Considerations for Rolling Out Oral PrEP to Target Populations through Social Marketing

in Bondo and Rarieda, Kenya

FEM-PrEP

BONDO AND RARIEDA, KENYA
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ARV	antiretroviral
ART	antiretroviral therapy
CSW	commercial sex worker
FDA	Food and Drug Administration
FP	family planning
FSW	female sex worker
HCT	HIV counseling and testing
IRDO	Impact Research and Development Organization
KNBS	Kenya National Bureau of Statistics
Ksh.	Kenyan shillings
MCH	maternal and child health
MSM	men who have sex with men
PDMS	Provincial Department of Medical Services
PMTCT	prevention of mother-to-child transmission
PrEP	pre-exposure prophylaxis
PSC	patient support center
PWP	prevention with positives
STI	sexually transmitted infection
TDF	tenofovir disoproxil fumarate
VCT	voluntary counseling and testing
VMMC	voluntary medical male circumcision

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Executive Summary

FHI 360 and Impact Research and Development Organization (IRDO) partnered in 2009 to 2011 to conduct a study to facilitate local discussions about the introduction of pre-exposure prophylaxis (PrEP) for HIV prevention, using Bondo and Rarieda districts of Nyanza Province, Kenya as a case study. The product of this study is a social marketing plan of considerations for encouraging initiation and sustained use of the antiretroviral drug Truvada to reduce the risk of HIV infection. The plan is outlined in this executive summary and described in greater detail in the full report.

The FHI 360-IRDO study was conducted as part of the FEM-PrEP clinical trial of daily use of Truvada to prevent HIV infection. It included interviews with 15 civil society leaders at the district level, 16 public health stakeholders at the district and provincial levels, 27 members of potential target populations, and 20 trial participants. The researchers also conducted a focus group discussion with community members and held three workshops with community and public health stakeholders. In addition, they completed an inventory of 29 facilities offering HIV and reproductive health services in Bondo and Rarieda. The researchers were unable to complete all planned data collection because the study was stopped early when the FEM-PrEP clinical trial closed early when an independent data monitoring committee advised that FEM-PrEP would be unlikely to demonstrate that Truvada prevents HIV infection in the study population, even if the trial continued to its originally planned conclusion. New HIV prevention methods are needed in addition to abstinence, monogamy, reduction of multiple partnerships, use of male and female condoms, and voluntary medical male circumcision to curb HIV incidence rates in Kenya. Truvada, an antiretroviral, is currently used for HIV treatment in Kenya and other countries and was recently shown to be effective as pre-exposure prophylaxis (PrEP) for HIV prevention[1-3]. If the government of Kenya decides to pursue approval of Truvada as PrEP, a social marketing campaign will be needed to encourage uptake and sustained use of PrEP by target populations prioritized at the government level.

This social marketing plan is intended to contribute to discussions and planning in Kenya regarding the potential rollout of oral PrEP. Specifically, it is meant to assist the public health stakeholders and creative agency who would spearhead a social marketing campaign for PrEP in their campaign planning efforts. The contents of the plan are grounded in the data that was collected in the study and reflect local priorities and concerns of different stakeholders in Kenya. It is our hope that if policy makers decide to implement oral PrEP, they will consider whether the three target populations suggested in the plan (i.e., female sex workers, HIV-negative members of discordant couples, and new widows) align with current thinking, and if so will submit the plan to a creative agency for further development and implementation.

Strengths, Weaknesses, Opportunities, and Threats

Several recent trials of daily oral use of Truvada — a combination of the antiretroviral (ARV) drugs tenofovir disoproxil fumarate (TDF) and emtricitabine — have shown that it is effective as PrEP against HIV infection. In the Partners PrEP trial, Truvada reduced HIV risk by 73 percent among both men and women.[1] Similarly, the smaller TDF2 trial in Botswana showed an HIV reduction of 62 percent in men and women.[2] And in the iPrex trial, daily use of a Truvada pill by men who have sex with men reduced the risk of HIV infection by 44 percent.[3]

These positive trial findings are one of the strengths identified in a SWOT (strengths, weaknesses, opportunities, and threats) analysis prepared as part of the FHI 360-IRDO study. The SWOT analysis provides a framework for assessing whether PrEP introduction is an appropriate option for HIV prevention in Kenya. It also offers insights into the factors that would support or challenge a social marketing campaign to promote adoption and sustained use of daily PrEP.

The SWOT analysis noted that Nyanza Province's role as one of the sites of the FEM-PrEP trial is both strength and a weakness for PrEP rollout. As a result of extensive outreach by FEM-PrEP trial staff in Bondo and Rarieda, community members may be familiar with the concept of PrEP. These communities also have a relatively high knowledge of HIV prevention methods, because several clinical trials of different methods were conducted in Nyanza. On the other hand, the early closure of FEM-PrEP after it was determined that the trial was unlikely to demonstrate a protective effect of Truvada against HIV may have raised doubts in the community about the drug's effectiveness for PrEP. The low adherence to the daily Truvada regimen among FEM-PrEP study participants could also be a challenge for a PrEP program, as could low levels of awareness of personal HIV risk and high levels of HIV-risk behavior among potential users of PrEP.

The U.S. Food and Drug Administration's approval of Truvada for PrEP in 2012 represents an opportunity because it has prompted international discussion of PrEP introduction. The momentum from recent trials with positive findings and the discounted price of the generic form of Truvada present additional opportunities for PrEP rollout, while the threats include shortages of ARVs for treatment and a funding gap in the HIV prevention budget in Kenya. These and other findings of the SWOT analysis are summarized in Diagram 1 in section 2.1.

Target Populations

To identify target populations for the social marketing plan, the study used an iterative, participatory approach that emphasized identification of local priorities for target populations. The approach was also used to develop strategies for working with the populations to be included in the social marketing plan. Target populations suggested by participants in most of the data collection activities included two groups

recognized globally as being at higher risk of HIV infection — female sex workers (FSWs) and discordant couples (one partner is HIV-positive and one is HIV-negative) — as well as a locally specific group, fisher folk working in and around Lake Victoria. Widows were also considered an important group to reach because of the Luo cultural tradition that a widow must have unprotected sex with the member of her husband's family who inherit her, and because uninherited widows often engage in some form of transactional sex to support themselves and their families.

Youth were mentioned in all of the research activities but were not identified as a target population for the initial introduction of PrEP because of the lack of clinical trial data on PrEP and youth. Fisher folk were also ruled out as a target population for the social marketing plan because of fishermen's reportedly negative attitudes toward HIV prevention and the need for additional research on female fish traders.

Thus, the target populations selected for the social marketing plan were FSWs, discordant couples, and widows. FSWs were further segmented to focus on self-identified FSWs. The target population of discordant couples was further segmented to focus on couples who would use PrEP while trying to conceive a child, when they would have to engage in unprotected sex.

The researchers triangulated data from the four different research activities and from the literature to gain a better understanding of the target populations, the factors that put them at risk of HIV infection, and the reasons why they might be motivated to use PrEP. Channels for communicating with the target audiences and secondary audiences who might influence them were also identified. This information is summarized in Tables 1, 2, and 3 in section 3.

Participants in the workshop for national public health stakeholders agreed that the PrEP program should give preference to people ages 15 to 45 years old who are generally considered to be at high risk of HIV infection, are able to adhere to the drug regimen and other program requirements, married at an early age or will soon marry early, and live near the dispensing health facility for easy access and monitoring. Other recommended criteria are listed in section 3.4.

Objectives and Goals

In social marketing, the behavior objective is the desired behavior. The knowledge objectives are what the members of the target population must know, and the belief objectives are what they must believe, to perform the behavior. The objectives of this social marketing plan are summarized in Table A.

Table A. Objectives of the social marketing campaign

Behavior Objective	Knowledge Objective	Belief Objective
To initiate and maintain the use of PrEP to prevent HIV infection	To understand: • How HIV is transmitted • What PrEP is • The purpose of PrEP • How PrEP is used • Percent efficacy of the drug • The need to pair condoms with PrEP to maximize protection • Side effects of the drug • Program requirements for taking PrEP • Where services are located • Eligibility criteria • How long one can take PrEP • Any program incentives (e.g., counseling opportunities) • Time costs • Financial costs (e.g., for PrEP drug, transport)	To believe that: • They are at risk of HIV infection • PrEP is effective for HIV prevention • They have self-efficacy to take PrEP and can overcome challenges related to taking PrEP (e.g., partner objection, remembering to take the pill, attending appointments)

Given that the behavior objective is twofold —to initiate and maintain the use of PrEP —three goals and associated measures are suggested:

Goal 1: Maximize the target population's exposure to the campaign (based on available campaign budget).

Suggested measures: Number and/or percentage of people who are exposed to the campaign within the target population

Goal 2: Reach target PrEP initiation numbers for the target population(s).

Suggested measures: Number of people who: 1) screen for eligibility to take PrEP, 2) screen eligible, 3) fill the first prescription

Goal 3: Sustain PrEP use among the target population.

Suggested measures: Number of people who 1) adhere to the program requirements for a given period of time, 2) discontinue PrEP, including reasons why, and 3) seroconvert

Barriers, Benefits, and Competition

Barriers

In social marketing methodology, the barriers are the reasons why members of the target populations may not be able to perform the behavior they are being encouraged to adopt. During the district workshop with community stakeholders who are experienced in working with these populations, as well as in our interviews with members of target populations and civil society leaders and gatekeepers, potential barriers to PrEP were identified for each group. Factors expected to be barriers to PrEP for all target populations include fear of HIV testing, cultural norms and traditions, fear of the stigma associated with taking an ARV, and fear of taking a pill. Other barriers are summarized in table 4 in section 5.1.

Benefits

The key benefits in social marketing consist of what would motivate the target population to perform the behavior (i.e., initiate and sustain use of PrEP). The researchers asked members of potential target populations about their dreams for the future to gain insight into what might motivate them to use PrEP. Most respondents said that they wanted to have "a good life," to be free of HIV and other diseases, to be able to raise their children, and to have more money. More research is needed to identify what else may comprise "a good life" for discordant couples, FSWs, and widows.

Competition

The competition in social marketing is what people are currently doing instead of the behavior promoted by the campaign. The main behaviors that people are currently practicing instead of HIV prevention behaviors would also compete with enrolling in and sustaining use of PrEP. For example, rituals that require unprotected sex, such as sexual "cleansing" of widows by relatives or professional "cleansers," competes with widows' ability to abstain from sex or use condoms consistently. The HIV prevention behaviors that seem unattainable and the competing behaviors that put members of each target population at risk are listed in table 5 in section 5.3.

Positioning Statements

In social marketing, the positioning statement frames how the campaign wants members of the target population to view initiating and sustaining the use of PrEP. This statement would be used in a three-step process for communicating with target populations and the general public about PrEP: 1) high-level endorsement, 2) a community campaign, and 3) sensitization of target populations.

For example, potential positioning statements for sensitizing each target population are:

- We want discordant couples to see PrEP as a way to protect the negative partner while they try to conceive a child, and as better than the risk of having unprotected sex to conceive a child.
- We want female sex workers to see PrEP as a way to protect themselves when they are unable to have protected sex with regular partners (including boyfriends and regular clients), and as easier than risking intimate partner violence by discussing condoms with these partners.
- We want widows to see PrEP as a way to live to raise their children whether or not they become inherited, and as better than having completely unprotected sex due to financial necessity or cultural norms.

Marketing Mix – Product, Price, Place, Promotion

Product

In social marketing, the "product" consists of what members of the target population will be offered if they are "sold" the desired behavior (i.e., initiating and sustaining use of PrEP). It includes the core product (i.e., the major perceived benefit of the behavior), the actual product, and the package of augmented products and services that will be offered.

The benefits of initiating and sustaining use of a daily PrEP pill are reduced risk of HIV infection and the potential for "a good life."(As noted, additional research is needed to learn more about what would comprise "a good life.") The actual product is the behavior we are selling, i.e., to initiate and maintain the use of PrEP to reduce one's risk of HIV infection. Augmented products include additional tangible

objects or services, as well as improvements to existing products and services. New tangible objects to be included in the program and campaign efforts could include a welcome kit and male and/or female condoms to be distributed with each prescription of PrEP pills. The kit could include the first prescription of pills, a brochure with pictorial instructions on taking the pill at the same time daily and a description of possible side effects, and mnemonic devices such as a pill box and calendar with stickers to mark appointments.

New services to be offered to all PrEP users could focus on providing information and psychological support and could include support groups, couple-based counseling, and adherence counseling. Improvements to existing services include increasing mobile or home-based HIV testing for initial screening; optimizing the existing laboratory infrastructure by improving networks between central and non-central labs; and increasing the number of staff members trained to provide HIV risk-reduction counseling. Suggested improvements to existing services and new services to address each target population's particular barriers to initiation and sustained use of PrEP are listed in Table 6 in section 7.1.

Price

In social marketing, "price" refers to the monetary and non-monetary costs, incentives, and disincentives related to selling a behavior.

The monetary costs of a PrEP program and campaign would consist of the costs of tangible objects (e.g., the PrEP pill) and any services related to PrEP service delivery. Tangible objects and services related to PrEP service delivery include what the target populations will pay for things like the PrEP pill, HIV testing and counseling, laboratory tests, and the cost of transportation to and from clinic appointments. (Programmatic costs related to the execution of a social marketing campaign would likely be funded at the level of government, NGOs, and/or private organizations delivering PrEP services and would incur no costs to clients, e.g., for staff training, mentorship, and follow-up.) Line items for these potential costs appear in the budget templates in section 9, Budget.

The non-monetary costs of a PrEP program and campaign are the intangible costs related to using PrEP. Intangible costs to PrEP users include time (e.g., away from work, clinic wait time, travel time to and from clinic appointments), lost wages (income averted due to clinic visits), psychological costs, and physical discomfort (see Table 7 in section 7.2). Possible monetary and non-monetary incentives are also suggested in section 7.2.

Place

In social marketing, "place" involves where target populations would be encouraged and expected to perform the desired behavior. Considerations of place include making services as accessible as possible to the target populations (e.g., convenient location and hours of services), as well as providing support where target populations make decisions about performing the desired behavior.

Qualifying to initiate PrEP use will likely take place in several contexts. People interested in taking

PrEP would need to get tested for HIV as part of initial screening for eligibility. This could be effected through community-based HIV testing such as mobile testing services or at facility-based testing centers. To improve HIV testing services so that they could test PrEP users regularly, such as every three months, community stakeholders recommended service delivery innovations and improvements for each target group (see section 7.3.2). For example, for FSWs the following were suggested:

- Provide moonlight HCT outreach targeting FSWs.
- Provide home-based HCT.
- Conduct follow up of clients using schedule cards and home visits.
- Develop a reminder system, e.g., phone calls to regularly remind clients to go for the test.
- Mobilize clients to form support/buddy groups through which they can encourage each other to go for the test.

Potential PrEP users who test negative for HIV and who are interested in learning more about PrEP would then need to be referred to a facility that provides PrEP services, where they would meet with a counselor or provider knowledgeable about PrEP and obtain laboratory tests for liver and kidney function. PrEP users would also need to access pharmacy services to receive their supply of PrEP.

