



WEBINAR

I Am More Than HIV Prevention:

Results from the HPTN 091 Study with Transgender Women

Thursday, December 19

9:00 a.m. – 10:30 a.m. ET

Register at tinyurl.com/iammorethanhiv



HPTN
HIV Prevention
Trials Network



HIV prevention research - a new forum
for advocacy on the latest





WEBINAR

I Am More Than HIV Prevention:

Results from the I Am More Than HIV Prevention Study
Study of HIV Prevention for Women

Featuring simultaneous live translation in Portuguese and Spanish.

19
10:30 a.m. ET

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HPTN
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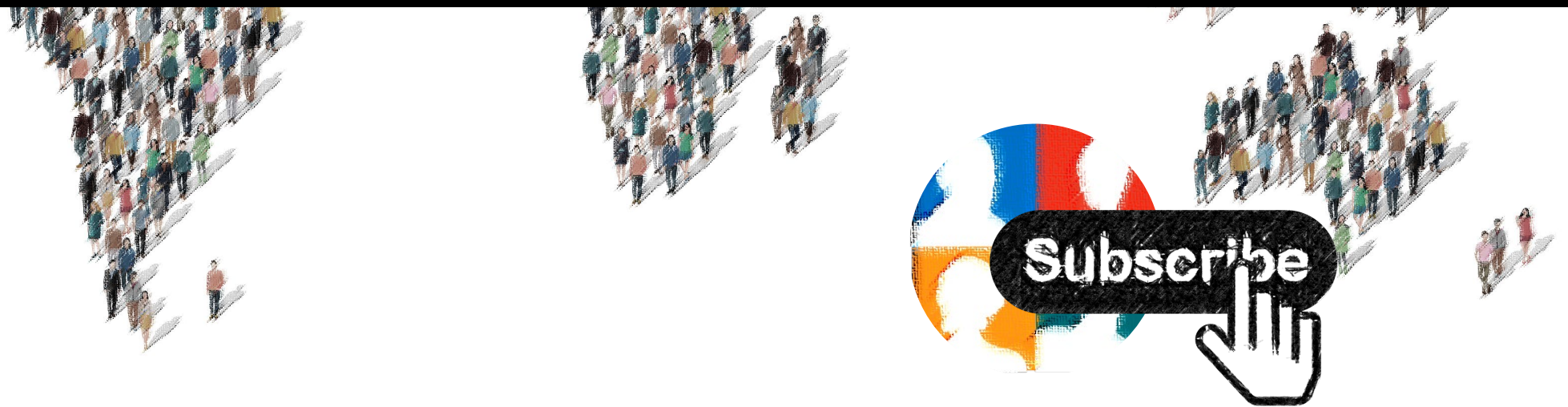



HIV prevention research - a new forum
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avac.org/project/choice-agenda



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TCA Playlist Dec 19

Fall On Me
Andrea Bocelli +
Mateo Bocelli

Beautiful
Christina Aguilera

More Than A Woman
(Paradise Edit)
Bee Gees + SG Lewis

I Am What I Am
Gloria Gaynor



PrEP uptake and adherence among transgender women: findings from an RCT of a multicomponent intervention (HPTN 091)

T. Poteat, G. Beauchamp, M.A. Marzinke, K. Gomez-Feliciano, B. Akingbade, J. Beck, I. Bell, V. Cummings, L. Emel, J. Franks, E.M. Jalil, J.E. Lake, A. Liu, J. Lucas, K.H. Mayer, A.E. Radix, J. Rooney, H. Spiegel, D.L. Watson, S. Zangeneh, S.L. Reisner, HPTN 091 Study Team



Objectives

1. Briefly review HIV epidemiology and PrEP continuum among transgender women
2. Outline the design and implementation of the “I Am” Study (HPTN 091)
3. Describe characteristics of study participants
4. Review primary study results
5. Discuss implications of study findings

PLOS ONE

98 published studies
48,604 TW from 34 countries

- Prevalence **19.9%**
- Odds Ratio **66.0**

RESEARCH ARTICLE

The worldwide burden of HIV in transgender individuals: An updated systematic review and meta-analysis

Sarah E. Stutterheim *, Mart van Dijk, Haoyi Wang, Kai J. Jonas

Department of Work and Social Psychology, Maastricht University, Maastricht, The Netherlands

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No reduction in HIV prevalence after oral PrEP introduction

Table 6. HIV prevalence and odds ratios for trans feminine individuals compared to all adults (age 15+) in US-based studies, according to whether data was collected before or after the introduction of PrEP (2012).

