A pill to prevent HIV

HIV prevention implementation in Peru: A large scale PrEP demonstration project in conjunction with the Ministry of Health

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ImPrEP
profilaxia pré-exposição

Disclosures

In the past 12 months, Dr. Konda has received: salary from USC as well as Universidad Peruana Cayetano Heredia, DAIDS, and UCLA

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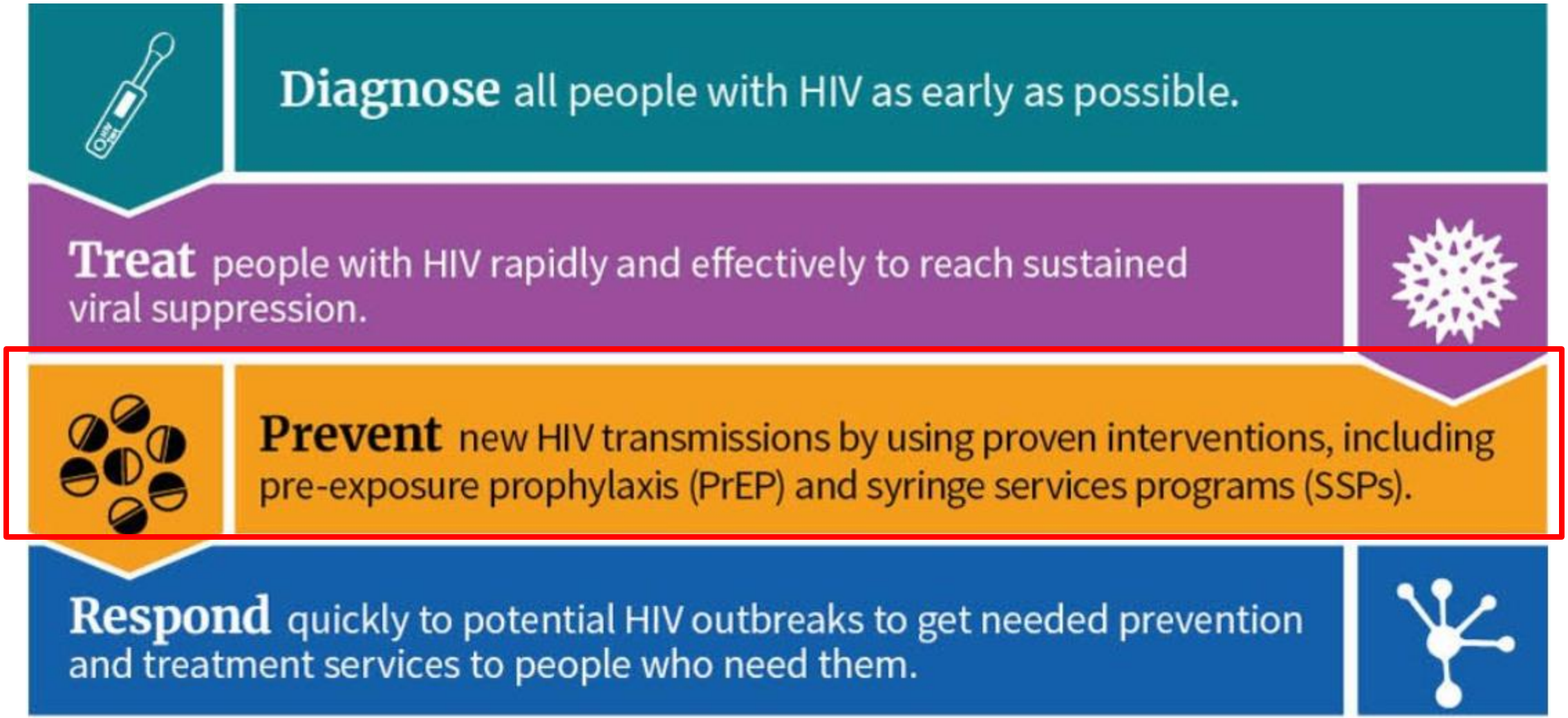
We have the technologies to end the HIV epidemic however, access remains highly inequitable



https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview

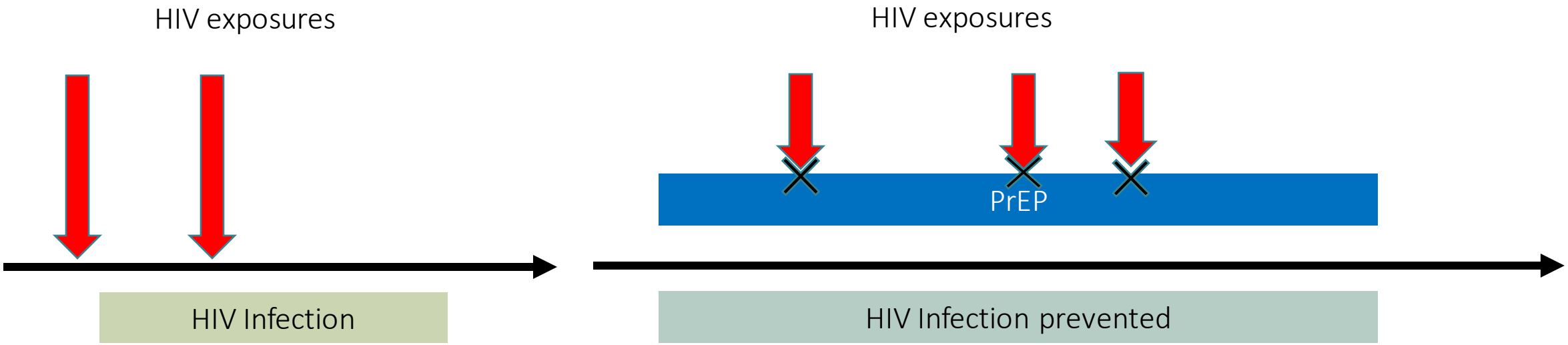
What is PrEP?

