

HIV treatment update

Issue 215
Spring
2013

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HIV treatment update

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ISSN 17567890

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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

NAM is a charity that exists to support the fight against HIV and AIDS with independent, accurate, up-to-date and accessible information for affected communities, and those working to support them.

For more information, and details of our other publications and services, please contact us, or visit our website, www.aidsmap.com.

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In this issue

**Gus Cairns**
Editor

The day before I write this, 29 April, a pilot of Universal Credit (UC) started in areas of greater Manchester and Cheshire. UC is a new monthly welfare benefit which will unify six major benefits currently claimed – it excludes Personal Independence Payment (the new Disability Living Allowance) and Council Tax Benefit. The government initially planned to move everyone except people in Northern Ireland to Universal Credit by 2017, though they've gone a bit quiet on that one lately as rumours surface of rows between the Department of Work and Pensions and the Treasury.

The biggest single change UC entails is that Housing Benefit and Support for Mortgage Interest are eventually to be abolished; the new Credit will cover your rent or mortgage interest as well as your other income needs.

Housing Benefit won't exactly be mourned. Separately run, as it is, by local authorities and paid direct to landlords, it is too often a cause of homelessness, via bureaucratic delay, rather than a cure for it.

But, as Philip Glanville shows on page 8, this is just one of a number of changes that may in the future severely restrict the availability and quality of housing for people in housing need. These changes may have a disproportionate impact on people with HIV for all sorts of reasons – perhaps because we are more likely to be disabled, or dependent on social housing for other reasons such as refugee status.

On another note entirely, we're not *Hepatitis treatment update*: if we were, then this issue would be filled from cover to cover with all that's been emerging from the recent International Liver Congress, and from CROI before that, on the astonishing pace of development in drugs to treat hepatitis C. It really does look as if there will be a tolerable oral combination therapy for hep C soon: who would have guessed this even three years ago? The sheer number of drugs and combinations on trial may be bewildering to the non-specialist, so read Ingo van Thiel's piece for a good succinct update on where we stood at the beginning of 2013. It will be interesting to go back to it in 12 months' time.

Finally, from one area that is changing rapidly to one that has, sadly, scarcely changed at all: the social stigma against people with HIV and, in particular, the way people stigmatise themselves. As the work of social scientists like Nadine Ferris France and Seth Kalichman shows – see *The diminished self*, page 4 – we have a long way to go before we find really effective ways of tackling the shame and isolation people with HIV, often so unnecessarily, impose on themselves. Maybe it won't go away entirely until we find a cure for HIV – which we will be looking at in the next, and last, issue of *HTU* (see *Upfront*, opposite). Watch this space!

Upfront

HIV treatment update: the future

by Gus Cairns

The next issue of *HIV treatment update*, this summer's edition, will be the last one. *HTU*, 21 years old this year, is one of the oldest continuously published HIV newsletters in the world and has kept up a high standard of news, comment and reportage. It remains one of NAM's best-recognised publications: but it has started to make less sense than in the past to dedicate increasingly pressured resources to a print magazine, no matter how high its production values.

We still have a loyal group of print-issue subscribers and, for subscribers reading this, we are grateful for your continued interest, your loyalty, and your suggestions and queries. From what we know (through the results of readers' surveys over the years), many of you are of the generation that helped set up NAM and immediately benefited from it: people like me, mostly older gay men, infected in the early days of HIV, long-term survivors – or friends of those who did not survive. We're a group who got into the habit of educating ourselves about the treatment and science of HIV at a time when rapidly acquiring such knowledge might be a life and death issue: you might learn about a potentially lifesaving clinical trial just in time, for instance.

Two things have changed fundamentally since then: the nature of HIV treatment and the way people acquire knowledge.

These days, although HIV infection may still have serious health consequences, we know, essentially, how to deal with it. If you are diagnosed with HIV, even with a low CD4 count, you're unlikely to have to do your own research into frontier science. If you come down with a rare cancer you may have to, but that's not necessarily a health issue specific to your HIV (though we will continue to cover news on conditions strongly related to HIV, as in the hepatitis C treatment update in this issue).

The crucial factor in stopping HIV infection in its tracks is access to HIV

treatment. However, access to information is still central to living well with HIV. And access is overwhelmingly about social, economic and psychological circumstances. If you are a well-informed, well-connected, well-adjusted person who tests regularly for HIV, gets diagnosed in plenty of time, works with your doctor to choose the best treatment regimen to start on, and are able to look after your health more generally... then you are highly likely to live a normal lifespan. The people who still die early from HIV are most often the poor, the homeless, the refugees, the survivors of abuse, the depressed, the alone. And even if you are one of those people whose health hasn't suffered, you may have concerns related to other, non-health-related, aspects of living with HIV.

That's why *HTU*, starting about four years ago, consciously widened its coverage to include pieces on everything from housing (in this issue), employment and benefits, through the science of mind and of society (as in the piece on self-stigma in this issue), to psychology and mental health, to faith and religion.

Broader coverage implies a broader audience. Although funded as a newsletter for people with HIV in the UK, we know that when *HTU* articles appear on NAM's website, aidsmap.com, they are also read by patients, researchers, doctors and people working with HIV all over the world. To preserve the added value of a print subscription, we originally published articles online three

months later. But once the decision was taken to publish them online at the same time as in print, it started making less sense to do a print edition for an ever-reducing group of print subscribers – especially as surveys also tell us that readers have easy internet access and are comfortable with finding their HIV and health information online.

This links to the second reason we have decided to change. It is not so long ago that when I wanted to do in-depth research for the background to a treatment piece, I had to go to the British Library, sit at a desk, and send for physical copies of articles to look at. These days that's almost inconceivable; we've got so used to a world in which information is instantly available online that the idea of it hidden away on shelves deep underground sounds like something out of a spy thriller.

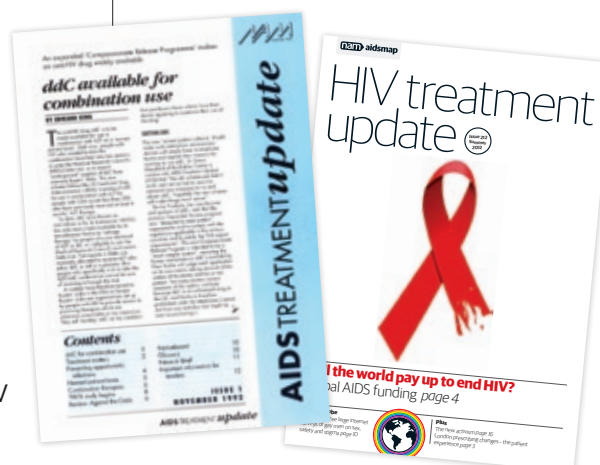
These days, the skill lies not in mining for the information you need, but in panning the gold from the gravel – distinguishing the flood of commentary, opinion, argument, axe-grinding and just plain crankiness from the trickle of stuff that tells us something new. This we have tried to do in *HTU*: draw together the kind of information that may appear as isolated news stories on [aidsmap](http://aidsmap.com) and elsewhere, and synthesise, summarise and look for the significance in them.

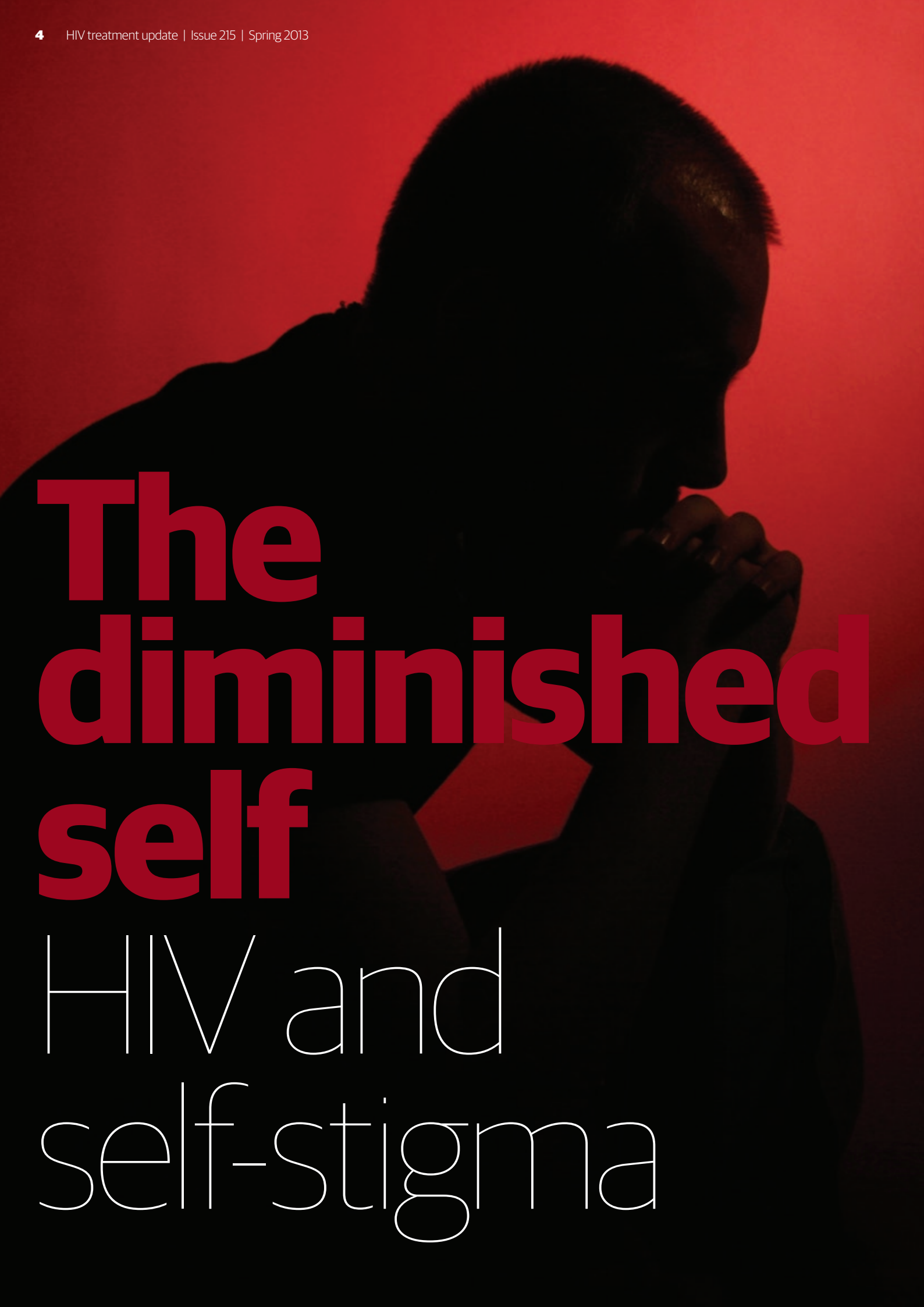
We've always tried to do this for treatments, but in a world where the big decisions and dilemmas in HIV are largely about more nebulous and difficult things like global funding priorities and human behaviour, this feels more important than ever.

