

HIV treatment update

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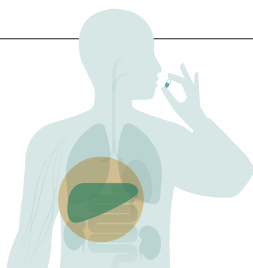


Overhauling health

NHS reform, HIV and patient power *page 4*

Full speed ahead to curing hepatitis C

A new era of hepatitis C treatment *page 8*



Plus

Life insurance and HIV *page 12*

Conference news in brief *page 16*

Treat everyone, say US guidelines *page 17*

HIV treatment update**Editor** Gus Cairns**Sub-editing & proofreading** Greta Hughson**Design** Kieran McCann**Printing** Cambrian Printers**ISSN** 17567890**Copyright** ©NAM Publications 2012

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For more information about *HTU's* medical review panel, please visit www.aidsmap.com/page/1445504

Each feature in *HTU* is also reviewed in advance by a readers' panel of people living with HIV. We are grateful to our panel for their knowledge, attention and enthusiasm. If you would like to be a member of the *HTU* readers' panel, please email info@nam.org.uk.

About NAM

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In this issue

**Gus Cairns**
Editor

When I write this editorial, I often scratch my head about whether there's a theme or issue that unites the different articles we have in each edition of *HTU*. This spring, what we have may look like a particularly disparate bunch. What unites the complexities of the English NHS reforms (page 4), the hectic pace of research into hepatitis C drugs (page 8), and the concerns about financial security for people who are just trying to have a normal life (page 12)?

This variety of topic was also a feature of the 19th Conference on Retroviruses and Opportunistic Infections (CROI) last month, which we cover extensively in the news pages and in *Upfront* opposite, as well as in the hepatitis C article. There wasn't one big topic or result that dominated the news; further research into prevention, hepatitis C drugs, new HIV drugs and basic research into a cure all jostled for attention.

In fact, it hasn't been difficult to find a theme, and that theme can be summed up in one word: access. We are at a particularly crucial point in the way the world treats HIV. US funding for HIV is no longer growing, and the Global Fund, in disarray after accusations of mismanagement – partly fed by politicians who never liked it – has had to cancel its 2012 round of grant giving. UNAIDS estimates that the total amount donated towards HIV treatment and care went down last year – for the first time ever, from \$7.6 to \$6.9 billion.

One study at CROI showed that in eight African countries, one in six of the general population might now be dead had it not been for treatment and care paid for by the US President's Emergency Plan for AIDS Relief (PEPFAR) programme: an extraordinary figure, but one imperilled by the global financial situation and the deprioritisation of HIV as a topic.

The same theme can be seen in our features. Will the high cost of the treatments bar access to the new generation of hepatitis C drugs for the people who might best respond to them? Will the NHS reforms be used as an excuse to erode the standard of care patients, particularly those with chronic or complex conditions, can expect? How can we persuade a reluctant insurance industry that we are as entitled to financial security as anyone with any other long-term condition?

There is more hope among scientists about the possibility of ending HIV than there has ever been, whether by extending treatment and effective prevention methods to as many people as possible, or by finding a cure or vaccine. All this takes money, though. It would be bitterly ironic if, at a point when we could end the epidemic, the means to do so were snatched away.

Upfront



Eliminating HIV: latest progress

by Gus Cairns

At the 19th Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle last month there were three main areas of discussion. Prevention and hepatitis C, which we cover in *News in brief* (page 16) and in the feature on page 8, were the first two.

The third hot topic was a permanent cure for HIV. We covered the approaches being explored in *HTU 204*, a year ago, and followed with Matt Sharp's account, in *HTU 206*, of being a pioneer participant in a trial of one of the ideas being explored: genetically altering people's CD4 cells to make them resistant to HIV.

Many other avenues are being explored. In symposia, poster presentations and a community-sponsored meeting before the main conference, many of these were presented.

There are four key approaches being explored. They are largely in early stages so predicting their future importance is difficult, and an effective cure might need to combine more than one:

- Eliminating the 'sleeper' cells that contain latent HIV.
- Containing low-level viral replication without drugs.
- Enhancing HIV-specific immunity.
- Making cells resistant to HIV.

Researchers were calling the first approach 'kick and kill' at CROI. A small number of long-lived 'reservoir' cells in the body hold on to the instructions for making HIV in their genetic cores. As soon as you stop taking the HIV drugs that inhibit them, they start spewing out HIV again, which is why HIV infection is lifelong. They also appear to maintain smouldering HIV replication even in the presence of HIV therapy, which keeps the number of these cells constant.

The idea is to use drugs that stimulate the reservoir cells to come out of hiding ('kick') and then either hope the business of actively producing HIV will kill them and enable non-infected cells to take over or to use special molecular missiles to pick them off ('kill').

Several classes of drugs are being investigated for their ability to do this.

A generalised immune activator could be highly toxic: you could both set off a lethal immune over-reaction and end up seeding a new generation of cells with HIV. So you need drugs that unblock the processes that suppress HIV reproduction by the cells, without overstimulating them. One example is the cancer drug vorinostat, which in one study¹ involving five people produced an up-to-tenfold increase in HIV expression within resting cells, despite their being on HIV treatment, but did not cause HIV to enter the bloodstream.

“As well as scientific barriers to overcome, there are practical ones.”

Drugs like vorinostat are like flooring the accelerator when it comes to HIV production within infected cells; another approach is more like taking the brake off. A cellular protein called PD-1 is responsible for keeping the HIV reservoir cells dormant and antibodies can be devised that neutralise the keep-quiet message that PD-1 sends round the immune system.

The results are similar to vorinostat, but with an added promising twist: it's beginning to look as if HIV-infected cells won't die off by themselves but will only do so if viral replication is accompanied by an increase in the CD8 cells that destroy HIV-infected cells. In one monkey study², giving previously ART-treated animals anti-PD-1 antibodies not only produced an increase in HIV production but also, while not increasing the number of anti-HIV CD8 cells, did increase their sensitivity.

A research consortium has been set up in the name of the late treatment activist Martin Delaney, and one of the avenues it is exploring is the development of aptamers: these are 'flag' molecules that stick to specific

cell-surface molecules. The idea is that if you enticed HIV-infected cells out of hiding, you could inject aptamers at the same time and these would stick to the cells' markers of immune activation. These would serve either as beacons for cell-killing drugs or contain cytotoxic compounds themselves.

A therapeutic vaccination that helps the body contain HIV replication has long been an unrealised ambition in cure research. A team from the Norwegian company Bionor Pharma, using a vaccine against the HIV p24 protein called Vacc-4x, produced a nearly threefold decline in the 'set point' average viral load of a group of participants taken off ART for a treatment interruption. Results like this have been seen before, but HIV usually manages to mutate its way round the immune response produced by the vaccine. However, a therapeutic vaccine could contain viral replication in people where the number of reservoir cells had been reduced to the bare minimum.

As well as scientific barriers to overcome, there are practical ones. Cure researcher Steven Deeks told the community symposium that, as there have been with HIV vaccine research, mechanisms needed to be put in place that achieve sustained funding for plausible but hard-to-achieve strategies, while also finding cash for left-field approaches and serendipitous discovery. And since a cure will probably combine several approaches, we need to start thinking now about ways highly disparate academics, companies and government bodies could work together.

There may be many wrong turns in cure research but at least we now believe it actually exists as a destination. **nam**

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For the latest news and features on HIV cure research keep an eye on our topic webpage 'The search for a cure'.
 ➔ www.aidsmap.com/cat/80321

Overhaul

NHS reform, HIV a

The *HTU* guide to the NHS reforms, how they'll affect you and how you can make the most of them. By *Gus Cairns*.



On 22 March, the government finally had its NHS reform bill passed by parliament. This wholesale reshaping of the National Health Service (NHS) in England has scarcely left the front pages in the last two years, and the effect on HIV services took centre stage recently at prime minister's questions.¹ But what's actually going to happen is as clear as mud to most of us.

HTU interviewed five people with a better grasp than most of the NHS reforms and their implications for HIV. They were: Francis Kaikumba, Chief Executive Officer of the African Health Policy Network; Yusef Azad, Director of Policy & Campaigns for the National AIDS Trust; Lisa Power, Policy Director of the Terrence Higgins Trust (THT); Jane Anderson, Chair of the British HIV Association (BHIVA); and Claire Foreman, the Lead Commissioner for HIV in the London Specialised Commissioning Group.

The answers below are a consensus on what's happening and likely to happen: where people disagree, we'll say so.

ing health

and patient power

What do the changes to the NHS mean, in general, for my HIV treatment and who is in charge of it?

In general terms, this will be one of the most significant reforms of the NHS since its creation. Many governments have tinkered with the NHS but this is the first restructuring since 1946 to require actual changes in the law. The most significant of these changes are, firstly, the abolition of local primary care trusts (PCTs) and their replacement with consortia of GPs that will control 60% of the health budget; secondly, enabling a wider variety of providers to bid to run services (hence the fears of 'privatisation' of the NHS); and thirdly, transferring all responsibility for sexual health (except HIV) and public health services away from the NHS and to local authorities.

