IMPROVING PREP SERVICES FOR TRANS PEOPLE

Session 4: Gender Affirming PrEP Care and Clinical Pearls

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‘I AM NOT A “HIGH-RISK” PERSON; I AM A MEMBER OF A COMMUNITY THAT IS PUT AT HIGH RISK.’

Marcela Romero, Coordinator of REDLACTRANS, a Latin American and Caribbean transgender network

- Many TGNB people are in need of social services, medical care and basic access to employment and housing. TGNB people face many barriers to adequate service and health care, including discrimination, ignorance, poverty, prejudice, and fear.

- Many TGNB, people avoid care for preventive and urgent/life-threatening conditions

- There are very few health providers and hospitals in the country that have supportive and sensitive health services for TGNB people.

FACTS

ANATOMICAL INVENTORY

IMPORTANT NEXT STEPS IN THE STANDARDIZATION OF CARE FOR TRANS/GENDER DIVERSE PATIENTS

- Reports the absence or presence of organs, as well as surgeries related to those organs
- Some TGNB folks undergo medical and surgical interventions to affirm gender identity while others do not
  - GAHT, chest reconstruction, breast augmentation, hysterectomy, genital surgery
- Important to capture this information in an EMR
  - Update regularly in order to keep up to date with recommended health screenings and other interventions/supports
  - Limit the number of times a patient will need to be asked the same general questions repeatedly by providers which is burdensome

ANATOMIC INVENTORY

ORGANS PRESENT

- ❑ BREASTS
- ❑ CERVIX
- ❑ OVARIES
- ❑ PENIS
- ❑ PROSTATE
- ❑ TESTES
- ❑ UTERUS
- ❑ VAGINA

SURGICAL HX

- ❑ BILATERAL BREAST AUGMENTATION
- ❑ BILATERAL ORCHIECTOMY
- ❑ VAGINOPLASTY (PENILE INVERSION, COLON GRAFT)
- ❑ BILATERAL TOTAL REDUCTION MAMMOPLASTY
- ❑ VAGINECTOMY
- ❑ METOIDIOPLASTY
- ❑ PHALLOPLASTY
- ❑ SCROTOPLASTY

TAKING A GENDER AFFIRMING SEXUAL HEALTH HISTORY

NO “MEN, WOMEN, OR BOTH?”

AVOID ASSUMPTIONS ABOUT:

- KINDS OF SEX
- BODY PARTS USED FOR SEX
- PREGNANCY INTENTIONS

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FIGURE 1
Suggested sexual health language[1,34,79]

Use (less gendered language) [1]	*Instead of (gendered language)*
People who menstruate, people who are pregnant	Female, women; pregnant women
People who produce sperm	Male, men
Not trans, non-trans, cisgender	Biologically male/female
Assigned male at birth	Biologically male
Assigned female at birth	Biologically female
Sexual or genital (gen) health	Women's/gynecological healthcare
External genitals, external pelvic area	Vulva, clitoris
Outer parts	Penis, testicles
Genital opening, frontal opening, internal canal	Vagina
Outer folds	Labia, lips
Internal reproductive organs	Female reproductive organs
Internal organs	Uterus, ovaries
Internal gland	Prostate
Chest	Breasts [2]
Chest or breastfeeding [2]	Breastfeeding
Absorbent product	Pad/tampon
Internal condom	Female condom
Uterine bleeding	Period/menstruation
Parent or gestational parent	Mother
Hypothalamic pituitary gonadal – ovarian axis	Female gonadal steroid axis
Hypothalamic pituitary gonadal – testicular axis	Male gonadal steroid axis

Superscript number [1] The terms in these columns are offered as suggestions, but we recommend asking patients which words they use for their own body parts and experiences. *Superscript number* [2] Transfeminine persons may prefer breasts.

Krempasky. Contraception for transmasculine persons. Am J Obstet Gynecol 2019.

GENDER AFFIRMING HORMONES

Considerations when talking about sexual health/PrEP

MOST COMMON EFFCTS OF HRT ON TRANS FOLKS

Folks taking Estrogen
Folks taking Testosterone
Folks taking blockers

How can this impact potential HIV risk?

