Primary Care Gender Affirming Hormone Therapy Initiation Guidelines

Aotearoa New Zealand guidelines for commencing GAHT for adults in primary care.

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Contents

Glossary of terms

In the field of transgender health, language continues to change and evolve. When in doubt about what language to use with patients, clarify the patient's preferred terminology and use their preferred language.

Transgender (or trans)

People whose genders differ from societal expectations based on their sex assigned at birth; in this document we use this term to include transgender men, transgender women, non-binary people (who do not solely identify as a man or a woman), tangata ira tāne, whakawāhine, irawhiti, and some takatāpui and MVPFAFF+[a] people.[1]

Cisgender (or cis)

A term for someone whose gender identity aligns with their sex assigned at birth.

Gender dysphoria

The distress or discomfort some trans people experience when their gender and body do not feel connected or congruent. Not all trans people experience gender dysphoria.

Gender euphoria

Feeling comfortable in your body. Some people experience this as joy and happiness.

Gender incongruence

A marked and persistent incongruence between an individual's presumed and experienced gender. Often referred to as a diagnostic code from the ICD-11 as outlined in Appendix A.

Gender affirming hormone therapy (GAHT)

The hormone therapy taken by some transgender people to embody and affirm their gender, often leading to improved psychological wellbeing and quality of life.

E-GAHT is used to abbreviate oestrogen-based gender affirming hormone therapy, and T-GAHT to mean testosterone-based gender affirming hormone therapy.

[a] MVPFAFF+ is an acronym to describe Pasifika gender identities: Mahu (Hawai'i and Tahiti), Vaka sa lewa lewa (Fiji), Palopa (Papua New Guinea), Fa'afafine (Samoa), Akava'ine (Rarotonga), Fakaleiti (Tonga) and Fakafifine (Niue).

Purpose and scope

This guideline aims to facilitate a primary care-based approach and to give general practitioners (GPs) and nurse practitioners (NPs) tools and information to safely initiate gender affirming hormone therapy (GAHT) in collaboration with their patients. They remove a standard requirement for a mandatory mental health assessment, instead encouraging an individualised approach which utilises psychological support and input only when needed.

Referral to secondary care is only initiated when needed and the primary care prescriber remains the primary or sole treating clinician for the majority of people. This aims to reduce unnecessary barriers and improve access to GAHT, in turn improving health outcomes for transgender adults in Aotearoa New Zealand (NZ).

All transgender people have a right to self-determination, autonomy and dignity when accessing healthcare, including gender affirming healthcare. This guideline aims to outline an open and transparent, person-centred approach to commencing GAHT which views the patient as a competent adult who has the capacity to make their own decisions about their body and health.

By working in partnership with the patient, this approach aims to empower patients by helping them to understand the benefits and risks of GAHT, enabling them to make an informed decision about starting GAHT.

Many transgender people will be well informed about their healthcare and patients will arrive with a wide range of levels of knowledge about GAHT. The prescriber's role is to ensure safety by following prescribing and dosing guidelines, assessing medical risk, providing education about expected outcomes, and monitoring treatment, in collaboration with their patient.

This document describes an approach to care for adults. Whilst the principles of self-determination, autonomy and informed consent remain the same in adolescents, there are added considerations and complexities in working with a younger population which were felt to be beyond the scope of this guideline. These considerations include the importance of youth development, family support, safety and the potential differences in both medications used and dosing. We recommend healthcare providers refer to the latest Standards of Care version 8 (SOC-8), released by the World Professional Association for Transgender Health (WPATH), for guidance for working with transgender children and adolescents.[2]

It is intended that these guidelines are used in conjunction with the *Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa New Zealand* [3] and local health pathways. They sit within the context of these national guidelines, which have a broader scope of all types of gender affirming care for people of all ages. These national guidelines were informed by Tā Mason Durie's models of health: Te Pae Māhutonga, using guiding principles of te mana whakahaere (autonomy) and ngā manukura (community leadership),[4] and Te Whare Tapa Whā, considering physical health, spiritual health, whānau health, and mental health.[5]

Importantly, GAHT is only one aspect of the wider process of gender affirmation, which may include medical, legal and social steps. Every transgender person is unique, and so may want to undertake some, none, or all of these steps to affirm their gender. Similarly, they may place different weight upon each of these and so pursue these in different orders. How to affirm one's own gender is a very individual decision, and there is no right or wrong way to do so.

Introduction

GAHT refers to the hormone therapy taken by some transgender people to embody and affirm their gender, often leading to improved psychological wellbeing and quality of life.[6] As outlined in the national guidelines,[3] gender affirming care, including GAHT, is a key part of transgender people's lives, and should be considered holistically in the context of their social and whānau relationships and spiritual wellbeing.[5]

Historically, the provision of GAHT has been limited to specialised secondary care services, which has contributed to restricted access to gender affirming care. Transgender people continue to face many barriers to accessing appropriate care in a timely manner, including cost, travel (particularly for patients in rural areas) and waiting times, partly due to increasing numbers of people accessing this type of care.[7] The increase in numbers of people seeking GAHT is thought to be due to greater awareness and reduced societal stigma when compared with previous decades. In the 2018 Counting Ourselves transgender health survey, 19% of participants reported an unmet need for GAHT.[8] The most commonly reported barriers were not knowing where to go (40%), cost (28%) and fear (26%). An informed consent model of care (further explained below), distributed among primary care providers, is the best model of care to reduce the current unmet need for GAHT.

In NZ, GAHT is currently initiated by a variety of health professionals in different clinical settings. This can include GPs, NPs, endocrinologists, sexual health physicians, adolescent health physicians and paediatricians. At the time of writing, pathways to access GAHT vary depending on locality. However, initiation of GAHT is increasingly being provided in primary care settings due to increasing demand and greater recognition of the barriers that transgender people, particularly those living outside of main cities, face when accessing secondary care services. Patients have a right to access GAHT in a timely manner within their local communities. To work towards this, these guidelines have been developed to assist all primary care providers by providing the information they need to initiate and provide repeat prescriptions of GAHT, with the aim of supporting their patients' gender affirmation and removing barriers for transgender adults accessing hormones. These guidelines are informed by the *Aotearoa Guidelines for Gender Affirming Health Care*[3] and overseas guidelines which have been adapted for local use.[9-13]

This document is a partnership between transgender and cisgender professionals; its authors include general practitioners, a primary care nurse, endocrinologists, a sexual health physician, an adolescent health physician, psychologists, academics and peer supporters. Whilst we appreciate that not all GPs and NPs will choose to initiate GAHT, this guideline has been written for those who do want this guidance.[b]

Many of the current pathways to access GAHT in NZ include the requirement of a psychosocial assessment by a mental health professional. These are often performed by psychologists and psychiatrists, resulting in long wait times for clients or a high cost barrier if more timely care is sought in the private system (which is not available or affordable to many people). Many transgender people experience this approach as pathologising, and may worry they have to prove they are 'transgender enough' or say the right thing in order to access the treatment they know they need to affirm their gender.[14] It is not the role of a health professional to make a judgement on whether a patient's gender (e.g. a non-binary gender) is valid or whether a patient is male or female enough. In some parts of NZ, it can be challenging to find a mental health professional to conduct this assessment at all.

[b] We recognise that not all primary care prescribers will want to initiate GAHT, and that challenges such as funding, appointment length and availability, increasing workloads and burnout all exist in NZ at this time. However, we feel it is important that those who wish to provide this care have access to practical guidance as provided in this document and are supported to prescribe GAHT for their patients. Supporting transgender patients to access GAHT in a timely manner which recognises their autonomy is very rewarding work, and we encourage primary care to get involved.

These guidelines outline an approach where the primary care team works in collaboration with patients to meet their gender goals, provides education about GAHT and general health, and helps to support patients' understanding of the risks and benefits of GAHT to make well-informed decisions about their health. This is often referred to as an 'informed consent model' and is the approach used in this document (see 'Informed consent' below for more detail).

Being transgender is not a mental illness.[15] Societal stigma and prejudice can lead to transgender people experiencing disproportionately high levels of discrimination, harassment, homelessness, unemployment, abuse and violence. The resulting gender minority stress can lead to the inequitable rates of poor mental health experienced by transgender people as a population.[16-18]

As a result, some transgender people will present with mental health conditions which require input from secondary care. As with any patient seen in primary care, psychologists, psychiatrists or secondary mental health services only need to be involved for those who are experiencing moderate to severe mental illness. Everyone else can, in theory, be managed in the community with their regular primary care team, which could include support from counsellors, health improvement practitioners or other mental health providers as needed.

For those who request it, counselling or psychotherapy can be of benefit, not as an assessment tool or mandatory part of accessing GAHT, but instead to provide psychological support during a time of change which can be stressful due to both personal and societal factors. For example, people may find it helpful to have support with exploring their gender or sexuality (particularly adolescents), the 'coming out' (or disclosure) process (especially to family or their workplace), and navigating experiences and concerns around transphobia, social stigma and other aspects of adjusting to this time of change. Ideally this support would be provided by mental health professionals such as counsellors or psychologists (or peer supporters where appropriate) who have high levels of transgender cultural safety.

Primary care is the ideal place for meeting most of the healthcare needs of transgender people, including hormone initiation, as primary care teams are part of patients' local communities, and are experts in whole life experience, including normal life events which may require their input. GPs and NPs take a holistic approach which considers a patient's physical health, mental health, culture, social supports, environment and lifestyle factors, which is well suited to providing gender affirming healthcare.

Primary care practitioners are able to work together with each transgender person to understand their gender embodiment goals, discussing options and together finding the most appropriate care for the individual. A patient with more complex mental health issues can still be referred to a psychologist or mental health team as needed, but there is no good reason for this to be the default approach. Likewise, a patient with more complex physical health issues can still be referred to an endocrinologist or sexual health physician. The Counting Ourselves survey[8] found that 48% of respondents felt that their doctor did not know enough about transgender healthcare, so health provider education is an important aspect of ensuring health needs can be adequately met.

The authors recognise that this is a rapidly evolving field of medicine. The guidelines were written in February 2023 and will require review in three years' time. We welcome and encourage research to evaluate the impact and outcomes of these guidelines, as well as the experiences of patients and providers.

Informed consent

The informed consent model of care views treatment as collaborative between the patient and healthcare provider. It is a term commonly used in medical practice to describe the interactive process of a health practitioner providing a patient with information and the patient using this to make an informed decision about their healthcare. In gender affirming healthcare, the term acknowledges that transgender people are the experts on their own gender, and the experiences, goals and needs that are related to their gender, while also acknowledging that healthcare providers have the expertise to provide this care in a way that maximises safety and efficacy.[19]

Informed consent is a process that respects patient autonomy and dignity and assumes capacity. As such it does not require a routine referral to secondary services or the private equivalent for a psychosocial assessment prior to initiating GAHT. We acknowledge the varied interpretations of the term 'informed consent' within transgender healthcare, and so have described here what is meant by informed consent in this guideline.

The use of 'informed consent' in this guideline reflects that used by the Medical Council of New Zealand (MCNZ)[20] to describe the process of providing information, including risks and benefits about a treatment, in a way that the patient can understand, as part of a trusting clinician–patient relationship, so that the patient can make a fully informed decision about care. In the case of a patient-centred approach to GAHT, the patients bring their own individualised gender embodiment goals and are active participants in the process.

Informed consent is an important component of the biomedical ethics principle of respect for patients' autonomy; this respect for autonomy should be balanced against the principles of beneficence and nonmaleficence.[21] This is reflected in *Cole's Medical Practice in New Zealand*, which states that the principle of informed consent serves to protect patient autonomy and a patient's right to determine what they want to do with their body, but that patients do not have a right to be provided treatment that is not clinically indicated.[22]

Primary care is the ideal place to create a safe and affirming space for gender affirming care. Primary care clinicians work as collaborative partners to establish lifelong relationships with the patient as the primary decision-maker. This partnership supports patient understanding of the risks and benefits of GAHT, including the impact on other areas of life such as work or education, relationships, sexual function and fertility, and works to promote general health and wellbeing. These guidelines serve as a starting point for patients and clinicians to develop a care plan appropriate to each individual's needs. Peer supporters, primary care nurses, primary mental health services, counsellors, psychologists and social workers may be involved in the delivery of hormones and GAHT health education. A multi-disciplinary approach is useful, although we recognise this is not always possible.

Like other medical interventions with similar risks, an external mental health assessment is not mandatory before accessing GAHT for adult patients. Providers should be aware that GAHT is often associated with improvements in a patient's mental health.[23] A patient who has severe mental health difficulties will likely still be able to provide informed consent, but may require support and treatment from a mental health professional alongside starting GAHT. For adults with a complex presentation or those who are requesting less common treatments or treatments with limited research evidence, further advice or assessment from different health professionals is likely to be required.[2] Remember that gender affirming healthcare may reduce mental distress, and that withholding or delaying care unnecessarily is unethical and could worsen a person's mental health. See FAQ 2 for more details.

The starting point when assessing capacity is always to presume that an adult has capacity to make the decision.[22] A patient has capacity to make a decision if they understand the nature and effects of the treatment; can weigh up options; balance risks and benefits; foresee consequences of consenting (or not consenting); demonstrate consistency in their decision-making; have no undue influence from a third party and can communicate their decision. In most cases for patients with diminished capacity to consent, external support may be required to assess capacity.

