Manual for Conducting a Gender Analysis for Microbicide Introduction

Michele Lanham, Elizabeth Goslin Doggett, Rose Wilcher, Robyn Dayton

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ACRONYMS

ARV	antiretroviral
DHS	Demographic and Health Surveys
FP	family planning
GBV	gender-based violence
HCT	HIV counseling and testing
HIV	human immunodeficiency virus
IGWG	Interagency Gender Working Group
IPV	intimate partner violence
NGO	nongovernmental organization
PrEP	pre-exposure prophylaxis
RH	reproductive health
RSHR	sexual and reproductive health and rights
SRH	sexual and reproductive health
STI	sexually transmitted infection
USAID	United States Agency for International Development

EXECUTIVE SUMMARY

Women's HIV risk is driven in large part by gender norms and structural inequalities between women and men. Microbicides have been hailed as a much-needed female-initiated HIV prevention method; however, women will still likely face gender-related barriers to accessing and using microbicides if an effective product is identified and licensed for introduction. To ensure the future success of this product, it is vital that policy and programs be informed by a sound understanding of how gender norms and inequalities are likely to affect women's microbicide use.

A gender analysis aims to strengthen the effectiveness of health and development programming by identifying gender inequalities that may affect program outcomes and potential ways to address them. As part of USAID's *Proposal for a Shared Vision and Strategic Plan for Microbicide Introduction*, FHI 360 developed a gender analysis process specific to microbicide introduction. We pilot tested it in South Africa (in partnership with Sonke Gender Justice) and Kenya, two countries where early introduction of a microbicide is likely.

This manual provides guidance for conducting a gender analysis in a country preparing to introduce microbicides. A gender analysis for microbicide introduction answers two key questions:

- How will gender relations affect women's access to and use of a microbicide product?
- How will microbicide introduction affect the relative status of women/girls and men/boys?

We outline the steps to conducting a gender analysis for microbicide introduction, share lessons learned from pilot testing in Kenya and South Africa, and provide tools and resources for conducting your own gender analysis for microbicide introduction.

This manual is intended for government officials, funders, program designers, staff of nongovernmental organizations (NGOs), or advocates who wish to conduct a gender analysis to help them design a gender-integrated program for microbicide introduction. Conducting a gender analysis will enable policymakers and program planners to design a microbicide introduction program that effectively takes gender issues into consideration, ultimately helping make microbicides a game changer for women's HIV prevention.

OVERVIEW OF GENDER ANALYSIS FOR MICROBICIDE INTRODUCTION

A gender analysis aims to strengthen the effectiveness of health and development programming by identifying gender inequalities that may affect program outcomes and potential ways to address them (1). USAID requires the projects it supports to conduct gender analyses to inform project or activity design. A gender analysis is a social science tool used to examine differences in women's and men's, and girls' and boys', roles, responsibilities, and use of time; access to assets; and exercise of power. It also seeks to understand how norms, beliefs, and perceptions, as well as laws, policies, and institutional practices, affect men and women differently. The influence of all of these factors is considered as it relates to differences in women's and men's lives and health (2).

Microbicides are a potential HIV prevention method for women. While these products are still being tested in clinical trials, funders, policymakers, and other stakeholders are considering how microbicides could be introduced if an effective product is identified. As part of USAID's *Proposal for a Shared Vision and Strategic Plan for Microbicide Introduction*, FHI 360 developed a gender analysis process specific to microbicide introduction. We pilot tested it in South Africa (in partnership with Sonke Gender Justice) and Kenya, two countries where early introduction of a microbicide is likely. **This manual provides guidance for conducting a gender analysis in a country preparing to introduce microbicides.**

A gender analysis for microbicide introduction answers two key questions:

1. How will gender relations affect women's access to and use of a microbicide product?
2. How will microbicide introduction affect the relative status of women/girls and men/boys?

This manual is intended for government officials, funders, program designers, NGO staff, or advocates who wish to conduct a gender analysis to design a gender-integrated microbicide introduction program.

It should be noted that this gender analysis process was developed in 2013, and microbicides have not yet been approved for use. Nevertheless, it is important to begin planning for a gender-integrated

microbicide program during this pre-approval phase so that once a microbicide product is licensed for distribution, it can be rolled out as efficiently and effectively as possible. This gender analysis process is designed for the beginning of a microbicide program. It can either be implemented before a microbicide product is approved, as we did in Kenya and South Africa, or once an effective microbicide product has been identified and a country is considering whether and how to introduce it. If a gender analysis is not conducted at the beginning of a microbicide program, this process can easily be adapted to assess how well a microbicide program is addressing gender norms and inequalities after it has begun. Ideally, the gender analysis would be revisited throughout the program cycle (see program life cycle in Appendix A).

Ultimately, conducting a gender analysis will enable policymakers and program planners to design a microbicide introduction program that effectively takes gender issues into consideration. In turn, implementing a gender-integrated program could help:

- Improve the quality of microbicide services
- More effectively meet the needs of program participants
- Improve program sustainability
- Better inform and empower clients
- Improve couple communication
- Improve utilization of services
- Broaden development impact and enhance synergies across sectors (3)

GENDER AND MICROBICIDES

What are microbicides and why do women need them?

HIV is the leading cause of death among women of reproductive age worldwide (4). Globally, 50 percent of people living with HIV are women, and the incidence of HIV infection among women has been rising for more than a decade (5). Women's risk of HIV infection is driven in part by gender norms and structural inequalities between women and men. Gender norms often encourage men to dominate sexual decision-making, have multiple partners, and aggressively pursue sex — sometimes to the point of coercion (6). Gender norms often promote the expectation that women, on the other hand, should be submissive on sexual matters. Coupled with differential access to education and livelihoods, gender norms establish power inequalities between women and men that limit women's ability to negotiate safer sex practices, especially in the context of marriage, violent relationships, and intergenerational partnerships (6, 7). These practices, ideologies, and inequalities are harmful to both women and men, making it more difficult for them to mitigate the risk of HIV acquisition (7). Addressing gender norms and inequalities is a critical undertaking that requires sustained investment. In the meantime, women need additional ways to protect themselves from HIV.

Sex is the classification of people as male or female. At birth, infants are assigned a sex based on a combination of bodily characteristics, including chromosomes, hormones, internal reproductive organs, and genitalia.

Gender refers to a culturally defined set of economic, social, and political roles, responsibilities, rights, entitlements, and obligations associated with being female and male, as well as the power relations between and among women and men and boys and girls. The definition and expectations of what it means to be a woman or girl and a man or boy, and the sanctions for not adhering to those expectations, vary across cultures and over time and often intersect with other factors such as race, class, age, and sexual orientation. Transgender individuals, whether they identify as men or women, are subject to the same set of expectations and sanctions.

Gender equity is the process of being fair to women and men and to boys and girls. To ensure fairness, measures must be taken to compensate for cumulative economic, social, and political disadvantages that prevent women and men — and boys and girls — from operating on a level playing field.

Gender equality is the state or condition that affords women and men equal enjoyment of human rights, socially valued goods, opportunities, and resources. Genuine equality means more than parity in numbers or laws on the books; it means expanded freedoms and improved overall quality of life for all people.

Empowerment means expansion of people's capacity to make and act upon decisions affecting all aspects of their lives — including decisions related to health — by proactively addressing socioeconomic and other power inequalities in a context where this ability was previously denied. Programmatic interventions often focus specifically on empowering women, because of the inequalities in their socioeconomic status.

Gender analysis draws on social science methods to examine relational differences in women's/girls' and men's/boys' roles and identities, needs and interests, and access to and exercise of power, as well as the impact of these differences on their lives and health. It includes assessing gender-based opportunities and constraints, which we also refer to as gender-related facilitators and barriers in this manual.

> **Gender-based opportunities** – gender relations that facilitate men's or women's access to resources or opportunities of any type.
>
> **Gender-based constraints** – gender relations that inhibit either men's or women's access to resources or opportunities of any type.

Gender integration refers to strategies applied in programmatic design, implementation, monitoring, and evaluation to take gender considerations (as defined above, in "gender") into account and to compensate for gender-based inequalities.

Gender-transformative programming fosters critical examination of gender norms and dynamics and strengthens or creates systems that support gender equality or change inequitable gender norms and dynamics. The USAID Interagency Gender Working Group's Gender Equality Continuum Tool provides a framework for assessing how and to what degree a program takes gender inequalities and norms into account and whether it can be classified as "gender transformative" (see Appendix B).

Microbicides are women-initiated methods of HIV prevention (8). Currently, microbicide products are undergoing testing in clinical trials and are not yet on the market. In 2010, the CAPRISA 004 trial demonstrated that a vaginal microbicide gel containing 1% tenofovir reduces a woman's chance of acquiring HIV by 39 percent and genital herpes by 51 percent when used before and after sex (9). The FACTS 001 trial is currently being implemented in South Africa to verify the CAPRISA 004 result (10). Two other pivotal microbicide trials are ASPIRE (MTN 020) and The Ring Study (IPM 027), both testing dapivirine

delivered in a vaginal ring worn for four weeks (11, 12). These trials could provide sufficient evidence to support product licensure and introduction. Together with oral pre-exposure prophylaxis (PrEP), these antiretroviral-based products could create an HIV prevention landscape, akin to that of the contraceptive field, where women have choices of different formulations of woman-initiated HIV prevention products. For more information on the latest microbicide research, visit: www.avac.org/microbicides.

The term "microbicide" refers to substances being studied that could be used in the vagina or rectum to reduce the risk of HIV infection via sexual exposure (13). The microbicide products that are in the most advanced stages of testing are:

- **For women** — they are formulated for vaginal use and do not directly protect men from HIV.
- **ARV-based** — they contain antiretroviral drugs like the ones used for HIV treatment.
- Unlikely to be available over the counter — because they require HIV testing to avoid use by HIV-positive women, which could promote drug resistance.
- **Formulated as a gel or a ring** — the gel is inserted into the vagina before and after sex, and the ring is worn in the vagina continuously and changed every 28 days.
- **Partially protective** — if they are effective, they will reduce a woman's HIV risk but will not protect her completely. Microbicides are likely to be less effective than male and female condoms.

