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Evaluation of the diagnostic performance of the Eazyplex platform for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* among women in Zimbabwe

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ABSTRACT

Background Gaps in sexually transmitted infection (STI) diagnosis hinder effective STI control particularly in low-resource settings where syndromic management is often the standard of care. Rapid and affordable point-of-care (POC) diagnostics for STIs such as *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) are needed. This study evaluated the diagnostic performance of Eazyplex (a point-of-care test (POCT)) to screen CT and NG among sexually active women in Zimbabwe.

Methods We enrolled 220 sexually active women aged 18–35 (median 28 years) years attending a family planning clinic in Zimbabwe. Samples collected from vaginal swabs were tested for CT and NG using Eazyplex, GeneXpert and PRESTO CT/NG. Diagnostic performance metrics (sensitivity, specificity, positive predictive value and negative predictive value) were calculated against GeneXpert, PRESTO CT/NG and a GeneXpert+PRESTO CT/NG combined reference standard. For the combined reference standard, a participant was categorised as having a positive result for CT or NG if either of the two tests yielded a positive result.

Results Overall, Eazyplex reported high specificity and low sensitivity. CT results demonstrated sensitivities of 60.9%, 76.2% and 64.0% compared with GeneXpert, PRESTO CT/NG and GeneXpert+PRESTO CT/NG combined, respectively. NG results demonstrated sensitivities of 57.1%, 66.7% and 66.7% compared with GeneXpert, PRESTO CT/NG and GeneXpert+PRESTO CT/NG combined, respectively. All results had specificity ≥98.5%.

Conclusion Eazyplex was highly specific but moderately sensitive in detecting NG and CT. While not suitable as a standalone screening tool, its rapid turnaround gives it potential for use as near POCT in low-resource settings.

INTRODUCTION

Sexually transmitted infections (STIs) continue to be a significant health challenge globally. Over 1 million adults aged 15–49 years acquired a curable STI each day in 2020.¹ In most low-resource settings, syndromic management, which has low sensitivity and specificity, remains the standard of care, resulting in overtreatment and missed asymptomatic infections.² The rise of antimicrobial resistance means STI overtreatment has long-term public health consequences, and rapid testing and

KEY MESSAGE

- ⇒ Limited access to accurate and rapid sexually transmitted infection (STI) diagnostics hinders effective STI management in low-resource settings.
- ⇒ This study evaluated the Eazyplex point-of-care platform for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* detection among women in Zimbabwe, finding high specificity but moderate sensitivity.
- ⇒ The results highlight both the promise and current limitations of point-of-care tests for screening purposes and to inform policies advancing accessible and context-appropriate STI screening.

results can facilitate quick diagnosis and accurate treatment.^{2,3}

No well-performing, commercially available point-of-care test (POCT) broadly suitable for low-resource settings currently exists for the diagnosis of *Chlamydia trachomatis* (CT) or *Neisseria gonorrhoeae* (NG). Some rapid POCTs have been developed;^{4,5} however, many have suboptimal sensitivity.^{4,5} Molecular diagnostics, which require equipment, remain the main choice. Some platforms have advantageous features such as short analytic times and easy-to-use instruments. Loop-mediated isothermal amplification (LAMP) assays do not require thermal cycling, making them faster, simpler and less costly than nucleic acid amplification tests (NAATs).⁶

Although not completely a POCT due to reliance on specialised equipment and trained personnel, the Eazyplex STD complete platform (Amplex-Diagnostics, Gars-Bahnhof, Germany) is based on LAMP of nucleic acids and tests two aliquots of a sample (urethral, anal, vaginal, cervical or pharyngeal) simultaneously for up to six bacterial STI pathogens (CT, NG, *Ureaplasma urealyticum*, *Mycoplasma hominis*, *Mycoplasma genitalium*, *Treponema pallidum*). Qualitative results for each pathogen-specific reaction are available in approximately 30 min. Eazyplex has been validated among symptomatic men who have sex with men (MSM) with sensitivity and specificity of 88% and 98% for NG, and 82% and 100% for CT, respectively.⁷

Eazyplex has not been validated in asymptomatic, primarily heterosexual populations within a low-resource setting with high STI prevalence, like Zimbabwe.