	Number of studies	Sample size	Frequency of HIV among TF in the samples	Prevalence (95%CI)*	Odds Ratio (95%CI)
Before PrEP	18	21022	1475	18.4 (14.8–22.0)	53.5 (29.7–96.5)
After PrEP	6	1401	358	23.7 (20.2–27.2)	58.0 (12.3–275.9)

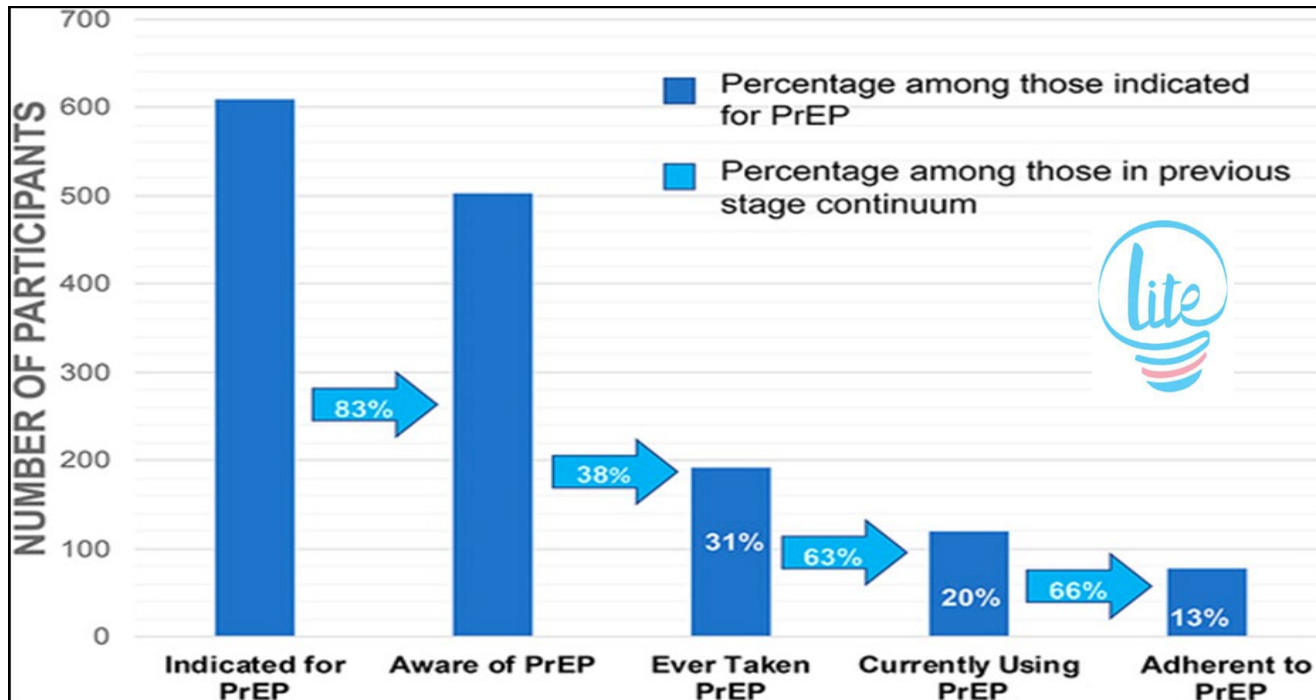
Note. *Overall prevalence was calculated by direct standardization based on country-year weights used in meta-analysis.

