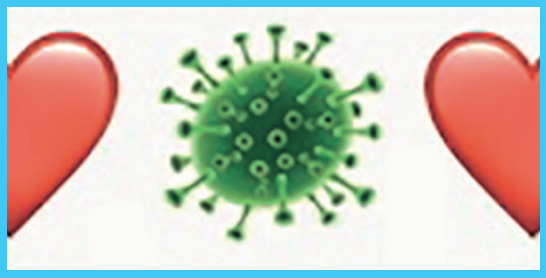
ISSN 1472-4863

HTB no. 10 – HIV and COVID-19 no. 7

hiv treatment bulletin (e)



AIDS 2020; HIV and COVID-19 supp. 7 (28 August 2020)

CONTENTS

EDITORIAL: HIV and COVID-19 issue 7 3
i-BASE APPEAL 3
- Please support i-Base with £5 or £10 a month...

CONFERENCE REPORTS 4
23rd International AIDS Conference (AIDS 2020), 6 – 10 July 2020, virtual meeting.
- Introduction: AIDS 2020 online
- Capsid inhibitor lenacapavir (GS-6207) allows for 6-monthly dosing
- Weight gain with integrase inhibitors and TAF: three reports from AIDS 2020
- Switching from efavirenz- to dolutegravir-based ART second-line achieved good rates of suppression: first results from the VISEND study
- Dolutegravir non-inferior to efavirenz at week 96 in the NAMSAL study but associated with substantial weight gain
- Paediatric dolutegravir dosing: AIDS 2020
- COVID-19 outcomes in HIV positive people in two large US cohorts
- AIDS 2020: virtual content now available free and on-demand

CONFERENCE REPORTS 11
2020 Pathways to an HIV cure, 4 – 5 July 2020, virtual conference
- Introduction and online presentations

ANTIRETROVIRALS 12
- ViiV resubmits cabotegravir plus rilpivirine long-acting injections (Cabenuva) to FDA for approval
- US FDA approves dolutegravir/lamivudine (Dovato) as switch option

HIV PREVENTION 13
- EMA supports use of dapivirine vaginal ring to prevent HIV in high-incidence countries

OTHER NEWS 14
- HIV organisations challenge government proposal to abolish Public Health England

ON THE WEB 15
- Modern ART - community video
- AVAC web interviews about new treatments to prevent HIV

HIV and COVID-19 SUPPLEMENT issue 7

COVID-19: HIV & COVID-19 COINFECTION 16
- HIV associated with worse outcomes from COVID-19 in UK ISARIC and OpenSAFELY databases

Contents continued inside...

Published by HIV i-Base

HTB no.10 – HIV and COVID-19 supplement ISSUE 7

Contents continued

- European and UK doctors review latest studies on HIV and COVID-19 coinfection

COVID-19: INVESTIGATIONAL TREATMENTS **19**
- Tocilizumab associated with better outcomes from COVID-19 in US study
- Famotidine associated with better outcomes from COVID-19
- INSIGHT network to study monoclonal antibody LY-CoV555 for COVID-19

COVID-19: VACCINE RESEARCH **21**
- US activists ensure people living with HIV can enrol in COVID-19 vaccine studies
- HIV organisations oppose active challenge COVID-19 vaccine studies
- AVAC webinar with Barney Graham: COVID-19 vacines: targets, timelines, efficacy and ethical issues
- Equitable access to vaccines against COVID-19

FUTURE MEETINGS **24**
- Conference listing 2020/21 - including new meeting changes

HTB CREDITS **25**

PUBLICATIONS & SERVICES FROM I-Base **26**

ORDER FORM **27**

EDITORIAL

This issue of HTB is again combined with a supplement on COVID-19.

We continue to report from the virtual AIDS 2020 conference: mainly focused on the continued data linking second-generation integrase inhibitors (dolutegravir and bictegravir) with weight gain, especially when combined with tenofovir alafenamide (TAF). This effect disproportionally affects women compared to men and global role-out of dolutegravir-based ART is now using fixed-dose combinations that use TDF rather than TAF.

AIDS 2020 also included data on 6-monthly dosing for the investigational capsid inhibitor lenacapavir, paediatric dosing of dolutegravir and two larger US studies on COVID-19 in HIV positive people.

Regulatory news includes that long-acting cabotegravir and rilpivirine injections (Cabenuva) have now been resubmitted to the US FDA and that the EMA has given a positive opinion on the efficacy and safety of the dapivirine vaginal ring as an HIV prevention option in high-incidence countries.

In the UK, the proposal to abolish Public Health England during the current COVID-19 crisis, with little notice or concern for its broad remit for other aspects of health, drew immediate

response from HIV organisations and is included here. As we went to press, wider community responses were also being organised that will be publicised next week.

Our coverage of COVID-19 includes two large cohorts that took different approaches to looking at risk of mortality in HIV positive people. While these studies need further analyses for potential confounding it is notable that they both report higher risks compared to HIV negative people.

The monthly review of COVID-19 studies from BHIVA, EACS and other European HIV groups still minimises the impact of HIV on COVID-19 outcomes, calling for more data.

Other COVID-19 news includes positive reports from use of tocilizumab and famotidine, with news of an upcoming study using monoclonal antibodies led by the INSIGHT research network.

An update on vaccine news includes the role of HIV activists in ensuring HIV positive people can enrol in vaccine studies and in cautioning against ethics of participants receiving challenge with active SARS-CoV-2, however altruistic this might seem.

Plus plenty to watch online: we highlight the ART in Africa video that i-Base was involved with and a range of webinars from AVAC including an interview on vaccine advances.

Finally, two more HIV medical conferences have been reorganised as virtual meetings, including both BHIVA and R4P, both of which were rescheduled from earlier in the year in the hope that an effective response to coronavirus might have allowed a return to face-to-face meetings.

Please continue to support these important events as for all the focus on COVID-19, developments in HIV still depend on these essential platforms.

i-Base 2020 appeal

i-base appeal 2020

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

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

Plus a BIG thank you all all supporters over the years including in the recent Solidarity2020 campaign.

More than 70 people bought one or more posters curated by Wolfgang Tillmans and the Between Bridges Foundation, to who we are also really grateful :)

CONFERENCE REPORTS

23rd International AIDS Conference (AIDS 2020)

6 – 10 July 2020, virtual meeting (was San Francisco and Santa Barbara)

The conference website is now available as an open access resource that no longer needs registration details.

Abstracts are now online, although the portal is still not always easy to navigate.

Many presentations are also online, but many also have withheld permission for these to be posted online. Perhaps these should not have been accepted for a virtual conference.

https://cattendee.abstractsonline.com/meeting/9289

The following reports are included in this issue of HTB.

- Capsid inhibitor lenacapavir (GS-6207) allows for 6-monthly dosing
- Weight gain with integrase inhibitors and TAF: three reports from AIDS 2020
- Switching from efavirenz- to dolutegravir-based ART second-line achieved good rates of suppression: first results from the VISEND study
- Dolutegravir non-inferior to efavirenz at week 96 in the NAMSAL study but associated with substantial weight gain
- Paediatric dolutegravir dosing: AIDS 2020
- COVID-19 outcomes in HIV positive people in two large US cohorts
- AIDS 2020: virtual content now available free and on-demand
- Pathways to an HIV cure: online presentations

AIDS 2020: ANTIRETROVIRALS

Capsid inhibitor lenacapavir (GS-6207) allows for 6-monthly dosing

Simon Collins, HIV i-Base

The potential for HIV drugs to allow very long-term ART, potentially with an injection every six months, was presented for a new compound called lenacapavir.

Previously know as GS-6207, lenacapavir is the first compound in a new class of HIV drugs called capsid inhibitors. A phase 1 monotherapy study reported mean viral load reductions of 2.2 log copies/mL after nine days. Although still only in early stages of development, a study presented at AIDS 2020 showed that a single injection produced drug levels that stayed above the minimum target for more than six months.

Slower drug absorption means that oral dosing will be needed for the first two weeks, but this is actually a safer approach in case of individual reactions to the drug.

This phase 1 pharmacokinetic study in 30 HIV negative volunteers after single administration of two subcutaneous doses (300 mg and 900 mg). Tmax was reached at 11 to 14 weeks post dose and therapeutic drug levels were maintained for six months using the 900 mg dose. Further studies will be based on 6-montly dosing.

No serious grade 3/4 adverse reactions or laboratory results were reported.

Reference

Begley R et al. Lenacapavir sustained delivery formulation supports 6-month dosing interval. AIDS 2020, 6–10 July 2020.

AIDS 2020: SIDE EFFECTS

Weight gain with integrase inhibitors and TAF: three reports from AIDS 2020

Polly Clayden, HIV i-Base

More presentations at AIDS 2020 showed weight gain among people with HIV treated with integrase strand inhibitors (INSTI) and tenofovir alafenamide (TAF).

We previously reported data showing weight increase from several African studies also presented at the conference. [1, 2, 3, 4]

First-line studies ADVANCE and NAMSAL showed persistent weight gain at week 96 – and that this was worse among women and participants also taking TAF. Second-line study VISEND showed greater weight gain with DTG and TAF compared to other ART regimens at 36 weeks. And the AFRICOS observational study reported weight gain among people receiving DTG-based ART.

As well as these, three other reports of weight gain with newer antiretrovirals at the conference were notable.

- An analysis of the US OPERA cohort showed switching to TAF from tenofovir disoproxil fumarate (TDF) to be associated with pronounced weight gain soon after switch, regardless of concurrent INSTI. [5]
- Centers for AIDS Research Network of Integrated Clinical Systems, another US cohort, showed short-term weight gain among people receiving first-line ART. People in this group receiving DTG or bictegravir (BIC) and TAF-based regimens six months after starting ART initiation gained more weight than those receiving other INSTI-based regimens. [6]
- And DTG was associated with an increase in the odds of becoming either overweight or obese in virally suppressed adolescents with HIV in Eswatini switching from an NNRTI. [7]

Tenofovir alafenamide

In the OPERA TDF to TAF switch evaluation, ART-experienced, virologically-suppressed (<200 copies/mL) participants in this large US cohort were included if they maintained all other antiretrovirals or switched to an INSTI.

