Guidelines and Protocols for Comprehensive Primary Health Care for Trans Clients

The term *trans* refers to transgender, transsexual, 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 Comprehensive Primary Health Care for Trans Clients

Part I
Protocol for Treatment with Hormone Therapy

Prepared by Kate Greenaway, MD CCFP, Sherbourne Health Centre

Disclaimer
Sherbourne Health Centre (SHC) is a multidisciplinary clinic providing primary care to an urban population. Our mandate is to serve marginalized populations: our communities of focus are lesbian, gay, bisexual, transsexual and transgender communities; homeless and underhoused people; and newcomer/immigrant populations. Our focus on LGBTT people has resulted in our clinic having a larger than average population of transsexual and transgender clients as compared to other clinics in the area.

Because transsexual hormone treatments have been a major component of our practice, a working group of health care providers at SHC, working together with trans community members, developed a protocol to reflect and inform hormone administration in the clinic. The original document was prepared in early 2003 and was meant to be an internal guideline to maintain consistency in hormone provision. In the past six years, we have received many requests from physicians across Ontario (and Canada) for advice around management of their transsexual clients.

The medical team at Sherbourne is made up of family physicians and nurses; we are not gender specialists by training, but rather we have developed some expertise by virtue of the volume of clients we see and manage. We recognize that this gives us the ability to provide peer support for other clinicians who are providing similar care. The revision of the original protocol has been prepared with this secondary purpose in mind. It is meant to reflect our management of transsexual clients and to thus help other physicians by demystifying 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. 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. And, as with other medical conditions, if complications arise in hormone treatment it may be necessary to consult with an expert.

We hope that this document will enable more family physicians to be involved in care of transsexual 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 will, at some point, be involved in the care of transsexual clients. International estimation of the prevalence of transsexual people (1 in 12000 for male-to-female, and 1 in 30000 female to male) likely significantly underestimates the actual numbers since researchers often use data around sexual reassignment surgery, which many transsexual people do not (or cannot) access. Urban centers often have higher concentrations of transsexual people, thus, practitioners in cities may have more familiarity than their rural counterparts with health care issues of this population. At Sherbourne Health Centre (SHC), lesbian, gay, bisexual, transsexual, and transgendered people are a community of focus – resulting in a larger-than-average population of transsexual clients at the clinic.

Because transsexuality and transgenderism are not concepts explored in traditional medical training, the management of transsexual clients can be confusing for physicians. Working as health care providers at Sherbourne Health Centre, we receive many requests for information and support from community physicians. Providers indicate a lack of understanding of transsexuality and also a lack of clear, specific tools to aid with diagnosis and management. Internationally, there are a number of protocols and guidelines used for care of transsexual and transgender 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).ii The Standards of Care provide international professional consensus around management of gender identity disorders. While it is the ‘gold standard’ consensus, it does not provide specifics around hormone provision, and it does not discuss the role of the family physician in the care of transsexual clients. Many clinics have developed protocols for their own practitioners, also available to the public, which are more specific in their details around management.1 Likewise, SHC presents this guideline to summarize the current clinical practice at the centre.

For most transsexual clients, the focus of the medical encounters will be to bring the physical appearance more in-line with the internal gender identity of the individual. This is achieved through use of hormones and surgeries. Since the family physician usually has familiarity with the individual client, he or she is in a good position to formulate the diagnosis and develop a management plan. Many family physicians seek consultation with an endocrinologist; this is often an appropriate and helpful referral (especially if there is an endocrinologist available with experience treating transsexual clients). However, it is certainly within the scope of family physicians to provide hormone treatments to their transsexual clients.

There is a great deal of variation among family physicians around comfort level of beginning hormones, and also around titration and maintenance of doses. Ideally, this document will provide some guidance with regards to the usual doses and monitoring manoeuvres and more familiarity with general considerations. At the Sherbourne Health Centre, we are privileged to work on a health care team that provides support to a large number of transsexual clients, thus we are able to provide peer support for one another. Our hope is that this discussion of our general guidelines and practice will help other physicians feel supported in their endeavours to serve their transsexual clients.

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1 Examples include Tom Waddell Health Center, Castro-Mission Health Centre, Callen-Lorde Community Health Centre, Vancouver Coastal Health
The comfort level of the prescribing physician with hormone treatments for gender transition may dictate the approach to hormone start. For example, it is certainly reasonable to obtain the opinion of an endocrinologist or another more experienced physician about hormone regimens, in the case of a physician who feels he/she needs support. However, in many areas of Ontario, access to endocrinologists is quite limited, and clients may thus have a prolonged waiting period. It may be helpful to the provider and client to consider starting on low-dose hormones (e.g. half the regular dosage) until the consultation can be obtained.

Alternatively, some physicians may feel more comfortable taking over prescribing after hormones have been recommended and/or started by another physician, or after the client has already undergone some form of sex reassignment surgery. If the client has undergone gonad removal, they should be maintained on hormone therapy. Physicians can also provide “bridging” support by prescribing hormones for a client who has previously received hormone treatment, and who is seeking care from a provider more expert in this field. In this case, clinicians may provide short-term (i.e. a few months) support; clinicians should use current recommendations for hormone administration to choose the safest hormone treatments.

Certainly, at Sherbourne Health Centre, we provide both long-term pre-operative support (for clients who either delay surgeries, or decide to not have any) and hormone support for clients through all stages of transition. In each of the above examples, it is still appropriate to clarify client’s medical history and readiness for treatment, as well as reviewing previous medical files.

**Decision to start hormones**

Hormone therapy in transsexual clients should reduce secondary sexual characteristics of the biological sex, and induce the characteristics of the non-biological sex. This goal of treatment is to help clients to integrate internal sense of gender with the external expression of gender, thus decreasing gender dysphoria – the distress associated with the discordant gender identity.

The decision to implement treatment with hormones for a transsexual client is individualized, however, there are some common guidelines undertaken by our clinic. These guidelines are designed to maximize the safety of the client; fulfill the legal and ethical requirements of the physician; and reduce the possibility of inappropriate treatment. The transsexual population has suffered a great deal of prejudice, misunderstanding and harm from the medical community, thus, although we must act as “gatekeepers” to medical services and medications, we acknowledge that the systemic oppression experienced by our transsexual clients has often resulted in denial of service. We do not wish to participate in this discrimination, and instead, we aim to increase the appropriate provision of hormone therapy for transsexual clients.

Many providers are concerned about the possibility of regret, that is, of treating a client with hormone therapy who later decides he/she prefers the sex of origin. This is, in fact, a fairly rare occurrence. The experience of regret after sex reassignment has been studied largely by case study; the prevalence of people who regret their transitions is estimated at 1-2% of all transsexuals. We aim to help providers develop realistic goals and expectations with their clients in order to prevent post-hoc regrets as much as possible.
Our criteria for determining readiness are:

- Diagnosis of Gender Identity Disorder;
- Psychosocial readiness to begin treatment;
- Completion of a period of evaluation including appropriate physical and laboratory investigations;
- Absence of contraindications;
- Client understanding of risks, precautions and side effects of treatment.

Diagnosis
The provision of hormone therapy is generally preceded by a diagnosis of Gender Identity Disorder (GID) as outlined in the Diagnostic and Statistics Manual, Volume 4 (DSM-IV-TR). There has been a great deal of debate in both the medical and transgender communities around the appropriateness of using a psychiatric diagnosis for transgender individuals. Certainly, there is potential for stigmatization and mistreatment of transgender people if they are seen to have a psychiatric illness. However, there is also the ability to provide good care and make appropriate interventions based on the diagnosis. Thus, for many physicians, the use of a psychiatric diagnosis is not meant as judgment or stigmatization of transsexual individuals, but as a tool to defend appropriate medical intervention and treatment. The DSM-IV-TR diagnosis is as follows:

- There must be evidence of a strong and persistent cross-gender identification.
- This cross-gender identification must not merely be a desire for any perceived cultural advantages of being the other sex.
- There must also be evidence of persistent discomfort about one's assigned sex or a sense of inappropriateness in the gender role of that sex.
- The individual must not have a concurrent physical intersex condition (e.g., androgen insensitivity syndrome or congenital adrenal hyperplasia).
- There must be evidence of 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 physician work to rule out other psychiatric diagnoses that may explain the presentation. Possible differential diagnoses include schizophrenia, psychosis, dissociative disorder or internalized homophobia. If the presentation is unclear, it is appropriate to get the opinion of a psychiatrist. Care should be taken, however, to refer to a psychiatrist who has some experience in gender identity disorder.
Psychosocial Readiness

Psychosocial readiness to begin treatment is a subjective evaluation, well-suited to the family practitioner. Gender transition is a phase of serious 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”\(^2\)). The client may benefit from individual therapy with a trans-positive therapist to assist in support and encouragement through the transition. Inquiring around how transitioning will influence the vocational or educational situation of the client is important; we can help the client develop strategies for dealing with gender change in the workplace or school. As discussed in the “social supports” section, transition often results in a loss of job or struggle in the academic setting. Though not a requirement for initiation of transsexual hormone treatment, we encourage clients to discuss the transition with family members and friends. It will be, at the least, a crucial conversation for the health care provider to initiate.

Possible questions to open 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?

The WPATH group has advocated for real life experience for at least 3 months prior to surgical intervention.\(^3\) This step was developed to establish coping mechanisms for the abovementioned social stressors, and it requires people to live in the gender role of their internally-experienced gender, with or without hormone administration. This step can be problematic for clients if it requires them to adopt a role prior to having any physical changes commensurate with that gender. The real life experience will certainly be valuable to evaluate the client’s ability to cope with the stressors associated with expressing gender, but we do not consider it a necessary step prior to hormone administration.