What does 'commissioning' actually mean?

Commissioners start by assessing the needs of a group of people, then plan services to meet those needs. Then they draw up contracts with providers (e.g. GPs, hospitals, voluntary agencies, private healthcare providers) to provide those services. And finally those services are monitored for value for money. Monitoring used to, in the main, look at *output* – making sure the service was being provided as agreed – but these days increasingly looks at *outcomes* – seeing if the commissioned service produces measurable improvements in people's health. The intention of the *Health and Social Care Bill* is to remove the PCT level of the structure and have non-specialist

services directly commissioned by groups of GPs, provisionally called clinical commissioning groups (CCGs).

I've heard that GPs will be responsible for commissioning health services. Does it mean my GP will be in charge of my HIV treatment?

“The single thing people have grasped about the NHS reforms is that in the future GPs will commission and run their treatment and care, including HIV. That understanding is wrong.”
Francis Kaikumba

No. In fact most people with HIV will probably notice very little difference in their current care; in particular, you will *not* start having to go to your GP for your HIV check-ups and you will still be able to choose which HIV clinic you go to.

Currently, HIV treatment and care is commissioned locally by PCTs but, because it's still a relatively uncommon and specialist condition, regional groups called consortia do it in practice (you may have heard about the changes in drug provision negotiated by the London HIV Consortium, for instance). After the changes, HIV commissioning in England, far from going local, gets kicked upstairs to a new national body called the NHS Commissioning Board (NHS CB).

The NHS CB takes charge in April 2013. It's unclear as yet exactly how much local provision of treatment and care will be allowed to vary across the country and who will make the decisions locally. There will have to be some variations because

the prevalence of HIV – and the populations affected by it – vary widely from place to place. England will be split into four super-regions ('commissioning sectors') – north; midlands and east; south and southwest; and London – and it is possible that, in London at least, what we'll be left with will look pretty much like current arrangements.

As for what HIV treatment you should be getting, this remains the responsibility of your HIV consultant: but, as last year's changes in the recommended drug regimens for London patients show,² cost will become an ever-more important constraint on your and your doctor's free choice in an era where several drug regimens are roughly equivalent.

Does national commissioning imply that one standard 'Brit-HAART' regimen will be forced on us by a shadowy bunch of bureaucrats?

Hopefully not, because the NHS CB will be advised by so-called clinical reference groups of experts for every condition it commissions. It is unclear what mix of experts are going to be included in these groups, but they are the obvious place where bodies like BHIVA, and documents like the BHIVA treatment guidelines, will influence treatment. There is no reason why clinical reference groups might not include patient representatives. BHIVA is also currently revising its *Standards for HIV clinical care* document,³ with the same aim of guiding national commissioners on what good HIV service provision should look like. It will include a larger and more detailed section on how GPs and other primary care providers should be involved in HIV.

I keep on hearing that the changes are not going forward or are going to be altered by Parliament. What's happened so far and do you think the reforms will happen as planned?

The bill, put forward by Secretary of State for Health Andrew Lansley, has been accepted in its final vote in parliament, is about to be sent to the Queen for royal assent, and is expected to become law by the time you read this.

“An awful lot of NHS structures have already been dismantled. It would be as hard to turn back now as it is to carry on. The thing we have to do is make sure it works for us.”

Jane Anderson

One of the odd aspects of the furore around the bill is that many of its reforms are in fact supported and have even been proposed by doctors and other healthcare workers. The government's biggest problem is that the reforms are happening in a time of economic recession and that every reform is suspected as being a way of making cuts. Hence the fears expressed by GPs and patients groups that local health services will be taken over by large commercial healthcare companies who will provide care for straightforward patients and bundle off anyone who has complicated or expensive health needs to hospitals, or into an untreated limbo.

What will GPs be in charge of? What if I've got something like chronic hepatitis B, which has always been managed by my hospital? Or diabetes, which is already managed by my GP? Who will take ultimate responsibility for my health?

A very good set of questions; particularly in the context of the ageing of the HIV-positive population. We'd be asking them anyway, but the NHS reforms have perhaps given a chance for us to codify responsibility in more detail.

The London boroughs of Lambeth, Southwark and Lewisham (LSL), which have the highest HIV prevalence in the

country, recently published a report on who should ultimately be responsible for the care of people with HIV in the area. They interviewed local professionals and discovered that, far from people with HIV being disowned, everyone thought they were in charge of their care: HIV consultants, GPs, social workers and key workers in voluntary agencies all thought they had ultimate responsibility. LSL's report said that, in line with the NHS reforms, the person who should be in charge of co-ordinating the care of the health and social care needs of people with HIV should be their GP, but gave little guidance on how this should be achieved. “The assumption that GPs will automatically be able to fulfil this role is tenuous given their performance in this area historically,” commented THT in their response to the LSL report.

“The direction of travel is inexorably towards shared care, but the problem is that in all the reports I've seen on how to achieve treatment and care co-ordination, accurate analysis mixes with a desire to cut and save money.”

Yusef Azad

The issue is not just one of better communication, but of real power and of money: it's about which professional has the power to decide whether someone should get an expensive drug or social support programme and who should pay for it. On the one hand, at present people are often left dangling in situations where, say, their HIV consultant recommends a treatment but the GP won't refer because it would be expensive; on the other hand we don't want to see a situation in which every professional involved in someone's care has to refer decisions to their GP.

We are not likely to see GPs take over deciding which antiretrovirals you take, however; apart from anything else, the problem that non-exempt patients would have to pay prescription charges has not yet been sorted out.

In addition, central HIV commissioning and cash shortages are likely to mean that you are less and less likely to get treatment and care for conditions that are not directly related to HIV from your HIV clinic. HIV doctors are not necessarily experts on the sort of common conditions like heart disease, diabetes and dementia that GPs see every day and HIV patients over 50 may miss out if they don't visit their GPs for a health check now and then: GPs have

to offer regular 'MOTs' for older patients. If there are confidentiality reasons that mean you don't want your GP to know you have HIV, it *should* next year become easier to register with a GP in a wider catchment area than is currently possible, or even in the area where you work.

“Testing seems to be a lever for creating genuine interest in HIV in GPs. Once a patient comes back with a positive result then the GP has a patient they already have a relationship with; it's beginning to unpick the circular argument that GPs aren't interested in HIV and HIV patients aren't interested in seeing them.”

Claire Foreman

My hospital is a foundation trust. Does this give it more freedom to decide what kind of treatment I get?

Foundation trusts were part of the last wave of NHS reform. Eventually the government wants all hospitals to become foundation trusts, but initially the status was a reward for staying in the black. It gives hospitals more financial autonomy and means that they can both raise their own funds as an independent body and decide what to spend them on. So yes, they might decide to raise money and spend it on a nice new HIV clinic, which is what they did at the Homerton hospital in east London, where Jane Anderson practises; the hospital, in a poor and multi-ethnic area with high HIV prevalence, decided to make its HIV service a flagship one. But with so many competing demands on a cash-strapped NHS, there's no guarantee of that and the best way of ensuring HIV is not forgotten is to make sure there's good patient lobbying inside the hospital and support from sympathetic consultants: see *Supporting patient power* in the last issue of *HTU** for more on patient groups.

What if I need treatment for a sexually transmitted infection? Or contraception?

Now we're talking about the other radical reform. Lansley's bill will mean that responsibility for public health, which includes sexual health, will leave the NHS

altogether and go to local councils. Some people worry that local authorities are ill-prepared to run this kind of service and it could easily get politicised; will we see situations as we do in the US where services like pregnancy termination are subject to the whims of politicians with a religious or moral agenda? In fact this can only be done to a certain extent: running a proper sexual health service will be a statutory duty and the local director of public health will have powers to overrule soap-boxing politicians. There's still a lot of ignorance amongst local government as to what it involves, however.

“We went to a recent conference of local authorities with a poster saying ‘Do you know what the biggest slice of your public health budget will go on from next year?’. Most councillors thought it was something to do with smoking, drinking or exercise; they hadn’t a clue it would probably be sexual health.”

Lisa Power

The public health remit includes HIV prevention too, I gather. How is that going to work?

With some difficulty, probably. There will be a new ringfenced public health grant provided to local authorities, meaning it cannot be spent on treating illness but must go on preventive measures. Here, there really is a danger of services becoming politicised and of councils preferring to spend their grant on measures that are more *Daily Mail*-friendly than sexual health.

Working against this is the fact that, thanks in part to the recent House of Lords enquiry led by Lord Fowler, the government is aware that HIV prevention has not had enough put into it in recent years and that public ignorance about HIV is growing. Meanwhile, in a separate development, the Department of Health has recently held a competitive tender for the national HIV prevention contract in England (which will merge previously separate programmes for African people and gay men).

This could mean that *paying* for HIV prevention becomes more localised at a time when *providing* it is becoming more centralised, and there are calls for a national awareness campaign. Local prevention is not a bad idea if it funds decent sexual

health support services for local populations but it requires expertise at a time when services are being handed over to bodies that may have none.

In HTU's report on the UK conference for people with HIV⁵ last September you said that there are new bodies people will be able to get involved in if they want to advocate for better HIV services. You mentioned health and wellbeing boards. What are these?

