Duo: HIV PrEP and Doxy-PEP

Susan Buchbinder, MD
San Francisco Department of Public Health & UCSF
October 4, 2024



Presentation Highlights



- 1. This is a description of an HPTN study to be conducted in Latin America and the US
- 2. The study will evaluate 3 mobile health tools for their ability to increase use of PrEP (to prevent HIV) and doxycycline PEP (to prevent STIs) in young MSM and non-binary persons assigned male at birth
- 3. If proven successful, these tools could eventually be used to drive down rates of HIV and STI acquisition in Latine individuals.

HPTN 113





Leadership Team





Jorge Gallardo Cartagena
UNMSM
Lima, Peru
Protocol Co-chair



Thiago Torres
Fiocruz
Rio de Janeiro, Brazil
Protocol Co-chair



Caitlin Scoville
FHI 360
Clinical Research Manager



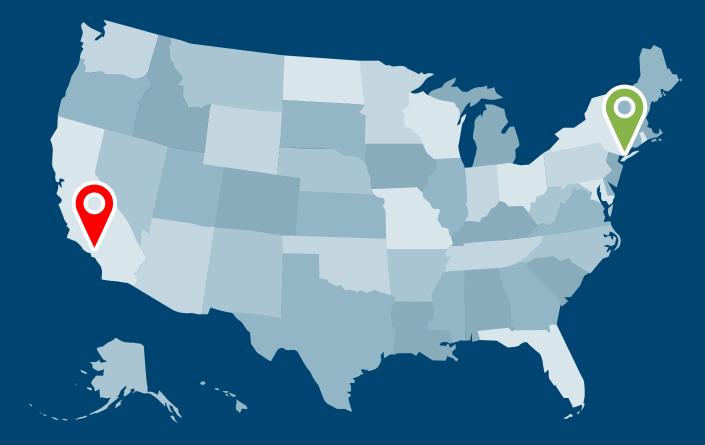
Jayla Harris-Wisecarver FHI 360 Clinical Research Manager

Objectives and Study Sites



Primary

- Adapt and test a suite of 3 mHealth tools to:
 - Increase HIV PrEP uptake
 - Increase HIV PrEP adherence
- Evaluate the uptake, patterns of use, and acceptability of doxy-PEP



Lima, Peru | San Miguel Rio de Janeiro, Brazil | Fiocruz Buenos Aires, Argentina | Fundación Huésped Bronx, USA | Bronx Prevention Center Los Angeles, USA | UCLA Vine St. Clinic



Study Population



Eligibility Criteria

Assigned Male at Birth and identifies as male or nonbinary

Age 18-29 years

Latino/e/x (in the US)

Certain sexual risk behaviors for HIV:

- Condomless sex
- Multiple partners
- STI diagnosis
- Stimulant use

HIV negative

Interested in learning more about, or starting, PrEP

Owns a phone

Able to speak, read, and write in country-specific language

mHealth Tools (1/3)



MyPrEP

Website

Shows PrEP options to help make an informed decision about PrEP start

In African women, doubled PrEP uptake



Take all the worry out of sex.

PrEP, or Pre-exposure prophylaxis, is a pill or a shot that can prevent HIV. It empowers your sexual health by removing concerns about getting HIV so you can get on with living your best life. Choose peace of mind. Choose PrEP.

LEARN ABOUT PYEP







mHealth Tools (2/3)

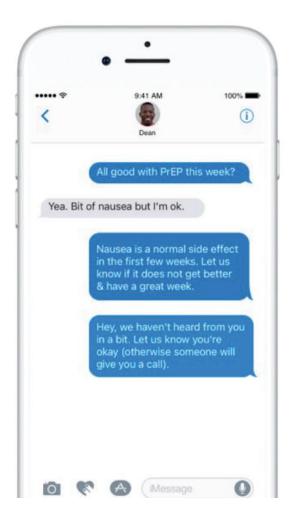


PrEPmate

Two-way SMS platform

Supports PrEP users with interactive SMS message to address concerns between study visits and provide daily reminders

First CDC EBI for PrEP adherence; doubled adherence/retention in young MSM





mHealth Tools (3/3)

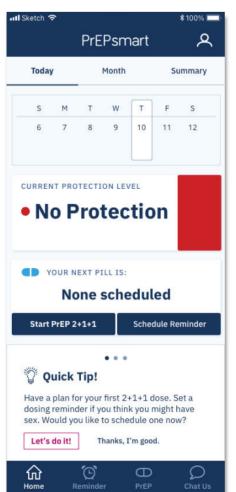


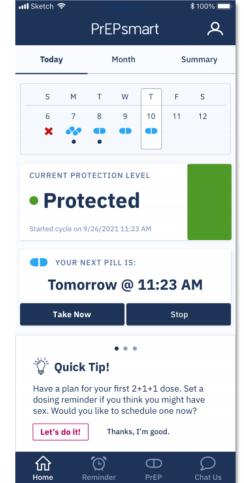
PrEPsmart

Smartphone application

Provides 2-1-1 PrEP users with reminders and tracking tool to see level of protection

In an earlier version, 94% of MSM said it helped with taking PrEP; 97% would use in the future





Study Design - Screen/Enroll



- All participants will:
 - Undergo HIV & STI testing
 - Be randomized to the mHealth intervention or control groups
 - Be provided paper handouts about HIV PrEP and doxy-PEP
 - Be offered their choice of HIV PrEP*
 - Be offered doxy-PEP for STI prevention
- Participants in the mHealth intervention will also:
 - Be counseled and onboarded to the 3 mHealth tools

PrEP Choices



 All participants can choose to use any PrEP type approved within their country (provided by the study):

	Daily Truvada	2-1-1 Truvada	Daily Descovy	CAB-LA
Argentina	✓	✓	✓	
Brazil	✓	\checkmark		✓
Peru	✓	✓		✓
US	✓	\checkmark	\checkmark	✓

Study Design – Follow-up



- All participants will:
 - Be followed for 52 weeks
 - Have regular HIV/STI testing
 - Answer quarterly CASI questionnaires
 - Able to start/stop/switch methods at any time

HPTN 113-01



- Separate protocol for focus group discussions (FGDs)
- Objective is to assess cultural and linguistic relevance of the mHealth tools and paper handouts to be used in the main HPTN 113 study
- Goal is to complete the FGDs faster by uncoupling from the clinical trial procedures and review processes

Timelines



- Phase I: Focus Group Discussions (HPTN 113-01)
 - Training during the annual meeting (June 2024)
 - Refresher trainings online
 - First FG launched September 2024 (Argentina); other sites by Q4 2024
- Phase II: Randomized Study (HPTN 113)
 - Depending on when study drug is available, Q2-3 2025

Acknowledgments



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 (HPTN Leadership and Operations Center), UM1AI068617 (HPTN Statistical and Data Management Center), and UM1AI068613 (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.









