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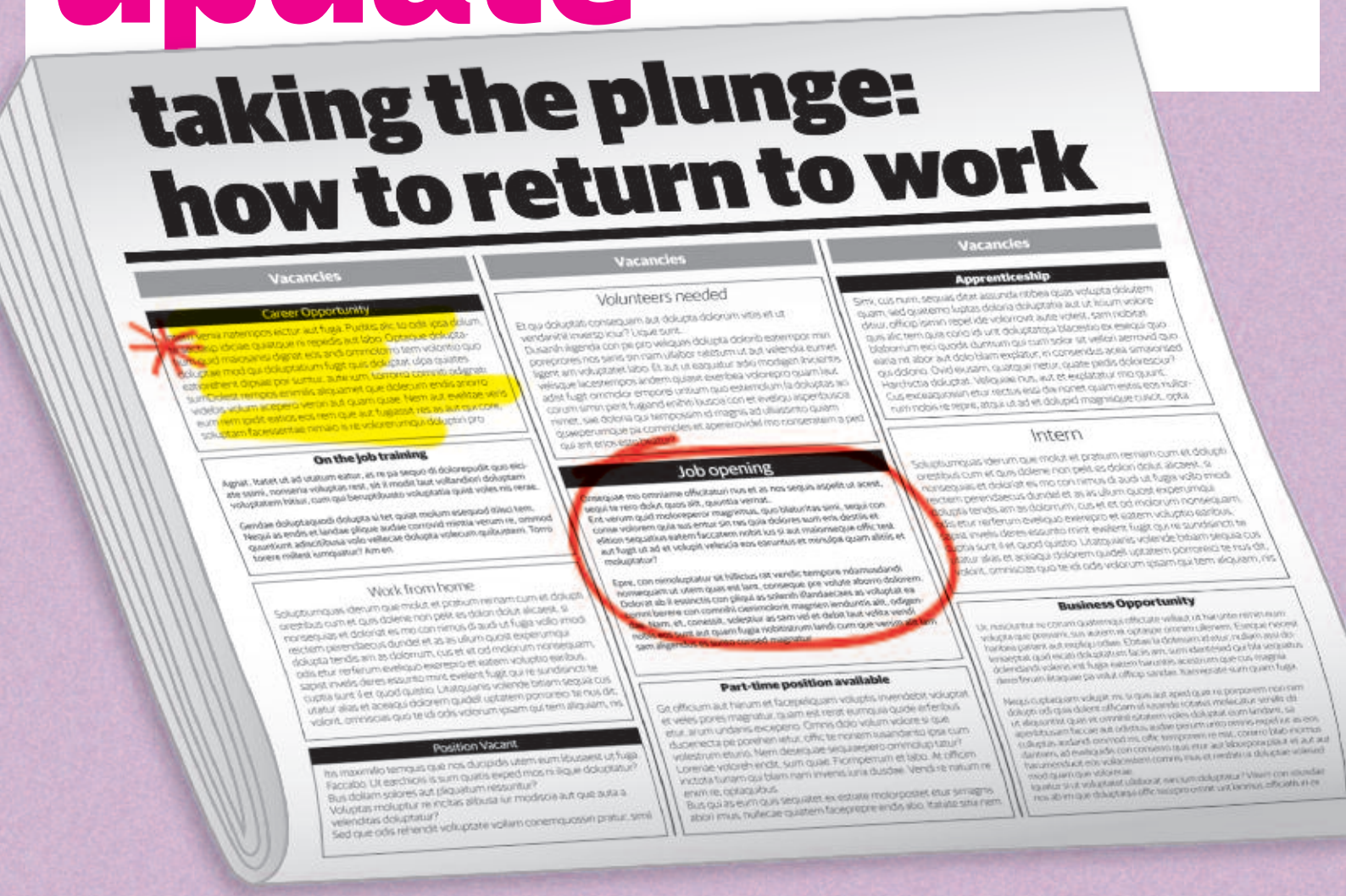
hiv treatment update


taking the plunge: how to return to work

Vacancies

Career Opportunity

On the job training

Work from home

Position Vacant

Vacancies

Volunteers needed

Job opening

Part-time position available

Vacancies

Apprenticeship

Intern

Business Opportunity

Gus Cairns

in this issue

What connects the commonplace experience of hunting for jobs (page 4) with the rarefied world of gene therapy (page 10)? One factor is our improving physical health.

As Matt Sharp explains in his account of being a guinea pig, he was in the HIV generation that only just scraped through: damaged as much by early tries at therapy as by HIV itself, it's been a long journey for Matt and others to re-establish a properly functioning immune system, and it required some pretty whizz-bang technology.

For Matt's and my generation, being able to return to work, if we haven't already, is a real piece of good news. Being a contributor to the economy rather than just a beneficiary may start with improvements in physical health, but it may end in big boosts to mental health and self-esteem.

We AIDS dinosaurs are only a minority of the community of people with HIV. But, as Sue Murphy and both of the people interviewed for their stories show, more recent HIV diagnosis can spur you to re-evaluate your career and to bring your work nearer into line with what you'd really like to do.

Others don't have such a choice. Modern medicine may enable people with HIV to return to work but coming to terms with diagnosis, especially if it's associated with illness, may make it very difficult to struggle on when already working.

Returning to work and needing, if only temporarily, to stop both occur within a bleak current economy and a squeeze on public funds, documented in recent pieces on cutbacks in HIV services (*The Whether Forecast*, HTU 202) and benefits (*What's Happening to Benefits*, HTU 203).

People with HIV, alongside many disadvantaged others, are being pressurised to return to work at the same time as jobs are scarce and services that could help them are being withdrawn. In next month's *HTU* we'll investigate some innovative social care models that try to get round this squeeze on HIV-specific services.

The global and local squeeze on finance threatens scientific research like gene therapy too. This doesn't just apply to ways of curing HIV, but to new ways of preventing it.

Although this month we saw a setback in the shape of the non-result of the Fem-PrEP trial (see page 14), the positive results from the iPrEx trial of oral *Truvada* in gay men and the CAPRISA 004 trial of tenofovir vaginal gel in women continue to stimulate new thinking about HIV prevention.

Opposite we unveil a proposal by the Health Protection Agency for a radical reshaping of gay men's sexual health services, including a trial of PrEP. At the moment, however, this is just a proposal, with absolutely no funding secured. An idea like this will need the backing of a strong coalition of researchers, clinicians and advocates if it is to become a reality within our cut-to-the-bone NHS.

This is not the only radical new idea in prevention around at present, and *HTU* will keep you updated on this rapidly changing field.

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

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

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upfront

The new prevention?

The Health Protection Agency (soon to become part of Public Health England) has proposed a radical shake-up in HIV prevention for gay men at the highest risk of acquiring HIV. The new idea was unveiled at the 17th British HIV Association (BHIVA) conference last month.

Noel Gill, the HPA's head epidemiologist, said, "it's clear that we need to do something new" to reduce the stubbornly high HIV infection rate in gay men in the UK. Gill showed that, allowing for late reports, the number of men who have sex with men testing positive last year topped 3000 for the first time, representing an 11% increase on the previous year.[1]

Heterosexual infections acquired in the UK have also doubled in the last decade but, at just over 1000 last year, are still one-third the rate amongst gay men. Since gay men probably form at most 5% of the adult population, this means a gay man has at least a 60 times greater risk of acquiring HIV in the UK than a heterosexual person.

