

aids treatment update

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in this issue

Since HIV treatment is life-long, it's important that we have as many drug options available to us as possible, in order to make sure anti-HIV treatment can be tailored to fit our specific needs: the more suited it is for us, the more likely we'll tolerate it, and adhere to the daily regimen for longer.

So where does convenience fit in? Of course it has its place – after potency, toxicity, side-effects and other tolerability issues. But with the stark reality of NHS financial cuts – and the even starker reality that only 28% of people worldwide who need anti-HIV drugs have access to any drugs at all – it's not going to be easy to argue that *Atripla's* promise of 'one pill once a day' is worth paying a premium for, since it replaces an already convenient regimen of two pills once a day.

We're used to waiting six months or so to get a new drug in Europe following US approval, but *Atripla* is likely to take closer to 18 months, primarily due to complex marketing arrangements. Let's hope that Gilead, BMS and MSD – who are collaborating on its European marketing – can come up with a price that satisfies all parties when the pill is finally approved.

page 3 In this month's *Upfront*, we revisit the controversial issue of superinfection and examine the latest report which suggests that, whilst apparently rare, it can happen even on treatment.

page 4 In *Atripla and the ART of once-daily dosing*, Derek Thaczuk examines the pros and cons of taking anti-HIV drugs once a day, and asks whether the forthcoming one pill, once a day combination of efavirenz, tenofovir and FTC is worth waiting for.

page 9 An important new set of standards from the British HIV Association (BHIVA) promises to provide much needed guidance, stability – and, for some, noticeable improvements – in the way we will experience our HIV care in future.

page 12 Amongst the items in *News in Brief* is a report on preliminary findings of a test tube study that suggests green tea may benefit people with HIV, and a surprising report that suggests anti-HIV drugs may not risk additional harm to the livers of people with viral hepatitis as much as previously thought.

page 14 The National AIDS Trust's Deborah Jack explains why they've launched HIV reporting guidelines for journalists and how people living with HIV can help fight stigma in the media through the 'Press Gang'.



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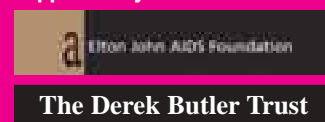
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serosorting and superinfection

by NAM's editorial team

In early 2005 the world's media was summoned by officials at New York City's health department and told that a gay man in the city had become infected with a fast progressing, highly drug-resistant strain of HIV that was virtually 'untreatable.' Health officials suggested that this case was a harbinger of a second-wave of even deadlier, harder to treat HIV, and should serve as a 'wake-up call' to promiscuous, drug-taking gay men in the city and elsewhere who had grown 'complacent' about HIV, given the success of antiretroviral therapy.

But two years on, the first fully scientific report of the case in a medical journal has shown that most of the initial assumptions about the case were wrong. Rather than progressing rapidly to AIDS, the 'New York patient' was experiencing a drop in his CD4 cell count that is associated with the early stages of HIV infection, and he did not have any AIDS-defining illnesses. In addition, the highly unusual 'dual tropic' (i.e. using both CXCR4 and CCR5 receptors) HIV that the New York patient was found to have was actually transmitted to him, and did not develop rapidly within him (it normally takes years to emerge) as was originally assumed.

The scientific investigation identified the probable source of the New York patient's infection: two highly treatment-experienced long-time partners from Connecticut with multidrug-resistant HIV. The news-worthy finding from this newly published study is that it appears that one of the partners (known as CT01)

reinfected, or superinfected, the other (CT02) with multidrug-resistant HIV at least seven years after CT02 was initially infected, **and** whilst CT02 was taking anti-HIV drugs.

Although 23 case reports so far have suggested that superinfection can definitely occur, until this report it was thought that the people who were most at risk of superinfection were recently-infected (ie. within three or four years) individuals who had either never started, or who took a break from, anti-HIV therapy. The build-up of what researchers call an 'innate immune response' has been thought by many to protect people with longer-term HIV infection from superinfection. In addition, it was thought that anti-HIV drugs may protect someone exposed to HIV from becoming superinfected, just as pre- or post-exposure prophylaxis (PrEP or PEP) may do for HIV-negative people.

The two Connecticut men had been 'serosorting' - choosing to have unprotected anal sex with each other and with other HIV-positive partners - for many years. Some researchers think that serosorting is a useful harm-reduction tool, because it reduces the risk of HIV-positive individuals who want to have unprotected sex from infecting an HIV-negative individual. Now we're seeing that it might not necessarily be harm-reduction for two HIV-positive people.

Although superinfection appears to be rare, the consequences can have a major impact on prognosis. Since being superinfected in 2001/2, CT02

has not been able to achieve an undetectable viral load and his CD4 cell count has fallen to below 200 cells/mm³. Unprotected sex between two HIV-positive people can also transmit other infections with serious health consequences - especially syphilis and hepatitis C - and this risk increases as the number of partners increase.

An editorial accompanying the scientific report says that they "believe that existing evidence continues to suggest that superinfection is uncommon after the first few years of infection, and this report should not lead to the abandonment of serosorting as one strategy to reduce HIV transmission." But it also emphasises, "this case is an important cautionary tale that drug-resistant HIV can truly be transmitted to a chronically HIV-infected partner."

