WHO. To evaluate current algorithms for treatment of gonorrhoea, chlamydial infection and trichomoniasis, we conducted laboratory testing with vaginal specimens from women presenting with cervicitis or vaginitis syndromes at a sexually transmitted infections clinic in Kingston and at follow-up to assess cure rates for these infections.

Methods From August, 2010 through January, 2011, vaginal swab specimens were obtained from 258 women >18 years old during a routine clinical examination prior to syndromic treatment according to local guidelines. Treatment for gonorrhoea, chlamydial infection and trichomoniasis was prescribed for women with cervicitis. Treatment for trichomoniasis, bacterial vaginosis and candidiasis was prescribed for women with abnormal vaginal discharge. Women returned the next week for follow-up assessment and specimen collection. Specimens were tested for *Neisseria gonorrhoeae* (NG) and *Chlamydia trachomatis* (CT) using APTIMA Combo2 and for *Trichomonas vaginalis* (TV) using APTIMA analyte-specific reagents. All baseline specimens were tested. Follow-up specimens from women with a positive baseline test or who remained symptomatic were also tested. Patients with a positive follow-up test were contacted and instructed to return to the clinic for additional treatment. Cure was defined as a positive baseline test and a negative follow-up test.

Results Baseline prevalence of infection with NG was 11.7%, CT was 20.7%, TV was 25.6%. At least one of these STIs was detected by laboratory testing in 40.7% of women. Co-infections were common. Women with TV were more likely to have NG or CT than women without TV (OR: 2.6, 95% CI 1.4 to 4.8). STI testing at follow-up indicated cure rates of 77.3% for NG, 43.5% for CT and 47.1% for TV infections. CT incidence at follow-up was 5.9%; no incident NG or TV infections were detected.

Conclusions With syndromic management, just over half of the STIs in women that were detected by laboratory testing at baseline were cured at follow-up. Reinfection, incorrect or inadequate treatment, failure to comply with treatment instructions or treatment failure could potentially explain prevalent STIs that were detected at follow-up. The low cure rates for chlamydial infection and trichomoniasis are cause for concern.

P3-S1.18 SIDE EFFECTS OF DOXYCYCLINE IN ADOLESCENTS TREATED FOR PELVIC INFLAMMATORY DISEASE

doi:10.1136/sextrans-2011-050108.418

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Background Our purpose was to assess adverse reactions to doxycycline in adolescents under treatment for PID.

Methods At the Harris County (Houston), Texas, USA Juvenile Detention Center from May 2008 through January 2010, we evaluated adolescents in whom we diagnosed PID. We used the diagnostic criteria and outpatient antibiotic regimen for PID recommended by the CDC. We gave 250 mg ceftriaxone intramuscularly once, and, if they were not pregnant, vomiting, or ill enough to also require metronidazole, we prescribed doxycline, 100 mg twice a day for 14 days. The doxycycline was given before, during, or after breakfast, and approximately 2 h after supper. With the medicine, patients were routinely given a packet of two crackers. We re-assessed these patients at 48–72 h and again at least at 7 and 14 days. At each follow-up, we discussed side effects of doxycycline.

Results We evaluated 141 consecutive patients in whom we made the diagnosis of mild to moderate PID: 55% were black, 31% Hispanic, and 15% white. The mean age (SD) was 15.4 (1.2) years. Of the 141 patients, 86 (61%) had no problems when the doxycline was given with two crackers. Forty-five (32%) required more substantial food to avoid nausea and/or vomiting: the medication was given immediately after breakfast or with a sandwich after supper. Those who had side effects in the morning had usually skipped breakfast. Ten (7%) complained of significant gastrointestinal side effects that were not relieved by the simultaneous ingestion of food, and we gave a dose of promethezine 1 h before the doxycycline.

Conclusion 39% of our patients required more than a small amount of food (two crackers) to avoid gastrointestinal side effects from doxycline. Our results suggest that clinicians should advise adolescents to take this antibiotic after eating a greater amount of food if a small snack does not prevent this problem. Because some patients (7%) did not tolerate doxycline even after they ate a meal or a sandwich, we also recommend early contact with patients who have PID to assess the need to change medications or to add an anti-emetic.

P3-S1.19 EVALUATION OF THE COBAS® 4800 CT/NG TEST USING CLINICIAN AND SELF-COLLECTED VAGINAL SWABS, CERVICAL SPECIMENS IN PRESERVCYT SOLUTION, AND PHARYNGEAL THROAT WASH SPECIMENS

doi:10.1136/sextrans-2011-050108.419

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Objective To evaluate the limit of detection (LOD), inclusivity, exclusivity, and interfering substances of the cobas® 4800 CT/NG Test using vaginal, PreservCyt, and pharyngeal specimens.

