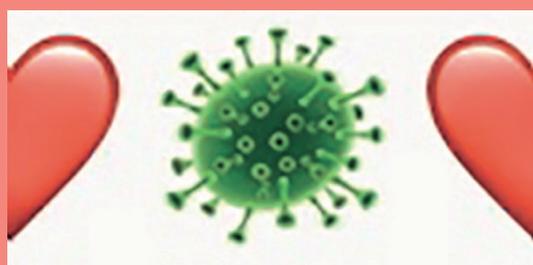


hiv treatment+ bulletin (e)



BHIVA, lenacapavir, third vaccines and more (1 July 2021)

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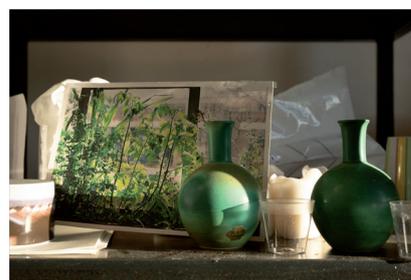
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EDITORIAL

This issue contains a good balance of HIV and COVID-19 reports.

For HIV this includes data on the low rates of vertical transmission in the UK. There is also exciting news that 6-monthly lenacapavir had been submitted to the US FDA as a treatment for MDR HIV. An also from the US, the latest updated to the main treatment guidelines.

And for COVID-19, reports of lower vaccine efficacy in people with reduced immune systems, including when the CD4 count is very low (< 50 cells/mm³).

As these reports have increased, the UK releases plans to allow a third vaccinations, but without reporting the data that support a proposed universal programme, rather than one limited to highest risk groups.

This raises questions about expected prediction of current vaccine efficacy against the Delta variant, but also suggests a widening gap between vaccine coverage in high- compared to low-income countries.

ISSN 1473-8883 HTB: vol 22 no 5: plus COVID-19 supplement



BHIVA/BASHH 2021 + 15 COVID reports (3 May 2021)

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Published by HIV i-Base

CONFERENCE REPORTS

5th joint BHIVA/BASHH conference 2021

19 to 21 April 2021

Introduction

This year the BHIVA spring conference was jointly organised with BASHH and held as a three-day virtual meeting, attended by more than 750 delegates.

Access to conference materials, including webcasts and PDF posters originally restricted to delegates, will become open access four weeks after the meeting.

<https://bhiva-bashh.org>

The abstract book and programme are at this link:

<https://www.bhiva.org/AnnualConference2021>

Earlier reports were included in the May and June issues of HTTB.

The following report in this issue concludes our coverage..

- Few vertical HIV transmissions in the UK but contributing factors remain associated with inequality

Few vertical HIV transmissions in the UK but contributing factors remain associated with inequality

Polly Clayden, HIV i-Base

Vertical HIV transmission is rare in the UK, occurring mainly among undiagnosed women and often reflecting poor social circumstances – according to surveillance data presented at the 5th Joint Conference of the British HIV Association (BHIVA) with the British Association for Sexual Health and HIV (BASHH).

The UK vertical transmission rate has been below 0.3% since 2012. Despite very high uptake of antenatal screening, a small number of vertical transmissions still occur.

These transmissions are monitored by the Integrated Screening Outcomes Surveillance Service (ISOSS), part of Public Health England's Infectious Diseases in Pregnancy Screening programme. ISOSS performs the following:

- Conducts active surveillance of all pregnancies to women living with HIV, their infants and any children diagnosed with HIV at less than 16 years of age.
- Conducts enhanced data collection of vertical transmissions in children born since 2006.
- Collects supplementary maternal and infant information through interviews with paediatric, maternity and HIV clinicians involved in each case.
- Establishes circumstances surrounding transmissions and any contributing factors through a Clinical Expert Review Panel (CERP).

A poster presentation at the conference described the latest findings on vertical transmissions from a review of cases reported between January 2014 and December 2019.

There were 35 vertical transmissions in infants born to 33 mothers (including 1 set of siblings and 1 pair of twins). Years of birth ranged from 2006 to 2019 and infant age at diagnosis from birth to 11 years. The CERP identified the main factors contributing to transmission – in some cases there were overlapping and multiple factors. Two thirds of children were born to women diagnosed after pregnancy: 24 (69%) after, 4 (11%) during and 7 (20%) before pregnancy.

Almost half were born in London: 15 (43%), 7 (20%) Midlands and east England, 6 (17%) north England, 3 (9%) south England and 4 (11%) Wales and Scotland.

The median maternal age at delivery was 33 years (IQR 28 to 36). Three quarters of mothers were born in sub-Saharan Africa: 26 (74%), 3 (9%) Eastern Europe and 6 (17%) UK.

Over half the mothers (54%) reported adverse social circumstances: 5 safe guarding, 9 mental health, 7 housing, 3 drug/alcohol use, 5 intimate partner violence, 5 uncertain immigration status, 4 financial issues and 7 English language issues.

Of the 24 women diagnosed after pregnancy, 16 tested negative in pregnancy and seroconverted during pregnancy or breastfeeding. Some reported new or multiple partners during pregnancy. And some women had partners who did not disclose their HIV status and partners who died of HIV related symptoms.

There were 5 transmissions among women who declined HIV testing, all occurring before 2010 – the authors noted that these women accepted all other infectious disease tests. One woman declined testing in two pregnancies and both children were diagnosed with HIV.

Among the 11 women who were diagnosed before or during pregnancy, in 5 cases transmission was post-natal and likely due to non-disclosure of breastfeeding. These women had complicating factors including mental health issues and involvement by social services. Some women also had difficulties with engagement with health care services.

C O M M E N T

This ongoing enhanced data collection provides valuable insights into the circumstances behind the few vertical transmissions still occurring in the UK. ISOSS can also provide data on evolving patterns in this group, including maternal demographics, to inform work to address their needs.