Of 6919 included, 80% were men, approximately 40% were black and 25% Hispanic. They were approximately 45 years old and BMI was about 27 kg/m^2.

The TAF switches were grouped by regimen characteristics: maintained NNRTI (n=1454), maintained boosted (n=747), maintained INSTI (n=3288) and switched to INSTI (n=1430).

The groups were similar except those that stayed on a boosted PI and switched to an INSTI were closer to 50 years old.

Using data documented from up to 48 months before switch and up to 36 months after, the investigators modelled weight change before and after switching, adjusting for age, sex, race, (including age-sex, race-sex interactions), BMI, CD4 count, endocrine disorders and concurrent medications that can affect weight.

The referent for the model was a 45 year old non-black man with baseline BMI 27 kg/m^2, baseline CD4 count 700 cells/mm^3 without endocrine disorders or concurrent medications.

Adjusted models revealed modest weight gain over time with TDF before switch: 0.42 kg/year (95% CI 0.26 to 0.59). But there was a steep increase in weight in the 9 months from TAF switch, followed by more modest gains or plateau after 9 months: 2.64 kg (95% CI 2.26 to 3.01) and then 0.29 kg/year (95% CI: 0.08 to 0.51).

The effect with TAF switch was seen both among participants who maintained other antiretrovirals and those switching to an INSTI. The investigators reported no difference between INSTIs but noted that there was insufficient data for BIC after 9 months.

Seventy-eight per cent of participants who switched to an INSTI received elvitegravir (EVG); 12% switched to DTG and 9% to BIC.

The investigators concluded: “That this effect was observed across regimens suggests an independent effect of TAF on weight” .

Bictegravir

In the second US study, investigators evaluated ART-naive participants starting INSTI-based ART between 2012– 2019 across eight Centers for AIDS Research Network of Integrated Clinical Systems (CNICS) sites. [6]

Regimens included raltegravir (RAL), EVG, DTG, and BIC-based regimens with TDF, TAF or abacavir (ABC) and emtricitabine (FTC) or lamivudine (3TC).

The study compared weight gain with BIC vs other INSTI-based regimens within six months after starting ART using models adjusted for age, sex, race, hepatitis B and/or C virus coinfection, nadir CD4, smoking, diabetes, site, anti-psychotic medication use and regimen (including interaction between time and regimen).

There were 2080 participants included in the analyses. They were 84% male, 48% black, 34% white and 11% Hispanic. Age at baseline was 37 years and weight was 79 kg.

Those who began a DTG/TAF- or BIC/TAF-based regimen gained the most weight in the first six months after starting ART: 5.1 kg (95% CI: 3.0 to 7.2) and 4.6 kg (95% CI: 3.2 to 6.0), respectively.

Weight increase with DTG/TDF-based ART was 3.3 kg (2.3 to 4.3) and with other regimes 2.5 to 3 kg.

Although the p-values were not presented, the investigators noted that participants receiving DTG/TAF- or BIC/TAF-based ART gained significantly more weight than those on EVG/TDF- and EVG/TAF-based regimens. But this difference was not significant compared to participants receiving RAL/TDF-, DTG/TDF-, and DTG/ABC-based ART.

Dolutegravir in adolescents

The adolescent study looked at BMI measurements in a retrospective observational cohort of 605 virally suppressed (< 200 copies/mL) adolescents receiving care at Baylor Children's Foundation clinic in Mbabane Eswatini between one year before starting DTG and up to one year after. [7]

During the study period, 295 girls and 310 boys had an average of 6.4 visits; 30% were 10–12, 46% 12–16 and 24% 17–19 years of age. About three quarters of the group switched from efavirenz and the rest nevirapine; the majority (88%) received TDF/3TC backbone and the remainder ABC/3TC.

The investigators modelled rate of change in BMI and the odds of becoming obese or overweight, adjusting for sex, other antiretrovirals in the DTG regimen, previous ART and age at DTG switch.

Adjusted models showed adolescents receiving TDF/3TC/DTG had a BMI 0.66 kg/m2 greater than those receiving ABC/3TC/DTG, p<0.001. Girls BMI was 1.371 kg/m^2 greater than boys, p<0.001.

After switching to DTG, the odds of becoming overweight or obese increased by approximately 1% every day: OR 1.010, p=0.015.

But the investigators noted that this increase was largely among adolescents who were defined as thin at baseline and experienced greater BMI increase.

Further investigation into the risks of weight gain in adolescents receiving DTG-based ART with longer duration of treatment is needed, they explained.

They are planning future work in a larger sample of this cohort to estimate a predictive tool to identify adolescents who are most likely to become overweight or obese after being receiving DTG.

C O M M E N T S

There were a number of sessions, presentations and posters at the conference reporting weight gain – especially associated with DTG.

These presentations stood out as they demonstrate an independent effect of TAF and very rapid early weight gain with BIC as well as DTG (of note this second analysis was funded by ViiV, the originator manufacturer of DTG and the title suggests this was a BIC effect but the two agents seem to be very similar). Both these cohorts are at least 80% men and it is likely, from what we have seen in previous studies, that this weight increase could be worse in women, particularly black women.

The observation in adolescents is also important as weight change in children and adolescents is both harder to evaluate (as they are growing) and has been poorly documented to date. The investigators urge caution in interpreting these data and the need for further investigation both from their own cohort and other groups.

References

1. Clayden P. ADVANCE 96-week results: dolutegravir weight gain continues, especially in women and when used with TAF – no evidence of a plateau. HTB. 22 July 2020.
https://i-base.info/htb/38493
2. Clayden P. Dolutegravir non-inferior to efavirenz at week 96 in the NAMSAL study but associated with substantial weight gain. HTB. 20 August 2020.
https://i-base.info/htb/38778
3. Clayden P. Switching from efavirenz- to dolutegravir-based ART second-line achieved good rates of suppression: first results from the VISEND study. HTB. 20 August 2020.
https://i-base.info/htb/38780
4. Clayden P. Dolutegravir associated with weight gain in African ART programmes: findings from AFRICOS. HTB.
https://i-base.info/htb/38392

5. Mallon P et al. Weight gain before and after switch from TDF to TAF. AIDS 2020 virtual. 6–10 July 2020. Oral abstract OAB0604. https://cattendee.abstractsonline.com/meeting/9289/presentation/84 (abstract)
6. Ruderman SA et al. Early weight changes associated with bictegravir-based regimens compared to other integrase inhibitors following ART-initiation in ART-naive people living with HIV. AIDS 2020 virtual. 6–10 July 2020. Poster abstract PEC0450. https://cattendee.abstractsonline.com/meeting/9289/Presentation/1560 (poster)
7. Thivalapill N et al. Optimization to dolutegravir-based ART in a cohort of virally suppressed adolescents is associated with an increase in the rate of BMI change and odds of becoming overweight. AIDS 2020 virtual. 6–10 July 2020. Oral abstract OAB0106. https://cattendee.abstractsonline.com/meeting/9289/presentation/60 (abstract)

Switching from efavirenz- to dolutegravir-based ART second-line achieved good rates of suppression: first results from the VISEND study

Polly Clayden, HIV i-Base

In the VISEND study, looking at second-line ART, participants with viral load <1000 copies/mL at time of switch, receiving tenofovir alafenamide/emtricitabine/dolutegravir (TAFED) and tenofovir disoproxil fumarate/lamivudine/dolutegravir (TLD) showed similar efficacy, with low rates of virologic failure at week 36. [1]

Participants with >1,000 copies/mL at the time of switch showed slightly higher rates of suppression with TLD compared to other treatment arms. These data were shown at AIDS 2020.

In ART programmes in sub-Saharan Africa, people taking NNRTI-based first-line regimens are being switched to TLD, often without recent viral load results.

The ongoing VISEND study is looking at virologic outcomes among ART-treated adults switched from tenofovir disoproxil fumarate/lamivudine or emtricitabine/efavirenz (TLE or TEE) or less frequently nevirapine-containing regimens to TLD or TAFED with and without virologic suppression at the time of switch. There was no resistance testing before switching.

Participants with viral load <1,000 copies/mL were randomised to either TLD or TAFED: arm A. Those with viral >1,000 copies/mL were randomised to TLD, TAFED, zidovudine/lamivudine + ritonavir-boosted lopinavir or atazanavir (AZT/3TC + LPV/r or ATV/r): arm B.

Study visits are: baseline, week 4, 12, 24, 48, 72, 96 and 144. The primary treatment failure endpoint is week 24 and 48 viral load >50 copies/mL. The investigators reported week 36 efficacy (Observed data analysis) and safety data at the virtual conference.

Participants in arm A were approximately 42 years old at baseline and in arm B they were about 38 years. Over 60% of VISEND participants are women.

A total of 1,126 participants were randomised to arm A (n=419) and arm B (n=707). In arm A, the percentage of participants with viral load <50 copies/mL was 90% and 87% for TLD and TAFED. In arm B, the percentage with viral load <50 copies/mL was 78%, 72% and 70% for TLD, TAFED and LPV/r or ATV/r, respectively.

In arm A weight change was +1.8 kg and +0.4 kg for TAFED and TLD ($p<0.05$). In arm B this was +2.7 kg, +1.9 kg and +1.3 kg for TAFED, TLD and LPV/r or ATV/r, respectively ($p<0.05$ for differences TAFED and TLD vs LPV/r or ATV/r).

C O M M E N T

Switching to TLD and maintaining NRTI backbone second-line (as well as in people stable on TLE or TEE or with unknown viral load results) is becoming more common in low- and middle-income countries. The switch is partly supported by results from DAWNING, although this trial included viral load and resistance testing before switch. [2]

Currently, in the era of COVID-19, many treatment changes are happening without viral load testing (even in settings were this was usually standard) so these data from VISEND are reassuring.

