

Attachment 3c In-depth Interview (IDI) Guide

Assessing the acceptability and adoptability of HIV-1 pre-exposure prophylaxis (PrEP) technologies with and without contraceptive formulation among African American women in the southeastern United States

Public reporting burden of this collection of information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-1091).

In-depth Interview (IDI) Semi-structured Guide

INTRODUCTION

Thank you for agreeing to take part in this interview. Because there will be a lot of information that I will not be able to remember in detail or write down, I would like to audio record this interview. Your name will not be linked to any or your responses. If you should mention another person's name, we will omit the name from the transcript.

There are no right or wrong answers to any of the questions that I will be asking you. I really am interested in learning about how you see things and what your experiences have been. I would like you to be as honest as you are comfortable being so that we can get the best information possible. Please remember that your participation is voluntary. You do not have to answer any questions that you do not wish to answer, and you are free to leave/stop interview at any time. There will be time after the interview to address any questions or comments that you might have.

I will begin audio-recording the interview now. Is that okay?

INSTRUCTIONS TO THE INTERVIEWER:

1. Turn on tape recorder
2. Verbally label audio file with the case ID, site, date, and your interviewer ID

OBJECTIVE 2: Explore behavioral, psychological, interpersonal, and sociocultural factors that influence decisions about whether or not an HIV 1 biomedical intervention can and should be considered.

Let's start by talking about contraception. To make sure that we are on the same page, I am talking about methods used by sexually active women to avoid getting pregnant. I am asking questions in terms of your personal thoughts, behaviors, and feelings. However, if you are more comfortable talking about what other women, such as friends or family, think or do, please do so.

1. What do you think about when considering a birth control method?
 - 1a. What has been most important to you in selecting a birth control method?
 - 1b. What types of birth control methods would you not consider using?
 - 1bi. What makes this a/these method(s) no-go(es) for you?
 - 1c. In your opinion, what is the most difficult part of using birth control?
2. Tell me about any discussions that you have had with a doctor or nurse about pregnancy prevention.
3. If you were talking to other women you know, such as family, friends or co-workers, how would you explain what the term "reproductive health" means?
4. How would your description of reproductive health compare to an explanation that you might give them about "sexual health"?

For the purposes of this study, think of sexual health broadly in terms of physical, emotional, mental and social well-being as it relates to your sexuality.

5. How do you think women usually get information on sexual health?
 - 5a. In general, how useful do you think the information that women receive is?
 - 5b. What types of information would be more useful to women?
6. Describe sexual health services that you have used?

OBJECTIVE 2: Explore behavioral, psychological, interpersonal, and socio-cultural factors that influence decisions about whether or not an HIV-1 biomedical intervention can and should be considered.

Now, I would like to talk about infections that might be due to sexual activity.

7. What steps, if any, do you take to protect yourself against STDs (sexual transmitted diseases)?
8. How are these steps possibly related to steps taken to avoid pregnancy?
9. Tell me about any discussions that you have had with a doctor or nurse about preventing STDs, including HIV.

OBJECTIVE 1: Describe knowledge of PrEP and gain practical insights on how acceptance of HIV-1 biomedical prevention technologies is arrived at by targeted end-users and how this may influence adoptability.

Now, I would like to talk about HIV.

10. What steps, if any, do you take to protect yourself against HIV?

Imagine that we have available a way to effectively protect women against unwanted pregnancy, HIV, and STDs. We are now going to talk about products for preventing HIV. These would be products that were developed by a drug company and eventually made available to women by a doctor, a pharmacy, or drug store.

11. First, please tell me what you have heard about a pill that is taken daily to prevent HIV infection. This pill is referred to as oral PrEP.

OBJECTIVE 1: Describe knowledge of PrEP and gain practical insights on how acceptance of HIV-1 biomedical prevention technologies is arrived at by targeted end-users and how this may influence adoptability.

Next, I am going to tell you a little bit about 3 products to help prevent HIV among women ([Appendix G](#)). These products are either in early phases of development or they are being tested in human trials. One of these products may also be used to prevent pregnancy. For each product I will ask you the same set of questions.

INSTRUCTIONS TO THE INTERVIEWER:

Each of the products will be presented separately to the participant. Show the Showcard for the product. After presenting the first question, show the demo product, and then ask the remaining three (3) questions about it before moving onto the next product.

1. PRESENT SHOWCARD ON LONG-ACTING INJECTABLE & ASK FOUR QUESTIONS (*substitute long-acting injectable for “this product”*)
2. PRESENT SHOWCARD ON IMPLANT & ASK FOUR QUESTIONS (*substitute implant for “this product”*)
3. PRESENT SHOWCARD ON INTRAVAGINAL RING & ASK FOUR QUESTIONS (*substitute intravaginal ring for “this product”*)

12. SHOWCARD: What first comes to mind in hearing about this product?

13. SHOW DEMO PRODUCT: What first comes to mind now that you are actually seeing this product?

13a. Optional probes [*INTERVIEWER: ASK IF NOT ALREADY COVERED IN RESPONSES TO FIRST TO QUESTIONS*]: What could affect whether or not you would consider using this product?

13b. What could affect whether or not other women would consider using this product?

13c. What challenges might one face when using a method like this product?

Now I would like to talk about things that would help women actually using these products in their everyday lives.

