

# aids treatment update

## lipodystrophy and criminalisation

This summer, *ATU*'s double issue examines two of the most pressing concerns for people with HIV in the UK: lipodystrophy, and the criminalisation of reckless HIV transmission.

The British HIV Association's latest treatment guidelines suggest a step-by-step approach to avoiding lipodystrophy in individuals starting anti-HIV therapy for the first time, and a harm reduction strategy for those already on therapy, including yearly assessment for cardiovascular disease risk.

Going one step further, a recent editorial in the *British Medical Journal*<sup>1</sup> suggests assessing coronary heart disease risk prior to starting therapy, and if the risk is above normal, to wait until an individual's CD4 count is closer to 200 (rather than 350) cells/mm<sup>3</sup>, and to undertake lifestyle changes in the meantime.

Although knowledge continues to improve regarding ways to avoid and reverse the various manifestations of lipodystrophy syndrome - body shape and metabolic changes that affect the quality and, possibly, the quantity of life - it is evident that we still have much more to learn.

We also still have some way to go before it is clear exactly what HIV-positive individuals in the UK must do in order to avoid the risk of prosecution for "recklessly" transmitting HIV. On page ten, *ATU* presents the latest information on this troubling subject.

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# lipodystrophy:

2 how the new bhiva guidelines are dealing with lipodystrophy, by edwin j bernard

## a step-by-step approach

In the eight years since the first reports of a range of symptoms – abdominal fat gain and fat wasting in the face, arms, legs and buttocks – that turned out to be part of the lipodystrophy syndrome, much time and effort has been spent on researching exactly what lipodystrophy is, what causes it, and how to prevent and treat it.

Despite ongoing discussions over definitions of what exactly constitutes lipodystrophy syndrome (generally understood as a disruption to the way the body produces, uses and distributes fat), current knowledge regarding its causes, as well as how to avoid and treat its various symptoms, is slowly advancing, as evidenced in the latest British HIV Association (BHIVA) HIV treatment guidelines.

However, this may not be fast enough for the many individuals with HIV whose quality and quantity of life are already adversely affected by this distressing syndrome.

### Defining lipodystrophy

*Lipodystrophy syndrome* is a collective term for a wide variety of unintentional fat changes seen in people with HIV. These changes can occur to a person's body shape, including fat loss beneath the skin (subcutaneous) in the face, buttocks and limbs, known as *lipoatrophy*; fat gain around the organs inside the abdomen, at the front and/or back of the neck and upper back, or breasts, known as *lipohypertrophy*; or a combination of both.

Changes can also occur inside a person's body, known as *metabolic* changes: these include fat (lipid) abnormalities - too much low density (LDL, or 'bad') cholesterol, too little high density (HDL, or 'good') cholesterol and high

triglycerides - in the blood, which is known as *dyslipidaemia*; and a change in the way the body processes sugar, known as *insulin resistance*.

### The effects of lipodystrophy

- Loss of fat affects an individual's psychological and emotional well-being, often resulting in loss of confidence and less motivation to take anti-HIV drugs as and when they are prescribed. It can also cause physical discomfort due to less padding in the buttocks and the feet.
- Fat gain, particularly around the abdomen, possibly means an increased risk of *cardiovascular events* like heart disease and stroke, in addition to affecting self-confidence and adherence to anti-HIV medications.
- Metabolic changes are associated with an increased risk of diabetes and cardiovascular events.
- Although any of these symptoms can occur independently, there is often a link between them. For example, insulin resistance can lead to diabetes, which can either lead to, or be a result of, a change in body fat distribution; and both diabetes and fat gain around the abdomen are associated with an increased risk of cardiovascular events.

### What causes lipodystrophy?

A recent review<sup>1</sup> of all of the major lipodystrophy studies published so far summarised the most significant risk factors related to fat redistribution. None of the studies completely agreed with each other, but there were some common factors.

Of the nine studies examining causes of fat loss, the most commonly found risk factors were: exposure to, and duration of, anti-HIV drug therapy containing d4T (stavudine, *Zerit*) and/or AZT (zidovudine, *Retrovir*) (6 out of 9 studies); aging (5/9); disease severity, including lower CD4 cell counts and higher viral loads (5/9); duration of any anti-HIV drug therapy (3/9); and white ethnicity (3/9).

Of the eight studies examining causes of fat gain, the most commonly found risk factors were: protease inhibitor use (4/8); duration of any anti-HIV drug therapy (3/8); disease severity, including lower CD4 cell counts and higher viral loads (3/8); and aging (3/8).

This suggests that there is no one cause of lipodystrophy in people with HIV, but rather it is thought to be due to a complex combination of many factors. These include: an individual's age and genetic make-up; infection with HIV itself; and the anti-HIV drugs they have taken and/or are currently taking.

Several studies have found that a combination of two nucleoside reverse transcriptase inhibitors (NRTIs or nucleoside analogues) and a protease inhibitor (PI) is associated with the greatest risk of developing lipodystrophy, but it is unclear whether these two classes of drugs amplify each others' effects on body fat.

### What's new in the BHIVA guidelines?

The latest BHIVA HIV treatment guidelines – available in draft form as this article goes to press, and published in *HIV Medicine* in July – acknowledge that there is no one cause for lipodystrophy in people with HIV and suggest that lipodystrophy "is likely to assume a central role in guiding choices for antiretroviral therapy". This is the result, say the guidelines writing committee, "of the growing awareness of the increase of stigmatisation and reduction of adherence associated with lipodystrophy, especially lipoatrophy, and for the increased cardiovascular risk associated with drug induced metabolic abnormalities."