Health and wellbeing boards (HWBs) are supposed to be the crucial bodies when it comes to the co-ordination of public health, sexual health services and social services. Their membership will consist of key players in health in a local area: the director of public health, local councillors, directors of the local GP consortia, other council officers such as the director of social services and key local voluntary organisations. There will be a reserved place for a representative from HealthWatch (see below). In theory, they could serve as an efficient co-ordinator of services that have historically been hard to join together: health, mental health, social services and housing. In practice, they could be a bureaucratic logjam that spends all their time in a monitoring role, commissioning reports, needs assessments and public relations, and too little time on co-ordinating service provision. There was a huge range of feeling about HWBs in my interviewees, from cautious enthusiasm to downright cynicism. They are an experiment and no-one knows how well they will work.

What is HealthWatch and how do you get involved?

This is the latest replacement for the bodies that are officially supposed to serve as the voice of health service users locally. The predecessor to HealthWatch were local involvement networks (LINKs) and before them, community health councils. There is an obligation to provide them but a weird arrangement where they can't organise themselves: another body has to offer to 'host' them, and in recent years some voluntary organisations – an example is the housing charity Hestia – have made a lot of money hosting local LINKs. The problem is that any patient can bring any kind of problem to their local HealthWatch

and people with HIV may have a hard time raising HIV-related issues if they are outnumbered by people who are more concerned with hospital cleanliness, disabled parking bays, services for the elderly or other such issues.

“My previous job was to help set LINKs up and in two years there, I never heard a single mention of HIV. How do you set up mechanisms to listen to the ‘patient voice’ for a disease people don't want to be identified as having?”

Francis Kaikumba

What other opportunities are there for having some say in HIV and sexual health services in my area, or nationally?

Historically, getting the needs of people with HIV met has never started off with lobbying through the official channels. The verdict amongst my interviewees seemed to be that in high-prevalence areas it might be worth having a go at raising HIV as an issue in your local HealthWatch, as they do have a statutory place at the local table, but that you are probably more likely to get your concerns heard by other means such as:

- forming or joining a clinic patient group
- visiting or writing to your MP
- getting local businesses, serving your community, interested in HIV prevention and provision of support
- writing to the media
- raising issues in e-forums such as THT's MyHIV or general campaigning websites such as 38 Degrees.⁶ Ministers really do pay attention to websites with a strong collective voice.

HIV is likely to remain an issue for populations that are both stigmatised and marginalised but who also have their own solidarity and countercultures.

There are opportunities for the voices of people with HIV to be heard in the new NHS but, as ever, many campaigns will probably start with one or two people, or small groups, and take off when they strike a chord in peer groups and with sympathetic professionals who can help, such as doctors and MPs, and can support their bid to get a place at the committee table. Activists don't have to start by going through the 'proper channels' but it's important to know they are there. **ran**



**Full speed
ahead to curing
hepatitis C**

New drugs that directly target the hepatitis C virus usher in a new era of treatment, *Liz Highleyman* reports.

Combined with interferon injections and ribavirin pills, the latest hepatitis C drugs are dramatically more effective. Two have now been licensed and there are others on the horizon. At present they will have to be taken with the standard hepatitis C treatment of pegylated interferon and ribavirin, but interferon-free, all-oral combinations are likely to follow.

Interferon (given by injection) works by stimulating the body's own immune response, but the new drugs work just like antiretroviral drugs for HIV, attacking the virus at different stages of its lifecycle.

The first of these new drugs – the hepatitis C protease inhibitors boceprevir (*Victrelis*) and telaprevir (*Incivo*, or *Incivek* in the US) – were approved in Europe and the US for mono-infected people (those who don't also have HIV) last summer. Drugs like these can overcome some of the causes of a poor response to interferon, such as having the difficult-to-treat hepatitis C genotypes 1 and 4, the unfavourable IL28B gene variation, advanced liver fibrosis or prior treatment failure.

Hepatitis C protease inhibitors for co-infection

About one-third of people with HIV also have hepatitis C, including a majority of injecting drug users and a growing number of HIV-positive gay and bisexual men. Hepatitis C-related liver disease is a major cause of death for people with HIV in high-income and resource-limited countries. HIV-positive people generally have higher hepatitis C viral load, experience more rapid liver disease progression and do not respond as well to interferon-based treatment as people with hepatitis C alone.

The new drugs can help overcome the disadvantage of co-infection. "This is a huge leap forward in treatment of hepatitis C in HIV patients," said Douglas Dieterich from Mount Sinai School of Medicine in New York. "The virus is cleared, gone forever, and shouldn't come back."

Dieterich presented the first co-infection cure findings at the 19th Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle this March. His study enrolled HIV-positive people with hepatitis C genotype 1 who had not tried interferon before.¹ They took telaprevir or a placebo three times daily in combination with pegylated interferon and ribavirin for twelve weeks, then continued on interferon and ribavirin alone for another 36 weeks.

The trial included 60 participants: 13 with CD4 counts of at least 500 cells/mm³ who were not yet taking antiretroviral therapy for HIV, 24 taking an efavirenz-based

“There is no access to the new hepatitis C treatments for co-infected patients on a routine basis. But you can get the drugs from major centres...who will be doing the clinical trials people need to join.”

**Dr Mark Nelson,
Chelsea and Westminster Hospital**

antiretroviral regimen and 23 taking one based on atazanavir.

Overall, 74% of people who used telaprevir triple therapy achieved 'sustained virological response' (SVR, a continued undetectable hepatitis C viral load) twelve weeks after ending treatment (known as SVR 12). This is a good predictor of 24-week SVR, which is considered a cure. Results were similar in the no-ART, efavirenz and atazanavir groups.

Another study, presented by Mark Sulkowski from Johns Hopkins School of Medicine, looked at boceprevir triple therapy in co-infected people.² They were assigned to receive boceprevir or placebo three times daily, plus pegylated interferon and ribavirin, for 48 weeks. All were on fully suppressive HIV protease inhibitor regimens.

Here, the SVR 12 rate was 61% with boceprevir triple therapy versus 27% with pegylated interferon/ribavirin alone, with three other people still undergoing follow-up.

Hepatitis C rebound during treatment was reassuringly rare in both studies, allaying fears that HIV-positive people might be more likely to relapse. "The vast majority who responded on therapy sustained their virological response and achieved a cure," Sulkowski emphasised.

The side-effects of triple therapy generally were not more common or more severe among co-infected people. However, one drawback of the new drugs is that they do add new side-effects to the ones already familiar to people taking pegylated interferon and ribavirin, such as depression and flu-like symptoms. Telaprevir frequently causes a skin rash and itching, which can be severe in some cases, while boceprevir can worsen the anaemia and white blood cell deficiencies already caused by ribavirin. Both can cause gastrointestinal symptoms and odd taste sensations.

It may be worth it, though. "I didn't expect results for either drug to be so good," Dieterich summarised. Cure rates were "shockingly comparable" in HIV/hepatitis C-co-infected and hepatitis C-mono-infected people, while side-effect rates were "virtually the same" and did not present an obstacle to treatment.

Beware: drug interactions

Along with the good news, however, there were also some concerns. One of the biggest challenges of co-infection treatment is the risk of drug-drug interactions, which can raise or lower concentrations of other medications, leading to worsened side-effects, or viral breakthrough and treatment failure.

Ideally, interactions between hepatitis C antivirals and HIV antiretrovirals should be assessed in laboratory studies and HIV-negative volunteers before a new drug is tested in co-infected patients, but this does not always happen. The European Medicines Agency and US Food and Drug Administration encourage such studies but do not require them.

Telaprevir's drug-drug interactions with antiretrovirals were well studied in advance, enabling well-informed choices about which HIV drugs to allow in its co-infection trial; those taking efavirenz had to increase their telaprevir dose to compensate for the reduced levels of the drug caused by an interaction with efavirenz.

But in the boceprevir trial, researchers made educated guesses based on drugs' pharmacokinetic profiles and how they are processed in the body.

The hazards of the second approach came to light when belated testing in HIV-negative volunteers showed that adding boceprevir to ritonavir-boosted HIV protease inhibitors could lower blood levels of both drugs to ineffective levels.³ Boceprevir reduced minimum concentrations of boosted atazanavir (*Reyataz*), darunavir (*Prezista*) and lopinavir (*Kaletra*) by as much as 60%, while these HIV drugs reduced boceprevir levels by up to 45%.

As a result, in February Merck issued a 'Dear health care professional' letter⁴ stating that the company "does not recommend" co-administration of boceprevir with boosted HIV protease inhibitors. Given that we already know that efavirenz causes substantial drops in boceprevir levels, HIV regimens based on raltegravir (*Isentress*) look like the best bet for combining with this drug.

"We should have had this data earlier," stressed Renaud Persiaux of the French treatment activists' coalition TRT-5. "We ask pharmaceutical companies to do drug/drug interaction studies early on, as this will increase safety for patients."

And yet, given the good result of the trial presented by Sulkowski, this may not have mattered in this case. Given this conflicting data, what should someone with both HIV and hepatitis C do now?

What to do now?