Sustained PrEP use will also require regular clinic visits, HIV and laboratory testing, and adherence and risk-reduction counseling on a schedule corresponding with the national protocol. PrEP use will also involve taking the PrEP pill at about the same time each day, at a convenient location of the user's choice. Sustained PrEP use could be supported by use of augmented products such as a pill box or calendar, as well as client follow-up procedures such as program staff reminding PrEP users of clinic appointments by phone or in person.

Public health stakeholders who participated in the workshops and interviews recommended several types of facilities in which to integrate the PrEP services that clients would need to access. Their recommendations including existing services rather than stand-alone clinics, maternal and child health (MCH) clinics, HIV patient support centers (PSCs), family planning (FP) clinics, voluntary counseling and testing (VCT) points, and prevention-of-mother-to-child transmission (PMTCT) clinics, as well as rural dispensaries. Service delivery challenges for specific types of facilities and suggestions for addressing them are summarized in Table 8 in section 7.3.1.

Other recommendations from public health stakeholders are provided in section 7.3.1. We were unable to collect potential target populations' preferences for where to access services due to the unexpected early closure of the study.

Promotion

"Promotion" in social marketing includes key messages to communicate to target populations, people to sponsor and deliver the messages, channels for communicating those messages, and a campaign slogan.

Key messages for each target population should be based on information in the positioning statements (see section 6). We do not provide the messages in this social marketing plan because they will need to be developed in collaboration with a creative/health communication agency and tested with the target populations, both of which were beyond the scope of our study. A campaign slogan will also need to be developed.

However, we do provide recommendations for spokespeople and channels for communicating messages to target populations. During our district workshop with community stakeholders, we asked participants to create strategies for educating their respective target populations about PrEP based on their experience working with those populations. The strategies in Table 9 in section 7.4 include their recommendations for when and where target populations should be exposed to messages about PrEP, who should share the information, and in what format the messages should be communicated. Many of the places suggested would also be appropriate for educating the general community about PrEP, so that no single group of people would be singled out and potentially stigmatized.

We also provide recommendations for promoting PrEP to the larger community. National public health stakeholders in our workshop said that the Ministry of Health should spearhead the promotional effort to introduce PrEP as an HIV prevention method to the community, and that it should collaborate with other stakeholders and partners, including HIV implementing partners that offer HIV testing, funding organizations, the private sector, faith-based organizations such as mission hospitals, and civil society organizations. They cautioned that if PrEP promotion appeared to single out particular populations, it could exacerbate stigma and discrimination. National stakeholders in the dissemination meeting for this social marketing study also stressed this point, saying that target groups themselves should be involved in promotional efforts and that messages should be clear.

Civil society leaders interviewed in Bondo and Rarieda recommended that the community in general be introduced to PrEP at village barazas, church groups and other public forums. Other suggested channels include electronic media, radio, funerals, community health workers, posters around the community, peer educators, village elders, church leaders, comedians, community dramas, hospitals, dispensaries, shops, markets, schools, homes, beaches and loudspeakers on vehicles driven around the community.

Many people felt that media would not be the best way to introduce PrEP because of concerns about accuracy and the need to communicate details. If media were to be used as part of the promotional effort, respondents recommended the local radio station, Ramogi, for disseminating news about PrEP.

Civil society leaders also recommended the following specific components of the media message:

- Target audiences of PrEP: The mass media component of the campaign should not single out high-risk groups and risk associating PrEP with stigmatized groups. A possible message for the mass media component is that PrEP is for "people who have unprotected sex with someone of unknown status or who is known to have HIV."
- Limited availability of PrEP: Campaign organizers may want to develop a message that could be disseminated if demand for PrEP exceeds supply.
- Pill effectiveness: Messages explaining Truvada's partial effectiveness against HIV infection will be needed.
- How the pill works and how it is taken
- Where to access the pill

Other possible message components include discouraging behavioral disinhibition (increases in risky sexual behavior among PrEP users and their partners), discouraging stigma related to taking an ARV, and emphasizing the need for strict adherence to the drug regimen.

National public health stakeholders recommended that community education about PrEP emphasize the benefits of the program to the client, the need for strict adherence, the need for a willingness to practice other risk-reduction strategies in addition to PrEP, and the requirement for regular HIV testing.

Monitoring and Evaluation Plan

Monitoring a PrEP campaign and intervention will enable program planners to gain efficiencies when scaling up to a larger geographical area, more facilities, and/or an increased number of people. It will also enable them to decide if course corrections are needed in any area of the plan, such as in communication strategies, messaging, or client follow-up. Suggestions for ways to measure the three goals from section 4 (Objectives and Goals) appear in Tables 10 to 12 in section 8. Measurement techniques, reporting frequencies, and parties responsible are provided.

Budget Considerations

Templates that stakeholders could use to develop budgets for a PrEP social marketing campaign and intervention are provided in section 9.

Plan for Campaign Implementation and Management

The plan for campaign implementation and management describes specific phases of the campaign and includes who will do what and when, and for what cost. Ideally, this plan will be designed to track the progress made over the life of the PrEP campaign and intervention. This working document is typically made available to share with all responsible parties (e.g., government public health administrators, funders, facility administrators, etc.). It is developed prior to initiation of the campaign and takes into account the total budget and timeline. A sample plan for campaign implementation and management is provided (Table 13 in section 10).

Introduction

Introduction

1.1 Social marketing plan background

The specific recommendations in this social marketing plan are based on the results of a study entitled "Sociobehavioral Research and Community Planning to Develop Site-specific Pilot Intervention Plans for PrEP Rollout" that was conducted as part of the FEM-PrEP clinical trial testing the antiretroviral pill Truvada as pre-exposure prophylaxis (PrEP) when taken daily, at the trial's Bondo, Kenya site. In 2009 to 2011, FHI 360 collaborated with Impact Research and Development Organization to conduct this study, which was designed to help facilitate local discussions about rollout of a PrEP pill for HIV prevention in Kenya, using Bondo and Rarieda districts in Nyanza Province as a case example. The study was reviewed and approved by FHI 360's Protection of Human Subjects Committee, as well as from Kenyatta National Hospital Ethics and Research Committee.

The qualitative research consisted of:

- Semi-structured interviews with:
  - Civil society leaders at the district level (n=15)
  - Public health stakeholders (government public health officials and leaders of non-governmental organizations [NGOs]) at the district and provincial levels (n=16)
  - Members of potential target populations (using two question guides) (n=27)
  - Trial participants (n=20)
- A focus group discussion with community members

Additional study activities, which were considered "non-research" by the ethics committees were:

- Workshops with community stakeholders from Bondo and Rarieda districts (n=1), public health stakeholders from Nyanza Province (n=1), and

national-level public health stakeholders (from government, universities, NGOs, and research) in Nairobi (n=1)

- An inventory of facilities offering HIV and reproductive health services in Bondo and Rarieda (n=29 facilities)

Additional interviews, focus groups, and workshops were planned. However, we were unable to complete all planned data collection because in April 2011 the trial was stopped early, after an independent data monitoring committee advised that FEM-PrEP would be unlikely to demonstrate that Truvada prevents HIV infection in the study population, even if the trial continued to its originally planned conclusion.

1.2 Campaign background

New HIV prevention methods are needed in addition to abstinence, monogamy, reduction of multiple partnerships, use of male and female condoms, and voluntary medical male circumcision to curb HIV incidence rates in sub-Saharan Africa and elsewhere. Truvada, a pill combining the antiretroviral (ARV) drugs tenofovir disoproxil fumarate (TDF) and emtricitabine, is currently used for HIV treatment in Kenya and other countries and was recently shown to be effective as pre-exposure prophylaxis for HIV prevention in three clinical trials.[1-3] Adherence to the daily drug regimen among trial study populations was essential for ensuring effectiveness, but proved challenging.

This challenge was evidenced in the early closure of the FEM-PrEP clinical trial, also testing Truvada as PrEP, when it became clear that the trial would not be able to determine whether or not the drug was effective in preventing HIV infection. It was later determined that study participants' adherence to the study regimen had been low.[4]

Given the positive findings from the other trials, however, the U.S. Food and Drug Administration (FDA) approved Truvada for use as PrEP in the United States in July 2012.[5]

If the government of Kenya decides to pursue approval of Truvada for PrEP, and if approval is obtained, a social marketing campaign will be needed to encourage uptake and sustained use of PrEP by target populations prioritized at the government level. It is our hope that this social marketing plan using target populations in Bondo and Rarieda in Nyanza Province as a case study will assist public health stakeholders in planning such a campaign. The location for the case study may be appropriate because Nyanza Province is likely to be a candidate for PrEP rollout in Kenya given that it has the country's highest HIV prevalence rate: 14 percent.[6] Nyanza is bounded by Lake Victoria on the west and has a total population of more than 5.4 million. The majority of the province's population are Luo—a traditionally non-circumcising ethnic group—which has an HIV prevalence of 22.8 percent among women and 17.1 percent among men.[6]

1.3 Campaign purpose and focus

In social marketing methodology, the campaign purpose is the intended social or health benefit of the campaign. The campaign focus is the method for achieving the benefit. This social marketing plan has the following campaign purpose and focus:

Campaign purpose: To reduce HIV incidence among people vulnerable to HIV infection in Bondo and Rarieda districts in Nyanza Province, Kenya.

Campaign focus: To generate demand for initiating PrEP (e.g., Truvada pill) and sustaining use of PrEP to reduce their risk of HIV infection.

Note: Although this social marketing plan describes strategies and considerations specific to an oral PrEP campaign and intervention, the information contained herein has applicability for other forms of ARV-based HIV prevention formulations that may become available in the future (e.g., gel, vaginal ring, injectable).

Situation Analysis

Situation Analysis

2.1 SWOT

A SWOT analysis details the internal strengths (S) and weaknesses (W) of an organization in relationship to the campaign focus, as well as external opportunities (O) for and threats (T) to its activities. This type of analysis was used because it provides a framework for assessing how appropriate it would be to introduce PrEP in Kenya's environmental and political context.

Typically, the SWOT analysis is conducted from the perspective of the implementing organization. In this case, however, the authors of the social marketing plan are the study researchers, and the implementing organizations would be the government of Kenya (if decision makers elect to make use of some or all of the plan) and the creative design or marketing agency with whom it may collaborate. Therefore, for this social marketing plan we have adapted the SWOT approach to describe the strengths and weaknesses internal to Kenya and the field of HIV prevention, and the opportunities and threats external to a PrEP campaign in Kenya.

The analysis identified the strengths, weaknesses, opportunities, and threats that could either support or challenge a PrEP intervention. It also identified internal and external environmental factors that would be favorable or unfavorable to the social marketing of PrEP. A summary of the findings of the analysis is shown in Figure 1.

Figure 1 Summary of SWOT analysis for implementing PrEP in Kenya, with Bondo and Rarieda as a case study

Strengths	Weaknesses
• Clinical trials have shown the effectiveness of PrEP for reducing one's risk of HIV infection when taken adherently • Local community may be familiar with PrEP due to PrEP trials taking place in Nyanza • Local community is reported to have baseline knowledge about HIV prevention • Existence of local health care infrastructure supporting HIV treatment • Some task shifting of health care staff is practiced and could be applied to PrEP service delivery • Potential key target populations for PrEP are being discussed	• FEM-PrEP trial closure may have raised doubts in the community about efficacy of Truvada as PrEP • PrEP adherence in FEM-PrEP trial was low and could be a challenge for PrEP implementation • Stigma associated with taking an ARV is likely • Possibility of increases in high-risk sexual behavior among PrEP users (risk disinhibition) is a concern among public health and community stakeholders • Low personal awareness of HIV status and high levels of risk behaviors among target populations • Poor health infrastructure and inequitable distribution of human resources for health services • Potential ARV stock-outs

Opportunities	Threats
• Global discussion generated by US FDA approval of Truvada as PrEP • Truvada licensed for generic versions • Positive momentum from recent clinical trials that show effectiveness of PrEP for reducing risk of HIV infection when taken adherently • Reduction of HIV incidence is part of national HIV prevention policy goals • High HIV incidence and prevalence in the community make it an appropriate context for PrEP use	• ARV supply is insufficient to meet demand for treatment and would be further constrained by a need for ARVs for HIV prevention • ARVs are not yet approved for prevention in Kenya • HIV prevention budget may be insufficient for incorporating PrEP

2.1.1 Strengths

The key strength that supports the social marketing plan for a PrEP program is the effectiveness of ARV-based PrEP products for HIV prevention shown in recent clinical trials. In the CAPRISA 004 trial, HIV-negative women who received the 1% tenofovir gel reduced their risk of HIV infection by 39 percent.[7] Other trials have reported the effectiveness of Truvada as a daily oral PrEP pill.[1-3] In the Partners PrEP trial, daily oral use of TDF or Truvada reduced HIV risk by 62 percent and 73 percent, respectively, in both men and women.[1] Similarly, the TDF2 trial in Botswana showed that daily Truvada reduced HIV risk by 62 percent in men and women.[2] Truvada was also tested among men who have sex with men and transgender women who have sex with men in the iPrEx trial, which showed an HIV reduction of 44 percent.[3] The results of these trials are promising for the use of PrEP for HIV prevention.

The second key strength is that several HIV prevention clinical trials (Partners PrEP, HPTN 052, and FEM-PrEP) have been conducted in Nyanza Province, providing local communities with some potential familiarity with PrEP. In the FEM-PrEP trial, which tested the safety and efficacy of daily oral TDF-FTC in Bondo and Rarieda districts,[4] trial participants and public health and community

stakeholders were involved at various stages prior to, during, and after the trial, receiving information and providing input on the trial. Knowledge of PrEP through outreach conducted by clinical trial staff, together with relatively high baseline knowledge of HIV prevention methods in Nyanza Province,[6] are strengths that support social marketing of PrEP.

Another strength is the existing health care infrastructure to provide HIV care and treatment services in Bondo and Rarieda districts. These districts already have many of the services, laboratory tests, and staff that would be needed for a PrEP program. The emphasis on shifting some health care tasks from clinical officers to nurses and other staff as a strategy for distributing human resources equitably is also a strength. Such task shifting is supported by the Kenya National AIDS Strategic Plan[8] and will be essential for a new PrEP program to address potential staff shortages.

Finally, discussions regarding potential appropriate target populations for PrEP in Kenya are already ongoing. Stakeholder meetings and working groups in Kenya are including discussion about who may be appropriate target populations for new HIV prevention methods, including early ARV treatment of HIV-infected individuals. This social marketing study also facilitated discussions about potential target populations for PrEP through interviews and workshops with public health stakeholders, community stakeholders, and civil society leaders.

2.1.2 Weaknesses

The FEM-PrEP clinical trial created awareness about PrEP for HIV prevention. However, the trial was stopped early in 2011 after a planned interim analysis determined that the trial was unlikely to demonstrate a protective effect of oral Truvada. Results from the trial showed that despite intensive counseling on the need to take the study drug every day as directed, drug adherence appeared to be low.[4] The early closure of the FEM-PrEP trial may have raised doubts in the community about the efficacy of Truvada as PrEP, and this is a weakness that would need to be addressed. The low adherence to the drug regimen among study participants may also be indicative of future challenges for a PrEP program.

