nam national aids manual

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# Viral load

information series for positive people

## Introduction

This booklet focuses on blood tests called viral load and CD4 counts. These tests are crucial in helping you decide when to start treatment, and to monitor the effects of your treatment.

This booklet is not intended to replace discussion with your doctor about your treatment or test results. However, it may help you to decide what questions to ask your doctor about any course of treatment you may be considering.


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# CD4 counts

## What is the CD4 count?

CD4 cells, or T-helper cells, are white blood cells which organise the immune system's response to some micro-organisms, including bacteria, fungal infections and viruses.

The CD4 count is the measurement of the number of CD4 cells, in a cubic millimetre of blood (not the whole of your body). This is sometimes written as CD4 cells/$mm^3$.

The CD4 count of a person who is not infected with HIV may lie anywhere between 500 and 1200. HIV can infect CD4 cells and use them to produce more HIV copies.

Even while a person with a HIV feels well and has no symptoms, millions of CD4 T-cells are infected by HIV and are destroyed each day, and millions more CD4 T-cells are produced to replace them.

## What CD4 counts predict

Most people with HIV find that their CD4 count usually declines over a number of years.

A CD4 count between 500 and 200 indicates that some damage to the immune system has occurred.

If your CD4 count drops below 350, or starts falling rapidly, your doctor should talk with you about whether you need to start anti-HIV treatment.

If your CD4 count falls below 250-200 and you are not taking anti-HIV drugs, your doctor should talk with you about starting treatment that will prevent PCP (a form of pneumonia).

The most important information that your CD4 count can give you is the overall trend of your immune system's health - whether it is declining or improving.

## Changes in the CD4 count

Your CD4 count can go up and down in response to infections, stress, smoking, exercise, the menstrual cycle, the contraceptive pill, the time of day and even the seasons of the year. Different types of CD4 counting-machine also give different readings.

This is why it is important to monitor its trend over time, rather than to focus too much on individual test results. It's also best to have your CD4 count measured at the same clinic and at roughly the same time of day wherever possible.

If you have an infection like flu or herpes it is best to delay having a CD4 count until you are feeling better. If you have a relatively high CD4 count, no symptoms and you are not taking anti-HIV drugs, you only need to measure your CD4 count once every three months.

However, if your count has been falling rapidly, or you are taking part in a clinical trial, or you have just started new treatment, your doctor may suggest that your count should be monitored more often.

# Viral load

'Viral load' is the term used to describe the amount of HIV in your blood. The more HIV in your blood, the faster your CD4 cells are likely to disappear, and the greater your risk of developing symptoms or further illness within the next few years.

## What is the viral load test?

Viral load tests estimate the number of HIV particles in a sample of blood. They do this by looking for HIV's genes, which are called HIV RNA.

The result of a viral load test is described as the number of 'copies' of HIV RNA per millilitre.

There are several different viral load tests in use at the moment. Each test uses a different technique to measure the number of HIV particles, but all the tests are equally reliable at determining whether your viral load is low, medium or high.

All the viral load tests are now equally accurate at measuring types of HIV which are common in Africa and Asia. In the past, some tests couldn't always pick up these HIV strains.

## Natural variations

Viral load measurements can rise and fall from one blood sample to the next but this may have no long-term impact on the health of the person being tested.

Researchers have investigated viral load changes in people not on treatment and found that two separate tests on the same sample of blood can give results which differ by as much as three fold.

For example, this means that you shouldn't necessarily be worried if your viral load goes up from 5,000 to 15,000 at a time when you are not on treatment.

Similarly, a rise from 50,000 to 100,000 if you aren't on treatment may not be significant, although it may seem like a big increase. Viral load appears to have doubled, but it's within the margins of error for this test.

## Significant changes

The time to be concerned is when viral load results over several months show an upward trend, or when the increase is greater than threefold.

For example, a rise from 5,000 to 25,000 is significant. It represents a fivefold increase in the amount of virus in your blood since your last viral load test. However, it is still best to confirm this trend on a repeat test.

