Engaging Male Partners in Women's Microbicide Use

Evidence and Recommendations

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ACRONYMS

ARV – antiretroviral

FGD – focus group discussion

IDI – in-depth interview

IGWG – Interagency Gender Working Group

IPV – intimate partner violence

KEMRI – Kenya Medical Research Institute

m4RH – Mobile for Reproductive Health

PMTCT – prevention of mother-to-child transmission

PrEP – pre-exposure prophylaxis

SRH – sexual and reproductive health

USAID – United States Agency for International Development

WHO – World Health Organization

EXECUTIVE SUMMARY

Vaginal microbicides were conceived of as a woman-initiated tool that could mitigate the effects of harmful gender norms and inequalities on HIV prevention because they could be used without the knowledge or consent of a male partner. However, evidence from microbicide trials shows that although they appreciate that the product could be used without their partners' knowledge, women often tell their steady partners about their microbicide use. Furthermore, male partners' awareness and acceptance of product use influenced acceptability and self-reported adherence to microbicide regimens among women. Participants in several trials have also reported that involving male partners in microbicide use benefited their relationships. Microbicides are still being tested in clinical trials but could be made commercially available in the next few years. Thus, as we prepare for the future rollout of microbicides as an additional HIV prevention option, we must consider the role male partners may play in women's microbicide use and ask ourselves a fundamental question:

How can we balance the promotion of a method that is revolutionary because it does not require men's involvement with the reality that men often play an important role in their partners' effective use of this woman-centered technology?

To help answer this question, we conducted new qualitative research with former microbicide trial participants, their partners, community members, and health care providers in Kenya; held two consultations that brought together microbicide researchers and male engagement experts; and synthesized findings from seven qualitative studies conducted in conjunction with microbicide trials. The goal was to better understand how women involve their male partners in their microbicide use during clinical trials and how men could be effectively engaged in the future.

We found that women preferred to have a steady partner's agreement to use microbicides, and that they used their knowledge of their relationships to decide whether and how to engage partners. Women who decided to involve their male partners used a number of strategies to obtain partner approval, including using the product for a while before telling their partners, giving men information gradually, and continuing to bring up microbicides until resistant partners acquiesced. Among men who were aware of their partners' microbicide use, involvement ranged from opposition to agreement/non-interference to active support. Both men and women expressed a desire for men to have access to information about microbicides. Some women and men said that it would be helpful if male partners could talk with a health care provider about microbicides; however, men rarely went to the clinics during the trials because of their work schedules, fear of HIV testing, and stigma.

Our findings lead us to recommend that any effort to engage men in women's microbicide use should support an individual woman as the gatekeeper of her partner's involvement. Not only is each woman best equipped to understand whether it is safe and/or will be productive to discuss microbicide use with her partner, she is also likely to be most skilled in introducing the subject and ultimately gaining his support.

With this foundation, this document aims to support effective male engagement in women's microbicide use by:

- Proposing a goal, objectives, and an approach for male engagement in women's microbicide use
- Detailing clinic- and community-based programmatic strategies that would likely support effective men's engagement in microbicides
- Offering considerations for selecting, adapting, implementing, and evaluating proposed strategies
- Addressing practical issues in male engagement in microbicides, such as intimate partner violence and how male engagement may differ depending on the type of microbicide formulation being introduced

The recommendations on male engagement in women's microbicides use outlined in this document are aligned with a gender-synchronized approach to programming, as well as best practices for male engagement in health programs broadly. They are rooted firmly in the belief that each woman has the right to decide whether, when, and how to engage her partner in her own HIV prevention. Enabling women to make those decisions and effectively act on them will help make microbicides the game-changer for women's HIV prevention that they were intended to be. Furthermore, acting now to prepare for male engagement in microbicides rollout is an opportunity to both broaden the evidence base on effective male engagement strategies and strengthen existing sexual and reproductive health programs.

BACKGROUND

HIV is the leading cause of death among women of reproductive age worldwide (1). In sub-Saharan Africa, where the majority of new HIV infections occur, young women ages 15 to 24 are at particularly high risk of acquiring HIV (2).

Historically, many HIV prevention programs focused on women have perceived men as barriers to better health outcomes for women (3). Experiences from diverse settings illustrate why these perceptions emerged and persist: some men refuse to wear condoms, engage in risky sex outside of their relationships, and perpetrate intimate partner violence (IPV) (4, 5). These behaviors, as well as the inability of many women to negotiate safer sex or refuse unwanted sex, are rooted in gender norms and inequalities that are harmful to both men and women but place the disproportionate burden of HIV on women.

More recently, however, the idea that men can and should play a positive role in their partners' and their own health has gained support (6, 7). Engaging men is now acknowledged as both something many women want and an important strategy for successful sexual and reproductive health (SRH) programming. Male engagement in family planning and prevention of mother-to-child HIV transmission (PMTCT) has been shown to improve acceptability, uptake, adherence, and health outcomes (6, 8-11). Moreover, new thinking in HIV prevention calls into question the assumption that men do not have an interest in HIV prevention for themselves, their partners, or their families (3). Not only is this assumption inaccurate for many individuals, but it also disadvantages both men and women and undermines HIV prevention efforts. Finally, many programs primarily focused on improving health by promoting gender equality are moving away from working exclusively with either women or men and are starting to take a more comprehensive "gender-synchronized" approach (see box next page) (7).

Gender terms

Gender is 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 women and men.

Gender integration refers to the strategies applied in programmatic design, implementation, monitoring, and evaluation to take gender considerations into account and to compensate for gender-based inequalities.

Male engagement is a programmatic approach that involves men and boys as a) clients and beneficiaries, b) partners, and c) agents of change in actively promoting gender equality, women's empowerment, and the transformation of inequitable definitions of masculinity. In the health context, this approach comprises engaging men and boys in addressing their own, and supporting their partners' reproductive, sexual, and other health needs (12).

This document focuses on male partner engagement in women's microbicide use. For this reason, references to "male engagement" made throughout this document refer to male partners unless otherwise stated. While our primary focus is male partners, strategies in this document may also help garner other influential men's support and acceptance of microbicides.

Microbicides

The term "microbicide" refers to substances being studied that could be used in the vagina and/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.
- **Antiretroviral (ARV)-based** — they contain ARV 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. 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.

Microbicides were developed in response to power differentials within relationships and gender norms that make it difficult for women to negotiate other forms of HIV protection, such as condom use or mutual monogamy. Vaginal microbicides were designed to give women an HIV prevention tool that they could control — one that they could use without their male partner's compliance or even consent (14). However, evidence from microbicides studies suggests that although women appreciate a product that they could use without a partner's knowledge (15-20), trial participants usually choose to talk to steady partners about their product use (17, 19, 21-25). Evidence also suggests that male partners' knowledge and acceptance of microbicide use promoted product acceptability and self-reported adherence to microbicide regimens among women (26-30). In addition, participants in several trials have reported that involving male partners in microbicide use benefited their relationships, including improving communication and relationship quality and increasing shared responsibility for HIV protection (26, 31-34).

Gender-synchronized approaches

The shift to gender-synchronized approaches was prompted by the realization that, "What is generally missing from every single-sex approach is the broader awareness of how gender norms are reinforced by everyone in the community." (7) To that end, gender-synchronized approaches:

- Involve intentional efforts to reach both women and men (simultaneously or sequentially)
- Seek to increase understanding of how everyone is influenced and shaped by social constructions of gender and how all actors in society exist in relation to each other
- Identify or create shared values among men and women that promote human rights, mutual support for health, non-violence, equality, and gender justice

Findings from gender analyses conducted in Kenya and South Africa offer insight into how gender inequalities and relationship dynamics affect women's microbicide uptake and adherence. Microbicides are not a "magic bullet" for women's HIV prevention. For women to be able to effectively use microbicides,

power differentials, relationship dynamics, and gender norms need to be addressed (see box below for additional findings).

