Genital InFlammation Test (GIFT) for HIV prevention and reproductive health: point-of-care screening tool for sexually transmitted infections and bacterial vaginosis

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Background: Female genital tract inflammation increases risk of HIV acquisition and adverse reproductive outcomes. This inflammation is primarily caused by sexually transmitted infections (STIs) and vaginal dysbiosis, predominantly bacterial vaginosis (BV). In resource-limited populations, etiological tests are currently too expensive for implementation and women are only treated if they have signs/symptoms (syndromic management). However, many women with these infections are asymptomatic, but have equivalent vaginal inflammation and HIV risk as symptomatic women. We identified biomarkers of vaginal inflammation caused by STIs and BV and are optimizing a low-cost Genital InFlammation Test (GIFT) to measure these biomarkers.

Methods: We validated the performance of three biomarkers (IL-1α, IL-1β, IP-10) in five cohorts of South African and Kenyan women. Biomarkers were measured using Luminex/ELISA, STIs diagnosed using nucleic acid amplification tests (NAATs) and BV using Nugent scoring. We conducted cost, budget impact, cost-effectiveness analyses and a DELPHI survey to evaluate stakeholder recommendations for implementation.

Results: We found that GIFT identified 76% of the women with a STI/BV with 71% specificity and improved accuracy compared to syndromic management (sensitivity 41%, specificity 57%; p=0.0003). Inclusion of vaginal pH with only one biomarker (IL-1α or IL-1β) increased the accuracy to 82%. GIFT was more cost-effective than NAATs and Nugent scoring (incremental cost-effectiveness ratio USD11.08 per woman diagnosed). Sixty-four stakeholders, mainly healthcare professionals, responded to the DELPHI survey. The majority (84%) would offer sexually active asymptomatic women screening with GIFT and most agreed that GIFT could be included in the WHO-recommended management guidelines for symptomatic women.

Conclusion: If offered to women attending primary healthcare clinics in resource-limited settings or used for self-testing, GIFT could provide a cost-effective means to increase STI and BV case-finding. The next step will be to test the GIFT device in three settings in Africa to evaluate performance, feasibility, user experience and cost-effectiveness.

Disclosure of Interest Statement: Lindi Masson and Jo-Ann Passmore are on European and South Africa patents for a Method for Diagnosing an Inflammatory Condition in the Female Genital Tract and co-lead the development of the GIFT device.