Section 12. Counseling Considerations

12.1. Overview of Section 12

This section contains guidance on HIV Pre -/ Post-Test counseling provided in HPTN 083-01.

HIV Pre-/ Post-Test counseling is required at all study visits, since all study visits now mandate HIV testing, inclusive of HIV RNA viral load testing. All counseling should be provided in a non-judgmental participant-centered manner that responds to current participant needs for information, education, support, skills building, and/or referrals. Participants' needs are likely to change over time; counseling provided should also change over time accordingly.

All counseling process outcomes should be documented in participant study records. Proper documentation may be achieved by using counseling checklists, worksheets, and other tools, as well as counselors' chart notes. To support ongoing participant-centered counseling over time, documentation of each counseling session should include enough information and detail to inform and guide the participant's next counseling session.

During counseling, a site-specific tool may be used to guide any of the counseling sessions. During the session, counselors should engage in the discussion and be client oriented rather than focusing on taking notes. A summary of the counseling session should be written once the session is completed.

12.2. HIV Pre- /Post-Test Counseling

HIV testing is required at each scheduled HPTN 083-01 study visit, for as long as the participant is not found to be HIV infected.

Each site is encouraged to develop a Standard Operating Procedure (SOP) for this counseling. It is suggested that the SOP be site-specific and the following elements be incorporated:

- Each participant should be provided with information that allows them to decide whether to be tested (informed decision with informed consent). However, if a participant elects not to undergo HIV testing they may not receive study product and the Clinical Management Committee (CMC) must be contacted for participant management. CMC guidance will then be followed by the site.
- The HIV testing procedure should be organized to maximize confidentiality.
- HIV antibody testing should be linked with information and recommendations regarding HIV.
- Adequate pre- and post-testing counseling should be provided to all individuals being tested.
- Disclosing HIV status to others should be discussed with all participants.
- The need for additional and appropriate referrals should be addressed where possible.

All HIV counseling should be provided in accordance with local counseling standards. Study staff who provide HIV counseling should be trained to do so per local practice standards. Counseling staff should also be trained on study-specific HIV testing methods and interpretation of test results per the study testing algorithms in SSP manual Section 11. Information on interpretation of screening, enrollment, and follow-up test results is provided as part of the testing algorithms. These figures should be referenced as needed when providing pre-test and post-test counseling.

Given that HIV counseling will be provided at all HPTN 083-01 study visits, when providing pre-test and post-test counseling, it is especially important to avoid repetition of the same information at each counseling session. Participant-centered approaches should be used to assess participant knowledge of relevant information, dispel any misconceptions, ensure participant readiness for HIV testing, and ensure participant understanding of why HIV testing is being done at every visit and understanding test results.

HIV test results should be provided in the context of post-test counseling, which should begin when the first test results (rapid test results) are available the day of testing, and continued, as results become available. If it is convenient for the participant, or it is part of a site's standard of care, interim visits may be scheduled to give HIV test results and conduct post-test counseling.

Additionally, mechanisms for linking individuals to appropriate HIV specialty care who acquire HIV infection during study participation is required to be detailed in an SOP for each site. “Appropriate care” should be locally defined and include consideration of developmental age, language, geography, insurance status and type, provider cultural sensitivity, and resource availability.

Risk reduction counseling should be incorporated into the HIV counseling approach noted above. Participant-centered approaches should be used when providing risk reduction counseling. For HPTN 083-01, risk reduction counseling will include condom use, data on the known effectiveness of both TDF/FTC and long-acting cabotegravir (CAB LA) as HIV pre-exposure prophylaxis. The counselor should ask open-ended questions, actively listen to participant responses, probe as needed for further information, and guide the participant in identifying their risk factors and barriers to risk reduction, as well as strategies and action plans to try to address these.

12.3. Product Use Instructions and Adherence Counseling

Participants will be provided product use instructions and adherence counseling for the first time at their study enrollment visit, and per the schedule on the protocol. The person providing product use instructions and adherence counseling will discuss with participants adherence to protocol requirements such as returning for study visits and not sharing product. Adequate time should be taken to explain the product use instructions thoroughly and to answer any questions the participant may have. Any questions or concerns raised by the participant should be documented in his/her study records, so this information is easily available for reference at follow-up visits.

