Transgender / Gender Non-Binary Populations & HIV

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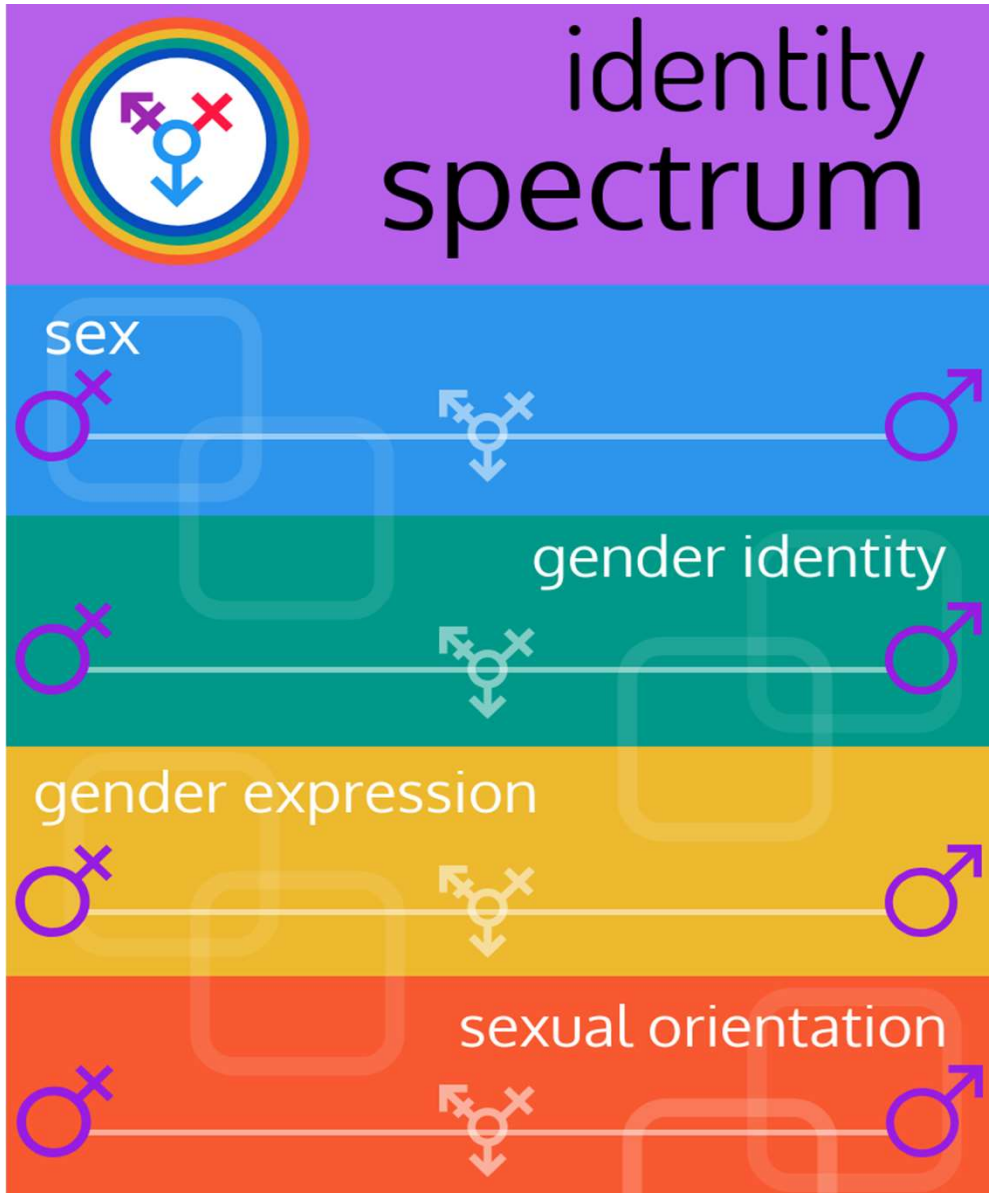
21 May 2019

Variables in the Equation of Self

- **Sex:** chromosomes, hormones, anatomy; designated at birth
- **Gender identity:** core sense of self, attitudes, emotions, societal role & ways of relating
- **Gender expression:** presentation including clothing, hair, body language, manner, voice



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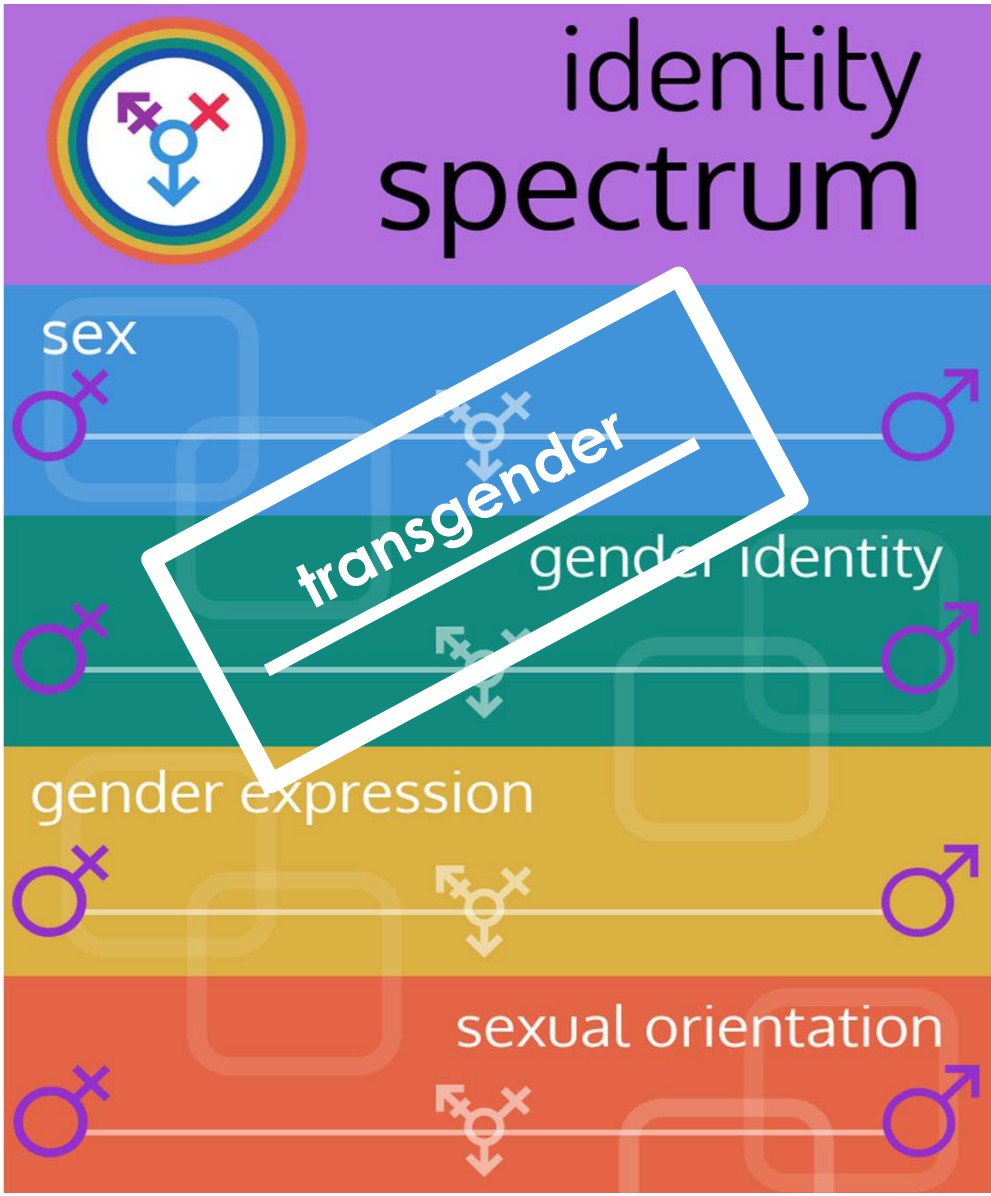

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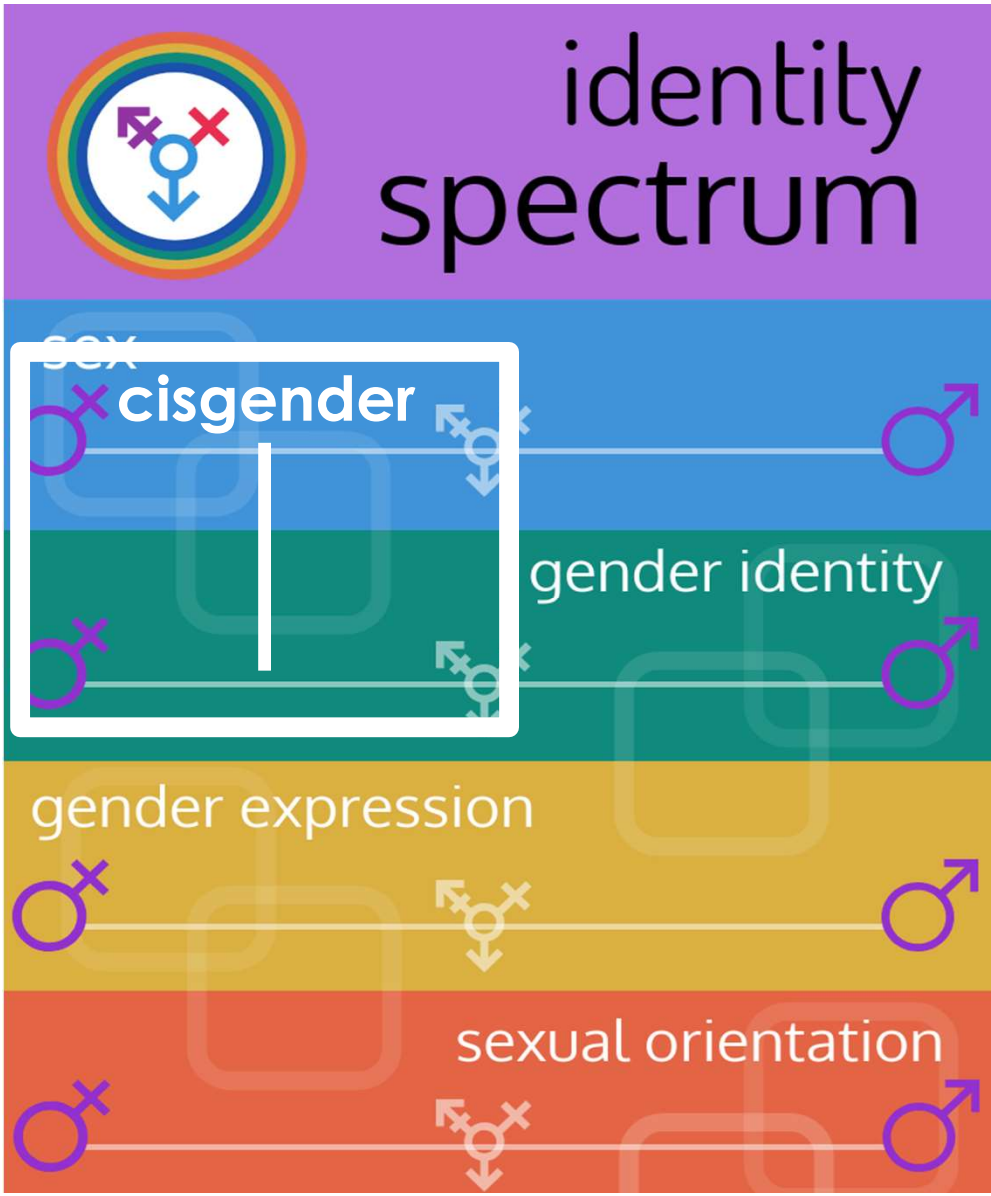

