PMI & Drug Quality

Jennifer Wray
PMI from 2005-2015: A Decade of USG Leadership

<table>
<thead>
<tr>
<th>Year</th>
<th>Funding Level</th>
<th>Milestones</th>
<th>Countries Added</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>$30M</td>
<td>President Bush launches PMI</td>
<td>Angola, Tanzania, Uganda</td>
</tr>
<tr>
<td>2006</td>
<td>$135M</td>
<td>PMI begins operations</td>
<td>Malawi, Mozambique, Rwanda, Senegal</td>
</tr>
<tr>
<td>2007</td>
<td>$300M</td>
<td>Malawi joins PMI</td>
<td>Benin, Ethiopia, Ghana, Kenya, Liberia, Mali, Madagascar, Zambia</td>
</tr>
<tr>
<td>2009</td>
<td>$585M</td>
<td>DRC, Mekong, Nigeria, Guinea, Zimbabwe</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>$618M</td>
<td>19 countries in Africa receiving PMI support + Mekong Subregional program</td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>$650M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>$656M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>$665M</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>$669M</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
All-cause mortality rates of children under the age of five have declined in 17 PMI focus countries.

Declines range from 18% (in Liberia and Nigeria) to 55% (in Senegal and Zambia).
PMI Areas for Strategic Focus

1. Achieving and sustaining scale of proven interventions

2. Adapting to changing epidemiology and incorporating new tools

3. Improving country capacity to collect and use information

4. Mitigating risks against the current malaria control gains

5. Building capacity and health systems
Antimalarial drugs & quality
Ubiquity of poor quality antimalarials
Quantification and categorization

- "WHO estimates that 10 to 30% of all medicines in developing markets are SSFFCs"
- "In a 2011 study of six-countries in sub-Saharan Africa, 30% of antimalarial samples failed to comply with quality standards"
- "Up to 36% of antimalarial drugs collected in southeast Asia were falsified, whereas in sub-Saharan Africa, a third failed chemical assay analysis."

PQM studies 2003-2013: 10.4% of all medicines tested in Africa and 2.9% in Asia failed quality tests.
Antimalarial products

- Anti parasitic products (antimalarial and anthelmintic) make up just under ¼ of all products reported to the WHO database (23% of reports; 212 occurrences)
- Antimalarial products make up 93% of all reported anti parasitic products (198 occurrences)
- ACTs make up 74% of all reported antimalarial products (147 occurrences)
- 93% of all reported ACTs are falsified (6% pending classification)
ACT Diversion

- PMI-funded diversion studies conducted in collaboration with the OIG.
  - PMI-financed ACTs donated to one country, but ended up elsewhere, including in private sector markets
  - Detected through small-scale surveillance activities, coordination with pharma
  - ‘Big pharma’ investments to protect products
Procurement practices

PMI ensures procurement of only good quality drugs/nets/diagnostics

• Follows hierarchy of sourcing, preferentially from SRAs for drugs
• Adheres to internationally accepted standards and programs for nets & RDTs.
• TEST, TEST, TEST!
Some tools

• Technology
  – Portable “labs”
  – Handheld devices
  – Laboratory testing

• Technical assistance
  – Medicines regulatory agencies
  – National reference laboratory

• Awareness
  – Consumer education
  – Health care worker training