Global PrEP Learning Network

PrEP Delivery Strategies & Universal Access to PrEP: Findings from the POWER & SEARCH studies

February 25, 2021

CHOICE Collaboration for HIV Prevention Options to Control the Epidemic

PEPFAR

USAID FROM THE AMERICAN PEOPLE

EpiC Meeting Targets and Maintaining Epidemic Control

RISE Reaching Impact, Saturation, and Epidemic Control

Welcome & Introductions

SEARCH

Q & A with the SEARCH team

POWER

Q & A with the POWER team

PrEP advocacy message

Final Q & A

Today's Speakers

James Ayieko, Kenya Medical Research Institute

James Ayieko is a medical doctor who holds an MPH and a PhD in Epidemiology. James' career over the last decade has centered around HIV care and ways of improving treatment outcomes in low resource settings as well as prevention of new infections. His area of interest has been improving treatment outcomes by optimizing the HIV care cascade right from linkage of HIV infected individuals to care, retention, viral suppression and HIV prevention for the uninfected. Currently he works with the Kenya Medical Research Institute (KEMRI) as a research scientist and is an investigator in the SEARCH test-and-treat trial as well as the SEARCH Youth trial.

Catherine Koss, University of California, San Francisco

Catherine Koss, MD is an infectious disease physician and Assistant Professor in the Division of HIV, Infectious Diseases, and Global Medicine at the University of California, San Francisco in the United States. Dr. Koss conducts clinical and implementation research on HIV prevention, with a major focus on developing strategies to optimize uptake of and adherence to PrEP among women in East Africa and the United States. She also has a major interest in adherence measurement for both HIV treatment and prevention. Dr. Koss is an attending physician on the HIV and Infectious Diseases consult service at San Francisco General Hospital and a primary care provider at the Ward 86 HIV clinic.

Today's Speakers

Connie Celum, University of Washington

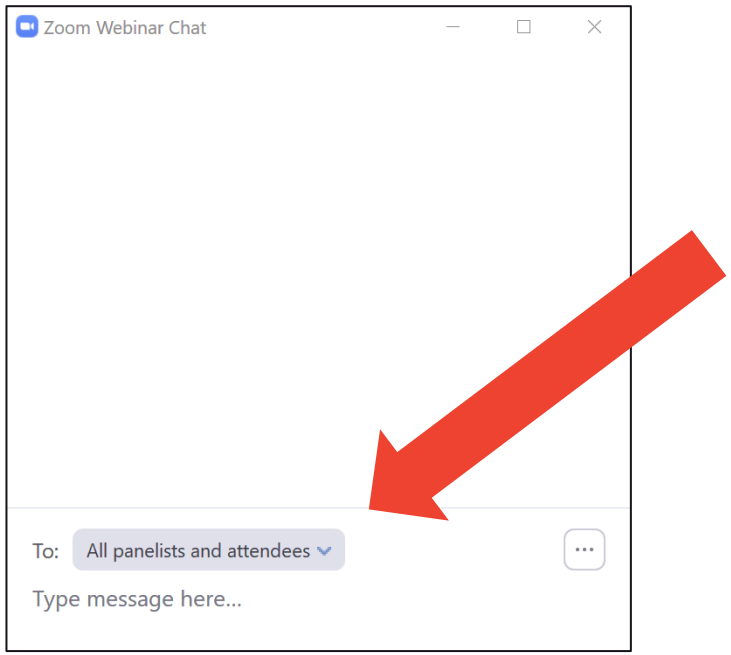
Connie Celum, MD, MPH, is Professor of Global Health, Medicine, and Epidemiology and Director of the International Clinical Research Center at the University of Washington. She is an infectious disease physician, epidemiologist, and clinical researcher. Her research interests focus on HIV prevention strategies and include oral pre-exposure prophylaxis, longer-acting antiretroviral and broadly neutralizing antibodies for prevention, and prevention and treatment of sexually-transmitted infections.

Jason Reed, Jhpiego

Jason Reed, Biomedical HIV Prevention Technical Advisor, offers more than 15 years of experience in public health surveillance and medical epidemiology, specifically in HIV surveillance systems, biomedical prevention programming, and implementation research at state, national and international levels. At Jhpiego, he provides technical oversight of biomedical HIV prevention programs, including PrEP for HIV, supports research development and analysis, and contributes to overall strategic planning for the HIV and Infectious Diseases Unit.

Reminder: Use "Chat" Function

Please feel free to ask questions and add comments to the chat box at any point during today's presentations. At the end of the session, we will dedicate time to Q&A.



Choose *"all panelists and attendees"* from the drop-down menu when adding a question or comment to the chat box.

Opening & Introductions

SEARCH

Q & A with the SEARCH team

POWER

Q & A with the POWER team

PrEP advocacy message

Final Q & A

PrEP Uptake, Engagement, and Impact after Population-level HIV testing in Rural Kenya and Uganda: Findings from the SEARCH study

James Ayieko, MBChB, MPH, PhD[1] and Catherine Koss, MD[2]

On behalf of the SEARCH Collaboration

[1]Kenya Medical Research Institute, Kisumu, Kenya
[2]University of California, San Francisco, United States

PrEP Learning Network Webinar
February 25, 2021

SEARCH
SUSTAINABLE EAST AFRICA RESEARCH IN COMMUNITY HEALTH

Outline

(1) SEARCH study and PrEP intervention

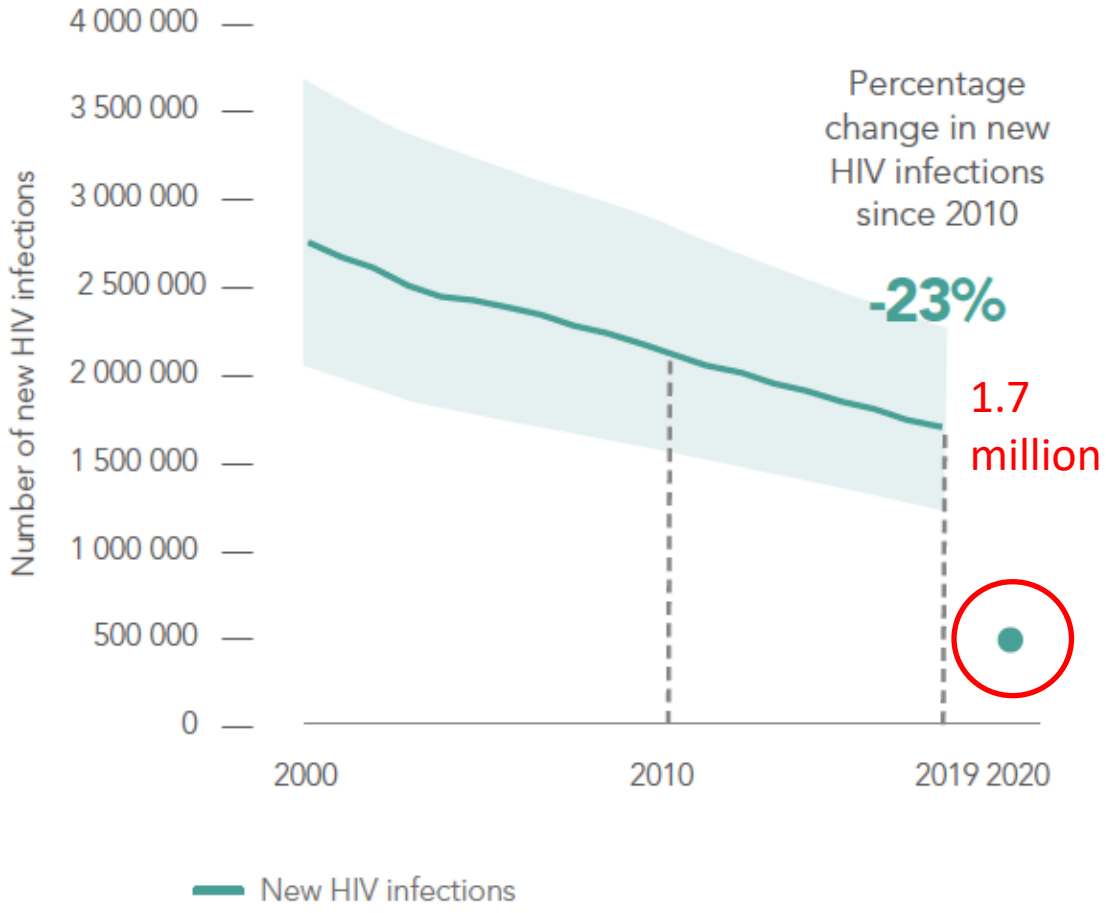
(2) Findings on PrEP uptake, engagement, and HIV incidence

(3) Lessons learned and considerations for future service delivery

New HIV infections continue to exceed global targets

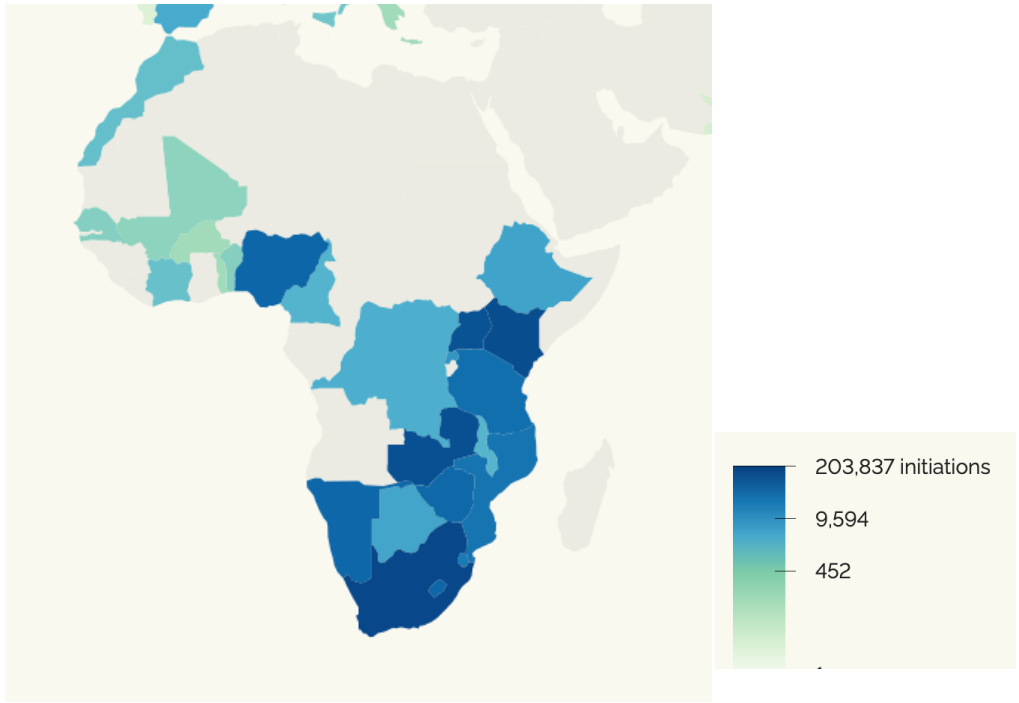
1.7 million new HIV infections globally in 2019[1]

– UNAIDS 2020 target of 500,000 new infections



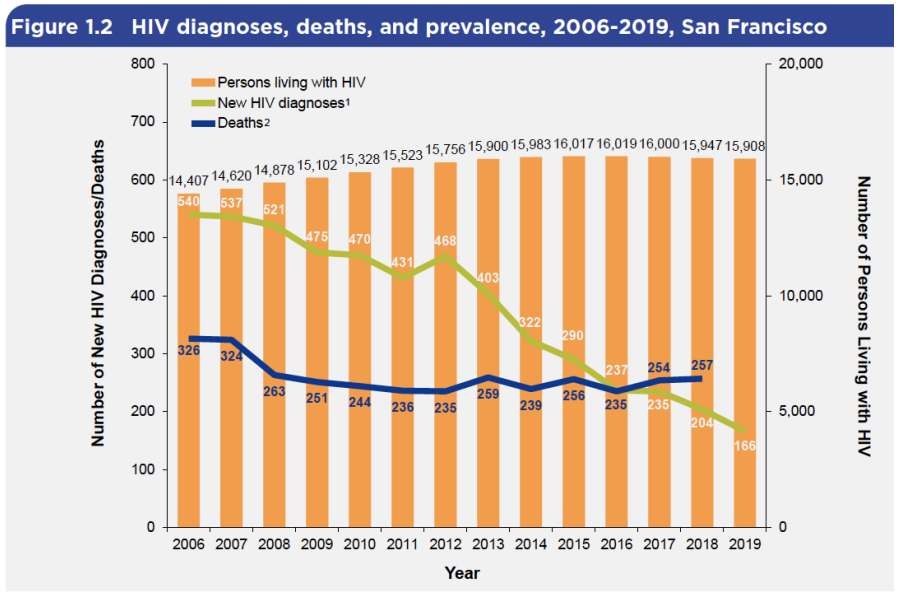
Oral PrEP is highly effective[2,3]

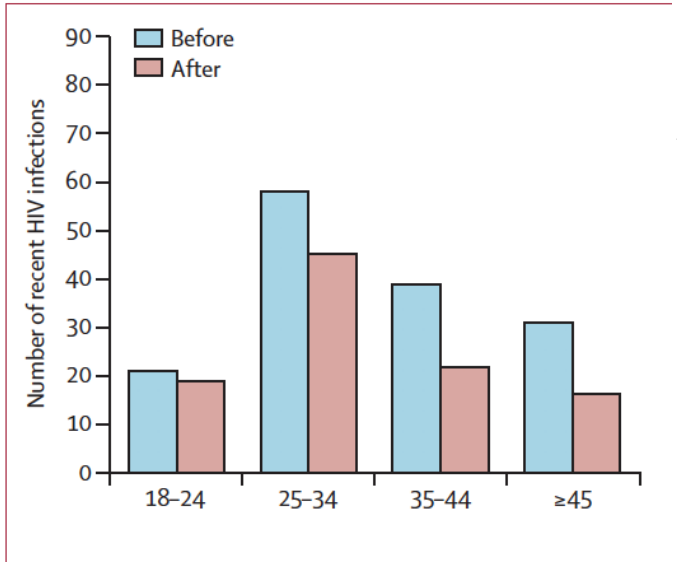
Could substantially reduce HIV incidence



1. UNAIDS Global AIDS Update 2020. 2. Grant et al. NEJM 2010. 3. Baeten et al. NEJM 2012. 4. AVAC Global PrEP Tracker.

Declines in HIV diagnoses where HIV testing + ART + PrEP scaled up

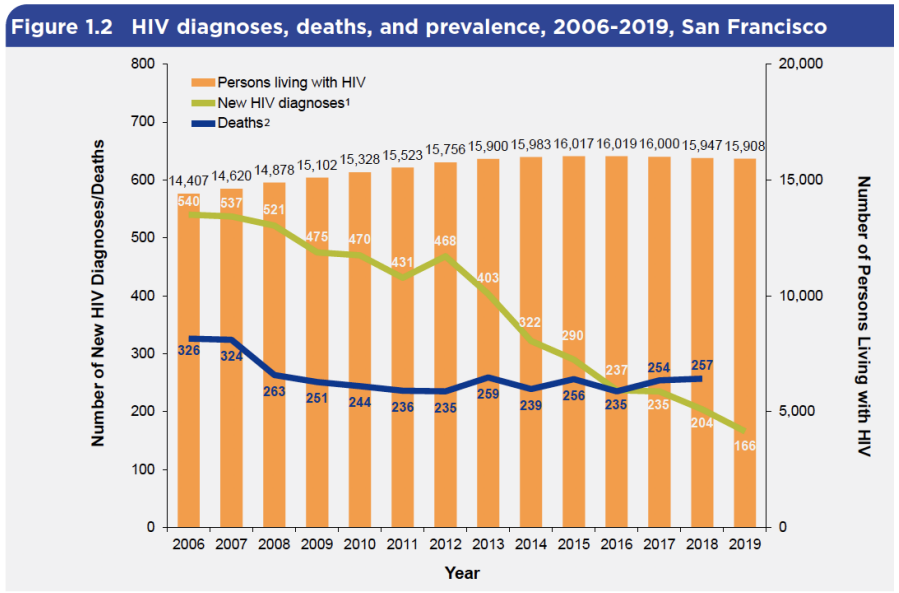




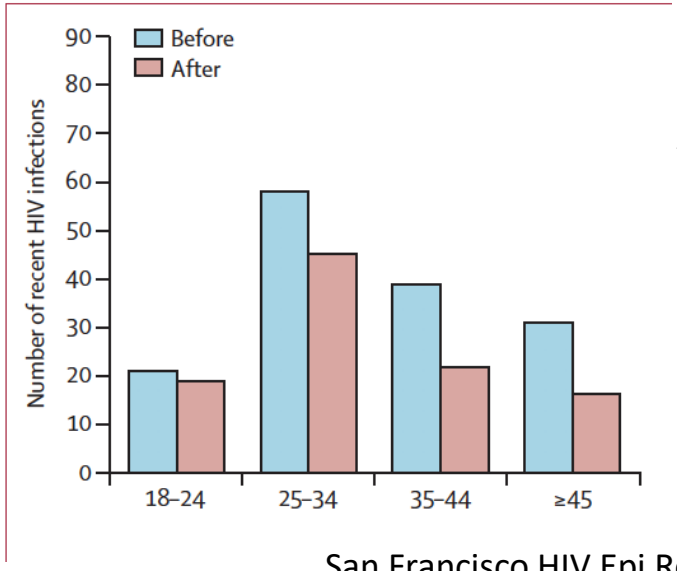
New South Wales, Australia

San Francisco HIV Epi Report 2019. Buchbinder, Havlir JAIDS 2019. Grulich Lancet HIV 2018.

