factors may play a role, but the exact etiology of gender dysphoria remains unknown (de Vries & Cohen-Kettenis, 2012; Hembree et al., 2017; Martinerie et al., 2018).

Gender dysphoria in prepubertal children can be expressed by dislike of their physical sex characteristics and gender incongruent behavior. In many children, gender dysphoria will not persist, but if the gender dysphoric feelings intensify during puberty, they are thought to be unlikely to subside (de Vries & Cohen-Kettenis, 2012; Hembree et al., 2017; Zucker et al., 2011). When puberty starts (Tanner genital/breast stage

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2) and gender dysphoria persists, adolescents are eligible to start with puberty suppression using gonadotropin-releasing hormone analogues (GnRHa) (Coleman et al., 2011; Hembree et al., 2017). GnRHa treatment aims to give the adolescent the opportunity to explore their gender identity and time to consider if they wish to pursue gender-affirming treatment while development of unwanted secondary sex characteristics is suppressed in order to reduce distress (Hembree et al., 2017; Zucker et al., 2011). Effects of GnRHa on pubertal development are reversible. This is in contrast to gender-affirming hormones which have largely irreversible effects on secondary sex characteristics and may compromise fertility after prolonged use (De Roo, Tilleman, T'Sjoen, & De Sutter, 2016; Hembree et al., 2017).

Short-term adverse effects of GnRHa are hot flushes at the start of the treatment and sometimes mood alterations and fatigue (Delemarre-van de Waal & Cohen-Kettenis, 2006; Hembree et al., 2017; Schagen, Cohen-Kettenis, Delemarre-van de Waal, & Hannema, 2016). Few data are available on long-term adverse effects. Bone mineral density may be affected (Klink, Caris, Heijboer, van, & Rotteveel, 2015; Vlot et al., 2017), and since puberty is an important period for brain development (Sisk & Zehr, 2005), puberty suppression with GnRHa might also influence brain development. There is a lack of studies investigating effects of GnRHa on the brain. One study examined executive function and concluded that GnRHa treatment had no detrimental effects on performance (Staphorsius et al., 2015). However, a longitudinal study among 25 adopted girls treated with GnRHa for early puberty reported a decrease in IQ from 100.2 ± 12.7 to 93.1 ± 10.5 with a significant decline of performance score during treatment, but it was concluded that the decrease in IQ was not clinically relevant (Mul et al., 2001). A limitation of the study was the lack of a control group. A second small cross-sectional study of girls treated with GnRHa because of precocious puberty found no significant difference in cognitive functioning, behavioral, and social problems compared to healthy age-matched controls, but the study did not have enough power to detect differences smaller than one standard deviation (Wojniusz et al., 2016). Wojniusz et al. did report that emotional reactivity was possibly higher in girls treated with GnRHa although these results were not conclusive. Girls with early or precocious puberty are treated at a younger age so it is unclear to what extent these results apply to adolescents treated with GnRHa for gender dysphoria. Further studies are needed to assess if and what effects GnRHa have on various aspects of brain development in adolescence.

Opinions about the use of GnRHa vary (Vrouenraets, Fredriks, Hannema, Cohen-Kettenis, & de Vries, 2015). Arguments for the use of GnRHa that have been brought forward are the benefit of early treatment with GnRHa for mental health and quality of life (de Vries, Steensma, Doreleijers, & Cohen-Kettenis, 2011). Furthermore, it gives the adolescent and treatment team more time to explore the adolescent's gender identity and treatment wishes (Hembree et al., 2017). If the adolescent pursues gender-affirming treatment, some surgeries may not be necessary or less invasive as secondary sex characteristics are less developed. Early treatment is correlated with better postsurgical outcomes, possibly because of a physical appearance more in line with the affirmed gender (Cohen-Kettenis & van Goozen, 1997; Leibowitz & de Vries, 2016). However, this may not be of equal importance to all adolescents and early puberty suppression also precludes certain surgeries such as penile inversion vaginoplasty by limiting penile growth. Some have argued that puberty-blocking treatment prevents devastating psychological and physical harms including suicide and that adolescents should therefore be able to access this treatment even without parental approval (Dembroff, 2019; Priest, 2019), but others have underscored that there is no evidence that puberty suppression prevents suicide and that the risk of suicide, although high, should not be overstated and should be seen in comparison with a clinical comparison group rather than the general population (Antommaria, Shapiro, & Conard, 2019; Baker, 2019; Zucker, 2019).

Arguments against the use of GnRHa that have been raised include possible long-term adverse effects on health, psychological, and sexual functioning (Laidlaw, Cretella, & Donovan, 2019; Richards, Maxwell, & McCune, 2019; Vrouenraets et al., 2015). Some state that adolescents may be unable to make far-reaching decisions at a young age, especially in the presence of comorbid psychiatric conditions, which are common among youth with gender dysphoria (Korte et al., 2008; Laidlaw et al., 2019; Vrouenraets et al., 2015). Furthermore, gender identity develops and may change during adolescence. Concerns have been raised that the use of GnRHa may influence this process and might increase the likelihood of persistence of gender dysphoria (Korte et al., 2008; Laidlaw et al., 2019; Richards et al., 2019; Stein, 2012; Vrouenraets et al., 2015). It is unknown if the use of GnRHa prevents resolution of gender dysphoria (Korte et al., 2008). Many prepubertal children with gender dysphoria no longer experience gender dysphoria in adolescence, and the experience of romantic and sexual attraction is thought to play an important role in this process (Steensma, Biemond, de Boer, & Cohen-Kettenis, 2011). Some may come to understand themselves as homosexual or bisexual (Steensma et al., 2011). GnRHa, by blocking sexual development, might interfere with this process (Korte et al., 2008). Another concern is that although GnRHa treatment is to be used as an extended diagnostic phase, the start of it may lead the adolescents and parents to assume that transgender outcome is the only possible outcome which may prevent exploration of other possibilities (Leibowitz & de Vries, 2016).

To gain more insight into the use of GnRHa in adolescents with gender dysphoria, the current study aims to document trajectories after the initiation of GnRHa, i.e., discontinuation

of GnRHa, prolonged use of GnRHa, and initiation of gender-affirming hormones; to investigate the duration of GnRHa treatment; and to explore reasons for extended use and discontinuation of GnRHa.

Method

Participants

This is a single-center retrospective study. Out of 269 children and adolescents registered at the Curium-Leiden University Medical Centre gender clinic in Leiden, the Netherlands, 214 were pubertal and within the appropriate age range for treatment at our pediatric clinic. Out of these, 143 (67%) had started GnRHa treatment between November 2010 (when the clinic first started) and January 1, 2018. The study population consisted of these 143 adolescents (38 transgirls, 105 transboys). Not included in the study were children and adolescents in whom gender dysphoria was not diagnosed ($n = 39$), those who had coexisting problems that interfered with the diagnostic process and/or might interfere with successful treatment ($n = 9$), those that did not wish hormonal treatment ($n = 4$), those in whom the diagnostic evaluation was still ongoing ($n = 10$), and those who had stopped to attend appointments ($n = 9$).

Of adolescents who had started GnRHa, treatment status as of 1 July 2019 was reviewed. If they had used GnRHa monotherapy for more than 3 months longer than minimally required before the start of gender-affirming hormones according to the local protocol (see below for description of the treatment protocol), the reason for this was noted. The 3 months was chosen to select those who may have had a prolonged diagnostic phase rather than those in whom gender-affirming hormone therapy started slightly later due to logistical issues such as rescheduling of an appointment. Adolescents who had started GnRHa treatment and had stopped this treatment were included in a detailed review. Baseline characteristics such as age and gender and data on the start, duration, and discontinuation of treatment were recorded from the medical files, as well as reasons given for the discontinuation of GnRHa treatment and the adolescents' and parents' views on the treatment.

Procedure

Before the start of GnRHa treatment, all adolescents had a diagnostic evaluation by a pediatric endocrinologist and mental health professional (MHP) to confirm the diagnosis of gender dysphoria according to the DSM-5 criteria (American Psychiatric Association, 2013), to assess the presence of any medical, psychiatric, or psychosocial problems that might interfere with treatment, to assess if the adolescent was able to give informed consent for the treatment and to confirm that puberty had started, as recommended by current guidelines (Hembree et al., 2017). This evaluation usually consisted of approximately six visits (more if necessary) of the adolescent with an MHP in 6–12 months in addition to interviews with parents/guardians. All adolescents gave written informed consent for the treatment. Informed consent from parents/guardians was also required if the adolescent was < 16 years old. After the start of GnRHa treatment, follow-up visits were scheduled with the pediatric endocrinologist and MHP, usually every 3 months in the first year and every 3–6 months thereafter, to evaluate satisfaction with the treatment, adequacy of puberty suppression, and any side effects. In the case of mental health issues (psychiatric morbidity but also issues such as difficulty to express oneself and doubts about one's gender identity), adolescents were either seen more frequently by the psychologist of the gender team or referred to a local MHP for therapy.

According to the local protocol, adolescents were eligible for gender-affirming hormone treatment from the age of 16 years and after at least 6 months of GnRHa treatment. No maximum time of use of GnRHa was defined in the protocol. From 2016, adolescents who had already been treated with GnRHa for at least 3 years were eligible for gender-affirming hormone treatment from the age of 15 years. From 2017, those who had been treated with GnRHa for at least 2 years and were 15 years old were eligible. Before the start of gender-affirming hormones, evaluation by a MHP and pediatric endocrinologist took place to assess the indication, any contraindications, and ability to give informed consent for this treatment. If adolescents had discontinued GnRHa treatment, there was a follow-up appointment at which adolescents and parents were asked about current feelings regarding gender identity and how they looked back on the treatment.

Results

During the study period, 143 adolescents started GnRHa treatment (38 transgirls, 105 transboys). Median age at the start of treatment was 15.0 years (range, 11.1–18.6 years) in transgirls and 16.1 years (range, 10.1–17.9 years) in transboys. Of these adolescents, 125 (87%, 36 transgirls, 89 transboys) subsequently started treatment with gender-affirming hormones after 1.0 (0.5–3.8) and 0.8 (0.3–3.7) years of GnRHa treatment (see Fig. 1). Median age at the start of gender-affirming hormones was 16.2 years (range, 14.5–18.6 years) in transgirls and 17.1 years (range, 14.9–18.8 years) in transboys. Five adolescents who used GnRHa had not started gender-affirming hormones at the time of data collection, because they were not yet eligible for this treatment due to their age. At the time of data collection, they had used GnRHa for a median duration of 2.1 years (1.6–2.8). Six adolescents had been referred to a gender clinic elsewhere for further treatment. One of these was

17 years old and eligible for gender-affirming hormones but initially indicated he needed more time to decide about testosterone treatment and subsequently stated that he wished to delay the start of this treatment until after his school examinations. The other five were not eligible yet due to their age at the time of referral. Nine had discontinued GnRHa treatment (see below), one of whom restarted GnRHa after 5 months. This individual and two others subsequently started gender-affirming hormone treatment (Fig. 1).

Prolonged Use of GnRHa

Twenty adolescents (3 transgirls and 17 transboys) had used GnRHa for longer than minimally required by protocol. One was the transboy mentioned above who needed more time to decide about testosterone treatment. He had used GnRHa for 2.5 years when he was referred from the pediatric clinic to a clinic for adults elsewhere. The other 19 adolescents had subsequently started gender-affirming hormones. The median duration of GnRHa monotherapy in these 19 adolescents was 1.0 year (0.8–2.4). Reasons for prolonged use of GnRHa were (sometimes there was more than one reason): unstable situation due to family issues such as lack of parental support and/or acceptance of gender dysphoria ($n=6$) or social problems such as lack of a safe home, excessive school absenteeism ($n=5$); (psychiatric) comorbidity ($n=8$) such as autism or depression; more time needed for decision about gender-affirming hormone treatment by the adolescent ($n=1$) or for further diagnostics by the gender team ($n=1$, because of non-binary aspects); and logistic issues such as missed/rescheduled appointments ($n=8$; in 7 this was the only reason). The 11 adolescents who received prolonged GnRHa treatment because of mental health and/or psychosocial problems had regular (approximately monthly on average) appointments with a psychologist at the gender clinic ($n=5$) and/or received support from a local MHP ($n=9$) during this period.

Discontinuation of GnRHa Treatment

From the 143 adolescents who started GnRHa treatment, nine (6%; one transgirl, eight transboys) stopped this treatment after a median duration of 0.8 years (0.1–3.0), at a median age of 15.0 years (13.4–18.9). Four individuals discontinued although they did wish further endocrine treatment because of gender dysphoria. One stopped treatment because of an increase in mood problems and suicidal thoughts and confusion attributed to GnRHa treatment and restarted treatment (gender-affirming hormone treatment) at an adult gender clinic elsewhere. He later indicated: "I was already fully matured when I started GnRHa, menstruations were already suppressed by contraceptives. For me, it had no added value" (transboy, age 19 years).

Another transboy experienced hot flushes, an increase in migraine, and had fear of injections in addition to stress due to problems at school and unrelated medical issues and therefore wished to temporarily discontinue GnRHa treatment after 4 months. He restarted 5 months later and subsequently started testosterone treatment. A third transboy experienced mood swings starting 4 months after he had begun GnRHa treatment. A year later, he started to frequently feel unwell and miss school. After 2.2 years, he developed severe nausea and rapid weight loss for which no cause was identified. Because of this deterioration of his general condition, he wished to discontinue GnRHa treatment after 2.4 years. He gradually recovered over the next 2 years. He subsequently started lynestrenol and testosterone treatment. The last adolescent had stopped GnRHa because his parents were unable to regularly collect medication from the pharmacy and take him to appointments for the injections. He subsequently started lynestrenol to suppress menses; he is not eligible yet for testosterone treatment.

The five others (3.5%) no longer wished gender-affirming treatment. One adolescent had been very distressed about breast development at the start of GnRHa. She later thought

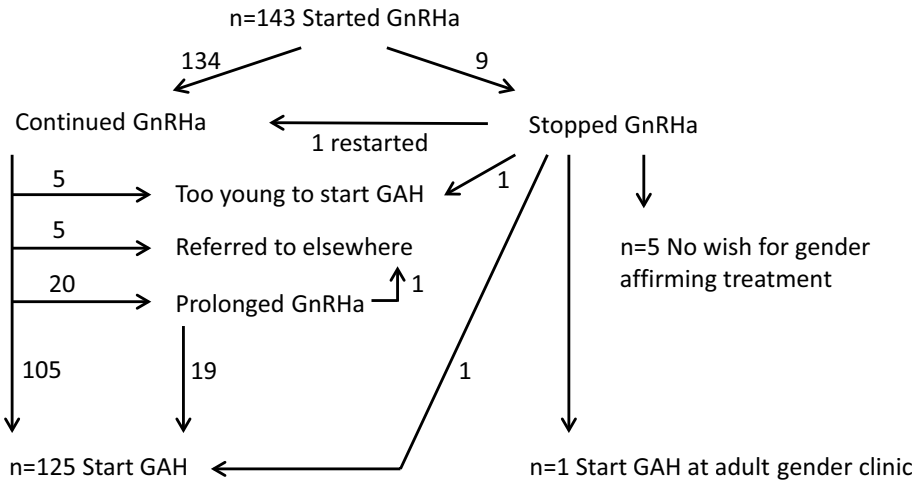

Fig. 1 Flow chart showing the trajectories of adolescents who started GnRH analogue (GnRHa) treatment. *GAH* gender-affirming hormone treatment

that she might want to live as a woman without breasts. She did not want to live as a boy and did not wish testosterone treatment and decided to discontinue GnRHa although she dreaded breast development and menstruation. Another adolescent had concurrent psychosocial problems interfering with the exploration of gender identity and did not currently wish treatment. When looking back on GnRHa treatment this individual said: "The decision to stop GnRHa to my mind was made by the gender team, because they did not think gender dysphoria was the right diagnosis. I do still feel like a man, but for me it is okay to be just me instead of a he or a she, so for now I do not want any further treatment" (adolescent assigned female sex at birth, age 16 years).

One adolescent felt more in between man and woman and therefore did not wish to continue treatment: "At the moment, I feel more like 'I am' instead of 'I am a woman' or 'I am a man'" (adolescent assigned female sex at birth, age 16 years).

Another individual made a social transition while using GnRHa and shortly afterward decided to discontinue treatment. He indicated that he had fallen in love with a girl and had never had such feelings, which made him question his gender identity. At subsequent visits, he indicated that he was happy living as a man.

The last adolescent stated: "After using GnRHa for the first time, I could feel who I was without the female hormones, this gave me peace of mind to think about my future. It was an inner feeling that said I am a woman" (adolescent assigned female sex at birth, age 18 years).

The adolescents and parents were also asked about their views on GnRHa in the treatment protocol for gender dysphoria. All of them saw it as the first step in treatment, but it was also clear that it was used as an extended diagnostic phase. They all felt free to stop GnRHa. They had varying visions on the role of GnRHa in the treatment of gender dysphoria. Some stated it gave them time to think and feel who they were and what they wanted in the future and felt that without GnRHa treatment they would not have been able to make these decisions. Others stated that GnRHa should not be routinely offered before the start of gender-affirming hormones when adolescents are already fully matured, because of the lack of physical benefits. Instead, a consideration time of 6 months with psychological follow-up was suggested.

Discussion

The great majority of adolescents who started GnRHa subsequently started gender-affirming hormones as soon as they were eligible for this treatment. Very few discontinued treatment, although slightly more than in previous studies in which cohorts of transgender adolescents were described. Out of 333 adolescents that had started puberty suppression at the VUmc gender clinic in the Netherlands up until December 2015, 1.9% stopped; reasons for discontinuation of GnRHa were not reported (Wiepjes et al., 2018). In the Canadian study by Khatchadourian, Amed, and Metzger (2014), one of 27 individuals who started GnRHa stopped the treatment due to emotional lability, not because the wish to pursue transition had subsided. In the current study, 6% of those who started GnRHa discontinued and 3.5% no longer wished gender-affirming treatment.

Several studies reviewed by Ristori and Steensma (2016) have found that much higher percentages (61–98%) of prepubertal children no longer experience gender dysphoria ("desist") as adolescents. The period between 10 and 13 years seems to be a crucial period in which social changes (for example starting secondary school), the physical changes of puberty, and first romantic and sexual experiences may lead to either an increase or a decrease/resolution of gender dysphoria (Steensma et al., 2011). The adolescents that start GnRHa treatment have entered puberty and are mostly older than 13 years and may be past this critical period so that gender dysphoria may be more likely to persist. This may explain the lower percentage of resolution of gender dysphoria found in the studies of treated adolescents. In addition, the groups that started treatment in previous studies and in the current study consisted of selected adolescents that had had an extensive diagnostic process to establish if they met the eligibility criteria for treatment as well as the diagnostic criteria for gender dysphoria (Wiepjes et al., 2018). Alternatively, concerns have been raised that GnRHa treatment itself may increase the chances of persistence of gender dysphoria (Korte et al., 2008; Richards et al., 2019; Stein, 2012; Vrouenraets et al., 2015). Whether or not GnRHa treatment influenced gender identity development cannot be concluded from the current study due to its observational nature. The study does show that gender identity development was not suppressed in all, as a few adolescents discontinued GnRHa because they no longer experienced gender dysphoria, but it is unknown if gender dysphoria would have subsided in more adolescents in the absence of GnRHa treatment.

For one adolescent, the experience of falling in love made him doubt whether he was transgender. This is in line with previous findings that the first romantic experiences and the awareness of one's sexual attraction play an important role in the resolution of gender dysphoria in adolescents (Steensma et al., 2011). This emphasizes the importance of this topic in the diagnostic evaluation. However, some adolescents may not have had any romantic or sexual experiences, especially if they present at an early age. In addition, transgender adolescents were shown to be less experienced, both sexually and romantically, compared to peers from the general population (Bungener, Steensma, Cohen-Kettenis, & de Vries, 2017). GnRHa treatment prevents the physical changes of puberty and is known to negatively affect sexual desire (Plosker & Brogden, 1994). Puberty suppression might thus decrease the chances of adolescents having romantic and sexual

experiences which might in turn influence gender identity development (Korte et al., 2008). This was not true for the adolescent in the current study who fell in love while using GnRHa and then decided to discontinue treatment, but it is uncertain if more adolescents would have had such experiences if they had not used GnRHa.

Two individuals who discontinued GnRHa indicated that they did not feel either male or female. A non-binary gender identity appears to be becoming more common among adolescents presenting at gender clinics (Butler, De Graaf, Wren, & Carmichael, 2018). For these adolescents, it may be more difficult to find out and understand their own gender identity and it is unclear what constitutes optimal care for this group.

Experienced side effects played a role in the decision to discontinue GnRHa treatment in three adolescents. However, for none of the adolescents who stopped GnRHa in the current study, were potential long-term side effects a reason to decline or discontinue GnRHa treatment. Lack of information about long-term effects of GnRHa use was not considered an important problem by interviewed adolescents with gender dysphoria in the study by Vrouenraets, Fredriks, Hannema, Cohen-Kettenis, and de Vries (2016), but is seen as a major problem by many professionals (Vrouenraets et al., 2015).

In the current study, 13 adolescents who were eligible for gender-affirming hormone treatment used GnRHa monotherapy for longer than the minimum time required by protocol for reasons other than logistics. During this time, they received mental health support from a local MHP or from a psychologist from the gender team. This supports the idea that the time on GnRHa is used as an extended diagnostic phase where the adolescents can further explore their gender identity and treatment wishes and work on issues that might interfere with successful treatment. The great majority started gender-affirming hormones as soon as was possible within the treatment protocol, after a median duration of approximately one year. This does not mean that for them this time was not used as an extended diagnostic phase. Those who were youngest at the start of GnRHa were treated the longest, up to 3.8 years, with visits to the clinic every 3–6 months. In this period of growing up, becoming more independent, and discovering oneself, their development was followed by the team and discussed in relation to the treatment. Older adolescents, who presented after age 16 years, were often treated with GnRHa for the minimum period of 6 months. Generally, they were more mature than the younger adolescents at the start of the diagnostic process and many already had clear ideas about their treatment wishes. In adults, gender-affirming hormones are usually started directly after the diagnostic phase (Wiepjes et al., 2018).

The period of puberty suppression used in adolescents is considered worthwhile by some of the adolescents, as the individual in the current study who indicated it gave peace of mind to think about the future. On the other hand, some postpubertal adolescents perceived little benefit of the treatment, as stated by one transboy who discontinued GnRHa in the current study. A possible benefit of GnRHa treatment for fully matured transgender boys may be the suppression of menstrual bleeding. Alternative methods may be used to achieve this, although GnRHa are more effective than progestins to immediately and fully suppress menstruation (Tack et al., 2016). Furthermore, many adolescents do not wish to use continuous oral contraceptives because of the fact that they contain "female" hormones and because of fear that breast size may increase. Adolescents should be counseled on all available treatment options and their (side) effects so that they can make an informed choice.

The relatively small size of the cohort that was described is a limitation of the current study as well as its retrospective character. The duration of follow-up was limited, and in some of the adolescents who stopped GnRHa treatment because they no longer experienced gender dysphoria, gender dysphoria might recur later in life. The observational design does not allow conclusions about any possible effect of GnRHa treatment on gender identity development. A randomized controlled trial in adolescents presenting with gender dysphoria, comparing groups with and without GnRHa treatment, could theoretically shed light on the effect of GnRHa treatment on gender identity development. However, many would consider a trial where the control group is withheld treatment unethical, as the treatment has been used since the nineties and outcome studies although limited have been positive (de Vries et al., 2014; Smith, van Goozen, & Cohen-Kettenis, 2001). In addition, it is likely that adolescents will not want to participate in such a trial if this means they will not receive treatment that is available at other centers. Mul et al. (2001) experienced this problem and were unable to include a control group in their study on GnRHa treatment in adopted girls with early puberty because all that were randomized to the control group refused further participation. An alternative approach that has been suggested to gain more insight into the effect of treatment on gender identity development is to collect baseline data at the time of referral from adolescents who are on a long waiting list for diagnostic evaluation and treatment and compare the percentage of these adolescents in whom gender dysphoria is still present after a certain period of time to that in adolescents on GnRHa treatment (Zucker, 2019).

In conclusion, this study shows that a small number of adolescents discontinued GnRHa treatment because they no longer wished gender-affirming treatment. This indicates that not all adolescents and parents assume that transgender outcome is the only possible outcome and shows that gender identity can still fluctuate when using GnRHa, at least in some adolescents. However, gender dysphoria subsided in a small number of adolescents and it is uncertain if this would have been different without GnRHa treatment. Some

adolescents used GnRHa for a prolonged period before starting gender-affirming hormones while regularly meeting with an MHP which is consistent with the use of GnRHa treatment as an extended diagnostic phase. The great majority who had started GnRHa treatment continued with gender-affirming hormones. It is important to take this into account when counseling adolescents who consider this treatment and their parents.

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Compliance with Ethical Standards

Conflict of interest MC de Vries and SE Hannema have received a lecture fee from Ferring. The other authors have nothing to declare.

Ethical Approval The study is part of an observational study on the effects of hormonal treatment in adolescents with gender dysphoria which was approved by the local medical ethical committee.

Informed Consent Adolescents who were included in the detailed review gave informed consent for the use of their data for this study, as well as their parents/guardians for adolescents younger than 16 years.

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An Evidence-Based Critique of "The Cass Review" on Gender-affirming Care for Adolescent Gender Dysphoria

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Introduction

In 2020, the United Kingdom's National Health Service (NHS) commissioned an inquiry to provide recommendations for the healthcare of transgender adolescents. This process was overseen by a pediatrician named Dr. Hillary Cass and reached completion in April 2024. The final product is a 388-page report called the "Cass Review,"[1] (henceforth "the Review") and is accompanied by seven systematic reviews conducted by authors affiliated with the University of York (henceforth "the York SRs").[2]

[1] The Cass Review, Final Report: Independent Review of Gender Identity Services for Children and Young People, April 2024, at https://cass.independent-review.uk/wp-content/uploads/2024/04/CassReview_Final.pdf

[2] Taylor J, Hall R, Langton T, et al. Care pathways of children and adolescents referred to specialist gender services: a systematic review. Archives of Disease in Childhood Published Online First: 09 April 2024. doi: 10.1136/archdischild-2023-326760; Taylor J, Hall R, Langton T, et al. Characteristics of children and adolescents referred to specialist gender services: a systematic review. Archives of Disease in Childhood Published Online First:

As researchers and pediatric clinicians with experience in the field of transgender healthcare, we read the Review with great interest. The degree of financial investment and time spent is impressive. Its ability to publish seven systematic reviews, conduct years' worth of focus groups and deeply investigate care practices in the UK is admirable. We hoped it would improve the public's awareness of the health needs of transgender youth and galvanize improvements in delivery of this care. Indeed, statements of the Review favorably describe the individualized, age-appropriate, and careful approach recommended by the World Professional Association for Transgender Health (WPATH) and the Endocrine Society.[3] Unfortunately, the Review repeatedly misuses data and violates its own evidentiary standards by resting many conclusions on speculation. Many of its statements and the conduct of the York SRs reveal profound misunderstandings of the evidence base and the clinical issues at hand. The Review also subverts widely accepted processes for development of clinical recommendations and repeats spurious, debunked claims about transgender identity and gender dysphoria. *These errors conflict with well-established norms of clinical research and evidence-based healthcare. Further, these errors raise serious concern about the scientific integrity of critical elements of the report's process and recommendations.*

In the short time since its release, the Review has been used to justify restrictions on healthcare for transgender youth. In March 2024, the NHS announced that it would deny puberty-pausing medications to those under age 18 outside of a research setting.[4] In June 2024, the NHS Health Secretary cited the Review as the rationale for emergency regulations that criminalize the supply of puberty-pausing medications to new patients under 18 in England, Scotland, or Wales.[5] This ban, which applies only to the treatment of gender dysphoria, labeled these medications as a

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[3] Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. 2022 Sep 6;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644. PMID: 36238954; PMCID: PMC9553112.; Hembree WC, Cohen-Kettenis PT, Louis Gooren L, et al. Endocrine Treatment of Gender Dysphoric/Gender Incongruent Persons: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 102, Issue 11, 1 November 2017, Pages 3869–3903, https://doi.org/10.1210/jc.2017-01658

[4]https://www.nhs.uk/conditions/gender-dysphoria/treatment/

[5]https://www.gov.uk/government/news/new-restrictions-on-puberty-blockers#:~:text=The%20government%20has%20today%20introduced,June%20to%203%20September%202024.

"serious danger to health." These medications remain freely available for other pediatric health needs, of which precocious puberty, endometriosis, and fertility preservation prior to chemotherapy are some.[6]

The Cass Review has already been cited in U.S. legal battles over transgender rights.[7] It is likely to feature heavily in the months and years to come. From 2022 through 2024, twenty-five US states enacted legislation that bans gender-affirming healthcare for transgender youth. Litigation is ongoing in at least ten states, and the nation's highest court has agreed to hear one case, *United States v Skrmetti*, in the fall 2024 term. Other nations' health ministries are anticipated to use the Cass Review to inform their own policies on access to youth gender care.[8]

Amongst our author group, we have 86 years of experience in caring for more than 4800 transgender youth and have published 278 peer-reviewed studies, 168 of which are in the field of gender-affirming care. The holistic care that the clinicians among us provide is rooted in decades of research; it is not controversial in the world-class pediatric health centers where we practice. The research we conduct is ethical and valued by our peers in medicine and epidemiology. We can also speak to how the evidence informs the positive clinical outcomes that our patients experience.

We produced this report to emphasize the Review's key tenets, to bring the critical yet buried findings to the forefront, and to provide evidence-informed critiques where merited. The transparency and expertise of our group starkly contrast with the Review's authors. Most of the Review's known contributors have neither research nor clinical experience in transgender healthcare. The Review incorrectly assumes that clinicians who provide and conduct research in transgender healthcare are biased. Expertise is not considered bias in any other realm of science or medicine, and it should not be here. Further, many of the Review's authors' identities are unknown.[9] Transparency and trustworthiness go hand-in-hand, but many of the Review's authors cannot be vetted for ideological and intellectual conflicts of interest.

Our concerns about the Cass Review reflect the politicized context for transgender healthcare, especially for youth. Transgender people of all ages face a critical inflection point in the UK and across the globe today. If politics continue to interfere with transgender healthcare, clinical services and research in this field may not recover. Peoples' lives will be drastically—and needlessly—upended. Further, the politicization of healthcare is a concern not just for transgender people, but for all people. Every person deserves the opportunity to make private and

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[6] https://www.legislation.gov.uk/uksi/2024/727/made

[7] Poe v Labrador, https://www.supremecourt.gov/DocketPDF/23/23A763/300889/20240220100700247_Poe%20v%20Labrador%20SCOTUS%20Application%20for%20Stay.pdf

[8] https://www.biobiochile.cl/noticias/nacional/chile/2024/05/29/pubertad-interrumpida-ninos-trans-inician-tratamiento-hormonal-en-medio-de-controversias.shtml

[9] Following the completion of the "research programme" by the University of York, "A Clinical Expert Group (CEG) was established by the Review to help interpret the findings" (p 26), defined as "clinical experts on children and adolescents in relation to gender, development, physical and mental health, safeguarding and endocrinology" (p 62). There is no further information about the qualifications of the members of the CEG, nor how they were selected.

deeply personal medical decisions in consultation with healthcare providers whose work is guided by sound evidence, appropriate training, and clinical expertise.

With these stakes in mind, the medical community, policymakers, and the media must understand what the Review is and what it is not. *It is* an important document for those considering the availability of health services for transgender young people in the UK. *It is* an attempt to engage many parties, some of whom have ideological opinions that conflict with medical consensus. *It is not* an authoritative guideline or standard of care, nor is it an accurate restatement of the available medical evidence on the treatment of gender dysphoria. *It is not* an effective framework for enhancing clinical services for a marginalized group of people. *Foremost, it is not an endorsement of a ban on medical care for transgender youth.*

Executive Summary:

Section 1: The Cass Review makes statements that are consistent with the models of gender-affirming medical care described by WPATH and the Endocrine Society. The Cass Review does not recommend a ban on gender-affirming medical care.

Section 2: The Cass Review does not follow established standards for evaluating evidence and evidence quality.

Section 3: The Cass Review fails to contextualize the evidence for gender-affirming care with the evidence base for other areas of pediatric medicine.

Section 4: The Cass Review misinterprets and misrepresents its own data.

Section 5: The Cass Review levies unsupported assertions about gender identity, gender dysphoria, standard practices, and the safety of gender-affirming medical treatments, and repeats claims that have been disproved by sound evidence.

Section 6: The systematic reviews relied upon by the Cass Review have serious methodological flaws, including the omission of key findings in the extant body of literature.

Section 7: The Review's relationship with and use of the York systematic reviews violates standard processes that lead to clinical recommendations in evidence-based medicine.

Section 1: The Cass Review makes statements that are consistent with the models of gender-affirming medical care described by WPATH and the Endocrine Society. The Cass Review does not recommend a ban on gender-affirming medical care.

The Review concurs with the WPATH Standards of Care and the Endocrine Society Clinical Practice Guidelines that: (1) medical care is appropriate for some transgender youth, (2) a holistic, comprehensive, and individualized assessment is needed, and (3) co-occurring mental health conditions should be properly treated before medically affirming interventions. The

Review also cites a York SR that favorably appraises the WPATH Standards of Care 8 and the 2017 Endocrine Society Clinical Practice Guidelines.[10] Exemplary quotes from the Review and the Guidelines in each of these areas appear in Table 1.

The Review *does not* conclude that gender-affirming medical care for adolescent gender dysphoria should be banned. Thus, it should not be cited in support of bans on medical treatments for gender dysphoria. Rather, the Review favorably describes the provision of individualized, evidence-informed clinical care, including robust assessments of the various medical and non-medical domains of support that an adolescent may require.

Agreement that certain youth with gender dysphoria benefit from medical care

The Review explicitly notes that, "for some, the best outcome will be transition" (p 21) while also acknowledging, as the WPATH Standards of Care and the Endocrine Society Clinical Practice Guidelines do, that gender-affirming medical interventions are not appropriate for all transgender adolescents. This is an essential point, as many who criticize this care inappropriately contend that medical consensus endorses medical transition for any minor seeking care. The Review states, and indeed WPATH and the Endocrine Society agree, that "there should be a clear rationale for providing hormones at this stage rather than waiting until an individual reaches 18." (p 187)

While the Review contains some non-technical language regarding gender-affirming medical interventions, it is essential to note that this language is followed by recommendations to conduct thoughtful, cautious assessments prior to considering medical care, rather than banning care or not providing it altogether.

Agreement on the need for a holistic, comprehensive, and individualized assessment and treatment plan

The WPATH Standards of Care and the Endocrine Society Clinical Practice Guidelines emphasize that an individualized, comprehensive biopsychosocial evaluation should be conducted prior to gender-affirming medical interventions during adolescence.[5,6] These assessments involve a careful evaluation of a young person's gender history, social supports, fertility considerations, and co-existing mental health challenges, among a broad range of other topics.[11]

The Review reads: "When conducting an assessment, it will be important that clinicians are mindful that presentations, pathways and outcomes for this cohort are very individual, and the focus needs to be on helping each person find the best pathway for them. Assessments should be

[10] The Review produces data that rates the WPATH Standards of Care 8 and the 2017 Endocrine Society Clinical Practice Guidelines among the top five of 23 analyzed documents (p 129), using the AGREE II tool. Further, the Review appraises these guidelines as particularly high in the areas of "rigor of development" and "editorial independence."

