

Interview Guide: INSERT PUEV IDI

MTN 035

IN-DEPTH INTERVIEW ON INSERT ADHERENCE AND ACCEPTABILITY

TEXT IN CAPS WILL NOT BE READ TO THE PARTICIPANT.

Hi! Are you able to see me well? Great. How are you doing?

Hello, my name is [Interviewer's name] and I'll be your interviewer today. I want to begin by thanking you for taking the time to talk with me. Your experience and thoughts about the study are very valuable to future research so we really appreciate you taking the time to participate in this interview today.

Some of the questions are sensitive but everything we discuss will be kept confidential. Audio from our session will be recorded and transcribed, but key identifiable information—such as names or places—will be removed from the transcript to protect your privacy. Any question you would rather not answer let me know and we can skip it. You have the right to withdraw at any point in the study. In total the interview should last about 15 minutes.

I want to stress that we're looking for feedback, whether it be good or bad. There are no right or wrong answers. We really want to know what you think, so please don't hold back with your responses and answer as honestly as possible.

In case of an adverse event or social harm that is reported during the interview, I will encourage you to report that information to clinical staff if you haven't already done so. I will also report an adverse event or social harm to study staff after our interview. An example of an adverse event is an undesirable experience associated with the rectal douche such as an allergic reaction. An example of a social harm is experiencing difficulties in personal relationships as a consequence of study participation.

I want to remind you that everything we talk about is confidential. I will not be reporting your answers to the study staff and whatever you say will not affect your participation in this study. We will record this conversation, is that okay with you?

[TURN ON RECORDER]

Do you have any questions before we get started?

SMS REPORTING

Before we begin, I would just like to review with you what you reported in the SMS system. I will then go on to ask you specifically about your experiences.

[IDI STAFF WILL REVIEW THE OUTPUT PRODUCED USING DATA REPORTED TO THE SMS SYSTEM PRIOR TO THIS TELECONFERENCE. THEY WILL REVIEW THE REPORTS WITH THE PARTICIPANT, CHECKING ITS ACCURACY AND HIGHLIGHTING:

- Number of SMS events
- Reports of Sexual Activity

- Reports of insert use with sexual activity
- Reports of insert use with no sexual activity

Probes:

- Are these information correct?
- Did we miss any events not reflected in the SMS summary?

PRODUCT USE AT CLINIC

What was it like to use the insert for the first time at the clinic?

Probes:

- How did the application of the insert in the clinic go?
- Did you have any difficulties learning how to use the insert during this clinic visit?

PRODUCT USE AT HOME

Now, thinking about your use of the rectal insert after you left the clinic, I'd like to learn about your use of the insert during the past 4 weeks.

Let's start with the first time you used the insert outside of the clinic....

Probes:

- Where were you the first time you used it outside of the clinic?
- How did it go?
- Did you need to use additional lubricant to apply the insert?

How, if at all, did your use of the insert change over time?

- How does using the insert compare to using other products you have used rectally before starting this study (ease or difficulty of use compared to lubricants)?

PRODUCT USE WITH RECEPTIVE ANAL SEX

[IF PRODUCT USED WITH SEX] You reported that you used the insert prior to receptive anal sex. Tell me more about that.

Probes:

- What was your experience using the insert before receptive anal sex?
- How, if at all, did the insert affect your sexual encounters (spontaneity, privacy, negotiation, pleasure, partner pleasure; overall and specific incident)?

Partner-specific Probes

- Tell me a little about the person(s) with whom you had receptive anal sex.
- What kind of relationship do you have with him (them)?
- Where did you have sex?
- Did you use condoms and lubricant during anal sex?
- How did you guys end up using (or not using) condoms?
- Did you tell your partner(s) about the insert?
- What was his (their) reaction?
- If you did not tell your partner, did they notice you had applied the insert? How so? How did they react?

Were there times that you wanted to use the insert prior to receptive anal sex but weren't able to? Tell me about that.

Probes:

- Why weren't you able to use the insert prior to receptive anal sex?
- Tell me a little about the person(s) with whom you had receptive anal sex.
- What kind of relationship do you have with him (them)?
- Where did you have sex?
- Did you use condoms and lubricant during anal sex?

[IF THE PARTICIPANT REPORTED NO RECEPTIVE SEX DURING 4 weeks] You reported that you used the insert outside of receptive anal sex. Tell me more about that.

- What was your experience using the insert when you didn't have receptive anal sex?
- When did you use the insert? (e.g., before bed, in the morning)

PROBLEMS

Did you encounter any challenges using the insert? Tell me more about that.

Probes:

- What problem did you have?
- What did you do about it?

STORAGE & PRIVACY

Where did you store the inserts over the past 4 weeks?

Probes:

- Did you keep your inserts private? If so, how?
- Did you have any difficulties accessing the inserts when you wanted to use them?
- Did you come up with any tricks to remember to use the insert as required by this study?

OTHER RECTAL PRACTICES

Tell me about any douches or products you may have used rectally over the past 4 weeks.

Probes:

- Did you use a douche/enema over the past 4 weeks?
- Did you use any other products over the past 4 weeks? (e.g. other lubricants)

WRAP-UP

Great. You have completed the interview. Do you have any questions for me before we conclude this interview?

Thanks again for participating in this study and for taking the time to speak with me today.

[END OF INTERVIEW]