

*Trichomonas vaginalis* (TV) by APTIMA TV on a TIGRIS instrument. Each patient was asked on a scale of one to five to express strength of agreement or disagreement with ease or comfort of the 6 step self collection process for the VSCT.

**Results** There were a total of 22 CT, 19 TV and 2 NG infections with dual infections in 6 people (one CT and NG, one NG and TV and four CT and TV). Prevalences were as follows: CT 3.9% (GYC 1.3% and YHC 12.6%); NG 0.3% (2.0% in YHC); TV 3.4% (GYC 0.4% and YHC 13.4%). Sensitivity for CT infections were CSCT 100%, PC 100%, SP 81.8%; VSCT-self 100%, VSCT-physician 95.4%: for TV infections CSCT 89.4%, PC 84.2%, SP 63.2%; both VSCT 100%: for NG all collections 100%. There were no false positives (% specificity 100). Results of the survey revealed that the majority of patients found opening the package, self sampling, insertion of the SCT swab into preservation media and uncapping and recapping the tube were relatively easy to perform. Eighty two per cent experienced no discomfort using the SCT kit for collection.

**Conclusions** APTIMA testing on the TIGRIS showed that the cervical and vaginal SCT and PC L-Pap samples were 100% sensitive in detecting CT and NG infections. VSCT samples detected all TV infections but cervical SCT and PC L-Pap were less sensitive. SP L-Pap samples showed reduced sensitivity for CT and TV. Overall, patients were in strong agreement with the ease of use of the VSCT and most found the process comfortable.

### 03-S3.02 PERFORMANCE OF THE BIO-RAD Dx CT/NG/MG ASSAY FOR SIMULTANEOUS DETECTION OF CHLAMYDIA TRACHOMATIS, NEISSERIA GONORRHOAE AND MYCOPLASMA GENITALIUM IN UROGENITAL SAMPLES

doi:10.1136/sextrans-2011-050109.116

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**Objectives** To investigate the performance of the Bio-Rad Dx CT/NG/MG Assay with an internal control for the detection of *Chlamydia trachomatis* (CT) and *Mycoplasma genitalium* (MG) in urogenital samples in comparison with the Roche Cobas TaqMan CT test and an in-house TaqMan PCR test for MG. For *Neisseria gonorrhoeae* (NG), only positive PCR results were controlled by culture.

**Methods** In this prospective study, urogenital samples were obtained from symptomatic and asymptomatic patients attending the STI center of Bordeaux, France, from January to April 2010. For symptomatic women and men, two endocervical swabs and two urethral swabs were collected, respectively. All patients and women collected first-catch urines and two vaginal swabs, respectively. Two swabs per site were used, a flocked swab in the universal transport medium and the Bio-Rad flocked swab in its transport medium. For the Bio-Rad CT/NG/MG assay, the DNA was manually extracted and amplified according to the manufacturer's instructions. For the comparator PCR tests, DNA was extracted using the MagNa Pure LC instrument (Roche Diagnostics) and amplified with the Cobas TaqMan CT 48 assay (Roche Diagnostics) and with a MgPa-targeted PCR assay on an ABI Prism 7000 (Applied Biosystems) for MG. The patient was considered as infected if at least two of the 4 or 6 PCR tests performed according to the gender and characteristics of patients, were positive. For asymptomatic men, in case of discrepancy, the urine sample was retested by both methods and the patient was considered infected if at least two of the four PCR results were positive for the considered microorganism.

**Results** A total of 658 clinical specimens (259 male and 180 female urines, 191 vaginal, 21 cervix and seven urethral swabs) from 453 patients were analysed. The prevalence of CT and MG infections was 7.7% (20/260) and 1.9% (5/260) in men and 10.3% (20/193) and

2% (4/193) in women, respectively. The Bio-Rad Dx CT/NG/MG test sensitivity was 100% for CT and MG in men and women. In male urines, the specificity was 99.6% for CT and 100% for MG. In women, the specificity was 99.5% for swabs and 100% for urines for CT and MG. All 7 NG-PCR positive samples were positive by culture. Patients were co-infected in 5/56 (9%) with CT/MG in three cases and CT/NG in two cases.

**Conclusion** The Bio-Rad Dx CT/NG/MG Assay was found to be very effective for the simultaneous detection of CT, MG, and NG infections in urogenital specimens.

