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Feasibility and acceptability of task sharing collection of HIV viral load dried blood spot samples with community lay cadres in Zimbabwe

[version 1]

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Abstract

Introduction

Viral load (VL) testing is a critical for clinical management of HIV. Healthcare worker (HCW) shortages are a key barrier that can impact VL sample collection. This study aimed to assess the feasibility and acceptability of community lay cadres (CLCs) collection of VL samples in facility settings in Zimbabwe, as compared to VL sample collection by trained HCWs.

Methods

Two dried blood spots (DBS) samples were collected from 374 participants, including a reference sample collected by a HCW and a validation sample collected by a CLC. A subset of 173 CLC collections were observed using a checklist, and surveys were conducted with participating clients and CLCs. This study was conducted in 10 public health facilities in Zimbabwe over 6 weeks in March-April 2024.

Results

No samples were rejected by the laboratory, but two samples (one collected by a HCW and one by a CLC) were classified as invalid. Of the 372 paired tests analyzed, 96.0% (95%CI 93.2-97.7%) of HCW and CLC sample pairs had results that matched (i.e. both designated as suppressed or unsuppressed). All of the critical checklist items were done properly in 90.2% (95%CI 85.7-94.7%) of observed CLC sample collections. All CLCs reported being confident to conduct DBS sample collection correctly (89% very confident, 11% somewhat confident), while 94% of clients reported that they would agree to receive sample collection by CLC in the future.

Conclusions

VL DBS results for samples collected by CLCs were comparable to the results from samples collected by HCWs, and CLCs demonstrated the ability to correctly and effectively use DBS VL sample collection kits. Clients reported CLC sample collection to be acceptable and even preferred for many. Results from this assessment indicate task-sharing VL DBS sample collection to CLCs is a feasible strategy. This opens opportunities to explore community-based DBS sample collection.

Keywords

Zimbabwe, Sub-Saharan Africa, HIV, viral load, dried blood spots, community health workers, task shifting, task sharing

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List of abbreviations

ART: Antiretroviral Therapy
 CARG: Community ART Refill Group
 CATS: Community Adolescent Treatment Supporter
 CHAI: Clinton Health Access Initiative, Inc.
 CLC: Community Lay Cadre
 DBS: Dried Blood Spot
 DSD: Differentiated Service Delivery
 HCW: Health Care Worker
 HIV: Human Immunodeficiency Virus
 ICC: Intraclass Correlation Coefficient
 LIMS: Laboratory Information Management System
 MoHCC: Ministry of Health and Child Care
 PLHIV: People Living with HIV/AIDS
 VL: Viral Load
 WHO: World Health Organization

Introduction

Viral load (VL) is a critical indicator of the body's response to antiretroviral therapy (ART) for human immunodeficiency virus (HIV). Since the World Health Organization (WHO) issued guidance in 2013 recommending VL as the preferred HIV monitoring method, extensive investments have been made in molecular laboratory systems for VL testing programs. The availability of VL testing through clinic-based care has been an important contributor to reaching the estimated 93% of patients with suppressed VL among those on treatment globally.¹ Further enhancements in service delivery are required to ensure equitable progress, to reach the target of 95% viral suppression by 2025, and to strengthen the sustainability and success of long-term ART for both individuals and national programs.

In Zimbabwe, approximately 79% of the 1.18 million people on ART have had a VL test within the last year in 2022.² Challenges for VL coverage in Zimbabwe include health worker staff shortages to collect and process samples, poor coverage of clients in rural and hard-to-reach areas, long waiting times at facilities, availability of reagents, and VL funding issues.^{3,4}