Examples of situations where capacity to consent may be diminished include cognitive impairment, intellectual disability, dementia, psychosis, or mania of a degree that it may be impacting on their ability to adequately understand and balance necessary information. In these cases only, a formal capacity assessment is an essential part of the informed consent process, ideally conducted by a health professional who knows the patient well.[24] A mental health professional may be able to assist with a capacity assessment. Providers should be aware that patients with diminished capacity still have a right to timely access to care, and this may involve the use of a supported decision-making process; see the section on diminished capacity in the Frequently Asked Questions section (FAQ 4) for more details.

We encourage prescribers to take a harm reduction approach to the initiation of GAHT, particularly when a patient is self-sourcing GAHT. If a patient is taking GAHT formulations which are unavailable in NZ or outside of recommended dose ranges, a plan to transfer onto NZ medications and doses in line with these guidelines should be negotiated in partnership with your patient.

WPATH Standards of Care Version 8

These guidelines align with the GAHT recommendations from the WPATH Standards of Care version 8.[2] Full details of the SOC-8 criteria for GAHT can be found in Appendix A, and these have been incorporated throughout this guideline. The SOC-8 recommendations refer to the International Classification of Diseases and Related Health Problems (ICD-11)[25] coding for Gender Incongruence, the details of which can also be found in Appendix A.

Stages of gender affirming hormone therapy initiation

These guidelines are based on providing individualised care in a staged format with a new patient. There is no set number of appointments that a patient must be seen for prior to starting GAHT, and this will vary depending on complexity, practitioner experience and appointment length. In some situations, several stages could be completed in one longer appointment, whilst in other situations it might take multiple appointments to work through one stage. Similarly, each person's body and gender embodiment goals are different, and it may take more appointments, working with your patient, for you both to understand what works best for them. This may require trialling different dosages and types of hormones and making changes where needed.

When patients consent to treatment it is good practice to allow reasonable time for the patient to make their decision. The MCNZ states that a key principle of informed consent is that it is an interactive process and not a one-off event.[20] For this reason, prescribers may wish to separate stages 3 and 4 into separate appointments, to allow patients time to consider the information provided, and to provide an opportunity to ask further questions.

The stages outlined below help to ensure that GAHT is prescribed as safely as possible, and help to ensure the best outcome for the patient's overall wellbeing. Stages 1 to 3 should be completed prior to prescribing hormones. These can be undertaken by a GP, NP, primary care nurse, or a combination of these colleagues working together in one practice.

Terminology used in this guideline

E-GAHT is used to abbreviate *oestrogen-based GAHT* (previously known as feminising GAHT).

T-GAHT is used to abbreviate *testosterone-based GAHT* (previously known as masculinising GAHT).

Stages in starting GAHT	
Stage 1	Introduction, relationship building, information gathering
Stage 2	Medical review (including fertility discussion)
Stage 3	Hormone information and education
Stage 4	Hormone initiation (first prescription)
Stage 5	Maintenance prescribing and long-term follow-up

Stage 1:

Introduction, relationship building, information gathering

Stage 1

Introduction, relationship building, information gathering

- General introduction to the service and how the process of getting started on GAHT will work.
- Check patient's name, gender and pronouns and ensure they are recorded accurately on the Practice Management System (PMS). Check which name your patient would like you to use when calling them from the waiting room. Adding this information as an alert or a 'post-it note' on the PMS may be helpful.
- Explore gender embodiment goals for gender affirming care.
  - You could ask: Think about your body as it is now, what would you like to stay the same? What would you like to change?
  - See Tables 1 and 2 for physical effects of GAHT. Sometimes people's goals may not require or be achievable with GAHT, so it is important to explore this with your patient.
  - People's goals are individual and may change over time. Work together with your patient over time, adjusting medication as needed in response to their needs and goals.
- Current and recent past gender experiences (see example questions in Appendix B).
- Give information about other supports. These may be available on your health pathways. Some examples can be found here:

  Gender diversity support services – Health Navigator

  Rainbow organisations – Te Ngākau Kahukura
- Give hormone information sheet (Appendix E) if appropriate at this stage (this will be explained to patient fully at Stage 3, but this gives the patient an opportunity to take it home and read it).
- HEeADSSS[26] or similar psychosocial assessment, including asking about patient supports.

Stage 2:

Medical review (includes fertility discussion)

Stage 2

Medical review (includes fertility discussion)

- Past medical and surgical history – for E-GAHT ask specifically about breast cancer, venous thromboembolism (VTE), cardiovascular disease (CVD), migraines, liver disease.
- Review mental health including current supports and strengths (consider PHQ-9 and GAD-7 if relevant) – arrange any extra support or referrals if indicated.
- Social history – including alcohol, drugs, and smoking/vaping. Discuss risk reduction, e.g. smoking cessation.
- Family history – ask specifically about VTE, CVD, breast cancer and liver disease.
- Medications and allergies – you may wish to check if the patient is 'self-medicating' with hormones (e.g. self-sourcing hormones online).
- Sexual health review (including discussion about the need for any STI testing, contraception and/or HIV PrEP where relevant).
- Any increased risks from hormonal therapy to manage – there are very few, if any, medical contraindications.
  - For E-GAHT consider discussion with secondary care if there is migraine with aura, CVD, VTE history or significant liver disease. (See E-GAHT section and FAQ 5 for more detail.)
  - Pregnancy is an absolute contraindication for T-GAHT (consider checking a Beta hCG level). Relative contraindications include severe hypertension, sleep apnoea and polycythaemia since these conditions can be exacerbated by testosterone.[2]
- Recommend cervical screening for patients who are over 25 years old and have a cervix.
- Update or establish baseline observations – blood pressure and weight.
- Offer trans culturally safe counselling or peer support – this can be very useful alongside GAHT.
- For those starting E-GAHT offer speech and language therapy referral for voice therapy (in some regions this may be available for those starting T-GAHT, but as T-GAHT lowers the voice this is less often required).

Note: There is no need for a routine genital or breast examination.

Stage 2

Medical review (includes fertility discussion)

Baseline bloods

- E-GAHT – LFT, lipids, FSH, LH, oestrogen, testosterone. Electrolytes if starting spironolactone. HbA1c if indicated by risk factors.
  - If referring for fertility preservation include HIV, syphilis, hepatitis B&C.
- T-GAHT – LFT, lipids, FSH, LH, oestrogen, testosterone FBC and Beta hCG. HbA1c if indicated by risk factors.
- Prolactin measurement is not usually required, see FAQ 6.

Fertility (reproductive options)

You will need to assess your patient's capacity to understand the effect of GAHT on reproduction and explore reproductive options with the individual prior to the initiation of gender affirming treatment. This is discussed in more detail at Stage 3 (hormone information) but is also included here so that relevant blood tests can be included in the baseline bloods if required for those starting E-GAHT.

A pamphlet about fertility preservation for transgender people can be found here: Transgender fertility: Preservation and treatment (PDF, 813KB)

- E-GAHT (assigned male at birth): E-GAHT may result in permanent loss of fertility.[27] There is funding available for fertility preservation (check with your local service for current eligibility criteria).

  Fertility preservation is not a requirement for GAHT, but it is essential to discuss this with your patient. If referral for fertility preservation is desired, include HIV, Syphilis and Hepatitis B & C on baseline bloods.
- T-GAHT (assigned female at birth): T-GAHT usually causes ovarian suppression. This may be reversible on stopping testosterone (which may result in a return of spontaneous fertility) but may also be irreversible.[28-30] Patients should be aware that if they wish to become pregnant in the future, they will need to stop testosterone (as it is a teratogen) and that they may require fertility assistance in the form of egg harvesting. Egg harvesting can usually be undertaken at the time of desired pregnancy (and egg quality is unaffected by testosterone), so is not necessarily required prior to starting GAHT.[30] For this reason, egg harvesting is currently only funded for those having a surgical removal of reproductive organs. A funded assessment with a fertility specialist to discuss options prior to starting T-GAHT may be available if your patient wishes to discuss this in more detail.

Menstrual cessation

Many transgender and non-binary people assigned female at birth experience dysphoria with menstruation. This can be significant, and for some may contribute to poor mental health or even suicidality. It is important to discuss this and to offer menstrual cessation options if this is desired. Although testosterone usually results in amenorrhoea, starting menstrual cessation sooner is often welcomed and desired by patients.

When considering which option to use it is important to take into account whether contraception is required. Table 1 outlines options for menstrual cessation. Medication used for menstrual cessation can usually be stopped (if not needed for contraception) once the patient is established on testosterone and menstruation has ceased. Menstruation may persist despite adequate testosterone levels in 5–10% of people,[31] in which case progesterone therapy could be continued.

Table 1: **Menstrual cessation options**

Contraceptive	Depo-provera Mirena Combined contraceptive pill	Usual contraception dose	Oestrogen containing medication may not be desired by trans masculine people.
Not contraceptive	Norethisterone (Primolut)	5mg BD	Can increase to 10mg BD for 1 week if breakthrough bleeding then reduce slowly. Occasionally need to stay at higher doses.
	Medroxyprogesterone (Provera)	10–20mg once daily – up to 10mg TDS	
	Utrogestan	100–200mg daily	

Note: Testosterone is NOT a contraceptive.

Stage 3:

Hormone information and education

Stage 3

Hormone information and education

Check blood results and discuss these with the patient as necessary.

Address any remaining concerns or questions.

Ensure referrals are completed and that the patient is linked to appropriate supports.

Prior to starting E-GAHT: check that fertility preservation has been organised (if desired).

Go through hormone information and education (detailed in the following pages), including gender embodiment goals, side effects, risks, permanent effects, and time frame for changes. Some people may decide not to continue with GAHT in the future, so it is important to discuss the permanent and non-permanent changes. (See also FAQ 1.)

Highlight that changes will be gradual, occurring over years. Explain the need for regular review and monitoring in the first year and ongoing need for bloods and clinical review thereafter.

Provide written information and a copy of the consent form.[c] These forms can be found in Appendices E and F.

Document whether the patient has capacity to provide informed consent to commence GAHT, whether they meet the SOC-8 criteria for hormone treatment (see Appendix A) and that you have discussed fertility (see PMS shortcuts in Appendix C).

The checklist in Appendix D can be used to ensure all steps have been completed prior to prescribing.

[c] A consent form can be a useful addition and may act as a guide to the clinician to check all of the relevant points have been discussed, but is not a requirement. We have included it here as an option. By far the most important aspect of informed consent is the conversations between the patient and clinician outlined here. If these are well documented and the patient has had time to consider the information and ask questions, this is more important than a written consent form. See the MCNZ statement on informed consent for more detail.

Stage 3

Hormone information and education

T-GAHT — Information to cover in the consent process

We recommend using the patient information sheet in Appendix E to make it easier to cover this information with the patient. This will provide a handy reminder and prompt of what you need to cover when providing information about GAHT.

- Explain which preparations of testosterone are available (and check patient preferences for which to use), frequency of administration and the option of self-injecting (full medication details can be found below in 'GAHT initiation protocol').
- Recommended monitoring for T-GAHT:
  - Bloods and blood pressure (BP) 3–6-monthly in the first year, thereafter annually or as clinically indicated. Note the timing of the blood test when measuring testosterone levels (see below).

Discuss the changes expected with T-GAHT

Changes occur gradually over months to years (see Table 2). Physical examinations are not necessary. Often reassurance is required, especially in the first 6 months.

The following infographic can be helpful: Effects and expected time course of a regimen consisting of testosterone

Note – your patient may prefer the use of non-gendered language when describing their genitals, so we recommend asking them what words they prefer and then using those. Commonly used terms (at the time of writing) include 'front hole' or 'internal genitals'.

- Permanent effects:
  - Deepening of the voice,
  - Increased body hair growth including facial hair,
  - Androgenetic alopecia,
  - Genital changes: clitoral enlargement (may be up to 1–3cm) and this can feel uncomfortable and even painful initially. Vaginal dryness can be relieved with oestrogen cream or an over-the-counter product for vaginal dryness and ensuring use of extra lubrication for vaginal sex.
- Sex – vaginal dryness increases the risk of STIs including HIV, so it is advisable to use condoms if having sex using this part of the body. Lubrication can help with any associated discomfort. Testosterone is not a contraceptive.
- Effects which are likely reversible: acne/oily skin, increased muscle mass/ strength, redistribution of body fat, increased libido. Irritability and frustration may be variably present.
- Menstruation stops in most people (around 90%) after 1–6 months.[31] *(Many patients prefer the term 'monthly bleeding'.)*
- Fertility – You may have already discussed this in Stage 2, but it is repeated here to ensure it isn't missed. T-GAHT usually causes ovarian suppression. This may be reversible on stopping testosterone (which may result in a return of spontaneous fertility) but may also be irreversible.[28-30] Patients need to understand that if a future pregnancy is desired it will mean stopping testosterone (as it is a teratogen) and may require fertility assistance in the form of egg

harvesting. Egg harvesting is more effective at the time of desired pregnancy (and egg quality is unaffected by testosterone), so is not required prior to starting GAHT.[28]

It is possible to become pregnant while taking testosterone even if menstruation has stopped, so **contraception is essential if there is any sexual contact that would put someone at risk of pregnancy**. Testosterone is likely to be harmful to a developing fetus and should not be used during pregnancy.

