



TRANSGENDER WOMEN and PrEP: What's the Latest?

Thursday, July 31, 2015

9am – 10:30am PST

12pm – 1:30pm EST

Audio Dial in 1 (415) 655-0051 Access Code: 774-211-337

Manju Chatani-Gada, Co-Coordinator, Working Group



Welcome Participants

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AGENDA

- Working Group Overview – Manju
- Welcome and Webinar Instructions - Shikora
- Fitting PrEP to At-Risk Trans People - Zil Goldstein,
- Community Partners Transgender inclusion in HIV clinical trails - Bob Bucklew,
Division of AIDS Cross-Network Transgender Working Group
- Rona Siskind,
- First Person Perspective - Cecelia Gentili
- First Person Perspective - Prudence Mendiola
- Questions and Answer - Sikora
- Wrap up and Next Steps - Manju

Zil Goldstein, Family Nurse Practitioner, Persist Health Project and Beth Israel Medical Center,



Zil Garner Goldstein is the Clinical Director and the primary referral clinician for Persist. She practices primary care, focusing on LGBT/queer health, transgender health and HIV primary care. For the past decade, she has been working as a healthcare provider and advocate for people involved in the sex trade, as well as a health worker in the trans* and queer communities. She is also an author and editor for *Trans Bodies*, *Trans Selves* and loves teaching other healthcare providers how to take care of transgender and sex worker patients. Zil can be reached at zil@persisthealthproject.org

Fitting PrEP to at-risk trans people

Zil Garner Goldstein, FNP
Persist Health Project
Mount Sinai Beth Israel

What is PrEP?

- Pre-Exposure chemoProphylaxis for HIV
- When taken daily by HIV negative people, certain medications used to treat HIV can greatly reduce the risk of acquiring HIV among folks who are at higher risk of contracting the virus
 - The medication that has shown the most success is called Truvada
 - Truvada is a combination of two medications, tenofovir and emtricitabine, and manufactured by a drug company called Gilead

What are transgender?

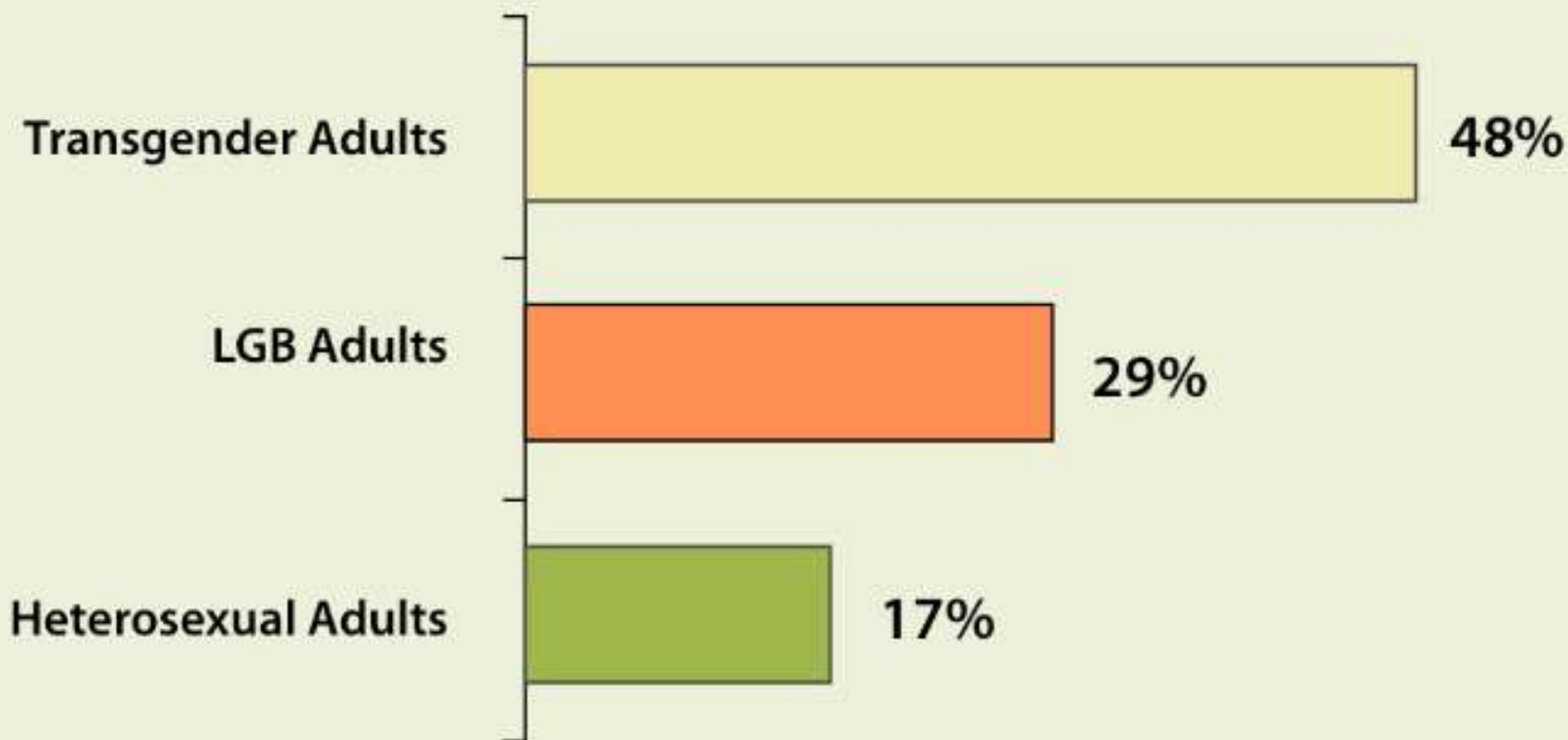
- Transgender women are people who were assigned male at birth and currently identify as women
 - High degree of health disparities for a variety of reasons
- Transgender men are people who were assigned female at birth and currently identify as men

