ASSESSING THE MARKET LANDSCAPE FOR AN INFECTION DETECTION TEST AIMED AT MALARIA ELIMINATION

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BACKGROUND

More sensitive tests are needed to identify individuals with low parasite density infections who cannot be diagnosed with current rapid diagnostic tests (RDTs) but who contribute to malaria transmission. The Diagnostics for Malaria Elimination Towards Eradication (DIAMETER) team is working to enable access to highly sensitive, and temporally efficient malaria diagnostic tools to support malaria elimination. As a subset of this activity we sought to evaluate the potential market demand for infection detection tests (IDTs), a new test with 10x improved limit of detection for Plasmodium falciparum (Pf).

METHODOLOGY

Similarities and differences between RDTs and the IDT

<table>
<thead>
<tr>
<th>RDT vs. IDT</th>
<th>Current RDTs on the market</th>
<th>IDT (Minimum requirement from TPP)¹ ¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target population</td>
<td>Pf only, Pf/Pv, Pf/Pan</td>
<td>Pf only</td>
</tr>
<tr>
<td>LOD</td>
<td>~800 pg HRP2/ml in whole blood</td>
<td>80 pg HRP2/ml in whole blood</td>
</tr>
<tr>
<td>Sensitivity / Specificity</td>
<td>Varies by manufacturer, product, parasite density and type, test operator, interpretation of results²</td>
<td>Sensitivity: 95% (LL95%CI) Specificity: 95% (LL90%CI)</td>
</tr>
<tr>
<td>Min. time to results</td>
<td>15-30 minutes²</td>
<td>Less than 15 minutes</td>
</tr>
<tr>
<td>Ease of use</td>
<td>One timed step</td>
<td>One or no timed steps</td>
</tr>
<tr>
<td>Throughput</td>
<td>~10 tests/hour</td>
<td>~7 tests/hour</td>
</tr>
<tr>
<td>Pricing/test</td>
<td>USD 37 (2012) and USD 32 (2013) for Pf-only RDTs³</td>
<td>&lt;USD 2.00 (at volumes of 10 million)</td>
</tr>
</tbody>
</table>

¹ These minimum requirements were discussed at the Strategic and Technical Advisory Group (STAG) Meeting in Geneva in September 2015.

² As determined by benchmarking SD Bioline Malaria Ag Pf.

Current RDT market

The total volume of the RDT market has grown steadily (Figure 1a), but market value has not increased due to declining unit prices (Figure 1b).

METHODOLOGY CONTINUED

Potential IDT market

Several requirements should be met before the IDT is adopted by countries (Figure 2). Because the IDT is still under development and neither evidence nor policy have been established, there is currently no clear market for an IDT.

Figure 2. “Typical” timeline towards achieving our objective

Assumptions and Unknowns

The IDT has several potential use scenarios as indicated in Figure 3. Each use scenario represents a unique set of defined users, training requirements, infrastructure, and location of IDT use and can also differ based on the countries’ programmatic phases (control, pre-elimination, or elimination) and epidemiological needs.

Figure 3. Potential use scenarios of the IDT⁵

Developing an accurate estimate of the IDT market size based on these use scenarios is challenging at this stage because of limited evidence supporting its effectiveness. Thus these scenarios are based on multiple assumptions, uncertainties, and non-scope factors documented in Table 2.

RESULTS AND CONCLUSIONS

The results suggest that within the first 3 years of the IDT receiving the necessary international guidance, the total volumes for all use scenarios will be under 30 million units (Figure 4). This number represents close to 10% of the 2013 RDT market (Figure 1a). A more realistic estimate of the IDT market could be between 1% (pessimistic) and 10% (optimistic) of the current RDT market in number of tests sold. The model will continue to be updated as more data and information become available during the IDT development phase.

ACKNOWLEDGMENTS

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REFERENCES

1. PATH. Target Product Profile: Point of Care Malaria Infection Detection Test. Seattle. PATH; 2014.
3. UNITAID, Malaria Diagnostics Technology And Market Landscape, 2014.