- Risks – Polycythaemia, liver dysfunction, pelvic pain, raised cholesterol and raised blood pressure.[32-34] Studies in cisgender men indicate a slight increased VTE risk in the first 6 months on testosterone therapy.[35]
- Cancer screening
  - Discuss the importance of cervical screening for anyone with a cervix.
  - Breast screening is recommended from age 45 years for anyone who has breasts. Those who have had 'top surgery' (this commonly used term refers to chest reconstruction surgery or bilateral mastectomy) should follow the advice of their surgeon, as this may depend on the extent of the surgery performed. Some people may be advised to have clinical examinations and possibly ultrasound screening.
  - Ensure recalls are not removed if gender is changed on the PMS.
- Gender affirming surgery – provide information on local pathways for surgery. Your patient may be especially interested in accessing top surgery. Availability varies between localities; check your local health pathways. A stocktake of availability as of 2021 can be found here: An update for the provision of gender affirming healthcare across the district health boards of Aotearoa New Zealand – PATHA. Gender affirming genital surgery referral forms can be found here: The Gender Affirming (Genital) Surgery Service – Ministry of Health.

Table 2: **Effects of testosterone-based hormones (T-GAHT)**

Effect of testosterone	Expected onset	Expected maximum effect	Reversibility
Skin oiliness/acne	1–6 months	1–2 years	Likely
Facial body/hair growth	6–12 months	4–5 years	Unlikely
Scalp hair loss	6–12 months[a]	Variable	Unlikely
Increased muscle mass/strength	6–12 months	2–5 years	Likely
Redistribution of body fat	1–6 months	2–5 years	Likely
Cessation of periods	1–6 months		Likely
Clitoral enlargement	1–6 months	1–2 years	Unlikely
Vaginal atrophy	1–6 months	1–2 years	Unlikely
Deepening of the voice	6–12 months	1–2 years	Not possible
Increased sexual desire	Variable	Variable	Likely

[a] Highly dependent on age and inheritance; may be minimal.

(Reproduced with permission from the *Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa, New Zealand*)

Stage 3

Hormone information and education

E-GAHT — Information to cover in the consent process

We recommend using the patient information sheet in Appendix E to make it easier to cover this information with the patient. This will provide a handy reminder and prompt of what you need to cover when providing information about GAHT.

- Explain that E-GAHT involves using two medications – an oestrogen and a testosterone blocker:
  - — Oestrogen:

    Explain which preparations of oestrogen are available (tablets or patches). Explain that there is no good evidence yet that one form of oestrogen is better than another in terms of effects, but that oestrogen patches are likely to carry a lower risk of VTE and LFT dysfunction than tablets.[36, 37]
  - — Testosterone blocker:

    Discuss options for androgen blockade (spironolactone or cyproterone). There are no studies yet that compare efficacy in E-GAHT, therefore patients can select their preferred approach, in discussion with their prescriber and taking into account potential side effects and risks, and any relevant health conditions or medications.
    - o Spironolactone is a blood pressure tablet at low doses but works as a weak anti-androgen at higher doses. It will not suppress testosterone levels but will block the effects of testosterone in the body, promoting breast growth and slowing down body hair. Common side effects include dizziness and urinary frequency.
    - o Cyproterone in very small doses (12.5mg daily or less) will suppress testosterone to < 2 nmol/L but does not suit everyone. Side effects can include fatigue and low mood. Shortness of breath is an uncommon side effect but should be counselled for. Larger doses have been associated with liver function abnormalities and there is a dose-dependent and cumulative risk of meningioma thought to be related to doses of 25mg daily or greater.[38-40] Evidence in other areas of healthcare shows the risk of VTE is increased with cyproterone use.[41]
- Recommended monitoring for E-GAHT
  - — Bloods and blood pressure 3–6-monthly in first year, thereafter annually or as clinically indicated.

Discuss the changes expected with E-GAHT

- Changes occur gradually over months to years (see Table 3). Physical examinations are not necessary. Often reassurance is required, especially in the first 6 months. The following infographic can be helpful: Effects and expected time course of a regimen consisting of an anti-androgen and estrogen.
- Permanent effects:
  - — Fertility is thought to be permanently affected by E-GAHT.[27, 42] Fertility preservation is recommended in young people and is usually funded. It is essential to have and document this discussion prior to prescribing E-GAHT.

  - Breast development is gradual over 2–years.[32] It can be helpful to manage expectations as many people develop an A cup or smaller after 1 year on E-GAHT.[43] This can be a common source of dissatisfaction.[44]
- Effects which are likely reversible: softer skin, decreased muscle mass, thinning of body hair, fat redistribution to buttocks, hips and thighs.
- Libido usually reduces when taking androgen blockers. Erections usually reduce in frequency and may be less firm and shorter lasting (Sildenafil can be helpful for some people). Testicles can shrink to less than half their original size.
- E-GAHT does NOT change:
  - Voice pitch (voice therapy may be available via a speech and language therapist depending on local pathways)
  - Facial bone structure
  - Prominence of the tracheal cartilage (Adam's apple)
  - Growth of facial and body hair, which slows but does not stop completely (laser hair removal if desired can be funded by a WINZ disability allowance if the patient has a community service card or is on a low income.
- Side effects – breast tenderness and weight gain. In the first few days to weeks there may be nausea and headaches which usually settle.
- Risks – VTE (risk can be lowered, see FAQ 5), raised cholesterol, gallstones, raised BP, possible increase in breast cancer risk.[32] We recommend explaining the symptoms of deep vein thrombosis and pulmonary embolism and advising patients to seek urgent medical help if these occur.
- Cancer screening – Breast screening is recommended from age 45 years for anyone who has breasts.
- Gender affirming surgery – provide information on local pathways for surgery. Availability varies between localities; check your local health pathways. A stocktake of availability as of 2021 can be found here: An update for the provision of gender affirming healthcare across the district health boards of Aotearoa New Zealand – PATHA. Gender affirming genital surgery referral forms can be found here: The Gender Affirming (Genital) Surgery Service – Ministry of Health.

Table 3: **Effects of oestrogen-based hormones (E-GAHT)**

Effect of oestrogen	Expected onset	Expected maximum effect	Reversibility
Redistribution of body fat	3–6 months	2–3 years	Likely
Decrease in muscle mass and strength	3–6 months	1–2 years	Likely
Softening of skin/decreased oiliness	3–6 months	Unknown	Likely
Decreased sexual desire	1–3 months	3–6 months	Likely
Decreased spontaneous erections	1–3 months	3–6 months	Likely
Breast growth	3–6 months	2–3 years	Not possible
Decreased testicular volume	3–6 months	2–3 years	Unknown
Decreased sperm production	Unknown	>3 years	Unknown
Thinning and slowed growth of body and facial hair	6–12 months	>3 years[a]	Possible
Male pattern baldness	Variable	[b]	
Voice changes	None	[c]	

[a] Complete removal of hair requires laser treatment. [b] Familial scalp hair loss may occur if oestrogens are stopped.
[c] Treatment by speech-language therapists for voice training is most effective.

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Stage 4:

Hormone Initiation

Stage 4

Hormone Initiation

- Ensure Stages 1–3 are complete and that patient is happy to start GAHT (see checklist in Appendix D). If using the consent form, ensure this has been signed by the patient.
- Document patient's capacity to provide informed consent, whether they meet the SOC-8 criteria for GAHT (see Appendix A) and that you have discussed fertility (see Appendix C for PMS shortcut suggestions).
- Inform the patient that using these medications for gender affirmation is an unapproved use of an approved medication.[45] These medications are widely used around the world for this purpose and there is a recognised clinical justification for their use. This is also known as 'off-label' use.

  As a prescriber you must explain what is being prescribed, and why, and obtain informed consent from your patient. It is acknowledged, however, that when off-label use of a medicine is so common that it is regarded as usual practice, obtaining separate consent (for off-label use) may not be considered necessary, and this is at the clinician's discretion.[46]
- Give GAHT prescription as per GAHT initiation protocol below. Arrange to follow up in 3 months.
- T-GAHT: arrange a nurse appointment for ongoing injections.

Stage 5:

Maintenance prescribing and long term follow up

Stage 5

Maintenance prescribing and long term follow up

In the first year, follow up every 3 months, or more often if needed; thereafter as needed depending on individual needs. Generally, an annual review is recommended, but for patients who have been stable on GAHT for a significant time it may be appropriate to extend this.

- Review effects of medications and check the patient is happy to continue taking GAHT.
- Adjust doses as per hormone protocol.
- Monitor BP and bloods 3–6-monthly in the first year (or more often if necessary) then annually or as clinically indicated. Monitoring is primarily with dose changes, which is likely to be every 3 months, but flexibility may be needed. Monitor weight as appropriate.
- Monitor mental and physical health. Encourage lifestyle/health behaviours which reduce the risks associated with GAHT, e.g. smoking cessation, cholesterol reduction, moderate alcohol use.
- If needed, connect to mental health and peer support.
- Make referrals for other gender affirming care as desired by your patient.
  - Gender affirming genital surgery referrals are via the Ministry of Health. For further detail see 'Gender affirming (genital) surgery service forms' here: The Gender Affirming (Genital) Surgery Service – Ministry of Health
  - For other gender affirming surgeries refer to your locality health pathways.

GAHT Initiation Protocol

GAHT Initiation Protocol

This protocol relates only to the initiation of gender affirming hormone therapy in adults and is to be used by prescribers after following GAHT Stages 1–3 described above.

The starting protocols below are for adults who have NOT been on gonadotropin releasing hormone (GnRH) agonists (also known as puberty blockers) from a young age (Tanner stage 2–3). For those who have been on puberty blockers from Tanner stage 2–3, GAHT initiation should progress more gradually.[32]

This section outlines the medications used in GAHT, dosage guidance, recommended monitoring, and a protocol for initiating GAHT.

Oestrogen-based Gender Affirming Hormones (E-GAHT)

Table 4: **Overview of E-GAHT**

Oestrogen formulation	Starting dose	Maximum (usual maintenance dose)	Notes
Oestradiol valerate (Progynova)	1–2mg daily	4–6mg daily	Increasing by 1–2mg every 3–6 months is generally recommended.
Oestradiol patch (Estradot)	25–50mcg patch twice weekly	100-200mcg patch twice weekly	Increasing by 25–50mcg every 3–6 months is generally recommended. Lower VTE risk than oral oestrogen. Recommended if liver or lipid dysfunction or >45 years old.
Androgen blocker*	**Starting dose**	**Maximum (usual maintenance dose)**	**Notes**
Spironolactone	50–100mg daily	200mg daily	Unable to use serum testosterone for clinical guidance as spironolactone blocks the effect of testosterone on the tissues rather than its production. Monitor potassium level.
Cyproterone	12.5mg daily (or 12.5-25mg on alternate days)	12.5mg once daily (or 12.5-25mg on alternate days)	Use lowest effective dose. Use of higher doses long-term has been linked to meningioma. Consider review and discussion every 5 years if remaining on this long term. Contra-indicated in history of thromboembolic disorders as increases VTE risk. Monitor liver function.
Goserelin	10.8mg SC implant insertion into lower abdomen every 12 weeks		Not first line in adults due to high cost and good availability of alternative options.

***The androgen blocker is no longer required if the patient has had an orchiectomy.**

For guidance on E-GAHT in individuals with increased cardiovascular or VTE risk, see FAQ 5. For a comment on Progesterone use See FAQ 8.

Table 5: **E-GAHT recommended monitoring**

Investigation	Comment
Electrolytes	If patient is on spironolactone.
Liver function tests	If abnormal, use transdermal oestrogen as first choice. Monitor if on cyproterone.
Lipids	
Oestrogen	Only checked to ensure levels are not supraphysiological. Some guidelines would recommend an upper limit of 700–750 pmol/L[32] but there is insufficient evidence to definitively recommend any target range. Experience suggests that oestrogen levels or dose do not correlate well with physical effects or self-reported satisfaction with E-GAHT, and exogenous oestrogen is not well measured in the serum.
Testosterone	On cyproterone – levels would typically be <2nmol/L (or higher if wanting to maintain erectile function). On spironolactone – no need to measure as it doesn't usually suppress (see above); instead, be guided by clinical response.

E-GAHT
Starting Protocol

Prior to first prescription	Complete Stages 1–3 in the primary care protocol for starting GAHT. This includes a psychosocial assessment, medical review, baseline blood tests, blood pressure, weight, fertility preservation (if desired), and informed consent outlining effects (including permanent changes) and risks of GAHT by a knowledgeable healthcare provider. Provide the patient with information sheet and document consent.
Commence GAHT – first prescription	**Oestrogen** – *one of*: Estradiol (Progynova) 1–2mg OD *or* Estradot patches 25–50mcg twice weekly ***AND*** **Testosterone blocker** – *one of*: Spironolactone 50–100mg OD *or* Cyproterone 12.5mg OD (or 12.5–25mg on alternate days)
3 months after commencing hormones	If no concerns, adjust androgen blocker to maintenance dose and commence gradual increase in oestrogen dose: • Oestrogen can be increased: — Progynova by 1–2mg every 3–6 months up to maximum of 6mg — Estradot by 25–50mcg every 3–6 months up to maximum of 100–200mcg twice weekly. • Spironolactone – consider increasing to 200mg OD (if potassium level is normal). • Cyproterone – continue 12.5mg OD (or 12.5–25mg on alternate days). • Bloods for potassium (if taking spironolactone), liver function, lipids. • Check blood pressure.
3-monthly appointments in first year, can be 12-monthly thereafter if stable	At each follow-up visit: • Review progress and discuss any issues or questions. • Check on physical and mental health and social supports. • If your patient has an orchiectomy the androgen blocker can be stopped. • Ensure monitoring is up to date: — Check blood pressure 3–6-monthly in the first year, thereafter 12-monthly. — Monitor blood tests 3–6-monthly in the first year, thereafter 12-monthly or as clinically indicated (see Table 5 for details).