Other weaknesses that could affect the success of PrEP implementation include low awareness of personal HIV status and high levels of risk behavior among the target populations. The 2008-2009 Demographic and Health Survey found that 45 percent of men and 36 percent of women in Nyanza Province had never been tested for HIV, and only 34.3 percent had been tested and had received the results of their HIV tests during the past year.[6] Among those who had had sexual intercourse in the previous 12 months, 22.4 percent of men and 1.8 percent of women reported having multiple sexual partners and higher-risk sexual intercourse during the past 12 months.

Concerns about PrEP, including the potential for stigma and risk disinhibition, would also need to be addressed. In this study, public health and community stakeholders voiced concerns about access to PrEP resulting in a false sense of security and more high-risk behaviors among PrEP users. Because participants in clinical trials took PrEP in a controlled setting, with HIV prevention counseling and monthly tests for HIV, it is difficult to predict how PrEP users will behave in a real-world setting and whether taking the drugs for HIV prevention will lead to an increase in risky sexual behaviors.

A final weakness is the concerns raised in our study about the quality and distribution of health care resources. Poor infrastructure was highlighted: in some districts in Nyanza, half of the rural facilities are not equipped with a regular power supply, clean water or sanitation services.[9] Staff shortages and inequitable distribution of staff also pose challenges for health care delivery, and stock-outs of drugs have been reported, particularly in government facilities.

2.1.3 Opportunities

The SWOT analysis identified a number of opportunities that support the rollout of PrEP. First of all, Truvada was approved by the US FDA in July 2012 as PrEP for HIV prevention[5] based on the positive results of PrEP clinical trials. Although Truvada has not been approved for HIV prevention in Kenya, consultations and discussions among public health stakeholders are under way. There is also positive momentum from recent clinical trials that have shown the effectiveness of PrEP for HIV prevention. Together with the potential price reduction for Truvada in developing countries through the licensing of generic versions[10] and the signs of a potential shift from a focus on HIV treatment to HIV prevention, these developments provide opportunities for PrEP implementation in Kenya.

As mentioned, among the majority Luo ethnic community in Nyanza Province, HIV prevalence is 17.1 percent in men and 22.8 percent in women.[6] This high prevalence rate makes Nyanza an appropriate context for PrEP implementation. National policy guidelines to reduce new HIV infections by at least 50 percent by 2013[8] and strong support for PrEP rollout by public health stakeholders interviewed in this study represent additional opportunities for the successful introduction of PrEP.

2.1.4 Threats

There are a number of threats to PrEP implementation. First, PrEP is not approved for HIV prevention in Kenya. Second, although budgets have been increasing over recent years, there is a financial gap between budgets and actual allocations for HIV programs. For the fiscal year 2012-2013, potential gaps of US$120 million for HIV prevention and US$449 million for HIV treatment are estimated.[8]

A third threat is the insufficient supply of ARVs for HIV treatment. The National AIDS Control Council has set as a target for 2013 that 80 percent of health facilities report no stock-outs of more than one week over 12 months.[11] The increased demand

for ARVs that a PrEP program would create would pose a challenge for policy makers, who would have to determine how ARVs should be allocated between prevention and treatment programs. In the HIV services inventory we conducted among 29 facilities in Bondo and Rarieda, four of the 15 facilities that offered ARV-based treatment had experienced ARV drug stock-outs in the previous six months. Eight of the facilities reported being unable to offer HIV tests or confirmatory HIV tests because kits were unavailable. Therefore, supply issues would need to be addressed.

2.2 Findings from similar and prior efforts

The roll out of PrEP should be informed by lessons learned from past efforts, whether the introduction of HIV treatment, contraceptives, or other HIV prevention methods such as male and female condoms and voluntary medical male circumcision (VMMC). The lessons below are organized according to general themes and fields of practice.

Client Behavior

Lessons from antiretroviral therapy (ART) show that knowledge about HIV transmission, behavioral risk reduction, and HIV treatment drugs may lead to better adherence to ART and reduced risk behaviors. Knowledge about HIV and HIV treatment are linked to better drug adherence,[12] whereas poor social support, stigma, and misconceptions about antiretroviral drugs hinder the initiation of ART.[13] High-risk sexual behavior is common among people living with HIV (PLHIV) who are not receiving treatment services, possibly because they are not receiving the messaging about HIV prevention that is typically provided with ART.[14] An integrated behavioral intervention was found to improve ART adherence, reduce HIV transmission risks, and minimize risk compensation.[15]

In family planning (FP), providing clients with a wide range of contraceptive options has been found to increase overall contraceptive use, and widespread adoption of new contraceptive methods in many African countries took time;[16] both could also be the case for adoption of different formulations of ARV-based HIV prevention methods. In addition, attention to the management of side effects is important for the correct and sustained use of contraceptive methods[16] and will likely be important for PrEP.

HIV prevention research indicates that adherence to a PrEP strategy may depend on users' personal circumstances and motivations. Among serodiscordant couples in the Partners' PrEP study, adherence may have been related to a couple's desire to reduce risk while preserving their relationship. The use of PrEP among stable couples in that study may be associated with improved adherence and thus greater effectiveness.[17] HIV

prevention research also shows that adherence to experimental HIV prevention products may differ from real-world use. Pregnant women were less likely to adhere to a microbicide study gel than non-pregnant women, possibly because they were concerned about the unknown effects of the gel on the fetus.[18] Finally, HIV prevention research shows that behavioral interventions encouraging people to continue condom use will be needed as part of PrEP implementation. Men who have sex with men reported that they would be likely to use PrEP if it were at least 80% effective in preventing HIV. Among these men, more than 35% said they would probably decrease condom use while on PrEP. Decreased condom use was associated with risk perception and the belief that condoms reduced arousal and pleasure. The results underscore the importance of behavioral interventions during the wide-scale provision of PrEP to high-risk populations.[19]

Risk compensation among PrEP users is a possibility that should be addressed in PrEP messaging and then monitored, as has been done with voluntary medical male circumcision (VMMC). For example, risk compensation was not associated with male circumcision in Kisumu, Kenya, but continued monitoring and evaluation of this possibility is necessary.[20] Although HIV counseling can promote protective behaviors among men who have received VMMC, risk compensation nonetheless occurred among a small minority of men in Swaziland for a short period after VMMC.[21]

Communications

In ART, entertainment has been used successfully to reach audiences with HIV prevention messages. Radio and theater-based programs can improve HIV-related knowledge, attitudes, and behavior among the general public and at-risk populations.[22]

Social marketing campaigns show that sustainable changes in behavior require continuous interactions between the social marketing campaign and the target audience. Messages and delivery mechanisms must be updated throughout the campaign as changes in behavior and outcomes are evaluated.[23] Campaigns also show that messages should be reviewed and pre-tested with the target audience and with relevant organizations that understand the behavior of the target audience,[24] and that setting goals and measuring the impact of a campaign can be challenging but essential; it is important to determine whether the target population was exposed to the campaign and to measure the impact of the messages.[25]

Lessons learned from VMMC indicate the need to form a communications subcommittee to monitor the dissemination of information and that media can successfully be used to popularize and market the intervention (Provincial public health stakeholder workshop).

Economics and Logistics

In ART, program managers have made buying decisions to reduce program costs, including decisions affecting in-country availability, price, convenience, and the logistics of the supply chain and the program requirements (e.g., testing). Because of the scale of the HIV epidemic, cost savings can be significant within any given country or region, such as sub-Saharan Africa.[26] However, inadequate supply, poor distribution, low remuneration, and migration of skilled health workers limit the expansion of HIV treatment services, showing that strong national stewardship of antiretroviral treatment programs is important.[27] Scale up and access to ART in Kenya has been hindered by the global economic crisis, which has decreased country revenue and donor support. In addition, the national health care system is unprepared for chronic care due to lack of human resources, poor infrastructure (e.g., space, laboratory), poor drug procurement and supply management, and weak monitoring and evaluation systems.[28] Lessons from ART also show that stock outs and a lack of staff confidentiality regarding client information can delay the initiation of HIV treatment and interrupt treatment.[13] Provincial-level public health stakeholders involved with ART rollout in Kenya recommend that PrEP be provided in a few facilities with sufficient capacity and then rolled out to other facilities (Provincial public health stakeholder workshop).

Approaches used in HIV prevention trials may be applicable to real-world interventions. During the late phases of the iPrEx study, researchers used "next-step counseling (NSC)" for adherence support and "neutral assessment (NA)" for the promotion of accurate reporting" by clients. The implementers of these approaches believed that the methods were generally acceptable and feasible.[29] In addition, HIV prevention research indicates that programs will need to focus on management of side effects to maximize adherence. Users of the active medication (Truvada) in the iPrEx study experienced side effects, such as nausea and reversible renal abnormalities, suggesting that PrEP users will need ongoing clinical monitoring. The prophylactic benefits of Truvada were significantly reduced by non-adherence, suggesting that an effective PrEP implementation programs will need to focus on this behavior, in addition to safer-sex counseling.[30]

Lessons from social marketing show that product availability — a desirable price and easy access — is critical for behavior change.[31]

Policy

In Kenya, experiences in HIV testing and counseling (HTC) suggest that policies must be aligned with limited resources available. For example, HCT services were changed to allow HIV testing by lay counselors rather than laboratory staff, and to employ serial testing rather than parallel testing (Provincial public health stakeholder workshop).

Successful social marketing campaigns show that policy and partnership can enhance the 4 "Ps" of social marketing — product, price, place and promotion — as the basis of all programs.[32]

In VMMC, government collaboration with community stakeholders was essential to the success of the new interventions. In Kenya, the government's early and continuous engagement with community leaders/elders, politicians, youth, and women's groups led to the rapid endorsement and acceptance of VMMC since 2008.[33] Provincial public health stakeholders experienced in VMMC efforts recommend establishing a collaboration between the government and the implementers of the intervention in the formulation and implementation of relevant policies (Provincial public health stakeholder workshop).

Staffing and Local Capacity

Lessons from ART and HTC show that task shifting or sharing can expand services. Task shifting can circumvent the shortage of experts by training selected patients as "peer health workers" to provide care to others receiving antiretroviral therapy.[34] In addition, simplifying and standardizing a delivery model of ARV provision through task sharing (e.g., training nurses to provide HIV treatment services) can increase the number of delivery sites.[35] HIV rapid testing originally performed by laboratory personnel can be shifted to counselors with the application of quality controls and training (Provincial public health stakeholder workshop).

ART also shows that attention to human resource needs is needed to strengthen health systems. The health systems in resource-poor countries must be strengthened through education, job-specific training, recruitment, and retention of health-care workers. Innovative models of care delivery are needed.[36]

Provincial public health stakeholders urged improvements in staff training based on their experiences with ART provision, including:

- Move from class- or hotel-based trainings to facility-based trainings where staff members can be observed and mentored and so that trainings can be given in small doses to avoid interrupting services.
- Create a pool of trainers at the district and facility levels to allow for continuous training and to accommodate the schedule at the facility. Continuous education and training will enable staff members to maintain their knowledge and skills and will ensure the sustainable delivery of PrEP services.
- Schedule a follow up with staff members after PrEP training to learn how well they are delivering PrEP services. This could be accomplished through mentorship programs to monitor the services and to give the program a "push." (This is important because the staff members did not translate their training into practice in an ART program.)
- Give careful consideration to the selection of staff members who will be trained. Supervisors should be sensitized to select staff members who will be helpful in supporting the delivery of PrEP services. To maximize the use of resources at start-up of PrEP service delivery, provide

targeted training to staff members who will implement PrEP, e.g., do not train laboratory staff to dispense drugs. But the entire staff should be trained to facilitate interdepartmental staff movement and interaction. (Source: FEM-PrEP rollout study's provincial public health stakeholder workshop)

Also related to staffing issues, FP efforts indicate that if the existing health systems are inadequate, it is important to ensure that people are available to supervise and staff a new program. These people should be trained for the appropriate tasks and have clear clinical guidelines to improve adherence.[37]

Public health stakeholders involved in prevention of mother-to-child transmission of HIV (PMTCT) programs recommended that PrEP program planners:

- Integrate compatible interventions. For example, antenatal clinics can be matched with PMTCT programs.
- Engage traditional healers. For example, traditional birth attendants (TBAs) can refer mothers to antenatal and PMTCT services during pregnancy.
- Use laboratory networks if local equipment, supplies, or personnel are unavailable, including taking specimens from collection points to a single, central laboratory (Provincial public health stakeholder workshop).

Stakeholder Engagement

Lessons from ART include the recommendation to promote staff ownership of PrEP services by integrating PrEP into all relevant departments in hospitals (e.g., outpatient, maternity, etc.), rather than setting it up as a stand-alone service or clinic. Antiretroviral services that were started in parallel to other services were not perceived as being "owned" by most Ministry of Health staff members. A second recommendation is to create local ownership by involving community stakeholders and partnering with nongovernmental organizations (Provincial public health stakeholder workshop).

Female condom social marketing efforts show that community-level support and participation in the promotion and distribution of a method is beneficial. For female condoms, it was found to (a) increase awareness and use of female condoms, (b) increase access to female condoms, and (c) overcome perceptions of promiscuity linked to the use of the female condom.[38] Work in HTC also shows a need to work with stakeholders to create awareness and increase demand (Provincial public health stakeholder workshop).

From VMMC comes the recommendation to engage with and inform community leaders, gate keepers, and opinion leaders throughout the intervention period to encourage acceptability and ownership of the intervention. This helped because VMMC was initially rolled out in communities where circumcision

was traditionally not done among males. Without this approach, any intervention program contrary to local traditional practice will meet resistance from the community (Provincial public health stakeholder workshop).

Target Populations

A lesson from VMMC is to target the most-affected population in the intervention. VMMC has targeted the most affected population, i.e., the youth. The government policy is to offer VMMC to boys from 15 years of age—just before many boys become sexually active—up to 49 years. PrEP should plan to target even younger girls due to the risks of acquiring HIV at earlier age (Provincial public health stakeholder workshop).

In social marketing it is recommended to identify subgroups among the target populations to determine the best mix of marketing strategies according to the population.[25]

Target Populations

Target Populations

It would not be feasible for all people at risk of HIV to take PrEP for HIV prevention due to the economic constraints likely to limit the availability of PrEP. Therefore, to segment the target market and identify target populations for the social marketing plan, the study used an iterative, participatory approach that emphasized identification of local priorities for target populations. Our approach was intended to help facilitate a local dialogue around key populations that would inform the target populations selected for this social marketing plan. Our systematic process included triangulating data from the literature and study activities to identify target populations considered as priorities by local and national stakeholders and then developing strategies for working with the populations to be included in the plan.

