

Caring for Gender Diverse Patients in Clinical Practice

A Review of Pharmacological and Non-Pharmacological Best Practices

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Presenter Disclosure

- **Presenter name:** Greg Richard (he/him), BSc (Pharm) RPh
- **Speaker Fee:** I have received a speaker fee for this presentation.
- **Other:** Owner and pharmacy manager of Boyd's Pharmasave, an independent community pharmacy in Halifax, Nova Scotia

Learning Objectives

1. Explore the epidemiology of gender diversity in Canada.
2. Briefly discuss the assessment strategies used in initiating gender affirming care.
3. Describe non-pharmacological strategies and pharmacological therapies used in gender affirmation.
4. Review practical considerations for providing gender affirming care in clinical practice.

Before we get started...

How confident are you in providing care to TGD patients?

- A. Not confident at all
- B. Somewhat confident
- C. Very confident

Before we get started...

Why do you think clinicians may be hesitant to provide care to TGD patients? (choose all applicable)

- A. Lack of knowledge
- B. Personal bias
- C. Lack of interest
- D. Religious or cultural beliefs
- E. Poor understanding of the importance of providing this type of care

Epidemiology



Gender Diversity in Canada

What is Gender Diversity

- Gender is a felt sense of one's identify (e.g. boy, girl, man, woman, nonbinary), whereas sex is a category assigned at birth mainly based on genitalia and chromosomes.
- Cisgender is the term used to describe individuals whose gender identity and sex assigned at birth (SAAB) are aligned.
- Transgender and gender diverse (TGD) is an inclusive umbrella term used to describe individuals whose gender identity is not aligned with their SAAB.

