**Objectives** Neisseria gonorrhoeae (NG) and Chlamydia trachomatis (CT) are sexually transmitted infections (STIs). Most infections are asymptomatic, representing an important reservoir for transmission. Without treatment, complications such as infertility may occur. Moreover, 33% of CT/NG co-infection rate has been reported. Since 2010, combined screening of CT and NG by PCR in asymptomatic population has been recommended by the French Health Authority. Thus, the aim of this study was to assess the interest of the new Cepheid Xpert® CT/NG Assay, a real-time PCR test for the automated and rapid detection and differentiation of CT and NG genomic DNA, in population with systematically screening such as induced abortion.
**Methods** Between July and November 2012, 634 urogenital samples were received in our laboratory to detect CT and/or NG infections with the Xpert CT/NG assay.
**Results** Of the 634 samples included in this study, 61 (9.6%) were CT positive, 19 (2.9%) were NG positive. Among the 61 CT positives, 10 (1.6%) were positive for both CT and NG. Concerning the 177 samples performed in case of induced abortion, 27 (15.3%) were CT positive, 9 (5.1%) were NG positive and 5 (2.8%) were positive for both pathogens.
**Conclusion** The results revealed a global prevalence (9.6%) of CT infections, this percentage being higher in women screened for induced abortion. Although, many clinicians tend to only request testing for CT, our results demonstrate the value of the detection of both CT and NG by Xpert CT/NG. This new test allows a more rapid, accurate detection and optimises the management of STIs by clinicians. Finally, the screening of asymptomatic population helps also to reduce the transmission and is a more cost effectiveness alternative in screening settings.

## P2.012 CLINICAL CARE PATHWAYS USING CHLAMYDIA AND GONORRHOEA TESTS ARE EVOLVING: POINT OF CARE NUCLEIC ACID AMPLIFICATION TESTS MAY REDUCE GENITOURINARY MEDICINE SERVICE DELIVERY COSTS

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**Background** We aimed to explore new patient pathways using a chlamydia/gonorrhoea (CT/NG) point of care nucleic acid amplification tests (POC NAAT), and estimate and compare the costs of the new pathways to the current pathways using standard laboratory-based NAAT testing.
**Methods** A qualitative and quantitative approach was used. Focus groups were conducted with four sexual health clinics in the UK. They mapped out current pathways in which a CT/NG test was used, and then constructed new pathways using a POC NAAT. These pathways were then costed using a model built in Excel, and the cost of the current and POC NAAT pathways compared.
**Results** Pathways using a POC NAAT for asymptomatic and symptomatic patients and CT/NG only tests were shorter and less expensive than most of the current pathways (average savings of £6–8 per pathway if the POCT costs £18 per test). Clinicians identified several potential benefits to introducing the test including faster time to treatment, more accurate diagnosis of symptomatic patients, and therefore less syndromic management, which is likely to result in better care for patients. Several theoretical risks and limitations were identified in the workshops although these were not assessed in the study.
**Conclusion** A point of care test could be introduced to services and reduce current costs, and may mean more appropriate and quicker care for positive patients.

## P2.013 LYMPHOGRANULOMA VENEREUM CASES IDENTIFIED IN PATIENTS ATTENDING A STD OUTPATIENTS CLINIC IN ITALY

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**Background** Lymphogranuloma venereum (LGV) is a systemic sexually transmitted infection caused by *Chlamydia trachomatis* (CT) serovars L1-L3. In the recent outbreaks the classic clinical presentation with inguinal syndrome is giving way to anorectal primitive syndrome in men having sex with men (MSM). Here we report about 6 cases of LGV identified during 2012.
**Methods** A prospective study was performed with 78 rectal specimens obtained from MSM attending the STD Outpatients Clinic of S. Orsola Hospital, Bologna. All the patients were enrolled because having unsafe receptive anal sex intercourses. Samples were tested by Versant CT/GC DNA 1.0 (Siemens). Genotyping was performed with RFLP method for *ompl* gene, using *AluI* and *DdeI* as restriction enzymes.
**Results** We found a total of 11 rectal swabs positive for CT. RFLP analysis showed 6 L2 genotypes and 5 non-LGV genotypes (3 were E, and the others H and J).

