

# 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

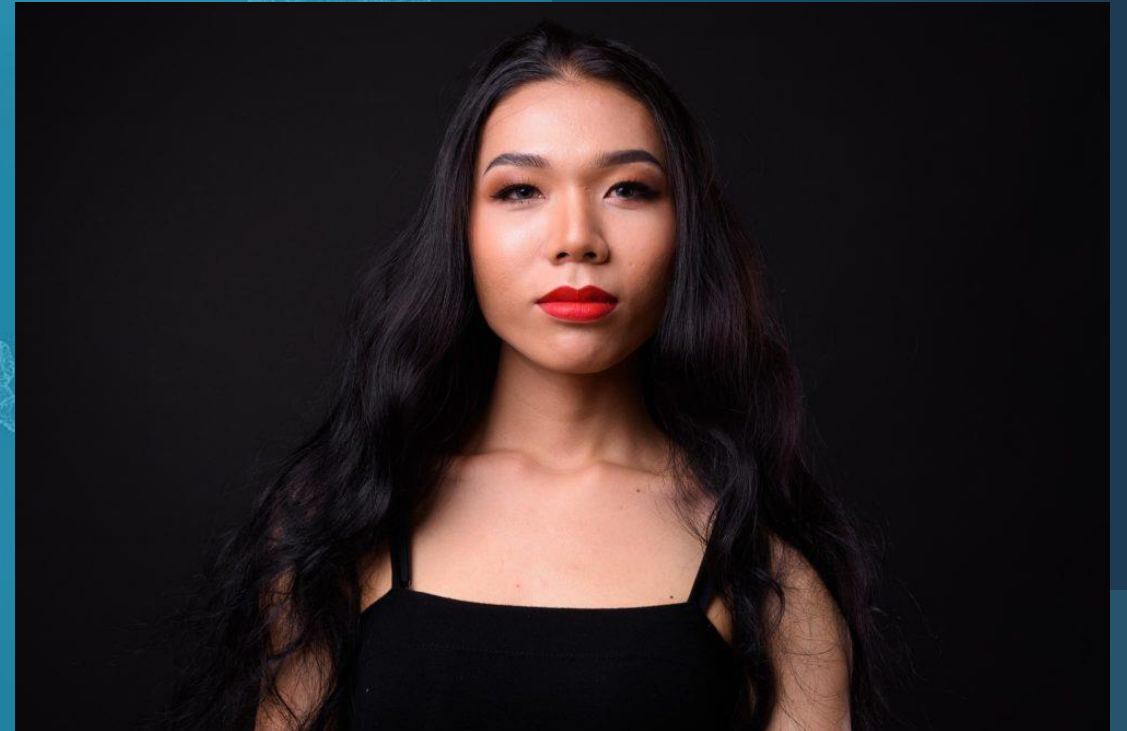
TGW have a 49-fold increased odds of HIV infection compared to other adults