In general, adherence counseling will be provided in accordance with recommendations from PrEP clinical guidance documents and in-country implementation strategies (Centers for Disease Control [CDC], World Health Organization [WHO]). Using a participant-centered approach to frame discussions, adherence counseling will include education around the importance of daily pill adherence (for Step 1 and Step 3, if TDF/FTC is chosen by the participant) and supporting strategies that link pill taking to the participant’s daily routine (i.e., daily calendar, plans for travel, daily habits). Counseling will be tailored based on which Step of the study the participant is currently in. For Step 1, counseling should be focused on daily adherence to oral CAB tablets; for Step 2, counseling should be focused on attending study visits to receive the CAB injections and what to expect before, during, and after injections; and for Step 3, counseling should be focused on either adherence to open-label daily oral TDF/FTC or attending study visits to receive injection – depending on whether the participant chooses Step 3 – Oral PrEP or Step 3 - Injection.

Please note, throughout the study, participants should be counseled that simultaneous use of TDF/FTC as PrEP is not permitted. If a participant meets local criteria to initiate daily oral PrEP during follow up, or would prefer to do so, they should discuss this with the study team. If the participant decides to proceed with daily PrEP, they should be transitioned to Step 3.

12.4. Study Product Use Instructions

Oral Product

Participants will be instructed to take one tablet by mouth daily during Step 1. The oral tablets should be taken as close to the same time each day as possible. If a participant misses a dose, the participant can take the missed dose within the same calendar day as soon they remember. The next dose will be taken by mouth as originally scheduled. Participants should be instructed not take two doses on the same day. If the participant vomits a dose or there are any other problems with dosing, please contact the CMC per individual case.

Participants should be reminded to store study tablets at room temperature, in a safe place and out of reach of small children. Although tablets should be kept in original container with labels intact, participants may use pill boxes or other mechanisms they find helpful to assist with adherence or protect privacy. Such containers would need to accompany participants to their visits to perform pill counts as appropriate and medication reconciliation.

Injection Product

See section 8 of this manual for information.

*Note that, per protocol, neither brand name nor generic TDF/FTC are considered "study product" in HPTN 083-01. Participants should follow product use instructions for either brand name or otherwise FDA-approved TDF/FTC available in the U.S., if Step 3 – Oral PrEP is chosen.

12.5. Step 1 Counseling Considerations

Participants should be counseled on the purpose of the oral phase of the study, with an emphasis placed on the fact that it is being conducted specifically to rule out any serious side effects of the study drug prior to the administration of injections, and that therefore it is important that the study drug be taken every day. Participants will be able to identify reminder cues to assist with daily dosing, including reviewing calendars for daily habits, setting phone alarms, etc. The counseling should also include clear instructions about the product, any side effects anticipated, and strategies for maintaining daily adherence. Counseling may also incorporate conversations around disclosure of study participation

to supportive others (see optional tools Appendix 12-A). This counseling should be provided at the Enrollment, Week 2, and Week 4 visits. In addition, pill counts will only be done at Weeks 2 and 4.

Sites should refer to the HPTN 083-01 protocol for side effects of oral cabotegravir (CAB) (Section 1 and the Sample Informed Consent Form Template), as well as the Investigator's Brochure (IB) and Section 9 of this manual.

At the enrollment visit, sites must observe participants take oral study product. During Week 2 and 4 study visits, participants should be observed taking oral study products on site. However, while directly observed therapy (DOT) during Weeks 2 and 4 is recommended, it is not required if participants have already taken study product on the day of the study visit. Those participants must not be asked to take a second dose of study product.

Participants should be instructed not to take their oral study product on the day of their Week 5 study visit. However, if a participant takes study product on the day of Week 5 visit, DO NOT defer injection and document on participant's file.

NOTE: Antacid products containing divalent cations (e.g., aluminium, calcium and magnesium) must be taken at least 2 hours before or at least 4-6 hours after the oral formulation of CAB.

12.6. Step 2 Counseling Considerations

Counseling conducted prior to each injection should focus mainly on what to expect before, during, and after each injection is given, including any side effects that participants may experience, and that the same drug that they took during the oral phase is now being given as an injection, and is the long-acting formulation of the drug, and that it will stay in their system for a long time (a year or more after a single injection) with clear explanation why participants get injections at different intervals yet the long acting formulation drug lasts for a year or more after a single dose . Participants should be informed of the schedule of injections and the expected timeframe they will receive them (based on their enrollment date, see Protocol Section 5 and SSP manual Section 6, and refer to study schema graphic, Appendix IV of the SSP).

