S3.3 USE OF TRANSMISSION DYNAMICS MODELS TO DESIGN AND EVALUATE THE IMPACT OF LARGE SCALE HIV/STI PREVENTION INTERVENTION: HOW, WHY AND WHEN?

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When HIV or STI prevention programmes (eg, large core group intervention, human papillomavirus vaccination programme) are being scaled up to entire populations, it often becomes difficult to conduct randomised experiments to evaluate their impact. In this talk, I will discuss some of the challenges often present when evaluating large scale interventions and how and why transmission dynamics models, in combination with surveillance data, should be used to address some of these issues and to help estimate the intervention impact more objectively. Mathematical models should also be used at an early stage, not only to choose the most optimal prevention package, but to optimally design and validate evaluation studies in a cost-effective manner.

S3.4 MULTI-LEVEL STRATEGIES TO EVALUATE THE IMPACT OF HIV PREVENTION PROGRAMMES IN ZIMBABWE

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Zimbabwe has experienced one of the largest and most rapid declines in HIV prevalence in sub-Saharan Africa. This presentation will describe the range of evidence has been assembled and examined to distinguish the contribution of HIV prevention programmes to this decline from the effects of the natural dynamics of the epidemic, spontaneous responses to high AIDS mortality, and changes in socio-economic context. Some of the practical challenges, advantages and limitations of the different methods of evaluation used—observational studies, mathematical modelling, randomised trials—will be discussed.

S3.5 SCALING UP NOVEL BIOMEDICAL HIV PREVENTION STRATEGIES: EVIDENCE FOR ACTION

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Randomised controlled trial results can provide the scientific rationale for implementing new biomedical HIV prevention strategies but are not sufficient. Generalisability of trial findings, good participatory trial conduct, acceptability studies, demand creation, costing and impact studies, human resource constraints, supply chain management, risk compensation, gender implications, opportunity costs, regulatory issues, and sociopolitical considerations also influence policy makers and programme planners considering adoption and implementation. Knowledge translation examples drawn from male circumcision, tenofovir gel microbicide, and oral pre-exposure prophylaxis will be presented to illustrate the evidence to be considered in scale-up.

Symposium 4: Speeding up elimination of congenital syphilis with rapid syphilis testing: progress and challenges (sponsored by WHO)

S4.1 CHALLENGES IN GLOBAL ESTIMATES OF SYPHILIS IN PREGNANCY

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Background Estimates of the current number of pregnant women infected with syphilis (maternal syphilis) are necessary for the global Elimination of Congenital Syphilis initiative such that advocacy, program implementation, and monitoring are based on a clear understanding of the current situation. In addition to understanding morbidity in pregnant women, an accurate estimate of maternal syphilis is also the cornerstone of calculations of the burden of adverse outcomes associated with syphilis in pregnancy.
Methods A MEDLINE search from January 2003 to September 2010 was conducted to identify studies of syphilis prevalence in women attending antenatal care with the following inclusion criteria: sample size of at least 100, use of both reaginic and non-reaginic tests, English language, and no apparent selection bias. Methods are similar to those used by Schmid *et al* in 2007 to estimate maternal syphilis, except that current estimates include Europe and North America, and will be compared with syphilis seropositivity data reported by countries through the WHO HIV Universal Access reporting system for 2008 through 2010 (reported data may or may not use both reaginic and non-reaginic tests). Global and regional estimates will be based on country data where available, and where not available, a regional pregnancy-weighted mean based on live births (per United Nations Population Division) and known country seropositivity will be used. Country and regional estimates will be validated by WHO regional advisors to assess if estimates are reasonable.
Results Studies on approximately 35 of 193 countries (18%) met the inclusion criteria for the MEDLINE search, and 96 countries (50%) reported seropositivity in either 2008 or 2009; additional reported data for 2010 will be available in May 2011, at which time estimates will be completed.
Conclusions Data on maternal syphilis are available in recent published literature for only a small proportion of countries. Therefore, global and regional estimates of maternal syphilis must rely on alternative data sources such as the WHO HIV Universal Access reporting system. Increased efforts are required globally to highlight the importance of having sufficient high-quality data to guide implementation of congenital syphilis elimination efforts.

