



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

Leadership Workshop, 22<sup>nd</sup> International AIDS Conference  
27 July 2018 - 11:00-12:30h, Room E105-108, Amsterdam



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Foundation



# Agenda

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%

#### EARLY INFANT DIAGNOSIS

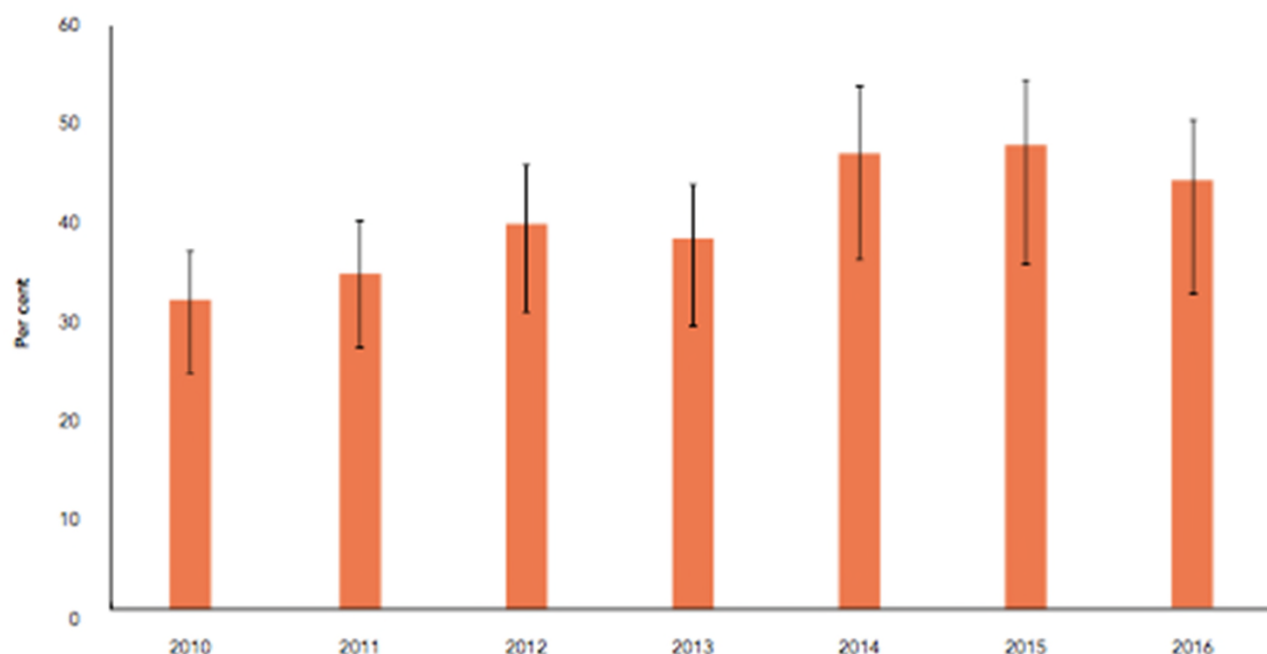


FIGURE 3.12. PERCENTAGE OF HIV-EXPOSED INFANTS WHO HAVE BEEN DIAGNOSED WITHIN TWO MONTHS OF BIRTH, 21 HIGH-BURDEN COUNTRIES, 2013 AND 2016

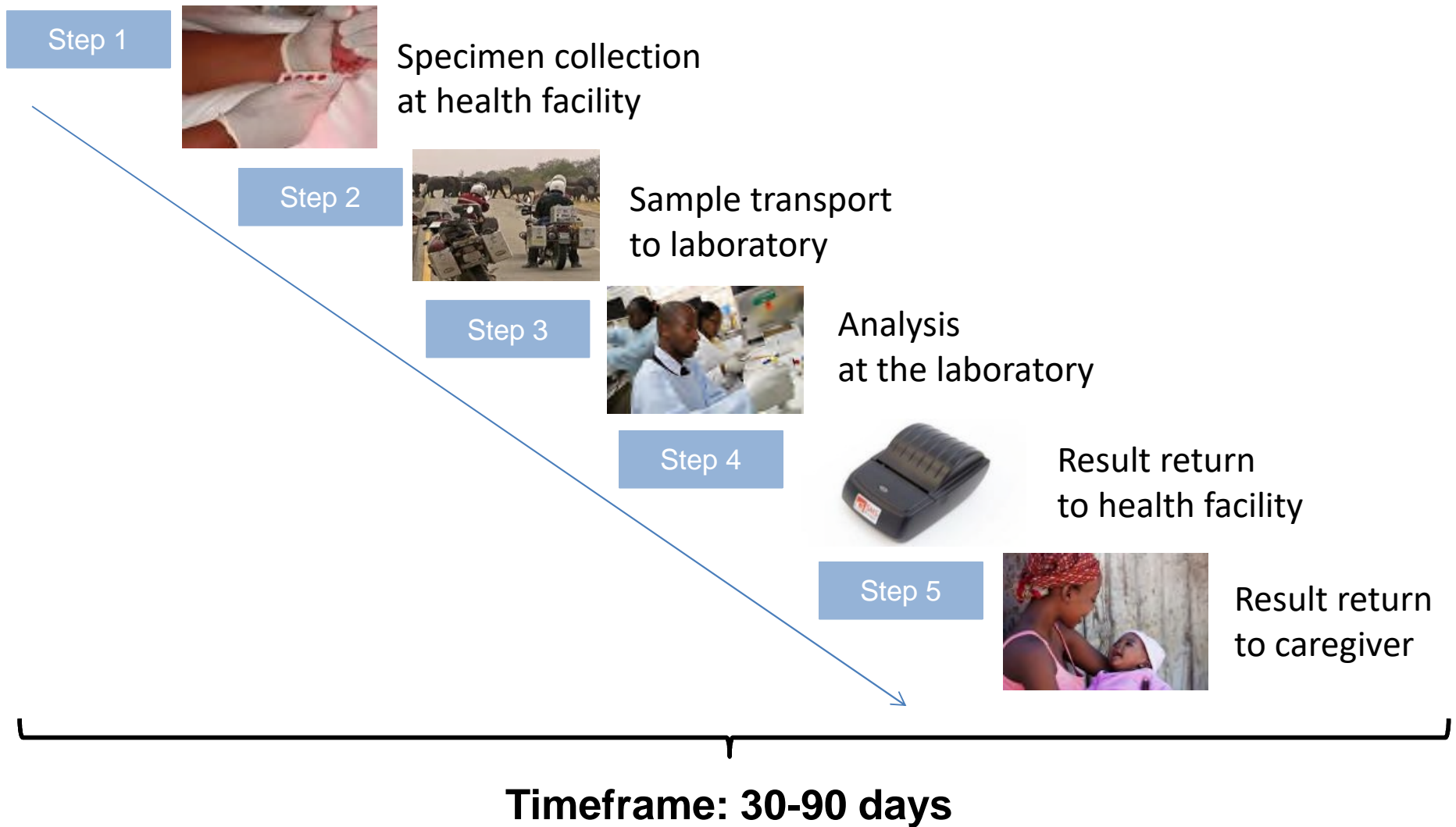
Source: Global AIDS Monitoring, 2017; UNAIDS 2017 estimates.

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

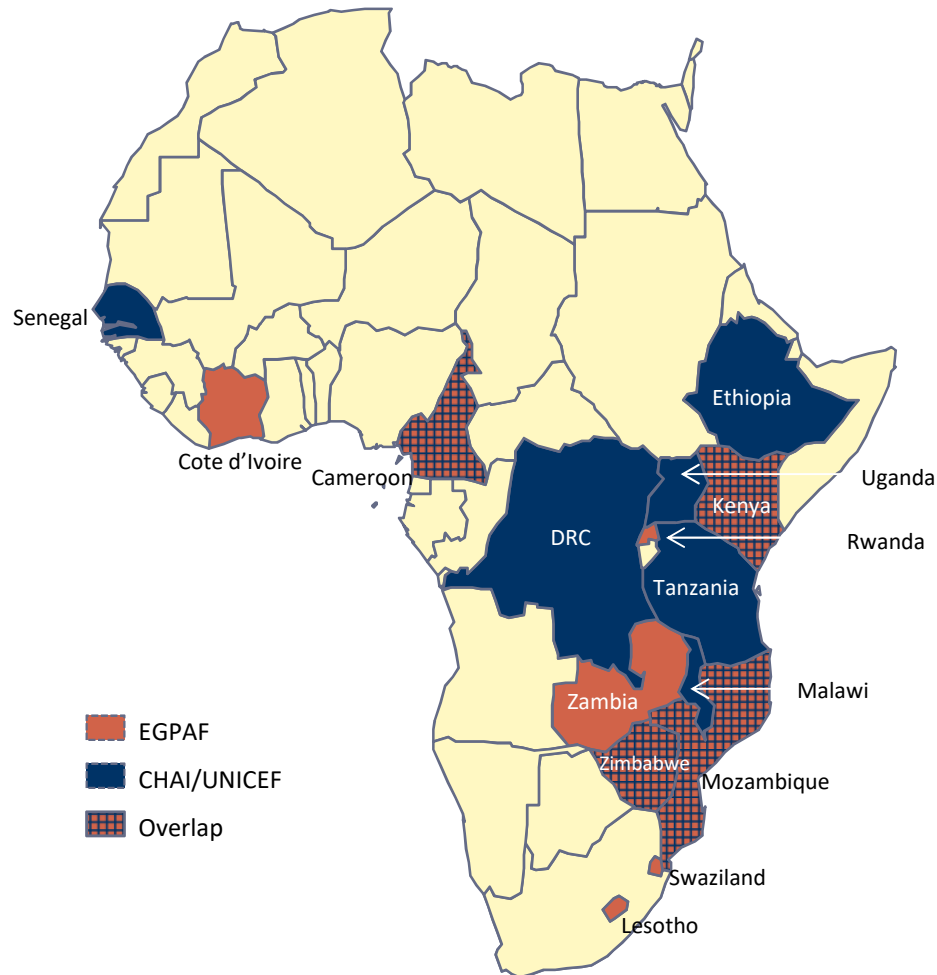
During the same period the number of EID tests nearly doubled. However long turnaround times (TAT) and a high proportion of results not returned have remained problems.

