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# hiv treatment update

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These days, when one talks of vaccines in the context of HIV, thoughts immediately turn to the current expert view that, despite intensive global efforts, a vaccine for HIV-negative people that prevents them becoming infected with HIV remains elusive, and might never be found.

In fact, most researchers now believe that a preventive vaccine will be unlikely to completely prevent HIV infection, but rather might be able keep viral load under control should infection occur. This would also preserve the immune system and prevent, or at least delay, the need for anti-HIV drugs.

This is much closer to the long-held concept of therapeutic vaccines, aimed at restoring immune function (and possibly keeping viral load under control without anti-HIV drugs) in people who are already living with HIV, and where research continues at some pace, despite many setbacks.

Although some experts doubt the concept will work, researchers at London's Chelsea & Westminster Hospital are about to start a new trial that combines a therapeutic vaccine with several other immune modulating agents that they hope will eventually lead towards a new kind of treatment strategy – one that doesn't require a lifetime of antiretroviral treatment.

However, Dr Graeme Moyle tells HTU that a previous UK therapeutic vaccine study recruited poorly and that "it is all very well to enthuse about research but ultimately research requires volunteers and this ethic appears to have largely been lost in the community and by many physicians."

An alternative to lifelong daily therapy would be a huge step forward. Let's hope we have some answers soon.



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upfront

# Don't forget the children

by Edwin J Bernard

Next month, a one-day conference, 'Don't forget the children', will discuss how to persuade HIV-positive parents to make sure that all of their children are tested for HIV.

The conference, organised by the British HIV Association (BHIVA) and the Children's HIV Association (CHIVA), was inspired by the recent death of an adolescent in London whose HIV status was missed during childhood, and who presented with TB and died soon after being diagnosed HIV-positive.

Untested children, and the issue of late presentation and delayed diagnosis of adolescents infected at birth, was also the subject of the CHIVA parallel session held at the BHIVA Autumn Conference in London last month.

By examining UK and Ireland's paediatric and adult HIV databases, Dr Katia Prime of St George's Hospital in south London identified 42 adolescents aged between 13 and 20 who had acquired HIV, survived childhood untested and untreated, and who had presented to healthcare providers in the UK and Ireland up to the end of 2007.[1]

The average age of these remarkable adolescents was 14 years; just over half were female and most were born in sub-Saharan Africa, with an average time between arrival in the UK and diagnosis of almost three years, and with 30% being diagnosed more than five years after arrival.

Although half had symptoms that prompted an HIV test, half only tested following the diagnosis of a relative. Dr Prime also presented data showing delays between first being seen by a doctor and being diagnosed with HIV – the average time being six months, with one in four taking a year to be diagnosed.

Most are doing well, and all but one is still alive. However, one adolescent, who presented with TB co-infection, died shortly after being diagnosed with HIV. One of the doctors involved in this case said this was because "the family refused to have their child tested" and said it was "a massive issue".

"It can be really difficult when you're seeing HIV-positive mothers to encourage them to test their children, particularly when their mothers haven't disclosed their HIV status to their children," replied Dr Prime.

A presentation from Dr Michael Eisenhut of Luton and Dunstable Hospital highlighted that at this HIV clinic, the majority of children of HIV-positive mothers remain untested, despite the clinic's best efforts. Only 42% of mothers knew the HIV status of their children aged 16 years or younger.[2]

When he asked the mothers why they had not tested their children, the most common response was the belief that because the child appeared to be well, it could not be infected. Other reasons included feeling unable to cope with a child's positive diagnosis; a fear of confronting the child with the mother's own HIV diagnosis; and a fear of feeling guilty if a child turned out to be HIV-positive.

A discussion ensued following both these presentations regarding the ethics of testing teenagers without disclosing why they were being tested (in order to avoid breaching the mother's confidentiality); the legal impact of not testing, or not disclosing, if a teenager consequently transmits HIV sexually; the possibility that some assumed mother-to-child infections may be due to childhood sexual abuse by a family member; and the possible use of child protection laws to force testing when parents are unwilling.

Newly published HIV testing guidelines (see *News in brief*) have begun to address some of these issues. They state that if a parent does not want the child to be tested, consent issues are complex, but "the overriding consideration must be the best interests of the child".

The 'Don't forget the children' conference, which will take place on Wednesday 10th December at the Royal Society of Medicine in London, plans to discuss and understand the extent of the problem, its underlying causes and consequences, and to develop a consensus strategy to overcome barriers to testing and diagnosis. Further details can be found on the CHIVA website (www.chiva.org.uk/news/dontforget.html).

# can we create 'elite controllers'?

Is combination immunotherapy the future? ask **Edwin J Bernard and Derek Thaczuk**

### The search for 'elite controllers'

Not all immune systems are created equal. Without appropriate antiretroviral treatment, most people who have been infected with HIV will progress towards more serious disease – some more slowly, others more quickly. However, about one-in-a-hundred HIV-positive people show a natural ability to at least partially control HIV infection and really slow down disease progression. These so-called 'long-term non-progressors' are able to maintain close-to-normal health, low viral loads, and high CD4 cell counts for up to three decades (so far), without the need for treatment. In addition, some non-progressors, so-called 'elite controllers', are able to maintain 'undetectable' viral loads (i.e. below 50 copies/ml) without the use of antiretrovirals.

Research into long-term non-progression began in the early 1990s when researchers in San Francisco realised that they had patients infected between 1978 and 1980, in the very earliest phase of the epidemic, who were still healthy, with normal immune systems and very low levels of HIV in their blood. The research[1], by Susan Buchbinder and colleagues, caused excitement at the 1993 International AIDS Conference in Berlin, and led to the establishment of other studies around the world. It also led to an understanding that the phenomenon was more common than expected.

