

# Transgender women, feminizing hormones, and PrEP: What we know and what we need to know

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# Outline

- I. Context: Fenway's work, COE's work on transgender health
- II. PrEP clinical trials and transgender women
- III. Where PrEP research is going
- IV. Findings from SF focus groups with transgender women March 2014
- V. Regulatory developments, CDC and WHO guidance
- VI. Recommendations

Fenway Health,  
Boston, Mass.



# I. Fenway Health

- FQHC, 30,000 patients
- About half are LGBT, and about 2,000 are transgender
- 2,500 patients living with HIV
- Ryan White Part C provider: Largest provider of HIV care in New England
- Have provided HIV/AIDS care, conducted research on HIV/AIDS since early 1980s

POLICY FOCUS

**PRE-EXPOSURE  
PROPHYLAXIS FOR  
HIV PREVENTION:  
MOVING TOWARD  
IMPLEMENTATION**

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# Promoting cervical cancer screening among transgender men





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The National LGBT Health Education Center provides educational programs, resources, and consultation to health care organizations with the goal of optimizing quality, cost-effective health care for lesbian, gay, bisexual, and transgender (LGBT) people.

The Education Center is a part of [The Fenway Institute](#), the research, training, and health policy division of [Fenway Health](#), a Federally Qualified Health Center, and one of the world's largest LGBT-focused health centers.

**HIV and STI Prevention  
Strategies for  
Gay/Bisexual Men and  
Transgender People in**



# Best Practices for a Transgender-Affirming Environment



## Affirmative Care for Transgender and Gender Non-Conforming People: Best Practices for Front-line Health Care Staff

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Post this sheet on your wall or desk as a helpful reminder.

### Best Practices for a Transgender-Affirming Environment



BEST PRACTICES	EXAMPLES
When addressing patients, avoid using gender terms like "sir" or "ma'am."	"How may I help you today?"
When talking about patients, avoid pronouns and other gender terms. Or, use gender neutral words such as "they." <i>Never</i> refer to someone as "it".	"Your patient is here in the waiting room." "They are here for their 3 o'clock appointment."
Politely ask if you are unsure about a patient's preferred name.	"What name would you like us to use?" "I would like to be respectful—how would you like to be addressed?"
Ask respectfully about names if they do not match in your records.	"Could your chart be under another name?" "What is the name on your insurance?"
Did you goof? Politely apologize.	"I apologize for using the wrong pronoun. I did not mean to disrespect you."
Only ask information that is required.	Ask yourself: What do I know? What do I need to know? How can I ask in a sensitive way?

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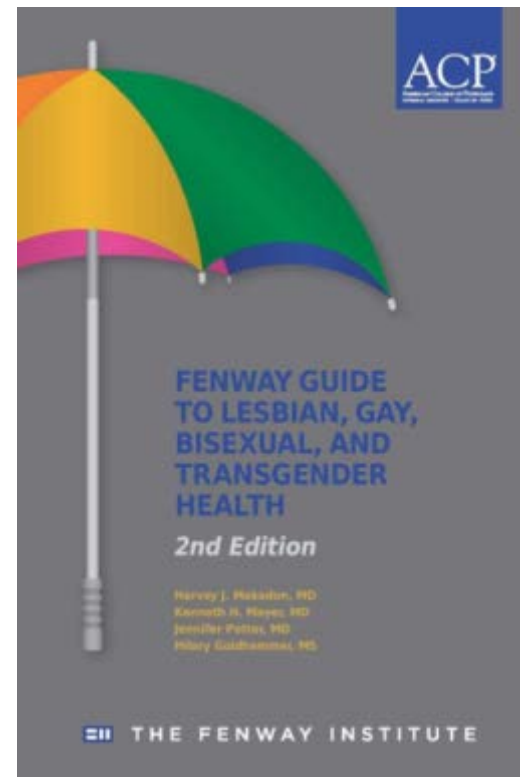


# Fenway Guide to LGBT Health

2008



2015



FENWAY  HEALTH

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DISCRIMINATION AND HEALTH IN  
MASSACHUSETTS: A STATEWIDE SURVEY OF  
TRANSGENDER AND GENDER  
NONCONFORMING ADULTS

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Reisner SL, White JM, Dunham EE, Heflin K, Begenyi J, Cahill S, and the Project Voice Team



Our mission is to increase access to comprehensive, effective and affirming healthcare services for trans and gender-diverse communities



