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Reader survey 2020

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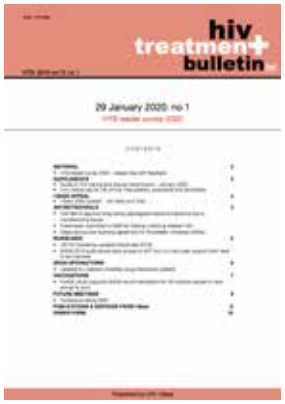
EDITORIAL



Welcome to the first edition of HTB for 2020 which in the lull between the New Year and CROI is mainly concerned with new drug submissions and treatment guidelines.

Catching most people by surprise, at the end of last year, the FDA held back from approving long acting cabotegravir and rilpivirine injections, despite impressive efficacy and safety results from phase 3 studies.

This was due to manufacturing questions linked to scaling up production which will hopefully be resolved quickly.

Also from ViiV, fostemsavir has now been submitted to both EMA and FDA as a new drug for people with multidrug resistance to current HIV medicines.

As balance, Gilead have negotiated an exclusive global license to develop and market very interesting early bNAbs that have been developed by Rockefeller University in New York.

In December, the main US HIV treatment guidelines were published. In addition to including the latest approved HIV medicines, the document includes new sections on U=U and HIV and ageing.

BHIVA have given a consistently high profile to the U=U campaign since Professor Chloe Orkin, the then chair, stated in July 2017 that anyone with "sustained, undetectable levels of HIV in their blood CANNOT transmit HIV to their sexual partners."

However, despite further development work, the 2019 BHIVA audit shows that there is still more work to do - although the UK is doing better at routinely starting ART within three months of diagnosis, with many people starting within four weeks.

A new i-Base guide to HIV Testing and Transmission is now available free to UK clinics.

In the hope you might be able to help financially support i-Base during this difficult time, we also include information about our 2020 appeal

HTB survey 2020 - please help with feedback

As we are starting the New Year, we would like your help with the HTB reader survey.

This only includes 10 short questions with space for additional comments and your feedback will help us with HTB development this year.

https://www.surveymonkey.co.uk/r/KCXXT3F

SUPPLEMENTS

i-Base guide to HIV testing and sexual transmission (January 2020)

This updated booklet includes information on all aspects of HIV testing and sexual transmission.

The printed version has been reduced by 20 pages - signposting to information that is still online.

It is updated throughout to include both U=U and PrEP.

U=U resources for UK clinics: free posters, postcards and factsheets

Please continue to order these free resources.

Customise U=U posters for your clinic

i-Base can customise U=U posters to include pictures of your doctors, nurses, pharmacists, peer advocates or any other staff that would like to help publicise U=U.

For further information please contact Roy Trevelion at i-Base: roy.trevelion@i-base.org.uk

i-Base 2020 appeal

This year we are continuing a funding appeal to help i-Base continue to provide free publications and services during 2020.

i-Base now recieve more than 12,000 questions each year and the website has more than 500,000 view each month. We also distribute more than 80,000 booklets and leaflets free to UK clinics every year.

If 1000 people support us with £5 a month we will be on course to meet our funding shortfall. All help is appreciated.

http://i-base.info/i-base-appeal-we-need-your-help

Subscriptions

To join the email list for HTB please register free online:

http://i-base.info/htb/about/subscribe

ANTIRETROVIRALS

FDA decision on long-acting cabotegravir/rilpivirine (Cabenuva) injections delayed due to scale-up manufacturing problems

Simon Collins, HIV i-Base

On 21 December 2019, ViiV Healthcare issued a press release on the recent FDA decision not to approve cabotegravir/rilpivirine (CAB/RPV LA) long-acting injections. [1]

This was unexpected, given that CAB/RPV LA had successfully completed phase 3 studies (ATLAS and FLAIR), showing high efficacy and low side effects. CAB/RPV was non-inferior to standard of care combinations in treatment-naive and switch studies and reported improved quality of life compared to oral combinations in study participants.

Instead, the FDA has issued a complete response letter relating to chemistry and manufacturing controls (CMC), but the press statement stresses that there are no new safety concerns for these compounds.

The letter itself has not been published and specific details about these concerns were not included.

Cabotegravir is an integrase inhibitor developed by ViiV Healthcare and rilpivirine is an NNRTI developed by Janssen Sciences. Development of CAB/RPV long-acting combination is led by ViiV, with the trade name Cabenuva.

