

Symposia

S.01 - Microbicides to prevent HIV/STD 2013: An Update

S01.1 AN UPDATE ON TOPICAL MICROBICIDE DEVELOPMENT

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Microbicides are products that can be applied to vaginal or rectal mucosa with the intent of preventing, or at least significantly reducing, the transmission of sexually transmitted infections including HIV-1. Unfortunately, the last 5–10 years of microbicide research have generated a number of disappointments. Large scale phase 2B/3 studies or topical microbicides have failed to demonstrate product efficacy, have been stopped prematurely for futility, or in the worst case scenario have possibly demonstrated microbicide induced harm including increased risk of HIV acquisition. Although the CAPRISA 004 study of vaginal peri-coital tenofovir gel demonstrated a significant reduction in HIV acquisition (39%; $p = 0.017$), the most recently completed microbicide effectiveness study, MTN-003 (the VOICE study), did not demonstrate the effectiveness of daily tenofovir gel, largely due to product non-adherence by study participants. However, the ongoing FACTS-001 study has the potential to confirm the results of the CAPRISA 004 study and may lead to licensure of tenofovir gel. In addition, current microbicide research is increasingly focused on technology, such as intravaginal rings, that provide sustained release of antiretrovirals to the cervico-vaginal mucosa and may minimise adherence problems associated with peri-coital or daily use of vaginal gels. Two Phase 3 studies of a dapivirine vaginal ring are currently ongoing. The development of combination products that might provide contraceptive and antiretroviral drug delivery is also gathering momentum. Rectal microbicide research has moved from Phase 1 to Phase development. The MTN-017 study, which will be conducted in the USA, Peru, Thailand, and South Africa, will evaluate the safety and acceptability of oral Truvada and rectal tenofovir gel in men who have sex with men and transgender women. This talk will provide a comprehensive update on the challenges and opportunities associated with microbicide development.

S01.3 MAKING ANAL SEX SAFE: CURRENT STATUS OF PRODUCTS FOR RECTAL USE

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There are no products available that make anal sex completely safe from the point of view of HIV acquisition, and the likelihood of this happening in the future is slim. However, in terms of risk reduction, there are practical interventions to implement, the possibility of new concepts to explore, and the promise in the future of an effective rectal microbicide.

The individual risks of anal intercourse (apart from those posed by the insertive partner) are multifactorial and may be broadly broken down to three main areas: trauma, co-infection, and products that may all facilitate inflammation and so increase HIV acquisition risk.

1. Trauma: The anal canal is a high pressure environment due to the combined effects of both internal and external anal sphincters and requires preparation prior to anal intercourse that may be usefully discussed in directed sex education to reduce traumatic injury.
2. Co-infection: Human papillomavirus is an almost ubiquitous infection in sexually active adults and is an independent risk factor for HIV acquisition by both vaginal and anal intercourse.

The vaccination of both boys and girls prior to sexual debut may have the potential to reduce HIV acquisition risk.

3. Products: These may potentially harm and also protect. Many unregulated off the shelf sexual lubricant products have high osmolality and may contain Nonoxonyl 9 that can both injure and induce inflammation in rectal epithelium and so provide an environment conducive to HIV infection. However, the gel formulation of tenofovir has shown efficacy in reducing both HIV and herpes simplex virus acquisition (a cofactor for HIV infection) following vaginal application. The reduced glycerin rectal formulation of this product has been shown to be safe in a short Phase 1 study and is currently entering an extended safety Phase 2 study.

These elements will be explored during this presentation.

S.02 - Translating and implementing the results of diagnostic assay evaluations: From the research laboratory to patient care

S02.1 THE PUBLIC HEALTH NEED FOR DIAGNOSTICS AND THE DIFFERING PATHWAYS TO APPROVAL AND USE AROUND THE WORLD

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The global impact of STIs is difficult to understand due to the lack of systematic, coordinated, and standardised surveillance of disease prevalence and incidence. A barrier to these efforts is the lack of easy to use, rapid, diagnostic tests in all regions of the world. Regulatory evaluation and approval of diagnostics varies by country. Common to most approval processes is the need for the diagnostic test to be evaluated for the performance characteristics in an appropriate clinical setting. Parameters that need to be understood are the sensitivity and specificity of the test, as well as practical considerations such as stability and ease of use. The degree of clinical validation and the various ways to design the studies are some of the areas that are approached differently by the various regulatory authorities. Understanding of the various regulatory pathways is important to understanding the scientific considerations necessary to map out a product development plan as diagnostic developers embark on product development in this arena.

S02.2 OVERVIEW OF RAPID/POINT OF CARE DIAGNOSTIC TESTS FOR HIV AND CURRENT CHALLENGES ASSOCIATED WITH HIV TESTING

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Advances in rapid/point of care testing (RPOCT) for HIV have transformed global capacity to reach individuals who might not otherwise have been tested for HIV, particularly in non-traditional health care settings. In addition to reducing patient anxiety associated with awaiting the results of standard laboratory tests, a positive HIV RPOCT may allow for urgent medical interventions which could in turn reduce the risk of transmission of HIV, e.g. in the mother to child setting and in blood and body fluid exposures. The availability of a rapid test result also has the potential to allow immediate linkage to care and to modify behaviour which might result in reduced transmission of infection.

Despite these benefits, RPOCT has also resulted in new challenges to health systems. For example, false positive results create unnecessary anxiety and occasionally, unnecessary medical interventions.

The majority of currently available HIV RPOCT detect HIV-1 and sometimes HIV-2 antibody. Some newer test kits include the