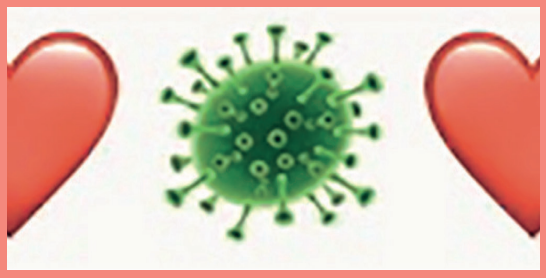
ISSN 1472-4863

HTB: vol 22 no 9: plus COVID-19 supplement

hiv treatment bulletin (e)



IAS 2021 + COVID reports (17 September 2021)

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Published by HIV i-Base

HTB no.9 (2021): HIV and COVID-19 supplement ISSUE 9

Contents continued ...

i-Base 2021 appeal

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 :)

EDITORIAL

This issue contains further reports from the IAS 2021 virtual conference and the linked 13th International Paediatric Workshop.

It also includes the 2021 adult pipeline review on the most recently approved HIV drugs and compounds in the pipeline.

Lenacapavir has been submitted to the EMA for use in multidrug resistance, using a long-acting 6-monthly subcutaneous injection.

ART access news includes reducing the annual price for darunavir/r to $210, which should improve second-line therapy globally.

Plus a review on the disappointing results from the large phase 3 HIV vaccine Imbokodo study.

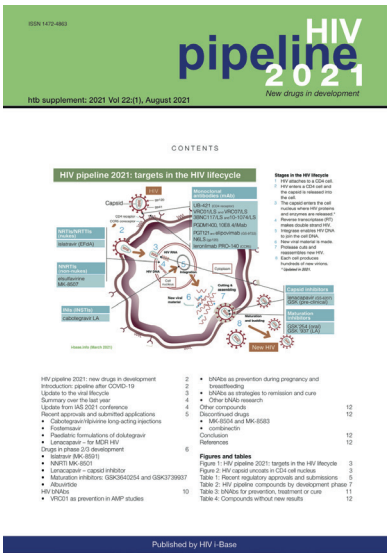
COVID-19 news includes an i-Base project with Modern ART for South Africa that produced new information on COVID-19 vaccines.

We also cover UK plans for some HIV positive people to be able to have a third vaccine dose and the largest analysis of COVID-19 outcomes in people living with HIV.

Plus short reports on other vaccine studies.

i-Base also has two staff vacancies – please see details online.

This issue of HTB might be a double issue to also cover the October issue.



CONFERENCE REPORTS

11th IAS Conference on HIV Science (IAS 2021)

18 – 21 July 2021

Introduction

The 11th IAS Conference on HIV Science was held from 18 – 21 July 2021 as a virtual conference.

Conference presentations and materials are all now available as open access.

https://www.ias2021.org/the-programme

The following reports are included in this issue.

- IAS 2021 website now open access
- Substudies from the ODYSSEY trial: results July 2021
- Trial design for next generation PrEP

IAS 2021 website now open access

Simon Collins, HIV i-Base

The 11th Conference on HIV Science (IAS 2021) held from 18–21 July 2021 is now available online as open access.

https://www.ias2021.org/the-programme

This includes more than 150 webcast presentations, 40 satellite sessions and 600 posters.

The original links used during the conference to abstracts, sessions and PDF files are still active.

However, the original links to individual webcasts now default to the conference programme. This will involve organisations having to edit earlier media reports and link to session pages.

Links to individual talks are no longer available, only to the full session.

C O M M E N T

The financial challenges involved in organising these meetings are appreciated.

But from a community perspective, enabling active links to presentations in real time, is more important than open access several months later.

This view might be shared by major funders and the scientists who work is being featured. There might be a persuasive business model if virtual meetings enable many thousands more attenders globally that could ever attend physical meetings.

Keeping the same URLs would also make is easier to ensure reports remain active over time when the conference platform changes.

Substudies from the ODYSSEY trial: results July 2021

Polly Clayden, HIV i-Base

Findings from several sub studies of the ODYSSEY trial – presented at the 13th International Workshop on HIV Paediatrics 2021 and 11th IAS Conference on HIV Science – provided valuable insights into a number of issues previously observed with adult ART.

ODYSSEY is a multi-country randomised trial, that demonstrated superior treatment efficacy for dolutegravir (DTG) plus two NRTIs vs standard-of-care in children weighing at least 14 kg starting first- and second-line ART.

Week 96 results from the main trial were presented earlier this year at CROI. [1]

The trial also included a cohort of younger children who were evaluated separately. Late breaking results for these additional 85 children, weighing less than 14 kg, who completed 96 weeks follow-up on 28 June 2021, were also shown at the paediatric workshop. [2, 3]

ODYSSEY included a number of sub studies. As well as generating pharmacokinetic (PK) data, which contributed data for DTG's approval, several of these took the opportunity to look at phenomena previously seen in adults. The following results were presented:

- The first randomised data in children and adolescents looking at weight gain with DTG-based ART, which was not associated with excessive weight gain in this population. [4, 5]
- The first randomised data in children and adolescents looking at DTG-associated with neuropsychiatric adverse events, which were infrequent. [6, 7]
- An evaluation of resistance that found DTG to have a high genetic resistance barrier in children and adolescents. [8, 9]
- An evaluation of folate that found no evidence that DTG-based ART was associated with decreased levels of plasma folate or red blood cells (RBC) folate. [10]
- PK data in children for paediatric formulations of DTG.
- Data on DTG glucuronide/DTG molar metabolic ratio (DTG-MR) and DTG clearance/kg in children and adolescents – also not previously studied in this population.

Main study summary and baseline characteristics

- DTG + 2NRTIs vs standard-of-care in children and adolescents starting first- or second-line ART.
- 707 children and adolescents randomised: 88% sub-Saharan Africa, 9% Thailand, 4% Europe.
- 311 started first-line (92% efavirenz [EFV]-based in standard-of-care); 396 second-line (72% lopinavir/ritonavir [LPV/r], 25% atazanavir/ritonavir [ATV/r] in standard-of-care).
- 65% started abacavir (ABC)/lamivudine (3TC), 23% tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC) or 3TC, 11% zidovudine (AZT)/3TC.
- At baseline, median age was 12.2 years (IQR 9.1 to 14.9; range 2.9 to18.0).
- 49% were girls.
- Median follow-up 142 weeks (IQR 124 to 159).

Weight gain

DTG-based ART was not associated with excessive weight gain in children and adolescents in ODYSSEY. But children grew better after starting DTG. Few participants became newly overweight or obese in either arm.

There were small differences between arms in weight, height and BMI that stabilised before two years, with few participants becoming newly overweight/obese in each arm. Differences between arms were similar by first- or second-line, sex, age and NRTI backbone.

