Final Report

Sociobehavioral Research & Community Planning

to Develop Site-Specific Pilot Intervention Plans for PrEP Rollout

FEM-PrEP

SOSHANGUVE, PRETORIA, SOUTH AFRICA
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Executive Summary

We conducted qualitative research in Soshanguve, Pretoria, South Africa for the study entitled Sociobehavioral Research and Community Planning to Develop Site-specific Pilot Intervention Plans for PrEP Rollout. The objectives of this social marketing study were (a) to conduct formative research to inform the development of a pilot intervention for the social marketing of PrEP to specific target populations, (b) to facilitate a process of community planning for a local pilot intervention, and (c) to develop a social marketing plan based on the qualitative research results and community planning process. Data collection commenced in January 2010 and was stopped early in August 2010 when the study site was eliminated due to budget cuts.

Originally, data collection was to include semi-structured interviews with public health stakeholders, civil society leaders, members of potential target populations, and trial participants; two focus groups with community members; three workshops with community and public health stakeholders; and an inventory of facilities delivering HIV-related services. Six of the planned 15 semi-structured interviews were conducted with public health stakeholders. We conducted all 15 planned interviews with civil society leaders. None of the other planned interviews, focus groups, or workshops were conducted. We also implemented thirty-two inventories of facilities offering HIV-related services; the results of the inventory are provided in the companion final report to the HIV services inventory.

Public health stakeholders were asked their opinions on public policy matters, including incorporating PrEP into the National Strategic Plan, the development of policies and guidelines, integrating PrEP into existing health programs, creating capacity in the public health system for PrEP, and PrEP use in Pretoria. We also asked them questions about PrEP programs, including criteria for program enrollment, monitoring clients' performance, duration of taking PrEP, and potential partners to involve in PrEP planning and implementation. In addition, we asked public health stakeholders for their general perspectives regarding whom an effective PrEP pill should be made available to and to identify the best target populations for initial and expanded phases of a potential pilot PrEP program.

We also asked civil society leaders to identify the best target populations for initial and expanded PrEP program phases. Civil society leaders were asked whom they considered to be at risk for HIV infection, which groups might be able to fulfill program requirements, and about cultural beliefs and factors that may affect people's ability to fulfill program requirements. We also asked them questions regarding communication messages and strategies associated with introducing PrEP to the community, limited availability of the PrEP pill, partial effectiveness, behavioral disinhibition, promoting risk-reduction behaviors for pill users, and stigma. Lastly, we asked them about distribution of a daily HIV prevention pill.

All six public health stakeholders thought that PrEP should be incorporated into the National Strategic Plan (NSP) so that the government would provide information, budgeting, and guidance for rollout. They also said that some sort of national policy or guidelines for PrEP introduction should be developed in collaboration with service providers, researchers, and the community. When asked how to integrate a daily HIV prevention pill into existing public health programs and services, suggestions included having a separate section in a clinic, incorporating it into other services rather than having a separate section, incorporating it into family planning centers, allow for monthly pickup of medication at a pharmacy window, and figuring out who would have the authority to distribute PrEP. They said that creating capacity would involve staff training, increased staffing, funds, a supply of the drug, infrastructure, monitoring support, and pharmaceutical support.

Public health stakeholders suggested criteria for PrEP program eligibility, including that users belonged to specific populations, had particular sociodemographic profiles, and possessed characteristics like honesty, responsibility, and willingness to change their behaviors. They provided suggestions for prioritizing populations and had varying opinions on whether and how participants should be required to prove their risk of HIV in order to qualify for taking PrEP. Over half of the respondents thought that a client should be discontinued from PrEP if he/she were not adherent about taking PrEP. The majority were unsure of how long people should be able to take PrEP, saying it depended on scientific information.

Public health stakeholders provided suggestions for what their organization's roles should be in implementing a PrEP program, as well as recommended organizations to include in the program planning and implementation phases.

Suggestions from public health stakeholders of who should be targeted in the first phase of a pilot PrEP intervention included poor people, teenagers, women, black African women, people in informal settlements, men, young men and women, and everyone. Civil society leaders said that the following groups should be targeted: young adults, youth, single women, women in general, married women, and female sex workers. For an expanded phase, public health stakeholders recommended people in rural areas, men, homeless people, women, people of all ages, younger children, and black women. Civil society leaders recommended: youth and young adults, married women, adults, female students, taxi drivers, and sex workers. Civil society leaders also made recommendations on how to recruit different kinds of people to take PrEP.

Program requirements for PrEP users will likely include: taking a pill at about the same time every day, refilling the pill supply regularly, getting regular HIV tests, giving blood samples regularly, receiving regular adherence and risk-reduction counseling, and potentially getting pregnancy tests. Civil society leaders mentioned a variety of groups they believed would be able to fulfill program requirements, including youth, single women, women in general, female sex workers, married couples, students, young girls, and elderly women. They also reported which groups may find individual program

requirements challenging. Populations described as potentially unable to fulfill program requirements included youth/young people, married people, men, substance abusers, pregnant women, married women, party goers, people who do not take contraceptive pills, small children, young women, and the elderly. When asked whether potential target populations would be able to stay in an HIV prevention pill program for an extended period of time, civil society leaders responded yes for nearly all groups. Groups described as unable to stay in a pill program for an extended period included: sexually active and HIV negative people, 13-16 year olds, widows, men 14-35, and female teens.

Cultural beliefs that civil society leaders cited as making it difficult for people to fulfill the program requirements included the belief in traditional medicine, the cultural norm that women must get permission from men when making decisions, prohibitions about sex before marriage, and men's desire to make babies (prohibitive for the condom requirement). Pill-taking was viewed as not easy. Women were described as liking to go to healthcare facilities, but challenges with personnel, stigma, and long queues may make people in general not want to attend healthcare facilities for PrEP. Some respondents described people as disliking giving blood samples, but other respondents said that people do not mind.

Civil society leaders recommended different media channels to announce that PrEP works to reduce the chance of HIV infection, including television and radio stations and programs and newspapers. They also suggested locations in which to announce and discuss it, and other strategies such as taking advantage of community mobilization programs, going through HIV organizations, and holding public meetings, forums, workshops, and seminars. They recommended peer educators and community leaders/council members to act as spokespeople.

For communication strategies, they recommended "sensationalizing" the pill on television advertisements, using celebrities as spokespeople, airing advertisements before, during, and after popular programs, incorporating the daily HIV prevention pill into storylines or topics of programs, creating a new program with PrEP as the topic, and attracting young people by including music that youth like in advertisements. Other media strategies included using dramas in radio or television, explaining the history of the research process about the pill to the community, featuring spokespeople that were part of the initial research so they can relate their experiences, using program participants as spokespeople in the media to tell people about the pill, and explaining clearly that the pills are not 100% effective.

Respondents suggested strategies and messaging to address as part of community education about PrEP. Most civil society leaders said that community reactions would be negative if the daily HIV prevention pill had to be limited to certain target populations, and they suggested strategies and messages for addressing the community's concerns. Civil society leaders and public health stakeholders also suggested strategies and messages to describe how they would explain to the community that the daily HIV prevention pill is not 100% effective. Both civil society leaders and public health stakeholders suggested simply emphasizing the message that the pill is not 100% effective. Most civil society leaders and public health stakeholders recommended some type of education to help address the concern that people may increase their risk behaviors while taking a daily HIV prevention pill. They also suggested messages to address this concern. Civil society leaders provided strategies and messages for condom adherence, limiting the number of sex partners, and having sex with only one partner. Over half of civil society leaders did not think there would be any stigma associated with taking an ARV as prevention if the community is well-informed. Of those who felt there would be stigma, several people said that people will think program participants are HIV positive if they are taking ARVs. Strategies and messages to address stigma were provided.

Most civil society leaders and public health stakeholders said that the pill should be free in public sector health facilities. Both sets of respondents made suggestions for discouraging program clients from selling the daily HIV prevention pill to others. Nearly all civil society leaders thought the pill should be distributed in clinics, though other locations were suggested. Both civil society leaders and public health stakeholders suggested potential names under which to market an HIV prevention pill.

Public health stakeholders expressed doubts and concerns about the use of a daily PrEP pill in Pretoria, including: viral resistance, suicide among seroconverters, logistics, the budget for PrEP, whether people will be given sufficient information about the pill, side effects, and the effects of the drug on behaviors such as drug sharing. They also suggested strategies on how to address some of these concerns.

Introduction

Introduction

FHI 360 and local partners conducted a Phase III clinical trial called FEM-PrEP to assess the effectiveness and safety of oral Truvada taken daily by women at risk of HIV infection as pre-exposure prophylaxis (PrEP) to prevent HIV acquisition. FEM-PrEP was a multi-centered, double-blind, randomized, parallel, placebo-controlled effectiveness and extended safety trial, jointly funded by USAID and the Bill & Melinda Gates Foundation. Additionally, a social marketing study entitled Sociobehavioral Research and Community Planning to Develop Site-specific Pilot Intervention Plans for PrEP Rollout was implemented in association with the FEM-PrEP clinical trial to facilitate local discussions around the potential rollout of a PrEP pill shown safe and efficacious. Sites for the social marketing study were Pretoria, South Africa, in collaboration with Setshaba Research Centre, and Bondo, Kenya, in collaboration with Impact Research and Development Organization.

Study Objectives

The objectives of this social marketing study were to conduct formative research to inform the development of a pilot intervention for the social marketing of PrEP to specific target populations, to facilitate a process of community planning for a local pilot intervention, and to develop a social marketing plan based on the qualitative research results and community planning process.

Unfortunately, funding for the study at the Pretoria site was eliminated in August 2010 due to budget cuts. Therefore, it was not possible to complete the study and create the plan of site-specific recommendations based on study findings. However, the site research team had already completed part of the data collection, and those results are presented here. We believe that public health stakeholders may find these results useful in their discussions about the potential rollout of a PrEP pill in South Africa.

Methods

2.1 Ethics Approval

Ethical approval for the study was obtained from FHI's Protection of Human Subjects Committee (PHSC) in December 2008 and from the local Ethics Committee, Medunsa Research and Ethics Committee (MREC), in September 2009.

Qualitative question guides were developed at FHI for in-depth interviews with public health stakeholders, civil society leaders, clinical trial participants, clinical trial staff target populations, and community members, as well as focus groups with community members. An inventory of HIV-related services was also developed. These study instruments were piloted and finalized in collaboration with site staff during study-specific training in July 2009. Site staff then translated all relevant instruments into Setswana. We submitted finalized and translated instruments to MREC for ethical approval in October 2009 and obtained approval in November 2009.

2.2 Staff Training

Training of study staff was conducted prior to data collection. It included refresher training in qualitative methods and an overview of the social marketing methodology and stages of change theory. Study staff were also trained on the study protocol, SOPs, interview and focus group guides, consent forms, and other study documents. The staff had received prior training in research ethics. The interview and focus group guides and the HIV Services Inventory were pilot tested, revised, and finalized during the training.

2.3 Data Collection and Sub-objectives

Data collection commenced in January 2010 and was terminated early in August 2010 when the study site was closed due to budget cuts.

Six of the planned 15 in-depth interviews were conducted with public health stakeholders. The research question the interviews were intended to answer was identifying what needs to happen at the level of public health systems in order to design and implement a pilot intervention for oral PrEP. The following topics were addressed:

- Public policy
- Discussion of appropriate target populations
- Intervention management and decision-making
- Integration of PrEP into existing HIV prevention programs
- Client participation criteria
- How to create capacity for PrEP rollout

We conducted all 15 planned interviews with civil society leaders. The interview questions focused on the perceptions of civil society leaders regarding target population selection and exploring issues related to PrEP implementation including the respondents' potential roles in communication with the community, community education, recruitment and retention, stigma related to the PrEP drug being an ARV, and discouraging behavioral disinhibition/ risk compensation.

We also implemented thirty-two HIV services inventories, whose results are detailed in a companion final report.

2.4 Study Population

The 15 civil society leaders we interviewed included a person who works to make sure HIV/ AIDS programs are implemented, two pastors, an HIV educator, a director of youth development programs, a community member who participates in political meetings, a concerned community member, an adherence counselor who also dispenses ARVs, a person involved with teachers, a peer educator for university students, a person who works with people in the taxi industry, a tavern owner and football club sponsor, an HIV testing counselor, a ward councilor, and a sports council member who creates HIV awareness through sports.

The six public health stakeholders we interviewed included individuals at the district level from governmental and non-governmental organizations. They included physicians, an ART clinic project manager, a facility manager, and a traditional doctor.

2.5 Recruitment

The study team recruited the public health stakeholders with assistance from the Community Advisory Board (CAB) members. The stakeholders interviewed also referred the study team to additional individuals who could potentially be interviewed. Recruitment was challenging due to the busy schedules of the individuals interviewed.

Civil society leaders were recruited by identifying influential stakeholders with whom SRC had an existing relationship. We also asked respondents to identify others who would be relevant to interview.

2.6 Data Processing and Analysis

Staff recorded the in-depth interviews using digital voice recorders. Interviews in English were transcribed into electronic files, and interviews conducted in Setswana were transcribed and translated simultaneously. Electronic files were then sent to FHI for coding via a secure server.

An FHI data analyst coded the transcripts for qualitative analysis using QSR NVivo 8; prepared coded text reports; and created memos and summary tables of the data. A deductive coding approach was used, with transcripts coded by question. We chose this type of coding due to the nature of the interview questions, which solicited very specific information in each question.

Results

Public health stakeholders were asked their opinions on public policy matters, including incorporating PrEP into the National Strategic Plan, the development of policies and guidelines, integrating PrEP into existing health programs, creating capacity in the public health system for PrEP, and PrEP use in Pretoria. We also asked them questions about PrEP programs, including criteria for program enrollment, monitoring clients' performance, duration of taking PrEP, and potential partners to involve in PrEP planning and implementation. In addition, we asked public health stakeholders for their general perspectives regarding whom an effective PrEP pill should be made available to and to identify the best target populations for initial and expanded phases of a pilot PrEP program.

We also asked civil society leaders to identify the best target populations for initial and expanded PrEP program phases. Civil society leaders were asked whom they considered to be at risk for HIV infection, which groups might be able to fulfill program requirements, and about cultural beliefs and factors that may affect their ability to fulfill program requirements. We also asked them questions regarding communication messages and strategies associated with introducing PrEP to the community, limited availability of the PrEP pill, partial effectiveness, behavioral disinhibition, promoting risk-reduction behaviors for pill users, and stigma. Lastly, we also asked them about distribution of a daily HIV prevention pill.

