Reaching High-Risk Women for PrEP: Learning from ARV-based HIV prevention trials

Summary of Findings

April 2018
The objective of the OPTIONS Consortium is to develop a streamlined, adaptable product delivery platform for current and future microbicide and ARV-based HIV prevention options, with a particular focus on women.
OPTIONS refers to PrEP as the product category (inclusive of all formulations of ARV-based HIV prevention), and refers to specific products by formulation designation and/or name (e.g. oral PrEP/TDF-FTC, topical PrEP/dapivirine ring, injectable PrEP/cabotegravir, etc).
OPTIONS is one of five projects in the USAID-funded Microbicide Product Introduction Initiative (MPii)

- **OPTIONS**: Systems Thinking, Technical Assistance, National/Sub-national
- **POWER**: Cost Effective, Scalable Delivery, Facility Level
- **CHARISMA**: Intimate Partner Violence
- **EMOTION**: Human Centered Design
- **GEMS**: Resistance Monitoring

**End User Level**
How OPTIONS Works

**Country Level:** Support policymakers and implementers in South Africa, Kenya and Zimbabwe to take a strategic approach to PrEP rollout.

**Regional Level:** Develop evidence-based tools and build capacity for PrEP introduction in sub-Saharan Africa.

**Global Level:** Coordinate global action to support PrEP rollout.
Study Background & Methods
Background

- In sub-Saharan Africa women account for:
  - 56% of new infections among adults (15 and older)
  - 66% of new infections among young people (aged 15-24)
- Linking at-risk women to PrEP services is important for effective and efficient PrEP introduction.
- Little documented guidance on how best to identify and reach women most at risk of acquiring HIV.
- Having documented HIV incidence > 3% in the placebo arm, many clinical trials have clearly been successful in identifying and recruiting at-risk women.
Study Objectives

1. To take inventory of strategies used to recruit high risk women in HIV prevention trials

2. To seek study staff perspectives on successful and ineffective elements of different recruitment strategies in the research context

3. To gain perspectives on the feasibility of transferring selected elements of successful recruitment strategies to real-world service delivery settings
Methods

- **Design**: descriptive study examining recruitment methods used in trials (phase IIb, III) testing the effectiveness of ARV-based HIV prevention products

- **Eligibility**: study conducted in Africa, included HIV-negative females, started recruitment between January 2007 and January 2017, and had a placebo arm HIV incidence of 3% or higher

- **Data Collection**:
  - Desk review to compile information about each study
  - Key informant interviews with study leadership or staff responsible for recruitment and eligibility screening

- **Analysis**: Data structurally coded in NVivo, and an applied thematic analysis was conducted
Methods

- 7 HIV prevention studies, across 5 countries*
- HIV prevention products studied included: 1% tenofovir gel, TDF/FTC (Truvada), and the dapivirine ring
- 17 interviews were conducted with 31 staff members

* FEM-PrEP sites in Kenya and Tanzania could not be reached for an interview
<table>
<thead>
<tr>
<th>Study</th>
<th>Participant Cadres</th>
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| MTN-003/MTN-020       | • Site PI  
                          • Study Coordinator  
                          • Community Liaison Officer (CLO)/Community Manager  
                          • Recruitment team |
| FEM-PrEP              | • CLO/Community Manager                                |
| FACTS 001             | • Site PI  
                          • Co-Investigator  
                          • Study Coordinator  
                          • CLO/Community Manager |
| The Ring Study        | • Site PI  
                          • Study Coordinator  
                          • CLO |
| TDF2                  | • CLO                                                  |
| CAPRISA 004           | • Recruitment team                                     |
Participating research sites

- **Botswana:** CDC-Botswana, HIV Prevention Research Unit
- **Malawi:** Malawi College of Medicine John Hopkins University Clinical Research Site
- **South Africa:** Center for the AIDS Programme for Research in South Africa (CAPRISA), Desmond Tutu HIV Foundation Clinical Trials Unit, HIV Prevention Research Unit/Medical Research Council, Madibeng Centre for Research, MatCH Research Unit, Qhakaza Mbokodo Research Clinic, Setshaba Research Centre, The Aurum Institute Tembisa CRS, Wits Reproductive Health and HIV Unit
- **Uganda:** Makerere University - John Hopkins University Research Collaboration and MRC/UVRI Uganda Research Unit on AIDS
- **Zimbabwe:** University of Zimbabwe College of Health Sciences Clinical Trials Research Centre
Results
Results Overview

PART I
• Engaging the Community Advisory Board (CAB) and Gatekeepers
• Community Mapping
• Discussion

PART II
• Door-to-door recruitment
• Word of Mouth/Snowballing
• Recruitment from targeted areas
• Discussion

PART III
• Community Events
• Media as a tool for recruitment
• Clinic-based recruitment
• Discussion
Results Part 1: Strategies for Community Engagement
Engaging CAB and Gatekeepers

Community gatekeepers are individuals in contact with the community or a certain target population, and have the potential to motivate and support them.

