



ARV-BASED HIV PREVENTION: STATE OF THE SCIENCE AND CONSIDERATIONS FOR IMPLEMENTATION

Consultation Report
Naivasha, Kenya
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List of Acronyms

AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Care
ARVs	Anti-retrovirals
BMGF	Bill & Melinda Gates Foundation
CCC	Comprehensive Care Center
CDC	Centers for Disease Control and Prevention
CHAK	Christian Health Association of Kenya
FBOs	Faith-based Organizations
FDA	Food and Drug Administration
FGDs	Focus Group Discussions
FIDA	Federation of Women Lawyers
FP	Family Planning
FSWs	Female Sex Workers
HIV	Human Immunodeficiency Virus
KEC	Kenya Episcopal Conference
KEMRI	Kenya Medical Research Institute
MSM	Men who have sex with men
PEP	Post-exposure prophylaxis
PoD	Proof of Deliverability
PMTCT	Prevention of Mother-to-Child Transmission
PrEP	Pre-exposure prophylaxis
MARPS	Most-at-risk populations
MCH	Maternal and Child Health
NACC	National AIDS Control Council
NASCOP	National AIDS & STD Control Programme
NEPHAK	National Empowerment Network for People with HIV/AIDS, Kenya
NGOs	Non-Governmental Organizations
SDCs	Sero-discordant Couples
SWOP	Sex Workers Outreach Programme
TasP	Treatment as Prevention
TB	Tuberculosis
TDF	Tenofovir disoproxil fumarate
TDF/FTC	Tenofovir disoproxil fumarate/emtricitabine (Truvada)
USAID	United States Agency for International Development
VCT	Voluntary Counseling and Testing
VMMC	Voluntary Medical Male Circumcision

Executive Summary

The National AIDS and STI Programme (NASCOP), under the Ministry of Public Health and Sanitation and the Kenya Medical Research Institute (KEMRI) co-chaired a meeting in collaboration with FHI 360 to assist Kenya policy makers, program managers and civil society advocates to consider issues related to the potential introduction of new anti-retroviral (ARV)-based HIV prevention technologies, specifically pre-exposure prophylaxis (PrEP) and microbicides. The meeting was funded by the United States Agency for International Development (USAID) and the Bill and Melinda Gates Foundation (BMGF).

Rationale

Pre-clinical and clinical research has examined the safety, efficacy, and effectiveness of oral PrEP and topical PrEP (also called microbicides) products that include ARV drugs to reduce HIV acquisition by uninfected women. In July 2010, the CAPRISA-004 clinical trial provided proof-of-concept for the pericoital use of tenofovir 1% gel, a vaginal microbicide. Women randomized to the tenofovir gel arm had 39% fewer HIV infections than women randomized to the placebo gel, and women with high gel adherence had 54% fewer infections. Additionally, tenofovir gel was found to reduce genital herpes (HSV-2) infection by 51%. The FACTS 001 clinical trial in South Africa is evaluating tenofovir 1% gel in the same dosing regimen as used in CAPRISA-004 in hope of showing efficacy in preventing HIV infection. The MTN-020 and IPM-027 clinical trials are also currently testing microbicide rings containing the ARV dapivirine for HIV prevention.

Three clinical trials evaluating the safety and effectiveness of oral PrEP had mixed results. The FEM-PrEP trial in women in Africa, which evaluated the effectiveness and safety of oral Truvada (a combination of emtricitabine and tenofovir disoproxil fumarate), was closed early in 2011 for futility, whereas the same product was shown to be 63% effective among uninfected heterosexual women and men in the CDC TDF2 study, and 72% effective among uninfected men and women in HIV-discordant partnerships in the Partners PrEP study. While the Partners PrEP study found oral tenofovir alone to be 63% effective in preventing HIV infection in couples, the VOICE trial, which is evaluating two daily oral ARV-based pills (Truvada and tenofovir-only) and daily tenofovir gel, announced in 2011 closure of its oral and topical tenofovir arms for futility. The VOICE trial continues to evaluate oral Truvada; results are anticipated in 2013. Further analyses of these trials have suggested that adherence is key to achieving high levels of effectiveness. Nonetheless, in July 2012, the United States Food and Drug Administration (FDA) approved Truvada for use as PrEP among individuals at high risk of HIV acquisition. Additionally, the United States Centers for Disease Control and Prevention (CDC) and WHO have recently released guidance documents for the use of oral PrEP.

Given promising results from some of the recent PrEP and microbicide trials, international donors and organizations have been working with governments and communities to consider whether to implement PrEP and microbicides for HIV prevention and when and how to do so. Beginning this conversation now is an important step in reducing the gap between research and implementation. Consequently, NASCOP, KEMRI, and FHI 360 worked together to hold a two-day consultation 'ARV-Based HIV Prevention: State of the Art Science and Considerations for Implementation.'

The consultation had the following goals:

1. To review the state-of-the-evidence around oral PrEP, microbicide gels and rings, and ARV injectables as HIV prevention tools, especially for women
2. To review recent work done in Kenya on PrEP and microbicide development and introduction
3. To facilitate discussion and feedback on potential service delivery channels, end user groups and approaches for introduction of PrEP and microbicides in Kenya

The meeting was attended by 43 individuals including policy makers from NASCOP, the National AIDS Control Council (NACC) and the World Health Organization (WHO); funders from USAID and BMGF; researchers from Moi University, the University of Nairobi, Kenyatta National Hospital, the Kenya Medical Research Institute, Liverpool Voluntary Counseling and Testing (LVCT), the London School of Hygiene and Tropical Medicine (LSHTM), Imperial College of London, the Population Council and FHI 360; and other non-governmental organizations (NGOs) and faith-based organizations (FBOs), including the Kenya Episcopal Conference (KEC), Federation of Women Lawyers (FIDA), Christian Health Association of Kenya (CHAK), the Network of People Living with HIV/AIDS in Kenya (NEPHAK), and AVAC.

Content

The meeting included overview presentations on the need for HIV prevention methods and combination HIV prevention, the state of the evidence on PrEP and microbicides, and lessons learned from HIV Prevention and advancing PrEP and microbicides in Kenya. It also included presentations and discussion of potential focus populations and service delivery channels for PrEP and microbicides. These presentations were informed by four FHI 360 PrEP and microbicides projects:

1. **The BMGF-funded study *Assessing Physical Delivery of PrEP in Support of Proof of Deliverability*** – implemented in Nakuru and Nairobi, Kenya, and KwaZulu-Natal in South Africa, to identify potential delivery channels, barriers to access the inputs necessary to deliver ARV-based HIV prevention technologies, including oral PrEP, vaginal microbicides, and an injectable form of PrEP.
2. **The USAID-funded study *Social Marketing Planning for Oral PrEP Rollout in Targeted Populations*** – a sub-study of the FEM-PrEP clinical trial, aimed to facilitate local planning for PrEP rollout. Results will be disseminated in the form of a social marketing plan with considerations for rolling out PrEP in Bondo and will include both service delivery and campaign components for three potential target populations.
3. **The USAID-funded *Microbicides Communication Strategy*** – aims to develop and evaluate a comprehensive communication strategy for microbicide end-users and health care providers.
4. **The USAID-funded *Gender Analysis for Microbicide Introduction*** – aims to identify how gender norms, roles, and relations will likely affect women's ability to successfully access and adhere to tenofovir gel.

Take Home Messages

Now is the time to be thinking about how to implement ARV-based HIV prevention methods in Kenya

From the welcoming remarks in which presenters acknowledged potential and exciting achievements in HIV prevention, to the closing summation, the timely nature of a meeting on ARV-based HIV prevention in Kenya was evident. The feeling was that *now* is the time to lay a foundation for the introduction of new and potential ARV-based HIV prevention methods. The meeting was likened to one held ten years ago in which the potential implementation of ARVs for HIV treatment was first discussed; and despite many naysayers and logistical challenges at the time, HIV treatment programs have had many successes. Yet, participants were also reminded that with 22.5 million HIV infections in Sub-Saharan Africa and three new infections for every two people started on treatment, *prevention* must also be a priority. AIDS remains the most common cause of death in Africa, yet the emergence of new prevention methods, such as treatment as prevention (TasP) and PrEP, provide evidence that an HIV/AIDS-free world is, in fact, a viable goal, and that we can accomplish this through both treatment and prevention. Successful PrEP demonstration projects, currently being conducted in Kenya, serve to reiterate this point as they show promise for reducing the incidence of HIV in Kenya. In the meeting evaluations, 95% of respondents either agreed or strongly agreed that it is necessary to deliver new HIV prevention methods in Kenya. A total of 60% thought that Kenya should currently be rolling out PrEP to potential users, and 90% felt that we should be planning for the introduction of microbicides in Kenya.

Leadership and support from the Kenyan government should be a priority

Participants were reminded of Kenya's successful voluntary medical male circumcision (VMMC) program, which benefited from advocacy and consultation within the Kenyan Parliament, State House, the Luo Council of Elders, the Cabinet, and specific communities where VMMC was being implemented. The success of the VMMC program hinged on the fact that it was driven by the Kenyan people and supported by the government; the same should be true for the implementation and roll out of other new HIV prevention methods. Participants felt civil society groups should work closely with the government to develop implementation procedures and regulations that are appropriate for Kenya. When asked about necessary next steps for ARV-based HIV prevention, participants felt strongly that the government should drive the ARV-based HIV prevention agenda, including the development of national guidelines.

Identification of focus populations and appropriate service delivery channels should include consideration of sociocultural norms and potential stigma

Participants indicated that community members, and women in particular, are excited about the potential of PrEP and microbicides. Participants discussed the different sociocultural and sexual contexts in which potential focus populations—women in stable relationships, discordant couples, female sex workers, and adolescents—find themselves. Many felt a need to prioritize high-risk groups for PrEP implementation, while microbicides could be implemented among the general population of women and potentially among adolescents. Participants were informed that over

50% of new HIV infections occur in young women, as widespread cross-generational and transactional sex between adolescent women and older men places young women at an increased risk of HIV. Although recent trials have excluded these women due to ethical considerations, it was clear that we should not forget their heightened vulnerability. On-going discussions may be necessary to finalize priority populations.

Successfully targeting specific populations would involve not only the need to tailor communication and advocacy messages, but also identifying the most appropriate service delivery channels and combination of prevention methods for each of these populations.

Service delivery channels and their impact on acceptability, adherence and coordination of care were also presented. Results from the BMGF-funded Proof of Deliverability Study revealed that the biggest challenges to effective service delivery of PrEP and microbicides centered on stigma, lack of perceived risk, knowledge and attitudes of clinic staff, and concerns about access and cost. Stigma and lack of perceived risk were common themes when discussing potential end-users as well.

Participants also engaged in discussions regarding the importance of conducting a gender analysis to identify the gender norms and sexual power imbalances that are likely to affect women's ability to access and use new HIV prevention products. Male-dominated gender norms, particularly surrounding sexual activity, make it difficult for women to negotiate the use of HIV prevention methods. Communicating with partners about HIV prevention is particularly important and also challenging for women in long-term relationships.

And finally, throughout the consultation, minimizing stigma was also seen as an important factor for increasing interest in and uptake of potential ARV-based HIV prevention methods among at-risk populations. However, participants felt that offering combinations of microbicides and family planning or other services might help to reduce stigma. And although female sex workers were identified as a potential target population for both PrEP and microbicides, there was much discussion about the potential harm of focusing microbicide implementation on populations who were already stigmatized by society. Careful consideration will need to be placed on how to target new prevention methods without stigmatizing their use.

Sustainable funding allocations and cost-effective programming must be prioritized

The need to plan for and identify sustainable funding of new HIV prevention methods was evident throughout the meeting. Most thought that funding for PrEP was somewhat likely to come out of the national budget, but that it would take several years to be allocated. Once allocated, understanding how new prevention funds will complement funds already allocated for treatment will also be necessary, as participants expressed concern about the limited human and financial resources necessary to deliver services, whether for treatment or for prevention. Participants felt that we must make a concerted, focused effort to empower effective combination prevention and treatment options so as to maximize the impact of limited resources. The importance of providing a range of products such that women *and* men have the opportunity to choose the method that best fits their needs was stressed. The idea that new methods and combination approaches should be considered for various seasons of a person's life was also discussed in the meeting, and should be

considered when conducting cost analyses. An example of this included the potential benefit of an HIV-negative partner using PrEP until the HIV-positive partner is on treatment. Focusing on a holistic approach and cost-effective guidelines will be crucial to the success of any new program.

Conclusion

Many questions remain regarding how and when to implement PrEP and microbicides as part of a combination HIV prevention package in Kenya. This consultation provided an important and timely opportunity to bring together key stakeholders to discuss key questions regarding PrEP and microbicides implementation.