So, while *HTU* may be ending, the type of features *HTU* carries will not be and we plan to expand the range of news features we write for [aidsmap](http://aidsmap.com). The more wide-ranging and analytic pieces *HTU* has carried will have a prominent place there.

We look forward to your continued attention and interest as readers of an ever-developing [aidsmap](http://aidsmap.com) in this new world.

Best wishes,
Gus Cairns, Editor, *HIV treatment update*.





The diminished self

HIV and
self-stigma

Gus Cairns investigates the negative beliefs people with HIV can have about themselves, and what to do about them.

Let's suppose you're part of a community where HIV is common, but you hold negative views about people who have the virus: because of fear, or ignorance or a generally conservative viewpoint.

You might say things like "Most people with HIV get it from being weak and foolish" (22%); "You can't trust people like that" (24%); "They should feel guilty for what they've done, really" (36%).

Secretly, you fear HIV and are too scared to be tested. You know it's common in your community but you'd rather not know your status (48%), mainly because *you know* people would leave you if you had HIV (41%).

As the percentages indicate, this is based on a real survey, in this case of 500 black South Africans living in a township.¹

The stigma people with HIV encounter from other people is obviously problematic. But this article is about what happens to someone with such opinions if they are diagnosed with HIV themselves. In some cases, people may realise that much of what they thought was wrong. But in other cases, they may hold on to the disapproval, turning the stigma in on themselves, into guilt, shame and silence.

This is internalised stigma, or self-stigma (we'll look later at the difference between those two).

Stigma and shared stigma

What is stigma? We've written about it before in *HIV treatment update*, for example in an article about the Stigma Index (www.stigmaindex.org) in issue 191.

The sociologist Erving Goffman described stigma in this way:

"While a stranger is present before us, evidence can arise of his possessing an attribute that makes him different from others...and of a less desirable kind - in the extreme, a person who is quite thoroughly bad, or dangerous, or weak. He is thus reduced in our minds from a whole and usual person to a tainted, discounted one. Such an attribute is a stigma, especially when its discrediting effect is very extensive."

He also added that, to understand stigma, "a language of relations, not attributes, is really needed."² What's uniquely painful about stigma is that it's transactional: something stigmatiser and stigmatised do together.

In the article about the Stigma Index,

Yusef Azad, director of policy and communications at the National AIDS Trust, put it this way:

"In stigma, a belief system is actually shared by the stigmatiser and the stigmatised. The stigmatiser fears becoming the type of person they hate, and the stigmatised person feels [that] shame...It's dependent on the stigmatised person actually giving a damn. Stigma has a grip on people: that's what's so toxic and unfair about it."

So, you can be prejudiced against people and think them inferior, but they might not give a damn; you can discriminate against them, but discrimination is something that can be shown to be visibly unfair and can often be redressed. But stigma alters the way

“It's dependent on the stigmatised person actually giving a damn. Stigma has a grip on people: that's what's so toxic and unfair about it.”

Yusef Azad, director of policy and communications at the National AIDS Trust

the stigmatised person thinks of themselves, and only really has one answer: the person (perhaps with support and positive role models) must decline to be stigmatised.

The damage of stigma

Communities that are themselves stigmatised can be especially hard on one of their own who is seen to be deviant or bad. HTU 187 looked at HIV-related stigma within gay and African communities in *Stigma begins at home*.

The theme is underlined by the US behavioural researcher Seth Kalichman. He has investigated the powerful difference

stigma can make to the lives and health of people with HIV or at risk of it. He found that those with stigmatising attitudes were three times less likely to get tested for HIV.

People who hadn't tested were also far less likely to have ever used a condom, and far more likely to have been diagnosed with another sexually transmitted infection. They were also 40% more likely to be male and 50% more likely to have dangerous beliefs about HIV (for instance, that you could get rid of AIDS by having sex with a virgin). In some other cases, they shared these attitudes with the surprisingly high proportion of people - 18% - who had tested for HIV but said they did not know their status.

Stigma research is complex in part because it is usually impossible to untangle causation in the research findings: "Better self-image leads to positive health behaviours, and positive health behaviours lead to better self-image," comments Kalichman. "These things happen in clusters."

So, stopping stigma, giving people correct information about HIV, and encouraging testing are more likely to change people's HIV risk for the better if addressed together, rather than singly.

In another paper from South Africa,³ Kalichman and colleagues investigated traditional beliefs about HIV, such as AIDS being caused by spirits and supernatural forces. They found that the people who held these beliefs were overwhelmingly more likely to believe that people with HIV have the virus through being weak and foolish, should be isolated (both nine times more likely), and had done something wrong and deserved to be punished (six times more likely).

Even when the figures were adjusted for people having correct knowledge about HIV transmission, people with strong traditional beliefs were still three times more likely to believe that people with HIV should be punished and seven times more likely to describe them as weak and foolish, though this knowledge largely stopped them thinking that they should be isolated.

Stigma is resistant to information: it is an overall mindset that may only change slowly - even in response to the shock of finding yourself one of the people you'd previously stigmatised.

Measuring self-stigma

Kalichman and colleagues have turned a questionnaire that reliably correlated

stigmatising attitudes with risk-taking and avoidant behaviour around HIV into a seven-item instrument that measures how people feel about themselves.⁴

Even the questionnaire is an uncomfortable read. It combines two questions that rate people's ease with disclosure ("It is difficult to tell people about my HIV infection" and "I hide my status from others"), with one about blame ("It is my own fault I am HIV positive") and four on whether people have the following negative feelings about themselves: dirty, guilty, ashamed, worthless. The degree to which people concur with these finely differing feelings can provide quite an accurate measure of self-stigmatisation.

In a recent study in the US,⁵ Kalichman and colleagues paired up HIV status disclosure – an important factor not only in helping prevent the spread of HIV, but in helping people combat social isolation – with internalised stigma, as well as with depression score, age, education and income. They found that depression, age, education and income had no influence on whether someone was 'out' as HIV positive; indeed, when they looked at whether people had disclosed to a primary sexual partner, they found that depression was associated with a small but statistically significant increase in the likelihood of disclosure.

When they added in internalised stigma, though, the difference was stark: people with internalised stigma were half as likely to disclose their HIV status to their partner and less than half as likely to disclose it to their family.

Contrary to what one might expect, depression and internalised stigma were not strongly associated.

The Centre for Epidemiological Studies Depression Scale (CES-D) is one of the standard measuring instruments for depression. It asks about the degree to which people have experienced specific depressed emotions at times during the past week ("I have felt I could not shake off the blues even with help from family and friends" and "I have thought my life has been a failure" are two examples).

The self-stigma index, in contrast, asks about whether people *generally* feel bad about themselves in particular ways. Because it's less tied to moments of intensity, it may be capturing something colder and less changeable: their considered verdict on themselves as human being. Self-stigma may be experienced as a grim acceptance that things are the way they are.

"In some places," Kalichman says, "People may have good reason to hold some of these beliefs. Disclosure is a problem: people may react badly. But when you yourself hold the

“People with self-stigma pull away from you so they don't get rejected: but they're pulling away on the basis of what they think you think of them – even when it isn't what you think.”

Nadine Ferris France

beliefs you think those you disclose to will hold, it makes disclosure impossible.”