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



With funding and support from Unitaaid, 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

Country	Setting	Device/ Sample	# of sites	n (infants)	% result return to caregiver		TAT result return	% ART initiation		TAT ART Initiation
					≤ 30 <sup>#</sup> days	Same day		≤ 60 days	Same day	
Mozambique (Maputo, Sofala)	Randomized controlled trial (cRCT)	Alere q/ Whole blood	SOC - 8	1,876	0.32%	0%	125	12.8%	NA	127
			POC - 8	2,034	98.7%	98.2%	0	89.7%		0
Malawi	Observa- tional pre/post	Alere q/ Whole blood	7 pre POC	963	18.1%	0%	56	41.9%	43.8%	38
			7 post POC	789	100%	99.5%	0	91.1%	70.7%	0

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

Nine countries (Dec 2016 – March 2018)*	M&E	Alere q/ Whole blood & Xpert/ Whole blood	SOC – 102	2,867	19.7%	0%	55	41.3%	0%	50
			POC – 339	25,102	98.3%	67%	0	91.7%	65%	0

<sup>#</sup>Mozambique SOC: 7.2% within 60 days; Malawi pre: 41% within 60 days

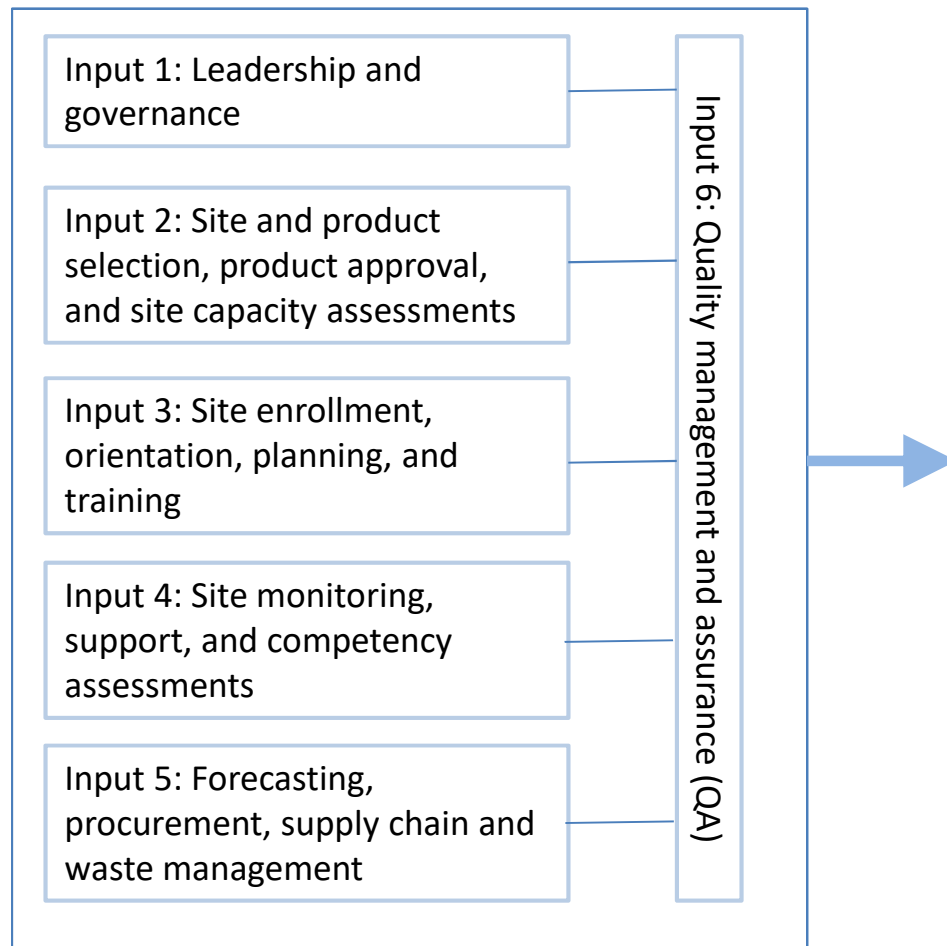
NA = not available

\* 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

# What inputs were needed to achieve desired outcomes?

## Key Inputs



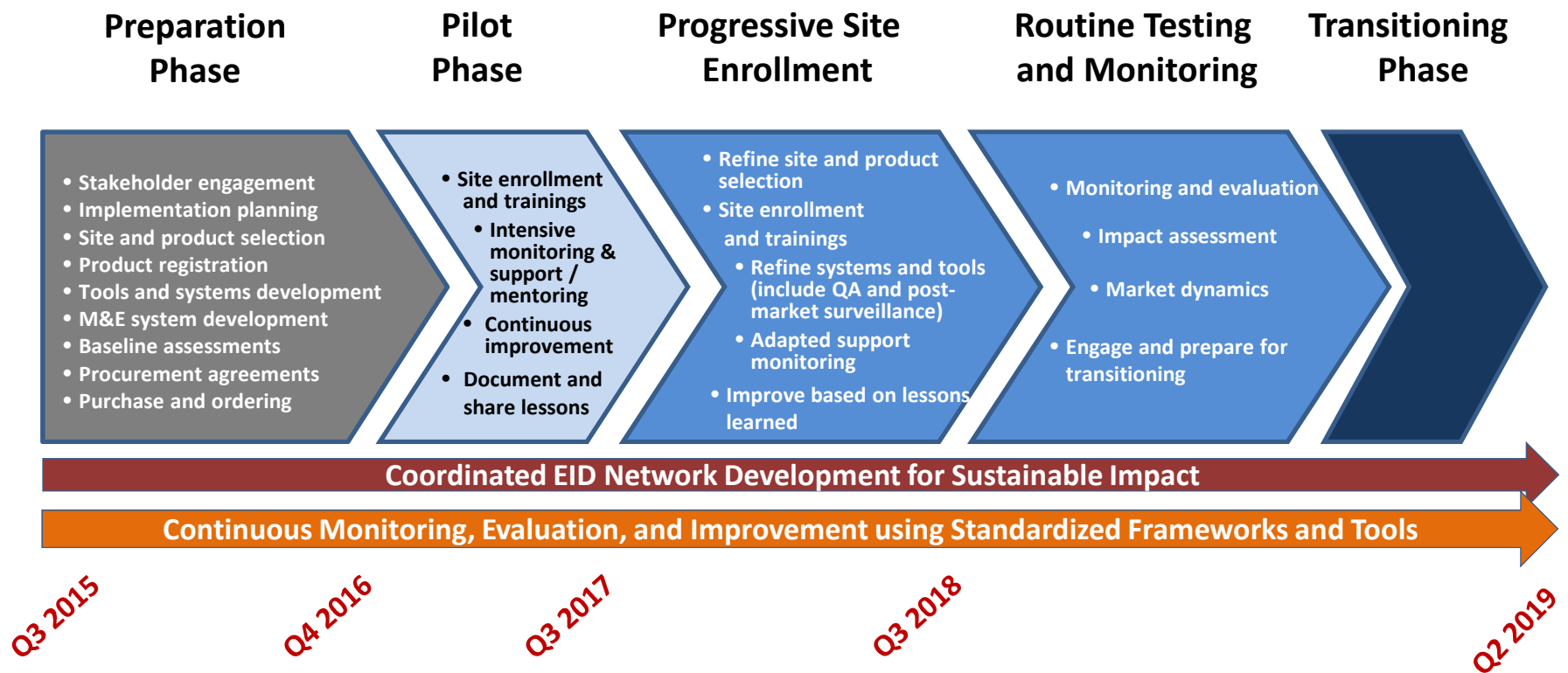
## Outcomes

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

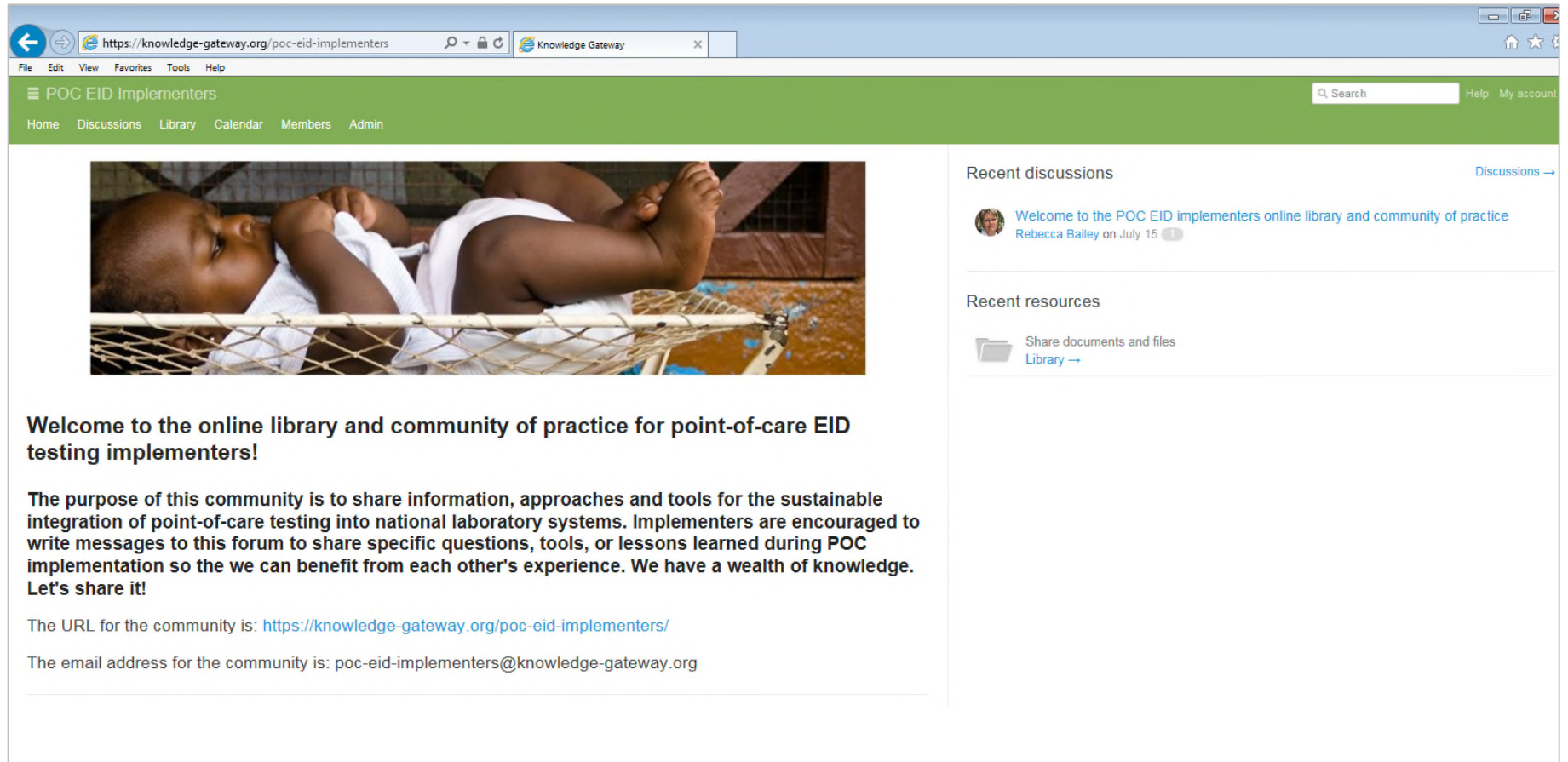
- Hand-in-hand with the Ministry of Health (MOH) and key stakeholders in each country
- Frequent stakeholder consultation and coordination
- Gradual and staged selection and enrollment of testing sites



# Activities and tools used to support the approach

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