SURGICAL OPTIONS FOR THE TRANSGENDER/NB PATIENT

Considerations when talking about sexual health/PrEP

SURGERY FOR TRANSMEN/NB AFAB

- Mastectomy
- Hysterectomy and oophorectomy
- Genital Reconstruction
  - Phalloplasty
  - Metoidioplasty

SURGERY FOR TRANSWOMEN/NB AMAB

- Facial Feminization
- Removal of Adam’s Apple/ Tracheal Shave
- Augmentation Mammoplasty
- Genital Reconstruction

Pre-Exposure Prophylaxis for HIV

PRE-EXPOSURE PROPHYLAXIS (PREP) HAS TWO FDA-APPROVED FORMULATIONS:

- Truvada or Descovy
  - Truvada (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) approved in 2012. Approved for individuals 35kg or more, MSM, transwomen, AFAB, PWID
  - Descovy (emtricitabine 200 mg/tenofovir alafenamide 25 mg) was approved in 2019. Approved for AMAB folks engaging in oral and anal sex.

99% EFFECTIVE

- in preventing HIV seroconversion when used correctly!

WHO IS ELIGIBLE FOR PREP?

- HIV negative
- CDC: Those who engage in sex with someone of unknown HIV status and does not use condoms, engage in sex with individuals who are living with HIV, has a history of STIs in last 6 months...
- Really... anyone who thinks they need it!

Truvada (Emtricitabine/Tenofovir disoproxil fumarate)

Drug Class: NRTI/NRTI
Dosed: One tablet (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) PO
Taken daily or 2-1-1 Regimen
Long-term side effects?

Descovy (Emtricitabine/Tenofovir alafenamide)

Drug Class: NRTI/NRTI
Dosed: One tablet (emtricitabine 200 mg /tenofovir alafenamide 25 mg) PO
Must be taken daily
Considered “latest and greatest”

LABORATORY CONSIDERATIONS

- PrEP Initiation:
  - HIV test (serum or rapid 4th Generation)
  - Metabolic panel (Chem-10 + liver function tests)**
  - Urinalysis
  - Hepatitis A and C serology
  - Hepatitis B core, Hepatitis B surface antibody, and Hepatitis B surface antigen
  - CBC with differential
  - STI screening: RPR, NAAT for GC/CT at all involved sites, and Trichomonas if applicable
  - Pregnancy test (if applicable)
- Follow-up Visits:
  - HIV test (serum or rapid 4th generation)
  - Pregnancy (if applicable)
  - STI Screening Tests
  - Serum Creatinine**
  - Urinalysis

Although there is a risk of decline in kidney function and bone mass accumulation with Truvada, these adverse effects are extremely rare

REPRODUCTIVE/SEXUAL HEALTH CONSIDERATIONS

- Considerations for TGNB patients
- Consistent HIV serum Ag/Ab testing to r/o seroconversion
- Ensure routine f/u appointments are available
- Ensure confidentiality
- Comprehensive sexual health screening based on sexual activity
- Risk and Benefit considerations for Truvada v. Descovy for each patient

PREP AND TRANS PEOPLE

SOURCE: HTTPS://WWW.POSITIVELYAWARE.COM/ARTICLES/PREP-AND-TRANSGENDER-PEOPLE

The largest PrEP study, called iPrEx, enrolled about 2,500 HIV-negative gay men and transgender women from six countries. They took either a placebo (inactive pill) or Truvada. The study showed that the rate of HIV infection was reduced by 44% in people who were assigned to take Truvada. When people took their pills consistently they had even greater protection against HIV, over 92%.

A subanalysis that only looked at the 339 (14%) transgender women in the iPrEx study showed that there was no difference in the rates of new infections among those assigned to take Truvada and those assigned to take the placebo; i.e., the drug did not appear to be effective. Further investigations showed that transgender women who seroconverted while assigned to take Truvada had no evidence of the drug in their blood. The investigators concluded that adherence may be more difficult for transgender women who may be dealing with structural barriers to care and psychosocial issues, such as homelessness, depression, and substance use. It is also possible that women may prioritize other health issues, such as access to hormone care, over HIV prevention, especially if they are concerned that Truvada may affect the effectiveness of their hormones. It does appear that when taken consistently, Truvada is just as effective at preventing HIV infection among transgender women, since no infections occurred among those who had adequate drugs levels, equivalent to at least 4 tablets per week. Unfortunately we do not have good data about PrEP uptake or effectiveness among transgender men and non-binary people. Transgender men are often excluded from studies that enroll MSM, even if they have significant HIV risk factors.

