

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

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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

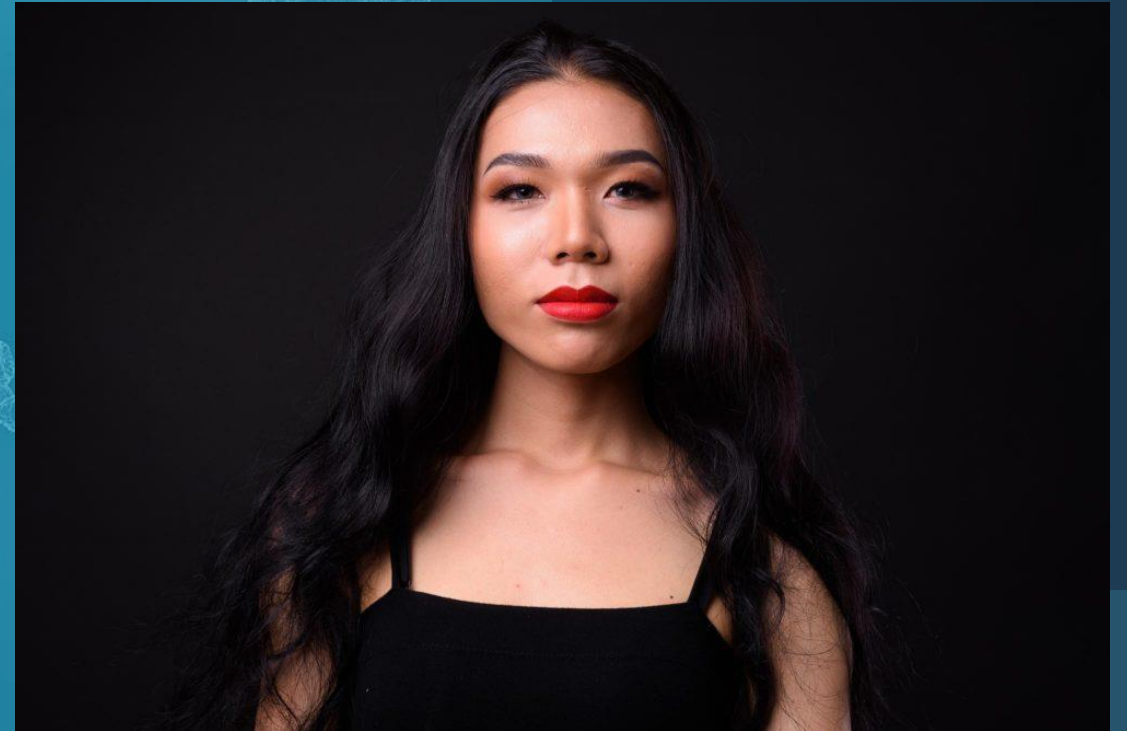
TGW have a 49-fold increased odds of HIV infection compared to other adults

