

Annals of Infectious Diseases & Preventive Medicine

Open Access | Short Communication

Recommendations for Routine HIV-1 RNA Testing Need Updating

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Received: Sep 06, 2022 Accepted: Sep 29, 2023 Published Online: Oct 06, 2023 Journal: Annals of Infectious Diseases & Preventive Medicine Publisher: MedDocs Publishers LLC Online edition: http://meddocsonline.org/

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Keywords: HIV-1 viral load, HIV-1 PCR sustained viral suppression, routine blood testing anti-retroviral therapy.

Short Communication

Measurement of plasma HIV-1 RNA, known as 'viral load,' is commonly used to monitor the effectiveness of Anti-Retroviral Therapy (ART). Repeated viral load values below 200 copies RNA/ μ l of plasma define 'sustained viral suppression', the goal of ART and achievable by most patients.

HIV-1 RNA measurement by PCR was introduced in clinical practice in the early 1990s. Initially, the test was performed often, even though little could be done to affect the viral load. Eventually however, consensus settled upon testing at least once a quarter. However, the treatment of HIV has changed dramatically over 30 plus years, especially with today's use of the very powerful and durable ART. Nevertheless, recommendations for viral load testing have not changed to keep pace with the times. For example, current government websites such as Clinicalinfo.hiv.gov [1], Medlineplus.gov, [2] the much-consulted UpToDate, [3] and others [4,5] recommend a viral load every 3-6 months and a minimum of twice a year for patients successfully controlled with ART.

We attempted in this study to measure the utility of these recommendations against their real-world value and have found the viral load test to be much overutilized. In lieu of a rigorous review of a patient's ART compliance, instead reliance was upon obtaining a viral load. But, we found the cheapest and most accurate predictor of viral suppression was determining ART compliance, not reflexively ordering a viral load. We found that patients who achieved sustained viral suppression do not lose viral control unless ART is interrupted. Conversely, patients with viral loads >200 copies of RNA/µl are easily identified by history. These patients are either new diagnoses or have failed to renew their ART for various reasons such as emotional crisis, incarceration, or hospitalization. Routinely obtaining viral loads every 3-6 months will not "discover" high viral loads, this is more rapidly revealed by the history. Little is accomplished by routinely ordering viral loads, except to force patients to expend time and money to provide a test result. Current ART regimens are so durable and powerful that the need for checking "their efficacy" could safely be reduced to once a year.



Cite this article: Stephen A Klotz, Lawrence D York. Recommendations for Routine HIV-1 RNA Testing Need Updating. Ann Infect Dis Prev Med. 2023; 2(2): 1006.

MedDocs Publishers

Methods

HIV patients attending a single physician's Telemedicine Clinic during 2022 were included in the study. The clinic receives federal funding from Health Resources Services Administration including Ryan White funding, and thus is subject to federal guidelines, meaning, viral load tests at least twice a year are ordered on each patient. Patient data was abstracted from an eMR and de-identified. Viral load test results and progress notes were recorded for all patients attending clinic in 2022. Additionally, for each patient who attended clinic in 2022, the same data were recorded for the years 2019-2021 to establish continuity in time. In many cases patients did not perform viral loads within our hospital system and results were not recorded in the eMR. In such cases progress notes were searched for mention of viral loads and/or patient compliance with ART. This allowed us to assume whether the patient was virally suppressed or not. The patient's age, ART regimen, and concurrent diagnoses or drugs were also recorded. The pharmacist attended every Telemedicine clinic, took a thorough interim history regarding ART including compliance estimates, missing doses, new prescriptions and over-the-counter medications. The pharmacist also reviewed refill requests, renewed ART, and entered a separate note into the eMR.

Results

2022 Encounters. During 2022 there were 274 total patient encounters including 11 follow up encounters, thus, 263 unique patient encounters occurred for the year. In 2022, 8/263 of the encounters involved patients with >200 copies of HIV-1 RNA/ μ L plasma. Sustained viral suppression occurred in 255 or 97.0% of patients.

It is seen in **Figure 1** that the majority of patients are virally suppressed throughout 2022. Some had >200 copies or RNA but after beginning ART were virally suppressed within the year. Eight (8) patients did not demonstrate sustained viral suppression for 2022, one (1) patient was a newly diagnosed HIV infection and was begun on ART for the first time; six (6) patients had run out of ART for various reasons and were returned to their prior ART regimen; and one (1) poorly compliant patient was counseled to adhere to the ART regimen. One patient seen in 2021 as a new diagnosis was seen again in 2022 but had not started ART (white block) (Table 1 & Figure 1). Figure 2 shows that like 2022 the cohort of patients were by far and away virally suppressed. This figure shows that the same cohort of patients seen in 2022 achieved and maintained viral suppression. However, it is also apparent that a number of patients will experience interruption of ART as well as blips which are of minor interest.

