Unmasking the Undetectable: Identifying and Troubleshooting a Series of Falsely Elevated HIV Viral Load Results Reported in a Series of Patients in a Community Clinic in San Antonio, Texas

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Introduction

- Effective antiretroviral therapy (ART) to consistently suppress plasma HIV RNA levels to <200 copies/mL is known to improve morbidity and mortality at all stages of HIV infection and prevent transmission to sexual partners.(1)
- Accuracy of reported Viral Load (VL) results may be affected by logistical processes such as the tubes used, transporting, processing, and storing.(2)
- Samples for VL processing can be collected in Plasma Preparation tubes (PPT) or Ethylene Diamine Tetra Acetic Acid (EDTA).(fig. 1)
- PPT tubes contain an inert gel that migrates during centrifugation, forming a barrier between the plasma and cellular elements. Adequate separation of cellular elements may not always occur, and this can result in falsely elevated HIV VL readings due to measurement of integrated intracellular virus (3,4).
- PPT Samples are routinely centrifuged at least twice, once at the time of collection and once again prior to processing to avoid this error. This is not necessary with EDTA tubes.
- Reports suggest that HIV RNA levels may be higher when PPT tubes are used, compared to EDTA tubes.(5)

Fig. 1. Plasma preparator tube (PPT) on left, Ethylene Diamine Tetra Acetic Acid (EDTA) tube on the right.

Materials and Methods

- IRB approval was obtained for this is a quality improvement project.
- The project took place in the Alamo Area Resource Center, a community clinic that dedicates to integral care for LGBTQ+ population in San Antonio, TX.
- This is a prospective review of a series of unexpectedly elevated HIV VL results that were discordant with the patient's history of adherence, drug interactions and drug resistance.
- Blood draw is obtained in our clinic location, which allowed us to review protocols and processes to identify factors that led to falsely elevated VL results.
- We met with laboratory personnel, clinic staff and clinic administration to troubleshoot potential causes of erroneous laboratory results.

Results

- A total of 20 unexpectedly elevated HIV VL were identified from January to March of 2020 after introduction of a new phlebotomist in the clinic.
- VL results ranged from 200-2530 copies/ml.
- This led to patient reported anxiety, repeat bloodwork and repeat clinic visits to better understand the significance of these results.
- Most patients (18/20) had history of virologic suppression and reported absolute adherence.
- We initially standardized our process by using only PPT tubes and centrifuging samples twice prior to sending to laboratory.
- Our nurses reported visible residual cellular elements in some of the plasma specimens in the tubes even after appropriate centrifugation. We continued to see suspected erroneous results.
- We repeated the test in EDTA tubes in 19/20 patients. 16/19 patients had HIV VL <20, the remainder values ranged from 27-41 copies/ml. (table 1)
- We then implemented the use of EDTA tubes for all HIV VL samples.
- No further cases of falsely elevated VL have been identified since the change was implemented.

PT #	Undetectable for the past 6 moths	Referred absolute adherence	Baseline VL	PPT VL	EDTA VL	days from PPT to EDTA
1	yes	yes	<20	296	<20	8
2	yes	yes	<20	595	<20	15
3	yes	yes	<20	233	<20	6
4	yes	yes	<20	1050	<20	6
5	yes	yes	<20	270	<20	5
6	yes	yes	<20	490	<20	20
7	yes	yes	<20	169	<20	6
8	yes	yes	<20	121	<20	22
9	yes	yes	<20	357	27	13
10	yes	yes	<20	453	41	6
11	yes	no *	<20	610	<20	6
12	yes	yes	<20	1030	<20	10
13	yes	yes	<20	875	<20	7
14	yes	yes	<20	246	<20	6
15	no	yes	160,000	397	<20	6
16	yes	yes	<20	539	30	30
17	yes	yes	<20	368	<20	30
18	yes	yes	<20	158	<20	41
19	no	yes	356	2530	<20	90
20	yes	yes	<20	588	not done	
* missing one dose per month						

Table 1. VL results in PPT tubes vs EDTA tubes.

Conclusions

- We were able to rapidly identify and troubleshoot a critical step that caused inaccurate HIV VL results in our community clinic.
- Detailed review of the patient's history, drug resistance, drug interactions, and adherence to treatment is essential to identify systematic problems that may lead to errors.
- Close communication with patients, staff and laboratory will be key to overcome such challenges.

References

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