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, PhD¹ and Catherine Koss, MD²

On behalf of the SEARCH Collaboration

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

PrEP Learning Network Webinar
February 25, 2021
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

---

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

New South Wales, Australia

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

How to reduce HIV incidence and improve community health?


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?

**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-attendees²

---

How to reduce HIV incidence and improve community health?


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?

**Intervention:**

* Among all persons with HIV

**Universal ART eligibility** +

**Patient-centered care delivery**

Facilitated linkage

Rapid ART start

Flexible hours

Phone hotline to contact provider

**Community-wide testing for**

HIV

Hypertension

Diabetes

Malaria

**Health fairs** +

Home-based testing for non-attendees

---

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. Reduction in perinatal transmission

Proportion of children who are living with HIV or have died by Year 3 (adjusted)*

<table>
<thead>
<tr>
<th>Year 3</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.3%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.4%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Ruel, CROI 2020

2. Reduction in HIV mortality

Kamya, Clin Infect Dis, in press

3. Reduction in HIV-associated TB

Incidence of Tuberculosis Over Time Among HIV-Infected Residents

<table>
<thead>
<tr>
<th>Year</th>
<th>TB Incidence Rate (per 100,000 PY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>600</td>
</tr>
<tr>
<td>Year 2</td>
<td>400</td>
</tr>
<tr>
<td>Year 3</td>
<td>200</td>
</tr>
</tbody>
</table>

Havlir, NEJM, 2019

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

Among Residents with Baseline Hypertension

Three-Year All-Cause Mortality Risk

<table>
<thead>
<tr>
<th>Interception</th>
<th>Control</th>
<th>All RR: 0.72 (95% CI: 0.56-0.93) p=0.02</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1: 3.2%</td>
<td>2.6%</td>
<td>RR: 0.78 (95% CI: 0.58-1.05)</td>
</tr>
<tr>
<td>Grade 2: 3.0%</td>
<td>2.9%</td>
<td>RR: 0.62 (95% CI: 0.39-0.97)</td>
</tr>
<tr>
<td>Grade 3: 4.7%</td>
<td>6.0%</td>
<td>RR: 0.88 (95% CI: 0.55-1.37)</td>
</tr>
</tbody>
</table>

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?

Community sensitization and provided information on PrEP
- Group-based education on PrEP upon arrival at health fairs

Universal 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)

SEARCH PrEP delivery model

**Same-day 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

**Same-day 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**

- Clinic nurses
  - Community nurses
  - Supported by clinical officers

**WHAT**

- HIV testing
- Counseling
- PrEP refills
- Phone hotline to contact provider

**WHERE**

- Location preferred by client:
  - Health facility
  - Community sites: Home
  - Beaches
  - Trading centers
  - Near schools

**WHEN**

- Baseline
- Week 4
- Week 12
- Every 12 weeks

Adapted from differentiateservicedelivery.org
Results: One-third of persons at elevated HIV risk started PrEP

76,132 individuals ≥15 years not previously diagnosed with HIV who received HIV testing in 16 communities

- 1,591 HIV-infected or status not established

74,541 individuals tested negative for HIV

- 58,909 assessed not to be at elevated risk of HIV

15,632 (21%) assessed to be at elevated risk of HIV acquisition and targeted for enhanced individual counseling on PrEP

- 10,185 did not initiate PrEP

- 5,447 (35%) initiated PrEP

- 1,187 no subsequent HIV test

4,260 (78%) had at least one HIV test after PrEP start

1 83% of residents not previously diagnosed with HIV attended community-wide testing
### Who started PrEP?

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

**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

Program engagement, refills, adherence among PrEP initiators

A. Overall

![Bar chart showing engagement, refills, and adherence among PrEP initiators.]

- 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

- 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 $\geq$ 30 days late.

**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

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

- 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

PrEP cascade among subgroups (week 24)

A. Participants by risk group

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Fishing/bar/transport</th>
<th>Women with serodifferent partners</th>
<th>Men with serodifferent partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engagement</td>
<td>Program engagement: 54%</td>
<td>Self-assessed risk: 23%</td>
<td>Medication refill: 49%</td>
</tr>
<tr>
<td>Eligible for visit</td>
<td>542</td>
<td>363</td>
<td>231</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Risk Group</th>
<th>Fishing/bar/transport</th>
<th>Women with serodifferent partners</th>
<th>Men with serodifferent partners</th>
<th>Young women</th>
<th>Young men</th>
<th>Mobile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engagement</td>
<td>Program engagement: 49%</td>
<td>Self-assessed risk: 47%</td>
<td>Medication refill: 47%</td>
<td>Self-reported adherence: 54%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eligible for visit</td>
<td>231/389</td>
<td>219/256</td>
<td>128/157</td>
<td>116/236</td>
<td>103/220</td>
<td>40/57</td>
</tr>
</tbody>
</table>

