Webinar Debrief: An Update on the STI R&D Pipeline and Investments
Date: November 14, 2024
Time: 8–9am ET; 2:00–3:00pm CET; 3:00–4:00pm CAT
Speakers: Cécile Ventola, Birgitta Gleeson, and Mandisa Mdingi
Moderators: Alison Footman

Introduction

Each year, approximately 374 million new cases of sexually transmitted infections (STIs) occur worldwide, meaning more than 1 million new infections of chlamydia, gonorrhea, syphilis, and trichomoniasis are acquired every day. Left untreated, these infections can lead to serious health complications, including pelvic inflammatory disease, infertility, and increased susceptibility to HIV transmission. To address the critical need for advancements in STI diagnostics and prevention, AVAC and Impact Global Health co-hosted a webinar focused on the current STI R&D pipeline.

This collaborative event brought together leading researchers and developers to share insights on recent innovations in STI diagnostics, explore the latest funding trends, and highlight a novel lateral flow assay developed for gonorrhea testing. Although diagnostics for gonorrhea are available, they remain costly and challenging to implement. Moreover, long delays between testing, results, and treatment contribute to a cycle of undertreatment. In many countries with limited testing resources, syndromic management is the primary approach due to its affordability, but this method often results in undertreatment and overtreatment of infections—issues that drive antimicrobial resistance (AMR).

The need for affordable, accessible, and rapid diagnostic is clear. Better tools are essential for timely detection, treatment, and prevention of STIs, ultimately reducing their transmission and alleviating the broader public health burden.

Speaker Bios

- **Cécile Ventola** (Impact Global Health, Germany)
  Cécile Ventola holds a PhD in Public Health from the University of Paris 11 (2017). She is a Senior Technical Officer for sexual and reproductive health at Impact Global Health. Her research has covered a broad range of topics in sexual and reproductive health, including male contraceptives, sexuality surveys, access to healthcare for LGBTQI+ populations, gender-affirming healthcare, and intersections of gender and health.

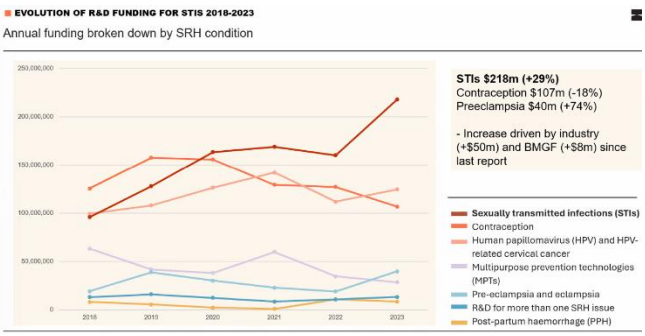
- **Birgitta Gleeson** (FIND, Switzerland)
  Birgitta Gleeson is a seasoned scientist with over 12 years of experience in life sciences and global health. She holds a PhD in Medicine, an MSc in Immunology and Global Health, and a BSc in Microbiology. Birgitta specializes in developing and implementing innovative diagnostic solutions for low- and middle-income countries, with a particular focus on antimicrobial resistance (AMR). Her background includes work with Médecins Sans Frontières (MSF) in challenging settings such as remote and conflict-affected areas.

- **Mandisa Mdingi** (Foundation for Professional Development, South Africa)
  Mandisa Mdingi is a registered professional nurse with a master's degree in public health. As a

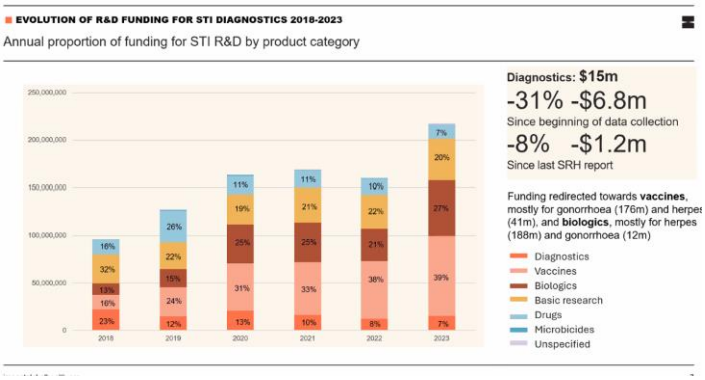
research manager for the Foundation for Professional Development's clinical research unit in East London, South Africa, she leads STI research projects. Mandisa has worked on the development and implementation of STI diagnostic tests, including a novel point-of-care test for Neisseria gonorrhoeae, and is pursuing a PhD in molecular epidemiology of STIs in South Africa.

