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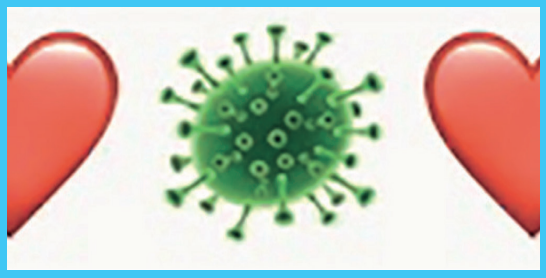
HTB no. 12 – HIV and COVID-19 no. 9

hiv treatment bulletin (e)



Latest UK HIV statistics & COVID-19 vaccine (11 November 2020)

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i-Base 2020 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


HTB no. 12 – HIV and COVID-19 no. 9

hiv treatment+ bulletin

Latest UK HIV statistics & COVID-19 vaccine (11 November 2020)

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SPECIAL REPORT: COVID-19 VACCINE 13
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Published by HIV i-Base

The most important news in this issue - for HIV or COVID-19 - is the early efficacy results from the Pfizer/BioNTech COVID vaccine. It gives us proof that not only can the scientific challenge of making a vaccine be overcome, but at a much higher efficacy level that was first hoped.

This produces optimism for other candidate vaccines (another nine are also in phase 3 studies) and for a future that will not be dominated by fear of future waves.

The main HIV news include the publication of latest UK HIV statistics which are still continuing to fall - although late diagnosis is still a serious challenge.

We also include news that cabotegravir/rilpivirine long acting injections have received a positive opinion for approval in the EU. This has been a long process and although there has always been really high interest in alternatives to oral ART. Implementation studies are already ongoing, although not so far in the UK.

Early results from the HPTN 084 study also show that cabotegravir LA is highly effective as PrEP for cisgender women - with similar results to HPTN 083 in gay men and transgender woman.

The issue is being distributed shortly after the UK enters the second lockdown we continue to include leading news about coronavirus and COVID-19.

As predicted in April, a second wave of corovavirus developed during October with dramatically higher rates of people testing positive, due to wider availability of testing.

Although the options for treatment are not greatly different for the second wave - with notable exceptions for dexamethazone and remdesivir - the experience from managing the first crisis means that outcomes will hopefully be better.

This is going to be critical because there have been several disappointments over the last weeks with some of the more promising treatments. In the last issue we reported disappointing results with tocilizumab (although other studies continue), and this issue includes lack of benefit from convalescent plasma in a randomised study in moderate COVID-19.

Development of the monoclonal antibody bamlanivimab by Eli Lilly has been stopped after a recommmendation from a DSMB showing no early signal of benefit - based on lack of positive response after five days.

The dual monoclonal antibody combination from Regeneron - REGN-COV2 - has also stopped enrolling participants with severe COVID-19, after a DSMB recommendation due to a safety concern.

Finally, the large randomised international WHO SOLIDARITY study reported no survival benefit from hydroxychloroquine or lopinaivr/r - both or which were already known - but also from using interferon-Beta or, controversially, remdesivir. It had been hoped that the much larger numbers (more than other remdesivir studies combined), might have had sufficient power to show improved survival - when instead the SOLIDARITY results didn't even showed faster recovery. These results have been blamed on the open label trial design and limited data collected across very different health settings.

Although the US FDA has just granted full approval to remdevir based on reducing symptoms, the decision was only based on results from positive studies.

It will now be important to see the role of remdesivir in the upcoming WHO COVID-19 guidelines.

CONFERENCE REPORTS

HIV Therapy Glasgow 2020

5-8 October 2020, virtual conference

Introduction

Simon Collins, HIV i-Base

This year, the biennial Glasgow HIV Congress was held from 5-8 October as a virtual meeting.

The conference website is easy to navigate, with most oral presentations already prerecorded but with presenters also being online for Q&A discussions afterwards. However, although webcasts remained online for several weeks for registered delegates, they have since been taken down and are not yet posted to the main conference website.

The programme this year was particularly strong, with a focus on COVID-19 and how it affects people living with HIV and our care, and on important concerns about women's health and weight gain experienced by some people as a side effect of ART. As always, there are also exciting studies on next generation treatment.

https://hivglasgow.org

The following reports from the meeting are in this issue of HTB.

- Adverse pregnancy outcomes among Spanish women hospitalised with COVID-19

Adverse pregnancy outcomes among Spanish women hospitalised with COVID-19

Polly Clayden, HIV i-Base

High proportion of Caesarean sections and preterm delivery among pregnant women with COVID-19 in a Spanish cohort – according to data presented at HIV Glasgow 2020.

There was no vertical transmission in this study but one reported case of horizontal transmission through family contact.

This main objective of this analysis was to describe clinical and epidemiological characteristics of a cohort of women with SARS-CoV-2 during pregnancy and their neonates. It was a prospective, multicentre, observational study of five hospitals in the GESNEO-COVID cohort.

The study enrolled women with confirmed SARS-CoV-2 by PCR and/or serology during pregnancy, diagnosed and delivering between 15 March and 31 July 2020 – there were 105 women included.

The median age of pregnant women was 34.1 (IQR: 28.8 to 37.1) years. The majority (93.3%) were diagnosed in the third trimester and remainder (6.7%) during the second trimester. Over half (64.8%) had symptoms, 30.8% of pneumonia. Almost half of the cohort (43.8%) received treatment for COVID-19 and 4.8% were admitted to ICU, for a median of 10 days (IQR: 6.5 to 18.5).

Overall, 36.2% of pregnant women had a Caesarean delivery. Severe COVID-19 was indicated for almost 30% of them.

There were two sets of twins so 107 neonates were included in the analysis.

The rate of preterm delivery was 20.2% and small for gestational age was 5.6%. The proportion neonates needing intensive care was 16.8%, for a median duration of 3 days (IQR: 1 to 8) – mostly due to complications with prematurity. And 66.4% of neonates were breastfed.

One extremely preterm neonate died at 20 days of life due to prematurity-related complications. Another full-term infant died due to unexpected sudden death during early skin-to-skin contact after delivery. Both were born to women with severe pneumonia, admitted to ICU.

Nasopharyngeal PCR was performed at birth and 100% of neonates tested were negative. One neonate then tested positive at 15 days of life. The mother was in the ICU with pneumonia – this was considered to be intra-family transmission. No vertical transmission was reported.

In multivariate analysis pneumonia was associated with higher risk of Caesarean section: OR 4.2 (95% CI 1.47 to 11.99).

Pneumonia and positive PCR at delivery were associated with preterm delivery: OR 6.73 (95% CI 2.30 to 21.31) and OR 6.44 (95% CI 1.82 to 31.38), respectively.