Evaluation Period

At Sherbourne Health Centre, new clients are seen for a period of 3 months - during which the client has at least five visits – in order to determine readiness for hormone therapy. This period allows the physician to become acquainted with the client, to make the appropriate diagnoses, and to rule out contraindications to

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\(^2\) Gender Journeys is an 8-week peer education program run out of Sherbourne Health Centre, in Toronto. The program is facilitated by 2 gender specialists, and explores topics related to transition. Copies of the manual for this program can be obtained from Sherbourne Health Centre for a cost of $10 plus postage and handling.
treatment. It also allows the client to become accustomed to regular meetings with health care providers – a necessary component of ongoing treatment.

**Proposed progression of visits**

<table>
<thead>
<tr>
<th>Visit 1:</th>
<th>General medical intake, initial discussion of gender history. Attempt to get old records from previous physician if this is a new client.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 2:</td>
<td>More detailed gender history including childhood gender presentation, experience of puberty, current expression/understanding of gender. Explore supports and determine reaction of family and friends to client’s gender identity.</td>
</tr>
<tr>
<td>Visit 3:</td>
<td>Full physical exam including appropriate screening measures commensurate with client’s biological sex. Height, weight and waist circumference should be included in the vital signs, as well as baseline chest and hip measurements for male-to-female clients. Blood work should be done to evaluate liver function, renal function, lipid profile, fasting glucose, blood cell analysis. Hormonal profile may be considered (to rule out intersex condition and exogenous hormone administration).</td>
</tr>
<tr>
<td>Visit 4:</td>
<td>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 and sign.</td>
</tr>
<tr>
<td>Visit 5:</td>
<td>Review risks of treatment and obtain consent. Choose initial hormone regimen.</td>
</tr>
</tbody>
</table>

The physical exam, like the general periodic health exam, is used to rule out dysfunction of a major body system. Many transsexual 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 genitals and breast are often very uncomfortable for these clients. Nonetheless, a full physical is a prerequisite to hormone administration; if carefully explained to the client ahead of time, it can act as a rapport-building experience.

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3 For female-bodied clients, this will include breast and pelvic exam. If the client is sexually active with female partners only, a Pap smear is nonetheless required since cervical cancer is a real concern in this population. If the client has not been sexually active with any partners, a speculum exam and Pap may not be necessary. A bimanual exam, if tolerated, may still be indicated.

For male-bodied clients, a testicular exam is indicated, +/- prostate exam, depending on age.
The exam should include investigations for problems such as hypertension and obesity, which increase the risks of hormone therapy. Inquiry should be undertaken into smoking status, since we recommend stopping smoking before starting hormones. The exercise program of the client should be explored, since this will become important to combat some of the negative endocrine side effects of hormones. Genital exam will provide routine screening (i.e. for cervical, testicular or prostate cancers) 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.

Laboratory exam should reveal any co-morbidities such as liver dysfunction, high cholesterol, diabetes. If present, these conditions must 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 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.

Precautions with hormone use
Each hormone will have its own specific contraindications; however, it is worthwhile to address general contraindications (or precautions) to hormone use. Many uncontrolled conditions can be potentially worsened by hormone administration. These include: psychiatric illnesses, diabetes, hypertension, and high cholesterol. If any of these conditions are present, they should be managed prior to initiation of hormone therapy.

Smoking and obesity will increase risks associated with hormones. It is worthwhile for the physician and client to act 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 harm reduction approach may be necessary. Drug addiction – whether alcohol, illicit or prescription drugs – makes hormone use more risky and should be considered a precaution to administration.

Clients must be able to attend regular appointments with the medical team. This capacity is usually revealed by the evaluation visits but, in addition, the client can contract with the physician to return for regular follow-up exams and blood tests.

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4 Consider offering a chaperone to the client for genital exam, especially when it will be difficult for the client to undergo. 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 issue should be revisited periodically by the provider.

5 Similar to lesbian, gay and bisexual populations, transsexual and transgender populations have higher than average rates of addiction to cigarettes, alcohol and other drugs. 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 dangerous for a trans person to enter a mainstream treatment program.

6 See Consent Forms, Appendix B and C.
Fertility issues should be discussed prior to hormone use. For female-to-male transsexuals, pregnancy is a contraindication to testosterone use and the client must take precaution against becoming pregnant while taking it. We advise clients to not start testosterone if they would like to become pregnant in the future, since fertility may be permanently affected. Male-to-female clients should also be cautioned to use birth control if sexually active with partners who may become pregnant, since hormonal impact on fertility can be variable. We also advise clients to bank sperm prior to starting hormones if they suspect they may wish to have children in the future.\(^7\)

As with any other medical intervention, clients must demonstrate understanding of the risks and benefits of hormone treatment. This is usually a straightforward evaluation; the major questions around capacity to consent generally arise for us with younger clients. If the client is under 18, it may be advisable to seek consultation with psychiatry and/or pediatric endocrinology.

It is the role of the prescribing physician 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: male-to-female clients will maintain narrow hips, existing facial bone structure, and will require hair removal to remove existing body and facial hair. Female-to-male clients will also maintain pre-transition facial and body structure. For these reasons, people may not easily “pass” as the sex they are transitioning into. This can be very stressful and disheartening to the individual, and should be foreseen and discussed by the physician. 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 physician’s role to explain the risks with overuse of hormones, as well as to provide rationale for the approach he or she is using. As previously stated, the prescribing physician must act within his/her comfort level as well as in the interest of the client.

**Special Considerations**

Provision of hormone treatment may be undertaken, in some cases, without definitively establishing a diagnosis of Gender Identity Disorder 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 significant distress regarding their gender presentation.

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\(^7\) Clients may use a hospital-based sperm bank, or a commercial sperm bank. Storage costs $1000.00 for five years. See, for example, ReproMed at [www.repromed.ca](http://www.repromed.ca).
Summary

Example of clinician checklist for use at initiation of hormone treatment:

Criteria for Gender Identity Disorder (GID):

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Yes ( )</th>
<th>No ( )</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Persistent cross-gender identification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Severe discomfort in assigned sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Absence of intersex condition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Severe distress/ functional impairment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Old records reviewed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other differential diagnoses ruled out</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical contraindications ruled out</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychiatric co-morbidity</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

List:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Yes ( )</th>
<th>No ( )</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bloodwork</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECG if risk factors or over 40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If smoker, smoking cessation counsel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discussed contraception/ infertility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supports in place to assist with transitioning</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good understanding of the risks and benefits of hormones</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Competent to consent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consent signed</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Hormone Therapy for Male-to-Female Transsexuals
The goal of hormone therapy in male to female transsexuals (MTF) is to reduce male secondary sex characteristics such as coarse body hair, facial hair; and to increase 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. Irreversible components are breast development and fat redistribution, and possibly loss of fertility. More reversible changes include thinning of body hair, and skin changes.

Most of the serious adverse effects associated with transsexual hormone provision are due to estrogen administration. As reported by the Women’s Health Initiative (WHI), risks associated with combination estrogen and progesterone include increased rates of heart disease, breast cancer, and development of blood clots, and strokes. These risks appear to be less with estrogen alone.

Anti-Androgens
Because of the serious side effects of estrogen, one of the goals of therapy is to achieve the best feminization possible with the lowest dose of estrogen. This goal is achieved with the use of androgen-suppressing agents; androgen suppression can be started prior to estrogen administration. 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 affects through blockage of peripheral androgen receptors. Because its major action is androgen blockade, it will not always affect a significant change in blood testosterone levels. However, it has a minor action through interference with testosterone conversion to active dihydrotestosterone (DHT). Use caution when using spironolactone with medications which may contribute to hyperkalemia or in health conditions which may result in increased potassium-retention. It is contraindicated in patients with renal dysfunction.

Cyproterone has activity similar to progesterone; it often has a more rapid suppression of testosterone than does spironolactone. It acts primarily through androgen-receptor blockade, but also inhibits production of LH via negative inhibition of the hypothalamic pituitary axis. Cyproterone is more expensive than spironolactone. It has been noted to cause severe liver dysfunction (with extended use) and depression (in early treatment). It, thus, should not be used in people with hepatic or renal disease nor with a history of depression.

Table 1. Recommended doses of anti-androgens for male-to-female transsexuals

<table>
<thead>
<tr>
<th></th>
<th>Spironolactone</th>
<th>Cyproterone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starting Dose</td>
<td>50 – 100 mg OD</td>
<td>25 - 50 mg OD</td>
</tr>
<tr>
<td>Maximum Dose</td>
<td>200 mg BID</td>
<td>100 mg OD</td>
</tr>
</tbody>
</table>
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.\textsuperscript{ix} If this medication is being considered, we would recommend consultation with an endocrinologist. Flutamide has also been reported for use in male-to-female transsexuals.\textsuperscript{x} It has been reported to have hepatotoxic effects; it is not used at our clinic.

**Progesterone**

The use of progesterone in male to female transsexuals is controversial.\textsuperscript{xi} There has not been a clear feminizing benefit shown with the use of progesterone, although some individuals and some clinicians feel it has been a useful adjunctive medication. It is used by some clinicians for clients experiencing decreased libido.\textsuperscript{xii} Progesterone has a suppressive effect on LH, thus decreasing androgen production.

The common side effects associated with progesterone are weight gain, depression, and edema. Serious long-term outcomes with combined estrogen and progesterone have been examined in post-menopausal women by the Women’s Health Initiative; the 2007 updates support the original findings, which were increased incidence of breast cancer, increased strokes and blood clots, and increased heart disease.\textsuperscript{xiii} These same outcomes were not found to the same extent with estrogen alone.

If used, the usual dose of progesterone would be micronized progesterone 100-400mg daily; or medroxyprogesterone acetate 5 – 30mg daily.