A new feature of the guidelines is a step-by-step protocol for the management of lipodystrophy. This includes monitoring for cardiovascular disease and avoiding drugs associated with fat

changes."It is important that all patients are made aware of the potential manifestations of lipodystrophy, especially in terms of body shape changes," say the guidelines, which divides the management of lipodystrophy or individual metabolic problems into five categories:

- Adequate assessment and follow-up.
- Lifestyle changes, including smoking, diet, dietary supplementation and exercise.
- Additional therapies, generally focussing on managing individual manifestations.
- Modifying the treatment regimen away from d4T, and possibly AZT to abacavir (*Ziagen*), and tenofovir (*Viread*).
- Corrective procedures.

However, the guidelines' main focus is on either avoiding or switching from the drugs that appear to be associated with lipodystrophy.

### Avoiding fat wasting

For people who are currently fortunate enough not to have any symptoms of lipodystrophy, the main issue is how to avoid it. Fear of body shape changes and the longer-term risks of diabetes and cardiovascular disease may prevent some people from starting highly active antiretroviral therapy (HAART) even if such avoidance increases their chances of becoming ill. It may also lead to individuals stopping therapy, or to poor adherence, resulting in HIV drug resistance.

The latest BHIVA guidelines suggest that since d4T appears to have the highest risk of lipoatrophy, only people who have no other nucleoside analogue options should use it. They stress that taking d4T and ddI (didanosine, *Videx EC*) together "should be especially avoided."

Although some studies have not found a clear link between AZT and lipoatrophy, it is becoming increasingly more likely that the oldest anti-HIV drug is implicated in fat loss, although it seems to take much longer than d4T. BHIVA suggests weighing up the possible benefits of AZT therapy - and in particular, the benefits of *Combivir* (AZT/3TC) for someone starting their first anti-HIV combination – with the increased likelihood that AZT may eventually lead to lipoatrophy.

### further information

The 2005 HIV treatment guidelines can be downloaded from BHIVA's website: [www.bhiva.org](http://www.bhiva.org)

The step-by-step protocol for managing lipodystrophy can be found at: <http://www.bhiva.org/guidelines/2005/BHIVA-guidelines/Algorithm.pdf>

For more details on all aspects of lipodystrophy, visit NAM's website: [www.aidsmap.com](http://www.aidsmap.com)  
Look for *Body fat and metabolic changes whilst on treatment* in the 'Treatment and Care' section.



## lipodystrophy: a step by step approach continued

For those already on an AZT-containing regimen, BHIVA suggests considering switching to another NRTI, provided that anxiety over developing lipoatrophy outweighs the drug's possible benefits.

### Reversing fat wasting: switching

Avoiding lipoatrophy in the first place is a far better option than trying to reverse it once it has occurred. However, many treatment-experienced people living with HIV have already experienced some fat loss. If you are currently doing well on your HAART regimen, and have a stable or rising CD4 count and a viral load that is 500 copies/ml or less, it is likely that switching from d4T and/or AZT to either abacavir or tenofovir – or *Kivexa* (abacavir/3TC) or *Truvada* (tenofovir/FTC) – will prevent further fat loss and may restore some lost fat. However studies so far have only measured this in the limbs, and it is possible that facial fat loss will not be restored.

A recent study<sup>2</sup> suggests that due to its better tolerability profile, tenofovir might have the upper hand over abacavir. Although limb fat increases were similar after study participants switched from d4T or AZT to abacavir or tenofovir – an average of 12-15% over a year – three times as many people dropped out of the study due to abacavir's side-effects (6%), compared to tenofovir (2%).

Another option is to switch to what is called a *nucleoside-sparing* regimen. This means avoiding all NRTIs, and taking HAART that only includes non-nucleoside reverse transcriptase inhibitors (NNRTIs) and PIs. Again, this is only recommended if you have a very low or 'undetectable' viral load on your current HAART regimen.

Two recent studies have reported on this strategy. The first used lopinavir/ritonavir (*Kaletra*) with efavirenz (*Sustiva*)<sup>3</sup>, and the second used *Kaletra* with nevirapine (*Viramune*)<sup>4</sup>. Somewhat disappointingly, the

participants taking *Kaletra/efavirenz* experienced an increase in limb fat mass of just 13% after two years. This was only apparent due to very specific testing (DEXA scans) and did not appear to affect facial fat loss. After six months, people taking *Kaletra/nevirapine* experienced an average of eight percent increase in thigh fat mass; results after a year on this combination will be presented soon.

The longer-term *Kaletra/efavirenz* study also found that metabolic problems worsened on that combination, with increases in both total cholesterol and triglycerides. People considering switching to a nucleoside-sparing regimen would need to assess the benefits of partial fat restoration with the possible increase in cardiovascular risk. The guidelines also warn that "individuals switching therapy must consider that they may risk their long-term HIV management in exchange for an uncertain outcome with regard to their lipodystrophy."

### Reversing fat wasting: facial fillers

The latest BHIVA guidelines say that for people with mild facial lipoatrophy, switching away from AZT and/or d4T "should be tried before recourse to using any facial filler." However, if a switch is not possible, or where moderate facial wasting exists, poly lactic acid (*New-Fill* in the United Kingdom, *Sculptra* elsewhere) "is recommended as the facial filler of choice."

*ATU* last covered *New-Fill* extensively in Issue 132 (December 2003/January 2004), and very little new information regarding its effectiveness has become available since then. Access has improved a little in London, but according to the guidelines, "availability and funding for poly lactic acid remain major issues for many other patients and physicians."