"If you talk to anyone who has a practice of 300 HIV patients, they will have [an 'elite controller'], " noted Bruce Walker of Harvard University Medical School during the 2006 launch of the HIV Elite Controllers Consortium, an international collaboration between researchers in the United States, Canada, Europe and Australia.[2]

Naturally, there has been great interest in why some people are able to control their HIV for long periods of time without antiretrovirals. Part of the reason may be due to the particular strain of virus that person has been infected with. HIV has evolved into a wide variety of strains – some more potent, some less so. Infection with a 'wimpy' strain of virus may mean it does less damage and is more easily controlled by the immune system.

On the other hand, it may have something to do with characteristics of the infected person, rather than the virus – these are known as 'host factors'. Professor Frances Gotch and her colleagues from Imperial College, based at London's Chelsea & Westminster Hospital, have identified a number of long-term non-progressors and, together with several other groups of researchers worldwide, have shown that there may be a genetic component to non-progression – some people may simply be lucky enough to have inherited a protective genetic make-up from their parents.

For those lucky enough to be 'elite controllers', however, both factors – 'wimpy virus' and inherited genes – may apply.

Of course, we cannot pick and choose the virus we are infected with nor the genes we are born with. But Prof. Gotch and others are investigating what we might be able to learn from the more genetically fortunate. Once we have identified the characteristics that keep non-progressors well, the next question is whether it is possible to induce these characteristics in others.

"Of most interest to us as immunologists," Prof. Gotch tells *HTU*, "is the fact that many long-term non-progressors have exceptionally good HIV-specific immune responses." Using sophisticated technology to measure the quantity and quality of such HIV-specific cellular immune responses, Prof. Gotch and her colleagues at Imperial College have found that their group of long-term non-progressors "show particularly high levels of CD8 'killer cells' as well as high levels of effective CD4 T helper cells in the blood; together these seem able to keep the levels of virus down."

## Immunotherapy: giving the immune system a boost

It would obviously be more desirable to be a long-term non-progressor – or even better, an 'elite controller' – than to be entirely reliant on anti-HIV drugs for the rest of your life. While we do not yet know whether this is realistically achievable for the majority of people with HIV, immunotherapy studies may yield ways of delaying (or possibly even avoiding) the need for HIV treatment – hopefully without introducing prohibitive costs or complications of their own.

"It seems possible that the necessary immune cells are not destroyed completely during chronic, progressive infection," says Prof. Gotch. "They may be present, yet unable to respond properly to HIV." Immunotherapy aims to boost the body's own immune response – especially the HIV-specific response – that may be waiting for a boost.

One widely investigated therapy is a cytokine (a cellular messenger chemical) called interleukin-2 (IL-2). In its natural form, as produced by immune cells, IL-2 stimulates the production and maturation of CD4 cells. Clinical trials have shown that manufactured versions of IL-2 (*Proleukin*) can result in very dramatic increases in CD4 cell counts. However, despite ongoing trials, there is still little evidence as to whether this translates into long-term clinical benefit. Still, a recent study[3] found that short courses of IL-2 (twice-daily injections over five days, every eight weeks) may boost CD4 counts enough to delay the need for antiretroviral therapy by up to two years. Results from two trials, ESPRIT and SILCAAT, expected next year, should help us understand better the clinical benefits and risks of IL-2.