**Estrogen**

**Absolute Contraindications to Estrogen Therapy:**

- Ischemic Cardiovascular disease
- Cerebrovascular disease
- History of DVT or PE
- Marked hypertriglyceridemia
- Hyperprolactinemia
- Estrogen-dependent cancer
- Uncontrolled high blood pressure or diabetes
- Psychiatric conditions which limit the ability to provide informed consent.
Precautions with Estrogen Therapy:

- Other cardiac disease
- Family history of abnormal clotting
- Smoker
- History of benign intracranial hypertension
- Metabolic Syndrome
- Hepatic dysfunction
- Refractory migraine or focal migraine
- Seizure disorder
- Strong family history of breast cancer
- Family history of porphyria.

Estrogen acts directly on peripheral receptors to initiate feminization. Because of this, it is usually the focus of hormonal transition. However, in order to achieve adequate suppression of androgens, estrogen alone would need to be administered in dangerously high doses. Thus, the combination of androgen suppressors and estrogen is the favoured approach.

Estrogen has the most serious risk profile as compared to other medications used in transsexual clients. The potential negative outcomes of estrogen therapy have been illustrated in both post-menopausal females and male-to-female transsexuals. 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 women. This study showed increased incidence of breast cancer, heart disease, and stroke. The greatest increase was seen with a combination of estrogen and progesterone as opposed to estrogen alone. In transsexual women, rates of venous thrombosis and pulmonary embolism have been shown to greatly increase with administration of estrogen; however, these rates have declined with the use of transdermal estrogens. There have been 3 case reports of male-to-female transsexuals developing breast cancer while on hormonal therapy.

In Ontario, the most common form of estrogen administered to trans women is synthetic conjugated estrogen (CES). This is the cheapest formulation, and is covered by the Ontario Drug Benefit with an ICR request. This type of estrogen is not readily measurable in the blood. It is subject to first pass liver metabolism. This formulation may be associated with higher rates of deep vein thrombosis as compared to estradiol formulations, especially transdermal preparations.

In other parts of Canada, estradiol is the more common form of estrogen used for hormonal transition. It can be administered in oral or transdermal formulations. Because transdermal formulations bypass liver metabolism...

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8 See Appendix in Social Supports section.
metabolism, it is thought to have less hepatic side effects. Compared to conjugated estrogens, estradiol has a better safety profile in terms of thrombosis risk. Transdermal estradiol seems to have an even better safety profile than oral estradiol, and is thus recommended for transsexual women over 40. This decreased risk has been demonstrated in both post-menopausal women and transsexual women. 

Injectable estrogens (in the form of estradiol valerate) are available in Ontario through some compounding pharmacies. 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 a transdermal method. However, in otherwise healthy young clients, it is a possible alternative.

Table 2. Recommended estrogen doses for male-to-female transsexuals without orchiectomy.

<table>
<thead>
<tr>
<th></th>
<th>Starting Dose</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conjugated Estrogen</td>
<td>0.625mg OD</td>
<td>1.25mg OD</td>
</tr>
<tr>
<td>Estradiol (oral)</td>
<td>1-2mg OD</td>
<td>4mg OD</td>
</tr>
<tr>
<td>Estradiol (transdermal)</td>
<td>0.1mg OD/ apply patch 2x/week</td>
<td>0.2mg OD/ apply patch 2x/week</td>
</tr>
<tr>
<td>Estradiol valerate (injectable)</td>
<td>10mg q 2/52</td>
<td>10mg q 1/52</td>
</tr>
</tbody>
</table>

Clients who have genital reassignment surgery and/or orchiectomy, will have different hormone requirements to maintain feminization. We recommend that transsexual 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 transsexual women will not require androgen suppression by spironolactone or cyproterone. They will require ongoing estrogen supplementation to preserve bone strength, etc. Younger clients may require the same dose of estrogen post-operatively as they did pre-operatively, however, older clients can usually be maintained on the starting dose.

For clients over 50 years old, estrogen doses should be similar to post-menopausal dosing – 0.025mg – 0.05 mg patch.

**Monitoring and Dose Changes**

Standard monitoring of estrogen administration should be employed at baseline, 1 month, 3 months, 6 months and 1 year. This should include both bloodwork and targeted physical exam – including screening maneuvers commensurate with the physical attributes of the client. For example, a client who is taking estrogen but has not undergone any surgery will require breast exam, testicular exam and/or prostate exam,
while a client who has undergone genital reassignment will require breast exam, prostate exam, and exam of the neo-vagina as required. The targeted physical exam will also include blood pressure, weight, waist circumference and liver palpation.

Dose titration may be done over a few months and will depend both on physical response and measured suppression of testosterone. If an anti-androgen is started first, the clinician may look for early feminization changes and loss of spontaneous erections as indication of successful treatment. Estrogen can be added after the first month of treatment. Starting dose of estrogen can be maintained for 1-2 months, then consider increasing if not adequate effect.

At every visit, the clinician should review risks of treatment and teaching around monitoring for venous thromboembolism.

Testosterone level may be the most useful test for monitoring in male-to-female clients; the provider should check for suppression of testosterone into the female range. 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 using estradiol formulations, estradiol levels can be checked and should fall within the female range. This is not always useful since the range of estradiol levels is quite large. If misuse is suspected, this test will be helpful. Prolactin should be checked at least annually; many trans women will have elevation of prolactin with estrogen administration. Since the risk of pituitary adenoma is increased in this population (because of estrogen use), this level should be carefully monitored. If the level is >70, MRI of the sella may be indicated.

Liver enzymes and renal function need regular monitoring. LH should be monitored annually – if LH is not adequately suppressed, this may have implications for bone density (see below). Cholesterol panel can be checked every 6 months, since estrogen has shown an effect on HDL, LDL and triglyceride levels.

Table 3. Recommended blood work measurements in male-to-female transsexuals.

<table>
<thead>
<tr>
<th>Baseline</th>
<th>1 month</th>
<th>3 months</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBC, ALT/AST, Cr/lytes/urea, testosterone, LDL/HDL/TG, fasting glucose, +/-estradiol, LH, prolactin</td>
<td>CBC, ALT/AST, Cr/lytes/urea, testosterone, +/-estradiol, prolactin</td>
<td>CBC, ALT/AST, Cr/lytes/urea, testosterone, +/-estradiol, prolactin</td>
<td>CBC, ALT/AST, Cr/lytes/urea, testosterone, LDL/HDL/TG, fasting glucose, +/-estradiol, prolactin</td>
<td>CBC, ALT/AST, Cr/lytes/urea, testosterone, LDL/HDL/TG, fasting glucose, +/-estradiol, LH, prolactin</td>
</tr>
</tbody>
</table>

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

---

9 See Appendix A for laboratory ranges.
redistribution take longer. The amount of breast tissue developed is largely based on the genetic potential 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. Generally,
physical changes are considered to be complete after 2-3 years on hormone therapy.

Bone Density
If male-to-female clients are maintained on estrogen – especially post-orchietomy – it is likely that bone
support will be adequate. 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. If the client has undergone orchiectomy and has been off hormones for any length of time, testing
should be offered sooner. Additionally, if the client has other risks for bone loss (including glucocorticoid
therapy, previous fracture, family history of osteoporosis), BMD screening may be offered sooner.
Supplementation of 1500mg of calcium and 800IU of Vitamin D is recommended for all.

ASA
Individuals with moderate to high risk for developing cardiovascular disease should be offered aspirin as
primary prevention.
Hormone Therapy for Female-to-Male Transsexuals

Testosterone

Absolute/Relative contraindications to testosterone therapy:
- Coronary artery disease/uncontrolled HBP
- Hepatic disease
- Uncontrolled diabetes
- Pregnancy
- Psychiatric conditions which limit the ability to provide informed consent
- Active psychosis or acute suicidality/homicidality
- Chronic respiratory disease that may be worsened by erythrocytosis
- Hypersensitivity to one of the components.

The cornerstone of therapy for female-to-male transsexuals 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, hirsutism, clitoral growth, and increased muscle mass. Breast tissue may lose glandularity, but will not decrease in mass with use of testosterone. Voice changes, clitoral growth, and fat redistribution are irreversible changes. Fertility is decreased - this, however, is variable. If clients have biologically male partners, a permanent method of birth control should be employed.

Typically, clients taking testosterone develop a male phenotype over a period of months to years. Menses should cease in the first 6 months of therapy. If they are ongoing at this point, testosterone dosage may need to be increased. Some clients wish to have cessation of menses without significant virilization. For these individuals, progesterone may be administered independently, either in the form of injectable birth control, or with the insertion of an intra-uterine device. The advantage of this intervention is its complete reversibility. Similarly, GnRH analogs (leuprolide or Lupron) could be used to suppress the expression of female hormones.

Coarsening of body hair, as well as facial hair growth, will begin soon after initiation of testosterone, but will take a number of years to reach full growth. Clitoral growth usually begins in the first few months of therapy.

Clients taking testosterone should be advised to maintain an exercise program to avoid excess weight gain. With regular exercise, lean muscle mass begins 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.
Mood changes can occur with testosterone; many clients describe a feeling of well-being associated with testosterone administration and a decrease in this well-being 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. Namely, researchers have looked at incidence of hypomania, mania, increased aggression and psychosis with testosterone. Some recent studies have showed a small incidence of these occurrences. It is worth inquiring about mood changes on follow-up visits. Caution should be exercised in clients with uncontrolled bipolar disorder or another history of psychosis.

As with most medical interventions, a number of health risks have been postulated to be related to testosterone therapy. Observational studies of clients undergoing testosterone therapy have shown increased weight and acne, as well as more serious side effects such as liver toxicity, increased risk for coronary artery disease, lipid abnormalities, increased erythropoiesis, and possible malignancy. In terms of malignancy, there have been 3 reported cases of ovarian cancer in transsexual men, and one case of breast cancer post-mastectomy. While there have been cases of endometrial hyperplasia, there have been no reported cases of endometrial cancer. In clients without hysterectomy, annual pelvic exams should be undertaken. If bleeding occurs in the setting of testosterone administration, clients should be worked up for possible endometrial hyperplasia.