Testosterone-based Gender Affirming Hormones (T-GAHT)

Table 6: **Overview of T-GAHT**

Testosterone formulation	Standard starting dose	Maximum (usual maintenance) dose	Notes
Depo-testosterone (testosterone cypionate)	100mg IM/SC* every 2 weeks or 50mg SC weekly	200mg IM/SC* every 2 weeks or 100mg SC weekly	Testosterone level should be measured mid-way between injections. Patient can be taught to self-inject.
Sustanon (testosterone esters)	125mg (0.5ml) IM* every 3 weeks	250mg (1ml) IM* every 3 weeks	Testosterone level should be measured mid-way between injections. Patient can be taught to self-inject.
Reandron (testosterone undecylate)	Less commonly used as a starting testosterone, but can be started at 500mg IM The second dose can be given after 6 weeks to achieve steady state and thereafter continue 12-weekly	750–1000mg IM every 10–14 weeks	Testosterone level should be checked immediately prior to injection. Injection must be given by a health professional (due to risk of oil embolism).
Androderm patches	5mg daily	5–10mg daily	Testosterone level should be measured in the morning. Skin irritation is common.

* Depo-testosterone is licensed for IM use. It is not licensed for subcutaneous administration in NZ but can be administered this way if preferred, with weekly dosing appearing to be most commonly used.[47]

Low dose testosterone is discussed in FAQ 7.

Table 7: **T-GAHT recommended monitoring**

Investigation	Comment
Full blood count	If the haematocrit > 0.52 reduce the dose of testosterone and/or discuss with an endocrinologist or haematologist.
Liver function tests	
Lipids	
Testosterone	• Aim for usual male reference range for standard doses. • Check 6–12-monthly once patient has been on testosterone for around 6–9 months (it takes time for levels to stabilise initially). • Timing of blood test is dependent on testosterone formulation – see Table 6 above. • If raised, reduce testosterone dose and repeat level in 3 months.

T-GAHT
Starting Protocol

Prior to first prescription	Complete Stages 1–3 in the primary care protocol for starting GAHT. This includes a psychosocial assessment, medical review, baseline blood tests, blood pressure, weight, and informed consent, outlining effects (including permanent changes) and risks of hormones by a knowledgeable healthcare provider. Provide the patient with an information sheet and document consent.
Commence GAHT – first prescription	Depo-testosterone 100mg IM/SC fortnightly (or 50mg SC weekly) *or* Sustanon 125mg (0.5ml) IM every 3 weeks *or* Reandron 500mg IM with 750–1000mg IM at 6 weeks (thereafter 3-monthly) *or* Testosterone patch 5mg daily
3 months after commencing hormones	• Review progress and discuss any issues. • Bloods for complete blood count (monitor haematocrit), liver function, lipids. • Blood pressure. • If no concerns, increase hormones to maintenance therapy. If patient wishes to switch testosterone preparation, the preferred testosterone can be administered at the time the next dose of the previously used testosterone is due. • Plan for testosterone level measurement at the appropriate time (after at least 6 months on GAHT. See Table 6 for timing of blood test).
3-monthly appointments in first year, can be 12-monthly thereafter if stable	At each follow-up visit: • Review progress and discuss any issues or questions. • Check on physical and mental health and social support. • Ensure monitoring is up to date: — Blood pressure 3–6-monthly in first year, thereafter 12-monthly. — Bloods 3–6-monthly in first year, thereafter 12-monthly or as clinically indicated (see Table 7 for details, including timing of testosterone measurements). • Provide education about self-injection if appropriate.

Frequently Asked Questions (FAQs)

1. What if my patient stops taking hormones?

Affirming one's gender is not necessarily a linear process and may take place over a lifetime. Some people experience their gender more fluidly than others and it is common for someone's understanding of, and comfort with, their gender identity and gender expression to evolve throughout their lives. Someone's decision to start GAHT and a later decision to stop GAHT can both be the right decision for them at that stage of their lives. This is not – and should not – be viewed as a mistake or a failure. Similarly, some patients may shift from identifying with a binary gender to non-binary gender (or vice versa), and their goals from their transition may change accordingly. Stories of this nature are common, and often referred to as 'non-linear transitions'. They are simply reflective of the variety of human experience.

Some providers may feel anxious about 'getting it wrong' or worry that their patient may later regret their decision. The informed consent process outlined in this document respects the autonomy of the patient as a competent adult who has the capacity to make their own decisions about their body and health once they have been given the necessary information. Patients accessing GAHT have an equal right to receive support from health professionals and from family/friends/whānau where needed. By working in partnership, this approach seeks to enhance a given patient's understanding of the potential benefits and risks of GAHT. The provider's role is to provide support and information, and to ensure safety by following prescribing and dosing guidelines, monitoring treatment and monitoring for potential risk. As part of a patient-centred approach, the patient should be an active partner in decisions about GAHT based on their own gender embodiment goals, and information provided to them about likely changes to them (both reversible and irreversible) and risks.

We are beginning to understand more about non-linear transitions (sometimes discussed in the context of 'retransition' or 'detransition') and the reasons people's goals, gender identities, gender expressions, or engagement with treatment change. Frequently, people who have stopped affirming their gender (whether temporarily or permanently) do so due to external factors, including pressure from family, discrimination and social stigma.[48] Detransition is not the same as regret. Social connections and support can be a preventative factor by allowing people to be themselves despite external pressures. Trying to ensure that patients have relational support for their decision-making –for example, from family, friends, whānau and health professionals – where this is requested or needed is important. It is essential that healthcare providers are available to support patients with non-linear transitions, and it can be useful to make this support clear when initiating GAHT. If hormones are stopped, it is important to ensure restoration of physiological sex hormone levels to remove risks of longer-term hypogonadism.

2. Can I still prescribe GAHT where there are significant mental health concerns?

Many (but not all) transgender people experience mental health conditions, often due to gender minority stress.[49] This is caused by negative social attitudes, discrimination, prejudice and violence. Discomfort between a person's intrinsic sense of identity, their body and how they are perceived by others also contribute to distress, as can difficulty in accessing gender affirming services (including GAHT) in a timely manner.[50] Symptoms of anxiety, low confidence, depression, anxiety, disordered eating and trauma are common.

Where a patient has severe mental health concerns that meet the criteria for secondary mental health services, then refer them to these services. However, if a patient's mental health concerns *do not* affect their capacity to provide informed consent for GAHT, then you can concurrently commence GAHT. If you are concerned about your patient's capacity to give consent to GAHT due to their mental health, then this may need to be addressed first and onward referral may be recommended (refer to FAQ 4 on diminished capacity below for more detail). If you are unsure, you can seek consultation from secondary services to see if an onward referral would be recommended. If secondary mental health input is not required,

give your patient advice, support, and treatment for mental health as with any other patients.

Gender affirming healthcare may reduce mental distress, so withholding or delaying care unnecessarily is unethical and could worsen a person's mental health. It is important to weigh up the risks and benefits of these decisions, noting that onward referral may at times come with barriers for patients such as long wait times, transport issues or cost. Doing nothing is not a neutral option and can result in harm to your patient. There should always be the option to refer more complex situations to secondary care for input if a GP or NP feels it is outside of their scope or experience.

3. My patient is autistic. Does this impact on their capacity to give informed consent to start GAHT?

It has been consistently shown that transgender or non-binary people are more likely to be autistic than cisgender people, although there is no consensus as to why.[51] Autism is a neurodevelopmental phenomenon that manifests in a wide variety of ways dependent on the individual. Autistic people may have different cognitive, sensory or social processing, and as a result they may see the world and interact with others differently.

Being neurodivergent does not routinely impact on an individual's capacity to give informed consent. However, some autistic people may need more time to provide information about themselves or may need questions to be asked in a different way, so they are able to communicate their gender identity, embodiment goals for GAHT, and/or demonstrate their understanding of the risks and benefits. It is important to recognise these differences and to create an environment where autistic patients are supported to communicate and engage in a way which feels more comfortable to them, to share the cognitive load, increase their overall comfort, and reduce their feelings of stress. Where a patient is not able to provide you with the information you need, or demonstrate understanding, then it is hard for them to show capacity. It is the job of providers to reduce barriers in any way we can to maximise their ability to demonstrate this.

For patients whose social communication difficulties impair their ability to demonstrate their understanding, in a way required to give informed consent, additional support may be required. This could include referral to communication, mental health or Autism support services (if timely access to these services is available locally).

4. When does a patient have diminished capacity to provide consent?

In Aotearoa New Zealand, adult patients have the right to be presumed to have capacity to give informed consent, unless there are reasonable grounds to believe otherwise.[52] Reasons for diminished capacity might include intellectual disability, brain injury or cognitive impairment, e.g. dementia, psychosis and mania. Some people may have capacity but have difficulty in communication and may need support to aid this process.

If a patient can retain information that they need about GAHT (i.e. risks and benefits), demonstrate understanding of how this will affect their lives (e.g. changes to their body, including permanent changes), weigh the information to come to a decision and clearly communicate a decision based on this understanding and reasoning, then they have capacity to give informed consent to GAHT.

Patients without full capacity still have a right to access care in a timely manner and to have a supported role in decision-making for their care, as indicated under Right 7(4) HDC Code of Rights:[52] The usual procedure for this is for the GAHT prescriber to come to a decision that is in the patient's best interest based on:

(1) the patient's views, level of capacity, wishes and assent.

(2) the views of a suitable person suitable person who is interested in the welfare of the patient, such as a caregiver or family member who knows the person well, or a wider circle of people that includes friends and whānau. This may include an enduring power of attorney or a welfare guardian if one is appointed.

(3) the prescriber's and other

health professionals' expertise of the risks and benefits to the patient.[53]

Prescribers should take care to ensure to provide information to patients in a way that is accessible and appropriate to their level of understanding. Referral to a colleague or appropriate secondary service may aid the decision-making process for patients with diminished capacity.

5. What if my patient starting E-GAHT has a heightened risk of thrombosis or cardiovascular disease?

Patients need to be informed that oestrogen increases the risk of thrombosis and cardiovascular disease. Smoking cessation should be strongly supported. However, it would be unethical to withhold E-GAHT on these grounds. Instead, clinicians should discuss both benefits and risks of E-GAHT with their patients and mitigate any increased risk as much as possible.

In someone with risk factors for thrombosis and/or increased cardiovascular risk (e.g. smoking, ischaemic heart disease, migraine with aura, older age) it is recommended:

- To use transdermal rather than oral oestrogen, as evidence suggests the risk of VTE with transdermal use is similar to population risk.[36, 37] It is sensible to use the lowest effective dose.
- Cyproterone at higher or contraceptive doses (Ginet) increases the risk of VTE[41] and is contraindicated in those with a history of thromboembolic disorders.[54] There are insufficient data to be certain as to whether these risks are removed through the use of lower doses (12.5mg daily). Clinicians should consider alternative androgen blockade options (spironolactone or Gosarelin) in those with an increased VTE risk.

6. Do I need to measure prolactin?

Several guidelines recommend measuring prolactin at baseline and during follow-up in those on E-GAHT, but at present there is no compelling evidence to suggest that E-GAHT increases the risk of pathological hyperprolactinaemia outside of cyproterone use at higher than contemporary recommended doses.[55] There is no such recommendation for cisgender women using contraceptive doses of oestrogen, oestrogen for menopausal therapy, or during pregnancy when oestrogen levels would be expected to be similar or higher to those achieved with E-GAHT. Indeed, oestrogen therapy is frequently used in women with known prolactinomas who are intolerant of dopamine agonist therapy. Furthermore, mildly elevated prolactin measurements that are unlikely to be significant are very common, and the routine measurement of prolactin therefore raises the risk of unnecessary further investigations. We suggest clinicians use clinical judgement when determining if prolactin measurements are required.

7. My patient is requesting low-dose testosterone.

Some people, often those who are non-binary, choose to start on lower doses of testosterone (sometimes referred to by patients as 'micro-dosing'). There is a lack of any evidence to guide low-dose hormone regimens. Patients may choose to remain on a low dose long term, or more slowly increase up to standard maintenance doses over time. A more gradual increase may give some control over the speed of onset of the experienced effects, although this is not guaranteed. When obtaining consent, it is essential to inform the patient about all the same effects, including the permanent changes, as standard testosterone dosing, as all of these occur at lower doses.

There is a lack of evidence to support an optimum testosterone level in this context. Testosterone supplementation is indicated in hypogonadal cisgender men to reduce an increased cardiovascular and bone health risk that is otherwise seen. However, there is currently no literature to indicate an absolute testosterone level below established local reference ranges at which this increased risk becomes apparent. Acknowledging this, and the lack of data in the context of T-GAHT, it is not yet possible to define a minimum testosterone

level when using T-GAHT and patients should be aware of this. In practice, many clinicians would recommend a minimum testosterone level of 6–8 nmol/L.

