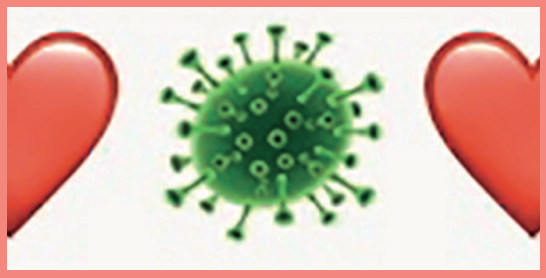
ISSN 1472-4863

HTB: vol 22 no 12: plus COVID-19 supplement

# hiv treatment bulletin (e)



## *EACS, injectable PrEP and BHIVA on COVID (20 December 2021)*

CONTENTS



Contents continued inside...

Published by HIV i-Base

**Contents continued**



## i-Base 2021 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 2021.**

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

# EDITORIAL


**Welcome to the last issue of HTB this year.**

**And the range of reports show that very little in HIV should be taken for granted. Services have been severely challenged for almost two years due to COVID-19 and we approach the upcoming holidays still facing uncertainties over the Omicron variant.**

Our final news from EACS includes a case study about the difficulty of diagnosing HIV on PrEP, perhaps controversial for differing from current guidelines, and positive news that the EACS award this year recognised the value of advocacy as part of HIV care.

Unfortunately, we also report further news that the investigational compound islatravir has been linked to lower CD4 and total lymphocyte counts and that many studies are now on hold. This is especially difficult because of the potential of several long-acting formulations for both treatment and prevention.

Other prevention news includes FDA approval of long-acting cabotegravir injections for PrEP in the US, and a UK report from the PrEP service at the 56 Dean Street clinic in central London.

We include three short reviews on HIV complications: diagnosing hypertension and diabetes, ECG abnormalities in the REPRIEVE study and rare cases on PML despite effective ART.

Although we are slowly stepping down our coverage of COVID-19 in the last few issues, BHIVA have just issued four important new guidance papers related to HIV care, including an outline to retain key HIV services. Plus information on vaccine complications and WHO recommendations against the use of convalescent plasma.

Finally, a review for a film that shouldn't be watched and details of an impressive series of podcasts from activist Marc Thompson on the early community responses to HIV in the UK.

We would also like to thank all readers, contributors and supporters for their help during this difficult year. Best wishes for the upcoming holidays and for the new year ahead.

# CONFERENCE REPORTS

## 18th International European AIDS Conference (EACS 2021)

**27–30 October 2021, hybrid, London**

### Introduction


**The 18th International European AIDS Conference (EACS 2021) ran from 27-30 October 2021 as a hybrid conference.**

EACS are to be congratulated for taking this decision.

Approximately a quarter of the more than 3000 delegates attended the ExCel Centre in London, reconnecting for the first time since COVID-19 with interactions that can only come from face-to-face meetings - many commenting on how important this felt.

Other delegates were able to watch all the same sessions simultaneously as a live virtual meeting - with instant access to all content. Many of the sessions were also simultaneously translated into Russian.

This means that the conference immediately became available online for delegates.

The programme and abstract book from the meeting are available as open access,

https://eacs2021.abstractserver.com/program (programme)

https://onlinelibrary.wiley.com/toc/14681293/2021/22/S3 (PDF abstract book)

https://eacs2021.opade.events/en/event (conference platform - needs registration)

Abstracts can also be accessed through the online programme (first link above). For oral sessions this involves click on the day of the presentation and for posters this is through clicking the two elibrary listings in the programme (for Thursday and Friday).

Reports in this issue of HTB are below.

- EACS case study: how to diagnose HIV on PrEP - stopping PrEP or intensify to ART?
- European AIDS Clinical Society honours Simon Collins for longstanding contribution to the field of HIV

## EACS case study: how to diagnose HIV on PrEP – stopping PrEP or intensify to ART?

**Simon Collins, HIV i-Base**

**Once of the case studies presented at EACS highlighted the difficulty of diagnosing HIV while on PrEP. In this example, both the case and the panel discussion differed from the recommendations in current guidelines.**


Although PrEP is highly effective at protecting against HIV, transmission can still occur with low adherence, in rare cases after exposure to PrEP-resistant HIV or due to missed seroconversion at baseline.

Continuing to take PrEP after infection risks accumulating drug resistance mutations to the PrEP drugs that are also expected to be used in ART. It can also act as suboptimal PEP, delaying seroconversion by several months and suppressing viral load, making diagnosis more difficult.

Discontinuing PrEP for 4-6 weeks will enable more accurate HIV antibody and viral load testing. However, this will also leave someone who is at high risk of HIV vulnerable to infection, if they are not already infected.

This case was a 31 year-old gay man who used ChemSex and who started PrEP in December 2020 with a negative 4th generation Ab/Ag test.

At a follow-up visit on 10 February eight weeks later, the 4th generation rapid test was negative but the 4th generation at the lab was positive. Western Blot was indeterminate, showing p24. At this point PrEP was stopped to avoid risk of developing drug resistance. Although this person confirmed daily adherence, this was not supported by pharmacy receipts. Drug levels were not tested.

A week later, on 16 February, the rapid test was positive and the lab test was negative – and viral load was negative – still making it impossible to know which of these were true results.

After another week, on 26 February, the rapid test was negative, but the lab test was positive. Western Blot was indeterminate but viral load, although <20 copies/mL detected HIV.

On 4 March, these results were similar, other than viral load was now positive at 490 copies/mL, leading to a confirmed HIV diagnosis.