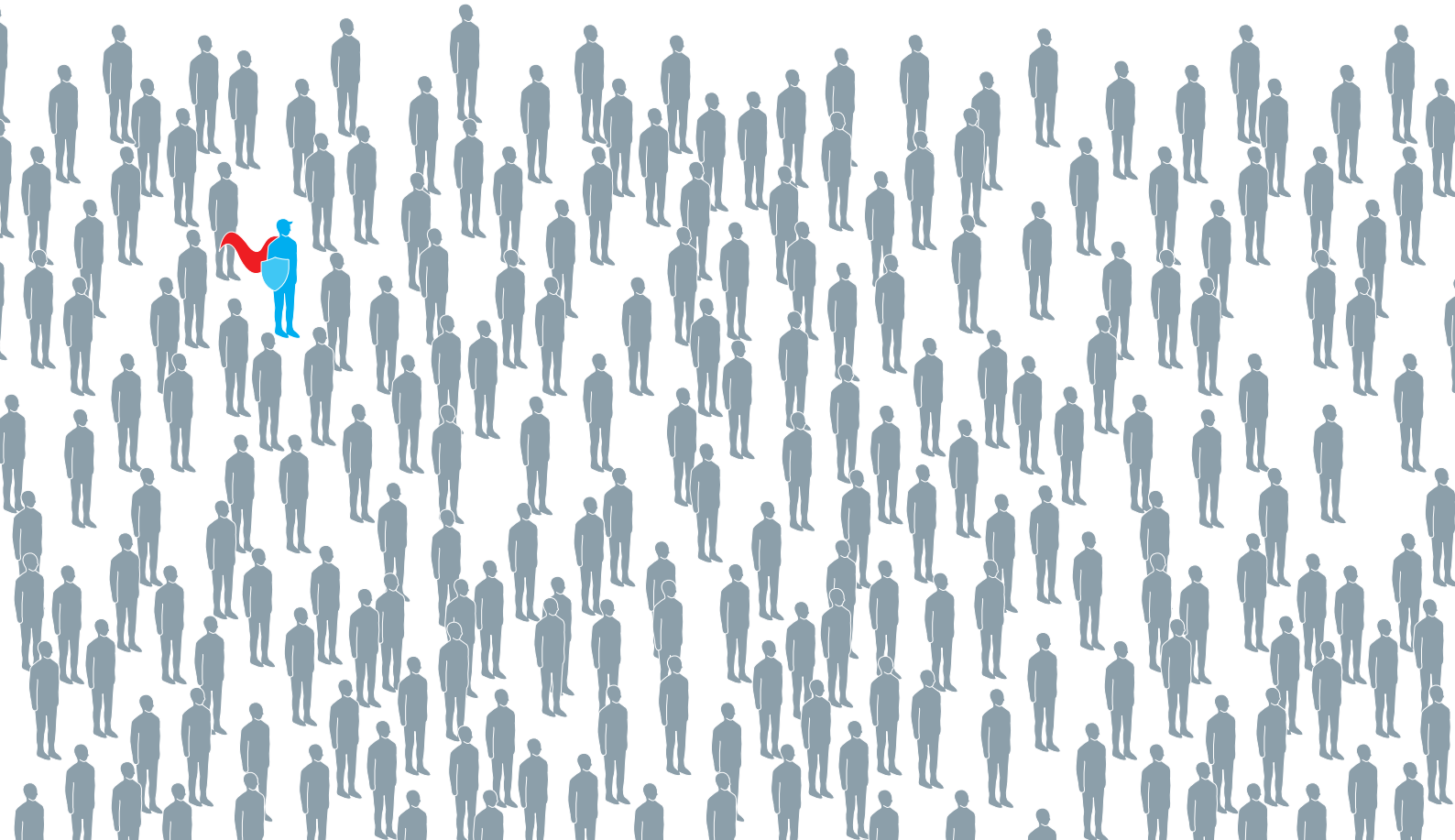
### 'Killer' cells

While most people with HIV are well acquainted with their CD4 cells, which communicate with other immune cells and co-ordinate the overall immune response, CD4s are actually just one of many types of immune cells that play distinct but interlocking roles in fighting infections. CD8 cells, often overlooked, are also extremely important. CD8 cells, in addition to being 'killers', are also able to act as 'suppressors' of viral replication. Killer CD8 cells destroy infected human cells, sacrificing them in a bid to keep infection from spreading further.

IL-2 has been around for more than a decade, but in a much more 21st century approach, several researchers are experimenting with using a person's own immune cells, modified to create a more effective response to HIV. In such 'autologous cell' techniques, an individual's white blood cells are reintroduced into the body after being treated in specific ways – typically, by exposing the cells to distinctive pieces of the virus that 'teach' them to respond more robustly to HIV. While still highly experimental – and extremely costly – several autologous cell techniques have so far appeared safe and promising. Ultimate feasibility, effectiveness and safety of this technique remains to be seen.[4,5]

## Therapeutic vaccines: an alternative to lifelong treatment?

Back in May 2006 (*ATU* 156), when we examined the fallout from the SMART



study – which found that treatment interruptions are not a safe long-term treatment strategy, due to the increased risk of serious illness and death when coming off HIV treatment compared to staying on it – we wondered whether this now means that triple-drug-combination HIV treatment is a lifelong prospect. When we examined whether therapeutic vaccines were a viable alternative to lifelong treatment we found short-lived early success and quite a few potential drawbacks.

In fact, when we interviewed two of the foremost HIV experts in the UK for our January/February 2007 edition (*ATU* 163), both were definitely unenthusiastic about the prospects of therapeutic vaccines making a difference to our treatment options. "Therapeutic vaccines won't work," said Dr Mike Youle, of London's Royal Free Hospital. "At best they're going to be mildly beneficial." Professor Brian Gazzard, of Chelsea & Westminster Hospital agreed: "I think the chances a therapeutic vaccine will have any impact is virtually zero."

Although there have been several promising candidates, including *Remune* (developed by Jonas Salk, discoverer of the polio vaccine, and no longer being studied) and *DermaVir* (applied to the skin, and still being studied) the best results so far have come from a team of French researchers who created a cocktail of two therapeutic vaccines – the ALVAC 1433 vaccine and HIV lipopeptide – plus IL-2. During viral load-guided treatment interruptions (this study was done before SMART) they found that the trial participants who received the therapeutic vaccine/IL-2 combination had, on average, viral loads ten times lower, and remained off anti-HIV drugs for 40% longer, than non-vaccinated patients.[6]

However, earlier this year, an international collaboration reported that a similar therapeutic vaccine – ALVAC 1542 – actually increased viral loads and reduced time off treatment – the opposite of what had been hoped.[7] The investigators believe these disappointing results may be down to bad luck – they found a higher proportion of 'natural' non-progressors in the group that didn't receive the vaccine than in the vaccine group. But it may also be possible that instead of stimulating anti-HIV CD8 cells, which would kill HIV-infected cells, the vaccine mainly stimulated the formation of HIV-specific CD4 cells – which might only serve as targets for more HIV replication.

**Our goal is to make chronically infected people act more like 'elite controllers'. Our hope is that, in the future, we may be able to take people off antiretroviral therapy.**
Prof. Frances Gotch

### Isn't HIV treatment enough?

Currently, the most commonly used immune-boosting therapy is HIV treatment itself. Most people who respond well to antiretroviral therapy have a dramatic increase in their CD4 count in the first few months of treatment, followed by a more gradual rise during subsequent months. This later phase is accompanied by improved function and restoration of a wider range of immune responses. So why do we need a therapeutic vaccine?

"Taking antiretroviral therapy does not normally rejuvenate the HIV-specific immune responses needed to keep the virus under control [if you ever stop treatment]," argues Professor Gotch. "Consequently, if the drugs are stopped or fail in some way, the levels of virus will rebound and CD4 cell counts will plummet." She also argues that antiretroviral therapy is not available to at least 70% of HIV-positive people in the developing world who require it, although some experts wonder whether potentially expensive and complex combination immunotherapy could be a realistic alternative for resource-limited settings.

