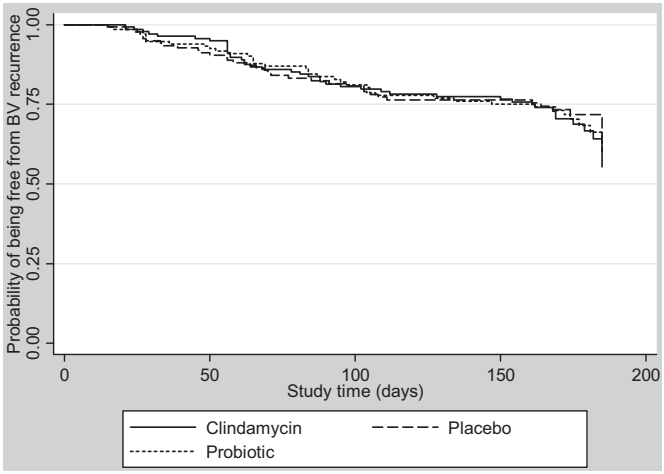
participant demographic or behavioural characteristics between arms. Adherence to study medication did not differ between arms: 382 (91%) took all or most oral metronidazole and 330 (80%) all or most vaginal therapy. Retention rates were high, with 77 (17%) lost to follow-up over 6 months, and did not differ between arms. Participants contributed 153.7 person years of follow-up to analyses. On exit survey 88% of participants did not know or correctly guess the vaginal therapy they had received. Six month cumulative BV recurrence rates did not differ between study arms by per protocol analysis: MetPlac (32%, 95% CI 24% to 41%) MetProb (33%, 25% to 42%) and MetClin (34%, 26% to 42%), p>0.05 (Abstract O3-S5.06 figure 1), or intention-to-treat analysis (noncompleter=recurrence) [recurrence range 44-9%].




Abstract O3-S5.06 Figure 1

**Conclusions** The addition of vaginal clindamycin or a vaginal probiotic to oral metronidazole does not improve 6 month BV recurrence rates. This is the first RCT to evaluate the efficacy of combination clindamycin/metronidazole for BV treatment, and has important implications for clinical practice. Combination therapy is often used in patients with recurrent BV, but evidence to support this practice has not been available.

# Clinical sciences oral session 6—clinical advances in diagnosis & screening

## O3-S6.01 IMPROVED DIAGNOSTICS OF BACTERIAL VAGINOSIS WITH MOLECULAR TECHNIQUES

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**Background** *Bacterial vaginosis* (BV) is a disturbance of the vaginal microflora. BV can cause discharge complaints and lead to pelvic inflammatory disease, ectopic pregnancy and premature birth. We evaluated a combination of PCR assay's and whole bacterial community analysis with the standard diagnostic algorithm to validate a molecular assay for the determination of BV.

**Methods** 160 women with vaginal discharge complaints were included. 80 women were classified as BV and 80 as non-BV according to Amsel criteria. Gram stains from vaginal smears were made for Nugent scoring. Vaginal swabs were tested with PCR assays for *Gardnerella vaginalis*, *Atopobium vaginae*, BV associated bacterium type 2 (BVAB2) and Megaspheara type 1 (MS1). Whole bacterial community analysis was performed by fluorescent Terminal Restriction Fragment Length polymorphism (TRFLP) of 16S-rDNA. TRFLP patterns and predictive fragments of a number of BV associated bacteria were analysed with Bionumerics software (Applied Maths, Belgium).

**Results** Compared to Amsel criteria, the highest sensitivity of 100% was achieved with a duplex PCR for G. vaginalis and/or *A vaginae* and the highest specificity of 86% was found with a singleplex BVAB2 specific PCR. Best overall performance was shown using a duplex real time PCR for BVAB2 and/or MS1 with a sensitivity of 90% and a specificity of 78% with respect to Amsel criteria. Using Nugent criteria as a standard, this duplex PCR has a sensitivity of 84% and specificity of 86%. From TRFLP results, the presence of predictive fragments of *Prevotella, Aerococcus, Megaspheara, Mycoplasma, Peptostreptococcus, Leptotrichia, Eggerthella, Gardnerella, Atopobium* and *Dialister* was most associated with BV positive samples. Cluster analysis of microbial profiles revealed clear differences between BV and non-BV and indicated possible intermediate or transition stages.