3.1 Public Policy Concerns

3.1.1 Incorporating PrEP into the National Strategic Plan

We asked public health stakeholders if they thought a daily HIV prevention pill should be incorporated into the National Strategic Plan (NSP) on HIV/AIDS. All six respondents said yes, for the following reasons:

- It would mean that the government will budget for the pill and roll it out.
- *"Because the aims or the goals of the NSP is to prevent, to treat and to manage HIV so if this pill is included in the NSP it will serve as a guideline in terms of preventing HIV."* (Interview with public health stakeholder)
- If the HIV prevention pill is introduced from the top downwards there will be resources to give the information to the media and health facilities.
- To make the policy workable, otherwise there would be chaos.
- It would cut down on new infections immediately.

One respondent cautioned that it is necessary to see how the pills affect people long term before making it available.

Two respondents cited difficulties associated with incorporating PrEP into the NSP:

- Expansion of staff and facilities will be needed: *"You will need more personnel to roll out, you need more facilities, more health workers ehh I mean we've seen it with the rollout [of ARVs], it's huge, it's not and counselors, psychologists and the whole multidisciplinary team to make it work, because if you don't have adherence and compliance you won't win anything."* (Interview with public health stakeholder)
- Diversion of money from treatment to prevention, and securing funding for prevention.

We then asked them for the steps for incorporating a daily HIV prevention pill into the National Strategic Plan:

- Once the scientific data is available and backed up by international studies, have meetings with government and policy makers (n=2).
- Include business people in the planning of public policy because they have employees who are or will be infected with HIV (n=1).
- It will not take long as HIV is currently part of the millennium goals (n=1).
- Include the community, as they are the stakeholders (n=1).
- *"Get people who are experts in the area, but my own feeling and understanding I don't know how close we are to say this should be included, I mean look at circumcision, look at how long it took to say thing must be included, WHO and UNAIDS pushed so it is not an easy thing to say today you get prevention and tomorrow it is rolled. Especially if it is medication I think medication, I think drugs, we don't want to roll things out and later people blame us for them."* (Interview with public health stakeholder) (n=1)

3.1.2 PrEP policies and guidelines

We asked public health stakeholders their opinions on whether there should be a national policy or national guidelines about access to a daily HIV prevention pill at public health facilities and what the advantages and disadvantages of each were. Most respondents conflated policies and guidelines. Five of the six respondents agreed that there should be some sort of policy or guideline for PrEP:

"The protocols give us very clear directions as it is what we should do. Then we remove the gray areas as to I don't know what I must do." (Interview with public health stakeholder)

"Circular that states exactly who should be eligible for that tummy flue [as an example] and who shouldn't be and what tests we should conduct and how we should proceed… It gives the information down to all the structures." (Interview with public health stakeholder)

"Your policies and guidelines you make sure that emm the doctors that's sitting day out in the same clinic not having contact with everything else, that they also get the knowledge." (Interview with public health stakeholder)

The sixth respondent said that it is difficult to say whether there should be a policy or guidelines because *"if you want to bring government into play things take long."*

The advantages of having policies and guidelines were cited as:

- They remove uncertainty.
- They provide rules for personnel in facilities: *"Everybody follows the same procedure.. everybody is doing exactly the same thing at the same time."* (Interview with public health stakeholder) *"It gives you a guideline of exactly what needs to happen.. the how, where, what, why."* (Interview with public health stakeholder)
- They remove personal beliefs from the equation, unlike a recommendation.
- Disadvantages of having policies and guidelines were cited as:
- *"If it's formulated you cannot change it up until it's amended and reviewed."* (Interview with public health stakeholder)
- They can act against values.

One respondent who did distinguish between policies and guidelines stated that *"the guidelines that you hand out on ground level emm would be then the explanation of a circular [policy] with much more information, and that gives the relevant dosages and the side effects and everything else included, while the circular [policy] is just stating the procedure of changing to a new drug."* (Interview with public health stakeholder)

We asked public health stakeholders to provide the steps for creating a PrEP policy or guidelines. Five respondents provided answers, including:

- Having workshops or meetings involving service providers and researchers to advocate for PrEP (n=2): *"You have to have your clinicians and your researchers together, where they sit around and emm work on this where everybody gives their input with the knowledge of the research together."* (Interview with public health stakeholder)
- *"Involve the community or people who can represent the community, and the second step might be to get emm more money injected in that policy, to make sure that money is there for that policy to be implemented, and then to go back to the community and report about the planning of that policy."* (Interview with public health stakeholder) (n=1)
- Create a plan and then divide it into short-term steps (n=1).
- *"Number one they should educate the community, that's number one. Number two they should interact with the community. They should [find] out from the community, how they want to be helped. It is the community that should help government to come with ways.. of putting the strategies in place."* (Interview with public health stakeholder) (n=1)

We then asked them what obstacles there might be to creating a policy or guidelines and how these could be addressed. One respondent said that there would be no obstacles. Other obstacles included:

- Stakeholders might not buy in if they feel FEM-PrEP study results are "cooked", so it is important to produce scientific and truthful results. (n=1)
- If there is not enough evidence to convince the government. (n=1)
- People in the government may not be cooperative, so they must be educated on HIV matters. (n=1)
- If there is not enough continuous engagement with government and if you don't *"engage policy makers on their level of understanding."* (n=1)
- *"[I]f the people don't believe you," "if your data was not well enough or good enough presented," "if there are doubts about the benefits," "if there's no money and then you will run into trouble."* A strategy to address these obstacles was described as making sure that your presentation of your data has visual impact so that the health managers can identify with what you are trying to say and so that you prove to them that the method will be beneficial. (n=1)
- If those making decisions do not consult with the people/communities/stakeholders. (n=1)
- If education is not provided to people: *"If they don't educate.. people would not know about it and it is supposed to work for them."* To address this problem, *"We can't leave education out.. people should be told, people should be.. there is still a lot that needs to be done. People will have to be told that this pill is for HIV negative people. It is.. what happens, blah, blah, blah. It doesn't mean sleeping around like."* (Interview with public health stakeholder) (n=1)

We then asked public health stakeholders what the role of their organization or position could be in creating a policy or guidelines.

- The Department of health was said to be able to:
  - Develop policies and guidelines: *"Once all the research have been done and you have proven that it's working, you will take your results to them so that they can develop policies and guidelines, because as a researcher you won't have that part available to you, while the department do have teams that can do that, emm they have teams that together they can develop essential drug lists at the hospitals, guidelines and treatment and so forth."* (Interview with public health stakeholder) (n=1)
  - *"Make sure that ehh the policy is effectively implemented, make sure that they policy that gets developed is really understandable to the people who will be using it."* (Interview with public health stakeholder) (n=1)
- Health facility managers can provide input for the policies: *"We give inputs you know because we are at functional level people up there they do not know anything because I am sorry they don't experience what we are experiencing here, we are the ones burning so we push, we give inputs at the meetings we start at the clinic meetings because I also need to get feedback from the clinic personnel they are the ones who are next to the patient on daily basis.. they give me that report I take it to.. the top management, top management take it to the provincial then to national and then at the national that is where protocols are formed. So, they cannot do anything without us at functional level because we are the ones who see everything."* (Interview with public health stakeholder) (n=1)
- [Name] is a social science organization that can help inform policy development. For example, study results can illuminate how a lay person understands partial protection. *"Those are issues we tackle and also get information to those on the ground and lobby policy makers and make our studies available to government working together with SANAC that is able to make policies based on our study results."* (Interview with public health stakeholder)

3.1.3 Integrating PrEP into existing health programs

We asked public health stakeholders for their suggestions on how to integrate a daily HIV prevention pill into existing public health programs and services. Respondents gave a wide variety of answers, including:

- Advocate for incorporating PrEP into the public health system.
- Have user-friendly guidelines.
- Have a separate section in a hospital or clinic dedicated to HIV prevention so that people know where to go to get PrEP.
- Incorporate it into other services rather than

have a separate section or a corner in the ARV clinic: *"I would suggest that if you want to move away from this stigma of putting it aside somewhere around the corner in the ARV clinic, it must be easily accessible like a lady walking in to do a vaccination of a baby, it must be in the same kind of set up, where you walk in there must be no prejudice or ehh obstacles from the health workers."* (Interview with public health stakeholder)

- Incorporate it into family planning centers: *"The only place I can see it fitting is reproductive health with contraceptives."* (Interview with public health stakeholder)
- Allow for pickup of monthly packet of pills at a pharmacy window, just like chronic disease medication.
- After the government has formulated the policy, *"they will cascade it down to our pharmaceutical.. and then we order..."* (Interview with public health stakeholder)
- Remove stigma associated with PrEP by showing that protection is better than treatment.
- Make it available to everyone.
- Follow the same process as with antiretrovirals (ARVs) but with more community education.
- Figure out who would have the authority to distribute PrEP, i.e., who can roll out Truvada, whether doctor or nurses, just as is being discussed for ARVs.

3.1.4 Creating capacity in the public health system for PrEP

We asked public health stakeholders how to create the capacity to offer a daily HIV prevention pill within the public health system. Responses included providing:

- Staff training – for medical doctors, nurses, pharmacists (n=4)
- Increased staffing/human resources (n=1)
- Funds (n=4)
- Medication/supply (n=2)
- Infrastructure, specialized clinics (n=2)
- Attention to how monitoring will be provided in a health system *"that is already not coping at the moment."* (Interview with public health stakeholder) (n=1)
- Pharmaceutical support in that pharmacies will keep the pills and order them (n=1).

3.1.5 Regulations for integrating PrEP

We asked public health stakeholders what regulations and approvals program planners should be aware of as they potentially plan how to integrate a daily HIV prevention pill into the public health system. Respondents provided the following regulations/approvals: MCC approvals (n=2); Pharmaceutical regulations, the Pharmacy Act and the Medicines Regulation Act (n=2); and get a letter from the Department of Health (n=1). One respondent referred to a different type of regulation focusing on pill distribution: *"There must be regulations based on how who get this pill, and how they get it, so that we can avoid people selling the pill for them to get money, so the regulations must be around, how often do you get this, there must be I think some method to monitor who got this pill and when did that person get the pill."* (Interview with public health stakeholder)

3.1.6 Daily HIV prevention pill use in Pretoria

We asked public health stakeholders how they thought a daily HIV prevention pill should be used in Pretoria. One respondent expressed concerns about the pill causing HIV-resistant viral strains. Another said that a long-acting HIV prevention pill would be better due to pill fatigue for people taking oral contraceptives and/or TB drugs. A third respondent said that the pill should be given to both HIV positive and negative people. Another respondent expressed concern about side effects, resistance, and care for people who become positive while using the pill. This person also said that an irregular-use pill is much more practical than a daily pill: *"We do not want to pump people with medication when they are not sick. We don't know how it [will] affect them long term"* (Interview with public health stakeholder).

3.2 PrEP Programs

3.2.1 Target areas for PrEP programs

We also asked public health stakeholders which other communities besides Soshanguve/Pretoria were appropriate for a PrEP program. Responses included: in mining towns such as Rustenburg, along the coast in KwaZulu-Natal, Durban, Johannesburg, Mpumalanga, Western Cape, Eastern Cape, and where statistics indicate.

3.2.2 Criteria for PrEP program enrollment

We asked public health stakeholders what they thought the client enrollment criteria should be for PrEP programs. The following responses were given by one person each:

- Negative partners in discordant relationships
- Children born to pregnant women who are on PMTCT program
- People from age 18-50, specifically women from 18-36 (child-bearing age)
- The highest prevalence age group
- People who have a history of STIs and are willing to change their behaviors
- People who give their permission and come for adherence counseling

- People who are not planning to make money out of the program, willing to test, and who will be available
- Someone who is very responsible
- First look at the response that the pill generates, then make criteria based on that
- A cross-section of the population targeting people at risk (usually unemployed) and people in higher classes

We asked public health stakeholders for their suggestions on how to prioritize among eligible people if there turned out to be high demand for the pill among people who meet the enrollment criteria. One person suggested reducing the inclusion criteria so that less people make it into the program. A second respondent said to give preference to teenage girls and women above forty-five years, whereas another respondent said to reduce the age to 18 to 30 because they are the most sexually active. A fourth respondent said, *"It's not going to be possible to screen them that way, so it means that you either have a pilot depending on time and everybody arriving in the first two weeks will be in the pilot, or you would say the first thousand depending on your budget, but I don't think while you are busy with your pilot you can turn people away, it will cause anger and frustration."* (Interview with public health stakeholder) Another respondent recommended assessing each individual who presented to see who could wait and who should be put on PrEP immediately. A sixth respondent felt that it was important to *"explain to people that there is no favoritism. People should understand it is done randomly, so your community entry point is important. No one is getting in because they are friends with someone at the research."* (Interview with public health stakeholder)

We also asked them if participants would need to prove that they are at high risk of HIV infection, and if so, what sort of proof should be required. One respondent said that for clients to tell them this information they will need to gain their confidence and show that they are patient-centered. Another suggested creating a questionnaire for self-completion that will ask the clients for the requisite information, otherwise clients will not reveal the information. Another recommended that *"there should be ways to interview people to.. like end up being convinced that this one is true.. there should be questions asked.. like, like what made you think that you are at risk?"* (Interview with public health stakeholder) Two respondents felt that it should not be necessary for a client to prove that he/she is at high risk. For example, one person explained:

"It's an effort to come into a clinic, emm you would definitely feel that you need it, that's why you are presenting yourself at the clinic, and I feel that if people are presenting them to get a tablet like that and then is going to help them then you need to really help them in getting it." (Interview with public health stakeholder)

A sixth respondent said it would be difficult to assess risk because many people who get infected have only one partner and may not appear to be at risk; however, their partner's behaviors may put them at risk and this may not be apparent.

3.2.3 Monitoring clients' performance in a PrEP program

We asked public health stakeholders how program staff should monitor a client's performance in a PrEP program. Two respondents noted that this will be difficult because they will be depending on clients to truthfully report their risk behaviors. In addition, one respondent said biomarkers like taking swabs would be needed to check if self-reported data is correct. Another said that clients could be monitored *"by encouraging them to go for VCT maybe on quarterly basis or six monthly basis."* (Interview with public health stakeholder). Physical exams, blood testing, and STI testing were other suggestions.

When we asked public health stakeholders what should be done if a client is not adherent about taking the HIV prevention pill every day, four of the six respondents said the client should be discontinued:

"If a client is not adherent they will obviously be out of the program.. you would ehh incorporate that into the agreement between you and the patient that there must be a 90% adherence." (Interview with public health stakeholder)

"They should be kicked off the program." (Interview with public health stakeholder)

"Release them, you can continue monitoring them if you need to but if the person has stopped you need to release them and say if you stop for whatever reason we discontinue you." (Interview with public health stakeholder)

The remaining two respondents recommended counseling and education for the client.