Agenda

Tuesday 25 September

8:00-9:00am	Breakfast & Registration
9:00-9:15am	Welcome and Introductions (Dr. Irene Mukui, René Berger, Dr. Elizabeth Bukusi, Mr. Peter Mwarogo)
9:15-9:30am	The Need for New HIV Prevention Methods and Combination HIV Prevention (Dr. Nduku Kilonzo)
9:30-10:00am	Overview of Oral PrEP: Clinical Trial Findings and Next Steps (Dr. Nelly Mugo)
10:00-10:30am	Overview of Future Potential ARV-Based Products: Microbicide Gels, Rings, Injectables (Dr. Betty Njoroge)
10:30-11:00am	Tea Break
11:00-11:15am	Overview of the <i>USAID Shared Vision and Strategic Plan for Microbicide Introduction</i> (Mr. René Berger)
11:15-12:15pm	Lessons Learned from HIV Prevention and Advancing PrEP & Microbicides in Kenya (Panel: Ms. Lucy Ghati, Ms. Pauline Irungu, Dr. Joshua Kimani, Dr. Rex Mpazanje, Facilitator: Ms. Stacey Hannah)
12:15-12:30pm	Overview of Gates PrEP Proof of Deliverability Study (Dr. Emily Evens)
12:30-12:45pm	Overview of PrEP Rollout Study (Mr. Jacob Onyango)
12:45-1:45pm	Lunch
1:45-2:45pm	Potential User Groups (Dr. Betsy Tolley)
2:45-3:45pm	Product Access & Service Delivery (Dr. Emily Evens)
3:45-4:00pm	Tea Break
4:00-5:30pm	Breakout Sessions 1) <i>Proof of Deliverability: Potential PrEP and Microbicide Delivery Channels</i> 2) <i>Considerations for Social Marketing of PrEP</i>

Wednesday 26 September

8:00-9:00am	Breakfast
9:00-9:30am	Breakout Sessions Report Back from Day 1
9:30-9:45am	PrEP Effectiveness and Efficiency (Mr. Daniel Mwai)
9:45-10:00am	Overview of Gender Analysis for Microbicide Introduction (Ms. Michele Lanham)
10:00-10:15am	Overview of Communications & Advocacy for Microbicide Introduction (Dr. Betsy Tolley)
10:15-10:30am	Tea Break
10:30-12:15pm	Breakout Sessions <i>1) Gender Analysis for Microbicide Introduction</i> <i>2) Communications Research Plan for Microbicide Introduction</i>
12:15-12:45pm	Breakout Sessions Report Back
12:45-1:00pm	Summary of the Meeting (Dr. Elizabeth Bukusi)
1:00-2:00pm	Lunch
2:00pm	Departure to Nairobi

Setting the stage

During the morning session, Kenyan researchers, policy makers, program managers, and community advocates set the stage by describing the concept of combination prevention, providing an overview of PrEP and microbicide clinical research, and discussing some of the critical factors which should be addressed in terms of PrEP and/or microbicide introduction.

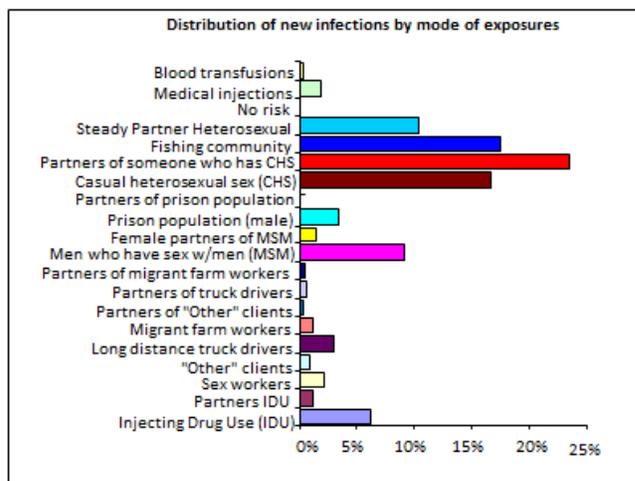
A. Need for New HIV Prevention Methods

In her presentation, Dr. Nduku Kilonzo, Executive Director of the LVCT, emphasized the need to sustain HIV prevention efforts, even in the face of financial constraints and the prevention benefits of early treatment for HIV-infected individuals. With three new infections for every two persons on treatment, ignoring HIV prevention would be like “wiping the floor with the tap running”. However, for these efforts to be successful, it is imperative to consider who is being targeted, with which interventions, and at what scale.

Dr. Kilonzo highlighted the case of a young Kenyan woman whose boy-friend may sometimes force her for sex, knowing that the fear of social reaction will keep her silent. For such women, HIV risk is intertwined with intimate partner violence and fear of social rejection. Referring to the “Modes of Transmission Study” (shown in the figure below), Dr. Kilonzo suggested that more research was needed to better understand who was most at risk.

Figure 1: Percentage New Infections by Different Risk Groups in Kenya

Kenya’s Modes of Transmission study: Do we really know who we are targeting?



An HIV Prevention Revolution is needed. At its core is the need to shift to a focus on populations, rather than interventions; to address the structural – and not just behavioral factors influencing risk; and to consider how best to intervene within the context of a combination of HIV prevention options that include existing prevention technologies (such as condoms, post-exposure prophylaxis (PEP) and voluntary medical male circumcision (VMMC), HIV testing and counseling, and

eventually new technologies, such as PrEP, microbicides, vaccines and other approaches.

Looking to the future, several types of activities are required to move the prevention agenda forward. They include further research to better understand who is at risk and how to most effectively intervene; investment in stakeholder engagement and advocacy; leveraging the efforts of other sectors (i.e., education, income-generation) to work on the structural drivers of HIV;

conducting pilot studies in order to determine how best to introduce PrEP and microbicides into the context of combination prevention; and most importantly – to make the tough political and technical decisions about which efforts are working and which can be stopped.

B. Overview of Oral PrEP

Dr. Nelly Mugo, Senior Research Scientist and Obstetrician-Gynecologist at the Kenyatta National Hospital, provided an overview of oral PrEP, including a review of current or recent PrEP clinical trials and discussed the opportunities and challenges of PrEP implementation. As an introduction, Dr. Mugo reminded the group about the tremendous success of Prevention of Mother-to-Child Transmission (PMTCT), which was first initiated through the provision of nevirapine to the babies of HIV-infected mothers, and through more recent regimens has all but eliminated mother-to-child transmission in some places.

Like the provision of antivirals for PMTCT, PrEP involves the use of antiretroviral drugs by HIV-uninfected individuals to prevent HIV acquisition. Thus far, two different drugs have been evaluated, including tenofovir (TDF) and Truvada (a daily pill co-formulated with emtricitabine and tenofovir). Their choice has been based on their high potency, safety profiles and ease of use. PrEP was first proposed as a concept in 2001. Early trials were met with difficulties; a proposed trial in Cambodia was not initiated and a safety trial among sex workers in West Africa was closed early due to community concerns. Since that time, three different trials have shown the products to be effective in reducing HIV transmission, two trials have closed at least one of their study arms early and one is on-going.

Figure 2: Results of Six PrEP Trials Show Divergent Levels of Efficacy

Divergent oral PrEP efficacy trial results			
Study	Population	N	Results
iPrEx	MSM	2499	44% efficacy FTC/TDF
TDF2 Study	Young men and women	1200	62% efficacy FTC/TDF
Partners PrEP Study	Heterosexual couples	4758	67% efficacy TDF 75% efficacy FTC/TDF
FEM-PrEP	Women	2021	6% efficacy FTC/TDF
VOICE	Women	3021 (oral arms)	No efficacy TDF FTC/TDF ongoing
Bangkok Tenofovir Study	IDUs	2400	TDF ongoing

 There is a clear relationship between PrEP use and HIV protection in clinical trials

The trials showing effectiveness include iPrEx, a multi-country trial in men-who-have-sex-with-men (MSM); TDF 2, a trial of heterosexual men and women in Botswana; and Partners PrEP, a trial of heterosexual HIV discordant couples in Kenya and Uganda.

The Partners PrEP evaluated both TDF alone and Truvada. While Truvada showed a higher estimate of effectiveness (75%) than tenofovir

alone (67%), Dr. Mugo reminded participants that these differences were not statistically significant. In fact, most encouraging was that the lower estimated level of effectiveness for both arms is 44-55%. Two additional trials, the FEM-PrEP trial conducted in high-risk women in Kenya, Tanzania, and South Africa, and VOICE, a trial that aimed to evaluate the daily use of oral TDF, oral Truvada, and a vaginal tenofovir gel have not met the same success. The FEM-PrEP trial closed early

due to “futility” – an assessment that the trial would not be able to show effectiveness if it were allowed to continue. At closure almost equal numbers of HIV infections had occurred in both the Truvada and the placebo arms. The inability of the trial to determine the effectiveness of Truvada was attributed to low adherence, as indicated through low drug levels in participants’ blood samples. Similarly, the VOICE trial closed two of its three active study arms early – the oral tenofovir arm and the tenofovir gel arm. The oral Truvada arm is continuing, however.

Taken as a whole, these trials point to several conclusions. First, both TDF and TDF/FTC (Truvada) continue to be shown as safe. Across six trials involving approximately 20,000 participants, there have been no serious safety concerns. Second, the detection of HIV resistance has been uncommon or non-existent; all cases of resistance occurred among those who turned out to have acute HIV infection (and HIV-seronegative) at the time they were started on study product. The data shows that when PrEP is taken, it is highly efficacious in preventing HIV infection.

Nevertheless, there are both challenges and opportunities to implementation of PrEP. One challenge is the need to be adherent. Regardless of whether participants were in the iPrEx trial or Partners PrEP, when PrEP was taken (as detected in the blood), protection was very high. However, differences between findings from Partners PrEP, in which sero-discordant couples had a known risk of HIV, and FEM-PrEP, in which 70% of trial participants perceived little to no HIV risk, suggest that low adherence may be driven by risk perception. Understanding the interface between risk perception and HIV prevention will be critical for any strategy. However, PrEP may also be an opportunity – a strategy meant not for a lifetime (as ARVs for treatment are currently), but for a *season of risk*. Dr. Mugo suggested that adolescent women represent one season of risk. Others might include that period when HIV sero-discordant couples attempt to conceive, among MSM or couples where there is intimate partner violence, alcohol or drug use.

On July 16, 2012, the US Food and Drug Administration (FDA) approved the use of Truvada to reduce the risk of sexual acquisition of HIV among high-risk heterosexuals and MSM. Moving forward, several demonstration projects are planned, including one in Kenya, to evaluate whether the use of PrEP by the uninfected partner in a sero-discordant couple can act as a bridge to protection until the infected partner can be established on ARV treatment.

C. Microbicides Gels, Rings and Injectables

Dr. Betty Njoroge, Senior Research Officer at KEMRI, provided an overview of several ARV-based prevention technologies that are still under development, including microbicide gels, vaginal rings and an injectable ARV for prevention. The need for such products remains critical, because current HIV prevention approaches – in particular, abstinence, faithfulness, condom use, and voluntary medical male circumcision – are often not feasible HIV prevention options for women due to gender, economic and socio-cultural disparities that render women powerless to negotiate safer sex.

Female microbicides are products that are inserted in the vagina; they come in several forms, including gels, films, rings and softgel capsules. A first generation of microbicide efficacy trials

tested seven (7) non-specific products, including Nonoxynol 9, Savvy, Carraguard, BufferGel, Cellulose Sulphate, PRO 2000 (2%) and PRO 2000 (0.5%). These products were coitally-dependent in the sense that a new dose of gel was to be inserted prior to each new sex act. None of these products were shown to effectively reduce HIV transmission. A next generation of ARV-based microbicide gels is currently in clinical testing. The CAPRISA 004 assessed the safety and effectiveness of a coitally-related “BAT 24” regimen of tenofovir 1% gel, which comprised insertion of one gel up to 12 hours **Before** sex, one gel as soon as possible within 12 hours **After** sex, but no more than **Two** gels within **24** hours. Women randomized to the tenofovir gel arm had a 39% reduction in HIV acquisition and 51% reduction in herpes simplex-2 (HSV-2) acquisition, compared to women randomized to the placebo arm. The level of protection provided by tenofovir gel was even higher among trial participants with better adherence. A second trial, FACTS 001, is currently being conducted in South Africa to confirm the results of CAPRISA 004.

In addition to tenofovir-based products, other products are also under investigation. One such product, dapivirine, has been shown to be a potent ARV, safe and well-tolerated in over 20 early or expanded safety clinical trials to date. Through collaboration between KEMRI, the University of California-San Francisco (UCSF) and the University of Washington (UW), the safety and acceptability of the new ARV-based dapivirine gel was assessed in Kenya.

At the same time, efforts to develop an ARV-based vaginal ring have also been underway. Vaginal rings have been used safely for contraception and for hormonal replacement therapy in post-menopausal women in the US and some other countries. A phase 1 trial was conducted by the KEMRI/UCSF/UW collaboration to assess the safety and acceptability of a dapivirine matrix vaginal ring in Kenya. The study showed good acceptability and high willingness to use such a product to reduce HIV risk. Two trials to assess the safety and effectiveness of the dapivirine ring in reducing HIV acquisition have recently been initiated through the International Partnership for Microbicides (IPM) and the Microbicide Trials Network (MTN).

Finally, an injectable ARV, TCM 278 (rilpivirine), that has shown promise for HIV treatment, is being evaluated in terms of HIV prevention.

There are several benefits to these new ARV-based technologies. It is hoped that injectables or rings, which may only need to be obtained or applied monthly or less, will show higher levels of adherence. Similarly, ARV-based gels will not require daily use, at least when sex itself does not occur daily. Gels and rings provide protection at the site of infection, rather than systemically. Finally, they may have a “separate product space”, meaning they are new products only used for HIV prevention whereas oral PrEP products are already available as HIV treatment.

Dr. Njoroge concluded her presentation by emphasizing three factors that would be critical for successful microbicide introduction and rollout. They included the need to both optimize and measure adherence; to involve male partners and to expand product choices.

D. Lessons Learned: Perspectives from Policy, Program and Civil Society Representatives

Ms. Stacey Hannah, Senior Program Manager at AVAC chaired a panel discussion composed of four individuals representing the perspectives of service delivery (Dr. Joshua Kimani), policy (Dr. Rex Mpazanje), and community perspectives (Ms. Lucy Ghati and Ms. Pauline Irungu.) After giving a brief introduction and describing the process of the panel, Ms. Hannah directed her first question to Dr. Kimani, asking him:

“From a service delivery standpoint, what are important factors to consider regarding where and how to rollout new HIV prevention methods like PrEP and microbicides?”