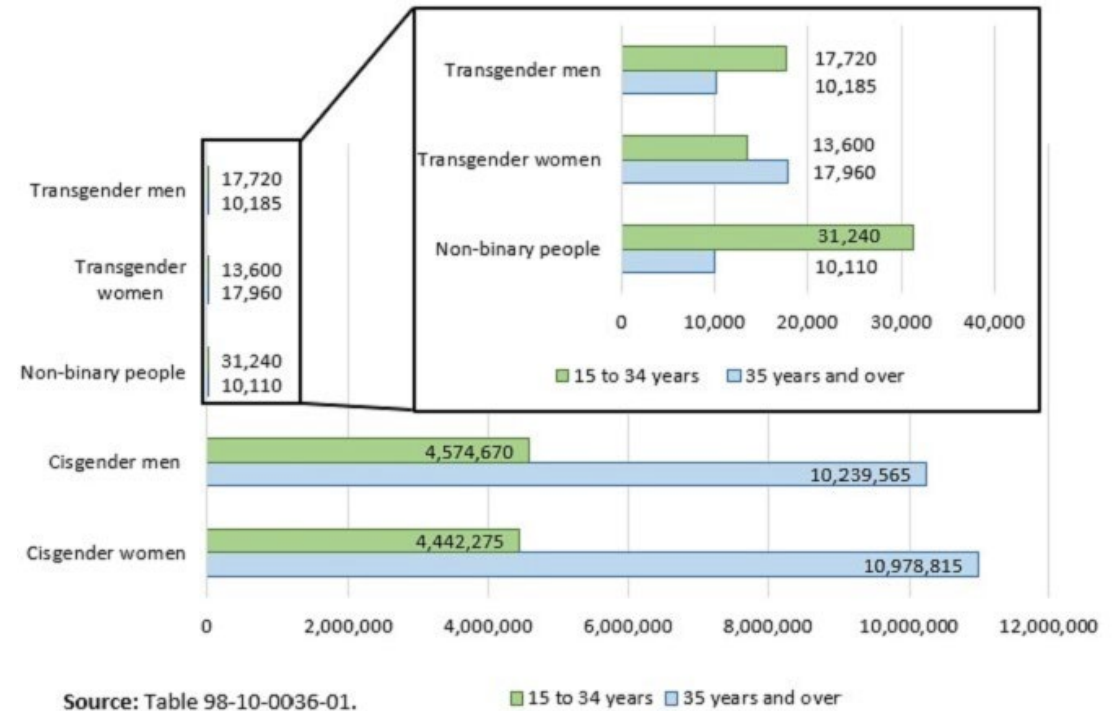
What is Gender Incongruence

- Gender incongruence is characterized by a marked and persistent incongruence between an individual's experienced gender and their sex assigned at birth. Some individuals may experience feelings of dysphoria and distress associated with this incongruence.
- Gender affirming care is the care required to support TGD individual's identity and can be achieved through *social, legal, psychological* and/or *medical* means.

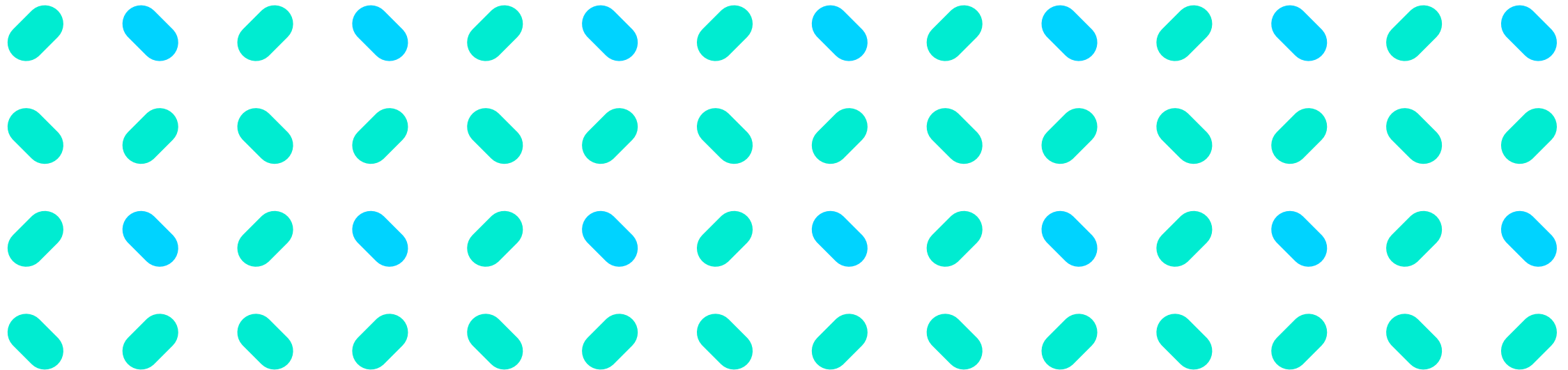
Gender Diversity in Canada

Epidemiology

- Statistics Canada collected data on gender for the first time through the Canadian Census of Population in 2021.
- 1 in 300 people ≥ 15 years of age are transgender or non-binary, equating to just over 100,000 individuals.
- Of the above number, 27.68% identify as transgender men, 31.30% identify as transgender women and 41.02% identify as non-binary.
- It is important to note that the number of people who identify as TGD is increasing and will likely continue to do so with better clarity of survey terminology, reduction in social stigma and greater legal protection.



Assessment



Goals of Therapy & Assessment

Goals of Therapy

- Promote overall health and well-being of TGD individuals.
- Enable the participation of TGD individuals in decisions about their health by providing them, and their families where applicable, with the necessary information.
- Alleviate gender dysphoria, if present.
- Provide individualized gender-affirming care that is centered around the individual's desires, goals and gender expression.

Assessment

- The WPATH Standards of Care 8 provide guidance on the assessment of gender dysphoria.
- It is important to note that since an individual's gender identity is an internal identification and experience, the assessment is aimed at identifying gender incongruence and any other coexisting mental health concerns, offering gender-affirming medical and/or surgical treatments, providing support to transgender and gender diverse individuals when considering medical and surgical options, and assessing the capacity to understand the treatment being offered.