# Knowledge Gateway online library and community




The screenshot shows a web browser window with the address bar displaying <https://knowledge-gateway.org/poc-eid-implementers>. The page has a green header with the title "POC EID Implementers" and navigation links: Home, Discussions, Library, Calendar, Members, and Admin. A search bar and links for "Help" and "My account" are also present. The main content area features a photograph of a baby in a white cloth lying in a woven basket. Below the image, the text reads: "Welcome to the online library and community of practice for point-of-care EID testing implementers!". This is followed by a paragraph explaining the community's purpose: "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 the we can benefit from each other's experience. We have a wealth of knowledge. Let's share it!". Below this, the URL <https://knowledge-gateway.org/poc-eid-implementers/> and the email address [poc-eid-implementers@knowledge-gateway.org](mailto:poc-eid-implementers@knowledge-gateway.org) are provided. On the right side, there are sections for "Recent discussions" (with a link to "Discussions") and "Recent resources" (with a link to "Library").

POC EID Implementers

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**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 the 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/>

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Recent discussions [Discussions →](#)

Welcome to the POC EID implementers online library and community of practice  
[Rebecca Bailey](#) on July 15

Recent resources

Share documents and files  
[Library →](#)

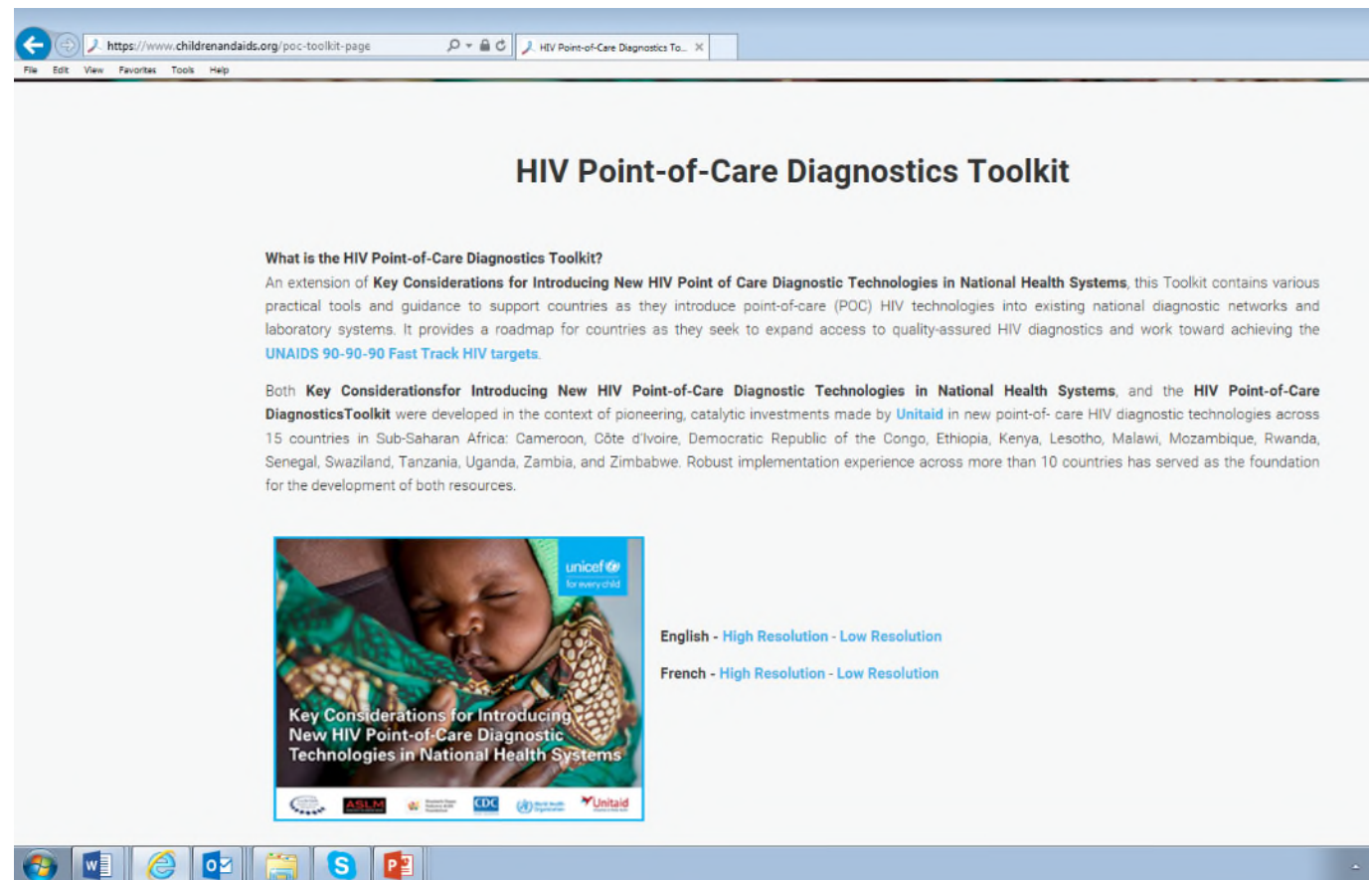
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# HIV POC diagnostics toolkit (hosted on the UNICEF website)

## Tools for:

- Product and site selection
- Forecasting and supply planning
- Regulations
- Quality assurance
- *Others under development*



