PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM
Pregnant Women

Full 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, sexual health, and well woman clinics in Papua New Guinea.

Short title: Evaluation of the NG LFA among asymptomatic and symptomatic people in Papua New Guinea. *The "GO PNG study"*

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Please read this information sheet (or ask a friend to read it to you) before you decide to take part. Please ask if there is anything that is not clear.

Why is this study being done?

We are conducting a study that evaluates a new type of test for the detection of a sexually transmitted infection called gonorrhoea. This document provides information about this research project and will help you to decide if you would like to take part.

Sexually transmitted infections are very common among pregnant women in Papua New Guinea. Our earlier work in PNG showed that around half of all pregnant women coming to antenatal clinic had at least one infection – either chlamydia, gonorrhoea, trichomonas and another infection called bacterial vaginosis.

Research tells us that having one or more of these infections could cause problems during pregnancy. This includes a baby being born too early or being born too small.

A big problem is that many women don't know if they have an STI because these infections do not cause any symptoms in most pregnant women. In PNG, only people with symptoms are treated for STIs.

Many pregnant women in PNG therefore do not get treatment if they need it.

In our recent study in PNG, we found that only women with gonorrhoea had babies born too early or too small

Sexually transmitted infections, including gonorrhoea may present as genital discharge or abdominal pain, but can also occur without symptoms. This means that you do not know if you have it. The only way to check for gonorrhoea is by doing a test. However, many of the tests are not available on PNG. Recently, a new type of test has been developed that may be used within the facilities at point-of-care. This test can provide a diagnosis of gonorrhoea.

The PNGIMR is conducting a study to test and treat pregnant women for gonorrhoea using the new type of test.

The new test is called a lateral flow assay. In our study we want to compare how this new test performs against another test that we have used before in PNG to look for gonorrhoea and other STIs. That test is called the GeneXpert. In our new study, we would like to test you for gonorrhoea using the new lateral flow assay and with the GeneXpert test. The GeneXpert machine will also test for another STI called Chlamydia. If you test positive for gonorrhoea or chlamydia on the GeneXpert we will give you treatment.

What does joining the Study involve?

The study is taking place at three antenatal clinics in three provinces in PNG. About 1000 pregnant women will take part.

At the antenatal clinics you will receive normal antenatal care from the clinic staff. The study team will want to ask you some additional questions and will ask you to self-collect two swabs from your vagina. They will provide clear instructions on how you can do this. Your swab will be tested for gonorrhoea while you wait in the clinic. If the test is positive, you will be given treatment the same day. We will also want to treat your husband if he is with you. If he didn't come with you, we can give you tablets to take home for him.

Who can participate in this study?

Any pregnant woman aged 16 years or over attending antenatal clinic can join the study.

What will happen to me if I agree to take part?

Our research nurse will talk to you more about the study and explain what taking part would mean for you. After you have had all your questions answered, you will be asked to sign (or put your thumbprint on) a **Consent Form,** to confirm that you agree to take part. If you cannot read then we recommend that you have a witness present for the discussion, who will sign the Consent Form on your behalf. You will then be given a **Study Number** which is unique to you. This will help us make sure that that the answers you give to our questions and your test results remain confidential.

During your antenatal visit

You will receive routine antenatal care, as recommended for all women who come to antenatal clinic in PNG. This will include a general medical and pregnancy check-up, collection of blood to test for HIV, syphilis, malaria and anaemia, and collection of urine to test for sugar or protein. You will also be given routine medicines such as iron and malaria tablets and a tetanus injection.

In addition to this routine antenatal care, we will provide additional investigations and ask some extra questions as part of this study:

- We will ask you some general questions about you, and your circumstances. For example, we will ask you about your level of education; if you are married, how old you are and how many times you have been pregnant.
- We will also ask some more sensitive questions e.g. about your sexual practices. If you feel uncomfortable answering any of the questions please tell our staff – **you do not have to answer questions that you do not want to.**
- We will ask you to collect 2 vaginal swabs that we will test in the clinic for gonorrhoea. We will show you how you can collect these swabs yourself. A private place will be provided for you to carry out the collection. Nobody will be able to see you collecting the swabs. **We will give you your test results and any treatment that you need the same day.**
- When we give you your test result we also ask you a few more questions about your experience of being in the study and how you felt about taking the swab.
- We may ask you to take part in an additional interview about your experience in being involved in this study.