8. My patient is requesting a medication that is either not in these guidelines or not licensed in New Zealand.

In these guidelines, we recommend the use of medications that either have an established evidence base in the use of GAHT, have a long history of use in GAHT, or are widely used in other populations and risk profiles are therefore well understood. These guidelines align with and support many other guidelines in this area. However, overseas practice may differ, and patients may ask about the use of medications not included in these guidelines. The following are frequently encountered enquiries:

T-GAHT

Oral testosterone

Andriol capsules are not licensed in Aotearoa New Zealand for GAHT, and at the time of writing are not funded. Oral testosterone is not used as a first-line option in T-GAHT due to the fluctuation in testosterone levels throughout the day and the need for frequent dosing, as well as being less effective at stopping menstruation.[12] They can be used on a case-by-case basis, particularly in someone who is needle-phobic and is unable to tolerate transdermal testosterone. They should be avoided if liver disease is present[54] and LFTs should be monitored as with other testosterone regimes. If this option is used, Andriol can be started at 40mg daily and be increased up to 120mg daily in 2 divided doses. When measured, testosterone levels should be checked prior to the morning dose.

E-GAHT

Progesterone

Progesterone is occasionally prescribed as part of gender affirming care. Anecdotally, some people who take E-GAHT have reported benefits of using progesterone on breast development, sleep, mood, and other physical changes. Micronised progesterone (utrogestan) is prescribed for menopausal hormone therapy in many cisgender women and is now funded in Aotearoa New Zealand.

However, there are no current high-quality data to indicate any effect of progesterone for gender affirmation,[56, 57] and no data on safety. It is therefore not included in the majority of international guidelines for gender affirming hormone therapy.[2, 3, 10, 32] Authors of the WPATH SOC-8 attempted to complete a systematic review on this issue but failed to identify enough data to make any recommendations for or against the use of any progesterone in this context, and noted 'existing data suggest harm is associated with extended progestin exposure'.[2] Progesterone treatment in other contexts is associated with weight gain, mood disturbance, fatigue, an increased risk of breast cancer, and venous thromboembolism (VTE).[2, 58] It is not clear how generalisable the data from cisgender women is to transgender populations, who tend to be younger and less likely to use equine oestrogen.[2, 59] Utrogestan is likely to have a lower risk of side effects than older progesterones,[60, 61] and emerging evidence suggests a lower associated risk of breast cancer. Further studies in cisgender and transgender people are required however to confirm this.

This guideline is therefore unable to make a recommendation for or against progesterone use in GAHT at this stage, and we await the outcome of research trials designed to address these questions with interest.

Clinicians may be asked to prescribe progesterone as part of E-GAHT. This should prompt a discussion about expectations and outcomes, potential risk, and current evidence. This discussion may reveal other ways in which doses of existing medications can be adjusted to support your patient's gender embodiment goals. Prescribing decisions ultimately rest with the clinician, but patient autonomy, gender embodiment goals and self-determination for patient choice should be considered and respected.

Anti-androgens

There are no high-quality data to indicate that the use of any particular anti-androgen is superior to any other. We support the use

of spironolactone or cyproterone as both have been used widely in E-GAHT for several decades, and experience with both medications is now extensive in both transgender and other populations. Both are funded for use in GAHT. Cyproterone is associated with an increased risk of liver dysfunction, VTE[41] and meningioma,[38, 39] however, and the lowest effective dose (12.5mg daily or on alternate days) should be used if this is chosen. GnRH agonists (Goserelin) are licensed for use in GAHT and are an option if oral options are not tolerated, with the available evidence suggesting a comparable effect.[62]

Flutamide is recommended by some overseas guidelines on E-GAHT, but is associated with hepatotoxicity, and its use is recommended against by many guidelines on the management of hirsutism in cisgender women for this reason.[63] 5α-inhibitors (often termed dihydrotestosterone blockers) are less effective than other anti-androgens but are occasionally used to reduce androgenic hair loss. Bicalutamide is a potent anti-androgen but is associated with hepatotoxicity and reported cases of fulminant hepatitis.[64] While there remains a lack of any evidence to indicate superiority of Flutamide, 5α-inhibitors or Bicalutamide as anti-androgens in E-GAHT, we recommend against their use because of likely increased treatment risks.[62]

Oestrogen

The goal of GAHT is to provide physiological hormone levels. To achieve this with E-GAHT, oestrogen must be administered, and testosterone must be blocked or lowered, and neither approach is effective in isolation. Unfortunately, many of the physical effects of having progressed through a testosterone-based puberty are not reversed through hormonal therapy alone, and the effect of E-GAHT commenced beyond this age may therefore be less than optimal.

— Higher doses of oestrogen

There is currently no evidence to suggest that a dose of oestrogen higher than 200mcg/24 hours via patch or 6mg daily orally is helpful, and, indeed, poor evidence to suggest any strong correlation between oestrogen doses at recommended levels and outcomes at all.[65] The recommended upper limits of oestrogen dosing in these guidelines align with SOC-8 and the Endocrine Society.[2, 32] While some guidelines recommend a target oestrogen level, there are few available data to definitively specify any target range, and those guidelines that do incorporate such a target generally acknowledge this.

— Oestrogen use without anti-androgen therapy

Some patients advocate for the use of oestrogen therapy alone at higher doses to suppress testosterone production in lieu of additional anti-androgen therapy. By definition, however, this requires the use of oestrogen at supraphysiological levels, with high circulating levels of oestrogen required to suppress pituitary gonadotrophin output and therefore lower testosterone levels to the desired target. There is no evidence to suggest this approach results in improved physical outcomes, and, while there is little evidence specifically on this approach, the use of oestrogen at higher than physiological levels is likely to increase the risks associated with oestrogen use.[65] Aligning with most guidelines on this subject,[32] we therefore recommend against this approach.

— Intramuscular oestrogen

Some international guidelines include IM oestrogen alongside oral and transdermal options,[10, 32] but it is neither licensed nor funded in Aotearoa New Zealand. There is no evidence to suggest that IM oestrogen is any more effective than transdermal oestrogen, and both are likely to be associated with a lower risk of liver dysfunction than oral oestrogen. It is unclear whether the VTE risk may also be lower than seen with oral oestrogen. However, in contrast to transdermal oestrogen, significant variation in oestrogen levels is noted with IM oestrogen, with levels far in excess of those recommended by most guidelines often seen shortly after administration in particular.[32] There are no high-quality data to advise on whether this may increase oestrogen-related risks. There is little guidance on monitoring levels in patients on intramuscular oestrogen as part of GAHT but dosing guidance can be found in the Endocrine Society guidelines.[32]

References

1. Leva. Rainbow/LGBTQI [Internet]. 2022. Available from: https://www.leva.co.nz/our-work/suicide-prevention/finding-help/support-services/rainbow.
2. Coleman E, Radix AE, Bouman WP, Brown GR, de Vries ALC, Deutsch MB, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. International Journal of Transgender Health. 2022;23(sup1):S1-S259.
3. Oliphant J, Veale J, Macdonald J, Carroll R, Johnson R, Harte M, et al. Guidelines for gender affirming healthcare for gender diverse and transgender children, young people and adults in Aotearoa New Zealand: Transgender Health Research Lab; 2018.
4. Durie M, editor Te Pae Māhutonga: A model for Māori health promotion. Health Promotion Forum of New Zealand Newsletter; 1999.
5. Durie M. Whaiora: Maōri health development: Oxford University Press; 1998.
6. van Leerdam TR, Zajac JD, Cheung AS. The Effect of Gender-Affirming Hormones on Gender Dysphoria, Quality of Life, and Psychological Functioning in Transgender Individuals: A Systematic Review. Transgender Health. 2021.
7. Delahunt JW, Denison HJ, Sim DA, Bullock JJ, Krebs JD. Increasing rates of people identifying as transgender presenting to Endocrine Services in the Wellington region. NZ Med J. 2018;131(1468):33-42.
8. Veale J, Byrne J, Tan KK, Guy S, Yee A, Nopera TM-L, et al. Counting ourselves: the health and wellbeing of trans and non-binary people in Aotearoa New Zealand: Transgender Health Research Lab; 2019.
9. Deutsch MB. Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People; 2nd edition [Internet]. June 2016. Available from: transcare.ucsf.edu/guidelines.
10. Radix A, Meacher P, Vavasis A, Mukerjee R, Weiss S, Widoff J, et al. Protocols for the provision of hormone therapy. [Internet]. Available from: http://callen-lorde.org/graphics/2018/05/Callen-Lorde-TGNC-Hormone-Therapy-Protocols-2018.pdf: Callen-Lorde; 2014.
11. Cundill P, Brownhill A, Locke P. Protocols for the Initiation of Hormone Therapy for Trans and Gender Diverse Patients. Equinox Gender Diverse Health Centre. [Internet]. June 2020. Available from: https://equinoxdotorgdotau.files.wordpress.com/2021/07/protocol-for-the-initiation-of-hormone-therapy-v2-aug-2020.pdf.
12. Coleman E, Bockting W, Botzer M, Cohen-Kettenis P, DeCuypere G, Feldman J, et al. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, version 7. International journal of transgenderism. 2012;13(4):165-232.
13. Trans Care BC. Gender-affirming Care for Trans, Two-Spirit,and Gender Diverse Patients in BC: A Primary Care Toolkit. [Internet]. August 2021. Available from: www.phsa.ca/transcarebc/Documents/HealthProf/Primary-Care-Toolkit.pdf.
14. Fraser G, Brady A, Wilson M. “What if I’m not trans enough? What if I’m not man enough?”: Transgender young adults’ experiences of gender-affirming healthcare readiness assessments in Aotearoa New Zealand. International Journal of Transgender Health. 2021:1-14.
15. World Health Organization. International Classification of Diseases 11th Revision. [Internet]. 2018. Available from: https://icd.who.int/en.
16. Clark TC, Lucassen MF, Bullen P, Denny SJ, Fleming TM, Robinson EM, et al. The health and well-being of transgender high school students: results from the New Zealand adolescent health survey (Youth'12). Journal of Adolescent Health. 2014;55(1):93-9.

17. Tan KK, Ellis SJ, Schmidt JM, Byrne JL, Veale JF. Mental health inequities among transgender people in Aotearoa New Zealand: findings from the Counting Ourselves Survey. International journal of environmental research and public health. 2020;17(8):2862.

18. Tan KK, Treharne GJ, Ellis SJ, Schmidt JM, Veale JF. Enacted stigma experiences and protective factors are strongly associated with mental health outcomes of transgender people in Aotearoa/New Zealand. International Journal of Transgender Health. 2021;22(3):269-80.

19. Transhub. Informed consent. [Internet]. 2021. Available from: www.transhub.org.au/informed-consent.

20. Medical council of new zealand. Informed consent: helping patients make informed decisions about their care. [Internet]. 2021, June. Available from: www.mcnz.org.nz/assets/standards/55f15c65af/Statement-on-informed-consent.pdf.

21. Beauchamp TL, Childress JF. Principles of Biomedical Ethics. 8th: 230–42. New York, NY: Oxford University Press; 2019.

22. Medical Protection Society. Cole's Medical Practice in New Zealand: MCNZ; 2021.

23. 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. Journal of the Endocrine Society. 2021;5(4):bvab011.

24. Plesner E EM. Performing capacity assessments, information for GPs HealthNZ. [Internet]. Available from: http://www.ourhealthhb.nz/assets/Publications/Performing-Capacity-Assessments-electronic-book.pdf.

25. World Health Organization. International Classification of Diseases 11th Revision. [Internet]. 2018. Available from: https://icd.who.int/en.

26. Starship clinical guidelines. Adolescent Consultation and the HEeADSSS Assessment: Starship Child Health. [Internet]. 2022. Available from: https://starship.org.nz/guidelines/adolescent-consultation.

27. De Roo C, Tilleman K, T'Sjoen G, De Sutter P. Fertility options in transgender people. International Review of Psychiatry. 2016;28(1):112-9.

28. De Roo C, Lierman S, Tilleman K, Peynshaert K, Braeckmans K, Caanen M, et al. Ovarian tissue cryopreservation in female-to-male transgender people: insights into ovarian histology and physiology after prolonged androgen treatment. Reproductive biomedicine online. 2017;34(6):557-66.

29. Leung A, Sakkas D, Pang S, Thornton K, Resetkova N. Assisted reproductive technology outcomes in female-to-male transgender patients compared with cisgender patients: a new frontier in reproductive medicine. Fertility and Sterility. 2019;112(5):858-65.

30. Borrás A, Manau MD, Fabregues F, Casals G, Saco A, Halperin I, et al. Endocrinological and ovarian histological investigations in assigned female at birth transgender people undergoing testosterone therapy. Reproductive BioMedicine Online. 2021;43(2):289-97.

31. Meyer G, Mayer M, Mondorf A, Flügel AK, Herrmann E, Bojunga J. Safety and rapid efficacy of guideline-based gender-affirming hormone therapy: an analysis of 388 individuals diagnosed with gender dysphoria. European Journal of Endocrinology. 2020;182(2):149-56.

32. Hembree WC, Cohen-Kettenis PT, Gooren L, Hannema SE, Meyer WJ, Murad MH, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: an endocrine society clinical practice guideline. The Journal of Clinical Endocrinology & Metabolism. 2017;102(11):3869-903.

33. Grimstad FW, Boskey E, Grey M. New-onset abdominopelvic pain after initiation of testosterone therapy among trans-masculine persons: a community-based exploratory survey. LGBT health. 2020;7(5):248-53.

34. Zwickl S, Burchill L, Wong AFQ, Leemaqz S, Cook T, Angus L, et al. Pelvic pain in transgender people using testosterone therapy: A national survey. Authorea Preprints. 2022.

35. Walker RF, Zakai NA, MacLehose RF, Cowan LT, Adam TJ, Alonso A, et al. Association of testosterone therapy with risk of venous thromboembolism among men with and without hypogonadism. JAMA internal medicine. 2020;180(2):190-7.