Weight gain with dolutegravir, particularly in regimens with TAF has come to be expected.

References

1. Hill A et al. A randomized prospective study evaluating virologic outcomes among patients switching with detectable and undetectable viral loads from efavirenz and nevirapine-based first line ART regimens to DTG regimens in Zambia. AIDS 2020 virtual. 6–10 July 2020. Poster abstract LBPEB07. https://cattendee.abstractsonline.com/meeting/9289/Presentation/3761
2. Clayden P. Dolutegravir outperforms lopinavir/ritonavir second-line: interim results from the DAWNING study. HTB. 10 August 2017. https://i-base.info/htb/32241

Dolutegravir non-inferior to efavirenz at week 96 in the NAMSAL study but associated with substantial weight gain

Polly Clayden, HIV i-Base

Week 96 results from NAMSAL confirmed non-inferior efficacy of dolutegravir (DTG)- vs efavirenz (EFV)-based ART reported at week 48 and no emergence of DTG resistance. [1]

Virological suppression remained lower in participants with a high baseline viral load (across both study arms). There was continuous weight gain in the DTG arm.

These results were presented at AIDS 2020.

NAMSAL (ANRS 12313) is a phase 3 randomised, open label, multicentre study conducted at three sites in Yaoundé, Cameroon. ART-naive adults with viral load >1000 copies/mL were randomised to DTG 50 mg or EFV 400 mg once daily, both with tenofovir disoproxil fumarate (TDF)/lamivudine (3TC).

The primary endpoint was the proportion of participants with <50 copies/mL at week 48 and week 96 (10% non-inferiority margin). Week 48 data showing non-inferiority of DTG were reported previously. [2] At this timepoint a notably fewer participants with >100,000 copies/mL at baseline achieved viral suppression <50 copies/mL compared with those with <100,000 copies/mL.

A total of 613 participants were randomised, received at least one dose of study drug and were included in the ITT analysis: 310 DTG arm and 303 EFV 400 mg arm.

Participants were a median of 36 years old, 68% were women and baseline BMI was 23 kg/m^2. There were no differences between the treatment arms.

At week 96, the proportion of participants with viral load <50 copies/mL was 73.9% (229/310) and 72.3% (219/303) respectively: difference 1.6% (95% CI -5.4 to 8.6), p=0.66.

The differences in suppression observed at week 48, when stratified by viral load, persisted.

Among participants with <100,000 copies/mL at baseline, 80.6% (83/103) in the DTG arm and 82.5% (85/105) in the EFV 400 mg arm achieved viral suppression, compared to 70.5% (146/207) and 67% (134/200) of those in the respective arms with baseline viral load >100,000 copies/mL.

For participants with baseline viral load >500,000 copies these respective proportions were 66.7% (62/93) and 70.5% (67/95) in the DTG and EFV 400 arms.

At week 48, 15 participants in the EFV 400 mg and none in the DTG arm had NNRTI and NRTI resistance. By week 96, a further six participants had developed resistance. Of these three participants in the DTG arm had been switched to EFV 400 mg following the 2018 WHO safety alert on periconception DTG.

Weight gain observed at week 48 persisted. At week 96 this increase was 6.7 kg in the DTG arm and 4.2 kg in the EFV arm, p<0.001.

By week 96, weight gain >10% occurred in 45% of participants in the DTG arm (increasing from 38% at week 48) and 33% (from 29%) among those in the EFV arm, p=0.004. Obesity incidence was 22% and 16% in the respective arms. Weight gain was more pronounced in women than men.

There were 58 (19%) and 46 (15%) adverse events reported in the DTG and EFV arms, respectively.

Among the 404 women receiving ART in the study there were 62 pregnancies: 27 and 35 in the DTG and EFV arms, respectively. Fourteen pregnancies were ongoing at the time of analysis. There was no vertical transmission among the 26 live births.

The investigators concluded that these data confirm the non-inferiority of DTG vs EFV but DTG is associated with substantial and continuous weight gain.

Reference

1. Kouanfack C et al. Dolutegravir- versus low-dose Efavirenz-based regimen for the initial treatment of HIV-1 infection in Cameroon: Week 96 results of the ANRS 12313 – NAMSAL trial. AIDS 2020 virtual. 6–10 July 2020. Oral abstract OAB0402. https://cattendee.abstractsonline.com/meeting/9289/presentation/791
2. Clayden P. Dolutegravir non-inferior to low dose efavirenz in real-life African study conducted in Cameroon. HTB. 13 November 2020. https://i-base.info/htb/35235

AIDS 2020: COVID-19

COVID-19 outcomes in HIV positive people in two large US cohorts

Simon Collins, HIV i-Base

Several cohorts reported on COVID-19 data in HIV positive people at AIDS 2020.

The largest of these was from the US Veterans Ageing Cohort Study (VACS). This is an open cohort of HIV positive veterans matched (1:2) to a control group by age, race, sex and clinic site. Laboratory results for COVID-19 were linked to demographics and HIV clinical history records to look for associations with severity of COVID-19. [1]

Among more than 107,000 VACS participants (30,948 HIV positive, 76,618 HIV negative), 8.4% vs 6.5% tested for COVID-19. Over 16 weeks, similar percentages of tests were positive: 253 (9.7%) vs 504 (10.1%) in the positive vs negative groups [OR]: 1.05, 95% CI: 0.89 to 1.24).

Irrespective of HIV status, higher rates of COVID-19 were seen in black (aOR 1.70, 95% CI: 1.41 to 2.05) and Hispanic (aOR 1.43, 95% CI: 1.06 to 1.92) participants compared to white participants.

Risk of more severe outcomes were also similar in both the positive and negative groups: hospitalisation (34% vs 35%), ICU admission (14% vs 15%), intubation (6.3% vs 7.9%) and death (9.5% vs 11%); HR approximately 1.0, with confidence intervals all crossing 1.0.

The study concluded that future investigation was planned for potential linkages between antiretroviral treatment and CD4 count with COVID-19 severity and progression.

A second study compared COVID-19 outcomes in 4600 participants hospitalised in the Bronx, New York. Although this was a late-breaking oral presentation, only the abstract is still available online. [2]

This was a retrospective cohort study of 4,662 PCR positive patients hospitalised at a single centre between 10 March and 11 May 2020, of whom 77 (1.7%) were HIV positive. Most recent CD4 was <200, 200-499 and >500 cells/mm^3 in 16%, 44% and 40% respectively and 83% had viral load <40 copies/mL.

Outcomes were similar: length of stay (median 5 days, IQR: 3 to 9), 13% (10/77) vs 14% (634/4585) were intubated and 38% vs 41% developed chronic kidney disease.

In this study, surprisingly, higher CD4 counts were linked to intubation and all cases of intubation were in people with undetectable viral load.

Another retrospective US study presented outcomes of 93 HIV positive people with COVID-19 who presented to five emergency departments in NYC from 2 March to 15 April 2020. Of these, 72/93 were hospitalised, 53/72 recovered and 19/72 died. [3]

Median age was 58 (IQR: 52 to 65), 25% were women and 3% were transgender. Approximately 40% were black, 22% white and 36% unknown, with 31% Hispanic/Latinx.

Various levels of HIV history in this cohort included median duration of HIV 20 years (IQR: 15 to 26) (n=57), nadir CD4 320 (IQR: 139 to 490) (n=81), recent CD4 554 (IQR: 339 to 752) (n=64), undetectable viral load 83% (n=68) and 70% used ART with either TDF or TAF (n=89).

On presentation, participants showed significant lymphopenia (compared to previous CD4 count) for both absolute lymphocyte counts and CD4 T cell (both p<0.0001) and CD4% (p-0.0012). Inflammation markers (CRP, fibrinogen and d-Dimer) were also elevated (above the upper limit of normal in 100%, 84% and 98% respectively). In a subset of participants with additional samples, IL-6, IL-8 and TNF-a were also significantly elevated at presentation.

Although presenting CD4 counts were not associated with higher mortality (p=0.12), both nadir and final total lymphocyte count were (p=0.0005 and 0.002, respectively). Mortality was associated with higher inflammation markers but not with age, sex, BMI or HIV history (CD4, viral load or ART). This included a conclusion that HIV positive people on effective ART with high CD4 counts are still at risk of serious COVID-19.

Some of these results were previously published in JID. [4]

References

1. Park LS et al. COVID-19 in the largest US HIV cohort. AIDS 2020, 6 - 10 July. Late-breaking poster LBPE023. https://cattendee.abstractsonline.com/meeting/9289/presentation/3924
2. Patel VV et al. Clinical outcomes by HIV serostatus, CD4 count, and viral suppression among people hospitalized with COVID-19 in the Bronx, New York. AIDS 2020, 6 - 10 July. Oral late breaking abstract OABLB0102. https://cattendee.abstractsonline.com/meeting/9289/presentation/3501
3. Ho JH et al. Immunologic characteristics of acute COVID-19 in people with HIV. AIDS 2020, 6 - 10 July. Oral late breaking abstract OABLB0104. https://cattendee.abstractsonline.com/meeting/9289/presentation/3502

4. Ho JH et al. Clinical Outcomes and Immunologic Characteristics of Coronavirus Disease 2019 in People With Human Immunodeficiency Virus. JID, jiaa380. DOI: 10.1093/infdis/jiaa380 (30 June 2020).
https://academic.oup.com/jid/advance-article/doi/10.1093/infdis/jiaa380/5864898

AIDS 2020: PAEDIATRICS

Paediatric dolutegravir dosing: AIDS 2020

Polly Clayden, HIV i-Base

Matching paediatric pharmacokinetic (PK) exposures to those in adults works well for dose finding of dolutegravir (DTG)-containing formulations, despite higher variability in paediatric exposures. [1] These data from IMPAACT 1093 were presented at AIDS 2020.

