treatmen+ bulletin(e)



CAB/RPV-LA and pre-CROI (7 February 2022)

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i-Base 2022 appeal

Please support i-Base with £5 or £10 a month...

Our appeal to help i-Base continue to provide free publications and services continues through 2022.

i-Base answer more than 8,000 questions each year and the website has more than 200,000 view each month.

We also distribute more than 80,000 booklets and leaflets free to UK NHS 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

Feedback

This iss always welcomed:

http://i-base.info/feedback

EDITORIAL

Welcome to the first issue of HTB in 2022.

And we start with a reference to Paul Blanchard, HTB's inaugural editor. Paul liked that we catalogue each issue as a volume, and so we still do, and remarkably this year we are now at volume 24.

Much of HTB still follows a similar activist format that Paul developed, but one change is that we now post articles online as soon as they are written. So reports from CROI over the next two weeks, will be added online, before being collated in the March issue.

The current issue a reduced one though, to cover the more limited news in January before the upcoming CROI 2022 which will now be a virtual only meeting.

It was also to give the editorial team a short break: 24 volumes is a significant block of work...

ART news includes the FDA expanding the indication for injectable long-acting cabotegravir/rilpivirine to allow for two-monthly dosing. This brings US prescribing in line with the EU.

BHIVA have also published new recommendations for access to long-acting cabotegravir/rilpivirine which is already available in Scotland and due across the rest of the UK shortly.

Other ART news is that the long-running legal dispute between Gilead and ViiV Healthcare over bictegravir infringing the dolutegravir patent has been settled.

We cover two interesting papers on details of HIV.

One that shows effective ART stops HIV-associated telemere shortening – important for both ageing and mortality. The other describing resistance mutations associated with integrase inhibitors when treating HIV-2.

Most people will not be surprised that the UK RECOVERY study didn't find a benefit from aspirin to treatment COVID-19 - but a review of effective treatments is covered in the updated IDSA guidelines.

Finally, i-Base is looking to expand our advocacy team. Ideal candidates will have experience of HIV and be driven by an active interest in treatment advances and in helping people understand their treatment options.

Please apply if interested and circulate this in your networks.

And as we look forward to what we hope will be a better year, we also thank Paul and our other supporters again, including the editorial comment group, many of whom have been involved as long as we have.

Happy 2022, happy CROI and happy reading...



CONFERENCES

CROI 2022 to only be virtual: programme online

Simon Collins, HIV i-Base

The following information has been posted to the CROI 2022 website about the meeting next month.

"The 29th Conference on Retroviruses and Opportunistic Infections (CROI), will be live for virtual participation only. February 12 to 16 will include the Opening Session, technical workshops, plenary presentations, interactive sessions, oral sessions, and poster presentations. NEW: February 22, 23, and 24, 2022, will include symposia with state-of-the-art talks and responses to audience questions.

The programme begins each day at 8:30 AM Mountain Time **US** (3.30 pm in the UK). For your convenience, use theis Mark Your Calendar link to add all the live session times of the conference on your calendar."

https://www.croiconference.org/wp-content/uploads/sites/2/CROI2022-Calendar.ics

A PDF file of the full programme is also now online

https://www.croiconference.org/wp-content/uploads/sites/2/resources/2022/croi2022-program-abstract-ebook.pdf (PDF)

Community cure workshops

The **2022 Community HIV Cure Research Workshop**, sponsored by Treatment Action Group (TAG), many of the Martin Delaney Collaboratory Community Advisory Boards, and other advocacy groups, will be virtual again this year, breaking up into two 2 hour sessions—one before the 2022 Conference on Retroviruses and Opportunistic Infections (CROI 2022) on **February 8**; and one session afterwards on **March 1**.

Please register here: https://bit.ly/3sVgtun

Community breakfast meetings

As with previous recent years, informal community breakfast meetings will be held an hour or so before each of the main conference days.

These virtual meetings are also open to people who are not registered for CROI. They include leading researchers and community advocates to lead open discussion on the most important studies from the previous day. They also include suggested highlights for the day ahead.

Registration details will be added to this page once they are available.

For further information please email:

jimberlypickett@gmail.com

ANTIRETROVIRALS

US FDA approves 2-monthly dosing option for long-acting injectable cabotegravir/rilpivirine

Simon Collins, HIV i-Base

On 1 February 2022, the US FDA expanded the indication for long-acting cabotegravir and rilpivirine to allow two-months dosing.

This now matches the indication approved by the EMA in Europe.

This was based on similar viral efficacy and tolerability in the phase 2b ATLAS-2M study where two-monthly injections were non-inferior to monthly dosing.