What disparities

- Let's talk about HIV
 - 0.6% of the general population is HIV+
 - 3% of the transgender population is HIV+
 - 11.8% of cisgender female sex workers internationally are HIV+
 - 15.3% of transgender sex workers are HIV+
 - 25.9% of transgender sex workers of color are HIV+
 - 40.6% of black and black multiracial transgender sex workers are HIV+

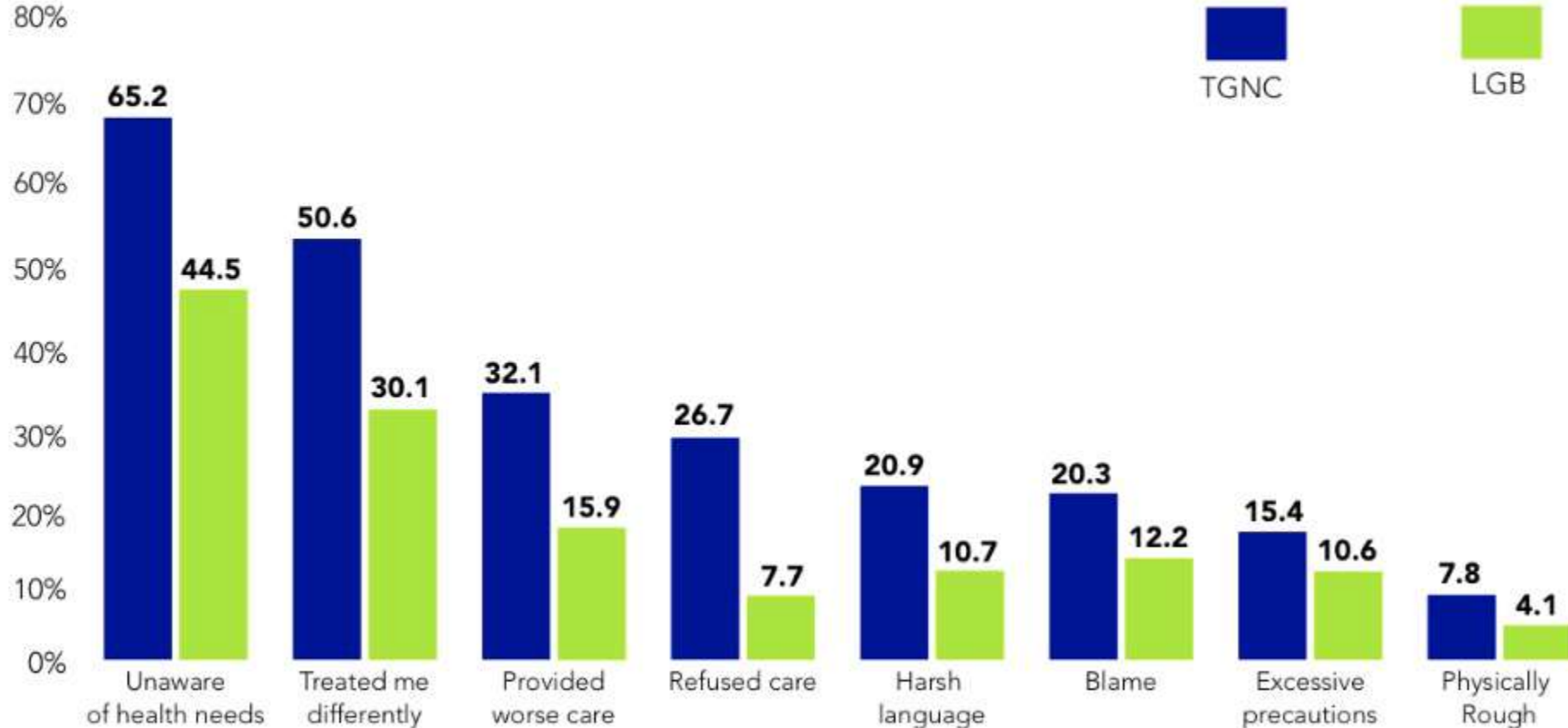
(NCTE, 2011; Baral, et al. 2012; Persist 2015)