This is anticipated stigma: the expectation that people will hold the same poor opinion of you as you do yourself. It can make it difficult to disentangle cause and effect: are people reluctant to disclose to others because they have experienced discrimination in the past, or because they anticipate it?

People in one South African survey⁶ who had sex without disclosing were twice as likely to say they had lost a job or housing because of their status, and 50% more likely to have experienced discrimination in general. "But," as Seth Kalichman says, "people with high levels of internalised stigma may blame everything on their status. They may attribute being fired or evicted to their HIV because they feel it's the worst thing about them."

Equally, though, high rates of self-stigma and high rates of external stigma are linked. "We found higher levels of both discrimination, including violence, and stigma in South Africa than in the US – and as a result more attempt to hide who you are. In Atlanta, in the clinic I worked in, we found a few people would take their antiretroviral pills out of their bottles and put them in

another container to conceal being HIV positive. In South Africa, the clinic parking lot was *full* of discarded drug bottles: everyone would put them in a bag or in their pocket."

With, no doubt, knock-on effects on adherence – and on the viability of pre-exposure prophylaxis (PrEP).

The assumption of rejection

"Being gossiped about." This is the fear most often cited by people with high levels of self-stigma. Not so much overt rejection, discrimination or even violence, but what's said behind your back, the avoided glance, the assumed dislike.

"People with self-stigma pull away from you so they don't get rejected: but they're pulling away on the basis of what they think you think of them – even when it isn't what you think."

So says Nadine Ferris France, a researcher who has worked on violence against women for the World Health Organization, and was the Executive Director of Health Development Networks, a Thai/Irish collaboration for people affected by HIV and TB, including helping them self-advocate.

Now back in Ireland, she has set up a project to understand and delineate the core beliefs and characteristics of people attending the Open Heart House HIV Centre in Dublin.

The as-yet unpublished research is based on in-depth, searching interviews with 17 people with HIV chosen to be representative of affected communities. Its title – *An unspoken world of unspoken things*⁷ – is based on a remark made by an interviewee about how self-stigma is all about absence: the disclosure not made, the friendship unattempted, the touch never reached for.

"Self-stigma reduces your expectations," says France. "It makes you reduce your life to just living."

France is specific about using the term self-stigma rather than internalised stigma. The latter assumes that stigma starts as a set of negative assumptions about HIV held by society, manifested in a set of discriminatory acts inflicted on the person with HIV – who then starts believing in some of the assumptions themselves, a sort of collaboration with one's abusers.

"But the individual, as part of that society, already has strong beliefs and self-stigmatising views," says France. If you fail to take the effects of self-stigma into account, you may over-estimate the hostility that people with HIV have to cope with.

She praises the Stigma Index project as an important piece of community-led social investigation, but urges caution in using participants' accounts of being gossiped about as a measure of social stigma.

"We find, in fact," she says, "that people self-stigmatise about two to three times as much as people actually stigmatise them."

In the studies in Cape Town, for instance, while 10% of the general public thought that people living with HIV were 'dirty', 27% of people living with HIV felt dirty; whereas 38% of people living with HIV felt ashamed of their condition, only 16% of HIV-negative people thought they *should* be ashamed of it.⁸

Hence the core assumption in self-stigma that people are talking about you behind your back: faced with little direct evidence of hostility, the person's own negative self-beliefs force them to conclude that people regard them with *concealed* hostility – when they probably don't. "They think you are a migrant and sponging off resources, or a gay man who's morally redundant anyway, or a drug addict...parasitic deviant individuals," said one of France's interviewees. But how does he know?

This perception of social ostracism has tragic consequences which emerge as separate but linked threads in France's analysis: it leads to fear of disclosure, which leads to social isolation, a life of no sex or anonymous sex that avoids disclosure, negative body image, feelings of hopelessness and what France calls "restricted agency": a feeling there is very little you can do to change your life. "I have to live with a secret that takes up a lot of energy, so I have less energy to focus on work, which means I won't be as successful as I could be," said one interviewee.

"One of the things that really jumped out," says France, "is not so much that our interviewees were avoiding having sex – though some were – but that self-stigma and disclosure anxiety took all the pleasure out of sex."

"My sex life...the intimacy, you know, is gone," said one woman. "You know, the experiment, the stuff, all that's gone, it's just basic with the condom. I tried to say to him, you know I'm undetectable, this is what the doctors say, but then I feel guilty about saying that, because I'm thinking, sure he must be thinking 'this one just wants to have sex without using a condom'."

"The other thing that really surprised us," says France, "is that unless you work on the core beliefs, self-stigma persists. Two of our interviewees were recently diagnosed, and one had been living with HIV for 27 years: yet there was no difference in their perceptions. You'd think self-stigma would ebb as time went on, but it's impervious to new experience or knowledge if it's something that's founded in a pre-existing set of negative beliefs about yourself."

Self-stigma can stick because it actually serves a protective function. The person's

“Going around speaking about HIV, wearing 'HIV positive' T-shirts: it makes sense that this would work, but not to the extent we'd hope, and there's not much data that the effect lasts.”

Seth Kalichman

low expectations of others' expectations of them give them an excuse never actually to put those expectations to the test. "You can say to yourself, I'm not going to do that course or apply for that job, because I'm a bad person or because I'll be stigmatised," says France. "Losing the self-stigma may involve a lot of courage and a feeling that you are stripping off a protective cover."

Addressing self-stigma

Given this, how can self-stigma be addressed?

One thing talked about at Open Heart House was the value of peer support. If they could steel themselves to meet other people with HIV, participants often discovered a wonderful sense of social solidarity and support, especially in helping others.

This has limitations, though. Seth Kalichman comments: "Going around speaking about HIV, wearing 'HIV positive' T-shirts: it makes sense that this would work, but not to the extent we'd hope, and there's not much data that the effect lasts." Activism does not always fix a person's damaged sense of self. The recent death of prominent US AIDS activist Spencer Cox – a pioneering treatment activist in ACT UP, who spoke openly about depression, campaigned for

better mental health for people with HIV, but in the end apparently gave up taking his HIV meds – bears witness to this.

So it's ultimately about changing self-beliefs – which may involve having to change beliefs held well before one's HIV diagnosis, such as feeling dirty about being gay, or grieving for the loss of family, friends and lovers, or being traumatised by abuse (child sexual abuse has a very strong association with subsequently becoming HIV positive).


Nadine Ferris France recommends a number of methods of strengthening 'mindfulness', the ability to question your own thoughts. Given not everyone can get in-depth counselling, she is an advocate of inquiry-based stress reduction, a slimmed-down version of cognitive behavioural therapy devised by US self-help guru Byron Katie.⁹

This invites people to question negative self-beliefs by asking of themselves whether those beliefs are true, how they know they are true, how they react when believing they are true, and who they would be if they didn't believe they were true; finally, it gets them to explore the opposite belief.

This sort of affirmative work can do wonders, especially in people who've never experienced it before, though people with a deeper sense of doom and 'wrongness' may require more in-depth psychotherapy. But whatever method is used, demolishing self-stigma is about helping people get to the point when they can decline to be stigmatised – where, in France's words, they can say: "If I don't believe I'm a bad person, why would I believe you believe I'm a bad person?"

Every bully needs a victim. If one day the person simply stops thinking of themselves as a victim, whatever prejudice or discrimination is happening ceases to have its power to degrade and can be better fought. If you can achieve that freedom in your head, it's catching.

France offers an example: "Jo Manchester was one of the founders of ICW, the International Community of Women Living with HIV and AIDS. When she was diagnosed, terrible things happened including her losing her job. I remember her saying to me: 'One day, I just thought "Right, go on, stigmatise me then. I don't care."' From then on, I remember her saying, she never experienced stigma directed against her again." And she's become an example for other women with HIV.

Gandhi is supposed to have said "Be the change you want to see in the world". But actually he didn't. He said something better, more precise and less prescriptive. "As a man changes his own nature...so does the attitude of the world change towards him." 

Hurdles to

How new social housing and benefits

Having somewhere safe, secure and comfortable to live is something we all want, and is an important part of looking after our physical and emotional health. But for some people with HIV, finding or keeping somewhere suitable to live may be about to get harder. *Philip Glanville*, policy and parliamentary officer at the National AIDS Trust, looks at the issues.

Housing rarely seems to be out of the news these days, whether it's fluctuations in the housing market, growing homelessness, changes to the benefits system, exposés on rogue landlords, or rising rents. That housing, as an issue, is changing and rising up the national agenda is unmistakable. However, what has been less clear is the impact that increasing interest in these issues and the changes to the housing and benefits system may have on people living with HIV.

At the National AIDS Trust (NAT), we published a report looking into HIV and housing-related issues in January 2009,¹ and followed it up a year later with a practical guide for housing officers, providing guidance on the impact of HIV on housing need.²

We regularly respond to enquiries on housing from individuals with HIV and organisations supporting them. The nature of these queries has been changing, however, and a recent survey of organisations supporting people living with HIV confirms that changes to the welfare system and the growing pressures on the supply of new, affordable housing are combining to have a significant impact on people living with HIV. Eighty-six per cent of organisations responding to a recent NAT³ survey reported a rise in housing-related cases, highlighting benefits and housing allocations as the key areas of concern.

