



# **HIV Care for Transgender Women**

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# Disclosure

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**I have no real or perceived vested financial interests that relate to this presentation nor do I have any relationships with pharmaceutical companies, biomedical device manufacturers, and/or other corporations whose products or services are related to pertinent therapeutic areas.**

**Tonia Poteat, PA-C  
11/23/2013**



# Objectives

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- 1. Describe ways to create a welcoming environment for transgender patients**
- 2. List medications commonly used for cross gender hormone therapy**
- 3. Identify common drug-drug interactions between antiretrovirals and hormone therapy**



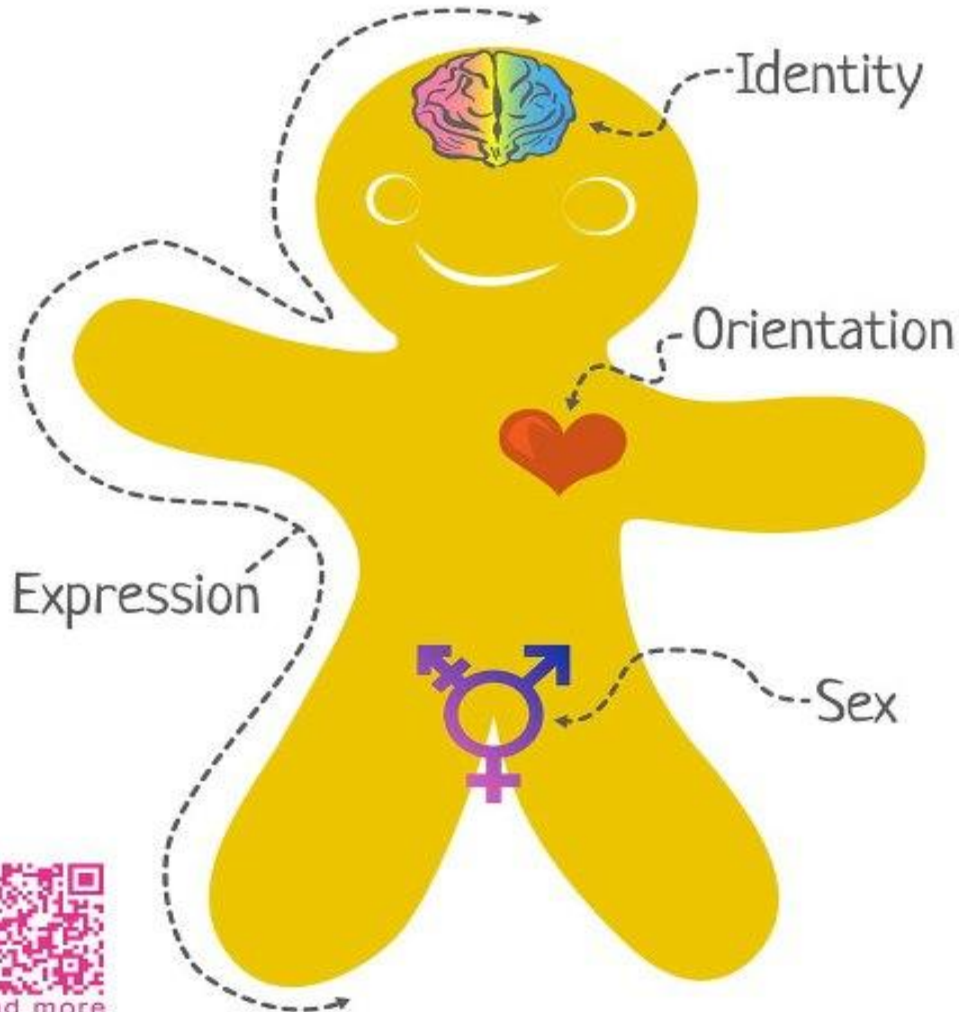
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# Definitions



# The Genderbread Person

by [www.ItsPronouncedMetrosexual.com](http://www.ItsPronouncedMetrosexual.com)



Gender identity is how you, in your head, think about yourself. It's the chemistry that composes you (e.g., hormonal levels) and how you interpret what that means.



Gender expression is how you demonstrate your gender (based on traditional gender roles) through the ways you act, dress, behave, and interact.



Biological sex refers to the objectively measurable organs, hormones, and chromosomes. Female = vagina, ovaries, XX chromosomes; male = penis, testes, XY chromosomes; intersex = a combination of the two.



Sexual orientation is who you are physically, spiritually, and emotionally attracted to, based on their sex/gender in relation to your own.

# Definitions

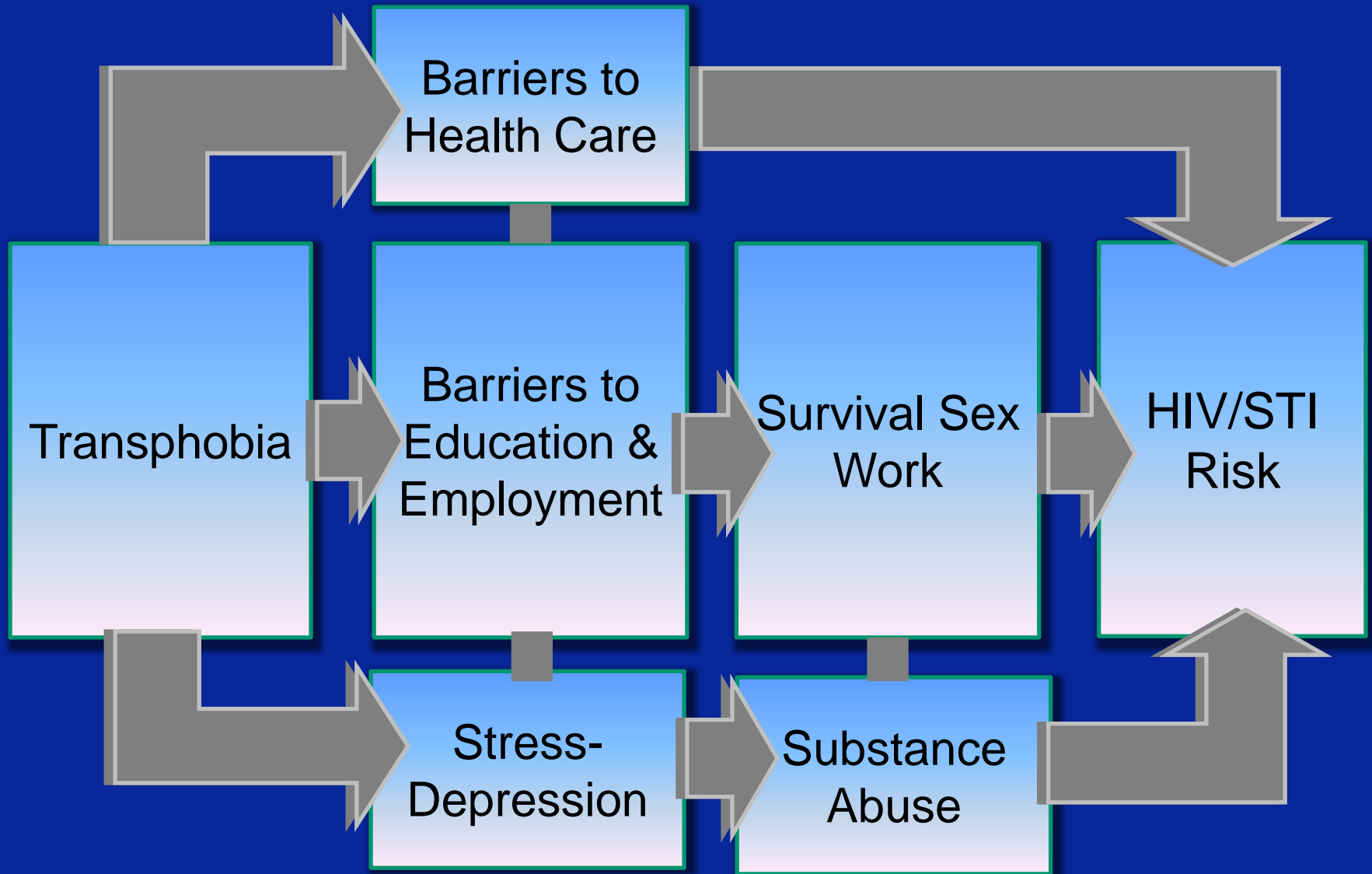
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- **Transgender or Trans\***
  - Umbrella term to describe people who identify with a gender that differs from their natal sex
- **Trans woman**
  - One who was born male who identifies as a woman
- **Trans man**
  - One who was born female who identifies as a man



