Bringing the test to the patient: methods and tools for integrating innovative point-of-care HIV testing into national laboratory networks

Leadership Workshop, 22nd International AIDS Conference
27 July 2018 - 11:00-12:30h, Room E105-108, Amsterdam
1. Results from routine point-of-care testing for early infant diagnosis of HIV (POC EID), including an overview of implementation phases, activities and tools applied (Rebecca Bailey)

2. Introduction to site and product selection, product approval, site capacity assessments, and placement models for POC testing (Naoko Doi)

3. Key elements of site enrollment, orientation, planning, training, monitoring and quality assurance, including logistics for a short-haul, hub-and-spoke testing model (Jeff Lemaire)

4. Special considerations for the procurement and supply chain management of POC HIV diagnostics (Esther Turunga)

5. Question and answer session (Jennifer Cohn)
Why POC testing for EID of HIV?

• Early HIV testing, prompt return of test results, and rapid initiation of treatment are critical for reducing morbidity and mortality among HIV-infected infants

• In order to achieve the UNAIDS 90-90-90 targets, the World Health Organization recommends:
  – All HIV-exposed infants receive a virological test at 4-6 weeks of age, or at the earliest opportunity thereafter;
  – Test results are returned to caregivers quickly (i.e. within 4 weeks); and
  – HIV-infected infants are promptly linked to care and treatment services.
In spite of a decade-long effort to scale-up access to conventional EID testing services, which has nearly doubled the number of tests, the coverage of HIV-exposed infants receiving a timely EID test remains below 50%.

The proportion of HIV-exposed infants receiving a timely virlogical test for HIV by 2-months of age remained below 50% from 2010-2016.

During the same period the number of EID tests nearly doubled. However long turnaround times (TAT) and a high proportion of results not returned have remained problems.

Only 51% of HIV-infected children are on life-saving ART.
With laboratory-based EID testing, the number of steps from sample collection to return of results to caregiver and clinical action are mired in persistent delays and a high proportion of lost results.

**Timeframe: 30-90 days**

1. **Specimen collection at health facility**
2. **Sample transport to laboratory**
3. **Analysis at the laboratory**
4. **Result return to health facility**
5. **Result return to caregiver**
With funding and support from Unitaid, CHAI/UNICEF and EGPAF are collaborating with the Ministries of Health in 15 African countries to speed up clinical decision making by integrating POC EID testing into national laboratory systems.

**Goal:** Increase the number of HIV-exposed infants with known HIV status and facilitate early initiation of care and treatment

**Purpose:** Ensure that at-risk infants have timely access to HIV testing, diagnosis and treatment through the incorporation of POC testing into national EID networks

**Scale:**
- 15 countries – 4 overlapping
- 5 years
  - EGPAF 2015-2019
  - CHAI/UNICEF 2016 – 2020
- $157 million
Early results from the routine use of POC EID in nine African countries confirm findings from published studies on reduced TAT for test results, increased rates of results returned, and quicker initiation of ART.

### Study Results of POC EID Use

<table>
<thead>
<tr>
<th>Country</th>
<th>Setting</th>
<th>Device/Sample</th>
<th># of sites</th>
<th>n (infants)</th>
<th>% result return to caregiver</th>
<th>TAT result return</th>
<th>% ART initiation</th>
<th>TAT ART Initiation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mozambique (Maputo, Sofala)</td>
<td>Randomized controlled trial (cRCT)</td>
<td>Alere q/Whole blood</td>
<td>SOC - 8</td>
<td>1,876</td>
<td>0.32%</td>
<td>0%</td>
<td>125</td>
<td>12.8%</td>
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<td></td>
<td></td>
<td></td>
<td>POC - 8</td>
<td>2,034</td>
<td>98.7%</td>
<td>98.2%</td>
<td>0</td>
<td>89.7%</td>
</tr>
<tr>
<td>Malawi</td>
<td>Observational pre/post</td>
<td>Alere q/Whole blood</td>
<td>7 pre POC</td>
<td>963</td>
<td>18.1%</td>
<td>0%</td>
<td>56</td>
<td>41.9%</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>7 post POC</td>
<td>789</td>
<td>100%</td>
<td>99.5%</td>
<td>0</td>
<td>91.1%</td>
</tr>
</tbody>
</table>