Gender analysis for microbicides introduction

With funding from USAID, FHI 360 conducted a gender analysis in Kenya and partnered with Sonke Gender Justice[1] to conduct a gender analysis in South Africa to identify gender norms and inequalities that could promote or inhibit women's access to and use of microbicides. For more information on the process, findings, and recommendations, visit the FHI 360 Microbicides and Gender webpage (listed in Appendix C).

Key findings include:

- Women often have limited access to resources; this could make it difficult for women to travel to a clinic and/or purchase microbicides.
- Stigma associated with women's sexual activity and a lack of respect for women's right to protect themselves from HIV could result in microbicide use raising suspicions regarding women's promiscuity and infidelity.
- Women's use of microbicides may be perceived by men as an accusation of men's infidelity; framing the product as improving overall sexual health instead of focusing on HIV prevention may help distance microbicides from an association with (men's or women's) infidelity.
- Intimate partner violence poses a number of challenges. Women in violent relationships reported more difficulty with microbicide adherence in clinical trials (35). IPV raises important concerns about providers' ability to counsel women in violent relationships on safe use of microbicides.

[1] Sonke Gender Justice is a South Africa-based nongovernmental organization that works in South Africa and across the continent to strengthen government, civil society, and citizen capacity to prevent domestic and sexual violence, reduce the spread and impact of HIV and AIDS, enhance sexual and reproductive health, and promote gender equality and human rights for men and women of all ages.

PURPOSE AND AUDIENCE

A fundamental question for the field of microbicides is: How can we balance the promotion of a method that is revolutionary because it does not require men's involvement with the reality that men often play an important role in their partners' effective use of this woman-centered technology?

Thus, a fundamental question for the field of microbicides is: How can we balance the promotion of a method that is revolutionary because it does not require men's involvement with the reality that men often play an important role in their partners' effective use of this woman-centered technology?

This document seeks to answer this fundamental question by reviewing best practices in male engagement in SRH programs as well as evidence on male engagement in microbicide clinical trials. Using this information as a foundation, we recommend a goal, objectives, and an overall approach, and propose specific strategies for engaging male partners in women's microbicide use. We also explore how these recommendations can be used in the immediate and mid-term by microbicides researchers, funders who are supporting microbicide research and development and may support microbicide rollout in the future, and individuals and organizations that deliver women's health services and programs. Notably, while this document focuses on microbicides, the findings and recommendations may also be relevant to male engagement in other programs designed to improve women's and men's health and advance gender equality, including the introduction of other new HIV prevention technologies such as pre-exposure prophylaxis (PrEP).

PROCESS

Microbicides researchers and male engagement experts collaborated to synthesize the evidence on male engagement in women's microbicide use and develop recommendations. This process consisted of:

- An initial experts' meeting to discuss the state of the evidence on microbicides and male engagement
- Primary and secondary analysis of qualitative data collected in conjunction with microbicide clinical trials[2] in South Africa, Kenya, and Tanzania
- A follow-up experts' meeting at which investigators from each of the studies presented and discussed their results and identified the central themes and programmatic implications of the data, in collaboration with male engagement experts (36)

[2] A description of the cited trials is available in Appendix A.

EVIDENCE ON MALE ENGAGEMENT IN HEALTH PROGRAMS

Microbicides are a new technology that will require their own nuanced approach to male engagement, but efforts to involve men in women's microbicide use should build on lessons learned about male engagement in health more broadly.

Overall, health-related interventions are more effective and sustainable when they are gender transformative (37, 38), meaning that they foster critical examination of gender norms and dynamics, strengthen or create systems that support gender equality, and/or change inequitable gender norms and dynamics (12). The USAID Interagency Gender Working Group's (IGWG) Gender Equality Continuum Tool provides a framework for assessing how and to what degree programs take gender inequalities and norms into account and whether they can be classified as "gender transformative." It can be found in Appendix B.

When engaging men in women's health, specific health issues should always be addressed within broader messages related to gender equality and should be accompanied by protective measures for women.

Similarly, health programs that seek to engage men in transforming harmful gender norms and promoting gender-equitable relationships are more effective than those that do not address gender inequalities (6). In fact, programs that involve men in SRH, such as family planning use, but do not explicitly promote gender equality can cause a negative backlash in which men assume control instead of supporting their female partners. Thus, when engaging men in women's health, specific health issues should always be addressed within broader messages related to gender equality and should be accompanied by protective measures for women. For example, women from the community should be engaged in program design and monitoring and evaluation to ensure that their needs are represented and met throughout programming.

The 2007 World Health Organization (WHO) review "Engaging men and boys in changing gender-based inequity in health: Evidence from programme interventions" (6) and the 2011 review "Engaging boys and young men in the prevention of sexual violence: A systematic and global review of evaluated interventions" (39) offer insights into potentially effective program design[3]:

[3] Both reviews acknowledge the need to strengthen program evaluations for male engagement interventions by adopting experimental designs and broader triangulation of findings (e.g., more extensive reports and follow-ups from the intimate partners of the male participants to determine whether the effects of the interventions on attitude and behavior change are lasting). They also emphasize the need for a greater understanding of the program components being tested, and of the ways in which differences across regions and cultures may affect programmatic outcomes. In particular, the reviews stress the importance of exploring how social norms may change both in the group setting and in the immediate social settings (such as schools, communities, and peer groups) in order to measure the impact beyond the participants to their communities as a whole.

- Providing **safe spaces** where men can reflect on their current attitudes and behaviors and what it means to be a man, internalize messages, and try new, more gender-equitable behaviors is vital.
- **Changing gender norms takes time**: sessions of 2 to 2.5 hours over 10 to 16 weeks show the most evidence of effectiveness in terms of sustained changes in attitudes.
- Group sessions for men can lead to changes in self-reported attitudes and behavior. The same is true for community awareness and mass media campaigns. However, **combining approaches is most effective**. For example, group sessions combined with community campaigns, mass-media campaigns, or individual counseling are more effective than any of those components individually.
- Effective and promising media and community outreach campaigns used positive **messages showing that men can change negative attitudes and behaviors** toward women and portrayed men changing and acting in positive ways. Other effective campaigns appealed to men's sense of justice or their desire to care and support their partners and children. The most effective campaigns lasted four to six months.
- Service provision campaigns need to **train providers on how to work with men**. Such training has been shown to change provider attitudes toward men, helping them perceive men as allies, partners, or clients rather than antagonists.

NEW EVIDENCE ON MALE ENGAGEMENT IN MICROBICIDES

We conducted primary and secondary analyses of data from six qualitative studies implemented in conjunction with microbicide trials in South Africa, Kenya, and Tanzania. The goal was to better understand how men have been involved in women's microbicide use during clinical trials and how they could be effectively engaged in the future. FHI 360 and the Kenya Medical Research Institute (KEMRI) conducted new qualitative research with former microbicide trial participants, their male partners, community members, and health care providers in Kisumu, Kenya. Social scientists who collected qualitative data in conjunction with the MDP301, VOICE-C, and Carraguard® trials, and a mock clinical trial with adolescents in Tanzania conducted secondary analyses of their data.[4] All analyses addressed four overarching research questions:

- What existing gender norms could facilitate or hinder male engagement in microbicide use?
- Why and how do women involve their male partners in their microbicide use?
- What was men's role in women's microbicide use during trials?

[4] A description of the cited qualitative studies and clinical trials is available in Appendix A.

- What roles would women and men like men to play in microbicide use, and what are potential strategies for men's inclusion?

The analyses included 535 interviews and 107 focus groups with trial participants, male partners, and community members. At the follow-up experts' meeting, the researchers presented the findings of their analyses. Meeting participants synthesized the findings across studies and discussed the programmatic implications. (For more details on the findings summarized below, see Lanham et al., in press.)

