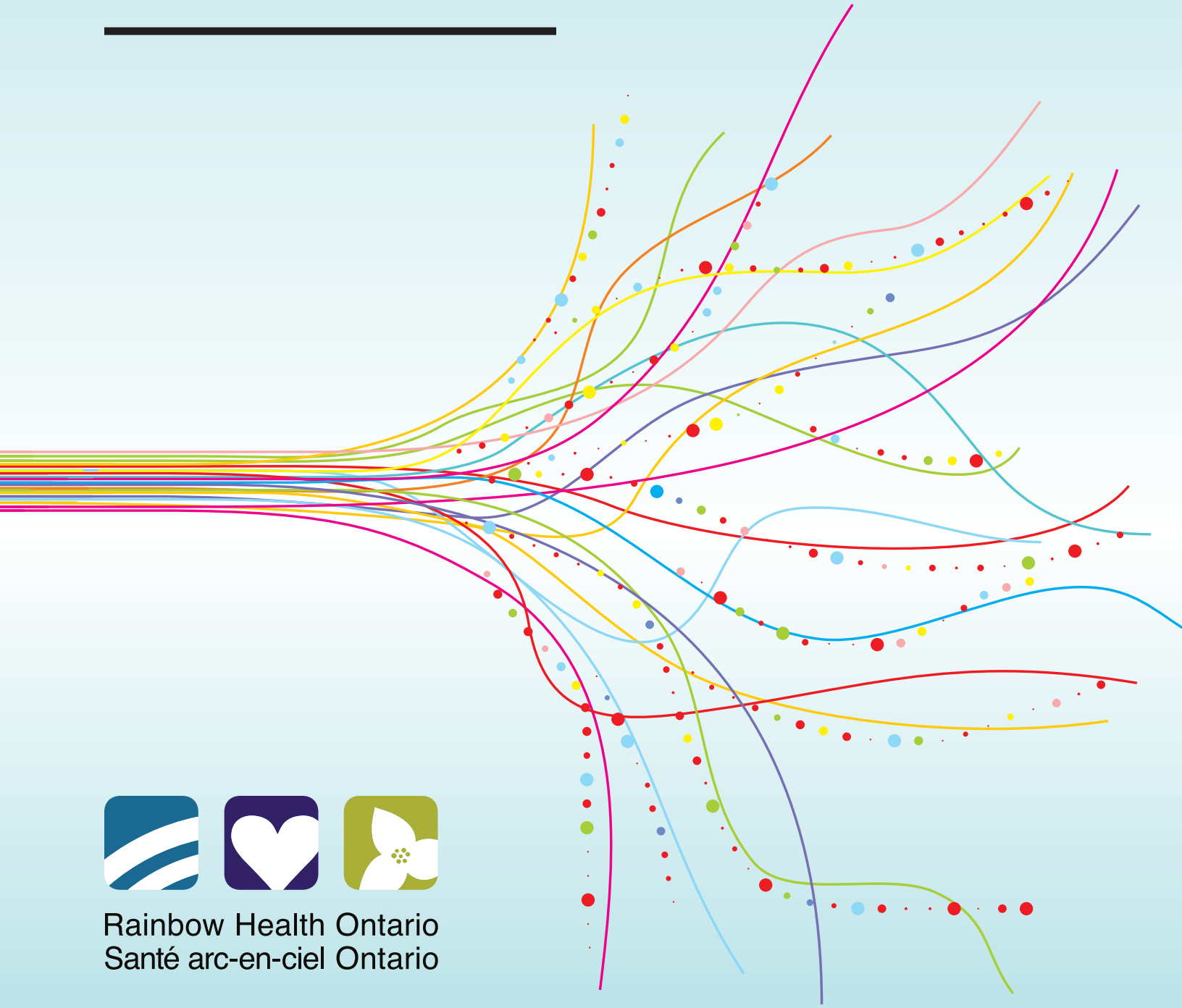
GUIDELINES AND PROTOCOLS

For Hormone Therapy and Primary Health Care for Trans Clients

SHERBOURNE Health Centre



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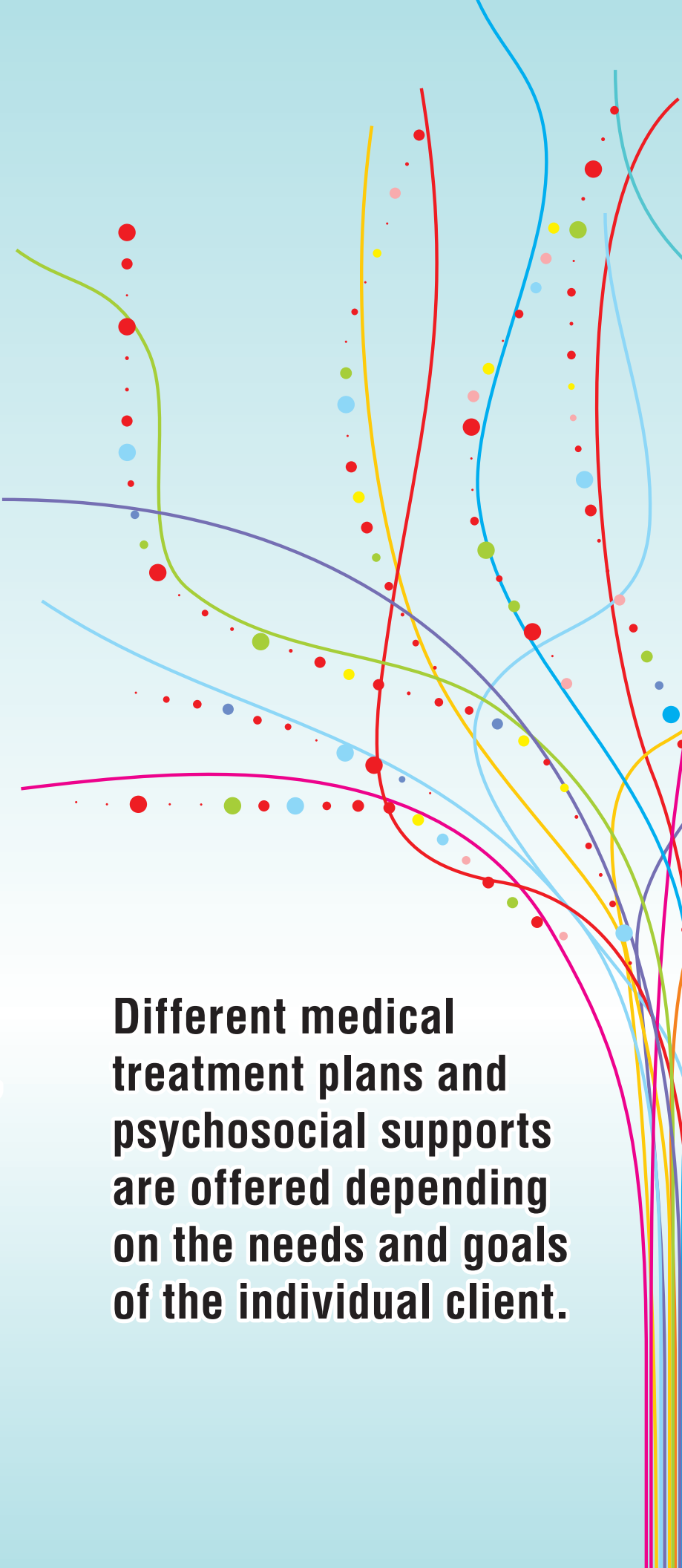

The term trans refers to transsexual, transgender, gender non-conforming, and gender questioning clients.

Different medical treatment plans and psychosocial supports are offered depending on the needs and goals of the individual client.

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Guidelines and Protocols for Hormone Therapy and Primary Health Care for Trans Clients

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Disclaimer

Sherbourne Health Centre (SHC) is a community based primary health care centre in downtown Toronto. Our mandate is to serve marginalized populations: our communities of focus are lesbian, gay, bisexual, and trans (LGBT) communities; homeless and under-housed people; and newcomer/immigrant populations. Our focus on LGBT people has resulted in our Centre attracting a large and diverse population of transsexual, transgender and gender non-conforming clients who receive a range of clinical, health promotion and support services. Rainbow Health Ontario, a program of Sherbourne Health Centre, provides information, training and resources on LGBT health throughout Ontario and has delivered specialized training using these protocols since 2011.

The first edition of the protocols were developed in collaboration with trans community members in 2003. There were few clinics offering trans-specific primary care and the need was great. At the same time, trans people were concerned that Sherbourne might adopt an approach that would be too conservative and restrictive. Together, the team at Sherbourne and trans community representatives met to review other protocols, discuss issues and concerns on both sides, and arrive at an approach that met the needs of all parties.

The original document was meant to be an internal guideline but requests from healthcare providers across Ontario (and Canada) for advice around management of their trans clients led to the development of the first widely available version of the protocols in 2009. The current iteration of the protocols herein builds on the success of Sherbourne's experience in caring for trans clients and incorporates new evidence, standards of practice and the evolution of our understanding of gender identity and expression. This edition presents an expansion of the discussion around long-term preventive care and introduces new tools for practice designed to be used at the point-of-care.

The medical team at SHC is made up of family physicians, nurse practitioners and nurses; we are not gender specialists by training, rather we have developed some expertise by virtue of the volume of clients we see and whose care we manage. We recognize that this gives us the ability to provide guidance to other clinicians who are providing similar care. These protocols have been prepared with this purpose in mind, and are meant to reflect our management of trans clients and thus, help other providers by describing our practice. We also hope that this may stimulate discussion around our practice, and as such we welcome any comments or criticisms other providers may have.

This document does not represent an exhaustive review of the medical literature. Of course, many research articles and other protocols have been reviewed to inform the medical aspects of care, but much of the information simply reflects our routine practice. Because of this, we do not present it as a "standard of care," but instead as a guide to help clinicians in their day-to-day practice. In addition, these protocols are meant to be applied with flexibility in order to meet the diverse health care needs of transsexual, transgender and gender nonconforming people. Adaptations may be considered relating to each client's unique anatomic, social, or psychological situation, patient or systemic resource limitations, or the need for harm reduction strategies.

We have presented a number of contraindications, precautions and risks associated with hormone administration, but we did not examine every possible permutation. Clinicians must use their own expertise and decision-making skills within each clinical encounter instead of relying on this document to provide complete answers. We encourage providers to consult other sources of information and seek peer support when needed. Appendix I - Trans Health Resources for Primary Care Providers, lists additional resources, suggestions for keeping up to date on topics in trans health, and opportunities for peer discussion.

We hope that this document will enable more primary care providers to be involved in the care of trans clients. It is a rewarding experience to assist someone with the integration of their gender identity, and we feel privileged to be a part our clients' transitions. We wish to share this experience with other clinicians.

Introduction

Many family physicians and nurse practitioners (henceforth referred to as primary care providers) will, at some point, be involved in the care of transsexual, transgender and gender non-conforming clients. Recent population based surveys in the United States suggest that the number of self-identified trans people are growing and currently represent approximately 0.1-0.5% of the population[1,2] with one study showing significantly higher prevalence amongst youth.[3] The Trans PULSE Project,[i] which studied trans people in Ontario, showed that although urban centres are often sought out by trans people wishing to access health care, approximately 70% of trans Ontarians live outside the Greater Toronto Area.[4] It is our hope that as many practitioners as possible become proficient in trans care so that people who wish to transition have the choice to remain in their communities.

Because transsexualism, transgenderism and gender non-conformity are not concepts explored in traditional medical training, the management of trans clients can be confusing for healthcare providers. Internationally, there are a number of protocols and guidelines in the care of transsexual, transgender and gender non-conforming people, many of which will be referenced in this document.

The best-known example is the "Standards of Care" document from the World Professional Association for Transgender Health (previously known as the Harry Benjamin International Gender Dysphoria Association).[5] The Standards of Care provide an international professional consensus around current knowledge and the role of the clinician in working with trans clients. While it is the 'gold standard' consensus, it does not provide specifics around hormone provision or direction around aspects of primary care that merit consideration. Many clinics have developed protocols[ii] for their own practitioners, also available to the public, which are more specific in their details around management. Likewise, SHC presents this guideline to summarize the current clinical practice at the Centre.

For many trans clients, the focus of the medical encounters will be to bring their physical appearance more in-line with their internal gender identity. The medical field can assist with this through the provision of hormones and/or surgeries. Since primary care providers usually have familiarity with the individual client, they are in a good position to formulate the diagnosis (i.e. of Gender Dysphoria) and develop a management plan. In the large majority of cases, it is within the scope of primary care to provide hormone treatments to trans clients. In total, 67% of trans people in Ontario who are on hormone therapy receive this treatment through their primary care provider.[6] Finding a primary care provider who will assist with medical transition and provide sensitive, knowledgeable primary care however, remains a frequent challenge.[7]

Some primary care providers would prefer to seek consultation with an endocrinologist; while this may be an appropriate and helpful referral in the case of a medically complex client, it is typically not needed in relatively straightforward cases. Additionally, outside major urban areas, an endocrinologist with experience treating trans clients may not be available; requiring such a consultation may result in an unduly long and stressful wait for the client. If consultation is sought, it may be helpful to the provider and client to consider starting an androgen blocker +/- low-dose estrogen (e.g. half the regular dosage) for trans women or low-dose testosterone for trans men, until the consultation can be obtained.

There is a great deal of variation amongst providers around comfort level of beginning hormones, and also around titration and maintenance of doses. Ideally, this document will provide some guidance with regard to common dosages and monitoring strategies as well as references and resources for further learning and support.

i Trans PULSE is an ongoing community-based research initiative that has used mixed-methods to better understand the health of trans communities in Ontario. Its most significant component was a large 2009-2010 survey (n=433) of trans persons that, through the use of respondent-driven sampling, was able to produce data that could be generalized to all Ontario trans people. An overview by Schiem & Bauer, 2015 can be downloaded for free at **www.tandfonline.com/doi/full/10.1080/00224499.2014.893553#abstract** see **www.transpulse.ca** for more information

ii Examples include Tom Waddell Health Center, Callen-Lorde Community Health Centre, and Vancouver Coastal Health (VCH). The Tom Waddell protocols are available online at **https://www.sfdph.org/dph/comupg/oservices/medSvs/hlthCtrs/TransGendprotocols122006.pdf**, while the the revised VCH protocols are pending at the time of publication of this document.

At Sherbourne Health Centre, we are privileged to work on a health care team that provides support to a large number of trans clients, thus we are able to provide peer support for one another. For providers elsewhere, a weekly conference call about providing care to trans clients is coordinated by Rainbow Health Ontario as a way to mirror the support we have on our team. Our hope is that this discussion of our general guidelines and practice will help other providers feel supported in their endeavours to serve their trans clients.

For some providers it is easier to get started by taking over the care of a client who has already been started on hormones by another clinician until there is a greater level of confidence in starting clients on hormones. There is also value in working with counsellors who have skills in individual and group therapy who can work alongside the prescriber in attending to the social and psychological aspects of transition. At Sherbourne Health Centre, we are fortunate to have a range of other services for trans clients including support groups for pre and post-operative clients, youth, and the partners of trans people.

What's new in this edition?

- Adaptations to recognize and address the needs of clients whose gender identity does not align with binary gender categories
- An emphasis on an individualized approach to client care
- Medication cost estimates to help inform decision-making for those paying 'out-of-pocket'
- Suggestions for mitigating the increased risks of hormone therapy associated with pre-existing health conditions
- An expanded discussion of primary care considerations and long-term preventive care recommendations
- A discussion of the management of commonly encountered side effects
- Exciting new tools for practice designed to provide guidance at the point-of-care (see Appendices A, D+E, F+G)
- Additional resources for primary care providers including opportunities for peer discussion and online case consultation
- Active hyperlinks to key resources in the electronic version

Part I: An Approach to Trans Care

A Note on Language

The use of language regarding gender identity and gender expression is constantly evolving. Over the past several years, there has been a proliferation of terms whose meanings vary over time, and within and between disciplines.[5] In particular, terminology has expanded to reflect a spectrum of identities outside the traditional 'binary' understanding of gender. In line with the most recent version of WPATH's Standards of Care[5], we aim to recognize and support the full spectrum of gender identity and gender expression.

> "*Gender nonconformity* refers to the extent to which a person's gender identity, role, or expression differs from the cultural norms prescribed for people of a particular sex. *Gender dysphoria* refers to discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics). Only some gender nonconforming people experience gender dysphoria at *some* point in their lives".[5]

It is important to use respectful and affirming language commensurate with a client's self-identification whenever possible. Settling with any terminology is bound to be imperfect, but for the sake of practicality, we have made some generalizations.

In this document, we will use the terms 'transgender men' and 'trans men' to refer to clients who were assigned 'female' at birth but whose sense of self is of being a man or on the masculine spectrum. Similarly, we will use the terms 'transgender women' and 'trans women' to refer to clients who were assigned 'male' at birth but whose sense of self is of being a woman or on the feminine spectrum. Non-binary clients (eg. genderqueer, gender fluid, pangender, agender) may feel that their gender falls somewhere between the binary notions of 'man' or 'woman', is both, neither, or in flux. Just as other trans clients do, non-binary clients may seek medical assistance with modification of secondary sex characteristics that contribute to clinically significant gender dysphoria. Those seeking minimization of the endogenous effects of testosterone and/or feminization may follow the protocols outlined for trans women (see Part II: Feminizing Hormone Therapy). Those seeking minimization of the endogenous effects of estrogen and/or masculinization may follow the protocols outlined for trans men (see Part III: Masculinizing Hormone Therapy).

We encourage the use of the prefix 'cis' to refer to non-trans people over the terms "natal", "biological", or "genetic" or simply as "men" or "women" as these terms can imply that trans people have a less valid claim to their gender than do cis people. Using "cis" to describe non-trans clients challenges the expectation that all our clients are, and will be cis. Dealing with cissexism (i.e. the privileging of cis bodies and identities over trans ones) and transphobia, are unique challenges that are faced by our trans clients.[8]

See Appendix H: Glossary of Terms, for a summary of the meanings of several terms as we feel they are most commonly understood within our current cultural context.

***cis* pr. 'sis', Latin origin**

- A prefix meaning 'on the same side of'
- In chemistry: denotes a geometric isomer having a pair of identical atoms or groups attached on the same side
- Refers to a state of alignment of one's gender identity with the gender assigned at birth

***Trans* pr. 'trans' Latin origin**

- A prefix meaning 'across', 'beyond'
- In chemistry: denotes a geometric isomer having a pair of identical atoms or groups attached on the opposite side
- Refers to a state of incongruence of one's gender identity with the gender assigned at birth

An Individualized Approach to Care

Given the spectrum of gender identity and the variation in each person's expression of this identity, it follows that there is no single pathway for a trans person to follow in order to actualize the expression of their authentic self. Though hormones and/or surgery are medically necessary for many trans people, others may obtain relief of gender dysphoria through other means of modifying their self-expression such as changes in legal identification and modifications to their dress, gait, and/or voice.

When hormones are chosen as part of a care plan, some clients may seek maximum feminization/masculinization, while others experience relief with a more androgynous appearance.[9] Hormone therapy may also provide significant relief for clients who do not wish to make a social gender role transition or are unable to do so.[10] Both the dose and route of hormone treatments may

be individualized to meet a client's specific treatment goals for gender expression and need for relief from gender dysphoria. The duration of therapy may also be personalized, as clients who have not undergone gonadectomy may opt to discontinue hormone therapy if the irreversible effects are sufficient to maintain relief from dysphoria. If hormone therapy is discontinued, it is preferable to slowly taper the dose over a period of several weeks in order to minimize the side effects that may be associated with a more sudden change in serum hormone levels.

With the exception of genital surgery and gonadectomy, hormone therapy is not considered necessary prior to accessing surgical procedures.[5] The decision to undergo surgical interventions is also highly individual.

Decision to start hormones

Although the decision to implement treatment with hormones for a trans client is individualized, there are some common guidelines undertaken by our health centre. These guidelines are designed to maximize the safety of the client, fulfill the legal and ethical requirements of the primary care provider, and reduce the possibility of inappropriate treatment. The trans population has suffered a great deal of prejudice, misunderstanding and harm from the medical community, and systemic oppression experienced by trans clients has often resulted in the denial of service.[11,7] The health care provider's role in assessing a client's eligibility and readiness for hormone therapy can create an unfortunate dynamic, with the provider positioned as the 'gatekeeper' to treatment.[12,13] In response to this, a number of community health centres in the US have implemented what has become known as the 'informed consent model' for hormone provision.[12,14] In this model, the focus is on obtaining informed consent as the threshold for the initiation of hormone therapy, with less emphasis on meeting DSM diagnostic criteria for Gender Dysphoria or requiring a mental health assessment unless significant mental health concerns are identified.[5]

At SHC, we approach the decision to initiate hormone therapy as a collaborative, client-centred process that focuses on both psychosocial readiness and informed consent. We feel that the primary care provider (ideally with the support of a multi-disciplinary team) can facilitate a decision-making process that informs, educates, guides, and supports clients. The provider or care team can take an active role in assisting a client in addressing any existing barriers to the safe administration of hormone therapy. An expanded discussion of this approach, aimed at building the capacity of primary care and other health care providers to directly assess and assist clients in this process, is in press.[15]

Many providers are concerned about the possibility of regret, that is, of treating a client with hormone therapy who later decides he/she/they prefer the sex of origin. This is, in fact, a very rare occurrence. The experience of regret after sex reassignment has been examined largely by case study; the prevalence of people who regret their transitions is estimated at 1-2% of all trans people.[16,17] We aim to help providers develop realistic goals and expectations with their clients in order to prevent post-hoc regrets as much as possible.

Providers may additionally have concerns regarding the impact of hormonal therapy on a client's physical health. Long-term, prospective studies for most trans-specific health issues are lacking.[18] The few long-term studies on cross sex hormone therapy out of the Netherlands do present some reassuring long-term safety data,[19-25] yet much is still to be learned. Known risks, which will be discussed herein, need to be carefully considered and mitigated when possible. As the risk of significant adverse effects from hormone therapy is highly dependent on pre-existing risk factors, applying the principles of risk stratification to inform clinical decision-making regarding cross sex hormones can be particularly helpful.[26]

For each client seeking hormone therapy, it is important to not only consider the possible risks of treatment, but to consider the often substantial risks of not undergoing hormonal therapy as part of the management plan for significant gender dysphoria. Data obtained as part of Trans PULSE[iii] demonstrate that the highest risk for suicide amongst trans people occurs in those who are planning to transition but who have not yet begun.[27] Those who are not able to access hormone therapy through a health care provider may opt to take hormones from illicit sources (in the case of feminizing hormones this may include less safe forms of estrogen) and without monitoring for adverse effects, thus potentially putting themselves at risk.[6] Two studies pointedly illustrate that the bulk of morbidity and mortality suffered by transgender clients is related to the challenges of being trans in our society that have nothing to do with hormone therapy.[19,28]

iii Trans PULSE found that past-year suicide attempts were 27% in those who wanted to undergo a medical transition but were not yet able to start or find a provider to help them. Past-year suicide attempts decreased to 1% in trans people who, by their own definition, had "completed" a medical transition.[27]

Our Criteria for Hormone Therapy

- Diagnosis of Gender Dysphoria
- Psychosocial readiness to begin treatment
- Completion of a period of assessment including appropriate physical and laboratory investigations
- Absence of absolute contraindications
- Optimal mitigation of risks related to pre-existing health conditions
- Client understanding of risks, precautions and side effects of treatment

The Gender History

Speaking with clients about their history and experience with gender is not something that healthcare providers are typically taught during their training. It is, however, an important part of getting to know a trans client and informs the discussion around the development of an individualized care plan. Below are suggestions for questions that may be asked to start the conversation regarding a client's experience of gender. It may be helpful to explain the rationale for obtaining this history, and to reassure the client that there are no 'wrong answers', nor any specific narrative that the provider is looking to hear. Not all trans people experience gender dysphoria or display gender non-conformity in childhood; trans identities may emerge at any point in the life cycle.