ART was started with F/TAF, rilpivirine and dolutegravir, which was simplified to bictegravir/F/TAF after four weeks following confirmation of wild-type HIV.

### C O M M E N T

**Although the panel supported stopping PrEP in this case, this decision should be really be individualised based on HIV risk. Stopping sex or changing to use condoms is not always easy or possible in some circumstances, including with ChemSex.**

**Current EACS and BHIVA guidelines generally recommend intensifying PrEP to triple-drug ART if infection is suspected. [2, 3]**

**EACS 2021:**

**PrEP should be changed to triple-drug ART without interruption in case of early clinical signs of HIV seroconversion or a positive HIV diagnostic test.**

**BHIVA/BASHH 2019:**

**If a seroconversion event is suspected on PrEP, the writing group recommends that current best practice is to intensify ART while investigations are ongoing. If an atypical result is first detected when off PrEP, then it is advised that no further PrEP is prescribed until an expert consensus is reached regarding the individual's HIV status.**

Reference

1. Jimenez CC. The difficulty to diagnose HIV infection in a person on pre-exposure prophylaxis: a case report. Clinical case session. EACS 2021. Saturday 30 October, 8.45 am. https://eacs2021.opade.events/en/event/2051 (registration required)
2. EACS guidelines. Version 11.0, section 2, page 22, (October 2021). https://www.eacsociety.org/media/final2021eacsguidelinesv11.0_oct2021.pdf (PDF)
3. BHIVA/BASHH guidelines on the use of HIV pre–exposure prophylaxis (PrEP) (2018), section 7.5.1. HIV Medicine, 10.1111/hiv.12718 (March 2019). https://onlinelibrary.wiley.com/doi/10.1111/hiv.12718

## European AIDS Clinical Society honours Simon Collins for longstanding contribution to the field of HIV

**Polly Clayden, HIV i-Base**

**HIV i-Base's Simon Collins received the biennial European AIDS Clinical Society (EACS) award, announced at the October 2021 conference.**

The EACS award recognises an individual's "…longstanding, impactful and sustained professional contribution to the field of HIV" and is presented at the two-yearly meeting. Nominations are reviewed by a committee, representing a diversity of expertise and experience.

This year the committee was unable to come to a consensus and honour just one nominee, so the award was given jointly to Professor Andrzej Horban of the University of Warsaw, Poland, for his outstanding contribution to HIV, both in his native country and throughout Eastern Europe, and to Simon.

Presenting the award, Professor Peter Reiss, of Amsterdam University and the committee chair, explained that Simon co-founded i-Base in 2000, and that he has always campaigned for the rights of people living with HIV to be actively involved in both their own health and studies that may affect them and described some of Simon's many contributions to this end over the last two decades.

He applauded Simon's detailed critiques of the latest HIV research, often before it appears in peer-reviewed publications and his commitment to developing and promoting community engagement and advocacy. He also noted how he has more recently applied this expertise to COVID-19.

On hearing that he would be receiving this award, Simon responded: "This is a great honour that is definitely appreciated. It is also a really good as a way to recognise advocates as partners in HIV healthcare, many of whom work for many years, often as volunteers, and often in much more difficult circumstances."

i-Base also congratulates joint awardee Professor Horban who has specialised in infectious diseases for 50 years. He developed and led HIV services in Poland, from treating the first cases to establishing and running the largest national clinic for over 25 years.

Professor Horban also co-chaired the EACS conference when it was held in Warsaw in 2003 and brought a long-needed focus on the importance of the HIV epidemic in eastern Europe.

Simon Collins, co-recipient of the EACS Award, 2021.

Professor Andrzej Horban, co-recipient of the EACS Award, 2021

ANTIRETROVIRALS

# Selected islatravir studies stop enrolment: further complications with important investigational drugs

**Simon Collins, HIV i-Base**

**For the third time in just over two weeks, MSD/Merck have issued a press release reporting that investigational drug studies are have been stopped due to unexpected complications.**

The latest press statement, issued on 6 December 2021, reported that the two large international phase 3 trials studying islatravir as a monthly oral tablet for PrEP were pausing further enrolment. [1]

Current participants in these studies – IMPOWER 22 (MK-8591-022) and IMPOWER 24 (MK-8591-024) – will continue to receive study drugs with additional monitoring. These randomised, double-blind, placebo-controlled studies compare monthly islatravir to either daily F/TAF or daily F/TDF.

The decision is based on a recommendation from an external data and monitoring committee.

Although the specific reason for the decision is not given, islatravir studies will include more frequent monitoring of total lymphocyte and CD4 cell counts.

Significant drops in both these immune markers led to a press statement on 18 November 2021 on stopping the development of the investigational NNRTI MK-8507. [2]

The limited details in that communication were based on a phase 2 study using MK-8507 and islatravir dual therapy. However, it also included references to islatravir monitoring.

