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Task shifting for point-of-care early infant diagnosis: Lessons learned from involving non Lab workers into the process of analysing EID Samples

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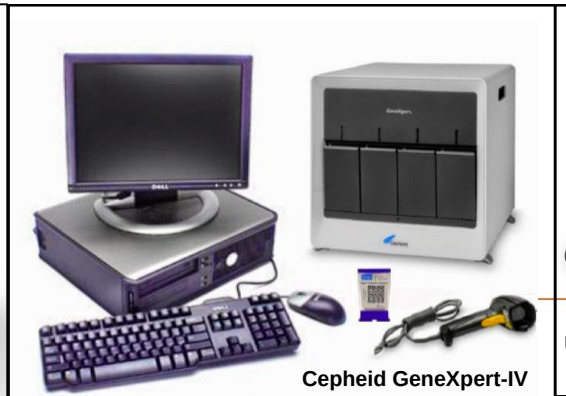
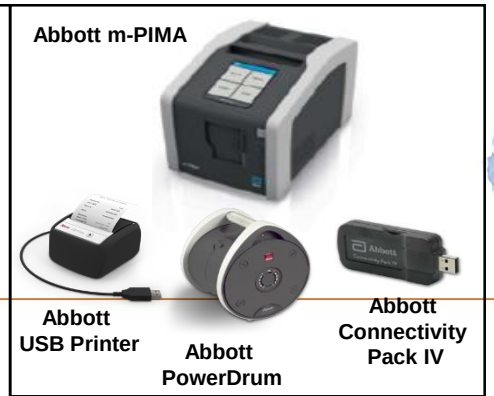
ASLM 2022

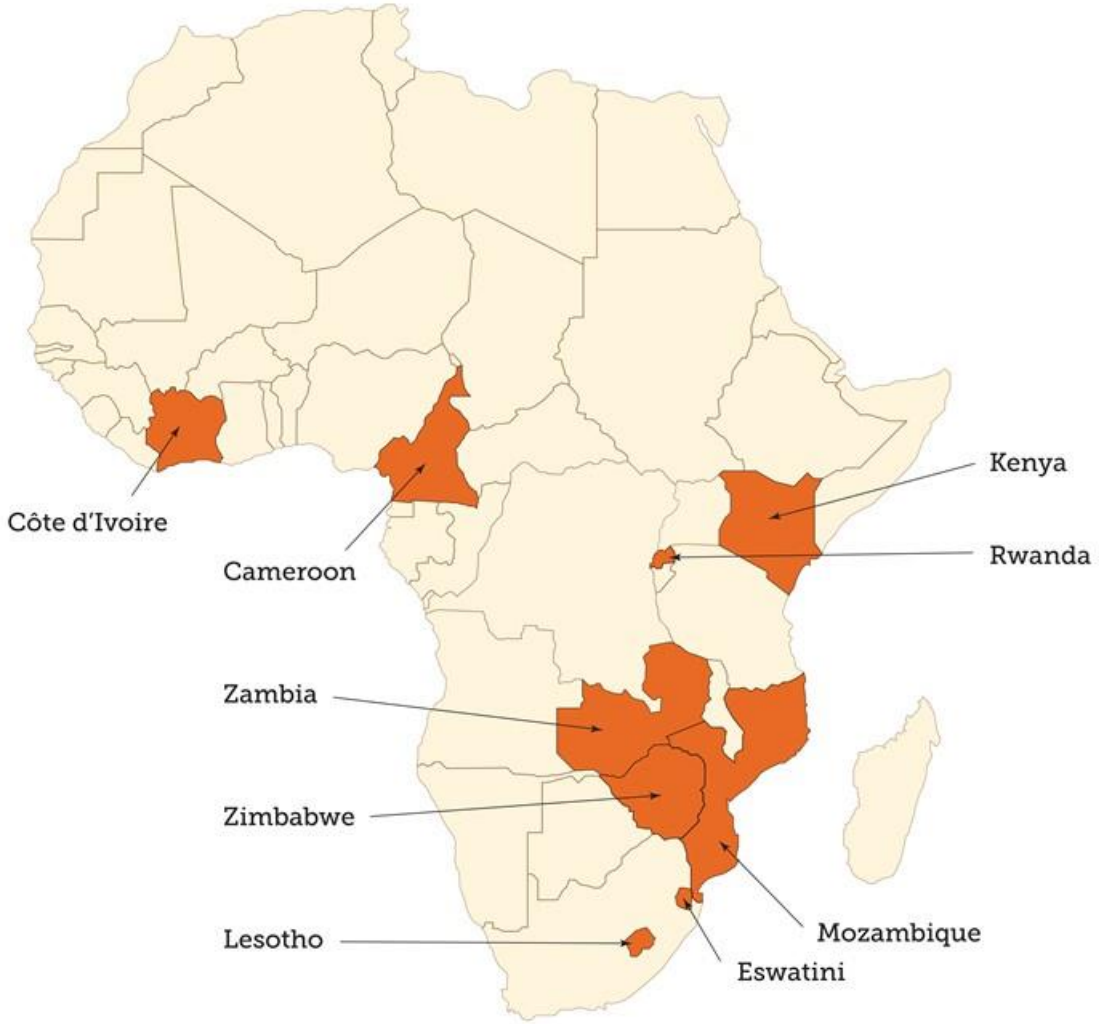
Point-of-Care Nucleic Acid Testing Instruments