# Current Programs

- CDC- National Capacity Building and Technical Assistance Provider
- UCSF Trans Clinical Services
- HRSA-SPNS TETAC + 9 demonstrations sites
- NIH Research & Intervention Development
- CHRP PrEP Study (new)

## II. Biomedical prevention: using ARVS for prevention

- Transgender women 49x more likely to be HIV-infected
- About 19% of trans women are HIV+ worldwide  
(Source: Baral, Poteat, Stromdahl, et al., *The Lancet*, 2013)
- Pre-exposure prophylaxis (PrEP): taking HIV medications that makes it harder for the virus to infect you
- We do something similar with Malaria medications before we visit places with high Malaria prevalence
- A related prevention approach: post-exposure prophylaxis (PEP)



# iPrEx: First PrEP trial to show efficacy

- Study of MSM and transgender women
- Oral emtricitabine and tenofovir disoproxil fumarate (FTC-TDF) once a day
- 44% lower risk of HIV overall among those who took study drug vs. placebo
- In a nested case-control study, among subjects with a detectable study drug level (i.e. the most treatment adherent), there was a 92% lower rate of HIV infection than among those without a detectable level of FTC-TDF tested in the visit before seroconversion

# Other PrEP trials

- Heterosexual, IDU studies show effectiveness
- Partners PrEP study:
  - 4758 serodiscordant couples in Kenya and Uganda
  - HIV-negative partners/spouses receiving TDF were 62% less likely to contract HIV; those receiving FTC-TDF were 73% less likely
  - Those with detectable drug had 90% lower rate of HIV infection
- Botswana PrEP study
  - 1200 heterosexual men and women
  - Those receiving FTC-TDF were 62.6% less likely to contract HIV than those receiving the placebo.

# Other PrEP trials

- PROUD study
  - English study of oral PrEP with gay and bisexual men, transgender women: PrEP prevented 86% of HIV infections (CROI, 2015)
  - Daily oral PrEP—open label (everyone got PrEP)
- Ipergay study
  - French study of oral PrEP with gay and bisexual men, transgender women: PrEP prevented 86% of HIV infections (CROI, 2015)
  - Intermittent PrEP: 2 pills 24-48 hours before sex, 1 pill 24 hours after, 1 48 hours after; double blind placebo trial

# Other PrEP trials

- IDU study: Bangkok oral PrEP study prevented 49% of HIV infections (74% among those fully treatment adherent)
- Double blind placebo trial with 80% men, 20% women

Source: Choopanya K et al., *The Lancet*, 2013.

# Transgender women in iPrEx

- iPrEx enrolled 2,499 individuals born male who have sex with men in Latin America, the US, South Africa and Thailand
- 2,470 MSM
- 29 said their sex was female; the other 2,470 said male
- When iPrEx first reported in *NEJM* in December 2010, significant transgender participation in the study was not reported
- Subsequent conference presentations reported that 366 of 2,499 iPrEx participants said they were transgender



# Different interpretations of what iPrEx means for trans women

- Grant, Anderson, McMahan et al. (*The Lancet*, 2014) reporting on an open label extension study, describe iPrEx as indicating that “PrEP...prevents the acquisition of HIV among men and transgender women who have sex with men.” (Cite: iPrEx study in *JAMA*, 2010)

