POINT-OF-CARE TESTING IMPROVES EARLY INFANT DIAGNOSIS IN THE PUBLIC HEALTH SECTOR

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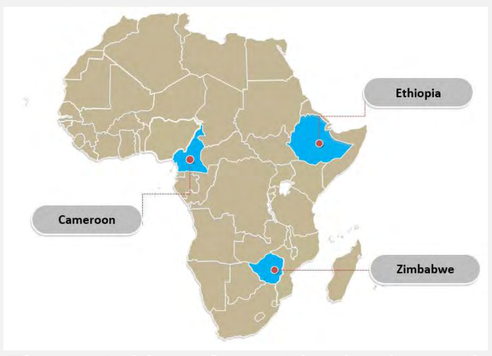
Background

- Despite progress in the scale-up of early infant diagnosis (EID) programs in the last decade, only 51% of HIV-exposed infants received a diagnostic nucleic-acid test within the recommended 4-6 weeks of birth in 2018.
- Point-of-care (POC) testing has been shown to dramatically increase rates and timeliness of early diagnosis and initiation of ART for HIV-positive infants.
- As national programs in sub-Saharan Africa incorporate POC EID, it is critical to monitor the impact of POC EID within routine public sector programs to better guide national scale-up.

Methods

- A 6-month pre-/post-evaluation comparing conventional laboratory (pre) to POC (post) EID testing using either Cepheid GeneXpert (GX) or Abbott m-PIMA devices was conducted in 36 facilities across three countries, Cameroon, Ethiopia and Zimbabwe, between 2017 and 2019.
- On-site trainings for POC device use were held for facility and laboratory staff prior to implementation.
- Data were retrospectively extracted from routine records at health facilities for all infants (aged 0-2 years) tested.
- The primary outcome was the proportion of infants tested in which the infant's caregiver received the test results within 28 days of sample collection (WHO recommendation, 2010). ART initiation within 28 days of sample collection was also analyzed for HIV-positive infants.



- A meta-analysis was conducted to compare the overall (pooled) results from all three countries.

Figure 1. Map of countries implementing POC EID and included in meta-analysis

Country	Study Design
Cameroon	• 9 sites (3 GX, 6 m-PIMA) • Pre: Jul-Dec 2017 (GX); Apr-Sep 2017 (m-PIMA) • Post: Jul-Dec 2018 (GX) Apr-Sep 2018 (m-PIMA)
Ethiopia	• 7 sites (GX) • Pre: Apr-Sep 2018 • Post: Nov 2018-Jun 2019
Zimbabwe	• 20 sites (9 GX, 11 m-PIMA) • Pre: Oct 2017-Mar 2018 (GX); Jul-Dec 2017 (m-PIMA) • Post: Oct 2018-Mar 2019 (GX); Jul-Dec 2018 (m-PIMA)