Boceprevir and telaprevir are currently only approved for hepatitis C-mono-infected people by the EU and US licensing agencies. But in the UK, NICE (the body producing clinical standards in health and social care) recently gave a favourable opinion on boceprevir and telaprevir-based triple therapy with interferon and ribavirin.⁵

"This 'approval' includes co-infected

“This is a huge leap forward in treatment of hepatitis C in HIV patients.”

Douglas Dieterich,
Mount Sinai School of Medicine

patients," says Dr Sanjay Bhagani of London's Royal Free Hospital, "though whether commissioners will pay for this or not is a different matter."

These new drugs are not cheap. The 'list prices' (the ones the NHS ends up paying are likely to be lower) are £30,800 for a 44-week course of boceprevir and £22,398 for a 12-week course of telaprevir – and, on top of that, you have to add in £11,000 for the interferon and ribavirin.

At this stage, your best chance of receiving these new drugs is through being part of a clinical trial, as the drug company has to pay for the cost of these. "There is no access to the new hepatitis C treatments for co-infected patients on a routine basis," says Dr Mark Nelson of London's Chelsea and Westminster Hospital. "But you can get the drugs from major centres like us and the Royal Free, who will be doing the clinical trials people need to join."

Whether you should try the new drugs depends primarily on whether you have progressive liver disease. Just as HIV treatment has been based on worsening immune deficiency, hepatitis C treatment should be based on worsening liver fibrosis.

Not everyone with hepatitis C will need treatment. Only a quarter of hepatitis C-mono-infected people develop serious liver disease, and this typically takes 10 to 40 years, often with no symptoms until advanced stages. For co-infected people without an urgent need for hepatitis C treatment, there's probably time to wait.

Even if the approved drugs were more readily available, Mark Nelson comments, they're like the first-generation HIV protease inhibitors.

"Telaprevir and boceprevir are relatively difficult to take and relatively toxic compared to the second generation. If you have minimal liver disease, probably the best option is to wait."

Daniel Fierer from Mount Sinai Hospital in New York adds that boceprevir and telaprevir are "unpleasant, onerous drugs... Think AZT if we're lucky or, if we're unlucky, ddC... If you don't need it, don't take it." He's even more pessimistic when it comes to re-treatment. "If patients have failed treatment a number of times, their chances of cure with the new drugs are pitiful," he said.

"Taking treatment now may prevent you from getting into a clinical trial further down the line, and you may develop resistance."

Other patients, however, do not have the luxury of time. The risk of progression to liver damage is higher and it happens faster in co-infected people; successful treatment can slow, halt or even reverse it. Doctors do not want to give treatment to people who never would have progressed to liver damage without it, but are also concerned not to delay too long because once people get to the stage of cirrhosis, treatment becomes more difficult and less effective.

"If people need to be treated, they need to be treated now," said Dieterich. "If they have significant liver disease, I think it's definitely indicated to go ahead. If you need to take pegylated interferon and ribavirin with all their side-effects, you want to optimise your chance of success."

At a CROI symposium on treating HIV/hepatitis C co-infected patients, Jürgen Rockstroh from the University of Bonn proposed an algorithm for deciding when to consider therapy:

- People with no or minimal fibrosis (stage FO-F1) may defer treatment and wait for better therapies.
- People with moderate to advanced liver disease (stages F2-F3) have the biggest risk of progression that could be controlled with treatment now.
- People with cirrhosis (stage F4) have the highest need, but also the lowest response rate and greatest risk of complications, and should only be treated in specialised centres.

It is not as easy to predict who will experience liver disease progression, or even to tell if it is occurring, as it is to measure CD4 cells. Liver biopsy remains the gold standard for staging liver damage, but it is too invasive and expensive to repeat often. *Fibroscan* (which uses sound waves to measure liver stiffness) and various blood biomarkers are widely used, but they may not be able to distinguish between intermediate stages where decision-making is most critical.

"It's a balancing act," Rockstroh concluded. "How much progression will happen in one, two, or three years, versus the window of development of new therapies?"

On the ground

Despite the long wait and eager reception of the first hepatitis C protease inhibitors, their use does not yet appear to be widespread in practice.

"I've met one person who is taking telaprevir," said Tracy Swan, a long-time community advocate with the Treatment Action Group in New York. "My hunch is that people are waiting for something better if they can."

In the UK, Robert James, patient representative on the BHIVA hepatitis group, says the same. "Only a few people so far are taking telaprevir or boceprevir here and only the BHIVA hepatitis group doctors and their close colleagues are prescribing them," he says.

Breaking free from interferon

Fears about interferon side-effects remain a major reason people delay or refuse treatment, making interferon-free regimens the holy grail of hepatitis C research. As with HIV therapy, we can expect hepatitis C drugs to become more effective and easier to take over time, with fewer side-effects, more convenient dosing, and shorter treatment durations.

A whole raft of new hepatitis C drugs is on the horizon, with many pharmaceutical companies involved.

They include:

Protease inhibitors

- asunaprevir (BMS);
- danoprevir (Roche);
- vaniprevir (Merck);
- BI 201335 (Boehringer);
- TMC435 (Janssen)

Polymerase inhibitors

These act in a similar way to reverse transcriptase inhibitors (RTIs) in HIV and like them can be nucleoside analogues or non-nucleoside drugs.

NRTIs

- mericitabine (Roche)
- GS 7977 (Gilead)
- NNRTIs
- setrobuvir (Roche)
- tegobuvir (Gilead)
- BI 207127 (Boehringer)
- VX-222 (Vertex)

“My hunch is that people are waiting for something better if they can.”

Tracy Swan,
Treatment Action Group

Others

These include the promising NS5A inhibitor daclatasvir, the cyclophilin inhibitor alisporivir, and other classes of drugs such as entry inhibitors and TLR agonists.

Roche combined two new drugs, danoprevir and mericitabine, in 2010, proving that oral drugs alone could suppress hepatitis C; viral loads fell 100,000-fold in 13 days in both previously untreated mono-infected patients and prior non-responders.⁶

More recently, an interferon-free combination of BI 201335, BI 207127 and ribavirin for 16 weeks produced SVR24 rates of about 60% in treatment-naive, hepatitis C-mono-infected, genotype 1 patients.⁷ A Japanese trial found that 90% of genotype 1 mono-infected patients who had previously not responded to interferon reached SVR after 12 weeks of asunaprevir plus daclatasvir.⁸

Another trial, though, illustrated the hazards of making things too simple. It found that 100% of previously untreated genotype 2 or 3 hepatitis C-mono-infected patients were cured with 12 weeks of GS7977 plus ribavirin.⁹ So researchers brought patients with the harder-to-treat genotype 1 and who had never responded to interferon into the trial. All of them achieved rapid virological response after four weeks – but after finishing the twelve-week course of treatment, the hepatitis C reappeared in all but one of them.¹⁰ People in this situation may need an additional drug or longer treatment duration.

Drug developers are looking to produce co-formulations and, ultimately, single-tablet regimens, sometimes buying up

other companies to gain access to promising compounds. But this could potentially limit the mix of drugs being tested together.

"We don't want companies to develop in-house combinations only," says Tracy Swan. "They should be using best-in-class drugs to create regimens."

Trials for HIV/hepatitis C-co-infected people are still not moving as quickly as we'd like, but they are happening. Boceprevir and telaprevir are in Phase 3 trials and daclatasvir, BI 201335 and TMC435 are each being tested with pegylated interferon and ribavirin in co-infected people. Interferon-free direct-acting antiviral combinations are not yet being studied in co-infected people. Before they are, researchers are trying to get a handle on to what extent interferon contributes to HIV suppression in the face of drug-drug interactions and what might happen if it's left out. In addition, some hepatitis C drugs, especially the NRTIs, may have a degree of activity against HIV too.

"Hepatitis C drug development is like HIV drug development at warp speed, but that doesn't mean we're going to have that magic bullet without interferon soon," says Douglas Dieterich.

Sanjay Bhagani also worries about the public health consequences of giving the impression that hepatitis C is 'easy to treat'. "We need to be acutely aware of rising hepatitis C rates amongst gay men, especially in Europe," he says. "If we don't address risk-taking, we may find ourselves trying to treat multiple re-infections, which could be disastrous."

Most experts predict several more drugs will be approved for hepatitis C-mono-infected people to use with pegylated interferon and ribavirin over the next few years. The first interferon-free combinations for hepatitis C mono-infection may hit the market in three to five years. Treatment for HIV/hepatitis C-co-infection is running a generation behind and, under existing procedures, interferon-free combinations for co-infected people are not expected for seven or so years. But knowledge gained from mono-infection trials and pressure from advocates could hasten that process.

"We are at that transition period where patients that need treatment based on disease stage should get it today and others will be able to wait," concludes Mark Sulkowski. "That will be the art of hepatitis C treatment in HIV-infected patients for the next several years". [aidsmap.com](http://www.aidsmap.com)

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INSURANCE

Rest assured

Life insurance for
people with HIV

Relatively few people with HIV in the UK take out life insurance, but is that actually because it isn't available to them? *Gus Cairns* investigates.

Let's see now...life insurance is impossible to get for people with HIV in the UK, right? So you can't get a mortgage over a certain price? And that's a really good reason not to have HIV on your GP records, isn't it?

