

IAC 2019

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Lost in Translation: PrEP Implementation & Transgender People

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Disclosures

No Conflicts of Interest to Disclose

Sex & Gender

Sex

- Assigned at birth: male, female
- Based on biology: anatomy, chromosomes, hormones
- Gender Identity
 - One's sense of self as a gendered or non-gendered person (man, woman, both, neither)
 - Children aware of gender differences by ages 1-3 years
 - Can label themselves boy/girl by age 3
 - Gender constancy age 4

Campbell et al,. *Br. J. Psychol*, 2002; Zosuls et al., *Dev Psychol* 2009; Martin et al,. *Annu Rev Psychol* 2010; Zmyj & Bischof-Köhler, *J Cognition Dev* 2015

Transgender Populations

- People whose gender identity or expression is different from their sex assigned at birth
- Cultural/linguistic differences
- Transgender women: people who were assigned male at birth but identify as women
- Transgender men: people who were assigned female at birth but identify as men
- Other genders: nonbinary, genderqueer, gender nonconforming, agender, gender expansive

two spirit travesti meti waria hijra kothi fa'afafine travesti kinnar genderqueer transpinoy aravani aruvani jagappa shiv-shakthis jogti hijras third gender trans thirunangi

Global Estimates of Transgender Persons

- Approximately 25 million transgender people worldwide
- USA
 - 1 million trans adults (0.4%)
 - 2% of US high school students
- Europe (UK, Belgium, Netherlands) 0.6-0.9%

Winter S, Lancet. 2016; Meerwijk & Sevelius. AJPH, 2017; Johns MM, *MMWR* 2019; Glenn & Hurrell, Equality and Human Rights
Commission 2012; Kuyper and Wijsen, Arch Sex Behav 2014; Van Caenegem et al. Arch Sex Behav 2015; Winter, et al. Lancet 2016



35% trans youth bullied in schools

- Johns MMWR 2019

47% face family rejection
- USTS 2015

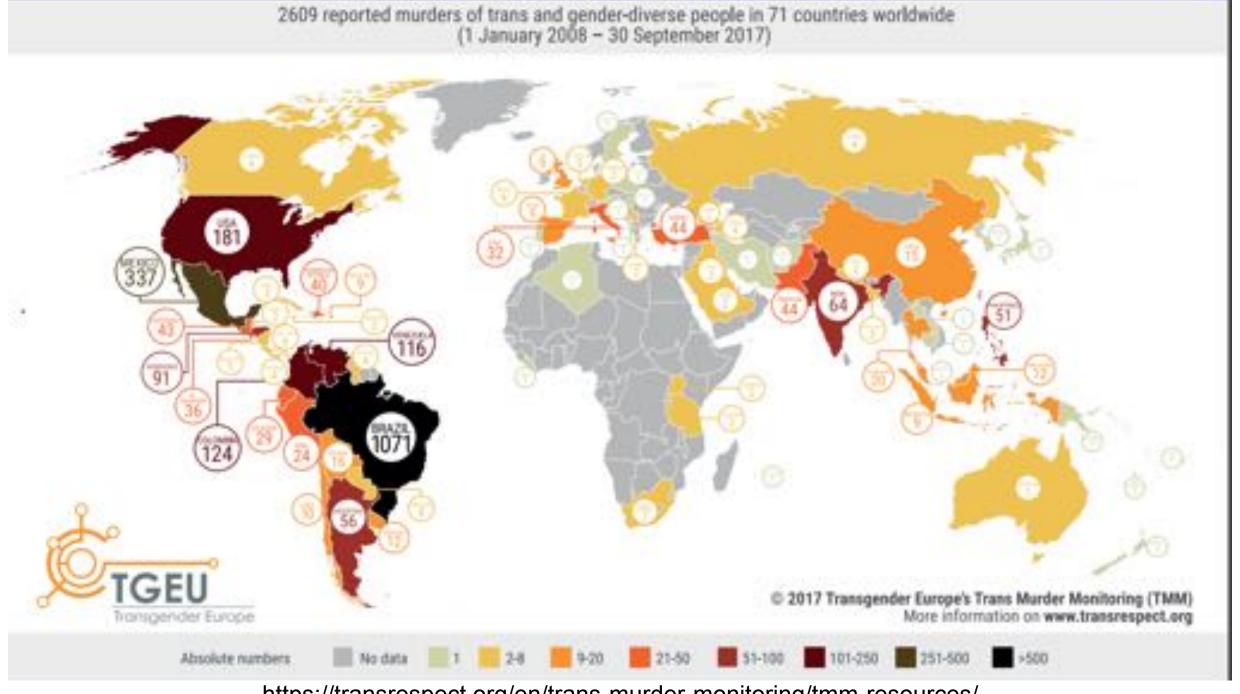
40% reported ever attempting suicide 10% within the last year – USTS 2015, Bauer 2015