PREP AND TRANS PEOPLE

SOURCE: HTTPS://WWW.POSITIVELYAWARE.COM/ARTICLES/PREP-AND-TRANSGENDER-PEOPLE

TRANSGENDER PEOPLE ON PREP

Before starting PrEP, people are screened for HIV infection, hepatitis B, and STIs and evaluated for kidney problems. While on PrEP, testing for HIV, STIs, and kidney function is usually repeated every 3 months. For transgender men who start PrEP, it is important to remember that they will also need to be regularly screened for pregnancy if they are having frontal (vaginal) sex with cisgender men, even if they are on testosterone, since this doesn't completely protect against pregnancy. Other differences also exist for transgender men. Those who take testosterone will have an increase in muscle mass, which can elevate the serum creatinine. Since the creatinine level is used to evaluate kidney function, transgender men on testosterone should have their values interpreted using the usual male range of test results. Although PrEP is thought to reach adequate levels in rectal tissue after 7 days, it may take up to 20 days for maximum levels in vaginal tissue. Transmen who have vaginal sex will need to know that they may not be fully protected against HIV until they have been on PrEP for about 3 weeks.

PREP AND TRANS PEOPLE

SOURCE: HTTPS://WWW.POSITIVELYAWARE.COM/ARTICLES/PREP-AND-TRANSGENDER-PEOPLE

Some TGNB people may have had gender-affirming surgeries, including genital reconstruction. For transgender women who have had vaginoplasty surgery, the vagina is usually created using scrotal and penile tissue. Although the skin is thought to be more resistant to infections than mucosal tissue, the neovagina does not naturally lubricate, and may be prone to small tears, ulcers, and abrasions, which may theoretically increase susceptibility to HIV and STIs. Transgender men may decide to have genital reconstruction to create a phallus (phalloplasty) or to extend the clitoris (metoidioplasty) and can choose to retain or remove the vagina, uterus and ovaries. It is important for providers to ask questions about surgeries and sexual behaviors in order to give appropriate information on HIV and STI risks, screening, and prevention. There is not a lot of information about the best ways to screen for STIs in those who have had genital surgeries, but the general rule is that testing should be based on the existing anatomy and the sexual behaviors that people engage in. We also do not have information about how these surgeries impact the tissue concentrations of PrEP drugs.

What is the evidence for PrEP among transgender people?

- **iPrEX:** This trial of TDF/FTC versus placebo included 339 transgender women out of 2499 total participants. Drug level monitoring suggested that good adherence to PrEP prevented HIV among the transgender participants.

- **DISCOVER:** This trial of TDF/FTC versus TAF/FTC for PrEP included 74 transgender women out of 5387 total participants. TAF/FTC was non-inferior to TDF/FTC for PrEP overall. No transgender woman contracted HIV in the study.

Deutsch MB, Lancet HIV, 2015; Mayer KH, Lancet 2020

How to choose between TDF and TAF

Clinical feature	Use
Pre-existing renal or bone disease/risk factors	TAF/FTC
Patient has anal sex only	TDF/FTC or TAF/FTC
Patient has receptive vaginal sex (trans woman with a neovagina, trans man without genital surgery)	TDF/FTC

Preexposure prophylaxis for prevention of HIV infection in the United States. CDC. 2018.

Monitoring is the same as for cisgender people

At least every 3 months	At least every 6 months
HIV test, preferably antibody/antigen assay	Serum creatinine to estimate creatinine clearance
STI screening (syphilis serology and 3-site gonorrhea/chlamydia NAAT)	
Urine pregnancy test in those who could become pregnant	

At most visits: Assess tolerability and adherence, re-assess HIV risk and need for PrEP

Preexposure prophylaxis for prevention of HIV infection in the United States. CDC. 2018.