Possible questions to open the conversation about gender identity and expression:

- How would you describe your gender identity?
- Have there been changes to your gender identity over time?
- What was puberty/adolescence like?
- How does your gender identity impact how you feel about work, relationships, family, or other aspects of your life?
- If you could change your external appearance in any way you wanted, what would this look like in terms of your gender?
- Have you taken any steps to change your outward appearance to make it more closely match your identity? If so, what was that like for you?
- How do you want to be perceived in terms of your gender?
- What are your feelings about the parts of your body that are often associated with gender (e.g. genitals, chest/breasts)?
- What leads you to want to start hormones at this time in your life?
- Which changes are you most looking forward to? Are there any changes you are not sure about?

Source: Adapted from Endocrine Therapy for Transgender Adults, Vancouver Coastal Health, 2006[29]

Diagnosis

The provision of hormone therapy is generally preceded by a diagnosis of Gender Dysphoria as outlined in the Diagnostic and Statistics Manual, Volume 5 (DSM-V-TR).[30] There has been a great deal of debate in both the medical and trans communities around the appropriateness of using a psychiatric diagnosis for trans individuals. The recent revisions of the diagnosis (previously called Gender Identity Disorder) and associated diagnostic criteria in the DSM-V represent a step towards depathologizing gender difference and validating the spectrum of gender identity and expression. Certainly, there is potential for stigmatization and mistreatment of trans people if they are seen to have a psychiatric illness. However, there is also the ability to provide good care, make appropriate interventions, and guide research efforts based on the diagnosis. Thus, for many providers, the use of a psychiatric diagnosis is not meant as judgment or stigmatization of trans individuals, but as a tool to defend appropriate medical intervention and treatment.

The criteria for the DSM-V-TR diagnosis of Gender Dysphoria[30] are as follows:

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months duration, as manifested by at least two of the following:
   1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics).
   2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).
   3. A strong desire for the primary and/or secondary sex characteristics of the other gender
   4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
   5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
   6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

In addition to establishing this diagnosis, it is recommended that the provider work to rule out other psychiatric diagnoses that may explain the presentation. Possible differential diagnoses include schizophrenia and other psychotic disorders, dissociative disorder and internalized homophobia. If the presentation is unclear, it is appropriate to get the opinion of a psychiatrist. Care should be taken to refer to a psychiatrist who has some experience in gender dysphoria. If the presentation is clear, however, consultation with psychiatry is not necessary. The Gender Identity Clinic (GIC) at the Centre for Addiction and Mental Health (CAMH) currently has a wait list of approximately 18 months, and as such, discourages providers from referring uncomplicated clients for hormone assessments, as this results in a potentially unnecessary delay in treatment.

Psychosocial Readiness

Psychosocial readiness to begin treatment is a subjective assessment, well suited to the primary care provider. Gender transition can be a phase of significant adjustment in the life of the client. Like any major life stressor, the aim is to ensure the client has supports that facilitate healthy adjustment. When available, we recommend the client consider a support group setting (such as "Gender Journeys").[iv] The client may benefit from individual therapy with a trans-positive therapist with whom to discuss concerns about the transition process and to receive psychological support. Though not a requirement for the initiation of cross-gender hormone treatment, we encourage clients to discuss the transition with family members and friends as they too will have their own reactions and be affected by the client's transition. Inquiring around how transitioning will influence the vocational or educational situation of the client is important, as providers can help the client develop strategies for dealing with gender change in school or the workplace. Unfortunately, it is not uncommon for transition to result in the loss of a job or struggle in the academic setting.[v]

Possible questions to open the conversation about psychosocial readiness:

- Who makes up your support system? How readily accessible are they?
- Do you know anyone else who has transitioned? What were the major struggles they had? How can you address those issues?
- What are the challenges you foresee with your family/friends?
- How will you manage your transition at work/school?

In the past, the WPATH group had advocated for a 3-month period of life experience in the congruent gender role prior to cross-sex hormone therapy. This step was developed to establish coping mechanisms for the above-mentioned social stressors. This requirement for a 'Real Life Experience' has been shown to be both stressful and potentially dangerous for the client, as it requires them to adopt a gender role prior to acquiring any physical changes commensurate with that gender. Accordingly, there is no longer a requirement for a gender role experience of any duration prior to the provision of hormone therapy or surgical interventions with the exception of genital surgery and gonadectomy.[5]

The Assessment Period

At Sherbourne Health Centre, new clients are usually seen for a period of 2-3 months, during which the client has a number of visits in order to assess and optimize readiness for hormone therapy. This period allows the provider to become acquainted with the client, to make the appropriate diagnoses, and to rule out contraindications to treatment. It also allows the client to become more informed about the process, clearly understand the risks and benefits of hormone treatment, and to become accustomed to regular meetings with health care providers – a necessary component of ongoing treatment.

A Suggested Progression of Steps

It is more important that the tasks of the assessment period are completed, than a certain number of visits logged or period of time elapsed. The following progression of steps is a suggestion for how the tasks of the assessment period may be structured, but certainly does not need to be rigidly followed. In the absence of complicating factors, the assessment may be completed in relatively few visits; for example, tasks for Steps 1 and 2 may be combined into a single visit, as well as Steps 4 and 5. While this outline may be particularly helpful for those without a lot of experience with hormone prescribing, it may be adapted and individualized as the provider becomes more familiar and comfortable with the process. See Appendix A for a checklist designed for use at the point-of-care.

iv Gender Journeys is an 11-week psycho-educational program that was developed at Sherbourne Health Centre and has been running since 2005. The program is run by two trans-identified facilitators, and explores topics related to transition. Copies of the manual for this program can be downloaded for free from: **www.rainbowhealthontario.ca/resources/**

v See Rainbow Health Ontario's Fact Sheet 'We've Got Work To Do: Workplace Discrimination and Employment Challenges for Trans People in Ontario' available at **www.rainbowhealthontario.ca/resources/**

Step 1: General medical intake, initial discussion of gender history. Attempt to get old records from previous provider(s) if this is a new client. Review the outline and rationale for the assessment period.

Step 2: More detailed gender history including childhood gender presentation, experience of puberty, current expression/understanding of gender. Discussion of client's physical transition goals. Explore supports and determine reaction of family and friends to client's gender identity. Discussion of the potential effects of exogenous hormones on fertility and offer referral to fertility clinic to discuss options for fertility preservation as indicated.
Submit Exceptional Access Program (EAP) form if client is on the Ontario Drug Benefit (ODB) Program (discussed below).

Step 3: Full physical exam including appropriate screening measures commensurate with client's biological sex. Height, weight, abdominal and waist circumference should be included in the vital signs, and chest and hip measurements can be considered for trans women. Blood work should be performed to evaluate liver function, lipid profile, fasting glucose, blood cell analysis, +/- renal function. Hormonal profile may be considered (to rule out intersex conditions and exogenous hormone administration).

Step 4: Discussion around expected physical changes with hormone provision – reversible versus irreversible; desired versus nuisance. Discuss the side effects and risks associated with hormone treatment. Give consent form for client to review (See Appendices K-M).

Step 5: Review risks of treatment and obtain consent.
Choose initial hormone regimen.
Assess client interest in gender affirming surgery.

The physical exam, like the general periodic health exam, is used to rule out dysfunction of a major body system and to offer opportunities to prevent and screen for disease. Many trans clients have avoided medical practitioners because of fear of mistreatment or stigmatization, thus have often not had routine screening maneuvers employed. Also, screening tests of the breasts and genitals are often very uncomfortable for trans clients. Nonetheless, a full physical is generally a prerequisite to hormone administration; and if carefully explained to the client ahead of time, it can act as a rapport-building experience.

The exam should include investigations for problems such as hypertension and obesity, which increase the risks of hormone therapy. Genital exam[vi] will provide routine screening and, if normal, will help rule out an intersex condition. Presence of an intersex condition (e.g. congenital adrenal hyperplasia) merits consultation with an endocrinologist prior to treatment. In younger clients, these examinations will also establish the pubertal Tanner stage. Adolescent clients who have not reached Tanner stage 5 should be referred to a pediatric endocrinologist or specialized clinic such as the Transgender Youth Clinic at The Hospital for Sick Children or the Diversity Clinic at the Children's Hospital of Eastern Ontario, as initial treatment options may include pubertal suppression by a GnRH analogue.

Laboratory tests should reveal any existing health problems such as liver dysfunction, high cholesterol, or diabetes. If present, these conditions should ideally be managed prior to starting hormones. The values will also provide a useful baseline to help with future monitoring for endocrine changes. Measurements of hormone levels may reveal whether any exogenous hormones are being taken; any major irregularities could also indicate an intersex condition. If this is a concern, chromosomal analysis or endocrine consultation may be indicated prior to starting hormones. An EKG should be completed if the client is over age 40, and a stress test should be considered if any additional risk factors for coronary artery disease are present.

General Precautions and Client Education

Each hormone will have its own specific considerations and precautions; however, it is worthwhile to address general considerations and precautions with hormone use.

Lifestyle Considerations and Mental Health

Smoking and obesity will increase the risks associated with hormone therapy. It is worthwhile for the provider and client to work to decrease these risks as much as possible, thus an exercise program, or smoking cessation program are recommended. Completion of these programs is not always feasible before starting treatment, and a

vi Any client with a cervix who has been sexually active with another person (and falls within standard cervical screening recommendations) should be encouraged to undergo a Pap test. If the client has not been sexually active with any partners, a speculum exam and Pap are not needed. For male-bodied clients, a testicular exam is suggested. Consider offering a chaperone to the client for genital exam, especially when it will be difficult for the client. In cases where the client feels they cannot tolerate the procedure, it may be necessary to carefully explain the risk of not having the exam (e.g. cervical cancer) and allow the client to refuse it. In this case, the client may begin hormone treatment without the examination. The provider should revisit the issue periodically.

harm reduction approach may be necessary. Substance use disorders – whether involving alcohol, illicit or prescription drugs – may introduce additional risks that should be considered.[vii]

Acute suicidality has previously been considered an absolute contraindication to hormone administration, particularly testosterone. The observations of the Trans PULSE study, which demonstrate higher rates of suicidality prior to hormone administration with decreasing rates following access to transitional treatments, begs a reconsideration about future best practice. Certainly if a client is in acute crisis such that the provider feels they are unable to provide informed consent, this would constitute an absolute contraindication. If an acute safety issue exists, hospitalization may be necessary, and this would certainly become the immediate priority for the primary care provider.

There may be cases however, where a client who is at significant risk of suicide, but is able to provide informed consent, may in fact benefit greatly from the initiation of hormone therapy. This may be particularly true when intense gender dysphoria is the main source of the psychological distress experienced by the client.

We suggest that these types of situations may be best approached on a case-by-case basis, with an assessment of the risks and benefits of hormone provision in relation to the individual client's mental health. There may be situations in which the best course of action would be to start the client on low-dose therapy while strategizing around suicide risk reduction, for example by establishing a crisis plan and connecting the client with additional mental health support. If a client is experiencing a major depressive episode, pharmacotherapy for clinical depression should be discussed.

Trans clients invariably experience some degree of minority stress. Adapting Meyer's definition of minority stress in lesbian, gay, and bisexual populations,[31] minority stress in the trans population may be thought of as the chronic psychological strain resulting from stigma and expectations of rejection and discrimination, decisions about disclosure of gender identity, and the internalization of transphobia that trans people face in a cissexist society. Minority stress may be associated with the adoption of unhealthy behaviours such as smoking, and excessive substance and alcohol use. In addition, gender dysphoria may impact a person's relationship with their body and contribute to the development of unhealthy behaviours. The prospect of aligning the body with internal sense of gender may create an opportunity for a client to begin to develop a new relationship with their body and to initiate lifestyle changes that positively impact the body's health. We have often witnessed this time of change provide the impetus and inspiration for lasting positive lifestyle changes.

Fertility and Birth Control

Fertility issues must be discussed prior to hormone use. For trans men, pregnancy is a contraindication to testosterone use and the client must take precautions against becoming pregnant while taking it. Clients who are sexually active with people with sperm should be counselled on contraceptive options including progesterone-only oral contraception or an intrauterine device (IUD). Anecdotally, it may be easier to insert an IUD prior to initiating testosterone, due to the subsequent atrophic changes of the vaginal and cervical tissues.[32]

If testosterone is initiated, the provider should check in with the client periodically regarding their sexual behaviour and reiterate the necessary precautions should the client become sexually active with people who produce sperm. If accidental pregnancy does occur, counselling regarding options for pregnancy termination should be provided. It may be helpful for the provider to directly contact a local abortion clinic to ensure that the client will be received appropriately. While many trans men have become pregnant intentionally after discontinuing testosterone to pursue pregnancy, clients may wish to consider postponing testosterone initiation if they would like to become pregnant in the future, since fertility may be permanently affected. Another option, although costly and potentially stressful, includes ova harvesting followed by ova or embryo cryopreservation. Associated costs are highly variable depending on the degree of ovarian stimulation required by the individual client.

Transgender women should also be cautioned regarding the need for birth control if sexually active with partners who may become pregnant, since hormonal impact on fertility in trans women is also variable. Clients should be advised to bank sperm prior to starting hormones if they suspect they may wish to have children in the future. The cryopreservation of sperm is much less costly than the harvesting and cryopreservation of ova. However, in both scenarios, budgeting in the short and the long-term for the upfront and ongoing storage costs will be required.

vii Like lesbian, gay and bisexual populations, trans populations have higher than average rates of substance use disorders. Screening for drug use should always be part of the initial evaluation. Unfortunately, there are few treatment programs targeted to trans people specifically, and it may be difficult or even dangerous for a trans person to enter a mainstream treatment program. Larger cities may have Alcoholic Anonymous and Narcotics Anonymous groups with an LGBT focus. In the Toronto area, **Rainbow Services at CAMH** provides counselling and treatment services that are tailored to the needs of LGBT clients.

Cost is often a significant barrier to seeking fertility preservation. We are hopeful that OHIP coverage will soon be extended to trans people for fertility preservation. In this case, it is likely that some fees will still apply. Currently, some hospital-based clinics such as Mount Sinai Hospital's Centre for Fertility and Reproductive Health, may offer a discounted rate for medically necessary gamete preservation and subsequent fertility treatment, such as in the case of gender transition. If indicated, referral to a fertility clinic should be initiated early in the hormone assessment period as this process takes time. For more information on current fertility options for trans people, see Rainbow Health Ontario's Fact Sheet '**Reproductive Options for Trans People**'.[33]

Hair Removal

An additional cost consideration for trans women who have already gone through male puberty is the removal of facial (and, in some cases body) hair using laser treatments and/or electrolysis. While hormone administration may slow the growth of hair, it will not substantially reduce the amount of facial (or other body) hair that trans women possess. These services are also not presently covered by OHIP and it can be a challenge to find a provider who is both sensitive to the trans client and able to work within fixed budgets. Permanently eliminating the bulk of facial hair may cost up to several thousand dollars and this should be discussed up-front and considered in the timeline of the client's medical and social transition.

Sexuality

Exogenous hormones may affect not only libido, but may in fact have an impact on sexual attraction. The client may notice an expansion of their sexual interests or a shift in their sexual orientation, which can be transient or permanent. This is often unforeseen and may create challenges for existing relationships.

This effect has been most commonly noted with masculinizing therapies,[34] but should be discussed as a possibility in all clients considering hormone therapy. Integrating a respectful ongoing sexual health history is helpful in assessing for changes in risks for sexually transmitted infections and unplanned pregnancy.

Client Expectations

It is the role of the prescribing clinician to help the client develop reasonable expectations about the treatment before it is initiated. Firstly, changes associated with hormones can be slow. It may take years to exhibit secondary sex characteristics. Secondly, the underlying body structure will not change with hormones. Trans women will maintain narrow hips and existing facial bone structure. Trans men will also maintain pre-transition facial and body structure. Additionally, feminizing hormone therapy does not affect the pitch of the voice in trans women. Hormonal treatment of adults cannot impact a person's height. For these reasons, people may not easily "pass" as the sex they are transitioning to. This can be very stressful and disheartening to some individuals, and should be foreseen and tactfully discussed by the provider. It may be helpful to provide the client with a copy of the estimated timelines for hormonal effects, while emphasizing that physiologic response to hormone therapy is highly individual (See Tables 2 and 7).

Finally, there are resources available on the Internet that espouse a "more is better" approach to hormone administration. This approach is neither better nor safe. It is the clinician's role to explain the risks with overuse of hormones, as well as to provide rationale for the approach he, she, or they are using. As previously stated, the prescribing clinician must act within his/her/their comfort level as well as in the interest of the client.

Capacity to Consent

As with any other medical intervention, clients must demonstrate an understanding of the risks and benefits of hormone treatment. Obtaining informed consent is a process that primary care providers engage in daily, and when prescribing hormones to trans clients, the same basic principles apply.[35] Questions may arise around capacity to consent in individuals with cognitive or development disabilities, mental health and substance use challenges, or younger clients.

As there is no specific age determining when an individual is eligible to provide consent for medical interventions in Canada, it is thus determined on a case-by-case basis and at the discretion of the provider.[35] If there are persistent concerns regarding a client's capacity to consent, a referral to a psychiatrist familiar with gender dysphoria may be helpful. In addition to considerations around consent, when working with vulnerable individuals, particular care should be taken to ensure that adequate social supports are in place.

Harm Reduction and Fast-tracking

Provision of hormone treatment may be undertaken, in some cases, without definitively establishing a diagnosis of Gender Dysphoria or excluding other possible diagnoses. This is primarily under the rubric of harm reduction; namely, there are situations wherein it would cause harm to the client if treatment were delayed. Examples of this would include a client who is using illicit hormones already, or someone who has marked distress regarding their gender presentation. In trans women, the early initiation of an anti-androgen often carries little risk, is generally not associated with irreversible changes, and can be helpful in alleviating some distress while the remainder of the assessment is completed.

Other situations may warrant a degree of 'fast-tracking' through the assessment period. This includes instances in which the client and their medical and/or gender history are well known to the provider prior to the client seeking hormone therapy. Similarly, if another knowledgeable provider has recently performed part or all of the assessment and the associated records are available for review or a conversation with the prior provider can be arranged, all tasks of the assessment period need not be repeated. Clients must be able to attend regular appointments with the medical team. When this capacity is not assessed by virtue of a series of assessment visits, the client can instead contract with the provider to return for regular follow-up exams and blood tests.

Referrals and Advocacy in Support of Trans Clients

As with cis clients, trans clients often seek assistance from their primary care provider in order to access services and supports they may need. When supporting trans clients, it may be helpful to be familiar with some of the most common requests. This section provides an overview of the referrals and support letters that primary care providers are frequently asked about. Samples can be found in Appendices N through R.

Gender Affirming Surgery - Referrals

Clients often express a sense of urgency around accessing gender affirming surgery (GAS) as it is seen as an integral way of alleviating some aspects of gender dysphoria. If a client is 18 or older and wishes to access funding through the Ontario Health Insurance Plan (OHIP) for GAS, referral to the Gender Identity Clinic at the Centre for Addiction and Mental Health (CAMH) should be made as soon as possible. CAMH is the only approved assessor site for OHIP-covered GAS and thus there is a lengthy wait list. OHIP-covered surgeries currently include chest reconstruction, hysterectomy and bilateral salpingo-oophorectomy, metaoidioplasty, and phalloplasty for trans men, and orchiectomy and vaginoplasty for trans women. Once the provider submits the CAMH Adult Referral Form (available online at **www.camh.ca**) to CAMH's centralized intake, the client will receive a questionnaire in the mail. The client will be placed on the wait list once the completed questionnaire is received by the GIC.

Because there are some limitations with respect to the specific surgeons OHIP will provide coverage for, some clients may choose to pay directly for GAS, provided they have the resources. In such instances, providers may be asked to provide a letter of support to the surgeon stating the client's diagnosis (i.e. of gender dysphoria) and recommending the client as an appropriate candidate for GAS. In most cases, surgeons will also require a letter from a qualified mental health professional with familiarity in working with trans clients.[5] A list of providers (including mental health professionals) with knowledge and experience in working with trans clients may be found through Rainbow Health Ontario's online service directory.[viii]

Hormone Coverage with Ontario Drug Benefits - Exceptional Access Program (EAP) Forms

For clients covered by the Ontario Drug Benefit (ODB) program, oral estrogen (Estrace, Premarin) and intramuscular (IM) testosterone are covered with the submission of an Exceptional Access Form (EAP) (See Appendices N and O, respectively). We suggest submitting the EAP application early in the process of assessment given that the processing time by the Ministry of Health and Long Term Care is variable and may take two months or more. Approval does not commit the provider to prescribing hormone therapy but prevents undue delays once the assessment period is complete. **Blank EAP forms can be downloaded from the Ontario Ministry of Health and Long-term Care website.**

Changing Sex Designation on Government ID - Support Letters

Medical providers have historically played a significant role as gatekeepers to changing one's sex marker on various forms of government-issued identification documents. While having had GAS is no longer a requirement for changing one's sex marker in Ontario, primary care providers still frequently provide letters of support attesting to the fact that they agree a change in sex designation is appropriate. Appendices P and Q provide sample letters that can be used as a basis to

viii See **www.rainbowhealthontario.ca/service-directory/**

draft letters of support for clients seeking to change the sex marker on their Ontario birth certificate and driver's license, respectively. Beyond the support letter, clients will also have to provide other documentation and forms of identification. Clients seeking information about the precise requirements may be directed to Rainbow Health Ontario's fact sheet on these processes.[ix]

Clients Seeking Employment Insurance Benefits - Support Letters

Being trans does not, in and of itself, constitute a permanent disability. That said, the conflux of gender dysphoria with profound experiences of cissexism and transphobia in the workplace can make working through parts of one's transition not only difficult, but potentially unsafe. While beyond the scope of this document to explore fully, a number of factors shape why some clients face particularly difficult challenges when transitioning in the workplace. These include: the type of work that they may be doing (e.g. if it is a very gendered workplace); their role and relationship to other staff and management (i.e. transition can exacerbate pre-existing tensions); the extent to which they need to work with the general public (i.e. encountering more persons every day leads to more opportunities to experience transphobia or cissexism); the extent to which an individual is able to be 'assumed cis' (or pass as cis) in their day-to-day lives; and variations in resiliency and social support unique to each client.

Gender dysphoria can be time limited for some, alleviated by their social and/or medical transition, and it can be persistent for others. For many trans clients, their everyday challenges improve with time over one's transition; however for others, these challenges can persist.

In particularly challenging cases, providers may choose to write a letter of support to assist clients in applying for Employment Insurance if they have left work with 'just cause'. Alternatively, some clients may be able to access short-term disability benefits through their workplace benefits package. Appendix R provides an example of a support letter that the provider can use as a starting point in developing letters for specific clients accessing these supports.

Clients may ask for support letters in other instances, such as carrying injectable medication and supplies internationally, confirming that a client has a particular diagnosis, or the completion of a guarantor form. In general, since these are not significantly different from those for cis clients they have not been included here.

ix See **www.rainbowhealthontario.ca/wp-content/uploads/2015/03/Changing-Sex-Designation-on-Documents-in-Ontario-.pdf**

Part II: Feminizing Hormone Therapy

The goal of hormone therapy in transgender women is to reduce the endogenous effects of testosterone such as coarse body hair and facial hair; and to induce female secondary sex characteristics such as breast and hip development. Physiologically, this requires a suppression of endogenous androgens and the addition of estrogen. This treatment results in both reversible and irreversible feminization.[36] Irreversible components are breast development and possibly loss of fertility. More reversible changes include thinning of body hair and skin changes. Fat redistribution is generally considered a reversible effect but some degree may be irreversible.

Anti-Androgens

Because of the potential for serious side effects with estrogen (reviewed below), one of the goals of therapy is to achieve the client's goals for feminization with the lowest possible dose of estrogen. This goal is achieved with the use of androgen-suppressing agents; androgen suppression can be started prior to estrogen administration. The effects of anti-androgens may generally be considered reversible. The most common anti-androgens used at our Centre are spironolactone and cyproterone.