### Routine Use of POC EID (monitoring and evaluation [M&E] data)

<table>
<thead>
<tr>
<th>Nine countries (Dec 2016 – March 2018)*</th>
<th>M&amp;E</th>
<th>Alere q/Whole blood &amp; Xpert/Whole blood</th>
<th>SOC – 102</th>
<th>2,867</th>
<th>19.7%</th>
<th>0%</th>
<th>55</th>
<th>41.3%</th>
<th>0%</th>
<th>50</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>POC – 339</td>
<td>25,102</td>
<td>98.3%</td>
<td>67%</td>
<td>0</td>
<td>91.7%</td>
<td>65%</td>
<td>0</td>
</tr>
</tbody>
</table>

*Mozambique SOC: 7.2% within 60 days; Malawi pre: 41% within 60 days

*Cameroon, Côte D’Ivoire, Kenya, Lesotho, Mozambique, Rwanda, Swaziland, Zambia, Zimbabwe (EGPAF)

SOC = Standard of Care (Conventional, lab-based testing)  
POC = Point-of-Care testing  
NA = not available
What inputs were needed to achieve desired outcomes?

Key Inputs

Input 1: Leadership and governance

Input 2: Site and product selection, product approval, and site capacity assessments

Input 3: Site enrollment, orientation, planning, and training

Input 4: Site monitoring, support, and competency assessments

Input 5: Forecasting, procurement, supply chain and waste management

Input 6: Quality management and assurance (QA)

Outcomes

Compared to conventional, lab-based testing:

- Consistent delivery of a larger proportion of test results faster.
- Rapid diagnosis of more HIV-positive infants.
- Shorter time from sample collection to ART initiation for HIV-positive infants.
Gradual and phased implementation approach

- Hand-in-hand with the Ministry of Health (MOH) and key stakeholders in each country
- Frequent stakeholder consultation and coordination
- Gradual and staged selection and enrollment of testing sites

**Preparation Phase**
- Stakeholder engagement
- Implementation planning
- Site and product selection
- Product registration
- Tools and systems development
- M&E system development
- Baseline assessments
- Procurement agreements
- Purchase and ordering

**Pilot Phase**
- Site enrollment and trainings
- Intensive monitoring & support / mentoring
- Continuous improvement
- Document and share lessons

**Progressive Site Enrollment**
- Refine site and product selection
- Site enrollment and trainings
- Refine systems and tools (include QA and post-market surveillance)
- Adapted support monitoring
- Improve based on lessons learned

**Routine Testing and Monitoring**
- Monitoring and evaluation
- Impact assessment
- Market dynamics
- Engage and prepare for transitioning

**Transitioning Phase**

Coordinated EID Network Development for Sustainable Impact

Continuous Monitoring, Evaluation, and Improvement using Standardized Frameworks and Tools

- Q3 2015
- Q4 2016
- Q3 2017
- Q3 2018
- Q2 2019
### Activities and tools used to support the approach