Testosterone is administered by either injectable or transdermal preparations. Injectable formulations are most commonly used, both because of their superior efficacy and lower price. If transdermal formulations are used in a client without hysterectomy, progesterone may need to be added to achieve suppression of menses. The advantage of transdermal preparations is the relatively steady state of testosterone, as opposed to the fluctuations with injectables. In Ontario, injectable testosterone is the form generally approved by special request to the Drug Benefit Program. It is substantially cheaper than transdermal formulations, making the preferred medication by most of our clients.

**Table 4. Recommended dose of testosterone for female-to-male transsexuals.**

<table>
<thead>
<tr>
<th>Testosterone enantate/ testosterone cypionate (IM)</th>
<th>Starting Dose</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>50-100mg q week, or 100 – 200 mg q 2-3 weeks</td>
<td>100mg q week, or 200mg q 2-3 weeks</td>
</tr>
<tr>
<td>Testosterone – transdermal patch</td>
<td>2.5-5mg OD</td>
<td>5-10mg OD</td>
</tr>
<tr>
<td>Testosterone - gel</td>
<td>2.5 – 5 g OD</td>
<td>5-10 g OD</td>
</tr>
</tbody>
</table>
If using an injectable formulation, it is advisable to teach the client how to self-inject the medication.\textsuperscript{10}

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.

**Monitoring and Dose Changes**

As with treatment for male-to-female transsexuals, monitoring should be done at 1, 3, 6 and 12 months after starting therapy. Titration of doses will occur in the early phases of treatment (i.e. after bloodwork done at 1 or 3 months). Usually, the target dose will bring the client into physiologic male testosterone ranges. If the client shows hepatic dysfunction or erythropoiesis, it is advisable to lower the dose.

Because of the risk of erythropoiesis and liver inflammation, liver enzymes and a complete blood count should be measured on each occasion. Free and total testosterone can be monitored, and should generally fall within the male range.\textsuperscript{11} We recommend checking blood levels the day before the injection is due. Cholesterol profiles should be measured every 6 months, since testosterone has been shown to alter both LDL and HDL levels. In terms of physical exam, blood pressure, weight, waist circumference and liver palpation should be performed each visit. Routine screening physical examination including Pap smears (for clients without hysterectomy), bimanual exam and breast/chest exam (even post-mastectomy) should be performed annually.

**Table 5. Recommended bloodwork for monitoring hormones in female-to-male transsexuals.**

<table>
<thead>
<tr>
<th>Baseline</th>
<th>1 month</th>
<th>3 months</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBC, ALT/AST, testosterone, LDL/HDL/TG, fasting glucose, Hep A,B,C serology, pregnancy test</td>
<td>CBC, ALT/AST, testosterone</td>
<td>CBC, ALT/AST, testosterone</td>
<td>CBC, ALT/AST, testosterone, LDL/HDL/TG, fasting glucose</td>
<td>CBC, ALT/AST, testosterone, LDL/HDL/TG, fasting glucose</td>
</tr>
</tbody>
</table>

**Bone Density**

Sex hormones are well known to effect bone mineral density (BMD), and the subsequent risk of osteoporosis. It appears that female-to-male transsexuals are more at risk of osteoporosis than male-to-female transsexuals, who are likely getting good bone support through estrogen. Testosterone must be

\textsuperscript{10} Self-injection teaching video for clients, “Taking Care of Business,” is available from Sherbourne Health Centre.

\textsuperscript{11} Laboratory testosterone ranges – see Appendix A.
continued post-oophorectomy to maintain bone mineral density. If clients are unable or unwilling to stay on hormones continuously, bisphosphonates may be considered as a preventative measure. As with male-to-female clients, calcium and vitamin D are recommended for all.

There is some research suggesting that LH level may be associated with bone density, that is, if LH is unsuppressed, the client may not be achieving adequate hormonal support for bone maintenance. Bone mineral density testing may be undertaken in clients with unsuppressed LH, or in clients who have been off hormones for a period of time, or in clients with other risk factors.

**Metabolic Effects**
The prevalence of polycystic ovarian disease has been found to be increased in transsexual men prior to use of testosterone. This prevalence is estimated to be as high as 40%. Administration of testosterone has been found independently to increase insulin resistance. Additionally, long term treatment of testosterone is associated with increased deposition of visceral fat. These facts taken together suggest that transsexual men on testosterone treatment may be at higher risk of glucose intolerance, and the cardiovascular risks associated with insulin resistance.

Therefore it is important to emphasize minimizing other risk factors for CAD disease and diabetes. Smoking cessation should be strongly encouraged, as well as a regular exercise schedule, maintenance of healthy body weight, and dietary control of lipids. In some cases, statins may be needed.

**Conclusion**
Providing comprehensive care for transsexual clients can be a rewarding part of family practice. The family physician is well-suited to care for this population. Clinicians can apply their knowledge of hormone use in other populations (e.g. post-menopausal women or hypogonadal men) to clients using hormones for gender transition. Large scale studies of transsexual people and outcomes with hormones are required to improve evidence-based care, however, in the meantime, it is possible to rely on smaller studies and expert opinion.

Often transsexual clients will require consultation with specialist – psychiatrists, endocrinologists and surgeons. In Ontario, sex reassignment surgery (SRS) has recently been ‘relisted’ after being an uninsured service for many years. It is not yet clear how easily accessible surgery will be to clients, or who will be qualified to assess readiness for surgery. If clients wish to have surgery and have the means to pay for it themselves, it is necessary to ask the surgeon what documentation they require to proceed. Some surgeons need only the request of the family physician (often this is true for mastectomy) while others need letters from a psychiatrist and psychologist with experience in gender identity disorders (for genital surgery).

As with many marginalized populations, care of transsexual clients requires ‘cultural competence’ – an understanding and awareness of the barriers to care. The sections on mental health support and social support address these issues. Wherever possible, it is advisable to make your clinic accessible to transsexual people. This may be through staff training around common office issues that affect transsexual people, such as use of appropriate pronouns and discrepancy of presenting gender and the sex on client’s OHIP card. Trouble-shooting these issues in advance may help reduce stigmatization of transsexual clients in the office.
Appendix A: Reference ranges (Lifelabs)

**17-Beta-Estradiol**

<table>
<thead>
<tr>
<th>Gender</th>
<th>Phase</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>follicular phase</td>
<td>70-905 pmol/L</td>
</tr>
<tr>
<td></td>
<td>midcycle</td>
<td>130-2095 pmol/L</td>
</tr>
<tr>
<td></td>
<td>luteal</td>
<td>82-940</td>
</tr>
<tr>
<td></td>
<td>post-menopause</td>
<td>up to 163</td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td>41-151 pmol/L</td>
</tr>
</tbody>
</table>

**LH**

<table>
<thead>
<tr>
<th>Gender</th>
<th>Phase</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>prepubertal</td>
<td>1-6 IU/L</td>
</tr>
<tr>
<td></td>
<td>follicular phase</td>
<td>1-25 IU/L</td>
</tr>
<tr>
<td></td>
<td>midcycle</td>
<td>25-55 IU/L</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(3-5 X follicular)</td>
</tr>
<tr>
<td></td>
<td>luteal</td>
<td>1-25 IU/L</td>
</tr>
<tr>
<td></td>
<td>post-menopause</td>
<td>40-105 IU/L</td>
</tr>
<tr>
<td></td>
<td>or ovariectomized</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td>2-6 IU/L</td>
</tr>
</tbody>
</table>

**FSH**

<table>
<thead>
<tr>
<th>Gender</th>
<th>Phase</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>follicular</td>
<td>1-11 IU/L</td>
</tr>
<tr>
<td></td>
<td>midcycle</td>
<td>2-22 IU/L</td>
</tr>
<tr>
<td></td>
<td>luteal</td>
<td>1-8 IU/L</td>
</tr>
<tr>
<td></td>
<td>post menopause</td>
<td>&gt;35</td>
</tr>
<tr>
<td></td>
<td>or ovariectomized</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td>2-8 IU/L</td>
</tr>
</tbody>
</table>
Appendix A: Reference ranges (Lifelabs) continued

**Free Testosterone**

<table>
<thead>
<tr>
<th>Female:</th>
<th>Age</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;20</td>
<td>1.5-11.6 pmol/L</td>
</tr>
<tr>
<td></td>
<td>20-39</td>
<td>0.8-12.1 pmol/L</td>
</tr>
<tr>
<td></td>
<td>40-59</td>
<td>0.3-6.9 pmol/L</td>
</tr>
<tr>
<td></td>
<td>&gt;60</td>
<td>0.3-5.4 pmol/L</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Male:</th>
<th>Age</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;20</td>
<td>21-103 pmol/L</td>
</tr>
<tr>
<td></td>
<td>20-39</td>
<td>31-94 pmol/L</td>
</tr>
<tr>
<td></td>
<td>40-59</td>
<td>25-80 pmol/L</td>
</tr>
<tr>
<td></td>
<td>&gt;60</td>
<td>19-66 pmol/L</td>
</tr>
</tbody>
</table>

**Testosterone (total)**

<table>
<thead>
<tr>
<th>Female</th>
<th>Less than 2.7 nmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>8.4-28.7 nmol/L</td>
</tr>
</tbody>
</table>
Appendix B: Consent Form for Hormone Therapy for Men Of Transgender Experience

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

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:

__________________________________________ 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 Client                      Date

__________________________________________
Legal Name of Client (Printed)

_________________________________________________________________________  ________________
Signature of Witness                   Date

__________________________________________
Name of Witness (Printed)
Appendix C: Consent Form for Hormone Therapy for Women of Transgender Experience

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 risk of the following:
  - Blood clots, (deep venous thrombosis, pulmonary embolism);
  - Breast tumors/cancer;
  - Heart disease, arrhythmias, and stroke;
  - High blood pressure;
  - Liver inflammation;
  - Pituitary tumors (tumor of small gland in the brain which makes prolactin);
  - Decreased number of red blood cells (anemia);
  - Acne (if progesterone is used);
  - Increased or decreased sex drive and sexual functioning;
  - 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,
- Genital changes (i.e. smaller testes),
- Infertility.