This study compared weight, height and BMI-for-age Z-scores (BAZ) between treatment arms and described proportions becoming newly overweight (BAZ >1 to ≤2) or newly obese (BAZ >2).

At baseline, median weight 31 kg (IQR 24 to 43, range 14 to 85), height 138 cm (IQR 125 to 153, range 89 to 182), BMI 16.3 kg/m2 (IQR 14.9 to 18.5, range 9.8 to 34.5) and BAZ -0.6 (IQR -1.4 to 0.0, range -7.8 to 2.8).

And, 11% of participants had WHO-defined severe thinness/thinness, 5% were overweight and 1% obese.

Weight change from baseline was slightly more with DTG than standard-of care at week 96: 1 kg (95% CI 0.3 to 1.7), p=0.004. As was height change: 0.8 cm (95% CI 0.2 to 1.4), p=0.007.

Similar differences were reported with BMI and BAZ: 0.3 (95% CI 0.0 to 0.6), p=0.03 and 0.12 (95% CI -0.01 to 0.24), p=0.06, respectively.

These early differences between groups stabilised. At 96 weeks there were no differences in BAZ by sex, baseline age group or TDF at baseline.

Overall, 25 (4%) participants were newly overweight or obese at 96 weeks: 14 (4%) DTG and 9 (3%) in standard-of care, p=0.55.

Those that did become newly overweight or obese were a median age at enrolment of 13 years (IQR 10.3 to 15.4); 5% were on first-line and 3% second-line ART; 4% were girls vs 3% boys and 6% were on TDF vs 3% not on TDF.

Neuropsychiatric adverse events

Neuropsychiatric adverse events and participant-reported neuropsychiatric symptoms were infrequent.

There were no difference in the reported low mood or anxiety symptoms nor in sleep problems by trial arm.

Although there were more psychiatric events in the DTG arm, the numbers were small and the difference between trial arms was not significant.

More participants reported self-harm or suicidality ideation on mood questionnaires in the DTG arm but the investigators suggested: “This difference should be interpreted with caution in an open-label trial”.

This study compared neuropsychiatric adverse events, including serious adverse events grade 3 and above events, ART-modifying events and suicidality-related events, as well as participant/carer mood-and-sleep questionnaire responses between the two treatment groups.

Overall, there were 31 neuropsychiatric adverse events (in 23/707; 3% participants): 18 (15) in DTG vs 13 (8) in standard-of-care, p=0.125. Hazard ratio (HR) for time to first neuropsychiatric adverse event: 0.154 (95% CI 0.79 to 4.41). Of these events, 16/362 (4%) were in boys vs 7/345 (2%) in girls; 16/311 (5%) on first-line vs 7/396 (2%) on second-line.

Median age at first event was 15.9 years (IQR 10.4 to 17.5). Median time (IQR) from enrolment at first event was 72 weeks (IQR 47 to 124) weeks.

There were 12 neurological adverse events (in 11 participants): 6 (6) in DTG vs 6 (5) in standard of care, p=0.736. The most common were epilepsy/convulsions with 4 (4) events reported in each arm. There were 4 serious adverse events in 3 participants in each arm. None in the DTG and 1 in the standard of care arm required ART modification. HR for time to first event DTG vs standard of care was 1.18 (95% CI 0.36 to 3.87), p=0.784.

There were 19 psychiatric adverse events: 12 (10) in DTG vs 7(4) in standard of care, p=0.097. Suicidal ideation/behaviour was most common, with 8 (8) and 7 (4) events in the respective arms. There were 3 (2) vs 2 (1) serious adverse events. And 2 (1) vs 1 (1) ART-modifying events. HR for time to first event 2.48 (95% CI 0.78 to 7.90), p=0.125. Of note, 2 events in the DTG arm (depression and insomnia) occurred months after switching treatment.

The investigators noted that although DTG doses increased during the study – following PK substudies and subsequently approved by FDA and EMA – most neuropsychiatric adverse events occurred on the initial lower doses.

There were no differences between treatment groups in low mood/feeling sad, problems concentrating, feeling worried or feeling angry/aggressive, time to fall asleep, nightmares/vivid dreams or sleep quality.

In the mood-and-sleep questionnaires, small numbers of participants/carers reported symptoms of: self-harm (8 DTG vs 1 standard of care, p=0.038), “life was not worth living” (17 DTG vs 5 standard of care, p=0.009) or suicidal thoughts (13 DTG vs 0 standard of care, p<0.001). These symptoms were transient, rarely occurred more than once and did not lead to treatment modification.

Overall, the results on neuropsychiatric manifestations from ODYSSEY are reassuring but the investigators noted that clinicians should be aware of suicidality ideation among adolescents and screen appropriately.

Resistance

The study found DTG to have a high genetic resistance barrier in children, preventing emergent resistance to NRTIs.

There was no post-failure resistance to any drug class in children starting first-line DTG – this was significantly less than for those on standard-of-care.

There was no new NRTI resistance in children on second-line DTG, but 4 developed new INSTI resistance (4 were on AZT).

Participants reaching virological failure by 96 weeks were included in the resistance analysis. This was defined as confirmed viral load ≥400 copies/mL after week 36 or lack of virological response by week 24 and ART switch.

Those with virological failure were retrospectively tested for post-failure resistance up to week 96. The latest sample with viral load ≥1000 copies/mL after failure and before treatment change was used. Earlier samples, including baseline, were sequenced if one or more major IAS mutation was identified post-failure.

Among participants on first-line, 11 (7%) DTG vs 30 (19%) standard-of-care experienced viral failure by 96 weeks, and on second-line, 31(16%) DTG vs 40 (20%) standard-of-care.

The estimated proportion with emergent resistance was none on first-line DTG vs 20 major IAS drug resistance mutations post-failure in standard of care: 13 NRTI, 18 NNRTI. On first-line standard-of-care 62% of participants with virological failure had new NRTI resistance and 88% had new NNRTI resistance.

On second-line DTG, 4 participants had a major mutation (INSTI) vs 5 on standard of care: 3 NRTI, 2 NNRTI, 1 PI. There was no new resistance to NRTI on DTG vs 3 (10%) in standard-of care.

Of those exposed to PIs in standard-of-care, only 3% with virological failure developed PI resistance.
Both participants with virological failure on NNRTI-based second-line standard-of-care had emergent NNRTI resistance.

The investigators reported a variety of emergent mutations to NRTI and NNRTI among participants on first-line standard-of-care – M184 was most common NRTI mutation and K103 was most common NNRTI mutation.

There were 2 emergent PI mutations in one participant on second-line standard of care. The 4 children on second-line DTG had 3 different emergent INSTI mutations.