The approval of antiretroviral dosing in children mostly depends on matching adult PK exposure parameters. But, higher variability in paediatric exposures suggests that efficacy cannot be assumed to be identical to that in adults.

IMPAACT P1093 is a phase 1/2, open-label PK and safety study.

The investigators evaluated the relationship between DTG exposure and virologic response in children. To do this they modelled the probability of viral load 50 or <400 copies/mL at weeks 4, 24 and 48 as associated with DTG exposure (C24, Cavg or AUC0-24) based on sampling between days 5–10, weeks 4, 12 and 24.

Covariates included baseline viral load, CD4 count, CDC HIV infection stage and baseline viral load >100,000 copies/mL.

At weeks 4, 24 and 48, there were 143, 135 and 112 viral load measurements available, respectively.

The investigators found DTG exposure parameters (C24, AUC0-24 and Cavg) gave a wide range of exposures which were not predictive of viral response within the dose ranges tested.

They suggested that the doses tested maintained exposures near maximum drug effect and added that this might also be because of the small sample size for each dose and high PK variability.

Baseline VL >100,000 copies/mL was a significant predictor of response and associated with a lower probability of achieving <50 copies/mL (p<0.001).

“These results suggest that matching paediatric PK exposure parameters to those in adults is a reasonable approach for dose determination of DTG-containing formulations”, they concluded.

comment

Data from IMPAACT P1093 on safety and PK (as well as two weight-band-based PK substudies of the PENTA ODYSSEY trial) informed the recent FDA approval of 10 mg tablets and 5 mg paediatric tablets for oral suspension. [2]

This approval gives more antiretroviral options to infants and young children – a woefully underserved population.

A generic 10 mg scored, dispersible formulation of DTG, to simplify weight-band dosing, is currently under review by the FDA (with approval expected by the end of the year) and another version close behind.

References

1. Singh R et al. Plasma exposure-viral load response analysis for dolutegravir in children with HIV-1: results from IMPAACT P1093. AIDS 2020 virtual. 6–10 July 2020. Oral abstract OAB0706.
https://cattendee.abstractsonline.com/meeting/9289/presentation/91 (abstract)
2. Clayden P. FDA approves dolutegravir formulations to treat infants and young children. HTB. 26 June 2020.
https://i-base.info/htb/38222

AIDS 2020: ONLINE RESOURCES

AIDS 2020: virtual content now available free and on-demand

IAS press release

The AIDS 2020 website is now open access for all sessions from the 23rd International AIDS Conference (AIDS 2020: Virtual).

https://cattendee.abstractsonline.com/meeting/9289

This includes:

- **12 prime sessions** spotlighting abstracts on advancements in HIV prevention, treatment and the search for a cure.
- **70+ satellite sessions** organised by IAS and global partners covering topics from mental health and HIV to global targets as well as experiences of transgender communities.
- **100+ on-demand sessions**, including symposia and abstract-driven sessions on diverse subjects including decriminalisation of HIV, gender identity, ageing with HIV and women-powered solutions.
- **10 pre-conferences** including the IAS Towards an HIV Cure pre-conference, the Latina Forum in HIV and a number of events exploring the effects of the COVID-19 pandemic on HIV programmes and research.
- **1800+ e-Posters** spanning biomedical, policy and programme insights.
- **Global Village sessions** exploring the experiences of young people**,** sex workers, rural women, and the next generation of HIV researchers, among other communities.

CONFERENCE REPORTS

Pathways to an HIV cure: online presentations

4 – 5 July 2020, virtual conference

The excellent annual IAS community cure workshop was also held as a virtual meeting this year

Presentations are available online using the following links.

Opening session and advancing the HIV cure field and debunking myths and misconceptions

https://cattendee.abstractsonline.com/meeting/9289/session/192

Challenges of clinical trials in cure

https://cattendee.abstractsonline.com/meeting/9289/session/227

Expanding the research pool for HIV cure

https://cattendee.abstractsonline.com/meeting/9289/session/226

Gene therapy vs. immunotherapy: which is more likely to work?

https://cattendee.abstractsonline.com/meeting/9289/session/191

Coming up next in the cure field & Closing Session

https://cattendee.abstractsonline.com/meeting/9289/session/195

HIV: ANTIRETROVIRALS

ViiV resubmits cabotegravir plus rilpivirine long-acting injections (Cabenuva) to FDA for approval

Simon Collins, HIV i-Base

On 29 July 2020, a press statement from GSK included information that the long-acting formulation of cabotegravir plus rilpivirine injections (CAB/RPV-LA) have been resubmitted to the US FDA. A decision on approval is expected in early 2021. [1]

The application for the first injectable HIV combination was expected to be decided last December, but outstanding questions relating to manufacturing delayed this decision. [2, 3]

The application includes safety and efficacy data from the phase 3 ATLAS and FLAIR studies that have already reported. This is for monthly injections, rather than two-monthly injections used in the ATLAS-2M study and reported at CROI 2020. [4]

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 Healthcare with the trade name Cabenuva.

C O M M E N T

It is good that a regulatory decision is closer given the high expectation among HIV positive people for an alternative to daily tablets. Access though in many countries will be dependent on price.

Although CAB/RPV-LA was approved in Canada in March 2020, it is not expected to be available through the public health system until September, when a price will also hopefully be announced. [5]

Several studies at AIDS 2020 also reported on the challenges for health systems in different settings to adapt to this new way of delivering ART and on results from a small expanded access programme. [6, 7, 8, 9]

The same press release also reported that development of the entry inhibitor combinectin in early stage development (GSK '934) has been ended due to "portfolio prioritisation". [1]

References

1. GSK press release. Second quarter 2020 report. (29 July 2020).
https://www.gsk.com/media/6064/q2-2020-results-announcement.pdf (PDF)
2. FDA decision on long-acting cabotegravir/rilpivirine (Cabenuva) injections delayed due to scale-up manufacturing problems. HTB (29 January 2020).
https://i-base.info/htb/37064
3. 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
4. Long-acting cabotegravir and rilpivirine injections support two-monthly dosing. HTB (12 March 2020).
https://i-base.info/htb/37301
5. ViiV Healthcare press statement. ViiV Healthcare announces first global regulatory approval of CABENUVA; the first complete, long-acting, regimen for the treatment of HIV. (20 March 2020).
https://viivhealthcare.com/en-gb/media/press-releases/2020/march/viiv-healthcare-announces-first-global-regulatory-approval-of-ca
6. Czarnogorski M et al. Perceived implementation barriers decrease during initial stages of the first implementation science hybrid III study (CUSTOMIZE) of cabotegravir and rilpivirine long-acting (CAB+RPV LA) in US healthcare settings: Healthcare team perspective.AIDS 2020 virtual, Late-breaker poster LEPEE42.
https://cattendee.abstractsonline.com/meeting/9289/Presentation/3781
7. Delany-Moretlwe S et al. Long acting cabotegravir (CAB LA): Planning for success across global at-risk populations. AIDS 2020 virtual, Late-breaker poster PEB0263.
https://cattendee.abstractsonline.com/meeting/9289/Presentation/1006708
8. D'Amico R et al. Compassionate use of long acting (LA) cabotegravir (CAB) and rilpivirine (RPV) for patients in need of parenteral antiretroviral therapy. AIDS 2020 virtual, Poster abstract PEB0263.
https://cattendee.abstractsonline.com/meeting/9289/Presentation/1319
9. Odongpiny EL et al. Willingness to use injectable antiretroviral therapy (ART) among women who disengage from prevention of mother-to-child transmission programmes in Uganda. AIDS 2020 virtual, Poster abstract PEB0262.
https://cattendee.abstractsonline.com/meeting/9289/Presentation/1399
10. Kerrigan D et al. Feasibility of implementing long-acting injectable anti-retroviral therapy to treat HIV: A survey of health providers from the 13 countries participating in the ATLAS-2M trial. AIDS 2020 virtual, Poster abstract PEB0260.
https://cattendee.abstractsonline.com/meeting/9289/Presentation/1375

US FDA approves dolutegravir/lamivudine (Dovato) as switch option

Simon Collins, HIV i-Base

On 6 August 2020, the US FDA extended the indication for the two-drug fixed dose combination of dolutegravir/lamivudine (DTG/3TC) to include use as a switch combination in people for people stable on other treatment. [1]

DTG/3TC was initially only approved by the FDA in April 2019 as first-line antiretroviral treatment (ART).

The new use as a switch option is restricted to people who have an undetectable viral load on their current ART, and who do not have a history of treatment failure or resistance to either drug.

In Europe, DTG/3TC is already approved as both first-line ART and as a switch option so long as there is no resistance to either drug.

Dolutegravir/3TC is manufactured by ViiV Healthcare and is marketed with the tradename Dovato.

For full details see the full product characteristics. [2]

Reference

ViiV press release. ViiV Healthcare announces FDA approval of an expanded indication for Dovato (dolutegravir/lamivudine), a complete two-drug regimen for virologically suppressed adults with HIV-1. (6 August 2020).

EMA extends indication for darunavir/r to include adolescents >12 years

EMA monthly review

On 23 July 2020, the Committee for Medicinal Products for Human Use (CHMP) recommended extending the indication for daruavir/r to adolescents age 12 and older who weigh >40 kg.

For full details please see the updated summary of product characteristics.

Darunavir/r is marketed by Janssen-Cilag with the trade name Prezista.

Reference

EMA. Prezista.

https://www.ema.europa.eu/en/medicines/human/summaries-opinion/prezista

HIV PREVENTION

EMA supports use of dapivirine vaginal ring to prevent HIV in high-incidence countries

Simon Collins, HIV i-Base

On 24 July 2020, the EMA adopted a positive opinion for the safety and efficacy of a dapivirine vaginal ring to be used to protect against HIV.

This was only for use in high incidence countries though, rather than within the EU.

Efficacy data reported a 35% reduction in HIV rates compared to placebo but as with other prevention studies, higher protection was reported with good adherence.