PrEP – pre-exposure prophylaxis is a biomedical medication for people not living with HIV

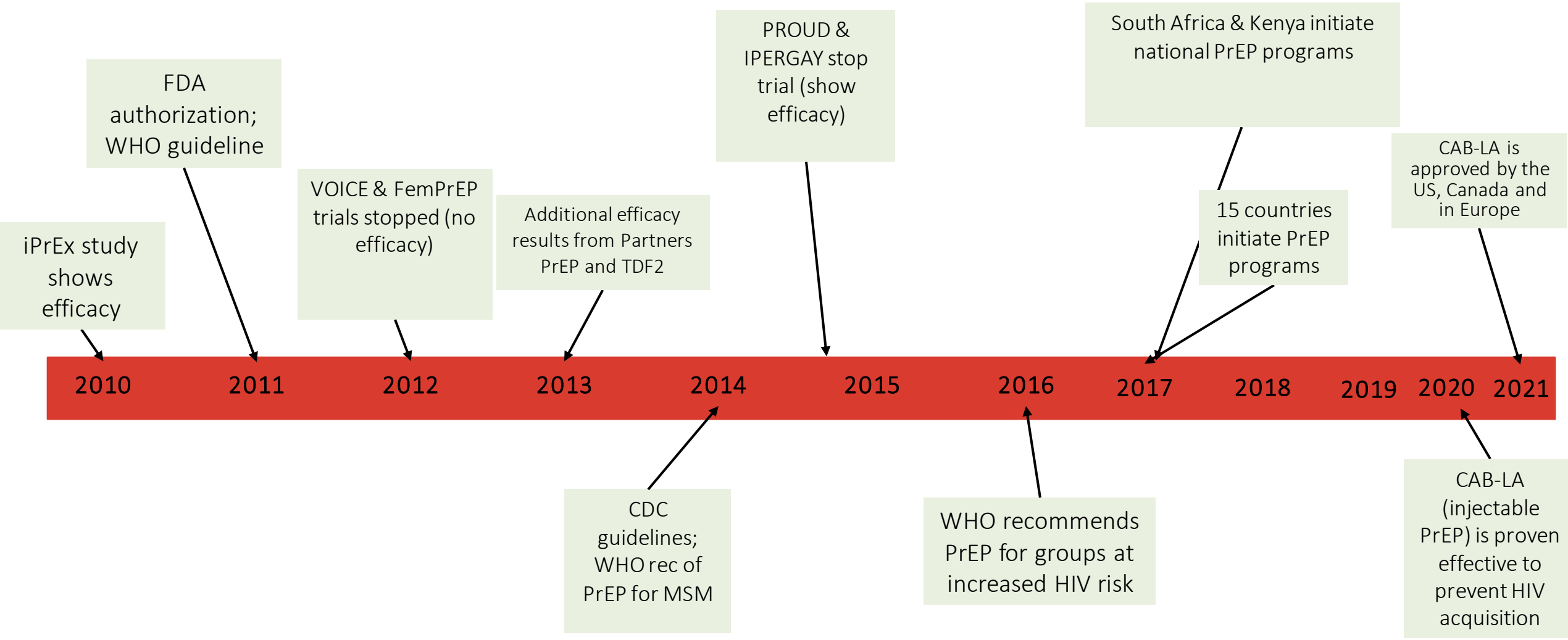
Anyone can take daily oral PrEP, event-driven PrEP (PrEP 2-1-1) is recommended for men who have sex with men