Even if the risk of superinfection appears to be extremely low - and even more so for people who have been living with HIV for a long time and are on antiretroviral therapy - for some, the possibility of acquiring drug resistance might not be a risk worth taking.



atripla and the art of

is one pill, once a day worth waiting for? by Derek Thaczuk

More than two decades into the history of antiretroviral therapy, its first and biggest challenge - developing drug combinations capable of keeping HIV suppressed - has been met. With a score of distinct agents now available, viral suppression - the ability to reduce HIV viral load to 'undetectable' levels (i.e. below 40 or 50 copies per millilitre of blood) and keep it there for decades - is now at least theoretically possible for most HIV-positive people in the UK and elsewhere in the developed world.

The next major challenge is making these drugs available to everyone who needs them wherever they live in the world. For those of us fortunate enough to have a wide choice of anti-HIV drugs, however, the ideal is now to make anti-HIV therapy as tolerable, convenient, and 'user-friendly' as possible - primarily by reducing its associated side-effects and toxicities, but also by reducing the number of necessary pills and the frequency of dosing, if possible.

The move to once-daily regimens

Over the past few years doctors have been prescribing increasingly more once-daily (or *qd*, Latin for *quaque die*, medical shorthand for 'once daily') regimens, wherever they are supported by clinical evidence, and drug companies are continuing to pursue two separate yet interrelated goals: reduced pill burden (the number of pills needed per dose), and once-daily treatment.

One of the ways that pill burden has been lowered is through the use of 'fixed-dose combinations' (FDCs), which combine two or more anti-HIV drugs into a single pill. The dual-drug formulations *Combivir* (AZT/3TC), *Kivexa* (abacavir/3TC) and *Truvada* (tenofovir/FTC) have managed to cut the pill burden at least by half compared with their components taken individually. But none of these three FDCs lays claim to be an effective stand-alone combination: each must be combined with at least one other drug to form an effective treatment regimen.

Trizivir (AZT/3TC/abacavir) was the first attempt to pack a fully-fledged antiretroviral combination into one (twice-daily) pill. *Trizivir* - a triple-nucleoside combination - has successfully suppressed HIV viral load in some people, particularly in those who are treatment-naïve, with viral loads less than 100,000 copies/ml. However, clinical trials have shown that triple-nucleoside regimens are less effective than standard multi-class combinations; and the latest British HIV Association (BHIVA) guidelines

note that *Trizivir* is not, by itself, usually considered adequate treatment.¹

Enter *Atripla*, which became available in the United States last July. According to clinical evidence so far, *Atripla* - a fixed-dose combination of 600mg efavirenz (*Sustiva*), 200mg FTC (emtricitabine, *Emtriva*) and 300mg tenofovir (*Viread*) - appears to constitute an effective, tolerable treatment regimen all by itself. *Atripla's* US product website² bills it as the "first and only complete HIV regimen in one pill daily." But is it the 'holy grail' of anti-HIV drugs; the treatment we've all been waiting for?

Atripla is significant primarily because its development was the result of an unprecedented collaboration between two rival drug companies - Gilead, which markets FTC and tenofovir globally, and Bristol-Myers Squibb (BMS), which markets efavirenz in the US. In the European Union (EU), approval for *Atripla* is taking a lot longer primarily due to the more complex drug company marketing arrangements that will be necessary once it is approved. While BMS markets efavirenz in the UK, Ireland, France, Spain, Italy and Germany, another drug company, Merck Sharp & Dohme, markets efavirenz as *Stocrin* in the rest of the EU. A Gilead spokesperson tells *ATU*: "We have an application under review with the EMEA [European Agency for the Evaluation of Medicinal Products] and, barring any unanticipated issues, it's possible *Atripla* could receive marketing authorisation in Europe as early as year's end."

of once-daily dosing

The US Food and Drug Administration (FDA) approved *Atripla* based on 48-week clinical trial results of *Atripla*'s components, not the single pill itself. Study participants (all treatment-naïve) were assigned to either a once-daily combination of *Atripla*'s components (tenofovir, emtricitabine, and efavirenz in **two** pills, *Truvada* plus *Sustiva*), or once-daily efavirenz plus twice-daily *Combivir*. After 48 weeks, 80% of those on the *Atripla* components had viral loads below 40 copies/ml, versus 70% of the efavirenz/*Combivir* group. People taking the *Atripla* components also saw slightly higher CD4 count increases (190 vs. 158 cells/mm³), and were less likely to drop out of the trial due to side-effects (4% vs. 9%).

Although the 48-week study that led to *Atripla*'s FDA approval, and many other pieces of evidence, bode well for the future of once-daily therapy, the study did not measure the impact of one pill once a day. A Gilead spokesperson confirms that "there have been no studies on the impact of *Atripla* on patient adherence." We also do not yet know how effectively *Atripla*, or other once-daily combinations, will be able continue to control HIV over the long term: as qd treatment has only become feasible fairly recently, few long-term clinical trial data are yet available. Other questions remain: which other once-daily combinations might be feasible? And in what circumstances should qd therapy be treated cautiously - or avoided outright?