- Members of the CAB, chiefs, ward councilors, priests, traditional healers, sports coaches, teachers
- The importance of engaging with the gatekeepers was discussed in every interview (17/17)
- Gatekeepers provide permission, both formal and informal, to work in the community
Engaging CAB and Gatekeepers

Gatekeepers support recruitment by:

• Encouraging confidence and trust

“People listen to traditional healers more than anybody. So we want them to say this is a good thing to do.”
Engaging CAB and Gatekeepers

Gatekeepers support recruitment by:

• Encouraging confidence and trust
• Supporting more targeted recruitment

“By working with the CAB members from that area [...] they have a list of the number of people who are employed, number of people who are unemployed. They help us decide which area to focus on.”
Engaging CAB and Gatekeepers

Gatekeepers support recruitment by:

• Encouraging confidence and trust
• Supporting more targeted recruitment
• Gatekeepers can serve as an ear to the community, so negative perceptions or potential challenges can quickly be identified and addressed
Engaging CAB and Gatekeepers
Potential implications for PrEP rollout

Gatekeeper engagement is essential for real-world rollout.

• Information should be given to community leaders prior to rollout so that they can be supportive.

• To the extent possible, gatekeepers should provide input into rollout strategies.

• Gatekeepers could go on radio or other media channels and express support for PrEP.
  – Young women could be motivated by this strategy.
Community Mapping

Community mapping is the systematic process of gaining information about the community.

- Approach used by the majority of study teams (10/17)
- Gather information by:
  - Talking to gatekeepers
  - Using data

"In terms of statistics [...] we said, ‘Where are our seroconverters coming from?’ Then from there we gather these places are where we got our seroconverters [...] And to date, those places still remain high risk."
Community Mapping

Benefits of community mapping included:

- Identification of important gatekeepers

“Community mapping helped us get the community profile... we found out who the gatekeepers were and how to reach them and get approval for community entry.”
Community Mapping

Benefits of community mapping included:

• Identification of important gatekeepers
• Understanding of high-risk areas or “hotspots”

“First we did the community mapping and talked to community members to understand where the study could get a good number of women.”
Community mapping is a helpful approach to guide outreach strategies supporting PrEP rollout.

- Strategies should be community specific.
- A good understanding of the community is necessary.
- NGOs working in communities already have done community mapping.
Why talk about community-based recruitment?

Our results showed that community-based strategies are essential to oral PrEP rollout to reach people most at need.

"When you compare with recruiting from the clinics—recruiting from the STI and family planning clinics—community was the most effective. It was most effective in reaching high-risk participants because it was diverse [...] it was not restricted to a clinic."
Results Part 2: Recruitment Strategies (1/2)
Door-to-Door Recruitment

Outreach workers go door-to-door to provide information about the study, sometimes in addition to health services and other health information.

- Used in just under half of sites (8/17)
- Targeted high risk neighborhoods identified during community mapping
  - Never target specific houses, to prevent stigma
Benefits of door-to-door recruitment:

- Allows for education and assessment of risk in private

“With door to door you spend time with the person. You don't leave there until that person is clear about what you're talking about [...] unlike a group setting where you have limited time to explain and they may be afraid to ask personal questions.”
Door-to-Door Recruitment

Benefits of door-to-door recruitment:

• Allows for education and assessment of risk in private
• Increases reach

“You must move beyond health clinics. Because young women are rarely showing up in health clinics [...] It is important to do something to make the young women openly talk about HIV.”
Door-to-Door Recruitment
Potential implications for PrEP rollout

Door-to-door recruitment can serve as an effective outreach strategy in areas with high HIV prevalence.

- Barriers include time and human resource requirements
- Feasible for rollout if partnered with a group already doing community outreach
- Can be done in conjunction with other services, such as HIV testing or other health promotion outreach.
Word of Mouth Recruitment

Many researchers encouraged community members or study participants to invite others to participate.

• Used in the majority of sites (12/17)
• Works well to find high risk people

“That works kind of both ways. If you find a high-risk participant they are likely to have a high-risk friend. But also if you find a participant who is going to be poor with retention then their friend also likely poor at retention.”