Other microbicide formulations are also being developed and tested, including non-ARV-based microbicides, rectal microbicides, and multipurpose technologies to protect against pregnancy, HIV, and sexually transmitted infections (STIs). Eventually microbicides could come in multiple formulations, such as films, injectables, suppositories, and nanofibers. In this document we focus on vaginal gel and ring microbicide formulations.

What do we know about the influence of gender on women's microbicide use from microbicide studies?

The same gender-related factors that make women vulnerable to HIV are likely to pose barriers to women being able to access and effectively use microbicides. As a first step in developing the gender analysis process for microbicide introduction, we reviewed published microbicide studies to identify gender and relationship norms that may affect microbicide user groups and acceptability, product access,

relationship dynamics and partner communication, microbicide adherence, and condom use. We included microbicide clinical trials; surrogate studies in which a vaginal gel, ring, or diaphragm but no active ingredient was used; and hypothetical studies in which no product was used. We also conducted interviews with global microbicide researchers, advocates, and community engagement experts to verify and contextualize the themes that emerged from the literature review. Some of the key gender issues that emerged included the following:

Gender and relationship norms affect men's and women's perceptions about whom microbicides are for and how acceptable they will be. For example, many recognized and accepted that women in steady partnerships need microbicides, because in many contexts, it is acceptable for married men to have multiple partners and many married women have limited control over negotiating sex and condom use (14-19).

However, some people still think microbicide use is more acceptable for women in casual partnerships and women having transactional sex, viewing microbicides within steady partnerships as unnecessary, inappropriate, and potentially difficult to negotiate (19-21). Despite these conflicting views, microbicides were highly acceptable among women who used microbicides in clinical trials and surrogate studies and among their male partners — including couples in steady partnerships (19, 20, 22-32).

Although adolescent girls are a key population at high risk of acquiring HIV infection and could benefit from advances in a female-initiated technology, few data are currently available on how adolescent microbicide use would be perceived. In the few published studies, there was an interesting dichotomy in responses: health providers and policymakers in South Africa and Zimbabwe thought that condoms were the most appropriate HIV prevention method for adolescents (33), but health providers, community members, and parents in South Africa and Kenya thought adolescents needed access to microbicides because of their high HIV risk and low rates of condom use (15, 34, 35).

Microbicides marketing and promotion will need to be sensitive to gender norms. For example, marketing could try to normalize microbicide use among couples by promoting it as part of a caring, healthy relationship rather than highlighting fears about infidelity and trust. In some contexts it might be effective to promote the potential for microbicides to offer increased sexual pleasure and hygiene by using sex-positive messaging, especially among those whose expectations

about sexual pleasure and hygiene may deter them from using condoms. However, in other contexts women will not react as favorably to the marketing of pleasure as a benefit of microbicides (36).

As with other health services and commodities — such as condoms and contraception — gender inequality is likely to limit women's access to microbicides. Participants in microbicide studies said that microbicides should be priced to be affordable but not so inexpensive that potential users might mistrust their effectiveness (19, 34, 37-40). Women's lack of access to transportation is likely to be an important barrier to accessing microbicides, because women will need to obtain these ARV-based products at clinical settings, at least initially.

Women's process of deciding whether and how to communicate with their male partners about microbicide use will be complex. Studies have confirmed that women value having a product they can use without communicating with their partners (17, 22, 26-28, 38, 41-43). However, study findings suggest that many women will likely talk with their partners about using microbicides. Men and women say they prefer for steady partners to make joint decisions about microbicide use (19, 21, 24, 31, 34, 37, 40, 43-48), and microbicide trial participants usually talked with their partners about microbicide use (23, 27, 32, 48-53). Nonetheless, many recognize that there are some cases where women will want to use the product without telling their partners (15, 21, 30, 45).

The type of microbicide formulation will likely affect the feasibility of using the product without a partner's knowledge. For example, the change in lubrication that occurs with gel use might be more noticeable to a steady male partner than to a casual partner (19, 26, 31, 32, 43, 47). Also, a ring might be easier to store and insert without a partner noticing, compared to a gel.

Fear of violence can influence a woman's decision in both directions: she may use the product without telling her partner for fear of a violent reaction, or she may tell her partner about the product for fear that he would discover it and react violently (47, 49). We also know that deciding whether to communicate is not a one-time decision: some women in microbicide trials told their partners they wanted to use the product at the beginning, but then decided to use it without telling their partners after the partners reacted negatively. Other women used the product for a while without telling their partners, but eventually discussed it with their partners — pointing out that the men had not minded the feel of the product. Open communication about sexuality

and microbicides has the potential to lead to increased intimacy and improved relationship quality, shared responsibility for protection, and increased adherence to gel regimens (26, 47, 51, 54).

The effectiveness of microbicides for preventing HIV depends on whether a woman is able to use the product consistently and correctly. We know more about adherence to a gel product than a ring product, though the hope is that adherence will be less of a challenge with a ring. Evidence from microbicide gel trials tells us that male partners and partnership dynamics appear to play a major role in adherence to microbicide regimens. Gender-related factors that supported adherence include having partners who were aware of and in agreement with their use (28, 50, 55), men's active support of their partners' adherence (e.g., reminding or helping the woman to insert the gel) (26, 28, 47, 50, 53, 54, 56), and being in a casual partnership (26, 57). Conversely, gender-related barriers to adherence included men's complaints about excessive wetness of the gel, women's lack of privacy and control over the timing of sex (14, 22, 24, 26, 30, 45, 46, 58-60), and being in a violent relationship (5, 26, 61, 62).

Finally, relationship dynamics influence the feasibility of negotiating condom use with microbicides. Some women and men already view microbicides as an appealing alternative to using male condoms even though consistent use of condoms offers more HIV protection than microbicides (18, 22, 54, 63).

In several trials and surrogate studies, women reported increased condom use while participating in microbicide trials (9, 16, 52, 63, 64), and they were able to use the clinical trial requirement of using condoms as a bargaining tool with their partners (52, 65). Condom use might be difficult to sustain outside of a trial, though. A microbicide program will need to exercise caution to ensure that the introduction of microbicides does not make it even more difficult for women to negotiate condom use.

It is important to note that most of the gender issues highlighted here are based on research on microbicide gels, diaphragms, and rings. Many of the same gender issues will be relevant to other microbicide formulations; however, as additional research is conducted, gender-related findings from those studies should be considered. For example, partner communication may differ for an injectable, because it would likely be easier for a woman to use without her partner's knowledge.

KEY STEPS IN CONDUCTING A GENDER ANALYSIS FOR MICROBICIDE INTRODUCTION

Step 1: Plan a gender analysis

A gender analysis is essential to understanding how and to what extent the gender issues identified in the global literature matter in your country, and to identifying effective, locally relevant solutions.

A gender analysis can take different forms depending on the time, resources, and information available. We recommend considering the following questions when planning for a gender analysis:

Who can conduct a gender analysis? A gender analysis can be conducted by program designers employed by ministries of health; civil society groups, including NGOs; funders supporting microbicide introduction; or advocates who want to influence the development of a microbicide program. To obtain the highest quality information and greatest impact, it is preferable for more than one of these groups to work together to conduct the analysis, provide input or other support during the process, and promote the use of the findings.

How long will it take? Where time and resources are sufficient, a thorough gender analysis may take up to a year. Additional time will be needed to promote utilization of the findings. However, it is worthwhile to conduct a gender analysis even if you have only a few days or weeks.

When should it be conducted? Ideally, the gender analysis will be conducted as part of the process of planning for microbicide introduction. However, as mentioned in Step 1, a gender analysis can also be conducted during other phases of microbicide rollout.

What are the information sources? The analysis should draw on as many different types of high-quality information sources as possible, including:

- **Desk review** of 1) published and unpublished microbicide research and 2) population-level indicators related to the health, education, and economic well-being of women
- **Policy analysis** to assess ways in which existing HIV and/or gender policies may facilitate or impede the implementation of a gender-integrated microbicide program
- **Interviews with key stakeholders** regarding gender-related constraints to and opportunities for microbicide introduction

Ideally, information used in a gender analysis is evidence-based. However, if resources and information are truly limited, the gender analysis team's own anecdotal, experiential knowledge of gender norms, roles, and relationships can be a useful source of information. Obviously, such anecdotal knowledge is much more valid when the team is composed of local staff rather than expatriates or external consultants.

What should the budget include? The budget for a gender analysis can vary depending on its scope. Resource requirements for a gender analysis typically include staff time, travel expenses if interviews are to be conducted in more than one location, expenses for stakeholder meetings (such as venue costs, food, participant travel, and meeting supplies), and design and printing of final reports or other products.

Gender analysis versus more comprehensive research

Research can be an extremely costly and time-consuming undertaking, and extensive social and behavioral research has already been conducted with potential and actual microbicide users. To keep the gender analysis for microbicide introduction efficient and replicable, we did not conduct interviews with actual or potential microbicide users and their partners. Instead, we reviewed findings from published microbicide studies, which included interviews with thousands of women and men. We also interviewed health care providers and NGO staff who work directly with potential microbicide users. Gender analyses and gender assessments, while they involve "research" of sorts, are typically exempt from ethics committee review because they are intended to contribute directly to programmatic improvements (66).

However, if microbicide study findings are not available from the country you are working in or if potential target groups differ substantially from the women who were involved in previous microbicide research in that country, it may be advantageous to conduct some focus group discussions with potential users and their partners to make sure that the gender issues in your context are similar to those identified in the global literature. Ethics committee review may be required to talk with potential users and their partners.

At a minimum, conduct a desk review and policy review to identify gender norms that are likely to influence women's microbicide access and use. Then, hold a meeting with key stakeholders to present what you found in the desk review and policy review. Enlist their help in identifying and prioritizing the gender-based constraints and opportunities and in developing recommendations for how to address

these constraints and opportunities. If you have time and resources for a full gender analysis, conducting stakeholder interviews adds a wealth of local knowledge and can provide a more nuanced understanding of the key gender issues. More detail about each of these steps is provided in the following table.