[11] Turban, J. L., Thornton, J., & Ehrensaft, D. (2024). Biopsychosocial Assessments for Pubertal Suppression to Treat Adolescent Gender Dysphoria. Journal of the American Academy of Child and Adolescent Psychiatry, S0890-8567.

respectful of the individual's experience and be developmentally informed." (p 28) The Review highlights that the assessment process should include, "co-develop[ing] a plan for addressing gender issues, which may involve any combination of social, psychological and physical interventions." This widely used approach aims to create a comprehensive support plan that may involve non-medical and/or medical interventions, depending on the clinical scenario.

Agreement that optimized treatment of co-occurring mental health conditions is essential

WPATH and the Endocrine Society consistently highlight that comprehensive care for transgender youth includes optimal treatment of any other mental health conditions, with appropriate evidence-informed medical and/or non-medical interventions.[5, 6] The Review states, as youth gender experts would agree, "for those young people for whom a medical pathway is clinically indicated, it is not enough to provide this without also addressing wider mental health and/or psychosocially challenging problems such as family breakdown, barriers to participation in school life or social activities, bullying and minority stress." (p 30) There is no evidence that co-occurring mental health conditions cause a person to adopt a transgender identity, nor is there evidence to support that treatment of co-occurring mental health disorders ameliorates the core symptoms of gender dysphoria. Individual patients require treatment plans that are tailored to the diagnoses made by qualified professionals.

Table 1: Shared core principles between the Cass Review, the Endocrine Society Clinical Practice Guidelines and WPATH's Standards of Care 8[12]	
Agreement that certain youth with gender dysphoria will benefit from medical aspects of gender-affirming care	Cass Review: "The skills of those working within the service need to reflect the broad and varied needs of this heterogeneous group and the service needs to include the appropriate skill mix to support both individuals for whom medical intervention is clinically indicated and those for whom it is not." (p 37) Endocrine Society: "We suggest that adolescents who meet diagnostic criteria for GD [gender dysphoria]/gender incongruence, fulfill criteria for treatment, and are requesting treatment should initially undergo treatment to suppress pubertal development." (p 3871) WPATH SOC 8: "For example, some youth will realize they are transgender or more broadly gender diverse and pursue steps to present accordingly. For some youth, obtaining gender-affirming medical treatment is important while for others these steps may not be necessary. For example, a process of exploration over time might not result in the young person self-affirming or embodying a different gender in relation to their assigned sex at birth and would not involve the use of medical interventions." (p S51)
Agreement regarding the need for a holistic, comprehensive, and individualized assessment and treatment plan	Cass Review: "When conducting an assessment, it will be important that clinicians are mindful that presentations, pathways and outcomes for this cohort are very individual, and the focus needs to be on helping each person to find the best pathway for them. Assessments should be respectful of the individual's experience and be developmentally informed." (p 28) Endocrine Society: "Gender-affirming treatment is a multidisciplinary effort. After evaluation, education, and diagnosis, treatment may include mental health care, hormone therapy, and/or surgical therapy" (p 3871) WPATH SOC 8: "We recommend health care professionals involve relevant disciplines, including mental health and medical professionals, to reach a decision about whether puberty suppression, hormone initiation, or gender-related surgery for gender diverse and transgender adolescents are appropriate and remain indicated throughout the course of treatment until the transition is made to adult care" (p S48)
Agreement that optimized treatment of co-occurring mental health conditions is essential	Cass Review: "Standard evidence based psychological and psychopharmacological treatment approaches should be used to support the management of the associated distress and co-occurring conditions. This should include support for parents/carers and siblings as appropriate" (p 31) Endocrine Society: "Adolescents are eligible for GnRH agonist [and subsequent sex hormone] treatment if: any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment." (p 3878) WPATH SOC 8: "We recommend health care professionals assessing transgender and gender diverse adolescents only recommend gender-affirming medical or surgical treatments requested by the patient when… the adolescent's mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and/or gender-affirming medical treatments have been addressed." (p S48)

[12] While not a guideline, the American Academy of Pediatrics (AAP) Practice Statement on Gender Affirming Care is often referenced by policymakers and the media. Its core themes also align with the areas discussed in Table 1. For instance, "The decision of whether and when to initiate gender-affirmative treatment is personal and involves careful consideration of risks, benefits, and other factors unique to each patient and family." and "Many protocols suggest that clinical assessment of youth who identify as TGD is ideally conducted on an ongoing basis in the

The Review's statements often conflict with its own recommendations

The Review's statements and its recommendations often diverge. For a document that offers guidance on clinical care, this internal inconsistency is highly unusual. Acknowledgment that certain youth may benefit from medically affirming interventions is undercut by the Review's recommendation to limit care to a nonexistent clinical trial framework that it proposes but does not describe. Discussion of the need for an individualized assessment is eclipsed by a call for all youth to be a certain age before they may obtain guideline-recommended care. Agreement with WPATH and the Endocrine Society on optimal treatment of co-occurring mental health conditions is disingenuous when, in later pages, the Review speculates, without evidence, about the possibility of gender dysphoria emerging as a result of mental illness,[13] pornography consumption,[14] neurodiversity,[15] social media, and peer influence.[16]

While the Review's narrative statements often concur with existing evidence-based standards in the field of transgender health, its recommendations—which actually impact people's access to care—discard these standards and conflict with medical consensus.

Section 2: The Cass Review does not follow established standards for evaluating evidence and evidence quality.

The Review casually discusses evidence quality and does not define it, contravening standard practice in scientific evaluations of medical research. Here, we compare the Review's approach with one of the most widely accepted frameworks for determining evidence quality: Grading of Recommendations Assessment, Development and Evaluation (GRADE).[17] According to

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setting of a collaborative, multidisciplinary approach, which, in addition to the patient and family, may include the pediatric provider, a mental health provider (preferably with expertise in caring for youth who identify as TGD), social and legal supports, and a pediatric endocrinologist or adolescent-medicine gender specialist, if available." (p 5)

[13] p 117 "…in the same way that distress can manifest through eating disorders or depression, it could also show itself through gender-related distress."

[14] The Review cites a commentary supposing that pornography consumption drives youth to be transgender. This article was written by an individual from an organization with an ideological rather than scientifically informed perspective on gender identity. That organization, Therapy First, advocates for a singular approach to everyone who expresses gender diversity and pathologizes non-cisgender identity. Nadrowski, K. (2023). A New Flight from Womanhood? The Importance of Working Through Experiences Related to Exposure to Pornographic Content in Girls Affected by Gender Dysphoria. Journal of Sex & Marital Therapy, 50(3), 293–302. https://doi.org/10.1080/0092623X.2023.2276149

[15] Of the York SR on care pathways, Grijseels writes: "Notably, they wrongly report the incidence of autism spectrum condition (ASC) as reported by Morandini et al., writing "[o]ne study reported data separately for 2012 and 2015 and demonstrated an increase from 1.8% to 15.1%" (Taylor et al., p. 5), when the reported numbers were a non-significant increase from 13.8% to 15.1% (p= .662) (Morandini et al.)." Grijseels, D. M. (2024). Biological and psychosocial evidence in the Cass Review: a critical commentary. *International Journal of Transgender Health*, 1–11. https://doi.org/10.1080/26895269.2024.2362304

[16] Page locations where the Review speculates causes of gender dysphoria: mental illness (p 30, 85, 91, 111, 117), pornography (p 110), neurodiversity (p 308, 309, 311), social media (p 117), and peer influence (p 27, 104, 106, 117, 120, 122).

[17] This is the only evidence grading system that uses quality terminology to our knowledge and is widely respected in the medical community. It was also used by both the Endocrine Society and WPATH in developing the guidelines. The Review describes GRADE (p 55) but does not state that it used this method, or any other method, to

GRADE, *well-conducted* randomized controlled trials (RCTs) and systematic reviews (SRs) are typically considered the highest-quality form of evidence. Observational studies rarely meet the criteria to be considered high quality evidence,[18] and yet they supply most of the evidence that guides clinical care across all fields of medicine.

As the drafters of the GRADE framework have explicitly acknowledged, evidence and its quality are one of many considerations in caring for patients.[19] Clinical practice guidelines throughout medicine consider all relevant factors, but the Review takes the unusual step of elevating its own assessment of evidence quality above the considerations that guideline developers value. The Review also uses misleading, subjective terminology and misuses technical language regarding evidence quality. In any other field of medicine, this practice would be deemed unacceptable and harmful to patients.

The Review's discussion of evidence quality is scientifically unsound

Under GRADE, quality designations such as "high," "moderate," "low," and "very low" are used to describe evidence.[10] There is a shared understanding of what these terms mean in medical science, which allows experts to use them in developing clinical recommendations for broad application.

The Review introduces GRADE (p 55) but never evaluates the evidence using the GRADE framework. The Review borrows GRADE terminology in repeatedly expressing a desire to see "high quality" evidence dominate the field of transgender health. Thus, the Review falls seriously short in not describing or applying a formal method for assigning evidence quality.

Thus, the Review speaks a language that may seem familiar, but its foundations are pseudoscientific and subjective. For instance, unscientific evidence quality descriptors such as "weak" and "poor" were identified 21 times and 10 times respectively.[20] The Review's reliance on such ambiguous terms leads readers to draw their own conclusions, which may not be scientifically informed. Such terms also undermine the rigor of the actual research, which presents much more nuanced findings than subjective descriptors convey.

The Review fixates on evidence quality to the exclusion of many other factors that are rigorously considered by the developers of clinical practice guidelines

In developing guidelines that provide recommendations on clinical care, panels of experts consider the evidence of a treatment's efficacy. They also consider the benefits and harms of

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appraise evidence. Guyatt GH, Oxman AD, Kunz R, et al; GRADE Working Group. What is "quality of evidence" and why is it important to clinicians? BMJ. 2008 May 3;336(7651):995-8. doi: 10.1136/bmj.39490.551019.BE. PMID: 18456631; PMCID: PMC2364804.

[18] An observational study can be deemed high quality if it shows a large effect, if biases in the study design lead to an underestimation of the treatment effect and if the effect is dose-dependent (meaning the magnitude of effect depends on the amount of intervention). This is often not the case in observational studies.

[19] Balshem H, et al., GRADE Guideline: 3. Rating the Quality, 64 J. Clin. Epidem. 401, 402-404 (2011).

[20] "Weak" or "weakness": p 13, 20, 22, 25 (twice), 31, 33, 36, 44, 47, 77, 163, 164, 184, 196, 202, 210, 222, 229, 231, and 320; "poor": p 30, 34, 114, 130 (twice), 134, 154, 179, 193, 194, and 385

both treatment and no treatment, patients' values and preferences, and the resources required to offer treatment.[21] *This is precisely why evidence quality is not synonymous with clinical recommendations.*

On the surface, it may seem perplexing that clinical care does not proceed directly from medical evidence. But if this were the case, real patients in the real world would not receive appropriate, feasible care that aligns with their preferences and values. GRADE, for instance, describes four areas that guideline developers should rigorously consider in issuing recommendations: evidence certainty and quality, balance between benefits and harms, patient values and preferences, and resource utilization. Here, we show how the Review's consideration of three of these areas is inadequate.

1. Evidence certainty and quality: The Review does not describe the positive outcomes of gender-affirming medical treatments for transgender youth, including improved body satisfaction, appearance congruence, quality of life, psychosocial functioning, and mental health, as well as reduced suicidality. *It is highly unusual for a document issuing clinical recommendations to not sufficiently describe the evidence on the effects of treatment.*
2. Balance of benefits and harms: The Review does not consider the harms of not offering gender-affirming medical care to a young person with gender dysphoria. The most concrete and tangible effect of not providing treatment is the development of permanent physical characteristics that do not align with a person's gender. These include voice deepening, hair growth, breast tissue development, final height, and body habitus. The Review ignores the significant psychological pain suffered by adolescents with gender dysphoria, for whom these permanent physical changes are highly distressing. The Review also ignores the consequences for teens who, left untreated, must present to the world a physical appearance that is at odds with their own identity. In adulthood, these physical effects can be ameliorated to some degree with costly and invasive treatments such as surgery, hair removal, and speech therapy. These treatments do not erase the intervening years of psychological distress. The Review also selectively identifies the purported harms of treatment while failing to engage with the harms of no treatment. For example, the Review theorizes that those who have been treated with puberty-pausing medications and wish to pursue vaginoplasty may have a more challenging postoperative course.[22] But the Review does not consider how puberty-pausing medications prevent development of unwanted breast tissue and can prevent the later need for mastectomy, which the most commonly sought surgery by transgender adults.[15]
3. Patient values and preferences: The Review does engage with transgender young people, but it often makes recommendations that conflict with their expressed values and preferences. The prevailing theme of the focus groups with transgender youth is that they want improved access to appropriate gender-affirming medical services from clinicians who have appropriate training and experience. They want their needs and concerns taken

[21] Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines; Graham R, Mancher M, Miller Wolman D, et al., editors. Clinical Practice Guidelines We Can Trust. Washington (DC): National Academies Press (US); 2011. Available from: https://www.ncbi.nlm.nih.gov/books/NBK209539/ doi: 10.17226/13058

[22] van de Grift TC, van Gelder ZJ, Mullender MG, et al. Timing of Puberty Suppression and Surgical Options for Transgender Youth. Pediatrics. 2020 Nov;146(5):e20193653. doi: 10.1542/peds.2019-3653. PMID: 33106340.

> seriously. *The Review completely disregards the expressed values and preferences of transgender youth in its most emphatic recommendation, which is to limit care to research settings that do not yet exist.*

The Review solicited invalid professional viewpoints

The Review conducted a series of focus groups with healthcare workers of varying backgrounds, some of whom are not even clinicians. It is not clear what the expertise of these individuals might be in the field of transgender health. Of note, 34% stated that their understanding of "gender questioning children and young people" came from the public discourse and the media. Further, 32% of respondents strongly agreed or agreed with the statement "There is no such thing as a trans child."[23,24] *Denying the existence of transgender people of any age is an invalid professional viewpoint. The involvement of those with such extreme viewpoints is a deeply concerning move for a document that issues recommendations on clinical care.* A guideline that solicits opinions from those who will not acknowledge the condition for which care is sought should not be used. These individuals may express these ideological views, but their involvement in a process that led to recommendations for clinical care is a failure of the Review.

The Review fails to recognize the nuances of evidence quality measures

In fixating on evidence to make recommendations for patient care, the Review bets the house on a concept that itself has flaws. The usefulness of evidence quality terminology is thoughtfully debated in the medical community. Different assessors often disagree and make divergent evidence quality assessments. There are no well-described processes by which such disagreements should be resolved. With more research, the quality of evidence in many fields of medicine does not neccessarily improve, as the study designs needed to detect smaller and smaller effects become infeasible.[25] Thus, many areas of medicine may have inherent, real-world upper limits on quality of evidence—and that level of quality rarely accords with the theoretical ideal described by evidence-grading methodologies.

Proponents of restrictions on healthcare for transgender youth often call attention to the purported absence of high-quality evidence in this field. If high-quality evidence were a prerequisite for medical care, we would all be worse off. Moderate, low, and very low-quality evidence (using the terms as defined in GRADE) informs necessary, high-value care at every stage of life. A review of Cochrane systematic reviews across numerous areas of medicine showed that 86.5% of reviews reported moderate (30.8%), low (31.4%), and very low (24%) levels of evidence.[17] Less than 1 in 7 systematic reviews had evidence of high quality for a primary outcome and less than 1 in 5 systematic reviews had evidence of high quality for any

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[23] Horton, C. (2024). The Cass Review: Cis-supremacy in the UK's approach to healthcare for trans children. *International Journal of Transgender Health*, 1–25. https://doi.org/10.1080/26895269.2024.2328249

[24] https://cass.independent-review.uk/wp-content/uploads/2022/03/REPORT-Cass-Review-professional-panel-FINAL.pdf

[25] Howick J, Koletsi D, Pandis N, et al. The quality of evidence for medical interventions does not improve or worsen: a meta-epidemiological study of Cochrane reviews. J Clin Epidemiol. 2020 Oct;126:154-159. doi: 10.1016/j.jclinepi.2020.08.005. Epub 2020 Sep 2. PMID: 32890636.

outcome.[26] The authors found that the quality of evidence in 52 areas of medicine was often not high. These areas included procedures and treatments in fields as diverse as anesthesia, breast cancer, cystic fibrosis, pancreatic disease, blood cancers, multiple sclerosis, obstetrics, schizophrenia, and stroke, among many others. Further, there is no published research showing that evidence quality designations improve patient care.[27]

The Review's fixation on "high-quality" evidence is inappropriate

The Review's calls for "high-quality" evidence in the care of transgender youth cannot be separated from the fact that evidence deemed high-quality by systems like GRADE most often comes from RCTs.[28] In any area of medicine, the presence or absence of "high-quality evidence" alone should not be used to decide whether to offer a treatment that has been shown to be beneficial, and care in any area of medicine should not be stopped while awaiting specific study designs. Moreover, RCTs specifically are ill-suited to studying the effects of many interventions on psychological wellbeing and quality of life among transgender people.[29] For the following ethical and methodological reasons, the type of evidence that the Review advocates for is neither possible nor appropriate in the field of gender-affirming care.

1. *Masking*: This is the process that blinds participants and investigators to whether patients receive treatment or placebo. Puberty-pausing medications and gender-affirming hormones have physiologically evident impact. Those who were randomized into the treatment arm would clearly notice lack of physical change from pausing puberty or physical changes related to hormone therapy. Those in a non-treatment arm would experience obvious gender-incongruent physical change. *Thus, masking is impossible.*
2. *Adherence*: Individuals with gender dysphoria seek a difficult-to-access, much-desired treatment. Being placed into the non-treatment arm would likely lead to their discontinuation in the study to pursue treatment elsewhere. *Thus, adherence would be severely compromised.*
3. *Coercion:* Coercion occurs when research participation is one of the only ways to obtain a much-needed treatment. An RCT model to assess whether to give medically affirming interventions to youth with gender dysphoria may appeal to those who cannot obtain affirming interventions another way. Per international regulations on medical and

[26] Fleming PS, Koletsi D, Ioannidis JP, Pandis N. High quality of the evidence for medical and other health-related interventions was uncommon in Cochrane systematic reviews. J Clin Epidemiol. 2016 Oct;78:34-42. doi: 10.1016/j.jclinepi.2016.03.012. Epub 2016 Mar 29. PMID: 27032875.

[27] Kavanagh BP. The GRADE system for rating clinical guidelines. PLoS Med. 2009 Sep;6(9):e1000094. doi: 10.1371/journal.pmed.1000094. Epub 2009 Sep 15. PMID: 19753107; PMCID: PMC2735782.

[28] Guyatt GH, Oxman AD, Kunz R, et al HJ; GRADE Working Group. What is "quality of evidence" and why is it important to clinicians? BMJ. 2008 May 3;336(7651):995-8. doi: 10.1136/bmj.39490.551019.BE. PMID: 18456631; PMCID: PMC2364804.

[29] This article presents an in-depth analysis of why the RCT model is inappropriate: Ashley, F., Tordoff, D. M., Olson-Kennedy, J., & Restar, A. J. (2023). Randomized-controlled trials are methodologically inappropriate in adolescent transgender healthcare. *International Journal of Transgender Health*, 1–12. https://doi.org/10.1080/26895269.2023.2218357

scientific ethics, coercion, even when unintended, must be avoided in study design.[30] *Restricting all care to a research setting, as recent UK rules have done based on the Review, is coercive and unethical.*

4. *Generalizability*: Coercion is not only unethical, but it also draws a population into research that likely does not resemble the wider population who may benefit from treatment. *Thus, generalizability is not achievable with a coercive RCT model.*

Section 3: The Cass Review fails to contextualize the evidence for gender-affirming care with the evidence base for other areas of pediatric medicine.

Despite the Review's recommendations, the continuum of research and care for transgender youth is well-aligned with standards across pediatrics. Here, we discuss how the Review fails to recognize the intricacies of pediatric research and how other types of pediatric care have comparable evidence and practices to care for transgender youth but are not targeted for comparable restrictions.

The Review fails to recognize the realities and nuances of pediatric medical research

The Review expresses an appropriate desire to see longer, larger studies on the impacts of gender-affirming medical treatment, and this aligns with leading organizations' views. The Review's desire to see only high-quality evidence dominate this field, however, is not realistic or appropriate *because no other area of pediatrics is held to this standard.*

Research in youth gender care involves pediatric patients and thus, is subject to unique, necessary considerations that are not present in adult research. These considerations include:

1. *Consent:* Informed consent and voluntary participation form the bedrock of ethical research. Minors cannot independently consent, and parents must be heavily involved. Many pediatric trials have failed to launch because the necessary but arduous informed consent process meant too few participants were recruited.[13] (RCTs must enroll large numbers of study subjects to detect an effect.) Combining the need for parental involvement and the problem of coercion, issues with consent would most certainly limit large-scale enrollment for an RCT in youth gender care.
2. *Rarity:* Conditions that affect children are often different from and/or rarer than those that affect adults. Thus, these conditions must be studied in different ways.
3. *Inadequate resources:* Legislative and policy initiatives significantly underfund pediatric research relative to research on adult care. Even with governmental and private sector investment, the annual number of published pediatric RCTs is already far less than amongst adults and is decreasing.[31]

[30] The Declaration of Helsinki outlines authoritative ethical principles for research with human subjects. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

[31] A review of publication trends in adult versus pediatric RCTs demonstrated that adult RCTs increased by 4.71 RCTs/year, while pediatric RCTs only increased by 0.44 RCTs per year from 1985-2004. From 2005-2018, adult RCTs increased by 5.1 RCTs per year, while pediatric RCTs decreased by 0.4 RCTs per year. Cohen E, Uleryk E, Jasuja M, Parkin PC. An absence of pediatric randomized controlled trials in general medical journals, 1985-2004. J Clin Epidemiol. 2007 Feb;60(2):118-23. doi: 10.1016/j.jclinepi.2006.03.015. Epub 2006 Nov 13. PMID: 17208117., Groff ML, Offringa M, Emdin A, , et al. Publication Trends of Pediatric and Adult Randomized Controlled Trials in

Parallels between youth gender care and other aspects of pediatric care

In an interview, Dr. Cass said, "I can't think of any other situation where we give life-altering treatments and don't have enough understanding about what's happening to those young people in adulthood."[32] In fact, due to the realities of the research dynamics described above, many pediatric medical treatments are based on limited research.

While no comparison is perfect, parallels between gender-affirming medical care and other areas of pediatrics are abundant. All types of pediatric practices begin with a dearth of evidence and yet must deliver care to a heterogeneous population in need. An exhaustive and nuanced analysis of evidence-based pediatric medicine is outside the scope of this report, but we discuss some practices within pediatric and neonatal critical care. The practices we discuss are based on less-than-high-quality evidence (by definitional standards) and—like gender-affirming care for transgender youth—were guided by informed clinical practice and became accepted in high-stakes scenarios even while long-term data are still in the process of being collected.

Neonatology is the care of critically ill, often preterm infants. Pediatric critical care deals with the care of children and teens with unstable, life-threatening medical conditions, including sepsis, brain injuries, organ failure, and cancer crises. Clinicians in these fields routinely make hundreds (if not thousands) of high-stakes, evidence-informed decisions for their patients each day. These decisions are often not straightforward:

1. Should a premature infant with respiratory problems be supported with a breathing tube or a non-invasive measure? When and how should that support be weaned to see if the infant can breathe on their own?
2. Should a premature infant whose mother cannot produce breast milk be given synthetic formula or donor breast milk? One predisposes to severe intestinal infections while the other is associated with slow weight gain.
3. What is the best way to manage intravenous fluids to support blood pressure in a child with life-threatening systemic infection (i.e., sepsis)? Too much could tax the heart and the kidneys and too little could limit oxygen delivery to the body's tissues, which are in dire need.

The evidence that helps answer these and other questions is rarely "high quality" (as the term is used in GRADE).[33] And yet, clinical outcomes are good and improving: more children leave

General Medical Journals, 2005–2018: A Citation Analysis. *Children*. 2020; 7(12):293. https://doi.org/10.3390/children7120293

[32] Ghorayshi A. "Hilary Cass Says U.S. Doctors Are 'Out of Date' on Youth Gender Medicine" New York Times. Accessed May 30, 2024.

[33] We sourced literature on evidence quality in many areas of neonatal and pediatric care. In lieu of a thorough inventory, we present evidence quality in the care of neonatal respiratory distress syndrome. In guidelines on the care of premature infants with severe breathing difficulty, 92% of recommendations were based on expert consensus (33%), very low (25%), low (12%), or moderate (16%) quality evidence. Huang Y, Zhao J, Hua X, et al. Guidelines for high-flow nasal cannula oxygen therapy in neonates (2022). *J Evid Based Med*. 2023; 16: 394–413. https://doi.org/10.1111/jebm.12546; Zhang, Z., Chen, L., Cai, H. *et al.* Low Quality Evidence Supporting Recommendations in the 2021 Sepsis Guideline: An Indication for Precise Medicine?. *Intensive Care Res* **2**, 23–25 (2022). https://doi.org/10.1007/s44231-022-00007-2

intensive care units better off than ever before.[34] Most aspects of neonatal and pediatric critical care became accepted clinical practice because of their immediate and short-term benefits, without following patients into adulthood. Even now, the degree to which children discharged from intensive care achieve full neuro-developmental and functional recovery is not well-known and this is a new, active area of research in the critical care world. The quest for longer and more data is never-ending, but when the answers are only partially available, patients cannot wait for care.

Perhaps the newest area is in the use of glucagon-like peptide-1 (GLP-1) analogues for treatment of pediatric metabolic syndrome.[35] Children now have pre-diabetes, non-alcoholic fatty liver disease, high blood pressure, sleep apnea and other health issues at higher rates than ever before. We are gravely concerned about a generation of youth aging into adulthood with devastatingly high rates of illnesses that increase the risk of early death. In light of these concerns, these medications are now recommended for children. The evidence on GLP-1s can be critiqued in many of the same ways that transgender healthcare is. GLP-1s in children have only been studied for 1-2 years. We do not yet know what the long-term impacts of profound weight loss in adolescence are on bones and disordered eating. Will they be able to enjoy food in adulthood? Can these medications ever be stopped without rebound weight gain?

In youth gender care, we have evidence that these medications effectively treat gender dysphoria, that young people continue these medications into adulthood, that their satisfaction with gender-affirming medical treatments is high, that their bone density recovers after puberty-pausing medications, and that their transgender identities persist.

The point is not to compare to the point of destructive criticism. The point is that careful use of the treatment options we have now, with the best evidence we have, defines pediatric care. We invite those who are interested in the care of transgender youth to consider the wide range of practices within pediatrics where the long-term effects are fully well known. Children benefit from innovative medical treatments that improve their survival and quality of life. Pediatric care would all but cease if physicians denied treatments for which the evidence base is imperfect.

The Review has outsized and vague concerns about long-term data

It is difficult to discern validity in the Review's preoccupation with long-term data in youth gender care. It claims there is no long-term data, but does not define what it considers "long-term" to mean; it does not describe what long-term outcomes would satisfy its concerns, and

[34] Pollack MM, Banks R, Holubkov R, Meert KL; and the Eunice Kennedy Shriver National Institute of Child Health and Human Development Collaborative Pediatric Critical Care Research Network. Long-Term Outcome of PICU Patients Discharged With New, Functional Status Morbidity. Pediatr Crit Care Med. 2021 Jan 1;22(1):27-39. doi: 10.1097/PCC.0000000000002590. PMID: 33027242; PMCID: PMC7790876.; Biban P, Marlow N, Te Pas AB, et al. Advances in Neonatal Critical Care: Pushing at the Boundaries and Connecting to Long-Term Outcomes. Crit Care Med. 2021 Dec 1;49(12):2003-2016. doi: 10.1097/CCM.0000000000005251. PMID: 34380942.

[35] Hampl SE, Hassink SG, Skinner AC, et al. Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity. Pediatrics. 2023 Feb 1;151(2):e2022060640. doi: 10.1542/peds.2022-060640. Erratum in: Pediatrics. 2024 Jan 1;153(1):e2023064612. doi: 10.1542/peds.2023-064612. PMID: 36622115.

does not consider evidence that has followed patients for over a decade.[36] The Review expects researchers to report on the solitary, long-term impacts of puberty-pausing medications, but these medications are nearly always part of a staged process that includes other treatments. Further, the Review expects an abundance of long-term data on treatments that have only been more readily available for gender-affirming purposes over the past 8-10 years. The medical community's ability to describe transgender patients' experiences is commensurate with the improved access to care over the past decade.

While long-term data are costly and difficult to obtain, the field of transgender health is meeting this challenge at exactly the appropriate time. Clinician researchers representing 39 studies in the US have been awarded $12.1 million by the National Institutes of Health (NIH) to study the physiologic and psychosocial impacts of this care in thousands of patients over the years to come, with direct applicability to transgender youth.[37]

Section 4. The Cass Review misinterprets and misrepresents its own data.

The Review leverages the UK's National Health Service (NHS) to gather a great deal of data about youth gender services in the UK. Indeed, the reason that the Review was initially commissioned was to address the failure of the NHS to provide timely, competent, and high-quality care to transgender youth across the country. This valuable information sheds light on the needs of the UK's population of transgender youth, the barriers they face in the pursuit of care, and intricacies of the burdened system. These data, when carefully examined, are a significant contribution to the field of transgender health. But the Review's interpretation and representation of these data are often incorrect.

One of the Review's central points is that the UK's rise in referrals is so dramatic that it cannot be explained by social acceptance of transgender identity. This position is repeated throughout its 388 pages and best expressed here:

> "While it certainly seems to be the case that there is much greater acceptance of trans identities, particularly among younger generations, which may account for some of the increase in numbers, the exponential change in referrals over a particularly short five-year timeframe is very much faster than would be expected for normal evolution of acceptance of a minority group." (p 26)

If the expectation is that referral trends conform to the "normal evolution of acceptance for a minority group," one would expect the Review to define this concept. It does not. This is not surprising: there is no so-called normative pattern of social acceptance for a minority group. This

[36] One of the York systematic reviews omitted a study presenting the longest outcome data regarding bone density. This 2023 study described normal bone density after 11 years of gender affirming hormone treatment. The Review mentions this landmark study only passingly and without recognizing its key findings. van der Loos MATC, Vlot MC, Klink DT, et al. Bone Mineral Density in Transgender Adolescents Treated With Puberty Suppression and Subsequent Gender-Affirming Hormones. JAMA Pediatr. 2023 Dec 1;177(12):1332-1341. doi: 10.1001/jamapediatrics.2023.4588. PMID: 37902760; PMCID: PMC10616766.

[37] This is a non-systematic, non-exhaustive search of the NIH RePORTER database of awarded grants. This search does not include any research that may be privately funded.

is one of many grave and misleading errors packed into this statement. While we agree that referrals to gender-competent services are increasing, we disagree with the way that increase is described. In this section, we use the Review's own data to show why.

An increase in referrals is not cause for concern. A referral for evaluation does not equate to the provision of gender-affirming medical care. Some youth who are referred will be treated, while others will not. Each referral signifies at least one thoughtful conversation between a pediatric clinician, a young person, and their family. Pediatric clinicians in the UK who ask thoughtful questions about gender identity should be applauded for considering their patients' needs in a holistic, patient-centered, and non-judgmental fashion.

The Review does not accurately describe trends in referrals

Here, we show the Review's most complete depiction of GID referral data here with emphasis on our areas of concern.[38] The Review's interpretation of this data is that it shows an "exponential" increase from 2010-2022, particularly for those assigned female sex at birth. However, this graph clearly depicts a leveling off followed by a decrease in referrals, starting in 2018. This leveling off *predates the COVID-19 pandemic* and cannot be explained by the resource limitations imposed by a public health emergency. Further, there is a clear plateau in the *accurately* recorded data from 2017 to 2022. Data shaded in gray are described in the Review as potentially representing *double-counted* referrals: the figure caption in the Review states that there "is a strong possibility that there was double counting during 2021/22," indicated by the gray areas under the curve. Single data points should not be counted multiple times and doing so may overestimate the referral numbers by as much as 100%.

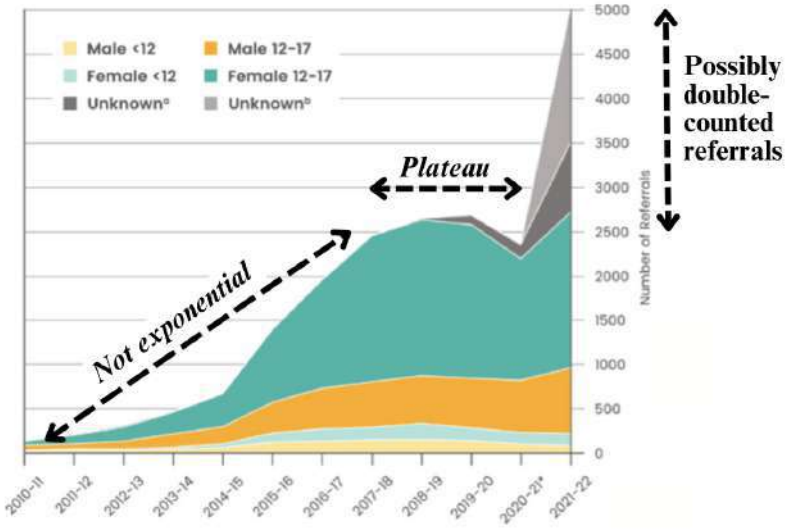

Figure 1: The Review's referral increases are not exponential and do not consistently increase. Graphed data shown above includes double-counted referrals.

Despite the Review's repeated claims, the increase in referrals to the UK's Gender Identity Service *is not exponential*. An exponential increase describes a particular type of growth pattern where there is a fixed time interval over which the quantity increases by a certain factor, and then over that same time interval the quality again increases by that factor. Even if one considers the double-counted referrals, there is no discernable exponential pattern. A mathematical, logarithmic transformation of the data shows this. While there certainly is an increase in referrals, describing this increase as "exponential" is a serious error that fuels concern that the

[38] Partial reproductions of this data are shown twice in the Review (p 24 and 72). "Figure 11" is the only time that the entire referral dataset is graphically depicted.

Review is too often more interested in subjective polemics than in scientific accuracy. This language has been cited in US litigation justifying bans on gender-affirming care.[39]

What the Review's data actually describe

The Review's referral data demonstrate one objective fact: most transgender adolescents in the UK are not referred for care. There are likely about 44,000 transgender adolescents in the UK based on 2021 census data.[40] Every year people age into and out of this figure. With 3585 referrals reported as in 2021 (and less in years prior), we can safely assume that less than 10% of all youth who may benefit from care have received any opportunity to do so.