References

- ViiV press release. ViiV Healthcare announces US FDA approval of Cabenuva (cabotegravir, rilpivirine) for use every two months, expanding the label of the first and only complete long-acting HIV treatment. (1 February 2022). https://viivhealthcare.com/hiv-news-and-media/news/press-releases/2022/january/viiv-healthcare-announces-fda-approval-of-cabenuva-for-useevery-two-months
- 2. Overton E et al. Long-acting cabotegravir and rilpivirine dosed every 2 months in adults with HIV-1 infection (ATLAS-2M), 48-week results: a randomized, multicentre, open-label, phase 3b non-inferiority

Gilead to pay \$1.25 billion plus royalties to ViiV Healthcare for bictegravir infringing on dolutegravir patent

Simon Collins, HIV i-Base

A long-running legal challenge that bictegravir was so similar to dolutegravir that Gilead infringed the ViiV patent has now been resolved. [1, 2]

In a press release on 1 February 2022, Gilead announced that it will pay a one-time payment of \$1.25 billion for ViiV to withdraw all claims. Gilead will also pay "an ongoing royalty payment of 3% until 2027 on future sales of Biktarvy and on the bictegravir component of any future bictegravir-containing products sold in the US."

In 2020, Gilead sales were more than \$6b in the US with 17% growth in 2021. [2, 3]

C O M M E N T

This is a relatively small settlement. Gilead year-to-date sales including 3Q2021 were \$11.8b. Biktarvy is the most widely prescribed US treatment with a patent claim until 2030. Gilead drugs account for 75% of US market share. [3]

Dolutegravir was approved in the US in August 2013 and Biktarvy (containing bictegravir) was approved in February 2018.

The similarity between these two integrase inhibitors is so close that the side effect profile of dolutegravir – which has been described for an additional five years – is believed by many researchers to also apply to bictegravir. unless proved otherwise.

References

- Gilead Sciences press statement. Gilead announces global resolution of bictegravir patent dispute with ViiV Healthcare. (1 February 2022). https://www.gilead.com/news-and-press/company-statements/gilead-announces-global-resolution-of-bictegravir-patent-dispute-with-viiv-healthcare
- ViiV Healthcare press statement. GSK announces settlement between ViiV Healthcare and Gilead Sciences resolving litigation relating
 to Biktarvy and ViiV's dolutegravir patents and entry into a patent licence agreement. (1 February 2022).
 https://viivhealthcare.com/hiv-news-and-media/news/press-releases/2022/january/gsk-announces-settlement-between-viiv-healthcare-and-gilead-sciences/
- Gilead presentation. innovation for sustainable growth. JP Morgan Healthcare Conference. (10 January 2022). https://investors.gilead.com/events/event-details/gilead-sciences-40th-annual-jp-morgan-healthcare-conference(webcast and link page) https://investors.gilead.com/static-files/5808fec3-0d26-4d9f-8df7-c4ecba89204d (PDF)

GUIDELINES

BHIVA interim guidance on long-acting cabotegravir and rilpivirine injections

Simon Collins, HIV i-Base

On 7 February 2022, BHIVA published interim guidance on long-acting cabotegravir and rilpivirine injections (CAB/RPV-LA).

This is ahead of the expected update to the full ART guidelines that are due to be published in April.

As with the EU indication this will limit access to people who have had undetectable viral load for more than six months on their current ART. This includes having no history of viral failure or drug resistance to INSTIs or NNRTIs.

Unlike previous BHIVA guidance, it also includes and an editorial criteria for potential recipients to agree to a specified risk of viral failure, despite good adherence.

People currently using this treatment in a study or on expanded access can continue.

Viral load monitoring is recommended with every two-monthly dose. This should be immediately repeated if results become detectable.

Nine recommendations for new use of CAB/RPV-LA

- 1. Have a significant need for injectable antiretroviral therapy (ART); and
- 2. Have been virally suppressed to <50 copies/mL for at least 6 months; and
- 3. Have no known or suspected non-nucleoside reverse transcriptase inhibitor (NNRTI) or integrase inhibitor (INSTI) resistance; and
- 4. Have no history of virological failure or unplanned treatment interruption on NNRTI- or INSTI-containing ART; and
- 5. Have no history of INSTI monotherapy; and
- 6. Can tolerate and commit to 2-monthly attendance for injections; and
- 7. Accept the risk of virological failure despite complete adherence (approximately 1 in 70 at year 1 and 1 in 60 at year 2); and
- 8. Have a BMI <30 kg/m2 AND non-A1/6 subtype if baseline resistance is unavailable; and
- 9. Do not need a tenofovir-containing regimen for the treatment or prevention of hepatitis B.

