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±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.

O3-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. κ 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: ? 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.

O3-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 envelops. 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

tested positive for chlamydia compared to 8 in the Clinic Group, and the rate of reinfection was 12.9% in the Home Group and 14.6% in the Clinic Group (p=0.8).

Conclusions Use of home-based, self-obtained vaginal swabs resulted in a significant increase in rescreening rates compared to rescreening in the clinic. Our findings indicate a role for home-based specimen collection as an alternative to clinic-based rescreening for chlamydia in women.

Clinical sciences oral session 4: Treatment: Chlamydia, Gonorrhoea and related syndromes

03-S4.01 THE NEW SUPERBUG *NEISSERIA GONORRHOEAE* MAKES GONORRHOEA UNTREATABLE?—FIRST HIGH-LEVEL CEFTRIAXONE RESISTANCE WORLDWIDE AND PUBLIC HEALTH IMPORTANCE

doi:10.1136/sextrans-2011-050109.121

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Background The first *Neisseria gonorrhoeae* strain (H041) worldwide that is highly resistant to the extended-spectrum cephalosporin (ESC) ceftriaxone, which is the last remaining option for empirical treatment of gonorrhoea, has now been identified! This is a large public health problem and the era of untreatable gonorrhoea may now have been initiated. The present study completely characterised H041, phenotypically and genetically, to confirm the finding, comprehensively examine its antimicrobial resistance (AMR) and in detail elucidate the resistance mechanisms. Finally, public health actions for preventing and/or detaining global spread of ceftriaxone-resistant and untreatable gonorrhoea will be discussed.

Methods H041 was examined using seven species-confirmatory tests, antibiograms (30 antimicrobials) with Etest and agar dilution (only for ESCs), porB sequencing, *N gonorrhoeae* multi-antigen sequence typing (NG-MAST), multilocus sequence typing (MLST) and sequencing of ESC resistance determinants (penA, mtrR, penB, ponA and pilQ). Transformation, using appropriate recipient strains, was performed to confirm the ESC resistance determinants.

Results H041 was assigned serovar Bpyust, MLST ST7363 and the new NG-MAST ST4220. H041 proved highly resistant to ceftriaxone (2—4 mg/l, which is 4-8-fold higher than any previously described isolate) and all other cephalosporins, as well as most other antimicrobials tested. A new penA mosaic allele, containing only four not previously described amino acid alterations, caused the ceftriaxone resistance, which was all proven using several transformation experiments.

Conclusions The new superbug *N gonorrhoeae* has now developed also ceftriaxone resistance and an era of untreatable gonorrhoea may have been initiated. A reduction in global gonorrhoea burden by enhanced disease control activities combined with wider strategies for general AMR control and enhanced understanding of mechanisms of emergence and spread of AMR, which need to be monitored globally, is crucial. Furthermore, a public health response plan (including sustainable clinical, microbiological and epidemiological components) for a global perspective is essential. Ultimately, new drugs are essential to develop for efficacious gonorrhoea treatment.

03-S4.02 IS SINGLE DOSE AZITHROMYCIN ADEQUATE FOR ASYMPTOMATIC RECTAL CHLAMYDIA?

doi:10.1136/sextrans-2011-050109.122

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Background Azithromycin is the recommended first-line therapy for asymptomatic rectal chlamydia. However a recent European study reported significant numbers of treatment failures, with higher failure rates in HIV positive men. In 2009, the Sydney Sexual Health Centre instituted a 6 week re-test policy for all cases of asymptomatic rectal chlamydia to assess the extent of azithromycin treatment failures.

Methods We conducted a retrospective audit of all men who have sex with men (MSM) diagnosed with asymptomatic rectal chlamydia in 2009. MSM with anal symptoms were excluded from this analysis, due to the possibility of lymphogranuloma venereum. We then categorised the infections present at re-testing as probable re-infections (men reported ongoing sexual activity with an untreated partner) or probable treatment failures (men did not have any obvious ongoing exposure, either because they did not report any further anal sex with any existing partners or because condoms were used consistently with all partners).

Results In the 12-month period there were 116 asymptomatic MSM treated for rectal chlamydia with 1 gram azithromycin as a single dose. Fourteen (12%) of the men were HIV positive. The median age was 33 years (range 20—64 years). Of the 116 men, 85 (73%) returned at varying times; median time of 10 weeks (78 days, range 21—372 days. Of the 85 men who returned, 11 (13%) were persistently positive and the median time to re-test was 11 weeks (78 days, range 47—209 days). Six of the 11 men were classified as probable re-infection and five as probable treatment failures, equating to an efficacy of 94%. None of the men classified as probable treatment failures were HIV positive.

Conclusions Interpreted conservatively, the azithromycin treatment failure rate could have been as high as 13% in our study. However most of these cases could be explained by re-infection suggesting an actual treatment failure rate of 6%. There was no evidence azithromycin is an ineffective first-line therapy for asymptomatic rectal chlamydia in MSM, but prospective studies would be welcome.

03-S4.03 SAFETY AND EFFICACY OF WC2031 VS VIBRAMYCIN FOR THE TREATMENT OF UNCOMPLICATED UROGENITAL *CHLAMYDIA TRACHOMATIS* INFECTION

doi:10.1136/sextrans-2011-050109.123

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Background Recent studies report that treatment failure rates for single-dose azithromycin for urogenital chlamydia in females may be as high as 8%. There has been sparse research investigating new antibiotics for chlamydia, especially those that may reduce adherence difficulties with the CDC recommended doxycycline regimen (100 mg orally twice daily for 7 days).

Methods The safety and efficacy of WC2031 (doxycycline hyclate delayed-release 200 mg tablet) orally once daily for 7 days vs