<https://doi.org/10.1371/journal.pone.0260063.t006>

CAVEAT: PrEP would be expected to impact **incidence (new HIV acquisitions), not **prevalence** (everyone with HIV)**

PrEP Continuum in Transgender Women

Globally, PrEP willingness is high (~80%), but uptake and adherence are low (~35%)



Baseline data from U.S. LITE cohort of trans women without HIV

Barriers include:

- Hardship, stigma, distrust

Facilitators include:

- Social cohesion, peer support

Sevelius JM et al. *Journal of the International AIDS Society* 2016, **19**(Suppl 6):21105
<http://www.jiasociety.org/index.php/jias/article/view/21105> | <http://dx.doi.org/10.7448/IAS.19.7.21105>



Review article

The future of PrEP among transgender women: the critical role of gender affirmation in research and clinical practices

Jae M Sevelius^{§,1,2}, Madeline B Deutsch^{1,3} and Robert Grant^{4,5}

[§]Corresponding author: Jae M Sevelius, 550 16th Street, Suite 300, San Francisco, CA 94158, USA. Tel: +415 476 6358. (Jae.Sevelius@ucsf.edu)

PrEP & STI Screening



Gender Affirming Hormones & Peer Health Navigation (6 sessions)



- Session One: Let's Be Real
- Session Two: Be Fierce
- Session Three: Get It?

- Session Four: Keeping it Together
- Session Five: Work It!
- Session Six: Healthy Diva!

Co-Location of PrEP with Gender Affirming Care & Strengths Based Case Management Services

COMMENT | [VOLUME 6, ISSUE 9, E566-E567, SEPTEMBER 2019](#)



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Transgender HIV research: nothing about us without us

[Ayden I Scheim](#)  • [Max Nicolai Appenroth](#) • [S Wilson Beckham](#) • [Zil Goldstein](#) • [Mauro Cabral Grinspan](#) • [JoAnne G Keatley](#) • et al. [Show all authors](#)

Published: August 19, 2019 • DOI: [https://doi.org/10.1016/S2352-3018\(19\)30269-3](https://doi.org/10.1016/S2352-3018(19)30269-3) •  Check for updates

