

Title: Diagnosing and treating more infants, faster: Findings from the first multi-country evaluation of routine point-of-care early infant diagnosis in eight sub-Saharan countries.

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Background: Point-of-care early infant diagnosis (POC-EID) may improve the care of HIV-exposed infants compared to conventional testing. POC-EID is being implemented in eight sub-Saharan African countries at POC ("testing") and near-POC ("spoke") sites. A program evaluation was undertaken to assess the impact of POC- or near POC-EID implemented as part of routine care, compared with conventional testing.

Methods: Using a pre-post intervention design, key EID outcomes were compared in each country. Pre-intervention conventional EID data were collected retrospectively from registers across a purposively sampled sub-set of sites. Post-intervention data for specimens processed between December 2016 and December 2017 were collected prospectively using a POC-EID testing form. Median turnaround times (TATs) were compared using Wilcoxon rank-sum test, and proportions with Pearson chi-square test. Kaplan-Meier Estimator was used for the proportion of caregivers who received results within 30 days of sample collection. Prospective data were analyzed by entry point and compared between testing/hub and spoke sites. The cost per test result returned was calculated using Global Fund's total cost of ownership estimates for POC and conventional EID.

Results: POC-EID resulted in a significantly higher percentage of results returned to caregiver and percentage of infants started on treatment sooner, as compared to conventional EID (Table 1). There were no significant differences in percent results returned between testing and spoke sites (Figure 1). Valid, non-confirmatory tests from different entry points revealed 3.2%, 19.6%, 15.5%, and 2.5% HIV-positivity rates from prevention of mother-to-child transmission entry points, pediatric inpatient, outpatient, and vaccination clinics, respectively. The cost per test result returned (regardless of TAT) was \$20-38 for POC and \$21-33 for conventional.

Conclusions: Routine use of POC-EID in sub-Saharan Africa is feasible and significantly improves key patient outcomes. Spoke sites can expand access to POC-EID, with minimal differences in patient-level outcomes. POC-EID is particularly important for high-yield entry points such as pediatric wards, where patients may be less likely to receive results from conventional testing with long TATs. Given similar costs per test result returned to caregiver for conventional testing, POC-EID represents an efficient and effective way to identify HIV-infected infants and initiate on antiretroviral treatment.

Table 1: Comparing conventional and POC EID on primary service delivery outcomes

	Conventional EID (96 sites, 2891 samples)	POC-EID (287 sites, 16,159 samples)	<i>p</i> value*
% results received by caregiver within 30 days	21.18%	99.13%	$p < 0.001$
Median TAT from blood sample collection to result returned to caregiver	55 days (IQR: 31-76)	0 days (IQR: 0-1)	$p < 0.001$
% of HIV-infected infants started on treatment	67.33%	90.6%	$p < 0.001$

Median TAT from result returned to caregiver to ART initiation for HIV-infected infants	0 days (IQR: 0-4.5)	0 days (IQR: 0 – 1)	NS
Median TAT from blood sample collection to ART initiation for HIV-infected infants	49.5 days (IQR: 32-68)	0 days (IQR: 0-2)	p<0.001

*The significance threshold was set at .05

** IQR = Interquartile Range

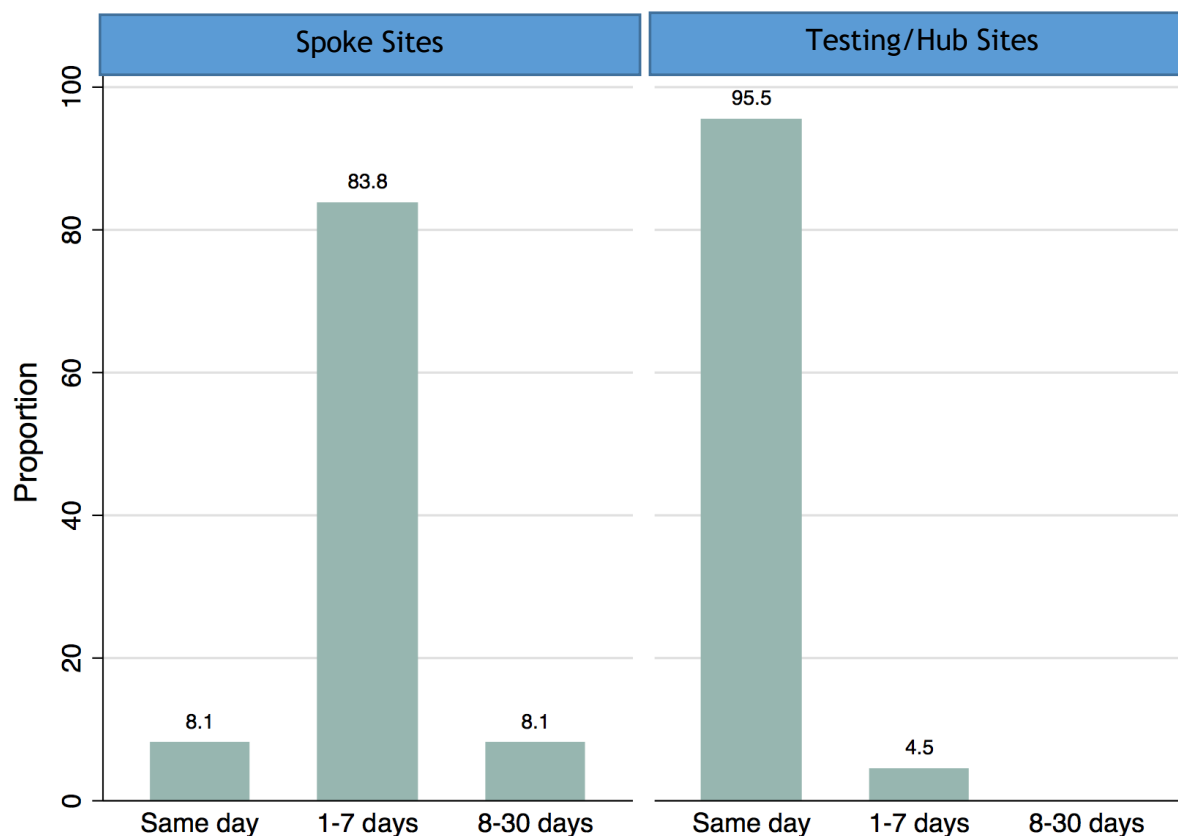


Figure 1: Proportional distribution of POC hub and spoke sites according to their median turnaround time from sample collection to communication of results to caregiver.