However, *New-Fill* isn't the only filler option, and the guidelines note that *New-Fill* cannot correct "severe" facial wasting "durably or completely." In this case, BHIVA suggests the

use of polyalkylamide (*Bio-Alcamid*), "a permanent filler which has been demonstrated to correct HAART-associated [lipoatrophy] without significant side-effects...although insufficient scientific information exists on *Bio-Alcamid* to base any guidance on." They admit, however, that "long-term safety data are important," but also add, "this should not be used as an obstacle to treatment for patients requiring treatment now."

A study comparing *New-Fill* with *Bio-Alcamid* is necessary before *Bio-Alcamid* becomes available on the NHS: until then, it is only accessible through private clinics.

One option that is available for some people on the NHS is the transplantation of fat cells from other parts of the body into the face, known as *autologous fat transfer*. However, it is likely to be suitable "for only a minority of patients".

## Reversing fat wasting: experimental options

Early evidence suggests that the diabetes drug rosiglitazone (*Avandia*) may restore lost fat, but possibly only for individuals who have insulin resistance (a pre-cursor to diabetes). Further studies are now underway in the United Kingdom, United States and Australia.

Stopping therapy altogether for a period of time (also known as structured treatment interruptions or planned drug holidays) is not a BHIVA-recommended strategy for reversing lipoatrophy, not least because of the concern of disease progression. BHIVA recommends that anyone considering stopping therapy do so within a clinical trial.

## Avoiding fat gain and metabolic side-effects

BHIVA does not differentiate between the drugs that are associated with fat gain and the drugs associated with an increased risk of cardiovascular disease and/or diabetes. This is because there is a relationship between these two areas of lipodystrophy. However, there are not enough data to know with any certainty which occurs first: lipodystrophy-associated fat gain or metabolic problems.

The guidelines say that there are "convincing data to suggest that avoiding protease inhibitors as first line [therapy], or switching from them, leads to a better lipid profile and possibly a reduction of insulin resistance." The only exception is the recently approved protease inhibitor, atazanavir (*Reyataz*). In the UK, as in the rest of Europe, atazanavir has only been approved for use by treatment-experienced patients, and should be boosted with a small dose of ritonavir. However, some treatment-experienced individuals who have already 'failed' a PI-containing regimen may not be able to switch to atazanavir since it may not be as active against PI-resistant virus, depending on the number of protease mutations.

In order to avoid insulin resistance, BHIVA suggests avoiding most PIs, "but the NRTIs might also have an indirect affect by promoting changes in fat distribution. Although most PIs are associated with significant glucose intolerance, saquinavir has relatively little effect, and atazanavir has no discernable effect." However, recent data<sup>5</sup> from the Multicenter AIDS Cohort Study (MACS) suggest that, in addition to PIs, d4T and efavirenz are also associated with the development of insulin resistance and diabetes.

## Reversing fat gain and metabolic side-effects: lifestyle and drug options

Although the guidelines recommend assessing and changing lifestyle choices that may increase the risk of cardiovascular disease and diabetes, such as "smoking, diet, possibly dietary supplementation and exercise," their advice in this area is inadequate, covered in around sixty words: "Broadly, dietary advice should include a Mediterranean diet rich in omega-3 fatty acids, fresh fruit and vegetables," the guidelines say. "Fibre is known to improve insulin sensitivity. Evidence of benefit for specific food supplements is not established. Regular exercise, a mixture of cardio and weight training may also improve some metabolic parameters and abdominal shape."

Dr Barry Peters of London's St Thomas' Hospital, was one of the 21 members of the BHIVA writing committee. "A firm decision was made that the BHIVA guidelines were not the appropriate vehicle for detailed dietary advice," he tells *ATU*,

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## lipodystrophy: a step by step approach continued

adding that "this important information is well documented elsewhere, including *ATU*."

*ATU* last covered diet and exercise in depth in 2003 (Issue 130) and although little has changed, it might be time for BHIVA to also create more detailed side-effect management guidelines.

The BHIVA guidelines give more space to the use of lipid-lowering drugs, like statins and fibrates, which are used to help reduce high triglycerides and high total or LDL ('bad') cholesterol, or increase low HDL ('good') cholesterol. However, they have been found to have no effect on body shape. *ATU* last covered the use of these drugs in 2003 (Issue 131), and again, little has changed.

Finally, BHIVA recommends that "insulin resistance should be treated with metformin." Although there is some evidence that metformin may also be effective in reducing abdominal fat, the data are not currently persuasive enough for a firm recommendation. It should be noted that metformin is not necessarily an easy drug to tolerate: nausea, vomiting and diarrhoea are all common when starting therapy, and there is a risk of lactic acidosis, a potentially fatal side-effect that is also associated with NRTIs.

### Reversing fat gain: surgical and experimental options

There is no proven treatment for body fat gain associated with anti-HIV treatment. However, a number of treatment strategies have been used with varying success.

The BHIVA guidelines state: "Growth hormone may improve fat management and lead to improvements in appearance of both fat accumulation and lipoatrophy, including facial changes." However, they go on to suggest that "its use is likely to be limited by expense and adverse effects" including joint pain and an increased risk

of developing diabetes. Access through the NHS is extremely unlikely due to its very high cost and the fact that it is currently unlicensed for any HIV-related illness in the UK.

We recently examined the use of anabolic steroids in the January/February 2005 edition of *ATU*, (Issue 143). Apart from using them for hormonal replacement in people with naturally-occurring low levels, anabolic steroids like testosterone or nandrolone are, says BHIVA, "best avoided, due to concerns regarding worsening lipid profiles, fat loss and potential for liver function disturbances".

The removal of abdominal fat by liposuction is regarded risky because liposuction is a technique designed to remove fat from under the skin, rather than the harder fat that accumulates around the body's organs (visceral fat) which often develops with lipodystrophy. However, liposuction might be an effective strategy to deal with the accumulation of fat between the shoulder blades – commonly known as 'buffalo hump', although this name can increase the stigma of the condition.

