Background

- *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis* and bacterial vaginosis are highly prevalent among pregnant women in many low- and middle-income countries worldwide, and have been associated with increased risk of preterm birth, low birth weight and other adverse outcomes.
- In a majority of women, these curable genital infections are asymptomatic and therefore remain undiagnosed and untreated because of a lack of suitable diagnostic technologies.
- Conflicting evidence on the potential risks and benefits of STI screening and treatment in pregnancy has hindered policy and practice, and led to calls for definitive field trials.
- Newly-available, easy to use and highly-accurate point-of-care assays for chlamydia, gonorrhoea, trichomonas and bacterial vaginosis are now available for use in routine clinical settings, making such field trials possible for the first time.

Methodology

- The Papua New Guinea Institute of Medical Research (PNGIMR) and The Kirby Institute, UNSW Sydney, are leading the WANTAIM Trial: a cluster randomised crossover trial to evaluate the effectiveness, health system implementation requirements, cost-effectiveness and acceptability of antenatal point-of-care testing and immediate treatment of STIs to improve birth outcomes in high-burden, low-income settings.
- The primary outcome of the trial is the proportion of women and their newborns who experience preterm birth and/or low birth weight.
- WANTAIM is being conducted in 10 clusters in three provinces (Madang, East New Britain and Milne Bay) and will enrol and follow-up 4600 women and their newborns over 4 years.
- The trial started recruitment in July 2017.

Procedures at point-of-care

1. Obstetric ultrasound
2. Point-of-care GeneXpert testing for *C. trachomatis*, *N. gonorrhoeae* and *T. vaginalis*
3. Point-of-care testing for bacterial vaginosis using BV Blue Test (Gryphus Diagnostics)

Cross over design

- First phase
  - A
  - B
- Second phase
  - B
  - A

Flow diagram

- Control clusters (5 clusters)
  - Enrolment (SGA > 16-26 weeks)
  - Antenatal Follow-up #1 (SGA > 16-26 weeks)
  - Antenatal Follow-up #2 (SGA > 22-32 weeks)
  - First Antenatal Follow-up #3 (SGA > 28-34 weeks)
  - Postnatal Follow-up (within 72h of birth)
- Intervention clusters (5 clusters)
  - Enrolment (SGA > 16-26 weeks)
  - Antenatal Follow-up #1 (SGA > 16-26 weeks)
  - Antenatal Follow-up #2 (SGA > 22-32 weeks)
  - First Antenatal Follow-up #3 (SGA > 28-34 weeks)
  - Postnatal Follow-up (within 72h of birth)

Significance and Outcomes

- If antenatal point-of-care STI testing and treatment is proven to have an impact on birth outcomes, the WANTAIM Trial will hasten access to these new technologies and could thereby improve maternal and neonatal health in high-burden, low-income settings worldwide.