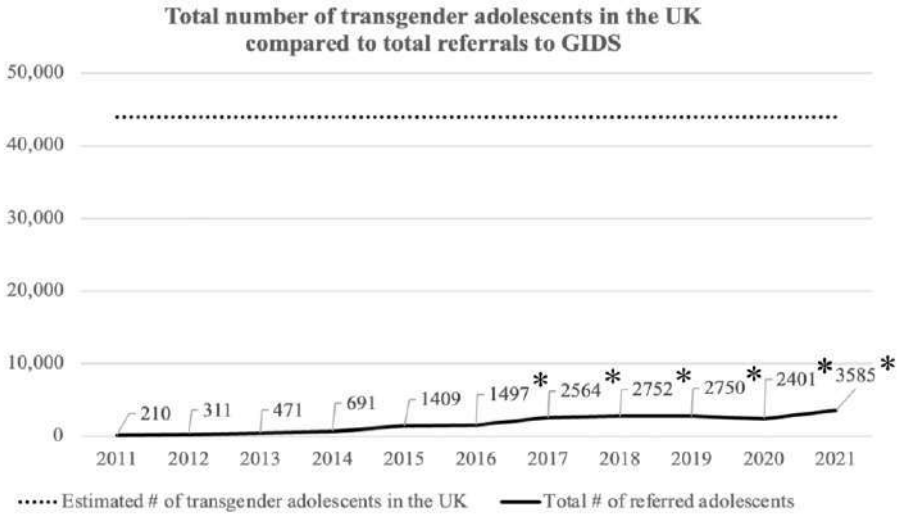

*Figure 2: Comparing a population prevalence estimate of transgender-identifying youth in the UK to those who received referrals to GIDS from 2011-2021, * indicates referrals that may be double-counted*

Figure 2 shows a graph plotting total referred adolescents against an estimation of the total population of transgender youth in the UK. One thing is abundantly clear: the gap between youth who may benefit from care and those who receive even the first opportunity to consider this care is astronomical. The Review is overly concerned with overtreating this population, but the data are clear that transgender youth in the UK are vastly underserved, just as they are throughout the world.

The Review wrongly contends that gender-affirming care is rushed, careless, and common

[39] In a filing with the US Supreme Court in *Poe v Labrador*, the Attorney General of Idaho states "For reasons no one knows, gender dysphoria has grown exponentially among young people. App.D.74, 80–82, 84–85, 92, 104–05. Indeed, diagnoses increased ten-fold between 2009 and 2016. Dr. Hilary Cass, Independent Review of Gender Identity Services for Children and Young People: Interim Report 33 (Feb. 2022), https://bit.ly/4bzkiJI ("Cass Review")."

[40] We use a conservative prevalence estimate of 0.6% being transgender, and about 7.4 million adolescents in the UK using Office for National Statistics data. (Other population estimates project that about 1% of people in the UK are transgender.) Youth disclosing self-identification as transgender has likely increased over the past several years. However, this is distinct from our population of interest for this particular point as we seek to describe youth who are transgender and may wish to consider the opportunity to discuss specialized, supportive interventions. Gender identity: age and sex, England and Wales: Census 2021. Accessed June 15, 2024. https://www.ons.gov.uk/peoplepopulationandcommunity/culturalidentity/genderidentity/articles/genderidentityageandsexenglandandwalescensus2021/2023-01-25#how-gender-identity-age-and-sex-profiles-varied-across-england-and-wales

Without evidence, the Review states that "practitioners abandoned normal clinical approaches to holistic assessment" (p 13) and that puberty-pausing medications are "available in routine clinical practice." (p 25) However, the Review's own data shows that about only 178 youth with gender dysphoria in the UK currently receive medications that pause puberty. It is difficult to see how a medication is both "routine" and only in use by 0.0024% of the adolescent population.[31]The Review's own data lend insight into how hard it is to access care within the UK's NHS, and the slow, careful decision making that characterizes this care. First, it reports over two years of waiting for assessment. (p 77) Then, of the 3306 patients seen twice in the GIDS clinic or discharged from April 2018-December 2022, only 27% (892) were referred to endocrinology for consideration and consultation of medical interventions.[41] (p 168) Those referrals were preceded by an average of 6.7 appointments, often with several months between each appointment. Of those seen by endocrinology, 81.5% received puberty-pausing treatment (about half of whom were 15-16 years old which is on the upper end of the age spectrum in which these medications are even usable).[42]

These trends are not unique to the UK. Throughout the world, wait lists are long[43,44] and only a small proportion of youth with gender dysphoria receive medical interventions.[45,46] In the United States, an analysis of insurance claims showed that 2-4% of youth diagnosed with gender dysphoria receive puberty-pausing medications or gender-affirming hormones. The data are clear: most transgender youth do not receive medical treatments for gender dysphoria, despite the supportive international medical consensus and evidence documenting the benefits of this care.

Section 5. The Cass Review levies unsupported assertions about gender identity, gender dysphoria, standard practices, and the safety of gender-affirming medical treatments, and it repeats claims that have been disproved by sound evidence.

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[41] Based on the data provided in Appendix 8 of the Review.

[42] This is not an age at which a patient is likely to benefit from puberty pausing medication, as most youth have completed puberty at this time.

[43] Strauss, P., Winter, S., Waters, Z., Wright Toussaint, D., Watson, V., & Lin, A. (2022). Perspectives of trans and gender diverse young people accessing primary care and gender-affirming medical services: Findings from Trans Pathways. International Journal of Transgender Health, 23(3), 295–307. https://doi.org/10.1080/26895269.2021.1884925

[44] Reporting wait times globally of several months to several years: Kearns S, Kroll T, O'Shea D, Neff K. Experiences of transgender and non-binary youth accessing gender-affirming care: A systematic review and meta-ethnography. *PLOS ONE*. 2021;16(9). doi:10.1371/journal.pone.0257194; *Reporting an average wait time in a Canadian clinic of 269 days*: Lawson ML, Gotovac S, Couch B, Gale L, Vandermorris A, Ghosh S, Bauer G. Pathways to care for adolescents attending a first hormone appointment at Canadian Gender Affirming Medical Clinics: A cross-sectional analysis from the Trans Youth Can! Study. Journal of Adolescent Health. 2024;74(1):140-147. doi:10.1016/j.jadohealth.2023.07.021

[45] Respaut R, Terhune C. Putting numbers on the rise in children seeking gender care. Reuters. October 6, 2022. Accessed May 31, 2024. https://www.reuters.com/investigates/special-report/usa-transyouth-data/.

[46] In a large study from the Netherlands, the percentage of evaluated patients who started treatment has decreased over time. Diagnostic criteria for treatment remain stringent, but the threshold for seeking an evaluation is likely lower. van der Loos MA, Klink DT, Hannema SE, et al., Children and adolescents in the Amsterdam Cohort of Gender Dysphoria: trends in diagnostic- and treatment trajectories during the first 20 years of the Dutch Protocol The Journal of Sexual Medicine, Volume 20, Issue 3, March 2023, Pages 398–409, https://doi.org/10.1093/jsxmed/qdac029

While the Review places a high value on evidence quality and certainty, its recommendations frequently emanate from insufficiently supported assertions that have been disproven by scientific evidence. A recent commentary describes at least eight instances where the Review's citation of a peer-reviewed study was blatantly incorrect.[47] Here, we discuss major areas where unfounded speculation dominates the Review's contents.

The Review speculates that social transition and puberty-pausing medications may cause harm by putting youth onto a medical path

The Review expresses concern that early supportive interventions, such as social transition and puberty-pausing medications, lock young people into irreversible care: "...it is clear that social transition is cause for concern for many people," and it may "[culminate] in medical intervention which will have lifelong implications." (p 158) The Review also states that "those who had socially transitioned at an earlier age and/or prior to being seen in clinic were more likely to proceed to a medical pathway" and that "the vast majority of young people… proceed from puberty blockers to masculinising/feminising hormones." (p 83)

The Review claims that these interventions may "change the trajectory of psychosexual and gender identity development." (p 83) There is no description of how developmental trajectories might be impacted, nor are any data cited. The Review contends that youth who transition may miss a purportedly valuable opportunity to experience adulthood as the gender they do not identify with: "In the absence of any experience as an adult ciswoman, they may have no frame of reference to cause them to regret or detransition, but at the same time they may have had a different outcome without medical intervention and would not have needed to take life-long hormones." (p 195) This statement ties back to our earlier concern that the Review's fixation on over-treating occurs without reciprocal consideration for the harm a transgender youth endures when undergoing puberty that opposes their identity. It is completely unscientific and inappropriate to expect a young person, regardless of their gender identity, to "try out" life as a gender they do not identify with – as the Review supposes transgender youth should.

The Review's own data show that most referred patients are never subsequently referred to pediatric endocrinology and even fewer receive medical interventions (See Section 4). While most who receive puberty-pausing medications do then choose to pursue gender-affirming hormones, not all do.[48] Also, we emphasize that continuation of care is not a negative outcome.

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[47] Grijseels, D. M. (2024). Biological and psychosocial evidence in the Cass Review: a critical commentary. *International Journal of Transgender Health*, 1–11. https://doi.org/10.1080/26895269.2024.2362304

[48] In these studies, continuation rates range from 96-98%. Wiepjes, C. M., Nota, N. M., de Blok, C. J. M., Klaver, M., de Vries, A. L. C., Wensing-Kruger, S. A., de Jongh, R. T., Bouman, M. B., Steensma, T. D., Cohen-Kettenis, P., Gooren, L. J. G., Kreukels, B. P. C., & den Heijer, M. (2018). The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets. The journal of sexual medicine, 15(4), 582–590. https://doi.org/10.1016/j.jsxm.2018.01.016; Kuper LE, Stewart S, Preston S, Lau M, Lopez X. Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy. Pediatrics. 2020 Apr;145(4):e20193006. doi: 10.1542/peds.2019-3006. PMID: 32220906; Carmichael P, Butler G, Masic U, Cole TJ, De Stavola BL, Davidson S, Skageberg EM, Khadr S, Viner RM. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. PLoS One. 2021 Feb 2;16(2):e0243894. doi: 10.1371/journal.pone.0243894. PMID: 33529227; PMCID: PMC7853497.

The Review does not consider the most likely explanation for why most youth who receive early, supportive interventions continue onto gender-affirming hormone therapy: *that they are indeed transgender.* It is not social transition and puberty-pausing medications that drive a persistent transgender identity. It is a transgender identity that drives social transition and subsequent medical interventions.

The Review's statements about "desistance" are unsupported

Studies in the 1980s demonstrated that most gender non-conforming children would not meet criteria for gender dysphoria after progression through puberty. These studies inappropriately conflated concepts of gender identity, sexual orientation, and behavior inappropriately. From this arose the concept of "desistance," meant to describe youth who met criteria for a now outdated diagnosis of "gender identity disorder"[49] as pre-pubertal children but no longer did after they entered puberty. *This is not the same as a loss of transgender identity.*

Studies that claim high rates of "desistance" in children rely on data collected before there was a formal definition for gender dysphoria. Children's behaviors[50] were classified as "gender non-conforming" if they did not adhere to gender stereotypes.[51] The Review cites such studies uncritically, even though their findings have no relationship to a contemporary understanding of gender. Concerningly, despite stating opposition to so-called conversion therapy, the Review favorably cites literature proposing methods that claim to suppress transgender identity in children[52] and uses the "desistance" data from this literature unquestioningly. One piece of useful information from the older studies on gender identity in childhood bears emphasis here: true cross-gender identification—*being* a different gender rather than *acting* like a different gender—is one of the predictors of persistence of gender identity into adulthood.[53] The Review cites the

[49] "Gender identity disorder" was eliminated from the DSM-V because this diagnosis pathologized gender nonconformity, which is a natural state of being. "Gender dysphoria" is the most contemporary term and guides our modern understanding of distress related to incongruence between gender identity and one's physical body.

[50] Green et al 1987 noted that boys with effeminate traits (i.e. playing with dolls) were more likely to identify as cisgender males with same sex-attraction as adults. Parents provided report, children were never directly observed, and no patients with gender dysphoria are reported to have been enrolled. All early studies on "persistence" of gender identity from childhood to adolescence are reviewed in: Ristori J, Steensma TD. Gender dysphoria in childhood. Int Rev Psychiatry. 2016;28(1):13-20. doi: 10.3109/09540261.2015.1115754. Epub 2016 Jan 12. PMID: 26754056.

[51] Temple Newhook, J., Pyne, J., Winters, K., et al (2018). A critical commentary on follow-up studies and "desistance" theories about transgender and gender-nonconforming children. International Journal of Transgenderism, 19(2), 212–224. https://doi.org/10.1080/15532739.2018.1456390; Ansara, Y. G., & Hegarty, P. (2011). Cisgenderism in psychology: pathologising and misgendering children from 1999 to 2008. Psychology & Sexuality, 3(2), 137–160. https://doi.org/10.1080/19419899.2011.576696

[52] Per one such individual: "In my view, offering treatment to a child (either on his or her own or through parental consent) can be justified for a relatively simple reason. Cross gender identification constitutes a potentially problematic developmental condition. Taken to its extreme, the outcome appears to be transsexualism. To make children feel more comfortable about their sex does not, in my view, constitute an unreasonable treatment goal. Although there is considerable disagreement about how one might achieve this aim, the goal itself seems relatively benign." (Zucker, 1985, p. 117) Zucker, K. J. (1985). Cross-gender-identified children. Gender Dysphoria, 75–174. https://doi. org/10.1007/978-1-4684-4784-2_4

[53] Steensma, T. D., McGuire, J. K., Kreukels, B. P., Beekman, A. J., & Cohen-Kettenis, P. T. (2013). Factors associated with desistence and persistence of childhood gender dysphoria: a quantitative follow-up study. Journal of the American Academy of Child & Adolescent Psychiatry, 52(6), 582-590.

study that draws this conclusion but does not note this core finding that has been widely acknowledged by those with clinical expertise in the field.

The Review's statements about "regret" and "detransition" are unsupported

Clinicians who work with transgender people of any age, including youth, follow expert standards of care and adhere to ethical practices that guide them in engaging patients in serious discussions of their full range of options and the associated possible outcomes, including the rare possibilities of regret, treatment discontinuation, and re-identification with birth-assigned sex. And while these outcomes are similar, they are not synonymous. A person who regrets receiving care may continue to identify as transgender; another who stops medications may not experience regret, and one who stops identifying as transgender may not regret receiving medical care. It is exceedingly rare that an individual would later determine that they are not transgender.[54]

The Review's own data contradicts its assertion that "The percentage of people treated with hormones who subsequently detransition remains unknown." (p 33)[55] In its an audit of 3,306 patient records from the UK Gender Identity Service, the Review reports that "< 10 patients detransitioned back to their [birth-registered] gender." (p 168) *This is a "detransition" rate of 0.3%.*

The Review's data is consistent with robust, long-term studies on regret, medication discontinuation and re-identification with birth-assigned sex. Amongst 882 youth with gender dysphoria in the Netherlands who received puberty suppression, 1% discontinued this medication due to resolution of gender dysphoria.[56] Amongst 720 youth in the Netherlands with gender dysphoria who received puberty-pausing medication and gender-affirming hormones, 98% continued gender-affirming hormone treatment as adults.[57] Among 196 youth receiving care in Western Australia's Gender Diversity Service, 1% who received gender-affirming medications re-identified with their birth-assigned sex.[58] These studies report findings in well-resourced, nationalized health systems where insurance lapses are rare and care is reliably accessible. These studies could have been systematically analyzed by the Review, but they were not.

While no comparable national registry exists in the United States, a survey of 27,715 transgender adults describes the challenges associated with changes in gender expression. Of the 13.1% who

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[54] Cavve et al found that 1% of youth who received gender-affirming medications re-identified with their birth-assigned sex: Cavve BS, Bickendorf X, Ball J, et al. Reidentification With Birth-Registered Sex in a Western Australian Pediatric Gender Clinic Cohort. JAMA Pediatr. 2024;178(5):446–453. doi:10.1001/jamapediatrics.2024.0077

[55] The Review defines "detransition" as "the process of discontinuing or reversing a gender transition, often in connection with a change in how the individual identifies or conceptualises their sex or gender since initiating transition." (p 239)

[56] van der Loos et al. (2023).

[57] van der Loos MA, Hannema SE, Klink DT, et al. Continuation of gender-affirming hormones in transgender people starting puberty suppression in adolescence: A cohort study in the Netherlands. The Lancet Child & Adolescent Health. 2022;6(12):869-875. doi:10.1016/s2352-4642(22)00254-1 (hereinafter, "van der Loos et al. 2022").

[58] Cavve BS, Bickendorf X, Ball J, et al. Reidentification With Birth-Registered Sex in a Western Australian Pediatric Gender Clinic Cohort. JAMA Pediatr. 2024;178(5):446–453. doi:10.1001/jamapediatrics.2024.0077

reported "living as [their] sex assigned at birth, at least for a while" after pursuing some form of transition, 82.5% reported familial pressure, social pressure, employment difficulty, inability to access care, and financial reasons as influential factors.[59] These reasons do not pertain to a change in identity, but rather the systemic and structural social forces that stigmatize and ostracize transgender people. Other studies have similarly found a variety of reasons that people may temporarily pause or discontinue treatment.[60] These reasons include not only the external pressures cited above but also the fact that, for some transgender people, gender is a journey rather than binary existence or a single destination. People may access hormone therapy for a specific period of time in order to achieve their gender goals—such as feeling comfortable in their body as a non-binary person—and cessation of treatment does not indicate "detransition" or regret, but rather a level of comfort and body satisfaction that could not have been realized without medical treatment.

Rather than consider these studies, the Review relies research plagued by poor methodology, heavy selection bias, and sampling from anti-transgender websites.[61,62] In many of the studies it cites, "detransition" is vaguely defined and incorrectly conflated with discontinuing treatment.[63] The Review criticizes and ultimately discards numerous rigorous research studies on transgender identity and medical treatments for gender dysphoria in youth, while confidently citing pseudoscience in support of outdated and debunked notions around rare phenomena like regret after gender-affirming care.[52,53] In considering the value of the Review's contributions to the field of transgender health, this discrepancy should not be overlooked.

The Review reanimates the debunked notion of "social contagion"

The Review repeatedly describes "peer and socio-cultural influence" as driving the increase in referrals. The theory that such factors influence gender identity development in youth originates

[59] Turban JL, Loo SS, Almazan AN, Keuroghlian AS. Factors Leading to "Detransition" Among Transgender and Gender Diverse People in the United States: A Mixed-Methods Analysis. LGBT Health. 2021 May-Jun;8(4):273-280. doi: 10.1089/lgbt.2020.0437. Epub 2021 Mar 31. PMID: 33794108; PMCID: PMC8213007.

[60] A qualitative study of 28 adults with heterogeneous gender identities; a majority of respondents reported no decisional regrets about gender-affirming interventions. MacKinnon KR, Kia H, Salway T, et al. Health Care Experiences of Patients Discontinuing or Reversing Prior Gender-Affirming Treatments. JAMA Netw Open. 2022;5(7):e2224717. doi:10.1001/jamanetworkopen.2022.24717

[61] Littman 2018 was an anonymous online survey of 100 "detransitioners" who were recruited on social media, professional listservs, and snowball sampling. Many online communities for detransitioned individuals have been co-opted by anti-trans social media users, including the subreddit Littman references r/detrans. With these sampling and recruitment methods, there is a high risk of bias.

[62] Vandenbussche through an online survey of 237 self-identified detransitioning respondents. Participants were recruited from r/detrans, private Facebook groups, public Instagram and Twitter posts, and www.post-trans.com, "a platform for female detransitioners." Vandenbussche E. (2022). Detransition-Related Needs and Support: A Cross-Sectional Online Survey. Journal of homosexuality, 69(9), 1602–1620. https://doi.org/10.1080/00918369.2021.1919479

[63] The Review cites Hall et al. (2021), an adult study where "detransition" is vaguely defined. These authors report that 12/175 "detransitioned" but 4 were later re-referred and two expressed regret about transition. The Review also cites Boyd et al. (2022), an adult study which found that 8/41 participants ceased hormone therapy, half of whom reported "detransition" or a change in gender identity as a cause.

from a single article[64] that has been heavily corrected for numerous well-documented fatal flaws.[65] Using sound methods, no link has been found between peer influence and gender identity development.[66] A more plausible and appropriate explanation for the increase in referrals to gender-competent services exists: there is greater awareness and acceptance of gender diversity and improved access to effective medical care with insurance coverage. In some countries, including the UK per the Review's own data (Section 4), referrals to gender services are leveling off.[67] Further, the Review's own data casts doubt on its claims about dramatically increasing referrals (Section 4).

While coming out as transgender may come as a surprise to people in a young person's life, disclosure often occurs several years after a transgender person realizes their gender. A large study of 27,715 transgender adults found that one's knowledge of gender identity predates gender identity disclosure by an average of 14 years.[68] Further, 40.8% of transgender adults reported realizing their gender identity after 10 years of age. A study of 173 adolescents under 16 years attending their first referral visit for puberty-pausing medication or gender-affirming hormones found that the majority of participants (56.4%) had realized their gender identity within three years of their referral.[69] Many factors have been analyzed to see if they correlate with recency of gender knowledge, including having gender-supportive or transgender online friends.[70] And despite the repeated concern that gender diversity amongst youth is somehow new, ethnographic and historical accounts of transgender youth date back to the 19th century, and further, transgender youth have sought medically affirming interventions since the 1920s.[71]

Any discussion of social contagion naturally leads to what *does* shape gender identity. Gender identity has strong biological underpinnings that do not completely overlap with sex assigned at

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[64] Littman L. Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. PLoS One. 2018 Aug 16;13(8):e0202330. doi: 10.1371/journal.pone.0202330. Erratum in: PLoS One. 2019 Mar 19;14(3):e0214157. PMID: 30114286; PMCID: PMC6095578.

[65] Restar AJ. Methodological Critique of Littman's (2018) Parental-Respondents Accounts of "Rapid-Onset Gender Dysphoria". Arch Sex Behav. 2020 Jan;49(1):61-66. doi: 10.1007/s10508-019-1453-2. Epub 2019 Apr 22. PMID: 31011991; PMCID: PMC7012957.

[66] Bauer GR, Lawson ML, Metzger DL, Do Clinical Data from Transgender Adolescents Support the Phenomenon of "Rapid Onset Gender Dysphoria"?, The Journal of Pediatrics, Volume 243, 2022, Pages 224-227.e2, ISSN 0022-3476, https://doi.org/10.1016/j.jpeds.2021.11.020. (hereinafter, "Bauer et al. 2022").

[67] Indremo M, Jodensvi AC, Arinell H, Isaksson J, Papadopoulos FC. Association of Media Coverage on Transgender Health With Referrals to Child and Adolescent Gender Identity Clinics in Sweden. JAMA Netw Open. 2022;5(2):e2146531. doi:10.1001/jamanetworkopen.2021.46531

[68] Turban JL, Dolotina B, Freitag TM, King D, Keuroghlian AS. Age of Realization and Disclosure of Gender Identity Among Transgender Adults. J Adolesc Health. 2023 Jun;72(6):852-859. doi: 10.1016/j.jadohealth.2023.01.023. Epub 2023 Mar 17. PMID: 36935303.

[69] Bauer GR, Pacaud D, Couch R, et al. Trans Youth CAN! Research Team. Transgender Youth Referred to Clinics for Gender-Affirming Medical Care in Canada. Pediatrics. 2021 Nov;148(5):e2020047266. doi: 10.1542/peds.2020-047266. Epub 2021 Oct 7. PMID: 34620727.

[70] Recency of gender knowledge was not associated with any negative issues, including depressive symptoms, mental health issues or neurodevelopmental disorders, severity of gender dysphoria, or gender-related support from parents. Bauer GR, Lawson ML, Metzger DL; Trans Youth CAN! Research Team. Do Clinical Data from Transgender Adolescents Support the Phenomenon of "Rapid Onset Gender Dysphoria"? J Pediatr. 2022 Apr;243:224-227.e2. doi: 10.1016/j.jpeds.2021.11.020. Epub 2021 Nov 16. PMID: 34793826.

[71] Gill-Peterson, J. (2018). Histories of the transgender child. U of Minnesota Press.

birth. In the truest scientific sense, gender and sex are multidimensional concepts with complex expressions that are related—and distinct from each other—in ways that modern science is still exploring.[72] What we do know is that gender identity is as real for transgender people as it is for cisgender people. Drawing on outdated and biased notions that being transgender is a pathological condition, however, the Review still attempts to find additional explanations for "the cause" of being transgender. It circumvents the known science by drawing a flawed parallel between gender diversity and cancer:

> "Expressions of being human vary greatly in how much biological versus psychological versus social (environment) causes contribute. As an unrelated but illustrative example to help explain this, people who carry the BRCA gene have a high genetic risk of breast cancer, whereas for those without the BRCA gene and with no family history, factors like smoking, obesity and lack of exercise play a much greater part. In other words, the end result is the same, but the causes are different." (p 117)

Many would contest the assertion that breast cancer is "an expression of being human." Others might balk at using an example of disease to describe gender, which is a natural aspect of human life. But moreover, this is an oversimplification. Many people do develop breast cancer with no known genetic cause, but just because that cause is not known does not mean it does not exist. Investigations into the genetic causes of breast or any other cancer are far from done, and there are many other genes besides BRCA 1 and 2 that are implicated in the development of breast cancer. This example does not cast doubt on the role that biology plays in shaping gender. Most concerningly, its serious lack of scientific rigor should lead readers to question what position the Review is operating from: is it science or is it speculation?

The Review's concerns about the cognitive effects of puberty-pausing medications are poorly evidenced and unbalanced

The Review expresses concern about the safety of puberty-pausing medications. Most of its concern centers on the supposed impact of these medications on adolescent cognitive development. This is an important area of ongoing study, with researchers currently conducting some of the largest studies with longest follow up periods to date.[73] The currently available evidence does not support the Review's concern.

The largest and longest study on this topic showed that intelligence quotient and educational achievement amongst youth receiving puberty-pausing medications did not substantially differ from a population of similarly aged Dutch teens.[74] The York SR on puberty-pausing medications misrepresented the evidence by failing to include this study, and also erroneously reported that

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[72] A helpful primer on the multidimensionality of biological sex: Karkazis K. The misuses of "biological sex". Lancet. 2019 Nov 23;394(10212):1898-1899. doi: 10.1016/S0140-6736(19)32764-3. Epub 2019 Nov 21. PMID: 31982044.

[73] A database of all studies funded by the National Institutes of Health: https://reporter.nih.gov/search/sF2XlRReqU-36s8d3bpPOQ/project-details/10883566

[74] Arnoldussen M, Hooijman EC, Kreukels BP, de Vries AL. Association between pre-treatment IQ and educational achievement after gender-affirming treatment including puberty suppression in transgender adolescents. Clin Child Psychol Psychiatry. 2022 Oct;27(4):1069-1076. doi: 10.1177/13591045221091652. Epub 2022 May 31. PMID: 35638479; PMCID: PMC9574895.

"the only study [on puberty-pausing medications and cognition] showed worse executive functioning at > 1 year…". This latter study actually showed significantly better executive functioning in those receiving gender-affirming hormones compared to puberty-pausing medications.[75] Executive functioning was worse amongst those who received puberty-pausing medication for a long time compared to those who received gender-affirming hormones earlier. The appropriate conclusion is not that puberty-pausing medications worsen executive function: rather, it is that cognitive development of transgender youth may be affected in concerning ways by prolonged delays before affirming physical changes with appropriate treatment.

Also, medications to pause puberty have long been used for central precocious puberty without negative impact on cognitive development.[76] Delayed puberty is not associated with delays in cognitive development. In fact, many cisgender youth present after age 14, and not uncommonly at age 16 or 17, for evaluation of absent or delayed puberty, and do not display delays in cognitive development.

There is much uncertainty about the role of puberty in broader adolescent development. The Review seems bound to the position that sex hormones are the most influential determinants of a healthy adolescence, to the exclusion of many other complex, interdependent factors.[77] Cognitive development during adolescence is a complex process relying on several different mechanisms, including the psychosocial environment. Chronic stress, particularly during adolescence, does indeed impact cognitive development.[78] Gender diverse youth with gender dysphoria who are denied the option of medically affirming interventions are thus forced to undergo unwanted physical development. This can cause significant distress that then limits learning, building friendships, future orientation, and other developmental milestones in adolescence. The harms this poses to healthy cognitive development cannot be ignored. Clinicians, parents, and youth themselves are rightly concerned with the cognitive impact of untreated gender dysphoria, but the Review clearly is not.

The Review asserts that puberty-pausing medications are not beneficial to transgender youth

The Review casts doubt on the benefits of puberty-pausing medications for the treatment of gender dysphoria:

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[75] Strang JF, Chen D, Nelson E, Leibowitz SF, Nahata L, Anthony LG, Song A, Grannis C, Graham E, Henise S, Vilain E, Sadikova E, Freeman A, Pugliese C, Khawaja A, Maisashvili T, Mancilla M, Kenworthy L. Transgender Youth Executive Functioning: Relationships with Anxiety Symptoms, Autism Spectrum Disorder, and Gender-Affirming Medical Treatment Status. Child Psychiatry Hum Dev. 2022 Dec;53(6):1252-1265. doi: 10.1007/s10578-021-01195-6. Epub 2021 Jun 19. PMID: 34146208.

[76] Wojniusz S, Callens N, Sütterlin S, Andersson S, De Schepper J, Gies I, Vanbesien J, De Waele K, Van Aken S, Craen M, Vögele C, Cools M, Haraldsen IR. Cognitive, Emotional, and Psychosocial Functioning of Girls Treated with Pharmacological Puberty Blockage for Idiopathic Central Precocious Puberty. Front Psychol. 2016 Jul 12;7:1053. doi: 10.3389/fpsyg.2016.01053. PMID: 27462292; PMCID: PMC4940404.

[77] Berenbaum SA, Beltz AM, Corley R. The importance of puberty for adolescent development: conceptualization and measurement. Adv Child Dev Behav. 2015;48:53-92. doi: 10.1016/bs.acdb.2014.11.002. Epub 2015 Jan 22. PMID: 25735941.

[78] Eiland L, Romeo RD. Stress and the developing adolescent brain. Neuroscience. 2013 Sep 26;249:162-71

> "The systematic review undertaken by the University of York found multiple studies demonstrating that puberty blockers exert their intended effect in suppressing puberty, and also that bone density is compromised during puberty suppression… However, no changes in gender dysphoria or body satisfaction were demonstrated." (p 32)

Here, the Review expresses the expectation that an intervention would lead to an outcome that experts in youth gender care do not: experts do not expect lessened gender dysphoria or increased body satisfaction with puberty-pausing medications alone, because these medications do not change the *current* physical characteristics of one's body. They only prevent *future* changes. Puberty-pausing medications only *pause* development of puberty-induced characteristics that might be detrimental to the psychosocial well-being of a transgender young person. For example, puberty-pausing medications halt growth of breasts, but they do not reverse any breast growth that has already occurred; puberty-pausing medications can prevent the deepening of one's voice, but they will not raise the pitch of a voice that has already deepened.

The Review's implication that puberty-pausing medication should lead to a reduction in current gender dysphoria or improve one's current body satisfaction indicates ignorance or misunderstanding at best, and intentional deception about the basic function of these medications at worst. In an era of abundant misinformation, it is important remember the exact function of these medications. The Review, as a document of such influence and importance in the field of transgender health, should not operate from any position of ignorance about this care.

The true effects of puberty-pausing medications are far more nuanced than the Review contends. Some studies show no change in certain mental health scores, which indicates *stability* rather than no effect.[79,80] Stability is a deeply meaningful short-term outcome for youth who are otherwise expected to experience increased gender-related distress without intervention.

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[79] Carmichael P, Butler G, Masic U, Cole TJ, De Stavola BL, Davidson S, Skageberg EM, Khadr S, Viner RM. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. PLoS One. 2021 Feb 2;16(2):e0243894. doi: 10.1371/journal.pone.0243894. PMID: 33529227; PMCID: PMC7853497. (hereinafter, "Carmichael et al. 2021").

[80] van der Miesen, A. I. R., Steensma, T. D., de Vries, A. L. C., Bos, H., & Popma, A. (2020). Psychological Functioning in Transgender Adolescents Before and After Gender-Affirmative Care Compared With Cisgender General Population Peers. The Journal of adolescent health: official publication of the Society for Adolescent Medicine, 66(6), 699–704.

Other studies[81,82,83,84] do demonstrate short-term improvement in some mental health scores in relation to treatment with these medications.[85]

Despite its protocol, which claimed the SRs would analyze qualitative data, the SR on puberty-pausing medications did not (See Section 6). Thus, the Review's conclusions are incompletely informed. The studies themselves draw different conclusions from the Review. For example, Carmichael and colleagues describe their nuanced findings: "Participant experience of treatment as reported in interviews was positive for the majority, particularly relating to feeling happier, feeling more comfortable, better relationships with family and peers and positive changes in gender role. Smaller numbers reported having mixed positive and negative changes. A minority (12% at 6–15 months and 17% at 15–24 months) reported only negative changes, which were largely related to anticipated side effects. None wanted to stop treatment due to side effects or negative changes."[86] Newer studies, not analyzed by the Review, demonstrate that avoiding a non-affirming puberty confers benefits that expand and evolve over time.[87]

Importantly, this newer study was able to study the effects of puberty-pausing medications in a cohort of adolescents who started treatment while still in early puberty (and are thus most likely to benefit). This point is highly relevant to assessing the evidence around these medications, since other studies' inclusion of young people who started puberty-delaying medications at a time when they were already in late puberty or had finished puberty—which has been common practice in many places, including the UK—will have reduced the chances of seeing benefits from use of these medications. Thus, being able to stratify recipients of puberty-delaying

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[81] R. Costa, M. Dunsford, E. Skagerberg, et al. Psychological support, puberty suppression, and psychosocial functioning in adolescents with gender dysphoria J Sex Med, 12 (2015), pp. 2206-2214

[82] C. Achille, T. Taggart, N.R. Eaton, et al. Longitudinal impact of gender-affirming endocrine intervention on the mental health and well-being of transgender youths: Preliminary results Int J Pediatr Endocrinol, 2020 (2020)

[83] L.E. Kuper, S. Stewart, S. Preston, et al. Body Dissatisfaction and mental health outcomes of youth on gender-affirming hormone therapy. Pediatrics, 145 (2020), Article e20193006

[84] de Vries, A. L., Steensma, T. D., Doreleijers, T. A., & Cohen-Kettenis, P. T. (2011). Puberty suppression in adolescents with gender identity disorder: a prospective follow-up study. The journal of sexual medicine, 8(8), 2276–2283. https://doi.org/10.1111/j.1743-6109.2010.01943.x

[85] The Review acknowledges this: "Neither [study] reported any change before or after receiving puberty suppression…the original Dutch protocol (de Vries et al., 2011) found improvements in mental health in a pre-post study without a comparison group, but the GIDS early intervention study (Carmichael et al., 2021) did not replicate this finding. The systematic review on interventions to suppress puberty (Taylor et al: Puberty suppression) identified one other good quality study (van der Miesen et al., 2020), which produced an intermediate result with improvements in some mental health measures but not others." (p 176) The Costa, Achille and Kuper studies were not included in the Review's analysis of puberty-pausing medications, but these studies offer valuable insight.

