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.

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STI prevalences among pregnant women in PNG

<table>
<thead>
<tr>
<th>Author</th>
<th>Klufio et al., 1995</th>
<th>Mgone et al., 1997</th>
<th>Suarkia et al., 1999</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study population</td>
<td>206 pregnant women attending first antenatal clinic visit at Port Moresby General Hospital</td>
<td>105 women presenting in labour to Goroka Base Hospital</td>
<td>581 women presenting in labour to Goroka Base Hospital</td>
</tr>
<tr>
<td>Bacterial vaginosis</td>
<td>23.3 (17.7, 29.7)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>C. trachomatis</td>
<td>17.7 (12.4, 24.0)</td>
<td>36.8 (29.2, 44.9)</td>
<td>34.1 (30.2, 38.1)</td>
</tr>
<tr>
<td>N. gonorrhoeae</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>T. pallidum</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>T. vaginalis</td>
<td>18.2 (13.6, 25.0)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>HIV</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>HSV-2</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

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

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.

• 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.
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

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)

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Informing women about the study and obtaining informed consent

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

Collecting a self-administered vaginal swab
Clinic-based testing for bacterial vaginosis using the Gryphus Diagnostics BVBlue Test

Acknowledgments

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