The case for once-daily regimens

Antiretroviral therapy can be complex, but the goal is simple: to reduce HIV viral load to 'undetectable' levels, and keep it suppressed as long as possible. To succeed, therapy must be both virologically potent (i.e., strong enough to keep HIV under control) *and* tolerable - that is, have minimal side-effects and a dosing schedule that can be lived with over the long run.

Does once-daily dosing, then, actually make for better adherence? (This might seem a no-brainer, but such questions are often less straightforward than they appear.) Several studies do seem to indicate that it does. At the recent 14th Conference on Retroviruses and Opportunistic Infections (CROI) in Los Angeles, an Italian group presented a comparison of once-daily to twice-daily combinations in the ICoNA study group. The finding was that viral

rebound (viral load that persistently rose back up from previously 'undetectable' levels) happened four times as frequently with twice-daily, compared to once-daily, combinations, which was attributed to differences in rates of adherence.³ However, this study did not distinguish once-daily regimens according to the number of pills they contained; hence, it cannot shed any light on whether *Atripla* would perform better adherence-wise than its separate components.

Other studies have shown similar results. In 2004, a Spanish group found that people on once-daily regimens reported significantly better adherence, viral load outcomes, and satisfaction with their treatment.⁴ Among participants in that study who had switched from more complex to simpler regimens, viral loads below 400 copies/ml were maintained in 91.4% on once-daily, vs. 83.4% on twice-daily



combinations. As this study was actually based on treatments available in 2002 (when, for instance, tenofovir was not yet available as a first-line treatment), the investigators expected that outcomes would actually improve given the wider range of present-day options. In the more recently reported French ALIZE study, people on successful protease inhibitor-based therapy (i.e., whose viral loads were below 50 copies/ml) either stayed on the same therapy, or switched to a once-daily regimen of efavirenz, FTC and ddI (*Videx EC*). After 48 weeks, those who switched were more likely to maintain viral loads below 50 copies/ml (87% vs. 79%) than those who stayed on PI therapy.⁵

Nevertheless, one dose per day is not synonymous with treatment simplicity. When asked what would most help their adherence, HIV-positive people have cited fewer pills (and other factors, like a lack of dietary restrictions) at least as often as fewer doses per day.⁶ Other studies have confirmed that adherence actually does improve as the number of pills diminishes.⁷ According to one patient

If you already have a comfortably established routine, 'improvements' may not necessarily succeed. This was the case for "Andrew" (not his real name, but a real story). Aiming for easier dosing, Andrew's doctor switched him from his long-standing twice-daily combination to a once-daily regimen of efavirenz, tenofovir and 3TC. Andrew found his rhythm thrown off, causing him to actually miss more doses than before. It took a bit of strategy to nail down his new routine - which, for Andrew, meant keeping his pill box with the contact lens case he'd be sure to grab every night. The moral, of course, is that only you can determine what's 'most convenient' for you.

survey⁸, when the total number of pills per day exceeds six, most people prefer two separate smaller doses per day to a single all-at-once dose.

Once-daily options

Excluding *Atripla*, seven distinct antiretroviral agents are currently approved for qd dosing in Europe and the UK. (See *what are we working with?* on page 7) Abacavir, tenofovir, ddI, and 3TC or its near-equivalent FTC can be paired to construct the two-nucleoside 'backbone' of a triple-drug combination; the resultant pill count can frequently be lowered by means of the fixed-dose combinations, *Truvada* or *Kivexa*.

The third component is most commonly efavirenz (*Sustiva*), a long-established once-daily non-nucleoside (NNRTI). The ritonavir-boosted protease inhibitor atazanavir (*Reyataz*) is another possibility; however, boosted atazanavir - the only once-daily PI to be recommended in Europe - is approved only as part of a second-line or later regimen, not as first-line therapy. Once-daily *Kaletra* and nevirapine - neither of which is recommended as first-line therapy in the UK or elsewhere in Europe - require more explanation.

Dosing considerations aside, nevirapine (*Viramune*) is not recommended as first-line therapy according to the latest BHIVA guidelines: while comparably effective to efavirenz, it is considered an "alternative" agent primarily due to its association with liver toxicity. Clinical trials have compared a once-daily 400mg nevirapine dose to the longer-established 200mg twice-daily dose: while similarly effective, the higher daily dose tends to worsen nevirapine's side-effects, notably rash and liver toxicity. A recent Canadian review of the large '2NN' study found that considerably more people (29% vs. 22%) had to discontinue nevirapine at the 400mg single daily dose, compared to 200mg twice daily.⁹ In addition, nevirapine-related rash forced

treatment interruption or discontinuation in 14% (once daily) vs. 8% (twice daily), leading the researchers to state, "once-daily nevirapine cannot be recommended at this time."

