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information series for hiv-positive people

hiv therapy

acknowledgments

This edition edited by Michael Carter

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NAM is a charity that publishes information for people affected by HIV and those working with them. We believe information helps people to make decisions about, and be in control of, their lives, health and treatment options.

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hiv therapy

The British HIV Association (BHIVA) is the UK's professional body for doctors who care for people with HIV and AIDS. BHIVA produces guidelines on how the medical care of people with HIV should be managed. Recently, BHIVA has agreed revised practice guidelines for 2005/6 on the use of drugs given to treat HIV infection.

This booklet has been written to help you decide what questions to ask your doctor about any course of treatment you might be considering. We don't intend for it to replace discussion with your doctor about treatment.

contents

1 BHIVA HIV treatment guidelines

This booklet is a summary of the BHIVA HIV treatment guidelines: a set of recommendations about how anti-HIV therapy should be used to treat people with HIV infection in the United Kingdom. Several of the subjects covered within the guidelines are not included in this booklet, a few examples being the side-effects of treatment including lipodystrophy, the syndrome of blood and body fat changes which can affect people taking HIV therapy; detailed information on the treatment of HIV if you also have hepatitis B or (and) hepatitis C virus; and details of HIV treatment for people with tuberculosis (for more information on these subjects see the booklets *Lipodystrophy*, *HIV and hepatitis* and *HIV and TB* in this series). If you would like to read the 2005/6 BHIVA treatment guidelines in full, they are available on www.bhiva.org.

BHIVA formulates its recommendations through a consensus-building exercise where advice is based primarily on evidence from clinical trials, and where there is no such evidence, on the opinion of HIV experts. This is because there is not enough scientific research to answer all the questions about the best use of HIV treatments. Research in the HIV field

moves unusually quickly, which means that the guidelines summarised in this booklet should be seen as a "best practice" based on what we know about HIV infection and its treatment at the moment.

These guidelines are not a recipe book for treating your HIV infection. HIV always requires individualised care, which is based both on your past and present state of health, and on the wider factors which influence your daily life.

3 What is anti-HIV therapy?

Drugs given to treat HIV are also called antiretrovirals. Another name commonly used is HAART, which stands for highly active antiretroviral therapy. This means taking combination therapy of three or more anti-HIV drugs, and is the standard way of treating HIV in most people.

Currently available anti-HIV therapy does not eliminate the virus from the body. Instead, it can prolong life and good health by suppressing HIV replication and therefore reducing the harmful effects of HIV on the immune system.

When should anti-HIV therapy be started?

There is no clear evidence on when is the best time for you to start taking anti-HIV drugs. This means that you must weight up with your doctor, on an individual basis, the likely benefits and risks of taking treatment now, as opposed to waiting until later. The current view is that treatment is clearly beneficial:

- If you have symptoms of HIV or AIDS.
- If you have a low CD4 count, another sign that the immune system is damaged.

BHIVA's recommendations about the timing of starting treatment depend upon your disease stage, meaning the length of time since you were infected, your CD4 count and the amount of HIV in your blood (viral load), and whether or not you have symptoms of HIV. These are summarised in Table 1 on the following page.

Table 1: When should anti-HIV threatment be started?

HIV disease stage	CD4 Count	Recommendation
Early (primary) infection	Any CD4 level	If treatment is being considered, start as soon as possible, and certainly within six months of infection
Established (chronic) infection without symptoms	CD4 above 350	Take treatment later
	CD4 between 200 and 350	Start treatment, taking into account the rate of CD4 decline, symptoms, patient's wishes and viral load
	CD4 below 200	Start treatment
Established (chronic) infection with symptoms	Any CD4 level	Start treatment

If you have contracted HIV very recently

The six month period which follows immediately after you contracted HIV is called primary infection. There is no proof that starting treatment at this time will definitely lead you to live a longer, healthier life.

Some doctors believe, however, that this time may offer a unique chance to intervene which may be lost later in infection as your immune system sustains ongoing damage, and so may be less able to respond to HIV itself.