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**
  - 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

<table>
<thead>
<tr>
<th>Seroconversions</th>
<th>25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Person-years</td>
<td>7150</td>
</tr>
<tr>
<td>Incidence Rate per 100 PY (95% CI)</td>
<td>0.35 (0.22-0.49)</td>
</tr>
</tbody>
</table>

Koss, Havlir, Ayieko et al., PLOS Med 2021
Observed HIV incidence among PrEP initiators, stratified by sex

Seroconversions
- Overall: 25
- Women: 17
- Men: 8

Person-years
- Overall: 7150
- Women: 3735
- Men: 3415

Incidence Rate per 100 PY (95% CI)
- Overall: 0.35 (0.22-0.49)
- Women: 0.46 (0.24-0.68)
- Men: 0.23 (0.09-0.41)

Koss, Havlir, Ayieko et al., PLOS Med 2021
Comparison to expected HIV incidence without PrEP

<table>
<thead>
<tr>
<th>Incidence Rate Ratio (95% CI)</th>
<th>0.26 (0.09-0.75)</th>
<th>p=0.013</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.92</td>
<td>0.32</td>
<td></td>
</tr>
<tr>
<td>0.26 (0.09-0.75)</td>
<td>p=0.013</td>
<td></td>
</tr>
</tbody>
</table>

74% lower HIV incidence among PrEP initiators compared to matched controls from the year prior to PrEP availability

Koss, Havlir, Ayieko et al., PLOS Med 2021
<table>
<thead>
<tr>
<th>Incidence Rate Ratio (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>0.26 (0.09-0.75)</td>
</tr>
<tr>
<td>Women</td>
<td>0.24 (0.07-0.79)</td>
</tr>
<tr>
<td>Men</td>
<td>0.60 (0.12-3.05)</td>
</tr>
</tbody>
</table>

76% lower among women
40% lower among men

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

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

• **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

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Mucunguzi Atukunda
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Gilead Sciences

US National Institutes of Health
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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
Q&A
<table>
<thead>
<tr>
<th>Topic</th>
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<tbody>
<tr>
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<tr>
<td>Final Q &amp; A</td>
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POWER

Prevention Options for Women Evaluation Research:

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

PrEP Learning Network
February 25, 2020
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).
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
### Characteristics of POWER participants

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

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

**Notes:**
- **PrEP:** Pre-exposure prophylaxis.
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

Enrolled
N = 2550

Initiated PrEP
N = 2397/2550 (94%)

Did not initiate PrEP
N = 153/2550 (6%)

Persisted through 1 month
N = 750/2397 (31%)

Stopped by 1 month
N = 1647/2397 (69%)

Persisted through 6 months
N = 128/646* (20%)
* n=104 could not reach 6 months of post-initiation follow up

Restarted by 6 months
N = 76/510* (15%)
* n=8 could not restart within 6 months of post-initiation follow up

Did not restart by 6 months
N = 434/510* (85%)
* n=8 could not restart within 6 months of post-initiation follow up
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
## Strategies being used to support adherence

<table>
<thead>
<tr>
<th>Contact &amp; follow-up</th>
<th>Combination of services</th>
</tr>
</thead>
<tbody>
<tr>
<td>POWER Clubs</td>
<td>Access to psychosocial care</td>
</tr>
<tr>
<td>Youth-Friendly Services</td>
<td>Couples counseling</td>
</tr>
<tr>
<td>Flexibility</td>
<td>Disclosure</td>
</tr>
<tr>
<td>Self identified initiation</td>
<td>Differentiated care</td>
</tr>
</tbody>
</table>
### HIV seroconversions, incidence & resistance

<table>
<thead>
<tr>
<th>HIV seroconversions</th>
<th>HIV incidence (per 100 p-yrs)</th>
<th>Antiretroviral resistance (n=13 with results)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within 3 months after enrollment</td>
<td>8</td>
<td>3.6 (1.6 - 7.1)</td>
</tr>
<tr>
<td>&gt;3 months after enrollment</td>
<td>9</td>
<td>1.6 (0.7 - 3.0)</td>
</tr>
<tr>
<td>Total</td>
<td>17</td>
<td>2.1 (1.3 - 3.4)</td>
</tr>
</tbody>
</table>
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.**
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
Introduction of PrEP: What is it and why take it?