Goals of Therapy & Assessment

Criteria for Gender-affirming Hormone Therapy

Criteria for Gender-affirming Hormone Therapy for *Adults*

Adults are eligible for hormone therapy if:

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

Goals of Therapy & Assessment

Criteria for Gender-affirming Hormone Therapy

Criteria for Gender-affirming Hormone Therapy for *Adolescents*

Adults are eligible for GnRHa treatment and subsequent sex hormone treatment if:

1. Gender diversity/incongruence is marked and sustained
2. They meet diagnostic criteria of gender incongruence in situations where a diagnosis is necessary to access health care
3. They demonstrate the emotional and cognitive maturity required to provide informed consent/assent for the treatment
4. Mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed; sufficiently so that gender-affirming medical treatment can be provided optimally
5. They are informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility
6. They have reached Tanner stage 2.

Goals of Therapy & Assessment

Capacity to Consent

- Assessing a patient's ability to consent to proposed treatment is critical during the assessment for hormone and surgical treatment.
- Consent requires that the patient has the cognitive capacity to understand the risks and benefits of treatment, as well as the potential outcomes, both positive and negative.
- It also requires the ability to retain the information provided for the purposes of making the decision, as well as the cognitive ability to use that understanding to make an informed decision.
- Clinicians can consider initiating treatment for patients unable to directly consent provided “an appropriate legal guardian or regulator-approved independent decision maker with the power to determine healthcare treatment grants consent and confirms the propped treatment aligns with the patient's needs and wishes”

Therapeutic Choices



Therapeutic Choices: Non-Pharmacological Choices

Gender Affirming Care

- Gender affirmation is a unique determinant of transgender health and well-being globally and refers to the the process of having one's gender affirmed or recognized.
- Given the spectrum of gender identity and variation in each person's expression, there is no single pathway for a TGD individual to affirm their identity. For some TGD individuals, a reduction in dysphoria may be achieved through changes in legal identification and modifications to their gait, dress, voice and/or body hair, while others may prefer strategies involving hormones and/or surgeries.
- There are four key gender affirmation domains: social, psychological, legal and medical (which includes both surgical and hormonal gender affirming therapy).

Therapeutic Choices: Non-Pharmacological Choices

Gender Affirming Care: Key Domains

- **Social**: includes concepts such as name, pronouns and gender presentation
 - Name: individuals may use a different name than what is found in their legal documents.
 - Pronouns: individuals may use a different pronoun or pronouns than could be assumed from their assigned sex.
 - Gender presentation: individuals may use many strategies to affirm their gender through aesthetic choices, body language, speech and language. They may also implement non-surgical body-modifications to affirm their gender presentation, which may include tucking, padding, packing and binding.
- **Psychological**: includes concepts such as possessing a sense of self or authentic identity and having access to trans-competent mental healthcare
 - The WPATH recommends that healthcare providers are appropriately trained to provide gender-affirming care and understand the impact of social attitudes, laws, economic circumstances and health systems on the lived experiences of TGD individuals.

Therapeutic Choices: Non-Pharmacological Choices

Gender Affirming Care: Key Domains (continued)

- **Legal**: includes effective anti-discrimination legislation, right to autonomy and self-determination, right to recognition under the law and the abilities for legal name changes and legal change of gender marker/designation
 - Although Canada is regarded as a leader in legal and human rights for TGD people, access to care related to gender affirmation, sexual and reproductive health, and general health is still a challenge for many.
- **Medical**: includes procedures and therapies aimed at reducing symptoms of gender incongruence

Therapeutic Choices: Non-Pharmacological Choices

Gender Affirming Care: Medical Domain

- **Voice and Communication Therapies**

- Not every TGD person experiences challenges with or requires support for voice and communication.
- While both testosterone hormone treatment and laryngeal surgery may be used to modify voice and communication, other practices such as behavioral training by a specialist can also bring desired changes.