### Conclusion

BHIVA have provided a generally up-to-date, evidence-based practical approach to dealing with lipodystrophy. However, although lifestyle changes are highlighted in their new step-by-step protocol, the guidelines lack the kind of detail that could help HIV-positive individuals make life-prolonging and – enhancing changes to their own lives.

It is also frustrating how much we still don't know about lipodystrophy. For example, due to the fact that many researchers have defined and measured lipodystrophy in different ways, we still have no idea how common it is; estimates range from between eleven to 83 percent.

# women and lipodystrophy

why body shape changes and heart disease and diabetes risk are different for women,  
by bridget haire

In the past few years it has become clear that women do not experience symptoms of lipodystrophy in exactly the same way as men. In fact, it appears that HIV-positive women on highly active antiretroviral therapy (HAART) are experiencing body shape changes – particularly fat gain – more often than men on similar treatment.

The exact reasons for these gender differences are not completely understood. However, we do know that sex hormones, such as oestrogens (female hormones) and testosterone (a male hormone), play an important role in determining how and where body fat is used and stored.

## Apples and pears

Most women store fat in a pear shape below the waist on hips, thighs, lower abdomen and buttocks. Hormonal changes at menopause can cause a shift in fat distribution patterns toward a more apple-like shape, with more fat stored around the waist and on the breasts. Although younger women traditionally have a lower risk of cardiovascular (heart) disease than men, this change in body shape at menopause is accompanied by an increase in the risk of cardiovascular disease. The same shift from pear to apple shape has been occurring in some HIV-positive women taking HAART, regardless of age.

## Establishing the difference

The differences between the genders first came to light in an Italian study published in 2002<sup>1</sup>. This study investigated risk factors associated with fat accumulation and fat loss in 472 men and 183 women who had been taking either dual anti-HIV therapy or HAART for at least six months. The researchers looked at fat loss under the skin in the limbs, face and buttocks (lipoatrophy) and fat gain around the abdomen and/or breasts (lipohypertrophy) separately, based on the theory that different metabolic processes may be involved.

They found that there was a strong relationship between two particular patterns of body fat change (lipohypertrophy, and lipohypertrophy together with lipoatrophy) and being female. In addition, fat gain was associated with being overweight before the study began. Participants in this study had average or above-average weights compared to the general population, and this may have affected the changes seen in body fat redistribution, the investigators suggested.

A year later, another Italian study<sup>2</sup> examined gender-related differences in fat distribution patterns in over 2250 HIV-positive participants, of whom almost 30% (673) were women. It was noted that the women in this study were

## women and lipodystrophy continued

more likely than men to have had a treatment break or to have taken an anti-HIV combination comprising two rather than three anti-HIV drugs. They were also less likely to have taken protease inhibitors than the men.

Again, this study found that women were significantly more likely than men to experience lipohypertrophy (most commonly fat gain around the abdomen; fat gain on the breasts was the second most common), or a combination of lipohypertrophy and lipodystrophy. However, the risk of lipodystrophy alone was similar for both women and men.

The investigators suggested that hormonal differences might be the reason for this difference. However, in this study changes in body shape were not linked with any physical signs of the hormonal changes seen at menopause – such as developing facial hair, increased body hair or ceasing to menstruate – and blood levels of the male hormone testosterone, which women have in small amounts, were in the normal range.

### No straightforward answers

One of the many problems associated with drawing any firm conclusions about the causes of lipodystrophy are that an individual's inherited genetic make-up also has a role to play in fat distribution. There are also differences between how studies define or measure lipodystrophy-associated fat loss and fat gain; some studies use a person's own perception of their body changes while others use sophisticated scanning devices that measure body composition. In addition, there are differences between study populations, such as different rates of hepatitis C co-infection or injecting drug use – both of which can also affect how the body uses and stores fat.

To confuse things further, a 2003 analysis of the United States Women's Interagency HIV Study (WIHS)<sup>3</sup> did not find significantly higher levels of fat gain in HIV-positive women compared

with HIV-negative women. However, they did find that HIV-positive women were two-and-a-half times more likely than HIV-negative women to experience lipoatrophy.

A 2005 study on body shape changes from the WIHS<sup>4</sup> confirmed these fat loss findings. They found that HIV-positive women on HAART, regardless of whether or not their regimen included a protease inhibitor, had significantly less leg fat – as measured by DEXA (dual-energy x-ray absorbiometry) scanning – than HIV-negative women. This was in spite of the majority of women in this study being overweight.

However, the investigators noted that the fat change pattern they found differed from previous studies. Where previous studies of fat distribution changes in HIV-positive women have generally reported fat gain around the middle (stomach and/or breasts), in this study they found that this kind of fat remained the same and did not increase. The investigators also noted that while increasing age increased the risk of body shape changes for men, this was not found to be the case for the women in this study.

### Women and metabolic changes

An Austrian study<sup>5</sup> published in 2001 concluded that the changes they observed in blood fats indicated that women on HAART had lost some of the 'natural' protection that women usually have from cardiovascular disease.

A very recent study<sup>6</sup> suggests that changing from a pear to an apple-shaped body before menopause does affect a woman's susceptibility to heart disease. The study found that cardiovascular disease risk increased the wider an HIV-positive woman's waist became in proportion to her hips. However, it wasn't the anti-HIV drugs that caused this directly; it was HAART's effect on where the body stored fat that appeared to affect cardiovascular risk.

As far as being diagnosed with diabetes or other problems with the processing of sugar (insulin resistance), there is no evidence from recent studies that HAART is a direct cause of this in women. Rather, it appears that well-established risk factors for diabetes – such as not exercising, being significantly overweight, a family history of the disease, and infection with hepatitis C – are more likely to be present in women living with or at risk of HIV in the US, where all the recent studies come from.