Over the coming year, and in response to changes in housing policy, NAT is planning

to do more targeted work on the impact of these changes. So having this opportunity to outline some of the key issues facing people living with HIV could not have come at a more appropriate time.

It is worth noting that, although the changes to the welfare and benefits system apply across the UK, the housing powers in the *Localism Act 2011* discussed below only apply to England.

How these changes interact with welfare reform and what impact they will have on people living with HIV in England is also discussed below.

The Localism Act 2011 and how it might affect you

The *Localism Act 2011* changes the powers of local government in England. As a consequence the rules governing the access to, and regulation of, social housing (housing owned by local authorities or 'registered social landlords', rather than privately owned) are going through one of the biggest changes in a generation due to this new piece of legislation.

Depending on where you live, whether you are homeless, claim Housing Benefit or need access to social housing, or are likely to need this support in the future, these changes may have a significant impact on you. The *Localism Act 2011* is also going to alter substantially the types of homes on offer to you, and may change whether or not you are able to access social housing at all.



o housing

fit rules may affect people with HIV



Changes to how social housing will be allocated

The changes have been brought in by national government, but decisions on the implementation of the new powers, and how or whether they are used (or not), are by and large left to local authorities.

Under the *Localism Act 2011*, local authorities now have greater powers in deciding how to manage their housing waiting lists, who will have access to them, how they will be assessed, who will be prioritised, and – in many cases – what type of housing those on the list will be offered and allocated. Currently, not all local authorities are using these powers, but over the coming months more and more will be making decisions about how they respond to the legislation and its requirements, which powers they will use, and in what way they will choose to use them.

Traditionally, when someone made a

'homelessness' application to their local council, their needs were assessed based on whether or not they met the eligibility criteria to be classified as homeless, as well as on other factors including their relationship to the local area, the size of their household, and their medical needs.

Assuming they were deemed to be homeless (according to the legal definition used by councils), they would then be allocated a certain level of priority based on their need. After that, it was a question of waiting for suitable housing. The system was also broadly the same for those wishing to move into, or within, social housing: an assessment would be made, a level of need determined, and then someone would join the housing waiting list.

Often local authorities operated a banding system to determine priority for homeless applicants and/or those in acute need, with factors including domestic violence, disability, families with children, severe overcrowding or health needs taken into account to allocate a higher priority than those deemed to be 'adequately housed'.

Depending on where people were living at the time of the application, and their assessed housing need, the wait for suitable housing might involve a period in temporary accommodation or, in some more urgent cases, an immediate offer of a suitable property.

More recently, in high-demand areas such as London, local authorities were increasingly encouraging those on the waiting list to consider renting in the private sector, to reduce waiting times and overcrowding. Ways they encouraged people to move into the private rented sector included financial assistance through rent deposit or bond schemes, or cash payments to encourage people to take this option. Nonetheless, for the vast majority of people waiting for housing, the goal would remain a lifetime tenancy in social housing and critically this option, even if it involved a

Abbreviation guide

AR: Affordable Rent – properties let at a new higher rent level which can be up to 80% of the local private rents. Existing social and council rent levels tend to be 40 to 50% of the local private rents

HB: Housing Benefit

LHA: Local Housing Allowance (Housing Benefit for those living in the private rented sector)

PRS: private rented sector

RSL/RPs: Registered Social Landlord (increasingly called Registered Providers)

Social housing: Housing where your landlord is a council, arms-length management organisation (ALMO) or RSL/RP.

SRR: Shared Room Rate (colloquially known as the 'bedroom tax' or 'spare room subsidy')

long wait, remained open to them.

While there were often concerns about the assessment process, and many people waited a substantial time for suitable housing, everyone generally understood the system. For people living with HIV, the main issues were poor levels of HIV awareness amongst housing providers and those assessing housing need, the impact of poor quality or unsuitable housing on their health, and, for people going through the immigration process, restricted access to housing.

The new local authority powers

The new powers granted by the *Localism Act 2011* will allow each local authority much more autonomy to determine its own priorities when allocating housing. The status of 'homelessness' and the statutory duties on local authorities to find 'suitable housing' will remain.

However – critically – this housing will not have to be social housing and doesn't necessarily even have to be in the local area; all it will need to be is 'suitable' for a local authority to have discharged its homelessness duty. Moving someone into the private rented sector would discharge this duty – effectively cutting the link between homelessness and access to social housing.

Local authorities will also be able to prioritise access to housing for those in work, training, volunteering or for service in the armed forces.

There is a new power to change the length of time applicants for housing have to live or have a connection with an area before they are eligible to access the local housing list. Currently this period is usually around six to twelve months, but some local authorities are now increasing this to two, three or even five years. This is likely to have a significant impact on how migrants, those leaving prison and others who have been placed in a given area by another local authority can access housing.

NAT fears there is a risk that some people living with HIV and others living with long-term conditions will be sent to the back of the queue unless they are appropriately assessed during this process.

We need to ensure that, when local authorities assess the suitability of a housing offer, especially one in the private rented sector or outside the local area, they take into account all the needs of people living with HIV. This should include considering the impact of poor or unsuitable housing on health and the need for someone to be near their HIV clinic and any support organisations or systems, given how critical this can be to them staying well.

Recently NAT campaigned for, and was successful in ensuring, a change to the UK

“The substantial changes to housing and related benefits, cuts to housing funding, and the localisation of allocations policy will all have a significant impact on people living with HIV and in need of housing support.”

Border Agency's policy⁴, so it no longer routinely disperses asylum seekers with HIV away from their HIV clinic if suitable accommodation is available.

We believe local authorities should also take such issues into account as they decide how to use their new allocation powers.

Changes to social housing tenure and rent levels

The *Localism Act 2011* also changes the types, tenures and rent levels of existing and new social housing on offer.

Under the Act, local authorities and registered social landlords (RSLs) will have the power to decide on the length of new social tenancies; rather than being offered a lifetime tenancy, successful applicants may only be offered a five-year tenancy, followed by a tenancy review. The terms of that review, and what might be involved, are unclear and NAT has concerns about the disruption and uncertainty this might cause for people living with HIV.

At the same time, the Government has created a new type of social housing called 'affordable rent' (AR), where the rent can be set at up to 80% of local private rents. Currently AR housing is likely to be largely restricted to new-build housing constructed over the coming years, but those local authorities and RSLs building for this new tenure are, as part of the financing of these new homes, allowed to convert a percentage of their existing housing stock from 'social rent' to this new higher 'affordable rent' level as they become vacant.

AR tenancy properties are, increasingly, going to be the only type of social housing being built. In areas like London where private rents are high, there are questions

about how viable and suitable this type of housing will be for people on Housing Benefit or low incomes. The effect is likely to increase the pressure on traditional social housing. In some areas, the knock-on effect might be longer waiting times if people hold out for council housing with lower rents.

Housing allocations are likely to become ever more fragmented, making the system harder to navigate for housing applicants, and more complex for organisations that provide support and advice. People living with HIV will face some of the same issues on rent and tenure as anyone else in the social housing system. In other aspects of the process, such as the changes to assessment and prioritisation, those living with HIV and who have more serious health problems and can't work could be at a substantial disadvantage.

Changes to Housing Benefit

For people already living in social housing, their situation will depend on whether they are wholly or partly relying on Housing Benefit to pay rent. Those relying on Housing Benefit, of working age, and not in work will face the greatest impact.

From 2013, rather than seeing Housing Benefit paid directly to landlords, this payment will now be made monthly directly into individual bank accounts (with some small exceptions). It will bring social tenants into line with tenants in the private sector who already receive the Local Housing Allowance directly, according to the Government it will help people develop budgeting skills. It might also help those on low incomes to open and sustain a wider range of bank accounts.

But the potential downside will be the increased pressure of having to budget, especially for vulnerable people receiving a substantial amount of money directly into their bank accounts at the start of the month. While landlords, advice providers and others are going to do what they can to help people adapt to these changes by making sure people are encouraged to use direct debits to pay their rent, there are understandable fears that, for some people, this may increase rent arrears, put tenancies at risk, and increase the use of 'payday' loan companies.

Other recent or prospective changes to Housing Benefit and related benefits may also have implications for people with HIV.

- Since January 2012, those living in the private rented sector, aged under 35, and claiming Housing Benefit, have only been eligible for support at the new Local Housing Allowance (LHA) 'shared room rate' (SRR). This only covers the rent equivalent to a bedsit or room in a shared house. Currently,

this does not apply to social housing tenants or those in supported accommodation. For people living with HIV this can create issues around confidentiality, stigma and harassment especially if they don't have somewhere private and secure to store medication.⁵

- In April 2013, the Government introduced changes to Housing Benefit for social housing tenants of working age – the so-called 'bedroom tax'. It will lead to reductions in Housing Benefit for those deemed to be 'underoccupying': by 14% if you have one extra bedroom or 25% if you have two or more.

- In 2013, the Government is planning to introduce Universal Credit. (It will be introduced on a small scale initially, followed by a national launch in October.) This will result in one payment into a bank account, comprising all the benefits someone is eligible to receive. It will include Housing Benefit and be subject to the 'benefit cap' of £500 a week for couples (with or without children living with them); £500 a week for single parents whose children live with them; and £350 a week for single adults who don't have children, or whose children don't live with them.