[86] Regarding the Carmichael study, the Review fails to mention that well-being was not "clinically concerning" at the study start. The authors also address that there is no expectation of profound improvement in mental health scores with a medication that simply pauses the further development: "...the lack of change in an outcome that normally worsens in early adolescence may reflect a beneficial change in trajectory for that outcome, i.e. that GnRHa treatment reduced this normative worsening of problems."

[87] McGregor K, McKenna JL, Williams CR, Barrera EP, Boskey ER. Association of Pubertal Blockade at Tanner 2/3 With Psychosocial Benefits in Transgender and Gender Diverse Youth at Hormone Readiness Assessment. J Adolesc Health. 2024 Apr;74(4):801-807. doi: 10.1016/j.jadohealth.2023.10.028. Epub 2023 Dec 13. PMID: 38099903.; Chelliah P, Lau M, Kuper LE. Changes in Gender Dysphoria, Interpersonal Minority Stress, and Mental Health Among Transgender Youth After One Year of Hormone Therapy. J Adolesc Health. 2024 Jun;74(6):1106-1111. doi: 10.1016/j.jadohealth.2023.12.024. Epub 2024 Feb 9. PMID: 38340124.

medications based on the pubertal stage at which they started treatment is critical, but neither the Review itself nor the associated systematic review appear to have considered this.

Section 6: The systematic reviews relied upon by the Cass Review have serious methodological flaws, including the omission of key findings in the extant body of literature.

Clinical recommendations should be informed by SRs of the evidence. SRs are a type of research study that combine the findings of multiple individual studies to answer a specific research question, based on a thorough and standardized search of the literature. SRs are considered the strongest form of evidence *if they are well-conducted*.[88] Best practices in conducting SRs aim to minimize bias so that the final product is a clear, precise, and accurate assessment of the body of evidence. These best practices include: (1) Devising, pre-registering, and following a protocol, (2) an exhaustive and up-to-date search of the literature, (3) use of validated assessment tools to examine the quality of individual studies and (4) use of a validated method to describe the quality of the entire body of evidence.

SRs are vulnerable to many forms of bias and are not inherently superior to other forms of evidence.[89] The Review's recommendations are informed by seven SRs,[2] which addressed research questions on gender-affirming hormones, puberty-pausing medications, referral trends to gender-competent services, care pathways, social transition, and psychosocial support for youth with gender dysphoria. In each of the four steps of the process, these reviews (collectively, the "York SRs," because they were conducted by researchers affiliated with the University of York) deviated substantially from standard practices and are rife with bias.

The York SR protocol is inadequate and deviations from it are not justified

The York SR authors pre-registered one vague protocol for all seven of their vastly different reviews.[90] The registered protocol bears no relation to what was actually done, and none of the components of the systematic reviews conducted on puberty-pausing medications or gender-affirming hormones were included in the registration. In fact, it is inaccurate to say that the York SRs were pre-registered, given that none of their key methodological details were described.

In the pre-registered protocol, the SR team planned to appraise the quality of studies using the Mixed Methods Appraisal Tool (MMAT).[91] However, they switched to the Newcastle-Ottawa

[88] Well-conducted SRs use pre-specified, transparent, and reproducible methods to identify relevant studies, determine inclusion/exclusion, extract study data, appraise the risk of bias in included studies, and synthesize results using quantitative (meta-analysis) or qualitative (narrative synthesis) approaches.

[89] Shea B J, Reeves B C, Wells G, Thuku M, Hamel C, Moran J et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both BMJ 2017; 358 :j4008 doi:10.1136/bmj.j4008

[90] Fraser, L. et al. The epidemiology, management, and outcomes of children with gender-related distress / gender dysphoria: a systematic review. PROSPERO. Available at: https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=289659. Accessed: May 27, 2024.

[91] Hong QN, Pluye P, Fàbregues S, Bartlett G, Boardman F, Cargo M, Dagenais P, Gagnon M-P, Griffiths F, Nicolau B, O'Cathain A, Rousseau M-C, Vedel I. Mixed Methods Appraisal Tool (MMAT), version 2018. Registration of Copyright (#1148552), Canadian Intellectual Property Office, Industry Canada.

Scale (NOS), but with several adaptations performed by the York SR authors. In their published SRs, they neither mention nor justify this deviation from their protocol. This is a divergence from standard practices designed to minimize bias in systematic reviews and it is not a minor one. This change may have had a decisive impact on the conclusions in the York SRs. In particular, the developers of the MMAT encourage SR authors to include *all* studies in analysis.[92] Using NOS and the arbitrary cutoff that the York SR authors determined, only a portion of the evidence was considered. This is discussed in greater detail as we describe use of the quality appraisal tool below.

The SR search of the literature is incomplete and outdated

The York team used a single search strategy for all SRs, which likely excluded many relevant studies in each of the specific areas. Also, SR authors face a challenge in performing a systematic review of the literature while new research is actively being published. SR authors should update their systematic search and apply the same quality appraisal tools to new literature. The York SR team did not systematically search the literature after April 2022, despite submission for publication 18 months later. In the SRs on puberty-pausing medications and gender-affirming hormone therapy, the authors state, "More recent studies published from April 2022 until January 2024 also support the conclusions of this review." The authors do not describe how those studies were identified or assessed. Highly impactful studies, such as the longest and largest study to date on gender-affirming medical treatments in youth,[93] received only passing mention: "A single study assessing outcomes during the 2 years after hormone initiation found that scores for gender congruence and life satisfaction increased, but there were differences by birth-registered sex and timing of hormone initiation." This fails to engage with the study's core findings that such treatments lead to improved mental health by targeting appearance congruence.

The York SR team used quality appraisal tools inappropriately

As we have discussed, quality appraisal tools are used to determine the quality of individual studies. These tools consider a variety of domains of the individual study, including the population selected and the statistical analyses performed on gathered data, among others. The York SRs used two quality appraisal tools incorrectly.

The first is the Appraisal of Guidelines for Research & Evaluation (AGREE) II tool, used in the systematic review of "guidelines" for medical care. The SR team included 23 documents for analysis, but 8 were not guidelines at all. These documents were position papers and affirmative statements that explicitly deferred to actual guidelines. Naturally, such documents fared poorly

[92] Studies deemed low-quality studies by the modified NOS should have been included and analyzed separately, rather than excluded altogether. A sensitivity analysis could be performed to see if the excluded studies provided relevant information, but this was not done.

[93] Chen D, Berona J, Chan YM, Ehrensaft D, Garofalo R, Hidalgo MA, Rosenthal SM, Tishelman AC, Olson-Kennedy J. Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. N Engl J Med. 2023 Jan 19;388(3):240-250. doi: 10.1056/NEJMoa2206297. Erratum in: N Engl J Med. 2023 Oct 19;389(16):1540. doi: 10.1056/NEJMx230007. PMID: 36652355; PMCID: PMC10081536.

when judged by the standards for clinical guideline development; this is akin to using a diamond quality scale to assess a heterogeneous group of gemstones.

The second quality appraisal tool is NOS and we analyze the Review's misuse of this tool in depth. We first discuss some of the robust criticisms of NOS from others in the field of evidence-based medicine:

1. NOS is not recommended by any leading organizations in the field of evidence-based medicine; it is not considered a gold standard or used in guideline development processes.
2. Using NOS, reviewers often come up with different quality appraisals.[94] This is also called "low interobserver reliability" and is precisely why NOS is not recommended by Cochrane.
3. Quality appraisal under NOS leads to a numerical score. Despite a veneer of singular objectivity, numerical scores flatten nuanced assessments and are inherently arbitrary and unreliable.
4. NOS gives equal weight to all scored items equally, though the scientific importance of these items varies.[95]
5. NOS includes items that are immaterial to assessing risk of bias.[80,96] NOS includes an item about representativeness of the study population, which pertains to generalizability of the results to a wider population. While representative samples are critical for estimating population characteristics, they are not essential for determining treatment effectiveness.

Furthermore, the York SR team did not implement the NOS as it is presented by its authors. They modified the scale in an arbitrary way that permitted the exclusion of studies from further consideration, for reasons irrelevant to clinical care. For instance, in the York SR on social transition, the modified NOS asked if study samples were "truly representative of the average child or adolescent with gender dysphoria." There is no such thing as the "average child or adolescent with gender dysphoria" —this is an inexpertly devised and meaningless concept that is neither defined by the authors nor used in clinical research. And yet it was grounds for excluding several important studies from consideration.

Also, the York SR team made a concerning error in citing NOS. In the SR on social transition, the authors accidentally cite a critical commentary on the scale and *not the scale itself*.[97] The authors of that critical commentary have subsequently written "It appears that the vast majority of systematic review authors who cited this commentary did not read it. Journal reviewers and

[94] Hartling L, Milne A, Hamm MP, et al. Testing the Newcastle Ottawa Scale showed low reliability between individual reviewers. Journal of clinical epidemiology. 2013 Sep 1;66(9):982-93.
[95] Jüni P, Witschi A, Bloch R, Egger M. The Hazards of Scoring the Quality of Clinical Trials for Meta-analysis. JAMA. 1999;282(11):1054–1060. doi:10.1001/jama.282.11.1054
[96] AHRQ also recommends against considering generalizability when assessing risk of bias. https://effectivehealthcare.ahrq.gov/products/methods-guidance-bias-individual-studies/methods
[97] Stang A. Critical evaluation of the Newcastle-Ottawa scale for the assessment of the quality of nonrandomized studies in meta-analyses. Eur J Epidemiol 2010;25:603–5. doi:10.1007/s10654-010-9491

editors did not recognize and correct these major quotation errors."[98] The York SR team's error calls into question the care with which they approached their task and the thoroughness of the peer review process undertaken by its journal of publication.

The York SR team does not demonstrate expertise in the clinical matters at hand

Upon review of the methodology and conclusions of the York SRs, it becomes clear that its authors are unaware of essential concepts in youth gender care.

1. In the SR on puberty-pausing medications, for instance, the authors or the Review's authors (unknown without transparency about the process), determined that a reduction in gender dysphoria was an appropriate outcome. As we discussed in Section 5, puberty-pausing medications themselves are not gender-affirming: they simply aim to pause the anatomical and physiological changes associated with puberty. Thus, the studies on puberty-pausing medications were held to an inappropriate standard.
2. Also, the York SR authors treated puberty-pausing medications and gender-affirming hormone treatments as distinct, reviewed them separately, and excluded studies from analysis that could not comment on the independent impact of each therapy. This is deeply problematic because most patients who receive puberty-pausing medications progress to gender-affirming hormone therapy. The imposition of a strict delineation of the impact of one modality versus another is divorced from the fact that these interventions are part of a continuum of care, and it led to the exclusion of numerous important studies assessing the impacts of this care continuum on the well-being of transgender adolescents.
3. The York SRs do endorse that puberty-pausing medications are effective in temporarily halting puberty and that gender-affirming hormone therapy is effective in developing congruent secondary sex characteristics, *but they do not consider that this is the actual goal of the gender-affirming model.* If the York SRs focused on body satisfaction and appearance congruence, and outcomes were assessed against the avoidance of unwanted pubertal changes and the induction of masculinizing or feminizing body changes, the discussion of the evidence would be quite different — and, indeed, it would be aligned with the goals of gender-affirming medical care.
4. Lastly, there is an undue prioritization of mental health as an expected outcome of all gender-affirming medical treatments, without considering the role that minority stress plays in the psychosocial well-being of transgender young people.

Using a rigorous assessment tool, the York SRs demonstrate high risk of bias

Systematic reviews—like the studies they seek to evaluate—are far from perfect. Just as there are bias assessment tools for individual studies, there are also bias assessment tools for systematic reviews. The Cochrane Collaboration encourages use of risk of bias instruments in systematic reviews of healthcare interventions. The ROBIS tool is one such instrument

[98] Stang, A., Jonas, S. & Poole, C. Case study in major quotation errors: a critical commentary on the Newcastle–Ottawa scale. *Eur J Epidemiol* **33**, 1025–1031 (2018). https://doi.org/10.1007/s10654-018-0443-3

rigorously developed to inform those using systematic reviews.[99] This tool considers risk of bias in four areas: (1) study eligibility criteria, (2) identification, and selection of studies, (3) data collection and study appraisal, and (4) synthesis and findings. Noone et al applied ROBIS to the York SRs and found a high risk of bias in each of these domains.[100] Their findings are described in Table 2.

Table 2: Application of the Cochrane ROBIS tool for bias assessment to the York SRs by Noone et al demonstrates systemic high risk of bias

	York SRs and Risk of Bias Determination							
ROBIS Domain	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**Concerns noted**
Study eligibility criteria	High	High	High	High	High	High	High	From the outset, "gray" literature, non-English literature, and qualitative research was excluded
Identification and selection of studies	High	High	High	High	High	High	High	Single search strategy used for seven different reviews despite widely divergent topics
Data collection and study appraisal	High	High	Low	High	High	High	High	Misused MMAT and AGREE-II, adapted and non-validated version of NOS used and not justified
Synthesis	High	High	High	High	High	High	High	No method described, 48% of studies on puberty-pausing medications and 36% of studies on hormones excluded from consideration without justification

Method description: *"Each of the seven systematic reviews were assessed by two independent assessors using the ROBIS tool. A third and fourth assessor resolved any disagreements by consensus…" (p 3)*

1 = SR on hormones; 2 = SR on puberty-pausing medications; 3 = SR on referral trends; 4 = SR on care pathways; 5 = SR on guidelines; 6 = SR on social transition; 7 = SR on psychosocial support

The York SR team's findings and conclusions conflict

Moreover, the York SR team's evidentiary findings and conclusions conflict. In the SR on gender-affirming hormone therapy, the "moderate and high quality" studies showed improved depression, anxiety, and suicidality (see Supplementary Table). *Every* study showed statistically significant improvements with a substantial magnitude of effect. No study showed a lack of improvement and no study showed worsening outcomes. It is thus peculiar that the York SR team concluded that "There was limited evidence regarding gender dysphoria, body satisfaction, psychosocial and cognitive outcomes, and fertility." There are five studies that were classified as

[99] Whiting P, Savović J, Higgins JP et al. ROBIS: A new tool to assess risk of bias in systematic reviews was developed. J Clin Epidemiol. 2016 Jan;69:225-34. doi: 10.1016/j.jclinepi.2015.06.005. Epub 2015 Jun 16. PMID: 26092286; PMCID: PMC4687950.

[100] Noone, C., Southgate, A., Ashman, A., et al. (2024, June 11). Critically appraising the Cass Report: methodological flaws and unsupported claims. https://doi.org/10.31219/osf.io/uhndk

"low quality" and discarded. Of note, Tordoff et al[101] was excluded due to scoring low on the authors' adapted NOS. However, this study shows statistically significant reductions in depression and suicidality.

No accepted method to determine quality of the entire body of evidence was used

Once a quality appraisal tool has been used, the quality of the entire body of evidence should be assessed with an accepted method. This is the final product of an SR and, to be sure, it's reason for being conducted. Accepted methods for appraising the entire body of evidence include GRADE and the Agency for Healthcare Research and Quality (AHRQ) approach.[102] This process is not perfect, but it is rigorous, replicable, and widely used by panels of experts who make recommendations. In an SR commissioned by WPATH[103], the authors describe their application of this process:

> "One reviewer graded strength of evidence for each outcome using the Agency for Healthcare Research and Quality Methods Guide for Conducting Comparative Effectiveness Reviews. We considered the directionality and magnitude of effects reported in cross-sectional studies as additional context for our evaluation of evidence from trials and prospective and retrospective cohorts. Each strength of evidence assessment was confirmed by a second reviewer."

Use of a validated method to translate quality appraisals of individual studies into an assessment of quality for the entire body of evidence is necessary, as is disclosure of that validated method. It is completely unclear and unknown how the York SR team moved from appraising individual study quality to the entire body of evidence. (Many studies were assessed as being of "moderate" quality according to NOS and it would be incorrect to carry over these designations to the entire body of evidence.) *Without a clear description of how the quality of the entire body of evidence was determined, the final conclusions of the York SRs lack substance.*

Section 7: The Review's relationship with and use of the York systematic reviews violate standard processes that lead to clinical recommendations in evidence-based medicine.

The University of York was commissioned to conduct a series of SRs to inform the Review, but the York SRs' findings were inappropriately applied to healthcare policy and practice recommendations made in the Review. In Section 2, we discussed how evidence is one of many factors that are considered as clinical recommendations are developed, that the Review failed to consider those factors, and further, that the Review's recommendations are informed by a flawed

[101] Tordoff DM, Wanta JW, Collin A, Stepney C, Inwards-Breland DJ, Ahrens K. Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care. JAMA Netw Open. 2022 Feb 1;5(2):e220978. doi: 10.1001/jamanetworkopen.2022.0978. Erratum in: JAMA Netw Open. 2022 Jul 1;5(7):e2229031. doi: 10.1001/jamanetworkopen.2022.29031. PMID: 35212746; PMCID: PMC8881768.

[102] https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/methods-guidance-grading-evidence_methods.pdf

[103] Baker KE, Wilson LM, Sharma R, Dukhanin V, McArthur K, Robinson KA. Hormone Therapy, Mental Health, and Quality of Life Among Transgender People: A Systematic Review. J Endocr Soc. 2021 Feb 2;5(4):bvab011. doi: 10.1210/jendso/bvab011. PMID: 33644622; PMCID: PMC7894249.

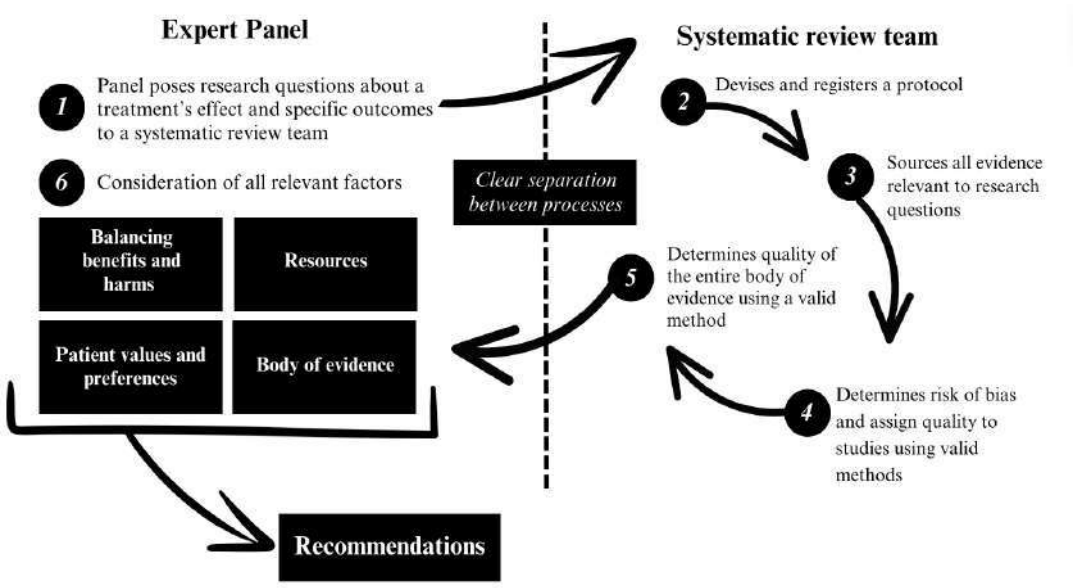
concept of evidence. Here, we discuss how the Review's relationship with and use of the York SRs goes against the grain of conventional processes used widely in evidence-based medicine.

The Review subverted the well-established process for making clinical recommendations from systematic review findings

SRs intended to inform clinical recommendations should follow a standardized and rigorous process that assesses quality of the entire body of evidence. In Section 6, we described many of the ways that the York SR team failed to adhere to such a process.

Here, we discuss the normative process for collaboration between expert panels who issue clinical recommendations and an SR team.

Figure 3: How an expert panel and a systematic review team should collaborate



1. Those who seek to make recommendations should be subject matter experts. Those experts first devise detailed research questions pertinent to a condition and its treatment.
2. A systematic review team then writes and registers a research protocol to answer those questions with the existing evidence. They adhere to this research protocol where possible and justify the need to deviate from it, should that need arise.
3. The SR team sources all evidence relevant to the research questions.
4. It then assigns quality to individual studies using valid methods.
5. The final work of the SR team is determining the quality of the entire body of evidence, again using a valid method. At this point, the work of the systematic review team is done.
6. The expert panel then considers all relevant factors, of which the body of evidence is one.

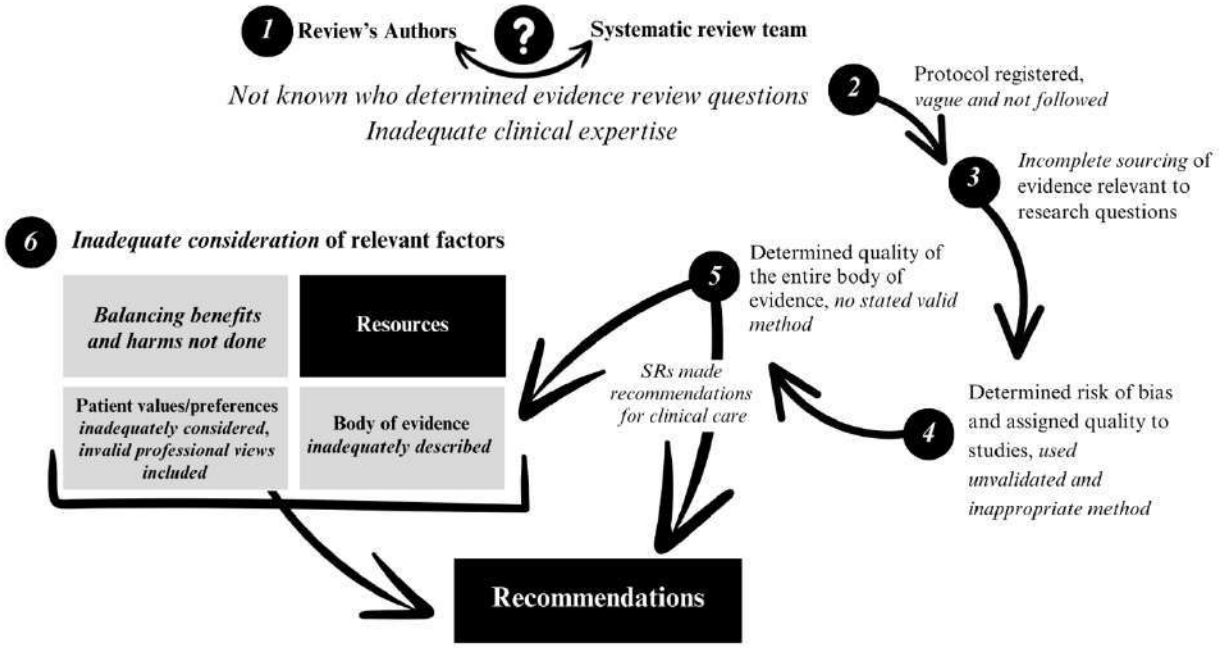
This process is well-established, in gender-affirming care and beyond.[104] In the SR commissioned by WPATH, the authors state:

> "WPATH provided the research question and reviewed the protocol, evidence tables, and report. WPATH had no role in study design, data collection, analysis, interpretation, or drafting… The authors are responsible for all content, and statements in this report do not necessarily reflect the official views of or imply endorsement by WPATH."

Such descriptions of the relationship between the expert panel forming recommendations and the SR team are conventional in SRs that inform clinical recommendations. Members of expert panels may have authored research that the SR team considers. Members of expert panels may not be familiar with best practices in conducting quality appraisals. The separation between evidence appraisals and the expert panel preserves objectivity and consolidates expertise.

With deviations from normative guideline development at every stage, the Review's recommendations cannot be given the weight that the authors expect. These deviations are noted at the outset and snowball throughout the process.

Figure 4: The Review's authors and the York systematic review team's processes



1. The earliest flaws in this process begin with ambiguity in how the first steps of the systematic reviews unfolded. The relationship between the Review's authors and the SR team is unclear. There are no descriptions, either in the Review or the York SRs, about who devised the

[104] Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines; Graham R, Mancher M, Miller Wolman D, et al., editors. Clinical Practice Guidelines We Can Trust. Washington (DC): National Academies Press (US); 2011. Available from: https://www.ncbi.nlm.nih.gov/books/NBK209539/ doi: 10.17226/13058

research questions informing the evidence review. Without disclosure of *all* of the Review's authors, we cannot say for sure, but inadequate subject matter expertise is quite likely.
2. The SR team did register a protocol, but that protocol was not followed (see Section 6).
3. The SR team did not conduct a complete review of the evidence pertinent to its research questions (see Section 6).
4. The individual studies were assigned a quality designation based on an unvalidated, never-before-used tool that was adapted from a tool with flaws of its own (see Section 7).
5. There is no description of a valid method used to determine quality of the entire body of evidence and, in some cases, recommendations for clinical care were made by the SR authors themselves *in the SRs themselves*.[105]
6. The Review inconsistently used the evidence assessments, alongside incomplete or absent analyses of other relevant factors to issue its recommendations (see Section 2).

Conclusion

The Cass Review was commissioned to address the failure of the UK National Health Service to provide timely, competent, and high-quality care to transgender youth. These failures include long wait times—often years—and resulting delays in timely treatment by skilled providers. Instead of effectively addressing this issue, however, the Review's process and recommendations stake out an ideological position on care for transgender youth that is deeply at odds with the Review's own findings about the importance of individualized and age-appropriate approach to medical treatments for gender dysphoria in youth, consistent with the international Standards of Care issued by the World Professional Association for Transgender Health and the Clinical Practice Guidelines issued by the Endocrine Society. Far from evaluating the evidence in a neutral and scientifically valid manner, the Review obscures key findings, misrepresents its own data, and is rife with misapplications of the scientific method. The Review deeply considers the possibility of gender-affirming interventions being given to someone who is not transgender, but without reciprocal consideration for transgender youth who undergo permanent, distressing physical changes when they do not receive timely care. The vast majority of transgender youth in the UK and beyond do not receive an opportunity to even consider clinical care with qualified clinicians—and the Review's data demonstrate this clearly.

[105] SRs should not make recommendations, but the SR on gender-affirming hormones does: "Clinicians should ensure that adolescents considering hormone interventions are fully informed about the potential risks and benefits including side-effects, and the lack of high-quality evidence regarding these. In response to their own evidence review, the Swedish National Board of Health and Welfare now recommends that hormone treatments should only be provided under a research framework, a key aim for which is to develop a stronger evidence base. As they point out, this approach is common practice in other clinical specialties, where to receive treatments for which the benefits and risks are uncertain, patients must take part in research." (p 7)

Supplemental Table: Studies on gender-affirming hormones rated by York SR team as high or moderate quality* demonstrate clinically relevant, statistically significant outcomes not adequately discussed	
Study	Findings
López de Lara D et al.[a]	Significant reduction in gender dysphoria in trans group ($p<0.001$), comparable to cisgender youth after one year Significantly improved anxiety ($p<0.001$) Significantly improved depression ($p<0.001$)
Grannis C, et al.[b]	Anxiety & depression significantly lower in testosterone-treated group compared to untreated group Lower suicidality observed Testosterone-treated group - less distress with body features, stronger connectivity within amygdala-prefrontal cortex circuit compared to untreated group
Green AE et al.[c]	Among those who wanted gender-affirming hormones at the start of the study: ● More depression (77.9% v 60.9%, $p<0.001$) ● More seriously considered suicide (61.6 v 51.1%, $p<0.001$) ● More attempted suicide (27.7 v 16.0%, $p<0.001$) After adjustment for covariates, GAHT associated with: ● Less depression (aOR 0.73, $p<0.001$) ● Less seriously considered suicide (aOR 0.74, $p<0.001$) ● Trend to less attempted suicide (aOR 0.84, $p=0.16$) ● Less attempted suicide in age 13-17 age group (aOR 0.61, $p=0.04$)
Kaltiala R, et al.[d]	Significantly less depression, anxiety, suicidality, and self-harm ($p < 0.001$) Depression 54% v 15%, anxiety 48% v 15% Suicidality/self-harm 35% v 4%
Allen, L. R., et al.[e]	Significantly lower suicidality after gender-affirming hormones ($p<0.001$) Significantly higher general well-being after gender-affirming hormones ($p<0.002$)
aOR = adjusted odds ratio, which includes control for confounders a - López de Lara D, et al. Psychosocial assessment in transgender adolescents. An Pediatr (Engl Ed). 2020 Jul;93(1):41-48. doi: 10.1016/j.anpedi.2020.01.019. Epub 2020 Mar 3. b - Grannis C, et al. Testosterone treatment, internalizing symptoms, and body image dissatisfaction in transgender boys. Psychoneuroendocrinology. 2021 Oct;132:105358. doi: 10.1016/j.psyneuen.2021.105358. Epub 2021 Jul 17.	

c - Green AE et al. Association of Gender-Affirming Hormone Therapy with Depression, Thoughts of Suicide, and Attempted Suicide Among Transgender and Nonbinary Youth. J Adolesc Health. 2022 Apr;70(4):643-649. doi: 10.1016/j.jadohealth.2021.10.036. Epub 2021 Dec 14.

d - Kaltiala R, et al. Adolescent development and psychosocial functioning after starting cross-sex hormones for gender dysphoria. Nord J Psychiatry. 2020 Apr;74(3):213-219. doi: 10.1080/08039488.2019.1691260Epub 2019 Nov 25.

e - Allen, L. R., et al (2019). Well-being and suicidality among transgender youth after gender-affirming hormones. *Clinical Practice in Pediatric Psychology, 7*(3), 302-311. https://doi.org/10.1037/cpp0000288

*In Taylor J, Mitchell A, Hall R, et al (2024) Masculinising and feminising hormone interventions for adolescents experiencing gender dysphoria or incongruence: a systematic review. Archives of Disease in Childhood Published Online First: 09 April 2024. doi: 10.1136/archdischild-2023-326670

Una crítica basada en la evidencia de "The Cass Review" sobre los cuidados de reafirmación de género para la disforia de género en adolescentes.

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Introducción

En 2020, el Servicio Nacional de Salud (NHS) del Reino Unido encargó una investigación para formular recomendaciones sobre la atención sanitaria a los adolescentes transexuales. Este proceso fue supervisado por una pediatra llamada Dra. Hillary Cass y finalizó en abril de 2024. El producto final es un informe de 388 páginas denominado "Cass Review",[1] (en adelante, "la Revisión") y va acompañado de siete revisiones sistemáticas realizadas por autores afiliados a la Universidad de York (en adelante, "las RS de York").[2]

[1] The Cass Review, Informe final: Independent Review of Gender Identity Services for Children and Young People, abril de 2024, en https://cass.independent-review.uk/wp-content/uploads/2024/04/CassReview_Final.pdf.

[2] Taylor J, Hall R, Langton T, et al. Vías de atención de niños y adolescentes derivados a servicios especializados en género: una revisión sistemática. Archives of Disease in Childhood Published Online First: 09 April 2024. doi: 10.1136/archdischild-2023-326760; Taylor J, Hall R, Langton T, et al. Characteristics of children and adolescents referred to specialist gender services: a systematic review. Archives of Disease in Childhood Published Online First:

Como investigadores y clínicos pediátricos con experiencia en el campo de la atención sanitaria a transexuales, leemos la Revista con gran interés. El grado de inversión financiera y de tiempo dedicado es impresionante. Su capacidad para publicar siete revisiones sistemáticas, llevar a cabo grupos de discusión durante años e investigar en profundidad las prácticas asistenciales en el Reino Unido es admirable. Esperábamos que mejorara la concienciación pública sobre las necesidades sanitarias de los jóvenes transexuales e impulsara mejoras en la prestación de esta atención. De hecho, las afirmaciones de la Revisión describen favorablemente el enfoque individualizado, apropiado para la edad y cuidadoso recomendado por la Asociación Profesional Mundial para la Salud Transgénero (WPATH) y la Sociedad Endocrina.[3] Lamentablemente, la Revisión hace un uso erróneo de los datos en repetidas ocasiones y viola sus propias normas probatorias al basar muchas de sus conclusiones en especulaciones. Muchas de sus afirmaciones y la conducta de los RE de York revelan profundas
malentendidos de la base empírica y de las cuestiones clínicas en cuestión. La Revisión también subvierte procesos ampliamente aceptados para el desarrollo de recomendaciones clínicas y repite afirmaciones espurias y desacreditadas sobre la identidad transgénero y la disforia de género. *Estos errores entran en conflicto con normas bien establecidas de investigación clínica y atención sanitaria basada en la evidencia. Además, estos errores suscitan serias dudas sobre la integridad científica de elementos críticos del proceso y las recomendaciones del informe.*

En el poco tiempo transcurrido desde su publicación, la Revisión se ha utilizado para justificar restricciones en la atención sanitaria a los jóvenes transgénero. En marzo de 2024, el Servicio Nacional de Salud anunció que denegaría la medicación para frenar la pubertad a los menores de 18 años fuera de un entorno de investigación.[4] En junio de 2024, el Secretario de Sanidad del NHS citó la Revisión como justificación para una normativa de emergencia que penaliza el suministro de medicamentos para frenar la pubertad a nuevos pacientes menores de 18 años en Inglaterra, Escocia o Gales.[5] Esta prohibición, que sólo se aplica al tratamiento de la disforia de género, calificaba estos medicamentos de

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09 abril 2024. doi: 10.1136/archdischild-2023-326681; Hall R, Taylor J, Hewitt CE, et al. Impacto de la transición social en relación con el género para niños y adolescentes: una revisión sistemática. Archives of Disease in Childhood Published Online First: 09 April 2024. doi: 10.1136/archdischild-2023-326112; Heathcote C, Taylor J, Hall R, et al. Intervenciones de apoyo psicosocial para niños y adolescentes que experimentan disforia o incongruencia de género: una revisión sistemática. Archives of Disease in Childhood Published Online First: 09 April 2024. doi: 10.1136/archdischild-2023-326347; Taylor J, Mitchell A, Hall R, et al. Intervenciones hormonales masculinizantes y feminizantes para adolescentes que experimentan disforia o incongruencia de género: una revisión sistemática. Archives of Disease in Childhood Published Online First: 09 April 2024. doi: 10.1136/archdischild-2023-326670; Taylor J, Mitchell A, Hall R, et al. Intervenciones para suprimir la pubertad en adolescentes que experimentan disforia o incongruencia de género: una revisión sistemática. Archives of Disease in Childhood Published Online First: 09 April 2024. doi: 10.1136/archdischild-2023-326669; ; Taylor J, Hall R, Heathcote C, et al. Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1).
Archives of Disease in Childhood Published Online First: 09 April 2024. doi: 10.1136/archdischild-2023-326499; Taylor J, Hall R, Heathcote C, et al. Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of recommendations (part 2). Archives of Disease in Childhood Published Online First: 09 April 2024. doi: 10.1136/archdischild-2023-326500

[3] Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Versión 8. Int J Transgend Health. Int J Transgend Health. 2022 Sep 6;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644. PMID: 36238954; PMCID: PMC9553112.; Hembree WC, Cohen-Kettenis PT, Louis Gooren L, et al. Endocrine Treatment of Gender Dysphoric/Gender Incongruent Persons: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 102, Issue 11, 1

November 2017, Pages 3869-3903, https://doi.org/10.1210/jc.2017-01658.

