Performance of GeneXpert® CT/NG in the Diagnosis of Neisseria gonorrhoeae and Chlamydia trachomatis Among Men and Women with Genital Discharge Syndrome in Zimbabwe

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Background

- In resource-constraint countries like Zimbabwe, sexually transmitted infections (STI) are treated syndromically.
- New testing technologies, including GeneXpert® (Cepheid) may be employed at the point of care and facilitate aetologic diagnosis for the purpose of:
  - Patient management
  - Epidemiologic assessment of STI aetiology

Objectives

To determine the performance of the GeneXpert platform when compared with Prodetec and multiplex PCR in a study of the aetiology of STI syndromes in Zimbabwe

Methods

- Between June 2014 and April 2015, a mobile team recruited 600 men and women in 6 clinics:
  - Harare
    - H-1 (N=157)
    - H-2 (N=55)
  - Bulawayo
    - B-1 (N=110)
  - Beitbridge
    - B-2 (N=105)
  - Gutu
    - G-1 (N=11)
- The following patients were enrolled:
  - 200 women with vaginal discharge*
  - 200 men with urethral discharge*
  - 200 men and women with GUD**
- Demographic, and STI/sexual history data were collected using a standardized questionnaire and entered in an online database
- Specimens collected:
  - Blood (all patients)
  - Urethral Smears (Men)
  - Urine (men with GDS)
  - Vaginal Smears (women)
  - Vaginal swabs (women with GDS)
- All specimens were shipped by courier to the study receiving laboratory in Harare (ZCIHRe)

Results

Xpert NG/CT – Sensitivity and Specificity

Compared with concordant results on Prodetec and Multiplex PCR

- Gonorrhea (N=382)
  - Sensitivity: 179/183 - 97.8%
  - Specificity: 196/199 - 98.5%
- Chlamydia (N=383)
  - Sensitivity: 68/69 – 98.6%
  - Specificity: 310/314 - 98.7%

Concordance / Discordance of Test Results

<table>
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<th>Test</th>
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<th>Gonorrhea</th>
<th>Prodetec</th>
<th>Multiplex PCR</th>
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Limitations

- Tests performed at different laboratories
- Discrepancy analysis still ongoing

Conclusions

- New nucleic acid amplification test (NAAT) devices, including the GeneXpert platform:
  - Are increasingly available in resource-restricted countries
  - Can be deployed at the point of care setting
  - Can be used for STI aetiological diagnosis
- In this study, Xpert NG/CT was shown to have excellent performance characteristics when employed in real-world setting

Labatory Tests

- Genital Discharge Syndromes:
  - Prodetec™ (Becton Dickinson)
  - C. trachomatis and N. gonorrhoeae
  - Xpert CT/NG® (Cepheid)
  - C. trachomatis and N. gonorrhoeae
  - Multiplex polymerase chain reaction (in-house assay NICD*)
  - C. trachomatis
  - N. gonorrhoeae
  - T. vaginalis
  - M. genitalium
- Genital Ulcer Disease:
  - M-PCR
  - T. pallidum
  - H. ducreyi
  - Herpes simplex virus (HSV)
  - C. trachomatis (LGV strains)
- HIV Serology
  - First Response
  - Determine
  - Syphilis Serology
  - Treponemal: SD Bioline
  - Non-treponemal: KPR

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The Zimbabwe STI Aetiology Study

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