Table 1. Summary of country POC EID study profiles

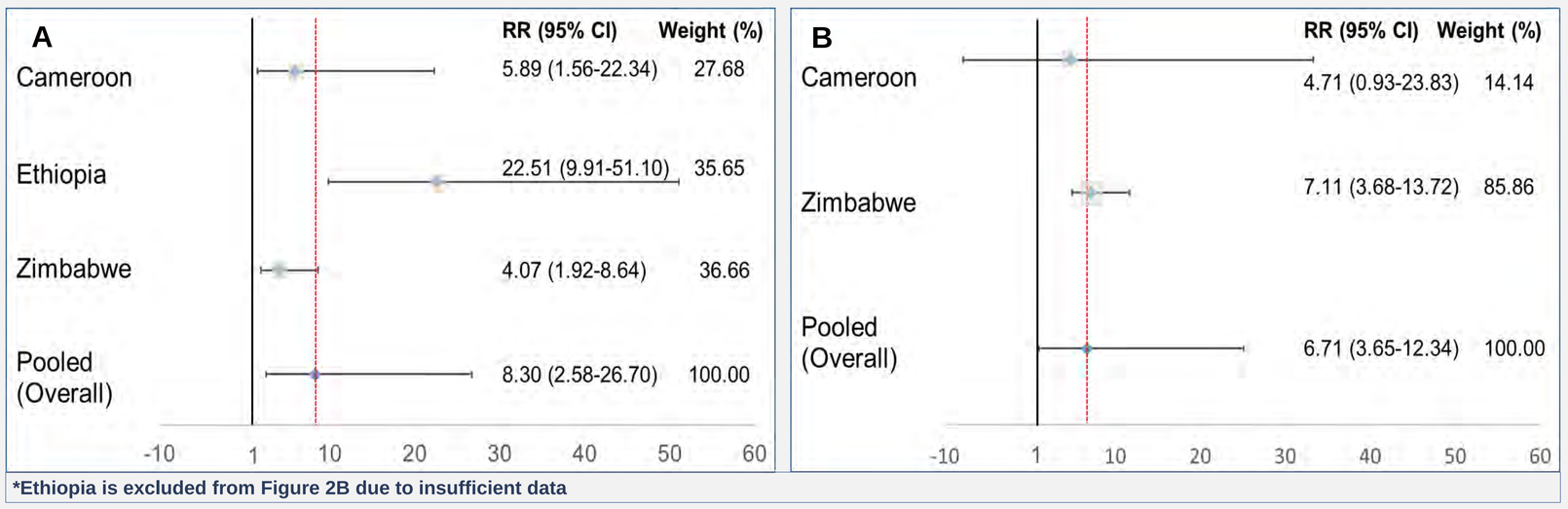
Findings

	Cameroon				Ethiopia				Zimbabwe			
	Conventional (pre)		POC (post)		Conventional (pre)		POC (post)		Conventional (pre)		POC (post)	
	N	n(%)/ median(IQR)	N	n(%)/ median(IQR)	N	n(%)/ median(IQR)	N	n(%)/ median(IQR)	N	n(%)/ median(IQR)	N	n(%)/ median(IQR)
Infant age (days)	349	52 (44 - 94)	506	72 (46 - 210)	141	46 (45 - 64)	135	48 (45 - 76)	2177	45 (42-54)	3700	44 (7-52)
Infant sex, female	257	112 (44%)	514	250 (49%)	143	79 (55%)	135	72 (53%)	1934	926 (48%)	3691	1917 (52%)
Valid Results*	351	318 (91%)	514	512 (100%)	143	117 (82%)	136	131 (96%)	2200	2030 (92%)	3766	3645 (97%)
Positive Results	318	12 (4%)	512	28 (5%)	117	3 (3%)	131	3 (2%)	2030	108 (5%)	3645	158 (4%)
ART Initiations	12	7 (58%)	28	26 (93%)	3	2 (66%)	3	1 (33%)	108	34 (31%)	158	119 (75%)

*Valid Results are positive or negative test results and omit any tests reported as invalid or missing

Table 2: Descriptive analysis of infants receiving a conventional or POC EID test, by country

- Pre-POC implementation, 2,524 conventional EID tests were conducted, of which 2,465 (97.7%) had a valid result and 123 (5.0%) were HIV-positive. Post-POC implementation, 4,295 tests were conducted, 4,288 (99.8%) had a valid result and 189 (4.4%) were HIV-positive.
- POC EID resulted in faster turnaround times [median of 0 days (POC) vs. 40 days (conventional)] and POC EID results were more than eight times as likely to be received by a caregiver within 28 days of sample collection (19.5% for conventional vs. 86.1% for POC; RR: 8.30; 95% CI: 2.58-26.70).
- The proportion of caregivers receiving results within 28 days of POC sample collection varied from 76.0% in Cameroon to 96.2% in Ethiopia (Table 3). Infants tested on POC had a much greater probability of initiating ART within 28 days (9.8% for conventional vs. 67.2% for POC; RR: 6.71; 95% CI 3.65-12.34).



*Ethiopia is excluded from Figure 2B due to insufficient data

Figure 2: Meta-analysis on the relative risk (RR) of EID test result returned to the caregiver within 28 days (A) and HIV-positive infants initiating on ART within 28 days (B)

	Conventional (pre)			POC (post)			Relative Risk	
	N	%	(95% CI)	N	%	(95% CI)	(RR)	(95% CI)
Caregiver result received within 28 days								
Cameroon	318	12.9%	(3.1% - 40.3%)	512	76.0%	(27.0% - 96.4%)	5.89	(1.56-22.34)
Ethiopia	117	4.3%	(1.9% - 9.4%)	131	96.2%	(87.6% - 98.9%)	22.51	(9.91-51.10)
Zimbabwe	2030	21.4%	(8.8% - 43.4%)	3645	87.2%	(77.1% - 93.2%)	4.07	(1.92-8.64)
Pooled	2465	19.5%	(8.8% - 38.0%)	4288	86.1%	(76.6% - 92.2%)	8.30	(2.58-26.70)
Initiated on ART within 28 days								
Cameroon	12	16.7%	(3.1% - 55.4%)	28	78.6%	(30.2% - 96.9%)	4.71	(0.93-23.83)
Ethiopia	3	0.0%	--	3	33.3%	(0.3% - 98.9%)	--	--
Zimbabwe	108	9.3%	(5.4% - 15.4%)	158	65.8%	(46.2% - 81.2%)	7.11	(3.68-13.72)
Pooled	123	9.8%	(6.1% - 15.2%)	189	67.2%	(50.2% - 80.7%)	6.71	(3.65-12.34)

Table 3: Multi-country comparison of Conventional and POC EID among valid test results on caregiver result received and ART initiation

Conclusions and Recommendations

POC EID significantly improved rates of test result returned to caregiver and ART initiation within routine care at public health facilities in three unique country settings in sub-Saharan Africa. However, in some settings, gaps remained in timely results return and treatment initiation. To maximize the impact of faster testing through POC, programs must focus on ensuring test results are used in a timely manner and appropriate follow-up care is provided to HIV-positive infants.

Unitaid Innovation in Global Health

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