S4.2 INTRODUCTION OF RAPID SYPHILIS TESTING STRENGTHENS HEALTH SYSTEMS AND HEALTH WORKER CAPACITY TO PROVIDE INTEGRATED PMTCT SERVICES

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Background In partnership with Ministries of Health of Uganda and Zambia, we piloted the introduction of rapid syphilis testing (SD Bioline) in large scale PMTCT programs. Both countries provide PMTCT services within integrated maternal newborn child health programs. Point of care (PoC) testing for HIV, malaria and haemoglobin are routine. While Uganda did not have routine access to syphilis testing prior to the study, Zambia was using RPR as part of the standard package of antenatal care (ANC) services although access was inconsistent and not available in remote clinics.
Methods A mixed method study using both qualitative and quantitative indicators was used to assess acceptability, feasibility and affordability of the rapid syphilis testing. Ongoing engagement of Ministries of Health and clinic staff was used to assess health system ability to integrate rapid syphilis testing within PMTCT programs.
Results The use of rapid syphilis testing in ANC was acceptable, feasible and cost effective see Abstract S4.2 table1 with statistically significant increases in same day testing and treatment and high

levels of healthcare worker satisfaction as reported elsewhere (IAS, 2011). This study has resulted in measurable improvements to the health system including: the development of robust internal and external laboratory quality assurance (QA) systems and an integrated training for health workers on congenital syphilis prevention, treatment and quality assured use of PoC technologies. Use of integrated registers in MCH for data collection allowed for seamless initiation of the service into ANC. Supply chain systems were developed and enhanced especially in Uganda where syphilis testing was previously not routine. 13 131 women in Uganda and 12 761 women in Zambia received syphilis testing during the 5 month study period with a significant number of tests successfully carried out by nurse/midwives. Integrating syphilis and HIV supply chains led to reduced days of stock out of HIV test kits due to better ordering practices in some sites and did not negatively impact or integration significantly improved HIV service uptake.

Conclusions In addition to being acceptable, feasible and affordable, the systematic introduction of a PoC diagnostic for syphilis can lead to wider health system improvements and enhanced HIV service uptake in ANC. Wider use of PoC technologies is encouraged.

Abstract S4.2 Table1 Uptake of HIV services in sites with concurrent rapid syphilis testing

	Baseline	Rapid syphilis test study period	Result
	Zambia		
HIV testing	7,479 (95.5%)	11 151 (97.7%)	(χ^2=74.75; p<0.0001)
ARV prophylaxis	1,303 (98.3%)	2,036(100.1%)	(χ^2=35.56; p<0.0001)
Referral to care and treatment	977 (75%)	1,721(84.6%)	(χ^2=60.63; p<0.0001)
	Uganda		
HIV testing	6,479 (95.6%)	11 192 (96.4%)	(χ^2=7.01; p=0.008)
ARV prophylaxis	570 (78.5%)	964 (83.6%)	(χ^2=7.72; p=0.006)
Referral to care and treatment	85 (16.9%)	118 (16.1%)	(χ^2=0.168; p=0.68)

S4.3 IMPLEMENTATION OF RAPID TESTS FOR PRENATAL SYPHILIS SCREENING: OVERCOMING HEALTH SYSTEM CONSTRAINTS

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Background Congenital syphilis and syphilis in pregnancy in Peru persist as important public health issues, and improvement of screening/treatment for pregnant women remains challenging. rapid syphilis testing (RST) allows simple and immediate diagnosis and treatment at a single clinic visit and could increase screening and treatment coverage and thereby reduce the incidence of stillbirth and congenital syphilis and generate in the long term a sustainable cost effective intervention.

