Piloting, Measuring Impact and Scaling Up Innovation: What Are the Barriers?

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Barriers to Introducing Diagnostic Innovations

• Availability
  • Does the product exist
  • Is it registered
  • Is it being produced and procured (to match demand)
  • Is it optimally placed for access

• Adaptability
  • Fit to health system context of use
  • Fit to users
  • Robust

• Affordability
  • Sticker price and willingness to pay
  • Value for money
UNITAID-funded point-of-care early infant diagnosis project

Cascade of EID through initiation of treatment, across nine African countries, 2017 *

*Extrapolated from Unicef HIV/AIDS statistical tables (https://data.unicef.org) and an analysis of pooled data on conventional EID testing collected in 2016 and 2017 across 102 selected sites in nine countries: Cameroon, Côte d’Ivoire, Kenya, Lesotho, Mozambique, Rwanda, Swaziland, Zambia and Zimbabwe
### Point-of-care diagnostics products

<table>
<thead>
<tr>
<th>Assay</th>
<th>Evaluator</th>
<th>Sample type</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alere q (POC)</td>
<td>WHO PQ CDC/NHLS</td>
<td>WB</td>
<td>98.67% (95.27-99.84)</td>
<td>100.00% (97.59-100.00)</td>
</tr>
<tr>
<td>Cepheid Xpert (Near POC)</td>
<td>WHO PQ CDC/NHLS</td>
<td>WB</td>
<td>98.86% (93.83-99.97)</td>
<td>100.00% (97.55-100.00)</td>
</tr>
<tr>
<td></td>
<td>WHO PQ CDC/NHLS</td>
<td>DBS</td>
<td>99.34% (96.40-100.00)</td>
<td>100.00%(97.60-100.00)</td>
</tr>
</tbody>
</table>
UNITAID-funded point-of-care early infant diagnosis project

1. Optimize EID networks
2. Strategic placement of products
3. Pragmatic implementation
4. Ensure sustainability and access:
   a. Available
   b. Adapted
   c. Affordable
Product Availability: Can we get the product?

• Product Registration
  – Requirements for in-country lab and field validation severely delayed uptake in several countries
  – Lack of clarity on regulatory pathways = lack of clarity to get to a sustainable approval
  – Short term: Sharing of available evidence and implementation results/post-market intel
  – Longer term: Improved country regulations and more collaborative procedures with WHO PQ or SRAs

• Early market growing pains
  – Supply-demand shortages
  – Provide advanced forecasts
  – Phased implementation
  – Close monitoring of stocks
Product Availability: Where to place the product

• Product placement 1: Network creation or integration
  – Non-optimized network results in underutilization and/or poor clinical outcomes
  – Separate programs and funding streams may reduce ability to integrate testing or optimize networks
  – Placement strategy to maximize access and optimize existing and planned products – plan for potential market segmentation
  – Determine goal, strategy and indicators to create a successful network depending on clinical indication.
  – Work across programs

• Product placement 2: Population access
  – Use of new diagnostics should be clinically meaningful
  – Yield vs numbers
Hub and spoke sites using POC EID can further increase access to those sites with low demand.

Number of health facilities identified as eligible to access POC EID testing.

- Sites analyzed: 100%
- Sites ≥0.5 EID/day: 5%
- Sites & Hubs ≥0.5 EID/day: 4%
- Referring Spokes: 18%
- Total Sites (Hubs & Spokes): 22%
A combination of POC device placement strategies

To increase access to testing; expand case findings; decrease result turnaround time; and optimize platform utilization.

**Stand-Alone Sites**
Receive samples directly from clients, perform POC EID tests on site

**Multiple-Entry-Point Sites**
Stand-alone or hub test sites receive samples from units or wards within the same health facility

**Hub-and-Spoke Networks**
Hub sites test patients at that site and for spoke sites. Nearby spoke sites send samples to the hub sites for testing

**Integrated Testing Sites**
Process different types of POC tests (e.g. EID, TB)
Product and System Adaptability: How to use the product

• Site requirements and infrastructure
  – Product misuse or failure
  – Match product profile to sites or budget for infrastructure upgrades

• System growing pains
  – The shiny new thing is not well supported and becomes the rusty old thing
  – Early and intensive QI

• Quality assurance of decentralized diagnostics
  – Fit the QA scheme to the product – leverage on site monitoring and connectivity monitoring

• Health workforce requirements
  – Products that allow decentralization and task shifting
Use of Non-Lab Staff: Zimbabwe

- 10 sites
  (6 sites nurses, 2 sites lab techs, 2 sites both)
- Error rate analysis by cadre and over time
- Earlier dates have fewer total tests
  (65 in Jan. vs. 477 in June)

<table>
<thead>
<tr>
<th>Error Category</th>
<th>Testing Cadre</th>
<th>Error Rate</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Errors</td>
<td>MLSc/Techs</td>
<td>7.69%</td>
<td>0.36</td>
</tr>
<tr>
<td></td>
<td>Nurse</td>
<td>9.24%</td>
<td></td>
</tr>
<tr>
<td>End User Errors</td>
<td>MLSc/Techs</td>
<td>5.22%</td>
<td>0.38</td>
</tr>
<tr>
<td></td>
<td>Nurse</td>
<td>6.41%</td>
<td></td>
</tr>
</tbody>
</table>

Error Rates by Type of Operator over time

- Overall
- MLSc/Techs
- Nurses
Product and System Affordability

• Non-equivalent products
  – Comparisons based solely on ex works costs may be false
  – Consider everything needed in order to make a product really work in the field
  – Estimating fully loaded costs and ensuring apples-to-apples comparison

• Costs vs cost-effectiveness
  – Sticker shock may reduce demand
  – Critical to look at cost-effectiveness and compare waste

• Sustainability
  – Consider costs of warranty and product lifespan (if applicable)

• Budgeting
  – Replacement technology vs additive technology
  – Early and granular budgeting is critical
## Evaluation Results: Conventional vs. POC EID

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Conventional EID</th>
<th>POC EID</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median TAT from blood sample collection to result returned to caregiver</td>
<td>55 days</td>
<td>0 days (IQR:0-1)</td>
<td>p&lt;0·001</td>
</tr>
<tr>
<td>(IQR: 31-77)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Results received by caregiver within 30 days</td>
<td>18·70 %</td>
<td>98·32% (18,737/19,058)</td>
<td>p&lt;0·001</td>
</tr>
<tr>
<td>(542/2,899)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percent of HIV-infected infants started on antiretroviral therapy within 60 days of sample collection</td>
<td>43·30% (42/97)</td>
<td>92·34% (639/692)</td>
<td>p&lt;0·001</td>
</tr>
<tr>
<td>Median TAT from blood sample collection to ART initiation for HIV-infected infants</td>
<td>49 days (IQR:30-68)</td>
<td>0 days (IQR:0-3)</td>
<td>p&lt;0·001</td>
</tr>
</tbody>
</table>
Conclusions

• Begin with a network perspective – may need to involve stakeholders across disciplines and disease areas
• Plan for the whole package – from a systems and product perspective
• Start slow – phase implementation
• Early intensive QI and flexibility
• Document, document, document – additional data is needed early on
• Consider diagnostic fully-loaded costs and value for money
• Identify and tackle key systems barriers (e.g. overly complex regulatory frameworks)
Thank you