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

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Poster # THP 59

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

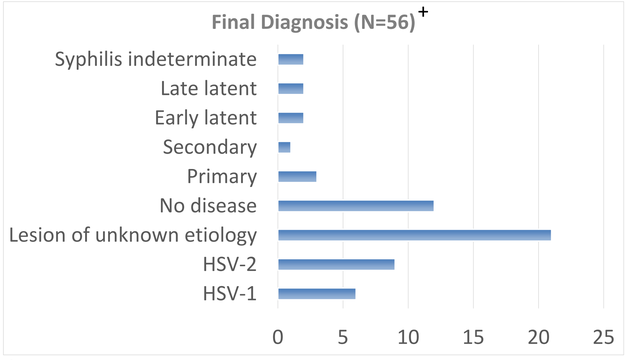
Methods

- 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

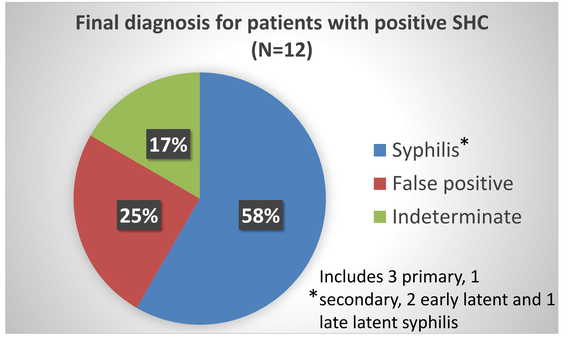
Results

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

Characteristic	Tested with SHC (N=56) N (%)
Male	53 (95)
MSM	47 (89)
Reason for testing	
Oral or anogenital lesion(s)	41 (73)
Positive VDRL with pending lab based TPPA	5 (9)
Contacts to syphilis	9 (16)
Reason for testing unknown	1 (2)
SHC Positive	12 (21.4)



+1 patient was indeterminate for syphilis and positive for HSV-2; 1 patient was positive for both primary syphilis and HSV-2



Results

Positive SHC, Indeterminate syphilis status
Case 1: 34 yo MSM with proximal non-tender lesion on lateral aspect of tongue; minimally reactive stat RPR, weakly reactive VDRL, negative lab-based TPPA
Case 2: 41 yo MSM with non-tender penile lesion with right inguinal lymphadenopathy; negative stat RPR, weakly reactive VDRL, negative lab-based TPPA; Positive HSV-2 PCR

- SHC was negative in one patient with late latent syphilis
- Of the 3 primary syphilis cases identified by SHC, one had a positive stat RPR, one had a weakly reactive stat RPR and one had a negative stat RPR

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

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