Presenting author, Helen Peters explained that although exact dates for vertical transmissions were not included the majority occurred in the earlier period of this surveillance and there has been a decline over the years.

But the issues identified here support findings from previous reviews highlighting that social circumstances associated with inequality still drive the small numbers of vertical HIV transmissions that remain in the UK.

Reference: Peters HP et al. Vertical transmissions in the UK- insights and remaining challenges. 5th Joint Conference of the British HIV Association (BHIVA) with the British Association for Sexual Health and HIV (BASHH). 19–21 April 2021. Poster abstract P027.

<https://www.bhiva.org/file/6091178219915/AbstractBook2021.pdf> (abstract book)

<https://www.bhiva.org/AnnualConference2021Presentations> (webcast – Themed poster discussion: ongoing challenges)

ANTIRETROVIRALS

Lenacapavir submitted to FDA as long-acting treatment for multidrug resistant HIV: individual access available based on urgent need

Simon Collins, HIV i-Base

On 28 June 2021, Gilead Sciences submitted a new drug application to the US FDA for lenacapavir as a treatment for HIV in people with multiple drug resistance MDR. [1]

An application to the EMA in Europe will follow in the next months, with final decisions expected to take a year. Submission to the MHRA in the UK is likely to follow the EU decision. Over this extended period, a limited programme will hopefully enable access for individuals in critical need, although details have not yet been released.

Lenacapavir is a capsid inhibitor, and as the first drug in a new class, will have activity against HIV that has developed resistance to other antiretroviral drugs. It needs to be used in a combination with other drugs that are active in order to prevent drug resistance.

The application is based on results from the phase 2/3 CAPELLA trial presented at CROI 2021.

CAPELLA included 36 participants in a double-blind randomised placebo controlled cohort and another 36 participants that used open label lenacapavir. Lenacapavir was significantly more likely to produce a viral load reduction >0.5 log after 14 days (median reduction of 2.0 logs) and a significantly greater chance of an undetectable viral load after 4 weeks after two weeks of optimised background therapy.

Tolerability was good with the most common side effects related to injection site reactions - full details are included in the HTB report from CROI. [2]

Lenacapavir is a long-acting treatment that is given as a subcutaneous injection every six months.

C O M M E N T

The prospect of 6-monthly dosing for an HIV drug is astonishing: this is therefore a particularly exciting and important submission.

Lenacapavir will enable anyone with extensive drug resistance to make an effective combination as two other recently approved first-in-class drugs (fostemsavir and ibalizumab) have also been recently approved. The long-acting formulation should considerably help cases where adherence was difficult.

Although this is a tiny dataset, the FDA must have indicated this could be sufficient for a strict MDR indication.

A regulatory decision in the EU has a timeline of an expected decision in mid-2022. Submission to the MHRA in the UK will follow EU final decision on approval.

An individual patient supply is also likely to be available for people in the UK and Ireland with MDR HIV who would be dependent on lenacapavir in their next combination. This would be decided on a case by case basis, with entry criteria likely to be similar to the CAPELLA study.

Health care professional's should contact their Gilead medical scientist for information on whether access Individual Patient Supply is available.

This filing also marks the start of an era where extremely long-acting treatments could offer very easy options compared to taking daily oral tablets.

The depends on having other drugs to use with lenacapavir. In March 2021, Gilead announced a new partnership with Merck/MSD that will enable access to islatravir and other long-acting pipeline antiretrovirals. [3]

ViiV Healthcare, the third large research based company involved in HIV, also have a pipeline that includes similarly long-acting compounds in earlier stages of development.

Reference

1. Gilead PR. Gilead submits new drug application to U.S. Food and Drug Administration for lenacapavir, an investigational, long-acting capsid inhibitor for the treatment of HIV-1 in people with limited therapy options. (28 June 2021). <https://www.gilead.com/news-and-press/press-room/press-releases/2021/6/gilead-submits-new-drug-application-to-us-food-and-drug-administration-for-lenacapavir-an-investigational-longacting-capsid-inhibitor-for-the-tre>
2. First results using capsid inhibitor lenacapavir against MDR HIV: potential for six-monthly ART and PrEP. HTB (1 April 2021). <https://i-base.info/htb/40290>

3. Collins S. Gilead and Merck/MSD to collaborate on long-acting HIV combination of lenacapavir and islatravir. HTB (15 March 2021). <https://i-base.info/htb/40280>

HIV: TREATMENT GUIDELINES

US HIV treatment guidelines updated (June 2021)

Simon Collins, HIV i-Base

On 3 June 2021, the main US HIV treatment were updated. The main changes to this 450-page document, many already integrated into clinical practice, are summarised below.

- The guidelines strongly recommend routinely starting ART soon after diagnosis. They include a new discussion on same-day ART and on the importance of removing structural barriers that might limit this.
- Dolutegravir can now be routinely used by women during pregnancy. This is because longer follow-up failed to confirm any significant risks of neural tube defects (NTD).
- Raltegravir is no longer recommended as preferred choice for starting ART. This is based on having a higher pill count and lower protection against drug resistance, compared to other first-line options. It is now only recommended as an alternative in certain situations.
- Changing treatment for viral failure can now be to a combination with two fully active drugs, so long as one of these has a high barrier to drug resistance (ie dolutegravir or boosted darunavir. The previous guidelines recommended “at least two, and preferably three, fully active drugs”.
- The dual combination of long-acting cabotegravir/rilpivirine injections is recommended as a switch option for people on stable ART. It is not recommended for first-line ART. Practical issues related to are discussed, including dosing recommendation and continued use where adherence is suboptimal.
- The dual combination of dolutegravir plus rilpivirine is also recommended as a switch option for people with undetectable viral load.
- Fostemsavir has been added as a recommended treatment for multidrug HIV resistance.
- People with extensive drug resistance and who still have detectable viral load are also recommended to consider pipeline drugs that are currently only available in research studies. These investigational compounds include islatravir and lenacapavir (and, more surprisingly, leronlimab).
- The discussion on CD4 non-responders and role of ART to reduce inflammation is expanded to include recent research, even though there are no new options for clinical treatment.
- The section on ART for adolescents and young adults has a major revision with a focus on transition to adult services and complications due to low adherence.
- The section on women and ART includes significant additions on weight gain, drug interactions with hormone treatment and considerations related to the menopause.
- Considerations about choice of ART when isoniazid and rifampentine is prescribed for three months to treat latent TB.
- The guidelines retain and update the section on drug pricing and cost effectiveness of treatment.
- Tables on drug interactions and side effects have been updated to include latest treatments.