Reference

Carrasco I et al. SARS-CoV-2 infection in pregnancy and newborn in a Spanish multicentric cohort (GESNEO-COVID). HIV Glasgow – virtual. 5–8 October 2020. Oral abstract 0444.

https://vimeo.com/466268384/be0793cb39 (webcast: 40.45)

CONFERENCE REPORTS

51st World Conference on Lung Health

20–24 October 2020. Virtual meeting

Introduction

Polly Clayden, HIV i-Base

Organised by the century-old International Union Against Tuberculosis and Lung Disease (The Union), this conference is the largest annual lung health event focusing on the issues as they affect low- and middle-income populations.

As is the current norm, this year's meeting was virtual.

Abstracts are published in a supplement of the International Journal of Tuberculosis and Lung Disease(IJTLD). The abstract book is open access and available online:

https://conf2020.theunion.org/programme/abstract-book/

International workshop on clinical pharmacology of HIV, hepatitis, and other antiviral drugs virtual meeting. 28–30 September 2020.

Reports in this issue of HTB are:

- No increase in adverse birth outcomes with IPT-exposure in pregnancy in two African cohorts

No increase in adverse birth outcomes with IPT-exposure in pregnancy in two African cohorts

Polly Clayden, HIV i-Base

Izoniazid preventative therapy (IPT) did not increase the risk of adverse birth outcomes among pregnant women with HIV in analyses from South Africa and Kenya, presented at the Union 51st World Conference on Lung Health 20–24 October 2020. [1, 2]

There was a greater number of live births and fewer miscarriages among the South African women who received IPT than those who did not. And no difference in risk of preterm delivery and other adverse birth outcomes between the Kenyan women starting and not starting IPT in pregnancy.

South Africa

In this study, the South African Medical Research Council analysed data from 1215 HIV positive pregnant women in their second or third trimester. Women were prospectively enrolled from six facilities in three provinces (Gauteng, KwaZulu-Natal and Mpumalanga) between October 2017 and May 2019.

Of 1215 women, 833 (68.6%) started IPT in pregnancy and 786 of these had known pregnancy outcomes. Less than 20% of the women who were not receiving IPT reported having taken it previously.

Over 90% of live births were recorded among the participants. In multivariate analysis, women receiving IPT were significantly more likely to have a live birth than IPT-unexposed women: 94.9% vs 92.6%, p=0.017. They were also less likely to have a miscarriage or a still birth.

Kenya

This was a retrospective chart review of antenatal and birth records of mother-infant pairs, attending two facilities in Kisumu province between 2015 and 202. The review was conducted by investigators from Emory University, Atlanta and University of Washington, Seattle.

They screened 779 medical records, of these, 576 mother-infant pairs had complete data. Women were a median age of 29 years and most were receiving ART (99%) with viral load <1000 copies/mL (97%). About one-third of women received IPT during pregnancy (27%), started a median gestational age of 23 weeks.

Adverse birth outcomes were frequent, occurring in 25.7% and 22.4% of IPT-unexposed births and IPT-exposed births, respectively.

There were slightly fewer preterm births among women receiving IPT than among those who did not: 18% vs 22%, NS.

There was no difference in the frequency of other adverse birth outcomes (low birth weight, congenital anomaly and perinatal death) between the two groups. Nor was there greater risk of composite adverse birth outcomes among women receiving IPT compared with those who did not.

C O M M E N T

These data are reassuring, particularly following concerns raised by the randomised IMPAACT P1078 TB that found adverse pregnancy outcomes to be higher among women starting IPT in pregnancy compared with postpartum. [3, 4]

In contrast, programmatic data from Western Cape, South Africa suggests that IPT was protective against poor pregnancy outcomes with lower proportions of miscarriage, stillbirth, low birth weight, and neonatal death. [5]

As did a sub-analysis of the Tshepiso cohort – a prospective observational study looking at maternal and infant outcomes among HIV positive women with and without TB in South Africa – although this was a secondary analysis with a small sample size. [6]

Clearly IPT exposure in pregnancy needs continual monitoring in large cohorts.

And as investigators from the South African Medical Research Council noted: "With recent changes in TB and HIV treatment regimens, more research is needed to determine the safety of these therapies during each trimester of pregnancy and to evaluate pregnancy outcomes."

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CONFERENCE REPORTS

International workshop on clinical pharmacology of HIV, hepatitis, and other antiviral drugs

28–30 September 2020, virtual meeting

Introduction

Polly Clayden, HIV i-Base

This long-running annual meeting was the first of Virology Education's now extensive list.

The presentations (provided speaker's consent has been received) are available online at:

www.academicmedicaleducation.com

Articles in this issue are:

• New neonatal liquid formulations of dolutegravir have comparable bioavailability to dispersible paediatric tablet

New neonatal liquid formulations of dolutegravir have comparable bioavailability to dispersible paediatric tablet

Polly Clayden, HIV i-Base

Two investigational neonatal liquid formulations of dolutegravir had comparable bioavailability to the dispersible paediatric tablet formulation in a single dose pharmacokinetic study conducted in HIV negative men. [1]

These results were shown at the virtual International workshop on clinical pharmacology of HIV, hepatitis, and other antiviral drugs, 28–30 September 2020.

There are currently two approved originator (ViiV Healthcare) paediatric formulations of dolutegravir: 10 mg and 25 mg film-coated tablets and 5 mg dispersible tablets (for infants at least four weeks of age and weighing at least 3 kg).

This study evaluated two liquid formulations of dolutegravir that are under development: prototype A, 5-mg/mL dolutegravir suspension in miglyol, and prototype B, 2 mg/mL dolutegravir solution in glycerol. It analysed the pharmacokinetics and safety of the two liquid formulations vs the dispersible tablet after single dose administration to HIV negative men.

The study was open label, single centre, single-dose, non randomised, 3-period and fixed-sequence. [2] Participants received dolutegravir doses in three periods with at least 7 days washout between: Period 1, prototype A dolutegravir suspension; Period 2, two 5 mg dispersible dolutegravir tablets dispersed in water (reference); Period 3, prototype B dolutegravir solution. All doses were equivalent to 10 mg of dolutegravir.

Twenty-two HIV negative men aged 21–49 years old (mean 31.3 years) were included in the study. Their mean weight was 79.2 kg and BMI 25.4 kg/m^2; 19 (86%) were white, 2 (9%) black and 1 (5%) Asian. Twenty-two received the dispersible tablet, 18 received prototype A liquid and 19 prototype B liquid.

The investigators looked at time concentration profiles over 72 hours. This evaluation of AUC0-inf, Cmax and AUC0-t found prototype A (miglol suspension) to have similar bioavailability to dispersible tablets (within bioequivalence range of 0.8 to 1.25). With prototype B (glycerol solution) both AUC parameters were also similar but Cmax had slightly higher relative bioavailability, with upper CI bound outside the range for bioequivalence: geometric mean square ratio 1.22 (90% CI 1.13 to 1.33).

Based on these relative bioavailability results, the investigators concluded that no dose adjustment of either liquid formulation will be needed for neonates.

There were no safety concerns after single dose administration in adult participants.

