Gender-affirming Hormone Therapy for Adults: Initiation, Monitoring, and Management
Handout and quick guide, AAPA 2023
Jo Rolls, MEHP, MPAS, PA-C
University of Utah Health

**Keep Your Resources Close!**

| Resource | Overview |
|---|---|
| Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People | UCSF guidelines. Comprehensive, evidence based, primary care considerations and initiating, maintaining, adjusting gender affirming hormone regimens and complications. |
| TransLine Hormone Therapy Prescriber Guidelines | TransLine. Collaborative project including clinical guidelines, quick prescribing guide, referral services and other resources. Excellent quick guide for clinic. |
| WPATH Standards of Care, Version 8 | Comprehensive clinical guidance for care of transgender, gender nonconforming persons across specialties, including primary and specialty care, speech/language pathology, mental health services. Available in 19 languages. Updated in 2022 |

**Minimum Criteria for Gender Affirming Hormone Therapy (Masculinizing or Feminizing from SOC 8)**

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

**Informed Consent Process** (Example forms from Fenway Institute):

- Informed consent for masculinizing therapy
- Informed consent for feminizing therapy

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**Initiating Feminizing Therapy in Adults**

- Gather a comprehensive history
- Assess for minimum criteria
- Informed consent
- Baseline Labs:
  - Should Obtain: CMP, Lipids, HgbA1c
  - May Obtain: Testosterone, STI testing, HIV, Hep B/C
- Start therapy:
  - Typical doses:
    - Estradiol 2mg daily oral
    - Spironolactone 50mg oral twice daily, or 100mg oral once daily
- 1 month f/u
  - Tolerability? Questions? BMP (for K+ and CrCl), dose increase? BP.
  - Consider increasing estradiol by 1 mg daily and spironolactone by 50mg total daily.
- 3 month f/u
  - Changes noted? Side effects? BP
  - BMP/CMP*
  - Total Testosterone
  - Dose change? Consider increasing estradiol by 1 mg daily and spironolactone by 50mg total daily.
- 6 month f/u after maintenance dose (optional)
  - Testosterone, Estradiol, BP
- Yearly
  - BMP/CMP*, Testosterone, Estrogen, Prolactin?

Tips for monitoring estradiol

- Injectable: mid-injection cycle draw. Goal: midrange cisgender follicular phase
  - If high? First check timing and injection/drawing up technique
- Oral and Transdermal: trough (no patch or pill that morning)
- Testosterone: Goal <50ng/dL

**Notes:**

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**Initiating Masculinizing Therapy in Adult Patients.**

Gather a comprehensive history
Assess for minimum criteria
Informed consent
Baseline Labs:
- Must obtain: CBC, HCG.
- May obtain: CMP/BMP, Lipids/A1c, STI screen

Start therapy!
- Typical dose: Testosterone Cypionate 200mg/ml, 50mg SQ or IM every 7-14 days.

1 month f/u
- Tolerability? Questions? Dose increase, by 10mg?

3 month f/u
- Changes noted? Side effects?
- CBC, total Testosterone (mid injection cycle), CMP, hcg*, STI*

6 months after reaching stable dose
- CBC, total Testosterone, hcg*

Yearly
- CBC, total Testosterone, hcg*, CMP, Lipids

Titrate Dosing:
- To patient response/desired side effects
- Max 100mg SQ or IM weekly
- Mid-injection cycle Total Testosterone of 500-700ng/dL
- Safety, Hct <55%

Tips for lab monitoring Testosterone
- Injectable Testosterone: Mid cycle check, goal mid-range male
- Patch or topical: Trough check. No patch or application that morning.

**Notes:**

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**References:**

UCSF Transgender Care, Department of Family and Community Medicine, University of California San Francisco. Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People; 2nd edition. Deutsch MB, ed. June 2016. Available at transcare.ucsf.edu/guidelines. Last accessed February, 2023.

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# GENDER-AFFIRMING HORMONE THERAPY FOR ADULTS: INITIATION, MONITORING, AND MANAGEMENT

JOANNE ROLLS, MEHP, MPAS, PA-C
UNIVERSITY OF UTAH SCHOOL OF MEDICINE
UNIVERSITY OF UTAH TRANSGENDER HEALTH PROGRAM



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*I have no relevant relationships with ineligible companies to disclose within the past 24 months. (Note: Ineligible companies are defined as those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.)*

