

PrEP for

Transgender Individuals

SOUTH CAROLINA HIV PrEP INITIATIVE



HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)
EDUCATION TRAINING CONSULTATIVE SUPPORT CO-MANAGEMENT

KAMLA SANASI-BHOLA, MD
PRONOUNS: SHE, HER, HERS
ASSISTANT PROFESSOR OF IM
DIVISION OF INFECTIOUS DISEASES
PHUSCMG
KAMLA.SANASI@USCMED.SC.EDU

OMAR LUCAS, PHARM D
PRONOUNS: HE, HIM, HIS
CLINICAL PHARMACIST
DIVISION OF INFECTIOUS DISEASES
PHUSCMG
OMAR.LUCAS@USCMED.SC.EDU

Disclosures

- None

Learning Outcomes

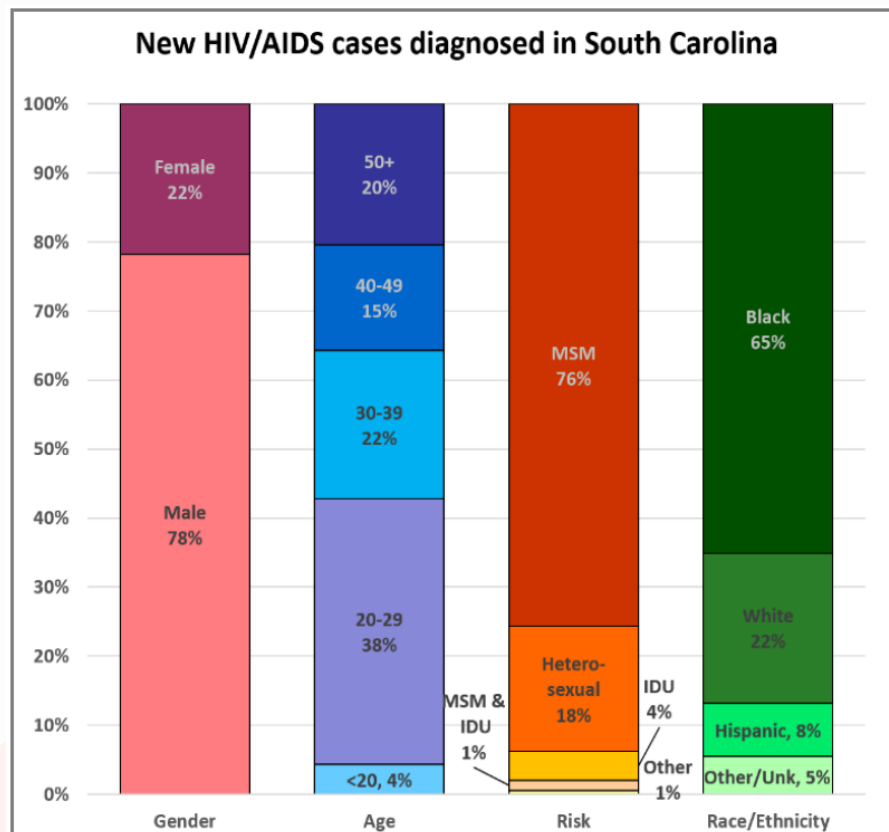
1. Review data supporting HIV PrEP in Transgender individuals
2. How to engage- provide culturally competent healthcare for Transgender individuals

1. Why focus on the transgender community

Focus Group for PrEP in SC: Based on HIV Cases

- Of the 1,520 (375 in Low country) newly diagnosed HIV cases in SC (2016+2017)

- 76% were **MSM**
 - Low country 71%
- 65% were **Black**
 - Low country 66%
- 42% between **<30**
 - Low country 44%

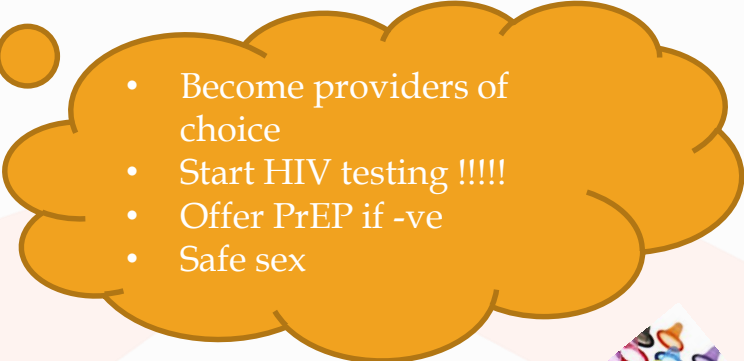


- <https://www.scdhec.gov/sites/default/files/media/document/Epi%20Fact%20Sheet.SC%20State.2018.pdf>
- <https://www.scdhec.gov/sites/default/files/media/document/Epi%20Fact%20Sheet.Upstate.2018.pdf>

Health Disparities:

- Transgender and HIV Risk

- ~1 million adults in the US are transgender (underreported, pooled data)
- Time between identifying as transgender/ gender non confirming and HIV + = 5 years!

- 
- Become providers of choice
 - Start HIV testing !!!!!
 - Offer PrEP if -ve
 - Safe sex

1. 2011 The National Gay and Lesbian Task Force and the National Center for Transgender Equality
2. Chung, et al. Positively Trans: Initial report of a national needs assessment ... Oakland, California: Transgender Law Center. 2016
3. Herbst, Estimating HIV prevalence and risk behaviors of transgender persons in the US AIDS Behav 2008
4. <https://www.cdc.gov/hiv/group/gender/transgender/index.html>

Health Disparities:

- Transgender and HIV

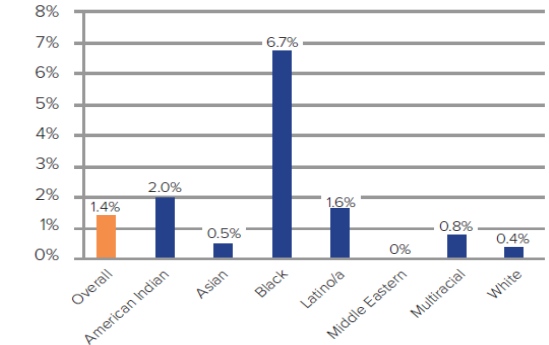
¹Overall rate of HIV in trans = 1.4%

- > 4X higher than US pop. (0.3%)
- Higher rates in blacks
- Higher rates in trans women (MtF) 3.4%

- ^{2,3}More recently HIV prevalence
 - Transgender women= 18.8%
 - Transgender men= 2.0%
 - Majority of new HIV infections in TG are between 13-24 years old

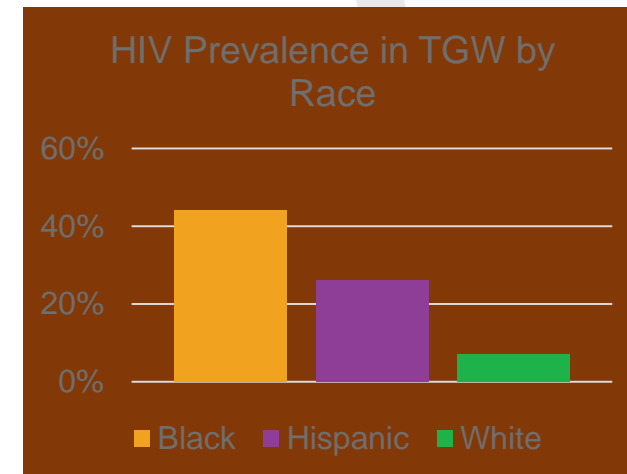
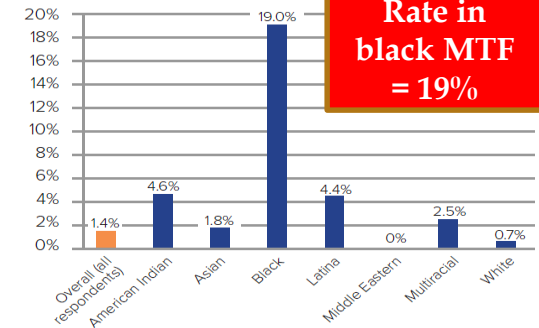
1. Center for Transgender Equality- 2015 survey (n=27,715)
2. Becasen J, et al. AJPH 2018,
3. Habarta N, et al. AJPH, 2015

Figure 7.42: Living with HIV RACE/ETHNICITY (%)



2015 US Transgender Survey

Figure 7.43: Living with HIV among transgender women RACE/ETHNICITY (%)



Focus Group for PrEP - Transgender

Why is this group high risk?