- Point-of-care (POC) diagnostic technologies allow for decentralization of laboratory services.
- POC NAT instruments often allow testing of a variety of assays (TB, DR-TB, HIV EID, HIV VL, HCV &HBV VL, Chlamydia, Gonorrhea, HPV, Ebola, COVID-19,etc.)
- The ease of use of POC NAT assays enable non-laboratory medical staff, such as nurses and doctors to be involved in the process of performing the analysis





UNITAID/EGPAF POC EID project



Goal: to increase the number of HIV-exposed infants whose HIV status is known and facilitate early initiation on treatment.

Purpose: to ensure that at-risk infants have timely access to HIV testing and diagnosis through the incorporation of point-of-care testing into national EID networks

Scale:
- 9 countries
- 4 years (2015 – 2019)

Targets:
- 250,000 infants
- 14,617 HIV+ (5.8%)

90%
Diagnosed & knowing their status

90%
on treatment

< 7 days
Turnaround Time to Result

< 14 days
Turnaround Time to Treatment

EGPAF Program Approach

1. To **optimize early infant diagnosis** in each of the nine countries

2. through the **strategic placement** of new POC platforms, driven and **informed by a national EID plan**, in order to:

   ↑ access to EID

   ↑ % test results returned

   ↓ Turnaround time (TaT) from sample collection to result return

   ↓ TaT from sample collection to ART initiation

3. and through the **selection of products based on set objective criteria**, while

4. using a **phased implementation** approach*, based on the use of:*
   - **existing staff** and, where possible, **existing sample transport** networks
   - Comprehensive, yet pragmatic, **site-level trainings**
   - **QA** approach that leverages site monitoring visits and platform connectivity

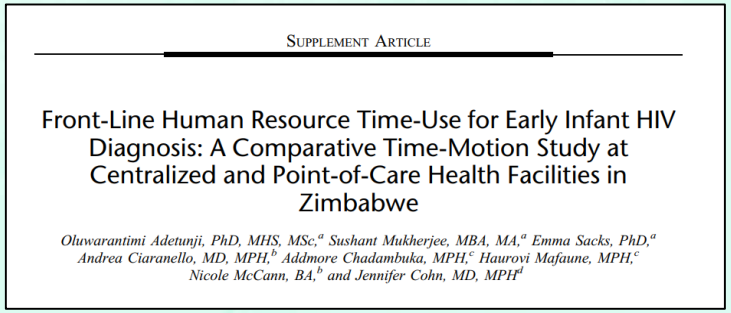
5. While fostering **linkage to treatment**, and

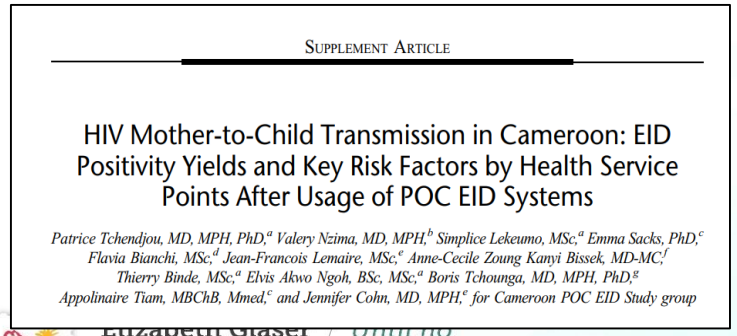
6. **generating evidence** critical to inform future scale-up & donor support

