

HPTN 074 – Mock Scenarios and questions

SCREENING & ENROLLMENT

- 1. How long should the index and partner have known each other?**
Answer: At least one month, interacting (risk behaviors) at least once per week during that time. Needle sharing or risk behavior includes sharing needles, syringes, or injection solution.
- 2. A partner comes to the clinic for screening, but does not have a referral ID card. Can they be screened?**
Answer: Yes, but must match the Index's description according to local procedures.
- 3. An Index comes in for screening on February 9. All eligibility criteria (including HIV confirmation) are verified by February 16. However, the partner does not come in for Enrollment until April 20. What do you do?**
Answer: Since more than 60 days have passed since HIV confirmation of the Index participant to when the partner enrolled, the Index would need to be re-screened- minus HIV testing.
- 4. What do you do if a participant expresses suicidal thoughts during screening?**
Answer: Follow the SOP for suicide ideation. Administer the Suicide/Risk Assessment Form (non-datafax). First, ask whether the participant has attempted to hurt her/himself in any way in the past 2 weeks. If 'not at all', then s/he is considered a low risk. You may continue the screening. If they're actively suicidal, you may wish to exclude them from the study for this reason. The participant may need referrals or additional counseling as per your local procedures.
- 5. A potential partner at screening has a positive rapid test, but is later proven HIV negative. Can she or he enroll as a partner?**
Answer: No. Even if s/he would be the only partner in the study, s/he still cannot enroll as a partner.
- 6. A site has enrolled 50% (total 83 or 84/167) of their allotted participants that are ART exposed or on ART. Can they enroll another participant who is not ART naïve?**
Answer: Yes. The protocol is only a target. This would not be a protocol violation. The site should aim for at least 50 percent ART naïve.
- 7. An index has enrolled 5 separate partners during the trial, and all 5 are no longer injecting with him. Can he enroll 1 more?**
Answer: According to the protocol, no - so long as 5 are still being followed. If one partner drops out, another may replace this partner. Would we continue to follow these partners? Yes.
The only time we could enroll one more partner is if another partners leaves the study.
- 8. Can a partner who tests positive be re-screened as an Index?**
Answer: Yes. The original referring Index cannot enroll in the future.

9. For Index re-screening, will the index use the same PTID as in the original/previous screening?

Answer: Yes.

10. If the first eligible partner of an Index screens more than 60 days after screening blood draw of Index-what happens?

Answer: They both must rescreen.

11. How should the information from the second screening for re-screened participants be submitted?

Answer: The original screening forms should be updated and should remain coded at 1.0 on the CRFs. SCHARP/the SDMC does not need information from the first screening in the database.

12. How are you tracking re-screens to ensure that you are not screening the same individuals multiple times?

Answer: You can re-screen only one time. This information is captured in the participant tracking database. At reception, staff will ask for this information and will check with the database.

FOLLOW-UP

1. Will the index and partners have the same target visit dates?

Answer: Yes. Both are technically enrolled at the moment in time when the index is randomized.

2. If a partner's week 4 visit and the index participant's follow-up visit (e.g., week 26 visit) coincide, will the partner still complete a week 4 visit before following the index's schedule?

Answer: Yes. If a partner's week 4 visit and the index participant's follow-up visit coincide, the partner completes the week 4 visit first and does not jump into the schedule for the index participant yet. Therefore, the partner does not complete 2 visits at that time (the week 4 and the week 26 visit). In this scenario, the partner would complete the week 4 visit and then complete the *next* follow-up visit that the index has, the week 39 visit.

3. A participant enrolled late in the study. How long will s/he be in the study?

Answer: It depends on when they enroll. The end of the study follow-up may be truncated for those who enrolled late. Therefore, weeks 52, 65, 78, 91, or 104 may be an Exit visit for some participants. The protocol states that participants will be in the study "a minimum of 12 months and a maximum of 24 months". All participants will terminate after 27 months have passed since the first enrollment.

4. What do you do if a participant has had suicidal thoughts during the study?

Answer: Follow the SOP for suicide ideation. Administer the Suicide/Risk Assessment Form (non-datafax). First, ask whether the participant has attempted to hurt her/himself in any way in the past 2 weeks. If 'not at all', then s/he is considered a low risk. You may continue the study visit. Any other answer will prompt a series of questions on present and past thoughts of suicide or suicide attempts. The participant may need referrals or additional counseling as per your local procedures.

5. What happens if a participant is jailed?

Answer: The participant will be counted 'on study' up until the scheduled exit visit. However, we will not try to contact those participants in jail. If the participant's exit window closes while he is still in jail, he will be terminated only at that time as lost to follow-up. However, we will be able to stratify the lost to follow up by really lost, compared to incarcerated, dead or hospitalized. If you do terminate him and he gets out, you can cancel the termination.

6. If a partner seroconverts, what should happen?

Answer: We confirm within 14 days. Then we continue to follow the partner. They would be referred for ART per national guidelines or as soon as possible for participants in the intervention arm.

INTERVENTION

1. Can you conduct study procedures in a participant's home?

Answer: Right now we do not have ability to do home visits. This would require consent as well as approval from DAIDS as they would require specific plans for home visits to be written including data collection and transfer, specimen collection and transfer, security, confidentiality, etc.