The manufacturer has chosen the miglyol suspension for further development.

C O M M E N T

As the options for neonates with HIV are few, this liquid formulation of dolutegravir is good news.

There are also two generic scored 10 mg dispersible paediatric dolutegravir tablets awaiting approval.

It is hoped that the role for this liquid formulation in now seen in low- and middle-income countries, where the need for paediatric formulations is greatest.

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1. Singh R et al. Comparison of relative bioavailability of Tivacy neonatal liquid formulations to pediatric dispersible tablets. International workshop on clinical pharmacology of HIV, hepatitis, and other antiviral drugs virtual meeting. 28–30 September 2020. Oral Abstract 8. https://academicmedicaleducation.com/meeting/international-workshop-clinical-pharmacology-hiv-hepatitis-and-other-antiviral-drugs-130 (webcast)
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ANTIRETROVIRALS

EMA issues positive opinion to approve cabotegravir LA/rilpivirine LA injections (Vocabria/Rekambys) as new HIV treatment

Simon Collins, HIV i-Base

On 16 October 2020, the European Medicines Agency (EMA) published a positive opinion to approve long-acting injections of cabotegravir and rilpivirine as a new HIV treatment. [1, 2]

This decision has also been long-awaited as submission to the EMA was made in July 2019. [3]

Cabotegravir is an integrase inhibitor and rilipivirine is an NNRTI, and long acting intramuscular injections are given concurrently, rather than in the same formulation. Rilpivirine LA requires cold-chain storage.

Although approval was largely based on results from three phase 3 studies using monthly injections, the EMA decision includes the option to use either monthly or two-monthly dosing schedules. A lead-in phase using oral versions of both drugs is also required.

This recommendation from the EMA's human medicines committee (CHMP) still has to be approved by the European Commission, but CHMP opinions are routinely adopted. However, discussions about price are not finalised until after full approval.

ViiV Healthcare developed cabotegravir LA and also led dual therapy with rilpvirine LA.

Trade names in the EU are Vocabria for cabotegravir LA injections and oral formulations and Rekambys for rilpivirine LA injections. Oral rilpivirine is already approved as Edurant.

In Canada (and probably in the US, though not yet approved by the FDA), the tradename for the dual injection is Cabenuva. This is because both injections are packaged together, whereas in the EU they will be packaged separately.

References
1. EMA. First long-acting injectable antiretroviral therapy for HIV recommended for approval. (15 October 2020). https://www.ema.europa.eu/en/news/first-long-acting-injectable-antiretroviral-therapy-hiv-recommended-approval
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3. Cabotegravir/rilpivirine long-acting injectable HIV drugs submitted to EMA. HTB (23 August 2019). https://i-base.info/htb/36531

HIV PREVENTION

HIV in the UK: PHE report shows diagnoses continue to fall during 2019 but that 42% are still late

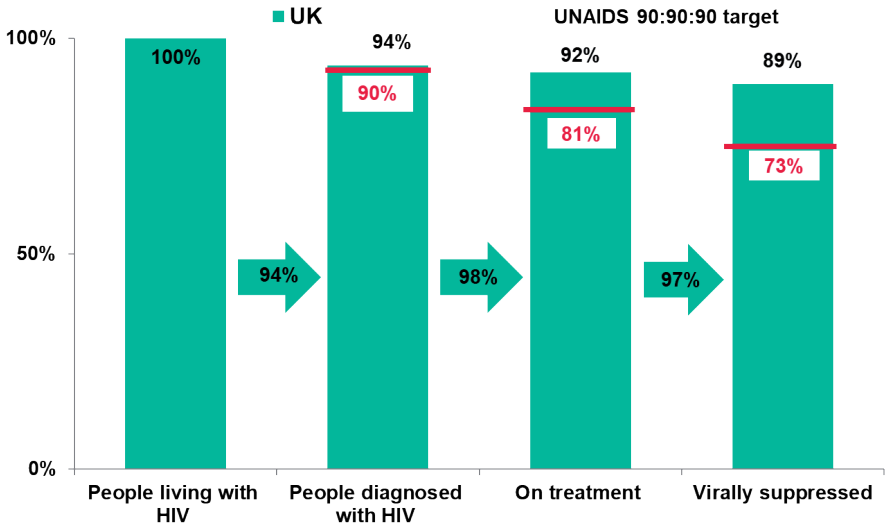
Simon Collins, HIV i-Base

On 3 November 2020, Public Health England (PHE) published the annual statistics from last year on HIV in the UK. [1, 2, 3]

The results showed a continued decline in diagnoses across all risk groups people easily meeting overall aim for more that 73% of people to be virally suppressed. The UK now reports 94%, 92% and 89% for the UNAIDS targets of 90:90:90, for the percentage of HIV positive people overall who are diagnosed, on treatment, and virally suppressed respectively. See Figure 4.

However, late diagnoses continues to be a serious concern and the 42% of people were diagnosed with a CD4 count <350 cells/mm^3 and this was associated with an 8-fold higher risk of dying.

Figure 4: Continuum of HIV care in the UK, 2019



A summary of findings are included below.

- 105,200 people are estimated to be HIV positive in the UK, with 6,600 undiagnosed (6%). About half are gay and bisexual men and half are heterosexual.
- During 2019 there were 4,139 new HIV diagnoses (1,139 women and 3,000 men). This was a 10% fall from 4,580 in 2018.
- The drop in gay and bisexual men was from 1,425 in 2018 to 1,107 in 2019.
- A total of 98,552 people (30,388 women and 68,088 men) accessed HIV care in the UK.
- 622 HIV positive people died (124 women and 498 men) which was similar to 2018. This represents a crude mortality rate of 631 per 100,000 population.
- 1279 people were diagnosed late (42%) with a CD4 <350 cells/mm^3), Late diagnosis was associated with 8-fold higher risk of mortality: 23 (95%CI: 17 to 32) vs 3 (95%CI: 1 to 7) per 1000.
- 65 cases of vertical transmission were reported, 5 of who (currently aged less than 15) were born in the UK.
- About 1 in 4 people (974) had been previously diagnosed outside the UK.

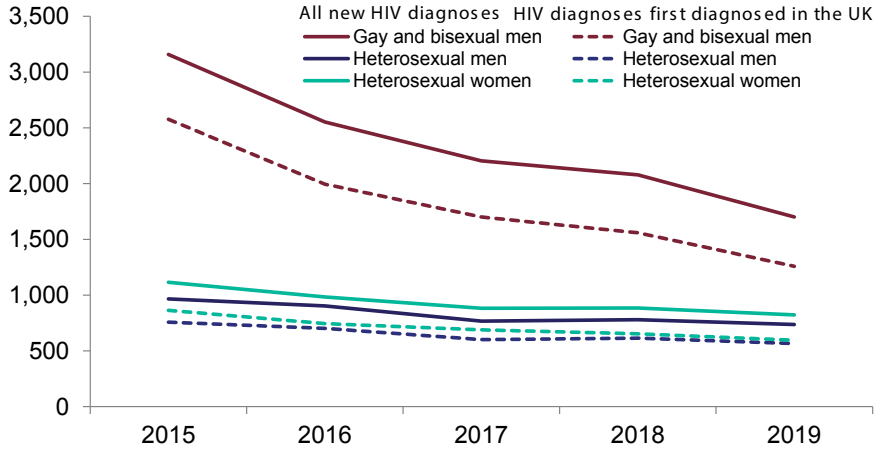
Gender is not recorded, so figures for transgender women and men is not available.