It is important to note three considerations for the interpretation and application of these findings. First, these studies investigated male engagement in women's use of vaginal gel and a microbicide ring. Male engagement in other microbicide formulations may differ. For example, a woman may be less inclined to involve her partner if she is using an injectable or may find it easier to discuss a formulation that also prevents pregnancy. Second, the women who join clinical trials may be more empowered or more motivated to prevent HIV or differ from the larger population in other important ways. Finally, the clinical trial environment is different from the "real world" in which a product will be used. For example, the trial requirements can be used as leverage to negotiate microbicide or condom use with a reluctant male partner — an approach that will not be available to women outside of the trial context. Alternatively, women may find it easier to communicate with their partners about microbicides once a microbicide has been proven effective. Even though these findings may not be generalizable to all formulations and use outside of the trial environment, they provide a starting point for efforts to engage male partners effectively in ongoing and future research and, ultimately, microbicides service delivery programs.

GENDER NORMS THAT COULD AFFECT MALE ENGAGEMENT

Prevailing gender norms about sexuality and complex relationship dynamics affected how women addressed their trial participation and microbicide use with male partners. Couples were more likely to discuss HIV risk, get tested, and use condoms at the beginning of a relationship. Such discussions were considered less acceptable later in a relationship, making it more difficult to introduce microbicides in established partnerships. For some men, a partner's use of microbicides was a sign that she suspected he was unfaithful or that she had outside partners. Gender norms that discourage explicit acknowledgment of men's infidelity and place great value on women's monogamy made these suspicions — accurate or not — barriers to use. However, women found ways to work within the existing patriarchal gender relations, such as negotiating microbicide use without openly challenging male authority or voicing suspicions of infidelity. In some cases men and women implied that men felt they needed to maintain an outward

image of authority, but were more willing to be flexible within the privacy of their relationships.

WHY AND HOW WOMEN INVOLVE THEIR MALE PARTNERS

Women and men agreed that, ideally, women would discuss microbicide use with their steady partners, and most women wanted agreement from their steady partners to use microbicides. Many trial participants told their partners about their microbicide use early during trial participation for emotional, logistical, and strategic reasons. All of these factors were more salient for women in steady relationships — they reported a stronger sense of desire or obligation to discuss microbicide use, as well as more logistical considerations compared to casual partnerships. Their reasons included:

- Promoting an open, trusting relationship
- Preventing a disagreement or breakup
- Gaining the partner's support in case the woman later experienced side effects or other problems
- Feeling it was "the right thing to do" because their partners would also be exposed to an experimental product
- Difficulty explaining the sudden need to use condoms, frequent visits to the clinic, and (for gel users) change in lubrication during sex
- Potential challenges hiding the applicators and inserting the gel

Women gave two main reasons for not discussing microbicide use with partners:

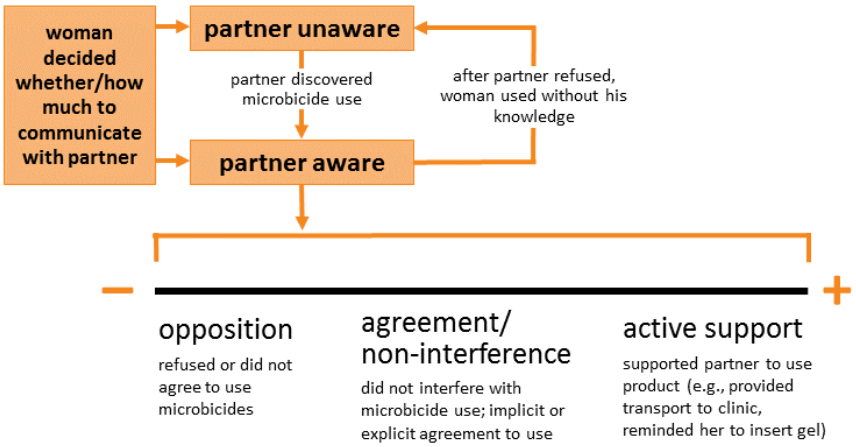
- Fear of a negative reaction, ranging from objection to violence
- Belief that their partners did not need to know, particularly in casual relationships

Some male partners were resistant to using microbicides at first, so women used a number of strategies to obtain their agreement. Some women used the product for a while before telling their partners about it. If a partner objected, the woman reminded him that he had not noticed a difference or, in some cases, that he had noticed but was enjoying their sexual experience. This was particularly the case with microbicide gels; many couples found the lubrication from the gel increased pleasure or at least decreased pain. Other women gave their partners incomplete information (e.g., not mentioning that the microbicide contained an antiretroviral drug) or misinformation (e.g., saying it was a family planning method). Other strategies included giving men information gradually or continuing to bring up microbicides until resistant partners acquiesced. Some women made their partners feel that they were making the decision, playing into the gender norm that men dominate decision-making. When partners did not agree on microbicide use, some women succeeded in using it without their partners' knowledge.

MEN'S ROLE IN WOMEN'S MICROBICIDE USE DURING TRIALS

Among men who were aware of a partner's microbicide use, there was a broad spectrum of involvement, as reflected in the following continuum. As described above, an individual male partner's involvement could also vary over time, placing one person at different points on the continuum during the course of the trial.

Among men who were aware of a partner's microbicide use, there was a broad spectrum of involvement.



Opposition. Some men were opposed to their partners participating in the trial and/or using microbicides because they had concerns about product safety, potential partner infidelity, or the researchers' intent. Some men were resistant because they lacked knowledge about the product or trial, and some did not want their partners participating in something beyond their control or understanding. Male partner opposition ranged from voicing unease or uncertainty to outright refusal.

Agreement/Non-interference. Some men gave their partners permission to use microbicides. In other cases, male partners' "agreement" was tacit — they did not give express permission, but knew their partners were using microbicides and did not interfere.

Active support. Some men provided their partners with instrumental or emotional support to participate in a trial and use microbicides. Some reminded their partners to use the gel or in some cases inserted it for them as part of foreplay. Some helped their partners attend clinic visits by reminding them of their appointments, occasionally accompanying them, or giving them transport money. The men's most common form of active support was adapting their sexual practices to meet the trial requirements of regular condom and microbicide use.

ROLES FOR MEN AND STRATEGIES FOR THEIR INCLUSION

As stated, most women wanted their partners to agree to their microbicide use. In some cases, women expressed frustration with their partners, desiring them to be more open to communicating, and more supportive and

open-minded about microbicide use. In one study in Kenya, women were asked to rank their support preferences. Women said that in addition to agreeing to microbicide use, they would most like their partners to 1) get tested for HIV, 2) use other forms of HIV protection (such as male circumcision or mutual monogamy), and 3) attend couples' counseling on microbicides.

Both men and women expressed a desire for men to have access to information about microbicides. Men wanted to know about the safety and side effects of the product. They also wanted to know whether microbicides prevent pregnancy, protect men from HIV, and affect fertility or the sexual experience. Some had questions (and suspicions) about the clinical trial process.

Information requested by men

- Safety and side effects of the product
- Whether microbicides prevent pregnancy
- Whether microbicides protect men from HIV
- Effects on fertility or the sexual experience

Some women and men said it would be helpful if male partners could talk directly with a health care provider about microbicides because providers carry authority and could legitimize the product and the research, thereby convincing men to accept their partners' microbicide use. Some women wanted assistance from providers because they felt their own ability to convey information in the most accurate and persuasive way was limited.

However, having men come to the clinic to receive information could be difficult. Several of the studies experienced challenges recruiting men for interviews and focus groups. Men were often unavailable because they were working. Others were hesitant to go to the study clinic because they were afraid it would involve HIV testing or thought, "the clinic was meant for women only." Some studies had more success recruiting men if they conducted interviews and focus groups outside of the clinic.

RECOMMENDATIONS FOR MALE ENGAGEMENT IN MICROBICIDES

The recommendations for male engagement in microbicides outlined in the remainder of this document are: 1) aligned with a gender-synchronized approach to programming, 2) based on evidence of effective male engagement in health programs broadly and male engagement in microbicide trials specifically, and 3) rooted firmly in the belief that each woman has the right to decide whether, when, and how to engage her partner in her own HIV prevention.

