Field Evaluation of Standard Diagnostic Duo HIV and Syphilis Test Among Female Sex-Workers in Johannesburg

Black V[1], Maseko V[2], Venter FW[1], Radebe F[2], Mullick S[1], Rees HV[1], Lewis DA[2,3]
1. Wits Reproductive Health & HIV Institute, South Africa
2. Centre for HIV and STIs, National Institute for Communicable Diseases (NHLS)
3. Western Sydney Sexual Health Centre and University of Sydney, Sydney, Australia
World STI & HIV Congress 2015
14 September 2015

NATIONAL INSTITUTE FOR COMMUNICABLE DISEASES
Division of the National Health Laboratory Service

THE UNIVERSITY OF SYDNEY

Introduction

- Point-of-care tests (POCT) for STI/HIV provide immediate results with the opportunity for same day treatment, counselling and partner notification.
- Combination POCTs for HIV and syphilis are particularly beneficial for pregnant women and key populations as treating these infections early reduces vertical and community transmission.

Objective

Determine field sensitivity, specificity and positive and negative predictive value of the SD Bioline HIV/syphilis Duo Assay (Standard Diagnostics, Korea) among inner-city Johannesburg female sex workers.

Method

Participants

From March to December 2014 all female sex workers:

- attending a dedicated sex-worker clinic within Esselen Street Clinic, Johannesburg South Africa and
- those who accessed services at the outreach clinics (hotels)

Were invited to participate in this study.

Method

- Women completed informed consent to participate in the study and then to be tested for HIV.
- The study was approved by the Human Research Ethics Committee University of Witwatersrand, **M130907**.

Method

- Testing for HIV was conducted following pre and post-test counselling.
- Concordant results were given to women.
- Discordant results were determined by a laboratory ELISA test.
- Women who tested HIV positive were referred for HIV management.
- Participants who tested positive for syphilis were treated with penicillin, unless they had a history of previous syphilis treatment.

Method

HIV – on site
- Testing was done according to NDoH guidelines using two rapid HIV tests:
  – First response HIV 1-2.0 (Premier Medical Corporation Ltd, India).
  – ABON (Abon Biopharm, China).
- In addition :
  – SD bioline HIV/syphilis duo test (Standard Diagnostics, Korea)
- Tests were performed according to manufacturers instructions using whole blood.

Method

HIV – laboratory (gold standard)
- Serum was collected and sent to the National Institute of Communicable Diseases for processing.
- Laboratory technicians were blinded to the point of care result.
- The EIA – Genscreen HIV ½ V2 – 3rd generation assay and EIA – Vironostika Ag/Ab – 4th generation assay were used to confirm HIV status.
- A negative 3rd generation with a positive 4th generation test were considered as seroconversion.

Method

Syphilis
- SD bioline HIV/syphilis duo test.
- Serum was be collected for Rapid Plasma Reagin/ RPR (macroscopic) test and *T. pallidum* particle agglutination (TPPA) test
  – Negative RPR and TPPA = no syphilis
  – Positive RPR ≥ 8 = syphilis positive TPPA
  – Negative or ≤ 4 RPR and positive TPPA = past infection
  – Positive RPR and a negative TPPA = biologic false-positive RPR

Method

Analysis

- Sensitivity, specificity, positive predictive values and negative predictive values were calculated for HIV and syphilis according to standard methods using Vassar Stats calculator and 95%confidence intervals (95%CI) were calculated.

(Richard Lowry (http://vassarstats.net/clin1.html))

Results

We recruited 263 women.

Of these 14 (5.3%) women refused to have an HIV test.

Among the remaining 249 women 187 (75.1%) were HIV positive and 51 (20.5%) had evidence of ever having syphilis with 9 (3.6%) of these having active syphilis.

No cases of biologic false-positive RPR.

Performance of the SD Bioline HIV/Syphilis Duo test for HIV among female sex workers in Johannesburg

Number of true cases	Prevalence % (95%CI)	Sensitivity % (95%CI)	Specificity % (95%CI)	PPV % (95%CI)	NPV % (95%CI)
HIV n=187	75.1 (69.0-80.1)	98.8 (95.8-99.8)	100 (92.7-100)	100 (97.5-100)	96.9 (88.2-99.5)
TPPA n=51	20.5 (15.8-26.1)	66.7 (52.0-78.9)	98.0 (94.5-99.3)	89.5 (74.3-96.6)	91.9 (87.2-95.1)
Active syphilis n=9	3.6 (0.7-4.9)	88.9 (50.7-99.4)	87.5 (82.4-91.3)	21.1 (10.1-37.8)	99.5 (97.0-100)

The performance for HIV testing of SD Bioline HIV/Syphilis Duo

- For HIV it is on par with other established HIV tests and can be used in testing/screening programme.

The performance for HIV testing of SD Bioline HIV/Syphilis Duo

- The two active cases of syphilis that were missed (RPR 8 or more) had previously been treated.
- The performance for TPPA detection has a high specificity and negative predictive value, but lower sensitivity and positive predictive value.
- PPV will be lower in lower prevalence settings.
- Limitation is the small number of women with active syphilis.

Compared to other evaluations

- Comparable results with other evaluations for HIV.
- Our evaluation performed worse for syphilis compared to previous published results. Most of these evaluations were performed in a laboratory.
- A previous field evaluation conducted in Uganda showed sensitivity of 100% and specificity of 99% for syphilis. The tests were performed by laboratory technicians using centrifuged samples.

Omoding D, et al. BMC Res Notes, 2014
Bristow CC et al. Open Forum Infect Dis, 2014
Jafari et al 2013

Other POC syphilis evaluation

- Our results are similar to other POC evaluations where syphilis tests show a lower sensitivity compared to laboratory standards when evaluated in the field rather than the laboratory, but HIV testing does not.
- This highlights the need for quality insurance for POC testing to ensure correct procedures are performed

Benzaken AS et al 2008;
Bristow CC et al 2014

Clinical use of SD Bioline HIV/Syphilis Duo:

- Challenge of the dual test is that women who refuse an HIV test will not automatically have a syphilis test. Will need to have another syphilis only test available, such as the RPR test.

Conclusion

- Although the SD bioline performs well for HIV diagnosis, the assay has lower sensitivity for syphilis detection in our field setting compared to published laboratory evaluations. Using the test in screening programmes will detect both HIV and most cases of active syphilis.
- Further field evaluations are warranted.

Disclosure of Interest Statement:

- The study was funded by USAID/PEPFAR and AIDS Fonds.
- SD bioline tests were provided by SD diagnostics.