Diagnoses in gay men had been static or even fallen slightly for the previous three years, creating tentative hopes we were starting to see the benefits of increased testing rates and an increasing proportion of HIV-positive people on treatment. Although the evidence is still not rock-solid, this seems to be happening in some other gay communities, such as in San Francisco.[2]

The new idea is to do a large pilot trial of a concept called Intensive Combination Prevention (ICP) in ten genitourinary medicine (GUM) clinics in England. In five of those, this would comprise six-monthly appointments including a full sexually transmitted infection (STI) screen, an HIV test, a behavioural questionnaire, and a standardised package of safer-sex advice, counselling and support. In the other five, pre-exposure prophylaxis (PrEP) would be added, via a daily tenofovir/FTC (*Truvada*) pill. This is the regimen used in the global iPrEx study, which found PrEP reduced HIV infections in gay men by 42%, and by more in those who took the pills consistently.[3] Being prescribed PrEP would mean having to attend two more appointments a year to guard against undetected new HIV infections and to monitor any side-effects.

This package would only be offered to men at 'high risk' of HIV infection – those who either turned up with an acute STI or reported having unprotected sex with partners of HIV-positive or unknown status.

It is likely to be extremely hard to secure funding for this bold new prevention idea. Firstly, of course, the NHS is strapped for cash. In London, new prescribing guidelines recommend new HIV patients take the cheaper *Kivexa* (abacavir/3TC) instead of *Truvada* where possible. This would create the odd situation in which some HIV-negative gay men would be taking *Truvada* while their HIV-positive friends would not: but, as the only pill studied for PrEP, *Truvada* it has to be.

Secondly, some funding would have to come from local authorities, now responsible for public health, including running GUM/sexual health services. This could be presented as an opportunity – a way of providing a standardised and good-quality package of prevention for a local authority new to running clinics.

Thirdly, the idea probably won't be viable if *Truvada* has to be bought at full cost: this means making the case to Gilead, a company facing an unexpected shortfall in UK-generated profits owing to the London procurement decision.

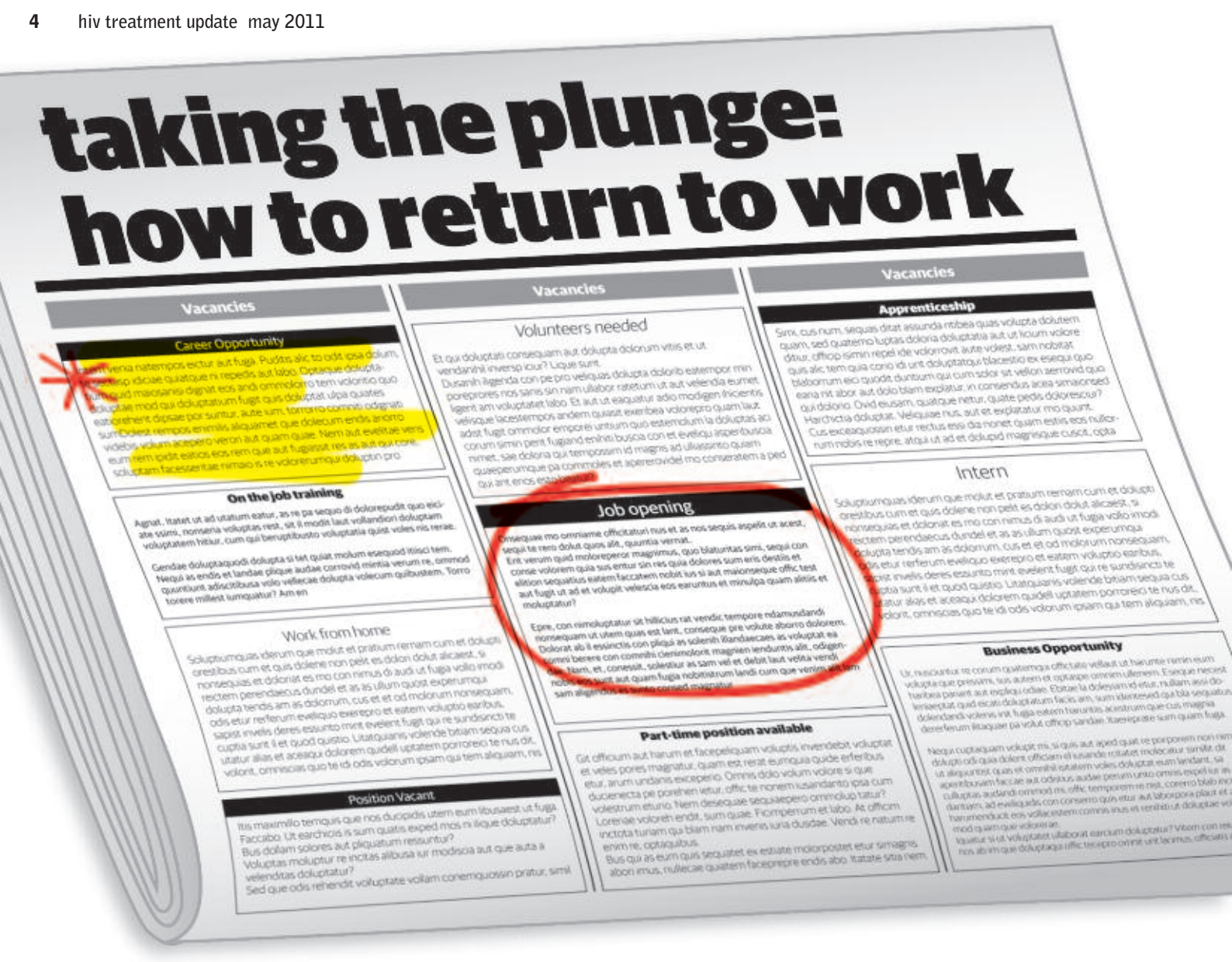
It may be deemed that the PrEP part, at least, is simply not cost-effective. The annual rate of new infections in repeat visitors (excluding those diagnosed on the first visit) to the 29 clinics involved in an existing collaboration with the HPA is 1.1% a year. That means you'd have to give 91 men PrEP for a year to prevent one new infection, at a cost of about £250,000, even if PrEP is 95% effective.

Lastly, a major spanner was thrown in the works at the end of April when the FemPrEP study was stopped (see *News*) because PrEP was making no difference to HIV infection amongst the women participating. This result is unexpected and may indicate that there is more we need to learn about whether antiretrovirals can prevent infections in different populations.

BHIVA, along with BASHH, the UK's association of GUM physicians, is preparing a position statement on the use of PrEP. This is an independent project, but will form part of the guidance for the HPA project, should that prove to be feasible. BHIVA and BASHH are consulting a large number of community prevention experts and organisations in order to get views from all over the community.

With a trial of PrEP in gay men planned to start in France in September and other trial results expected soon, we are going through a period of unprecedented change in prevention policy. HIV has proven to be a lot harder to prevent than treat, and so far we have not found any 'magic bullet' that will stop the epidemic in its tracks. We need to make some very careful decisions about what to do next to make best use of the bullets we do have.

NAM is the community partner in the BHIVA/BASHH position statement project. To find out more email info@nam.org.uk



In February, *HTU* looked at how changes in benefits might affect people with HIV. We quoted a doctor and a patient rep who both said that if people could manage a return to work, it often paid huge dividends in terms of health and self-esteem. *Sue Murphy*, careers adviser at London HIV charity Positive East, provides a step-by-step guide to rejoining the workforce. Thanks also to *Chris Morley* from George House Trust for his contribution.

Returning to employment or entering the labour market for the first time can be a daunting prospect, especially if you have been out of the workplace for a long time or are looking for your first job. It is important to think about the work you want to do and how this can be managed in relation to your physical and mental health. For some, this might mean returning to a previous occupation. For others this may not be possible; a change of direction may not only be a more realistic option but can also provide an opportunity to take a step back and think "What would I *really* like to do?".