We conducted semi-structured interviews with civil society leaders at the district level and with public health stakeholders at the district and provincial levels to understand their priority target populations for PrEP. To learn more about the potential target populations specified in the interviews, we held a one-day workshop in Bondo with 20 community stakeholders who helped us develop strategies for delivering PrEP to four specific target populations: female sex workers (FSWs), HIV-negative members of discordant couples (one partner is HIV-positive and one is HIV-negative), widows, and fisher folk. We also conducted semi-structured interviews with members of potential target populations. To learn national public health stakeholders' views on appropriate target populations and to communicate the views of stakeholders at other levels, we also convened a one-day workshop in Nairobi with 25 participants.

Interview and workshop questions about potential target populations appropriate for PrEP generated a list of 24 subpopulations for an initial pilot phase and 29 populations for an expanded phase of PrEP implementation. Target populations suggested by different levels of stakeholders in at least three of the four data collection activities included two groups recognized globally as being at higher risk of HIV infection —FSWs and discordant couples — as well as a locally specific group, fisher folk working in and around Lake Victoria.

Widows were mentioned during both workshops as a target population for the pilot phase, but in interviews they were recommended only for an expanded phase. The Luo cultural tradition prescribing that a widow have unprotected sex with inheritors (members of her husband's family or professional cleansers) render this group particularly relevant for a PrEP intervention in Nyanza, whereas uninherited widows often engage in some form of transactional sex to support themselves and their families; therefore, widows were included in the final selection of target populations.

Youth were also mentioned in all of the research activities but are an unlikely initial target population for PrEP due to the lack of clinical trial data on PrEP and youth. We later ruled out fisher folk as a target population for this social marketing plan based on reports of fishermen's negative attitudes toward HIV prevention (making them unlikely to be adherent PrEP users) and the need for additional research on female fish traders before specialized strategies can be developed for them.

The final selection of primary target population candidates for this social marketing plan consisted of:

- FSWs
- HIV-negative women and men in discordant couples
- Widows

We further segmented these populations into self-identified FSWs, HIV-negative men and women in stable discordant couples who are trying to conceive, and new widows.

3.1 Female sex workers

Transactional sex — when sex is exchanged for food or resources —is practiced by a range of women in Kenya who may not consider themselves sex workers. One source indicates that in 1999, 6.9 percent of women in Kenya had exchanged sex for money, gifts, or favors.[39] Our suggested target market consists of the subset of women who self-identify as sex workers. They are an appropriate population for PrEP because FSWs account for 14.1 percent of the new HIV infections in Kenya[8] and have a high HIV prevalence. In Kenya as a whole, prevalence among FSWs is reported to range from 50 to 80 percent.[40-42]

Our recommendations focus on self-identified FSWs in Bondo and Rarieda. Based on Voeten's 2007 description of self-identified FSWs in Saida and Bondo districts of Nyanza, these are women in their early to mid-twenties. They tend to be unmarried (more than half are separated or divorced), with children who depend on them economically.

Each has at least two regular sexual partners — including some former clients — who may also pay them for sex directly or indirectly (e.g., rent, food, clothing, or school fees). Regular partners who are not former clients may not know that the FSW engages in sex work. FSWs in Saida and Bondo also have a relatively low number of partners whom they consider to be paying clients (e.g., three clients over the course of four weeks). As in other sex worker populations, consistent condom use is lower with regular partners (about 25 percent) than it is with clients (about 60 percent).[43]

This population's risk factors for HIV infection include the following:

Possible exposure to HIV through sexual networks. FSWs have multiple concurrent partners who often have multiple partners themselves[44] (District workshop with community stakeholders). One FSW we interviewed in this study noted that regular partners may get drunk and have unprotected sex with other women, putting FSWs at risk of HIV infection when they in turn have unprotected sex with those partners.

Low condom use with regular partners. Sex workers in Kenya and other locations in sub-Saharan Africa have been found to use condoms more frequently with clients than they do with boyfriends or primary partners, but they may use condoms less frequently with regular clients due to a perception that HIV risk is low with regular partners in general[44-47] (Interview with FSW).

- Forced unprotected sex with clients and regular partners. One respondent in our study described forced unprotected sex as a personal risk factor. She said, "...[S]ince he had given me these things, he is forcing me...he wants to do it without condoms. That can make me to get it [HIV]" (Interview with FSW).
- Drug and alcohol abuse: FSWs may engage in high-risk sexual behaviors as a result of using or abusing drugs and alcohol[40, 44] (District workshop with community stakeholders).
- Economic deprivation: Many women engage in sex work to meet subsistence needs and may lack an alternative source of equivalent income. As a result, they may relapse into high-risk behaviors despite continuous exposure to HIV prevention information and services (District workshop with community stakeholders). Sex without condoms may be more highly remunerated than protected sex,[48] and other types of work may pay less.[44] In addition, working in locations where transactional sex is common, such as bars, may lead FSWs to engage in transactional sex.[44]
- Early onset of sexual activity.[44] One study among FSWs in Nairobi found that the age at first sex was younger among those who were HIV-positive.[11]
- Anal sex as a result of client demand.[44] Anal sex increases the likelihood that a woman will become infected with HIV.[49] In one study in Kenya, more than a third of sex workers reported engaging in anal sex, using condoms less frequently in anal than vaginal sex, and having anal sex more often with non-primary partners.[50]

Another factor contributing to FSWs' vulnerability to HIV is the illegal status and clandestine nature of sex work in Kenya. As a result, women may not admit to doing sex work, making it difficult to reach them with interventions[44] (District workshop with community stakeholders). In addition, FSWs' lack of power to negotiate condom use may result in physical abuse, for which they have limited legal recourse.[44, 51] They may also be stigmatized by community members, have a low level of education and be illegal migrants.[44]

3.1.1 Challenges

In the community stakeholder workshop conducted as part of this study (District workshop with community stakeholders), the challenges of working with FSWs were identified as follows:

- They are a hard-to-reach population. Sex work is illegal in Kenya, so women who are engaged in the profession do not want to be identified as sex workers. The illegal status of commercial sex work also makes it challenging to assist sex workers in seeking legal redress when their rights are violated (mostly sexual violence).
- FSWs often use drugs and alcohol, which may lead to risky sexual behaviors that could expose them to HIV infection and poses challenges for behavior change. They are economically deprived and lack an alternative source of income, which leads to behavioral relapses despite continuous exposure to HIV prevention information and services.
- FSWs' typical working hours (working at night and sleeping during the day) make it difficult to reach this population with HIV prevention information and services.
- FSWs cannot access female condoms because they are not available or, if they are available, they cost much more than male condoms. It is challenging to talk to FSWs about protected sex when they do not have access to an affordable method of HIV protection that women can control.
- They fear going for an HIV test, which makes it challenging to mobilize them to access HIV testing and counseling services.
- They have multiple (often concurrent) sexual partners, which poses a challenge to behavior change education among this target group.
- They are mobile due to the nature of their work, which forces them to move from one place to another in search of clients. This makes it difficult to reach them with consistent HIV prevention information and services.

3.1.2 Strategies

The community stakeholders in our workshop also listed strategies they considered successful or unsuccessful for influencing the behavior of sex workers in Bondo and Rarieda. The strategies they cited as successful were:

- Initiating income-generating activities and microfinance to get them out of sex work as means of survival
- Organizing workshops on human rights, legal issues, and risk-reduction methods to empower FSWs and minimize the risk of HIV infection

- Offering "moonlight" voluntary counseling and testing (VCT) and HIV awareness outreach services at night using peer FSWs as entry points
- Developing information, education, and communication (IEC) materials that specifically target sex workers
- Organizing regular community education on drug and substance abuse
- Strategies community stakeholders considered unsuccessful in influencing sex workers included:
- Daytime mobile VCT outreach
- Partner involvement. FSWs have multiple sexual partners, so it is difficult to identify which one to involve.
- Mobilizing FSWs to form groups where they can be reached. They are very mobile and have no time to engage in such forums.
- Involving employers of FSWs. FSWs would not wish to be identified as sex workers to their employers. Many of them who work in bars, hotels or salons and also engage in sex work.

3.1.3 Secondary target audiences

When asked whom else to involve in campaigns targeting FSWs, workshop participants recommended the following secondary target audiences—groups that may, with capacity building, influence sex workers' decisions:

- Establishment owners and managers
- Other members of the FSW community
- Their sexual partners/clients

To help educate FSWs about PrEP, workshop participants recommended that the following secondary audiences be involved through PrEP advocacy meetings:

- Health care providers and health workers involved in follow-up care and adherence counseling
- Local government officials: chiefs, assistant chiefs, and district officers
- Local leaders, including political and church leaders

3.1.4 Potential benefits/demand drivers for PrEP

A study in Nairobi found that FSWs were amenable to taking PrEP, with over 50 percent saying they would probably use PrEP upon availability and around 40 percent saying they would likely use it once it became available. Mild, temporary side effects were not seen as a deterrent to use, nor was regular HIV testing; only about a quarter of the women said they would not take PrEP if routine testing were required. Most women indicated that PrEP would give them a lot or some hope. A quarter of women said they would definitely or probably tell partners they were taking PrEP, and about a third said they would not mind either way.[52]

From our interviews with FSWs in this study, we learned that the benefits/demand drivers for PrEP for this population are the ability to care for their children and "have a good life" if they can remain HIV free. Additional research is warranted to help learn more about what it means to "have a good life."

Table 1 Summary of FSW characteristics

Variable	Description
Geographic	Bondo and Rarieda districts, Nyanza Province
Demographic	• Self-identified FSWs • Comprise 6.9% of the national female population[39] • HIV prevalence among FSWs in Kenya is 50% to 80% • Aged early to mid-20s • Unmarried (about half separated or divorced) • 1+ children • At least 2 regular sexual partners (some former clients) who may also pay them for sex directly or indirectly (e.g., rent, food, clothing, school fees) • Low number of partners considered clients (e.g., 3 clients over 4 weeks)
Life circumstances	Subsistence living

Variable	Description
HIV risk factors	• Multiple concurrent partners who also have multiple concurrent partners • Low prevalence of condom use with regular partners • Forced unprotected sex with clients and regular partners • Drug and alcohol abuse • Economic deprivation, leading them to engage in sex work and make behavioral choices based on money • Early onset of sexual activity • Unprotected anal sex as a result of client demand
Factors contributing to vulnerability	• Illegal status and clandestine nature of sex work in Kenya, which make it difficult to reach them with interventions • Lack of power to negotiate condom use • Stigmatized by the community • Low level of education • Some are illegal migrants

Challenges of working with this population	• Hard to reach due to legal repercussions of being identified as sex workers
	• Behavior change is difficult due to:
	  • Alcohol and drug abuse
	  • Lack of alternate source of income
	  • Having multiple concurrent partners
	• Non-traditional working hours makes it difficult to reach them with services
	• Female condoms unavailable
	• Fear of HIV testing
	• Mobility of the population, which makes it difficult to reach them with consistent messages and services

Variable	Description
Secondary target audiences	• Establishment owners and managers • Their peers (other FSWs) • Their sexual partners/clients • Health care providers • Local government officials: chiefs, assistant chiefs, and district officers • Local leaders, including political and church leaders
Potential benefits/ demand drivers for PrEP	• Ability to care for children and "have a good life" if they can remain HIV-free

3.2 HIV-negative members of stable discordant couples trying to conceive

Our second target population for the social marketing plan is HIV-negative members of HIV-serodiscordant couples who are trying to conceive. Current behavioral risk-reduction options for discordant couples include abstinence, correct and consistent condom use, and reduction of outside sexual partnerships,[53] but most of these measures are not applicable for couples trying to conceive. When the infected partner is the man, strategies for minimizing the risk of transmission to the uninfected woman include sperm washing plus intrauterine insemination (which may not be accessible in resource-limited settings), screening and presumptive treatment for sexually transmitted infections (STIs), delaying efforts to conceive until viral load is controlled, and limited, unprotected sexual encounters around the time of ovulation. When the woman is the infected partner, options include artificial insemination (which may not be accessible in resource-limited settings), screening and presumptive treatment for STIs, delaying efforts to conceive until viral load is controlled, limited unprotected sexual encounters timed to ovulation, self-insemination, and male circumcision.[54, 55]

Discordant couples are an appropriate population for PrEP because they may have unprotected sex in order to conceive[56, 57] and their use of PrEP could be limited to the period leading to conception, after which they could use condoms. Their short-term use of PrEP could limit the risks and disadvantages associated with long-term usage, including fetal exposure, side effects, high monetary costs, and potential adherence challenges.[58] One mathematical modeling study in South Africa found that providing PrEP to HIV-negative members of discordant couples could be at least as cost-effective as providing early antiretroviral therapy (ART) to the infected partner.[59]

A study conducted in Nairobi found that PrEP would likely be highly acceptable to serodiscordant couples. Over 50 percent said they would definitely use PrEP upon availability, and over a third said they would likely use it once it became available. Most respondents were definitely or probably willing to take PrEP with mild, temporary side effects, and about three-quarters reported that they would either definitely or probably take PrEP if regular HIV testing were required. Partner disclosure was unproblematic, with over 60 percent wanting their partner to know they were taking PrEP.[52]

In 2007, there were nearly 350,000 discordant couples in Kenya.[60] In Nyanza Province, 13 percent of couples were discordant in 2008-2009.[6] Discordant couples have been identified as an at-risk group in the Kenya National AIDS Strategic Plan,[8] but prevention strategies have been weakly implemented, contain no systematic messages, and have been left to research pilot projects.[11]

Discordant couples may not always discuss their fertility intentions with providers. However, making providers and clients aware of PrEP as a means for couples to try to conceive while reducing HIV risk could provide an opportunity for them to initiate a dialogue about pregnancy intentions. It has been shown that couple-based interventions have been most effective for reducing transmission among discordant couples through behavioral interventions.[61]

Demographic and behavioral characteristics of discordant couples in general (not just those trying to conceive) were reported in the Partners study on the use of acyclovir for HSV-2 suppression to reduce HIV-1 transmission in serodiscordant couples at 14 sites in Africa, including four sites in Kenya. In this study, the HIV-negative partners were primarily male, with a median age of 35 years. Two-thirds of HIV-positive partners were women, with a median age of 33 years; 76 percent of them were married.[62] However, others have found that men and women in discordant couples in Africa were equally as likely to be the uninfected partner. Most couples in the Partners study had cohabitated for a median of five years. Nearly 30 percent of them reported at least one unprotected sex act in the previous month. In addition, 5 percent of the men —both HIV-positive and HIV-negative —reported sex with outside partners, as did less than 2 percent of the women.[62]

Discordant couples in general may be difficult to identify for several reasons that contribute to their vulnerability, as described by community stakeholders in our district workshop. First, one or both members of the couple may be unaware of

their HIV status. Couples who are aware of their status often fear stigma in the community and family if they come out publicly. In particular, HIV-positive members of discordant couples are often labeled as promiscuous and blamed for bringing "death" to the family or community. These couples may also be difficult to follow over time because they tend to have high rates of divorce or separation, leading to changes of residence.