The risk of both cardiovascular disease and diabetes is increased by lifestyle factors such as being overweight, eating a diet that is high in saturated fats, not exercising, and smoking. Changing these patterns of behaviour reduces the risk of both diseases if it is done on a systematic, ongoing and long-term basis.

This commonsense approach is, however, far from simple when it means modifying the habits of a lifetime and can be particularly difficult for women with family responsibilities and/or those on low incomes.

However, although changing diet, exercise and smoking habits reduce some of the serious health risks associated with lipodystrophy, they may not significantly affect body shape changes caused by lipodystrophy.

## In conclusion

Although we are still learning about gender differences and lipodystrophy, it does appear that in comparison to men, women taking HAART are more likely to experience changes to their body fat distribution, and this is likely to include fat accumulation around the middle of the body. This change, accompanied by higher levels of fats in the blood increase the risk of heart attack or stroke.

A woman's risk of experiencing loss of fat from under the skin in the limbs, face and buttocks, appears to be similar to a man's. Although there has been some conflicting research on this matter, it is possible that this is due to the fact that the women being studied were somewhat above average weight to begin with.

What is clearer is that women who are overweight before taking HAART may be more likely to accumulate fat around the stomach and/or breasts and to accumulate fat at a faster

## does ethnicity make a difference? asks edwin j bernard

There is currently no consensus of opinion regarding the impact of ethnicity on whether a person is more or less likely to experience lipodystrophy symptoms although studies from the United States and Australia have found that non-caucasian HIV-positive individuals appear to have a slower rate of lipoatrophy than caucasians. However, Dr Tomas Campbell, Head of Clinical Health at Newham University Hospital in east London, suggests that "lipoatrophy is an issue for Africans, although they don't seem to make an issue of it." Dr Campbell recently presented a case review study at the AIDS Impact conference<sup>7</sup>, which found that one-in-five of the HIV-positive Africans on HAART attending the clinic (where 63% of people taking HAART are African) had lipodystrophy syndrome. Although most cases of lipodystrophy were diagnosed by doctors based on high levels of blood fats, some of the lipodystrophy cases were, in fact, lipoatrophy (28.6% had fat loss from limbs and 14.3% from the face). "The case notes indicated that lipodystrophy syndrome was more frequently diagnosed by physicians than by patient self-report," says Dr Campbell. "This might reflect a feeling on the part of African people that they were not entitled to complain about lipoatrophy. Many have experienced HIV-related deaths amongst their own families and friends and might feel that they are lucky to be receiving antiretrovirals. Our sample wasn't big enough to make any statistically significant statements about gender but it appeared that women were more concerned about it than men."

rate than thinner people. This changed body shape, where the waist increases in size and the upper body becomes as wide as or wider than the hips, is linked to an increased risk of diabetes, heart attack and stroke. In effect, younger women's 'natural' protection from these illnesses is reversed, and the risk increases the longer a woman is on HAART.

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# criminalising hiv transmission

10 the latest information on hiv transmission and the law, by edwin j bernard

*update*

Since November 2003, when *AIDS Treatment Update* last examined the issues surrounding the law in England, Wales and Northern Ireland regarding the transmission of HIV, there have been numerous developments, not least the conviction and sentencing of four men under the *Offences Against the Person Act 1861, Section 20*, for "recklessly inflicting grievous bodily harm" by transmitting HIV to their sexual partners.

Earlier this year, the Court of Appeal's decisions in the cases of Mohammed Dica and Feston Konzani have now defined what constitutes "reckless" transmission of HIV (and any other serious infection) in England, Wales and Northern Ireland. The Court has also determined the circumstances in which consent may provide a defence to a person charged with reckless transmission.

What remains unclear, however, is who might be prosecuted for this offence; how often such prosecutions may happen; and how HIV-positive individuals might best avoid the risk of prosecution.

## **Reckless transmission**

It now appears that if someone knows they are HIV-positive, is aware of the risk of transmission, and takes an unjustifiable risk that results in the transmission of HIV, they are potentially guilty of recklessly inflicting grievous bodily harm. If found guilty this offence carries a maximum prison sentence of five years in

respect of each proven offence. However, the question of what constitutes an unjustifiable risk is not defined by law; it is something that the jury decides, based on the facts of each individual case.

## **Informed consent**

It appears that a valid defence is to claim that the person who became infected with HIV consented to the risk of transmission. However, consenting to sex is not the same as consenting to the risk of HIV transmission, according to the Court of Appeal in the Konzani case; the kind of consent needed to avoid prosecution is "informed consent". In most cases informed consent will be established if there has been disclosure by the HIV-positive person of their HIV status, although the Court did say that it could be established in some other exceptional circumstances (for example, where the complainant is aware that the defendant was receiving hospital treatment for an HIV-related illness.)

## **What the law doesn't say**

These rulings do not explicitly say how they expect a person to know they are HIV-positive. In the case of Kouassi Adaye - who had not taken an HIV test prior to transmitting HIV to his sexual partner - the judge, administering the sentence after accepting the guilty plea, asserted that Mr Adaye should have known his status because his doctor had previously asked him to take an HIV test.

There is also no clarity on whether transmission of HIV under any circumstances is considered "reckless" – e.g. when a condom fails, or through oral sex – or whether it only applies to when condoms are not used in vaginal or anal intercourse.

In addition, the cases do not make clear the relationship between non-disclosure and recklessness.

### Sources of information and advice

A suitably qualified solicitor is best placed to provide specific legal advice in this area.

