An Investigation of Fingerstick Blood Collection for HIV Viral Load Testing

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Introduction

Viral load (VL) quantification is an important tool in identifying when to initiate antiretroviral therapy (ART) and in determining when an ART regimen is failing.[1] Testing in resource-limited settings may require sampling by fingerstick due to shortages in skilled phlebotomists and the expense of venipuncture supplies. The Northwestern Global Health Foundation is developing a point-of-care (POC) instrument and VL nucleic acid test (NAT). A minimum of 150 µl blood is required for a limit of quantification of 1,000 copies/ml of plasma.[2] If this volume can be obtained by fingerstick instead of venipuncture, the test could potentially become available in many clinics.

Primary objectives:

1. proportion of collection attempts that obtained 150 uL capillary blood
2. number of puncture sites required
3. study nurse compliance with fingerstick protocol
4. study nurse comparison of fingerstick vs. venipuncture
5. patient comparison of fingerstick vs. venipuncture.

Materials and Methods

Eligible patients were HIV-positive, currently receiving ART, and had previously been tested for CD4 and/or HIV viral load. Primary exclusion criteria included presence of heavy callouses, severe dehydration, poor finger circulation, or other illness or opportunistic infection.

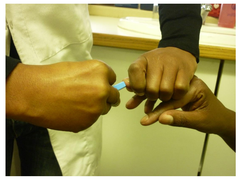


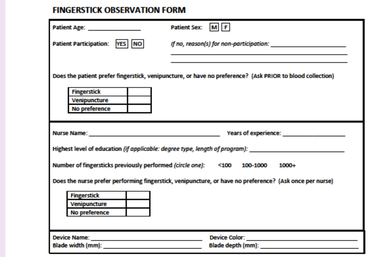
FIGURE 1. Fingerstick device demonstration.

Patients were recruited by the study nurse as they queued in the blood room. They were asked to participate after a phlebotomist administered venipuncture and collected the requested blood specimens. Each patient was asked to sign an informed consent waiver prior to receiving a fingerstick. receiving a fingerstick, patients were asked if they had a preference for fingerstick, venipuncture, or no preference.

FIGURE 2. Collection device demonstration.

Each fingerstick was administered using a BD Genie Lancet (depth = 2.0 mm, width = 1.5 mm) (Figure 1). The study nurse was blinded with respect to the fingerstick and blood collection protocol. Each step of the protocol was observed, and their completion or omission was recorded on a protocol template for every patient. A novel EDTA-treated blood collection device capable of holding 150 uL was used to discriminate between successful and unsuccessful collection attempts (Figure 2). The site of each fingerstick and the result of each collection attempt were recorded.

Following the collection attempt, every patient was asked again if they had a preference for fingerstick, venipuncture, or no preference. A verbal questionnaire was then administered. The study nurse was asked after the study if she had a preference for fingerstick, venipuncture, or no preference. Her years of experience, specific qualifications, and insights were recorded.



FINGERSTICK OBSERVATION FORM

Patient Age: _____ Patient Sex: M F

Patient Participation: YES NO *If no, reason(s) for non-participation:* _____

Does the patient prefer fingerstick, venipuncture, or have no preference? *(Ask PRIOR to blood collection)*

Fingerstick	
Venipuncture	
No preference	

Nurse Name: _____ Years of experience: _____

Highest level of education *(if applicable: degree type, length of program)*: _____

Number of fingersticks previously performed *(circle one)*: <100 100-1000 1000+

Does the nurse prefer performing fingerstick, venipuncture, or have no preference? *(Ask once per nurse)*

Fingerstick	
Venipuncture	
No preference	

Device Name: _____ Device Color: _____

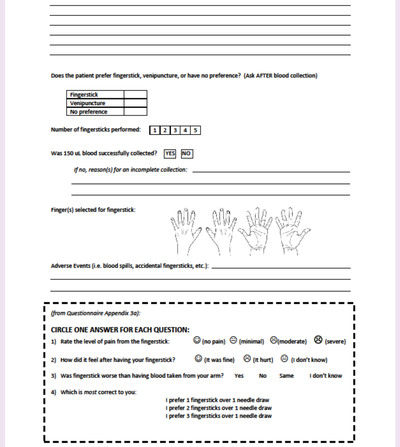
Blade width [mm]: _____ Blade depth [mm]: _____

(start timer now)

PROTOCOL OBSERVATION CHECKLIST	#1	#2	#3	#4	#5
Gloves worn by nurse	Y N	Y N	Y N	Y N	Y N
Patient sitting	Y N	Y N	Y N	Y N	Y N
Fingers warmed in advance using any method	Y N	Y N	Y N	Y N	Y N
Puncture site disinfected with alcohol pad	Y N	Y N	Y N	Y N	Y N
First drop of blood wiped away with sterile gauze pad	Y N	Y N	Y N	Y N	Y N
Hand positioned palm down	Y N	Y N	Y N	Y N	Y N
Hand positioned below elbow	Y N	Y N	Y N	Y N	Y N
Collection device held slightly above skin; scraping across skin avoided	Y N	Y N	Y N	Y N	Y N
Gentle pressure applied; strong "milking" avoided	Y N	Y N	Y N	Y N	Y N
Pressure applied after collection with sterile gauze pad	Y N	Y N	Y N	Y N	Y N