### 03-S3.03 DIFFERING NEISSERIA GONORRHOAE BACTERIAL LOADS IN THE PHARYNX AND RECTUM: IMPLICATIONS FOR GONOCOCCAL DETECTION, TRANSMISSION AND CONTROL

doi:10.1136/sextrans-2011-050109.117

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**Background** To help improve our understanding of the potential transmissibility of gonococcal infections from the pharynx and rectum we measured gonococcal bacterial loads at these sites and examined clinical and laboratory determinants of these loads.

**Methods** Men who had sex with men were tested for pharyngeal and rectal gonorrhoea by culture using modified Thayer Martin medium and by two real-time quantitative qPCRs targetting opa gene, and porA pseudogene.

**Results** 1011 rectal and 1076 pharyngeal specimens were obtained from 1076 MSM. Forty three (3.9%) pharyngeal specimens were PCR positive of which 17 were culture positive (sensitivity 39%, 95% CI: 25% to 54%). Forty seven (4.6%) rectal specimens were PCR positive of which 25 were also culture positive (sensitivity 58%, 95% CI 44% to 71%). The median bacterial load among PCR positive rectal infections (18 960 copies per swab) was significantly higher than that for PCR positive pharyngeal infections (2,100 copies per swab) ( $p=0.001$ ). The median bacterial load among men with symptomatic rectal infection was higher (278 800 copies per swab) than with asymptomatic men, PCR positive rectal infections (13,980 copies per swab,  $p<0.001$ ). The median bacterial load of gonorrhoea was significantly higher in culture positive than culture negative specimens. This applied for both rectal ( $p<0.001$ ) as well as pharyngeal infections ( $p=0.03$ ).

**Conclusion** Higher bacterial loads of gonorrhoea were observed in rectal infections, particularly with symptomatic rectal infections. This has implications for gonococcal transmission and control.

### 03-S3.04 SELF-ADMINISTERED NEISSERIA GONORRHOAE AND CHLAMYDIA TRACHOMATIS TESTING IN THE PHARYNX AND RECTUM AMONG MEN WHO HAVE SEX WITH MEN IN WASHINGTON, DC

doi:10.1136/sextrans-2011-050109.118

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**Background** Recent studies have demonstrated a high prevalence of pharyngeal (P) and rectal (R) *Neisseria gonorrhoeae* (GC) and *Chlamydia trachomatis* (CT) infections among men who have sex with men (MSM), which is concerning given the potential for harmful

sequelae and their relationship to increased HIV transmission. CDC guidelines advocate testing MSM at least annually for these infections, but surveys of medical providers suggest that adherence to these guidelines is minimal. Because providers cite limited time and staff as common reasons for not following the guidelines, we evaluated the feasibility and accuracy of performing self-administered testing for GC and CT.

**Methods** 286 clients who attended Whitman-Walker Clinic in Washington, DC for HIV/STI testing participated in the study. Enrolled clients had a mean age of  $36 \pm 11$ , represented a variety of racial/ethnic backgrounds with 52.8% identifying as Caucasian, and had an average of two male partners in the last 30 days. Clients performed screening using the GenProbe APTIMA 2 Combo (AC2) kit after viewing written and pictorial instructions. A trained provider also performed the testing with the order of client vs provider randomised to adjust for any training effect. This provider remained in the room while the client performed screening to observe, but did not provide assistance.

**Results** The overall prevalence of GC and CT in this sample was 8.9% for P-GC, 8.5% for R-GC, 1.77% for P-CT, and 13.3% for R-CT. McNemar tests were performed stratified by type of infection and anatomic site to evaluate concordance of the client vs provider results. Clients were found to be significantly better at identifying P-GC (91.3% vs 94.4%; 8.8% vs 5.6%;  $p=0.01$ ) and R-GC (91.5% vs 94.3%; 8.5% vs 5.7%;  $p=0.03$ ) and to have results equivalent to providers for P-CT (98.3% vs 98.9%; 1.8% vs 1.1%;  $p=0.50$ ) and R-CT (88.7% vs 88.2%; 13.3% vs 11.9%,  $p=0.25$ ) detection.

**Conclusions** The positive predictive value of the AC2 test makes it unlikely that clients obtained false positives, and observation of subjects while they performed screening ruled out cross-contamination of samples. Therefore, the higher detection rate among the clients is most likely attributable to a more rigorous swabbing technique that sampled an increased surface area. These results suggest that individuals are capable of performing their own STI screening and that allowing them to do so may increase infection detection rates and treatment.