C O M M E N T

As always, this update is an important summary of the most significant research.

Although many changes are already established practice, updates are essential as a reference for minimum standard of care.

As with all treatment information, guidelines are dependent on being routinely updated.

References

US Department of Health and Human Services. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. (3 June 2021).

<https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines> (html web pages)

<https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf> (PDF)

CURE RESEARCH

Predicting likelihood of post treatment control in HIV cure-related studies that interrupt ART

Simon Collins, HIV i-Base

HIV cure research often includes asking study participants to take an analytic treatment interruption (ATI) to look at the range of viral load responses without ART. These generally small studies, also need to allow for people whose immune response might control viral load independently of the intervention being studied (called post treatment controllers).

A research letter in the journal AIDS reports on the frequency of post treatment controllers and how they are defined in ATI studies. [1]

The study modelled likelihood of being able to identify post treatment controllers using an interactive viral rebound calculator (<http://jonathanliab.bwh.harvard.edu/rebound-calc/>). This was developed from a pooled analysis of plasma viral load results from over 700 participants in 12 ATI trials. [2]

The paper concludes that four weeks is sufficient time to identify post treatment control with 100% sensitivity and 90% specificity.

References

1. Fajnzylber J et al. Frequency of post treatment control varies by ART restart and viral load criteria. AIDS, doi: 10.1097/QAD.0000000000002978. (14 June 2021).
https://journals.lww.com/aidsonline/Abstract/9000/Frequency_of_Post_Treatment_Control_Varies_by_ART.96371.aspx
2. Sharaf R et al. An interactive tool to estimate viral rebound in HIV-1 treatment interruption trials based on ACTG & CHAMP studies
<https://jonathan-li-lab.shinyapps.io/shinyapp>

HIV and COVID-19 - bulletin



COVID-19: HIV and COVID-19 coinfection

London HIV study to look at responses to COVID-19 vaccines and natural infection

Simon Collins, HIV i-Base

A study enrolling at the Royal Free Hospital (RFH) in London is looking to look at immune responses to SARS-CoV-2 in people living with HIV. [1]

This will include responses both to natural infection and to vaccinations against COVID-19.

The results will help understand how HIV affects risk for COVID-19 and whether alternative vaccines strategies are needed for some HIV positive people.

The study involves one additional blood sample, with additional samples dependent on the initial results together with a questionnaire on COVID risk.

The study is being run by Dr Tristan Barber and is open to all HIV positive people whose HIV care is at the RFH. [2]



C O M M E N T

This is an easy study to recommend.

Currently there is very limited data in HIV positive people and this is generally only in people with high CD4 counts and undetectable viral load on ART.

There are increasing reports of limited vaccine responses in people with significant immune suppression without clear guidelines for managing care in this situation.

References

1. SARS CoV-2 antibody prevalence in an adult HIV cohort (SCAPE-HIV Study). IRAS ID 290112.
<https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/scape-hiv>
2. Contact for the research team is 02074 726 232.

Failure of mRNA vaccines to produce antibody responses in late diagnosed HIV with low CD4 count and high viral load

Simon Collins, HIV i-Base

A letter to the 1 June 2021 edition of the Lancet HIV reports a UK case of someone diagnosed HIV positive in late infection 16 days after the second dose of the Pfizer mRNA vaccine. The vaccine failed to produce antibody responses. [1]

This person was from HIV positive people on effective ART are also compared to responses in HIV negative controls.

At baseline high HIV viral load was high (831,764 copies/mL) and the CD4 count was low (20 cells/mm³, indicating likely late diagnosis (rather than recent seroconversion). The CD4% was 4.6% and CD4:CD8 ratio was 0.05. No SARS-CoV-2-specific neutralisation or spike-specific T-cell responses were found at days 16 and 44 after the second vaccine.

This case was part of a cohort looking at vaccine responses that included 13 HIV positive people on stable ART (median CD4 count 590 cells/mm³ (range: 310 to 940) and 43 HIV-negative controls, [2]



The majority of HIV positive people mounted SARS-specific antibodies with neutralising activity and T cell responses.

The letter suggests careful monitoring for COVID-19 in people with very low CD4 counts and repeating the vaccine schedule after increased CD4 responses to ART.

As follow-up, within one month on ART (bictegravir/TAF/FTC), the CD4 count in this case increased to 70 cells/mm³ and HIV viral load was <50 copies/mL.

C O M M E N T

Although limited results support the efficacy of COVID-19 vaccines in HIV positive people COVID-19, these data are generally in people with an undetectable viral load in people on stable ART. [3]

The mechanism for caution on vaccine efficacy is that a lower HIV-related CD4 count might be less able to generate B-cell responses to vaccine, which we know is already the case with vaccines against influenza and hepatitis B.

This case highlights the lack of data on vaccine efficacy in the context of HIV viraemia. This is especially when the CD4 count is also low. Although the threshold CD4 count for vaccine response is not known, this should be an additional monitoring recommendation in all cases of late HIV diagnosis.