In our interviews with HIV-negative men and women in discordant couples, self-described risk factors for HIV infection included unprotected sex with their stable partners or other partners and having multiple sexual partners, including after taking alcohol. These findings are supported by other studies of discordant couples in which HIV-positive partners have been found to have unprotected sex with outside partners[63, 64] and HIV-negative partners have reported less condom use with outside partners. Condom use is reported to be low among married couples in Kenya.[65]

Other risk factors may include fear of disclosure of HIV-positive status to a discordant partner due to concerns about stigma, and a belief that serodiscordance within couples is not possible.[66] In one study in Rift Valley, Kenya, HIV-positive women in discordant couples reported fearing that if their status was seen as indicative of infidelity, their children could be disinherited.[66]

However, in the Kenya AIDS Indicator Survey 2007, members of married or cohabitating couples were found to be more likely to disclose their status to a partner (86.2 percent of women and 76.4 percent of men) than people with girlfriends/boyfriends or in casual relationships.[60]

3.2.1 Challenges

The following challenges of working with discordant couples were identified in our district-level workshop with community stakeholders:

- There is stigma and discrimination within the community and family against those who are HIV-positive. Those who are HIV-positive in discordant relationships are labeled as promiscuous and are blamed for bringing "death" to the family or community. This stigma makes it challenging to provide HIV services to such couples.
- They are hard to find because they do not come out publicly.
- They tend to have high rates of divorce or separation, which leads to changes of residence, making it difficult to provide consistent HIV services to this target group.

3.2.2 Strategies

These community stakeholders also cited strategies they considered successful or unsuccessful in influencing discordant couples' behavior to prevent HIV infection. Strategies cited as being successful were:

- Mobilizing them to form discordant couple support groups
- Enhancing prevention with positives (PWP) activities
- Promoting VCT, particularly couples' testing
- Organizing education sessions on HIV/AIDS and how to cope with discordant status
- Strategies considered unsuccessful were:
- Organizing trainings and workshops for discordant couples, due to the lack of local-level health workers trained on HIV-discordant couple relationships.

3.2.3 Secondary target audiences

District workshop participants also suggested the following secondary target audiences who would need to be reached due to their influence on discordant couples' decisions:

- Family members
- Health care providers – both public and private sector
- Community development program planners and implementers (leaders and community workers from community-based organizations and NGOs)
- Community members at large, e.g., could include peers
- Local government officials: chiefs, assistant chiefs, and district officers

3.2.4 Potential benefits/demand drivers for PrEP

We suggest that this population may find PrEP attractive as a means to conceive while reducing the risk of HIV transmission or acquisition, which could provide access to a family life previously seen as inaccessible or achievable only by the negative member of the couple risking HIV infection. Message concepts will need to be developed and tested to determine how to best describe and communicate a relevant benefit for PrEP to HIV-negative men versus HIV-negative women.

Table 2 Summary of characteristics of discordant couples trying to conceive

Variable	Description
Geographic	Bondo and Rarieda districts, Nyanza Province

Demographic	• Discordant couples trying to conceive
	• 13% of couples in Nyanza are serodiscordant
	• High rate of divorce among discordant couples in general
	• Proportion of male vs. female HIV-negative partners unknown, but in the Partners study among discordant couples:
	  • Over half of HIV-negative partners were men (67%), with a median age of 35 years
	  • Two-thirds of HIV-positive partners were women (67%), about 75% of whom were married; median age of 33
	  • Cohabitated for median of 5 years

Life circumstances	Most discordant couples can only try to conceive at a risk to the uninfected partner

Variable	Description
HIV risk factors	HIV-negative women in discordant couples • Unprotected sex with stable partner • May also have unprotected sex with outside partners HIV-negative men in discordant couples • Unprotected sex with stable partner • May also have unprotected sex with outside partners • Having multiple sexual partners, including after taking alcohol • Lower condom use among HIV-negative partners with outside partners
Factors contributing to vulnerability	Difficult to identify due to: • Lack of awareness of status • Stigma, especially HIV-positive members labeled as promiscuous and bringing "death" to family or community • Reluctance to express fertility intentions to providers
Secondary target audiences	• Family members • Health care providers – both public and private sector • Community development program planners and implementers • Community members at large, e.g., could include peers • Local government officials: chiefs, assistant chiefs, and district officers
Potential benefits/ demand drivers for PrEP	Suggested approach: PrEP provides an opportunity to conceive a child without transmitting or becoming infected with HIV, which may provide access to a life previously seen as inaccessible without risk of infecting the negative partner.

3.3 Widows

Our third target population consists of widows of the Luo ethnic group in Bondo and Rarieda districts. The Luo are a patrilineal, polygynous ethnic group who practice widow inheritance when a woman's husband dies. Traditionally, a widow is inherited by relatives of her deceased husband. Unprotected sexual intercourse is required for "sexual cleansing" as part of inheritance rituals, as well as before major events.

Relatives of the deceased husband are increasingly hiring non-relative professional inheritors or "cleansers" because many women's husbands are feared or known to have died of AIDS.[67-71] The rise of professional inheritors/cleansers may also be related to the high demand for this service due to the large number of HIV-related deaths.[71]

Both professional inheritors/cleansers and inheritors related to deceased husbands typically have multiple sex partners (e.g., their wives and potentially other widows), increasing the risk of HIV transmission. Uninherited widows are also at risk of HIV infection—they are often in dire economic straights and may have unprotected sex with multiple men who may help them economically (sometimes considered a form of transactional sex). The population of Luo widows is therefore appropriate for PrEP because of their high risk of HIV infection.

The Kenya Demographic and Health Survey 2008-09 reports HIV prevalence among widows as 43.1 percent.[6] Agot and colleagues (2010) categorized Luo widow inheritance by type of inheritor (brothers or cousins of deceased husband, or non-relatives) and purpose of inheritance (companionship, to fulfill sexual cleansing rituals for widows after the husband's burial or upon the birth, marriage, or death of a close family member, or to establish homes) to identify whether HIV prevalence varied according to these variables. Widows inherited for companionship and support tend to form long-term relationships with their inheritors, whereas those inherited to fulfill sexual rituals have short-term relationships with different inheritors, who may include professional inheritors.[67, 69] Agot et al. found that widows inherited by non-relative males for sexual rituals were more likely to be infected with HIV than those not inherited, and that widows inherited for companionship by relative males were less likely to be infected than uninherited widows.[67]

Social pressures within the community encourage widows to be inherited. For example, they otherwise may not be permitted to enter homesteads or work, they are prohibited from and impede other family members from planting, and misfortune is said to be likely to befall their children.[69, 71] In our district workshop, community stakeholders experienced in working with widows suggested that it can be difficult to get them to change their behavior, such as insisting upon condom use, given the pressure

of cultural norms and traditions, including those requiring sexual cleansing through unprotected sex. Others have noted that condoms are often not used due to local beliefs that HIV cannot be transmitted during cleansing rituals.[71]

Widows often consider widow inheritance beneficial because it allows them to gain social acceptance in the community, prevents them from having multiple sexual partners, enables them to conceive more children, can be economically beneficial, and allows for satisfaction of sexual needs.[69] However, whereas traditionally widow inheritance meant economic and social support for the widow, many inheritors are reported to no longer contribute financially to the household and may in fact expect to be provided with food and services. Furthermore, children fathered by the inheritor are believed to belong to the deceased husband and are often not supported financially by the father as in the past.[68, 69]

Although Agot et al.'s study showed that widows inherited by men related to the deceased were in actuality less likely to be infected than uninherited women, Luke 2002 found that inherited widows are more likely than married women and uninherited women to believe that they are at higher risk of HIV infection.[72] As a result, some widows elect not to be inherited.

Luo widows tend to be in their thirties, with several children. In a 1991-1992 study among 92 Luo widows over age 25 in South Nyanza district, the mean age was 34 years, with 96 percent younger than 55 years of age. Each widow supported a mean of five children and earned an average annual income of Ksh 7000 (US$200) per year. Over half had been inherited, and 34 percent had plans to be inherited.[69] A 2002 study among eight widows in Nyanza Province found them to be in their thirties with between four and six children.[70]

Widows' risk factors for HIV infection include being members of the Luo ethnic group, which practices widow inheritance. As mentioned, as part of these cultural rituals, they have unprotected sex with inheritors, who are increasingly professional inheritors who have multiple partners, including multiple widows.[71] Widows also have multiple partners when they make use of multiple professional inheritors or cleansers for different events. In addition, widows often divorce their partners and take on new partners, increasing their sexual networks.[69, 73] Widows who are not inherited may have boyfriends who are older and married. They may not use condoms with boyfriends, who are perceived to be less risky sexual partners than inheritors and an economic necessity.[72]

In addition, widows we interviewed described believing that their partners' behavior put them at risk because the partners have sex with other women without a condom. One widow noted that her partner may have sex with other women after drinking, and another said she was at risk from her partner because she does not know "the way he moves." Another widow we interviewed noted that she was in a polygamous relationship and herself had multiple partners (Interviews with widows).

An additional consideration for HIV risk is that a husband's death often results in economic deprivation,[70] which leads widows to engage in income-generating activities such as fish trading — which carries its own risks for HIV including fish-for-sex relationships with fishermen[74, 75] — and prostitution or transactional sex.[68] Daily challenges for widows include taking care of their children despite their poverty, and land inheritance and property grabbing.[70]

3.3.1 Challenges

Community stakeholders in our district workshop described the challenges of working with widows to prevent HIV as follows:

- It is challenging to work with this group in the context of the discriminatory cultural norms and traditions that are imposed on young women of reproductive age. These cultural norms and traditions have a negative effect on this group's ability to access and use HIV prevention services and methods. For example, the cultural practice of widow cleansing and inheritance prohibits a widow to fulfill sexual rituals using a condom.
- Economic deprivation and a lack of alternative sources of income make widows more vulnerable. It is challenging to convince such women to change their behaviors.

3.3.2 Strategies

Participants in the district workshop also cited strategies they considered successful and unsuccessful in influencing widows' behavior. The strategies they had found effective include:

- Encouraging widows to form groups, which provide a forum for reaching them. Through these groups, the women can initiate income-generating activities to pull themselves out of economic deprivation and dependency.
- Organizing community meetings to educate widows about their human rights
- Involving widows directly in planning and implementing HIV prevention interventions

Conversely, interventions initiated without involving widows in planning and implementation were described as unsuccessful.

3.3.3 Secondary target audiences

Secondary target audiences recommended for a social marketing campaign to reach along with widows include:

- Community gatekeepers and opinion leaders
- Local women's group/organization leaders, e.g., local Maendeleo ya Wanawake, Federation of African Women Educationist in Kenya (FAWE)
- Church leaders
- Local government officials: chiefs, assistant chiefs, and district officers
- Health care providers
- Beach Management Unit leaders
- Friends and relatives, e.g., in-laws
- Widows' sexual partners

The workshop participants suggested that members of these secondary audiences be involved in providing information about PrEP to the general community, as well as in community sensitization and creation of awareness about HIV/AIDS.

In addition, they noted that friends and relatives could encourage and motivate PrEP users to adhere to the drug regimen and that health care providers could be involved in the education and monitoring of clients.

3.3.4 Potential benefits/demand drivers for PrEP

We suggest that PrEP may be appealing to widows to help them fulfill their desire to take care of their children. More research is needed to develop and test this message.

Table 3 Summary of characteristics of widows

Variable	Description
Geographic	Bondo and Rarieda districts, Nyanza Province
Demographic	• Widows in Luo ethnic group • 43.1% prevalence in Kenya among widows • Most are inherited and participate in inheritance and sexual cleansing rituals before important events • May make use of professional inheritors and cleansers, who pose greater risk of HIV infection due to having unprotected sex with more partners, including other widows whose husbands may have died from AIDS • ~165,000 • In their 30s • Average of 5 children • Living in poverty • High rate of subsequent divorce
Life circumstances	• Aware of risk of HIV through widow inheritance practices but may not make distinction between professional inheritors and those related to deceased husband (greater prevalence among widows involved with the former) • Low awareness of risk among uninherited widows with boyfriends • Difficult to change their behavior of unprotected sex due to social norms

Variable	Description
HIV risk factors	• Unprotected sex: widow inheritance and cleansing with professional inheritors or cleansers (greater risk) • Unprotected sex: widow inheritance and cleansing with relatives of deceased (relatively lower risk) • Unprotected sex with multiple partners, including inheritors and boyfriends • Partners having unprotected sex with multiple partners
Factors contributing to vulnerability	• Extreme poverty may lead them to engage in high-risk activities, such as transactional sex including fish trade and having married boyfriends who help them economically
Secondary target audiences	• Community gatekeepers and opinion leaders • Local women's group/organization leaders • Church leaders • Local government officials: chiefs, assistant chiefs, and district officers • Health care providers • Beach Management Unit leaders • Friends and relatives, e.g., in-laws • Widows' sexual partners
Potential benefits/ demand	Suggested message: Ability to continue to care for children

3.4 PrEP client enrollment criteria

In addition to asking interview and workshop participants to suggest and prioritize target populations for PrEP, we also asked national public health stakeholders to develop preferred program enrollment criteria for PrEP users. These criteria could be used to develop a screening tool. Sociodemographic, biomedical, sexual behavior, and other behavioral factors they specified were as follows:

- Sociodemographic factors
- People 15 to 45 years old who are generally considered to be at high risk
- Able to adhere to drug and requirements (ages 15 to 59, generally able to adhere)
- People who marry early
- Proximity to the dispensing health facility for easy access and monitoring
- Sexual behavior factors
- Sexually active
- Have multiple partners
- In a relationship with an HIV-positive partner or a partner of unknown status
- Biomedical criteria
- Normal liver and kidney functions
- Normal blood functions
- Behavioral factors
- Mentally stable

We would also emphasize the need to include on the screening tool the potential user's self-assessment that he/she is someone at higher risk of HIV infection, given the need for high adherence to the 4 Objectives and Goals

Objectives and Goals

Objectives and Goals

4.1 Objectives

In social marketing, there three types of objectives. The behavior objective is the specific behavior the intervention is intended to influence people to adopt. The knowledge objectives are what the members of the target population must know, and the belief objectives are what they must believe, in order to perform the behavior. The following are the objectives of this social marketing plan:

Behavior Objective: To initiate and maintain the use of PrEP to reduce the risk of HIV infection

Knowledge Objectives: In order to initiate and maintain PrEP use, target populations must have an understanding of:

- How HIV is transmitted
- PrEP:
    - What PrEP is
    - The purpose of PrEP
    - How PrEP is used, including how often to take it
    - Percent efficacy of the drug when taken as PrEP to reduce risk of HIV infection, and the recommendation to pair condoms with PrEP to maximize protection
    - Side effects of the drug
    - Program requirements for taking PrEP, including:
- Frequency of visits with a provider or health worker
- Frequency of HIV testing and counseling, kidney and liver function testing, and pill refills
- Commitment of time for appointments
- The use of contraception, if applicable
    - Where PrEP services are located
    - Eligibility criteria for taking PrEP
    - How long they can remain on PrEP

- Any program incentives (e.g., counseling opportunities, ongoing HIV testing for health monitoring)
- Time costs
- Financial costs (e.g., for PrEP drug, transport)

Belief Objectives: It is essential for PrEP users to believe that:

- They are at risk of HIV infection
- PrEP is effective for reducing one's risk of HIV infection
- They have the self-efficacy to take PrEP and can overcome challenges related to taking PrEP (e.g., partner objection, remembering to take the pill, attending clinic appointments)

Other beliefs that would benefit PrEP users include that:

- They have the self-efficacy to affect their health
- The benefits of reducing their risk of HIV are worth the costs
- There are economic benefits to staying HIV negative
- It is possible to think about and plan for the future.

