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EACS: women and pregnancy; HTB reader survey 2020

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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 online:

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known as DrFax.**

EDITORIAL

This compact edition of HTB includes our last reports from the EACS conference last year relating to women's health and use of ART during pregnancy.

It is reassuring that there is no signal that long acting cabotegravir and rilpivirine injections act any differently in women compared to results overall.

There are updated results for the association between dolutegravir and the risk of neural tube defects in conception and pregnancy - and the first tentative data looking at this risk with bictegravir, a very similar molecule.

Also, although the numbers are small, a report from Switzerland where discontinuing use of neonatal PEP has been recommended since 2016 for babies from mothers who have an undetectable viral load during the third trimester of pregnancy. This is the first high-income country to try this.

It is disappointing to report the early closure of another phase 3 HIV vaccine study due to lack of effect (adding pressure on other existing studies to be more promising).

Also, although not in HIV positive participants, an interesting study of older people using the Mediterranean diet, reported anti-inflammatory effects that might be relevant to HIV positive people (and where there is no evidence of harm).

Next month, travel permitted, we will bring news from CROI 2020 which is being held in Boston from 8 to 11 March.

And while reading time this issue month might be shorter, it would really help i-Base if readers could help with feedback using this short online survey.

<https://www.surveymonkey.co.uk/r/KCXXT3F>

HTB survey 2020 - please help with feedback

As we are starting the New Year, we would like your help with the HTB reader survey.

This only includes 10 short questions with space for additional comments and your feedback will help us with HTB development this year.

<https://www.surveymonkey.co.uk/r/KCXXT3F>



htb
reader
survey

SUPPLEMENTS

i-Base guide to HIV testing and sexual transmission (January 2020)

This updated booklet includes information on all aspects of HIV testing and sexual transmission.

The printed version has been reduced by 20 pages - signposting to information that is still online.

It is updated throughout to include both U=U and PrEP.



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

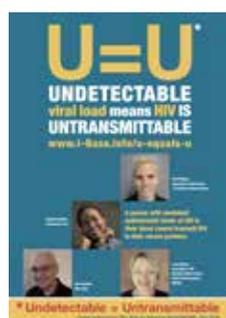
Please continue to order these free resources.



Customise U=U posters for your clinic

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

For further information please contact Roy Trelvelion at i-Base: roy.trelvelion@i-base.org.uk



i-Base 2020 appeal

This year we are continuing a funding appeal to help i-Base continue to provide free publications and services during 2020.

i-Base now receive more than 12,000 questions each year and the website has more than 500,000 views 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>

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To join the email list for HTB please register free online:

<http://i-base.info/htb/about/subscribe>



CONFERENCE REPORTS

17th European AIDS Conference (EACS 2019)

6 – 9 November 2019, Basel

The 17th biennial European AIDS Conference was held in Basel from 6 to 9 November 2019.

This issue of HTB continues our coverage.

The programme, with links to abstracts is online:

<http://www.professionalabstracts.com/eacs2019/iplanner/#/grid> and also

<https://onlinelibrary.wiley.com/doi/10.1111/hiv.12814>

<https://onlinelibrary.wiley.com/doi/epdf/10.1111/hiv.12814> (pdf)

Slides and webcasts are already available as open access on the EACS library website, after the conference, although only for three months for non-EACS members.

<http://resourcelibrary.eacs.cyim.com>

Articles from the conference included in HTB are:

- Long-acting cabotegravir and rilpivirine: similar results in women and men
- Antiretroviral pregnancy registry: dolutegravir update
- Bictegravir/emtricitabine/tenofovir alafenamide appears to be safe and effective in women: results from a pooled analysis
- No HIV transmission among Swiss infants born to mothers with undetectable viral load and who did not receive neonatal PEP

Long-acting cabotegravir and rilpivirine: similar results in women and men

Polly Clayden, HIV i-Base

A pooled analysis of two phase 3 trials of monthly long acting cabotegravir and rilpivirine (CAB + RPV LA) found similar efficacy among women and men at 48 weeks. [1]

There were also no significant differences between women and men in adverse events (AEs), injection site pain or study withdrawals. And treatment satisfaction was higher among women in the CAB + RPV LA arm vs control.