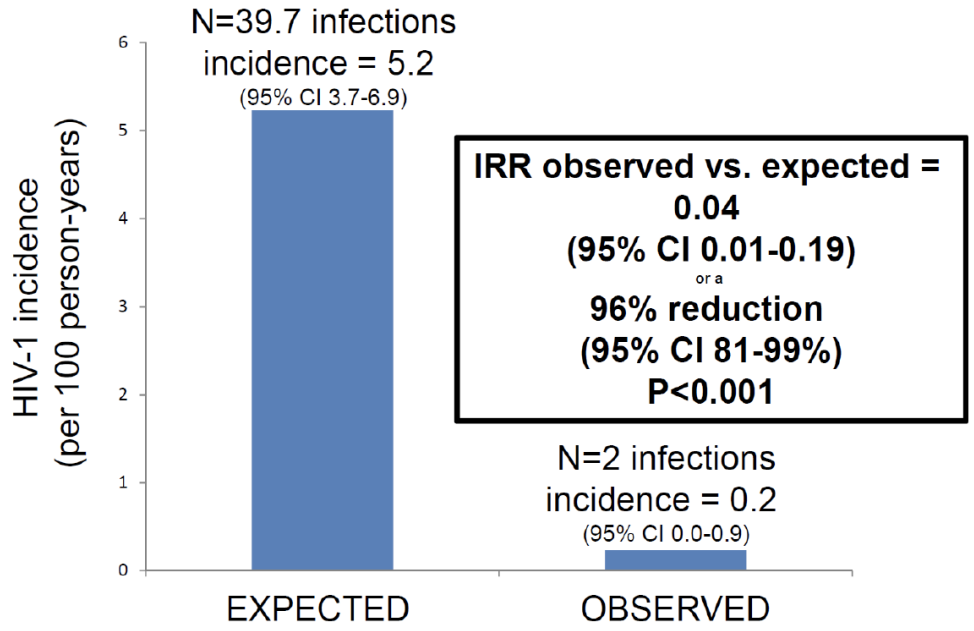
Declines in HIV diagnoses where HIV testing + ART + PrEP scaled up



Accumulating evidence of
lower HIV incidence in PrEP studies
in eastern and southern Africa
compared to controls or modelled data



New South Wales, Australia



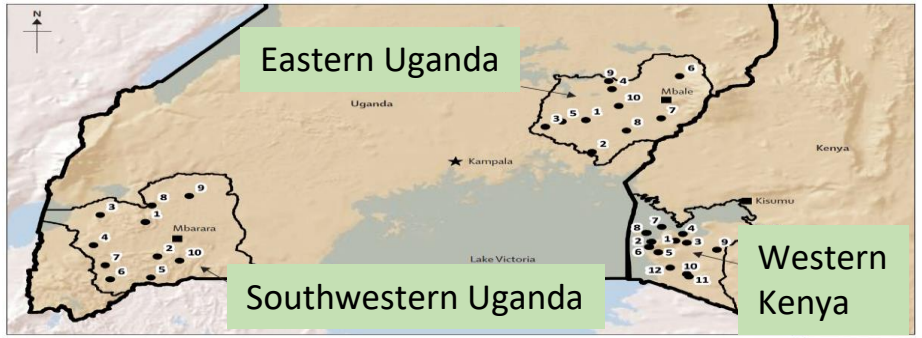
San Francisco HIV Epi Report 2019. Buchbinder, Havlir JAIDS 2019. Grulich Lancet HIV 2018. Baeten PLOS Med 2016. Celum IAS 2019.

How to reduce HIV incidence and improve community health?

SEARCH
SUSTAINABLE EAST AFRICA RESEARCH IN COMMUNITY HEALTH

Universal test-and-treat trial (2013-2017 – *before PrEP*)[1]
32 communities in rural Kenya and Uganda

Can HIV "test and treat" with universal ART using a
multi-disease, patient-centered care model
reduce new HIV infections and improve community health
compared to a country guideline approach?



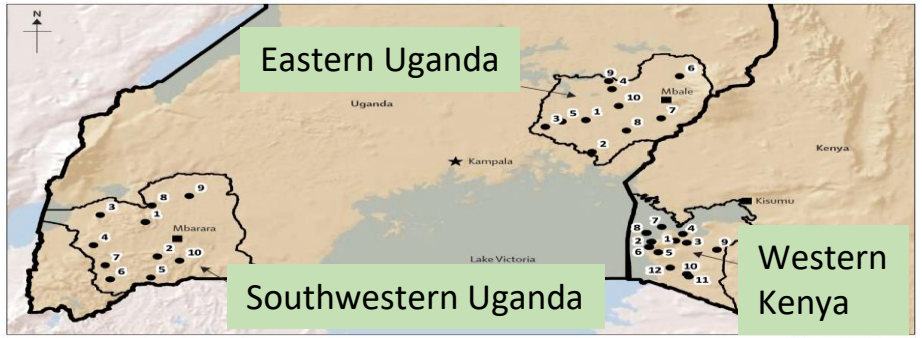
1. PIs: **Diane Havlir, Moses Kamya, Maya Petersen**.

How to reduce HIV incidence and improve community health?

SEARCH
SUSTAINABLE EAST AFRICA RESEARCH IN COMMUNITY HEALTH

Universal test-and-treat trial (2013-2017 – *before PrEP*)[1]
32 communities in rural Kenya and Uganda

Can HIV "test and treat" with universal ART using a
multi-disease, patient-centered care model
reduce new HIV infections and improve community health
compared to a country guideline approach?



Community-wide testing for
HIV
Hypertension
Diabetes
Malaria

Health fairs +
Home-based testing for non-attendees[2]

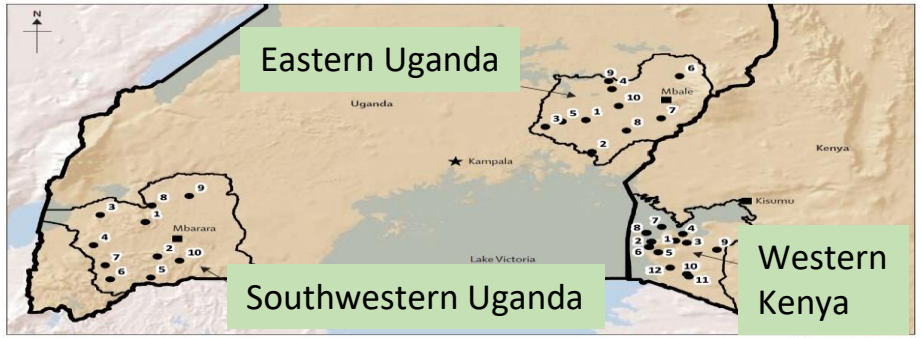
1. PIs: **Diane Havlir, Moses Kamya, Maya Petersen**. Havlir DV. NEJM 2019. 2. Chamie G. Lancet HIV 2016. 3. Kwarisiima D. JIAS 2017. 4. Ayieko J. JAIDS 2019.

How to reduce HIV incidence and improve community health?

SEARCH
SUSTAINABLE EAST AFRICA RESEARCH IN COMMUNITY HEALTH

Universal test-and-treat trial (2013-2017 – *before PrEP*)[1]
32 communities in rural Kenya and Uganda

Can HIV "test and treat" with universal ART using a
multi-disease, patient-centered care model
reduce new HIV infections and improve community health
compared to a country guideline approach?



Community-wide testing for
HIV
Hypertension
Diabetes
Malaria

Health fairs +
Home-based testing for non-attendees[2]

Intervention:
Among all persons with HIV

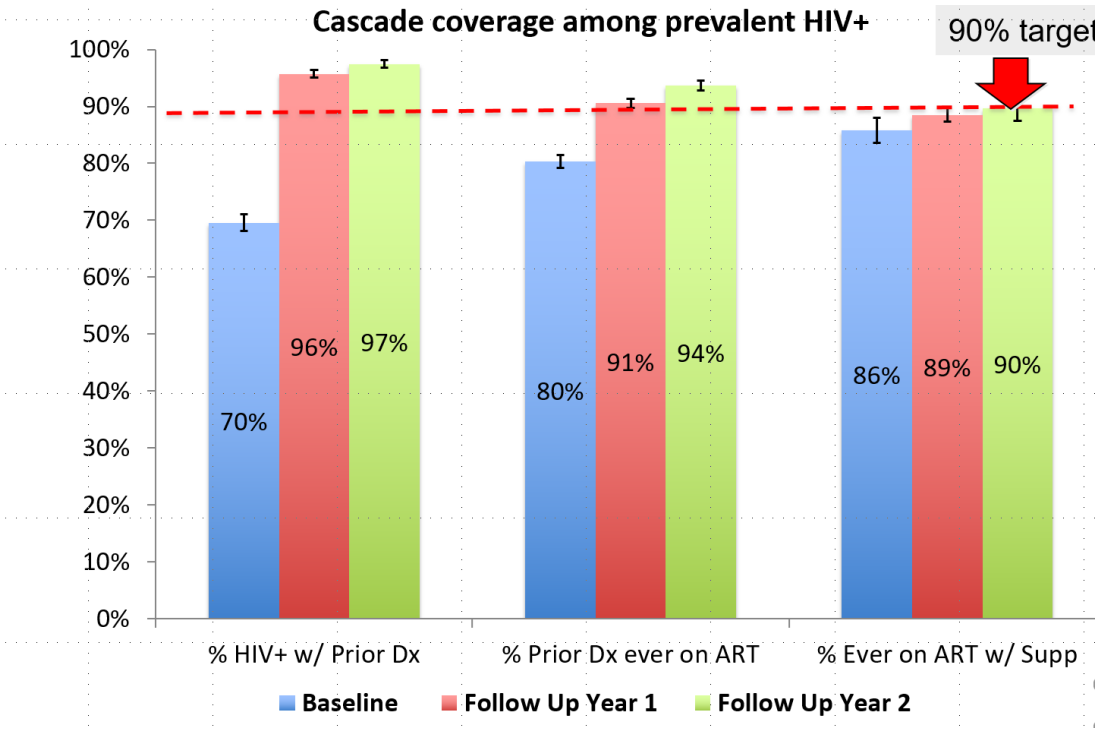
Universal ART eligibility
+
Patient-centered care delivery[3]
Facilitated linkage[4]
Rapid ART start
Flexible hours
Phone hotline to contact provider

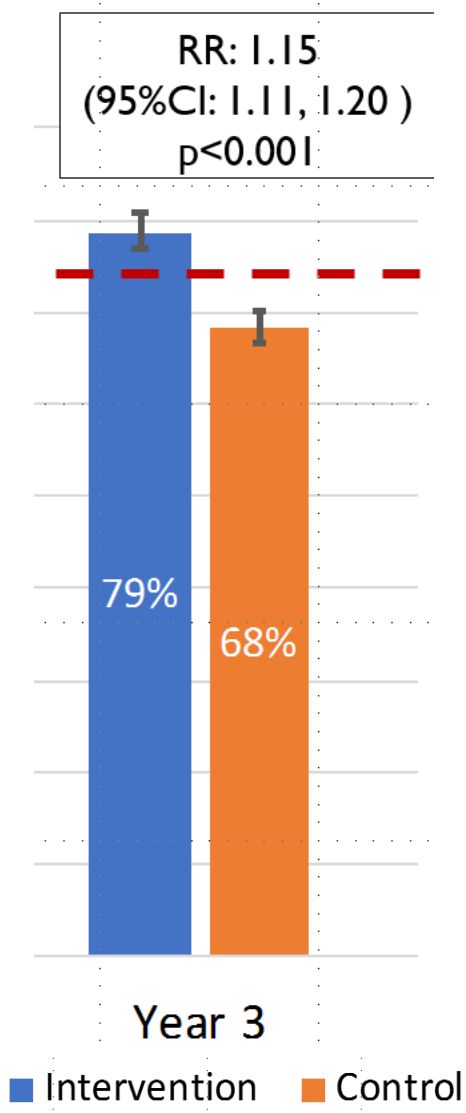
1. PIs: **Diane Havlir, Moses Kamya, Maya Petersen**. Havlir DV. NEJM 2019. 2. Chamie G. Lancet HIV 2016. 3. Kwarisiima D. JIAS 2017. 4. Ayieko J. JAIDS 2019.

Key findings: universal test + treat

In 2 years, population testing + universal ART exceeded 90-90-90 targets

- Targets achieved in both men and women
- Viral suppression lower in youth



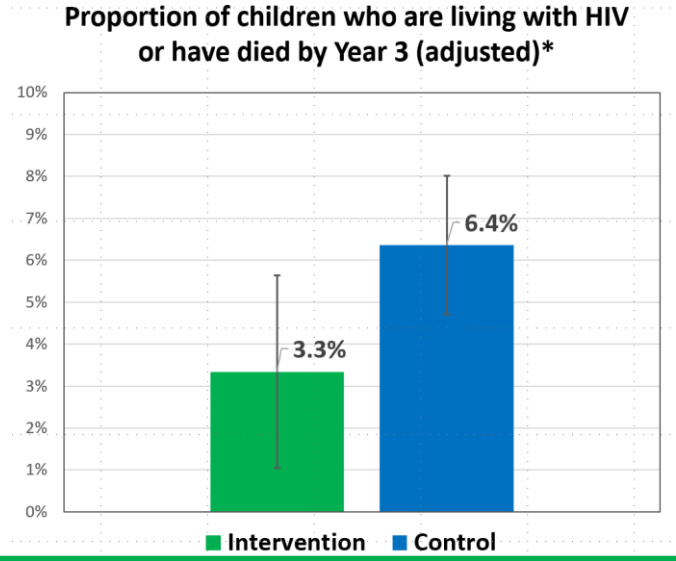


At 3 years, viral suppression higher in intervention vs control

HIV incidence did not differ between arms (possibly due to guideline change in control arm)

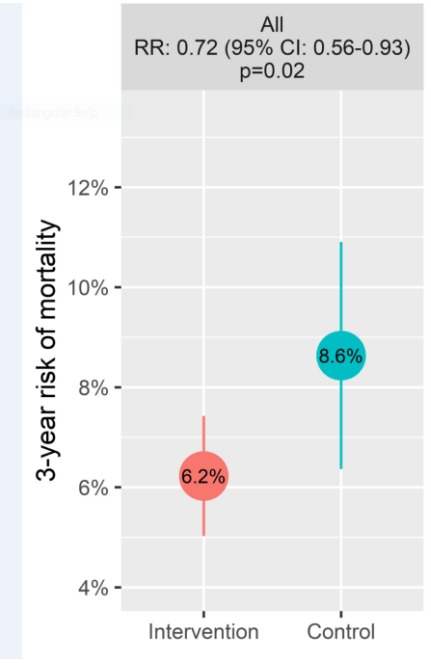
1. Petersen ML et al. JAMA 2017. Havlir DV et al. NEJM 2019.

