

Section 12. Counseling Considerations

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12.1 Overview of Section 12

This section contains guidance on HIV Pre -/ Post-Test counseling and adherence counseling provided in HPTN 084.

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 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 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 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 084 study visit for as long as 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 her to decide whether to be tested (informed decision with informed consent). However, if a participant elects not to undergo HIV testing she 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 084 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 on 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.

When results from the HIV tests are discordant, participants as well as staff members may feel anxious about the ambiguity of their HIV status. While following the HIV testing algorithm, participants should also be engaged in a discussion about the pros and cons of starting ART.

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 language, geography, insurance status and type, provider cultural sensitivity, and resource availability. Ideally sites should build relationships with HIV care providers ahead of time so that discussions about participants with atypical results can be easily facilitated.

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 084, risk reduction counseling will include condom use, data on the known effectiveness of both Truvada (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 his/her risk factors and barriers to risk reduction, as well as strategies and action plans to try to address these.

12.2.1 Counseling consideration for participants with discrepant results

Here are some counseling messages based on the tests results. It is advisable that clinicians provide counselling support in the context of discrepant blood results so that the can provide information in response to participant questions. Counsellors can provide additional counseling support but should seek guidance from clinicians on the interpretation of the test results and appropriate counseling messages.

| First test positive | |
|------------------------------|--|
| Same day rapid test positive | <p><i>“Your initial results indicate that you may be infected with HIV and we need to do additional testing in order to confirm this result.</i></p> <p><i>We will draw a new blood sample and results will be available in about XX days”</i></p> |

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| Non-rapid test positive | <p><i>Your HIV status is not clear to us because while your first test was negative for HIV, your second test was reactive. We would like to conduct additional testing in order to feel sure about your HIV status.</i></p> <p><i>We will draw more blood today and results will be available in about XX days.”</i></p> |
| Subsequent test results | |
| HIV infection status uncertain; additional testing needed | <p><i>Your HIV status is not clear to us</i></p> <p><i>Thank you for your patience as we continue to work to determine your HIV status. We would like to draw more blood today. Those results should be available in about XX days.”</i></p> |
| Likely false positive | <p><i>“We do not believe that you have HIV. Even though your very first test was reactive, no subsequent tests have indicated HIV infection. The first test was likely a false-positive.”</i></p> |
| Likely infected | <p><i>Based on the results from additional tests, it is likely that you have HIV infection. It is important that we get you started on ART as soon as possible.</i></p> <p><i>It is also important that we draw additional bloods for study purposes, but we do not expect these tests to show a different result.”</i></p> |

In some instances, final determination of HIV status may be challenging particularly in participants with prior CAB exposure. In that situation, there may be uncertainty about whether to reinstitute PrEP or start ART. In this scenario, clinicians should engage participants in shared decision-making about the best possible treatment option based on her personal life circumstances. Clinicians should ideally address the following issues in their conversations with participants:

- False negative: In the context of long-acting CAB use, CAB may suppress virus replication and delay seroconversion making diagnosis with conventional diagnostics difficult.
 - Participants in this scenario may benefit from ART initiation to avoid potential emergence of INSTI resistance if they are infected and have a prolonged period of CAB monotherapy.
- False positive: False reactive test results are possible when testing is frequent. False reactive results can occur in the context of pregnancy, syphilis, malaria, other co-infections.
 - Participants in scenario may benefit from re-testing to exclude any lab errors.
- Risk balance:
 - In some scenarios it may not be possible to know for certain whether a participant has HIV infection e.g. an isolated HIV RNA result >200 copies where no other tests are positive
 - Consideration needs to be given to whether the participant needs to reinstitute PrEP to avoid ongoing HIV risk or start ART to avoid emergence of resistant infection. This decision will be influenced by available test results, and participants should be kept informed regarding the tests and timing of results so that they remain engaged in care.
 - It may be preferable to initiate ART when diagnosis is uncertain to avoid potential resistance and to plan for a treatment interruption in 12-18 months when CAB is considered cleared.
 - These decisions should be shared with participants so that the participant can make the most informed decision at that point in time. Study staff should communicate that those decisions may be revisited at a later timepoint if needs be as new information becomes available.