Continuing CAB/RPV-LA

- Have received LA-CAB/RPV in a clinical trial.
- Are on LA-CAB/RPV as part of a compassionate access or named patient programme.

Recommended monitoring

- HIV-RNA quantification at every visit.
- Prompt recall for repeat testing and resistance testing if viral rebound occurs.

Reference

BHIVA. 2022 interim BHIVA guidance on long-acting cabotegravir/rilpivirine (LA-CAB/RPV) for antiretroviral therapy. (7 February 2022).

https://www.bhiva.org/HIV-1-treatment-guidelines (download page)

https://www.bhiva.org/file/62012a06e2920/interim-BHIVA-guidance-on-LA-CAB-RPV-for-antiretroviral-therapy.pdf (PDF) and the properties of the properties of

COINFECTIONS AND COMPLICATIONS

HIV-associated reductions in telomere length are stopped by effective ART

Simon Collins, HIV i-Base

Results from a 17-year study report that untreated HIV is associated with significant reductions in telemere length (TL) but that effective ART stopped further damage.

TL is associated with ageing, coronary artery disease (CAD) and all-cause mortality in the general population. In people living with HIV, TL has also been associated with metabolic syndrome, neurocognitive impairment and concerns about accelerated or accentuated ageing.

This was a longitudinal analysis from the Swiss HIV Cohort Study where 107 participants were followed for a minimum of three years before starting ART (median 7.7 years; IQR: 4.7 to 11) and for a minimum of three years after (median 9.8 years; IQR: 7.1 to 11.1).

Change in TL was measured in PBMCs by quantitative PCR and the analysis adjusted age, sex and CD4:CD8 ratio.

In the years before ART, TL significantly dropped by a median -2.12% per year (IQR, -3.48% to -0.76%) p=0.002). This compared to no significant changes when on suppressive ART: median change + 0.54% per year (IQR, -0.55% to + 1.63%) p=0.329.

No association was found between changes in TL and individual HIV drugs. However, an individual TL risk score based on 239 single-nucleotide polymorphisms identified in the group's previous work did continue to correlate with reductions (global p=0.019).

This impressive dataset reports both an under-appreciated concern of untreated ART and a benefit from suppressive ART that is large enough to likely have clinical significance. It further supports the importance of universal ART on long-term health.

Reference

Schoepf IC et al for the Swiss HIV Cohort Study. Telomere length declines in persons living with HIV before antiretroviral therapy start but not after viral suppression: a longitudinal study over >17 years. J Infect Dis. 2021 Dec 15:jiab603. doi: 10.1093/infdis/jiab603. (21 December 2021).

https://pubmed.ncbi.nlm.nih.gov/34910812

RESISTANCE

Drug resistance profile of integrase inhibitors when treating HIV-2

Simon Collins, HIV i-Base

Treatment quidelines for HIV-1 have for many years recommended integrase inhibitor-based ART as first-line ART.

A study just published in JID includes an analysis of drug resistance mutations that are specific to HIV-2, with significant loss in phenotypic sensitivity.

These will be an essential reference for optimal management of HIV-2 where maintaining sensitivity to integrase inhibitors will be essential for long-term care.

The abstract results note: "We observed extensive cross-resistance between raltegravir and dolutegravir in HIV-2ROD9. HIV-2–specific integrase mutations Q91R, E92A, A153G, and H157Q/S, which have not been previously characterised, significantly increased the EC50 for raltegravir when introduced into one or more mutational backgrounds; mutations E92A/Q, T97A, and G140A/S conferred similar enhancements of dolutegravir resistance. HIV-2ROD9 variants encoding G118R alone, or insertions of residues SREGK or SREGR at position 231, were resistant to both INIs."

Reference

Smith RA et al for the University of Washington-Senegal HIV-2 Study Group. Spectrum of activity of raltegravir and dolutegravir against novel treatment-associated mutations in HIV-2 integrase: A phenotypic analysis using an expanded panel of site-directed mutants, Journal of Infectious Diseases, 2022; jiac037. DOI: 10.1093/infdis/jiac037. (3 February 2022).

https://academic.oup.com/jid/advance-article-abstract/doi/10.1093/infdis/jiac037/6521074

HIV and COVID-19 - bulletin











COVID-19: INVESTIGATIONAL DRUGS

UK RECOVERY study shows no benefit from aspirin in people hospitalised with COVID-19

Simon Collins, HIV i-Base

The large randomised, controlled, open-label RECOVERY trial, comparing various repurposed drugs to standard of care continues to publish results, that in this case are another negative finding.



