



PATHWAYS TO HIGH ADHERENCE

Supporting Adherence Through Research Literacy



WHAT YOU WILL FIND IN THIS APPENDIX

Appendix A contains guidance on conducting individual and group education and discussions to promote product use and research literacy. Study teams can help create an environment that supports full participant engagement and high adherence by providing education to community members and participants about clinical trials and by encouraging high levels of research literacy among these groups. Although improving research literacy requires that a certain amount of information be provided by study staff to participants and community members, it is important to remember that there is as much, if not more, to learn from participants and the community during educational conversations. Staff-facilitated education discussions are one step in building a supportive environment in which participants can share their **experiences**, both with the investigational vaginal ring and with the study as a whole. Education sessions for individuals and groups that focus on core concepts used in research can create transparency and facilitate buy-in from participants and community stakeholders, both of whom are central to participant engagement in the trial. They can also help study staff understand where myths and misperceptions exist and where participants and community members may have concerns about trial conduct. High levels of research literacy will assist participants in their efforts to adhere to the study product by increasing their understanding of the study and heightening their trust in the trial when skepticism or concerns might otherwise limit women's full participation in the trial and use of the study vaginal ring.

WHO SHOULD USE IT

Community outreach workers and any staff who will lead educational discussions with participants in the clinic.

HOW TO USE IT

In the pages that follow, we outline several key educational topic areas that will help study teams increase research literacy among participants and relevant segments of their communities, and in turn support adherence. We refer to these as **core literacy areas (CLAs)**. Regardless of whether educational messages are delivered to participants or communities, individually or in groups, and within or outside of the study clinic, the CLAs described below should be a high priority early in the trial process and should also be supported throughout implementation of the study. Without high levels of research literacy, participants and communities are likely to

Core literacy areas (CLAs) are key topic areas for increasing research literacy among participants and their communities.



TIP

In communities where there is ongoing skepticism about the integrity of the study, the intentions of researchers, and/or the safety of the study vaginal ring, efforts to increase research literacy will also need to focus on building trust by increasing the transparency of study activities. For example, in addition to talking about study procedures, it may be necessary to invite community representatives to the clinic to see how and where the procedures are performed.

have high levels of distrust, uncertainty, or ambivalence about the trial, which may undermine efforts to maximize adherence.

Study teams are encouraged to use the Plan-Do-Check-Act process described earlier in this manual to determine which messages are most important for their particular population of potential participants, enrolled participants, and relevant community members. During this process, teams should also focus on identifying the methods for addressing the CLAs that are likely to be most effective at their particular research site for promoting trial engagement and ultimately supporting high adherence among participants. Creative strategies, such as those using multi-media and multiple learning channels (e.g., discussion, debate, role-playing, demonstration) are strongly encouraged. Study teams are reminded that the list of CLAs included in this manual is not comprehensive and that individual participants and different segments of the community require different types of educational support from the study clinic.

CORE LITERACY AREAS

CLA #1: Information about Clinical Research, the Study, and Study Procedures

Why is this a core literacy area for adherence?

An understanding of clinical research in general, as well as the details of a specific research study, is vital for community support and full participant engagement in the trial. If communities and participants do not understand why the research is being done, the purpose of the study procedures, what the ultimate goals are, and how adherence to the ring affects study results, their support for ring adherence and participants' motivation to adhere will be low.

What are the key educational components of this core literacy area?

- Explain what clinical research is, why it is important, and how previous research studies have informed or led to the current trial.
- Describe available HIV prevention methods, the goal of this study, and how the results might affect the community.
- Educate on the basics of the trial design and research concepts that may be difficult to understand, like randomization, placebo, and blinding.
- Summarize the key trial procedures and why each one is necessary.
- Identify what the study endpoints are and why (including information about how study endpoints will be achieved when HIV risk-reduction counseling and condom provision are included as study procedures).

- Outline participant rights and researchers' responsibilities, including:
 - » Duty of researchers to not harm participants, to track and treat adverse events, and to provide new information about HIV prevention if/when it becomes available.
- Encourage open conversation by reviewing/addressing the concerns and benefits identified by participant(s) and communities. It may also be important to clarify what will happen if/when participants report challenges with ring use or non-adherence (e.g., "If you have any challenges with ring use, we want to know what those are so we can work with you to overcome them. The staff will be happy with you for openly reporting your challenges, and you will not be dropped from the study just because you do not use the ring perfectly.")

What are some tools and resources to help educate about this core literacy area?

- ✓ Stakeholder Engagement Toolkit for HIV Prevention Trials.
<https://www.fhi360.org/resource/stakeholder-engagement-toolkit-hiv-prevention-trials>
- ✓ Site-designed educational booklets or information sheets.
- ✓ Props to help explain research concepts (e.g., coin flip to demonstrate randomization).
- ✓ How Research Happens: AVAC resource materials.
<http://www.avac.org/how-research-happens>

CLA #2: Information about the Vaginal Ring and the Drug in the Ring

Why is this a core literacy area for adherence?