### A new study in combination immunotherapy

With these things in mind, and with lessons learned from past immunotherapy and therapeutic vaccine studies, Prof. Gotch and her colleagues are about to start a Medical Research Council-funded study (called IMIRC1003) in HIV-positive people who are on successful HIV treatment (defined as viral loads below 50 copies/ml and CD4 T-cell counts over 400 cells/mm$^3$) that will combine several new immunotherapeutic approaches.

They will use a new kind of DNA vaccine boosted with several different cytokines and hormones (see below) in a strategic attempt to regenerate missing HIV-specific cellular immune responses. "Our goal," says Prof. Gotch, "is to make chronically infected people act more like 'elite controllers'. Our hope is that, in the future, we may be able to take people off antiretroviral therapy." She adds that the study has been reviewed and approved by GTAC[8] (the Gene Therapy Advisory Committee – the ethical review panel for all research involving gene therapies in the UK).

What is different about this study, compared to those in the past, is that this one combines several different immune modulating cytokines and hormones with a therapeutic vaccine, notes Dr Nesrina Imami, a colleague of Prof. Gotch who is working on the study. They have also thought long and hard about the timing and dosage of each of the individual components. "No consensus has yet emerged concerning the optimal timing and dosing regimens of vaccines and cytokines," Dr Imami tells *HTU*, "but recent studies from ourselves and others have suggested that sustained responses may be induced by:

- Treating patients with antiretrovirals before CD4 T-cell counts fall below 200 cells/mm$^3$.
- Allowing reconstitution of CD4 T cells to a level equal to or above 400 cells/mm$^3$.
- Inducing or reintroducing specific cellular and humoral (antibody) responses by priming with vaccines representing a broad spectrum of antigens with novel adjuvants.
- Increasing survival of vaccine responses through the administration of cytokines/hormones.
- Boosting memory responses with further immunisation."

## What's in the vaccine?

GTU [Gene Transport Unit]-Multi-HIV clade B vaccine is produced by a small Finnish biotech company, called FITBiotech. It is a DNA vaccine containing parts of HIV's genetic material (for the geeks amongst you, these are: complete sequences of Rev, Nef, Tat, p17/p24 proteins, and an epitope stretch of previously identified T cell epitopes in *pol* and *env*) and is designed to stimulate cellular immune responses to HIV.

The vaccine has been evaluated in phase I/II clinical trials in Finland, both in healthy volunteers and in anti-HIV-treated individuals, all of whom were infected with subtype B. In these studies, the vaccine was found to be safe.

Initial results from a phase II study[9] of 60 treatment-naïve individuals in South Africa (all of whom were infected with subtype C) were presented last month at the AIDS Vaccine 2008 meeting in Cape Town. The participants had an average CD4 count of 560 cells/mm$^3$ and an average viral load of 41,000 copies/ml. A total of 20 participants received 0.5mg of the vaccine injected under the skin, 20 received 1mg injected into the muscle, and 20 received a placebo (a fake vaccine) at the start of the study, and one and three months later. These were then boosted after 19 and 20 months with two more injections at double the initial doses. None took HIV treatment during the study.

The investigators found that there were no vaccine-related serious adverse events although there were some mild to moderate side-effects including bruising, itching and swelling at the injection site. Interestingly, although the intramuscular injection resulted in stable CD4 counts (whereas those on the placebo fell) and a small but significant (0.5 log) decrease in viral load compared to those on placebo, increases in immune function were only observed in those receiving the under-the-skin vaccination (which is how the Chelsea & Westminster study will deliver the vaccine).

## What is being used along with the vaccine, and why?

Along with the GTU vaccine, the study will be using the following cytokines and hormones (chemicals which serve as 'triggers' to immune functions):

- Recombinant human granulocyte macrophage colony-stimulating factor (rhGM-CSF). This is a naturally occurring protein. When produced as a medicine by Novartis it is known as sargramostim (brand name, *Leukine*), and is used to stimulate the production of white blood cells.

- Recombinant human IL-2, which is manufactured by Novartis under the brand name *Proleukin*. IL-2 is normally produced in the body during an immune response and will be used in this trial to boost the immune response to the vaccine.

- Recombinant human growth hormone (rhGH) has mainly been used in studies to treat the central weight gain that might accompany lipodystrophy, although recent studies[10] suggest it may also have a beneficial effect on the immune system. The therapeutic form of rhGH is produced by Serono International with the brand name *Saizen*.

The theory is that the vaccine will induce useful cellular immune responses able to recognise HIV, and that such immune responses will be maximally enhanced by the use of this combination of cytokines and hormones. Eventually, following a booster vaccination, this should result in a long-lived pool of mature memory cells which mimic those seen in long-term non-progressors and 'elite controllers' and may be able to control HIV without the need for antiretroviral therapy (although a treatment interruption to try to show this will not be part of this study).

## Taking part

If you are considering taking part in this study, you should be aware that there may well be drawbacks as well as potential benefits. As with most trials, some side-effects can be anticipated. In particular, flu-like symptoms (such as fever, muscle aches and tiredness) may accompany injections of IL-2 and GM-CSF, although the investigators will be using low doses of these substances, which should help to minimise these symptoms (and which can be controlled by taking ibuprofen or paracetamol). IL-2 may also sometimes cause mood changes, including irritability, insomnia, confusion, or depression, and which can continue for several days after they are stopped. Side-effects of rhGH can include headache, muscle pain, joint pain, salt and water retention and rare instances of carpal tunnel syndrome (pain or tingling in the first three or four fingers of the hand).

"We cannot, of course, promise that the study will directly help the participants," says Prof. Gotch, "but we sincerely hope that the information we get from the trial may help improve treatment for others with HIV in the future. In the absence of an effective preventative vaccine, thousands of people are still becoming infected with HIV every day. It is essential to design novel therapies to enable people living with HIV/AIDS to lead long and productive lives." ■

If you are interested in the trial, and think you may be suitable, email f.gotch@imperial.ac.uk; n.imami@imperial.ac.uk or mark.nelson@imperial.ac.uk for further information.