This potential benefit has to be weighed against the risk of you getting side-effects, finding that treatment reduces your quality of life, and the possibility that if the treatment you take stops working effectively against HIV, you may be left with a drug resistant virus.

A few people who took anti-HIV treatment very soon after infection seem to have maintained extremely low levels of HIV, even after stopping treatment. Others who have tried the same strategy have not had this response. Because there is a lack of clarity, it's recommended that you join a clinical trial wherever possible if you do choose to take treatment in primary infection.

Taking treatment at this stage may also be beneficial if your are experiencing a severe HIV seroconversion illness. It is not clear if you do start treatment at this time if you will have to continue to take it indefinitely. It is also possible that if you had symptoms they will come back if treatment is stopped.

If you have established (chronic) infection but not had HIV symptoms

Ideally, you should begin treatment before your CD4 count falls below 200. This is because if you start treatment when your CD4 count is below 200, you may face a greater risk of ill health and even death, in the short-term, than if you start while your CD4 count is still above 200.

At higher CD4 counts, the picture is less clear. Most studies suggest that there seems to be no difference in the short-term risk of ill health if you begin treatment at CD4 counts above the 200 level. Therefore, the timing in these circumstances will depend on the level of your viral load, the speed at which your CD4 count is falling, the likelihood of you achieving good adherence to treatment, the presence of symptoms, the presence of hepatitis C virus coinfection and your wishes.

You may choose an earlier start, particularly if your CD4 count is falling by more than 80 cells per year, because this is likely to mean that the count will fall below 200 within the near future. Similarly, if you have a high viral load, and are not taking treatment, then you lose CD4 cells more quickly than others, and are at greater risk of illness or death in the short-term, and you may, therefore, choose to start treatment sooner.

You may wish to consider starting treatment earlier if you are also infected with hepatitis C virus (HCV), as liver disease becomes worse when the CD4 cell count is lower. The booklet *HIV and hepatitis* in this series has more information.

Delaying therapy reduces the impact of long-term side-effects and the development of drug resistance. Future therapies may be easier to take, less toxic and perhaps more effective against HIV. The best responses to anti-HIV treatment are generally seen with the first drug combination, so starting too early, or with the wrong drug combination may not be the best option.

If you are advised to start treatment but choose not to, then you should review your decision regularly and have your CD4 count and viral load monitored more frequently than usually recommended, for example every two months.

People with symptoms of HIV disease or AIDS

Everyone who has symptoms of HIV infection and has a CD4 count consistently below 200, or who has previously been diagnosed with AIDS or a severe or recurring HIV-related illness, should start treatment. If you have reached any of these points you have a high risk of opportunistic infections.

A possible exception, however, are people with tuberculosis (TB). There are potential interactions between anti-HIV drugs and a key medicine used to treat tuberculosis. Because of this, many doctors recommend delaying treatment with HAART until an individual has taken at least two months of tuberculosis treatment. Similarly, if you become ill with tuberculosis whilst taking HAART, you may be recommended to stop taking anti-HIV drugs for the first two months of tuberculosis treatment. There is a lot more information about this in the booklet, *HIV and TB*.

What to start therapy with

Standard anti-HIV treatment for people who are taking it for the first time will involve a combination, or "regimen" of three antiretrovirals. There are exceptions to this, for example if you are a woman and taking treatment when you are pregnant; or if you have a very high viral load and need to take more than three drugs to get a powerful anti-HIV effect.

Most British doctors think that it is probably best to start with a combination that involves a non-nucleoside reverse transcriptase inhibitor (NNRTI), or a "boosted" protease inhibitor.

This should be taken with a combination of two nucleoside/ nucleotide reverse transcriptase inhibitors (NRTIs).

Either:

- tenofovir/FTC
  (available in a combination pill, *Truvada*)
- abacavir/3TC
  (available in a combination pill, *Kivexa*)
- AZT/3TC
  (available in a combination pill, *Combivir*)

However, AZT has been associated with body fat changes and your doctor should discuss the risks of these occurring, and side-effects which abacavir and tenofovir can cause, before you decide which drugs to take.

