**HOPE Counseling Q&A**

This document was developed to help counselors address some of the obstacles and questions that participants often have about the Ring. It is divided into two sections. Part 1 provides guidance on some possible solutions that you can share with the participant to help her overcome some common obstacles to using the Ring. Part 2 provides answers to some of the questions that participants asked during ASPIRE. Each part begins with an example of how this information can be shared with the participant. We anticipate that over time, we will add to this document as we hear about new questions being asked by participants and we learn about new ways to overcome some of the common obstacles that participants experience in using the Ring.

**PART 1:** **OVERCOMING COMMON OBSTACLES TO USING THE RING**

This document was developed to assist counselors in problem-solving issues that can impede consistent Ring use among study participants. Note that it is meant to be used as a resource and not something to be distributed or read word for word to the participant. The counselor should provide the information and possible solutions to the participant in a client-centered way, meaning that permission should first be obtained from the participant before proceeding with information or suggestions. Here is an example:

*Counselor: One of the challenges to using the ring that you mentioned was that you feel that keeping it inside you for a month is not clean. Can I offer you some information about that?*

*Participant: Yes, okay.*

*Counselor: Because the vagina is a self-cleaning environment, it is not necessary to clean the ring. The vagina naturally takes care of that. What do you think about that?*

*Participant: Yes, that is what I was told. But, you know it still does not feel clean to leave it in there.*

*Counselor: I can understand that, for you feeling clean is very important and regardless of that information, it just still does not feel clean to you. Can we discuss some possible solutions to that?*

*Participant: Sure!*

*Counselor: Well, it’s okay to clean the ring. What is important is to remember to use clean water at room temperature or cool; and remember to not use hot water or soap to clean the ring. If you decide to clean the ring, the other thing we recommend is that you figure out when is the best time to do it so that you can remove it, clean it, and reinsert it immediately so that you don’t lose the protection from HIV.*

*Participant: Oh, that would be great if I can clean it sometimes.*

*Counselor: I am glad that was helpful to you in overcoming that concern. As you think about taking it out to clean, when would you do it, so that you are able to reinsert it right away?*

*Participant: Well, I can probably do it maybe once per week when I take my bath, that way I am in private and can take it out, rinse it, and put it back in.*

**1. PARTICIPANT HAS CONCERNS ABOUT USING THE RING DURING MENSES**

INFORMATION:

* The ring is safe to use during menses.
* It is recommended that the ring remain in place during a woman’s period to maintain consistent protection from HIV, especially if she may be having sex during this time.
* The ring will not block the menstrual flow.
* The ring does not require cleaning after menses.
* It is safe to use tampons and the ring at the same time.

POSSIBLE SOLUTIONS:

* Women who still prefer to clean the ring during or after menses can rinse it with clean, room temperature or cool water and reinsert it right away. Do not use soap or hot water to clean the ring.
* For women who prefer not to use the ring during menses or still have concerns about cleanliness:
	+ If the participant prefers to remove the ring during menses, consider what other HIV prevention method(s) can be used if she is having sex during this time. The ring can only reduce the risk of HIV infection if inserted.
	+ If the ring is removed, store the ring in a clean and safe place during the time it is removed and consider strategies to remember to reinsert the ring immediately after the end of the menstrual period.
	+ Depending on timing of menses and personal preferences, the participant could choose to insert a new ring at the end of menses.  This strategy may be appealing to participants who remove their rings during menses as well as those who leave the ring inserted during menses, but have concerns about its cleanliness.

**2. PARTICIPANT HAS CONCERNS ABOUT HYGIENE/WANTS TO CLEAN THE RING**

INFORMATION:

* It is not necessary to clean the ring.
* Inside the vagina is a self-cleaning environment.

POSSIBLE SOLUTIONS:

* Women who still prefer to clean the ring can rinse the ring in clean water which is at room temperature or cool before reinsertion.
* Do not use soap or hot water to clean the ring .
* Consider the best time to do this so that the ring can be reinserted immediately afterwards.

**3. WHAT TO DO IF THE RING FALLS OUT**

INFORMATION:

 - It is unlikely that the ring will fall out, but sometimes this does happen.