- The Universal Credit 'benefit cap' will

not currently apply to those who qualify for and receive Working Tax Credit, or if they receive any of the following benefits: Disability Living Allowance (for new claimants Personal Independence Payment from April 2013), Attendance Allowance, or Employment and Support Allowance (with the support component).

Changes for existing tenants

People living with HIV and not claiming Housing Benefit are at the moment less likely to see changes to their housing situation. If they have a lifetime tenancy (the traditional form of tenancy in social housing), the security of tenure they enjoy will not be affected as long as they don't want to move and are able to continue paying their rent. However, if circumstances were to change, and they needed to claim Housing Benefit, the same issues such as the 'benefit cap', 'shared room rate' or 'bedroom tax' might apply.

There are various changes mooted by the Government to change the rights of existing tenants, but it would require further legislation to implement changes to the length of someone's tenancy, their rights to succession or the level of rent they pay. As this article goes to press the idea of 'pay to stay', where tenants who earn above a certain threshold would be forced to pay a higher rent to stay in social housing has

moved a step closer. It was announced by the Chancellor in the Budget in March that it would be introduced, and the household income threshold where it will start will be set at £60,000 a year.⁶ Households earning over this amount could end up paying full private market rent and this could have a significant impact in London where the gap between social and private rents is widest.

Conclusions


The substantial changes to housing and related benefits, cuts to housing funding, and the localisation of allocations policy will all have a significant impact on people living with HIV and in need of housing support.

The changes to Housing Benefit and the Local Housing Allowance will restrict the amount people have to spend on rents, at a time when housing supply is failing and demand continues to rise. The *Localism Act 2011* now grants local authorities substantial new powers to making decisions about who can access social housing, the rents they will pay, and for how long they can occupy it.

This is happening at a time when the supply of new homes of all tenures is decreasing (with the supply of new social and affordable housing at an all-time low), it's more difficult to get a mortgage and private sector rents are rising. For people living with HIV and needing social housing it is going to become increasingly difficult for them to access and afford the stable housing they need.

Organisations such as NAT, and others that support people living with HIV, need to be alert to the impact these changes are going to have, and campaign to ensure that HIV and the impact poor quality and unsuitable housing can have on health is considered properly when a local authority assesses someone's eligibility and housing needs.

This will mean understanding the positions taken by local authorities in their Tenancy, Homelessness, Allocations and Housing Strategies, and related policy documents. All these policies, if they haven't already, will be being developed, or revised, in the coming months and there is a role for all of us to make sure the voice of people living with HIV – emphasising the need for good-quality, stable and safe housing to stay well and live independent lives – is heard loud and clear.

Responding to these issues NAT, through our HIV Activists Network, is campaigning on housing and HIV by asking local councils to better support the housing needs of people living with HIV. If you would like to know more, or are interested in taking part, please visit the HIV Activists' 'ask' page: www.lifewithhiv.org.uk/hiv-activists-network-campaigns 

Help and advice on housing, benefits and HIV

NAT

www.nat.org.uk/Information-and-Resources/Housing.aspx

www.nat.org.uk/media/Files/Policy/2012/June_2012_Benefits_and_Housing_in_the_UK_factsheet.pdf

THT

www.tht.org.uk/myhiv/Your-rights/Housing

NAM

www.aidsmap.com/Housing/page/1497495

Your local HIV support organisation

www.aidsmap.com/e-atlas/uk

Stonewall Housing

www.stonewallhousing.org/home.html

Shelter

<http://england.shelter.org.uk>

Citizens Advice Bureau (CAB)

www.citizensadvice.org.uk

UK government

www.gov.uk/housing-benefit/overview

Local council

If you are at risk of homelessness or want to make a housing application you need to contact your local council. In some circumstances they may also be able to help temporarily if you are seeing a reduction in your Housing Benefit:

www.gov.uk/browse/housing/local-councils

Your elected representatives

If you are having problems with your landlord or in accessing housing you can contact the organisations above for advice, but if you have already made a complaint and were dissatisfied with the response you might want to consider contacting your local councillor or MP. You can find your local representatives here: www.writetothem.com



The beginning of the end of hepatitis C?

A convenient and tolerable cure for nearly all hepatitis C infections may be here by the end of this decade, as new drugs appear at a pretty astounding rate. *Ingo van Thiel* of Deutsche Leberhilfe (the German liver patients' association) reports from the 2012 American Association for the Study of Liver Disease (AASLD) meeting.

Edited by *Gus Cairns*. All the news stories reporting on studies referred to in this article can be seen in full at www.aidsmap.com/conferences.

About one-third of people with HIV also have hepatitis C, including a majority of injecting drug users and a growing minority of gay and bisexual men with HIV. Hepatitis C-related liver disease is a major cause of death for people with HIV in high-income and resource-limited countries.

The 2012 AASLD meeting (the 'Liver Meeting') in Boston showed that the noose around the hepatitis C virus is tightening further. New drug regimens with and without interferon are being developed, and we are seeing cure rates of well above 90% in people who only have hepatitis C (that is, without HIV co-infection).

We do not know yet how well the new hepatitis C treatments will work for people living with HIV, but such studies are ongoing. The Liver Meeting also showed improved hepatitis C cure rates with current interferon-containing regimens in people with HIV.

In just a few years, hepatitis C treatment might be revolutionised.

Current treatment

At present, however, we're still in a difficult transitional period where two or three drugs, each with significant side-effects, are needed to treat hepatitis C. Pegylated interferon and ribavirin (pIFN/RBV) are still the backbone of today's approved treatments. These two medications are often enough to treat infections involving hepatitis C virus (HCV) genotypes 2 and 3, with up to 80% cure rates.

The most common variety of hepatitis C in the UK, western Europe and US, however,

is genotype 1 (G1) – split into 1a and 1b – and here, cure rates with pIFN/RBV are only 40 to 50% and 30% respectively in people co-infected with HIV.

To combat this more stubborn virus we now have the new, HCV G1-specific protease inhibitors telaprevir (*Incivo/ Incivek*) and boceprevir (*Victrelis*). One of them is now often added to a regimen, still combined with pegylated interferon and ribavirin. Neither is suitable nor approved for genotypes except G1.

The cure rates of current treatments are already much higher than those of five years ago. For the first time, people with G1 achieved 67 to 75% cure rates in approval studies.

However, the likelihood of cure depends on someone's individual situation.

People who already have cirrhosis respond to treatment less often than people in earlier stages of liver disease. If previous treatment with pegylated interferon and ribavirin had little or no effect on the HCV viral load during treatment (null responders), the prospects are less good if the same medications are taken again with the addition of only one extra drug.

Only around one-in-three people who has previously taken hepatitis C treatment without viral response (null responders) eliminates the virus using current triple-drug treatment; the other two-thirds not only remain infected but usually develop drug-resistant virus. In studies to date, null responders with cirrhosis who took telaprevir-containing triple therapy only had 14% response rates (there were no such data for boceprevir at the Liver Meeting).

On the other hand, relapsers with

genotype 1 have good prospects. In approval studies with boceprevir and telaprevir, 75 to 88% of relapsers became hepatitis C free.

Triple therapy in people with HIV co-infection

People who are concurrently infected with HIV and hepatitis C have a greater risk of developing late-stage liver disease such as cirrhosis and liver cancer. In addition, previous dual therapies with pegylated interferon and ribavirin were less successful for people in this situation. A new study¹ now reveals that triple therapy with telaprevir, pegylated interferon and ribavirin can cure hepatitis C in people with HIV co-infection just as often as in people with hepatitis C alone. In 74% of previously untreated people, hepatitis C was eliminated using triple therapy, whereas only 45% of trial subjects achieved this using two medications. As there can be many interactions with HIV drugs, it is important that this treatment is monitored by doctors who are experienced in treating both HIV and hepatitis C and who can customise the range of HIV medications. A second study by the same team² has found a 62.5% SVR12 response rate with boceprevir. But, for the moment, the new drugs are mostly being studied in people who have hepatitis C only (mono-infection). This is the case for the rest of the reports in this article – research with people with HIV and hepatitis C co-infection will come later.

Additional side-effects

There is a drawback to the new triple therapies: an increased rate of side-effects,

Some definitions

SVR SVR stands for 'sustained virologic response'.

SVR24 means there is no hepatitis C virus evident in the blood 24 weeks after treatment has ended, currently the accepted definition of a cure. Subsequent relapses are very rare. If there is no virus evident twelve weeks after treatment has ended, in over 99% of cases this is still the case after 24 weeks. The European and American drug regulatory bodies, the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA), also recognise SVR12 as a cure.

SVR4 Viral load data four weeks after treatment has ended, frequently presented at conferences. SVR4 results are somewhat provisional, and there may still be some relapses; results

should be interpreted with caution and confirmed by 12- and 24-week results.

Genotype (G1a, 1b, 2, 3, 4 etc.)

Hepatitis C comes in many different genotypes (varieties), with very different rates of virulence and resistance to treatment. In general, G1 and G4 (especially G1a, which is the commonest genotype in the US and western Europe) are the hardest to treat – though now with new drugs G1b in particular is more treatable. G4 is common in the Middle East. G2 and G3 are more common in Asia and Australia.