36. Canonico M, Oger E, Plu-Bureau G, Conard J, Meyer G, Lévesque H, et al. Hormone therapy and venous thromboembolism among postmenopausal women: impact of the route of estrogen administration and progestogens: the ESTHER study. Circulation. 2007;115(7):840-5.

37. Sweetland S, Beral V, Balkwill A, Liu B, Benson VS, Canonico M, et al. Venous thromboembolism risk in relation to use of different types of postmenopausal hormone therapy in a large prospective study. Journal of Thrombosis and Haemostasis. 2012;10(11):2277-86.

38. Millward CP, Keshwara SM, Islim AI, Jenkinson MD, Alalade AF, Gilkes CE. Development and Growth of Intracranial Meningiomas in Transgender Women Taking Cyproterone Acetate as Gender-Affirming Progestogen Therapy: A Systematic Review. Transgender Health. 2021.

39. Gil M, Oliva B, Timoner J, Maciá MA, Bryant V, de Abajo FJ. Risk of meningioma among users of high doses of cyproterone acetate as compared with the general population: evidence from a population-based cohort study. British journal of clinical pharmacology. 2011;72(6):965-8.

40. Nota NM, Wiepjes CM, De Blok CJ, Gooren LJ, Peerdeman SM, Kreukels BP, et al. The occurrence of benign brain tumours in transgender individuals during cross-sex hormone treatment. Brain. 2018;141(7):2047-54.

41. Dragoman MV, Tepper NK, Fu R, Curtis KM, Chou R, Gaffield ME. A systematic review and meta-analysis of venous thrombosis risk among users of combined oral contraception. International Journal of Gynaecology and Obstetrics. 2018;141(3):287.

42. Rodriguez-Wallberg K, Häljestig J, Arver S, Johansson AL, Lundberg FE. Sperm quality in transgender women before or after gender affirming hormone therapy-A prospective cohort study. Andrology. 2021.

43. de Blok CJM, Klaver M, Wiepjes CM, Nota NM, Heijboer AC, Fisher AD, et al. Breast development in transwomen after 1 year of cross-sex hormone therapy: results of a prospective multicenter study. The Journal of Clinical Endocrinology & Metabolism. 2018;103(2):532-8.

44. Van De Grift TC, Elaut E, Cerwenka SC, Cohen-Kettenis PT, De Cuypere G, Richter-Appelt H, et al. Effects of medical interventions on gender dysphoria and body image: a follow-up study. Psychosomatic medicine. 2017;79(7):815.

45. New Zealand Medicines and Medical Devices Safety Authority. Use of Unapproved Medicines and Unapproved Use of Medicines: Medsafe. [Internet]. 2020. Available from: www.medsafe.govt.nz/profs/riss/unapp.asp.

46. Best Practice Advocacy Centre New Zealand. Upfront: Unapproved medicines and unapproved uses of medicines: keeping prescribers and patients safe. [Internet]. 2013. Available from: https://bpac.org.nz/bpj/2013/march/unapproved-medicines.aspx.

47. Figueiredo MG, Gagliano-Jucá T, Basaria S. Testosterone Therapy With Subcutaneous Injections: A Safe, Practical, and Reasonable Option. The Journal of Clinical Endocrinology & Metabolism. 2022;107(3):614-26.

48. 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.

49. Tan KK, Schmidt JM, Ellis SJ, Veale JF, Byrne JL. 'It's how the world around you treats you for being trans': mental health and wellbeing of transgender people in Aotearoa New Zealand. Psychology & Sexuality. 2021:1-13.

50. Bauer GR, Scheim AI, Pyne J, Travers R, Hammond R. Intervenable factors associated with suicide risk in transgender persons: a respondent driven sampling study in Ontario, Canada. BMC public health. 2015;15(1):1-15.

51. Warrier V, Greenberg DM, Weir E, Buckingham C, Smith P, Lai M-C, et al. Elevated rates of autism, other neurodevelopmental and psychiatric diagnoses, and autistic traits in transgender and gender-diverse individuals. Nature communications. 2020;11(1):1-12.

52. Health and Disability Commissioner. Code of Health and Disability Services Consumers' Rights HDC. [Internet]. 1996. Available from: www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights.

53. Grimstad F, Boskey E. How should decision-sharing roles be considered in adolescent gender surgeries? AMA Journal of Ethics. 2020;22(5):452-7.

54. The New Zealand formulary: NZF. [Internet]. 2022. Available from: https://nzformulary.org

55. Bisson JR, Chan KJ, Safer JD. Prolactin levels do not rise among transgender women treated with estradiol and spironolactone. Endocrine Practice. 2018;24(7):646-51.

56. Nolan BJ, Frydman AS, Leemaqz SY, Carroll M, Grossmann M, Zajac JD, et al. Effects of low-dose oral micronised progesterone on sleep, psychological distress, and breast development in transgender individuals undergoing feminising hormone therapy: a prospective controlled study. Endocrine Connections. 2022;11(5).

57. Wierckx K, Gooren L, T'Sjoen G. Clinical review: breast development in trans women receiving cross-sex hormones. The journal of sexual medicine. 2014;11(5):1240-7.

58. Skovlund CW, Mørch LS, Kessing LV, Lidegaard Ø. Association of hormonal contraception with depression. JAMA psychiatry. 2016;73(11):1154-62.

59. Iwamoto SJ, T'Sjoen G, Safer JD, Davidge-Pitts CJ, Wierman ME, Glodowski MB, et al. Letter to the Editor:"Progesterone Is Important for Transgender Women's Therapy—Applying Evidence for the Benefits of Progesterone in Ciswomen". The Journal of Clinical Endocrinology & Metabolism. 2019;104(8):3127-8.

60. Chlebowski RT, Hendrix SL, Langer RD, Stefanick ML, Gass M, Lane D, et al. Influence of estrogen plus progestin on breast cancer and mammography in healthy postmenopausal women: the Women's Health Initiative Randomized Trial. Jama. 2003;289(24):3243-53.

61. Barsoum MK, Heit JA, Ashrani AA, Leibson CL, Petterson TM, Bailey KR. Is progestin an independent risk factor for incident venous thromboembolism? A population-based case-control study. Thrombosis research. 2010;126(5):373-8.

62. Glintborg D, T'Sjoen G, Ravn P, Andersen MS. Management of endocrine disease: Optimal feminizing hormone treatment in transgender people. European journal of endocrinology. 2021;185(2):R49-R63.

63. Javier B, Magdalena B, Roberto S, Ricardo L, Rodrigo Z, Jaime P, et al. Acute and fulminant hepatitis induced by flutamide: case series report and review of the literature. Annals of hepatology. 2011;10(1):93-8.

64. O'Bryant CL, Flaig TW, Utz KJ. Bicalutamide-Associated Fulminant Hepatotoxicity. Pharmacotherapy: The Journal of Human Pharmacology and Drug Therapy. 2008;28(8):1071-5.

65. Moore E, Wisniewski A, Dobs A. Endocrine treatment of transsexual people: a review of treatment regimens, outcomes, and adverse effects. The Journal of Clinical Endocrinology & Metabolism. 2003;88(8):3467-73.

Appendix A:

WPATH SOC-8 hormone criteria and ICD-11 gender incongruence

The statements below outline a summary of the SOC-8 criteria for GAHT. However, there are a lot of nuances around each point, which are discussed in more depth in the full SOC-8 document, which can be found here: Standards of Care for the Health of Transgender and Gender Diverse People, Version 8

SOC-8 Summary Criteria for hormonal treatment for adults and adolescents[2]

- Gender incongruence is marked and sustained;
- Meets diagnostic criteria for gender incongruence prior to gender-affirming hormone treatment in regions where a diagnosis is necessary to access health care;
- Demonstrates capacity to consent for the specific gender-affirming hormone treatment;
- Other possible causes of apparent gender incongruence have been identified and excluded;
- Mental health and physical conditions that could negatively impact the outcome of treatment have been assessed, with risks and benefits discussed;
- Understands the effect of gender-affirming hormone treatment on reproduction and they have explored reproductive options.

ICD-11 description of Gender Incongruence[25]

Gender Incongruence of Adolescence and Adulthood is characterised by a marked and persistent incongruence between an individual´s experienced gender and the assigned sex, which often leads to a desire to 'transition', in order to live and be accepted as a person of the experienced gender, through hormonal treatment, surgery or other health care services to make the individual´s body align, as much as desired and to the extent possible, with the experienced gender. The diagnosis cannot be assigned prior to the onset of puberty. Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis.

Appendix B:

Sample questions for gender history and embodiment goals

- How would you describe your gender?
- How did you come to learn your gender as it is now?
- What steps have you taken to feel more comfortable in your gender? For example, changed your name or pronouns, dressing differently? How does that feel for you?
- Are you hoping to take any other steps in your transition? What are your current goals? How would you like to embody your gender?
  - *Thank you for sharing that with me. I'm going to make a note of your goals – please let me know if these goals ever change so I can continue to recommend the best care for you.*
- Have you thought about how you will manage a change in appearance at school/work/study/home?
- Who is/are your support/s with this process?
- Have you talked to anyone about your gender identity and your plans to affirm your gender through medical treatment?

  (Of course, there is no requirement for a person to discuss this with others, but this question can help to identify support – or lack of it – and thereby facilitate conversations around this. For example, if a younger person hasn't got parental support, it might be worth having a conversation about how they plan to approach this when there are noticeable physical changes. Family support is important and if not available then other supports should be identified.)
- When did you start thinking about taking hormone therapy?
- What do you think will be the main benefits of hormone therapy? What are you looking forward to?
- Think about your body as it is right now:
  - What would you like to stay the same?
  - What would you like to change?
- How do you imagine your life will change if you start hormone treatment?
- Are there any changes that you are not sure about?
- Do you foresee any concerns or challenges?
- Are you aware of the impacts of hormones on your fertility/ability to have children in the future? Would you consider a referral to a fertility service to store gametes?
  - *Lots of people find it quite difficult to think about how our fertility might affect us in the future, so I'd really encourage you to take your time when you're thinking about this. You don't have to answer now but we should talk about this again before you start hormones.*
- Some people find it useful to have the support of a peer support worker or talk therapist to help with decisions or support. Would you like a referral to a talk therapist with experience around this?
- Some people change their minds about taking hormones, often because of family or society pressures. Have you thought about this at all? (You can emphasise that this does not worry you and encourage them to talk to you, let them know that you are available for support whatever decisions they make in the future.)

Appendix C:

Examples of Practice Management System shortcuts

These can be added to your practice management system (PMS) to use as personal shortcuts to save time when writing your notes.

Capacity

Patient has the capacity to provide informed consent to start gender affirming hormone therapy.

WPATHSOC-8

Patient meets the criteria for hormonal treatment from the WPATH Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (SOC-8).

T-GAHT

We have discussed the information on the consent form and patient information sheet, and I have provided copies of both. Discussed effects of hormones, time taken to see changes, which changes are permanent, risks, side effects, medication options and monitoring, cervical screening, and importance of not getting pregnant on testosterone and need for contraception even if periods have stopped. Discussed potential impact on future fertility including that testosterone needs to be stopped if wishing to conceive and that egg harvesting may be required to achieve a pregnancy.

E-GAHT

We have discussed the information on the consent form and patient information sheet, and I have provided copies of both. Discussed effects of hormones, time taken to see changes, which changes are permanent, risks, side effects, medication options and monitoring.
I have explained that GAHT does not change voice, bone structure or Adam's apple.
Discussed permanent effect on loss of fertility and fertility preservation has been offered.

Appendix D:

Checklists which can be used prior to first GAHT prescription

T-GAHT Checklist

- ☒ Discussed gender embodiment goals and expectations of GAHT
- ☒ PMH, DH, FH, SH, HEeADSSS
- ☒ MH review – offer support options as needed
- ☒ Check on family/community support
- ☒ Fertility/reproductive options discussed
- ☒ Information on consent form and info sheet explained and copy provided to patient
- ☒ Offered menstrual cessation options
- ☒ Discussed contraception
- ☒ Discussed cervical screening and set recall
- ☒ Baseline bloods (FBC, LFT, LH, FSH, oestrogen, testosterone, lipids and consider HbA1c & Beta hCG)
- ☒ Baseline BP & Wt
- ☒ Document capacity to provide informed consent and whether they meet the SOC-8 criteria for hormone treatment
- ☒ Consent form signed (if using)
- ☒ Arrange for nurse appointment for injection, GP appointment for follow-up in 3 months and set recall for 3–6-monthly bloods and plan to measure testosterone after 6–9 months

E-GAHT Checklist

- ☒ Discussed gender embodiment goals and expectations of GAHT
- ☒ PMH, DH, FH, SH, HEeADSSS
- ☒ MH review – offer support options as needed
- ☒ Check on family/community support
- ☒ Discuss likely infertility and offer fertility preservation
- ☒ Information on consent form and info sheet explained and copy provided to patient
- ☒ Discussed – voice therapy, other supports
- ☒ Baseline bloods (LFT, lipids, electrolytes, LH, FSH, testosterone, oestrogen, consider HbA1c & HIV, syphilis, hep B & C if preserving fertility)
- ☒ Baseline BP & Wt
- ☒ Document capacity to provide informed consent and whether they meet the SOC-8 criteria for hormone treatment
- ☒ Consent form signed (if using)
- ☒ Arrange for follow-up in 3 months and set recall for 3–6-monthly bloods

Appendix E:

Patient information sheets

Oestrogen-based gender affirming hormone therapy

The person prescribing your hormones should go through and discuss all of this information with you. If you have any questions or anything is unclear, please discuss this with your health provider.