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## DISCLOSURES



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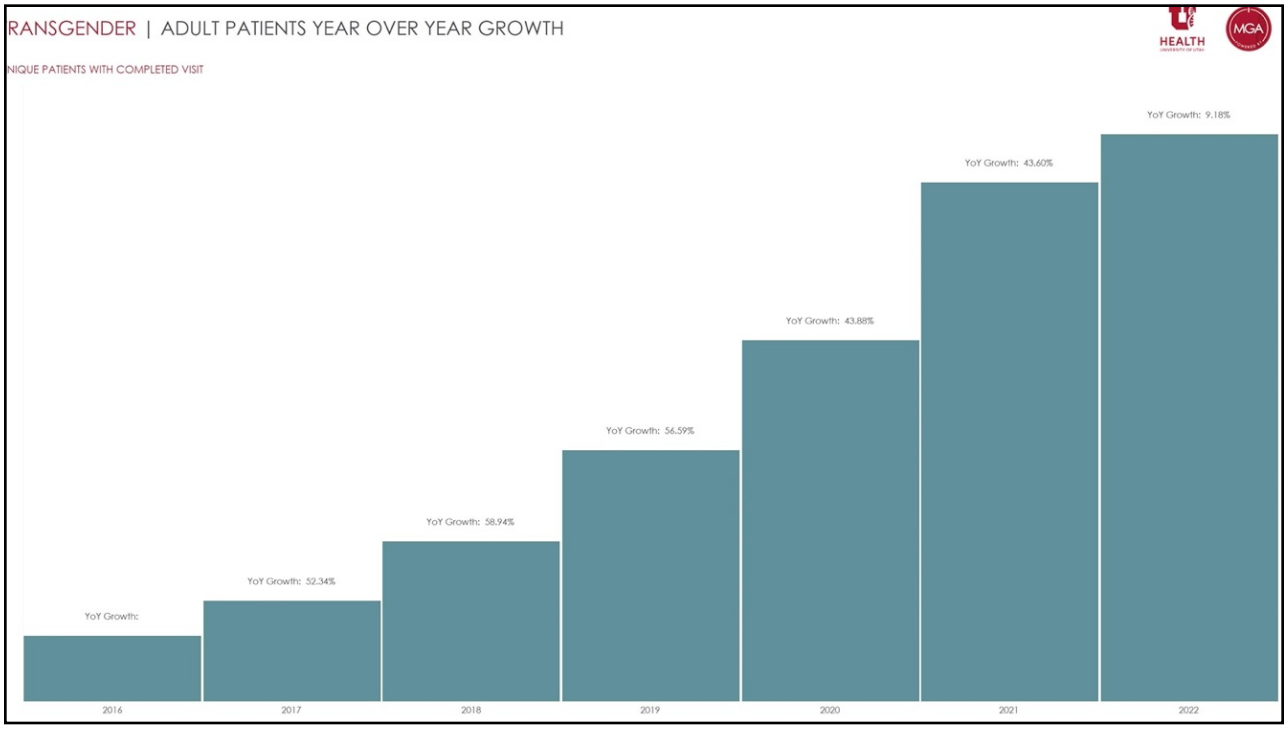


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Gender identity different from sex assigned at birth

At least 0.7% of US Adult population, >1.8m

Higher rates of healthcare disparities

Opportunity for PAs to improve care

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# Inclusive History Taking

SOGI/Gender-inclusive language


Name and pronouns

Inclusive sexual history taking

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## GENDER INCLUSIVE LANGUAGE

Sex: **Biologic variable**

Gender: **Social construct**, informed by sex

Gender identity: **Internal sense** of being Male, Female or Other

Sexual Orientation: **Attraction or non-attraction** to others

Sexual Activity: **Sexual behavior**, important for assessing risk

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# SEXUAL ORIENTATION AND GENDER IDENTITY





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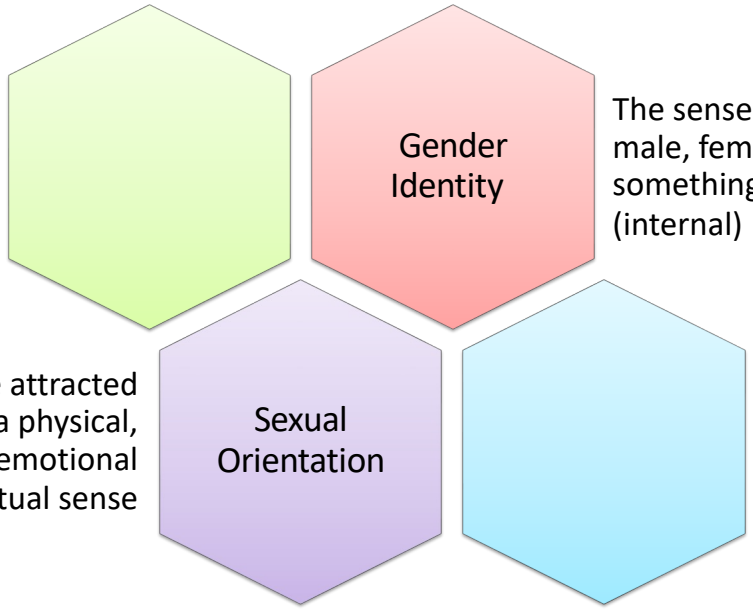




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## LANGUAGE TO AVOID

Hermaphrodite

Transvestite

Transsexual

Sex change/sex change operation

Gender Identity Disorder (more later)

Transgender as a noun (ex. She is a transgender)

Transgender as a "lifestyle"




## NAME AND PRONOUNS

| What would you like me to call you? | What pronouns do you prefer? | 2-step validated gender question (open ended) | Best Practices? |
|---|---|---|---|
| | | • What was your sex assigned at birth?<br>• What is your current gender identity? | • EMR<br>• Self-disclose<br>• Check yearly |

## INCLUSIVE SEXUAL HISTORY TAKING

**"Partners"**

Identity vs Behavior

"Can you tell me about the genders of the people you have sex with?"