1. Risky behavior: multiple partners, anal/vaginal sex + no condoms or sharing needles to inject hormones/drugs (or pumping party)

Silicone Injections Given at Party Blamed in Transgender Woman's Death

By Vikki Vargas and Asher Klein

Published at 9:16 AM PST on Jan 30, 2015 | Updated at 12:17 PM PST on Jan 30, 2015
2. Social: stigma, discrimination, rejection/exclusion, commercial sex work
3. Providers not sensitive to trans issues → barrier for trans people living with HIV for treatment and care
4. HIV prevention programs may not address needs of trans people
5. Current HIV testing programs may not be enough to reach

Reporting Requirements/ Disparity Identification



- Reporting changes rolled out in Spring 2016 for 2017
- Health centers to report sexual orientation and gender identity information about the population served
- Sexual orientation data from patients <18 years, not mandated

Line	Patients by Sexual Orientation	Number (a)
13.	Lesbian or Gay	
14.	Straight (not lesbian or gay)	
15.	Bisexual	
16.	Something else	
17.	Don't know	
18.	Choose not to disclose	
19.	Total Patients (sum lines 13 to 18)	

Line	Patients by Gender Identity	Number (a)
20.	Male	
21.	Female	
22.	Transgender Male/ Female-to-Male	
23.	Transgender Female/ Male-to-Female	
24.	Other	
25.	Choose not to disclose	
26.	Total Patients (sum lines 20 to 25)	

8

Key terminology and concepts

The difference among gender, sex and sexuality

LGBTQ+
or
LGBTQQIAA

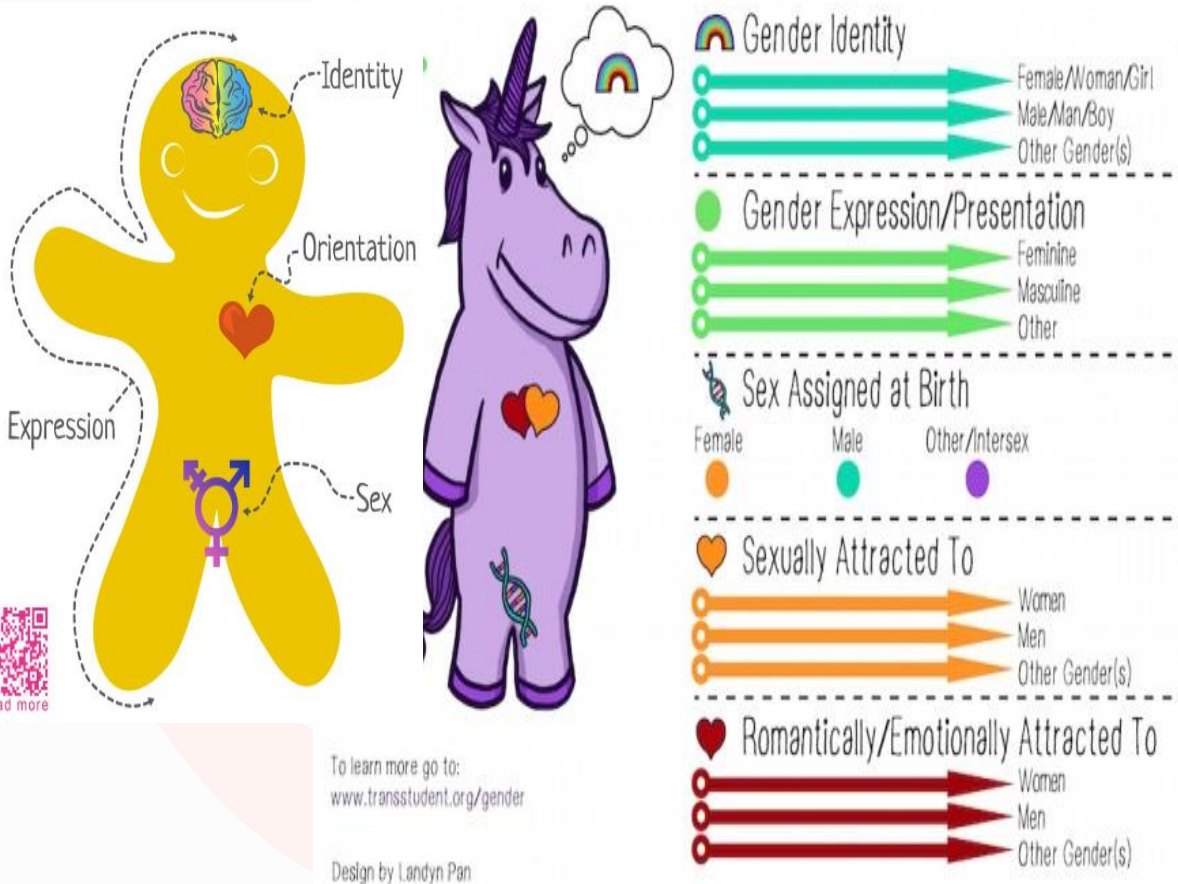
Lesbian
Gay
Bisexual
Transgender
Transsexual
2/Two-Spirit
Queer
Questioning
Intersex
Asexual
Ally

An Ally is a person who considers themselves a friend to the LGBTQ+ community

Definitions

The Gender Unicorn

Graphic by:
TSER
Trans Student Educational Resources



Gender identity(GI) – labels used when socially constructing sexed personas
How you feel, who you are

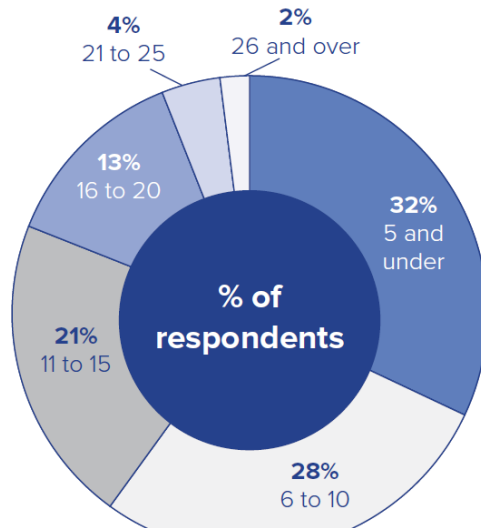
Gender expression - situational expression of cultural cues which communicate GI
How you dress

Gender orientation- subjective experience of one's body, including it's sexed attributes

Gender Dysphoria and Health Care Needs

- Gender dysphoria: distress experienced by some whose gender identity does not correspond with assigned sex at birth
- 60% of persons start gender thoughts ≤ 10 years

Figure 4.3: Age they began to feel gender was different from the one on their original birth certificate



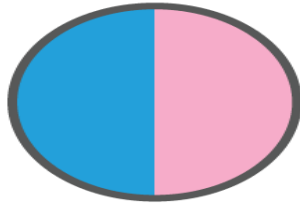
Need for Behavioral Health Support

- Psychiatrist
- Counsellors
- Peers/support group

James, (2016). *The Report of the 2015 U.S. Transgender Survey*. Washington, DC: NCFE

Definitions: Gender Identity

GENDER DEFINITIONS



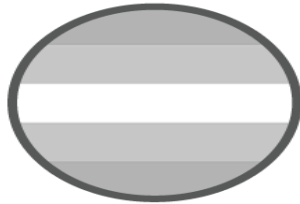
GENDER

The state of being male or female in typically regarding to social constructs rather than physical attributes.