14. Using your own experiences or those of others, what would be needed for women to adopt these 3 products?

OBJECTIVE 1: Describe knowledge of PrEP and gain practical insights on how acceptance of HIV-1 biomedical prevention technologies is arrived at by targeted end-users and how this may influence adoptability.

15. If you had to pick from these 3 products for yourself, which one would you pick and why?

15a. Which one(s), if any, would you automatically say no to?

15b. What are the reasons that you would not be interested in this/these products?

16. Is there anything else you'd like us to know?

Thank you for your thoughtful responses. I have a few questions on the tablet to close out this interview.

Showcard #1:

Intramuscular Injection with Long-Act Cabotegravir

INTERVIEWER READ:

- The first product is a long-acting injection.
- An injection is commonly referred to as a shot.
- Cabotegravir (CAB) is an investigational drug that is being studied currently.
- The injection contains drugs that would prevent HIV infection.
- These drugs would stop HIV from getting into the body or spreading around in the body.



Intramuscular Injection with Long-Act Cabotegravir

Important information to know about this shot is that:

- The CAB shot is not currently licensed for use.
- Before it can be made available it must be shown to work in a large clinical trial involving people at risk for HIV infection.
- It would be given into a muscle in the butt or upper thigh.
- A shot once per month would probably be required, but it may be less often.
- It does not protect against other sexually transmitted infections.
- It does not prevent pregnancy.
- It is intended for women at risk of getting HIV.
- It can also be used for men.
- People at low or unknown risk of getting HIV should not use this product.
- Side effects may include pain or tenderness at the injection site.

If it is found to work to prevent HIV and is approved for use by the U.S. government:

- A doctor or nurse does an assessment to figure out if it is the right HIV prevention option for you.
- The shot would then be given by a doctor or nurse during a medical visit.

Showcard #2:

Subdermal Implant

INTERVIEWER READ:

- The second product is a thin tube inserted beneath the skin, usually in the inside of the upper arm.
- This rod is referred to as an implant.
- The tube contains drugs that prevent HIV.
- These drugs stop HIV from infecting cells and spreading through the body.



Subdermal Implant

Important information to know about the implant is that:

- It is in the very early stages of development.
 - It has not yet been tested in people.
- A doctor will need to insert the implant.
 - An anesthetic shot will be used to numb the skin.
 - The doctor will make a small cut and use a special device to place the implant under the skin.
 - The device is a little like a tattoo needle.
 - The cut will not need stitches.
 - The wound will be bandaged.
 - The wound will soon heal just like any other small cut.
 - It is possible that the area around the implant could be bruised and tender for a few days.

Subdermal Implant

Important information to know about this implant is that:

- Once the implant is placed beneath the skin, it is expected to last about 6 months.
 - After six months, the old implant has to be removed by a doctor and a new one inserted.
- It does not protect against sexually transmitted infections.
- It does not prevent pregnancy.
- It is intended for women at risk of getting HIV.
- It can also be used by men.
- People at low or unknown risk of getting HIV should not use the product.
- Side effects may include some pain or tenderness at insertion site.
 - Redness may occur, but probably rare.

If it is found to work to prevent HIV and is approved for use by the U.S. government:

- An assessment is done by a doctor or nurse to figure out if it is the right HIV prevention option for you.
- The implant is inserted by a doctor during a doctor's visit.

Showcard #3:

Multi-Purpose Intravaginal Ring (IVR)

INTERVIEWER READ:

- The third product is a flexible ring that is inserted into the vagina for one month or longer.
- The ring prevents both pregnancy, and HIV.
- The ring releases hormonal birth control drugs as well as drugs to prevent HIV infection.
- A ring for only preventing pregnancy is licensed in the US.
- Some women using the contraception-only ring have reported that they or their sexual partners are able to feel the ring during sex.
- The same may be true of a ring that prevents both pregnancy and HIV.



Multi-Purpose Intravaginal Ring

- Important information to know about the implant is that:
 - An initial clinical trial has been completed among 50 women not at risk for HIV infection to see if a 21-day ring is safe.
 - Additional trials are being conducted currently among women at risk for HIV infection to see if the same ring is safe for 3-months of continuous use.
 - It does not protect against sexually transmitted infections.
 - It is intended to only provide HIV protection for vaginal sex.
 - It does not provide protection from HIV if a woman has oral or anal sex.
 - It is intended for women at high risk of getting HIV who also do not want to get pregnant.
 - It should not be used by women at low or unknown risk of getting HIV, women who want to get pregnant, or women who are unable to take hormonal contraception (e.g. history of clotting problems).
 - A woman can insert the ring herself.

Multi-Purpose Intravaginal Ring

Important information to know about this implant is that:

- The ring is worn for three months straight and then removed so that she can insert a new ring.
 - Either a woman's period may stop completely or she may have a very light flow.
- There are usually no side effects.
 - There may be slight vaginal discharge, but this has been rarely reported.
- A woman's partner may be able to feel the ring during sex.
- A woman may feel discomfort until she get used to wearing the ring.
 - The discomfort should not involve pain.

If it is found to work to prevent HIV and is approved for use by the U.S. government:

- An assessment is done by a doctor or nurse to figure out if it is the right HIV and pregnancy prevention option for you.
- During a doctor's visit, a doctor prescribes the ring.
 - The doctor may assist a woman with ring insertion the first time.

INSTRUCTION TO THE INTERVIEWER: Turn off audio recorder(s) and administer Demographic and Behavioral CAPI.