Study ID Number	

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

Full title: Cluster randomized crossover trial to evaluate point-of-care testing and treatment of sexually transmitted infections to improve birth outcomes in high-burden, low-income settings

Short title: WANTAIM: Women And Newborn Trial of Antenatal Interventions and Management

Research Team:

Chief Investigators	
Dr Andrew Vallely	Professorial Research Fellow, Sexual and Reproductive Health, Papua New Guinea Institute of Medical Research, Goroka, Eastern Highlands Province, Papua New Guinea; and Associate Professor, Public Health Interventions Research Group, The Kirby Institute, University of New South Wales, Wallace Wurth Building, Sydney, NSW 2052, Australia
Dr William Pomat	Deputy Director, Science, and Head, Infection and Immunity Unit, Papua New Guinea Institute of Medical Research, PO Box 60, Goroka, Eastern Highlands Province EHP 441 Papua New Guinea
Principal Investigators	
Prof Caroline Homer	Director of Centre for Midwifery, Child and Family Health, Faculty of Health, University of Technology Sydney, NSW, Australia
A/Prof Rebecca Guy	Head, Surveillance Evaluation and Research Program, The Kirby Institute, University of New South Wales, NSW, Australia
Prof John Kaldor	Professor of Epidemiology and NHMRC Senior Principal Research Fellow, Head, Public Health Interventions Research Group, The Kirby Institute, University of New South Wales, NSW, Australia
A/Prof Stanley Luchters	Head, Women and Children's Health, Centre for International Health, Burnet Institute, VIC, Australia
Prof Glen Mola (Trial Medical Expert)	Head of Reproductive Health, Obstetrics and Gynaecology, School of Medicine and Health Sciences, University of Papua New Guinea, PNG
Dr Grace Kariwiga (Trial Medical Expert)	Consultant Obstetrician and Gynaecologist, Alotau Provincial Hospital, Milne Bay Provincial Health Authority, PNG
Dr Lisa Vallely	Lecturer, The Kirby Institute, University of New South Wales, NSW, Australia
A/Prof Virginia Wiseman (Trial Health Economist)	Health Economist, School of Public Health and Community Medicine, University of New South Wales, NSW Australia London School of Hygiene & Tropical Medicine, London UK
Dr Chris Morgan (Health Systems Specialist)	Principal Fellow, Centre for International Health, Burnet Institute, VIC Australia
A/Prof Handan Wand (Trial Statistician)	The Kirby Institute, University of New South Wales, NSW, Australia
Prof Stephen Rogerson	Department of Medicine, University of Melbourne, VIC Australia.
Prof Sepehr Tabrizi	Department of Microbiology, The Royal Women's Hospital / The Royal Children's Hospital, Melbourne University of Melbourne, VIC, Australia
A/Prof David Whiley (Chair, Laboratory Sub-group)	NHMRC Career Development Fellow, The University of Queensland, UQ Centre for Clinical Research; Research Scientist, Microbiology, Pathology Queensland; Building 71/918, Royal Brisbane Hospital, Herston Qld 4029, Australia
Prof Suzanne Garland	Director of Microbiological Research and Head of Clinical Microbiology and Infectious Diseases Royal Women's Hospital, Department of Obstetrics and Gynaecology University of Melbourne Vic. Australia
Prof Nicola Low	Professor of Epidemiology and Public Health, Director of Research, University of Bern, Switzerland
Prof Rosanna Peeling	Professor and Chair of Diagnostics Research, Department of Clinical Research, London School of Hygiene & Tropical Medicine, London UK
Prof Peter Siba	Director, Papua New Guinea Institute of Medical Research, Goroka, EHP, Papua New Guinea
Co-Investigators	
Dr Michaela Riddell (Trial Coordinator)	Clinical Trial Coordinator, Papua New Guinea Institute of Medical Research, PO Box 378, Madang 511, Papua New Guinea
Dr Moses Laman	Senior Clinical Research Fellow, Papua New Guinea Institute of Medical Research, PO Box 378, Madang 511, Papua New Guinea
Dr John Bolnga	Consultant Obstetrician and Gynaecologist, Department of Obstetrics & Gynaecology, Modilon General Hospital, Madang, Papua New Guinea.
Dr Leanne Robinson	Head, Vector Borne Disease Unit, Papua New Guinea Institute of Medical Research, Madang, Papua New Guinea
Dr Jacob Morewaya	Head, Public Health Division, Milne Bay Provincial Health Authority, Alotau, Milne Bay Province, Papua New Guinea

Study ID Number	

Steve Badman (Laboratory QC/QA Coordinator)	The Kirby Institute, University of New South Wales, NSW, Australia
Dr Neha Batura	Research Associate (Economics), Institute for Global Health, University College London, London UK
Dr Angela Kelly-Hanku	Head, Sexual and Reproductive Health Unit, Papua New Guinea Institute of Medical Research, Goroka, EHP Papua New Guinea; and Public Health Interventions Research Group, The Kirby Institute, University of New South Wales, NSW, Australia
Pamela Toliman	Sexual & Reproductive Health Unit, Papua New Guinea Institute of Medical Research, Goroka, EHP Papua New Guinea
Wilfred Peter	Communications and Public Relations Officer, Modilon General Hospital, Madang, Papua New Guinea.
Dr Liz Peach	Research Program Manager - Healthy Mothers Healthy Babies The Burnet Institute, Kokopo, East New Britain Province, Papua New Guinea

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?