4.2 Goals and measures

Setting goals for a social marketing campaign provides a means to evaluate whether the campaign and the associated interventions are successful in encouraging the target population to fulfill the behavior objective — in this case, to initiate and maintain the use of PrEP to reduce one's risk of HIV infection. We suggest three goals and associated measures:

Goal 1: Maximize the target population's exposure to the campaign (based on available campaign budget).

It is unlikely that it will be possible to reach everyone in the target population, but we can estimate the percentage of the population that can be reached, depending on budget constraints, using the following formula:

Campaign budget ÷ cost per person exposed to the campaign = # of people exposed to campaign

Then calculate: # of people exposed ÷ size of target population = % of target population exposed to campaign

Suggested measures: Number and percentage of people within the target population(s) who are exposed to the campaign. This may include exposure to campaign messages through various media or

channels, including but not limited to:

- Radio – measured in number of listeners per radio program per month
- Video – viewers per location (i.e., clinical setting) per month
- Community meetings – attendance per month
- Community theatre – attendance per month
- Brochures – number of brochures distributed in a clinical setting and at community meetings per month
- Posters – number distributed and posted in clinical settings at program initiation and x months into the campaign
- Publications – circulation and/or distribution per month
- Outdoor media – unique impressions (e.g., # people exposed to a billboard) per month
- Internet – impressions/hits to a program website per month (with unique visitors counted only once even if exposed multiple times)
- Text messages – number sent, read, and responded to per month
- Hotline – number of callers per month

Goal 2: Reach target PrEP initiation numbers for the target population(s).

Those who enroll in a PrEP program are likely to be a small percentage of those exposed to the campaign, and less than 100 percent of the people who screen for eligibility. Campaign tactics that employ personal interaction with target population members commonly have the highest rates of enrollment. Enrollment rates for campaigns can be as low as 0.001 percent or as high as 30 percent of those exposed to the campaign.

Suggested measures: Number of people who:

- **Screen for eligibility to take PrEP.** Screening tests could include:
  - HIV test
  - Liver and kidney function
  - Personal risk assessment
- **Screen eligible.** We anticipate that eligibility criteria would be specified in national PrEP guidelines and may include:
  - Testing negative for HIV
  - Meeting liver and kidney function requirements
  - Client's self-assessment that she/he is at risk of HIV infection

- Additional criteria could include that the client:
  - Demonstrates an understanding of what is required from the individual in order to take PrEP
  - Asserts that she/he has the self-efficacy and intention to use PrEP to reduce her/his risk of HIV infection
- **Fill first prescription.** The number of people who fill their first prescription and reference some portion or deliverable from the social marketing campaign would be a measure of program outcome and would represent the effectiveness of the social marketing campaign. A target number for enrollment must be set at the beginning of the intervention.

Goal 3: Sustain PrEP use among the target population.

Suggested measures: Number of people who:

- **Adhere to the program requirements for a given period of time (e.g., six months)**, individually measuring:
  - Clinic appointments attended
  - HIV testing and counseling received
  - Blood tests for liver and kidney function received
  - Adherence counseling received
  - Self-reported adherence
  - Pills refilled
- **Discontinue PrEP**, including reasons why (e.g., assessment that no longer at risk of HIV; for discordant couples, upon conception of a child)
- **Seroconvert**

Barriers, Benefits, and Competition

Barriers, Benefits, and Competition

In social marketing methodology, the barriers are the reasons why members of the target population(s) may not be able to perform the behavior they are being encouraged to adopt. The benefits are what members of target populations see as the positive reasons for performing the behavior. The competition is what they are currently doing instead of the behavior promoted by the campaign. Potential barriers, benefits, and competition must be considered in the design of a social marketing campaign.

5.1 Barriers

During our district workshop with community stakeholders experienced in working with these populations, as well as in our interviews with members of target populations and civil society leaders, we identified potential barriers that local populations may have to initiating and sustaining use of PrEP (Table 4). (Note: The barriers in Table 4 are not organized by target population because many of the barriers cited for a given target population were potentially applicable to the other target populations.)

Table 4 Potential barriers to initiation and sustained use of PrEP

Types of Barriers	Potential Barriers
Access	Difficult to follow up because of change of residence following divorce and separation (discordant couples)
	Difficult to identify members of these target populations (discordant couples, FSWs)
	Distance for pill refills
	Evening working hours (FSWs)
	Mobile population (FSWs)
	No financial compensation for clinic visits
	Not wanting to pay for pills
Adherence	Cannot remember clinic appointments
	Cannot remember to take a daily pill
	Drug burden[1]
	Non-adherence to clinic appointments
	Non-adherence to drug
	Pregnancy and fertility concerns (women)
	Side effects[2]

Types of Barriers	Potential Barriers
Attitudes and beliefs	Community not accepting of PrEP
	Don't believe in HIV/AIDS
	Fear of giving blood (e.g., belief that it may be used for witchcraft, will cause HIV infection, too much blood is taken)
	Fear of HIV
	Fear of HIV testing
	Fear of taking the pill (may include fear of side effects)
	General suspicion
	May have negative attitudes towards HIV prevention
	People do not take pills if they are not sick
	Rumors and fears of side effects about PrEP
Cultural norms	Cultural and religious, norms, traditions and beliefs[3]
	Luo customs[4]
	Widow inheritance (widows)
Gender dynamics	Gender dynamics affecting decision making.[5]
	Men might think women are more susceptible to or responsible for HIV
	Partner Conflict
	Perception of being promiscuous (women)

Types of Barriers	Potential Barriers
Other	No likely barriers
Stigma	Fear of stigma and discrimination due to status disclosure (e.g., to partner, family, others)
	Fear of stigma and discrimination related to taking an ARV for HIV prevention

[1] Drug burden refers to when people may experience fatigue from taking a pill on a frequent basis.

[2] Side effects cited for women include changes in menstruation, reduced libido, reduced sexual pleasure, and weight gain.

[3] Religious beliefs cited were the prohibition against condom use, giving blood, taking drugs, and attending clinics or hospitals.

[4] The Luo custom cited was that men have to have sex with women "no matter what."

[5] The gender dynamics affecting decision making that were cited were that a woman might need a man's permission to take PrEP and men may need to feel superior and powerful [by controlling women's access].

Other potential barriers that may be important to consider include:

- Transport costs
- Time away from work
- Pill size
- Lack of family support
- Low HIV risk perception
- Fatigue with PrEP program requirements

5.2 Benefits

The key benefits in social marketing consist of what would motivate the target population to initiate and sustain use of PrEP. We sought to learn this by asking members of potential target populations about their dreams for the future. Most respondents in all target populations described an ideal future as to have "a good life," to be free of HIV and other diseases, to be able to raise their children, and to have more money. More research is needed to identify what else may comprise "a good life" for FSWs, discordant couples, and widows.

5.3 Competition

In social marketing, the competition consists of the main behaviors that people are currently practicing instead of the behavior we want them to adopt. In our case, given that PrEP was not available and therefore PrEP use was not possible to adopt as a behavior, we considered which behaviors were in competition with currently possible HIV prevention behaviors. These behaviors would also compete with initiating and sustaining use of PrEP. The HIV prevention behaviors that were described as difficult to achieve and the competing behaviors that put members of each target population at risk of HIV infection are listed in Table 5.

Table 5 Desired HIV prevention behaviors and competing risk behaviors for HIV

Target Population	HIV Prevention Behavior Difficult to Attain Source: Target population interviews	Competing Behavior that Puts Them at Risk Source: District community stakeholder workshop and national public health stakeholder workshop
FSWs	• Abstaining from sex • Consistent condom use • Not having sex when you have an STI • Limiting multiple partnerships	• Multiple sexual partners • Unprotected sex with regular partner
Discordant Couples	• Abstaining from sex • Limiting multiple partnerships	• Desire for children (unprotected sex)
Widows	• Abstaining from sex • Using condoms • Not having sex when you have an STI • Limiting multiple partnerships	• Rituals that require unprotected sex (e.g., widow inheritance, sexual "cleansing" of widows) • Engaging in high-risk behaviors due to financial needs

Positioning Statement

Positioning Statement

The positioning statement serves to frame how we want members of the target population to view initiating and maintaining the use of PrEP. The positioning statement typically consists of the following formulaic statement: We want (target population) to see (behavior objective) as (benefit) and as more beneficial than (competing behavior). This statement will be used in a three-step process for communicating with target populations and the general public about PrEP: 1) high-level endorsement, 2) a community campaign, and 3) sensitization of specific target populations.

Step 1: High-level endorsement

First, appropriate high-level government and/or public health stakeholders known to the public must endorse PrEP to the community. The specific message will need to be developed by these stakeholders to align with country priorities for target populations and use of PrEP. Some possible messages for the endorsement of PrEP include:

We want the community to see PrEP as a new HIV prevention option among other options to help people further reduce their risk of HIV infection and as more beneficial than inconsistent use of other risk-reduction methods alone.

We want the community to see PrEP as a new HIV prevention option for people to use on a short-term basis until they are able to reduce their risk of HIV through behavioral risk reduction, and as better than inconsistent use of other risk-reduction methods.

Step 2: Community campaign

Second, a public campaign will be needed to make the community at large aware of PrEP and encourage potential users to be screened. It will be important to develop messages that do not stigmatize particular target populations. Possible messages include:

- We want people who are at risk of HIV infection because they do not know their partner's status or because their partner is HIV positive to consider use of PrEP along with other risk-reduction methods as a way to ensure lower HIV risk and as better than not actively protecting themselves.
- We want people at risk of HIV infection to see themselves as empowered to reduce their risk of HIV through use of PrEP along with safer-sex behaviors and as better than inconsistent use of other risk-reduction methods.

- We want people at risk of HIV infection to see PrEP as a way to enjoy their families for years to come and as better than not effectively reducing their risk of HIV.
- We want the community to see PrEP as a way to generate health and wealth for the community through HIV prevention and as less costly than treatment.

Step 3: Target population-specific sensitization

Third, sensitization must occur with the specific target populations. This would likely not be done through a public campaign, because singling out particular target populations for PrEP might stigmatize them and/or PrEP. Rather, sensitization of target populations would need to occur more discreetly in appropriate contexts. Potential positioning statements for each target population include:

- We want discordant couples to see PrEP as a way to prevent the negative partner from becoming infected with HIV while they try to conceive a child, and as better than the risk of having unprotected sex to conceive a child.
- We want female sex workers to see PrEP as a way to protect themselves when they are unable to have protected sex with regular partners (including boyfriends and regular clients), and as easier than risking intimate partner violence by discussing condoms with these partners.
- We want widows to see PrEP as a way to live to raise their children whether or not they become inherited, and as better than having completely unprotected sex due to financial necessity or cultural norms.

Marketing Mix – Product, Price, Place, Promotion

Marketing Mix — Product, Price, Place, Promotion

7.1 Product

In social marketing, the "product" consists of what you will offer members of the target population if you sell them the desired behavior (i.e., initiating and sustaining use of PrEP). It includes the core product (the major perceived benefit of the behavior), the actual product, and the package of augmented products and services that you will offer.

The **core products** of initiating and sustaining use of a daily PrEP pill are reduced risk of HIV infection and therefore the potential for "a good life." (As noted, additional research on what comprises "a good life" would enhance social marketing efforts.)

The **actual product** is the behavior we are selling, i.e., to initiate and maintain the use of PrEP to reduce one's risk of HIV infection.

Augmented products include additional tangible objects or services, as well as improvements to existing products and services. **New tangible objects** to be included in the program and campaign efforts could include:

- A welcome kit. Providers could give each client who screens eligible a new-user voucher. The client would exchange the voucher for a welcome kit that could include the first prescription of pills, a brochure with pictorial instructions on taking the pill at the same time daily and a description of possible side effects, mnemonic devices such as a pill box and calendar, stickers to mark dates of clinic appointments and support group meetings on the calendar, a supply of male and/or female condoms to ensure maximum protection against HIV, and the manufacturer's brochure detailing instructions for taking PrEP and the drug's side effects.

- Male and/or female condoms to be distributed with each prescription of PrEP pills

New services we suggest to be offered to all PrEP users focus on providing information and psychological support and include the following:

- Support groups to address barriers related to:
  - Adherence to the drug regimen and other program requirements
  - Partner conflict
  - Family support
- Couple-based counseling, as applicable, that would take into account gender norms that affect decision making and that would address barriers related to:
  - Adherence
  - Risk reduction
  - Partner conflict
- Adherence counseling that would address:
  - Benefits of compliance
  - Side effects
  - Pill size
  - Ongoing follow-up visit requirements

New services suggested in the study data to address the particular barriers of each study population to initiation and sustained use of PrEP include education sessions, support groups, group counseling, couples' counseling and couples' HIV counseling and testing (HCT), moonlight, mobile, and home-based HCT, workshops, and fora (Table 6).

Improvements to existing services that were suggested for PrEP users in general include:

- Increasing mobile and/or home-based HIV testing for initial screening for PrEP eligibility
- Optimizing the existing laboratory infrastructure by improving networks between central and non-central labs
- Increasing the number of staff members trained to provide HIV risk-reduction counseling

Suggestions for improvements to existing services specific to target population were limited to discordant couples and included increasing numbers of staff trained in couples' counseling and enhanced prevention with positives (Table 6).

Table 6 New services and improvements to existing services that could be offered to address population-specific barriers

Target Population Barrier	New Service	Improvement to Existing Service
Discordant Couples		
Difficult to identify members of target population	• Support groups where members can come together to support each other • Couples' HCT	
Difficult to follow up because of change of residence following divorce and separation	Continuous couples' counseling to help couples understand serodiscordance and avoid transmission	• Increase the number of staff trained to counsel discordant couples, including counseling to help couples stay together • Enhance prevention with positives (PWP) activities
Fear of stigma and discrimination due to status disclosure	• Education sessions on how to cope with discordant status • Couples' counseling • Group counseling	Enhance PWP activities
Non-adherence to drug, drug burden	Couples' adherence counseling	
Partner conflict	Couples' counseling	

Target Population Barrier	New Service	Improvement to Existing Service
FSWs		
Difficult to identify members of target population due to nontraditional working hours and legal status	• Moonlight VCT • Daytime mobile VCT outreach • Workshops on human rights, legal issues, and risk-reduction methods to empower FSWs	
Non-adherence to drug, drug burden	Continuous drug adherence education/counseling on the benefits of compliance	
Partner conflict	Couples' counseling with primary partner	
Widows		
Difficult to identify	Forums for widows	
Fear of HIV testing	Moonlight VCT Home-based HCT	
Non-adherence to drug	Adherence counseling	

7.2 Price

In social marketing, "price" refers to the monetary and non-monetary costs, incentives, and disincentives related to selling a behavior.

