A Comparison of Three Methods to Estimate G6PD Activity in the Chittagong Hill Tracts, Bangladesh

The G6PD status of patients should be used to guide administration of primaquine for preventing relapse (WHO Guidelines for the treatment of Malaria 3rd ed., 2015).

A number of qualitative diagnostic assays but no handheld quantitative assay available for field use.
Aim

- Evaluate two new quantitative G6PD diagnostics against spectrophotometry.
  - WST-8 test
  - The Biosensor (1st generation)

- Evaluate the Carestart Hb MHD-1 (Accessbio, USA) against the Hemocue 301+ (Angelholm, Sweden)
Methods

• Cross sectional survey

• August 2015 – January 2016

• Participant enrolment
  – Purposive selection of villages
  – Random selection of households
  – Random selection of 1 household member / household
Methods

3ml venous blood collected from all participants:

- **On site:**
  - Consent
  - Biosensor (G6PD)
  - Carestart Hb MHD-1
  - Hemocue (Hb)

- **At reference centre:**
  - Spectrophotometry (Randox)
  - WST-8
• **Adjusted male median G6PD activity:**
  – Median activity of all male participants
  – Participants with <10% activity excluded
  – Median re-calculated on remaining subset = AMM = 100% activity

• **G6PDd** defined as <10%, <30% & <60% of AMM

• **Positive result** = G6PD deficient (G6PDd) result

• **Gold standard:**
  – Spectrophotometry (Randox)
  – Hemocue (Hb)
Results

- 1002 participants enrolled
  - 60% females, 40% males

- Median age: 31 years
  - IQR: 17-45, range: 5-80

- 9 different Hill Tribes + Bengali population
  - Approx. similar numbers
Results

G6PD activity / test assay (all)
## Results

### Spectrophotometry vs. Biosensor

<table>
<thead>
<tr>
<th>Comparison</th>
<th>n</th>
<th>Spearman’s Rank Correlation ($r_s$)</th>
<th>Mean difference U/gHb (G6PD activity) or g/dL (Hb)</th>
<th>95% limits of agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spectrophotometry vs. Biosensor</td>
<td>994</td>
<td>0.44</td>
<td>-1.70</td>
<td>-7.63 to 4.23</td>
</tr>
<tr>
<td>Spectrophotometry vs. WST-8</td>
<td>995</td>
<td>0.51</td>
<td>-0.12</td>
<td>-5.45 to 5.20</td>
</tr>
<tr>
<td>Hemocue vs. Carestart Hb</td>
<td>1002</td>
<td>0.80</td>
<td>0.09</td>
<td>-2.15 to 2.34</td>
</tr>
</tbody>
</table>

![Spectrophotometry vs. Biosensor](image1.png)

![Spectrophotometry vs. WST-8](image2.png)
## Results

<table>
<thead>
<tr>
<th>G6PD activity</th>
<th>&lt;10%</th>
<th>10-30%</th>
<th>30-60%</th>
<th>&gt;=60</th>
<th>Total</th>
<th>&lt;10%</th>
<th>10-30%</th>
<th>30-60%</th>
<th>&gt;=60</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Spectrophotometry</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;10%</td>
<td>5 (0.5%)</td>
<td>7 (0.7%)</td>
<td>21 (2.1%)</td>
<td>17 (1.7%)</td>
<td>50</td>
<td>0 (0.0%)</td>
<td>31 (3.1%)</td>
<td>9 (0.9%)</td>
<td>9 (0.9%)</td>
<td>49</td>
</tr>
<tr>
<td>10%-&lt;30%</td>
<td>2 (0.2%)</td>
<td>3 (0.3%)</td>
<td>17 (1.7%)</td>
<td>17 (1.7%)</td>
<td>39</td>
<td>0 (0.0%)</td>
<td>18 (1.8%)</td>
<td>11 (1.1%)</td>
<td>11 (1.1%)</td>
<td>40</td>
</tr>
<tr>
<td>30%-&lt;60%</td>
<td>0 (0.0%)</td>
<td>2 (0.2%)</td>
<td>9 (0.9%)</td>
<td>73 (7.3%)</td>
<td>84</td>
<td>0 (0.0%)</td>
<td>4 (0.4%)</td>
<td>14 (1.4%)</td>
<td>66 (6.6%)</td>
<td>84</td>
</tr>
<tr>
<td>&gt;=60%</td>
<td>3 (0.3%)</td>
<td>7 (0.7%)</td>
<td>37 (3.8%)</td>
<td>774 (78.5%)</td>
<td>821</td>
<td>0 (0.0%)</td>
<td>16 (1.6%)</td>
<td>42 (4.2%)</td>
<td>764 (78.5%)</td>
<td>822</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>10</td>
<td>19</td>
<td>84</td>
<td>881</td>
<td>994</td>
<td>0</td>
<td>69</td>
<td>76</td>
<td>850</td>
<td>995</td>
</tr>
</tbody>
</table>
• **WST and BS are technical improvements**
  – Neither assay is currently suitable for deployment
    • The WST-8 is being modified and a complementary Hb test developed
    • A new generation of the Biosensor will be introduced in the coming months that will combine Hb and G6PD measurement

• **Carestart Hb machine performed comparable to Hemocue**
Many thanks for your attention!
Additional