However, acutely aware of the necessity for some kind of public guidance for HIV-positive people, the National AIDS Trust (NAT) – the UK's HIV/AIDS policy and campaigning charity - has added a short advice section to the June 2005 update of their policy paper on criminalisation.

"I don't think it yet meets all the advice needs positive people have around criminalisation, but we thought it important to at least get the basics into the public domain," says Yusef Azad, NAT's Director of Policy and Campaigns, who stresses that the information "does not substitute for personal and expert advice."

Their understanding of the current state of the law is as follows:

- You are only likely to be prosecuted for reckless HIV transmission if your partner does not know you have HIV.
- and you don't tell them
- and you don't always use a condom for penetrative sex
- and they become infected as a direct result
- and they decide to make a complaint to the police.

This is broadly similar to advice contained in a document written by Terrence Higgins Trust's policy and public affairs department to aid the staff and volunteers who operate the national HIV information helpline, THT Direct. It also deals with the question of whether HIV disclosure is now mandatory, regardless of safer sex. "THT thinks that this is unrealistic and also thinks that the Crown Prosecution Service (CPS, responsible for prosecuting people in

### criminalisation timeline

**October 2003:** Mohammed Dica is convicted in London for recklessly infecting two women with HIV, and sentenced to a total of eight years in prison.

**January 2004:** Kouassi Adaye pleads guilty in Liverpool to recklessly infecting a woman with HIV, and is sentenced to six years in prison.

**March 2004:** The Court of Appeal quashes Dica's conviction and orders a retrial.

**May 2004:** Feston Konzani is convicted in Middlesbrough for recklessly infecting four women with HIV, and sentenced to a total of ten years in prison.

**February 2005:** The Court of Appeal upholds Konzani's conviction and sentence.

**March 2005:** Dica is convicted at an Old Bailey retrial for recklessly infecting one woman with HIV, and sentenced to four-and-a-half years in prison.

**May 2005:** Paulo Matias pleads guilty in Leicester to recklessly infecting a woman with HIV, and is sentenced to three-and-a-half years in prison.

England and Wales charged with a criminal offence) would be very unlikely to take forward a case where the defendant had clearly tried to avoid risk by using condoms consistently."

Both NAT and THT suggest that since prosecutions have only taken place when HIV has been transmitted, if a situation occurs where HIV transmission could occur (for instance, if a condom breaks during sex), the ideal course of action would be for the HIV-positive person to inform their partner about the risk and advise them to get post-exposure prophylaxis (PEP) immediately. However, if HIV transmission were to occur despite the use of PEP, it is unclear whether this course of action would protect the HIV-positive person from potential prosecution.

### acknowledgements

ATU would like to thank NAT's Yusef Azad, James Chalmers, Sigma Research's Catherine Dodds, THT's Lisa Power, and Matthew Wait for their assistance with this article.

### reference

1. Chalmers J. *Mandatory HIV and Hepatitis Testing: the flaws in the Executive's proposals*. *ScoLAG Legal Journal* 332, 116-119, 2005.



## criminalising hiv transmission continued

### Differing opinions

*ATU* consulted with two legal advisors to the UK HIV sector on the criminalisation of HIV transmission - James Chalmers, Lecturer in Law at the University of Aberdeen, and Dr Matthew Weait, Lecturer in Law at Keele University. The two have differing opinions regarding whether practising safer sex without necessarily disclosing HIV status would protect someone from prosecution in the event that HIV transmission occurred.

Chalmers says that the advice from NAT and THT "is exactly right." He notes that although "the courts have not ruled out the possibility of a conviction even where condoms have been used

throughout the relationship, there is some suggestion, from the ruling of Lord Justice Judge in the *Dica* appeal, that someone who uses condoms may be viewed as not having acted recklessly - and therefore not criminally liable. This is not a rule of law, however, but rather a matter for the jury to consider." But Chalmers feels strongly that the Crown Prosecution Service (CPS) "is not going to prosecute all cases of alleged criminal transmission, and are highly unlikely to bring a prosecution based solely on protected intercourse."

However, Matthew Weait wonders whether Chalmers' opinion is "optimistic," although, he adds, "I hope I am wrong."

### the scottish perspective

Although there have been no further convictions since 2001, when Stephen Kelly was convicted under Scottish common law of "culpable and reckless conduct", two further prosecutions have been brought in Scotland. One has been halted temporarily due to the defendant awaiting extradition from Italy. The other concerns a defendant who was found to be mentally incapable of standing trial, and who is currently being detained in a medium-security mental hospital. It is thought that the legal issues discussed here are not greatly dissimilar to those in Scotland, with one possible exception: it is theoretically possible that reckless exposure to the risk of HIV infection ("reckless endangerment") might also lead to prosecution. HIV Scotland's Roy Kilpatrick tells *ATU* of plans to host a seminar that will include seeking a consensus on advice to people with HIV.

Equally worrying are the Scottish Executive's Justice proposals, lobbied for by the Scottish

Police Federation, seeking mandatory HIV, hepatitis B and hepatitis C testing of anyone "suspected" of being infected, and who may have infected a police officer or others in the course of alleged criminal activity or an accident connected with such activity. In a recent article<sup>1</sup> James Chalmers argues that, although they may be well-intentioned, the Scottish Executive's proposals are misguided, "rest on almost no evidence whatsoever, and offer little, if anything, of benefit to persons exposed or potentially exposed to blood-borne viruses."

The proposals are part of the Police Bill which will come before the Scottish Parliament in September. "HIV Scotland has co-ordinated much of the campaign against the proposals and is trying to present the Scottish Executive with alternatives, along with attempts to influence MSPs and the Justice Committee," says Kilpatrick.