GOAL, OBJECTIVES, AND APPROACH

We recommend that the **goal** of male engagement in microbicides be to increase women's agency to safely and effectively use microbicides.

Primary objectives that would contribute to this goal are:

- To promote women's ability to decide if, when, and how to involve their partners in microbicide use, and to act on these decisions
- To increase male partners' awareness, acceptance, and willingness to use microbicides

Secondary objectives, which would likely be beneficial but are not necessary to accomplish the goal, are:

- To promote the perception among community members that microbicides contribute to a safe, healthy, and satisfying sex life
- To increase male partners' behaviors that support microbicide use (e.g., reminding partner to use microbicide, providing transport to the clinic)
- To increase HIV testing among male partners
- To increase men's willingness to use condoms or adopt other HIV-protective behaviors
- To increase couples' communication, including about HIV
- To promote gender-equitable relationships

Notably, some of the secondary objectives may also lead to improvements in other aspects of couples' relationships, such as men's respect for their partners' SRH decisions and increased communication and more equitable negotiation/joint decision-making on SRH matters, such as the use of family planning. They may also improve men's health by encouraging men to use health services.

Overall approach

Our recommended approach — giving both men and women information about microbicides, but promoting women's right to determine whether and how to involve their partners — is aligned with the recent evolutions in the fields of HIV prevention and gender equality because it:

1) Does not treat all women and/or all men as uniform groups (e.g., women as victims and men as perpetrators or women as interested in HIV prevention and men as risk-takers who bring HIV into their homes)
2) Engages men in a way that is guided by dialogue and collaboration with women and ultimately determined by individual women's needs and priorities
3) Gives men a space to be more gender-equitable in their own homes instead of openly in public — recognizing the ways in which men are also harmed by gender norms and may wish to overcome them, but may experience social barriers in the process
4) Works at the community level to promote positive messages that reinforce change occurring within individual households
5) Assumes that men could play an important positive role, but that this role should be mediated by their partners, for whom gender inequality and biological factors increase HIV risk
6) Moves from seeing men solely as enablers of women's positive health and highlights their potential to be partners in promoting gender equality and health for themselves and their partners

Any effort to engage men in women's microbicide use should make an individual woman the gatekeeper of her partner's involvement.

Any effort to engage men in women's microbicide use should make an individual woman the gatekeeper of her partner's involvement. Not only is each woman best equipped to understand whether it is safe and will be productive to discuss microbicide use with her partner, she is also likely to be most skilled in introducing the subject and ultimately gaining his support.

In addition, efforts should be made at the community level to inform men and women about microbicides. Community-based efforts will expand access to basic knowledge about the product and help address misconceptions that could be barriers to use. If men are aware of microbicides and the basic facts about their safety and properties, it will likely be easier for women to introduce them to their partners.

STRATEGIES FOR MALE ENGAGEMENT

Potential strategies for engaging men in women's microbicide use are presented in the following tables. Each was suggested at the second experts' meeting. Following the meeting, we further investigated each strategy for evidence of effectiveness in family planning and PMTCT programs that sought to engage men.[5] Family planning and PMTCT programs were chosen based on their similarity with microbicides — both primarily address a woman's health issue or technology, but one in which men can play an important role. Lack of evidence from published evaluations does not necessarily suggest that a specific strategy has never been used or is not effective. Similarly, a male engagement strategy with proven effectiveness may not necessarily be effective in a different geographical location or in the context of microbicides. Male engagement is still a relatively new field and the evidence base is evolving. Furthermore, evaluations of the use of some of these strategies in current microbicide trials were not available at the time this document was produced. In summary, these are all potentially effective strategies for engaging men in women's microbicide use, but they must be adapted for different populations and tested to determine their effectiveness.

In addition to presenting the evidence of effectiveness for each strategy, we include information on the potential inputs required as well as outputs that could be measured to gauge successful implementation and reach. Finally, the tables contain specific considerations for implementation and highlight ways in which these strategies respond to the evidence on male engagement in microbicides.

[5] Strategy 8, which focuses on changing gender norms and promoting gender equality, refers to evidence from the field of HIV prevention.

Working with women	
Strategy 1	Providers counsel women regarding whether/how to communicate with partners about microbicide use
Inputs	• Microbicides counseling curriculum for training providers • Counseling job aid • Trained providers
Outputs	# women considering microbicide use who talk to a provider about whether/how to discuss microbicide use with their partners

Evidence from other male engagement efforts[6]	Considerations
• No literature was found on evaluations of this practice in family planning or PMTCT, likely because it is not evaluated as a stand-alone component rather than because it is not used in counseling on these topics.	This strategy creates an entry point for male partner engagement that ensures the individual woman is the gatekeeper of her partner's involvement and provides her with support as she decides whether and how to discuss microbicide use with her partner. Trained providers can support women initiating or discussing the initiation of microbicide use to assess whether and how to communicate with their partners about microbicides. While this will be most important during the first visit, it may be important to also address in later visits at the woman's request. For providers to play this role effectively, they must be sensitized as to why women would or would not want to involve their partners, provide unbiased support during counseling, and respect women as the authorities on their own relationships. As part of the counseling process, providers should help each woman assess her partner's investment in HIV prevention, her partner's health, and her own health, as well as whether he would actively present a barrier to her microbicide use if engaged. One of the most important elements of counseling is helping each woman think through how her partner would react if she talked to him versus how he would react if she used microbicides without his knowledge and he found out. Note that providers will need to be trained to screen and refer for IPV. The strategies that women used to engage their male partners in the clinical trials (detailed in Why and how women involve their male partners, page 13) could also be presented to women as they think through their options. Evidence from family planning suggests that women who believe their husbands are opposed to family planning may be inaccurate in their perceptions (40); thus, counselors should be trained to bring up this possibility during counseling.

[6] All results presented in this column, in this and each of the following tables, were statistically significant unless otherwise noted.

Working with women *(continued)*	
Strategy 2	Providers give women written materials on microbicides to share with male partners or provide women with information on how to sign up for a mobile message service that can be used to answer questions about microbicides
Inputs	• Written materials for women to share with men • Mobile messages to share with men and a message delivery platform
Outputs	# women who receive materials they can share with male partners # women who share materials/messages with partners

Evidence from other male engagement efforts	**Considerations**
• No literature was found on interventions where women were given literature to educate their partners on family planning or PMTCT, likely because such interventions are not evaluated as a stand-alone component rather than because this approach is not used in counseling on these topics. • The Mobile for Reproductive Health (m4RH) intervention in Kenya — where users send a text to request information on specific family planning methods and then receive that information on their phones — found that women showed their partners messages that they received on family planning and that women felt these messages increased the validity of information they shared with their partners. However, there was no evidence as to whether women's use of family planning increased as a result (41, 42).	This strategy responds to women's desire for support in communicating with their male partners about microbicides. In particular, it helps them fully explain the effects of the product. These materials should address the information men said they most needed, including: • Safety and side effects of the product • Whether microbicides prevent pregnancy • Whether microbicides protect men from HIV • Effects on fertility or the sexual experience If mobile phone messages are used, those developing the service should consider how to make it safe for women. Many women may wish to share messages with their partners, but if they do not, they should know how to safely receive messages without a partner's knowledge. For example, each message could be followed by a reminder to delete the previous message. Furthermore, before women sign up to receive messages, they should be counseled on the safest ways to receive those messages.

Strategy 3	Women's groups discuss SRH, including partner involvement in microbicides
Inputs	• Women's groups • Informational materials on microbicides • Discussion guide for involving male partners
Outputs	# women who attend a women's group meeting in which microbicides are discussed

Evidence from other male engagement efforts	**Considerations**
• No literature was found on interventions where women's groups were used as spaces for discussion on how to effectively involve or keep male partners from acting as barriers to use of family planning or PMTCT services.	This strategy builds on the creativity demonstrated by women in microbicide trials, as they found ways to successfully engage even reluctant partners. Women's groups could provide spaces where women can learn from one another, including techniques that have proven useful for communicating with partners about microbicides or using microbicides without a partner's knowledge. The women's groups could be existing groups that discuss health or non-health issues, such as microcredit, or new women's groups could be formed.