- **Gender-affirming Surgeries and Procedures**

- Medically necessary gender-affirmation surgery (GAS) refers to the constellation of procedures designed to align a person's body with their gender identity.
- GAS is recognized as playing a significant role in increasing health-related quality of life and decreasing the symptoms associated with gender incongruence.
- Commonly used surgical interventions include but are not limited to mastectomy, breast augmentation, metoidioplasty, phalloplasty, vaginoplasty, vulvoplasty, orchiectomy.

Therapeutic Choices: Pharmacological Choices

Gender Affirming Care: Pharmacological Choices

- **Screening and Hormonal Planning Period**

- The hormonal planning period allows the healthcare provider to become acquainted with the patient, educate the patient regarding the effects and risks of treatment, and discuss the need for interventions such as fertility planning.
- The duration of the hormonal planning period can vary depending on the provider's history with the patient and experience in providing hormone treatment, as well as the patient's readiness for initiating treatment.
- It is important to note that the provision of hormone therapy may occur without completion of all recommended tasks, and consideration must be taken when the delay of treatment will cause significant harm to the patient.

Therapeutic Choices: Pharmacological Choices

Gender Affirming Care: Pharmacological Choices (continued)

- **Screening and Hormonal Planning Period**

- Examples of tasks that may be included in the planning period include:

General intake and medical history	Explaining rationale for planning period	Discussing goals
Exploration of gender identity and expression	Review potential benefits and risks	Explore social supports, lifestyle, and mental health considerations
Ensuring capacity to consent	Discussing funding and economic considerations	Discussing options and choosing initial hormone regimen

Question

KL (they/them) is a 24-year-old patient seeking and urgent appointment for gender affirmation care. They have been a patient in your family practice since they were 12 years old, and you are very familiar with their medical history. You have little experience in offering gender-affirming care, although you understand the importance of providing this care. KL has made an appointment with you to discuss ongoing symptoms of gender incongruence that they say they have been experiencing “ever since they can remember”. They report that they are not experiencing suicidal ideation, although they have been having “dark thoughts” over the past few months. They have no comorbid psychiatric conditions, take no current medications other than a daily multivitamin, and have a strong social and family support system. KL is seeking testosterone-based therapy and asking to be prescribed testosterone *today* as they are “unable to cope with these feelings for much longer”. How would you proceed?

- A. Discuss their symptoms and experience and ask they schedule a follow up to discuss further
- B. Ensure that KL has the capacity to consent to therapy and understands the risks and benefits to therapy, offer a prescription for testosterone with the expectation of follow up in a few weeks to assess tolerability
- C. Refer KL to an endocrinologist as you have little experiencing in providing gender-affirming care

Therapeutic Choices: Pharmacological Choices

Puberty Suppression

- Gender-affirming hormone therapy in TGD youth may include a puberty suppression phase followed by initiation of estrogen-based or testosterone-based therapy. Tanner staging describes the timing and sequence of development of secondary sex characteristics that occur during puberty and is used to determine the appropriate time to initiate gonadotropin-releasing hormone analogs (GnRHa).
- Gonadotropin-releasing hormone analogs are often used in trans youth between Tanner stages 2-5 to suppress puberty. GnRHa flood the pituitary glands' GnRH receptors, resulting in a down-regulation of the response to endogenous GnRH and sustained suppression of both luteinizing hormone (LH) and follicle-stimulating hormone (FSH).
- This suppression results in the cessation of sex hormone production by the gonads, thereby preventing further development of the endogenous secondary sex characteristics corresponding to the sex designated at birth.
- **Leuprolide**, a long-acting GnRHa available in 1-, 3- and 6-month dosages is the most commonly used agent. **Triptorelin** is a long-acting GnRHa which may be considered if leuprolide is contraindicated or unavailable.