TRANSGENDER

Refers to someone who does not identify with the gender they were assigned at birth.



CISGENDER

Refers to someone who identifies with the gender they were assigned at birth.



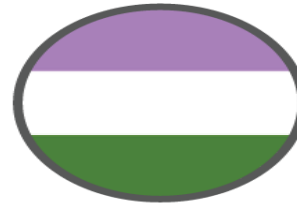
NON-BINARY

Refers to someone who does not identify as exclusively male or female.



GENDER FLUID

Refers to someone whose gender identity changes over time from one end of the spectrum to the other.



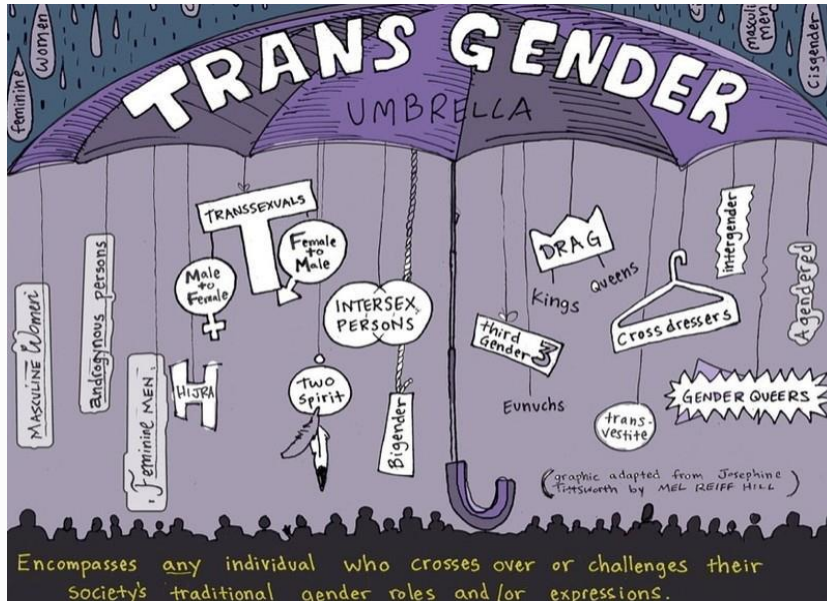
GENDERQUEER

Refers to someone whose gender identify falls on the spectrum between male and female.

<https://www.liveaboot.com/what-does-it-mean-to-be-gender-non-conforming-1415327>

Gender Identity of Transgender People

- Various terminologies used
 - In the largest survey of trans people , an additional 500 gender terms were listed
- Do not assume, just ask



James, (2016). *The Report of the 2015 U.S. Transgender Survey*.
<https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf>

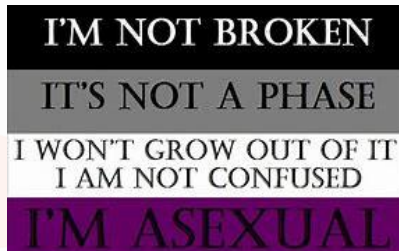


Gender identity terms	% of respondents
Transgender	65%
Trans	56%
Trans woman (MTF, male to female)	32%
Trans man (FTM, female to male)	31%
Non-binary	31%
Genderqueer	29%
Gender non-conforming or gender variant	27%
Gender fluid/fluid	20%
Androgynous	18%
Transsexual	18%
Agender	14%
Two-spirit	7%
Bi-gender	6%
Butch	5%
Crossdresser	5%
Multi-gender	4%
Third gender	4%
Intersex	3%
Drag performer (king/queen)	2%
A.G. or aggressive	1%
Stud	1%
Travesti	1%
Bulldagger	<1%
Fa'afafine	<1%
Mahu	<1%
A gender not listed above	12%

Definitions: Gender Orientation

Gender orientation terms

- Lesbian (used by females)
- Gay (used by females or males)
- Bisexual (attraction to male or female)
- Queer (umbrella term for sexual and gender minorities)
- Pansexual (attraction toward people of any sex or gender identity- gender blind)
- Questioning
- Asexual (no sexual attraction)
- Straight



Gender orientation terms

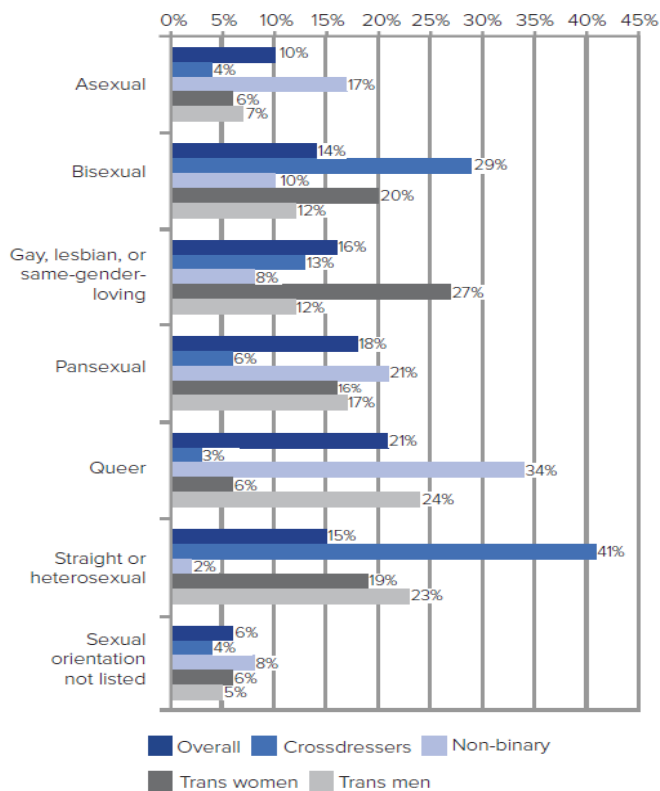
- Gender non confirming
- Other non binary terms
 - Pangender/Genderqueer
 - Polyamorous
 - Bi-gender (moves between feminine and masculine gender identities)
 - Two-Spirit (indigenous North Americans to describe gender-variant individuals)
 - Agender (gender free)
 - Gender Bender
 - Androgyne
 - Genderfluid

<https://www.liveabout.com/what-does-it-mean-to-be-gender-non-conforming-1415327>

<https://ok2bme.ca/resources/kids-teens/what-does-lgbtq-mean/>

Gender Orientation of Transgender People

Figure 4.28: Sexual orientation



Conversations - Don't assume

- Open ended questions (should to be role appropriate)
 - What is your sexual orientation
 - Types of partner(s)
 - What part(s) you use for sex
- STI screening and PrEP

James, (2016). *The Report of the 2015 U.S. Transgender Survey*. Washington, DC: NCYE

Barrier to Providing Transgender PrEP Care

Perceived Barriers

Top concerns of Transgender Patients:

1. Gender affirming and non discriminatory care (59%)
2. Hormone therapy and side effects (53%)
3. Mental Health care, including trauma recovery (49%)
4. Personal care (nutrition, healthy living (47%)
5. ART and side effects (46%)

.....