Minimum	Full
Desk review, policy review (Step 2)	Desk review, policy review (Step 2)
	Gather additional information from stakeholders (Step 3)
Identify gender-based constraints and opportunities (Step 4)	Identify gender-based constraints and opportunities (Step 4)
Review findings with stakeholders, develop recommendations (Step 5)	Review findings with stakeholders, develop recommendations (Step 5)
Promote utilization (Step 6)	Promote utilization (Step 6)

Sample timeline – Full Gender Analysis for Microbicide Introduction

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
Desk review	X							
Policy review	X							
Stakeholder interviews		X	X					
Synthesize information, identify constraints & opportunities				X				
Review findings with stakeholders, develop recommendations					X			
Promote utilization						X	X	X

Step 2: Synthesize existing data

Once the scope of the gender analysis has been defined, the next step is to gather and analyze existing data on the social, economic, and political roles, relations, and inequalities between men and women in your country and how they may affect successful uptake and adherence to a microbicide product.

The gender issues relevant to microbicide introduction summarized in Gender and Microbicides (page 6) point to the areas that you will want more information on, specific to your country context.

The following table suggests some of the country-specific questions or issues to explore with a desk and policy review, potential sources of data, and a brief explanation of why each issue is important to microbicide introduction. A sample desk review and policy analysis from the Kenya pilot are included in Appendix C.

Key Questions and Issues	Possible Data Sources	Why This is Important to Microbicide Introduction
HIV epidemic • How do women/girls and boys/men of different ages experience the HIV/AIDS epidemic in this country differently? • What practices increase women's/girls' and men's/boys' risk of HIV? • How much power do women have in their relationships, families, and communities?	Demographic and Health Survey (DHS) reports, Joint United Nations Programme on HIV/AIDS (UNAIDS) data on HIV, country HIV and AIDS reports (e.g., Kenya AIDS Indicator Survey) Illustrative indicators: • HIV prevalence by sex, age, marital status • Percentage of men and women who have been tested for HIV • Percentage of men and women aware of condoms as a method of HIV prevention • Percentage of girls ages 15 to 19 who are married • Percentage of women and men who are employed • Percentage of women who say they have some control over household earnings • Percentage of women who have experienced sexual violence	Helps provide rationale for introducing a woman-initiated HIV prevention product; may help make the case for offering microbicides to certain groups of women, such as adolescent women, if approved for those groups; offers a broad sense of women's status in a particular country and how empowered they may or may not be to access and use a microbicide product

Key Questions and Issues	Possible Data Sources	Why This is Important to Microbicide Introduction
Policy environment • How enabling is the health policy environment to practices that promote or impede gender equality? • Are there specific constraints or opportunities in HIV or other health policies to introducing a women-initiated HIV method? • To what degree does the current health policy environment already recognize and try to address gender inequality? • How are HIV policies linked to other sexual and reproductive health issues?	National, regional, and local laws or policies, such as: • HIV prevention strategies or frameworks • HIV testing strategies • Adolescent health frameworks or guidelines • Gender-based violence policies or guidelines • Gender policies	Identifies potential policy constraints and opportunities for gender-sensitive microbicide introduction, including potential institutional allies
Gender programming • How have other health programs tried to address gender inequality or promote gender equality? • Are there successful program examples or existing best practices?	• Country-specific published research and/or project reports	Provides insight into gender integration strategies that work or do not work in the country, lessons learned from prior experiences, and local institutions with expertise and experience implementing gender-integrated programs
Microbicides • What has been women's experience with microbicides in this country, if any?	• Published literature from microbicide acceptability studies and clinical trials conducted in the country, if available • Reports from any microbicide-related advocacy or education projects that may have been implemented in the country	Provides insight into which gender issues might be most relevant to address in microbicide introduction

In some countries, gender analyses or assessments on health issues, including HIV, already exist. These can be a good place to start, as they may have done much of the work of pulling together existing epidemiological and programmatic data and relevant policy issues. In those cases, your team will only need to fill in gaps related to microbicide introduction.

Once data have been gathered, it is important to analyze it collectively to identify the most pressing questions that need to be answered and the key issues to address in the future microbicide program. In our pilot process, we used the desk review primarily to inform the questions we asked stakeholders in Step 3. However, it may also be useful to include information from the desk review in the products of your gender analysis, especially if awareness of gender issues among decision-makers in your country is low.

Step 3: Gather additional information from stakeholders

This step involves gathering insights, perspectives, and other information from in-country stakeholders. It provides:

1. More details and insight about the gender-based obstacles women may face to accessing and using microbicide products
2. Additional information on existing policy and programmatic efforts to address gender disparities and promote women's empowerment, especially within the context of HIV prevention and other health programming
3. Potential strategies to overcome gender constraints and to capitalize on opportunities for successful microbicide introduction

Conducting interviews can help create buy-in for microbicides as a potentially important HIV prevention option for women and for the gender analysis findings and recommendations. If little is known about microbicides in your country, the interviews may elicit less nuanced discussion of the gender issues relevant to microbicide introduction, but conducting them can still be a good opportunity to raise awareness among stakeholders.

When planning for this step, it is important to use any connections you have to the most relevant stakeholders, including asking stakeholders you have interviewed for additional recommendations on people to contact. We recommend interviewing:

- **Policymakers**, including government officials

- **Funders** supporting HIV prevention and women's health programming and research
- **NGO staff**, including advocates, researchers, women's groups, and individuals providing services to potential microbicide users
- **Health care providers**, including providers delivering women's health and HIV services and those involved in any microbicide research

If possible, include individuals from different areas of the country to get more representative perspectives.

Pilot experiences

When we piloted the gender analysis for microbicide introduction process in Kenya and South Africa, two trained interviewers in each country conducted interviews with NGO staff, government staff, health care providers, and funders. They conducted 67 interviews in Kenya and 38 interviews in South Africa in a three-month period.

Scheduling interviews can be a time-consuming task, so be sure to allow sufficient time to fit interviews into people's busy schedules. Conduct enough interviews to feel you have gotten diverse perspectives and are starting to hear similar responses in the interviews (in research, this is often referred to as reaching saturation). At the same time, conduct only as many interviews as is possible with the time and resources available.

If possible, identify skilled interviewers who have a background in gender or at least a background in public health and HIV prevention. All interviewers should undergo training on how to conduct interviews for the gender analysis. This training should cover:

- Gender definitions and concepts, if the interviewers do not have a background in gender. The USAID Interagency Gender Working Group's Gender 101 Training (http://www.igwg.org/training/) is a good resource for these terms.
- Basics of microbicides, including the state of the research, different formulations, safety, and side effects (see www.avac.org/microbicides).
- Overview of the gender analysis for microbicide introduction process.
- How gender relations and norms are likely to affect the potential future introduction of microbicides (based on the information

presented in Gender and Microbicides (page 6) and the desk and policy review in that country).

- Review and adaptation of interview guides, including discussion of how to prioritize questions on the guide so that interviews do not last longer than 30-60 minutes.
- Discussion of how to identify stakeholders to interview.
- Techniques for interviewing, probing, and note-taking.
- Logistics of scheduling and conducting interviews.
- Practice conducting interviews with observation and feedback from the gender analysis technical team.

We recommend that, depending on time and resources, either: 1) two interviewers work together in each interview, with one leading the interview and the other taking notes, or 2) an interviewer works alone, asking permission to audio-record the interview so she/he can later write detailed notes. You should explain to stakeholders the purpose of the gender analysis and give them basic information on microbicides. (See Appendix D for an information sheet that was shared with stakeholders in advance of the interview and reviewed at the beginning of the interview to give them background on microbicides and the purpose of the gender analysis.) Also, explain that because a gender analysis does not require ethics committee review, formal written consent is not required; however, all responses will be anonymous.

Interviewers should be trained to take notes on the main points elicited by each interview question. These notes will later be used to summarize and synthesize information from the interviews. They will also help interviewers probe better in subsequent interviews and determine when saturation has been reached.

We recommend that the interview guides cover these key topics, which the literature shows are influenced by gender norms and inequalities:

1. **User groups** – which women are seen as the most appropriate users of microbicides, including whether women in steady relationships and adolescent women are viewed as appropriate microbicide users

2. **Acceptability** – whether the product is viewed as acceptable by women, partners, and the broader community

3. **Marketing** – how microbicides should be marketed and promoted, including whether marketing should address sexual pleasure and whether it should emphasize HIV prevention or general health as well as how to talk about condoms in relation to microbicides

4. **Access** – women's ability to access microbicide products, including cost, transport, where services are offered, and interactions with service providers

5. **Partner dynamics, male engagement** – whether and how women involve their male partners in their decisions about and use of microbicides and how a microbicide program can support women in this process

6. **Adherence** – women's ability to use a microbicide consistently and correctly, including the influence of partner dynamics and relationship power, privacy, control over timing of sex, and intravaginal practices on adherence

7. **Empowerment** – whether/how microbicides affect women's ability to protect themselves from HIV and their power in sexual relationships and in society

In Appendix E, we provide illustrative interview questions for the following types of stakeholders:

- Funders
- Policymakers
- NGO staff
- Health care providers

USAID's domains for gender analysis

USAID recommends five domains for a gender analysis (Automated Directives System 205):

1. Laws, policies, regulations, and institutional practices
2. Cultural norms and beliefs
3. Gender roles, responsibilities, and time used
4. Access to and control over assets and resources
5. Patterns of power and decision-making

While we primarily used the seven key topics listed above to structure the gender analysis for microbicide introduction, these five domains were useful in unpacking the information within the key topics and are all addressed as cross-cutting issues. For example, patterns of power and decision-making were a key consideration in *access* (women's interactions with providers), *partner dynamics* (whether and how women should engage male partners), *adherence* (women's ability to control the timing of sex and her ability to successfully negotiate microbicide use or use it without her partner's knowledge), and *empowerment*.

In some cases, adaptation may need to continue after the interviews have begun if certain questions are not evoking the quality of responses desired.

Once the interviews have been completed, the interviewers should summarize main themes, highlighting places where stakeholders agreed and disagreed, for each of the key topics listed above (and any additional topics you are focusing on). Only focus on gender-related information. For example, if stakeholders said that women may find it challenging to remember to use a microbicide every time they have sex, that is not necessarily gender-related. But if stakeholders said that women may find it difficult to predict when they will have sex because men usually control the timing of sex, that is a gender-related constraint and is worth including in your summary.

An alternate approach is having individuals other than the interviewers summarize the interviews. These individuals should first read through the notes for each interview and briefly summarize what each stakeholder said about the key topics. After completing summaries for all the individual interviews, they should review all the summaries for an individual key topic (e.g., marketing and promotion) and summarize themes for that key topic and points of disagreement among stakeholders.