When we asked public health stakeholders what should be done if a client reports that he/she is increasing his/her high-risk behaviors due to feeling protected by PrEP against HIV infection, three respondents recommended education and counseling, one respondent recommended revisiting the personal plan and making adjustments, and one respondent said that thorough documentation of increased risk behaviors will be important. One respondent suggested learning lessons from what people taking ARVs do and recommended not kicking out of the program clients who increase their risk behaviors.

Messages that public health stakeholders suggested included:

- The pill is not a license to increase your risk behaviors. (n=1) *"This is not a license to promiscuity my sister."* (Interview with public health stakeholder)
- The effectiveness of the pill is not 100%. (n=2)

3.2.4 Duration of taking PrEP

When we asked public health stakeholders how long people should have access to PrEP, two respondents said that it depends on other factors such as scientific information regarding efficacy and *"the life span of the pill in the blood system"* (Interview with public health stakeholder). Two others said that people should be able to take the pill long-term or for life:

- *"Just like taking ehh ehh prevention or pregnancy pill, if you don't want to get HIV you take this pill for the rest of your life.. unless you stop having sex or you become faithful to your partner."* (Interview with public health stakeholder)
- *"If this ehh preparation of pill shown to be ehh dramatically reduce HIV infections you would emm make it available to people emm that's at risk, and then it doesn't help you if you make it available just for a month, what should happen next month then? So then you make it available long term."* (Interview with public health stakeholder)
- The final two respondents said that they did not know how long people should have access to PrEP because they did not have adequate scientific information.

3.2.5 Organization's role in implementing a PrEP program

When we asked public health stakeholders what role their organization could play to help implement a daily HIV prevention pill program, they gave the following responses:

- Department of Health:
  - Will help to monitor and keep records of the clients and to help monitor stock since they have systems in place to do that.
  - *"Can help you with policies and guidelines, emm they have the .. partial infrastructure.. it won't help for a researcher and his company to set up new facilities just to rollout a new pill, worldwide is never done like that, it's usually a joint venture."* (Interview with public health stakeholder)
- Government:
  - Make sure that there are enough staff.
  - *"[M]ust also make sure that there is enough material to distribute or to give service of this prevention method.. a room for giving that service, there are chairs, furniture, equipment, stationery."* (Interview with public health stakeholder)
  - Make sure there are no stock outs.
- Clinics:
  - Training in collaboration with NGOs and CBOs.
  - Monitoring and evaluation of implementation of the policy.
- Traditional healer:
  - Education
  - Counseling
- Social science organization:
  - Workshops
  - Presenting their work to NGOs and health programs like Soul City (on SABC1) and other media

3.2.6 Organizations to include in the program planning phase

When we asked public health stakeholders which other organizations or individuals they recommended that we contact during the program planning phase, they provided the following responses:

- Community leaders and churches so they can mobilize and communicate with the community (n=1)
- Non-medical sites where they conduct VCT services (n=1)
- Private doctors (n=1)
- General practitioners (n=1)
- NGOs and CBOs to get the communities and because *"they are the ones who go around the community see the problems that people have, they can advice people to come to the health facilities"* (Interview with public health stakeholder) (n=2)
- Media (n=1)
- Traditional healers: *"When we open clinics we invite them just to make them feel that they are also important like I said we re-modify their behaviors we don't just tell them no, no, no. so, even the traditional healers need to be involved."* (PrePRPHO3) (n=1)
- WHO because they have a lot of experience (n=1)
- Community businesses (n=1)
- Department of Health and National Health because they have the contacts of WHO (n=1)

3.2.7 Potential partners for a PrEP program

When we asked public health stakeholders whom they suggested as potential partners for an HIV prevention pill program, they provided the following responses:

- Doctors
- Private medical doctors (n=2)

  "You can find that people are getting this pill at private doctors, can no longer afford this pill so those people will be coming back to the public sector, so we must make sure that we are doing ehh uniform method of distributing this pill between the private and the public sector." (Interview with public health stakeholder)
- Hospitals
- Crisis centers
- Casualty offices
- NGOs
- HAST (HIV, AIDS, STI, TB) Department: *"in HAST we have partners like NGOs where they do VCT"* (PRPHO3)
- Community
- Community leaders (not necessarily politicians) (n=3)
- Community businesses
- Department of Health
- "The research company"
- Church ministers
- Scientists

- Laboratory technicians
- Social scientists
- Traditional healers
- Government
- Donors

3.3 Target Populations

3.3.1 Populations at risk of HIV infection

We asked civil society leaders to identify which groups of people they consider to be at risk of HIV infection. They provided a wide variety of responses, including men, the poor, married women, children, young people, young women, everyone, school girls, students, women, youth, the elderly, substance users, children of HIV positive mothers, young men, people with money, medical professionals, commercial sex workers, and taxi drivers. They also mentioned married couples, everyone who is sexually active, the working class, grandmothers, steady partners of female sex workers, girls with sugar daddies, young single mothers, teachers, queue marshals, car washers, street hawkers, partners of those who are unfaithful, and people who are "innocent" (i.e., not infected).

3.3.2 Whom the pill should be made available to

We asked public health stakeholders whom the daily HIV prevention pill should be made available to and why. Responses included:

- People who are raped (n=1)
- Poor societies (n=1)
- Prisoners (n=1)
- Women (n=2) *"because of our social background in terms of the way women are so submissive to their male.. you find that in ehh typical traditional home or house the men will ask sex from women, that woman doesn't have the right or the power to say no, to that's typical traditional man, she has to give that man what ehh what the man wants, that is sex.. Most of the women in typical traditional household, they don't have a say in terms of using condoms or protection, to say it correctly"* (Interview with public health stakeholder).
- Teenage girls (n=1) because they are at risk of HIV due to dating older men to get money from them
- Everybody (n=1) starting from age 12 when challenges begin
- Men and children (n=1) after focusing on women first
- Women with unfaithful partners (or who suspect infidelity) (n=1)
- People who fear they are at risk (n=1)
- People who cannot negotiate condom use (n=1)

When asked if PrEP should be made available to everyone, four of the six public health stakeholders interviewed said that it should be made available to everyone because the challenges start from a young age and whoever wants it should be able to get it.

One respondent said that only people at high risk should be able to get access to it because, *"If it's like that, people tend to become too loose. The morning after pill now it's been used as.. prevention.. your abortion is also used as prevention so I would not want it to be freely available"* (Interview with public health stakeholder).

When we asked public health stakeholders if PrEP should be available to all ages, five of the six respondents said yes, with one respondent saying that people of all ages should get access after the target groups. Similarly, a sixth respondent said, *"As I said, I think you should start first with your childbearing age women and then roll out to males and then to the rest of the population"* (Interview with public health stakeholder).

All respondents felt that both men and women should get access to PrEP. One person explained:

"That is what I prefer.. to be available to everybody so that they will carry the same responsibility.. for your health. Otherwise we lock them outside then they think they are not part of the struggle. So, if everybody is made responsible maybe we can manage to fight the problem." (Interview with public health stakeholder)

Another recommended involving men:

"It's important that we should bring men on issues of HIV prevention, for me it's a big, big issue. My PhD is on HIV risk. I a lot has happened and we left out men on HIV prevention we have made it a women's issue. If the drugs work for men then give them those drugs. Also get them to participate because if you say a woman is going to take this medication everyday of her life then men need to be involved.. if you do not involve me we are going to have problems." (Interview with public health stakeholder)

An additional respondent qualified the response saying that a smaller pilot group should first target women of childbearing age before others are given access.

3.3.3 Initial and expanded target populations

Both public health stakeholders and civil society leaders were asked to identify the best target populations for initial and expanded phases of a pilot PrEP program and to explain why the groups were appropriate.

Civil society leaders said that for the first phase of a pilot daily HIV prevention pill program lasting for two years, for example, the following groups should be targeted:

- Young adults (n=3) because they change partners often and are in a challenging time of life
- Youth (n=4) because they are in a challenging time of life, often practice unsafe sex, and are at high risk
- Single women (n=3) because they are free to do as they wish and have multiple partners
- Women (n=2) because they sometimes become a victim of circumstances
- Married women (n=2) because they cannot negotiate condom use with their husbands
- Sex workers (n=2) due to their high risk

Also mentioned by one person each were the poor, young girls with sugar daddies, young women, teachers, policemen, nurses, army men, farm workers, infants of HIV+ parents, and adults.

Public health stakeholders said that the first phase of a pilot PrEP program should target the following groups:

- **Poor people** (n=2) because they are more at risk and have more sex
- **Teenagers** 15-19 (n=1) "because they are at a higher risk of getting involved with multiple partners throughout their relationships and dating older men getting money, for the sake of getting money from them." (Interview with public health stakeholder)
- **Women** (n=2) because they are at high risk and because they *"are very responsible and they will follow the program well."* (Interview with public health stakeholder)
- **Black African women** (n=1) because they have a higher HIV prevalence
- **People in informal settlements in Soshanguve** (n=1)
- **Men** (n=1) *"because they are the ones who need to understand this better and for them to support their partners."* (Interview with public health stakeholder)
- **Young males and females** (n=1) because they are at childbearing age
- **Everyone** (n=2) because everyone who has sex and cannot use condoms is at risk of HIV, including older people. Everyone who feels they are at risk should be included.

For an expanded phase, civil society leaders recommended the following target groups:

- **Youth and young adults** (n=5) because it will be easier to sell the idea to them once we can show the effectiveness statistics among the first target populations, they are at the age where they want to experiment and are therefore at risk, and the program can help teach them what is right and wrong
- **Married women** (n=4) because they cannot say anything when their husbands have affairs, they are at risk due to their husbands visiting sex workers, and they will be more willing to participate once they see that the program is working with other groups, making it easier to sell the idea to their husbands
- **Adults** (n=3) so they can teach their children and grandchildren
- **Female students** (n=2) because they will have time for the program during breaks and because they are at high risk of HIV due to dating rich men
- **Taxi drivers** (n=2) because if the taxi organization gives them permission they will have time to come for the program and because they are at risk due to lack of education
- **Sex workers** (n=2) because their numbers are increasing, there are high, middle, and low income sex workers, and they have multiple sex partners

Also mentioned once each were single women and men, unemployed males, grandmothers, widowers, chronic people, army men, menial workers, married men, and men.

Public health stakeholders recommended for an expanded phase the following target groups:

- **People in rural areas** (n=1) because they are at risk. *"We thought HIV is not a problem there but rural areas are very vulnerable because you know, people take HIV from cities to them.. and these are the people who think they are not exposed."* (Interview with public health stakeholder)
- **Men** (n=1) because they do not get tested for HIV infection as often as women
- **Homeless people** (n=1)
- **Females** (n=1) because they are organized and responsible
- **People of all ages, everybody** (n=3) because nobody should be left behind
- **Younger children** (n=1) whose risk is due to sexual abuse

Black women (n=1) because they are the group at high risk of HIV infection. *"If you tested it on this risk group then why do you need to take it to white females who are not at risk or have a low HIV prevalence. There is only one group that is at risk, we all know it, black women, not only sex workers."* (Interview with public health stakeholder)

3.3.4 Target populations for an irregular-use HIV-prevention pill

We told public health stakeholders that clinical trials may be conducted to see if taking a PrEP drug like Truvada just when a person has sex—instead of every day—reduces the chance of HIV infection, and we asked them which populations they would recommend for such a pill. Responses included:

- **Young people** (n=2) because they are not regular with sex and because they *"are very active.. they still have a lot of energy.. they are still starting to see sex"* (Interview with public health stakeholder).
- **People who frequent the shebeens, taverns, and prostitutes** (n=1) because they are involved in risky behavior.
- **Women who are sexually active, especially those in relationships where they have no say about sex** (n=1) because "*some of them are forced, some of them have no say in the whole set-up and then to be able to protect themselves will be fantastic*" (Interview with public health stakeholder).
- **Black women** (n=1) because *"to be taking medication for prevention everyday is not practical, for me the irregular taking sounds reasonable than everyday taking. We do not want to pump people with medication when they are not sick. We don't how how it affect them long term. This is for HIV prevention and we try it as prevention so we don't know side effects they will get"* (Interview with public health stakeholder).
- **People with partners who are away** (n=1) because *"people can take pills when their partners come in town"* (Interview with public health stakeholder).

3.3.5 Number of people to include in pilot programs

We asked public health stakeholders to provide what they thought was a reasonable number of people to include in a pilot HIV prevention pill program in Pretoria for a hypothetical period of two years. Responses included: 1%, 7%, or 35% of the population; as many as possible (thousands); and whatever is recommended by statisticians (n=2). When asked what would be a reasonable target number for Pretoria after five years, respondents replied: 50%; plus or minus 1.3 thousand people; double it from 7 to 15%; depends on budget and cost of pills; *"maybe to five thousands, maybe to ten thousands.. about how many, I don't know. But we should have a great number*"; and 4000 people ("if you have 5 years you need to build it up start with 800 from first year and add 800 every year").

3.3.6 Recruitment of Target Populations to a Program

We asked civil society leaders for their recommendations on how to recruit different kinds of people to take the daily HIV prevention pill. They made the following recommendations for each group:

Everybody, people in general, and sexually active people:

- Community education including counseling
- Door-to-door
- One-on-one
- In groups of no more than 10 people
- Peer recruiters
- NGOs should recruit people
- Workshops
- Clinics
- Schools (high schools and tertiary)
- Hospitals
- Churches
- Media
- Provide support including contact information
- Go out to the community and talk to people
- Use bartenders to talk to people
- Have doctors and nurses talk to people

People residing in far west or east and Soshanguve central:

- Door-to-door
- Pamphlets
- Radio announcements on Soshanguve Community Radio

Sexually active youth:

- Meet with and inform those groups and individuals working with youth and have them spread information to youth.