Even more notably, a recent prospective trial of once-daily nevirapine, tenofovir and 3TC had to be stopped early because of high rates of treatment failure.¹⁰ In preliminary results presented at CROI in February, a 25% virologic failure rate was seen early in the study, and there was also a high dropout rate - likely due to increased nevirapine-associated side-effects.

Antiretroviral 'forgiveness' is another concern: longer intervals between doses mean longer intervals without drugs if a dose is missed - with, potentially, a greater risk of drug resistance from missed doses. If drug levels have fallen to barely adequate levels at the end of a 24-hour period (just before the next dose), a missed dose could then result in a full day of levels low enough to begin to breed resistance. *Kaletra* (lopinavir/ritonavir) may be a case in point. The US FDA has approved the (normally twice-daily) *Kaletra* at a once-daily dose (four tablets, yielding 800mg lopinavir + 200mg ritonavir) for treatment-naïve - but not for treatment-experienced - individuals. However, lopinavir has been observed to fall to worryingly low levels in a significant number of people at this dose.¹¹ (It may also be less effective for people with viral loads greater than 100,000 copies/ml.¹²) In the UK and the rest of Europe, once-daily *Kaletra* is not approved for anyone, because drug regulators want to see more evidence of its safety.



what are we working with?

Atripla, the first "all-in-one", once-daily pill, is currently being reviewed by the European Agency for the Evaluation of Medicinal Products (EMA) and may be approved by the end of year. The following drugs are currently approved by the EMA for once-daily administration. (Listed doses are standard; they may need to be adjusted in individual cases.)

- **3TC** (lamivudine, *Epivir*), 300mg (one tablet).
- **FTC** (emtricitabine, *Emtriva*), 200mg (one capsule).
- **abacavir** (*Ziagen*), 600mg (two 300mg tablets).
- **ddI** (*Videx EC*), 250 or 400mg, depending on the person's weight (one capsule, at either dose).
- **efavirenz** (*Sustiva*), 600mg (one tablet).
- **tenofovir** disoproxil (*Viread*), 300mg (one tablet).
- **atazanavir** (*Reyataz*), 300mg (two 150mg capsules) plus one 100mg ritonavir (*Norvir*) capsule. (Not recommended as first-line therapy.)

once-daily FDCs:

Several "fixed-dose combinations" combine multiple medications into single tablets; the following are suitable for once-daily use:

- **Kivexa: 300mg 3TC plus 600mg abacavir.**
Taken as one tablet per day; replaces 3TC plus abacavir taken separately.
- **Truvada: 200mg FTC plus 300mg tenofovir.**
Taken as one tablet per day; replaces FTC plus tenofovir taken separately.

Some evidence suggests that non-nucleosides like efavirenz may actually 'forgive' less than perfect adherence. In one Italian clinical trial, people with 'suboptimal' adherence - those who took their pills on time for 75% to 95% of the time - did better on NNRTIs than on PIs.^{13,14} (While NNRTI-based therapy may be more forgiving of occasional slips, continual, persistent nonadherence has unfortunate consequences for any therapy - possibly even more so if it is NNRTI-based, as fewer mutations are needed for resistance to develop.)

We should also be mindful that, unless held in check, drug company marketing has a tendency to run ahead of science. Back in 1998, the then-widely-prescribed PI indinavir (*Crixivan*) was dosed at an awkward *three* times daily, on an empty stomach (ritonavir, at that point, not having come into use as a drug level booster). Indinavir's manufacturer Merck-Frosst pushed twice-daily dosing into clinical trials, despite protests from doctors and activists that no pharmacokinetic (bodily drug level) data supported such a premature study. That concern proved well founded: twice-daily indinavir failed, leaving many study

participants cross-resistant to existing protease inhibitors.

Purely financial costs (increasingly under scrutiny in the UK) may or may not become a consideration as well. Thus far, *Atripla* has been well received in the US, with sales of over US\$200 million in 2006, and 2007 estimates running close to US\$800 million. A Gilead spokesperson tells *ATU* that, "*Atripla* is currently the most commonly prescribed antiretroviral regimen in the United States." *Atripla*'s US retail price has been set essentially equal to the combined cost of *Truvada* and efavirenz - about US\$1150 per month. However, there is no guarantee the same will be true in the UK - and given the financial squeeze facing HIV clinics, it is unlikely that *Atripla* will be frequently prescribed if it costs more than the already approved and available two pill, once daily combination of efavirenz/*Truvada*.

Is it right for you?

The next major considerations are toxicity and side-effects followed by tolerability and convenience. Tenofovir is not recommended for those with existing kidney function problems, and BHIVA treatment guidelines warn against efavirenz use in people with a

history of depression or in women who are pregnant: any of these would rule out *Atripla* as an appropriate choice.