"What kinds of sex are you having?"

"What do you do to prevent STIs/HIV?"

Pregnancy?



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## INCLUSIVE SEXUAL HISTORY TAKING

"Partners"

**Identity vs Behavior**

"Can you tell me about the genders of the people you have sex with?"

"What kinds of sex are you having?"

"What do you do to prevent STIs/HIV?"

Pregnancy?



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## INCLUSIVE SEXUAL HISTORY TAKING

"Partners"

Identity vs Behavior

**"Can you tell me about the genders of the people you have sex with?"**

"What kinds of sex are you having?"

"What do you do to prevent STIs/HIV?"

Pregnancy?



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## INCLUSIVE SEXUAL HISTORY TAKING

"Partners"

Identity vs Behavior

"Can you tell me about the genders of the people you have sex with?"

**"What kinds of sex are you having?"**

"What do you do to prevent STIs/HIV?"

Pregnancy?



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## INCLUSIVE SEXUAL HISTORY TAKING

"Partners"

Identity vs Behavior

"Can you tell me about the genders of the people you have sex with?"

"What kinds of sex are you having?"

**"What do you do to prevent STIs/HIV?"**

Pregnancy?



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## INCLUSIVE SEXUAL HISTORY TAKING

"Partners"

Identity vs Behavior

"Can you tell me about the genders of the people you have sex with?"

"What kinds of sex are you having?"

"What do you do to prevent STIs/HIV?"

**Pregnancy?**



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# HORMONE THERAPY





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# MINIMUM CRITERIA FOR GENDER AFFIRMING HORMONE THERAPY

- Gender incongruence is Marked and Sustained
- Meets diagnostic criteria for Gender Incongruence
- Demonstrates capacity for consent
- Identify and exclude other possible causes
- Assess for any mental health and physical conditions, risks/benefits
- Understands impact on reproduction

Source: WPATH SOC 8



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## ICD-11 GENDER INCONGRUENCE

**Depathologize** and **destigmatize** being Trans

Removed from mental health conditions

Differentiates gender *incongruence* from gender *dysphoria*



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## ICD-11 GENDER INCONGRUENCE

A Marked and Persistent incongruence between the gender felt or experienced and the gender assigned at birth:

*Strong dislike or disagreement with primary or secondary sexual characteristics due to incongruence with the experienced gender*



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## ICD-11 GENDER INCONGRUENCE

A Marked and Persistent incongruence between the gender felt or experienced and the gender assigned at birth:

*Strong desire to get rid of some of those sexual characteristics*



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## ICD-11 GENDER INCONGRUENCE

A Marked and Persistent incongruence between the gender felt or experienced and the gender assigned at birth:

*Strong desire to have the primary or secondary sexual chacteriscs of the experienced gender*

*Strong desire to be treated and accepted as a person of the felt gender*



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## THE MEDICINE IS EASY!

| The Drugs | The Labs |
|---|---|
| Testosterone | BMP/CMP |
| Estradiol | CBC |
| Spironolactone | Lipids |
| | HgbA1c |
| | STIs |
| | Total Testosterone |
| | Estradiol |
| | Urine HCG (Urine Preg) |



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## CASE #1- EMMA

28 y.o. Female, AMAB, (She/her/hers)

Has felt female since at least age 5

Hx: Healthy, no concerns

Straight

Goals: breast growth, decreased upper body muscles, smoother skin, FFS, other surgeries?

Sx Hx: Air Force logistics, good support, No smoking



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## MINIMUM CRITERIA FOR GENDER AFFIRMING HORMONE THERAPY

- Gender incongruence is Marked and Sustained
- Meets diagnostic criteria for Gender Incongruence
- Demonstrates capacity for consent
- Identify and exclude other possible causes
- Assess for any mental health and physical conditions, risks/benefits
- Understands impact on reproduction