Married women:

- Media
- Churches
- Workplaces
- Hold forums
- Involve unmarried men and women

Married couples:

- Churches
- Homes
- Pamphlets
- Door-to-door

Single women:

- Churches
- Clinics
- Hospitals
- The streets

Single men:

- Churches
- Clinics
- Taverns

Adult women:

- In the clinics *"every morning after they pray before they open their sessions, they should give people health talks about that.. and one by one the message will go from one person to the other."* (PrePRCS13)

Women 14-20/35:

- Youth forum, groups
- Schools
- Public meetings for those 22 years and older

Women 40-60:

- Public meetings
- Councilors

Women who drink (21-35)

- Social clubs

Sex workers:

- Go to the streets where they work and tell them about the pill and they will tell others.
- Media
- Volunteers from sex workers
- Flyers

Truck drivers:

- Go to their parking bays and unions

Taxi drivers:

- Go to taxi ranks
- Go to taxi offices and get liaison to talk to drivers about program

Men 18-25/35:

- Streets
- Taverns
- Make appointment with school principal
- Post flyers on street corners, in shops, and at car washes

Men 40-60:

- Flyers
- Loudspeaker
- Attend community activities

Students:

- Play popular music on speakers
- Get highly skilled people who know how to talk to them
- Have people who have tried the drug with success become recruiters because *"you need to speak from experience in order to reach out to the people."* (Interview with civil society leader)

Farm workers:

- Go to them and address them
- Menial workers
- Media, including newspapers and radio
- Churches, take messages to the priest

3.3.7 Target populations' ability to fulfill program requirements

We described the potential requirements of a future PrEP program to civil society leaders to learn their opinions about which populations might be able to fulfill those requirements. These potential requirements were:

- Take a pill at about the same time every day
- Refill their pill supply regularly
- Get regular HIV tests
- Give blood samples regularly so that providers can monitor the effects of the pill on their organs
- Receive regular counseling to help them take the pill every day
- Receive counseling about how to reduce risk of HIV infection through safer sex behaviors
- Pregnancy tests may also be required

Civil society leaders mentioned a variety of groups whom they believed would be able to fulfill the program requirements:

- **Youth** because they are at risk, like testing new things, and will want to try the pill, with those who already take the contraceptive pill described as more likely to take it.
- **Single women** because they will not have the problem of disclosing taking the pill to their partners, and they do not have to seek permission from anyone.
- **Women in general**. One respondent said, *"We [female adults] are the heads now in the families, you look at what if I die? What about my children? So, I have to live for my children. So, even when you go to collect treatment, you go collect it knowing that you are not doing this for yourself only. You are doing it for your family, for a community, for everyone"* (Interview with civil society leader).
- **Female sex workers** because they are more vulnerable to HIV and if they are worried about their health or status they will make time for the program.
- **Married women** *"who feel they are at risk and cannot do much about the situation, so to them it can be handy and they would more likely be involved"* (Interview with civil society leader). Another respondent said regarding married women, *"because if her partner is unfaithful, hoo, ja, even the married ones they will be trying it"* (Interview with civil society leader).
- **Married couples including newlyweds** because they will be able to get information about the pill together.
- **Students** because it will be easy for them to understand.
- **Young girls** because they can do it if they understand their status and care about life, and *"since they like doing family planning, prevention of children, they can do prevention of HIV"* (Interview with civil society leader). They are also at risk because they date sugar daddies.
- **Elderly women** and grandmothers because *"if you explain to them the importance they will agree freely"* (Interview with civil society leader).

Other groups mentioned were **dedicated individuals who have been given counseling, HIV negative people, single males, taxi drivers, those who are sexually active, those who are falling in love for the first time,** and **truck drivers.**

We also asked civil society leaders which groups of people would not be able to fulfill the program requirements and why. They named the following groups:

- **Youth/young people** because *"they can be very much carefree, so they can be also not see the importance of taking the pill every day"* (Interview with civil society leader), and *"it's possible for them to undermine to take the treatment because to them everything is fun.. they don't think of consequences"* (Interview with civil society leader). Regarding teenage boys, one respondent said they do not tend to visit doctors, unlike girls who visit doctors for menstrual pains.
- **Married people** because *"they will have to get permission at some stage from their partners who might not give them consent or agree that they should participate"* (Interview with civil society leader) and *"they think they are always safe"* (Interview with civil society leader). One respondent singled out young couples

because the woman's husband will accuse her of cheating and not allow her to participate. Referring to youth and married people, one respondent said that people will not feel motivated to take the pill if there is nothing wrong with them. Another respondent said, *"If the female goes alone it is going to be a problem and if a male goes alone there is going to be a problem but if they agree there will be no problem because they will be saving each other you see"* (Interview with civil society leader).

- **Men** because they drop out of lengthy pill-taking programs like TB medication. Once they start feeling better they stop taking medication. For a PrEP program, they will not even be sick so they will not have motivation to take the pill. Men are naturally forgetful and ignorant when it comes to taking medication. Another respondent said that men will lose patience and grow tired: *"I have to carry a bag of pills everyday, I can't do this anymore."*
- **Substance abusers** because they are drunk and cannot keep track of what is going on in their lives and may fail to keep appointments and take the pill on a daily basis.
- **Pregnant women** because *"we are not sure of the risk it will pose on the child"* (Interview with civil society leader).
- **Married women** because *"they will have to get permission at some stage from their partners who might not give them consent or agree that they should participate"* (Interview with civil society leader).
- **Party goers** because *"fun is number one on their list and everything comes after the rest"* (Interview with civil society leader).
- **People who do not take contraceptive pills and small children** because they won't be able to remember to take the pill.
- **Young women** because *"they think they are independent"* (Interview with civil society leader).
- **The elderly** because *"most of them are illiterate so they do not know such information"* (Interview with civil society leader).

Other groups were described as not being able to fulfill the program requirements because they do not believe they are at risk, including **professionals** who do not think they are at higher risk of HIV infection due to being more educated, and **widows** because they do not believe they are at risk since they are not very sexually active. **Taxi drivers** were also mentioned as unable to fulfill the program requirements.

We also asked the civil society leaders to name one or two kinds of people at risk of HIV who may most easily and willingly be able to do each of the individual program requirements. We asked which requirements would be the most challenging and why.

Respondents said that <u>all requirements</u> would be easy for female adults, married couples, married women, young girls dating sugar daddies, newlyweds if they have good communication, single men and women, and women.

<u>Taking a pill at about the same time every day</u> was described as easy for female teenagers, grandmothers, HIV negative people, men, sexually active people, single men, single women, young couples, and youth, in addition to the groups named as able to do all requirements easily. Taking the pill every day was reported as challenging for:

- **Female teenagers** because they are often away from home, but they could be educated about the use of cell phones as reminders and about keeping medications in their pockets.
- **Female sex workers** because they might have a client during that time. They could be helped by making sure *"they have a helper to assist in reminding about the pill"* (Interview with civil society leader) and by provision of education on adherence aids and why it is important to take the pill.
- **People who are HIV negative** because they are fearful of side effects.
- **Married couples** if they do not agree about participating in the program, so couples should communicate and be open about their participation.
- **Married women** because they are too busy to remember to take the pill. They could be helped by partner support.
- **Men** because they may believe that prevention is something for women. *"To help them, men should be taught to discuss health matters and not just concentrate on politics and cars. Men should learn to care for their health and be involved in health matters. They need to be educated"* (Interview with civil society leader).
- **Newlyweds** because partners might not understand, so couples should discuss their participation openly and participate together.
- **Sexually active people** because they have no time and are carefree, but this could be addressed by giving them information.
- **Single women** because they may not be not fully committed to the program.
- **Taxi drivers and truck drivers** because they are always on the road and have no time to think about pills or they may be busy with a client. They must make sure they have a helper to remind them to take the pill and must be provided with adherence aids and education on why it is important to take the pill.
- **Women 14-35**, who will need to be encouraged and motivated via workshops.
- **Youth** because they are not responsible enough to take the pill daily and will not have the tablet with him/her when away from home. They must be educated and reminded to take the tablets with them when they leave their homes.

<u>Refilling their pill supply regularly</u> at a provider was cited as easy for female adults, female teenagers, married couples, married women, young girls dating sugar daddies, men, newlyweds, single women, and women 40-60, in addition to the groups named as able to do all requirements easily. Some groups were described as likely to find refilling pills as difficult:

- **Married couples** may find it challenging because refilling pills has to be done without suspicion from others.

- **Men** need to be able to pick up pills discreetly and/or when they pick up contraceptives (condoms).
- **Men (40-60)** may not refill their pills if travel is required, which could be addressed through mobile pill dispensing.
- **Women 14-35** will need to be encouraged and motivated via workshops.
- **Youth** may have difficulty refilling the pills at a clinic each month because it may incite suspicion, and they would therefore need to be convinced to take the pill.

Getting regular HIV tests was perceived to be difficult for most groups, but easy for female teenagers, female sex workers, taxi and truck drivers, and women 14-35, in addition to the groups named as able to do all requirements easily. Groups described as likely to find this challenging were the following:

- **Female sex workers** may not want to know their status or may be unsure of their status and will thus require education on HIV testing.
- **Grandmothers** may fear that they have HIV and will not want to get tested.
- **Married couples** get anxious about HIV testing and would need to be convinced.
- **Men** may find HIV testing challenging because *"something in men that makes them not want to do it"* (Interview with civil society leader).
- **Men 14-35** may be scared of testing and should be encouraged and motivated via workshops.
- **Old widowers** are angry, stubborn, and moody and should be tested for HIV individually in their homes.
- **Sexually active younger women** may be promiscuous and not know the behaviors of their partners. They must be continuously encouraged to get tested and encouraged to test together with their partners.
- We must emphasize to **single women** the importance of knowing their status.
- **Substance abusers** would have difficulty taking HIV tests over time and should participate for a short period of time.
- **Taxi drivers** may be unsure of their status and would need education.
- **Women 14-35** would need to be encouraged and motivated.
- **Young couples** would find HIV testing challenging because they do not test alone or frequently.
- **Youth** would find regular HIV testing challenging because it is difficult to get them to test for HIV even once a year, and tests make them anxious. A group workshop on HIV testing may help them.

Giving blood samples regularly so that providers can monitor the effects of the pill on their organs was described as easy for female teenagers, female sex workers, men, substance abusers, taxi drivers, and youth, in addition to the groups named as able to do all requirements easily. It was described as difficult for men because *"being seen at the clinic raises concerns"* (Interview with civil society leader), so clinic visits should be made private.

Receiving regular counseling to help them take the pill every day and learn how to reduce their risk through safer sex behaviors would be easy for married couples, men, and youth, in addition to the groups named as able to do all requirements easily. Coming to the clinic for the counseling may be difficult for men 14-35.

Pregnancy testing was described as easy for female teenagers, female sex workers, and sexually active younger women, in addition to the groups named as able to do all requirements easily, and was not cited as difficult for any group.

3.3.8 Length of program participation for target populations

When asked whether potential target populations would be able to stay in an HIV prevention pill program for an extended period of time, civil society leaders responded yes for nearly all groups. When asked what would make it difficult for those same groups, reasons included:

- For single women if they get married.
- Unmarried women and students if they lack financial, emotional, and spiritual support.
- Men if they have no encouragement or if they have peer pressure from other men.
- Taxi drivers if they are given non-cash rewards for adherence and if their employers do not grant them time to participate.
- Newlyweds if they want to have children.
- Substance abusers if they do not have a set time for taking their pills and due to a lack of knowledge.
- 18-35 year olds if they do not have time, but they may stay in the program if they know the time frame in advance.
- Grandmothers if they have no babies to take care of.
- Sexually active youth if they have no money for transport and are busy with school.
- Married women if they become pregnant.
- Sex workers if they feel forced without proper explanation; distance; relocation; if they get married, or if they get a decent job.
- Truck drivers due to relocation.
- Men 18-25 because they may shift their life focus to other issues like school or a new job.
- Married couples if they have a child.
- Youth if they worry about what the pills are doing in their body.
- Sexually active women if they get married and have children.
- Young girls if they are distracted by sugar daddies who can provide them with material gain.
- Women 21-35 due to lack of commitment.
- Men 40-60 due to alcohol consumption.

Some groups were described as unable to stay in a pill program for an extended period, including:

- **Sexually active and HIV negative people** because they will get tired and quit because nothing is forcing them, and they may quit because of side effects.
- **Thirteen to 16-year olds** if it is outside the school premises and because they won't be responsible enough to adhere to taking the pill.
- **Widows** because they are too stubborn, may lose interest easily, and are easily irritated.
- **Men 14-35** because they believe these things are for women.
- **Female teens** were said to be "50/50" because teens who repeatedly test HIV negative will just relax and not want to continue.

3.4 Cultural beliefs and factors

3.4.1 General cultural beliefs and factors for fulfilling program requirements

Civil society leaders were asked what cultural beliefs or practices may make it difficult for people to fulfill the program requirements. The most common response was the belief in traditional medicine versus western medicine (n=4). Some people may use home remedies and go to the Inyanga (traditional healer). One respondent said that this would be a problem with older people rather than younger people. Another respondent said that people might use Truvada and traditional medicine at the same time.

Others said cited the cultural norm that women must get permission from men when making decisions (n=3) as prohibitive to their participation in a PrEP program.

"I think for women there is this challenge that well men are the head of the family so in most cases they cannot take decisions even if it's in their bodies without consulting their husbands you know for that fact men may just say you are not going to do that." (Interview with civil society leader)

"And there are other cultures where a woman takes orders from the man and she must get permission first from her husband, so they won't come and take the pill, even if you rollout the pill they won't come because they believe that their husband must give permission first." (Interview with civil society leader)

"Our culture has an impact because; let me talk about women because it is like we are too much into them. You see when I am staying with a woman in my house and she is in this program voluntarily and I didn't marry her. When she comes home because we are cohabitating you know how we blacks are I will tell her that her rights ends outside the gate inside the house runs my rules, so the African beliefs which we think they are there but according to me they are not there they are the ones which are going to be obstacles for what we want to achieve." (Interview with civil society leader)

Two respondents said that sex before marriage is prohibited (n=2), and that if unmarried people are taking the pill this could lead to problems.

"According to our culture, sex before marriage is prohibited neh? And then our children do that thing by stealing. So, when they have to, to undergo such kind of a program, when she thinks that our culture does not allow us so that we.. isn't it that now for her to undergo this program is for her to be safe, to, to, to be sexual active but be safe. So, once she thinks about the culture, it's going to be difficult that what are they going to say when they hear that I am taking this? This program. And then I am not allowed to have sex at this stage." (Interview with civil society leader)

Two respondents said that men having to show their manhood by making babies would be prohibitive because they do not want to wear condoms. Other responses were that religious beliefs prohibit the use of medications and blood draws (n=2) and some people deny that HIV exists (n=2).

The following were cited once each as cultural factors that may adversely affect people's ability to participate in a PrEP program: some people do not believe in condom use, polygamy, newly married couples will want children, and uncircumcised men cannot undress in front of doctors.