POSSIBLE SOLUTIONS:

* If the ring is removed or falls out, rinse the ring in clean water which is at room temperature or cool before reinsertion.
* If the ring falls out somewhere that is unsanitary (not clean), like the toilet, it is okay not to retrieve the ring.
* Dirty rings should not be reinserted. Instead, insert a new ring right away. If you do not have a new ring, contact or return to the clinic to get a new ring as soon as you can. Make sure to use other HIV prevention methods while the ring is not inserted.
* If you find that the ring falls out often, you can try to reposition it by inserting a clean finger into your vagina and pushing the ring farther in.
* You can also contact us or come to the clinic to review how to insert the ring so it does not continue to happen.

**4. PARTNER DISCLOSURE AND ADDRESSING PARTNER QUESTIONS**

INFORMATION:

* Study staff can help you think through whether or not to disclose to your partner(s), but only you can decide which option is best for you.
* Partner disclosure is an individual choice and will not impact your ability to participate in HOPE. Disclosure can range from telling your partner(s) about the study, the ring, or both. Some women may decide to disclose to some partners but not others.
	+ *Potential* positive outcomes of disclosure: support of participation or ring use, feeling increased openness or closeness in relationship(s), minimize risk of harm or problems in relationship(s) due to ring use or participation without partner knowledge
	+ *Potential* negative outcomes of disclosure: disapproval of participation or ring use, risk of harm or problems in relationship(s) if partner does not approve
* Partners who are aware of study participation and/or ring use may have questions about how the ring impacts them. In general:
	+ The ring cannot protect your partner from HIV.
	+ The ring will not harm or impact your partner’s health in any way.
	+ Most men cannot feel the ring during sex, but it is possible.
	+ Partners are welcome to come to the clinic any time.

POSSIBLE SOLUTIONS:

* Study staff will support whatever decision you make about partner disclosure and give you tools to help you successfully implement your plan (e.g. help you think through how to talk to your partner or how to use the ring discretely).
* Study staff can help you practice what you may want to say to him.
* Study staff can be available to speak with your partner.
* Study staff can also offer you written information to share with your partner(s) at home.
* If the Ring is uncomfortable for you or your partner, you can try readjusting the position of the ring. We encourage you to speak to study staff if you continue to have this difficulty.

**5. USING THE RING DURING SEX**

INFORMATION:

* Some women or their partners may feel the ring in the vagina during sex, but this will not harm either of them.
* We know that protection from HIV is highest when the ring is used all the time, and that the ring offers no protection if it is not used. It is important to know that if you wear the ring most of the time, but it is not in place when you are exposed to HIV (for example, if you take it out when you have sex), you may not be protected.
* Some women or their partners report changes in how sex feels while using the ring. These changes can be positive or negative and may relate to libido, enjoyment of sex, vaginal tightness and wetness, odor, or comfort during sex.
* If you have discomfort, or if your partner tells you he can feel the ring during sex, this may be due to the placement of the ring.

POSSIBLE SOLUTIONS:

* Discomfort or Partner Feeling the Ring: Wash hands, and try to gently push the ring further into the vagina. It’s impossible for the ring to be pushed too far up or get lost inside the body.
* Partner Concerns: It may help to understand what your partner’s concerns are with the ring. If you do not feel comfortable having these conversations, we are here to help. We can provide informational material, or even speak with your partner directly about his concerns if he is willing.
* For women who have challenges or still prefer not to use the ring during sex:
	+ Consider what other methods of HIV prevention can be used to help reduce the risk of HIV infection.
	+ If the ring is removed for sex, it should be inserted for as long as possible before sex and reinserted immediately afterwards.
	+ Consider ways to remember to reinsert the ring immediately afterwards.

**6. USING THE RING BEYOND 1 MONTH**

INFORMATION:

* The ring is designed to be used for approximately one month, after which time it should be replaced with a new ring.
* Replacing the ring with a new ring each month ensures that there is enough drug left in the ring to protect against HIV infection.
* There is no maximum time that would require removal of the ring for safety reasons. However, the same ring should not be worn forever, and we do not know how well the ring works to prevent HIV when worn longer than one month.