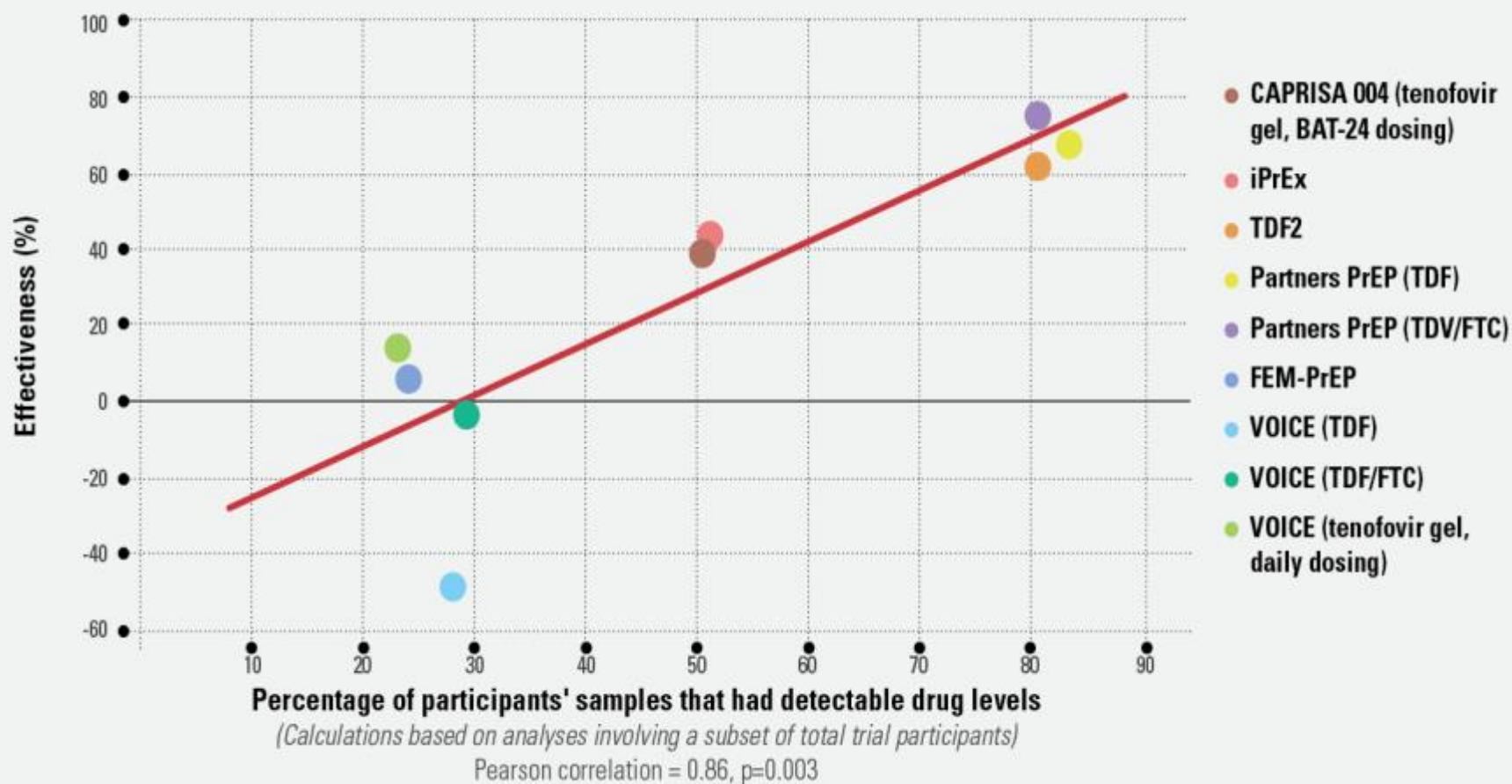
## Grant et al., Uptake of PrEP among MSM, trans women, *The Lancet*, 2014

- 3 open label extension studies (iPrEx, ATN082, US Safety Study).
- 140 transgender women receiving PrEP had lower drug concentrations than the cisgender MSM in the study (O.R. of 0.72).
- “might be a result of lower adherence or different pharmacokinetics: more info is needed.”
- No specific biological reason explains the differences. Hormones should not affect tenofovir levels, since it is primarily renally excreted.

# Thai PrEP acceptability study

- Yang et al., “Acceptability of PrEP among MSM and transgender women in Northern Thailand,” *PLOS ONE* 2013
- 131 MSM, 107 transgender women
- Nearly half of trans participants took oral medicine regularly;  $\frac{3}{4}$  of these feared drug interaction, including with hormones
- Important to address issue of treatment interactions in education campaigns
- Leverage high prevalence of regular medication use into improved PrEP adherence