Just as with interviewers, if the people summarizing the information are not members of the technical team, it is important to train them and brief them thoroughly on both microbicides and related gender issues so that they understand the comments in the interviews. If there is more than one person summarizing interviews, it is important to ensure consistency between (or among) them. This can be achieved by having them all review the same interview and compare their summaries to ensure they are highlighting similar information and providing the same level of detail. Ideally, after the summaries are completed, the interviewers would read through them to ensure accuracy.

When deciding which approach to use to summarize interviews, consider the resources available, the skill levels of the interviewers, and rigor. The first approach is likely preferable if the interviewers are very gender-savvy because it will take less time and money. The second approach is more rigorous but also more resource intensive.

Step 4: Synthesize information across sources, identifying gender-based constraints and opportunities for microbicide introduction

The next step is to synthesize information collected from different sources and identify programming needs and priorities based on that information. As a first step, look at all your information sources (desk review, policy analysis, stakeholder interviews) and list gender-based constraints and opportunities that could limit or facilitate women's ability to access and use microbicides. Then, identify recommendations from the stakeholder interviews about potential ways to address these constraints and opportunities when introducing microbicides. For example, the South Africa pilot identified the following constraints, opportunities, and potential solutions related to access/service provision.

Constraints related to access/service provision:

- Stakeholders confirmed that lack of transportation will likely be a barrier women may face in accessing microbicides.
- Stakeholders said that a potential barrier that may impede young women's access to microbicides was stigma from health providers.
- While some stakeholders said that health care workers receive gender sensitivity training, they said it is not often put into practice.
- A few stakeholders felt that requiring an HIV test (and other tests) before receiving microbicides would deter women from accessing the product.
- Laws regarding adolescents' ability to access sexual and reproductive health-related services are unclear. For example, the Children's Act allows for HIV testing and contraceptive provision without parental consent after age 12, but The Sexual Offenses Act state that a young person cannot legally engage in sexual intercourse until age 16.
- Violence against women remains a major issue in South Africa. A 2009 study conducted in the Eastern Cape and KwaZulu-Natal found that 27 percent of men reported raping at least one woman or girl (67). Studies have shown that young women in particular accept that sexual coercion is part of relationships (68, 69). According to the Joint United Nations Programme on HIV/AIDS, women who have experienced violence are up to three times more likely to be infected with HIV than those who have not.

Opportunities related to access/service provision:

- Stakeholders said that providers can facilitate women's access to microbicides by being a trustworthy source of information and counseling.
- Many women attend family planning and antenatal clinics, as evidenced by a relatively high contraceptive prevalence rate of more than 60 percent among sexually active women in 2011 and high uptake of antenatal care (70).
- The National Department of Health's new framework for sexual and reproductive health (SRH) and rights requires that SRH and rights services be fully integrated into all levels of the primary health care/district health systems. This framework provides a key opportunity for microbicides to potentially be introduced as part of the package of essential SRH and rights services.

Potential solutions suggested by interviewees to overcome the constraints identified and capitalize on the opportunities:

- Stakeholders said that microbicides should be offered broadly in primary health care and integrated health services as a way to reach women already visiting clinics for other services. They said this approach would maximize women's access to the product and reduce stigma.
- To further promote access, stakeholders said that microbicides should be distributed outside of the clinic setting, in community settings "where people are" and through mobile clinics as a means of addressing lack of transportation. A few of them suggested offering microbicides over the counter.
- Many stakeholders felt that there was a need for increased training for health providers in gender sensitivity, screening for intimate partner violence (IPV) and referral to services, and counseling on adherence and partner communication.
- Stakeholders suggested that providing the product in youth-friendly service centers and schools could increase young women's access.
- The majority of respondents stated that microbicides should be offered for free because cost may be a barrier to their use. Others felt that microbicides should be offered free of charge in the public sector and for a fee in the private sector. Several cited condoms as an example of this tiered approach.

Step 5: Review gender analysis findings with key stakeholders and collaboratively develop recommendations

Once the team develops a draft of the gender analysis findings, it is critical to work in collaboration with local stakeholders to make sure the findings were interpreted correctly and to develop concrete recommendations for packaging and using the findings. One efficient and collaborative way to do so is to bring together key stakeholders for an interpretation meeting.

Any stakeholder who was actively involved in the gender analysis process — either in helping design the analysis or as an interviewee — is a potential invitee to the interpretation meeting. While all interviewees do not need to be invited, several people from each group should be represented (health providers, government staff, NGO representatives, and funding agency staff). It is also important to invite people with influence and decision-making power regarding the country's HIV prevention agenda and the broader health system; they may offer ideas on how to maximize the utility of findings and may champion their use. Consider co-hosting the interpretation meeting with the ministry of health or influential women's health and rights groups to foster their commitment to advocating for and addressing gender in a future microbicide program.

We found that a half day or full day is needed to present and discuss the findings and their implications. Keeping the meeting brief also allows stakeholders to find time in their busy schedules to attend. The agenda from our interpretation meeting in South Africa appears in Appendix F. Depending on the composition of the group and whether microbicides are widely known in a given setting, it may be important to begin with a basic introduction to microbicides. In Kenya, we found that stakeholders had a lot of questions about microbicides and the status of the microbicide research and development. It is important to give stakeholders a grasp of the basics of microbicides but not spend so much time on this part of the meeting that gender issues relevant to microbicides cannot be fully discussed. Next, gender issues relevant to women's HIV risk and prevention options should be briefly outlined. (These issues often affect women's sexual and reproductive health and lives more broadly.) Many of the same gender norms and inequalities that influence women's risk of HIV infection may also affect their microbicide use and are therefore a well-understood starting point for outlining the gender issues specific to microbicide use and adherence.

Presenting findings from the literature

As has been discussed, a gender analysis will not always include interviews with women who have used microbicides or are interested in using them. However, published microbicides studies — especially studies that were conducted in the country in which you are working — offer important insights into individual women's experiences and needs with microbicides. Ensure that the voices of these women — including trial participants — are represented in your findings and that interpretation meeting attendees understand all of the sources of information used in the gender analysis.

Next, the gender analysis process should be described and preliminary findings on constraints, opportunities, and potential solutions presented. Time for presentations should be minimal in order to allow sufficient time for attendees to discuss the findings and any questions they may have about them, determine which issues are the highest priorities, and offer feedback on potential solutions. Ideally, the recommendations should include concrete actions that can be taken by individuals in the room. Notably, these recommendations may cover elements beyond microbicide rollout that affect larger HIV prevention efforts or the health system itself. For example, at the South Africa interpretation meeting there was strong support for more to be done to prioritize women's HIV prevention overall and to make all methods — including female condoms — more widely available.

Analysis to action

Once a microbicide product has been licensed for use, gender analyses can inform microbicide program design. In this case, the "analysis to action" tool may be particularly useful. Once priority constraints and opportunities have been identified, this tool helps stakeholders develop corresponding specific program objectives, activities, and indicators, drawing on potential solutions mentioned in interviews. (See Appendix G for both the tool and an example.)

The meeting should be facilitated by multiple people with different areas of expertise, such as ministry of health representatives, microbicide researchers to answer technical questions, members of the gender analysis technical team to accurately present the findings and ensure that the discussions result in useful feedback, and members of key grassroots women's or feminist groups to ensure that women's voices are adequately represented. HIV activists may also contribute ideas on effective ways to move governments or other decision makers

to act to overcome gender-related barriers and make microbicides more widely available. Members of the facilitation team can be responsible for different parts of the presentations at the beginning of the meeting, as well as for facilitating small group discussions related to their areas of expertise. It is important, though, that all the individuals who will help facilitate the meeting have a clear and common understanding of the meeting's goal and the objectives of each of the sessions.

In addition to interpreting the gender analysis findings and developing recommendations, the other key outcome of an interpretation meeting is feedback on how the findings can be packaged to be the most useful. The gender analysis team should use this feedback to determine how to best present the findings and recommendations.

Step 6: Package findings and recommendations and promote utilization

Once the findings are finalized, the team will need to write them up according to the recommendations of the stakeholders and within the scope of the gender analysis budget. Findings can be packaged in different ways for different audiences who are most likely to use them. Examples include policy briefs; detailed programmatic recommendations; videos, posters, or slogans targeting community members; informational materials for religious or community leaders; and advocacy tools for use by NGOs or women's groups.

In both Kenya and South Africa, stakeholders who participated in the interpretation meetings indicated they did not want a lengthy written report detailing the gender analysis process and findings for their country. Instead, the Kenyan stakeholders recommended we package the findings into short, easy-to-understand briefs to be used as advocacy materials for various audiences. Thus, the main deliverable from the gender analysis in Kenya is a tool, HIV Prevention for Women in Kenya: An Advocacy Guide for Gender-Sensitive Microbicide Introduction. It has three components intended for different, but overlapping, audiences: 1) a summary of the issues identified in the gender analysis in Kenya that will affect women's access to and use of microbicides; 2) guidance for policymakers and program designers that describes a gender-transformative microbicide introduction program; and 3) three case studies that NGOs and other advocates in the community can use to provoke discussion about microbicides.

In South Africa, stakeholders identified two distinct deliverables as important for the dissemination and use of the gender analysis findings. The first was a two-page brief summarizing the rationale for and key findings from the gender analysis in South Africa that could be shared widely through both electronic channels and in-person meetings and events. The second was a "pocket card" designed in partnership with the South Africa National AIDS Council (SANAC) to spark discussion among policymakers.

Once the findings are packaged, the gender analysis team should develop and execute a dissemination strategy to reach as many potential users of the findings as possible. In-country dissemination can take many forms, such as:

- Formal presentations at relevant national/district conferences
- Informal presentations at relevant task force or working group meetings
- One-on-one meetings with influential decision makers or potential "champions" of the work
- Meetings with grassroots advocates for women's health and HIV prevention who could integrate key messages from the gender analysis into ongoing advocacy work
- Workshops with implementing partners who could apply the findings in existing programs
- Sharing of findings and deliverables via relevant local electronic channels (e.g., listservs, discussion forums, webinars, and websites)

Ideally, dissemination efforts will tap into both electronic and people-centered opportunities to share the findings. The findings should not just be disseminated passively. The gender analysis team should also follow up with potential users of the findings to support their use. For example, after disseminating the product electronically to all stakeholders who participated in interviews for the gender analysis and/or the interpretation meeting in Kenya, our team hosted a meeting with the members of the Gender Technical Working Group of the National AIDS Control Council to discuss specific, concrete actions they might take to use the findings.

