

The challenge of defining standards of prevention in HIV prevention trials

Abstract:

As new HIV prevention tools are developed, researchers face a number of ethical and logistic questions about how and when to include novel HIV prevention strategies and tools in the standard prevention package of ongoing and future HIV prevention trials. Current Joint United Nations Programme on HIV/AIDS (UNAIDS)/World Health Organization (WHO) guidance recommends that participants in prevention trials receive 'access to all state of the art HIV risk reduction methods', and that decisions about adding new tools to the prevention package be made in consultation with 'all relevant stakeholders'. The guidance, however, leaves open questions of both process and implementation. In March 2009, the Global Campaign for Microbicides, UNAIDS and the Centers for Disease Control and Prevention convened a consultation to develop practical answers to these questions. Fifty-nine diverse participants, including researchers, ethicists, advocates and policymakers, worked to develop consensus criteria on when to include new HIV prevention tools in future trials. Participants developed a set of questions to guide decision-making, including: whether the method has been recommended by international bodies or adopted at a national level; the size of the effect and weight of the evidence; relevance to the trial population; whether the tool has been approved or introduced in the trial country; whether adding the tool might lead to trial futility; outstanding safety issues and status of the trial. Further work is needed to develop, implement and evaluate approaches to facilitate meaningful stakeholder participation in this deliberative process.