[4]https://www.nhs.uk/conditions/gender-dysphoria/treatment/

[5]https://www.gov.uk/government/news/new-restrictions-on-puberty-blockers#:~:text=The%20government%20has%20today%20introduced,June%20to%203%20September%202024.

"grave peligro para la salud". Estos medicamentos siguen estando disponibles libremente para otras necesidades sanitarias pediátricas, entre las que se encuentran la pubertad precoz, la endometriosis y la preservación de la fertilidad antes de la quimioterapia.[6]

La Cass Review ya ha sido citada en batallas legales estadounidenses sobre los derechos de los transexuales.[7] Es probable que tenga un gran protagonismo en los próximos meses y años. Entre 2022 y 2024, veinticinco estados de EE.UU. promulgaron leyes que prohíben la asistencia sanitaria de afirmación de género para jóvenes transexuales. Hay litigios en curso en al menos diez estados, y el más alto tribunal del país ha acordado juzgar un caso, *Estados Unidos contra Skrmetti*, en el mandato de otoño de 2024. Se prevé que los ministerios de sanidad de otros países utilicen la Cass Review para fundamentar sus propias políticas de acceso a la atención sanitaria para jóvenes transgénero.[8]

Entre nuestro grupo de autores, contamos con 86 años de experiencia en la atención a más de 4800 jóvenes transgénero y hemos publicado 278 estudios revisados por pares, 168 de los cuales se encuentran en el campo de la atención para la afirmación del género. La atención holística que proporcionamos los médicos entre nosotros se basa en décadas de investigación; no es controvertida en los centros de salud pediátrica de categoría mundial en los que ejercemos. La investigación que realizamos es ética y valorada por nuestros colegas en medicina y epidemiología. También podemos hablar de cómo la evidencia informa los resultados clínicos positivos que experimentan nuestros pacientes.

Hemos elaborado este informe para subrayar los principios fundamentales de la Revisión, sacar a la luz las conclusiones críticas pero ocultas y aportar críticas basadas en pruebas cuando sea necesario. La transparencia y la experiencia de nuestro grupo contrastan claramente con las de los autores de la Revista. La mayoría de los colaboradores conocidos de la Revisión no tienen ni experiencia clínica ni investigadora en la atención sanitaria a transexuales. La Revisión asume incorrectamente que los clínicos que proporcionan y llevan a cabo investigación en atención sanitaria transgénero son parciales. La experiencia no se considera sesgo en ningún otro ámbito de la ciencia o la medicina, y no debería serlo aquí. Además, se desconoce la identidad de muchos de los autores de la revisión.[9] La transparencia y la fiabilidad van de la mano, pero muchos de los autores de la Revisión no pueden ser investigados por conflictos de intereses ideológicos e intelectuales.

Nuestra preocupación por la Revisión Cass refleja el contexto politizado de la atención sanitaria a las personas transgénero, especialmente a los jóvenes. Las personas transgénero de todas las edades se enfrentan hoy a un punto de inflexión crítico en el Reino Unido y en todo el mundo. Si la política sigue interfiriendo en la atención sanitaria a los transexuales, es posible que los servicios clínicos y la investigación en este campo no se recuperen. La vida de las personas se verá drástica e innecesariamente alterada. Además, la politización de la atención sanitaria no sólo preocupa a las personas transgénero, sino a todas las personas. Todas las personas merecen tener la oportunidad de hacer

[6] https://www.legislation.gov.uk/uksi/2024/727/made
[7] Poe v Labrador, https://www.supremecourt.gov/DocketPDF/23/23A763/300889/20240220100700247_Poe%20v%20Labrador%20SCOTUS%20Application%20for%20Stay.pdf
[8] https://www.biobiochile.cl/noticias/nacional/chile/2024/05/29/pubertad-interrumpida-ninos-trans-inician-

tratamiento-hormonal-en-medio-de-controversias.shtml

[9] Tras la finalización del "programa de investigación" por parte de la Universidad de York, "la Revisión creó un Grupo de Expertos Clínicos (CEG) para ayudar a interpretar los resultados" (p 26), definido como "expertos clínicos en niños y adolescentes en relación con el género, el desarrollo y la salud física y mental", salvaguardia y endocrinología" (p 62). No hay más información sobre las cualificaciones de los miembros del CEG, ni sobre cómo fueron seleccionados.

tomar decisiones médicas profundamente personales consultando a profesionales sanitarios cuya labor esté guiada por pruebas sólidas, una formación adecuada y conocimientos clínicos.

Teniendo esto en cuenta, la comunidad médica, los responsables políticos y los medios de comunicación deben entender qué es y qué no es la Revisión. *Es* un documento importante para quienes están considerando la disponibilidad de servicios sanitarios para jóvenes transexuales en el Reino Unido. *Es* un intento de implicar a muchas partes, algunas de las cuales tienen opiniones ideológicas que entran en conflicto con el consenso médico. *No es* una directriz autorizada ni un estándar de atención, ni tampoco una reafirmación exacta de las pruebas médicas disponibles sobre el tratamiento de la disforia de género. *No es* un marco eficaz para mejorar los servicios clínicos para un grupo marginado de personas.
Ante todo, no es un respaldo a la prohibición de la atención médica a los jóvenes transexuales.

Resumen ejecutivo:

Sección 1: El informe Cass hace afirmaciones que son coherentes con los modelos de atención médica de afirmación de género descritos por WPATH y la Endocrine Society. El informe Cass no recomienda la prohibición de la atención médica de afirmación del género.

Sección 2: La revisión de Cass no sigue las normas establecidas para evaluar la evidencia y su calidad.

Sección 3: La Revisión Cass no contextualiza la evidencia para la atención que afirma el género con la base de evidencia para otras áreas de la medicina pediátrica.

Sección 4: The Cass Review malinterpreta y tergiversa sus propios datos.

Sección 5: The Cass Review hace afirmaciones sin fundamento sobre la identidad de género, la disforia de género, las prácticas habituales y la seguridad de los tratamientos médicos de afirmación de género, y repite afirmaciones que han sido refutadas por pruebas sólidas.

Sección 6: Las revisiones sistemáticas en las que se basa la Revisión Cass tienen graves defectos metodológicos, incluida la omisión de hallazgos clave en el corpus bibliográfico existente.

Sección 7: La relación de la Revisión con las revisiones sistemáticas de York y el uso que hace de ellas viola los procesos estándar que conducen a las recomendaciones clínicas en la medicina basada en la evidencia.

Sección 1: El informe Cass hace afirmaciones que son coherentes con los modelos de atención médica de afirmación de género descritos por WPATH y la Endocrine Society. El informe Cass no recomienda la prohibición de la atención médica de afirmación del género.

La Revisión coincide con las Normas de Atención de WPATH y las Directrices de Práctica Clínica de la Endocrine Society en que: (1) la atención médica es apropiada para algunos

jóvenes transexuales, (2) es necesaria una evaluación holística, exhaustiva e individualizada, y (3) las afecciones concurrentes de salud mental deben tratarse adecuadamente antes de las intervenciones de afirmación médica. El sitio

La revisión también cita una RS de York que valora favorablemente las Normas de Atención de WPATH 8 y las Guías de Práctica Clínica de la Sociedad de Endocrinología de 2017.[10] En el cuadro 1 figuran citas ejemplares de la revisión y de las directrices en cada uno de estos ámbitos.

El Informe *no* concluye que deba prohibirse la atención médica de reafirmación del género para la disforia de género en adolescentes. Por lo tanto, no debe citarse en apoyo de la prohibición de los tratamientos médicos para la disforia de género. Por el contrario, la Revisión describe favorablemente la prestación de una atención clínica individualizada y basada en pruebas, que incluya evaluaciones sólidas de los diversos ámbitos médicos y no médicos de apoyo que pueda necesitar un adolescente.

Acuerdo para que ciertos jóvenes con disforia de género se beneficien de la atención médica

La Revisión señala explícitamente que, "para algunos, el mejor resultado será la transición" (p. 21), aunque también reconoce, como hacen las Normas de atención de la WPATH y las Guías de práctica clínica de la Endocrine Society, que las intervenciones médicas de reafirmación del género no son apropiadas para todos los adolescentes transgénero. Este es un punto esencial, ya que muchos de los que critican esta atención afirman de forma inadecuada que el consenso médico avala la transición médica para cualquier menor que solicite atención. La Revisión afirma, y de hecho WPATH y la Endocrine Society están de acuerdo, que "debería haber una justificación clara para proporcionar hormonas en esta etapa en lugar de esperar hasta que el individuo cumpla 18 años". (p 187)

Aunque la Revisión contiene cierto lenguaje no técnico en relación con las intervenciones médicas de afirmación del género, es esencial señalar que este lenguaje va seguido de recomendaciones para llevar a cabo evaluaciones reflexivas y cautelosas antes de considerar la atención médica, en lugar de prohibir la atención o no proporcionarla en absoluto.

Acuerdo sobre la necesidad de una evaluación y un plan de tratamiento holísticos, exhaustivos e individualizados.

Las normas de atención de la WPATH y las directrices de práctica clínica de la Endocrine Society hacen hincapié en que debe realizarse una evaluación biopsicosocial individualizada y exhaustiva antes de realizar intervenciones médicas de reafirmación del género durante la adolescencia.[5,6] Estas evaluaciones implican una cuidadosa valoración de la historia de género del joven, los apoyos sociales, las consideraciones de fertilidad y los problemas de salud mental coexistentes, entre una amplia gama de otros temas.[11]

La Revisión dice: "Cuando se lleve a cabo una evaluación, será importante que los clínicos sean conscientes de que las presentaciones, las trayectorias y los resultados de esta cohorte son muy individuales, y la atención debe centrarse en ayudar a cada persona a encontrar la mejor trayectoria para ellos. Las evaluaciones deben

[10] La Revisión arroja datos que califican las Normas de Atención 8 del WPATH y las Guías de Práctica Clínica de la Sociedad de Endocrinología de 2017 entre los cinco mejores de 23 documentos analizados (p 129), utilizando la herramienta AGREE II. Además, la Revisión valora estas guías como particularmente altas en las áreas de "rigor de desarrollo" e "independencia editorial".

[11] Turban, J. L., Thornton, J., & Ehrensaft, D. (2024). Biopsychosocial Assessments for Pubertal Suppression to

Treat Adolescent Gender Dysphoria (Evaluaciones biopsicosociales de la supresión de la pubertad para tratar la disforia de género en adolescentes). Journal of the American Academy of Child and Adolescent Psychiatry, S0890-8567.

respetuosa con la experiencia del individuo e informada sobre su desarrollo". (p 28) La Revisión destaca que el proceso de evaluación debe incluir "el desarrollo conjunto de un plan para abordar las cuestiones de género, que puede implicar cualquier combinación de intervenciones sociales, psicológicas y físicas". Este enfoque ampliamente utilizado pretende crear un plan de apoyo integral que puede incluir intervenciones no médicas y/o médicas, dependiendo del escenario clínico.

Acuerdo en que es esencial optimizar el tratamiento de las enfermedades mentales concurrentes.

WPATH y la Endocrine Society subrayan sistemáticamente que la atención integral a los jóvenes transgénero incluye el tratamiento óptimo de cualquier otro trastorno de salud mental, con intervenciones médicas y/o no médicas apropiadas basadas en pruebas. [5,6] La Revisión afirma, y los expertos en género juvenil estarían de acuerdo, que "para aquellos jóvenes para los que está clínicamente indicada una vía médica, no es suficiente proporcionarla sin abordar también problemas más amplios de salud mental y/o psicosociales desafiantes como la ruptura familiar, las barreras a la participación en la vida escolar o las actividades sociales, el acoso y el estrés de las minorías" (p 30). (p 30) No hay pruebas de que los trastornos mentales concurrentes provoquen que una persona adopte una identidad transgénero, ni tampoco de que el tratamiento de los trastornos mentales concurrentes mejore los síntomas básicos de la disforia de género. Los pacientes individuales requieren planes de tratamiento adaptados a los diagnósticos realizados por profesionales cualificados.

Tabla 1: Principios básicos compartidos entre la Revisión Cass, las Guías de Práctica Clínica de la Endocrine Society y las Normas de Atención de WPATH 8[12]	
Acuerdo de que ciertos jóvenes con disforia de género se beneficiarán de los aspectos médicos de la atención de afirmación de género.	Revisión de Cass: "Las competencias de quienes trabajan en el servicio deben reflejar las amplias y variadas necesidades de este grupo heterogéneo y el servicio debe incluir la combinación de competencias adecuada para apoyar tanto a las personas para las que la intervención médica está clínicamente indicada como a aquellas para las que no lo está". (p 37) Sociedad de Endocrinología: "Sugerimos que los adolescentes que cumplan los criterios diagnósticos de DG [disforia de género]/ incongruencia de género, cumplan los criterios para recibir tratamiento y lo soliciten, se sometan inicialmente a un tratamiento para suprimir el desarrollo puberal." (p 3871) WPATH SOC 8: "Por ejemplo, algunos jóvenes se darán cuenta de que son transgénero o más ampliamente de género diverso y tomarán medidas para presentarse en consecuencia. Para algunos jóvenes, la obtención de tratamiento médico de afirmación de género es importante, mientras que para otros estos pasos pueden no ser necesarios. Por ejemplo, un proceso de exploración a lo largo del tiempo podría no dar lugar a que el joven se autoafirmara o encarnara un género diferente en relación con su sexo asignado al nacer y no implicaría el uso de intervenciones médicas". (p S51)
Acuerdo sobre la necesidad de una evaluación y un plan de tratamiento holísticos, exhaustivos e individualizados.	Revisión de Cass: "Al llevar a cabo una evaluación, será importante que los clínicos sean conscientes de que las presentaciones, los itinerarios y los resultados de esta cohorte son muy individuales, y la atención debe centrarse en ayudar a cada persona a encontrar el mejor itinerario para ellos. Las evaluaciones deben ser respetuosas con la experiencia individual y estar basadas en el desarrollo". (p 28) Sociedad de Endocrinología: "El tratamiento de afirmación del género es un esfuerzo multidisciplinar. Tras la evaluación, la educación y el diagnóstico, el tratamiento puede incluir atención de salud mental, terapia hormonal y/o terapia quirúrgica" (p 3871). WPATH SOC 8: "Recomendamos a los profesionales sanitarios que impliquen a las disciplinas pertinentes, incluidos los profesionales médicos y de salud mental, para llegar a una decisión sobre si la supresión de la pubertad, la iniciación hormonal o la cirugía relacionada con el género para los adolescentes transgénero y de género diverso son apropiadas y siguen estando indicadas durante todo el curso del tratamiento hasta que se realice la transición a la atención de adultos" (p S48).
Coincidencia en que es esencial optimizar el tratamiento de las enfermedades mentales concomitantes.	Revisión de Cass: "Deben utilizarse enfoques de tratamiento psicológico y psicofarmacológico estándar basados en la evidencia para apoyar el tratamiento de la angustia asociada y las afecciones concurrentes. Esto debe incluir el apoyo a los padres/cuidadores y hermanos, según proceda" (p 31). Sociedad de Endocrinología: "Los adolescentes son elegibles para el tratamiento con agonistas de la GnRH [y hormonas sexuales posteriores] si: se ha abordado cualquier problema psicológico, médico o social coexistente que pudiera interferir con el tratamiento (por ejemplo, que pueda comprometer la adherencia al tratamiento), de forma que la situación y el funcionamiento del adolescente sean lo suficientemente estables como para iniciar el tratamiento." (p 3878) WPATH SOC 8: "Recomendamos a los profesionales sanitarios que evalúan a adolescentes transgénero y con diversidad de género que sólo recomienden tratamientos médicos o quirúrgicos de afirmación de género solicitados por el paciente cuando... se hayan abordado los problemas de salud mental del adolescente (si los hubiera) que puedan interferir con la claridad del diagnóstico, la capacidad de consentimiento y/o los tratamientos médicos de afirmación de género." (p S48)

[12] Aunque no se trata de una directriz, los responsables políticos y los medios de comunicación suelen hacer referencia a la Declaración práctica sobre la atención sanitaria con afirmación de género de la Academia Americana de Pediatría (AAP). Sus temas centrales también coinciden con las áreas tratadas en la Tabla 1.

Por ejemplo, "La decisión de iniciar o no un tratamiento de afirmación de género y cuándo hacerlo es personal e implica una cuidadosa consideración de los riesgos, beneficios y otros factores exclusivos de cada paciente y su familia" y "Muchos protocolos sugieren que la evaluación clínica de los jóvenes que se identifican como TGD se realice idealmente de forma continua en el

A menudo, las declaraciones del Informe contradicen sus propias recomendaciones.

Las afirmaciones de la Revisión y sus recomendaciones divergen a menudo. Para un documento que ofrece orientación sobre la atención clínica, esta incoherencia interna es muy inusual. El reconocimiento de que ciertos jóvenes pueden beneficiarse de intervenciones de afirmación médica se ve socavado por la recomendación de la Revisión de limitar la atención a un marco de ensayos clínicos inexistente que propone pero no describe. El debate sobre la necesidad de una evaluación individualizada queda eclipsado por la exigencia de que todos los jóvenes tengan una determinada edad para poder recibir la atención recomendada por las directrices. El acuerdo con WPATH y la Endocrine Society sobre el tratamiento óptimo de las enfermedades mentales concurrentes no es sincero cuando, en páginas posteriores, la Revisión especula, sin pruebas, sobre la posibilidad de que la disforia de género surja como resultado de una enfermedad mental, el consumo de pornografía[13] , la neurodiversidad[14] , los medios sociales[15] y la influencia de los iguales.[16]

Aunque las afirmaciones narrativas de la Revisión coinciden a menudo con las normas basadas en pruebas existentes en el campo de la salud de las personas transgénero, sus recomendaciones -que en realidad repercuten en el acceso de las personas a la atención sanitaria- ignoran estas normas y entran en conflicto con el consenso médico.

Sección 2: La revisión de Cass no sigue las normas establecidas para evaluar la evidencia y su calidad.

La Revisión discute casualmente la calidad de la evidencia y no la define, contraviniendo la práctica habitual en las evaluaciones científicas de la investigación médica. A continuación, comparamos el enfoque de la Revisión con uno de los marcos más ampliamente aceptados para determinar la calidad de la evidencia: Grading of Recommendations Assessment, Development and Evaluation (GRADE).[17] Según GRADE

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el marco de un enfoque colaborativo y multidisciplinar, que, además del paciente y la familia, puede incluir al proveedor pediátrico, un proveedor de salud mental (preferiblemente con experiencia en la atención a jóvenes que se identifican como TGD), apoyos sociales y legales, y un endocrinólogo pediátrico o especialista en género en medicina del adolescente, si está disponible". (p 5)

[13] p 117 "...del mismo modo que la angustia puede manifestarse a través de trastornos alimentarios o depresión, también podría manifestarse a través de angustia relacionada con el género".

[14] La Revista cita un comentario que supone que el consumo de pornografía lleva a los jóvenes a ser transexuales. Este artículo fue escrito por un individuo de una organización con una perspectiva ideológica más que científicamente informada sobre la identidad de género. Esa organización, Therapy First, defiende un enfoque singular para todos los que expresan diversidad de género y patologiza la identidad no cisgénero. Nadrowski, K. (2023). ¿Una nueva huida de la feminidad? The Importance of Working Through Experiences Related to Exposure to Pornographic Content in Girls Affected by Gender Dysphoria. Journal of Sex & Marital Therapy, 50(3), 293-302. https://doi.org/10.1080/0092623X.2023.2276149

[15] De la RS de York sobre las vías de atención, Grijseels escribe: "Notablemente, informan erróneamente la incidencia de la condición del espectro autista (ASC) según lo informado por Morandini et al., escribiendo "[u]n estudio informó datos por separado para 2012 y 2015 y demostró un aumento del 1,8% al 15,1%" (Taylor et al., p. 5), cuando los números informados fueron un aumento no significativo del 13,8% al 15,1% (p= .662) (Morandini et al.)." Grijseels, D. M. (2024). Biological and psychosocial evidence in the Cass Review: a critical commentary. *Revista Internacional de Salud Transgénero*, 1-11. https://doi.org/10.1080/26895269.2024.2362304

[16] Páginas en las que la Revista especula sobre las causas de la disforia de género: enfermedad mental (p 30, 85, 91, 111, 117), pornografía (p 110), neurodiversidad (p 308, 309, 311), redes sociales (p 117), e influencia de los iguales (p 27, 104, 106,

117, 120, 122).

[17] Este es el único sistema de clasificación de la evidencia que utiliza terminología de calidad que conocemos y es ampliamente respetado en la comunidad médica. También fue utilizado tanto por la Endocrine Society como por el WPATH en la elaboración de las directrices. La Revisión describe GRADE (p 55) pero no afirma que haya utilizado este método, o cualquier otro, para

GRADE, los ensayos controlados aleatorizados (ECA) *bien realizados* y las revisiones sistemáticas (RS) suelen considerarse la forma de evidencia de mayor calidad. Los estudios observacionales rara vez cumplen los criterios para ser considerados evidencia de alta calidad,[18] y, sin embargo, proporcionan la mayor parte de la evidencia que guía la atención clínica en todos los campos de la medicina.

Como han reconocido explícitamente los redactores del marco GRADE, la evidencia y su calidad son una de las muchas consideraciones a tener en cuenta a la hora de atender a los pacientes.[19] Las guías de práctica clínica de toda la medicina tienen en cuenta todos los factores relevantes, pero la Revisión da el paso inusual de elevar su propia evaluación de la calidad de la evidencia por encima de las consideraciones que valoran quienes elaboran las guías. La Revisión también utiliza una terminología engañosa y subjetiva, y hace un uso incorrecto del lenguaje técnico relativo a la calidad de la evidencia. En cualquier otro campo de la medicina, esta práctica se consideraría inaceptable y perjudicial para los pacientes.

La discusión de la Revisión sobre la calidad de la evidencia no es científicamente sólida

En GRADE, se utilizan denominaciones de calidad como "alta", "moderada", "baja" y "muy baja" para describir la evidencia.[10] En la ciencia médica existe una comprensión compartida de lo que significan estos términos, lo que permite a los expertos utilizarlos en la elaboración de recomendaciones clínicas de amplia aplicación.

La revisión introduce el sistema GRADE (p. 55), pero nunca evalúa las pruebas utilizando el marco GRADE. La Revisión toma prestada la terminología GRADE al expresar repetidamente su deseo de que las pruebas de "alta calidad" dominen el campo de la salud transexual. Así pues, la Revisión se queda muy corta al no describir ni aplicar un método formal para asignar la calidad de la evidencia.

Así, la Revisión habla un lenguaje que puede parecer familiar, pero sus fundamentos son pseudocientíficos y subjetivos. Por ejemplo, descriptores de la calidad de las pruebas sin base científica como "débil" y "deficiente" aparecen 21 y 10 veces, respectivamente.[20] El uso de términos tan ambiguos lleva a los lectores a sacar sus propias conclusiones, que pueden no estar fundamentadas científicamente. Dichos términos también socavan el rigor de la investigación real, que presenta resultados mucho más matizados de lo que transmiten los descriptores subjetivos.

La Revisión se fija en la calidad de la evidencia excluyendo muchos otros factores que son rigurosamente considerados por los desarrolladores de guías de práctica clínica

A la hora de elaborar directrices que ofrezcan recomendaciones sobre atención clínica, los grupos de expertos tienen en cuenta las pruebas de la eficacia de un tratamiento. También tienen en cuenta los beneficios y perjuicios de

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valorar la evidencia. Guyatt GH, Oxman AD, Kunz R, et al; Grupo de Trabajo GRADE. ¿Qué es la "calidad de la evidencia" y por qué es importante para los médicos? BMJ. 2008 May 3;336(7651):995-8. doi: 10.1136/bmj.39490.551019.BE. PMID: 18456631; PMCID: PMC2364804.

[18] Un estudio observacional puede considerarse de alta calidad si muestra un gran efecto, si los sesgos en el diseño del estudio conducen a una subestimación del efecto del tratamiento y si el efecto depende de la dosis (lo que

significa que la magnitud del efecto depende de la cantidad de intervención). Esto no suele ocurrir en los estudios observacionales.

[19] Balshem H, et al., GRADE Guideline: 3. Rating the Quality, 64 J. Clin. Epidem. 401, 402-404 (2011).

[20] "Débil" o "debilidad": p 13, 20, 22, 25 (dos veces), 31, 33, 36, 44, 47, 77, 163, 164, 184, 196, 202, 210, 222, 229, 231 y 320; "pobre": p 30, 34, 114, 130 (dos veces), 134, 154, 179, 193, 194 y 385

tanto el tratamiento como la ausencia de tratamiento, los valores y preferencias de los pacientes y los recursos necesarios para ofrecer el tratamiento.[21] *Precisamente por ello, la calidad de la evidencia no es sinónimo de recomendaciones clínicas.*

A primera vista, puede parecer desconcertante que la atención clínica no proceda directamente de la evidencia médica. Pero si así fuera, los pacientes del mundo real no recibirían una atención adecuada y factible que se ajustara a sus preferencias y valores. GRADE, por ejemplo, describe cuatro áreas que los creadores de directrices deben considerar rigurosamente a la hora de emitir recomendaciones: certeza y calidad de la evidencia, equilibrio entre beneficios y daños, valores y preferencias de los pacientes y utilización de recursos. Aquí mostramos cómo la consideración de tres de estas áreas por parte de la Revisión es inadecuada.

1. Certeza y calidad de la evidencia: La Revisión no describe los resultados positivos de los tratamientos médicos de reafirmación de género para jóvenes transexuales, incluyendo la mejora de la satisfacción corporal, la congruencia de la apariencia, la calidad de vida, el funcionamiento psicosocial y la salud mental, así como la reducción de la suicidalidad. *Es muy poco habitual que un documento en el que se formulan recomendaciones clínicas no describa suficientemente las pruebas sobre los efectos del tratamiento.*
2. Balance de beneficios y daños: La Revisión no tiene en cuenta los perjuicios de no ofrecer atención médica de reafirmación de género a un joven con disforia de género. El efecto más concreto y tangible de no ofrecer tratamiento es el desarrollo de características físicas permanentes que no coinciden con el género de la persona. Entre ellas se incluyen el engrosamiento de la voz, el crecimiento del vello, el desarrollo del tejido mamario, la estatura final y el hábito corporal. La Revisión ignora el importante dolor psicológico que sufren los adolescentes con disforia de género, para quienes estos cambios físicos permanentes son muy angustiosos. La Revisión también ignora las consecuencias para los adolescentes que, si no reciben tratamiento, deben presentar al mundo una apariencia física que no concuerda con su propia identidad. En la edad adulta, estos efectos físicos pueden mejorarse hasta cierto punto con tratamientos costosos e invasivos como la cirugía, la depilación y la logopedia. Estos tratamientos no borran los años de angustia psicológica. La Revisión también identifica de forma selectiva los supuestos perjuicios del tratamiento, mientras que no aborda los perjuicios de la ausencia de tratamiento. Por ejemplo, la Revisión teoriza que las personas que han sido tratadas con medicamentos para retrasar la pubertad y desean someterse a una vaginoplastia pueden tener un postoperatorio más difícil.[22] Sin embargo, la revisión no tiene en cuenta cómo los fármacos inhibidores de la pubertad previenen el desarrollo de tejido mamario no deseado y pueden evitar la necesidad posterior de una mastectomía, que es la intervención quirúrgica más solicitada por los adultos transexuales.[15]
3. Valores y preferencias de los pacientes: La Revisión cuenta con la participación de jóvenes transexuales, pero a menudo hace recomendaciones que entran en conflicto con sus valores y preferencias expresados. El tema predominante de los grupos de discusión con jóvenes transexuales es que quieren mejorar el acceso a servicios médicos apropiados que afirmen su género, prestados por médicos con la formación y la experiencia adecuadas. Quieren que se tengan en cuenta sus necesidades y preocupaciones.

[21] Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines; Graham R, Mancher M, Miller Wolman D, et al., editors. Guías de práctica clínica en las que podemos confiar.

Washington (DC): National Academies Press (US); 2011. Disponible en: https://www.ncbi.nlm.nih.gov/books/NBK209539/ doi: 10.17226/13058

[22] van de Grift TC, van Gelder ZJ, Mullender MG, et al. Momento de la supresión de la pubertad y opciones quirúrgicas para jóvenes transexuales. Pediatrics. 2020 Nov;146(5):e20193653. doi: 10.1542/peds.2019-3653. PMID: 33106340.

> seriamente. *La Revisión ignora por completo los valores y preferencias expresados por los jóvenes transexuales en su recomendación más rotunda, que consiste en limitar la atención a entornos de investigación que aún no existen.*

La Revista solicitó puntos de vista profesionales no válidos

La Revisión llevó a cabo una serie de grupos de discusión con trabajadores sanitarios de diversa formación, algunos de los cuales ni siquiera son clínicos. No está claro cuál e s la experiencia de estas personas en el campo de la salud transgénero. Cabe destacar que el 34% afirmó que su conocimiento de los "niños y jóvenes con problemas de género" procedía del discurso público y de los medios de comunicación. Además, el 32% de los encuestados estaba muy de acuerdo o de acuerdo con la afirmación "No existen los niños trans".[23,24] *Negar la existencia de personas transgénero de cualquier edad es un punto de vista profesional inválido. La participación de personas con puntos de vista tan extremos es un paso profundamente preocupante para un documento que emite recomendaciones sobre atención clínica.* No debería utilizarse una directriz que solicita la opinión de quienes no reconocen la condición para la que se busca atención. Estas personas pueden expresar sus opiniones ideológicas, pero su participación en un proceso que da lugar a recomendaciones sobre la atención clínica es un fallo de la Revisión.

La Revisión no reconoce los matices de las medidas de calidad de la evidencia

Al fijarse en la evidencia para hacer recomendaciones sobre la atención al paciente, la Revisión apuesta la casa por un concepto que en sí mismo tiene defectos. La utilidad de la terminología sobre la calidad de la evidencia es objeto de un profundo debate en la comunidad médica. Diferentes evaluadores suelen discrepar y hacer valoraciones divergentes de la calidad de la evidencia. No existen procesos bien descritos para resolver estos desacuerdos. Con más investigación, la calidad de la evidencia en muchos campos de la medicina no mejora necesariamente, ya que los diseños de estudio necesarios para detectar efectos cada vez más pequeños se vuelven inviables.[25] Así pues, muchas áreas de la medicina pueden tener límites máximos inherentes a la calidad de la evidencia en el mundo real, y ese nivel de calidad rara vez coincide con el ideal teórico descrito por las metodologías de clasificación de la evidencia.

Los partidarios de restringir la atención sanitaria a los jóvenes transexuales suelen llamar la atención sobre la supuesta ausencia de pruebas de alta calidad en este campo. Si la evidencia de alta calidad fuera un prerrequisito para la atención médica, todos estaríamos peor. La evidencia de calidad moderada, baja y muy baja (utilizando los términos definidos en GRADE) sirve de base para una atención necesaria y de alto valor en todas las etapas de la vida. Una revisión de las revisiones sistemáticas Cochrane en numerosas áreas de la medicina mostró que el 86,5% de las revisiones presentaban niveles de evidencia moderados (30,8%), bajos (31,4%) y muy bajos (24%).[17] Menos de 1 de cada 7 revisiones sistemáticas tenía pruebas de alta calidad para un resultado primario y menos de 1 de cada 5 revisiones sistemáticas tenía pruebas de alta calidad para cualquiera de los resultados primarios.

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[23] Horton, C. (2024). The Cass Review: Cis-supremacy in the UK's approach to healthcare for trans children. *Revista Internacional de Salud Transgénero*, 1-25. https://doi.org/10.1080/26895269.2024.2328249

[24] https://cass.independent-review.uk/wp-content/uploads/2022/03/REPORT-Cass-Review-professional-panel-FINAL.pdf

[25] Howick J, Koletsi D, Pandis N, et al. La calidad de la evidencia para las intervenciones médicas no mejora o worsen: a meta-epidemiological study of Cochrane reviews. J Clin Epidemiol. 2020 Oct;126:154-159. doi: 10.1016/j.jclinepi.2020.08.005. Epub 2020 Sep 2. PMID: 32890636.

resultado.[26] Los autores descubrieron que la calidad de las pruebas en 52 áreas de la medicina no solía ser alta. Estas áreas incluían procedimientos y tratamientos en campos tan diversos como la anestesia, el cáncer de mama, la fibrosis quística, la enfermedad pancreática, los cánceres de sangre, la esclerosis múltiple, la obstetricia, la esquizofrenia y el ictus, entre muchos otros. Además, no hay ninguna investigación publicada que demuestre que las designaciones de calidad de la evidencia mejoren la atención al paciente.[27]

La fijación de la Revisión en las pruebas de "alta calidad" es inadecuada

Los llamamientos de la Revisión a una evidencia de "alta calidad" en la atención a los jóvenes transexuales no pueden separarse del hecho de que la evidencia considerada de alta calidad por sistemas como GRADE procede en la mayoría de los casos de ECA.[28] En cualquier área de la medicina, la presencia o ausencia de "pruebas de alta calidad" por sí sola no debería utilizarse para decidir si se ofrece un tratamiento que ha demostrado ser beneficioso, y la atención en cualquier área de la medicina no debería interrumpirse a la espera de diseños de estudios específicos. Además, los ECA son especialmente inadecuados para estudiar los efectos de muchas intervenciones sobre el bienestar psicológico y la calidad de vida de las personas transexuales.[29] Por las razones éticas y metodológicas que se exponen a continuación, el tipo de pruebas que defiende la Revisión no es posible ni apropiado en el ámbito de la atención para la afirmación de la identidad de género.

1. *Enmascaramiento*: Es el proceso por el que se oculta a los participantes e investigadores si los pacientes reciben tratamiento o placebo. Los medicamentos para frenar la pubertad y las hormonas de reafirmación de género tienen un impacto fisiológico evidente. Las personas asignadas aleatoriamente al grupo de tratamiento notarían claramente la falta de cambios físicos derivados de la pausa de la pubertad o los cambios físicos relacionados con la terapia hormonal. Los del brazo de no tratamiento experimentarían cambios físicos evidentes e incongruentes con el género. *Por tanto, el enmascaramiento es imposible.*
2. *Adherencia*: Las personas con disforia de género buscan un tratamiento de difícil acceso y muy deseado. Si se les colocara en el grupo sin tratamiento, probablemente abandonarían el estudio para buscar tratamiento en otro lugar. *Por lo tanto, la adherencia se vería gravemente comprometida.*
3. *Coacción: La* coacción se produce cuando la participación en la investigación es una de las únicas formas de obtener un tratamiento muy necesario. Un modelo de ECA para evaluar la conveniencia de administrar intervenciones de reafirmación médica a jóvenes con disforia de género puede resultar atractivo para aquellos que no pueden obtener intervenciones de reafirmación de otra forma. Según la normativa internacional sobre

[26] Fleming PS, Koletsi D, Ioannidis JP, Pandis N. La alta calidad de la evidencia para las intervenciones médicas y otras relacionadas con la salud fue infrecuente en las revisiones sistemáticas Cochrane. J Clin Epidemiol. 2016 Oct;78:34-42. doi: 10.1016/j.jclinepi.2016.03.012. Epub 2016 mar 29. PMID: 27032875.