In this analysis, 14892 participants were randomly allocated (1:1) to receive aspirin (150 mg a day) or usual care alone. Overall, mortality at day 28 was 17% in each arm (1222/7351 vs 1299/7541), rate ratio 0. 96 (95% CI: 0.89 to 1.04; p=0·35). Similar results were reported for all subgroups.

Aspirin use had a slightly shorter time in hospital (median 8 vs 9 days) and 75% vs 74% were discharged alive by day 28 (p=0.0062) but there were no differences in use of invasive mechanical ventilation or death (p=0.23).

Although aspirin reduced thrombotic events (4.6% vs 5.3%) it also increased major bleeding events (1.6% vs 1.0%).

Reference

RECOVERY Collaborative. Aspirin in patients admitted to hospital with COVID-19 (RECOVERY): a randomised, controlled, open-label, platform trial. Lancet 399(10320);p143-151. DOI: 10.1016/S0140-6736(21)01825-0. (08 January 2022).

https://www.the lancet.com/journals/lancet/article/PIIS0140-6736 (21) 01825-0/full text and the lancet of the la

COVID-19: GUIDELINES

IDSA update COVID-19 guidelines (January 2022)

Simon Collins, HIV i-Base

On 18 January 2022, the Infectious Diseases Society of America (IDSA) updated their Guidelines on the Treatment and Management of Patients with COVID-19.

The guidelines were originally published in April 2020 and this is the 6th edition.

The guidelines have five sections. with treatment included in part 1.

Part 1: Treatment and Management

Part 2: Infection Prevention

Part 3: Molecular Testing

Part 4: Serologic Testing

Part 5: Antigen Testing

Reference

IDSA Guidelines on the Treatment and Management of Patients with COVID-19. 6th edition, January 2022. https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management

OTHER NEWS

EACS HIV Summer School 2022: Applications are open

EACS press release

Applications for the EACS HIV Summer School are now open.

The course will take place from 6-9 September 2022 in Bordeaux, France.

This 4-day residential course is designed for clinicians involved in HIV management who wish to deepen their knowledge about all aspects of HIV medicine and research methodology.

The course is delivered by an experienced faculty of key opinion leaders in the fields of HIV clinical care and research. Teaching is based around a combination of plenary sessions, which provide updates on the recent advances in HIV clinical science and a general introduction to clinical research methodology, and interactive small working groups led by faculty members.

A maximum of 70 participants will be accepted.

A moderate fee of EUR 300 is charged which will cover registration and accommodation (payment is due on confirmation of a place in the course). A limited number of scholarships are available to applicants from low-income countries.

Applications are open until 18 April 2022. On confirmation of your acceptance, you will be required to become an EACS member. Reduced fees are available for young clinicians/scientists (35 years or younger) and low/middle-income countries.

https://www.eacsociety.org/education/hiv-summer-school



JOB VACANCIES

i-Base vacancy: HIV treatment advocate and information officer

HIV i-Base (i-Base) is looking for an HIV Treatment Advocate and Information Officer.

This is being advertised as a full-time role, however there may be flexibility to create two part time posts.

i-Base is a HIV treatment activist group founded in 2000. We are committed to peer advocacy and to providing timely HIV treatment information for both positive people and health care professionals.

i-Base has developed key resources and services and we are recognised and trusted for providing treatment information both nationally and internationally.

Job summary

This post involves helping will all aspects of treatment advocacy at the project. This includes:

- Responsibility for running the treatment information phoneline.
- Answering other questions that are sent by email and posted on the i-Base website (www.i-Base.info).
- Phoneline hours are Monday to Wednesday, 12 to 4 pm.
- This is an office-based post.
- Contributing to other i-Base resources. This includes writing, research, updating i-Base printed guides. Hopefully also writing for HIV Treatment Bulletin.

Training will be provided for all areas of work, but candidates need to already have a good knowledge of HIV treatment and good written and spoken English.

This includes, for example, knowing about the online i-Base Q&A service and range of i-Base treatment guides. Also, an awareness of the current BHIVA guidelines.

HIV i-Base is an equal opportunities employer.

Applications from HIV positive people are encouraged.

For further details and an application form please see links below.

Application form (January 2022) - Word.docx

https://i-base.info/htb/wp-content/uploads/2022/01/Application-form-Treatment-Information-Officer-role-January-2022.

