P3-S1.44 COMPARISON OF SELF-TAKEN VULVO-VAGINAL SWABS AND CLINICIAN-TAKEN ENDOCERVICAL SWABS USING THE GEN-PROBE APTIMA COMBO 2 ASSAY VS CLINICIAN-TAKEN URETHRAL AND ENDOCERVICAL SWABS FOR CULTURE OF GONORRHOEA

doi:10.1136/sextrans-2011-050108.444

J Wilson, C Stewart, S Schoeman, R Booth, S Smith, M Wilcox. *Leeds Teaching Hospitals NHS Trust, Leeds, UK*

Background The role of non-invasive testing for gonorrhoea (GC) in women has not yet been fully established in the UK. Validation of NAATs in low prevalence populations has been recommended. Our study is the first to compare gonorrhoea detection on self-taken VVSs by AC2 assay with gold-standard culture of clinician-taken urethral and endocervical (endocx) samples. As it is unclear whether a VVS or endocx swab is better for the detection of chlamydia (CT) by AC2 assay in women needing an examination we also compared the sensitivities of these samples for CT detection.
Methods Women aged 16+ requesting STI testing consenting to perform a self-taken VVS prior to routine examination were included. Clinicians took urethral and endocx samples for gonorrhoea culture and an endocx swab for AC2 assay. AC2 positives were confirmed with Aptima GC and Aptima CT assays.
Results 3973 women included, 100 (2.5%) were infected with GC. Overall sensitivities were culture 82%; clinician taken endocx AC2 96%; self-taken VVS AC2 99% (p=0.0002). The specificity of all the AC2 tests was 100%. In women with symptoms the sensitivities were culture 84%; clinician taken endocx AC2 100% and VVS AC2 100% (p=0.003). In women with no symptoms 1.9% had GC. The sensitivities were culture 79%; clinician taken endocx AC2 91% and self-taken VVS AC2 97.5% (p=0.015). The endocx AC2 performed less well in women without symptoms, 91% vs 100% (p=0.031); the VVS AC2 assay performed equally well, 97.5% vs 100% (p=0.41). Overall sensitivities for CT were clinician taken endocx AC2 89%; self-taken VVS AC2 97% (p=0.0001). In women with symptoms the sensitivities were clinician taken endocx AC2 88%; self-taken VVS AC2 97% (p=0.001). In women with no symptoms the sensitivities were clinician taken endocx AC2 89%; self-taken VVS AC2 98% (p=0.002).
Conclusion AC2 assay of self-taken VVSs was significantly more sensitive for the detection of GC than culture of urethral and endocx samples and equivalent to detection by AC2 assay from clinician-taken endocx swabs. The specificity and PPV of the AC2 assay was very high in this low prevalence population. AC2 assay of self-taken VVSs was significantly more sensitive for the detection of CT than AC2 assay of clinician-taken endocx samples. On the basis of these findings a self-taken VVS is the sample of choice in women who do not need an examination. In those who are being examined either a self-taken or clinician-taken VVS is the sample of choice giving better detection rates of GC and CT than an endocx swab.