On 23 November 2021, a joint press statement with Gilead Sciences announced that further enrolment into a phase 2 study of once-weekly oral lenacapavir plus islatravir for HIV treatment was also now on hold. [3]

## C O M M E N T

**Given the potential for islatravir for both prevention and treatment this is another disappointment. It is important though that the studies are continuing, with additional monitoring to include CD4 monitoring. Recruitment will also hopefully resume, with modified entry criteria.**

**An earlier communication included that mean reductions in total lymphocytes of 21% and 36% were reported in the phase 2 islatravir PrEP study in the 60 mg and 120 mg arms monthly dose arms respectively (vs +4% increase in the placebo group). [2]**

**It is especially difficult that two different drugs from different classes both reported similar adverse event.**

**NOTE: On 13 December a further press release included details of additional studies that the FDA has put on hold - see next article in HTB. [4]**

References

1. MSD/Merck press statement. Merck announces pause in enrollment for two phase 3 clinical trials of investigational, once-monthly, oral islatravir for pre-exposure prophylaxis (PrEP) of HIV-1 infection enrolled participants will continue to receive study medicine. (6 December 2021). https://www.merck.com/news/merck-announces-pause-in-enrollment-for-two-phase-3-clinical-trials-of-investigational-once-monthly-oral-islatravir-for-pre-exposure-prophylaxis-prep-of-hiv-1-infection
2. MSD/Merck stop once-weekly NNRTI MK-8507: islatravir studies continue with closer monitoring. HTB (November 2021). https://i-base.info/htb/41647
3. Gilead press statement. Gilead and Merck announce temporary pause in enrollment for phase 2 study evaluating an oral weekly combination regimen of investigational islatravir and investigational lenacapavir. (26 November 2021). https://www.gilead.com/news-and-press/company-statements/gilead-and-merck-announce-temporary-pause-in-enrollment-for-phase-2-study-evaluating-an-oral-weekly-combination-regimen-of-investigational-islatravir-and-investigational-lenacapavir
4. MSD/Merck press statement. FDA further limits use of islatravir in ongoing studies. HTB (December 2021). https://i-base.info/htb/41866

# FDA further limits use of islatravir in ongoing studies

**Simon Collins, HIV i-Base**

**On 13 December 2021, Merck/MSD announced a further development concerning islatravir as an investigational compound for HIV treatment and prevention. [1]**

This includes that the US FDA has now put clinical holds on the investigational new drug applications (INDs) for several compounds and indications,

- The oral and implant formulations of islatravir (MK-8591) for HIV-1 PrEP.
- The injectable formulation of islatravir for HIV-1 treatment and prophylaxis.
- The oral doravirine/islatravir (DOR/ISL) HIV-1 once-daily treatment.

This based on the concerns for mean reductions in total lymphocyte and CD4 counts reported in three earlier press statements. [2, 3]

This includes now stopping further dosing of the weekly oral formulation being studied with Gilead's lenacapavir. [1, 4]

The following studies have been placed on full clinical hold. This includes stopping use of islatravir:

- MK-8591-016 – A phase 2a PrEP study evaluating the safety and pharmacokinetics of oral islatravir once-monthly in participants at low risk of HIV-1 infection
- MK-8591-022 (IMPOWER 22) – A phase 3 PrEP study evaluating oral islatravir once-monthly in cisgender women at high risk for HIV-1 infection
- MK-8591-024 (IMPOWER 24) – A phase 3 PrEP study evaluating oral islatravir once-monthly in cisgender men and transgender women who have sex with men, and are at high risk for HIV-1 infection
- MK-8591-034 – A phase 1 study evaluating injectable islatravir (dosing complete)
- MK-8591-035 – A phase 2 PrEP study evaluating once-monthly oral islatravir in trans and gender diverse individuals (study had not yet opened)
- MK-8591-043 – A phase 2a PrEP study evaluating islatravir implant once-yearly in individuals at low risk for HIV-1 infection (study had not yet opened)

The following studies have been placed on partial clinical hold. This stops further enrolment but allows continued used of islatravir.

- MK-8591-011 – A phase 2 dose ranging study of oral DOR/ISL once-daily and lamivudine (3TC) in treatment-naïve adult participants with HIV-1 infection (fully enrolled)
- MK-8591A-017 (ILLUMINATE SWITCH A) – A phase 3 oral once-daily, open label study evaluating a switch from antiretroviral therapy (ART) to DOR/ISL in adults with HIV-1 who are virologically suppressed (fully enrolled)
- MK-8591A-018 (ILLUMINATE SWITCH B) – A phase 3 oral once-daily study evaluating a switch from bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) to DOR/ISL in adults with HIV-1 who are virologically suppressed (fully enrolled)
- MK-8591A-019 (ILLUMINATE HTE) – A phase 3 study evaluating oral islatravir and DOR/ISL once-daily in heavily treatment-experienced (HTE) participants with HIV-1 infection
- MK-8591A-020 (ILLUMINATE NAIVE) – A phase 3 study evaluating oral islatravir and DOR/ISL once-daily in treatment-naïve participants with HIV-1 infection
- MK-8591A-028 (ILLUMINATE YOUTH) – A phase 2 open label study evaluating oral DOR/ISL once-daily for the treatment of HIV-1 infection in paediatric participants who are virologically suppressed on ART for ≥3 months or are treatment-naive
- MK-8591A-033 – A phase 3 open label follow up of adult and paediatric participants with HIV-1 who were treated with oral DOR/ISL once-daily in earlier clinical studies

References

1. Merck/MSD press release. Merck announces clinical holds on studies evaluation islatravir for the treatment and preventions of HIV-1 infection. (13 December 2021).
https://www.merck.com/news/merck-announces-clinical-holds-on-studies-evaluating-islatravir-for-the-treatment-and-prevention-of-hiv-1-infection
2. Selected islatravir studies stop enrolment: further complications with important investigational drugs. HTB (6 December 2021).
https://i-base.info/htb/41833
3. MSD/Merck stop once-weekly NNRTI MK-8507: islatravir studies continue with closer monitoring. HTB (November 2021).
https://i-base.info/htb/41647

4. Gilead press statement. Gilead and Merck announce temporary pause in enrollment for phase 2 study evaluating an oral weekly combination regimen of investigational islatravir and investigational lenacapavir. (26 November 2021).
https://www.gilead.com/news-and-press/company-statements/gilead-and-merck-announce-temporary-pause-in-enrollment-for-phase-2-study-evaluating-an-oral-weekly-combination-regimen-of-investigational-islatravir-and-investigational-lenacapavir

# HIV: COMPLICATIONS

## Confirming screening tests for diabetes and hypertension halves need for referrals

**Simon Collins, HIV i-Base**

**A study from South Africa involving more than 18,000 participants reported that referrals for diabetes mellitus and hypertension were reduced by 48% and 66%, respectively, when single screening results were confirmed by a second test,**

This was part of a community study looking at the positive predictive values (PPV) of a single screening result of glycated haemoglobin A1c (HbA1c) above 6.5% and the World Health Organization STEPS protocol above 140/90 mmHg respectively at the initial screen.