Globally, HIV ribonucleic acid (RNA) levels in plasma samples are considered the gold standard for monitoring VL, but in settings where plasma tests or cold chain sample transport are not available, dried blood spot (DBS) tests are considered an acceptable alternative and key tool for access.⁵ In Zimbabwe, and many other countries, health care workers (HCWs) are responsible for collecting DBS samples for HIV VL.⁶ However, overburdened facilities and HCW shortages can be bottlenecks to access, and as differentiated service delivery (DSD) models expand, fewer patients are interacting with a HCW during routine visits.⁷ DBS samples are used for early infant diagnosis (EID) of HIV, and in other countries in Sub-Saharan Africa, EID DBS sample collection has been task-shared with lay cadres in order to overcome health workforce challenges.⁸ Task sharing with lay cadres has also been successful for other blood-based tests, such as for malaria.^{9,10} However, it has been noted that adequate training and assessment of skills is important to maintain quality of care in the context of task-shifting or task-sharing.¹¹

In Zimbabwe, community lay cadres (CLCs) play a crucial role in the provision of ART services. CLC is a term used to refer to community health workers (called Village Health Workers in Zimbabwe), and peer-to-peer support mechanisms such as Community Adolescent Treatment Supporters (CATS), Community ART Refill Group leaders (CARGs), DSD group leaders, and expert clients. CLCs already interact with ART clients regularly, in the community and in facilities, and provide a range of services. This study aimed to assess the feasibility and acceptability of CLC collection of DBS samples for VL testing as compared to DBS sample collection by trained HCWs.

Methods

This study was conducted in March-April 2024. Two DBS samples were collected from each participant, including a reference sample collected by a HCW and a validation sample collected by a CLC. A basic DBS test kit was developed by Lasec, including modifications such as self-retracting safety lancets and simplified packaging and instructions. Both samples were sent to the same laboratory for testing, but only the HCW-collected sample results were returned to the client. The laboratory staff were blinded to which cadre had collected each sample, and the test pairs were run on the same testing platform. A sub-sample of CLC collections were observed using a checklist, and surveys were also conducted with participating clients and CLCs.

Study sites

This study was conducted in 10 public health facilities in Zimbabwe. We purposefully selected sites to include: primary care or level 1 hospital sites only; sites with at least 750 active ART clients; and diversity across the sample in terms of province, partner support and rural/urban location.

Data collection and analysis

CLCs received training in DBS sample collection, and HCWs from the study sites were trained to refresh their skills. A structured training program was implemented to ensure competency. CLCs participated in a 5-day training covering HIV basics, the role of viral load monitoring in HIV patient management, DBS sample collection, infection control, and patient interaction. Before conducting sample collection, all CLCs demonstrated competency through supervised practice/mock collection, passing a skills assessment. All ART clients who visited a study site during the study period (until the data collection sample size target was met) and were due for VL testing were invited to participate in the study. DBS samples were collected by a CLC and then an HCW. For approximately every second CLC collection, an observer (the facility in-charge or laboratory staff) made observations using the checklist. After both samples were collected, the client was invited to participate in a survey. All participating CLCs were invited to complete a survey at the end of study. Written informed consent was sought from clients and CLCs prior to participation.

Study staff entered survey and participant data into a study database using [SurveyCTO](#) (Dobility, Inc. Cambridge, MA, USA). All analyses were conducted in [Stata SE 15](#) (StataCorp, College Station, TX, USA). Ethical approval for this study was provided on 28 December 2023 by the Medical Research Council of Zimbabwe, Ref: MRCZ/A/3099.

Results

Study sample

A total of 375 clients consented to participate in this study ([Table 1](#)). One client withdrew from the study after the collection of one DBS sample, so samples from 374 clients were included in the study. Sixty CLCs, including primarily Village Health Workers (68%), were trained and enrolled to collect DBS samples. Fifty-eight HCWs participated in the study with 61% acting as DBS sample collectors and 38% as observers.