Treatment Advocate and Information Officer - further details (Word .docx)

https://i-base.info/htb/wp-content/uploads/2021/09/Treatment-Advocate-and-Information-Officer-post-January-2022. docx

Treatment Advocate and Information Officer - further details (PDF)

https://i-base.info/htb/wp-content/uploads/2022/01/Treatment-Advocate-and-Information-Officer-post-January-2022.pdf

FUTURE MEETINGS

Future meetings and webinars 2022/23

The following listing covers selected upcoming HIV-related meetings and workshops: more will be added through the year.

Registration details, including for community and community press are included on the relevant websites.

Although some in-person meetings have been held, some are likely to continue to be virtual, including some that are optimistically first planned face-to-face.

Academic Medical Education (AME) meetings and workshops

Several AME workshops (previously Virology Education) are highlighted below but 35 meetings are planned each year. Many virtual meetings include free registrations for health workers, researchers and community. https://academicmedicaleducation.com (meetings listings)

Webcasts from meetings (YouTube listing)

https://www.youtube.com/channel/UCwicqFc2gFwBzUB1efApsTw

2022

Community HIV Cure Research Workshop (2022)

Session 1:

Tuesday 8 February 2022, 11:00 to 1:00 Eastern, virtual

Register: https://bit.ly/3sVgtun

Session 2:

Tuesday 1 March 2022. 11:00 to 1:00 Eastern, virtual

Register: https://bit.ly/34otfHJ

Conference on Retroviruses and OIs (CROI 2022)

13 – 16 February 2022, now only virtual. https://www.croiconference.org

Australasian Chapter of Sexual Health Medicine (AChSHM) Annual Scientific Meeting (ASM)

19 March 2022, virtual

http://www.sexualhealthmedicineasm.com.au

HIV Prevention Review Meeting 2022

30-31 March, virtual

https://academicmedicaleducation.com

BHIVA Spring Conference 2022

20-22 April 2022, Manchester

https://www.bhiva.org/AnnualConference2022

24th International AIDS Conference (AIDS 2022)

29 July – 2 August 2022, Montreal, Canada, and virtually https://www.aids2022.org

13 International Workshop on HIV & Aging

13 - 14 October 2022, USA (tbc)

https://academicmedicaleducation.com

2023

19th European AIDS Conference (EACS 2023)

18-21 October 2023, Warsaw, Poland https://www.eacsociety.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 webpage 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:

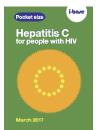
roy.trevelion@i-Base.org.uk

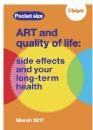
Order publications and subscribe online

All publications can be ordered online for individual or bulk copies. All publications are free. Unfortunately bulk orders are only available free in the UK. http://i-base.info/order













h-tb

HIV TREATMENT BULLETIN

HTB is published in electronic format by HIV i-Base. As with all i-Base publications, subscriptions are free and can be ordered using the form on the back page or directly from the i-Base website:

http://www.i-Base.info

by sending an email to: subscriptions@i-Base.org.uk

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HTB is a not-for-profit community publication that aims to provide a review of the most important medical advances related to clinical management of HIV and its related conditions as well as access to treatments. Comments to articles are compiled from consultant, author and editorial responses.

Some articles are reproduced from other respected sources. Copyright for these articles remains with the original credited authors and sources. We thank those organisations for recognising the importance of providing widely distributed free access to information both to people living with HIV and to the healthcare professionals involved in their care. We thank them for permission to distribute their work and encourage HTB readers to visit the source websites for further access to their coverage of HIV treatment.

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http://www.i-Base.info

HIV i-Base is a registered charity no 1081905 and company reg no 3962064. HTB was formerly known as DrFax.



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		—		
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Pocket leaflets - A7 small	concertina-folded leaflets (201	17)		
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Pocket ART	quantity	Pocket pregnancy	quantity	
Pocket side effects	quantity	PrEP for women	quantity	
Booklets about HIV treats	ment			
Introduction to ART (/	quantity			
UK Guide To PrEP (Fe	quantity			
ART in pictures: HIV to	quantity			
Guide to HIV, pregnan	quantity			
Guide to changing tre	atment: what if viral load re	bounds (Aug 2021): 24-page A5 book	klet quantity	
HIV and quality of life: side effects and long-term health (Sept 2016): 96-page A5			quantity	
Guide to HIV testing a	and risks of sexual transmis	sion (June 2021): 52-page A5 booklet	quantity	
Other resources				
U=U resources:				
A3 posters quanti	ty A5 leaflets of	quantity A6 postcards	quantity	
HIV Treatment 'Passp	orts' - Booklets for patients t	o record their own medical history	quantity	
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