Clinical sciences poster session 2: herpes simplex virus

P3-S2.01 NON SEXUALLY TRANSMITTED GENITAL ULCERS; PATIENTS REFERRED TO A STD CLINIC

doi:10.1136/sextrans-2011-050108.445

A Palit. *BLDE University, Bijapur, India*

Introduction Non-sexually transmitted genital ulcers are a cause of significant morbidity among sexually active young men and women. Establishing the underlying cause of the genital ulcer and differentiation from sexually transmitted infections may be challenging for the treating physician.
Case reports Patient data were collected from a STD clinic in a tertiary care hospital in south India from 2008 to 2010. All the patients were routinely screened for syphilis and HIV infection. Smears from the ulcers were taken and stained with Gram stain and/or Giemsa stain. Biopsy from the ulcer edge was taken whenever indicated. Following causes for non-sexually transmitted genital ulcers were recorded: Behcet's disease was seen in two male patients. Infectious ulcers; One pregnant woman presented with multiple painful genital ulcers caused by *Klebsiella* spp. An HIV infected man on antiretroviral therapy presented with ecthyma gangrenosum of scrotum with unilateral lymphadenopathy caused by *Pseudomonas sp.* Chancroid-like ulcers; a monogamous, HIV-negative office worker and an HIV positive widow, sexually inactive since 5 years, presented with multiple, small shallow genital ulcers with excruciating pain simulating herpes genitalis. The ulcers did not respond to adequate therapy with acyclovir and organism could not be demonstrated on gram stain or bacterial culture. In both the cases, the ulcers healed completely with azithromycin. Factitious ulcer; seen over the shaft of penis in an unmarried man. Genital apthae due to chikungunya fever; during an epidemic of chikungunya fever in the region, 25 patients with acute disease presented with multiple aphthous ulcers involving scrotum, penoscrotal junction and adjacent crural region. Skin biopsy from the ulcers reveals lymphocytic vasculitis.
Conclusion Causes of genital ulcers in patients referred to STD clinic may be varied. Atypical cases must be examined with care to identify the cause. Counselling plays an important role in the management of patients with non-sexually transmitted genital ulcer.

P3-S2.02 VARIATIONS IN TESTING AND TREATMENT RECEIVED BY INFANTS WITH POSSIBLE NEONATAL HERPES

doi:10.1136/sextrans-2011-050108.446

[1]E Meites, [1]F Xu, [1]K Hutchins, [2]B Ackerson, [1]J Gee, [3]E Eriksen, [4]A Naleway, [1]L Markowitz, [3]K Zangwill. *[1]Centers for Disease Control and Prevention, Atlanta, USA; [2]Southern California Kaiser Permanente Medical Group, Los Angeles, USA; [3]UCLA Center for Vaccine Research, Torrance, USA; [4]Kaiser Permanente Northwest Center for Health Research, Portland, USA*

Background Data are scarce on clinical care of infants with possible neonatal herpes simplex virus (HSV) infection, a rare and serious condition that should be treated with systemic acyclovir for 14–21 days. We reviewed HSV testing and treatment in a large cohort of US infants in order to assess clinical care received.
Methods We investigated >270 000 infants born from 1997 to 2002 at three managed care organizations participating in the US Vaccine Safety Datalink. Medical records were abstracted if an infant had a discharge ICD-9 code compatible with HSV infection, a positive laboratory test for HSV, or neonatal death. Abstracted data included symptoms, testing, and treatment. Two physicians reviewed likely HSV infections. We identified confirmed cases (compatible symptoms and positive laboratory test), probable cases (compatible symptoms only), and others (with an alternate diagnosis). Descriptive frequencies were calculated.
Results We abstracted records from 770 infants, identifying 35 cases (24 confirmed and 11 probable) and 735 others. HSV infection manifested as skin, eye, and mucosal (SEM) disease in 20 cases, central nervous system (CNS) disease in 8 cases, and disseminated disease in seven cases. Among 35 cases, all 35 (100%) had symptoms compatible with HSV infection; these included vesicular lesions in 20 (57%) and seizure in 7 (20%). Overall, 35 (100%) were ever tested for HSV. At least 34 (97%) received some acyclovir; median time to treatment, available for 32 cases, was 3 days (range 0–35 days). Only 8 (23%) received systemic acyclovir for the recommended

14–21 days, while 18 (51%) received <14 days and 8 (23%) received more than 21 days. Among 735 others, 701 (95%) had symptoms compatible with HSV infection; these included vesicular lesions in 10 (1%) and seizure in 244 (33%). Overall, 172 (23%) were ever tested for HSV, including 7/10 (70%) with vesicular lesions and 69/244 (28%) with seizure. At least 98 (13%) received some acyclovir, including 2/10 (20%) with vesicular lesions and 18/244 (7%) with seizure. Of these, 32 (4%) infants received acyclovir for ≥7 days.