Weait agrees that "in principle, the consistent use of condoms should provide a person with a defence, on the basis that the defendant is not taking an unjustifiable risk. This should mean that the defendant cannot be considered reckless. The difficulty is that people will only stand trial where there is evidence that the defendant did in fact transmit HIV to a complainant (which is evidence in itself that condom use was ineffective).

"Furthermore," he says, "the Court has stated in the strongest terms that a defendant can only rely on a partner's consent to the risk of transmission as a defence where that partner is fully informed of the defendant's HIV-positive status in advance. General awareness on their part about the risks associated with unprotected sex does not appear to provide evidence of consent to the risk of transmission. It is for this reason," he argues, "that some of us have concluded that, if a person wants to avoid potential criminalisation and a maximum of five years imprisonment on each count, there is, in effect, a positive duty to disclose known HIV-positive status prior to sex that carries the risk of transmission.

"At the moment, with such an unformed and constantly developing area of law, I don't think I could say to someone with any certainty that using a condom in the absence of disclosure would necessarily protect them from liability, because depending on the circumstances and the ongoing unfolding of these cases, we cannot have a one-size-fits-all answer. Furthermore, people need to be aware that the outcome of these cases will often depend on the respective credibility of the people involved. A person may in fact have told a partner that they are HIV-positive, or have tried to use condoms, but if a jury believe the complainant's version of events – which could be that there was no disclosure, or that they never agreed to sex without condoms – then the defence will in all probability fail."

### Strong reactions

The criminalisation of HIV transmission in the UK has evoked strong reactions from many organisations involved in HIV/AIDS campaigning, research and policy. They are concerned about the effect that this

discriminatory law will have on many aspects of HIV-positive individuals' lives. They argue that the inflammatory language and inaccurate portrayal of life with HIV used in court, and in the reporting of these cases, have added greatly to the stigma of living with HIV. They point out that by exclusively prosecuting non-UK nationals, the CPS has created fear of, and within, the HIV-positive immigrant community. And by legally placing the burden of responsibility for HIV transmission on the HIV-positive person, the law contradicts the Government's own sexual health strategy which stresses individual responsibility for sexual health.

Later this year, the CPS will be consulting with the HIV sector on how best to move forward. This, it is hoped, will include public meetings in London and in the north of England; consultations with HIV clinicians – possibly at the BHIVA/BASHH London conference in September; and a full written consultation to which anyone can contribute.

NAT's Azad hopes that, by working together, the HIV sector can persuade the CPS to end prosecutions for reckless transmission of HIV, or at least produce guidelines for prosecutors which minimise the occasions where it is considered appropriate to prosecute. Nevertheless, at the time of writing, it would appear that by the end of the year the CPS is planning to bring at least one case, involving two gay men, to court. However, it is impossible to gain advance knowledge of cases with much certainty, as there is no centralised system that keeps track of complaints or their progress to trial.

Finally, it should be noted that those hoping for a change in the law that would decriminalise the transmission of HIV might have to wait for a very long time. Mr Justice Roger Toulson, Chairman of The Law Commission – an independent body set up by Parliament to review and recommend reform of the law in England and Wales – told BBC Radio 4's 'Unreliable Evidence' programme in May that the criminalisation of HIV transmission is "a good development... If you pass a really serious disease in a way which is seriously irresponsible, the criminal law should be available there, because it's about protecting the vulnerable."

### Further information

THT's *Frequently asked questions about HIV and the criminal law* can be downloaded from [www.tht.org.uk](http://www.tht.org.uk), along with a THT policy paper on the subject.

The full NAT policy update on the criminalisation of HIV transmission can be downloaded from [www.nat.org.uk](http://www.nat.org.uk)

A new Sigma Research briefing paper, produced for CHAPS, provides a detailed review of debates and responses to criminalisation, as well as an overview of existing cases to date. It is available free from [www.sigmaresearch.org.uk](http://www.sigmaresearch.org.uk)

The forthcoming British HIV Association (BHIVA) criminalisation guidelines, available from [www.bhiva.org](http://www.bhiva.org), will provide a consensus on what the law may mean for HIV healthcare providers around issues of liability and partner notification.

The latest information on the situation in Scotland will be posted on HIV Scotland's website, [www.hivscotland.com](http://www.hivscotland.com).

NAM's website, [www.aidsmap.com](http://www.aidsmap.com), will provide further information when more is known regarding the HIV sector's consultation process with the CPS.



## Long-term HAART linked to high blood pressure

A study that examined blood pressure values in more than 5500 HIV-positive gay men over almost 20 years has found that taking highly active antiretroviral therapy (HAART) for more than two years can lead to high blood pressure in a small minority. Blood pressure is measured in two values: a systolic value, taken when the heart is beating, and a diastolic value, which is taken between heartbeats. Blood pressure is usually quoted as the systolic pressure 'over' the diastolic. In this analysis from the United States' Multicenter AIDS Cohort Study (MACS), high systolic blood pressure was defined as a value over 140mmHg (millimetre of mercury), and diastolic hypertension as a value over 90mmHg. High blood pressure can lead to problems such as heart disease and stroke.

The investigators found that 7% of the systolic and 8% of the diastolic blood pressure measurements were high, and that even when allowing for the usual factors associated with high blood pressure – smoking, older age, being overweight and being African-American – length of time on HAART increased the chances of having high blood pressure. The investigators think that the effect of HAART on blood pressure could be due either to a direct effect on blood vessel walls or to an indirect effect of lipodystrophy-associated raised blood fats and sugars. "Our findings underscore the importance of monitoring blood pressure and for signs and

symptoms of hypertension-related complications among HIV-positive men taking HAART," they conclude.

