HIV/AIDS TREATMENT INFORMATION SERVICE

Understanding Viral Load

March 1997

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ATIS would like to acknowledge the AIDS Clinical Trials Group for their contribution.

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Introduction

Measurements of HIV- RNA blood levels (viral load) are increasingly being used by health care providers to determine when to start antiretroviral therapy and when to change current therapies. This test has become very important in the management of HIV infection because studies have shown that the level of virus in the blood is a predictor of disease progression. In other words, people with high levels of HIV-RNA in their blood, are more likely to rapidly progress to AIDS than people with low levels of the virus.

Because viral load testing is an integral part of the management of HIV disease, it is important to learn what this test is and how it is used. Trying to understand viral load testing isn't easy. This fact sheet was developed to help clarify information about viral load testing.

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What Is Viral Load And How Is It Measured?

Viral load or viral burden is the quantity of HIV-RNA (HIV virus) that is in the blood. RNA is the genetic material of HIV that contains the information needed to make more virus. Viral load tests measure the amount of HIV-RNA in a small amount of blood (one milliliter, ml). There are three different viral load tests currently being used:

- PCR (polymerase chain reaction) is the most common of these tests and is the only test approved by the FDA. Test results are reported as copies/ml of plasma.
- bDNA (branched chain DNA assay) is also frequently used. These results are reported as units/ml of plasma.
- NASBA (nucleic acid sequence-based amplification) is less frequently used and reports test results as units/ml of plasma.

Because the tests do not give exactly the same results, it is important to have the same type of viral load test done each time. This will give the physician a baseline measurement against which changes can be evaluated. Since the results of this test can vary greatly, they should be interpreted in the context of clinical management with an experienced physician.

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When Should Viral Load Be Measured?

An Expert Panel for the International AIDS Society-USA (1) has issued guidelines indicating when viral load should be measured. The following is the Panel's timetable for testing:

- Take two different viral load measurements 2-3 weeks apart to determine a baseline measurement.
- Repeat every 3-6 months thereafter in conjunction with CD4 counts to monitor viral load and T-cell count.
- Repeat the test 4-6 weeks after starting or changing antiretroviral therapy to determine the effect on viral load.

Avoid measuring viral load in the 3-4 weeks following an immunization (including flu shots) or within one month of an infection. Temporary increases in viral load have been seen in these instances. To minimize misleading results, it's best to avoid testing at these times.

Another consideration for measuring viral load is cost. Because the test is expensive (tests can range between $63-$292 with a commonly reported cost of

$200 per test), it is important to have them drawn at appropriate times.

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What Prompts Changes In Viral Load?

Changes in viral load are often reported as logarithmic or "log changes." This mathematical term denotes a change in the value of what is being measured by a factor of 10. For example, if the baseline viral load by PCR were 20,000copies/ml plasma, then a 1 log increase equals a 10-fold (10 times) increase or 200,000 copies/ml plasma. A 2 log increase equals 2,000,000 copies/ml plasma, or a 100-fold increase.

Using the same starting point of 20,000 copies/ml plasma, a 1 log decrease means that the viral load has dropped to 2,000 copies/ml. A 2 log decrease equals a viral load of 200 copies/ml plasma. An easy way to figure out log changes is to either drop the last "0"or add "0"to the original number.

Any change of less than one-half log is considered insignificant. More simply, if the viral load measurement has not tripled or dropped to one-third of its previous level, the difference might be unimportant. For example,if the baseline viral load were 20,000 copies, a rise to 60,000 or a fall to 7,000 copies might just be the result of transient changes. Repeat testing of a single specimen may give two quite different results and natural biological day-to-day variability of samples from the same person may cause measurements to vary slightly. Researchers believe that clinical decisions made on the basis of changes in viral load ideally should be based on measurements taken 2-3 weeks apart.

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What Does An "Undetectable" Level Mean?

Many individuals now have an "undetectable" level of virus in their blood after taking combination therapy. "Undetectable" levels do not mean that the person is "cured" or no longer infectious. "Undetectable" levels mean that current tests are not sensitive enough to measure very low levels of virus in the blood, for example less than 400 copies/ml. There are experimental assays used in research which are more sensitive and can detect levels of virus as low as 20 copies/ml but they are not generally available in clinics and doctor's offices.

Even if the measurement of virus is less than 20 copies/ml in the blood, HIV may be present and infectious in blood, genital secretions (such as semen),

lymph nodes, other lymphoid tissues, and elsewhere in the body. There are insufficient data to say that individuals with "undetectable" levels of virus are no longer infectious or no longer at risk of disease progression in the future. We simply do not know yet what an "undetectable" level of virus means over the long term. Individuals with "undetectable" levels of virus still need to be monitored by their health care providers regularly and they need to practice risk free behaviors.

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Is There Still a Need to Have CD4+ Levels Monitored?

Even with ongoing monitoring of viral load, it is important to monitor CD4+ levels. CD4+ levels provide information about the status of the immune system. Research has shown that when viral load is lowered, CD4+ levels usually increase. However, research is still ongoing to determine whether the increase in CD4+ levels represent normal, functioning immune cells. CD4+ levels continue to be used as the basis for deciding what type of opportunistic infection prophylaxis a patient should take. Some physicians feel decisions about prophylaxis should be based on the lowest CD4+ level recorded for a person. CD4+ cell levels are also used to measure response to antiretroviral treatment, although most regard viral load as more important indicator. In order to provide the physician with the best possible information about a patient's disease status, it is important to have routine viral load *and* CD4+ levels measured.

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Additional Information

For additional information about viral load testing or other treatment issues, contact:

> HIV/AIDS Treatment Information Service
> 1-800-448-0440 (Voice)
> 1-800-243-7012 (TTY)
> 1-301-738-6616 (Fax)
> atis@cdcnac.org
> http://www.hivatis.org

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1. Saag MS, Holodniy M, Kuritzkes DR, et al. HIV viral load markers in clinical practice: recommendations of an International AIDS Society-USA Expert Panel. *Nature Medicine*. **1996;2:625-629.**

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