Romina Quercia from ViiV Healthcare presented these results at EACS 2019 from an analysis of efficacy, safety and patient satisfaction among women participants in the ATLAS and FLAIR trials.

ATLAS and FLAIR are randomised (1:1), international, open label studies that demonstrated non-inferiority of switching to monthly intramuscular (IM) injections of CAB + RPV LA vs current antiretroviral regimen.

ATLAS enrolled ART-experienced participants on stable ART (two NRTIs and a third agent). FLAIR participants were ART-naïve and the study included a 20-week induction phase with dolutegravir/abacavir/lamivudine oral fixed dose combination.

At randomisation, participants in the CAB + RPV LA arms in both studies received oral CAB + RPV for four weeks before receiving IM injections.

Both studies were designed with enrolment targets for women: ATLAS at least one in four and FLAIR one in five participants.

Pooled subgroup analysis by sex at birth was pre-planned and based on week 48 primary endpoint of viral load ≥ 50 copies/mL and secondary endpoint of <50 copies/mL.

Across the two trials there were 27% (162/591) women in the CAB + RPV LA arms and 28% (168/591) in the control arms.

At baseline, 28% of women had BMI ≥ 30 kg/m² compared with 13% of men. Almost 40% of women were black or African American compared with just below 15% of men.

At week 48, 3.1% and 0.6% of women in CAB + RPV LA and control arms had viral load ≥ 50 copies/mL. These proportions were similar for men, respectively 1.4% and 2.1%. Suppression rates were also similar between women and men.

Seven confirmed virological failures occurred in both arms including 5/7 and 2/7 women in the CAB/RPV LA and control arms respectively. These cases are under analysis and currently considered to be multifactorial.

There were no significant differences between women and men in AEs and injection site reactions (no grade 4 or 5). Women reported less injection site pain than men: 66% vs 82%. Two women and four men withdrew from the studies due to injection site reactions (both approximately 1%).

Retention in the studies was high for women receiving CAB + RPV LA: 90% (overall 92%).

In a post-hoc analysis at week 44, CAB + RPV participants showed higher treatment satisfaction vs those in the control arm. This increased from baseline and was greater among women participants.

C O M M E N T

The enrollment of almost 30% in these trials is laudable and considerably more than what we have come to expect in industry phase 3 trials of antiretrovirals.

One notable sex difference reported for CAB is longer half-life for women and men. CAB is still detectable after 3.5 years following a single injection in some women vs 2.5 years in some men.

In a related presentation in this session, we were reminded that about 38 million people are living with HIV of which just over 19 million are women. This proportion of 50.4% is in stark contrast to the 18.9% of women study participants in HIV clinical trials shown in a recent analysis. [2]

The investigations in the pooled analysis of CAB + RPV LA did not reveal any significant sex differences at 48 weeks. But having a larger group of women meant that this information was not based on a meaningless subgroup analysis among only a handful of participants.

Having enrolment targets for women was also associated with a more diverse population than often seen in phase 3 studies. In the pooled analysis, almost 40% of women were black or African American (compared with less than 15% of men). Less than half of the women were recruited from Western Europe or North America (compared with 75% of men) and 21% were from South Africa compared with 4% of men.

References

1. Quercia R et al. Outcomes for women in phase 3 trials of long-acting cabotegravir + rilpivirine: pooled ATLAS and FLAIR week 48 results. 17th European AIDS Conference (EACS). Basel, Switzerland. 6–9 November, 2019. Oral abstract PS1/1.
<http://resource.library.eacs.cyim.com/?mediald=78023> (webcast)
2. Sander F et al. Are there gender and age differences in ARV PK? 17th European AIDS Conference (EACS). Basel, Switzerland. 6–9 November, 2019. Oral presentation ML1.
<http://resource.library.eacs.cyim.com/?mediald=78017> (webcast)

Antiretroviral pregnancy registry: dolutegravir update

Polly Clayden, HIV i-Base

Antiretroviral pregnancy registry (APR) data do not demonstrate an increased risk of overall birth defects with dolutegravir (DTG) use above the expected population rate. [1,2]

And, although one neural tube defect (NTD) is reported in this data set, the denominator is too small to draw any conclusions about an association between periconception DTG and NTDs.