Dr. Joshua Kimani described his work with most-at-risk-populations (MARPs) – primarily sex workers – through the Sex Worker Outreach Program (SWOP), a program conducted in close collaboration with the CDC. The city center clinic serves approximately 7800 female sex workers and a smaller (potentially more hidden) population of male sex workers.

The program provides both HIV positive and HIV negative sex workers with a range of treatment and prevention services. Thinking about the potential demand for new HIV prevention methods, Dr. Kimani described the high demand for PEP, which had become very popular among HIV-negative sex workers. He estimated that approximately 1600 SWOP clients have taken PEP in last two years; 450 of them more than once. While PrEP might indeed fill the prevention gap that was currently driving demand for PEP, several challenges would need to be addressed prior to PrEP introduction. First, was the need to establish a supportive regulatory and policy framework for PrEP implementation; Dr. Kimani asserted that nothing will happen without that. Additionally, resources for implementation would be very important. And finally was the need to establish a well-functioning healthcare system capable of monitoring clinical issues, including hepatitis, breakthrough infections, and pregnancy. In closing, Dr. Kimani suggested that *“PrEP is not for everyone; it should be a niche product.”* This would entail identifying and well-characterizing high risk groups, such as those served by the SWOP clinic. Dr. Kimani estimated the HIV prevalence rate among female sex workers to be 28%, with an incidence rate of 2.2%. Among MSM sex workers, HIV prevalence was approximately 40%, with an incidence rate of 11.8%.

Ms. Hannah’s second question was for Ms. Lucy Ghati:

“What are you hearing in your conversations with civil society members regarding opportunities and barriers to implementing PrEP and microbicides?”

Ms. Ghati introduced herself as a program officer for the National Empowerment Network for People Living with HIV/AIDS of Kenya (NEPHAK), as well as an AVAC Fellow involved in new HIV prevention technologies. She is currently implementing a research advocacy fellowship program: *Realizing the Potential of ART Treatment as Prevention in Kenya*. She is also a community representative in new tuberculosis (TB) vaccines, working with the Stop TB Partnership of WHO. Based on community consultations she has undertaken, Ms. Ghati suggested there was widespread

willingness on the part of communities to use PrEP and microbicides. For example, when talking to women, they desired a prevention tool that would put the power of prevention in their hands.

Effective public education and promotion was needed prior to introduction of new HIV prevention strategies. While Kenya has a good record of implementing HIV prevention programs, several barriers must first be addressed. They included the following:

- Limited infrastructure, especially in terms of number of health providers - How will they be trained? Where will PrEP be made available (through family planning or antenatal care clinics, or other clinics)?
- Knowledge gap between providers, communities, and policymakers related to new prevention options. These audiences all need information about PrEP and microbicides.
- Costs - PrEP and microbicides are not one-time interventions, as is a vaccine or VMMC. Who is going to provide for this cost?
- How long will it take between approval/licensure and rollout?

Next, Ms. Pauline Irungu was asked the following question:

“What should we take into consideration regarding the realities of women’s lives as we think about implementing PrEP and microbicides? How can the lessons learned from clinical trials be used for real-world implementation?”

Ms. Pauline Irungu, currently a Family Health Advocacy Officer at PATH, reflected on lessons learned from her prior work with the Global Campaign for Microbicides. She commented that women’s desires for HIV prevention methods are varied. Some want a microbicide ring, some want a pessary, and some want a gel. In other words, we need to think about the different needs of different women. Women’s different needs encompassed their perspectives on effectiveness. For example, she suggested that women in stable relationships want “*very strong tea*” – something that works very well (to compensate the risk of initiating this conversation with her partner), whereas higher risk women (FSWs) say they will use even a moderately effective product. Disclosure of product use also differs by women’s contexts. For example, some women – especially those in stable relationships, prefer to discuss product use with a partner, while women in casual relationships may feel less need to discuss use with a partner.

Ms. Irungu pointed out that women’s access to these new products will be influenced by several factors, including their perception of HIV risk and the dynamics of their sexual relationships. She described the case of women whose sexual behavior might be considered “transactional”, but did not consider themselves to be FSWs. Such a woman might wash clothes for a living, but be requested by her male client to provide “other (sexual) services” as well in order to keep her job. Whether or not such a woman perceives her behavior to put her at risk would determine whether she feels the need to access a microbicide or PrEP product. Finally, because gender-power dynamics affect how and/or whether women will be able to access HIV prevention methods, it will be essential to engage men as sexual partners, when planning for PrEP and/or microbicide introduction. In her previous dialogues with different types of men, she learned that men want to have more information about microbicides and are likely to play a strong role – either helpful or

hindering – in access to new methods. So, the question is how to introduce new products. She asked, “Do we focus on HIV prevention or do we talk about it in larger context of protecting family?”

Ms. Hannah addressed the following question to Dr. Rex Mpazanje, the HIV Country Officer in Kenya for the WHO:

“Right after the International AIDS Conference in July, WHO released guidelines on implementing PrEP demonstration projects. What are your plans for supporting the government of Kenya and NGOs to implement PrEP demonstration projects here?”

Dr. Mpazanje was involved in establishing the National Health Program in Malawi. He believed it was possible to have women-centered prevention methods. However, to do so, we would need to make some difficult choices. For example, he stated that the current service delivery programs are not sustainable; we need to increase the number of new people on ART. In fact, he stated, treatment programs are facing many problems; retention rates which had been in the 90% range were now falling into the 80% range. At the same time, we are talking about combination prevention, adding interventions into the HIV prevention basket but not taking any (interventions) out. The basket, he suggested, is overflowing.

Several initiatives are currently underway that may help to address the financial and other resource constraints that must be faced by introduction of new HIV treatment and prevention initiatives. For example, UNAIDS is developing an investment model that is looking at different elements of combination prevention in order to determine appropriate service delivery models. Similarly, WHO is working on a set of guidelines for the strategic use of ARVs within a combination prevention setting; it includes interventions like TasP, option B+ (the initiation of lifetime treatment for HIV-infected pregnant women, regardless of CD4 count or clinical stage), and PrEP. He added that they hope to release the guidelines in June 2013. In addition to considering how best to introduce new technologies into a combination prevention package, Dr. Mpazanje described the need to optimize current treatment interventions, so that they would be more cost effective. This would include identifying ways to strengthen current service delivery channels to reach populations in need of prevention services with effective interventions. He noted most interventions that successfully targeted at-need populations were implemented through NGOs. He informed the group that the WHO would be meeting next month to discuss how to facilitate such approaches in the public sector.

After each panel member provided their thoughts related to PrEP and microbicide introduction, Ms. Hannah asked several follow-up questions, which led into a more general discussion by the meeting participants. The questions and responses were as follows:

What were lessons learned from VMMC rollout?

Dr. Kimani responded that, first; the evidence about the effectiveness of VMMC was very compelling. Therefore, the government took it on and communities accepted it. Similarly, for PrEP

introduction to be successful, someone needs to push it within the government. We need champions at policy and community levels. Second is a question of resources. VMMC programs were well-resourced.

Dr. Mpazanje added that when the VMMC Guidance document was released, it was first meant to be a policy statement, but then was turned into guidelines. Many consultations were conducted at higher policy levels and at community levels; there was much advocacy around VMMC, as well as the promise that resources would be available.

Do you think we're moving in the right direction re: PrEP and microbicides to get favorable policy environment, buy-in from key stakeholders?

Dr. Kimani responded, *"Yes, consultations like this are very helpful."* Although we have just started, we are on the right track. HIV testing is still a big challenge though. We need to develop a better strategy around testing, if we are to be successful in introducing these new prevention strategies.

PrEP and microbicides – should they be niche products?

Ms. Irungu replied that oral PrEP is likely to go the way of being a niche product – for use among certain populations and during certain periods of life. Oral PrEP would be a great tool for sero-discordant couples, including during periods when they might want to have children. MSM would be another group to consider for oral PrEP. Irungu felt it was unimaginable for oral PrEP to be rolled out to everyone. Conversely, she asked: *"If we make microbicides a niche product, could it be stigmatized for women who are not considered "higher risk" to use?"* She followed up this question by suggesting that women in long-term relationships are at risk of HIV (based on recent data from Kenya), but have limited ability to use condoms. Microbicides are a tool for these women. Perhaps microbicides could be promoted to a small number of women at first, but could eventually be rolled out to as many people as possible.

Dr. Kimani added that he would prefer TasP rather than PrEP for use by sero-discordant couples, and would leave PrEP for FSWs and MSM.

From the audience, one researcher shared plans for a demonstration project looking at PrEP as a bridge to ART for HIV sero-discordant couples. Such couples would be offered the option of early anti-retroviral therapy, but given the need to achieve viral suppression in the infected partner, the negative partner would also be given the option of PrEP for six months. However, given that about 30% of infections (from their Partners Prevention trial) were outside of the sero-discordant partnership, the need for PrEP might remain.

One of the NGO representatives asked how we might reach women who are engaged in transactional sex but don't consider themselves to be FSWs, since they're unlikely to go to programs targeting sex workers?

Ms. Irungu responded that there was a need to go beyond HIV prevention, to focus more efforts on structural interventions to address challenges women face. She asked: *“How do we keep girls in school longer? How do we empower women economically?”* We need to strengthen other health services that reach women – like family planning and antenatal care – to ensure that women are getting HIV testing and referrals to other services on a routine basis. She suggested the need to strengthen the “family focus” of interventions to include men.

Another question, addressed to Dr. Rex Mpazanje, was related to the role of FBOs and how to make programs sustainable. Dr. Mpazanje replied that as innovations emerge, the WHO is working on one strategy that includes them all. For example, WHO has issued interim guidance on TasP, option B+, couples counseling and testing, self-testing, and PrEP. He wondered whether it might be feasible in the future to have one guidance document that encompasses all of these innovations. WHO assisted Kenya to come up with guidelines on self-testing in 2008, although it has not been easy to rollout. PrEP and microbicides will require testing; we need to figure out how to scale up self-testing.

One of the policy makers emphasized the need to know what is not working, and raised the example of PEP. Noting that many sex workers were taking it, the policy maker asked how effective PEP is and whether we should be working with PEP, rather than PrEP. Dr. Kimani replied that PEP was fairly effective; few sero-conversions had been observed after taking it.

This led into a discussion about HIV testing. As one researcher emphasized, knowing one’s HIV status is a key challenge. Given the current status of testing, how can we improve uptake? What about the recent announcement of self-testing? In terms of HIV testing, another researcher felt the issue was to obtain an accurate estimate for most-at-risk populations - how many are there? Dr. Kimani estimated approximately 170,000 sex workers in Kenya, with approximately 34,000 in Nairobi alone. He stated that testing was high within this population - 95% of those who come to SWOP get tested. Ms. Ghati added that there was a need to scale up HIV testing and to better understand why people were not getting tested. She saw the need to address HIV stigma, which was likely to be part of the problem underlying low testing rates.

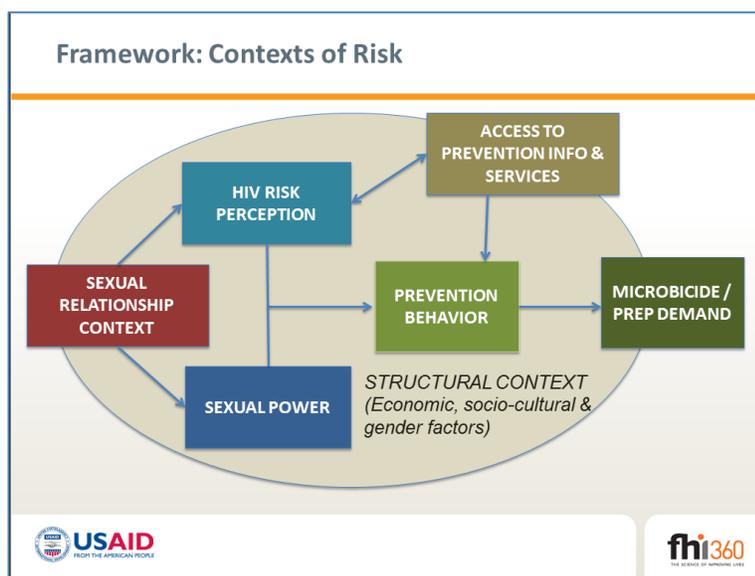
In terms of guidelines (for HIV testing or PrEP introduction), it was noted that other countries have involved associations beyond their government in the development process. One participant asked how Kenya might go about involving others in the process of developing guidelines, which might ensure better linkages between policy and program. Dr. Mpazanje mentioned receiving support from faith-based organizations during the process of developing WHO interim guidance on TasP, couple counseling and testing.

As a final comment, one researcher reminded the group that adolescents are not usually enrolled in HIV prevention trials; nevertheless, they experience very high HIV incidence. She added, *“Let’s remember the adolescents”*, as we plan for the roll-out of new prevention approaches.

Potential user groups for new ARV-based prevention

Building on presentations made earlier in the morning, the goal of Dr. Elizabeth Tolley’s presentation was to examine in greater depth the sociocultural and sexual contexts of different potential user populations that would likely influence their demand for and ability to use new ARV-based prevention products. Drawing on information from four FHI 360 projects (described in section VI), she presented four different contexts within which Kenyan women experience HIV risk and might benefit from PrEP or microbicides. They included female sex workers; women in stable relationships; women in HIV sero-discordant couples; and adolescents.

Figure 3: Framework for Examining the Context of Risk for Different User Groups



For each user group, she described a framework of risk. Women’s ability to use existing HIV prevention behaviors – and eventually PrEP or microbicides, are influenced by a host of factors including a backdrop of economic, socio-cultural and gender factors within which women live; the sexual relationship contexts within which women live; sexual power and HIV risk perception which are shaped by women’s structural and sexual contexts; and the service delivery environment to which women may or may not

access information and services.