Results from the abstract include: "Of 18,027 participants enrolled, 10.2% (1,831) had a screening BP over 140/90 mmHg. Of those without a prior diagnosis, 871 (47.6%) received follow-up measurements. Only 51.2% (451) of those with completed follow-up measurements had a repeat BP>140/90 mmHg at the home visit and were referred to care. To achieve a 90% correct referral rate, a systolic BP threshold of 192 was needed at first screening. For DM screening, 1,615 (9.0%) individuals had an HbA1c > 6.5%, and of those without a prior diagnosis, 1,151 (71.2%) received a follow-up blood glucose. Of these, only 34.1% (395) met criteria for referral for DM. To ensure a 90% positive predictive value i.e. a screening HbA1c of >16.6% was needed."

Reference

Olivier S et al for the Vukuzai study team. Pitfalls of single measurement screening for diabetes and hypertension in community-based settings. Global Heart. 2021; 16(1): 79. DOI: https://doi.org/10.5334/gh.1083. (3 December 2021).

https://globalheartjournal.com/articles/10.5334/gh.1083

## ECG abnormalities reported by 44% of people older than 40 on ART: results from REPRIEVE study

**Simon Collins, HIV i-Base**

**Results from the large international randomised REPRIEVE study looking at statin use for cardiovascular risks in the context of effective ART reported ECG abnormalities in 44% of participants (aged 40 and older).**

The main study enrolled 7,750 participants between 2015 and 2019 and included ECG tests at baseline and follow-up visits.

Median age was 50 (IQR: 45 to 55) years, 69% were males with 43% Black or African American, 35% white, 15% Asian and 7% identified as other race. Most (97%) had baseline HIV viral load <400 copies/mL and median CD4 count was 620 cells/mm$^3$ (IQR: 447 to 826).

Results included that: "nearly half of participants had at least one ECG abnormality (44%). QTc prolongation was more common among males than females (9% vs. 6%, p=0.001), and nearly twice as common among Asian participants (12%) compared with other racial groups (7%) (p<0.0001). Participants with viral load >400 copies/mL had approximately twice the odds of prolonged QTc compared to those that were undetectable (adjusted OR 2.05, 95% CI: 1.22 to 3.45).

Reference

Bloomfield GS et al. Prevalence and correlates of electrocardiographic abnormalities in adults with HIV: Insights from the randomized trial to prevent vascular events in HIV (REPRIEVE). JAIDS, doi: 10.1097/QAI.0000000000002877. (6 December 2021).

https://journals.lww.com/jaids/Abstract/9000/Prevalence_and_Correlates_of_Electrocardiographic.95753.aspx

## Rare cases of PML diagnosed at CD4 >200 with undetectable viral load

**Simon Collins, HIV i-Base**

**Although progressive multifocal leukoencephalopathy (PML) is now uncommon, a review published in AIDS reports rare cases from a large French of PML at higher CD4 counts and with undetectable viral load.**

From 571 cases of PML reported in the Dat'AIDS cohort between 2000 and 2019, 10 cases (1.75%) occurred at a CD4 cell count >200 cells/mm$^3$ and an undetectable HIV RNA viral load after at least 6 months of ART.

Median CD4 cell count at PML diagnosis was 395 cells/mm$^3$ [IQR: 310 to 477]. The median time of undetectable HIV viral load was 41 months (IQR: 8 to 67).

Other details include that: "only one person treated with rituximab-based chemotherapy for a large B-cell lymphoma had an established risk factor for PML. Among the nine others, multiple factors of impaired immunity could have led to PML: HCV co-infection (n=6), cirrhosis (n=4), HHV-8 co-infection (n=3) with Kaposi's sarcoma (n=2) in association with Castleman's disease (n=1) and indolent IgA multiple myeloma (n=1).

Reference

Dalla-Pozza P et al. Progressive multifocal leukoencephalopathy in patients with immuno-virological control and at least 6 months of combination antiretroviral therapy. AIDS, doi: 10.1097/QAD.0000000000003145. (6 December 2021).

https://journals.lww.com/aidsonline/Abstract/9000/Progressive_multifocal_leukoencephalopathy_in.96259.aspx

# HIV: PREVENTION

## US FDA approves long-acting cabotegravir injections for PrEP

**Simon Collins, HIV i-Base**

**On 20 December 2021, the US FDA approved long-acting cabotegravir injections for pre-exposure prophylaxis (PrEP) against HIV infection. [1]**

The indication is for HIV negative adults and adolescents weighing at least 35 kg who are at risk of HIV. Dosing involves a single 600 mg (3 mL) intramuscular gluteal injection given monthly for the first two doses, and then given every two months. The use of a monthly oral lead-in period to test for sensitivity is optional.

Dosing can be brought forward by up to seven days but missed injections include the recommendation to use various schedules of daily oral cabotegravir, depending on timing of missed doses.