**This presentation will focus on  
trans women who bear the  
heaviest burden of HIV**

# Vulnerabilities to HIV



# HIV Risk

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- **Individual Risk**
  - High rates of sex work (>40%)
  - Validation sex
  - Low condom use
  - Increased rates STIs
  - Needle sharing for hormones/silicone?
- **Gender Discrimination (linked to):**
  - Unprotected anal receptive sex
  - Depression and substance use
- **Non-inclusion in HIV prevention campaigns**
- **HIV prevention lower priority than gender affirmation and survival**





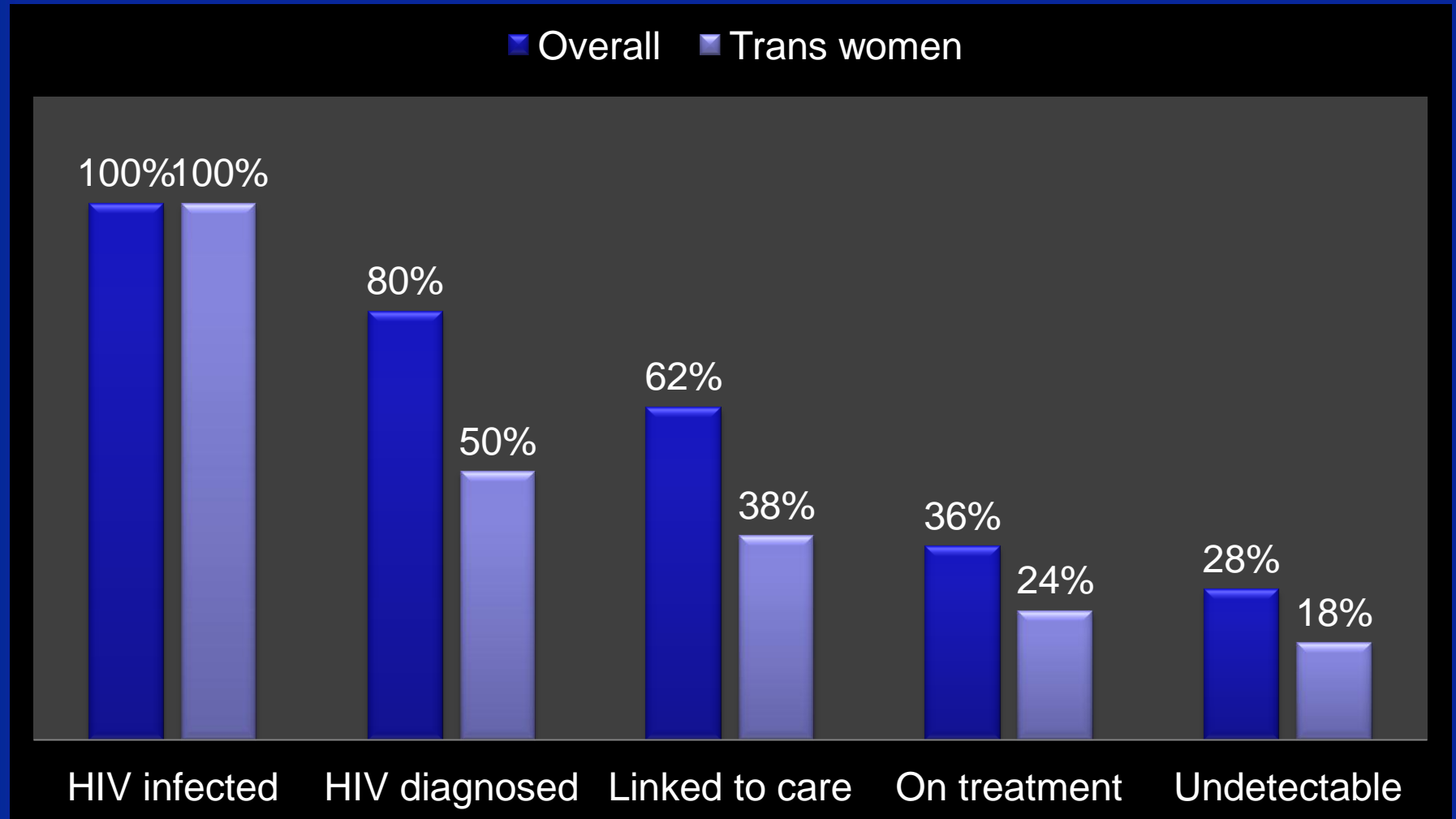
# HIV Prevalence

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- **First published meta-analysis (2008)**
  - 28% among all trans women
  - 56% among AA trans women
  - Most studies among street-based sex workers
- **Recent global meta-analysis (2012)**
  - 22% in the United States
  - OR = 34 (CI: 31-38) compared to general population