29% live in poverty
- USTS 2015

14% experienced homelessness
- USTS 2015

1 in 3 faced discrimination in healthcare settingsUSTS 2015

1 in 4 avoided medical care due to fear of mistreatment – USTS 2015



https://transrespect.org/en/trans-murder-monitoring/tmm-resources/

Summary of the Global HIV Epidemic (2017)

People living with HIV in People newly infected HIV-related deaths 2017 2017 with HIV in 2017 36.9 million 1.8 million 940 000 [1.4 million – 2.4 million] [670 000 – 1.3 million] [31.1 million – 43.9 million] 1.6 million 35.1 million 830 000 [1.3 million – 2.1 million] [590 000 – 1.2 million] [29.6 million – 41.7 million] 18.2 million [15.6 million – 21.4 million] Women 16.8 million [13.9 million – 20.4 million] 110 000 1.8 million 180 000 [63 000 – 160 000] [1.3 million – 2.4 million] $[110\ 000 - 260\ 000]$

Source: UNAIDS/WHO estimates





"What message are we sending to young people who are trans and gendernonconforming when we don't everveustiggest that their identities don't even matter."

- Laverne Cox 2015



Global Burden of HIV in Transgender Women

THE LANCET

Infectious Diseases

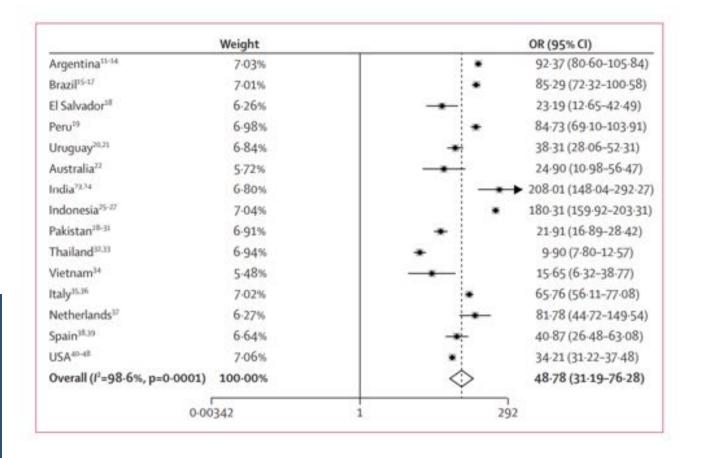


Articles

Worldwide burden of HIV in transgender women: a systematic review and metaanalysis

39 studies, 15 countries: Pooled HIV prevalence of 19.1% (95% CI 17.4–20.7) in 11,066 transgender women worldwide

OR 49-fold higher than general population

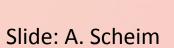




Global burden of HIV among Transmasculine Persons

- Quantitative data very limited^{1,2}
 - Lab-confirmed HIV+: 0-4%
 - Self-report: 0-10%
- Choosing the right denominator
 - e.g., 63% of trans men identified as gay, bi, queer but only 1/3 of this group had sex with cis men³





¹ Reisner & Murchison. Global Public Health. 2016.

² Poteat et al. JAIDS, 2016.

³ Scheim et al. *JAIDS*. 2017.

HIV Incidence Transgender Women

• Spain: 1.2/100 p-y

Peru: 2.3/100 p-y

• USA: 2.8/100 p-y

• iPrEX: 3.6/ 100 p-y

Argentina: 10.7 per 100 p-y

Kenya 20 per 100 p-y

Castillo R, JAIDS 2015; Diez M, Euro Surveill. 2014; Buchbinder SP, Lancet Infect Dis. 2014; Nuttbrock L, AIDS Behav. 2015; Buchbinder SP, Lancet Infect Dis. 2014; Kimani M JIAS 2019