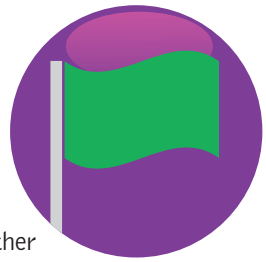
Thinking about work choices may also include decisions about full- or part-time work, education or training, or updating skills and experience in other ways.

People living with HIV who are looking to return to work, seeking a first job or looking for employment in the UK for the first time, need to be confident that the advice they receive is confidential, impartial and informed.

I find there are three major issues faced by long-term unemployed people: loss of confidence; lack of knowledge about the current labour market; and, especially, that market's requirements for qualifications and skills. There are two additional concerns more specific to people with HIV: working with a fluctuating health condition, and disclosure. People are often particularly concerned about variable health and whether they will have the stamina for a full-time job; that's why it's important to talk to a careers or return-to-work adviser about what kind of work, and what hours, might suit you.

At Positive East, we provide advice to people in east London through face-to-face interviews and group courses, held in a safe environment where professional and peer support is available. We've designed programmes that combine practical and psychological support; using the principles of self-empowerment; we encourage service users to be independent and in control of their lives. There may be similar services local to you but, if not, you can still take control of the situation and the following tips can help.

How to start



A good starting point is to research your **career goal**. This should be realistic and achievable. Whether returning to a previous occupation, or if you are changing careers, it is vital to find out what skills and qualifications employers are currently looking for.

Basic requirements for many jobs are literacy, numeracy, basic IT skills and the ability to communicate appropriately. If you are rusty in these areas, make them a priority. In addition to job-specific skills, employers tell us they look for oral and written communication, flexibility, people skills, the ability to organise, the ability to work in a team and problem-solving skills.

Your CV

A logical next step is the preparation of a **CV**. A good CV (*curriculum vitae*) should be factual, containing your work and educational history and a personal profile which captures the reader's interest. Ideally no more than two pages, keep the document simple and avoid waffle or jargon. Your personal profile can be very important as it sets you apart from others and allows you to demonstrate how you would 'add value' to a workplace. Get a friend or adviser to review your CV before you send it anywhere.

Many employers use application forms in their recruitment process, but some still prefer to receive a CV. Job search websites and recruitment agencies will usually ask for a CV, or will have a template. An up-to-date CV is also useful for keeping details of employment and educational history in chronological order so that the information can be transferred easily to an application form.

In addition, you'll need the originals of qualifications and certificates as employers may ask to see them.

There are a host of sample CV layouts available free on the internet; it's even possible to find samples tailored for specific jobs. It is really important that the CV's style and format matches the requirements of the job.

It is a good idea to obtain an application pack for the type of job you hope to do, to make sure you have the necessary skills and up-to-date qualifications. Look at job descriptions and person specifications to identify any areas where you do not currently meet the criteria.

Action planning

When you have identified any training or qualification needs, then writing an **action plan** is a useful process. It should not be a huge wish-list of ambitions. It is a tool to help you break down longer-term goals into small steps that can be achieved progressively. You could plan to complete a couple of actions that are 'STARs' – specific, time-limited, achievable and realistic – within a certain time period (usually a month, or even a week): applying for a course, downloading and completing a CV form, contacting a specific number of organisations to ask about employment – whatever you choose. Highlight your priorities and regularly review your progress.

Volunteering, apprenticeships and internships

Employers are naturally wary about gaps in the employment history on a CV. Many people with HIV feel this is a significant barrier to finding work, especially at a time when unemployment is high. The National AIDS Trust (NAT) booklet *Advice for job applicants living with HIV* gives practical advice on dealing with employment gaps which relate to health, such as "explain that gaps in your CV are the result of a disability covered by the *Equality Act*, but one which does not impact on your eligibility for consideration for ... a particular role", or "state that gaps in employment result from a specific health condition which is now managed and you would be happy to provide further information to an occupational health specialist if required". (This booklet is available online and from NAT.)

Think about skills you have developed in other ways. Many people reading this will have **volunteered** even when they were unable to do paid work. Employers often look favourably on periods of volunteering and are happy to consider them as a valid alternative to paid employment. If you are finding it hard to get paid work or want to reintroduce yourself gradually, volunteering can be a great way to gain valuable experience in a chosen field, with opportunities to update your skills, re-engage with the work environment and obtain a current reference.

It is important to make sure that volunteering does not conflict with the terms of any benefits you are receiving. The Citizens Advice Bureau (CAB) volunteering factsheet (see *Help and advice*) gives an overview, or your local Volunteer Centre, or other advice centre should be able to give guidance.

Although the *Equality Act 2010* doesn't give volunteers disability rights protection at work, most organisations should follow the legal and good practice standards that apply to their employees – see the George House Trust article in *Help and advice*.

Another way to deal with employment gaps before going for a permanent job is by seeking temporary work through agencies. Downsides include low wages and job insecurity, but it can help you regain confidence and see how you cope with working, while only doing the hours you think you can manage.

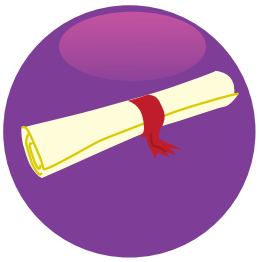
Other routes into specific fields of employment are apprenticeships and

internships. Not all **apprenticeship** schemes have an upper age limit. Apprentices earn a wage and work alongside staff to obtain job-specific skills, usually receiving training towards qualifications. The minimum salary is £80 per week but it can be more; you should seek advice on other benefit entitlements.

Competition for apprenticeship places is fierce, but more are planned. So is the competition for **internships**, particularly within sectors like fashion, media and journalism. Internships are offered by employers to provide on-the-job training and may be paid, unpaid or part-paid. If, as an intern, you do work of value for the employer, rather than just 'shadowing' others, you are likely to have a right to the national minimum wage.

Apprenticeship, internship and volunteer or work placement opportunities are often advertised online and newspapers.

Training and qualifications



If you need additional qualifications for the job you want, details of courses can be found online, from helplines or from your local library.

Fee reductions may be available for people on benefits; look online, or call or visit colleges offering the courses you are interested in.

Disabled Student Allowances (DSA) are available for undergraduate and postgraduate courses, including distance learning, to help meet extra costs students may face as a result of a disability or ongoing health condition. They don't have to be repaid and are based on need, covering items such as specialist equipment, non-medical helpers and travel costs. You can check eligibility criteria on www.direct.gov.uk or with Disabled Student Advisers at colleges and universities.

Help for people with a disability

When you are ready to start looking for employment, help is available. If you are claiming benefits and feel that your health issues are impeding your search for work, you may be able to get specialist help from **Jobcentre Plus** by requesting a referral to a **Disability Employment Adviser** (DEA).

Services include assessments to identify what type of work or training is most suitable for you, and appropriate referrals. This may be to a **Jobcentre Plus personal adviser**, or to two work programmes for disabled people, **Work Choice** or **Access to Work**. DEAs may also be able to offer a job-matching service and referral to specific employment initiatives but there can be up to eight weeks' wait for an appointment. Any disclosure made to Jobcentre Plus will be kept on file and should remain confidential.

Jobcentre Plus offers support for people on any benefit that may be issued on condition that the claimant returns to work within a specific time – as the new Employment and Support Allowance (ESA) often does. The new **Work Programme**, being introduced this year, replaces the old Pathways to Work scheme for ESA or Incapacity Benefit claimants. Jobcentre Plus support is available until claimants are referred to the Work Programme, or as an alternative when they are not referred. It will, according to the Department of Work and Pensions, "be available to customers across all working age benefits" and "will be delivered by advisers whose skills are developed to support customers according to their need rather than benefit type". For more on ESA and the other new and planned benefits, see *HTU* 203.