# HIV Treatment Cascade

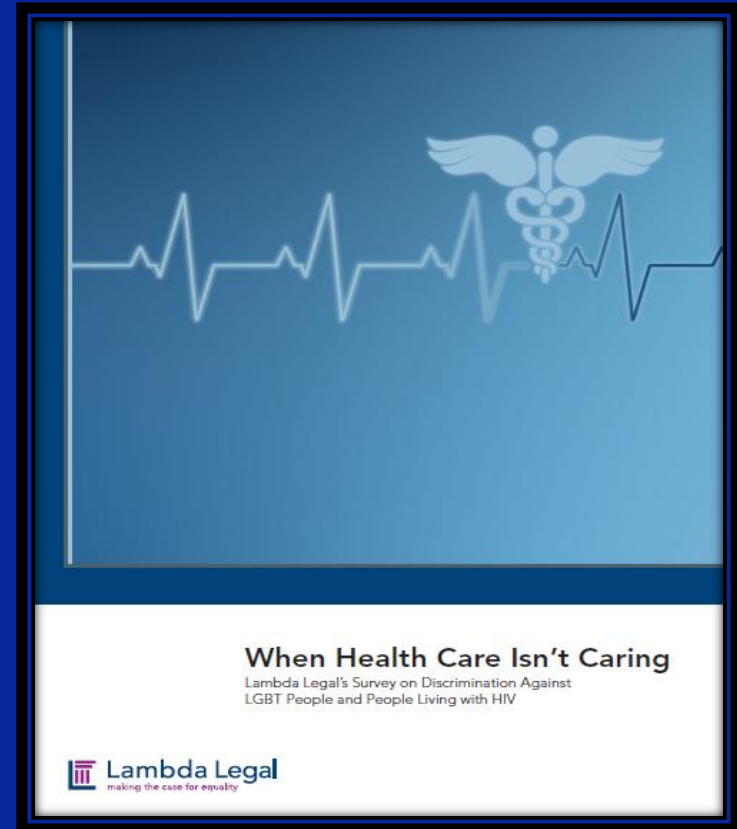
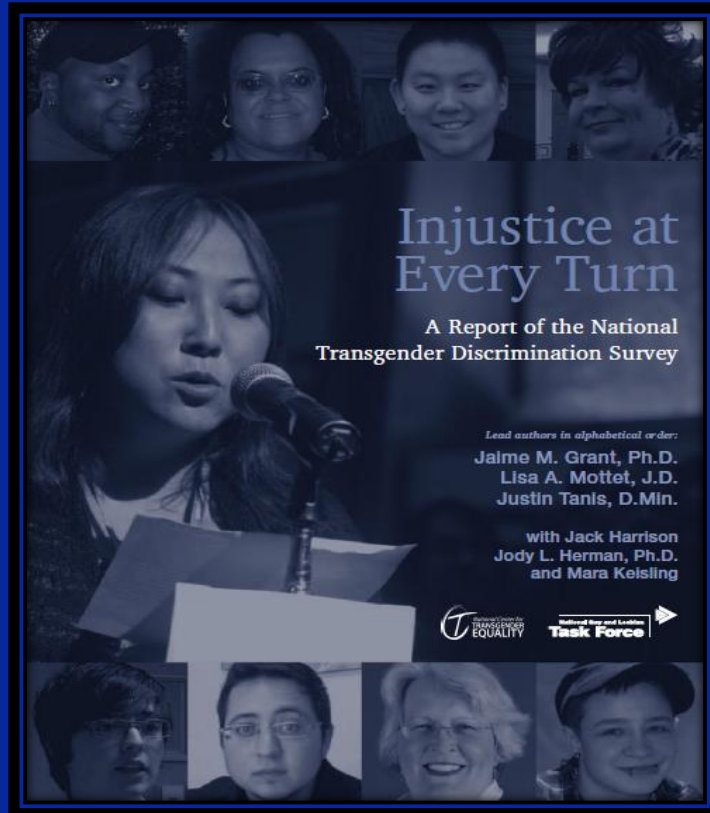


# Transgender Women with HIV

- **Less likely to receive antiretroviral therapy**
- **Less likely to be adherent**
  - **less confidence in ability to integrate treatment regimens into daily lives**
  - **fewer positive interactions with health care providers**
- **Stigma associated with poor adherence**



# Why do we need a welcoming environment?



# Realities for Many Trans Women

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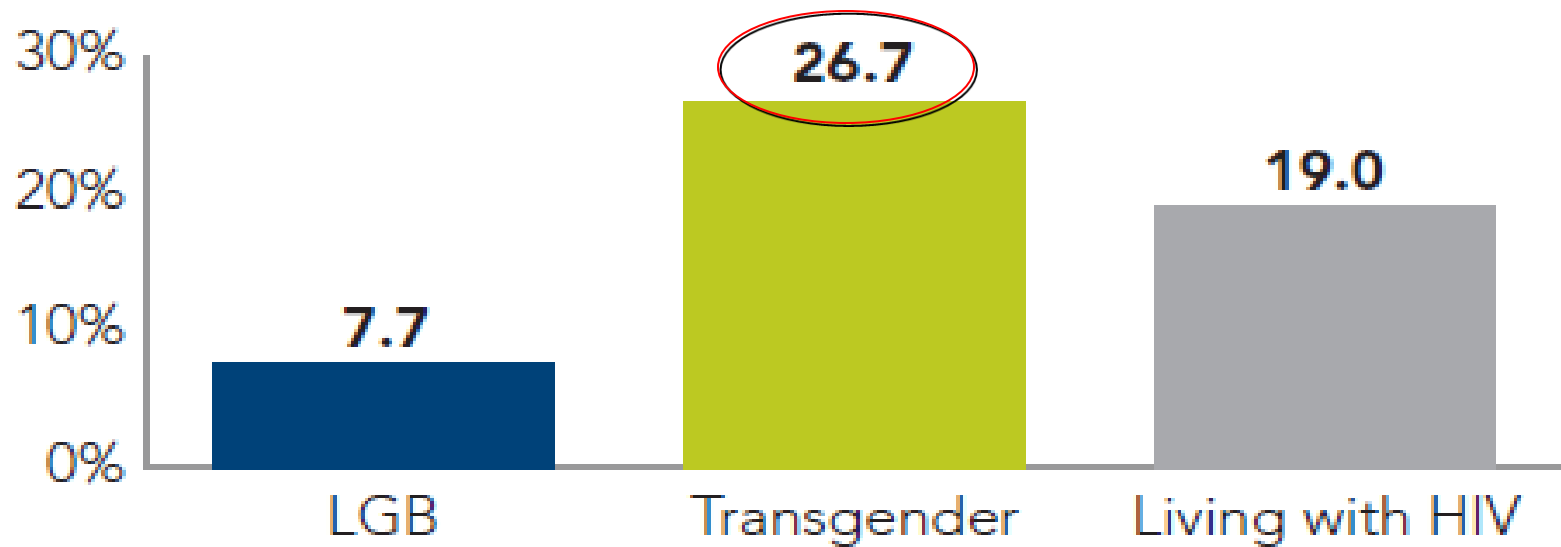
- **Employment Barriers**
  - Twice the rate of unemployment
  - 60% live below poverty line
  - 15% live on <\$10,000 a year
- **Legal Barriers**
  - Identification documents
  - Public bathrooms
  - Adult incarceration, domestic violence shelters, and homeless facilities



# Barriers to Health Care

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Table 1: I was refused needed health care



# Health Care Discrimination

Table 2: Health care professionals refused to touch me or used excessive precautions