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

________________________________ 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 Client       Date

__________________________________________ ________________
Legal Name of Client (Printed)

__________________________________________ ________________
Signature of Witness       Date

__________________________________________
Name of Witness (Printed)
**Appendix D: Male to Female Hormone Monitoring Summary**

(Collaborative MD and Nursing Team)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Month 1</th>
<th>Month 3, 6, 9, 12, 18, 24</th>
<th>Annual</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Review</strong></td>
<td>Contraindications</td>
<td>Review of hormone effects</td>
<td>Review of hormone effects</td>
<td>Health Maintenance</td>
</tr>
<tr>
<td>Risk factors for CAD</td>
<td>Old records</td>
<td>Spontaneous erections</td>
<td>Spontaneous erections</td>
<td>Review bone health</td>
</tr>
<tr>
<td>Mental Health []</td>
<td>Lifestyle counseling *</td>
<td>Mental Health []</td>
<td>Lifestyle counseling *</td>
<td>(vit D, Ca, exercise)</td>
</tr>
<tr>
<td>Bone health</td>
<td>Health Maintenance¹</td>
<td>Lifestyle counseling</td>
<td>Psychosocial {}</td>
<td></td>
</tr>
<tr>
<td>Health Maintenance</td>
<td>Health Maintenance</td>
<td>Review of hormone effects</td>
<td>Psychosocial {}</td>
<td></td>
</tr>
</tbody>
</table>

| **Exam**               | Full PE | BP, weight, Abdominal exam including liver palpation, waist cir. | BP, weight, Abdominal exam including liver palpation, waist cir. | Full PE with breast exam |
|                       | Measure: weight, breast, AC, hips, waist cir. | Extremity exam | Extremity exam | |
|                       | **      | Measure: weight, breast, AC, and hips | ** | ** |

| **Lab**                | See Protocols for Hormone Therapy** | ** | ** | ** |

| **Other**              | EKG if over 40 or risk factors | Vaccinate for Hep A & B, Td, pneumovax if indicated | -Mammogram if over 50 |
|                       |                                |                                | -DRE if over 50 |
|                       |                                |                                | -Consider BMD 5 yrs post treatment start |
|                       |                                |                                | -75 GTT if BMI >30 |

¹Health maintenance refers to: PPD status, Immunization history, Breast/Testicular self-exam, HIV risk assessment, Stool for OB if over 50, consider vaginal exam if clinically indicated post operatively, etc...
Mental Health:
Body image:
Mood changes: irritability, anger, “mood swings,” depressed mood, andhedonia, etc... (SIGECAPS & MANIA in Clin Care)
Libido:
Thought content: suicidality, homicidality

*Lifestyle counseling:*
Nutrition:
Active lifestyle and exercise:
Cigarette smoking (cessation, stages of readiness, etc...)
Alcohol intake: (refer to screening assessment tool **)
Other substances: (anabolic steroids, cannabis, cocaine, ecstasy, GHB, hallucinogens, heroin, inhalants, ketamine, methadone, methamphetamine, opioids)
Sexual health:

{} Psychosocial
Family, partner(s), friends, social network (support, acceptance, safety, respect):
Economic status:
Housing status:
Change of name, identification, etc...:
Discrimination and barriers:

**Alcohol Screening Assessment Tool:**

1. Have you ever felt you ought to cut down on your alcohol consumption?
2. Have people annoyed you by criticizing your alcohol consumption?
3. Have you ever felt guilty about your alcohol consumption?
4. Have you ever had a drink first thing in the morning to steady your nerves or to get rid of a hangover?
5. How many drinks do you have a week? Do you know what the guidelines are?
6. Have you driven while impaired?
7. How does your alcohol consumption affect your relationships, work, school, finances, physical and mental health?
## Appendix E: Female to Male Monitoring Summary

<table>
<thead>
<tr>
<th>Review</th>
<th>Baseline</th>
<th>Month 1</th>
<th>Month 2</th>
<th>Month 3, 6, 9</th>
<th>Annual</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Contraindications</td>
<td>Review of hormone effects</td>
<td>Review of hormone effects</td>
<td>Review of hormone effects</td>
<td>Health Maintenance</td>
</tr>
<tr>
<td></td>
<td>Risk factors for CAD</td>
<td>Cessation of menses</td>
<td>Cessation of menses</td>
<td>PV bleeding</td>
<td>Review bone health (vit D, Ca, exercise)</td>
</tr>
<tr>
<td></td>
<td>Old records</td>
<td>Mental Health []</td>
<td>Mental Health []</td>
<td>Mental Health []</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mental Health []</td>
<td>Lifestyle counseling *</td>
<td>Lifestyle counseling *</td>
<td>Lifestyle counseling *</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lifestyle counseling *</td>
<td>Psychosocial ()</td>
<td>Psychosocial ()</td>
<td>Psychosocial ()</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Health Maintenance¹</td>
<td>Pregnancy screen</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exam</td>
<td>Full PE w/breast, PAP and pelvic exam</td>
<td>BP, weight, abdominal exam including liver palpation, waist cir.</td>
<td>BP, weight, waist cir.</td>
<td>BP, weight, abdominal exam including liver palpation, waist cir.</td>
<td>Full PE w/breast exam, PAP and pelvic if pre-op</td>
</tr>
<tr>
<td>Lab</td>
<td>Pregnancy test prior to 1ˢᵗ injection. <em>See Protocols for Hormone Therapy</em>*</td>
<td>**</td>
<td>**</td>
<td>**</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>EKG if over 40 or risk factors</td>
<td>Vaccinate for Hep A &amp; B, Td, pneumovax if indicated</td>
<td></td>
<td></td>
<td>-Mammogram if &gt;50 and if breast tissue present</td>
</tr>
</tbody>
</table>

¹Health maintenance refers to: PPD status, Immunization history, Breast self-exam, HIV risk assessment, Stool for OB if over 50, etc...
Mental Health:
Body image:
Libido:
Mood changes: irritability, anger, “mood swings,” depressed mood, anhedonia, etc... (SIGECAPS & MANIA in ClinCare)
Thought content: suicidality, homicidality,

* Lifestyle counseling:
Nutrition:
Active lifestyle and exercise:
Cigarette smoking (cessation, stages of readiness, etc...)
Alcohol intake: (refer to screening assessment tool **)

Other substances: (anabolic steroids, cannabis, cocaine, ecstasy, GHB, hallucinogens, heroin, inhalants, ketamine, methadone, methamphetamine, opioids)

Sexual health (review also potential for pregnancy):

{} Psychosocial:
Family, partner(s), friends, social network (support, acceptance, safety, respect):
Economic status:
Housing status:
Change of name, identification, etc...:
Discrimination and barriers:

** Alcohol Screening Assessment Tool:

1) Have you ever felt you ought to cut down on your alcohol consumption?
2) Have people annoyed you by criticizing your alcohol consumption?
3) Have you ever felt guilty about your alcohol consumption?
4) Have you ever had a drink first thing in the morning to steady your nerves or to get rid of a hangover?
5) How many drinks do you have a week? Do you know what the guidelines are?
6) Have you driven while impaired?
7) How does your alcohol consumption affect your relationships, work, school, finances, physical and mental health?
References


xvi van Kesteren et al, 1997;


Part 2

Guidelines for Social Supports
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Guidelines and Protocols for Comprehensive Primary Health Care for Trans Clients

Part II
Guidelines for Social Supports

Prepared by Vlad Wolanyk, Sherbourne Health Centre

Introduction

Gender is viewed as the most fundamental signifier of individual identity. Although this is a reality from which nobody is exempt, it is important to consider the tremendous social and institutional barriers transgender individuals face. In addition to hormone therapy and sex re-alignment surgery (SRS), there are many other considerations social service and medical providers need to be cognizant of when developing a care plan. The following is intended as a brief introduction to providing resources, support and advocacy for transgender clients.

NOTE: A glossary of frequently used terms can be found in Appendix C.

Understanding Barriers

Whether it is due to fear, ignorance or lack of experience, society in general is not very accepting of trans and alternate gender identities. In addition to transphobia, transgender individuals may also face discrimination and hardship related to their race, ethnicity, religion, sexual orientation, class, ability etc... The decision to "come out" as transgender or embark upon a transition process can be exciting, cause for relief and boost self confidence. But, it also brings a myriad of complications and social stigmatization. Some issues/barriers trans people face can include, but are not limited to:

A) Social Isolation
   • loss of family, friends, supports
   • no longer being able to participate in cultural, religious or community groups and functions

B) Fear of Not Passing
   • afraid to use public restrooms or change rooms
   • increased risky behaviour in order to "fit in"
   • threat of violence if discovered
C) Loss of Personal History

- a new name and/or gender presentation can cause an erasure or fear of disclosing past history (i.e. employment, rental history, medical)

D) Loss of Income

- Being fired or "let go" for various reasons
- leaving or taking time off from work because of stigma or to have surgical procedures
- unable to attain similarly gainful employment when re-entering workforce
- not able to access employment training or further schooling
- needing to go on social assistance or take lower paying jobs
- cost of surgery/cosmetic procedures
- cost of new wardrobe and accessories related to transition process
- loss of partner or family support

E) Limited Access to Social and Medical Services

- Personal ID does not match gender presentation (e.g. OHIP, driver's lisc. etc..)
- Trans people are often turned away from services and agencies because staff claim they do not understand trans issues or they claim they are not "experts"
- Trans people have traditionally been pathologized and in turn stigmatized by clinical providers
- Afraid to access services due to past negative experiences
- Transphobia from staff and clients
- Service providers focus on gender identification rather than presenting issue (e.g. a grief counsellor focusing on trans issues when individual is dealing with the death of a family member)
Resources
There is no clear cut formula or care plan for working with transgender clients. Each trans person is a unique individual with their own personal identity and social needs. Although the barriers outlined in the previous section seem to paint a negative picture, the decision to transition is also a very rewarding experience. It can be likened to finally resolving a complicated lifelong case of mistaken identity.