These findings were presented at EACS 2019 and are also described in the most recent version of the APR interim report.

By 31 July 2019, 667 pregnancies with exposure to DTG were prospectively reported to APR: 357 periconception (2 weeks before through 28 days after conception) exposures, 67 later during the first trimester, and 243 during the second/third trimesters.

Median maternal age at conception was 29 years; just over 60% of women were black and approximately 80% were from the United States. At enrollment over 80% had CD4 count greater than 200 cells/mm³.

Among the 667 DTG exposed pregnancies there were 614 live singleton births: 312 with periconception exposure, 63 later during the first trimester, and 239 during the second/third trimesters.

There were 21/614 defects overall: prevalence 3.4% (95% CI 2.1 to 5.2). With periconception exposure there were 10/312 defects: prevalence 3.2% (95% CI 1.6 to 5.8). Defect prevalence for later first trimester and second/third trimester were both similar.

These data do not show a risk of overall defects above the population expected rate of defects: 2.72 and 4.17/100 live births from Metropolitan Atlanta Congenital Defects Program (MACDP) and Texas Birth Defects Registry (TBDR) respectively.

There was 1/312 neural tube defect (NTD) case of anencephaly with periconception DTG exposure.

The next interim APR report will include data through 31 January 2020.

C O M M E N T

Although 1/312 gives an NTD prevalence of 0.3%, similar to data from the Tsepamo study in Botswana, the number of periconception outcomes is not sufficient (2000 needed to rule out a 3-fold increase) to refute or confirm an association between DTG and NTD.

References

- Vannappagari V et al. - Dolutegravir (DTG) use during pregnancy and birth outcomes: data from the Antiretroviral Pregnancy Registry (APR). 17th European AIDS Conference (EACS), Basel, Switzerland. 6–9 November, 2019. Oral abstract PS1/2.
<http://europeanaidconference.eacs.cyim.com/mediatheque/media.aspx?mediald=78029&channel=28172> (webcast)
- Antiretroviral Pregnancy Registry Steering Committee. Antiretroviral Pregnancy Registry Interim Report for 1 January 1989 through 31 July 2019.
http://www.apregistry.com/forms/interim_report.pdf (PDF)

Bictegravir/emtricitabine/tenofovir alafenamide appears to be safe and effective in women: results from a pooled analysis

Polly Clayden, HIV i-Base

A pooled analysis of women and girls receiving bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in five clinical trials showed high rates of virological suppression at 48 weeks, according to data presented at EACS 2019.

Rates of adverse events (AEs) were similar to those seen among participants receiving comparator regimens.

There were not sufficient numbers of B/F/TAF-exposed pregnancies to draw any conclusions.

Co-formulated B/F/TAF 50/200/25 mg is a once-daily fixed dose combination manufactured by Gilead Sciences.

This analysis included 679 women and girls receiving B/F/TAF or comparators (373 B/F/TAF) across five phase 2/3 originator clinical trials, conducted in ART naive adults and virologically suppressed children, adolescents and adults through 48 weeks. See Table 1.

The comparator arm in study 1489 was dolutegravir/abacavir/lamivudine (DTG/ABC/3TC) and in 1490 DTG/F/TAF. Notably the total number of participants in these naive studies was 1274 of which only 139 were women.

Women in study 1961 were previously enrolled in the women-only WAVES study (elvitegravir/cobicistat/emtricitabine/tenofovir E/C/F/TDF or E/C/F/TAF vs atazanavir/r-based ART) and its open label extension in which they all received elvitegravir-based ART.

Paediatric switch study 1464 had 100 participants in total, of which 59 were young women and girls. And switch study 4449, in participants aged 65+, had 86 in total of which 11 were women.