Null responder A person who has previously taken hepatitis C therapy but has shown no or little viral response to it, and has never achieved viral undetectability during their treatment.

Relapse/Relapser People often achieve viral undetectability by the end of treatment, but their hepatitis C virus subsequently reappears after it ends. They therefore do not achieve an SVR and this is called relapse.

Fibrosis Scarring to the liver (but the liver is still largely able to do its job). There are various grades of fibrosis.

Cirrhosis Large portions of the liver are replaced with scar tissue; blood flow through the liver is restricted and the person will probably be suffering from symptoms caused by poor liver function.

Decompensated cirrhosis Blood flow through the liver is almost completely blocked and the liver is unable to perform its vital functions. This is a life-threatening condition and can usually only be resolved with a liver transplant.

added to a regimen already notorious for them (interferon causes flu-like illness and depression, amongst other things, and ribavirin causes anaemia). In everyday clinical practice, more people seem to be stopping treatment than in the approval studies. For example, it was reported from three American clinics that up to 21% of people taking telaprevir stopped treatment early.

With boceprevir, changes in taste perception, in particular, were observed more frequently than with dual treatment. With telaprevir, skin rashes are very common, sometimes requiring treatment; in addition, pain or itching in the anal area is frequently reported.

The most significant side-effect of boceprevir and telaprevir is probably a raised rate of anaemia (lack of red cells, and therefore oxygen, in the blood). If boceprevir or telaprevir is added then ribavirin-related anaemia can intensify. On one hand, anaemia is a sign that treatment is working; people who experience anaemia as a side-effect are cured more often than people who do not. On the other hand, anaemia weakens people and increases the risk of them falling ill with other infections during treatment. The more severe the anaemia, the more medical intervention is required.

The dose of the HCV protease inhibitor cannot be reduced, as drug resistance can develop. However, the dose of ribavirin can be reduced with less concern about viral breakthrough than in the past – in fact, with triple treatment, taking a lower ribavirin dose barely diminishes the chances of cure at all. A study has found that cure rates remained as high regardless of whether doctors reduced the ribavirin due to anaemia, or whether the drug erythropoietin was given to treat the anaemia instead.³ (If you are on treatment, don't reduce your ribavirin dose without medical advice.)

Not every person with genotype 1 requires three medications. One study⁴ suggests that some people, despite having G1, would have a good chance of eliminating their hepatitis C with two medications. This group is characterised as having had no previous treatment, no cirrhosis, low viral load (under 600,000 units before treatment) and a rapid response to pIFN/RBV, meaning viral undetectability after four weeks. If all these favourable factors come together, the chances of success in the study were just as high regardless of whether the trial participants added boceprevir or not after the fourth week (90 versus 89%). This applied to around a tenth of people with G1.

Telaprevir two or three times a day?

Until now, boceprevir capsules and telaprevir tablets have had to be taken three times a day and at eight-hour intervals, in order to avoid the emergence of drug-resistant virus. The drugs must also be taken with food, and while with boceprevir a snack is sufficient, with telaprevir 20g of fat must be consumed – three times a day. This is not easy for many people especially as hepatitis C treatment can cause nausea and loss of appetite.

Now a study shows that telaprevir tablets can also be taken twice a day: instead of three 750mg doses, two 1125mg doses resulted in the same cure rates.⁵ Even the side-effects were similar in both groups, regardless of whether people had cirrhosis or not, except that anaemia occurred slightly more often in the twice-daily dose. Twice-daily telaprevir has now been approved for use in Europe. This is seriously good news as it may turn a regimen that is almost impossible to fit into some people's lifestyles into a practicable one.

Current triple treatment for people with cirrhosis

People with cirrhosis, who are already seriously ill, have less time to wait for future treatments but respond less often to current triple therapies and also have a significantly higher risk of complications.

In the French CUPIC study,⁶ half of the people with cirrhosis suffered complications such as infections, and more than 4% progressed to decompensated cirrhosis. In some cases, infections caused blood poisoning (sepsis). There were ten deaths. Severe complications usually occurred in people whose liver function was already impaired before treatment was started: warning signs were a low albumin level under 3.5g/dl and a blood platelet count under 100,000. As you might expect, the more diseased the liver, the greater the treatment-related risks.

Without treatment, however, people with cirrhosis are at risk of dying within a few years. The decision for or against starting current triple therapy is therefore not easy for those who have cirrhosis. Individual cases should be discussed in great detail with the doctor and treatment should be well supervised. The further advanced the cirrhosis, the more likely the possibility that a transplant will also be considered.

What the future might hold

Numerous new drugs are being explored. The first innovations we can expect will be more triple therapies, in which another drug with fewer side-effects is added to pegylated interferon and ribavirin, while for

particularly stubborn infections, quadruple therapies will be tested. See the boxed list of drugs on page 15.

In addition, a novel version of interferon called pegylated interferon lambda is being explored. This produces fewer side-effects than pegylated interferon alfa (used in current standard treatment) but appears to be at least as effective.

The biggest focus of excitement at the Liver Meeting, however, was interferon-free regimens. It's important to remember that the new drugs don't work equally well for everyone, and in particular, some only work, or work well, with certain HCV genotypes. In future, doctors and patients will have to consider the choice of medications very carefully.

Danoprevir and mericitabine: better with interferon than without?

Roche studied results for mericitabine and ritonavir-boosted danoprevir⁷ taken in different combinations by people with G1 who were either null responders or relapsers. They devised a study involving people with G1a and G1b using the two drugs alongside IFN/RBV, and used them either with RBV alone or IFN alone in people with G1b.

There were a lot of relapses following interferon-free treatment, with only 39 to 55% achieving SVR12. The best results were achieved with quadruple therapy, with a 100% SVR12 rate in former relapsers or null responders with G1b, and 96% in relapsers with G1a. However, only 73% of previous null responders with G1a achieved SVR12 and thus a likely cure.

Interferon-free studies

Faldaprevir, BI 207127 and ribavirin

Boehringer Ingelheim studied the use of treatment which combined faldaprevir with BI 207127 and ribavirin in different doses over different periods of time.⁸ The combination that performed the best was in the group of participants who took faldaprevir once a day and BI 207127 and ribavirin twice a day over 28 weeks. People with G1b achieved a cure (SVR24) in 85% of cases but those with G1a only in 43% of cases. This was the first interferon-free hepatitis C study that also included people with cirrhosis – 9% of participants in this study had cirrhosis. As this was only 33 individuals, not many conclusions can be drawn yet as to how successful this treatment is in people with cirrhosis, but six out of nine people who had cirrhosis, with G1a or with G1b, were able to eliminate their hepatitis after 28 weeks of treatment. In the approval studies, this interferon-free treatment will only be examined in people with G1b; people with G1a will no longer

be included, which may restrict this drug's applicability.

Sofosbuvir and ribavirin

A year ago, ten out of ten previously untreated people with G2 or G3 were cured after taking Gilead's protease inhibitor sofosbuvir with ribavirin for only twelve weeks. This caused quite a stir, but hepatitis C is generally easier to treat in people with G2 and G3 who have not taken treatment before.

The hope that this relatively simple treatment regimen could be effective for all other people with HCV such as people with G1, especially null responders, has been dashed. In people with G1 being treated for the first time with sofosbuvir and ribavirin, 84% were cured; in former null responders of genotype 1, however, nine out of the ten people suffered a relapse shortly after completing treatment.⁹ With difficult-to-treat virus, sofosbuvir obviously needs to be combined with something stronger than ribavirin alone – ideally another direct-acting antiviral substance.

Sofosbuvir and daclatasvir

A pioneering study was presented at the International Liver Congress, the annual meeting of the European Association for the Study of the Liver (EASL), in April 2012. Gilead's sofosbuvir, then called GS-7977, was combined with Bristol-Myers Squibb's daclatasvir, with and without ribavirin.¹⁰ After 24 weeks of treatment in previously untreated people with genotypes 1, 2 and 3, cure rates of over 93% were achieved. This was the first time cure rates like this had been achieved in an interferon-free regimen, and the study received wide publicity. However, co-operation between the two companies was only maintained for the period of this study, and combination treatments like this are now being followed up by both companies independently.

Indeed, what all companies are looking for is an equally potent and tolerable version of this combination, using their own drugs. Both sofosbuvir and daclatasvir have good chances of being approved independently of one another, and so using this combination is not completely out of the question if both drugs were available, could be combined 'off-label' in everyday clinical practice, and were affordable.

Daclatasvir, asunaprevir and BMS-791325

Bristol-Myers Squibb has drugs of three classes in development and, at the AASLD meeting, reported on a study combining all three: daclatasvir (an NS5A inhibitor), asunaprevir (a protease inhibitor) and BMS-791325 (a non-nucleoside polymerase inhibitor), in a combination therapy without

The new hepatitis drugs

These new drugs are direct-acting antivirals, drugs that directly attack the ability of the hepatitis C virus to make copies of itself (replicate) – unlike interferon (which stimulates the immune system to attack HCV) and ribavirin.