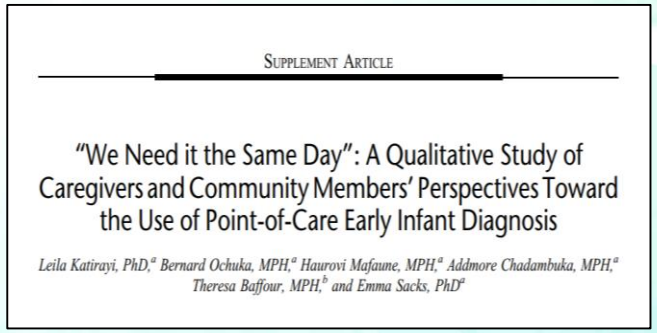
Different facilities involved – Many Questions explored

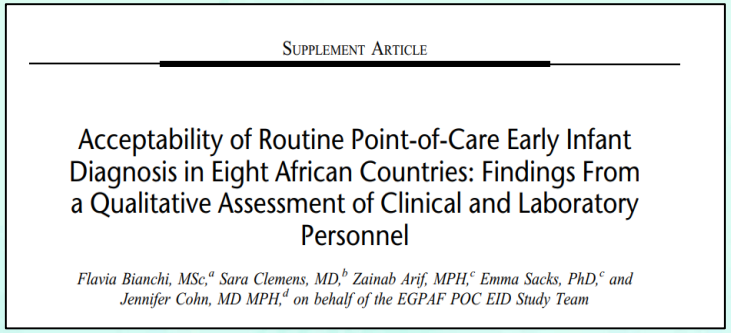
- Cross-sectional study covering facilities enrolled in urban, semi urban and rural settings
  - National hospitals
  - Provincial /Regional hospitals
  - District hospitals
  - Integrated health centers

- Published more than 15 articles in peer-reviewed journals (e.g. Lancet, JAIDS Supplement)
- Presented more than 30 abstracts at major international conferences (e.g. AIDS, ASLM, ICASA)
- Developed and disseminated 9 fact sheets and technical briefs; and
- Led or contributed to more than 30 presentations to national and global stakeholders, including through satellite meetings at global conferences









Task shifting of some laboratory services to non-laboratory staff

UNITAID POC-EID project experience

1. *Internal Quality Control failures (IQC)*
2. *Turn around time from samples collection to issuing of results to caregiver (TAT)*
3. *Health care worker experiences*
4. *Lessons learned*

Medical Biologist

Nurse

Lab Technician

POC EID testing

- In some of the facilities, testers were non-specialized laboratory-personnel who were trained and received regular monitoring and supervision
- Progressive Integration of EID package of Activities into existing services offered to mother-baby pairs (with emphasis to HEIs) – no additional Human resources
  - Example of gradual introduction in Cameroon
- All routine testers had to pass Proficiency test - Program implemented in different countries by a reference national laboratory [examples: CIRCB for Cameroon; ZINQAP for Zimbabwe]
- Site-level assessment to proper identify where to place EID Platforms technology (Laboratory, MNCH services with minor improvement; PMTCT services)

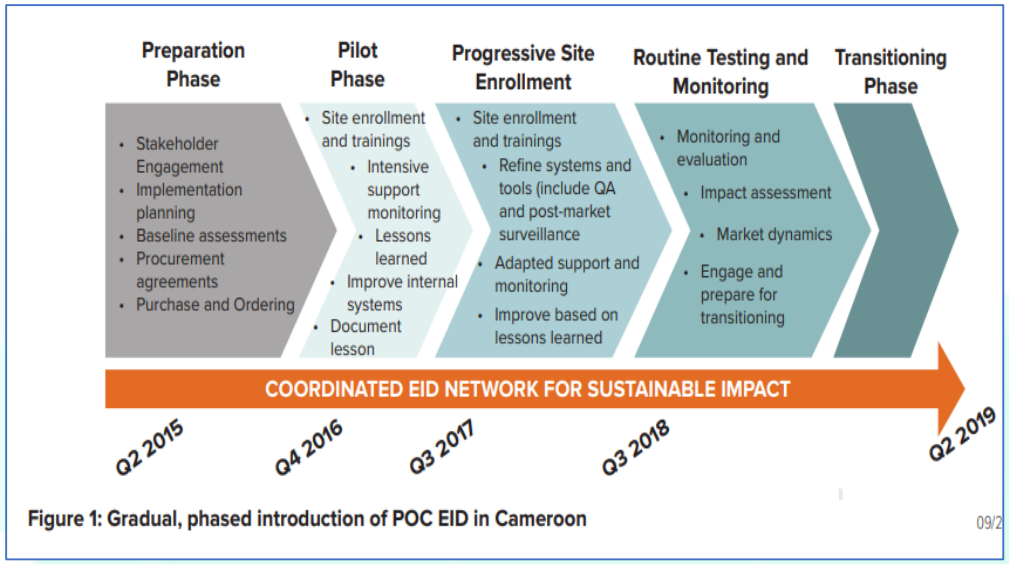
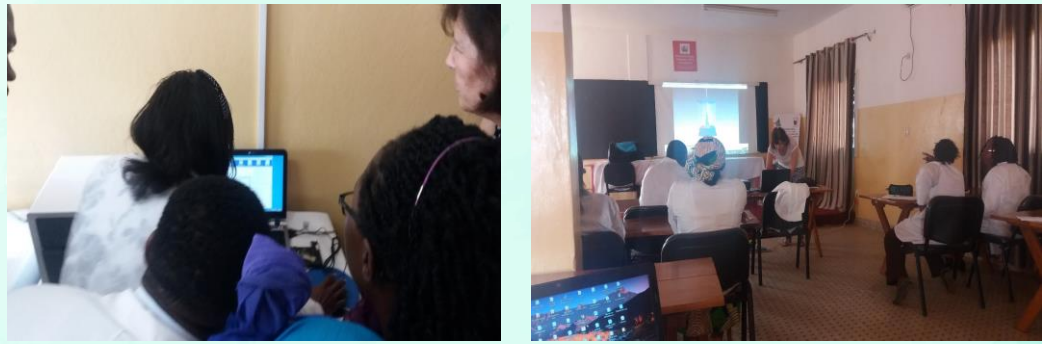