URL: <https://www.childrenandaids.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 plans



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:**

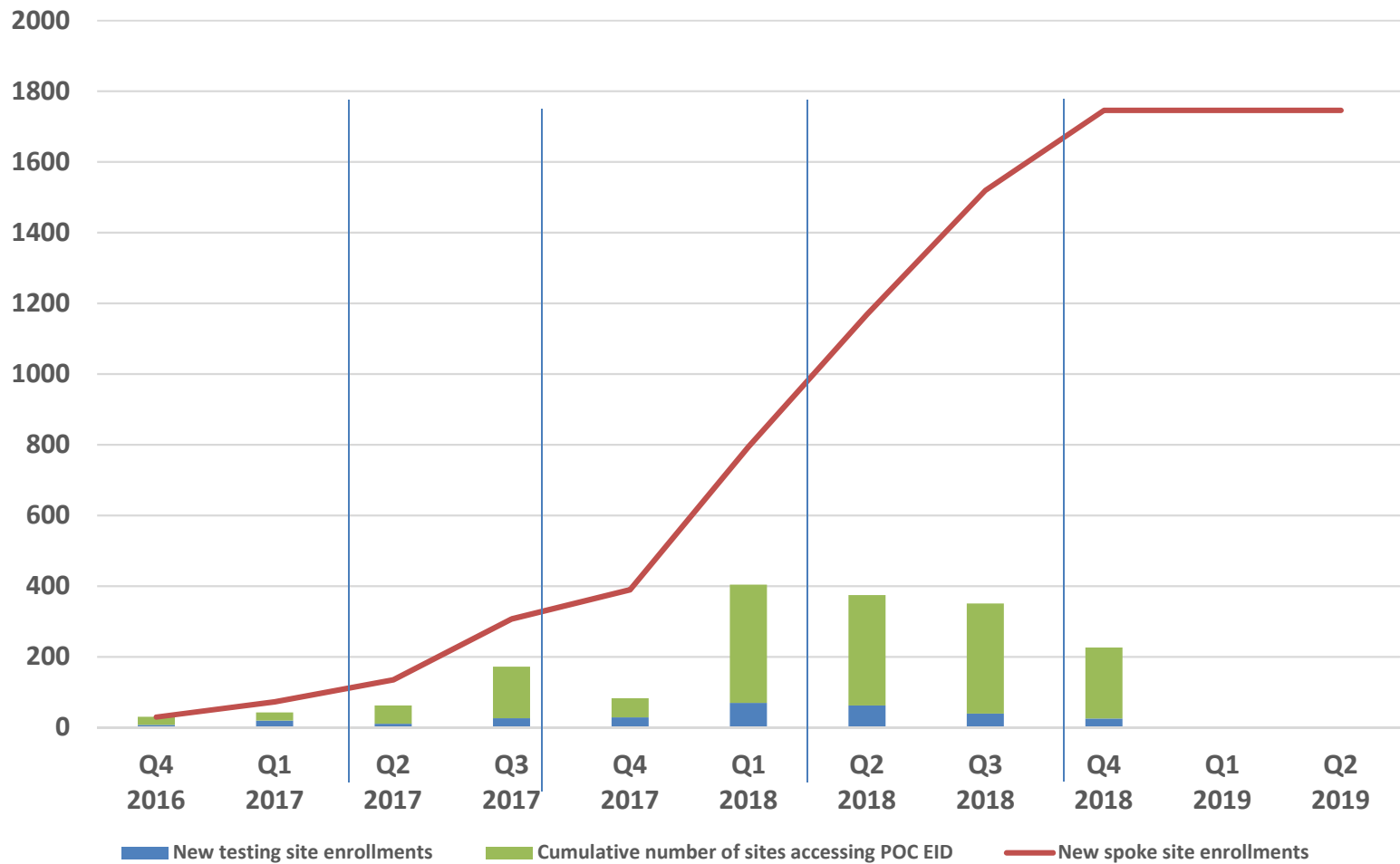
- Site and platform selection is completed
- All training, planning and monitoring tools developed and available
- Instruments and cartridges have been ordered and about to arrive in-country

### **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

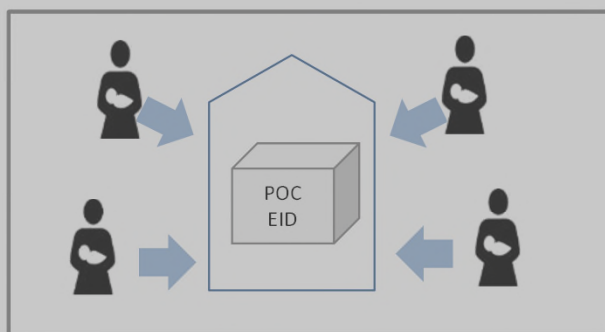
# Phased site enrollment



# Using hub-and-spoke networks to increase access to POC testing and optimize device utilization rates

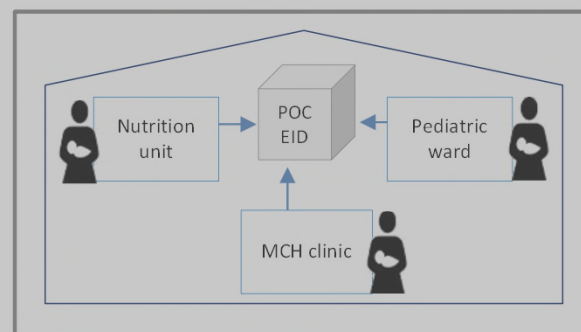
## Stand-Alone Sites

Receive samples directly from clients and perform POC EID tests on site



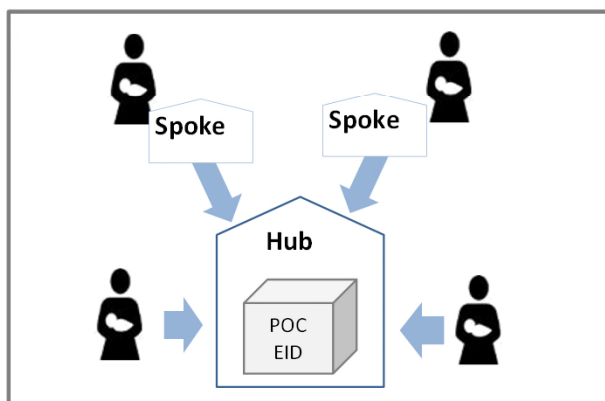
## Multiple-Entry-Point Sites

Stand-alone or hub testing sites receive samples from different units or wards within the same health facility