Long-acting Injectable PrEP was approved in 2022

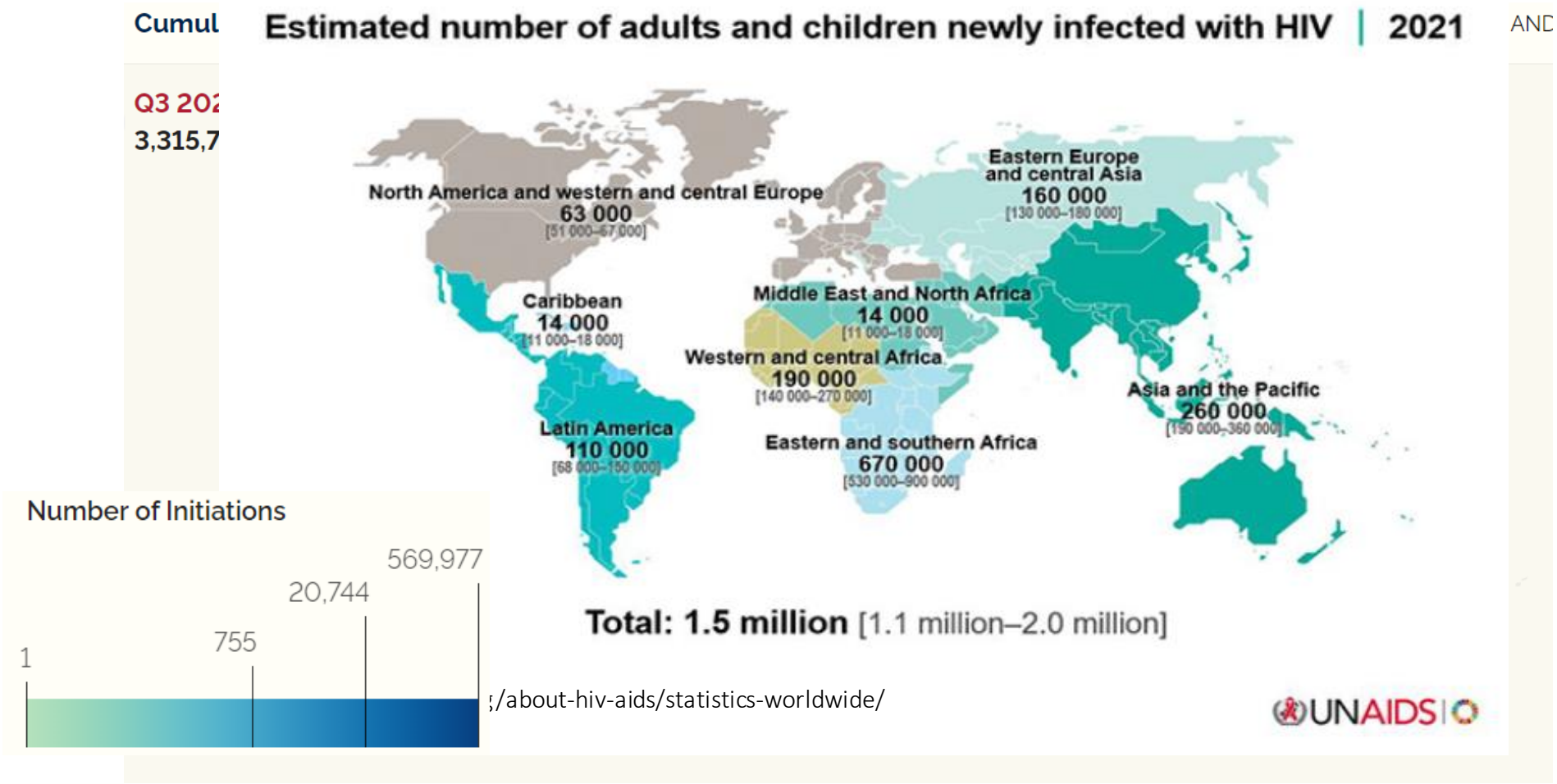
When taken as directed, PrEP is 99% effective in preventing sexual HIV acquisition



PrEP: Timeline



Global PrEP Implementation



Outside of the global north, sub-Saharan Africa has the best overlap bt. HIV infections and PrEP initiations

https://data.prepwatch.org/

Even in countries with widespread access, impediments remain

A Texas judge rules coverage of anti-HIV medicine violates religious freedom

September 8, 2022 · 5:11 AM ET

Most PrEP users in the US are white, urban, gay men

– This does not match HIV incidence

- Disparities do match issues with healthcare access

NPR.org; Bonacci, R. et al. Toward Greater PrEP Equity. AJPM. 2021.; Philbin and Perez-Brumer Curr. Opin. HIV AIDS. 2022.

USC PrEP studies in the US

Keck School of Medicine of USC

Proyecto Facil (**F**acilitating **A**ccess to **C**are in the **I**nland Empire and **L**os Angeles)

- Study to evaluate promote sharing of PrEP information among young Latinx MSM/TW using TikTok
- Facil.usc.edu

Also, conducting a survey of SGM in the inland empire

- To understand PrEP knowledge and Barriers to PrEP uptake

USC PrEP studies around the world

Vietnam: (NIH K01 and R21, PIs Adamson and Klausner) Cohort study with MSM using PrEP to measure STI incidence and AMR resistance in gonorrhea

Botswana & South Africa (NIH and Merck funded projects, PI Klausner)

- Discrete choice experiment and cohort study to understand PrEP preferences among pregnant and breastfeeding women

India (NIH Fogarty K award, PI Fehrenbacher)

- Qualitative research and discrete choice experiments to understand how stigmatized groups in India can be engaged and retained in PrEP programs

South Africa Foundation for Professional Development (East London Team)

Photos courtesy of Chibz Babalola

Access to PrEP in Latin America and the Carribean (LAC) – a review

22/33 (67%) LAC countries had policies approving daily oral PrEP for HIV prevention, most for specific key populations (MSM, sex workers, and sero-discordant couples)

- Generic TDF-FTC has been approved in 14/33 (42%) of countries and 13/33 (39%) have incorporated PrEP into their public health system (often only via small studies)

No countries have approved long acting injectable PrEP – CAB-LA will be provided at a lower cost to low income countries, i.e. not to most LAC countries

Cost data is absent & in some countries policies limit the use of the generic

- PAHO includes TDF/FTC as an essential medicine and LACs can request to purchase it at a reduced price
- Ex. in Peru Truvada® is $100/month, the generic TDF/FTC is $25/month at private clinics or $7/month if purchased through the PAHO program

Murphy, L et al. PrEP Policy Implementation Gaps and Opportunities in Latin America and the Caribbean: A Scoping Review. Under Review.