This study evaluates Eazyplex diagnostic performance for CT and NG screening only among sexually active women attending a family planning clinic in Zimbabwe compared with GeneXpert (Cepheid, California, USA) and PRESTO CT/NG combined qualitative real-time CT/NG assay (Goffin Molecular Technologies, The Netherlands).

METHODS

Setting and participants

This study was nested within the Genital InFLammation Test (GIFT) study—a multicentre multidisciplinary prospective observational clinical study to evaluate the performance and feasibility of a Genital InFLammation Test, which was conducted at the Spilhaus Family Planning Centre in Harare.³ Sexually active women (aged 18–35 years) attending family planning services were recruited, irrespective of STI symptoms. A participant was enrolled if they met the following eligibility criteria: (1) aged 18–35 years, (2) provided informed consent, (3) self-reported being sexually active and (4) accessing family planning services. Eligible participants on their menstrual period were requested to return for enrolment after their menses. Exclusion criteria were: (1) refusal to participate, (2) treatment for any STI or bacterial vaginosis in the past 30 days and (3) pregnancy.

Procedures

Enrolled women were interviewed using a structured questionnaire including demographics, sexual behaviour, reproductive history and symptoms. Thereafter, 10 vaginal swab samples were collected by a research nurse. Swab 4 was used for CT/NG diagnosis in the on-site laboratory using the GeneXpert platform with Xpert CT/NG cartridges (Cepheid). Samples were collected using individually wrapped swabs supplied in a GeneXpert collection kit. The vaginal swab samples were immediately put into the GeneXpert transport media tube and taken to the on-site laboratory for testing within 10 min. Swab 6 was sent to Institut Pasteur de Madagascar (Madagascar) and used for diagnosis of CT/NG via quantitative PCR NAAT (PRESTO CT/NG combined qualitative real-time CT/NG assay, Goffin Molecular Technologies). Swab 9 was used for CT and NG testing on the Eazyplex platform (AmplexDiagnostics), with aliquots from the same specimen used for separate reactions, at the Biotech Institute, Harare.³ Dry Copan Floq swabs (Copan, USA) and Labocare collection swabs (Labocare, India) were used to collect swabs 6 and 9, respectively. The vaginal swabs were immediately placed into sterile dry tubes and transported to the on-site laboratory for temporary storage in a -20°C freezer. Each day, samples were transported in temperature-monitored biological sample transport bags containing frozen ice packs to the Biomedical Research and Training Institute laboratory, where they were stored at -20°C . Samples were tested after 6–12 months. The remaining swabs were used for procedures in the larger GIFT study.

Testing was performed blinded to clinical information and to results from other platforms. Data were captured on paper or electronic case report forms.

Statistical analysis

A composite variable was created using results from GeneXpert testing and PRESTO CT/NG testing. A person was categorised as having a positive CT or NG result if either of the two tests

was positive. This approach acknowledges that test results can vary based on bacterial burden (which may be associated with swab sequence) and sample collection. Data were analysed using RStudio (2021.09.0 Build 351; PositBC, Massachusetts, USA).

A complete case analysis approach was employed. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of the Eazyplex assay was assessed taking the GeneXpert and PRESTO CT/NG as reference diagnostics; 95% CIs were calculated using binomial distributions.

RESULTS

Overall, 220 participants were enrolled, with a median age of 28 years (IQR 24–32). Of the 220 participants, 97 (44.0%) reported engaging in sexual activity within the past 48 hours. Most (146, 66.0%) participants had never received STI treatment before. 11 (5.1%) participants were living with HIV. 130 (59%) women self-reported having either abnormal vaginal discharge and/or low abdominal pain.

Among the 220 participants, 11 participants with either incomplete, invalid and/or missing STI testing results were excluded from the analysis. Results were considered incomplete or invalid if samples were not tested due to power outages, had insufficient sample yield or were flagged for resampling.

The prevalence of CT and/or NG was 16.3% based on the composite result of Xpert CT/NG and PRESTO CT/NG, and 14.4% based on standalone PRESTO CT/NG. Among the 122 symptomatic women included in the analysis, the prevalence of CT and/or NG was 16.4% based on the composite result of Xpert CT/NG and PRESTO CT/NG, and 13.9% using standalone PRESTO CT/NG.