What will happen to the samples?
The vaginal swabs will be tested for gonorrhoea. We will use two different tests.

- Testing will be carried out in the clinic by our staff and results will be available after **about 2-3 hours**. If you test positive for any of the infections, we will provide you with immediate treatment. We will also provide treatment for your husband.
- If you test positive for gonorrhoea we will ask you to provide another vaginal swab. This swab will be tested outside of the clinic to make sure the treatment we have given you is the most effective treatment possible.

None of your personal information will be linked to your samples.

How long will I be in the study?
We will only meet with you once at the clinic. We do not need to see you again for other checks.

Do I have to take part?
No. It is up to you to decide. You can also decline to answer any questions or to change your mind about being part of the study if you want to.

Can I stop taking part?
Yes, you can decide to stop taking part whenever you choose. This would mean that you do not need to explain why you want to stop taking part to anyone, just that you want to stop. This will not affect any care you receive now or in the future.

What are the risks in participating?
The risks involved with the study are likely to be minimal or none. You may experience some slight embarrassment or discomfort while collecting the vaginal swabs. The procedure for collection will be explained to you by the nurse to make sure this is minimised as much as possible.

You may feel slightly uncomfortable or embarrassed by the questions we ask you about your sexual health. We will always keep your answers private and confidential. All the study staff are trained and experienced in asking such questions. We hope that this will avoid any such feelings during the study.

If the test results show us that you have an infection, we will ask you to bring your husband to clinic for treatment. If you think this may be difficult, the study staff can discuss how to tell your husband.

There are no other risks from taking part in the study.

What are the benefits in taking part in the study?
Being involved in this study provides you with the opportunity to be tested for gonorrhoea that may harm you and/or your baby. These tests are not usually available to you. All testing and treatment will be provided free of charge. The information the research team and health staff learn from this study will help to improve the health of pregnant women and their families.

Will my details and the information I give you be kept secret?
Yes. Your contact details will only be available to clinic staff. Staff that monitor the study (e.g. members of the research team named on page 1 of this information sheet) have to check the consent forms and they will see your name briefly when this is being done. All the other information that is collected for the study will not be identified by your name, only by your **Study Number**, including any test results.

All the information we collect will remain secret and will be stored in locked filing cabinets in our offices.

We will **NOT** enter anyone's name or address into the computer.

You will **NOT** be identified in the write up of the results in any report or publication.

What is the cost of participating in the study?
It will not cost you anything to participate in this study. All your tests and treatment will be provided free of charge.

What rights do participants have?
You have the right to withdraw from the study at any point in time. You have the right not to answer any question at any time. This will not affect any treatment or service provided to you by the antenatal clinic.

Will samples be stored and used for future studies?
Samples will only be stored and used for future studies if you give your permission.

How will I find out about the results of this study?
After the study has been completed the results will be analysed. This can take up to 6-12 months. After this a plain language summary report in *tok pisin* and English will be produced and provided to women who participated in the research, community groups and key stakeholders, including policy makers and health service providers.
The results of the study will also be written up and submitted for review by a medical journal. They may also be presented at national and international meetings and scientific conferences.

You will **NOT** be identified in any conference presentation, report, or medical journal article.

Who has approved this study?
This study has been approved by the PNG IMR Institutional Review Board and the Medical Research Advisory Committee in PNG. It has also been approved by the Human Research Ethics Committee of the University of New South Wales in Australia.

Who can I speak to if I have questions or problems?
If you would like any more information about this study please contact:

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If you would like to speak to someone not directly involved with the study you may contact the Ethics Committee in Australia by phone or e-mail using the details given below:

Ethics Secretariat, the University of New South Wales, Sydney 2052, Australia
Tel: +61 2 9385 4234 / **Fax:** +61 2 9385 6648 / **E-mail:** humanethics@unsw.edu.au

Any complaint you make will be confidential and investigated promptly. You will also be informed of the outcome. If you are unable to make international calls or do not to access e-mail, you may contact **Dr Riddell** at the **PNG IMR** who will contact the Ethics Committee in Australia on your behalf.

You will be given a copy of this form to keep.