No - none of the above are true. But they're all things many people still believe about life insurance and HIV.

In fact, it is possible for people with HIV to get life insurance in the UK, and not at unaffordable prices.

However, there are still problems. You can get coverage of any amount, though something that would cover the whole of a £250,000 mortgage would cost you in the region of £125 a month. But currently in the UK, it's very hard to get coverage for a term of more than ten years. You will probably be able to renew after those ten years if your health stays the same. In this era of high deposits, life insurance is no longer a condition for getting most mortgages, but if you want cover for the full term of your mortgage, ten years isn't usually long enough.

The companies that do offer cover to people with HIV in the UK at present only offer it to people taking HIV treatment - which is tough on the minority who maintain high CD4 counts off treatment. Companies usually want their own medical tests done, even though most people with HIV have the same tests done by their clinic two or three times a year. Although you are entitled to nominate your HIV consultant as your physician, an insurance company may still check your GP records for non-HIV risk factors and conditions (ranging from mentioning sexual risks to other risk factors such as mental illness). And they may take a lot longer to arrange coverage.

"I'm finding that, at the moment, it's taking companies between three and six months to agree to coverage for our clients," says Chris Morgan, marketing manager of Unusual Risks, an insurance broker that arranges cover for the people companies are reluctant to provide cover for without some bargaining, including people with pre-existing medical conditions and people with dangerous jobs. "This compares with six weeks or so for regular coverage."

Making assumptions

Chris made his name in the 1990s as director of Compass, a financial advice firm for gay people, but he soon found heterosexual people with HIV needing his services too. The unavailability of life insurance for people with HIV is more assumption than reality, he adds. Unusual Risks does annual surveys to find out whether companies offer it and whether people with HIV are aware they can get it.

“People with HIV need to read the terms and conditions of any insurance they take out very carefully. And they will still need a specialist policy; there is no point in applying for a general policy and not mentioning you have HIV, you will just be wasting your money.”

**Chris Morgan, marketing manager,
Unusual Risks**

"I have phoned up some companies," he says, "and when I ask if they insure people with HIV the person I spoke to has said 'Don't be silly, why would we do that?' - even though I know their company does it."

Potential customers make this assumption too. In the last Unusual Risks survey, 80% of respondents did not know they could get life insurance.

Why do people want life insurance?

Covering a mortgage is only one reason to get life insurance (or assurance, as many companies call it). Most mortgage providers will suggest you take out life insurance, but it is usually not a condition of granting the mortgage. You might want life insurance to cover an endowment mortgage, but you and your partner might also share expenses, loans and unsecured debts and he or she would be liable for the whole lot if you died. Maybe you want to ensure your children are cared for should you die during their childhood - the payout, if needed, can be assigned to a trust fund rather than a beneficiary.

Life insurance isn't a necessity for everyone. A lot of people have savings, property, assets that can be sold, and pensions to protect their loved ones from disaster in the event of their death. But with them, especially in these days of low interest, you pretty much get out what you put in - and some of us may not have anything like the money children or partners might need if we died early. With life insurance, you take a gamble for a 'prize' you hope no-one will have to collect. Your loved ones get a big bonus on top of the money paid in, but only if disaster strikes.

It is the likelihood of that disaster that determines how much you have to pay for it: life insurance is one of those things that get less available as you become more likely to need it. It's a gamble for the insurance company too; you do occasionally hear about huge losses, as when members of Lloyd's had to fork out for floods a few years back. But in general, insurers make sure the odds are stacked in their favour, and employ actuaries to establish exactly what those odds are.

To eliminate the possibility of high risks slipping through their net, companies do sometimes explicitly exclude specific groups or insured risks from their policies. But in other cases they may make blanket exclusions which don't explicitly mention your particular situation (such as mentioning 'pre-existing conditions' instead of HIV) or may simply assume that potential customers will volunteer information that may make them an insurance risk. Legally, it is up to the customer to volunteer relevant information

rather than for the company to fish it out; just because a life insurance, health insurance or travel insurance policy doesn't explicitly mention HIV, or even long-term medical conditions as an exclusion, doesn't mean you are covered.

"People with HIV need to read the terms and conditions of any insurance they take out very carefully," says Chris Morgan. "And they will still need a specialist policy; there is no point in applying for a general policy and not mentioning you have HIV, you will just be wasting your money."

What are the risks?

Wayne Dam is Senior Products Actuary of the Life and Health section of Swiss Re, a multinational company. The 'Re' stands for reinsurance: the company insures insurance companies, which also means they have a role in establishing pricing and availability for the whole market.

Dam says: "In life insurance, the risks you are insuring against have usually been fairly predictable, unlike other types of risk like natural disaster or economic collapse. People die at a fairly predictable rate and we know how life expectancy changes with age and which groups tend to die younger." In general, for instance, people's annual risk of dying increases in a predictable manner as they age: at 40 you only have a 0.2% risk of dying in the next year, by 65 that risk has increased to 1.5% and by the age of 90, for those still alive, it's 16%.¹

These calculations go awry, however, if life expectancy changes with time. "For someone to be insurable the loss insured against has to be genuine: it must be due to bad luck, not human interference; it must be significant, a real loss; and it must be predictable." HIV, he adds, blew predictability out of the water in two ways: firstly, in the 1980s-90s, by sharply increasing the proportion of people dying early due to infectious disease (even in rich countries) and then a decade later when, due to HIV treatment, the death rate started falling in people with HIV and (in some sub-groups within the HIV-positive population) approaching normality.

Many of the life expectancy data featured in a piece *HTU* ran in April 2010 (see *How long have I got, doc?* in *HTU* 195).² There have been few big life expectancy studies since then.

One cohort of HIV-positive people in the UK, the UK CHIC group, published new life expectancy data in October 2011.³ Among this group of over 35,000 patients, surveyed from 1996 to 2008, 1248 people died out of a total of 91,203 patient-years of data collected. That's an annual mortality rate of 1.4%. The life expectancy at age

“In life insurance, the risks you are insuring against are fairly predictable, unlike other types of risk like natural disaster. People die at a fairly predictable rate and we know how life expectancy changes with age.”

Wayne Dam, Senior Products Actuary, Swiss Re

20 – how many more years someone in the group could expect to survive – was 40 in men and 50 in women, compared with 58 and 62 in men and women respectively in the general population – deficits of 18 and 12 years respectively. Life expectancy improved considerably over the study period, especially in women. In 2006 to 2008, annual mortality was 0.95% and life expectancy at age 20 had risen from 30 years in 1996-98 to 46 years (56 years in women).

Late diagnosis contributed a huge amount to mortality: most of the risk of dying in people with HIV, at least until they get old, is concentrated into the first year after diagnosis. Life expectancy at age 20 in people diagnosed with a CD4 count of less than 100 cells/mm³ was 38 years, compared with 53 years in people diagnosed with a CD4 count between 200 and 350 cells/mm³ (people starting treatment with CD4 counts over 350 cells/mm³ were excluded from the study). In this group, life expectancy tended to approach normality with age; as people got older and survived, their continued survival approached that of the general population, whereas in people diagnosed with less than 200 cells/mm³, the risk of dying continued to be elevated.

As we found in *How long have I got, doc?* certain groups of people with HIV have near-normal life expectancy: people diagnosed early; those maintaining high CD4 counts; and people diagnosed in recent years.

Contrary to expectations, older people

also have less risk, relative to others of their own age. People with HIV who are 25 are more than twice as likely to die within the next year as HIV-negative 25-year olds: HIV-positive 65-year olds, conversely, are only 14% more likely to die than their HIV-negative contemporaries. This is due to two things: firstly, since most of the excess mortality is concentrated into the first year or two after diagnosis, the longer you survive with HIV the longer you're likely to survive and secondly, older people have better adherence to medications.

Specific groups of people with HIV are now relatively 'insurable'. The risk of dying in any one year is still roughly twice what it is in the general population, but this is similar to smokers, people with diabetes and people who have been successfully treated for cancer, all of whom can get life insurance.

Wayne Dam says that continued uncertainties tend to make companies wary of offering more than relatively short-term, low-payout life insurance for people with HIV. We don't know if the improvement in life expectancy in people with HIV will continue; improvements in drug regimens may not continue; late diagnosis and the long-term impact of HIV infection and treatment may continue to raise mortality.

Perhaps companies should not be so cautious. There's one country in the world where 18% of the population has HIV and collectively they own 39 million US dollars' worth of life insurance: South Africa. That's one in every two dollars'-worth of life insurance for someone in the world with HIV. The South African government instructed companies to make life insurance available as a general way of reducing the burden that early death from HIV was imposing on the population, and realised it would only work if it was available to everyone, regardless of HIV status, in order to avoid the 'those that need it most get it least' factor.

This is nothing unusual in some countries that have an insurance-based healthcare system, such as France: the burden is spread so that the sickest people get coverage. Even in the US, as long as you're in work and can afford the huge salary slice that health insurance costs, having HIV does not exclude you. Simply barring a defined group of people from coverage is generally used as a last resort by insurance companies, who would rather take your money if they can calculate your risk.