In the pooled analysis, demographics among women and girls by age and baseline treatment group were as follows. Virologically suppressed: 6–17 years (n=59); 18–49 years (n=191); 50–64 years (n=43) and 65–75 (n=11). ART naive: 18–49 years (n=54) and 50–68 (n=15).

There was considerable variation in ethnicity, particularly among virologically suppressed participants: from 78% black among 6–17 year-olds to 91% white in the 65–75 years age group. In the ART-naive group just under half of the participants were black and 35–40% were white.

At week 48 there were high and similar rates of virologic suppression across age and treatment groups (B/F/TAF 87–100% and comparators 88–95%). These findings are consistent with those seen overall in the B/F/TAF studies across both sexes. No treatment-emergent resistance was seen with B/F/TAF across the programme.

Table 1: Pooled analysis of women in phase 2/3 bictegravir/emtricitabine/tenofovir alafenamide studies

| Study | Population | Comparator regimen(s) | Women B/F/TAF arm (n) | Women comparator arm (n) |
|-----------|--|--|-----------------------|--------------------------|
| 1489/1490 | ART naive adults | DTG/ABC/3TC (1489) DTG+F/TAF (1490) | 69 | 70 |
| 1961 | Suppressed women | E/C/F/TAF E/C/F/TDF ATV/r/F/TAF | 234 | 236 |
| 1464 | Suppressed (2 NRTIs + 3rd agent) children and adolescents 6–17 years | | 59 | |
| 4449 | Suppressed (2 NRTIs + 3rd agent) adults 65+ | | 11 | |

Key: ABC, abacavir; ATV/r, atazanavir/ritonavir; B, bictegravir; DTG, dolutegravir; E, elvitegravir; F, emtricitabine; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate; 3TC lamivudine

Drug-related AEs were similar among participants taking B/F/TAF versus comparators. Overall rates of grade 3/4 AEs were low and similar to comparators. One adolescent (0.1%) discontinued B/F/TAF due to anxiety.

Weight gain was reported as an AE in 3/314 women receiving B/F/TAF (all in ART-naïve group aged 18–49); weight loss was reported in 1/314. There was 1/306 weight gain and 1/306 weight loss among the participants receiving comparator ART.

At week 48 the median change from baseline weight in the virologically suppressed participants receiving B/F/TAF was 1.5 kg vs 0.4 kg in the comparators ($p < 0.001$). Among these participants 53% received TAF and the remainder TDF.

The difference in median change between B/F/TAF and comparators in the ART-naïve participants was non-significant at weeks 48 and 144. The respective weight gain from baseline at week 144 was 5 kg, 7.9 kg and 4.9 kg in the B/F/TAF ($n=50$), DTG/ABC/3TC ($n=29$) and DTG + F/TAF ($n=29$) groups. But numbers were very small.

The presentation also included weight gain in men. Of note in the ART-naïve group differences in weight gain from baseline for men receiving B/F/TAF vs DTG/ABC/3TC were significant: 3 kg vs 1.4 kg ($p < 0.0001$) and 4.2 kg vs 3.2 kg ($p=0.03$) at 48 and 144 weeks respectively. There were no significant differences in weight gain among men receiving B/F/TAF and DTG+F/TAF. There were over 1000 men in the ART naïve group.

Cumulative to 17 October 2019, there were 30 B/F/TAF exposed pregnancies across the Gilead trials: 25 prospective, 4 retrospective and one unknown reports.

Among the prospective reports 21 exposures were preconception/first trimester, 2 were second/third trimester and 2 unknown. The 4 retrospective reports were all preconception/first trimester as was the unknown prospective or retrospective pregnancy.

Of these there were 15 live births with no congenital anomaly; 1 live birth with patent urachus; 3 with unknown outcome; 7 spontaneous abortion; 1 still birth and 3 elective terminations.

There were no cases of CNS congenital anomalies or neural tube defects but no prevalence can be calculated as retrospective reports are drawn from a population in which the number of exposed pregnancies is unknown.

Presenting author Chloe Orkin made a plea to the audience to report pregnancies retrospectively and reminded us that in the US only 10% are reported.