Spironolactone is commonly used as a potassium-sparing diuretic; it also has anti-androgenic effects through blockage of peripheral androgen receptors. Because its major action is androgen blockade, it will not always effect a significant change in blood testosterone levels. However, it has a minor action through interference with testosterone conversion to active dihydrotestosterone (DHT). Exercise caution when using spironolactone with medications that may contribute to hyperkalemia (e.g. trimethoprim-sulfamethoxazole (Septra), ACE inhibitors, Angiotensin receptor blockers) or in health conditions that may result in increased potassium-retention (e.g. mild renal dysfunction). Spironolactone is contraindicated in clients with significant renal dysfunction and as such, cyproterone (or orchiectomy) should be considered in this setting. Common side effects of spironolactone include dizziness and gastrointestinal symptoms.[37]

Cyproterone has progestational activity; and often has a more rapid suppression of testosterone than does spironolactone. It acts primarily through androgen-receptor blockade, but also inhibits production of luteinizing hormone (LH) via negative inhibition of the hypothalamic pituitary axis. Cyproterone is more expensive than spironolactone (see Table 1). It has been noted to cause severe liver dysfunction (with high dose extended use) and depression (in early treatment). Thus, it should not be used in people with hepatic disease and caution should be taken when used in clients with a history of depression.

We have traditionally started with spironolactone preferentially as it was thought to have a superior safety profile. This practice has recently come in to question as anecdotally some clinicians have noted adequate anti-androgen effects and testosterone suppression into the female range with lower doses of cyproterone (i.e. 25 mg daily) at which adverse effects are less likely. In the absence of sufficient data to guide the preferential choice of one anti-androgen over another, the decision should be made individually for each client based on their medical history and preference regarding respective side effect profiles. If an adequate response is not achieved with maximum doses of the chosen agent, or side effects prohibit its titration to adequate effect, we suggest initiating a trial of the alternative agent (in the absence of contraindications). It should be noted that the long-term use of anti-androgens in the absence of exogenous estrogen may negatively affect bone mineral density.

Table 1.
Options and recommended doses of anti-androgens in feminizing therapy

	Starting Dose	Maximum Dose	Cost* (4 weeks)
Spironolactone	50 -100 mg OD	200 mg BID	$16.56[a] - $40.58[b]
Cyproterone	25 - 50 mg OD	100 mg OD	$32.98[c] - $101.92[d]

a 50mg OD given as 2 x 25mg tablets OD;
b 200mg BID given as 2 x 100mg tablets BID;
c 25mg OD given as ½ x 50mg tablet OD;
d 100mg OD given as 2 x 50mg tablets OD
* Price quotes are provided by **www.pharmacy.ca**. The above-mentioned prices are accurate as of February 4th, 2015 and represent the price for a 4-week supply of a generic brand of medication. Prices include a usual and customary dispensing fee of $9.99 that may vary from pharmacy to pharmacy.
Note: For clients on ODB, spironolactone and cyproterone are covered without the submission of an EAP form.

Other options for suppressing endogenous androgens include GnRH analogs (leuprolide or "Lupron") and nonsteroidal anti-androgens, such as flutamide. Leuprolide can be used in adults or adolescents undergoing gender transition to suppress GnRH.[38] If this medication is being considered, we would recommend consultation with an endocrinologist. Flutamide has also been reported for use in trans women.[29] It has been reported to have hepatotoxic effects and thus it is not used at our clinic.

If anti-androgens are contraindicated or result in significant side effects, another option is the removal of the major source of endogenous testosterone, i.e. orchiectomy. For trans women who are waiting for or unable to access vaginoplasty (as a part of which orchiectomy is routinely performed), orchiectomy alone is a choice that may be considered.

Progestins

With the exception of cyproterone, the use of progestins in trans women continues to be controversial.[36] There has not been a clear feminizing benefit shown with the use of progestins,[23] although some individuals and some clinicians feel it has been a useful adjunctive medication. Progestins have a suppressive effect on LH, thus decreasing androgen production. It is used by some clinicians for clients experiencing decreased libido and may have a positive or negative impact on mood.[36]

The common side effects associated with progestins are weight gain, depression, and edema. The Women's Health Initiative has examined serious long-term outcomes with combined estrogen and progestin in post-menopausal women. The 2007 updates support the original findings, which were increased incidence of breast cancer, increased strokes and blood clots, and increased heart disease.[39] These same outcomes were not found to the same extent with estrogen alone. These risks may be higher with medroxyprogesterone than with micronized progesterone. In addition, the latter may be better tolerated and have a more favourable impact on the lipid profile than medroxyprogesterone.[40]

If used, the common doses of progestins are micronized progesterone 100-400mg daily; or medroxyprogesterone acetate 5 – 30mg daily. Some clinicians advise limiting progestin treatment duration to a maximum of two to three years. Because it is not part of our regular protocol, if a progestin is being considered, some of our clinicians will have the client sign an additional consent form acknowledging that they specifically understand the increased risks and lack of established benefit (See Appendix L).

Estrogen

Estrogen acts directly on estrogen receptors to initiate feminization. Because of this, it is usually the focus of hormonal transition for trans women. However, in order to achieve adequate suppression of androgens, estrogen alone would need to be administered in higher doses, with associated increased risks. Thus, the combination of an anti-androgen and estrogen is the favoured approach.

The effects and expected time course of a regimen consisting of an anti-androgen and estrogen are shown in the Table 2. The degree and rate of physical effects is dependent on the dose, route, and medications used (which are selected in accordance with a client's specific medical goals and risk profile)[40], as well as client-specific factors such as age, genetics, body habitus and lifestyle. As previously mentioned, feminizing therapy does not affect the pitch of the voice in trans women. Some clients may obtain benefit from voice therapy with a qualified and supportive speech and language therapist who can work with the client to modify their vocal characteristics.

At our Centre, the most common form of estrogen administered to trans women is oral estradiol (Estrace). It has a preferable safety profile compared to conjugated estrogen (e.g. Premarin), and is now covered by the Ontario Drug Benefit (ODB) program. with an Exceptional Access Program (EAP) request (See Appendix N).[x]

Table 2.
Effects and expected time course of feminizing hormones

Effect	Expected Onset	Expected Maximum Effect [a]
Body fat redistribution	3-6 months	2-5 years
Decreased muscle mass/strength	3-6 months	1-2 years[b]
Softening of skin/decreased oiliness	3-6 months	Unknown
Decreased libido	1-3 months	1-2 years
Decreased spontaneous erections	1-3 months	3-6 months
Erectile dysfunction	Variable	Variable
Breast growth	3-6 months	2-3 years
Decreased testicular volume	3-6 months	2-3 years
Decreased sperm production	Variable	Variable
Thinned/slowed growth of body/ facial hair	6-12 months	>3 years[c]
MPB[d] (no regrowth, loss stops)	1-3 months	1-2 years

a Estimates represent published and unpublished clinical observations
b Significantly dependent on amount of exercise
c Complete removal of male facial and body hair requires electrolysis, laser treatment, or both
d Male Pattern Baldness
Sources: Hembree et al., 2009[41]; Feldman and Safer, 2009[40]

Unlike conjugated estrogen, estradiol is readily measurable in the bloodstream. All oral formulations are subject to first pass liver metabolism. Because transdermal and intramuscular formulations bypass liver metabolism, they are thought to have fewer hepatic side

x Previously only Conjugated Equine Estrogen (Premarin) was covered by ODB.

effects. Transdermal estradiol seems to have an even better overall safety profile than oral estradiol, and is thus recommended for transgender women who are over 40 or have risk factors for cardiovascular or thromboembolic disease. This decreased risk has been demonstrated in both post-menopausal women and transgender women.[42,43,19] Unfortunately, transdermal estradiol is significantly more expensive, and only covered by ODB under extreme circumstances such as inability to swallow. Private drug plans will often cover it however.

Injectable estrogens (in the form of estradiol valerate) are available in Ontario through some compounding pharmacies for intramuscular injection. This formulation is not subject to hepatic first pass metabolism, and has the benefit of weekly or bi-weekly administration. Some clients prefer this route of administration, and report faster breast development than with oral medications. Because of the fluctuation of estrogen levels with injection, it is likely not as safe as the transdermal route. However, in otherwise healthy young clients, it is a possible alternative.

Table 3.
Formulations and recommended doses of estrogen for feminizing hormone therapy

	Starting Dose	Maximum Dose	Cost (4 weeks)
Conjugated Estrogen*	0.625mg OD	1.25mg OD	$20.01[e]
Estradiol (oral)*	1-2mg OD	4mg OD	$18.53-$40.14[f]
Estradiol (transdermal, patch)*[g]	0.1mg OD/ apply patch 2x/week	0.2mg OD/ apply patch 2x/week	$39.97-$69.95[h]
Estradiol valerate*** injectable (IM)[i]	10mg q 2/52	10mg q 1/52	$14.20-28.40

e the cost of 28 tablets of Premarin® 0.625mg or 1.25mg is the same
f 4mg OD given as 2 x 2mg tablets
g Estradot® brand
h 0.2mg OD given as 2 x 100mcg patches applied twice weekly (4 patches/week)
i given as 1mL of 10mg/mL Estradiol valerate
* Price quotes provided by **www.pharmacy.ca**
** estradiol valerate IM must be prepared by a compounding pharmacy, price quote provided by Pace Pharmacy
The above-mentioned prices are accurate as of February 4th, 2015 and represent the price for 4 weeks' supply of a generic brand of medication where available (unless indicated otherwise). Prices include a usual and customary dispensing fee of $9.99 ($10.99 for Pace), which may vary from pharmacy to pharmacy.

Clients who have had orchiectomy and/or vaginoplasty, may have different hormone requirements to maintain feminization. We recommend that transgender women achieve androgen suppression for 6 to 12 months prior to undergoing orchiectomy. The testicular volume can be expected to decrease roughly 25% in that time.

Post-operatively, most transgender women will not require androgen suppression by spironolactone or cyproterone. The androgen-blocker can be tapered over the course of 4-6 weeks or more post-operatively. Ongoing estrogen supplementation will be required to preserve bone strength. Younger clients may require the same dose of estrogen post-operatively as they did pre-operatively, however, older clients may be able to be maintained on a lower (i.e. starting) dose.

In clients over 50 years old who have been on estrogen for several years, doses may be reduced to those administered to post-menopausal cis women (i.e. 0.025mg – 0.05 mg patch). For women starting transition over 50 years old, an 'active period' of treatment with suggested doses used for younger women may be considered following a thorough assessment and discussion of relative risks and benefits.

Absolute Contraindications to Estrogen Therapy:

- Unstable ischemic cardiovascular disease
- Estrogen-dependent cancer
- End stage chronic liver disease
- Psychiatric conditions which limit the ability to provide informed consent
- Hypersensitivity to one of the components of the formulation

Precautions and Risk Mitigation with Estrogen Therapy:

Estrogen has a more serious risk profile as compared to other medications used in trans clients. The potential negative outcomes of estrogen therapy have been illustrated in both post-menopausal females and trans women.[28,39] The largest group of study clients on hormonal therapy has been through the Women's Health Initiative, which looked at a large cohort of menopausal cisgender women. This study showed an increased incidence of breast cancer, heart disease, and stroke. The greatest increase was seen with a combination of estrogen and a progestin as opposed to estrogen alone.[39]

Several pre-existing medical conditions and risk factors may increase the risks associated with estrogen administration. When these are present, a careful evaluation of risks and benefits should be completed and

fully discussed with the client. All reasonable measures should be taken in order to reduce the risks associated with the particular condition. Table 4 summarizes the precautions (i.e. relative contraindications) with estrogen therapy as well as suggested measures that may be taken by the primary care provider to minimize these risks including the involvement of specialists if available. A number of these precautions are expanded upon below.

Venous Thromboembolism

Historically, studies on trans women have revealed a significant increase in thromboembolic events with estrogen administration. Many of the women in the original studies evaluating thromboembolic risk were taking ethinyl estradiol, which is now known to be significantly more thrombogenic than estradiol.[19] Thus, the risk of thromboembolic events when using estradiol, especially in transdermal form, is significantly less than the risk reported in these older studies.[43] Risk is significantly increased in clients who are over age 40, smokers, highly

Table 4.
Precautions with estrogen therapy and suggested measures to minimize associated risks

Precaution to Estrogen Therapy	Suggested Measures to Minimize Associated Risks
Stable ischemic cardiovascular disease*	Consider referral to cardiology, ensure optimal medical (including prophylactic anticoagulation) and/or surgical management as indicated, aggressive risk factor optimization, use transdermal route of administration +/- lower dose
Cerebrovascular disease*	Consider referral to neurology, ensure optimal medical management (including prophylactic anticoagulation) and aggressive risk factor optimization, use transdermal route of administration +/- lower dose
Personal history of DVT or PE, hypercoagulable state	Identify and minimize co-existent risk factors, consider prophylactic anti-coagulation, consider referral to hematology, use transdermal route of administration +/- lower dose
Marked hypertriglyceridemia	Identify and address barriers to optimal lipid control, refer to dietician, minimize alcohol consumption, consider anti-lipemic pharmacologic therapy, consider endocrinology referral, encourage deferral of estrogen until controlled, consider transdermal route of administration
Uncontrolled high blood pressure	Identify and address barriers to optimal BP control, use spironolactone as anti-androgen, add additional antihypertensives as needed (avoid ACEs/ARBs with spironolactone), encourage deferral of estrogen until controlled, consider cardiac stress test, consider transdermal route of administration
Uncontrolled diabetes	Identify and address barriers to optimal glycemic control, refer to dietician, encourage lifestyle modification, initiate antiglycemic agent(s), encourage deferral of estrogen until controlled, consider cardiac stress test, consider transdermal route of administration
Smoker	Encourage and support smoking cessation, offer NRT and/or bupropion/varenacline, or negotiate a decrease in smoking, consider lower dose, consider cardiac stress test, use transdermal route of administration
Family history of abnormal clotting	Consider referral to hematology, rule out genetic clotting disorder, consider prophylactic anticoagulation, use transdermal route of administration
Metabolic syndrome	Dietary and medical management of component disorders, encourage deferral until components adequately managed, consider cardiac stress test, consider transdermal route of administration
Severe, refractory or focal migraine*	Consider referral to neurology, consider daily migraine prophylaxis, ensure all other cerebrovascular risk factors are optimized, consider transdermal route of administration
Seizure disorder	Consider referral to neurology, consult with a pharmacist re: impact of estrogen interaction with anticonvulsant medication
Other cardiac disease	Consider referral to cardiology
Hyperprolactinemia	Refer to endocrinology, defer initiation until etiology determined, manage based on etiology
History of benign intracranial hypertension	Consider referral to neurology/ neurosurgery
Hepatic dysfunction	Dependent on etiology, eg. minimize alcohol consumption, weight loss in NAFLD, consider referral to hepatology/ GI, use transdermal or injectable route of administration
Strong family history of breast cancer	Refer to genetics/familial breast cancer program for further risk stratification and BRCA1/2 testing as indicated
Personal or Family history of porphyria (rare)	Consider referral to porphyria clinic or internist with experience in porphyria

* imparts moderate to high risk of an adverse outcome without risk mitigation [40]

sedentary, obese, and who have underlying thrombophilic disorders. It is suspected that the risk is highest in the first 1-2 years on treatment. Transdermal formulations should be used whenever possible in clients with one or more of the risk factors above. Routine screening for thrombophilic disorders prior to estrogen initiation is not recommended and should be restricted to those with a personal or strong family history of deep vein thrombosis/ pulmonary embolism (DVT/PE).[44] If the existence of a thrombophilic disorder is known or identified, prophylactic anticoagulation can be considered as part of a careful risk/benefit analysis.

It is currently common practice to discontinue estrogen therapy 2-4 weeks prior to surgical procedures including vaginoplasty due to the presumed increased risk of DVT/ PE. The necessity of this practice has recently come into question by some experts who cite a lack of evidence in addition to suspecting a strong association between hormone cessation and post-operative depression. More research is needed to address this question. In the meantime, we encourage our clients to discuss hormone cessation recommendations with their surgeon. In general, post-operatively, estrogen can be restarted once the client is ambulatory.

Cardiovascular and Cerebrovascular Disease

Historically, studies of menopausal women on oral conjugated estrogens have shown an increased number of cardiac events in the first one to two years of hormone replacement, with a decrease in subsequent years.[45] The (conjugated) estrogen-only arm of the WHI trial demonstrated an increase in cerebrovascular events but not cardiac events.[39] It is unclear whether these effects extend to estradiol preparations, which have shown a reduced risk of venous thromboembolic events. In their 2009 literature review, Feldman and Safer summarized the existing evidence as follows "estrogen use increases the risk of cardiovascular events in clients over age 50 with underlying cardiovascular risk factors. Additional progestin use may increase this risk."[40]

Estrogen may impact individual cardiovascular risk factors. The risk of hypertension is possibly increased: systolic and diastolic blood pressures may be slightly increased but the impact on overt hypertension is unknown.[40] Furthermore, impact is likely dependent on type of estrogen; conjugated estrogens (e.g. Premarin) and ethinyl estradiol appear to increase blood pressure while estradiol may even decrease blood pressure.[46] The risk of diabetes type II is possibly increased, particularly with the presence of additional risk factors.[47] While there is minimal impact on LDL and HDL, there is likely a significantly increased risk of hypertriglyceridemia with oral estrogen.[48, 44, 40]

Accordingly, we recommend the aggressive management of vascular risk factors prior to and during estrogen administration. We agree with the UCSF Centre for Excellence in Transgender Health recommendation to maintain systolic BP ≤130 mmHg and diastolic BP ≤90 mmHg. Spironolactone should be used preferentially for androgen blockade in clients whose blood pressure is of concern.[18] Cholesterol should also be aggressively managed. Unfortunately, Framingham calculations are less reliable with exogenous hormone use. It is reasonable to consider using high-risk category lipid targets in trans women who have any significant risk factors for cardiac disease. Individuals at high risk for developing cardiovascular disease should be offered aspirin as primary prevention. While oral estrogen causes an increase in triglyceride levels, transdermal estrogen is neutral in this regard and should be used preferentially if hypertriglyceridemia is an issue.

Breast Cancer

There have been case reports of transgender women developing both benign and malignant breast disease while on hormonal therapy.[24,49,50,51] How this risk compares with that of cis women or cis men has been a matter of debate. Longer duration of feminizing hormone exposure (i.e. number of years taking estrogen), family history of breast cancer, obesity (BMI >35), and the use of progestins likely increase the level of risk.[40] Those with a strong family history of breast and/or ovarian cancer should be referred to a familial breast cancer program and should undergo genetic screening for BRCA 1/2 as indicated.

Hyperprolactinemia/Prolactinoma

Estrogen use increases the risk of hyperprolactinemia in trans women, especially during the first year of treatment. It is unclear whether estrogen increases the risk of prolactinoma or promotes the clinical appearance of pre-existing but clinically unapparent prolactinoma. There is also the potential for estrogen to mask the symptoms of a prolactinoma as they are similar to the desired effects of estrogen.[22,23,24] Elevated prolactin at baseline should be investigated prior to initiating estrogen.

Liver/Gallbladder

Estrogen may be associated with transient liver enzyme elevations and, rarely, clinical hepatotoxicity.[40] Base-line elevation in liver enzymes should be investigated and any existing hepatic disease optimized prior to the initiation of estrogen therapy. Intramuscular and transdermal routes are preferable in those with pre-existing liver disease given that they bypass first pass metabolism by the liver. Estrogen use also increases the risk of cholelithiasis and subsequent cholecystectomy.[40]

Seizure Disorders and Anticonvulsant Therapy

Hormones appear to influence seizure occurrence by multiple mechanisms. Higher estrogen levels in particular are associated with an increased frequency of seizures in cisgender women.[52] Consultation with a neurologist can be considered in those with pre-existing seizure disorders.

In addition, some anticonvulsant drugs impact estrogen metabolism via induction of the CYP450 isoenzyme, resulting in the accelerated conversion of estrogen to inactive metabolites. Of the common anti-convulsants used in Canada, phenobarbitol, phenytoin, carbamazepine, and topiramate are all CYP450 inducers, whereas valproic acid, gabapentin and lamotrigine do not appear to interact with estrogen.[53] If a client is on a CYP450 inducing anticonvulsant for a seizure disorder, neuropathic pain, or mood stabilization, it is reasonable to consult a specialist or pharmacist to inquire about switching to a non-inducer or considering dosage adjustments prior to the initiation of estrogen.

Monitoring and Dose Adjustments

Standard monitoring of estrogen administration should be employed at baseline, 1 month, 3 months, 6 months and 1 year. This should include a functional inquiry, targeted physical exam, bloodwork, and health promotion/disease prevention counselling as indicated. The suggested tasks for each of these follow-up visits are summarized and expanded upon in Appendix B.

Functional inquiry should include noted positive or negative impacts on mental health as well as any noted physiologic changes. Changes related to androgen blockade and estrogen administration may take months. The first changes will likely be loss of spontaneous and morning erections. Breast development, skin and hair changes, and fat redistribution take longer. Generally, physical changes are considered to be complete after 2-3 years on hormone therapy (See Table 2). At every visit, the clinician should review risks of treatment and counsel around monitoring for signs and symptoms of venous thromboembolism. Clients should be reminded about the importance of adequate Calcium and Vitamin D intake.

Physical examination should include manoeuvres commensurate with the physical attributes of the client. Examination should also include blood pressure, weight, abdominal and waist circumference, liver palpation, and examination of the extremities.

Blood work should be completed according to Table 5 below, with more frequent monitoring as deemed necessary if concerns are identified.

Table 5.
Recommended blood work for monitoring feminizing hormone therapy

Test	Baseline	1 Month	3 Months	6 Months	12 Months
CBC	X	X	X	X	X
ALT/AST[a]	X	X	X	X	X
Creatinine/ Lytes/Urea[b]	X	x	x	x	X
Fasting Glucose	X				X
LDL/HDL/TG	X			X	X
Testosterone (+/- Estradiol)	X	X	X	X	X
Prolactin[c]	X	x	x	x	X
LH[d]	x				x
Other	Hep ABC				

a for Ontario providers who may be restricted in ordering OHIP-covered AST levels, ALT alone may be used to screen for liver dysfunction
b Cr, lytes, urea need not be monitored at every visit unless the client is on spironolactone
c Prolactin should be monitored at least yearly, and more frequently if elevation is noted
d Elevated LH post-gonadectomy may have implications regarding bone mineral density (See Osteoporosis and BMD Screening)

Dose titration may be done over the course of a few months and will depend on client goals, physical response and measured suppression of testosterone. If an anti-androgen is started first, the clinician may look for early signs of feminization and loss of spontaneous erections as indication of successful treatment. Estrogen can be added after the first month of treatment. The starting dose of estrogen can be maintained for 1-2 months, after which a dose increase can be considered barring any concerning effects. It is important to note that the amount of breast tissue development is largely based on the genetic potential and body habitus of the individual, thus, increasing the dose of estrogen or changing the formulation may not result in significant differences. Clients may notice a more rapid increase of breast tissue with injectable estrogen.

Testosterone level may be the most useful test for monitoring in trans women; for many clients, the goal will be to achieve the suppression of testosterone into the female range (See Appendix J for Lab Reference Ranges). That said, the client may have clinically relevant results without total suppression of testosterone because of androgen blockade, which is not easily measured.

If the client is on an estradiol formulation, serum estradiol levels can be checked, however this is not always useful given the large range of estradiol levels throughout the menstrual cycle in premenopausal cis women. If misuse is suspected, this test can be helpful. According to the Endocrine Society Guidelines,[40] serum estradiol levels should not exceed the mean daily level for cis women (approximately 700 pmol/L). It is important to keep in mind that clinical effects are the goal of therapy, not specific lab values. Anecdotally, we have found that most clients attain considerable feminization at estradiol levels between 200-500 pmol/L. The measurement of estradiol levels may be unreliable depending on the assay used by the laboratory, and we have occasionally seen very high estradiol levels reported. In this situation, reviewing the dose with the client and the assay with the lab may be necessary. An alternate assay (e.g. at another lab) may also be helpful. When monitoring injectable estrogen, some clinicians prefer to check serum levels at trough (i.e. just before the next injection is due) while others prefer midcycle. There may be utility varying the timing of bloodwork to gather information regarding serum levels throughout the cycle.

