Providing timely access to pre-referral treatment for severe malaria: how ready is the market in sub-Saharan Africa?

Ioana Ursu and Meghan Kumar, on behalf of Medicines for Malaria Venture, discuss recent progress and challenges in the fight against malaria

Major progress has been achieved in reducing the incidence of malaria in sub-Saharan Africa, yet 584,000 deaths each year are attributed to severe malaria, 75% of which are those of children under the age of 5. The recommended intravenous (IV) or intramuscular artesunate (IM) treatment for severe malaria is often not available at the first point of care for sick patients. In such cases, the World Health Organization (WHO) recommends the use of rectal artesunate (RAS) suppositories administered at community level followed by referral to a higher-level facility, thus ‘buying time’ for caregivers to reach facilities within 6-12 hours’ travel time.

However, pre-referral treatment for severe malaria is not yet prioritised by most national malaria control programmes (NMCPs) in Africa. In addition, the lack of a pre-qualified (PQ) RAS product has impeded procurement by large donor organisations like the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), the United Nations Children’s Fund or President’s Malaria Initiative, which together procure a significant percentage of malaria commodities.

With funding from UNITAID, Medicines for Malaria Venture (MMV) is currently working with two manufacturing companies, Cipla Limited and Strides Arcolab Limited, to prepare dossiers for RAS submission to WHO for pre-qualification before the end of 2015. If approved, the introduction of this new product would require:

- Revision of national malaria policy and guidelines, where required and dissemination thereof;
- Change to the training curriculum for existing and future community health workers (CHWs);
- Additional quantification and supply chain capacity for the new product.

New financial resources may be needed to support these technical changes to domestic health systems and to support commodity procurement, increasing uptake of RAS.

To understand the health need, the barriers to use, and the potential market demand for a pre-referral severe malaria treatment, MMV conducted a qualitative research study in 20 high-burden malaria countries in sub-Saharan Africa. In total, 150 interviews were conducted with policymakers, implementers, practitioners and CHWs. Information was collected on the current status of severe malaria policy and community-level treatment implementation, to help identify gaps between theory, policy and practice.

**Market readiness assessment**

Market readiness for RAS was assessed on the presence of two conditions: policy and trained CHWs as a delivery channel for RAS. If both conditions existed, then a further assessment of quantification and supply chain efforts for current and potential new products was conducted.

**Seven of 20 countries are currently policy-ready to launch and use RAS**

Of the 20 high-burden countries surveyed, only seven countries (in green) had RAS in both their policy and treatment guidelines (Benin, Ethiopia, Ghana, Mali, Malawi, Mozambique, Senegal; see Figure 1). This low number was mitigated by the willingness of many countries to add RAS once it becomes WHO pre-qualified.

Increasingly, a change in guidelines is not equivalent...
to introduction in procurement lists, due to the increased number of stakeholders involved in procurement decisions. There is increased need for early engagement by manufacturers and international organisations not just with NMCPs, but also with the National Drug Authority and procurement offices, as well as international bodies like GFATM.

The quantification step necessary to prepare for procurement presents several sets of challenges, from national to local level (these challenges have largely been identified and discussed in other papers).6,7 Findings confirm that despite strides made in procurement and supply chain management in the 20 countries researched, stock-outs of antimalarial commodities had occurred in the previous 6-12 months in all rural areas visited. This was attributed to problems throughout the supply chain (quantification, consumption reporting, and timely re-distribution of available stock).

This research also highlights the fact that countries are reluctant to include new and future technologies if they are not readily available at the time of the grant submission, as under the current funding model they are viewed as competing with budgets for current commodities. In approximately half of the 20 countries, the national programmes were reluctant to add RAS to their quantifications and National Strategic Plans, as the product is not yet WHO pre-qualified, and they would lose budget allocated for that commodity in later years of the GFATM three-year funding cycle.

**CHWs are a viable delivery channel for RAS in five of 20 high-burden countries**

The initial assumption in this research was that CHWs would be the main delivery channel for any malaria-related commodities at the community level. As such, investigations into CHW training and geographic scale were conducted. As observed by other researchers, we found a broad range of cadres denoted by the term CHW, encompassing both ‘health promoters’ as well as ‘treatment providers’.8

Malaria forms part of the basic CHW training in just two of the five in-depth study countries, Ethiopia and Ghana, although CHWs conduct malaria treatment/prevention activities to some extent, whether formally or informally, in all the countries studied. Training was often

<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage of uncomplicated malaria cases estimated to be treated through CHW channel**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burkina Faso</td>
<td>40-60%</td>
</tr>
<tr>
<td>DRC</td>
<td>&lt;10%</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>60-80%</td>
</tr>
<tr>
<td>Ghana</td>
<td>10-20%</td>
</tr>
<tr>
<td>Kenya*</td>
<td>20-40%</td>
</tr>
</tbody>
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*for priority countries only
**note that this is perceived usage from qualitative interviews not service delivery volume tracking

Figure 3: Perceived usage of Community Health Workers for malaria treatment.

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**The way forward**

By engaging in an assessment of market readiness, MMV has been able to identify likely early adopters of prequalified RAS (see dark green countries in Figure 4 – Benin, Ethiopia, Ghana, Malawi, Mali, Senegal, Zambia), where both policy and CHW availability, and capacity are conducive to scale-up delivery of such an intervention.

These countries are likely to form the first wave in a sequential approach to the launch of RAS. With this approach, lessons learned in the first wave of product roll-out will be transferable to second and third wave countries, ensuring higher cost-effectiveness ratios, and decreasing the delay between launch and widespread availability.

Other potential channels for delivering RAS were also identified in the course of this research. For instance,
primary care centres, which are often the first link in the referral chain from CHWs, identified frequent stock-outs of the recommended IV treatment for severe malaria. As these facilities often serve as stocking points for CHWs, allowing them to utilise RAS that is already in their facility (when stocked out of the IV product) seems a straightforward solution, particularly for patients who bypass the CHW and directly seek care at a facility. In addition, private sector outlets such as pharmacies and drug stores remain the first point of care for many caregivers of children with fever, particularly in non-business hours, and might be a potential future source of pre-referral treatment, if policy and referral chains were aligned to support this alternative.

MMV has taken forward the results of this research and shared it with other stakeholders, and will work together with countries to support the scale-up and usage of RAS, with the ultimate goal of increasing timely access to appropriate treatment for all.

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References
5. Note that the research was conducted between February and September of 2014 and as such may not reflect current status.
9. These early adopter countries represent those which were either yellow or green in both policy and delivery viability assessments (Figures 1 & 2). Burkina Faso, shaded in paler green in Figure 4, is currently not policy-ready but shows credible willingness to change immediately when PQ IRAS becomes available.