The anti-HIV drugs which are currently available on prescription in the UK, and the drug class to which they belong, are shown on the following page.

Table 2: Anti-HIV Drug names

Anti-HIV drug class	Common names	Brand name
Nucleoside/ nucleotide analogues	AZT, zidovudine #§	*Retrovir*
	ddc, zalcitabine +	*Hivid*
	ddI, didanosine	*Videx*
	d4T, stavudine	*Zerit*
	3TC, lamivudine #§~	*Epivir*
	abacavir §~	*Ziagen*
	tenofovir %	*Viread*
	FTC, emtricitabine %	*Emtriva*
NNRTI (Non nucleoside reverse transcriptase inhibitors)	efavirenz	*Sustiva*
	nevirapine	*Viramune*
PI (Protease inhibitors)	fosamprenavir *	*Telzir*
	atazavavir *	*Reyataz*

Anti-HIV drug class	Common names	Brand name
PI (Protease inhibitors) continued	lopinavir/ ritonavir¥	*Kaletra*
	indinavir	*Crixivan*
	nelfinavir	*Viracept*
	saquinavir (hard gel capsule)*	*Invirase*
	saquinavir (soft gel capsule)	*Fortovase*
	ritonavir	*Norvir*
Fusion Inhibitors	T20, enfuvirtide	*Fuzeon*

Notes for Table 2:

AZT and 3TC available in combined pill called *Combivir*

§ AZT, 3TC and abacavir available in combined pill called *Trizivir*

¥ lopinavir/ ritonavir is a 'boosted' PI where the effects of lopinavir are enhanced through the use of a small dose of ritonavir

* saquinavir hard gel capsules, fosamprenavir and atazanavir should be "boosted" by ritonavir

~ abacavir and 3TC are available in a combined pill called *Kivexa*

% FTC and tenofovir are available in a combined pill called *Truvada*

+ Production of ddc and saquinavir soft gel capsules will cease in 2006

Two nucleoside/ nucleotide analogues plus one non-nucleoside analogue

- If you are starting anti-HIV treatment for the first time, you are recommended to take a combination of two nucleoside/ nucleotide analogues and one NNRTI.

NNRTIs appear to present fewer problems with side-effects than protease inhibitors. This, together with the potential for easier adherence, are the main reasons why many doctors choose NNRTI-based combinations for use in people starting anti-HIV treatment. Their major disadvantage is that it is very easy to develop drug resistance to an NNRTI drug, and if this happens, it is unlikely that you will benefit from any other NNRTI.

If you choose to take an NNRTI, efavirenz (*Sustiva*) is usually prescribed, unless you are a woman and thinking about becoming pregnant. An alternative is nevirapine (*Viramune*). To reduce the risk of potentially serious side-effects you should not start taking nevirapine if you are a man with a CD4 cell count above 400 or a woman with a CD4 cell count above 250.

Two nucleoside/ nucleotide analogues plus a "boosted" protease inhibitor

- If you are starting anti-HIV treatment you may consider taking a combination of two nucleoside/ nucleotide analogues and a "boosted" protease inhibitor.

"Boosted" protease inhibitors have a small amount of ritonavir added. This increases the blood levels of the protease inhibitor being boosted and may allow both fewer pills and fewer doses, which may improve your adherence. Boosted protease inhibitors may also have a stronger anti-HIV effect, and may be less vulnerable to the risk of drug resistance.

The main disadvantages of protease inhibitor-based combinations are that they may have a higher risk of longer-term side-effects and be less easy to adhere to.

If you choose to take a boosted-protease inhibitor, it is likely that your doctor will recommend that you take lopinavir/ ritonavir (*Kaletra*). Other options are saquinavir/ritonavir (*Invirase* 500mg) and fosamprenavir/ritonavir (*Telzir*). At the moment, there is not enough evidence for atazanavir/ritonavir (*Reyataz*) to be recommended for first-line therapy.

