

Appendixes

Appendix A: *Participant List*

Appendix B: *Consultation Agenda*

Appendix C: *Selected Readings on Ethical Issues in
Microbicide Development*



Appendix A

PARTICIPANT LIST

International Consultation on Ethical Issues in the Clinical Testing of Microbicides

Council on Foundations

October 23–24, 2003

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Appendix B

CONSULTATION AGENDA

Pre-Meeting on Clinical Trials and Ethical Reasoning

October 22, 2003

PATH

1800 K Street, NW, Suite 800

Washington, DC

Prior to the consultation the Global Campaign for Microbicides sponsored a one-day pre-meeting on clinical trials and ethical reasoning. This course, now available upon request, is designed to familiarize participants with the basics of clinical trial design; provide background data on ethical guidance and principles; and provide an opportunity, through case studies, to apply these principles in practice.

- | | |
|---------------------|---|
| 1:00 to 1:30 | Welcome and Introductions |
| 1:30 to 2:15 | Overview of Clinical Trials |
| 2:15 to 2:50 | Introduction to Ethical Reasoning (Part 1) |
| 3:00 to 3:30 | Informed Consent Case Study |
| 3:30 to 3:45 | Ethical Reasoning (Part 2) |
| 4:00 to 5:00 | Vaccine Trial Case Study |

International Consultation on Ethical Issues in the Clinical Testing of Microbicides

October 23, 2003

Council on Foundations

1828 L Street, NW, Suite 505

Washington, DC

Day One:

- | | |
|-------------|--|
| 8:30 | Welcome and Introductions |
| | Kim Dickson, Reproductive Health Research Unit, South Africa
Steering Committee, Global Campaign for Microbicides |

9:00 Contextualizing the Field Since the 1997 Ethics Consultation

Lori Heise, Director, Global Campaign for Microbicides

Meeting goals and agenda; history of the earlier consultation; shifts that emerged in thinking and strategy because of the 1997 consultation; significant events that have occurred since that time; and the evolution of HPTN ethics guidance.

9:15 Design Issues in Clinical Trials of Microbicides

Alan Stone, International Working Group on Microbicides, UK

Basic introduction to the design of microbicide trials; clinical trial pathway for microbicides; and discussion of key challenges: finding a placebo; selection of trial populations. Why are most microbicide trials in the developing world? Measuring effectiveness versus efficacy; and challenges of measuring sexual behavior, gel and condom use. Current controversies: one control arm or two? Length of participant follow-up.

9:45 International Research Ethics and Debates

Carel IJsselmuiden, University of Pretoria, South Africa

Historical origins of modern bioethics. Introduction to ethical reasoning and key principles. What makes research ethical? Basic concepts and principles; debates over universal versus pluralistic standards of care; and recent controversy around placebo-controlled trials. Dealing with culture and community. What makes HIV prevention trials different—stigma, healthy individuals, etc.?

10:30 Session 1: Informed Consent: From Theory to Practice

Marge Chigwanda, UZ-UCSF Collaborative Research Program, Zimbabwe
Cynthia Woodsong, Family Health International, USA

Discussion of the microbicide field's efforts to address informed consent. Issues that remain; examples of creative approaches to achieving and sustaining informed consent, including videos, assessment of comprehension, etc.

11:30 Session 2: Benefits and Burdens to Participants and Communities—Conceptualizing Fair Benefits

Reidar Lie, National Institutes of Health, USA/Norway

Evolution of ethical thinking on this issue; insights from guidance; balancing risks and benefits; NIH consultation on fair benefits; balancing benefits and “undue inducement;” What is the difference between inducement and “undue” inducement? Ensuring reasonable availability of interventions post trial.

**1:15 Session 2: (Continued): Benefits and Burdens
Evaluating Carraguard—A look at burdens and benefits from multiple vantage points**

Heidi Jones, Population Council—General reflections
Barbara Friedland—Population Council—Phase II coordinator
Mabitso Marumo—counseling coordinator, MEDUNSA
Esther Maleka, Former Phase II trial participant, South Africa
Discussant: Alex London, Carnegie Mellon University



3:00 **Session 3: Defining the Standard of Care**
Considering Standard of Care from a Research Ethics Perspective

Liza Dawson, Fogarty International Center

Multiple uses of this concept; insights from Guidance; context of global health inequities; moral basis of standard of care debates; health care versus research ethics; international debates and tensions (local standard; best proven; highest attainable and sustainable; ratcheting up).

Ethics Meets the Rough Grounds

Kathleen MacQueen, HPTN Ethics Working Group

Defining the range of care issues at stake (beyond ARVs). Insights from FHI's SOC survey at HPTN sites—variations between care available in different settings. Findings of how HPTN 035 participants conceptualize "fair."

Discussants: Anatoli Kamali (MRC-Uganda), Miriam Katende (TASO), Promise Mthembu, ICW.

Day Two:

8:30 **Session 4: Men, Ethics and Microbicide Trials**
What are the issues? How is the field responding?

Panel discussion:

Busisiwe Nkala, Soweto, South Africa

Neelam Joglekar, Pune, India

Michael Gross, consultant, USA

Experience from audience members

Concerns about penile safety; expectations around men's right to control female behavior; issues around trials "excluding" men, partner consent, etc.