NAM's patient information booklet, Clinical Trials, is available to download here: www.aidsmap.com/files/file1000884.pdf. A free copy should also be available in your HIV clinic, or can be obtained by calling NAM on 020 7840 0050.

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# the consequences of fear

How the myth of 'health tourism' is harming people with HIV, by **Edwin J Bernard**

In April 2004, following a public consultation by the Department of Health (DH), the government amended legislation to exclude from free NHS hospital care "anyone who is identified as being in the UK without the proper authority," including "failed asylum seekers, whose entitlement to free NHS [care] ends once their claim (including any appeals) has been finally refused; overstayers, who entered the UK legitimately but whose visa or entry clearance is no longer valid..; and illegal entrants who have no entitlement to free NHS treatment at all."[1]

This change in policy was primarily a response to media and popular concern over 'health tourism' – a concept based on myth not fact – the results of which are now a "public health disaster" according to Yusef Azad, Director of Policy and Campaigns for the National AIDS Trust (NAT), which launched a new report, *The Myth of HIV Health Tourism*, at last month's British HIV Association (BHIVA) Autumn Conference.

By pandering to public opinion, the government removed access to HIV treatment and care not only from temporary visitors, but also from irregular migrants (also called 'illegal', 'undocumented' or 'unauthorised' migrants – people who are liable to be deported for issues related to immigration status) – the most vulnerable members of UK society, inevitably some of whom live with HIV.

In April, the High Court ruled that one 'class' of irregular migrants – refused asylum seekers – should be considered 'ordinarily resident' and therefore entitled to free NHS treatment, including for HIV. However, a DH appeal against this ruling is being heard at the Court of Appeal later this month, which may change the rules again.[2]

**The problem is asking healthcare workers to do immigration officers' work for them. To use health care provision as a lever in immigration policy, when that immigration policy fails, is a public health disaster. It is as simple as that.**
Yusef Azad, NAT

## The myth of 'HIV health tourism'

The NAT report argues that there is no evidence to demonstrate that 'HIV health tourism' to the UK exists. "Allegations of 'HIV health tourism'", says the report, "make a serious charge against the integrity and truthfulness of many HIV-positive migrants to the UK, effectively alleging that stated reasons for migration to the UK are at best a pretext and at worst totally untrue. Given the discrimination and marginalisation experienced by many migrants we must question very carefully any claim which might add to social hostility."

The report also notes, "the claim of health tourism has been central to the Government's policy of charging refused asylum seekers and other migrants without lawful residency status for healthcare. The Government argues that free NHS care for those without what they deem to be a legitimate reason to migrate to the UK acts as a 'pull factor', encouraging illegal immigration and discouraging refused asylum seekers from leaving. Charges for NHS care for certain categories of migrant were introduced to end the 'pull' of free NHS care and address the so-called problem of 'health tourism'.

"Is there really evidence of HIV health tourism which would justify on grounds of immigration policy the singling out of HIV for NHS charges alone amongst all serious or sexually transmitted infections?" asks NAT.

## Who began the myth of 'HIV health tourism'?

From the mid-to-late 1990s, the migration of people from high prevalence countries to the UK began to forever change the demographics of HIV. This change, alongside increased new HIV diagnoses acquired in the UK via sex between men and better survival of people previously diagnosed with HIV due to the advent, in 1996, of potent antiretroviral therapy, led to genuine concerns within the HIV sector about the lack of adequate NHS funding for HIV treatment and care.

These concerns hit the mainstream in 2003, when articles in *The Spectator*[3] and *The Daily Telegraph*[4] began to fan the flame of xenophobic and anti-immigration sentiment, adding to concerns over limited NHS resources, and fears of foreigners bringing disease with them and 'spreading' it to the UK population. The articles, which were based purely on conjecture and anecdotal evidence, painted an inaccurate but compelling picture suggesting that: asylum seekers are primarily Black African; that most Black Africans are infected with HIV; that they are already aware of their HIV status; and are misrepresenting their claims for refugee

status or political asylum in order to access treatment and care which is either not available in their home country, or which costs more than they can afford.

In fact, the DH highlighted in its 2003 consultation on changes to NHS charges "much media coverage [of health tourism] is confused and inaccurate, e.g. concerns about health care for asylum seekers, who are entitled to necessary hospital care while their claim and any subsequent appeals are considered."[5]

**They say you are a health tourist but how can you be a tourist when you have this hanging over your head? You are HIV+, how much worse can it get? If you are from Africa you don't know anything about medication. All you know is if you are HIV you are dead. How can you even think of jumping on a plane if you think you are going to die? It is expensive to come here, if you are sick you can't work, you can't afford it. If you can afford the plane you can afford to buy medication.**
HIV-positive African migrant[12]

### Where is the evidence?

The Department of Health's main justifications for amending the regulations for charging ineligible overseas visitors for hospital care were overburdened health services and inappropriate diversion of taxpayers' money. However, these justifications were criticised by the House of Lords and House of Commons Joint Committee on Human Rights due to a lack of evidence for either large-scale health tourism or its financial burden on the NHS.[6]

Neither the DH, nor the government, have any reliable data regarding the existence of 'HIV health tourism', nor do they have any evidence that it is a significant burden on the NHS. In 2005, Melanie Johnson, then Minister for Public Health, told the Health Select Committee on new developments in HIV/AIDS and sexual health policy (appointed by the House of Commons to examine the expenditure, administration, and policy of the DH): "I do not have any figures to supply you with on this. I concur with the point that it is difficult to measure it, and we do not have reliable information."[7]