An interesting paper in the same issue of Lancet HIV (Spinelli et al) reported potentially lower immune responses to natural infection in a cohort of HIV positive people in San Francisco and that they had higher risks of serious outcomes. [4]

Reference

1. Touizer E et al. Failure to seroconvert after two doses of BNT162b2 SARS-CoV-2 vaccine in a patient with uncontrolled HIV. Lancet HIV, correspondence. 8(6):e317–318. DOI: 10.1016/S2352-3018(21)00099-0. (1 June 2021). [https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018\(21\)00099-0/fulltext](https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(21)00099-0/fulltext)
2. Alrubayyi A et al. Characterization of humoral and SARS-CoV-2 specific T cell responses in people living with HIV. bioRxiv. 2021 preprint. DOI: 10.1101/2021.02.15.431215. (16 Feb 2021). <https://www.biorxiv.org/content/10.1101/2021.02.15.431215v1>
3. Collins S. Similar immune responses to the Oxford/AZ COVID vaccine reported in HIV positive and HIV negative participants. HTB (3 May 2021). <https://i-base.info/htb/40465>
4. Spinelli MA et al. SARS-CoV-2 seroprevalence, and IgG concentration and pseudovirus neutralising antibody titres after infection, compared by HIV status: a matched case-control observational study Lancet HIV. 8(6):e334–342. DOI: 10.1016/S2352-3018(21)00072-2. (1 June 2021). [https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018\(21\)00072-2/fulltext](https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(21)00072-2/fulltext)

COVID-19: VACCINE RESEARCH

Special report on background incidence of adverse events in vaccine studies

Simon Collins, HIV i-Base

The background incidence of the 15 most important and serious adverse events associated with vaccines against COVID-19 have been analysed from a multinational cohort study and published as a special report in the BMJ.



This includes records from more than 126 million people from 13 databases in the three years before COVID-19 who were observed for at least a year. Results stratified by age and sex.

The events included non-haemorrhagic and haemorrhagic stroke, acute myocardial infarction, deep vein thrombosis, pulmonary embolism, anaphylaxis, Bell's palsy, myocarditis or pericarditis, narcolepsy, appendicitis, immune thrombocytopenia, disseminated intravascular coagulation, encephalomyelitis (including acute disseminated encephalomyelitis), Guillain-Barré syndrome, and transverse myelitis.

Older age generally increased the risk of most events although anaphylaxis, narcolepsy and appendicitis were exceptions more common at younger ages. The incidence of most events (reported as rates per 100,000) varied significantly between different databases.

For example, incidence of Bell's Palsy ranged from 4 to 174/100,000 patient years in an Italian and US database, respectively. There was also a 3-fold difference between the highest and lowest incidence rates for deep vein thrombosis in each database.

The tables compiling these results are notably impressive and are an important reference resource.

Reference

Li X et al. Characterising the background incidence rates of adverse events of special interest for covid-19 vaccines in eight countries: multinational network cohort study. *BMJ* 2021;373:n1435. doi: 10.1136/bmj.n1435 (14 June 2021).
<https://www.bmj.com/content/373/bmj.n1435>

Third vaccine dose increases immune response to 68% in French transplant recipients

Simon Collins, HIV i-Base

A higher percentage of people on immunosuppressive treatment due to solid organ transplants showed increased immune responses to a third dose of the Pfizer mRNA vaccine against COVID-19. Despite these improvements, more than 30% still showed no detectable antibody responses, with a need for continued caution.



This retrospective analysis from a French cohort included 101 transplant recipients (78 kidney, 12 liver, 8 lung or heart, and 3 pancreas). Mean age was 58 (SD: +/- 2) and 69% were men and average time since the transplant was about eight years. The results were published in a letter to the *NEJM*. [1]

Immunosuppressive treatment included glucocorticoids (in 87% of patients), calcineurin inhibitors (in 79%), mycophenolic acid (in 63%), mammalian target of rapamycin inhibitors (in 30%), and belatacept (in 12%).

The first two doses were given one month apart with the third dose approximately two months later.

The percentage of people with antibody responses to SARS-CoV-2 steadily increased from 0% before the first dose to 4%, 40% and 68% after each of the three doses respectively.

Table 1: Percentage of antibody responses 4 weeks after injections

	%	95%CI
Baseline	0%	0 to 4
After dose 1	4%	1 to 10
After dose 2	40%	31 to 51
After dose 3	68%	58 to 77

The third dose generated new antibody responses in 26/59 (44%) people with no responses after the second dose. Strength of antibody titres in the 40 people with responses after the second dose from 36 ± 12 before the third dose to 2676 ± 350 1 month after the third dose ($p < 0.001$).

Factors linked to lack of response to the third dose included older age, greater immune suppression and lower eGFR. However, this cohort was still relatively young with good CD4 counts, although eGFR showed more serious kidney function. [2]

Mean age was 54 (+/- 2) vs 65 years (+/-3), $p < 0.001$; CD4 T cell count was 529 (+/- 37) vs 339 cells/mm³ (+/-38) ($p = 0.002$); and eGFR was 60 +/- 3 vs 45 mL/min/1.73m² (+/-4), $p = 0.005$; in the responders vs non responders respectively.

No serious events were reported from the third dose.

Despite the positive results, the authors still cautioned the importance of maintaining barrier protection and encouraging vaccination of relatives given the relatively high percentage of people who still didn't develop antibody responses.

C O M M E N T

These results are important for supporting use of a third vaccine dose in people who are unlikely to generate immune responses to a two-dose schedule.

Access to test to access immune responses in the small percentage of HIV positive people in this situation is likely to significantly affect decisions about relaxing lock down with a similar impact on improving their quality of life.