Source: WPATH SOC 8



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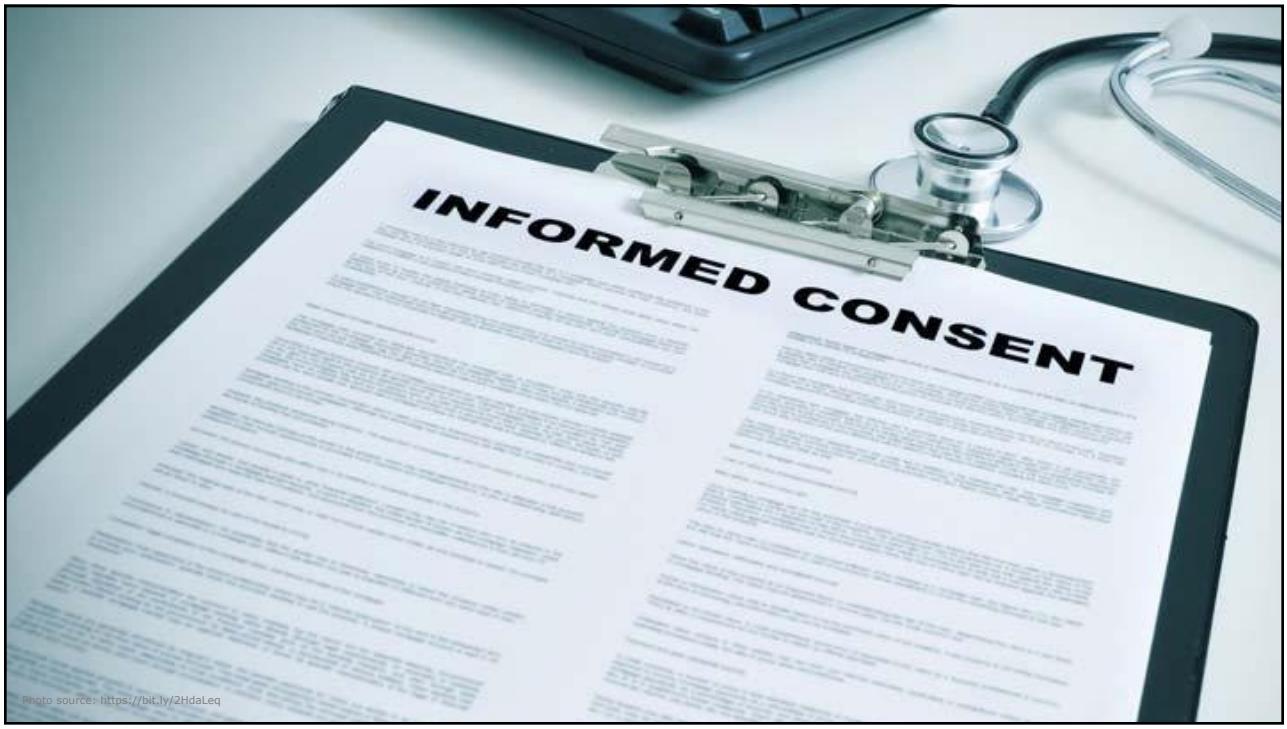


Photo source: https://bit.ly/2HdaLeq

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# FEMINIZING RISKS

| Estradiol | Spironolactone |
|---|---|
| Venous thromboembolic disease | Hyperkalemia |
| Gallstones | Hypotension/dizziness |
| ↑ LFTs | Fluid/electrolyte disturbance |
| ↑ TG | |
| CVD risk* | |
| Weight gain | |
| HTN | |
| T2DM* | |



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## EFFECTS AND EXPECTED TIME COURSE OF A REGIMEN CONSISTING OF AN ANTI-ANDROGEN AND ESTROGEN