Post virological failure, participants on first-line DTG remained susceptible to most NRTI backbones. Those on first-line standard-of care and both second-line treatment groups had higher levels of resistance, particularly to ABC and 3TC (or FTC).

The cumulative probability of re-suppression/switch by 72 weeks after failure in the DTG vs standard of care arms respectively: 0.58 (95% CI 0.40 to 0.73) vs 0.42 (95% CI 0.28 to 0.55), p=0.047.

The investigators explained that these results support using DTG-containing regimens for children starting first-line or second-line ART, but ongoing adherence support is required for children on second-line.

Folate

There was no evidence that DTG-based ART was associated with decreased levels of plasma folate or red blood cells (RBC) folate in ODYSSEY.

Plasma folate levels at four weeks and RBC folate levels at week 96 and later were higher than on standard-of-care. But the investigators noted that the mechanism is unclear. Vitamin B12 levels were similar in both arms.

This study compared folate and vitamin B12 levels among participants at three Ugandan sites in the trial.

Plasma folate was measured on stored samples at baseline and 4 weeks. RBC folate and vitamin B12 levels were measured using samples collected prospectively at 96 weeks or more.

A total of 229 children were randomised: 51% female, at baseline and median age was 12.3 years (IQR 9.0 to 14.7).

Seventy-five (33%) started first-line (100% EFV in standard-of-care) and 154 second-line (99% PI in standard-of-care)

The mean change in plasma folate from baseline (mean 6.1 ng/mL) to week 4 was 0.4 ng/mL (SE 0.3) in the DTG arm (n=110) vs -1.1 ng/mL (SE 0.3) in the standard-of-care arm (n=107). Difference DTG/standard-of-care: 1.6 ng/mL (95% CI 0.8 to 2.4), p<0.01.

At week 96, mean RBC folate was 887 pg/mL (SE 29) in the DTG-arm (n=109) vs 855 pg/mL (SE 28) in the standard-of-care arm (n=105). Difference: 73 ng/mL (95% CI 3 to 143) p=0.04.

At week 96, vitamin B12 levels were similar: 478 pg/mL (SE 21) in the DTG arm and 504 pg/mL (SE 26) in standard-of-care, p=0.42.

The results suggest any increased risk of NTDs in infants conceived on DTG is unlikely to be due to DTG causing decreased folate and vitamin B12 levels.

Formulations

PK data were also shown on paediatric formulations of DTG.

DTG formulations for children include film-coated tablets (FCTs) of different strengths and dispersible tablets (DTs). A previous bioequivalence study in healthy adults showed a 1.6-fold higher area under the curve (AUC) with DTs compared to FCTs.

Similarly in children, DTG exposure for those receiving DTs was 1.76 times higher compared to FCTs of the same dose: 30 mg DTs gave equivalent exposure to 50mg FCTs.

The investigators compared DTG PK parameters between DTs and FCTs in children weighing 14 to <25kg.

There were 64 PK curves available: in 14 to <20 kg weight-band 19 children had 25 mg FCT and 13 children 25 mg DT; in 20 to <25 kg 14 children had 25 mg FCT, 9 children 50mg FCT and 9 children 30 mg DT.

Paired data were available for 11 children. DTG C24h was lower than in adults (0.83 mg/L) for children receiving 25 mg FCT: geometric mean C24h (CV%) was 0.44 mg/L (50%) in weight-band 14 to <20 kg and 0.32 mg/L (94%) in 20 to <25 kg.

DTG C24h was similar to adults for 25 mg DT in weight-band 14 to <20 kg and 50 mg FCT and 30 mg DT in weight-band 20 to <25kg: 0.85 mg/L (67%), 0.75 mg/L (44%) and 0.76 (73%) respectively.

GMR (90%CI) for DTG AUC0-24 25 mg DT vs 25 mg FCT was 1.76 (1.46 to 2.12) for children 14 to <20 kg. GMR (90%CI) for DTG AUC0-24 30 mg DT vs 50 mg FCT was 1.12 (0.86-1.46) for children 20 to <25kg.

Glucuronidation ratio

There was positive relationship between DTG-MR and DTG clearance/kg in children in the trial. And there was no association between DTG-MR and age. DTG-MR in children was in line with adult values.

ODYSSEY (and IMPAACT-P1093) found lower and more variable DTG exposure in children compared to adults based on mg/kg dose. Estimates of DTG-MR are 0.05–0.08 in adults but this has not previously been studied in children.

A subset of children was selected from PK substudies within the trial, including all children less than 2 years of age and a random sample of older children receiving DTG FCT or DT. A total of 37 children (3 months to18 years of age) were included.

This evaluation found a positive relationship between DTG-MR and DTG clearance/kg in children: r(37)=0.64, p<0.001. And no association between DTG-MR and age: r(37)=-0.12, p=0.50. GM(CV%) DTG-MR in children was 0.051(66%), similar to adult values.

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Trial design for next generation PrEP

HIV Forum

The extremely high efficacy of current PrEP raises new challenges for next-generation PrEP.

Placebo-controlled studies are seen as unethical, now that oral PrEP should be standard of care prevention. It is also impractical to use randomised studies with active controls: **w**hether looking for non-inferiority or superiority endpoints, the studies would need to be too large.

This satellite session organised by the HIV Forum discussed new approaches that are already being used in phase 3 PrEP studies using longer-acting drugs like islatravir and lenacapavir. The webcast is now online.

Reference

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ANTIRETROVIRALS

Lenacapavir submitted to EMA for MDR HIV

Simon Collins, HIV i-Base

On 19 August 2021, Gilead submitted data on lenacapavir to the EMA for a limited indication of treatment for HIV with multidrug resistance (MDR). [1]

The application is based on 26-week data from the phase 2/3 CAPELLA study.

Lenacapavir us given as a sub-cutaneous long-acting injection every six months.

The submission to the US FDA was in June 2021.

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HIV pipeline report 2021: new drugs in development

Simon Collins, HIV i-Base

For all the focus and difficulties over COVID-19, this year is still an exciting year for HIV pipeline research.

This short annual review, produced as an HTB supplement, references 120 papers on key developments over the last 14 months.

It is also updated to include results presented at the IAS 2021 virtual conference.

Read the report online.

https://i-base.info/htb/41142

Download/open PDF file - (500 Kb)

https://i-base.info/htb/wp-content/uploads/2021/09/PIPELINE-Aug-2021.pdf (PDF)

Contents

TREATMENT ACCESS

Darunavir/ritonavir price achieved at US $210 for global access

Polly Clayden, HIV i-Base

Unitaid and Clinton Health Access Initiative (CHAI) recently announced a new pricing agreement to make darunavir/ritonavir (DRV/r) available as a second-line HIV treatment in low- and middle-income countries for US$ 210 per patient, per year. [1]

Hetero Labs LTD's World Health Organization (WHO) prequalified DRV/r will be available in 90 countries at a cheaper price than the most commonly-used second-line option lopinavir/ritonavir (LPV/r). Through the agreement, the price for DRV/r works out at US$ 17.50/pack (plus shipping and insurance).