Additionally, it should be explained that the injection site (the buttocks) may have localized pain, be tender to palpitation, itch, swell, bruise, be temporarily discolored, feel warm or have a pulsing sensation. Participants must be encouraged to contact site staff after they have left the study clinic if any side effects occur, including suspected injection site reactions.

While the HPTN 083-01 protocol provides instructions regarding when to contact the CMC about adverse events, the CMC may be contacted at any time there is a question about any side effects of the oral or long-acting study product.

At Week 33 (and Week 34, if necessary), site staff should discuss with participants desires about their product choice, whether to remain on CAB LA injections or move to TDF/FTC for the remainder of the study (Step 3). Sites will not document these discussions in the CRFs, but rather indicate decision on the date of visit (DOV) form. There are new fields asking which product was chosen at Step 2 Week 34 and at every visit in Step 3, and those fields can be populated retroactively. Sites should, however, incorporate a discussion form into site source documentation regarding the discussions held at Weeks 33 and 34.

12.7. Step 3 Counseling Considerations

Adherence counseling during Step 3 should emphasize the effectiveness of daily oral TDF/FTC (when taken as directed), if the participant chooses that route for Step 3. Counselors will continue to work with participants to identify strategies to maximize adherence and minimize adherence barriers. The counseling should also include clear instructions about the product, and any side effects anticipated. This counseling should be provided at all Step 3 Visits.

If the participant chooses to remain on CAB LA injections for Step 3, counseling in Step 3 will mimic that of Step 2.

Sites should refer to the HPTN 083-01 protocol, the Sample Informed Consent Form Template, as well as the Package Insert.

Appendix 12-A: PrEP Disclosure Activities

Disclosure tools should be approved by local IRB/EC prior to distributing to participants.

ACTIVITY A: SAFE TALK- HOW DO I DISCLOSE THAT I AM ON PREP?

ASK PARTICIPANT	*How do you feel about telling people that you are taking PrEP?*
DISCUSS	Participant's views on disclosing or not disclosing PrEP
STATE	*If you are struggling with how to tell someone that you are taking PrEP, here is an acronym, T.A.L.K. that can help guide you through the process.*
HANDOUT	"Safe TALK" handout. **T**iming **A**ssertive Communication **L**ocation **K**now What to Say
STATE	*Timing, Assertive Communication, Location, Know What to Say.*
ASK	**Have the participant read text** on the "SAFE Talk" handout. **T**IMING Choose an appropriate time to talk with your person. If the person that you need to talk with has a busy lifestyle, then it might be easier for you to set a meeting time. This way, each person's attention can be focused on the issue. **A**SSERTIVE COMMUNICATION Clearly tell the person how you feel and what you want or need by being honest and direct. Think carefully about your relationship and pay attention to others' responses. Depending on the specific person, you might have to address issues differently. Remember to use "I" statements, take deep breaths, keep a reasonable tone, and actively listen to the other person. **L**OCATION Choose a quiet place where you cannot be interrupted or overheard by others. **K**NOWING WHAT TO SAY Think about what you want to say in advance by sorting out your own feelings about the issue before talking with the other person. You might find that making a list or writing a letter of your thoughts and feelings will help you focus.

DISCUSS	Handout and answer any questions.
EMPHASIZE	*You have control over whether you tell people, who you tell and how you tell them. Think about what is best for you and make sure YOU are ready.*
STATE	*Now we are going to practice telling someone you are on PrEP by doing some role-playing, even if you aren't ready to tell someone yet. Choose someone who you may want to tell about PrEP in the future. Let me know who it is and provide me with some details about where the conversation is taking place. The more details you provide, the better. I will then pretend to be the person and react as I think the person might respond.*
ALLOW	Time for participant to prepare then Conduct the role-play.
ASK	*What was the most challenging thing about this role-play?* *What part of this was easier than you thought it would be?* *What surprised you going through this role-play?*
ENCOURAGE	Participant to share one thing they liked, and one thing they wish they would do differently.
ALLOW	Time for discussion

ACTIVITY B: ACTION PLAN: DISCLOSURE

NOTE	This activity is ONLY for participants who are interested in telling someone about being on PrEP.
STATE	*You have said that you are interested in telling someone that you are taking PrEP. Let's develop an action plan to outline what steps you will take.*
HANDOUT	"Action Plan: Disclosure" handout
STATE	*Think about the specific person whom you would like to disclose your PrEP use to. Use this worksheet to think through the reasons why you want to disclose to that person. Then use this form to plan out the process.* *Decide when you would like to tell them, where you will have the talk, what you will say, and how you will do it. Finally, think about what the potential costs and benefits of disclosing to this person would be.*
ALLOW	Participants time to fill out their action plan. They may leave the worksheet with the counselor or take it home if they wish.