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

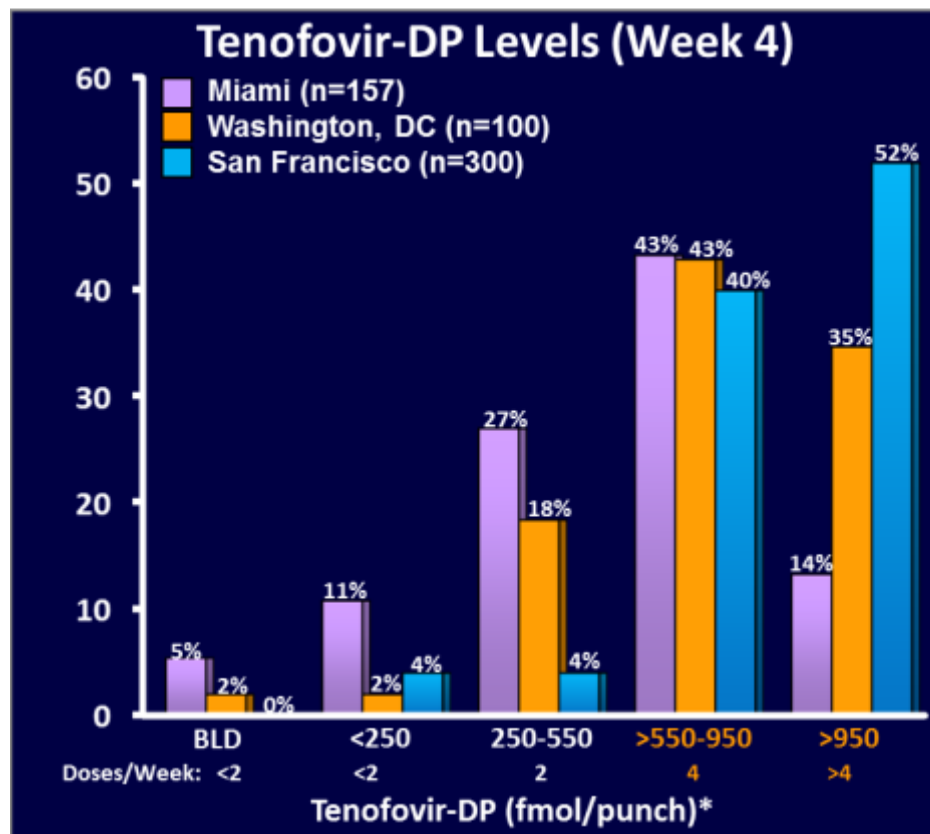


Trials of oral and topical tenofovir-based PrEP show that these strategies reduce risk of HIV infection if they are used correctly and consistently. Higher adherence is directly linked to greater levels of protection.

Source: Salim S. Abdool Karim, CAPRISA

# High Levels of Adherence are Feasible: US PrEP Demonstration Project: (2012-2014)

- STD clinics in San Francisco, Miami, Washington, DC (n=831)
  - MSM, transgender women (1.4%)
  - Clinic referrals (63%)
  - Self-referrals (37%): more likely to be white, higher education level, higher sexual risk behaviors and risk perception versus clinic referrals
- Offered up to 48 weeks of open-label emtricitabine/tenofovir DF
  - Accepted PrEP: 60.4%
    - 77% had TDF-DP levels consistent with taking  $\geq 4$  doses/week
- PrEP uptake associated with
  - Self-referral, prior PrEP awareness, higher-risk sexual behaviors





# Recent analysis of transgender participants in iPrEx and iPrEx OLE

- Deutsch M, Glidden D, Sevelius J, Keatley J, et al. “HIV pre-exposure prophylaxis in transgender women: a subgroup analysis of the iPrEx trial.” *The Lancet*. 2015.
- Reported slightly lower number of trans participants in iPrEx: 339 (14%)
- 11 HIV infections among trans women in PrEP group, 10 infections in placebo group
  - None of the trans women who became infected had detectable drug at visit where HIV first detected
  - Lack of protection for 11 in PrEP group “seems to be primarily a result of low adherence”

# Recent analysis of transgender participants in iPrEx and iPrEx OLE

- Key finding: **PrEP protective in subgroup of trans people with high adherence**
- iPrEx OLE: seroconversion only occurred among trans women using less than two tablets per week on average
  - **No HIV infections among trans women with drug levels consistent with 4+ tablets a week**

# III. Where PrEP research is going

- Less than daily dosing (Ipergay showed effectiveness)
  - Pericoital or intermittent PrEP
- Other oral medications
- Vaginal ring study (Dapivarine)
- Injectable PrEP
- Implants
- Related research: Rectal and vaginal microbicides

# Feminizing hormones and PrEP

- Researchers should explore whether exogenous female hormones interfere with the effectiveness of PrEP
- UCSF analysis indicates no reason to think using feminizing hormones interferes with PrEP
  - Different metabolic pathways of PrEP and estrogens
  - However, no current data on interaction between oral contraceptives or cross-sex hormone therapy and PrEP

# Comprehensive literature review of transgender women, hormone therapy, and HIV treatment

- Radix et al., “Transgender women, hormonal therapy and HIV treatment: a comprehensive review of the literature and recommendations for best practices.” *Jnl of International AIDS Society*. 2016
- Published articles predominantly address drug-drug interactions between ethinyl estradiol (key component of oral contraceptive) and ART components
- No studies examined interactions between ART and types/doses of oestrogens found in feminizing regimens
- Urgent need for more research on interactions between ART and feminizing hormone regimens