The ring contains 25 mg of dapivirine and lasts for one month.

Reference

EMA. Vaginal ring to reduce the risk of HIV infection for women in non-EU countries with high disease burden. (24 July 2020).

https://www.ema.europa.eu/en/news/vaginal-ring-reduce-risk-hiv-infection-women-non-eu-countries-high-disease-burden

HIV: OTHER NEWS

HIV organisations challenge government proposal to abolish Public Health England

Simon Collins, HIV i-Base

On 18 August 2020, the UK Government announcement proposing to close and/or merge Public Health England (PHE) with NHS Test and Trace and the Joint Biosecurity Centre (JBC) under a single leadership. [1]

This proposal is likely to further increase political accountability and reduce any independent remit for public health that marked the move from Health Protection England to PHE in 2013. The announcement only mentions COVID-19, with no reference to other work of PHE.

The Independent SAGE issued a press release objecting to these "hasty and far reaching changes" that were developed without transparency in the middle of a public health crisis. [2]

Several leading UK HIV associations issued the following statement below. [3]

Joint response to the announcement of the National Institute for Health Protection and the future of public health

Following today's announcement regarding the National Institute for Health Protection, and the implications for the future of public health, five of the nation's leading HIV and sexual health organisations have issued a joint response.

The Secretary of State's speech today leaves us with more questions than answers.

Public Health England (PHE) is responsible for far more than its scientific work – it plays a significant role in the response to HIV, sexual health and reproductive health and has driven innovative national health improvement efforts. Today's announcement provides no clarity on the future of this important health improvement function and we are concerned that structural changes could risk a reversal of the progress that has been made to date.

We also need urgent clarity on the future home of the world-leading PHE HIV and sexual health epidemiology and surveillance work that has underpinned our national efforts in tackling HIV and sexually transmitted infections (STI's) and delivering care to vulnerable population groups at this crucial moment in the fight against HIV and the delivery of better sexual health in England.

At this juncture a kneejerk restructure of the public health system which is non-transparent, ill-thought through and leads to more fragmentation in accountability structures risks holding us back.

We know from past reforms that any sudden structural changes by government can result in poorer outcomes and risk leaving key policy areas falling through the cracks. Experience has shown us that any new agencies must to be free of politics and be science and expert led.

Any changes to PHE must also protect the prevention and policy work that it currently leads in HIV, sexual health and reproductive health and ensure that there is no backtracking, or slowing down of existing commitments, particularly:

- To end new HIV transmissions by 2030 in England.
- To deliver a national PrEP programme.
- To consider and act on the recommendations of the independent HIV Commission.
- To improve access to contraception including LARC.
- To oversee the development of a much needed new national sexual and reproductive health strategy.

The announcement made today focuses on "new" and "external" health threats whilst not acknowledging the public health emergencies that already exist in the UK. While attention has rightly been given to the ongoing COVID-19 pandemic, focus must not be lost in tackling longstanding HIV and STI infection rates and reversing sexual health inequalities.

It is not acceptable that these changes are being proposed in a vacuum. All changes in regard to the new National Institute for Health Protection must be fully consulted on, which includes a meaningful conversation with charities, community organisations and healthcare professionals in the HIV and sexual health sectors, to ensure that there is no harmful impact.

We urge the Government to think carefully before major changes to PHE are enacted. Any change must strengthen the national action around public health including sexual health and HIV. National accountability must be transparent, and it is

essential that PHE, or its successor, is provided with the power to drive change and improvements to continue to make progress on HIV and tackle sexual ill-health.

References

1. gov.uk. Government creates new National Institute for Health Protection. (18 August 2020). https://www.gov.uk/government/news/government-creates-new-national-institute-for-health-protection
2. Independent SAGE. Press release on abolition of Public Health England. (16 August 2020). https://www.independentsage.org/press-release-on-abolition-of-public-health-england-16-august-2020
3. THT, NAT, British HIV Association (BHIVA), British Association for Sexual Health and HIV (BASHH), the UK Community Advisory Board (UK-CAB) HIV treatment advocates network. HIV organisations challenge government proposal to abolish Public Health England. (18 August 2020).

ON THE WEB

Modern ART - community video

Treatment Action Campaign (TAC), African Community Advisory Board (AfroCAB), HIV i-Base and UNITAID

The 30-minute video that was included in the AIDS 2020 virtual conferences includes interviews, live clips from workshops, printed resources and features a new App.

It shows community engagement with science, the roll out of new antiretrovirals and the understanding of benefits and risks of ART in the community.

https://cattendee.abstractsonline.com/meeting/9289/Session/612

AVAC web interviews about new treatments to prevent HIV

A series of webinars from AVAC relating to research into new ways to prevent HIV infection.

A conversation about long-acting PrEP for cisgender women

Conversation between Sinead Delany-Moretlwe, HPTN 084 Study Chair, & Awelani Neluonde, CAB Member

https://www.youtube.com/watch?v=Y9J3cmm4gck&t=1497s

A conversation about long-acting PrEP for MSM & transgender women

Conversation between Raphael Landovitz, UCLA and HPTN 083 Study Chair, and Jessica Salzwedel, AVAC

https://www.youtube.com/watch?v=TYy-pbyTiyY

A look at the broadly neutralizing antibody pipeline: what happens after AMP results?

Led by Devin Sok & Olayinka Fagbayi, IAVI

https://www.youtube.com/watch?v=bwcolBqk4aw

A conversation with advocates on preparing for AMP trial results

Led by Shelly Karuna, Fred Hutch Cancer Research Center and HVTN

https://www.youtube.com/watch?v=Utio67vzCv0

A conversation about HIV cure research

Led by Thumbi Ndung'u, Africa Health Research Institute

https://www.youtube.com/watch?v=QuTb4TYwVCY

Do Africans need COVID-19 research? A conversation with advocates and researchers

Moderated by Ntando Yola, APHA & Nandsile Luthuli, AVAC

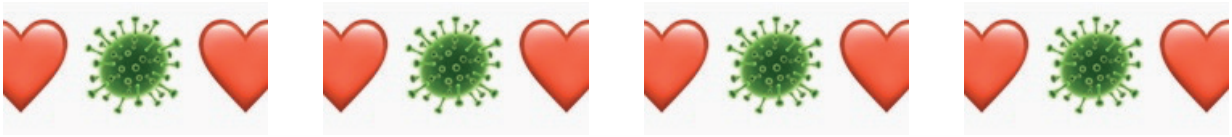
https://www.youtube.com/watch?v=A4C3W-FrUBU

Advocates reflect on the latest UNAIDS report: What does it mean for research and access?

Conversation between Micheal Ighodaro & Maureen Luba of AVAC with Rev. Rob Newells, AIDS Project of the East

https://youtu.be/keTR_reLJ-g

HTB SUPPLEMENT ON COVID-19: Issue 7



COVID-19: HIV and COVID-19 COINFECTION

HIV associated with worse outcomes from COVID-19 in UK ISARIC and OpenSAFELY databases

Simon Collins, HIV i-Base

Two UK studies, both published online ahead of peer review in the same week have reported worse outcomes from COVID-19 in HIV positive people compared to HIV negative general population. [1, 4]

Both have limited data on HIV history including details on ART, CD4 count and viral load, which for HIV-related research are essential.

Also, while one of the studies has been included as evidence for the UK Scientific Advisory Group for Emergencies (SAGE) the other prompted a statement from BHIVA and several community groups that cautioned the results ahead of peer review. [3, 6]

UK ISARIC database in people hospitalised with COVID-19

A UK cohort study based on one of the national COVID-19 databases has reported worse outcomes for HIV positive people compared to HIV negative people in the general population hospitalised with COVID-19. [1]

This was in an analysis that adjusted for baseline demographics, HIV and COVID-19 factors (age, gender, ethnicity), a series of 10 co-morbidities, whether the SARS-CoV-2 infection was acquired while already in hospital, and severity of disease at time of admission (to account for the fact that the decision to admit into hospital may be increased in someone known to have HIV).

The study was prompted by an early concern about the lack of data on HIV and COVID-19, including the lack of routine inclusion of HIV status on hospitalisation. Also, that early reports were generally case studies and very small cohorts. Funders included NIHR, the MRC, Wellcome and Public Health England.

The main ISARIC cohort was started on 17 January 2020 and data was included until cut-off of 18 June for this analysis, with primary outcome of cumulative mortality at day-28. [2] HIV researchers collaborated with the ISARIC group from March 2020.

The analysis included records from 47,539 patients who were hospitalised with laboratory confirmed (or highly likely) COVID-19 from 207 centres across the UK enrolled into the ISARIC CCP-UK study. Of these, 115 (0.24%) were confirmed HIV positive and 103/115 (89%) had a record of antiretroviral therapy.

At baseline, HIV positive people were significantly younger [median age 55 (IQR: 49 to 61) vs 74 (IQR: 60 to 84) years; p<0.001), had a higher prevalence of obesity (18% vs 11%, p=0.03), and moderate/severe liver disease (5.4% vs 1.9%, p=0.008), higher lymphocyte counts (p<0.001) and C-reactive protein (p=0.02), and more systemic symptoms.

Other difference at baseline included black ethnicity (45% vs 3%), fewer comorbidities [median 1 (IQR: 0 to 2) vs 2 (IQR: 1 to 3)], and less cardiovascular disease (18% vs 32%) and dementia (2.7 to 16.8), all p<0.001)

Although cumulative mortality was non-significantly lower in the HIV group (25.2% vs 32.1%, p=0.12) in the initial analysis that did not take into consideration confounding factors, stratification for age revealed a higher mortality among HIV positive people aged below 60 years. There was no significant effect of either gender or ethnicity, and taking into account co-morbidities did not modify the estimates. After considering the severity of disease at presentation (as indicated by the needs for oxygen therapy), HIV positive people showed a 63% increased risk of mortality compared to the HIV negative group (aHR 1.63; 95%CI: 1.07 to 2.48; p=0.02).