ACTIVITY C: Negotiating PrEP Use in a Sexual Relationship

STATE	*You may decide that you want to talk to your significant other or a sexual partner about using PrEP at some point. This might seem a bit difficult, but if you prepare yourself, it will be easier. Remember last time we discussed the "Safe TALK" strategy?* Show "Safe TALK" handout and review <u>if participant hasn't seen it or doesn't remember it</u> <u>**T**IMING</u> Choose an appropriate time to talk with your person. If the person that you need to talk with has a busy lifestyle, then it might be easier for you to set a meeting time. This way, each person's attention can be focused on the issue. <u>**A**SSERTIVE COMMUNICATION</u> Clearly tell the person how you feel and what you want or need by being honest and direct. Think carefully about your relationship and pay attention to others' responses. Depending on the specific person, you might have to address issues differently. Remember to use "I" statements, take deep breaths, keep a reasonable tone, and actively listen to the other person. <u>**L**OCATION</u> Choose a quiet place where you cannot be interrupted or overheard by others. <u>**K**NOWING WHAT TO SAY</u> Think about what you want to say in advance by sorting out your own feelings about the issue before talking with the other person. You might find that making a list or writing a letter of your thoughts and feelings will help you focus. *Tell your partner some of the things you have learned about STIs and HIV. It's also important to negotiate and listen to your partner. Keep in mind that it's not only your right, but also your RESPONSIBILITY to make decisions that will help you stay healthy.* *It's very important to know what you will say in response to your partner's questions, complaints, or efforts to change your mind. You can anticipate their reactions and responses and make the conversation a little easier for you.*
STATE	*Let's practice discussing PrEP with your partner***.**

DISPLAY	How to talk PrEP with your partner handout… What if your partner says… • "I am faithful to you, you don't need PrEP." • "PrEP doesn't work." • "If you need PrEP, you must be sleeping around." • "You must have HIV and aren't telling me."
ASK	*How would you respond to these statements by your partner? Let's practice.*
ROLE PLAY	Different ways to respond to the partner statements
DISCUSS	Alternative responses with the participant.
THANK	Participant for sharing her feelings and being open and honest about the process of disclosure.

SAFE T.A.L.K

TIMING

Choose an appropriate time to talk with your family or significant others. If the family member that you need to talk with has a busy lifestyle, then it might be easier for you to set a meeting time. This way, each person's attention can be focused on the issue.

ASSERTIVE COMMUNICATION

Clearly tell your family member or significant others how you feel and what you want or need by being honest and direct. Think carefully about your relationship and pay attention to others' responses. Depending on the specific person, you might have to address issues differently. Remember to use "I" statements, take deep breaths, keep a reasonable tone, and actively listen to your family member or significant others.

LOCATION

Choose a quiet place where you and your family member or significant others cannot be interrupted or overheard by others.

KNOWING WHAT TO SAY

Think about what you want to say in advance by sorting out your own feelings about the issue before talking with your family member or significant others. You might find that making a list or writing a letter of your thoughts and feelings will help you focus.

ACTION PLAN: DISCLOSURE

Think about one specific person to whom you would like to disclose your PrEP use. Let's use this worksheet to think through the reasons why you might want to disclose to that person. Then use this form to plan out the process.

*List all the reasons **WHY** you want to disclose to_____.*

***WHO** am I disclosing to?*

***WHAT** will I say?*

***WHERE** will I say it?*

***WHEN** will I have this conversation?*

***HOW** will I do it?*

Potential Costs:

Potential Benefits:

How to talk PrEP with your partner…

Your partner says:

“I am faithful to you, you don’t need PrEP.”

“PrEP doesn’t work.”

“If you need PrEP, you must be sleeping around.”

“You must have HIV and aren’t telling me.”