Approval is based on results from two large international randomised phase 3 studies (HPTN 083 and 084) that used daily oral TDF/FTC as an active control.

For full details see the full product information, including for side effects, risk of developing drug resistance and that residual concentrations of cabotegravir can persist for more than a year after a single injection.

Cabotegravir injections for PrEP are manufactured by ViiV Healthcare and marketed by under the trade name Apretude.

Long-acting injections of both cabotegravir plus rilpivirine were approved by the FDA as HIV treatment in January 2021. [2]

References

1. FDA news release. FDA approves first injectable treatment for HIV pre-exposure prevention (20 December 2021). https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention
2. US FDA approves long-acting injectable HIV treatment: monthly dosing. HTB, (22 January 2021). https://i-base.info/htb/39697

# 56 Dean Street reports M184V common with recent low adherence to PrEP and seven transmissions with good adherence

**Simon Collins, HIV i-Base**

**Although PrEP is highly effective at preventing HIV, a recent report from 56 Dean Street Clinic in central London includes seven cases of HIV transmission with self-reported good adherence. Also, that there is a risk of developing drug resistance if adherence to PrEP is low.**

Of 1030 HIV diagnoses between 2016 and 2020, roughly 5% (n=52) reported recent PrEP use. Of these, 98% were gay or bisexual men, with median age 34 (IQR: 28 to 42), 65% white and 65% non-UK-born.

PrEP use was reported by 35% on the day before diagnosis with 46% reporting intermittent adherence. Of these, 11/24 were using daily PrEP and 13/24 were using 2:1:1 dosing. Supply/access difficulties were reported by 9/52 (17%).

Other reasons included: "5/52 (10%) interrupted PrEP after starting a monogamous relationship, 3/52 (6%) did not plan to have sex, 3/52 (6%) chose to interrupt PrEP and 1/52 (2%) was taking an antiretroviral regimen not licensed for PrEP (raltegravir)".

However, reasons for PrEP failure could not be explained in 7/52 (13%) who reported excellent adherence (though drug levels were not available). Of these 2/7 had the M184V mutation on diagnosis that might indicate infection after exposure to drug-resistant HIV.

Delayed HIV seroconversion and/or unrecognised HIV infection when starting PrEP could be a factor in 5/7 cases who were sourcing PrEP online, and the median time since their last HIV negative test was 124 days. HIV was then detected with the first clinic test.

The M184V mutation was more common in the recent PrEP use group (30% vs 1%, $p<0.01$). PrEP use also increased over time, reaching 20% by 2020.

The paper reported that all people who intensified from PrEP to ART achieved an undetectable viral load at week 24. ART was tenofovir-based, with the third drug boosted-darunavir (n=28), bictegravir (n=8), dolutegravir (n=7) or raltegravir (n=4). The clinic protocol includes switching from darunavir to integrase inhibitors 3 months from ART initiation, but this only occurred in 14/28 participants.

## C O M M E N T

**Although the short-term response to intensified ART is important, longer follow-up is really needed to show a durable response to ART in case of suboptimal ART due to M184V.**

**Access to PrEP at 56 Dean Street is impressive: the clinic recently reported prescribing PrEP on the NHS to more than 25,000 people since 2020. [2]**

**Also, while the primary analysis focussed on M184V resistance, the otherwise unexplained cases of HIV acquisition in the context good adherence are important enough to deserve a more detailed analysis.**

References

1. Girometti N et al. Rising rates of recent PrEP exposure among MSM newly diagnosed with HIV: antiviral resistance patterns and treatment outcomes. AIDS, doi: 10.1097/QAD.0000000000003143.
   https://journals.lww.com/aidsonline/Abstract/9000/Rising_rates_of_recent_PrEP_exposure_among_MSM.96256.aspx
2. Dean Street press release. HIV PrEP awareness week: 29th November – 5th December.
   https://www.dean.st/prep

# HIV: CURE-RELATED RESEARCH

## Reducing the risk of COVID-19 in research that involves interrupting ART

**Simon Collins, HIV i-Base**

**These two papers, published as letters in JAIDS, discuss ways to reduce risks to participants in cure-related studies that involve a treatment interruption.**

Some earlier studies were rightly put on hold during the early pandemic but wider availability of vaccines have enabled many of these studies to now reopen.

References

1. Peluso ML et al. SARS-CoV-2 booster vaccination for participants in "HIV cure"-related clinical trials. JAIDS. Letter. doi: 10.1097/QAI.0000000000002875. (26 November 2021).
   https://journals.lww.com/jaids/Citation/9000/SARS_CoV_2_booster_vaccination_for_participants_in.95756.aspx
2. Peluso ML et al. SARS-CoV-2 Vaccination in the context of ongoing HIV cure-related research studies. JAIDS JAIDS. Letter, 87(4)e232-e233. doi: 10.1097/QAI.0000000000002690. (1 August 2021).
   https://journals.lww.com/jaids/Fulltext/2021/08010/SARS_CoV_2_Vaccination_in_the_Context_of_Ongoing.13.aspx

# HIV: FILM REVIEW

## Right to Try: activists challenge a flawed film about a potential HIV cure

**Simon Collins, HIV i-Base**

**A short US film that promotes promotes a single case that's suggested to represent a possible cure of HIV has been criticised by US activists for numerous inconsistencies and dishonesty. [1, 2]**

These problems are carefully and calmly detailed in a review by Richard Jefferys from the Treatment Action Group, a leading treatment activist who is an expert on HIV cure-related research and who also has an impressive history of challenging dangerous conspiracy theories, including HIV denialism.

