

APPENDIX II:
Qualitative Interview Topics, Questions, and Probes – Post-Unblinding

An interview guide for HPTN 083-02: Factors Influencing Adherence to Injectable Prep and Retention in an Injectable PrEP Research Study

(Updated October 13, 2020)

PARTICIPANT NUMBER:	DATE (DD/MM/YY):	START TIME:	END TIME:	INTERVIEWER INITIALS:

Reminder to interviewers:

Questions in the left-hand column will be asked of all participants, while questions in the right-hand columns are probes, and are to be asked only to help the participant describe his/her experience **or** if the participant does not bring up these topics spontaneously. **Please remember to ask participants all questions in the left-hand column.**

Interview script:

Introduction (*NOTE: informed consent will already have been completed*)

- Thank you again for agreeing to do this interview.
 - As you know from the consent, I am [INTERVIEWER NAME], and I work here at [SITE NAME].
 - We are conducting interviews with participants in HPTN 083, the study of injectable PrEP that you are in.
 - We would like to understand your experiences in the study. For example, we are interested in things that make it difficult and things that make it easier to take the medications or get the injections, and your thoughts about HIV prevention. As you have heard, recently released results from this study demonstrated that long-acting injectable PrEP is highly effective for preventing HIV infection in cisgender men and transgender women who have sex with men.
- As we go through the interview, please remember:
 - No study is perfect; please do not worry about hurting my feelings. We want to know how you really feel.
 - One of the major goals of this interview is to find out what might may not have worked for you, so please let us know, so we can make things better.

- As a reminder, you are not required to answer my questions, and you may skip any questions that make you uncomfortable. If you decide that you no longer want to participate in this interview, you can still get medical care at [SITE NAME] and participate in the study. As a reminder, I will use a digital recorder to record our conversation. After all interviews are completed, audio files will be transcribed. We will de-identify the transcripts before they are analyzed.
- What questions do you have before we begin the interview?
- The interview will take around 30-60 minutes. Please set your mobile phone in silence mode during this time.
- May I turn on the digital recorder?

(TURN ON DIGITAL RECORDER)

I am [INTERVIEWER NAME] interviewing participant [PARTICIPANT #] on [DATE] [START TIME].

Topics and Main Questions	Probes
(1) Product preferences and unblinding of study condition	
<p>Now that you have taken pills and also taken injections as a way to prevent HIV, and we know that the injections work better than the pills, I would like to ask about what you prefer (the pill or the injection) and why.</p> <p>Taking all this together, which do you prefer, and what is the main reason why?</p>	<p>What makes a biomedical prevention method/medication for preventing HIV acceptable to you?</p> <p>What are the reasons for preferring pills?</p> <p>What are the reasons for preferring injections?</p> <p>What are the reasons for not liking pills?</p> <p>What are the reasons for not liking injections?</p> <p>How else do these products compare?</p> <p>What else can you share to help us learn about preferences for these two options (pills versus injections)?</p>

<p>Some people might prefer pills at one time in their lives and injections at another. What might come up that would affect whether you would prefer pills or injections?</p> <p>How has the COVID-19 pandemic impacted your thoughts on which product might work better for you?</p>	
<p>What condition were you assigned to in this study?</p>	<p>How did you feel about this condition?</p> <p>How did being assigned to this condition affect your preferences around injections and pills?</p>
<p>(2) Implementation</p>	
<p>After the study ends, our hope is that both daily pills and injections for HIV prevention will be available to everyone. Please share with me your thoughts on how we can most successfully get these HIV products available to people in the community.</p> <p>How can we support people in using <u>injections</u> over time?</p> <p>How can we support people in using <u>pills</u> over time?</p>	<p>How can we best reach men who have sex with men and transgender women who may benefit from pills or injections designed to prevent HIV?</p> <p>What messages are important to communicate about pills and injections?</p> <p>What specific support will people need to use injections well?</p> <p>Who should provide that support?</p> <p>With respect to injections, who is the most desirable provider to give an injection? Why?</p> <p>What is the best venue to receive injections? Why?</p> <p>What specific support will people need to use pills well?</p>

<p>What will be most challenging about introducing these tools (that is, injections and pills) at the community level?</p> <p>What else you would like to share with me about your how we can help people in the community access and use these products (that is, injections and pills)?</p>	<p>Who should provide that support?</p> <p>With respect to pills, what is the best way for people to receive their pills? Why?</p>
<p>(3) Overall experience</p>	
<p>Next we are going to talk about your overall experience in the study, including study visits, getting injections, and taking pills. We will also ask whether your feelings about these things have changed now that we know the results of the study.</p> <p>Please tell me what made you decide to join the injectable PrEP trial.</p> <p>Now that we know the results of the study I would like to hear how you feel about your participation and the effort you contributed to the study.</p>	<p>What other studies of HIV prevention did you consider participating in?</p> <p>Why did you choose this study?</p> <p>What motivated you to participate in this study?</p> <p>What did you expect the study to be like?</p> <p>How did your expectations compare to your actual experience?</p>
<p>(4) Facilitators of injection adherence / visit attendance</p>	
<p>Next we are going to talk more about some of the things that may have <i>helped</i> you do the things you needed to for the study, such as coming to the clinic for injections and taking your pills, as well as the things that</p>	