In the HIV positive group, mortality was more common among who presented with more advanced disease (hypoxia: 75% vs 38%, p=0.001) with higher heart rate (p<0.001 and among people with obesity and diabetes with complications).

However, important factors about HIV history, including nadir and current CD4 cell count, viral load and history of complication were not routinely collected in the study. Use of ART was included but often without details. The study is currently connecting ISARIC data to HIV clinic records.

The study has been accepted as evidence by the UK Scientific Advisory Group for Emergencies. [3]

The study group also conducted a data review of HIV and COVID-19 coinfection studies that is currently in press.

UK OpenSAFELY primary care database

A second UK study, also published online ahead of peer review in the same week as the ISARIC study, also reported worse outcomes from COVID-19 in HIV positive people. [4]

This used the OpenSAFELY database that uses primary care medical records from GP surgeries linked to national death registrations in the UK from 1 February to 22 June 2020. Although this study is introduced as being "on behalf of the NHS" the research was not directly funded and OpenSAFELY was set up in response to COVID-19 by the medical journalist Ben Goldacre, working with NHS and other researchers.

OpenSAFELY contains the medical records of 17.3 million adults (approximately one-third of the UK population) of which 27,480 (0.16%) include a record of HIV positive status. The most significant baseline differences between the two groups included higher percentage of men (65% vs 50%), Black ethnicity (26% vs 1.9%), more social deprivation (ie 31% vs 19% in the most deprived category) and more chronic liver disease (3.4% vs 0.6%) in HIV positive vs negative groups respectively. By contrast, other factors, including median age [48 years (IQR: 40 to 55) vs 49 (IQR: 34 to 64)], BMI, smoking status and other comorbidities (diabetes, hypertension, asthma, heart disease, COPD, kidney disease and cancer etc) were broadly similar.

There were 25 (0.087%) vs 14,857 (0.038%) deaths in people with COVID-19 in the HIV positive vs negative groups respectively. After adjusting for age and sex, HIV was associated with a nearly 3-fold higher risk of death (HR 2.90, 95% CI: 1.96 to 4.30). This was reduced after further adjustment for deprivation, ethnicity, obesity, smoking, and comorbidities (HR 2.30, 95%CI: 1.55 to 3.41).

Black ethnicity had a greater association between HIV and COVID-19 death (HR 3.80, 95%CI: 2.15 to 6.74) compared with other ethnic groups (HR 1.64, 95%CI: 0.92 to 2.90), p-interaction=0.045.

Perhaps most surprisingly, and in contrast to other COVID-19 research, comorbidities did not have a strong association with poorer outcomes.

Although this study was based on a very large database the limitations of primary care records include under-reporting of HIV status and lack of any HIV-related history including ART status and CD4 and viral load history.

C O M M E N T

The ISARIC study is the largest UK cohort to date on HIV and COVID-19 coinfection and OpenSAFELY is the largest general population database to look at HIV.

Both studies show the importance of recording HIV status for all people hospitalised with COVID-19 and being able to adjust for demographic, HIV and COVID-19-related factors.

They still show the need for further research, which in a setting with electronic medical records should be readily possible.

A large study from South Africa, also reported an approximately 2-fold increased risk of mortality compared to the general population. Although it didn't adjust for TB, COVID-19 outcomes were not significantly different for people with viral suppression on ART. [5]

Similar to the South African study, these UK papers report that being HIV positive might increase the risk of mortality with COVID-19 compared to the general population. This is independent of gender or ethnicity and comorbidities including obesity and diabetes and the ISARIC results were especially in younger people (less than 60).

A joint statement from BHIVA and several HIV organisations (THT, NAT and NAM) highlighted additional concerns with the OpenSAFELY study. This included limitations with coding and HIV records in primary care records, missing data on weight and incorrect attribution of COVID-19 as a cause of death. [6]

BHIVA is also planning to collect data from all HIV clinics to investigate the risk of worse COVID-19 outcomes in people living with HIV.

Simon Collins is a community representative and co-author on the ISARIC paper.

References

1. Geretti AM et al. Outcomes of COVID-19 related hospitalisation among people with HIV in the ISARIC WHO Clinical Characterisation Protocol UK Protocol: prospective observational study. Pre peer review. DOI: 10.1101/2020.08.07.20170449. (11 August 2020).
   https://www.medrxiv.org/content/10.1101/2020.08.07.20170449v1
2. International Severe Acute Respiratory and Emerging Infection Cohort (ISARIC) clinical characterisation protocol (CCP).
   https://isaric.tghn.org (main website)
   https://isaric.tghn.org/UK-CCP
3. UK SAGE, papers for August 2020 meeting.
   https://www.gov.uk/government/collections/sage-meetings-august-2020
4. Bhaskaran K et al. HIV infection and COVID-19 death: population-based cohort analysis of UK primary care data and linked national death registrations within the OpenSAFELY platform. Pre peer review. DOI: 10.1101/2020.08.07.20169490v1. (7 August 2020).
   https://www.medrxiv.org/content/10.1101/2020.08.07.20169490v1
5. Clayden P. HIV positive people in South Africa at increased risk of dying from COVID-19: first data from country with high prevalence of HIV and TB. HTB (26 June 2020).
   Https://i-base.info/htb/38232
6. BHIVA and others. HIV and COVID-19: a statement on the Open SAFELY pre-print. (13 August 2020).
   https://www.bhiva.org/a-statement-on-the-Open-SAFELY-pre-print

European and UK doctors review latest studies on HIV and COVID-19 coinfection

BHIVA, DAIG (Germany), EACS, GESIDA (Spain) & the Polish Scientific AIDS Society

On 5 August 2020, a joint statement by leading European HIV medical organisations reviewed the most recent research on COVID-19, especially in relation to HIV coinfection and news on latest treatment.

These monthly references reviews compiled by leading doctors from BHIVA, DAIG (Germany), EACS, GESIDA (Spain) & the Polish Scientific AIDS Society includes essential editorial commentary on the studies covered.

COVID-19 & HIV

Case series of people living with HIV (PLWH) with COVID-19 have been published from China, Spain, Germany, Italy and the United States (1-15) with no clear evidence for a higher COVID-19 infection rate or different disease course in people with and without HIV. Of note, most case series of PLWH report a younger age in their study population than in HIV-negative hospitalised COVID-19 patients, but comparable rates of comorbidities.

In a cohort study from the United Kingdom a small potential increase in the risk of mortality among PLWH once hospitalised with COVID-19 was reported at the July 2020 BHIVA conference, albeit with no data around the risk of developing severe COVID-19 or hospitalisation among this cohort in the first place and no data on antiretroviral therapy (ART), viral load (VL) or CD4 count. [16]

More recently an analysis of risk factors for COVID-19 deaths in the Western Cape was presented at the virtual AIDS 2020 conference [17]. After adjusting for other risk factors, they found HIV increased a COVID-19 patient's death risk by a factor of 2.14 (95% CI 1.70 to 2.70), and active TB by a factor of 2.70 (95% CI 1.91.4.04). The larger prevalence of HIV in Africa permits study of higher participant numbers but there may be differences in baseline characteristics compared to populations from Western Europe or China with regard to other risk factors for mortality including age, concomitant comorbidities, obesity rate and socioeconomic status (the latter two were not captured in this data set)

Finally, in the Annals of Internal Medicine, Spanish researchers described the incidence of COVID-19 and risk of hospitalization among 77,590 PLWH receiving ART [18]. During a 3-month period, 236 PLWH were diagnosed with COVID-19, and 151 were hospitalized. The risk of hospitalization by NRTI treatment per 10,000 persons was lowest for TDF/FTC (10.5), while other NRTI strategies were similar (TAF/FTC 20.3, ABC/3TC 23.4, single or no NRTI 20.0) [14]; TDF/FTC recipients also had a lower overall incidence of infection and none died or were admitted to the intensive care unit. Noteworthy, PLWH remaining on TDF/FTC today are less likely to have some of the medical comorbidities associated with worse COVID-19 outcomes [19]. Older PLWH, in particular those with renal or cardiovascular disease, increasingly receive either TAF/FTC or just 3TC as NRTI backbone [19]. A recently published further analysis of the Spanish cohort suggests that confounding due to unmeasured clinical characteristics does not completely explain the association between TDF/FTC and a lower COVID-19 diagnosis and hospitalization [20]. Nevertheless, the somewhat diverse observations ranging from potentially improved outcome on TDF/FTC to two-fold increased mortality risk associated with HIV clearly underline the need for additional data from larger cohorts.

Current evidence indicates that the risk of severe COVID-19 illness increases with age, male gender and with certain chronic medical problems such as arterial hypertension, cardiovascular disease, chronic lung disease, obesity and

diabetes. Whether or not PLWH on treatment with a normal CD4 count and suppressed VL are at an increased risk of serious illness or death, many will have other conditions that increase their risk. Indeed, almost half PLWH in Europe are older than 50 years and chronic medical conditions, including cardiovascular and chronic lung disease, are more common in PLWH. As a risk factor for respiratory infections smoking cessation should be encouraged for all. Influenza and pneumococcal vaccinations should be kept up to date as recommended by BHIVA/EACS guidelines.

Despite the lack of evidence for an association between HIV surrogate markers and COVID-19 mortality in the Western Cape data, we continue to advise that immune suppression, indicated by a low CD4 (<200 cells/mm^3), or not receiving ART, should be considered a risk factor. Data in such PLWH is sparse as so far most COVID-19 patients with HIV have been on suppressive ART. For PLWH with low CD4 counts (<200 cells/mm^3), or who experience a CD4 decline during a COVID-19 infection, remember to initiate opportunistic infection (OI) prophylaxis. This is not aiming at preventing a more severe course of COVID-19 but rather complications through additional OIs. More information regarding recommendations for prophylaxis and treatment of specific opportunistic infections can be found in the BHIVA/EACS guidelines for HIV/AIDS.

