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Evaluation of a new lateral flow test for the diagnosis and treatment of Neisseria gonorrhoeae among men and women in Papua New Guinea

Submission date
29/10/2025

Recruitment status
Recruiting

Registration date
09/11/2025

Overall study status
Ongoing

Last Edited
31/10/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is testing a new rapid test to help diagnose and treat gonorrhoea, a common sexually transmitted infection. The test is designed to work at the clinic, giving quick results without needing to send samples to a lab. Researchers want to find out how well this new test works compared to an existing laboratory test. The study will take place in antenatal and sexual health clinics in Papua New Guinea.

Who can participate?
People attending antenatal or sexual health clinics in Papua New Guinea may be invited to take part. This includes pregnant women, women and men attending sexual health services, and men who have sex with men.

What does the study involve?
Participants will be asked to provide a sample for testing. This could be a self-collected vaginal swab (for pregnant women), an anal swab, or a urine sample. The sample will be tested using the new rapid test. Another test called GeneXpert will also be used to confirm the results. If the GeneXpert test shows an infection, treatment will be offered on the same day.

What are the possible benefits and risks of participating?
Benefits include getting tested and treated quickly for gonorrhoea, which can help prevent health problems and stop the infection from spreading. Risks are expected to be low, but may include mild discomfort when collecting samples or sharing personal health information.

Where is the study run from?
Papua New Guinea Institute of Medical Research

When is the study starting and how long is it expected to run for?
December 2024 to November 2026

Who is funding the study?
Foundation for Innovative New Diagnostics

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Clinical performance of a novel lateral flow assay for point-of-care diagnosis and treatment of Neisseria gonorrhoeae among asymptomatic and symptomatic people attending antenatal and sexual health clinics in Papua New Guinea

Acronym
GO study

Study objectives
1. To determine the clinical performance of the NG-LFA for the detection of N. gonorrhoeae in self-collected vaginal samples from pregnant women attending antenatal clinic compared with

Xpert® CT/NG as the reference standard.
2. To determine the clinical performance of the NG-LFA for the detection of N. gonorrhoeae in self-collected vaginal samples from symptomatic women attending sexual health clinics compared with Xpert® CT/NG as the reference standard.
3. To determine the clinical performance of the NG-LFA for the detection of N. gonorrhoeae in urine samples from symptomatic men attending Sexual Health Clinics compared with Xpert® CT /NG as the reference standard.
4. To determine the clinical performance of the NG-LFA for the detection of N. gonorrhoeae in self-collected anorectal samples from symptomatic men attending Sexual Health Clinics compared with Xpert® CT/NG as the reference standard.
5. To determine the acceptability, usability, and preferences of the NG-LFA compared with Xpert® CT/NG testing and with standard care based on STI syndromic management among healthcare workers and policy makers.
6. To assess the acceptability and preference of the NG-LFA compared with standard care among women and men attending participating clinic services in PNG.
7. To determine the prevalence of N. gonorrhoeae antimicrobial resistance (AMR) among women and men attending participating clinic services in PNG.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 06/12/2024, Papua New Guinea Institute of Medical Research Institutional Review Board (PO Box 60, Goroka, 441, Papua New Guinea; + 675 532 2800; general@pngimr.org.pg), ref: 2416

2. approved 06/05/2025, Medical Research Advisory Board (PO Box 807, Waigani, NCD, 4315, Papua New Guinea; + 675 3013650; psiba@dwu.ac.pg), ref: MRAC#25.14

3. approved 07/07/2025, iRECS UNSW (UNSW, Sydney, 2052, Australia; +61 (02) 9385 1000; humanethics@unsw.edu.au), ref: iRECS9127

Study design
Observational cross-sectional single-time-point study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
N. gonorrhoeae among antenatal women and men and women attending sexual health services

Interventions
This mixed methods cross-sectional, single-time-point study will determine the clinical performance of the point-of-care NG-LFA compared with the Xpert® CT/NG test as the reference standard in different clinical populations and settings in PNG.
Both tests will be conducted at point-of-care. Clinical treatment and management decisions will

be based on the Xpert® CT/NG test results only. Patients with any positive test result on the original sample will be asked for an additional sample, which will be sent for microbiological antimicrobial susceptibility testing.