The product is manufactured as 400/50 mg pills, two of which are taken as a once-daily dose of 800/100 mg DRV/r.

It will be registered widely in eligible countries using the WHO Collaborative Registration Procedure (CRP) for prequalified products. This procedure accelerates registration through information sharing between the WHO Prequalification of Medicines Programme (PQP) and national regulatory authorities.

Governments and international agencies such as PEPFAR and the Global Fund will be able to purchase DRV/r at this price.

C O M M E N T

Originator manufacturer Janssen has not enforced patents for darunavir when it is used in sub-Saharan Africa and least developed countries since 2012. But access has been thwarted by slow approval and a complex process to develop a stable, generic co-formulation and complete successful bioequivalence studies.

At present DRV/r is recommended by WHO as an alternative second-line HIV treatment.

The new generic product, plus recent findings from the NADIA trial – first shown at CROI earlier this year and now published in the NEJM [3, 4] – both support the argument to reposition DRV/r in the hierarchy of PIs.

Wider availability should lead to an upgrade to "preferred" rather than "alternative" in WHO recommendations and increased use of this PI. Although dolutegravir (DTG)-based treatment (which is still considerably cheaper than a PI) is likely to be most commonly used for people failing efavirenz-based first-line, those who receive DTG first-line will need a PI second-line.

Unitaid expects DRV/r to be introduced in countries by early 2022. But, they note that COVID-19 could affect this timeline.

CHAI is currently engaging with high-burden countries and trying to accelerate their procurement of this product. Carolyn Amole, Senior Director of the HIV access programme at CHAI, said they are "hoping there will be a loud cry for this product from the community as well!"

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HIV COMPLICATIONS

HPV vaccine prevent penile infection in young gay men

Simon Collins, HIV i-Base

A US cross-sectional study from 2016 to 2018 comparing penile swab samples in 687 gay men and transgender women aged 18 to 26 found similar rates of HPV overall in the roughly half who had been vaccinated vs those with no recorded vaccine: 12% vs 15% respectively (aPR 0.69, 95%CI: 0.47 to 1.01).

However, prevalence to the four strains in the quadrivalent vaccine was significantly reduced by 85% in those who had been vaccinated when younger than 18 years (aPR=0.15, 95%CI: 0.04 to 0.62).

This doesn't mean there are not additional benefits from those vaccinated later, but does show the benefits or earlier vaccination.

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HIV PREVENTION

Imbokodo trial results highlight challenge of developing an HIV vaccine and urgent need for access to proven prevention tools

Richard Jefferys, TAG

At the end of August, disappointing results were released from **Imbokodo, a phase IIb clinical trial evaluating the efficacy of an HIV vaccine candidate developed by the Janssen Pharmaceutical Companies of Johnson & Johnson. [1]**

Among cisgender women recruited in five African countries, the vaccine regimen didn't offer significant protection against acquisition of HIV infection. The outcome underscores the difficulty of inducing protective immunity against HIV compared to other pathogens, and highlights the importance of making effective biomedical prevention options – oral or injectable pre-exposure prophylaxis (PrEP) and the dapavirine ring – accessible to those in need, including women in the communities where Imbokodo took place.

The Imobokodo Trial

The trial enrolled 2,637 cisgender women aged 18–35 years old in Malawi, Mozambique, South Africa, Zambia, and Zimbabwe. The vaccine comprised priming immunisations with adenovirus serotype 26 (Ad26) vectors encoding four different HIV mosaic antigens that include elements from multiple virus clades, followed by boosts combining the Ad26 vector with an HIV gp140 envelope protein (from a clade C virus) in alum adjuvant.

HIV clades are groups of similar virus variants that primarily circulate in particular geographic regions across the globe (e.g. clade B is predominant in the Americas while clades A, C and D are most common on the African continent). A key idea behind the vaccine was to induce immune responses capable of targeting HIV from many clades.

Behavioral risk factors for HIV acquisition were evenly distributed between the vaccine and placebo groups in the trial. Uptake of oral PrEP, which was made available to all participants, was low – only around 3% of participants displayed detectable tenofovir levels, and the proportion in each arm with levels considered likely to be effective was even lower at 0.2% in the placebo group and 0.4% in the vaccine group (this slight difference was not statistically significant).

Trial results

The results were that 63 of 1,109 participants (5.68%) who received a placebo or dummy immunisation acquired HIV over a two-year period, compared with 51 of 1,079 participants (4.73%) given the vaccine. There were 25% fewer HIV infections in the vaccine group compared to placebo, but the difference was not statistically significant – in other words, it may have resulted from chance.

Statisticians calculate a confidence interval (CI) that gives a range of possibilities for where the true result may lie and, in this case, it was anywhere from a 10% increase in the risk of HIV acquisition to a 49% reduction (–10% to +49%). For a result to be considered statistically significant, the lower end of the CI must be above zero.

Some researchers have speculated that the apparent 25% difference between the vaccine and placebo arms might have reached statistical significance if the trial had been larger, but this is not certain.

The hint of a slight reduction in HIV incidence among vaccine recipients cannot be considered formal evidence of vaccine-induced protection from infection. But it does allow researchers to explore whether there might be notable differences between vaccine recipients who acquired HIV and those who did not, such as particular types of vaccine-induced immune responses.

Importantly, the vaccine regimen was found to be safe, with the typical reaction of mild local injection site pain and redness reported as more common among vaccine compared to placebo recipients.

Implications for the HIV vaccine field

The most immediate question for HIV vaccine research was whether another ongoing efficacy trial of the Johnson & Johnson vaccine should continue. Mosaico is studying a similar regimen in 3,600 cisgender men and transgender people who have sex with cisgender men and/or transgender people. After review by the trial's Data Safety Monitoring Board (DSMB), it was recommended that Mosaico continue for several reasons: it includes a slightly different protein boost immunisation (consisting of a mosaic rather than clade C gp140 protein), the prevalent HIV clade where the trial is taking place is different from Imbokodo (clade B versus clade C), and the route of exposure to HIV is also likely to be different (rectal versus vaginal).

The potential for Mosaico to produce a better result is unclear. There may be some reason to hope that the larger sample size of the trial could lead to a similar degree of vaccine efficacy achieving statistical significance. But it would be surprising if the Mosaico results showed a level of efficacy sufficient to justify licensure (e.g. >50% reduction in risk of HIV acquisition).