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

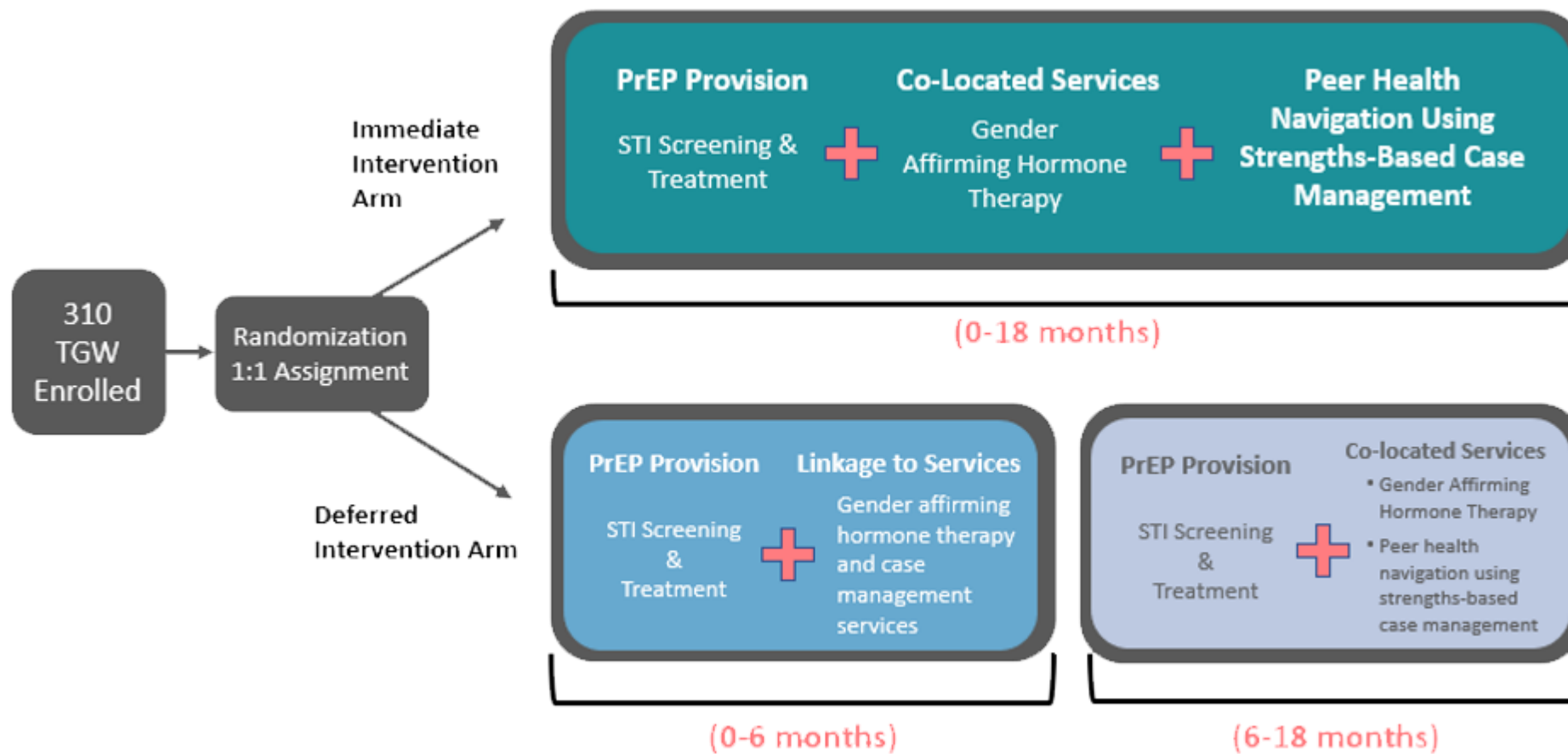
- To assess acceptability and feasibility of delivering integrated HIV prevention services co-located with GAHT and PHN using SBCM for TGW.
- To assess PrEP uptake, adherence, and persistence in both the Immediate Intervention Arm and the Deferred Intervention Arm and compare uptake, adherence and persistence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

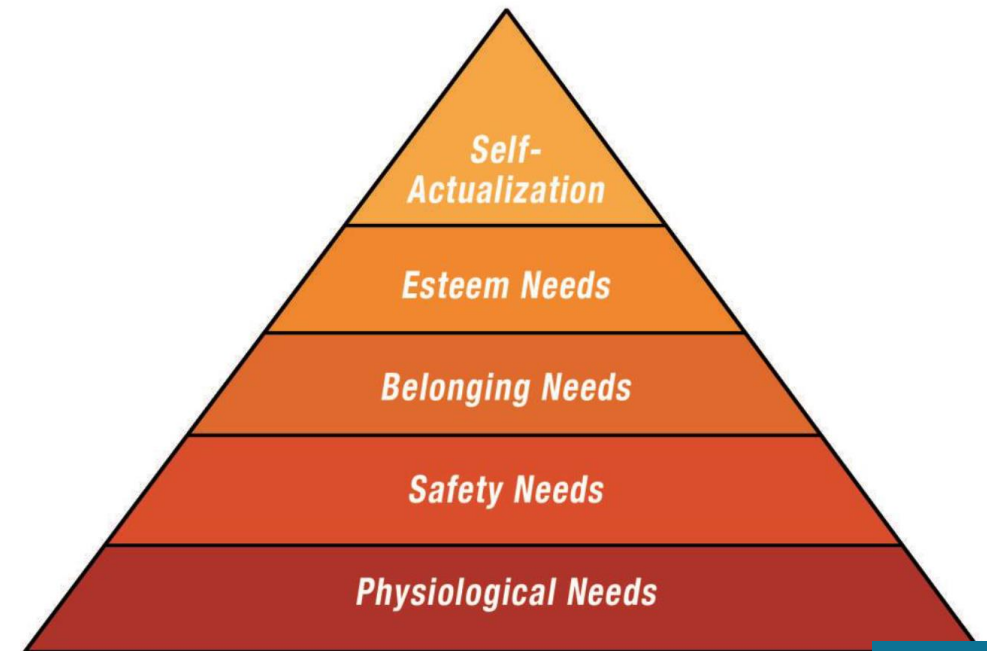
Researchers have identified TGWs concerns about drug-hormone interactions as a barrier to PrEP uptake

