00812

Patient-Collected Dried Blood Spots Provide Accurate Measurement of HIV Viral Load

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BACKGROUND

HIV viral load (VL) is a robust measure of antiretroviral therapy (ART) effectiveness and adherence and is used for clinical management of HIV.

While VL is typically measured in blood plasma, dried blood spots (DBS) of finger-prick blood provide similar performance (sensitivity: 91%, specificity: 99% at 1000 copies/mL) and are well suited to collection outside the clinic setting since they do not require phlebotomy and can be transported at ambient temperature.

Here we evaluate patient self-collection of DBS specimens, which would further simplify collection in a flexible, decentralized approach to viral load monitoring.



METHODS

In a randomized trial of community-based delivery of ART in South Africa (DO ART Study) 261 persons living with HIV provided a pair of DBS specimens at their 6 and/or 12 month visit from Nov 2018 through Nov 2019.

Study staff collected an initial DBS card while training participants, who then independently used a lancet to self-collect a second DBS card at the same visit. Venous blood was also collected for plasma VL.



Specimens were collected in KwaZulu-Natal, in the DO ART Study.

Specimens were transported 100 - 250 km to Global Labs (Durban), which used the bioMérieux NucliSENS EasyQ HIV-1 v2.0 assay to measure viral load.

Values below the DBS VL lower limit of quantification (100 copies/mL) were assigned half that value (50 copies/mL) for the reliability measurements.

We compared 315 pairs of results using concordance correlation coefficients (CCC), scatterplots, mean-difference plots, and two by two tables in R.

RESULTS

There was high correlation and agreement between log-transformed viral load results from staff-collected and patient-collected DBS cards.

CCC: 0.97 (95% CI: 0.97 - 0.98)

Mean difference:
0.02 $\log_{10}$ copies/mL

96% were within 0.5 $\log_{10}$ copies/mL

Figure 1: Staff-collected vs patient-collected DBS HIV viral loads

Correlation and agreement was also high between the plasma VL and both the staff-collected (CCC: 0.94 [95% CI: 0.93 – 0.95]) and patient-collected (CCC: 0.92 [95% CI: 0.90 – 0.94]) DBS VL.

At the limit of quantification, 12 pairs (4%) of DBS cards were discrepant:

	Staff-collected < 100	Staff-collected ≥ 100
Patient-collected ≥ 100	3	54
Patient-collected < 100	249	9

Using the WHO threshold for viral suppression, two pairs (0.6%) were discrepant:

	Staff-collected < 1000	Staff-collected ≥ 1000
Patient-collected ≥ 1000	1	46
Patient-collected < 1000	267	1

There were no clinically meaningful differences by sex or CD4 count.

CONCLUSIONS

VL results from patient-collected DBS are highly comparable to those collected by clinical staff.

Self-collection of DBS specimens could be integrated into self-care and included in a package of services for a decentralized approach to monitoring ART adherence and response outside the clinic.

Further research could evaluate patient self-collection of DBS cards in a setting without staff supervision.

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