In fact the Health Select Committee found no evidence for 'allegations of HIV health tourism', but rather evidence *against* it: "What little evidence exists in this area in fact seems to suggest that HIV tourism is not taking place. It suggests that HIV-positive migrants do not access NHS services until their disease is very advanced, usually many months or even years after their arrival in the UK, which would not be the expected behaviour of a cynical 'health tourist' who had come to this country solely to access free services."[8]

Nevertheless, the government claims that 'HIV health tourism' does exist, and suggests that it exists in the following way: HIV-positive migrants wait until they are extremely ill before coming to the UK and then immediately attend A&E for treatment: "It is precisely because that kind of immediate access is available that the UK is a popular destination – people out to abuse the system do not seem to wait for weeks or months before seeking out services, they do it as soon as possible after they get here... The Government remains convinced that deliberate abuse of the NHS by overseas visitors, across a range of services, is not just a potential threat but a very real one... That applies as much to HIV treatment as to any other hospital service."[9]

The new report from NAT provides very strong evidence that this is not the case. "If migrants travel to the UK knowing their HIV status with the aim of accessing lifesaving treatment, we would expect data to reveal that migrants with HIV access tests and/or clinical care and treatment soon after arrival," it says. "In fact the opposite is the case. Recent data from the HPA [Health Protection Agency] supports previous studies showing that there is a significant amount of time between arrival in the UK and HIV diagnosis. In 2007, the average time between UK arrival and HIV diagnosis was almost five years, and this has increased over time – from almost four years in 2005, and four-and-a-half years in 2006."[10]

The report provides a wealth of evidence to robustly argue that there is no evidence to demonstrate that 'HIV health tourism' is "a significant or real motivation for migration to the UK" and that there is considerable evidence to demonstrate otherwise, "in particular the lower rates of HIV prevalence compared with country of origin, the long average delays between arrival in the UK and accessing HIV testing and care, and the evidence available on the actual motivations of migrants coming to the UK."[11]

### The costs of late diagnosis

Black African migrants are disproportionately affected by late diagnosis compared with other vulnerable groups, and evidence strongly suggests that this is not linked to recent arrival in the UK. In 2006, more than 40% of Black African adults had their HIV infection diagnosed late, which greatly increased their risk of illness and death in the short-term.[13]

A 2006 BHIVA audit of AIDS-related deaths suggests that some deaths were due to migrants not attempting to access HIV care because of the perception that they were not eligible. In fact, thirteen patients who had received a previous positive HIV test had not been under regular care and re-presented too late for effective treatment. This included one individual who had not returned to receive the test result.[14]

So, rather than targeting the NHS, evidence suggests that, due to a variety of factors, including language barriers and fear and misinformation about their rights to use medical resources, migrants often under-use health services legitimately available to them, and that even migrants who suspect they might be HIV-positive are not testing or accessing care for fear that an HIV-positive test may lead to deportation.[15]

A 2005 review from the pan-London HIV Consortium found that just 20 people who were not deemed to be eligible were receiving HIV treatment from the NHS in London.[16] So, even if a small minority of ineligible HIV-positive individuals were accessing HIV treatment, this would cost a tiny fraction of the NHS budget, as it is estimated that HIV prevention, treatment and care costs the NHS £440m per year, less than 1% of the total NHS treatment and care bill.

On the other hand, providing free HIV treatment and care to everyone in the UK is far more cost-effective than denying access to certain ineligible individuals. This is because the cost of treating a neglected condition in an emergency (which the NHS must do, regardless of the ability to pay) is likely to exceed the cost of preventive or maintenance treatment. The annual cost of antiretroviral therapy is now less than £8000; one week's stay in intensive care can cost more than twice as much.[17] There are also important public health benefits – by reducing infectiousness, HIV treatment greatly reduces the risk of onward transmission, both sexually, and from a mother to her child.

## The impact of the myth

The overall impact of the April 2004 guidance, in terms of cost-savings to the NHS, is unknown as the DH and the government are not only unable to produce figures regarding the costs of alleged 'HIV health tourism', but are also unable to show that any money has been saved.

Rather, evidence suggests that the costs, in terms of human health and suffering, have been great. Baroness Gould told the House of Lords in March 2008 that: "It is clear that these changes to the regulations are causing serious hardship...These measures actually prevent vulnerable people, including pregnant women, accessing the vital treatment that they need because they cannot afford the charges."[18]

One of the consequences of the policy change has been widespread confusion regarding entitlement to care on the part of healthcare providers, as well as immigrant and refugee communities. This has been exacerbated by a second DH consultation, issued in May 2004, on changing entitlement to primary care, which, although it has not yet been implemented, has led to some GP practices excluding eligible patients.[19]

NAT has compiled a dossier of case studies[20] that highlight further problems resulting from the 2004 guidance. It shows that some people who are entitled to free hospital treatment have had it mistakenly denied by NHS officials and clinicians confused over the regulations. Other case studies show the misery and suffering caused by the regulations: often destitute, those unable to pay upfront have had their treatment delayed, denied, interrupted or withdrawn. In addition, many individuals have been aggressively pursued by debt collectors. These, and other "extremely shocking examples" of the impact of the charging regulations were reported to the House of Lords and House of Commons Joint Committee on Human Rights in 2006.[21]

In addition, the confusion over the so-called 'easement' clause – which allows doctors to provide 'immediately necessary treatment' regardless of the ability to pay – may also have harmed many HIV-positive migrants, and is somewhat duplicitous: the government is publicising one message – that ineligible individuals are not entitled to free HIV treatment although they are entitled to free HIV testing – and obscuring life-saving information – "that anyone who has already begun treatment, including HIV treatment, on the understanding that they are entitled to receive it free of charge must continue to receive that course of treatment free until it is completed, or they leave the country or are deported. This applies even if it is established that they are no longer eligible for free treatment or, indeed, that they never were eligible. This means that there is absolutely no question of, for example, an asylum seeker who has begun a course of HIV treatment, suddenly being asked to pay for it to continue because their asylum application has been turned down."[22]

Even then, confusion over the actual definition of 'a course of treatment' has meant that many clinicians had perceived a pressure to begin their patient on antiretroviral therapy sooner than necessary so as to avoid having to charge for it in the event that asylum was denied. Again, the government obfuscated on this, providing a recent supplementary letter to clinicians clarifying this policy and stating that 'treatment' begun prior to the asylum decision does not necessarily mean antiretroviral therapy, but in fact, can simply mean continued monitoring of immune and clinical status due to an HIV diagnosis.