In addition to the country-specific products of the gender analysis, we developed a two-page advocacy brief synthesizing the findings from both countries as well as a summary slide deck. We intend for the brief to inform global microbicide advocacy efforts. The slides can be used by microbicide experts in presentations they give at conferences and

The tools and briefs summarizing the findings and recommendations from the Kenya and South Africa pilots are available at: http://www.fhi360.org/projects/microbicides-and-gender

meetings to highlight the intersection between gender and microbicides.

Notably, the gender analysis pilots in Kenya and South Africa were conducted well in advance of a microbicide product having regulatory approval for introduction. Dissemination and utilization plans will likely vary depending on whether the gender analysis is conducted before or after a microbicide product is approved and brought to market. For example, more concrete opportunities to influence product introduction plans may exist if the analysis is conducted after a microbicide has been approved and government leaders have decided to introduce it into their national HIV prevention portfolio. In that case, you should tailor your dissemination and utilization plan toward those opportunities. Prior to the availability of a product, however, you should consider how the findings could be applied to existing HIV prevention efforts to help set the stage for a gender-integrated microbicide rollout (see text box).

Applying gender analysis findings to other health and development programs

Many of the programmatic recommendations that emerge from a gender analysis for microbicide introduction apply just as easily to other kinds of programs, including HIV prevention programs, as well as programs promoting gender equality. This is a particularly important consideration in the time before microbicides are brought to market, when the findings cannot yet directly inform a microbicide introduction program.

When disseminating the findings, be aware of opportunities to discuss the possibility of using them in other programs. Stakeholders may appreciate ideas for addressing gender issues in other contexts. For example, stakeholders in Kenya were eager to discuss how the findings could inform forthcoming updates to the Kenya National AIDS Strategic Plan.

Other steps we identified in Kenya and South Africa as important to take now to prepare for gender-integrated microbicide introduction include:

- Educate decision-makers on the importance of prioritizing HIV prevention for women and the promise of microbicides for women.
- Strengthen and expand programs that promote positive male engagement and couples' communication, particularly about issues of sex and sexuality.
- Advocate for a stronger IPV screening and referral system.
- Strengthen or create platforms at the community level for women to voice their needs.

Conclusion

Microbicides were conceived to fill the need for a female-controlled HIV prevention method. However, biomedical technology will not, by itself, alter the underlying gender inequalities that make women vulnerable to HIV. If microbicides are found to be effective enough to licensed, women will likely face barriers to access and use. To maximize the potential microbicides offer for women to protect themselves from HIV, these barriers must be identified and addressed in product introduction plans. Conducting a gender analysis offers a systematic way of understanding gender-related barriers to women's microbicide use, identifying potential solutions, and generating support for gender-transformative microbicide introduction among key country stakeholders.

We hope the practical guidance contained in this manual and the lessons learned from pilot testing a gender analysis for microbicide introduction in Kenya and South Africa will enable implementation of gender analyses in other countries planning to one day introduce microbicides. If so, the microbicide introduction programs that emerge should have the potential to accelerate progress toward both better health outcomes and greater gender equality.

KEY RESOURCES

AVAC Microbicides Page.
www.avac.org/microbicides

USAID Guide to Gender Integration and Analysis.
http://www.usaid.gov/sites/default/files/documents/1865/201sab.pdf

A Manual for Integrating Gender into Reproductive Health and HIV Programs: From Commitment to Action (2nd Edition).
http://www.igwg.org/igwg_media/manualintegrgendr09_eng.pdf

USAID Interagency Gender Working Group's Gender 101 Training.
http://www.igwg.org/training/

A Practical Guide for Managing and Conducting Gender Assessments in the Health Sector. http://www.igwg.org/igwg_media/IGWG-GenderAssessmentGuide-2013.pdf

Gender Analysis in Health: A Review of Selected Tools.
www.who.int/gender/documents/en/Gender.analysis.pdf

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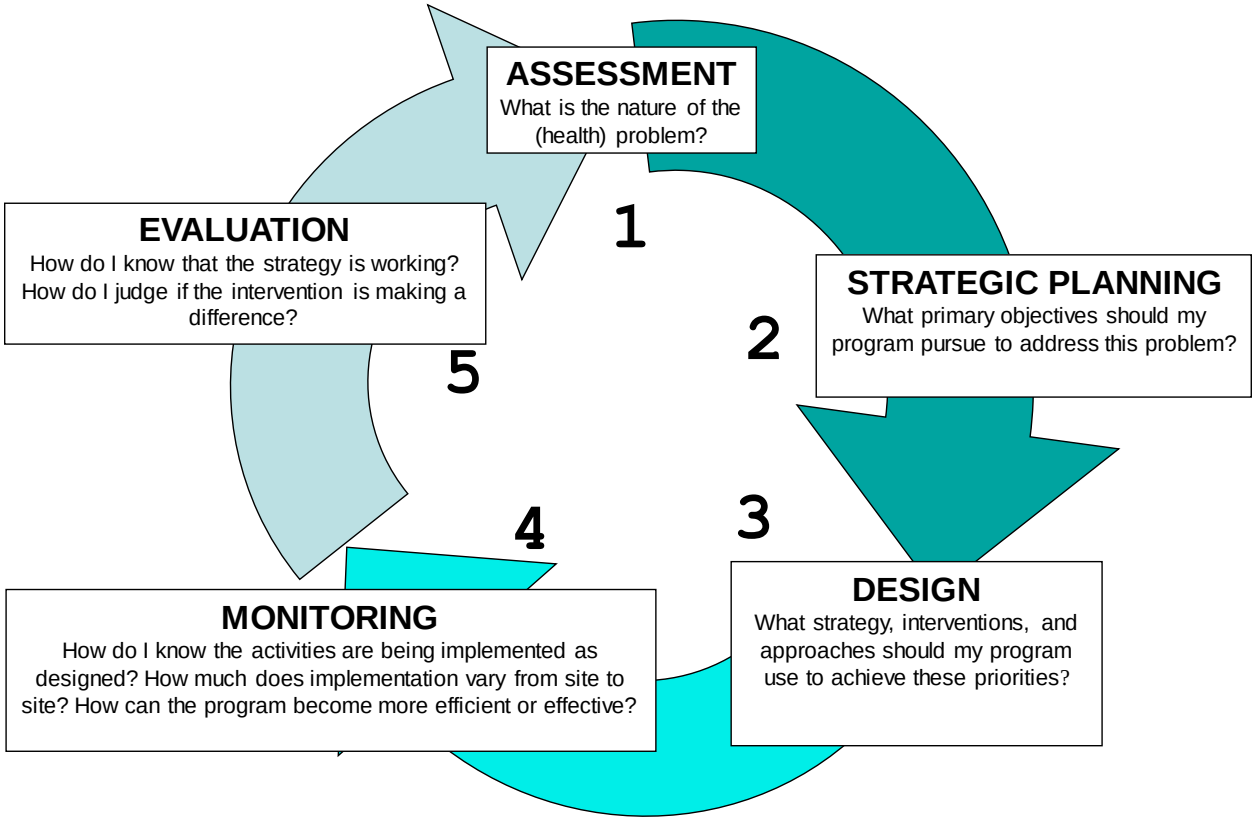
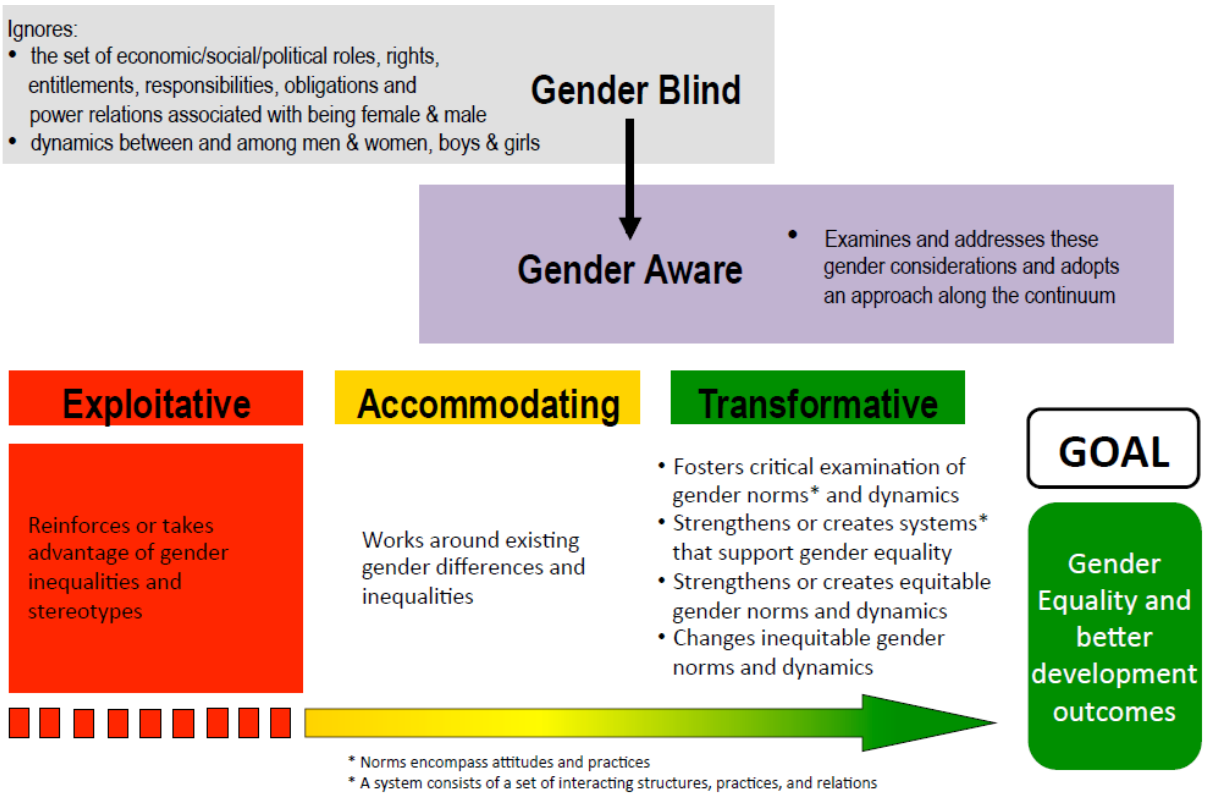
APPENDIX A. STRATEGIC INFORMATION AND PROGRAM LIFE CYCLE



Source: Interagency Gender Working Group

APPENDIX B. GENDER EQUALITY CONTINUUM TOOL



Source: Interagency Gender Working Group

APPENDIX C. SAMPLE DESK REVIEW AND POLICY ANALYSIS FROM KENYA PILOT

All statistics come from the 2008-09 Kenya Demographic and Health survey (71)

In Kenya, microbicides will likely be an important HIV prevention tool for women. HIV prevalence is high among women, due in part to a number of factors related to gender inequality. The HIV prevalence rate in Kenya is 8.0 percent for women and 4.3 percent for men. This ratio of women to men with HIV is higher than it is in most countries in Africa. The trend of higher prevalence among women is true for all age groups except 35- to 39-year=olds. For young women the disparity is especially pronounced, with 3.0 percent of women ages 15 to 19 living with HIV compared to less than one percent of men of the same age, suggesting that younger women may have a particularly urgent need for effective HIV prevention methods. The highest HIV prevalence among women is 14.3 for women ages 40 to 44. Six percent of couples interviewed for the DHS knew they were HIV-discordant.