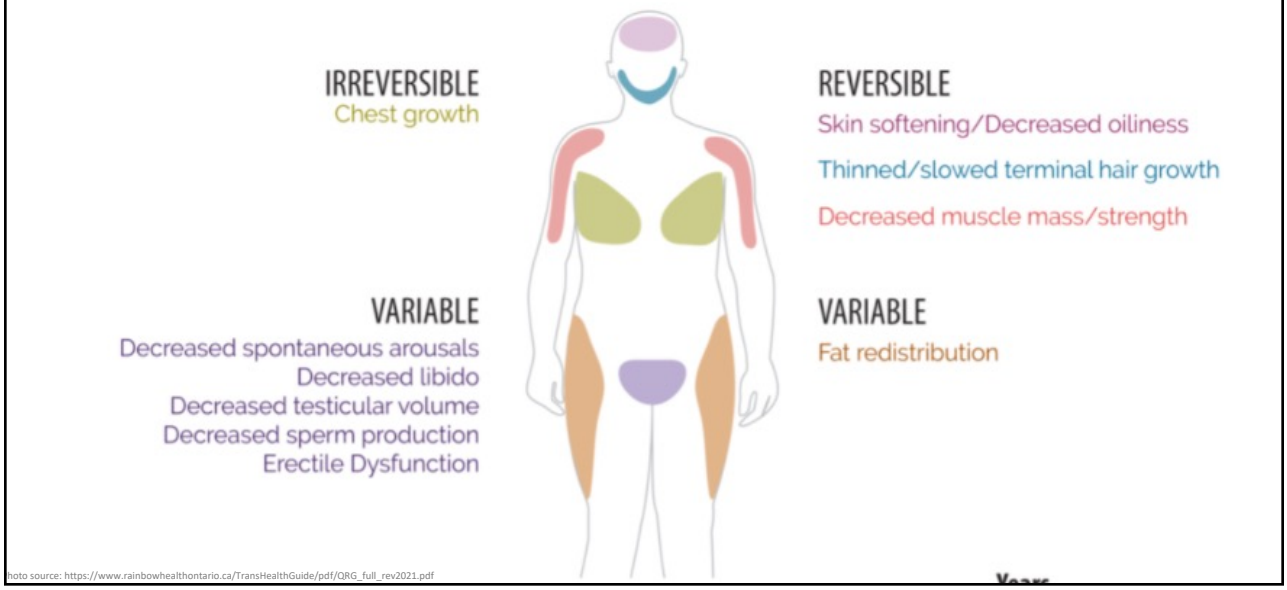


Photo source: https://www.rainbowhealthontario.ca/TransHealthGuide/pdf/QRG_full_rev2021.pdf

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## EFFECTS AND EXPECTED TIME COURSE OF FEMINIZING HORMONES

The degree and rate of physical effects are largely dependent on patient-specific factors such as age, genetics, body habitus and lifestyle, and to some extent the dose and route used (selected in accordance with a patient's specific goals and risk profile).[8]

| Physical Effects | Reversibility | Onset[a] | Expected maximal effect[a] |
|---|---|---|---|
| Softening of skin/ decreased oiliness | Reversible | 3-6 months | Unknown |
| Body fat redistribution | Reversible/ Variable | 3-6 months | 2-3 years |
| Decreased muscle mass/strength[b] | Reversible | 3-6 months | 1-2 years |
| Thinned/slowed growth of body/facial hair[c] | Reversible | 6-12 months | >3 years |
| Scalp hair loss (loss stops, no regrowth) | Reversible | 1-3 months | Variable |
| Breast growth | Irreversible | 3-6 months | 1-2 years |
| Decreased testicular volume | Variable | 3-6 months | 2-3 years |
| Decreased libido | Variable | 1-3 months | 3-6 months |
| Decreased spontaneous erections | Variable | 1-3 months | 3-6 months |
| Decreased sperm production | Variable | Variable | Variable |
| Reduced erectile function | Variable | Variable | Variable |

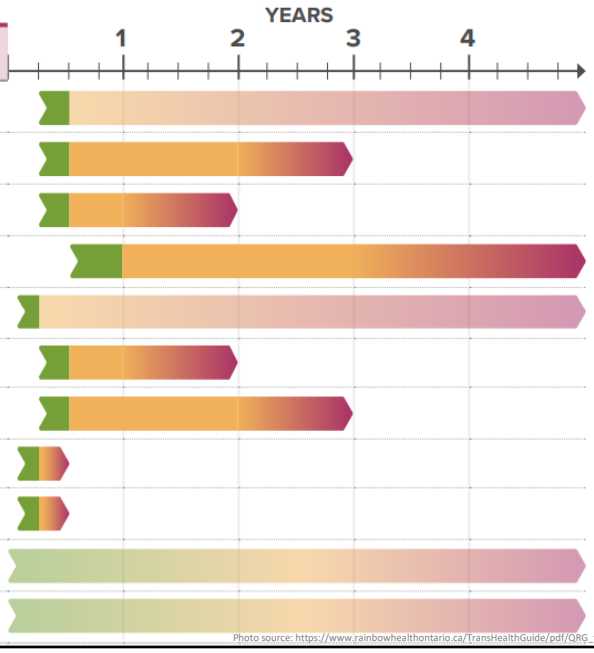


Photo source: https://www.rainbowhealthontario.ca/TransHealthGuide/pdf/QRG_full_rev2021.pdf

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## BASELINE LABS- FEMINIZING THERAPY

| | |
|---|---|
| CMP | LFTs, K+, renal function |
| Lipids/HgbA1c | ↑ CVD and DM risk |
| Hep B/C | if indicated |
| STI Screen +HIV | if indicated |
| Testosterone | consider |



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## CASE #1 EMMA – START THERAPY!

### Estradiol

Oral estradiol 2mg daily

-Or-

Estradiol patch 0.1mg transdermal twice weekly

### Spironolactone

50mg twice daily or 100mg once daily



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## CASE #1 EMMA

### 1 mo. follow up

- Tolerability
- BMP
- Dose increase?