Diagnostic comparability and sample integrity

A total of 748 DBS samples were collected, and none were rejected by the laboratory. The results for two samples, each pertaining to separate clients, were classified as invalid; one was collected by a HCW and the other collected by a CLC. Both invalid results originated at the same hospital, were tested by the same laboratory, and were excluded from the analysis. This brought the final sample for diagnostic comparison to 372 unique clients, each with a paired set of VL results. DBS results were classified as suppressed if VL was below 1000 copies/mL and unsuppressed if VL was equal to or above 1000 copies/mL. In 96.0% (95% CI 93.2-97.7%) of paired results, the HCW- and CLC-collected samples had matching results (i.e. both designated as suppressed or unsuppressed) ([Table 2](#)).

Several other approaches to diagnostic comparability were leveraged to further explore and pressure test the observed result. First, the sensitivity and specificity of CLC-collected samples compared to HCW-collected samples were 43.8% and 98.3%, respectively, though HCW-collected DBS samples cannot be considered as a gold standard.⁵ We also evaluated agreement via Cohen's kappa, a statistical measure to assess the reliability between two raters by adjusting observed agreement beyond what would be expected by chance alone. This approach yields a Cohen's kappa value of 0.4620, representing a "moderate" level of agreement according to Landis and Koch.¹² Such a scenario with a high level of observed agreement and a relatively lower kappa value has been described as Kappa's paradox; a statistical phenomenon often driven by high prevalence of the outcome, in this case VL suppression.¹³⁻¹⁵ Gwet's A1C is another statistical measure that aims to mitigate the issues of kappa's paradox in cases of high prevalence,^{16,17} and the Gwet's A1C for this data was 0.9564, categorized as an "almost perfect" level of agreement according to Landis and Koch. Finally, the intraclass correlation coefficient (ICC) has also been used to compare two DBS samples,^{18,19} and in this case the ICC for a two-way model of absolute agreement was 0.63, which is "good" agreement according to Cicchetti.²⁰

CLC skills assessment

The CLC sample collection was observed for a sub-sample of 173 clients (46.5%). Among the 52 CLCs who collected any DBS samples, 49 of them were observed at least once. The observation checklist included 23 items, of which 11 items were designated as critical. In 90.2% (95% CI 85.7-94.7%) of observations, all of the critical items were done properly. Observation scores were similar across CLC cadres and improved weekly over the six-week data collection period.

CLC acceptability survey

Twenty-eight CLCs participated in an acceptability survey at the end of the study. Among them, 64% had never performed a blood-based test before, while others had done blood-based HIV or malaria testing. All participants reported

Table 1. Study participant characteristics.

Category	Characteristic	Number (%)
ART Client Characteristics		
<i>Total clients consented</i>		375 (100%)
<i>Gender</i>	Male	125 (33.3%)
	Female	250 (66.7%)
<i>Age</i>	18-25 years	37 (9.9%)
	26-35 years	39 (10.4%)
	36-45 years	106 (28.3%)
	46-55 years	126 (33.6%)
	Greater than 55 years	67 (17.9%)
<i>Education</i>	No formal schooling	21 (5.6%)
	Some primary schooling	48 (12.8%)
	Completed primary school	122 (32.5%)
	Completed high school	171 (45.6%)
	Completed college or higher	13 (3.5%)
<i>Site location</i>	Rural	258 (68.8%)
	Urban	117 (31.2%)
<i>Site type</i>	Hospital	105 (28.0%)
	Primary care facility	270 (72.0%)
CLC Characteristics		
<i>Total CLCs enrolled</i>		60 (100%)
<i>Type of CLC</i>	Village Health Worker (VHW)	41 (68.3%)
	Community Adolescent Treatment Supporters (CATS)	9 (15.0%)
	Community Referral Facilitator (CRF)	3 (5.0%)
	Community Outreach Agent Coordinator (COAC)	2 (3.3%)
	Other	5 (8.3%)
<i>Average number of samples collected (among the CLCs that collected samples)</i>		7.2; min = 1, max = 18
<i>Number of trained CLCs that did not collect any samples</i>		8 (13.3%)
HCW Characteristics		
<i>Total HCWs enrolled</i>		58 (100%)
<i>Study role</i>	DBS sample collector	36 (62.1%)
	Observer	22 (37.9%)
<i>Cadre</i>	Nurse	32 (55.2%)
	Sister in charge	16 (27.6%)
	Primary counsellor	6 (10.3%)
	Other	4 (6.9%)
<i>Average number of samples collected per sample collector</i>		10.7
<i>Average number of observations completed per observer</i>		7.5

HCW = Health Care Worker; CLC = Community Lay Cadre.