Key Gaps Identified

- There is extreme heterogeneity in country-level policy roll out impacting access *and* which populations are focused on

- Need to leverage opportunities for incorporating lessons learned for health systems integration

- Need to better understand PAHO pricing and supporting process to include PrEP on essential medications list to become more accessible

- The disparities that underlie both HIV risk and access to PrEP are not part of the consideration for pricing decisions

ImPrEP

A large scale PrEP demonstration project in conjunction with the Ministry of Health

The ImPrEP Study

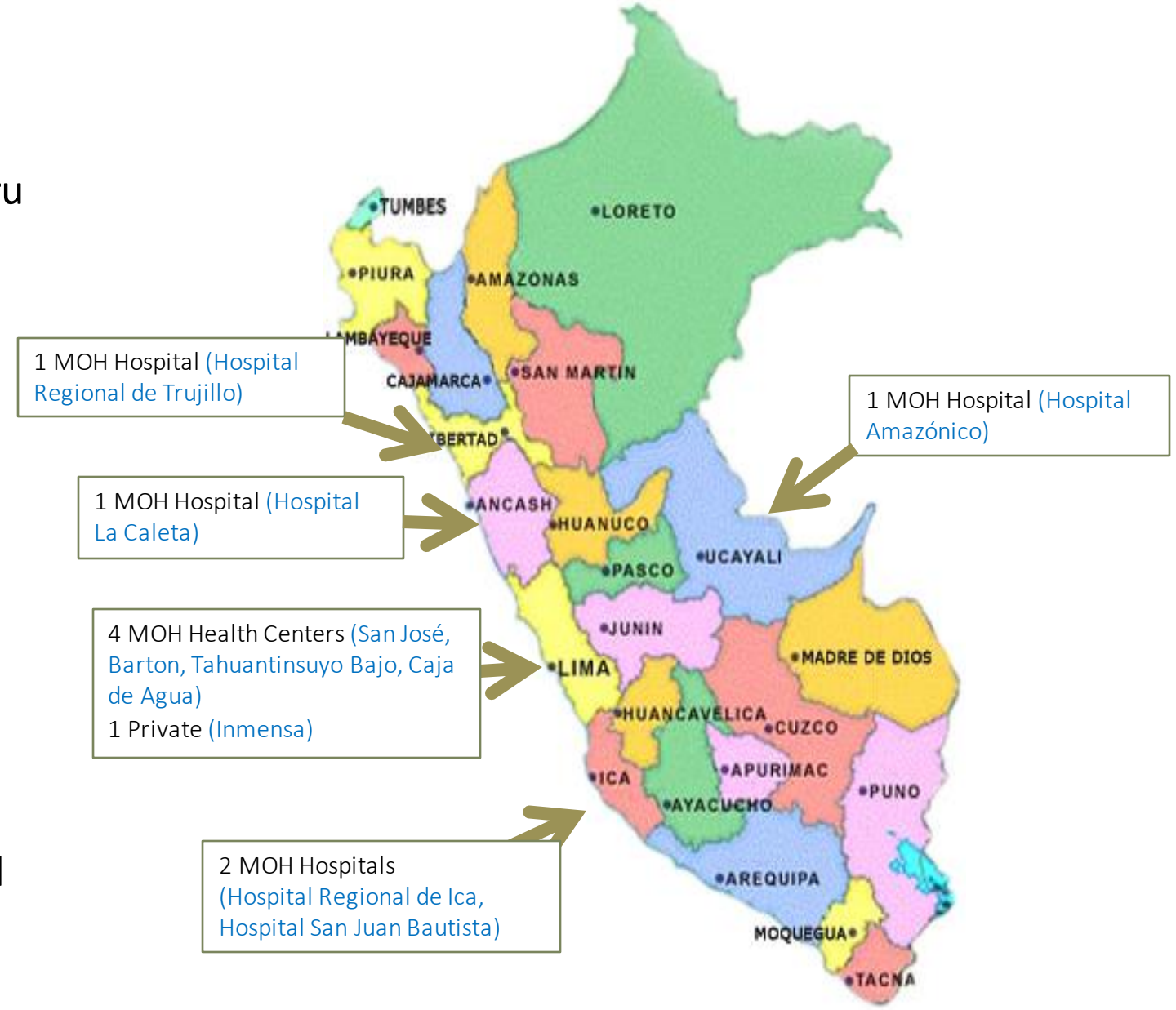
- 3 country study with 28 clinical sites in Peru (10), Mexico (4), and Brazil (14)

In Peru:

  - 9 Public (CERITS / UAMP)
  - 1 Private (INMENSA)

- Recruitment : May 2018 to Feb 2021
- Follow-up: Dec 2021

- This study was funded by UNITAID, which works toward the scale up of underutilized technologies



Planning & Staff Training

There was an initial planning period with the Ministry of Health

- Including site selection – not focused on HIV treatment sites, but HIV prevention sites
- Centers had to want to participate & have experience working with MSM and trans women

Providers expressed reservations about the logistics and noted potential adherence challenges

Provider training – 4 mornings or afternoons and a full day pilot

Topics: PrEP, HIV diagnosis, combination prevention, study procedures, and best practices for working with sexual and gender minorities

Caceres, C. F., et al. (2019). Challenges and Barriers to PrEP Implementation in Public Health Facilities in Latin America: Initial Lessons from the ImPrEP Demonstration Project in Peru. IAS2019. Mexico City, MX.