The ongoing discussion about potential COVID-19 vertical transmission remains controversial. Although few case reports have claimed perinatal transmission several other large case series could not find any case of vertical transmission [21-25]. Pregnant women with critical COVID-19 who deliver during their disease course mostly deliver preterm via caesarean section [21]. Although the majority of mothers have been discharged without any major complications, severe maternal morbidity as a result of COVID-19 and perinatal deaths have been reported. Careful monitoring of pregnancies with COVID-19 and measures to prevent neonatal infection are warranted.

Existing national guidelines should be followed in terms of reducing risk for acquiring a COVID-19 infection and managing symptoms [26-29].

Source:

BHIVA, DAIG, EACS, GESIDA & Polish Scientific AIDS Society Statement on risk of COVID-19 for people living with HIV (PLWH). (5 August 2020).

https://www.bhiva.org/updated-BHIVA-DAIG-EACS-GESIDA-Polish-Scientific-AIDS-Society-statement-on-risk-of-COVID-19-for-PLWH

COVID-19: INVESTIGATIONAL TREATMENTS

Tocilizumab associated with better outcomes from COVID-19 in US study

Simon Collins, HIV i-Base

Another large observational cohort has reported positive results from using the anti-IL-6 monoclonal antibody tocilizumab to treat COVID 19. [1]

The rationale for benefit is related to high levels of IL-6 associated with the cytokine storm in late and more serious COVID-19. This study adds to growing evidence suggesting benefit including those previously reported in this bulletin. [2, 3]

The current study, published on 14 August 2020 in Lancet Rheumatology, was a retrospective cohort analysis from 13 hospitals in New Jersey, US.

Between 1 March and 22 April 2020 a total of 764 adults with COVID-19 hospitalised in the intensive care units and 210 (27%) of these used tocilizumab.

Significant baseline differences in people using tocilizumab included being younger: median age 62 years (IQR: 53 to 71) vs 68 years (IQR: 58 to 78); p=0.0003; more likely to be male (74% vs 63%, p=0.0037); and less likely to be in nursing home (5% vs 14%, p=0.0004). There were no significant differences in terms of comorbidities but a higher likelihood of using hydroxychloroquine or azithromycin.

A propensity score-matched population included 630 adults, 210 who received at least one infusion of tocilizumab and 420 who did not receive tocilizumab. Nearly everyone (206/210, 98%) received 400 mg flat dosing, two received 8 mg/kg, and two received other doses; 185 (88%) received one infusion and 25 (12%) received a second infusion.

Mortality was 57% (358/639) overall but in adjusted analysis was significantly lower in the tocilizumab group 102 (49%) vs 256 (61%): HR 0.64 (95% CI: 0.47 to 0.87); p=0·0040.

Median survival from time of admission was not reached for tocilizumab (95% CI 23 days to not reached) vs 19 days (16 to 26), with a hazard ratio 0.71 (95% CI: 0·56 to 0·89) p=0·0027.

These associations were similar in subgroups requiring mechanical ventilatory support and with baseline C-reactive protein of 15 mg/dL or higher.

C O M M E N T S

These results add to the growing number of studies that have reported potentially positive results with tocilizumab. Four earlier studies were reviewed in a recent earlier issue of HIV and COVID-19. [3]

Many other prospective studies are already ongoing, including the large UK RECOVERY study, using a randomised design. [4]

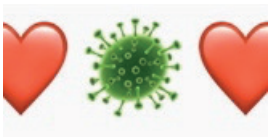
Based on limited success with all approaches based on monotherapy, combination approaches should be prioritised, with at least one study looking at tocilizumab plus remdesivir. [5]

References

1. Biran N et al. Tocilizumab among patients with COVID-19 in the intensive care unit: a multicentre observational study. The Lancet Rheumatology. DOI: 10.1016/S2665-9913(20)30277-0. (14 August 2020). https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913(20)30277-0/fulltext
2. Further positive reports from tocilizumab to treat COVID-19. HTB (22 July 2020). https://i-base.info/htb/38523
3. Potential for tocilizumab to treat moderate to severe COVID-19. HTB (14 May 2020). https://i-base.info/htb/37877
4. RECOVERY study http://www.recoverytrial.net
5. Tocilizumab and remdesivir in new dual therapy study. (1 June 2020). https://i-base.info/htb/38076

Famotidine associated with better outcomes from COVID-19

Simon Collins, HIV i-Base



Two studies have reported positive outcomes from COVID-19 in adults using the histamine-2 receptor antagonist famotidine.

The larger study included 1620 adults hospitalised with COVID-19 between 25 February and 13 April 2020 of whom 84 (5.1%) received famotidine. Home use of famotidine on admission was documented in 15% of those given famotidine group vs in 1% of those who were not (p=0.01). [1]

Overall, 28% of the famotidine group were dosed intravenously: 17% were 10 mg, 47% were 20 mg and 35% were 40 mg. Total median dose of 136 mg (63 to 233 mg) was given over a median of 5 days.

A total of 340 participants (21%) met the primary composite endpoint of death or intubation: 142 (8.8%) patients were intubated and 238 (15%) died.

In adjusted analyses, famotidine was independently associated with risk for death or intubation (adj. HR 0.42, 95% CI: 0.21 to 0.85) which remained after propensity score matching to further balance the covariables (HR: 0.43, 95%CI: 0.21 to 0.88).

This study also found no benefit of proton pump inhibitors or impact of famotidine in people hospitalised who did not have COVID-19.

A second more recent study also reported reduced mortality and intubation associated with famotidine. [2]

This was a retrospective analysis of 878 adults hospitalised with COVID-19 of whom 83 (9.5%) used famotidine. The control group were slightly younger (mean 63 vs 67 years, p=0.02) but propensity-matched for baseline demographics and comorbidities.

Famotidine was associated with decreased risk of in-hospital mortality (OR 0.37, 95%CI: 0.16 to 0.86, p=0.021) and combined death/intubation (OR 0.47, 95%CI: 0.23 to 0.96, p=0.040).

C O M M E N T

Although these associations are important enough to report and famotidine is safe and widely used, results from two phase 3 randomised studies are needed to demonstrate efficacy. [3. 4]

Reference

1. Freedberg DE et al. Famotidine Use Is Associated With Improved Clinical Outcomes in Hospitalized COVID-19 Patients: A Propensity Score Matched Retrospective Cohort Study. Gastroenterology, DOI: 10.1053/j.gastro.2020.05.053. (22 May 2020). https://www.sciencedirect.com/science/article/pii/S0016508520347065

2. Mather JF et al. Impact of famotidine use on clinical outcomes of hospitalised COVID-19 patients. American Journal of Gastroenterology. (14 August 2020).
https://journals.lww.com/ajg/Documents/AJG-20-2074_R1.pdf
3. Role of Famotidine in the Symptomatic Improvement of COVID-19 Patients.
https://clinicaltrials.gov/ct2/show/NCT04504240
4, Multi-site Adaptive Trials for COVID-19.
https://clinicaltrials.gov/ct2/show/NCT04370262

INSIGHT network to study monoclonal antibodies for COVID-19 including LY-CoV555

Simon Collins, HIV i-Base

On 4 August 2020 the US NIH announced a new study of a monoclonal antibody LY-CoV555 as a treatment for COVID-19, in a study run by the INSIGHT network (responsible for the SMART and START studies).

The ACTIV-3 study will use an adaptive two-stage phase 3 design that can be adapted to test additional experimental treatments at either stage 1 or stage 2.

If a treatment appears to be safe and effective in the initial stage, the investigational therapeutic proceeds to stage 2 testing, with more participants.

LY-CoV555 was isolated from an adult who recovered from COVID-19 and was discovered by Abcellera Biologics in collaboration with NIAIDs vaccine research centre and developed by Eli Lilly.

Stage 1 will randomise approximately 300 volunteers who have been hospitalised with mild to moderate COVID-19 with fewer than 13 days of symptoms to either active treatment or placebo. An additional 700 participants will be enrolled if the compound progresses to stage 2. Standard of care for all participants will also include remdesivir.

The use of a shared placebo group means that as new compounds are added, the chances for new participants to receive an active antibody treatment also increases.

Reference

NIH press release. NIH launches clinical trial to test antibody treatment in hospitalized COVID-19 patients. (4 August 2020).

https://www.nih.gov/news-events/news-releases/nih-launches-clinical-trial-test-antibody-treatment-hospitalized-covid-19-patients

COVID-19: VACCINE RESEARCH

US activists ensure people living with HIV can enrol in COVID-19 vaccine studies

Simon Collins, HIV i-Base

The last issue of HTB reported on the launch of large randomised placebo controlled phase 3 COVID-19 vaccine studies, that will be used to prove safety and efficacy of vaccine candidates that already have shown promising results in smaller phase 1 and 2 studies.

We reported this with an assumption that enrolment would be open to people living with HIV, certainly if on affective ART and without other complicated health issues. [1]

This expectation turned out to be wrong - at least for US studies. Although the Moderna vaccine was supported by US public funding and planned the phase 3 study using HIV research sites, the company ignored requests for actively allow HIV positive people to be enrolled.

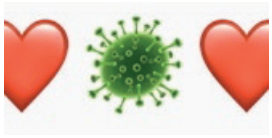
In response, a dozen high profile HIV organisations, led by Lynda Dee from AIDS Action Baltimore, engaged the leadership of the US National Institues of Health (NIH) and challenged Moderna. Exclusion from these key studies risk HIV positive people do not have insurance cover and access to the final vaccine if it proves to be effective.

