P3-S1.26 NOVEL *CHLAMYDIA TRACHOMATIS* POINT OF CARE RAPID TEST SHOWS DISAPPOINTINGLY LOW CLINICAL SENSITIVITY IN UROGENITAL *CHLAMYDIA* INFECTIONS IN PARAMARIBO, SURINAME

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Background Affordable and reliable point of care (POC) tests to diagnose urogenital chlamydia infections (POC-Ct) are needed, especially in resource limited settings. WHO has formulated standards that POC tests have to meet. One of those is that the test should be sensitive. Three POC-Ct tests currently on the market all showed poor sensitivity between 12% and 17% in a non-manufacturer sponsored clinical study (van Dommelen 2010). One POC-Ct test evaluated in a manufacturer-sponsored study claims over 80% sensitivity (Mahilum-Tapay 2007). We evaluated the performance of this POC-Ct in two outpatient clinics in Suriname, S.A.

Methods Between July 2009 and February 2010 963 women were included in a high risk STI clinic (n=181) and a low risk birth control clinic (n=782) in Paramaribo, Suriname. Nurse collected vaginal swabs were obtained for the POC-Ct (Diagnostics for the Real World, LTD, Cambridge, UK) and control NAAT (APTIMA Combo 2, Gen-Probe, San Diego, USA) in a cross-over model. Swabs were processed according to the manufacturers instructions. POC-Ct was compared to NAAT and sensitivity, specificity, positive- and negative predictive value (PPV, NPV) were calculated. Quantitative Ct load was determined with a real-time PCR targeting the cryptic plasmid. Ct load was expressed as inclusion forming units (IFU) based on defined serial dilutions. An independent t-test was used to compare log-transformed Ct loads between true positive and false negative POC-Ct results.

Results Ct prevalence, determined by NAAT, was 23% at the high risk STI clinic and 9% at the low risk birth control clinic. Four samples were excluded due to discrepancy in POC-Ct result between two lab technicians (n=3) and failure of POC-Ct (n=1). Performance results of POC-Ct compared to NAAT are shown in Abstract P3-S1.26 table 1. Quantitative Ct bacterial load was 65 times higher when POC-Ct detected Ct infection (geometric mean 115 IFU) compared to loads that POC-Ct did not detect (geometric mean 1.8 IFU, $p<0.001$). Human DNA concentration did not differ between the true positive and false negative POC-Ct results ($p=0.904$). Sensitivity of POC-Ct in samples with low Ct load was 16%.

Abstract P3-S1.26 Table 1 Performance results of POC-Ct compared to NAAT

	NAAT +	NAAT -	Sensitivity	Specificity	PPV	NPV
POC-Ct +	48	30	41.7%	97.6%	61.5%	92.4%
POC-Ct -	67	814				

Conclusion The sensitivity and to a lesser extend the PPV of the POC-Ct did not meet the expectations as described previously (83.5%). The POC-Ct missed samples with a low Ct load. With a sensitivity of 41.7% the Diagnostics of the Real World POC-Ct test does not meet the ASSURED criteria of a sensitive test formulated by the WHO.

P3-S1.27 IS ANTIMICROBIAL RESISTANCE IN *CHLAMYDIA TRACHOMATIS* A REALITY?

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Introduction The use of single dose therapy and the emergence of a stable tetracycline resistant strain of *Chlamydia suis* has raised concerns regarding potential development of antimicrobial resistance (AMR) in *C trachomatis* (CT). Specimens sourced from patients with persistently confirmed CT infections after treatment with first line recommended therapies were examined for the presence of AMR determinants identified in other organisms.

Methods CT DNA positive specimens were examined for viable bacteria by tissue culture. Sequencing for mutations in three genes known to be involved in azithromycin (AZM) AMR; rplV, rplD and 23S rRNA (two alleles) and for the presence of six tetracycline AMR determinants; tet(A), tet(B), tet(C), tet(D), tet(E) and tet(M) was done. Susceptibility testing was performed using isolates grown in duplicate serial dilutions of AZM followed by quantitative RT-PCR. Isolates with a log or more increase in plasmid copy number were deemed resistant and those with a static or decreased copy number were deemed sensitive. Isolates were also screened for contaminating bacteria.