<table>
<thead>
<tr>
<th>Stage 1: Pre-Procurement</th>
<th>Stage 2: Preparation</th>
<th>Stage 3: Implementation</th>
<th>Stage 4: Continuous Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engage with relevant <strong>MOH Units and/or national technical working groups</strong></td>
<td>Update policies, algorithm, etc.</td>
<td>Print POC EID testing algorithms, SOPs, job aids and distribute to sites</td>
<td>Remote monitoring of stocks and testing</td>
</tr>
<tr>
<td><strong>Site selection</strong></td>
<td>Develop training plans and materials</td>
<td><strong>Transport</strong> cartridges and other consumables to sites</td>
<td>Remote monitoring and analysis of IQC failures</td>
</tr>
<tr>
<td><strong>Platform selection</strong> (based on sites selected)</td>
<td>Review and adapt, or develop, <strong>standard operating procedures (SOP) and job aids</strong> for POC EID, including inventory management</td>
<td><strong>Install</strong> POC EID platforms at sites</td>
<td>Post-market surveillance</td>
</tr>
<tr>
<td><strong>Product registration</strong></td>
<td>For <strong>hub and spoke</strong> sites, establish: 1) sample transport and/or patient referral network systems; 2) result relay systems; 3) systems to track samples</td>
<td>Performing comprehensive <strong>trainings at site</strong>: 1) Sample collection, labelling, handling, transport 2) Operating the instrument 3) Equipment maintenance 4) Recording, reporting, and M&amp;E 5) Quality assurance 6) Waste disposal 7) Inventory management</td>
<td>Frequent <strong>site monitoring visits</strong> (especially soon after enrollment)</td>
</tr>
<tr>
<td><strong>Prepare for importation</strong> (customs, consignee, warehousing)</td>
<td><strong>Upgrade physical infrastructure</strong>, including procurement of furniture and equipment</td>
<td>Implement <strong>M&amp;E system</strong>, including connectivity</td>
<td>Use lessons learned to optimize implementation</td>
</tr>
<tr>
<td><strong>Establish a supply chain system</strong></td>
<td><strong>Site preparedness</strong> (communication, focal point, patient flow, referral system, etc.)</td>
<td><strong>Community mobilization</strong> to create demand</td>
<td>Use testing data to inform procurement and policies</td>
</tr>
<tr>
<td>Identify <strong>waste disposal</strong> plan</td>
<td>Put in place <strong>M&amp;E system</strong> and tools</td>
<td>Implement <strong>sample referral, and supply chain systems</strong></td>
<td>Meet with national stakeholders to share results and lessons</td>
</tr>
<tr>
<td><strong>Procurement forecast</strong> based on historical demand</td>
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<tr>
<td><strong>Ordering system</strong> and scheduling (accounting for short shelf life of products)</td>
<td>Define minimum package for internal quality control, <strong>external quality assurance</strong> (EQA) and <strong>post-market surveillance</strong> (PMS)</td>
<td><strong>Governance</strong> and support structure in place</td>
<td>Account for <strong>phased enrollment timelines</strong> and coordination needs</td>
</tr>
</tbody>
</table>
Knowledge Gateway online library and community

Welcome to the online library and community of practice for point-of-care EID testing implementers!

The purpose of this community is to share information, approaches and tools for the sustainable integration of point-of-care testing into national laboratory systems. Implementers are encouraged to write messages to this forum to share specific questions, tools, or lessons learned during POC implementation so that we can benefit from each other’s experience. We have a wealth of knowledge. Let’s share it!

The URL for the community is: https://knowledge-gateway.org/poc-eid-implementers/

The email address for the community is: poc-eid-implementers@knowledge-gateway.org

URL: https://knowledge-gateway.org/poc-eid-implementers
Email address: poc-eid-implementers@knowledge-gateway.org
HIV POC diagnostics toolkit (hosted on the UNICEF website)

Tools for:
- Product and site selection
- Forecasting and supply planning
- Regulations
- Quality assurance
- Others under development

URL: [https://www.childrenandaid.org/poc-toolkit-page](https://www.childrenandaid.org/poc-toolkit-page)
Input 1: Leadership and governance

MOH and technical working groups (e.g. lab, PMTCT, HIV) representing:

- MOH units (lab and clinical)
- Technical experts and agencies
- Implementing partners
- Local nongovernment and faith-based organizations
- Donors
- etc.

Example activities and outputs:

- Criteria for site selection
- POC roadmaps, manuals, plans
- Product registration
- Adapted testing guidelines, algorithms and SOPs
- Updated policies, strategies and plants
Input 2: Site and product selection, product approval, site capacity assessments, and placement models

NAOKO DOI
Input 3: Site enrollment, orientation, planning and training

Assuming the following:
• Site and platform selection is completed
• All training, planning and monitoring tools developed and available
• Instruments and cartridges have been ordered and about to arrive in-country

Ready for POC EID Roll-out?

Not quite....
• Testing algorithm, policies, request forms, registers, etc. need to account for POC EID
• Site assessment and site improvement plan are required to allow adequate patient flow, HR and infrastructure capacity (secured room, table, storage cabinet, charger-inverter, etc.).
• Detailed phased-enrolment plan, as all sites won’t be able to start at the same time
• Comprehensive training package (not only instrument training), from sample collection to cartridges disposal, including inventory management, reporting, etc.
• Supply chain needs to be adapted to short shelf-life and high-value of commodities
• Detailed plan for site monitoring activities with responsible personnel identified
Phased site enrollment

- New testing site enrollments
- Cumulative number of sites accessing POC EID
- New spoke site enrollments
Using hub-and-spoke networks to increase access to POC testing and optimize device utilization rates