Such a model could not apply in countries where people need considerably higher sums insured than in South Africa and where, unlike the US, there is no state interest in *making* companies offer insurance. A market like the UK's leaves companies free to apply outdated

knowledge to people whose risks may be changing for the better.

Even outside HIV, statisticians and actuaries have consistently underestimated the improvements in life expectancy that have in fact taken place in the last half-century. In 1971, a paper by Swiss Re reveals,⁴ statisticians estimated that by 2007 average life expectancy in the UK would have increased from 69.2 to 70.4 years. In fact it was 77.2 years – and has grown another year since then.

Making life insurance available – and acceptable

Robert Kneepkens is Chief Medical Officer of the life and pension section of Achmea, a Dutch insurance company that originally offered life insurance to people with HIV in 1999 but got no takers because it could not offer good terms. He was part of a working group on insurance and HIV, set up by the Verbond van Verzekeraars (VVV – the Association of Insurers), in collaboration with HIV Vereniging Nederland (HVN), the Dutch organisation of people with HIV. The country has been more advanced than the UK in liaison between the HIV community and the insurance industry. The ADI/HVN issued two reports exploring the insurability of people with HIV, the first of which received wide publicity in the Netherlands and elsewhere when it was published in 2005. It⁵ said that people on “at least moderately effective” antiretroviral therapy were insurable while the second report extended this to people who were not on treatment.⁶ This second report found that people with diagnosed HIV who were not yet on treatment had no greater mortality over the next year than people who were on treatment, as long as they were over 35 (over 30 in women) and had not had an HIV-related illness in their first six months after diagnosis.

Yet since 2005, only 400 life insurance policies have been taken out by people with HIV in the Netherlands, out of an estimated eligible HIV-positive population of 15,000 (2.7%). Why so few? Kneepkens thinks it's for two reasons. Firstly, after a huge improvement between 1996 and 2006, the mortality rate in people with HIV compared to the general population has not improved further and so the premiums they are offered are still pricey. This comparable rate is called the standardised mortality ratio and for people who've never had a low CD4 count or an AIDS-related illness it's stayed stuck at two or more. This means that in any one year a person with HIV is at least twice as likely to die as an HIV-negative contemporary. The reason is not because life expectancy in people with HIV is no longer improving. It is, but it's no longer

“Why are they treating this differently to any other form of insurance? Why don't they just take something like their over-50s plan and apply it to people with HIV?”

Chris Morgan, marketing manager, Unusual Risks

outripping the general improvement in people's life expectancy over the last decade.

Secondly, consumer pressure has driven premiums for the general public down, creating a bigger gap between what they pay and what people with added risks (like smokers) pay. Kneepkens sees this as a very unwelcome development – the opposite to the one-size-fits-all policies of South Africa. “I don't like this,” he says. “It's based on the lack of solidarity in modern society.”

Even if people are aware that HIV is no bar to getting insurance, and even though in the Netherlands you can get life insurance for terms of up to 30 years, they may decide that having to pay big premiums for short-term coverage just isn't worth it and (assuming they have some) put their money somewhere else.

What's on offer?

What's available in the UK at present? Chris Morgan says there are currently six companies offering life insurance policies for people with HIV: Prudential (who, according to Kneepkens, based their product on the Dutch model), Liverpool Victoria, Bright Grey, Scottish Provident, Zurich and Aviva.

Chris Morgan gives three examples of coverage his firm has arranged for people with HIV:

- A serodiscordant heterosexual couple where the woman (32) had had HIV diagnosed for six years, with a CD4 count of 827 and an undetectable viral load on treatment. They had one child. They were asked to take out life insurance on their new mortgage by their bank but were

intimidated by the HIV questions on their application form and asked Unusual Risks to act as intermediaries. They were able to get life insurance with £72,500 covered for £29.86 a month for the woman and £21.32 a month critical illness cover for her husband.

- In another serodiscordant heterosexual couple, the man had HIV diagnosed two years ago with a CD4 count of 403 and was on treatment with an undetectable viral load. The couple had a mortgage of £157,000 and two children. They had been turned down by their own brokers. Unusual Risks were able to get quotes ranging from £29.66 a month for £50,000 for ten years to £87.65 a month for the whole £157,000.

- A serodiscordant gay couple shared liabilities of about £100,000, which included a joint loan, credit card debts and a mortgage. The HIV-positive partner had a CD4 count of 584 and an undetectable viral load. He had also been turned down for life insurance. Unusual Risks were able to find quotes of £27.10 a month for £50,000 cover, £51.66 for £100,000 and £76.25 for £150,000.

At the moment, as you can see, being eligible for life insurance still depends on you being on treatment, with an undetectable viral load and a reasonable CD4 count, and terms of more than ten years are very hard to obtain. Chris is working with companies to try to extend eligibility and term, to get companies to accept recent clinic medical tests instead of insisting on their own, and to shorten the time that companies take to insure someone.

He still feels frustrated with the attitude of companies to potential customers with HIV – “Why are they treating this any differently to any other form of insurance? Why don't they just take something like their over-50s plan and apply it to people with HIV?” but hopes to expand the range of clients he can find insurance for.

In the meantime, it is as much the perception of people with HIV that they can't get life insurance as the reluctance of the industry to cater for them that is the reason life insurance for people with HIV is an option take up so rarely. **nam**

Unusual Risks – see www.unusualrisks.co.uk or phone 0845 474 3075.

www.aidsmap.com



For more information on personal finance, including insurance, visit www.aidsmap.com/page/1501282.

CR I 2012

Summaries of the news from the 19th Conference on Retroviruses and Opportunistic Infections held in Seattle last month

SUPERINFECTION

Superinfections as common as first ones



Koshet Ronen. (<http://retroconference.org>)

The rate at which people with HIV acquire second, subsequent infections of HIV (so-called superinfection) is little different from the incidence rate for first infections, studies from Kenya and Uganda show. In the Ugandan study, one in 40 people in the community acquired HIV every year (annual incidence 2.51%), and one in 70 people who already had HIV subsequently caught a second strain. In the Kenyan study, in a higher-risk population of sex workers, the figures were one new infection a year in every 31 HIV-negative women and one superinfection a year in every 33 HIV-positive women. The studies show that having HIV confers no immune protection against additional strains; this finding has implications for vaccine design. Although there was no evidence that superinfection had any health consequences, more research is being done to find out if it does.

➔ www.aidsmap.com/page/2282167

PREVENTION

Serosorting works - up to a point

Serosorting - restricting unprotected sex to partners with the same HIV status - does work as a prevention strategy in HIV-negative gay men, a study found, but not as well as other strategies, such as using condoms or being monogamous. Researchers looked at the HIV infection rate in 12,705 gay men who had signed up to four large HIV prevention trials between 1995 and 2007. It found that men who practised serosorting were infected half as often as men who used no HIV

prevention strategy (51% efficacy). This was however only half as effective as attempting to use condoms 100% of the time (74% efficacy) and less than a third as effective as always taking the insertive, top role in anal sex. The most effective strategy was having a monogamous relationship with another HIV-negative man, regardless of condom use, which was six times more effective than serosorting (92% efficacy).

➔ www.aidsmap.com/page/2287223

TREATMENT IN PREGNANCY

Keeping mothers in care is the challenge



Giving HIV-positive, pregnant women combination antiretroviral therapy (ART) regardless of CD4 count results in fewer infections of their babies, one study found, but it also showed they were more likely to be lost from care than women given short-course prevention therapy for 24 weeks of pregnancy and a week afterwards. Nearly 20% of the babies born to mothers given short-course therapy became infected with HIV, compared with fewer than 6% of those born to mothers on ART. But there were higher drop-out rates in women continuing on ART; in the six months after giving birth, 12% were lost to care, compared with 8% who had taken short-course therapy. Another study from South Africa compared death and attendance rates of women diagnosed with HIV - some in pregnancy and others when not pregnant - and found higher death rates in non-pregnant women (9 versus 3%) but higher drop-out from care in pregnant women (11 versus 19%). Researchers were unsure why pregnant women disappeared from care; it may be that they feel they can do without treatment or because they tend to be younger and have competing obligations.

➔ www.aidsmap.com/page/2280032

RESOURCE-LIMITED-SETTINGS

Which drugs to use in Africa?

First-line HIV treatment in resource-limited countries has been based on the non-nucleoside (NNRTI) drugs, plus the nucleoside (NRTI) ones. One study from the Democratic Republic of the Congo suggests using protease inhibitors (PIs) with NRTIs may make more sense, because if treatment fails people are less likely to have drug resistance, and will have a wider choice of second-line combinations. The trial found that while an equal proportion (63 to 64%) of people had undetectable viral loads after a year of treatment, only half as many patients taking boosted lopinavir (*Aluvia* in Africa, *Kaletra* in the UK) had actual treatment failure, compared with patients on nevirapine (*Viramune*), though more people on lopinavir dropped out of the study, leading to equal undetectability rates. Lopinavir also caused less drug resistance: 85% of people who experienced treatment failure on nevirapine had resistance to it and 75% to at least one NRTI; this compares with no PI resistance and 20% NRTI resistance in people who experienced treatment failure on lopinavir.