Percent of Adults Delaying or Avoiding Medical Care



Source: Jeff Krehely, "How to Close the LGBT Health Disparities Gap," Center for American Progress, December 2009; Jaime M. Grant, Lisa A. Mottet, Justin Tanis, Jack Harrison, Jody L. Herman and Sara Keisling, "Injustice At Every Turn: A Report of the National Transgender Discrimination Survey," National Center for Transgender Equality and National Gay and Lesbian Task Force, 2011.

Experiences of Discrimination and Substandard Care: Transgender or Gender-nonconforming Compared to Lesbian, Gay and Bisexual



Other considerations

- More of us live in poverty (NCTE, 2009)
- More of us are sex workers (Persist, 2015)
- We don't trust doctors (Krehley, 2009)
- Existing systems aren't working
 - Referencing astronomically high rates of HIV among transgender women (NCTE, 2009)
 - Transgender women don't take PrEP as reliably as MSM (Iprex, 2011)
- NNT~35 among people who are adherent to the medication and engaged in risky behaviors (Chen and Dowdy, 2014)

Possible solutions?

- Take medical providers out of health care
- Use existing underground economies and social networks to distribute tenofovir/emtricitabine
- Make a pill that says “take daily” instead of advertising the company that produces the pill
- More research!
 - Transgender health
 - Tenofovir/emtricitabine dosing

References available upon request

Please send your requests to

Zil@persisthealthproject.org

Bob Bucklew, Community Partners Research Priorities Working Group



Active in the fight against HIV since 1993, Bob currently serves as Outreach Coordinator for HIV treatment and prevention trials in Cleveland, Ohio. Bob currently serves on several local, national and international community advisory boards, including Community Partners.

Community Partners Transgender Inclusion in HIV clinical trials

Bob Bucklew, Community Partners
Research Priorities Working Group
July 30, 2015

NIH, NIAID, DAIDS and the Networks

National Institutes of Health (NIH)

National Institute of Allergy and Infectious Diseases (NIAID)

Division of AIDS (DAIDS)

HIV Vaccine Trials Network

HIV Prevention Trials Network

AIDS Clinical Trials Group

Microbicide Trials Network

International Maternal Pediatric
Adolescent AIDS Clinical Trials
Network

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History of Community Involvement

- In the 1980s and 1990s, HIV/AIDS activists in the US and Europe rallied to reform the research process by which researchers and regulatory officials developed new drugs for treatment.