Reference

1. Kamar N et al. Three doses of an mRNA COVID-19 vaccine in solid-organ transplant recipients. NEJM, correspondence. DOI: 10.1056/NEJMc2108861. (23 June 2021).
<https://www.nejm.org/doi/full/10.1056/NEJMc2108861>
2. Supplementary appendix
https://www.nejm.org/doi/suppl/10.1056/NEJMc2108861/suppl_file/nejmc2108861_appendix.pdf (PDF)

Third COVID-19 vaccine dose in US cohort of people on immune suppressing treatment: safety and ethical issues

Simon Collins, HIV i-Base

A US group has reported that using a third dose against COVID-19 can overcome low responses to standard two-dose vaccinations in some people on immune suppressing treatment. [1]



The study also generated correspondence that included further reports on this approach but also raised ethical issues on vaccine access. It also reported that one participant, a heart transplant recipient, had biopsy-proven antibody-mediated organ rejection, seven days after the third dose. Heart function remained normal without need to increase immune suppressive treatment.

This US cohort included 30 people (17 woman) who had received solid organs transplants who were taking immune suppressive treatment.

Median age was 57 years (IQR: 44 to 62 years), 29 white. In 25 patients, Maintenance immunosuppression included tacrolimus or cyclosporine plus mycophenolate in 25/30, corticosteroids in 24/30 with sirolimus and belatacept each used by one person. Median time since the transplant was 4.5 years (IQR: 2.3 to 10.5).

Responses to the first two doses after a median of 67 days (IQR: 54 to 81) had not produced antibody responses in 24/30 and only weak antibody titres in 6/30.

After the third dose, all 6 patients with previously low titres generated high-positive antibody responses. However, in people with no previous response, only 6/24 (25%) generated high responses, 2/24 had low positive titres and 16/24 remained antibody negative.

These results add to positive data reported from a French cohort where overall responses to a third dose increased to 67% in a similar population, without evidence of negative outcomes. [2]

The individual protection against COVID-19 from a third dose is important given the high risk of serious complications, including fatality, in transplant recipients who develop COVID-19, including after two-dose vaccinations. [3, 4]

The paper also discussed the difficult issue of COVID-19 variants developing in individuals who have extended periods (>6 months) of active infection. This has been reported in transplant recipients, people with cancer and some HIV positive people.

A South African report included breakthrough infections during prolonged COVID-19 with key mutations associated with clinically important variants (including early emergence of the E484K followed by other escape mutations and N501Y). [5]

This case of viral evolution was in an HIV positive person who had a CD4 count of 6 cells/mm³ and viral load of 35,000 copies/mL despite being on ART (efavirenz/TDF/FTC) before COVID-19 infection. Viral changes in SARS-CoV-2 were tracked in seven whole genome samples.

It is unclear why changing ART was delayed for six months in someone with such advanced HIV and resistance to current ART at baseline. This person was anecdotally receiving very close and supported care that included counselling and support to change, although the paper includes none of these details. [6]

However, viral load became undetectable (<50 copies/mL) two weeks after switching to TDF/lamivudine/dolutegravir (TLD) at approximately day 200, despite NRTI resistance that included K70KQ and M184V. Other studies showing viral evolution during prolonged COVID-19, where viral pressure have often been complicated by treatment with convalescent plasma or monoclonal antibodies.

This publication by Werbel et al also prompted two important comments.

One was from a second French cohort that only reported overall 30% response to a third vaccine dose in 74 transplant recipients (43% (6/14), 19% (5/26) and 35% (12/34) in liver, kidney and heart recipients, respectively). Independent factors associated with lack of response were more recent transplantations < 2 years (OR: 7.19; 95%CI: 1.17 to 44.28), $p=0.033$; and mycophenolic acid-based immunosuppression (OR 9.73; 95%CI: 1.61 to 58.68), $p=0.013$. This authors emphasized the important of family members being vaccinated.

The second comment reported cases where people had sought third vaccine doses without involvement of their transplant teams, at a time when vaccine supplies were also limited. It also questioned the ethics of the study by suggesting that written informed consent had not been provided.

C O M M E N T

These studies raise important issues both for individual and population-based health, all of which urgently need further data.

Firstly, a significant percentage of people with reduced immunity are likely to have suboptimal responses to current two-dose vaccinations. The high risk from COVID-19, reported in several studies, means that caution to avoid infection is still strongly recommended. Management guidelines to ensure optimal care for people in this situation is essential.

Secondly, expanding access to this option of a third dose should be prioritised in the UK, with consent that includes a potential safety risk. This should preferably be in the context of a research setting, and certainly earlier than the Autumn timeline currently proposed by the JCVI. [7]

This relatively small number of people would not impact on vaccine access given the advanced stage of the UK vaccine programme, and their earlier prioritisation was based on need for effective protection, irrespective of the number of doses.

Thirdly, this shows the importance of developing guidelines for careful management of cases of prolonged COVID-19, to minimise the risk of further transmission, including the potential for complex variants.

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<https://i-base.info/htb/40634>

Plans for universal third vaccine in the UK in September

Simon Collins, HIV i-Base

On 30 June 2021, the Joint Committee for Vaccination and Immunisation (JCVI) in the UK issued a statement outlining plans for extending the COVID-19 vaccine programme to routinely increase to a third dose. [1]



The statement falls short of recommending third doses, using language to outline plans “should a booster programme be needed”. Priority will closely follow the stages used for initial access. This includes “care home residents, people aged over 70, frontline health and social care workers, clinically extremely vulnerable adults and those who are immunosuppressed”.

However, the Welsh government reports the JCVI statement as providing “a level of certainty” around stage 3 of the vaccine programme. Wales has been planning a booster dose in September/October for priority groups 1 to 9. [2]

Both statements refer to booster doses as likely to be using current vaccines, rather than new versions that have been reformulated to overcome new variants. Neither statement discusses the evidence supporting a third vaccine or links directly to the JCVI report.

Several research groups have reported that current vaccines are likely to provide lower protection against variants, especially now that Delta (B.1.617.2) is now dominant in the UK.