Formative Research

QUALITATIVE INTERVIEWS

MSM n=10 / TGW n=10

They had questions about PrEP:

- Side effects
- Intermittent PrEP
- The level of adherence required for PrEP to work
- And interaction with hormonal treatment

They were interested in using PrEP, but wanted more information

Sosa et al. AIDS 2020.

ONLINE SURVEY

MSM, 18+, n=1900

47% had heard of PrEP

58% were interested in using PrEP

Informational barriers and beliefs were higher than behavioral barriers

- Informational: e.g. Worry about the side effects and effectiveness of PrEP
- Beliefs: e.g. Worry that people would think they have HIV if they are taking PrEP
- Behavior: e.g. Taking a daily pill

Ofori et al. CROI 2019
Torres et al. JMIR 2019.

ImPrEP Cohort study design

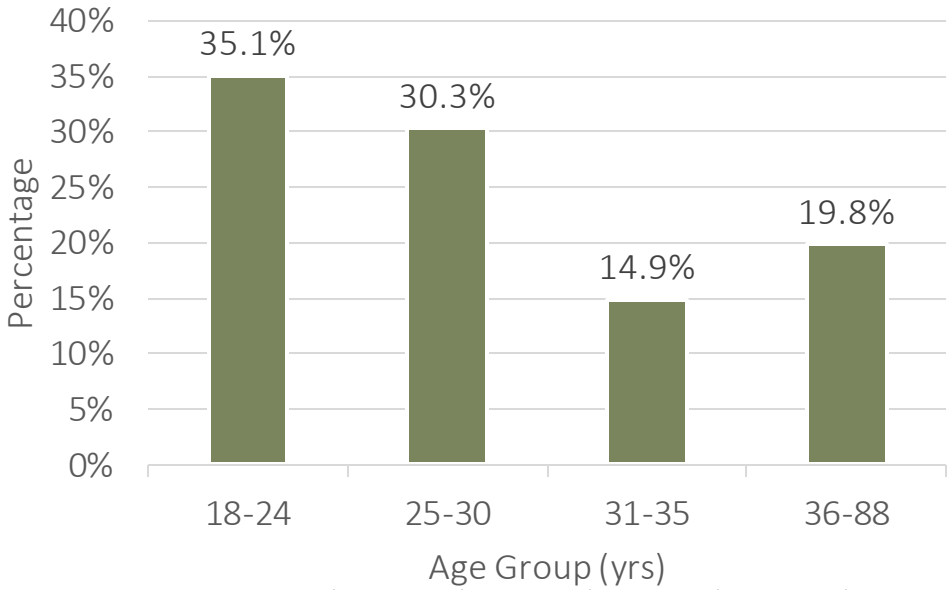
Potentially eligible individuals (MSM/TGW 18+) were recruited at the clinical sites as well as using social media and peer outreach

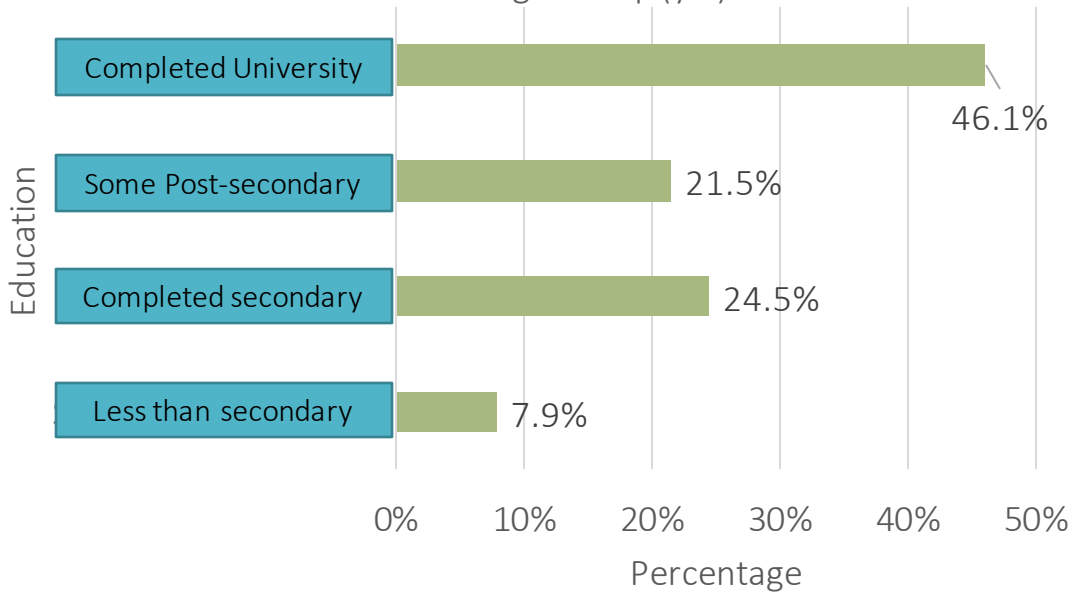
Eligibility included: behavioral factors (sexual risk in the last 6 months), laboratory results (being HIV negative), and clinical criteria (ex. creatinine clearance)

