Burden of Malaria

• The Global Malaria Picture
  • 97 countries and territories
  • Half world at risk (3.2 billion)

• The burden of malaria is highly concentrated in sub-Saharan Africa
  • There were an estimated 198 million cases of malaria (range 124–283 million) ≈ 81% in Africa
  • 584 000 deaths (range 367 000–755 000) - 90% in Africa, 78% in children under 5
Since 2000, substantial progresses achieved

Malaria incidence decreased by 37%

Global cases
- 2000: 262 M
- 2015: 214 M

Global deaths
- 2000: 839 000
- 2015: 438 000

Malaria mortality rates have decreased by 60% globally
In spite of the gains, malaria continues to have a devastating impact on people's health and livelihoods around the world.

**Insufficient funding**

Required to achieve global targets for control and elimination:

- **5.1 B$$**
- **2.7 B$$**

Available in 2013 through international and domestic funds.

**Far from universal coverage**

- 278 of the 840 million people at risk in Sub-Saharan Africa lived in households without even a single ITN.
- 15 of the 35 million pregnant women did not receive a single dose of IPTp.

**Still high prevalence & mortality**

- Approximately 198 million cases occurred globally.
  - Of which, 82% in the WHO Africa Region.
  - And 8% globally due to *P. vivax*.
- Approximately 584,000 malaria deaths occurred worldwide.
  - Of which, 78% occurred in children aged under 5.
  - And 90% in the WHO Africa Region.

Source: World Malaria Report 2014
To achieve the future, synergy amongst stakeholders
Global goals for 2030 with five year milestones

<table>
<thead>
<tr>
<th>Objective</th>
<th>2020</th>
<th>2025</th>
<th>2030</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduce malaria mortality rates vs. 2015</td>
<td>≥40%</td>
<td>≥75%</td>
<td>≥90%</td>
</tr>
<tr>
<td>Reduce malaria case incidence vs. 2015</td>
<td>≥40%</td>
<td>≥75%</td>
<td>≥90%</td>
</tr>
<tr>
<td>Eliminate malaria from countries</td>
<td>≥ 10 countries</td>
<td>≥ 20 countries</td>
<td>≥ 35 countries</td>
</tr>
<tr>
<td>Prevent re-establishment in all malaria-free countries</td>
<td></td>
<td></td>
<td>Prevented</td>
</tr>
</tbody>
</table>
This title is not appropriate. This table list the targets looking forward, not an assessment of what has happened in the past. These are the global goals and targets set for the next 15 years.

LR1 Right. I copied and pasted the wrong title.
Lou R, 19/11/2015

LR2 How's this?
Lou R, 19/11/2015
Increasing focus on elimination & surveillance
Acceleration of efforts and a shift on strategic priorities

1. **Ensure universal access** to malaria prevention, diagnosis and treatment
2. **Accelerate efforts towards elimination** and attainment of malaria-free status
3. **Transform malaria surveillance** into a core intervention

**Attractive Market**
- New medicines
- Manufacturing capacity
- New diagnostics
- Broader reach
- Funding

... *with less risk*
Several changes in guidelines have implications for manufacturers …

- Products
- Quantities
- new indications

http://www.who.int/malaria/publications/atoz/9789241549127/en/
Core Principles: Guides to the development of products

Early diagnosis and prompt effective treatment
  —within 24-48 of the onset of malaria symptoms

Combination therapy
  —improved efficacy; prevent or delay resistance

Rational use of antimalarials
  —reduce the spread of drug resistance, limit wastage, and ensure effective case management of febrile illnesses

Appropriate weight-based dosing
  —prolong the useful therapeutic life of medicines,

For market success, manufacturers must consider

- Products that can be used at the community level with minimal or no training of the provider
- Pediatric formulations
Products that can be used at the community level with minimal or no training of the provider
Rational Use of Diagnostics

All cases of suspected malaria should have a parasitological test (microscopy or RDT) to confirm the diagnosis.

– The results of parasitological diagnosis should be available within less than two hours of the patient presenting.
– In the absence or delay, patients with suspected severe malaria, and other high risk groups, should be treated on clinical grounds.

Major opportunity for companies with appropriate specifications and quality RDT’s
**Uncomplicated Falciparum Malaria**

**Therapeutic objectives**

- Cure the infection as rapidly as possible (elimination of the malaria parasites that caused the treated infection), thus preventing progression to severe disease
- Reduce transmission (reduce infectious reservoir)
- Prevent the emergence and spread of antimalarial drug resistance

- Expansion of indication
- Wider use of primaquine
- We need a pediatric formulation for primaquine
Treatment of uncomplicated falciparum malaria

Treat with an ACT.
- The recommended ACTs are:
  - artemether plus lumefantrine
  - artesunate plus amodiaquine
  - artesunate plus mefloquine
  - dihydroartemisinin plus piperaquine
  - artesunate plus sulfadoxine-pyrimethamine.

ACT regimens should provide three days’ treatment with an artemisinin-derivative.

**Big challenge ...**

Inadequate production of dihydroartemisinin plus piperaquine
→ only one manufacturer

**We need additional capacity and suppliers!**
Treatment of uncomplicated falciparum malaria

Reducing transmissibility of treated *P.falciparum* infections

- In low transmission areas, give a single dose of 0.25mg/kg primaquine with ACT to patients with *P. falciparum* malaria (except pregnant women, infants < 6 months and women breastfeeding infants aged <6 months) to reduce transmission. G6PD testing is not required.

An additional indication of disease transmission is leading to …

Expanded market AND opportunities for pediatric formulations
Treatment of uncomplicated non-falciparum Malaria

- In areas with chloroquine-susceptible infections, treat adults and children with uncomplicated non-falciparum malaria using either an ACT or chloroquine.
- In areas with chloroquine-resistant infections, treat adults and children with uncomplicated non-falciparum malaria (excluding pregnant women in their first trimester) with an ACT.
- To prevent future relapse, treat people with vivax or ovale malaria (excluding pregnant, infants aged <6months, women breastfeeding infants < 6 months of age, and people with G6PD deficiency) with primaquine in all transmission settings.

- Wider use and increased volumes of ACT for the treatment of non-falciparum malaria
- Incremental use of diagnostics
Treatment of severe malaria

Treat children and adults with severe malaria with intravenous or intramuscular artesunate for at least 24 hours and until able to tolerate oral medication and complete with and ACT.

Pre-referral treatment

- Where intramuscular injections are unavailable, treat children <6 years with a single rectal dose (10mg/kg) of artesunate, and refer immediately to an appropriate facility for further care.

Opportunities for Manufactures …

- For injection only 1 PQ’d manufacturer
  Only drug worldwide for this indication

- In rural and hard to reach areas, need anti malarial before brought to a clinic
  No suppository available

NOTE:
MMV is actively pursuing other manufacturers
Chemoprevention for special risk groups

- Intermittent preventive treatment in pregnancy with SP
- Intermittent preventive treatment in infancy with SP
- Seasonal malaria chemoprevention with monthly AQ+SP for all children aged <6y in areas with highly seasonal transmission

Low hanging fruit…

- Single manufacturer
- Limiting scale up of delivery is the availability of drugs.
- No issue with funding
Implementation & challenges

Formulations

- Fixed-dose combinations rather than co-blistered or loose single agent formulations.
- Paediatric formulations for children
  - Solid formulations rather than liquid (even in infants and young children)

Availability

- ACT (DHA-PPQ); anti-gametocyte; severe malaria (artesunate – injection and suppository); SMC (AQ+SP)
- Single source suppliers
Thank you