The **condition management programme**, based on cognitive behavioural therapy (CBT), helps people manage their health in relation to work.

People who take a job may be eligible for **Return to Work Credit**, £40 per week (tax-free) for up to 52 weeks. There are a number of conditions attached; Return to Work Credit is not paid to anyone on Jobseeker's Allowance (JSA).

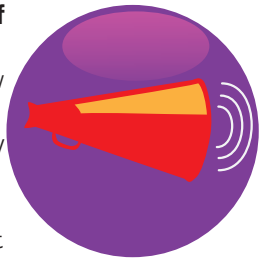
Some people can receive ESA and do some paid work, described as **Permitted Work**. The rules are complex and earnings from Permitted Work affect other benefits – always get advice from a benefits expert and ask them for a detailed 'better off' calculation to help you decide.

Disability-friendly employers

When you are ready to start making applications, it is worth considering employers who display the **disability symbol** (two ticks inside a circle and the words 'positive about disabled people') on vacancy advertisements. It is awarded to employers who have committed to a set of principles on employing, keeping and developing the abilities of staff who "consider themselves to be disabled". These employers guarantee to interview all disabled applicants who meet the minimum criteria for the vacancy and to consider them on their abilities. Symbol-holder employers are also required to develop appropriate levels of disability awareness and ensure disabled people are not disadvantaged in terms of training, retention or consultation.

Under the *Equality Act 2010*, people living with HIV are considered to have a disability from the point of diagnosis, with rights and protections against discrimination and harassment at work. You are covered whether you consider yourself 'disabled' or not.

Making yourself known



Think about how you can give yourself as many advantages as possible. Be proactive: target organisations you would like to work for and send out CVs with a clear and concise covering letter explaining why.

Vacancies are often circulated through networks and may even be filled through personal contacts, so let people know what you are looking for, attend job fairs and think about posting your CV online. This is also another good reason for

Help and advice

There is a range of help available from HIV and other organisations.

NAT (National AIDS Trust) provides excellent resources and advice for both employers and people living with HIV about employment and the *Equality Act*. Visit its website www.nat.org.uk to download or order publications, including the booklet *Advice for job applicants living with HIV*.

The **Terrence Higgins Trust** helpline, THT Direct, can offer advice and direct you to local sources of support: 0845 1221 200, 10am-10pm weekdays, 10am-6pm weekends. www.tht.org.uk

Positive East in East London offers specific career guidance to people: 020 7791 2855. www.positiveeast.org.uk

NAM's employment resources are at www.aidsmap.com/Employment/cat/1684/ and you can search for local services at: www.aidsmap.com/e-atlas.

First Point offers support and referrals to people with HIV in South London: 020 7160 0949. www.slhp.org.uk

George House Trust works across NW England: 0161 274 4499. www.ght.org.uk. Its guide to volunteering is here: http://bit.ly/gLv2KI

PACE for LGBT people in London: 020 7700 1323. www.pacehealth.org.uk

The **Next Step** adult service offers careers advice online, by telephone and face-to-face: http://nextstep.direct.gov.uk or 0800 100 900.

Other useful websites:
www.direct.gov.uk information on benefit entitlement, help for disabled jobseekers and details of Jobcentres.

Citizens Advice Bureau: www.adviceguide.org.uk Its guide to volunteering is at www.adviceguide.org.uk/index/b_volunteering.pdf

Equality and Human Rights Commission (EHRC): www.equalityhumanrights.com

TUC website on internships: www.rightsforinterns.org.uk

For information on courses:
Visit www.hotcourses.com or contact one of the following helplines:

Learn Direct: 0800 101 901 or Careers Advice Service: 0800 100 900

Northern Ireland

The rights and advice in this article apply in England, Wales and Scotland. The legal situation in Northern Ireland is different. Pre-employment medical questions on application forms and in interview are still legal there, for instance.

The Equality Commission for Northern Ireland website explains employment rights and equality law in Northern Ireland: www.equalityni.org

volunteering – to get your foot in the door and make yourself known.

Applying for a job

Once you've found a job you want to apply for, read the application details carefully. If the employer asks you to submit a CV, revisit your CV and think about it in relation to this specific job. Find out about the employer by looking at the company website and yearly accounts. This will allow you to tailor your CV, but will also give you confidence at interview.

If the employer asks you to complete an application form, read the instructions and complete the form carefully.

Often employers will ask you to address each point on the person specification or job description in turn, so the process of filling in the form can take some time, but not doing this, or simply sending a CV instead, will not make a good first impression.

Make sure you send the application form or CV in by the advertised deadline. If emailing them, check that your email address does not send the wrong message!

It's a good idea to keep a copy of your completed application form, along with the job description and person specification, so you can refer back to it later, when preparing for an interview, or applying for another job.

Disclosing HIV status

NAT, alongside other disability and mental health charities, succeeded in their campaign to ban the use of pre-employment health questionnaires (except in very limited circumstances) from October 2010, through an amendment to the *Equality Act* (except in Northern Ireland – see box).

In all but the most exceptional situations you cannot legally be asked for details about your health or disability until *after* a job offer has been made. Since there is no risk of HIV

transmission in everyday work situations, there is no need – or legal requirement – for the vast majority of employers to know about someone's HIV status after this point either, unless the person chooses to tell them.

A distinction needs to be made between asking about your medical status on the application form and asking about whether you have a disability on an equal opportunities (EO) monitoring form. EO forms are usually detachable and should be processed confidentially and anonymously. They are also optional (you don't have to fill them in). If in doubt, ask the employer how they process EO forms.

Currently, there are a few exceptional circumstances when an employer can ask about health or disability prior to a job offer: these are mainly healthcare jobs involving 'exposure-prone procedures'. The armed forces are also exempt from the *Equality Act* and can vet people for HIV. The Department of Health is currently reviewing guidelines in this area.

If you are asked questions about your health on a pre-offer questionnaire and you're not sure what to do, you could:

- ask for advice from an HIV or other advice organisation
- query it directly with the employer
- complain to the Equality and Human Rights Commission (EHRC) – it has powers to investigate employers and employment agencies if they do this.

After a job offer is made to you, the employer can ask health questions, although many employers do not. It is important to be honest, as knowingly giving wrong answers on a medical questionnaire is grounds for dismissal. If you are concerned about this, or about being asked to have an HIV test as part of a standard medical, you could seek advice from the EHRC or, if the employer has an occupational health service, send the health questionnaire answers direct to them.

If a job offer is withdrawn after the health questionnaire or a medical and your answers do not seem relevant to your ability to do the job, ask the EHRC helpline if you can make a disability discrimination claim, or contact an HIV organisation such as NAT or THT Direct for advice.

The NAT booklet has some good advice on disclosing your status at work, and on tackling employment discrimination.

Daniel's story

I was working in a small media company when I was diagnosed with HIV in 2001. It was one of those jobs you get married to: I found it really rewarding and had a strong personal loyalty to the company and my boss.

However I started getting really depressed in 2005. At first I put it down to *Sustiva* (efavirenz), one of my HIV meds, so my doctor changed them. But the depression didn't lift and in 2007 I started taking antidepressants.

This got me talking to a clinical psychologist and I realised it might be my job that was to blame. I was working 60- to 70-hour weeks and was always travelling, spending evenings eating and drinking too much with potential customers. I realised I had an emotional attachment to my work but it was making me ill. So I resigned.

I went to see my family in Italy but when I came back I was even more depressed. I just couldn't figure out what to do next.

So I contacted First Point, the assessment and referral service of the South London HIV Partnership. Terry, the worker there, identified several issues. There was the work one, but in addition, the job had isolated me from my old friends, and I also realised I'd never really come to terms with having HIV.