HCV protease inhibitors

- Boceprevir (*Victrelis*, produced by Merck – already licensed)
- Telaprevir (*Incivo/Incivek*, Janssen/Vertex – already licensed)
- Asunaprevir (Bristol-Myers Squibb)
- Danoprevir (Roche/Genentech)
- Faldaprevir (Boehringer Ingelheim)
- Simeprevir (Janssen/Vertex)
- MK-5172 (Merck)
- ABT-450 (AbbVie, formerly Abbott)

Nucleotide/nucleoside polymerase inhibitors (similar to NRTIs in HIV therapy)

- Sofosbuvir (Gilead)
- Mericitabine (Roche)

Non-nucleoside polymerase inhibitors (similar to NNRTIs in HIV therapy)

- BI 207127 (Boehringer Ingelheim)
- BMS-791325 (Bristol-Myers Squibb)
- ABT-333 (AbbVie)

HCV NS5A inhibitors (no equivalent in HIV therapy)

- Daclatasvir (Bristol-Myers Squibb)
- Ledipasvir (Gilead)
- ABT-267 (AbbVie)

interferon or ribavirin.¹¹ The study treated 32 previously untreated people with genotype 1a or 1b and without cirrhosis for either 12 or 24 weeks. Excitingly, twelve weeks of treatment with these three drugs was sufficient to achieve a provisional cure (SVR12) in all 16 people. In the group treated for 24 weeks, only SVR4 data are available: all are (so far) virus negative, with one exception which may simply be missing data. Some people reported headaches, diarrhoea and general weakness but no-one discontinued the treatment. It is particularly encouraging that genotype 1a saw the same cure rates.

Sofosbuvir, ledipasvir and ribavirin

Meanwhile, Gilead is developing its own NS5A inhibitor, ledipasvir or GS-5885, and has started studies combining it with sofosbuvir. At AASLD, results of a phase II study of these two drugs plus ribavirin were presented,¹² with 25 people with G1 who had

not previously taken treatment, and nine people who were former null responders. Everyone was still virus negative four weeks after the completion of treatment (SVR4), and at the 20th Conference on Retroviruses and Opportunistic Infections (CROI 2013) it was reported that all the participants had achieved a successful SVR12 response.

ABT-450r, ABT-267 and ABT-333 with ribavirin

AbbVie (formerly Abbott Laboratories) also has drugs of three different classes in development – a ritonavir-boosted protease inhibitor, a non-nucleoside polymerase inhibitor, and an NS5A inhibitor (see box). In a study called AVIATOR presented at AASLD, up to three of the new drugs, with or without ribavirin, were administered over different periods of time.¹³

Previously untreated people and null responders were both included in the study, all with G1 and the majority with the particularly stubborn G1a, though there were no people with cirrhosis in the study. The treatment duration varied in length depending on the patient group (8 to 24 weeks), and results were available for people treated for only eight to twelve weeks.

A lot of tablets, relatively short treatment duration – and impressive results. In 79 people given the three new drugs with ribavirin for twelve weeks, 77 people (97.5%) treated for the first time had an SVR12 response, as did 42 out of the 45 previous null responders (93.3%).

Just two of the 448 trial participants discontinued treatment due to side-effects but the virus was still cured despite the curtailment of the treatment. This combination will soon also be explored in licensing studies. AbbVie plans to reduce the number of tablets by combining ritonavir, ABT-450 and ABT-267 into one tablet.

Conclusion

In a few years' time, the treatment of hepatitis C will probably be vastly different, when the first interferon-free treatments are generally available. This conference demonstrated once again that a lot of interferon-free treatments appear not only to have fewer side-effects but in some respects to be even more effective than the current standard treatment. Several combination therapies achieved cure rates of over 90%, even in people with difficult-to-treat genotypes. To what extent these outstanding results will prove to be true in large approval studies and then in everyday clinical life remains to be seen. [nam](#)

Thanks to Dr Bernd Kronenberger for medical advice.

News in brief

As well as our news reporting, the news pages on our website include selected stories from other sources. Here we highlight stories from the last quarter – visit www.aidsmap.com/news for the full news reports and references to the original sources.

TESTING

Self-testing acceptable to at least three-quarters of people seeking a test

A meta-analysis of 21 studies of self-testing for HIV has found that self-testing was acceptable to between 74 and 100% of participants. Only seven of the 21 studies concerned completely unsupervised self-testing (in the others, a healthcare worker observed), and acceptability was 87 and 84% respectively in the two unsupervised studies that measured acceptability. No more than 5% of self-testers made mistakes in the testing process. False-negative results were almost non-existent, though one study had 7% false-positive results. In developed countries, US\$20 was the average price deemed acceptable for an over-the-counter HIV test kit.

www.aidsmap.com/page/2621239

ANTI-HIV DRUGS

New integrase inhibitors more potent and longer-lasting

The new integrase inhibitor dolutegravir is more effective and more tolerable than the first licensed integrase inhibitor, raltegravir (*Isentress*), a study presented at the Conference on Retroviruses and Opportunistic Infections (CROI) in March found. Seventy-nine per cent of people with highly drug-resistant HIV taking one 50mg dolutegravir pill a day achieved a viral load under 50 copies/ml compared with 70% taking the licensed raltegravir dose (400mg twice a day). The difference was greater in people who started with a viral load over 100,000 copies/ml (70 versus 53% under 50 copies/ml). Meanwhile, a study in monkeys of a third-generation

integrase inhibitor, GSK744, indicates that it may be possible to give it as an injection as infrequently as once every three months. Dolutegravir is likely to receive marketing approval in Europe during the the second half of 2013.

www.aidsmap.com/page/2595521

PREVENTION

Condoms '70% effective' in anal sex

An analysis of the effectiveness of condoms in preventing HIV transmission in anal sex between men has concluded that 100% condom use as a strategy (i.e. men reported using condoms every time, but not necessarily without accidents) stops about 70% of possible HIV infections. This is only the second-ever attempt to quantify condom effectiveness in anal sex, but the first study to do so, back in 1989, came out with exactly the same figure. This is about 10% less than the effectiveness of 100% condom use as a strategy in vaginal sex, which may be due to the greater likelihood of transmitting HIV via anal sex, or could be due to a higher likelihood of condom failure in anal sex. The study also found that, although two-thirds of gay men reported using condoms 100% of the time during a six-month period, only 16% maintained that over three years or more.

www.aidsmap.com/page/2595521

THE SEARCH FOR A CURE

French patients stop drugs but remain undetectable

Up to 15% of people with HIV who are given antiretroviral therapy within ten weeks of being infected could later stop taking antiretroviral therapy (ART) and maintain an undetectable viral load, French researchers

suggest. Their prediction is based on a study of 14 people who all started ART that early, stayed on ART for at least a year (on average, three years), and then discontinued it for various reasons, but who did not experience their HIV viral load 'rebounding'. Six had occasional low-level 'blips' of HIV but the other eight have never had another detectable viral load result in an average time of 7.5 years off ART (a minimum of four years). The researchers combed French medical records and found 70 similar cases, leading them to conclude that up to 15% of people who start ART early could come off the drugs later and experience a similar 'remission' of HIV.

www.aidsmap.com/page/2602347

PREVENTION

English sexual health framework says the right things but may have little power

Twelve years after the English Department of Health's first strategy on sexual health was published, a second *Framework for Sexual Health Improvement in England* has been issued. Setting out the government's "ambitions for improving sexual health", this document's language is revealing, as it was issued just before local authorities took over the commissioning of sexual health services on 1 April; the Department of Health has no power to mandate public health priorities for them. The Framework acknowledges the roles that HIV treatment and HIV testing in non-specialist settings have in reducing transmission; discusses primary HIV infection and pre-exposure prophylaxis (PrEP); highlights the sexual health needs of young people and people over 50; and considers the impact of drugs and alcohol on sexual health. But whereas local authorities will be required to commission clinical services for sexually transmitted infections

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News picks from other sources

(STIs) and contraception, the Framework draws less attention to HIV prevention and sexual health promotion. Local authorities will commission these sorts of services if they wish but the Framework does not say that they should. Casualties have already been seen since 1 April, most notably projects commissioned by the former Pan-London HIV Prevention Programme such as those run by gay men's HIV prevention charity GMFA, which recently announced the withdrawal of many of its services following the loss of all of its statutory funding from London.

➔ www.aidsmap.com/page/2606010

PREVENTION

Little change in gay men's condom use between 2001 and 2008

An analysis of data from two English gay men's sex surveys in 2001 and 2008 shows little change in the overall proportion of gay men having unprotected anal intercourse (UAI) during this time, though it does find a higher rate of gay men with HIV having UAI and a fall in the proportion of HIV-negative men with a large number of partners. The study also found that the proportion of men who had ever had an HIV test increased by 50% over this period and that the proportion who said they knew they had HIV almost tripled.