POSSIBLE SOLUTIONS:

* If you need to, it is better to use the ring for slightly longer than one month than to take it out and not have protection. If you have worn the same ring for longer than one month and need a replacement, contact the clinic to get a new ring as soon as you can.
* You should consult with the study staff ahead of time if you think you may need to wear the ring longer than one month.
* You should remove the ring if you do not want to participate in the study anymore.

**7. QUESTIONS ABOUT RING SIDE EFFECTS & SAFETY**

INFORMATION:

* The ring is flexible and small enough to fit inside of the vagina without causing any changes to the size of the vagina. It does not cause the vagina to widen.
* The material of the ring is very durable, and the ring will not break, dissolve, or disappear inside the body. During ASPIRE, it was proven that the ring could be kept in place without becoming damaged or causing harm to the vagina.
* Many previous trials with the ring, including ASPIRE, have proven that the ring is safe to use and the study drug does not cause any negative health effects in women. The ring does not cause infertility or cervical cancer, and it does not harm bodily tissue.
* The ring does not interfere with a woman’s menses or menstrual cycle. It will not cause increased menstrual flow or other changes to the cycle.
* *(See also the “Ring FAQ Factsheet” for more information)*

POSSIBLE SOLUTIONS

* If you experience any health issues or changes in your vagina during the study, please report them to study clinicians so that they can provide any necessary care and treatment, or referrals if they cannot provide the care you need at the clinic.
* If you experience any serious health issues, the clinician may decide it is best for your health to stop ring use until you are better.

**8. QUESTIONS ABOUT INTERMITTENT USE**

INFORMATION:

* We know that protection from HIV is highest when the ring is used all the time, and that the ring offers no protection if it is not used.
* It is important to know that if a participant wears the ring most of the time, but she is not wearing it when she is exposed to HIV, she may not be protected.
* *(See also “RING USE DURING SEX” and “PARTICIPANT HAS CONCERNS USING RING DURING MENSES” and “Choice, Adherence, and Open Reporting Factsheet” for more information)*

POSSIBLE SOLUTIONS

* If a participant does not feel comfortable wearing the ring with all of her partners, she could protect herself by using a backup method for HIV prevention when she is not using the ring.
* If a participant prefers only wearing the ring at certain times, it may help to review and consider adding other HIV options.

**9. SAFE STORAGE OF RINGS/OPTIONS FOR DISPENSATION**

INFORMATION:

* Used and dirty rings should always be stored sealed in the white bag provided to you. Store unused rings in their packaging until needed for use. If you do not have the bag provided, you may use another bag or container available to store your used ring.
* Do not store used or unused rings in the refrigerator or in direct sunlight.
* Store out of reach of children and pets.

POSSIBLE SOLUTIONS:

* If you have lost your rings, or at any point need a new ring for any reason, please contact the clinic for assistance.
* If you do not feel you are able to keep unused rings safely at home, staff can talk with you about options for receiving rings monthly.

**PART 2: RESPONDING TO COMMON QUESTIONS ABOUT THE RING**

The below information is meant to give further detail on questions that participants may ask during their counseling sessions. Counselors can provide this information to participants to help them become more informed and gain a greater understanding of these topics, but the information should not be used in an attempt to convince participants to make any particular decision. As is done in client-centered counseling, information is provided ONLY after obtaining permission to do so from the participant. This happens by either 1) the participant asking the question directly or 2) if the counselors asks the participant if she can provide some information to them. This second approach may be particularly relevant in situations in which the counselor hears the participant is doing something that is inconsistent with study recommendations and wants to provide correct information. Information should be provided and then followed by an open-ended question to the participant soliciting their reaction and thoughts in response to the new information. Here is an example:

*Counselor: So you are wondering whether you have to use condoms if you use the Ring. Can I share some information with you about that?*

*Participant: Yes, okay.*

*Counselor: PROVIDES THE INFORMATION IN #1, then asks, “What are your thoughts about that?”*

**OR**

*Counselor: You mentioned that you are thinking of sharing the Ring with your sister while her boyfriend is in town. Sounds like you want to take care of her. I am a little concerned about that and I am wondering if I can share my concerns with you?*