A. Female Sex Workers (FSWs)

In Kenya, published research estimates the total size of the sex worker population to be 185,000. In Nairobi alone, the sex worker population is around 30,000. Data from the 2012 Most-at-Risk Populations (MARPs) Surveillance Report estimates the HIV prevalence rate of the female sex worker population to be between 24-50%, with a 29% prevalence rate in Nairobi [1].

Sex workers may be single or married – many have been divorced or widowed. Nevertheless, *economic factors* are identified as one of the main motivations for sex work. Several studies in Kenya [2-5], including the Proof of Deliverability of PrEP study, suggest that FSWs ply their trade within a *culture of violence*, commonly triggered around discussions of condom use and payment – and that the perpetration of violent acts is both unpredictable and uncontrollable. Because sex work is illegal in Kenya, such violence cannot be reported – indeed SWs are often threatened by the police.

Sex workers report having *different kinds of sexual partners*, from husbands, boyfriends, or lovers, to regular – sometimes non-paying clients and casual, paying clients. Their use of prevention

behaviors has been found to vary by partner type. For example, female sex workers are often unable to negotiate condom use with primary partners, while use with clients is considered easier [6-8].

According to the 2012 MARPs Surveillance Report, *drug and alcohol use* among sex workers is common in Nairobi, with approximately 63% reported having used drugs in the past 12 months [1]. Substance use facilitates environments where the sex workers are vulnerable to violence, forced sex, or unprotected sex.

HIV risk perception is high among many sex workers in Kenya [5]. Furthermore, FSWs and their partners report considerable awareness of STI symptoms and high rates of treatment seeking behaviors [9], including HIV testing. Based on data from the Proof of Deliverability study FSW groups reported positive experiences with FSW-focused NGOs, while stigma was reportedly common when FSWs accessed care at public facilities and self-identified as sex workers – though many reported not disclosing their occupation (PoD) [10].

B. Women in Stable Relationships

According to the 2007 AIDS Indicator Survey, almost 60% of Kenyan women are married or cohabitating. HIV prevalence in this group of women is above the national average, accounting for approximately 7% of women in monogamous unions and 10% of women in polygamous unions.

In Kenya, the *sociocultural and gender context* within which women live is similar to many parts of the world; one in which marriage and monogamy are culturally expected – especially for women – and, fertility is highly prized. According to the latest Demographic and Health Survey (DHS), the average family size in Kenya is 4.6 [11].

Kenyan women marry relatively early – approximately half do so by the age of 20, compared to just 10% of men who marry at that age. However, within these relationships, men and women report different *patterns of sexual behavior*. While women reported approximately two lifetime partners, men reported more than seven – concurrent relationships were reported by 1% of women in monogamous relationships and 2.6% of women in polygamous relationships, compared to 7% and 10% of men [12]. Women's power to make independent decisions that influence their health is also strongly influenced by their sexual relationships. In Kenya, men are important decision-makers in sexual matters, from decisions about the number and timing of children to the use of contraceptive and disease prevention methods. In contrast, women have been socialized to acquiesce to their partner's desires for sex and to give priority to his pleasure [13]. Both women and men in stable relationships face *barriers to requesting condom use*, largely because such requests raise suspicions of unfaithfulness [14-16]. And, while condom use for contraception appears more acceptable than its use for disease prevention, less than 2% of women in stable unions report using condoms for contraception [11].

Another reason for low condom use in stable relationships may be that women's perception of HIV risk is not sufficiently high to overcome the stigma and communications challenges needed to obtain its use. Overall, women in stable relationships perceive their *risk for HIV* to be low [3, 17].

However, perception of risk and actual risk are not always synonymous. In fact, the majority of HIV-infected women in the KAIS 2007 couples sample were unaware of their HIV-positive status – about half of these women had never been tested – another 30-40% had tested in the past, but believed they were negative. According to the KAIS, most women (about 60%) are tested within the context of antenatal services [12]. Women and men who do not perceive themselves to be at risk are rarely tested for HIV outside of such contexts [18].

C. HIV-Negative Women in Sero-Discordant Couples (SDCs)

There are an estimated 350,000 discordant couples in Kenya [19]. However, prior to diagnosis, women and men in discordant relationships are like other stable couples – monogamy is expected and childbearing is an important aspect of their relationship. In fact, fertility continues to be important even within HIV-affected relationships. The KAIS 2007 reported that about one-fourth of women who self-declared as HIV+ reported wanting a/ another child [12]. These women face additional challenges to ensure their babies are born healthy. For example, when HIV+ women become pregnant, the fear of disclosing to their partner and family members may prevent or limit the use of necessary PMTCT services [20].

According to the KAIS 2007, an estimated 1 in 10 couples are HIV-affected, with 6% of them discordant and 4% of them concordant HIV+. HIV status is almost equally distributed between male and female HIV+ [21]. Yet risk perception is generally low for these couples prior to testing. Indeed, 75% of men and women who were tested as part of the 2007 KAIS and found to be in HIV-discordant relationships were unaware of their discordant status [12].

Once couples have been diagnosed, discordancy has been disclosed, and if they choose to remain together, both *HIV risk perception* and the ability to negotiate *risk reduction behaviors* like condom use and/or partner reduction tend to increase. However, results from the PoD study indicate that risk perception does not always increase as one would expect.

Several studies report that fear of abandonment and abuse may prevent HIV-infected women from disclosing their status to their male partner [22, 23]. Were (2008) noted potential gender differences in disclosure to a spouse [22]. For example, if the uninfected partner was a man, he might be more likely to disown any HIV-infected children, suggesting they were from a different sexual partner. And research has shown that when disclosure does occur and the couple chooses to stay together, condom use tends to be high – but damaging to the relationship and sex life (PoD Study). However, not all couples remain together after disclosure. In fact, the Partners Study revealed that after two years, 13% of uninfected partners engaged in sex outside the union – an increase from 3% at the time of disclosure. Furthermore, unprotected sex was higher in outside relationships than within the discordant couple [19].

D. Adolescents

Sexually active young women aged 15-24 represent 4.6% of the total population in Kenya [11]. This is roughly 2 million of the estimated 43 million people living in Kenya [24]. Among this age group, 5.6% of these sexually active young women are HIV-positive.

Adolescent women face a number of sociocultural barriers that increase their risk of HIV. They include limited access to employment and education opportunities. According to the DHS, less than one-third of women aged 20-24 (the age range where completion of secondary school would be possible) reported having completed secondary education. Proportions of high school educated young women ranged from 8% to 60%, depending on wealth quartile [11]. Young women with fewer individual resources and lower educational attainment reported less consistent condom use than those with lesser resources and lower educational attainment [25].

Several studies in Kenya suggest that young women initiate sex at young ages, and that Sexual activity often begins within the first month of a new relationship [26, 27]. Condom use among adolescents is inconsistent and varies by partner-type, occurring primarily when risk is perceived to be high [26, 28, 29], but abandoned when the relationship appears to be more established or when “trust” is desired [28]. Young women's power to negotiate condom use is especially compromised by age disparities and economic dependence [26, 30-32].

Like their adult counterparts, young women's HIV risk perception remains low and misinformation is high [31, 33, 34]. For example, young people believed they could identify someone who was HIV-positive based on their appearance [30], that young people were unlikely to contract sexually transmitted infections [35] and that partners in longer-term relationships were less likely to have HIV [36].

Overall, adolescents have relatively low access to HIV prevention information and services. Despite programs in school, adolescents receive much of their HIV/AIDS information through word of mouth from peers [37, 38]. Cultural taboos about adolescent sexuality pose barriers to purchasing condoms or requesting condom use with partners [39, 40], or getting tested for HIV or other sexual infections. Despite high HIV incidence rates in adolescent women, only 40% of young women who participated in the 2007 KAIS reported having used a condom at last sex. And, less than half (48%) reported having ever been tested for HIV and received results [12].

E. Demand for and Access to PrEP and Microbicides

Dr. Tolley referred to data from the PrEP Proof of Deliverability (PoD) study and to literature from previous PrEP and microbicide trials to examine potential demand for and access to new ARV-based prevention methods by different groups. Based on focus group discussions with FSWs and discordant couples from the PoD study, there was tremendous enthusiasm for new ARV-based prevention methods. Potential injectable prevention methods were preferred by both groups, primarily because they were perceived as being longer-acting than oral pills or microbicide gels. FSWs also appreciated the possibility of using an injectable clandestinely. Regarding PrEP, FSWs expressed some concern about the need for daily use, problems with concealment, and potential side effects or interactions with alcohol. Few discordant couples commented on a preference for PrEP pills, and there was no consistency in responses. Some discordant couples expressed interest in microbicide gel, largely because they perceived this product to be less painful than receiving an injection. Previous trials in these two populations showed varied levels of adherence to PrEP. The FEM-PrEP trial, which was conducted in high-risk, multi-partnered women (including widowed and/or fisherwomen in Bondo, Kenya) reported very low levels of adherence, while the Partners

PrEP study reported high adherence - 35-38% versus 81% of non-seroconverters had drug detected in blood samples from these two studies, respectively [41]. While some FSWs were expressly looking for a prevention product that could be used without condoms [42, 43], others worried about the potential negative effect on condom use that PrEP introduction might have. Discordant couples also reported reluctance, but high levels of condom use within their relationship; less use was reported with sexual partners outside their relationship. PrEP introduction might decrease condom use within discordant couples, yet provide additional protection in other sexual contexts.

Among women in stable relationships, previous microbicide clinical and behavioral research suggests mixed interest in using microbicide gel. Hypothetical interest appears to depend on risk perception, which might or might not be an accurate reflection of actual risk [44]. However, acceptability among women who have actually participated in microbicide trials has been overall quite high. Obtaining partner acceptance of microbicide use is considered important. Indeed, women in several trials have reported that their partners provided support for product adherence [45-47]. To date, there is little information about demand for or acceptability of PrEP or other ARV-based technologies among women in stable relationships. In addition, there is little information about these new ARV-based prevention technologies – including topical microbicides, for adolescents. Because condoms are not used consistently in stable relationships – there is less concern about potential decreases in condom use (and therefore protection) should ARV-based prevention products be introduced in these groups.

Tolley concluded the presentation by discussing several considerations for access to new PrEP and microbicide products. First, she noted that while PrEP could be available soon, pending regulatory approval and/or guidance in Kenya, a microbicide gel would not be available for at least several years (provided positive outcome from the FACTS trial occurred.) Availability of ARV-based rings or injectables would be even further in the future. In addition to differences in the availability of products, they might also have different requirements for delivery, including different levels of clinical testing and adherence monitoring. Such requirements will influence the choice of service delivery settings through which products would/could be offered, which in turn likely influence product access by different potential user groups. To this end, she suggested that it would be important to consider how best to position PrEP or microbicide products, to ensure access by prioritized groups. Cost may dictate prioritization of different products to user groups. Specifically, she acknowledged that there is a marketing challenge to positioning prevention products for those who do not – or perhaps cannot acknowledge their risk of HIV. If marketing of new products is narrowly targeted to those groups that have clearly perceived risk perception (for example, HIV discordant couples or sex workers), new products will likely be stigmatized in much the same way that condoms have been – meant for use when you cannot “trust” your partner. This would limit access by adolescents and women in stable relationships.

Discussion

A policy maker noted that the presentation had considered population groups based on their risk, but did not take into account the availability of other prevention products. He asked, “*How do we promote new products to them in light of all the products that are currently available?*” He then

elaborated that some groups have a known risk of HIV – like sero-discordant couples or those who come to the clinic with an STI—their risk is clear to providers. What about targeting those who come in for STI treatment to receive PrEP? Tolley replied that there may be issues with diagnosis. Based on some of her previous research, she has found that women often go undiagnosed for STIs, either because they are embarrassed or ashamed to come into clinics, or even because providers may not always communicate that their infection was sexually transmitted.

The same participant followed up with an additional question. Given that prevention products should be widely available, what would be the effect of using PrEP when already exposed to HIV? Tolley responded that while this presentation was focused on prevention products, many have already highlighted the importance of thinking about introduction of these new products within the context of “combination” prevention – which would include TasP and other strategies. The discussion should be country-focused. This is a good discussion to take place in Kenya.

A program manager commented that, by looking at messaging and promotion, we may lose sight of combination prevention and tend to think about just the one method. Tolley agreed, stating that it would be important to think holistically about gender-related issues and how to integrate product/technology-based strategies into more structural approaches.

Product access and service delivery issues

Building on previous presentations, the goal of Dr. Emily Evens’ presentation was to discuss issues related to access of ARV-based prevention products and associated service delivery factors. The *Product Access and Service Delivery* presentation drew on information from three projects – the Proof of Deliverability Study, the PrEP Roll out study and the Gender Analysis for Microbicide Introduction Project, each with a slightly different geographical focus. The Proof of Deliverability study was conducted in Nakuru and Nairobi, the PrEP Rollout Study primarily focused on Nyanza Province and the Gender Analysis for Microbicide Introduction literature search and key informant interviews were global. Both primary and secondary data informed the presentation, including information from literature reviews, interviews, focus groups discussions and workshops with potential user populations, service providers, program managers, and policymakers. Finally, facility inventories and assessments were included.

A. Description of Service Delivery System Characteristics

Characteristics of a service delivery system may be assessed in terms of the access to services it affords; the quality of those services; and how well the system facilitates coordinated care. **Access** includes financial, geographic and psychosocial components that are vital for the initiation and continuation of product use. Access issues such as: economic costs for the user, (particularly the cost of transport to a health facility), long waiting times and stock-outs have been found to be barriers to the use of both ARVs and PMTCT and are potential threats to PrEP. Another fundamental access question is how countries will pay for products.

one of the following services: STI testing, HIV care, and family planning clinics.

