

ROUND TABLE DISCUSSION: INTERGRATING PREVENTION RESULTS INTO HIV VACCINE TRIALS

RT.01

Changing landscapes - integrating emerging prevention data into clinical trials

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Phase 2B/3 HIV prevention trials are by their very nature large, logistically challenging, and expensive. Few such trials evaluate a single intervention but more commonly determine whether an intervention such as a vaccine or microbicide, on a background of safer sex counseling, condom provision, and STI management, can reduce HIV acquisition rates. Until earlier this year, 37 randomized controlled HIV prevention trials had only yielded five positive results. Three of these involved circumcision, one the treatment of STIs, and one use of an HIV vaccine. In July 2010, the results of the CAPRISA 004 trial, a Phase 2B trial evaluating tenofovir gel, demonstrated a significant reduction of HIV acquisition in the women randomized to receive the tenofovir gel. As a consequence of these data, WHO/UNAIDS are convening a meeting in South Africa in August 2010 to discuss the next steps in trying to provide women with access to tenofovir gel. Significant regulatory, operational, and manufacturing challenges will have to be overcome to achieve this goal. However, it is clear that as soon as efficacy signals are seen in prevention trials there will be pressure to license and/or distribute these products. It can be anticipated that the availability of new prevention technologies in communities at risk of HIV infection will impact on the ability to conduct HIV prevention trials. Trials with a placebo arm may be considered unethical and ongoing studies may have to incorporate new technologies into the prevention package offered to trial participants. The net effect of these developments will be to increase the challenge of demonstrating the efficacy of new HIV prevention interventions. The purpose of this talk is to describe the evolving HIV prevention landscape and to discuss the implications for ongoing and planned HIV prevention trials.

RT.02

Integrating HIV Prevention Interventions into HIV Vaccine Trial Designs: Statistical Issues

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There are several potential goals and associated statistical designs that can be considered when integrating a non-vaccine HIV preventive intervention into HIV vaccine trial designs. In this brief talk, I will discuss statistical issues associated with each of these possible designs including choice of a control group, use of factorial vs. multiple group designs and determination of sample size.

RT.03

Ethical Frameworks and Standards of Prevention in HIV Prevention Trials

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To properly test the safety and effectiveness of new HIV prevention tools like microbicides, pre-exposure prophylaxis and vaccines, it is necessary to enroll large numbers of at-risk individuals in randomized controlled trials of these experimental products. In order to minimize the risks and maximize the benefits to individual participants, it is also presumed that researchers must provide a state-of-the-art HIV prevention and care package to all volunteers. This presumption is reinforced by the most common interpretation of existing international guidance on the conduct of biomedical research, most notably the 2007 UNAIDS/WHO Guidance Document: Ethical Considerations in Biomedical HIV Prevention Trials. This presentation examines the ethical underpinnings of this assumption by exploring the evolution of current expectations regarding standards of prevention in HIV research, and by examining several of the key ethical principles and moral frameworks that inform ethical decision-making on this issue.