This includes >5-fold overall reductions in neutralising sensitivity to the Delta (B.1.617.2) variant. By comparison, >6-fold reductions against Beta (B.1.351) have already been associated with reduced vaccine efficacy. [3]

This study from the COVID-19 Genomics UK group, currently published ahead of peer review, reports phenotypic reductions in sensitivity of neutralising titres of 7.77, 11.30 and 9.56-fold respectively to pseudoviruses of the B.1.617.1, B.1.617.2 (Delta) and B.1.351 (Beta) variants, following two doses of the Pfizer mRNA vaccine.

Fold changes after vaccination with two doses of the Oxford/AZ vaccine were 0.69, 4.01 and 1.48 respectively, although this antibody responses to mRNA vaccines achieve significantly higher overall responses than the Oxford/AZ vaccine.

Public Health England have already reported vaccine efficacy against the Delta variant 'modestly' drops to 88% and 59% following two doses of the Pfizer vaccine and Oxford/AZ vaccines respectively. [4]

C O M M E N T

Access to a third vaccine will hopefully improve antibody responses in people with low levels after two doses.

However, the proposal for a universal third vaccine seems linked to concerns over reduced efficacy against variants and potentially to waning responses after six months on a population rather than individual level.

The makes access to the data used for the JCVI decisions of public interest and these should be published.

Access to the data is also needed to understand the political and ethical issues of providing a third vaccine to all adults in the UK, given the broad inequity of access to vaccines in low-income countries globally. This concerns will be multiplied if similar policy is adopted in other high-income countries.

A national UK trial of third-dose booster is also already underway. [5]

Several HTB articles since May 2021 have reported low or absent antibody responses in significant percentages of people with reduced immune function. [6, 7 8, 9, 10]

This is very different from all adults in the UK requiring a third vaccine dose - unless the JCVI data shows otherwise.

A more selected approach to boosting doses would be possible in individual tests for vaccine responses become available.

Although several research groups are already working on point-of-care technology, including lateral flow tests to detect neutralising antibodies, none have so far been approved. [11, 12]

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COVID-19 vaccines increase sperm quality: potential to help uptake

Simon Collins, HIV i-Base

A research letter published in JAMA might encourage vaccine uptake through subliminal messaging the mRNA vaccine improve sperm count, motility and volume.



A single-centre prospective study compared sperm samples before receiving the first dose of an mRNA vaccinations against COVID-19 to samples collected an average of 75 days after the second dose.

Median age of the 45 participants was 28 years (IQR: 25 to 31) with samples taken after an average of 3 days abstinence. Roughly half received the vaccine from Pfizer and half from Moderna.

All four markers of sperm quality (median (IQR) significantly improved.

- Volume increased from 2.2 mL (IQR: 1.5 to 2.8) to 2.7 mL (IQR: 1.8 to 3.6), $p=0.01$
- Sperm concentration increased from 26 million/mL (IQR, 19.5 to 34) to 30 million/mL (IQR, 21.5 to 40.5, $p=0.02$).
- Sperm motility increased from 58% (IQR: 52.5 to 65) to 64% (IQR: 58 to 70), $p=0.001$
- Total motile sperm count (TMSC) increased from 36 million (IQR, 18 to 51) to 44 million (IQR, 27.5 to 98; $p=0.001$).

Low sperm count was reported in 8/45 men before the vaccine this resolved for 7/8 of these men. No participants developed low sperm count after the vaccines.

Results, appropriately reported in a waterfall plot, showed the individual changes for individuals ranged from -22 to + 93 million

Although the changes were significant, the researchers noted that there is no expected mechanism for to explain these results and that the degrees of changes were within normal individual variation.

C O M M E N T

Although the changes reported in this study were all statistically significant, the researchers noted that there is no expected mechanism for to explain these results and that the changes were within normal individual variation.

The report though might subliminally help reduce vaccine hesitancy and certainly refute previous rumours that COVID-19 vaccines negatively affect fertility.

Reference

Gonzalez DC et al. Sperm parameters before and after COVID-19 mRNA vaccination. JAMA. doi:10.1001/jama.2021.9976. (17 June 2021).
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COVID-19: TREATMENT

Research approach to rapidly review candidate treatments for COVID-19: nine studies using ACTIV protocol

Simon Collins, HIV i-Base

This paper outlines a research approach to the urgency needed for medicines to treat COVID-19.



This includes a rapid early review of results, with early stopping rules, that limits the risk of extended exposure to inactive treatments.

The overall programme includes master protocols for interventions for prevention and treatment at different stages.

Reference

Lavange L et al. Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV): Designing Master Protocols for Evaluation of Candidate COVID-19 Therapeutics. Ann Int Med. DOI: 10.7326/M21-1269 (29 June 2021).

<https://www.acpjournals.org/doi/10.7326/M21-1269>

COVID-19 treatment: tofacitinib, REGN bNAbs, convalescent plasma

Simon Collins, HIV i-Base

The following brief reports are significant for COVID-19 treatment. Please refer to the online papers for context and full details.



Tofacitinib

A randomised placebo-controlled study in 289 participants hospitalised with COVID-19 pneumonia in Brazil reported reduced risk of mortality using the JAK inhibitor tofacitinib.

“The cumulative incidence of death or respiratory failure through day 28 was 18.1% in the tofacitinib group and 29.0% in the placebo group (risk ratio, 0.63; 95% CI: 0.41 to 0.97; $p=0.04$). Death from any cause through day 28 occurred in 2.8% vs 5.5% of the active vs placebo groups (hazard ratio 0.49; 95% CI: 0.15 to 1.63).”

Participants receiving tofacitinib also had significantly improved outcomes on an 8-point ordinal scale. Adverse events were similar in each group (14% vs 12%).

Guimarães PO et al. for the STOP-COVID Trial. Tofacitinib in Patients Hospitalized with Covid-19 Pneumonia. NEJM. DOI: 10.1056/NEJMoa2101643. (16 June 2021).

<https://www.nejm.org/doi/full/10.1056/NEJMoa2101643>

REGN dual bNAbs: casirivimab and imdevimab

The UK RECOVERY study report a mortality benefit using REGN dual bNAbs in people hospitalised with COVID-19, but only in the 30% who were seronegative at baseline.

