WANTAIM *(Women And Newborn Trial of Antenatal Interventions and Management) is a cluster randomised crossover trial being conducted at ten sites in Papua New Guinea.*

Background and study aims

Previous research has shown that sexually transmitted and genital infections (STIs) such as chlamydia, gonorrhoea, trichomonas and bacterial vaginosis can increase the risk of low birth weight, preterm birth and other adverse birth outcomes if these infections are not diagnosed and treated in pregnancy. The research evidence regarding the potential impact of antenatal STI screening and treatment is however conflicting. This has led to different screening guidelines being adopted in different countries worldwide.

WANTAIM is designed to provide the definitive evidence required for future public health policy and clinical practice in this area, particularly in high-burden, low-income countries.

The aim of the study is to measure the effectiveness, health system implementation requirements, cost-effectiveness and acceptability of antenatal point-of-care testing and immediate treatment of sexually transmitted infections to improve birth outcomes in high-burden, low-income settings.

Who can participate?

Pregnant women aged 16 years and above, attending their first antenatal clinic visit at 26 weeks of pregnancy or below, will be eligible to join the study.

What does the study involve?

Participating clinics will each have an opportunity to take part in the intervention and in the control arm of the study. At the end of the study we will compare findings from each study arm to see if the intervention had an impact on mother and newborn health.

Women attending antenatal clinics in both the control and intervention arms of the trial will receive standard antenatal care in accordance with PNG national guidelines. This includes routine screening for HIV infection and syphilis. Women in both trial arms will receive additional antenatal and postnatal care as per the trial protocol, and in accordance with study-specific procedures.

Additional antenatal care:

- An obstetric ultrasound scan for pregnancy dating purposes at enrolment (first antenatal clinic visit)
- Collection/testing of urine and/or vaginal specimens for sexually transmitted infections
- Additional testing of fingerprick blood specimens for malaria infection

Additional postnatal care:

- A postnatal follow-up visit conducted by a trained member of the clinical research team within 72 hours of birth. This will be carried out either at the health facility or in the community following birth.
- The visit will include the collection of information required for the trial (e.g. birth weight) and be an opportunity to provide additional care for both mother and newborn infant that would not be available as part of routine standard practice (e.g. provision of birth dose vaccinations)

If a trial participant or her newborn baby experience an adverse health outcome that cannot be managed by antenatal clinic staff or the clinical research team, a specialist referral will be organized by the research team. In the event of an emergency (e.g. postpartum haemorrhage, neonatal sepsis) the research team will use a project vehicle to assist in urgent hospital transfer.

1. Intervention summary

Women participating in the intervention arm of the trial will provide self-collected vaginal specimens for same-day, point-of-care testing for the curable STIs chlamydia, gonorrhoea, trichomonas and bacterial vaginosis, and will be given immediate treatment as indicated, at the following time points:

- At enrolment (preferably before 20 weeks gestation);
- One month after trial enrolment (to confirm that infections at enrolment have been cured and to detect new infections. Women with a positive test result at this visit will be asked to return for repeat testing one month later);
- At 34-36 weeks antenatal follow-up.

The rationale for this intervention schedule is based on:

a) current scientific evidence which suggests that diagnosis and treatment of chlamydia, gonorrhoea, trichomonas and bacterial vaginosis early in pregnancy would have the greatest impact on low birth weight and preterm birth;
b) the lack of scientific evidence on the association between incident (newly acquired) chlamydia, gonorrhoea, trichomonas and bacterial vaginosis in later pregnancy and risk of adverse birth outcomes, particularly preterm birth and premature rupture of membranes.

Point-of-care testing will be conducted in the clinic using the newly available Cepheid GeneXpert platform (chlamydia, gonorrhoea, trichomonas) and the Gryphus Diagnostics BVBlue Test (bacterial vaginosis).

2. Procedures in the control arm

The management of suspected STIs among women in the control arm of the trial will be carried out in accordance with WHO-endorsed PNG national syndromic management guidelines that are based on clinical symptoms alone without laboratory confirmation.

Urine specimens collected for routine urine glucose and protein testing in the control arm of the trial will be retained at enrolment, after one month and at 34-36 weeks. These specimens will be tested in an off-site laboratory for chlamydia, gonorrhoea and trichomonas. If positive, the research team will provide appropriate antibiotic treatment at the postnatal visit.

Are there any possible risks or benefits of being involved in the study?

The risks involved with the study are likely to be minimal or none. For example, women may experience some slight embarrassment or discomfort while collecting the vaginal swabs, or feel slightly uncomfortable by the questions asked about sexual health.

The potential benefits of participation include the opportunity to be tested and treated for genital infections during pregnancy. Women will be given light refreshments at each clinic visit and provided with a small gift to recognise their contribution e.g. a study T-shirt.

At the 36 week antenatal clinic visit women will be given a voucher to present to their local hospital to cover costs associated with health facility birth; a mobile phone scratch card (to enable women to notify the team that they have given birth); and a child health book.

At the first postnatal visit women will be given a Baby Bundle containing items such as sanitary pads, baby nappies and soap to recognise their time and valuable contribution to the study.

Timeline

WANTAIM started recruitment in mid-2017 and will take 3-4 years to complete all follow-up.

Study coordination and contacts

WANTAIM is led by the PNG Institute of Medical Research, Goroka, Eastern Highlands Province, Papua New Guinea; and the Kirby Institute, University of New South Wales, Sydney, Australia.

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