Conclusions Our results reveal variations in clinical care of infants with possible neonatal HSV infection. Among cases, duration of antiviral therapy rarely followed treatment recommendations. Among symptomatic infants, most with vesicular lesions but few with seizures were ever tested for HSV. These variations suggest opportunities for clinical quality improvements.

P3-S2.03 CLINICAL EVALUATION OF THE BD HSV1 QX ASSAY FOR THE DIRECT QUALITATIVE TESTING OF HSV1 AS COMPARED TO VIRAL CULTURE AND A LABORATORY-BASED PCR ASSAY USING MALE AND FEMALE EXTERNAL ANOGENITAL LESIONS

doi:10.1136/sextrans-2011-050108.447

[1]A Pantone, [1]B Van Der Pol, [1]J Williams, [2]L Corey, [3]E Hook, [4]B Body, [5]S Taylor, [6]P Fine, [7]S Ginde, [8]J Lebed. *[1]Indiana University School of Medicine, Indianapolis, USA; [2]University of Washington, Seattle, USA; [3]University of Alabama Birmingham, Birmingham, USA; [4]LabCorp, Burlington, USA; [5]LSU Health Science Center, New Orleans, USA; [6]Planned Parenthood Gulf Coast, Houston, USA; [7]Planned Parenthood of the Rocky Mountains, Denver, USA; [8]Planned Parenthood Southeastern Pennsylvania, Philadelphia, USA*

Background To compare the performance characteristics of the BD ProbeTecTM HSV1 Qx Assay* on the BD ViperTM System in Extracted Mode to viral culture and a well-characterised molecular assay for the detection of HSV1. External anogenital lesions were sampled with two different collection devices: a universal viral transport (UVT) kit and a BD Qx swab (QS) kit*.

Methods Eleven geographically diverse clinical centers participated in the study, with nine of the sites enrolling participants. The UVT was collected first followed by the QS specimen. A portion of each UVT specimen was transferred to a Qx Diluent tube (diluted UVT) and a cryovial. The remainder of the UVT in the original tube was frozen at −70°C and sent to one of two sites for HSV viral culture using the ELVIS®HSV ID and D3 Typing Test System (Diagnostic Hybrids, Inc). The diluted UVT and QS specimens were shipped to one of three sites for HSV testing on the BD Viper. The UVT aliquot in the cryovial was stored at −70°C and shipped to the University of Washington for PCR testing for HSV.

Results Subjects (n=508) were enrolled from February to August of 2010 with 312 UVT and 308 QS samples available for comparison to ELVIS culture, and 506 and 502 samples, respectively, for comparison to the PCR assay. Samples positive for HSV2 by viral culture did not have results for HSV1 per the ELVIS package insert and were excluded from further analysis. The sensitivity and specificity of the BD HSV1 Qx Assay as compared to ELVIS culture and the positive (PPA) and negative per cent agreement (NPA) of the assay compared to the HSV PCR assays were determined for both specimen types see Abstract P3-S2.03 table 1.

Conclusions The BD HSV1 Qx Assay on the BD Viper System had excellent agreement with viral culture and the lab developed PCR assay, which is currently recognised as one of the best available tests for the detection of HSV1. A commercially available molecular-based assay for the detection of HSV would not only improve detection and reduce turn-around time on results, but may also obviate the need for stringent transport conditions required for HSV culture. *Product not for sale, for investigational use only in the US.