Figure 1: Gradual, phased introduction of POC EID in Cameroon



Evaluation of Lab and Non-lab personnel Performance

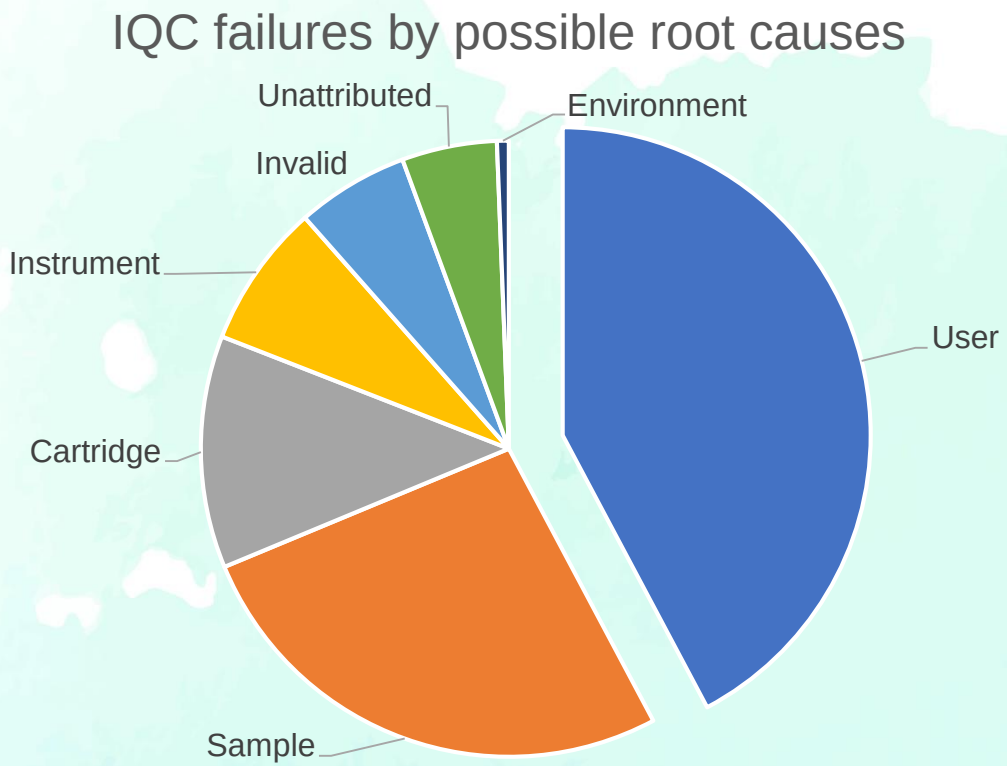
- We used **13.5 months** of routine POC EID data from **74,031 assay runs** across all **257 sites** from mid-September 2017 to October 2018.
- Combined country data from:
  - **Cameroon, Côte d'Ivoire, Kenya, Lesotho, Mozambique, Rwanda, Eswatini, and Zimbabwe.**
- **End-user related IQC failures**, identified using instrument error codes, were **aggregated per facility and categorized per end-user cadre**.
- We assessed **differences between laboratory and non-laboratory personnel**
- Analysis included samples from the hub and spoke model, all POC-EID platform (Cepheid GeneXpert & Abbott m-PIMA)
- Same site support supervision efforts were provided to all sites, irrespective of instrument type or end-user cadres, to ensure proficiency across the network