## Changing public opinion

At last month's BHIVA conference, a session on treating migrant populations and their eligibility for care brought into sharp focus the impact of these policies on HIV treatment and care. NAT's Yusef Azad pointed out that, "the problem is asking healthcare workers to do immigration officers' work for them. To use healthcare provision as a lever in immigration policy, when that immigration policy fails, is a public health disaster. It is as simple as that," he said.

Professor Jane Anderson, of Homerton University Hospital, east London, with a high proportion of HIV-positive patients who are migrants, is acutely aware of the many problems they face. She pointed out the paradox of one government department, the Department for International Development, committing £6 billion to universal access to HIV treatment and care overseas[23], but another two government departments, the Department of Health and the Home Office, "denying that [same] care free here and also sending people back through various legislation and legal decisions to places where there's no care. Why can't we have domestic policies that are the same as foreign policy?" she asked.

The government's continued insistence on the myth of 'HIV health tourism' is calculated political populism. Health and immigration were the two issues of greatest concern before the 2005 election[24], and perpetuating the myth may have won Labour much political capital by appearing to be tough on refused asylum seekers and protecting the NHS from 'abuse'. Indeed, the change in legislation featured in the Labour Party's 2005 election manifesto.

If public opinion changes, then government policy may soon follow. Yusef Azad told the conference that he hoped the new NAT paper, which is primarily aimed at journalists and politicians, might begin to make a real difference. "I don't think we should be pessimistic about changing public opinion and public understanding of what's going on," he concluded. ■

# news in brief

hiv testing

## New guidelines recommend normalisation of HIV testing

New guidelines for HIV testing[1], issued in September, urge healthcare workers of all specialities to consider HIV testing in a wide range of situations and settings. It is part of a package of recommendations to reduce the number of late and undiagnosed HIV infections in the UK. Moreover, in areas where HIV prevalence is high, testing is recommended for all adults in all healthcare services. Consequently, about 20% of the English population lives in areas where universal opt-out testing is now recommended.

In 2006, guidelines recommended that all patients at sexual health clinics should be offered HIV tests on an 'opt-out' basis. Opt-out means that a test is recommended to the patient and carried out if he or she gives consent. The 2008 guidelines go much further – HIV testing should not only be offered as part of a sexual health screen, but also during a wide range of other potential encounters with health services, particularly in areas where there is already a recognised high prevalence of diagnosed HIV infection (most of London, plus Blackpool, Brighton, Bournemouth, Luton, Crawley, Eastbourne, Harlow, Manchester, Reading, Salford, Slough, Southend and Watford).

The guidelines aspire to put an end to 'AIDS exceptionalism', which has suggested that HIV testing could not be handled by mainstream health services, and that specialised pre- and post-test counselling were required. The guidelines state that: "It should be within the competence of any doctor, midwife, nurse or trained healthcare worker to obtain consent for and conduct an HIV test."

The guidelines have been jointly produced by the British HIV Association (BHIVA), the British Association of Sexual Health and HIV (BASHH) and the British Infection Society (BIS). At the same time, the Medical Foundation for AIDS and Sexual Health (MedFASH) has released a practical guide for healthcare professionals who do not specialise in HIV, to help them implement the new guidance.[2]

travel

## US announces 'interim' measures for HIV-positive visitors

US consular officials will now have the authority to grant visas for short visits to the US without having to obtain a special 'waiver' according to a new rule, called the Human Immunodeficiency Virus (HIV) Waiver Final Rule and announced in September.

HIV-positive individuals who wish to visit the US for up to 30 days will still need to apply to their local US consulate and officials will have to be satisfied that HIV-positive visa applicants will not engage in activities in the US that will "pose a threat to public health". A visa, that will not mention HIV, will be granted the same day if someone meets all the normal conditions for the granting of a US visa.

It has taken almost two years since these measures were first announced, in December 2006, for them to be put into place. According to the US Department of Health and Human Services (DHHS), these are "interim" measures until they can remove HIV from the list of "communicable disease[s] of public-health significance", which was signed into law as part of the PEPFAR bill by President Bush in July.

Until then, unlike HIV-negative (or untested) citizens of the UK and many other countries, who can make short visits to the US without obtaining a visa in advance from the US consulate, HIV-positive individuals must still obtain a visa before travelling.

# news in brief

living with hiv

## One in three of us has suicidal thoughts

A UK study of HIV patients at four clinics in London and one in Brighton has found that 31% reported having had suicidal thoughts over the previous week. This is more than twice as high as that observed in gay men (13%), a group known for high suicide rates.

The authors say that it appears that HIV-related stigma and shame, poor health and "the burden of secrecy and lack of community and social support" appeared to be the most significant influences on suicidal thinking.

The study found that heterosexual men, people of black ethnicity and people who had not disclosed their HIV status to anyone were about twice as likely to have suicidal thoughts as other groups. In fact, 45% of heterosexual men recorded suicidal thinking compared with 30% of gay men.

Other factors that were associated with people being more likely to have suicidal thoughts included poor treatment adherence, being in poor physical and/or mental health, being unemployed, being single, and having stopped HIV treatment. However age, practising condomless sex, pessimism about treatment or being infectious, and type of treatment were found not to be a factor.