3.4.2 Opinions on pill-taking

We asked civil society leaders how people view taking pills in general. Over half of the respondents (n=8) said that taking pills is not easy. This is because there are too many restrictions associated with pill-taking such as no alcohol; they are difficult to swallow, annoying, have an unpleasant smell, and cause side effects; and some religions prohibit their use because it indicates that you lack faith in God to restore health.

"E!! [Expression of difficulty] people, when coming to taking pills, it's a job to take a pill." (Interview with civil society leader)

Four respondents said that people do not mind taking pills if they know their importance.

Interviewer: *"Do you think how people view taking pills daily could influence how the person taking pills, take their pills?"*

Respondent: *"That will depend on the commitment of the person taking pills. It will not affect them if they have a back bone."* (Interview with civil society leader)

Two respondents said that people stop taking pills when they feel better, usually before they have finished the pills.

"In general people are... it's not easy to take a pill everyday to be honest it's not easy, even when you're sick you will stop before finishing treatment, you will feel okay and you just stop taking the tablets, because it's annoying to take tablets every day, so imagine if I had to take the tablets for six months." (Interview with civil society leader)

Two others said that people take pills because they are sick and want to feel better. Other responses mentioned one time each included that a small segment of the population does not like taking pills based on misinformation; daily pill takers have HIV; most people do not like taking pills; most people see the benefit of taking pills for ailments or diseases;

people only take pills when they are obligated to; people like taking pills; some religions are becoming more accepting of modern medicine; and sometimes people experience pill fatigue.

When asked their opinions on how people feel about taking pills when a person is not sick, a third of the 15 respondents said that if you are not sick you cannot or will not take pills.

"I don't think they would, it would be something that people really don't want to do on a daily basis. I don't think I would want to take pills if I don't have a headache why would I want to take a Grandma [Headache powder] you understand. And, at, the end of the day it's that knowledge of pills are taken if you are sick if you are not sick you, you shouldn't be taking pills. You know like they usually say, doctors and grandmothers, if you take two of the pills and you are not sick, it affects your liver and it affects all those things. So nobody wants to take that because everybody wants to live for a longer time." (Interview with civil society leader)

"You can't drink pills when you are not sick [Participant smiling when saying this]" (Interview with civil society leader)

Another third said that people who are not sick do not mind taking pills if they know the benefits.

Three people said that taking pills when not sick is normal, as with pills for pregnancy prevention. One of these respondents noted that people who are motivated will want to take it. The same way people accepted and take pregnancy prevention pills, they will accept and take HIV prevention pills. She said those who have had experiences of friends or family members die due to HIV will want to prevent infection even more because of firsthand experience.

Two respondents said that it depends on how well people understand the reasons for taking it. One respondent mentioned that it is difficult because there is nothing that compels you to keep taking the pills. Another said that it is better not to take them because of concerns about side effects and addiction, and yet another said that people will drink pills for prevention.

"Even this one [Truvada], people will talk and spread rumours and discourages it but it comes from someone's bottom of their heart that this thing is safe they will take it. Not the next person, myself.[..] And I will also be looking at my behavior, the weak point that these old rich men with money come to me I say yes, then it is good for me." (Interview with civil society leader)

Interviewer: *"Okay, so what do you think can help them to stay with the mind set of waiting to take pills?*
Respondent: *"What can sustain their adherence is their behavior. If you know yourself, you know that you are not doing anything you will not take it but if you do things you will take it."* (Interview with civil society leader)

3.4.3 General opinions about healthcare facilities

Civil society leaders were asked how people view going to healthcare facilities. A third of respondents said that people, especially women, like going to healthcare facilities. Some mentioned challenges with personnel, including that they are rude, stigmatizing, unhelpful, provide poor medical advice, and neglect patients. Three people noted that people go to these facilities because they are sick, whereas three others mentioned fearing stigma of having HIV when they go to health facilities. Two people pointed out the challenges with long queues. Other opinions were that everyone minds their own business when they go to health facilities, and people go to health facilities because they want to see if they are okay.

3.4.4 General opinions about giving blood samples

When asked their opinions on how people feel about giving blood samples, several civil society leaders said people do not like it because they fear the test results (n=6). Others said that most people have no problems (n=5), and that they do it because it helps others (n=2) and because they like getting their health checked (n=2). One person said that it is not a problem if you are prepared to know your status. Several reasons were given for why people may not like it: you are never given results, mistreatment by staff, difficult for those who are infected, people do not want to donate blood to blood banks, and religion prohibits some from giving blood.

3.4.5 Opinions about the requirement to use condoms while taking oral PrEP

We asked civil society leaders their thoughts about the requirement that people must use condoms while taking the daily HIV prevention pill in order to ensure the highest protection against HIV infection, in the event that the pill is not 100% effective. Five respondents said that it would be best to adhere to this requirement because the pill is not 100% effective. Another five said that condoms are still needed to prevent STIs and pregnancy.

"I think that would be good because doesn't prevent pregnancy, it only prevents HIV. So, the condom one will still be needed." (Interview with civil society leader)

Additional respondents (n=4) noted that condoms provided added protection against HIV infection, with one person noting that a combination of prevention methods ensures the highest protection:

"But the pill is not 100% maybe it is 50% or 45% so it is better to use condom to be 100%. It is the pill, the condom and one partner and you will be 100% safe." (Interview with civil society leader)

Two people felt that it was important for people to continue using condoms. Less optimistic reactions were that condoms are not themselves 100% safe (n=1) and people will not agree to this requirement (n=1).

3.5 Communication with the Community about the Daily HIV Prevention Pill

3.5.1 Introducing the daily HIV prevention pill to the community

We told civil society leaders that if research studies show that the daily HIV prevention pill reduces the changes of HIV infection, this news would need to be announced to the community. We would need to make sure that people understand how the daily HIV prevention pill should be used. We then asked for respondents' recommendations for how to announce a daily HIV prevention pill to the general community.

Media:

Most respondents recommended announcing that the pill works to reduce the chance of HIV infection via newspapers (n=10) including those published at supermarkets, radio (n=10), and television (n=8). Others suggested using the media in general (n=5), and posters (n=2), pamphlets (n=1), magazines (n=1), and flyers (n=1). One individual recommended addressing people in their communities first and using the media later.

"I think before you go to the media, it's better to address the community and the media will serve as second hand, do you understand what I'm trying to say? Because if you go to the media it will look like you are advertising and people do not take every advertised thing seriously, because they think advertisers want money. [..] I'm recommending that people should be addressed first in their communities. [..] Churches, gatherings." (Interview with civil society leader)

Locations:

Locations to announce that the pill works included clinics (n=4), church gatherings (n=3), schools (n=3), social gatherings (n=2), hospitals (n=2), political gatherings (n=1), and youth groups (n=1).

Other strategies:

Other strategies included having one-on-one interventions; taking advantage of community mobilization programs; going through HIV organizations; holding public meetings, forums, workshops, and seminars; and holding stakeholder meetings (n=1).

"We can use groups that deal with issues of HIV because most of the time they spend in clinics with patients because they have all the people who are HIV positive and those who are HIV negative. But one thing we can do is to use public meetings that are being used by us counselors because in these meetings we do not say that just because you are not dealing with HIV issues we do not want you. We have business people attending our meetings, even stakeholders meetings and churches can assist us." (Interview with civil society leader)

Spokespeople:

Peer educators and community leaders/council members were suggested as spokespeople to tell people about the daily HIV prevention pill (n=2).

"Okay, you'll have to make awareness campaigns through the media, news paper, television, have peer educators those who will go out and tell people about this pill." (Interview with civil society leader)

Another suggestion was to form a team of people who will go around and give health talks in clinics, hospitals, and schools, including one person who is an example of a user of the pill who has remained HIV negative (n=1).

"[..] and in that team there must at least be one person who has been exposed in that pill and then, she must be negative after she has used it and she will be able to convince them that it has worked with her and she is still negative." (Interview with civil society leader)

3.5.2 Using media to announce that the pill works

When civil society leaders were asked how the media could be used to tell people about the daily HIV prevention pill, they provided a wide array of responses.

Respondents widely recommended advertising the daily HIV prevention pill on television, the radio, and in newspapers, in all languages.

Television:

The following television stations were recommended by respondents for information or programs about the daily HIV prevention pill:

- E-TV
- SABC 1
- SABC 2
- SABC 3
- All stations

The most commonly recommended television programs to incorporate information about the daily HIV prevention pill were:

- Generations
- Ads aired during soapies
- Isindingo
- Rhythm City
- Soul City
- Scandal

Other programs also mentioned include:

- 3Talk
- 7 de LAAN
- Backstage
- Beat It

- The Bold and the Beautiful
- Bonita's Health Talk/ Doctor Ramathesela
- House Call
- Jam Alley
- Leihlo la Setshaba
- The Need
- Programs dealing with health issues
- SABC youth program @1pm
- Special Assignment
- Live at 7 (on SABC)

For television announcements, most people recommended an evening time slot from 6-10pm, when soapies are aired. A couple of people recommended midday (11am-1pm) and Saturday mornings. Other suggestions were 3:30-8pm, before and after soccer matches (Saturdays at 3pm, Tuesdays and Wednesdays at 9pm), during cartoons, and mornings at 9am (n=1).

"I think SABC 1, eehm most people are watching SABC one especially if, the, the, the, the pill can be made as an I don't know how but as an advert in between Generations time [SNK: Generations is a soapies played on SABC one at 20:00pm everyday] because everybody likes Generations and eehm e-tv is it eeh e-tv between Isidingo time, the Bold and the Beautiful [SNK: Those are soapies played on e-tv] in between those soapies we should can a slot to advertise, eehm where it can be put in for maybe about 2-3 minutes so that people can get access because most people are watching TV around those times." (Interview with civil society leader)

Newspapers:

Advertisements and informational articles were recommended for newspapers. The following publications were recommended as affordable and widely read:

- Daily Sun newspaper (a National news paper mostly read in the townships)
- Sosh times (Soshanguve newspaper)
- Sowetan newspaper
- City Press newspaper (a National newspaper mostly read by Black Africans)
- Sunday Times
- Move magazine (a magazine that speaks mostly about recent topics of celebrities)
- Newsletters at supermarkets
- Radio

Many respondents felt that advertising the daily HIV prevention pill on the radio would reach a wide audience. One person noted that it would also allow those who are illiterate to learn about the daily HIV prevention pill. The following radio stations were cited as important to include:

- Soshanguve FM
- Metro FM
- Motsweding
- TUT FM
- Jacaranda FM
- Ikwekwezi (also mentioned as Ukwekwezi and Mkwekwezi)
- 702 Talk Radio
- Thobela
- Ukhozi
- SA FM
- Tsonga
- Tswana
- Sepedi
- YFM
- Lesedi
- Lethlabile
- All stations

The best radio programs to provide information about the pill were cited as:

- Programs related to health
- ON-AIR with Criselda Kananda (on Metro)
- Programs related to current affairs
- This and That (on Motsweding)
- Ngaka nkalafe (on Thobela)
- Programs that feature radio dramas

Most respondents felt that the best times for public health announcements to air on the radio were evenings (5-10pm) and mornings (5-9am). A few people recommended afternoons 3-6pm, midday, Saturday mornings, during the day for the working class, and before or after soapies.

Other media:

Other media that civil society leaders suggested included flyers to be distributed on corners for awareness campaigns (n=1), pamphlets (n=1), magazines (n=1), and electronic and "manual" forms of media (n=1).

3.5.3 Communication strategies for telling the community that the daily HIV prevention pill is effective via the media

Several communication strategies were recommended to announce the pill's effectiveness through the media:

Television:

- "Sensationalize" the pill on television advertisements (n=1).

  "I think in the very same ways that sell other products the Viagra's, your OMOs in the very same way I mean it should be sensationalized that people should come running to grab it." (Interview with civil society leader)

- Use celebrities as spokespeople in television advertisements targeting young people (n=1).

  "Yes, let's say you using the TV it should be advertised. [..] Maybe targeting young people you can use your young celebrities using it telling the benefit." (Interview with civil society leader)

- Air advertisements before, during, and after popular programs (n=12).

  "That's why I mentioned adverts, you can make use of them and soapies and then have logos about the tablet on screen so that people can know about this." (Interview with civil society leader)

- Incorporate the daily HIV prevention pill into storylines or topics of the programs themselves (n=7).

  "[S]o maybe if a program within them maybe the script writer can include it in your soapies like Backstage you know but then the challenge with that is that people cannot deduce that this is fiction this is factual so you need a program that is factual like your Special assignment your morning life." (Interview with civil society leader)

  "But now if the same story line was to be brought up that this is the treatment that, like for example aahm Soul City [SNK: Is a drama on SABC 1 that speaks of HIV] you know SOUL CITY is a HIV related Program where they talk about HIV, not HIV [SNK: participant was not sure of what the program is all about]. Soul City is one of the best programs that should be used." (Interview with civil society leader)

- Create a new program with PrEP as the topic (n=1).

  "Hm, which one can I say .No you must create your own program, and give it its own topic." (Interview with civil society leader)

- Attract young people by including music that youth like in advertisements (n=1).

  "Ja.. you first.. I think you first introduce it in a way of an advert. Then, in a way of an advert we put in an advert that will attract the young people. Isn't it that the youth, there are other adverts which when you look at it you can see that this is an advert for the youth. Like adverts to, adverts which advertise things that are for youth.. of pads and things like those. It's.. you know it's not everyone who is interested to watch that advert. I am just making an example. Ja.. it's.. in an advert of that excel.. of that sort, that speaks about the youth doing.. maybe it can have a sort of music, do you understand? A kind of a song, which is loved by young people, so, in that song. Even when they advertise that song must be played. When they look, they will see that it has this thing." (Interview with civil society leader)

Newspapers:

- Advertise in print media that people can afford (n=1).
- Newspaper advertisements or articles could provide statistics about the number of new infections since the pill was introduced (n=1).
- Use all languages (n=1).
- Other general strategies with media included:
- Using dramas in television or radio (n=1)
- Explaining the history of the research process about the pill to the community (n=3).

  "You have to first tell them about the research you did, that you did phase 1, phase 2, phase 3 and now it has passed and now it is time for roll out." (Interview with civil society leader)

  "You just give them the whole information about the.. study and the feedback that up to this far, this it works." (Interview with civil society leader)

- Featuring spokespeople that were part of the initial research so they can tell about their experiences (n=2)
- Using program participants as spokespeople in the media to tell people about the pill (n=3).

