

11. Conclusions and New Questions

As anticipated, the Consultation on clinical testing of microbicides raised as many questions as it answered. Yet everyone agreed that a necessary step was taken to better frame the issues and sharpen the terms of an evolving debate. Despite the healthy range of opinion and recognition of the continuing need for reflection and work, the group did arrive at several important points of consensus. Specifically, the following points were endorsed.

1. Researchers have a special, though not exclusive, obligation to the health and well-being of trial participants. In accordance with the principle of reciprocal justice, it is appropriate for research participants to have access to services or benefits that may not be available to others.
2. Nonetheless, investigators and sponsors must avoid undue exacerbation of local inequities in access to care. Since social change is incremental, all progress necessarily introduces temporary inequities. But investigators must remain attentive to this dynamic and seek to minimize negative consequences that could arise from some benefits being selectively available to trial participants.
3. Researchers and sponsors should use microbicide trials as an opportunity to strengthen and improve the local standards of care. Trials can act synergistically to improve local care while simultaneously advancing medical knowledge. The minimum objective should be to ratchet up care in a stepwise fashion to reduce global disparities in access to health care.
4. Trial implementation should seek to build upon and strengthen the capacity of local laboratories, facilities, clinics, and providers. A community should be left better off than before the trial began.
5. Providing access to medical care and services beyond those necessary to conduct the trial should not in themselves be construed as *undue* inducements. Inducements become morally problematic only when they become so appealing as to impair participants' ability to exercise proper judgment or cause them to ignore obvious risks.
6. Microbicide trials should be respectful of existing relationships and networks and attempt to minimize disruptive presence on the community and local services.
7. Microbicide researchers should invest in authentic partnerships with the community, and they should seek community input into decisions around fair benefits for trial participation, ensuring informed consent, reducing stigma, and other trial-related matters.

8. In consultation with the community, researchers and sponsors should develop and disseminate transparent plans on which health care benefits will be provided during and after the trial. Referral arrangements should be concretized through formal Memorandums of Understanding with local facilities.
 9. Researchers are not alone in their responsibility to meet the health-related needs of trial participants. The obligation of researchers is to ensure that those enrolled (and screened) in their trials have access to adequate health care, not necessarily to provide it themselves. Nonetheless, researchers should use the resources and power they do command to alleviate suffering whenever and wherever possible.
 10. Sponsors and study teams should consider developing formal exit or transition plans to help prepare trial participants and communities for the eventual closure of the trial. Such plans should anticipate the impact of trial completion on local services, arrange for any on-going obligations to participants, and prepare women emotionally for their departure from the study.
 11. Moreover, researchers and advocates should leverage resources not related to the research to benefit trial participants and host communities. Research networks, for example, could hire dedicated staff to mobilize non-trial-related resources from private foundations; local government; the Global Fund to fight AIDS, Malaria and Tuberculosis (the Global Fund); or other initiatives to supplement those provided by the trial. A trial advocate could negotiate locally with the national AIDS control board to give the trial community preferential access to ART as the government rolls out its program treatment program.
- In addition, the group recommended further in-depth work on several complicated issues discussed during the meeting. These include:
1. Questions related to establishing safety and effectiveness of microbicides in younger adolescents.
 2. Issues around men and clinical trials—how to address men’s legitimate concerns about safety and cultural expectations of male authority without undermining women’s autonomy.
 3. Teasing out the ethical and scientific issues posed by the testing of second-generation products.
 4. Mechanisms for ensuring access to ART for individuals who seroconvert during trials.

