

Point-of-care testing & treatment of sexually transmitted infections to improve pregnancy outcomes in high-burden settings

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Point-of-care STI testing and treatment to improve pregnancy outcomes in high-burden, low-income settings

- **Aug 2015:** PNGIMR-led collaborative group awarded funding under the **DFID/MRC/Wellcome Trust Joint Global Trials Initiative**.
- **Sep 2015:** Award announced at the 51st Annual Medical Symposium in Port Moresby.

K10m study boost for women's health

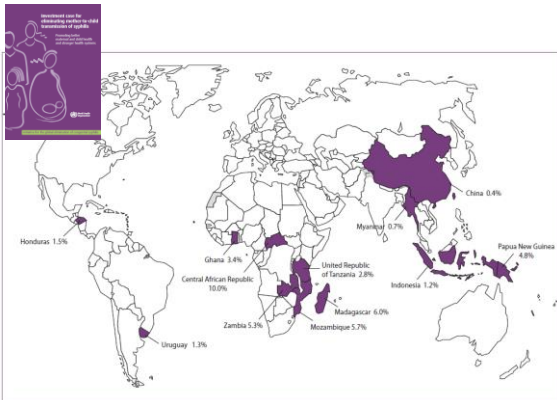
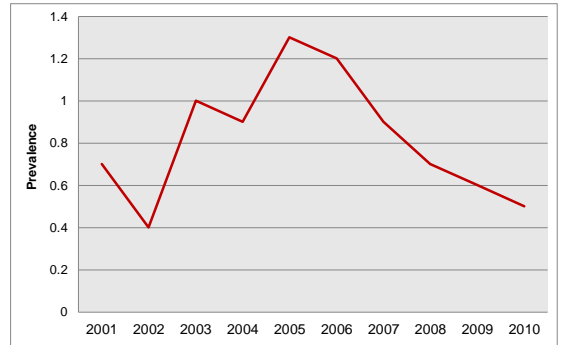


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Investigator Team

- | | | |
|--|---|--|
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HIV prevalence at ANC sites, PNG



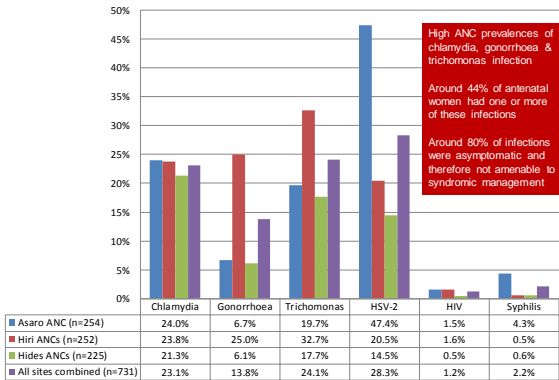
Investment Case for the Elimination of Mother to Child Transmission of Syphilis. WHO, 2012



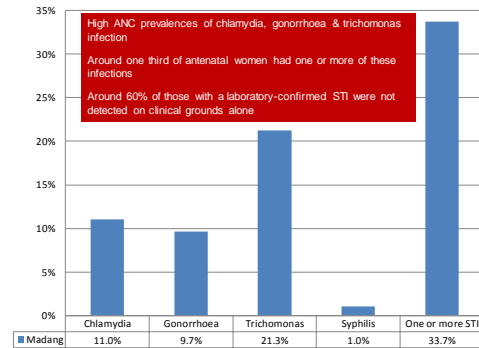
STI prevalences among pregnant women in PNG

| Author | Klufio et al, 1995 | Mgone et al, 1997 | Suarika et al, 1999 |
|-------------------------|--|--|--|
| Study population | 206 pregnant women attending first antenatal clinic visit at Port Moresby General Hospital | 155 women presenting in labour at Goroka Base Hospital | 581 women presenting in labour at Goroka Base Hospital |
| Bacterial vaginosis | 23.3 (17.7, 29.7) | - | - |
| <i>C. trachomatis</i> | 17.7 (12.4, 24.0) | 36.8 (29.2, 44.9) | 34.1 (30.2, 38.1) |
| <i>N. gonorrhoeae</i> | - | - | - |
| <i>T. pallidum</i> | - | - | - |
| <i>T. vaginalis</i> | 18.9 (13.8, 25.0) | - | - |
| HIV | - | - | - |
| HSV-2 | - | - | - |

Prevalences of HIV and STIs among 731 women attending 6 antenatal clinics (ANCs) at 3 sites in Papua New Guinea



Prevalences of STIs among 399 antenatal women participating in the IPTp malaria in pregnancy trial, Madang, Papua New Guinea



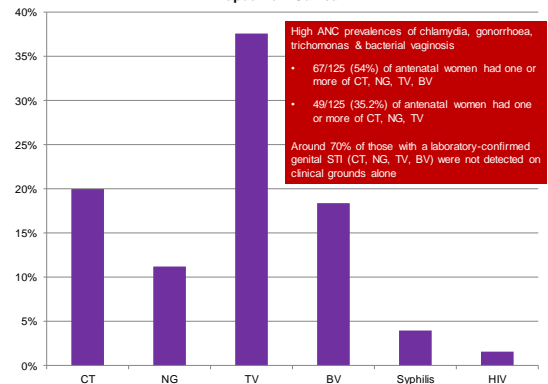
Wangnapi RA et al. *Sex Transm Infect* 2015; **91**(3):194-200