Since 1990, 271 or nearly 2% of the approximately 14,000 HIV-positive people who have died in the UK have taken their own lives, and the proportion of deaths due to suicide has increased in the period since effective HIV treatment became available.

hiv treatment

## HIV treatment keeps non-HIV-related illness at bay

New data from Johns Hopkins University in the US add to the evidence from the SMART study that antiretroviral treatment reduces the risk of serious non-HIV-related illness for people with a CD4 cell count below 350 cells/mm$^3$.

They found that the risk of experiencing serious problems relating to the liver, kidney, heart, lung and brain, as well non-HIV-related cancers, was halved in people on treatment compared to those not on treatment. However, people not on treatment, and with CD4 cell counts above 350 cells/mm$^3$ were only slightly more likely to develop these problems than those on treatment.

These new data support current treatment guidelines that recommend that people start treatment before their CD4 cell count drops below 350 cells/mm$^3$.

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# No allowances

An *HTU* reader's experience of the DLA review, **by Michael Ratsey**

Fifteen years after my initial diagnosis, I am still reasonably healthy. I have managed my HIV with determination and a holistic approach to life, healthy diet and regular exercise, and I'm lucky to live in a healthy rural environment.

My meagre finances consisted of two very small pensions, and the state benefits of Disability Living Allowance (DLA) and Income Support (IS) which had been set up by social services a few months after I was advised to give up work in 1995.

The immediate aftermath of the diagnosis is a period of which I have little recall. I was in shock. However I was assured I would be secure for life, and the added stress of worrying about money was removed. I'd had no cause to think about it since.

I first heard about the intended review of DLA in the March edition of *HIV Treatment Update* and read about it with interest but no great concern. By then I had already filled out a form from the Department of Work and Pensions (DWP), assuming it was their annual records update.

But as the *HTU* piece advised, I did contact THT [the Terrence Higgins Trust], and was reassured from the article and THT that at 59, I would be a long way down the review priority list.

The prospect of being financially 'trimmed' didn't daunt me much, as I felt I was moderately healthy (and didn't understand the implications), but within five days of completing a second form on 27th May I was shocked to receive a letter saying I was no longer eligible for ANY DLA. In consequence I would lose not only my Motability car but my Income Support too. The only surviving benefit would be £62.45 a week Severe Disability Allowance (SDA).

In panic, I did some sums and found that after mortgage repayments, Council Tax and prescription charges I would be left with £38 a week to live on.

My new financial plight and some health issues that arose at that time made June 2008 a time as frightening as the period in 1995 when I was diagnosed. However I knew I had to deal with it, so I set about it getting myself informed.

I telephoned THT, the NAM offices, the benefit agencies, my HIV consultant and my GP. I logged onto *hivbenefits.co.uk* to see what had happened to other people who had been reviewed. I visited my MP and saw a volunteer from the Citizens Advice Bureau (CAB) at my local surgery and I got in contact with the Disability Employment Agency (DEA) as I assumed the only solution was to somehow get a job.

Everyone I communicated with was appalled at what had happened, especially as the DEA had told me I was unemployable and they would not be able to help me. What rational employer would give a job to a man approaching sixty, who had not worked for 15 years, had numerous health issues leading to unpredictable working hours and was HIV-positive (that's if I disclosed this last bit)? Added to that, I learned that if I did get a job and it exceeded £88.50 a week, I'd lose the SDA.

All the above professionals said, 'You HAVE to appeal', but first to ask the DWP to reconsider their decision, and then to request an independent tribunal to state my case orally. The thought of this terrified me.

So I wrote a lot of letters, the first requesting the 'revision', and a 'Statement of Reasons'. I accompanied this with supporting letters from my consultant, GP, and someone who had seen my health decline over the years.

As my income was now £5000 below the figure the government had recently stated was an acceptable level to live on, I applied for help with housing costs, and with prescriptions through the NHS low-income scheme. Then I had to just sit back and wait, until the slow wheels started moving, whilst ensuring my weekly shopping bill did not exceed £20. Meanwhile the District Council sent a bill for £700 as Income Support was no longer paying Council Tax, even though they had agreed I was entitled to benefit.

All this happened within a month of losing my DLA entitlement. The only thing that kept me sane as I ploughed through red tape and bureaucracy was the confidence I was a mentally strong person with sufficient skills to articulate and survive. I became driven by what had to be done, and it told on my health – I lost 10kg that I could ill do without.

Then soon afterwards I received another letter saying an acknowledged Income Support overpayment which already was being reclaimed drip by drip would now have to be settled in full - to the tune of more than £20,000.

The turning point was my meeting with a legal adviser from the CAB. She reassured me I could win back what she felt should never have been removed, and that they would support me every step of the way. They have been brilliant!

When I received a letter from DWP saying my DLA mobility component was restored because of my revision request, CAB encouraged me to continue to fight for the reinstatement of the entire package. After CAB wrote a letter listing 20 health issues which I had learned to live with and accept, like daily diarrhoea and changing bedding, or asking someone to carry my vacuum cleaner upstairs, etc, the entire package was restored.

However, six weeks later I was still waiting for written confirmation that all of it had been reinstated, and once again CAB got involved. Within a couple of days I got a phone call telling me I was back on Income Support.

I have survived, but a few things have made me very angry. The first is the way weak minority groups are being targeted to bring down the numbers on benefits – on my journey I came across instances of people on dialysis and with congenital lung disease being similarly affected. None of us should have to endure this traumatic experience.

I'm also shocked by the speed at which money is removed, and how slowly it is reinstated.

But thank goodness for the Citizens Advice Bureau. Already I've been able to help another 'victim' by putting them in touch with CAB right at the beginning.

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**New guidelines recommend normalisation of HIV testing**


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