Table 2. Diagnostic accuracy results comparing sample pairs collected by CLCs and HCWs.

<i>Reference sample (HCW)</i>	<i>Validation sample (CLC)</i>	
	Suppressed	Unsuppressed
Suppressed	350	6
Unsuppressed	9	7
Agreement (95% CI)	96.0% (93.4 – 97.7%)	
Sensitivity (95% CI)	43.8% (19.8 – 70.1%)	
Specificity (95% CI)	98.3% (96.4 – 99.4%)	
Positive predictive value	53.8% (25.1 – 80.8%)	
Negative predictive value	97.5% (95.3 – 98.8%)	
Cohen's kappa	0.4620	
Gwet's AC1	0.9564	
Intraclass correlation coefficient ¹	0.63 (0.55 – 0.70)	

¹Based on a two-way model of absolute agreement using average agreement for all DBS results.

a Likert scale degree of confidence; namely that they were very (89%) or somewhat (11%) confident that they could conduct DBS sample collection correctly. The survey asked about six steps of the sample collection process, and at least 93% or more of participants rated each step as very or somewhat easy.

Client acceptability survey

A total of 375 clients participated in a brief survey after their DBS samples were collected. Clients provided generally positive feedback about CLC sample collection, with 90% feeling very comfortable or comfortable with CLC sample collection, and 94% indicating that they would do CLC sample collection again in the future. Participants were asked about their preferences on the setting for VL sample collection, and 49% preferred community-based sample collection by a CLC, 25% preferred facility-based sample collection by a HCW, and 26% had no preference. Differences in client demographics were not associated with variations in preferences, but clients who received ART care at hospitals (as opposed to health centers) were significantly more likely to prefer community sample collection (Table 3).

Discussion

Task-shifting and task-sharing can be valuable strategies to relieve human resources and other constraints in a health system, but it should not be undertaken without appropriate reassurances that quality and acceptability of care will be sustained.²¹ This assessment found that CLC collection of DBS samples for HIV VL was highly acceptable and feasible. Observational assessments demonstrated the ability of CLCs to correctly and effectively use DBS VL sample collection kits. Surveys conducted with participating clients underscored that DBS VL sample collection by CLCs was a popular and welcome alternative to the standard HCW option.

This assessment assessed the diagnostic accuracy and integrity of samples collected by CLCs. There was a high degree of observed agreement in the results of samples collected by CLC and HCWs. Sample integrity was excellent and invalid results were rare. Some challenges impacted traditional measures of diagnostic accuracy, but overall, these results were reassuring regarding the accuracy of results from CLC-collected samples. For example, sensitivity and specificity require comparison to a gold standard but any DBS cannot be considered as a gold standard for VL.⁵ In other words, it is possible that in cases where HCW- and CLC-collected samples did not have matching results, either set of results was incorrect. Cohen's kappa statistic was moderate, but the resulting value was influenced by a high prevalence of viral suppression within the sample, which is associated with the limitation known as kappa's paradox. Furthermore, the assumptions for Cohen's kappa do not fully reflect our actual study conditions, suggesting this statistical approach may not be the best method to assess HCW and CLC comparability. Specifically, 1) the raters are not themselves assigning an outcome classification since this is done by the laboratory equipment conducting the DBS test, 2) nor are the raters independent from one another since the DBS tests are often run in the same lab by the same equipment, and 3) as the raters are not themselves assigning an outcome based on their judgement, this method isn't useful in handling any change agreement or any underlying subjectivity that may exist.²² In cases where key assumptions for Cohen's kappa are not met, experts have suggested the use of Gwet's AIC,^{16,17} which indicated almost perfect agreement, or simply use on observed agreement.²³ The ICC was also classified as good.