Naturally, choosing an antiretroviral is often a matter of picking which side-effect you are most willing to risk: foregoing *Sustiva* for fear of central nervous system side-effects such as vivid dreams or that 'spacey' feeling may just as well mean running the risk of protease-related lipodystrophy. However, some rather surprising results from February's CROI conference have suggested that efavirenz may in fact be more of a culprit for lipoatrophy (fat loss) than the protease inhibitor *Kaletra*.¹⁵

An expert panel from Spain has called once-daily dosing "an added value which can have a positive effect on adherence."¹⁶ All other things being equal, fewer pills and fewer doses would doubtless be most people's choice. If *Atripla*'s components are right for you, and the drug becomes available in your clinic, it's obviously worth considering. However, another potent, tolerable once-daily regimen consisting of more than one pill - or even a twice-daily regimen - may still be preferable. Only you - in collaboration with your HIV doctor - can decide which is best for you.

acceptable standards

what bhiva's roadmap for hiv care in the uk will mean to you
by Edwin J Bernard



An important new set of standards from the British HIV Association (BHIVA) promises to provide much needed guidance, stability - and, for some, noticeable improvements - in the way we will experience our HIV care in future. If all the recommendations are implemented, it will mean:

- fewer missed, mistaken or late HIV diagnoses, and unnecessary deaths;
- consistent quality of HIV treatment and care throughout the UK;
- the most appropriate HIV treatment and care will be provided at locations that are convenient for us.

The document, *Standards for HIV Clinical Care*¹, comes at a time of widespread changes and uncertainty within the NHS, and was the result of unprecedented collaboration between BHIVA and three other major medical societies - the Royal College of Physicians (RCP); the British Association for Sexual Health and HIV (BASHH); and the British Infection Society (BIS).

The document broadly outlines who should provide HIV testing; who should provide treatment of HIV- and non-HIV-related issues; and how these services should be organised. It also addresses the initial and ongoing training of HIV clinicians, nurses and pharmacists.

Why do we need another set of standards?

Four years ago, the Medical Foundation for AIDS and Sexual Health (MEDFASH) published their own HIV standards document, making recommendations for twelve distinct and important aspects of HIV services, including the empowerment of people with HIV; good quality clinical care; the role of general practices (GPs); and the integration of social care with clinical care.²

BHIVA's document builds upon these standards, but goes much further by explicitly thrashing out the details of how these standards can be achieved. They are, in fact, a 'roadmap' illustrating what good quality HIV treatment and care should look like in the UK in the years to come.

"The primary aim is to make HIV care more efficient and to abolish the 'postcode lottery' as much as we can," says Gus Cairns, a member of the Board of Directors of the UK Coalition of People Living with HIV and AIDS (UKC) and editor of NAM's *HIV & AIDS Reference Manual*, who was the patient representative on the BHIVA standards subcommittee. "[It means the end of] patients with complex needs being treated in clinics that don't necessarily have the expertise to manage them."

The document also serves a political purpose: as the preferred vision of HIV treatment and care in an NHS increasingly constrained by finances, as detailed in *ATU 163* last January/February. "Just as BHIVA's treatment guidelines are in some ways a pre-emptive strike against a larger body like NICE [the National Institute of Clinical Excellence which approves NHS drugs and technologies based on cost-effectiveness] telling physicians what treatments to prescribe, so these standards are perhaps partly a pre-emptive strike against the NHS forcing HIV care into a one-size-fits-all straitjacket," says Cairns.

Over the past few years BHIVA audits³ of how people with HIV are being cared for throughout the UK have highlighted some of the problems that this document attempts to tackle:

- A 2003 audit found that one in four HIV diagnoses were being missed by hospitals, GPs and sexual health clinics which were not offering HIV tests despite obvious signs and symptoms;
- A 2004 audit found that HIV-positive individuals co-infected with hepatitis B or hepatitis C were not receiving uniformly optimum care, including inappropriate drug treatment and a lack of access to vital tests;
- A 2005 audit highlighted areas of concern in some areas for HIV-positive individuals co-infected with tuberculosis (TB), notably a lack of negative pressure facilities, and delays in the reporting of sputum smear results;
- And a 2006 report from the Health Protection Agency found that one in five people who should have been on anti-HIV treatment were not. Since the differences were regional, it suggested that some people were not receiving the best treatment and care due to a postcode lottery-type situation.⁴

More opportunities for HIV testing

A 2006 BHIVA audit⁵ found that late diagnosis continues to be a major cause of illness and death for people with HIV in the UK - at least a quarter of the deaths reported in HIV-positive individuals between 2004 and 2005

may have been prevented if diagnosis had occurred earlier.

Consequently, moving further than last year's recommendations from BASHH - which recommended 'opt-out' HIV testing for everyone attending sexual health clinics - BHIVA now recommends that "all general practices and acute [emergency] medicine services should provide diagnostic HIV testing, and such testing should routinely be considered for patients coming in contact with secondary care."

Professor Margaret Johnson, BHIVA's Chair, says: "One big change we want to see is much more widespread HIV testing to facilitate planned care, so that fewer people remain undiagnosed until they develop a major HIV-related illness."

How will the standards affect my care?

BHIVA's standards document is meant to complement other clinical guidelines from BHIVA - such as their treatment, coinfection, TB, and reproduction & sexual health guidelines - which make recommendations about the kind of monitoring, treatment and care we should receive. This document focuses on where, and by whom, this care should be provided.

