Social Harms: Expectations for Site Planning and Preparation

Objectives

At the end of this presentation, you should be able to:

- Define social harm
- Identify social harms described by study participants or witnessed
- Respond appropriately with counseling, referrals, and support for the participant
- Thoroughly document incidences that may arise in MTN-009 through resolution

What is social harm?

Non-medical adverse consequences of study participation, including:

- Difficulties in personal relationships
- Stigma or discrimination from family or community
- For example:
- Difficulties in their personal relationships with partners, family members, and friends.
- Stigma or discrimination from family members and members of their community.

Before Study Initiation

- Create a plan for how issues will be handled.
- Define roles and responsibilities so each staff member is aware of what actions s/he can appropriately take and what actions should be referred to others.
- Describe these roles, responsibilities, and procedures in site-specific SOPs.

Ongoing Review

- Continue to discuss actual participant experiences, successful and unsuccessful response strategies, and other lessons learned.
- Based on these discussions, reassess and refine procedures.
- Update SOPs if needed.

Ongoing Review

Ensure frequent communication and consider action that may be needed:

- At the clinic level
- At the community level

Ensure that participants' privacy/ boundaries are respected in these team/community discussions.

Identifying Social Harms

- Participants may report harms spontaneously to study staff.
- Health Visitors/Field Workers may observe during home visits.
- Drivers may observe social harms directly or the participant may discuss issues with the driver during a ride.

Can you think of other scenarios?

Social Harms, related or unrelated?

The participant may experience violence or social harms in her life, *unrelated to participation in the study.*

- How will your site identify the difference?
- How will your site respond to reports by a participant of a negative environment or relationship unrelated to her participation in the study?

Strategies

Actively listen to the participant's description of the problem and ask questions to obtain as much detail as possible about her perceptions of:

- Severity of the harm,
- Cause(s) of the harm,
- Effects/consequences of the harm

Strategies

- Ask the participant for her thoughts on what can/ should be done to address the problem, including what she would like study staff to do.
- Discuss additional or alternative strategies that you might suggest to address the problem and collaborate with the participant to develop a plan to address the problem.
- What are the legal obligations for your area?

Strategies

- Consult the Protocol Management Team if needed/ applicable.

Follow-through

- Take all possible action to try to address the problem, per the plan agreed upon with the participant.
- Follow all problems to resolution.
- Provide referrals as needed to other organizations, agencies, and service providers that may be able to help address the problem.

Documentation

- Chart notes
  - Complete, detailed notes
    - Who, when, what , how, why, results, action plan, including referrals
  - Track through resolution, at later visits
    - Was plan executed, was plan/ referral effective, are additional actions required, etc.

Example 1

Participant reports colleagues were ridiculing her for being in a MRC study.

- How will you probe further, and what will you document? What type of counseling would you provide? How would you respond and provide support to this participant?

Example 2

Participant came to the MRC clinic with a friend to screen for VOICE. She was offered participation in MTN-009 and agreed. She tested HIV+. Her friend, who did enroll in VOICE is being "being mean" because of her HIV status.

- How will you probe further, and what will you document? What type of counseling would you provide? How would you respond and provide support to this participant?

Example 3

Participant presents for her first follow-up visit and the counselor notices a large bruise on the participant's right arm.

- How will you probe further, and what will you document? What type of counseling would you provide? How would you respond and provide support to this participant?

Example 4

A participant calls the site to inform the staff that she will no longer come to the clinic because people found out there was a study for HIV+ women at the site and they thought she had HIV and she does not want anyone to know her status.

- How will you probe further, and what will you document? What type of counseling would you provide? How would you respond and provide support to this participant?

Example 5

A participant reports during follow-up that when she disclosed her HIV status to her partner, he became so mad, he punched her several times. The counselor noticed bruises on her face and arms.

- How will you probe further, and what will you document? What type of counseling would you provide? How would you respond and provide support to this participant? Who do you need to notify of this incident?

Communication of Social Harms

- Social harms that are judged by the Investigator of Record (IoR) to be serious or unexpected will be reported to responsible site Ethics Committees (EC) at least annually, or according to their individual requirements.
- Any unanticipated problems will be reported to the DAIDS Medical Officer and the MTN-009 management team

Questions