
General

Creating national and regional frameworks to support HIV vaccine development in developing countries (Report from a WHO-UNAIDS consultation)

[WHO/IVB/05.17](#)
page 5

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[WHO/IVB/05.17](#)
page 41

The following policy recommendations (from a WHO-UNAIDS consultation) were made with the goal of changing existing global, national, or regional policies.

- 1) Integrate national AIDS vaccine plans within overarching national AIDS strategies.
- 2) Align/integrate major HIV vaccine research into the national prevention, treatment and care framework and other public health research initiatives.
- 3) Develop national policies on treatment and care of study volunteers who seroconvert during trials.
- 4) Incorporate into national AIDS vaccine plans general principles and policies for negotiating with AIDS vaccine clinical trial promoters (funders and researchers) about treatment and care for intercurrent infections.
- 5) Review clinical trials legislation, where present, to ensure that HIV vaccine and microbicide trials are adequately addressed/covered.
- 6) Address HIV/AIDS vaccine development within the context of poverty alleviation efforts.

Conclusions and recommendations from the meeting of the immunization Strategic Advisory Group of Experts (SAGE) - November 2006

WER 2006, vol. 82, 1, pp 1-
[16](#)
page 15

SAGE recognized the importance of activities targeting capacity building and the development of clinical trial sites to ensure that all phases of clinical trials could be conducted in a way that meets the highest scientific, legal, ethical and regulatory standards as well as ensuring that communities are involved in the process. It will be important to develop such sites in developing countries where future vaccines would offer the most benefit.

Recognizing the complex scientific questions that need to be addressed with novel vaccine technologies, SAGE encourages efforts to facilitate close interaction and early discussions between researchers and national regulatory authorities. Additional training of members of national regulatory authorities in scientific aspects should also be included in the training programmes that are being implemented by WHO and other international sponsors.

SAGE expressed its support for the work of WHO in the area of developing vaccines against HIV, TB and malaria in close cooperation with other international and national partners and confirmed the critical role WHO has in developing relevant policies, norms and standards to facilitate the highest scientific, regulatory and ethical standards of clinical trials worldwide.

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page 21

In July 2003 WHO-UNAIDS organized an Intercurrent Infection Consultation with participants from funding agencies in microbicides, vaccines, and behavioral intervention trials; from organizations involved with HIV treatment and care; participants in HIV prevention research, community members, ethicists and legal experts, country representatives, and UN agency representatives.

In conclusion, the consultation agreed on the following points.

-Volunteers who become infected during a trial should have access to good quality care within the framework of WHO guidelines for resource-constrained settings.

-Approaches for care and treatment should be reached before a trial starts, and they need to be legally enforced beyond political changes in leadership.

-Funding mechanisms for care and treatment should be explored and formal agreements reached among participating organizations.

-Prevention trials ought to contribute constructively to infrastructure (human capacity, laboratory strengthening, etc.).

-In situations where good quality treatment and care is not available through the health system for trial participants, then alternatives need to be explored. This may include developing specific financial funds to cover drugs and care, obtained through overheads.

-Although the World Bank and Global Fund to fight AIDS, TB and Malaria do not specifically fund research, they can provide resources to develop human capacity (training) and clinical and laboratory infrastructure which will both support research as well as treatment and care outside of the trial context.

-For people found to be HIV-infected during trial recruitment, as well as partners/family members of volunteers who become HIV infected during trials, provision should be made for appropriate treatment and care through local facilities. If these are absent or sub-standard, stakeholders need to agree on separate arrangements to care for these people.

Policy

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[WHO/IVB/05.17](#)
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[16](#)
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SAGE - recommend to WHO

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WER 2006, vol. 82, 1, pp 1-16
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