Therapeutic Choices: Pharmacological Choices

Puberty Suppression (continued)

- Early initiation of puberty blockers may have better psychological and physical outcomes; however, it is important to discuss the limitations and adverse effects of such therapies before initiation
 - Cost, repeat injections which are often painful, ADRs such as local reactions, headache, mood changes, weight gain and decreased bone mineral density with prolonged use
- Impacts on fertility should be discussed prior to the initiation of a GnRHa. While GnRHa-based pubertal suppression is reversible, it does impact the maturation of germ cells which could affect fertility.

Therapeutic Choices: Pharmacological Choices

Estrogen-based Therapies

- Goal: reduce endogenous effects of testosterone and to induce feminine secondary sex characteristics congruent with the person's goals.
- This is achieved through the induction of estrogen and medications that inhibit testosterone (anti-androgen therapy).
- There is a lack of consensus on the preferred timing of the initiation of exogenous estrogen in relation to anti-androgen therapy. Approaches include initiating the anti-androgen therapy 1-3 months prior to starting estrogen, or simultaneously initiating both therapies.
- Monitoring and dose adjustments will depend on patient goals, physical response, measured serum hormone levels and other lab results.
- Estrogen-based therapy is associated with several medical risks that should be considered and discussed with patients, including the very high risk of thromboembolic disease (e.g. deep vein thrombosis, pulmonary embolism, stroke) and the moderate risk of macroprolactinoma (particularly in combination with cyproterone), breast cancer, coronary artery disease, cerebrovascular disease, cholelithiasis, hypertriglyceridemia, mood changes and depression, decrease in fertility, hypertension, diabetes and weight gain.

Therapeutic Choices: Pharmacological Choices

Estrogen-based Therapy Physical Effects

Physical Effects	Reversibility	Expected Onset	Expected Maximum Effect
Breast growth	Irreversible	3-6 months	1-2 years
Body fat redistribution	Partially reversible	3-6 months	2-3 years
Decreased muscle mass/strength ^[a]	Reversible	3-6 months	1-2 years
Skin softening/decreased sebum	Reversible	3-6 months	Unknown
Scalp hair loss cessation	Reversible	1-3 months	Variable
Decreased facial/chest/pubes hair	Reversible	6-12 months	>3 years
Decreased libido	Variable	1-3 months	3-6 months
Decreased spontaneous erections	Variable	1-3 months	3-6 months
Decreased testicular volume	Variable	3-6 months	2-3 years
Decreased sperm production	Variable	Variable	Variable

^a Impacted by exercise

Therapeutic Choices: Pharmacological Choices

Estrogen-based Therapies

- **Anti-androgens**

- Androgen blockade can minimize or suppress some masculine sex characteristics. They are used in combination with estrogens in TGD youth and adults with testes to lower and/or block testosterone and can be used to lower the dose of estrogen required for feminization.
- Anti-androgens do not reverse the permanent masculinization of the body that occurred during puberty.
- **Spironolactone** is a potassium-sparing diuretic that has direct anti-androgen receptor activity and a suppressive effect on testosterone synthesis. It may not reduce serum testosterone levels significantly on its own, and therefore effectiveness should be evaluated routinely. It can be stopped immediately after orchiectomy (\pm vaginoplasty) or tapered over 4-6 weeks in patients with hypertension or renal dysfunction.

1. Coleman et al. (WPATH Standards of Care 8)

2. Bourns et al. (Rainbow Health Ontario)

10. Prior JC, Vigna YM, Watson D. *Arch Sex Behv* 1989;18(1):49-57.

11. Gooren LJ, Giltay EJ, Bunck MC. *J Clin Endocrinol Metab* 2008;93(1):19-25.

12. Bessone F, Lucerna MI, Roma MG et al. *J Clin Endocrinol Metab* 2008;93(1): 19-25.

13. Fung R, Hellstern-Layefsky M, Lega I. *Int J Transgenderism* 2017;18(2):123-8.

Therapeutic Choices: Pharmacological Choices

Estrogen-based Therapies (continued)