Genital infections are very common among pregnant women in Papua New Guinea compared to other countries in Asia and the Pacific. Our earlier work in PNG showed that around half of all pregnant women coming to antenatal clinic had a genital infection. The most common infections were chlamydia, gonorrhoea, trichomonas and bacterial vaginosis.

We know that having one or more of these infections can 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 one of these infections because these infections do not cause any symptoms in most pregnant women. In PNG, only people with symptoms are treated for genital infections.

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

One way we might improve the health of women and their babies in PNG is to test mothers at the antenatal clinic. By testing for genital infections and giving medicine to the mother and father, the infection can be cured.

The PNGIMR is conducting the WANTAIM Study to see if testing and treating mothers for genital infections at antenatal clinic can improve the health of their babies compared to the current standard antenatal care that all mothers receive in PNG.

What does the WANTAIM Study involve?

The study is taking place at 10 antenatal clinics in three provinces in PNG. A total of around 4600 pregnant women will take part.

All of the 10 antenatal clinics will provide standard routine antenatal care, but in addition:

- Five (5) clinics will carry out testing in the clinic on all pregnant women for genital infections. Women who have a positive test result will be given treatment the same day;
- Five (5) clinics will collect urine from all pregnant women that will be tested in our laboratory. Women who have a positive test result will be followed-up by one of our nurses and given treatment after their baby is born.

The reason we are doing this is because **we do not yet know** if testing and treatment of genital infections during pregnancy improves the health of newborn babies. We also do not know if there is any benefit from testing and treating women **early** during pregnancy compared to testing and treatment **later on** after baby has already been born. This is why we are carrying out the WANTAIM Study.

Study ID Number	

Who can participate in this study?
Any pregnant woman aged 16 years or over attending their first antenatal clinic visit before 26 weeks (6 months) of pregnancy.

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 first 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; how much money you spend on health care; 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.
- You will then have a special scan, called an ultrasound scan. The scan will show us a picture on a computer screen of your baby. We will measure your baby to check how many weeks old he/she is. We might be able to tell you if you will have a boy or girl. You will be able to see the baby scan on the computer screen and to ask any questions you have about what you see.
- When you have your routine tests, we will also collect some extra blood that we will store and test later on for malaria in our laboratory. This test will help us understand how much malaria there is among pregnant women taking part in the study.

Depending on whether your local clinic is providing same-day testing in the clinic or collecting specimens to be tested later on in our laboratory:

- We will ask you to collect TWO (2) vaginal swabs that we will test in the clinic for genital infections. 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.**

OR

- We will store your routine urine sample so that we can test it later on in our laboratory for genital infections. **We will give you your test results and any treatment that you need when we visit you after your baby is born**.

You may also be asked to take part in an extra **interview**, or to keep a **diary** to record how you spend your money within the home. We will explain how to complete this, and a member of the study team may visit you in the village to help you with this.

You do not have to take part in these extra activities if you do not wish to

Follow up visits

You will have routine antenatal care, the same as all women who come to antenatal clinic. This will include any routine tests, treatment or medicines such as iron and malaria tablets.

We would like you to return to the clinic for a repeat antenatal check at least **THREE (3)** more times during your pregnancy. This means we can provide you and your baby with the best possible care and is the minimum number of visits recommended by the PNG National Department of Health.

At two of these follow-up visits you will be asked to collect either vaginal swabs **OR** to provide a urine specimen, as you did at your enrolment visit.

What will happen to the samples?

Vaginal swabs and urine samples will be tested for genital infections that we know are common in PNG. The names of these infections are chlamydia, gonorrhoea, trichomonas and bacterial vaginosis.

In clinics that are collecting vaginal swabs:

- 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. If necessary we will give you and the baby's father further treatment at the next antenatal clinic.
- If you agree, we will also store your vaginal samples in our laboratory to be used in further studies on sexual health in pregnancy in PNG.

In clinics that are collecting urine specimens:

- Urine samples will be stored in the freezer and later tested in our laboratory, which is located outside of the clinic. Test results and any treatment you require will be provided when we visit you after your baby is born.

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

What will happen after I have given birth?

You will be asked to let us know about the birth of the baby within 72 hours (2-3 days) of giving birth. We will come and check you and your baby. We will check the baby's weight and ensure he/she has received routine newborn care. We will provide any treatment required, including routine birth dose vaccinations. We will also check you to see if you have any health problems after childbirth.