WHAT IS PrEP?
- Pre = before
- Exposure = contracting HIV
- Prophylaxis = prevent infection

WHY TAKE PrEP?
- Many women use HIV prevention for many different reasons.
- Here’s one young woman’s story about why she decided PrEP was right for her:

  “I am 19 and decided to use PrEP because I live in a country where there are many people who have HIV. My boyfriend is much older than me and I don’t know his HIV status. I don’t know if he has other partners and don’t want what he does to determine whether or not I get HIV. By taking PrEP, I am in charge of my health and I feel more confident, safe and protected against HIV.”
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.

**HOW DO I TAKE PrEP?**

- **PrEP is one pill** that you take once a day to prevent HIV.
- **PrEP works best** if you take it every day.
- **You** have to take PrEP for at least a week before you have enough medicine in your body to prevent HIV.
- **PrEP doesn’t prevent STIs or pregnancy.** Don’t forget to use a condom to stay healthy and use family planning if you don’t want to get pregnant!
WHAT YOU NEED TO KNOW ABOUT PrEP

THE GOOD STUFF:
- Very safe.
- Keeps you healthy by preventing HIV.
- Private method that you control.
- Increases confidence and decreases fear of getting HIV.
- Safe with all types of family planning.
- Safe to use while pregnant and breastfeeding.

THE ANNOYING STUFF:
- A few people have mild side effects like headache or nausea that go away quickly (in a few weeks).
- PrEP does not protect against other sexually transmitted infections. Only condoms prevent against HIV and other infections.
- PrEP does not prevent pregnancy. PrEP is safe to take with all forms of family planning, though!

STUFF TO NOT WORRY ABOUT:
- You don’t have to take PrEP for your whole life! You can use PrEP for as long as you need it. We suggest talking to your provider before stopping PrEP.

WHAT’S TRUE AND FALSE ABOUT PrEP?
- TRUE: Only a few PrEP users have side effects. These symptoms usually happen in the first month, are mild, last a few days and then go away.
- FALSE: PrEP will make you sick.
- TRUE: It takes about a week to build up enough levels of PrEP in your body to be protected against HIV.
- FALSE: PrEP is like the morning after pill.
- TRUE: If it is possible to talk to your partner about PrEP, it can build intimacy and love. If you can’t talk to your partner about PrEP, you can feel more confident.
- FALSE: Using PrEP means you don’t trust your partner(s).
- TRUE: PrEP can be taken when you feel you need HIV protection, and stopped when you don’t need it.
- FALSE: PrEP needs to be taken forever.
- TRUE: PrEP doesn’t protect against other STIs. Only condoms prevent against other STIs.
- FALSE: Using PrEP means you don’t need condoms.
- TRUE: PrEP has no effect on your ability to get pregnant.
- FALSE: PrEP will make you not be able to have children.
**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:**

**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

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N (%) or median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall, N = 353</td>
</tr>
<tr>
<td><strong>Age, years</strong></td>
<td></td>
</tr>
<tr>
<td>18-20</td>
<td>134 (38%)</td>
</tr>
<tr>
<td>21-25</td>
<td>219 (62%)</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
</tr>
<tr>
<td>Single, no partner</td>
<td>4 (1.1%)</td>
</tr>
<tr>
<td>Single, with partner</td>
<td>339 (96%)</td>
</tr>
<tr>
<td>Married</td>
<td>8 (2.3%)</td>
</tr>
<tr>
<td>Divorced/separated</td>
<td>1 (0.3%)</td>
</tr>
<tr>
<td><strong>Lives with partner</strong></td>
<td></td>
</tr>
<tr>
<td>59 (17%)</td>
<td>25 (14%)</td>
</tr>
<tr>
<td><strong>Any previous pregnancy</strong></td>
<td></td>
</tr>
<tr>
<td>242 (69%)</td>
<td>126 (70%)</td>
</tr>
<tr>
<td><strong>Trying to get pregnant</strong></td>
<td></td>
</tr>
<tr>
<td>5 (1.4%)</td>
<td>3 (1.7%)</td>
</tr>
<tr>
<td><strong>On family planning</strong></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>32 (23%)</td>
</tr>
<tr>
<td>Injectable</td>
<td>86 (61%)</td>
</tr>
<tr>
<td>Implant</td>
<td>20 (14%)</td>
</tr>
<tr>
<td>IUD</td>
<td>1 (0.7%)</td>
</tr>
<tr>
<td>Emergency Contraception</td>
<td>2 (1.4%)</td>
</tr>
<tr>
<td>Tubal ligation</td>
<td>1 (0.7%)</td>
</tr>
</tbody>
</table>
## Risk characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N (%) or median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall, N = 353</td>
</tr>
<tr>
<td><strong>Sexual behaviors (in past 3 months)</strong></td>
<td></td>
</tr>
<tr>
<td>Had sex in past 3 months</td>
<td>353 (100%)</td>
</tr>
<tr>
<td>More than one sex partner</td>
<td>350</td>
</tr>
<tr>
<td>Used Condoms</td>
<td>352</td>
</tr>
<tr>
<td>Always</td>
<td></td>
</tr>
<tr>
<td>Sometimes</td>
<td>214 (61%)</td>
</tr>
<tr>
<td>Never</td>
<td>85 (24%)</td>
</tr>
<tr>
<td>VOICE risk Score (0-8)</td>
<td>351</td>
</tr>
<tr>
<td>Uses Alcohol</td>
<td>352</td>
</tr>
<tr>
<td>Sexually transmitted infections</td>
<td></td>
</tr>
<tr>
<td>Has STI symptoms</td>
<td>353</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td>290</td>
</tr>
<tr>
<td>Chlamydia</td>
<td>290</td>
</tr>
</tbody>
</table>
### PrEP uptake at enrollment