  "In the media you can use people who are already in the program to tell people that she was in this program for such a time and then she can tell people about the pill." (Interview with civil society leader)

  "Mm.. the media could be used maybe by someone who has been in the program and maybe giving a piece of note. [..] About the, the... the.. the.. pill, the program that she has been on or he has been on. And then, and then how it worked ja.. And then that's how the news should be spread. Many people will understand through media easier." (Interview with civil society leader)

  "Remember that before people engage themselves in something they would want to see the proof first or something. And nobody is going to start up and say there is this new drug I am going to try it out. Everybody is scared because if they say, for example I was reading there where it say eehm the person must be, the person must be HIV negative and so forth. People are very much stereotyped, one will say if I get myself involved what happens I'm negative now what if the drug, I trust myself, I trust the pill or the drug so much that it actually fails and I become positive. It will be, I mean it will be in a sense that people want the proof you understand. Not everybody I, I whether you explain to them that you cannot take in everybody but most people are going to back down until they know for sure that this person is speaking from experience that this is what happened to her you may hear that she took the drug and so forth." (Interview with civil society leader)

- Explaining clearly that the pills are not 100% effective in preventing HIV infection (n=1)

  "Tell them that the pill is not 100% it is not working 100%." (Interview with civil society leader)

3.5.4 Civil society leaders' role in communication

We asked civil society leaders what role people in similar positions (e.g., religious leaders, ward councilors, and government) could play in communicating about the daily HIV prevention pill with the community.

- Government and the ministries of Health were said to be able to produce leaflets and flyers and have platforms for communicating to the masses.
- A counselor and coordinator said she/he could help to deliver information.
- An HIV educator said he/she could continue work on awareness on a daily basis in one-on-one and group sessions.
- A director of youth development programs said her role could be to organize her peer recruiters to give education about the daily HIV prevention pill.
- The ANC Women's League could spread information about Setshaba research center.
- A pastor could invite researchers to explain the pill to elders, youth, and everyone in the church, and could speak to people he visits in their homes.
- A nurse could offer health talks.
- The teachers' union could tell people about the pill, including its advantages and disadvantages and why it is necessary to take the pill, and make sure the pill is rolled out to members.
- A pastor noted that he could talk to the married people, especially in situations where one member of the married couple attends church and another does not. However, he would not be able to introduce the pill to youth because he encourages youth to abstain.
- A peer educator said she could mentor others regarding the pill and to practice what she is preaching to set an example for others.
- A chairperson in the taxi association said he could encourage people to take the pills and follow them up with weekly meetings to see if they are still taking the pill. He said follow-up would be very useful to people.
- A tavern owner said he could put "posters there at the counter so that everyone who comes to buy see and read it and if interested you would like to know what's going on with the poster."
- An ART counselor said he/she would encourage those who are not HIV positive to follow the program.
- A ward councilor said that he/she could invite stakeholders who deal with these issues to meetings.
- A person on the sports council said that this organization serves as an umbrella body of other organizations so when they decide on the theme they would invite appropriate organizations and people from health and Love Life.

3.6 Limited Availability of the Pill

3.6.1 Community reactions about limited availability

We asked civil society leaders what reactions they would expect from the community if the daily HIV prevention pill had to be limited to certain target populations, versus making it available to everyone who may want it. The majority of respondents (n=10) stated that community reactions would be negative because everyone will want to be enrolled and be safe; people will be angry because they will think that everyone should have access; people will be mistrustful of a promise to enroll more people later; they will believe that those who are chosen are picked for unfair reasons; and they will feel excluded.

"They will react negatively because, when we look at our government, right? It's promise, promise, promise, promise so they will no longer trust you when you say you will come back to enroll the others." (Interview with civil society leader)

"I expect a lot of cry you know that everybody should have access to that. I expect the community to react like that." (Interview with civil society leader)

Others said that reactions were likely to be more positive (n=6). This was because they will accept that the program will expand to include everyone in the future; they will understand as long as they are given an explanation; they will be glad to know that the program is not being tested on them and that they will get access to a program sure to be working; and they will be happy to see something that will help those at risk.

Our people sometimes do understand that we are not going to help them all at the same time; there are those whom we are going to help and there are those whom we are not going to be able help. Like I said earlier on when they see it happening they will know it will come to them. (Interview with civil society leader)

Other reactions expected that were mentioned once each included skepticism about the pill until they are convinced with evidence; some will understand whereas others will not; and many people will not be interested anyway when they hear about the HIV testing requirement.

"[N]egative reaction.. people will chaw you if come and tell them that [meaning that people will kill you].. if people know they have to volunteer for [HIV] testing before they are put on that.. it will also assist in getting a smaller groups because most people don't like going for testing because of their life style, because of the risk they find themselves in." (Interview with civil society leader)

3.6.2 Strategies to address community concerns about limited availability of the pill

We asked civil society leaders to recommend strategies for addressing the community's concerns about limited availability of the pill. They responded with several suggestions, including:

- Providing community education (n=6), including in community halls, sports councils, public meetings, and workshops (n=4), in the media (e.g., newspapers and television advertisements) (n=2), during awareness talks (n=1), addressing small groups (n=1), and inviting people to a public meeting for discussion using television, newspapers, and loudspeakers (n=1).
- Providing people with background information and the history of the research (n=1).
- Providing all information about the pill (n=2).

  "And you should not hide anything and make it look good, tell them everything, and tell them the truth." (Interview with civil society leader)

  "It will be a bit difficult, because when you talk about prevention everybody wants to be the first one. But eeh I think having smaller groups of people addressing small groups of people and making them aware that it is voluntary [SNK: Birds singing] and giving them the rest of the information at telling them nothing else but the truth would help." (Interview with civil society leader)

- Making participants give reasons for why they want to be part of the pilot group (n=1).
- Explaining the rationale behind limited distribution and provide valid reasons (n=3).

  [E]ngage them and explaining exactly the rationale behind th at...will help. (Interview with civil society leader)

- Engaging with the community and have spokespeople prepared to address their concerns about wanting access to the pill (n=3).

  "[O]nce you say everybody cannot access you have to give valid reasons. And when you give reason they will also come up with they own reasons of wanting to participate, so you must have very strategic people to .. address those people." (Interview with civil society leader)

  "There must be re-assurance beforehand.. some might say 'we have money' because people are vulnerable out there they want to live, if they say they've got money you must be able to explain to them that money is not the issue." (Interview with civil society leader)

  "They will have to speak to the Department of Health and all other stakeholders and the Government that they ought to provide." (Interview with civil society leader)

- Providing the community with updates on the progress of the program (n=2).

  "[P]romise them to come back and give them the feedback about how are we now [the progress made with the program]." (Interview with civil society leader)

  "Give feedback to the community frequently to update them on progress of research [participant may have confused research with a future program] so that they are not violent." (Interview with civil society leader)

- Not deviating from key messages (n=1).

  "Just stick to delivering the message." (Interview with civil society leader)

- Do not turn away people who come for the pill, but do not publicly invite all people to come (n=1).

  "When a person comes, who has already appeared, saying here am I, and I am also having a problem. We cannot turn him back, we cannot turn him back. That person you can help him as well. As long as we do not put it in public that let them all come.. when many appear, then the supplier need to, need to help us cross that bridge." (Interview with civil society leader)

- Involve the suppliers (n=1).

3.6.3 Messages to explain limited availability

Civil society leaders were asked to describe how they would explain to the community that the new HIV prevention methods would not be available to everyone at the beginning. Messages they suggested involved explaining that:

- The program will start off small and include more people later in the next phase (n=7).

  Respondent: *"Because everybody will be interested in that pill, so everyone will be wanting it."*
  Interviewer: *"But what can we do to make them understand?"*
  Respondent: *"Unless you tell them that you will accommodate 50 then after another 50 maybe they will understand."* (Interview with civil society leader)

- The pill is being piloted with those who are more vulnerable (n=3).

  "Jaa.. [SE another way of saying yes] the concept of rolling out must be clearly understood that when you rollout something you kind use a snowballing approach that you start small and you will grow bigger so you will start with a group that you have seen that it is more vulnerable or needing the product more and with time you would move to the other groups so, I think if you have an understanding with people that indeed this is a group that is more vulnerable that need the product more then they will understand." (Interview with civil society leader)

- Not everyone can be involved due to limited resources (n=2).

  "I'll tell them that these resources are still scarce and later when the resources are enough then it can be given to everybody." (Interview with civil society leader)

- A limited number of people are needed for the program (n=1).
- There are rules and restrictions for participating in the program (n=1).

3.7 Partial Effectiveness

3.7.1 Strategies to explain partial effectiveness

We asked civil society leaders to describe how they would explain to the community that the daily HIV prevention pill is not 100% effective. Strategies included:

- Simply telling people that the pill is not 100% effective (n=7).

Interviewer: *"So how do we tell them it is not 100% effective?"*
Respondent: *"Just by telling them, only by telling them. As long as they listen, they will do what you say."* (Interview with civil society leader)

- Continuing to promote ABC methods (n=8).

You must teach them by telling them that, that pill is not 100% effective as you have already mentioned they mustn't have many boyfriends or girlfriends and they must use condoms. (Interview with civil society leader)

- Comparing Truvada to other prevention methods that are not 100% effective, such as condoms and pregnancy prevention methods (n=3).

I don't know how to answer that but usually we know that contraceptives are not 100% safe so you might as well tell them that this thing is not 100% safe. (Interview with civil society leader)

- Emphasizing the effectiveness verbally and on the pill packaging (n=1).

They must tell them about the information that is written on the packet, the must written it, it must be visible that this thing is not 100% so that she must see it everyday this thing, she must know about it. You will have told her with your mouth and written down. And she comes to collect her packet it must be written on the packet and then she will see it everyday. (Interview with civil society leader)

- Emphasize other disadvantages of having multiple partners, including STIs (n=2).

People who will be coming here, you tell them the disadvantages of sleeping around. That once you sleep around you have a better chance to contract HIV and STI so they will listen. (Interview with civil society leader)

- Disseminating information by the same channels used to communicate that condoms are not 100% effective (n=1).

The same way that they, they, the same way that people know or people found out that a condom is not 100% safe. It you know that a condom is not 100% safe and you go to a clinic and you get a pill, that the say it's for flu you know there is a possibility that is going to work or is not going to work. So I don't think that, that's the major thing you know, as long as we give out information about condoms, we give out information and somebody will tell you, but a condom has bust. You tell that you know a condom is not 100% safe is 99 you said is 99, 9% safe that 1% is the risk. And I'm saying that to people that some people are concerned about pregnancy rather than getting infected. That if the condom bust, the first thing they think of is the morning after pill. They don't think of that if there was a pill that they should take to prevent them from getting HIV infected. They don't think of that, the main thing they think of is I don't want to be pregnant, I'm not ready to be a father. So the same way that information is distributed about the condoms not being 100% safe, should also be the same way to distribute that information. (Interview with civil society leader)

We also asked public health stakeholders for their recommendations for communicating partial effectiveness to communities. Strategies included:

- Be honest and straightforward, and not give people false hopes (n=4).

  "We should call a spade a spade." (Interview with civil society leader)

- Provide education (n=2).

3.7.2 Messages to explain partial effectiveness

Civil society leaders suggested several messages, including:

- The pill is not 100% effective (n=7).
- Continue to use other HIV prevention methods including condoms, monogamy, and abstinence.

I am not sure but it looks like we have talked about it at the beginning; if we are going to do a rollout for this program people are not supposed to change their behaviors, If they were negative stay negative, If you were faithful to your partner remain being faithful because this pill is not a license that you must sleep around and another thing is it does not mean that when you were using condoms you must stop using them. That is the reason why before you start putting them in the program you must explain to them how they are supposed to behave. (Interview with civil society leader)

- The pill is not a "license" for risky behavior (n=2).
- The pill was created by humans, not God, and is therefore not 100% effective (n=1).

You can tell them that you know that if something was created by a human being it is not the same as natural things or created by God. [...] There is no way that something created by a human being can be 100%. Somewhere, somehow there will be mistakes. (Interview with civil society leader)

- You can still get other STIs [if you do not use a condom and/or have multiple partners] (n=2).

You must explain that STI, gonorrhea or whatever, whatever, if you give yourself to the whole world sexually, you will contract other sexual diseases and maybe there are other sexually transmitted diseases that we don't know. (Interview with civil society leader)

Messages that public health stakeholders suggested included:

- The pill is effective but not 100% (n=4).
- HIV mutates now and again, so it is difficult to get a prevention method that will be stable forever (n=1).
- If you become drunk, the effects of alcohol may lower the effectiveness of this pill (n=1).
- We are fighting this battle against HIV together (n=1).

  "I think if you tell a person the truth he/she becomes sharp other than when you hide. They will understand that at least somebody is meting them halfway to fight this battle, it is our battle and not the government or somebody's battle no, let's fight this battle together then she will comply." (Interview with civil society leader)

3.8 Behavioral Disinhibition/Risk Compensation

3.8.1 Strategies to address disinhibition

We asked civil society leaders to describe how they might help address the concern that people may increase their risk behaviors while taking a daily HIV prevention pill. They suggested several strategies. The majority of respondents (n=9) recommended some type of education, including behavior change workshops, health talks and motivational speaking for youth, training of trainers, education with patients in clinics, and bringing information into informal chats. One participant noted:

"As I said earlier that if a person has necessary information about the pill they will be in a knowhow, I don't think a person will go and have multiple sex partners." (Interview with civil society leader)

One person suggested support groups for those taking the pill. Five respondents recommended encouraging people to continue prevention behaviors (abstain, be faithful, condomise), one person recommended encouraging partner reduction, and two people said to encourage people to always use condoms.

We also asked public health stakeholders for their recommendations for discouraging people taking a daily HIV prevention pill from increasing the behaviors that put them at risk of HIV infection. Four respondents recommended education:

"Change is very difficult to embrace it is not easy but through our health education continuous and not getting tired they will get use to it and know." (Interview with public health stakeholder)

Two respondents said they did not know because *"it's very difficult to change a person's behavior"* (Interview with civil society leader). One respondent said to prevent participants from taking PrEP for too long because people tend to think that are secure and have false beliefs when they take medication for too long.