C O M M E N T

At a more recent community meeting, the company were more specific that the manufacturing problem was related to scale-up. [2]

This has been a problem with some earlier HIV meds as large scale production for a marketed drug is very different to smaller productions to just cover research studies.

ViiV are clear that the company are working with the FDA to resolve these issues. Phase 3 results meant that approval was expected, so this will hopefully be a short delay that can be resolved.

There has always been high interest in options for HIV treatment other than oral medicines and this announcement is likely to just extend the time a little longer before these become available.

However, certainly for people in the UK, access will depend on many factors, including cost.

There are many potential benefits from injectable ART, at least for people who have difficulty with pills, and this will also provide new options for how HIV treatment is delivered.

References
1. ViiV Healthcare press statement. ViiV Healthcare receives complete response letter from US FDA for use of investigational cabotegravir and rilpivirine long-acting regimen in the treatment of HIV. (21 December 2019).
https://viivhealthcare.com/en-gb/media/press-releases/2019/december/complete-response-letter-from-us-fda
2. Personal communication, UK-Community Advisory Board. 24 January 2020.
http://www.ukcab.net

Fostemsavir submitted to EMA for treating multidrug resistant HIV

Simon Collins, HIV i-Base

On 10 January 2020, ViiV Healthcare submitted a regulatory application for fostemsavir to the European Medicines Agency (EMA). [1]

The application seeks approval of fostemsavir, used in combination with other antiretrovirals, for the treatment of adults with multidrug resistant HIV who are otherwise unable to construct a suppressive antiviral regimen due to resistance, intolerance or safety considerations.

The EMA's Committee for Medicinal Products for Human Use (CHMP) has granted an accelerated assessment for fostemsavir. This reduces the timeframe for review based on meeting a currently unmet medical need.

Submission is based on the 96-week results from the phase 3 BRIGHTE study presented at the 10th IAS Conference on HIV Science (IAS 2019) in Mexico City. [2]

A similar application to the US FDA was submitted in December 2019, also with accelerated approval status. [3]

References
1. ViiV Healthcare press statement. ViiV Healthcare submits regulatory application to the European Medicines Agency for fostemsavir, an investigational, first-in-class attachment inhibitor for the treatment of HIV in adults with few treatment options available. (10 January 2020).
https://viivhealthcare.com/en-gb/media/press-releases/2020/january/viiv-healthcare-submits-regulatory-application-to-the-european-m
2. Fostemsavir: 96-week follow-up in people with multi-drug resistance. HTB, 24 July 2019.
https://i-base.info/htb/36390
3. Fostemsavir submitted to US FDA for multidrug resistant HIV. HTB December 2019.
http://i-base.info/htb/36951

Gilead announces licensing agreement for Rockefeller University bNAbs

Simon Collins, HIV i-Base

On 9 January 2020, Gilead Sciences announced that the company had signed an exclusive global licensing agreement for broadly neutralising monoclonal antibodies (bNAbs) that are in development at Rockefeller University in New York.

The significance of this news should not be underestimated.

Gilead is the most important developer of HIV drugs over the last 20 years, and the company has consistently out-performed larger and more established research-based companies. The income from their HIV drugs - together with sharp scientific foresight - enabled Gilead to acquire sofosbuvir for hepatitis C. Not only was sofosbuvir dramatically more effective than previous treatment (producing cure rates well-above 90% from a three month course of oral treatment) but the controversial decision to price sofosbuvir so high in Western countries ensured that their $11 billion investment was recovered many times over.

bNAbs are developed from individuals who develop strong immune responses, and work both from a direct antiretroviral effect and an immune-mediated response.

Although it is always expected that newer and better bNAbs will continue to be discovered, the two lead compounds at Rockefeller University - BNC117 and 10-1074 - are already amongst the best. Importantly, as with other HIV treatments, these immune-based treatments need to be used in combinations, so acquiring several bNAbs in the same license will put Gilead well ahead of other competitors in this field.

The press release notes that the Rockefeller University's bNAbs are "well studied and have shown exceptional promise in early clinical trials". Even though still in early stages of development this promise is certainly true. Both compounds have already been developed into long-acting formulations that might allow six-monthly dosing. Current studies involve stopping HIV oral treatment, with the expectation that viral load might be maintained at undetectable levels solely from the extended action of the bNAbs.