These data provide an example of public sector facilities from one region that helps us think about PrEP and microbicide provision. While facilities offering the necessary services are available in this region, challenges are posed by the distance a client would have to travel to a facility and the size of the population serviced by each facility.

B. Review of Potential Service Delivery Channels

The presentation then described the range of potential service delivery channels, their advantages and disadvantages and potential users and stakeholder perspectives.

Government facilities from dispensary to hospital level were mentioned as potential delivery channels by stakeholders. This included general care as well as VCT, CCC and FP services. Advantages of delivering services through government clinics included: wide access and coverage (including expanded working hours in some areas) and the ability to monitor safety and control distribution. Disadvantages included: high client volume, potential stock-outs, and staffing shortages. While these seemed to be more general rather than PrEP-specific concerns, respondents implied that PrEP services would be in great demand and therefore exacerbate these existing issues. Depending on the facility type and location, the distance to facilities was also considered a concern for some users.

Discordant couples identified hospitals, health centers and dispensaries as the best access points for all ARV-based prevention products (pills, gel & injectables). The access-related benefits of government facilities included: free or low cost services, expanded working hours and widespread locations; though potential users cited concerns with long waiting times and potential stock-outs. Data from the PrEP Rollout National Workshop also found that government facilities were suitable for discordant couples. FSWs identified government facilities as a secondary access point but were concerned about discrimination, especially if they self-identified as sex workers. We know that women in stable relationships, including some married adolescents, access FP, ANC and MCH services, and it is likely that government facilities would be acceptable for these women; unmarried adolescents, however, are less likely to have access to these services. Both providers and policy makers supported government facilities at the lowest accredited level possible as delivery channels. These facilities were seen as the best option to maximize access while guaranteeing supply and ensuring safe use.

HIV services, including both Comprehensive Care Centers (CCCs) and VCT services were discussed next. Advantages included: accessibility, established supply mechanisms for ARVs and experience with the provision of HIV services (especially testing and counseling). Disadvantages were similar to those for government facilities in general—the lack of supplies (especially test kits), and the lack of personnel. The potential for stigma (especially for groups not already attending these services) was also noted as a disadvantage. There was little variation by product type—HIV prevention channels were seen as generally appropriate for both PrEP and microbicides.

Discordant couples identified HIV services as an ideal delivery channel for many reasons: they felt that products obtained at CCCs would be consistently available and of high quality, that

relationships already existed with the CCC services and providers, and that PrEP services would be convenient and synergistic. However there was also concern for deductive disclosure for negative partners.

Unfortunately, little data exist on the acceptability of these channels for adolescents and women in stable relationships, but access to products through HIV services is likely to be fairly difficult for these populations, especially due to stigma. Finally, service providers and policy makers supported HIV services as potential delivery points, but expressed the need for education of providers and potential users to trigger demand and respond with appropriate services.

NGOs were the next potential delivery channel. The primary advantage of NGOs was their success at providing services to hard-to-reach populations such as female sex workers or adolescents.

These services were widely perceived to provide friendly, non-judgmental services to groups that might not be comfortable accessing services in settings targeted to the general population. Services through NGOs were considered affordable as well. Disadvantages included: the limited clinic hours, limitations in staffing capacity and potential limitations in the ability to provide adherence counseling and resistance monitoring.

FSWs overwhelmingly preferred to access PrEP and microbicide products at targeted, sex worker friendly NGOs. These “friendly” clinics were identified by name and included: SWOP, LVCT, FHOK, AMREF, SASA DISK, and Bar hostess Kasarani; they were perceived to provide high-quality services and be easily accessible. Discordant couples identified NGOs as a secondary delivery channel. Service providers expressed a range of opinions on the feasibility of incorporating PrEP and microbicides into NGO services. For example, some said it would be easy to provide, while others expressed concern over challenges of merging new information into current practices and ensuring staff were adequately prepared to deliver products in a manner that supported appropriate use by clients.

Family planning (FP) services were the next potential access point discussed for PrEP and microbicides. Advantages included: the widely accessible and efficient use of services (for example, users could receive two products at one visit, potentially increasing uptake of both); the assurance of privacy and the lack of stigma. Much of this may be attributed to the acceptability of FP services and the fact that providers are already trained to provide counseling and involve couples. Disadvantages included: the high existing client load and concerns about whether groups who do not widely access FP services, like adolescents and men, would be comfortable accessing services. Again, there was little variation in these views by product type.

Discordant couples identified FP services as a secondary access channel, but worried that FP providers were not capable of providing PrEP counseling as they were perceived not to be current on new HIV products and services. Female sex workers did not identify FP services as an appropriate channel, though such services are likely to be acceptable for women in steady relationships, since many already access these services. In contrast, adolescents are likely to be concerned about stigma. Finally, providers and policy makers also identified FP services as a good potential channel.

Private facilities were perceived to generally provide high quality services and have more staff than public facilities, but at an increased cost, making them inaccessible for many. Provincial stakeholders in Nyanza emphasized that private partners should be engaged for PrEP roll out, but they should be sure to follow government guidelines and policies.

Chemists could be another potential channel because of their wide reach into communities, but there were many caveats. Disadvantages included: concerns over how chemists could provide or refer for HIV and lab tests; how they could be properly trained to counsel and provide products in a confidential manner; and concerns on whether the ease of access from chemists would lead to incorrect use or abuse.

Discordant couples saw chemists as a tertiary channel but expressed fear over counterfeit or expired drugs. Policy makers were cautiously supportive of chemists because of their potential to provide wide access; however policy makers were concerned about the for-profit status of chemists.

The final channel was **outreaches and community-based distribution** which included a wide range of potential service delivery options: mobile clinics, home-based delivery, support groups, churches, schools and workplaces. The advantages included: the ability to provide services to hard-to-reach populations where they were most comfortable and the potential to expand access and adherence. Disadvantages included: the fact that providers might lack sufficient skills and training for the provision of counseling, potential difficulty in ensuring confidentiality, and the need for testing and monitoring to be done by referral.

Discordant couples reported support groups and outreaches as options for receiving PrEP, because groups could provide: reminders for refills and positive support. Integrating microbicide programs into places youth frequent, such as schools and youth centers, is an option for reaching youth. Mobile clinics may be another way to increase microbicide access for women overall. Service providers expressed concerns over training providers sufficiently; and program managers and policy makers weighed the benefits of increased access and potential adherence with needing to monitor users and control products.

Table 1: Summary of Potential Channels by User Group

	FSWs	SDCs	Adolescents	Stable Couples
Government Facilities	X	X		X
HIV Services	X	X		
NGOs	X	X	X	
Family Planning Services		X		X
Chemists	X	X	X	X
Outreach & Community-based Distribution	X		X	X

C. Challenges to PrEP Provision

The provision of PrEP and microbicides entails considerable challenges: financial, logistical, social and behavioral. First, stigma will affect the accessibility and acceptability of products if they are made available only at HIV clinics. Integrating PrEP and microbicides into other reproductive health and family planning services or primary care could address this. Conversely, certain high risk populations, such as FSWs, may find it difficult to access products if they are not available through services that specifically target their group, as these women are unlikely to self-identify at services for a more general population of women. Other groups, like women in stable relationships may not perceive their risk (and therefore need) for prevention products, or may not perceive a product to be appropriate for them despite concern about risk.

Second, the knowledge and attitudes of clinic staff are vital. Health providers' attitudes towards high risk clients, their awareness of microbicides and their willingness to discuss them with clients will likely play a major role in women's interest in and ability to use products. Additionally, structural limitations such as the location of facilities and hours they are open, staffing shortages, client flow and waiting time at facilities are persistent concerns in the Kenyan setting that will remain important in the delivery of ARV-based prevention products.

Finally, issues of access and cost including: access to transportation to get product refills and attend scheduled clinic visits, funding for products, prioritization of user groups and client cost are other important financial components. Affordability must be balanced with a sense of faith in the quality of the product. Some research has found that products made available for free are seen to be of inferior quality, but products must be low cost or free-of-charge to ensure access. In addition to being affordable, services must be readily and consistently available.

The introduction of other technologies can provide valuable lessons for PrEP and microbicide products. New services should aim for effective integration early in all relevant hospital departments, not just in a stand-alone clinic. First, provide PrEP services should first be provided in a few facilities with sufficient capacity, and then scale up to others. Establishing collaboration between implementers, government, and political leaders in policy formulation and implementation is vital. Efforts must also involve community leaders, to encourage acceptability and ownership of the intervention and communication committees for information dissemination are essential. Finally, to address training concerns, facility-based trainings should be held where staff can be observed and mentored. Staff should be followed-up and mentored after training and provided with continuous education to maintain skills. Additionally, creating a pool of trainers at district and facility levels could be an important resource.

The questions of where PrEP and microbicides should be made available and how potential delivery channels vary by potential user group was raised to the group.

Discussion

The first question related to how the study had managed to reach 14-17 year olds in Kwa Zulu Natal as the majority of services do not target this age range. Dr. Evens replied that these women were recruited in neighborhoods through community health units and how important it was to obtain community buy-prior to recruitment.

A policy maker noted that comprehensive care centers are already overburdened. If NASCOP decides to develop PrEP policy, regular contact with clients will likely be required. This might be hard in CCCs, which have very high client volume. Providers would likely say they could meet these new demands, but it would be challenging to do so in a quality manner. This participant was nervous to pilot PrEP in Bondo, noting advocacy statements in Kenya about universal access, *"If you did a pilot study in Bondo, advocates in Thika might get upset that they're not also getting PrEP."* Dr. Evens responded that the PoD study was also doing a gap analysis with facilities. The plan was to give this information to the government to inform where it would be feasible to integrate services and what would be necessary to successfully deliver PrEP and microbicide products.

A second policy maker added that an important policy perspective was the context in which they were operating. For example, Kenyan policy makers were looking at strategic use of ARVs for treatment and for prevention. Many policy makers will probably ask: *"Why do we need to implement PrEP and microbicides? Is now the time to do it?"* We need to show why this needs to be discussed now. There are a cascade of things likely to happen between now and when WHO guidelines are released next year. Costing for PrEP is just one piece of the puzzle.

From a program perspective, one participant suggested that the development of a prioritization framework could help decide which prevention methods people needed, and wondered whether a gap analysis would be conducted with the government. Dr. Evens replied that policy makers, program managers, and service providers were included in the gap analysis she had presented.

They were asked about existing service delivery settings and what they thought would be needed to implement PrEP and microbicides.

A researcher noted that, if we are talking about the possibility of women-controlled methods, if we put them in health facilities only, we would diminish women's ability to access them. The researcher asked whether there was another way to deliver microbicides so more women would have access to them. For example, what about community health workers? To this, one gender advocate stated that, "*We have a population who is already using PrEP (unmonitored).*" The advocate then raised concern about whether vaginal microbicides might face similar issues – since vaginal microbicides were likely to be available before rectal microbicides were, would MSM use vaginal microbicides when they were available, even without proven effectiveness for rectal use?

Another participant also pointed out that the regulatory classification of these products would determine where they could be delivered, adding that it would also be important to think about health seeking behavior as ARV-based prevention would be an optional service/product. While the service would be initiated within a health facility, it would be up to the client to continue use of service/product. This participant suggested the need to map the location of groups who needed the services and where the services were available (nationally). It would also be important to consider the risks and benefits of targeting to certain groups.

One participant mentioned that data from the Partners PrEP study addressed at who was transmitting and who was acquiring HIV. The study revealed that after age 30, transmission events were very low. Based on this finding, this participant wondered whether prioritization should be based on age rather than user groups; a second participant noted, based on personal understanding, young FSWs were the ones at highest risk. Several others interjected additional thoughts about who to target and/or how – for example, reminding the group about the need to determine what the added benefits of incorporating these new methods into the existing HIV prevention package would be; raising the issue of female condoms; or asking how risk behaviors like alcohol use should be considered within programs. Dr. Evens responded to the discussion by observing that two different themes had emerged from the discussion: 1) the question of "venue" - based on current discussions, it appears that PrEP will be a facility-based service for now. Perhaps down the line, products could be delivered in the community to increase access; and 2) the question of priority group - she reiterated the importance of understanding more about the highest risk groups, including where they were and what services/methods they needed.

Dissemination of FHI 360 PrEP-related studies in Kenya

Several FHI 360 projects, shown in table 2, contributed information to the Naivasha consultation.

Table 2: Sources of Information for FHI 360 PrEP-Related Studies in Kenya

They included (1) a study, funded by BMGF, to assess the Physical Delivery of PrEP; (2) a social marketing study linked to the FEM-PrEP trial to inform PrEP Rollout in Nyanza Province in Kenya; and two new USAID-funded projects that entail (3) the implementation of a gender analysis for microbicide introduction, and (4) the development of a communication strategy related to microbicide introduction.

A. The PrEP Proof of Deliverability Study

The PrEP Proof of Deliverability Study is a BMGF-funded study on Assessing Physical Delivery of PrEP in Support of Proof of Deliverability. The project, implemented in Nakuru and Nairobi, Kenya and KwaZulu-Natal, South Africa, aims to identify potential delivery channels for a range of ARV-based HIV prevention technologies, including oral PrEP, vaginal microbicides, and an injectable form of PrEP. In-depth interviews were conducted with stakeholders in each country (including: policy makers, program managers, and service providers) and focus groups were convened with potential end-user groups (adolescent/young women, female sex workers, discordant couples) to determine possible delivery points for these products, as well as potential barriers to access and suggested solutions.