Reference

Orkin C et al. Efficacy and safety of bicitgravir/emtricitabine/tenofovir alafenamide vs comparators in cis-women and girls (living with HIV): an analysis of 5 clinical trials. 17th European AIDS Conference (EACS). Basel, Switzerland. 6–9 November, 2019. Oral abstract PS7/6.

<http://europeanaidconference.eacs.cyim.com/mediatheque/media.aspx?mediaid=78084&channel=28172> (webcast)

No HIV transmission among Swiss infants born to mothers with undetectable viral load who did not receive neonatal PEP

Polly Clayden, HIV i-Base

Swiss data suggests that neonatal post-exposure prophylaxis (PEP) might be unnecessary in HIV-exposed infants if maternal viral load is fully suppressed in the third trimester. [1] These findings were shown at EACS 2019.

Since January 2016 the Swiss Federal Office of Public Health (FOPH) guidelines no longer recommend PEP for infants born to HIV positive women with plasma viral load < 50 copies/mL in the third trimester (two viral load results at least 4 weeks apart including at or after 36 weeks).

The study was performed to investigate the implementation and safety of these national recommendations in Switzerland.

The investigators evaluated data from the Swiss Mother and Child HIV Cohort Study and the linked Swiss HIV Cohort Study database.

The evaluation included infants born between 2010 and 2018 and for whom information on maternal viral load in the third trimester was available. It compared the frequency of neonatal PEP in infants born before and after the introduction of the recommendations. Infant HIV status was assessed by PCR at 6 months of age.

Maternal viral load in third trimester was < 50 copies/mL for 363/383 (94.8%) infants born during the study period.

Of these, 264/267 (98.9%) infants born before the 2016 guideline change received PEP versus 12/96 (12.5%) born afterwards ($p < 0.001$).

PEP was given to all 20 infants with detectable maternal viral load in the third trimester. This included 5 infants born 2016 and after.

None of the 87 infants who did not receive PEP were HIV positive. PEP exposure was reduced by 86.4% and there was no vertical HIV transmission.

The evaluation showed that the new neonatal recommendations were rapidly implemented in Switzerland. This suggests that clinicians were well-informed and accepted the arguments provided to support the change.

The investigators recommend that neonatal PEP guidelines in other high-income countries should be reconsidered.

C O M M E N T

Switzerland is the first high-income country to make the recommendation not to use neonatal PEP in optimal maternal circumstances.

Although these data are reassuring with no transmissions they only include 87 infants.

BHIVA guidelines describe such circumstances as “very low risk” but recommend two weeks of AZT monotherapy for neonatal PEP. [2]

17th EACS 2019, Basel

References

1. Traytel A et al. Discontinuation of neonatal postexposure prophylaxis in infants born to HIV-infected mothers with suppressed plasma viral load: safety and implementation of the new Swiss recommendations. 17th European AIDS Conference (EACS). Basel, Switzerland. 6–9 November, 2019. Oral abstract PS1/5.
<http://resourcelibrary.eacs.cyim.com/mediatheque/media.aspx?mediald=78043&playlistId=78018&channel=28172> (webcast)
2. BHIVA guidelines on the management of HIV in pregnancy and postpartum 2018 (2019 second interim update).
<https://www.bhiva.org/file/5bfd30be95deb/BHIVA-guidelines-for-the-management-of-HIV-in-pregnancy.pdf> (PDF)

SIDE EFFECTS & LONG-TERM COMPLICATIONS

Mediterranean diet associated with maintaining bacterial diversity and markers of reduced frailty in older HIV negative study

Simon Collins, HIV i-Base

An international study of over 600 people aged 65 to 79 reported beneficial changes in gut microbiome in those who were randomised to a Mediterranean diet for more than 12 months, compared to those who had no dietary changes. [1]

The interventional diet had been specially tailored to older people (NU-AGE diet) and was rich in fruits, vegetables, nuts, legumes, olive oil and fish and low in red meat and saturated fats.

At baseline, the countries had significantly different microbiome profiles - linked to the closeness to the Mediterranean diets reported by the participants from Poland, Netherlands, UK, France and Italy. Although the study didn't report within-country benefits based on the randomised arms, it did report that closer adherence to the Mediterranean diet was linked to loss of microbiome diversity (which has been linked in other studies to poorer clinical outcomes).

