The rationale for STOPMIP trial in Indonesia & Performance of RDTs for screening malaria in pregnancy

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Both *P. falciparum* and *P. vivax* are associated with adverse pregnancy outcomes (maternal anaemia, LBW & preterm deliveries).

Source: Dellicour et al, PlosMed 2010
Current malaria in pregnancy control strategies

Lacks a MiP preventive strategic framework similar to that exists in the African region

**WHO AFRO region**

- Case management
- Provision of long lasting insecticide treated nets (LLITN)
- Intermittent preventive therapy (IPTp) with sulfadoxine-pyrimethamine (SP)
- Cotrimoxazole in HIV positive women

**Other malaria endemic WHO regions**

- Passive case detection (PCD) & case management
- LLITNs +/-
Challenges for MIP control in Asia-Pacific region

- Diverse exposure risks
- Needs to target both P.falciparum and P.vivax
- Sub microscopic infections are common; important?
- P. Vivax relapse
- Primaquine is not an option
- Multi-drug resistance, including to SP, the only antimalarial currently recommended for IPT
Why the MiP prevention trial was conducted in Indonesia

- Third highest malaria in pregnancy risk country in the SEARO-WIPRO region (6.3 million pregnancies at risk annually)
- Diverse epidemiology & diverse transmission (low to high)
- Extensive experience with DP including in pregnant women
- First country to have introduced malaria screening as national policy
- Proactive and supportive research environment and stakeholders
Are submicroscopic infections important?

Association between malaria and anaemia <9g/dL in antenatal women
Association between malaria and low birth weight (<2000g)

**P.falciparum**
- Relative risk: 2.1, 1.7
- LBW < 2500g: 21 (19.1%), 26 (15.4%), 1231 (9%)

**P.vivax**
- Relative risk: 4.7, 2.9
- LBW < 2500g: 7, 19, 1231

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Screen and Treat or Prevent Malaria in Pregnancy
STOPMIP: An open label matched cluster randomised 3 arm trial

- To determine if IST or IPT is more effective in reducing malaria infection at delivery compared to SST in women protected with LLITN
- To determine the acceptability, feasibility and cost effectiveness of these three strategies
Study overview

• All gravidae
• Unit of randomisation: antenatal clinics
• Two sites in Eastern Indonesia:
  – South west Sumba (‘low’ transmission)
  – Timika in Papua (‘moderate’ transmission)
• Malaria diagnosis
  – RDT at point of care for IST and SST and clinical cases in all arms
  – Microscopy and placental histology
  – LAMP, confirmed by qPCR and nested PCR
• Study drug: dihydroartesiminin-piperaquine (DP) Eurartesim (Sigma Tau)
• All arms used monthly visits, enrolled 16-30 weeks gestation
• Sample size: 57 clusters, 989 women in Sumba, 1290 women in Timika
Performance of four HRP-2/pLDH combination rapid diagnostic tests and field microscopy as screening tests for malaria in pregnancy in Indonesia: a cross-sectional study

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Accuracy of 4 RDTs and Field & Expert microscopy compared with PCR

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<thead>
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<th>Test</th>
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<tr>
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Summary

RDT performance was comparable to field microscopy

RDTs and Field microscopy missed the low density submicroscopic infections

Diverse malaria epidemiology in Indonesia, submicroscopic infections common

All three preventive strategies may have a role for the control of MiP in Indonesia

STOPMiP results would give an answer to which preventive strategy is effective
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