Working with couples and male partners	
Strategy 4	Providers or lay counselors (or community health workers, where appropriate) do outreach to male partners about microbicides at female partner's request
Inputs	• System for female partners to refer male partners • Curricula for providers and lay counselors on talking to male partners about microbicides • Trained providers, lay counselors • Audiovisual or written materials on microbicides • Travel or phone reimbursements for providers/others
Outputs	# Male partners who have received information on microbicides from a provider or lay counselor

Evidence from other male engagement efforts	Considerations
• In Ethiopia, in a study of the effects of counseling couples on family planning uptake and continuation, home visits were conducted by female health assistants and a traditional birth attendant. They discussed health, the importance of planning one's family, and contraceptive options with husbands and wives (intervention group) or the wife alone (control). At 12 months, twice as many women in the intervention group were using contraception as those in the control group (43). • Qualitative reports included in the WHO review (6) suggest that this strategy was particularly important among hard-to-reach, underserved, or minority groups who were suspicious of health and social services or did not have experience using them.	In response to men's and women's request that men have greater access to clinic staff (but outside of the clinic setting), this strategy involves outreach by providers or lay counselors. Outreach could occur by phone, during home visits, in communities, and/or using audiovisual materials. However, outside of clinical trials, limited resources will likely require task-shifting and work with community health workers and/or peer educators. If task-shifting does occur, additional inputs — such as audiovisual or written materials for distribution — may be even more important. It is important to note that this strategy is only appropriate when it is requested by female partners. Having providers reach out to men directly, without their female partner's knowledge or consent, could create an environment in which male partners have superior knowledge of microbicides and are able to use this knowledge and their power within their relationships to coerce their partners into using microbicides. This ultimately takes away women's agency and negatively affects gender equality.

Working with couples and male partners *(continued)*	
Strategy 5	Providers offer couples' counseling and group counseling (for groups of couples) on microbicide use
Inputs	• Microbicides curriculum for providers on counseling • Trained providers • Facilities for couples counseling
Outputs	# couples counseled on microbicide use

Evidence from other male engagement efforts	Considerations
• In Kenya, in an intervention to improve uptake of practices to prevent HIV transmission at birth, both men and women were invited to the clinic for HIV testing and counseling. Once there, both parties were invited to participate in couples' counseling. Use of nevirapine at birth was reported by 88% of HIV-positive women who received couples' counseling, 67% whose partners came to the clinic but did not participate in couples' counseling, and 45% whose partners did not present at the clinic (44). • A study in Bangladesh on men's role in their partners' contraceptive continuation invited husbands to be counseled when their wives received a levonorgestrel implant or at their one-month follow-up visit. There was 10% greater continuation among those whose husbands were counseled. This was not statistically significant but is considered promising (45). • The Men in Maternity intervention in India was designed to increase post-partum family planning by engaging men whose wives were using antenatal care through individual and group counseling of men as well as couples' counseling during visits. Researchers found increased use of family planning (predominantly condoms) among the intervention group at 6-9 months postpartum (59% compared to 45% in the control) and increased interspousal communication (64% versus 84%) and joint decision-making (77% versus 91%) about family planning (46).	This strategy is responsive to women's desire for men to come to couples' counseling and men's desire for greater access to providers. As the evidence suggests, it also offers an opportunity to build communication and joint decision-making skills between partners and can improve health behaviors. Notably, no consistent guidance exists on the components of effective couples' counseling for HIV prevention; therefore, any couples' counseling intervention needs to be carefully designed and monitored. As noted by Ghanotakis et al. (2012), "particular attention needs to be paid to potential negative consequences of promoting couples HIV testing and counseling and involving men in other clinic-based activities." (47) For example, if providers are not trained to challenge gender inequitable attitudes held by couples, couples' counseling could serve to reinforce men's role as decision-makers and disempower women. Indeed, one study found that male involvement in PMTCT services had a negative impact on women's uptake of PMTCT services and antenatal care (48). Any efforts made to encourage male partners to attend couple's counseling or other activities should not disadvantage women whose partners do not attend. There are anecdotal reports of antenatal clinics that prioritize serving couples over women who come alone for care. Unintended consequences, such as this one, should be considered and continually monitored in male engagement activities.

Building community awareness	
Strategy 6	Education by peers or community health workers
Inputs	• Community education activities on microbicides • Trained community health workers/peer educators • Community education events • Audiovisual materials on microbicides, or written materials for distribution
Outputs	# men and women who attend community education sessions

Evidence from other male engagement efforts	Considerations
• **Peer education** by "male motivators" in Malawi increased family planning use and couples' communication. The motivators — chosen based on their use of and enthusiasm for modern contraception — visited men in their homes multiple times to discuss the benefits of family planning and the harms of rigid gender norms regarding large families, and to role-play conversations on family planning with partners (11). • Couples who attended **single-sex groups,** led by trained facilitators at antenatal clinics in South Africa, had increased HIV- and PMTCT-related knowledge and uptake of PMTCT, as defined by infant medication dosing. Those in the experimental group discussed safer sex, sexual negotiation, and PMTCT issues and built skills in communication, adherence, and interpersonal negotiation during four sessions. Men and women in couples attended these sessions separately but were given homework to discuss between sessions. Couples in the control group met for the same amount of time in single-sex groups but received the standard of antenatal care: health-related videos on diabetes, hypertension, alcohol misuse, and exercise. This intervention demonstrated the difference between active male engagement and simple male involvement in PMTCT programming (49). • **Community education**, by "Triad Teams" (a physician, religious leader, and social worker) as part of the "Together for a Happy Family" intervention in Jordan used a video, discussion guide, and brochures to conduct discussion sessions about family planning themes with community leaders, who then shared them with family, friends, and community members. This intervention cannot be said to have caused these changes, but is associated with a country-wide decrease in ideal family size and an increase in the percentage of men who used a family planning method and discussed it with their wives (50).	This strategy is responsive to women's and men's desire for men to have more access to information on microbicides and to findings suggesting that men's lack of information could be a barrier to women's use. Depending on who conducts the outreach, this strategy may give men more access to health care providers or encourage communication about health with male peers (an important element of gender-transformative programming), and provide male role models in the community. As the evidence at left suggests, it can also be an appropriate strategy for skills building on communication in relationships. This strategy could be implemented for single-sex groups or mixed groups and could be either microbicide specific or contain information on microbicides as well as other health information. Although there is evidence of the effectiveness of peer education, in our primary data collection in Kisumu, Kenya, men's opinions of receiving microbicides education from peer educators were mixed. Some men were receptive to the idea; however, they noted that this might be an embarrassing topic for men, they might not want their friends to know about it, or their peers would not have accurate information.

Building community awareness *(continued)*	
Strategy 7	Positive messaging and marketing of microbicides via multimedia
Inputs	• Multimedia microbicides marketing materials (commercials, posters, radio, social media, etc.)
Outputs	# women in the community exposed to microbicide messages # men in the community exposed to microbicide messages

Evidence from other male engagement efforts	Considerations
• "Together for a Happy Family in Jordan" (also described above) included a mass media component to reframe family planning as socially acceptable and desirable. That campaign is associated with improved attitudes toward family planning among men and women, but cannot be said to have caused these changes (50).	This strategy is responsive to women's and men's desire for men to have more access to information on microbicides. It also addresses findings that men's lack of information or perception that microbicides are associated with infidelity could be barriers to women's use. Messages that normalize microbicides and market them as a product for general sexual and reproductive health may help prevent microbicides from becoming associated with infidelity while informing the public generally about what they are and how they work. In some instances, positive messages that highlight the role that microbicides could play in a pleasurable and fun sexual experience were seen as likely to be most persuasive to men. Marketing materials could feature steady couples to promote acceptability of microbicide use among this group and to show that men can play a positive role in microbicide use. Experiences from voluntary male circumcision also suggest that some men are motivated to get circumcised because they believe it will improve their sexual performance. Messages on sexual performance are not included in VMMC materials, but rather are spread through informal peer networks. Finally, although no mass media intervention was tested, research in Uganda suggests that men who have heard about PMTCT are twice as likely to become involved in their partners' antenatal visits as those who have not (51). Knowledge of microbicdes may facilitate a similar acceptance and involvement.