The decisional balance tool (Appendix 12A) can also be used as a tool to assist participants with indeterminate HIV test results to decide whether or not to start ART in the case of discrepant HIV test results where HIV diagnosis is uncertain and CAB monotherapy may be associated with the risk of emerging INSTI resistant infection.

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. 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 for those on TDF/FTC will include education around the importance of daily pill adherence and supporting strategies that link pill taking to the participant's daily routine (i.e., daily calendar, plans for travel, habits). For those choosing cabotegravir injections, 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 if the participant decides to take the oral lead-in.

12.4 Study Product Use Instructions

Oral Product (either CAB or TDF/FTC)

Participants will be instructed to take one tablet by mouth daily. 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 of the same product 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. 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 tablets due to 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: Antacid products containing divalent cations (e.g., aluminum, calcium and magnesium) must be taken at least 2 hours before or at least 4-6 hours after the oral formulation of CAB.*

Injection Product

See section 8 of this manual for information.

12.5 Counseling Considerations

Please refer to the decisional balance worksheet in Appendix 12A which can be used in your discussions with participants about the options in the OLE. Participants who opt into the oral CAB lead-in should be counseled on the purpose of the lead-in, 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. Sites should refer to the HPTN 084 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.

For participants choosing CAB LA, 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 it will last in their system for a long time (a year or more after a single injection) with clear explanation why participants get more than one injection 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).

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. Participants who report injection site reactions should be assessed by a clinician. Participants can be counselled on how best to minimize injection site pain using the guidance in section 9.

While the HPTN 084 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.

Participants choosing TDF/FTC will be counseled 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 12b).

Appendix 12A: Decisional Balance Worksheet for OLE

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| STATE | <i>Thank you for your ongoing participation in the HPTN 084 study. In this phase of the study, there are some choices for you to make. In order for you to weigh the pros and cons for yourself, you can use something called a decisional balance worksheet.</i> |
| HANDOUT | Decisional Balance Worksheet |
| STATE | <i>With a decisional balance sheet, you are listing pros and cons that are very specific to you, your life, your thoughts and your feelings. This allows you to weigh the drawbacks and benefits of all of your options in order to get a clearer understanding of what is right for you. Let's review this worksheet together.</i> |
| DISCUSS | <p>Decisional Balance Worksheet with participant. Help with pros and cons if needed. Examples are just for discussion if needed.</p> <p><u>Choice to stay on TDF/FTC:</u></p> <p>Pros may include:</p> <ul style="list-style-type: none"> • Used to taking daily pill • Don't like injections <p>Cons may include</p> <ul style="list-style-type: none"> • Not long-acting • Product storage <p><u>Choice of oral CAB lead-in or direct-to-inject:</u></p> <p>Pros may include:</p> <ul style="list-style-type: none"> • Getting used to the medication • Avoiding allergic reaction <p>Cons may include</p> <ul style="list-style-type: none"> • Taking a daily pill temporarily (if required) <p><u>Choice to join the pregnancy substudy:</u></p> <p>Pros may include:</p> <ul style="list-style-type: none"> • Help gather valuable information for pregnant women in the future • Monitoring of pregnancy by study staff; getting additional care <p>Cons may include</p> <ul style="list-style-type: none"> • Additional study procedures • Extra time at study visits <p><u>Choice to start ART following discordant results:</u></p> <p>Pros may include:</p> <ul style="list-style-type: none"> • Benefits of early treatment |

