Section 9. Counseling Considerations

The following types of counseling will be provided in MTN-015: HIV secondary prevention counseling, sexually transmitted infection (STI) risk reduction counseling, contraception counseling, and counseling related to social harms. Guidance is provided in this section on provision of the first three types of counseling listed above. Guidance on counseling related to social harms is provided in Section 11 of this manual.

All counseling should be provided in a non-judgmental client-centered manner that responds to current participant needs for information, education, emotional support, skills building, and referrals. Participant needs are likely to change over time, as are their willingness and ability to adopt certain types of behavior change. Participant willingness and ability to seek medical and psychosocial care will likely change over time as well.

As a condition for study activation, all sites must establish a standard operating procedure (SOP) for "care, counseling, support, and referral for HIV-related conditions." In this SOP, each site must specify procedures and staff responsibilities for providing all required types of counseling to study participants. This SOP also should specify how counseling will be documented.

9.1 Secondary Prevention and Risk Reduction Counseling

At the Screening and Enrollment Visit, participants will have two rapid HIV tests performed to confirm their HIV status. Care should be taken to counsel the participant that although her HIV status was confirmed in the parent study, this additional confirmation or "check" is needed for study purposes. In the unlikely event the participant is found to be HIV-negative, the participant will terminate from the MTN-015 study and will be referred to available sources of medical care and counseling.

Secondary prevention and risk reduction counseling will be provided routinely to all study participants to minimize participant risk of HIV re-infection, minimize participant risk of STI acquisition, and minimize the risk of HIV and STI transmission from participants to others. Condoms will be provided at all visits and counseling should include skills building on condom use and condom negotiation strategies.

Counseling should also include HIV/AIDS education, discussion of disclosure issues and emotional support, discussion of healthy living strategies, discussion of stressors and potential strategies to address these, and provision of referrals. For participants taking medications for opportunistic infection prophylaxis and/or taking antiretroviral therapy, counseling should include reinforcement of adherence support messages. At each counseling session, issues requiring follow-up from the prior session should be reviewed and updated, and plans should be made for actions to be taken between the current session and the next session.

In addition to the above, HIV counseling and testing should be offered for participants' partners. Counseling may be provided to partners individually and/or through couples counseling. Study sites are encouraged to provide counseling staff with training in both individual counseling and couples counseling.

All secondary prevention and risk reduction counseling should be documented in participants study records. The checklist appended to this section may be adapted by each site for this purpose. In addition to completing the checkbox items on the checklist, notes should be recorded on the checklist and/or on other source documents to document participant responses to the counseling, any concerns raised by the participant, action planned to be taken by the participant prior to the next counseling session, action to be taken by the counselor (or other study staff members, if applicable) prior to the next session, and issues to be reviewed or addressed at the next session.

At each visit after a referral is made, study staff should actively follow-up on the referral to determine whether the participant sought the services to which she was referred, determine the outcome of the referral, and determine whether additional referrals are needed. Additional counseling also may be needed to help ensure the participant receives services that may be beneficial to her. All follow-up actions, outcomes, counseling, and plans for next steps should be documented in chart notes.

9.2 Contraception Counseling

Contraception counseling will be provided routinely to study participants. Upon enrollment in MTN-015, contraception counseling should assess the intentions of the participant to conceive or not, and be responsive to the participant's intentions. Subsequent counseling sessions should re-assess the participant's pregnancy intentions over time and provide information, education, skills building, and referrals in response to her current needs. At each counseling session, issues requiring follow-up from the prior session should be reviewed and updated, and plans should be made for actions to be taken between the current session and the next session. It is recommended that contraceptive counseling be provided in accordance with World Health Organization (WHO) guidance available in the following resources:

- *Family Planning: A Global Handbook for Providers* (WHO/USAID/Johns Hopkins Bloomberg School of Public Health, 2007; update 2011): http://www.who.int/reproductivehealth/publications/family_planning/9780978856304/en/

- Medical Eligibility Criteria for Contraceptive Use (5th Edition, 2015): http://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/

For participants who are considering conception, and for those who conceive, counseling should be provided on available options for prevention of mother to child transmission (PMTCT) and active referrals should be made to antenatal care and PMTCT programs. In addition, counseling on infant feeding should be provided in accordance with current WHO/UNICEF guidelines, which are available at:

http://apps.who.int/iris/bitstream/10665/246260/1/9789241549707-eng.pdf

All counseling should be documented in participants study records. Chart notes should be used to document participant responses to the counseling, any concerns raised by the participant, action planned to be taken by the participant prior to the next counseling session, action to be taken by the counselor (or other study staff members, if applicable) prior to the next session, and issues to be reviewed or addressed at the next session.

At each visit after a referral is made, study staff should actively follow-up on the referral to determine whether the participant sought the services to which she was referred, determine the outcome of the referral, and determine whether additional referrals are needed. Additional counseling also may be needed to help ensure the participant receives services that may be beneficial to her. All follow-up actions, outcomes, counseling, and plans for next steps should be documented in chart notes.

MTN-015 HIV Counseling Checklist

PTID:

General

NA	Done	
	❒	Greet client and establish rapport.
	❒	Remind client of confidentiality of counseling sessions.
	❒	Briefly review client's last counseling session and ask if she has any immediate questions or concerns from the last session.
	❒	Assess client's emotional state vis-à-vis her HIV status and stigma-related issues.
	❒	Assess coping mechanisms and support systems.
❒	❒	Assess disclosure issues. If client had not previously disclosed her HIV status to anyone, ask if she has done this since the last session. If any disclosure issues remain unresolved, discuss client's concerns and potential strategies to address these.

HIV Education

	Done	
	❒	Ask if client remembers the difference between HIV and AIDS.
	❒	Ask if client has questions about modes of transmission and methods of protection. If applicable, correct any misinformation or myths.
	❒	Reinforce that although client is HIV-positive, there are ways to protect herself from re-infection and protect others (sexual partners, children) from infection.

Risk Reduction

NA	Done	
	❒	Discuss condom use since the last visit including: (1) frequency/consistency, (2) techniques, (3) actual experience, (4) barriers to use.
❒	❒	If applicable, ask if client was successful in overcoming barriers to condom use discussed at the last session.
❒	❒	If applicable, discuss strategies to overcome barriers to condom use.
❒	❒	If applicable, have client demonstrate condom use on a model.
❒	❒	If applicable, reinforce offer of HIV counseling and testing for partner, as well as couples counseling for client and partner together.
❒	❒	If applicable, discuss methods to prevent parent to child transmission.
	❒	Discuss health maintenance: (1) nutrition, (2) exercise, (3) sleep/rest, (4) hygiene, (5) seeking medical care, (6) following through on referrals, (7) taking prescribed medications as directed.
❒	❒	If applicable, follow-up on previously identified issues and determine if there are new issues regarding (1) family pressures and/or conflicts, (2) relationship instability, (3) violence or abuse, (4) child bearing, (5) breastfeeding.

Referrals

NA	Done	
❒	❒	If referrals were given at the last session, ask if client used the referrals and if she found them useful.
❒	❒	If applicable, provide initial or alternative referrals to support groups and/or other psychosocial services.
❒	❒	If applicable, and in consultation with site medical staff as needed, provide initial or alternative referrals to clinical care services.

Document all referrals per site SOP. Note referrals and other issues requiring follow-up at the next visit here (continue on additional sheets if needed)

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Staff Initials and Date

Staff Initials and Date