Methods We tested the feasibility, performance, impact and cost-effectiveness of implementing RST in an underserved urban area at a biggest maternity hospital in Peru and a network of 16 peripheral health centres offering prenatal care in a periurban poor area in Callao-Ventanilla, Peru. RST (integrated with HIV rapid test: the "two for one") were offered at the first prenatal visit (ANC), at delivery and within miscarriage/abortion services.

Results Data from the baseline pre-implementation evaluation revealed limited coverage of screening and treatment services for maternal syphilis and a complex and inefficient system for ANC. RST was started in January 2010. Overall success of implementation was measured by rates of maternal syphilis screening and treatment coverage, partner treatment, and acceptability of RST among providers and patients. Complementary evaluations comparing cost-effectiveness of RST against the Rapid Plasma Reagin, and a performance analysis of RST against the "multiple gold test" [Rapid Plasma Reagin + *Treponema pallidum* particle agglutination assay or fluorescent treponemal antibody absorption] were also simultaneously performed. Attention was paid to the successful development of a system of internal and external quality control for testing and test supplies and the process of dissemination and transfer activities to the Ministry of Health of Peru, through the involvement of both the National Program of STIs and HIV and the Reproductive Health Program. National guidelines have been modified, and recommend the use of both tests, RST and rapid HIV testing in the screening of pregnant women.

Conclusions RST implementation was feasible, successful, acceptable and cost effective. Its introduction catalysed improvements in the quality of care, and by the end of the project it has been introduced in the country as a national policy.

S4.4 PROGRESS IN DEVELOPMENT OF DUAL RAPID SYPHILIS TEST TECHNOLOGY

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Background Traditionally, most diagnoses of syphilis relies on serology and required testing for patient antibodies against cardiolipin (non-treponemal tests) as well as against treponemal antigens (treponemal tests). These serological tests must be performed in clinical laboratories, require considerable scientific resources and trained technicians to perform them, and test results often are not reported for several days. As a result, control in resource-poor countries has been problematic. Rapid tests provide a platform whereby patient antibodies can be quickly analysed (5–30 min) by their binding to immobilised antigens on a nitrocellulose membrane. Another advantage is that patient sera, blood, or plasma can be tested, thus requiring fewer resources and technician time to perform. One of the first rapid tests developed was the Abbot Determine (treponemal test results only) which has served as a useful rapid screening tool in some settings. Other treponemal only rapid tests include the Standard Diagnostics BioLine and the Fujirebio Espline. These rapid tests have a sensivitivity ranging from 92% to 100% and specificity ranging from 93.4 to 98.9% when compared to the TP-PA. The Eurostrip (Euromedi Equipment LTD, W. Harrow, UK), another treponemal only rapid test, was recently evaluated at CDC for a potential field study in Kenya. With 94 archived serum samples, the Eurostrip had a sensitivity of 98.6% and a specificity of 100% when compared to the TP-PA.

Methods and results A recent breakthrough in technology allows for modified cardiolipin to be attached to membranes, and the first generation of dual rapid tests were developed in collaboration with CDC: the ChemBio DPP Screen and Confirm (ChemBio Diagnostic Systems, Medford, New York, USA) and the Span Spirolipin (Span Diagnostics Inc., Surat, India). In a study with 1601 archived serum samples, the non-treponemal component of the ChemBio DPP had a sensitivity of 97.3% and a specificity of 98.6% when compared to the RPR; the treponemal component had a sensitivity of 97% and a specificity of 95.5% when compared to the TP-PA. In a similar study with 376 archived serum samples, the non-treponemal component of the Span Spirolipin had a sensitivity of 96.5% and a specificity of 97.7% when compared to the RPR and the treponemal component had a sensitivity of 97.3% and a specificity of 99.1% when compared to the TP-PA. These evaluations demonstrate that these dual rapid tests are as sensitive and as specific as traditional RPR and TP-PA tests.

Conclusions The emergence of dual rapid tests offers resource-poor countries the opportunity for improved point-of-care diagnostic