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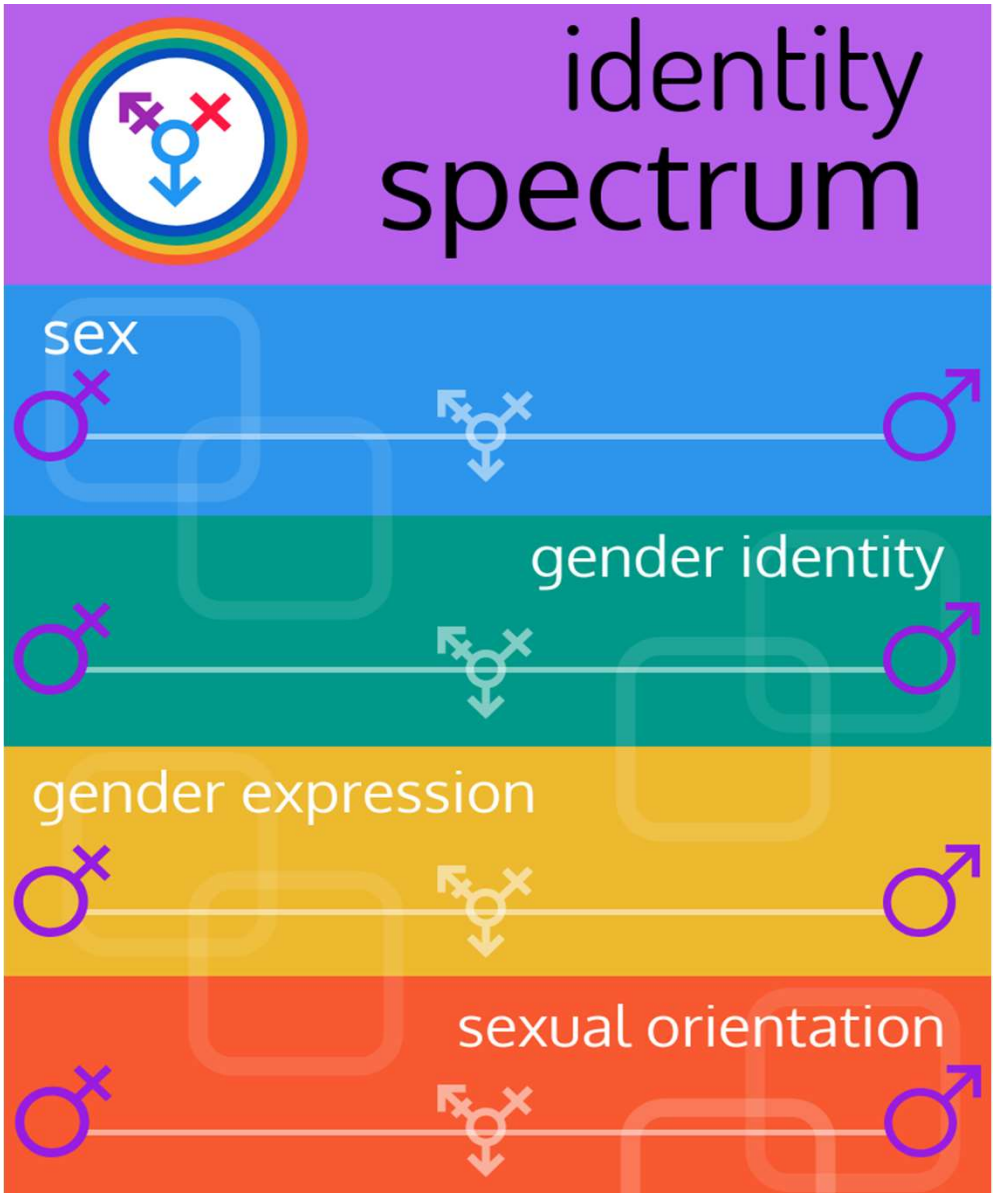


<u>Sexual orientation</u> is an entirely different characteristic, but it can evolve on hormones

Non-Binary Language

- **Gender non-binary or genderqueer:** Define their gender outside the binary construct of male/female – feel their gender identity is intermediate or contains elements of both; however, **often still identifies as transmasculine or transfeminine.**
- **Gender neutral:** Feel themselves to be between genders
- Often use they/them pronouns

Patient Language to Convey Identity

Female Identified → **Transgender woman / transwoman / transfeminine / woman**

(avoid MTF, they weren't truly male to begin with)

Male Identified → **Transgender man / transman / transmasculine / man** (avoid MTF)

Memory device: **Trans-woman = trans**itioning **=> woman**hood

Transsexual: clinical but "old school" term for one who has had complete transition

Terminology to convey sex

"**Assigned** male at birth" = AMAB &

"**Assigned** female at birth" = AFAB

are terms used to convey the gender originally thought to apply to a person based on anatomy

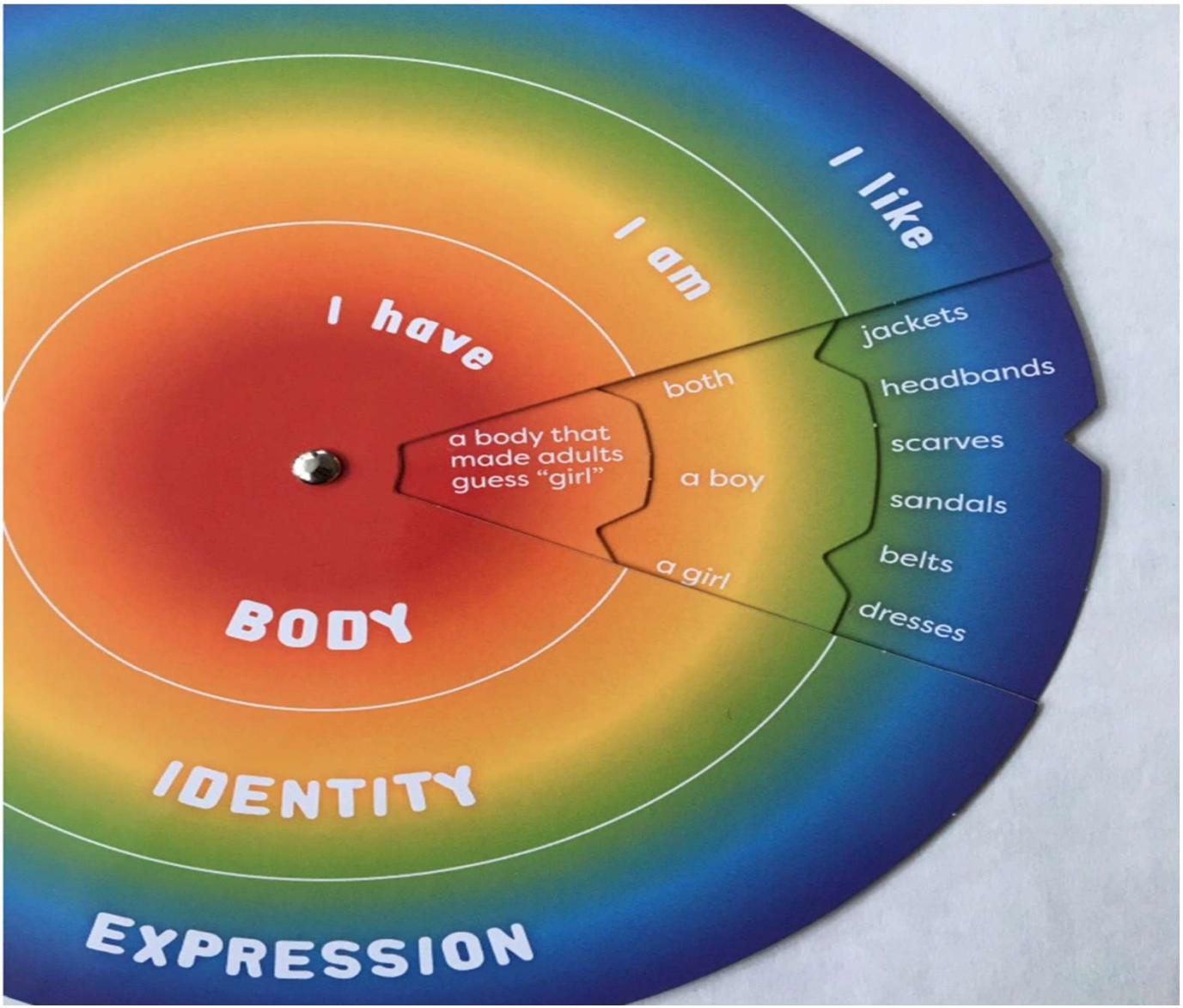
Words That Convey Concepts

Dysphoria: profound sense of unease or distress; can be accompanied by depression & anxiety

Dysmorphia: intense discomfort with a body part or feature

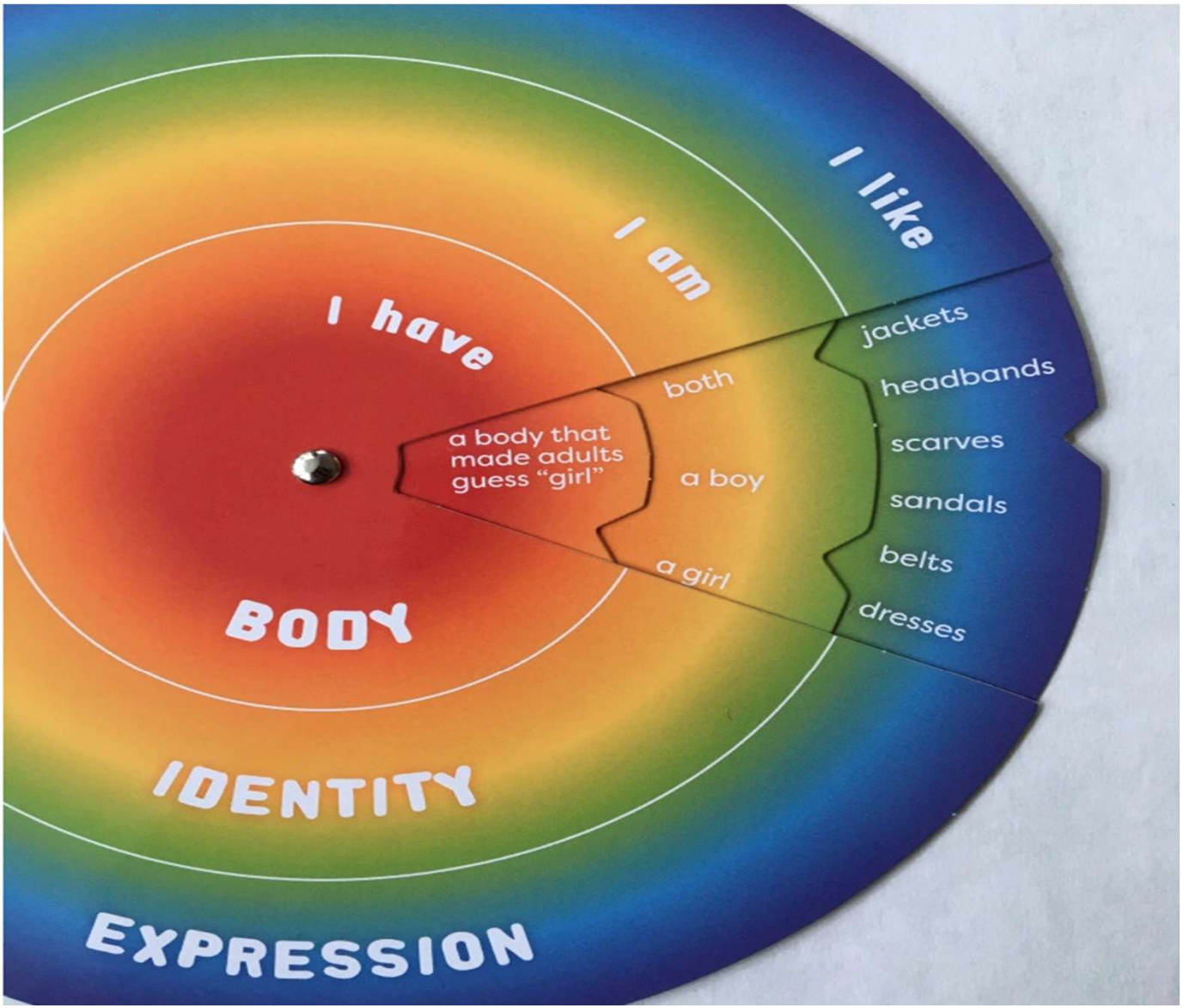
Misgendered: being attributed the wrong gender

Gender affirming: surgery or medication that affirms the patient's identity



What if my variables add up in a way that is not socially stereotypical for someone with my DNA?

UW Medicine
PATIENTS ARE FIRST



Stigma and discrimination

UW Medicine
PATIENTS ARE FIRST

Dramatic Health Disparities

- **Depression, anxiety, social disenfranchisement, PTSD** => **41%** rate of lifetime suicide attempt
- **HIV infection: 18.8**% rate transwomen, **2.0**% transmen
- **Victimization**, including IPV & homicide
- **Substance use**
- **Lack of healthcare** for **ANY** medical conditions

Due to a cascade of stigma, adverse social determinants of health & barriers to care

Social Determinants of Health

2015 US Transgender Survey – Washington

In the previous year

- **14%** unemployment, 3x average
- **28%** were living in poverty
- **13%** homeless
- **8%** were denied access to a bathroom

