Utility of the Syphilis Health Check™ in an STD Clinic Setting

SE Cohen1,2, R Kohn3, T Toles-Williams1, J Engelman1,2, SS Philip1,2
1San Francisco Department of Public Health, Disease Prevention and Control Branch, San Francisco City Clinic; 2University of California, San Francisco, CA

Background
- Rates of early syphilis are rising among men who have sex with men (MSM)
- Prompt and accurate diagnosis and treatment are important components of syphilis control
- Syphilis Health Check™ (SHC) is the first CLIA waived rapid syphilis test (RST) in the US
- Whether a treponemal specific RST improves the timeliness and accuracy of syphilis diagnosis and management in an STD clinic is unknown

Methods
- From September 2015 to January 2016 (Phase I) and from April 2016 to August 2016 (Phase II), the SHC was piloted at SF City Clinic (SFCC), the municipal STD clinic in San Francisco
- The SHC was used to guide clinical management in conjunction with other syphilis tests routinely used at the clinic: Darkfield (DF) microscopy, stat RPR, lab based VDRL, and lab based TPPA
- The SHC was used in patients with no known prior history of syphilis in the following scenarios:
  1) Diagnostic evaluation of oral or anogenital lesion(s) if syphilis status uncertain after clinical evaluation, DF and stat RPR
  2) Confirmation of a positive non-treponemal test
  3) Contact to syphilis (not all contacts were tested)
- Final determination of syphilis disease status (positive, negative or indeterminate) was based on serologic results and clinical findings

Results
- Patient volume and # syphilis cases evaluated and diagnosed at SF City Clinic during study interval
  - Total patient visits: 11714
  - Total visits by MSM: 7451
  - # VDRLs ordered: 5301
  - # Stat RPRs ordered: 790
  - # Darkfield exams ordered: 115
  - # Darkfield positives: 37
  - Primary syphilis: 62
  - Secondary syphilis: 90
  - Early latent syphilis: 100

Conclusions
- In this small pilot, 25% of SHCs were false positives
- Over-reading of a faintly positive test line may have contributed to the high false positive rate, and the false positive rate declined in phase II of the pilot after additional training was done
- SHC helped rule-out syphilis in several symptomatic patients who otherwise may have been empirically treated with penicillin and identified one stat RPR negative primary syphilis case
- SHC has a limited role in assessing genital ulcer disease in a clinical setting that has access to DF microscopy and stat RPR

SHC Kits were donated by the California DPH
STD Control Branch and Trinity Biotech

SF Department of Public Health, SF City Clinic, 356 7th Street, San Francisco, CA 94103
Phone (415) 487-5309 Fax (415) 487-5581 Website www.sfcityclinic.org Email stphila@sfphd.org