Which medications are used?

Two medications are used as part of oestrogen-based hormone therapy:

- Oestrogen to provide the hormone oestrogen.
- Testosterone blockers (or anti-androgens) are given alongside this to block the hormone testosterone. If you have an orchiectomy (removal of external gonads or testicles) this medication is no longer needed.

Oestrogen comes in tablets or patches. There is no evidence of a difference in feminising outcomes or effects between these, so you can choose which you prefer, in discussion with your prescriber and taking into account your medical history. Patches are likely to carry a lower risk of blood clots. Taking high doses does not cause changes to happen more quickly and can put your health at risk. There is no evidence to support higher doses or regimes outside of standard guidelines.

Oestrogen tablets are taken every day. Oestrogen patches are applied to the lower abdomen and changed twice a week.

Testosterone blocker options are spironolactone or cyproterone. Both are a tablet taken every day or every other day. There is no evidence of a difference in feminising effects between these.

Spironolactone is a blood pressure tablet at low doses but works as an anti-androgen at higher doses. It will not suppress testosterone levels but will block the effects of testosterone in the body, promoting breast growth and slowing down body hair. Side effects can be low blood pressure, dizziness and passing urine more often.

Cyproterone in very small doses (12.5mg daily or less) will suppress testosterone but it does not suit everyone. Side effects can include fatigue/tiredness and low mood. Shortness of breath is an uncommon side effect but is possible. Larger does have been associated with liver function abnormalities and with a benign brain tumour called a meningioma, but this is thought to be related to long-term use of doses greater than 25mg daily. Evidence in other areas of healthcare shows the risk of blood clots is increased with cyproterone use.

These hormones are fully funded by PHARMAC, which means they cost the same as other routine prescriptions.

What blood tests do I need?

A baseline blood test is often performed before starting hormone therapy, then ongoing monitoring blood tests are usually 3–6-monthly for the first year and 6–12-monthly thereafter (or as agreed with your healthcare provider). You will usually also need to have your blood pressure and weight checked every year.

The blood test will check your liver function and cholesterol levels, as well as monitoring hormone levels. If you are taking spironolactone your potassium level will be monitored.

When taking spironolactone, the testosterone level measured in your blood test may remain raised, as spironolactone mostly acts to blocks testosterone's effect on the tissues in the body, rather than reducing the release of testosterone. For this reason, there is no need to check testosterone levels on a blood test if you are taking spironolactone.

Oestrogen levels are only checked to ensure levels are not too high as this can lead to health risks. Oestrogen levels do not correlate well with physical effects or reported satisfaction, and there isn't enough evidence to suggest a target range. Instead your oestrogen dose will be adjusted in line with standard dose ranges and your experiences of the effects.

Expected effects

Effects are gradual and timing varies, but it can take years for the full effects to be seen. The effects are largely dependent on genetics and the age you start hormones, rather than the dose or type of medication you take. It is important to have realistic expectations about the effects of hormones. The table below outlines the expected timing of the effects, and this link shows the expected effects in a picture: Effects and expected time course of hormone therapy consisting of an anti-androgen and oestrogen

The following changes are permanent (these will not reverse if you stop taking hormones):

- Breast growth – breast growth is gradual over 2–3 years. Most people starting oestrogen-based hormone therapy after puberty can expect to develop an A cup or smaller. As with all people who develop breasts, these vary in size and shape.
- Loss of fertility – your external gonads (testicles) may shrink and eventually stop producing sperm. This may lead to a permanent loss of fertility. Fertility preservation is usually available free of charge. Your GP or nurse practitioner can refer you for this before you start hormones.

The following changes are not permanent (these may reverse if you stop hormones):

- Softer skin
- Decreased muscle mass and strength
- Less body hair – decreases in thickness and grows more slowly but it doesn't go away completely. Some people choose electrolysis or laser treatment for a more permanent solution.
- Redistribution of fat (more on hips, bum, thighs)

Things that don't change:

- Facial hair growth slows down but doesn't stop completely.
- Voice stays the same (voice therapy may be available in your region).
- Bone structure of your face and Adam's apple doesn't change.

Effect of oestrogen	Expected onset	Expected maximum effect	Reversibility
Redistribution of body fat	3–6 months	2–3 years	Likely
Decrease in muscle mass and strength	3–6 months	1–2 years	Likely
Softening of skin/decreased oiliness	3–6 months	Unknown	Likely
Decreased sexual desire	1–3 months	3–6 months	Likely
Decreased spontaneous erections	1–3 months	3–6 months	Likely
Breast growth	3–6 months	2–3 years	Not possible
Decreased testicular volume	3–6 months	2–3 years	Unknown
Decreased sperm production	Unknown	>3 years	Unknown
Thinning and slowed growth of body and facial hair	6–12 months	>3 years[a]	Possible
Male pattern baldness	Variable	[b]	
Voice changes	None	[c]	

[a] Complete removal of hair requires laser treatment.
[b] Depending on your family history, balding may occur if oestrogens are stopped.
[c] Treatment by speech-language therapists for voice training is most effective.

(Reproduced with permission from the *Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa, New Zealand*)

Sex

A baseline blood test is often performed Your sex drive is likely to be lower. You will soon notice that you get hardening or stiffening of your erectile tissue (erections) less often and when this does occur, it may be more difficult to sustain. If this is causing issues with sex, you can ask your GP for medication to help this. Lowering the dose of your testosterone blocker may also help. Your external gonads (testicles) will usually shrink to less than half of their original size. Although your sperm count is likely to be lowered (see below), it isn't always, and so if you have sex with someone who is able to become pregnant, you should use contraception.

Fertility

The impact on fertility is unclear but it is safest to assume that within a few months of starting oestrogen-based hormone therapy you could permanently and irreversibly lose the ability to create sperm. Fertility preservation is usually fully funded and your GP or nurse practitioner can refer you for this.

Side effects and risks

- Common side effects include breast tenderness and weight gain. Nausea and headaches can occur when starting oestrogen and usually settle in the first few days or weeks.
- Please tell your healthcare provider if you develop migraine headaches.
- Full medical effects and long-term safety are not known. For most people, benefits outweigh risks, but it depends on other risk factors you may have (such as family history, body size, smoking and blood pressure level).
- There is a small increased risk of liver problems and raised cholesterol (these are both monitored on the blood tests).
- There is an increased risk of blood clots. Using oestrogen patches instead of tablets reduces this risk.
- Risk of health problems are higher if you smoke or are overweight or are over the age of 45 years.
- There may be a slight increased risk of breast cancer compared with cisgender men.

Emotional health

You may feel more emotional. It is not known exactly how hormones will impact your mental health and this varies between individuals. It is a bit like going through a second puberty, so you may experience a rollercoaster of emotions, or you may notice no change. Some people experience mood swings or a worsening of anxiety or depression. You may prefer to start the hormones when you have an upcoming period without big life stressors. We know that gender affirmation can also be a stressful time and many people benefit from extra support through this. Please discuss this with your health provider who can give you options for counselling or peer support. Many people find it very helpful to talk to someone who understands gender affirmation, and it can be helpful to explore concerns around coming out (disclosure), stress with family, social and internalised transphobia, anxiety, uncertainty, acceptance etc. You can find details about support options here:

Gender diversity support services – Health Navigator

Rainbow organisations – Te Ngākau Kahukura

Cancer screening

Breasts – breast screening (mammograms) from the age of 45 years as per national screening guidelines is recommended for anyone with breasts. This is a free service. You can find out more about breast screening and mammograms here: Breast screening – Time to Screen

Prostate – the prostate is a small gland which surrounds the opening of the bladder. If you have a prostate gland it is possible to develop cancer in this. Prostate cancer is most common over the age of 50 years. If you develop trouble with peeing, such as poor flow, dribbling, trouble starting or stopping peeing, peeing more often or blood in your pee, you should speak to your health provider.

Appendix E:

Patient information sheets

Testosterone-based gender affirming hormone therapy

The person prescribing your hormones should go through and discuss all of this information with you. If you have any questions or anything is unclear, please discuss this with your health provider.

Testosterone

Testosterone comes in injections and patches. The most common form is injectable testosterone, as patches commonly cause skin irritation. These hormones are fully funded by PHARMAC, which means they cost the same as other routine prescriptions. There is no evidence of any difference in outcomes or effects between the different forms of testosterone.

There are three forms of injectable testosterone:

- Depo-testosterone is given every 2 weeks.
- Sustanon is given every 3 weeks.
- Reandron is given approximately every 3 months.

Depo-testosterone and Sustanon can be self-injected at home if you wish to do so (but can also be given in clinic by a nurse). The nurse can teach you how to safely self-inject if this is your preferred option. You can also find useful information about this here: Transgender health injection guide

Reandron must be given by a health professional, and you will be seen in clinic for these injections.

Monitoring

Monitoring blood tests are usually needed before starting hormone therapy, then usually 3–6-monthly for the first year and 6–12-monthly thereafter (or as agreed with your healthcare provider). You will usually need to have your blood pressure and weight checked every year. The blood test will check your liver function and cholesterol levels, as well as monitoring hormone levels.

While most monitoring is started at baseline and then 3-monthly, the exception to this is your testosterone level. It takes time for this to stabilise, so it is not usually measured until 9–12 months after starting testosterone. When having a blood test for testosterone, the timing of your blood test is important and depends on which formulation of testosterone you are on:

- Depo-testosterone and Sustanon – check testosterone level mid-way between injections.
- Reandron – check testosterone level just before next injection.

Expected effects

Everyone is different in how quickly they respond to testosterone, but you will start to notice changes in your body gradually over the first few months (see table below). It takes years for the full effects to be seen. This link shows this in a picture: Effects and expected time course of testosterone hormone therapy

The following changes are permanent (these will not reverse if you decide to stop taking testosterone):

- Deeper voice (this can start with a scratchy feeling in the throat)
- Increased hair growth on your body (chest, back, arms)
- Facial hair (the amount varies from person to person)
- Hair loss at temples, possibly becoming bald with time depending on your age and family history.
- Genital changes: Erectile tissue (clitoris) growth around 1–3cm. This can feel uncomfortable or even painful initially.

The following changes are not permanent (these may reverse if you stop testosterone):

- Skin oiliness and acne (acne is usually worst in the first year then gradually improves. You can discuss acne medications with your health provider if needed.)
- Redistribution of body fat (less fat on hips, bum and thighs)
- Increased muscle mass and upper body strength
- Increased sex drive
- Monthly bleeding (periods) usually stops after 1–6 months (for most people but not all. Your prescriber can give you medication to stop monthly bleeding in the meantime if you need this.) Please let us know if you experience any bleeding after your monthly bleeding has stopped.

Effect of testosterone	Expected onset	Expected maximum effect	Reversibility
Skin oiliness/acne	1–6 months	1–2 years	Likely
Facial body/hair growth	6–12 months	4–5 years	Unlikely
Scalp hair loss	6–12 months[a]	Variable	Unlikely
Increased muscle mass/strength	6–12 months	2–5 years	Likely
Redistribution of body fat	1–6 months	2–5 years	Likely
Cessation of periods	1–6 months		Likely
Clitoral enlargement	1–6 months	1–2 years	Unlikely
Vaginal atrophy	1–6 months	1–2 years	Unlikely
Deepening of the voice	6–12 months	Variable	Not possible
Increased sexual desire	Variable	Variable	Likely

[a] Highly dependent on age and inheritance; may be minimal.

(Reproduced with permission from the *Guidelines for Gender Affirming Healthcare for Gender Diverse and Transgender Children, Young People and Adults in Aotearoa, New Zealand*)

Fertility and contraception

Long-term effects on fertility are not clear. Testosterone stops the ovaries from working and it is not known whether this is reversible or not. If you wish to carry a pregnancy in the future, you will need to stop testosterone as it is harmful to a developing fetus (the exact length of time it needs to be stopped before getting pregnant is not known, so make sure you discuss this with your doctor).

After stopping testosterone your fertility could return allowing you to become pregnant without assistance. However, it may not return, and you may not be able to become pregnant without fertility assistance. This assistance usually involves egg harvesting which is an invasive procedure where eggs are removed using a needle. Testosterone does not usually affect the quality of the eggs, so if it is desired this procedure can be carried out at the time it is needed and is not usually recommended before starting hormone therapy.

If you have surgery which involves removing your reproductive organs, you may be able to access funded egg storage and can discuss this with your health provider. If you would like to discuss fertility options in more detail you can request a referral to a fertility specialist.

Testosterone is NOT a form of contraception. If you are having sex which could result in pregnancy (front hole (vaginal) sex with someone whose body produces sperm), you should use contraception even if your periods have stopped.

Sex

Your libido (sex drive) may increase and your genitals, especially your erectile tissue (clitoris), will grow. This can lead to sex and orgasms feeling different. Testosterone can cause the internal genitals (vagina) to become dry, which can cause sex to feel uncomfortable. This can be eased by using additional lubrication (lube). If you have ongoing problems with discomfort in this area, an oestrogen cream can make the internal genital area feel much more comfortable. Your GP or nurse practitioner can prescribe oestrogen cream, or you can try an over-the-counter cream for dryness such as the Vagisil range.