There are many ways social service or medical providers can assist transgender clients overcome and navigate some of the barriers they may face and support their transition. The appendices to this document contain a variety of resources that providers may utilize and distribute to their trans clients.

Social/Peer Support
Our diverse trans communities are their own best resource. Whether it is for a list of gender neutral washrooms, a trans positive community centre, safe housing, a good place to buy clothing or talking to someone who has already transitioned, contact with local trans people or online discussion groups can be invaluable. There are several websites and resources such as the Trans Pulse Project (www.transpulse.com), which provide information on peer support groups and resources. (See Appendix A: Community Resources)

Employment
While at present the Ontario Human Rights Commission’s Policy on Gender Identity does not name transgender status as a prohibited ground of discrimination, the OHRC’s policies are meant to be read as conferring such protections to trans people. The website www.ohrc.on.ca/en/issues/gender_identity contains guidelines for employers and protection for trans people in the workplace. Unfortunately, it is not always and effective or viable option for individuals to pursue. There are many resources and brochures available online to assist transgender individuals who are transitioning on the job. (see Appendix A: Community resources)

Employment Insurance
For some individuals, working while transitioning is not an option for a variety of reasons. Being fired from a job or quitting work does not entitle an individual to EI benefits. However, if a transgender person leaves a job due to a dangerous or hostile work environment, a detailed advocacy letter may help the applicant qualify for benefits. (See Appendix B: Sample Advocacy Letters)

Social Assistance
Accessing income supports such as Ontario Works(OW) or the Ontario Disability Support Program (ODSP) may be the best option for some transgender clients. Although these benefits may not be ideal, they provide
income assistance and membership in the Ontario Drug Benefits Program (ODB). Clients can contact their local OW or ODSP office to initiate intake.

Note: Hormone Therapy was delisted from ODB in 2006. Transgender clients are still covered for HRT when clinicians submit a Request for Unlisted Drug Product form. (See Appendix B for details)

**Personal Identification and Records**
Name, pronoun and legal sex designation changes can be vital to a transgender person’s sense of self. It is considered to be very disrespectful to address a transgender person with the wrong name or pronoun. If done intentionally or persistently, it may even be considered harassment. A guide to various identification changes can be found in Appendix A: Community Resources. Many legal document changes also require clinical advocacy letters. (See Appendix B: Sample Letters).

Often, transgender individuals face barriers to implementing name and pronoun changes as well as accessing gender appropriate services at work, school, medical/social services etc… Case advocacy from social and medical providers can be very helpful in these situations.

**Living Stealth**
When working with transgender clients it is imperative that providers respect personal lifestyle choices. Although many transgender individuals enjoy participating and identifying with the transgender communities, many do not. Once the transition process is complete, many trans people prefer to “live stealth” and blend into communities where nobody knows they are trans (with possible select exceptions). For these individuals, a loss or erasure of past personal history can be advantageous. It is not uncommon for individuals who are living stealth to relocate and/or change their careers and lifestyle.

**Sex Work**
There are many transgender women (and some trans men) who find stable income, empowerment, community and a personal sense of pride in the sex working community. At the same time it is a difficult occupation that can be filled with violence and abuse. It is important to consider the multifaceted stigma sex workers face from partners, family, friends, society in general, as well as social and medical services. Presenting medical issues should not automatically considered work related. As with any profession, individuals who work in the sex industry cannot be solely defined by their career choice or employment options.
Trans Positive Spaces
In addition to providing resources, advocacy and support there are many things that social and medical providers can do to make their clinic or agency more accessible to transgender individuals.

- Normalize gender variance and exploration
- Be Respectful of where people are at; when in doubt ask instead of assuming
- Raise awareness and educate other providers and staff at your clinic or agency about trans issues and transphobia
- Do not tolerate transphobic remarks or humour
- Single occupancy washrooms can be gender neutral washrooms
- Be aware of resources; Make a 1 page list of online or community resources to give out to clients (or use the resource list found in Appendix A)
- Be conscious of the fact that transition is about more than hormones and SRS
- Attend 1 or 2 Trans Community Events
- Have something trans positive in your office such as a poster
- Hire a trans person to consult with you for a few hours

There are several online resources for providers wishing to increase access for transgender clients or make their spaces safer for trans people:

The Trans Access Project at the 519 Community Centre, Toronto
Website: [www.the519.org/programs/trans/access_project/index.shtml](http://www.the519.org/programs/trans/access_project/index.shtml)

Trans@MIT Website: [www.mit.edu/trans/](http://www.mit.edu/trans/)

Opening the Door To The Inclusion of Transgender People:
[www.thetaskforce.org/downloads/reports/reports/opening_the_door.pdf](http://www.thetaskforce.org/downloads/reports/reports/opening_the_door.pdf)

Conclusion
Each transgender, genderqueer or gender questioning person has the right to choose their own personal transitional gender journey. This may or may or may not include; attending peer support groups or counselling, surgical procedures, hormone therapy, living stealth, changing legal documentation, or identifying as heterosexual. It is not possible, or in some cases even desired, for all transgender individuals to move through public spaces undetected. The threat of violence, harassment and discrimination is a reality many transgender people face. Social service and medical providers are in an excellent position to reduce transphobia in our society by normalizing gender variance and exploration while recognizing and supporting transgender people to overcome the negative barriers they face.
Appendix A: Community Resources

Personal Identification

Name Change (Ontario)
Contact or locate the nearest Office of the Registrar General (ORG) and request:

“Application to Change an Adult’s Name”

Current Cost: $137

Note: The ORG is usually required to publish any change of names in The Ontario Gazette. As of July 3rd 2007, transgender individuals can request an exemption by including a letter with their application stating that they are transgender and wish to have their change of name notice excluded from publication.

Contact: Office of Registrar General

Web: www.serviceontario.ca

Phone: 1-800-461-2156

Drivers License Gender Designation Change
Full surgery is NOT required to change gender designation on a driver’s license in Ontario.

Details: http://www.mto.gov.on.ca/english/dandv/driver/genderchange.htm

(See Appendix B for sample letter from clinician)

Sex Designation Change on Birth Certificate (If born in Ontario)
Contact or locate nearest Office of the Registrar and request:

“Application for Change of Sex Designation on Birth Registry” Package

The Package contains 3 forms:

- Application for Change of Sex Designation on Birth Registry – Individual
- Medical Certificate of Transsexual Surgery – Completed by SRS Surgeon
- Medical Certificate to Substantiate Transsexual Surgery was Performed – can be completed by individuals physician

Current Cost: $37
Sex Designation Change *(If born outside Canada)*

Immigration Canada Policy for Changing Sex Designation:

A person who has undergone sex change surgery must produce a statement from his or her surgeon confirming the surgical procedure and a statement from another person to the effect that he or she was known to him or her prior to the surgery and that he or she is one and the same person (see appendix X for sample letter). The statement from the surgeon confirming surgical procedure must indicate that the gender reassignment procedures are completed and that the person is now anatomically a male or female.

**Contact:** Citizenship and Immigration Canada

Ontario Human Rights Commission - Gender Identity Policy


Surgery/Transition Resources

MtF:  [www.tsroadmap.com](http://www.tsroadmap.com)

FtM:  [www.transster.com](http://www.transster.com)

[www.thetransitionalmale.com/](http://www.thetransitionalmale.com/)

**Employment**

Transgender @Work (TAW):  [www.tgender.net/taw/](http://www.tgender.net/taw/)

**Trans Resources (519 Community Centre):**

[www.the519.org/programs/trans/resources.shtml](http://www.the519.org/programs/trans/resources.shtml)

**Income Supports (Ontario)**

ODSP:  [www.mcss.gov.on.ca/mcss/english/pillars/social/odsp](http://www.mcss.gov.on.ca/mcss/english/pillars/social/odsp)

General Enquiries Toll Free: 1-888-789-4199


(Applicants must Contact Local Ontario Works Office)

**Parenting**

LGBT Parenting Network:

[www.lgbtparentingconnection.ca](http://www.lgbtparentingconnection.ca)

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*Sherbourne Health Centre, Toronto    Rev. April 2009*
**Sex Worker Resources**
Stella (based out of Montreal):  [www.chezstella.org](http://www.chezstella.org)

SPOC (Sex Professionals of Canada):  [www.spoc.ca](http://www.spoc.ca)

Maggie’s (based in Toronto):  [www.maggiestoronto.com](http://www.maggiestoronto.com)

**Community and Resource Listings**
Trans Pulse Project (Downloadable Resource Guide)  [www.transpulse.ca](http://www.transpulse.ca)

Trans Resource Guide (519 Community Centre)  [www.the519.org/programs/trans/resources.shtml](http://www.the519.org/programs/trans/resources.shtml)

Gender Mosaic  [www.gendermosaic.ca/](http://www.gendermosaic.ca/)

Transsexual Menace  [www.themenace.net/](http://www.themenace.net/)

Gender News  [www.ifge.org/news/nwshdln.htm](http://www.ifge.org/news/nwshdln.htm)

**Taking Care of Business: A DIY Guide to Self Injecting “T”**
You Tube Link:  [http://www.youtube.com/watch?v=PdlduQ4G20g](http://www.youtube.com/watch?v=PdlduQ4G20g)

OR

Appendix B: Forms and Templates

Sample Advocacy Letters

Letter For Ontario Driver’s License Sex Designation Change
[ use physician or health centre’s letterhead ]

[ Current Date ]

Dear Ministry of Transportation,

[ Client’s Name ] is under my care and [ is undergoing OR has undergone ] medically supervised gender transition from [ female to male OR male to female ]. It would be beneficial and medically necessary for the gender designation on [ Client’s Name ]’s drivers license to be changed from [ “F” to “M” OR “M” to “F” ].