HIV prevalence is highly variable by region in Kenya, with 65 percent of infections concentrated in three former provinces — Nyanza, Rift Valley, and Nairobi. These provinces also have 50 percent of the country's population. The data suggest that early microbicide introduction efforts could be focused in regions of the country with the highest HIV prevalence.

Coverage of HIV testing is relatively high, with 86 percent of eligible women and 79 percent of eligible men having been tested. However, only 35.3 percent of young people have been tested for HIV and received results in the past 12 months. Level of education is associated with HIV testing: women and men with no education are much less likely to be tested than those with some education. While HIV testing is fairly high, promotion of HIV testing will need to continue — particularly among young women — to identify HIV-negative women who would be good candidates for microbicide use.

Knowledge and Beliefs

Knowledge of HIV prevention methods is fairly high, though men have a slightly higher level of knowledge than women. For example, 70.9 percent of women and 77.7 percent of men are aware of both condom use and limiting to sex with one uninfected partner as methods of prevention. Misperceptions about HIV transmission are relatively low, although some misunderstandings about HIV remain: 90 percent of women know that a healthy looking person can have HIV, 71.5 percent know that HIV cannot be transmitted by mosquito bites, 89.7 percent know that a person cannot become infected by supernatural means, and 86.5 know that a person cannot become infected by sharing food with a person living with HIV. This high level of understanding of HIV transmission and prevention suggests that women have fairly good access to accurate information about HIV. Microbicide introduction programs may be able to build on this foundation of knowledge to help women better understand their risk of acquiring HIV and their options for preventing it.

Practices and Participation

Risky sexual practices driven by harmful gender norms and inequalities, including transactional sex, intergenerational sex, and sex with multiple overlapping partners, are common in Kenya and place women and men at high risk of HIV. In addition, condom use is low and, due to power imbalances within sexual relationships, many women may be unable to negotiate condom use. These factors reinforce the need for women-initiated HIV prevention methods in Kenya.

Of people ages 15 to 49 surveyed, women were more likely to be married than men, with 54.2 percent of women currently married compared to 46.9 percent of men. The difference is more striking for young people: 10.9 percent of girls ages 15 to 19 are married, compared to only 0.2 percent of their male peers. Earlier age of marriage for girls suggests that married girls — who are likely to have very limited power in their marriages to older men — may be a group in great need of woman-initiated HIV prevention methods such as microbicides.

Among women who reported having sexual intercourse in the last 12 months, 1.7 percent reported having two or more partners in the last 12 months. This figure is higher for women ages 15-19, at 4.6 percent. Reports of multiple partners are higher for men, with 13 percent of men (and 18 percent of men ages 20 to 24) who report having sexual intercourse in the last 12 months reporting sex with two or more partners. The DHS defines sex with a non-marital or non-cohabitating partner as higher risk sex. While only 4.2 percent of married young people reported higher risk sexual intercourse, condom use at last higher risk sex was lower for married women — 28.8 percent compared to 40.6 percent — than for unmarried women. Similar trends were reported by young men. While married young people are having less high risk sex, when they do they are less likely to use a condom, making them a potentially important target group for microbicide use. Condom use is also highest among young people with secondary or higher education. These statistics shed light on the complexity of determining which women are at highest risk and supports the notion of marketing microbicides for use by any women who are at risk and have difficulty negotiating condom use.

Age mixing among sexual partners is also practiced by some young women, with 4.6 percent of women ages 15 to 17 reporting high risk sex with older (10 years or more) men. Relationships between an older man and younger woman are often associated with unsafe sexual behavior, low condom use, and an increased risk of HIV infection. Due to the economic and gender inequalities exacerbated in intergenerational sexual relationships, these relationships are often characterized by less condom use and higher rates of sexual coercion than relationships between people of the same or similar ages.

Fewer than 25 percent of women and just over 30 percent of men report using a condom at last sex. Among young people ages 15 to 24 who had premarital sexual intercourse in the past 12 months, 40.3 percent of women and 63.8 percent of men reported condom use at last sexual intercourse. These low rates of condom use, especially among women, suggest that many women in Kenya could benefit from having another HIV prevention method available.

In Kenya, 2 percent of men ages 15 to 49 reported having paid for sexual intercourse in the past 12 months. More than two-thirds of men who reported having paid for sex in the 12 months before the survey said that they had used a condom the last time they paid for sex, which suggests that sex workers may have more power than women in the general population to negotiate condom use with clients. If microbicides are marketed to sex workers in Kenya, care must be taken that women do not abandon condoms in favor of microbicides, which are less effective and probably more costly.

The total fertility rate in Kenya is 4.6, and 39.4 percent of married women are currently using a modern method of contraception. However, contraceptive practices vary substantially by income, with only 16.9 percent of women in the lowest wealth quintile currently using a modern method of contraception compared to half of women in the upper wealth quintiles. Contraceptive use without the knowledge of the woman's partner is not the norm, although 8.7 percent of women did say that their husbands or partners did not know about their use of contraception. This varied by background characteristics. Younger women (ages 15 to 19) and less educated women were more likely to be using contraception without their partners' knowledge than older and more educated women. These data may help us understand whether women will want to communicate about microbicide use with their partners. Consistent with the findings in the microbicide trial literature, it is likely that many women will prefer to communicate with their partners about microbicide use, but that some will use the product without telling their partners.

Access to Assets

Women's access to assets — such as transportation and financial resources — will likely influence their ability to access and use microbicides. In Kenya, 66.6 percent of women are employed — formally or informally — compared to 99.1 percent of men. Among women who do paid work, 66 percent report that they earn less than their husband. Despite the fact that women earn less, the majority of married women say they have some control of their earnings: 42.3 percent say that they make their own decisions about their earnings and 48.8 percent have control jointly with their husband. Only 8.8 percent report that it is mainly their husbands who control their earnings. Those women who are not employed and/or do not have any control over household earnings may face significant obstacles to accessing transportation to clinics where microbicides are available and paying for the products if there is a fee for them.

Power

Gender-based violence (GBV) is a major public health issue in Kenya, with 24 percent of women reporting experiencing physical violence in the past 12 months and 38.5 percent experiencing physical violence at some point in their lives. More than 20 percent have experienced sexual violence at some point in their lives, and approximately 12 percent of women ages 15 to 49 report that their first sexual intercourse was forced. GBV is one of the most damaging forms of gender inequality and is a major driver of women's vulnerability to HIV. The prevalence of GBV in Kenya reinforces the need for new, women-initiated HIV prevention methods. However, microbicide introduction programs

must also consider the risk of violence some women may face as a consequence of communicating with partners about microbicide use or of partners discovering covert microbicide use.

Several indicators from the DHS provide measures of women's power or status within marriage. For instance, while 22 percent of women ages 15-49 believe that a husband is justified in hitting or beating his wife when she refuses sex (compared to 13.5 percent of men), about three-quarters of women say they have the final say or jointly have the final say with their husband about their own health care. The data on health care decisions suggest that many married women will have some decision-making power regarding microbicide use. However, strategies to engage men in microbicide introduction programs and support women to communicate with their partners about microbicide use will likely be important in contexts where joint decision-making over health care and household earnings is valued.

Kenya Policies Relevant to Microbicide Introduction

Overview

Because microbicides have not been approved for use, they are not yet explicitly addressed in the policy framework in Kenya. Certainly, the policy environment is likely to change once microbicides become available. The availability of microbicides may warrant the development of a focused, nationally endorsed microbicide policy or set of guidelines or introduction strategy. Policymakers and advocates should ensure that gender issues are taken into account in that case. Further, as existing policies are reviewed, ideally microbicides and gender would be integrated into those policies where appropriate.

However, it is important to recognize, even before microbicides are available, that sexual and reproductive health policies in Kenya openly recognize links between gender inequality and HIV vulnerability. This recognition suggests some level of an enabling policy environment for future introduction of a microbicide program that addresses harmful gender norms and promotes gender equality. It should be noted, though, that even as the majority of the policies express commitment to promoting gender inequality, few of them have concrete action items linked with performance indicators related to gender.

Below are brief summaries of policy provisions that offer a supportive platform for gender-sensitive microbicide introduction in Kenya.