Side effects and risks

- Increased red blood cells (this can thicken the blood increasing risk of stroke or heart attacks. Red blood cells are monitored on your blood tests.)
- Possible risk of liver problems or raised cholesterol (these are monitored on your blood tests).
- There may be an increased risk of blood clots.
- Risk of health problems are higher if you smoke or are overweight.
- Full medical effects and risks are not known.
- Potential risk of testosterone injections include pain at the site and infection. Steps are taken to reduce this risk. Reandron can rarely cause an oil embolism which is when a tiny amount of oil gets into the blood stream. This is why Reandron should be given by a health professional.

Emotional health

It is not known exactly how it will impact on your mental health and this varies between individuals. It is a bit like going through a second puberty, so you may experience a rollercoaster of emotions, or you may notice no change. You may prefer to start the hormones when you have an upcoming period without big life stressors. You may find your mental health improves, but we know that gender affirmation can also be a stressful time and many people benefit from extra support through this. Please discuss this with your health provider who can give you options for counselling or peer support. Many people find it very helpful to talk to someone who understands gender affirmation, and it can be helpful to explore concerns around coming out, stress with family, social and internalised transphobia, anxiety, uncertainty, acceptance, etc. You can find details about support options here:

Gender diversity support services – Health Navigator

Rainbow organisations – Te Ngākau Kahukura

Cancer screening

Cervical screening – this is recommended for anyone aged 25–69 years old who has a cervix. From July 2023 this can be done using a simple swab (which you can choose to do yourself in private). More details here: Cervical screening – Time to Screen

It is possible that changing your gender marker on your primary care practice computer system could result in you not getting a reminder when you are due for this test, so please discuss with your GP or nurse if you think this could be the case. The HPV vaccine greatly reduces your risk of cervical cancer. If you have not had this vaccine, please discuss this with a nurse or GP.

Breast screening – if you have breasts, screening mammograms are recommended from age 45 years. If you've had top surgery, you will need to follow the advice of your surgeon, which may be to perform regular self-exams and ask your GP about annual chest wall examinations with possible ultrasound scans. More information here: Breast screening – Time to Screen

Appendix F:
Consent forms

Consent form for starting oestrogen-based hormone therapy

This consent form outlines important information you might want to talk to your health team about before starting hormones to feminise the body.

Progynova (oestradiol valerate) tablets or **Estradot** (oestradiol hemihydrate) patches provide the feminising hormone oestrogen. Testosterone blockers are needed as well unless orchiectomy surgery has occurred.

Oestrogen tablets/patches will gradually feminise the body.

Permanent body changes (even if you stop taking the tablets):

- Gradual increase in breast size over 2–3 years.
- Your oestrogen dose is increased slowly for best breast development.
- It is not known if taking oestrogen increases the risk of breast cancer. Take care of your breasts – it is recommended to follow the normal breast screening guidelines for women.

Non-permanent body changes (that may reverse if you stop the oestrogen):

- Softer skin
- Decreased muscle mass
- Less body hair
- More fat on buttocks, hips and thighs

Things that don't change much:

- Facial hair slows down but doesn't stop completely
- Voice stays the same
- Bone structure of your face and Adam's apple doesn't change

If you stop taking your hormones some body changes stay but you may find that your body will slowly masculinise.

Fertility

Taking the hormones stops your testicles producing testosterone. Your testicles may shrink by up to 50% and may eventually stop sperm production. If it is important for you to preserve your fertility you might want to freeze your sperm before you start treatment. Your health team will talk to you about this.

Sex

Taking the blocker tablets may lower your sex drive so that you are not as interested in having sex any more. You may find that you get erections less often and that your penis doesn't get as hard any more. If you want to be able to use your penis for sexual pleasure talk to your health team and they will review your medications.

Mental health

Some people may feel more emotional taking oestrogen. Some people find their mental health improves – the effects of hormones on the brain are not fully understood. Transitioning can be a stressful time and many people need some help adjusting to the physical and emotional changes. It is really important that you let your health team know if you are having problems so that they can help you access the support you need.

Common side effects

- Nausea
- Headaches
- Tender breasts
- Weight gain

Most side effects should settle within a few days to weeks of starting the medications. Please tell your health team if you have any side effects, especially headaches or migraines.

Potential risks of oestrogen

The full medical effects and safety of taking hormones are not fully known. The potential risks of taking oestrogen must be weighed against the benefits that hormones can have on your health and quality of life.

Likely increased risk

- Blood clots – deep vein thrombosis (DVT), pulmonary embolism (blood clot in the lung), stroke, heart attack
- Changes to cholesterol (may increase risk of pancreatitis and heart disease)
- Gallstones

Possible increased risk

- Increased blood pressure
- Liver problems
- Increased prolactin and possibility of benign pituitary tumours

Possible increased risk if you have extra risk factors

- Heart disease
- Diabetes

No increased risk or unknown

- Breast cancer

Some of these risks are reduced by using oestrogen patches instead of tablets.

Go to the emergency department or seek medical help urgently if you have:

- A swollen painful leg
- Chest pain or difficulty breathing
- Vision or speech problems.

These symptoms might mean you have a serious problem like a blood clot.

The risk of having a blood clot is much higher if you smoke or are overweight.

Blood clots are more common as you get older. Stopping oestrogen before and after surgery can help reduce the risks of blood clots around this time.

Keeping in touch with your health team for regular check-ups and blood tests is an important part of your care and will reduce the risks of taking hormonal therapy.

Are there any other questions you want to ask?

It is your health team's responsibility to best support you to make the decisions that are right for you and to keep ourselves up to date so that we can best inform you.

For many different reasons people question whether or not they want to continue to take hormones. This can be a normal part of your journey. Please feel free to discuss this with your prescriber before you stop your medication. Come and talk – your health team is always ready to listen.

I wish to start feminising hormone therapy:

Name .....

Date .....

Prescribed by:

Name .....

Date .....

Appendix F:
Consent forms

Consent form for starting testosterone-based hormone therapy

This consent form outlines important information you might want to talk to your health team about before starting hormones to masculinise the body.

There are different types of testosterone that are taken to masculinise the body. Everyone is different in how quickly they respond to testosterone but you will start to notice changes in your body gradually over the first few months. It may take several years before the full effect is felt. While there are different ways of getting testosterone into the body most people are on injections.

Permanent body changes (even if you stop taking testosterone):

- Deeper voice
- Increased growth of hair – with thicker hairs on arms, legs, chest, back and abdomen
- Gradual growth of moustache/beard hair
- Hair loss at the temples – possibly becoming bald with time
- Genital changes – clitoral growth (typically 1–3 cm) and vaginal dryness.

Non-permanent body changes (that may reverse if you stop the testosterone):

- Skin changes – increased oil and acne
- Change in body shape – less fat on buttocks, hips and thighs
- Increased muscle mass and upper body strength
- Increased sex drive
- Periods usually stop after 1–6 months

Things that don't change much:

- Breast tissue looks a bit smaller due to fat loss
- Possible weight gain or loss

Fertility

While it is not known what the long-term effects are of taking testosterone some trans men find that if they stop their testosterone they will become fertile again and can get pregnant. There are no guarantees for anyone and it is probably harder to get pregnant the older you are and the longer you have been on testosterone.

Testosterone is dangerous for the developing fetus – you must not get pregnant while you are on testosterone. Even after your periods stop you might still be at risk of getting pregnant. If you are having any sexual contact that puts you at risk of pregnancy you must talk to your health team about contraception options.

Sex

Taking testosterone causes your vagina to become dryer and more fragile. This increases the risk of sexually transmitted infections (STIs), including HIV if you are having any sexual contact with this part of the body. Condoms provide good protection against STIs and lubricant helps to prevent any discomfort.

Mental health

Some people find that testosterone can cause emotional changes such as increased irritation, frustration and anger. Some people find their mental health improves – the effects of hormones on the brain are not fully understood.

Transitioning can be a stressful time and many people need some help adjusting to the physical and emotional changes. It is really important that you let your health team know if you are having problems so that they can help you access the support you need.

Potential risks of testosterone

The full medical effects and safety of taking hormones are not fully known. The potential risks of taking testosterone must be weighed against the benefits that hormones can have on your health and quality of life.

Likely increased risk

- Increased red blood cells (polycythemia) – might thicken the blood and increase the risk of a stroke or heart attack
- Sleep apnoea (sleep disorder)

Possible increased risk

- Increased blood pressure
- Liver problems
- Increased prolactin and possibility of benign pituitary tumours

Possible increased risk if you have extra risk factors

- Diabetes
- Increased blood pressure

No increased risk or unknown

- Breast cancer
- Cervical, ovarian, uterine cancer
- Blood clots – deep vein thrombosis (DVT)

The risk of health problems is higher if you are a smoker or overweight.

Keeping in touch with your health team for regular check-ups and blood tests is an important part of your care and will reduce the risks of taking hormonal therapy.

Are there any other questions you want to ask?

It is your health team's responsibility to best support you to make the decisions that are right for you and to keep ourselves up to date so that we can best inform you.

For many different reasons people question whether or not they want to continue to take hormones. This can be a normal part of your journey. Please feel free to discuss this with your prescriber before you stop your medication. Come and talk – your health team is always ready to listen.

I wish to start masculinising hormone therapy:

Name .....

Date .....

Prescribed by:

Name .....

Date .....

Appendix G:

Testosterone administration

Practical tips for health professionals

Visual overview of available formulations of injectable testosterone

NB: this is not patient information. Useful resources for patients wishing to self-administer Sustanon or Depo-testosterone can be found here: Transgender health injection guide

Reandron
(testosterone undecanoate)

Comes in a vial. Usually given 12-weekly. Single use vial, dose up to 4ml.

Sustanon
(testosterone esters)

Comes in a glass ampoule. Single use, usually given 3-weekly. Can be self-administered.

Depo-testosterone
(testosterone cypionate)

Comes in a vial, each vial contains 5-10 doses. Usually given fortnightly. Can be self-administered.

General advice for all formulations:

- The first injection can be very significant for people – they may have waited a long time to start. Important not to rush; ensure privacy.
- Obtain and document consent, ensure person is aware of potential side effects.
- All formulations should be administered slowly.
- 20-minute wait after the first injection is recommended in case of allergy.

Storage

- All formulations need to be stored below 30°C (e.g. in a cool cupboard away from direct sunlight). Do not refrigerate or freeze.
- Sustanon should be used immediately once the ampoule is open as it cannot be resealed.

Preparation

- As with all medicines, check expiry date first, and '5 rights of medication administration' (the right person, drug, dose, route, time).
- Slightly warming the formulation beforehand in one's hands it easier to prepare and administer.
- Injecting the same volume of air as the dose required into the vial for Reandron and Depo-T can break the vacuum and make it easier to draw up the liquid, but this is not essential. This will not be possible with Sustanon.
- Always check for air bubbles in the syringe and remove prior to administration.

Administration

- As with any deep intramuscular injection the ***ventrogluteal*** site is the best administration site for all formulations: reported to be less painful, less risk of injury to underlying nerve structures, less risk of oil embolism as no major blood vessels, and usually less adipose tissue and more muscle. However, it can be given in the ***dorsogluteal*** site. The same site should not be used every time, so rotate between left and right side each injection.
- Can be given standing or supine per personal preference (supine recommended for Reandron). People self-administering their testosterone usually use the vastus lateralis or rectus femoris sites as better access.
- All formulations are given as a deep intramuscular injection so best use a 38mm (1.5”) 22 G needle to administer. Important to inject into deep muscle as testosterone can cause necrosis or abscess formation if given too superficially/into adipose tissue.
- Depo T can also be given subcutaneously but there is not yet enough evidence around the safety and efficacy of giving Sustanon via this route. Note that the dose and regime for subcutaneous administration of Depo T is not the same as for the intramuscular route.
- As with all intramuscular injections, Z-track technique is recommended to prevent tracking of the medication into the subcutaneous tissue.
- Always aspirate first before injecting solution to ensure the needle is not in a blood vessel.
- All formulations should be administered ***slowly*** and at a steady, controlled pace.

Disposal

- Some people like to keep their ampoules/ vials so check first before disposal.
- Dispose of all syringes per usual protocol, e.g. via a sharps bin.
- Local needle exchanges often have facilities for safe sharp disposal for self-administration.

Reandron

- Ideally given over 4 minutes, very thick solution so takes time, be patient!
- Doses should not be split (i.e. needs to be given as 4ml dose not 2 x 2ml).
- Use an 18G needle to draw up medication then change to 38mm 22G or 21G needle to administer.
- For dose of 3ml or less, use a 3ml syringe as resistance will be less. For a dose of 4ml use a 5ml syringe.

Sustanon

- Contains arachis oil – check no peanut allergies first.
- When breaking the top, have the 'small blue dot' facing away from you. This indicates the weakest point of the vial. You can then break the vial by snapping the top off towards you. Use a gauze or tissue to do this to protect your fingers from the glass – can be sharp.
- Use a blunt filter needle in case of glass fragments to withdraw solution into the syringe.
- Change to 38mm 22G needle when ready to administer.
- Use a 1ml tuberculin syringe or 3ml syringe, depending on dosage. For a dose of 1ml, a 3ml syringe is usually easier to prepare.

Depo-testosterone

- Use within 28 days.
- Use alcohol swab to clean the rubber bung each time before drawing up (allow time to dry).
- Replace lid and secure until next visit.
- Can use 18G needle to draw up medication then change to 38mm 22G needle to administer.
- Can use 1ml tuberculin syringe or 3ml syringe, depending on dose.

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