[27] Kavanagh BP. El sistema GRADE para la calificación de guías clínicas. PLoS Med. 2009 Sep;6(9):e1000094. doi: 10.1371/journal.pmed.1000094. Epub 2009 Sep 15. PMID: 19753107; PMCID: PMC2735782.

[28] Guyatt GH, Oxman AD, Kunz R, et al HJ; Grupo de trabajo GRADE. ¿Qué es la "calidad de la evidencia" y por qué lo es? ¿importante para los médicos? BMJ. 2008 mayo 3;336(7651):995-8. doi: 10.1136/bmj.39490.551019.BE. PMID:

18456631; PMCID: PMC2364804.

[29] Este artículo presenta un análisis en profundidad de por qué el modelo ECA es inadecuado: Ashley, F., Tordoff, D. M., Olson-Kennedy, J., & Restar, A. J. (2023). Randomized-controlled trials are methodologically inappropriate in adolescent transgender healthcare. *International Journal of Transgender Health*, 1-12. https://doi.org/10.1080/26895269.2023.2218357

ética científica, la coerción, aunque no sea intencionada, debe evitarse en el diseño de los estudios.[30] *Restringir toda la atención a un entorno de investigación, como han hecho las recientes normas británicas basadas en la Revisión, es coercitivo y poco ético.*

4. *Generalizabilidad*: La coerción no sólo es contraria a la ética, sino que además atrae a la investigación a una población que probablemente no se parezca a la población más amplia que podría beneficiarse del tratamiento. *Por lo tanto, la generalizabilidad no es posible con un modelo de ECA coercitivo.*

Sección 3: La Revisión Cass no contextualiza la evidencia para la atención que afirma el género con la base de evidencia para otras áreas de la medicina pediátrica.

A pesar de las recomendaciones de la Revisión, la continuidad de la investigación y la atención a los jóvenes transgénero está bien alineada con los estándares pediátricos. A continuación, analizamos cómo la Revisión no reconoce las complejidades de la investigación pediátrica y cómo otros tipos de atención pediátrica cuentan con pruebas y prácticas comparables para atender a los jóvenes transgénero, pero no son objeto de restricciones comparables.

La Revisión no reconoce las realidades y matices de la investigación médica pediátrica

La Revisión expresa un deseo apropiado de ver estudios más largos y amplios sobre los impactos del tratamiento médico de afirmación de género, y esto coincide con las opiniones de las principales organizaciones. Sin embargo, el deseo de la Revisión de que sólo la evidencia de alta calidad domine este campo no es realista ni apropiado*, ya que ningún otro ámbito de la pediatría se rige por este estándar.*

La investigación en el ámbito de la atención al género juvenil implica a pacientes pediátricos y, por lo tanto, está sujeta a consideraciones únicas y necesarias que no están presentes en la investigación con adultos. Estas consideraciones incluyen:

1. *Consentimiento:* El consentimiento informado y la participación voluntaria constituyen la base de la investigación ética. Los menores no pueden dar su consentimiento de forma independiente, y los padres deben estar muy implicados. Muchos ensayos pediátricos han fracasado en su lanzamiento debido a que el necesario pero arduo proceso de consentimiento informado significó que se reclutaran muy pocos participantes.[13] (Los ECA deben inscribir a un gran número de sujetos de estudio para detectar un efecto.) Combinando la necesidad de la participación de los padres y el problema de la coacción, los problemas con el consentimiento limitarían con toda seguridad la inscripción a gran escala para un ECA en la atención del género juvenil.
2. *Rareza: Las* enfermedades que afectan a los niños suelen ser diferentes y/o más raras que las que afectan a los adultos. Por lo tanto, estas afecciones deben estudiarse de forma diferente.
3. *Recursos inadecuados: Las* iniciativas legislativas y políticas infrafinancian significativamente la investigación pediátrica en relación con la investigación sobre la atención a adultos. Incluso con la inversión gubernamental y del sector privado, el número anual de ECA pediátricos publicados es ya muy inferior al de los adultos y está disminuyendo.[31]

[30] La Declaración de Helsinki esboza principios éticos autorizados para la investigación con seres humanos.

https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

[31] Una revisión de las tendencias de publicación de ECA de adultos frente a ECA pediátricos demostró que los ECA de adultos aumentaron en 4,71 ECA/año, mientras que los ECA pediátricos solo aumentaron en 0,44 ECA al año entre 1985 y 2004. De 2005 a 2018, los ECA de adultos aumentaron en 5,1 ECA por año, mientras que los ECA pediátricos disminuyeron en 0,4 ECA por año. Cohen E, Uleryk E, Jasuja M, Parkin PC. An absence of pediatric randomized controlled trials in general medical journals, 1985-2004. J Clin Epidemiol. 2007 Feb;60(2):118-23. doi: 10.1016/j.jclinepi.2006.03.015. Epub 2006 Nov 13. PMID: 17208117., Groff ML, Offringa M, Emdin A, , et al. Publication Trends of Pediatric and Adult Randomized Controlled Trials in

Paralelismos entre la atención al género juvenil y otros aspectos de la atención pediátrica

En una entrevista, el Dr. Cass afirmó: "No se me ocurre ninguna otra situación en la que administremos tratamientos que alteran la vida y no tengamos suficientes conocimientos sobre lo que les ocurre a esos jóvenes en la edad adulta."[32] De hecho, debido a las realidades de la dinámica de investigación descrita anteriormente, muchos tratamientos médicos pediátricos se basan en investigaciones limitadas.

Aunque ninguna comparación es perfecta, los paralelismos entre la atención médica de afirmación de género y otras áreas de la pediatría son abundantes. Todos los tipos de prácticas pediátricas parten de una escasez de pruebas y, sin embargo, deben prestar asistencia a una población heterogénea necesitada. Un análisis exhaustivo y matizado de la medicina pediátrica basada en la evidencia queda fuera del alcance de este informe, pero comentamos algunas prácticas dentro de los cuidados críticos pediátricos y neonatales. Las prácticas que analizamos se basan en pruebas de calidad inferior a la alta (según los estándares de la definición) y, como la atención de afirmación de género para jóvenes transgénero, se guiaron por la práctica clínica informada y se aceptaron en escenarios de alto riesgo incluso cuando los datos a largo plazo aún están en proceso de recopilación.

La neonatología es el cuidado de niños en estado crítico, a menudo prematuros. Los cuidados críticos pediátricos se ocupan de los niños y adolescentes con enfermedades inestables y potencialmente mortales, como sepsis, lesiones cerebrales, insuficiencia orgánica y crisis oncológicas. Los clínicos de estos campos toman cada día cientos (si no miles) de decisiones de alto riesgo basadas en la evidencia para sus pacientes. A menudo, estas decisiones no son sencillas:

1. ¿Un bebé prematuro con problemas respiratorios debe recibir apoyo con un tubo respiratorio o con una medida no invasiva? ¿Cuándo y cómo debe retirarse esa asistencia para ver si el bebé puede respirar por sí solo?
2. Un bebé prematuro cuya madre no puede producir leche materna, ¿debe recibir leche artificial o leche materna de donante? Una predispone a infecciones intestinales graves, mientras que la otra se asocia a un lento aumento de peso.
3. ¿Cuál es la mejor forma de administrar líquidos intravenosos para mantener la tensión arterial en un niño con una infección sistémica potencialmente mortal (sepsis)? Una cantidad excesiva podría sobrecargar el corazón y los riñones, y una cantidad insuficiente podría limitar el aporte de oxígeno a los tejidos, que lo necesitan urgentemente.

Las pruebas que ayudan a responder a estas y otras preguntas rara vez son de "alta calidad" (como se utiliza el término en GRADE).[33] Y, sin embargo, los resultados clínicos son buenos y están mejorando: cada vez más niños abandonan

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Revistas de medicina general, 2005-2018: Un análisis de citas. *Children*. 2020; 7(12):293. https://doi.org/10.3390/children7120293

[32] Ghorayshi A. "Hilary Cass dice que los médicos estadounidenses están "desfasados" en medicina de género juvenil" New York Times. Consultado el 30 de mayo de 2024.

[33] Buscamos bibliografía sobre la calidad de la evidencia en muchas áreas de la atención neonatal y pediátrica. En lugar de una inventario, presentamos la calidad de la evidencia en el cuidado del síndrome de dificultad respiratoria neonatal. En las guías sobre el cuidado de los prematuros con dificultad respiratoria grave, el 92% de las recomendaciones se

basaron en pruebas de calidad consensuada por expertos (33%), muy baja (25%), baja (12%) o moderada (16%). Huang Y, Zhao J, Hua X, et al.
Directrices para la oxigenoterapia con cánula nasal de alto flujo en neonatos (2022). *J Evid Based Med*. 2023; 16: 394-413. https://doi.org/10.1111/jebm.12546; Zhang, Z., Chen, L., Cai, H. *et al.* Low Quality Evidence Supporting Recommendations in the 2021 Sepsis Guideline: An Indication for Precise Medicine? *Intensive Care Res* **2**, 23-25 (2022). https://doi.org/10.1007/s44231-022-00007-2

unidades de cuidados intensivos mejor que nunca.[34] La mayoría de los aspectos de los cuidados críticos neonatales y pediátricos se convirtieron en una práctica clínica aceptada por sus beneficios inmediatos y a corto plazo, sin realizar un seguimiento de los pacientes hasta la edad adulta. Incluso ahora, no se conoce bien el grado en que los niños dados de alta de cuidados intensivos logran una recuperación neurodesarrolladora y funcional completa, y ésta es un área de investigación nueva y activa en el mundo de los cuidados críticos. La búsqueda de más y mejores datos no tiene fin, pero cuando las respuestas sólo están disponibles parcialmente, los pacientes no pueden esperar a recibir atención.

Quizá el campo más novedoso sea el uso de análogos del péptido-1 similar al glucagón (GLP-1) para el tratamiento del síndrome metabólico pediátrico.[35] Los niños padecen prediabetes, hepatopatía grasa no alcohólica, hipertensión arterial, apnea del sueño y otros problemas de salud en mayor proporción que nunca. Nos preocupa seriamente que una generación de jóvenes llegue a la edad adulta con tasas devastadoramente altas de enfermedades que aumentan el riesgo de muerte prematura. A la luz de estas preocupaciones, estos medicamentos se recomiendan ahora para los niños. Las pruebas sobre los GLP-1 pueden criticarse de muchas de las mismas maneras que la atención sanitaria a transexuales. Los GLP-1 en niños sólo se han estudiado durante 1-2 años. Aún no sabemos cuáles son las repercusiones a largo plazo de una pérdida de peso profunda en la adolescencia sobre los huesos y los trastornos alimentarios. ¿Podrán disfrutar de la comida en la edad adulta?
¿Pueden suspenderse estos medicamentos sin que se produzca un aumento de peso de rebote?

En el ámbito de la atención a los jóvenes con trastornos de género, tenemos pruebas de que estos medicamentos tratan eficazmente la disforia de género, de que los jóvenes continúan con estos medicamentos en la edad adulta, de que su satisfacción con los tratamientos médicos de afirmación de género es alta, de que su densidad ósea se recupera tras los medicamentos que frenan la pubertad y de que sus identidades transgénero persisten.

No se trata de comparar hasta el punto de la crítica destructiva. El punto es que el uso cuidadoso de las opciones de tratamiento que tenemos ahora, con la mejor evidencia que tenemos, define el cuidado pediátrico. Invitamos a quienes estén interesados en el cuidado de los jóvenes transexuales a considerar la amplia gama de prácticas dentro de la pediatría donde los efectos a largo plazo son plenamente conocidos. Los niños se benefician de tratamientos médicos innovadores que mejoran su supervivencia y su calidad de vida. La atención pediátrica prácticamente cesaría si los médicos negaran tratamientos para los que la base de pruebas es imperfecta.

La Revisión tiene preocupaciones exageradas y vagas sobre los datos a largo plazo

Resulta difícil discernir la validez de la preocupación de la Revisión por los datos a largo plazo en la atención a los jóvenes en cuestiones de género. Afirma que no existen datos a largo plazo, pero no define lo que considera que significa "a largo plazo"; no describe qué resultados a largo plazo satisfarían sus preocupaciones, y

[34] Pollack MM, Banks R, Holubkov R, Meert KL; and the Eunice Kennedy Shriver National Institute of Child Health and Human Development Collaborative Pediatric Critical Care Research Network. Long-Term Outcome of PICU Patients Discharged With New, Functional Status Morbidity. Pediatr Crit Care Med. 2021 Jan 1;22(1):27-39. doi: 10.1097/PCC.0000000000002590. PMID: 33027242; PMCID: PMC7790876.; Biban P, Marlow N, Te Pas AB,

et al. Avances en cuidados críticos neonatales: Pushing at the Boundaries and Connecting to Long-Term Outcomes. Crit Care Med. 2021 Dic 1;49(12):2003-2016. doi: 10.1097/CCM.0000000000005251. PMID: 34380942.

[35] Hampl SE, Hassink SG, Skinner AC, et al. Guía de práctica clínica para la evaluación y el tratamiento de niños y adolescentes con obesidad. Pediatrics. 2023 Feb 1;151(2):e2022060640. doi: 10.1542/peds.2022-060640. Fe de erratas en: Pediatrics. 2024 Jan 1;153(1):e2023064612. doi: 10.1542/peds.2023-064612. PMID: 36622115.

no tiene en cuenta las pruebas que han seguido a los pacientes durante más de una década.[36] La Revisión espera que los investigadores informen sobre los efectos aislados y a largo plazo de los fármacos inhibidores de la pubertad, pero estos fármacos casi siempre forman parte de un proceso escalonado que incluye otros tratamientos. Además, la Revisión espera una abundancia de datos a largo plazo sobre tratamientos que sólo han estado disponibles más fácilmente con fines de afirmación del género en los últimos 8-10 años. La capacidad de la comunidad médica para describir las experiencias de los pacientes transexuales es proporcional a la mejora del acceso a la atención en la última década.

Aunque los datos a largo plazo son costosos y difíciles de obtener, el campo de la salud transexual está afrontando este reto en el momento oportuno. Investigadores clínicos que representan a 39 estudios de EE.UU. han recibido 12,1 millones de dólares de los Institutos Nacionales de Salud (NIH) para estudiar las repercusiones fisiológicas y psicosociales de esta atención en miles de pacientes durante los próximos años, con aplicabilidad directa a los jóvenes transexuales.[37]

Sección 4. El Cass Review malinterpreta y tergiversa sus propios datos.

La Revisión aprovecha el Servicio Nacional de Salud (NHS) del Reino Unido para recopilar una gran cantidad de datos sobre los servicios para jóvenes transgénero en el Reino Unido. De hecho, el motivo por el que se encargó inicialmente la Revisión fue abordar el fracaso del NHS a la hora de proporcionar una atención oportuna, competente y de alta calidad a los jóvenes transexuales de todo el país. Esta valiosa información arroja luz sobre las necesidades de la población de jóvenes transexuales del Reino Unido, los obstáculos a los que se enfrentan en la búsqueda de atención y los entresijos de un sistema sobrecargado. Estos datos, cuando se examinan detenidamente, son una contribución significativa al campo de la salud de los transexuales. Pero la interpretación y representación que hace la Revisión de estos datos son a menudo incorrectas.

Uno de los puntos centrales del Informe es que el aumento de las derivaciones en el Reino Unido es tan espectacular que no puede explicarse por la aceptación social de la identidad transexual. Esta postura se repite a lo largo de sus 388 páginas y se expresa mejor aquí:

> "Aunque ciertamente parece darse el caso de que hay una aceptación mucho mayor de las identidades trans, especialmente entre las generaciones más jóvenes, lo que puede explicar en parte el aumento de las cifras, el cambio exponencial de las referencias en un plazo especialmente corto de cinco años es mucho más rápido de lo que cabría esperar para la evolución normal de la aceptación de un grupo minoritario." (p 26)

Si lo que se espera es que las tendencias de remisión se ajusten a la "evolución normal de la aceptación de un grupo minoritario", cabría esperar que el Informe definiera este concepto. Pero no lo hace. No es de extrañar: no existe el denominado patrón normativo de aceptación social de un grupo minoritario. Este

[36] Una de las revisiones sistemáticas de York omitió un estudio que presentaba los datos de resultados más prolongados en relación con la densidad ósea. Este estudio de 2023 describía una densidad ósea normal tras 11 años de tratamiento hormonal de afirmación de género. La Revisión menciona este estudio de referencia sólo de pasada y sin reconocer sus hallazgos clave. van der Loos MATC, Vlot MC, Klink DT, et al. Bone Mineral Density in

Transgender Adolescents Treated With Puberty Suppression and Subsequent Gender-Affirming Hormones. JAMA Pediatr. 2023 Dic 1;177(12):1332-1341. doi: 10.1001/jamapediatrics.2023.4588. PMID: 37902760; PMCID: PMC10616766.

[37] Se trata de una búsqueda no sistemática y no exhaustiva en la base de datos NIH RePORTER de subvenciones concedidas. Esta búsqueda no incluye ninguna investigación que pueda estar financiada con fondos privados.

es uno de los muchos errores graves y engañosos que contiene esta declaración. Aunque estamos de acuerdo en que las derivaciones a servicios competentes en materia de género están aumentando, no estamos de acuerdo con la forma en que se describe ese aumento. En esta sección, utilizamos los propios datos de la Revisión para mostrar por qué.

Un aumento de las derivaciones no es motivo de preocupación. Una derivación para evaluación no equivale a la prestación de atención médica de afirmación de género. Algunos jóvenes que son remitidos recibirán tratamiento, mientras que otros no. Cada derivación significa al menos una conversación reflexiva entre un pediatra, un joven y su familia. Los pediatras del Reino Unido que plantean preguntas reflexivas sobre la identidad de género deben ser aplaudidos por considerar las necesidades de sus pacientes de una forma holística, centrada en el paciente y no discriminatoria.
de forma sentenciosa.

El Informe no describe con exactitud las tendencias de las remisiones

A continuación, mostramos la descripción más completa de la Revisión de los datos de derivación de TIG aquí con énfasis en nuestras áreas de preocupación.[38] La interpretación que hace la Revisión de estos datos es que muestran un aumento "exponencial" entre 2010 y 2022, en particular para las personas a las que se asignó sexo femenino al nacer.

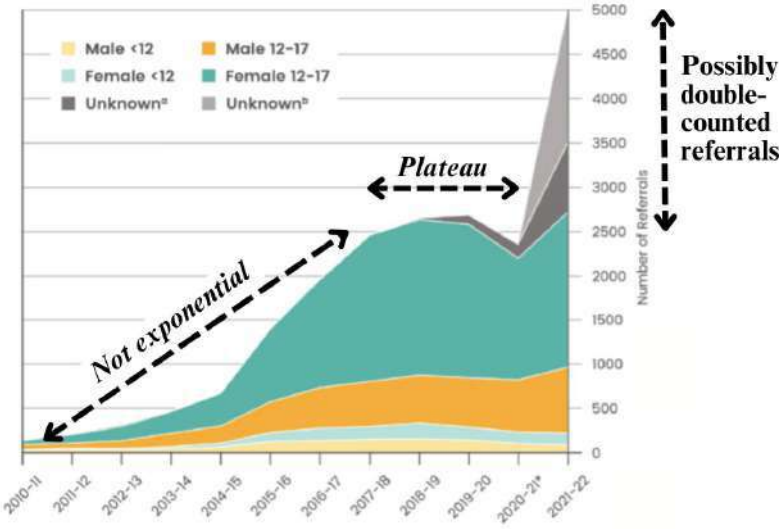

Figura 1: Los aumentos de las remisiones de la Revista no son exponenciales y no aumentan de forma constante. Los datos graficados arriba incluyen remisiones contabilizadas dos veces.

Sin embargo, este gráfico muestra claramente una estabilización seguida de una disminución de las remisiones a partir de 2018. Esta estabilización *es anterior a la pandemia de COVID-19* y no puede explicarse por las limitaciones de recursos impuestas por una *pandemia de COVID.*
emergencia de salud pública. Además, hay una clara meseta en los datos registrados *con precisión* de 2017 a 2022. Los datos sombreados en gris se describen en la Revisión como potencialmente representativos de remisiones *doblemente contabilizadas*: el pie de figura en la Revisión afirma que "existe una fuerte posibilidad de que se haya producido una doble contabilización durante 2021/22", indicada por las áreas grises bajo la curva.
Los puntos de datos individuales no deben contarse varias veces, ya que esto puede sobrestimar las cifras de remisión hasta en un 100%.

A pesar de las repetidas afirmaciones de la Revisión, el aumento de las remisiones al Servicio de Identidad de Género del Reino Unido *no es exponencial*. Un aumento exponencial describe un tipo particular de patrón de crecimiento en el que hay un intervalo de tiempo fijo en el que la cantidad aumenta en un factor determinado y, a continuación, en ese mismo intervalo de tiempo,

la calidad vuelve a aumentar en ese factor. Incluso si se tienen en cuenta las remisiones doblemente contabilizadas, no hay un patrón exponencial discernible. Una transformación matemática logarítmica de los datos lo demuestra. Si bien es cierto que hay un aumento de las remisiones, describir este aumento como "exponencial" es un grave error que alimenta la preocupación de que la

[38] En la Revista se muestran reproducciones parciales de estos datos en dos ocasiones (p 24 y 72). La "Figura 11" es la única vez que se representa gráficamente todo el conjunto de datos de remisión.

Con demasiada frecuencia, la revisión se interesa más por la polémica subjetiva que por la exactitud científica. Este lenguaje se ha citado en litigios en EE.UU. para justificar la prohibición de la atención sanitaria de afirmación de género.[39]

Qué describen realmente los datos del Informe

Los datos de derivación de la Revisión demuestran un hecho objetivo: la mayoría de los adolescentes transgénero del Reino Unido no son derivados para recibir atención. Según los datos del censo de 2021, es probable que haya unos 44.000 adolescentes transgénero en el Reino Unido.[40] Cada año hay personas que entran y salen de esta cifra.
Con 3585 derivaciones notificadas en 2021 (y menos en años anteriores), podemos suponer con seguridad que menos del 10% de todos los jóvenes que podrían beneficiarse de la atención han recibido alguna oportunidad de hacerlo.

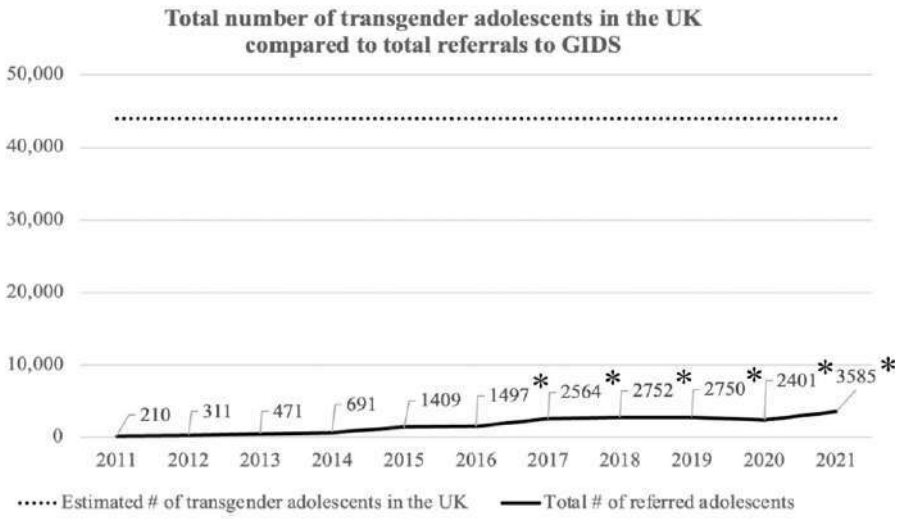

Figura 2: Comparación de una estimación de la prevalencia poblacional de jóvenes con identidad transgénero en el Reino Unido con los que recibieron derivaciones a GIDS entre 2011 y 2021,
** indica remisiones que pueden estar doblemente contabilizadas*

La figura 2 muestra un gráfico Comparación del total de adolescentes referidos con una estimación de la población total de transexuales.
jóvenes en el Reino Unido. Una cosa está muy clara: la brecha entre los jóvenes que pueden beneficiarse de la atención y los que reciben incluso la primera oportunidad de considerar esta atención es astronómica. La Revisión se preocupa demasiado por el tratamiento excesivo de esta población, pero los datos son claros: los jóvenes transexuales del Reino Unido están muy desatendidos, al igual que en todo el mundo.

La Revisión sostiene erróneamente que la atención de afirmación de género es apresurada, descuidada y común

[39] En un escrito presentado ante el Tribunal Supremo de los EE.UU. en el caso *Poe contra Labrador*, el Fiscal General de Idaho afirma: "Por razones que nadie conoce, la disforia de género ha crecido exponencialmente entre los jóvenes". App.D.74, 80-82, 84-85, 92, 104-05. De hecho, los diagnósticos se multiplicaron por diez entre 2009 y 2016. Dra. Hilary Cass, Revisión independiente de los servicios de identidad de género para niños y jóvenes: Informe provisional 33 (feb. 2022), https://bit.ly/4bzkiJI ("Cass Review")."

[40] Utilizamos una estimación conservadora de prevalencia del 0,6% de transexuales y de unos 7,4 millones de adolescentes en el mundo.
Reino Unido según datos de la Oficina Nacional de Estadística. (Otras estimaciones de población proyectan que alrededor del 1% de las personas en el Reino Unido son transgénero). Es probable que el número de jóvenes que se autoidentifican como transexuales haya aumentado en los últimos años. Sin embargo, esto es distinto de nuestra población de interés para este punto en particular, ya que buscamos describir a los jóvenes que son transgénero y pueden desear considerar la oportunidad de discutir intervenciones especializadas y de apoyo.
Identidad de género: edad y sexo, Inglaterra y Gales: Censo 2021. Consultado el 15 de junio de 2024. https://www.ons.gov.uk/peoplepopulationandcommunity/culturalidentity/genderidentity/articles/genderidentityageandsexenglandwalescensus2021/2023-01-25#how-gender-identity-age-and-sex-profiles-varied-across-england-and-wales

Sin pruebas, la Revisión afirma que "los profesionales abandonaron los enfoques clínicos normales para la evaluación holística" (p 13) y que los medicamentos que pausan la pubertad están "disponibles en la práctica clínica habitual". (p 25) Sin embargo, los propios datos de la Revisión muestran que aproximadamente sólo 178 jóvenes con disforia de género en el Reino Unido reciben actualmente medicamentos que pausan la pubertad. Es difícil entender cómo una medicación es "rutinaria" y sólo la utiliza el 0,0024% de la población adolescente.[31] Los propios datos de la Revisión dan una idea de lo difícil que es acceder a la atención en el NHS del Reino Unido, y la lenta y cuidadosa toma de decisiones que caracteriza esta atención. En primer lugar, informa de más de dos años de espera para la evaluación. (p 77) Luego, de los 3306 pacientes atendidos dos veces en la clínica GIDS o dados de alta entre abril de 2018 y diciembre de 2022, solo el 27% (892) fueron derivados a endocrinología para la consideración y consulta de intervenciones médicas.[41] (p 168) Esas derivaciones fueron precedidas por un promedio de 6,7 citas, a menudo con varios meses entre cada cita. De los atendidos por endocrinología, el 81,5% recibió tratamiento para frenar la pubertad (aproximadamente la mitad de los cuales tenían entre 15 y 16 años, lo que se sitúa en el extremo superior del espectro de edad en el que estos medicamentos son incluso utilizables).[42]

Estas tendencias no son exclusivas del Reino Unido. En todo el mundo, las listas de espera son largas[43,44] y sólo una pequeña proporción de jóvenes con disforia de género recibe intervenciones médicas.[45,46] En Estados Unidos, un análisis de las reclamaciones de seguros mostró que entre el 2% y el 4% de los jóvenes diagnosticados de disforia de género reciben medicamentos para frenar la pubertad u hormonas de reafirmación del género. Los datos son claros: la mayoría de los jóvenes transexuales no reciben tratamientos médicos para la disforia de género, a pesar del consenso médico internacional y de las pruebas que documentan los beneficios de esta atención.

Sección 5. El Cass Review hace afirmaciones sin fundamento sobre la identidad de género, la disforia de género, las prácticas habituales y la seguridad de los tratamientos médicos de afirmación de género, y repite afirmaciones que han sido refutadas por pruebas sólidas.

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[41] Basado en los datos facilitados en el Apéndice 8 de la Revisión.

[42] Esta no es una edad en la que un paciente pueda beneficiarse de la medicación de pausa de la pubertad, ya que la mayoría de los jóvenes han completado la pubertad en este momento.

[43] Strauss, P., Winter, S., Waters, Z., Wright Toussaint, D., Watson, V., & Lin, A. (2022). Perspectives of trans and jóvenes con diversidad de género que acceden a la atención primaria y a los servicios médicos de afirmación de género: Findings from Trans Pathways. International Journal of Transgender Health, 23(3), 295-307. https://doi.org/10.1080/26895269.2021.1884925

[44] Los tiempos de espera son globalmente de varios meses a varios años: Kearns S, Kroll T, O'Shea D, Neff K. Experiences of transgender and non-binary youth accessing gender-affirming care: A systematic review and meta-ethnography. *PLOS ONE*. 2021;16(9). doi:10.1371/journal.pone.0257194; *que informa de un tiempo medio de espera en una clínica canadiense de 269 días*: Lawson ML, Gotovac S, Couch B, Gale L, Vandermorris A, Ghosh S, Bauer G. Pathways to care for adolescents attending a first hormone appointment at Canadian Gender Affirming Medical Clinics: ¡Un análisis transversal del estudio Trans Youth Can! Study. Journal of Adolescent Health. 2024;74(1):140-147. doi:10.1016/j.jadohealth.2023.07.021

[45] Respaut R, Terhune C. Aumentan las cifras de niños que buscan atención de género. Reuters. 6 de octubre de 2022. Consultado el 31 de mayo de 2024. https://www.reuters.com/investigates/special-report/usa-transyouth-data/.

[46] En un amplio estudio de los Países Bajos, el porcentaje de pacientes evaluados que iniciaron el tratamiento ha disminuido con el paso del tiempo. Los criterios diagnósticos para el tratamiento siguen siendo estrictos, pero el umbral para solicitar una evaluación es probablemente más bajo. van der Loos MA, Klink DT, Hannema SE, et al., Children

and adolescents in the Amsterdam Cohort of Gender Dysphoria: trends in diagnostic- and treatment trajectories during the first 20 years of the Dutch Protocol The Journal of Sexual Medicine, Volume 20, Issue 3, March 2023, Pages 398-409, https://doi.org/10.1093/jsxmed/qdac029

Aunque la Revisión concede un gran valor a la calidad y la certeza de las pruebas, sus recomendaciones emanan con frecuencia de afirmaciones insuficientemente respaldadas que han sido refutadas por pruebas científicas. En un comentario reciente se describen al menos ocho casos en los que la cita por parte de la Revista de un estudio revisado por pares era manifiestamente incorrecta.[47] A continuación, analizamos las principales áreas en las que la especulación infundada domina los contenidos de la Revista.

La Revisión especula con la posibilidad de que la transición social y los medicamentos para frenar la pubertad causen daños al situar a los jóvenes en una vía médica

La Revisión expresa su preocupación por el hecho de que las intervenciones tempranas de apoyo, como la transición social y los medicamentos para frenar la pubertad, encierren a los jóvenes en cuidados irreversibles: "...está claro que la transición social es motivo de preocupación para muchas personas", y puede "[culminar] en una intervención médica que tendrá implicaciones para toda la vida". (p 158) La Revisión también afirma que "los que habían realizado la transición social a una edad más temprana y/o antes de ser atendidos en la clínica tenían más probabilidades de seguir una vía médica" y que "la gran mayoría de los jóvenes... pasan de los bloqueadores de la pubertad a las hormonas masculinizantes/feminizantes". (p 83)

La Revisión afirma que estas intervenciones pueden "cambiar la trayectoria del desarrollo psicosexual y de la identidad de género". (p 83) No se describe de qué manera pueden verse afectadas las trayectorias de desarrollo, ni se cita ningún dato. La Revisión sostiene que los jóvenes que realizan la transición pueden perder una oportunidad supuestamente valiosa de experimentar la edad adulta como el género con el que no se identifican: "En ausencia de cualquier experiencia como mujer cis adulta, puede que no tengan un marco de referencia que les haga arrepentirse o abandonar la transición, pero al mismo tiempo puede que hubieran tenido un resultado diferente sin intervención médica y no hubieran necesitado tomar hormonas de por vida". (p. 195) Esta afirmación enlaza con nuestra preocupación anterior de que la fijación de la Revisión por el tratamiento excesivo se produce sin una consideración recíproca por el daño que sufre un joven transgénero al someterse a una pubertad que se opone a su identidad. Resulta totalmente acientífico e inapropiado esperar que un joven, independientemente de su identidad de género, "pruebe" la vida como un género con el que no se identifica, como supone la Revisión que deberían hacer los jóvenes transgénero.

Los propios datos de la Revisión muestran que la mayoría de los pacientes remitidos nunca son derivados posteriormente a endocrinología pediátrica y aún menos reciben intervenciones médicas (véase la sección 4). Aunque la mayoría de los que reciben medicación para frenar la pubertad optan después por hormonas de reafirmación del género, no todos lo hacen.[48] Además, hacemos hincapié en que la continuación de la atención no es un resultado negativo.

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[47] Grijseels, D. M. (2024). Biological and psychosocial evidence in the Cass Review: a critical commentary. *Revista Internacional de Salud Transgénero*, 1-11. https://doi.org/10.1080/26895269.2024.2362304

[48] En estos estudios, las tasas de continuación oscilan entre el 96 y el 98%. Wiepjes, C. M., Nota, N. M., de Blok, C. J. M., Klaver, M., de Vries, A. L. C., Wensing-Kruger, S. A., de Jongh, R. T., Bouman, M. B., Steensma, T. D., Cohen-Kettenis, P., Gooren, L. J. G., Kreukels, B. P. C., & den Heijer, M. (2018). El estudio de la cohorte de disforia de género de Ámsterdam (1972-2015): Tendencias en prevalencia, tratamiento y arrepentimientos. The journal of sexual medicine, 15(4), 582-590. https://doi.org/10.1016/j.jsxm.2018.01.016; Kuper LE, Stewart S, Preston S, Lau M, Lopez X. Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming

Hormone Therapy. Pediatrics. 2020 Apr;145(4):e20193006. doi: 10.1542/peds.2019-3006. PMID: 32220906;
Carmichael P, Butler G, Masic U, Cole TJ, De Stavola BL, Davidson S, Skageberg EM, Khadr S, Viner RM. Resultados a corto plazo de la supresión puberal en una cohorte seleccionada de jóvenes de 12 a 15 años con disforia de género persistente en el Reino Unido. PLoS One. 2021 Feb 2;16(2):e0243894. doi: 10.1371/journal.pone.0243894. PMID: 33529227; PMCID: PMC7853497.