Sincerely,

[ Physician’s Name ], md

[ CPSO License Number ]
Letter for Educational Institutions

Note: The following is intended as an example of how clinicians may advocate for transgender clients who are in school, working, accessing multiple social service agencies and/or medical providers. It is strongly recommended that providers modify advocacy letters to better address the specific needs their clients have and the barriers they may be facing.

[ Physician or Clinic Letterhead ]

[ Current Date ]

Dear [ Whom It May Concern ],

I am the family physician caring for [ Client’s Name ]. As you know, [Client’s Name] is currently exploring gender transition from [ female to male OR male to female ].

Gender transition is a broad term which encompasses many aspects of physical, emotional and social changes. At this time, it would be appropriate for students, teachers and other staff to refer to [ him OR her ] with [ male OR female ] pronouns and [his OR her] chosen name. In terms of the school environment, it is often difficult for transsexual people to find washrooms and changing rooms that are safe and appropriate to use. If there are any single occupancy washrooms at the school, it may be helpful to identify them as “gender neutral washrooms”.

During transition, people usually require a good emotional and psychological support to deal with many rapid changes. This may come through friends, family or professional avenues. Additionally, there is evidence to show that people undergoing gender transition may struggle academically – characterized by a temporary drop in scholastic achievement. Hopefully, the involved teachers will be understanding if such a change occurs.

There are many schools that have had to deal with similar changes. It can certainly be a challenging time for everyone. If you are interested in accessing more resources or information, please feel free to contact [ me OR our clinic ].

Sincerely,

[ Provider’s Name]
Letter Supporting “just cause” Reason for Quitting Work (in support of EI application)

[clinician's letterhead]

[Current Date]

Human Resources & Skill Development
[address of branch office where client is applying for benefits]

Greetings,

I am writing to support [client's name]'s application for Employment Insurance benefits.

My client is a [bi-gendered person, female-to-male transsexual, male crossdresser, male-to-female transsexual, etc.]. As a transgender person, [he/she] reported experiencing severe and prolonged mistreatment in [his/her] workplace, including:

- breach of privacy and threat to safety through the nonconsensual 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 the 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 client had no reasonable alternative to leaving to ensure [her/his] safety and dignity.

Please feel free to contact me at [phone number] if you require any further information.

Sincerely,

[clinician’s name and signature]

Source: Social and Medical Advocacy with Transgender People and Loved Ones: Recommendations for BC Clinicians, 2006, Catherine White Holman and Joshua Mira Goldberg
Letter from 3rd Party to Citizen and Immigration Canada Supporting Sex Designation Change

[third party’s mailing address]

Citizenship and Immigration Canada
Communications Branch
Ottawa, ON K1A 1L1

Greetings,

I am writing in support of [client’s name] application for a change of legal sex designation from “F” to “M” or “M” to “F”). I have known [client’s name] in a [professional/personal] capacity prior to and since gender reassignment surgery, and can confirm that [she/he] is the same person. I affirm that the change of legal sex designation is appropriate and necessary to allow [client’s name] to safely work, study, and travel.

Please feel free to contact me at [phone number] if you require any further information.

Sincerely,

[3rd party’s name and signature]

Source: Social and Medical Advocacy with Transgender People and Loved Ones: Recommendations for BC Clinicians, 2006, Catherine White Holman and Joshua Mira Goldberg
Hormone Therapy & the Ontario Drug Benefit Plan

Effective March 1, 2006 there has been changes in how recipients of the ODBP (Ontario Drug Benefit Plan) can access HRT (hormone replacement therapy). All Transsexual/Transgender(TS/TG) people who participate in ODBP will need to have their physician fill out a Request for an Unlisted Drug Product-ICR form in order to maintain coverage of their hormone prescriptions. The process will be expedited (requests should be approved w/in 2 weeks) and the duration of approval for this form is lifetime.

Who is affected?

Ontario Residents eligible for ODBP include:

People over 65, residents of long term care facilities, people on OW or ODSP, Trillium Drug Benefit recipients.

Forms:

Request for an Unlisted Drug Product- ICR form can be downloaded from the Ministry of Health Web Site:  www.health.gov.on.ca/english/public/forms/form_menus/odb_fm.html

What types of hormones are currently covered?

For MTF: Oral Estrogen Products. Transdermal estrogen products will only be considered if specific criteria are met.

For FTM: Oral and Injectable testosterone. Transdermal testosterone products will NOT be considered.

How to Fill Out a Request For Unlisted Drug Product (ICR):

Any physician in Ontario can submit a Request for an Unlisted Drug Product - ICR. The information required for the purpose of obtaining approval for TS/TG clients is minimal compared to most other unlisted drug product requests which require detailed medical history. (Please see samples attached for details on how to fill out the form).

Where to Send a Completed Form:

Completed forms can be faxed to the Ministry of Health Drug Programs Branch at: (416)327-7526 or Toll Free: 1-866-811-9908.

Approval:

Once processed, response letters will be sent to the requesting MD. Only then, can the client take their prescription to their pharmacy. It is also helpful for the client to inform their pharmacy a Request for an Unlisted Drug Product – ICR approval is in place or to provide the client and pharmacy with a copy of the approval letter.
Please fax completed form and/or any additional relevant information to (416) 327-7526 or toll-free 1 866 811-8908; or send to the Drug Programs Branch at the address above. For copies of this and other ICR forms, please visit http://www.health.gov.on.ca/english/public/forms/formicb fm.html

Please ensure that the form is completed as fully as possible in order to expedite the review.

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 8 of the Ontario Drug Benefit Act, R.S.O. 1990, c. O.10 (Individual Clinical Review). This form is intended to facilitate requests for drugs under Section 8. The Ministry may request additional documentation to support the request. Please ensure that all appropriate information for each section is provided to avoid delays.

Sample: FTM

Section 1 – Prescriber Information

First name
Initial
Last name
Mailing address
Street no.
Street name
City
Postal code
Fax no.

Section 2 – Patient Information

First name
Initial
Last name
Health number
Date of birth (yyyy/mm/dd)

New request
Renewal of existing Section 8 approval (specify ICR#)

Section 3 – Drug Requested

Requested drug product
DELATESTRYL

Strength / Dosage form
200 MG/ML

Frequency of administration
Q 2 WEEKS

Expected start date
Duration of therapy
LIFETIME

Section 4 – Diagnosis and Reason for Use

Diagnosis for which the drug is requested:
TRANSSEXUALISM - GENDER IDENTITY DISORDER

Reason for use over formulary alternatives:
NO ALTERNATIVES ON FORMULARY

If the patient is currently taking the requested product, please provide start date & objective evidence of its efficacy:

START DATE:
IMPROVEMENT IN PSYCHOLOGICAL FUNCTIONING AND DECREASE IN GENDER DYSPHORIA SYMPTOMS

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 current or previously taken)
Dosage
Approximate timeframe of therapy
Reason(s) why formulary alternatives are not appropriate

N/A

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 AS TRANSSEXUAL AND QUALIFIES FOR HORMONAL THERAPY.
**Request for an Unlisted Drug Product**  
**Individual Clinical Review (ICR: Section 8)**

Please fax completed form and/or any additional relevant information to (416) 327-7626 or toll-free 1 866 811-0008; or send to the Drug Programs Branch at the address above. For copies of this and other ICR forms, please visit [http://www.health.gov.on.ca/english/public/forms/form_menu/ibd_forms.html](http://www.health.gov.on.ca/english/public/forms/form_menu/ibd_forms.html).

Ensure that the form is completed as fully as possible in order to expedite the review.

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 8 of the Ontario Drug Benefit Act, R.S.O. 1990, c. O.10 (Individual Clinical Review). This form is intended to facilitate requests for drugs under Section 8. 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

<table>
<thead>
<tr>
<th>First name</th>
<th>Initial</th>
<th>Last name</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Mailing address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street no.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>City</th>
<th>Postal code</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Fax no.</th>
<th>Telephone No.</th>
<th>Date of birth (yyyy/mm/dd)</th>
</tr>
</thead>
</table>

- [ ] New request
- [ ] Renewal of existing Section 8 approval (specify ICRs)

### Section 2 – Patient Information

<table>
<thead>
<tr>
<th>First name</th>
<th>Initial</th>
<th>Last name</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Health Number</th>
</tr>
</thead>
</table>

### Section 3 – Drug Requested

<table>
<thead>
<tr>
<th>PREMARIN</th>
<th>DIN 02943424</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Strength / Dosage form</th>
<th>Frequency of administration</th>
<th>Expected start date</th>
<th>Duration of therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.25 MG</td>
<td>OD/BID</td>
<td>LIFETIME</td>
<td></td>
</tr>
</tbody>
</table>

**Diagnosis for which the drug is requested:**

**TRANSGENDERISM/ GENDER IDENTITY DISORDER**

**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:

**START DATE:**

**DEFINITE IMPROVEMENT IN PSYCHOLOGICAL FUNCTIONING, 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:

<table>
<thead>
<tr>
<th>Name of drug (indicate if current or previously taken)</th>
<th>Dosage</th>
<th>Approximate timeframe of therapy</th>
<th>Reason(s) why formulary alternatives are not appropriate</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
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<tr>
<td>N/A</td>
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</tr>
<tr>
<td>N/A</td>
<td>current</td>
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</tr>
<tr>
<td>N/A</td>
<td>previous</td>
<td></td>
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</tr>
</tbody>
</table>