 PlumX Metrics

Trans protocol co-chair

Peer-led intervention

Trans representation in protocol development

Site-based community consultations

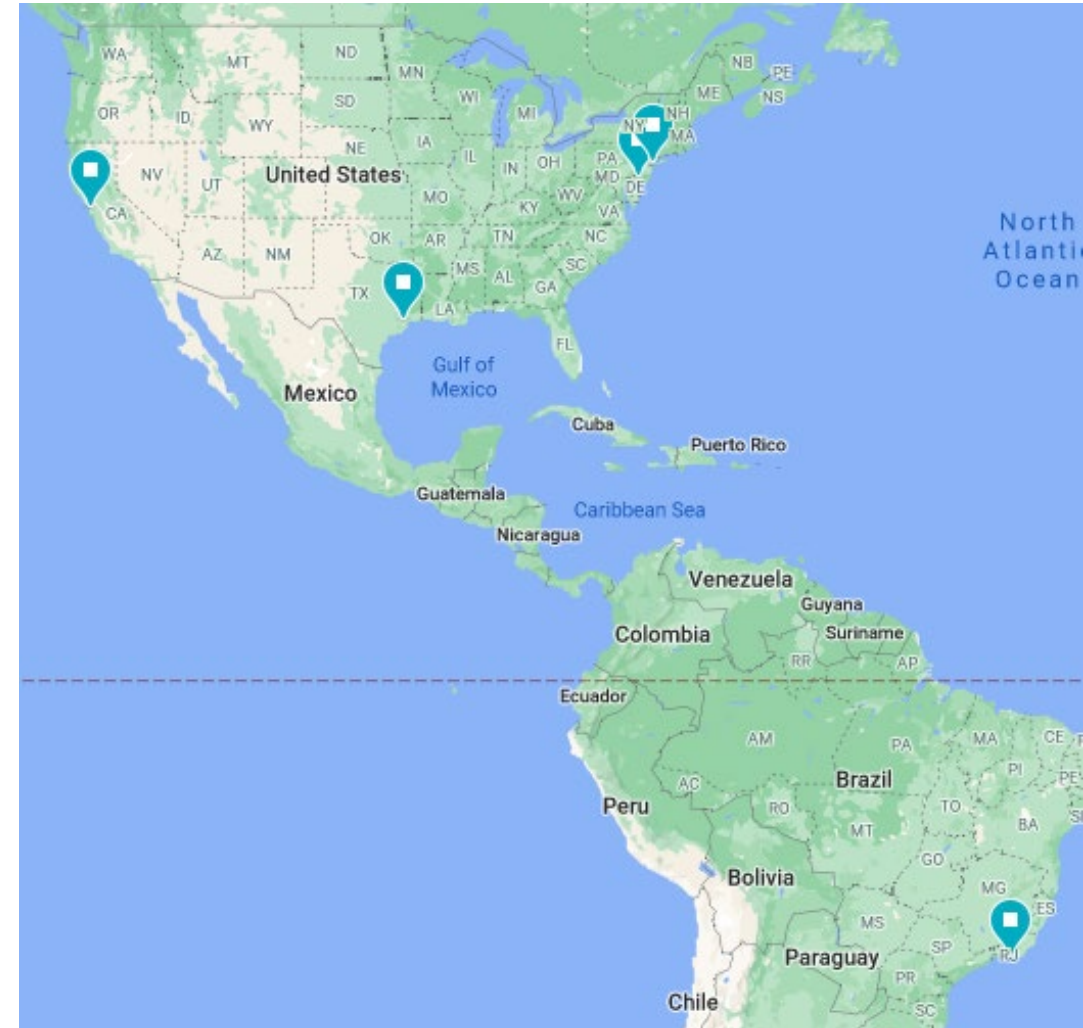
HPTN 091 Implementation Timeline

- **2017-2018**
 - Multiple iterations of proposal submitted
 - HPTN proposal approved in October 2018
- **January 2019**
 - First protocol development meeting
- **March – April 2019**
 - HPTN Executive Committee approval of sites
 - First Round of HPTN Community Consultations (virtual)
 - HPTN Scientific Review Committee (SRC) review
 - Second protocol development meeting
 - Study design updated based on community feedback and SRC review
- **July – October 2019**
 - Second Round of HPTN Community Consultations (in person)



Sites

- Bridge HIV, San Francisco, CA
- Harlem Prevention Center, New York, NY
- Penn Prevention, Philadelphia, PA
- Houston AIDS Research Team, Houston, TX
- Instituto de Pesquisa Clinica Evandro Chagas (IPEC), Rio de Janeiro, Brazil



Community Consultations & Responsiveness

Previous design:

- Randomize 1:1 to intervention vs SOC arms for 12 months



Revised design:

- Randomize 1:1 to **immediate** vs. 6-month **deferred** intervention arms
- Extend study follow-up to 18 months
 - All participants receive PrEP and hormones for 12 additional months

Additional concerns from community consultations:

- Ability to continue with current medical provider
- Linkages to services for participants in deferred arm
- Access to PrEP and hormones when the study is over