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



Study Objectives

Primary Objectives

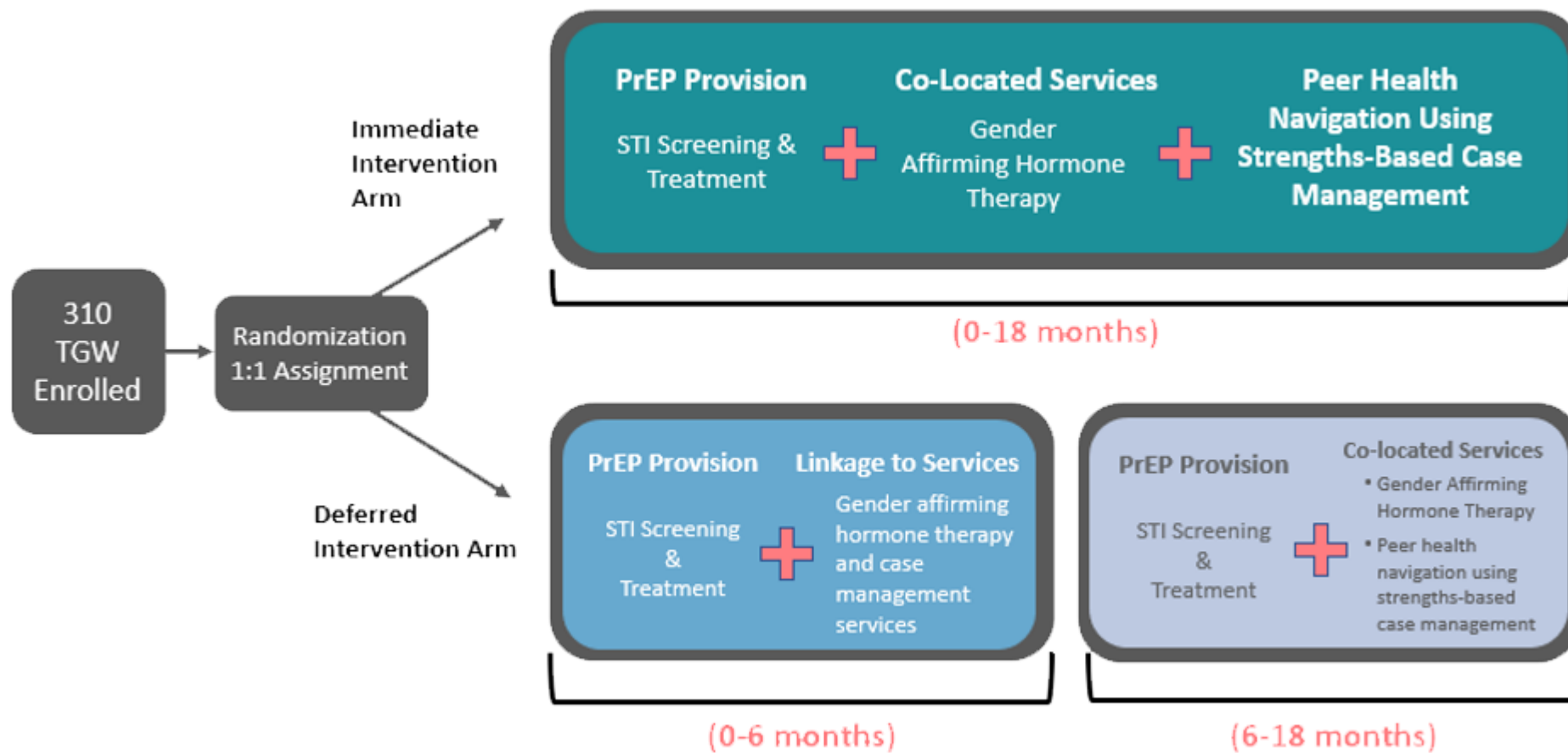
- To assess acceptability and feasibility of delivering integrated HIV prevention services co-located with GAHT and PHN using SBCM for TGW.
- To assess PrEP uptake, adherence, and persistence in both the Immediate Intervention Arm and the Deferred Intervention Arm and compare uptake, adherence and persistence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



Study Design Rationale

- Immediate and Deferred Arms
 - Having two arms (immediate and deferred) makes it possible to compare 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 participate 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

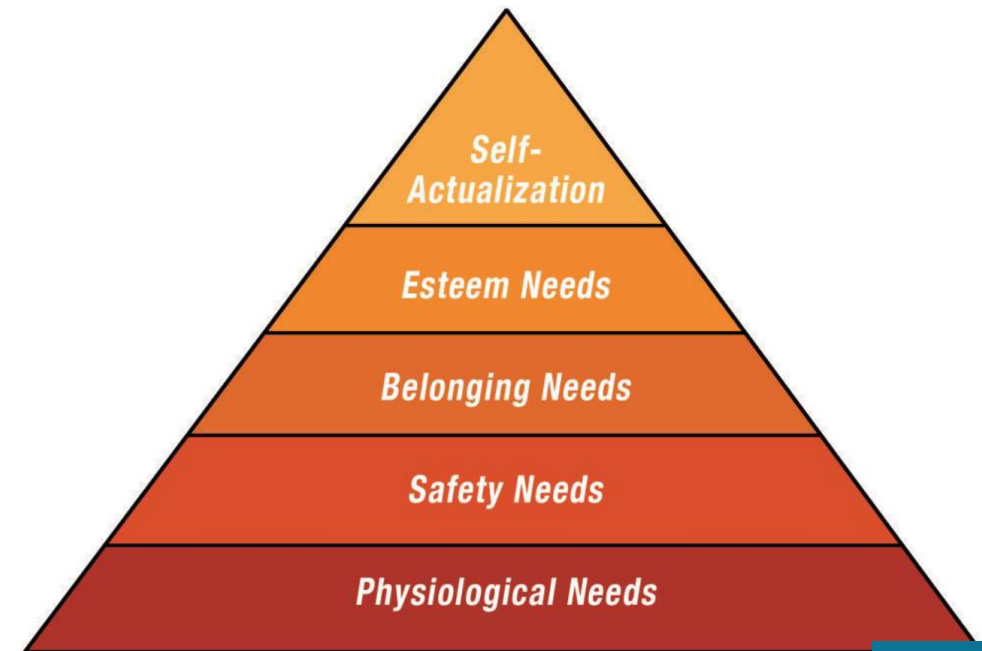
Researchers have identified TGWs concerns about drug-hormone interactions as a barrier to PrEP uptake

