

Treatment Questions and Answers

by Elijah Amooti & Simon Collins



When can an HIV-positive person on ARV treatment have a treatment break? How long can a drug holiday last?

These two questions are both very important because of results from a large study in January, called the SMART study. This study was due to last for nine years, but was stopped after only two years, because of safety concerns in people taking a treatment interruption. An early analysis found that there was a higher risk from stopping and then restarting treatment based on your CD4 count, than was previously thought. These results were not expected and surprised everyone, including the researchers. The results also make it more difficult to recommend treatment interruptions. Before the SMART Study, although you'd expect your viral load to increase and your CD4 count to drop, many doctors thought that so long as you restarted treatment before your CD4 dropped to below 250, you would be unlikely to become ill. SMART found that people who were on a treatment break, were at twice the risk for serious HIV-related illness or death. It also found that people off-treatment were at a higher risk of heart disease, and liver and kidney disease than people on-treatment. Although this increased risk was greater at the lowest CD4 counts, it happened at all CD4 levels. Given that CD4-guided treatment interruptions are not generally recommended, the question of how long a treatment break could last is very interesting. In SMART, people took one long break – some people were off treatment for several years, and the average break was 18 months. This may be why the risks were so high. The difference between staying on or off treatment was only seen after 4-6 months off-treatment. Some researchers, therefore, think that a 4-6 month break, for people who are having difficulty with ARVs, and who have a strong CD4 count, should not be ruled out. Restarting treatment before your CD4 count falls below 350 (*rather than 250 as in the SMART Study*) showed a reduced risk in several other smaller studies.



New medications - what are the new medications that will be available in the UK and the US?

There are five new drugs or formulations that have either been approved recently or are close to being approved, or are available in expanded access programmes. - *Tipranavir* was the most recent drug to be approved in Europe (*in October 2005*). Tipranavir is a protease inhibitor, which works against HIV that is resistant to current protease inhibitors. It needs to be used with a small boosting dose of ritonavir, like most other protease inhibitors. and used in a combination with other drugs that are active. - *Darunavir* (*also called TMC-114*) is likely to be approved later this year, but is available now on expanded access. Darunavir is a protease inhibitor that also works against HIV that is resistant to other PIs. - *Kaletra* is going to be replaced by a new formulation that requires fewer pills, and which doesn't need to be stored in the fridge. This will also help people in hot countries, when it becomes available. This is already approved in the US and it should be approved in Europe in summer 2006. The new formulation is available on expanded access from February 2006. - *Merck 0518* is an integrase inhibitor that is still in early trials, but which showed such promising results that its development is being fast-tracked. If nothing unexpected happens, this new drug that works in a different way to all existing drugs, might be available in an expanded access programme later this year. A one-pill, once-daily combination pill of efavirenz + tenofovir + FTC is also in development and may be available by the end of 2006 if the current ongoing studies are effective. There are also lots of other promising drugs in research, that may have advantages over current drugs, and which could change treatment in the next few years. We will cover other new drugs in future issues of African Eye.



Is it better to use T-20 or TMC-114?

Both these drugs are for people who have resistance to existing treatment. If you are in this situation, then just choosing one drug is not very good. You need to use as many new drugs in the next combination as possible – using only one will mean you just develop resistance very quickly and the drugs will then stop working. You need to use *both* T-20 and TMC-114, or *both* T-20 and tipranavir/r. Using two new drugs together almost doubles your chance of success than just using one of them.



What are the complications for children on ARV medication?

Children tend to tolerate HIV drugs very well. Generally, the side effects that occur in adults, also occur in children. Like adults though, whether an individual child gets a side effect, cannot be predicted. Also, like adults, most side effects can either be managed, or other drugs that the child could switch to if. Other things that make children's treatment complicated include: the size of pills, whether a children's formulation has been developed, whether the right dose is right for each child and when it needs to be changed as the child gets older. Very young babies and children can only take liquids, whereas older children can learn to swallow pills. Adherence involves a different set of challenges. Getting a child to talk about side effects if he or she is old enough to be talking is important.





What are the complications of pregnancy and medication?

Pregnancy involves some aspects of treatment that are different. Some drugs are not recommended (*efavirenz*) and others may be particularly good (*AZT*). In general, whatever combination a woman uses, it has to be tolerable (*few side effects*) and get her viral load to undetectable levels before the baby is born. This reduces the risk of the baby becoming HIV-positive to almost zero. *i-Base* produce a free guide that answers many questions relating to all aspects of pregnancy and an HIV-positive woman's health. Please call 0808 800 6013 for a free copy, or ask at your clinic.



When do partners of HIV-positive pregnant women need to change medication? Does the HIV-positive man need to change to the same treatment?

Generally speaking, an HIV-positive woman will use the best combination treatment for her own health. Sometimes couples decide to use the same treatment, often so they take treatment at the same time and to make adherence easier, but this will depend on the treatment history of both people. If both partners have an undetectable viral load, it doesn't matter if they are using the same or different combinations.



How safe are HIV vaccine trials?

Most vaccine trials study HIV-negative people. The vaccine is to protect people from HIV infection, and so the people studied cannot already be infected with HIV. These trials do not put people at risk of catching HIV, because the vaccine being used is not a full live virus.



Could an HIV-positive person who is on ARV treatment participate in vaccine trials?

Although most approaches to an HIV vaccine are in HIV-negative people, some researchers are looking at vaccines that work in two ways. As well as protecting an HIV-negative person from infection, they hope to generate stronger immune responses in someone who already has HIV. Some of this research is in HIV-positive people, who would usually be on ARV treatment.



Can people with side effects participate in vaccine trials?

If you are having side effects it is important to talk to your doctor about this now. Often, any underlying illness will make it difficult to take part in a research trial – unless the trial is specifically looking at that illness or side effect. If it is a mild side effect, then you can often take part in studies – but there aren't many vaccine trials for HIV-positive people in the UK anyway.



When should someone change their ARV medication?

There are two main times: i) if your viral load rebounds to become detectable, or if it never becomes undetectable; ii) if you cannot tolerate treatment - if you get side effects - when there are other drugs you could try that may be easier. Changing treatment is very individual, and choices for a new treatment also depend on your treatment history and current health, but there is nearly always a choice in any situation, including using new drugs that may be more effective or easier to tolerate.



to provide medication to HIV-positive people who are deported?

People who lose the right to stay in the UK, will not continue to be treated if they leave the UK. This is a terribly difficult and upsetting situation. Some doctors may find a way to provide a few months supply to people who lose their appeal but this is also difficult.



Is there any financial help for participants on trials?

A: Generally there is no special financial help for most trials. Sometimes clinics can pay expenses related to additional travel costs or child cover. Sometimes early trials of new drugs may offer a payment, but only if there is no medical benefit. This happens less frequently in the UK than in the US, and happens mainly for HIV-negative volunteers.

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If you would like to speak to an HIV-positive treatment advocate about any question relating to HIV and treatment, call the i-Base freephone Treatment Phoneline on 0808 800 6013 on Mon-Wed from 12.00 – 4.00pm. You can also email questions to: Info@i-base.org.uk

In each edition we will focus on different aspects of treatment for HIV, related illnesses and other social issues affecting African Communities living with and affected by HIV/AIDS.

If you have any suggestions please do write to:

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