Steeper declines from 2018 to 2019 are highlighted for the following groups (but not yet available for 681 people):

- White gay and bisexual men by –22% (from 1,425 to 1,107).
- People born in the UK by –25% (from 950 to 715).
- People aged 15 to 24 by –22% (from 299 to 222).
- People living in London by –15% (from 830 to 702).
- Heterosexual transmission by –6% (from 1,664 to 1,559).

Figure 3 from the report is included below to summarise declines in main risk groups since 2015.

Figure 3: New HIV diagnoses in the UK by probable exposure group and location of first diagnosis, 2015 to 2019



The number of HIV tests in sexual health services increased by 6% to 1,310,731. Take up in sexual health clinics was 65%, with approximately half of the 550,000 people who were not tested were not offered a test and half declined. Just under 1 in 5 tests were postal kits via internet services (up by 68%).

Between April and December 2019, there were more than 51,000 tests in prisons (46% uptake) which included 401 diagnoses.

Out of more than 670,000 tests during pregnancy (>99% uptake), approximately 93 were positive.

Screening more than 1,500,000 blood donations (presumably for antibodies rather than PCR, though not specified), led to 9 HIV positive results.

The report includes a new analysis this year estimating approximately 14,600 to 19,200 people have a detectable viral load (14% to 18%). Of these, approximately 40% are undiagnosed, 20% are not engaged in care, 10% are not on treatment, 13% have a detectable viral load on ART, and 24% have no viral load result recorded for the previous two years.

The data cover the year up until December 2019 and include:

- PHE HIV 12-page report
- Tables on new HIV testing, diagnoses and on people accessing HIV care
- HIV slide set

The report concludes with speculation on the likely impact of COVID-19 on HIV and STIs this year with a report from preliminary data for 2020 planned for later this month.

PHE will be holding a webinar on Thursday 19 November 10 am - 12 pm to present the latest statistics and progress in ending HIV transmission. Registration for this meeting is limited. (https://snapsurvey.phe.org.uk/snapwebhost/s.asp?k=160448975063).

C O M M E N T

These annual data and reports are essential to the UK response to HIV.

The continued production during the difficulties of COVID-19 and the plans to provide data for 2020 later this month are also notable and important.

The continued drop in new diagnoses is good news, but public health strategies are clearly needed to reduce late diagnoses which continues to be difficult in many other high income countries.

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Two-monthly cabotegravir injections prevent HIV infection in African women: HPTN 084 study recommends early unblinding

Simon Collins, HIV i-Base

On 9 November 2020, ViiV Healthcare announced new results showing that cabotegravir injections are highly effective as pre-exposure prophylaxis (PrEP) to prevent HIV infection in African women. [1]

This was based on a planned early analysis of the large randomised placebo-controlled international HPTN 084 study being run at 20 sites in seven countries in sub-Saharan Africa (Botswana, Kenya, Malawi, South Africa, eSwatini, Uganda and Zimbabwe). [2]

The results match a similar study last year in gay men and transgender women (HPTN 083). [3, 4]

Taken together cabotegravir injections could be submitted for approval as PrEP irrespective of sex and gender.

HPTN 084 randomised 3223 women at high risk of HIV to either cabotegravir injections every two months or to currently approved TDF/FTC taken as a daily oral pill, plus matched placebos. A planned interim analysis by the Data and Safety Monitoring Board (DSMB) found that cabotegravir was sufficiently better than oral PrEP that the comparative part of the study should finish early. This will mean that all participants will be offered cabotegravir injections.

So far, 38 women have become HIV positive. Of these, 4 were in the cabotegravir group and 34 were randomised to daily TDF/FTC. The HIV incidence rates for each group were 0.21% (95% CI: 0.06% to 0.54%) and 1.79% (95% CI 1.24% to 2.51%), respectively. This also made cabotegravir significantly more effective than TDF/FTC – by 89% (95% CI 68-96%).

However, the report also emphasised that both versions of PrEP were highly effective, which is important. With good adherence, oral PrEP is already known to be more than 99.9% effective, with low adherence usually explaining any infections. This is key to understanding the importance of the new results: many people find taking pills difficult so the option to only need six injections a year can provide a wider choice of PrEP, including to people who are not interested in taking oral pills.

Limited other details were included in the press statement, but serious side effects were rare in each group. Significantly more participants receiving active injections reported skin reactions at the injection site than with placebo injections (32% vs 9%), but these were generally mild and no women left the study for this reason.

C O M M E N T

The early results are good news and will hopefully allow for earlier application to regulatory agencies for approval.

The option to use either injections or pills will broaden the options for people who want to use PrEP. Many people find taking a daily pill difficult and missing doses of oral PrEP is the likely explanation for injections being more effective in both 083 and 084 studies.

HPTN 083 also reported cabotegravir injections were significantly more effective at preventing infections, with a similar explanation that the difference would be from people being less adherent with oral pills.

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ON THE WEB

AIDS 2020: Virtual online translated resources

IAS press statement

IAS Educational Fund has enabled webcast translations of key sessions from the 23rd International AIDS Conference (AIDS 2020: Virtual).

These are now subtitled and transcribed in French, Spanish, Portuguese, Russian and Arabic.

French

https://www.iasociety.org/IAS-Educational-Fund/Online-Resources-and-Webinars/French-Resources

Spanish

https://www.iasociety.org/IAS-Educational-Fund/Online-Resources-and-Webinars/Spanish-resources

Portuguese

https://www.iasociety.org/IAS-Educational-Fund/Online-Resources-and-Webinars/Portuguese-Resources

Russian

https://www.iasociety.org/IAS-Educational-Fund/Online-Resources-and-Webinars/Russian-Resources

Arabic

https://www.iasociety.org/IAS-Educational-Fund/Online-Resources-and-Webinars/Arabic-Resources

HTB SUPPLEMENT ON COVID-19: Issue 8

SPECIAL REPORT: COVID-19 VACCINE

Early results report 90% efficacy with from Pfizer/BioNTech COVID vaccine

Simon Collins, HIV i-Base

On 9 November 2020, Pfizer announced the first results from a COVID vaccine study and at 90% protection this showed much greater efficacy than experts previously expected. [1, 2]

These were from an ongoing phase 3 studies that has randomised more than 43,000 participants to either the investigational vaccine or a placebo. [3, 4]

The results are from a planned interim analysis of the first 94 SARS-CoV-2 infections in the study, more than 80 of which must have occurred in the placebo group. The study will continue until 164 infections occur.

