Failure of Test kits:
Ensuring the quality of HIV testing in Malawi

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Case Report: HIV test misdiagnosis

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A 43 years old married woman presented to a private clinic with repeated episodes of mouth sores. The clinician diagnosed her with oral candida. Her past medical history was significant only for bronchial asthma since childhood. Her asthma had been poorly controlled in the recent few weeks requiring high doses of oral prednisolone and regular salbutamol inhaler. She had been on this treatment for a month when she presented with these sores. She had neither had a blood transfusion nor experimental HIV vaccine.

Fig 2: Excess fat on the back
### Common Testing Issues

[Elizabeth Marum, Hetal Patel]

<table>
<thead>
<tr>
<th><strong>Observed</strong></th>
<th><strong>Recommendations</strong></th>
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</thead>
<tbody>
<tr>
<td>Disorganized work space</td>
<td>Clean work space</td>
</tr>
<tr>
<td>Safety concerns – Inconsistent use of gloves or proper disposal</td>
<td>Universal safety precautions should be followed</td>
</tr>
<tr>
<td>Poor finger-prick procedure</td>
<td>Follow job aide</td>
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<tr>
<td>Inadequate sample volume</td>
<td>Follow job aide</td>
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<tr>
<td>Run-time not followed</td>
<td>Mandatory use of timer</td>
</tr>
<tr>
<td>Testing algorithm not followed</td>
<td>Re-fresher training</td>
</tr>
<tr>
<td>Hand written record keeping</td>
<td>Official register use only</td>
</tr>
<tr>
<td>Over burdened sites (ANC, OPD)</td>
<td>No more than 5 clients per Batch</td>
</tr>
</tbody>
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Policy issues

• Test kit specifications
  • Time to read
  • Storage
• Post-market evaluation
• Task shifting
  • “Health Surveillance Assistants” (HSA)
  • Other duties
• Sheer volume
  • Option B+
  • “Batching”
Do we know how BIG the problem is?

• No
  – No systemic study as of yet
  – Some clues but hard to interpret and generalize
ANC sentinel surveillance: apples and oranges

<table>
<thead>
<tr>
<th></th>
<th>ANC rapid test</th>
<th>CRL; 4(^{\text{th}}) Generation ELISA</th>
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<tbody>
<tr>
<td>Total tests</td>
<td>23788</td>
<td>23218</td>
</tr>
<tr>
<td>Total Positive tests</td>
<td>2215</td>
<td>2532</td>
</tr>
<tr>
<td>Percentage</td>
<td>9.3</td>
<td>10.9</td>
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Extrapolate national: -/+9030
Total tests | 1701346
---|---
Total Positive | 140181
Discordant test | 5048
“Confirmatory inconclusive” | 745

**HTC 2013**
The Blantyre patient

• 45 years old
• On ARVs nice July 2007, started as “Stage 3”
• 2 VL done
  – LDL
• Re-tested while being screened for “HART vs HEART” study
• Awaiting a qualitative PCR and Western blot...
## Implementing a Comprehensive Approach to Ensure Quality

<table>
<thead>
<tr>
<th>Level</th>
<th>To strengthen Dry Tube Specimen EQA and QC</th>
<th>To strengthen data collection and use</th>
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</table>
| Central                | • Laboratory technologist  
                        | • Supervision to districts                                                                                     | • M and E (data) position  
                        | • IT equipment                                              | • IT training                                    |
| Zonal                  | • Training  
                        | • Supervision to Districts/sites                                                                               | • IT equipment                                              | • IT training                                    |
| District               | • Q-Corps (Supervision)  
                        | • Local IPs  
                        | • Q-Corps for distribution and results collection (**Riders for Health**)                                      | • IT equipment                                              | • IT training                                    |
| Sites (Health facility)| • Q-Corps  
                        | • Involve PEPFAR district implementing partners                                                               | • Monthly reporting to District Lab manager                           |
Conclusion

• In Malawi as in many countries, patients are started on ARVs based on 2 RTDs with no further confirmation.

• There has been no systematic study but anecdotal evidence exists for false positives and false negatives.

• EQA and mentorship needs to be intensified in Public health approach programs with task shifting.
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