- Symptomatic genitourinary medicine (GUM)
- Asymptomatic GUM
- Symptomatic primary care
- Asymptomatic primary care

**Methods** The Aptima TV NAAT test was performed on 9241 samples from women undergoing chlamydia and gonorrhoea NAAT testing in GUM and primary care.

Results The positivity of TV determined by TV NAAT was 4.8% (26/543) and 1.8% (28/1593) in women with and without symptoms attending GUM and 2.7% (95/3512) and 1.1% (41/3593) respectively in primary care. TV positivity rates were high, as expected, in those of black ethnicity attending GUM (15.5% in those with symptoms). However TV positivity rates in primary care varied by practice (0–5.8%) in a way that could not be attributed to ethnicity alone.

Conclusion This is the first study to report TV positivity, using a TV NAAT, in unselected women presenting for STI testing in primary care. Positivity proportions were higher than anticipated based on conventional testing methods particularly for symptomatic women in primary care. In view of the wide variation in TV positivity by locality, other factors e.g. deprivation may be important. This should be taken into consideration should targeted testing for TV be found to be cost effective, as targeting by ethnicity alone may miss cases.

Disclosure of interest statement Hologic provided the tests for the Aptima TV NAAT research study and have sponsored the authors to present this data at ISSTDR.

## 010.2 TRICHOMONAS VAGINALIS NUCLEIC ACID CLEARANCE FOLLOWING TREATMENT OF HIV NEGATIVE WOMEN

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Background Rescreening women for *Trichomonas vaginalis* (TV) post treatment is important as repeat infections are common, ranging from 5%–31%. Nucleic acid amplification testing (NAAT) too soon after treatment may result in false positive results due to detection of remnant TV nucleic acids. The goal of this study was to determine the rate of false positive NAAT results at weeks 1–4 post treatment completion using culture as the gold standard.

Methods Women attending an STI clinic in New Orleans who were InPouch culture positive and treated with metronidazole (MTZ) were included. Participants were scheduled for 4 weekly follow up visits beginning one week post-treatment completion. They provided self-obtained vaginal swabs (SOVS) and information regarding sexual exposure at each visit. SOVS were tested using InPouch culture and the Gen-Probe AptimaTV (GPATV) assay which targets ribosomal RNA. Women who were culture positive at follow-up were considered re-infected/treatment failure and were not followed further.

Results 39 women were InPouch+ at baseline and were followed. Of these, 3 (7.7%) were InPouch TV+ at follow-up (1 at 1 week and 2 at 2 weeks) and reported no sexual exposure. Thus, these women were considered to be treatment failures and were no longer followed. Of the remaining cases, 5/29 (17.2%) were GPATV+ at the 1 week follow up visit, and 1/34 (2.9%) was GPATV+ at 2 weeks. The six positive women denied vaginal sexual re-exposure. None of the women were InPouch TV culture positive at any of the follow up visits and no woman was GPATV+ at 3 and 4 weeks post treatment.

Conclusions These data demonstrate that TV ribosomal RNA is cleared from the vagina by 3 weeks post completion of successful MTZ treatment and that the GPATV assay can be relied on as a test-of-cure at this point and beyond.

Disclosure Drs Martin and Taylor have served as consultants for Hologic Inc.

010.3

LOW EFFECTIVENESS OF SYNDROMIC DISEASES
MANAGEMENT IN WOMEN INFECTED WITH
CHLAMYDIA TRACHOMATIS, TRICHOMONAS VAGINALIS
AND NEISSERIA GONORRHOEAE LEADS IN DELHI INDIA

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Introduction Besides a range of effective diagnostic tests and treatments, the extent of Sexually transmitted diseases (STDs) epidemic remains challenging. STDs are associated with enormous physical, psychological and economical consequences on the population of developing countries. World Health Organization emphasises on the syndromic approach, especially in areas having inadequate laboratory and transport facilities. Chlamydia trachomatis (CT), Trichomonas vaginalis (TV) and Neisseria gonorrhoeae (NG) are the most common STIs worldwide. They present similar clinical spectra in both women and men and are the leading cause of acquired infertility in women.