Prolactin should be checked at least annually. As discussed above, estrogen use increases the risk of hyperprolactinemia in trans women - especially in the first year on treatment; and may increase the risk of prolactinoma with long-term treatment (>10 years). Mild hyperprolactinemia often resolves spontaneously thus while minimal elevations (<40 mcg/L) should prompt inquiry regarding outside sources of estrogen, they can be managed with observation (i.e. repeat hormone levels in 2-3 months). Significant hyperprolactinemia in the absence of prolactinoma typically resolves when the estrogen is reduced.[40] Thus, a trial decrease of estrogen dosage by ½ if prolactin is > 40 mcg/L and a full taper off estrogen if >100 mcg/L, followed by a recheck in 6-8 weeks, is a reasonable approach. If the level does not decrease, an MRI of the sella turcica is indicated. If the level is falling, estrogen may be restarted at a lower dose and monitoring continued every 6-8 weeks.[14] Alternatively, some experts suggest an MRI of the sella turcica if the prolactin is >70 mcg/L.

Other Common Side Effects and their Management

Some trans women undergoing feminizing hormone therapy may experience fatigue and loss of libido, most likely as a result of androgen blockade and suppression. Those who have undergone gonadectomy may have free and total testosterone levels that are below the normal range for cis women. In this case, if a work-up for other causes of fatigue is negative and any contributing factors such as iron deficiency, hypothyroidism, or depression are optimally managed, one can consider supplementing with very small doses of topical testosterone (consider a lower concentration gel obtained through a compounding pharmacy) to bring serum levels into the female range. Dose ranges used in the treatment of sexual dysfunction is cis women may be used as a guide (typically 0.2 – 1mg of topical testosterone daily).

This must be done carefully, with close monitoring for any signs of masculinization. Serum levels should also be monitored closely until a therapeutic dose is established. Serum levels within the female range are unlikely to have significant metabolic implications. Such supplementation would be contraindicated in the presence of prostate or other androgen-sensitive cancer.

Sexual function in trans women on feminizing therapy who have not undergone vaginoplasty is variable. Loss of erectile function is common and although may be welcome for some, others may wish to retain sexual function. Phosphodiesterase-5 (PDE-5) inhibitors (e.g. sildenafil or tadalafil) can be helpful for trans women wishing to maintain erectile function. Contraindications and precautions apply as per cis men.

Long-term Preventive Care Recommendations for Trans Women

The long-term follow-up of trans women on feminizing hormone therapy should involve (at least) annual preventive care visits. Preventive Care Checklists© endorsed by the College of Family Physicians of Canada exist for cisgender clients[54], but use of these forms for trans clients is awkward and can lead to missed elements important in their comprehensive primary care. We have assembled recommendations for ongoing primary care of trans women into an Adapted Preventive Care Checklist for Transgender Women (See Appendix D), with accompanying explanations for trans-specific recommendations (See Appendix E) that can be accessed at the point-of-care. The use of these trans-specific forms assumes familiarity with the original forms and their explanations. The original forms contain graded evidence-based recommendations, which may or may not be the same for trans clients. Grades of evidence for individual recommendations have not been included on the adapted forms. The recommendations represent an effort to incorporate expert opinion, relevant research on cisgender populations, and limited trans-specific evidence, with standard National and Provincial primary care practices.

Recommendations regarding the impact of feminizing hormone regimens on bone mineral density, and the implications for breast and prostate cancer screening warrant further discussion and are elaborated on below. See above for discussion regarding the risk of prolactinoma.

Osteoporosis and BMD Screening

Sex hormones are well known to effect bone mineral density (BMD), and the subsequent risk of osteoporosis. A hypogonadal state induces loss of bone in both cis men and cis women.

Somewhat surprisingly, serum estradiol levels show a stronger association with BMD than testosterone levels. Although a recent study found a lower BMD in trans women prior to estrogen therapy when compared with age-matched cis men,[55] it is likely that bone support will be adequate in trans women who are maintained on estrogen. In accordance with national recommendations, bone mineral density testing should be offered to all people over age 65, and screening to find people at higher risk of osteoporosis can begin at age 50.[56] If the client has other risks for bone loss (including glucocorticoid therapy, previous fracture, and family history of osteoporosis), BMD screening should be offered sooner.

One small study suggested that LH level may be associated with bone density in clients who have undergone gonadectomy, that is, if LH is elevated, the client may not be achieving adequate hormonal support for bone maintenance.[25] Thus, bone mineral density testing may additionally be considered in agonadal clients with elevated LH. If the client has undergone orchiectomy and has been off hormones for any significant length of time, BMD screening should be performed. Lastly, BMD screening may be considered in those who have been on anti-androgens for a significant length of time without the co-administration of exogenous estrogen.

All trans women should ensure a daily intake of 1000 IU Vitamin D and 1200 mg of Calcium (total of diet + supplements). Weight-bearing exercise (i.e. exercise that involves moving the body against gravity) should also be encouraged. For those wanting to maintain muscle strength but minimize muscle bulk development, weight lifting with high repetitions and lighter weights is suggested.

Bisphosphonates should be considered in the circumstance that a trans woman has undergone orchiectomy and is not able to be maintained on estrogen therapy.

Breast Cancer and Mammography

Estrogens stimulate epithelial growth and the development of acini and lobules in the breasts of transgender women. There have been case reports of trans women developing breast cancer on hormone therapy,[57] but how this risk compares with that of cis women or cis men has been a matter of debate. A US-based cohort study published earlier this year[58] and a similar study out of the Netherlands[49] suggest that the risk in trans women on estrogen is comparable to that in cis men. The authors state however that the duration of the studies may have been inadequate to detect an increased incidence, as a longer duration of hormone exposure has been postulated to contribute to increased risk. Risk is likely increased by family history of breast cancer, obesity (BMI >35), and the use of progestins.[40] Annual clinical breast examination as a part of routine breast cancer screening is of questionable utility, but may be useful in trans women to assess the degree of breast development or to assess for implant complications if the client has undergone breast augmentation.

Recommendations for initiation and frequency of screening mammography in trans women vary between organizations. Some suggest screening as per cis women[40] while others recommend screening only in the presence of significant risk factors.[18] A recent study which assessed the feasibility and acceptability of screening mammography in trans women found that screening was technically possible, nearly painless, and of high personal importance.[59] In general, our approach is to consider mammography in trans women every 2 years if >50 and on estrogen for >5 years, and to consider initiating screening at a younger age if additional risk factors are present. Given the absence of consensus in this regard, an emphasis may be placed on client preference following a thorough discussion of the risks and benefits of screening. Trans women who have changed their OHIP gender marker to 'Female' can be screened as part of the organized Ontario Breast Screening Program and as such will receive correspondence letters for invitations, follow-up on abnormal results, and reminders. The presence of implants necessitates the technical approach of a diagnostic mammogram rather than routine screening mammography.[59] Trans women should receive counselling around breast self-awareness as recommended for cis women.

Prostate Cancer

The risk of prostate cancer is not increased by estrogen use, in fact it is reasonable to assume that the risk is significantly decreased by the associated androgen deprivation. Although rare, there have been cases of prostate cancer reported in trans women, generally occurring in those who started hormone therapy after the age of 50.[22,24] It is important to note that estrogen will lower PSA values even in the presence of prostate cancer, thus impacting its utility in this population. Routine PSA screening is not recommended in trans women in the absence of significant risk factors. There is little evidence to support a role for annual DRE in prostate cancer screening; however, it may be considered according to a provider's routine practice with cis men. In clients who have undergone vaginoplasty, the prostate remains in situ and may be palpated anteriorly via digital vaginal exam in a gender affirming lithotomy position.

Part III: Masculinizing Hormone Therapy

Testosterone

The cornerstone of hormone therapy for transgender men is testosterone. The goal of treatment is virilization – development of masculine secondary sexual characteristics. Desired androgenic effects of testosterone therapy include deepened voice, cessation of menses, clitoral growth, increased muscle mass, and hair growth in androgen dependent areas including facial hair.[60] Breast tissue may lose glandularity, but generally does not lose mass or hemi circumference.[61] Voice changes and clitoral growth are irreversible changes. Fat redistribution is generally considered a reversible effect but some degree of redistribution may be irreversible. Fertility is decreased - this, however, is variable. It is important not to make assumptions about the type of sex a client may be having: if clients are having penetrative sex with cis men or preoperative trans women, a permanent method of birth control should be employed. All clients regardless of current sexual practices should be counselled regarding the teratogenic impact of testosterone and the risk of pregnancy.

Typically, clients taking testosterone develop a male phenotype over a period of months to years. The timeframe of physiologic changes may be slightly slower with the use of transdermal preparations. Menses should cease in the first 6 months of therapy. If they are ongoing at this point, testosterone dosage may need to be increased. In clients who prefer low-dose testosterone, or occasionally in clients using transdermal preparations, a progestin may need to be added to achieve cessation of menses.[62] Some clients may wish to have cessation of menses without significant virilization. For these individuals, a progestin may be administered independently, either in the form of injectable birth control, or with the insertion of a levonorgestral-releasing intra-uterine device (e.g. Mirena). Similarly, GnRH analogs (leuprolide or "Lupron") could be used to suppress menses and the expression of endogenous female hormones. A weaker androgen, danazol, is sometimes used to arrest menses and to achieve very mild virilization. As with testosterone, some parts of the virilization process may be irreversible. This pertains to voice changes, androgenic alopecia, and possible infertility. The doses used for danazol are 100-200 mg BID.

The effects and expected time course of testosterone are shown in Table 6. The degree and rate of physical effects is dependent on the dose and route of administration,[40] as well as client-specific factors such as age, genetics, body habitus and lifestyle.

Coarsening of body hair, as well as facial hair growth, begin soon after initiation of testosterone, but take a number of years to reach full growth. Clitoral growth usually begins in the first few months of therapy and may be accompanied by mild clitoral discomfort.

Table 6.
Effects and expected time course of masculinizing hormones

Effect	Expected Onset[a]	Expected Maximum Effect[a]
Skin oiliness/acne	1-6 months	1-2 years
Facial/body hair growth	3-6 months	3-5 years
Scalp hair loss	>12 months[b]	Variable
Incr. muscle mass/strength	6-12 months	2-5 years[c]
Body fat redistribution	3-6 months	2-5 years
Cessation of menses	2-6 months	n/a
Clitoral enlargement	3-6 months	1-2 years
Vaginal atrophy	3-6 months	1-2 years
Deepened voice	3-12 months	1-2 years

a Estimates represent published and unpublished clinical observations.
b Highly dependent on age and inheritance; may be minimal
c Significantly dependent on amount of exercise

Sources: Hembree et al., 2009[41]; Feldman and Safer, 2009[40]

In Ontario, options for testosterone administration include injectable and transdermal preparations (patch or gel). Injectable formulations are most commonly used, both because of their superior efficacy and lower price. The advantage of transdermal preparations is the relatively steady state of testosterone, as opposed to the fluctuations with injectables. If a gel formulation is used, clients should be counselled regarding the risk of inadvertent exposure to others who come into contact with the client's skin. This is of particular importance for clients with young children and/or with intimate partners who are pregnant or considering pregnancy. This risk can be relatively easy to mitigate by applying the gel to areas that will be covered by clothing, allowing the gel to dry prior to getting dressed, and thorough hand

N.B. Nurse practitioners (NPs) in Ontario are unable to prescribe testosterone due to its classification as a controlled substance; NPs providing trans care may opt to work collaboratively with a physician to overcome this restriction

washing following application.[63] Some clients prefer the Axiron™ formulation as it is applied directly to the axillae and thus may carry less risk of transfer. Although more expensive, transdermal formulations are often covered by occupational or other private drug benefit programs.

In Ontario, injectable testosterone is the form generally approved by the Ontario Drug Benefit (ODB) program with an Exceptional Access Program (EAP) request (See Appendix O). It is substantially cheaper than transdermal formulations, making it the preferred medication for most of our clients. If using an injectable formulation, it is advisable to teach the client how to self-inject the medication.[xi]

Table 7.
Formulations and recommended doses of testosterone for masculinizing hormone therapy

	Starting Dose	Maximum Dose	Cost Per Unit	Approx. Cost Per 4 Weeks
Testosterone enanthate (IM)	50mg q week or 100mg q 2 weeks	100mg q week or 200mg q 2 weeks	$69.03 per vial (each vial contains 200mg/mL x 5mL = 1000mg)	$13.81 - $27.60
Testosterone cypionate (IM)			$43.31 per vial (each vial contains 100mg/mL x 10mL = 1000mg)	$8.66 - $17.32
Testosterone (transdermal) Patch	2.5-5mg OD	5-10mg OD	$159.27 / 60 x 2.5mg patches $159.27 / 30 x 5mg patches	$74.33 - $297.30
Testosterone Gel (transdermal)[i]	2.5–5g OD (2-4 pumps, equivalent to 25-50 mg testosterone)	5-10g OD (4-8 pumps, equivalent to 50-100 mg testosterone)	$85.90 / 30 x 2.5g sachets $147.29 / 30 x 5g sachets $167.55 / 2 pump bottles[j]	Sachets $80.17 - $274.94 Bottles $78.19 - $312.76
Testosterone Gel (transdermal, axillary)[k]	1.5-3mL OD (1-2 pumps, equivalent to 30-60 mg testosterone)	3-4.5mL (2-3 pumps, equivalent to 60-90 mg testosterone)	$166.89 / pump bottle[l]	$77.88 - $233.65

i Androgel® 1% gel
j each pump bottle provides 60 doses of 1.25g (=12.5mg testosterone)
k Axiron™ 2% solution
l each pump bottle provides 60 doses of 1.5 mL (=30mg testosterone)

Price quotes provided by **www.pharmacy.ca**. The above-mentioned prices are accurate as of February 4th, 2015 and represent the price of the generic brand of medication where available (unless otherwise indicated). Prices include a usual and customary dispensing fee of $9.99, which may vary from pharmacy to pharmacy.

We tend to employ and teach the intramuscular route with the 'z-track' method to minimize seepage, however a subcutaneous route can be considered and may be less painful. Some surgeons may advocate for the topical application of testosterone to the clitoris as an adjunct to growth prior to metoidioplasty (surgical reconstruction of the hypertrophied clitoris to more closely resemble a penis). There is no definitive evidence for this practice and as such we do not routinely recommend it, however if undertaken, the applied dose should be subtracted from the client's total testosterone dosage.[63]

Absolute Contraindications to Testosterone Therapy:

- Pregnancy or breast feeding
- Active known androgen-sensitive cancer
- Unstable ischemic cardiovascular disease
- Active endometrial cancer
- Poorly controlled psychosis or acute homicidality
- Psychiatric conditions which limit the ability to provide informed consent
- Hypersensitivity to one of the components of the formulation

Precautions and Risk Mitigation with Testosterone Therapy

As with most medical interventions, a number of health risks have been postulated to be related to testosterone therapy. Several pre-existing medical conditions and risk factors may increase the risks associated with testosterone administration. When these are present, a careful evaluation of risks and benefits should be completed and fully discussed with the client. All reasonable measures should be taken in order to reduce the risks associated with the particular condition. Table 8 summarizes the precautions (i.e. relative contraindications) with testosterone therapy as well as suggested measures that may be taken by the primary care provider to minimize these risks including the involvement of specialists if available. A number of these precautions are expanded upon below.

xi A self-injection teaching video for clients created by Sherbourne Health Centre, "Taking Care of Business," is available to view on YouTube at **https://www.youtube.com/watch?v=PdIduQ4G20g**

Table 8.
Precautions with testosterone therapy and suggested measures to minimize associated risks

Precaution to Testosterone Therapy	Suggested Measures to Minimize Associated Risks
Stable ischemic cardiovascular disease	Consider referral to cardiology, ensure optimal medical (including prophylactic anticoagulation) and/or surgical management as indicated, aggressive risk factor optimization, consider transdermal route of administration +/- lower dose
Uncontrolled high blood pressure	Identify and address barriers to optimal BP control, initiate antihypertensive(s) as needed, consider cardiac stress test, encourage deferral of testosterone until adequately controlled
Uncontrolled diabetes	Identify and address barriers to optimal glycemic control, refer to dietician, encourage lifestyle modification, initiate antiglycemic agent(s), consider cardiac stress test, encourage deferral of testosterone until adequately controlled
Uncontrolled dyslipidemia	Identify and address barriers to optimal lipid control, refer to dietician, initiate antilipemic pharmacologic therapy, consider endocrinology referral, consider cardiac stress test, encourage deferral of testosterone until addressed
Hepatic dysfunction	Dependent on etiology, e.g. minimize alcohol consumption, weight loss in NAFLD, consider referral to hepatology/GI
Polycythemia	Refer to hematology, identify etiology and address contributing factors, consider low-dose ASA, strongly encourage deferral until adequately managed, consider transdermal route of administration, monitor RBCs/Hct closely
History of DVT/PE or hypercolaguable state	Identify and minimize co-existent risk factors, monitor RBCs/Hct closely, consider transdermal route of administration
Chronic respiratory disease that may be worsened by erythrocytosis/ polycythemia	Consider referral to respirology, monitor RBCs/Hct closely, consider transdermal route of administration
Severe/ uncontrolled sleep apnea	Initiate CPAP or oral device, encourage weight loss if overweight, consider uvulopalatoplasty, monitor for changes in CPAP pressure requirements
Androgen-sensitive epilepsy	Refer to neurology
Smoker	Encourage and support smoking cessation, offer NRT and/or bupropion/varenacline, or negotiate a decrease in smoking, consider cardiac stress test especially in the presence of additional risk factors, consider transdermal route of administration
Migraines	Consider referral to neurology, consider daily migraine prophylaxis, consider transdermal route of administration
Inter-menstrual bleeding	Consider pelvic ultrasound (transvaginal if possible), consider gyne referral - especially if significant risk factors for endometrial cancer
Oligo-/ Amenorrhea	Consider pelvic ultrasound (transvaginal if possible), consider progesterone-induced menstrual bleed prior to testosterone initiation

Metabolic Effects and Cardiovascular Disease

The prevalence of polycystic ovarian disease (PCOS) is higher in transgender men prior to use of testosterone when compared to cis women. This prevalence is estimated to be as high as 40%.[64] Administration of testosterone has been found independently to increase insulin resistance.[21] Additionally, long-term treatment of testosterone is associated with increased deposition of visceral fat.[29] These facts taken together suggest that transgender men may be at higher risk of metabolic problems before and after the administration of testosterone.

A review of the data in trans men in 2009 led Feldman and Safer[40] to conclude that testosterone therapy does not appear to increase the risk of diabetes mellitus type II (DMII) among trans men overall, but may further increase the risk in clients with other risk factors such as significant weight gain, family history, and PCOS. A subsequent case control study of 138 trans men did reveal a statistically significant increase in the incidence of DMII with testosterone.[47]

The risk of hypertension among trans men using testosterone is unclear, as data have been inconclusive. Cis women with PCOS (a hyperandrogenic condition) are known to be at an increased risk of hypertension.[64] It appears that testosterone therapy likely leads to a small increase blood pressure that is statistically significant but may not be clinically significant.[40] For example, a recent meta-analysis revealed an average increase in systolic blood pressure of 1.74 mmHg.[48] We agree with the UCSF Centre for Excellence in Transgender Health recommendation to maintain systolic BP ≤130 mmHg and diastolic BP ≤90 mmHg.[18]

Testosterone therapy appears to decrease HDL but variably affects LDL and triglycerides. Adverse effects may be worse with supraphysiologic doses. Clients with risk factors such as PCOS or existing dyslipidemia may be at increased risk of further abnormalities with testosterone administration. Again, while found to be statistically significant, it remains unclear whether changes are of clinical significance.[48] Transdermal formulations appear to be lipid-neutral,[40] and should be used preferentially in those with dyslipidemia and/or other significant risk factors for or pre-existing cardiovascular disease. In some cases, statins may be needed.

Recent data has shown a significant increase in cardiovascular disease (CVD) and cardiovascular (CV) events in older cis men prescribed hormonal therapy for testosterone deficiency.[66] It is important to note however that transgender men generally initiate exogenous

testosterone at a younger age and with significantly less medical comorbidity than the population in this study. Following a review of the available data in trans men in 2009, Feldman and Safer[40] concluded that masculinizing hormone therapy does not appear to increase the risk of CV events among healthy clients at normal physiologic doses, but may increase the risk of CVD in clients with underlying risk factors. A subsequent case control study of 138 trans men on testosterone for an average of 7.4 years revealed no increase in CVD or CV events.[47]

Data suggest that, as with estrogen treatment, risk stratification can be a highly useful concept to apply when assessing individual clients. Risk factor modification should be emphasized. Smoking cessation should be strongly encouraged, as well as a regular exercise schedule, healthy food choices, and the maintenance of healthy body weight. Unfortunately, Framingham calculations are less reliable with exogenous hormone use. It is reasonable to consider using high-risk category lipid targets in trans men who have any significant risk factors for cardiac disease. Individuals at high risk for developing cardiovascular disease should be offered aspirin as primary prevention.

Hepatic Dysfunction

Elevation of liver enzymes may occur with testosterone therapy. These elevations are generally transient if no other cause of hepatic dysfunction is present.[67] Baseline elevation in liver enzymes should be investigated and any existing hepatic disease optimized prior to the initiation of testosterone therapy.

Polycythemia

Testosterone increases renal erythropoietin production, which in turn induces increased marrow production of red blood cells. In trans men, high levels of serum testosterone may cause polycythemia (an increase in red cell mass) and erythrocytosis (an increase in red cell concentration). Higher blood viscosity may lead to increased risk of adverse vascular events in those with predisposing risk factors. The transdermal route of testosterone administration may decrease the risk of developing clinically significant erythrocytosis by virtue of steady delivery and avoidance of serum peaks.[68] Transdermal formulations should be used preferentially in those with a history of or risk factors for this problem.

Obstructive Sleep Apnea

Sleep apnea may be worsened or unmasked by testosterone therapy.[69,70] Those with risk factors and/or suggestive signs or symptoms of sleep apnea should be screened via sleep study. CPAP should be initiated prior to testosterone in those with clinically significant sleep apnea. As CPAP pressure requirements may change with masculinizing therapy, they should be reassessed periodically via sleep study following testosterone initiation.

Psychiatric effects

Mood changes can occur with testosterone; many clients describe a feeling of wellbeing associated with testosterone administration and a decrease in this wellbeing as it wears off. Typically, this is the reason clients prefer a 7-10 day injection schedule when using intramuscular formulations. The half-life of testosterone is 8-9 days, which corresponds to the timing of mood change in these clients. There have also been concerns about other mood changes with testosterone use. A small number of case reports and observational studies note psychiatric effects including hypomania, mania, increased aggression and psychosis with the use of testosterone and testosterone precursors.[40] These adverse events seem to be associated with higher doses or supraphysiologic serum levels of testosterone. Caution should be exercised in clients with uncontrolled bipolar disorder, a history of psychosis, or a strong family history of these problems. Transdermal preparations result in a steady serum testosterone level and may be preferred in clients prone to mood or other psychiatric disturbances.

Endometrial cancer

There is some debate regarding the impact of testosterone on the endometrium. PCOS, which is associated with higher levels of circulating endogenous androgens, has been associated with an increased risk of endometrial cancer.[71] Data seem to suggest that exogenous testosterone has one of two effects on the endometrial lining: in some individuals it may become atrophic and non-proliferating,[72,40] while in others it may lead to endometrial hyperplasia.[73,40] This may be due to individual differences in the degree of aromatization of testosterone to estrogen in the uterine tissues. The proliferative pathway theoretically confers an increased risk of endometrial cancer, however no cases in trans men have been reported in the literature to date.

Unexplained intermenstrual bleeding should be investigated in those considering testosterone, especially in the presence of other risk factors for endometrial hyperplasia and cancer. Clients who may have a thickened lining at baseline (eg. due to oligo- or amenorrhea) may also warrant investigation. A pelvic ultrasound may reveal previously unknown PCOS and can provide an estimate of the endometrial thickness. Some gynecologists advocate for the induction of a menstrual period for such clients prior to starting testosterone, with the rationale that it is preferable to start out with a thinner lining. This may be emotionally difficult for some trans men, however,

anecdotally, it may have the added benefit of decreasing the length of time to achieving complete cessation of menses in oligomenorrheic clients initiating testosterone.