1. Reduction in perinatal transmission



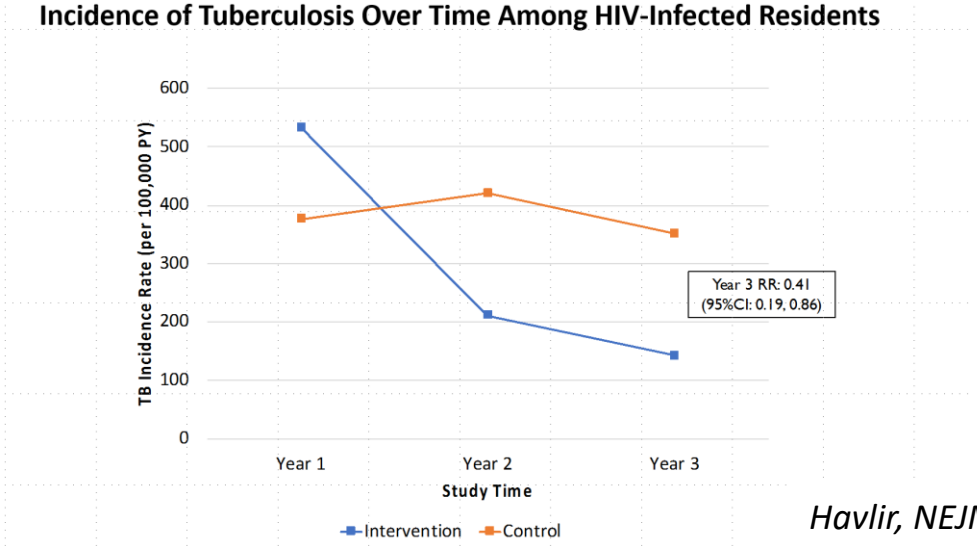
Ruel, CROI 2020

2. Reduction in HIV mortality



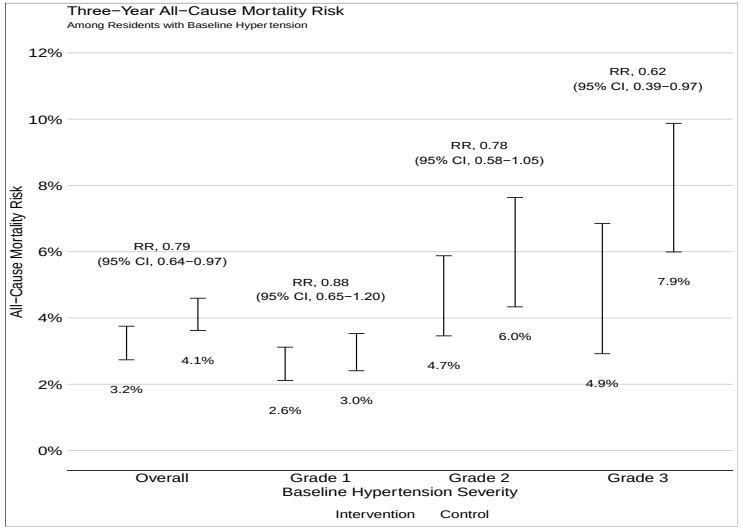
Kamya, Clin Infect Dis, in press

3. Reduction in HIV-associated TB



Havlir, NEJM, 2019

4. Reduction in hypertension and hypertension mortality (including when restricted to HIV-negative only)



Hickey, unpublished

Adding universal access to PrEP

We took what we learned about *community-wide testing* and *patient-centered care* and asked --

Could adding PrEP further reduce HIV incidence among persons at elevated HIV risk?

SEARCH: Population-level PrEP intervention

- Starting in 2016-2017, prior to scale-up of PrEP in Kenya and Uganda

- **PrEP intervention** in 16 communities

Community-wide testing for
HIV
Hypertension
Diabetes
Malaria

Health fairs +
Home-based testing for non-attendees

→

All persons with HIV

Universal ART eligibility
+
Patient-centered care delivery

SEARCH: Population-level PrEP intervention

- Starting in 2016-2017, prior to scale-up of PrEP in Kenya and Uganda
- **PrEP intervention** in 16 communities

Community-wide testing for
HIV
Hypertension
Diabetes
Malaria

Health fairs +
Home-based testing for non-attendees

All persons with HIV

Universal ART eligibility
+
Patient-centered care delivery

All persons without HIV

Universal access to PrEP

Enhanced counseling on PrEP for persons at elevated HIV risk

Same-day PrEP start

Flexible delivery system
Options for clinic or community-based visits

How was PrEP offered?

SEARCH
SUSTAINABLE EAST AFRICA RESEARCH IN COMMUNITY HEALTH

Community sensitization and provided information on PrEP

- Group-based education on PrEP upon arrival at health fairs

<u>Universal</u> access to PrEP + enhanced counseling on PrEP for persons at elevated risk (inclusive approach to eligibility):

- Serodifferent partnership
- Empiric risk score[6,7] – sociodemographic data
- Otherwise self-identified HIV risk[8]

PrEP offered during HIV testing events at health fairs or nearby clinics:

- During ***population-level*** HIV and multi-disease testing (2016-2017)
- During ***key population*** HIV testing for groups, e.g. SDC; youth; fishing, transportation workers (2017-2018)
- On an ***ongoing basis*** in each community (2016-2019)

1. Havlir DV. NEJM 2019. 2. Petersen ML. JAMA 2017. 3. Kamya MR. Clin Infect Dis 2021. 4. Ayieko J. JAIDS 2019. 5. Koss CA. Lancet HIV 2020.
6. Zheng W. Stat Med 2018. 7. Balzer LB. Clin Infect Dis 2019. 8. If not in serodifferent partnership or identified by risk score.

SEARCH PrEP delivery model

<u>Same-day</u> or rapid PrEP start on-site at health fairs or clinics

- Drew creatinine but started PrEP same-day prior to receiving results

Flexible delivery system for follow-up visits

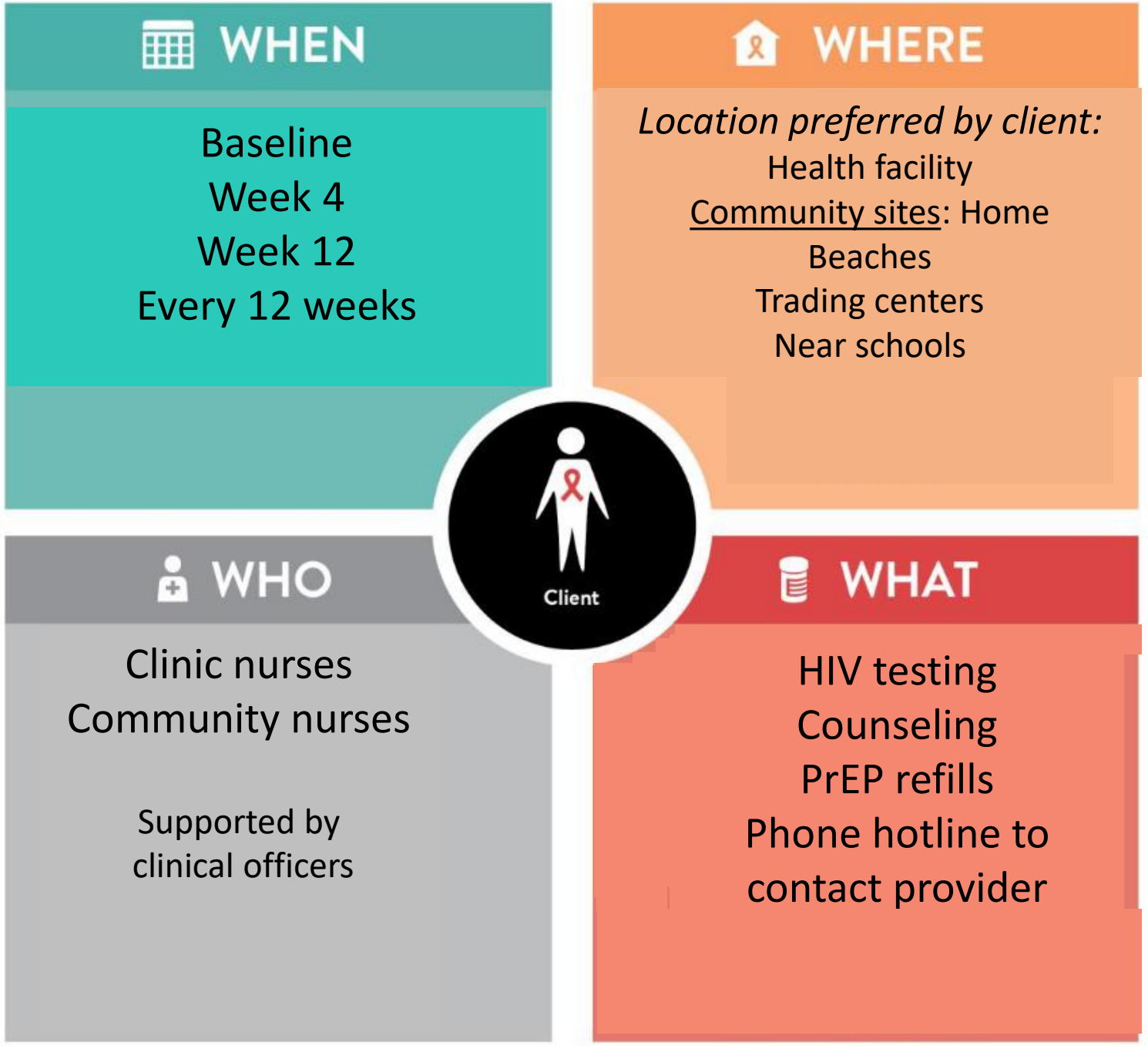
SEARCH PrEP delivery model

<u>Same-day</u> or rapid PrEP start on-site at health fairs or clinics

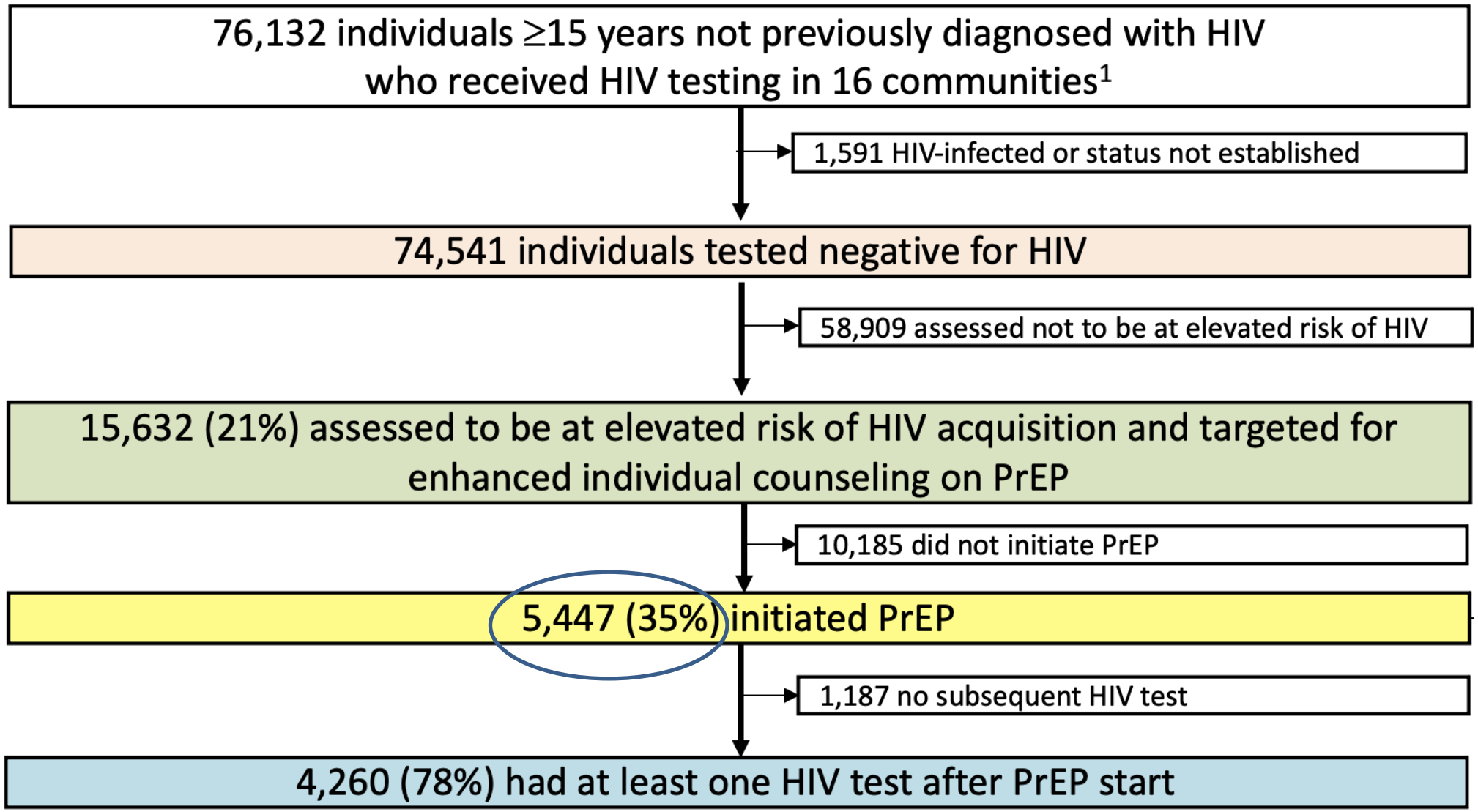
- Drew creatinine but started PrEP same-day prior to receiving results

Flexible delivery system for follow-up visits

Adapted from differentiatedservicedelivery.org



Results: One-third of persons at elevated HIV risk started PrEP



[1]83% of residents not previously diagnosed with HIV attended community-wide testing

Who started PrEP?

Characteristic	PrEP initiators N = 5447 %
Female sex	49%
Age 15-19 years **20-24 years** **25-34 years** **35-44 years** **≥45 years**	6% 23% 35% 21% 16%
Serodifferent partner	19%
Fishing, bar, or transportation occupation	22%
Unmarried **Married – monogamous** **Married – polygamous**	21% 51% 19%
Circumcision (men)	49%
Mobile	6%

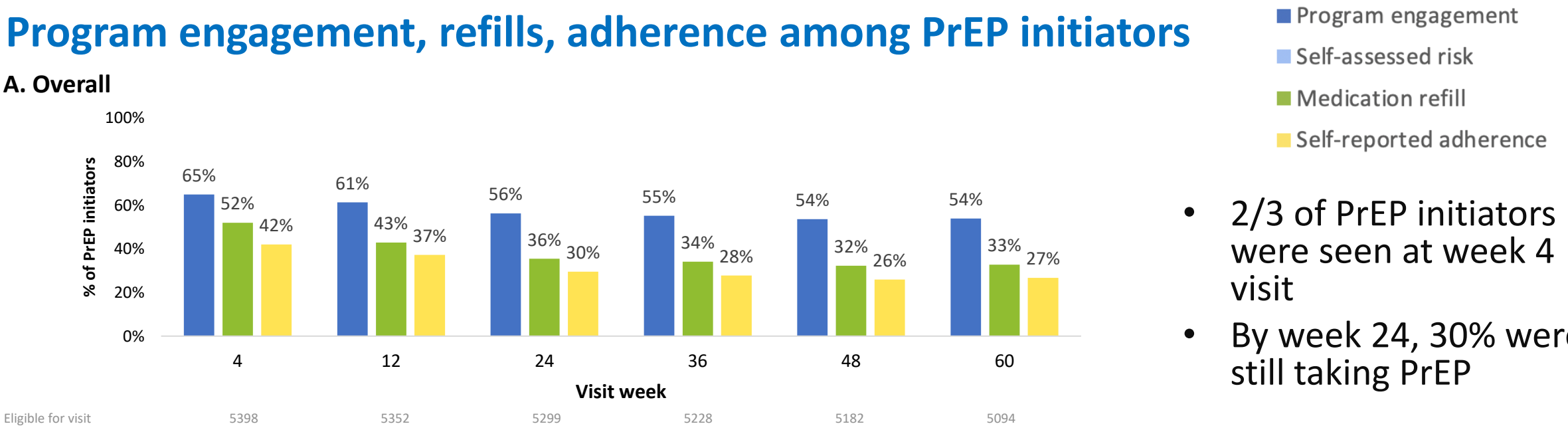
Uptake higher:
- serodifferent partners
- older adults
- polygamous

Uptake lower:
- mobile individuals
- youth
  - 37% of population at elevated risk
  - 29% of PrEP initiators

Mobility: migration out of community for at least one month or moved residence within past 12 months

Program engagement, refills, adherence among PrEP initiators

A. Overall



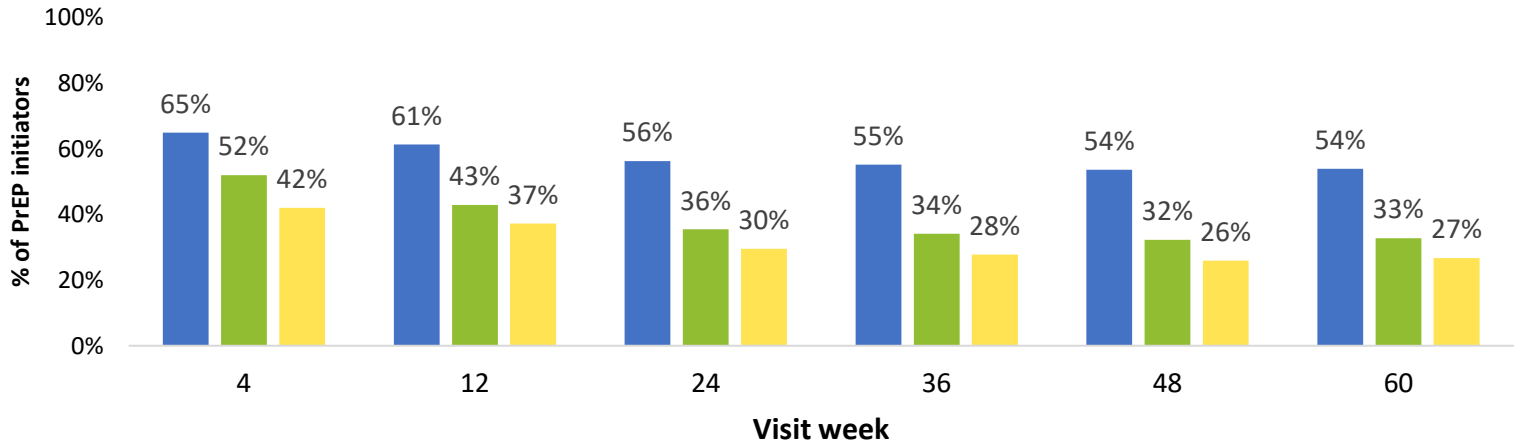
- 2/3 of PrEP initiators were seen at week 4 visit
- By week 24, 30% were still taking PrEP

1. PrEP stop: no refill in a visit period or refill ≥30 days late

Adapted from Koss, Charlebois, Ayieko et al. Lancet HIV 2020.