Point-of-care STI testing and treatment to improve pregnancy outcomes in high-burden, low-income settings



Pilot Study evaluated the operational feasibility of antenatal point-of-care STI testing and treatment for chlamydia, gonorrhoea, trichomonas and bacterial vaginosis using Xpert CT/NG, and TV (Cepheid, USA), and BVBlue Test (Gryphus Diagnostics)

Prevalences of STIs among 125 antenatal women attending Goilanai Clinic, Alotau, Papua New Guinea



Why a trial is needed

- Women in many low-income countries worldwide face a **high and unacceptable burden** of adverse pregnancy outcomes.
- Curable, genital STIs are major contributors to this disease burden but the majority of infections go untreated because:
 - most infections are **asymptomatic**
 - affordable, easy to use and accurate diagnostic tests are **unavailable** in such settings.
- At the same time, there is conflicting evidence on the potential **risks and benefits** of STI screening and treatment in pregnancy, hindering policy and practice, and leading to calls for **definitive field trials**.

Why a trial is needed

- Newly-available technologies make it possible **for the first time** to conduct such trials, and to answer questions that have remained unresolved for decades.
- We will undertake the first randomised trial to assess the **impact, cost-effectiveness, acceptability and health system requirements** of point-of-care STI testing and treatment to improve pregnancy outcomes in high-burden, low-income settings.
- If antenatal point-of-care STI testing is proven to have an impact on birth outcomes, the trial will hasten access to these technologies and could thereby improve maternal and neonatal health in all low-resource settings worldwide.

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Principal Research Question

Does point-of-care testing and immediate treatment of curable sexually transmitted infections in pregnancy reduce preterm birth and low birth weight compared with standard care?

Trial Design

Cluster randomized trial with parallel 1:1 allocation of clusters to control / intervention arms.

- **Control arm:** standard antenatal care + postnatal follow-up at 48h
- **Intervention arm:** antenatal POC testing and treatment + postnatal follow-up at 48h

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Primary outcome measures

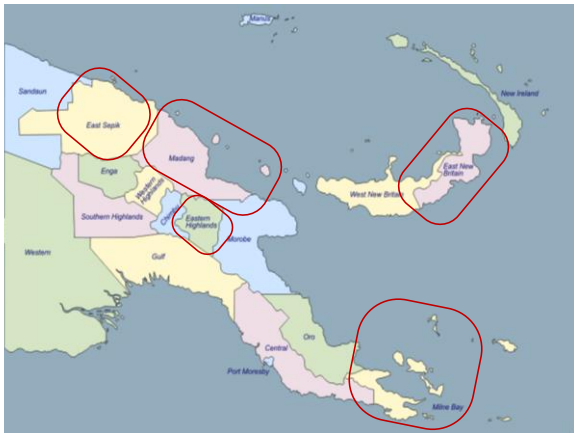
- The proportion of women who experience a **preterm birth**
- The proportion of **low birth weight** infants

Secondary outcome measures

- Premature rupture of membranes
- Cost-effectiveness
- Health system implementation requirements
- Client and health provider acceptability

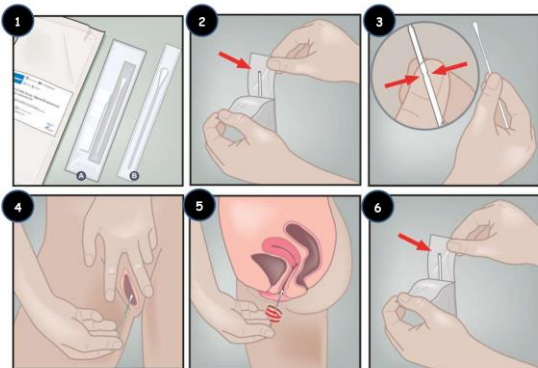
Sample size

- The trial is designed to detect **≥20% reduction in preterm birth + low birth weight** and will require x12 clusters of x350 women per cluster (N=4200 women)

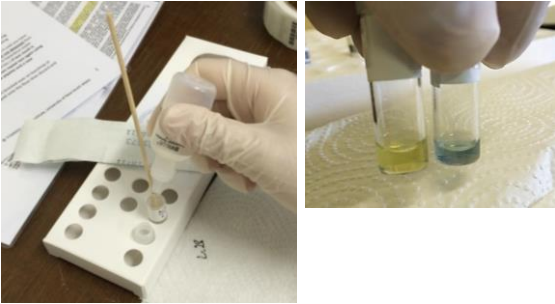


Informing women about the study and obtaining informed consent

Collecting a self-administered vaginal swab



Clinic-based testing for chlamydia, gonorrhoea and trichomonas using the Cepheid GeneXpert platform



Clinic-based testing for bacterial vaginosis using the Gryphus Diagnostics BVBlue Test

Acknowledgments

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Tonikú wu ma Eguatau kau*