Even though TGNB persons come from all walks of life & backgrounds

N = 1667 for state WA substudy; see http://www.ustranssurvey.org

Cascading Contributors to HIV Risk

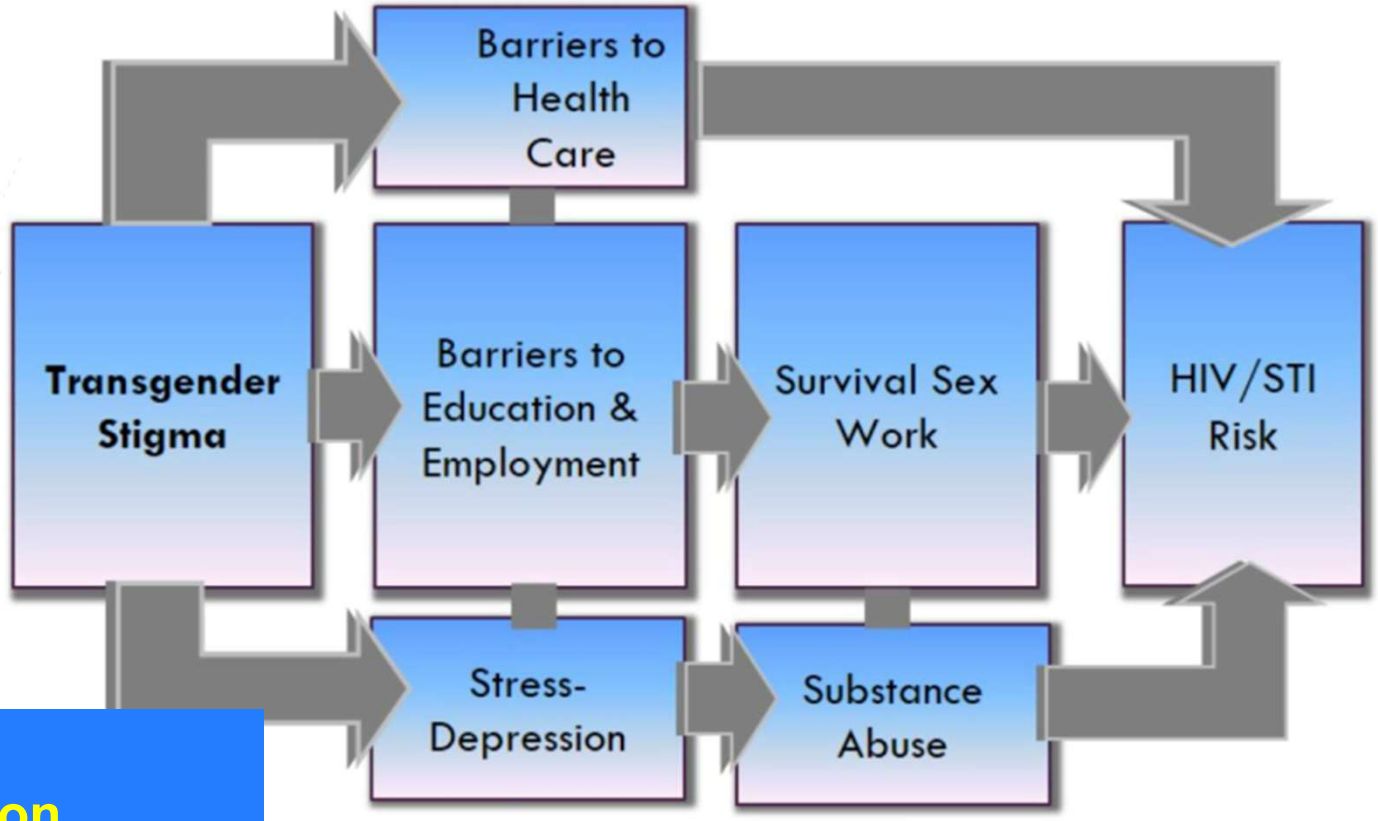
Loss of family & social support

Loss of educational opportunities

Decreased employability

Victims of violence: murder, intimate partner

Above contribute to homelessness, depression, anxiety & barriers to health care



Attribution: Asa Radix, MD

Barriers To Healthcare Access

Negative experience	% of those who had seen a provider in the past year
They had to teach their health care provider about transgender people to get appropriate care	24%
A health care provider asked them unnecessary or invasive questions about their transgender status that were not related to the reason for their visit	15%
A health care provider refused to give them transition-related care	8%
They were verbally harassed in a health care setting (such as a hospital, office, or clinic)	6%
A health care provider used harsh or abusive language when treating them	5%
A health care provider refused to give them care not related to gender transition (such as physicals or care for the flu or diabetes)	3%
A health care provider was physically rough or abusive when treating them	2%
They were physically attacked by someone during their visit in a health care setting (such as a hospital, office, or clinic)	1%
They were sexually assaulted[9] in a health care setting (such as a hospital, office, or clinic)	1%
One or more experiences listed	**33%**

2015 US Transgender National Survey
N = 27,715

24% had to teach their provider

15% were asked intrusive questions

8% were refused gender care

11% verbally maltreated

3% were refused any care

33% who had seen a provider had had a negative experience in a medical setting in the previous year

.

23% didn't seek care due to fear of being mistreated

Barriers To Healthcare Access

- Transgender patients have often experienced neglect, ridicule or other **maltreatment in medical settings** & so don't pursue care
- An **inadequate number of providers** to provide informed care due to lack of training
- **Historically there hasn't been insurance coverage** to be treated with hormones or surgeries

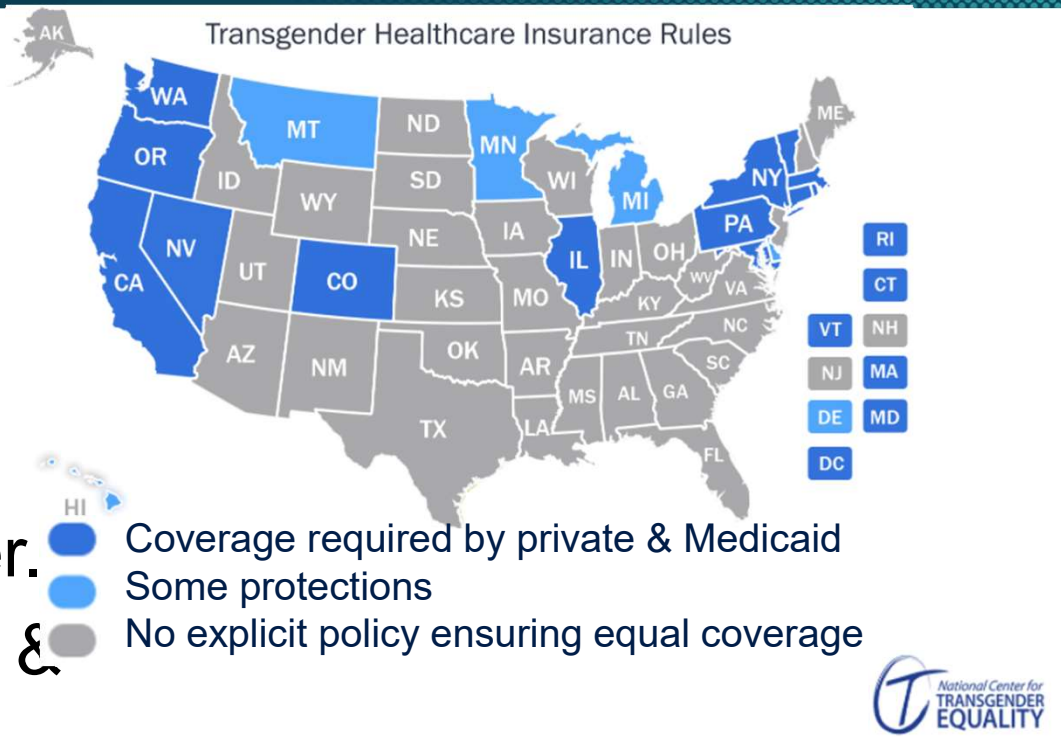
Barriers To Healthcare Access

- Transgender patients have often experienced neglect, ridicule or other maltreatment in medical settings & so don't pursue care → **IMPROVING**
- An inadequate number of providers to provide informed care due to lack of training → **BETTER** ?
- Historically there hasn't been insurance coverage to be treated with hormones or surgeries →

SIGNIFICANTLY IMPROVED

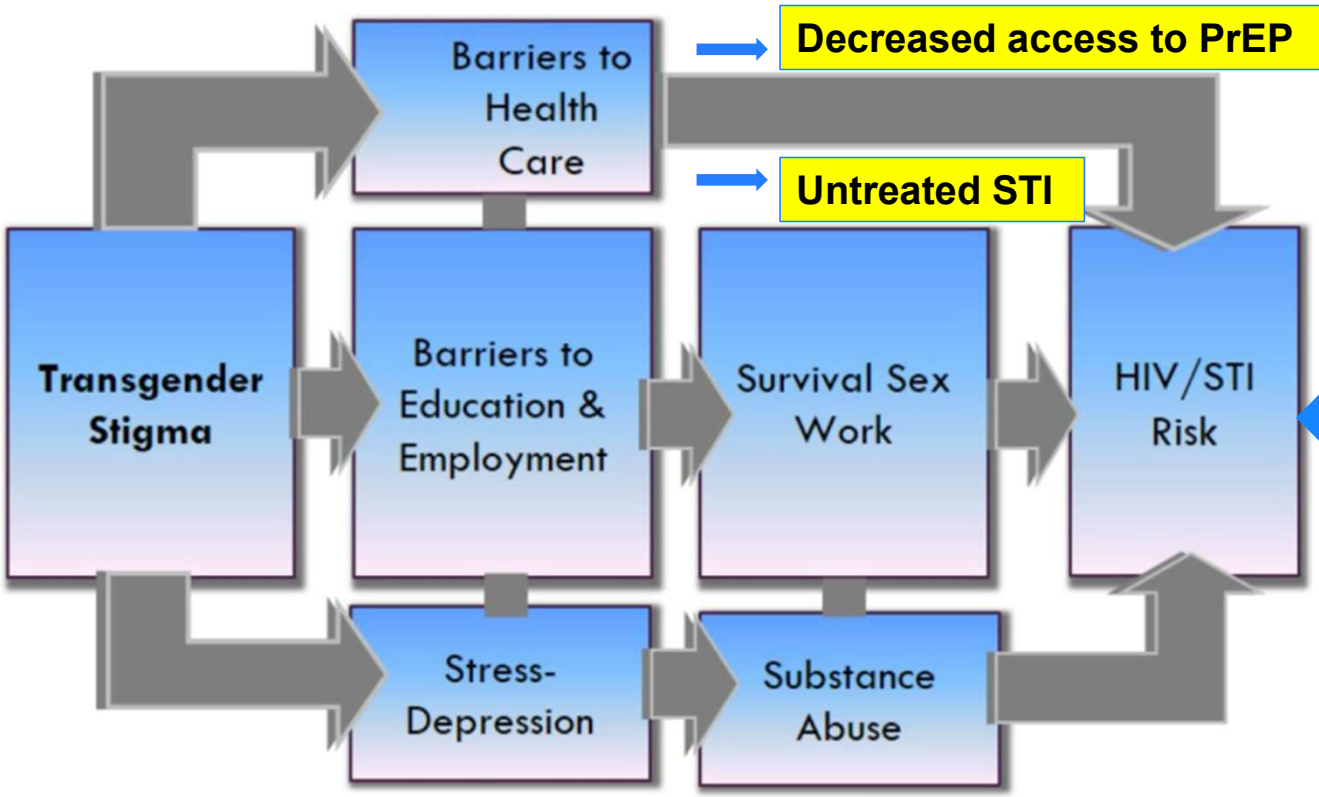
Improving Insurance Coverage for TGNB Care

Private & Apple Health insurance plans based in Washington were **required** to cover transgender care since 2014 per the Office of the Insurance Commissioner. **Medicare** has covered care & surgeries since 2014.



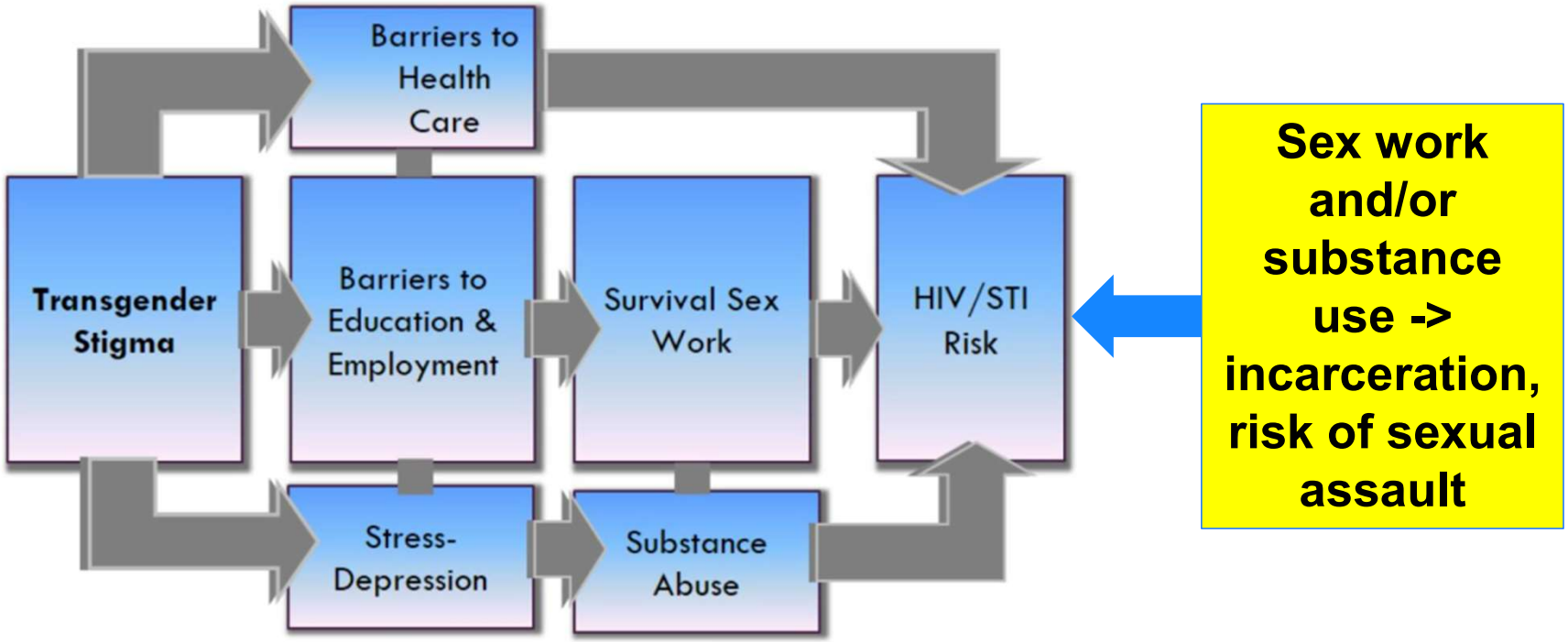
Rollback of the ACA shouldn't reverse these gains in Washington