“In the primary efficacy population of seronegative patients, 396/1633 (24%) vs 451/150 (30%) died within 28 days in the REGN-COV vs standard of care arms respectively (rate ratio 0.80; 95% CI: 0.70 to 0.91; $p=0.0010$).

Overall, (regardless of baseline antibody status), the results were 944/4839 (20%) vs 1026/4946 (21%) respectively (rate ratio 0.94; 95% CI: 0.86 to 1.03; $p=0.17$).

Ref: RECOVERY Study. Casirivimab and imdevimab in patients admitted to hospital with COVID-19 (RECOVERY): a randomised, controlled, open-label, platform trial. MedRxiv. Pre-peer review. doi: 10.1101/2021.06.15.21258542. (15 June 2021).

<https://www.medrxiv.org/content/10.1101/2021.06.15.21258542v1>

Convalescent plasma

No impact of convalescent plasma (CP) was found on 30-day mortality in participants with mild or moderate COVID-19 using data from an observational cohort from the Veteran's Affairs (VA).

Based on approximately 400 participants using CP and >10,000 controls, there were 40 vs 671 deaths, respectively. Mortality was 6.5% vs 6.2%, with a risk difference of 0.30% (95% CI: 2.30 to 3.60) and hazard ratio of 1.04 (95% CI: 0.64 to 1.62).

Ref: Cho K et al. Early convalescent plasma therapy and mortality among US veterans hospitalized with non-severe COVID-19: An observational analysis emulating a target trial. JID, DOI:10.1093/infdis/jiab330. (21 June 2021).

<https://doi.org/10.1093/infdis/jiab330>

COVID-19: LONG COVID

Resources on Long COVID

Simon Collins, HIV i-Base

Many of the following links were included in previous issues of HTB. Other related resources will be added in the future.



The HIV movement must come through

JD Davids, writes in POZ magazine about approaches to managing Long COVID through their experience of living with myalgic encephalomyelitis (ME) and the history of HIV activism. Also includes a resources section.

<https://www.poz.com/article/hiv-movement-must-come-through>

See online seminars from August 2020 that include many other community presentations.

<https://www.meaction.net/longcovid>

Long COVID website

<https://www.longcovid.org>

Body Politic website

<https://www.wearebodypolitic.com/covid19>

Webcasts of two-day US Workshop on Long COVID (PASC) now online

<https://i-base.info/htb/39624>

HTB (22 January 2021).

HTB report on meeting and webcasts from an important 2-day NIH workshop on Long COVID with online links.

NIHR. Living with COVID-19. (19 October 2020).

<https://evidence.nihr.ac.uk/themedreview/living-with-covid19>

A 29-page NIHR review also looks a personal experiences of COVID-19 including the increasing reports of long-term symptoms and how to manage them.

NICE issue UK guidelines on long COVID

HTB (22 January 2021).

<https://i-base.info/htb/39597>

Summary of UK guidelines for health workers managing Long COVID.

Long COVID: studies reporting on long-term follow up on COVID-19.

HTB (3 March 2021).

<https://i-base.info/htb/40575>

Review of five studies reporting duration of post-COVID that includes new symptoms after COVID was thought to have finished.

Long COVID: Mild infection and sustained long-term complications.

HTB (20 October 2020).

<https://i-base.info/htb/39126>

Pathogenesis and treatment of COVID-19 including Long COVID

HTB (14 October 2020).

<https://i-base.info/htb/39054>

HTB report from excellent talk by Professor Karine Lacombe from the Glasgow HIV Congress.

Management of post-acute covid-19 in primary care.

BMJ 2020; 370 doi:10.1136/bmj.m3026. (11 August 2020).

<https://www.bmj.com/content/370/bmj.m3026>

A BMJ podcast on post-acute and chronic COVID-19 to support management in primary care.

Characterizing long COVID in an international cohort: 7 months of symptoms and their impact.

Davis HE et al. Pre-review draft. MedRxiv. DOI: 10.1101/2020.12.24.20248802. (5 April 2021). <https://www.medrxiv.org/content/10.1101/2020.12.24.20248802v3>

An early community survey published as a pre-review paper that included approximately 4000 people self-reporting symptoms.

Recovery from severe COVID-19: leveraging the lessons of survival from sepsis.

Prescott HC et al. JAMA. 2020;324(8):739-740. DOI:10.1001/jama.2020.14103. (5 August 2020).

<https://jamanetwork.com/journals/jama/fullarticle/2769290>

A useful article on recovery from severe COVID-19 in JAMA.

COVID-19: EPIDEMIOLOGY

US likely to have had SARS cases in December 2020

Simon Collins, HIV i-Base

A paper published in CID looking at retrospective testing of more than 24,000 samples collected during the first months of 2020 from 50 US states before testing for SARS-CoV-2 was easily available.



Of these, 9 were seropositive, 7 of whom predated the first confirmed case in the states of Illinois, Massachusetts, Wisconsin, Pennsylvania, and Mississippi.

The authors report that their findings indicate SARS-CoV-2 infections weeks prior to the first recognised cases in 5 US states.

Reference

Althoff KN et al. Antibodies to SARS-CoV-2 in All of Us Research Program Participants, January 2-March 18, 2020, Clinical Infectious Diseases, 2021. (15 June 2021).

<https://academic.oup.com/cid/article-lookup/doi/10.1093/cid/ciab519>

COVID-19: COINFECTIONS AND COMPLICATIONS

Worse UK outcomes for people with cancer and COVID-19 compared to other EU countries

Simon Collins, HIV i-Base

People in the UK with cancer and COVID-19 had significantly worse health outcomes including increased mortality compared to other EU countries.



The results were from a retrospective analysis from the OnCovid study database that looked at the impact of COVID-19 on risk of death that adjusted for key related demographic and health factors.