Abstract P3-S2.03 Table 1 HSV1

	HSV1 Q^x assay performance			
	Compared to ELVIS HSV1 culture		Compared to HSV1 PCR assay	
Specimen type	Sensitivity	Specificity	PPA	NPA
Diluted UVT	96.8% (60/62)	97.6% (244/250)	98.6% (71/72)	100% (434/434)
Q^x Swab (QS)	96.7% (59/61)	95.1% (235/247)	100% (71/71)	98.8% (426/431)

P3-S2.04 CLINICAL EVALUATION OF THE BD HSV2 QX ASSAY FOR THE DIRECT QUALITATIVE TESTING OF HSV2 AS COMPARED TO VIRAL CULTURE AND A LABORATORY-BASED PCR ASSAY USING MALE AND FEMALE EXTERNAL ANOGENITAL LESIONS

doi:10.1136/sextrans-2011-050108.448

[1]L Hires, [1]B Van Der Pol, [2]J Williams, [3]L Corey, [4]E W Hook, [5]M Nye, [6]S Taylor, [7]M Martens, [8]L Mena, [9]T Warren. *[1]Indiana University, School of Medicine, Indianapolis, USA; [2]Indiana University, Indianapolis, USA; [3]University of Washington, Seattle, USA; [4]University of Alabama, Birmingham, USA; [5]LabCorp, Burlington, USA; [6]LSU Health Science Center, New Orleans, USA; [7]Planned Parenthood of Arkansas and Eastern Oklahoma, Tulsa, USA; [8]University of Mississippi, Medical Center, Jackson, USA; [9]Westover Heights, Portland, USA*

Background To compare the performance characteristics of the BD ProbeTecTM HSV2 Qx Assay* on the BD ViperTM System in Extracted Mode to viral culture and a well-characterised molecular assay for the detection of HSV2. External anogenital lesions were sampled with two different collection devices: a universal viral transport (UVT) kit and a BD Qx swab (QS) kit*.

Methods Eleven geographically diverse clinical centers participated in the study, with nine of the sites enrolling participants. The UVT was collected first followed by the QS specimen. A portion of each UVT specimen was transferred to a Qx Diluent Tube (diluted UVT) and a cryovial. The remainder of the UVT in the original tube was frozen at −70°C and sent to one of two sites for HSV viral culture using the ELVIS®HSV ID and D3 Typing Test System (Diagnostic Hybrids, Inc). The diluted UVT and QS specimens were shipped to one of three sites for HSV testing on the BD Viper. The UVT aliquot in the cryovial was stored at −70°C and shipped to the University of Washington for PCR testing for HSV.

Results Subjects (n=508) were enrolled between February and August of 2010 with 501 UVT and 498 QS samples available for comparison to ELVIS culture, and 506 and 503 samples, respectively, for comparison to the PCR assay. The sensitivity and specificity of the BD HSV2 Qx Assay were compared to ELVIS culture and the positive (PPA) and negative (NPA) per cent agreement of the assay was compared to the HSV PCR assays for both specimen types. Of the BD HSV2 Qx Assay positive, culture negative samples, 46/51 (90.2%) of the UVT and 49/60 (81.7%) of the QS were positive by HSV2 PCR see Abstract P3-S2.04 table 1.

Conclusions The BD HSV2 Qx Assay on the BD Viper had excellent agreement with the lab developed PCR assay for diagnosis of HSV2, which is currently recognised as one of the best available tests for the detection of HSV. A commercially available molecular-based assay for the detection of HSV would not only improve detection and reduce turn-around time on results, but may also obviate the need for stringent transport conditions required for HSV culture. *Product not for sale, for investigational use only in the USA.

Abstract P3-S2.04 Table 1 HSV2

	HSV2 Q^x assay performance			
	Compared to ELVIS HSV2 culture		Compared to HSV2 PCR assay	
Specimen type	Sensitivity	Specificity	PPA	NPA
Diluted UVT	98.4% (186/189)	83.7% (261/312)	97.5% (237/243)	98.1% (258/263)
Q^x Swab (QS)	98.4% (186/189)	80.6% (249/309)	98.8% (240/243)	95.8% (249/260)