Title/Year	Overview	Opportunities/Barriers for Microbicide Introduction
Kenya National AIDS Strategic Plan (KNASP) 2009-2013	The KNASP is the central strategic plan for the National AIDS Control Council, which coordinates the multi-sectoral response to HIV in Kenya.	Though the policy does not yet mention microbicides, microbicide introduction is aligned with KNASP's core objectives and goals related to reducing risky behaviors and the number of new HIV infections. Moreover, promoting gender equality is one of the plan's guiding approaches. The fact that this policy will likely be revised in the next year poses an important window for discussing the role of microbicides in HIV prevention in Kenya, as well as what a gender-transformative microbicide program might look like.
HIV Prevention and Control Act 2006	Prevention priorities include provision of information about HIV and how to prevent it, including information provision at schools, communities, and workplaces. The policy forbids compulsory HIV testing and requires confidentiality of testing and results.	Though the policy does not yet mention microbicides, women, or gender, this is the existing policy framework for HIV prevention and may need to be adapted once microbicides are available.
National Guidelines for HIV Counseling and Testing in Kenya	Stipulates protocols and expectations for HIV counseling and testing.	This policy stipulates that people ages 16-18 (with the exception of "emancipated minors") must have parental/guardian consent to give blood for an HIV test. Moreover, it dictates that people ages 16-18 should be given test results with a parent/guardian present. The policy may prevent some young women from being tested — a key requirement for accessing microbicides — for fear of the disapproval of their parents or because of a desire for privacy. However, it is not clear whether and how the restrictions on youth HIV counseling and testing (HCT) are implemented. This guideline is in direct contradiction with the two youth reproductive health policies (described below), which strive to offer access to comprehensive, youth-friendly services, including STI and HIV services. More favorably, the guidelines offer guidance on couples' HCT, including encouraging both partners to ask questions freely and screening couples for domestic violence. The guidelines do not specify whether tools are provided to HCT providers for GBV screening or whether referrals are made if violence is identified. Nonetheless, the guidelines seek to address critical gender issues related to HCT. Couples' HCT will likely be an important setting in which to offer microbicides.

Title/Year	Overview	Opportunities/Barriers for Microbicide Introduction
National Guidelines for HIV/STI Services for Sex Workers	The HIV/STI Package of Services for Sex Workers and Their Sex Partners includes behavioral (e.g., peer education, promotion of condoms), biomedical (e.g., HCT, emergency contraception, and post-exposure prophylaxis), and structural components (e.g., a 100% condom use policy and sexual violence-related services), as well as psychosocial support and programs for steady partners of sex workers.	The guidelines recognize that gender inequality limits female sex workers' ability to negotiate safer sex. They acknowledge that condom use is moderate with paying partners but low with steady partners. Consideration of microbicides as another HIV prevention option could potentially be incorporated into each of the intervention categories for sex workers.
Adolescent Reproductive Health Development Policy (2003) and Plan of Action (2005-2015)	Kenya's Adolescent Reproductive Health policy framework, including a policy and plan of action, seeks to provide high-quality and youth-friendly services to Kenya's youth, including HIV and STI-related health information and access to products and services.	Given the policy's openness towards youth sexual health, if the decision is made to offer microbicides to youth, it may be possible to add microbicides to the essential services package for youth SRH. Further, the youth policy framework recognizes gender inequality as a factor in HIV vulnerability and commits to promoting more equitable relations, suggesting that a gender-transformative microbicide program will fit nicely within the existing policy. The commitment to youth participation in program design and planning within the plan of action may be a unique opportunity to ensure that a potential future microbicide program targeting youth uses the most effective and relevant messages and delivery systems to maximize access for young women. Finally, one of the main implementation strategies in the plan of action is advocacy for an enabling environment for youth SRH. Given that advocacy will be a necessary component of microbicide introduction, it may be strategic to build on any existing efforts for advocacy on youth SRH issues.

Title/Year	Overview	Opportunities/Barriers for Microbicide Introduction
Kenya National RH-HIV Integration Strategy (2009) and the Minimum Package for Reproductive Health and HIV Integrated Services	Integrating reproductive health (RH) and HIV and AIDS services involves reorienting health systems to ensure that HIV and AIDS services and SRH services are delivered in the same settings. The RH-HIV Integration Strategy outlines the framework for integrated service delivery. The minimum package of RH-HIV services seeks to provide guidance to implementers or service providers on the minimum requirements for infrastructure; human resources; skills set and training materials; equipment; commodities and supplies; and monitoring and evaluation (M&E) that are necessary to provide effective integrated RH-HIV services.	As Kenya continues to build the health care system's capacity to provide integrated RH-HIV services, microbicides will be a key addition to those services if approved for introduction. Provision of microbicides in the context of family planning (FP) and maternal-child health services may be a key strategy for increasing women's access to microbicides.
Kenya Ministry of Gender, Children, and Social Development's Gender Policy	The Gender Policy provides a framework for mainstreaming gender in all policies, planning, and programming in Kenya and puts in place institutional mechanisms to ensure effective implementation. The policy stipulates that all departments and divisions of the Ministry of Gender, Children, and Social Development's will undertake gender analysis for their interventions, design gender-responsive indicators for monitoring and evaluation, and integrate gender responsiveness in all training activities. The policy also says that the Ministry of Gender, Children, and Social Development will coordinate with line ministries, state corporations, public bodies, and non-state actors.	The gender ministry and policy are well-positioned to play an invaluable role in ensuring that any future microbicide guidelines and programs take gender inequality into account.
Sexual Offences Act (2006)	The law prohibits various forms of sexual violence offences committed against women and men. These include rape, attempted rape, sexual assault, indecent acts, defilement, gang rapes, sexual harassment, child pornography, child prostitution, child sex tourism, exploitation of prostitution, incest, and deliberate transmission of HIV and other life- threatening STIs.	It is important to highlight the several existing policies related to gender-based violence, and particularly those that provide guidance for providing services and support to women who experience GBV.

Title/Year	Overview	Opportunities/Barriers for Microbicide Introduction
National Guidelines for Medical Management of Rape and Sexual Violence (2009)	The guidelines describe protocols for medical treatment of people who experience sexual violence (including women, men, and children), including provision of post-exposure prophylaxis against HIV. It also includes guidance on preparing forensic evidence for legal prosecution of the crime.	Information on microbicides, once they become available, may become an important component of counseling for women in violent relationships.
National Framework Towards Response and Prevention of Gender-Based Violence in Kenya (2009)	The framework has four thematic areas: legislative and policy reforms, capacity building, community involvement, and institutional strengthening. Each of these areas seeks to respond to GBV in different sectors, including health.	Moreover, the protocols to help people who experience violence are essential to have in place in order to support women who may experience violence related to their microbicides use.

International and Regional Treaties Ratified by Kenya

- Charter of the United Nations (1945) and the Universal Declaration of Human Rights (1948), each with a stated commitment to the equal rights of men and women and the dignity and worth of the human person
- The Vienna Declaration and Programme of Action (World Conference on Human Rights, 1993), which declared that women's rights were human rights
- The Programme of Action of the International Conference on Population and Development of (1994), which defines sexual and reproductive health and rights (RSHR), including youth rights and recognizing men's role in the SRHR of themselves and their female partners
- The Beijing Declaration and Platform for Action (1995), which endorses gender equality and greater opportunity for women and girls
- Convention on the Elimination of All Forms of Discrimination against Women (1979), which promotes gender equality
- The Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa (2005), which promotes women's rights in Africa
- The international commitments to scale up the response to HIV, such as the Declaration of Commitment on HIV/AIDS (2001) and the Political Declaration on HIV/AIDS (2006), which draw attention to the vulnerabilities of women and sex workers and speak to gender-sensitive strategies for HIV prevention and care
- All the above have been clarified more precisely as time-bound international commitments in the United Nations Millennium Declaration and the Millennium Development Goals (2000)

APPENDIX D. INFORMATION SHEET FOR STAKEHOLDER INTERVIEWS

There are a number of HIV prevention options currently available, but the female condom is the only method specifically for women. Microbicides offer an exciting new opportunity in HIV prevention for women because they can be used without her partner's knowledge.

Microbicides are products that can be inserted into the vagina or rectum to reduce women's risk of HIV. Microbicide gels and rings are still being tested in clinical trials to see if they are effective. The product that may be available first is a gel containing the antiretroviral drug tenofovir that a women inserts in her vagina before and after sex to prevent HIV. One clinical trial found that tenofovir gel reduced women's risk of HIV by 39 percent. To get closer to the truth of how effective the gel is in reducing HIV risk, another clinical trial is being conducted now. If the second clinical trial confirms that the gel reduces women's risk of HIV, microbicides may be rolled out in the future in South Africa. Clinical trials are also testing a microbicide ring that contains the antiretroviral drug dapivirine. The ring is inserted in the vagina, and one ring could provide protection against HIV for a month or longer.

Just to be clear, microbicides are for HIV-negative women, and we have no evidence about whether they provide any HIV protection to men. The requirements for using a microbicide outside of a clinical trial have not yet been established; however, they will likely involve HIV risk reduction counseling, lab tests for liver and kidney function, regular HIV testing, screening for other sexually transmitted infections, and pregnancy tests. Because of these requirements, microbicides will be available only in clinics, at least initially.

While microbicides are still being tested, the United States Agency for International Development (USAID) is supporting work to begin planning for the potential future introduction of microbicides. With support from USAID, Sonke Gender Justice Network and FHI 360 are collaborating in South Africa to conduct a gender analysis for microbicide introduction. FHI 360 is a global health and development organization that conducts research and implements programs in more than 60 countries, including South Africa. Sonke Gender Justice Network works across southern Africa using a human rights framework to build the capacity of government, civil society and citizens to achieve gender equality, prevent gender-based violence, and reduce the spread of HIV and the impact of AIDS. Together, FHI 360 and Sonke Gender Justice Network are trying to

understand women's HIV prevention needs, including how access to resources and services, decision-making power, and what society thinks are acceptable roles and behaviors for men and women may affect women's ability to access and use a microbicide. We also want to think about how these issues can be addressed in microbicide implementation.

To conduct the gender analysis, we will be interviewing and engaging with key stakeholders, including health providers, government officials, donors, and nongovernmental organizations. After the interviews are completed, we will be convening a meeting with many of these stakeholders to discuss the findings and their potential implications for future microbicide programs and policies. We will also share the results with you in writing and will explore ways in which we can collectively use the results of the analysis to advance HIV prevention efforts for women in South Africa. We do not know if or when a microbicide will be approved for introduction in South Africa. Nevertheless, it is important to begin considering what it will take to successfully introduce microbicide products. If the South African government decides to implement microbicides, we hope the information gathered in this process will inform programs and policies that maximize women's access to and use of microbicides.

APPENDIX E. STAKEHOLDER INTERVIEW QUESTIONS

These are suggested questions to include in your interview guides. We suggest tailoring the interview guides for each stakeholder type (funders, NGO staff, policymakers, providers). We indicate at the beginning of each question which types of stakeholders will likely have the most informative responses for that question. The highest priority questions to include in the interview guides are highlighted.