3.8.2 Messages to address disinhibition

Messages civil society leaders suggested included the following:

- Continue prevention behaviors (abstain, be faithful, condomise). (n=5)
- Use condoms. (n=2)
- Reduce your number of partners. (n=1)

  "Just tell them 'if you are on the pill you must have one partner only'.. end your sentence with 'only'. If the health workers talk about it and say 'only' they will take it." (Interview with civil society leader)

- Drinking that pill does not mean you are 100% protected from HIV. (n=2)

  "I will give them the information that drinking that pill does not mean you are 100% protected from HIV and must also be faithful. And the more you become exposed to many people the more you can be at risk." (Interview with civil society leader)

- Stop being irresponsible about your lives. (n=1)
- The pill is not 100% safe. (n=1)
- Your life goals are bigger than sex, sex work, and drug and alcohol abuse. (n=1)

Messages public health stakeholders suggested to address disinhibition included:

- Avoid increasing your risk behaviors. (n=1)
- Prevention methods are not 100% accurate in preventing HIV. (n=1)
- HIV mutates every now and again, so it is difficult to get a prevention method that will be stable forever. (n=1)

3.9 Promoting Risk-reduction Behaviors for Pill Users

3.9.1 Condom Adherence

3.9.1.1 Condom Adherence Strategies

We asked civil society leaders how to encourage people to continue using condoms while taking a daily pill for HIV prevention. Most respondents provided examples of messages to communicate, but two respondents suggested the strategy of providing access to pills and condoms at the same time.

"Give them both the condom and the pill so that they can use both." (Interview with civil society leader)

"They must both be available for them when they come, she must not find one of them not available." (Interview with civil society leader)

One respondent suggested education as an important strategy:

"They must forget what other people are saying. We tend not to use condoms because of what we hear on the streets 'You are not a man if you use condoms, it must be skin to skin" and people take that and after two days they contract HIV. So educate these people." (Interview with civil society leader)

Another respondent noted that it will be difficult to convince people to use the pill and condoms at the same time:

"Ja..that one is going to be a problem because one will say I'd rather use condoms if this thing is not 100% [..] Why should I in the first place, why should I use it when I still have to use condoms. So, if they come as two, one will prefer to use condoms if it's got.." (Interview with civil society leader)

The person went on to say that it may not make sense to encourage people to use the pill if it is not 100% and they also have to use condoms:

"Ja.. myself as a person, it gives me a problem that firstly why would I encourage it when I am not sure that it is 100%. That can be a problem. So I don't have any other means of encouraging a person that go for this. If it really, if the, the, the outcome will tell us that no, the pill is not 100%, then in the first place, I don't see why, why it, it will only give us a problem. It will be that it just reduces the chance of being infected, but it's not 100%. If it is not 100%, I as a person, it is going to give me problems." (Interview with civil society leader)

3.9.1.2 Condom Adherence Messages

Messages the civil society leaders suggested for encouraging condom adherence for pill users included:

- The pill is not 100% effective, so balance protection with a condom. (n=4)

  "They may find it useless but we have to encourage them that you see here, we are telling you that this thing works, but we cannot say it is 100%, balance it with this so that it at least work for you." (Interview with civil society leader)

  "Just the fact that it's not 100% safe. And the more the people know that the pill is not 100% safe the better." (Interview with civil society leader)

  "We must tell them about the pills and about condoms and the high risk of those pills." (Interview with civil society leader)

- Using condoms together with the pill will insure that your risk of being infected is low. (n=1)
- Continue to use condoms in order to achieve the most benefits from the pill. (n=1)

  "I would say 'If you want to be safe continue using condoms for this pill to be effective." (Interview with civil society leader)

- Continue to use condoms even though there is this other prevention method. (n=2)
- Use condoms to prevent other STIs. (n=1)

  "Tell them that, if you are taking this pill you also have to use a condom because we are preventing other sexually transmitted infections." (Interview with civil society leader)

- Use the pill to protect you from HIV infection and condoms to prevent pregnancy. (n=1)

3.9.2 Limiting the number of sex partners

3.9.2.1 Strategies to encourage limiting the number of sex partners

We asked civil society leaders how to encourage people to limit their number of sex partners while taking a daily pill for HIV prevention. One strategy suggested was to use advertisements.

"Remember that advert of Scrutinize, I think I'll keep saying I'm single even now [SNK: inaudible] it will Scrutinize messages that they should be printed out they should be pasted where people are going to see them and they are going to get sick of seeing them. Because when people see something over and over they get sick of it even when they are alone and they are about to have sex or unprotected sex they are thinking Scrutinize that they should.., that's what I'm saying it should be implemented more and more and more." (Interview with civil society leader)

Another strategy was to highlight the MCP (multiple concurrent partners) messages part of the OneLove campaign.

"Okay presently we are having [SNK: car hooting] eehm, eehm this campaign called the one love campaign where we are ahm, ahm, ahm encouraging to .. you know "MCP" multiple concurrent partners to reduce the number of sex partners and to stick on one sexual partner that you have. So I think that the campaign is about one love and MCP and correct consistent condom use should still be encouraged. To ehm .. to do what? To assist people to reduce their sexual partners, be faithful, still the relevant message." (Interview with civil society leader)

A third strategy was to remind people of the importance of life using their children as an example.

"It's only to show them how important life is. And others have kids. You show them making use of the children, your child is growing, think about if she misuses her life she will die and how will that child grow? She will grow in a difficult way isn't it? [..] If she can love her child, she will love life for the sake of the child's life." (Interview with civil society leader)

3.9.2.2 Messages to encourage limited the number of sex partners

Civil society leaders recommended several messages to encourage pill users to limit their number of sex partners:

- Be faithful to your partner to reduce your chance of HIV infection. (n=2)
- Having multiple partners puts you and others at risk of HIV infection. (n=3)

"Continue to preach the message of being faithful to one's partner and of course indicating those risks of multiple partners like they use with your live life media productions where they show that multiple partners poses a risk if one gets the virus then everybody is at risk, so we continue to emphasize that message." (Interview with civil society leader)

- Don't rely completely on the pill as it is not 100% effective. (n=2)

"I think we should firstly remind them that there's no cure for HIV/AIDS so these are just pills which are not 100% safe so it does not give them a ticket to having many sexual partners." (Interview with civil society leader)

- Continue the safer sex behaviors you were doing before you started taking the daily HIV pill. (n=1)

"We should just tell them to continue behaving the way they were behaving before they came into the program. If you were using condoms continue this pill does not change anything." (Interview with civil society leader)

- Take responsibility for your life and your actions and do not change partners. (n=2)

"The behavior of changing partners must be discouraged always because if we do not discourage it, it means we are not doing justice to our selves, people who change partners according to me does not value other people's lives. We should emphasize the issue of people owning up to their own lives and take responsibility for their actions." (Interview with civil society leader)

- Decrease your number of sex partners for the good of humanity. (n=1)

3.9.3 Being faithful to one partner

3.9.3.1 Strategies to encourage being faithful to one partner

We asked civil society leaders how to encourage people to have sex only with a main partner while taking a daily HIV prevention pill. Four respondents suggested strategies.

One strategy was to promote the moral regeneration movement saying that people should be faithful to their partner and terminate the current relationship before moving into another. A second strategy was to give them counseling, and a third was to provide education on life skills and communication so that people do not go outside their relationship for sexual partners. A fourth strategy was to refrain from taking a "don't do this" approach; rather, tell people about the advantages and disadvantages of having concurrent partners.

Several respondents noted the difficulty of getting people to abide by this message.

"There is nothing you can do because you will not be there when they have sex with their partners, so all you can do is to encourage them and tell them it is for their own good to have single partners not multiple partners." (Interview with civil society leader)

"That one comes from.. is the choice of that person you cannot just tell him to sleep with your one girlfriend because you are drinking the daily pill. It is from the heart of that person, that one we cannot control [SE laughter]." (Interview with civil society leader)

3.9.3.2 Messages to encourage being faithful to one partner

Messages that civil society leaders suggested to encourage PrEP users to be faithful to one partner included:

- Be faithful to only one partner. (n=5)
- Find new and interesting ways in the bedroom to enjoy sex with just one partner. (n=1)
- Get tested for HIV before you have sex with a new partner. (n=1)
- The Bible says man should be married to one woman. (n=1)
- Having one partner puts you at a lower risk of contracting HIV/AIDS. (n=1)
- Terminate your current relationship before sleeping with another person. (n=1)

3.10 Stigma

3.10.1 Stigma associated with the daily HIV prevention pill being an ARV

We reminded civil society leaders that Truvada is already used as an ARV in South Africa by people who have HIV. We asked them if they believed that HIV-negative people would encounter any programs of stigma if they take a pill that is being used as HIV treatment, even though they would be using it as HIV prevention, and to explain their responses.

Over half of respondents (n=9) did not think there would be any stigma associated with taking an ARV as prevention.

"As long as is HIV related because everybody now, people see that you know when somebody is HIV positive you look at the symptoms and everything they get scared so once you see that this person is HIV negative and she is trying to prevent herself from contracting or whatever it's somehow a motivation." (Interview with civil society leader)

About half of the respondents who thought this said there would be no stigma if the community is well informed.

"The issue of stigma says a lot about lack of information, ignorance of people so if people who are HIV negative are victimized for using a pill that is used by HIV positive people it will simply mean that information was not shared enough to the people. I

think that once people are informed there would not be that challenge of stigmatizing people taking the pill." (Interview with civil society leader)

"If they get necessary information when they must use a pill and that the pill is able to prevent HIV/AIDS I don't think there will be any problem." (Interview with civil society leader)

"As I have told you that you can't drink a pill when you are not sick unless if they know about the purpose of that pill. Jaa.. if they are going to know the purpose that is going to be no problem." (Interview with civil society leader)

One respondent explained that there is no way to distinguish those with HIV from those who are HIV negative. Another respondent said that everyone will want to take it:

"No I feel that everybody would want to drink it, everybody who is HIV negative feels she wants to stay negative and then it means those who were not included in the program they will be feeling that they are losing time to drink it because they also want to protect themselves. I don't think they will be stigmatized that they have HIV. Everybody will feel like she can take part." (Interview with civil society leader)

Other explanations from people who thought there would be no stigma were that people will view it the same as contraceptive pills and people will know that program clients are HIV negative.

Of those who felt that there would be stigma (n=6), four people said that people will think participants are HIV+ if they are taking ARVs.

"I think yes, because already you know with a PMTCT there are people who are on like children who are on stigma on formula feeding even those people who are not breastfeeding and they are HIV negative and they are giving their children same kind of formula feeding they are discriminated. So I think there won't be a difference in a level of stigma and discrimination. Most people still think that if HIV positive are taking ARVs then that means everybody that is taking ARVs is infected with HIV, do you understand my point if, if my son was getting formula feeding, I forgot the name of the milk and you son is on the same formula feeding they will think both sons are living with HIV. So people can not differentiate and they will not even confront to ask they will be doing that behind your back and just everywhere and that's the disadvantage." (Interview with civil society leader)

Isn't those who are drinking it they do not want to tell what exactly they are drinking, for example I am HIV positive and I am drinking them and my friend knows that I am drinking them and he is negative and show me that he is also drinking them I will say definitely that he is positive. So, I don't know how can we prevent that from happening because that is very difficult, I am not sure we can try to talk to them but they are going to be stigmatized. (Interview with civil society leader)

"As you've already mentioned that currently it's being used by people who are HIV positive, now if you give it to people who are negative there are people who are going to say even those who are negative, they will say they are also positive." (Interview with civil society leader)

Another respondent said that some people will say that the pills will infect participants with HIV.

3.10.2 Strategies to address stigma related to taking the pill

We also asked civil society leaders how they could help to address stigma in general associated with taking an HIV prevention pill. They responded with several strategies:

- Providing community education (n=4).
- Offering support groups for those who are stigmatized (n=2).
- Talking about stigma everywhere in the community, including in support groups, at home, and in taxis (n=2).
- Starting conversations about Setsheba and the programs they offer to make them free of stigma (n=1).
- Marketing the pill not as an ARV (n=1).

  "As chairperson I would tell them that it is not ARV because once you tell them it is ARV they will stigmatize so you must just say it is another pill, it is better." (Interview with civil society leader)

- Providing clear information about the pill (n=1).

  "So most main thing is the fact that information must be carried out, information must be enough and information must be clear if information is unclear nobody wants to be involved and obviously stigma will be there that she is telling us something she knows nothing about or something that it's unclear.." (Interview with civil society leader)

- Continue to use messages successful in reducing stigma, such as, "My friend with AIDS is my friend."

3.10.3 Messages to address stigma related to taking the pill

They also suggested several individual messages to address stigma:

- Do what is right for you, as people will talk regardless.

  "People are supposed to know that as long as you are concerned about your life, You must remove the other person from you due to the reason that when you are positive, people talk, you are negative, people talk. You must do what is right for you! So, isn't it that you know that if I take this step, I will benefit isn't it?" (Interview with civil society leader)

  Continue to destigmatize ARVs (n=1) by saying, *"Not every person who is on antiretroviral is HIV positive."* (Interview with civil society leader)

- Being in the daily HIV prevention pill program does not mean a person is positive for HIV.
- Tell stigmatizing people that those taking the pills could live longer than they will.

Interviewer: *"So, how could the tavern owners help to address stigma?"*
Respondent: *"We can help by talking to those people who are stigmatizing other people."*
Interviewer: *"What would you say?"*
Respondent: *"It is not the end of the world even that person can live more that you."* (Interview with civil society leader)

3.11 Distribution of a Daily HIV Prevention Pill

3.11.1 Price of daily HIV prevention pill

We asked civil society leaders if the daily HIV prevention pill should be free to clients or if they should pay some amount, and if so, how much would be a reasonable amount to pay per month. The majority of respondents said that the pill should be free to those going to public sector health facilities (n=10). Five respondents said that clients should pay a fee. This should be for those who can afford it and those going to private sector health facilities. One person said that the pill should be subsidized by 50% and another recommended that an affordable fee should be charged.

Five people recommended R50.00 per month as a reasonable fee. Three people did not know, and one person each recommended the following figures as monthly fees: between R10-R20, between R50-R60, R10, R100 (make it expensive so that people do not abuse it), and R55. One person said that R2.5 should be charged per pill.

We also asked public health stakeholders if clients should have to pay anything for Truvada as a daily HIV prevention pill. We reminded respondents that Truvada is also available for HIV treatment in South Africa. Four respondents recommended that clients not have to pay for Truvada in the public health system. Reasons were that ARVs are expensive, we don't sell contraceptives, and people may have to choose between food and the pill.

