FOUNDATION FOR PROFESSIONAL DEVELOPMENT

A novel lateral flow assay for point-of-care detection of *Neisseria gonorrhoeae*: Implementation experiences

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Disclosure

Any circumstances that could give rise to a potential conflict of interest related to the conference or topic under discussion	Name of company, organization or institution
Sponsorship	FIND
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Shareholder rights	None
Other relations	None

Need for affordable POC

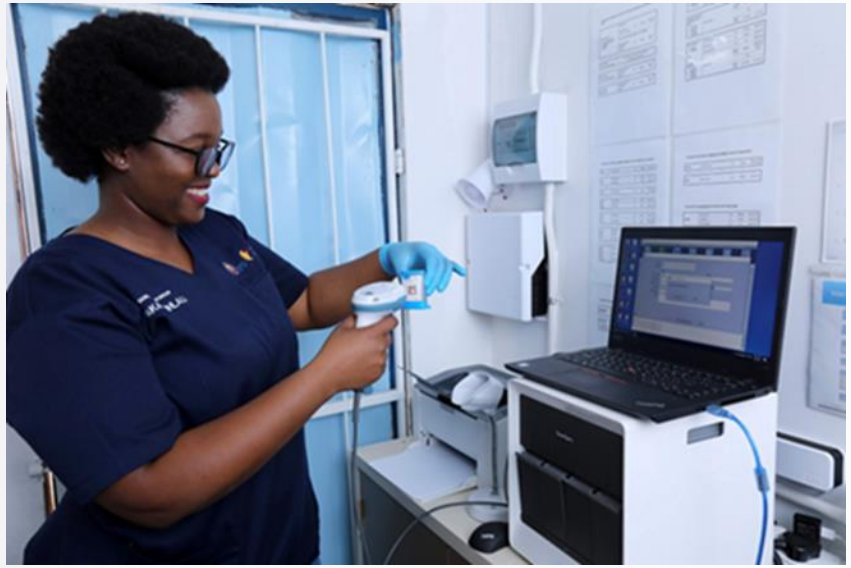
- Affordable point-of-care (POC) test is essential to reduce the global burden of *Neisseria gonorrhoeae* infection
- NG POC target product profile (TPP) was developed for intended use in syndromic management settings and screening of high-risk populations
- TPP requirements for non-molecular test for NG POC detection:

	Minimal requirement	Optimal requirement
Sensitivity	>80%	>90%
Specificity	>95%	>98%
Time to result	≤ 30 minutes	≤ 10 minutes

Ferreyra C et al. PLoS One 2020

Methods (1)

- **FIND team conducted training for managerial staff:**
  - followed by onsite training for field team
  - FIND provided "**procedure quick cards**" to be used for different samples collected
- **Step-by-step testing demonstration followed by hands-on practice with demo samples**
  - Different results scenarios were explored; negative, positive and invalid (to prepare the team for the real-life situation)

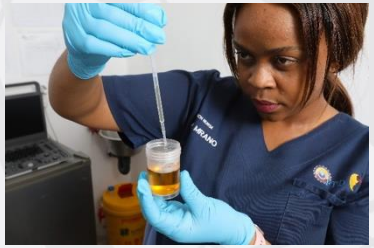


Methods (2)

- **Study design:** Cross-sectional study of diagnostic performance of LFA compared to Xpert® CT/NG Assay as gold standard
- **Study location:** 5 primary healthcare facilities
  - In-facility GeneXpert® testing
  - IRB approved: reference number 510/2021
- **Study population:**
  - Men with MUS (n=200)
  - Women with VDS (n=200)
  - Asymptomatic men (n=500) and Asymptomatic women (n=500)

Lateral flow assay procedure

Prepare buffer



Prepare specimen

Mix specimen and buffer

Prepare cartridge while waiting

Inoculate cartridge

Do other things while waiting

Use reader for result

RESULT!

Results

Symptomatic evaluation

	Male patients (n=200)	Female patients (n=200)
Neisseria gonorrhoeae prevalence	128 (64%)	36 (18%)
Sensitivity	96·1% (91·2–98·3)	91·7% (78·2–97·1)
Specificity	97·2% (90·4–99·2)	96·3% (92·2–98·3)
Positive predictive value	98·4% (94·4–99·6)	84·6% (70·3–92·8)
Negative predictive value	93·3% (85·3–97·1)	98·1% (94·7–99·4)
Accuracy	96·5% (93·0–98·3)	95·5% (91·7–97·7)

Data n (%) or % (95% Wilson's CI).