Perhaps the most optimistic possibility is that Mosaico, combined with prior results from Imbokodo and RV144 (an older vaccine trial in Thailand where a reduction in HIV incidence of around 30% crept above the threshold for statistical significance), could add to a body of evidence that current experimental vaccine approaches can offer a low level of protective efficacy. [2]

Work could then continue to try to figure out if there is any way of improving efficacy to reach the threshold considered necessary for licensure, or if it represents the ceiling for what these types of vaccine can achieve.

The broad common thread between all experimental HIV vaccines tested to date is that, while there are many nuances to each regimen, they induce immune responses against the virus that are known as non-neutralising. In the case of the Johnson & Johnson vaccine, these include T cell and antibody responses intended to mediate clearance of virus-infected cells. Induction of these responses was associated with protection against persistent infection in the SIV/macaque animal model. [3]

If researchers can't figure out a way to enhance the efficacy of vaccines that induce non-neutralising responses, the primary option that remains is solving the extremely difficult challenge of inducing broadly neutralising antibodies (bNAbs) with HIV vaccines.

Neutralising antibodies are considered a critical component of the protective response created by many licensed vaccines (including recently developed COVID-19 vaccines). Stimulating the production of bNAbs against HIV is far more difficult than for most other pathogens, for a variety of reasons, including:

- The virus's outer envelope protein is cloaked in glycan (sugar) molecules that are difficult for antibodies to penetrate or attach to.
- The mutation rate of the envelope protein is extremely high, with very few parts of the protein offering stable, conserved targets for antibodies.

Despite these challenges, rare bNAbs with strong anti-HIV activity have been identified and characterised using new techniques that allow researchers to fish the B cells that produce them out of blood samples taken from people with HIV. The bNAbs are typically not able to benefit the individuals they were sampled from, likely due to being present at low levels in the face of high amounts of virus. But the bNAbs can be grown to high levels in the lab and are being tested as both preventive and therapeutic interventions, delivered via infusion or subcutaneous injection. They also provide a guide for the type of bNAb response an HIV vaccine would need to induce to be successful.

In recent years, HIV vaccine constructs that aim to coax B cells down the first steps toward the long-term goal of bNAb production have begun to enter clinical trials. Results presented at the beginning of 2021 indicate that it's possible to bolster the number of B cells that may represent a starting point for bNAb production (these results, while promising, were unfortunately widely misunderstood in the media). [4]

Researchers are now employing Moderna's mRNA technology to test whether delivering specially engineered proteins into the body can enhance the numbers of B cells that may have the potential to produce bNAbs. The launch of these trials has generated considerable news coverage. But even if successful, additional vaccines will need to be designed to take the B cells further toward the goal of bNAb generation. An article in the UK's Independent newspaper does a good job of conveying that this work is at an early stage. [5]

In addition to bNAbs, some researchers are exploring whether there might be novel types of immune responses – not yet induced by any vaccine candidates – that could offer some protection against HIV. The main hope is a strategy that employs a weakened form of cytomegalovirus (CMV) as a vaccine vector to deliver HIV components into the body. The vaccine has shown promise in the SIV/macaque model, consistently protecting around 50% of immunised animals. Protection is associated with induction of an unusual type of CD8 T cell response. Phase I clinical testing in humans is now underway. [6]

Implications for access to biomedical prevention

In the absence of an imminent HIV vaccine, the Imbokodo results underscore the urgent need to make existing biomedical HIV prevention interventions accessible to those who most stand to benefit from them. The cisgender African women who participated in the trial represent a critically important population, as is demonstrated by the high rate of HIV infections that occurred. Many biomedical HIV prevention trials have recruited large cohorts of dedicated volunteers from communities of African women, but the payoff in terms of accessible interventions has so far been minimal.

This inequity must be addressed by scaling up availability of oral PrEP, and – when approved – the vaginal dapavirine ring and long-acting injectable PrEP. These points are emphasised in AVAC's statement on the Imbokodo results and in a follow up interview with their regional stakeholder engagement advisor Nandisile Luthuli and executive director Mitchell Warren (conducted by Tim Murphy for the Body.com). [7, 8]

Additional resources

AVAC Webinar: Imbokodo vaccine trial results and implications for the field – a global discussion. (9 September 2021).

https://youtu.be/gkNgkLCTnwY

Cohen J. Failed HIV vaccine trial marks another setback for the field. ***Science Insider***, August 31, 2021.

https://www.science.org/content/article/failed-hiv-vaccine-trial-marks-another-setback-field

Herper M. Johnson & Johnson's HIV vaccine fails first efficacy trial. ***STAT News***, August 31, 2021.

https://www.statnews.com/2021/08/31/first-efficacy-trial-of-johnson-johnsons-hiv-vaccine-fails/

HIV Vaccine Trials Network (HVTN). Experimental phase 2b HIV Vaccine regimen provides insufficient protection in preventing HIV. August 31, 2021.

https://www.hvtn.org/en/media-room/news-releases/experimental-phase-2b-hiv-vaccine-regimen-provides-insufficient-.html

Johnson & Johnson. Johnson & Johnson and global partners announce results from phase 2b Imbokodo HIV vaccine clinical trial in young women in sub-saharan Africa. August 31, 2021.

https://www.prnewswire.com/news-releases/johnson--johnson-and-global-partners-announce-results-from-phase-2b-imbokodo-hiv-vaccine-clinical-trial-in-young-women-in-sub-saharan-africa-301365918.html

C O M M E N T

These results are clearly disappointing the earlier hope that this approach might be more successful.

They should be clearly communicated to all participants in the Mosaico study together with a review of access to PrEP in the study.

Source:

Jefferys R. Imbokodo trial results highlight challenge of developing an HIV vaccine and urgent need for access to proven prevention tools. TAG. (13 September 2021).

https://tagbasicscienceproject.typepad.com/tags_basic_science_vaccin/2021/09/imbokodo-trial-results-highlight-challenge-of-developing-an-hiv-vaccine-and-urgent-need-for-access-t.html

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3. Science.
   https://www.science.org/doi/full/10.1126/science.aab3886
4. TAG Basic Science Blog.
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   https://www.independent.co.uk/news/health/hiv-vaccine-moderna-covid-b1904563.html
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   https://clinicaltrials.gov/ct2/show/NCT04725877
7. AVAC.
   https://www.avac.org/press-release/705-update
8. TheBody.com.
   https://www.thebody.com/article/hiv-vaccine-trial-disappointment

Moderna registers HIV vaccine study

Simon Collins, HIV i-Base

Although Moderna have not issued a press statement, several articles have reported on a new phase 1 study using mRNA vaccine approves for an HIV vaccine. [1]

The study is not yet recruiting but results are expected in 2023. [2]

References

1. BIO news 1109. mRNA HIV vaccine trial to start. (23 August 2021).
   https://www.bionews.org.uk/page_158574
2. ClinicalTrials.gov. A Phase 1 Study to evaluate the safety and immunogenicity of eOD-GT8 60mer mRNA vaccine (mRNA-1644) and Core-g28v2 60mer mRNA Vaccine (mRNA-1644v2-Core)
   https://clinicaltrials.gov/ct2/show/NCT05001373

HIV: RESEARCH STUDIES

START study: call for participants to attend final visit – please help

Simon Collins, HIV i-Base

Researchers from the large international START study are contacting study participants for a final follow-up visit.