- The results of their protests, active advocacy and governmental lobbying were the inclusion of the community in all aspects of the NIAID HIV-related research and programming.

Community Involvement with DAIDS Research

Division of AIDS (DAIDS)/Network Leadership

AIDS Clinical Trials Group

Microbicide Trials Network

HIV Vaccine Trials Network

HIV Prevention Trials Network

International Maternal Pediatric
Adolescent AIDS Clinical Trials
Network

Community Partners

Network CAB

Network CAB

Network CAB

Network CAB

Network CAB

Community Advisory Boards (CABs)

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Community Partners

Community Partners (CP) is charged by the Network Leadership & DAIDS with **promoting effective representation of the many communities** within which the National Institutes of Health (NIH) HIV/AIDS clinical trials networks conduct research.

CP provides input to the DAIDS/Networks research plans as they relate to **scientific agendas, ethical conduct of clinical trials, community education, community training and communication/information dissemination** in a manner that ensures respect for community priorities and continued community participation.

CP Transgender Inclusion Initiative

4/14/14: CP sends recommendations on transgender inclusion to DAIDS/Networks Leadership.

Recognition of pre-existing support from DAIDS, networks and communities.

Do no harm. Recognition that transgender people may face very real and severe physical, psychological, social and legal harms. All recommendations should be interpreted in light of safety of individuals.

Recommendations to DAIDS

- Presumptively & affirmatively include transgender people in DAIDS clinical trials.
- Provide cultural responsiveness training & resources to networks, sites, community advisory boards.
- Detailed & uniform gender identity data collection for cross-protocol and cross-network data comparison.
- Develop and initiate transgender-specific research agenda.

HIV/AIDS Network Coordination

www.hanc.info



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Community Partners Links

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- [Community Coordination Objectives for 2015](#)
- [Community Partners Locations](#)
- [Get Involved](#)
- [Resources for Communities](#)
 - [American Indian Alaska Native Two-Spirit HPR Module](#)
 - [Be the Generation HIV Prevention Research \(HPR\) Training Module](#)
 - [Basic Scientific Literacy \(BSL\) Training Module](#)
 - [Community pages on the Clinical Trials Networks Websites](#)
 - [Community Partners Training Materials](#)
 - [HIV/AIDS Cure Glossary](#)
 - [Legacy Project Webinars](#)
 - [NAEHCR Project Guidance and Best Practices Document](#)
 - [Recommendations for Community Engagement in HIV/AIDS Research Version 2.0](#)
 - [Recommendations for Community Engagement in HIV/AIDS Research Version 2.0 Spanish Translation](#)
 - [Site Close Out and Community Engagement](#)
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Community Partners

Community Partners (CP) is a cross-network body charged by the Network Leadership and the Division of AIDS (DAIDS) with promoting effective representation of the many communities within which the National Institutes of Health (NIH) HIV/AIDS clinical trials networks conduct research. CP conducts activities regularly through conference calls and online tools such as email and a web portal system that allows for document collaboration and discussion boards.

[More information](#) »

Community Partners Activities

Community Partners focuses on improving intra- and inter-network community input at all levels, identifying and developing programs to meet the training and support requirements of local Community Advisory Boards, increasing the representation and participation of community members from resource-limited settings and vulnerable populations, and identifying and addressing challenges to participation in clinical trials.

[More information](#) »

Working Groups and Committees

HANC coordinates cross-network working groups and committees.

[More information](#) »

Community Training Materials

The HANC-coordinated cross-network activities of Community Partners includes the development of documents and guidelines covering various aspects of community engagement in clinical research which are publicly available:



- [Understanding the clinical research process and The role of a CAB and principles of community involvement](#)
- [Recommendations for Community Involvement in NIAID Clinical Trials Networks](#)

[More Information](#) »



Research Participation

Get involved in HIV clinical research.

[More information](#) »



Community Partners Locations

Community Partners are located at many different sites around the world.