- **Anti-androgens**

- **Cyproterone** is a potent anti-androgen that works by creating negative feedback on the hypothalamo-pituitary pathway, leading to decreased testicular testosterone secretion, and competitively blocking active dihydrotestosterone in the prostate. Acute liver damage has been reported, but most reports are in patients taking higher doses than required for estrogen-based therapy. Baseline ALT and regular monitoring is recommended. Daily doses greater than 10mg and use beyond two years have also been associated with the development of meningiomas. Routine screening is not recommended, although patients should be aware of the risk and monitor for symptoms (changes in vision, hearing loss or ringing in the ears, loss of smell, headaches, memory loss, seizures or weakness in the arms and legs). Cyproterone can be stopped immediately after orchiectomy.
- The 5-alpha-reductase inhibitors **finasteride** and **dutasteride** are typically not used in estrogen-based therapy due to their minimal effectiveness as anti-androgens compared to typical agents but may be considered in individuals desiring mild anti-androgen effects, or for those who exhibit scalp hair loss.

1. Coleman et al. (WPATH Standards of Care 8)

2. Bourns et al. (Rainbow Health Ontario)

10. Prior JC, Vigna YM, Watson D. *Arch Sex Behv* 1989;18(1):49-57.

11. Gooren LJ, Giltay EJ, Bunck MC. *J Clin Endocrinol Metab* 2008;93(1):19-25.

12. Bessone F, Lucerna MI, Roma MG et al. *J Clin Endocrinol Metab* 2008;93(1): 19-25.

13. Fung R, Hellstern-Layefsky M, Lega I. *Int J Transgenderism* 2017;18(2):123-8.

Therapeutic Choices: Pharmacological Choices

Estrogen-based Therapies (continued)

- **Estrogens**

- Exogenous estrogen binds to estrogen receptors to trigger the development of feminine secondary sex characteristics. Physical effects attributable to estrogen therapy include breast development; decreased erectile function, testicular volume, sperm production and sexual desires; softer and less-oily skin; reduction in coarse facial and body hair; and increased proportion of body fat to lean-muscle mass.
- Options for estrogen therapy include oral or sublingual **17-beta estradiol**, transdermal **estradiol** (as a patch or gel) and injectable **estradiol valerate** or **estradiol cypionate** (these are not commercially available and but may be compounded).
- The synthetic estrogen, ethinyl estradiol, is associated with an increased risk of venous thromboembolism and should be avoided when possible. Conjugated equine estrogens have been used historically but they are no longer recommended due to challenges with monitoring serum levels and suggestions of risk of adverse events.

Therapeutic Choices: Pharmacological Choices

Estrogen-based Therapies (continued)

- **Estrogens**

- If oral formulation is desired, 17-beta estradiol is preferred due to its reduced thrombogenicity versus synthetic or conjugated estrogens.
- Expert opinion is that transdermal estrogen formulations are less thrombogenic than oral therapy and should be considered for patients >40 years of age or with risk factors for cardiovascular, thromboembolic or liver disease. Other risk factors prompting preference for transdermal estrogen therapy include thrombophilia, diabetes, smoking, obesity, major surgery and fractures.
- Note: it is common practice to discontinue estrogen therapy 2-4 weeks prior to surgical procedures (e.g. vaginoplasty) due to the increased risk of VTE during surgery, although this remains controversial.

Therapeutic Choices: Pharmacological Choices

Estrogen-based Therapies

- **Progestins**

- Many TGD patients request treatment with progestins as part of their estrogen-based therapy, although there is insufficient evidence to recommend progestin use for feminization.
- The low quality of evidence from relatively few studies suggest that the addition of progestin does not seem to enhance (nor prevent) breast development.
- Progestin therapy in TGD individuals has not been shown to reduce breast cancer rates or improve bone mineral density and there is data to suggest it is associated with VTE.
- If requested or offered, a frank discussion of risks and expectations is essential, and micronized progesterone would be the preferred agent.