Monitoring and Dose Adjustments

As with treatment for trans women, monitoring should be done at 1, 3, 6 and 12 months after starting therapy. This should include a functional inquiry, targeted physical exam, bloodwork, and health promotion/disease prevention counselling as indicated. The suggested tasks for each of these follow-up visits are summarized and expanded upon in Appendix C.

Functional inquiry should include noted positive or negative impacts on mental health including depressive symptoms, increased aggression, and anxiety as well as symptoms of hypomania, mania, or psychotic symptoms. It is useful to inquire about changes in libido and how the client is managing any change. Inquiry regarding physiological changes should include discussion of menstruation. It may take three months or longer to achieve complete cessation of menses. Time to cessation of menses may be somewhat slower with transdermal preparations.[62]

Once cessation is achieved, any vaginal bleeding without explanation (e.g. missed dose(s) or lowered dose of testosterone) warrants a full workup for endometrial hyperplasia and cancer including endometrial biopsy.

Clients should be reminded about the importance of adequate Calcium and Vitamin D intake and encouraged to participate in regular, moderate physical activity. With regular exercise, lean muscle mass tends to begin to increase soon after treatment begins. Clients should be advised to increase resistance in weight lifting slowly, as there has been evidence of tendon rupture with testosterone administration. This is likely due to the rapid increase of muscle mass without the ability for compensatory changes in the tendons.

Physical examination should include maneuvers commensurate with the physical attributes of the client. Examination should also include blood pressure, weight, waist and abdominal circumference, and liver palpation. Blood work should be completed according to Table 9, with more frequent monitoring as deemed necessary if concerns are identified. Because of the risk of polycythemia and liver inflammation, a complete blood count and liver enzymes should be measured on each occasion. Cholesterol profile should be measured every 6 months during the first year, given the potential impact on lipids.

Titration of doses will occur in the early phases of treatment (i.e. after bloodwork done at 1 or 3 months). When monitoring injectable testosterone, some clinicians prefer to check serum levels at trough (i.e. just before the next injection is due) while others prefer midcycle. There may be utility varying the timing of bloodwork to gather information regarding serum levels throughout the cycle.

For clients seeking maximum masculinization, the target dose will bring the free and total testosterone levels into the physiologic male range (See Appendix J for Lab Reference Ranges). It is important to keep in mind, however, that clinical effects are the goal of therapy, not specific lab values. If a client is happy with the rate and degree of masculinization, there is no need to increase the dose. Supraphysiologic levels should be avoided due to the increased risk of adverse events and side effects, as well the potential for the aromatization of excess testosterone into estrogen. Dose adjustment is warranted if supraphysiologic doses are measured at mid-cycle or trough.

As changes to the integument occur with testosterone administration, those on a transdermal formulation may require ongoing titration in order to maintain/obtain physiologic changes. Some men may require titration of topical testosterone such that they need to apply upwards of 6 or more pumps of gel daily. If clients are finding this cumbersome or 'running out' of surface area, many compounding pharmacies can create a higher concentration of gel (eg. 5% rather than the standard 1%) such that the volume applied is less. Axillary gel may also be considered in this circumstance.

Reduction of testosterone dose will need to be considered if monitoring reveals hepatic dysfunction or polycythemia.[xii] If polycythemia occurs in a client on intramuscular (IM) testosterone, minimizing the peak/trough associated with the injectable route may resolve the problem. This can be achieved by increasing the dosing frequency (for example 100 mg qweekly rather than 200 mg q2weeks), or by switching to a transdermal formulation. Clinically significant elevations in blood pressure or the lipid profile may be managed as in cis clients rather than necessitating dose reduction.

xii Hct >.5 L/L - results should be compared to the normal male range as with other sex-dependent parameters; if OHIP sex marker has not been changed, reported reference ranges may not be applicable

Table 9.
Recommended bloodwork for monitoring masculinizing hormone therapy

Test	Baseline	1 Month	3 Months	6 Months	12 Months
CBC	X	X	X	X	X
ALT/AST[a]	X	X	X	X	X
Fasting Glucose	X			X	X
LDL/HDL/TG	X			X	X
Testosterone	X	X	X	X	X
LH[b]	x				x
Other	Hep A,B,C, pregnancy test				

a for Ontario providers who may be restricted in ordering OHIP-covered AST levels, ALT alone may be used to screen for liver dysfunction
b Elevated LH post-gonadectomy may have implications regarding bone mineral density (See Osteoporosis and BMD Screening)

Other Common Side Effects and their Management

Many trans men will experience a significant increase or worsening of acne upon initiation of testosterone. This may be limited to the face, or may also involve the chest and back; in a minority of clients the acne may be severe. Acne is generally worse in the first few years of hormone therapy. Acne may be managed as for cis gender clients. Severe acne may also improve by changing the formulation, route, and/or frequency of testosterone. Dose reductions need only be considered once all treatments and alternatives have been exhausted.[63]

Androgenic alopecia may also occur as a result of testosterone therapy, and as is in cis men, is often genetically determined. Thinning is also related to the duration of therapy. Finasteride may be effectively used to treat male pattern hair loss in trans men by blocking the conversion of testosterone to DHT.[xiii] Clients considering this option should be counselled that this may also slow or stop facial hair growth. Minoxidil may alternatively be used as a topical agent applied to the scalp.[63]

Testosterone therapy may result in vaginal atrophy and dryness, particularly following oophorectomy. This may lead to discomfort or dyspareunia in clients who wish to have receptive penetrative vaginal sex. This may sometimes be improved with topical estrogen therapy as in postmenopausal cis women. Some systemic absorption does occur but is not likely sufficient to interfere with physiologic masculinization if testosterone is maintained. Caution as for any estrogen therapy applies.[63]

Some trans men may report significant pelvic pain secondary to uterine cramping following orgasm. The mechanism of this pain is poorly understood. Prevention may be attained through the administration of anti-inflammatory doses of an NSAID approximately one hour prior to sexual activity. Clients may also obtain some relief by adjusting testosterone route or frequency to minimize serum peaks and troughs. Definitive management with hysterectomy may also be an option, especially if other motivating factors for this procedure are present.

The peaks and troughs of serum testosterone associated with the IM route of administration may lead to fluctuations in energy and mood. Some men may report significant fatigue and poor mood as serum levels fall leading up to the next injection. If this is a problem, increasing the frequency of injections or changing to a transdermal route of administration in order to attain a more steady serum level is often helpful. An increase in libido and hypersexual behaviour can occur, and if distressing to the client, trial of an SSRI at low dose may be considered.[18]

Long-term Preventive Care Recommendations for Trans Men

The long-term follow-up of trans men on masculinizing hormone therapy should involve (at least) annual preventive care visits. Preventive Care Checklists© endorsed by the College of Family Physicians of Canada exist for cisgender clients[54], but use of these forms for trans clients is awkward and can lead to missed elements important in their comprehensive primary care. We have assembled recommendations for the ongoing primary care of trans men into an Adapted Preventive Care Checklist for Transgender Men (See Appendix F), with accompanying explanations for trans-specific recommendations (See Appendix G) that can be accessed at the point-of-care. The use of these trans-specific forms assumes familiarity with the original forms and their explanations. The original forms contain graded evidence-based recommendations, which may or may not be the same for trans clients. Grades of evidence for individual recommendations have not been included on the adapted forms. The recommendations represent an effort to incorporate expert opinion, relevant research

xiii The typical dose of Finasteride for androgenic alopecia is 1 mg per day. For those paying out of pocket, it is much more affordable to prescribe the 5 mg tablet and have the client carefully split the tablet and take ¼ tab daily

on cisgender populations, and limited trans-specific evidence, with standard National and Provincial primary care practices.

Recommendations concerning the impact of masculinizing regimens on bone mineral density and the implications regarding breast, cervical and ovarian cancer warrant further discussion and are elaborated on below. See above for discussion regarding endometrial cancer.

Osteoporosis and BMD Screening

Sex hormones are well known to effect bone mineral density (BMD), and the subsequent risk of osteoporosis. A hypogonadal state induces loss of bone in both cis men and cis women.

Somewhat surprisingly, serum estradiol levels show a stronger association with BMD than do testosterone levels. It is likely that the aromatization of testosterone to estrogen also contributes significantly to bone density in cis men.[74]

There is conflicting data on the effect of exogenous testosterone on bone mineral density. Some centers have found that testosterone does not seem to either increase or decrease BMD over time,[40,75,36] while others have found an increase in BMD after starting testosterone.[76] Some studies suggest that trans men are more at risk of osteoporosis than trans women, who are likely getting good bone support through estrogen.[19] As a result, recommendations for screening trans men tend to be more vigilant than for trans women.

The following **indications for BMD screening** in trans men are adapted from UCSF's Centre for Excellence in Transgender Health:[18]

- Trans men at any age having undergone oophorectomy and having been off exogenous hormones for any significant length of time
- <50 years old regardless of ovarian status if have taken testosterone for any significant length of time and have any other risk factors for osteoporosis
- >50 years old with ovaries intact and 5-10+ years on testosterone
- >50 years old post-oophorectomy and on testosterone >5 years
- >60 years old post-oophorectomy and on testosterone <5 years

Note: frequency of BMD screening will depend on the results of the initial scan

One small study suggested that LH level may be associated with bone density in clients who have undergone gonadectomy, that is, if LH is elevated, the client may not be achieving adequate hormonal support for bone maintenance.[36] Thus, as in trans women, bone mineral density testing may additionally be considered in agonadal clients with elevated LH.

All trans men should ensure a daily intake of 1000 IU Vitamin D and 1200 mg of Calcium (total of diet + supplements). Moderate and gradual weight-bearing exercise (i.e. exercise that involves moving the body against gravity) should also be encouraged. Bisphosphonates should be considered in the circumstance that a trans man has undergone oophorectomy and is not able to be maintained on testosterone therapy.

Breast Cancer and Screening

Testosterone therapy is not thought to significantly increase the risk of breast cancer in trans men.[40] Trans men who have undergone chest reconstruction in fact likely have a significantly lower risk than cis women as there is much less tissue present in which malignancy could develop, though there is residual breast tissue particularly in the axillary regions.

There are case reports, however, of trans men developing breast cancer on testosterone, even after chest reconstruction.[77,78] There is little evidence to support a role for annual clinical breast examination in breast cancer screening; however, it may be considered for trans men who have not undergone chest reconstruction according to a provider's routine practice with cis women.

For those who have undergone chest reconstruction, chest and axillary lymph node examination may be considered to assess for abnormalities in the remaining tissue, but again this is of questionable utility. If an abnormality is detected post-surgically by the client or by physical exam, ultrasound is recommended as an initial investigation given that mammography is technically impossible. Focused MRI may also be useful in the investigation of chest abnormalities in trans men who have undergone chest reconstruction. Trans men who have not undergone chest reconstruction should follow guidelines for screening mammography as for cis women. In the absence of other significant risk factors, no routine screening investigations are needed post-chest reconstruction. Breast/chest self-awareness should be encouraged for all trans men.

Cervical Cancer and Pap tests

Testosterone does not appear to impact the risk of cervical cancer. Transgender men with a cervix should be screened with pap smears following the guidelines for cis women. This examination may be emotionally difficult and/or painful for trans men. Several strategies may be employed to minimize the discomfort/trauma associated with this examination for some men (see Tips for Providing Paps to Trans men).[79] Barring contraindications, topical 2%

lidocaine jelly may be applied vaginally 5-10 minutes prior to the procedure in those who find speculum examination painful due to atrophic changes. It is important to note that a client is on testosterone on the cytology requisition in order to minimize histological misinterpretation. Inadequate samples are more common in clients on testosterone and repeat may be required.[80]

Ovarian Cancer

Analogous to cis women with elevated androgen levels, testosterone therapy in trans men may increase the risk of ovarian cancer, although evidence for this is limited. There have been a few cases of ovarian cancer in transgender men[24] but no long-term studies exist. Overall the evidence regarding the risk of ovarian cancer in trans men on testosterone is inconclusive.[40] Though evidence for their benefit in screening for ovarian cancer is limited, annual bimanual exam can be considered if ovaries are present, in accordance with the provider's routine practice with cis women.

Conclusion

Providing comprehensive primary care for trans clients can be an intensely rewarding part of family practice. The primary care provider is well suited to support and care for this population. Providers can apply their knowledge of hormone use in other populations (i.e. post-menopausal women and hypogonadal men) to clients using hormones for gender transition. Additionally, the continuity and scope of the primary care provider's relationship with the client are assets in providing this care.

Current recommendations regarding the provision of cross-sex hormone therapy and ongoing primary care for trans clients are informed by expert opinion, relevant data from the general population, and a small body of peer-reviewed trans-specific research. Large-scale studies of trans people and outcomes following cross-sex hormone administration are required to improve evidence-based care. As providers involved in the care of trans clients, we also have the opportunity to advocate for the allocation of research funds to address these gaps.

A review of the available literature, and the many combined years of experience at SHC and similar health centres suggest that cross-sex hormone therapy is a safe treatment for healthy trans adults. When existing medical conditions increase the risk of complications, measures can be taken to reduce the risk of an adverse outcome. The decision to initiate hormone therapy is a collaborative, client-centred process, and the potential risks of cross-sex hormones must be weighed against the risks of not treating clinically significant gender dysphoria. The emerging literature reinforces what we know from experience: that assisting trans clients in actualizing their gender identity can yield profound improvements in overall wellbeing.

As with many marginalized populations, care of trans clients requires cultural competence, which includes an understanding and awareness of the barriers to care. Wherever possible, it is advisable to make the clinic setting accessible to trans people. This may include staff training around common office issues that affect trans clients, such as the use of appropriate pronouns and discrepancy of presenting gender with the sex on a client's OHIP card. Anticipating these issues and strategizing around how to address them in advance in a way that affirms trans clients' gender identity (e.g. allowing non-legal chosen names, or not using titles such as "Mr." or "Mrs." on correspondence with all clients) can go a long way towards reducing stigmatization while increasing the comfort of trans clients in the medical setting.

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Note: Citations in-text and in this reference list are formatted in accordance with the International Committee of Medical Journal Editors (ICMJE) Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals available here: **http://www.nlm.nih.gov/bsd/uniform_requirements.html**

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Appendix A: Trans Care Assessment Period Checklist

The following is a tool to assist in undertaking assessments with new (or newly transitioning) trans clients in primary care settings who may be interested in or benefit from hormone therapy. This checklist is for clients who have completed puberty; if they have not, consider referral to a knowledgeable paediatric endocrinologist (For more info, see pg. 8).

NOTE: A "No" response does not necessarily preclude a client from being a candidate for hormone therapy however it does indicate an area that may need ongoing attention.

For tools related to primary care with trans clients more broadly, please refer to the Trans Preventive Care Checklists in Appendices D and F and Accompanying Explanations in Appendices E and G.

PG #'s/ APP	ITEM	YES/ DONE	NO	COMMENT
	CLIENT HISTORY			
5 7	Discussion of rationale for assessment period			
7	General medical intake & medical history			
7	Obtain/Review records from previous providers			
6	Obtain gender history (incl. childhood and puberty experiences)			
	BASELINE DATA			
8 B/C	Vitals (incl BP, Ht, Wt, Waist & Abdo circ.)			
8 B/C	Full physical exam			
8 18/27	Blood work (liver enzymes, lipids, fasting glucose, blood cell analysis, hormone levels, +/- renal function)			
8 D+E+(B)/ F+G+(C)	Health screening commensurate to age			
	CLIENT EDUCATION, READINESS & SUPPORTS			
4-5 (6)	Articulation of transition goals			
5 8-10 14+K+(L) /22+M	Risks + side effects, and ***potential benefits*** + expected changes (reversible vs. irreversible) associated with treatment discussed and client understanding demonstrated			
9-10	Effects on fertility and options for preservation discussed			
9	Pregnancy risk/options for contraception discussed & implemented if needed			

PG #'s/ APP	ITEM	YES/ DONE	NO	COMMENT
9-10 13+15 23	Potential costs (e.g. medication, hair removal, fertility) reviewed and considered			
7	Psychosocial readiness discussed			
(5) 10	Reasonable expectations expressed			
(5) 10	Possesses capacity to consent			
13-15 22-23	Medication options/routes reviewed			
(8) 11 N/O	EAP form submission (clients on ODB)			
	RISK MANAGEMENT			
8	EKG if over 40, EKG + cardiac stress test if additional risk factors			
(7) (9) 15/23	Absence of absolute contraindications			
(5) 8-9 16+(15-18)/ 24+(23-25)	Precautions optimally managed			
7 9	Psychiatric co-morbidity managed if present			
9	If smoker, smoking cessation counselling done			
	DIFFERENTIAL DIAGNOSIS			
7	Other possible diagnoses ruled out			
(5) 6	Meets criteria for Gender Dysphoria			
(6) 8	No evidence of intersex condition			
	FINAL / NEXT STEPS			
(10) 13-15+(18)/ 22-23+(26)	Choose initial hormone regimen			
10 K+(L)/ M	Consent Form signed			
(7) 11	Discuss interest in Gender Affirming Surgery (if yes, refer to CAMH)			

Appendix B: Hormone Monitoring Summary for Trans Women (Collaborative MD and Nursing Team)

	Baseline	Month 1	Month 3, 6, 9	Annual
Review	Contraindications and precautions to feminizing therapies, Old records, Mental Health[A], Education/Lifestyle counselling[B], Psychosocial[C], Bone health Health Maintenance[D]	Hormone effects, Spontaneous erections, Mental Health[A], Education/Lifestyle counselling[B], Psychosocial[C]	Review of hormone effects, Spontaneous erections, Mental Health[A], Education/Lifestyle counselling[B], Psychosocial[C]	*See Preventive Care Checklist for Trans Men and Accompanying Explanations (Appendices D & E)*
Exam	Full PE Measure: height, weight, waist & abdo circ., +/- breast, hips as per client preference	BP, weight, waist & abdo circ., Abdominal exam including liver palpation, Extremity exam	BP, weight, waist & abdo circ., Abdominal exam including liver palpation, Extremity exam, Measure breast and hips as per client preference	
Lab	*See Guidelines and Protocols for Hormone Therapy and Primary Health Care (p. 18, Table 5)*			
Other	EKG if over 40, EKG + cardiac stress test if additional risk factors	Vaccinate for Hep A & B, Td and Pneumovax as indicated, Consider HPV vaccine		

A Mental Health:

- Screen for depressive symptoms (including suicidality) and anxiety disorders
- Inquire re: symptoms of hypomania, mania, or psychotic symptoms
- Inquire re: current level of gender dysphoria and body image
- Screen for disordered eating
- Assess client interest in surgical treatments if not accessed
- Inquire re: libido/changes in libido

B Education/Lifestyle Counselling:

- Review healthy eating and general nutrition
- Adequate Calcium Intake – ensure a minimum intake of 1200 mg of Calcium daily (total: diet + supplements)
- Adequate Vitamin D – ensure 1000 IU of vitamin D daily
- Hormone Adherence – missed doses of estrogen impacts bone health if post-orchiectomy, while extra doses may lead to risks associated with supraphysiologic levels of estrogen
- Regular, moderate physical activity – encourage weight-bearing exercise for osteoporosis prevention as well as aerobic exercise
- Alcohol and other substances – inquire re: problematic use of substances including alcohol, cannabis, cocaine, opioids, hallucinogens, ketamine, ecstasy, and non-prescribed hormones; estrogen affects the metabolism of alcohol by the liver thus we suggest using the same safe-drinking guidelines for trans women as for cis women (see Canada's Low-risk Alcohol Drinking Guidelines[1])
- Smoking – cessation, stages of readiness, etc.
- STI Prevention – transgender women may be at high risk of STIs depending on behavioural factors; safer sex counselling and frequent screening (i.e. every 3 months) for those at high risk is imperative (for client-centred handout materials, see Brazen: a Trans women's Safer Sex Guide[2])
- Review the signs and symptoms of DVT and PE and advise immediate medical attention should these occur

C Psychosocial:

- An effort should be made to assess the impact of transition/trans identity on employment, housing, family, relationships, and economic wellbeing
- Social Supports – specific attention should be given to assessing the extent of a client's social supports, creating an opportunity to suggest additional resources if needed
- Name change/identification – assess client need/desire to change name and/or gender marker on identification and offer support for this process (see respective RHO Fact Sheets[3,4] and Appendices P & Q)

D Health Maintenance:

- Immunization history
- STI screening, HIV risk assessment and screening as indicated
- TB skin test as indicated

References:

1 Butt, P., Beirness, D., Gilksman, L., & Stockwell, T. Alcohol and health in Canada: a summary of evidence and guidelines for low-risk drinking. Ottawa: Canadian Center on Substance Abuse; 2011.
2 Brazen. Trans women's Safer Sex Guide© [Internet]. Toronto: The 519 Church Street Community Centre; 2013. Available from: http://orders.catie.ca/).
3 See www.rainbowhealthontario.ca/resources/
4 See www.rainbowhealthontario.ca/resources/

Appendix C: Hormone Monitoring Summary for Trans Men (Collaborative MD and Nursing Team)

	Baseline	Month 1	Month 3, 6, 9	Annual
Review	Contraindications and precautions to testosterone, Old records, Mental Health[A], Education/Lifestyle counselling[B], Psychosocial[C], Health Maintenance[D]	Hormone effects, Cessation of menses, Mental Health[A], Education/ Lifestyle counselling[B], Psychosocial[C]	Hormone effects, Cessation of menses, Mental Health[A], Education/ Lifestyle counselling[B], Psychosocial[C]	*See Preventive Care Checklist for Trans men and Accompanying Explanations (Appendices F & G)*
Exam	Full PE with PAP if indicated[E], Include height, weight, waist & abdo circ.	BP, weight, waist & abdo circ., abdominal exam including liver palpation	BP, weight, waist and abdo circ., abdominal exam including liver palpation	
Lab	Pregnancy test prior to 1st injection, *See Guidelines and Protocols for Hormone Therapy and Primary Health Care (p. 27, Table 9)*			
Other	EKG if over 40, EKG + cardiac stress test if additional risk factors	Vaccinate for Hep A & B, Td and Pneumovax as indicated, consider HPV vaccination series		

A Mental Health:

- Screen for mood changes including irritability, anger, depressive symptoms (including suicidality) and anxiety disorders
- Inquire re: symptoms of hypomania, mania, or psychotic symptoms
- Inquire re: current level of gender dysphoria and body image
- Screen for disordered eating
- Assess client interest in surgical treatments if not accessed
- Inquire re: libido/changes in libido

B Education/Lifestyle Counselling:

- Review health eating and general nutrition
- Adequate Calcium Intake – ensure a minimum intake of 1200 mg of Calcium daily (diet + supplements)
- Adequate Vitamin D – ensure 1000 IU of vitamin D daily
- Hormone Adherence – missed doses of testosterone will impact bone health if post-oophorectomy, while extra doses may lead to a host of problems associated with supraphysiologic levels
- Regular, moderate physical activity – weight-bearing exercise helps in osteoporosis prevention; to avoid tendon rupture, weight loads used in strength training should be increased gradually with an emphasis on repetitions and stretching
- Safe sex practices/STI counselling – trans men may be at high risk of STIs depending on behavioural factors; safer sex counselling and frequent screening (i.e. every 3 months) for those at risk is imperative (for client-centred handout materials, see Safer Sex for Transguys: A Guide for the Whole Spectrum[1] and PRIMED: The Back Pocket Guide for Trans men & the Men Who Love Them[2])
- Potential for pregnancy/need for birth control – trans men on testosterone may become pregnant even if menstrual suppression has been achieved and should be counselled in this regard; given that testosterone is a teratogen, reliable birth control should be instituted where pregnancy is a risk based on sexual activity
- Smoking – cessation, stages of readiness, etc.
- Alcohol and other substances – inquire re: problematic use of substances including alcohol, cannabis, cocaine, opioids, hallucinogens, ketamine, ecstasy, and anabolic steroids; trans men should follow the safe drinking guidelines as for cis women[3]

C Psychosocial:

- An effort should be made to assess the impact of transition/trans identity on employment, housing, family, relationships, and economic wellbeing
- Social Supports – specific attention should be given to assessing the extent of a client's social supports, creating an opportunity to suggest additional resources if needed
- Name change/identification – assess client need/ desire to change name and/or gender marker on identification and offer support for this process (see RHO Fact Sheets[4,5] and Appendices P & Q)

D: Health Maintenance:

- Immunization history
- STI screening, HIV risk assessment and screening as indicated
- TB skin test as indicated

E: Pap

- Follow cervical cancer screening guidelines as for ciswomen if the cervix is present
- Several strategies may be employed to minimize the discomfort/trauma associated with this examination for some trans men (see Tips for Providing Paps to Trans men)[6]
- Barring contraindications, topical 2% lidocaine jelly may be applied vaginally 5-10 minutes prior to the procedure in those who find speculum examination painful due to atrophic changes

References:

1 Cullen, J. Safer Sex for Transguys: A Guide for the Whole Spectrum [Internet]. James Cullen; 2004. Available from: http://www.scribd.com/doc/38989522/Safer-Sex-for-Transguys-A-Guide-for-the-Whole-Spectrum

2 Gay Men's Sexual Health Alliance. PRIMED: The Back Pocket Guide for Trans men and the Men Who Dig Them. Toronto: Gay Men's Sexual Health Alliance; 2009.

