

Access to care in HIV vaccine and other prevention trials: an institutional perspective

Christine Grady
Department of Bioethics
Clinical Center, National Institutes of Health

Disclaimer

- *The views expressed are mine and do not necessarily represent the position or policy of the National Institutes of Health, the U.S. Public Health Service, or the U.S. Department of Health and Human Services*

Access to care

- Care which is part of the scientific design
- Care needed to safely complete the trial
- Care for injuries and adverse events
- Care promised to participants
- Post trial care
- Ancillary care
 - Care that some participants will predictably need

HIV vaccine trials

- HIV vaccine and prevention trials
 - What kind of care is needed?
 - For how long?
 - By whom?
 - Whose responsibility?

HIV Vaccine and prevention

- “a comprehensive care package should be agreed upon through a host/community/sponsor dialogue which reaches consensus prior to initiation of a trial” (UNAIDS 2000, #16)..

HIV vaccine trials

- "...there is now broad though not unanimous agreement among sponsors of HIV vaccine trials that *ART and a clinical care package* should be provided to *those who become infected during the conduct of a trial.*" (Macklin 2007 citing WHO/UNAIDS 2004)

3 “flawed” assumptions

Changing the presumption; Macklin AJOB 2006

- *Sponsors* should bear the sole burden of providing treatment
- *Governmental agencies* that sponsor research (such as US NIH, UK MRC) should bear the burden of providing treatment
- Developing country *governments* should bear the burden

- Sponsor: an individual, company, institution or organization taking primary responsibility for the initiation, management, and/or financing of a clinical trial. It ensures that the design of the study meets appropriate standards..." Tarantola et al. Vaccine 2007
- Sponsor: An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial (ICH/GCP E6. 1.53)

Institutional perspective

- Institution: any public or private agency or medical or dental facility where clinical trials are conducted (ICH GCP E6, 1.30)
- an organization, establishment, foundation, society, or the like, devoted to the promotion of a particular cause or program www.dictionary.com

U.S. National Institutes of Health

- The primary U.S. government agency for conducting and supporting medical research.
- Comprised of 27 institutes and centers
- Annual budget ~ \$28 billion

National Institutes of Health

- NIH Authority: “...to encourage and support research...” (U. S. Code 42 USC 284 (b))
- NIH distributes most (>80%) of its funding in about 50,000 competitive research grants to researchers at universities, medical schools and other research institutions in all US states and territories, and many other countries

HIV Vaccine investment

- NIH is the largest funder of HIV vaccine research in the world
 - NIH HIV vaccine budget ~ \$511 million (2005)*
<http://www.nih.gov/news/fundingresearchareas.htm>
 - Global investment in HIV vaccine research (2005) ~ \$750 million <http://www.hivresourcetracking.org>
 - [Proposed FY2008 \$596 million

NIH guidance on provision of ART

- The NIH is committed to conducting and supporting HIV/AIDS research...to improve the health of people living with HIV/AIDS, particularly people in countries most affected by the epidemic
- “The NIH’s authority to “encourage and support research” does not extend to providing treatment following the completion of that research. 42 USC 284(b)(1)(A).
- NIH Guidance Addressing The Provision Of Antiretroviral Treatment For Trial Participants Following Their Completion Of NIH-funded HIV Antiretroviral Treatment Trials In Developing Countries (2005) <http://grants.nih.gov/grants/policy/antiretroviral>

NIH guidance on post trial ARVs

- "... the NIH expects investigators/contractors to address the provision of antiretroviral treatment"
- "[and] recommends investigators/contractors work with host countries' authorities and other stakeholders to identify available sources of antiretroviral treatment"
- "...in the selection of sites for antiretroviral treatment trials, priority may be given to sites where sources are identified for the provision of antiretroviral treatment following the completion of the trial."

NIH HIV Vaccine research

- May give priority to sites where treatment is available through a country's national plan, PEPFAR, or Global Fund.
- Requires that the informed consent clearly articulate what can/will be offered to the participant during the trial, including for example referrals for provision of ARV.

HIV Vaccine Trials Network (HVTN)

- HVTN- an international collaboration devoted to testing preventive vaccines against HIV, funded by NIAID/NIH
- “...participants who become infected during HVTN vaccine trials will receive long-term antiretroviral treatment” (Lancet 362, 2003)
- HVTN created a ARV fund based on contributions by private donors and solicited from commercial vaccine developers. ARV fund does not include US Government funds.
- HVTN works with the local PIs and CABs to develop treatment plans.

FY 2008 Trans-NIH Plan For HIV-related Research

US NIH Office of AIDS Research

- "...highest priorities for FY2008 are prevention research, including microbicides and vaccines."
- "...enlist participation of local representatives or community advisory boards in the development of appropriate trial protocols...establish networks within the community that will effectively, and on a continuing basis, address the social and medical concerns of participants... (p59)
- www.oar.nih.gov/public/public.htm#PLAN

Conclusion

- Needed care and treatment should be given to participants in HIV vaccine trials
- "...a comprehensive care package should be agreed upon through host/community/sponsor dialogue...prior to initiation of a trial" (UNAIDS 2000, #16)..