Records from February to September 2020 included 468 vs 924 people from the UK and EU respectively from 27 centres who were diagnosed with cancer and then COVID-19.

People in the UK had:

- Higher case fatality rates (40.38% versus 26.5%, $p < 0.0001$).
- Higher risk of death at 30 days (hazard ratio, HR 1.64 [95%CI 1.36-1.99]).
- Higher risk of death 6 months after Covid-19 diagnosis (47.64% versus 33.33%, $p < 0.0001$, HR 1.59 [95%CI 1.33-1.88]).
- Lower access to cancer treatment ($p < 0.001$).
- Lower access to COVID-19 treatment (including corticosteroids, antivirals and interleukin-6 antagonists ($p < 0.0001$)).

This was despite similar severity of Covid-19 (including ICU admission and use of mechanical ventilation).

Multivariable analyses adjusted age, gender, tumour stage and status, number of co-morbidities, COVID-19 severity, receipt of anti-cancer and anti-COVID-19 therapy.

UK patients were more often males, of older age and more co-morbid than EU counterparts ($p < 0.01$).

Reference

James D et al. Determinants of enhanced vulnerability to Covid-19 in U.K. cancer patients: Results from the OnCovid study. *Journal of Clinical Oncology* 2021 39:15_suppl, 1574-1574. (20 May 2021).

https://ascopubs.org/doi/abs/10.1200/JCO.2021.39.15_suppl.1574

COVID-19: ONLINE RESOURCES

Virology Education: monthly forums on COVID-19

Simon Collins, HIV i-Base

It is a challenge to follow the volume of important research on COVID-19, largely available as open access, but also rapidly changing.



These webinars from Virology Education are broadcast every month, with free registration to health professional and community. The meetings include leading researchers and doctors, many with an HIV background, and take place over two days (four hours each).

Presentations include the most important and relevant research, and are highly recommended.

Meetings are also available as enduring materials for a few months.

<https://academicmedicaleducation.com/covid-19-clinical-forum-2021>

COVID-19 timeline: global events from the last 18 months

Simon Collins, HIV i-Base

An ongoing resource tracking milestones for research into treatment, vaccines and the related political background related to inequitable global access for the last 18 months.

Developed by HIV and HCV treatment activist Tracy Swan as a project for Make Medicines Affordable.

<https://makemedicinesaffordable.org/covid-19-timeline>

The timeline plots the history of COVID-19, from the first reported case to current events, which are kept regularly updated.

It can be viewed chronologically, as things happened, or by most recent events first. It includes a detailed introduction and will be updated weekly.



COVIDsalon

Simon Collins, HIV i-Base

Website to report on potential treatments for COVID-19 and, just as importantly, cautions about interpretation of early and preliminary results. [1]

Written and compiled by John S James, a leading US activist who first published AIDS Treatment News in 1985 and continued to report potential treatment for almost two decades. [2]



Links

1. COVIDsalon.

<https://covid salon.com>

2. Archive of AIDS Treatment News. Archive 1986 -

<http://aidsnews.blogspot.com>

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>

HIV Prevention Review Meeting 2021

2 June 2021, Virtual (free registration for health workers, researchers and community).

International Workshop on HIV and Transgender People 2021

17 July 2021, Virtual

<https://www.virology-education.com>

11th IAS Conference on HIV Science (IAS 2021)

18 – 21 July 2021. Hybrid - virtual and in Berlin

<https://www.ias2021.org>

29th International Workshop on HIV Drug Resistance and Treatment Strategies

Virtual - four 120-minute sessions

6 September 2021, 18h00 – 20h00 SAST (UTC/GMT +2 hours)

13 September 2021, 18h00 – 20h00 SAST (UTC/GMT +2 hours)

20 September 2021, 18h00 – 20h00 SAST (UTC/GMT +2 hours)

27 September 2021, 18h00 – 20h00 SAST (UTC/GMT +2 hours)

<https://www.hivresistance.co.za>

12th International Workshop on HIV & Aging

23 – 24 September 2021. Virtual

<https://www.virology-education.com>

IDWeek 2021

29 September – 3 October 2021, Virtual

www.idweek.org

18th European AIDS Conference (EACS 2021)

27 – 30 October 2021, Hybrid - virtual and in London

<https://eacs-conference2021.com>

Workshop On Long-Term Complications Of HIV And SARS-CoV-2

6 – 9 December 2021, virtual

<https://www.intmedpress.com/comorbidities>

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 clinics.

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 ordered 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.

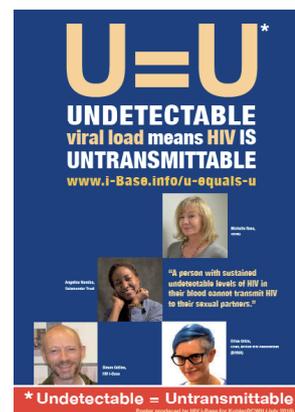
Personalising these for your clinic is cheap and easy and might be an especially nice way to highlight the good news.

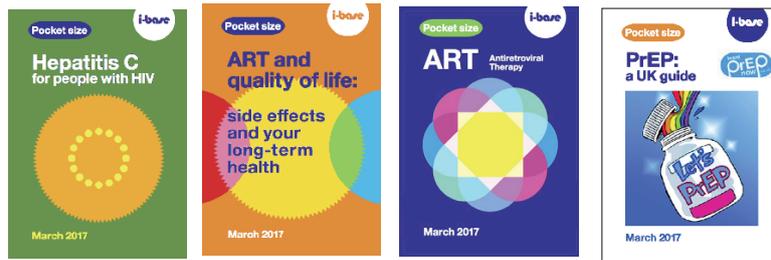
For further information please contact Roy Trelvelon at i-Base:

roy.trelvelon@i-base.org.uk

Order publications and subscribe online

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





h-tb

HIV TREATMENT BULLETIN

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

<http://www.i-Base.info>

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

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