2. Can navigators take index participants randomized to the intervention to their ART appointments?

Answer: Yes, if the participant and staff feel this is best. We do not anticipate this will happen often, and there is a CRF which accounts for such contacts.

3. An index (in the intervention arm) and her supporter wants more counseling sessions after the initial 2. Is this possible?

Answer: Yes - the protocol and intervention manual allow for as many as they wish/need as determined with site staff.

ART & SUBSTANCE USE

1. How do we determine what ART or substance use medications a participant is on?

Answer: This is all self-report. We want to encourage participants to bring their pill bottles with them to each visit, however, to help record the medication accurately.

CRFs & DATA COLLECTION TOOLS

2. How should the Index Screening Outcome CRF be marked if the index misses the enrollment window?

Answer: The CRF should be marked 4g, "Unable to recruit network partner within window after screening blood draw".

- 3. How should the Index Screening Outcome CRF be marked if a partner was screened within the 60 day window, but does not appear for enrollment?**
Answer: The CRF should be marked 4g, “Unable to recruit network partner within window after screening blood draw”. If more appropriate, you may mark 4l, “Did not complete screening procedures”.
- 4. For the Index Screening Outcome CRF, item 3 asks whether the participant has been enrolled or not, when the answer to this might not yet be clear until the Index actually enrolls or the 60 day window expires. Should this CRF be faxed twice (just following the visit and then after the enrollment result becomes known)?**
Answer: No, only re-fax this CRF if the data is updated. This CRF should be faxed once you know whether the participant will or will not enroll. This may happen at various time points.
- 5. A participant needs to be re-screened and you have already faxed in visit 1.0 CRFs for a participant for the first screening. How do you code the second visit?**
Answer: Mark the CRFs from the first screening for “delete” and fax those in at the same time that you fax in the new visit 1.0. If you don’t fax in screening forms until the screening is successful, you only have to fax once.
- 6. When should the ART Initiation CRF be submitted?**
Answer: The ART Initiation CRF should be submitted when the site team member becomes aware of the participant initiating ART. This information could be obtained during a meeting (and not a study visit). The visit code on the CRF allows for submission at interim visits (i.e., not scheduled visits). Sites should then follow the instructions for interim visit codes outlined in the SSP. In addition, items 15 and 16 on the SNE prompts the Systems Navigator to complete the initiation CRF if the participant reports ART initiation.
- 7. Do Counselors and Systems Navigators need to register an Interim Visit CRF when they learn about an Index’s ART initiation, or just fill out the SNE and PSY CRFs?**
Answer: Counselors and Systems Navigators should fill out and submit an Interim Visit CRF in this case.
- 8. When should an optional CRF be filled out and submitted?**
Answer: An optional form is only completed in the case that the CRF is relevant during that visit. Example: A participant reports initiating ART during an interim visit.
- 9. What do you do if you discover that a partner is injecting with another partner via the network questionnaires?**
Answer: This could be learned via the social/sexual network lists, and will be helpful in further characterizing network dynamics.

ADVERSE EVENTS & SOCIAL IMPACTS

- 1. Is HIV seroconversion an SAE?**
Answer: No - HIV is not considered an AE in HPTN. However, a diagnosis of AIDS is considered an AE and you would grade the severity of the condition(s) that lead to a diagnosis of AIDS (CD4 count and Kaposi’s sarcoma for instance).

2. Is an appendectomy at Week 26 an AE?

Answer: Yes - hospitalization qualifies as an SAE.

3. After a participant has exited the study, you learn that she was hospitalized. Is this an AE?

Answer: Not if the AE occurred after study participation and you do not believe it could have been related to their ARV or SU treatment. Yes, if the AE occurred while she was enrolled in the study and you find out after she has exited.

NOTE: The person did not have to be on ARV or SU during the study in order for an event to be considered Serious. However, in such cases, a SUSAR is impossible by definition- since SUSARS HAVE to be relate to ARV or SU, and unexpected.

4. A participant comes to the clinic stating that she has been raped by a stranger. Is this a social impact?

Answer: It depends on whether she believes it was related to study participation.

5. A participant is kicked out of his house by his parents because they find his partner referral card and they assume that he is using drugs again. Is this a social impact?

Answer: Yes – obviously, this is directly related to study participation.

6. A participant cannot be contacted and you call her mother, who is listed on the locator form. The mother says the participant has died. What do you do?

Answer: Obviously, provide your condolences. Ask if she is willing to provide information on what happened and when, and whether you can get a copy of the death certificate. If this is not possible, the mother's word will be enough in the source documents. You could also speak with friends or family members and document this conversation, but HPTN 074 only requires you to speak with one person who knows the study participant. Complete an AE form for death and perhaps SUSAR if the definition applies.

PARTICIPANT TERMINATION

1. Can a participant terminate his/her participation from the study at any time?

Answer: Yes. The Termination CRF should be completed.

2. When should a partner be terminated from the study if the index terminates early?

Answer: The partner should be terminated from the study (staff fills out the Termination CRF) at their next scheduled visit (i.e., the next time staff sees them). For example, if the index terminated at Week 26 on October 30, 2015, the partner will terminate at his/her next scheduled visit, which may be Week 39, at the end of January 2016.