Intervention Type
Other

Primary outcome(s)
1. Clinical performance characteristics of the NG-LFA (sensitivity, specificity, positive and negative predictive values) compared with the Xpert® CT/NG test as the reference standard. These will be calculated and reported as proportions and estimated with 95% confidence intervals (95% CI) using standard statistical methods. Samples will be collected at enrolment with all testing at the pint of care, and treatment as necessary.
2. Acceptability, usability and preference characteristics of the point of care screen and treta approach from health worker and participant perspectives. Measured using quantitative and qualitative data, collected via an exit survey among all participants and semi structured interviews among a sub-set of participants

Key secondary outcome(s))
Inhibitory concentrations and calculate the proportion of N. gonorrhoeae isolates which are susceptible, intermediate or resistant (or show reduced susceptibility) to antimicrobials, according to European Committee on Antimicrobial Susceptibility Testing (EUCAST) breakpoints, and present estimates with 95% CI. For those testing positive for N. gonorrhoeae, an additional sample will be requested prior to treatment being provided for microbiological evaluation using standardised antimicrobial susceptibility testing by culture (AST). Genomic materials will be extracted from these samples and tested for NG using two different genetic markers by PCR. The testing in the latter serves two purposes, to confirm NG positivity and to assess NG bacterial load in the samples. Samples that tested positive and had sufficient bacterial load will be further tested for the presence of genes (by PCR) and mutations (by genotyping PCR) that are predictive for resistance against the antimicrobials used for treating NG. Sequencing will be performed, and the sequences will be analysed using different tools including Multi-antigen sequence typing (MAST), Sequence typing for antimicrobial resistance (STAR), and Multi-locus sequence typing (MLST).

Completion date
30/11/2026

Eligibility

Key inclusion criteria
Antenatal Clinic (ANC):
1. Asymptomatic and symptomatic pregnant women will be eligible to participate if aged 16 years or over.
2. They must be attending a study site for antenatal care.
3. They must be willing to participate.
4. They must be able to complete informed consent procedures.
5. Women attending their first ANC visit (a ‘booking’ visit) will be eligible.
6. Women attending an ANC follow-up visit during their current pregnancy will also be eligible.

Sexual Health Clinic (SHC):
1. Women and men attending for sexual health services will be eligible to participate if aged 18

years or over.
2. They must be presenting with genital symptoms (vaginal discharge syndrome in women; urethral discharge syndrome in men; see Table 2).
3. They may also be presenting with anorectal symptoms (MSM/TG people).
4. They must be willing to participate.
5. They must be able to complete informed consent procedures.

Participant type(s)
Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
64 years

Sex
All

Key exclusion criteria
1. Genital symptoms that are not consistent with vaginal discharge syndrome (VDS) or urethral discharge syndrome (UDS), e.g. genital ulcer disease.
2. Currently taking treatment for Neisseria gonorrhoeae infection.
3. Neisseria gonorrhoeae treatment taken within two weeks before enrolment.
4. Received antibiotics (e.g. broad-spectrum) within 21 days prior to enrolment.
5. Use of vaginal douche or vaginal product in the previous 24 hours (all women).
6. Use of anal douche or anal product in the previous 24 hours (MSM/TG people only).
7. A medical condition, serious illness, or other condition that could interfere with study procedures or jeopardise participant safety.
8. Unable to provide specimens for testing.
9. Unable to provide informed consent.

Date of first enrolment
30/11/2025

Date of final enrolment
30/11/2026

Locations

Countries of recruitment
Papua New Guinea

Study participating centre
PNG Institute of Medical Research
Goroka
Eastern Highlands Province
Papua New Guinea
441

Sponsor information

Organisation
Papua New Guinea Institute of Medical Research

ROR
https://ror.org/01x6n0t15

Funder(s)

Funder type
Charity

Funder Name
Foundation for Innovative New Diagnostics

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			30/10/2025	No	Yes