The standards hope to ensure that access to HIV treatment and care will be more equitable and much better organised in the future, eliminating the uneven quality of care that may be found outside of the major HIV treatment centres.

In a nutshell, they recommend that HIV treatment and care for most

“One big change we want to see is much more widespread HIV testing to facilitate planned care, so that fewer people remain undiagnosed until they develop a major HIV-related illness.”

Professor Margaret Johnson, BHIVA's Chair

HIV-positive people in the UK should be provided by local HIV clinics (which they call *HIV units*). The HIV units will provide us with our HIV-related needs when we are well, including prescribing and dispensing our anti-HIV drugs; monitoring viral load, CD4 counts as well as physical and laboratory-measured side-effects. HIV units will also be a one-stop shop for other HIV, reproductive or sexual health-related healthcare issues, such as sexual health screens, conception and contraception needs. They should also be the places we go to for HIV-related mental health and anti-HIV drug adherence counselling services. This should mean that we will be able to be seen for good quality, routine care at an HIV unit of our choosing, ideally one that is close to home or work.

The local HIV units will form part of much larger, integrated regional HIV networks. At the heart of the network will be a major *HIV centre* (which can either be one large hospital or a cluster of smaller hospitals) to which we will be referred when we are seriously unwell (for example, with active TB, symptomatic hepatitis B or C co-infection, or experience HIV-related illnesses or opportunistic infections); have more complex needs (such as having extensive HIV resistance); or experience an emergency that requires being admitted to hospital.

What will change?

For those of us who already receive our care in major centres of HIV excellence, we are unlikely to notice any major changes at first.

In fact, the document specifies that if the standards of care are even higher than those specified in the document, they should not be 'dumbed down'. "Some HIV units, especially those serving large caseloads, may exceed these requirements," it states, "and are able to provide some more specialised aspects of HIV care. These standards should not be used as a reason for downgrading existing providers whose services are needed by patients."

However, it also notes that "most providers forming part of HIV centres are likely also to provide routine outpatient care identical to that available in HIV units, although this may change over time with the shift towards community provision of outpatient and non-acute services."

This may mean that those of us who travel from outside London to a major London treatment centre (e.g. London's Chelsea & Westminster or Royal Free Hospitals) but who need "routine outpatient care" may eventually be asked to transfer to a more local HIV unit.

For the increasing numbers of people who receive HIV care outside of the major HIV cities, the idea is to improve clinic standards so that someone receiving care in a rural setting will benefit from the expertise of the HIV centre that is part of their HIV unit's network, without having to travel there. The President of British Infection Society, Dr Nick Beeching, notes that the standards document "provides a realistic framework for optimising medical care for HIV-positive individuals wherever they live in Britain, and is particularly relevant for the large number of people receiving care outside London."

The role of GPs

One of the biggest changes - highlighted in *ATU 158* last July ('Better Practice: why GPs need to be integrated into HIV-positive care') - is that GPs will have to play a more active role in our some of our non-HIV-related care.

The document notes that "people with HIV infection experience many concurrent health problems including other chronic conditions such as asthma, hypertension etc. The standard of care for HIV patients with such diseases should be no lower than for other patients. HIV specialist clinicians generally lack the expertise to manage such all such conditions safely in line with relevant standards; GPs are better qualified to do so."

It goes on to suggest other conditions where GP-based care may be more appropriate than HIV clinic-based care. "[GPs] may also have appropriate skills in managing some conditions related to HIV and/or its treatment, e.g. dyslipidaemia [blood fat problems], metabolic syndrome and cardiovascular disease; erectile dysfunction and other sexual and relationship problems and some other aspects of sexual and reproductive health; alcohol and substance misuse; depression, dementia and other mental health problems."

Information sharing

This move towards including GPs in our care - and in order for the concept of care being shared between HIV units and HIV centres to succeed - means that information about our health (i.e. our patient records) will have to be



shared more widely than before. The document specifically highlights that "patients need to understand that care can only be safely delivered if the GP is kept informed about their HIV and is able to liaise with the HIV specialist," and goes on to recommend that "unless a patient specifically objects, HIV services should routinely update the GP regarding the patient's state of health, test results and medication."

The document is at pains for point out that because HIV is a highly stigmatised condition, "particular attention is therefore required to issues of trust, confidentiality and reducing inequalities." However, it also notes that "HIV care records should reflect the same access protocols as for other chronic diseases. While respecting the right of individual patients to opt out from record sharing, information relating

to HIV treatment and care should be recorded in ordinary NHS records."

Whilst the document shares some concerns over confidentiality in the era of electronic patient records, it also states that "it should not be assumed that electronic information storage and communication are inherently less secure than more traditional methods."

Consequently, it recommends that "the right of individual patients to opt out of record sharing or to place this information in a sealed [electronic] envelope should be respected, but clinicians should not encourage this practice."

Patient involvement

At the Autumn BHIVA Conference, to be held in London this October, there will be a BHIVA Community Symposium on electronic patient records, where doctors will hear about issues of confidentiality versus improved communication from a patient's perspective. *ATU* will report on the meeting, as well as cover this important issue in more detail in the near future.