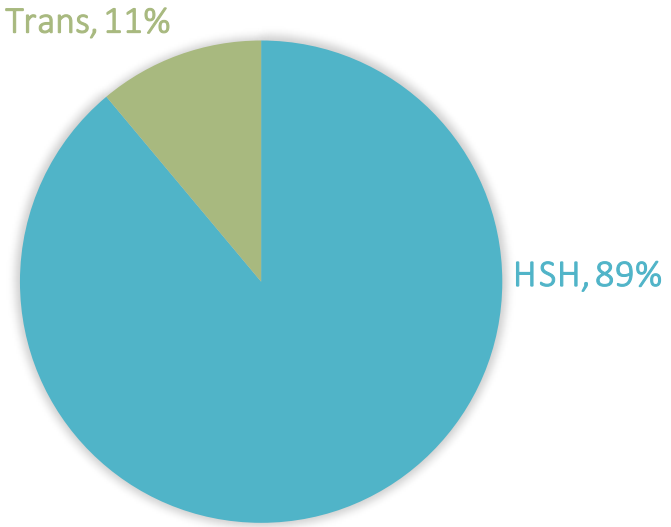
Eligible individuals started PrEP the day of enrollment, receiving 30 pills to return in 1 month

- After the first month, visits were every 3 months

Participant characteristics (Peru n=2299)







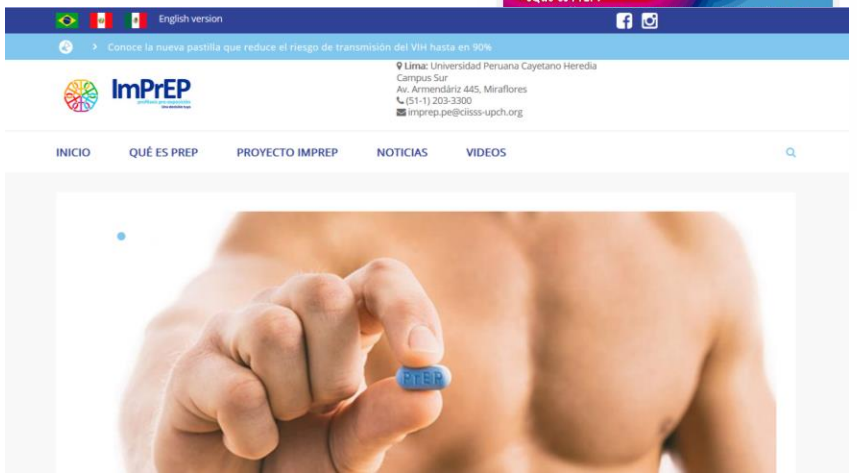
	Peru
Race	
White	10.0%
Non-white (almost all Metizo)	90.0%
Reason to attend the site	
Looking for PrEP	50.0%
Any other reason (primarily HIV testing)	50.0%

Interest and recruitment

There was interest in receiving more information about PrEP

Images of the campaigns carried out to promote PrEP awareness and support enrollment

- Via social media
- At the clinical sites
- Elsewhere (site outreach)



Continuation and Adherence

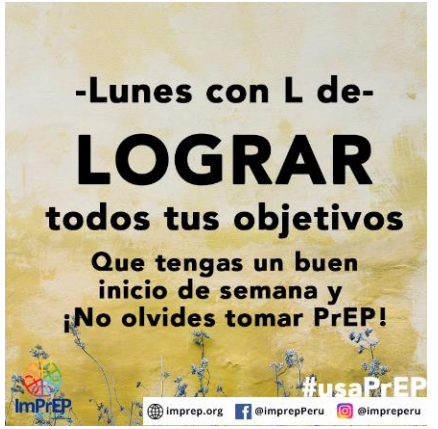
Protocol allowed participants to enroll and start PrEP on the same day

- For many it was the day they learn about the existence of PrEP, this had drawbacks

There were various main reasons for drop-out:

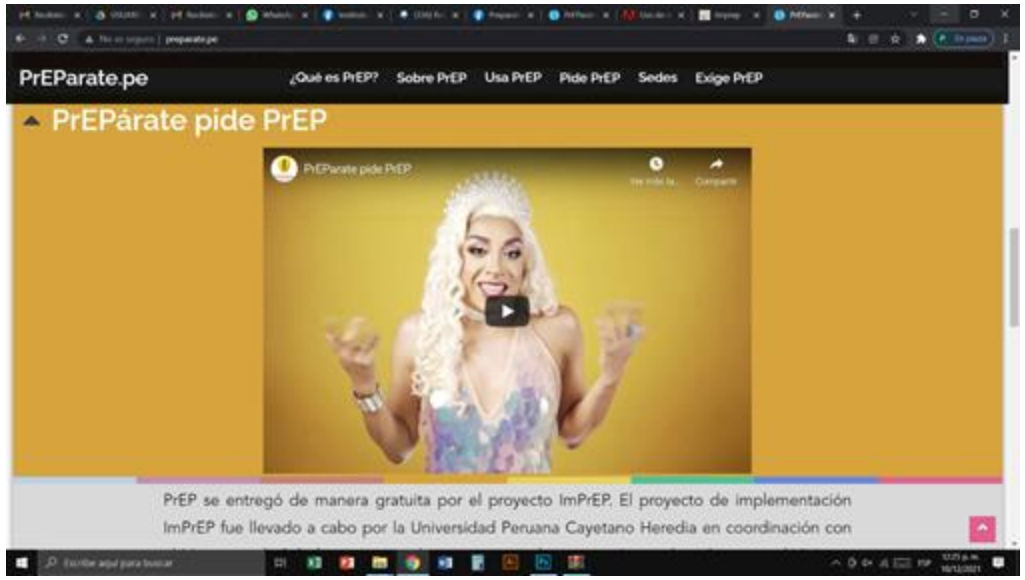
- Losing contact with the participant
- Lack of time
- Side effects