Cascading Contributors to HIV Risk



Biological components due to mucosal vulnerability: anal receptive sex & fragile vaginal mucosa /altered microbiome

Cascading Contributors to HIV Risk



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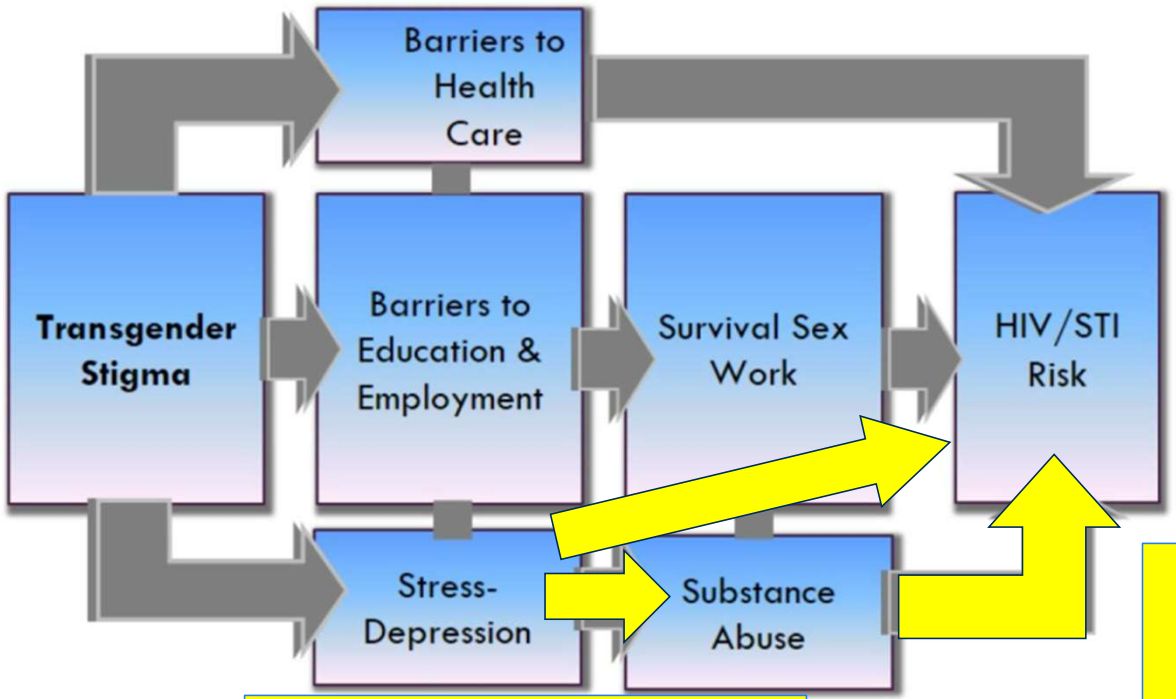


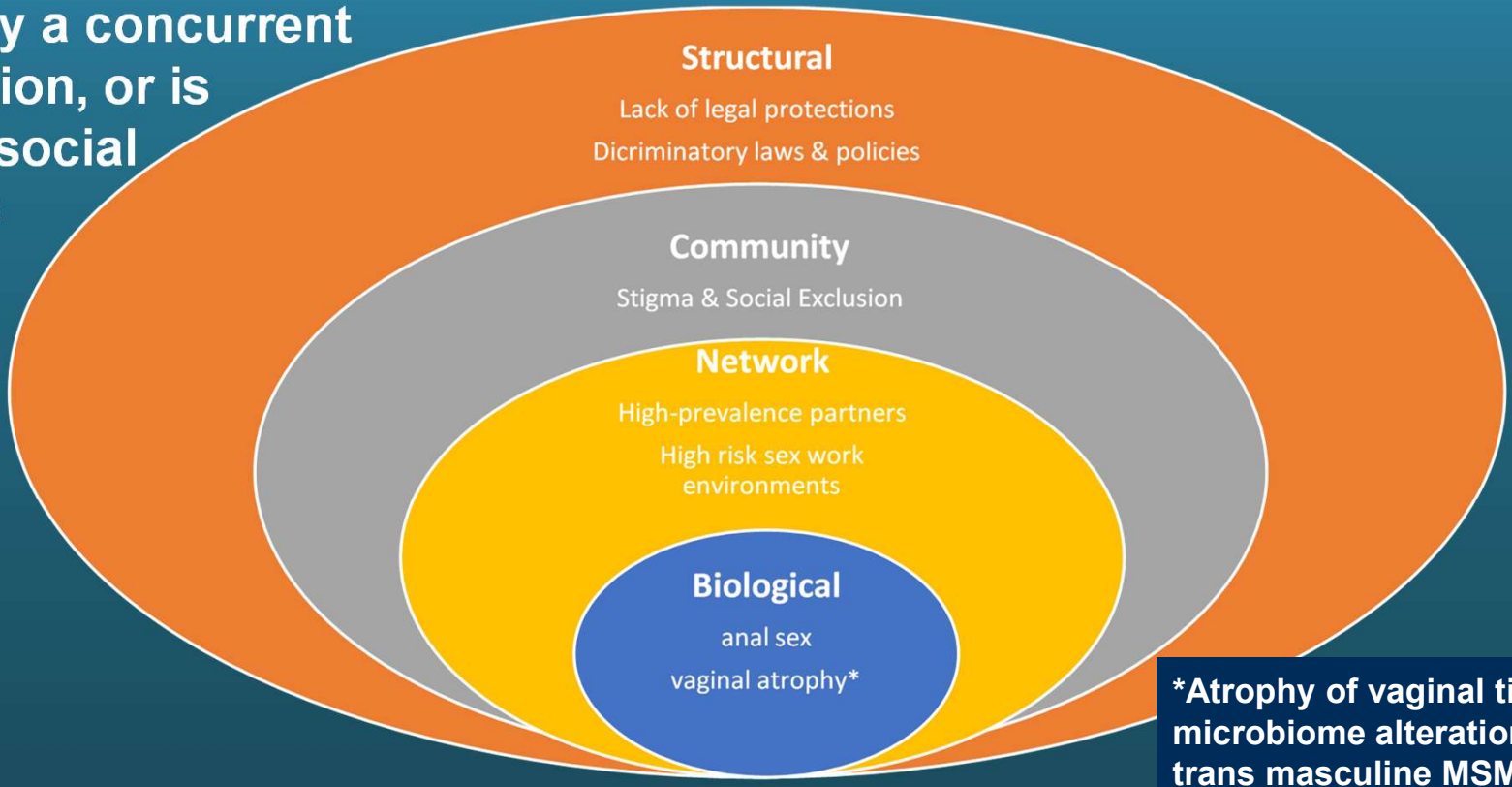
Stress & depression increase risk taking behaviors, lack of self care

Substance use-> impairs impulse control, judgment

Syndemics

Synergistic Epidemics Contributing to HIV Risk in Transgender People

Syndemics apply when a given disease is aggravated by a concurrent health condition, or is amplified by social determinants of health



Poteat,, J Acquir Immune Defic Syndr, Volume 72, Supplement 3, August 15, 2016

***Atrophy of vaginal tissue & microbiome alterations among trans masculine MSM taking testosterone**

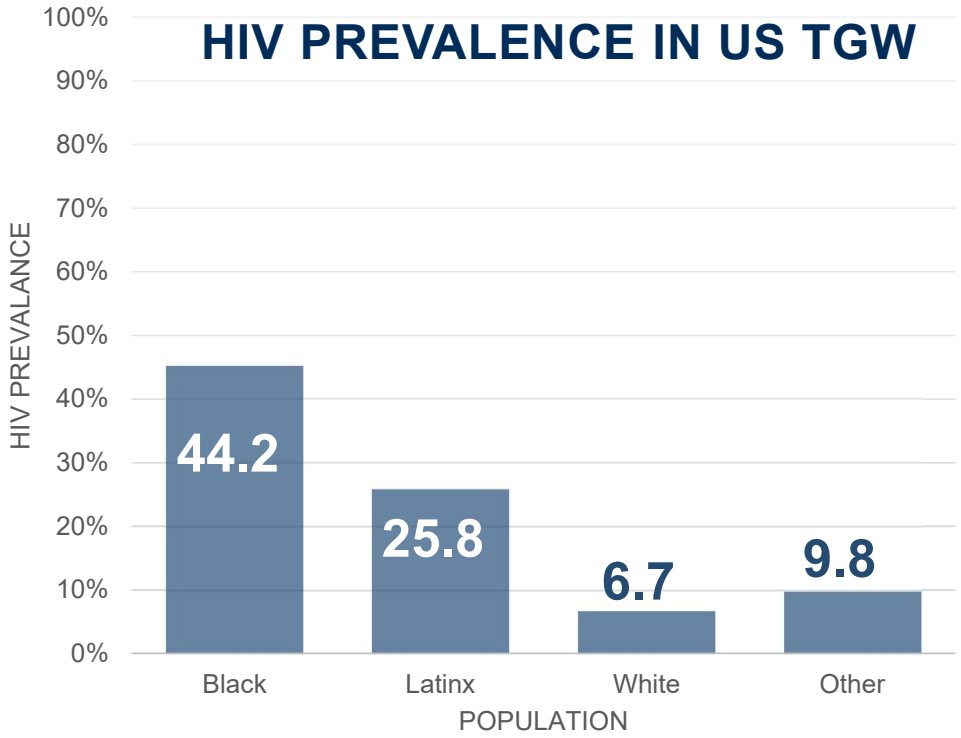
Demographics

- Transgender status is not queried on the US Census
- Estimates from the Williams Institute based on CDC state-based surveys from 2014:
  - 0.58% of the population in the US, = 1.4 million
  - **0.62%** of the population in **Washington** state,
    = 32,850 persons
  - **0.73%** of those in the **18-24 year old age group**

Estimated Prevalence of HIV & Sexual Behaviors in US Trans Population:
A Systematic Review & Meta-Analysis, 2006-2017

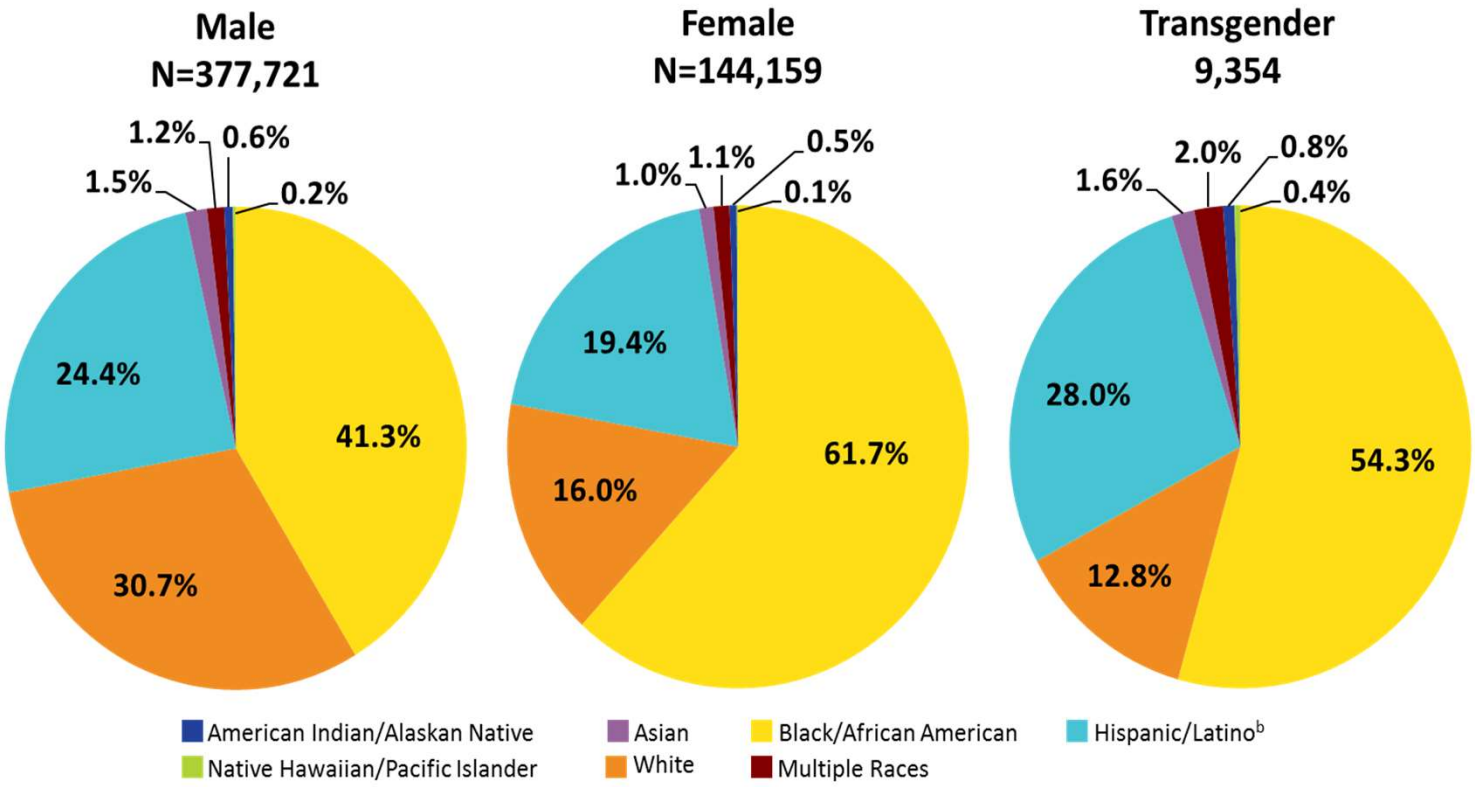
88 total studies

- HIV prevalence, weighted lab-confirmed + self report: **13.7%**
  - **18.8%** transwomen
  - **2.0%** transmen
- Sex work
  - 38% transwomen
  - 13% transmen
- HIV tested
  - 75% transwomen
  - 69% transmen



Beclasen, Am J Public Health, 2019; 109:e1-e8

Clients Served by the Ryan White HIV/AIDS Program, by Gender and Race/Ethnicity, 2017—United States and 3 Territories[a]



[a] Guam, Puerto Rico, and the U.S. Virgin Islands.
[b] Hispanics/Latinos can be of any race.