The monetary costs of a PrEP program and campaign would consist of the costs of tangible objects (e.g., the PrEP pill) and any services related to PrEP service delivery. Tangible objects and services related to PrEP service delivery include what the target populations will pay for things like the PrEP pill, HIV testing and counseling, laboratory tests, and the cost of transportation to and from clinic appointments. (Programmatic costs related to the execution of a social marketing campaign would likely be funded at the level of government, NGOs, and/or private organizations delivering PrEP services and would incur no costs to clients, e.g., for staff training, mentorship, and follow-up.) Line items for these potential costs appear in the budget templates in section 9, Budget.

The non-monetary costs are the intangible costs related to using PrEP. Intangible costs to PrEP users include time (e.g., away from work, clinic wait time, travel time to and from clinic appointments), lost wages (income averted due to clinic visits), psychological costs, and physical discomfort (Table 7).

Table 7 Examples of non-monetary costs related to initiating and sustaining PrEP use

Costs	Behavior Requirements
Time	• Spending time away from work to attend clinic visits • Waiting in clinic • Traveling to and from clinical appointments
Wages averted	Missing work due to clinic visits
Psychological costs	Fear of: • Blood draws • Side effects • Stigma and discrimination Embarrassment
Physical discomfort	Experiencing and managing side effects

Possible monetary incentives could include vouchers for initial enrollment or for sustained, adherent PrEP use for a given period of time (e.g., 18 months), some type of cash transfer agreement, or other types of culturally appropriate rewards. The financial sustainability of any monetary incentives would need to be carefully considered.

Non-monetary incentives that could be considered might include the chance for a PrEP user to be featured in user testimonials for awareness generation or in a future demand generation campaign. This would involve portraying an adherent PrEP user leading a happy, healthy life, which would provide "proof" of the benefits of taking PrEP consistently.

Monetary and non-monetary disincentives may not be appropriate for a PrEP program.

7.3 Place

In social marketing, "place" involves where target populations would be encouraged and expected to perform the desired behavior. Considerations of place include making services as accessible as possible to the target populations (e.g., convenient location and hours of services), as well as providing support where target populations make decisions about performing the desired behavior.

7.3.1 Planning for PrEP Service Delivery

Public health stakeholders who participated in the workshops and interviews recommended several types of facilities in which to integrate PrEP services, as detailed below and outlined in Table 8. We were unable to collect potential target populations' preferences for where to access services due to the unexpected early closure of the study.

Table 8 Integrating PrEP: Facilities, rationale, challenges, and recommendations

Type of Facility	Rationale	Challenges to PrEP Delivery	Ways to Address Challenges
MCH clinics	Already offering PMTCT to antenatal care clients: women who test HIV negative could be referred for PrEP Would help reduce stigma	Men unlikely to go to clinics associated with women only	Rebrand as parent and child health centers. Conduct activities to promote male involvement. Add or expand waiting bays to make separate spaces for men.

Type of Facility	Rationale	Challenges to PrEP Delivery	Ways to Address Challenges
PSCs	Already offering HIV services needed for PrEP, such as HCT PrEP could be integrated into prevention with positives activities	Staff already overburdened Plagued by stock-outs and lack of storage space Stigma likely to be an issue	Train enough staff to provide PrEP. Expand pharmacies to provide additional storage space. Have friendly staff members who can direct clients to PrEP waiting bays and ease stigma.
Rural dispensaries	Ensure access for rural populations	Lack of capacity	Training clinical officers and nurses working in the facilities to provide PrEP. Provide HIV testing and follow-ups at the community level; have confirmatory tests done at referral hospitals or other facilities. Rely on community pharmacies for pharmacy services

Most public health stakeholders who participated in the workshops and interviews recommended integrating PrEP into existing services rather than having stand-alone parallel clinics. District and provincial public health stakeholders recommended integrating PrEP into outpatient services, including maternal and child health (MCH) clinics, HIV patient support centers (PSCs), family planning (FP) clinics, VCT points and PMTCT clinics. Provincial stakeholders cited an increase in staff workload as a challenge for all types of clinics. They also recommended training of receptionists in all clinics to ensure that clients coming in for PrEP services feel welcome and are not stigmatized.

Provincial stakeholders explored how integration of PrEP could work in MCH clinics, specifically, and the challenges that would arise. They described MCH clinics as appropriate settings for integrating PrEP services because provider-initiated HIV counseling and testing is already offered for women accessing antenatal care services. Women who test HIV negative but are assessed as being at risk of HIV infection could be referred for PrEP, while women testing HIV positive could continue to be referred for PMTCT. One challenge is that MCH clinics, as well as FP clinics, are associated with women, and therefore men are unlikely to go to these clinics. This challenge could be addressed by rebranding MCH clinics as parent and child care clinics, to dissociate the services with women. Male involvement activities, including awareness creation in the community and engaging male members of the community, could motivate men to access these clinics. In addition, waiting bays would need to be larger to accommodate men (who may not wish to queue with women and children) and the larger numbers of clients coming for PrEP. Integrating most health services (FP, ANC, PMTCT, and ART) in the clinics could help reduce stigma.

National and provincial public health stakeholders felt that PCSs would be appropriate for PrEP because they already offer the necessary services for PrEP. National stakeholders noted that PrEP would be integrated into existing prevention with positives services. However, provincial stakeholders described PSCs as plagued by a lack of storage space and unpredictable stock-outs of ARVs. Care and treatment personnel were also described as some of the most overburdened staff in the health care. Provincial stakeholders added that stigma is likely to be an issue if PrEP is integrated into PSCs, because they are stand-alone sites and are associated with HIV-positive people; HIV-negative people may not access PrEP services at PCSs out of fear of being labeled HIV positive. Some of these challenges could be addressed by training enough service providers to attend to PrEP clients and by expanding pharmacies to accommodate the storage space needed for PrEP supplies. Having friendly staff to direct clients to a PrEP service bay could help address stigma.

To ensure access for rural populations, provincial stakeholders recommended integrating PrEP services into the rural health facilities (dispensaries) and training clinical officers and nurses working in the facilities to build their capacity to provide PrEP services. Community mobilizers could encourage people to come for PrEP. HIV testing and follow-

ups could be done at the community level, whereas laboratory safety tests for liver and kidney function could be done at the facility level. Community pharmacies could provide pharmacy services.

National stakeholders recommended public health facilities (e.g., PSCs) and mission hospitals as suitable for offering PrEP to discordant couples, and private health facilities for target groups, such as FSWs, who use those facilities. NGO-supported facilities should be linked to public health facilities to provide referrals to PrEP services. These could be NGOs located within or outside the public health facilities. Mobile and fixed outreach should be implemented for hard-to-reach populations such as FSWs.

National stakeholders noted that not all potential PrEP users would be able to avail themselves of the services during normal working hours; they therefore recommended establishing a shift system to provide 24-hour services.

Note: The companion report to this social marketing plan, the Final Report of the HIV Services Inventory, details the services offered by the 29 facilities inventoried in Bondo and Rarieda districts and discusses potential readiness of facilities in the area to integrate PrEP.[76]

7.3.2 Where target populations would qualify to initiate PrEP use

Qualifying to initiate PrEP use will likely take place in several contexts. People interested in taking PrEP would need to get tested for HIV as part of initial screening for eligibility. This could be effected through community-based HIV testing such as mobile testing services or at facility-based testing centers. To improve HIV testing services so that they could test PrEP users regularly, such as every three months, community stakeholders recommended the following service-delivery innovations and improvements for each target group:

- FSWs:
  - Provide moonlight HCT outreach targeting FSWs.
  - Provide home-based HCT.
  - Conduct follow up of clients using schedule cards and home visits.
  - Develop a reminder system, e.g., phone calls to regularly remind clients to go for the test.
  - Mobilize clients to form support/buddy groups through which they can encourage each other to go for the test.
- Discordant couples:
  - Develop effective follow-up mechanisms to reduce defaulters.
  - Establish adequate and well equipped laboratories to speed the process of testing samples.
  - Conduct regular home visits to discordant-couple clients for ongoing counseling.
  - Encourage discordant-couple clients to form and participate in support groups for peer support and encouragement.
- Widows:
  - Provide home-based HCT.
  - Deploy enough counselors to the community VCT sites to speed service provision.
  - Provide incentives to encourage people to go for the test every three months.

Potential PrEP users who test negative for HIV and who are interested in learning more about PrEP would then need to be referred to a facility that provides PrEP services, where they would meet with a counselor or provider knowledgeable about PrEP and obtain laboratory tests for liver and kidney function. PrEP users would also need to access pharmacy services to receive their initial supply of PrEP.

7.3.3 Where target populations would sustain PrEP use

Sustained PrEP use would also require regular clinic visits, HIV and laboratory testing, adherence and risk-reduction counseling, and refilling pills, all on a schedule corresponding with the national protocol. PrEP use would also involve taking the PrEP pill at about the same time each day, at a convenient location of the user's choice, such as their home. Sustained PrEP use can be supported by use of augmented products mentioned previously such as a pill box or calendar, as well as client follow-up procedures such as program staff reminding PrEP users of clinic appointments by phone or in person.

Table 6, which has recommendations for new services and improvements to existing services, also provides relevant "place" strategies for supporting potential and actual PrEP users to initiate and sustain PrEP use.

7.4 Promotion

"Promotion" in social marketing includes key messages to communicate to target populations, people to sponsor and deliver the messages, channels for communicating those messages, and a campaign slogan.

7.4.1 Promoting PrEP to target populations

Key messages for each target population should be based on information in the positioning statements (see section 6). We do not provide the messages in this social marketing plan because they will need to be developed in collaboration with a creative/health communication agency and tested with the target populations, both of which were beyond the scope of our study. A campaign slogan will also need to be developed.

However, we do provide recommendations for spokespeople and channels for communicating messages to target populations. During our district workshop with community stakeholders, we asked participants to create strategies for educating their respective target populations about PrEP based on their experience working with those populations. The strategies in Table 9 include their recommendations for when and where target populations should be exposed to messages about PrEP, who should share the information, and in what format the messages should be communicated. Many of the places suggested would also be appropriate for educating the general community about PrEP, so that no single group of people would be singled out and potentially stigmatized.

Target Population	Where	When	How	Who
FSWs	Residence	Appropriate time agreed	• One-on-one • IEC materials	• Program staff • Community health workers • Peers
	Discos	Friday evenings	• One-on-one	• Health workers • Peers
	Bars and restaurants	Weekends or at night on weekdays	• One-on-one • IEC materials	• Program staff • Community health workers • Peers
Discordant Couples	Home visits	During follow-ups	• One-on-one	• Health workers • Community volunteers • Peer educators • Program staff
	Health facilities	During clinic visits	• Health talk sessions • IEC materials • Educational video shows	• Health workers
	Market places	Market days	• Community education meetings • IEC materials	• Health workers • Community volunteers • Peer educators • Program staff

Target Population	Where	When	How	Who
	Barazas	During chiefs' barazas once a month	• Community education meetings • IEC materials • Educational video shows • Community theater	• Health workers • Community volunteers • Peer educators • Program staff
	Community groupings	During group meetings	• Community education meetings • IEC materials	• Health workers • Community volunteers • Peer educators • Program staff
	Support groups	Support group meetings	• Educational video shows • Community theater	• Counselors and group leaders
Widows	Chiefs' barazas	During chiefs' barazas	• Community education meetings	• Community leaders and opinion leaders, e.g., chiefs and assistant chiefs
	Media	Every Saturday at 6:00 pm, when not very engaged	• Interactive radio program	• Radio and TV presenters

Target Population	Where	When	How	Who
	Group meetings	Afternoons (not during market days and should be during dry season)	• Community education meetings	• Health workers and leaders of women's groups
	Pre- and post-natal clinics	Clinic visits, during appointments and during working hours	• Health talk sessions	• Health workers
	Church	After church services	• Community education meetings	• Church leaders
	• Place of work • Markets	Convenient time	• Workplace outreach sessions	• Program staff
	Homes	Convenient time	• One-on-one	• Village elders and peers

7.4.2 Promoting PrEP to the larger community

National public health stakeholders in our workshop said that the Ministry of Health should spearhead the promotional effort to introduce PrEP as an HIV prevention method to the community, and that it should collaborate with other stakeholders and partners, including HIV implementing partners that offer HIV testing, funding organizations, the private sector, faith-based organizations such as mission hospitals, and civil society organizations. They cautioned that if PrEP promotion appeared to single out particular populations, it could exacerbate stigma and discrimination. National stakeholders in the dissemination meeting for this social marketing study also stressed this point, saying that target groups themselves should be involved in promotional efforts and that messages should be clear.

In addition to recommending print and electronic media and information, education, and communication (IEC) materials as channels for communicating PrEP messages, national stakeholders recommended that awareness campaigns collaborate with the provincial administration and community gatekeepers to make target populations aware of PrEP services. They also recommended sensitization meetings with community members, linkages with other stakeholders and partners, and collaboration with community health workers.

Civil society leaders we interviewed in Bondo and Rarieda recommended that the community be introduced to PrEP at village barazas, church groups and other public forums. Other suggested channels for introducing PrEP to the community included electronic media, radio, funerals, community health workers, posters around the community, peer educators, village elders, church leaders, comedians, community dramas, hospitals, dispensaries, shops, markets, schools, homes, beaches, and loudspeakers on vehicles driven around the community.

Many people felt that the media would not be the best way to introduce PrEP to this particular community. Others explained limitations such as the need to thoroughly educate the media to ensure accurate messaging and stressed the importance of counseling to communicate details, which is often not possible through media channels.

If media were to be used as part of the promotional effort, respondents recommended the local radio station, Ramogi, for disseminating news about PrEP. Other radio stations cited include:

- Victoria (Luo radio station)
- Nam Lolwe (Luo radio station)
- Maendeleo (Luo radio station)
- KBC
- Dholes
- Radio Citizen (Swahili radio station)

News programs and health education programs broadcast in the evenings or at lunchtime were recommended, as were youth programs, leisure talk shows/joke shows, and programs on ARVs, family planning, reproductive health, and HIV/AIDS prevention.

Other media channels suggested included newspapers, television, the Kenya Broadcasting Cooperation, other print media (e.g., brochures), cinema, billboards, and theater groups.

Civil society leaders also recommended the following specific components of the media messages:

- Target audiences of PrEP

  As a note of caution, we recommend that even though the media effort may be intended to mobilize the target populations described in this plan (or other target populations prioritized by decision makers), the mass media component of the campaign should not single out high-risk groups. A possible message for the mass media component is that PrEP is for "people who have unprotected sex with someone of unknown status or who is known to have HIV."

- Limited availability of PrEP

  Depending on the anticipated demand for PrEP and the target populations selected by public health decision makers, the campaign may also need to address the issue of availability—that initially the PrEP pill may not be available to the entire community because a limited supply of ARVs is available for treatment and prevention. Campaign organizers may want to develop a message that could be disseminated if demand for PrEP exceeds supply.