[More information](#) »

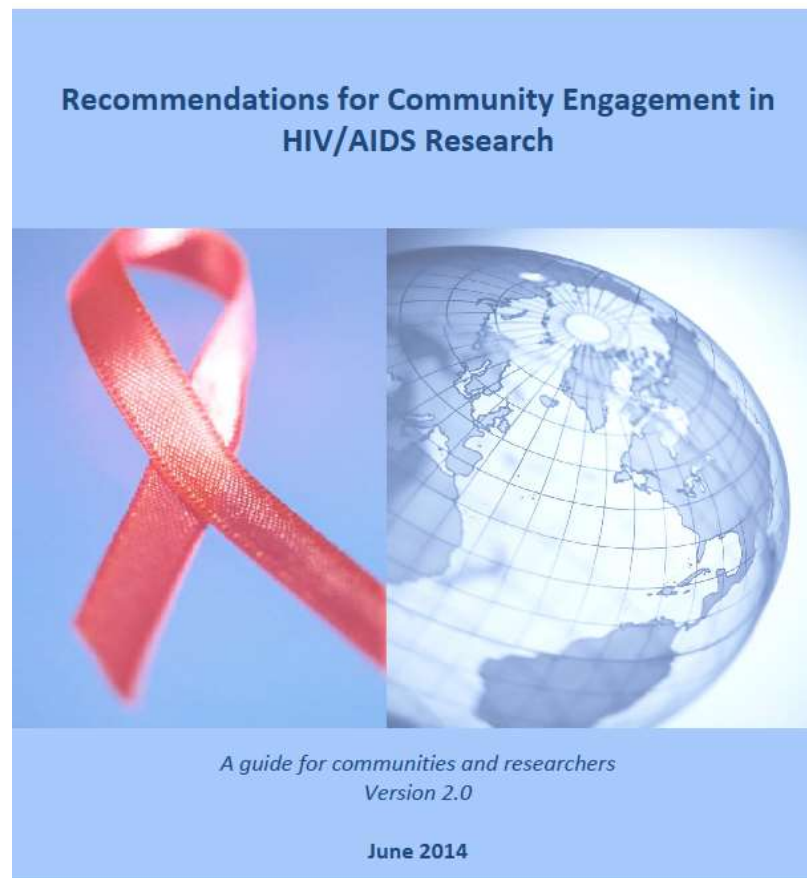


Community Advocacy

There are a variety of organizations to support community engagement activities in HIV/AIDS clinical trials.

[More information](#) »

Community Partners' Community Engagement Recommendations



Community Partners welcomes feedback

Community Partners

c/o Russell Campbell

HANC Community Partners Manager

rcampbel@fredhutch.org

www.hanc.info/cp

Bob Bucklew, Outreach Coordinator

Case Western Reserve/University Hospitals

Cleveland AIDS Clinical Trials Unit

rob2@case.edu

Rona Siskind



- Rona Siskind has worked in the Division of AIDS at NIAID for over 20 years. Committed to community engagement in research, she serves as the liaison to Community Partners and convenes the Cross Network Transgender Working Group.

Division of AIDS Cross-Network Transgender Working Group

PrEP and Transgender Women

Rona Siskind, MHS

Division of AIDS, National Institute of Allergy and Infectious
Diseases

National Institutes of Health

July 30, 2015



Division of AIDS Cross-Network Transgender Working Group

- Formed in response to a memo from Community Partners
- Representation from each NIAID-funded HIV/AIDS clinical trials network, Community Partners, Office of HIV/AIDS Network Coordination, Division of AIDS & transgender individuals
- Goals:
 - Address issues to facilitate inclusion of transgender people across the HIV/AIDS clinical trials networks
 - Discuss research opportunities/needs
 - Share resources, information, & ideas



Division of AIDS Cross-Network Transgender Working Group

- Developed a template for the uniform use of a two-step approach for gender identity & sex at birth data collection
- Reviewing & compiling training resources for application to research setting
- Advocating for transgender-specific research & increased enrollment in trials

Division of AIDS Cross-Network Transgender Working Group

[Questions to be read aloud to the participant]

1. The next question asks about gender. Gender is the social part of being male or female, and relates to your self-identity. I am asking whether you consider yourself to be male, female, transgender male, transgender female, gender queer, gender variant or gender-non-conforming or if you identify yourself in an additional category.