➔ www.aidsmap.com/page/2625697

PROGNOSIS

Life expectancy for people with HIV in South Africa begins to approach normal

As more people start antiretroviral therapy (ART) in South Africa, life expectancy among people with HIV has begun to rise, a survey finds. Although studies done in developed countries, including England, have found that life expectancy in some groups of people with HIV is approaching normal, and local studies in south Africa also find this, little is known yet about the national impact of ART in low- and middle-income

countries. The South African survey, which documented mortality in people with HIV between 2001 and 2010, found that there is still a way to go. Whereas HIV-negative South Africans can, at the age of 20, expect to live till 65 if they are men and 73 if they are women, men with HIV have an average life expectancy of 48 and women of 57, a 26 and 22% shortfall respectively. However, life expectancy in people starting HIV therapy after 2006 with a CD4 count over 200 only had a shortfall of about 15%. This is expected to improve further as the country has recently raised the CD4 cell count threshold for starting treatment to 350.

➔ www.aidsmap.com/page/2630355

VACCINES

Researchers stop the only current HIV vaccine efficacy trial

In a blow to HIV vaccine development, the US National Institute of Allergy and Infectious Diseases (NIAID) announced on 25 April that it was discontinuing the HVTN 505 HIV vaccine trial. This trial started in July 2009 and involved 2504 volunteers. Since the successful conclusion of the RV144 vaccine trial in September 2009, HVTN 505 has been the only ongoing HIV vaccine trial large enough to be a true test of vaccine efficacy. The trial's data and safety monitoring board (DSMB) found that the vaccine regimen was neither preventing HIV infection nor reducing viral load among vaccine recipients who acquired HIV. There were actually more HIV infections in volunteers receiving vaccine than placebo, but this difference was not statistically significant and may be due to chance. Nonetheless, as HIV prevention advocates AVAC comment, "even disappointing results like those of 505 are critical to refine future vaccine strategies. AIDS vaccine research is still in its most promising period in decades with breakthroughs in a number of approaches different from that studied in 505." Trials of the vaccine that produced the promising result in the RV144 trial, which used a different kind of vaccine to HVTN505, are ongoing.

➔ www.aidsmap.com/page/2640732

a Three types of HIV cure

amfAR | 15 April 2013

If you've been following the news lately, you may be starting to wonder why anybody ever thought curing HIV was so challenging. On March 3 we heard the news that a child appeared to have been cured. Hard on the heels of that report came the news that 14 individuals in France had been functionally cured. So what do these cases mean? How are they similar, and how do they differ? And importantly for HIV research, where do we go from here?

➔ <http://bit.ly/11jTJ1i>

GNP+ Option B+: Understanding perspectives and experiences of women living with HIV

GNP+ | 12 April 2013

Option B+ is a prevention of vertical transmission approach for expectant mothers living with HIV in which women are immediately offered treatment for life regardless of their CD4 count. This approach offers advantages such as protection of partner(s) and (unborn) child, as well as benefits to the woman's health, but also carries with it risks.

➔ <http://bit.ly/15htHAR>

P National AIDS Trust calls on London Councils to tackle drug use amongst gay men

Pink News | 27 March 2013

The UK's National Aids Trust (NAT) has called for urgent action from London Councils to tackle a recent rise in the use of drugs amongst the London gay community.

➔ <http://bit.ly/XSH1tl>

VOICE trial's disappointing result poses big questions for PrEP

Gus Cairns reports on some recent disappointment in HIV prevention research.



The failure of the VOICE trial¹, one of the largest trials yet conducted of HIV-drug based prevention methods, poses questions for how to turn vaginal microbicides and oral pre-exposure prophylaxis (PrEP) into methods people can use in real life.

Final efficacy results from VOICE (Vaginal and Oral Interventions to Control the Epidemic) were presented at the 20th Conference on Retroviruses and Opportunistic Infections (CROI) in March.

The trial recruited 5029 women from three sites in South Africa, two in Zimbabwe and one in Uganda; Durban, in South Africa, provided more than half the participants. Women were randomised to use one of three prevention methods or two placebos (dummy methods):

- A daily *Truvada* (tenofovir plus emtricitabine) pill as PrEP;
- A daily tenofovir-only pill as PrEP;
- A daily placebo pill looking like *Truvada*;
- A tenofovir-containing gel, similar to that

used in the CAPRISA 004 study, to be used as a vaginal microbicide;

- An inert gel as a placebo microbicide.

The tenofovir oral PrEP arm, and the tenofovir vaginal gel and placebo arms, of the trial were stopped due to futility in September and November 2011 respectively. ('Futility' means that the trial's data and safety monitoring board realised that there was no possibility that continuing these arms of the trial would produce a positive result.) The *Truvada* PrEP and placebo-pill arms, however, were continued.

But CROI heard that *Truvada* had also not proven effective in preventing HIV in the study and, therefore, that all three methods had proved no better than placebo.

No reduction seen in HIV infections

This was a group of relatively young (average age 25) and largely unmarried (79% single) women. Retention was good, with only 9% dropping out of the study.

Self-reported condom use at last vaginal sex was very high, at 85%, but needs to be regarded with a degree of scepticism given the extreme disconnect (see below) between self-reported and actual adherence to the methods being studied. Twenty-two per cent had had more than one male partner in the previous three months. Quite a high proportion of women (17%) reported anal sex in the last three months.

During the trial, 334 of the women tested HIV positive, but 22 of them turned out to have entered the trial while actually having been infected with HIV very shortly beforehand. This means 6.2% of participants became infected during the trial, an annual incidence rate (infection rate per year) of 5.7%, with strong geographical variance by site from 0.8 to 9.9%.

In the women using the tenofovir-gel microbicide there were 15% fewer infections versus placebo, but this was not statistically significant (which means the result could have been due to chance). In the oral PrEP arms there were actually more infections in

women taking PrEP compared to placebo. Women taking *Truvada* were 4% more likely and women taking tenofovir alone 49% more likely to become HIV positive than women taking placebo; in the latter case, this was almost statistically significant (95% confidence interval 0.97-2.29, $p = 0.07$).

Adherence – much lower than reported

Adherence was assessed both by counting returned pill bottles and gel applicators and by a computer-based questionnaire. According to these two different methods, women took their PrEP pill or used the microbicide on average nine out of ten times.

However, drug levels in the blood, and in the case of the microbicide in vaginal fluids, were also analysed in a randomised subset of participants (about 15%), plus in all women who acquired HIV. This showed a very different story, and that is starting to be familiar in PrEP and microbicide studies: only 28 to 29% of women taking tenofovir or *Truvada* PrEP had measurable drug levels in their blood, and only 25% of women using tenofovir microbicide.

The assays could detect whether drug had been taken in the last two days on oral PrEP, and used in the last three days in the case of microbicide gel, so some may possibly have used PrEP or microbicide some time since the previous trial visit, but 50 to 58% of women, depending on which arm they were in, had no detectable drug in their blood at any trial visit.

Women who were married, were aged over 25, or who had a primary partner aged over 28, were more likely to have detectable drug levels.

Married women were also very considerably less likely to acquire HIV than

unmarried women: annual incidence in married women in South Africa was 0.9%, compared with 7.5% in unmarried women. Women over 25 were half as likely to acquire HIV as women under 25.

There was another disconnect between adherence and result, too: using contraception was a requirement for entering the trial. Seventy-one per cent of women were using an injectable contraceptive and 23% took an oral contraceptive pill (the remainder used other methods, including condoms). Or so they said – and yet the annual pregnancy rate was 7.8%. This suggests that a high proportion of women – especially those on non-injectable methods – were not using contraception.

It was also not the case that women started with high adherence but were unable to keep it up. Just 38% of women allocated to oral PrEP and 34% allocated to the microbicide gel had detectable drug the first time it was measured, and adherence only got worse after that.

Why did they join the trial?

These results seem to back up what was found in the FEM-PrEP trial and in a recent pilot trial of PrEP in young gay men: young people seem to find it particularly difficult to adhere to these biomedical prevention methods, suggesting to the investigators that “products that are long-lasting and require minimal daily adherence may be more suitable for this population”. Investigators also called for more social research to determine which populations might benefit.

But the VOICE study results raise even more difficult questions. Thousands of women went to the bother of signing up

for a large clinical trial and often travelling to attend day-long clinic visits every three months, but the majority *never took a single pill* or used a dose of microbicide – and perhaps never intended to.

Yet there was excellent retention. As one audience member commented, the benefits of joining a trial like VOICE in a resource-poor setting may be so large as to make the disclosure of non-adherence feel very difficult for participants, who may fear being excluded from the trial.

These benefits include financial incentives: participants in clinical trials in South Africa are entitled to 150 rand per visit. Given the average black South African earns R5050 (£360) a month, this represents a fair sum.

The audience member was social scientist Dr Judy Auerbach, who comments in her blog: “A lot of folks in really resource-limited settings might quite sensibly say, ‘Well, I could get money for participating in this trial, and I’d get a lot of health benefits – monitoring of my health and wellness, good counseling, access to condoms – so it’s a good deal. I have no intention of taking the pill, but I’m not going to say that.’”

She adds: “In these clinical trials, researchers try to control out all the ‘noise’: You want similar women in similar circumstances so you can tease out the product effect. But social scientists say that the *differences* about women and their context – their community, their lives, their choices, their psychology, their culture, their age, all that stuff you’re trying to control for – are exactly what’s really important in these trials because they enter into how individuals think and (what they say) about taking a product.” [nam](#)

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