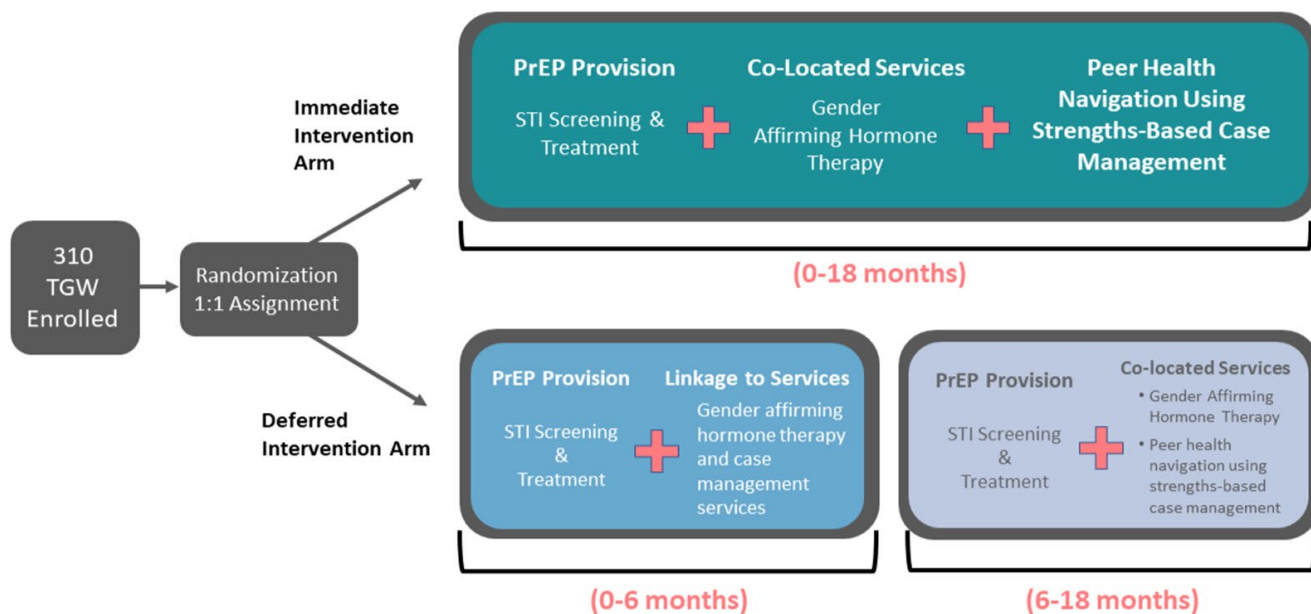


- Participants could **continue with current medical providers** and participate
- Comprehensive **linkage and referral** plans for each site to gender-affirming hormone therapy and other services
 - Deferred arm during the study
 - All participants after the study

HPTN 091: Aims & Design

Primary Aims:

- To assess acceptability and feasibility of the multicomponent intervention
- To assess PrEP uptake and adherence by study arm at Week 26 (6 months)



- **Study visits (every 3 months),**
 - Medication refills: PrEP +/- GAHT
 - Laboratory tests: HIV, STI, safety labs
 - CRFs and ACASI: self-report
- **Primary Outcome Data**
 - TFV levels (measure of adherence)
 - Survey responses (reported adherence)
 - **2 FGDs with 8 peer navigators**

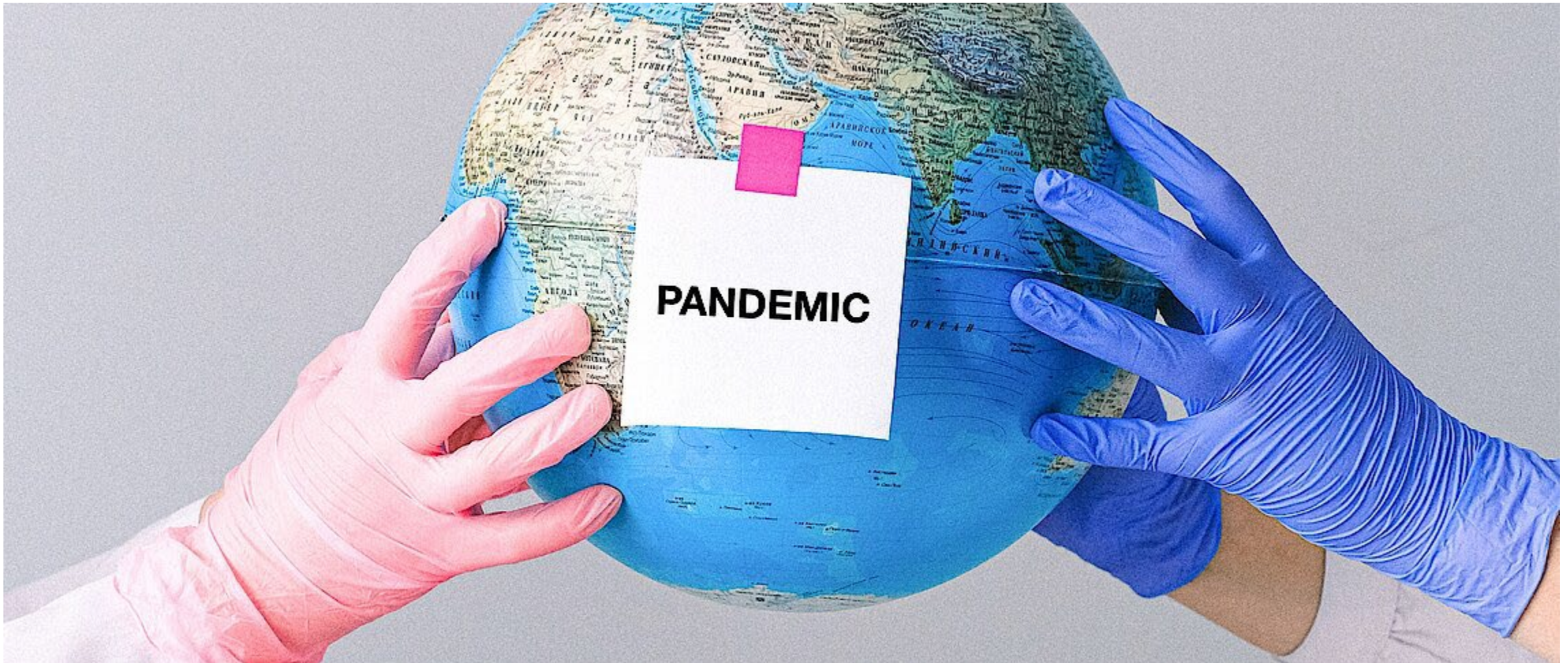
- **Qualitative Data Collection: In-Depth Interview**

