



Consultation on Standards of Prevention in HIV Prevention Trials

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With the development of novel HIV prevention tools, the HIV prevention field faces a number of challenges associated with the design of future clinical trials.

As various clinical trials demonstrate the partial efficacy or effectiveness of new prevention modalities (e.g. circumcision, but also potentially pre-exposure prophylaxis [PrEP] and microbicides), the HIV prevention field will face two key issues:

- When and under what circumstances are investigators in future trials obligated to make new prevention tools available to all study participants?
- Should the continued addition of partially effective tools to the standard prevention package make it otherwise impossible to test new technologies, would the urgent public need for additional HIV prevention technologies ever justify re-considering the level and type of prevention modalities provided to all trial participants?

The need for creative and thoughtful reflection on these topics is all the more apparent with the recent release of the circumcision, herpes suppression, Carraguard, and diaphragm trial results.

To catalyze discussion and to build consensus among investigators, advocates, ethicists, policymakers, regulators, and other stakeholders about the challenges of designing and conducting future HIV prevention trials, the Global Campaign for Microbicides (GCM), the Joint United Nations Programme on HIV/AIDS (UNAIDS), and the US Centers for Disease Control and Prevention (CDC) are working together to convene an international technical consultation to explore issues central to the design and conduct of these trials. These issues to be discussed at this consultation include:

- What are different approaches to meeting the challenges of designing future HIV prevention trials?
- What are the criteria that determine when new prevention tools should be considered part of standard of prevention offered to all participants in an HIV prevention trial?
- On what grounds could the exclusion of a newly developed prevention approach from the standard prevention package be justified?

The goals of this consultation include:

- To use evidence-based examples and case studies to inform local and international discussions of standard of prevention presently taking place among investigators, advocates, ethicists, policymakers, and regulators.
- To contribute to the HIV prevention field's ability to learn from previous trials and to meet the guidelines outlined in the recent UNAIDS/WHO guidance document, *Ethical Considerations in Biomedical HIV Prevention Trials*.
- To provide input useful for the design, conduct, and evaluation of future HIV prevention trials.