- Pill effectiveness

  Given that Truvada is only partially effective for HIV prevention and does not eliminate the chance of HIV infection, messages explaining partial effectiveness will be needed. Civil society leaders recommended being straightforward about telling people that PrEP is not 100 percent effective, giving people the actual percentage of efficacy, emphasizing that PrEP works to its maximum effectiveness only if taken as directed, and emphasizing that condoms should also be used to provide the maximum protection. Some respondents said to emphasize that people should not have sex thinking they are fully protected.

- How the pill works and how it is taken
- Where to access the pill

Other possible message components include:

- Discouraging behavioral disinhibition

  Civil society leaders recommended addressing the potential for behavioral disinhibition through education emphasizing the following points:

  - PrEP is not 100 percent effective.
  - Faithfulness is [still] important.
  - Disadvantages of having multiple partners and the advantages of using PrEP properly which includes limiting the number of sexual partners.
  - PrEP is only one HIV prevention strategy among many.
  - PrEP, like male circumcision and condom use, is not 100 percent effective.

  Other strategies suggested to discourage disinhibition include giving PrEP users consistent reminders, allowing them to come together to discuss disinhibition issues (e.g., in support groups), and properly training staff to address disinhibition.

- Discouraging stigma related to the PrEP pill being an ARV

  Civil society leaders recommended sensitizing the community to the fact that now with PrEP, one cannot assume that a person who is

taking an ARV is HIV positive. This community education message may best be disseminated via opinion leaders such as village elders, assistant chiefs, chiefs, beach leaders and teachers. Other respondents suggested working with stakeholders and influential people and using public forums, seminars, and barazas to address this issue.

National public health stakeholders recommended that community education about PrEP emphasize the following topics:

- Benefits of the program to the client
- Need for strict adherence
- Need for a willingness to practice other risk-reduction strategies in addition to PrEP
- Requirement for regular HIV testing

We asked public health stakeholders and civil society leaders to suggest names for an HIV prevention pill. Some public health stakeholders felt that keeping the name descriptive of the drug was best and suggested continuing to call it Truvada, "HIV daily prevention pill, "Pre-exposure pill", or "HIV PrEP." Because the pill is blue in color and oval shaped, names such as "Blu Gum" or "Blu Moon" were proposed. Kiswahili names were suggested by two stakeholders: Okoa Maisha, which means "save life," and Donge or Tonge, which means "something that can be taken easily." Other stakeholders felt that a name emphasizing the importance of the drug for preventing HIV was important. One stakeholder suggested naming the Truvada pill "Oxygen," explaining that without oxygen one would die, just as without the pill one could acquire HIV which could also be "deadly". Other proposals were "Prevention is Better than Cure", while another stakeholder suggested "A pill a day keeps HIV away" as the jingle to be used in marketing of the pill. Civil society leaders' suggestions for a name included:

- HIV preventive/HIV prevention drug
- CORE (Community rescuer)
- Disease stopper/HIV stopper
- Manyasi (traditional medicine)
- Okonyo oganda (it has helped the community)
- Shot

Monitoring and Evaluation Plan

Monitoring and Evaluation Plan

Monitoring the PrEP campaign and intervention will enable program planners to gain efficiencies when scaling up to a larger geographical area, more facilities, and/or an increased number of people. It will also enable them to decide if course corrections are needed in any area of the plan, such as in communication strategies, messaging, or client follow-up. In this section we suggest ways to measure the goals from section 4 of the social marketing plan (Tables 10 to 12).

Goal 1: Maximize the target population's exposure to the campaign (based on available campaign budget). Suggested measures include the number and percentage of people in the target population(s) who are exposed to the campaign through various media or channels.

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Table 10 Suggestions for measuring the number and percentage of people exposed to the campaign through media/channels (Goal 1)

Media/Channel	Measurement Techniques	Reporting Frequency	Reported by	Reported to
Radio	Radio station-generated algorithm to estimate listening audience, per time period	Monthly	Radio station	Social marketing campaign management
Video	Clinic estimate of potential video viewers based on patient population in the clinic, per time period	Monthly	Clinic	Social marketing campaign management
Community meeting	Actual record of the number of community meetings and estimated number of attendees	Monthly	Community meeting organizer	
Community theatre	Actual record of the number of community theatre performances and estimated number of attendees	Monthly	Community theatre organization	
Brochures and publications	Actual number of materials distributed and taken	Monthly	Clinic staff	
Posters	Estimate of the number of potential viewers based on patient population in the clinic, per time period	Monthly	Clinic staff	
Outdoor media (billboard, advertisements painted on buildings)	Estimate of the number of people who pass by and potentially view the media	Monthly estimate at initiation of contract	Owner or marketer of the outdoor media	

Media/Channel	Measurement Techniques	Reporting Frequency	Reported by	Reported to
Internet	Count of unique visitors and number of page hits	Monthly	Internet advertising agency	Social marketing campaign management
Text messages	Count of messages sent, received, and responded to	Monthly	Text message provider	
Telephone hotline	Count of number of calls received	Monthly	Hotline administrator	

Goal 2: Reach target numbers for PrEP initiation (i.e., program enrollment) for the target population(s). Suggested measures include the number of people who screen for eligibility, screen eligible, and fill their first prescription.

Table 11 Suggestions for measuring the number of people who initiate PrEP (Goal 2)

Measures (# of People Who)	Criteria	Measurement Technique	Reporting Frequency	Reported By	Reported to
Screen for Eligibility	Screening tests: HIV test, liver and kidney function test, personal risk assessment	Clinic records: Number of people screened	Monthly	Clinic staff	District, provincial, and/or national public health administration

Measures (# of People Who)	Criteria	Measurement Technique	Reporting Frequency	Reported By	Reported to
Screen eligible	Tests negative for HIV	Clinic Records: Number of people screened eligible and ineligible	Monthly	Clinic staff	District, provincial, and/ or national public health administration
	Meets liver and kidney function requirements				
	Client's self-assessment that she/he is at risk of HIV infection				
	Demonstrates understanding of what is required from the individual in order to take PrEP				
	Asserts that she/he has the self-efficacy and intention to use PrEP to reduce her/his risk of HIV infection				
	Obtains the PrEP pills	Pharmacy records: Number of PrEP pill prescriptions distributed		Pharmacy staff	

Goal 3: Sustain PrEP use among the target population. Suggested measures include the number of people who adhere to the program requirements for a given period of time (e.g., six months), discontinue PrEP, and seroconvert.

Table 12 Suggestions for measuring the number of people who sustain PrEP use (Goal 3)

Measures (# of People Who)	Criteria	Measurement Technique	Reporting Frequency	Reported By	Reported to
Adhere to the program requirements for an agreed upon period of time	Clinic appointments attended HIV testing and counseling received Blood tests for liver and kidney function received Adherence counseling received	Clinic records	Monthly	Clinic staff	District, provincial and/or national public health administration
Adhere to the program requirements for an agreed upon period of time	Patients reporting adherence	Clinic records: Number of people reporting each level of adherence	Monthly	Clinic staff	District, provincial and/or national public health administration
	Pills refilled	Pharmacy records: Number of PrEP pill prescriptions distributed		Pharmacy staff	
	No longer being prescribed PrEP	Clinic records: Number of people that discontinue (and reasons why, if known)		Clinic staff	
	Tests HIV positive	Clinic records: Number of seroconverters			

Budget Considerations

Budget Considerations

In this section we provide budget templates to assist in the development of budget estimates for the elements in the social marketing plan. Included are budget line items for both a social marketing campaign and the programmatic costs of a PrEP intervention.

Although we do not address identification of funding sources here, it is, of course, fundamental to implementation of the plan. Funding sources could include governments, foreign government grants, nonprofit organization and foundation support, partnerships and coalitions, and corporation donations.

Sample Budget Templates

Social Marketing Programmatic Costs

Potential Steps and Related Costs	Unit	Type	Unit	Type	Unit Cost (KSH)	Total Cost (KSH)		
Creative development								
Agency labor		Man		hours				
Agency material fees (storyboards with campaign messages and visuals)		Time and Materials						
Materials review and testing								
Agency material fees		Time and Materials						
Dissemination of focus group results with sponsor		Person		days				
Materials finilization								
Agency labor		Man		hours				
Agency material fees (printing of brochures, posters, etc.)								
Brochures								
Posters								
Videos								
Print advertisements								
Commercials								

Potential Steps and Related Costs	Unit	Type	Unit	Type	Unit Cost (KSH)	Total Cost (KSH)		
Media Buys/Placement								
Radio		Commercials/ PSA		During pilot program				
Television		Commercials/ PSA		During pilot program				
Soap opera storyline (radio and/or television)		Content/context negotiation						
Internet		Site PSA						
Newspaper/publications		Advertisement /article		During pilot program				
Outdoor media		Site						
Loudspeaker public service announcements		PSA		During pilot program				
Text messages		Message		During pilot program				
Hotline		Setup, training		During pilot program				
		Ongoing labor		During pilot program				

Potential Steps and Related Costs	Unit	Type	Unit	Type	Unit Cost (KSH)	Total Cost (KSH)		
Measurement of reach/awareness of campaign (if not collected as part of media buys/placement)								
Radio - number of listeners		listeners		show				
Television - viewing audience		viewers		show				
Internet - impressions (unique visitors, hits)		impressions (unique/hits)		placement				
Publication - circulation and/or distribution		circulation		journal				
Outdoor media - measure of foot traffic/ impressions		impressions		site				
Loudspeaker psa - people along car route/ impressions		reach		population				
Text messages - # sent, # read, # responses		sent, read, responses		message				
Hotline - # of callers		callers		period				

Product Costs

Resource	Unit	Type	Unit	Type	Unit Cost (KSH)	Total Cost (KSH)		
Pill Cost		Pill		month				
Patient Testing								
HIV Test Kits (rapid and confirmatory)		Test		kit				
Liver/Kidney Function Tests		Test		kit				
Laboratory Equipment		Test		system				
Staffing (labor)		Man		hours				
- HCT counselors		Man		hours				
- Laboratory staff		Man		hours				
- Driver for sample transport		Hours		trip				
Staff Training		Man		hours				
Patient Counseling								
Staffing (labor)		Man		hours				
Staff Training		Man		hours				

Provider Costs

Resource	Unit	Type	Unit	Type	Unit Cost (KSH)	Total Cost (KSH)			
Provider									
Initial training		session							
Ongoing training		session							
Training materials		Materials							
Programmatic materials									
Trainers		man		hours					
Refreshments/meals									

Costs of Two-day Provider and Counselor Training

Date/Location of Workshop:

Resource	Unit	Type	Unit	Type	Unit Cost (KSH)	Total Cost (KSH)				
Facilitation										
Facilitator 1	1	Person	2	days						
Facilitator 2	1	Person	2	days						
Venue fee										
Venue	1	Venue	2	Days						
Meals/Tea	2	Food/Tea	2	Days						
Other										
Per diem										
Physicians		Person	2	days						
Clinical Officers										
Nurses										
Counselors										
Laboratory Technicians										
Transport and other										
Grand Total					**Total**					

Additional Costs of Service Delivery (per site per month)

Site:

Resource	Unit	Type	Unit	Type	Unit Cost (KSH)	Total Cost (KSH)			
Additional Staff Time (if CVD duties fit in to workload, ignore this part)									
Nurse	1	Person		hrs					
Physician	1	Person		hrs					
Nutritionist	1	Person		hrs					
Pharmacist	1	Person		hrs					
Materials and supplies									
HIV test			1	test					
Kidney Function Test			1	test					
Liver Function Test			1	form					
Pregnancy Test									

Costs of Capital* Required for Service Delivery

Site:

Resource	Quantity	Current Purchase Price	Estimated Useful Life (yrs)				
Clinical Equipment							
Blood pressure apparatus							
Weighing Scale							
Height measurement equipment							
Other							

*Capital refers to items that are expected to last for one year or more, and have an initial purchase price of at least US$100.

Costs of Training Workshop

Province:
Dates of Workshop:

Resource	Unit	Type	Unit	Type	Unit Cost (KSH)	Total Cost (KSH)			
Facilitation									
Facilitator 1	1	Person	2	days					
Facilitator 2	1	Person	2	days					
Venue fee (specify site)									
			2	days					
Per diem									
Physicians		Person	2	days					
Clinical Officers									
Nurses									
Counselors									
Nutritionists									
Pharmacists									
Laboratory Technicians									
Transport and other									
Grand Total					**Total**				

Plan for Campaign Implementation and Management

Plan for Campaign Implementation and Management

The plan for campaign implementation and management describes specific phases of the campaign and includes who will do what and when, and for what cost. Ideally, this plan will be designed to track the progress made over the life of the PrEP campaign and intervention. This working document is typically made available to share with all responsible parties (e.g., government public health administrators, funders, facility administrators, etc.). It is developed prior to initiation of the campaign and takes into account the total budget and timeline.

Table 13 provides a sample template for a campaign implementation and management plan. This tracking tool assumes a four-year timeline from hypothetical government approval of oral PrEP through the end of the initial campaign. The template is not comprehensive but may serve as initial guidance for developing the implementation and management plan.

Table 13 Sample template for a campaign implementation and management plan

Key Activities	Responsible Party	Time to Complete	Cumulative Time to Complete (Years)	Associated Budget	Cumulative Budget
Conduct SWOT/situation analysis for consideration of PrEP for HIV prevention in Kenya	Government administration/designee				
Approval of PrEP for HIV Prevention	Government administration				
Allocate money for PrEP in budget	Government administration				
Develop positioning statement for high-level endorsement of PrEP	Government administration/designee				
Assess at-risk populations (including size)	Government administration/designee				
Designate potential target populations	Government officials				
Select specific target populations based on risk profiles, ease of accessing, and available funding	Government officials/designee				
Start of Social Marketing Plan					
Develop target population profile (including factors influencing behavior adoption)	Party responsible for campaign implementation	3 mos	0.25 years		
Set marketing objectives and goals	Party responsible for campaign implementation	1 mo	0.3 years		
Develop positioning statements for the target population	Party responsible for campaign implementation	2 mos	0.5 years		

Key Activities	Responsible Party	Time to Complete	Cumulative Time to Complete (Years)	Associated Budget	Cumulative Budget
Develop key messages for target population and test key messages and marketing materials	Party responsible for campaign implementation	3 mos	0.75 years	a	a
Develop strategies for product, price, place, and promotion	Party responsible for campaign implementation with support from the creative agency	4 mos	1.05 year	b	a+b
Develop social marketing materials and identify appropriate channels	Party responsible for campaign implementation	4 mos	1.35 years	c	a+b+c
Buy and schedule media time	Creative agency	1 month	1.5 years	d	a+b+c+d
Implement social marketing campaign plan	National, provincial, and/or district public health decision maker or authorized NGO	2.5 years	4		a+b+c+d
Collect PrEP initiation numbers	Clinic staff	Ongoing	4		a+b+c+d
Measure campaign effectiveness (by channel)	Creative agency	Ongoing	4	e	a+b+c+d+e

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