The five non-LGV infected patients showed no symptoms. On the contrary, at the enrollment perianal ulcers, proctitis and painful lymphadenopathy were found in three LGV cases, whereas perianal ulcers and proctitis in the remaining three ones.

Before the correct diagnosis the patients had been investigated for several months for a broad range of other conditions, including traumatic warts, and/or gastroenteric syndromes. Three patients had undergone endoscopic procedures and ultrasound scans.

All the LGV cases presented at least one more sexually transmitted infection. Treatment with doxycycline (100 mg b.i.d. for 21 days) was successful. At control, case 1 had a positive result for *Neisseria gonorrhoeae* in his rectal swab, thus demonstrating his high risk sexual behaviour.
**Conclusion** A firm diagnosis and early treatment of LGV can prevent the development of serious sequelae. Since the ulcerative nature of LGV may facilitate transmission and acquisition of other STDs, enhanced surveillance systems and strengthened case ascertainment would be desirable.

## P2.014 DEVELOPMENT AND ANALYTICAL PERFORMANCE OF NEW CT/NG NUCLEIC ACID AMPLIFIED TEST (NAAT)

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**Background** Moderately complex NAATs that can provide fast, actionable results could reduce the burden of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) infections. The Xpert® CT/NG Assay is a recently FDA-cleared, moderately complex assay for the detection of CT and NG in patient collected vaginal swabs, endocervical swabs, and male and female urines with a turnaround time of 87 minutes.
**Methods** Primers and probes were designed against specific CT and NG candidate genomic targets and screened for exclusivity with genomic DNA extracted from non-trachomal Chlamydia/Chlamydophila and non-gonococcal Neisseria species. For inclusivity, genomic DNA extracted from the 15 CT serovars and 230 geographically diverse NG strains was used. A multiplex assay, running on the GeneXpert platform, was designed to detect one CT target, two independent unique NG targets and two control targets. Analytical reactivity and specificity were determined by testing whole

organisms. Analytical sensitivity was determined using titered, purified CT elementary bodies and cultured NG cells.

**Results** The Xpert CT/NG assay detects all CT serovars, new variant CT, and 48 geographically diverse NG strains.

The CT primers and probes do not cross-react with DNA or RNA from non-trachomal species. All non-gonococcal *Neisseria* species yielded negative results, including N. mucosa and N. cinerea, because both NG targets must be PCR positive for a "NG DETECTED" result.

The LoDs for the Xpert CT/NG Assay for CT serovar D in male urine and vaginal swab matrix respectively were 75 and 84 Eb/mL; for CT serovar H, LoDs were 134 and 161 Eb/mL. In both matrices, the LoD for two NG strains was approximately 2 cfu/mL.

**Conclusion** The Xpert CT/NG assay is highly specific and sensitive. The ease of use and fast time to result could lead to reduced time to treatment of CT and NG infections.

## P2.015 EVALUATION OF THE TRIPLEX REAL-TIME PCR ASSAY FOR DETECTION OF CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE IN URINE AND VAGINAL SWABS

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**Background** Chlamydia trachomatis and Neisseria gonorrhoeae are among the most common causes of sexually transmitted bacterial infections worldwide. Infection with these organisms is mostly asymptomatic, however serious complications are also observed. Screening of the diseases is necessary to identify, treat and control the infection. In this study, we evaluated the performance of the triplex real-time PCR assay with internal control for detection of C. trachomatis and N. gonorrhoeae infections in urine and vaginal swabs.

**Methods** The performance of TaqMan probe-based triplex real time PCR targeting the cryptic plasmids of C. trachomatis (pCHL1) and N. gonorrhoeae (pJD1) and beta-globin gene as an internal control was assessed using 188 urine specimens and 118 vaginal swabs. The triplex real time PCR was compared with the Roche COBAS AMPLICOR CT/NG assay. The urine specimens were further tested using real-time PCR targeting the N. gonorrhoeae porA pseudogene.