Three nucleoside/ nucleotide analogues

A combination of three nucleoside/ nucleotide analogues is not recommended, even if you have a low viral load. However, in some exceptional cases it may be considered.

Nucleoside/ nucleotide backbone

It is not known which nucleoside/ nucleotide backbone is the most effective. However because of concerns about side-effects, d4T is not recommended as part of your first-line therapy. There are also concerns that AZT can cause fat loss and it is currently recommended that AZT should not normally be considered for first-line therapy. If you are currently taking AZT you should be offered the chance of switching to abacavir or tenofovir.

AZT, abacavir and tenofovir all have side-effects, and these should be explained to you before any treatment decision is reached.

If you have hepatitis B virus infection as well as HIV, then you are recommended to take FTC/ tenofovir, or 3TC as these drugs are active against both HIV and hepatitis B virus.

When to change therapy

The goal of anti-HIV treatment, if you are taking it for the first time, is to reduce your viral load to below the limit of detection, which is 50 copies/ml in the tests currently used. When your viral load does not fall to this level, it is more likely that your treatment will not suppress HIV for sustained periods of time. A continued rebound in your viral load from very low levels means that your treatment is failing. What may follow is a fall in your CD4 count, a possible risk of HIV-related illness, and an ongoing risk of developing drug resistance. This means that treatment which is not suppressing viral load to below the limit of detection should be changed if there are other drug combinations available to you which are likely to achieve this.

Sometimes your viral load may rise to just above the detectable level and then fall back below on the next test. This is called a "blip", and means that your viral load should be re-tested as soon as possible, ideally within two weeks. Though one-off blips may be caused by a problem with viral load testing itself, they should also be a trigger to consider other possible causes, such as drug interactions, adherence problems, illnesses or vaccinations. Regular blips may be a sign that your treatment is more likely to fail.

Your treatment is considered to be failing to control HIV only if you have had two viral load tests at least two weeks apart which both show that viral load is above 50 copies/ml. If you have two viral loads above 400 copies/ml a switch of treatment should be considered. It is recommended that a test for drug resistance is done to help choose the replacement treatment, or, if this is not possible (ie if your viral load is below 1000 copies/ml), that the new treatment involves a completely new set of drugs.

If your treatment is being changed because of side-effects, but your viral load is below 50 copies/ml, it is okay to switch only the drug(s) causing problems.

If you are currently taking d4T and have other treatment options available you are recommended to consider changing d4T because of concerns that it is associated with a high risk of lipodystrophy. AZT has also been associated with lipodystrophy and because of this, if you are currently taking AZT, your doctor should discuss the option of switching from this drug to abacavir or tenofovir. Both abacavir and tenofovir also cause side-effects and these too should be explained to you.

If you have had problems with adherence, your failing treatment regimen should ideally be replaced with drugs that are easier to take, and support with adherence

should be provided to you. For more information on the steps you can take to improve your adherence, see the booklet in this series called *Adherence.*

Some doctors may consider delaying a switch in treatment if viral load rebounds to a low level, such as between 500 and 1,000 copies/ml. This is because tests for drug resistance (which may help pinpoint which drugs are unlikely to be effective in the new treatment) are more reliable at viral loads above 1,000 copies/ml.

The timing of a switch in therapy will be influenced by the drug options you have available. If a second combination seems very likely to be able to reduce your viral load to undetectable levels and sustain the suppression, then an earlier switch will offer the least possible risk of developing resistance. If you have fewer drug options available, you may be more inclined to switch later.

The causes of treatment failure may be complex. The choice of new drugs should be guided by the availability of new treatment options, your previous treatment history, a resistance test, the chances of getting your viral load below 50 copies/ml, the tolerability of the drugs available to you, and the chances of you adhering to your treatment.

Your new combination of drugs should include three new drugs, including one drug from a completely new class of antiretrovirals, although it is likely to become harder to do this the more anti-HIV drugs you take. Options for people whose first anti-HIV drug combination is failing are shown in Table 3.