	Lab personnel	Non-lab personnel	Combined
Xpert sites	23	14	37
m-PIMA sites	79	141	220
Total	**102**	**155**	**257**

Results - IQC

- **<u>Total</u>** IQC failure rate observed of 6.1% over the entire period

- Main root causes of IQC failures:
  - **User-related** (42%)
  - Sample (27%)
  - Cartridge (12%)
  - Instrument (8%)



Results - IQC

- Despite a significant difference in the **total** IQC failure rates (all causes),
- No significant differences in the overall or the bi-weekly **end-user related** IQC failure rates between laboratory and non-laboratory personnel.
- **Both cadres routinely achieved an end-user related IQC failure rate below 2.7%.**

	Lab personnel (102 sites)	Non-lab personnel (155 sites)	p-value
Tests performed	27,342	46,443	
TOTAL IQC failure rate	5.27%	6.64%	p<0.0001
END-USER related IQC failure rate	2.60%	2.74%	p=0.2639
Median END-USER related IQC failure rate[1]	**2.30% [2.3-3.1]**	**2.60% [2.3-3.1]**	**p=0.7279**

[1]per bi-weekly periods

Routine Testing Results: Conventional vs. POC EID

	Conventional EID (100 sites)	POC EID (1171 sites)	p value
Median TAT from sample collection to result returned to caregiver [IQR]	**55 days** [31-77]	**0 days** [0-1]	p<0.001
Results received by caregiver within 30 days	**18.3%** (547/2,995)	**97.6%** (66,544/68,161)	p<0.001
Percent of ART within 60 days of sample collection	**41.3%** (43/104)	**93.2%** (2,374/2,546)	p<0.001
Median TAT from sample collection to ART initiation [IQR]	**50 days** [32-70]	**0 days** [0-1]	p<0.001

Interviews with 175 health care workers

Occupation	35.9% Nurses 4.8% Midwives 29.5% Lab technologist 5.8% Nurse assistant 5.1% Doctor 19.2% Other
Compared to laboratory-based EID, how complicated do you consider drawing the blood into the specimen container for POC EID?	12.8% More complicated 11.7% No difference 71.3% Less complicated 4.2% Other
How complicated do you consider running the POC EID machine?	1.75% Very complicated 10.6% Somewhat complicated 5.3% Neither easy or hard 8.8% Somewhat simple 73.7% Very simple

Interviews (cont')

Compared with laboratory-based EID, how does POC EID affect your ability to care for HIV-exposed infants?	93% Improves ability to care 6.3% No difference 0% Decreases ability to care 0.7% Other
Compared with laboratory-based EID, how has patient flow changed as a result of POC EID in this clinic?	3.8% More difficult flow 48.7% No difference 44.2% Easier/simpler flow 3.2% Other
Based on what you know about POC EID, do you recommend that the country increase the use of POC EID?	100% Yes 0% No 0% Other

36.5% of HCW reported a gap in POC EID functionality with a mean duration of 7.5 days, mostly due to machine malfunction or stock out of test kits

Lessons learnt (1/3)

- In general, we observed comparable Similar IQC failure rates between non-laboratory and specialized laboratory-trained operators
- These results suggest that non-specialized laboratory-trained personnel and close monitored can perform POC EID equally well
  - *This finding corroborates well with Nanji et al [6] who reported that for equipment-based near-patient testing, competency is independent of user laboratory qualifications*
- However, not all non-specialized laboratory –trained personnel had sufficient experience. Some were progressively replaced by more experienced testers who were the ones regularly running the test

Lessons learnt (2/3)

- Turn over of trained health care staff was higher than Lab staff, leading to need for frequent new trainings and less experienced testers
- Over time, IQC failure rates for both non-laboratory and specialized laboratory-trained testers decreased significantly
- At times sites experienced a challenge with accurate assessment of the stock of test kits in the field. Documentation of the kit stocks was sometimes missed due to different group of cadres manipulating the stock, leading to kit stock outs some sites.

Lessons learnt (3/3)

- In general, we observed comparable TATs between non-laboratory and specialized laboratory-trained operators

- Further analysis revealed that in terms of issuing results to caregivers within 14 days (the POC EID project implementation standard), nurse testers had a significantly higher proportion (96.3%) of results issued within 14 days from sample collection compared to the proportion (89.5%) of specialized laboratory-trained testers

Acknowledgements

- Mothers and babies
- Ministries of Health
- EGPAF global and country teams
- Other POC EID partners
- This project was made possible with Unitaid’s funding and support