Results Nine isolates were retrieved from twenty CT NAAT positive patients. When examined by AZM MIC assays, all isolates were sensitive. An identical non-silent single nucleotide polymorphism (SNP) was identified in three clinical specimens and one isolate from three patients in the rplD gene. A non-silent SNP was also identified in the rplV gene in one of these patients. The pre and post treatment specimen from a further patient showed a non-silent SNP in the rplD gene and identical point mutations in both alleles of the 23S rRNA gene. The tet(M) resistance determinant was identified in ten specimens and five isolates from eleven different patients. All screens for contaminating bacteria were negative.

Conclusions Previously unreported mutations in genes responsible for AZM AMR in other organisms have been identified however all isolates were found to be AZM sensitive. Whilst the SNPs identified may not be significant, detection of them demonstrates that CT has undergone mutation in these key genes. A fragment of the tetracycline AMR determinant, tet(M) (responsible for high level tetracycline AMR in *Neisseria gonorrhoeae*), was identified in several clinical specimens and in five isolates. The function of the tet(M) fragment in CT is currently unknown and the establishment of tetracycline MIC assays are a priority.

P3-S1.28 IS URETHRITIS OF UNKNOWN AETIOLOGY CAUSED BY BACTERIA ASSOCIATED WITH BACTERIAL VAGINOSIS?

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Background The aetiology of non-gonococcal urethritis (NGU) in men is unknown in 30%–50% of cases. Little is known about the relation of bacterial vaginosis (BV) associated bacteria in men with urethritis of unknown aetiology (UUE). Urethral swabs from men with and without NGU were analysed with PCR for BV associated bacteria to show a possible association with UUE.

Methods Urethral swabs from 9 and 19 men with symptomatic and asymptomatic NGU (>5 PMNL/hpf), respectively, and 30 asymptomatic men without NGU were collected. All samples were negative for *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Mycoplasma genitalium*, *Ureaplasma urealyticum* and *U parvum* with specific PCR assays. Quantitative real-time PCR with TaqMan based assays were

performed to detect *Atopobium vaginae* (Av), *Sneathia sanguinegens* (Ss), *Leptotrichia amnionii* (La) and *Gardnerella vaginalis* (Gv), and with SYBR green assays for BVAB 1, 2 and 3, and *Megasphaera* phylotype 1 (M1).

Results Gv was detected in 93% of cases with UUE and in 37% of controls ($p < 0.0001$). There was no difference in organism load. In the 28 NGU cases Av, Ss and La were found in 3, 2 and 1 samples, respectively, and in 6, 2 and 1 of the control samples, respectively. The median corresponding organism loads were 14, 95 and 51 for the NGU cases and 16, 10 566 and 353 for the controls. All samples were negative for BVAB 1, 2 and 3 and M1, except one control with 10 genome copies of BVAB 1.

Conclusions *Gardnerella vaginalis* was associated with male urethritis in this study, especially in men with asymptomatic urethritis, while BVAB 1, 2 and 3, *Megasphaera* phylotype 1, *Atopobium vaginae*, *Sneathia sanguinegens*, and *Leptotrichia amnionii* were not.

P3-S1.29 EFFECTIVENESS OF GENTAMICIN FOR GONORRHOEA TREATMENT: A SYSTEMATIC REVIEW

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Background The development of resistance to multiple antimicrobials has limited treatment options for gonorrhoea. Potential emergence of cephalosporin resistance in *Neisseria gonorrhoeae* and cephalosporin allergy in some patients make it necessary to evaluate the effectiveness of other available antimicrobials. Gentamicin is widely available in the USA and is used for gonorrhoea treatment in several countries.

Methods We conducted a systematic review of the medical literature to assess the effectiveness of gentamicin for treatment of uncomplicated urogenital gonococcal infections. Two reviewers assessed relevant articles and independently selected studies that met pre-specified selection criteria (including systematic enrolment and assignment to treatment and culture-confirmed diagnosis and outcome). Summary measures for selected studies were pooled using inverse variance-weighted averages with fixed effects. Heterogeneity was assessed using I-squared, which estimates proportion (from 0% to 100%) of variability attributable to heterogeneity between studies. Pooled percentage with negative follow-up culture was compared with CDC criteria for selection of recommended therapy (>95% efficacy with lower 95% CI >95%).