Understanding the study device and study drug will help increase participants' confidence in using the investigational vaginal ring. Myths and misconceptions about using antiretroviral drugs for HIV prevention can be addressed in these educational activities. Talking about and showing the ring can make it less mysterious to women and communities who may be unfamiliar with vaginal rings or only be familiar with contraceptive rings.

What are the key educational components of this core literacy area?

- Explain what a vaginal ring is and why it was chosen as the study product.
- Define the difference between a placebo and an active ring, if applicable.
- Describe the drug that is in the device, how it works, and how it gets from the ring into the body.
- Demonstrate how to insert the ring, show where it tends to be located inside the vagina following insertion, and demonstrate that a ring inserted too low in the vagina may be more likely to be expelled.

- Discuss why it is important to wear the ring all the time and how ring adherence affects the overall goals of the study.
- Encourage conversation about benefits and drawbacks of the device and the drug.
- Address any known myths or misconceptions about the ring (e.g., it will get lost, dissolve, stretch the vagina, cause cervical cancer).
- Address questions about ring use and male partners (e.g., ring use during sex, whether male partners will feel the ring, and if the ring will harm male partners).
- Review “What to do” instructions for participants about how to handle possible scenarios they might experience when using the ring (e.g., the ring falling out).

What are some tools and resources to help educate about this core literacy area?

- ✓ Site-designed educational booklets or information sheets (e.g., see IPM 027 Ring Use Instructions in Appendix F).
- ✓ Pelvic model and sample ring.
- ✓ Diagrams, photos, videos, and/or illustrations.

CLA #3: Information about the Body

Why is this a core literacy area for adherence?

A basic understanding of human anatomy and physiology is essential for high adherence because it helps research participants understand their bodies and how the ring interacts with it. Study teams can address common myths and misconceptions about the ring’s effects on the body (e.g., that the ring causes cancer or affects menses) by helping participants learn more about their own biology.

What are the key educational components of this core literacy area?

- Teach about the basic anatomy of the female body, with a focus on the sexual and reproductive organs and where a properly inserted ring sits.
- Review basic physiology of the female body, including information about menses and pregnancy.
- Provide information about possible side effects of the study drug and other common pharmaceuticals participants might use during study participation (especially contraceptives, as these often have side effects that are falsely attributed to the ring).
- Educate about infectious and non-infectious diseases, especially those that participants and/or community members fear might be associated with ring use (e.g., cervical cancer) or that cause genital symptoms (e.g., sexually transmitted infections).

- Discuss harmful vaginal practices that may be pervasive in the community and explain what effect these activities have on the body and the study and why they are discouraged.

What are some tools and resources to help educate about this core literacy area?

- ✓ Site-designed educational booklets or information sheets.
- ✓ Pelvic models, diagrams, videos.
- ✓ Examples of locally relevant products that should not be used vaginally with the ring.

CLA #4: Information about the Use of Research Data

Why is this a core literacy area for adherence?

Helping participants and communities understand the “big picture,” what is involved in demonstrating efficacy, and what is involved in bringing an investigational drug to the open market increases transparency and supports adherence by allowing participants to understand how their actions influence these long-term goals. Explaining how research data get used in this process also builds trust and helps study teams emphasize the importance of open conversation about adherence and women’s general study experiences.

What are the key educational components of this core literacy area?

- Explain what happens to research data after they are collected, including a discussion linking adherence data to the ability or inability to answer the research question.
- Describe the possible study outcomes and what each result means.
- Outline the process for making an effective product available to study participants and, ultimately, the community at large.

What are some tools and resources to help educate about this core literacy area?

- ✓ Communications Handbook for Clinical Trials.
<https://www.fhi360.org/resource/communications-handbook-clinical-trials-strategies-tips-and-tools-manage-controversy-convey>
- ✓ Site-designed educational pamphlets and information sheets.
- ✓ Diagrams showing steps of data collection and reporting and/or drug regulatory approval process.

CLA #5: Information about the Roles of Participant, Community, and Study Teams

Why is this a core literacy area for adherence?

Study staff can build a sense of teamwork by emphasizing the unique roles that the participant, the community, and the study team each have to play in reaching a common goal — preventing HIV. By explaining how trial participation, engagement, and successful results are mutually beneficial and rely on all three groups (participants, the community, and the study team) working in harmony, study staff can help create an environment in which participants feel motivated and supported to use the study product.

What are the key educational components of this core literacy area?

- Explain the main components of staff engagement (See “What is Staff Engagement?” text box on p. 17 of this manual) and participant engagement (see “What is Participant Engagement?” text box on p. 20 of this manual).
- Emphasize the concept that participants, the community, and the study staff are partners in the research.
- Identify the responsibilities and obligations each party must fulfill in order for the trial to be a success. Discuss what happens in and after the study when obligations are met, and when they are not.
- Note processes that the study team has in place to monitor study implementation, solicit and react to feedback from participants and the community, and provide updates on study progress.

What are some tools and resources to help educate about this core literacy area?

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- ✓ Communications Handbook for Clinical Trials.
<https://www.fhi360.org/resource/communications-handbook-clinical-trials-strategies-tips-and-tools-manage-controversy-convey>
- ✓ Improve Research Conduct (AVAC resources).
<http://www.avac.org/improve-research-conduct>