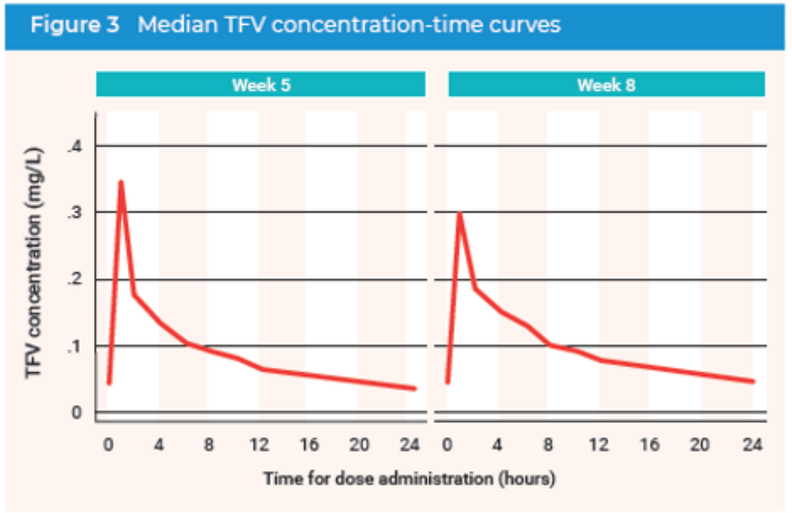
Does PrEP interact with gender-affirming hormones?

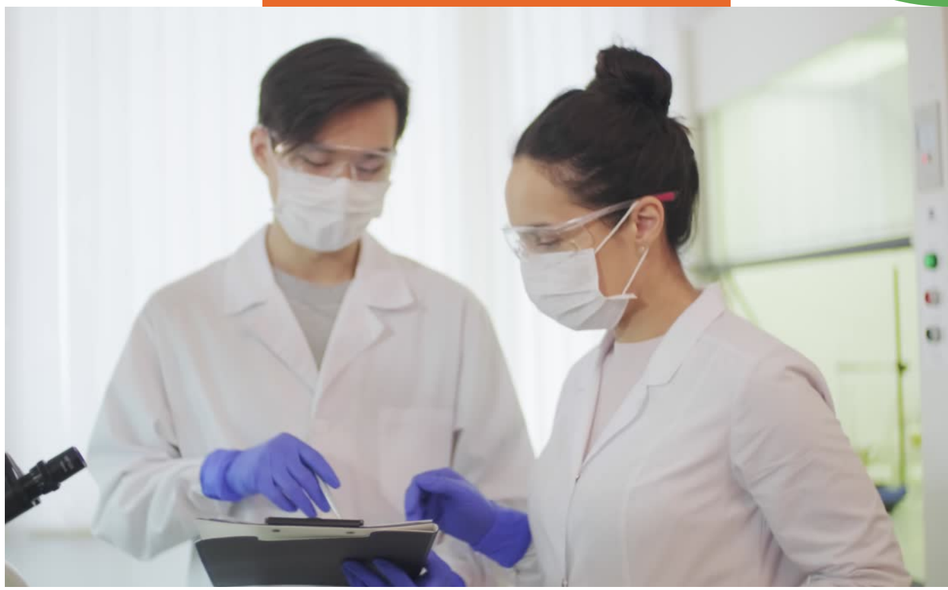
- Hormone therapy is a priority for many transgender and non-binary people.
- Concerns about drug-drug interactions between PrEP and hormones may impact willingness to take PrEP and/or adherence.
- The medications currently available for PrEP do not impact levels of feminizing or masculinizing hormones.
- Hormone therapy does not appear to impair the effectiveness of PrEP, provided patients take PrEP daily as prescribed.
  - No infections in those with high PrEP adherence in iPrEx.
  - Tenofovir concentrations adequate in women taking hormones in DISCOVER

Deutsch MB, Lancet HIV, 2015; Mayer KH, Lancet, 2020

Drug-drug interactions: the iFACT study

- **Population:** 20 transgender women who had not undergone orchiectomy
- **Methods:**
  - Prescribed estradiol valerate and cyproterone acetate weeks 0-5 and 8-15
  - Prescribed PrEP beginning week 3
- **Outcomes:**
  - No effect of PrEP on estradiol or testosterone levels
  - Tenofovir levels 13% lower with hormones, likely not clinically significant