STI Investments

In 2023, reported investments in STI research reached $218 million, marking a 29% increase since 2021. This growth has been primarily driven by contributions from industry and the Bill & Melinda Gates Foundation. Despite this overall increase, funding, specifically for STI diagnostics decreased by 8% since 2021 and has fallen by over 30% since the beginning of data collection in 2018. Much of the investment in STI R&D has been redirected toward vaccines, primarily for gonorrhea and herpes, as well as biologics, especially for herpes and gonorrhea.



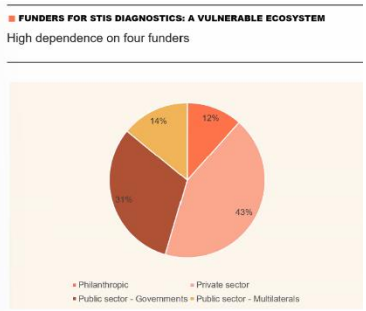
Within diagnostic investments, point-of-care (PoC) tests for the detection of multiple STIs have received the most funding, with several projects exploring self-collection methods and digital tools for test interpretation. Notably, some gonorrhea diagnostics include antimicrobial susceptibility testing, to better guide treatment.

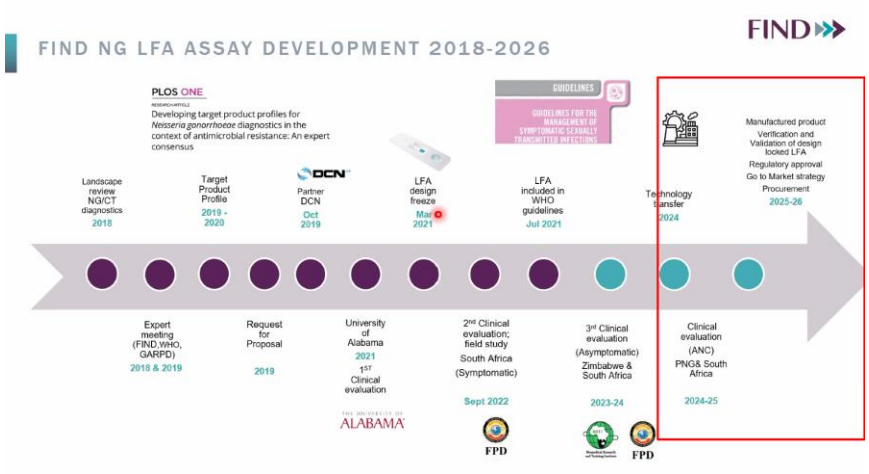


In 2023, 89% of the funding for STI diagnostics came from only four key funders: the Gates Foundation, US NIH, CARB-X, and one industry stakeholder. This concentrated funding landscape creates a vulnerable ecosystem heavily dependent on a limited pool of donors. Sustainable investment and partnerships with industry are essential to bring low- and middle-income country (LMIC)-appropriate diagnostic tests to market, ensuring accessibility and long-term impact.

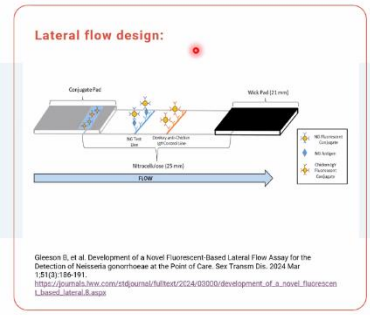
Gonorrhea Diagnostics

The need for effective PoC testing for gonorrhea has led to the development of lateral flow assay (LFA), a promising diagnostic tool tailored to improve accessibility and accuracy, particularly in low- and middle-income countries (LMICs). As gonorrhea presents significant challenges for timely diagnosis and treatment, FIND along with partners including the World Health Organization, has outlined a target product profile (TPP) to establish clear performance and usability standards for gonorrhea diagnostics, ensuring it meets specific needs in diverse healthcare settings.