Methods In this prospective study (from June 2012 to Feb 2015), the accuracy and performance of syndromic treatment given at Safdarjung hospital, as per NACO-NACP III Syndromic diagnosis of STI/RTI and treatment guidelines (Provision of directly observed therapy for single-dose regimes) were validated by comparing the diagnosis carried out by PCR based assay.

Results Out of 6000 visited patients, 820 female patients (14%) had vaginal discharge syndrome and given treatment as per NACO guidelines; using Kit-I, Grey Kit (UD, ARD, Cervivitis), Kit-II, Green Kit (Vaginitis) and Kit-VI, Yellow Kit (LAP). Out of 824, 634 (77%) patients were enrolled in this study. Based on syndromic management 20%, 0.5%, 46%, pateints were infected with CT, NG, TV respectively. Co-infections were common: 7%, 11%, 12%, with CT+TV, CT+NG, NG+TV, CT+NG+TV respectively. However, with Specific PCR assays, out of 634, 110 (17%) were positive and 524 (83%) patient were negative and/or positive for other STDs. Out of 110 patients, 7%, 5%, 2%, were CT, NG, TV infected while 1%, 2%, 1%, were co-infected with CT+TV, CT+NG, CT+NG+TV respectively.

Conclusion Our results provide evidence that, symptom based disease management leads to inaccurate diagnosis and over treatment of patients resulting in huge economic wastage and may also contribute towards the development of drug-resistance.

010.4

PERFORMANCE OF SELF-COLLECTED PENILE SWABS FOR THE DETECTION OF CHLAMYDIA TRACHOMATIS, NEISSERIA GONORRHOEAE, TRICHOMONAS VAGINALIS, AND MYCOPLASMA GENITALIUM

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Introduction Urethral swabs are used for culture of gonorrhoea (NG) in males and for detection of chlamydia (CT) and NG by nucleic acid amplification tests (NAATs). We hypothesised self-collected penile swabs would perform as well as urethral swabs for detection of CT, NG, trichomonas (TV) and mycoplasma (MG).

Methods Men having urethral swabs obtained for NG culture in the STD clinic volunteered to collect penile swabs. Urethral swabs were placed into NAAT transport media; then self-collected penile swabs were placed in transport media. NAATs were performed for CT, NG, TV, and MG for urethral and penile swabs. Acceptability questionnaires were given.

Results For 203 urethral/penile pairs, there were 32 penile positive for CT (15.8%), 31 urethral positive for CT (15.3%); [sensitivity 96.8% and specificity 98.8% compared to urethral swabs]. There were 29 penile positives for NG (14.3%) and 27 urethral positives for NG (13.3%); [sensitivity 100%, specificity 98.9%]. 25 were Gram stain positive; 21 by culture. For TV, there were 23 penile positives (11.3%), 20 urethral positives (9.9%); [sensitivity 85.0%, specificity 96.7%]. For MG, 24 penile swabs were positive (11.8%); and 29 urethral were positive (14.3%); [sensitivity 79.3%, specificity 99.4%]. CT: 2 samples were penile+/ urethral-, 1 was penile-/urethral+. NG: 2 samples were penile+/ urethral-. TV: 6 samples were penile+/urethral-, 3 were penile-/ urethral+. MG: 1 pair was penile+/urethral-, 6 were penile-/urethral+. There were no significant differences between self-collected penile swabs and clinician-collected urethral swabs for NAATs (p = 0.625 for CT; p = 0.248 for NG; p = 0.344 for TV; and P = 0.070 for MG). 100% of men preferred penile swabs for diagnosis.

Conclusions Self-collected penile swabs were as accurate as urethral swabs for the detection of sexually transmitted infections for NAAT assays and could expedite express visits in a busy STD clinic. Penile swabs show promise as a method of utilising one sample for multiple STIs.