Results 18 potentially relevant English-language studies were identified; three met inclusion criteria. Reviewer agreement for initial judgement on meeting selection criteria was substantial (κ 0.68). Two studies used 240 mg, and one study used 280 mg IM gentamicin. Percentages with negative culture after single-dose treatment were 90.7% (n=86), 91.4% (n=220), and 95.0% (n=40). Pooled percentage with negative culture after single-dose treatment was 91.5% (95% CI 88.1% to 94.0%, I-squared = 0%).

Conclusions Gentamicin does not meet current CDC criteria for recommended treatment of gonorrhoea. However, if cephalosporin resistance emerges, gentamicin may be a useful alternative agent. Evaluation of additional regimens, including combination therapy, is warranted.

P3-S1.30 SUCCESSFUL USE OF NON-INVASIVE SELF OBTAINED GLANS/MEATAL DRY FLOQSWABS (COPAN) FOR CT/NG DETECTION WITH THE BD PROBETEC ET ASSAY IN NORTHERN ITALY

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Background Increasing *Chlamydia trachomatis* (CT) rates and ever-present *Neisseria gonorrhoeae* (NG) infections worldwide in women

have led to the consideration of targeted male CT/NG screening programs in order to address the male reservoir. Effortlessly collected, non-invasive, painless, dry, self-obtained male swab specimens that are stable and easy to transport would enhance the success of male screening programs. We undertook a study to compare the results of self obtained glans/meatal swab (SOGS) (COPAN FLOQSwabs) specimens with conventional first catch urine (FCU) specimens. The aim of the study was simply to assess the usefulness of a SOGS specimen when compared to FCU given the SOGS specimen's ease of collection, ease of use and handling in challenged venues (ie, without toilet facilities), and ease of transport.

Methods 122 male patients attending an STD clinic and males incarcerated near the Italian city of Asti were tested for CT and NG using a SOGS. Patients were verbally instructed and shown a drawing to enhance standardised self-collection. A FCU specimen was also collected. SOGS and FCU specimens were then processed according to the manufacturer's recommended procedure using the BD ProbeTec ET system (Becton Dickinson and Company).

Results There were a total of 16 specimens detected positive for either CT or NG. Seven men were infected by both CT and NG. The CT prevalence was 5.7%. The NG prevalence was 13.1%. There was an overall SOGS specimen agreement of 97.5% when compared to FCU specimen results.

Conclusions High agreement was obtained with the self obtained glans/meatal COPAN FLOQSwabs when compared to standard FCU specimens. These results indicate that self obtained glans/meatal swab specimens are a viable specimen choice. Dry self obtained glans/meatal swab specimens with FLOQSwabs were easy to collect, transport and test using the BD ProbeTec ET system. The BD ProbeTec ET system showed high agreement when testing both of these specimen types. Simpler methods of collection and transport that produce reliable test results may increase the potential for screening difficult to test male populations, especially those who never test.

P3-S1.31 COMPARISON OF COPAN URISWAB WITH BD PROBETEC URINE PRESERVATIVE TRANSPORT KIT FOR PRESERVATION AND DETECTION OF CT AND NG IN THE PROBETEC ASSAY

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Background Urine specimen collection is better accepted by the patients than invasive collection techniques for detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG). Self-collection is useful for Sexually Transmitted Infection (STI) screening programs. Dedicated urine collection devices for molecular assay are unsuitable for other molecular assays and for bacteria culture investigation. Urine collection devices that are easy to collect and transport and are leak proof, that can be used for STD screening by culture and molecular assays are essential. Copan has introduced the UriSwab (US), that consists of a leak proof tube with a screw cap containing a plastic stick with sponges attached that absorb and retain the urine sample during transport while preventing bacterial overgrowth. The objective of this study was to compare the Copan UriSwab for collection, transportation and preservation of first catch urine (FCU) specimens to the BD ProbeTec Urine Preservative Transport Kit (UPT) for the detection of CT and NG with the BD ProbeTec assay.

Method FCU specimens were self-collected from 134 male patients attending an STD clinic or who were residents of a detention center in the Italian city of Asti. Duplicate FCU specimens were collected, one with the US and the other with the UPT. The US specimens were centrifuged and the urine pellets were eluted with