# IV. Findings from SF focus groups, 2014

- Hard for trans people to take a pill every day due to housing instability
- “We don’t know where we will be tomorrow.”
- Much interest in injectable PrEP
- There are acceptability and tolerability studies of injectable PrEP currently underway with men and women, heterosexuals and MSM, but not specifically with transgender women

# V. Regulatory developments

- Food & Drug Administration approved PrEP for MSM, heterosexuals in 2012
- CDC issued guidance spring 2014 recommending high risk MSM, IDUs, heterosexual women and men consider PrEP
- Doesn't address transgender women

# World Health Org. guidance 2012

- “In countries where HIV transmission occurs among men and transgender women who have sex with men and additional HIV prevention choices for them are needed, daily oral PrEP (specifically the combination of tenofovir and emtricitabine) may be considered as a possible additional intervention.”

# World Health Org. guidance 2015

- PrEP should be “considered for people at substantial risk of acquiring HIV rather than limiting the recommendation to specific populations”
- Substantial risk: incidence rate  $> 2$  per 100 person-years
- Also note that more information is needed on PrEP and transgender people

# VI. Recommendations

- Conduct more research on PrEP and trans women, separate from MSM studies (not as part of)
- Sari Reisner, Matthew Mimiaga – doing PrEP adherence intervention in Peru with trans women funded by amFAR
- CDC, WHO should issue guidance for providers re: PrEP and transgender women
- Educate transgender women about PrEP—what we know and don't know; explicitly address hormone interaction concerns

# VI. Recommendations

- Include more trans women in demonstration projects
- We need better surveillance on sex work, transactional sex in U.S. (Greg Millet point)
- A big factor in Africa, Asia, but not seen as big factor here in US.
- May be a big factor for some transgender women and men, young MSM
- Need for culturally competent health care for transgender people



# Competent and Affirming Health Care for Gay and Bisexual Men/MSM and Transgender Women as a Broader Context for HIV Care and Prevention

## AIDS 2016 Satellite Session



July 18<sup>th</sup>, 2016  
8:00 AM – 10:00 AM  
Room 5  
Durban Convention Centre



*Gay and bisexual/MSM and transgender women often experience barriers to accessing care that can exacerbate health disparities in HIV burden, risk behaviors, and treatment outcomes. This clinical skills-building session will focus on the medical and behavioral health care needs of sexual and gender minority patients, as well as the need for clinical program integration of behavioral and social services. Leaders in providing care to these populations from Africa, Asia, and the U.S. will describe best practices on how to deliver comprehensive care to transgender women and MSM to address their health care needs holistically and reduce disparities.*

### Clinically competent and affirming care for transgender women:

- Nittaya Phanuphak, MD, PhD, Thai Red Cross AIDS Research Centre, Bangkok, Thailand
- Tonia Poteat, PhD, Johns Hopkins Bloomberg School of Public Health, Baltimore, US
- Asa Radix, MD, Callen-Lorde Health Center, New York City, US
- Moderator: Joanne Keatley, MSW, International Reference Group on Transgender Women and HIV, San Francisco, US

### Clinically competent and affirming care for MSM:

- Kevin Rebe, MD, Anova Health Institute, Cape Town, South Africa
- Conall O'Cleirigh, PhD, Fenway Institute, Boston, US
- Caroline Maposhere, Consultant, Harare, Zimbabwe
- Moderator: Tri Do, MD, Asian Pacific Islander Wellness Center, San Francisco, US

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PEPFAR  
U.S. President's Emergency Plan for AIDS Relief



TRANSGENDER WOMEN AND  
PRE-EXPOSURE PROPHYLAXIS  
FOR HIV PREVENTION:

What We Know and What We Still Need to Know

By Samantha Marquez  
and Sean Cahill



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## INTRODUCING THE "PrEP PACKAGE" FOR ENHANCED HIV PREVENTION:

A Practical Guide for Clinicians

October, 2012

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## PROTECTING YOURSELF FROM HIV THROUGH PRE-EXPOSURE PROPHYLAXIS (PrEP):

What You Need to Know

October, 2012

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WHAT IS  
**PrEP?**



WHAT IS  
**PrEP?**



# Thank you. Questions?

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