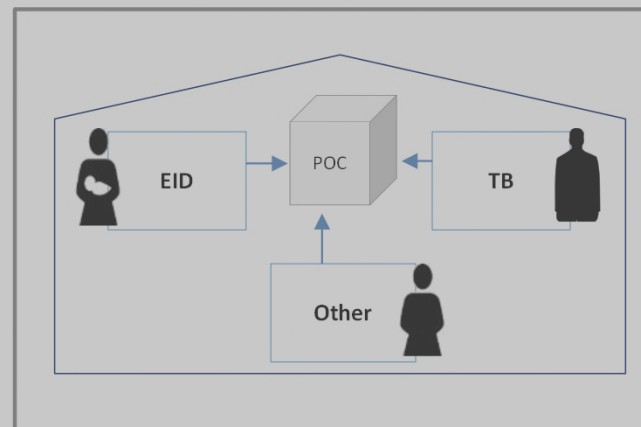
## Hub-and-Spoke Networks

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



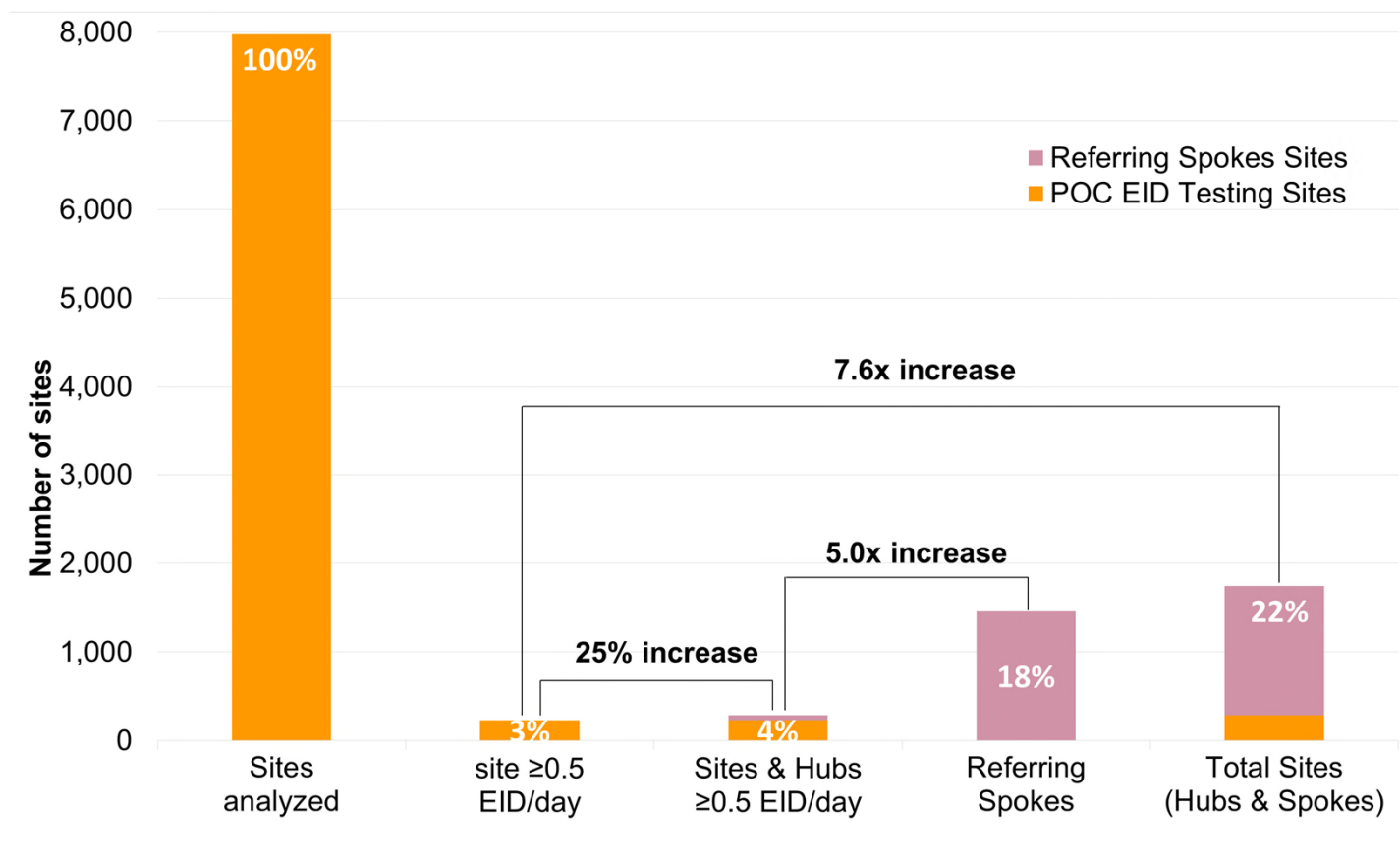
## Integrated Testing Sites

Process different types of POC tests (e.g. EID, TB, other)



# 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



# 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



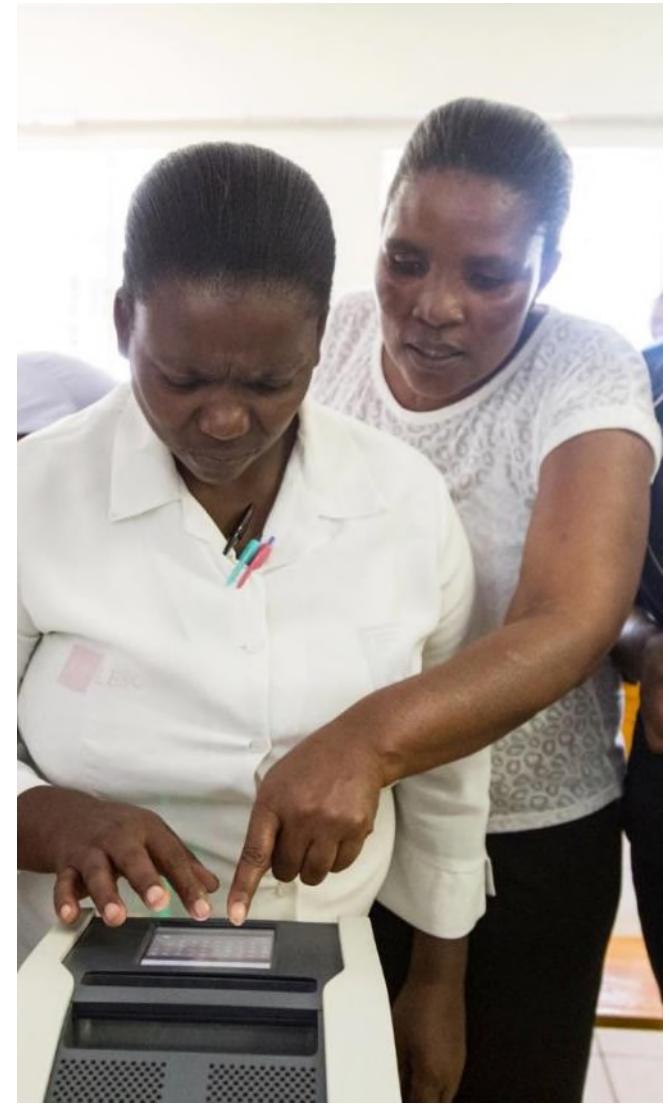
# Orientation, planning and training

## **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

<u>Activities</u>	Day 1	Day 2	Day 3	Day 4	Day 5
<b>Day One: Mentoring and supportive supervision training</b> 1. Training in all relevant content areas (e.g. EID testing form, instrument operation, sample collection, etc.) 2. The site visit process and tools (e.g. frequency, supervisory visit checklist, reporting) 3. Project M&E methods and tools 4. Recommended approaches for mentoring and supportive supervision, including troubleshooting 5. Training on how to perform competency assessment 6. Lines of communications 7. Education for clinicians on implications of same-day testing					
<b>Day Two: Orientation and training session for staff in hub and spoke facilities.</b> 1. Training on the use of the EID Testing Form (how to fill the form for each units, its workflow & documentation) 2. Sample collection training 3. Sample labelling, packaging and transportation training					
<b>Day Three: Orientation and training session for staff in hub and spoke facilities.</b> 1. Results communication (to caregiver/ patient) training 2. Training on the communication process. 3. Training on collecting treatment initiation data 4. Waste management training (sorting, labelling, disposal, transport, of destruction of waste)					
<b>Day Four: Orientation and training session for staff in hub and spoke facilities.</b> 1. Training on storage, inventory tracking, and ordering of POC EID supplies 2. Overview of mentoring and supportive supervision plans 3. Lines of communications					
<b>Day Five: Installation of Alere-Q platform.</b> 1. Manufacturer's End-User training, including operations (loading cartridge and operate instrument), preventive maintenance and cartridge disposal 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.) 3. Lines of communications with spokes and with EGPAF supervisor (naming 1 focal person per site)					



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

Ministry of Health  
National HIV/AIDS  
Control Programme

Moh Logo

unaid

# Point-of-Care HIV Early Infant Diagnosis Request Form

## TO BE FILLED BY REQUESTING HEALTH WORKER

### Requesting Health Facility Information:

Name of Requesting Facility:		Facility Contact Person:	
City/Town:		Tel (mobile):	
District/HQ:		Tel (facility):	

### Patient Information:

Infant First Name:		Infant Last Name:		Infant DOB:	
Sex:	<input type="checkbox"/> Male	<input type="checkbox"/> Female	Date of Birth:		
Every prior to birth/breast:	<input type="checkbox"/> Unknown/Mother	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Maternity:	<input type="checkbox"/> Home Visit
Did infant receive ART prophylaxis?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Unknown	Mother's HIV:	<input type="checkbox"/> Yes
Infant ever breastfed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Unknown	Infant was breastfed how?	<input type="checkbox"/> Yes
Name of caregiver:		Caregiver sex (provide):			

### PREGNANT HISTORY (if applicable):

Gestational age at delivery, the mother received:

ART regimen:	<input type="checkbox"/> started before pregnancy	ART regimen:	<input type="checkbox"/> started during labor/delivery
ART regimen:	<input type="checkbox"/> started during pregnancy or postnatal age of	<input type="checkbox"/> Unknown	
ART regimen:	<input type="checkbox"/> started during breastfeeding period	<input type="checkbox"/> No ART	

### Sample information:

Type of specimen:	DATE OF SAMPLE COLLECTION:	TIME:
capillary blood	<input type="checkbox"/> venous capillary	<input type="checkbox"/> EDTA
Testing schedule:	<input type="checkbox"/> G-test	<input type="checkbox"/> G-test + CD4 count
<input type="checkbox"/> G-test	<input type="checkbox"/> G-test + CD4 count	<input type="checkbox"/> Laboratory test (other > G-test positive)
<input type="checkbox"/> Rapid	<input type="checkbox"/> Following a positive RDT or ELISA	<input type="checkbox"/> Other

## TO BE FILLED BY POC HIV TESTING PERSONNEL

### Testing Health Facility Information:

Name of testing facility:		Facility contact person:	
City/Town:		Tel (mobile):	
District/HQ:		Tel (facility):	

### Sample information:

Date of sample reception:		Date of sample processing:	
POC test performed:	<input type="checkbox"/> Same day (G-T)	<input type="checkbox"/> Lab test (G-T) - Other	<input type="checkbox"/> Other
POC-RDT Result:	<input type="checkbox"/> Positive, negative, unknown result, no result	<input type="checkbox"/> At the health agency with a lab machine	
Test performed by:	<input type="checkbox"/> Tel (mobile):	<input type="checkbox"/> Tel (facility):	
Date the result is sent back to requesting unit:			