1. Coleman et al. (WPATH Standards of Care 8)

2. Bourns et al. (Rainbow Health Ontario)

16. UCSF Gender Affirming Health Program, Department of Family and Community Medicine, University of California San Francisco. *Guidelines for the primary and gender-affirming care of transgender and gender nonbinary people; 2nd edition.*

17. Wierckx K, Gooren L, T'Sjoen G. *J Sex Med* 2014;11(5): 1240-7.

18. Iwamoto SJ, T'Sjoen G, Safer JD et al. *J Blood Med* 2019;10:209-16.

Question

TS (she/her) is a 44-year-old transfeminine patient of your community pharmacy and has recently asked to sit with you to discuss her current estrogen-based therapy. She has been taking 17-beta-estradiol for 10 years, most recently at a dose of 2mg twice daily taken orally. She discontinued her cyproterone in 2018 after her orchiectomy and vaginoplasty were completed. As she often does, TS was reading patient experiences on a Subreddit discussing transgender issues and was reminded of the risk of blood clots with estrogen therapy. She is very concerned as her mother experienced a stroke in 2023. How would you address TS?

- A. Suggest TS begin taking her 17-beta-estradiol sublingually to minimize the risk of developing blood clots
- B. Assure TS that 17-beta-estradiol is safe and that going without therapy can have significant impacts on her mental health
- C. Offer to contact TL's prescriber (or offer a therapeutic adaptation if possible) to change her therapy to transdermal estradiol patches

Therapeutic Choices: Pharmacological Choices

Testosterone-based Therapies

- Goal: to develop androgenic sex characteristics congruent with the patient's goals.
- These goals may include effects such as deepened voice, cessation of menses, clitoral growth, increased muscle mass, fat redistribution and hair growth in androgen-dependent areas.
- These effects are achieved through the introduction of testosterone which acts to reduce endogenous estrogen levels, resulting in a shift in hormones that induce both reversible and irreversible changes.

Therapeutic Choices: Pharmacological Choices

Testosterone-based Therapy Physical Effects¹⁹

Physical Effects	Reversibility	Expected Onset	Expected Maximum Effect
Skin oiliness/acne	Reversible	1-6 months	1-2 years
Body fat redistribution	Reversible/Variable	1-6 months	2-5 years
Increased muscle mass/ strength ^{a)}	Reversible	6-12 months	2-5 years
Facial/body hair growth	Irreversible	3-6 months	4-5 years
Scalp hair loss	Irreversible	6-12 months	Variable
Cessation of menses	Reversible	1-6 months	N/A
Clitoral enlargement	Irreversible	3-6 months	1-2 years
Vaginal Atrophy	Reversible	1-6 months	1-2 years
Deepened voice	Irreversible	6-12 months	1-2 years
Infertility	Variable	Variable	Variable

^a Impacted by exercise

2. Bourns et al. (Rainbow Health Ontario)

19. Bourns et al. (Rainbow Health Ontario): *Guidelines for gender-affirming primary care with trans and non-binary patients a quick reference guide for primary care providers (PCPs). Masculinizing hormone therapy*