Table 3: What to change after first viral load failure

Initial combination	Replace with
2 NAs + 1 boosted PI	2 NAs + 1 NNRTI
	2 NAs + 2 PIs
	2 NAs + 1 NNRTI + 1 or 2 PIs
2 NAs + 1 NNRTI	2 NAs + 1 or 2 PIs
3 NAs (No longer recommended for first-line therapy)	2 NAs + 1 NNRTI
	2 NAs + 1 or 2 PIs
	2 NAs + 1 NNRTI + 1 or 2 PIs

Notes:

NA = Nucleoside/ nucleotide

PI = Protease inhibitor

NNRTI = Non-nucleoside reverse transcriptase inhibitor

Nucleoside/ nucleotide analogue combinations in the replacement regimen should, wherever possible, be new rather than recycled from the old combination.

When to change therapy: lipodystrophy

It is now known that anti-HIV therapy can cause changes in body shape and increases in blood fats. The booklet in this series called *Lipodystrophy* deals with this in detail.

The NRTI d4T has been associated with fat loss, and if you are taking d4T you are recommended to switch it for another drug if you have other treatment options available. In addition, there is evidence of an association between AZT with fat loss and your doctor should discuss the risk of this with you if you are thinking of starting an anti-HIV drug combination including AZT, or are currently taking AZT. You should be offered the opportunity to take abacavir or tenofovir as an alternative. Neither of these drugs have been associated with lipodystrophy, but they can cause other side-effects, and your doctor should explain what these are.

If you have increased blood fats and are taking a protease inhibitor, you may benefit from switching to an NNRTI where this is a viable option. Drugs to control blood fats called statins and fibrates can also be effective and your doctor may recommend them. Changes in diet and an exercise programme may also be helpful. Your risk of developing a cardiovascular disease should be assessed taking into

account factors such as smoking, your weight, and family history of heart disease.

Changes in treatment appear to have only a very limited effect on body fat changes once they have occurred. These can be very distressing, particularly fat loss from the face. The use of *New Fill* injections has been shown to help remedy the appearance of fat loss from the face and to improve people's sense of well-being.

Structured treatment interruptions

The value and safety of taking a structured break (called a structured treatment interruption) from your treatment, under close supervision by your doctor, is still under investigation.

Structured treatment interruptions have been studied in people who have recently been infected with HIV, have established (or chronic) HIV infection with a controlled viral load, and people with chronic HIV whose treatment has failed to control viral load.

The main potential benefit of taking a structured treatment interruption is fewer side-effects. However, some people who have taken treatment breaks have experienced complications, including a

rapid fall in CD4 count and HIV disease progression, and some have developed drug resistant HIV.

Unless you are participating in a clinical trial to assess the benefits and risks of taking a structured treatment interruption, you are only recommended to take a break from treatment if your CD4 count was above 400 when you first started taking HAART and has been above approximately 800 for a sustained period.

Changing your therapy after more than one regimen failure: "salvage therapy"

Doctors often make a distinction when talking about people who need to change their HIV drugs for the first time and those who've already made changes before because of the failure of their treatment to control viral load or increase viral load on more than one occasion. The term "salvage therapy" is often used to describe treatment if you have already taken drugs from all the major anti-HIV drug classes.

If your HIV is resistant to a number of anti-HIV drugs, you may find it difficult to assemble a new regimen which can lower

your viral load to undetectable levels. The aim of treatment should be to maintain or increase your CD4 count and to prevent you from becoming ill.

Structured treatment interruptions are not recommended if you are taking "salvage therapy."

If you are not at risk of rapidly becoming seriously ill because of HIV (for example you have a CD4 count above 100 which is not falling quickly) then you may wish to consider waiting until enough new drugs are available to give you a chance of getting your viral load below 50 copies/ml for a sustained period before you start taking a new combination of drugs. Doctors should not add a single drug which works into your combination to get a short-term reduction in your viral load.