Criteria for PrEP

WHO 2015: Incidence > 3 per 100 person-years

IAS-USA guidelines: Incidence > 2 per 100 person-years



PrEP: Results from Clinical Trials

	—						
	Modified ITT efficacy of the second s		ion in nof HIV	Adherence-adjusted efficacy based on drug detection in blood ^b			
Clinical trial	Participants	Number	Drug	%	(95% CI)	%	(95% CI)
iPrEx	Men who have sex with men & transgender women	2499	FTC-TDF	44	(15-63)	92	(40-99)
Partners	HIV discordant	4747	TDF	67	(44-81)	86	(67-94)
PrEP	couples		FTC-TDF	75	(55-87)	90	(58-98)
TDF2	Heterosexually active men and women	1219	FTC-TDF	63	(22-83)	85°	NS ^c
Bangkok Tenofovir Study	Injection drug users	2411	TDF	49	(10-72)	74	(17-94)
Fem-PrEP	Heterosexually active women	2120	FTC-TDF	NR		NR	
VOICE	Heterosexually active women	5029	TDF FTC-TDF	NR		NR	

a. Excluded only those enrolled patients later found to be infected at randomization and those with no follow-up visit or HIV test.

b. The percentage of reduction in HIV incidence among those with tenofovir detected in blood, compared with those without detectable tenofovir.

c. Finding not statistically significant.

PrEP Efficacy in Transgender Women

THE LANCET

296 identified as trans
29 as women
14 as men but using feminizing hormones
339 (14%)

of the iPrEx trial

Dr Madeline B Deutsch MD ^a $\stackrel{>}{\sim}$ $\stackrel{\boxtimes}{\sim}$, Prof David V Glidden PhD ^a, Jae Sevelius PhD ^a, Joanne Keatley MSW ^a, Vanessa McMahan MS ^b, Juan Guanira MD ^c, Esper G Kallas MD ^d, Prof Suwat Chariyalertsak MD ^e, Prof Robert M Grant MD ^{a, b, f} $\stackrel{\boxtimes}{\sim}$ $\stackrel{\boxtimes}{\sim}$, iPrEx investigators [†]

- Trans women: 339/2499 (14%)
- Lack of efficacy: HR 1.1
 - Low adherence to TDF 18%
 - TFV-DP detected in no trans women at seroconversion
 - No seroconversions observed in trans women with TDP levels on ≥ 4 pills/week
 - Hormone use associated with lower TFV-DP levels

Adherence? Interactions?

PrEP Efficacy in Transgender Women





Decreased Tenofovir Diphosphate Concentrations in a Transgender Female Cohort: Implications for Human

Resear

Estrogen levels do not change with TDF/FTC

Serum tenofovir levels are reduced in the presence of estrogen

Clinical significance is not known

Transgender women on hormones may need greater adherence to oral PrEP

Observed Dosing When Compared to Cis Men

Eugenie Shieh¹, Mark Marzinke¹, Edward Fuchs¹, Rahul Bakshi¹, Aung Wutyi¹, Tonia Poteat², Todd Brown¹, Namandje Bumpus¹, <u>Craig Hendrix</u>¹ Johns Hopkins University School of Medicine, United States, ²Johns Hopkins Bloomberg School of Public Health, United States

Hiransuthikul A et al. J Int AIDS Soc. 2019; Hendrix et al. HIV4RP 2018 #OA23.03; Cottrell ML, et al. CID 2019.

More to Consider



looking for something?

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The Vaginal Microbiome of Transgender Men

Gabrielle Winston McPherson, Thomas Long, Stephen J. Salipante, Jessica A. Rongitsch, Noah G. Hoffman, Karen Stephens, Kelsi Penewit, Dina N. Greene D0t: 10.1373/clinchem 2018 293654 Published January 2019

DNAinfo New York neighborhood news

More to Consider

Woman Killed 22-Year-Old With Silicone Butt Injections, Police Say

By Murray Weiss, Danielle Tcholakian and Aidan Gardiner | March 11, 2014 9:31am | Updated on March 11, 2014 2:45pm

MANHATTAN — A woman who fatally injected a 22-year-old mother's buttocks with silicone at a pay-by-the-hour Meatpacking District hotel left her patient writhing and foaming at the mouth for 90 minutes before summoning help, sources said.

Tamira M. Mobley, a 28-year-old from Wood Ridge, N.J., was arrested Monday and accused of



- View Full Caption

Facebook/Tamara Blaine

killing Tamara Blaine, who was found convulsing on a bed inside a second-floor room at the Liberty Inn Hotel, at 51 10th Ave., at 12:33 p.m. on July 8, police said.

