DEVELOPMENT OF A SMALL-MEDIA INTERVENTION TO BOOST HEALTHCARE PROVIDERS’ KNOWLEDGE AND AWARENESS OF SYPHILIS IN AN URBAN US COMMUNITY

Background St. Louis, Missouri remains a high-morbidity syphilis community. Implementation of a small-media intervention in 2005 to improve provider knowledge and awareness of syphilis led to transient declines in infectious syphilis, but rates have increased in recent years. We describe a formative collaborative project between university, health department, and community service organization workers to develop a pocket-sized visual aid for boosting healthcare providers’ awareness and understanding of syphilis epidemiology, clinical presentation, and treatment recommendations.

Methods In 2012, physician and nurse-practitioner key informants (N = 18) provided foundational data on essential areas of provider knowledge deficit, including (1) clinical aspects of syphilis management such as lesion characteristics, diagnostic tests, and treatment approaches; (2) epidemiological aspects such as populations affected and distribution by age, race/ethnicity, and gender; and (3) health department linkages for partner referral and evaluation. Best practices for reaching providers were also considered, including mail-based and internet-based modalities.

Results Several important aspects of current syphilis clinical presentation and epidemiological patterns were underappreciated by local healthcare providers, including high rates of syphilis among men who have sex with men (MSM), as well as high rates of syphilis-HIV co-infection. Rectal and oropharyngeal infection were also underrecognized. All of these were new developments since the previous version of small-media intervention. Informant recommendations led to the development of a high-contrast pocket-size small-media pamphlet containing text as well as visual prompts to boost provider knowledge and awareness of syphilis. The booster intervention is currently being rolled out city-wide through direct-mail and in-person distribution to primary healthcare providers.

Conclusion Changing syphilis epidemiology requires continued vigilance among provider groups tasked with early identification, treatment, and referral of populations at risk. Small-media visual aids to boost provider awareness and knowledge of syphilis transmission patterns are an important component of larger community-level syphilis prevention agendas.

Background The AFTIMA HIV-1 Quant Assay is a fully automated quantitative assay being developed on the PANTHER system and based on real-time Transcription-Mediated Amplification technology. This assay is intended for monitoring HIV-1 viral load in plasma specimens using a 0.5 mL sample.

Methods A cohort of 245 clinical specimens from University of Athens Medical School was tested using the COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v.2.0 (Roche Assay) and the AFTIMA HIV-1 Quant Assay (AFTIMA Assay). The specimens included subtypes A, B, C and G as well as circulating recombinant forms of HIV-1.

Results Using a lower limit of quantification for the AFTIMA Assay of 50 copies/mL, 175 specimens gave results quantifiable for both assays. The correlation between the two assays was excellent (0.98), with a slope of 1.06 and an intercept of –0.13. Sixty-nine specimens gave results that were either detectable but not quantifiable or not detectable in at least one assay. Thirty were not detectable in both assays and 14 were detectable in both assays. The AFTIMA Assay detected 13 specimens that were undetectable with the Roche Assay. There were 12 specimens that were detectable with the Roche Assay and undetectable with the AFTIMA Assay. One specimen was above the upper limit of quantification (10,000,000 copies/mL).

Conclusion The AFTIMA HIV-1 Quant Assay gave comparable viral load results when compared to the Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v.2.0. The sensitivity of the AFTIMA HIV-1 Quant Assay is similar to that of the Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v.2.0.

Background Chlamydia trachomatis (CT) is the most prevalent bacterial sexually transmitted infection (STI) reported worldwide. Accurate point-of-care diagnostic tests are urgently needed for the rapid treatment of patients. To address this need, we have previously developed a 16S rRNA-based Microwave-Accelerated Metal-Enhanced Fluorescence (MAMEF) assay for the detection of CT. Here we report the development of an additional CT cryptic plasmid-based MAMEF assay, the use of the assays on clinical samples and the implication of MAMEF as a point-of-care test.

Methods The cryptic plasmid-based assay was investigated with cultured, titered CT and vaginal specimens. Following the optimization of the assay, we tested a blinded cohort of dry-shipped vaginal swabs using both the 16S rRNA- and cryptic plasmid-based MAMEF assays, and compared the results to nucleic acid amplification tests (NAATs).