*Participant: Yes, okay.*

*Counselor: PROVIDES THE INFORMATION IN #3, then asks,* “*What are your thoughts about that?”*

**1. RING USE AND CONDOMS**

INFORMATION

* There are many ways women can reduce their risk of HIV and the goal of study staff is to help each participant maximize her chances of preventing HIV. That is why study staff encourage combining ring use with other prevention methods, including condoms.
* The ring reduces the risk of HIV but does not prevent pregnancy or other STIs. Correct and consistent condom use reduces the risk of HIV, other STIS, and prevents pregnancy.
* Consistent ring use reduces the risk of HIV infection, but is not 100% effective.
* Condom use has been encouraged as a way to prevent HIV for many years, but people continue to get infected with HIV because it is hard to use condoms correctly and consistently all the time. Using the ring can help protect women from HIV when condoms are not used or if they fail.
* It is safe to use the ring and condoms at the same time.
* *(See also “HIV Prevention Options Factsheet” for more information)*

**2. SEROCONVERSION & RESISTANCE CONCERNS**

INFORMATION

* Results from ASPIRE and other recent studies did not show increased levels of HIV drug resistance in women who seroconverted while using the dapivirine ring.
* Researchers are continuing to follow-up women who seroconverted in ASPIRE to check on their health and make sure the medicines they are taking for HIV treatment continue to work for them. You will be informed of any new information from these ongoing studies.
* Any HOPE participant who feels that she may have been exposed to HIV is encouraged to come to the research site for testing and support. If a participant seroconverts, the site team will collect the ring and provide her with referrals to HIV treatment and other resources.
* *(See also “HIV Resistance Factsheet” for more information.)*

**3. QUESTIONS ABOUT RING SHARING**

INFORMATION:

* For now, the ring is only available for women who are HOPE participants.
* It is important not to share the ring or give it away. Women who are not in the study may not get regular HIV or pregnancy testing, or regular medical care. If they use the ring and develop problems, they may not have access to the care they need.
* The ring can only protect you from HIV if you are using it at all times, which means not giving it to others.
* *(See also “Choice, Adherence and Open Reporting Factsheet” and “HIV Resistance Factsheet”)*

**4. RING EFFICACY AND AGE**

INFORMATION:

* In ASPIRE, women younger than 21 years old who were assigned to the dapivirine ring got HIV at the same rate as women assigned to the placebo ring.
* However, we know that the biggest factor limiting the dapivirine ring’s effectiveness for young women in ASPIRE was inconsistent use.
* Researchers are doing specific studies to confirm if any other factors might impact the effectiveness of the ring in younger women.
* High adherence among women who choose the ring in HOPE will allow us to understand more about the efficacy of the ring when used all the time.
* This information is important to know for potential future introduction of the ring in the community.
* *(See also “Choice, Adherence and Open Reporting Factsheet” for more information)*

**5. DURATION THE RING CAN BE OUT AND THEN REINSERTED**

INFORMATION:

* It is okay to reinsert the ring for the current month no matter how long it has been removed during that month, provided that it is intact and clean.
* If it gets close to the time you would normally be inserting a new ring (in other words, the next month), then insert a new ring instead.

**6. VAGINAL PRACTICES AND RING USE**

INFORMATION:

* Engaging in vaginal practices (such as cleaning the vagina with water and/or soap, using douches, or inserting herbs) can dry, irritate, or harm the vaginal tissue and make it more susceptible to infection, including HIV. As a result, medical professionals discourage vaginal practices (such as cleaning the vagina with water and/or soap, using douches, or inserting herbs) not only for participants in HOPE, but for all women.
* We recognize that these medical recommendations sometimes conflict with cultural norms, partner requests, and hygiene practices that are common in the community. We encourage all study participants to feel open to report vaginal practices they engage in so we can provide additional information and work together to help you make the best choices for your health.
* Although ASPIRE answered many questions about the ring and showed that it is safe and greatly reduces the risk of HIV infection, there are still many questions we do not know the answers to. Women who engage in vaginal practices can still use the ring, but one thing researchers still do not know is whether or not vaginal practices impact how well the ring works. This is something we are hoping to learn more about in this study.