3 Butt, P., Beirness, D., Gilksman, L., & Stockwell, T. Alcohol and health in Canada: a summary of evidence and guidelines for low-risk drinking. Ottawa: Canadian Center on Substance Abuse; 2011.

4 See www.rainbowhealthontario.ca/resources/

5 See www.rainbowhealthontario.ca/resources/

6 Potter, M. Tips for Providing Paps to Trans Men, Sherbourne Health Centre, 2010, www.checkitoutguys.ca

APPENDIX D: PREVENTIVE CARE CHECKLIST FOR TRANSGENDER WOMEN

Prepared by: Dr. A. Bourns • Adapted from the Preventive Care Checklist Form © Dec 2010

For annual health assessments of Transgender Women, applying to patients who were born with male genitalia and have a gender identity that is female or on the feminine spectrum, who may or may not have accessed hormonal and/or surgical treatments for gender dysphoria.

Please note:
- **Bold** = transgender-specific considerations, see Explanation Sheet for detailed recommendations
- Unbolded items should be followed according to the original Preventive Care Checklist Form© and the Explanations for the Preventive Care Checklist Form© for cisgender men

(see Duerksen A, Dubey V, Iglar K. Annual adult health checkup: Update on the Preventive Care Checklist Form© Canadian Family Physician, 2012 Jan; 58:43-47.)

IDENTIFYING DATA:

Name: _____

Tel: _____

DOB: _____

Age: _____

Date of examination: _____

MEDICAL TRANSITION HISTORY:

Androgen Blocker:
☐ Spironolactone ☐ Cyproterone ☐ N/A

Estrogen ☐ Yes ◉ No

If Yes, Start Date: _____

Orchiectomy ☐ Yes ◉ No

Vaginoplasty ☐ Yes ◉ No

Breast Aug ☐ Yes ◉ No

CURRENT CONCERNS:

MENTAL HEALTH: **Screen for:**

Depression	☐ **Positive**	◉ **Negative**
Anxiety	☐ **Positive**	◉ **Negative**
Suicidal Ideation	☐ **Positive**	◉ **Negative**
Persistent Gender Dyshoria	☐ **Positive**	◉ **Negative**

LIFESTYLE/HABITS/PSYCHOSOCIAL:

Diet: _____

Fat/Cholesterol _____

Fiber _____

Calcium _____

Sodium _____

Exercise: _____

Work/Education: _____

Income Below Poverty Level: ☐ Yes ◉ No

Family: _____

Relationships: _____

Social Supports: _____

Smoking: _____

Alcohol: _____

Safe Guidelines ≤10/week, ≤2/day

Recreational Drugs: _____

Sexual History: _____

Family Planning/Contraception: _____

Name change/identification: _____

Sleep: _____

UPDATE CUMULATIVE PATIENT PROFILE:

☐ Family History ☐ Medications
☐ Hospitalizations/Surgeries ☐ Allergies

FUNCTIONAL INQUIRY:

HEENT: ☐ Normal
CVS: ☐ Normal
Resp: ☐ Normal
Breasts: ☐ Normal
GI: ☐ Normal
GU: ☐ Normal
Sexual Function: ☐ Normal
MSK: ☐ Normal
Neuro: ☐ Normal
Derm: ☐ Normal
Constitutional Sx: ☐ Normal

PHYSICAL EXAMINATION:

HR:_____ BP: _____ RR: _____
Ht: _____ Wt: _____ BMI: _____

Waist Circumference: _____
Hip Circumference: _____ Ratio: _____

Or: See EMR Vitals ☐

Eyes: _____
Snellen sight card R _____
L _____
Ears: _____
Whispered voice test R _____
L _____
Nose: _____
Neck/Thyroid: _____
CVS: _____
Resp: _____
Breast: _____
Abdo: _____
Ano-Rectum: _____
Genito-urinary: _____
Neuro: _____
Derm: _____
MSK/Joints: _____
Extremities: _____

EDUCATION/COUNSELLING:

☐ **review S/Sx DVT/PE**

BEHAVIOURAL
☐ adverse nutritional habits
☐ **adequate calcium intake (1200 mg daily diet + supp)**
☐ **adequate vitamin D (1000 IU daily)**
☐ **hormone adherence**
☐ **regular, moderate physical activity**
☐ avoid sun exposure, use protective clothing
☐ **safe sex practices/STI counseling**

OBESITY - (BMI > 30) ☐ YES ◉ NO
☐ weight loss counselling
☐ **screen for mental health contributors**
☐ multidisciplinary approach

UNDERWEIGHT - (BMI < 18) ☐ YES ◉ NO
☐ **screen for eating disorders**

SMOKING ☐ YES ◉ NO
☐ smoking cessation
☐ nicotine replacement therapy/other drugs
☐ dietary advice on fruits and green leafy vegetables
☐ referral to validated smoking cessation program

ALCOHOL & OTHER SUBSTANCES: ☐ YES ◉ NO
☐ case finding for problematic substance use
☐ counselling for problematic substance use

ELDERLY ☐ YES ◉ NO
☐ cognitive assessment (if concerns)
☐ fall assessment (if history of falls)

ORAL HYGIENE
☐ brushing/flossing teeth
☐ fluoride (toothpaste/supplement)
☐ tooth scaling and prophylaxis
☐ smoking cessation

PERSONAL SAFETY
☐ hearing protection
☐ noise control programs
☐ seat belts
☐ **injection safety**

PARENTS WITH CHILDREN ☐ YES ◉ NO
☐ poison control prevention
☐ smoke detectors
☐ non-flammable sleepwear
☐ hot water thermostat settings (<54°C)

	21-64 YEARS	>65 YEARS
LABS/INVESTIGATIONS:	☐ **Mammography** (estrogen > 5 yrs and avg risk: age 50-64 q2 yrs) ☐ Hemoccult mutiphase (age 50-64 q2yrs) OR sigmoidoscopy OR Colonoscopy ☐ **GC/CT/Syphilis/HIV/HBV screen (high risk)** ☐ **Yearly trans bloodwork** Fasting glucose and lipid profile Cr, lytes if on spironolactone CBC, ALT+/-AST Estradiol, Prolactin, LH ☐ **Bone Mineral Density** if at risk	☐ **Mammography** (estrogen > 5 yrs and avg risk: age 65-71 q2 yrs) ☐ Hemoccult mutiphase 2 yrs (age 65-74 q2yrs) OR sigmoidoscopy OR Colonoscopy ☐ **GC/CT/Syphilis/HIV/HBV screen (high risk)** ☐ **Yearly trans bloodwork** Fasting glucose and lipid profile Cr, lytes if on spironolactone CBC, ALT+/-AST Estradiol, Prolactin, LH ☐ **Bone Mineral Density** ☐ Audioscope (or inquire/whispered voice test)
IMMUNIZATIONS:	☐ Tetanus vaccine q10yrs ☐ Meningococcal vaccine (high risk) ☐ Influenza vaccine q1yr ☐ Herpes zoster vaccine (age >60) ☐ Pneumococcal vaccine (high risk) ☐ Acellular pertussis vaccine ☐ Human papillomavirus vaccine (3 doses) (age 9-26, **consider up to age 45**) ☐ MMR vaccine (ensure 2 doses rec'd if born >1970) ☐ Measles immunity ☐ Varicella vaccine (2 doses) ☐ Varicella immunity ☐ **Hepatitis A/Hepatitis B** ☐ **Hep A immunity** ☐ **Hep B immunity**	☐ Tetanus vaccine q10yrs ☐ Influenza vaccine q1yr ☐ Pneumococcal vaccine ☐ Acellular pertussis vaccine ☐ Herpes zoster vaccine ☐ Varicella vaccine (2 doses) ☐ Varicella immunity

ASSESSMENT AND PLANS:

Appendix E: Accompaniment to the Preventive Care Checklist for Transgender Women

Explanations for Trans-specific Recommendations

Note: This form has been adapted with permission from Dr. V. Dubey from the CFPC-endorsed Preventive Care Checklist Form©. The use of these trans-specific forms assumes familiarity with the original forms and their explanations. The original form contains graded evidence-based recommendations[1], which may or may not be applicable to transgender clients. Unbolded recommendations should be followed as per the original forms. The specific recommendations herein represent an effort to incorporate expert opinion and limited trans-specific evidence with standard National and Provincial primary care practices in a practical format that can be accessed at the point-of-care.

Medical Transition History

Establishment of a client's status regarding gender-related treatments and timing of these treatments at the outset of a preventive care assessment allows for patient-centred tailoring of counselling, education, physical examination, and screening recommendations.

Lifestyle/Habits/Psychosocial

An effort should be made to assess the impact of transition/transgender identity on employment, housing, family, relationships, and economic wellbeing

Social Supports – specific attention should be given to assessing the extent of a client's social supports, creating an opportunity to suggest additional resources if needed

Alcohol – estrogen affects the metabolism of alcohol by the liver and has been associated with elevation in liver enzymes, thus we suggest using the same safe-drinking guidelines for trans women as for cis women (i.e. max 10 drinks a week with no more than 2 drinks a day most days, see Canada's Low-risk Alcohol Drinking Guidelines[2])

Sexual History – delineating the types of sex that the client is having and with whom will direct the indicated type and frequency of STI screening

Family Planning/Contraception – trans women planning to undergo hormonal and/or surgical treatments should be counselled regarding the option for sperm banking (see RHO Fact Sheet 'Reproductive Options for Trans People'),[3] those who have not undergone GAS and are on hormonal therapy should be counselled regarding the variable effect on fertility and the need for contraception if sexually active with a partner who may become pregnant

Name change/identification – assess client need/desire to change name and/or sex marker on identification and offer support for this process (see Appendicies P, Q and the related RHO Fact Sheets).[4,5]

Functional Inquiry

An effort should be made to use language consistent with a client's gender identity; if unsure - consider asking the client how they refer to their gendered body parts.

Breasts – inquire re: breast pain (may be normal in early phases of feminization), skin changes, lumps & bumps, and nipple discharge (latter may indicate hyperprolactinemia or local breast disease), if implants present consider inquiry re: symptoms of capsular contracture or rupture (pain, loss of contour, deflation)

GU – inquire re: urinary symptoms regardless of genital operative status (prostate remains post-vaginoplasty, while vaginoplasty itself may lead to urinary complications including increased frequency of UTIs, stricture, fistula), if post-op GAS inquire re: vaginal discharge, pruritus, pelvic pain; STIs and imbalances in neovaginal flora (particularly bacterial vaginosis) may occur, and can be treated as in cis women

Sexual Function – if client has not undergone GAS, inquire re: erectile dysfunction and if present, whether this is a problem for the client (PDE-5 inhibitors may be considered in trans women wishing to maintain erectile function), if the client has undergone GAS, inquire re: problems with dilation, dyspareunia, post-coital bleeding, and ability to achieve orgasm

Mental Health – screen for depressive symptoms and anxiety disorders (particularly social anxiety); suicidal ideation and attempts are particularly high in the trans population[6] and should be specifically inquired about; inquire re: current level of gender dysphoria and body image, (re-)assess client interest in surgical treatments if not accessed

Constitutional Symptoms – fatigue in the absence of other associated symptoms suggesting another cause may be due to testosterone levels below the physiologic female range (occurring more frequently post-orchiectomy); cautious supplementation of compounded testosterone gel to bring testosterone levels into the female range have anecdotally been successful at treating fatigue in this circumstance

Education/Counselling

Review S/Sx DVT/PE – review the signs and symptoms of DVT and PE for all trans women on feminizing hormone therapy, and advise immediate medical attention should these occur

Adequate Calcium Intake – all trans women on estrogen should ensure a minimum intake of 1200 mg of Calcium daily (total: diet + supplements)

Adequate Vitamin D – all trans women on estrogen should take 1000 IU of vitamin D daily

Hormone Adherence – missed doses of estrogen impacts bone health if post-orchiectomy, while extra doses may lead to risks associated with high serum levels of estrogen

Regular, moderate physical activity – some trans women may tend to avoid exercise for fear of unwanted muscle development; encourage aerobic exercise as well as high-repetition weight-bearing exercise for osteoporosis prevention; a sedentary lifestyle increases thrombosis risks associated with estrogen therapy

Obesity – obesity significantly increases the thromboembolic risks associated with estrogen therapy, weight loss counselling should be emphasized

Underweight - Screen for Disordered Eating – persistent gender dysphoria may be associated with a desire to maintain a thinner body habitus in order to hide indicators of natal sex, which may have negative health impacts; strategizing around other ways to address persistent gender dysphoria may be helpful

Alcohol and other substances – substance use is more prevalent in members of the LGBT community; inquire re: problematic use of substances including alcohol, cannabis, cocaine, opioids, hallucinogens, ketamine, ecstasy, and non-prescribed hormones; if referral to substance abuse program is indicated, consider an LGBT-specific or LGBT-positive program such as Rainbow Services at CAMH

Smoking – smoking greatly increases the thromboembolic risks associated with estrogen therapy, smoking cessation should be emphasized

STI Prevention – transgender women may be at high risk of STIs depending on behavioural factors; safer sex counselling and frequent screening (i.e. every 3 months) for those at high risk is imperative (for client-centred handout materials, see Brazen: a Trans women's Safer Sex Guide[7])

Injection safety – for clients who self-inject estrogen: confirm dose, review aseptic injection technique, inquire re: injection site reactions, ensure safe sharps disposal; counsel re: risks of injecting non-medical silicone (i.e. 'pumping' to enhance body shape) including chronic inflammation, disfigurement, pulmonary complications, sepsis, and death

Physical Examination

Blood Pressure – consider maintaining systolic BP≤130 mmHg and diastolic BP≤90 mmHg[8]

Breasts – it is unknown how the risk of breast cancer in trans women on feminizing hormones compares with cis women, but both benign and malignant breast disease can occur in trans women on hormone therapy;[9] annual routine clinical breast exams in trans women with or without implants are of questionable utility but can be considered, if implants are present attention should be paid to any sign of complications

Abdo – pay particular attention to stigmata of chronic liver disease and hepatomegaly

Ano-rectum – examine the perianal region visually for any evidence of anal warts (presence in HIV-positive clients warrants referral for high resolution anoscopy) or other anorectal problems such as hemorrhoids

Genitourinary – In clients who have not undergone orchiectomy, testicular examination may reveal testicular atrophy in the setting of feminizing therapy but is not routinely needed. For those who have undergone vaginoplasty, we do suggest annual neovaginal speculum examination to detect any abnormalities such as granulation tissue or active hair follicles (both of which may be treated with silver nitrate cauterization), warts, abnormal discharge, or malignancy; vault smears are not generally recommended as their utility in detecting

dysplasia or metaplasia in keratinized epithelium is not established, neovaginal tissue created from colon can be screened for malignancy by direct visual inspection; in the extremely rare case that a neo-cervix has been surgically created, Pap guidelines may be followed as for cis women; if examination of the prostate is indicated, the prostate may be palpated along the anterior wall of the neovagina by digital examination in the lithotomy position

Extremities – examine for signs of DVT/thrombophlebitis

Labs/Investigations

Mammography – consider mammography in women every 2 years if aged 50-71 and on estrogen for > 5 yrs, consider initiating screening at a younger age if additional risk factors are present (i.e. estrogen + progestin for > 5 yrs, family history, BMI>35), consider obtaining expert opinion regarding the need for annual mammography with MRI for those aged 30-69 with family history suggestive of hereditary breast cancer; the presence of breast implants necessitates diagnostic mammography rather than routine screening mammography

GC/CT/Syphilis/HIV/HBV screen – consider STI detection from the following sites as indicated: throat, urethra, neovagina, anorectum, and serum

Yearly trans blood work – yearly investigations listed are for those currently on an androgen blocker and estrogen, and are not necessary to be done yearly if the client is not on these treatments; blood work should be tailored to the client's risk factors and hormonal milieu, re: lipid profile and CV risk – Framingham calculations will be less reliable with exogenous hormone use; given the link between feminizing hormones and cardiovascular disease, consider using high risk lipid targets for trans women on estrogen who have any other significant risk factors for cardiac disease, low-dose ASA prophylaxis should be considered for all individuals considered high risk for CVD; if the prolactin level is persistently elevated, MRI of the sella may be indicated to rule out prolactinoma (See SHC Guidelines and Protocols, Precautions and Risk Mitigation with Estrogen Therapy: Hyperprolactinemia/Prolactinoma)

Bone Mineral Density (BMD) – exogenous estrogens appear to effectively maintain bone mass in trans women although trans women may have lower BMD than age-matched cis-men at baseline;[10] perform BMD testing in agonadal trans women of any age having been off exogenous hormones for any significant length of time, also consider screening agonadal trans women of any age who are or have been on lower-dose estrogen regimens, have elevated LH,[11] those who have been on anti-androgens without exogenous estrogen for a significant period, and those with additional risk factors (eg. including glucocorticoid therapy, previous fracture, family history of osteoporosis). Note: frequency of BMD screening will depend on the results of the initial scan.

Immunizations

Hepatitis A/Hepatitis B – trans women may be at higher risk of Hep A/B depending on behavioural risks, if behavioural risk factors are present, the client may qualify for publically funded vaccination similarly to men who have sex with men

HPV – consider HPV vaccination x 3 doses in trans women up to the age of 45, tailor to risk; for low-income clients without private drug insurance, Gardasil© may be covered for trans women by requesting an application form from Merck Canada's Patient Assistance Program

CFPC – College of Family Physicians of Canada, RHO – Rainbow Health Ontario, GAS – gender affirming surgery - in this context referring to orchiectomy, penectomy, construction of a neovagina and female external genital anatomy, STI – sexually transmitted infection, UTI – urinary tract infection PDE-5 – phosphodiesterase-5, IU – international units, DVT – deep vein thrombosis, PE – pulmonary embolus, LGBT – Lesbian, Gay, Bisexual, Transgender, CAMH – Cantre for Addiction and Mental Health, HIV – human immunodeficiency virus, GC – gonococcus, CT – chlamydia trachomatis, ASA – acetylsalicylic acid, BMD – bone mineral density, LH – luteinizing hormone, HBV – hepatitis B virus, HPV – human papilloma virus

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APPENDIX F: PREVENTIVE CARE CHECKLIST FOR TRANSGENDER MEN

Prepared by: Dr. A. Bourns • Adapted from the Preventive Care Checklist Form © Dec 2010

For annual health assessments of Transgender Men, applying to patients who were born with female genitalia and have a gender identity that is male or on the masculine spectrum, who may or may not have accessed hormonal and/or surgical treatments for gender dysphoria.

Please note:
- **Bold** = transgender-specific considerations, see Explanation Sheet for detailed recommendations
- Unbolded items should be followed according to the original Preventive Care Checklist Form© and the Explanations for the Preventive Care Checklist Form© for cisgender women

(see Duerksen A, Dubey V, Iglar K. Annual adult health checkup: Update on the Preventive Care Checklist Form© Canadian Family Physician, 2012 Jan; 58:43-47.)

IDENTIFYING DATA:

Name: _____

Tel: _____

DOB: _____

Age: _____

Date of examination: _____

MEDICAL TRANSITION HISTORY:

Testosterone: ☐ Yes ○ No

If Yes, Start Date: _____

Chest Reconstruction: ☐ Yes ○ No

TAH ☐ Yes ○ No

BSO ☐ Yes ○ No

CURRENT CONCERNS:

MENTAL HEALTH: **Screen for:**

Depression	☐ **Positive**	○ **Negative**
Anxiety	☐ **Positive**	○ **Negative**
Suicidal Ideation	☐ **Positive**	○ **Negative**
Persistent Gender Dyshoria	☐ **Positive**	○ **Negative**

LIFESTYLE/HABITS/PSYCHOSOCIAL:

Diet: _____

Fat/Cholesterol _____

Fiber _____

Calcium _____

Sodium _____

Exercise: _____

Work/Education: _____

Income Below Poverty Level: ○ Yes ○ No

Family: _____

Relationships: _____

Social Supports: _____

Smoking: _____

Alcohol: _____

Safe Guidelines ≤10/week, ≤2/day

Recreational Drugs: _____

Sexual History: _____

Family Planning/Contraception: _____

Name change/identification: _____

Sleep: _____

UPDATE CUMULATIVE PATIENT PROFILE:

☐ Family History ☐ Medications

☐ Hospitalizations/Surgeries ☐ Allergies

FUNCTIONAL INQUIRY:

HEENT: _____ ☐ Normal
CVS: _____ ☐ Normal
Resp: _____ ☐ Normal
Chest: _____ ☐ Normal
GI: _____ ☐ Normal
GU/PV Bleeding: _____ ☐ Normal
Sexual Function: _____ ☐ Normal
MSK: _____ ☐ Normal
Neuro: _____ ☐ Normal
Derm: _____ ☐ Normal
Constitutional Sx: _____ ☐ Normal

PHYSICAL EXAMINATION:

HR:_____ BP: _____ RR: _____
Ht: _____ Wt: _____ BMI: _____

Waist Circumference: _____
Hip Circumference: _____ Ratio: _____
Or: See EMR Vitals ☐

Eyes: _____
Snellen sight card R _____
L _____
Ears: _____
Whispered voice test R _____
L _____
Nose: _____
Neck/Thyroid: _____
CVS: _____
Resp: _____

Chest: _____
Abdo: _____
Ano-Rectum: _____
Pelvic: _____ Pap ☐
Neuro: _____
Derm: _____
MSK/Joints: _____
Extremities: _____

EDUCATION/COUNSELLING:

BEHAVIOURAL
- ☐ adverse nutritional habits
- ☐ **adequate calcium intake (1200 mg daily diet + supp)**
- ☐ **adequate vitamin D (1000 IU daily)**
- ☐ **hormone adherence**
- ☐ **regular, moderate physical activity**
- ☐ avoid sun exposure, use protective clothing
- ☐ **safe sex practices/STI counseling**
- ☐ **review potential for pregnancy/assess need for birth control**
- ☐ **assess need for folic acid**

OBESITY - (BMI > 30) ☐ YES ◉ NO
- ☐ weight loss counselling
- ☐ **screen for mental health contributors**
- ☐ multidisciplinary approach

SMOKING ☐ YES ◉ NO
- ☐ smoking cessation
- ☐ nicotine replacement therapy/other drugs
- ☐ dietary advice on fruits and green leafy vegetables
- ☐ referral to validated smoking cessation program

ALCOHOL & OTHER SUBSTANCES: ☐ YES ◉ NO
- ☐ case finding for problematic substance use
- ☐ counselling for problematic substance use

ELDERLY ☐ YES ◉ NO
- ☐ cognitive assessment (if concerns)
- ☐ fall assessment (if history of falls)

ORAL HYGIENE
- ☐ brushing/flossing teeth
- ☐ fluoride (toothpaste/supplement)
- ☐ tooth scaling and prophylaxis
- ☐ smoking cessation

PERSONAL SAFETY
- ☐ hearing protection
- ☐ noise control programs
- ☐ seat belts
- ☐ **injection safety (if on IM/SC hormones)**

PARENTS WITH CHILDREN ☐ YES ◉ NO
- ☐ poison control prevention
- ☐ smoke detectors
- ☐ non-flammable sleepwear
- ☐ hot water thermostat settings (<54°C)

	21-64 YEARS	>65 YEARS
LABS/INVESTIGATIONS:	☐ **Mammography** (age >50-64 q2 yrs if no chest reconstruction) ☐ Hemoccult mutiphase (age 50-64 q2 yrs) OR sigmoidoscopy OR Colonoscopy ☐ **Cervical cytology** (q3 yrs age >21) ☐ **GC/CT/Syphilis/HIV/HBV screen (high risk)** ☐ **Yearly trans bloodwork** Fasting glucose and lipid profile CBC, ALT+/-AST, Free+Total Testosterone ☐ **Bone Mineral Density** if at risk	☐ **Mammography** (age 65-71 q2 yrs if no chest reconstruction) ☐ Hemoccult mutiphase (age 65-74 q2 yrs) OR sigmoidoscopy OR Colonoscopy ☐ **Cervical cytology** (q 3yrs until age 70) ☐ **GC/CT/Syphilis/HIV/HBV screen (high risk)** ☐ **Yearly trans bloodwork** Fasting glucose and lipid profile CBC, AST+/-ALT, Free+Total Testosterone ☐ **Bone Mineral Density** ☐ Audioscope (or inquire/whispered voice test)
IMMUNIZATIONS:	☐ Tetanus vaccine q10yrs ☐ Meningococcal vaccine (high risk) ☐ Influenza vaccine q1yr ☐ Herpes zoster vaccine (age >60) ☐ Pneumococcal vaccine (high risk) ☐ Acellular pertussis vaccine ☐ Human papillomavirus vaccine (3 doses) (age 9-26, **consider up to age 45**) ☐ MMR vaccine (ensure 2 doses rec'd if born >1970) ☐ Rubella immunity ☐ Measles immunity ☐ Varicella vaccine (2 doses) ☐ Varicella immunity ☐ **Hepatitis A/Hepatitis B** ☐ **Hep A immunity** ☐ **Hep B immunity**	☐ Tetanus vaccine q10yrs ☐ Influenza vaccine q1yr ☐ Pneumococcal vaccine ☐ Acellular pertussis vaccine ☐ Herpes zoster vaccine ☐ Varicella vaccine (2 doses) ☐ Varicella immunity

ASSESSMENT AND PLANS:

Appendix G: Accompaniment to Preventive Care Checklist Form for Transgender Men

Explanations for Trans-specific Recommendations

Note: This form has been adapted with permission from Dr. V. Dubey from the CFPC-endorsed Preventive Care Checklist Form©. The use of these trans-specific forms assumes familiarity with the original forms and their explanations. The original form contains graded evidence-based recommendations[1], which may or may not be applicable to transgender clients. Unbolded recommendations should be followed as per the original forms. The specific recommendations herein represent an effort to incorporate expert opinion and limited trans-specific evidence with standard National and Provincial primary care practices in a practical format that can be accessed at the point-of-care.