HRSA Ryan White & Global HIV/AIDS Programs

Source: HRSA. Ryan White HIV/AIDS Program Services Report (RSR) 2017. Does not include AIDS Drug Assistance Program data.

The Breaks in the Care Continuum

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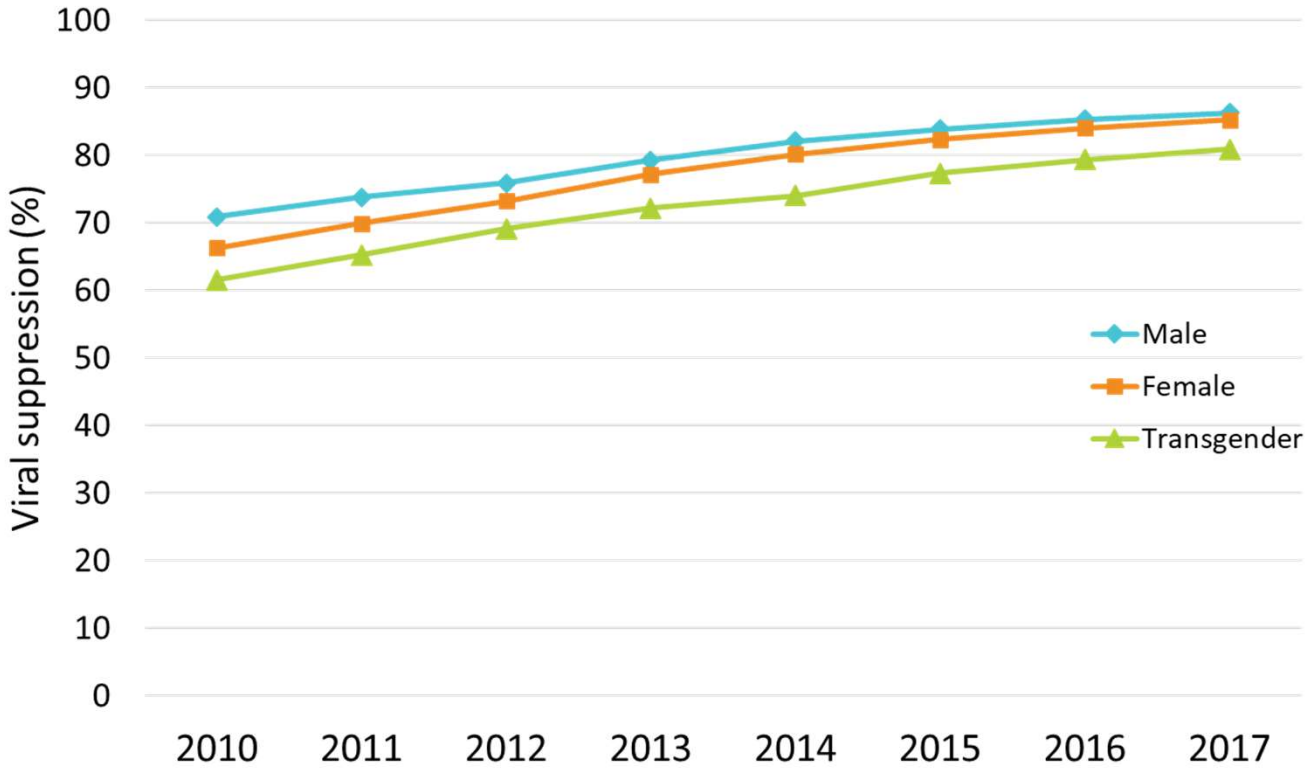
Viral Suppression among Clients Served by the Ryan White HIV/AIDS Program, by Gender, 2010–2017—United States and 3 Territories[a]



Viral suppression: ≥1 OAHS visit during the calendar year and ≥1 viral load reported, with the last viral load result <200 copies/mL.

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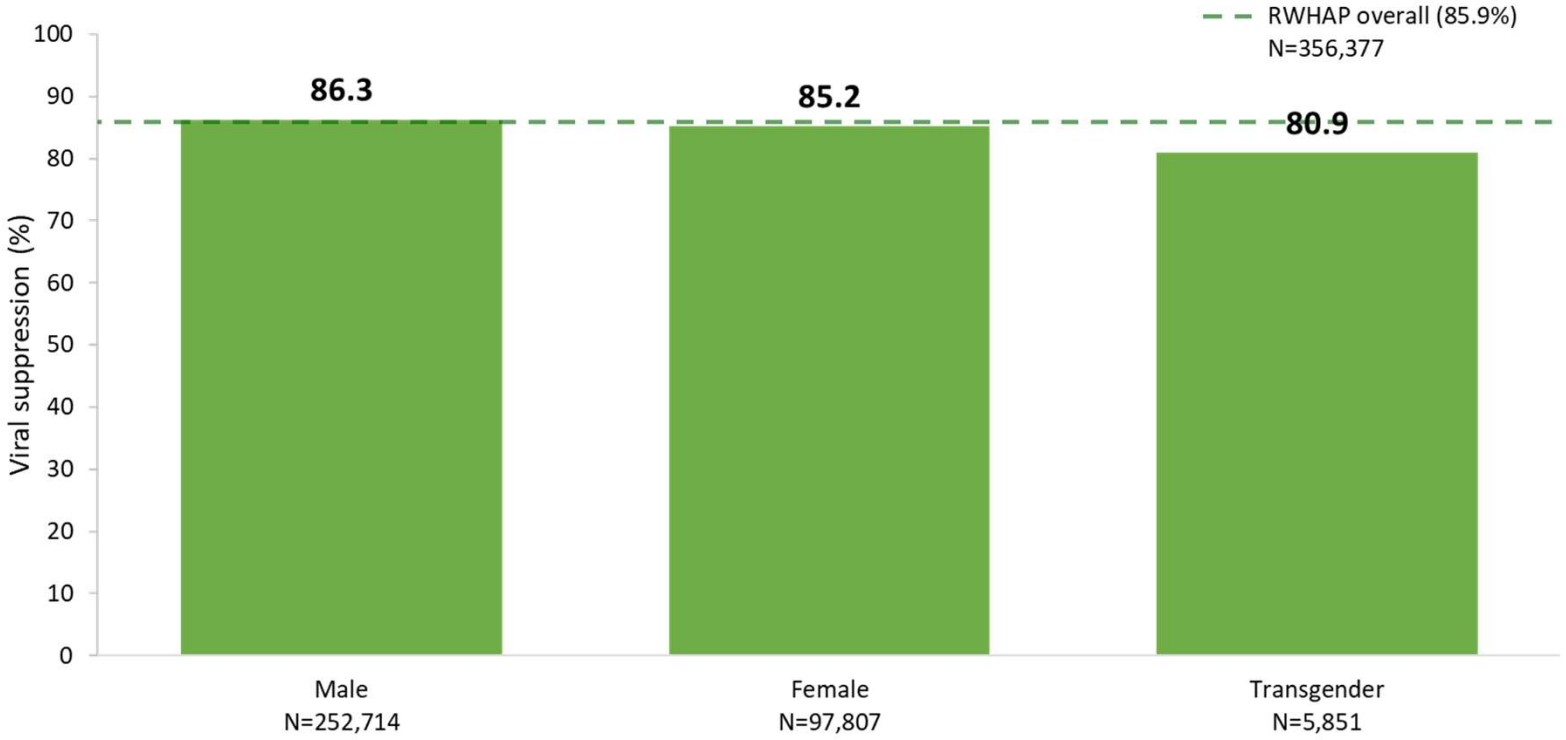

N represents the total number of clients in the specific population.
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Gender Care Improves Adherence to HIV Care

Positively Trans Survey, n = 157

Top 5 Health Concerns of HIV+ transgender persons, in order:

1. **Gender-affirming, non-discriminatory care**
2. **Hormone therapy and side effects**
3. Mental health care, including trauma
4. Personal care, eg. nutrition
5. Antiretroviral therapy and side effects

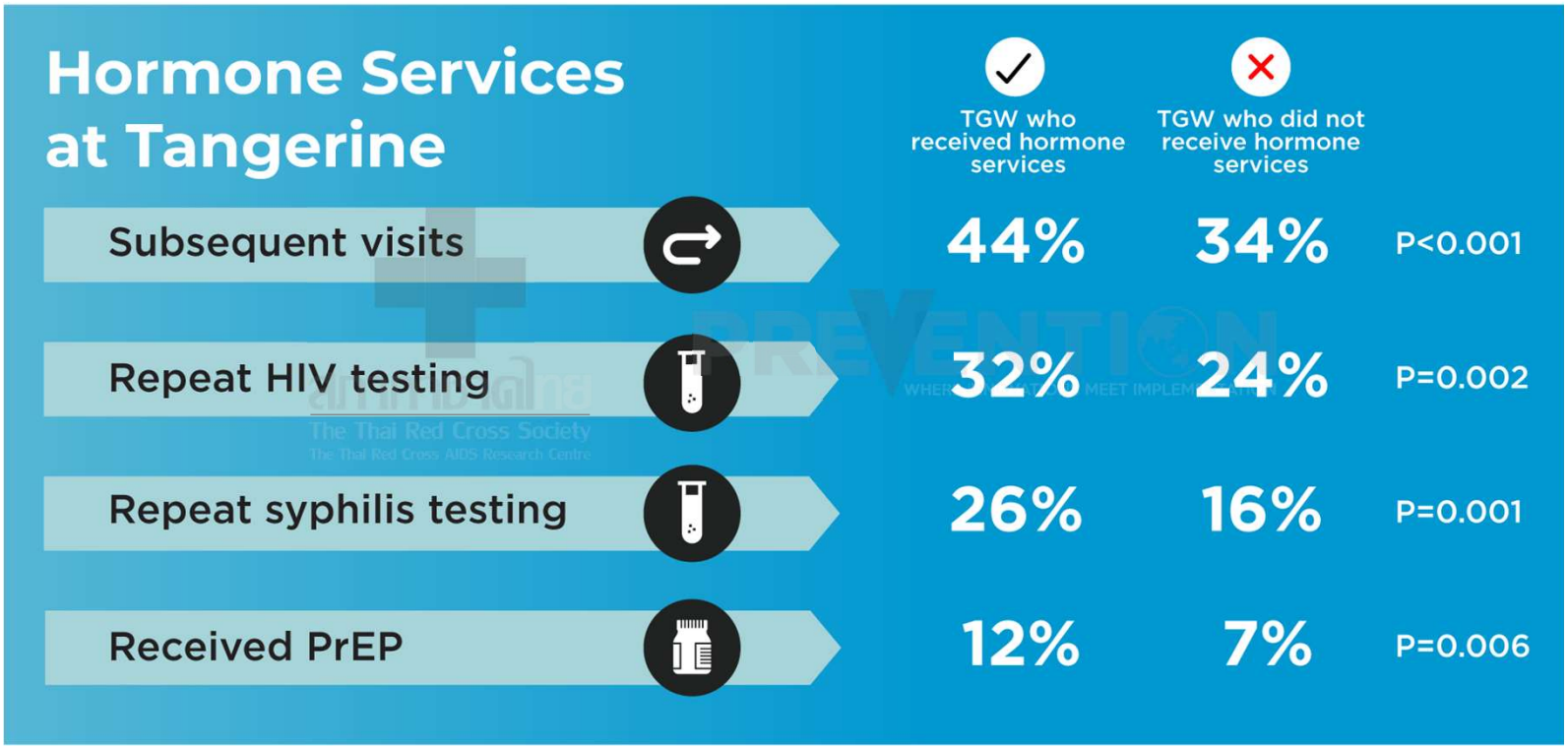
SPNS: Transgender women of color who has a HIV primary care provider who is also their hormone prescriber, more likely to:

- Have an undetectable HIV viral load
- Have had an HIV primary care visit in the previous 6 months

Chung, Cecilia, 2016; Some kind of strength: Findings on health care and economic wellbeing from a national needs assessment of transgender and gender non-conforming people living with HIV. Oakland, CA: Transgender Law Center.

Gender Affirming Hormone Treatment (GAHT) Increasing HIV Testing, Syphilis Testing and PrEP Uptake

Tangerine Clinic in Thailand



Reference: Tangerine Community Health Center, Oral Abstract Presentation, International AIDS Conference 2018, Amsterdam, The Netherlands

Why is Gender Affirming Care So Crucial?