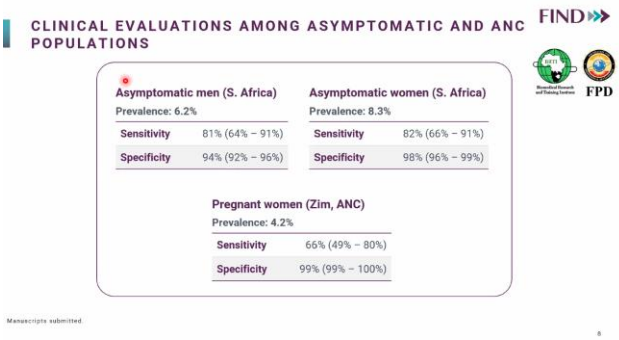
The LFAs clinical testing journey began in 2021 at the University of Alabama at Birmingham, focusing initially on symptomatic patients. In 2022, large-scale clinical evaluations were conducted in South Africa in partnership with Foundation for Professional Development (FPD), and by 2023-2024, testing expanded to asymptomatic populations in both South Africa and Zimbabwe in partnership with FPD and The Health Research Unit Zimbabwe (THRU-ZIM). These trials aim to ensure the assay's efficacy across various patient demographics, identifying any differences in performance between symptomatic and asymptomatic individuals.

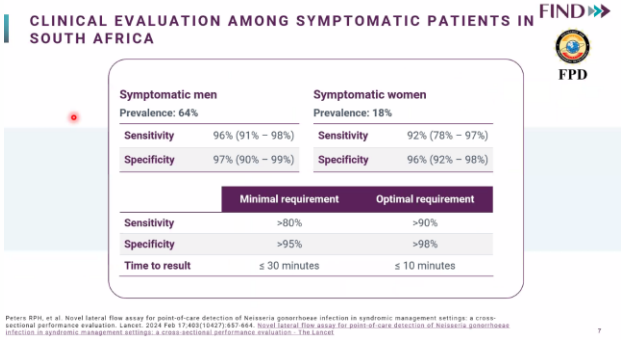


The LFA is designed for efficiency, delivering results within 20 minutes. The test is currently compatible with female vaginal swabs and male urine samples, adding a sample to the conjugate pad to initiate the testing process. Importantly, the results are visualized via a fluorescent reader, which provides accuracy while adding a requirement for specific equipment. The assay's

shelf life of one year at 40 degrees Celsius also makes it suitable for deployment in regions with limited refrigeration options.

Initial clinical trial data indicate that the assay aligns well with the TPP's sensitivity and specificity standards, although an unexpected drop in sensitivity was noted among patients in antenatal care (ANC) populations. Researchers are investigating this observation to understand the underlying factors and ensure the assay maintains reliable performance in all targeted populations.



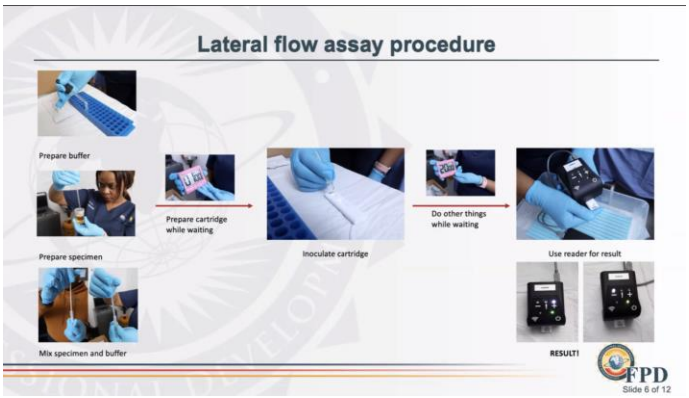


FIND is aiming for market release of the lateral flow assay by 2026, with hopes that this tool will significantly improve gonorrhea diagnosis and management in settings where healthcare resources are limited.

The COVID-19 pandemic's impact on diagnostic technology has also influenced gonorrhea testing. Innovations spurred by COVID-19 have led to the creation of smarter, faster, and more affordable diagnostic tools, many of which are being adapted for STI diagnostics. As COVID-19 cases decline, several diagnostic companies have pivoted toward STI testing, integrating these advancements into the development of new molecular tests for gonorrhea. This trend is likely to enhance the STI diagnostics field, as new tests emerge that complement the lateral flow assay and further support timely diagnosis and treatment.

Implementation of Lateral Flow Assay in South America

The implementation of LFA for gonorrhea aims to enhance access to rapid and accurate STI diagnostics in PoC settings, especially in limited-resource environments. To prepare for the rollout, the FIND team conducted a structured training program, starting with managerial staff and followed by on-site training for the field team. FIND provided "procedure quick cards" to ensure consistent sample collection and testing, with a hands-on demonstration of the process, practice sessions with demo samples, and training on interpreting different results scenarios—positive, negative, and invalid.