### 3 mo. follow up

- BMP/CMP*
- Total testosterone



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## CASE #1 EMMA

### Dose Increase?

Patient goals/response

Goal Testosterone range <50

>50? increase spironolactone by 25-50mg daily

Increase estradiol by 1mg total daily



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## CASE #1 EMMA

### Typical Max dose

Oral estradiol: 8mg daily, divided

Estradiol patch: 0.4mg twice weekly

Spironolactone: 400mg daily, divided



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# INJECTABLE ESTRADIOL OPTIONS

| Medication | Typical Starting Dose | Typical Max Dose |
|---|---|---|
| Estradiol Valerate | 5mg (0.25ml of 20mg/mL solution) IM every 14 days | 20mg (1ml of 10mg/mL solution) IM weekly |
| Estradiol Cypionate | 2mg IM every 14 days | 5mg (1ml of 5ml/mL solution) IM weekly |



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# CASE #1 EMMA

**Follow up in first year**

Every 3 months if dose changes, 6 mo. if stable
BMP/CMP, Total Testosterone, estradiol?

**Yearly if stable**

Lipids, HgbA1c, Total Testosterone, estradiol, BMP/CMP, prolactin?



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## CASE #1 EMMA – REFERRALS

- Voice Therapy
- Physical Therapy
- Psychology
- Laser Hair Removal
- Facial Feminization Surgery
- Fertility
- Top or Bottom Surgery (Urology, plastics)



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## CASE #2 DEREK

26 y.o, transmale, (he/him/his), AFAB

Healthy, controlled anxiety

Sense of being male x 17 years

Bisexual

Goals: facial hair, muscle/fat, top surgery, menses cessation

Sx Hx: prior smoker, IT, good support!



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## MINIMUM CRITERIA FOR GENDER AFFIRMING HORMONE THERAPY

- Gender incongruence is Marked and Sustained
- Meets diagnostic criteria for Gender Incongruence
- Demonstrates capacity for consent
- Identify and exclude other possible causes
- Assess for any mental health and physical conditions, risks/benefits
- Understands impact on reproduction

Source: WPATH SOC 8



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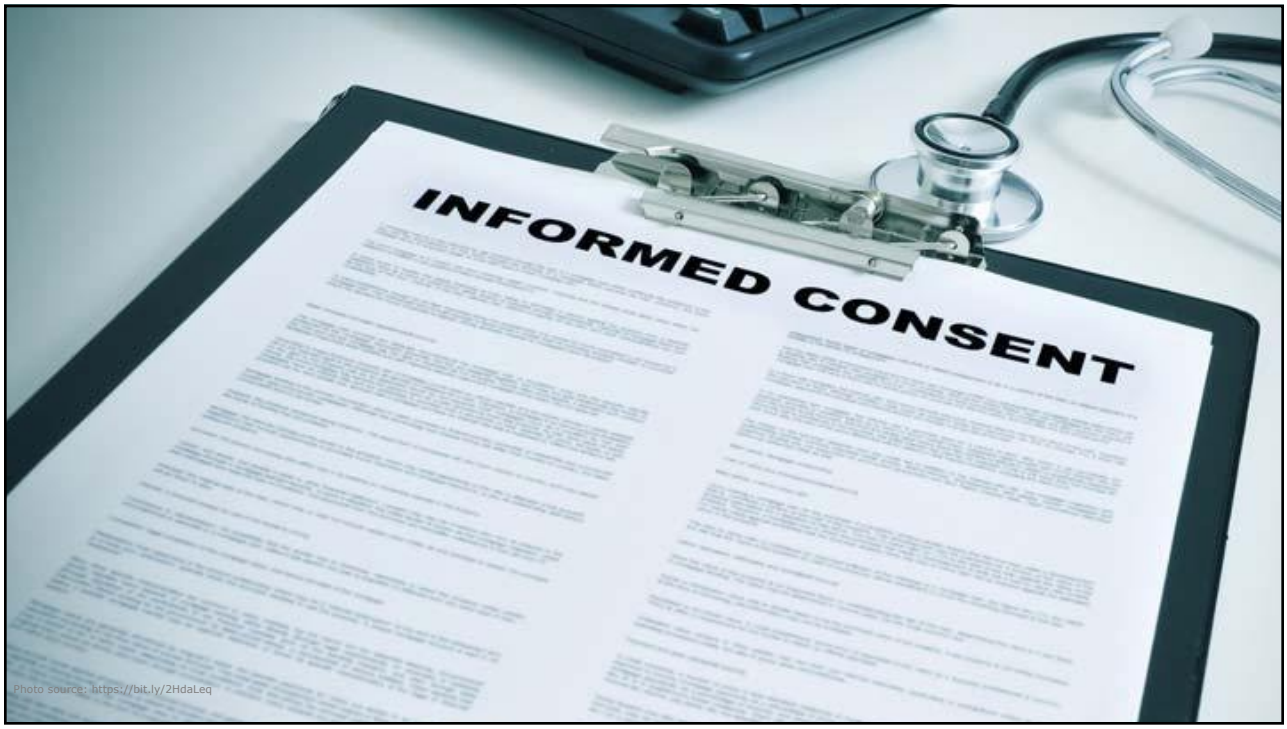