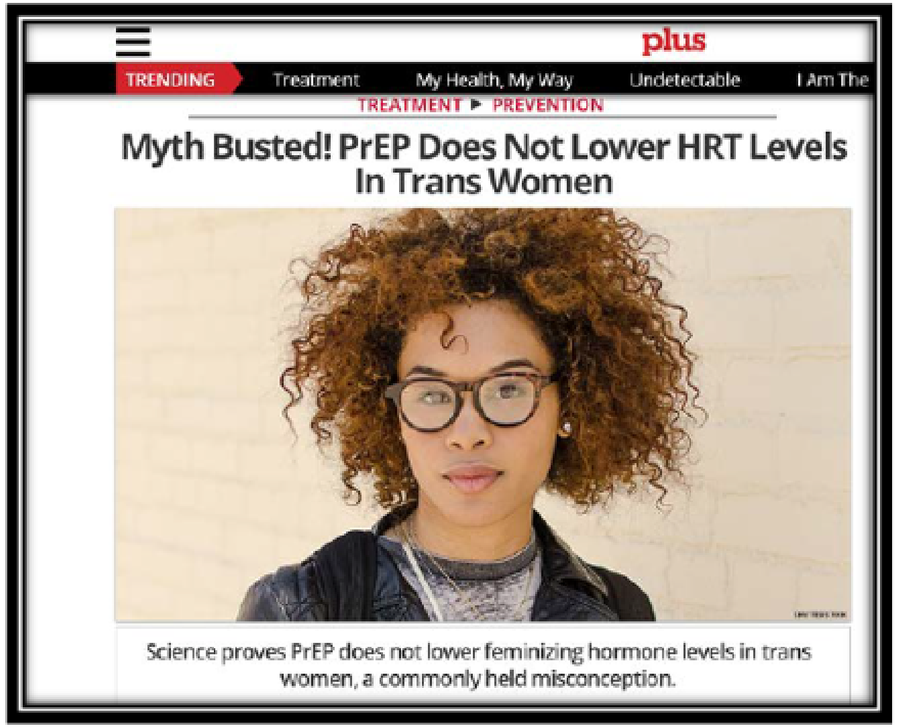
Hiransuthikul A, et al. J Int AIDS Soc, 2019

Barriers and facilitators to PrEP: Qualitative research

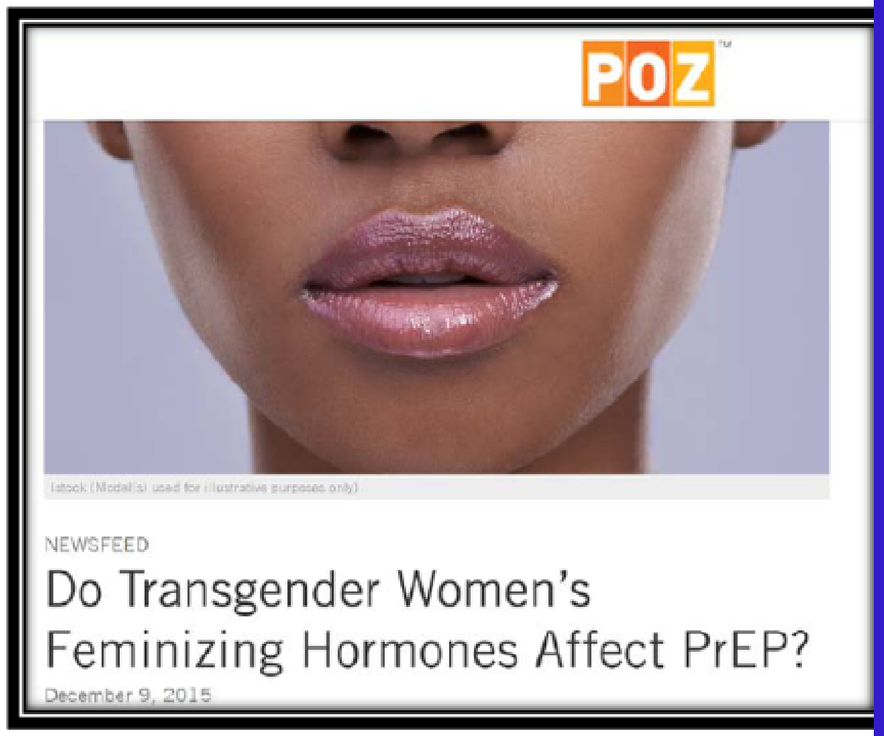
- PrEP messaging has been focused on MSM:
  1. MSM media do not reach transgender women
  2. Off-putting to transgender women
- Interest is generally high when PrEP is explained
- Desire to obtain PrEP from a prescriber of gender-affirming hormones
- Concerns about:
  1. Adding another medication to the multiple medications that many transgender people take
  2. Interactions between PrEP and hormone therapy

1. Sevelius JM, Keatley J, Calma N, Arnold E. "I am not a man": Trans-specific barriers and facilitators to PrEP acceptability among transgender women. Global Public Health. 2016;11(7-8):1060.
2. Rael CT, Martinez M, Giguere R, et al. Barriers and facilitators to oral PrEP use among transgender women in New York City. AIDS Behav. 2018. doi 10.1007/s10461-018-2102-9.