Building community awareness *(continued)*	
Strategy 8	Incorporate information on microbicides into programming that primarily focuses on gender equality
Inputs	• Content on microbicides designed to be incorporated into gender equality programming (for education sessions, this could be curriculum on microbicides; for mass media, this would include gender-transformative messages on microbicides) • Facilitators' training on microbicides (if education is used)
Outputs	# attendees of gender-transformative programs that include content on microbicides # men and women exposed to gender-transformative messaging

Evidence from other male engagement efforts	**Considerations**
• Stepping Stones in South Africa used participatory learning approaches in single-sex groups led by peer educators to build gender-equitable relationships and better communication between partners. They saw a decrease in HIV infections (15%) and herpes (31%) among women. There was also improved condom use among men and a decrease in numbers of partners, perpetration of partner violence, and transactional sex. Couple communication also increased (52). • Program H is a participatory gender-focused program that brings together men and women in a community to discuss and analyze factors that increase their vulnerability to HIV, and then to address these factors. The intervention includes intergenerational dialogues to change harmful gender norms. In Brazil, the intervention improved gender-equitable attitudes and beliefs, increased men's recognition that women have sexual rights and agency, increased HIV testing, and increased condom use (53).	This strategy could be used in conjunction with the others and is responsive to the importance of gender-transformative approaches to engaging men. The difference is the emphasis: whereas the other strategies focus on microbicides but may use gender-transformative messages, this strategy focuses on gender equality but also addresses microbicides. Implementation tips for gender-transformative programming with men include: • Tie the messaging to the multiple ways in which a man already cares for his health and his partner's. • Give men a sense that they're informed about the latest SRH information. • Where possible, encourage role modeling; have men talk to other men in the community. Male role models can reinforce positive messaging about microbicides and potentially strengthen men's support for women's SRH more generally, by openly discussing microbicides and their support of their partners' SRH decisions with other men.

Many of these strategies could be used to increase gender equality while improving microbicides-related outcomes. One way to increase the gender-transformative potential of these strategies is to train providers, peer educators, community health workers, and others who will deliver information on microbicides on the gender-related barriers to microbicide use that women may face as well as harmful gender norms more generally. This training should include content to help reframe providers' perspectives on men, encouraging them to see men as potential supportive partners of women's health. Training and support would need to be ongoing, as this shift in attitudes and practices takes time. Resources for programming of this type can be found in Appendix C.

CONSIDERATIONS FOR STRATEGY SELECTION AND ADAPTATION

Overall, the most important consideration for inclusion of any male engagement strategy is whether women in the community deem it safe, appropriate, and potentially useful.

Few programs or research studies will have the resources to invest in all of the strategies we propose, and some strategies will be more locally relevant than others. For example, peer education worked well in Malawi, but evidence suggests that peer education on microbicides may not be widely acceptable in Kisumu, Kenya. This section offers criteria that can be considered when selecting and adapting strategies to support male engagement in women's microbicide use and provides recommendations on the minimum package of strategies needed.

As circumstances will differ by region, culture, and country, one of the first steps in strategy selection is conducting a gender analysis to identify ways that men may act as barriers to women's microbicide use, as well as any opportunities for their constructive involvement. FHI 360's "Manual for Conducting a Gender Analysis for Microbicide Introduction" (2014) provides relevant guidance and tools for such an analysis.

Overall, the most important consideration for inclusion of any male engagement strategy is whether women in the community deem it safe, appropriate, and potentially useful.

Male-friendly services

- Trained, competent, and male-friendly staff who view men as partners and positive change agents
- Efforts to actively address stigma around male participation
- Initiatives exclusively for men and led by men
- More male providers and volunteers
- Reaching out to men directly and strategically (10)

Another important factor to consider is feasibility. The inputs listed in the tables above may help programmers determine what can be most easily integrated or added to existing programming. Existing services and workloads will also help determine who – for example, a provider versus a lay counselor – can implement the strategy. Task-shifting, where appropriate, is encouraged for purposes of sustainability.

Any efforts to bring men to the clinic are likely to require a larger review and adaptation of clinic facilities and services to make them more "male-

friendly." These revisions, which include training for counselors to address their attitudes toward men as well as their skills in interacting with male clients, can be resource intensive. Recent research suggests that these changes are successful at attracting men, but that they do require many inputs (54). However, if one of the intentions of the male engagement effort is to increase men's use of services for their own health, these activities may be of primary importance.

As mentioned previously, several different formulations of microbicides are being tested in clinical trials, and characteristics of the products should be considered in choosing and adapting male engagement activities. The following variables will be important to consider in strategy selection and adaptation:

- **Clinic guidelines on product use** will affect how often users must go to the clinic for either additional HIV testing or to restock the product. These requirements could affect the number of times a woman must conceal clinic visits from her partner, the number of opportunities her partner has to accompany her, and/or how often she is able to get support from providers at the clinic on how to communicate with her partner.
- **Product formulation** will affect both promotion efforts that could appeal to men (e.g., a gel can be marketed as promoting sexual pleasure) and women's desire to discuss microbicide use with their male partners. For example, some methods — such as a monthly injectable — are likely to be less noticeable than a gel and may remove some of the impetus to involve male partners.
- **Contraceptive property** is likely to influence both men's and women's perceptions of the acceptability of the product as well as how and where the product will be promoted. Family planning clinics are often regarded as women's spaces, and this perception would need to be addressed if men were to accompany their partners there.
- **Inclusion of ARVs** will determine where users will obtain microbicides. A microbicide that does not contain ARVs could be widely available outside of clinics and could even be something that men could pick up for their partners as an over-the-counter medication.

It is vital that efforts to engage men are guided by input from women and address harmful gender norms directly.

Regardless of the strategies selected, as the findings from the 2007 WHO review underscore (6), it is vital that efforts to engage men are guided by input from women and address harmful gender norms directly. Therefore, the top priority when selecting strategies should be determining what combination of activities would ensure that: 1) male engagement is directed by women and 2) locally relevant gender inequalities and harmful gender norms are addressed. The box on the next page details our recommendations for a minimum package of strategies.

Minimum package of strategies

The most important of all of the strategies described above is provider counseling for women on if, when, and how to engage their male partners (Strategy 1). This strategy supports women as the gatekeepers of their partners' involvement and enables each woman to decide what will work best for her. In addition, the provider/client interaction offers opportunities to assess and discuss some of the most difficult aspects of male partner engagement, such as the potential for IPV.

The second priority strategy is positive messaging about and marketing of microbicides (Strategy 7). This strategy could provide an entry point for women who wish to speak to their partners about microbicides or a point of reference if questions arise. It could also provide men with basic facts that address concerns about negative side effects. Finally, this strategy would also have the benefit of introducing potential new female users to the product.

WAY FORWARD

At the time that this document was published, microbicides were still being tested in clinical trials and were not yet licensed for introduction. During this stage, we recommend testing and evaluating various male engagement strategies in clinical trials, open-label studies, and demonstration projects. Building evidence on what works for male engagement now will lower barriers to using these strategies later. In addition, there are several ways in which existing SRH programs can be strengthened now to lay the ground work for a gender-transformative microbicides introduction that includes both men and women.