How long will I be in the study?

Participation in this study is throughout your pregnancy until your baby is 4-6 weeks old. If you do not return for any of your routine follow up visits, study staff may try and contact you in the community.

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 genital infections 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.

If you decide to join the study you will be given a small gift to thank you for your time and for waiting at the clinic. You will also be offered light refreshments that will be available at each clinic visit.

At your last antenatal clinic visit you will receive a voucher to present to the hospital which will cover your bed fee, a mobile phone Flex Card (so that you can notify us after your baby has been born) and a Baby Book.

At the first visit immediately after the birth of your baby you will receive a small Baby Bundle that will include items such as sanitary pads, baby nappies and soap. This is to thank you for your time and valuable contribution to the study.

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.

If you agree to take part in an interview, we will use a digital recorder to record your stories. This will record only your voice.

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. We will also pay your bed fee if you give birth at your local health facility or hospital.

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.

Study ID Number	

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 you will be told the results of the overall study. 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; by the Research Ethics Committee of the London School of Hygiene and Tropical Medicine in the United Kingdom; and by the Ethics Committee of the University of Bern in Switzerland; in accordance with the guidelines of the UK Medical Research Council and the Wellcome Trust, the National Health and Medical Research Council, Australia, and the Swiss Human Research Act.

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

Dr Michaela Riddell, Study Coordinator, PNG IMR, Madang Province PNG
Tel: Tel: +675 422 2909 / 422 2962 / Fax: +675 422 3289 E: mriddell@kirby.unsw.edu.au

Dr Moses Laman Senior Clinical Research Fellow, PNG IMR, Madang Province PNG,
Tel: +675 422 2909 / 422 2962 / Fax: +675 422 3289 / Mob: +675 7269 2548 E: drmlaman@yahoo.com

Dr William Pomat, PNG IMR, Goroka, Eastern Highlands Province, PNG
Tel: +675 532 2800 / **Fax:** +675 532 1998 / **E-mail:** william.pomat@pngimr.org.pg

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 Pomat** 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.

Study ID Number	

THE PAPUA NEW GUINEA INSTITUTE OF MEDICAL RESEARCH
and THE UNIVERSITY OF NEW SOUTH WALES

WANTAIM Study

You are making a decision whether or not to participate. Your signature indicates that having read the information provided, you have decided to join the study.

I, _____ (*please write name here*) have read the participant information sheet, or had the information sheet read to me, and I agree to take part in the study called the **'WANTAIM Study'**

I hereby confirm that:

1. I have been given an opportunity to ask questions about the study and my participation in it.
2. I understand that all the information I provide and the results of my tests will be kept strictly confidential and stored in a secure location.
3. I understand that my privacy will be maintained at all times and I will not be identifiable in any report or publication about this study.
4. I understand that I may benefit from the study because I will be tested for infections and offered treatment if my test results are positive.
5. I have been told how long the visits will take, and that the answers I give and my test results will be written down and entered into a computer.
6. I understand that I may be asked to provide TWO (2) vaginal swabs that I will collect myself as part of this study and confirm that I am willing to do this after the nurse explains how to do so. I understand that the results from testing these swabs will be made available to me today, if I am asked to collect these.
7. I understand that the urine sample I provide at the antenatal clinic may be stored and later tested. Results from this test will be made available after I have given birth. I will be provided treatment at this time if necessary.
8. I understand that by joining the study I agree to be followed-up at the antenatal clinic and within 72 hours (2-3 days) after I have given birth.
9. The study procedures have been explained to me and I am willing to take part in this study.
10. I understand that I am free to withdraw from the study at any time, and that if I do so, I can still receive treatment and other services as usual from my local clinic or hospital.

In addition to the above:	***Tick to agree***
I understand that I may be asked to have my baby checked at 1 – 2 weeks and 4 – 6 weeks after I give birth, and I consent to being followed up by the study team at these times.	
I understand that I may be asked to provide some additional information about the money I spend during my pregnancy, and I consent to participate in this activity.	
I understand and consent to my samples being stored for future testing relating to this study or for future studies associated with sexual health in PNG.	
I consent to being contacted about additional studies arising out of this study.	

Study ID Number	

Signature/Thumbprint of Participant

*Note to research staff: A thumbprint is to be provided **ONLY** if a participant cannot read and/or write. Thumbprints **MUST** be witnessed i.e. an appropriate witness must also sign below for this consent to be considered valid*

Signature or thumbprint	**Date:**
_____	_____

Signature of witness (if volunteer is unable to read or write)

I, _____ (*please write name*) hereby confirm that the person named above has acquired a full understanding of the research study and has freely consented to participating in the study.

Signature	**Date:**
_____	_____

Signature of clinic study staff obtaining consent

I, _____ (*please write name*) hereby confirm that the person named above has acquired a full understanding of the research study and has freely consented to participating in the study.

Signature	**Date:**
_____	_____