Medical Transition History

Establishment of a client's status regarding gender-related treatments and timing of these treatments at the outset of a preventive care assessment allows for patient-centred tailoring of counselling, education, physical examination, and screening recommendations.

Lifestyle/Habits/Psychosocial

An effort should be made to assess the impact of transition/transgender identity on employment, housing, family, relationships, and economic wellbeing

Social Supports – specific attention should be given to assessing the extent of a client's social supports, creating an opportunity to suggest additional resources if needed

Alcohol – we suggest that trans men, regardless of exogenous hormone use, follow the safe-drinking guidelines for cis women (i.e. maximum 10 drinks a week with no more than 2 drinks a day most days, see Canada's Low-risk Alcohol Drinking Guidelines[2])

Sexual History – delineating the types of sex that the client is having and with whom will direct the indicated type and frequency of STI screening

Family Planning/Contraception – trans men considering hormonal and/or surgical treatments should be counselled regarding reproductive options (see RHO Fact Sheet 'Reproductive Options for Trans People'[3]), also see potential for pregnancy/need for birth control below

Name change/identification – assess client need/desire to change name and/or sex marker on identification and offer support for this process (see Appendices P, Q and related RHO Fact Sheets[4,5])

Sleep – testosterone therapy may worsen or unmask obstructive sleep apnea, consider inquiring re: symptoms of sleep apnea; in those with sleep apnea, CPAP requirements may change with masculinizing hormone therapy and should be monitored[6,7]

Functional Inquiry

An effort should be made to use language consistent with a client's gender identity; if unsure, consider asking the client how they refer to their body parts.

Chest – inquire regarding skin changes, lumps/bumps and nipple discharge regardless of surgical status, if client has undergone chest reconstruction consider asking about scarring and patient-satisfaction with surgical outcome (in some cases, revisions can be considered to optimize cosmetic appearance), if client has not undergone chest reconstruction consider asking about binding and any associated MSK, dermatologic, or respiratory problems; encourage the use of a product designed specifically for the purpose of chest binding (several commercial brands are available, for a comparison see **www.transguys.com**) rather than the use of other products such as tensors or duct tape

GU/PV Bleeding – inquire about symptoms of vaginal atrophy (if on testosterone), vaginal bleeding, discharge, and pelvic pain. Problematic symptoms due to vaginal atrophy often respond to topical estrogen; NB: any unexplained vaginal bleeding once menstrual cessation has been achieved on testosterone warrants a full work-up for endometrial hyperplasia/malignancy

Sexual Function – inquire regarding libido/hypersexual behaviour, change in sexual attractions, dyspareunia (as indicated by surgical status and sexual activity), and post-orgasmic uterine cramping (See SHC Guidelines and Protocols, Masculinizing Hormone Therapy: Other common side effects and their management)

Derm – inquire re: acne and androgenic alopecia, both of which may be managed similarly to cisgender clients

Mental Health – screen for mood disturbances including irritability, anger, and depression, as well as anxiety disorders (particularly social anxiety); suicidal ideation and attempts are particularly high in the trans population[8] and should be specifically inquired about; inquire regarding symptoms of hypomania, mania, or psychotic symptoms in clients on testosterone who have underlying psychiatric disorders that include such symptoms; inquire re: current level of gender dysphoria and body image, (re-)assess client interest in surgical treatments if not accessed

Education/Counselling

Adequate Calcium Intake – all trans men on testosterone should ensure a minimum intake of 1200 mg of Calcium daily (diet + supplements)

Adequate Vitamin D – all trans men on testosterone should take 1000 IU of vitamin D daily

Hormone Adherence – missed doses of testosterone impacts bone health if post-oophorectomy, while extra doses may lead to a host of problems associated with supraphysiologic levels

Regular, moderate physical activity – weight-bearing exercise helps in osteoporosis prevention; to avoid tendon rupture in trans men on testosterone weight loads used in strength training should be increased gradually with an emphasis on repetitions and stretching

Safe sex practices/STI counselling – trans men may be at high risk of STIs depending on behavioural factors; safer sex counselling and frequent screening (i.e. every 3 months) for those at high risk is imperative (for client-centred handout materials, see Safer Sex for Transguys: A Guide for the Whole Spectrum[9] and PRIMED: The Back Pocket Guide for Trans men & the Men Who Love Them[10])

Potential for pregnancy/need for birth control – trans men on testosterone may become pregnant even if menstrual suppression has been achieved and should be counselled in this regard; given that testosterone is a teratogen, reliable birth control must be instituted where pregnancy is a risk based on sexual activity

Need for folic acid – trans men not on testosterone and in whom pregnancy is possible based on sexual activity, as well as for those who are hoping to achieve pregnancy, folic acid recommendations are the same as for cis women

Obesity - Screen for Mental Health Contributors – persistent gender dysphoria may be associated with a desire to maintain a larger body habitus in order to hide indicators of natal sex, which may have negative health impacts; strategizing around other ways to address persistent gender dysphoria may be helpful

Smoking – tobacco use can worsen polycythemia associated with testosterone administration and increases the risk of CVD and thromboembolic events

Alcohol and other substances – substance use is more prevalent in members of the LGBT community; inquire re: problematic use of substances including alcohol, cannabis, cocaine, opioids, hallucinogens, ketamine, ecstasy, and anabolic steroids; if referral to substance abuse program is indicated, consider an LGBT-specific or LGBT-positive program such as Rainbow Services at CAMH

Injection safety – for clients who self-inject testosterone: confirm dose, review aseptic injection technique, inquire re: injection site reactions, ensure safe sharps disposal

Physical Examination

Blood Pressure - consider maintaining systolic BP≤130 mmHg and diastolic BP≤90 mmHg[11]

Chest – testosterone therapy is not thought to increase the risk of breast cancer,[12] for trans men who have not undergone chest reconstruction, clinical chest (i.e. breast) exam is of questionable utility but can be considered according to a provider's common practice with cis women; trans men who have undergone chest reconstruction are at low risk and chest and axillary lymph node exam are of questionable utility but may be considered to assess for abnormalities in the remaining breast tissue; if an abnormality is noted in this case, ultrasound +/- MRI is indicated as mammography is technically impossible

Abdo – pay particular attention to stigmata of chronic liver disease and hepatomegaly

Ano-rectum – examine the perianal region visually for any evidence of anal warts (presence in HIV positive clients warrants referral for high resolution anoscopy) or other anorectal problems such as hemorrhoids

Pelvic/Pap – follow cervical cancer screening guidelines as for cis women if the cervix is present, there is no evidence to support the performance of a bimanual exam but if uterus and/or ovaries are present this can be considered according to the clinician's routine practice with cis women; several strategies may be employed to minimize the discomfort/trauma associated with speculum examination for some trans men (see Tips for

Providing Paps to Trans men).[12] Barring contraindications, topical 2% lidocaine jelly may be applied vaginally 5-10 minutes prior to the procedure in those who find speculum examination painful due to atrophic changes.

Derm – examine for acne and androgenic alopecia

Labs/Investigations

Mammography – for trans men who have not undergone chest reconstruction, follow guidelines as for cis women; mammography is not required following chest reconstruction; for all trans men, if a strong family history of breast cancer is present, follow the same guidelines as for cis women regarding indications for referral to a high risk screening program/genetic assessment

GC/CT/Syphilis/HIV/HBV screen – consider STI detection from the following sites as indicated: throat, urethra, vagina, ano-rectum, and serum

Cervical cytology – see Pelvic/Pap above, if patient is on testosterone, ensure to note this on the cytology requisition in order to minimize histological misinterpretation, inadequate samples are more common in clients on testosterone and repeat may be required

Yearly trans blood work – yearly investigations listed are for those currently on testosterone, and are not necessary to be done yearly if the client is not on testosterone; blood work should be tailored to the client's risk factors and hormonal milieu, re: lipid profile and CV risk – Framingham calculations will be less reliable with exogenous hormone use; consider using high risk lipid targets in trans men on testosterone with any other significant risk factors for CVD; low-dose ASA prophylaxis should be considered in all individuals considered at high risk of CVD

Bone Mineral Density – indications to perform BMD testing in trans men:

- At any age having undergone oophorectomy and having been off of exogenous hormones for any significant length of time
- <50 years old regardless of ovarian status if have taken testosterone for any significant length of time and have any other risk factors for osteoporosis
- >50 years old with ovaries intact and 5-10+ years on testosterone
- >50 years old post-oophorectomy and on testosterone >5 years
- >60 years old post-oophorectomy and on testosterone <5 years[11]

BMD testing may additionally be considered in agonadal trans men with elevated LH[14]

Note: frequency of BMD screening will depend on the results of the initial scan

Immunizations

Hepatitis A/Hepatitis B – trans men may be at higher risk of Hep A/B depending on behavioural risks, if behavioural risk factors are present, the client may qualify for publically funded vaccination as men who have sex with men

HPV – consider HPV vaccination in trans men up to age 45; for low-income clients without private drug insurance, Gardasil© may be covered by requesting an application form from Merck Canada's Patient Assistance Program

CFPC – College of Family Physicians of Canada, STI – sexually transmitted infection, RHO – Rainbow Health Ontario, MSK – musculoskeletal, GU – genito-urinary, PV – per vagina, IU – international units, CVD – cardiovascular disease, LGBT – Lesbian, Gay, Bisexual, & Transgender, CAMH – Centre for Addiction and Mental Health, BMD – bone mineral density, LH – luteinizing hormone, HPV – human papilloma virus

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Appendix H: Glossary of Terms

The following are definitions intended as useful references for this resource and for your work with trans and non-binary clients. As language is constantly evolving and seldom universally agreed upon, it is key to mirror back language people use to express their lived experience and understanding of self.

ASSUMED CIS: Previously known as **passing**. A trans person is "assumed cis" when they move through the world on an everyday basis with few/no persons being aware they are trans. When one is assumed to be **cis**, the social, economic, safety and other risks associated with **cissexist** discrimination and **transphobic** violence are decreased, thus conferring **conditional cis privilege**. Given such benefits, getting to a point where one is "assumed cis" may be a goal of one's transition, but this is not always the case. "Passing" should not be used as it implies that one is being mistaken for something they are not; it also has a particular historical meaning related to race and skin colour.

BINDING: For **trans men**, the process of flattening one's **chest** to disguise one's "breasts". This can be done utilizing a few different things from undershirts intended for this end to lower back supports. Using an ace bandage is discouraged as it may constrict breathing. Some trans men and **non-binary** people don't bind at all, some layer clothing to help hide their chests, some bind only on certain occasions and some bind all the time.

BOTTOM SURGERY: A type of **gender affirming surgery (GAS)**. These are a variety of genital modification procedures. Typically vaginoplasty for **trans women** and metaoidioplasty or phalloplasty for **trans men**.

BUTCH: A form of **gender expression**. A masculine identified person of any gender identity.

CHEST: The most common term used by **trans men** to describe this part of their anatomy, regardless of whether they have had **top surgery**. It is always important to use gender affirming language (or at least gender-neutral language) with body parts that have a strong gender attachment.

CIS: Having a non-trans gender identity. You may also sometimes see "cissexual" or "cisgender". Thus, non-trans men are "cis men" and non-trans women are "cis women". It is preferable (and more accurate) to use "cis" than to use terms such as "bio", "genetic" or "real". It is also preferable to use "cis" rather than only using "woman" or "man" to describe non-trans persons. If cis is not used as a descriptor for non-trans persons, then such persons may be presumed to be the more "normal" or "valid" instantiation of that particular gender, thus contributing to **cissexism**.

CIS PRIVILEGE: The privileges afforded to those who are **cis**. In health care settings, some common statements that reflect cis privilege include: as a client, not worrying that providers will see their gender as less "real" or "valid" if they read through their chart and learn about their medical history; not having to receive a psychiatric diagnosis in order to get medical help in actualizing my gender; not being concerned about having tests rejected because of the "wrong" sex marker being on one's OHIP card, and; not having to worry about questions concerning their gender distracting from care they may need that has nothing to do with gender.

CISNORMATIVITY: The assumption all people are **cis**, that those assigned male at birth always grow up to be men and those assigned female at birth always grow up to be women. Cisnormative assumptions are so prevalent that they are difficult at first to even recognize. For example, in health care settings cisnormativity associates "women's health" with things such as Pap tests and contraception when, in fact, these things are relevant to many men, specifically trans men.

CISSEXISM: The beliefs and actions resulting from the belief, that **cis** bodies or identities are more "real" or "valid" than **trans** ones. This is distinct from **transphobia** (which denotes hatred and fear towards trans persons).

COMING OUT: Usually in reference to one's **sexual orientation** or **gender identity**. It involves sharing something about one's identity that would not otherwise be known. One only has to "come out" when a heteronormative or **cisnormative** assumption (i.e. that one is "heterosexual" or "**cissexual**") has been made about them.

CONDITIONAL CIS PRIVILEGE: The privilege experienced by **trans** persons who are often **assumed cis** in their everyday life. Such privilege is condition on their trans identity or history not being known or revealed. Formerly referred to as "**passing privilege**".

CROSS DRESSER: Someone who wears clothes of another gender/sex but whose **gender identity** does not differ from the one assigned to them at birth. Most commonly, this term has been used to describe men wearing women's clothes on a part-time basis, however some may cross dress more frequently or all of the time. Cross dressing may not have a fetishistic or sexual association. Some persons who practice cross dressing may one day decide to undergo **transition**.

DISORDERS OF SEXUAL DIFFERENTIATION (DSD): A medical term used to describe the various conditions experienced by those who are intersex. Preferred by some to using "**intersex**". Persons with DSD may be **cis** or **trans** depending on how their gender identity relates to the one assigned to them at birth.

DRAG: The performance of one or multiple genders theatrically. "Drag queens" are men performing as women; "drag kings" are women performing as men. Some persons who practice drag may one day decide to undergo gender transition.

" E " : Slang for Estrogen

FEMME: A form of **gender expression**. A feminine identified person of any **gender identity**.

FTM: An old term to describe **trans men**. It has fallen out of favour as it implies that trans men are something categorically different or apart from being "men"; it also conflates **sex** and **gender identity** and forever identifies the sex that one is transitioning *away* from.

GENDER AFFIRMING SURGERY (GAS): Previously known as **sex reassignment surgery**. Can refer to any number of surgeries that a **trans** person may undertake in order to better align their **sex** with their **gender identity**. Often assists trans persons in acquiring greater **conditional cis privilege** and in being **assumed cis**. May include both **bottom surgery(ies)** and **top surgery**. Important for some trans persons, but others may not be interested in GAS as part of their transition.

GENDER DYSPHORIA: May refer specifically to the DSM-V diagnosis and/or to the experience of distress associated with having one's current gender presentation misaligned with their internal **gender identity**. Through a **medical transition** and/or **social transition**, gender dysphoria can usually be alleviated.

GENDER EXPRESSION: The social expression of gender. Often described as being on a spectrum between **masculine to feminine**. Often related to, but sometimes distinct from, **gender identity**. For example, some **trans** or **cis** women may identify **butch** or have a masculine presentation, and some cis or trans men may be feminine or identity as **femme**.

GENDER IDENTITY: A person's internal self-awareness of being a boy/man, girl/woman, something inbetween these, or something other altogether.

GENDER IDENTITY DISORDER (GID): An historical diagnosis used to diagnose and treat **trans** persons. Was replaced by **Gender Dysphoria** in the DSM-V. Unlike Gender Dysphoria, GID did not have a distress criteria and was a diagnosis that applied even after transition.

GENDER ROLE EXPERIENCE (GRE): Previously known as the **Real Life Test** or **Real Life Experience**. According to World Professional Association of Transgender Health's Standards of Care Version[7] it is the period of time during which a trans person is required to live full time in the role of the gender they identify with prior to accessing **bottom surgery** (i.e. genital (re)constructive procedures). It is not required, and potentially dangerous, for persons to undergo a GRE prior to taking **hormone treatment** or having **top surgery**.

GENDERQUEER: A person whose **gender identity** does not align with binary gender categories such as "man/woman", "boy/girl". Genderqueer persons often identify as an intermediary gender.

HORMONE TREATMENT: The medical management of **trans** persons with sex hormones. For **trans men**, this is typically testosterone; for **trans women** this may include estrogen and/or anti-androgens.

INTERSEX: The condition of being born with genitalia that is difficult to label as male or female, and/or developing secondary sex characteristics of indeterminate sex, or which combine features of both sexes. Some intersex people are also trans, but intersex is not considered a subset of transgender, nor transgender a subset of intersex.

MEDICAL TRANSITION: The process of seeking and receiving various medical interventions including, but not limited to hormone therapy (including anti-androgens for trans women), **gender affirming surgeries** and other related surgeries (incl. hair transplants), and hair removal (e.g. electrolysis).

MTF: An old term to describe **trans women**. It has fallen out of favour as it implies that trans women are something categorically different or apart from being "women"; it also conflates sex and gender and forever identifies the sex that one is transitioning *away* from.

NON-BINARY: Umbrella term for anyone who does not identify with static, binary gender identities. Includes persons who may identify as having an intermediary gender (e.g. **genderqueer**), as being multiple genders, as having a constantly shifting gender, or as not having a gender altogether.

NON-DISCLOSURE: A term that applies to **trans** persons who are **assumed cis** and who choose to not share that they are trans with others. May be specific to some situations (e.g. work, sex) or applicable to all situations. Also sometimes referred to as being "stealth." Often protective as it avoids having to face **cissexist** discrimination or **transphobic** violence that can occur if other know one is trans.

NON-OP: Trans individuals not seeking any **gender affirming surgery(ies)**.

PACKING: The process of creating a bulge in one's crotch that leads others to believe that one may possess a penis.

PASSING: See **assumed cis**.

PASSING PRIVILEGE: See **conditional cis privilege**.

PRE-OP: Trans individuals who are seeking, but who have not undergone, one or more **gender affirming surgery(ies)**.

POST-OP: Trans individuals who have undergone one or more **gender affirming surgery(ies)**.

QUEER: A term commonly used to describe persons with non-heterosexual **sexual orientations**. More common in younger generations than terms such as "gay" or "lesbian" because of the binary nature of these older terms.

REAL LIFE TEST (RLT) OR REAL LIFE EXPERIENCE: See Gender Role Experience (GRE)

SEX: Describes one's phenotype, often determined by genital configuration. Referred to in terms of "male" or "female". Due to **cisnormativity**, often conflated with **gender identity**.

SEXUAL ORIENTATION: Refers to the group(s) of persons that someone may desire intimate emotional and/or sexual relationships with. Examples of sexual orientations include, straight, queer, lesbian, gay, bisexual, pansexual, and asexual. Everyone, **cis** or **trans**, has a sexual orientation (e.g. trans persons can be bisexual, queer, or straight).

SEXUAL REASSIGNMENT SURGERY: See **Gender Affirming Surgery (GAS)**.

SHE-MALE: A derogatory term to describe some pre-operative trans women who have not undergone **gender affirming surgery (GAS)**.

SOCIAL TRANSITION: The various non-medical components of one's transition that help one affirm and realize one's **gender identity**. For example, this may include: changing one's legal identification with changes to sex markers and name; changing the clothes one wears, and changing one's voice, posture, and gait.

" T ": Slang for Testosterone

TOP SURGERY: For **trans men** involves the construction of a **chest**. For trans women, it may involve breast augmentation if desired results have not been achieved with **hormone treatment** (or if they cannot, or choose to not to, take estrogen).

TRANS: Umbrella term for people who are not **cis**, includes persons who are (or identify as) **non-binary** as well as **trans men** and **trans women**.

TRANSITION: The sum total of changes involved in moving from living as one gender identity to another. Typically a stage in a **trans** person's life. Includes **medical transition** and **social transition**.

TRANSPHOBIA: The fear and hatred of **trans** persons. Its expression usually involves some form of verbal, physical, and/or sexual violence. Also describes the ongoing microaggressions experienced by those who are assumed to be trans by others in their everyday lives.

TRANSSEXUAL: Describes persons who undergo **medical transition** and **social transition** to align the gender they live and present as with their internal **gender identity**.

TRANS MAN: An umbrella term to describe all persons assigned female at birth who **transition** to live as men/boys or somewhere on the masculine spectrum.

TRANS WOMAN: An umbrella term to describe all persons assigned male at birth who **transition** to live as girls/women or somewhere on the feminine spectrum.

TWO-SPIRIT: An umbrella term describing the diversity of gender and sexual identities present in traditional belief systems held by North American First Nations persons.

Appendix I:
Trans Health Resources for Primary Care Providers

The following is a compilation of resources for primary care providers as well as suggestions for keeping up to date on topics in the health care of trans clients. Additionally, opportunities for peer discussion and obtaining input regarding specific clinical scenarios are listed.