In terms of employment, the big step was getting career coaching at PACE, the lesbian and gay organisation in Islington. PACE's coach, Pete McCormack, took me on for eight sessions after an initial assessment interview.

For the first few sessions it felt like therapy and I wasn't sure how it was supposed to get me a job: I talked about what inspired me as a kid, things I enjoyed doing, my early fantasies about what I'd do. There was a lot of homework too. I had to complete a 'vision board' which confirmed that I love working with people and the media but opened up my thought processes about what I could do next.

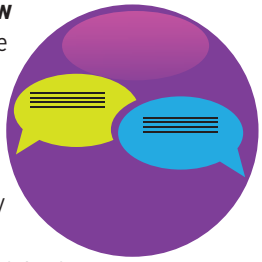
I did the European Computer Driving Licence course and a project management course: I realised I had managed plenty of projects in my old job, they just hadn't been called that.

A temporary employment opportunity came up in the shape of the 2011 Census, and I applied for and got a job as local co-ordinator. It's about three months' work, but I think it will really open doors for me once it's finished. It's not the sort of job I would have considered applying for before my career coaching.

I realised now my job crisis was symptomatic of my diagnosis with HIV. Yet it was the career-specific coaching that really helped me get over the bitterness and depression. My physical health has improved too, and I've started running again, something I haven't done for years.

To sum it up, it helped turn "I can't do this" into "What have I got to lose?"

The job interview



When you receive that all-important invitation to an **interview**, confirm promptly that you will be attending it. Make sure you have the details of the job description and person specification clear in your mind and have researched the organisation and its work.

There is lots of information and advice on the internet on the art of successful interviewing, including sample interview questions and suggested answers. If you do use these, make sure they are relevant to you – and that you are able to provide responses to any follow-up questions. It can be a really good idea to practise interviews with someone you know and to get some feedback on your answers.

On the day, dress smartly (as appropriate for the kind of job) and be on time!

If you are unsuccessful, ask the employer for some feedback. While some employers won't expand much on their rejection letter, others may give really useful feedback and tips.

Self-employment

You may be thinking about self-employment. This is sometimes thought of as the easy option, but in reality self-employed people often work longer hours than employees; it is important not to underestimate the stress that can come with running a business in line with legal and financial requirements as well as making a reasonable living. Research and a good business plan are essential, as is well-informed advice about starting, maintaining and developing a business.

Information and advice is available from Business Link in England, which has a telephone helpline to advise on a range of topics, including start-up grants and loans. See www.businesslink.gov.uk or telephone 0845 600 9006.

Support may also be available from Jobcentre Plus for Jobseeker's Allowance claimants, and people who have been unemployed for 13 weeks or more, with £50 per week paid for up to 16 weeks from the date you start trading or move into self-employment.

Anyone currently on benefits who is considering a job offer must get information from a benefits adviser at an HIV charity, CAB or local advice agency to clarify their position and to ensure they get relevant tax credits or entitlements. ■

Scott's story

After several years working erratic and unsocial hours in hospitality and a period of ill health, I decided I wanted to return to office-based work. So I went to Positive East for advice on the best route.

I found the prospect of full-time employment extremely daunting; I hadn't worked in an office for over six years, and there were several gaps in my CV and periods of unemployment due to deteriorations in health.

I researched the web and found that Positive East offered face-to-face interviews, which I considered really important because I wanted to fully explain my circumstances without discomfort. I spoke to the Careers Adviser at the charity.

She suggested that volunteering would enable me to try out working nine-to-five again without undue pressure or worry about my benefits being affected, and to check the overall effect on my health. She explained the *Equality Act* and its relevance and gave me an overview of Working Tax Credit: this was important because I realised I could still receive help towards my rent whilst working. This made my financial outlook much more secure as otherwise I would get a drop in income.

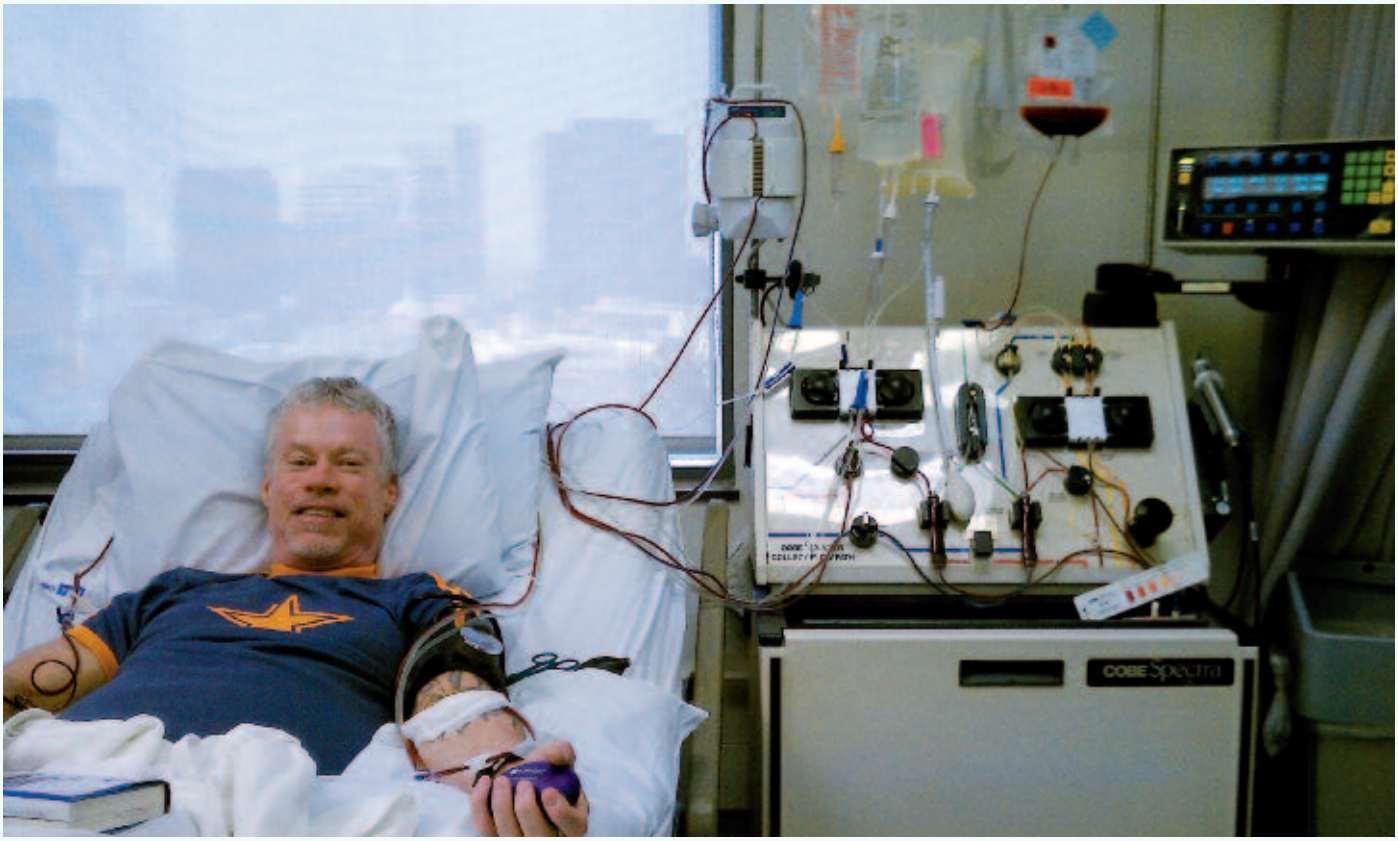
I had been given the details of the Volunteering England website to try to match my skills and availability to a demand. I went back for a follow-up appointment to review my CV and do an online skills check to bring home to me how many key and transferable skills I in fact had.