- Approximately 60 participants (12 from each site)
- Designed to better understand decision-making around PrEP, experiences with PrEP use, experiences with co-located services, and acceptability of co-located services.

- **Drug-Hormone Interaction Study**

- Up to 50 participants from both study arms
- The goal is to characterize the relationship between GAHT and TAF/FTC

March 2020 – Global Shutdown



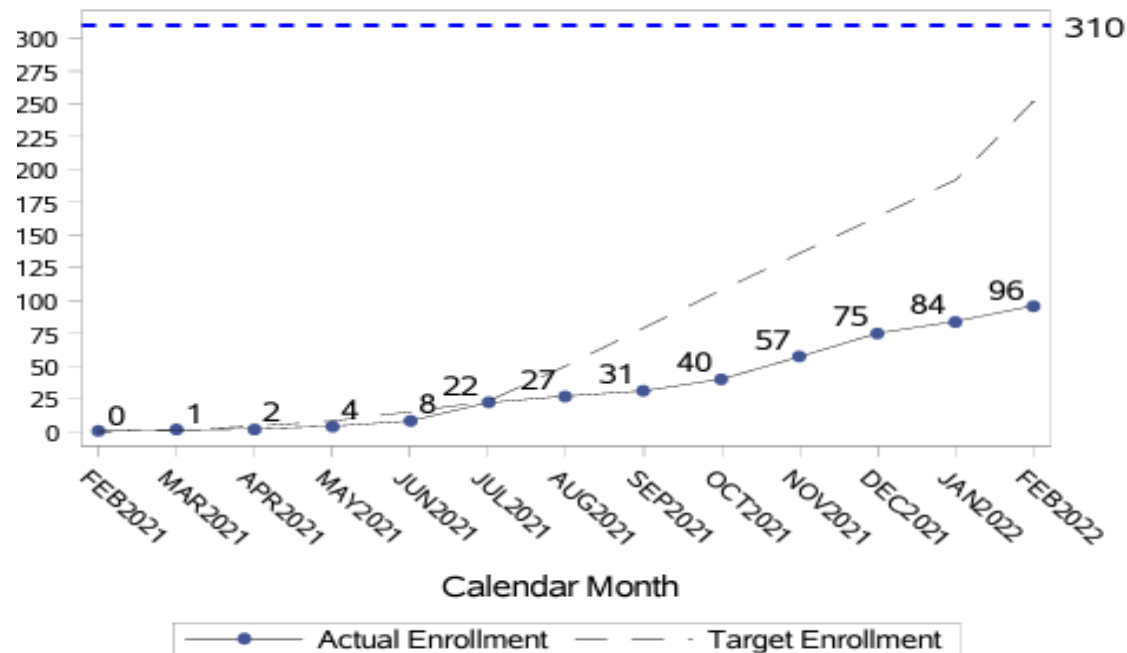
HPTN 091 Implementation Timeline

- **April 2020**
 - Final approval of protocol (HPTN and DAIDS)
- **May – December 2020**
 - Development of study materials (ACASI, IDIs, PHN)
 - Site specific trainings
 - Gender affirming environment
 - In-depth interviews
 - Peer Health Navigation
- **February 2021**
 - Study launched