Photo source: https://bit.ly/2HdaLeq

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## TESTOSTERONE RISKS

| | | | |
|---|---|---|---|
| Polycythemia | Weight gain | Acne | Androgenic Alopecia |
| Sleep apnea | ↑LFTs | ↑Lipids | ↑pre-DM Risk |
| Destabilizing psychiatric conditions* | CVD* | HTN* | T2DM* |

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## EFFECTS AND EXPECTED TIME COURSE OF A REGIMEN CONSISTING OF TESTOSTERONE

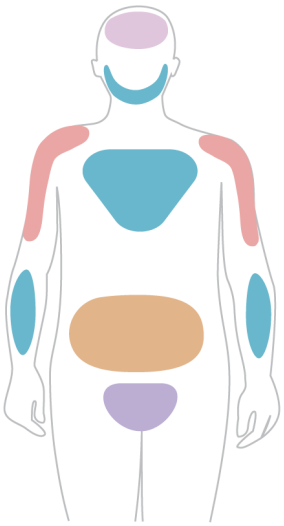
### IRREVERSIBLE

Scalp hair loss

Deepened voice

Facial and body hair growth

Clitoral enlargement



### REVERSIBLE

Skin oiliness/acne

Increased muscle mass/strength

Vaginal atrophy

### VARIABLE

Fat redistribution

Photo source: https://www.rainbowhealthontario.ca/TransHealthGuide/pdf/QRG_full_rev2

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therapy results in both reversible and irreversible masculinization.

| Physical Effects | Reversibility | Onset[a] | Expected maximal effect[a] |
|---|---|---|---|
| Skin oiliness/acne | Reversible | 1-6 months | 1-2 years |
| Body fat redistribution | Reversible/ Variable | 1-6 months | 2-5 years |
| Increased muscle mass/strength[b] | Reversible | 6-12 months | 2-5 years |
| Facial/body hair growth | Irreversible | 3-6 months | 4-5 years |
| Scalp hair loss | Irreversible | 6-12 months[c] | Variable |
| Cessation of menses | Reversible | 1-6 months | n/a |
| Clitoral enlargement | Irreversible | 3-6 months | 1-2 years |
| Vaginal Atrophy | Reversible | 1-6 months | 1-2 years |
| Deepened voice | Irreversible | 6-12 months | 1-2 years |
| Infertility | Variable | Variable | Variable |

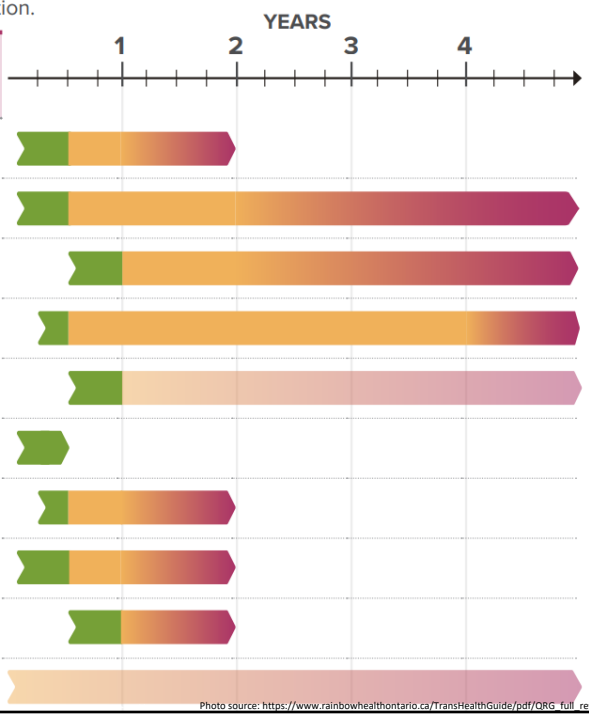


Photo source: https://www.rainbowhealthontario.ca/TransHealthGuide/pdf/QRG_full_rev2021.pdf

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## BASELINE LABS – MASCULINIZING THERAPY

| | |
|---|---|
| CBC | baseline H and H |
| HCG | r/o pregnancy |
| Lipids/HgbA1c | if indicated |
| STI Screen | if indicated |
| CMP/BMP | if indicated |



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## CASE #2 DEREK

**Testosterone cypionate 200mg/ml**

50mg per every 7-14 days. IM or SQ

**1 mo. follow up**

Tolerability
Increase dose?

