



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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Abstract #923



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 aetiological diagnosis for the purpose of:
 - Patient management
 - Epidemiologic assessment of STI aetiology

Objectives

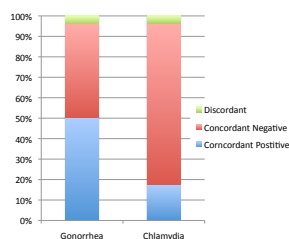
To determine the performance of the GeneXpert platform when compared with Probetec and multiplex PCR in a study of the aetiology of STI syndromes in Zimbabwe

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=106)
 - B-2 (N=105)
 - Beitbridge
 - D-1 (N=166)
 - 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 (ZiCHIRe)

Results

Concordance / Discordance of Test Results



Evaluable results for all 3 platforms:

- Chlamydia: 392
- Gonorrhea: 390
- Concordance Positive
 - Gonorrhea: 179
 - Chlamydia: 68
- Concordance Negative
 - Gonorrhea: 196
 - Chlamydia: 310
- Discordance
 - Gonorrhea: 15 (3.85%)
 - Chlamydia: 14 (3.57%)

Xpert NG/CT – Sensitivity and Specificity

Compared with concordant results on Probetec 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%

Discrepant Results - Gonorrhea

Obs	ID	GeneXpert	Probetec	M-PCR
65	MD23005	NEGATIVE	POSITIVE	POSITIVE
108	FD54045	NEGATIVE	POSITIVE	NEGATIVE
131	MD53005	NEGATIVE	POSITIVE	POSITIVE
139	MD53039	NEGATIVE	POSITIVE	POSITIVE
140	MD53044	NEGATIVE	POSITIVE	POSITIVE
263	MD13018	NEGATIVE	NEGATIVE	POSITIVE
356	MD43012	NEGATIVE	NEGATIVE	POSITIVE
395	FD54037	POSITIVE	POSITIVE	NEGATIVE
397	FD54039	POSITIVE	NEGATIVE	POSITIVE
462	FD34004	POSITIVE	NEGATIVE	POSITIVE
466	FD34015	POSITIVE	NEGATIVE	NEGATIVE
469	FD34019	POSITIVE	POSITIVE	NEGATIVE
474	MD33002	POSITIVE	NEGATIVE	POSITIVE
524	FD14032	POSITIVE	NEGATIVE	NEGATIVE
582	FD44044	POSITIVE	NEGATIVE	NEGATIVE

Discrepant Results Chlamydia

Obs	ID	GeneXpert	Probetec	M-PCR
179	FD14005	NEGATIVE	POSITIVE	NEGATIVE
372	MD53027	NEGATIVE	NEGATIVE	POSITIVE
381	MD53042	NEGATIVE	POSITIVE	POSITIVE
383	MD53045	NEGATIVE	POSITIVE	NEGATIVE
498	MD23005	POSITIVE	NEGATIVE	NEGATIVE
507	FD54054	POSITIVE	NEGATIVE	NEGATIVE
523	MD13018	POSITIVE	POSITIVE	NEGATIVE
528	FD44024	POSITIVE	POSITIVE	NEGATIVE
552	MD53040	POSITIVE	POSITIVE	NEGATIVE
553	MD53052	POSITIVE	POSITIVE	NEGATIVE
559	FD34015	POSITIVE	NEGATIVE	NEGATIVE
566	MD33009	POSITIVE	POSITIVE	NEGATIVE
568	MD33012	POSITIVE	NEGATIVE	NEGATIVE
583	FD14022	POSITIVE	POSITIVE	NEGATIVE

The Zimbabwe STI Aetiology Study
More Information and Poster Copies:
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Laboratory Tests

- Genital Discharge Syndromes:
 - Probetec™ (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: RPR

*NICD: National Institute of Communicable Diseases, Johannesburg, South Africa

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

Limitations

- Tests performed at different laboratories
- Discrepancy analysis still ongoing

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*Results of the GDS aetiology analyses are presented in P09.22
**Results of the GUD aetiology analysis are presented in P09.24