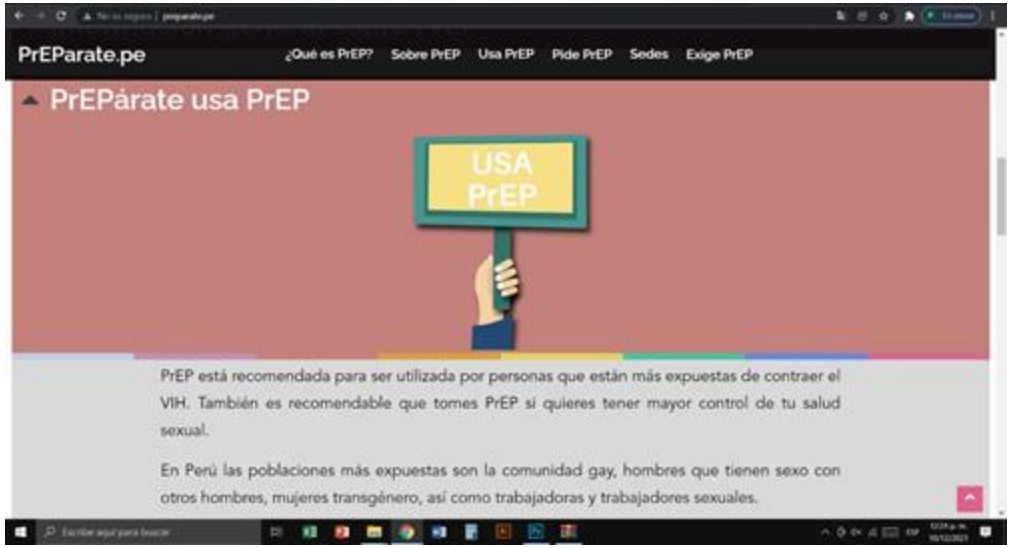
Individuals continuing on PrEP expressed more social support from family and friends



Jirón Sosa et al. HIVR4P 2021.

PrEParate.pe





PrEP adherence 68%
78% in Brazil, 70% in Mexico, and 48% in Peru

PrEP adherence was defined using the MPR = # of pills prescribed/# of days between study visits – perfect adherence for daily PrEP is 1, 0.6 was chosen as it represents sufficient adherence to achieve adequate protection (Anderson PL, et al. Sci Transl Med 2012; 4: 151ra125.)

PrEP adherence was lower among:

Transgender women (0.56), **Participants aged 18–24 years** (0.52) **& 25-30 years** (0.64), **Participants with primary education** (0.60) **or secondary education** (0.70), **Mexican** (0.61) **and Peruvian** (0.38) **participants, Participants with sex partners of unknown HIV status** (0.87), **Participants reporting transactional sex** (0.80)

PrEP adherence was higher among:

Individuals **seeking PrEP** (1.56), those self-identified as **white** (1.11), and those with **sexual risk behaviors** (adherence increased with # of sex partners, among those practicing unprotected receptive anal sex, and those with a sex partner living with HIV)

Veloso et al. Lancet HIV Dec. 2022.

Long-term PrEP engagement, 70.3%
81% in Brazil, 68% in Mexico, and 52% in Peru

Long-term engagement was define as attending 3+ visits within 52 weeks

Long-term PrEP Engagement was lower among:

Transgender women (0.56)

Participants with **secondary education only** (0.74)

Younger participants aged 18–24 years (0.56) & 25-30 years (0.70) compared to 30+

Mexican (0.44) and **Peruvian** (0.47) participants

Participants reporting **transactional sex** (0.81)

Long-term PrEP Engagement was higher among:

White participants (1.11)

Individuals **seeking PrEP** at enrollment (1.32)

Those reporting an **increased number of sex partners**, a **sex partner living with HIV**, or **condomless receptive anal sex**

Those self-reporting **4-week full adherence** (3.14)

PrEP with TW

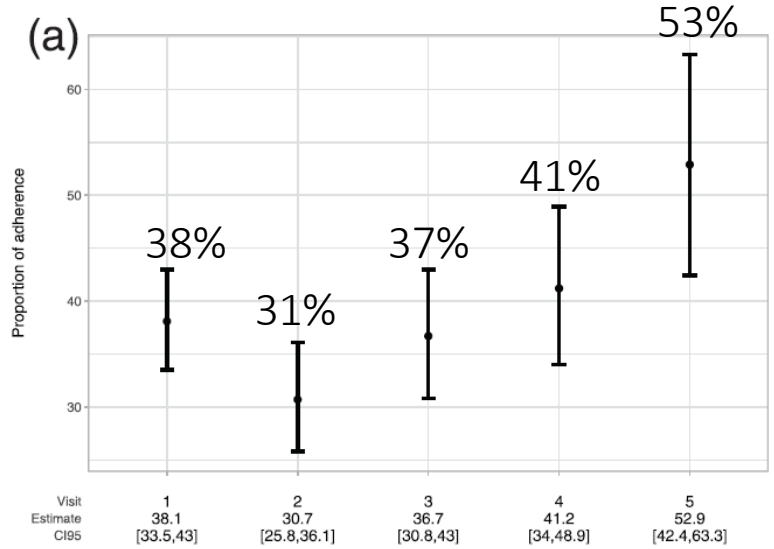
While ImPrEP was able to enroll over 500 transgender women, their outcomes were not great