The study started in July 2020 and, for this analysis, most participants (approximately 39,000) had received both doses of the vaccine schedule, with median of two months follow-up. The efficacy rate was based on the primary endpoint of infection status seven days after receiving the second dose of the vaccine. Final efficacy results may vary however, especially as this is based on protection in the relatively short time after vaccination.

The candidate vaccine called BNT162b2 uses a modified messenger RNA platform and was developed by BioNTech and, usually, the collaboration with Pfizer was developed independently of US public funding.

The press statement includes projections to produce 50 million doses of the vaccine by the end of 2020 and up to 1.3 billion doses in 2021.

C O M M E N T

The high level of early protection in this interim is incredibly positive. These are the first results that show the early immune responses shown in preliminary studies can translate to immune protection after vaccination. The US FDA have indicated that 50% protection would be sufficient for a vaccine to be approved. [5]

Even in terms of proof-of-principal, these results provide the first evidence that widespread protection should allow a return to normal life.

However, longer follow-up is needed to show how long protection continues, and this is planned for at least two-years in this study.

Other important questions not yet answered by this early data include:

Whether the effectiveness is similar for everyone or whether, for example, the immune response is lower in older people (similar to some other vaccines).

Whether the vaccine will reduce the severity of COVID-19 in people who still become infected by SARS-CoV-2.

How long the protection lasts and if a booster will be needed later.

The timeline for submitting data to the FDA for an emergency use authorisation requires having two-month follow-up safey data for at least half the participants in the study and this is expected to be reached by the third week of November. [6]

Access to any of the vaccines in development will also be limited and will take time. Pfizer estimate that 50 million doses could be available by the end of 2020 and another 1.3 billion doses by the end of 2021. However, more than 80% of these have already been bought by agreements with the US, UK, EU, Canada and Japan. [7, 8]

Unless other companies are also allowed to manufacture successful vaccines, global distribution to low and middle-income countries with be extremely limited.

An excellent summary of COVID-19 news including many of these wider issues is in the latest issue (18 November 2020) of a COVID-19 bulletin from AVAC. [9, 10]

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COVID-19: HIV and COVID-19 COINFECTION

COVID-19 antibody testing for HIV positive people in the UK: HIV organisations reverse previous exclusion

Simon Collins, HIV i-Base

Until recently, HIV positive people in the UK applying online for a free antibody test for COVID-19 found they were excluded. [1]

The antibody test shows whether you might have had coronavirus in the past (rather than the PCR test for current infection).

After confirming in the online applications that you are okay taking a fingerprick blood sample and you don't currently have symptoms, the website asks "Do you have a condition that weakens your immune system?" The examples include having chemotherapy, having had an organ transplant or spleen removed or having "HIV/AIDS". Answering yes to any of these questions generates a message: "Sorry, you cannot sign up for an antibody test right now".

As there is no reason for antibody testing for COVID-19 to be less effective for people living with HIV, several HIV organisations, led by the British HIV Association (BHIVA) collectively challenged this.

The first government reply wrongly suggested that the antibody response "is likely to be hampered by their condition making it highly likely that any test result would be negative".

The HIV organisations wrote back, asking for evidence supporting this policy (which doesn't exist) and offering to provide scientific and clinical support for future policies. The letter also pointed out the discriminatory nature of the current exclusion.

This time the reply was more appropriate. As a result, both HIV and other immune-related conditions will be removed as exclusion criteria and on 11 November 2020, BHIVA published this acknowledgement online.

Following a joint letter from BHIVA, BASHH, the HIV CRG, HIV Scotland, National AIDS Trust, THT, UK-CAB & HIV i-Base, the Department for Health & Social Care (DHSC) has agreed with our position that there is no clinical reason to exclude people living with HIV from the COVID-19 antibody testing offer. Moving forward, people living with HIV will be able to access an antibody test through Gov.uk. We welcome this immediate change, which will go beyond people living with HIV – to everyone living with an immunosuppressive condition. This rightly gives people the power to make their own decisions about testing. We thank the DHSC for their constructive engagement on this matter, and swift action. [2]

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Oxford COVID vaccine enrolling HIV positive people at two London sites

Simon Collins, HIV i-Base

The much publicised vaccine being developed at Oxford University has added a new substudy group to the main trial that will look at immune responses in people living with HIV.

The main study is randomising 20,000 participants to either an active vaccine or a control group (using a vaccine against meningitis). Initially restricted entry has steadily been expanded to include people who are older and who have other specific criteria. However, the current trial listing on either ClinicalTrials.gov or the Oxford University website does not currently reference the HIV study. [1, 2]

The HIV study (referred to as Group 12) will enrol 60 HIV positive adults but will not include a control group. This means that all participants will get the active vaccine. The study will last for a year and involve about 12 clinic visits.

Also, unlike the main study, the HIV substudy includes compensation for time and travel up to £550 (for all visits).

The HIV study will be run from two London sites, St Mary's and Guys and St Thomas', both with HIV expertise.

Inclusion criteria include:

- Age <55 years old.
- Having a CD4 count >350 cells/mm^3.
- Being on ART with an undetectable viral load.

Some of the many exclusion criteria for the substudy include:

- Not taking part in other COVID vaccine or drug trials.
- Not having other causes of immune suppressions (other than HIV).
- Not having other medical complications (including heart, kidney, liver, respiratory diseases etc).
- Alcohol or drug dependency.
- Pregnancy.

The vaccine being studied is called ChAdOx1 which uses an adenovirus as a viral vector to deliver the vaccine.

One caution (not included in the patient information leaflet) is that using this vaccine now means that you can't uses similar vaccines again in the future. If boosting is needed later, this will have to be with a vaccine that uses a different platform.

Contact details for further information include: 0203 312 1466 (phone), Imperial.ctc@nhs.net (email) and https://covid19vaccinetrial.co.uk (website). However the website doesn't currently include information about the HIV study.

The patient information leaflet is available at this link. [3]

C O M M E N T

Although places for this HIV study are currently limited, both study sites are also expected to run similar studies for the Janssen COVID vaccine, also within the next few weeks.

These sites might be able to include you in a waiting list if places are quickly filled.

Enrolment of HIV positive people in other vaccines study has been controversial. In the US, the initial exclusion from the Moderna and Janssen Phase 3 studies results in rapid community response that led to changes that enabled HIV enrolment. [4]

Preliminary immune response to this vaccine were promising, and published in the Lancet, although they don't guarantee protection will be seen in the phase 3 studies.[5]

Results have also been reported in mainstream press today (easy to Google for examples) that report similar immune response in older and younger participants, However, the source of these data have not been attributed or published.