Summary of Data on F/TDF for PrEP among Trans Women



By Desirée Guerrero, JULY 30 2018 3:23 PM EDT
https://www.hivplusmag.com/prevention/2018/7/30/myth-busted-prep-does-not-lower-hrt-trans-women



https://www.poz.com/article/prep-transgender-women-28163-7861

Implications for trans men using hormonal contraception?

Source: PrEP and Transgender Communities: Evidence Informed Practices presented by Tonia Poteat at Advancing Excellence in Transgender Health Conference

Little data on PrEP pharmacology among transgender men on T

After four weeks on PrEP, there was no change in blood estradiol concentrations in either trans women or trans men. As expected, estradiol concentrations among trans women were higher both at baseline and week 4 compared to trans men.

Similarly, there were no changes in blood testosterone concentrations after four weeks on PrEP for either trans women or trans men. As expected, testosterone concentrations among trans men were higher at both baseline and week 4 compared to trans women.

During the first two weeks on PrEP, there were no differences in drug concentration levels between trans men, trans women and cis men. The increase in drug concentration levels between weeks 2 and 4 was slightly higher among cis men. After 4 weeks, trans women and cis men had comparable drug concentration levels, but drug levels among trans men were slightly lower compared to cis women.

Importantly, all people in the study were anticipated to reach drug levels that have been shown to be "highly protective" against HIV.

GRANT, R.M. AND COLLEAGUES. SEX HORMONE THERAPY AND TENOFOVIR DIPHOSPHATE CONCENTRATION IN DRIED BLOOD SPOTS: PRIMARY RESULTS OF THE IBREATHE STUDY. CLINICAL INFECTIOUS DISEASES, AUGUST 2020.

Source: PrEP and Transgender Communities: Evidence Informed Practices presented by Tonia Poteat at Advancing Excellence in Transgender Health Conference

CDC Recommendations for PrEP

based on F/TDF studies

*Although the effectiveness of PrEP for **transgender women** has not yet been definitively proven in trials, and trials have not been conducted among **transgender men**, PrEP has been shown to reduce the risk for HIV acquisition during **anal sex and penile-vaginal sex**. Therefore, its use may be considered in **all persons at risk** of acquiring HIV sexually.*

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Published March 2018.

Co-locate prevention and treatment services with support services relevant to transgender people

Integrate transgender-specific medical care, especially hormone therapy into prevention and treatment

Hire transgender and gender non-binary staff

ENGAGEMENT

Identify ART regimens that do not interact with hormonal therapy

Train the entire support and health care team in making your clinical setting welcoming to and safe for transgender people

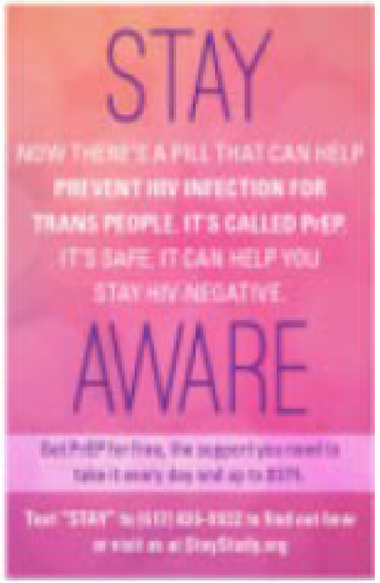
Ask about barriers transgender women and men encounter related to taking PrEP or ART

Citation: Davis, C., Lewis, O., & Cabezas, J. (2019, March). *HIV treatment and prevention with TGNB people*. Workshop presented at the HIV Planning Council, NY.

ANATOMY-BASED CARE (NOT GENDER-BASED)

- ☑ ASK ABOUT PREFERRED NAMES FOR BODY PARTS
- ☑ ASK ABOUT HORMONES AND SURGERIES
- ☑ DON’T MAKE ASSUMPTIONS ABOUT SEXUAL PARTNERS
- ☑ HAVE APPROPRIATE RESOURCES

Trans – Affirming Advertising



IF YOU HAVE IT....CHECK IT

QUESTIONS/DISCUSSION: PUTTING IT ALL INTO PRACTICE

WANT TO TALK MORE?

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