I decided to volunteer at Positive East itself to 'put something back' as the charity had helped me so much with my housing and benefits situation. I worked a three-day week shadowing an adviser, becoming accustomed once again to office discipline, obtaining relevant experience and updating my IT skills. I received on-the-job training for a qualification.

I decided to study at night class to broaden my knowledge of Microsoft Office. This gave me the confidence to enrol on a degree course at Birkbeck College (which is geared towards adult, part-time study, much like the Open University) so that I could compete in the current job market and move into paid employment.

I found working in a busy office environment again extremely worthwhile. It helped motivate and reprioritise things for me and helped me socially as well, as I was interacting with a broader range of people.

hiv gene therapy: more than survival



In April's *HTU*, we featured a news story, reporting that a group of patients had had their CD4 counts boosted by a form of gene therapy – and declaring that this could be the first step to a cure for HIV infection.[1] *Matt Sharp* wrote an article on lymphoma for that same issue. What we didn't tell you is that he was one of the six participants in the gene experiment and so far, he writes, it seems to be working just fine.

Gene therapy – the process of manipulating human genetic material in order to slow and stop disease and interfere with disease processes – is no longer science fiction for people with HIV. While there is more to learn and the research is new, gene therapy may lead to what is known as a 'functional HIV cure' by modifying part of the body's own genetic code in order to make cells resistant to HIV. If a functional cure is successful, the damage HIV causes could be halted without the use of antiretroviral drugs.

My personal story intersects perfectly with the advent of HIV gene therapy. I have been living with HIV almost half my life, since I was diagnosed in 1988, surviving with a mixture of resilience and determination to live.

Clearly, antiretroviral (ARV) drugs have kept me alive and relatively healthy. I was always keen to benefit from what medicine could do for me, and enrolled in several early-access programmes and clinical trials of unproven drugs in the late '80s and '90s.

Back then I didn't have the choices we have today, with now more than two dozen antiretroviral drugs available. As drugs were approved one at a time, many people added a new drug to an older one they were taking, which we now

understand leads to resistance. I always managed to stay ahead of the latest treatments, but since it was unclear how to best use the drugs in the early days of HIV, I developed resistance to almost every drug and now have a fragile immune system with few new treatment options in my future. Fortunately, the drugs were just useful enough to keep my health stable, but until quite recently I never achieved an undetectable viral load and my CD4 cells bottomed out at 30 cells/mm^3. The good news is that, thanks to careful monitoring, I never had an AIDS-defining infection.

I'm now thriving. In 2008 I was finally able to combine two new antiretroviral drugs that I had never tried before and reached undetectable HIV levels, remaining that way since then. But my CD4 cells remained stubborn, rarely crossing over the 200 cells/mm^3 benchmark that defines AIDS in the US, where I live.

I have never been reticent about participation in clinical trials. Back in the '90s, many people enrolled in studies just to get access to the latest drugs. I even signed up for a study looking at thymus transplantation, which involved opening my abdomen in a surgical procedure. People thought I was brave, if not a bit crazy, but I have always felt that if I sat around and waited for the research to prove successful, I would not survive.

Since the days of ACT UP Golden Gate when, as a dedicated treatment activist, I was arrested seven times in civil disobedience protests, I have sought immune-based therapies and advocated for research that would focus on CD4 cells, HIV's target. Until recently there have been no successful immune-based therapy studies to restore the CD4 cells in people with HIV. Two huge and expensive efforts, the ESPRIT[2] and SILCAAT[3] trials, used a synthetic version of interleukin-2 (IL-2), a naturally occurring protein also known as T-cell growth factor. Unfortunately, despite early promise in boosting important CD4 cells in trial participants, the treatment was found to be difficult to tolerate and in the end, ineffective. Before the study results came out, a doctor prescribed IL-2 for me. My CD4 count increased to over 600 cells/mm^3 from a low of 140 cells/mm^3, but in about a month they dropped back to where I started. Another failed treatment attempt!

My personal story intersects perfectly with the advent of gene therapy. I have been living with HIV for almost half my life, since I was diagnosed in 1988, surviving with a mixture of resilience and determination to live.

But today I may have hope for restoration of my immune system, or at the very least an expansion of CD4 cells. In 2009, I visited the Quest Research Clinic in San Francisco and met with Jay Lalezari, MD, a research physician I have known since the days of ACT UP Golden Gate.

He told me that his clinic was testing a new gene therapy technology called SB728. This is an enzyme from a family called zinc finger nucleases (ZFNs), which could theoretically make CD4 cells resistant to HIV. The ZFNs are like tiny molecular 'scissors' that cut out the CCR5 gene. This gene provides CD4 cells with the CCR5 molecule, a 'co-receptor' protein that studs CD4 cell surfaces and which is an essential anchoring point for the most common form of HIV. Cells without the CCR5 co-receptor are effectively protected from HIV infection.

After speaking with several treatment activists and researchers including Dr Jay, as he is affectionately known, I decided the risk was low and wanted to try it out. So far, six months later, it appears the strategy is at the least safe, if not showing some positive effects.

I enrolled in the study in the summer of 2010 and flew to Los Angeles for what is called an apheresis procedure. In this, you get hooked up to an oven-sized machine that removes blood and separates the cell types within it. First, an intravenous needle was placed in each of my arms; blood was removed from one arm and infused into the machine where it separated out the white cells (including CD4 cells). The remaining red blood cells were then replaced into my other arm. By the end of the procedure, only a small infusion bag a quarter full of blood had been taken from my arm. The apheresis was effortless and I was out of the clinic in a few hours.

The simplest explanation of the next steps of the process goes something like this. My white blood cells were sent to the laboratory and the CD4 cells were separated, made to replicate so there were more of them, and processed with the zinc finger nucleases to remove their CCR5 gene. The ZFNs were delivered to