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HIV positive people at higher risk of worse outcomes from COVID-19 in UK study

Simon Collins, HIV i-Base

Results from a prospective observational database study report that being HIV positive is associated with higher risks of 28-day mortality. [1]

The study as published on 23 October in Clinical Infectious Diseases and included results from more than 47,500 people hospitalised with COVID-19, of which 122 (0.26%) had a recorded HIV diagnosis.

In unadjusted analyses, cumulative risk of mortality was similar in the HIV positive vs HIV negative groups (26.7% vs. 32.1% respectively; p=0.16).

However, the HIV positive group was significantly younger (median 56 versus 74 years; p<0.001) and had more comorbitities.

After adjustment for these and other factors, mortality was higher among people with HIV (aHR: 1.47; 95% CI: 1.01 to 2.14; p=0.05). This association became stronger after adjusting for the other factors (aHR 1.69; 95% CI 1.15 to 2.48; p=0.008) and when restricting the analysis to people aged <60 years (aHR 2.87; 95% CI 1.70-4.84; p<0.001).

C O M M E N T

This study was previously reported in HTB ahead of peer review. [2]

It is important to show the importance of adjusting for the significant differences in HIV positive and negative cases.

This in turn should caution advice for HIV positive people to not rely on a lower age as protection against COVID-19 and also perhaps for HIV-positive people older than 60 to be even more careful to follow prevention advice to avoid catching COVID-19.

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COVID-19: INVESTIGATIONAL DRUGS

Remdesivir given full approval by the US FDA, but on limited data

Simon Collins, HIV i-Base

On 22 October 2020 the US FDA approved remdesivir as an antiviral treatment for COVID-19 in adults and children >12 years old, weighing at least 40 kgs. [1]

Approval was based on results from three randomised, controlled clinical trials that included patients hospitalized with mild-to-severe COVID-19. These were the NIAID ACTT-1 study (n=1062) and two phase 3 Gilead studies (GS-US-540-5773 and GS-US-540-5774). [2]

ACTT-1 reported a faster median recovery compared to placebo (10 vs 15 days) in 1062 participants. Updated (and full) results from this study were also recently published in the NEJM. [3]

GS-US-540-5773 reported improved symptoms after 5-day treatment but not from 10-day treatment, each compared to standard of care in 582 participants.

GS-US-540-5774 reported similar results at day 14 in 392 participants randomised to either 5-day or 10-day treatment.

However, this wasn't the regular FDA full review as studies that have reported negative findings were not included (for example, the early Chinese RCT published by Wang et al in the Lancet, or the more recent WHO SOLIDARITY study) – a point that has already been highlighted in other reports. [4]

Approval was based on Fast Track and Priority review status.

Remdesivir was previously approved under an Emergency Use Authorization (EUA) on 1 May 2020.

Remdesivir is manufactured and distributed by Gilead Sciences with the tradename Veklury.

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DSMB stops REGN-COV2 monoclonal antibody study in people with high-flow oxygen or ventilation: implications for UK RECOVERY study

Simon Collins, HIV i-Base

On 30 October 2020, the DSMB for a study of REGN-COV2 (a combination of two monoclonal antibodies against COVID-19), recommended stopping use in participants needing high-flow oxygen or ventilation due to a potential safety signal and an unfavourable risk/benefit profile in this group. [1]

The trial is designed to enrol patients in four independently randomized cohorts:

- Cohort 1: patients on low-flow oxygen.
- Cohort 1A: patients not requiring oxygen.
- Cohort 2: patients on high-flow oxygen.
- Cohort 3: patients on mechanical ventilation.

Continued enrolment is allowed in participants in earlier infection, and in the outpatient study.

This notice came only two days after a press release from the manufacturer reporting a second set of positive results from a phase 2/3 study. [2]

The report included reductions both in viral load and hospital visits in 524 participants with mild to moderate COVID-19 randomised to active treatment or placebo, both with standard of care.

Participants were prospectively categorised by whether or not they had already generated an antibody response to COVID-19 (38% positive, 51% negative and 11% unclear/unknown).

The results are similar to earlier results on an initial 275 participants released by press statement last month. [3]

The new results (n=524) included:

- Mean change from baseline in viral load was 0.68 log_{10} copies/mL lower at day 7 reduction with REGN-COV2 vs placebo (combined dose groups; p<0.0001).
- A 1.08 log greater reduction with REGN-COV2 vs placebo by day 5.
- In the overall patient group with detectable virus at baseline, the average daily reduction in viral load through day 7 was a 0.36 log10 copies/mL greater reduction with REGN-COV2 compared to placebo (combined dose groups; p=0.0003).
- Higher baseline viral load and/or no detectable antibodies at baseline was associated with greater benefit from REGN-COV2.

The results in the total analysis (n=799) included:

- On a primary clinical endpoint, REGN-COV2 reduced COVID-19 related medical visits by 57% through day 29 (2.8% combined dose groups; 6.5% placebo; p=0.024).
- Treatment with REGN-COV2 reduced COVID-19 related medical visits by 72% in patients with one or more risk factor (including being over 50 years of age; body mass index greater than 30; cardiovascular, metabolic, lung, liver or kidney disease; or immunocompromised status) (combined dose groups; nominal p=0.0065).

The results have been reported to the US FDA and will be compiled and submitted for publication.

REGN-COV2 is being developed in the US by Regeneron Pharmaceuticals and is currently in studies for hospitalised and non-hospitalised COVID-19 and as prophylactic prevention.

REGN-COV2 was also recently added as a new option in the UK RECOVERY study who have also been notified of the DSMB safety notice. [4]

In August Regeneron partnered with Roche Pharmaceuticals to increase production of REGN-COV2. [5]

C O M M E N T

Further clinical details about the DSMB decision were not included in the press release.

Although the virological results hint at a positive effect of the dual antibodies, any publication in a company press release needs to interpreted with caution. Without more details it is difficult to comment further.

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Monoclonal antibody stopped in ACTIV-3 study: bamlanivimab shows lack of benefit in people hospitalised with COVID-19

Simon Collins, HIV i-Base

On 26 October 2020, a press statement from Eli Lilly reported that it had stopped further recruitment of the monoclonal antibody bamlanivimab (LY3819253) into a study of people hospitalised with COVID-19. [1, 2]

A press release issued by the US NIAID who sponsor the ACTIV-3 study included more details - and although this compound has been stopped, the ACTIV-3 study will continue. [3]

This study is designed to investigate promising compounds as treatment for late-stage COVID-19. All participants receive standard of care that includes remdesivir.

The decision to stop bamlanivimab followed a predefined efficacy review by the Data and Safety Monitoring Board (DSMB) on the first 300 participants (stage 1), based on clinical benefits after five days on an ordinal scale. Recruiting a further 700 participants only occurs (stage 2) depends on seeing an early signal of efficacy.

The DSMB review showed that bamlanivimab was "unlikely to help" people with hospitalised COVID-19 "recover from this advanced stage of their disease". There were no significant safety issues.