➔ www.aidsmap.com/page/2284972

TREATMENT AS PREVENTION

Treatment cuts infection rate in Africa

A study from South Africa provides evidence that treating a high proportion of the HIV-positive population can cut infection rates in resource-limited as well as in rich countries. The study was from rural KwaZulu Natal, where one in four adults has HIV and 70% are diagnosed, a high proportion for Africa. Since 2004, the proportion of diagnosed HIV-positive people on treatment has increased from under 10% to over 40%, and over 60% with a CD4 count under 350 cells/mm³. Once more than 30% of the positive population was on treatment, the HIV infection rate among the community at large halved, from about one infection per 45 people a year to one per 80 people. This study follows similar ones from San Francisco and Vancouver that suggest a link between treatment and prevention.

➔ www.aidsmap.com/page/2287053

For full news reports and references to the original sources, visit:
www.aidsmap.com/news

ANTI-HIV DRUGS

Dolutegravir looks good



Hans-Jürgen Stellbrink. (<http://retroconference.org>)

The new once-daily integrase inhibitor dolutegravir (DTG) is at least as good as the standard-of-care drug efavirenz (EFV, *Sustiva*) in suppressing HIV in people new to therapy. After 22 months on treatment, 78 to 88% of people taking DTG (trialled at three different doses) had undetectable viral loads, compared with 72% on EFV, though this difference was not statistically significant. Fewer side-effects were associated with DTG: one in nine patients had side-effects classed as moderate or severe on DTG, compared with one in four patients on EFV. Dolutegravir once a day thus looks as potent as the only licensed integrase inhibitor, raltegravir, which has to be taken twice a day. However, dolutegravir will have to be taken twice a day by patients with extensive drug resistance.

➔ www.aidsmap.com/page/2281387

CONTRACEPTION

More on HIV risk and contraceptives

Last year, a seven-country study from Africa found that women who used hormonal contraceptives were twice as likely to become infected with HIV and, if already HIV-positive, twice as likely to pass it on to partners. This study produced consternation in the world of HIV treatment and prevention, as it implied a dilemma: would more lives be saved due to less HIV if women stopped using hormonal contraceptives, or would more be saved if they kept using them and had fewer deaths in childbirth? A new study has found a much weaker association between hormonal contraceptive use and HIV. It found no link between oral

contraceptives and HIV infections. It did find that women using injectable contraceptives were 37% more likely to acquire HIV but once behavioural factors – such as the fact that women using injectables were less likely to use condoms – were accounted for, this became a 16% greater risk, which was no longer statistically significant.

➔ www.aidsmap.com/page/2279470

FUNDING

PEPFAR prevents one in six deaths

The death rate in African countries receiving funding from the US President's Emergency Plan for AIDS Relief (PEPFAR) is 16% lower than it would have been without PEPFAR, a study shows. Eighty-five per cent of these deaths would have been due to HIV but some non-HIV-related deaths were also avoided. PEPFAR contributes over half of all the international development money spent on HIV, but focuses most of its resources on 15 'focus countries' that between them contain 50% of the people with HIV in the world. Researchers compared all-cause death rates in eight African focus countries with 18 countries with similar economic profiles. They found that, while annual mortality was a steady 0.75% a year in non-focus countries between 2004 and 2008, it fell to 0.4% in the focus countries during the same period. The fact that PEPFAR reduced deaths from all causes answers criticisms that, by throwing disproportionate amounts of money at HIV, programmes such as PEPFAR and The Global Fund were starving health systems of resources to fight other diseases such as malaria or infant diarrhoea.

➔ www.aidsmap.com/page/2280405

NEURO-COGNITIVE IMPAIRMENT

Brain impairment improves on ART

Studies on neuro-cognitive (brain) problems provided mixed news. A US study of providing antiretroviral therapy (ART) early to men diagnosed with HIV found that neuro-cognitive performance continued to decline in untreated patients – particularly fine motor skills – but reverted to normal in men given ART. A linked brain-scan study

found that two chemicals, choline and myoinositol, which indicate immune over-activation in the brain, increased slowly in untreated patients over time, but that levels stabilised in people on ART. However, a UK study measuring a protein that attaches to inflamed immune cells in the brain found that even in subjects on ART there were unusual levels of inflammation in parts of the brain that control memory, attention and decision-making. A study from the US showed that sensitive psychological tests that can detect almost unnoticeable slowness in performance can predict later deterioration. Another showed that neuro-cognitive decline was strongly associated with diabetes and central fat accumulation, while a study from Italy found that low levels of HDL or 'good' cholesterol were associated with brain impairment.

➔ www.aidsmap.com/page/2283344

PREVENTION

PrEP: adherence is everything



Jared Baeten. Photo by Gus Cairns.

Adherence rates explain the differences reported in the efficacy of PrEP (pre-exposure prophylaxis) seen in different trials. Efficacy rates reported from different studies in the last two years ranged from zero in FEM-PrEP (a study among 2056 women) to 75% in Partners PrEP (a study in 4758 HIV-serodiscordant couples). How could giving HIV-negative people antiretrovirals have no effect in one study, yet prevent three out of four HIV infections in another? Two studies showed that, although participants in both studies claimed high rates of adherence (95% in FEM-PrEP and 97% in Partners PrEP), measuring drug levels showed that fewer than 40% of the women given

Truvada in FEM-PrEP had actually taken it in the last two days. In contrast, the true adherence rate in Partners PrEP was over 80%. Another study, of the gay men's PrEP study iPrEx, showed that four or more doses of PrEP per week would be sufficient to provide near-complete protection against HIV.

➔www.aidsmap.com/page/2278778

ANTI-HIV DRUGS

New tenofovir is more potent

A new version of the drug tenofovir (*Viread*) that reaches higher levels inside cells than standard tenofovir produced greater drops in HIV viral load after eleven days of therapy. A study compared a dose of tenofovir with three different doses of the new tenofovir prodrug GS-7340, which is chemically different from tenofovir but is converted to it in the body. After eleven days, GS-7340 produced a 29-fold and 56-fold drop in viral load in patients given 25mg and 40mg doses respectively, compared with a 9.3-fold drop in patients on tenofovir. Patients taking 25mg of GS-7340 had a quarter as much tenofovir in their blood than patients taking the standard drug, but seven times more in their cells. Lower blood levels may mean that GS-7340 causes less kidney damage, the most serious side-effect of tenofovir. Manufacturers Gilead said they will look at substituting GS-7340 for tenofovir in their four-drug 'Quad' pill, which also contains elvitegravir, a new integrase inhibitor: in another study, this combination pill suppressed HIV at least as well as the triple-drug tablet *Atripla*.

➔www.aidsmap.com/page/2280627

TREATMENT GUIDELINES

Treat everyone, say US guidelines

The opening line of the new HIV treatment guidelines released by the US Department of Health and Human Services (DHHS) declares that "antiretroviral therapy (ART) is recommended for all HIV-infected individuals". The guidelines marshal a range of studies that show that measurable viral load at any CD4 count is associated with a higher risk of death and illness, and higher rates of cancer and heart disease. This blanket recommendation widens the gap between the US guidelines and the UK guidelines issued by BHIVA (currently in draft form after public consultation), which contain a general recommendation to start treatment at a CD4 threshold of 350 cells/mm³. BHIVA concluded there was no convincing evidence of either clinical harm or benefit to people given ART at higher CD4 counts. The BHIVA guidelines do, however, recommend treatment for people at higher CD4 counts who have early infection, hepatitis B or C, or a number of other conditions. Both guidelines recommend that the prevention benefits of treatment are discussed with patients but, while the US guidelines recommend that ART is prescribed to "all patients at risk of transmitting HIV to their partners", the UK guidelines make it the patient's decision and say that if, after discussing prevention with a doctor, they wish to start therapy, "this wish should be respected". It is estimated that only 51% of people diagnosed with HIV in the US regularly access care, compared with nearly 90% in the UK.

➔www.aidsmap.com/page/2295568

News picks from other sources

Teenagers born with HIV tell of life under society's radar

The Guardian | 11 Mar 2012

HIV-positive youngsters who were infected before or at birth reveal their secret lives.

➔<http://bit.ly/HxgtAV>

Reminders by text messages help HIV patients stick to antiretroviral drug therapy

Medical News Today | 14 Mar 2012

Mobile phones could play a valuable role in helping HIV patients to take their medication every day, according to a new Cochrane Systematic Review.

➔<http://bit.ly/HID4oO>

My Grindr experiment

UK Positive Lad | 5 Mar 2012

I started wondering last weekend what kind of responses someone would get if their Grindr profile said that they were HIV+.

➔<http://bit.ly/HoedKo>

Law on condoms threatens tie between sex films and Los Angeles

The New York Times | 7 Mar 2012

Since the early days of X-rated films, San Fernando Valley has been the industry's home. With year-round sun, access to Hollywood filmmaking expertise and beautiful young people flocking to the region from around the country, pornographic studios have filmed thousands of movies here each year.

➔<http://nyti.ms/H6R4ff>

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Overhauling health [p.4]

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- 3 See www.bhiva.org/ClinicalStandards.aspx
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Full speed ahead to curing hepatitis C [p.8]

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Rest assured [p.12]

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Looking to the future



Leaving a gift to a charity in your will is one of the most valuable and lasting ways you can support a cause you care about.