CT diagnostic performance

Overall, 13 participants tested positive for CT across all assays (online supplemental figure 1a). Among symptomatic women, 17 tested positive for CT with Xpert and 10 with Eazyplex. For CT, Xpert had the most positive results at 23.

In total, 16 swabs tested positive for CT by Eazyplex compared with 25 by Xpert CT/NG and/or PRESTO CT/NG (table 1). Eazyplex performance compared with the composite reference standard was as follows: sensitivity 64.0% (95% CI 44.5 to 79.8), specificity 100% (95% CI 98.0 to 100), PPV 100% (95% CI 80.6 to 100) and NPV 97.4% (95% CI 94.1 to 98.9).

With Xpert as the reference test, 14/23 women were positive for CT with Eazyplex, and with PRESTO CT/NG as the reference, 16/21 women tested positive for CT with Eazyplex (table 1).

NG diagnostic performance

For NG diagnosis, four participants tested positive across all platforms (online supplemental figure 1b). A total of nine, seven and seven swabs tested positive using the PRESTO CT/NG, Xpert CT/NG and Eazyplex platforms, respectively. Among symptomatic women, five tested positive for NG by Xpert and four by Eazyplex.

In comparison with the composite reference standard (Xpert and PRESTO CT/NG), six of nine women tested positive for NG with Eazyplex (table 1). The sensitivity, specificity, PPV and NPV for Eazyplex were 66.7% (95% CI 35.4 to 87.9), 99.5% (95% CI 97.2 to 99.9), 85.7% (95% CI 48.7 to 97.4) and 98.5% (95% CI 95.7 to 99.5), respectively.

Using Xpert as the reference test, four of seven women tested positive with Eazyplex, and when compared with PRESTO CT/NG, six of nine women tested positive with Eazyplex (table 1).

Table 1 Performance of Eazyplex versus other diagnostic tests for CT and NG diagnosis, stratified by reference diagnostic test (n=209)

	Test: Eazyplex					
	CT			NG		
	Positive	Negative	N	Positive	Negative	N
Test: GeneXpert						
Positive	14	9	23	4	3	7
Negative	2	184	186	3	199	202
Total	16	193	209	7	202	209
Sensitivity	60.9% (40.8 to 77.8)			57.1% (25 to 84.2)		
Specificity	98.9% (96.2 to 99.7)			98.5% (95.7 to 99.5)		
Test: PRESTO CT/NG						
Positive	16	5	21	6	3	9
Negative	0	188	188	1	199	200
Total	16	201	209	7	202	209
Sensitivity	76.2% (54.9 to 89.4)			66.7% (35.4 to 87.9)		
Specificity	100% (98 to 100)			99.5% (97.2 to 99.9)		
Test: GeneXpert+PRESTO CT/NG combined						
Positive	16	9	25	6	3	9
Negative	0	184	184	1	199	200
Total	16	193	209	7	202	209
Sensitivity	64.0% (44.5 to 79.8)			66.7% (35.4 to 87.9)		
Specificity	100% (98 to 100)			99.5% (97.2 to 99.9)		
CT, <i>Chlamydia trachomatis</i> ; NG, <i>Neisseria gonorrhoeae</i> .						

CT, *Chlamydia trachomatis*; NG, *Neisseria gonorrhoeae*.

DISCUSSION

In the context of screening, the Eazyplex assay demonstrated high specificity (>90%) across all reference standards for CT and NG among sexually active women (aged 18–35 years). Eazyplex sensitivity was moderate, ranging between 57.1% and 76.2%.

Currently available POCT, often validated in the context of testing symptomatic individuals, tends to have high specificity and low to moderate sensitivity, consistent with our findings in a study comprising mainly symptomatic women, thus potentially limiting its generalisability to asymptomatic populations.⁸ While Eazyplex CT sensitivity among symptomatic MSM was similar to our study (sensitivity for NG (75%–100%) and CT (77%–88%)), the higher NG sensitivity is likely attributed to the known symptomatic status of MSM participants, urethral, anal and pharyngeal sample sites, which likely have higher bacterial burden than vaginal samples.^{7,9} Similar results of lower sensitivity in the context of screening asymptomatic women have been shown in a recent study investigating a new lateral flow test for NG. Sensitivity was 66% when screening largely asymptomatic pregnant women compared with 92% when testing symptomatic women.⁴ Improvements in Eazyplex sensitivity may be observed in the context of diagnosing symptomatic women.