1. (All) Before this interview, had you heard anything about microbicides?
    a. [If yes] What have you heard? From what source(s)?
    b. [If yes] Is your organization/agency doing any work on microbicides?

2. (All) Do you think women's health, including HIV prevention for women, is a priority in [country]?
    a. [If yes] What gives you this impression?
    b. [If no] What strategies would you suggest to make women's health a higher priority?

3. (Funders) Do you think microbicide introduction is likely to be a priority HIV prevention intervention for your agency to support in this country?
    a. [If yes] What aspect of microbicide introduction is your agency likely to support?
    b. [If no] What funders do you think are best positioned to support microbicide introduction?

4. (NGOs, policymakers, providers) Do you think microbicides are a priority for HIV prevention in [country]?
    a. [If yes] What gives you this impression?
    b. [If no] What strategies would you suggest to position microbicides as a higher priority for HIV prevention?

Microbicide User Groups and Acceptability

5. (All) Do you think microbicides should be available to all women or to specific groups of women? For what reasons?
    a. What about young women ages 15-24?
    b. [If specific groups] Some people have raised the concern that if microbicides are made available only to specific groups of women, such as sex workers or women in serodiscordant couples, then microbicides could become stigmatized and difficult to use by women in steady relationships who are unable to use condoms and are at risk of HIV. What do you think about this?

6. (NGOs, providers) What do you think are the main barriers to steady/married couples using microbicides?
    a. How can we increase the acceptability of steady/married couples using microbicides?

7. (NGOs, providers) What do you think are the main barriers to young women ages 15-24 using microbicides?
    a. How can we increase the acceptability of young women ages 15-24 using microbicides?

8. (NGOs, providers) Many women who are at risk of HIV do not feel they are at risk of HIV. How can we ensure women have more accurate perceptions of their HIV risk?

Marketing and Promotion

9. (NGOs, providers) Microbicides, if found to be effective, will be less effective than condoms for preventing HIV; however, many women are unable to negotiate condom use. How should we communicate about microbicides and condoms to potential microbicide users?

10. (NGOs, policymakers, providers) Do you think microbicides should be promoted as something all women should use for their general sexual health or specifically for HIV prevention? Why?

11. (NGOs, policymakers, providers) Many women and their partners who have used the microbicide gel in clinical trials reported that the increased lubrication from the gel increased their sexual pleasure. Should sexual pleasure be promoted as a benefit of using microbicides?

Access and Service Provision

12. (NGO, policymakers, providers) Should women have to pay for a microbicide product, or should it be provided free-of-charge? For what reasons?

13. (NGOs, providers) We anticipate that women may have difficulty paying for or accessing transport to get to clinics. Is this true in the communities with which you are familiar? Are there strategies for addressing that barrier?

14. (NGO, policymakers, providers) If microbicides are found to be effective, they will be available only in clinics, at least at first. This is because HIV testing and other lab tests will be required. In what types of clinics/services should microbicides be offered?
    a. Where is the best place to offer microbicide services for young women?
    b. For women in married/steady relationships?
    c. What is the capacity around community-based distribution of health products and services in this country (e.g., mobile clinics, community health workers)? In the future, would community-based distribution be a feasible delivery method for microbicides?

15. (NGOs, policymakers, providers) Women will have to take an HIV test before using a microbicide. Are there successful programs in this country for increasing demand for HIV testing?
    a. Why have they been successful?
    b. Are there successful programs for promoting couples' HIV counseling?

16. (NGOs, policymakers, providers) Do health care providers receive training in gender awareness/sensitivity — i.e., training to treat women respectfully and support their decisions about their health care?

17. (NGOs, policymakers, providers) Some women who use microbicides may experience gender-based violence in their relationships — related or unrelated to microbicide use. How can we

improve screening for gender-based violence? How can we improve referrals to gender-based violence services?

   a. Are there any successful gender-based violence prevention programs that could be expanded?

18. (NGOs, providers) Women might experience stigma when using a microbicide — from health providers or from others who find out they are using a microbicide product — because it might call attention to their being sexually active or engaging in behaviors considered inappropriate or risky for women. How can this be addressed?

Couple Dynamics and Engaging Men

19. (NGOs, providers) How common is it for couples to talk about sexual issues?
    a. Are there examples of programs or services that promote positive couples' communication about sex?

20. (NGOs, providers) We know that some women will want to communicate with their partners about using a microbicide, and some will want to use it without telling their partners. For women who want to talk to their partners, how can they be supported to do so?
    a. For women who do not want to talk to their partners, how can they be supported?

21. (Funders, NGOs, providers) Do you think microbicide programs should engage men?
    a. If yes, in what ways do you think we should engage men (e.g., education sessions in the community, counseling in the clinic, mass media materials)?
    b. Do you know of any strategies or programs for male engagement in women's health issues in [country]?
    c. Do you know of programs that have successfully encouraged couples to communicate more openly or frequently about their sexual health and experiences? Would any elements of these programs be appropriate for microbicides?

Adherence

22. (NGOs, providers) We know from microbicide trials that women may have difficulty using the gel or ring as directed because of gender inequalities. Barriers to adherence include women lacking control over the privacy to insert microbicides, lack of control over the timing of sex, and being in a violent relationship. How can a microbicide program support women in overcoming these gender-related challenges to microbicide use?

23. (NGOs, providers) Microbicides are a product that women insert into their vaginas. Do you expect women will be comfortable inserting microbicides into their vaginas?
    a. If women are not used to insertion, how can we address any fears or discomfort?

Policy Implementation

24. (All) Given that microbicides are a product specifically for women, can you think of any legal or policy barriers to successfully implementing them?
    a. What about particular legal or policy barriers to young women ages 15-24 accessing microbicides?

25. (Policymakers) Do HIV policies in [country] address gender inequality? If so, how?
    a. How well are those policies financed and implemented? (Probe for specific examples.)

26. (Policymakers) Are there other policies that address gender inequality? (For example, national gender policies, gender-based violence policies, etc.) If so, how?
    a. How well are those policies financed and implemented?

27. (Policymakers) If microbicides are proven effective and eventually introduced, what role do you think the government would play in financing microbicide programs?
    a. Which government departments are likely to influence the decision of where the funding comes from?
    b. Which individuals may be particularly influential to this process?

28. (Policymakers) Once microbicides are approved (if they are found to be effective) what is the process to getting microbicides into the hands of women, from a policy perspective?
    a. Which government departments are likely to be involved?
    b. Which individuals may be particularly influential to this process?

Women's Empowerment

29. (NGOs, providers) Women in trials also expressed that they liked talking with other trial participants about sexuality issues. How can a microbicide program promote women talking with other women about sex and HIV protection?

30. (All) Given that microbicides are a woman-initiated method of HIV prevention, do you think they have the potential to contribute to women's empowerment?
    a. [If yes] How so?

Additional Information

31. (All) Are there any other gender issues that you think are important to consider in developing a microbicide program?

32. (All) Who else would you recommend that we interview?

APPENDIX F. SAMPLE INTERPRETATION MEETING AGENDA FROM SOUTH AFRICA PILOT

Meeting Objectives

1. To present gender analysis findings, raising awareness of key gender issues likely to affect women's future access to and use of microbicides
2. To provide a platform to affirm that the gender analysis findings are a true reflection of each sector's perspective
3. To identify the gaps and priority areas from the gender analysis, and make recommendations on how to respond to priority findings
4. To inform advocacy efforts around the utilization of gender analysis findings, both immediately and in the future

Agenda

Time	Event
9:00-9:30	Coffee and Registration
9:30-9:45	Welcome and Project Introduction
9:45-10:20	Introduction to Microbicides and the Key Role of Gender in HIV Prevention and Microbicide Discourse in South Africa
10:20-10:40	Question and Answer Session
10:40-10:50	Break
10:50-11:00	Overview of Gender Analysis Process
11:00-11:40	Presentation of Gender Analysis Findings
11:40-12:30	Group Discussion of Findings
12:30-13:30	Lunch
13:30-13:40	Upcoming Advocacy Work Around Microbicides in South Africa
13:40-15:30	Identifying Key Strategies for Moving Forward
15:30-16:00	Open Floor Discussion
16:00	Close

APPENDIX G. ANALYSIS TO ACTION TOOL

Adapted from A Manual for Integrating Gender into Reproductive Health and HIV Programs: From Commitment to Action (2nd edition) (3)

Critical constraints and opportunities	Gender-integrated objectives to address gender-based opportunities or constraints	Activities to address gender-related opportunities or constraints	Indicators for monitoring and evaluation that will show 1) a gender-based opportunity has been taken advantage of, 2) a gender-based constraint has been removed
• Transport could be a barrier • Women often attend FP and antenatal clinics	• Offer microbicides in clinics that women (including young women) already attend	• Offer microbicides at FP clinics and youth-friendly SRH clinics	• # and % of women (disaggregated by age) attending FP and youth-friendly clinics counseled on microbicides as an HIV prevention option
• There is a lack of clarity on what SRH services can be offered to adolescents • Policy could support microbicides as part of essential SRH services	• Advocate to make microbicides an explicit part of key SRH services, including for young women	• Engage with decision-makers to update guidance on SRH services so that 1) microbicides are an explicit component of key SRH services and 2) the age at which a young person can seek SRH services, including microbicides, without caregiver consent is clearly defined	• # of laws, policies, or procedures drafted, proposed, or adopted to promote women's access to microbicides at the regional, national, or local level • # of laws, policies, or procedures drafted, proposed, or adopted to promote young women's access SRH services at the regional, national, or local level
• Intimate partner violence is common	• Address IPV through strengthened screening, counseling, and referral	• Train health care providers to be sensitive to issues of gender, including how to screen and refer for IPV, as well as how to support women as they decide whether and how to engage their partners • Build effective IPV referral networks within the health system	• # and % trained counselors able to successfully screen and refer for IPV • % of women counseled (disaggregated by age) who are screened for IPV services • % of women (disaggregated by age) referred who receive IPV-related services

FHI 360/HEADQUARTERS
359 Blackwell Street, Suite 200
Durham, NC 27701 USA
Tel: 1.919.544.7040 Fax: 1.919.544.7261
Website: www.fhi360.org