## TO BE FILLED BY FACILITY PROVIDING DIRECT CARE TO PATIENT

### Linkage to care information:

(Date the patient is recommended to complete linkage) Patient: \_\_\_\_\_ Date of ART therapy initiation: \_\_\_\_\_

Date of referral to ART providing facility: \_\_\_\_\_ Name of ART providing facility: \_\_\_\_\_

COPY TO REMAIN AT REQUESTING FACILITY / NO PAYMENT FOR THIS FORM FULLY FILLED

Date of referral to ART providing facility: \_\_\_\_\_

Name of ART providing facility: \_\_\_\_\_

PROJECT COPY - TO RETURN TO THE TESTING FACILITY ONCE FULLY FILLED

Date of referral to ART providing facility: \_\_\_\_\_

Name of ART providing facility: \_\_\_\_\_

COPY TO REMAIN AT POC HIV TESTING LABORATORY ONCE RESULTS IS RECEIVED

Date of referral to ART providing facility: \_\_\_\_\_

Name of ART providing facility: \_\_\_\_\_

COPY TO REMAIN AT REQUESTING FACILITY BEFORE SENDING SPECIMEN FOR POC HIV TESTING

# Standardized site monitoring checklist

## Site monitoring visits should include review and observation of:

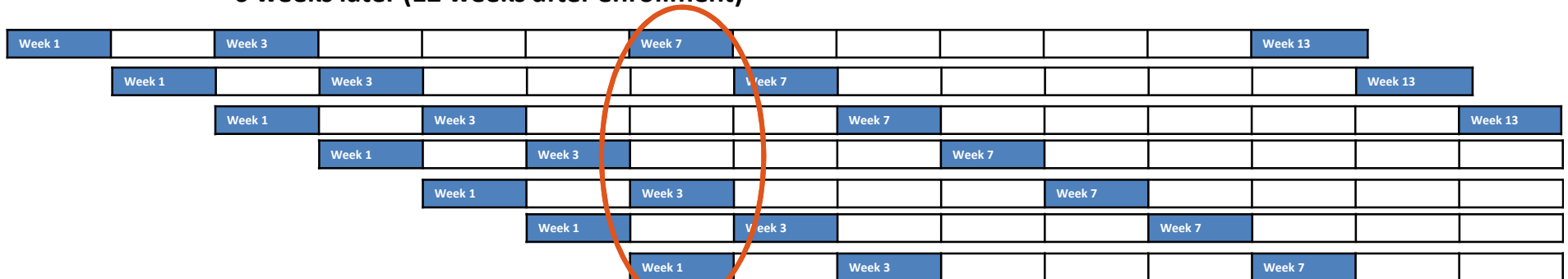
- Clinical Integration (i.e. adherence to testing algorithms, patient flow, etc.)
- Use of SOPs, job aids, registers, tracking logs, and testing forms
- Training and competency of instrument operators, including observation of operators, if possible
- Instrument placement and performance
- Inventory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

POC EID Implementation Site Monitoring Checklist: Stand-Alone Testing Site				
Facility name: _____				
Name(s) of trained instrument operators/end users: _____				
Date of monitoring visit: _____				
Name(s) of monitors or supervisors: _____				
Observe and ask about the activities in the table below. For each activity, check the appropriate box to indicate if the activity is being done (Yes), partially done (Partial) or not being done (No). If an activity is partially or not done, write a brief explanation and describe the assistance or mentoring provided. If possible, observe at least one instrument operator performing a test. Provide assistance and mentoring as needed or requested. Enter additional information as required, such as the number of POC EID Testing Forms collected.				
Part 1. Clinical Integration	Yes	Partial	No	Comments/Notes
<i>Adherence to testing algorithms: (NOTE: Review patient registers, POC EID testing forms, and discuss with facility staff)</i>				
1.1 All infants who qualify for EID testing have a sample drawn and analyzed on the same day.				
1.2 All EID test results are conveyed to caregivers on the same day as the sample is drawn.				
1.3 All infants who have a positive initial result have a second POC sample run for confirmation on the same day.				
1.4 All infants who have a positive initial POC result are initiated on ART the same day.				
1.5 For all infants who have a positive initial POC test result, but a negative second POC test result (i.e. discordant result), a DBS sample is sent to a reference lab, and contact information is collected from the patient for follow up.				
<i>Patient flow: (NOTE: Observe the facility and discuss with staff)</i>				
1.6 There is sufficient waiting room space for caregivers to wait for the results of POC tests.				
1.7 According to health facility staff, over the past two weeks, approximately how much time (in minutes) did caregivers typically wait between sample draw and return of results to the caregiver?				minutes
1.8 The health facility has more than one clinic, ward, or service from which HIV-exposed infants can be referred for POC EID testing (e.g. PMTCT clinic, nutrition ward, pediatric in-patient ward, immunization clinic).				
a. If yes, is the health facility taking actions to increase testing of infants from different entry points (e.g. clinics, wards, services)?				
1.9 The health facility is testing infants on POC EID who are referred from more than one entry point within the same health facility.				
a. If yes, are infants being tested from PMTCT clinics or services?				
b. From nutrition wards or services?				
c. From in-patient wards?				
d. From immunization clinics or services?				
e. Others (please describe):				
Part 2. SOPs, Job Aids and Documentation	Yes	Partial	No	Comments/Notes
<i>SOPs, job aids, registers, tracking logs, and testing forms: (NOTE: Observe the facility, discuss with staff, and review error logs and testing forms)</i>				
2.1 SOPs and job aids are available in the appropriate language.				
2.2 SOPs and job aids are available and visible to staff (e.g. job aids are hung on the wall, training manuals are near the testing platform).				
2.3 SOPs and job aids are used and adhered to by all staff.				
2.4 ANC, PMTCT and ART Initiation registers from the previous three months are properly and completely filled out.				
2.5 An Error and Specimen Rejection Log and sections from the training manual describing the meaning of error codes are placed next to the instrument.				
1   Page STAND ALONE SITE Version: March 2017				

# 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**

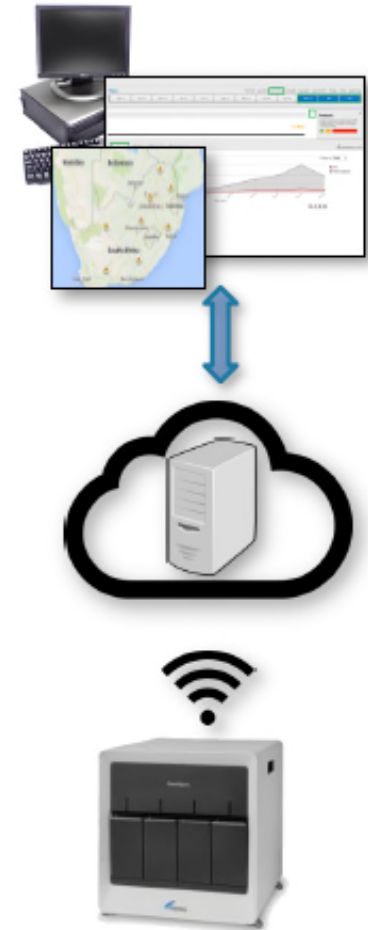
- ✓ Good governance and appointed coordinating body is crucial
- ✓ Feedback communication with appointed focal points is key
- ✓ District-level support is essential for follow-up and corrective action.
- ✓ Competency assessment and refresher training might be needed
- ✓ Instrument repair might be needed
- ✓ 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



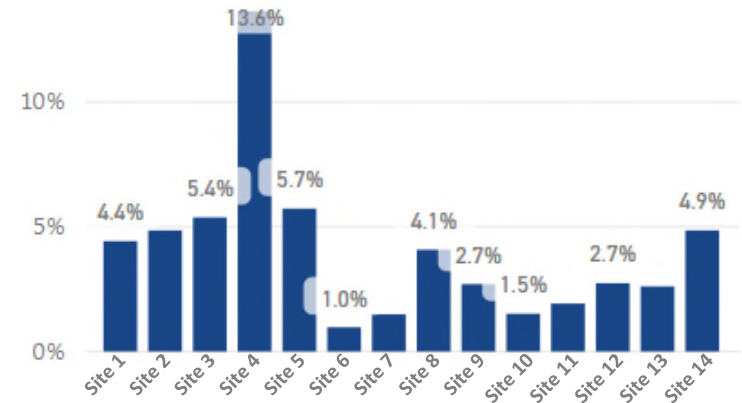
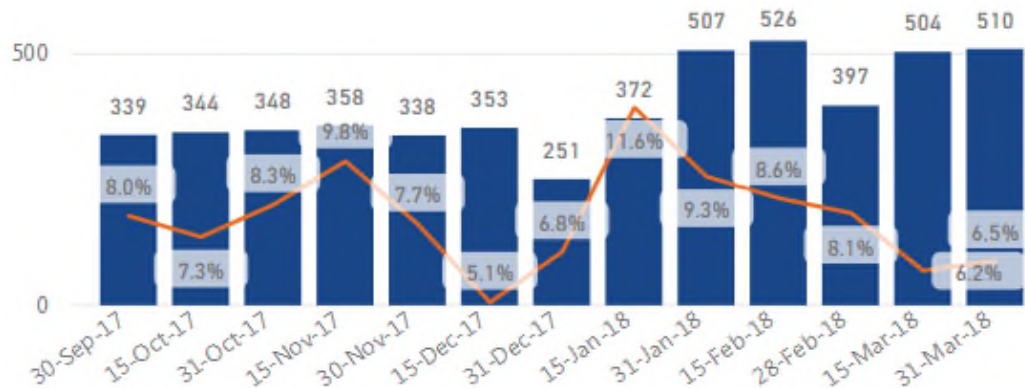
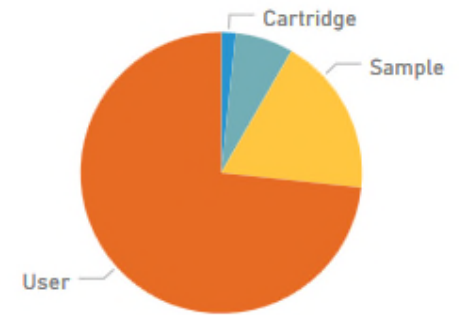
# Remote monitoring of POC EID testing