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

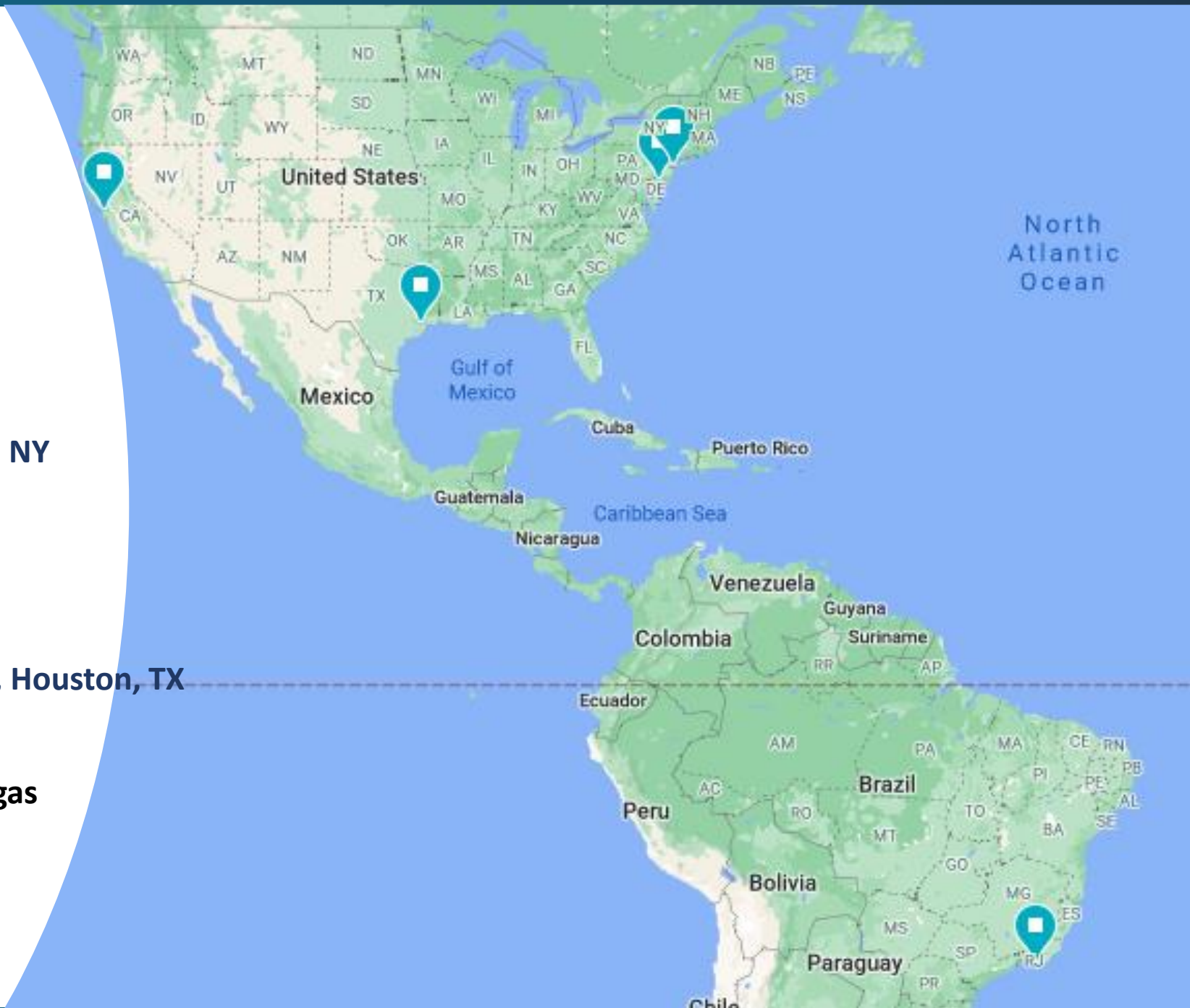
Bridge HIV CRS, San Francisco, CA

Harlem Prevention Center CRS, New York, NY

Penn Prevention CRS, Philadelphia, PA

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

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Thank you!



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