Methods *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) cultures were diluted into pools of negative patient specimens at six concentrations to determine the LOD (lowest concentration giving a ≥95% hit rate). A panel of 15 serovars of CT, plus the Swedish variant (nvCT), and 45 strains of NG was diluted into each sample matrix to determine inclusivity. To ensure specificity, a panel of 184 non-CT and non-NG organisms that may be found in the oral or urogenital region was tested at Ġ≥10^5 CFU or copies/ml. The organisms were diluted into CT/NG positive and negative samples. Ten CT/NG positive and negative samples were spiked with blood (up to 5%), leukocytes (up to 10^7 cells/ml), cervical mucus, and saliva at concentrations up to 10% to check for interference. Ten (for pharyngeal) and 18 (for urogenital) over-the-counter products were also tested.

Results LODs were as follows: Vaginal CT 10 IFU/ml, NG 100 CFU/ml; PreservCyt CT 0.6 IFU/ml, NG 3.5 CFU/ml, Pharyngeal CT 0.5 IFU/ml, NG 2.25 CFU/ml. All 15 serovars of CT, plus the Swedish variant (nvCT), and 45 strains of NG were detected at, or near the LOD. No cross reactivity was noted with 184 non-CT and non-NG organisms in any specimen type. Vaginal but not PreservCyt samples showed interference from leukocytes at >10^6 cells/ml. This interference was noted as clot detections and samples were not processed. Pharyngeal samples showed false negative results in the presence of blood at >0.25%, and saliva at >2.5%. No interference was noted with any over-the-counter products in any specimen type.

Conclusions Vaginal, PreservCyt, and pharyngeal specimens are suitable sample types for the cobas® 4800 CT/NG Test.

P3-S1.20 AETIOLOGY OF URETHRAL DISCHARGE SYNDROME AND ITS ASSOCIATION WITH SEXUAL PRACTICES AMONG MALES ATTENDING STI CLINICS IN INDIA

doi:10.1136/sextrans-2011-050108.420

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Background Studies to validate the aetiology of urethral discharge (UD) syndrome are limited in India. The objectives of the study

were to determine etiological agents of UD syndrome among males attending STI clinics and associated risk factors.

Methods We conducted a cross-sectional study among males presenting with complaints of dysuria and/or urethral discharge at eight government and non-governmental organization STI clinics in four Indian states from 2008 to 2009. A behavioural questionnaire was administered, clinical examination performed and urine was collected to test for *Neisseria gonorrhoeae* (GC) and *Chlamydia trachomatis* (CT) by Gen-Probe-APTIMA Combo II. In cases where a urethral discharge was elicited, urethral swabs were collected and tested for *Mycoplasma genitalium* (MG), *Ureaplasma urealyticum* (UU) and *Trichomonas vaginalis* (TV) by using PCR method. Data were analysed using STATA V10.

Results 246 clients diagnosed with UD syndrome as per the national algorithm were enrolled in the study. 29% of the participants had at least one of the infections. The overall prevalence of GC was 14% and CT was 4%. Among the 86 participants from whom urethral swabs were collected, prevalence of MG and UU was 33% and 34% respectively while TV was not detected. In this sub-group of 86 participants, the prevalence of GC and CT was higher at 24% and 7% respectively while 64% individuals had at least one infection. Factors such as younger age (<25 years), illiteracy, paid sex in last 2 weeks and penetrative anal sex in last 3 months were found to be significantly associated with having any infection (see Abstract P3-S1.20 table 1).

Abstract P3-S1.20 Table 1 Correlates of infections (gonococcal and/or non-gonococcal)

S. No.	Characteristic	OR (95% CI)	p Value
1	Age up to 25 years	1.7 (0.9 to 3.1)	0.06
2	Inability to read or write	2.2 (0.9 to 5.1)	0.05
3	Paid sex in last 2 weeks	2.1 (1.1 to 4.2)	0.02
4	Penetrative anal sex in past 3 months	2.1 (0.9 to 4.8)	0.05
5	Vaginal sex in past 3 months	2.8 (0.6 to 26.4)	0.16
6	No condom use at last sexual act	1.4 (0.7 to 2.7)	0.32

Conclusion The current practice of diagnosing UD syndrome based on the history of dysuria and/or discharge is leading to over-diagnosis. A detailed sexual history for determining risk factors and demonstration of urethral discharge on clinical examination will help to improve the diagnosis.