Table 3. Percentage of clients by preference for future sample collection and demographics.

Category	Characteristic	In the community by CLCs	In the health facility by HCWs	No preference	p value
	Full sample	49%	25%	26%	
<i>Gender</i>	Male	53%	26%	22%	p = 0.321
	Female	46%	26%	28%	
<i>Age</i>	18-25 years	43%	41%	16%	p = 0.095
	26-35 years	36%	38%	26%	
	36-45 years	54%	23%	24%	
	46-55 years	46%	25%	29%	
	Greater than 55 years	54%	16%	30%	
<i>Education</i>	No formal schooling	62%	24%	14%	p = 0.806
	Some primary schooling	50%	31%	19%	
	Completed primary school	45%	27%	28%	
	Completed high school	48%	23%	29%	
	Completed college or higher	57%	29%	14%	
<i>Site location</i>	Rural	48%	29%	23%	p = 0.026
	Urban	48%	18%	33%	
<i>Site type</i>	Hospital	60%	29%	12%	p < 0.001
	Primary care facility	19%	18%	63%	

HCW = Health Care Worker; CLC = Community Lay Cadre. P values are based on chi-squared tests.

In recent years, HIV programs in high-burden settings have developed and scaled DSD models for individuals which reduce reliance on the facility.²⁴ As people visit health care facilities less frequently, access to appropriate laboratory testing, particularly VL, becomes less consistent. VL collection may be done on the same day as clients' routine clinical visits and critical information around virologic response is not available until the next visit, which in some instances may be months away due to successes in multi-month refills.

Collection of VL samples in the community by CLCs could present an opportunity to innovate service delivery for decentralized and differentiated service delivery. Operational details of extending CLC sample collection into community settings need further investigation and piloting prior to deployment and implementation. Survey results from this assessment showed that some clients may prefer to continue receiving services at the facility for privacy or other reasons, but many would be open to VL sample collection in the community setting.

Even in the context of CLC sample collection for VL, the VL systems in Zimbabwe and other low resource settings still face a wide range of other challenges. These may include challenges related to sample transport and processing,²⁵ long turn-around times,²⁶ results return,²⁷ and appropriate clinical action in response to VL results.²⁸ However, because sample collection is a first step in the VL cascade, addressing any barriers to sample collection, such as lack of human resources and long waiting times for sample collection, is an important priority.

Conclusions

This assessment suggests that task-sharing VL DBS sample collection to CLCs is a feasible strategy. Observational assessments showcased CLC ability to correctly and effectively use DBS VL sample collection kits. Diagnostic assessment of lab test results comparing VL samples drawn by CLCs and HCWs were comparable. Surveys conducted with participating clients underscored that DBS VL sample collection by CLCs was a popular and welcomed choice alongside HCW collection. Based on these results, policy makers and other stakeholders in Zimbabwe and other similar

settings should consider advancing policy updates and operational efforts to enable task-sharing of VL DBS sample collection to trained CLCs at the facility level. Evidence is also needed regarding the feasibility and acceptability of CLC VL DBS sample collection in community settings.

Disclaimer

The authors alone are responsible for the views expressed in this paper and they do not necessarily represent the views, decisions or policies of the institutions with which they are affiliated.

Data Availability

OSF: Feasibility and acceptability of task sharing collection of HIV viral load dried blood spot samples with community lay cadres in Zimbabwe. <https://osf.io/z9q2r/files/osfstorage/681a223955e9064eb00a7b68>.²⁹

The project contains the following data:

- 2025-03-31 Zim VL task sharing dataset.xlsx
- Tool 4. Diagnostic comparison register.docx
- Tool 5. Usability observation checklist.docx
- Tool 6. Client acceptability survey (Phase 1).docx
- Tool 7. CLC acceptability survey (Phase 1).docx

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