## The effects of vaccinations and infections

If you currently have an infection or have recently received a vaccination, you may have a temporary increase in your viral load. In these cases it is best to avoid having a viral load test for at least one month after the vaccination or illness.

## Minimising variation

You are more likely to get accurate information on viral load trends if your blood is tested at the same clinic, using the same testing method. When your viral load is first tested, make a note in the box below of the method which was used. Was it:

- ❑ Roche Amplicor Ultra Sensitive HIV-1 Monitor
- ❑ Chiron Quantiplex b-DNA version 3.0
- ❑ Organon-Teknika Nuclisens
- ❑ other . . . . . .

When you are given future viral load results, check that the same method was used.

# Why do I need to know my viral load?

## If you are not currently taking anti-HIV treatment

If you are not taking anti-HIV drugs, your viral load can provide information on the likely course of HIV infection if left untreated.

A study of viral load levels in untreated people suggests that, in combination with your CD4 count, they may help you to predict your risk of developing symptoms in the future.

Among people with the same CD4 count, research shows that those with higher viral load tend to develop symptoms more quickly than those with lower viral load.

Among people with the same viral load, those with lower CD4 counts tend to develop symptoms more quickly.

Thinking about it another way, HIV disease is like a train heading for a crash, where a crash is the point at which you might become ill.

Viral load shows how fast the train is going: low, medium or high speed. The CD4 count shows how many miles of track are left before the crash.

As the diagram below shows, taken together both CD4 count and viral load provide valuable information to predict the likelihood of developing AIDS in the short to medium term.

If you look at the column for people whose CD4 counts were between 351 and 500, there is a big difference in the risk of disease progression, depending on their viral load.

## Predicting progression

**% OF PEOPLE WHO DEVELOP AIDS WITHIN 3 YEARS (ASSUMING NO TREATMENT)**

| Viral load | | CD4 count | | | | |
|---|---|---|---|---|---|---|
| **Roche test** | **Chiron test** | Below 200 | 201-350 | 351-500 | 501-750 | Above 750 |
| Below 1,500 | Below 500 | ** | ** | ** | 3.7 | 0 |
| 1,500-7,000 | 500-3,000 | ** | ** | 2.0 | 2.0 | 2.0 |
| 7,000-20,000 | 3,000-10,000 | ** | 8.1 | 8.1 | 8.1 | 3.2 |
| 20,000-55,000 | 10,000-30,000 | 40.1 | 40.1 | 16.1 | 16.1 | 9.5 |
| Above 55,000 | Above 30,000 | 85.5 | 64.4 | 42.9 | 32.6 | 32.6 |

** Indicates lack of data

## Deciding whether to start treatment

The level of your viral load, along with other indicators, may help you to decide whether to start anti-HIV treatment.

At the moment, some doctors recommend treatment when your viral load is still relatively low, in the 10,000 to 20,000 range, even if your CD4 count is high.

Others think that it may be better to delay treatment until your viral load is higher (e.g. above 30,000 copies), and to take note of your CD4 count too. At the moment there's no clear evidence which course of action is best. The table on the opposite page may help you to estimate your risk. It's up to you to decide whether you feel comfortable with that level of risk, or if you want to consider starting treatment.

## The effect of treatment

Effective anti-HIV treatment results in a reduction in viral load. If you start anti-HIV treatment your doctor will test your viral load after four to twelve weeks of treatment to see how much your viral load has gone down.

Changes in viral load are sometimes expressed using a logarithmic (log) scale.

EXAMPLE -

If your viral load falls from 100,000 to 10,000, this is a 1 log reduction.

EXAMPLE -

If your viral load falls from 100,000 to 1,000, this is a 2 log reduction.

EXAMPLE -

If your viral load falls from 100,000 to 100, this is a 3 log reduction.

Viral load

# Undetectable viral load

## What is undetectable viral load?

All viral load tests have a cut-off point below which they cannot reliably detect HIV. This point is called 'the limit of detection' and varies from one testing kit to another.