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

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

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

**Integrated Testing Sites**
Process different types of POC tests (e.g. EID, TB, other)
Hub-and-spoke improves access to POC EID for sites with low demand

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

- Sites analyzed: 100%
- Sites ≥0.5 EID/day: 3%
- Sites & Hubs ≥0.5 EID/day: 4%
- Referring Spokes: 18%
- Total Sites (Hubs & Spokes): 22%

7.6x increase
5.0x increase
25% increase
Hub-and-spoke networks: Sample transport

- Use of EDTA microtainer tubes (Ethylenediaminetetraacetic acid to avoid blood clotting)
- Specimen stable for 24 hours at room temperature or 72 hours at 2 to 8 °C
- Uniform guidance on labeling and packaging (i.e. triple packaging)
- Various models of transport, for example:
  - Kenya: Leverage existing EID sample transport (planned hubs that way)
  - Cameroon: Mix of motorcycle couriers, public transport
Orientation, planning and training

Pre-installation orientation and planning:

✓ Engage with sub-national authority and coordinate with in-country partners
✓ Plan enrolment with facility in-charge
✓ Perform infrastructure upgrades, if needed
✓ Appoint and train support monitoring staff and supervisors
✓ Conduct trainings of “master trainers”
✓ Coordinate with manufacturers for planning of instrument end-user trainings

Installation, trainings, and start-up:

✓ Confirm scheduling of training
✓ Instrument installation and end-user training
✓ Orientation session and trainings for all facility staff involved in EID services
✓ Start testing activities
## Comprehensive training plan

<table>
<thead>
<tr>
<th>Activities</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
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<tbody>
<tr>
<td><strong>Day One: Mentoring and supportive supervision training</strong></td>
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<tr>
<td>1. Training in all relevant content areas (e.g. EID testing form, instrument operation, sample collection, etc.)</td>
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<td>2. The site visit process and tools (e.g. frequency, supervisory visit checklist, reporting)</td>
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<td>3. Project M&amp;E methods and tools</td>
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<td>4. Recommended approaches for mentoring and supportive supervision, including troubleshooting</td>
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<td>5. Training on how to perform competency assessment</td>
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<td>6. Lines of communications</td>
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<td>7. Education for clinicians on implications of same-day testing</td>
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<td><strong>Day Two: Orientation and training session for staff in hub and spoke facilities.</strong></td>
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<tr>
<td>1. Training on the use of the EID Testing Form (how to fill the form for each units, its workflow &amp; documentation)</td>
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<td>2. Sample collection training</td>
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<tr>
<td>3. Sample labelling, packaging and transportation training</td>
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<tr>
<td><strong>Day Three: Orientation and training session for staff in hub and spoke facilities.</strong></td>
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<tr>
<td>1. Results communication (to caregiver/patient) training</td>
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<tr>
<td>2. Training on the communication process.</td>
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<td>3. Training on collecting treatment initiation data</td>
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<td>4. Waste management training (sorting, labelling, disposal, transport, of destruction of waste)</td>
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<tr>
<td><strong>Day Four: Orientation and training session for staff in hub and spoke facilities.</strong></td>
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<tr>
<td>1. Training on storage, inventory tracking, and ordering of POC EID supplies</td>
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<tr>
<td>2. Overview of mentoring and supportive supervision plans</td>
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<tr>
<td>3. Lines of communications</td>
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<tr>
<td><strong>Day Five: Installation of Alere-Q platform.</strong></td>
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<tr>
<td>1. Manufacturer’s End-User training, including operations (loading cartridge and operate instrument), preventive maintenance and cartridge disposal</td>
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<tr>
<td>2. Project’s related processes related to testing (transfer of specimen from Microvette to cartridge, how to deal/record/report errors, Sample rejection and error logbook, temperature monitoring, etc.)</td>
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<td>3. Lines of communications with spokes and with EGPAF supervisor (naming 1 focal person per site)</td>
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</tbody>
</table>
Examples of training materials, algorithms, SOPs and job aids
Installation and training are complete. Time to start testing.... with close monitoring and support.
Input 4: Site monitoring, support, and competency assessments