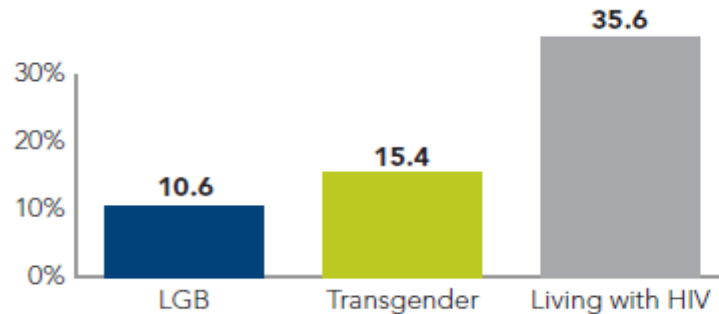


Table 4: Health care professionals blamed me for my health status

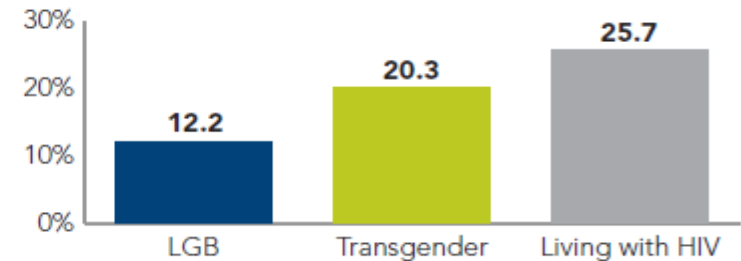


Table 3: Health care professionals used harsh or abusive language

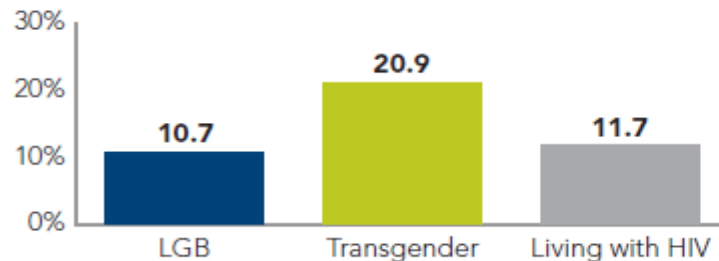
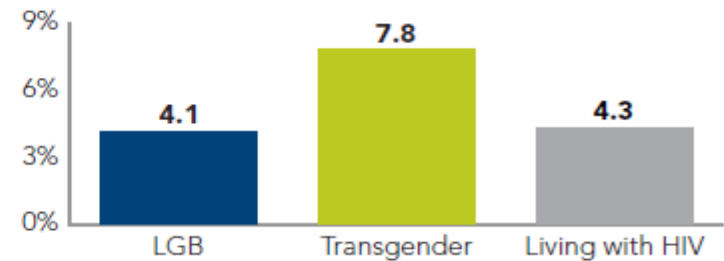
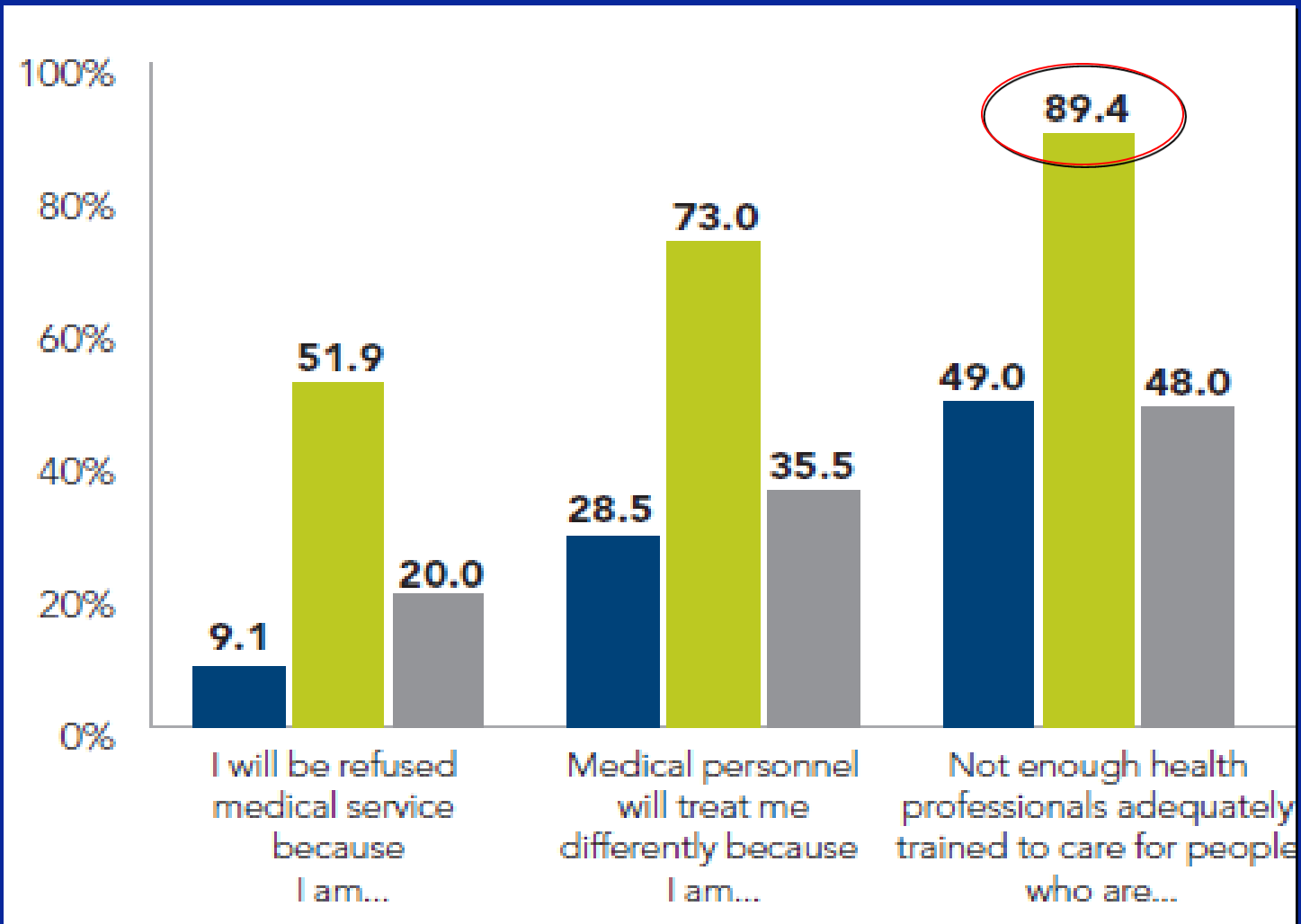


Table 5: Health care professionals were physically rough or abusive



# Fears about health care





# Consequences of Poor Access to Care

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- **Illicit hormone use**

- Internet, international, veterinary supply, “herbal”
- Doses are guessed at and usually are too high
- Sharing vials of hormones and/or syringes