#### 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 AS TRANSGENDER**

---

The information on this form is collected by the Ministry of Health and Long-Term Care under the authority of s. 13 of the Ontario Drug Benefit Act, R.S.O. 1990, c. O.10. This information is collected for the purpose of considering requests for coverage of unlisted drug products not listed in the Ontario Drug Benefit Formulary under Section 8. The information may also be used and disclosed for administrative purposes. If you have any questions about the collection of this information, call the Ontario Drug Programs Helpdesk at 1-800-660-4661 or contact the Director, Drug Programs Branch, 6050 Yonge St., 3rd Floor, Toronto ON, M4N 4G5.
# Request for an Unlisted Drug Product
### Individual Clinical Review (ICR)

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 the Individual Clinical Review (ICR) mechanism of the Ontario Drug Benefit Act. This form is intended to facilitate requests for drugs under the ICR mechanism. 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

<table>
<thead>
<tr>
<th>First name</th>
<th>Initial</th>
<th>Last name</th>
<th>Mailing address</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Street no.</td>
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<td></td>
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<td>Street name</td>
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<td>City</td>
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<td>Postal code</td>
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</table>

| First name | Initial | Last name | Health Number |

<table>
<thead>
<tr>
<th>Fax no.</th>
<th>Telephone no.</th>
<th>Date of birth (yyyy/mm/dd)</th>
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</table>

- [ ] New request
- [ ] Renewal of existing ICR approval (specify ICR#)

## Section 2 – Patient Information

<table>
<thead>
<tr>
<th>First name</th>
<th>Initial</th>
<th>Last name</th>
<th>Date of birth (yyyy/mm/dd)</th>
</tr>
</thead>
</table>

## Section 3 – Drug Requested

- Requested drug product
- DIN
- Strength / Dosage form
- Frequency of administration
- Expected start date
- Duration of therapy

## Section 4 – Diagnosis and Reason for Use

Diagnosis for which the drug is requested:

Reason for use over formulary alternatives:

If the patient is currently taking the requested product, please provide start date & objective evidence of its efficacy:

## Section 5 – Current and / or Previous Medications

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

<table>
<thead>
<tr>
<th>Name of drug (indicate if current or previously taken)</th>
<th>Dosage</th>
<th>Approximate timeframe of therapy</th>
<th>Reason(s) why formulary alternatives are not appropriate</th>
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</thead>
<tbody>
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<tr>
<td>previous</td>
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</tbody>
</table>

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):

---

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. 1990, c.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 Programs Help Desk at 1-800-968-8641 or contact the Director, Individual Eligibility Review Branch (IERB), Ministry of Health and Long-Term Care, 3rd floor, 5700 Yonge St., Toronto ON M2M 4K5.
### Partie 1 – Renseignements sur le prescripteur

<table>
<thead>
<tr>
<th>Prénom</th>
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<table>
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<th>Rue</th>
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<table>
<thead>
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<th>N° de téléphone</th>
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- [ ] Nouvelle demande
- [ ] Renouvellement de l’approbation existante (ICR#) __________

### Partie 2 – Renseignements sur le patient

<table>
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<th>Nom de famille</th>
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<table>
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<th>N° de carte Santé</th>
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</table>

<table>
<thead>
<tr>
<th>Date de naissance (aaaa/mm/jj)</th>
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</table>

### Partie 3 – Médicament demandé

- Produit médicamenteux demandé
- Concentration/forme posologique
- Date de début
- Fréquence d’administration
- Durée du traitement prévue
- DIN

### Partie 4 – Diagnostic et justification de l’usage

Diagnostic pour lequel le médicament fait l’objet de la demande :

Justification de son usage plutôt que d’autres produits comparables existants dans le formulaire :

Si le patient cède ce produit demandé prénent, veuillez indiquer la date de début et une oreuve objective de son efficacité :

### Partie 5 – Médicaments pris maintenant et antérieurement

#### a) Veuillez indiquer les autres produits (médicaments figurant dans la liste et/ou traitement autre que des médicaments) qui ont été essayés pour cette condition

<table>
<thead>
<tr>
<th>Médicament</th>
<th>Dosage</th>
<th>Période approximative du traitement</th>
<th>Raison pour laquelle d’autres produits comparables existants dans le formulaire ne conviennent pas</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

- [ ] maintenant antérieurement
- [ ] maintenant antérieurement
- [ ] maintenant antérieurement
- [ ] maintenant antérieurement

#### b) Veuillez indiquer l’emploi thérapeutique de médicaments concomitants pour d’autres conditions :

### Partie 6 – Renseignements cliniques

Veuillez fournir les données médicales pertinentes (p. ex., rapports de culture et de sensibilité, concentration sérique des médicaments, résultats de laboratoire)
Appendix C: Glossary of Trans Terms

**Bi-gender:** A form of transgenderism involving the adoption of differing feminine and masculine traits.

**Binding:** The process used by FTMs and other transgender people of flattening one's breast tissue in order to create a male-appearing chest. Some FTMs and trans men 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.

**Butch:** A person who identifies themselves as masculine.

**Cisgender:** Having a non-transgender gender identity. Some individuals may use the terms “bio-female/male” or “genetic female/male” to describe egender.

**Cross Dressing:** Someone who wears clothes of another gender/sex. The term cross dresser is most frequently used to describe a heterosexual male who cross dresses as a female some or all of the time, but does not typically desire gender transition.

**Drag:** The performance of one or multiple genders theatrically.

“E” : Slang for Estrogen

**FTM:** A Female to Male Trans Person, Trans Man

**Femme:** Feminine identified person of any gender/sex.

**Gender Dysphoria (Distress):** Also body dysphoria, the state of discomfort felt by some transgender people caused by the incongruity between one’s physical sex and one’s gender-identity.

**Gender Identity:** A person’s internal self-awareness of being either male or female, masculine or feminine, something in-between, or something other.

**Genderqueer:** A gender-variant person whose gender identity is neither male nor female, is between or beyond genders, or is some combination of genders.

**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. The term "hermaphrodite" had been used in the past to refer to intersex persons, but that term is now considered negative and inaccurate. Some intersex people are also transgender, but intersex is not typically considered a subset of transgender, nor transgender a subset of intersex.

**MtF:** A Male to Female Trans person, Trans Woman

**Packing:** The process of creating a male-looking bulge in one's crotch.

**Pangender:** A person whose gender identity is comprised of all or many gender expressions.
Passing: Being identified as your chosen gender regardless of birth/assigned sex. Some transsexual people object to the term "passing," as it implies that one is being mistaken for something they are not. Also known as: "being read as a man" or "being read as a woman."

Polyamory: The desire, practice, or acceptance of having more than one loving, intimate relationship at a time with the full knowledge and consent of everyone involved.

Post-op (also post-operative): Trans individuals who have attained one or more gender reassignment surgery procedures.

Queer: An umbrella term that embraces a matrix of sexual preferences, gender presentations, and habits of those who may not identify as exclusively heterosexual, monogamous, gender normative, or who may be into "alternative" sexual choices or lifestyles. Queer might include; lesbians, dykes, gay men, bisexuals, transgender people, intersex persons, radical sex communities, and many other sexually transgressive people.

Real Life Experience/Real life Test (RLE/RLT): A period of time in which a transsexual person is required to live full time in the role of the gender they identify with in order to demonstrate they can function in that role. Historically it was a prerequisite for access to hormone therapy.

Sex Reassignment Surgery (SRS): Also known as Gender Realignment Surgery (GRS) and commonly termed "sex change operation." This term is somewhat inappropriate as it implies that there is only one surgical procedure for successful transition.

Sexual Orientation: The desire for intimate emotional and/or sexual relationships with people of the same gender/sex, another gender/sex, or multiple genders/sexes.

She-Male: A term, sometimes derogatory, used to describe some pre-operative transsexual women who have breasts and an intact penis. Although this is a loaded term it is often used in the sex and porn industry by cisgender males seeking out transsexual women and/or men working as “show girls”. Many transsexual women who work in the sex industry (prostitution, dancing, porn, escort etc…), identifying themselves as she-males, for a variety of reasons including: money to survive, to pay for costly surgeries, personal empowerment, an inability to attain other employment during or after transition etc…

Stealth: A transgender individual, once transitioned, may choose not to reveal his or her transgender status to others (for example, to coworkers, friends, neighbours, etc.); this is referred to as "going stealth" or "being stealth."

“T ”: Slang for Testosterone

Transgender: Umbrella term for gender variant individuals

Transition: Process of moving (in presentation and/or lifestyle) from one gender to another.

Transphobia: Expression of aversive and oppressive behaviour towards trans people.

Tucking: The technique of hiding male genitals.

Two Spirit (2S): A term used by some Native persons who have attributes of both genders, may have distinct gender and social roles in their tribes.
**Appendix D: Team Based Client-Centred Care Plan**

**DATE:** ________________  
**CLIENT NAME:** ____________  
**CHART NO:** ________________  
**NEXT REVIEW DATE:** ______

**CIRCLE OF CARE:**  
Primary Care Provider(s): ________________________________
(Consulting) Psychiatrist: ________________________________
Mental Health Counsellor/Psychotherapist: ________________
Client Resource Worker: ________________________________
Other Providers/workers (specify): ________________________

<table>
<thead>
<tr>
<th>ISSUES</th>
<th>GOALS</th>
<th>TREATMENT/ACTION</th>
<th>PROVIDER(S)</th>
<th>TARGET DATE</th>
<th>COMPLETION DATE</th>
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</thead>
<tbody>
<tr>
<td>Biological/Medical:</td>
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<tr>
<td>Psychological/Emotional:</td>
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<tr>
<td>Relational/Social (partner/family/community):</td>
<td>Practical (socioeconomic, housing, ID, etc.):</td>
<td>Vocational (school/work/volunteer activity):</td>
<td>Spiritual/Existential:</td>
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