Post-installation monitoring and follow-up

- Ensure close follow-up for each POC EID testing facility and their respective spoke sites
- Data collection, monitoring, and analysis through supportive site monitoring visits, with MOH staff to observe, review data, etc.
- Ensure swift corrective improvement
- Document lessons learned
- Competency assessments of instrument operators and, if possible, certification
POC EID Testing Form

Single form with carbon copies

Section 1:
Filled by health worker

Section 2:
Filled by POC testing staff

Section 3:
Filled by treating staff
Site monitoring visits should include review and observation of:

- Clinical Integration (i.e. adherence to testing algorithms, patient flow, etc.)
- Use of SOPs, job aids, registers, tracking logs, and testing forms
- Training and competency of instrument operators, including observation of operators, if possible
- Instrument placement and performance
- Inventory and waste management
- Linkage to care
- Trouble shooting
- Mentoring, training and information sharing
Frequency of site monitoring visits

Site Enrollment Monitoring Schedule-testing and hub sites

- Supportive supervision needs are expected to decrease over time
- Site enrollment scheme is planned in a phased manner
- The team opted for the following supportive supervision visit scheme for each newly enrolled site:
  - 2 weeks after each site enrollment
  - 4 weeks later (6 weeks after enrollment)
  - 6 weeks later (12 weeks after enrollment)
  - If all is going well then move on to the...

Routine Site Monitoring Schedule:

- Quarterly supervision to all sites with a POC EID machine
- Choose one spoke from each hub to evaluate

Human resources for monitoring becomes a key consideration as more sites are rolled out.
Remote monitoring of POC EID testing

**Investigation and corrective actions**
- Good governance and appointed coordinating body is crucial
- Feedback communication with appointed focal points is key
- District-level support is essential for follow-up and corrective action.
- Competency assessment and refresher training might be needed
- Instrument repair might be needed
- Share information with supply chain to avoid stock outs
- Seek technical support from manufacturer if needed

**Post-market surveillance**
- Know how to identify potential problem in cartridge and instruments
- Similar problems seen across sites should raise a flag and prompt further investigation
- Sudden surge in problem following the use of a new lot should also raise a flag
Instrument connectivity

1. Most instruments are capable of being connected
2. Partial or complete connectivity solutions sometimes provided by manufacturers
3. Third-party companies specializing in connectivity exist (SystemOne, Savics, etc.)
4. Key for overall remote monitoring of implementation
5. Critical for quality assurance of a decentralized POC network.
6. Use of dashboard allows rapid visualization of data and network map
7. Can allow for result transmission to clinicians
8. Can connect to existing LIMS or electronic registers
9. Inventory Management
10. Use of GPS coordinates to map your network
11. Disease surveillance
12. Configurable data access permissions
Remote monitoring of POC EID testing

**Regular data collection**
- Allows to identify trends
- Collected manually (labor intensive) or automatically (seamless and better data quality)

**Frequent critical analysis of data**
- Site level analysis is essential
- Trends analysis are key
- Require a minimum quantity of data for each site
- Allows to identify outliers (e.g. a facility with higher error rates) when POC EID implementation is at scale
Hub-and-spoke networks: SMS for results return

1. Linkage-to-care integrated solution developed with ARDx (previously Alere)
2. Piloted in Côte d’Ivoire, Rwanda, Zimbabwe, and Cameroon (about to start)
3. DataPoint software, remote data storage, modem, SIM cards and data bundles are provided for FREE by ARDx
4. Purchasing pre-configured SMS printers for spokes directly from ARDx
5. Ability for spokes to request reprint
6. Ability of Alere to remotely push printers’ software update and troubleshoot
Standardized competency assessment tool

Observational checklist assesses three main steps in the testing cascade, namely:

1. Sample reception, handling, and labelling
2. Cartridge preparation
3. Starting and running the assay

<table>
<thead>
<tr>
<th>1.0 Receiving and Checking a Specimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the employee…</td>
</tr>
<tr>
<td>1. Check the sample package for damage or leakage?</td>
</tr>
<tr>
<td>2. Check that the number of samples in the package matches the number of POC EID Testing Forms?</td>
</tr>
<tr>
<td>3. Ensure that the ID of each sample perfectly matches the ID on the respective POC EID Testing Form, and the ID on the sample transport log (if transferred from source site)?</td>
</tr>
<tr>
<td>4. Visually check that each specimen is of sufficient quantity (tube should contain about 200µL)?</td>
</tr>
<tr>
<td>5. If the ID number on the sample tube is missing, altered, or doesn’t match the one on the POC EID Testing Form, contacts the requesting facility or unit for further information in identifying the sample?</td>
</tr>
<tr>
<td>6. If the ID number on the sample tube is missing, altered or doesn’t match the ID number of the POC testing form, and the identification of the sample is still impossible after contacting the requesting unit:</td>
</tr>
<tr>
<td>a. Rejects the specimen and notes it in the sample rejection logbook; and</td>
</tr>
<tr>
<td>b. Asks for a new specimen from the requesting unit using the POC EID Testing Form with a clear mention of the reason?</td>
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<tr>
<td>7. Assign laboratory numbers to the POC EID Testing Forms and POC EID logbook (if internal lab numbers are used)?</td>
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<tr>
<td>8. Arrange samples in a sequential order in the tube rack labelled “pre-testing” to avoid possible confusion?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.0 Cartridge Preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the employee…</td>
</tr>
<tr>
<td>1. Check the expiration date of the cartridge?</td>
</tr>
<tr>
<td>2. Ensure that the cartridge pouch is well sealed, open the cartridge pouch carefully, and check that there is no damage to the cartridge?</td>
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</tbody>
</table>
Input 6: Quality management and assurance (QM/QA)

**Fit-for-purpose quality management/assurance**

- Site and platform selection (right product at the right place)
- Site capacity assessment (infrastructure and HR) and upgrade (right conditions)
- Site enrollment steps and activities
- Model algorithms for testing and release of results
- Comprehensive on-site trainings, and refresher trainings, if needed (blood collection, packaging, transport, analysis, reporting, waste disposal)
- Defined communication lines, for technical support and reporting of issues
- Site monitoring and supervision visits
- IQC failures monitoring
- Use of monitoring logs (temperatures, sample transport, IQC failures, etc.)
- Use of connectivity
- Competency assessment
Input 5: Forecasting, procurement, supply chain and waste management.
1. **Forecasting and quantification**
   - Important to ensure no stock-outs or over-stocks
   - Mix of forecasting approaches necessary during introduction and scale up of new devices
   - Quarterly supply plan monitoring
   - Integrated forecasting of both POC and conventional laboratory-based diagnostics

2. **Procurement**
   - Contracts with manufacturers including service and maintenance agreements
   - Frequent orders due to shelf life of test kits
   - Lead time consideration of around 3 months from placing the order (i.e. production time + tax waiver process time + shipping time + custom clearance time)
Procurement and supply chain management cycle (2)

3. **Shipping and custom clearance**
   - Identification of incoterm
   - Air shipment due to test kit shelf life
   - Government tax and duties exemption
   - Customs clearance procedure

4. **Receipt and inventory management**
   - Inspection of received commodities
   - Inventory control system (FEFO)
   - Updated stock-keeping records (whether manual or automated)
5. Storage and distribution
   • Good storage practices (management; storage facilities; product rotation; storage conditions; and security)
   • If possible avoid parallel storage and distribution
   • Frequent orders (monthly)
   • If possible direct distribution to sites

6. Consumption reporting
   • Critical to inform calculations used to forecast and order new supplies
   • Monthly reporting recommended
7. Waste Management and Reverse Logistics

• Generation of waste should be minimized, as much as possible
• Medical waste should be segregated according to nature of waste
• National SOPs for the storage and transport of medical waste should be followed
• Depending on the type of waste to be treated, disposal can involve autoclaving, incineration, burial in a protected pit, or transfer to a landfill for disposal
• Reverse logistics can be undertaken by health facilities to return waste to a central level facility or warehouse for disposal
Special considerations for POC equipment

Equipment considerations:

- Site upgrades to ensure an appropriate environment (e.g. cooling system, thermometers, locked doors and windows)
- Power considerations (e.g. gel batteries or solar panel and battery system, if not included with the platform)
- Supporting equipment (e.g. printers)
- Routine maintenance
- Long-term service and maintenance agreements
Special considerations for test kits and consumables

Test kits and consumables:

- Shelf life of test kits (currently 9 to 12 months from manufacturing date)
- Sample collection kits – appropriate for the type of sample (e.g. DBS, whole blood)
- Sample transport materials (e.g. EDTA microtainer tubes, triple packaging, cooler boxes)
- Other consumables (e.g. printer paper)
- Waste management or reverse logistics for used and expired cartridges
Monitoring of manufacturer performance

**Purpose:**
- Inform how manufacturer is performing with regards to agreed service levels, quality and cost;
- Identify room for improvement; and
- Ensure immediate problem-solving and corrective action.

