A field trial to evaluate the performance of a point-of-care diagnostic for screening G6PD deficiency in a falciparum and vivax malaria endemic area of Western Cambodia

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Introduction

- Cambodia is moving towards malaria elimination
- Primaquine remains the only available drug capable of killing P. falciparum mature gametocytes and P. vivax hypnozoites
- Screening patients for glucose-6-Phosphate Dehydrogenase (G6PD) deficiency in the community remains critical for a safe and successful roll-out of primaquine
- G6PD rapid diagnostic tests (RDTs) are needed alongside malaria RDTs
- Comprehensive assessments to test their feasibility and performances under field conditions are still required prior to their wide-scale implementation

Methods

Cross-sectional survey conducted in six malaria endemic villages in Pailin Province in Cambodia (see map) in May–June 2013.

Data Analysis
Data entered and verified using Microsoft Excel® software, and was analyzed using EpiInfo 6.04® software (CDC, Atlanta, USA), Stat® version 12, and MedCalc® version 11.6.1 software (MedCalc, Mariakerke, Belgium). P-values < 0.05 were used to indicate statistically significant differences.

Laboratory Testing
The validity of the tests used in the study were monitored by the use of at least three levels of G-6-PDH controls (Deficient, Intermediate and Normal) for each run. To minimize the impact of heterozygosity on the definition of G6PD activity, and following the recent guidelines proposed by the G6PD working group, the adjusted median value of G6PD activity for the entire male population was calculated for which males with severe G6PD deficiency (activity less than 10% normal) were excluded.

Ethical review
Cambodian National Ethics Committee for Health Research (NEHCR) and Centers for Disease Control and Prevention. There was no conflict of interest.

Results

Table 1. Demographic and hematological characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total (n=938)</th>
<th>Males (n=494)</th>
<th>Females (n=444)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age (y)</td>
<td>9.5 (2.7)</td>
<td>11.4 (3.6)</td>
<td>7.7 (2.3)</td>
</tr>
<tr>
<td>Median WBC x103/l</td>
<td>6.6 (2.8)</td>
<td>6.9 (2.9)</td>
<td>6.4 (2.7)</td>
</tr>
<tr>
<td>Median hemoglobin g/dL</td>
<td>12.3 (1.8)</td>
<td>12.7 (2.2)</td>
<td>11.9 (1.5)</td>
</tr>
<tr>
<td>Median G6PD activity UI/g Hb</td>
<td>11.8 (3.8)</td>
<td>11.7 (3.7)</td>
<td>11.9 (3.9)</td>
</tr>
</tbody>
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1. Demographic characteristics (Table 1):
938 venous blood samples collected from individuals living in six villages in Pailin province. All were Khmer ethnic group. The male/female ratio was 472/466 (0.99) and age ranged from 18 to 75 years old (median=35 year).
The detection of malaria parasite carriers was positive for 28/750 (3.7%). P. vivax was the most prevalent species (24/750, 3.2%).

Methods

Table 2. Laboratory Testing results of the CareStart™ G6PD deficiency RDT

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Discussion and conclusions
Better performance compared to the previous generation of this RDT where sensitivity was low (68%) and therefore the risk of false “normal” status unacceptably high. 2
The evaluation of this test “outside of the laboratory” showed its capability of detecting reliably G6PD deficient individuals with enzyme activity levels <30% UI/g comparable to the fluorescent spot test. To accelerate the roll out of G6PD RDT use and primaquine in Cambodia, further evaluations are needed to access the operational challenges and programmatic usefulness of the tests when implemented by health workers in the field. In parallel, more clinical data on the optimal and safe primaquine doses for malaria elimination are needed urgently in order to improve the development of the next generation of tests which will aim at providing a reliable and safe “go vs. no-go” answer to using primaquine in routine practice.

References


Acknowledgements
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