*Seaberg EC et al. Association between highly active antiretroviral therapy and hypertension in a large cohort of men followed from 1984 to 2003. AIDS 19: 953-960, 2005.*

## Screen for STIs in rectum and throat too, says gay men's study

Sexual health screens that only include a urine test and a swab from the penis would miss the majority of cases of chlamydia and gonorrhoea in gay men, according to a San Francisco study. Although most clinics took swabs from the penis, only about 60% of men had rectal swabs and 85% had throat swabs. However, chlamydia was most often found in the rectum and gonorrhoea was most often found in the throat. Just over half of the men with chlamydia had the infection in the rectum alone. The investigators noted that "if only urethral screening for chlamydia was conducted in this population of men who had receptive anal sex during the previous six months, 90% of rectal chlamydia infections would be missed."

With regards to gonorrhoea, 36% of men with the infection had the bacteria in their throat only, and 28% were infected in multiple sites: "if only urethral screening for gonorrhoea was performed, 77% of rectal gonorrhoea infections would be missed," noted the investigators.

In addition, the investigators established that 70% of chlamydia infections would have been missed if men were only tested for gonorrhoea. A total of 23% of men with rectal gonorrhoea had rectal infection with chlamydia, 11% of men with gonorrhoea in their urethra also had chlamydia present in this site, and 4% of men with gonorrhoea of the throat also had chlamydia in their throats.

*Kent CK et al. Prevalence of rectal, urethral, and pharyngeal chlamydia and gonorrhoea detected in two clinical settings among men who have sex with men: San Francisco, California, 2003. Clin Infect Dis 41 (on-line edition), 2005.*

## More PI interactions discovered

Combining the protease inhibitor (PI) fosamprenavir (*Telzir*), which is taken twice daily with 100mg of ritonavir (*Norvir*), lowers levels of the antidepressant drug paroxetine (*Seroxat, Paxil*), according to a study in HIV-negative volunteers. Levels of the selective serotonin reuptake inhibitor (SSRI) were halved, and this should be taken into consideration when dosing these drugs together.

A similar halving of levels of the antiepileptic drug lamotrigine (*Lamictal*) was found when HIV-negative volunteers combined it with *Kaletra* (lopinavir/ritonavir). Doubling the dose of lamotrigine, which is also used to treat peripheral neuropathy, to 200mg twice daily in combination with *Kaletra* reached levels achieved with lamotrigine 100mg twice daily alone, with no difference in side-effects.

*Blenke A et al. Combined use of paroxetine and fosamprenavir/ritonavir: a pharmacokinetic interaction study in healthy volunteers. 6th Int Workshop Clin Pharm HIV Ther, Québec, abs 13, 2005.*

*van der Lee MJ et al. The effect of lopinavir/ritonavir on the pharmacokinetics of lamotrigine in healthy subjects. 6th Int Workshop Clin Pharm HIV Ther, Québec, abs 12, 2005.*

## Flu vaccine protects HIV-positive people

A study from a large clinical practice in Japan suggest that a yearly 'flu jab can reduce the risk of coming down with influenza by about two-thirds. Compared with those who received the jab, more than three-times as many HIV-positive individuals who didn't receive the

'flu jab came down with the 'flu. This was regardless of CD4 count or viral load. However, the researchers found that having a CD4 count below 200 cells/mm<sup>3</sup> reduced the creation of new antibodies to the vaccine, and that having a high viral load compromised the way T-cells attacked the 'flu virus. The investigators concluded: "Our prospective study in a large population demonstrated that influenza vaccine provides protection of HIV-1 infected patients...[and] annual vaccination of HIV-1 infected patients is thus recommended."

*Yamanaka H et al. Efficacy and immunologic response to influenza vaccine in HIV-1-infected patients. JAIDS 39: 167-173, 2005.*

## Vitamin and mineral supplementation needs more research

A respected researcher into nutrition and HIV has called for more research to establish the role of micronutrient supplementation in maximising both the quality and duration of life of HIV-positive individuals. In an editorial review in the journal *AIDS*, Assistant Professor Alice Tang from Tufts University School of Medicine, Boston, reminded HIV clinicians that the goal of HIV care in 2005 is to use all means possible to improve "the quality and duration of survival" of HIV-positive individuals, even if certain interventions, including micronutrients, might be outside of the "traditional care" or thought process of the HIV care provider.

*Tang AM et al. Micronutrients: current issues for HIV care providers. AIDS 19 (9); 847-861, 2005.*

## 500mg *Invirase* tablet approved in Europe

A 500mg tablet formulation of Roche's *Invirase* (saquinavir) has received marketing approval in the European Union. The new tablet is designed for dosing with ritonavir (*Norvir*) and the approved dosage is 1000mg with 100mg of ritonavir twice daily after meals. The 500mg tablet cuts the saquinavir pill burden substantially and is also better tolerated than the *Fortovase* formulation of saquinavir, which will disappear in 2006.

## nam/iapac forum ias conference feedback

The International AIDS Society (IAS) Conference, held in Rio de Janeiro this July, is one of the most important scientific meetings of the year. Immediately after his return from the conference, Dr Mike Youle, HIV Research Director of London's Royal Free Hospital, will be presenting the most important new information regarding HIV treatments and their side-effects. This special NAM forum, which is held in association with the International Association of Physicians in AIDS Care (IAPAC) will take place on Monday 1st August, between 7-9pm. Since the University of London Union is closed for the summer holidays, the forum will take place at an alternative location. Details will be available closer to the event on our website: <http://www.aidsmap.com/en/events/forums.asp>.

## september's *atu*

The September issue of *AIDS Treatment Update* will be looking at what made the headlines at the IAS Conference in Rio, in addition to examining how HIV and its treatments can affect our bones.

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NAM recommends that you discuss all your treatment decisions with your doctor.