**Two types of Key Performance Indicators (KPIs):**

1. **Procurement indicators**
   - *On-Time, In-Full* principle
   - Guaranteed shelf life
   - Quality of delivered devices and consumables
   - Service and maintenance costs

2. **In-country device performance indicators**
   - Reported device and module breakdowns
   - Response time from receipt of complaint and provision of replacement device
   - Repair time
Acknowledgements

• Mothers and babies
• Ministries of Health
• CHAI, UNICEF and EGPAF global and country teams
• Other POC EID partners
• Unitaid
Questions and Discussion

For more information, please contact: rbailey@pedaids.org
MOH-led site and product selection approach

Aims to expand access to POC EID, ensure the proficiency of instrument operators, and optimize previous investments in laboratory networks.

<table>
<thead>
<tr>
<th>Recommended Steps for Site and Product Selection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1: Analyze the EID Situation</strong></td>
</tr>
<tr>
<td>Review the epidemiology and national priorities with respect to PMTCT and to the diagnosis and treatment of pediatric HIV</td>
</tr>
<tr>
<td><strong>Step 2: Select POC EID Sites</strong></td>
</tr>
<tr>
<td>Identify and assess the capacity of potential POC EID sites. Determine the appropriate operational model(s) based on additional analysis. Finalize site selection.</td>
</tr>
<tr>
<td><strong>Step 3: Identify Product Needs</strong></td>
</tr>
<tr>
<td>Consider the product needs for each site, such as throughput, infrastructure, portability, ease-of-use and electrical stability requirements, as well as sample type and sample preparation needs.</td>
</tr>
<tr>
<td><strong>Step 4: Select POC EID Products</strong></td>
</tr>
<tr>
<td>Choose appropriate POC EID products based on which product’s characteristics are the best match for the product needs.</td>
</tr>
</tbody>
</table>
Uses an adapted version of the CDC SPI Point-of-Care Checklist (CDC SPI SPOCT Checklist) to assess the capacity of a site to implement POC EID and also helps to identify what site upgrades might be needed, if any.

Analyzes the ability of each site to:

✓ Integrate point-of-care testing into patient care
✓ Identify and train appropriate staff
✓ Provide the physical facilities required for POC EID testing, such as adequate space and electricity
✓ Ensure the safety of health workers and patients
✓ Implement POC EID tests
✓ Ensure a reliable supply of quality POC EID supplies, reagents and equipment; and
✓ Monitor the quality of testing
A combination of placement models and testing strategies can be used to increase access to POC testing while optimizing device utilization.

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

**Multiple-Entry-Point Sites**
Receive samples from different units or wards within the same health facility.

**Hub-and-Spoke Networks**
Hub sites provide testing for 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, other).
Task shifting: POC EID utilization by lab and non-lab staff

- Instrument utilization, various approaches among eight countries:
  - **Lab sites only**: Cameroon, Kenya, Rwanda
  - **Mix of lab and non-lab sites**: Côte d’Ivoire, Zimbabwe, eSwatini (only 1 out of 19 sites is lab)
  - **Non-lab sites only**: Lesotho, Mozambique

- 103 testing sites reporting (48 lab sites and 55 sites non-lab)

- 20,209 tests performed (lab: 6,670; non-lab: 13,539)

- Both GeneXpert and Alere q instruments were installed across both lab and non-lab staff settings
Performance of lab staff compared to non-lab staff

<table>
<thead>
<tr>
<th>IQC Failure Category</th>
<th>Testing Cadre</th>
<th>% IQC Failure</th>
<th>P-value (95%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>Lab Staff</td>
<td>5.5%</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>Non-lab Staff</td>
<td>6.7%</td>
<td></td>
</tr>
<tr>
<td>End-user related</td>
<td>Lab Staff</td>
<td>3.0%</td>
<td>0.003</td>
</tr>
<tr>
<td></td>
<td>Non-lab Staff</td>
<td>2.3%</td>
<td></td>
</tr>
</tbody>
</table>

*Unpublished data*