Although the early data is still very limited and preliminary, this outcome would have the potential to change the approach to HIV treatment that is at least as significant as sofosbuvir had for hepatitis C.

C O M M E N T

HIV research into bNAbs is some of the most exciting - with a role both for HIV prevention and HIV treatment - and with a potential role in development of an HIV cure. So this announcement is good news because taking their development to a new level requires the investment that Gilead can bring - and the company is already active in HIV cure-related research.

But if proven effective, cost and access will be an essential issue. Although in low incidence indications for cancer treatment they are often priced at higher than US$100,000 per treatment, bNAbs also have the potential to be affordably manufactured and priced - perhaps well below US$500.

The emphasis on Gilead having exclusive global rights might be encouraging for any eventual access in low income countries as generic versions of their other HIV drugs are available through the Medicines Patent Pool. However, if the results prove to be good access in middle- and high-income countries will also need to be at affordable prices that is very different to that used for sofosbuvir.

The press release did not include any financial details about the agreement.

A UK study with long versions of BNC117 and 10-1074 called RIO is expected to begin enrolment early in 2020.

Reference

Gilead press release. Gilead Sciences licenses portfolio of HIV antibodies from the Rockefeller University. (9 January 2020).

https://www.gilead.com/news-and-press/press-room/press-releases/2020/1/gilead-sciences-licenses-portfolio-of-hiv-antibodies-from-the-rockefeller-university

GUIDELINES

US HIV guidelines updated (December 2019)

Simon Collins, HIV i-Base

The latest edition of the US DHSS HIV guidelines is now published online. [1]

Main changes in this edition are summarised at the start of the main document. [2]

Selected key points are listed below.

- Inclusion of a new section on U=U. This stresses that an undetectable viral load <200 copies/mL with continued high adherence prevents HIV transmission.
- Restrictions on use of dolutegravir in relation to neural tube defects during pregnancy have been reduced - to be decided on individual risk/benefit.
- That random testing for pre-ART lipid and glucose can be used instead of previous recommendation for these to be fasted.
- That ART be routinely started either immediately or as soon as possible after diagnosis.
- Dolutegravir/lamivudine dual therapy is added to the list of recommended first-line combinations, unless viral load is >500,000 c/mL, HBV coinfection or still waiting for genotypic resistance test results or HBV serology.
- Bictegravir/FTC/TAF is included as a combination for immediate ART in resistance test results are not available.
- Updated and expanded section on HIV and older people. This includes awareness of HIV risk, age-related comorbidities, importance of ART, polypharmacy and management of HIV associated neurocognitive disorder (HAND).
- Option for short course regimen for latent TB.
- A new sub-section on drug pricing and access in the US.
- Updated tables on side effects and drug interactions.

References
1. US Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. 18 December 2019. https://aidsinfo.nih.gov/guidelines
2. What's new in the guidelines. https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/0

BHIVA 2019 audit shows early access to ART but U=U and peer support both need to be improved

Simon Collins, HIV i-Base

The main BHIVA audit for 2019 focused on timelines from HIV diagnosis to assessment by a specialist HIV doctor and to starting ART, based on case-note review of newly diagnosed adults (age 16 or over) who were first seen between 1 January 2018 and 31 March 2019.

Participation in the audit was good, with data being provided for 2281 individuals from 132 clinic sites, and a further three sites reporting no eligible individuals.

Key findings

- That nationally, only 67% of individuals were seen by an HIV specialist doctor within two weeks of their initial diagnosis, which is the standard of care. This varied widely between sites. Delays were more common among individuals tested in general practice or in non-GUM/HIV outpatient departments.
- Benefits of ART to the individual and partner notification were each covered for 85% of individuals at, or before, the first discussion of starting ART.
- However, information about U=U (undetectable equals untransmittable) was only discussed by 56%.
- The availability of peer/community support was discussed in 61% cases. There was wide variation between sites for both U=U and peer support.
- Most individuals (83%) met the NHS England measure of starting ART within 91 days of diagnosis. Excluding those with missing data, 51% started within 4 weeks and 79% within 8 weeks.

Recommendations

Following these results, BHIVA made three key recommendations for specialist HIV services.