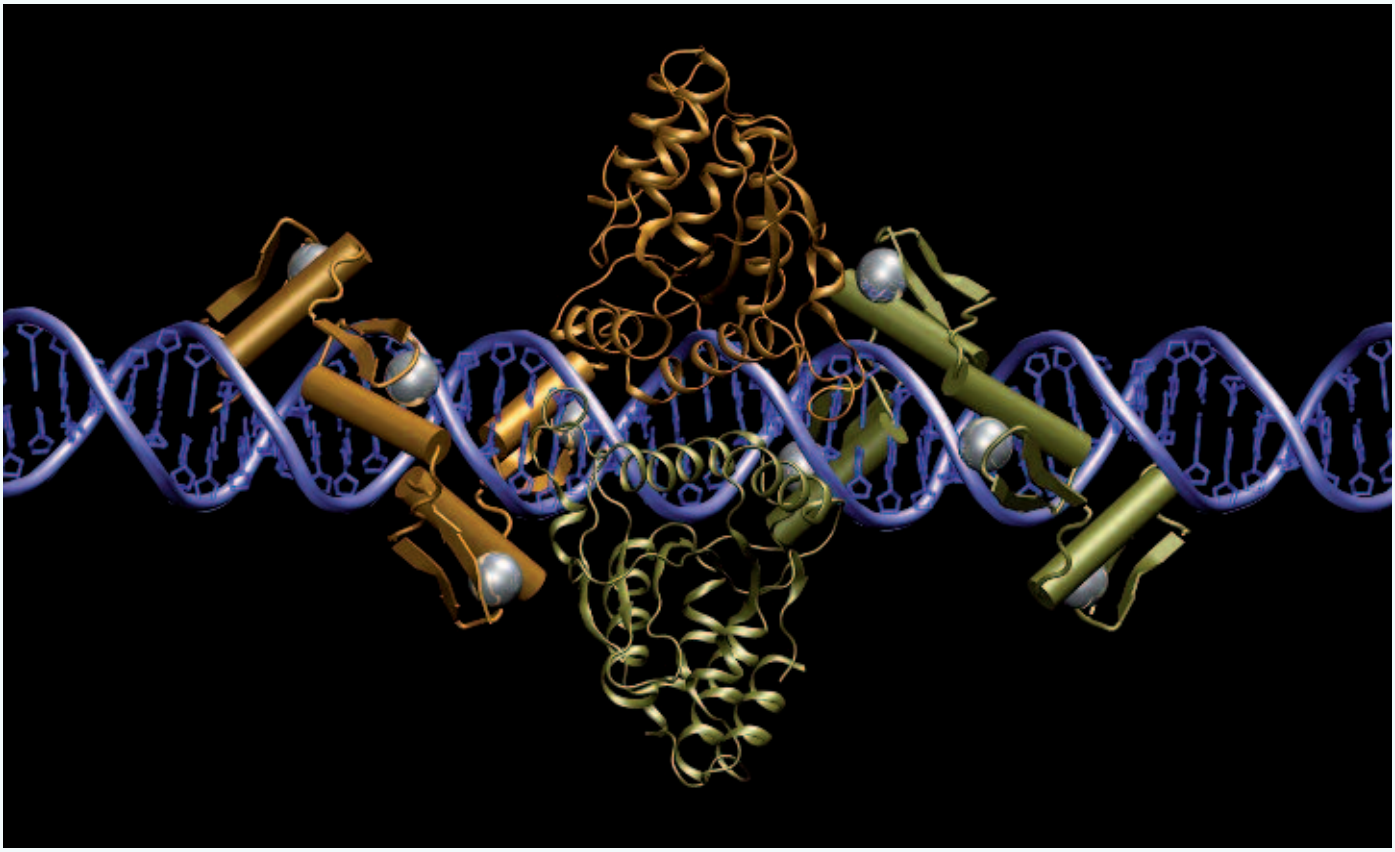


Image of two ZFNs bound to DNA. (Image courtesy of Dr Jeff Miller of Sangamo BioSciences, Inc.)

my cells inside the test tube enclosed in something called an adenovirus vector: the hollowed-out shell of a common cold virus, which is able to enter cells and deliver its contents to a cell's nucleus, but cannot cause an infection.

The newly modified cells were then frozen, sent to the study clinic, thawed and infused back into my arm – four billion of them. I experienced no side-effects during the 30-minute infusion.

My own results have been quite exciting given my lacklustre treatment history. My CD4 cell count doubled from 230 to 560 cells/mm^3. Now, six months later, my CD4 cells have remained at the higher level and I feel better than ever. I have had virtually no long-term side-effects, though I have had to endure extensive blood tests to follow up on my blood results.

Also, and less comfortably, the study has required rectal biopsies to see if the manipulated cells 'traffic' to the gut. This is important as it shows that the modified cells are acting exactly like other immune cells and successfully competing with them. It is also potentially exciting, since it is through CCR5-bearing cells in the mucous membranes of the genital and digestive systems that most people are infected with HIV. I have had about six 30-minute biopsy procedures, cutting 20 tissue samples from inside my sigmoid colon each time. The biopsies are relatively painless, save the amount of gas that's pumped in the colon so the doctor can remove the tissue with a tiny instrument. I have not learned the results of my own biopsies so far, but the other participants are showing good results.

This first study proved the gene therapy concept, and I experienced a CD4 boost, but there was never any danger of my HIV running out of control as I remained on antiretrovirals. The second study will enrol people who are not taking antiretroviral therapy.

Manipulating DNA, the genetic blueprint, through gene therapy can be risky but has been safely studied in cancer and degenerative diseases. This is not the first HIV-related gene therapy trial, but it is the first to show promise. Dr Lalezari recently presented data from the study I enrolled in at the Conference on Retroviruses and Opportunistic Infections (CROI) in Boston in February. He presented data on SB728 in six men who have been living with AIDS for over twenty years.[4]

Dr Jay told me: "The study has shown seven things: logistically we can

effectively get peripheral blood mononuclear cells [white cells inhabiting the blood] out of the body; the cells can be modified; the infusion is safe; the participants have shown an increase in CD4 cells; the cells persist and don't die off; and they traffic to the gut.

"The final thing is that there is also normalisation of the CD4:CD8 ratio."

This is particularly significant, because nearly all people with HIV, even with high CD4 counts, have about twice as many CD8 cells (the cells that kill off virus-infected cells) as CD4 cells (which direct a lot of the traffic of the immune system). In HIV-negative people the situation is the opposite, with twice as many CD4 as CD8 cells. Renormalising the CD4:CD8 ratio may imply that my immune system has been 'reset' to resemble one a bit more like that of an HIV-negative person.

Dr Jay continues: "The key task lies in whether we can use the technique to influence viral loads. We have almost completely enrolled a 14-patient trial looking at this question." This first study proved the gene therapy concept, and I experienced a CD4 boost, but there was never any danger of my HIV running out of control as I remained on antiretrovirals. The second study will enrol people who are not taking antiretroviral therapy to answer the bigger question of whether giving people a proportion of cells that are immune to HIV infection will reduce the available pool of cells that can be infected, reduce viral replication, and cause viral load to go down.

If you were able to manage that trick so well it drove down viral load to an undetectable level, then you might have your functional cure of HIV.

Even though my study was small, five of the six participants had an average increase of 200 CD4 cells/mm^3 in one year of follow-up after the infusion. There were no adverse events in the trial. One participant did not respond to the new cells – most likely because they had a very low CD4 count to begin with, or possibly because the adenovirus vector did not 'take' in enough cells.

Dr Jay's team showed that 25% of the total donated cells lacked the CCR5 co-receptor and that, after re-infusion, from 3 to 6% of those cells were present after three months.

That may not sound like a high proportion. However, the overall expansion of CD4 cells was high in all but one person and the fact that the CD4 cells reached the gut shows that they can access one of HIV's most important 'hiding places'. Furthermore, the hope is that, in a person not on HIV treatment, the proportion of healthy, replicating CD4 cells without CCR5 may grow in time as cells with the co-receptor are killed off by HIV.

The motivation for this approach in CCR5-deleted cells came from the successful treatment of Timothy Ray Brown, also known as the 'Berlin patient', which *HTU* covered earlier this year (see *Towards a Cure for All, part 1* in issue 203). Brown, living with AIDS and leukaemia, received a bone marrow transplant from a donor with CD4 cells naturally lacking the CCR5 receptor.

Five years later, I met Brown in San Francisco. He is considered cured of HIV, and the leukaemia is in remission. His case has spawned a new wave in HIV research, including disruption of the CCR5 gene. The experiments thus far have not found the cure for HIV, but answer important questions to further the research. It's truly an exciting time in HIV research.

I will now visit the clinic to be monitored every month for six more months, and then the study will be complete. As I look back on my treatment history I am positive that the zinc finger experiment may allow me to restore my immune system, perhaps reducing inflammation – the source of many non-AIDS-related complications like cancer and heart disease. I already see an improvement in the constant respiratory infections I used to get before I entered the study.

But best of all, I hope that one day I may be able to stop antiretroviral drugs by being infused once a year with such gene therapy techniques. Over the course of 22 years of taking meds, it's yet another risk that appears to have paid off. ■

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News in brief [page fourteen]

Study finds PrEP makes no difference to infection in women

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Brain impairment in HIV may not be as common as previously thought

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New hepatitis C drugs pose many questions

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news in brief

PrEP

Study finds PrEP makes no difference to infection in women

A large study of daily tenofovir/FTC (*Truvada*) used as pre-exposure prophylaxis (PrEP) in women has closed less than halfway through after investigators concluded there was no chance of it being able to demonstrate any difference in the HIV infection rate between women taking *Truvada* and women taking a placebo.