Program engagement, refills, adherence among PrEP initiators

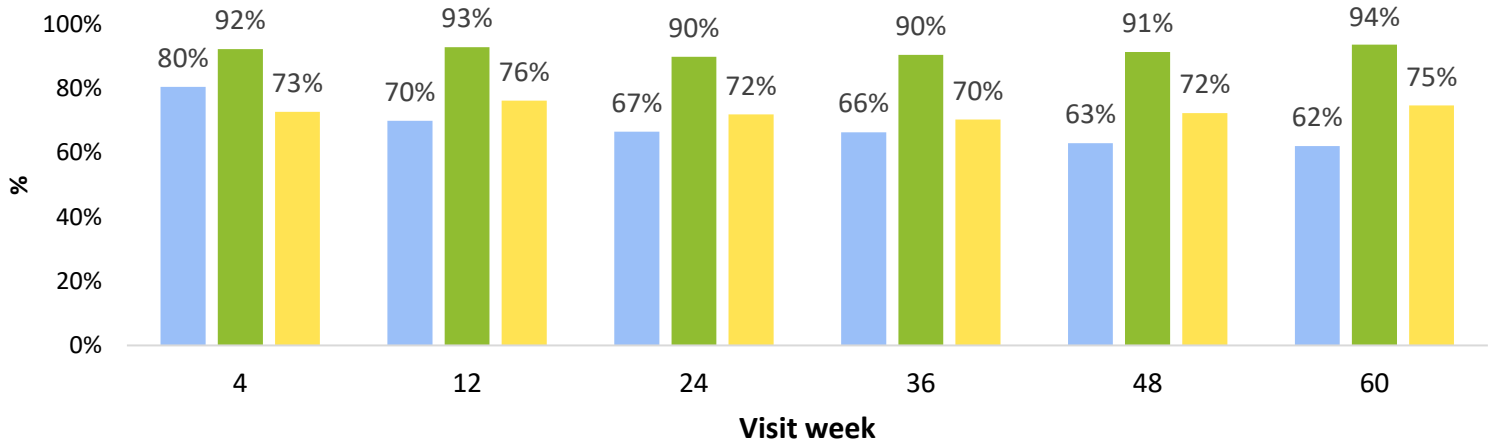
A. Overall



Eligible for visit	5398	5352	5299	5228	5182	5094

- 2/3 of PrEP initiators were seen at week 4 visit
- By week 24, 30% were still taking PrEP

B. Participants reporting current HIV risk at follow-up visits



Self-assessed current risk/ engaged in program	2826/3512	2297/3286	1987/2987	1919/2893	1752/2784	1711/2758

Many individuals who reported *current HIV risk* at follow-up visits stayed on PrEP

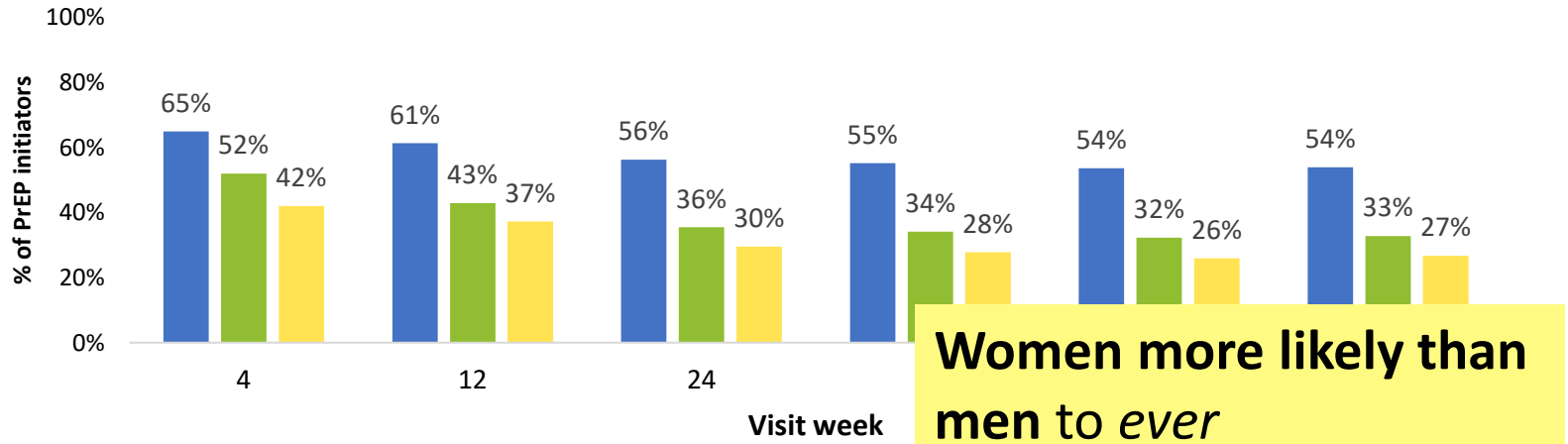
- At least 90% received PrEP refills
- At least 70% self-reported adherence

1. PrEP stop: no refill in a visit period or refill ≥30 days late

Adapted from Koss, Charlebois, Ayieko et al. Lancet HIV 2020.

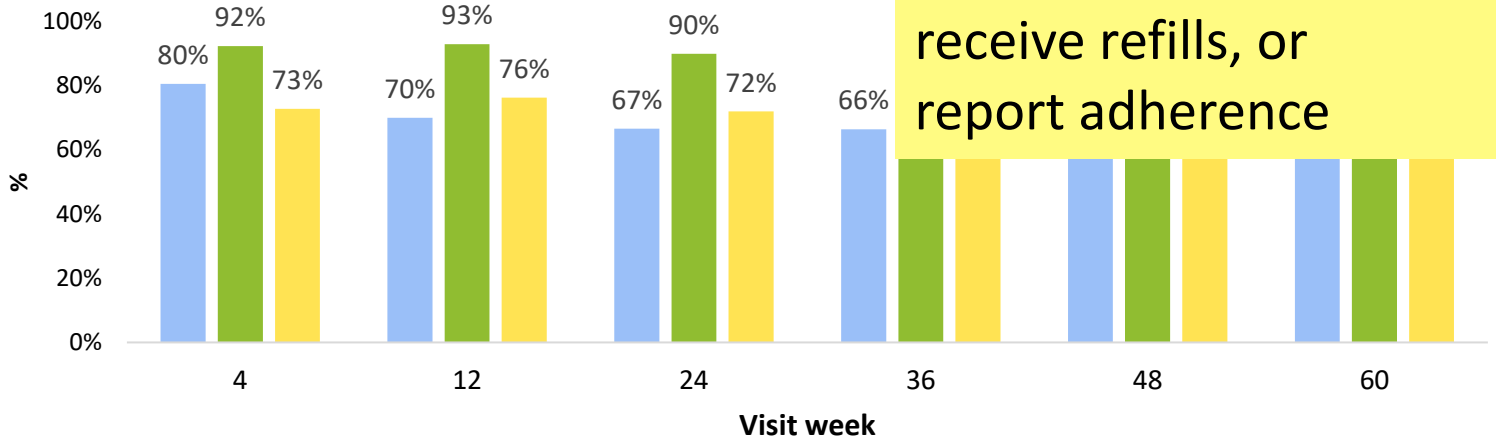
Program engagement, refills, adherence among PrEP initiators

A. Overall



Eligible for visit	5398	5352	5299

B. Participants reporting current HIV risk at follow-up visits



Self-assessed current risk/ engaged in program	2826/3512	2297/3286	1987/2987	1919/2893	1752/2784	1711/2758

Women more likely than men to *ever*

engage in visits, receive refills, or report adherence

- 2/3 of PrEP initiators were seen at week 4 visit
- By week 24, 30% were still taking PrEP

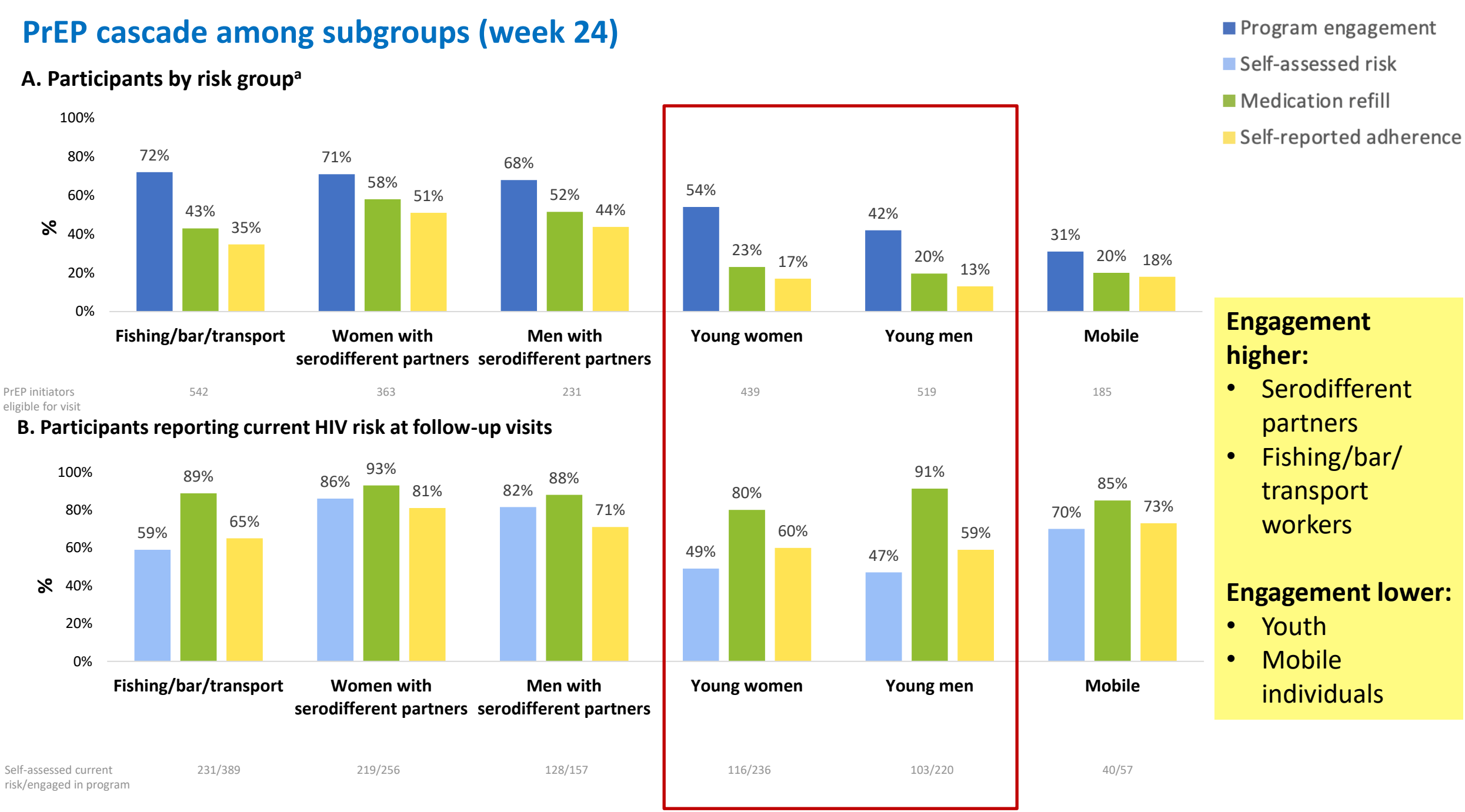
Many individuals who reported *current HIV risk* at follow-up visits stayed on PrEP

- At least 90% received PrEP refills
- At least 70% self-reported adherence

1. PrEP stop: no refill in a visit period or refill ≥30 days late

Adapted from Koss, Charlebois, Ayieko et al. Lancet HIV 2020.

PrEP cascade among subgroups (week 24)



Engagement higher:

- Serodifferent partners
- Fishing/bar/ transport workers

Engagement lower:

- Youth
- Mobile individuals

a. Mobile individuals could be in any age group.

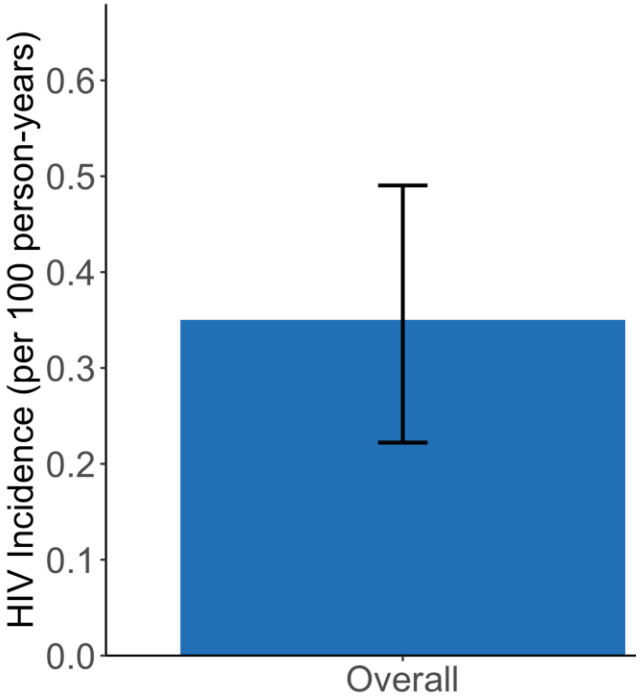
Many participants who stopped PrEP remained engaged in follow-up visits for HIV prevention

- **83% of participants stopped PrEP at least once**[1]
  - half of those who stopped later restarted

- Ongoing engagement in follow-up visits presented an opportunity for
  - repeat HIV testing, condom provision
  - discussions about HIV prevention
  - restarting PrEP