1. Ensure pathways into HIV care are readily accessible with clear guidance for all healthcare professionals and peer/community support organisations. This should be kept updated and communicated to colleagues, especially general practice.
2. Routinely discuss and document all relevant topics, including U=U and availability of peer/community support, with newly diagnosed individuals.
3. Review individuals who have not started ART within 6–8 weeks of diagnosis to identify possible support needs.

Reference

BHIVA. BHIVA Audit annual report, December 2019. https://www.bhiva.org/NationalAuditReports

https://www.bhiva.org/file/5e297ff862116/AuditRep2019.pdf (PDF)

DRUG INTERACTIONS

Updates to Liverpool University drug interactions website

Liverpool University newsletter

The Liverpool University drug interaction website now includes the following updates.

https://www.hiv-druginteractions.org

New antiretroviral: albuvirtide

The long-acting fusion inhibitor Albuvirtide (Aikening) to the interaction checker. Albuvirtide is administered once weekly by intravenous infusion and has marketing approval to treat HIV in China. It is also being studied in the US.

New comedications

Back on user suggestions the following drugs have been added to the interaction checker:

Benazepril (Hypertension and Heart Failure Agents)

Eletriptan (Anti-migraine Agents)

Etidocaine (Anaesthetics and Muscle Relaxants)

Ferrous fumarate (Herbals/Supplements/Vitamins)

Filgrastim (Other)

Lenalidomide (Cancer Therapies)

Minaxolone (Anaesthetics and Muscle Relaxants)

Moxonidine (Hypertension/Heart Failure Agents)

Piperacillin (Antibacterials)

Tazobactam (Antibacterials)

Tinidazole (Antibacterials)

Trastuzumab (Cancer Therapies)

Trastuzumab emtansine (Cancer Therapies)

Vinorelbine (Cancer Therapies)

Please send suggestions for other medicines, please use this feedback link:

https://www.hiv-druginteractions.org/suggestions

Comedication name changes

Some alternative/older names have been added that have another name in use in certain countries. You will now be able to find these drugs by searching for the alternative name, in addition to the name commonly in use in the UK.

Methotrexate changed to **Methotrexate (Amethopterin)**

Clomipramine changed to **Clomipramine (Chlorimipramine)**

Bupropion changed to **Bupropion (Amfebutamone)**

Clarification of interactions with vitamins

Finally, some of the names of comedications in the supplements class have been changed to make it clearer whether or not the interaction is due to a component of a multivitamin. The following vitamins can now be selected either as a single vitamin supplement or as part of a multivitamin:

Ascorbic acid (Vitamin C), Colecalciferol (Vitamin D3), Cyanocobalamin (Vitamin B12), Folic acid, Iodine, Nicotinamide (Niacinamide), Phytomenadione (Vitamin K), Pyridoxine (Vitamin B6), Retinol (Vitamin A), Riboflavin (Vitamin B2), Thiamine (Vitamin B1), Tocopherol (Vitamin E).

In particular, this makes a difference to oral integrase inhibitors, which are susceptible to chelation.

VACCINATIONS

FluAGE study supports BHIVA recommendations for HIV positive people to have annual flu shot

Simon Collins, HIV i-Base

Results from a UK study found that immune responses to influenza vaccination were similar for both HIV positive men on ART and healthcare workers used as a control group. This supports the British HIV Association (BHIVA) recommendation for HIV positive people to routinely have this annual vaccination.

The FluAGE study was led by Dr Katrina Pollock with colleagues from Imperial College London and the findings were published in Scientific Reports in October.

The group were able to identify distinct CD4 T cell subsets that generated immune responses to the 2017/18 inactivated quadrivalent influenza vaccine recommended by BHIVA.

The study included 16 HIV positive men - 8 who started ART during acute infection and 8 who started in chronic infection and 14 sex-matched health workers in the control group.

The median CD4 count at vaccination was 789 cells/mm3 (IQR: 665 to 1033) vs 609 cells/mm3 (IQR: 454 to 931) in the ART acute vs chronic groups respectively. Median CD4 nadir was 522 cells/mm3 (IQR: 466 to 734) vs 170 cells/mm3 (IQRL 80 to 410) in the two groups.

Despite the lower CD4 nadir in people who started ART during chronic infections, there were no differences in vaccine responses between the three groups. Functional immune recovery reflected in humoral and cellular responses were all similar to controls.

The researchers concluded that these data support the BHIVA recommendations that all HIV positive people be offered a vaccine containing four different types of flu (two A-strains and two B-strains). They also provide evidence that the immune system can function normally in response to vaccination, when HIV is treated and viral load is suppressed.