- Some transgender persons will not discuss their identity with their healthcare provider if they feel vulnerable, so that **important medical history or medications are not disclosed**
- Creating a comfortable environment enhances the therapeutic alliance & **increases participation in medical care**
- Otherwise **may not seek appropriate medical care** for any health conditions
- Or **may buy hormones off internet or perform self-orchiectomy**, which can cause major complications

Gender Affirming Approach to the Patient

- **Avoid ”Sir”,“Ms.” or other gendered titles**
- **Double check name:** “How do you like to be called”
- **Ask about pronouns;** some use neutral pronouns **= the singular “they”; use plural verbs as with the singular “you”**
- **Use the language the patient does** about their anatomy; **if uncertain, use anatomic terms.** Transmen: chest, not breast, tissue.
- **Keep the focus to what is relevant if in for acute care** – don’t ask about future plans about transitioning

Gender Affirming Approach to the Patient

- Ask open ended questions
- Ask for **self-descriptors**; people who are non-binary may still feel transmasculine/feminine applies to them
- Ascertain where your patient feels they fit on the **gender spectrum**

- **Remember their gender expression may not match with their identity** in the ways you may expect

Misgendering Mishaps

If you make a mistake with someone's name or prono

- **correct it**
- **own it**
- **learn from it &**
- **move on!**

Otherwise, the patient has to take care of your feelings

Or, make a repair before you start:

"Please correct me if I make a mistake."

Reference: Transgender Health Program, OHSU

Social & Psychological History

- Elicit sources of trauma & resilience
  - Assess support systems
  - As well as losses, which may be numerous – family, friends, church, coworkers, community
  - Substance use
  - Sexual history
  - History of abuse – sexual, physical, emotional, IPV
  - Mental health evaluation & treatment history
  - Depression & anxiety screening

An Inclusive Sexual History

- **Tell me about your recent sexual relationships**
  - How many partners have you had in the last 3 months?
  - What are the genders of your partners? *(may need to drill down on this to get at anatomy involved)*
- **What kinds of sex are you having?**
  - Which behaviors might expose you to others' fluids?
  - Which behaviors might expose others to your fluids?
  - How do you protect yourself? (Your partners?)
  - How often do you use barriers? In what situations do you use them, and what are the situations when you don't?

Physical Exam

Transmen

- For transmen on T for > 6 mos, they have will have some loss of elasticity -> consider an extra narrow Pederson speculum
- If have lead time, use intravaginal E2 for 4 weeks prior to help elasticity & lubrication
- Consider **HPV test only** rather than cytology
  - less uncomfortable
  - cytology often atrophic d/t T => ”abnormal Pap”
- Lorazepam prior to exam can be very helpful

Physical Exam

- Afford extra privacy when examining sensitive areas – allow to wait to change into gown & keep that curtain pulled
- Only examine parts of the body that are truly requisite
- Let the patient be in control of the e
- Act **unsurprised** if there are unanticipated or partially developed body parts

Image attribution Tonia Poteat, PhD

Physical Exam

Transwomen after vaginoplasty

- For neovaginal exam (which is almost never needed), use an anoscope or pediatric speculum
- Their prostates are anterior to t (these are not removed at the time of gender affirmation surgery)

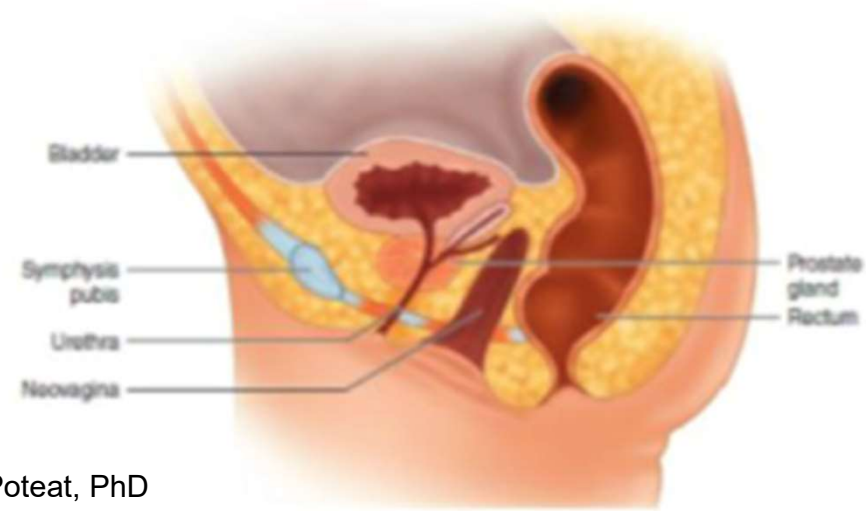


Image attribution Tonia Poteat, PhD

Gender Dysphoria – DSM V

Previously Gender Identity Disorder, soon(?)
Gender Incongruence in ICD 11

This diagnosis involves the significant distress or problems functioning due to the **dissonance** caused by the difference between one's experienced gender & assigned sex

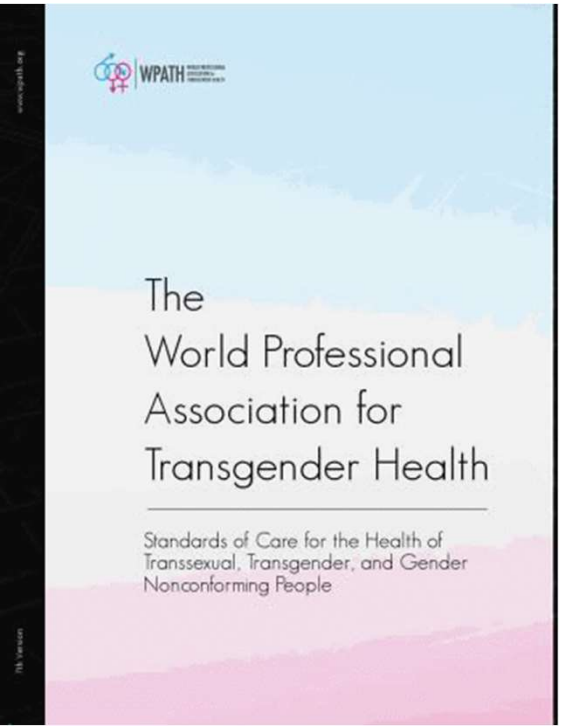
Being transgender doesn't equate with gender dysphoria

Gender Dysphoria – Criteria

Has at least 2 of the following features, present >6 mos:

- A marked **incongruence** between one's experienced/ expressed gender & primary &/or secondary sex characteristics
- A strong desire to **be rid of one's** primary &/or secondary sex **characteristics**
- A strong **desire for** the primary &/or secondary sex **characteristics of the other gender**
- A strong desire to be of the other gender
- A **strong desire to be treated as the other gender**
- A strong conviction that one has the typical feelings & reactions of the other gender

Who to Treat



Informed Consent Model:

1. Persistent, well-documented gender dysphoria;
2. Ability to make a fully informed decision and informed consent;
3. Age of majority (18);
4. If significant medical or mental health condition are present, they must be reasonably well-controlled.

I recommend using consent forms for patient education & to ensure all topics are discussed

Gender Affirming Surgeries

- **Top surgeries –**
  - Chest tissue reduction - TM
  - Breast augmentation - TF
- **Bottom surgeries –**
  - Gonadectomy - both
  - Vulvoplasty/ vaginoplasty - TF
  - Hysterectomy, vaginectomy – TM
  - Metoidoplasty/ phalloplasty – TM
- **Facial feminization surgeries -**
  - Nose, brow, cheeks, chin, larynx

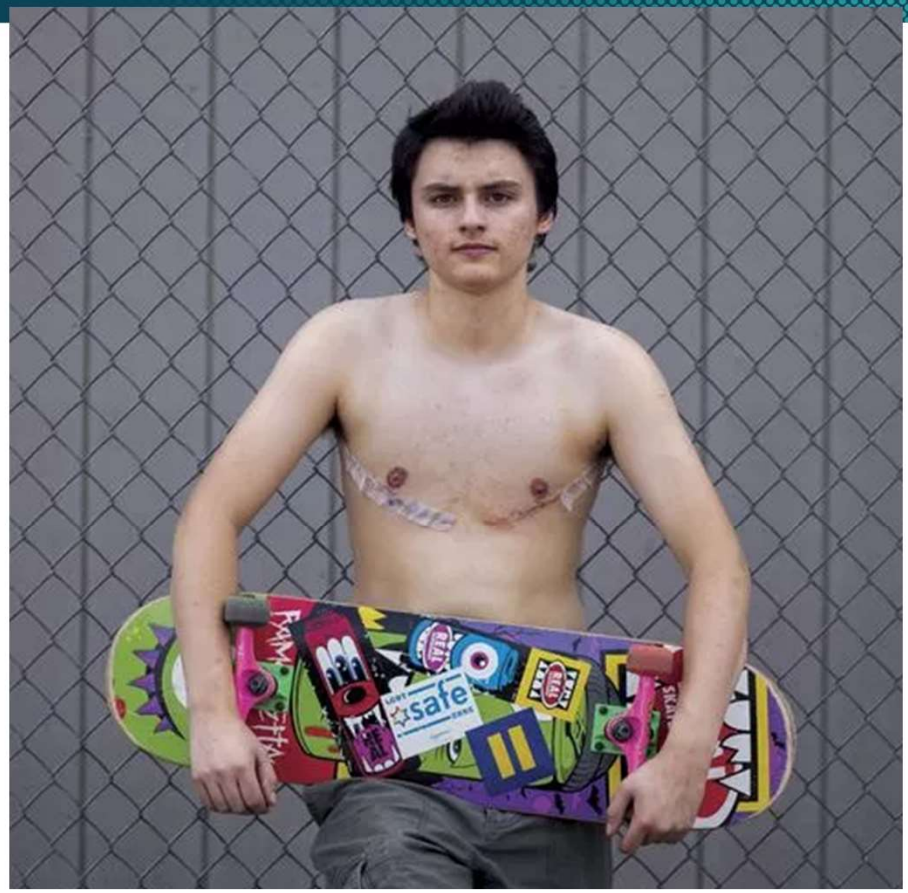
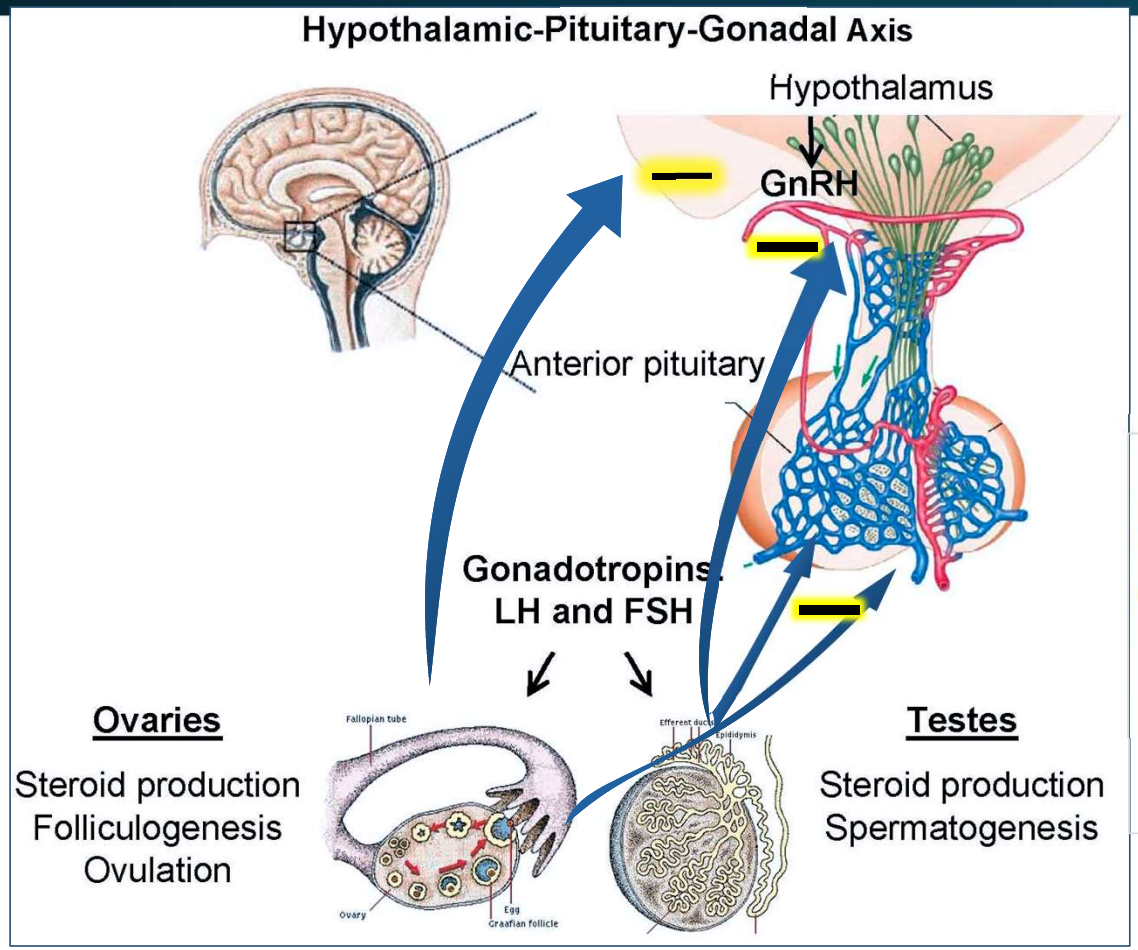