PrEP and post-exposure prophylaxis (16%)

Chung, et al. Positively Trans: Initial report of a national needs assessment ... Oakland, California: Transgender Law Center. 2016 (n=159)

Barriers for Patients in SC

Actual Challenges

- Actual Challenges faced by trans people in SC (n=233)
 - 10% unemployed
 - 28% living in poverty
 - 8% verbally harassed when accessing a restroom
 - 37% of those who saw a health care provider had at least 1 negative experience
 - Harassment
 - 37% of those who held/applied for job were fired, denied a promotion, or not hired
 - 87% of those who were out/perceived as transgender in K-12 had mistreatment

Creating A Welcoming Environment*

Gender Affirmative and Culturally Competent Care



1. No assumptions about gender identity, sexual orientation, or behavior

- HCP should be non judgmental



2. Inclusive language

- Appropriate pronouns /preferred name

- Adding a 'Transgender' or 'Agender' or 'Other' option on

records

3. Assurance of confidentiality

4. Training staff to increase their knowledge and sensitivity

- Including front desk, phlebotomist

5. The adoption and posting of a nondiscrimination policy (organizational support)



Gay and Lesbian Medical Association. Guidelines for care of lesbian, gay, bisexual, and transgender patients. Washington, DC: GLMA; 2006.

*http://www.glma.org/_data/n_0001/resources/live/GLMA%20guidelines%202006%20FINAL.pdf

A Welcoming Environment- Language Matters

Appropriate Pronouns

- Commonly used
 - She/her/hers (37% *)
 - He/him/his (37% *)
 - They/them/theirs (29% *)

- Gender-neutral pronouns or just their name may be use
 - He lost his money = Ze lost hir money

**Slurs/it/he-she =
Offensive =
Missed opportunity for
PrEP initiation/ retention or
Suicide prevention**

1	2	3	4	5
(f)ae	(f)aer	(f)aer	(f)aers	(f)aerself
e/ey	em	eir	eirs	eirself
he	him	his	his	himself
per	per	pers	pers	perself
she	her	her	hers	herself
they	them	their	theirs	themself
ve	ver	vis	vis	verself
xe	xem	xyr	xyrs	xemself
ze/zie	hir	hir	hirs	hirself

*James, (2016). *The Report of the 2015 U.S. Transgender Survey*, NCTE

Activity 1: Getting Comfortable

- Disclose your pronouns to around the office or write your pronouns



A Welcoming Environment

-Restrooms



“Gender-neutral” rooms- safe and private

- A single-stall, lockable room available to all genders, sexes and disability
- Appropriate signs

Gender neutral bathrooms have always been a thing, I dunno what the big deal is?



US transgender survey (27,715 respondents in 2015)

- 9% were denied access to restroom(1 in 10)
- 59% avoided public restrooms for fear of confrontation
- 32% limited the amount they ate or drank

Adding to their dysphoria !!!!

James, (2016). *The Report of the 2015 U.S. Transgender Survey*. Washington, DC: National Center for Transgender Equality
<https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf>

Barriers

Solutions

Access²

Training providers

Cost² / Insurance

Medication assistance programs

Adherence

Counseling/Reminders/Behavioral Intervention

Resistance¹

HIV testing while on PrEP

Side effects

OTC meds, Revisit need for PrEP
Q 12 months

Risk compensation

Emphasize condom use and screen
for STIs frequently

Heterosexism²

Training, Education on HIV public
health burden, checking biases

1. 2017 HIV PrEP guidelines; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4308722>
2. Calabrese. Racism and Heterosexism in Medical Students' Clinical Decision-Making Related to HIV PrEP: AIDS 2018

Healthcare Setting Discrimination

-Provider Biases

- 40% of Physicians are uncomfortable with lesbian or gay patients (1986)²
 - If providers aware of trans status, likelihood of discrimination increased (2011)¹
- Sexual history usually deferred: Primary care³, STI care⁴ and HIV care⁵⁻⁷
- Perceived Risk
 - Persons with greater heterosexism, more strongly anticipated increased risk behavior and adherence problems to PrEP → lower prescribing intention⁸

¹ 2011 The National Gay and Lesbian Task Force and the National Center for Transgender Equality.

² Matthews *et al.*, 1986

³ Wimberly YH *et al.* . Sexual history-taking among primary care physicians. *J Natl Med Assoc.* 2006

⁴ Kurth AE. A national survey of clinic sexual histories for sexually transmitted infection and HIV screening STD 2005

⁵ Laws MB, Discussion of sexual risk behavior in HIV care is infrequent and appears ineffectual: *AIDS Behav.* 2011

⁶ Metsch LR. Delivery of HIV prevention counseling by physicians at HIV medical care settings in 4 US cities. *Am J Public Health.* 2004

⁷ Duffus WA, Effect of physician specialty on counseling practices /referral patterns among physicians caring for disadvantaged HIV populations. *CID* 2003

⁸ Sarah K. Calabrese A Closer Look at Racism and Heterosexism in Medical Students' Clinical Decision-Making Related to HIV (PrEP): Implications for PrEP Education AIDS 2018

Need for STI Screen

- Can we blame PrEP

■ Baseline STI rates

- 60% with STI in 12 mths prior (PROUD)
- 38% of trans had STI in prior 6 mths (iPrEX Trans³)
- 27 % had STI at beginning of study (IPERGAY)

□ During studies

- Risk compensation⁴
 - **30% had more condomless sex @4 mths**
 - STI overall increased
- 30-35% had STI^{1,2}
 - **Rectal chlamydia & urethral GC**

□ PrEP independently associated with new STI ⁵

- Rate: 24.6 per 100 person yrs, vs 10.4 per 100 person-yrs in non-PrEP users

1 Volk JE, Marcus JL, Nonew HIV infections with increasing use of HIV PrEP. CID .2015

2. Volk, J et al. JAIDS 2016;73(5):540-46 (Kaiser:)

3 Deutsch HIV PrEP in transgender women: iPrEx trial. Lancet HIV. 2015

4. STRUT Gibson, S. et al. AIDS 2016

5 Mayer STI in MSM Boston community healthcenter (2005-2015). Open Forum Infect Dis. 2017

Screen more

!!!!

The Evidence:

1) The PrEP data

PrEP: Who Needs It?

