Title: Can a short-haul specimen referral system work efficiently to access "point-of-care" early infant diagnosis testing? Lessons from Lesotho and Zimbabwe.

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Background: Specimen referral systems can increase access to diagnostic services but are also vulnerable to logistical and system efficiency challenges. An efficient specimen referral over short distances (<1 hour) was adopted to increase access to point-of-care (POC) early infant diagnosis (EID). We compared key clinical and service delivery outcomes observed within testing facilities (POC model) to those within referring facilities (referral model), in Lesotho and Zimbabwe.

Methods: We used data from POC EID testing forms routinely used across all 109 facilities (27 testing facilities; 82 referring facilities) having access to POC EID from February to October 2017 across Lesotho and Zimbabwe combined. Key POC EID clinical outcomes (percentage of results returned to caregivers at facility and percentage of HIV-infected infants initiated on treatment) and key service delivery outcomes, including intermediate turnaround times (TAT) (between specimen collection, transport, processing, result transmission facility, and return to caregiver) and total TAT (from specimen collection to result return to caregiver at facility) were aggregated per facility. We assess differences between the two delivery models using the Wilcoxon rank-sum test on summary statistics (median, range intervals, proportions) from aggregated facility outcomes.

Results: In both POC and referral models, there were no significant differences in percent results returned (100%), or in the proportions of HIV-infected infants initiated on treatment (100%), despite the latter having a small but significant distribution difference (Table 1). The total TAT median observed in the referral model (2 days [0-28]) was only two days longer than in the POC model (0 days [0-3]), with a significant difference in the TAT groups' distributions (Figure 1 and Table 1). Whereas both models experienced same-day specimen transportation, caregivers took significantly longer (1 day vs 0 days) to collect the result from facility in the referral model (Table 1).

Conclusions: A short-haul POC EID specimen referral system showed no significant differences in key clinical outcomes, and a significant increment of only 2 days in the final TAT, (mostly due to time required for caregivers to collect results) as compared to patients seen at POC testing sites, and may be considered to increase access to POC EID.
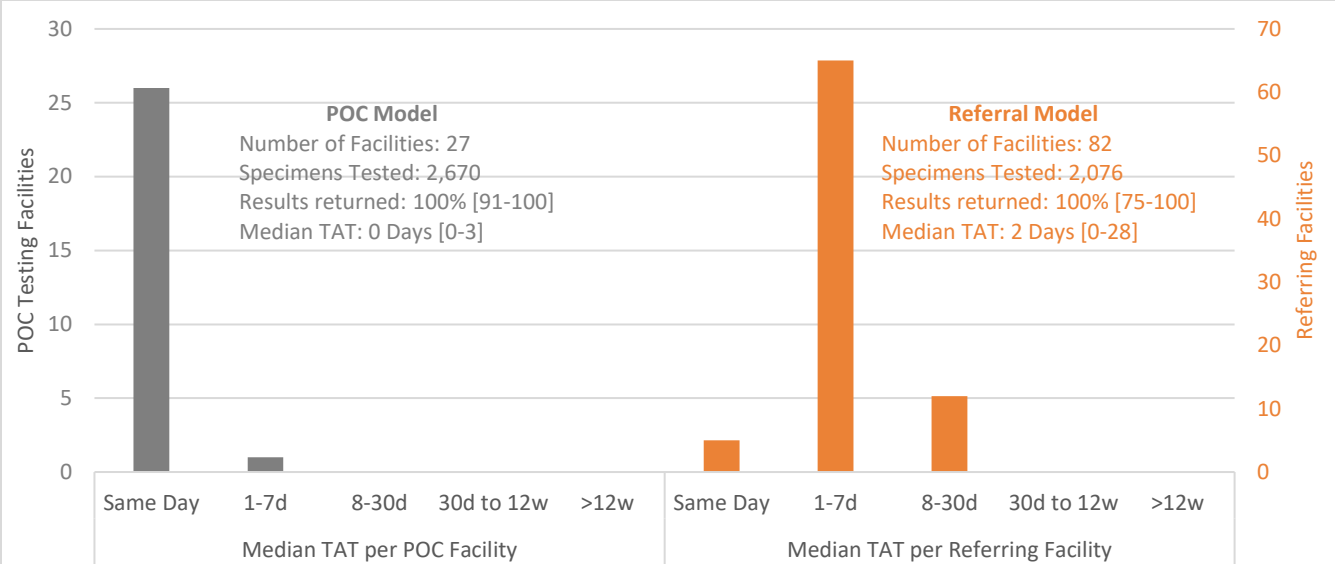
Figure 1: Median Turnaround Times from Sample Collection to Return of Results to Caregiver in Facilities of the POC and Referral Models

Table 1: Comparison of key POC EID clinical and service delivery performance indicators observed in facilities of the POC and the referral models

Indicator		POC Model	Referral Model	*p* value*
Number of facilities analyzed		27 testing facilities (2,670 specimens)	82 referring facilities (2,076 specimens)	
Percentage of results returned to caregiver (medians)		100% [91-100]	100% [75-100]	p=0.996
Percentage of HIV-infected infants initiated on treatment (medians)		100% [0-100] (n=67)	100% [0-100] (n=53)	**p=0.018**
Median TAT from:	Blood collection to reception at testing site (including sample transportation)	0 days [0-0]	0 days [0-2]	**p=0.004**
	Blood reception to processing at testing site	0 days [0-0]	0 days [0-1]	p=0.059
	Processing to result sent to requesting unit	0 days [0-0]	0 days [0-5]	**p=0.008**
	Result at Requesting unit to result received by caregiver	0 days [0-1]	1 days [0-24]	**p<0.001**
	Blood collection to result communication to caregiver	**0 days [0-3]**	**2 days [0-28]**	**p<0.001**

*The significance threshold was set at 0.05