However, just because the level of HIV is too low to be measured by these tests, it does not necessarily mean that the virus has disappeared entirely. The virus may still be present in your blood, but in amounts too low for the test to pick it up.

## What are the limits of detection of current tests?

For tests used in the past, the lower limit of detection was 400 or 500 copies. However, 'ultrasensitive' tests which measure down to 50 copies are now more widely used.

## The value of having undetectable viral load

Having undetectable viral load is desirable for two reasons:

- a very low risk of developing AIDS
- a very low risk of developing resistance to the drugs you are taking now.

Doctors now think that undetectable viral load (below 50 copies) should be the aim of treatment.

Some people take three to six months to reach this point, while others go below the limit of detection within four to twelve weeks, and others may never achieve this goal.

People taking anti-HIV drugs for the first time are more likely to reduce their viral load to these very low levels than those who have taken treatment previously.

Some doctors will recommend changing your combination or adding another drug if you don't have undetectable viral load after three months on a new combination of drugs.

However, doctors differ in their view of how quickly treatment should be changed. Some favour switching 'early' to reduce the risk of resistance. Others argue that this approach may cause you to stop treatments from which you were still benefiting.

Changing treatment should ideally involve switching to a combination involving drugs which you haven't taken before, and which are unlikely to be 'cross-resistant' to those you've taken previously. This may pose more of a challenge the more drug experience you have.

It may also be the case that the quicker your viral load falls below 50 copies, the longer it should stay there, providing you keep taking the drugs as instructed.

After six months on a first-line combination, your viral load should ideally have gone below 50 copies. Some people do not respond this well, however.

It may be useful to remember that even if your viral load is reduced to below 5,000 copies, your risk of developing an HIV-related illness is still very low while it stays at this level.

**At the moment, there's no clear evidence about when is the best time to change treatment when it comes to prolonging life and keeping people healthy in the long-term. But if your viral load is rising fast, or your CD4 count is falling, or you are developing symptoms, most doctors would advise you to change treatment, if options are available.**

# Viral load and drug resistance

## Developing resistance

If you develop HIV which is resistant to the drugs you are taking, this means that they will be unable to suppress HIV efficiently, and viral load usually begins to rise.

Keeping viral load below the level of detection is associated with a very low risk of developing resistance to the anti-HIV drugs you are taking.

This is because the chance of developing resistance when you are taking anti-HIV drugs depends on the amount of HIV which is still being produced in your body.

The lower your viral load, the lower your risk of developing resistance to the drugs you are taking.

So, suppressing viral load to undetectable levels (below 50 copies) is likely to delay the development of resistance for longer.

## Cross resistance

HIV that has developed resistance to one drug that you are taking may also be resistant to other drugs which you have not taken yet. This is called cross-resistance.

Cross-resistance can limit the range of drugs you can take in the future. In order to keep as many options open as possible, some doctors argue that treatment should always aim for undetectable viral load.

However, other doctors take the view that if you switch drugs every time your viral load rises above the limit of detection, you may run out of drugs relatively quickly.

For more information, see another NAM booklet in this series, *Resistance*.

# Viral load and HIV transmission

If you have high levels of HIV in the blood, you may also have high levels of HIV in semen and vaginal fluid. People with high viral load are likely to be more infectious.

Anti-HIV treatment which reduces viral load in the blood usually also reduces HIV levels in semen and in vaginal fluid.

However, even if your viral load becomes undetectable after treatment, this doesn't mean that HIV has disappeared from your semen or vaginal fluid. You still risk passing on the virus during sexual intercourse if you aren't using a condom with your partner.

Anti-HIV treatment has been proven effective in reducing mother-to-baby HIV transmission. If you are pregnant or planning to conceive, discuss your treatment options with your doctor.

If you have undetectable viral load whilst pregnant, the risk of passing HIV to your baby will be very low.

# How often should I have my viral load tested?

## If you are not on treatment

As the table on page 5 shows, there's a big difference between having a low viral load of 5,000 compared with a high viral load of 50,000, even when you have a CD4 count above 500.