EVALUATION

Recognizing that evaluation within programs and clinical trials requires complex designs, this document offers several ideas that could inform efforts to measure the effectiveness of the proposed male engagement strategies. The outputs from the strategy tables could be used to determine the level of exposure that each strategy achieves. If used in conjunction with costing tools, they could also help gauge cost per person reached. The objectives of male engagement can and should inform what is evaluated when male engagement occurs — ensuring that the strategies are assessed according to their impact on women's uptake or adherence to microbicides and gender equality. (See box next page for specific outcomes that could be measured based on those objectives; the gender scales in Appendix C may also be helpful in these efforts.)

Recommended outcomes to evaluate in male engagement strategies

- Women's interest in using microbicides
- Women's perceptions of personal agency regarding the ability to decide if/when/how to engage their male partners in microbicide use
- Women's self-efficacy to either discuss microbicides with a partner or use microbicides without his knowledge
- Male partner's awareness, acceptance, and willingness to use microbicides
- The perception among community members that microbicides contribute to a safe, healthy, and satisfying sex life
- Women's microbicide adherence
- Male partner interference in microbicide use
- Male partner behaviors supporting microbicide use
- Couples' communication (including joint-decision making)
- Shared responsibility between partners for HIV prevention
- Relevant gender-equitable attitudes and behaviors among men and women (the specific attitudes selected would be responsive to those identified in the gender analysis as most important to address)
- Recognition, by men and women, of women's right to protect themselves from HIV
- Men's health behaviors, including condom use and testing for HIV

Another important focus of future research and evaluation efforts is understanding and addressing IPV associated with women's microbicide use. Intimate partner violence is common among women participating in microbicides trials, although trial participants have pointed out that "violence is so pervasive in their communities that attributing IPV to the trial or the gel is problematic." (55) Regardless of the cause, partner violence needs to be better understood and addressed in trials as well as in eventual microbicides rollout. This will be of particular importance as strategies to engage men are implemented. Establishing whether there is a change in the incidence of IPV with the implementation of these strategies could be difficult, but is an important research objective because it could provide insight into whether these strategies have unintended negative consequences or could be used as tools for decreasing women's vulnerability to violence.

Finally, to ensure that the fundamental elements of any successful strategy are maintained if that strategy is scaled up, it is important to link a strategy's gender-transformative components to its ultimate success. Too often the gender-transformative elements of effective pilots fail to be scaled-up with the larger intervention because they are perceived as peripheral (56). Clearly linking these components to successful outcomes will highlight their importance for future implementation.

PROGRAM STRENGTHENING

Improving and expanding existing SRH programs can build capacity for future male engagement in microbicides. Immediate activities could include:

- Strengthening and expanding existing programs that promote positive male engagement and couples' communication, especially about issues of sex and sexuality. Gender-equitable relationships and improved communication about sex help women and men prevent HIV and pave the way for discussions on microbicide use. Couples' HIV counseling and testing is one opportunity to promote this type of healthy communication.
- Creating a stronger IPV referral system in the health sector and increasing training and sustained support for health care providers in order to improve services for women experiencing IPV.
- Helping strengthen or creating platforms at the community level for women to voice their needs and preferences for male engagement in women's sexual and reproductive health. These groups should continue to be involved as strategies to engage men in microbicides are discussed, designed, and implemented. They can also inform current women's SRH programs.
- Strengthen and expand gender-sensitivity training for providers to promote more gender-equitable attitudes and behaviors in service provision.

Building support for these activities, and ultimately for a gender-transformative microbicides rollout, will require advocacy. Efforts should be made now to educate funders and policymakers about the importance of supporting a gender-transformative microbicides rollout once a product is available, as well as the need for investments in current SRH programs to prepare for rollout.

CONCLUSION

Microbicides were developed to give women an HIV prevention tool that did not require their male partners' involvement; yet, evidence from clinical trials demonstrates that men play an important role in many women's successful microbicide use and that many women wish to tell their steady partners. Rather than seeing this reality as a loss for women's HIV prevention, researchers, advocates, and program planners can view it as an opportunity to think about male involvement in microbicides in a new way. A gender-transformative approach to male partner engagement in microbicides — one that engages men on women's terms — could not only improve product uptake and use, but could also improve couples' relationships and decrease women's underlying vulnerability to HIV. Positive messaging through mass media, community outreach, and counseling that encourages men's support for their partners' SRH, and provider training on gender sensitivity could promote greater gender equality within communities and the health system. Strengthening programs and systems to prepare for male engagement in microbicides can improve women's SRH programs operating today.

A gender-transformative approach to male partner engagement in microbicides — one that engages men on women's terms — could not only improve product uptake and use, but could also improve couples' relationships and decrease women's underlying vulnerability to HIV.

In addition, engaging men in women's use of microbicides could help shape the field of male engagement as a whole. Ongoing microbicides trials can be used to conduct rigorous research on male engagement strategies. Materials and guidance developed and tested now can inform the field for years to come.

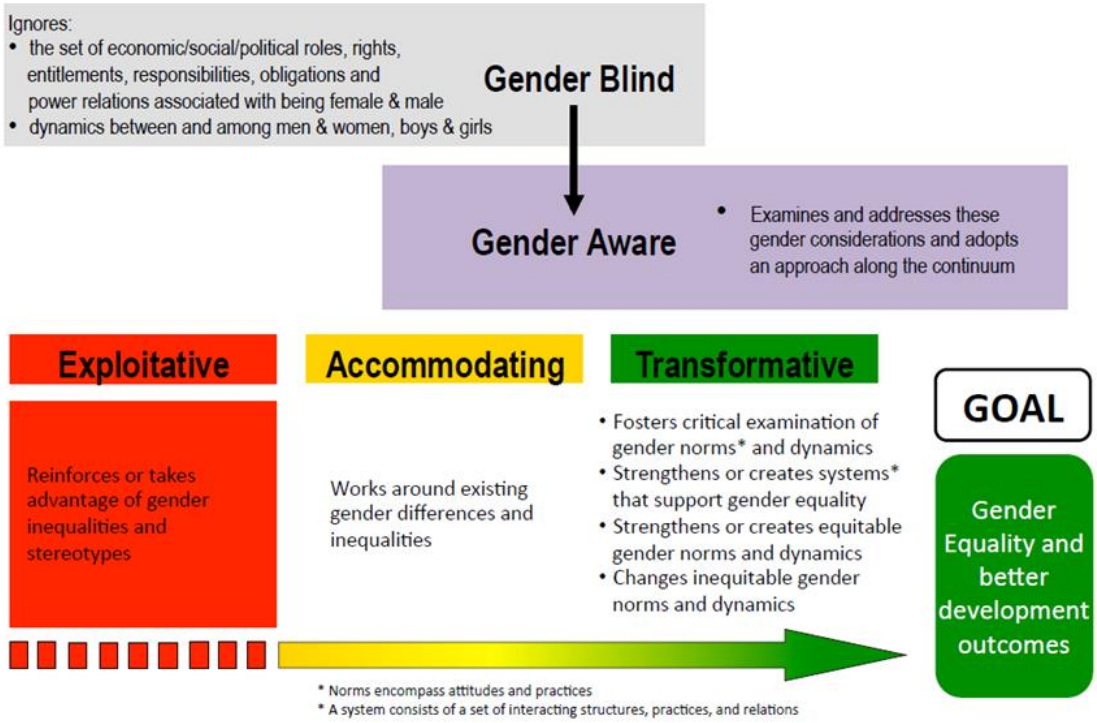
Returning to our fundamental question — how can we balance the promotion of a method that is revolutionary because it does not require men's involvement with the reality that men often play an important role in their partner's effective use of this woman-centered technology — we believe that the answer lies in trusting that women know what's best for them and creating an environment that enables women to both make decisions and carry them out effectively. This approach is fundamental to making microbicides the game-changer for women's HIV prevention they were intended to be.