Eazyplex offers rapid diagnosis of STIs and potential for scalability, despite challenges with sensitivity. Adapting the workflow to avoid manual handling of open tubes and reducing the price of kits could improve its position as a screening test. Validation of tests in the context of screening is important due to potential reductions in infertility, pelvic inflammatory disease, ectopic pregnancy and adverse birth outcomes.¹⁰ In the context of large-scale screening, a cheaper and easier-to-perform test with lower sensitivity may hold promise.

Key limitations of our study included a small sample size, low number of NG-positive samples resulting in imprecise effect estimates and focus on women only. Bacterial burden could have

differed systematically across tests as the sequence of sample collected was not randomised. Different storage and transportation may have potentially resulted in the degradation of detectable antigen in samples.

In conclusion, Eazyplex demonstrates high specificity but moderate sensitivity in diagnosing CT and NG in the context of screening sexually active women. It shows promise as a decentralised, near POCT to support same-day, test-based STI management in low-resource settings currently reliant on syndromic management, but requires further validation in asymptomatic populations before broader screening use in clinics.

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Contributors MM: literature search, data analysis, data interpretation, writing—and guarantor. TM: study design, data collection, writing—reviewing and editing. FM: study design, data collection, writing—reviewing and editing. BS: study design, data collection, writing—reviewing and editing. KK: study design, data collection, writing—reviewing and editing. CDC: study design, data collection, writing—reviewing and editing.

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Patient consent for publication Not applicable.

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REFERENCES

- 1 World Health Organization (WHO). Implementing the Global Health Sector Strategies on HIV, Viral Hepatitis and Sexually Transmitted Infections, 2022–2030. 2024. Available: <https://iris.who.int>
- 2 Wi TE, Ndowa FJ, Ferreyra C, *et al.* Diagnosing sexually transmitted infections in resource-constrained settings: challenges and ways forward. *J Intern AIDS Soc* 2019;22 Suppl 6:e25343.
- 3 Ramboarina S, Crucitti T, Gill K, *et al.* Novel point-of-care cytokine biomarker lateral flow test for the screening for sexually transmitted infections and bacterial vaginosis: study protocol of a multicentre multidisciplinary prospective observational clinical study to evaluate the performance and feasibility of the Genital Inflammation Test (GIFT). *BMJ Open* 2024;14:e084918.
- 4 Martin K, Dauya E, Dziva Chikwari C, *et al.* Evaluation of a novel point-of-care lateral flow assay screening for *Neisseria gonorrhoeae* infection among pregnant women in Zimbabwe. *PLOS Global Public Health* 2025;5:e0003839.
- 5 Peters RPH, Klausner JD, Mazzola L, *et al.* Novel lateral flow assay for point-of-care detection of *Neisseria gonorrhoeae* infection in syndromic management settings: a cross-sectional performance evaluation. *Lancet* 2024;403:657–64.
- 6 Kelly H, Coltart CEM, Pant Pai N, *et al.* Systematic reviews of point-of-care tests for the diagnosis of urogenital *Chlamydia trachomatis* infections. *Sex Transm Infect* 2017;93:S22–30.
- 7 Esitgen Germaner ET, Wassill L, Dichtl K, *et al.* Rapid point of care testing for four bacterial sexually transmitted infections using the portable isothermal loop-mediated nucleic acid amplification eazyplex platform. *Infection* 2023;51:1141–5.
- 8 Herbst de Cortina S, Bristow CC, Joseph Davey D, *et al.* A Systematic Review of Point of Care Testing for *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*. *Infect Dis Obstet Gynecol* 2016;2016:4386127.
- 9 Bissessor M, Tabrizi SN, Fairley CK, *et al.* Differing *Neisseria gonorrhoeae* bacterial loads in the pharynx and rectum in men who have sex with men: implications for gonococcal detection, transmission, and control. *J Clin Microbiol* 2011;49:4304–6.
- 10 Chesson HW, Mayaud P, Aral SO. Sexually transmitted infections: impact and cost-effectiveness of prevention. In: *Disease control priorities, third edition (volume 6): Major infectious diseases*. 2017: 203–32.