Reference

Cole M et al. Responses to quadrivalent influenza vaccine reveal distinct circulating CD4+CXCR5+ T cell subsets in men living with HIV. Scientific Reports. Doi: 10.1038/s41598-019-51961-9,

https://www.nature.com/articles/s41598-019-51961-9

MEETINGS

Conference listing 2020

The following listing covers some of the most important upcoming HIV-related meetings and workshops.

HIV and neurology 2020 - an update

30 January 2020, London

https://www.rsm.ac.uk

10th International Workshop on HIV & Women

6 – 7 March 2020

www.virology-education.com

Conference on Retroviruses and OIs (CROI 2020)

8–11 March 2020, Boston

www.croiconference.org

26th Annual BHIVA Conference (BHIVA 2020)

27 – 29 April 2020, Manchester

www.bhiva.org

INTEREST 2020

5 – 8 May 2020, Windhoek, Namibia

https://virology.eventsair.com/interest-2020/registration/Site/Register

21st International Workshop on Clinical Pharmacology of HIV, hepatitis, and other antiviral drugs

13 – 15 May 2020 (TBC), New York

www.virology-education.com

International Workshop on HIV Paediatrics 2020

3 – 4 July, San Francisco tbc

www.virology-education.com

Community Reclaiming the Global Response (HIV 2020)

5 – 7 July 2020, Mexico City

https://www.hiv2020.org/registration

23rd International AIDS Conference (AIDS 2020)

6 – 10 July 2010, San Francisco and Santa Barbara

www.aids2020.org

23rd International Workshop on Co-morbidities and Adverse Drug Reactions in HIV (2020)

12 – 13 September 2020, New York

https://www.intmedpress.com/comorbidities/default.cfm?itemtypeid=1&title=The%20Workshop

HIV Glasgow Congress 2020

4 – 7 October 2020

www.hivglasgow.org

HIV Research for Prevention (HIV R4P 2020)

11 – 15 October 2020, Cape Town

https://www.hivr4p.org

PUBLICATIONS & SERVICES FROM i-BASE

i-Base website

All i-Base publications are available online, including editions of the treatment guides.

http://www.i-Base.info

The site gives details about services including the UK Community Advisory Board (UK-CAB), our phone service and Q&A service, access to our archives and an extensive range of translated resources and links.

Publications and regular subscriptions can be ordered online.

The Q&A web pages enable people to ask questions about their own treatment:

http://www.i-base.info/qa

i-Base treatment guides

i-Base produces six booklets that comprehensively cover important aspects of treatment. Each guide is written in clear non-technical language. All guides are free to order individually or in bulk for use in clinics and are available online in web-page and PDF format.

http://www.i-base.info/guides

- Introduction to ART (May 2018)
- HIV & quality of life: side effects & long-term health (Sept 2016)
- Guide to PrEP in the UK (March 2019)
- HIV testing and risks of sexual transmission (June 2016)
- Guide to changing treatment and drug resistance (Jan 2018)
- Guide to HIV, pregnancy & women's health (April 2019)

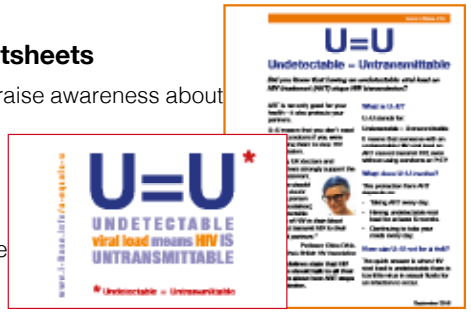
Pocket guides

A series of pocket-size concertina folding leaflets that is designed to be a very simple and direct introduction to HIV treatment.

The five pocket leaflets are: Introduction to ART, HIV and pregnancy, ART and quality of life, UK guide to PrEP and HCV/HIV coinfection.

The leaflets use simple statements and quotes about ART, with short URL links to web pages that have additional information in a similar easy format.

U=U resources for UK clinics: free posters, postcards and factsheets



i-Base have produced a new series of posters, postcards and leaflets to help raise awareness about U=U in clincs.