### 03-S3.05 CHLAMYDIA TRACHOMATIS DETECTION BY NUCLEIC ACID AMPLIFICATION ASSAY USING RECTAL SWABS

doi:10.1136/sextrans-2011-050109.119

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**Background** Rectal infection with *C. trachomatis* (CT) is increasing in many settings; however, there are currently no FDA approved NAAT for use with rectal specimens. Access to reliable diagnostics using rectal specimens is critical to both surveillance and disease management and control. This is important as CT culture has been shown to have lower sensitivity, 54.8 %, when compared to NAAT in our patient population. The objective of this study was to evaluate the performance of rectal swabs tested on the Abbott m2000 (m2000) as compared to the GenProbe APTIMA Combo 2 (AC2) for detection of CT.

**Methods** Rectal samples were collected and placed into chlamydia transport medium (CTM) for testing by both m2000 and AC2 for CT. CTM was split as follows; 1 ml into an empty m2000 tube; 100 ul into m2000 multi-collect tube containing buffer; 100 ul into an AC2 swab collection tube. From this point forward, testing was performed according to the package insert for both platforms with two CT negative samples being tested for every positive one.  $\kappa$  scores were determined to measure agreement between the m2000 and AC2 collection tubes.

**Results** A total of 59 samples were tested for CT by m2000 and AC2. AC2 was considered the reference standard for this study with

20 samples identified as positive and 39 as negative for CT. Neat CTM placed into an empty m2000 tube detected 95% (19/20) and had a single positive that was not detected by AC2 (38/39 agreed). The single neat CTM missed by m2000 was positive in the spiked multi-collect tube. CTM spiked into an m2000 multi-collect tubes also detected all but one of the infections identified by AC2 (19/20) and negatives agreed completely (39/39). The m2000 multi-collect miss was CT positive in the neat sample. Both collection methods on the m2000 generated results that had very good agreement with the reference test:  $\kappa$  scores were 0.924 for empty and 0.962 for multi-collect tubes.

**Conclusion** The m2000 has excellent performance characteristics compared to AC2 for the detection of CT. NAATs offer an alternative to culture for the detection of CT in rectal samples, and are less susceptible to transport conditions and sterility that are often a concern with culture. The collection of rectal specimens in CTM offers the opportunity for routine testing using multiple collection devices and platforms with the data suggesting that the m2000 assay can be used to meet the revised CDC recommendations for rectal testing for CT.

### 03-S3.06 RESCREENING FOR CHLAMYDIAL INFECTION USING HOME-BASED, SELF-OBTAINED VAGINAL SWABS: A RANDOMISED CONTROLLED TRIAL IN FAMILY PLANNING CLINIC CLIENTS

doi:10.1136/sextrans-2011-050109.120

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**Background** Family planning clinics provide contraceptive and preventive services for millions of low-income individuals. Screening and treatment for Chlamydia trachomatis infection in these clinics is a major part of the chlamydia control program in the USA. For women diagnosed with chlamydia, rescreening 3 months after treatment is recommended according to national guidelines. However, rescreening rates are low. The time and effort needed for patients to return to the clinic and the lack of access to follow-up care may contribute to the poor adherence to the rescreening recommendation.

**Methods** We conducted a randomised controlled trial in family planning clinics in three cities. After informed consent, women/girls >16 years treated for laboratory-confirmed chlamydial infection were randomly assigned to the Home Group (mailed a vaginal swab kit for self collection at home) or the Clinic Group (made a clinic appointment) for rescreening at 3 months following treatment. Reminder calls were made about 2 weeks before scheduled rescreening. The endpoint was rescreening within a 7 week window, 1 week before to 6 weeks after, the scheduled rescreening date.

**Results** 404 women were enrolled and their group assignments were randomised by opening centrally stuffed envelopes. Women assigned to the Home Group had higher rescreening rate than those in the Clinic Group: Overall, 40.8% of 196 in the Home Group and 20.7% of 208 in the Clinic Group were rescreened ( $p<0.001$ ). The rescreening rates were 38.4% (Home) vs 19.8% (Clinic) among those living with parents, and 48.2% (Home) vs 21.2% (Clinic) among those with a history of chlamydia infection prior to the treated episode at enrolment (both  $p<0.001$ ). Among women reached by a reminder call, rescreening rates were significantly higher in the Home Group (59.2% of 130) than in the Clinic Group (37.8% of 111) ( $p<0.001$ ). Among 163 women not reached by the reminder call, the rescreening rate were low (<5%) in both groups. In the Home Group, 12