Appendixes

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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
Mabito 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


Background Materials on Microbicides and Clinical Trials


Background Materials on Biomedical Ethics


Informed Consent


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


HIV Treatment in the Context of Prevention Trials