1. PrEP stop: no refill in a visit period or refill ≥30 days late

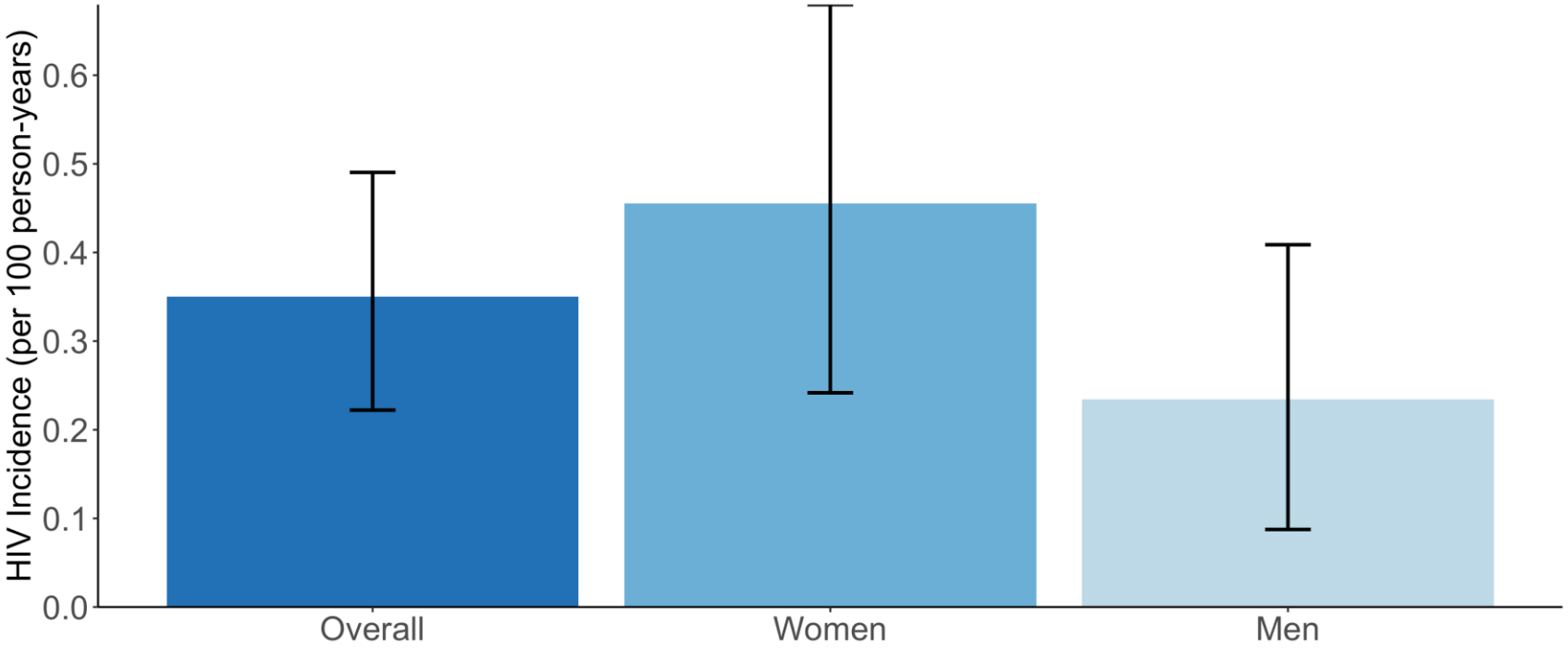
Observed HIV incidence among PrEP initiators



Seroconversions	25
Person-years	7150
Incidence Rate per 100 PY (95% CI)	**0.35 (0.22-0.49)**

Koss, Havlir, Ayieko et al., PLOS Med 2021

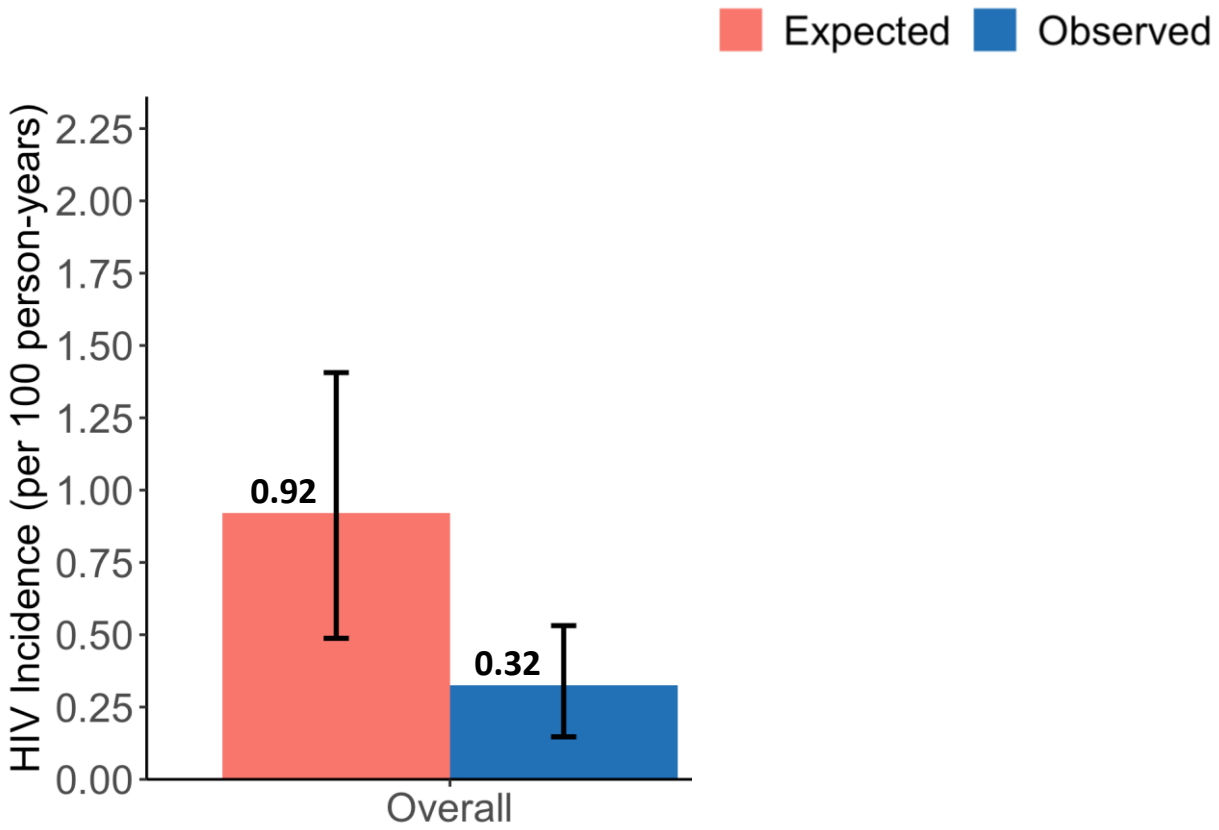
Observed HIV incidence among PrEP initiators, stratified by sex



	Overall	Women	Men
Seroconversions	25	17	8
Person-years	7150	3735	3415
Incidence Rate per 100 PY (95% CI)	**0.35 (0.22-0.49)**	**0.46 (0.24-0.68)**	**0.23 (0.09-0.41)**

Koss, Havlir, Ayieko et al., PLOS Med 2021

Comparison to expected HIV incidence without PrEP



74% lower HIV incidence among PrEP initiators

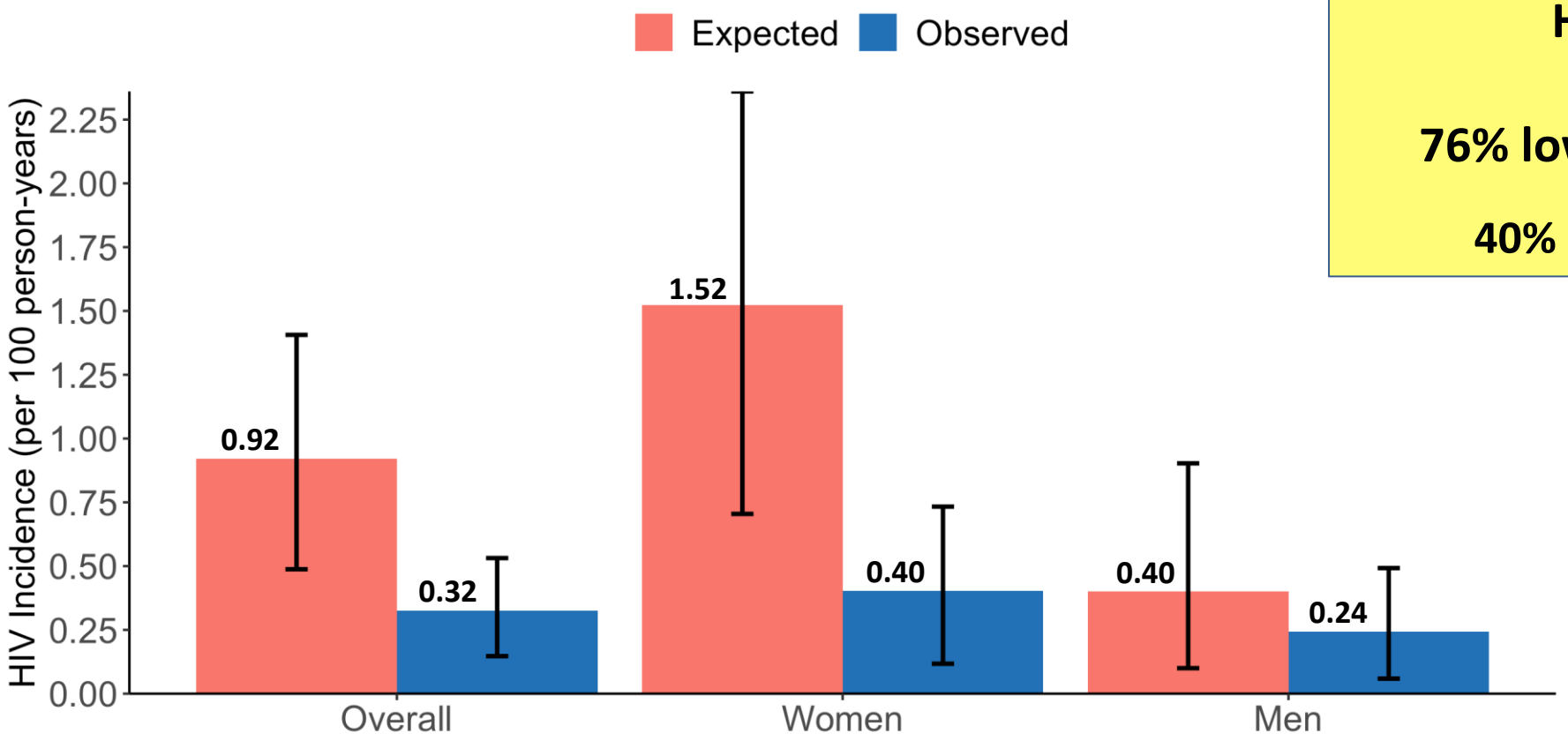
compared to matched controls from the year prior to PrEP availability

Incidence Rate Ratio (95% CI)

0.26 (0.09-0.75) p=0.013

Koss, Havlir, Ayieko et al., PLOS Med 2021

Comparison to expected HIV incidence without PrEP



HIV incidence

76% lower among women

40% lower among men

Incidence Rate Ratio (95% CI)	**0.26 (0.09-0.75) p=0.013**	**0.24 (0.07-0.79) p=0.019**	**0.60 (0.12-3.05) p=0.54**

Koss, Havlir, Ayieko et al., PLOS Med 2021

Many challenges and lessons learned

Barriers:

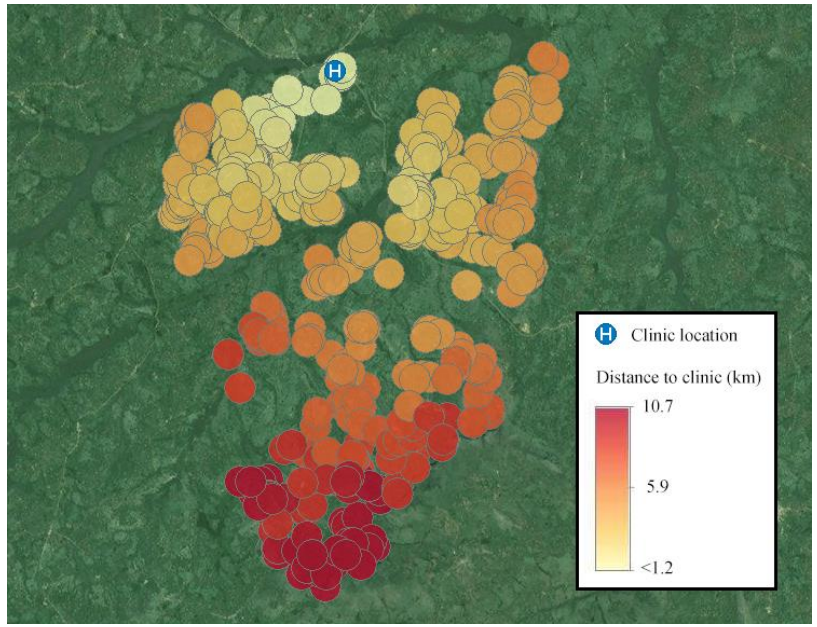
- Rumors – PrEP new in communities when study started
- Low perceived severity of HIV infection (with success of ART)
- Other health/life priorities took precedence over HIV prevention
- Stigma – wanted separate clinic entrances for PrEP and ART clients
- Fears of being seen as promiscuous
- Unsupportive partners
- Daily pill-taking, pill size
- Distance to health facility

Facilitators:

- Positive interactions with providers, e.g. support around management of side effects
- Out-of-facility visits
- PrEP to support achieving life goals

Continual efforts to overcome challenges and support PrEP use!

"I would love to use it to protect me from HIV, but my worry is that I have never seen anybody who has benefited from PrEP."
-Young woman, western Kenya



Camlin CS et al. AIDS Behav 2020. Mayer C et al. JIAS 2019.

Summary

- After population-level HIV testing
  - one-third of individuals assessed to be at elevated HIV risk started PrEP
  - of these, 78% engaged in the PrEP program for follow-up visits

- **Community-wide HIV testing and universal access to PrEP – *with rapid start and flexible, community-based service delivery*** associated with
  - lower HIV incidence among PrEP initiators (including women) vs. recent controls

- Evidence of the **added impact of PrEP** in communities that had exceeded UNAIDS 90-90-90 targets after universal test-and-treat (UTT)

- Lower PrEP uptake and engagement among **young adults and mobile populations**
  - Strategies to support communication about PrEP for young people and providers
  - Framing PrEP around other health/life goals may be more salient than HIV prevention

Considerations for future service delivery

SEARCH
SUSTAINABLE EAST AFRICA RESEARCH IN COMMUNITY HEALTH

- **Low-barrier testing** for HIV and other health services
  - entry point for linkage to HIV treatment or prevention services

- Inclusive or **universal offer of PrEP** may promote uptake

- **Same-day PrEP start** safe and feasible

- **Community-based delivery** may reduce barriers, stigma, and foster PrEP use

Considerations for future service delivery

- **PrEP cascade not expected to look like ART cascade**
  - Continuation may be higher among persons with ongoing risk
  - Need strategies to support adherence during periods of potential HIV exposure[1,2]

- As **new PrEP modalities** are introduced
  - Need systems to support delivery of diverse prevention options

- Lower-barrier access to HIV testing – with linkage to treatment and prevention services – is a promising approach to accelerate reductions in HIV incidence in generalized epidemic settings

Image: Hillier UCSF CFAR Seminar 2020

Acknowledgements

SEARCH study participants, community members, and community leaders

SEARCH
SUSTAINABLE EAST AFRICA RESEARCH IN COMMUNITY HEALTH

Univ. of California, San Francisco
Diane Havlir
Edwin Charlebois
Tamara Clark
Craig R. Cohen
Gabriel Chamie
Vivek Jain
Carol Camlin
Monica Gandhi
Starley Shade
Douglas Black
Carina Marquez
Lillian Brown
Rachel Burger
James Peng

Kenya Medical Research Institute
Elizabeth A. Bukusi
James Ayieko
Norton Sang
Kevin Kadede
Winter Olilo
Patrick Omanya
Benard Awuonda
Jackson Achando
Marilyn Nyabuti
Erick Wafula Mugoma

Univ. of Massachusetts, Amherst
Laura Balzer
Joshua Nugent

Makerere University
Moses Kamya

Infectious Diseases Research Collaboration
Jane Kabami
Dalsone Kwarisiima
Mucunguzi Atukunda
Florence Mwangwa
Asiphas Owaraganise
Geoff Lavoy
Yusuf Mwinike
Hellen Nakato
Samuel Okiror
Alan Asiimwe

Univ. of California, Berkeley
Maya Petersen
Mark van der Laan
Joshua Schwab

University of Pennsylvania
Harsha Thirumurthy

And the entire SEARCH team

Many thanks to our sponsors, partners, collaborators, and advisory boards

Funding:
NIAID (U01AI099959 and UM1AI068636)
NIMH (K23MH114760)
Bill & Melinda Gates Foundation (OPP1159068)
Gilead Sciences

US National Institutes of Health
Melanie Bacon (NIAID)
Susannah Allison (NIMH)

Gilead Sciences
James Rooney

Ministry of Health of Kenya
Ministry of Health of Uganda

Office of the US Global AIDS Coordinator

Bill & Melinda Gates Foundation
Siobhan Malone

NIH National Institutes of Health · GILEAD · BILL & MELINDA GATES foundation · REPUBLIC OF KENYA MINISTRY OF HEALTH · THE REPUBLIC OF UGANDA MINISTRY OF HEALTH · UCSF University of California San Francisco · IDRC INFECTIOUS DISEASES RESEARCH COLLABORATION · KENYA MEDICAL RESEARCH INSTITUTE KEMRI

Opening & Introductions

SEARCH

Q & A with the SEARCH team

POWER

Q & A with the POWER team

PrEP advocacy message

Final Q & A

Q&A

Opening & Introductions

SEARCH

Q & A with the SEARCH team

POWER

Q & A with the POWER team

PrEP advocacy message

Final Q & A

POWER

Prevention **O**ptions for **W**omen **E**valuation **R**esearch:

Connie Celum, MD, MPH
Departments of Global Health, Medicine & Epidemiology

PrEP Learning Network
February 25, 2020

POWER PrEP Delivery Locations

Where We Work

Objective

Develop cost-effective and scalable models for implementation of ARV-based HIV prevention products for young women in Cape Town and Johannesburg (South Africa) and Kisumu (Kenya).