This film's title refers to the recent US legislation that lets people with otherwise untreatable health conditions access treatment that have shown promise in early studies. But this doesn't apply for either HIV (which has safe and proven treatment) or the intervention (as there is no evidence to show it is either safe or effective).

And rather than emphasising the decades of progress from ART that has normalised life expectancy for many, the poster subheading is: "How much would you pay to live?".

The film provides little information about the procedure that was used, but instead claims to 'uncover the business of HIV'. This involves attacking current treatment, other cure researchers and HIV organisations, Previous promotional material includes a conspiracy plot that large companies would try to stop cure studies. In reality, the largest companies investing in cure research are the same companies that are developing better treatments.

The TAG review notes that the subject of the film, Jeffrey Drew, a long-term survivor living with HIV "comes across as warm and generous."

It does not say this about the film-makers.

References

1. IMDB. Right to try: how much would you pay to live. (26 mins).
   https://www.imdb.com/title/tt14915232
2. Jefferys R. Story: HIV Short Film, "Right To Try". (8 December 2021).
   https://www.treatmentactiongroup.org/cure/media-monitor/story-hiv-short-film-right-to-try

# HIV: ON THE WEB

## CAAB: new website and webcasts

**Simon Collins, HIV i-Base**

**A new website for the international COVID Advocate Advisory Board (CAAB).**

The network connects 135 advocates from 25 countries and is open for new members.

https://covidadvocates.org

A series of webcasts linked to the group.

https://covidadvocates.org/open-resources

**Webinar on Omicron and HIV with Salim Abdool Karim - December 15, 2021**

https://www.youtube.com/watch?v=ORS9k9EWchg

**Reality check about "global" COVID-19 vaccine production - October 2021**

https://www.youtube.com/watch?v=h60012rjiPA

**CAAB webinar with Dr. Wohl: COVID-19 treatment and research, September 2021.**

https://www.youtube.com/watch?v=KUu5tzdlSBM

**Investment and Engagement in HIV Cure Research: Looking Ahead**

https://www.youtube.com/watch?v=EVFhbt4sFmY

## We were always here - HIV podcast from Marc Thompson

**Simon Collins, HIV i-Base**

**A soon to be award-winning podcast from HIV activist Marc Thompson.**

**Nine episodes reliving a community based history of HIV in the UK, with generous involvement of the many friends and activists that Marc has collaborated with over many years.**

https://podcasts.apple.com/gb/podcast/we-were-always-here/id1587035513

### 1. They weren't Us

During the 1980's, Marc Thompson found his feet and his people as a young Black gay man in Brixton, South East London, enjoying everything that life and his community had to offer; family, parties and a safe space to express himself. At the same time, reports of a strange cancer that had been affecting young white gay men begun to emerge from America. It was like a mist, slowly creeping into the consciousness of Marc and his friends. But it was over there and these were white men, so there wasn't anything to worry about it, was there?

### 2. Kaleidoscope

Following the discovery of LAV and HTVL-III , the identical viruses believed to cause AIDS, a blood test is developed in 1985 to screen for the disease. Marc Thompson, then a teenager, was persuaded by friends to take it. The dialogue around AIDS is increasing, though there is still so much unknown. Rock Hudson, a prolific Hollywood actor has died at this point, but there is still nothing that really connects the Black, gay community in South East London to this disease. They felt safe in their world, but that world was about to change forever.

### 3. Don't Aid AIDS

Fear is a tool that is often used in interventions around healthcare. Public information films featuring images of car crashes and injured children have been used to encourage us not to drink alcohol and drive and in more recent years - images of human organs on cigarette packets to encourage us not to smoke. The HIV epidemic was no different and perhaps the most hard hitting of all. Following his positive diagnosis in 1986 at seventeen years old, Marc Thompson suddenly becomes aware of the prevalence of AIDS across the UK and Global Media and one campaign in particular that would go on to define the era.

### 4. First response

In 1987, 71,751 cases of AIDS had been reported to the world health organisation. They estimated that 5-10 million people were living with HIV worldwide. The epidemic didn't just affect individuals, it impacted households, and communities. Against the backdrop of a conservative government with Section 28 just around the corner, there was a tradition of volunteering and community involvement and a very 'English' approach to fighting the system. People looked out for people. And that was true of the response to the AIDS epidemic. You just had to find yours. This was the start of the response.

### 5. Body and Soul

Between the first case of HIV in 1981 and 1987, AIDS was unstoppable. The glimmer of hope came in 1987 when the drug, AZT, an antiretroviral medication was fast-tracked under enormous public pressure. What followed was a controversial trial. At the same time more and more cases of HIV were being reported, from both the African Continent and in Women.

### 6. Positive Women Part 1

Since the start of epidemic, women in many regions have been disproportionately affected by HIV. Today, women make up more than half of all people living with HIV and AIDS-related illnesses. In 1986 the ratio of male to female of HIV cases in the UK was 33 to one. By 1989, it was estimated that women accounted for a third of HIV cases worldwide, with several thousand diagnosed in the UK. In the first of this two part episode, women share their recollections of diagnosis.

### 7. Positive Women Part 2

Positively Women was created by HIV positive women for HIV positive women. Two of the founders discuss the groups inception, the services they offered, and Princess Diana's chic suit. But some women still fell through the cracks.

### 8. Human rights and wrongs

During the 1990's the prevalence of HIV increased across the mainstream media in part due to celebrities taking to the world stage to disclose their diagnosis. First it was Magic Johnson, a week later singer Freddy Mercury would announce he had aids. He died the next day. Then there would be tennis star Arthur Ashe who had contracted the virus during a blood transfusion in 1982. Up to 5000 people were thought to have been infected with HIV via contaminated blood transfusion in the 1980's. This episode looks at the role the media and the government played in stigma and those who fought to dispel it.