The Community Symposium is a good example of how BHIVA is involving

people living with HIV in their decision-making processes. Importantly, BHIVA's standards continues MEDFASH's focus on empowering people living with HIV. They note: "Clinical care should be provided through partnership between clinicians, NHS organisations, patients and the wider public. This entails patient and public involvement in planning and helping to design services, together with education and personalised information to support patients in taking part in shared decision-making about their individual care."

Patient advocate Paul Clift, who is also a member of the Board of Directors of UKC, welcomes this kind of patient empowerment: "The fact that BHIVA engages meaningfully with patients and is keen that more come forward to work with them is something to praise and promote, I feel." He adds that "the UK - and BHIVA in particular - is streets ahead of pretty much anywhere else [in the world] in terms of co-working between patients and doctors on matters of profound central importance, such as these standards. This puts us in the UK in an unusually strong position, and one that we should be aware of and not take for granted." ■

“ The process of involving patients and supporting shared decision-making about their individual care should start from post-diagnosis assessment onward and continue throughout the course of their HIV infection. It requires patient education and personalised information provision to be integrated as part of all HIV unit and centre services, including delivery in partnership with community or voluntary providers. ”

BHIVA standards document



news in brief

hiv transmission

Recently infected people responsible for half of HIV transmission

It's becoming more widely accepted among HIV prevention researchers that a large proportion of sexual HIV transmission takes place very soon after an individual becomes infected, during the months before the immune system brings viral load under some degree of control - the period known as primary HIV infection.

The latest estimate comes from a study carried out in Canada, which was able to use genetic techniques to look at linkages between the viruses of almost six hundred recently infected people in the province of Quebec. The study found that half of all the infections came from individuals who had themselves been very recently infected, and that these infections could be grouped into 75 clusters, highlighting the large numbers of individuals who could become infected from just one highly infectious individual.

In contrast only 15% of the infections could be attributed to diagnosed HIV-positive people who had not yet started treatment,

and 12% of the infections were attributed to individuals on treatment with a detectable viral load.

This suggests that targeting prevention at people who already know they are HIV-positive may have less effect than targeting people who still believe themselves to be HIV-negative.

Researchers suggest that more aggressive attempts are needed to identify people with primary HIV infection, including providing more information to people at risk of HIV infection about the symptoms of primary HIV infection.

Some go further, and argue that there are strong grounds to encourage treatment in the newly infected. By reducing viral load during the most infectious phase of HIV infection, the number of new infections could be curtailed.

However there is still no evidence that early treatment of primary HIV infection has any long-term benefit to the individual, so it could be hard to persuade people that they need treatment.

hiv and hepatitis

Anti-HIV drugs might not increase liver risk in HBV or HCV coinfecting

A large Italian study has concluded that people with HIV and either HBV (hepatitis B) or HCV (hepatitis C) coinfection may not be at a higher risk of experiencing liver enzyme increases that indicate liver damage after starting anti-HIV treatment.

The study of more than 5,000 HIV-positive people about to start anti-HIV drugs for the first time included around 2,500 HIV-positive people who were coinfecting with either HBV or HCV. It found that regardless of whether they had started antiretroviral therapy or not, these coinfecting people were five times more likely to experience a liver enzyme

increase during the study period than the other 2,500 HIV-positive people who were not

coinfecting. The study also found that men were more likely to experience liver enzyme increases than women.

More needs to be learned about why this is the case, since previous studies have suggested a link between starting anti-HIV drugs and an increased risk of liver damage in coinfecting individuals.



complementary therapies

Green tea has anti-HIV effect in test tube

Test tube studies have found that an ingredient in green tea may reduce HIV binding to human CD4 cells by approximately 40% within an hour of drinking two to three cups of green tea. Long promoted for its health-giving properties, recent research has found that chemical substances known as flavonoids found in green tea have anti-bacterial, anti-tumour and anti-viral effects in the test tube.

The latest test tube study has found that epigallocatechin gallate (EGCG), the main flavonoid in green tea, can prevent HIV from binding to human CD4 cells at levels that are "physiologically relevant", according to lead investigator, Dr Mike Williamson of Sheffield University.

However, the study has not yet proved that green tea can help prevent HIV infection, or that it is able to slow the progression of HIV disease by reducing the effect of HIV on CD4 cells.

Dr Williamson said that further studies were planned with Baylor College of Medicine in Texas in order to learn more about the clinical effects of green tea. "It is not a cure," he stresses, "nor is it a safe way to avoid infection." Research is also planned utilising the purified flavonoid rather than green tea itself. However it will be years before we discover whether the extracted EGCG is able to actually protect against HIV infection or disease progression.

He does suggest, however, that drinking green tea may be of some benefit for people with HIV as a complementary therapy and that "used in combination with conventional medicines [green tea could] improve quality of life for those infected."

sexual health

Syphilis can adversely affect viral load and CD4 counts

Although several studies have previously found that the sexually transmitted infection (STI), syphilis can cause increases in HIV viral load and declines in CD4 cell counts, a large Spanish study has now found that the people most vulnerable to a large CD4 cell decline are those who have higher CD4 counts when they contract syphilis. Study participants' CD4 cell counts fell by around 100 cells/mm³ when they contracted syphilis, but rose again after syphilis was successfully treated.

