Improving Standards of Care at Microbicide Clinical Trial Sites

Recommendations for the HIV Prevention Research Field

Katie West Slevin[1], Katharine Shapiro[2], Sean Philpott[2], Samu Dube[1], Lori Heise[3]

[1] Global Campaign for Microbicides; [2] Consultant; [3] London School of Hygiene and Tropical Medicine

Background

There is considerable public debate about the standards of care provided to participants in HIV prevention trials. Frequently, however, ethics deliberation in international fora proceeds with little connection to the daily realities of trial participants or the challenges of implementing trials. From mid-2006 to 2007, the Global Campaign for Microbicides undertook a standards of care mapping exercise to:

1. Conduct an **independent assessment** of the health care and prevention services provided to women enrolled in large-scale microbicide effectiveness trials.
2. Better understand the **factors that inform care-related decisions** at trial sites.
3. Explore the microbicide field's **progress toward achieving key ethical aspirations**.
4. Make recommendations to **strengthen the field's ability to respond to care-related challenges** in the future.

Findings

- **The majority of trials made significant progress toward meeting evolving ethical standards of care and prevention.**
- **All sites were providing high-quality prevention services,** including risk reduction counseling, male (and sometimes female) condoms, and STI screening and treatment.
- Despite concerns over potential conflicts of interest, we saw **no evidence that the intensity of prevention services was in any way compromised to ensure adequate endpoints for the trial**.
- Many **research sites are actively expanding services available** for women who are HIV positive at study screening but screened out of the trial.
- **Services provided by trial sites varied significantly** by:
  - The range of services provided.
  - To whom services were provided.
  - The types and strengths of partnerships forged to provide care during and after trials.
  - Where care was provided (study clinic versus referral facility).
  - The level of assistance and follow-up provided once someone was referred offsite.
  - Whether the trial established mechanisms to ensure post-trial access to ART for women who seroconvert during the study.

Recommendations

The mapping exercise resulted in a series of **28 consensus and author recommendations** regarding a wide range of issues.

These recommendations provide **evidence-based examples** to inform current discussions about standards of care and to improve the design and conduct of future trials. A sample of these recommendations are listed below.

CONSENSUS & AUTHOR RECOMMENDATIONS

Co-locating	Future trials should seek opportunities to **co-locate or partner with existing local care facilities.**
Referral Systems and HIV Care	Future trials should pursue concrete steps to **improve referral systems and facilitate access to government- or NGO-run HIV/ART programs** for women who screen HIV-positive at enrollment by providing WHO staging and CD4 counts at the initial screening visit. Trials should **proactively facilitate women's ability to access referrals and monitor the outcomes.**
STI Screening and Treatment	To build program capacity and contribute to improved STI care, **researchers should advocate for improved STI services that are appropriate and sustainable**. **Laboratory screening and treatment for STIs** should be provided to all women at least once, even those who screen out at enrollment.
Human Resource Capacity	Sponsors and donors should develop creative means, such as a human resources database of staff curriculum vitae, to **ensure that human resource capacity built up during trials is protected and every effort is made to absorb existing capacity of trained staff** into new trials before hiring new staff.
Trial Closures	**Trial sites need to develop concrete plans surrounding trial closure,** including plans for transitioning all trial volunteers into services provided by the public health sector or NGOs. Trials should explore ways to mobilize trial participants during and after the study closure as community assets, including providing roles as peer educators or community advisory board members.
Improving Local Care	HIV prevention researchers, sponsors, and donors should make every effort to use microbicide trials as an opportunity to **strengthen and improve local standards of care and services** in host communities, and in host countries where possible.
Clear Donor Policies	**Donors should be encouraged to develop and implement funding policies that are clear and understandable,** that are objectively and scientifically based, and that enable and encourage researchers to raise the local standard of care in a manner that is sustainable even after a study ends. **Donors should make resources available, within reason, that can be used for the provision of non-trial related services**.
Formative Research	**Field testing and operational research** are needed to determine **how to operationalize meaningful participation of community and trial participants in care-related decisions** from the beginning.
Trial Staff	Trial sponsors, donors, and research networks should **develop and implement standards of care policies for their staff**. Policies should take measures to ensure confidentiality of trial staff's HIV status.

For more information on "Mapping the Standards of Care at Microbicide Trial Sites" or to obtain a copy of the report, please visit www.global-campaign.org.

Global Campaign FOR Microbicides