- **Illicit soft tissue filler use**

- Injection of silicon gel, oils, and other substances
- Risks include
  - Infections/sepsis from unsterile technique
  - Blood borne pathogens from contaminated syringes
  - Inflammation, granulomas and scarring
  - Disfigurement due to shifts of silicone
  - Immediate death due to emboli

- **Delayed HIV testing**

- 45-65% of HIV-positive trans women unaware of status



# Barriers to engagement in care

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- **“We cannot have you in our waiting room, it would be embarrassing to our other patients”**
- **“Your back pain/diarrhea/headaches (substitute any sign/symptom) are caused by your taking hormones”**
- **“I cannot provide you with medical care” (nor will I refer you to anyone else...)**
- **Although Mrs. Jones is wearing a dress and appears obviously female, the nurse or receptionist insists on calling her Mr. Jones**
- **“The nurse kept referring to me as “it”**



# Creating a Welcoming Environment

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- Gender neutral or unisex bathrooms
- Images of trans people in posters, handouts, etc.
- Training staff in culturally competent care
- Hiring of trans staff
- Integration of gender care into HIV care
- Intake forms that allow choices other than M/F
- Use preferred pronouns and name
  - Ask what patient prefers if unsure
  - Include preferred name on chart
  - Avoid terms pre-op/post-op



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# Medical Management



# Devonne

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**27 year old African-American trans women presents as a walk-in complaining of 5 days rectal burning & discharge**

- **Sexual history**
  - Receptive anal sex with one male partner
  - Unemployed, previous sex work
  - HIV testing 3 years ago – negative
- **Socially transitioned at age 20**
  - Injectable estrogen & spironolactone for 5 years
  - Silicone injections breasts, buttocks
  - No genital surgery



# Devonne (continued)

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## Anal exam (anoscopy)

- Fissure noted, purulent blood-streaked discharge

## Differential

- Gonorrhea, Chlamydia / LGV, Syphilis, HSV

## Diagnostic testing

- Anal, urethral, and oral GC & CT (NAAT)
- Anal HSV culture
- RPR
- Oraquick

Treated: ceftriaxone, doxycycline, valacyclovir



# Laboratory results

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- Anal: *N gonorrhoeae*
- Urethral: *C trachomatis*
- Rapid HIV test – positive



# Sexual Health

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- **It may be uncomfortable, distressing, and even traumatic for a trans person to see a clinician about sexual health**
- **Trans people may use different words to describe body parts**
- **Ways to facilitate sensitive language in sexual health services include:**
  - **Using gender neutral terms**
  - **Avoid possessive pronouns**
  - **Ask patient what words they prefer**





# Initial Visits: Medical History

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- Document history of gender interventions
  - Hormone dose, duration, prescription and “street”
  - Use of needles for hormone injection (shared)
  - Silicone injections or other fillers, “pump parties”
- Review patient goals for gender transition
- Address psychosocial issues
  - Depression, PTSD, substance use history
  - Employment, sex work history
- Assess social support system
- Address safety concerns



# Initial Visits – Best Practices

- Transgender patients probably have had previous negative healthcare experiences
  - Developing trust and rapport may take longer than you expect
  - Pay attention to pronouns
- Avoid genital and rectal exams on first visit, if possible
  - History of sexual abuse and trauma is common
  - Discuss choice of language to describe anatomy



# **Routine Preventive Care: Anatomy appropriate screenings**

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- **Prostate screening**
  - All transwomen per current guidelines
- **Testicular exams**
  - All transwomen with testes
- **Breast exams and mammography**
  - When to start?
- **Anal and/or vaginal pap smears**
  - If receptive intercourse
- **STD screening based on sexual behavior**



# Physical Exam and Labs

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- **Routine exam**
  - **Assess patient comfort with exam**
  - **Problem oriented exam only**
  - **Avoid satisfying your curiosity**
  
- **Routine labs plus . . .**
  - **Testosterone level (if starting or on hormones therapy)**
  - **Prolactin level (?)**



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# Gender Care



# Two Models

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- **Standards of Care Models**

- WPATH
- Endocrine Society
- New England Journal of Medicine

- **Informed Consent Models**

- Howard Brown Health Center THInC
- Callen-Lorde Community Health Center



# WPATH Standards of Care, v7 (2011)

## Criteria for Hormone Therapy

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- 1. Persistent gender dysphoria (ICD 302.85)**
- 2. Capacity to make a fully informed decision and to consent for treatment**
- 3. Age of majority in a given country**
- 4. If significant medical or mental health concerns are present, they must be reasonably well controlled.**

*“It can be acceptable practice to provide hormones to patients who have not fulfilled these criteria...facilitating the provision of monitored therapy using hormones of known quality as an alternative to illicit or unsupervised hormone use or to patients who have already established themselves in their affirmed gender and who have a history of prior hormone use.”*



# Informed Consent Model

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- **Transgender Hormone Informed Consent process**
  - 1. Medical appointment for physical and labs**
  - 2. Hormone advocate appointment for info**
  - 3. Medical appt to review labs and rx hormones**
- **No letter required or provided**
- **Diagnosis: Endocrine Disorder (ICD 259.9)**
- **Focus on determining cognitive ability and providing comprehensive information**





# Responsibilities of Hormone Prescribers

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- 1. Perform an initial evaluation**
- 2. Discuss the expected effects of feminizing or masculinizing medications, including reproductive**
- 3. Confirm that patients have the capacity to understand the risks and benefits and make an informed decision**
- 4. Provide ongoing medical monitoring**
- 5. Communicate as needed with other providers**
- 6. If needed, provide patients with a brief written statement indicating that they are under medical supervision and care that includes feminizing or masculinizing hormone therapy**



# The Hormone Bridge

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**A study of HIV+ transgender women seen in a NY Clinic found combining hormone therapy with HIV care:**

- **Stopped their self-medication of hormones**
- **Stopped their sharing of needles to inject hormones**
- **Increased their adherence with their HIV meds**
- **Increased their condom use**
- **Decreased their reliance on sex work to pay for hormones**

**Grimaldi J. & Jacobs J. (1998) The HIV hormone bridge: connecting impoverished HIV+ transsexual sex workers to HIV medical care. *AIDSLine*, ICA12/98406957. Available online at: <http://www.aegis.com/aidsline/1998/dec/m98c1575.html>**



# Key Concepts for Hormone Therapy

- **Several protocols are readily available**
  - Endocrine Society, UCSF, Callen-Lorde
- **Higher doses may result in faster changes, but end result the same with higher risk**
  - Heredity limits tissue response
- **Second puberty**
  - It takes just as long the second time as the first time (3-5 years)
  - Only reverses (some of) the effects of the first puberty



# Feminizing Therapy

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- **Anti-androgens**

- Spironolactone blocks testosterone synthesis and receptors
- Finasteride blocks testosterone synthesis

- **Estrogens**

- Conjugated Equine Estrogen (CEE)
- Estradiol (oral, injectable, patch)

- **Progesterone**

- Use is controversial
- Helpful for weight gain and for early breast development (first 6 months)
- Side effects: depression, wt gain, hair loss, liver cancer, etc.