Consortium Partners

UNIVERSITY OF WASHINGTON
INTERNATIONAL CLINICAL RESEARCH CENTER

DESMOND TUTU HIV FOUNDATION

KENYA MEDICAL RESEARCH INSTITUTE
KEMRI

WITS RHI

Carnegie Mellon University

MASSACHUSETTS GENERAL HOSPITAL

RTI INTERNATIONAL

USAID FROM THE AMERICAN PEOPLE

PEPFAR

POWER
Prevention Options for Women Evaluation Research

Prevention Options for Women Evaluation Research (POWER)

Collaborating organizations: University of Washington, Desmond Tutu HIV Foundation, Kenya Medical Research Institute, Wits Reproductive Health and HIV Institute, Carnegie Mellon University, Harvard Medical School, RTI International, University of California – San Francisco, University of Pittsburgh

Formative Work

In-depth interviews and follow up surveys:
Surveys with young women and men

Key informant interviews:
Healthcare provider and other key informant interviews

PrEP Delivery

Understanding who takes PrEP:

- Characterize those who initiate vs those who do not
- **Determine persistence, adherence, and patterns of use**
- Assess HIV incidence and drug resistance

(qualitative and quantitative methods)

Evaluation of PrEP Delivery:

- Test PrEP delivery in a variety of models in various locations
- Assess cost and cost effectiveness

(M&E, time and motion studies)

*co-funded by NIMH R01MH114544

Prevention Options for Women Evaluation Research (POWER)

Collaborating organizations: University of Washington, Desmond Tutu HIV Foundation, Kenya Medical Research Institute, Wits Reproductive Health and HIV Institute, Carnegie Mellon University, Harvard Medical School, RTI International, University of California – San Francisco, University of Pittsburgh

Cape Town

Model:
Mobile delivery services

Johannesburg

Model:
Youth-friendly clinics

Kisumu

Model:
Family planning clinics – private & public

USAID FROM THE AMERICAN PEOPLE
PEPFAR
POWER
Prevention Options for Women Evaluation Research

Characteristics of POWER participants

	Total N=2550	Kisumu N=1000	Cape Town N=787	Johannesburg N=763
Age. Median (IQR)	21 (19 - 23)	21 (19 - 23)	20 (18 - 22)	21 (20 - 23)
Marital status				
Single, with partner	2154 (85%)	667 (67%)	762 (97%)	725 (95%)
Sexual behavior past 3 mos				
Current # SP	1 (1,1)	1 (1,1)	1 (1,1)	1 (1,1)
Has HIV+ SP	106 (4%)	49 (5%)	29 (4%)	28 (4%)
SP of unknown HIV status	1672 (66%)	607 (61%)	645 (83%)	420 (55%)
Never uses condoms	689 (27%)	385 (39%)	165 (21%)	139 (18%)
Contraceptive use				
Oral	92 (8%)	12 (3%)	13 (3%)	67 (17%)
Injectable	604 (51%)	100 (23%)	293 (77%)	211 (54%)
Implant	317 (27%)	226 (53%)	52 (14%)	39 (10%)
Other*	38 (3%)	20 (5%)	9 (2%)	9 (2%)
Ever pregnant	1213 (48%)	529 (53%)	250 (32%)	434 (57%)

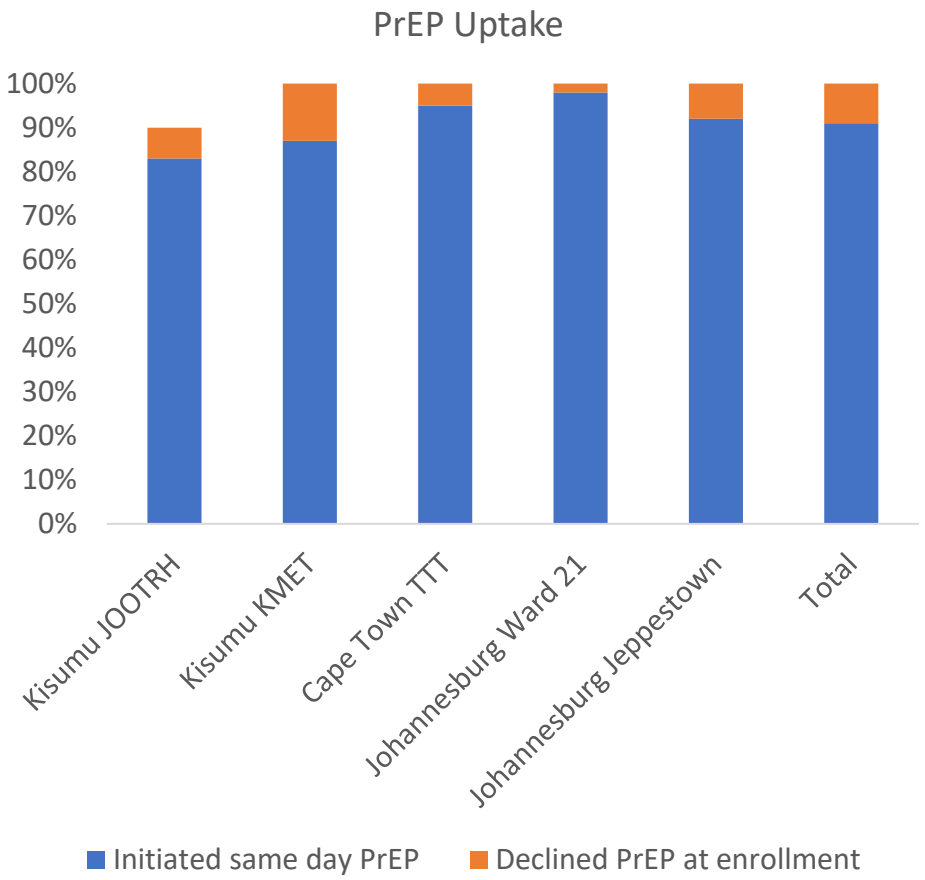
USAID FROM THE AMERICAN PEOPLE PEPFAR POWER Prevention Options for Women Evaluation Research

POWER: STIs at enrollment

	Total N=2550	Kisumu N=1000	Cape Town N=787	Johannesburg N=763
STIs				
Symptoms	179 (7%)	119 (12%)	33 (4%)	27 (4%)
Chlamydia	667 (29%)	172 (17%)	314 (42%)	181 (31%)
Gonorrhea	221 (10%)	61 (6%)	121 (16%)	39 (7%)
Accepted PrEP at enrollment**	2359 (93%)	871 (88%)	754 (96%)	734 (96%)

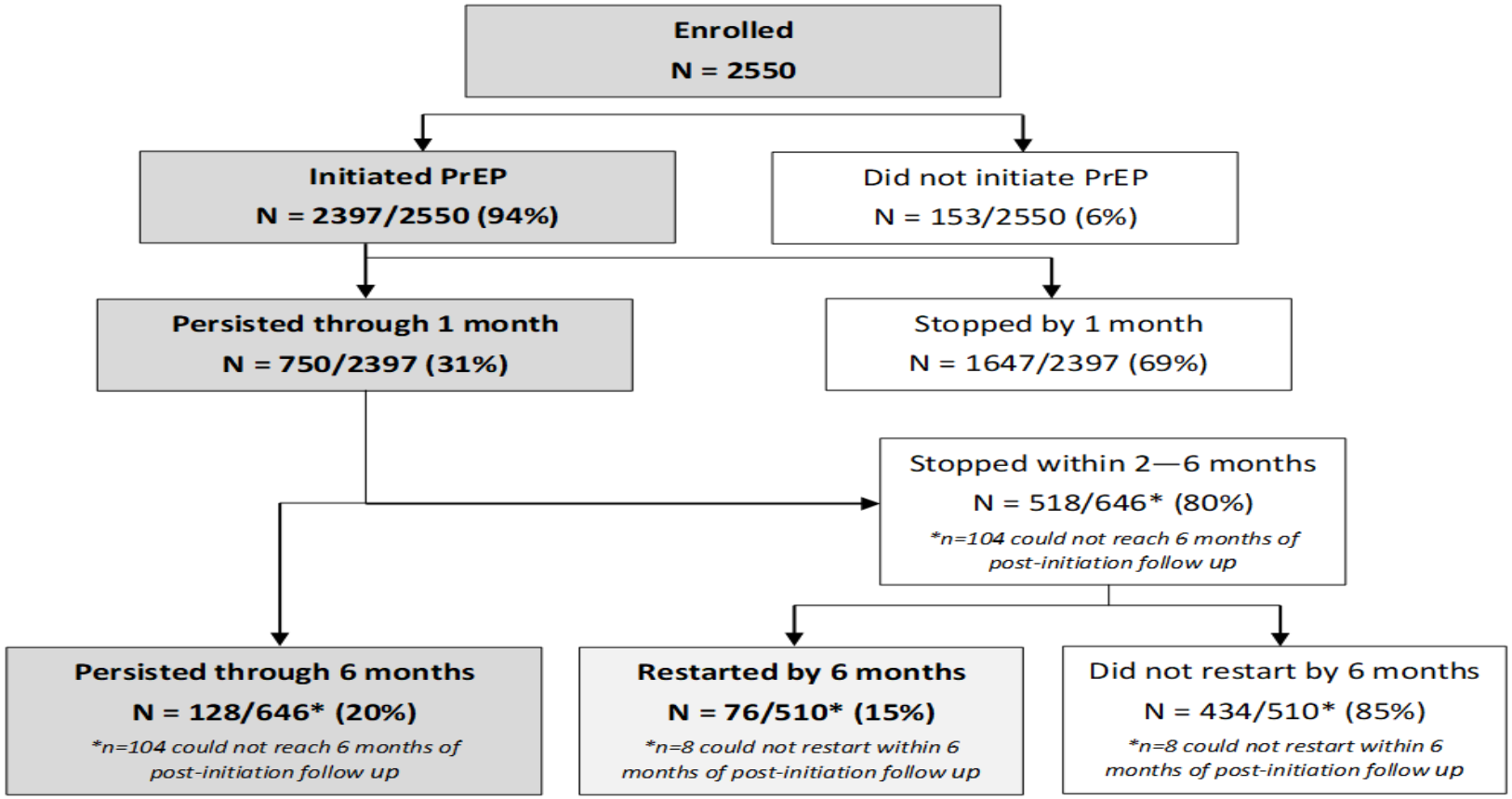
USAID FROM THE AMERICAN PEOPLE PEPFAR POWER Prevention Options for Women Evaluation Research

PrEP Uptake



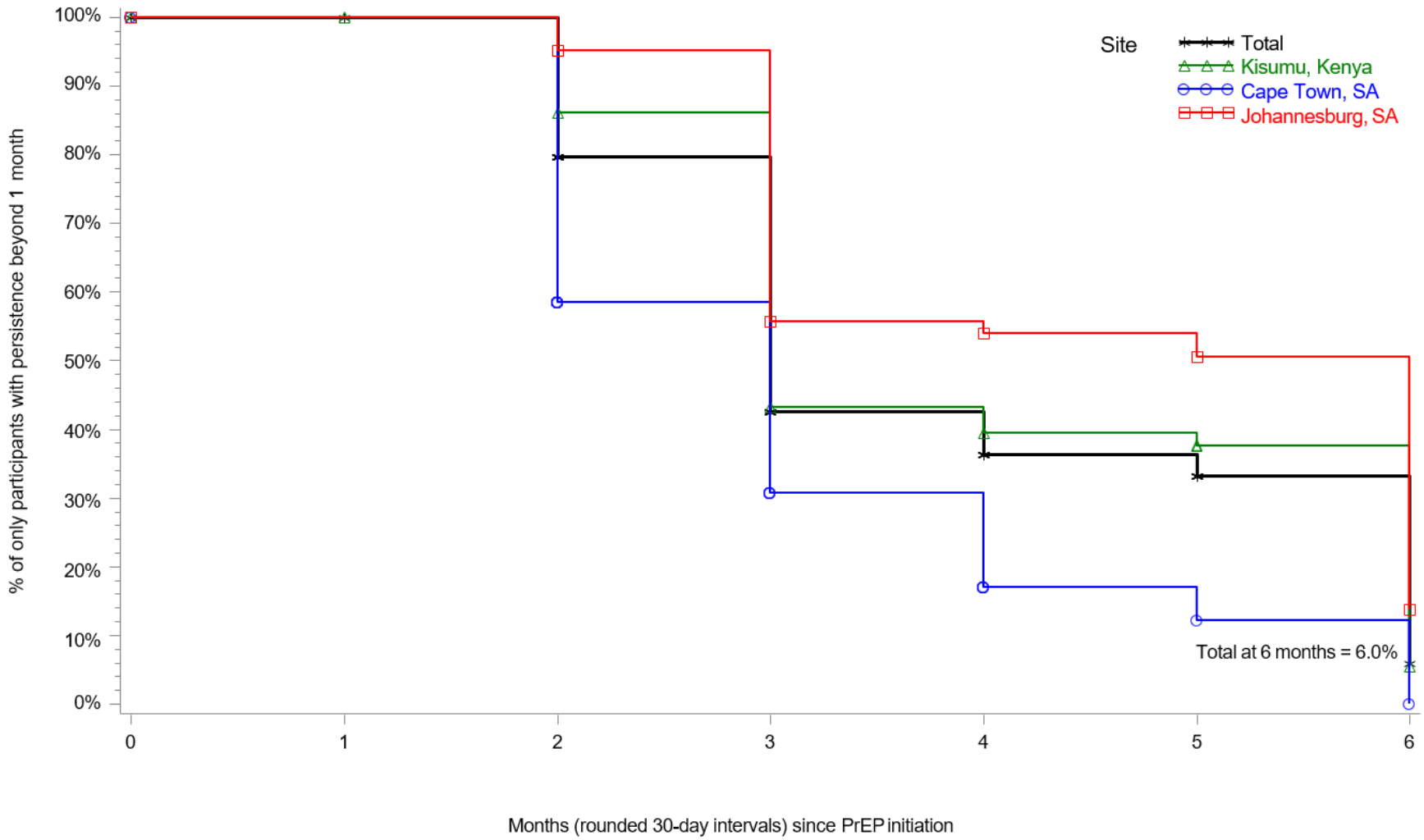
- 99% ‘medical eligible’ for PrEP
- High uptake (94%) across sites of those enrolled
- 92% initiated PrEP on the same day

Patterns of PrEP use



USAID FROM THE AMERICAN PEOPLE PEPFAR POWER Prevention Options for Women Evaluation Research

PrEP Persistence in first 6 months



USAID FROM THE AMERICAN PEOPLE

PEPFAR

POWER Prevention Options for Women Evaluation Research

Understanding PrEP persistence

- Routine measures of persistence, such as those for ART are challenging to apply to PrEP – continued development of better measures needed to fully comprehend persistence

- Whether PrEP persistence aligns with AGYW's need or desire for PrEP needs further research
  - Enhanced counseling on prevention-effective adherence may be needed, and how to stop/restart

- Further research into reasons for oral PrEP discontinuation and resumption is needed for AGYW populations

Barriers to adherence and persistence

- Scheduling
- Holidays and exam periods
- Travel
- Real/Perceived side effects
- Community PrEP knowledge
- Disclosure & support
- Convenient refills

USAID FROM THE AMERICAN PEOPLE PEPFAR POWER Prevention Options for Women Evaluation Research

Strategies being used to support adherence

- Contact & follow-up
- POWER Clubs
- Youth-Friendly Services
- Flexibility
- Self identified initiation
- Combination of services
- Access to psychosocial care
- Couples counseling
- Disclosure
- Differentiated care

USAID FROM THE AMERICAN PEOPLE
PEPFAR
POWER
Prevention Options for Women Evaluation Research

HIV seroconversions, incidence & resistance

	HIV seroconversions	HIV incidence (per 100 p-yrs)	Antiretroviral resistance (n=13 with results)
Within 3 months after enrollment	8	3.6 (1.6 - 7.1)	2 M184V (assoc with FTC)
>3 months after enrollment	9	1.6 (0.7 - 3.0)	No FTC or TFV mutations
Total	17	2.1 (1.3 - 3.4)	2 M184V (assoc with FTC)

Summary

- **PrEP initiation was 93% among Kenyan and South African AGYW.**

  Substantial risk: 2/3 having a partner of unknown HIV status, 1/4 reporting never using condoms, and 1/3 with chlamydia or gonorrhea.