**3 mo. follow up**

Testosterone (total)- mid cycle CMP, CBC, HCG*, STIs*



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## CASE #2 DEREK

### Dose Increase?

Patient response
'Normal' T range (500-700ng/dL)
Safety (H&H)
Max: 100mg weekly



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## OTHER TESTOSTERONE OPTIONS

| Medication | Typical Starting Dose | Typical Max dose |
|---|---|---|
| Transdermal Testosterone Topical Gel | Varies by formulation:<br>- Testosterone gel 1%, 12.5mg/actuation, 2-5 pumps<br>- Testosterone gel 1.62%, 20.25mg/act, 1-3 pumps | Varies by formulation<br>- Testosterone gel 1%, 12.5mg/actuation 8 pumps<br>- Testosterone gel 1.62%, 20.25mg/act, 5 pumps |
| Transdermal Testosterone Patch | 2-6mg (1-3 x 2mg patches) daily | 8mg (2x 4mg patches) daily |



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## CASE #2 DEREK

**Follow up?**

6 months after maintenance dose
CBC, Total Testosterone, HCG*

**Yearly**

CBC, Total T, CMP*, Lipids*



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## REFERRALS

| | | |
|---|---|---|
| Surgery (Urology, plastics, gynecology) | Voice Therapy | Physical Therapy |
| Psychology | Endocrinology | Fertility |



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## CASE #3 - KYLE

- 34 y.o. male, (he/him), AFAB
- Parent to 2 y.o. Zoe, partner cis-gender female, Rose.
- Hx of anxiety and treatment resistant depression-variable control
- Current hormone: Testosterone 100mg weekly
  - *Loves the effects on hair/muscle/libido/appearance*
  - *He and his wife are worried: mood swings/anger/irritability*



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## CASE #3 - KYLE

Other Medications:

- Sertraline 50mg daily
- Lamictal 100mg twice daily
- Buspar 10mg up to three times a day



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## CASE #3 - KYLE

*Are mental health medications maximized?*

*Non-pharmacologic interventions?*

*Concern with masculinizing therapy?*



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## CASE #3 KYLE

- Injection cycle effect?
- Consistent dose?
  - Transdermal cream?
    - Transfer to partner? Kiddo?
  - Transdermal patch?

| Medication | Typical Starting Dose | Typical Max Dose |
|---|---|---|
| Transdermal Testosterone Patch | 2mg-6mg (1-3x 2mg patches) daily | 8mg (2 x 4mg patches) daily |



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## CHANGING THERAPY AND MONITORING

Start low with formulation change

Transdermal monitoring : Trough. No dose that morning



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## CASE # 4 LESLIE

- 56 y.o. Transwoman. (she/her) AMAB
- Hormone Therapy: 6mg oral estradiol daily x 8 years. s/p orchiectomy
- Comes in for annual well-visit
- Changes in family history- father had an MI, worried!
- She exercises regularly, decent diet, no tobacco



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## CASE #4 LESLIE

- You check BP, which is 156/94 (Up from 140/89 a year ago) and obtain a lipid panel
- Not currently on any meds
- How do you interpret her lipids?
  - No clear recommendation
  - Can use sex assigned at birth, or affirmed gender or average
  - You determine a 10-year ASCVD risk between 9.5%-10.5%
- What are your next steps?



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## CHANGING THERAPY AND MONITORING

| Medication | Typical Starting Dose | Typical Max Dose |
|---|---|---|
| Estradiol Patch | 0.1mg-0.2mg (1-2x 0.1mg patches) biweekly | 0.4mg (4x 0.1,g patches) biweekly |

Reduce CVD Risk?

- Transdermal formula
- Statin
- Weight loss/increase activity
- Consider Aspirin



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## CASE #5 - MARCUS

45 y.o. transmale (he/him) AFAB
Testosterone 100mg SQ Weekly x 4 years
Here for 6-month follow up and med refill
Hgb of 19 g/dL and Hct of 57%
What are next steps in management?



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## CASE #5 - MARCUS

Causes?

- Testosterone Dose
  - Check total Testosterone
- Tobacco use
- Cardiopulmonary disease
- Sleep Apnea



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## CASE #5 - MARCUS

Management?

- More consistent dosing/dose adjustment
- Therapeutic phlebotomy
- Treat underlying causes



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## CONSIDERATIONS FOR GENDER NON-BINARY PATIENTS

- Chosen name and pronouns
- Gender affirmation
  - Internal, social, medical, surgical
- Low dose hormones
  - Consider bone health
  - Limited literature



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## OTHER THINGS TO LEARN ABOUT!

Non pharmacologic care

Your local community!

Other ways to help: letters, legal, support navigating the health system, legislation



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## COST?

| IM/SQ Testosterone | Spironolactone | Oral estradiol |
|---|---|---|
| $19-$114 per month | $4 to $15 per month | $15-19$ per month |



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## TAKE HOME POINTS

- This is an underserved group, that needs our help and PAs are poised to use the skills that we already have to provide this care
- Use dosing references, follow patients closely for first 1-12 months, monitor for safety and toxicity
- Know your referral networks and patient resources
- This will bring **JOY!!!** to your practice!



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*Thank you to my patients, my colleagues, especially Dr. Erika Sullivan, PA Johanna Greenberg, and Clinical Pharmacist, Dr. Karen Gunning for their help with this presentation and to my family for supporting this work.*

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# QUESTIONS?

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