Time required to collect 150 uL: _____ min _____ sec

Comments/Explanations:



Does the patient prefer fingerstick, venipuncture, or have no preference? *(Ask AFTER blood collection)*

Fingerstick	
Venipuncture	
No preference	

Number of fingersticks performed: 1 2 3 4 5

Was 150 uL blood successfully collected? YES NO

If no, reason(s) for an incomplete collection: _____

Finger(s) selected for fingerstick:

Adverse Events (i.e. blood spills, accidental fingersticks, etc.): _____

(from Questionnaire Appendix 3a):

CIRCLE ONE ANSWER FOR EACH QUESTION:

1) Rate the level of pain from the fingerstick: (no pain) (minimal) (moderate) (severe)

2) How did it feel after having your fingerstick? (It was fine) (It hurt) (I don't know)

3) Was fingerstick worse than having blood taken from your arm? Yes No Same I don't know

4) Which is most correct to you:

I prefer 1 fingerstick over 1 needle draw
I prefer 2 fingersticks over 1 needle draw
I prefer 3 fingersticks over 1 needle draw

FIGURE 3. Observation form and patient questionnaire.

Results

- Ninety-eight percent of collection attempts were successful and 86% required only one fingerstick to successfully collect 150 uL blood (Figure 4)
- The compliance of the study nurse to the protocol template was summarized (Table 1). After completion of the study, the study nurse indicated no preference for performing either fingerstick or venipuncture.

TABLE 1. Nurse compliance to protocol.

Protocol steps	Compliance (%)
Two gloves worn by nurse	0
Patient sitting	100
Fingers warmed in advance	7
Puncture site disinfected with alcohol pad	86.3
First drop of blood wiped away	4.5
Hand positioned palm down	100
Hand positioned below elbow	55.5
Collection device held above skin; scraping avoided	96.3
Gentle pressure applied; strong milking avoided	95.4
Pressure applied after collection	100

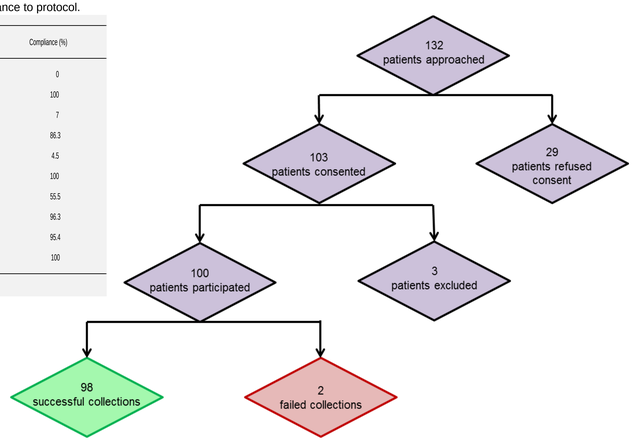


FIGURE 4. Flow diagram representing patient recruitment, exclusions, and successful collection attempts.

The results of the patient questionnaire were summarized (Table 2):

- 84% experienced no pain or minimal pain from their fingerstick(s)
- 86% indicated fingerstick was not worse than venipuncture
- 56% would prefer three fingersticks over a single venipuncture

TABLE 2. Patient questionnaire responses.

Question/Statement	Answer Choice	Responses (#)
Rate the level of pain from the fingerstick:	no pain minimal pain moderate pain severe pain	47 37 15 1
How did it feel after having your fingerstick?	It was fine It hurt	96 4
Was fingerstick worse than venipuncture?	Yes No	14 86
Which is MOST correct to you?	I prefer 1 fingerstick over 1 needle draw I prefer 2 fingersticks over 1 needle draw I prefer 3 fingersticks over 1 needle draw	28 16 56

Conclusion

- The findings from this study support the feasibility of collecting 150 uL capillary blood via fingerstick for POC HIV viral load testing in resource-limited settings.
- Omissions in many steps of the fingerstick protocol suggest that maintenance training, detailed written instructions for reference, and convenient placement of fingerstick materials may facilitate improved compliance.
- A patient-centered approach to viral load testing will include a transition from venipuncture to fingersticks for blood collection.

References

1. Saag MS, Holodniy M, Kuritzkes DR, et al. (1996) HIV viral load markers in clinical practice. Nat Med. 2:625.
2. VolumeBloodCollected x (1 – HematocritMax) x SeparationEfficiency = 50 copies/ml, where SeparationEfficiency = 75% and HematocritMax = 55%.

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FIGURE 5. Study nurse Matilda demonstrating on a blood room staff member.