- **PrEP persistence was moderate; 31% returned for a refill at 1 month and 15% restarted PrEP.**
  - 15% restarted PrEP, suggests that women can recognize when they need PrEP.
- **HIV incidence was 2.1/100 p-years. Most women who seroconverted had poor adherence or had stopped PrEP.**
  - 2 women who seroconverted in the first 3 months had M184V resistance, associated with FTC.
  - Other resistance mutations were minor variants, not associated with TFV or FTC.
- **Additional strategies to simplify PrEP delivery, support adherence and provide different PrEP options for young African women are needed to improve persistence and protection.**

USAID FROM THE AMERICAN PEOPLE PEPFAR POWER Prevention Options for Women Evaluation Research

POWER sub-studies

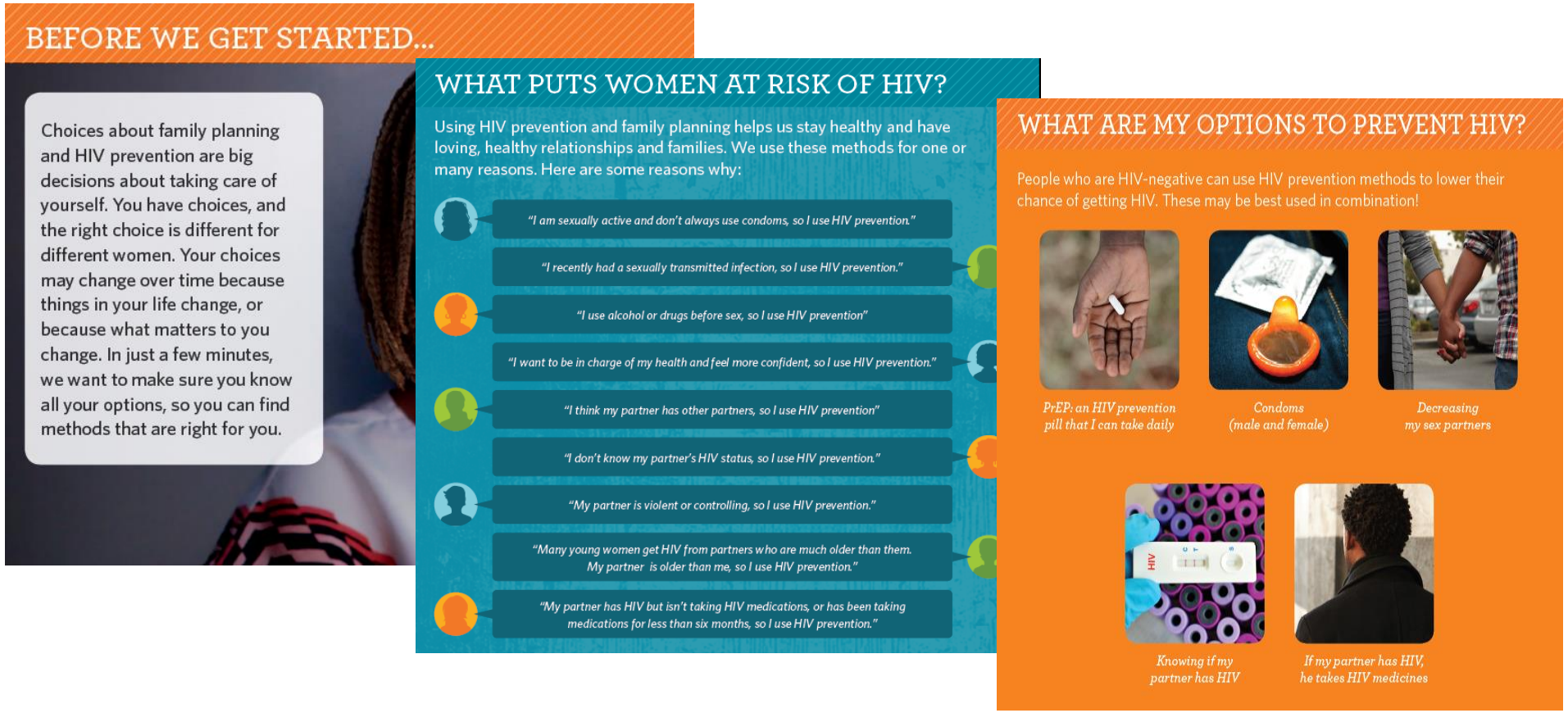
- Evaluation of PrEP decision support tool in Johannesburg primary care clinic on PrEP uptake and adherence
  (Seidman D, R4P)

- Qualitative study to understand the 'PrEP user journey'
  (Rousseau E, R4P)

My PrEP: a PrEP decision support tool

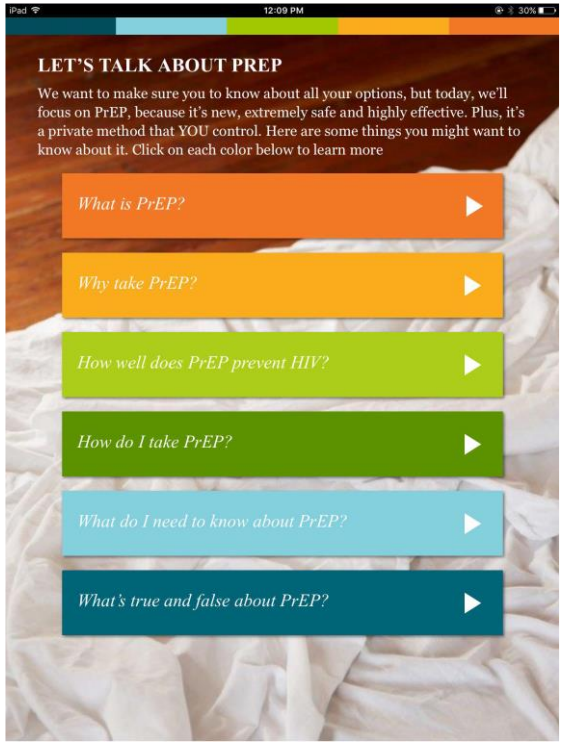
- Developed tool with Drs. Nika Seidman and Christine Dehlendorf, UCSF and Larry Swiader and Mike Roost at Bedsider.org
  - Based on format of My Birth Control decision support tool
- Cognitive testing of prototype of My PrEP decision support tool in Kisumu, Kenya with young women, FP providers and CAB
  - Made changes in the images and text
- Wits RHI youth CAB provided useful feedback
  - Final version of digital tool was developed
- Iterative process informed content, tone and graphics

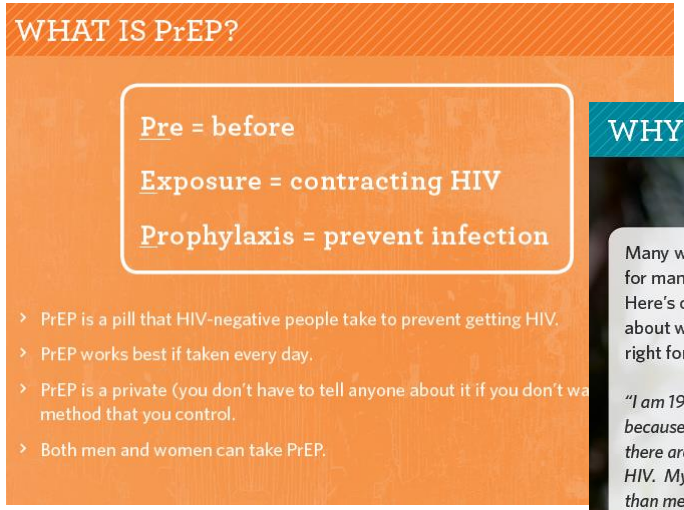
Structure of My PrEP decision support tool

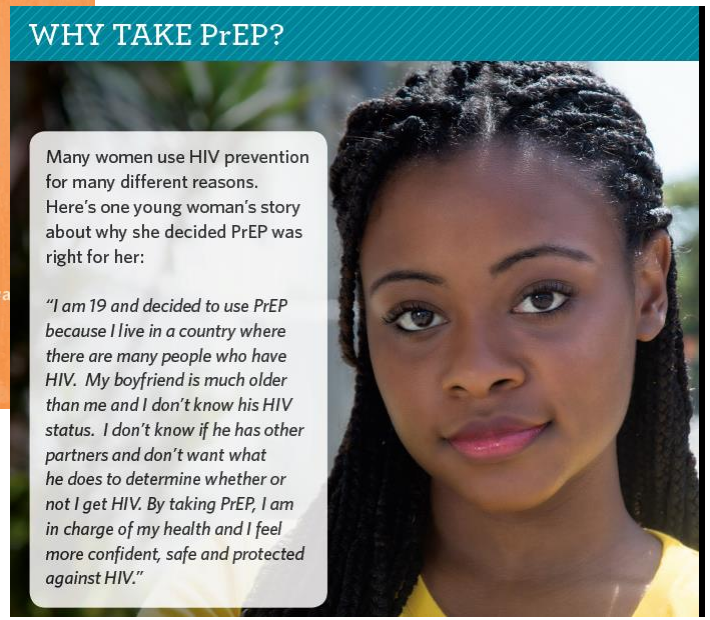


USAID FROM THE AMERICAN PEOPLE
PEPFAR
POWER Prevention Options for Women Evaluation Research

Introduction of PrEP: What is it and why take it?





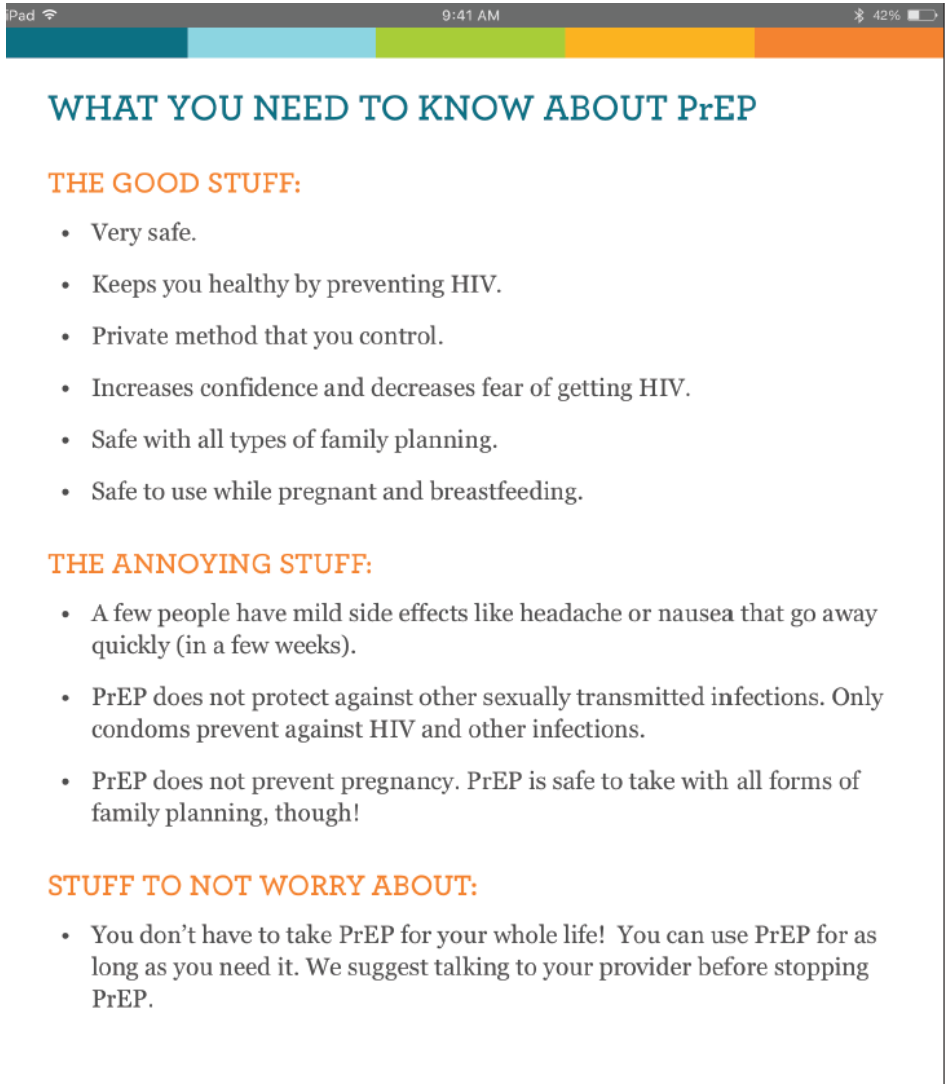


USAID FROM THE AMERICAN PEOPLE PEPFAR POWER Prevention Options for Women Evaluation Research

Introduction of PrEP: How to take it?

PrEP can give you peace of mind and feel more in control. PrEP isn't for everyone but it helps many women who aren't sure about their partner's HIV status or behaviors, or can't use condoms all the time. Let's talk about whether you think PrEP would be good for you.

USAID FROM THE AMERICAN PEOPLE
PEPFAR
POWER Prevention Options for Women Evaluation Research



USAID FROM THE AMERICAN PEOPLE
PEPFAR
POWER Prevention Options for Women Evaluation Research

Evaluation of My PrEP decision tool

Purpose:	To test the effect of a patient-facing decision support tool on PrEP uptake and use among young South African women
Design:	Randomize (by day) women who are coming for reproductive health services to receive standard of care counseling with or without the digital My PrEP decision support tool, which will be used prior to the provider encounter
Study Population:	350 HIV-uninfected women ages 18-25 in Johannesburg, South Africa.
Primary Objective:	• To determine the effect of a digital, patient-facing PrEP decision support tool on PrEP uptake
Secondary Objectives:	• To determine the effect of a digital, patient-facing PrEP decision support tool on PrEP uptake and continuation after 1 month • To qualitatively evaluate whether a digital PrEP decision support tool alters young women's decision-making about PrEP and provider attitudes about the patient-facing decision support tool
Study Sites:	Jeppestown Clinic, Johannesburg, South Africa

(NIMH R01MH114544; Celum & Delany-Moretlwe, coPIs)

Baseline characteristics

		N (%) or median (IQR)		
Characteristics	N	Overall, N = 353	Other website, N = 181	DST, N = 172
Age, years	353	21 (20, 23)	21 (19, 24)	21 (20,23)
18-20		134 (38%)	75 (41%)	59 (34%)
21-25		219 (62%)	106 (59%)	113 (66%)
Marital Status	352			
Single, no partner		4 (1.1%)	3 (1.7%)	1 (0.6%)
Single, with partner		339 (96%)	173 (96%)	166 (97%)
Married		8 (2.3%)	3 (1.7%)	5 (2.9%)
Divorced/separated		1 (0.3%)	1 (0.6%)	0 (0%)
Lives with partner	349	59 (17%)	25 (14%)	34 (20%)
Any previous pregnancy	351	242 (69%)	126 (70%)	116 (67%)
Trying to get pregnant	352	5 (1.4%)	3 (1.7%)	2 (1.2%)
On family planning	353	142 (40%)	76 (42%)	66 (38%)
Oral		32 (23%)	19 (25%)	13 (20%)
Injectable		86 (61%)	47 (62%)	39 (59%)
Implant		20 (14%)	8 (11%)	12 (18%)
IUD		1 (0.7%)	0 (0%)	1 (1.5%)
Emergency Contraception		2 (1.4%)	2 (2.6%)	0 (0%)
Tubal ligation		1 (0.7%)	0 (0%)	1 (1.5%)

USAID FROM THE AMERICAN PEOPLE PEPFAR POWER Prevention Options for Women Evaluation Research

Risk characteristics

Characteristics	N	N (%) or median (IQR) Overall, N = 353	Other website, N = 181	DST, N = 172
Sexual behaviors (in past 3 months)				
Had sex in past 3 months		353 (100%)	181 (100%)	172 (100%)
More than one sex partner	350	49 (14%)	21 (12%)	28 (16%)
Used Condoms	352			
Always		53 (15%)	22 (12%)	31 (18%)
Sometimes		214 (61%)	107 (59%)	107 (62%)
Never		85 (24%)	51 (28%)	34 (20%)
VOICE risk Score (0-8)	351	6 (5,7)	6 (5,7)	6 (5,7)
Uses Alcohol	352	164 (47%)	85 (47%)	79 (46%)
Sexually transmitted infections				
Has STI symptoms	353	7 (2.0%)	3 (1.7%)	4 (2.3%)
Gonorrhea	290	23 (7.9%)	12 (8.2%)	11 (7.6%)
Chlamydia	290	99 (34%)	46 (32%)	53 (37%)

USAID FROM THE AMERICAN PEOPLE PEPFAR POWER Prevention Options for Women Evaluation Research

PrEP uptake at enrollment

	N	PrEP uptake	OR	95% CI	P value
Decision Support Tool	172	166 (97)	1.79	0.67-5.30	0.262
Health website	181	170 (94)	Ref.		