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| | <ul style="list-style-type: none"> • Protecting sexual partners and potential pregnancies while waiting for determination of HIV status • Not life long, might only for a period until a treatment interruption 12-18 months later could confirm uninfected <p>Cons may include:</p> <ul style="list-style-type: none"> • Preparation for daily pill intake/adherence • Disclosure and stigma concerns • Challenges with transfer to local ART clinics |
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| DISCUSS | Any questions or concerns |
| STATE | <i>When making big decisions, it is important to consider who can provide you with support. “Supportive others” are the people or groups of people who are most important in our lives. Supportive others may include parents, peers, family members, schools, health providers, faith communities, and dating partners. We all rely on supportive others to listen when we need to talk, give us advice, and shape our ideas about the decisions we make and the consequences of each decision. In this activity, let’s identify the people who are supportive to you.</i> |
| ASK | <i>If you could fill a room with the most important people in your life, who would be in the room?</i> |
| DISCUSS | <ul style="list-style-type: none"> • <i>Who are the people/groups in the room?</i> • <i>Why are they important to you?</i> • <i>Are there some that have more influence than others?</i> • <i>Are these people/groups you can count on when you are in trouble or in need?</i> • <i>Do they help you make good decisions? Always? Most of the time? Sometimes? Never?</i> • <i>Do you feel good about the decisions they help you make?</i> |
| REVIEW | Who would help the participant make medical decisions – make sure that they have a qualified provider to support them if needed. |
| STATE | <i>Thank you for completing this activity. I’m glad to understand who is important to you and how they may help with decision-making for this study.</i> |
| DISCUSS | Any final questions or concerns |

Appendix 12B: 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?

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|------------------------|---|
| ASK PARTICIPANT | <i>How do you feel about telling people that you are taking PrEP?</i> |
| DISCUSS | Participants views on disclosing or not disclosing PrEP |
| STATE | <i>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.</i> |
| HANDOUT | <p>"Safe TALK" handout.</p> <p>Timing</p> <p>Assertive Communication</p> <p>Location</p> <p>Know What to Say</p> |
| STATE | <i>Timing, Assertive Communication, Location, Know What to Say.</i> |
| ASK | <p><u>Have the participant read text</u> on the "SAFE Talk" handout.</p> <p><u>TIMING</u></p> <p>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.</p> <p><u>ASSERTIVE COMMUNICATION</u></p> <p>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.</p> <p><u>LOCATION</u></p> <p>Choose a quiet place where you cannot be interrupted or overheard by others.</p> <p><u>KNOWING WHAT TO SAY</u></p> <p>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.</p> |

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| DISCUSS | Handout and answer any questions. |
| EMPHASIZE | <i>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.</i> |
| STATE | <i>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.</i> |
| ALLOW | Time for participant to prepare then <u>Conduct the role-play.</u> |
| ASK | <i>What was the most challenging thing about this role-play?</i> <i>What part of this was easier than you thought it would be?</i> <i>What surprised you going through this role-play?</i> |
| 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

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| NOTE | This activity is ONLY for participants who are interested in telling someone about being on PrEP. |
| STATE | <i>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.</i> |
| HANDOUT | "Action Plan: Disclosure" handout |
| STATE | <i>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.</i> <i>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.</i> |
| 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

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| STATE | <p><i>You may decide that you want to talk to your husband, boyfriend 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 with discussed the “Safe TALK” strategy?</i></p> <p>Show “Safe TALK” handout and review <u>if participant hasn’t seen it or doesn’t remember it</u></p> <p><u>TIMING</u></p> <p>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.</p> <p><u>ASSERTIVE COMMUNICATION</u></p> <p>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.</p> <p><u>LOCATION</u></p> <p>Choose a quiet place where you cannot be interrupted or overheard by others.</p> <p><u>KNOWING WHAT TO SAY</u></p> <p>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.</p> <p><i>Tell him some of the things you have learned about STIs and HIV. It’s also important to negotiate and listen to him. Keep in mind that it’s not only your right, but also your RESPONSIBILITY to make decisions that you will help you stay healthy.</i></p> <p><i>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 his reactions and responses and make the conversation a little easier for you.</i></p> |
| STATE | <p><i>Let’s practice discussing PrEP with your husband/boyfriend.</i></p> |

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| DISPLAY | <p>How to talk PrEP with your partner handout...</p> <p>What if your partner says...</p> <ul style="list-style-type: none"> • “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 | <i>How would you respond to these statements by your partner? Let’s practice.</i> |
| 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.”