MSM	Heterosexual Men and Women	Injection Drug Users
<ul style="list-style-type: none"> Commercial sex workers HIV+ partner Recent STI Multiple partners Inconsistent/No condom use 	<ul style="list-style-type: none"> Commercial sex workers HIV+ partner Recent STI Multiple partners Inconsistent/No condom use High prevalence area 	<ul style="list-style-type: none"> HIV positive injecting partner Sharing needles/injection equipment

Transgender People

Trans women of color²
(National HIV/AIDS Strategy 2010, 2015)

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/risk/prep/index.html> (2017 guidelines)
- Herbst JH, Jacobs ED, Finlayson TJ, et al. Estimating HIV prevalence and risk behaviors of transgender persons in US. AIDS Behav 2008
- https://www.cdc.gov/mmwr/volumes/68/wr/mm6827a1.htm?s_cid=mm6827a1_

GUIDANCE ON PRE-EXPOSURE ORAL PROPHYLAXIS (PrEP) FOR SERODISCORDANT COUPLES, MEN AND TRANSGENDER WOMEN WHO HAVE SEX WITH MEN AT HIGH RISK OF HIV: Recommendations for use in the context of demonstration projects
 July 2012



PrEP Options for transgender

1. TDF/FTC 1 pill taken daily (PrEP guideline supported)



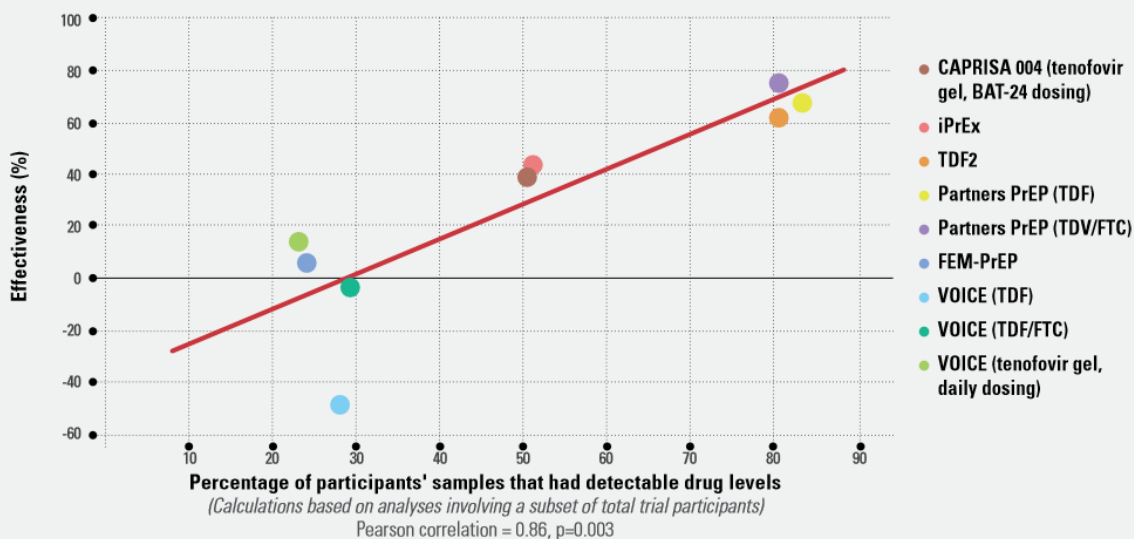
2. TAF/FTC –FDA Antimicrobial Drugs Advisory Committee has recommended for MSM and transgender women (July 2019)- pending FDA official approval and incorporation into guidelines



PrEP: Efficacy and Adherence

- If drug detected in blood, effectiveness of PrEP = **90-92%**
 - 92-100% if levels equivalent to daily use² (Post Hoc iPrEx)
 - 0 conversions if at least 4 doses taken³

Effectiveness and Adherence in Trials of Oral and Topical Tenofovir-Based Prevention



Adherence=
Efficacy

Trials of oral and topical tenofovir-based PrEP show that these strategies reduce risk of HIV infection if they are used correctly and consistently. Higher adherence is directly linked to greater levels of protection.

Source: Salim S. Abdoal Karim, CAPRISA

AVAC Report. 2013

2 Anderson . Intracellular TDF/FTC dried blood spots following DOT . Antimicrob Agents Chemother. 2017

3 Anderson iPrEx Study Team. PrEP efficacy in men who have sex with men. Sci Transl Med. 2012

PrEP: TDF/FTC in Transgender

The Earlier Studies

Trial	Where	Who	What	Efficacy	Efficacy by blood detection of drug
1. iPrEx ¹ n=2499 (2010)	SA, US, South Africa, Thailand	MSM high risk+ Trans women	TDF-FTC or placebo	44% TDF-FTC	0 conversions in those with levels consistent with daily use ²

Open Label Studies with good outcomes- TDF/FTC

What, where, when	Participants (n)	Efficacy Estimates %	Efficacy by blood detection of drug
Demo (3 centers, US)	MSM (552 [^]) MtF (5)	HIV incidence 0.43 per 100 py	2 seroconverters had levels equivalent to <2 doses/wk

<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>

1. Grant PrEP for HIV prevention in men who have sex with men. N Engl J Med. 2010

2 Anderson iPrEx Study Team. PrEP efficacy in men who have sex with men. Sci Transl Med. 2012

Demo - Liu JAMA. 2016[^]

PrEP: TDF/FTC in Transgender

iPrEx Trial had 339 Trans women (MtF) only

- Compared with MSM, MtF more frequently reported transactional sex, receptive anal intercourse without a condom, or >5 partners in the past 3 months
 - PrEP did not affect behavior
- Overall adherence, less for MtF
- 11 MtF converted vs 10 in placebo group
 - At time of conversion, none had detectable drug levels (n=6)
- **if > 4 tablets/week, rate of infection per 100,000 pt/yr = 0**

Deutsch HIV PrEP in transgender women: iPrEx trial. Lancet HIV. 2015

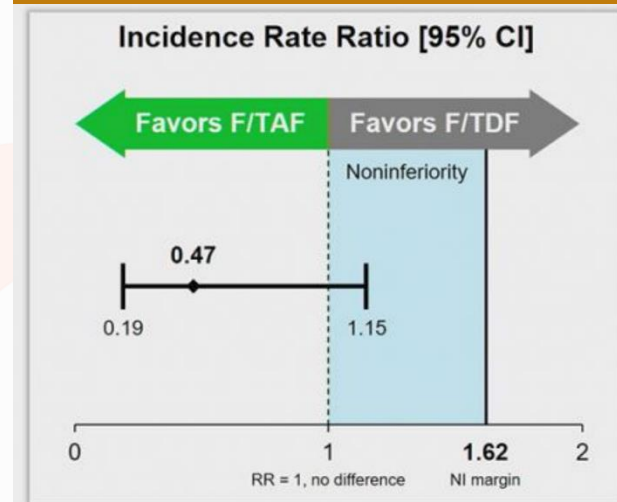
Similar barriers to adherence as women

PrEP: TAF/FTC in Transgender

- Truvada (FTC /TDF) only fully FDA approved drug for PrEP
- In treatment trials TAF less renal toxicity and bone toxicity than TDF
- Can FTC/TAF (Descovy®) be used for PrEP?

- RCT of Truvada® versus Descovy® for PrEP
 - MSM and TGW
 - Enrolled ~6000
 - **74 TGW**
 - Followed- 96 wks
 - 9% black
 - High rates STI and chem-sex