Table 3: **Diagnostic performance characteristics of *Neisseria gonorrhoeae* lateral flow assay compared with Xpert for the detection of *N gonorrhoeae* in symptomatic male and female patients**

Novel lateral flow assay for point-of-care detection of *Neisseria gonorrhoeae* infection in syndromic management settings: a cross-sectional performance evaluation

Remco P H Peters, Jeffrey D Klausner, Laura Mazzola, Mandisa M Mdingi, Hyunsul Jung, Ranjana M S Gigi, Jeremie Piton, Joseph Daniels, Lindsey de Vos, Paul C Adamson, Birgitta Gleeson, Cecilia Ferreyra

Asymptomatic evaluation

	Males (n=500)	Females(n=400)
Neisseria gonorrhoeae prevalence	6.2%	8.3%
Sensitivity	80.6% (63.7% - 90.8%)	81.8% (65.6% - 91.4%)
Specificity	94.2% (91.8% - 96.0%)	98.1% (96.1% - 99.1%)

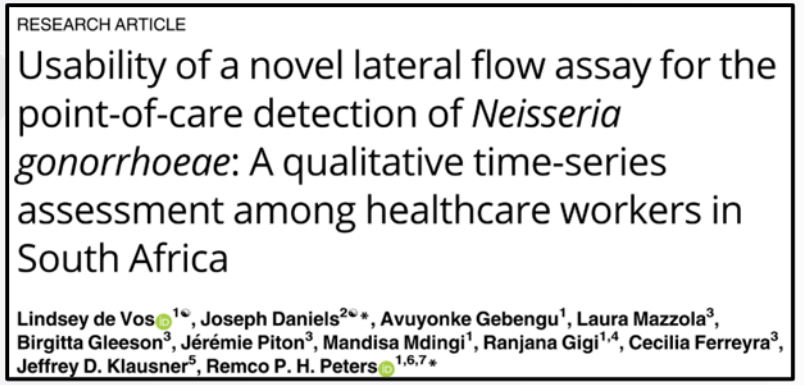
Peters (unpublished, submitted to Lancet Infectious Diseases)

Peters RPH et al. Lancet 2024

Usability and acceptability

- **<u>Results of the usability and acceptability:</u> highly acceptable and usable even among non-professional nurses (field workers)**

de Vos (2023) PloS ONE
DOI:10.1371/journal.pone.0286666


RESEARCH 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

Lindsey de Vos[1☯], Joseph Daniels[2☯*], Avuyonke Gebengu[1], Laura Mazzola[3], Birgitta Gleeson[3], Jérémie Piton[3], Mandisa Mdingi[1], Ranjana Gigi[1,4], Cecilia Ferreyra[3], Jeffrey D. Klausner[5], Remco P. H. Peters[1,6,7*]

de Vos (2024) BMC Health Service Research
DOI: 10.1186/s12913-023-10478-8


RESEARCH Open Access

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

Lindsey de Vos[1†], Joseph Daniels[2*†], Avuyonke Gebengu[1], Laura Mazzola[3], Birgitta Gleeson[3], Benjamin Blümel[3], Jérémie Piton[3], Mandisa Mdingi[1], Ranjana M.S. Gigi[1,4], Cecilia Ferreyra[3], Jeffrey D. Klausner[5] and Remco P.H. Peters[1,6,7*]

Potential impact of the assay on clinic flow

- **Any staff category can perform the test**
  - alleviates pressure from the professional nurses
  - reduce waiting times
- **Accommodates space constraints and potential stigma concerns**
- **Increased awareness of STI types amongst patients**
- **Investment in health improving technologies**

Next steps

- **Performance of LFA in symptomatic non-pregnant women using self-collected samples**
  - Usability and acceptability
- **Performance of LFA in pregnant women**

Conclusion

- **The novel lateral flow assay provides a promising POC test that may strengthen STI treatment in syndromic management settings**

Thank you

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