Results The MAMEF assays detected as few as 10 IFU/mL of CT in less than 10 minutes including DNA extraction and detection. A total of 257 vaginal swabs from 245 adolescent women (ages 14–22) were analysed by MAMEF. The overall prevalence of CT by NAAT was 17.5%. Of the 45 NAAT CT-positive samples and 212 CT-negative samples, 33/45 and 197/212 were correctly identified by both MAMEF assays (sens 73.3%, spec 92.9%). Using the plasmid-based assay alone, 37/45 CT+ and 197/212 CT- were detected (sens 82.2%, spec 92.9%). Using the 16S rRNA assay alone, 34/45 CT+ and 197/212 CT- (sens 75.5%, spec 92.9). For the overall % agreement with NAAT, the individual 16S rRNA and cryptic plasmid were 89.8% and 91%, respectively.

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**Conclusions** Both CT MAMEF assays demonstrated moderate sensitivity and high specificity when using dry-shipped vaginal swabs. The cryptic plasmid assay was more sensitive than the 16S rRNA assay. MAMEF is an ultra-rapid platform with results in less than 10 minutes making it ideal as a point-of-care test.

**Results** Ct could be detected in all clinical samples and spiked media and cycle thresholds were stable over time with few exceptions. For Ct DNA detection in spiked COBAS Amplicor medium, cycle thresholds increased within the first month at –20°C and –80°C (both p < 0.01), but decreased in the samples frozen after two years of storage. In spiked urine and pooled clinical urine samples, the cycle threshold decreased within the first month (p < 0.01), including all but one (4°C, p = 0.09) of the studied temperatures, but increased after two years in the frozen samples.

**Conclusion** Our results demonstrate that storage conditions and duration hardly affect Ct DNA detection by PCR in a negative manner, although frozen urine samples, stored for prolonged periods (more than two years), could become Ct negative.

**P5.063** **INFLUENCE OF TEMPERATURE, MEDIUM AND STORAGE DURATION ON CHLAMYDIA TRACHOMATIS DNA DETECTION BY POLYMERASE CHAIN REACTION**

**Background** Chlamydia trachomatis (Ct) is the most prevalent bacterial sexually transmitted microorganism worldwide. Many researchers conveniently use stored samples for Ct research.

**Methods** The Xpert test is a modular, cartridge-based, “walk-away” platform for testing which requires no manipulation from specimen loading until results are available (90 minutes). We compared results from the Xpert assay to results from two currently approved nucleic acid amplification assays (Aptima Combo2 and ProbeTec) in 1,722 females and 1,387 males. Results included a sensitivity for endocervical, vaginal, and urine samples of 100.0%, 99.9%, and 97.6%, respectively.

**Conclusion** The GeneXpert® System is a closed, self-contained, fully-integrated, automated platform for CT/NG testing that demonstrated excellent sensitivities and specificities in women and men. This relatively rapid short-turn-around-time test can provide results to guide treatment decisions before patients leave the clinical setting. Such rapid treatment could potentially improve chlamydia and gonorrhoea control efforts.

**P5.064** **PRELIMINARY ANALYTICAL EVALUATION OF ARTUS® CT/NG, FOR SIMULTANEOUS DETECTION OF NEISSERIA GONORRHOEAE AND CHLAMYDIA TRACHOMATIS**

**Introduction** Currently there are a number of molecular amplification assays for detection of Neisseria gonorrhoeae and Chlamydia trachomatis. Prior to introduction of any new assay, it should be thoroughly evaluated for potential false positive and false negative results due to cross reaction with other species, and potential mutations and genetic exchanges with other closely related organisms. Artus® CT/NG is currently a research use only kit (with the fully automated version to be released later this year) for simultaneously detection of C. trachomatis and N. gonorrhoeae. We performed preliminary analytical evaluation of this assay.

**Methods** This study evaluated the Artus® CT/NG assay with 290 characterised culture isolates obtained from the Neisseria Reference Laboratory at the World Health Organization Collaborating Centres for Sexually Transmitted Disease (STD) in Sydney and WHO Collaborating Centre for Gonorrhoea and other STIs in Örebro, Sweden. Strains included 148 N. gonorrhoeae isolates, 130 isolates of non-gonococcal Neisseria species, 12 isolates of other species closely related to Neisseria and 16 C. trachomatis strains of different serovars (including LGV and nCV strains).

**Results** All C. trachomatis and N. gonorrhoeae isolates were detected. A detection sensitivity of 10 genome copies per reaction was obtained with all C. trachomatis serovars as well as a representative N. gonorrhoeae control strain. All 142 non-gonococcal isolates were negative on the assay.