Therapeutic Choices: Pharmacological Choices

Testosterone-based Therapies

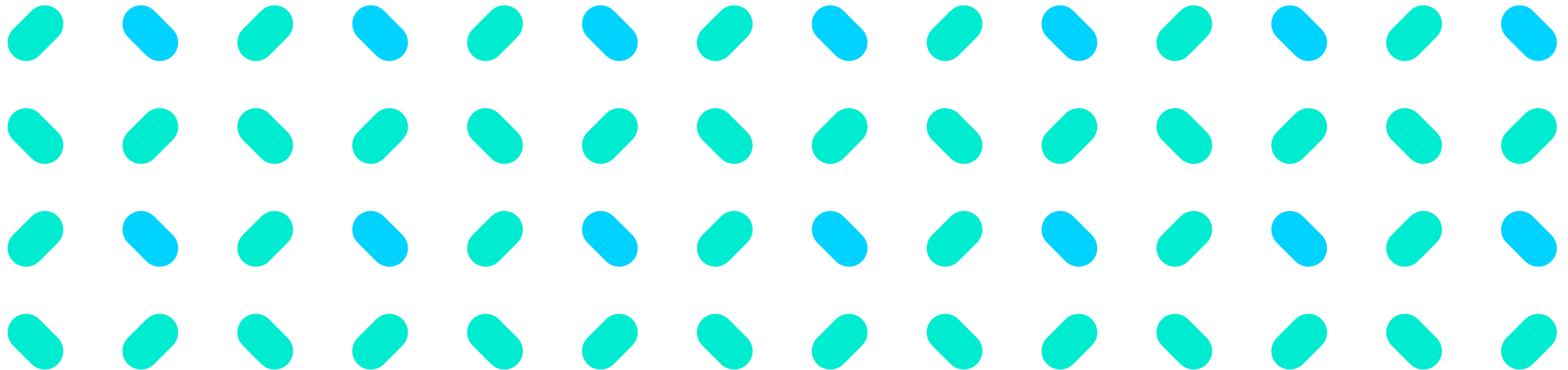
- **Testosterone**
 - Testosterone is the cornerstone of hormone therapy for transmasculine patients.
 - Irreversible effects include changes to the voice and clitoris, and it is essential that patients understand this prior to initiating therapy.
 - The goal of therapy is to achieve serum testosterone concentrations no higher than the male reference range, but clinicians should aim for serum levels that provide changes in line with the patient's individual goals rather than purely focusing on attaining a specific level.

Therapeutic Choices: Pharmacological Choices

Testosterone-based Therapies (continued)

- **Testosterone**
 - Options for testosterone therapy include injectable testosterone (**testosterone cypionate** and **testosterone enanthate**), and **transdermal testosterone**. Transdermal preparations provide relatively steady-state testosterone delivery, as opposed to the periodicity associated with injectable dosage forms.
 - A thorough risk assessment should be completed prior to initiating testosterone-based therapy, with a particular focus on potential metabolic impacts, cardiovascular events and malignancies.
 - Testosterone is contraindicated in patients who are pregnant or breastfeeding and in those who have active, known sex hormone-sensitive cancer, unstable ischemic cardiovascular disease, poorly-controlled psychosis or acute homicidality.

Practical Considerations



Practical Considerations & Tips

Fertility

- TGD individuals do not receive adequate fertility counseling despite desiring parenthood at rates similar to cisgender counterparts.
- Healthcare providers should be familiar with TGD reproductive health and the potential barriers to care.
- As some medical and surgical gender-affirming therapies may impact the ability to reproduce, comprehensive fertility counseling, including options for fertility preservation, before the initiation of such therapies is critical to the care of gender-diverse patients.

Practical Considerations & Tips

Contraception

- Estrogen-combination hormone therapy does not always lower sperm count, and therefore it is commended that TGD individuals with testes use a method of birth control to prevent unwanted pregnancy if they are sexually active with someone who is able to become pregnant.
- Testosterone therapy may suppress ovulation; however, it is not considered to be an adequate form of contraception for TGD individuals with ovaries. In addition, there is data to indicate testosterone can cause abnormal fetal development should pregnancy occur. Patients may consider progesterone-only contraception, or an intrauterine system (UCS).

Practical Considerations & Tips

Injection Administration

- Clinicians should be prepared to provide guidance on injection administration for testosterone and estradiol valerate:

	Intramuscular	Subcutaneous
Draw Needle Gauge ^[a]	18-20 G	18-20 G
Injection Needle Gauge	22-23 G	25-26 G ^[b]
Needle Length	1-1.5 inch (depending on thickness of site)	1/2-5/8 inch
Syringe Size	1 mL (preferable) to 3 mL	1 mL (preferable) to 3 mL
Injection angle	90 degrees	45 degrees

^a Patients may choose to draw and inject with same needle to avoid added costs, in which case injection needle gauge should be followed.

^b Patients may choose to use insulin syringes for SC injections.

Thank you



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