# Anti-Androgens

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Medication Name	Starting Dose	Average Dose	Maximum Dose
Spironolactone (Aldactone)	50 mg/day	100 mg/day	200 mg/day
Finasteride (Proscar)	1 mg/day	5 mg/day	5mg/day



# Anti-Androgens: Spironolactone

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- **Benefits:**
  - Modest breast development
  - Softening of facial and body hair
  - Enable feminization on a lower dose of estrogen
- **Risks**
  - Hyperkalemia
  - Hypotension
  - Drug Interactions
- **Contraindications**
  - Renal insufficiency
  - Serum potassium > 5.5
  - ACE/ARB therapy



# What to prescribe: Estrogens

Hormone Name	Starting Dose	Average Dose	Maximum Dose
CEE (Premarin)	1.25 – 2.5mg/day	5 mg/day	10 mg/day
17- $\beta$ Estradiol oral	2 mg/day	4 mg/day	8mg/day
17- $\beta$ Estradiol IM	20mg IM q 2wks	20-40 IM q 2wks	40mg IM q 2wks
17- $\beta$ Estradiol patch	0.1-0.2 mg/day	0.2-0.3 mg/day	0.3 mg/day



**Ethinyl estradiol (OCPs) NOT recommended  
due to higher embolic risk**

# Estrogens

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- **Desired Effects**

- Breast growth
- Redistribution of body fat
- Softening of skin
- Decrease in body hair
- Slowing or stopping scalp hair loss
- Higher HDL, lower LDL

- **Other Effects**

- Testicular atrophy and loss of fertility
- Loss of erections and decreased libido
- Decreased upper body strength
- Emotional changes
- Weight gain





# Contraindications to Estrogen

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- **Absolute**

- Presence of estrogen-dependent cancer
- Current embolic disease/hypercoagulable state
- End-stage chronic liver disease

- **Relative**

- Smoking
- Uncontrolled hypertension
- Uncontrolled diabetes
- Desire to maintain fertility
- History of clotting disorder, DVT, PE
- Liver disease
- Hyperprolactinemia
- Untreated or treatment resistant depression
- Migraine



# Risks of Estrogen Therapy

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- **Venous thrombosis/pulmonary emboli (oral)**
  - Use minimum effective dose
  - Add aspirin if > 40 yo
  - Use transdermal patch if smoker >40yo
  - STOP SMOKING
  - Stop estrogen 2 weeks before surgery or immobilization
- **Other**
  - Hypertriglyceridemia (oral)
  - Elevated blood pressure
  - Decreased glucose tolerance
  - Gallbladder disease
  - Benign pituitary prolactinoma ? (rare)
  - Breast cancer ?



## Summary: standard feminizing regimen

Estradiol 1 mg to 6 mg daily  
or

Conjugated estrogens 0.625 to 5.0 mg daily

and

Spiroonolactone 100-200 mg QD or divided BID  
or

Finasteride 5 mg daily

plus aspirin 81-325 mg daily if over age 40



# Expected Effects and Timing of Feminizing Hormone Therapy (SOC7)

Expected Effect	Expected Onset	Expected Maximum Effect
Body fat redistribution	3-6 months	2-5 years
Decreased muscle mass/strength	3-6 months	1-2 years
Softer skin/decreased oiliness	3-6 months	unknown
Decreased libido	1-3 months	1-2 years
Decreased spontaneous erections	1-3 months	3-6 months
Erectile dysfunction	variable	variable
Breast growth	3-6 months	2-3 years
Decreased testicular volume	3-6 months	2-3 years
Decreased sperm production	variable	variable
Thinning/reduced growth face/body hair	6-12 months	> 3 years
Improvement in male pattern baldness (no regrowth)	Loss stops 1-3 months	1-2 years



# Risks associated with hormone therapy

Level	Risk
Likely increased risk	Venous thromboembolic disease Hypertriglyceridemia Gallstones Elevated liver enzymes Weight gain
Likely increased risk when additional risk factors present	Cardiovascular disease
Possible increased risk	Hypertension Hyperprolactinemia or prolactinoma
Possible increased risk when additional risk factors present	Type 2 Diabetes Mellitus
No increased risk or inconclusive	Breast cancer



# Follow-up labs

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- Check potassium 1-2 months after starting or increasing dose of spironolactone
- Check testosterone, liver enzymes, fasting lipids, and glucose 1-3 months after starting or increasing estrogen, then every 3-6 months.
- Consider repeating prolactin at 1, 2, and 3 years.
  - If normal, no further tests are necessary
- Monitoring therapy
  - Goal is to keep testosterone in normal female range OR to achieve patient's desired clinical response, if that can be achieved at a higher testosterone level.
- It's not necessary to check estradiol levels.



# Follow-Up Care

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- **Assess feminization**
- **Review medication use**
- **Monitor mood and social impact of transition**
- **Counsel regarding sexual activity**
  - **STD screening as indicated**
- **Instruction in self breast exam and care**
  - **Mammography – after at least 5 yrs**
- **Prostate screening**
- **Smoking cessation**
- **Discuss silicone injection risks**
- **Social needs**
  - **Identity documents, bathrooms, etc.**



# Feminizing surgeries

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- **Breast augmentation**
- **Implants to hips/buttocks**
- **Penectomy/Vaginoplasty**
- **Orchiectomy**
- **Facial feminization**
- **Tracheal shave (reduce Adam's apple)**
- **Laryngeoplasty (vocal cord)**





# **Barriers to surgery**

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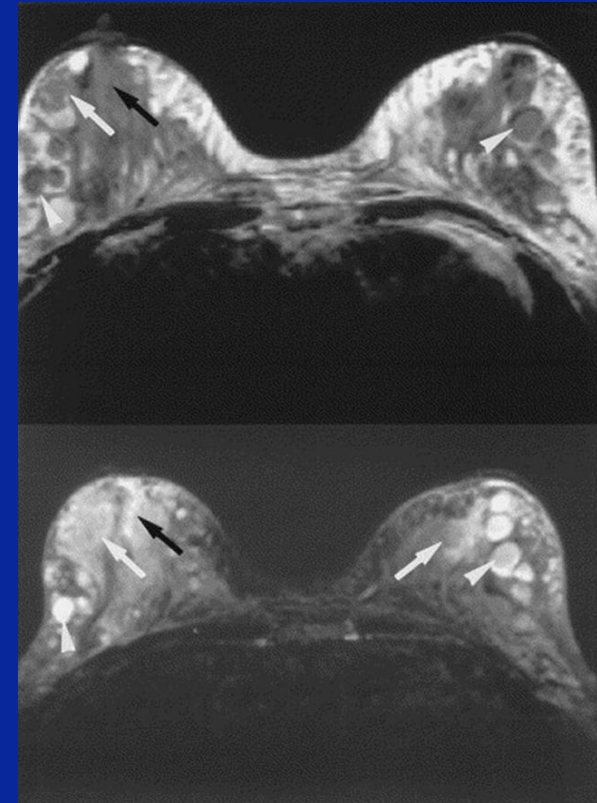
- **Few US insurance policies cover it**
- **Most trans people will never be able to afford genital surgery: vaginoplasty \$32,000**
- **Some can afford “top” (chest) surgery: \$5,000 – \$10,000**
- **Many use silicone or other fillers to feminize appearance**