Blaine, whose obituary listed her as a college freshman at the time, was taken to St.





LITE Study*

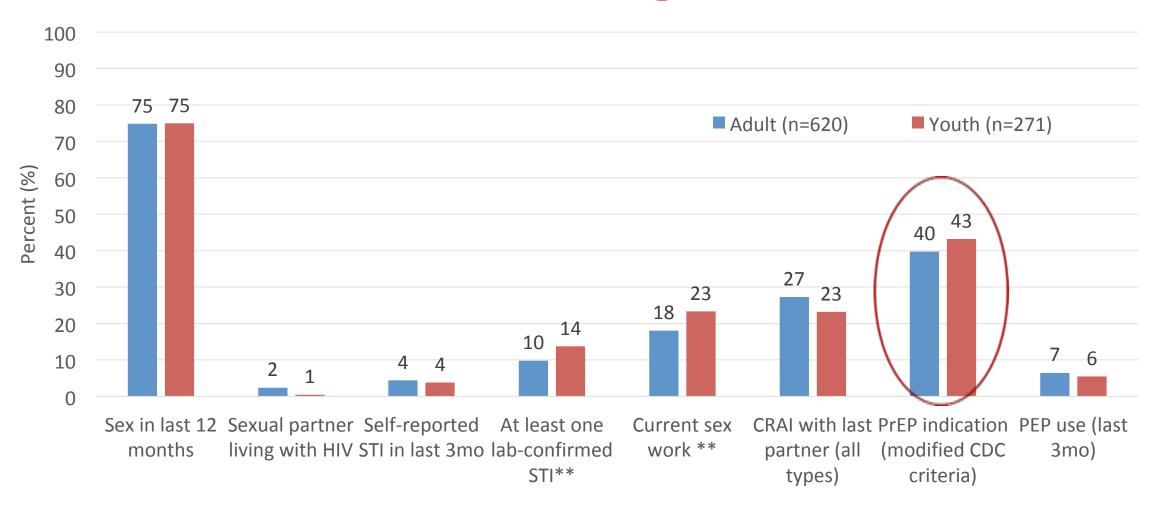
- Enrollment: 1,100 HIV uninfected transgender women in 6 cities, eastern and southern United States
- Study visits: every 3mo. for 24 months
 (facility-based or online)
 Survey + oral HIV testing every 3 months
 STI testing inc. self-collected swabs every 12
- App-based GPS data collection