How do you identify your gender? (mark all that apply)

Male

Female

Transgender Male

Transgender Female

Gender Queer

Gender Variant or Gender Non-Conforming

Self-Identify, specify: _____

Prefer not to answer

Division of AIDS Cross-Network Transgender Working Group

2. This question is about your sex. When I ask about your sex, I am asking about what sex you were determined to be at birth, which is generally done by looking at a baby's genitals (sex organs).

What was your sex at birth?

Male

Female

Intersex

3. What is your sexual orientation (mark only one)?

Gay/Lesbian/Homosexual

Bisexual

Queer

Two-Spirit

Straight/Heterosexual

Additional Category, Please Specify _____

Not sure

Prefer not to answer

HIV/AIDS Clinical Trials Networks – Transgender Inclusion

HIV Prevention Trials Network – HPTN

- HPTN Workshop, June 2015: *Developing HIV Prevention Interventions for Transgender Men and Women, and other Gender Non-Conforming Individuals*
- Purpose:
 - Review of transgender health & HIV
 - Discuss how the HPTN can contribute to new knowledge
- Takeaways:
 - Appropriateness of data collection forms
 - Transgender representation in CWG/local CABs
 - Staff training to be culturally competent
 - Consider transgender people when enrolling large efficacy studies
 - Consideration of future trials:
 - Multinational vanguard studies to assess risk contexts, behaviors, HIV incidence
 - Transgender PrEP studies focusing on the interaction of different hormonal agents & regimens with TDF/FTC



Courtesy K. Mayer, Fenway Health, Harvard, BIDMC
HPTN Annual Meeting, June 2015

HIV/AIDS Clinical Trials Networks – Transgender Inclusion

HIV Prevention Trials Network – HPTN

➤ HPTN 081/HVTN 703:

A phase 2b study to evaluate the safety & efficacy of VRC01 broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection (in development)

— Will begin late 2015

— Enrollment: 3,900 HIV-uninfected transgender men, transgender women, MSM & at-risk women

➤ HPTN 083:

Phase 2b/3 study of injectable Cabotegravir vs. daily oral Truvada for PrEP in HIV (in development)

— Enrollment: 4,500 HIV-uninfected men & transgender women who have sex with men

HIV/AIDS Clinical Trials Networks – Transgender Inclusion

HIV Vaccine Trials Network – HVTN

- Formed an ongoing, multidisciplinary Transgender Working Group in 2007
- Reviewed participants in 6 Phase 1-2a trials: 14 out of 694 were transgender
- HVTN 505 was the first HVTN study to name transgender women as an eligible population distinct from MSM:
 - A Phase 2b, test-of-concept trial testing the safety and efficacy of a prime boost vaccine regimen in HIV-uninfected adenovirus type 5 neutralizing antibody negative, circumcised men and male-to-female (MTF) transgender persons who have sex with men
- Focus Groups and Environmental Survey to identify barriers and facilitators

HIV/AIDS Clinical Trials Networks – Transgender Inclusion

HIV Vaccine Trials Network – HVTN

Barriers to Trial Participation

- Stigma & marginalization
- Being unaware & misinformed
- Perceived exclusion of transgender women in research
- Mistrust of scientific community
- Perceived possible vaccine side effects
- Discomfort with visitor IDs & complications related to name change
- Concerns about pregnancy testing especially among those with long-term testosterone use who perceived themselves as unable to become pregnant

HIV/AIDS Clinical Trials Networks – Transgender Inclusion

HIV Vaccine Trials Network – HVTN

Facilitators of Trial Participation

- Increased information & awareness
- Cultural competency training for clinic staff
- Recommendation from trusted transgender-friendly health care provider
- Assistance with basic needs
- Trans-friendly environments, e.g., gender neutral bathrooms
- Increase trans-visibility: outreach materials, posters/wall displays, brochures
- True partnerships with trans-friendly organizations/providers
- Trials focused on transgender-specific issues (i.e., vaccine interactions with hormones)
- Accurate data collection & tracking of transgender individuals
- Revise protocols to be more transgender-competent (i.e., pregnancy tests, language)