Sources of Information					
PROJECT	LOCATION	LIT REVIEW	INTER-VIEWS	FOCUS GROUPS	WORK-SHOPS
Delivery channels study	Nakuru; Nairobi	X	X	X	
PrEP Rollout	Nyanza	X	X	X	X
Gender Analysis	Global	X	X		
Communications Strategy	Kenya	X			

1. Overview

PrEP products have demonstrated effectiveness among selected populations in clinical trial settings. However, by definition, trials run in a controlled environment where the supply of the product is guaranteed and the service delivery context is enhanced. Additional research is needed to answer operational questions about PrEP. Specifically, public health stakeholders must establish whether, and how, PrEP can be delivered outside trials – they must establish what is called the “Proof of Deliverability”.

The BMGF has identified four key sets of issues to be answered in order to determine whether PrEP products can be delivered, what together is called the “Proof of Deliverability” of PrEP. First, the clinical proof of concept must determine that PrEP has sufficient efficacy and is safe for HIV negative populations. Four components come next: cost effectiveness looks to determine whether

PrEP is a cost-effective prevention intervention; affordability/funding seeks to identify projected costs and resources; market acceptability identifies whether the products will be acceptable to users, providers, policy makers and regulators; and finally, physical deliverability assesses whether PrEP can be delivered to target populations, what channels are best suited for delivery and the associated infrastructure gaps that must be closed. FHI 360 has focused on the Physical Deliverability component; with additional partners of the BMGF conducting research on the others components.

When considering whether ARV-based prevention products can be delivered to user groups, several service delivery issues emerged including: What makes a service acceptable? What types of products do users want? Are the products where the users want, and are able, to access them? Are users treated appropriately? In addition to concerns around product acceptability, the effect of adding other services to existing delivery channels is also a concern. Questions on whether potential delivery channels have sufficient staff, space and time and what else potential delivery channels need in order to provide products were important. Knowledge of how the service delivery environment could support or impede product adherence knowing there could be variations by product type, user group and delivery locations were also seen as important. Finally, we were interested in how to deliver services users needed for product use such as routine HIV testing and lab tests and linkages to care if they seroconvert. The research team acknowledged that the resources needed to add these HIV prevention products and services may vary by country, delivery channel, user groups and product type.

To address these questions, the Proof of Deliverability study examined ARV-based prevention product delivery among groups most at risk of HIV infection. This included female sex workers whose behavior may be stigmatized or illegal and other groups at high risk, such as discordant couples and adolescent and young women. As clinical research continues and product formulations evolve, multiple product types were included in this study. Specifically, the study examined daily oral PrEP (with considerations of variations for intermittent oral products), a monthly injectable and microbicide gels.

The study had three objectives:

- To identify and assess the most likely PrEP delivery channels for each target population
- To evaluate the impact of PrEP on the quality and delivery of services in existing delivery channels and define the additional capacity and support required for product introduction
- To propose a PrEP delivery plan for each target population including how to address key infrastructure gaps, with time and cost estimates

Study results were intended to be used both to programmatically inform BMGF's PrEP portfolio and, if appropriate, to inform policy and programmatic efforts at the country level. Four different populations in two countries were included: in Kenya the study looked at female sex workers in Nairobi and discordant couples in Nakuru, two populations who were likely to be early users of ARV-based prevention products. Kenya was a priority location for the Gates Foundation and, as the site of several PrEP studies; ethically it should receive early benefit from products if and when they

become available. In South Africa the study examined adolescent and young women between the ages of 14 and 24 in KwaZulu-Natal and worked with MatCH (Maternal, Adolescent and Child Health) at the University of Wits.

Key informant interviews were conducted with policy makers, program managers and service providers. Focus group discussions (FGDs) were conducted with female sex workers, discordant couples, and adolescent and young women. Additionally, facility assessments were performed to look at existing capacity in a variety of service delivery settings.

Data collection for the PoD study was completed in both Kenya and South Africa; analysis of the South African data is on-going. Following the consultation costing exercise will be conducted to identify the costs of “activating the channel” or making products available through the selected service delivery locations. Additionally, the incremental cost per person-year on product will be calculated. The final analysis for both countries will be completed in December of this year.

2. Breakout Session

During the breakout session for the Proof of Deliverability Study, participants examined two potential service delivery channels for two different potential user groups. For female sex workers, the potential channels were sex-worker focused clinics and government health services. For discordant couples, channels included Comprehensive Care Centers (CCCs) and family planning services. For each potential channel the group discussed the appropriateness and feasibility of the channel, key challenges for the channel and the inputs required to facilitate the channel’s successful delivery of ARV-based prevention services.

The group began by discussing the stigma and discrimination sex workers face when accessing services at government facilities. As a result, many FSWs prefer going to sex-worker focused NGO facilities where they are not stigmatized and services are free. These services were seen as friendly, accessible and successful at providing services to a “forgotten” and marginalized population. In addition to the challenge of stigma, providing ARV-based prevention for FSWs through government facilities was challenged by human resources limitations and attitudes that prevention services were not a priority in government services, especially for the population of FSWs. The point was made that while service coverage for FSWs was still low, about 45% were covered; PrEP was, therefore, an opportunity to increase coverage to this relatively small but important population who accounted for about 14% of new infections.

Government facilities were seen as more sustainable than NGOs, which were dependent on donor funding. Suggestions were made for donors to put more funding into NGO facilities, with a plan to eventually transition FSW services from NGO facilities into government facilities to increase sustainability. The suggestion was made for NGOs to share evidence-based programs with the government. In order to transition to government, special training would be needed to improve the interactions between FSWs and public-sector providers; as well as restructuring of staff to improve support and reduce burden.

Next, the group discussed Comprehensive Care Centers and family planning services as potential delivery channels for discordant couples. CCCs were identified as a good outlet since couples were already used to attending them for 'Prevention With Positives' services, and since the centers were already equipped with needed services. Increased workload could be an issue at CCCs, though this could be mitigated through changes to the triage of client needs on a given day; the idea of creating a checklist to streamline the evaluation of client need was raised. Another CCC-related issue was the focus of government facilities on treatment, not prevention; the group felt that, to implement in CCCs, prevention programs must be improved. This included bridging gaps in services including – training, human resources, advocacy for providers and clients and a major scale up of HIV testing and other services. Participants were also positive regarding the potential of family planning services as a delivery channel, although it was noted that FP clinics were a weaker choice since such clinics were viewed as unfriendly to men, making it harder to bring in male partners for PrEP/microbicide services. Additionally, FP clinics had similar challenges as other facilities, such as the need to improve client flow, treatment of clients and the need to strengthen routine testing services.

B. Social Marketing Planning for Oral PrEP Rollout in Targeted Populations

The Social Marketing Planning for Oral PrEP Rollout in Targeted Populations is a USAID-funded project, conducted as part of the FEM-PrEP clinical trial, which aimed to facilitate local planning for PrEP rollout in Bondo, Kenya. Research consisted of qualitative interviews with a range of stakeholders to identify barriers and solutions to PrEP rollout and uptake, including service delivery and logistical issues and cultural norms. Community planning activities consisted of district, provincial, and national workshops in which participants strategized on the most effective ways to provide PrEP to local populations at risk of HIV infection. A facility inventory was also conducted to explore the possible integration of PrEP into existing services. Results of this study will be disseminated in the form of a social marketing plan of recommendations for rolling out PrEP in Bondo and will include both service delivery and campaign components for four potential target populations.

1. Overview

Mr. Jacob Odhiambo provided an overview of the FEM-PrEP PrEP rollout study conducted by Impact Research and Development Organization and FHI 360 in Bondo and Rarieda districts, Nyanza province, Kenya from 2009 to 2011. Study objectives were to conduct qualitative research to inform site-specific planning for PrEP rollout that could be implemented by stakeholders if PrEP is demonstrated effective, and to facilitate local planning for PrEP rollout. The study outcome will be a forthcoming social marketing plan with considerations for a pilot PrEP intervention.

The study design used social marketing methodology, a consumer-sensitive, research-driven approach to selling a behavior, e.g., participating in a PrEP program. Key questions for social marketing planning and for the research include: Who should be the target populations for PrEP and what are their characteristics? What are their logistical and psychological barriers to fulfilling

program requirements? What communication strategies can be used to promote PrEP to target populations? How can we tailor service delivery to facilitate target populations' access to PrEP?

Social marketing involves both “downstream” and “upstream planning.” Downstream planning targets potential users and involves identification of their A to Z needs to be able to fulfill program requirements. The intent is to design an intervention that target populations can use easily. Our downstream data collection included interviews with FEM-PrEP clinical trial participants (n=20), as well as members of potential target populations (n=25). Topics included their motivation for staying HIV negative, life circumstances related to HIV risk, ability to reduce their risk behaviors, interest in taking a daily pill, and their views on trial requirements similar to a potential PrEP program.

Upstream planning targets decision-makers, public health and community stakeholders, providers, community-based organizations, and non-governmental organizations. It involves identification of priorities and concerns for local PrEP use, as well as problem-solving and planning to address barriers. Our upstream data collection included interviews with public health stakeholders (n=16) at the district and provincial levels on public health system requirements for designing or implementing a PrEP program, priority target populations, and their views on eligibility criteria for PrEP users. We also interviewed civil society leaders (n=15), including leaders/gatekeepers from women's organizations, churches, beach management unit, village elders, community health workers, and medical personnel, a local politician, and a program facilitator. Interview topics included how to introduce the daily pill to the community, stigma, gender-specific concerns, and target population selection.

Our upstream planning also included three stakeholder workshops. The first was in June 2010, when we conducted a community stakeholder workshop on “Strategies for rolling out PrEP to different target populations” (i.e., fishermen, widows, sex workers, and HIV-negative members of discordant couples). In October 2012 we held a provincial level workshop with public health stakeholders in Nyanza province on “Integrating PrEP into the Public Health System.” We also held a national workshop in March 2011 on “Integrating PrEP into the Public Health System in Kenya.”

In addition, we conducted an HIV services inventory in Bondo and Rarieda to capture a snapshot of HIV-related services in facilities where PrEP could potentially be rolled out. We developed maps indicating where key services were located, including HIV testing and counseling, pharmacy, and a laboratory. A report of the inventory is forthcoming.

2. Breakout Session

In response to the question, “What behavior do we want to sell and what is its impact to the society?” the group discussed the possibility of developing messages that encouraged people to go to the clinic to hear about new HIV prevention options. Given discussions about implementation of combination prevention, the group suggested that this approach would avoid a focus on a single method, instead promoting preventive health seeking behaviors more generally. Providers could help clients determine which new methods (including PrEP, microbicides, and treatment as prevention) were best for them. This could be done in combination with messages encouraging

people to know their HIV status, which would be a necessary starting point for new HIV prevention methods. The downside of this approach was that it would require: a) health systems strengthening to make sure counselors were able to help clients choose the most appropriate HIV prevention method; and b) potentially task shifting because health care workers were so overburdened. Also, it might be necessary to offer new methods in different clinics; for example, PrEP might be offered in CCCs, while microbicides might be made available in FP clinics. Also, adolescents were often hesitant to access traditional health services and high risk populations like FSWs, SDCs, and MSMs often attended particular health services targeted for them.

Table 3: Summary of Responses to Social Marketing Questions in Breakout Group

Questions	Responses	Policy (N=2)	Researcher (N=3)	Other (N=5)	Multiple affiliations indicated (N=4)	Total (N=14)
<i>Is now the time to roll out PrEP?</i>	Yes	1	2	3	4	10
	No	0	1	2	0	3
	Unknown	1	-	-	0	1
<i>What would be the best method(s) to deploy PrEP?</i>	Pilot Program	1	1	4	3	9
	Demonstration Project	1	2	2	3	8
<i>What is the likelihood of funding being allocated for PrEP in the national budget?</i>	Somewhat likely	1	3	2	2	8
	Unlikely	1	-	3	1	5
<i>Do you think these target populations presented will benefit from a PrEP program?</i>	Discordant couples trying to conceive	2	3	3	4	12
	Self-identified sex workers	1	3	5	3	12
<i>If PrEP is approved, is it possible to overcome the tension between ARVs for treatment and prevention at the policy maker level?</i>	Yes	1	2	4	3	10
<i>What other target population (s) should be prioritized for PrEP? (write in)</i>	MSM (7) Sexually active youth (6) Adults/ women who engage in casual sex (3) People with high-risk relationships (1)					

Regarding the seasons of life approach to promoting PrEP, participants said that HIV-negative partners in a SDC could be put on PrEP until the positive partner was on treatment. They pointed out there was often a lag between when someone was diagnosed as HIV-positive and when they were ready to start treatment. Participants also said that PrEP could be a good intervention for when SDCs wanted to conceive. Some raised concern about promoting PrEP for times when condoms were not used because they felt condom use needed to continue to be promoted for PrEP users. Others pointed out the reality – many people were not currently using condoms; if a man was not willing to use condoms, the woman could use PrEP to protect herself. Participants discussed the possibility of promoting PrEP to people based on certain HIV risk behaviors, rather than based on being part of a particular group like FSWs. One reason for this approach would be that promoting PrEP for certain risk groups could stigmatize those groups.

Regarding how to market PrEP, participants brought up key questions that required answers, including whether PrEP will be available for free? How will it be packaged? Will it be branded or

unbranded? These are questions that can be addressed in the social marketing plan once decisions are made at the country level.

PrEP Effectiveness and Efficiency

Mr. Daniel Mwai presented his work on estimating the cost and impact of implementing PrEP at scale-up in the Kenya setting. Through the USAID-supported Health Policy Project (HPP), a global project led by Futures Group and its partners, he is assisting the Kenya government to address the following question:

Following the evidence from Partners PrEP and other trials, should PrEP for serodiscordant couples, key populations or most-at-risk populations be scaled up in Kenya?