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

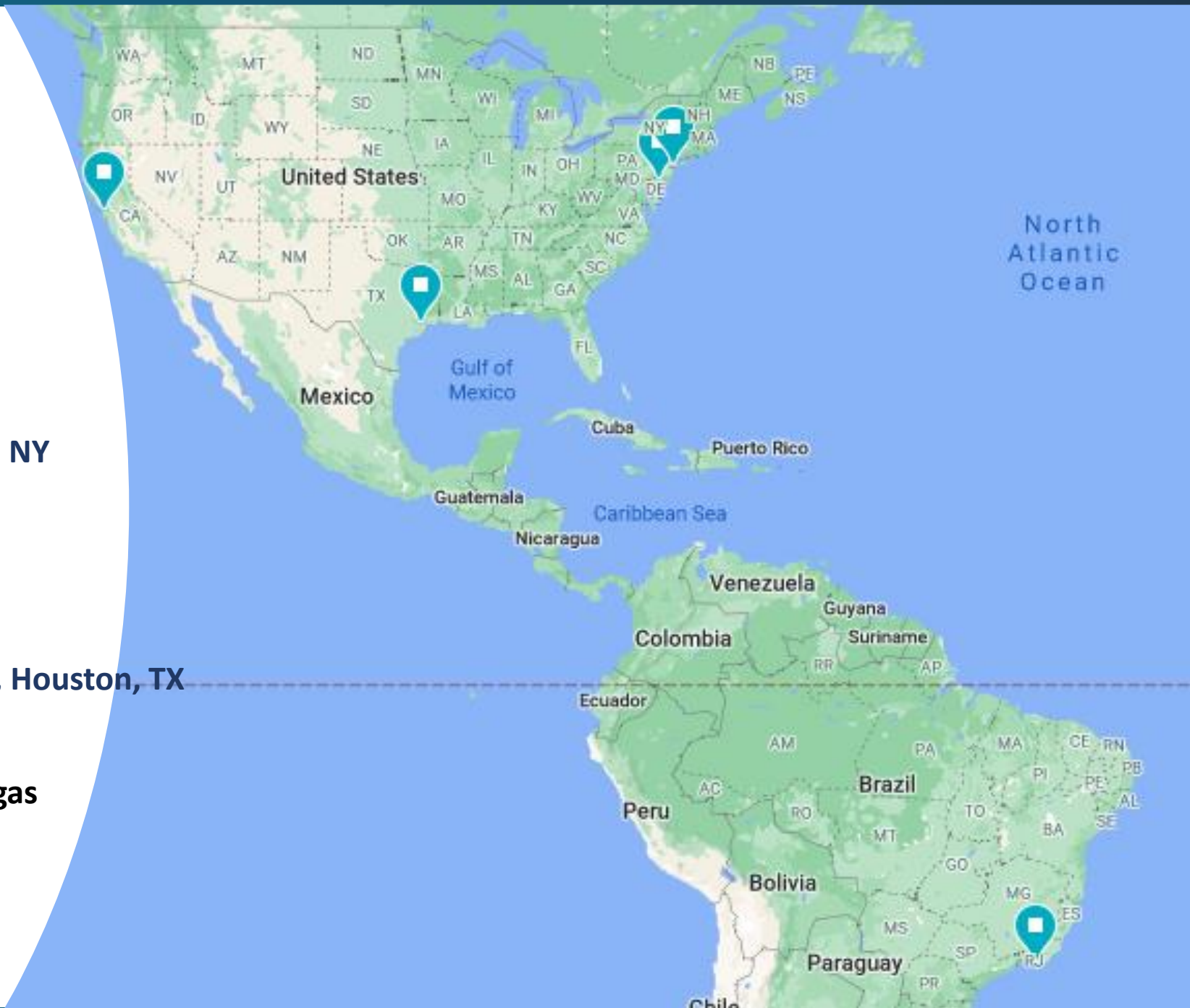
**Bridge HIV CRS, San Francisco, CA**

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# Thank you!



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