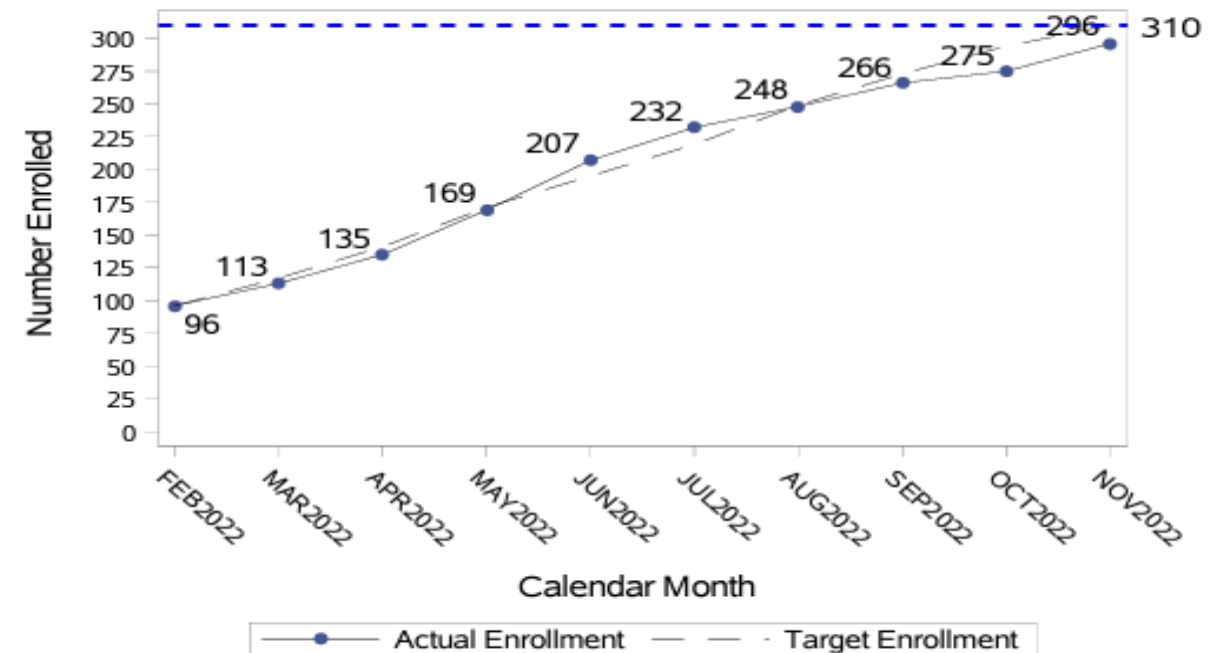
HPTN 091: >95% target enrollment reached

Enrollment completed on 16 December 2022 Final study visit in September 2024

(i) - Original Projection



(ii) - Revised Projection



Baseline Participant Characteristics

Characteristic	Overall (N=304)	Immediate Arm (n=149)	Deferred Arm (n=155)
Age in years (median, IQR, range)	28 (25, 35)	27 (25, 35)	29 (24, 36)
Race & ethnicity (n, %)			
Hispanic/Latina	163 (54%)	82 (55%)	81 (52%)
Black	96 (32%)	46 (31%)	50 (32%)
White	107 (35%)	53 (36%)	54 (35%)
Education			
High school graduate or higher	238 (79%)	116 (78%)	122 (79%)
Enough money for housing, food, and utilities	165 (54%)	84 (56%)	81 (52%)
Ever homeless, n (%)	152 (50%)	77(52%)	75 (48%)
Went to sleep hungry in last 30 days, n (%)	87 (29%)	44 (30%)	43 (28%)