**Conclusions** A combination of bacterial species are involved in BV. For molecular diagnostics a duplex PCR of Gardnerella en/of Atopobium can be used for initial screening confirmed by a BVAB2 specific PCR. A more effective alternative is a real time duplex PCR targeting BVAB2 and/or MS1. Microbial profiling supports most targets used in the PCR assays. Cluster analysis of microbial profiles can be used to interpret discordant validation results and possibly for diagnosis.

## O3-S6.02 SCREENING FOR *MYCOPLASMA GENITALIUM*, *CHLAMYDIA TRACHOMATIS* AND *BACTERIAL VAGINOSIS* IN A PUBLIC HOSPITAL, PREGNANCY TERMINATION SERVICE

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Garland SM1, Marceglia AH2, Tabrizi SN1Costa AM1 1 Microbiology Infectious Diseases, 2 Choices and Sexual Health Service, Royal Women's Hospital, Parkville, Victoria, Australia The Royal Women's Hospital is the largest public provider of therapeutic abortions in Victoria, Australia. Prior to their medical or surgical termination, all women presenting to the Pregnancy Advisory Service (PAS) have been screened for *Mycoplasma genitalium* utilising an in-house PCR assay 1 in addition to *Chlamydia trachomatis* using a commercial PCR and bacterial vaginosis (BV) by Gram stained smear of posterior fornix secretions. From August 2009 to December 2010, the prevalence for *M genitalium* was 4.6% (CI 3.5% to 5.6%), *C trachomatis* 5.3% (CI 4.2% to 6.4%) and BV 16.2% (CI 14.4% to 18.0%). Most women had a normal genital tract on clinical examination. Of the women infected with *C trachomatis* and *M genitalium*, 42% and 34% respectively had abnormal genital tract signs. The average age of women attending the PAS clinic was 26.4 years, with 45.3% of the women being under 25. The average age for women with *M genitalium* was 24.6 years, whilst for those with *C trachomatis* it was 22.4 years. The 50 test of cures completed after treatment for *M genitalium* to date have all been negative. This is in contrast to local treatment failure rates in similar aged males (symptomatic with nonspecific urethritis in a sexual health clinic) and females (screening within a general practitioner setting) of 28% and a population treatment failure rate of 12%. We are uncertain what role our direct observed patient treatment plays in this low failure rate. This presentation will report on the first 17 months of screening for *M genitalium* in the PAS clinic and its implications for service provision within The Women's. Given the role of *M genitalium* in cervicitis, and the increasing evidence for its role in upper

genital tract disease, screening for this bacterium should be considered, particularly with a surgical procedure such as termination of pregnancy, although the lack of a commercial test is problematic.

## O3-S6.03 THE DIAGNOSIS OF LYMPHOGRANULOMA VENEREUM AT ONE'S FINGERTIPS

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**Background** Outbreaks of Lymphogranuloma venereum (LGV) in sexual networks of men who have sex with men (MSM) are reported in several countries in Europe. Although accurate laboratory diagnosis is required to provide adequate patient management, the laboratory identification of LGV can be problematic.
**Objective** To establish a fast and reliable testing algorithm for the identification of *Chlamydia trachomatis* L serovars.
**Methods** Previously, anal specimens from MSM suspected to be positive for *C trachomatis* were tested with a testing algorithm using commercial molecular amplification assays. Confirmed *C trachomatis* samples were then analysed in batches by RFLP to identify the L serovars. From September 2010 onwards, the Abbott CT/NG Real Time PCR has been used for the detection of *C trachomatis* in biological specimens collected at or referred to the ITM for Chlamydial infection diagnosis. Furthermore, confirmation of *C trachomatis* and identification of the L serovar types are performed with an in-house Real Time PCR assay. This assay uses DNA extract obtained with the Abbott assay. The selection of the primers and test procedure is based on the publication by Chen et al. and includes two specific probes for the detection of the L and the non L serovars.
**Results** Out of a total of 940 samples tested with the new methods, we detected 58 (6.2%) positive samples for *C trachomatis* and of those 12 (20.7%) were L serovars. Eight were detected in specimens collected from the anus, two in urethral specimens, one in urine, and one in a vaginal specimen. All non vaginal specimens were collected from men. With the Abbott CT/NG Real Time PCR for screening and the in house RT PCR assay for confirmation, we were able to confirm positive results for *C trachomatis* and to distinguish the L serovar from the non L serovar types within 2 days after specimen reception. In addition the in house RT PCR assay was more sensitive, more discriminative and at least 4 times cheaper compared to the RFLP method.
**Conclusion** The detection of L serovar of *C trachomatis* can be done on a routine basis at a very acceptable cost and test around time. The L serovar types may be more frequent in Belgium then initially thought, they are present in various biological specimens and possibly in women.