La Revisión no tiene en cuenta la explicación más probable de por qué la mayoría de los jóvenes que reciben intervenciones tempranas de apoyo continúan con la terapia hormonal de reafirmación de género: *que son realmente transgénero.* No son la transición social ni los medicamentos para frenar la pubertad los que impulsan una identidad transgénero persistente. Es la identidad transgénero la que impulsa la transición social y las posteriores intervenciones médicas.

Las afirmaciones de la Revista sobre el "desistimiento" carecen de fundamento

Los estudios realizados en la década de 1980 demostraron que la mayoría de los niños con disconformidad de género no cumplirían los criterios de disforia de género tras pasar por la pubertad. Estos estudios mezclaban de forma inapropiada los conceptos de identidad de género, orientación sexual y comportamiento. De ahí surgió el concepto de "desistencia", con el que se pretendía describir a los jóvenes que cumplían los criterios de un diagnóstico ya obsoleto de "trastorno de identidad de género"[49] cuando eran niños prepúberes, pero que dejaban de cumplirlos tras entrar en la pubertad. *Esto no es lo mismo que una pérdida de identidad transgénero.*

Los estudios que afirman que los niños presentan altas tasas de "desistimiento" se basan en datos recogidos antes de que existiera una definición formal de la disforia de género. Los comportamientos de los niños[50] se clasificaban como "no conformes con el género" si no se adherían a los estereotipos de género.[51] La Revisión cita estos estudios de forma acrítica, a pesar de que sus conclusiones no guardan ninguna relación con la comprensión contemporánea del género. Resulta preocupante que, a pesar de manifestar su oposición a la denominada terapia de conversión, la Revista cite favorablemente la literatura que propone métodos que afirman suprimir la identidad transgénero en los niños[52] y utilice los datos de "desistimiento" de esta literatura sin cuestionarlos. Un dato útil de los estudios más antiguos sobre la identidad de género en la infancia merece ser destacado aquí: la verdadera identificación transgénero -*ser de* un género diferente en lugar de *actuar* como de un género diferente- es uno de los factores predictivos de la persistencia de la identidad de género en la edad adulta.[53] La Revista cita el

[49] El "trastorno de identidad de género" se eliminó del DSM-V porque este diagnóstico patologizaba la disconformidad de género, que es un estado natural del ser. "Disforia de género" es el término más actual y guía nuestra comprensión moderna de la angustia relacionada con la incongruencia entre la identidad de género y el propio cuerpo físico.

[50] Green et al 1987 observaron que los chicos con rasgos afeminados (es decir, que jugaban con muñecas) tenían más probabilidades de identificarse como
varones cisgénero con atracción por el mismo sexo en la edad adulta. Los padres proporcionaron el informe, nunca se observó directamente a los niños, y no se ha informado de la participación de pacientes con disforia de género. Todos los primeros estudios sobre la "persistencia" de la identidad de género desde la infancia hasta la adolescencia se revisan en: Ristori J, Steensma TD. Disforia de género en la infancia. Int Rev Psychiatry. 2016;28(1):13-20. doi: 10.3109/09540261.2015.1115754. Epub 2016 ene 12. PMID: 26754056.

[51] Temple Newhook, J., Pyne, J., Winters, K., et al (2018). Un comentario crítico sobre los estudios de seguimiento y las teorías de "desistencia" sobre niños transgénero y no conformes con el género. International Journal of Transgenderism, 19(2), 212-224. https://doi.org/10.1080/15532739.2018.1456390; Ansara, Y. G., & Hegarty, P. (2011). Cisgenderism in psychology: pathologising and misgendering children from 1999 to 2008. Psychology & Sexuality, 3(2), 137-160. https://doi.org/10.1080/19419899.2011.576696

[52] Según uno de ellos "En mi opinión, ofrecer tratamiento a un niño (ya sea por sí mismo o mediante consentimiento paterno) puede estar justificado por una razón relativamente sencilla. La identificación de género cruzada constituye una condición de desarrollo potencialmente problemática. Llevado a su extremo, el resultado parece ser el transexualismo. Hacer que los niños se sientan más cómodos con su sexo no constituye, en mi opinión, un objetivo

irrazonable del tratamiento.
Aunque existe un desacuerdo considerable sobre cómo se puede lograr este objetivo, el objetivo en sí parece relativamente benigno". (Zucker, 1985, p. 117) Zucker, K. J. (1985). Cross-gender-identified children. Gender Dysphoria, 75-174. https://doi. org/10.1007/978-1-4684-4784-2_4

[53] Steensma, T. D., McGuire, J. K., Kreukels, B. P., Beekman, A. J., & Cohen-Kettenis, P. T. (2013). Factores asociados con la desistencia y persistencia de la disforia de género infantil: un estudio de seguimiento cuantitativo. Revista de la Academia Americana de Psiquiatría Infantil y Adolescente, 52(6), 582-590.

estudio que llega a esta conclusión, pero no señala este hallazgo fundamental que ha sido ampliamente reconocido por los expertos clínicos en la materia.

Las afirmaciones de la Revista sobre el "arrepentimiento" y la "detransición" carecen de fundamento

Los médicos que trabajan con personas transgénero de cualquier edad, incluidos los jóvenes, siguen normas de atención expertas y se adhieren a prácticas éticas que les guían a la hora de implicar a los pacientes en conversaciones serias sobre toda la gama de opciones y los posibles resultados asociados, incluidas las raras posibilidades de arrepentimiento, interrupción del tratamiento y reidentificación con el sexo asignado al nacer.
Y aunque estos resultados son similares, no son sinónimos. Una persona que se arrepiente de haber recibido atención médica puede seguir identificándose como transgénero; otra que deja de tomar medicamentos puede no arrepentirse, y otra que deja de identificarse como transgénero puede no arrepentirse de haber recibido atención médica. Es extremadamente raro que una persona determine posteriormente que no es transgénero.[54]

Los propios datos de la Revisión contradicen su afirmación de que "Se desconoce el porcentaje de personas tratadas con hormonas que posteriormente se destransicionan". (p 33)[55] En su auditoría de 3.306 historiales de pacientes del Servicio de Identidad de Género del Reino Unido, la Revisión informa de que "< 10 pacientes se detransicionaron a su género [registrado al nacer]". (p 168) *Esto supone una tasa de "detransición" del 0,3%.*

Los datos de la Revisión concuerdan con estudios sólidos a largo plazo sobre el arrepentimiento, la interrupción de la medicación y la reidentificación con el sexo asignado al nacer. Entre los 882 jóvenes con disforia de género de los Países Bajos que recibieron supresión de la pubertad, el 1% abandonó la medicación debido a la resolución de la disforia de género.[56] Entre los 720 jóvenes con disforia de género de los Países Bajos que recibieron medicación inhibidora de la pubertad y hormonas de reafirmación del género, el 98% continuó con el tratamiento hormonal de reafirmación del género en la edad adulta.[57] Entre los 196 jóvenes atendidos en el Servicio de Diversidad de Género de Australia Occidental, el 1% de los que recibieron medicación para reafirmar su género volvieron a identificarse con el sexo que se les asignó al nacer.[58] Los resultados de estos estudios se han obtenido en sistemas sanitarios nacionalizados y bien dotados de recursos, en los que es raro que se produzcan bajas en el seguro y se puede acceder a la atención de forma fiable. La Revisión podría haber analizado sistemáticamente estos estudios, pero no lo hizo.

Aunque en Estados Unidos no existe un registro nacional comparable, una encuesta realizada a 27.715 adultos transexuales describe los retos asociados a los cambios en la expresión de género. Del 13,1% que

[54] Cavve et al. descubrieron que el 1% de los jóvenes que recibieron medicación para la reafirmación de género volvieron a identificarse con su sexo asignado al nacer: Cavve BS, Bickendorf X, Ball J, et al. Reidentification With Birth-Registered Sex in a Western Australian Pediatric Gender Clinic Cohort. JAMA Pediatr. 2024;178(5):446-453. doi:10.1001/jamapediatrics.2024.0077

[55] La Revista define la "detransición" como "el proceso de interrumpir o invertir una transición de género, a menudo en en relación con un cambio en la forma en que el individuo identifica o conceptualiza su sexo o género desde que inició la transición". (p 239)

[56] van der Loos et al. (2023).

[57] van der Loos MA, Hannema SE, Klink DT, et al. Continuación de las hormonas de afirmación del género en

personas transexuales que inician la supresión de la pubertad en la adolescencia: A cohort study in the Netherlands. The Lancet Child & Adolescent Health. 2022;6(12):869-875. doi:10.1016/s2352-4642(22)00254-1 (en adelante, "van der Loos et al. 2022").

[58] Cavve BS, Bickendorf X, Ball J, et al. Reidentification With Birth-Registered Sex in a Western Australian Pediatric Gender Clinic Cohort. JAMA Pediatr. 2024;178(5):446-453. doi:10.1001/jamapediatrics.2024.0077

El 82,5% de las personas transgénero que declararon "vivir como [su] sexo asignado al nacer, al menos durante un tiempo" después de realizar algún tipo de transición, señalaron como factores influyentes la presión familiar, la presión social, las dificultades laborales, la imposibilidad de acceder a la atención sanitaria y las razones económicas.[59] Estas razones no tienen que ver con un cambio de identidad, sino con las fuerzas sociales sistémicas y estructurales que estigmatizan y condenan al ostracismo a las personas transexuales. Otros estudios también han hallado diversas razones por las que las personas pueden interrumpir temporalmente el tratamiento.[60] Estas razones incluyen no sólo las presiones externas citadas anteriormente, sino también el hecho de que, para algunas personas transexuales, el género es un viaje más que una existencia binaria o un único destino. Las personas pueden acceder a la terapia hormonal durante un periodo de tiempo concreto para alcanzar sus objetivos de género -como sentirse cómodas en su cuerpo como personas no binarias- y el cese del tratamiento no indica "detransición" o arrepentimiento, sino más bien un nivel de comodidad y satisfacción corporal que no podría haberse alcanzado sin el tratamiento médico.

En lugar de tener en cuenta estos estudios, la Revisión se basa en investigaciones plagadas de una metodología deficiente, un fuerte sesgo de selección y un muestreo de sitios web antitransgénero.[61,62] En muchos de los estudios que cita, la "detransición" se define vagamente y se confunde incorrectamente con la interrupción del tratamiento.[63] La Revisión critica y, en última instancia, descarta numerosos estudios de investigación rigurosos sobre la identidad transgénero y los tratamientos médicos para la disforia de género en los jóvenes, al tiempo que cita con confianza pseudociencia en apoyo de nociones anticuadas y desacreditadas en torno a fenómenos raros como el arrepentimiento después de la atención de afirmación de género.[52,53] Al considerar el valor de las contribuciones de la Revista al campo de la salud transgénero, no debe pasarse por alto esta discrepancia.

The Review reanima la noción desacreditada de "contagio social"

La Revisión describe repetidamente la "influencia sociocultural y de los compañeros" como la causa del aumento de las remisiones. La teoría de que dichos factores influyen en el desarrollo de la identidad de género en los jóvenes tiene su origen en

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[59] Turban JL, Loo SS, Almazan AN, Keuroghlian AS. Factors Leading to "Detransition" Among Transgender and Gender Diverse People in the United States: A Mixed-Methods Analysis. LGBT Health. 2021 mayo-junio;8(4):273-
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280. doi: 10.1089/lgbt.2020.0437. Epub 2021 Mar 31. PMID: 33794108; PMCID: PMC8213007.

[60] Estudio cualitativo de 28 adultos con identidades de género heterogéneas; la mayoría de los encuestados afirmaron no arrepentirse de las decisiones tomadas en relación con las intervenciones de reafirmación de la identidad de género. MacKinnon KR, Kia H, Salway T, et al. Health Care Experiences of Patients Discontinuing or Reversing Prior Gender-Affirming Treatments. JAMA Netw Open. 2022;5(7):e2224717. doi:10.1001/jamanetworkopen.2022.24717

[61] Littman 2018 fue una encuesta anónima en línea de 100 "detransitioners" que fueron reclutados en las redes sociales, listas de distribución profesionales y muestreo de bola de nieve. Muchas comunidades en línea para personas detransitioned han sido cooptadas por usuarios de medios sociales anti-trans, incluyendo el subreddit Littman referencias r/detrans. Con estos métodos de muestreo y reclutamiento, existe un alto riesgo de sesgo.

[62] Vandenbussche mediante una encuesta en línea a 237 encuestados autoidentificados como detransicionistas. Los participantes fueron
reclutados en r/detrans, grupos privados de Facebook, publicaciones públicas en Instagram y Twitter, y www.post-

trans.com, "una plataforma para mujeres detransicionarias". Vandenbussche E. (2022). Detransition-Related Needs and Support: A Cross- Sectional Online Survey. Journal of homosexuality, 69(9), 1602-1620. https://doi.org/10.1080/00918369.2021.1919479

[63] La Revisión cita a Hall et al. (2021), un estudio sobre adultos en el que la "detransición" está vagamente definida. Estos autores informan de que 12/175 "detransitioned" pero 4 fueron posteriormente re-referidos y dos expresaron arrepentimiento sobre la transición. La Revisión también cita a Boyd et al. (2022), un estudio de adultos que halló que 8/41 participantes abandonaron la terapia hormonal, la mitad de los cuales informaron de una "detransición" o un cambio de identidad de género como causa.

de un único artículo[64] que ha sido muy corregido por numerosos defectos fatales bien documentados.[65] Utilizando métodos sólidos, no se ha encontrado ninguna relación entre la influencia de los compañeros y el desarrollo de la identidad de género.[66] Existe una explicación más plausible y adecuada para el aumento de las derivaciones a servicios competentes en materia de género: hay una mayor concienciación y aceptación de la diversidad de género y un mejor acceso a una atención médica eficaz con cobertura de seguro. En algunos países, incluido el Reino Unido según los propios datos de la Revisión (Sección 4), las derivaciones a servicios competentes en materia de género se están estabilizando.[67] Además, los propios datos de la Revisión ponen en duda sus afirmaciones sobre un aumento espectacular de las derivaciones (Sección 4).

Aunque salir del armario como transgénero puede ser una sorpresa para las personas que forman parte de la vida de un joven, la revelación suele producirse varios años después de que la persona transgénero se dé cuenta de su género. Un amplio estudio de 27.715 adultos transexuales reveló que el conocimiento de la identidad de género es anterior a la revelación de la misma en una media de 14 años.[68] Además, el 40,8% de los adultos transgénero declararon haberse dado cuenta de su identidad de género después de los 10 años de edad. Un estudio de 173 adolescentes menores de 16 años que acudieron a su primera consulta para recibir medicación para frenar la pubertad u hormonas de reafirmación de género reveló que la mayoría de los participantes (56,4%) se habían dado cuenta de su identidad de género en los tres años siguientes a su consulta.[69] Se han analizado muchos factores para ver si se correlacionan con el conocimiento reciente de la identidad de género, como tener amigos en línea que apoyen la identidad de género o que sean transexuales.[70] Y a pesar de la reiterada preocupación de que la diversidad de género entre los jóvenes es algo nuevo, los relatos etnográficos e históricos de jóvenes transgénero se remontan al siglo XIX y, además, los jóvenes transgénero han buscado intervenciones de afirmación médica desde la década de 1920.[71]

Cualquier debate sobre el contagio social conduce naturalmente a lo que determina la identidad de género. La identidad de género tiene sólidos fundamentos biológicos que no coinciden totalmente con el sexo asignado en el momento de la adopción.

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[64] Littman L. Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. PLoS One. 2018 Aug 16;13(8):e0202330. doi: 10.1371/journal.pone.0202330. Fe de erratas en: PLoS One. 2019 Mar 19;14(3):e0214157. PMID: 30114286; PMCID: PMC6095578.

[65] Restar AJ. Crítica metodológica de los relatos de Littman (2018) sobre "género de inicio rápido" de los padres-repondientes. Disforia". Arch Sex Behav. 2020 Jan;49(1):61-66. doi: 10.1007/s10508-019-1453-2. Epub 2019 abr 22. PMID: 31011991; PMCID: PMC7012957.

[66] Bauer GR, Lawson ML, Metzger DL, ¿Apoyan los datos clínicos de adolescentes transexuales el fenómeno de la "disforia de género de aparición rápida"?, The Journal of Pediatrics, volumen 243, 2022, páginas 224-227.e2, ISSN 0022- 3476, https://doi.org/10.1016/j.jpeds.2021.11.020. (en lo sucesivo, "Bauer et al. 2022").

[67] Indremo M, Jodensvi AC, Arinell H, Isaksson J, Papadopoulos FC. Association of Media Coverage on Transgender Health With Referrals to Child and Adolescent Gender Identity Clinics in Sweden. JAMA Network Open. 2022;5(2):e2146531. doi:10.1001/jamanetworkopen.2021.46531

[68] Turban JL, Dolotina B, Freitag TM, King D, Keuroghlian AS. Age of Realization and Disclosure of Gender Identity Among Transgender Adults. J Adolesc Health. 2023 Jun;72(6):852-859. doi: 10.1016/j.jadohealth.2023.01.023. Epub 2023 Mar 17. PMID: 36935303.

[69] ¡Bauer GR, Pacaud D, Couch R, et al. Equipo de investigación Trans Youth CAN! Research Team. Transgender Youth Referred to Clinics
para la atención médica de afirmación de género en Canadá. Pediatrics. 2021 Nov;148(5):e2020047266. doi: 10.1542/peds.2020- 047266. Epub 2021 Oct 7. PMID: 34620727.

[70] El conocimiento reciente del género no se asoció con ningún aspecto negativo, incluidos los síntomas depresivos, los problemas de salud mental o los trastornos del neurodesarrollo, la gravedad de la disforia de género o el apoyo de los padres en relación con el género. ¡Bauer GR, Lawson ML, Metzger DL; Trans Youth CAN! Equipo de investigación. ¿Apoyan los datos clínicos de adolescentes transexuales el fenómeno de la "disforia de género de inicio rápido"? J Pediatr. 2022 abr;243:224-227.e2. doi: 10.1016/j.jpeds.2021.11.020. Epub 2021 Nov 16. PMID: 34793826.

[71] Gill-Peterson, J. (2018). Historias del niño transgénero. U of Minnesota Press.

nacimiento. En el sentido científico más estricto, el género y el sexo son conceptos multidimensionales con expresiones complejas que están relacionadas -y son distintas entre sí- de formas que la ciencia moderna aún está explorando.[72] Lo que sí sabemos es que la identidad de género es tan real para las personas transexuales como para las cisgénero. Sin embargo, basándose en nociones obsoletas y sesgadas de que ser transgénero es una condición patológica, la Revista sigue intentando encontrar explicaciones adicionales para "la causa" de ser transgénero. Elude la ciencia conocida estableciendo un paralelismo erróneo entre la diversidad de género y el cáncer:

> "Las expresiones del ser humano varían enormemente en la medida en que contribuyen las causas biológicas frente a las psicológicas frente a las sociales (entorno). Como ejemplo no relacionado pero ilustrativo para ayudar a explicar esto, las personas portadoras del gen BRCA tienen un alto riesgo genético de padecer cáncer de mama, mientras que para las que carecen del gen BRCA y no tienen antecedentes familiares, factores como el tabaquismo, la obesidad y la falta de ejercicio desempeñan un papel mucho mayor. En otras palabras, el resultado final es el mismo, pero las causas son diferentes". (p 117)

Muchos rebatirían la afirmación de que el cáncer de mama es "una expresión del ser humano". Otros se opondrían a utilizar un ejemplo de enfermedad para describir el género, que es un aspecto natural de la vida humana. Pero, además, se trata de una simplificación excesiva. Muchas personas desarrollan cáncer de mama sin una causa genética conocida, pero que esa causa no se conozca no significa que no exista.
Las investigaciones sobre las causas genéticas del cáncer de mama o de cualquier otro cáncer distan mucho de estar acabadas, y hay muchos otros genes además de los BRCA 1 y 2 que están implicados en el desarrollo del cáncer de mama. Este ejemplo no pone en duda el papel que desempeña la biología en la configuración del género. Lo más preocupante es que su grave falta de rigor científico debería llevar a los lectores a preguntarse desde qué posición opera la Revista: ¿es ciencia o es especulación?

La preocupación de la Revisión por los efectos cognitivos de los fármacos inhibidores de la pubertad está poco fundamentada y desequilibrada.

La Revisión expresa su preocupación por la seguridad de los medicamentos inhibidores de la pubertad. La mayor parte de su preocupación se centra en el supuesto impacto de estos medicamentos en el desarrollo cognitivo de los adolescentes. Se trata de un importante campo de estudio en curso, en el que los investigadores están llevando a cabo algunos de los estudios más amplios con periodos de seguimiento más largos hasta la fecha.[73] Las pruebas actualmente disponibles no respaldan la preocupación de la Revisión.

El estudio más extenso y prolongado sobre este tema demostró que el cociente intelectual y el rendimiento educativo entre los jóvenes que recibían medicación antipuberal no diferían sustancialmente de una población de adolescentes holandeses de edad similar.[74] La RS de York sobre la medicación inhibidora de la pubertad tergiversó las pruebas al no incluir este estudio, y también informó erróneamente de que

[72] Un útil manual sobre la multidimensionalidad del sexo biológico: Karkazis K. The misuses of "biological sex". Lancet. 2019 Nov 23;394(10212):1898-1899. doi: 10.1016/S0140-6736(19)32764-3. Epub 2019 nov 21. PMID: 31982044.

[73] Una base de datos de todos los estudios financiados por los Institutos Nacionales de Salud: https://reporter.nih.gov/search/sF2XlRReqU-36s8d3bpPOQ/project-details/10883566

[74] Arnoldussen M, Hooijman EC, Kreukels BP, de Vries AL. Association between pre-treatment IQ and educational logro después del tratamiento de afirmación de género incluyendo la supresión de la pubertad en adolescentes transgénero. Clin Child Psychol Psychiatry. 2022 Oct;27(4):1069-1076. doi: 10.1177/13591045221091652. Epub 2022 May 31. PMID: 35638479; PMCID: PMC9574895.

"el único estudio [sobre los medicamentos que frenan la pubertad y la cognición] mostró un peor funcionamiento ejecutivo en > 1 año...". En realidad, este último estudio mostró un funcionamiento ejecutivo significativamente mejor en quienes recibían hormonas de reafirmación del sexo en comparación con los fármacos para frenar la pubertad.[75] El funcionamiento ejecutivo fue peor entre los que recibieron medicación para la pubertad durante mucho tiempo en comparación con los que recibieron hormonas de afirmación del género antes. La conclusión adecuada no es que los medicamentos que retrasan la pubertad empeoren la función ejecutiva, sino que el desarrollo cognitivo de los jóvenes transexuales puede verse afectado de forma preocupante por los retrasos prolongados antes de afirmar los cambios físicos con el tratamiento adecuado.

Además, los medicamentos para pausar la pubertad se han utilizado durante mucho tiempo para la pubertad precoz central sin impacto negativo en el desarrollo cognitivo.[76] El retraso de la pubertad no se asocia a retrasos en el desarrollo cognitivo. De hecho, muchos jóvenes cisgénero se presentan después de los 14 años, y no es infrecuente que lo hagan a los 16 o 17 años, para la evaluación de una pubertad ausente o retrasada, y no muestran retrasos en el desarrollo cognitivo.

Existe mucha incertidumbre sobre el papel de la pubertad en el desarrollo general del adolescente. La Revisión parece atada a la postura de que las hormonas sexuales son los determinantes más influyentes de una adolescencia sana, con exclusión de muchos otros factores complejos e interdependientes.[77] El desarrollo cognitivo durante la adolescencia es un proceso complejo que depende de varios mecanismos diferentes, incluido el entorno psicosocial. El estrés crónico, en particular durante la adolescencia, afecta al desarrollo cognitivo.[78] Los jóvenes con disforia de género a los que se niega la opción de someterse a intervenciones de reafirmación médica se ven obligados a someterse a un desarrollo físico no deseado. Esto puede causar una angustia significativa que luego limita el aprendizaje, la creación de amistades, la orientación futura y otros hitos del desarrollo en la adolescencia. No se pueden ignorar los daños que esto supone para un desarrollo cognitivo sano. Los médicos, los padres y los propios jóvenes están preocupados, y con razón, por el impacto cognitivo de la disforia de género no tratada, pero es evidente que la Revisión no lo está.

La Revisión afirma que los medicamentos para frenar la pubertad no son beneficiosos para los jóvenes transexuales

La Revisión arroja dudas sobre los beneficios de los medicamentos inhibidores de la pubertad para el tratamiento de la disforia de género:

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[75] Strang JF, Chen D, Nelson E, Leibowitz SF, Nahata L, Anthony LG, Song A, Grannis C, Graham E, Henise S, Vilain E, Sadikova E, Freeman A, Pugliese C, Khawaja A, Maisashvili T, Mancilla M, Kenworthy L. Funcionamiento ejecutivo de jóvenes transgénero: Relationships with Anxiety Symptoms, Autism Spectrum Disorder, and Gender- Affirming Medical Treatment Status. Child Psychiatry Hum Dev. 2022 dic;53(6):1252-1265. doi: 10.1007/s10578- 021-01195-6. Epub 2021 Jun 19. PMID: 34146208.

[76] Wojniusz S, Callens N, Sütterlin S, Andersson S, De Schepper J, Gies I, Vanbesien J, De Waele K, Van Aken S, Craen M, Vögele C, Cools M, Haraldsen IR. Cognitive, Emotional, and Psychosocial Functioning of Girls Treated with Pharmacological Puberty Blockage for Idiopathic Central Precocious Puberty (Funcionamiento cognitivo, emocional y psicosocial de niñas tratadas con bloqueo farmacológico de la pubertad para la pubertad precoz central

idiopática). Front Psychol. 2016 Jul 12;7:1053. doi: 10.3389/fpsyg.2016.01053. PMID: 27462292; PMCID: PMC4940404.
[77] Berenbaum SA, Beltz AM, Corley R. La importancia de la pubertad para el desarrollo adolescente: conceptualización y medición. Adv Child Dev Behav. 2015;48:53-92. doi: 10.1016/bs.acdb.2014.11.002. Epub 2015 enero 22.
PMID: 25735941.
[78] Eiland L, Romeo RD. El estrés y el cerebro adolescente en desarrollo. Neuroscience. 2013 Sep 26;249:162-71

> "La revisión sistemática llevada a cabo por la Universidad de York encontró múltiples estudios que demostraban que los bloqueantes de la pubertad ejercen su efecto previsto de supresión de la pubertad, y también que la densidad ósea se ve comprometida durante la supresión de la pubertad... Sin embargo, no se demostraron cambios en la disforia de género ni en la satisfacción corporal." (p 32)

En este caso, la Revisión expresa la expectativa de que una intervención conduzca a un resultado que los expertos en atención al género juvenil no esperan: los expertos no esperan una disminución de la disforia de género ni un aumento de la satisfacción corporal sólo con los medicamentos que frenan la pubertad, porque estos medicamentos no cambian las características físicas *actuales del* cuerpo. Sólo previenen cambios *futuros*. Los fármacos inhibidores de la pubertad sólo *detienen el* desarrollo de características inducidas por la pubertad que podrían ser perjudiciales para el bienestar psicosocial de un joven transexual. Por ejemplo, los medicamentos inhibidores de la pubertad detienen el crecimiento de los senos, pero no revierten el crecimiento que ya se ha producido; los medicamentos inhibidores de la pubertad pueden evitar que la voz se haga más grave, pero no elevarán el tono de una voz que ya se ha hecho más grave.

La insinuación de la Revisión de que la medicación para la pubertad debería reducir la disforia de género actual o mejorar la satisfacción corporal actual indica ignorancia o malentendido, en el mejor de los casos, y engaño intencionado sobre la función básica de estos medicamentos, en el peor. En una época de abundante desinformación, es importante recordar la función exacta de estos medicamentos. La Revista, como documento de tanta influencia e importancia en el campo de la salud transexual, no debería operar desde ninguna posición de ignorancia sobre estos cuidados.

Los verdaderos efectos de los fármacos inhibidores de la pubertad son mucho más matizados de lo que afirma la Revista. Algunos estudios no muestran cambios en determinadas puntuaciones de salud mental, lo que indica *estabilidad* y no ausencia de efectos.[79,80] La estabilidad es un resultado a corto plazo profundamente significativo para los jóvenes que, de otro modo, se espera que experimenten un aumento de la angustia relacionada con el género sin intervención.

[79] Carmichael P, Butler G, Masic U, Cole TJ, De Stavola BL, Davidson S, Skageberg EM, Khadr S, Viner RM. Resultados a corto plazo de la supresión puberal en una cohorte seleccionada de jóvenes de 12 a 15 años con disforia de género persistente en el Reino Unido. PLoS One. 2021 Feb 2;16(2):e0243894. doi: 10.1371/journal.pone.0243894. PMID: 33529227; PMCID: PMC7853497. (en adelante, "Carmichael et al.

2021").

[80] van der Miesen, A. I. R., Steensma, T. D., de Vries, A. L. C., Bos, H., & Popma, A. (2020). Psychological Funcionamiento en adolescentes transexuales antes y después de la atención afirmativa de género en comparación con compañeros cisgénero de la población general. The Journal of adolescent health: publicación oficial de la Society for Adolescent Medicine, 66(6), 699-704.

Otros estudios[81,82,83,84] sí demuestran una mejora a corto plazo en algunas puntuaciones de salud mental en relación con el tratamiento con estos medicamentos.[85]

A pesar de su protocolo, en el que se afirmaba que las RS analizarían datos cualitativos, la RS sobre los medicamentos que detienen la pubertad no lo hizo (véase la Sección 6). Por lo tanto, las conclusiones de la Revisión están incompletamente fundamentadas. Los propios estudios extraen conclusiones diferentes de las de la Revisión. Por ejemplo, Carmichael y sus colegas describen sus conclusiones matizadas: "La experiencia de los participantes en el tratamiento, tal y como se recoge en las entrevistas, fue positiva para la mayoría, sobre todo en lo relativo a sentirse más felices, más cómodos, mejores relaciones con la familia y los compañeros y cambios positivos en el rol de género. Un número menor de participantes declaró haber experimentado cambios positivos y negativos. Una minoría (12% a los 6-15 meses y 17% a los 15-24 meses) informó sólo de cambios negativos, relacionados en gran medida con los efectos secundarios previstos. Ninguno quiso interrumpir el tratamiento debido a los efectos secundarios o a los cambios negativos".[86] Estudios más recientes, no analizados por la Revisión, demuestran que evitar una pubertad no afirmativa confiere beneficios que se amplían y evolucionan con el tiempo.[87]

Es importante destacar que este estudio más reciente pudo estudiar los efectos de los fármacos que retrasan la pubertad en una cohorte de adolescentes que iniciaron el tratamiento cuando aún estaban en la pubertad temprana (y, por tanto, tienen más probabilidades de beneficiarse). Este punto es muy relevante para evaluar la evidencia en torno a estos medicamentos, ya que la inclusión en otros estudios de jóvenes que empezaron a tomar medicamentos retrasadores de la pubertad en un momento en el que ya estaban en la pubertad tardía o habían terminado la pubertad -lo que ha sido una práctica común en muchos lugares, incluido el Reino Unido- habrá reducido las posibilidades de ver beneficios del uso de estos medicamentos. Por lo tanto, poder estratificar a los receptores de fármacos retrasadores de la pubertad

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[81] R. Costa, M. Dunsford, E. Skagerberg, et al. Apoyo psicológico, supresión de la pubertad y funcionamiento psicosocial en adolescentes con disforia de género J Sex Med, 12 (2015), pp. 2206-2214.

[82] C. Achille, T. Taggart, N.R. Eaton, et al. Impacto longitudinal de la intervención endocrina de afirmación de género en la salud mental y el bienestar de los jóvenes transgénero: Resultados preliminares Int J Pediatr Endocrinol, 2020 (2020)

[83] L.E. Kuper, S. Stewart, S. Preston, et al. Insatisfacción corporal y resultados de salud mental de jóvenes en terapia hormonal de afirmación de género. Pediatrics, 145 (2020), Artículo e20193006

[84] de Vries, A. L., Steensma, T. D., Doreleijers, T. A., & Cohen-Kettenis, P. T. (2011). Puberty suppression in adolescentes con trastorno de identidad de género: un estudio prospectivo de seguimiento. The journal of sexual medicine, 8(8), 2276-2283. https://doi.org/10.1111/j.1743-6109.2010.01943.x

[85] La Revisión reconoce esto: "Ninguno [de los estudios] informó de ningún cambio antes o después de recibir la supresión de la pubertad... el protocolo holandés original (de Vries et al., 2011) encontró mejoras en la salud mental en un estudio pre-post sin grupo de comparación, pero el estudio de intervención temprana del GIDS (Carmichael et al., 2021) no replicó este hallazgo". La revisión sistemática sobre intervenciones para suprimir la pubertad (Taylor et al: Puberty suppression) identificó otro estudio de buena calidad (van der Miesen et al., 2020), que produjo un resultado intermedio con mejoras en algunas medidas de salud mental pero no en otras." (p 176) Los estudios de Costa, Achille y Kuper no se incluyeron en el análisis de la Revisión sobre los fármacos inhibidores de la pubertad, pero estos estudios ofrecen información valiosa.

[86] En cuanto al estudio Carmichael, la Revisión no menciona que el bienestar no era "clínicamente preocupante" en el inicio del estudio. Los autores también abordan que no cabe esperar una mejora profunda en las puntuaciones de salud mental con una medicación que simplemente pausa el desarrollo posterior: "...la falta de cambio en un resultado que normalmente empeora en la adolescencia temprana puede reflejar un cambio beneficioso en la trayectoria de ese resultado, es decir, que el tratamiento con GnRHa redujo este empeoramiento normativo de los

problemas".

[87] McGregor K, McKenna JL, Williams CR, Barrera EP, Boskey ER. Association of Pubertal Blockade at Tanner 2/3 With Psychosocial Benefits in Transgender and Gender Diverse Youth at Hormone Readiness Assessment. J Adolesc Health. 2024 abr;74(4):801-807. doi: 10.1016/j.jadohealth.2023.10.028. Epub 2023 Dic 13. PMID: 38099903.; Chelliah P, Lau M, Kuper LE. Changes in Gender Dysphoria, Interpersonal Minority Stress, and Mental Health Among Transgender Youth After One Year of Hormone Therapy. J Adolesc Health. 2024 Jun;74(6):1106-1111. doi: 10.1016/j.jadohealth.2023.12.024. Epub 2024 Feb 9. PMID: 38340124.

medicamentos en función del estadio puberal en el que iniciaron el tratamiento es fundamental, pero ni la propia Revisión ni la revisión sistemática asociada parecen haberlo tenido en cuenta.

Sección 6: Las revisiones sistemáticas en las que se basa la Revisión Cass tienen graves defectos metodológicos, incluida la omisión de hallazgos clave en el corpus bibliográfico existente.

Las recomendaciones clínicas deben basarse en las RS de la evidencia. Las RS son un tipo de estudio de investigación que combina los hallazgos de múltiples estudios individuales para responder a una pregunta de investigación específica, basándose en una búsqueda exhaustiva y estandarizada de la literatura. Las RS se consideran la forma más sólida de evidencia *si están bien realizadas*.[88] Las mejores prácticas en la realización de RS tienen como objetivo minimizar los sesgos para que el producto final sea una evaluación clara, precisa y exacta del conjunto de evidencias. Estas mejores prácticas incluyen: (1) Elaborar, registrar previamente y seguir un protocolo,
(2) una búsqueda exhaustiva y actualizada de la literatura, (3) el uso de herramientas de evaluación validadas para examinar la calidad de los estudios individuales y (4) el uso de un método validado para describir la calidad de todo el conjunto de pruebas.