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Characteristic	Overall (N=304)	Immediate Arm (n=149)	Deferred Arm (n=155)
Gender Affirmation			
Ever on GAHT, n (%)	250 (82%)	123 (83%)	127 (82%)
Baseline GAHT use, n (%)*	124 (41%)	59 (40%)	65 (42%)
Sexual Behavior			
Condomless sex past 3 mo, n (%)	151 (50%)	74 (50%)	77 (50%)
Substance use during sex past 3 mo, n (%)	137 (45%)	59 (40%)	78 (50%)
Ever sex work, n (%)	150 (49%)	77 (52%)	73 (47%)
PrEP Use			
Baseline PrEP use, n (%)	34 (11%)	18 (12%)	16 (10%)
PrEP acceptance at enrollment, n (%)	222 (73%)	105 (71%)	117 (76%)

*Baseline GAHT for Deferred arm calculated at week 26 when they become eligible for co-located services and PHN

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Results: Uptake and Adherence

Week 26 Results, n (%)	Overall (N=304)	Immediate Arm (n=149)	Deferred Arm (n=155)	P-values
Study Retention	260 (86%)	125 (84%)	135 (87%)	0.43
Completed ≥ 1 Peer Health Navigation session		147(99%)	1 (1%) ^a	<0.0001
PrEP Uptake	262 (86%)	127 (85%)	135 (87%)	0.64
Self-reported PrEP adherence last 3 months	186/260 ^b (72%)	86/125 (73%)	100/135 (74%)	0.35
TFV-DP above lower limits of detection	199/260 ^b (77%)	93/124 (73%)	104/135 (77%)	0.43
TFV-DP > 4 pills per week	132/260 ^b (51%)	63/125 (50%)	69/135 (51%)	0.91

^a One participant had first PHN session prior to start of 26 weeks

^b Denominator includes only participants who had initiated PrEP *at the clinic* by week 13

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Peer Health Navigators (PHNs): Focus Group Results

- In addition to conducting peer navigation sessions by arm, PHNs engaged in recruitment and retention activities with *all participants*, regardless of arm
- PHNs “improvised” the peer navigation curriculum to *meet the participants’ needs*: “Guidelines for PHN went out the window”
- PHNs often provided support well beyond structured sessions to any participant in need (e.g., name change, food stamps, mental health): “I would go further than information being shared. *Resources were being shared.*”
- Participants shared information and resources across study arms; including hormones. Desire to “build a trans family” – *community-building* encouraged by the peer navigators, “together we are stronger than we imagine”

- PrEP engagement was high among all participants
 - All sites were trained to provide a gender-affirming environment
 - Referrals available to all participants, regardless of arm or PHN
 - Peer support was available to all participants, regardless of arm or PHN
- Co-location and structured PHN sessions were not associated with PrEP uptake or adherence
- Findings highlight flexibility available to PrEP programs
 - Co-locate or facilitate access to external GAHT
 - Context of peer support and gender-affirming environment

Next steps for HPTN 091

- Share primary study findings as widely as possible
- Analyze longitudinal survey and lab data out to 18 months
- Analyze qualitative interviews with participants
- Identify what next HIV prevention research questions are a priority for trans and gender diverse communities

Acknowledgments



Immense gratitude to the all the trans and gender diverse individuals who contributed their time, energy, and data to HIV research as participants, study staff, and investigators

Overall support for the HIV Prevention Trials Network (HPTN) is provided by the National Institute of Allergy and Infectious Diseases (NIAID), Office of the Director (OD), National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) under Award Numbers UM1AI068619-15 (HPTN Leadership and Operations Center), UM1AI068617-15 (HPTN Statistical and Data Management Center), and UM1AI068613-15 (HPTN Laboratory Center). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.



Discussion