### 9. Still here

As we move into the 2000's, the demographic of HIV is changing as are the policies surrounding treatment. At an International medical trail, PrEP (pre-exposure prophylaxis) is found to be highly effective for treating people with HIV, reducing the risk of infection from sex by about 99% when taken as prescribed. It was a breakthrough and it was assumed by many that PrEP would be rolled out by the NHS. But it wasn't going to be that simple. The thread of activism that runs through the last decade is reminiscent of the early 80's and 90's and a reminder that the fight to end HIV still very much includes the fight to end stigma.



# New BHIVA statements on HIV and COVID-19 (December 2021)

**Simon Collins, HIV i-Base**

**On 17 December 2021, BHIVA posted and updated six guidance documents related to HIV and COVID-19 related to four aspects of care.**

Two of these include different versions for health workers and people living with HIV.

### 1. Considerations for critical care for people with HIV during COVID-19

https://www.bhiva.org/updated-statement-on-considerations-for-critical-care-for-people-with-HIV-during-COVID-19

These guidelines are for health workers with limited experience of HIV but who are managing HIV positive people diagnosed with COVID-19.

They cover the importance of equitable access to care for people living with HIV and includes specialist information on potential interactions between some HIV medicines and corticsteroids.

### 2. BHIVA guidance for HIV services during COVID surges

https://www.bhiva.org/updated-BHIVA-guidance-for-HIV-services-during-COVID-surges

These guidelines outline how HIV services should be organised and delivered for as long as COVID-19 is affecting NHS services. They outline core outpatient and other services that people with HIV should continue to receive, including monitoring and access to ART. This includes access to specialist care for HIV and TB, malignancies and other services.

This also includes access to mental health alcohol/drug issues and domestic abuse with clear pathways for appropriate referral and/or signposting where issues are identified.

The guidelines are mainly for people responsible for providing services but are also important for HIV positive people to see how their care might change.

### 3. JCVI recommendations on COVID vaccines, third doses and boosters

*Update for service users 17 December 2021*

https://www.bhiva.org/recommendations-from-the-JCVI-on-COVID-vaccines-third-doses-and-boosters

*Update for health workers and service providers*

https://www.bhiva.org/JCVI-recommendations-for-3rd-COVID-vaccine-doses-and-boosters

These statements looks at the difference between third doses and booster doses and include details for how to access both.

Booster doses ate recommended for all people living with HIV. Third doses are only recommended for some people living with HIV.

### 4. BHIVA updates on treatments for COVID-19

*Information for people living with HIV*

https://www.bhiva.org/update-on-COVID-treatments-for-people-with-HIV

*Information for health workers*

https://www.bhiva.org/update-on-COVID-treatments-for-people-with-HIV

Guidance on new treatments for COVID-19 including access is also provided with one version for people living with HIV and another for health workers.

This information is  expected to change quickly and both documents recommend checking NHS, NICE, JCVI & GOV.UK websites for updates, especially about access.

All treatments have guidelines for when they can be used. Some need to be used within 3-5 days of symptoms. Some treatments are available for all HIV positive people, but acces to others depends on having additional risk factors. Some are available as part of routine NHS care and some through your GP.

There are now several COVID treatments from three drug classes.

Antivirals: target SARS-CoV-2 (the virus that causes COVID-19) to stop it reproducing.

Remdesevir: by injection into a vein and used in some hospitalised people only.

Molnupiravir: given as a course of tablets and available through the PANORAMIC trial or routine NHS care.

Neutralising monoclonal antibodies (nMAB): are proteins designed to 'mop up' SARS-CoV-2 so that it can't infect cells. They reduce the risk of hospital admission if given early and of dying from COVID.

Casirivimab + imdevimab: injection into a vein, this combination treatment is less effective against the Omicron variant, so it is only used in some hospitalised people;

Sotrovimab: given by injection into a vein, used in some hospitalised people and also available for non-hospitalised people (see below).

Anti-IL-6 monoclonal antibodies: these are used to reduce levels of inflammation in some hospitalised people. There are two types, tocilizumab and sarilumab

A table covering these treatments and any HIV specific advices is available online and also as a separate PDF file.

**https://www.bhiva.org/file/61bcb2063a43e/Summary-of-current-COVID-treatments-and-HIV-specific-advice.pdf (PDF**

# COVID-19: VACCINE RESEARCH

## Myocarditis and pericarditis after COVID-19 vaccines

**Simon Collins, HIV i-Base**

A UK government report covers reports of myocarditis and pericarditis following vaccines against COVID-19 and includes guidance for health workers.

By 17 November 2021, there have been 432 and 332 reports respectively following the Pfizer vaccine, equivalent to 10 and 7 cases per million doses. The figures for Moderna are 101 and 57 reports, equivalent to 36 and 21 cases per million doses.

The fewer cases reported following the AstraZeneca vaccine are thought to reflect the expected background rate.

In those aged under 18 years, the reported rate for heart inflammation (myocarditis and pericarditis) is 10 per million doses (first dose or unknown dose) of the Pfizer vaccine. The Pfizer COVID-19 vaccine is recommended for use in this age group.