- The UCSF Centre for Excellence in Transgender Health, **www.transhealth.ucsf.edu**

- The Vancouver Coastal Health Transgender Health Information Program, **www.transhealth.vch.ca**

- World Professional Association for Transgender Health, **www.wpath.org**
  - Biennial conferences on Transgender Health
  - Download a free copy of the Standards of Care Version 7
  - Download the free WPATH Standards of Care Version 7 App on your smart phone
  - Become a member to sign up for listserv discussions and receive the quarterly 'International Journal of Transgenderism'

- Canadian Professional Association for Transgender Health, **www.cpath.ca**
  - Biennial conferences

- Trans Health Connection, Rainbow Health Ontario, **www.rainbowhealthontario.ca**
  - Weekly mentorship call for case discussions and selected topic reviews
  - Training sessions for your health organization or regional group of healthcare providers
  - An interdisciplinary directory of providers with experience in trans health

- TransLine – Free online medical consultation offering healthcare providers clinical information and individualized case consultation service, **http://project-health.org/transline/**

Appendix J: Reference ranges (Lifelabs)

Accurate as of March 2, 2015

17-Beta-Estradiol		
Female	follicular phase	70-530 pmol/L
	midcycle	235-1310 pmol/L
	luteal	205-790
	post-menopause	up to 120
Male		<150 pmol/L

LH		
Female	prepubertal	1-6 IU/L
	follicular phase	1-25 IU/L
	midcycle	25-55 IU/L (3-5 X follicular)
	luteal	1-25 IU/L
	post-menopause or ovariectomized	40-105 IU/L
Male		2-6 IU/L

FSH		
Female	follicular	1-11 IU/L
	midcycle	2-22 IU/L
	luteal	1-8 IU/L
	post-menopause or ovariectomized	>35
Male		2-8 IU/L

Total Testosterone	
Female	Less than 1.8 nmol/L
Male	8.4-28.8 nmol/L

Free Testosterone		
Female	<10-29	<56 pmol/L
	>30	<30 pmol/L
Male	<10-49	196-636 pmol/L
	>50	179-475 pmol/L

Note: the free testosterone ranges are calculated via the Vermeulen equation according to the updated practice at Lifelabs; some labs may not yet use this method and there may be a significant difference in reference ranges depending on the method used, thus it is best to compare levels to the reference ranges listed by the particular lab that is being used

Appendix K:
Consent Form for Feminizing Hormone Therapy

Initiation of Care

A. The full medical effects and safety of hormone therapy are not fully known. Potential adverse effects may include, but are not limited to:

- Increased or decreased cholesterol and/or fats in the blood, which may increase risk for heart attack or stroke.
- Increased levels of potassium in the blood, which may cause abnormal heart rhythms (if spironolactone is used)
- Increased or decreased sex drive and sexual functioning, shifts in sexual attraction/orientation
- Fatigue
- Increased risk of the following:
  - Blood clots, (deep venous thrombosis, pulmonary embolism)
  - Breast tumours/cancer
  - Heart disease, arrhythmias, and stroke
  - High blood pressure
  - Liver inflammation
  - Gallstones and need for gallbladder removal
  - Pituitary tumors (tumor of small gland in the brain which makes prolactin)
  - Decreased number of red blood cells (anemia)
  - Psychiatric symptoms such as depression and suicidal feelings, anxiety, psychosis (disorganization and loss of touch with reality), and worsening of pre-existing psychiatric illnesses

B. Some side effects from hormones are irreversible and can cause death.

C. The risks for some of the above adverse events may be INCREASED by

- Pre-existing medical conditions
- Pre-existing psychiatric conditions
- Cigarette smoking
- Alcohol use

D. Irreversible body changes (potential increases with length of time on hormones) resulting from hormone therapy may include, but are not limited to:

- Breast growth
- Fat redistribution (largely reversible but some degree may be irreversible)
- Genital changes (i.e. smaller testes)
- Infertility

E. My signature below constitutes my acknowledgement of the following:

_____

(name of care provider)

has discussed with me the nature and purpose of hormone therapy; the benefits and risks, including the risk that hormone therapy may not accomplish the desired objective; the possible or likely consequences of hormone therapy; and all feasible alternative diagnostic or treatment options.

- ❑ I have read and understand the above information regarding the hormone therapy, and accept the risks involved.
- ❑ I have had sufficient opportunity to discuss my condition and treatment with my medical provider and all of my questions have been answered to my satisfaction.
- ❑ I believe I have adequate knowledge on which to base an informed consent to the provision of hormone therapy.
- ❑ I authorize and give my informed consent to the provision of hormone therapy.

_____

Signature of Witness

_____

Date

_____

Name of Witness (Printed)

_____

Signature of Client

_____

Date

_____

Legal Name of Client (Printed)

Appendix L: Consent Form for Progestin Therapy

A. Evidence suggests that the addition of progestin to my hormone regimen adds significant risks to my treatment over and above the risks of estrogen

B. Sherbourne Health Center's "Guidelines and Protocols for Hormone Therapy and Ongoing Primary Care for Trans Clients" does not suggest the use of progestins

C. The full medical effects and safety of a hormone therapy including progestin are not fully known. Potential serious adverse effects may include, but are not limited to:

- Coronary heart disease
- Stroke
- Deep vein thrombosis
- Pulmonary embolism
- Invasive breast cancers
- Psychiatric symptoms (depression and suicidal feelings)

D. Other potential adverse side effects of progestins may also include, but are not limited to, the following:

- High blood pressure
- Liver inflammation
- Breast tenderness
- Migraines or other headaches
- Increased cholesterol
- Diabetes
- Acne
- Body hair growth
- Weight gain / bloating and fluid retention
- Worsening of asthma
- Worsening of seizures

E. Some side effects of progestins are irreversible and can cause death

F. The risks for some of the above adverse events may be INCREASED by

- Pre-existing medical conditions
- Pre-existing psychiatric conditions
- Cigarette smoking
- Alcohol use

G. I understand that progestins should not be taken by people who have, or who have had, any of the following

- Active liver dysfunction
- Allergy to progestins, soy, peanuts
- Estrogen or progestin-dependent breast cancer
- Coronary artery disease
- Myocardial infarction
- Stroke
- Blood clots
- Migraine with aura

H. My signature below constitutes my acknowledgement of the following:

_____

(name of care provider)

has discussed with me the benefits and risks of progestins, including the risk that hormone therapy may not accomplish the desired objective; the possible or likely consequences of progestin; and all feasible alternative diagnostic or treatment options.

- ❑ I have read and understand the above information regarding the hormone therapy, and accept the risks involved.
- ❑ I have had sufficient opportunity to discuss my condition and treatment with my medical provider and all of my questions have been answered to my satisfaction.
- ❑ I believe I have adequate knowledge on which to base an informed consent to the provision of hormone therapy.
- ❑ I authorize and give my informed consent to the provision of hormone therapy.

_____

Signature of Witness

_____

Date

_____

Name of Witness (Printed)

_____

Signature of Client

_____

Date

_____

Legal Name of Client (Printed)

Appendix M:
Consent Form for Masculinizing Hormone Therapy

Initiation of Care

A. The full medical effects and safety of hormone therapy are not fully known. Potential adverse effects may include, but are not limited to:

- Increased cholesterol and/or fats in the blood, which may increase risk for heart attack or stroke
- Increased number of red blood cells (increased hemoglobin), which may cause headache, dizziness, heart attack, confusion, visual disturbances, or stroke
- Acne
- Increased risk of the following:
  - Heart disease and stroke
  - High blood pressure
  - Liver inflammation
  - Increased or decreased sex drive and sexual functioning, shifts in sexual attraction/ orientation
  - Psychiatric symptoms such as depression and suicidal feelings; anxiety; psychosis (disorganization and loss of touch with reality), and worsening of pre-existing psychiatric illnesses

B. Some side effects from hormones are irreversible and can cause death.

C. The risks for some of the above adverse events may be INCREASED by

- Pre-existing medical conditions
- Pre-existing psychiatric conditions
- Cigarette smoking
- Alcohol use

D. Irreversible body changes (potential increases with length of time on hormones) resulting from hormone therapy may include, but are not limited to:

- Deepening of voice
- Development of facial & body hair
- Fat redistribution
- Genital changes (i.e. enlargement of clitoris & labia, vaginal dryness)
- Infertility
- Male pattern baldness

E. My signature below constitutes my acknowledgement of the following:

_____

(name of care provider)

has discussed with me the nature and purpose of hormone therapy; the benefits and risks, including the risk that hormone therapy may not accomplish the desired objective; the possible or likely consequences of hormone therapy; and other alternative diagnostic or treatment options.

- ❑ I have read and understand the above information regarding the hormone therapy, and accept the risks involved.
- ❑ I have had sufficient opportunity to discuss my condition and treatment with my medical provider, and all of my questions have been answered to my satisfaction.
- ❑ I believe I have adequate knowledge on which to base an informed consent to the provision of hormone therapy.
- ❑ I authorize and give my informed consent to the provision of hormone therapy.

_____

Signature of Witness

_____

Date

_____

Name of Witness (Printed)

_____

Signature of Client

_____

Date

_____

Legal Name of Client (Printed)

Appendix N: Sample Request for an Unlisted Drug Product, Oral Estradiol

Ontario **Ministry of Health and Long-Term Care**

Exceptional Access Program Branch
5700 Yonge Street 3rd floor
Toronto ON M2M 4K5

Request for an Unlisted Drug Product
Exceptional Access Program (EAP)

Please fax completed form and/or any additional relevant information to 416 327–7526 or toll–free 1 866 811–9908; or send to Exceptional Access Program Branch (EAPB), 3rd floor, 5700 Yonge Street, Toronto ON M2M 4K5. For copies of this and other EAP forms, please visit http://www.health.gov.on.ca/english/public/forms/form_menus/odb_fm.html

The Ministry of Health and Long-Term Care (the "ministry") considers requests for coverage of drug products not listed in the Ontario Drug Benefit Formulary under Section 16 of the *Ontario Drug Benefit Act*. This form is intended to facilitate requests for drugs under the Exceptional Access Program. The ministry may request additional documentation to support the request.
Please ensure that all appropriate information for each section is provided to avoid delays.

Section 1 – Prescriber Information

First name	Initial	Last name
sample		

Mailing Address
Street no. | Street name

City | Postal code

Fax no. ( ) | Telephone no. ( )

Section 2 – Patient Information

First name	Initial	Last name
sample		

Health Number

Date of birth *(yyyy/mm/dd)*

☐ **New request** ☐ **Renewal of existing EAP approval** *(specify EAP#)* _____–_____

Section 3 – Drug Requested

Requested drug product: Estradiol-17B (Estrace) | DIN: 02148587

Strength / Dosage form: 1 mg po | Frequency of administration: ob/bid, may require adjustment

Expected start date | Duration of therapy: indefinite

Section 4 – Diagnosis and Reason for Use

Diagnosis for which the drug is requested:
Gender Dysphoria

Reason for use over formulary alternatives:
No alternative on formulary

If the patient is currently taking the requested product, please provide start date & objective evidence of its efficacy:
Definitive improvement in psychosocial functioning and decrease in Gender Dysphoria

Section 5 – Current and / or Previous Medications

a) Please provide details of alternatives *(listed drugs and/or non-drug therapy)* tried for this condition:

Name of drug *(indicate if currently or previously taken)*		Dosage	Approximate timeframe of therapy	Reason(s) why formulary alternatives are not appropriate
Anti-androgen if Rx'd	☒ current ☐ previous			n/a
	☐ current ☐ previous			
	☐ current ☐ previous			
	☐ current ☐ previous			

b) Provide patient's concomitant drug therapies for other conditions:

Section 6 – Clinical Information

Please provide relevant medical data *(e.g. culture and sensitivity reports, serum drug levels, laboratory results):*
Patient has been diagnosed with Gender Dysphoria and qualifies for hormone therapy

The information on this form is collected under the authority of the *Personal Health Information Protection Act*, 2004, S.O. 2004, c.3, Sched. A (PHIPA) and Section 13 of the *Ontario Drug Benefit Act*, R.S.O. 1990c.O.10 and will be used in accordance with PHIPA, as set out in the Ministry of Health and Long–Term Care "Statement of Information Practices", which may be accessed at www.health.gov.on.ca. If you have any questions about the collection or use of this information, call the Ontario Drug Benefit (ODB) Help Desk at 1 800 668–6641 or contact the Director, Exceptional Access Program Branch (EAPB), Ministry of Health and Long-Term Care, 3rd floor, 5700 Yonge St., Toronto ON M2M 4K5.

Prescriber signature *(mandatory)*	CPSO number	Date

4406-87 (2009/04)

Appendix O:
Sample Request for an Unlisted Drug Product, IM Testosterone

Ontario **Ministry of Health and Long-Term Care**

Exceptional Access Program Branch
5700 Yonge Street 3rd floor
Toronto ON M2M 4K5

Request for an Unlisted Drug Product
Exceptional Access Program (EAP)

Please fax completed form and/or any additional relevant information to 416 327–7526 or toll–free 1 866 811–9908; or send to Exceptional Access Program Branch (EAPB), 3rd floor, 5700 Yonge Street, Toronto ON M2M 4K5. For copies of this and other EAP forms, please visit http://www.health.gov.on.ca/english/public/forms/form_menus/odb_fm.html

The Ministry of Health and Long-Term Care (the "ministry") considers requests for coverage of drug products not listed in the Ontario Drug Benefit Formulary under Section 16 of the *Ontario Drug Benefit Act*. This form is intended to facilitate requests for drugs under the Exceptional Access Program. The ministry may request additional documentation to support the request.
Please ensure that all appropriate information for each section is provided to avoid delays.

Section 1 – Prescriber Information

First name	Initial	Last name
sample		

Mailing Address
Street no. | Street name

City | Postal code

Fax no. ( ) | Telephone no. ( )

Section 2 – Patient Information

First name	Initial	Last name
sample		

Health Number

Date of birth *(yyyy/mm/dd)*

☐ **New request** ☐ **Renewal of existing EAP approval** *(specify EAP#)* _____–_____

Section 3 – Drug Requested

Requested drug product	DIN
Depo-testosterone	00030783
Strength / Dosage form: 100 mg/mL, 1 mL IM, may require titration	Frequency of administration: weekly, may require adjustment
Expected start date	Duration of therapy: indefinite

Section 4 – Diagnosis and Reason for Use

Diagnosis for which the drug is requested:
Gender Dysphoria

Reason for use over formulary alternatives:
No alternative on formulary

If the patient is currently taking the requested product, please provide start date & objective evidence of its efficacy:
Definitive improvement in psychosocial functioning and decrease in Gender Dysphoria

Section 5 – Current and / or Previous Medications

a) Please provide details of alternatives *(listed drugs and/or non-drug therapy)* tried for this condition:

Name of drug *(indicate if currently or previously taken)*	Dosage	Approximate timeframe of therapy	Reason(s) why formulary alternatives are not appropriate
N/A ☐ current ☐ previous			
☐ current ☐ previous			
☐ current ☐ previous			
☐ current ☐ previous			

b) Provide patient's concomitant drug therapies for other conditions:

Section 6 – Clinical Information

Please provide relevant medical data *(e.g. culture and sensitivity reports, serum drug levels, laboratory results):*
Patient has been diagnosed with Gender Dysphoria and qualifies for hormone therapy

The information on this form is collected under the authority of the *Personal Health Information Protection Act*, 2004, S.O. 2004, c.3, Sched. A (PHIPA) and Section 13 of the *Ontario Drug Benefit Act*, R.S.O. 1990c.O.10 and will be used in accordance with PHIPA, as set out in the Ministry of Health and Long–Term Care "Statement of Information Practices", which may be accessed at www.health.gov.on.ca. If you have any questions about the collection or use of this information, call the Ontario Drug Benefit (ODB) Help Desk at 1 800 668–6641 or contact the Director, Exceptional Access Program Branch (EAPB), Ministry of Health and Long-Term Care, 3rd floor, 5700 Yonge St., Toronto ON M2M 4K5.

Prescriber signature *(mandatory)*	CPSO number	Date

4406-87 (2009/04)

Appendix P: Template Letter in Support of an Application For Change of Sex Designation on an Ontario Birth Registration

Note: the letter must be from a **physician**, **psychologist**, or **psychological associate** authorized to practice in Canada and must be on the medical professional or clinic's letterhead providing an address and phone number

---

Date: _____

To: SERVICE ONTARIO, THE OFFICE OF THE REGISTRAR GENERAL

Re: Application by (_____) for a change in gender designation on their birth registration
name of client

I am a practicing member in good standing with the _____.
specify the appropriate regulatory body

License No: _____.

I have evaluated the applicant, (_____), who is requesting
name of client as shown on the birth registration

a change in gender designation from _____ to _____.

I confirm that the applicant's gender identity does not accord with the gender designation on the applicant's birth registration and I am of the opinion that the change of gender designation on the birth registration is appropriate.

Yours truly,

_____
signature and name of provider

Appendix Q: Template Letter in Support of an Application For Change of Sex Designation on an Ontario Driver's License

Note: the letter must be from a **physician**, **psychologist**, or **psychological associate** authorized to practice in Canada and must be on the medical professional or clinic's letterhead providing an address and phone number

---

Date: _____

To: THE ONTARIO MINISTRY OF TRANSPORTATION

Re: Application by (_____) for a change in gender designation on their driver's license
name of client

I am a practicing member in good standing with the _____.
specify the appropriate regulatory body

License No: _____.

I have evaluated the applicant, (_____), who is requesting
name of client as shown on the driver's license

a change in gender designation from _____ to _____.

I confirm that the applicant's gender identity does not accord with the gender designation on the Applicant's driver's license and I am of the opinion that the change of gender designation on the driver's license is appropriate.

Yours truly,

_____
signature and name of provider

Appendix R:
Sample Support Letter for Trans Clients Applying for EI through the Just Cause Mechanism

Date: _____

To: Human Resources & Skill Development

Re: Application by (_____) for Employment Insurance benefits.
name of client

My *(patient/client)* is a *(transgender woman, transgender man, gender fluid person, etc.)* As a transgender person, *(he/she/they)* report experiencing severe and prolonged mistreatment in *(his/her/their)* workplace, including:
Edit details to accurately reflect client's case, providing as much specific detail as possible; the types of incidents commonly reported include:

- Breach of privacy and threat to safety through the non-consensual disclosure of transgender status by a co-worker/supervisor to others in the workplace
- Verbal harassment, including derogatory jokes and transphobic comments by other co-workers
- Deliberate and repeated use of the wrong gender pronoun by co-workers and supervisor – a practice which is considered harassment by anti-discrimination legislation in some jurisdictions
- Threats to the safety of self or loved ones by co-workers and customers
- Significant change to work duties and reduction of hours of work following disclosure or discovery of transgender status
- Sexual harassment following disclosure or discovery of transgender status
- Persistent hostility by the supervisor following disclosure or discovery of transgender status
- Pressure on the claimant to leave employment and pursue other work

I believe this meets the criteria for 'just cause' outlined in paragraph 29(c) of the Employment Insurance Act, as my *(patient/client)* had no reasonable alternative to leaving to ensure *(his/her/their)* safety and dignity.

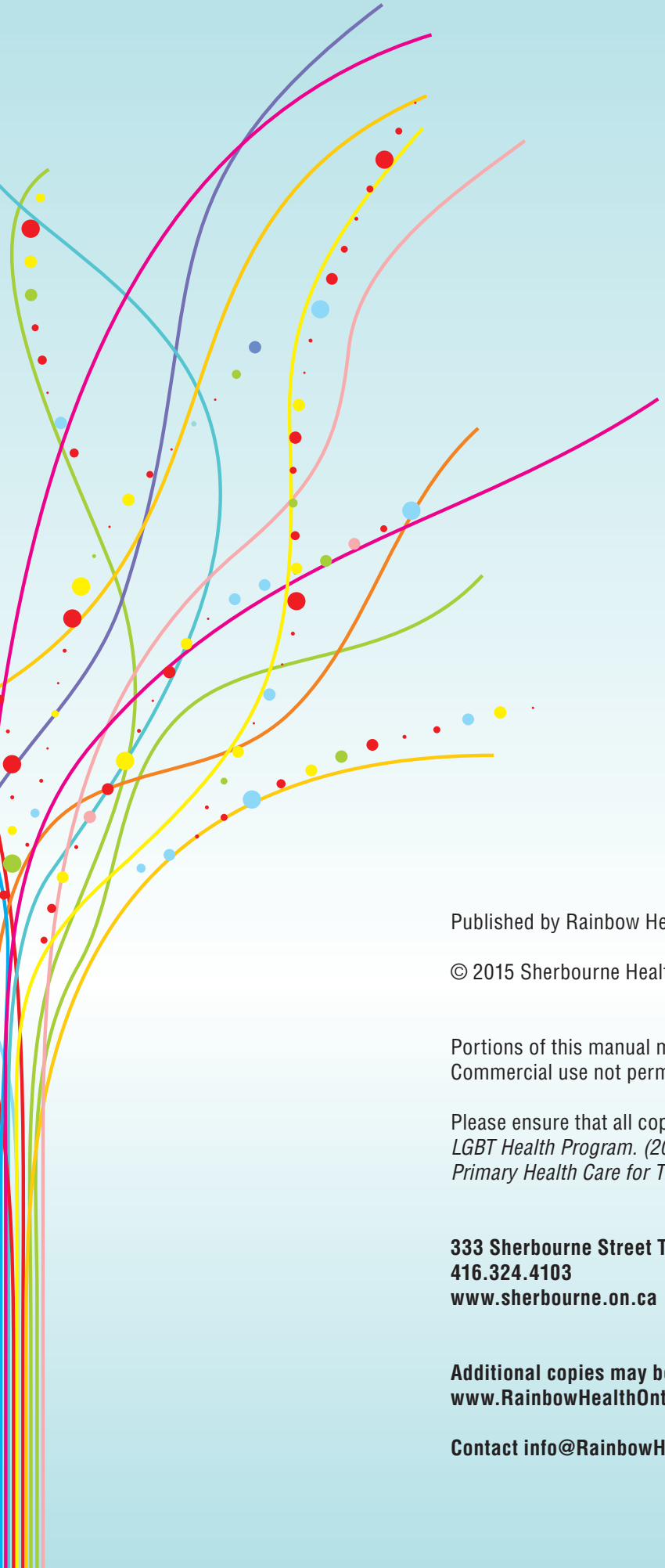
Please feel free to contact me if you require any additional information.

Yours truly,

_____
signature and name of provider

NOTES:

NOTES:



Published by Rainbow Health Ontario, a program of Sherbourne Health Centre

Please ensure that all copied materials are referenced as follows:
LGBT Health Program. (2015) Guidelines and Protocols for Hormone Therapy and Primary Health Care for Trans Clients. Toronto: Sherbourne Health Centre.

333 Sherbourne Street Toronto ON M5A 2S5
416.324.4103
www.sherbourne.on.ca

Additional copies may be ordered at
www.RainbowHealthOntario.ca, under the 'Resources' section

Contact info@RainbowHealthOntario.ca for comments or inquiries.

ACKNOWLEDGEMENTS

We would like to thank all the providers who generously donated their time to provide peer-review and invaluable feedback on this document: Dr. Ray Fung, Sue Hranilovic, Dr. Ed Kucharski, Hershel T. Russel, Dr. Marria Townsend, and Dr. Blair Voyvodic. Thank you to all those who contributed informally to this document through email and numerous hallway and lunchtime conversations, including Rupert Raj, Andy Inkster, and Dr. Thea Weisdorf. A big thank you to Dr. Jane Dunstan for contributing the literature review on bone mineral density and cancer risk and screening, and to Rebecca Hammond for contributing her expertise and lived experience and strengthening this document's approach to language. Thank you to Bianca Brooks at pharmacy.ca for contributing the medication price comparison charts and to Robyn Butcher, librarian at the Department of Community and Family Medicine at the University of Toronto for her tireless literature searches. Thanks to all the LGBT team members over the years and the wider Sherbourne provider group for your dedication to this work which has been essential in developing this body of experiential knowledge, particularly Dr. Kate Greenaway, Dr. Leslie Shanks, and Vlad Wolanyk who authored previous versions of this protocol. Lastly, a heartfelt thank you to all the clients who have allowed us the privilege of being involved in their care and who have taught us so much about authenticity, resilience, and the strength of the human spirit.