<p>FOR PARTICIPANTS STILL RECEIVING INJECTIONS: Please tell me how it's been different or similar to the time before you knew injectable PrEP worked.</p> <p>How did the COVID-19 pandemic affect your ability to get to your injection visits?</p> <p>Tell me about any pain you experienced as a result of the injections. How did you manage that?</p>	<p>this affect the way you got to your injection visits?</p> <p>Sometimes peoples' HIV risk changes over time depending on what is going on in life (such as an increase or decrease in sexual activity or partners). How did this affect the way you got to your injection visits?</p> <p>How did drinking / using drugs affect how you got to your injection visits?</p> <p>How did the environment at the clinic and study staff affect how you got to your injection visits?</p> <p>What else made it difficult to get to your injection visits?</p>
<p>(6) Facilitators of pill adherence</p>	
<p>Now we are going to talk about taking pills. You were asked to take one pill, once a day as part of your participation in the study. What was it like trying to take this pill every day?</p>	<p>How did you feel about taking this pill?</p> <p>How did taking this pill go for you?</p> <p>How did your feelings about taking the pill affect how often you took it?</p> <p>What made you want to take this pill?</p> <p>What helped you take this pill? By help, I mean things you did to try to take the pill daily.</p> <p>Tell me about things you did to avoid</p>

<p>FOR PARTICIPANTS STILL USING ORAL PREP: Please tell me how it's been different or similar to the time before you knew injectable PrEP worked.</p>	<p>forgetting your pill.</p> <p>Tell me about any people who supported you in taking your pill. How did they help?</p> <p>Tell me about what you did to take your pills: (a) when drinking / using drugs and (b) travelling or spending a night away from home.</p> <p>Where did you store your pills?</p> <p>What else helped you take your pill?</p>
<p>(7) Barriers to pill adherence</p>	
<p>Thank you for sharing with me the things that might have helped make it easier to take your pill. I would now like to talk about the things that made it difficult.</p> <p>Please tell me about the things that <i>got in the way</i> of taking your pills daily.</p>	<p>Sometimes people worry about what others might think. Tell me how you feel about this. How did this affect the way you took your pills?</p> <p>Some people may have worried about whether the pills would work. Tell me how you felt about this. How did this affect the way you took your pills?</p> <p>How did you feel about taking a pill for an illness you did not have? How did this affect the way you took your pills?</p> <p>Sometimes peoples' HIV risk changes over time depending on what is going on in life (such as an increase or decrease in sexual activity or partners). Tell me how you feel about this. How did this affect the way you took your pills?</p> <p>How did drinking / using drugs affect how you took your pills?</p>

<p>FOR PARTICIPANTS STILL USING ORAL PREP: Please tell me how it's been different or similar to the time before you knew injectable PrEP worked.</p> <p>How did the COVID-19 pandemic affect your ability to take your pills daily?</p>	<p>What changes, if any, did you make to your drinking / drug use while you were in the study?</p> <p>How did the environment at the clinic and study staff affect how you took your pills?</p> <p>How did your relationships with others, including your family, friends, and co-workers affect how you took your pills?</p> <p>What else made it difficult to take your pills?</p>
<p>(8) Perceptions of adherence support</p>	
<p>As part of the study, you may have met with a study staff member to discuss how things were going with taking your pills and getting your injections. This study staff member may have helped you think about what was getting in the way of taking your pills or getting to visits, and solved those problems with you.</p> <p>How did you feel about those conversations?</p>	<p>What could have made those conversations more helpful?</p> <p>How comfortable did you feel having those conversations?</p> <p>How would you improve those conversations?</p> <p>What else could the study staff have done to help you with taking your pills or receiving your injections?</p>
<p>(9) Reasons for drop-out / study discontinuation</p>	
<p>NOTE TO INTERVIEWER: THE FOLLOWING QUESTIONS ARE TO BE ASKED ONLY OF those who terminated participation in the study (i.e., drop outs, those who declined additional injections but agreed to follow-up, and those lost to follow-up).</p> <p>You [DROPPED OUT OF THE STUDY,</p>	<p>How did you make that decision?</p> <p>What was the main reason?</p> <p>Who helped you make that decision?</p> <p>What, if anything, would have led you to make a different decision?</p> <p>Are there any differences in how you have</p>

<p>DECLINED FURTHER INJECTIONS] before we knew that injectable PrEP works. Please tell me about your decision to leave the study / decline additional injections.</p>	<p>thought about this decision since we learned that injectable PrEP is effective? What could the study team have done differently to support participants?</p>
<p>(10) Impact of COVID-19 pandemic</p>	
<p>How has the COVID-19 pandemic impacted your overall experience with the study?</p>	<p>How has the COVID-19 pandemic impacted your sex life?</p>
<p>(11) Conclusion</p>	
<p>What else can you share with me about your experiences in HPTN 083, the injectable PrEP study?</p> <p>I would like to take a moment to summarize what you have shared with me. [INTERVIEWER TO BRIEFLY SUMMARIZE KEY POINTS FROM EACH SECTION.] What did I get wrong?</p>	
<p>I want to thank you for your time today and for participating in our interview. Your answers to our questions help us understand how to improve our HIV prevention efforts.</p>	