No further details have been released yet on the study or these early results.

Other studies with bamlanivimab, in different populations, are continuing. These include:

1. ACTIV-2 in people recently diagnosed in mild to moderate COVID-19, also sponsored by the US NIH (also overseen by the same DSMB). [4]
2. BLAZE-1, an ongoing phase 2 trial in people recently diagnosed with earlier stage non-hospitalised COVID-19, also in combination with etesevimab. Interim results were just published in NEJM. [5, 6]
3. BLAZE-1, an ongoing phase 3 study of bamlanivimab as prophylaxis in residents and staff living in care facilities. [7]

C O M M E N T

Although the results are disappointing the study itself shows the importance of being able to rapidly identify likely futility with this particular monoclonal antibody.

The ACTIV-3 study is an adaptive platform study that is designed to study multiple investigational compounds compared to placebo and further drugs are due to be added shortly.

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Convalescent plasma: randomised controlled study finds no benefit in moderate stage COVID-19

Simon Collins, HIV i-Base

Disappointing results from a randomised controlled study of convalescent plasma as a treatment for people hospitalised with COVID-19 unfortunately removes the early hopes, supported by smaller observational studies, that this might be a widely-used, safe and effective option.

The results, published on 23 October 2020 in the BMJ, reported no reduction of either progression to severe disease or mortality at 28 days. [1]

The PLACID study was an open label, parallel arm, phase 2 study at 39 public and private hospitals in India in 464 participants with moderate confirmed COVID-19 (defined as PaO/FiO ratio 200 to 300 mm/Hg or a respiratory rate >24/min with oxygen saturation 93% or less on room air). Participants were randomised to standard of care plus two doses of convalescent plasma (ideally from different donors), 24 hours apart (n=235) or a control arm of current standard of care only (n=229).

Standard of care was based on national guidelines and included antivirals (hydroxychloroquine, remdesivir, lopinavir/r, oseltamivir), broad spectrum antibiotics, immunomodulators (steroids, tocilizumab), and supportive management (oxygen through a nasal cannula, face mask, non-rebreathing face mask; non- invasive or invasive mechanical ventilation; awake proning).

Baseline characteristics were balanced between arms and included approximate median age 52 (IQR: 42 to 60), 76% men, mean BMI 26, with high rates of comorbidities including diabetes (38 - 48%) and hypertension (35 - 39%).

The primary composite endpoints of progression to severe disease or all cause mortality at 28 days occurred in 44 (19%) vs 41 (18%) in the active vs control group respectively. This was a risk difference of 0.008 (95% CI: –0.062 to 0.078) with a risk ratio 1.04 (95% CI: 0.71 to 1.54).

Overall, 34 participants (15%) died in the intervention arm and 31 participants (14%) in the control arm (RR: 1.04, 95%CI: 0.66 to 1.63). Progression to severe disease occurred in 17 participants in each arm.

For one of the secondary outcomes of improved symptoms by day 7, convalescent plasma was associated with earlier resolution of shortness of breath and fatigue and higher rates of negative conversion of SARS-CoV-2 RNA (supporting a virus neutralising effect). However, there was no evidence of immunomodulator functions and no differences in inflammatory markers.

Antibody titres of the donated plasma and from participants on days 0, 3 and 7, were only measured at the end of the study.

At enrolment, 348/418 participants with samples (83%) had detectable neutralising antibodies with median titre of 1:90 (interquartile range 1:30-1:240).

Donors were mostly men (n=247, 94%), with a mean age of 34.3 (SD 9.3) years, most (n=245, 94%) also reporting mild disease. The median disease duration was 6 days (IQR: 3 to 11 days). Nearly two thirds (n=161, 64%) of the donors had a neutralising antibody titre of more than 1:20, with a median titre of 1:40 (interquartile range 1:30-1:80). Plasma was donated after a median of 41 (IQR: 31 to 51) days from PCR confirmed diagnosis.

Study results were not affected by baseline levels of antibody in either participants or donors or from symptoms at enrolment.

Although future research could look at use in people who don't already have neutralising antibodies or by using plasma with higher titres this would be more difficult to match donors and would limit use to a minority of patients and the researchers conclude that their results don't support routine use of convalescent plasma as a treatment for COVID-19.

COMMENT

Previous studies, include two RCTs that were stopped early, including one due to high levels of neutralising antibodies in participants at baseline. [2, 3]

An earlier Cochrane review, recently updated, is also unable to conclude on either safety or effectiveness. [4]

However, a very large open label US expanded access programme (n >35,000 transfused patients) in an adjusted analysis, reported reductions in both 7- and 30-day mortality with earlier use (within 3 vs >4 days) of diagnosis and greater IgG antibody levels in the transfused plasma. [5]

This suggests that any benefit will need both early use and high antibody titres in the donated plasma, and that ongoing studies should review their design to improve the likelihood of more positive outcomes.

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No survival benefit from remdesivir, hydroxychloroquine, lopinavir/r or interferon-β1a in moderate and severe COVID-19: interim results from the WHO SOLIDARITY study

Simon Collins, HIV i-Base

On 15 October 2020, the World Health Organization published results from the large international SOLIDARITY study, ahead of peer review. The findings included that none of the four treatments reduced deaths in people hospitalised with moderate or severe COVID-19. [1, 2]

While some of these drugs were already known not to work (hydroxychloroquine and lopinavir/r), it was hoped that the results for interferon-β1a and for the approved drug remdesivir would be better – although they have already been challenged due to the study design.

Launched in March 2020, the SOLIDARITY study randomised 11,266 participants hospitalised with COVID-19 to one of four open-label treatment groups: (i) remdesivir (n=2750), (ii) hydroxychloroquine (n=954), (iii) lopinavir/r (n=1411) and (iv) interferon-β1a, initially with lopinavir/r (n=651) but from 4 July as a single treatment (n=1412), or to a control group receiving standard of care in each country but without any of the study drugs, even if available (n=4088). The study was run at more than 400 hospital sites in 30 countries and required minimum reporting other than survival outcomes and a few baseline characteristics. This design was to broaden participation from different settings at a time when hospital resources were limited. However, it also limits the data available for interpreting more complicated results. Additional details will be available from some European countries in a substudy of SOLIDARITY called DISCOVERY. [3, 4]

The primary endpoint was mortality, measured by death in hospital within 28 days of joining the study. Follow-up was stopped after first discharge from hospital (ie subsequent outcomes are not recorded).

Unusually, the decision to release the interim results was decided by a steering group who were still blinded to the study results. The study was also designed without estimates for the number of people to be enrolled or the number of deaths that would be needed to produce definitive results. Results were stratified by severity of COVID-19 at baseline as moderate or severe depending on whether or not a participant was already ventilated.

Limited data available on baseline characteristics included 62% men and history of comorbidities included 25% diabetes, 21% heart disease, 6% chronic lung disease, 5% asthma and 1% chronic liver disease. Current smoking was reported for 7%.