## Regular data collection

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

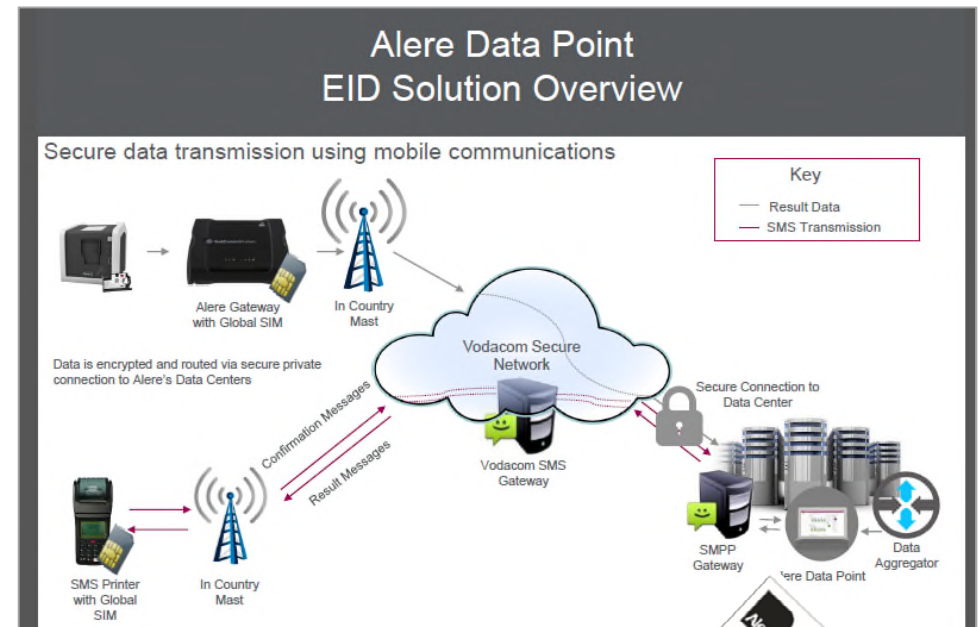
## Frequent critical analysis of data

- ✓ 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



**Alere Test Report**

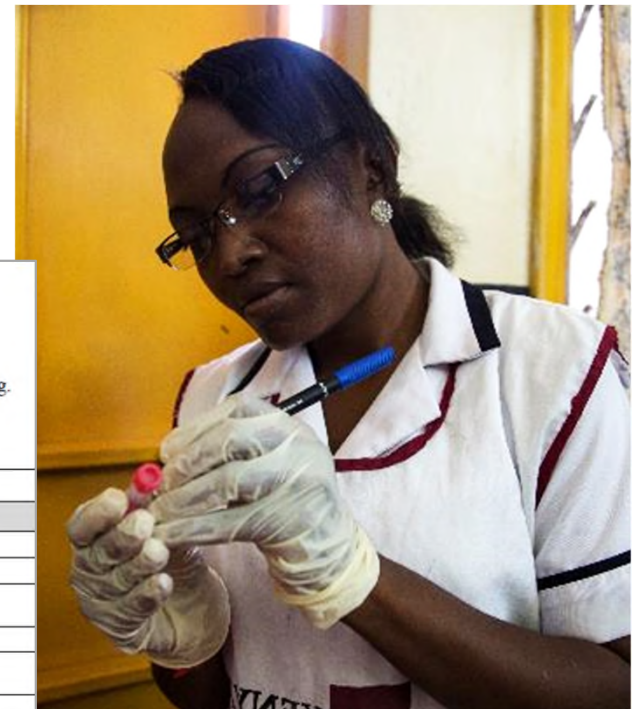
Alere™ q HIV-1/2 Detect

Sample ID	22-07-2014-MC
HIV-1 M/N	Detected
HIV-1 O	Undetected
HIV-2	Undetected
Result No.	107
Date / Time	2014-07-22 15:50
Cartridge ID	0123456789
Operator	Sam Miller
Device Serial	Nat-04000035
Software	0.20.0
QC	
Sample Detection	
Device	
HIV-1 Positive Control	Pass
HIV-2 Positive Control	Pass
Reagent Control	Pass
Analysis	Pass
Signature	

# 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



### Observe the employee as he/she completes the tasks in the table below, and fill in the form as follows:

- Check the box in the “Yes” column, if the task is done according to the relevant SOP, guideline or operating procedure.
- Check the box in the “No” column, if the Employee deviated from the relevant SOP, guideline or operating procedure, even if partially deviating.
- If you check the “No” box, describe in the “Comments” box how the Employee deviated from the recommended standards.
- Check “N/A” if the task is not applicable or relevant.

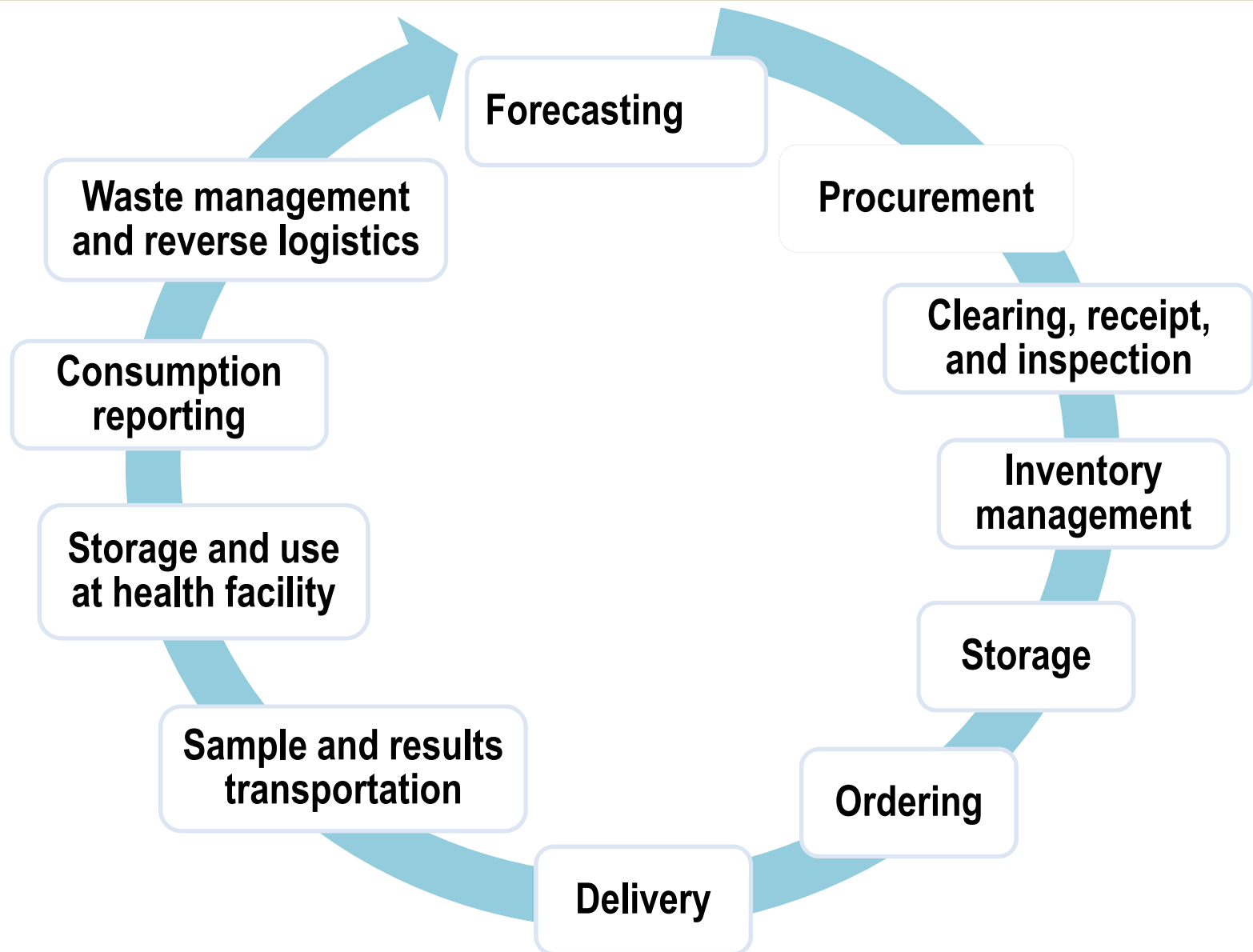
1.0 Receiving and Checking a Specimen				
Does the employee...	Yes	No	N/A	COMMENTS
1. Check the sample package for damage or leakage?				
2. Check that the number of samples in the package matches the number of POC EID Testing Forms?				
3. Ensure that the ID of each sample perfectly matches the ID on the respective POC EID Testing Form, and the ID on the sample transport log (if transferred from spoke site)?				
4. Visually check that each specimen is of sufficient quantity (tube should contain about 200µL)?				
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?				
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: a. Rejects the specimen and notes it in the sample rejection logbook; and b. Asks for a new specimen from the requesting unit using the POC EID Testing Form with a clear mention of the reason?				
7. Assign laboratory numbers to the POC EID Testing Forms and POC EID logbook (if internal lab numbers are used)?				
8. Arrange samples in a sequential order in the tube rack labelled “pre-testing” to avoid possible confusion?				
2.0 Cartridge Preparation				
Does the employee...	Yes	No	N/A	COMMENTS
1. Check the expiration date of the cartridge?				
2. Ensure that the cartridge pouch is well sealed, open the cartridge pouch carefully, and check that there is no damage to the cartridge?				

