Update on Effectiveness of Combined vector control
Original design

143 clusters

LLIN arm   IRS arm   LLIN+IRS arm

Design due to LLIN UC

140 clusters

LLIN arm   LLIN+IRS arm
Sudan study design

140 clusters

Randomisation ensured *kdr* frequency in all 140 clusters was balanced between study arms

LLIN arm

LLIN+IRS arm

Phenotypic resistance measured in 66 sentinel clusters
Sudan study design

LLIN arm

LLIN+IRS arm

Compare LR:HR within the LLIN clusters, and do same within the LLIN+IRS clusters
# Distribution of clusters by study area and study arm

<table>
<thead>
<tr>
<th>Past main vector control intervention</th>
<th>El Hoosh (South Gezira)</th>
<th>Hag Abdallah (South Gezira)</th>
<th>Galabat (Gadaref)</th>
<th>New Halfa (Kassala)</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRS with Bendiocarb</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRS with Bendiocarb</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LLINs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRS with Pyrethroid (Deltamethrin)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Study arms</strong></td>
<td><strong>LLIN only</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>LLIN+IRS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insecticide class</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Bend + Pyr)</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>4</td>
</tr>
<tr>
<td>(Bend + Pyr)</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>4</td>
</tr>
<tr>
<td>(Pyr +Pyr)</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>4</td>
</tr>
<tr>
<td>(Bend + Pyr)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Under 10 cohort per cluster</strong></td>
<td>200</td>
<td>200</td>
<td>200</td>
<td>200</td>
<td></td>
</tr>
<tr>
<td><strong>Number of clusters</strong></td>
<td>38</td>
<td>38</td>
<td>26</td>
<td>38</td>
<td>140</td>
</tr>
<tr>
<td><strong>Cohort size</strong></td>
<td>7,600</td>
<td>7,600</td>
<td>5,200</td>
<td>7,600</td>
<td>28,000</td>
</tr>
</tbody>
</table>
Study milestones in 2011

• Clusters have been randomly allocated to receive either universal coverage LLINs or universal coverage LLINs plus IRS (57 with two rounds of bendiocarb and 13 with two rounds of deltamethrin during year 1)
• Randomisation was restricted to ensure that the study arms were balanced on the following cluster specific indicators: baseline prevalence of infection, existing ITN use, kdr frequency, cluster population size and proximity of health facility (y/n)
• 66 clusters (33 in each study arm) have been randomly selected as sentinel clusters for collecting phenotypic insecticide resistance data
• Cohorts of 200 children 6 m to <10 years recruited in 140 clusters in four study areas, following written informed consent procedures
Epidemiological data collected in 2011:

- Cohort follow-up and case data are recorded in a special MS Access database designed for this purpose.
- Community Health Workers have been trained in each cluster to visit each cohort household at weekly intervals during the malaria season (every 2 weeks outside the malaria season).
- At each visit current and recent fever are recorded. In case of observed or reported fever, parasitaemia status is determined by RDT and/or microscopy at the nearest health facility.
Summary of data collection

• Cohort visit data have been collected and recorded since August 2011
• Current status of epidemiological database (Aug, Sept, Oct):
  – 247,242 recorded follow up visits on 31,522 subjects
  – 1,242 confirmed malaria episodes
  – 6,021 person years of follow-up
• Overall incidence 206 per 1000 person years
• Overall reported net usage by cohort members: 86%
• Data collection will continue through to 2014
• Detailed measurement of resistance in this study will make it possible to estimate the effect of combined vector control vs LLIN alone both in the presence and absence of insecticide resistance
Other evidence of combined effect

1. Programmatic/non CRT data
   - Kenya (Hamel et al 2011)
   - Bioko 2011

2. CRT
   - Yemen: 2 arm cluster randomised trial due to start