PrEP Continuation at 1 month

	N	Attended 1 month visit	PrEP Continuation	OR	95% CI	P value
Decision Support Tool	172	40 (23%)	33 (20%)	**1.97**	**1.08-3.69**	**0.029**
Health website	181	31 (17%)	19 (11%)	Ref.		

Discussion

- No difference in PrEP uptake with PrEP decision tool
  - Although very high (95%) uptake in both arms
- Continuation of PrEP at 1 month is low; mostly characterized by not returning for the visit.
  - In context of primary health clinic that had contraceptive interruptions & Johannesburg civil unrest in fall 2019
- Those randomized to My PrEP decision support tool had 20% continuation, compared to 11% in the other website,
  - Two-fold higher odds of PrEP continuation at month 1 than those viewing general health website (p = 0.029)

ADOLESCENT GIRLS AND YOUNG WOMEN'S (AGYW) PREP-USER JOURNEY DURING AN IMPLEMENTATION SCIENCE STUDY IN SOUTH AFRICA AND KENYA

E. Rousseau, A.W.K. Katz, S. O'Rourke, L.-G. Bekker, S. Delany-Moretlwe, E. Bukusi, D. Travill, V. Omollo, J. Morton, G. O'Malley, R. Johnson, C. Celum, J.M. Baeten, A. van der Straten

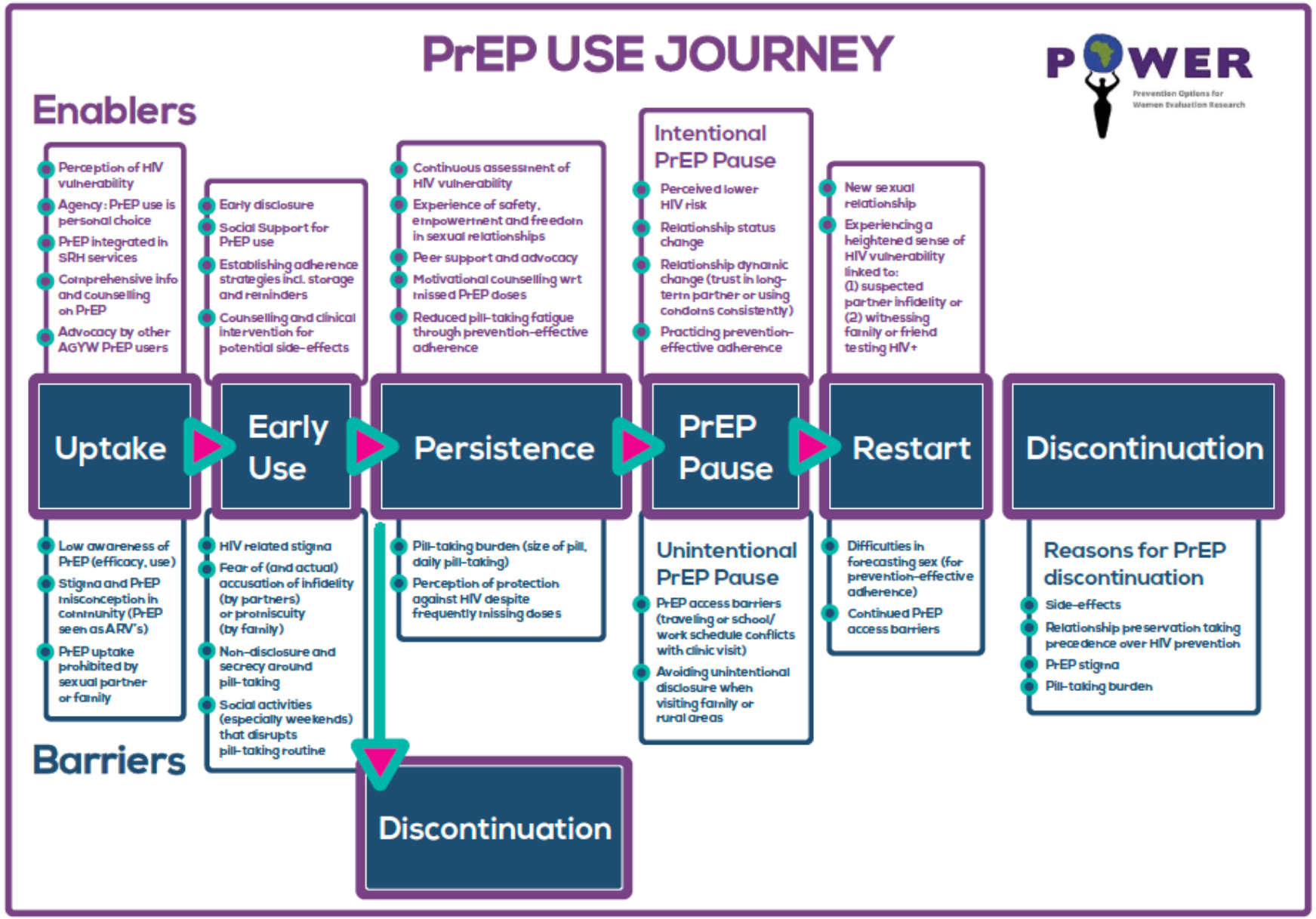
Background

Oral pre-exposure prophylaxis (PrEP) efficacy in preventing HIV is well established. However, adhering to a daily regimen can be challenging, especially for adolescent girls and young women (AGYW) in Africa. With PrEP scale-up ongoing, it is important to understand AGYW's motivations and lived experiences in the uptake and use of PrEP.

Methods

In-depth interviews were conducted with a purposive sample of **91 AGYW (ages 16-25)** in the POWER implementation project offering PrEP from adolescent-friendly, mobile, and family planning clinics, in Johannesburg and Cape Town, South Africa and Kisumu, Kenya. Rapid analysis explored AGYW's PrEP-user journey.

E Rousseau, R4P 2021



E Rousseau, R4P 2021

USAID FROM THE AMERICAN PEOPLE
PEPFAR
POWER Prevention Options for Women Evaluation Research

PrEP User Journey Findings

- AGYW who initiated PrEP early in study displayed high awareness of HIV vulnerability.
- Community stigma and PrEP misconceptions influenced uptake and early use.
- Disclosure to family and/or partners occurred early for AGYW who persisted with PrEP.
- Unplanned PrEP pauses occurred due to PrEP access problems. Planned PrEP pauses occurred during periods of no sexual activity.
- Many AGYW who had PrEP interruptions restarted PrEP.
- PrEP discontinuation was often due to perceived side effects and low social support.

Conclusion

AGYW in South Africa and Kenya recognize their HIV vulnerabilities and the benefits of PrEP, however implementing use is impacted by their social relationships and circumstances. Tailored flexible interventions are needed to address young women's diverse PrEP motivations, social contexts and understandings of prevention-effective adherence.

E Rousseau, R4P 2021

USAID FROM THE AMERICAN PEOPLE PEPFAR POWER Prevention Options for Women Evaluation Research

POWER Study Team

University of Washington

- Project Directors: Connie Celum & Jared Baeten
- Project Manager: Rachel Johnson
- Research Manager: Jenn Morton
- Data Analyst: Lara Kidoguchi
- Monitoring and Evaluation Lead: Gabrielle O'Malley

Implementation Leaders

- Desmond Tutu HIV Foundation, Cape Town, South Africa: Linda-Gail Bekker, Elzette Rousseau
- Kenya Medical Research Institute, Kisumu: Elizabeth Bukusi, Victor Omollo, Felix Mogoko
- Wits RHI, Johannesburg, South Africa: Sinead Delany-Moretlwe, Danielle Travill

Collaborators

- Research Triangle Institute: Ariana Katz, Sarah Roberts, Ariane van der Straten
- UCSF: Nika Seidman, Christine Dehlendorf
- Massachusetts General Hospital: Jessica Haberer

USAID FROM THE AMERICAN PEOPLE PEPFAR POWER Prevention Options for Women Evaluation Research

Click here to watch the video: https://youtu.be/wnSM_R43T1w

Opening & Introductions

SEARCH

Q & A with the SEARCH team

POWER

Q & A with the POWER team

PrEP advocacy message

Final Q & A

Q&A

Opening & Introductions

SEARCH

Q & A with the SEARCH team

POWER

Q & A with the POWER team

PrEP advocacy message

Final Q & A

Global PrEP Learning Network

It's Been 5 Years Already: How are we doing with HIV PrEP

Jason Reed

February 25, 2021

	VMMC Questions in 2012 (5 years after WHO recommendations)	VMMC Solutions in 2012	PrEP Questions in 2021 (5 years after WHO recommendations)
Pace:	Why were we off-target/moving “too” slowly?	White House commitment to “stretch” target of 4.7 million VMMCs to accelerate agenda	Will there be a higher level commitment to a number?
Budget:	Would there ever be sufficient funding given legacy programs and treatment mortgages?	White House commitment accompanied by traceable, dedicated funding to meet target	Who is paying to start 3 million on PrEP, where is the funding, how can we know it is dedicated without a budget code?
Service Model:	How should we implement, given integrated services less productive; vertical models unsustainable?	Mobile services that are client-centered vs. convenient for the health system	Will we decentralize and de-medicalize PrEP as a self-care service?
Innovation:	Should surgical services be held back given device-based solutions in trials promised easier implementation?	Technology never distracted from full-steam-ahead approach to what was available	Will we give 100% effort to the oral PrEP available today while we await options with less frequent dosing?
Client Behavior:	Were men risk compensating after VMMC, ameliorating risk?	Don’t withhold services over suspicions and biases and counsel like you care	Why is continuous indefinite use assumed necessary for all, and discontinuation viewed as failure?

Why Now is the Time to Move Ahead

- Momentum is key
  - Stopping or reducing scale threatens confidence among stakeholders and clients not just in sustained availability of oral PrEP but in prevention
  - Constant program recalibration diverts funding away from services to management
- Perfect oral PrEP use ***not*** required to reduce incidence
  - Funding to date has been good investment
  - Continued scale-up will reduce incidence even in context of 95-95-95
  - Goal should be to get as many at-risk people to try PrEP as possible
    - First use is the first step in a longer prevention journey
    - Evidence that repeated use increases use regularity
- New & improved formulations coming, but oral PrEP prevents infections now
  - Delaying oral PrEP expansion today (waiting for the next best thing) results in more individuals needing treatment tomorrow, not cost savings

If Past were Prologue

- Prevention excels with high-level commitment to targets and funding
  - VMMC succeeded with White House target of 4.7 million clients and dedicated funding at approx. $100 per target, the consensus avg unit cost
  - UNAIDS PrEP target of 3 million by 2020 presents an unfulfilled opportunity for donors' commitments
  - PrEP is first PEPFAR technical area is go without a budget code; monitoring past and future investments in PrEP challenging
    - As PrEP expands to multiple products, knowing how much funding is going to various products will be important for reasons of equity

Advocacy During COP 2021

- How much of the COP 2021 funding is allocated to prevention? How do we know this, given some prevention costs are supposed to be covered by other budget codes? How does this compare to the funding level in COP 2020, overall and by country?

- How much of the COP 2021 funding is allocated to the forms of “PrEP” stated in COP 2021 Guidance?
  - Specifically to oral PrEP?
  - Specifically to DVR?
  - Specifically to CAB-LA?

Opening & Introductions

POWER

Q & A with the POWER team

SEARCH

Q & A with the SEARCH team

PrEP advocacy message

Final Q & A

Q&A

Upcoming Sessions

Developing Guidelines and Plans for the Delivery of Event-Driven PrEP

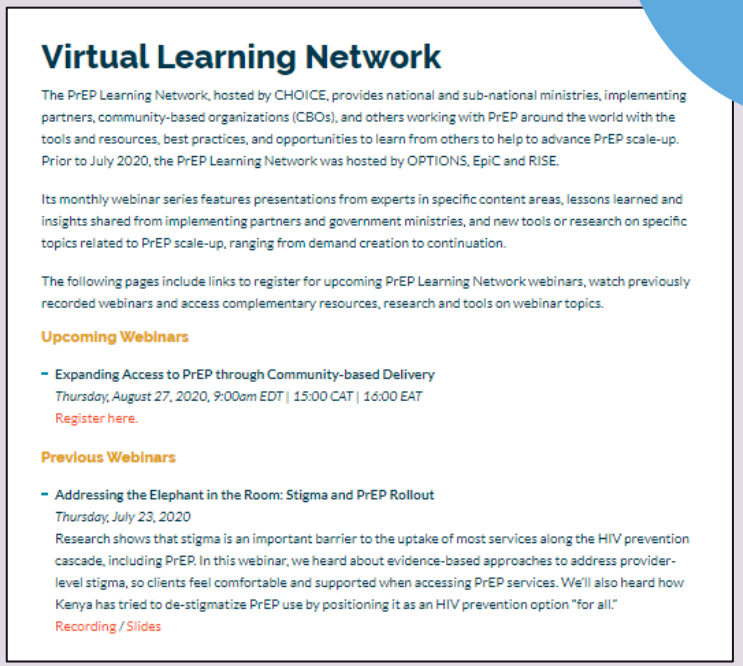
PrEP Continuation

TBD

Visit www.prepwatch.org/virtual-learning-network for up-to-date information.

Follow Us & Visit PrEPWatch

- Follow **@PrEP_LN** on Twitter!
- All **webinars are recorded** and will be accessible on PrEPWatch within a week post-presentation date.
- Complementary **resources** will also be shared on PrEPWatch—including relevant research articles and tools.
- Registration for **upcoming webinars** is also located on PrEPWatch.



Virtual Learning Network

The PrEP Learning Network, hosted by CHOICE, provides national and sub-national ministries, implementing partners, community-based organizations (CBOs), and others working with PrEP around the world with the tools and resources, best practices, and opportunities to learn from others to help to advance PrEP scale-up. Prior to July 2020, the PrEP Learning Network was hosted by OPTIONS, EpiC and RISE.

Its monthly webinar series features presentations from experts in specific content areas, lessons learned and insights shared from implementing partners and government ministries, and new tools or research on specific topics related to PrEP scale-up, ranging from demand creation to continuation.

The following pages include links to register for upcoming PrEP Learning Network webinars, watch previously recorded webinars and access complementary resources, research and tools on webinar topics.

Upcoming Webinars

- **Expanding Access to PrEP through Community-based Delivery**
  Thursday, August 27, 2020, 9:00am EDT | 15:00 CAT | 16:00 EAT
  Register here.

Previous Webinars

- **Addressing the Elephant in the Room: Stigma and PrEP Rollout**
  Thursday, July 23, 2020
  Research shows that stigma is an important barrier to the uptake of most services along the HIV prevention cascade, including PrEP. In this webinar, we heard about evidence-based approaches to address provider-level stigma, so clients feel comfortable and supported when accessing PrEP services. We'll also heard how Kenya has tried to de-stigmatize PrEP use by positioning it as an HIV prevention option "for all."
  Recording / Slides

Visit www.prepwatch.org/virtual-learning-network for up-to-date information.

Thank You!