The activist challenge was successful for both the Moderna and upcoming Pfizer studies and as a result, HIV positive people on effective ART are now to be included in these studies. [2, 3]

References
1. Vaccine candidates report phase 3 studies after early safety and immune responses in phase 1/2 studies. HTB (22 July 2020). https://i-base.info/htb/38589
2. Murphy T. Moderna reverses decision to exclude people with HIV from their COVID-19 vaccine trial. TheBody.com. (6 August 2020). https://www.thebody.com/article/joe-biden-strongest-option-to-end-hiv-epidemic
3. Guasco R. HIV activists win fight for includion in major COVID-19 vaccine trial. (10 August 2020). https://www.positivelyaware.com/articles/hiv-activists-win-fight-inclusion-major-covid-19-vaccine-trial

HIV organisations oppose active challenge COVID-19 vaccine studies

Simon Collins, HIV i-Base



Numerous HIV community groups recently circulated a statement against the use of active challenge studies on COVID-19 vaccine studies. [1]

This was in response to a proposal in an open letter from a group of prominent scientists to directly expose volunteers on COVID-19 vaccine studies to SARS-CoV-2. [2] This proposal is also being considered by the Oxford Vaccine Group and had been discussed several months earlier in a paper in JID. [3, 4]

For many community advocates, the lack of an effective treatment for COVID-19 makes the proposal to use active challenge unethical. Even in younger paritcipants at lower population risk, COVID-19 related fatalities would just be a factor of chance and study numbers. Serious reactions to COVID-19 are also increasingly associated with long-term complications.

Also, importantly, the number of regions where incidence of COVID-19 are sufficiently high to evaluate responses to candidate vaccines: challenge studies wouldn't generate faster or more effective vaccines against COVID-19.

Referencs
1. AVAC and TAG. Statement on Human Challenge Studies for COVID-19 Vaccine Development. (17 July 2020). https://www.avac.org/blog/statement-human-challenge-studies-covid
2. 1DaySooner. COVID-19 Human Challenge Trials. https://1daysooner.org/openletter
3. Coronavirus vaccine: Oxford team aim to start lab-controlled human trials. The Guardian. (16 July 2020). https://www.theguardian.com/science/2020/jul/16/coronavirus-vaccine-oxford-team-volunteers-lab-controlled-human-challenge-trial
4. Eyal N et al. Human challenge studies to accelerate coronavirus vaccine licensure. JID, 221(11);1752–1756. DOI: 10.1093/infdis/jiaa152. (31 March 2020). https://academic.oup.com/jid/article/221/11/1752/5814216

AVAC webinar with Barney Graham: COVID-19 vaccines: targets, timelines, efficacy and ethical issues

Simon Collins, HIV i-Base

An excellent webinar from AVAC on developments in COVID-19 vaccine research is now online featuring a talk by Barney Graham, Director of US NIH Vaccine Research Centre (VRC).

The talk reviews the rapid development timeline for COVID-19 vaccines, including the role played by HIV researchers and trial networks, and covers some of the recent research developments.

This includes an update on the rapid development of the mRNA-1273 vaccine developed by Moderna and the NIH that started in January 2020 with phase 1, 2 and 3 studies in March, May and July, respectively. The phase 3 study has already enrolled 14,000 of the projected 30,000 participants. Endpoints will be collected two weeks after the second dose but early efficacy results will depend on enrolling participants in high incidence geographical regions.

Efficacy is also discussed in terms of overlapping but different aims. For example, whether the primary aim is to reduce mortality in highest risk (elderly) groups or to reduce transmission among the general population. Research into candidate vaccines has already focused on generating immune responses with older ages, including in mice and NHP studies.

The webinar covers some ethical issues of research including early access to effective compounds for participants who received placebo in phase 3 studies, and that by implication this will delay long-term data from the loss of the control group.

Practical supply issues dependent on multiple companies to manufacture and supply any effective candidate and the balance between public/private collaborations are also discussed.

References

AVAC. Learning from Historic Vaccine Research & the Latest on the mRNA-1273 Candidate

https://www.avac.org/event/learning-historic-vaccine-research-latest-mrna-1273-candidate

https://www.youtube.com/watch?v=uXcA-mByGfw (YouTube webinar)

https://www.avac.org/sites/default/files/u81/AVAC_COVID19_vaccine_webinar_25_Aug2020_Dr_Barney_Graham.pdf (slides)

Equitable access to vaccines against COVID-19

Simon Collins, HIV i-Base

In response to the inevitable limited vaccine supply a US project supported by the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC) is posting a programme of webinars featuring presentations on access to successful vaccines. [1]

These are designed to help US policymakers and global health communities in planning for allocation of vaccines against COVID-19, but have relevance for wider viewing.

Co-Chaired by Helene Gayle several open meetings are already online.

The third meeting, held on 7 August 2020 included plans for distributing a vaccine to 300 million people in the US from January 2021 or earlier based on backing many approaches to vaccines already in large phase 3 studies (or about to start). These include mRNA vaccines (Moderna/NIH and Pfizer/BioNTech, non-replicating vectors (AstraZeneca/Oxford) and protein adjuvant (Novavox and Sanofi/GSK). Partners for a live attenuated vaccine have not yet been finalised.

This meeting included a presentation on WHO prioritisation and allocation of vaccines globally to low and middle-income countries. Another presentation looked at different prioritisation depend on whether aim is to reduce mortality or limit spread. Also models at vaccines where efficacy is lower for different age groups.

Reference

1. Committee on Equitable Allocation of Vaccine for the Novel Coronavirus
https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus
2. Committee on Equitable Allocation of Vaccine for the Novel Coronavirus: Committee Meeting 3. (10 August 2020).
https://www.nationalacademies.org/event/08-07-2020/committee-on-equitable-allocation-of-vaccine-for-the-novel-coronavirus-committee-meeting-3

COVID-19: 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 are now virtual including those that were rescheduled in the hope that COVID-19 restrictions would be relaxed.

New dates for workshops organised by Virology Education are at this link:

https://www.virology-education.com/covid0-19-update/

Community Reclaiming the Global Response (HIV 2020)

NOW VIRTUAL. (Was 5-7 July, Mexico City).

Now reprogrammed as a series of 2-hour zoom sessions between July and October 2020.

https://www.hiv2020.org/program (summary)

https://www.hiv2020.org/post/the-program-for-hiv2020-online-is-now-available

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

12 – 13 September 2020. NOW VIRTUAL.

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

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

28 – 30 September 2020. NOW VIRTUAL.

www.virology-education.com

11th International Workshop on HIV & Ageing (2020)

30 September – 2 October 2020. NOW VIRTUAL.

https://www.virology-education.com

HIV Glasgow Congress 2020

5 – 8 October 2020, Glasgow. NOW VIRTUAL

www.hivglasgow.org

International Workshop on HIV Paediatrics 2020

16 – 17 November 2020. NOW VIRTUAL

www.virology-education.com

26th Annual BHIVA Conference (BHIVA 2020)

22–24 November 2020 (rescheduled from April). NOW VIRTUAL

www.bhiva.org

International Conference on HIV Treatment, Pathogenesis, and Prevention Research in Resource-Limited Settings (INTEREST) 2020

1 – 4 December, Windhoek, Namibia (rescheduled from May)

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

HIV Research for Prevention (HIV R4P 2020)

27 – 28 January and 3 - 4 February 2021, Cape Town (reshedulled from October 2020). NOW VIRTUAL

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)

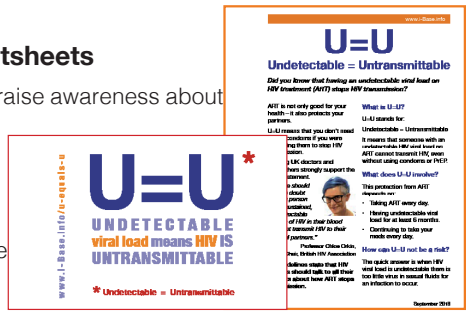
Pocket guides

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.

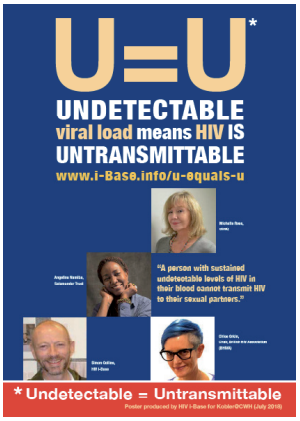
This project was developed with the Kobler Centre in London.

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.

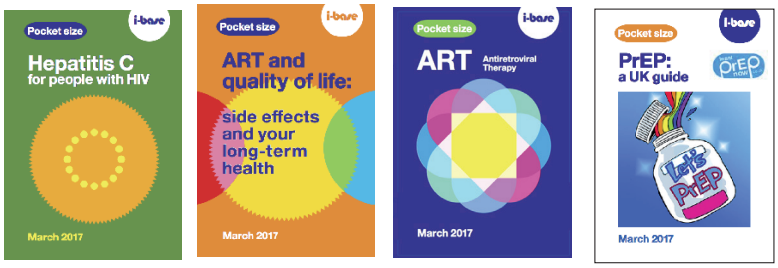
Personalising these for your clinic is cheap and easy and might be an especially nice way to highlight the good news.

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

roy.trevelion@i-Base.org.uk

Order publications and subscribe online

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

Medical consultants:
Dr Tristan Barber, Royal Free Hospital, London.
Dr Karen Beckerman, Albert Einstein College of Medicine, NYC.
Dr Sanjay Bhagani, Royal Free Hospital, London.
Prof. Diana Gibb, Medical Research Council, London.
Dr Gareth Hardy, PhD.
Prof. Saye Khoo, University of Liverpool Hospital.
Prof. Clive Loveday, International Laboratory Virology Centre.
Prof. James McIntyre, Chris Hani Baragwanath Hosp. South Africa
Dr Graeme Moyle, Chelsea & Westminster Hosp, London.
Dr Stefan Mauss, Düsseldorf.
Prof. Caroline Sabin, UCL Medical School, London.
Dr Graham P Taylor, Imperial College, London.
Dr Stephen Taylor, Birmingham Heartlands Hospital.
Dr Gareth Tudor-Williams, Imperial College, London.
Dr Edmund Wilkins, Manchester General Hospital, Manchester.

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.

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

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.

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**

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