Photo attribution National Geographic, January 2017

Gender Affirming Hormone Therapy



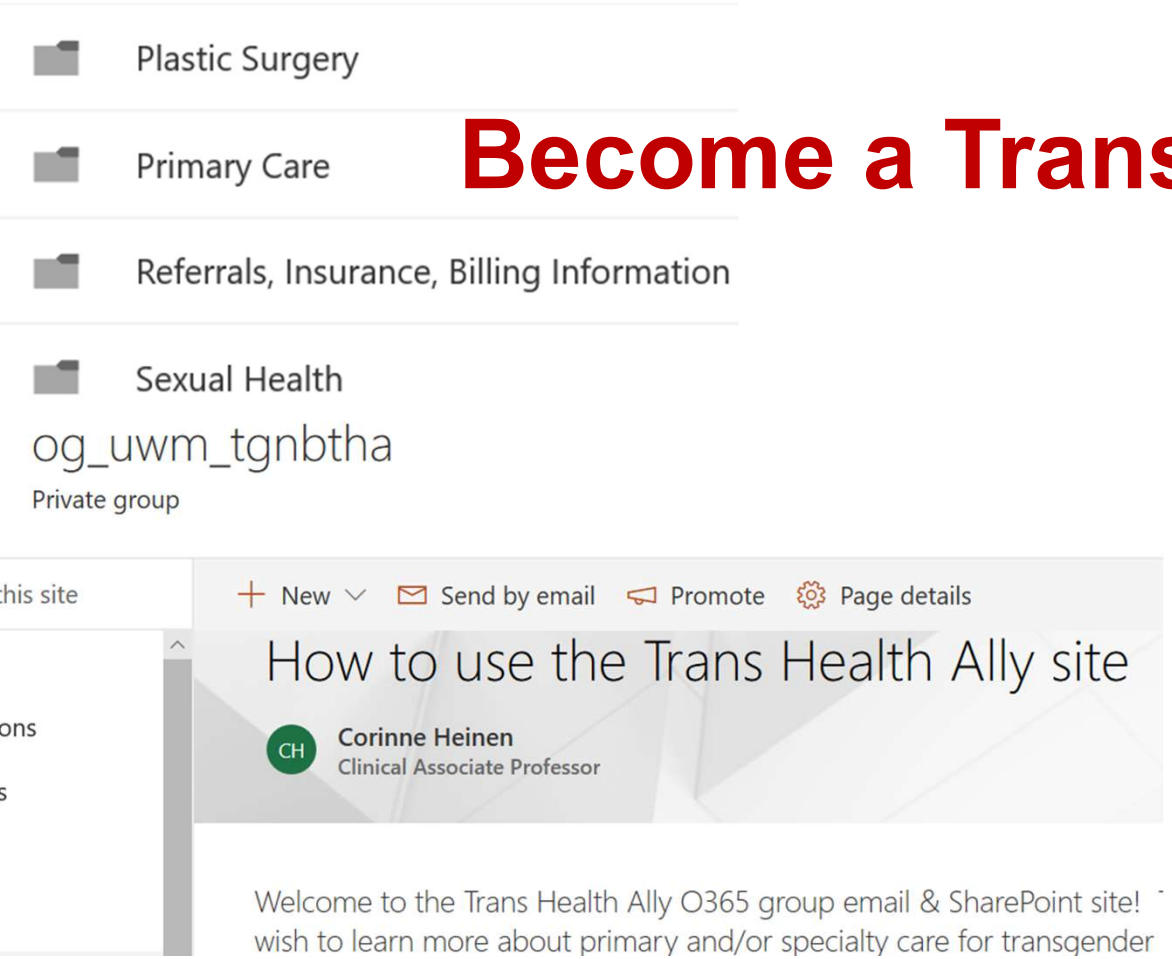
- Transmasculine: **Testosterone**
- Transfeminine: **Estradiol, androgen blockers**

Estrogen & testosterone, even if exogenous, create negative feedback loops that affect LH & FSH production, so that innate gonads will not be stimulated to produce sex steroids.

Gender Affirming Hormone Therapy

Medication	Formulations	Dosing	Comments
Estradiol	Transdermal Oral IM	0.1-0.4 mcg/hr 1-6 mg daily Weekly to biweekly	Transdermal has lowest VTE risk; next safest 17 beta E2; avoid conjugated estrogens & ethinyl estradiol
Adjunctive feminizing options: **Spironolactone** **Progesterone**	Oral Oral, micronized/ medroxyprogesterone	50-200 mg qd, can split dose prn 100-200 mg qd 2.5-10 mg qd	Spiro helps with decreasing body hair, some breast development Progesterones not routinely used, ? benefit for breast development, mood. Medroxy has been implicated in VTE in TGW
Testosterone	Gel IM/ SC Patch	20-100 mg daily 25-100 mg weekly 2-6 mg qd (1-3 patches)	Can use T IM every other week if wishes

Want to learn about managing gender affirming hormones & referring for surgeries?



Become a Trans Health Ally!

- Access to our group email & Sharepoint site
- Recorded lectures including gender affirming hormone discussion in depth
- Monthly Zoom meetings for cases, didactics – will count as low cost CME
- Email me: cheinen@uw.edu

Efficacy of TDF-FTC for HIV PrEP in Setting of Cross Sex Hormones

What do we know?

Feminizing Hormone Therapy:

- iPrEx OLE, multicenter
- iFACT, Thai Red Cross Centre
- Cottrell, UNC
- Shieh, Johns Hopkins

Masculinizing Hormone Therapy:

- Unexplored

iPrEx RCT & Open Label Extension - Transfeminine Subanalysis

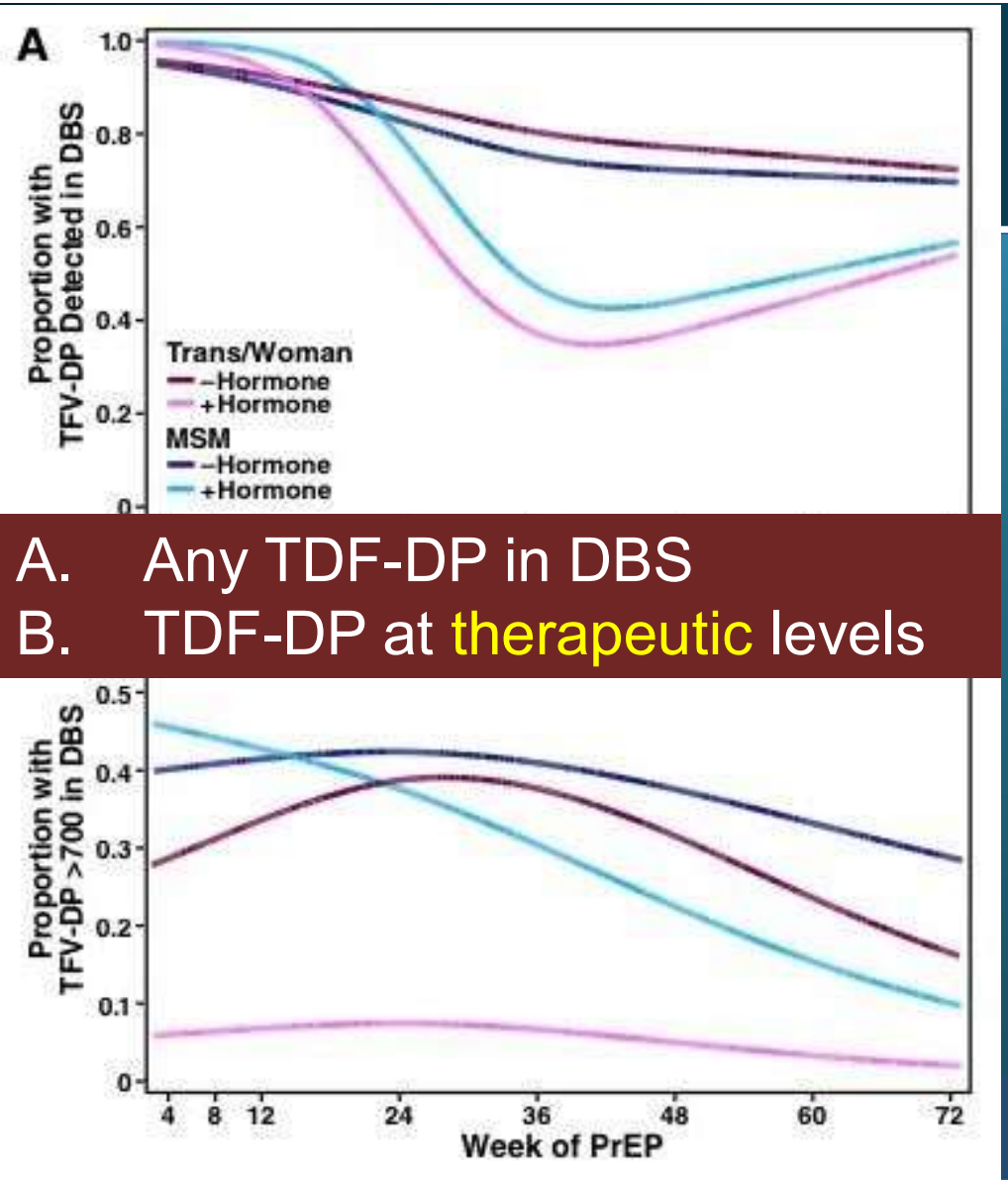
iPrEX (Iniciativa Profilaxis Pre-Exposición) RCT

- N=2499, enrollment from Brazil, Ecuador, Peru, South Africa, Thailand & US. All participants were AMAB. 12% identified as TGW, 1% men on FHT, 1% women.
- 25% (163) on FHT: 72% estrogens, 74% progestogens, 23% anti-androgens
- **TGW more**: partners, condomless AR sex, STIs, & transactional sex

iPrEX Open Label Extension – all offered TDF/FTC

- Intention to treat, N=1225, with 151 being TGW. PrEP uptake: 79% TGW, 76% MSM

Lancet HIV. 2015 Dec;2(12):e512-9.



A. Any TDF-DP in DBS
B. TDF-DP at therapeutic levels

iPrEX OLE Results

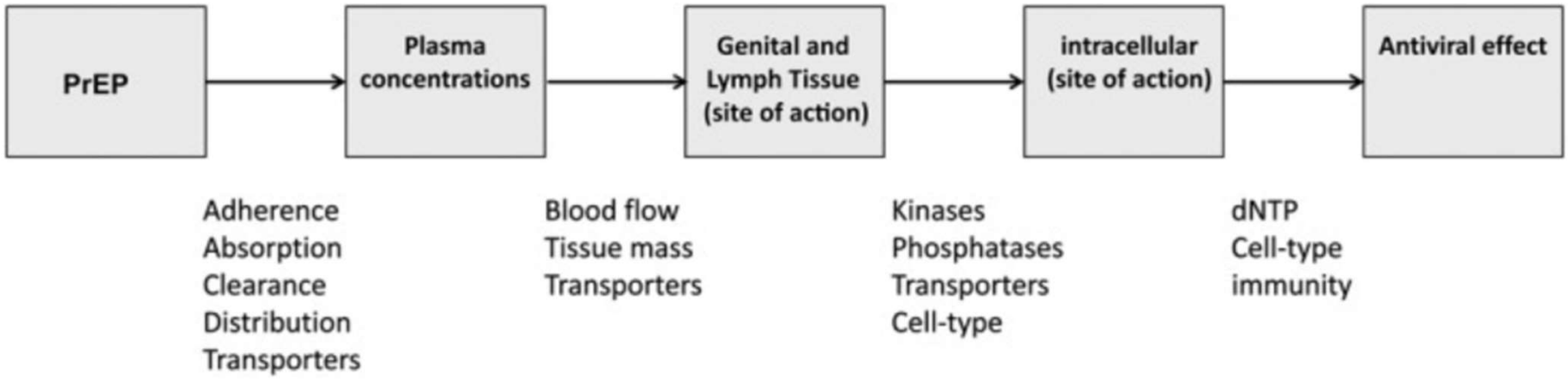
- TGW using hormones less likely to have any (OR 0.32, p=0.002) or protective (OR0.14, P<0.001) drug levels compared to TGW not using hormones
- TGW using hormones less likely to have any (OR0.41, p=0.003) or protective (OR0.10, P<0.001) drug levels compared to MSM
- No difference by use of 17-beta estradiol vs synthetic estrogens (p=0.74)

IPrEx OLE Takeaways

- Intention to treat: 11 seroconversions in the intervention group vs 10 in placebo
- As treated: None of the TGW who seroconverted had protective drug levels at the time of detection
- TGW who reported sexual practices conferring the highest risk of HIV infection tended to be less likely to have PrEP drug detected

How Is the Effect on TDF-FTC Levels Mediated?

Pharmacodynamics of TDF-FTC



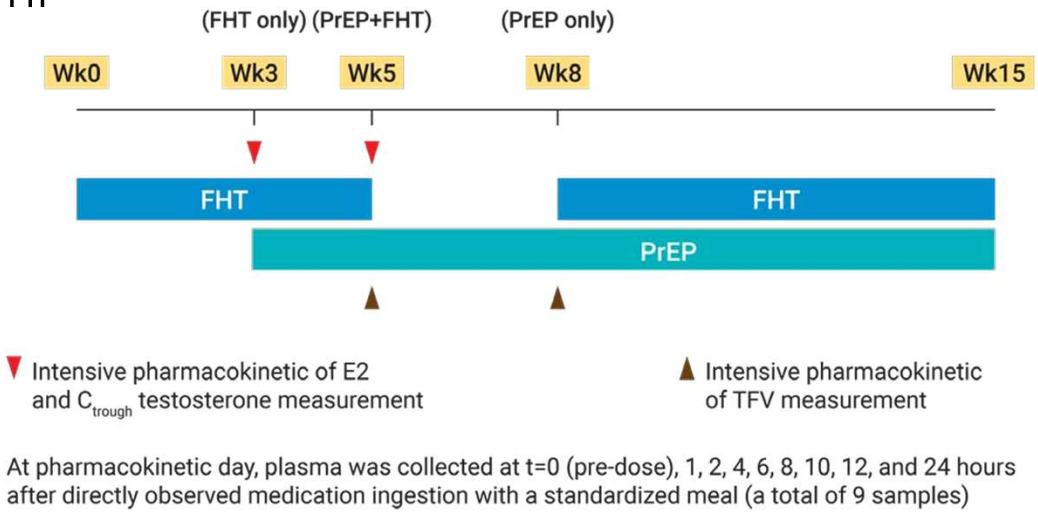
The pharmacologic continuum for TDF-FTC–based PrEP. Potential factors governing this continuum are noted at each step.