months



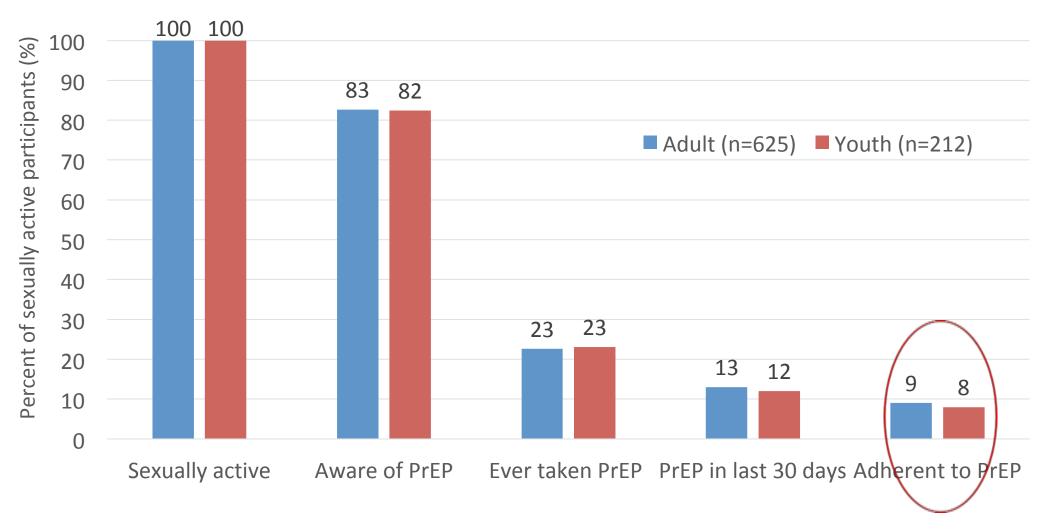


Indications for PrEP among LITE Participants





PrEP continuum among Transgender Women

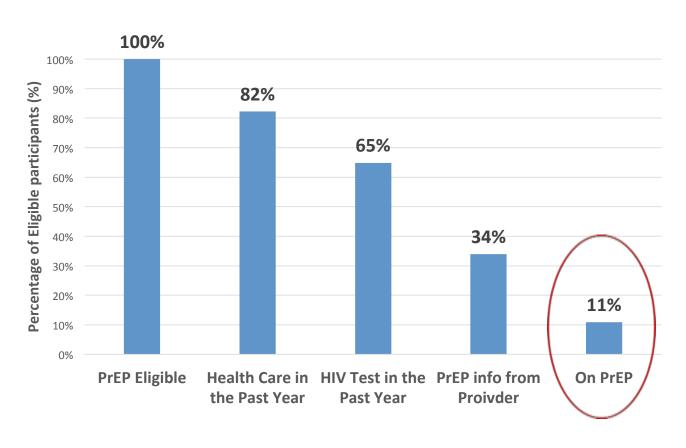


^{*}Poster TUPEC482

PrEP Continuum for Transgender Men

- USA online survey conducted (2017) among 1808 transmasculine individuals, ages 18-60
- Almost one quarter of the sample (n = 439; 24.3%) met one or more criterion for PrEP

N=1808	#	%
Any Condomless receptive anal or vaginal sex	130	18.3%
Condomless receptive anal sex	129	7.1%
Condomless vaginal receptive sex	290	16.0%
STI history in past year	99	5.5%
Sex work in past 6 months	62	3.4%
Heroin use	5	0.3%
5 or more cismale/trans female partners in past year	103	5.7%
PrEP Eligible	439	24.3%



Golub & Klein, JAIDS 2019

Barriers/Facilitators for PrEP in Trans People



- Transgender-inclusive and gender affirming sexual health
- Trans-competent providers
- Materials/health promotion
- Hormones prescribed at clinic
- Active provider engagement and assistance around PrEP
- Community mobilization

Barriers to PrEP

- Conflating TW with MSM
- Mistrust of providers
- Worried about side effects
- Low HIV-risk perception
- HIV stigma
- Lack of trans-inclusive marketing
- Concerns about hormone interactions
- Consent (minors)
- Pill size

Affirming Spaces



Tangerine Clinic, trans-led hormone integrated sexual health, Thailand

First impressions are important

- Assess and change current clinical environment
 - Intake forms inclusive of multiple gender identities and sexualities
 - Affirm gender: Use chosen names and pronouns
 - Knowledgeable providers
 - Assess psychosocial/material needs
 - Use trans images on education materials, brochures, website
 - Gender neutral/inclusive bathrooms
 - Hire trans-identified staff



HIV Screening





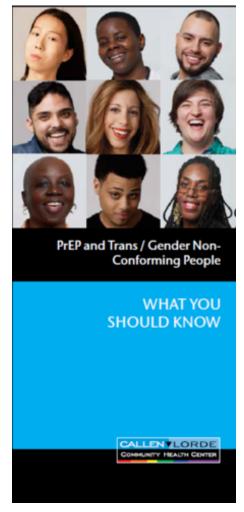






Scaling up PrEP



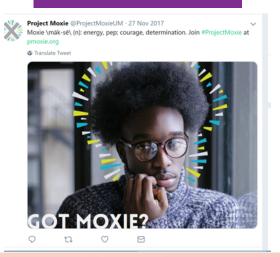




Projects in Progress

- PrEP 3 demonstration studies (18+)
 - TRIUMPH Project ("Trans Research-Informed communities United in Mobilization for the Prevention of HIV")
 - The Stay Study: A Demonstration Project Advancing PrEP Delivery in the San Francisco Bay Area Transgender Community
 - iM-PrEPT! Study
- PrEP clinical observation studies
 - FIRED UP ("Furthering Investigation into Retention, Engagement and Dynamics of Utilization of PrEP")
- HIV Testing
 - Project Moxie (trans youth 15-24)
- HPTN 091: Integrating HIV Prevention, Gender-Affirmative Medical Care, and Peer Health Navigation to Prevent HIV Acquisition





Take Home Messages

- Trans people experience disproportionate risk for HIV
- Challenges exist with HIV prevention access
- Gender affirmative care essential to PrEP scale-up
- What is needed
 - Uniform collection of gender identity data
 - Meaningful inclusion of trans people in research
 - Not just about PrEP, understand social and structural vulnerabilities to HIV and PrEP access and uptake

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