However, even though the study found that the only statistically significant factor associated with an increase in HIV viral load was not being on antiretroviral therapy (ART), eleven of forty-four participants on ART with an 'undetectable' viral load before their syphilis diagnosis had a detectable viral load during their syphilis infection. In agreement with several other studies of syphilis in HIV-positive people, the study found no reduction in viral load after the syphilis was treated. These findings are thought to be the result of persistent immune activation.

Syphilis can be contracted through unprotected anal or vaginal intercourse, but also through oral sex. It can also be transmitted by close physical contact with syphilitic rashes and lesions, which can be anywhere on the body, and from contact with blood.

Regular blood tests are the only way to be certain that you do not have syphilis. It is recommended that all sexually active HIV-positive people should be screened for syphilis routinely, and this should be every three months if you have had more than one sexual partner. If your clinic does not routinely test you for syphilis at every clinic visit, you should ask for a regular sexual health screen.



A major concern for people living with HIV in the UK and the organisations that support them is the number of articles in the media that sensationalise and stigmatise HIV and represent individuals living with the virus unfairly. Inaccurate or stigmatising media coverage can increase misconceptions about HIV and fuel discrimination against HIV-positive people.

An article suggesting that HIV can be spread through spitting, for example, might lead to someone refusing to share crockery with an HIV-positive person. Media coverage of criminal prosecutions for the 'reckless' transmission of HIV which refers to a defendant as an "HIV sex beast" or "HIV siren" can encourage prejudice by casting people living with HIV as malicious criminals who want to pass on the virus to others.

Yet the power of the media to communicate news and information, to influence opinions and raise awareness, means that the media can be a valuable tool in the fight against HIV. Many people look to the media for reliable and up-to-date information on issues, and with inadequate sex education in schools and no mass public awareness campaigns, the media is most people's main source of information on HIV. Accurate media coverage is therefore

vital in terms of tackling the discrimination experienced by people living with HIV and helping to prevent the spread of the virus. Journalists should therefore always be challenged when they get it wrong and helped to get it right.

The National AIDS Trust is extremely concerned about the standard of reporting on HIV in the UK, and for several years it has actively challenged any articles that are inaccurate or stigmatising. This normally involves writing a letter of complaint and correction to the editor. Replies are often positive with assurances that measures will be put in place to prevent future incorrect reporting.

The National AIDS Trust has also worked successfully with the Press Complaints Commission (PCC), an independent regulatory body that deals with complaints about the editorial content of newspapers and magazines. With the support of the Press Complaints Commission the National AIDS Trust has managed to secure a retraction from *The Sun* and a formal apology from the *Daily Telegraph* following inaccurate reporting about HIV.

To help journalists ensure that their reporting on HIV is correct and non-stigmatising, the National AIDS

Trust and the National Union of Journalists (NUJ) are jointly launching *HIV: a guide for journalists*. This guide gives journalists up-to-date information on HIV and sources of further information to help stop misleading or inaccurate articles being published. Over thirty thousand copies will be distributed to NUJ members across the UK and it is hoped that giving journalists easy access to correct information about HIV will lead to more accurate and positive coverage about HIV in the media.

What the National AIDS Trust's work with the media has proven so far is that it takes people to speak out and engage with journalists to create a more positive media climate towards HIV, and help educate the public about HIV issues. People living with HIV can make a significant difference by making their voices heard and challenging inaccurate coverage. The National AIDS Trust encourages all people living with HIV to print off a free copy of *HIV: a guide for journalists* from www.nat.org.uk and write a letter of complaint to the publication whenever they see an article that does not follow the guidelines.

People living with HIV who are interested in regularly challenging stigmatising coverage in the media could also consider joining 'Press Gang'. The National AIDS Trust formed

nat's press gang

why it's important to challenge inaccurate hiv reporting,
by Deborah Jack

this online group to help people living with HIV speak out against negative coverage and make their voices heard in the media.

The National AIDS Trust keeps 'Press Gang' members informed of any stigmatising or inaccurate coverage and gives them advice on how to challenge it. The National AIDS Trust scans many online newspapers and other media for mentions of HIV and AIDS on a daily basis, and any articles that are identified as stigmatising or inaccurate are sent to 'Press Gang' members via email as a 'stigma alert'.

Members are then encouraged to write a letter to the editor or add a comment online pointing out why this article is stigmatising or inaccurate and informing readers about the realities of living with HIV in the UK. In addition, members are provided with contact details to enable them to contact journalists and editors with their feedback. These letters can also be sent to editors for publication, and if people wish to remain anonymous they can request this. By making their voices heard in this way, people living with HIV are bringing about change and improving the way that HIV is reported in the media.

Deborah Jack is the Chief Executive of the National AIDS Trust

join press gang

Anyone living with HIV who is interested in challenging stigma in the media can join 'Press Gang'; to sign up email press@nat.org.uk or call 020 7814 6730.

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