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>PrEP uptake</th>
<th>OR</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Decision Support Tool</strong></td>
<td>172</td>
<td>166 (97)</td>
<td>1.79</td>
<td>0.67-5.30</td>
<td>0.262</td>
</tr>
<tr>
<td><strong>Health website</strong></td>
<td>181</td>
<td>170 (94)</td>
<td>Ref.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## PrEP Continuation at 1 month

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Attended 1 month visit</th>
<th>PrEP Continuation</th>
<th>OR</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decision Support Tool</td>
<td>172</td>
<td>40 (23%)</td>
<td>33 (20%)</td>
<td>1.97</td>
<td>1.08-3.69</td>
<td>0.029</td>
</tr>
<tr>
<td>Health website</td>
<td>181</td>
<td>31 (17%)</td>
<td>19 (11%)</td>
<td>Ref.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
• 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


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.
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.
- 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
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
Click here to watch the video: https://youtu.be/wnSM_R43T1w
<table>
<thead>
<tr>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opening &amp; Introductions</td>
</tr>
<tr>
<td>SEARCH</td>
</tr>
<tr>
<td>Q &amp; A with the SEARCH team</td>
</tr>
<tr>
<td>POWER</td>
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</tr>
<tr>
<td>PrEP advocacy message</td>
</tr>
<tr>
<td>Final Q &amp; A</td>
</tr>
<tr>
<td>Section</td>
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<td>----------------------------------</td>
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</tr>
</tbody>
</table>
Global PrEP Learning Network

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

Jason Reed
February 25, 2021
<table>
<thead>
<tr>
<th>VMMC Questions in 2012 (5 years after WHO recommendations)</th>
<th>VMMC Solutions in 2012</th>
<th>PrEP Questions in 2021 (5 years after WHO recommendations)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pace:</strong></td>
<td>Why were we off-target/moving “too” slowly?</td>
<td>White House commitment to “stretch” target of 4.7 million VMMCs to accelerate agenda</td>
</tr>
<tr>
<td><strong>Budget:</strong></td>
<td>Would there ever be sufficient funding given legacy programs and treatment mortgages?</td>
<td>White House commitment accompanied by traceable, dedicated funding to meet target</td>
</tr>
<tr>
<td><strong>Service Model:</strong></td>
<td>How should we implement, given integrated services less productive; vertical models unsustainable?</td>
<td>Mobile services that are client-centered vs. convenient for the health system</td>
</tr>
<tr>
<td><strong>Innovation:</strong></td>
<td>Should surgical services be held back given device-based solutions in trials promised easier implementation?</td>
<td>Technology never distracted from full-steam-ahead approach to what was available</td>
</tr>
<tr>
<td><strong>Client Behavior:</strong></td>
<td>Were men risk compensating after VMMC, ameliorating risk?</td>
<td>Don’t withhold services over suspicions and biases and counsel like you care</td>
</tr>
</tbody>
</table>
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?
<table>
<thead>
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<td>PrEP advocacy message</td>
</tr>
<tr>
<td>Final Q &amp; A</td>
</tr>
</tbody>
</table>
Q&A
Upcoming Sessions

- **MAR 25**: Developing Guidelines and Plans for the Delivery of Event-Driven PrEP
- **APR 22**: PrEP Continuation
- **MAY 27**: TBD

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• 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.

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