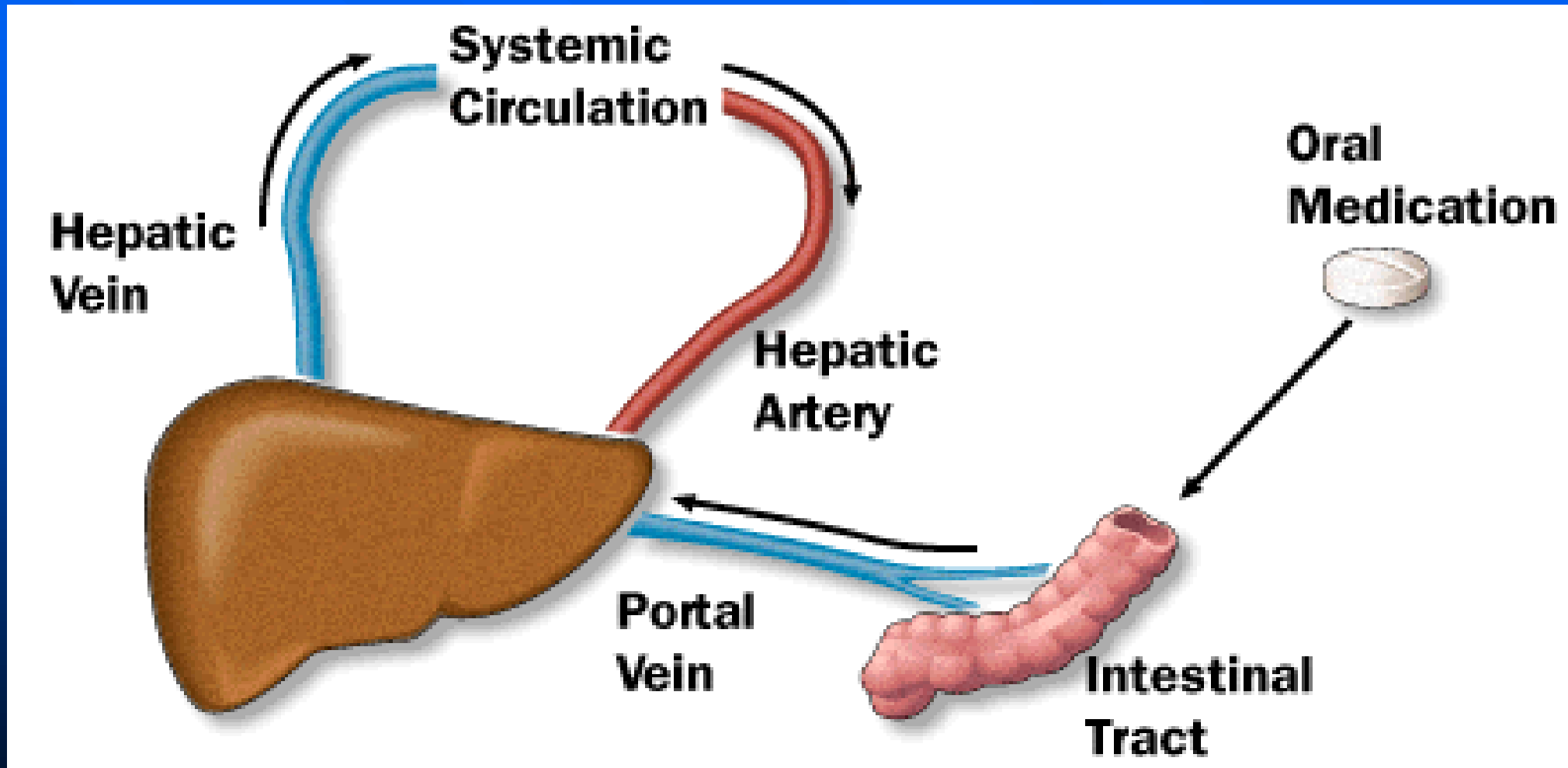
# Soft Tissue Fillers (Silicones)

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- More than 1 in 4 trans women inject “silicone” to enhance feminine appearance
- Infectious complications
  - Local infections, HCV, MRSA, mycobacteria
- Non-infectious complications
  - Pulmonary embolism, ARDS, disfigurement, siliconomas, migration, systemic illnesses



# Antiretrovirals and Hormones



# Cytochrome (CYP) P450 metabolism

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- **Common inducers (they reduce drug levels)**
  - Smoking
  - St. John's Wort
  - All Protease Inhibitors
  - NNRTI's
- **Common inhibitors (they raise drug levels)**
  - Grapefruit
  - Statins
  - Azoles (anti-fungals)
- **Mixed inducer/inhibitor**
  - Efavirenz



# Chanelle

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- 32 year old trans woman with HIV
- +THC (no cigarettes), non-drinker
- History of depressive symptoms, none now
- Injecting estrogen on the street whenever she can get it. Unsure of dose.
  - CD4 count 250 & VL 173,000
  - ALT 60, Cr 1.0, Hep C+, Hep A&B immune
  - Rest of CBC and CMP are unremarkable
- Feels ready to start ARVs



# Chanelle - 3 months later

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- Switched to oral estradiol 4mg daily plus 100mg twice daily of spironolactone.
- Started on TDF/FTC + ATV + RTV
- Denies any side effects
  - CD4 increased to 400, UDVL
  - ALT increased to 100, Cr 1.45
  - Complains of hot flashes
- What drug interactions may be at play?



