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

detection of p24 antigen with the potential to enhance diagnostic sensitivity in early infections. Future research should focus on better combination antigen/antibody rapid assays or rapid tests to detect nucleic acid to improve the diagnosis of early HIV seroconversion and for early infant diagnosis. Another area of unmet need is the accurate detection of infection in individuals who have received HIV vaccine who may screen positive on rapid tests making distinguishing vaccination and disease difficult. Finally, future directions should combine testing for multiple infections (e.g. HIV, HBV, HCV and syphilis) in a single test kit.

S02.3 EXTRA-GENITAL CT/GC TESTING BY NAATS: USE IN SCREENING AND PREVALENCE OF INFECTION IN MSM, ISSUES IN VALIDATION

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Most *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) infections in men who have sex with men (MSM) are not in the urethra. This has been confirmed often since it was shown by Kent and colleagues, in 2 clinics in San Francisco, (*J. Infect. Dis.* 2003). All of these studies have been made possible by the use of highly sensitive and specific nucleic acid amplification tests (NAATs) that are currently recommended for routine diagnosis of CT/GC infections. The increment in sensitivity for NAATs compared to culture is greater with pharyngeal and rectal specimens than with cervical and urethral specimens; doubling the number of rectal or pharyngeal infections detected.

In MSM attending STD clinics the prevalence of rectal or urethral CT and GC is often in the 7–10% range. GC is found in the oropharynx at about the same level, but CT is less common there, typically 1–2%. Most STD clinics' routine has been to test urethral specimens when evaluating males, with rectal or oropharyngeal specimens tested in symptomatic MSM. We need a paradigm shift: in MSM routine testing of oropharyngeal and rectal sites, as well as urethra, must become the norm. Whether testing should be based on a history of sex practises needs more research.

Unfortunately, no NAATs have received FDA clearance for pharyngeal or rectal specimens. But CDC, recognising the superior performance of NAATs with these specimens, took an unusual step recommending NAATs for diagnosing CT/GC in oropharynx and rectum, despite absence of FDA clearance.

It is possible to use tests that have not received FDA clearance for patient management. Large laboratories can verify use of NAATs for rectal and pharyngeal specimens by following Clinical Laboratory Improvement Act (CLIA) guidelines. We need NAATs with FDA clearance for use on oropharyngeal and rectal specimens to further expand clinical access to these tests.

S02.4 WHAT ARE THE MOST EFFICIENT WAYS TO COMMUNICATE RESEARCH DERIVED INFORMATION TO CLINICAL PRACTISE: THE ROLE OF DIAGNOSTIC AND TREATMENT GUIDELINES, PACKET INSERTS, CLINICIANS' PERSPECTIVE

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When implementing innovative diagnostics or novel therapeutics in medicine, the modern process of knowledge transfer can be described in a stepwise progression from (1) knowledge creation, to (2) diffusion and dissemination, and finally (3) organisational adoption and implementation. We can observe how such processes have contributed to the STI testing and treatment guidelines that we use currently.

As clinicians we strive to keep abreast of developments in our field that enable us to deliver the best quality management to our patients. The experience and intuition of an individual clinician is

valuable, but all our practises should be subject to rigorous evaluation to ensure they are safe and effective. Without such processes, different and conflicting practises can persist, examples of which will be discussed. The need to implement evidence-based best practise has become widely accepted; however, this can still be hampered by financial constraints as well as the unavailability of specific resources locally. In addition, there is often a lag time in our ability to adopt new tests or treatments due to the need to adhere to local or national guidelines or a lack of evidence such as randomised controlled trials that drive changes in practise.

This symposium allows us to examine the most effective ways of getting research into practise and this session will focus on the clinician's viewpoint. Many knowledge gaps remain where further work is needed to better guide STI testing and treatment. More consideration is needed as to how new information is best disseminated to enable our patients to benefit most promptly from implementation of new information.

S.03 - Advancing prevention of sexually transmitted infections through sexual health promotion: Opportunities and lessons learned (organised by CDC/WHO/ECDC)

S03.1 SEXUAL HEALTH: CONCEPTUAL FRAMEWORK AND RECOMMENDATIONS FOR INDICATORS

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Background In 2010 WHO convened an expert consultation to formulate recommendations and strategic directions for sexual health. Two specific recommendations, derived from the consultation were: (a) to develop a conceptual framework on sexual health that clearly outlines the elements of sexual health and how it overlaps and differs from reproductive health and the role of sexuality; (b) to develop, operationalize and promote sexual health indicators. **Method** The WHO Department of Reproductive Health and Research established consultative processes, including a review of the existing evidence, conducted interviews with key informants and held expert consultations to address the aforementioned recommendations.

Results Two documents; *Towards a conceptual framework for sexual health: understanding and improving sexual health for all* and *Core Set of Sexual Health Indicators* were developed during 2011–2013.

The conceptual framework outlines the central role that key sexual health concepts of autonomy, individual choice and protection of human rights play in achieving health and development outcomes. The document proposes new ways of 'framing' sexual health in order to reach the widest audience, which in turn can influence and deliver positive approaches for ensuring sexual health for all.

The proposed indicators cover the following areas of sexual health: adolescent sexual health, family planning, harmful practises, healthy sexuality, sexual dysfunctions and concerns, STI/HIV, and sexual violence. Indicators range from policy, to services (access) to outcome/impact. Most of the proposed indicators have previously been validated, however some new population-based survey indicators have been submitted for validation through special surveys among men who have sex with men and people who inject drugs, to be conducted throughout 2012/2013 in the WHO European region. Preliminary validation results are available.