Global Campaign FOR Microbicides

Consensus Points on Access to Treatment and Standards of Care in Microbicides Trials

On May 30-31st 2005 the Steering Committee of the Global Campaign for Microbicides (GCM) met for two days in Barcelona to discuss issues of access to treatment and standard of care in microbicide trials. The recommendations below represent the points of consensus that emerged from this dialogue. Please see the reverse side for more information on the process of developing this statement.

1. Clinical trial sponsors and researchers have a responsibility to ensure appropriate care for any negative health consequences that participants experience as a direct result of trial participation.

2. People who seroconvert during the course of a microbicide trial should be assured access to high quality HIV care, including antiretroviral treatment (ART) when it is needed.

    - Trial sponsors and donors should commit to assuring the availability of such care either directly or through explicit and durable partnerships with other care providers. Such agreements should be formalized in consultation with relevant stakeholders and trial communities before a trial starts.

    - There is no consensus among ethicists as to whether the provision of ART to those who seroconvert during a microbicide trial is ethically obligatory, or "morally praiseworthy" but not mandatory. Nonetheless, we call on the wider microbicides community to ensure access to ART based on ethical aspirations and existing social and political realities.

    - UNAIDS or another such body should convene a task force of clinicians, people living with HIV/AIDS, advocates, health economists, legal and insurance experts and entities with relevant experience (such as Pharm Access and Médecins Sans Frontières) to develop and evaluate concrete mechanisms for operationalizing ART access for those who seroconvert during microbicide trials, recognizing that they may not need ART for many years into the future.

3. Researchers and sponsors, in collaboration with local and national health authorities, should use microbicide trials as an opportunity to strengthen and improve local standards of care. The minimum objective should be to "ratchet up" care in a stepwise, sustainable fashion to reduce global disparities in access to health care.

4. Explicitly defining each site's standard of care must be a mandatory part of trial planning. Negotiations should include agreement with stakeholders, including relevant community and/or civil society groups, on the package of prevention services provided to participants as well as on what other care will be ensured either through direct provision or through effective referral mechanisms.

    - Referral arrangements should be formalized in writing. Researchers and/or trial sponsors should work to ensure that adequate care is actually received through monitoring and support programs for participants (e.g. transportation, accompaniment programs, etc.).

    - Microbicide trials have a special obligation to attend to the sexual and reproductive health needs of participants, including offering direct provision of safe, appropriate contraception for trial participants. Avoidance of unwanted pregnancy will also improve trial power through participant retention.

5. Trial participants should have preferential access to any test product that is shown to be effective. Although ensuring immediate access is complicated by regulatory, manufacturing and licensing issues, researchers and donors should actively seek to accelerate access to product post-trial through

implementation of observational/introductory studies and negotiation with host country governments and product sponsors.

In addition, the Global Campaign for Microbicides commits itself to:

1. Advocate relentlessly for the right of trial communities to have preferential access to any product proven safe and effective, while being completely candid with communities about the likely timeframe of this access.

2. Emphasize in our advocacy the importance of other aspects of standards of care—especially sexual and reproductive health care and the prevention package offered participants—in addition to HIV care and access to ART.

3. Advocate for the right of host communities and countries to have an authentic voice in decisions around trial related matters, including negotiations of fair benefits.

4. Work to increase research and ethics literacy among advocates and host communities.

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Origins of this consensus

These conclusions evolved over a three-year period of structured discussion and debate among Global Campaign partners, allies and staff. They draw on three major consultations organized by the GCM, including:

1. A meeting co-organized with International AIDS Vaccine Initiative (IAVI) in 2003, entitled ***Consultation on HIV Treatment in the Context of Prevention Trials***;
2. A global ***Consultation on Ethical Issues in the Clinical Testing of Microbicides***, which brought together 64 people from 12 countries – including advocates, ethicists, clinical investigators, community members, drug regulatory authorities, and past participants in microbicide trials; and
3. A special two-day meeting of the GCM Steering Committee[i] held in Barcelona in May 2005.

The consensus presented here represents the collective points of agreement that emerged from the May GCM Steering Committee. We are currently circulating this document among our partners for formal institutional endorsement. Until that time it should be considered a work in progress. For more information contact: Lori Heise at lheise@path-dc.org.

List of Organizational Endorsers

ActionAIDS
AIDS Committee of North Bay and Area
Aids Fonds
AIDS Foundation of Chicago
AIDS Taskforce of Greater Cleveland
AIDS Treatment Initiatives (ATI)
Aradia Women's Health Center
Association of Nurses in AIDS Care (ANAC)
Atlantic Centre of Excellence for Women's Health, Dalhousie University
California Microbicides Initiative (CaMI)
Canadian AIDS Society
Canadian Federation for Sexual Health *(formerly Planned Parenthood Federation of Canada)*
Canadian HIV/AIDS Legal Network
Canadian Treatment Action Council (CTAC)

CARE Canada
CARE International UK
European AIDS Treatment Group (EATG)
Global Network of People Living with HIV/AIDS North America (GNP+NA)
Grupo de Trabajo sobre Tratamientos del VIH (gTt)
Grupo Português de Activistas sobre Tratamentos de VIH/SIDA (GAT)
HivNorge (tidligere/former Pluss-LMA)
Interact Worldwide
International Planned Parenthood Federation (IPPF)
Journalists Against AIDS, Nigeria
The National AIDS Trust, UK
Naz Foundation International
Nigerian HIV Vaccine and Microbicide Advocacy Group
Northern AIDS Connection Society
PATH
Planned Parenthood of Connecticut
Positive Women's Network
Positively Women
STI AIDS Netherlands
STOP AIDS NOW!
Voices of Positive Women
Women's Health Advocacy Foundation

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[i] The Steering Committee of the Global Campaign for Microbicides is comprised of:

Deborah Arrindel	American Social Health Association	US
Manju Chatani	African Microbicide Advocacy Group	Ghana
Paddy Connolly	Cairde	Ireland
Kim Dickson	DFID Nigeria	Nigeria
Chris Elias	PATH	US
Marc-André LeBlanc	Canadian AIDS Society	Canada
Sheena McCormack	UK Medical Research Council Clinical Trials Unit	UK
Promise Mthembu	International Community of Women Living with HIV/AIDS	South Africa
Margaret Muganwa	Society of Women and AIDS in Africa	Uganda
Vimla Nadkarni	Tata Institute for Social Sciences	India
Cory Richards	The Alan Guttmacher Institute	US
Moniek Van der Kroef	AIDS Fonds	The Netherlands
Shira Saperstein	Moriah Fund	US
Laurie Sylla	Connecticut AIDS Education and Training Center	US
Joan Tallada	Grupo de Trabajo sobre Tratamientos del VIH	Spain
Gaye Tharawan	Women's health advocate	Thailand
Janneke Van de Wijgert	International Antiviral Therapy Evaluation Centre	The Netherlands