Adherence to PrEP was low, with few trans individuals returning for follow-up visits and low MPR

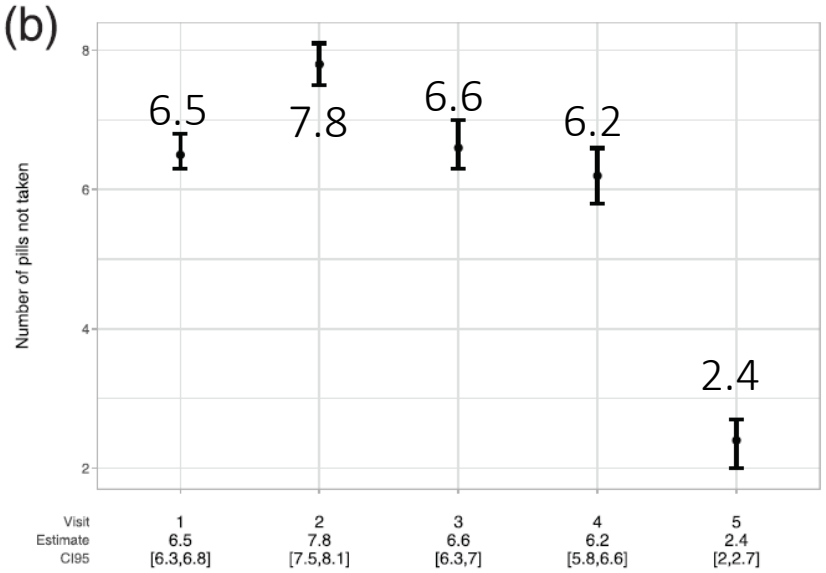
- 20.5% attended 1 follow-up visit, 13.4% 2 visits, 14.6% 3 visits, 16.2% 4 visits, only 17.2% completed all five visits

HIV incidence was found only among Peruvian transwomen, among them incidence was 3.8 cases per 100 person-years

A. % complete self-reported adherence



B. # of PrEP pills not taken by visit



Konda et al. JIAS Sept. 2022.

HIV incidence in ImPrEP

Overall HIV incidence was 0.85 per 100 person-years (95% CI 0.70–1.03)

2.6 (95% CI 2.0-3.4) in Peru

In a multivariable cox model, HIV incidence was higher for **Peruvians**, those **younger than 35** years of age, **Black and mixed-race** participants, participants with an **STI at enrollment**, those reporting **unprotected sex** and participants who were **non-adherent to PrEP**

Being from Peru (aHR 3.9)

Being 18-24 years old (aHR 4.2) or 25-34 years old (aHR 1.9)

Condomless receptive anal sex (aHR 1.8)

STI at enrollment (aHR 1.7)

MPR <1 (aHR 2.1) or <0.53 (aHR 2.8)

Caceres, C. AIDS 2020.

Results summary

Enrollment and delivery of PrEP was feasible

Overall adherence and long-term engagement were achieved by the majority of participants

Inequalities were highlighted across the study outcomes

Implementation Challenges in Peru

Available human resources (doctors and laboratory technicians) prolonged visits, while simultaneously limiting clinic times

- The study centers, even with provision of ART, have few doctors with most care being provided by midwives and nurses

  Currently PrEP requires a doctor's prescription

- Few laboratory staff or dependence on a central laboratory

March 2020, all sites were shutdown entirely for 2-5.5 months due to COVID-19 restrictions

The semi-understood weakness of the Peruvian public health system became very clear very quickly, Peru had the highest per capita death rate from COVID and had twice the normal death toll in 2020

This economic consequences of both COVID and the COVID response impacted participants and their continuation in the study

Caceres, C. F., et al. (2019). IAS2019.
Konda, K. A., et al. (2020). AIDS

PrEP post-ImPrEP

More advocacy is needed

BUT Advocacy from marginalized groups is a hard ask

- Advocacy is needed, they also need support and engagement
- Putting the onus on them is unfair

Continuing to push the government to provide better services and improve PrEP access and care are ongoing research goals

Conclusions

At least in Peru, there were 2 mayor issues –

1. A weak public health system and
2. Need to continue/bolster community outreach and advocacy

   Brazil did better: a more comprehensive health care system & community advocacy

The public system *can* implement PrEP, but focused interventions are needed

Our results are specific, but poor outcomes accentuating existing inequalities are likely universal

- PrEP, like most new technologies, becomes most available to those most able to access and negotiate services (likely CAB-LA is not the answer…)
- With more marginalized groups lagging behind

Muchas gracias!!!
Many thanks!!!

- Participants
- ImPrEP teams
- Unitaid and OMS technical teams
- Ministries of Health of Brazil, Mexico and Peru

Unitaid
Innovation in Global Health

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CAYETANO HEREDIA

CONDESA

World Health Organization

INI
Instituto Nacional de Infectologia
Evandro Chagas

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