Disclosure of interest statement The research group has previously received research funding from GenProbe/Hologic. No pharmaceutical grants were received in the development of this study.

010.5

## RAPID DIAGNOSIS OF *TRICHOMONAS VAGINALIS* BY TESTING VAGINAL SWABS IN AN ISOTHERMAL HELICASE-DEPENDENT AMPLIVUE® ASSAY

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Introduction Infections due to *Trichomonas vaginalis* are treatable. Diagnostic methods such as wet mount microscopy are rapid but insensitive. Culture or traditional molecular assays are more sensitive but lack rapid results. Biohelix (a Quidel company) has created an isothermal, cassette-based, point-of-care molecular amplified test for the diagnosis of *T. vaginalis* in vaginal samples which can provide a diagnosis in 5 min. The objective was to demonstrate the clinical performance of the AmpliVue<sup>®</sup> Trichomonas assay on vaginal swabs from women with or without symptoms living in 5 geographical areas of North America.

Methods Women attending STD, family planning, colposcopy and OB/GYN clinics were invited to participate using an

investigational research board approved consent form. A health-care worker collected 4 swabs. The first and second swabs were randomised for wet mount and culture (In-Pouch system, Biomed Diagnostics). Cultures were inoculated and read at 2 and 3 days, and wet mount microscopy performed within 1 h of collection. The third was tested in AmpliVue® and the fourth in Aptima TV (ATV; Hologic, Inc), a transcription-mediated amplification assay. AmpliVue® and ATV testing was performed within 48 h. Positives by diagnostic method were compared to each other and agreements with kappa values were calculated between AmpliVue® and ATV.

Results A total of 1132 women (373 symptomatic and 759 asymptomatic) were enrolled. Comparing AmpliVue<sup>®</sup> to culture and wet mount as a patient infected status demonstrated 100% sensitivity, 98.2% specificity and 87.9–100% positive and negative predictive values in patients with or without symptoms. AmpliVue<sup>®</sup> showed strong overall agreement with ATV (97.5% 0.89 kappa).

Conclusion The AmpliVue Trichomonas Assay identified substantially more *T. vaginalis* infections and yielded accurate results in 45 min for the diagnosis and treatment of *Trichomonas vaginalis* in symptomatic and asymptomatic patients representing high and low-prevalence clinics. Clinicians can use this information for their clinics.

Disclosure of interest statement Dr. Chernesky has received research funding from Quidel.

## O11 - Partners, places and STI risk

011.1

PATIENT-DELIVERED PARTNER THERAPY (PDPT)
INCREASES THE FREQUENCY OF PARTNER
NOTIFICATION AMONG MSM IN LIMA, PERU: A
RANDOMISED CLINICAL TRIAL

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Background Patient-Delivered Partner Therapy (PDPT) improves treatment outcomes among sexual partners of individuals with curable STIs. Although use of PDPT with MSM has been questioned due to the high prevalence of undiagnosed HIV and syphilis in MSM networks, increasing partner notification (PN) through PDPT may promote testing and treatment of otherwise unidentified partners. We assessed the impact of PDPT on self-reported partner notification (PN) among Peruvian MSM with gonorrheal (GC) and/or chlamydial (CT) infection.

Methods We screened 898 MSM in Lima, Peru for GC and/or CT between 2012–2014. Screening included syndromic management of urethritis/proctitis and nucleic acid testing for GC/CT at urethral, pharyngeal, and rectal sites (Aptima Combo-2 TMA). Enrollment was limited to participants with symptomatic urethritis/proctitis (n = 44) and/or laboratory-diagnosed GC/CT infection (n = 263). 173 eligible participants were randomly assigned to receive either standard PN counselling (n = 84) or counselling and PDPT (Cefixime 400 mg/Azithromycin 1 g) for up to 5 recent partners (n = 89). Self-reported notification of recent partners was assessed by CASI with 155 participants who returned for 14-day follow-up.