In a sub analysis looking at markers of frailty by baseline frailty status (using the Fried score to categorise participants as non-frail, pre-frail and frail) adherence to the Mediterranean diet was associated with reduced frailty, improved cognitive function and reduced markers of inflammation – high-sensitivity C reactive protein (hsCRP) and interleukin 17 (IL-17).

C O M M E N T

Beneficial changes in people who kept to the Mediterranean diet for 12 months included maintaining bacterial diversity including those beneficial short chain fatty acids and a decrease in bacteria linked to a heightened risk of bowel cancer, insulin resistance, fatty liver and cell damage.

The changes were largely driven by an increase in dietary fibre and associated vitamins and minerals (vitamins C, B6, B9 and copper, potassium, iron, manganese, and magnesium) and were independent of the age and weight (body mass index) which both influence the microbiome.

Although this is a complex paper and some of the hoped for differences by diet were not always significant, the associations with reduced frailty and inflammation across different countries is interesting.

While associations do not prove a causative link, the overlapping concerns for older HIV positive people might make the results relevant.

References

Ghosh TH et al. Mediterranean diet intervention alters the gut microbiome in older people reducing frailty and improving health status: the NU-AGE 1-year dietary intervention across five European countries. *Gut*, 17 February 2020. doi: 10.1136/gutjnl-2019-319654. Open access.

<http://gut.bmj.com/lookup/doi/10.1136/gutjnl-2019-319654>

PREVENTION & TRANSMISSION

HIV in the UK - 2019 report and data

Simon Collins, HIV i-Base

The full HIV in the UK epidemiological reports are now online.

The results include reporting a continued drop in new diagnoses, especially among gay and bisexual men. Overall new diagnoses dropped from 6278 in 2014 to 4453 in 2018. In gay men this drop was from 3480 in 2014 to 2250 in 2018.

The estimated drop in new infections (HIV incidence) has also dropped in gay and bisexual men: from approximately 2,800 in 2012 to 800 in 2018.

Overall, approximately 7,500 people are not yet diagnosed, half of who are gay and bisexual men. Late diagnosis continues to be a major concern in all demographic groups, including, for example in more than 30% of gay men.

In the UK, UNAIDS 90:90:90 targets are reached with 93% of people diagnosed, 97% of those diagnosed are on ART, and 97% of those on ART have undetectable viral load.

The full reports and dataset are available online, including analyses for all demographics.

The 2019 reports are based on data until December 2018.

References

Public Health England. HIV in the UK: towards zero HIV transmissions by 2030, 2019 report (88 pages)

HIV in the UK: towards zero HIV transmissions by 2030, 2019 appendix (28 pages)

Prevalence of HIV infection in the UK in 2018 (6 pages)

<https://www.gov.uk/government/publications/hiv-in-the-united-kingdom>

Phase 3 HIV vaccine study in South Africa is stopped early due to lack of efficacy

Simon Collins, HIV i-Base

On 3 February, the US National Institute for AIDS and Immune Disorders (NIAID) issued a press release about the early stopping of a large HIV vaccine study due to lack of efficacy. [1]

Since 2015, the phase 3 HVTN 702 (Uhambo) study had randomised 5407 HIV negative volunteers to either receive a prime-boost vaccination adapted for HIV clade C or a matched placebo injection, with six injections planned over 18 months. The study was being run in 14 sites in South Africa.

The vaccine regimen included of two experimental vaccines: a canarypox vector-based vaccine called ALVAC-HIV and a two-component gp120 protein subunit vaccine with an adjuvant to enhance the body's immune response to the vaccine (both modified from those found to have a modest effect in the Thai RV144 vaccine study).

On 23 January 2020, an interim analysis by the studies independent Data and Safety Monitoring Board (DSMB) reported 129 vs 123 HIV new infections in the vaccine vs placebo recipients, and recommended that the study be closed early.

NIAID followed the DSMB recommendation and has stopped any further injections, although safety follow-up with continue.