Although HIV sites are leading on this, many people may have changed their clinics during what is now a 12 year study.

Although the main results were reported in 2015, additional funding supported extending the follow up. This unique data set will now look at long-term risks from delaying ART.

This is not for historical interest. The results from the final follow-up will have clinical relevance in 2021.

Late diagnosis is still a serious problem in all countries. More than 40% of people in the UK are still diagnosed with a CD4 count <350 cells/mm^3. It is associated with an 8-fold risk of mortality. [1]

C O M M E N T

In the UK sites around 300 participants helped this important research.

If you were part of START please contact your current clinic who will arrange everything.

You can also email Claire Rappoport, the community coordinator for the study network:

insightclairer@gmail.com

Thank you...

Additional background

In 2015, the START study reported clinical benefits of early ART, even when CD4 counts were above 500 cells/mm^3. At this level HIV was thought to cause few serious problems. [2]

The evidence was so important that the WHO announced plans to change the guidelines within weeks. It also show the importance of universal access globally. [3, 4]

Compared to starting when the CD4 count was still high at 350 cells/mm^3, early ART halved the risk of serious infections, including mortality. These results showed ART was safer than expected and that untreated HIV was more dangerous with a high CD4 count that previously though. And START found this 18 months earlier than predicted.

References

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   https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/959330/hpr2020_hiv19.pdf (PDF)
2. Early START results recommend ART for all study participants: starting HIV meds when the CD4 count is above 500 reduces AIDS-related events. HTB (1 June 2015).
   https://i-base.info/htb/28261
2. New directions in the 2015 WHO ART guidelines. (1 August 2015).
   https://i-base.info/htb/28597
3. WHO guidelines for when to start ART and use of PrEP. HTB (September 2015).
   https://i-base.info/htb/28949

New COVID-19 vaccine information from Modern ART for South Africa

Polly Clayden, HIV i-Base

South Africa is ramping up its vaccination programme.

People who are 18 years and older will be eligible for vaccination by September. The government is looking to vaccinate 3 million people by the end of the year.

Modern ART – a collaboration between the Treatment Action Campaign (TAC) and i-Base – has produced new materials that answer some of the questions from people with HIV about COVID-19 vaccination.

These frequently-asked questions are from our followers on the Modern ART for South Africa Facebook page:

https://www.facebook.com/modernARTforSouthAfrica

More COVID-19 vaccination information on the Modern ART for South Africa YouTube channel:

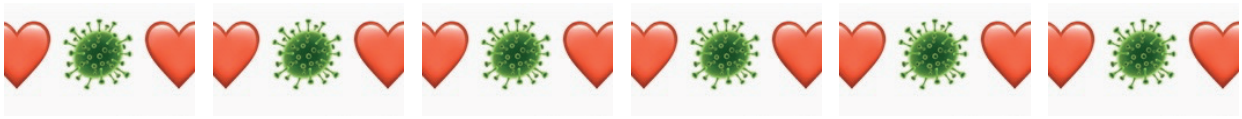
https://m.youtube.com/watch?v=BtbHIhzZb9M&feature=youtu.be

Modern ART for South Africa website:

https://modernartforsouthafrica.co.za

Booklets and posters are on the way…

HIV and COVID-19 - bulletin



COVID-19: HIV and COVID-19 coinfection

BHIVA statements on third vaccine doses for people living with HIV

Simon Collins, HIV i-Base

On 3 September 2021, the British HIV Association (BHIVA) published an online statement on the use of third primary doses of vaccinations against COVID-19 by people living with HIV. This also helpfully included a community summary. [1, 2]

These explain the latest recommendations from the UK Joint Committee on Vaccination and Immunisation (JCVI) where immunosuppression, including HIV, is included as one of the criteria for having a third dose. Importantly, although the JCVI documents define a CD4 threshold less than 200 cells/mm^3 they also allow for flexibility that lets doctors make this decision on an individual patent level. Access to the third dose requires the HIV specialist to provide clear advice when notifying the GP. [3]

The documents from BHIVA stress that most people living with HIV do not current need a third dose. They emphaise that vaccine responses at high CD4 counts (above 350 cells/mm^3) will be similar to the general population. The CD4 threshold is a conservation suggestion given the lack of data at lower CD4 counts.

Additional criteria for a third dose includes HIV-related symptoms (at any CD4 count), persistent detectable viral load (after > 1 year on ART) and people not yet on ART.

Both the BHIVA documents were updated two weeks later. [4, 5]

Please see these latest updates for full details.

C O M M E N T

These third doses are to supplement potential suboptimal responses to standard COVID-19 vaccine schedules. They are to equalise protection expected in the general population.

This is separate to discussions about the need for booster doses, to support waning immune responses approximately 6-8 months after a full vaccine schedule.

They are different again to the use of redesigned booster vaccines that might in the future be developed specifically to overcome current and future variants.

All documents also recognise that these guidelines and discussions are based on limited evidence.

References
1. BHIVA. BHIVA statement on JCVI recommendations for a third COVID-19 vaccine dose. (3 September 2021). https://www.bhiva.org/BHIVA-statement-on-JCVI-recommendations-for-a-third-COVID-19-vaccine-dose
2. Guidance for People Living with HIV from the British HIV Association (BHIVA), National AIDS Trust (NAT) and the Terrence Higgins Trust (THT). (3 September 2021). https://www.bhiva.org/recommendations-from-the-JCVI-on-a-third-COVID-vaccine-dose
3. JCVI. Report from the Joint Committee on Vaccination and Immunisation (JCVI) advice on third primary dose vaccination. (1 September 2021). https://www.gov.uk/government/publications/third-primary-covid-19-vaccine-dose-for-people-who-are-immunosuppressed-jcvi-advice/joint-committee-on-vaccination-and-immunisation-jcvi-advice-on-third-primary-dose-vaccination
4. BHIVA. BHIVA statement on JCVI recommendations for a third COVID-19 vaccine dose. (16 September 2021). https://www.bhiva.org/updated-BHIVA-statement-on-JCVI-recommendations-for-a-third-COVID-19-vaccine-dose
5. Guidance for People Living with HIV from the British HIV Association (BHIVA), National AIDS Trust (NAT) and the Terrence Higgins Trust (THT). (16 September 2021). https://www.bhiva.org/updated-recommendations-from-the-JCVI-on-a-third-COVID-vaccine-dose

HIV increases risk of severe COVID-19 in largest US study

Simon Collins, HIV i-Base

The largest national US cohort study so far, reports that people living with HIV have significantly higher risks of more severe COVID-19 and that these risks increase further with lower CD4 counts and higher viral load.