HIV/AIDS Clinical Trials Networks – Transgender Inclusion

HIV Vaccine Trials Network – HVTN

Changes Implemented

- A series of trainings & resources for network/site staff
- Recruitment partnerships & collaborations with community organizations & local transgender-serving organizations
- Pregnancy testing not required for people who have had a total hysterectomy or a bilateral oophorectomy
- Result: 44 transgender women in HVTN 505 vs. 14 in six previous Phase 1-2a studies
- HVTN 703/HPTN 081: will enroll transgender men, transgender women, MSM, and at-risk women



Courtesy M. Andrasik, HVTN Social Scientist

HIV/AIDS Clinical Trials Networks – Transgender Inclusion

Microbicide Trials Network - MTN

- Convened a consultation in collaboration with the Be the Generation Bridge: May 2013
- 29 representatives: US-based organizations, Peru (2), Thailand (2) and South Africa (2)
- Purpose:
 - Overview of ARV-based prevention, focusing on rectal microbicides
 - Platform to discuss opportunities & challenges
- Takeaways:
 - Few studies include transgender people
 - Conflate transgender women & MSM
 - Should be able to identify as they want
 - Fear of participation, e.g., not knowing outcome & impact of medication
 - Need to be included in trial design & conduct
 - Appreciated direct information & dialog
 - Call to action



Courtesy C. Collins, Associate Director,
Communications & External Relations, MTN

HIV/AIDS Clinical Trials Networks – Transgender Inclusion

Microbicide Trials Network - MTN

- MTN 017: First phase 2 trial of a rectal microbicide
 - 195 participants enrolled between September 2013 & November 2014
 - 12.1% participants identified as transgender women
 - Study completed follow-up May 2015, analyses ongoing
- Rectal Phase 3 Consultations
 - Clinical trial design
 - Ethics
 - Community consultation
- Premature to undertake a Phase 3 study; Phase 2A expanded safety study, include access to oral PrEP
- Adonis Study: evaluate finger/penile delivery
- Commitment to inclusion of transgender participants in future studies



Courtesy C. Collins, Associate Director,
Communications & External Relations, MTN

HIV/AIDS Clinical Trials Networks – Transgender Inclusion

Acknowledgements

- DAIDS Cross-Network Transgender Working Group
- Michelle Andrasik, HVTN
- Bob Bucklew, Community Partners
- Wairimu Chege, DAIDS
- Clare Collins, MTN
- Vanessa Elharrar, DAIDS
- Jonathan Lucas, HPTN
- Kenneth Mayer, HPTN

Cecelia Gentili - First Person Perspective



Since leaving Argentina, Cecilia Gentili has embarked on an incredible journey of transformation, ultimately turning her into a widely respected advocate for trans rights in New York City. Currently, she serves as the Trans Health Coordinator for the [APICHA Community Health Center](#), while continuing her work as a mentor and an advocate within her local community in Jackson Heights, Queens.

“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

Transgender people often face high levels of stigma and discrimination

Agencies and medical providers have usually a tendency to associate transgender folks and transwomen of color with HIV (and nothing else)



Perpetuates stigma and the idea of transgender women of color as a factor of spread of HIV



Trans people not wanting to be a part of campaigns

Stigma and Discrimination

HIV Prevention initiatives lead by transgender people are the most effective, but...



Most of the times we see cisgender folks doing that work, which...



Makes Trans people feel less about themselves as a community and individually

Generalizations about the sexual behavior of transgender people exist, which can impact upon the effectiveness of HIV prevention interventions

My personal experience with PrEP

- ❖ During many encounters with medical providers I was directed to the “HIV talk” without even evaluating my risk
- ❖ Assumptions about my sexual life were made
- ❖ Which led me to never coming back to those providers

Ideas to work around PrEP

- ❖ Lead this work with the same population you are trying to work for
- ❖ Associate PrEP with the REAL needs of the community (linkage to the workforce, Access to medical services, work around violence)

Prudence Mendiola First Person Perspective



INTERVIEW....

QUESTIONS AND ANSWERS

- You may raise your hand to be unmuted to ask your questions directly to the group
- You may also type your questions in the chat feature



Wrap Up: Feedback and final thoughts



Manju