Table 4: Range of Costs for PrEP Model

Costs will depend on the potential PrEP program structure				
	Awareness Education & Counseling	Initiation Screen & Enroll	Maintenance Recurring delivery	Transition Link to care
Objectives	<ul style="list-style-type: none"> Raise awareness and educate target populations about availability and applicability of PrEP Generate demand 	<ul style="list-style-type: none"> Conduct testing necessary for initiation of PrEP Deliver 1st round of drugs Deliver counseling to promote adherence 	<ul style="list-style-type: none"> Deliver follow-up counseling Deliver recurring HIV testing Provide recurring prescription 	<ul style="list-style-type: none"> Ensure proper linkages to care upon seroconversion
Analogs	<ul style="list-style-type: none"> Existing VCT services RH services HPV Vx MC 	<ul style="list-style-type: none"> VCT RH services, incl. STI clinics ART services 	<ul style="list-style-type: none"> RH services TB 	<ul style="list-style-type: none"> Current VCT systems
Means to alter model	<ul style="list-style-type: none"> Level of effort 	<ul style="list-style-type: none"> Level of effort devoted to education Level of effort and human resources required Testing regimen 	<ul style="list-style-type: none"> Level of effort and human resources required Testing regimen 	<ul style="list-style-type: none"> Formality of linkage

Source: Bill & Melinda Gates Foundation, 2009

The development of costing models will require researchers to identify the different types of program inputs needed to support PrEP users as they transition from awareness to initiation and maintenance of PrEP use, as shown in table 4 to the left. These include costs for educational materials and activities; drugs, test kits and other clinic supplies; personnel training and staff time for counseling, service provision, monitoring and other activities.

Research steps to inform the policy question include:

- Pilot projects on PrEP to explore issues of implementation and adherence in a community setting outside a trial setup
- Cost, cost-effectiveness and other modeling analyses to explore alternatives and to anticipate resource needs
- Comparison to other biomedical and behavioral prevention approaches

In anticipation of a need to look at the scale-up of PrEP, HPP has consulted with clinical trial researchers, as well as the team that considered the 'bottom-up cost model' for Oral PrEP in South

Africa for the Bill & Melinda Gates Foundation, reviewed the literature and engaged with stakeholders at NASCOP.

The way forward includes:

1. Discussion with NASCOP and technical experts (Dr. Mugo, Dr. Celum, etc.) to define the potential PrEP program design, to cost scale up
2. Preparation of a detailed concept note in 2012 and validation of the analysis approach
3. Collection of secondary data on unit cost and required program resources
4. Modeling analysis of possible prevention impact with uncertainty analysis on the impact parameters, to cater to unknown levels of adherence and different program designs
5. Preparation of results brief and other dissemination.

New microbicide-related initiatives

Mr. René Berger provided an overview of USAID's *Shared Vision and Strategic Plan for Microbicide Introduction*. The genesis of this initiative was a November 2010 meeting, convened by USAID following the results of CAPRISA 004, to examine the challenges associated with introducing 1% tenofovir gel. One of the commitments made by USAID at that meeting was to develop a strategy for product introduction. Originally drafted in early 2011, the *Shared Vision* focused on the expectation that 1% tenofovir gel would be confirmed by the VOICE Trial in 2013. However given the early closure of the tenofovir gel arm in VOICE, the field must now await the FACTS 001 trial being conducted in South Africa to provide large scale confirmation in 2015 with an aim to have a licensed product by 2016.

Nevertheless, the goals of the *Shared Vision* remain unchanged. USAID is engaging an ever-growing list of collaborators including WHO, UNAIDS, BMGF, stakeholders from African governments, civil society and the international research community. By focusing on the interval between completion of the FACTS trial and introduction of the product, this project aims to identify the practical steps that can bring a microbicide product to market and maximize its impact. In doing so, it will also inform future product introduction – beyond tenofovir gel. The USAID-funded *Shared Vision* comprises 7 high-priority strategy elements, two of which are further discussed below (bolded). They include:

- 1) External Inter-Disciplinary Microbicide Access and Introduction Stakeholder Group
- 2) Provide support for regulatory, licensure, manufacturing, and financing needs
- 3) Develop and implement a comprehensive communication and advocacy strategy**
- 4) Design and implement a microbicide readiness assessment tool
- 5) Adapt and pilot cost modeling for microbicide introduction as an intervention for HIV prevention

- 6) **Adapt and implement gender analysis tool(s) to assess women’s access to microbicides and the impact of microbicides on reducing women’s vulnerability to HIV infection**
- 7) Develop and implement a social science and operations research agenda for microbicide introduction, demand, and delivery

A. Gender Analysis Methodology and Toolkit

The Gender Analysis Methodology and Toolkit is part of a larger USAID-funded strategy to support future, potential introduction of microbicides to women if tenofovir gel is proven effective. The project aims to adapt a gender analysis methodology and tools endorsed by USAID to examine how gender norms, roles, and relations will likely affect women’s ability to successfully access and adhere to a tenofovir gel regimen. The work will include pilot testing the adapted methodology and tools in Kenya and one other country; interpretation of pilot test findings in collaboration with in-country stakeholders; development of recommendations on how gender-based obstacles could be addressed in microbicide introduction plans; and dissemination of finalized methodology, tools, and guidance.

1. Overview

Microbicides were originally conceived as female-controlled HIV prevention methods. However, the technology will not, by itself, alter the underlying structural and social determinants of women’s vulnerability to HIV. Previous microbicide acceptability research reinforced the notion that topical gel might be female initiated—but not in all cases female controlled. We can extrapolate from the field of contraception and from microbicide acceptability studies and trial literature that women will face gender-related barriers to accessing and adhering to microbicide products. These include social, structural, and behavioral barriers. Identifying these barriers and developing strategies to deal with them in advance of tenofovir gel roll-out will help maximize the likelihood that women will be able to access and adhere to microbicides. This will help maximize the potential that microbicides offer for women to protect themselves from HIV.

The way we plan to take these various factors into account is to conduct a gender analysis, which is a systematic examination of gender norms and inequities between men, women, and sexual minorities to answer two questions:

- (1) How will gender relations affect the achievement of women’s access to and use of a microbicide product?
- (2) How will microbicide introduction affect the relative status of women and men? For example, will the availability of a woman initiated method be a source of empowerment for women? Or will it make men even more unwilling to use condoms, thus putting the burden of HIV prevention on women and relying too heavily on a less effective method?

This project has 4 main objectives:

Objective 1: The project will adapt a gender analysis methodology and tools endorsed by USAID and its InterAgency Gender Working Group. The project team has reviewed and synthesized gender-related data from microbicides acceptability studies and clinical trials. They also interviewed researchers, community engagement experts, and advocates involved in PrEP and microbicides work to discuss any other gender related information that had not emerged in the literature synthesis. They also reviewed national-level data on gender from DHS.

Objective 2: Next, the gender analysis methodology and tools will be pilot tested in Kenya and one other country. This will include meeting with key in-country stakeholders like health service providers, policymakers, NGO staff, and funders. These meetings will focus on filling in any information gaps identified through the review of available data and to learn more about the local gender norms and practices that could affect tenofovir gel access and use. The methodology and tools will be further refined based on these meetings with stakeholders in Kenya and the other pilot country.

Objective 3: Once the gender analysis tools and methodology are finalized, the adapted tools, methodology, and accompanying implementation guidance will be disseminated globally and in countries where early rollout is likely.

Objective 4: Finally, throughout the project, an intensive utilization plan will be implemented to promote the gender analysis findings in Kenya and the second pilot country. This plan will include working with stakeholders to understand the gender analysis findings and their policy and practice implications for country-specific tenofovir gel introduction plans.

2. Breakout Session

Breakout session participants discussed key gender-related issues in microbicide introduction including: (1) user populations and marketing, (2) communicating with male partners, (3) microbicide acceptability, and (4) adherence and behavior change. This discussion was informed by an FHI 360 synthesis of the microbicides acceptability and clinical trial literature and breakout sessions participants' own experiences.

In terms of **user populations** and **microbicides marketing**, participants agreed that microbicides should be promoted to a general population of sexually active women, including adolescents. They felt this was appropriate because if microbicides were promoted only to the highest risk women, like female sex workers and women in serodiscordant couples, it would stigmatize use of the product by other women, who also needed a way to protect themselves from HIV. Participants felt that adolescents should be explicitly targeted with microbicides because they were at high risk of HIV infection and this risk was underpinned by gender norms, such as assumptions that young women should abstain from sex to preserve their virginity. The group agreed that family planning (FP) clinics should be strongly considered as a service delivery channel for rolling out microbicides, as many sexually active women already accessed FP clinics. They noted that adolescents, however,

did not usually access health services and alternative delivery channels such as pharmacies and youth services should be considered. The group also discussed the potential of marketing microbicides for women's general health, similar to how pap smears are promoted as something all women should do for their health. This would remove the element of HIV risk, as many women who are at risk of HIV may not believe themselves to be at risk, keeping them from trying microbicides. Additionally, they said that if microbicides were promoted as a way for women to protect themselves from HIV, this might make men fear that women would seek additional partners. Finally, they cautioned against promoting microbicides as a way to empower women; because of the societal disempowerment of women, men would fear that women were gaining control and men were losing control.

In terms of **partner communication**, the group identified two overarching groups of women—(1) those in steady relationships, and (2) those in casual relationships. Based on the literature, women in steady relationships preferred to discuss microbicide use with their partners (either at the beginning of use or after initiating use). Factors that influence whether communication happens include how strong taboos around sexuality and sexual communication are in the community, fear of negative reactions from male partners (including violence), fear of initiating a conversation about microbicides implying a lack of trust in relationship, and age. Participants pointed out that women may be more hesitant to discuss microbicides in a newer relationship or in a relationship where her partner was much older than she was. On a positive note, microbicides could give couples an opportunity to discuss HIV risk and protection. In casual relationships, including sex work, women would be less likely to discuss microbicide use with her partner.

Microbicide acceptability will be affected by gender norms on sexuality and intravaginal practices. Participants pointed out that Kenyan women might be hesitant to insert a microbicide gel because insertion was not a common practice. The safety and effectiveness of the gel would also affect its acceptability. Participants said that women would want to know whether the gel prevented pregnancy and whether it affected fertility, and men would be concerned about its effect on their sexual potency and sexual pleasure. Microbicides messages should address these concerns.

In terms of **adherence**, participants said that the BAT 24 regimen would be a challenge because women did not have control over when they had sex. They emphasized that constructive male engagement in microbicide programs would help support women's adherence. Regarding **behavior change** resulting from microbicide use, participants said that condom use could decrease because it might be easier for women to use microbicides than condoms. This could be especially true for populations who were already using condoms like FSWs, SDCs, and women with casual partners. Communications campaigns would need to consider how to create messages about microbicide use that incorporated condoms and microbicides into a package of HIV prevention options.

After discussing these specific gender issues, the group gave feedback on the proposed gender analysis piloting plan for Kenya. They emphasized that communities needed to be involved in microbicide implementation because their views were very different from policymakers'. They said interviews and dissemination should take place at the regional and provincial levels, as they would

be involved in microbicide implementation. Finally, they said that the gender analysis findings would be most valuable to the Ministry of Health and NGOs, but the findings would need to be owned by the MOH in order to have maximum impact on microbicide programs.

B. Microbicides Communications Strategy

The Microbicides Communication Strategy is part of a larger USAID-funded initiative to support future, potential introduction of microbicides to women if tenofovir gel is proven effective. The project aims to develop and evaluate a comprehensive communication strategy for end-user audiences and health care providers. The work will include identification of priority audiences and message types; collaborative in-country development of messages and materials; and a final strategy report of key outcomes, describing the process of each phase, approach to message development and testing, key outcomes and lessons learned.

1. Overview

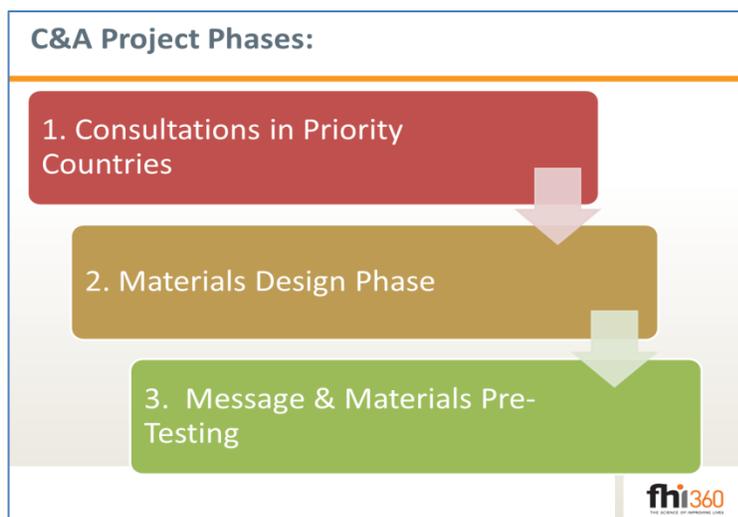
The overall goal of the Microbicide Communications Strategy is to develop a comprehensive communications strategy, including **audience-specific** processes, **messages and materials** in *two priority countries in which microbicide introduction is likely to occur first*. After extensive discussions internally and with key stakeholders in Kenya and other countries, we propose working with Kenyan partners as one of the priority countries. We are still in discussions in terms of a second country.

The project aims to be conducted based on the following criteria:

- Collaborative: Local partners guide selection of priority audiences
- Theoretically Informed: Message development informed by behavioral and communications theory
- Evidence-based: Mixed method research to assess comprehension & appeal of messages/ materials by audience, and communication process & final strategy by country

Project activities would occur in three phases, including 1) In-country consultations; 2) a materials design phase; and 3) a message and materials pre-testing phase (as shown in Figure 5 below.)