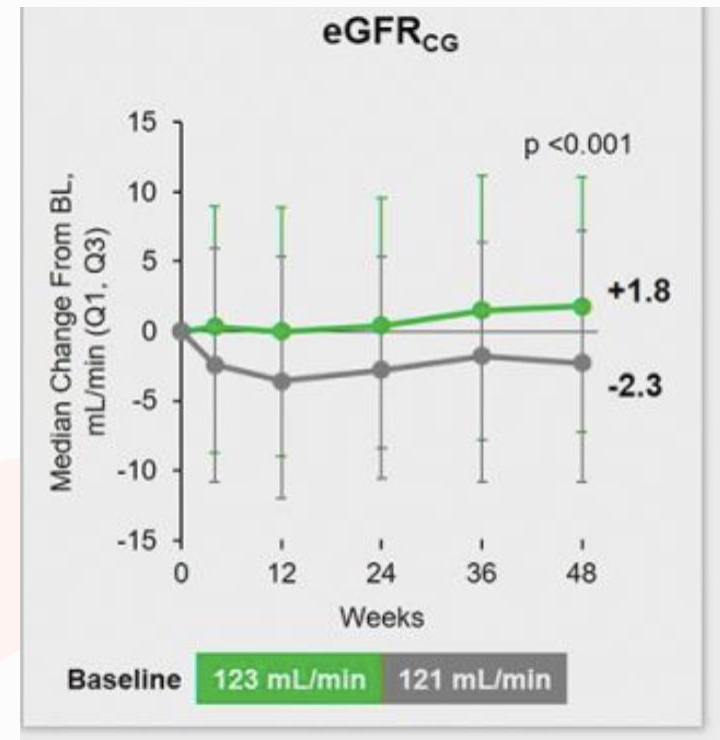
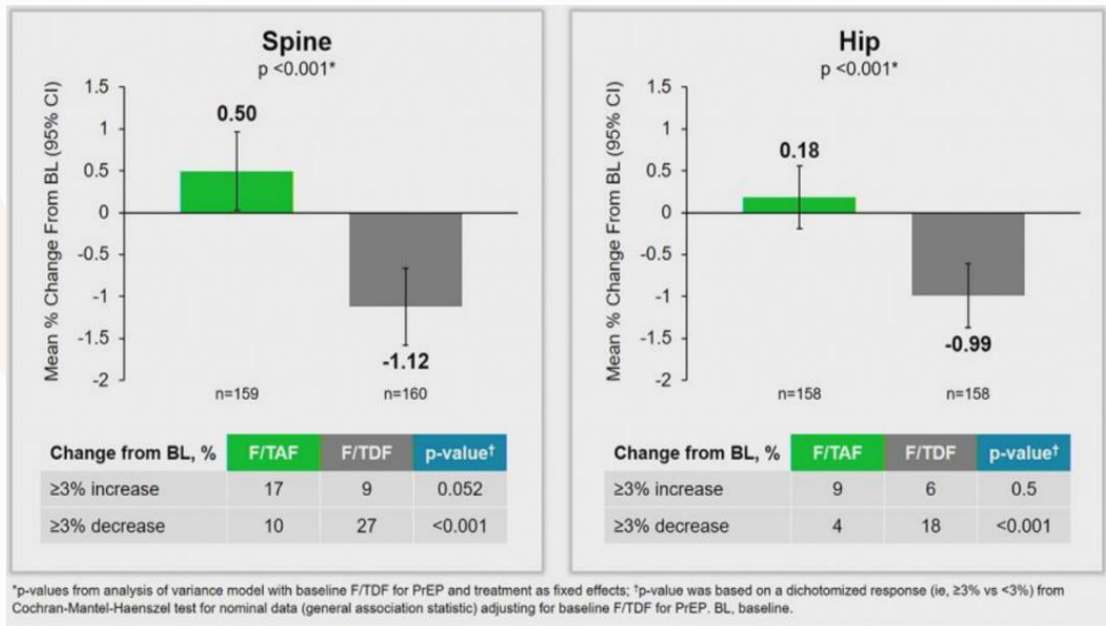
- 22 HIV transmission
- 7 TAF and 15 TDF



CROI 2019-Discover: Phase III RCT of F-TAF vs. F-TDF for PrEP

PrEP: TAF/FTC in Transgender

F-TAF safer for bone and kidney health



CROI 2019-Discover: Phase III RCT of F-TAF vs. F-TDF for PrEP

On-Demand or Event-Driven PrEP ("2-1-1") Pericoital TDF/FTC

International Antiviral
Society–USA Panel
Saag et al JAMA 2018

Approved in France

- **MSM** with infrequent sexual exposures (IPERGAY^{1,2})
 - 2 doses with food 2-24hrs before sex
 - 1 dose 24 hours after the first (double) dose
 - 1 dose 24 hours later
- Detectable levels in colorectal tissue in 81% and 98% of the population when administered 2 and 24 hours prior³
- For consecutive sexual contacts,
 - Initiate double dose, then 1 pill/day until 2 days after the last encounter
- Not if Hep B+

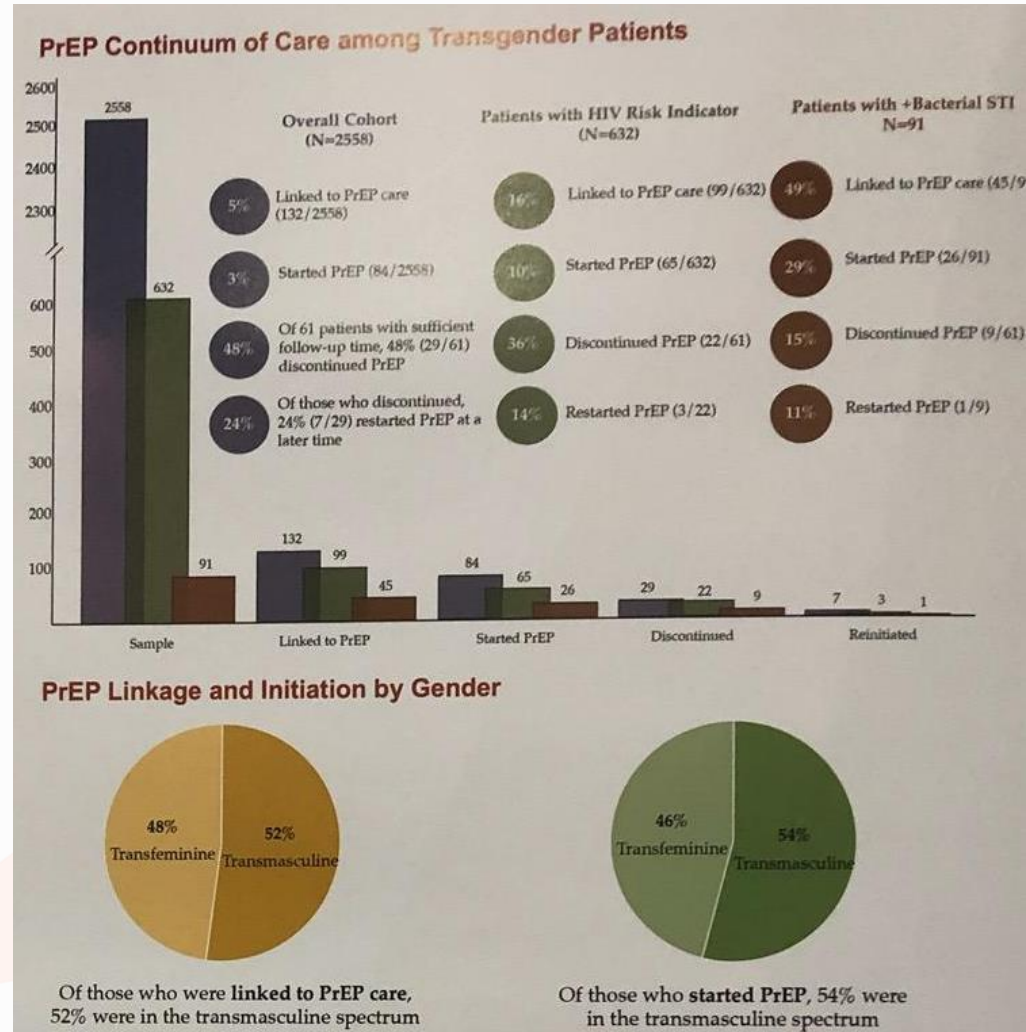
Lack of data:
transgender

1. Molina *N Engl J Med.* 2015; 2 Molina 9th International AIDS Society Conference 2017; 3 Cottrell *J Infect Dis.* 2016

The Reality: PrEP Continuum of Care

PrEP Continuum in Transgender

- Kaiser gp (2012-2019)- n=2558 pts (HIV negative)
- Majority of trans pt in care – white, average age 33, 51% trans woman
- Higher rates of Discontinuation in those with ETOH/ Substance abuse