APPENDIX A.
STUDIES REPRESENTED IN MALE ENGAGEMENT IN MICROBICIDES DATA PRESENTED

Clinical trial	Qualitative data included in analysis
Trial: MDP301 (57) **Phase:** III **Product:** PRO2000 vaginal gel **Length of product use:** 12 months (24 in Uganda) **Years:** 2005-2009 **Sites:** 13 sites in South Africa, Tanzania, Uganda, and Zambia **Participants:** 9,385 sexually active women, ages 18 years or older (≥16 years in Tanzania and Uganda)	**Study name:** MDP301 (23, 58-60) **Main focus:** Social Science Sub-study to Assess the Accuracy of Behavioural and Adherence Data, Acceptability of the Gel and the Trial Procedures, and Understanding of the Trial and the Consent Procedure **Years:** 2005-2009 **Sites:** 3 sites in Johannesburg, Durban, rural KwaZulu Natal, South Africa **Ethics approvals**: Witwatersrand University Human Research Ethics Committee; University of KwaZulu-Natal Biomedical Research Ethics Committee; The Medicines Control Council of South Africa **Participants:** • 154 individual in-depth interviews (IDIs) with 90 men and women (45 couples). These women shared information about the trial and involved their partners from early on. • 60 IDIs with 30 women who did not immediately inform their partners • 31 focus group discussions (FGDs) with trial participants, 18 FGDs with women in the community, and 18 FGDs with men in the community. **Methods for Secondary Analysis:** NVivo software was used to analyze IDIs and FGDs through additional coding and extraction of themes relevant to male engagement
Trial: Carraguard Phase 3 Trial (61) **Phase:** III **Product:** Carraguard vaginal gel **Length of product use:** 9-24 months **Years:** 2004-2007 **Sites:** 3 sites in South Africa (Gugulethu, Soshanguve and Isipingo) **Participants:** 6,202 women, ages 16 and older	**Study name:** Evaluation of the Informed Consent Process in the Phase 3 Study of the Efficacy and Safety of the Microbicide Carraguard in Preventing HIV Seroconversion in Women (62-66) **Main focus:** Informed consent **Years:** 2006-2007 **Sites:** Gugulethu and Soshanguve, South Africa **Ethics approvals**: Population Council Institutional Review Board; Ethics Committee of the University of Cape Town; the Research Ethics and Publication Committee of the University of Limpopo, Medunsa Campus **Participants:** • 103 IDIs with trial participants • 5 FGDs with trial participants (n=29) • 1 mixed-gender FGD (n=3 trial participants, 2 male partners) • 2 FGDs with male partners (n= 8) **Study Name:** Microbicides Acceptability: A Qualitative Study to Explore Social and Cultural Norms, Interpersonal Relations and Product Attributes (67, 68) **Main focus:** Sexual norms and gender roles affecting microbicide acceptability **Years:** 2006-2007 **Sites:** all 3 sites **Ethics approvals**: Population Council Institutional Review Board; Ethics Committee of the University of Cape Town; the Research Ethics and Publication Committee of the University of Limpopo, Medunsa Campus; the Biomedical Research Ethics Committee, University of Kwa-Zulu Natal **Participants:** • 62 IDIs with trial participants • 14 FGDs with trial participants (n=97) • 2 FGDs with male partners (n=13) • 3 IDIs with male partners **Methods for Secondary Analysis:** Thematic analysis of the previously coded data was conducted for codes most pertinent to the research questions

Trial: MTN-003 - "VOICE-C" (69) **Phase:** IIb **Product:** Vaginal 1% tenofovir gel, oral tenofovir, oral tenofovir/ emtricitabine **Length of product use:** Up to 36 months **Years:** 2008-2012 **Sites:** South Africa (3 sites), Zimbabwe, and Uganda **Participants:** 5,029 women, half were ages 18-24	**Study name:** MTN-003C - "VOICE-C" (70) **Main focus:** Household- and community-level factors associated with study product adherence in VOICE **Years:** 2010-2012 **Site:** Johannesburg, South Africa **Ethics approvals**: Office of Research Protection Institutional Review Board, RTI International; Human Research Ethics Committee of the University of the Witwatersrand **Participants:** • 22 male partners in 14 IDIs and 2 FGDs (n=8) • 102 randomly-selected female VOICE participants in IDIs (n=41), ethnographic interviews (n=21), and 7 FGDs (n=40) **Methods for Secondary Analysis:** Thematic analysis of coded transcripts from all IDI, EI, and FGD data from male partners and female study participants described above
Trial: IPM 014A **Phase:** I/II **Product:** Dapivirine vaginal gel 4759, 0.05% 2.5G **Length of product use:** 6 weeks **Years:** 2009 **Sites:** Kenya, Malawi, Rwanda, and South Africa **Participants:** Approximately 320 women, ages 18-40 **Trial:** IPM 015 **Phase:** I/II **Product:** Dapivirine vaginal ring **Length of product use:** 12 weeks **Years:** 2010 **Sites:** Kenya, Malawi, Rwanda, South Africa and Tanzania **Participants:** Approximately 280 women, ages 18-40 **Trial:** MTN-004/ VivaGel® (71) **Phase:** I **Products:** VivaGel (SPL7013 gel) vaginal gel **Length of product use: 14 days** **Years:** 2006-2007 **Sites:** United States, Kenya **Participants:** 54 sexually active women, ages 18 to 24	**Study name:** Male Engagement in Microbicides **Main focus:** Identifying strategies for engaging men in future trials, open-label studies, demonstration projects, and microbicide introduction so they will support their female partners in using microbicide products for HIV prevention or, at least, to minimize men's interference in women's microbicide use. **Years:** 2013 **Site:** Kisumu, Kenya **Ethics approvals:** Kenya Medical Research Institute Ethical Review Committee; FHI 360's Protection of Human Subjects Committee **Participants:** • 30 IDIs with former female trial participants • 25 IDIs with women who were not trial participants • 14 IDIs with men who were partners of trial participants at the time of the trial • 29 IDIs with men who were not partners of trial participants **Methods for Analysis:** Thematic analysis of IDIs using NVivo 9 software. The saliency of themes was assessed via frequencies, degrees of emphasis and elaboration, co-occurrences, and contrasts of themes across interviews, and compared among participant groups.
Trial: Adolescents and Microbicide Clinical Trials: Assessing the Opportunities and Challenges of Participation (72-75) **Phase:** Mock clinical trial **Product:** Proxy vaginal gel (Pre-Seed lubricant) and proxy oral pill (Vitacap multivitamin) **Length of product use:** optional, 0-2 months **Years:** 2011-2013 **Sites:** Tanzania **Participants:** 135 sexually active adolescents and young women, ages 15-21	**Study Name:** Adolescents and Microbicide Clinical Trials: Assessing the Opportunities and Challenges of Participation (76-78) **Main focus**: Sociocultural factors that hinder young women's participation in topical or oral microbicide trials **Years**: 2010-2011 **Site**: Dar es Salaam, Tanzania **Ethics approvals**: Muhimbili University of Health and Allied Sciences; National Institute for Medical Research (Tanzania); FHI 360's Protection of Human Subjects Committee **Participants**: • 3 FGDs with mothers of adolescents in the community (n=25) • 2 FGDs with fathers of adolescents in the community (n=18) • 2 FGDs with unmarried male partners of adolescents in the community (n=14) **Methods for Secondary Analysis:** Thematic analysis of coded excerpts from all FGD data from male partners, fathers, and mothers of adolescent girls

APPENDIX B.
GENDER EQUALITY CONTINUUM TOOL



APPENDIX C.
KEY RESOURCES

- AVAC, Global Advocacy for HIV Prevention: Microbicides Page – http://www.avac.org/prevention-option/microbicides
- Gender and Microbicides FHI 360 website – http://www.fhi360.org/projects/microbicides-and-gender
- Men Engage – http://menengage.org/
- Compendium of Gender Scales – https://www.c-changeprogram.org/content/gender-scales-compendium/

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