12 – Counseling Considerations

12.1. Overview of Section 12

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

HIV Pre -/ Post-Test counseling is required at all study visits. 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 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 sufficient 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 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 study visit for as long as participant is not found to be HIV infected.

Each site is encouraged to develop an 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).

- 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 found in Appendix IE of the HPTN 083 protocol and in SSP manual Section 11.3.1, Figures 11.1 to 11.3. 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 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 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.

An additional specific SOP detailing the mechanisms for linking individuals to appropriate HIV specialty care who acquire HIV infection during study participation is required for each site. "Appropriate care" should be locally defined and include consideration of 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, risk reduction counseling will include condom use, data on the known effectiveness of TDF/FTC as PrEP, and the unknown efficacy of CAB LA in protecting against acquiring HIV infection. The counselor should ask open-ended questions, actively listen to participant responses, probe as needed for further information, and guide the participant in identifying his/her 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 and the adherence counseling protocol/flipbook. The person providing product use instructions and adherence counseling will inform participants of study requirements for product use and adherence to protocol requirements such as returning for study visits and not sharing study product with anyone, including other participants in the study. It is recommended that the staff person providing product use instructions and protocol adherence counseling should not be the same person who provides participant-centered product adherence counseling. This is to ensure honest and accurate reporting of potentially less than perfect product use by participants to the product adherence counselor.

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. Detailed adherence counseling procedures is described in the flipbook per the adherence counseling training. Generally, counseling will be based on which Step of the study the participant is currently in. For Step 1, counseling should be focused on daily adherence to oral tablets; for Step 2, counseling should be focused on attending study visits to receive the injections and what to expect before, during, and after injections, as well as daily adherence to oral tablets; and for Step 3, counseling should be focused on adherence to open-label daily oral TDF/FTC.

Please note, throughout the study, participants should be counseled that simultaneous use of TDF/FTC as PrEP is not permitted.

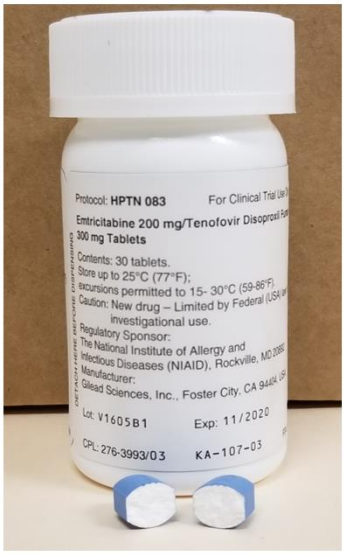
12.4. Study Product Use Instructions

Oral Product

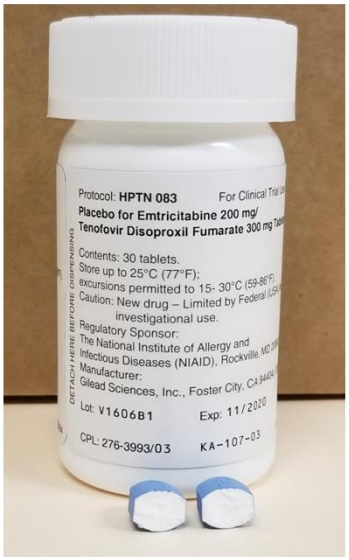
Participants will be instructed to take one tablet by mouth daily during the three study Steps. The oral tablets should be taken as close to the same time each day as possible. If a participant misses a dose, the participant can take the missed dose within the same calendar day as soon as they remember. The next dose will be taken by mouth as originally scheduled. Participants must not take two doses on the same day. Participants should be reminded to store study tablets at room temperature, in a safe place and out of reach of children. If participant shares housing with another study participant, remind participant to store product in a place that minimizes the chances of mixing study product. 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.

If a participant reports issues swallowing the Truvada/ placebo tablets due to its size, they may split the tablet in half and then swallow immediately. Although a pill cutter is preferred, it's not required for pill-splitting.

NOTE: Active Truvada tablets used in the study do not have the same markings or identifiers (e.g. number or names) as commercial Truvada, thus is not possible to distinguish between active and placebo, even when the tablets are split



Blinded Truvada Active Tablet



Blinded Truvada Placebo Tablet

Injection Product

See section 9.4 of this manual for information.

12.5. Step 1 Counseling Considerations

Following the guidance in the adherence counseling manual (see link below), 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 (this is unlike other counseling strategies for PrEP drugs, in which while perfect adherence is the goal, a more realistic counseling approach of "just do the best that you can" is employed). The counseling should also include clear instructions about the product, any side effects anticipated, and strategies for maintaining daily adherence. 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 protocol for side effects of oral CAB (Section 1.4-1.5 and the Sample Informed Consent Form Template), as well as the Investigator's Brochure.

At the enrollment visit, sites are strongly encouraged to either open one bottle of each oral study product and show the participant what each tablet looks like or use visual descriptors or pictures to emphasize taking one oblong blue pill and one round white pill every day.

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 cabotegravir.

12.6. Step 2 Counseling Considerations

Following the guidance in the adherence counseling manual (see link below), 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 they 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 last in their system for a long time (a year or more after a single injection). 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 2.5 and SSP manual Section 5.2).

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 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.

In addition to injections, participants will receive tablets (either TDF/FTC or placebo). Discuss with participants that we don't know to which arm they are randomized to, possible side effects with tablet use, and how to correctly take the tablets.

12.7. Step 3 Counseling Considerations

Daily adherence to oral TDF/FTC should emphasize the effectiveness of daily oral TDF/FTC when taken as directed. The counseling should also include clear instructions about the product, any side effects anticipated, and strategies for maintaining daily adherence. This counseling should be provided at all Step 3 Visits except at Week 48.

Sites should refer to the HPTN 083 protocol for side effects of oral TDF/FTC (Section 1.4-1.5 and the Sample Informed Consent Form Template), as well as the Package Insert and Table 9-1 of this manual.

Counseling manual can be found at: HPTN 083 webpage: https://www.hptn.org/research/studies/176. Please note, the manual is posted under Study Training. You need to log in to the HPTN website to be able to access these materials. Information on how to log in can be found at: https://www.hptn.org/contact/logininstructions.