25 Adherence

The success of your anti-HIV drugs requires an unusually high level of dedication from you. Adherence is the term used to describe taking your HIV drugs exactly as prescribed, with no missed or late doses, and eating the correct type of food at the right time in relation to your drugs if that's required. Missing even a few doses can cause your drugs to fail - adherence levels of over 90-95% are what's needed for you to get the best response. This means missing no more than one dose a month if you are taking once-daily therapy, or two doses a month if you are taking your anti-HIV drugs twice a day.

Adherence is more likely when you have taken part in decisions about your treatment and are committed to taking it. Adherence support should be part of the routine care you receive from your clinic. The following issues are important elements within effective adherence and should be considered periodically as part of your HIV care, and whenever you start a new HIV drug combination:

- Your motivation to start and continue with your treatment.
- Your understanding of adherence and drug resistance.

- The impact of treatment on your lifestyle and well-being.
- Your mental health.
- Risk of side-effects, and their management.
- The risk and benefits of treatment
- That you have the information you need to be able to take your treatments, including information in written form.

For more information, see the booklet *Adherence* in this series.

27 Gender and race

In the UK and many other industrialised countries, HIV was initially predominately an illness affecting gay men. This is changing rapidly and increasing numbers of women in the UK are being diagnosed with HIV. Although there are some differences in CD4 count and viral load between men and women, it is known that HAART is equally effective in both sexes, but side-effects of medication may affect men and women differently. In addition, your choice of anti-HIV drugs may be affected if you are a woman considering pregnancy (see the booklet, *HIV and women* in this series for more information).

There is also an increasing diversity in the ethnic populations affected by HIV in the UK. HAART works well regardless of ethnic origin, but your chances of experiencing certain side-effects (for example, lipodystrophy) may be affected by your ethnic origins. Your HIV clinic should also recognise that there are particular barriers to accessing HIV treatment and care in certain communities.

Summary

- People with HIV always require individualised care.
- Currently available HIV therapy does not eliminate HIV from your body.
- There is no clear evidence for the best time to start taking anti-HIV therapy. Decisions need to be taken with your doctor on an individual basis.
- If you are ill because of HIV, or have a low CD4 count, you are advised to take treatments.
- It is unclear which is the best combination to start with, but it is currently recommended that if you are starting HIV therapy for the first time, you take a combination of two NRTIs and an NNRTI or two NRTIs and a "boosted" protease inhibitor.
- HIV therapy which is not suppressing viral load to undetectable levels should be changed if there are other drugs available which seem likely to achieve this.
- Special treatment strategies are needed if you have taken lots of different HIV drugs.
- To work, HIV drugs have to be taken properly. This is more likely to happen if you have taken part in decisions about

your treatment and are supported in, and committed to, taking it.

- Your sex and ethnic origins can have implications for your choice of HIV therapy and your risk of certain side-effects.

Glossary

adherence The act of taking treatment exactly as prescribed.

antiretroviral A substance that acts against retroviruses such as HIV.

CD4 A molecule on the surface of some cells onto which HIV can bind. The CD4 cell count reflects the state of the immune system.

genotype The genetic make-up of an organism.

hypersensitivity An allergic reaction.

lipodystrophy A disruption in the way the body produces, uses and distributes fat.

NNRTI Non nucleoside reverse transcriptase inhibitor. The family of antiretrovirals which includes efavirenz and nevirapine.

nucleoside analogue Family of antiretrovirals which includes AZT, ddI, 3TC, d4T, ddC, abacavir and FTC.

nucleotide analogue Family of antiretrovirals which includes tenofovir.

protease inhibitor Family of antiretrovirals which includes atazanavir, fosamprenavir, indinavir, lopinavir, nelfinavir, ritonavir and saquinavir.

regimen A drug or treatment combination and the way it is taken.

resistance A drug resistant HIV strain is one which is less susceptible to the effects of one or more anti-HIV drugs because of its genotype.

resistance test Blood test which detects resistance to anti-HIV drugs.

salvage therapy Any treatment regimen used after a number of earlier regimens have failed.

undetectable viral load A level of viral load which is too low to be picked up by the viral load test being used.

viral load The amount of virus in the blood.

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