Reference

Gov.UK. Myocarditis and pericarditis after COVID-19 vaccination: guidance for healthcare professionals. Guidance. (29 November 2021).

https://www.gov.uk/government/publications/myocarditis-and-pericarditis-after-covid-19-vaccination/myocarditis-and-pericarditis-after-covid-19-vaccination-guidance-for-healthcare-professionals

# COVID-19: TREATMENT

## WHO advises against use of convalescent plasma for COVID-19

**Simon Collins, HIV i-Base**

**Despite its initial promise, the WHO has made a strong recommendation against the use of convalescent plasma in patients with non-severe illness.**

It also recommends against its use in people with severe and critical illness, except in the context of a randomised controlled trial (RCT). This recognises sufficient uncertainty in severe and critical illness to warrant continuation of RCTs.

The recommendations are based on evidence from 16 trials involving 16,236 patients with non-severe, severe, and critical covid-19 infection.

They also noted several practical challenges, such as the need to identify and test potential donors, as well as collect, store and administer donor plasma, which they say further limits its feasibility and applicability.

Reference

WHO Guideline Development Group. Rapid Recommendations: A living WHO guideline on drugs for covid-19. BMJ. 2020;370:m3379. (4 September 2021).

https://www.bmj.com/content/370/bmj.m3379

# FUTURE MEETINGS

**The following listing covers selected upcoming HIV-related meetings and workshops. Registration details, including for community and community press are included on the relevant websites.**

Due to the new coronavirus health crisis, most meetings will now be virtual, including those that were rescheduled in the hope that COVID-19 restrictions would be relaxed.

**Virology Education meeting and workshops**

Several VE workshops are highlighted below but 35 meetings are planned for 2021:

https://www.virology-education.com

**2022**

**Conference on Retroviruses and OIs (CROI 2022)**

13 – 16 February 2022, hybrid (Denver and virtual).

https://www.croiconference.org

**24th International AIDS Conference (AIDS 2022)**

29 July – 2 August 2022, Montreal, Canada, and virtually

https://www.aids2022.org

**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 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.

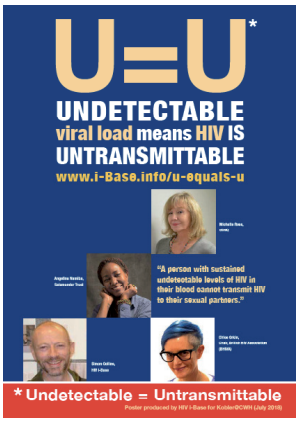
This project was developed with the Kobler Centre in London.

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.

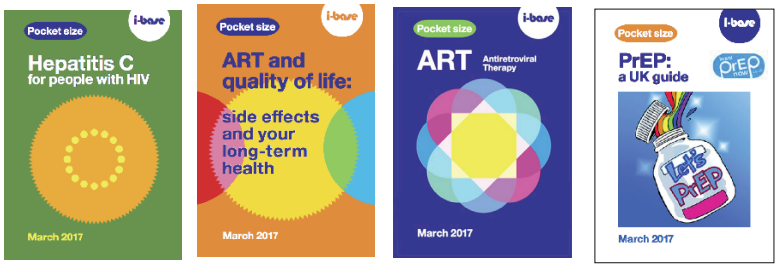
Personalising these for your clinic is cheap and easy and might be an especially nice way to highlight the good news.

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

roy.trevelion@i-Base.org.uk

## Order publications and subscribe online

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

Editor: Simon Collins

Contributing Editor: Polly Clayden





**HIV i-Base, 107 The Maltings,169 Tower Bridge Road, London, SE1 3LJ. T: +44 (0) 20 8616 2210. F: +44 (0) 20 8616 1250**

## 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.**


## HIV i-Base

**All publications are free, including bulk orders, because any charge would limit access to this information to some of the people who most need it.**

**However, any donation that your organisation can make towards our costs is greatly appreciated.**

**STANDING ORDER DONATION** **THANK YOU FOR YOUR SUPPORT**

Title: _____ First Name _____ Surname _____

Address _____

_____

_____ Postcode _____

Email _____ @ _____

Telephone (s) _____ _____ _____

Please pay HIV I-Base £ _____ each month until further notice

Please debit my account number _____

Name of account (holder) _____ Bank sort code _____/_____/_____

Starting on _____/_____/_____ (DD/MM/YY)

Signature _____ Date _____/_____/_____ (DD/MM/YY)

To: Manager: (Bank name, branch and address)

_____

_____

Please complete the above and return to: HIV i-Base, 107 Maltings Place,169 Tower Bridge Road, London, SE1 3LJ

(Our bank details for donations: NatWest, Kings Cross Branch, 266 Pentonville Road, London N1 9NA.
Sort Code: 60-12-14. Account Number: 28007042)

**ONE-OFF DONATION**

I do not wish to make a regular donation at this time but enclose a one-off cheque in the sum of £ _____ .

**GIVE AS YOU EARN**

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

**REFUNDS FROM THE TAX MAN**

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.**

REG IN ENGLAND WALES WITH LIMITED LIABILITY REG NO 3962064 CHARITY REG 1081905

i-base

107 Maltings Place,169 Tower Bridge Road, London, SE1 3LJ
T: +44 (0) 20 7407 8488

# Orders and subscriptions

Please use this form to amend subscription details for HIV Treatment Bulletin and to order single or bulk copies of publications. All publications are free, but donations are always appreciated - please see the form on the previous page.

**Name** _____ **Position** _____

**Organisation** _____

**Address** _____

_____

**Telephone** _____ **Fax** _____

**e-mail** _____

☐ I would like to make a donation to i-Base - *Please see inside back page*

- **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**

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

**UK Guide To PrEP** *(June 2021): 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** *(August 2021): 8-page A5 leaflet* **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**