This result comes as a major surprise after the international iPrEx study[1] in men who have sex with men reported that PrEP had an overall efficacy of 42%.

The FEM-PrEP study recruited 1951 HIV-negative women aged 18 to 35 at risk of HIV infection in South Africa, Kenya and Tanzania.

Last month the trial's Data and Safety Monitoring Board found that, unexpectedly, there were exactly the same number of infections in women taking *Truvada* as in women taking placebo – 28 each.

It calculated that, even in the unlikely event that every single future infection was in women on placebo, the trial would be incapable of demonstrating a statistically significant advantage to *Truvada*.

Prevention advocates and experts were surprised at the lack of efficacy seen in the trial. "We really didn't see this one coming," said Mitchell Warren, Executive Director of the AIDS Vaccine Advocacy Coalition.

But, he added: "Even with this finding, there is still a strong rationale for continuing other trials, including those in women, in hopes of obtaining better results in the future."

It is important to emphasise that, lacking a detailed explanation of the results, we are essentially in the same position as before; we do not know if PrEP will work for women.

The investigators will now concentrate on two linked areas: a detailed investigation of adherence, and of drug levels in women taking *Truvada*.

One thing the iPrEx study found was that self-report cannot be relied on as a measure of adherence: reported adherence was over 90%, but when researchers measured blood drug levels, they found that only 50 to 60% were taking the pills.

Monitoring will also discover whether blood drug levels are matched by levels in the vagina. Studies have found that oral tenofovir tends to reach higher levels in rectal tissues than in vaginal tissue and though a study presented at this year's CROI found adequate levels in vaginal tissue, presenter Craig Hendrix warned that "what is 'enough' for prevention is yet to be defined".[2]

There were significantly more pregnancies in women taking *Truvada* than placebo. This could explain the lack of efficacy. Pregnancy excluded women from the trial, which would mean women on *Truvada* spent more time not taking pills, on average, than women on placebo. Any protective effect of *Truvada* may be so attenuated that it was not demonstrably better than placebo.

The more troubling possibility is that *Truvada* had an unexpected drug interaction with the women's contraception. If tenofovir or FTC altered levels of contraceptive, this could also alter the thickness of the vaginal mucous membrane and thus alter a woman's vulnerability to HIV. However, no such interaction has been described.

The third possibility is that side-effects amongst women taking *Truvada* might have caused their adherence to be poorer than in women taking placebo; the iPrEx study found a higher rate of nausea in men taking *Truvada* in the first month.

The result indicates that antiretroviral drugs may show different levels of effective prevention according to population, locations in which they are studied and prevention method used: last year the CAPRISA 004 study found that tenofovir used as a vaginal gel was 39% effective at stopping HIV infection in South African women.

Two studies will continue to test the use of *Truvada* to prevent HIV infection in women: the Partners PrEP study is testing PrEP in 4700 serodiscordant heterosexual couples in Kenya and Uganda, and the VOICE study is comparing the effectiveness of oral tenofovir or oral *Truvada* to a vaginal gel containing tenofovir in 5000 heterosexual women in South Africa, Uganda and Zimbabwe. Both studies are expected to report results in 2013.

Testing

HIV testing discouraged by other medical bodies

HIV testing guidelines developed by the British HIV Association (BHIVA) and others recommend that a wide range of non-HIV physicians should offer HIV testing, especially as a quarter of newly diagnosed people are thought to have had a 'missed opportunity' for an earlier diagnosis.[1]

However, these recommendations are not supported or are contradicted by a significant number of clinical guidelines developed by other professional bodies, Dr Martin Fisher, lead author of the testing guidelines, told the BHIVA conference last month.

In 2008, the guidelines, developed by BHIVA, the British Association for Sexual Health and HIV (BASHH) and the British Infection Society (BIS), urged healthcare workers of all specialities to consider HIV testing in a wide range of situations and settings, including GP surgeries and most hospital departments. More recently, the National Institute for Health and Clinical Excellence (NICE) issued recommendations endorsing most of the 2008 guidelines. But implementation outside of sexual health settings has been limited. Fisher's investigation confirms previous findings that the most important barriers to implementation have not been with patients, but with healthcare staff.

One key aspect of the 2008 testing guidelines was the identification of a number of health conditions which may indicate underlying HIV infection.

Fisher did a survey of guidelines prepared by non-HIV specialist societies and other bodies describing the management of 13 'indicator' diseases. In only four of the guideline documents is HIV testing considered or recommended.

For example, whereas BHIVA recommends an HIV test for some women with abnormal cervical screening results, recommendations from the UK National Screening Committee and the Royal College of Obstetricians and Gynaecologists specifically discourage the offer of an HIV test.

Fisher said it was "staggering" that the guideline on pulmonary tuberculosis developed by NICE and BTS (British Thoracic Society) suggests HIV testing should only be considered on a case-by-case basis. In BTS guidelines on bacterial pneumonia, its management in people with diagnosed HIV is excluded from scope, but the possibility of the condition being caused by undiagnosed HIV is not mentioned.

An audit of general practice showed that in only 16% of cases where a patient had a clinical indicator disease was HIV testing done or considered.[2]

Neurology

Brain impairment in HIV may not be as common as previously thought

Two studies presented at the BHIVA conference suggest that the proportion of people who have subtle brain impairment due to HIV may not be as high as previously thought.

About 16% of the general population has some degree of neurocognitive deficit. In 2010 the large CHARTER trial in the US caused concern when it found that 52% of 1526 people with HIV had evidence of neurocognitive impairment,[1] including 28% with no disabling neurological symptoms and no HIV-related illness.

One of the studies presented last month, of 31 young people born with HIV and aged 16 to 25, found they had rates of neurocognitive impairment no higher than HIV-negative siblings, though it did find more memory problems reported. It also found changes in brain function in MRI scanning, of unknown significance.[2,3]

The other study found a rate of asymptomatic neurocognitive impairment of only 19% in a group of older patients with suppressed viral loads (average age 55), very little in excess of the general population rate.

Researcher Dr Lucy Garvey explained: "This is one of the first studies to look at neurocognitive impairment only in stable HIV-asymptomatic patients on suppressive antiretroviral therapy."

Hepatitis

New hepatitis C drugs pose many questions

A vast array of hepatitis C antivirals currently in clinical trials is opening up new horizons for treatment of hepatitis C. At last month's International Liver Congress in Berlin, agents from four new classes of drugs, as well as potential improvements to current therapy, were presented.[1]

The key issue is how to use telaprevir and boceprevir, the new hepatitis C protease inhibitors (PIs) available later this year – and who can afford them (see *HTU* 205).

For patients with previously untreated hepatitis C, new drugs will offer a substantially higher cure rate and possibly reduced treatment time.

However, the headline trial outcomes conceal several caveats. People who didn't respond to standard therapy of pegylated interferon and ribavirin still have low response rates when the new PIs are added. Lower rates were also observed in patients with cirrhosis.

People with advanced liver disease will need to decide whether to attempt a cure now or wait for a greater choice of drugs. There are concerns that premature use of new agents in people with a poor chance of response could cause resistance that may reduce effectiveness of subsequent new treatments.

Other PIs being developed have improved results, such as TMC-235. In studies of this drug, 92 to 96% of people who had responded to interferon/ribavirin before but had not been cured *were* cured, as were 70 to 87% of people who had not previously responded at all.

Some studies have also produced cures in some patients (without HIV) without any need to take interferon or ribavirin.

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