By age, 35% were 50 years old or younger, 45% were 51 to 69 and 19% were 70 or older. When joining the study, 63% were on oxygen, 8% of all participants were already ventilated and 38% had already been hospitalised for two or more days.

By region, 22% were from Europe or Canada, 17% were from Latin America and 61% were from Asia and Africa.

There were 1253 deaths at median of 8 days (IQR: 4 to 14). Mortality was 12% overall but 39% in participants who were already ventilated at randomisation.

None of the study drugs reduced mortality compared to the control arm. There were no differences in any baseline subgroups including for ventilation, initiation of ventilation or time in hospital. Deaths for each drug reported as rate ratios with 95% CIs are included in Table 1 below, with the confidence intervals highlighted as being more important than either the rate ratio or p-value as these were all within the range of previously published studies (but also adding that narrower intervals would have been helpful). Adherence was reported as >93% in all groups, defined by still being on allocated treatment halfway through the dosing schedule.

Table 1: Mortality rate ratios (95%CI) from interim analysis of the SOLIDARITY study

Study drug	RR	95% CI	p-value
Remdesivir	0.95	0.81 to 1.11	0.50
Hydroxychloroquine	1.19	0.89 to 1.59	0.23
Lopinavir	1.00	0.79 to 1.25	0.97
Interferon	1.16	0.96 to 1.39	0.11

In addition to these results, the researchers also included meta-analyses of outcomes from other studies of each drug. Also, in terms of participant numbers, the SOLIDARITY study now provides more than 75% of total randomised results available on remdesivir and interferon.

Most controversially, the researchers report that "this absolutely excludes the suggestion that remdesivir can prevent a substantial fraction of all deaths". Taking this further, they write the results are "compatible with prevention of no deaths" and that "this would be consistent with the lack of reduction in the initiation of ventilation or the duration of hospitalisation". However, they also note that benefits might be seen in some subpopulations.

The study is being led by WHO, but local costs were covered by participating countries and all study drugs were donated by the manufacturers.

COMMENT

These results are significant for the size of this randomised study and it is surprising that their publication, even though ahead of peer review, hasn't generated more coverage in mainstream media.

While producing clear evidence on lack of survival benefit, the news is difficult and disappointing for not finding more positive results, including for remdesivir which is already approved for COVID-19. However, as an antiviral, remdesivir would be expected to be more active in earlier stages of COVID-19.

Gilead Sciences (who developed remdesivir) have challenged the results as "inconsistent with more robust evidence from multiple randomised controlled studies published in peer-reviewed journals", noting that WHO have also prequalified remdesivir. [5]

Even though the hydroxychloroquine, lopinavir/r and interferon arms have now been discontinued, the SOLIDARITY study is still ongoing (with remdesivir) and is recruiting about 2000 patients per month. Although the factorial design allows it to add further investigational treatments including immune-modulators and monoclonal antibodies, it is unclear whether new drugs have already been added. [2]

However, as this publication has commented many times, future studies should be looking at combination therapies and planning for longer follow-up. This is needed to capture important outcomes related to long-term recovery that were not appreciated earlier in the epidemic.

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COVID-19: FUTURE MEETINGS

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

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

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

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

International Workshop on HIV Paediatrics 2020

16 – 17 November 2020. NOW VIRTUAL

www.virology-education.com

26th Annual BHIVA Conference (BHIVA 2020)

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

www.bhiva.org

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

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

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

HIV Research for Prevention (HIV R4P 2020)

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

https://www.hivr4p.org

Conference on Retroviruses and Opportunistic Infections (CROI 2021)
NOW VIRTUAL
6 – 10 March 2021
https://www.croiconference.org

PUBLICATIONS & SERVICES FROM i-BASE

i-Base website

All i-Base publications are available online, including editions of the treatment guides.

http://www.i-Base.info

The site gives details about services including the UK Community Advisory Board (UK-CAB), our phone service and Q&A service, access to our archives and an extensive range of translated resources and links.

Publications and regular subscriptions can be ordered online.

The Q&A web pages enable people to ask questions about their own treatment:

http://www.i-base.info/qa

i-Base treatment guides

i-Base produces six booklets that comprehensively cover important aspects of treatment. Each guide is written in clear non-technical language. All guides are free to order individually or in bulk for use in clinics and are available online in web-page and PDF format.

http://www.i-base.info/guides

- Introduction to ART (May 2018)
- HIV & quality of life: side effects & long-term health (Sept 2016)
- Guide to PrEP in the UK (March 2019)
- HIV testing and risks of sexual transmission (June 2016)
- Guide to changing treatment and drug resistance (Jan 2018)
- Guide to HIV, pregnancy & women's health (April 2019)

Pocket guides

A series of pocket-size concertina folding leaflets that is designed to be a very simple and direct introduction to HIV treatment.

The five pocket leaflets are: Introduction to ART, HIV and pregnancy, ART and quality of life, UK guide to PrEP and HCV/HIV coinfection.

The leaflets use simple statements and quotes about ART, with short URL links to web pages that have additional information in a similar easy format.

U=U resources for UK clinics: free posters, postcards and factsheets

i-Base have produced a new series of posters, postcards and leaflets to help raise awareness about U=U in clincs.

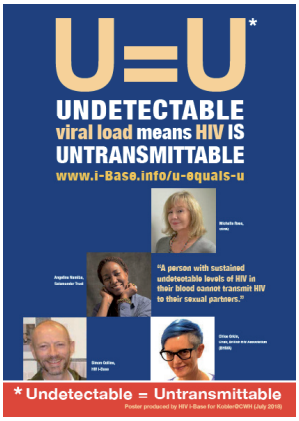
This project was developed with the Kobler Centre in London.

As with all i-Base material, these resources are all free to UK clinics.

Until our online order form is updated to include the U=U resources, more copies can be orded by email or fax.

email: subscriptions@i-base.org.uk

Customise U=U posters for your clinic



i-Base can customise U=U posters to include pictures of doctors. nurses, pharmacists, peer advocates or any other staff that would like to help publicise U=U.

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

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

roy.trevelion@i-Base.org.uk

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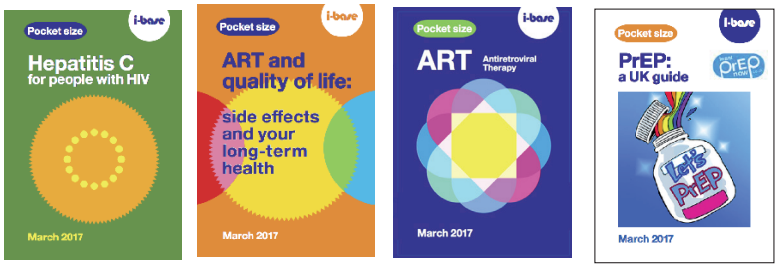

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NEW: UK Guide To PrEP *(November 2019): 24-page A5 booklet* **quantity** _____

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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** _____

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