Discussants: Ethical- and rights-based reflections on men, culture, and trials

Carel IJsselmuiden—University of Pretoria

Brendon Christian—Gender AIDS Forum, South Africa

10:15 **Session 5: HIV Treatment in the Context of Prevention Trials**
Introduction to On-Going Deliberations and Debates

Lori Heise, Global Campaign for Microbicides

Providing ART: Examining the ethical arguments

Catherine Slack, University of Natal, South Africa

Scientific and Practical Challenges of Treating HIV Infections

Paula Munderi, MRC Uganda

WHO/UNAIDS Consultation on ART in Prevention Trials

Eduard Beck, McGill University, Canada

Opportunities to Partner and Leverage Outside Resources

Camille Massey, International AIDS Vaccine Initiative

Discussion

1:30 Session 6: Establishing Safety and Effectiveness in Younger Adolescents

Younger Adolescents: Do We Need Separate Data?

Barbara Moscicki, Division of Adolescent Medicine, UCSF

Ethical Reflections on Enrolling Adolescents in Trials

Audrey Rogers, NICHD Adolescent Clinical Trial Unit

A View from Botswana

Dawn Smith, BOTUSA Project, Gaborone, Botswana
Discussion

3:00 Session 7: Ethics of Second-Generation Microbicide Trials

If a RCT demonstrates some effectiveness for a first-generation product what implications would this have on the design of future trials. What role can post-approval trials play? Under what circumstances could we ethically do a confirmatory trial in a different setting?

Equipoise and the Issue of Second-Generation Trials

Alex London, Carnegie Mellon University

Scientific Challenges in Testing Next-Generation Products

Anne Coletti, Family Health International

The Potential Role for Post-Approval Studies

Forrest Greenslade, Consultant
Discussant: Tim Farley, World Health Organization

5:00 Summary Reflections and Rapporteur Report

Kim Dickson, South Africa



Appendix C

SELECTED READINGS ON ETHICAL ISSUES IN MICROBICIDE DEVELOPMENT

Contextualizing the Field Since 1997

Heise L, McGrory E, Wood S. *Practical and Ethical Dilemmas in the Clinical Testing of Microbicides: A Report on a Symposium*. New York: International Women's Health Coalition; 1998.

MacQueen K, Sugarman J. Back to the rough ground: working in international HIV prevention as ethical debates continue. *IRB: Ethics and Human Research*. 2003;25(2): 11–13.

MacQueen K, Sugarman J. *HIV Prevention Trials Network: Ethics Guidance for Research*. Arlington Virginia: HPTN Ethics Working Group; 2003.

Lo B, Bayer R. Establishing ethical trials for treatment and prevention of AIDS in developing countries. *British Medical Journal*. 2003;327:337-339.

→ 74

Background Materials on Microbicides and Clinical Trials

Harrison P, Rosenberg Z, and Bowcut, J. Topical microbicides for disease prevention: status and challenges. *Clinical Infectious Disease*. 2003;36:1290–1294.

Stone A. Clinical trials of microbicides. *The Microbicide Quarterly*. 2003;1(2):13–18. Available at: <http://www.microbicide.org/microbicideinfo/reference/final.TMQ.jul.aug.sep.2003.pdf>

Background Materials on Biomedical Ethics

Emanuel E, Wendler D, Killen J, Grady C. What makes clinical research in developing countries ethical? The benchmarks of ethical research. *Journal of Infectious Diseases*. 2004;189:930–937.

Nuffield Council on Bioethics. The ethics of research related to health care in developing countries: Follow up discussion paper. London: Nuffield Council; 2005. Available at: http://www.nuffieldbioethics.org/fileLibrary/pdf/HRRDC_Follow-up_Discussion_Paper001.pdf

Informed Consent

Lindegger G, Richter LM. HIV vaccines trials: critical issues in informed consent. *South African Journal of Science*. 2000;96:313–318.

Molyneux CS, Wassenaar DR, Peshu N, Marsh K. Even if they ask you to stand by a tree all day, you will have to do it (laughter)...!: Community voices on the notion and practice of informed consent for biomedical research in developing countries. *Social Science and Medicine*. 2005, 61: 443-454.

Standard of Care

Benetar SR, Singer PA. A new look at international research ethics. *British Medical Journal*. 2000;321:824–826.

Lie RK, Emanuel E, Grady C, Wendler, D. The standard of care debate: the Declaration of Helsinki versus the international consensus opinion. *Journal of Medical Ethics*. 2004; 30:190–193.

Shapiro K, Benetar SR. HIV prevention research and global inequality: steps towards improved standards of care. *Journal of Medical Ethics*. 2005;31:39–47.

HIV Treatment in the Context of Prevention Trials

Berkley S. Thorny issues in the ethics of AIDS vaccine trials. *The Lancet*. 2003;362.

Bass E. HIV Treatment in the Context of HIV Prevention Trial. Proceedings of a meeting cosponsored by the Global Campaign for Microbicides and the International AIDS Vaccine Initiative, Washington DC, February 28, 2003. Available at: <http://www.global-campaign.org/clientfiles/ethicsreport.pdf>

Slack C, Stobie M, Milford C, Lindegger G, Wassenaar D, Strode A, Ijsselmuiden C. Provision of HIV treatment in HIV preventive vaccine trials: A developing country perspective. *Social Science and Medicine*. 2005;60:1197–1208.

WHO/UNAIDS. Treating people with intercurrent infection in HIV prevention trials: report of a WHO/UNAIDS consultation. *AIDS*. 2004;18(15):W1-W12.