The analysis included almost 1.5 million people diagnosed with COVID-19 from January 2020 to May 2021. It looked at outcomes in more than 8,200 people living with HIV and more than 11,300 who had a solid organ transplant (SOT) (and 267 with both) and used multivariate analyses that also adjusted for demographics, medical and social factors. Severity of outcome used a 5-point scale, including hospitalisation, invasive ventilation, and death.

The paper, not yet peer-reviewed was published on 28 July 2021.

Baseline demographics for the cohort included median age 47 (IQR: 32 to 61), 55% were female, 52% were non-Hispanic white, 13% were non-Hispanic black, and 16% were current or former smokers.

People who were HIV positive and those with SOT were more likely to be older, male, non-Hispanic Black, and have more comorbid conditions (all $p<0.01$).

Overall results reported significantly increased risk of more severe COVID-19 for both groups, compared to people without immune dysfunction (all $p<0.01$). See Table 1.

Within the HIV positive group, lower CD4 count and higher viral load increased the risk of all outcomes. See Table 2.

Tor people with undetectable viral load on ART, having a lower CD4 count of 350 to 500 and <350 cells/mm^3 was associated with 2.9- and 6-fold increased odds of hospitalisaton, respectively, compared to those with CD4 counts >500.

Similarly, among people with a high CD4 count (>500 cells/mm^3), detectable viral load independently had a 2-fold increased risk of hospitalisation.

Table 1: Summary of risk of severe COVID-19 for HIV and SOT *

	HIV+	SOT
Hospitalisation	1.28 (1.27 to 1.29)	2.61 (2.58 to 2.65)
Invasive ventilation	1.43 (1.43 to 1.43)	4.82 (4.78 to 4.86)
Death	1.20 (1.19 to 1.20)	3.38 (3.35 to 3.41)

* adjusted odds ratio (95%CI), including for sociodemographics and comorbidities.

Table 2: Impact of CD4 and viral load on risk of severe COVID-19 *

	CD4 <350	VL 50 to <1000	VL >1000
Hospitalisation	4.4 (3.6 to 5.3)	1.8 (1.2 to 2.7)	3.5 (2.2 to 5.5)
invasive ventilation	5.4 (3.2 to 9.0)	–	–
Death	7.6 (3.9 to 14.9)	4.4 (1.4 to 13.7)	7.3 (2.1 to 25.7)

* Odds ratio compared to CD4 >500 and undetectable viral load

C O M M E N T

Although not yet peer-reviewed, this is the largest study to include such comprehensive CD4 count and viral load data.

The clear associations with more severe COVID-19 over the first 17 months of the epidemic convincingly overcome the earlier concerns with smaller studies that reported no link.

The results show the importance of including HIV as a criteria for priority access to vaccines. They also show the importance of greater care to reduce risk of transmission, especially as lock down measures are being relaxed and Delta variant is so dominant.

The CD4 and viral load results show the importance of being on effective ART, but that this still does not normalise risk compared to being HIV negative.

Reference

Sun J et al. COVID-19 disease severity among people with HIV infection or solid organ transplant in the united states: a nationally-representative, multicenter, observational cohort study. medRxiv 2021.07.26.21261028; doi: 10.1101/2021.07.26.21261028. (28 July 2021).

https://www.medrxiv.org/content/10.1101/2021.07.26.21261028v1.full#T2

SARS-CoV-2 variants and immunosuppression

Simon Collins, HIV i-Base

A review in the NEJM includes case reports of SARS-CoV-2 infections in people with immunosuppression.

It is notable for a higher risk for prolonged infection – and that this had enabled viral evolution in these individuals that was similar to main variants of interest (VOI) and concern (VOC).

These cases included recipients of solid organ transplantation and people with uncontrolled HIV infection. It also suggested that certain forms of immunosuppression might drive the development of mutations.

Prioritised access to vaccines is recommended for both personal protection and to limit the risk of prolonged infection - and also the importance of isolation until viral shedding is proved negative.

The article also discusses the potential role of monoclonal antibody treatment for people who do not generate immune responses to vaccines, recognising that these often have limited activity against later variants.

Reference

Corey L et al. SARS-CoV-2 Variants in Patients with Immunosuppression. N Engl J Med 2021; 385:562-566. DOI: 10.1056/NEJMsb2104756. (5 August 2021).

https://www.nejm.org/doi/10.1056/NEJMsb2104756

COVID-19: VACCINE RESEARCH

UK vaccine programme saved 100,000 lives

Simon Collins, HIV i-Base

Public Health England (PHE) regularly update the impact of the COVID-19 vaccination programme in England.

So far the programme has prevented:

- More than 105,000 deaths.
- More than 230,000 hospitalisations in those aged 45 and over.
- More than 140,000 hospitalisations in those aged 65 and over.
- More than 24 million infections.

Ref: PHE surveillance report. Revised monthly. (16 September 2021).

https://www.gov.uk/government/news/covid-19-vaccine-surveillance-report-published

Large US registry confirms safety of COVID-19 vaccines during pregnancy

Simon Collins, HIV i-Base

A large prospective case-control study that used a validated algorithm for pregnancy outcomes in more than 105,000 pregnancies reported no association between spontaneous abortion and recent mRNA vaccination against COVID-19 (within four weeks).

There date, published as a research letter in the journal JAMA, are important because of the higher risks of COVID-19 during pregnancy, including severe maternal mortality.

Ref: Kharbanda EO et al. Spontaneous abortion following COVID-19 vaccination during pregnancy. Research letter. JAMA. doi:10.1001/jama.2021.15494. (8 September 2021).

https://jamanetwork.com/journals/jama/fullarticle/2784193

US FDA grants full approval to Pfizer vaccine

Simon Collins, HIV i-Base

On 23 August 2021, the FDA fully approved the Pfizer's mRNA the first COVID-19 vaccine for adults aged 16 and over. Previous use had been supported by an emergency use authorisation (EUA).

The EUA is still supports use in people aged 12 to 15 years old.

Full authorisation enables the vaccine to be a requirement by hospitals, colleges, businesses and other organisations.

Ref: FDA news release. FDA approves first COVID-19 vaccine: approval signifies key achievement for public health. (23 August 2021).

https://www.fda.gov/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine

Immune responses against Delta variant in people vaccinated in the UK

Simon Collins, HIV i-Base

A large community based survey of randomly selected households in the UK reported reduced generally high efficacy of the three main vaccines against the Delta variant.

