VALIDATION OF A NOVEL LATERAL FLOW ASSAY FOR SCREENING FOR *NEISSERIA GONORRHOEAE* INFECTION AMONG PREGNANT WOMEN IN ZIMBABWE

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Background:
Across many regions in the Global South, testing for *Neisseria gonorrhoeae* (NG) is unavailable. High costs and limited diagnostic infrastructure are major barriers. A novel lateral flow assay for NG (NG-LFA) has been shown to have high sensitivity and specificity (>90%) in symptomatic individuals in South Africa. However, performance as a screening tool has not been assessed. We investigated the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the NG-LFA among pregnant women.

Methods:
This study was embedded within a prospective study evaluating point-of-care STI screening in antenatal care (ANC) in Harare, Zimbabwe. Provider-collected vaginal swabs were tested on-site for NG using the NG-LFA as well as molecular testing using the GeneXpert platform (reference test).

Results:
913 pregnant women attending routine ANC were enrolled, with a median age of 25 (IQR 22 – 30) years and a HIV prevalence of 10.0% (91/913). Only 5.6% (51/913) reported any of abnormal vaginal discharge, pelvic pain, or dyspareunia.
Based on GeneXpert, NG prevalence was 4.2% (38/913). The sensitivity, specificity, PPV, and NPV of the NG-LFA were 65.8% (25/38; 95% CI 48.6%–80.4%), 99.2% (868/875; 95% CI 98.4–99.7%), 78.1% (25/32; 95% CI 60.0-90.7%), and 98.5% (868/881; 95% CI 97.5-99.2%), respectively.
Of 13 false-negative results, 8 (61.5%) had an GeneXpert NG2 and/or NG4 target cycle threshold (Ct) value of above 30.

Conclusion:
Among predominantly asymptomatic pregnant women, the NG-LFA had high specificity and NPV, but lower sensitivity than in studies in symptomatic individuals. Although the NG-LFA correctly ruled out infection in the majority of individuals, one in three cases of NG were not detected. Most false-negative cases had high Ct values, suggestive of low bacterial load. Further studies are needed to assess the NG-LFA in different settings and populations, and to explore the relationship between NG-LFA positivity and bacterial load.

Disclosure of Interest Statement:

This study was funded by the Wellcome Trust and via FIND by the UK Department of Health and Social Care as part of the Global AMR Innovation Fund (GAMRIF), by UK International Development from the UK government and with support from the Ministry of Foreign Affairs of the Government of the Netherlands. GAMRIF is a One Health UK aid fund that supports research and development around the world to reduce the threat of antimicrobial resistance in humans, animals and the environment for the benefit of people in low- and middle-income countries (LMICs). The views expressed in this publication are those of the author(s) and not necessarily those of the UK Department of Health and Social Care and they do not necessarily reflect the UK government's official policies. No pharmaceutical grants were received for this study.