"I don't think it is necessary because we don't sell contraceptives. As health workers we are hre to promote health, prevent diseases, to rehabilitate, and manage infections.. I don't think people should buy this drug it should be in our budget." (Interview with public health stakeholder)

"What happens if they run out of money?... Like I said the people you are targeting are poor people so if you say the pill is R1 then they have to choose where to take their R1 between a loaf of bread and buying pills. I don't think they'll buy a pill." (Interview with public health stakeholder)

One respondent said that it should be a shared cost between the public health system and the client:

"The moment when you have all your data and it's proven emm and then there must be a fee, because our health system can't carry all the rollouts and all the drugs.. there must be a public private partnership where there are certain amount of funds, that's sponsored and where the patient also have to give a little bit, contribute a little bit and then the health department will also contribute." (Interview with public health stakeholder)

Another respondent said he/she was amenable to there being a low fee for Truvada.

3.11.2 Sale of the daily HIV prevention pill

3.11.2.1 Strategies to discourage sale of the pill

When we asked civil society leaders how programs could discourage clients from selling the daily HIV prevention pills to others, they provided a variety of strategies. Some respondents said that giving education and information would help to discourage pill sales (n=3). Others suggested decreasing the amount of pills that are given at each visit (n=2), for example, seven pills at a time. Two people thought that selling the pills should be made illegal with penalties enforced, and another recommended having a warning label on the pill packet saying that selling pills is illegal. Still two others said there should be supporters who watch people take the pills, as with DOTs for TB. One person suggested putting pills in a packet that is labeled with every day of the week: *"[Put] pills.. in a packet that is labeled Monday, Tuesday, Wednesday till Sunday then people will feel guilty to sell them"* (Interview with civil society leader). One respondent said that Setshaba should have support groups for program clients that help to remind them not to sell the pills. Another person suggesting monitoring the people who are providing the pills to the community. Two respondents said it was out of the program's control whether people sold the pills or not. One person said people should not sell the pills if they are free, and another said that people would be motivated to keep the pills for themselves: *"If I get the pills and I know that I'm going to be helped I won't sell them to someone"* (Interview with civil society leader).

We asked public health stakeholders how programs could discourage clients from selling the daily HIV prevention pills to others, e.g., to people who are HIV-positive, to people who are HIV-negative, and to people who want to smoke ARVs. Strategies they suggested included:

- Monitor the clients by doing pill counts or a drug concentration blood test. (n=3)
- Intensive education on the intentions of the program (to prevent HIV infection by ingesting the drug), on the fact that the pills are free. (n=2)
- Impose regulations/laws prosecuting people who sell the drug. (n=1)
- Increase accessibility of the drug: *"Even if we can make ourselves available and accessible like right now we do not open on Sunday so you will find that this woman buys this pills because she does not find time to come to the clinic and find that some employers don't want sick notes. Meaning that the policy of the health need to be revisited that we need to be accessible twenty-*

four seven, then maybe it will make people stop selling because maybe she buys because she does not have time to come." (Interview with public health stakeholder)

- Regulate distribution of the drug in the pharmacy and providing only a small supply to individuals that they have to sign for. (n=2)
- Do a media campaign. (n=1)
- Collaborate by getting a lot of input on this issue from others. (n=1)

One respondent said that sale of the pill will not be a problem if the drug is free. Another said that there is not much that can be done about pill sale, as sharing is part of the culture.

3.11.2.2 Messages to discourage sale of the pill

Civil society leaders also provided individual suggestions for messages discouraging pill sales:

- Pills are for clients only, and others need to consult a doctor before taking ARVs.
- The pills are not for curing HIV, they are for prevention.
- The pills should not be sold to others because they are not receiving the counseling and blood tests that clients are getting.

Explain that [program clients] get counseling on pill usage and get blood draws for check ups but other people they are selling the pill to, are not getting any of that so they are putting them in danger if they are selling them pills. (Interview with civil society leader)

- Selling pills to others will decrease the client's supply of pills, which will decrease efficacy.

If she sell to that person she won't have enough to drink. And if she does not drink enough it means it won't work the way it is supposed to work. (Interview with civil society leader)

- Take your pills daily and do not sell them.
- There are risks to not taking the pills as instructed. (n=1)

You must also tell her the risk of not drinking it accordingly. Because if she cannot drink it accordingly it is not going to do its work. (Interview with civil society leader)

3.11.3 Places to distribute the pill

When asked where the daily HIV prevention pill should be distributed, civil society leaders provided a wide array of suggestions. Nearly all respondents (n=12) thought the pill should be distributed in clinics. Five people recommended private doctors, and four each recommended hospitals and pharmacies/chemists. Three people suggested churches, and two each suggested schools and taverns. Other locations mentioned by one person each included: ARV sites, sports council, counseling facilities, social grant offices, centers for HIV/AIDS, community health centers only with counselors, community centers, NGOs, Setshaba Research Center, higher education institutions, home visits, social clubs, places where there are health workers, and places with the red cross of health sign. Although taxi ranks and taverns/pubs were suggested as distribution points, they were also described as places to avoid distribution, along with shops.

3.11.4 Marketing of the pill

We discussed the importance of marketing of the pill with both groups of respondents. Several respondents agreed that this was important:

"Yes, because the name should be attractive to people, must include everything that people feel it's more important to them, especially life wise.." (Interview with civil society leader)

"Ja.. if it's not, it's not going to be classified with ARVs, it will be us who drink ARV who will understand that it's an ARV. But for other people, not to give them an understanding that this is an ARV. But we are using it as an.. as a.. [..] HIV prophylaxis like that, ja.. prevention." (Interview with civil society leader)

We asked civil society leaders to suggest a potential name for the daily HIV prevention pill. Their suggestions were:

- Iphidiseng (Setswana for "Make yourself alive")
- Ke a Iphidisa (Setswana for "I am keeping myself alive"). The respondent preferred this name over Iphidiseng (also his/her suggestions) because it emphasizes personal commitment to taking the daily HIV prevention pill.
- New Every Morning – so that every morning when you take it is a new day
- New Dawn—because it will be a new start even after other clinical trials like Carraguard have failed.
- Phuza uphile manje (isiZulu for "Drink and live now")
- Pilisi ya Setshaba (Setswana for "Community pill")
- Leka o phele (Setswana for "Try and live")
- Impilo (IsiZulu word for "life")
- Truvada
- Not Truvada
- Tsosolotso (Setswana for "to renew")

We also asked public health stakeholders to suggest a good name for a daily HIV prevention pill. Their responses included:

- Beater because we want to beat this virus.
- One Love translated into different local languages.
- Everyday push or Push 24/7. *"The push is for the fight against HIV/AIDS.. it's also for the collective efforts of the whole community.. it's pushing, pushing, pushing together.. and every day is just to remind people that it should be done every day"* (Interview with public health stakeholder).
- *"It definitely has to be something simple that people can remember. Drugs tend to have these names like Neverapine, Truvada, whatever, something you can't even pronounce. Maybe something African for a change."* (Interview with public health stakeholder).

3.12 Doubts and Concerns

We asked public health stakeholders if they had any doubts or concerns about the use of a daily PrEP pill in Pretoria and how to address those concerns. Concerns and ways to address them included
the following:

- Viral resistance among users due to inconsistent pill taking could be addressed through education to clients. (n=1)
- The potential for those who become HIV positive to commit suicide could also be addressed through education to clients. (n=1)
- The logistics of the government rolling out this pill could be addressed through monitoring and evaluation. (n=1)

  "I'm not sure if government on its own would be able to roll out this pill, so my worry is about the logistics, in terms of getting enough staff, getting enough ehh building structure or the facilities. [..] Do a very intense monitoring and evaluation involved in their plan or strategies in terms of rolling out the pill." (Interview with public health stakeholder)

- The budget/how much it will cost the government to make it available to everyone needing the pill. (n=2)
- If people will be given sufficient information about the pill. (n=1)
- Resistance and side effects on people who are not sick could be addressed by continuing to engage with government, researchers, the community, and funders. (n=1)
- The effects of the drug on behavior, such as sharing, and the tension between prevention and treatment could be addressed by engaging TAC (Treatment Action Campaign). (n=1)

  "I mean when rolled both negative and positive people will get it so people will share it, we need to engage TAC about, I mean what are the implications. It is prevention for you and a treatment for me." (Interview with public health stakeholder)

One respondent said that there should be no problems with resistance and side effects if the problems are discovered and addressed in research before rollout of the drug.

Discussion

Discussion

As governments of South Africa and other countries consider whether oral and topical PrEP or other new potential ARV-based HIV prevention formulations may be appropriate in their country contexts given their local priorities, the available scientific evidence for effectiveness, and international guidance such as that put forth by the WHO or CDC, people working in HIV prevention have begun to explore the views of different stakeholders vis-à-vis PrEP implementation.

The objectives of this social marketing study were to conduct formative research (a) to inform the development of a pilot intervention for the social marketing of PrEP to specific target populations, (b) to facilitate a process of community planning for a local pilot intervention, and (c) to develop a social marketing plan based on the qualitative research results and community planning process. The major limitation of the study was that due to its early closure, we were unable to meet these overall study objectives because we were unable to conduct interviews with trial participants and members of potential target populations, focus groups with community members, and workshops at the local, provincial and national levels. However, we did meet the objectives of the individual interview categories that we were able to conduct. In the public health stakeholder interviews we identified their perspectives on what needs to happen at the level of public health systems in order to design and implement a pilot PrEP intervention. We also explored respondents' opinions about target populations appropriate for PrEP. In the interviews with civil society leaders we explored their perceptions regarding target population selection and issues related to PrEP implementation, including communication with the community, community education, recruitment and retention, stigma related to the PrEP drug being an ARV, and discouraging behavioral disinhibition/risk compensation.

Public health stakeholders voiced the need for tailored training programs for providers who will be responsible for various aspects of PrEP implementation, a need that has been identified for providers in the United States as well.[1, 2] Additional recommendations to create capacity to deliver PrEP were increased staffing, funds, a supply of the drug, infrastructure, monitoring support, and pharmaceutical support. When asked how to integrate a daily HIV prevention pill into existing public health programs and services, public health stakeholders suggested having a separate section in a clinic, incorporating it into other services rather than having a separate section, incorporating it into family planning centers, allowing for monthly pickup of medication at a pharmacy window, and figuring out who would have the authority to distribute PrEP. The need for national decision makers to collaborate with multiple levels of stakeholders, such as service providers, researchers, and the community, in the development of national policies or guidelines related to PrEP use was also highlighted in the data and has been suggested as important by authors writing about PrEP implementation.[3]

The variety of potential target populations that public health stakeholders and civil society leaders suggested in our study indicates the need for new HIV prevention methods for a wide range of people in South Africa, as well as the difficulty of identifying who would be the best users of oral PrEP and the need for potential user perspectives (which would have been collected in this study had it not been terminated early). Identifying target populations for PrEP in each country context will be important and challenging.[4]

Acceptability of oral PrEP itself may be distinct from acceptability of the programmatic requirements demanded of PrEP users, including safety screenings, HIV testing, behavioral interventions, and potential costs.[3] Civil society leaders mentioned a variety of groups they believed would be able to fulfill program requirements, including youth, single women, women in general, female sex workers, married women, married couples, students, young girls, and elderly women. They also reported which groups may find specific individual program requirements challenging. Populations described as unable to fulfill program requirements included youth/young people, married people, men, substance abusers, pregnant women, married women, party goers, people who do not take contraceptive pills, small children, young women, and the elderly. Notably, civil society leaders mentioned the cultural norm that women must get permission from men when making decisions as prohibitive. Other deterrents to being able to fulfill program requirements were personnel attitudes, stigma, and long queues at health facilities.

Awareness campaigns will be needed to encourage PrEP acceptability and discourage stigma among target populations and the general public.[3] Civil society leaders made recommendations for a public campaign that included use of different media, public fora, spokespeople, and communication strategies. For example, they recommended "sensationalizing" the pill on television advertisements, using celebrities as spokespeople, airing advertisements before, during, and after popular programs, incorporating the daily HIV prevention pill into storylines or topics of programs, creating a new program with PrEP as the topic, and attracting young people by including music that youth like in advertisements. Other media strategies included using dramas in radio or television, explaining the history of the research process about the pill to the community, featuring spokespeople that were part of the initial research so they can relate their experiences, using program participants as spokespeople in the media to tell people about the pill, and explaining clearly that the pills are not 100% effective. Respondents also suggested communication strategies and messaging for community education about PrEP, including to address limited availability, partial effectiveness, behavioral disinhibition, and pairing PrEP with behavioral risk-reduction strategies, and stigma.

This study was conducted prior to clinical trial results on oral PrEP, but clinical trials conducted in several populations have since demonstrated that when taken adherently on a daily basis, the oral Truvada pill has efficacy as PrEP: this was shown to be the case among East African HIV-negative partners in discordant couples [Partners for PrEP trial],[5] men who have sex with men in multiple settings [iPrEx trial],[6] and young heterosexuals in Botswana [TDF2 trial].[7] However, the FEM-PrEP trial was unable to demonstrate effectiveness of Truvada as PrEP due to problematic adherence to the study pill (Truvada or placebo) among the trial's study populations—women at higher risk of HIV infection in South Africa, Kenya, and Tanzania.[8, 9] Despite the FEM-PrEP results, in July 2012 the United States Food and Drug Administration approved Truvada for a new use as pre-exposure prophylaxis for high-risk groups in the United States.[10] In March 2013, the VOICE study among women at higher risk in Zimbabwe, South Africa, and Uganda announced a similar result to FEM-PrEP, underscoring the importance and challenge of adherence.

In addition to PrEP pills, other ARV-based HIV prevention delivery methods are being explored. One such product is tenofovir 1% gel, shown to be 54% efficacious in the South African CAPRISA 004 trial among women who used it for more than 80% of sex acts;[11] this gel is currently being tested again with the same dosing regimen in the South African FACTS 001 trial. Other formulations and delivery systems for ARV-based HIV prevention products are also in the development and testing stage in diverse settings and include an injectable (TMC278 study), a vaginal ring (IPM 027 - The Ring Study; MTN 020 - ASPIRE study), and a diaphragm (SILCS Diaphragm Plus TFV study), formulations which may help to address adherence challenges posed by pills and gel.[12]

Given the strong possibility for eventual choice in ARV-based HIV prevention methods, for example, there is growing interest in learning the opinions of potential users regarding the methods, including in acceptability studies among potential female users in Latin America,[13, 14] Eastern Europe,[14] Asia,[14-17] and Africa.[14, 18-20] The views of men who have sex with men have also been solicited,[21, 22] as well as providers and policy makers to a limited extent.[23]

New HIV prevention methods are desperately needed in the face of continued HIV acquisition in South Africa and elsewhere. Next steps are continued discussions at the national level regarding South Africa's priorities for new HIV prevention methods, additional research with potential user groups, and development of appropriate social marketing campaigns for whichever method(s) is/are prioritized.

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