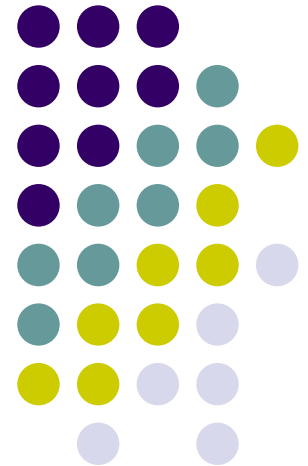


Counseling Considerations

MTN 005
Study-Specific Training



Overview



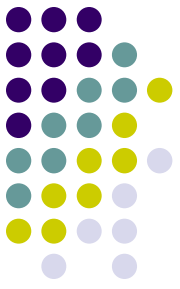
- Contraceptive Counseling
- HIV pre- and post-test counseling
- STI/HIV risk reduction counseling
- Seroconversion counseling
- Study product
- Protocol adherence counseling
- Documentation

Contraceptive Counseling



- According to Protocol Section 5.3, women must be using an effective method of birth control throughout the study:
 - Hormonal contraceptives
 - IUD
 - Study provided male condoms
 - Sterilization (participant or her male partner)

Contraceptive Counseling



- Guide and support the participant in making the best choice for her and in maintaining adherence to an effective method.
- The participant's pregnancy intentions should also be assessed.

Contraceptive Counseling

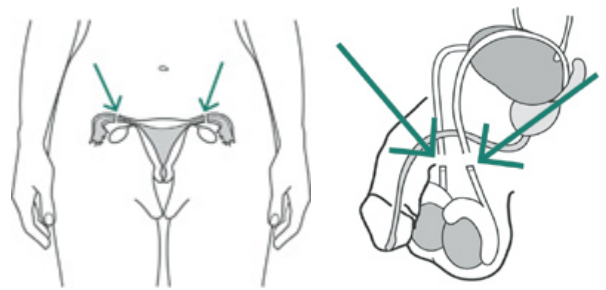


- Are contraceptives offered at your clinical sites?
 - Which ones?
- Where do you refer potential participants for contraceptives?
- If participants begin oral contraceptives when they begin the study, be conscience of the cause of potential adverse events, particularly spotting

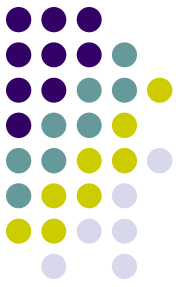
Questions?



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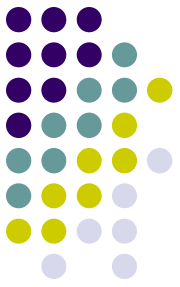


HIV Pre- and Post-Test Counseling



- HIV testing will occur at the Screening and 16-Week/ Study Termination visit, and when clinically indicated.
- HIV pre- and post-test counseling will occur in conjunction with a participant's HIV test.
- Client-centered approach to assess participant knowledge, dispel misconceptions, ensure readiness for testing and understanding of results

STI/HIV Risk Reduction Counseling



- STI/HIV risk reduction counseling is required at every study visit
 - Client-centered approach utilizing open-ended questions, probe for further information, guide participant in identifying her risk factors and barriers to risk reduction
 - Strategize, action plan to address barriers

STI/HIV Risk Reduction Counseling



- Condoms should be offered at every visit
- Who at your site is responsible for risk reduction counseling?

Seroconversion Counseling



- In the event of a seroconversion, site staff can refer to the MTN-005 SOP that describes HIV treatment and care
 - This may simply be procedures for providing appropriate referrals to local care facilities
 - Post-test counseling for HIV testing should also include support and appropriate referrals

What is standard for your site?

Protocol Adherence Counseling



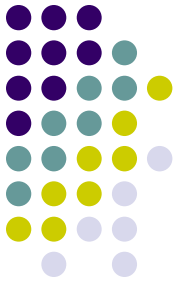
- Participants must agree to abstain from non-study vaginal products and practices:
 - Spermicides
 - Diaphragms
 - Vaginal antibiotic or antifungal medication
 - Sex toys
 - Lubricants or condoms that contain silicone
 - Menstrual cup and douching

Study Product Adherence Counseling



- At Enrollment, 4-Week and 8-Week visits (IVR group only):
 - Product use instructions
 - Study product use counseling
- SSP Section 15.3 and the Adherence Counseling checklists outline the key messages for study product adherence counseling.

Counseling Checklist



Section Appendix 12-2b Enrollment, 4-Week and 8-Week Follow-up Visit Counseling Checklist

PTID: _____

Visit Code: _____

Date: _____

HIV Risk Reduction Counseling

- Perform HIV risk reduction counseling per site SOPs.

- Offer condoms.

Comments:

Signature/Date: _____

Product Use Adherence Counseling

- Wash your hands thoroughly before and after study product insertion and/ or removal.

- Try not to remove the ring for the entire 12 week period of the vaginal ring regimen except as directed during study visits, even during menses.
 - If the ring accidentally comes out of your vagina before your next clinic visit, clean it with warm water and put it back in your vagina.
 - If you have any problems putting the ring back in your vagina, call or come to the clinic.

- Contact study staff if you have any questions or need another study vaginal ring between visits.

- The study staff are here to help and support you. Please contact us if you have:
 - Problems inserting the vaginal ring
 - Any other problems (such as partner or family issues)

Comments:

Signature/Date: _____

Contraceptive Counseling

- What method of contraception are you currently using?

- Have you experienced any problems with your current form of contraception?

- Do you plan to continue using this method throughout study participation?

Comments:

Signature/Date: _____

Documentation



- All counseling activities should be documented in chart notes and/or visit checklists
- These will not be documented on case reports forms

Questions?