Figure 5: Three Phases of Project Activities



The current consultation was meant to fulfill a key activity for phase 1. Prior to holding this meeting, we conducted a pre-consultation landscape analysis. It included a review of the social-behavioral research related to determinants of HIV risk for potential communication audiences.

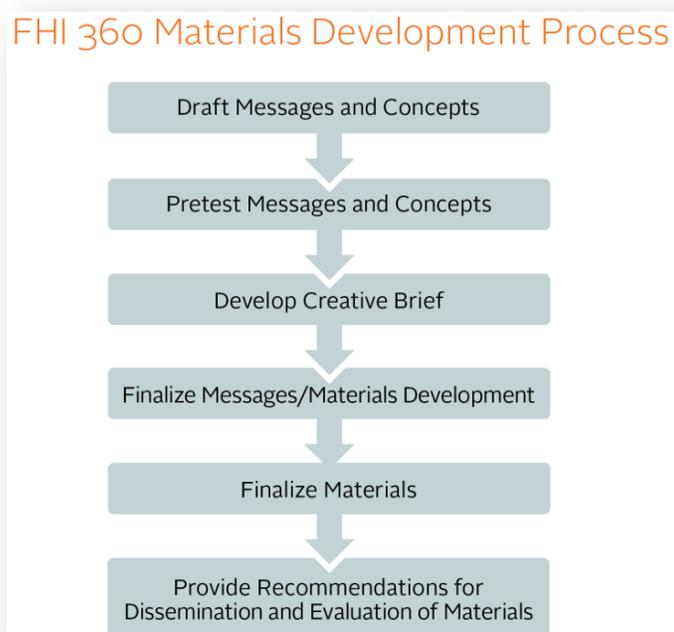
For this consultation we have convened you in the capacity of policy makers, providers or representatives of potential end user groups in order to obtain guidance on priority audiences and programmatic considerations and to begin to understand the communication needs and preferences of different groups.

During phase 2, we envision conducting one or more message development workshops, attended by local microbicide advocates, community representatives, social scientists & behavior change communication expertise, in order to more carefully examine the results of literature review, identify the behavioral objectives of each priority audience, and draft message concepts for each audience. This information would form the basis of one or more creative briefs that would guide the development of materials – posters, leaflets, radio shows or other formats that are meant to influence the specific audience’s knowledge or behaviors. Examples of possible behavioral objectives (to be finalized during the message development workshops) might be to:

- Raise awareness about new female-initiated products that may reduce risk of infections (HIV, HSV) among women, men, or healthcare providers;
- Increase healthcare workers’ ability to identify and counsel women who could benefit from microbicide use;
- Increase discussions between women and male partners about potential use of microbicide products;
- Increase willingness among target audiences to consider use of a vaginal microbicide product

The final objective of this strategy relates to the development of communication materials and job aids, targeting potential providers and user populations, in order to test their effect on method knowledge, feasibility, acceptability and potential for stigmatizing the end user. Figure 6 shows the overall materials development process.

Figure 6: Message Development Process



During phase 3, a research protocol will be developed with local research partners, submitted to Kenya and US IRBs for approval. We will use a mixed methods approach to assess the design elements, as well as the effect of messages on selected behavioral outcomes. The end products of this project include a final report, describing the process of each phase, the approach of message development and testing, key outcomes and

lessons learned. A strategy document will be developed for each country that describes policy maker guidance on priority audiences, presents information from the environmental scan, describes message development and testing processes and outcomes, and makes recommendations about how a microbicide should be positioned to generate demand and access for key end user groups. Research papers may be developed to report key outcomes of message testing by country and/or audience segments.

This work will be critical to ensuring women have access and the ability to use tenofovir gel – or other female initiated methods once they become available. While some of the message development activities can and should be initiated sooner – testing the effectiveness of such strategies must follow *regulatory approval of the gel*.

2. Breakout Session

The objectives of the Communications breakout session were to begin to 1) identify priority audiences and those who influence them; 2) brainstorm potential messages tailored to the needs of that/those group(s) and 3) consider potential channels for delivery messages to specific groups.

The breakout session was attended by approximately 18 participants (although only 9 filled surveys related to the group discussion.) In order to help narrow the discussion, Cornelius Baker, who facilitated the discussion, proposed that the group focus on adolescents – one of the groups proposed by consultation participants as an important potential user group for microbicides.

As the breakout group members began by thinking more concretely about the characteristics of an adolescent audience, they noted that adolescents are a diverse group. Some decisions would be needed about how to better segment adolescents, based on:

- Age and legal status – between ages 16 and 24, those considered “mature minors”
- Sexual behaviors – do we target sex workers, young women in semi-stable relationships, people co-habiting
- Educational or work status – should we target domestic workers, migrant workers, or those in- or out-of-school
- Place of residence - people living in urban and rural areas, or in certain parts of the country

The group then considered the potential benefits to using a microbicide. In other words, they thought about why an adolescent might be interested in using a microbicide gel. Some of the responses included:

- Protection – it (potentially) reduces the chance of HIV infection and is easy to use
- It is another option for those who cannot (or will not) use a condom
- For male partners, it is easier to use compared to a condom
- It may be more discreet. People cannot know whether a person is using the product or not
- It can be co-marketed by VHMC (village health management committees)
- It makes sex more comfortable or pleasurable

The group then turned its attention to identifying messages that might be destined to an adolescent population. Some of the messages proposed by the group included:

- Importance of adherence “If you don’t use it, there is no protection.”
- “It protects **if** you are HIV negative. ”
- “You still need to use a condom.”
- “Always know your HIV status.”
- “Please use as directed. It is not intended for anal use.”
- “There is a new choice. Go to your doctor to learn more.”
- “Microbicides - for pleasure plus protection.”

The group also noted that a number of messages would be needed related to the product, how it should (or shouldn’t) be used – dosing instructions, level of effectiveness, safety, and potential side effects. These messages and materials would be especially important for providers to be able to share with potential clients. Some might need to be tested for package inserts or client-oriented brochures.

This led into another discussion about who might be secondary audiences – those who might influence the use behaviors of adolescent women. They included:

- Male partners, because microbicides might be considered easier to use than condoms
- Providers - they will need to discuss with clients about safety, side effects, dosing instructions and how to use the products
- Teachers - they mold most of the youth during their studies
- Peers - because they discuss a lot and can influence each other
- Faith leaders and the church – Most people trust their church leaders
- Celebrities/comedians

Some of the channels that were considered most appropriate for adolescents included:

- Music
- Peer to peer communication
- Social media (Tweeter, Facebook)
- FM radio, TV, mobile phones
- FBOs (Faith Based Organizations)
- Government announcements
- Service providers – who might need to be sensitized to adolescent issues
- Teachers
- Brochures and posters
- Youth-friendly centers

Finally, the group discussed some of the challenges to promoting a topical microbicide for this audience. For example, they mentioned the need to deal with the fact that such products would not necessarily protect from STIs or pregnancy; that they were likely to be only partially protective and that it would be important not to encourage reduction in condom use, when groups were already using this strategy effectively. Finally, they acknowledged that cultural, geographic and/or ethnic differences would also influence how information should be communicated – even when working within a similar priority audience.

In addition to the above discussion, the group was asked to fill out a quick survey for additional feedback on the communication breakout session. Below is a summary of responses from the group.

Table 4: Summary of Responses related to the Communications Breakout Session

Questions	Responses	Researcher (N=3)	Other (N=3)	Affiliation not Indicated (N=1)	Multiple affiliations indicated (N=2)	Total (N=9)
<i>Which population groups would you prioritize for microbicides?(Circle 2)</i>	Female sex workers	3	1	1	2	7
	Adolescents	2	2	1	1	6
<i>What kinds of communication materials or approaches would be most useful for your highest priority population group? (Circle all that apply)</i>	TV	1	3	0	0	4
	Brochures/pamphlets	2	0	1	1	4
	Radio	2	3	0	1	6
	Social media	2	2	0	0	4
Question	Open ended responses					
<i>What processes do we need to go through to ensure that we engage with population groups appropriately?</i>	<p>Initiate the program with the government; get government buy-in (2) Community mobilization Good introduction Ensure availability of product, monitor Understanding how diff. pop. groups are influenced and make decisions Mapping process Use known champions with experience Organize meetings with their associations or groups Analyse where the group is; engage them in conversations to see acceptability/accessibility Avail information</p>					
<i>What specific groups or individuals should we interact with to access these populations circled above?</i>	<p>NGOs (4) Government (3) Health care providers (2) Peer groups (2) Support groups (2) Schools (2) Religious centers, Pastors (2) Sex worker clinics Youth centers House girls Peers to FSW Couples CBOs, FBOs Advocacy group for women fighting AIDS in Kenya Advocacy group for associations of sex workers Counselors Partners, Community gate keeper</p>					

What specific groups or individuals should we interact with to develop these messages?	Adolescents (3) FSWs (2) Government authorities (2) Discordant couples All beneficiaries Local social marketers MSM Media consultants University and other college students, teachers Healthcare providers Pastors Counselors Advocates Researchers
Other comments	The adolescents are very hard to reach and also ignored group. However, they accept things very easily when they realize you mean well. Get our community entry right.
What concerns do you have about microbicides in general?	Partial protection, Low-medium effectiveness (3) Adherence (2) Product misuse (2) Stigma Behavioral disinhibition They seem to take a long process to be available in the public arena The vaginal gel condom could be used rectally
What are your suggestions on how to address these concerns?	Communication strategy (2) More research in different settings and with larger sample sizes Microbicides should be made available only in HIV testing centers Fast tracking the remaining process/procedures We should start the conversation on rectal microbicides

Appendices

A. Closing and Evaluation

In closing, Dr. Bukusi asked each person if they could sum up the meeting in one word. Some of the words used to describe the consultation included:

Possibility, Insightful, Empowerment, Interactive, Needed, Strategic, Inspiring, Reevaluate, Collaborate, Timely, Suggestive, Informative, Good, Implementation, Service, Educational, Youthful, Hope, Breakthrough, Eye-Opener, Powerful, Yes!

She reminded participants that this consultation was just one of a number of meetings that had taken place and would take place in the future. It was meant to engage people in the discussion about the possibility of introducing new ARV-based products for HIV prevention, so that we could raise concerns and understand each other better. The more engaged people are in the discussion,

the more robust the response would be, because both HIV prevention and treatment are needed in Kenya.

Evaluation Summary

A total of 20 participants (46.5%) completed the consultation evaluation survey, out of the 43 participants who attended the consultation. Table 5 provides summary information from select survey questions.

Table: 5 Summary of Evaluation Responses

Questions	Response categories	Policy (N=4)	Research (N=7)	Other (N=6)	No Affiliation indicated (N=3)	Total (N=20)
<i>Overall evaluation of the consultation</i>	Good	4	3	4	1	12
	Excellent	0	4	2	2	8
<i>Important to deliver new HIV prevention methods in Kenya</i>	Agree	2	0	1	0	3
	Strongly agree	2	7	4	3	16
<i>Information presented helped me think about who PrEP and microbicides should be delivered to</i>	Agree	2	1	1	2	6
	Strongly agree	2	6	4	0	12
<i>Information presented helped me think about what service delivery channels are appropriate for PrEP and microbicides</i>	Agree	1	3	2	2	12
	Strongly agree	0	4	3	0	6
<i>Now is the time to roll out PrEP, given recent trials</i>	Agree	4	3	2	0	7
	Strongly agree	0	2	1	2	5
<i>We should start planning for microbicide introduction now</i>	Agree	1	4	2	0	10
	Strongly agree	3	2	3	2	8
<i>It is important to consider gender issues that will affect women's ability to access and use microbicides</i>	Agree	2	1	1	2	4
	Strongly agree	2	5	4	1	14
<i>What was most useful to you?</i>	Gender analysis (5) Breakout sessions (4) Overview of future potential ARV use in Kenya (3) Social marketing (2) Communications and advocacy strategies (2) Potential user groups (2) Everything Issues related to implementation USAID Shared Vision Study findings The presentations and Q&A					

<p><i>What suggestions do you have to improve the consultation?</i></p>	<p>Needed to hear more from Kenyan participants/stakeholders from civic societies, professional and legal organizations (8) Let MOH/ NASCOP/ NACC take the lead (6) More discussion (5) Needed more time (2) Reduce number of lectures More on cost-benefits of new tools should happen More on how PrEP and microbicides will be combined with existing tools Need for continued communications (email) to increase ideas</p>
<p><i>What are your remaining questions?</i></p>	<p>What is the government position on future funding for roll out? (2) Still concerned about the tension between TAP and PrEP (2) What happens if Tenofovir is not proven effective? What are the legal implications of ARV based HIV prevention and how to prevent overflow of ARVs in the community? What are potential side effects of TDF and use if already compromised kidneys? What is there for adolescents? What about concern for affordability? Where will ARV-based prevention fit with current interventions? How should we emphasize condom use? More research needs to be done How do we ensure people want to use PrEP and microbicides because we know they are needed? A clear road map is lacking</p>
<p><i>What are the necessary next steps?</i></p>	<p>Open ended responses Sensitization, social marketing, communication, advocacy (7) More discussions with policy-makers (6) Develop Governmental Guidelines (4) Cost benefit analysis for implementation (2) Create a prioritization matrix to guide implementation discussions Training of HR to deliver services Pilot program on PrEP Professional orgs should develop guidelines and not wait for the government Dissemination of scientific information Merge scientific evidence to implementation framework Plan for increasing access Real time preparedness, funding, acceptability Start small then go full blast We still need to hear from the general population about acceptability</p>

B. Participant List

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