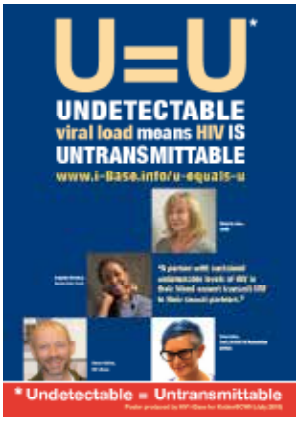
This project was developed with the Kobler Centre in London.

As with all i-Base material, these resources are all free to UK clinics.

Until our online order form is updated to include the U=U resources, more copies can be orded by email or fax.

email: subscriptions@i-base.org.uk

Customise U=U posters for your clinic



i-Base can customise U=U posters to include pictures of doctors. nurses, pharmacists, peer advocates or any other staff that would like to help publicise U=U.

Personalising these for your clinic is cheap and easy and might be an especially nice way to highlight the good news.

For further information please contact Roy Trevelion at i-Base:

roy.trevelion@i-Base.org.uk

Order publications and subscribe online

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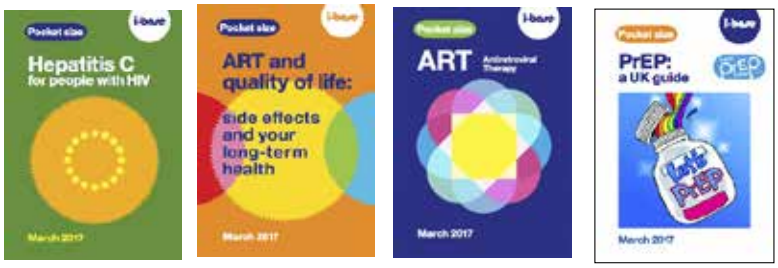

h-tb

HIV TREATMENT BULLETIN

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Editor: Simon Collins
Contributing Editor: Polly Clayden

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HIV i-Base receives unconditional educational grants from charitable trusts, individual donors and pharmaceutical companies. All editorial policies are strictly independent of funding sources.

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http://www.i-Base.info

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- **HIV Treatment Bulletin (HTB) every two months** ☐ **by e-mail**
- **Pocket leaflets** - *A7 small concertina-folded leaflets (2017)*

Pocket HCV coinfection	**quantity** _____	**Pocket PrEP**	**quantity** _____
Pocket ART	**quantity** _____	**Pocket pregnancy**	**quantity** _____
Pocket side effects	**quantity** _____	**PrEP for women**	**quantity** _____

- **Booklets about HIV treatment**

NEW: Introduction to ART *(October 2019): 48-page A5 booklet* **quantity** _____

NEW: UK Guide To PrEP *(November 2019): 24-page A5 booklet* **quantity** _____

ART in pictures: HIV treatment explained *(June 2019): 32-page A4 booklet* **quantity** _____

Guide to HIV, pregnancy and women's health *(April 2019): 36-page A5 booklet* **quantity** _____

Guide to changing treatment: what if viral load rebounds *(Jan 2018): 24-page A5 booklet* **quantity** _____

HIV and quality of life: side effects and long-term health *(Sept 2016): 96-page A5* **quantity** _____

Guide to HIV testing and risks of sexual transmission *(July 2016): 52-page A5 booklet* **quantity** _____

Guide to hepatitis C coinfection *(April 2017): 52-page A5 booklet* **quantity** _____

- **Other resources**

U=U resources:

A3 posters quantity _____ **A5 leaflets quantity** _____ **A6 postcards quantity** _____

HIV Treatment 'Passports' - Booklets for patients to record their own medical history **quantity** _____

Phoneline *posters (A4)* **quantity** _____

Please post to the above address, or email a request to HIV i-Base:

subscriptions@i-Base.org.uk

HIV i-Base

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If your employer operates a Give-As-You-Earn scheme please consider giving to i-Base under this scheme. Our Give-As-You-Earn registration number is **000455013**. Our Charity registration number is 1081905

Since many employers match their employees donations a donation through Give-As-You-Earn could double your contribution. For more information on Give-As-You-Earn visit www.giveasyouearn.org

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From April 2005 the Inland Revenue is operating a system whereby you can request that any refunds from them should be paid to a charity of your choice from the list on their website. If you feel like giving up that tax refund we are part of this scheme and you will find us on the Inland Revenue list with the code: **JAM40VG** (We rather like this code!) Any amount is extremely helpful.

However you chose to donate to i-Base,
we would like to thank you very much for your support.

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