Las RS son vulnerables a muchas formas de sesgo y no son intrínsecamente superiores a otras formas de evidencia.[89] Las recomendaciones de la Revisión se basan en siete RS,[2] , que abordan cuestiones de investigación sobre hormonas de reafirmación de género, medicamentos para la pubertad, tendencias de derivación a servicios competentes en materia de género, vías de atención, transición social y apoyo psicosocial para jóvenes con disforia de género. En cada uno de los cuatro pasos del proceso, estas revisiones (colectivamente, las "RS de York", porque fueron realizadas por investigadores afiliados a la Universidad de York) se desviaron sustancialmente de las prácticas habituales y están plagadas de sesgos.

El protocolo de la RS de York es inadecuado y las desviaciones del mismo no están justificadas

Los autores de la RS de York registraron previamente un vago protocolo para las siete revisiones tan diferentes que realizaron.[90] El protocolo registrado no guarda ninguna relación con lo que realmente se hizo, y ninguno de los componentes de las revisiones sistemáticas realizadas sobre los medicamentos para la pubertad o las hormonas de afirmación del género se incluyeron en el registro. De hecho, es inexacto decir que las RS de York fueron prerregistradas, dado que no se describió ninguno de sus detalles metodológicos clave.

En el protocolo prerregistrado, el equipo de RS planificó evaluar la calidad de los estudios mediante la Herramienta de Evaluación de Métodos Mixtos (MMAT).[91] Sin embargo, cambiaron a la Newcastle-Ottawa

[88] Las RS bien realizadas utilizan métodos preespecificados, transparentes y reproducibles para identificar los estudios pertinentes, determinar su inclusión/exclusión, extraer los datos de los estudios, evaluar el riesgo de sesgo en los estudios incluidos y sintetizar los resultados mediante enfoques cuantitativos (metanálisis) o cualitativos (síntesis narrativa).

[89] Shea B J, Reeves B C, Wells G, Thuku M, Hamel C, Moran J et al. AMSTAR 2: a critical appraisal tool for revisiones sistemáticas que incluyan estudios aleatorizados o no aleatorizados de intervenciones sanitarias, o ambos BMJ 2017; 358 :j4008 doi:10.1136/bmj.j4008

[90] Fraser, L. et al. The epidemiology, management, and outcomes of children with gender-related distress / gender

dysphoria: a systematic review. PROSPERO. Disponible en: https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=289659. Accedido: 27 de mayo de 2024.
[91] Hong QN, Pluye P, Fàbregues S, Bartlett G, Boardman F, Cargo M, Dagenais P, Gagnon M-P, Griffiths F, Nicolau B, O'Cathain A, Rousseau M-C, Vedel I. Herramienta de evaluación de métodos mixtos (MMAT), versión 2018. Registro de derechos de autor (#1148552), Oficina Canadiense de Propiedad Intelectual, Ministerio de Industria de Canadá.

(NOS), pero con varias adaptaciones realizadas por los autores de las RS de York. En sus RS publicadas, no mencionan ni justifican esta desviación de su protocolo. Se trata de una divergencia de las prácticas estándar diseñadas para minimizar el sesgo en las revisiones sistemáticas y no es una divergencia menor. Este cambio puede haber tenido un impacto decisivo en las conclusiones de las RS de York. En particular, los desarrolladores del MMAT animan a los autores de RS a incluir *todos los* estudios en el análisis.[92] Utilizando NOS y el punto de corte arbitrario que determinaron los autores de la RS de York, sólo se tuvo en cuenta una parte de la evidencia. Esto se discute en mayor detalle cuando describimos el uso de la herramienta de valoración de la calidad más adelante.

La búsqueda bibliográfica de la RS es incompleta y obsoleta

El equipo de York utilizó una única estrategia de búsqueda para todas las RS, lo que probablemente excluyó muchos estudios relevantes en cada una de las áreas específicas. Además, los autores de las RS se enfrentan al reto de realizar una revisión sistemática de la literatura mientras se publican activamente nuevas investigaciones. Los autores de RS deberían actualizar su búsqueda sistemática y aplicar las mismas herramientas de valoración de la calidad a la nueva literatura. El equipo de la RS de York no realizó una búsqueda sistemática de la literatura después de abril de 2022, a pesar de que se presentó para su publicación 18 meses después. En las RS sobre medicamentos que retrasan la pubertad y terapia hormonal de afirmación del género, los autores afirman: "Estudios más recientes publicados desde abril de 2022 hasta enero de 2024 también apoyan las conclusiones de esta revisión." Los autores no describen cómo se identificaron o evaluaron esos estudios. Los estudios de gran impacto, como el estudio más largo y más grande hasta la fecha sobre tratamientos médicos de afirmación de género en jóvenes,[93] , solo recibieron una mención de pasada: "Un único estudio que evaluó los resultados durante los 2 años posteriores a la iniciación hormonal descubrió que las puntuaciones de congruencia de género y satisfacción vital aumentaban, pero había diferencias según el sexo registrado al nacer y el momento de la iniciación hormonal". Esto no tiene en cuenta las conclusiones principales del estudio, según las cuales estos tratamientos mejoran la salud mental al centrarse en la congruencia de la apariencia.

El equipo de RS de York utilizó inadecuadamente las herramientas de evaluación de la calidad

Como hemos comentado, las herramientas de evaluación de la calidad se utilizan para determinar la calidad de los estudios individuales. Estas herramientas consideran una variedad de dominios del estudio individual, incluyendo la población seleccionada y los análisis estadísticos realizados sobre los datos recogidos, entre otros. Los SR de York utilizaron incorrectamente dos herramientas de valoración de la calidad.

La primera es la herramienta Appraisal of Guidelines for Research & Evaluation (AGREE) II, utilizada en la revisión sistemática de "directrices" para la atención médica. El equipo de RS incluyó 23 documentos para su análisis, pero 8 no eran directrices en absoluto. Se trataba de documentos de posición y declaraciones afirmativas que remitían explícitamente a directrices reales. Naturalmente, estos documentos obtuvieron malos resultados.

[92] Los estudios considerados de baja calidad por la NOS modificada deberían haberse incluido y analizado por separado, en lugar de excluirse por completo. Podría realizarse un análisis de sensibilidad para ver si los

estudios excluidos aportaban información relevante, pero no se hizo.

[93] Chen D, Berona J, Chan YM, Ehrensaft D, Garofalo R, Hidalgo MA, Rosenthal SM, Tishelman AC, Olson-. Kennedy J. Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. N Engl J Med. 2023 Jan 19;388(3):240-250. doi: 10.1056/NEJMoa2206297. Fe de erratas en: N Engl J Med. 2023 Oct 19;389(16):1540. doi: 10.1056/NEJMx230007. PMID: 36652355; PMCID: PMC10081536.

cuando se juzgan con arreglo a las normas para la elaboración de directrices clínicas; esto se asemeja a utilizar una escala de calidad de diamantes para evaluar un grupo heterogéneo de piedras preciosas.

La segunda herramienta de evaluación de la calidad es NOS y analizamos en profundidad el mal uso que hace la Revisión de esta herramienta. En primer lugar, analizamos algunas de las críticas más contundentes que han recibido las NOS por parte de otros expertos en el campo de la medicina basada en la evidencia:

1. La NOS no está recomendada por ninguna organización líder en el campo de la medicina basada en la evidencia; no se considera un patrón oro ni se utiliza en los procesos de elaboración de directrices.
2. Utilizando NOS, los revisores a menudo obtienen diferentes valoraciones de la calidad.[94] Esto también se denomina "baja fiabilidad interobservador" y es precisamente la razón por la que Cochrane no recomienda la NOS.
3. La evaluación de la calidad en el marco de NOS conduce a una puntuación numérica. A pesar de una apariencia de objetividad singular, las puntuaciones numéricas aplanan las evaluaciones matizadas y son intrínsecamente arbitrarias y poco fiables.
4. NOS da el mismo peso a todos los ítems puntuados por igual, aunque la importancia científica de estos ítems varía.[95]
5. NOS incluye ítems que son irrelevantes para evaluar el riesgo de sesgo.[80,96] NOS incluye un ítem sobre la representatividad de la población del estudio, que se refiere a la generalizabilidad de los resultados a una población más amplia. Aunque las muestras representativas son fundamentales para estimar las características de la población, no lo son para determinar la eficacia del tratamiento.

Además, el equipo de la RS de York no aplicó la NOS tal como la presentan sus autores. Modificaron la escala de forma arbitraria, lo que permitió excluir estudios de ulterior consideración, por razones irrelevantes para la atención clínica. Por ejemplo, en la RS de York sobre transición social, la NOS modificada preguntaba si las muestras de los estudios eran "verdaderamente representativas del niño o adolescente medio con disforia de género". No existe tal cosa como el "niño o adolescente medio con disforia de género" -este es un concepto inexpertamente ideado y sin sentido que ni está definido por los autores ni se utiliza en la investigación clínica. Y, sin embargo, fue motivo para excluir varios estudios importantes de la consideración.

Además, el equipo de la RS de York cometió un error preocupante al citar la NOS. En la RS sobre transición social, los autores citan accidentalmente un comentario crítico sobre la escala y *no la escala en sí*.[97] Los autores de ese comentario crítico han escrito posteriormente "Parece que la gran mayoría de los autores de revisiones sistemáticas que citaron este comentario no lo leyeron. Los revisores de revistas y

[94] Hartling L, Milne A, Hamm MP, et al. Testing the Newcastle Ottawa Scale showed low reliability between individual reviewers. Revista de epidemiología clínica. 2013 Sep 1;66(9):982-93.

[95] Jüni P, Witschi A, Bloch R, Egger M. The Hazards of Scoring the Quality of Clinical Trials for Meta-analysis. JAMA. 1999;282(11):1054–1060. doi:10.1001/jama.282.11.1054

[96] La AHRQ también recomienda no tener en cuenta la generalizabilidad a la hora de evaluar el

riesgo de sesgo. https://effectivehealthcare.ahrq.gov/products/methods-guidance-bias-individual-studies/methods

[97] Stang A. Critical evaluation of the Newcastle-Ottawa scale for the assessment of the quality of nonrandomized studies in meta-analyses. Eur J Epidemiol 2010;25:603-5. doi:10.1007/s10654-010-9491

Los editores no reconocieron ni corrigieron estos importantes errores de cita".[98] El error del equipo de la RS de York pone en tela de juicio el cuidado con que abordaron su tarea y la minuciosidad del proceso de revisión por pares emprendido por su revista de publicación.

El equipo de RS de York no demuestra experiencia en las cuestiones clínicas en cuestión

Al revisar la metodología y las conclusiones de las RS de York, queda claro que sus autores desconocen conceptos esenciales en la atención al género juvenil.

1. Por ejemplo, en la RS sobre los medicamentos que detienen la pubertad, los autores o los autores de la Revisión (desconocidos sin transparencia sobre el proceso), determinaron que una reducción de la disforia de género era un resultado apropiado. Como ya se ha comentado en la sección 5, los fármacos de pausa de la pubertad en sí mismos no afirman el género: simplemente pretenden pausar los cambios anatómicos y fisiológicos asociados a la pubertad. Por lo tanto, los estudios sobre los fármacos para la pausa de la pubertad se sometieron a un criterio inadecuado.
2. Además, los autores de la RS de York trataron la medicación para el retraso de la pubertad y los tratamientos hormonales de reafirmación de género como dos tratamientos distintos, los revisaron por separado y excluyeron del análisis los estudios que no podían comentar el impacto independiente de cada terapia. Esto es muy problemático, ya que la mayoría de los pacientes que reciben medicación para la pubertad evolucionan hacia una terapia hormonal de reafirmación del género. La imposición de una delimitación estricta del impacto de una modalidad frente a otra no tiene en cuenta el hecho de que estas intervenciones forman parte de un proceso continuo de atención, y llevó a la exclusión de numerosos estudios importantes que evaluaban el impacto de este proceso continuo de atención en el bienestar de los adolescentes transexuales.
3. Las RS de York sí respaldan que los medicamentos para la interrupción de la pubertad son eficaces para detener temporalmente la pubertad y que la terapia hormonal de *afirmación del* género es eficaz para desarrollar características sexuales secundarias congruentes, *pero no consideran que éste sea el objetivo real del modelo de afirmación del género.* Si las RS de York se centraran en la satisfacción corporal y la congruencia de la apariencia, y los resultados se evaluaran en relación con la evitación de cambios puberales no deseados y la inducción de cambios corporales masculinizantes o feminizantes, el debate sobre las pruebas sería muy diferente y, de hecho, estaría en consonancia con los objetivos de la atención médica de afirmación del género.
4. Por último, se da una prioridad indebida a la salud mental como resultado esperado de todos los tratamientos médicos de afirmación de género, sin tener en cuenta el papel que desempeña el estrés de las minorías en el bienestar psicosocial de los jóvenes transexuales.

Utilizando una herramienta de evaluación rigurosa, las RS de York demuestran un alto riesgo de sesgo

Las revisiones sistemáticas, al igual que los estudios que pretenden evaluar, distan mucho de ser perfectas. Al igual que existen instrumentos de evaluación de sesgos para los estudios individuales, también existen instrumentos de evaluación de sesgos para las revisiones sistemáticas. La Colaboración Cochrane fomenta el uso de instrumentos de riesgo de sesgo en las revisiones sistemáticas de intervenciones sanitarias. La herramienta ROBIS es uno de estos instrumentos

[98] Stang, A., Jonas, S. & Poole, C. Estudio de caso en los principales errores de cita: un comentario crítico sobre la escala de Newcastle- Ottawa. *Eur J Epidemiol* **33**, 1025-1031 (2018). https://doi.org/10.1007/s10654-018-0443-3

desarrollado rigurosamente para informar a quienes utilizan revisiones sistemáticas.[99] Esta herramienta considera el riesgo de sesgo en cuatro áreas: (1) criterios de elegibilidad de los estudios, (2) identificación y selección de los estudios, (3) recogida de datos y valoración de los estudios, y (4) síntesis y conclusiones. Noone et al aplicaron ROBIS a las RS de York y encontraron un alto riesgo de sesgo en cada una de estas áreas.[100] Sus hallazgos se describen en la Tabla 2.

Tabla 2: La aplicación de la herramienta Cochrane ROBIS para la evaluación del sesgo a las RS de York de Noone et al demuestra un alto riesgo sistémico de sesgo.

	Las RS de York y la determinación del riesgo de sesgo							
Dominio ROBIS	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**Preocupaciones observadas**
Criterios de elegibilidad del estudio	Alta	Alta	Alta	Alta	Alta	Alta	Alta	Desde el principio, se excluyó la literatura "gris", la literatura en lengua no inglesa y la investigación cualitativa.
Identificación y selección de estudios	Alta	Alta	Alta	Alta	Alta	Alta	Alta	Se utilizó una única estrategia de búsqueda para siete revisiones diferentes a pesar de que los temas eran muy divergentes
Recogida de datos y evaluación del estudio	Alta	Alta	Bajo	Alta	Alta	Alta	Alta	MMAT y AGREE-II mal utilizados, versión adaptada y no validada de NOS utilizada y no justificada
Síntesis	Alta	Alta	Alta	Alta	Alta	Alta	Alta	Ningún método descrito, 48% de los estudios sobre medicamentos que detienen la pubertad y 36% de los estudios sobre hormonas excluidos de la consideración sin justificación.

Descripción del método: "*Cada una de las siete revisiones sistemáticas fue evaluada por dos evaluadores independientes utilizando la herramienta ROBIS. Un tercer y cuarto evaluador resolvieron cualquier desacuerdo por consenso..." (p 3)*

1 = RE sobre hormonas; 2 = RE sobre medicación para la pubertad; 3 = RE sobre tendencias de derivación; 4 = RE sobre vías de atención; 5 = RE sobre directrices; 6 = RE sobre transición social; 7 = RE sobre apoyo psicosocial.

Los resultados y conclusiones del equipo de la RS de York entran en conflicto

Además, los hallazgos y conclusiones probatorios del equipo de la RS de York son contradictorios. En la RS sobre terapia hormonal de reafirmación de género, los estudios de "calidad moderada y alta" mostraron mejoría de la depresión, la ansiedad y la suicidalidad (ver Tabla Suplementaria). *Todos los estudios mostraron* mejoras estadísticamente significativas con una magnitud sustancial del efecto. Ningún estudio mostró una falta de mejoría y ningún estudio mostró un empeoramiento de los resultados. Por lo tanto, resulta peculiar que el equipo de la RS de York concluyera que "había pruebas limitadas con respecto a la disforia de género, la satisfacción corporal, los resultados psicosociales y cognitivos y la fertilidad". Hay cinco estudios que se clasificaron como

[99] Whiting P, Savović J, Higgins JP et al. ROBIS: Se desarrolló una nueva herramienta para evaluar el riesgo de sesgo en las revisiones sistemáticas. J Clin Epidemiol. 2016 Jan;69:225-34. doi: 10.1016/j.jclinepi.2015.06.005.

Epub 2015 jun 16. PMID: 26092286; PMCID: PMC4687950.

[100] Noone, C., Southgate, A., Ashman, A., et al. (2024, 11 de junio). Critically appraising the Cass Report: methodological flaws and unsupported claims. https://doi.org/10.31219/osf.io/uhndk

"baja calidad" y se descartaron. Cabe destacar que Tordoff et al[101] fue excluido debido a su baja puntuación en la NOS adaptada de los autores. Sin embargo, este estudio muestra reducciones estadísticamente significativas de la depresión y la suicidalidad.

No se utilizó ningún método aceptado para determinar la calidad de todo el conjunto de pruebas

Una vez utilizada una herramienta de valoración de la calidad, debe evaluarse la calidad de todo el conjunto de pruebas con un método aceptado. Este es el producto final de una RS y, sin duda, su razón de ser. Entre los métodos aceptados para valorar el conjunto de la evidencia se encuentran GRADE y el enfoque de la Agency for Healthcare Research and Quality (AHRQ).[102] Este proceso no es perfecto, pero es riguroso, reproducible y ampliamente utilizado por los grupos de expertos que formulan recomendaciones. En una RS encargada por WPATH[103] , los autores describen su aplicación de este proceso:

> "Un revisor calificó la fuerza de la evidencia para cada resultado utilizando la Guía de Métodos para la Realización de Revisiones de Efectividad Comparativa de la Agency for Healthcare Research and Quality. Se consideraron la direccionalidad y la magnitud de los efectos informados en los estudios transversales como contexto adicional para nuestra evaluación de las pruebas de los ensayos y las cohortes prospectivas y retrospectivas. Cada evaluación de la fuerza de la evidencia fue confirmada por un segundo revisor".

Es necesario utilizar un método validado para traducir las evaluaciones de la calidad de los estudios individuales en una evaluación de la calidad de todo el conjunto de pruebas, así como divulgar dicho método validado. No está nada claro y se desconoce cómo el equipo de RS de York pasó de evaluar la calidad de los estudios individuales al conjunto de la evidencia. (Muchos estudios fueron evaluados como de calidad "moderada" según NOS y sería incorrecto trasladar estas designaciones a todo el cuerpo de la evidencia). *Sin una descripción clara de cómo se determinó la calidad de todo el conjunto de pruebas, las conclusiones finales de las RS de York carecen de fundamento.*

Sección 7: La relación de la Revisión con las revisiones sistemáticas de York y su uso violan los procesos estándar que conducen a recomendaciones clínicas en la medicina basada en la evidencia.

Se encargó a la Universidad de York la realización de una serie de RS que sirvieran de base a la Revisión, pero las conclusiones de las RS de York se aplicaron de forma inadecuada a las recomendaciones sobre políticas y prácticas sanitarias formuladas en la Revisión. En la sección 2, analizamos cómo la evidencia es uno de los muchos factores que se tienen en cuenta a la hora de elaborar recomendaciones clínicas, que la Revisión no tuvo en cuenta esos factores y, además, que las recomendaciones de la Revisión se basan en un enfoque erróneo.

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[101] Tordoff DM, Wanta JW, Collin A, Stepney C, Inwards-Breland DJ, Ahrens K. Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care. JAMA Netw Open. 2022 Feb 1;5(2):e220978. doi: 10.1001/jamanetworkopen.2022.0978. Fe de erratas en: JAMA Netw Open. 2022 Jul 1;5(7):e2229031. doi: 10.1001/jamanetworkopen.2022.29031. PMID: 35212746; PMCID: PMC8881768.

[102] https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/methods-guidance-grading-evidence_methods.pdf

[103] Baker KE, Wilson LM, Sharma R, Dukhanin V, McArthur K, Robinson KA. Hormone Therapy, Mental Health,

and Quality of Life Among Transgender People: A Systematic Review. J Endocr Soc. 2021 Feb 2;5(4):bvab011. doi: 10.1210/jendso/bvab011. PMID: 33644622; PMCID: PMC7894249.

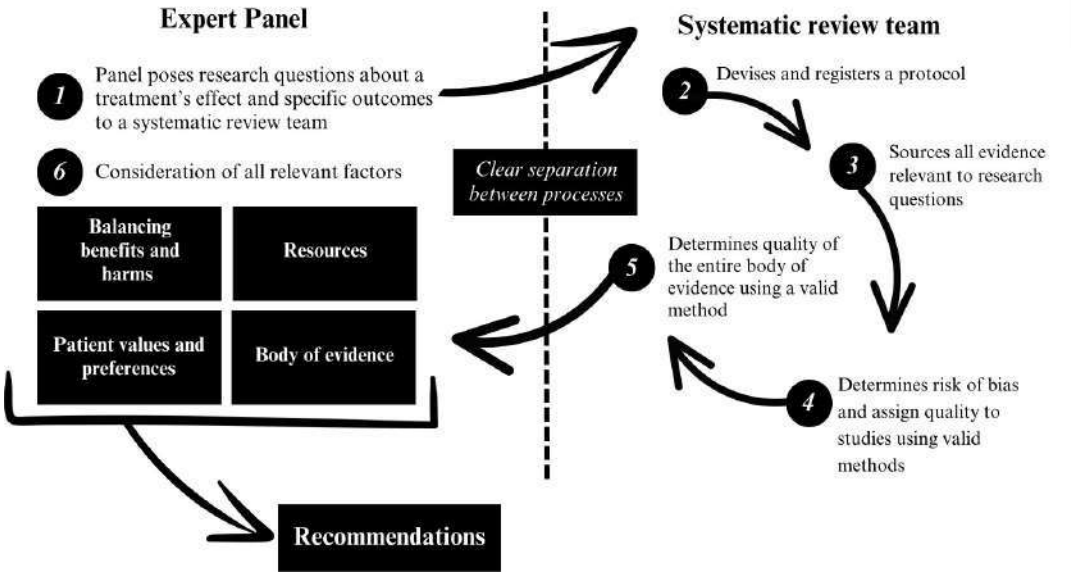
concepto de evidencia. En este artículo analizamos cómo la relación de la Revisión con las RS de York y el uso que hace de ellas va en contra de los procesos convencionales utilizados ampliamente en la medicina basada en la evidencia.

La Revisión subvirtió el proceso bien establecido para hacer recomendaciones clínicas a partir de los resultados de revisiones sistemáticas

Las RS destinadas a informar recomendaciones clínicas deben seguir un proceso estandarizado y riguroso que evalúe la calidad de todo el conjunto de evidencias. En la sección 6, describimos muchas de las formas en que el equipo de RS de York no se adhirió a dicho proceso.

Aquí se analiza el proceso normativo de colaboración entre los paneles de expertos que emiten recomendaciones clínicas y un equipo de RS.

Figura 3: Cómo deben colaborar un panel de expertos y un equipo de revisión sistemática



1. Quienes deseen hacer recomendaciones deben ser expertos en la materia. En primer lugar, estos expertos elaboran preguntas de investigación detalladas sobre una enfermedad y su tratamiento.
2. A continuación, un equipo de revisión sistemática redacta y registra un protocolo de investigación para responder a esas preguntas con las pruebas existentes. En la medida de lo posible, se adhieren a este protocolo de investigación y justifican la necesidad de desviarse de él, en caso de que surja esa necesidad.
3. El equipo de RS busca todas las pruebas relevantes para las preguntas de la investigación.
4. A continuación, asigna la calidad a estudios individuales utilizando métodos válidos.
5. El trabajo final del equipo de RS es determinar la calidad de todo el conjunto de pruebas, de nuevo utilizando un método válido. En este punto, el trabajo del equipo de revisión sistemática ha terminado.
6. A continuación, el grupo de expertos examina todos los factores pertinentes, entre los que se encuentra el conjunto de pruebas.

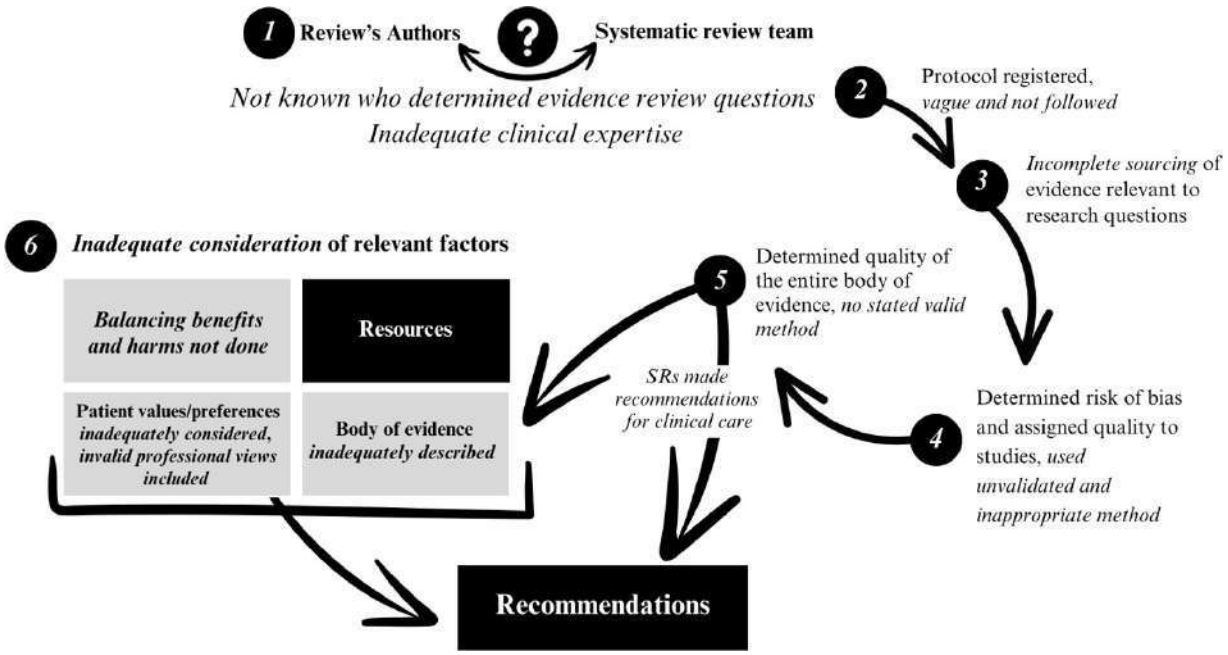
Este proceso está bien establecido, en la atención que afirma el género y más allá.[104] En la RS encargada por WPATH, los autores afirman:

> "WPATH formuló la pregunta de investigación y revisó el protocolo, las tablas de evidencia y el informe. WPATH no tuvo ningún papel en el diseño del estudio, la recopilación de datos, el análisis, la interpretación o la redacción... Los autores son responsables de todo el contenido, y las declaraciones en este informe no reflejan necesariamente las opiniones oficiales de WPATH ni implican su aprobación".

Tales descripciones de la relación entre el panel de expertos que forma las recomendaciones y el equipo de RS son convencionales en las RS que informan las recomendaciones clínicas. Los miembros de los paneles de expertos pueden ser autores de investigaciones que el equipo de RS tiene en cuenta. Los miembros de los paneles de expertos pueden no estar familiarizados con las mejores prácticas en la realización de valoraciones de calidad. La separación entre la valoración de la evidencia y el panel de expertos preserva la objetividad y consolida la experiencia.

Las desviaciones con respecto a la elaboración de directrices normativas en cada una de las fases no permiten dar a las recomendaciones de la Revisión la importancia que sus autores esperan. Estas desviaciones se observan desde el principio y se multiplican a lo largo del proceso.

Figura 4: Autores de la revisión y procesos del equipo de revisión sistemática de York



1. Los primeros fallos de este proceso comienzan con la ambigüedad de cómo se desarrollaron los primeros pasos de las revisiones sistemáticas. La relación entre los autores de la Revisión y el equipo de RS no está clara. No hay descripciones, ni en la Revisión ni en las RS de York, sobre quién ideó la

[104] Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines; Graham R, Mancher M, Miller Wolman D, et al., editors. Guías de práctica clínica en las que podemos confiar.

Washington (DC): National Academies Press (US); 2011. Disponible en: https://www.ncbi.nlm.nih.gov/books/NBK209539/ doi: 10.17226/13058

preguntas de investigación en las que se basa la revisión de la evidencia. Sin la revelación de *todos* los autores de la revisión, no podemos asegurarlo, pero es bastante probable que no se disponga de conocimientos especializados adecuados.
2. El equipo de RS registró un protocolo, pero éste no se siguió (véase el apartado 6).
3. El equipo de RS no llevó a cabo una revisión completa de la evidencia pertinente a sus preguntas de investigación (véase la Sección 6).
4. A los estudios individuales se les asignó una designación de calidad basada en una herramienta no validada y nunca antes utilizada que se adaptó a partir de una herramienta con defectos propios (véase la sección 7).
5. No se describe un método válido utilizado para determinar la calidad de todo el conjunto de evidencias y, en algunos casos, las recomendaciones para la atención clínica fueron realizadas por los propios autores de *las RS en las propias RS*.[105]
6. La Revisión utilizó de forma inconsistente las evaluaciones de la evidencia, junto con análisis incompletos o ausentes de otros factores relevantes para emitir sus recomendaciones (ver Sección 2).

Conclusión

El Cass Review se encargó para abordar el fracaso del Servicio Nacional de Salud del Reino Unido a la hora de proporcionar una atención oportuna, competente y de alta calidad a los jóvenes transexuales. Estos fallos incluyen largos tiempos de espera -a menudo años- y los consiguientes retrasos en el tratamiento oportuno por parte de proveedores cualificados. Sin embargo, en lugar de abordar esta cuestión de forma eficaz, el proceso y las recomendaciones de la revisión defienden una posición ideológica sobre la atención a los jóvenes transgénero que está en profunda contradicción con las propias conclusiones de la revisión sobre la importancia de un enfoque individualizado y adecuado a la edad de los tratamientos médicos para la disforia de género en los jóvenes, en consonancia con las normas internacionales de atención publicadas por la Asociación Mundial de Profesionales de la Salud Transgénero y las directrices de práctica clínica publicadas por la Endocrine Society. Lejos de evaluar las pruebas de forma neutral y científicamente válida, la revisión oculta hallazgos clave, tergiversa sus propios datos y está plagada de aplicaciones erróneas del método científico. La Revisión considera profundamente la posibilidad de que se realicen intervenciones de afirmación del género a alguien que no es transgénero, pero sin consideración recíproca por los jóvenes transgénero que sufren cambios físicos permanentes y angustiosos cuando no reciben la atención oportuna. La inmensa mayoría de los jóvenes transexuales del Reino Unido y de otros países no tienen la oportunidad siquiera de recibir atención clínica por parte de médicos cualificados, y los datos de la revisión lo demuestran claramente.

[105] Las RS no deben hacer recomendaciones, pero la RS sobre las hormonas de afirmación del género sí lo hace: "Los médicos deben asegurarse de que los adolescentes que se plantean someterse a intervenciones hormonales

estén plenamente informados de los posibles riesgos y beneficios, incluidos los efectos secundarios, y de la falta de pruebas de alta calidad al respecto". En respuesta a su propia revisión de la evidencia, la Junta Nacional Sueca de Salud y Bienestar recomienda ahora que los tratamientos hormonales sólo se proporcionen bajo un marco de investigación, uno de cuyos objetivos clave es desarrollar una base de pruebas más sólida. Como señalan, este enfoque es una práctica común en otras especialidades clínicas, donde para recibir tratamientos cuyos beneficios y riesgos son inciertos, los pacientes deben participar en investigaciones". (p 7)

Tabla suplementaria: Los estudios sobre hormonas de afirmación del género calificados por el equipo de RS de York como de calidad alta o moderada* demuestran resultados clínicamente relevantes y estadísticamente significativos no discutidos adecuadamente.	
Estudiar	Hallazgos
López de Lara D et al.[a]	Reducción significativa de la disforia de género en el grupo trans (p<0,001), comparable a la de los jóvenes cisgénero al cabo de un año. Mejora significativa de la ansiedad (p<0,001) Mejora significativa de la depresión (p<0,001)
Grannis C, et al.[b]	La ansiedad y la depresión son significativamente menores en el grupo tratado con testosterona que en el no tratado. Menor suicidalidad observada Grupo tratado con testosterona: menos angustia con las características corporales, mayor conectividad dentro del circuito amígdala-corteza prefrontal en comparación con el grupo no tratado.
Green AE et al.[c]	Entre los que querían hormonas de afirmación de género al inicio del estudio: ● Más depresión (77,9% frente a 60,9%, p<0,001) ● Consideraron más seriamente el suicidio (61,6 frente a 51,1%, p<0,001) ● Más intentos de suicidio (27,7 frente a 16,0%, p<0,001) Tras ajustar por covariables, la GAHT se asoció con: ● Menos depresión (aOR 0,73, p<0,001) ● Consideración menos seria del suicidio (aOR 0,74, p<0,001) ● Tendencia a menos intentos de suicidio (aOR 0,84, p=0,16) ● Menos intentos de suicidio en el grupo de edad de 13-17 años (aOR 0,61; p=0,04)
Kaltiala R, et al.[d]	Significativamente menos depresión, ansiedad, suicidio y autolesiones (p < 0,001) Depresión 54% frente a 15%, ansiedad 48% frente a 15%. Suicidalidad/autoagresión 35% frente a 4%.
Allen, L. R., et al.[e]	Disminución significativa de la suicidalidad tras la administración de hormonas de afirmación del género (p<0,001). Bienestar general significativamente mayor tras la administración de hormonas de afirmación del género (p<0,002).
aOR = odds ratio ajustada, que incluye el control de factores de confusión a - López de Lara D, et al. Evaluación psicosocial en adolescentes transexuales. An Pediatr (Engl Ed). 2020 Jul;93(1):41-48. doi: 10.1016/j.anpedi.2020.01.019. Epub 2020 mar 3. b - Grannis C, et al. Testosterone treatment, internalizing symptoms, and body image dissatisfaction in transgender boys. Psychoneuroendocrinology. 2021 Oct;132:105358. doi: 10.1016/j.psyneuen.2021.105358. Epub 2021 Jul 17.	

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