From "Pharmacologic Considerations for Preexposure Prophylaxis in Transgender Women"

J Acquir Immune Defic Syndr. 2016 Aug 15; 72(Suppl 3): S230–S234.

iFACT: A Careful Look at Pharmacokinetics

- To determine drug-drug interactions (DDI) between FHT and PrEP
- 20 TGW who had testes & had not received injectable FHT within 6 months were enrolled January - March 2018.
- FHT = estradiol valerate 2mg/day + cyproterone acetate 25 mg/day (no spironolactone)



At pharmacokinetic day, plasma was collected at t=0 (pre-dose), 1, 2, 4, 6, 8, 10, 12, and 24 hours after directly observed medication ingestion with a standardized meal (a total of 9 samples)

Hiransuthikul A et al. *Drug-drug interactions between the use of feminizing hormone therapy and pre-exposure prophylaxis among transgender women: The iFACT study.* 22nd International AIDS Conference (AIDS 2018), Amsterdam. Abstracts TUPDX0107LB, 2018.

iFACT Conclusions

- **Our study demonstrated lower plasma TFV exposure (13%) in the presence of FHT**, suggesting that FHT potentially affects PrEP efficacy among TGW

- **Estrogen exposure was not affected by PrEP**

- Further studies are warranted to determine whether these
  - DDIs occur in PBMC & target tissues as well?
  - DDIs occur with other FHT regimens.
  - Reductions in TFV are clinically significant

Hiransuthikul A et al. *Drug-drug interactions between the use of feminizing hormone therapy and pre-exposure prophylaxis among transgender women: The iFACT study.* 22nd International AIDS Conference (AIDS 2018), Amsterdam. Abstracts TUPDX0107LB, 2018.

TGW on E2 Have Lower TDF/FTC Concentrations During Directly Observed Dosing When Compared to Cis Men

- 8 TGW & 8 CGM, all HIV neg, age 18-65
- DOT
- Very variable FHT regimens, more "real world" E2 dosing than iFACT
- Didn't assess effect of TDF/FTC on hormone levels
- Had to have E2>100, CrCl >70

Varying Hormone Regimens

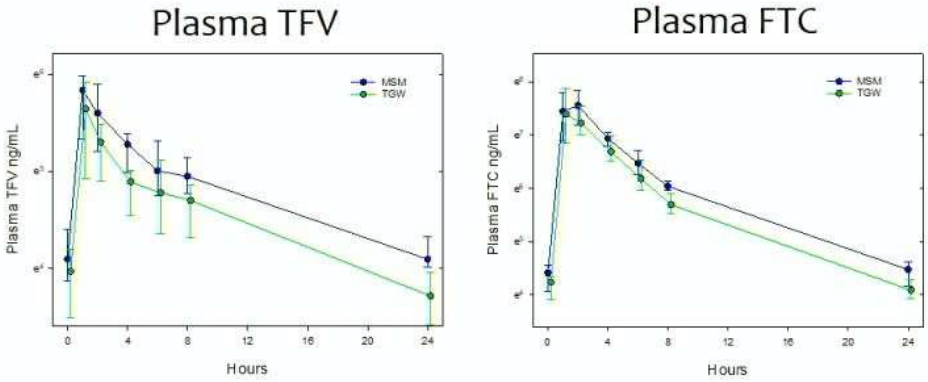
PID	Estradiol Oral	Estradiol IM	Premarin	Spironolactone	Medroxyprogesterone
1010			1.25 mg qd		
1011	6 mg q day			200 mg q day	
1012			1.25 mg qd	50 mg q day	
1017		0.5 mg q 2 wks		50 mg q day	
1018	6 mg q day	20 mg q 2 wks		200 mg q day	
1019	2 mg q day	40 mg q 2 wks	6.25 mg qd		
1020		20 mg q 2 wks		100 mg q day	5 mg q day
1021		1.5 mg q wk		200 mg q day	

Shieh, TGW on E2 Have Lower TDF/FTC Concentrations During Directly Observed Dosing When Compared to Cis Men, HIVR4P Madrid, Oct 2018

TGW on E2 Have Lower TDF/FTC Concentrations During Directly Observed Dosing When Compared to Cis Men

- TGW plasma TFV & FTC plasma concentrations lower by 20%-27%
- Values in range of 4 doses a week
- Caution: 4 doses a week of TDF/FTC may not be adequate; daily dosing key

Pharmacokinetics - Plasma



	Plasma TFV		Plasma FTC	
	C_{tau}	AUC_{0-24}	C_{tau}	AUC_{0-24}
% Reduction	20%	27%	26%	24%
p value	0.02	0.07	0.03	0.03

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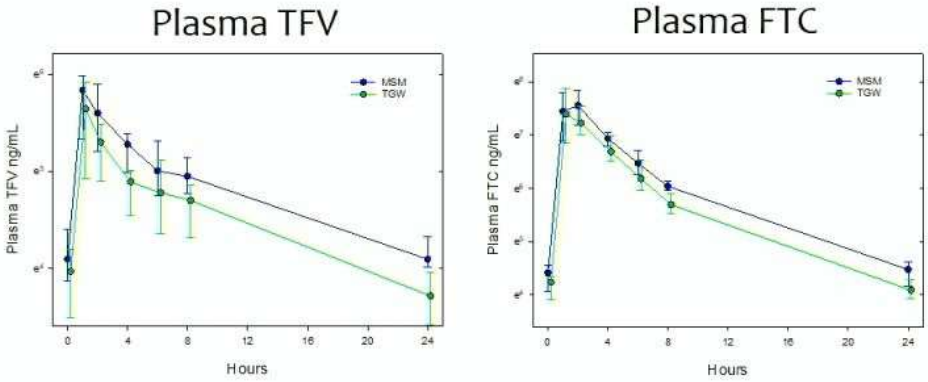

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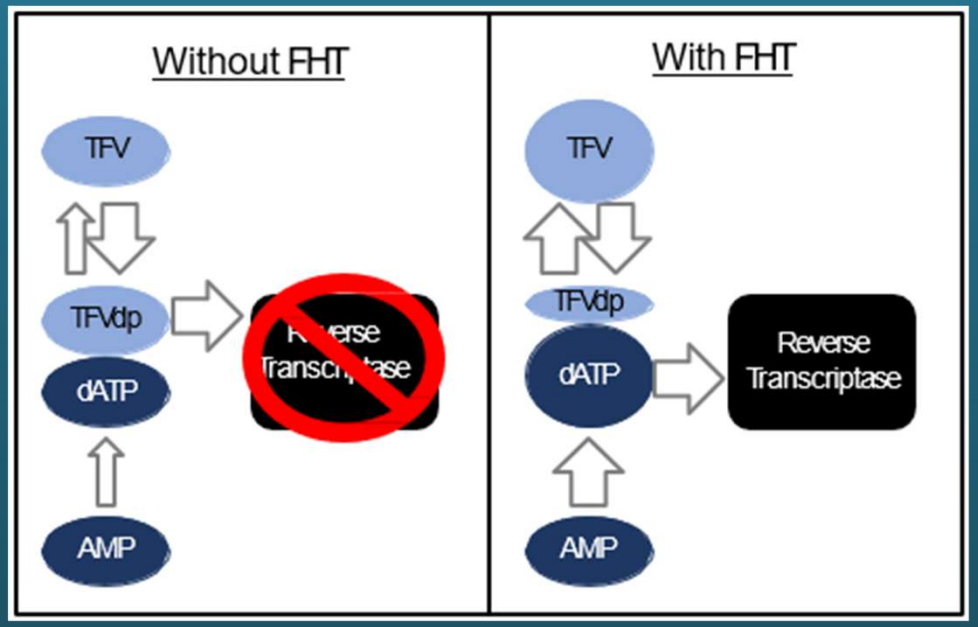
Altered TDF/ Pharmacology in TGW: Implications for PrEP

- **Cottrell:**
- - Compared plasma & rectal tissue levels of hormones, TFV, dATP
- - 4 TGW, all on E2 & spironolactone (1 on progesterone) compared to postmenopausal ciswomen & cismen

Effect of FHT on TFVdp to dATP ratio: TFV modulates dATP concentrations In a counterproductive way

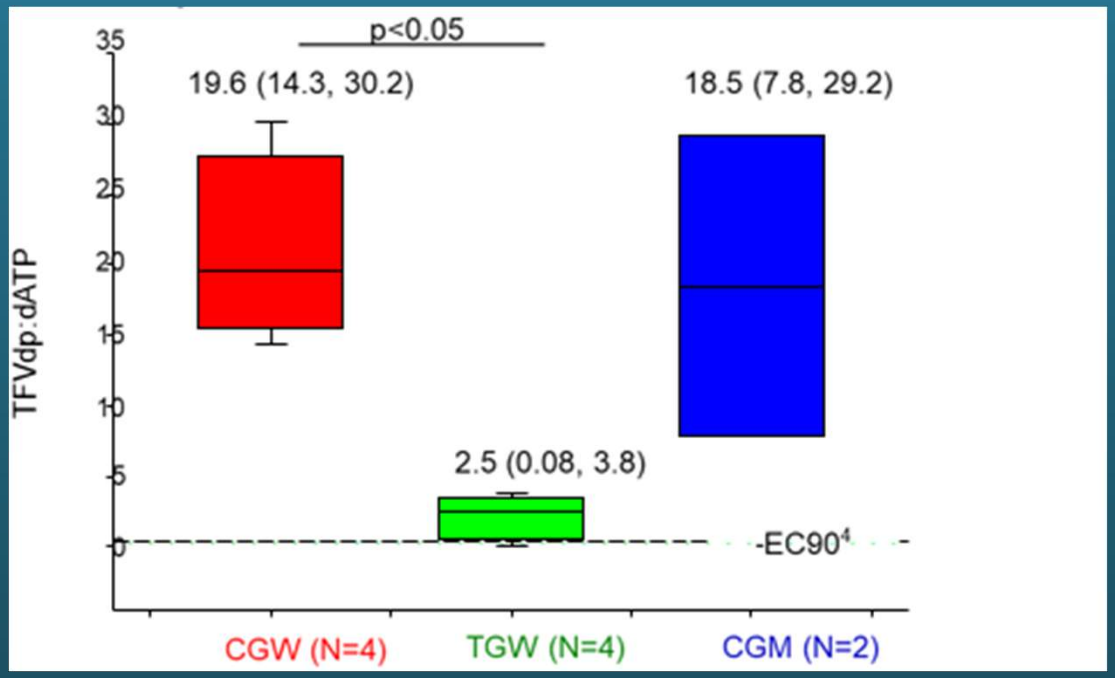


Altered TDF/FTC pharmacology in a transgender female cohort: implications for PrEP, 22nd International AIDS Conference (AIDS 2018), Amsterdam. Abstracts

***Cottreal, Clinical Infectious Diseases*, ciz290, accepted manuscript**

Altered TDF/ Pharmacology in TGW: Implications for PrEP

Median rectal TFVdp:dATP by 10-fold among TGW vs CGW or CGM



"We found transgender women taking FHT exhibited a 7-fold lower rectal tissue ratio of PrEP's active metabolites vs competing deoxynucleotides compared to cisgender women and men ($p=0.03$) that inversely correlated with estradiol ($\rho=-0.79$; $p<0.05$).

Thus, FHT may negatively impact PrEP efficacy."

***Cottreal, Clinical Infectious Diseases*, ciz290, accepted manuscript**

Provider Resources

Medical care, including hormone therapy

- http://transhealth.ucsf.edu/ - complete primary care protocols
- https://www.lgbthealtheducation.org/ - webinars with free CME
- http://callen-lorde.org/transhealth/
- **TransLine Guidelines** (Google same): Collection of expert opinion on hormonal treatment, with pragmatic details & ~equivalent doses
- PrEP Prophylaxis in Trans Populations: DOI:10.1089/lgbt.2018.0086

Endocrine Society Guidelines 2017:
https://academic.oup.com/jcem/article/102/11/3869/4157558

Surgical guidelines & policy

- http://www.wpath.org (Standards of Care 8 under development)

Case Management Resources

- **Cardea:** organizational change: www.cardeaservices.org -> Training -> Providing Culturally Proficient Services to Transgender and Gender Nonconforming People
- **Special Projects of National Significance: Transgender Women of Color Initiative Intervention Manuals:** https://targethiv.org/library/spns-transgender-women-color-initiative-manual. The Howard Brown report is most salient.
- **National Center for Transgender Equality** to change name, legal status & federal documents: https://transequality.org/documents
- WA DOL for license change
- Gender Justice League for legal matters and insurance access