**Results** For urine specimens, the sensitivity and specificity of the triplex real time PCR were 100% and 97.6%, respectively, for C. trachomatis, and 100% and 95.2%, respectively, for N. gonorrhoeae. For vaginal swabs, the sensitivity and specificity were 100% and 100%, respectively, for C. trachomatis, and 100% and 98.1%, respectively, for N. gonorrhoeae. There were 5 (2.84%) from 176 urine specimens that were negative for cryptic plasmid, but positive for N. gonorrhoeae porA pseudogene.

**Conclusion** The performance of the triplex real time PCR assay was comparable to that of the Roche COBAS AMPLICOR CT/NG assay. This assay is easy to perform and the results can be achieved in 3–4 hours, including sample preparation. The estimated cost of triplex real time PCR was less than 20 USD. Taken together with using non-invasive urine sampling, this assay is convenient and suitable for epidemiological studies in screening large number of samples.

## P2.016 COMPARISON OF THREE REAL-TIME PCR TESTS FOR THE DETECTION OF CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE IN YOUNG PREGNANT WOMEN

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At the Bordeaux University Hospital, among pregnant women aged less than 25 years-old the prevalence of C. trachomatis (CT) and N. gonorrhoeae (NG) is 12.5% and 2.4%, respectively for those requesting abortion by using the Abbott m2000 CT/NG test, and 7.9% and 0%, respectively, for those consulting for monitoring pregnancy by using the Roche Cobas 4800 CT/NG test.

The objective of this study was to evaluate and compare the performances of both of these tests along with a third one, the Cepheid GeneXpert CT/NG, for the detection of CT and NG in vaginal swabs collected from pregnant women consulting for abortion or for monitoring pregnancy. A patient was considered infected if at least two tests were positive.

Among 304 pregnant women included, from September 2012 to January 2013, 34 were infected, leading a prevalence of 11.7% (26/222) for patients requesting abortion and 9.7% (8/82) for patients consulting for monitoring pregnancy. There were two false CT-positive results with the Abbott m2000, one false negative result reported by Roche and the Cepheid GeneXpert. The sensitivity and specificity were 97% and 100% for the Roche and the Cepheid GeneXpert tests, and 100% and 99.3% for the Abbott assay. The positive predictive value ranged from 94.4% to 100% according to the test.

For NG, 297 specimens were negative and 7 were positive using the three tests. All results were concordant, leading to a sensitivity and specificity of 100% for all the assays. The prevalence of NG among pregnant women requesting abortion was 2.7% (6/222) and 1.2% (1/82) for those consulting for monitoring pregnancy.

In the populations studied, all three assays have similar performances for CT/NG detection.

## P2.017 CLINICAL EVALUATION OF THE PELVOCHECK® CT/NG FOR THE DETECTION OF CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE

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**Background** In the present study the performance of the PelvoCheck® CT/NG, a microarray-based nucleic acid amplification assay for the detection of Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG), was evaluated in single and pooled urine specimen of young women.

**Methods** A total of 1649 female urine specimens were collected and examined for urogenital chlamydia infections. Because of a low prevalence (2.12%), 50 CT-negative urine specimens were enriched with CT reference material mimicking the natural chlamydial distribution in female urine. The results were compared to those of the Roche COBAS® TaqMan® CT assay as the first and the Abbott RealTime CT/NG assay as the second reference method.

Similarly, NG pre-screened female urine specimens (60 NG-positive and 60 NG-negative specimens) were analysed with the PelvoCheck® CT/NG test and compared to a validated in-house Q-PCR method and the Abbott RealTime CT/NG assay.

Furthermore, the PelvoCheck® CT/NG assay was tested for pooled urine specimens (52 CT-negative and 55 CT-positive specimens). Each pool consisted of either five individual CT-negative specimens or four CT-negative and one CT-positive individual specimens.

**Results** For the detection of CT the overall positive agreement (sensitivity) and overall negative agreement (specificity) of the PelvoCheck® CT/NG were 98.8% and 100%, for the detection of NG 98.3% and 98.2%, respectively.

The comparison of data obtained with the PelvoCheck® CT/NG for pooled urine specimens resulted in a positive agreement of 90.9% and a negative agreement of 100%. Four CT-positive pooled specimens with final CT-concentrations of 0.05 – 0.13 IFU/ml were not detected.