USE CASE FOR NEAR POINT OF CARE HIV VIRAL LOAD: TARGETED TESTING AT LARGE FACILITIES

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BACKGROUND

Point-of-care (POC) technologies in resource-limited settings can circumvent challenges of centralized laboratory testing, improving clinical management. However, high device costs and uncertain indications for use have inhibited scaling-up POC modalities.

We implemented targeted POC viral load (VL) testing in two large HIV clinics in Lilongwe, Malawi and investigated the clinical process and cost implications in a programmatic setting.

METHODS

- POC VL testing using GeneXpert was targeted for patients suspected of treatment failure or returning to care following an elevated VL (>1,000 copies/ml) from January to December 2017. (suspected of ART failure [WHO stage 3/4 or low CD4], previously high VL, or switched to 2nd line ART 6 months prior)
- Demographic and clinical data were abstracted from the Electronic Medical Record System (EMRS).
- Process outcomes were extracted from lab registers and request forms and included a clinical risk assessment of treatment failure, time to clinical action.
- Nursing staff primarily operated the GeneXpert platform with support from a laboratory technologist.

Cost Analysis

- Retrospective data on the costs incurred during the study period was entered into the Health Economics and Epidemiology Research Office's Testing Technology Cost Model to analyze the 'all in' cost per test.
- Inputs included were commodity costs of the tests and equipment, human resources, waste management, and facility overhead.

RESULTS (Table 1)

- 2,813 POC VL tests were conducted. Documentation of testing was complete for 1,511 (54%).
- **53%** (794/1511) of tests were to confirm a previously high VL, and **31%** (462/1511) were due to clinical indications.
- **39% (585/1511) of those with suspected failure had suppressed VLs.**

***Targeted** POC VL testing is feasible, economical, and consistently enables prompt clinical action. National programs should combine such targeting with centralized testing to optimize national VL testing programs.*

Table 1. Characteristics of POC VL Testing

	N(%) (N=1511)
Demographics	
Sex – Female	812 (61%)
Age (mean [IQR])	35 (27 – 44)
Reason for testing	
Clinical indication (multiple choices possible)	462 (31%)
Loss of weight	193 (42%)
Night sweats	96 (21%)
Chronic cough	78 (17%)
Weakness	47 (10%)
Frequent hospital admission	32 (7%)
Low CD4 count	18 (4%)
New WHO III or IV disease	165 (36%)
Previous elevated VL	794 (53%)
VL after switch to 2nd line	50 (3%)
Other	83 (6%)
Missing	122 (8%)
VL result	
Suppressed (<1000 copies/ml)	585 (39%)
Elevated VL (≥1000 copies/ml)	926 (61%)

RESULTS (Table 2)

- **61% (926/1511) of patients had a high VL**, of whom 78% (719/926) had a recorded clinical action:
  1. 77% (557/719) switched to second line ART and
  2. 15% (194/719) were referred for intensive adherence counseling.
- **79% (567/719) of patients received a clinical action on the same day as testing.**

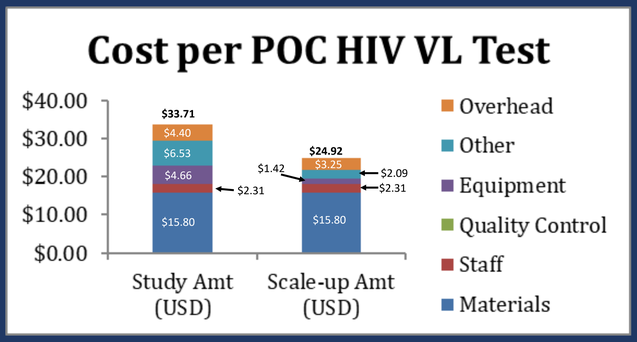
Table 2. Clinical management and time to action for patients with elevated VL (VL ≥1000 copies/ml) (full results not shown)

	N(%)
Elevated VL (≥1000 copies/ml)	**926**
"Clinical Action" taken on high VL result	**719 (78%)**
Referral for adherence counselling	104 (15%)
Switch to 2nd line	557 (77%)
No action†	19 (3%)
Other	39 (5%)
Time from sample collection to Clinical Action†	**719**
Same day	567 (79%)
Next day	67 (9%)

RESULTS (Figure 1)

- The **'all-in' cost** was **$33·71** for a valid POC VL test, compared to an international benchmark for a centralized VL test of $28·62.
- Using the study data, the cost for **national scale up** was estimated at **$24·92, a**ssuming an optimized testing environment with 75% device utilization.
- Materials, accounted for the largest portion, **47%** ($15·80) of the cost per test. The remaining **53%** of the test cost was comprised of staff, equipment, other, and overhead.

Figure 1. Cost per test and per result broken down by the main categories of cost components for the study and in a scale up scenario.



CONCLUSIONS

- This study shows the benefit of providing targeted POC VL testing for people in need of urgent clinical management while most patients, who require more routine clinical decisions, receive centralized testing.
- 68% (634/926) of those with an elevated VL had a documented clinical action the same or next day from collection, which is not possible with a centralized system.
- The difference between the 'all in' cost of POC VL and centralized testing of $5·09 could be further reduced in an optimized national program that leverages existing instruments and strategically offered patients either targeted POC testing or centralized testing based on their clinical needs and the facility context.
- The theoretical costs saved from repeat visits and follow up likely outweigh the minimal increased expense.

LIMITATIONS

- This is an observational study without a concurrent comparator.
- While we had 54% of the complete process/results documented there was no reason to assume the patients without documentation were different from those with documentation.
- During the study period, we instituted a file flagging system to capture patients without recent VLs, which led to overall increases in testing coverage, but may have not influenced testing among the targeted population substantially.