Abstract O3-S6.03 Table 1 LGVV Testing

| Year | specimens tested* | L serovar | non L serovar | not typable |
|---|---|---|---|---|
| 2011 January | 196 | 4 | 11 | 0 |
| 2010 Sept-Dec | 744 | 8 | 35 | 0 |
| 2010 Jan-Aug | 23 | 14 | 9 | 0 |
| 2009 | 23 | 17 | 5 | 1 |
| 2008 | 13 | 11† | 1 | 1 |
| 2007 | 19 | 13 | 5 | 1 |
| 2006 | 14 | 7 | 4 | 3 |
| 2005 | 6 | 2 | 1 | 3 |
| 2004 | 11 | 8 | 2 | 1 |

*Until September 2010 only male anal specimens or rectal biopsies were tested except for 2008 when 2 specimens from penile ulcers were tested.
†Two penile ulcer specimens.

## O3-S6.04 MULTI-SITE SCREENING FOR LYMPHOGRANULOMA VENEREUM (LGV) IN THE USA

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**Background** Lymphogranuloma venereum is a clinical condition caused by infection with one of the *Chlamydia trachomatis* (CT) L serovars. Proper diagnosis of LGV is critical as the treatment varies significantly from antibiotic therapy utilised for other CT infections. LGV has re-emerged in Europe as an important sexually transmitted infection (STI), particularly in men who have sex with men (MSM), due to an outbreak in the Netherlands. LGV surveillance data for the USA is lacking as LGV screening is not routinely performed, even in high risk populations. This study presents LGV surveillance data from multiple sites in the USA.
**Methods** 1671 rectal samples from African-American MSM participating in a study of the HIV Prevention Trials Network (HPTN 061) BROTHERS Project, were collected from six different cities: Los Angeles and San Francisco CA, Atlanta, GA, Boston MA, Washington D.C., New York, NY; and tested for CT by Aptima Combo 2 (Gen-Probe). Additionally, 127 samples from men from Baltimore, MD who reported anal sex or were symptomatic for CT, and had rectal swabs positive for CT by Combo 2 were also included. All samples were screened for LGV utilising a previously verified LGV specific real-time PCR to determine if the samples were positive for any one of the CT L serovars.
**Results** Of the 1671 HPTN 061 samples, 112 (6.75%) were positive for CT and 102 of these have been screened thus far for LGV; none were LGV+. Of 127 CT+ samples from Baltimore, two were LGV+. Thus, of 229 CT+ rectal samples, only 2 (0.87%), tested positive for LGV by real-time PCR.
**Conclusions** Less than 1% of the CT positive samples obtained from rectal swabs from MSM in the US tested positive for LGV. The samples utilised for this study were from a population presumably at high risk for acquisition of LGV, as all samples tested were from men who had either tested positive for CT, reported anal sex, or were symptomatic for CT infection. The prevalence for LGV in this study was quite low, while the non LGV CT prevalence was high in African American MSM from the six cities. Concomitant STDs are thought to drive the disproportionate HIV epidemic among African American MSM and the low prevalence of LGV in this study is of interest. LGV has re-emerged as an important STI in Europe, however this data suggests that it has either not re-emerged in the U.S. or has re-emerged in a population that is not being screened.

## O3-S6.05 PERCEPTIONS ON POINT-OF-CARE TESTS FOR SEXUALLY TRANSMITTED INFECTIONS-disconnect between frontline clinicians and professionals in industry

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**Background** Some recently developed or available sexually transmitted infection (STI) point-of-care tests (POCTs) are not very accurate and are not feasible for use in clinical settings. We conducted a study to determine if a gap exists between STI clinicians/academic experts and industry professionals regarding perceptions of the ideal types and characteristics of STI POCTs.
**Methods** Our online survey design informed by a large-scale focus group study among STI professionals contained sections on