## 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.



# Procurement and supply chain management cycle (1)

## 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)

# Procurement and supply chain management cycle (3)

## **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

# Procurement and supply chain management cycle (4)

## **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](mailto:rbailey@pedaids.org)



Elizabeth Glaser  
Pediatric AIDS  
Foundation





**EXTRA SLIDES**

# 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.

Recommended Steps for Site and Product Selection	
<b>Step 1: Analyze the EID Situation</b>	Review the epidemiology and national priorities with respect to PMTCT and to the diagnosis and treatment of pediatric HIV
<b>Step 2: Select POC EID Sites</b>	Identify and assess the capacity of potential POC EID sites. Determine the appropriate operational model(s) based on additional analysis. Finalize site selection.
<b>Step 3: Identify Product Needs</b>	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.
<b>Step 4: Select POC EID Products</b>	Choose appropriate POC EID products based on which product's characteristics are the best match for the product needs.

# Site capacity assessments

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.

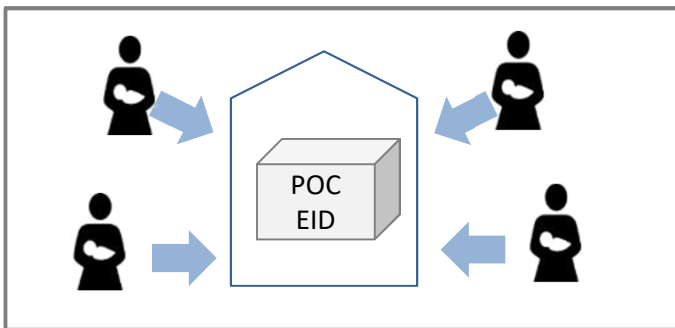
Analyzes the ability of each site to:

- ✓ 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

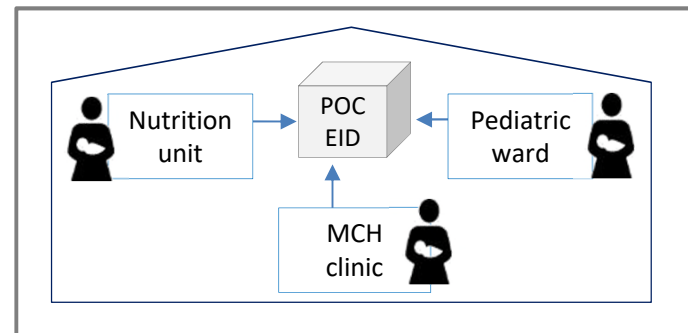
### Stand-Alone Sites

Receive samples directly from clients and perform POC EID tests on site



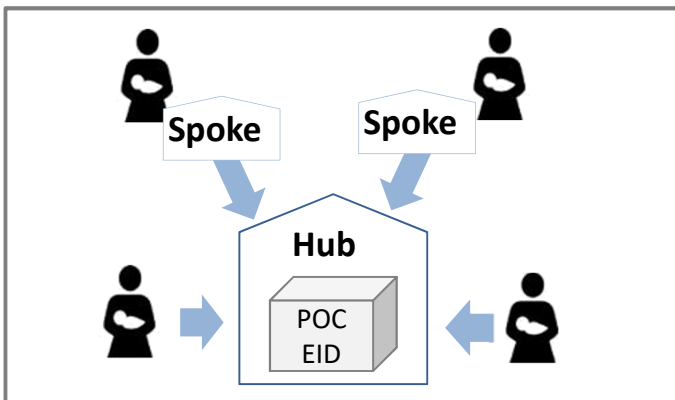
### Multiple-Entry-Point Sites

Receive samples from different units or wards within the same health facility



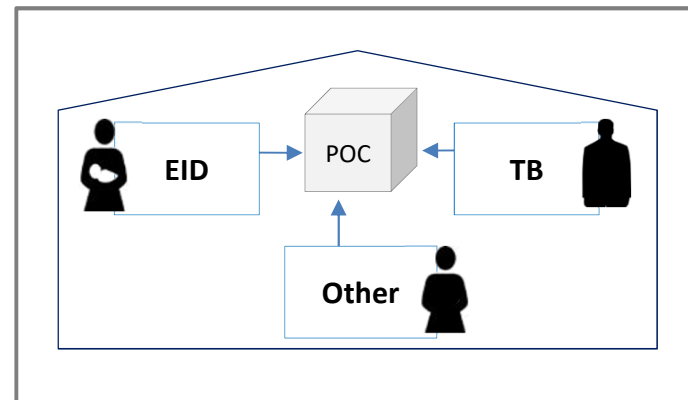
### Hub-and-Spoke Networks

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

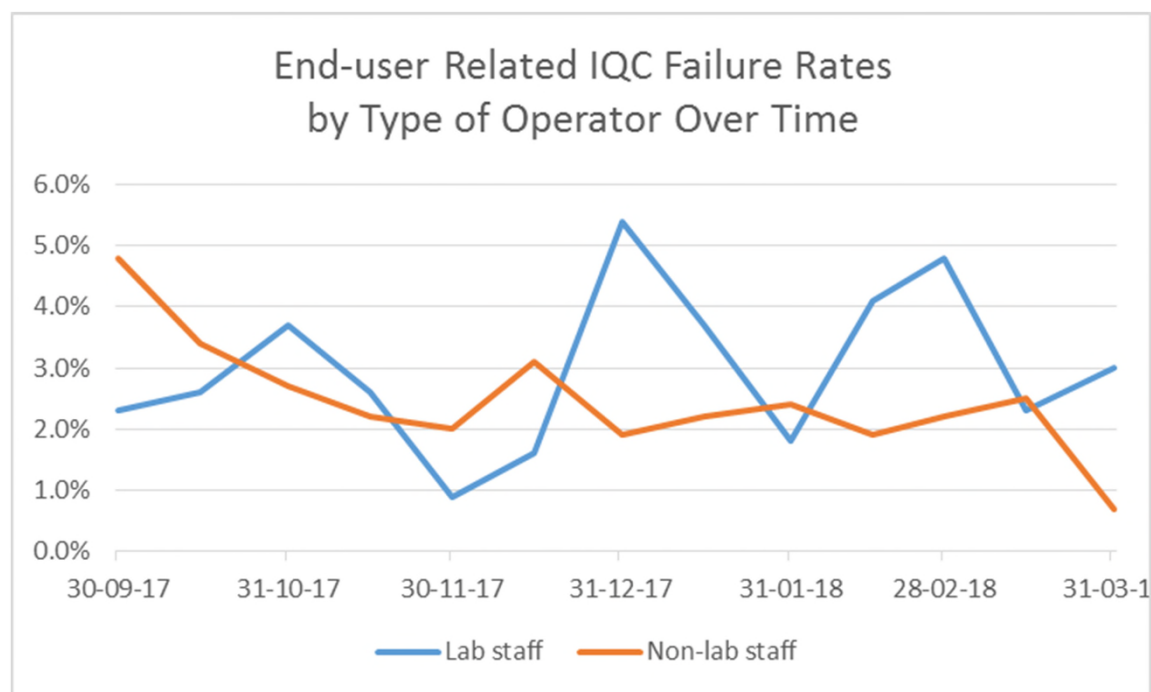
Process different types of POC tests  
(e.g. EID, TB, other)



# 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



IQC Failure Category	Testing Cadre	% IQC Failure	P-value (95%)
All	Lab Staff	5.5%	0.001
	Non-lab Staff	6.7%	
End-user related	Lab Staff	3.0%	0.003
	Non-lab Staff	2.3%	

\*Unpublished data