• To avoid misinformation, all interested clients should be encouraged to visit a health facility for information
Word of Mouth Recruitment
Potential implications for PrEP rollout

• Promote “tell your friends” among those satisfied with PrEP

• Those who have bad experiences with side effects could discuss negative experiences through word of mouth.

• Misinformation could still be a problem.
  – Would be helpful to provide pamphlets for people to give their friends to prevent misconceptions
Recruitment from Targeted Areas

Researchers often went to areas where women congregate or known hotspots to find potential participants.

Used in most sites (10/17)

Areas included places like

- Bars and clubs
- Brothels
- Shopping malls
- Community taps
Recruitment from Targeted Areas

Benefits:

• Reach
  – Reach people who don’t utilize health services
• Good way to recruit young people
  – More willing to talk among friends than when surrounded by adults.

Challenges:

• Safety
• Unwillingness of people to talk when they’re having fun
Recruitment from Targeted Areas
Potential implications for PrEP rollout

Feedback was mixed.
• Some found it very successful
• Others expressed concerns with privacy and safety

A good relationship with gatekeepers and an understanding of the community are essential for targeted recruitment to be successful.
Results Part 3: Recruitment Strategies (2/2)
Community Events

Researchers participated in community events and holiday celebrations to get the word out about the study and recruit participants.

• Mentioned in all but one interview (16/17)
• Events included things like:
  – World AIDS Day
  – Public holiday celebrations
  – Events targeting churches or women’s groups
Community Events

Benefits:

• Helped build trust in the community towards the researchers

"We try our best to do the events before the recruitment, so that the communities we are going to work with, they can know us, so that we can be familiar to them."
Community Events

Benefits:

• Helped build trust in the community towards the researchers
• Community leaders at an event can help build trust.

Challenges:

• Lack of privacy to talk with potential participants and answer questions
Community Events
Potential implications for PrEP rollout

Community events can be expensive and time-consuming, and would work best in conjunction with other organizations.

- Ask NGOs already working in HIV prevention or with PrEP target populations to educate about PrEP at events.
- Partner with those already doing events, instead of hosting them.
Media was used both for education and recruitment.

- **Most popular methods:**
  - Radio (11/17)
  - TV (4/17)

- **Provide information about PrEP generally, then ask audience to visit the clinic**
  - Information should focus on key messages and avoid discussion of risk
Media was essential in building trust around PrEP.

"You find that when speaking to people... they sometimes don't believe what we are saying to them, they don’t believe that the PrEP is really available because they haven't heard about it on radio, they haven't seen it in the newspaper.... I think that we should involve the media as much as we can.”
Media as a tool for recruitment

Radio shows

• Used both local and national radio
• Greatly increase the number of people showing up to the clinic
• Not all people who show up are high risk

TV commercials

• Used MoH logos to add legitimacy
Media as a tool for recruitment
Potential implications for PrEP rollout

Outreach via media is essential to build trust and combat stigma during PrEP rollout.

• Reach large numbers of people
• Reach everybody, not just key populations or targeted users
• Focus on basic knowledge and avoid anything that could cause stigma
  – Don’t mention “high risk” or associate PrEP with ARVs.
  – Don’t say PrEP is only for a certain population.
Recruitment occurred in facilities providing services for women:

- Family planning
- STI testing and treatment
- HIV testing and counseling

Points of contact:

- Talking to women in waiting room
- Provider consultations

"What I think works best is the fact that we kept on reminding them. When a young woman would come, we would track her contraception and keep in touch with her until she was ready to screen...."
Clinic-based recruitment
Potential implications for PrEP rollout

• Educate clients via printed materials and health promoters

“You have a massive number of people waiting to be seen who are not doing anything at that point in time, so it is a perfect strategy. People employed by Department of Health who are health promoters should spread the word of new methods.”
Clinic-based recruitment
Potential implications for PrEP rollout

- Educate clients via printed materials and health promoters
- Educate providers to instill knowledge and strengthen counseling skills

“When we started to push contraception methods, people weren't good at counseling for contraceptive mix. They would counsel only on the ones they know. But after training, uptake of IUCD, implants become very high. Increased training and capacity building supported this.”
Clinic-based recruitment
Potential implications for PrEP rollout

• Educate clients via printed materials and health promoters
• Educate providers to instill knowledge and strengthen counseling skills
• Support health systems strengthening. Current barriers include:
  – Health provider workload
  – Health provider turnover
  – Quality of care
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