The study was conducted in five primary healthcare facilities equipped with GeneXpert® systems, where the Xpert® CT/NG Assay served as the gold standard comparator. A cross-sectional design was employed to evaluate the LFA's diagnostic performance against GeneXpert®, with a study population of 1,400 individuals: 200 men with male urethral syndrome (MUS), 200 women with vaginal discharge syndrome (VDS), and 1,000 asymptomatic participants (500 men and 500 women).

In symptomatic participants, gonorrhea prevalence was 64% in males and 18% in females. The LFA demonstrated high sensitivity and specificity, 96.1% and 97.2%, respectively, in symptomatic men, and 91.7% and 96.3%, respectively, in symptomatic women. For asymptomatic participants, prevalence was lower at 6.2% in men and 8.3% in women, with the LFA showing a sensitivity of 80.6% and specificity of 94.2% in men, and 91.8% sensitivity and 98.1% specificity in women.

The LFA also scored high in terms of usability and accessibility. Field workers, including non-professional nurses, reported that it was easy to use, and the assay's adaptability to different staffing levels reduced waiting times for patients and eased workloads for professional nurses. Its flexibility also allows for use in space-limited settings, helps mitigate stigma associated with STI testing, and promotes awareness among patients about STI types and the benefits of health-improving technologies.

Next steps for the LFA will include expanding testing to assess usability, acceptability, and performance in symptomatic non-pregnant women who self-collect samples, as well as in pregnant women. Overall, the LFA shows considerable promise as a PoC test that can reinforce STI management in syndromic treatment settings, especially in LMICs.

FAQ

1. **What symptoms are considered when diagnosing STIs in men and women?**
    - Both vaginal and urethral discharge were considered, but abdominal pain was not included.

2. **What is the cost of the new diagnostic device?**
    - The test is being transferred to the manufacturer so currently the price is unknown.

1. **For implementation, did you conduct qualitative studies to gather feedback from providers, clients, and policymakers on adopting point-of-care (PoC) tests?**
    - Initial phases of research focused on the experiences of research staff (research nurses and field workers). Future phases (for studies in pregnant women) will include client, policymaker, and clinic provider perspectives, especially regarding sample collection.

3. **How can we increase funding for STI research and development?**
    - Emphasizing the consequences of inadequate funding can help secure more investment. Further strategies and discussions are necessary to develop a comprehensive funding approach.

4. **Why is antigen-based testing preferred over molecular tests like Visby and Binx for STI diagnostics?**
    - Antigen-based tests are more affordable and simpler to use at the point of care. They offer several advantages, such as being easier to implement in resource-limited settings, and patients can receive results in minutes compared to other tests that require hours to days for results.

5. **Will you include other key populations, like men who have sex with men (MSM), in future studies?**
    - Yes, future studies will likely expand to include other high-risk populations, including MSM and vulnerable communities. OBJ

Resources

- **AVAC Clinical Trials Database**
  The STI Clinical Trials Dashboard provides information about trials focused on vaccines, diagnostics, and the use of doxycycline post-exposure prophylaxis (DoxyPEP) for STIs.
  Visit the STI Trials Dashboard

- **GFINDER Data Portal**
  The G-FINDER project tracks R&D funding for new products and technologies addressing global health challenges. The G-FINDER data portal provides open access to all data captured by the G-FINDER project.
  Explore the GFINDER Data Portal

- **GFINDER Sexual and Reproductive Health Report**
  The 2023 report, "Beyond Spillovers," examines R&D funding trends for sexual and reproductive health products, including STIs, HPV, contraception, and more.
  Read the GFINDER SRH Report

- **AVAC's STI R&D Pipeline and Investments Report**
  This report tracks STI vaccine and diagnostic R&D funding from major funders like the NIH and

Gates Foundation, offering valuable insights into the STI pipeline.
Access the AVAC STI R&D Report

- **Development of a Novel Fluorescent-Based Lateral Flow Assay for the Detection of Neisseria gonorrhoeae at the Point of Care**
  Access the Article

- **Usability of a novel lateral flow assay for the point-of-care detection of *Neisseria gonorrhoeae***: A qualitative time-series assessment among healthcare workers in South Africa
  Access the Journal

- **Implementation considerations for a point-of-care Neisseria gonorrhoeae rapid diagnostic test at primary healthcare level in South Africa:** A qualitative study
  Access the Article

- **FIND's DxConnect Test Directory**
  Access the Test Directory