However, reduced and waning protection against Delta variant over time supports third vaccine for people with reduced immune responses after two doses.

Ref: Pouwels KB et al. Impact of Delta on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK.

https://www.ndm.ox.ac.uk/covid-19/covid-19-infection-survey/results/new-studies

Neutralising antibody levels from COVID vaccines correlate negatively with age

Simon Collins, HIV i-Base

A small US study looking at levels of neutralising antibody levels after a complete Pfizer vaccine schedule correlated negatively with age, with lowest levels in the oldest participants.

The study included 50 people, half women, with median age 50 years and ranging from 21 to 82.

The study reported strength of response against the original US strain and the P.1 variant, which were reduced by approximately 75%.

Although the overall association with age was highly significant, there was also considerable variance in the results ($p=0.002$; $R^2=0.19$).

"For the USA-WA1/2020 strain, the youngest participants (20 to 29 years; n=8) had a geometric mean titre (GMT) of 938 (95% CI: 608 to 1447) and the oldest participants (70 to 82 years; n=9) had a GMT of 138 (95% CI: 74 to 257), representing an 85% reduction (p<0.001). For the P1 variant, the youngest participants had a GMT of 165 (95% CI: 78 to 349) and the oldest participants had a GMT of 66 (95% CI: 51 to 86), representing a 60% reduction (p=0.03)."

Importantly, although levels of neutralising antibodies strongly correlate with levels of protection, the relevant threshold for protection has not yet been determined.

Ref: Bates TA et al. Age-dependent neutralization of SARS-CoV-2 and P.1 variant by vaccine immune serum samples. JAMA. doi:10.1001/jama.2021.11656. (21 July 2021).

https://jamanetwork.com/journals/jama/fullarticle/2782428

Evolution of neutralising antibody responses to natural infection and after vaccination

Simon Collins, HIV i-Base

A detailed reviewed of the development of quantitative and qualitative antibody responses reports differences from when vaccination follows an earlier infection.

The paper describes the increasingly broad and potent antibody responses from B cells, including against recent variants, and that these are significantly boosted after mRNA vaccination.

In contrast, SARS-CoV-2 naive participants, the second vaccine dramatically increases neutralising activity, but doesn't develop further breadth. The paper suggest that further boosting with currently available vaccines is unlikely to change this qualitative aspect of protection.

Ref: Cho A et al. Antibody Evolution after SARS-CoV-2 mRNA Vaccination. BioRxiv DOI: 10.1101/2021.07.29.454333. (29 July 2021).

http://dx.doi.org/10.1101/2021.07.29.454333

COVID-19: EPIDEMIOLOGY

Outbreak of 469 symptomatic Delta cases in fully vaccinated adults during Bear Week

Simon Collins, HIV i-Base

On 30 July 2021, the US MMWR included a case study of outbreaks of symptomatic Delta infections associated with large public events in Provincetown, Massachusetts.

The average 14 day cases rose from an average of 0 before the events to a maximum of 177/100,000 within three weeks.

The case study is notably for several reasons.

- 346/469 (74%) were in people who were fully vaccinated >14 days before being diagnosed. Of these, 46% had used Pfizer, 38% Moderna and 7% J&J - roughly similar to percentages in the local vaccination programme. Over half were residents.
- Median time since end of 14-day post vaccine was 86 days (range: 6 to 178 days).
- Nearly all 133 cases tested were the Delta variant (90%), with the remaining 10% not producing a result.
- 274/469 (79%) were symptomatic. Asymptomatic infections were likely underestimated.
- Only 4/469 (1.2%) were hospitalised - with 3/4 having received the single dose J&J vaccine. One additional unvaccinated person was also hospitalised. There were no deaths.
- 85% were male - reflecting the demographics of the public events.

These data provide further evidence that currently approved vaccines are highly effective at preventing severe COVID-19.

Also, that continued use of masks and physical distances are important as restrictions are lifted.

C O M M E N T

The report is important for showing the high level of protection from hospitalisation against the Delta variant.

However, although the report referred to social events that were more likely to be attended by men they didn't specify this was for two annual LGBT events in Provincetown Independence Week and Bear Week.

This might have increased the risk of transmission if people felt able to relax social mixing because of the high level of vaccination.

More than 900 cases have now been reported.

Reference

Brown CM et al. Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings – Barnstable County, Massachusetts, July 2021. MMWR Morb Mortal Wkly Rep. ePub: DOI:10.15585/mmwr.mm7031e2. (30 July 2021).

https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm

JOB VACANCIES

Treatment Advocate and Information Officer

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

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

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

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

Further details are available online.

https://i-base.info/htb/40810

Medical writer

We are currently looking for an HIV treatment advocate/writer to work on freelance projects. The can be separate or included in the post above.

If you are interested in this position, please email an introductory letter and examples of written work to: jobs@i-base.org.uk

Equal opportunities

HIV i-Base is an equal opportunities employer. We welcome applications from people living with HIV.

For further details on both positions please see the addtional information on the i-Base website:

http://i-base.info/about-us/volunteering-and-staff-vacancies/

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

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

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.

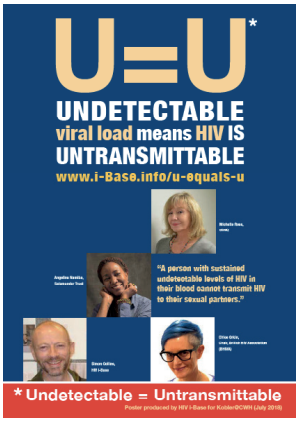
This project was developed with the Kobler Centre in London.

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.

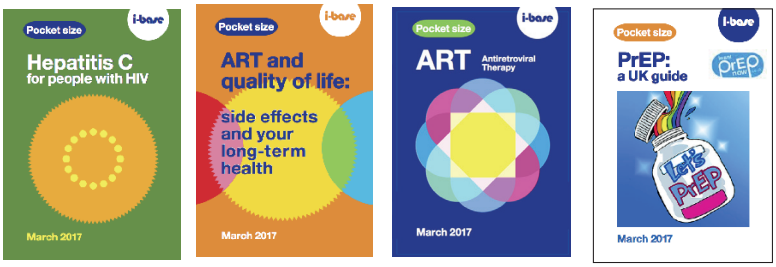
Personalising these for your clinic is cheap and easy and might be an especially nice way to highlight the good news.

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

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

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

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

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Name _____ **Position** _____

Organisation _____

Address _____

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Telephone _____ **Fax** _____

e-mail _____

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

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

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

- **Booklets about HIV treatment**

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

UK Guide To PrEP *(June 2021): 24-page A5 booklet* **quantity** _____

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

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

Guide to changing treatment: what if viral load rebounds *(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