HPTN 091: Lessons Learned
Incorporating Lived Experiences to Strengthen Research Design

Nora Howell
Senior Recruitment Specialist

Harlem Prevention Center
Columbia University Medical Center
Integrating HIV Prevention, Gender-Affirmative Medical Care, and Peer Health Navigation for Transgender Women in the Americas: A Vanguard Study
Why Transgender Women?
Background – Why TGW?

TGW are a key population and priority for HIV prevention and treatment.

Individual, interpersonal, and structural factors increase TGW’s risk for HIV acquisition.

TGW have a 49-fold increased odds of HIV infection compared to other adults.

There is an urgent need for HIV prevention strategies that are effective and acceptable for TGW.
Rationale for HPTN 091

• First HPTN study focused solely on trans women
• HIV vulnerability is in the context of other unmet needs
• Access to gender affirming care
• Case management services
• Peer support and navigation
• Research can provide scientific evidence for what community knows
Primary Objectives

- To assess acceptability and feasibility of delivering integrated HIV prevention services co-located with GAHT and PHN using SBCM for TGW.
- To assess PrEP uptake, adherence, and persistence in both the Immediate Intervention Arm and the Deferred Intervention Arm and compare uptake, adherence and persistence of PrEP between the two arms.
Study Objectives

Secondary Objectives

• To determine annual incidence of HIV infection among study participants.
• To determine baseline prevalence and annual incidence of STIs and to examine changes in STI incidence over time by study arm.
• To examine changes in sexual risk-taking behavior.
• To obtain baseline lab data to evaluate the cohort’s suitability for future PrEP intervention studies.
• To identify demographic, behavioral, socioeconomic and psychosocial factors related to: (1) PrEP uptake and adherence over time, (2) PrEP persistence, (3) interest in future HIV research, including research involving injectable implantable agents for PrEP among HIV-uninfected TGW.
• To assess use of medically-prescribed and non-prescription gender-affirming interventions, including exogenous hormones, soft tissue filler/silicone, and feminizing surgeries.
Study Design

- **Immediate Intervention Arm**
  - 310 TGW Enrolled
  - Randomization 1:1 Assignment
  - PrEP Provision: STI Screening & Treatment
  - Linkage to Services: Gender affirming hormone therapy and case management services
  - (0-6 months)

- **Deferred Intervention Arm**
  - PrEP Provision: STI Screening & Treatment
  - Co-located Services: Gender Affirming Hormone Therapy, Peer Health Navigation Using Strengths-Based Case Management
  - (0-18 months)

- **(0-18 months)**
  - Peer Health Navigation Using Strengths-Based Case Management

- **(0-6 months)**
  - Gender affirming hormone therapy and case management services
Study Design Rationale

• Immediate and Deferred Arms
  • Having two arms (immediate and deferred) makes it possible to compared differences in outcomes between participants who receive the intervention and those that do not receive the intervention immediately.

• 18 Months of Follow-up
  • Needed to assess the impact of the intervention on PrEP persistence by following participants for a year after the last possible visit (Week 39) that they can initiate PrEP at the site.

• Peer Health Navigation Using Strengths-Based Case Management
  • Peer Health Navigators share the same experiences and community membership as participants and are trained to provide effective linkages to health and social services
  • Transgender peers play a virtual role in fostering trust and engagement therefore peer-to-peer engagement is a necessary strategy for TGW to participant in HIV prevention research
  • This is an evidence-based approach health promotion model
Background – Why Co-located Services?

Data suggests that providing gender affirming hormonal therapy may facilitate PrEP uptake and adherence.
Researchers have identified TGW’s concerns about drug-hormone interactions as a barrier to PrEP uptake.
Integrated HIV prevention and gender affirming services supported by peer health navigation and strengths-based case management is a potential strategy that could significantly impact the HIV epidemic among TGW.
Why Peer Health Navigation?

HIV epidemic for transgender women occurs in the context of social and economic exclusion and marginalization. Stigma-related health and social conditions drive HIV vulnerabilities. Unmet health and social service needs. Transgender peers play a vital role in fostering trust and engagement. Peer-to-peer engagement may help transgender women to prevent HIV acquisition (e.g., PrEP).

Maslow’s Hierarchy of Needs
Overview of the Peer Health Navigation Intervention

The HPTN 091 PHN intervention integrates evidence-based strategies from:

**Strengths-based case management (SBCM)** - an intervention that identifies the unique strengths of individuals to help link and navigate them to gender-affirming health and social services

**Healthy Divas (HD)** - a peer counseling intervention designed “by” and “for” transgender women that promotes positive change and enhances gender affirmation
Study Population:

- Transgender Women
- ages 18 or older
- HIV-uninfected
- at risk of acquiring HIV infection
Sites

Bridge HIV CRS, San Francisco, CA

Harlem Prevention Center CRS, New York, NY

Penn Prevention CRS, Philadelphia, PA

Houston AIDS Research Team (HART) CRS, Houston, TX

Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS, Rio de Janeiro, Brazil
Thank you!

Nora Howell
Senior Outreach Specialist
ICAP Harlem Prevention Center

nh2689@cumc.Columbia.edu
www.icap.Columbia.edu
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