In the dark, early years of the HIV epidemic, when so many people with AIDS were dying, HIV organisations felt deeply uncomfortable following other charities in promoting legacy donations. Nevertheless, many people left gifts in their wills and their generosity helped build remarkable, dynamic services.

It's perhaps a sign of how the lives of people with HIV have transformed, thanks to effective treatment, that we can write today about the benefits of remembering NAM in your will, with far less concern that we may cause offence.

Of course, deciding whether to include a charity in your will is a very personal decision, and we understand and respect that the ones you love will come first in your thoughts.

If the time ever feels right for you though, a gift to NAM, no matter how big or small, would make a huge difference to the work we are able to achieve for people with HIV.

Where we've come from

In the 1980s, over 40% of people with HIV did not survive for more than two years after diagnosis. Today, thanks to phenomenal advances in science, the right treatment and care can mean a near-normal lifespan.

In 1987, NAM started out producing a simple ring binder containing the information there was at the time about HIV (the National AIDS Manual). NAM became a beacon of trustworthy, reliable and accurate information amidst the chaos at that time – an organisation that could help to calm the hysteria and fear by providing the facts.

Thanks to years of loyal support from our generous donors – and some of you will be reading this – NAM has been able to respond to changing needs every step of the way; from providing information on taking the multitude of pills early treatment required and how to deal with their often devastating side-effects, to information about ageing, living well and, now, information about prospects for a cure.

Where we are now

Far more than a ring binder, NAM now has audiences in over 185 countries around the world and our website, www.aidsmap.com, is one of the world's leading HIV websites.

HIV treatment update has been keeping people up to date with the latest treatment news, research and developments for 20 years. In that time, people have relied on it to keep them informed – and they still do, with over 60% of respondents from our latest reader survey telling us *HTU* is the only printed source of information about HIV they receive.

NAM's award-winning patient information range has been praised by clinicians, the British Medical Association and, most importantly, people with HIV themselves. We work with 775 clinics and support groups in the UK to ensure that as many people as possible can access the vital information they need to stay healthy. Last year alone we distributed over 81,000 patient information resources across the UK.

Throughout our development one thing has remained constant, and that is the profound effect NAM's information can have on people's lives.

We know that accessing reliable and accurate information can have an extremely positive, and sometimes life-changing, effect. We know that people are able to change their lives for the better thanks to the information they have

In the documentary *We Were Here* – a deeply moving account of AIDS in San Francisco in the early 80s – a clinician who worked at San Francisco General Hospital recalls how, often, patients were so well informed about their illness that their care became a remarkable partnership between them and their healthcare workers, something which medicine had not previously seen. It's a wonderful testimony to the role health and treatment information, like NAM's, has played over the years.



received from NAM. And we know this because people tell us.

Earlier this year Patrick told us:

“I was diagnosed with HIV in early December at the age of 24... I was scared and felt alone. I initially couldn't bring myself to talk to even my closest friends or family about the diagnosis. aidsmap.com has helped me beyond belief and helped me to be able to talk to others in person. You are an invaluable resource, thank you! Seriously, thank you.”

Looking to the future


HIV is a long-term condition and this brings with it a different set of challenges. A person living with HIV needs reliable information to understand their treatment and care options, how to monitor their health, how to deal with side-effects – the list goes on.

We want to continue to be there for people like Patrick who rely on us to keep them informed at often frightening times in their lives, and to reach and empower more people with HIV to live longer, healthier lives. There is still a huge variation in the quality of information available worldwide and so, above all, we want to create a future where access to accurate, impartial and up-to-date information is a right, not a luxury.

Leaving a gift in your will can make such a huge difference to the work NAM can achieve. No matter how big or small, whether it's five or five thousand pounds, you can make your money count, and make a real change to the lives of people with HIV.

With your help we can do more

The commitment and generosity of people like you has been at the heart of NAM's success over the years. Crucially, your support also allows us to remain wholly independent; leaving a gift to NAM will help us to ensure there is always accurate, reliable and unbiased HIV information available to anyone who needs it.

If the time is right for you to consider leaving a gift to NAM in your will, you can find out more at www.aidsmap.com/gift, or call 020 3242 0820 and ask to speak to Beth. 

Revised and updated to include the newest HIV treatment options, the eleventh edition of NAM's **Anti-HIV drugs** booklet is now available at: www.aidsmap.com/booklets.

With information on individual drugs, including side-effects and drug interactions, it aims to help you decide what questions to ask your doctor about starting or changing treatment.

If you work in a clinic or support group in the UK, you can order multiple copies for free. To order your copies, contact us at info@nam.org.uk or call **020 3242 0820**.

Anti-HIV drug chart

| Generic name | Trade name | Formulation | Standard adult dose | PK/PD | Major side effects |
|---|------------|------------------------|---------------------|-------|---|
| Reverse transcriptase inhibitors | | | | | |
| Zidovudine (ZDV) | | | | | |
| ZDV | Retrovir | Tablets, oral solution | 300mg b.i.d. | 1 | Neutropenia, anaemia, myelosuppression |
| Didanosine (ddI) | | | | | |
| ddI | Videx | Tablets, oral solution | 200mg b.i.d. | 1 | Peripheral neuropathy, lactic acidosis |
| Zalcitabine (ddC) | | | | | |
| ddC | Abdica | Tablets | 375mg b.i.d. | 1 | Myelosuppression, peripheral neuropathy |
| Stavudine (d4T) | | | | | |
| d4T | Zeneca | Tablets | 40mg b.i.d. | 1 | Myelosuppression, peripheral neuropathy |
| Lamivudine (3TC) | | | | | |
| 3TC | Epivir | Tablets, oral solution | 150mg b.i.d. | 1 | Myelosuppression, peripheral neuropathy |
| Abacavir (ABC) | | | | | |
| ABC | Ziagen | Tablets | 300mg b.i.d. | 1 | Myelosuppression, peripheral neuropathy |
| Tenofovir (TDF) | | | | | |
| TDF | Adavert | Tablets | 300mg q.d. | 1 | Myelosuppression, peripheral neuropathy |
| Emtricitabine (FTC) | | | | | |
| FTC | Emtriva | Tablets | 200mg b.i.d. | 1 | Myelosuppression, peripheral neuropathy |
| Non-nucleoside reverse transcriptase inhibitors (NNRTIs) | | | | | |
| Efavirenz (EFV) | | | | | |
| EFV | Sustiva | Tablets, oral solution | 600mg q.d. | 1 | Neurotoxicity, rash, dizziness |
| Delamanvir (DMV) | | | | | |
| DMV | Prezista | Tablets | 1200mg q.d. | 1 | Neurotoxicity, rash, dizziness |
| Protease inhibitors | | | | | |
| Atazanavir (ATV) | | | | | |
| ATV | Ziagen | Tablets | 300mg q.d. | 1 | Neurotoxicity, rash, dizziness |
| Dolutegravir (DTG) | | | | | |
| DTG | Tivicay | Tablets | 50mg q.d. | 1 | Neurotoxicity, rash, dizziness |
| Integrase strand transfer inhibitors (INSTIs) | | | | | |
| Raltegravir (RAL) | | | | | |
| RAL | Isentrop | Tablets | 400mg b.i.d. | 1 | Neurotoxicity, rash, dizziness |
| Maraviroc (MVC) | | | | | |
| MVC | Lexiva | Tablets | 600mg b.i.d. | 1 | Neurotoxicity, rash, dizziness |



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NAM would also like to acknowledge the generous support of its individual donors.

Donate to NAM

Every year NAM provides information resources, like *HIV treatment update*, to thousands of people living with HIV around the world, completely free of charge. To do this we really do rely on the generosity of people like you to help us continue our vital work. No matter how big or small, your donation can make a huge difference to the work we are able to achieve. Make a difference today, please donate whatever you can by visiting www.aidsmap.com/donate or by calling us on 020 3242 0820. Thank you.



Where to find out more about HIV

Find out more about HIV treatment: NAM's factsheets, booklets, and website keep you up to date about key topics, and are designed to help you make your healthcare and HIV treatment decisions. Contact NAM to find out more and order your copies.

www.aidsmap.com

Visit our website for the latest news and free web versions of our resources. You can also explore HIV services local to you in our e-atlas, find out more about us in our blog and sign up for free email bulletins.

THT Direct

Offers information and advice to anyone infected, affected or concerned about issues relating to HIV and sexual health.

☎ 0808 802 1221
Mon-Fri, 10am-10pm
Sat-Sun, 12pm-6pm

i-Base Treatment Phonenumber

An HIV treatment phonenumber, where you can discuss your issues with a treatment advocate.

☎ 0808 8006 013
Mon-Wed, 12pm-4pm



Everyone who uses clinical HIV services in London is encouraged to give their feedback in an anonymous survey, *My Care, I Care*.

The NHS London Specialised Commissioning Group has commissioned the survey, which is open until 30th April.

The results will be used to improve NHS services for people living with diagnosed HIV.

➔ www.mycareicare.org.uk