# PI's and Hormonal Contraceptives

## DHHS Guidelines

Ritonavir-boosted Protease Inhibitors			
Atazanavir/r	↓ EE	↑ norgestimate	Use OCP >35mcg EE
Darunavir/r	↓ EE	↓ norethindrone	Use alternative method
Fosamprenavir/r	↓ EE	↓ norethindrone	Use alternative method
Lopinavir/r	↓ EE	↓ norethindrone	Use alternative method
Saquinavir/r	↓ EE		Use alternative method
Tipranavir/r	↓ EE	no Δ norethindrone	Use alternative method
Protease Inhibitors without Ritonavir			
Atazanavir	↑ EE	↑ norethindrone	Use OCP >35mcg EE
Fosamprenavir	APV ↑ EE ↓	EE and norethindrone APV by 20%	Use alternative method



# Other ARVs Hormonal Contraceptives

<b>NNRTI</b>		
<b>Efavirenz</b>	$\leftrightarrow$ EE ↓ Levenorgestrel ↓ Norelgestromin	Use alternative methods. Norelgestromin & levonorgestrel are active metabolites of norgestimate.
<b>Etravirine</b>	↑ EE No $\Delta$ Norethindrone	No dose adjustment necessary
<b>Nevirapine</b>	↓ EE ↓ Norethindrone	Use alternative methods
	No $\Delta$ DMPA	No dose adjustment necessary
<b>CCR5 Antagonist</b>		
<b>Maraviroc</b>	No $\Delta$ EE or levonorgestrel	Safe to use together
<b>Integrase Inhibitor</b>		
<b>Raltegravir</b>	No clinically significant effect	Safe to use together





# Chanelle - 6 months later

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- Pt was switched back to Delestrogen at 40mg IM every other week and continues spironalactone at previous doses.
- She returns with resolution of symptoms
- Stable on ARVs and hormone therapy
- Wants to address her Hepatitis C
  - CD4 count 500, UDVL, Hep C genotype 1
  - HCV RNA 750,000; ALT 80; Cr 1.2
  - No known contraindications to treatment
- What are potential drug interactions?



# Drug Interaction

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Estradiol levels are **DECREASED** by:

- Cigarette smoking
- Nelfinavir
- Nevirapine
- Ritonavir
- Lopinavir
- Rifampin
- Progesterone
- Dexamethasone
- Naphthoflavone
- Telaprevir
- Sulfamidine
- Carbamazepine
- Phenytoin
- Phenobarbital
- Phenylbutazone
- Benzoflavone
- Sulfinpyrazone



## **Chanelle – 4 weeks later**

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- **She has started Peg-IFN, RBV, and Telaprevir**
- **She complains of depressive symptoms; denies suicidal ideation**
- **She doesn't want to take pharmaceuticals and wants to try something natural like St. John's Wort.**
- **What do you recommend?**



# Cytochrome (CYP) P450 metabolism

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- **Common inducers**
  - Smoking
  - **St. John's Wort**
  - All Protease Inhibitors
  - NNRTI's
- **Common inhibitors**
  - Grapefruit
  - Statins
  - Azoles (anti-fungals)
- **Mixed inducer/inhibitor**
  - Efavirenz



# Drug Interaction

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Estradiol levels are ***INCREASED*** by:

- Isoniazid
- Fluvoxamine
- **Fluoxetine**
- **Sertraline**
- **Paroxetine**
- Diltiazem
- Verapamil
- Cimetidine
- Astemizole
- Itraconazole
- Ketoconazole
- Fluconazole
- Miconazole
- Clarythromycin
- Erythromycin
- Grapefruit



## **Chanelle – 8 weeks later**

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- **She was started on citalopram and depressive symptoms have improved**
- **Her labs are stable and she continues on the following medications:**
  - **Peg-IFN, RBV, and Telaprevir**
  - **Tenofovir/Emtricitabine, Atazanavir, Ritonavir**
  - **Delestrogen, Spironolactone**
- **While she doesn't like the pill burden, she is tolerating meds well and happy to be able to get her all her care in the same place.**



# Summary: Estrogens & Antiretrovirals

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- **DHHS evidence based on oral contraceptives**
  - Oral contraceptives use ethinyl estradiol at contraceptive doses
  - Hormones for transgender patients usually are 17- $\beta$  estradiol or conjugated equine estrogen (CEE)
- **Most PI interactions decrease estrogen levels**
  - If estrogen is continued and antiretrovirals are stopped, this may lead to dangerously high estrogen levels with associated risk of adverse effects
- **Non-nucleosides (NNRTI)**
  - Nevirapine decreases estrogen levels
  - Efavirenz may increase or decrease estrogen levels



# Drug Interactions -Take Homes

- Amprenavir and Fosamprenavir are the only antiretrovirals that should not be co-administered with estrogen due to risk of virologic failure.
- No interactions between androgen blockers and antiretrovirals, but lower doses may be adequate.
- Gender affirming hormone therapy is not contraindicated with antiretroviral therapy.
  - Some HIV medications change the levels of estrogens, therefore estrogen dose adjustment may be necessary
  - Many patients prioritize hormone therapy HIV treatment and will discontinue their ARVs if they notice “masculinization”.





# Medical Resources

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- **World Professional Association for Transgender Health**
- (SOC version 7, update released in September 2011)
  - [http://wpath.org/publications\\_standards.cfm](http://wpath.org/publications_standards.cfm)
  - **Tom Waddell Clinic** (2006 Protocols)
  - <http://www.sfdph.org/dph/comupg/oservices/medSvs/hlthCtrs/TransGendprotocols122006.pdf>
- **Endocrine Society** (Clinical Practice Guidelines 2009)
  - <http://www.endo-society.org/guidelines/final/upload/Endocrine-Treatment-of-Transsexual-Persons.pdf>
- **British Columbia**
  - <http://transhealth.vch.ca/resources/library/tcpdocs/guidelines-endocrine.pdf>
- **New England Journal of Medicine** (Gooren 2011)
  - <http://www.nejm.org/doi/full/10.1056/NEJMcp1008161?query=TOC&>
- **Transgender COE** (Primary Care Protocols 2011)
  - <http://www.transhealth.ucsf.edu/tcoe?page=protocol-00-00>



# Medical Resources

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- **World Professional Association for Transgender Health**
- (SOC 2001, update expected in September 2011)
  - [http://www.wpath.org/publications\\_standards.cfm](http://www.wpath.org/publications_standards.cfm)
- **Tom Waddell Clinic (2006 Protocols)**
  - <http://www.sfdph.org/dph/comupg/oservices/medSvs/hlthCtrs/TransGendprotocols122006.pdf>
- **Endocrine Society (Clinical Practice Guidelines 2009)**
  - <http://www.endo-society.org/guidelines/final/upload/Endocrine-Treatment-of-Transsexual-Persons.pdf>
- **British Columbia**
  - <http://transhealth.vch.ca/resources/library/tcpdocs/guidelines-endocrine.pdf>
- **New England Journal of Medicine (Gooren 2011)**
  - <http://www.nejm.org/doi/full/10.1056/NEJMcp1008161?query=TOC&>
- **Transgender COE (Primary Care Protocols 2011)**
  - <http://www.transhealth.ucsf.edu/tcoe?page=protocol-00-00>



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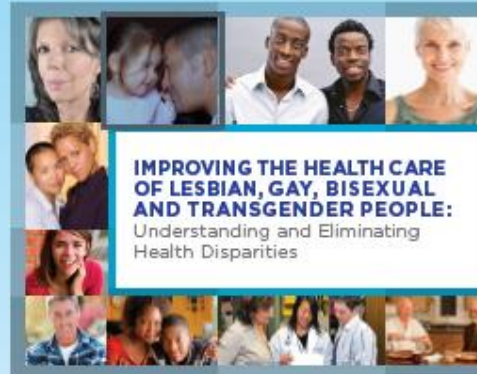


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