Even if your CD4 count is currently above 500, it is a good idea for you to attend your clinic for viral load testing every three months, and to get the results back quickly.

## If you are about to start treatment

Get two 'baseline' viral load measurements before starting, so that later you will be able to see just how well your treatment has worked.

## If you have started treatment

It is possible to get an indication of how well your combination therapy is working by testing your viral load after a month or so, and again after three months of treatment. Subsequent tests should occur every twelve weeks. Additional tests may be needed from time to time, for example if you develop symptoms. You should get these results within a week if they are to provide an accurate picture of the current effect of your treatment.

The level which your viral load has reached at these points usually predicts how long this particular combination will keep your viral load low, or undetectable.

The initial fall in viral load after four months is also an accurate indicator of how much benefit you'll get from this combination in the next few years in terms of a reduced risk of developing AIDS or further illness.

The greater the fall in viral load at this point, the better your prognosis.

## If you have just had an increase in viral load on treatment

Another test should be carried out within two to four weeks to confirm this result.

You should always have viral load and CD4 counts tested at the same time.

# Summary Flow Chart

Take two viral load tests a few weeks apart to get the baseline viral load and CD4 cell count

If viral load is more than 30,000 copies, and/or your CD4 count is below 350, talk to your doctor about whether to begin treatment or wait

If viral load is less than 30,000 copies,and/or your CD4 count is above 350, take another test in 3 months to check it remains the same

Test viral load and CD4 count every 3 months. If your viral load goes up,or your CD4 count falls, review with your doctor and discuss whether treatment is now advisable

Begin finding out which treatment may be most suitable for you

Begin treatment

Take viral load and CD4 counts after 4-12 weeks to see if new treatment is lowering viral load and boosting CD4 cells.

If viral load hasn't fallen below 50 copies by week 12, discuss intensifying or changing treatment

If remaining on the same combination take viral load and CD4 counts at 24 weeks to check that viral load has fallen below 50 copies.

If your viral load remains above 50 copies after 24 weeks, your doctor may recommend that you change to a new combination. The strength of this recommendation is likely to depend on the drug options available to you.

If your viral load has fallen below 50 copies, continue monitoring both viral load and CD4 count every 12 weeks.

If your viral load rises above 50 copies take another test within 2 to 4 weeks to confirm this result

Consider switching to a new treatment combination if your viral load is rising.

# Where to go for further information

## NAM Publications

**020 7627 3200**
NAM/BHIVA website:
http://www.aidsmap.com
Email: info@nam.org.uk

NAM Publications produces the *HIV and AIDS Treatments Directory*, the monthly newsletter *AIDS Treatment Update*, monthly factsheets, and information booklets about HIV/AIDS and treatments. NAM also produces a directory of all HIV/AIDS services, clinics and community organisations throughout the UK.

## AIDS Treatment Project.

**020 7407 0777**
**Treatments helpline 0845 9470 047**
Mon and Wed 3-9pm, Tue 3-6pm
St Stephen's House
115-129 Southwark Bridge Road
London SE1 OAX
Email: admin@atp.org.uk

## Body Positive

**020 7287 8010**
**Positiveline 0800 616 212**
Sun-Fri 7-10pm, Sat 4-7pm
14 Greek Street, Soho, London W1V 5LE
Email: bp@bodypositive.demon.co.uk

## Positively Women

**020 7713 0444**
**Helpline 020 7713 0222**
Mon-Fri 10-4, except Tuesday 10-2
347-349 City Road, London EC1V 1LR
Email: poswomen@dircon.co.uk

## Terrence Higgins Trust

**020 7831 0330**
**Helpline 020 7242 1010**
daily 12 noon-10pm
52-54 Grays Inn Road
London WC1X 8JU
Email: info@tht.org.uk

## Vanguard AIDS Information Service

**For African refugee communities**

**020 7627 5170**
26b Thames House
South Bank Commercial Centre
140 Battersea Park Road
London SW11 4NB
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