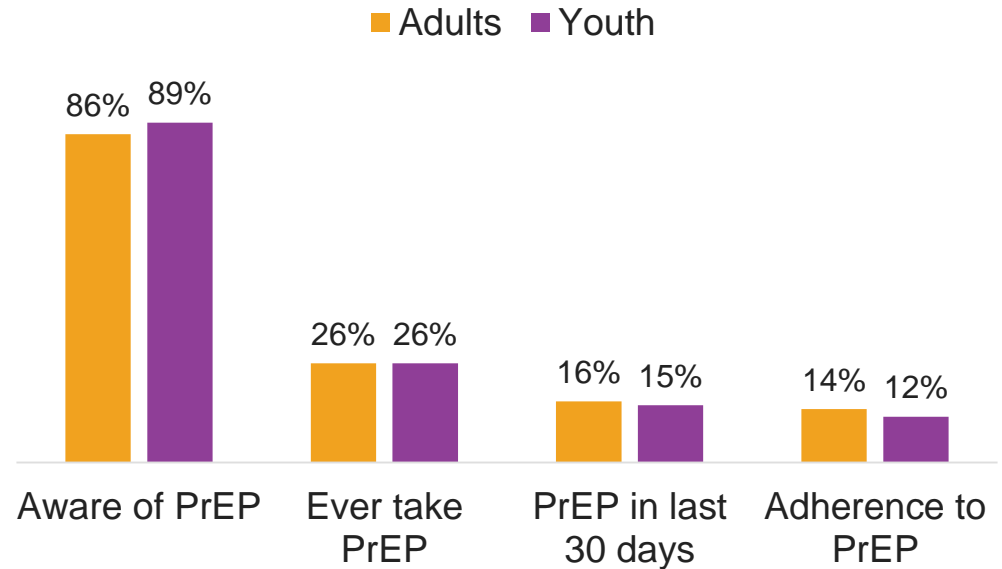


PrEP continuum in Transgender Women

The LITE Study

- HIV uninfected MtF(TGW) in 6 cities (incl. South)
- 3 months visits with testing and survey
- App-based GPS data collection, some self testing

PrEP Continuum in TGW



PrEP: The Reality for Transgender

- Does PrEP interfere with gender affirming hormones? No
 - No significant drug interactions observed: sex hormones and PrEP^{1,2}
 - TDF/FTC cleared by kidney
 - Estrogens metabolized by liver
 - Lower TFV(metabolite) levels for TW on feminizing hormones
 - When not addressed with patients, adherence with PrEP declined due to fear of drug-drug interaction with hormones³

1 WHO endorsed

2 Kearney Lack of effect of TDF on pharmacokinetics of hormonal contraceptives. *Pharmacotherapy*. 2009

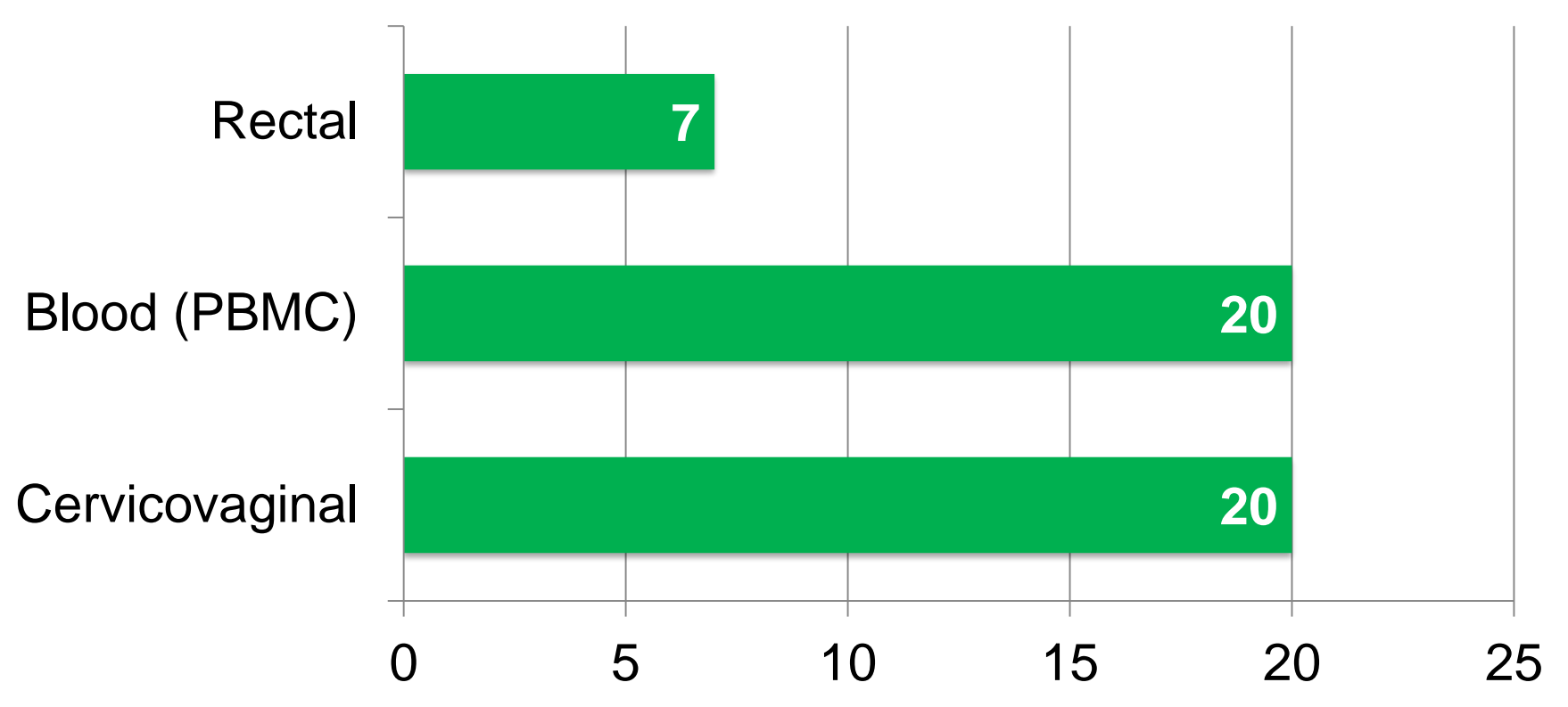
3 Deutsch HIV PrEP in transgender women: iPrEx trial. *Lancet HIV*. 2015

Additional Reasoning for Sexual History

When does protection start (daily PrEP)

Special consideration for Trans

Time to Maximum Intracellular Concentration of Tenofovir Diphosphate (TFV-DP)



The Work Flow

PrEP Algorithm/ Workflow

Every visit(Q 3mths):

- Greet appropriately
- Assess adherence
- Risk reduction counseling
- Provide condoms
- HIV Screen → refills
- STI screen

**Bolded items
mandatory**

PrEP Orientation Visit:

- Discuss PrEP use
- Review insurance coverage/med. assistance
- Perform baseline laboratory tests:
 - **HIV Ab/Ag screen[^] (4th generation)**
 - Cr
 - **Hepatitis Bs Ag/Ab** and cAb
 - Hepatitis C Antibody
 - RPR/Trep Ab
 - Triple site GC/CH testing- Urine, Rectal, Oral (based on exposure)
 - **Pregnancy test** (if female)

Initial Provider Visit:

- Discuss PrEP use (7 day interval before adequate levels in rectal tissue and 20 days for vaginal tissue/blood; compliance; SE)
- Risk reduction counselling, condoms
- PrEP Clinic Questionnaire(initial)
- Provider visit
- Symptom history to r/o acute HIV
- 30-day supply of PrEP (**start within 7 days of HIV screen**)

30-day visit:

- Adherence review with nurse/ PharmD, risk reduction counselling, assess side effects
- Cr

60-day supply of PrEP

3-month visit:

- PrEP Clinic Questionnaire (short)
- Provider visit, risk reduction counselling, condoms
- **HIV Ab/Ag Test, Pregnancy test, STI screen in MSM[^] (RPR/Trep Ab, GC/CH(triple site))**

90-day supply of PrEP

6-month visit/ 12 month visit:

- PrEP Clinic Questionnaire (long)
- Provider visit, risk reduction counselling, condoms
- **HIV Ab/Ag , Pregnancy test, Cr, RPR/Trep Ab, GC/CH(triple site), Hep C ab annually**

90-day supply of PrEP

9-month visit:

- PrEP Clinic Questionnaire (short)
- Provider visit , risk reduction counselling, condoms
- **HIV Ab/Ag, STI screen in MSM(RPR/Trep Ab, GC/CH(triple site))**

90-day supply of PrEP

After the 12 month visit: (Re-evaluation of need for continuing PrEP)

Q 3 monthly visit with Adherence nurse/ Pharm D, risk reduction counselling, , condoms.

- PrEP Clinic Questionnaire (short)
- **HIV ab/ab q 3 monthly** and STI screen q 3 monthly in MSM
- 90 day supply of PrEP

Q 6 monthly visit with Provider

- **Pregnancy test, Cr, RPR/Trep Ab, GC/CH(triple site) ,Hep C**
- 90-day supply of PrEP, condoms

Provider Name: _____ Site Name: _____

Age: 24 Race: W Gender: Male Female Trans-female Trans-male

Concomitant Medical Diagnosis	Current Medications
	Testosterone cypionate 20mg weekly
	Adderall 15mg twice daily

Insurance: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Copay assistance needed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Drug assistance needed <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Risk factors: (Check all that apply)				
MSM <input type="checkbox"/>	Recent STI <input type="checkbox"/>	Multiple sex partners <input type="checkbox"/>	HIV positive partner <input type="checkbox"/>	IVDU/Sharing needles <input type="checkbox"/>
Inconsistent condom use <input checked="" type="checkbox"/>	Commercial sex work <input type="checkbox"/>			

Health Maintenance	Description	Risk Reduction Counselling/Intervention
1. Smoking		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
2. Use of Alcohol/Amount		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
3. Substance Use		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
4. Mental Health Assessment		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
5. Pregnancy/Contraception		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
6. Condoms use		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Laboratory Test results and date					
HIVAg/Ab screen	Non-reactive	Cr 0.74		CrCl 113	
Hepatitis Bs Ag	Non-reactive	Hepatitis Bs Ab	6.33	Pregnancy test	
HCV ab with reflex	Non-reactive		Heplisav-B		

1. What to address first PrEP or Medical gender affirmation?
2. Pregnancy test / PAP smear ?
3. Types of partner/orientation?
4. How often needs to be seen?

Case 2- Here for PrEP

Provider Name: _____ Site Name: _____

Age: 20 Race: W Gender: Male Female Trans-female Trans-male

Concomitant Medical Diagnosis	Current Medications
	Estradiol 2mg daily
	Spirolactone 50mg daily
	h/o Adderall

Insurance: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Copay assistance needed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Drug assistance needed <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Risk factors: (Check all that apply)				
MSM <input type="checkbox"/>	Recent STI <input type="checkbox"/>	Multiple sex partners <input type="checkbox"/>	HIV positive partner <input type="checkbox"/>	IVDU/Sharing needles <input type="checkbox"/>
Inconsistent condom use <input checked="" type="checkbox"/>	Commercial sex work <input type="checkbox"/>			

Health Maintenance	Description	Risk Reduction Counselling/Intervention
1. Smoking		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
2. Use of Alcohol/Amount		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
3. Substance Use		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
4. Mental Health Assessment		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
5. Pregnancy/Contraception		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
6. Condoms use		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Laboratory Test results and date					
HIV Ag/Ab screen	Non-reactive	Cr 1.0		CrCl 113	
Hepatitis Bs Ag	Non-reactive	Hepatitis Bs Ab	3.04	Pregnancy test	
HCV ab with reflex	Non-reactive		Heplisav-B		

1. Potential drug-drug interactions?
2. Types of partner/orientation?
3. How often needs to be seen?

Overcoming Barriers for PrEP in Trans

- **HIV behavioral interventions not adequate**
 - 2017, CDC awarded \$11 million/year for 5 years to 30 CBOs for HIV testing in young gay/bisexual men & trans youth of color (1 SC site)
- Many transgender people **face stigma, discrimination, social rejection, and exclusion**
 - Education for HCP and Staff
- Transgender women and men **might not be sufficiently reached by current HIV testing** measures
 - Tailoring HIV testing activities to overcome the unique barriers
- **Transgender men's sexual health** has not been well studied
 - FtM, who have sex with cisgender men are at high risk for infection

Overcoming Barriers for PrEP in Trans

- **Insensitivity to transgender issues** by providers
 - Few with proper training /knowledge about transgender health issues → negative health care encounters
- **Transgender people might not fully engage in medical care**
 - Medical gender affirmation/stigma in HIV care associated with missing appointments¹ → **risk of HIV transmission**
 - 40% of FtM in care for HIV had detectable VL over prior 12 mths²
 - 50% of MtF had detectable VL over the prior 12 mths³
- **Transgender-specific data are limited**
 - Two-step data collection method of asking for sex assigned at birth and current gender identity → Accurate data on transgender status

1 Reisner Characterizing the HIV Prevention and Care Continua in a Sample of Transgender Youth in the U.S. AIDS Behav. 2017

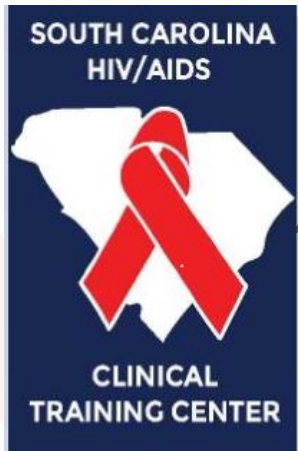
2 Lemons, Characteristics of HIV-Positive Transgender Men Receiving Medical Care: United States, 2009–2014 . ajph 2018

3 Mizuno , Characteristics of Transgender Women Living with HIV LGBT Health. 2015

<https://www.cdc.gov/hiv/group/gender/transgender/index.html>



Palmetto Health USC
MEDICAL GROUP



PrEP for Transgender

QUESTIONS?

SOUTH CAROLINA HIV PrEP INITIATIVE



HIV PRE-EXPOSURE PROPHYLAXIS (PrEP)
EDUCATION TRAINING CONSULTATIVE SUPPORT CO-MANAGEMENT

KAMLA SANASI-BHOLA, MD

PRONOUNS: SHE, HER, HERS
ASSISTANT PROFESSOR OF IM
DIVISION OF INFECTIOUS DISEASES
PHUSCMG
KAMLA.SANASI@USCMED.SC.EDU

OMAR LUCAS, PHARMD

PRONOUNS: HE, HIM, HIS
DIVISION OF INFECTIOUS DISEASES
PHUSCMG
OMAR.LUCAS@USCMED.SC.EDU