We tabulated encounters with viral loads >200 copies of RNA for each of the years, 2019-2022 (lower part of **Table 1**). The commonest reasons for elevated viral loads were new diagnosis (13 patients), running out of medications (11 patients), non-compliance (7 patients) and 2 patients who stopped their medication. One patient had begun pantoprazole, which was stopped, and the patient regained viral suppression. Only one patient seen in all 4 years never achieved viral suppression, likely because of non-compliance. Otherwise, all the foregoing issues with patients were successfully addressed, either by starting ART on new diagnoses, or returning patients to their former ART. Events during the calendar year had some influence on our measurements. For example, in 2021 the clinics were a mix of Brick-and-Mortar or Telemedicine clinics (patients chose which venue to attend) in response to the COVID 19 pandemic. In 2022 clinics were almost entirely conducted by Telemedicine where attendance was 94.7% of those scheduled for clinic whereas, in Brick-and-Mortar clinics the attendance was 78.7% of those scheduled [6].

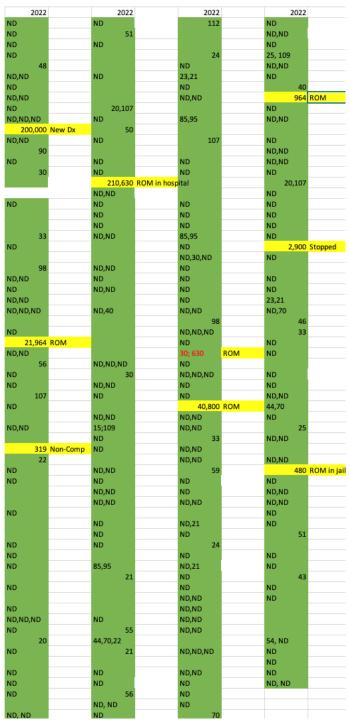


Figure 1: Viral load values for 263 unique patients encountered in 2022. **Green blocks**: Individuals demonstrating sustained viral suppression (viral loads are <200 copies of RNA/μl) as measured or from progress notes or history; **Yellow blocks**: patients with >200 copies of RNA (explanations provided in column to the right); **White block**: patient newly diagnosed with HIV in 2021 but had not taken ART when seen in 2022. **Red print**: patient's viral load was >200 copies of RNA in 2022 but later values in the same year were not detectable. **ND**: not detectable RNA <20 copies); **New Dx**: newly diagnosed HIV; **ROM**: ran out of medications; **Non-Comp**: poor compliance with ART.



Figure 2: Viral load values for 2021 to 2019 for patients who attended clinic in 2022. **Green blocks**: viral loads are <200 copies of RNA/µl or as determined from outside progress notes; **White block**: viral load >200 copies RNA. **Red print**: patient's viral load was >200 copies RNA/µL in the respective year but later values in the same year were <200 copies of RNA/µL, thus, these encounters are in Green. **ND**: no detectable HIV-1 RNA by PCR of plasma (<20 copies of RNA); **New Dx**: newly diagnosed HIV; **ROM**: ran out of medications; **Non-Comp**: poor compliance with ART.

Discussion

A great deal of HIV patients' time and resources are expended each year to meet arbitrary requirements regarding viral load testing. Currently it is recommended by federal agencies and "Authorities" that HIV patients have anywhere from 2-4 viral loads performed each year [1-5]. This seemed a sensible approach when adopted years ago, however, ART regimens today are extremely powerful and resistant to viral mutation.

We found that 97% of patients in 2022 were virally suppressed and the 3% (8) who were not will achieve viral suppression within a year based upon previous experience of a patient cohort from 2019-2021 (see **Figure 1 & 2**). Perusal of the figures shows that over time new HIV diagnoses and those patients with interrupted ART regain viral suppression. Viral resistance to ART is rarely encountered in this scenario. This is important since over years ART interruption occurs to a substantial number of individuals and we always return them to their previous ART. It has been years since we have encountered de novo viral resistance. The last time viral resistance was not infrequently seen was during the period when protease and nucleoside inhibitors were common regimens or early raltegravir regimens. Table 1: Viral load measurements for patients encountered in2022 for the years 2019-2022.

	2022 (%)	2021 (%)	2020 (%)	2019 (%)	Total (%)
Viral Loads	210	257	160	127	754
Non Detectable Viral Loads	146 (70)	185 (72)	116 (72)	107 (84)	554 (74)
"Blips"	56 (27)	59 (23)	33 (21)	18 (14)	166 (22)
Viral Loads >200 copies	8 (4)	13 (5)	11 (7)	2 (2)	34 (4)
New diagnosis	1	8	4		13
Non-compliance	1	3	2	1	7
Ran out of medications	6	1	3	1	11
Stopped medications		1	1		2
Drug interaction			1*		1

Breakdown of reasons for patients with viral load >200 copies of RNA/ µl. **Blips**: this refers to test results with >20 but <200 copies of HIV-1 RNA. *: pantoprazole was added to a regimen of elvitegravir/cobicistat/emtricitabine/tenofovir (Genvoya) by an outside physician.

As long as patients continue ART as prescribed there is no advantage to ordering a routine viral load. Also, when patients experience a lapse in their ART, there is no reason to order a viral load, rather the first step is to place the patient on their previous ART regimen and then check the viral load several months later. This is the quickest way to confirm whether drug resistance, albeit highly unlikely, has occurred.

We have found that once patients have achieved viral suppression the interim history is the most rapid and accurate gauge of sustained viral suppression. This can be accomplished without routine viral load testing. Sustained viral suppression is the goal of therapy, and once achieved, persists unless ART is interrupted. Performing a viral load once a year is likely to be adequate. Its value lies in reassuring the patient, more so than the medical provider.

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