P3-S1.21 NON-CULTURE BASED *NEISSERIA GONORRHOEAE* ANTIMICROBIAL RESISTANCE SURVEILLANCE

doi:10.1136/sextrans-2011-050108.421

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Background Increased reliance on nucleic acid amplification tests for the diagnosis of gonorrhoea, and issues with transporting viable *Neisseria gonorrhoeae* (NG) isolates, particularly from remote regions, undermines bacterial-culture-based NG antimicrobial resistance (AMR) surveillance. In this study, we explored non-culture based NG AMR surveillance by developing and validating a real-time PCR assay for direct detection of penicillinase-producing NG (PPNG) in clinical samples.

Methods The PPNG-PCR assay was designed as an indirect marker of penicillinase activity, by targeting a region of sequence conserved across all NG plasmid types harbouring the β-lactamse gene, while not targeting the actual β-lactamase encoding sequence. The assay was evaluated using 118 characterised NG clinical isolates, and then applied to samples collected from the Australia's Northern Territory (years 2008–2009) where penicillin is still used for treatment. These comprised 214 NG-positive clinical samples from which *N gonorrhoeae* were isolated and phenotypic penicillinase results were available and an additional 209 samples that were positive by NG-PCR only.

Results The PPNG-PCR2 assay provided 100% sensitivity and 98.5% specificity compared to bacterial culture results for the detection of PPNG in clinical specimens. PPNG-PCR false-positive results, presumably due to cross reaction with unrelated bacterial species, were observed in four clinical samples but were distinguished on the basis of late cycle threshold values. A total of 15/423 (3.6%) samples were positive by PPNG-PCR. These data vary from phenotypic surveillance rates for this region (2.5%–2.9%).

Conclusion In tandem with phenotypic surveillance, the PPNG-PCR assay provides enhanced epidemiological surveillance of *N gonorrhoeae* penicillin resistance and is of particular relevance to regions where penicillin is still used to treat gonorrhoea. We are currently evaluating assays targeting NG chromosomally-mediated resistance mechanism to β-lactam antibiotics.

P3-S1.22 EVALUATION OF PERFORMANCE OF SIX COMMERCIAL ASSAYS FOR DETECTION OF CHARACTERISED ISOLATES OF *NEISSERIA GONORRHOEAE* AND OTHER *NEISSERIA SPP.*

doi:10.1136/sextrans-2011-050108.422

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Background Molecular detection of *Neisseria gonorrhoeae* in urogenital samples is now routinely conducted in many diagnostic laboratories with the demand also expanding to testing of extragenital samples. Testing of extragenital samples poses a challenge as it may result in false positive results due to cross-reaction with commensal *Neisseria spp.* and *N meningitidis*. Adequate evaluation of molecular assays is essential prior to expanding utilisation of the assays to such specimens.

Method This study aimed to examine 450 characterised clinical isolates comprising of 216 *N gonorrhoeae* and 234 other *Neisseria spp.* and closely related bacteria from various geographical regions worldwide with six commercial assays including GenProbe APTIMA Combo 2 and APTIMA GC; Roche COBAS Amplicor CT/NG and COBAS 4800 CT/NG; BD ProbeTec GC Qx Amplified DNA Assay and Abbott RealTime CT/NG.

Results Among 216 *N gonorrhoeae* isolates included in the study, all assays except COBAS Amplicor where four (1.9%) gonococcus isolates were not detected, showed a positive result with all *N gonorrhoeae* isolates. Among 234 *Neisseria spp.* evaluated, initial results showed all assays evaluated to display cross reaction with non-gonococcal Neisseria isolates. COBAS Amplicor and ProbeTec showed highest number of false positives, detecting 33 (14.1%) and 26 (11%) non-gonococcal Neisseria isolates respectively. Abbott RealTime, APTIMA Combo and APTIMA GC, and Roche COBAS 4800 showed initially low level of cross reaction, that is, detected 2 (1%), 5 (2.1%), 4 (1.7%) and 2 (1%) of the isolates respectively. When retested by the company using a fresh culture, none of these nine isolates showed cross reaction with the respective assays.

Conclusion COBAS Amplicor and ProbeTec displayed highest number of false positives among assays evaluated, with the remaining assays only showing sporadic low level false positivity. Especially when examining extragenital specimens, supplementary testing for all assays and platforms remains recommended.