C O M M E N T

Although this is disappointing news, several other large HIV prevention studies are ongoing.

These include the phase 3 Imbokodo and Mosaico studies using a mosaic vaccine developed by Janssen (results due 2022) and the AMP studies using the bNAb VRC01 (results due end 2020).

The press statement also noted that participants in HVYN 702 were able to use daily PrEP (as this is currently standard of care in South Africa), although this has not been allowed for Imbokodo and Mosaico or in the South African VRC01 study.

References

1. NIAID press release. Experimental HIV vaccine regimen ineffective in preventing HIV. (03 February 2020).
<https://www.hiv.gov/blog/experimental-hiv-vaccine-regimen-ineffective-preventing-hiv>
2. NIH press statement. NIH and partners launch HIV vaccine efficacy study. (30 November 2017).
<https://www.niaid.nih.gov/news-events/nih-and-partners-launch-hiv-vaccine-efficacy-study>
3. NIH press statement. NIH and oartners to launch HIV vaccine efficacy trial in the Americas and Europe. (15 July 2019).
<https://www.niaid.nih.gov/news-events/nih-and-partners-launch-hiv-vaccine-efficacy-trial-americas-and-europe>
4. NIH launches large clinical trials of antibody-based HIV prevention. (7 April 2016).
<https://www.niaid.nih.gov/news-events/nih-launches-large-clinical-trials-antibody-based-hiv-prevention>

ON THE WEB

Leave no one behind: A manifesto for hepatitis C elimination

Hepatitis C Trust

A report from the Hep C Trust calling for government funding and policies to diagnose the estimated 100,000 people in the UK currently living with HCV who are not aware of their status.

This includes the importance of improved care within the prison system and reinvesting in support services for drug and alcohol services.

Reference

Hepatitis C Trust. Leave no one behind: A manifesto for hepatitis C elimination. (November 2019).

<http://www.hepctrust.org.uk/blog/nov-2019/leave-no-one-behind-manifesto-hepatitis-c-elimination>

http://www.hepctrust.org.uk/sites/default/files/attachments/HCT%20Manifesto%202019_0.pdf (PDF)

FUTURE MEETINGS

Conference listing 2020

The following listing covers some of the most important upcoming HIV-related meetings and workshops.

10th International Workshop on HIV & Women

6 – 7 March 2020

www.virology-education.com

Conference on Retroviruses and OIs (CROI 2020)

8–11 March 2020, Boston

www.croiconference.org

26th Annual BHIVA Conference (BHIVA 2020)

27 – 29 April 2020, Manchester

www.bhiva.org

INTEREST 2020

5 – 8 May 2020, Windhoek, Namibia

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

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

13 – 15 May 2020 (TBC), New York

www.virology-education.com

International Workshop on HIV Paediatrics 2020

3 – 4 July, San Francisco tbc

www.virology-education.com

Community Reclaiming the Global Response (HIV 2020)

5 – 7 July 2020, Mexico City

<https://www.hiv2020.org/registration>

23rd International AIDS Conference (AIDS 2020)

6 – 10 July 2010, San Francisco and Santa Barbara

www.aids2020.org

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

12 – 13 September 2020, New York

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

HIV Glasgow Congress 2020

4 – 7 October 2020

www.hivglasgow.org

HIV Research for Prevention (HIV R4P 2020)

11 – 15 October 2020, Cape Town

<https://www.hivr4p.org>



ask a
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by email,
online
or phone

questions@
i-Base.org.uk

www.i-Base.info/qa

0808 800 6013

take
control
of your
treatment

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

Pocket guides

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

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

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



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

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

This project was developed with the Kobler Centre in London.

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

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

email: subscriptions@i-base.org.uk

Fax: 0208 616 1250

Other i-Base resources can still be ordered online as usual.

<http://i-base.info/forms/order.php>

Customise U=U posters for your clinic

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

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

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

roy.trelvelon@i-Base.org.uk

Order publications and subscribe online

All publications can be ordered online for individual or bulk copies. All publications are free. Unfortunately bulk orders are only available free in the UK.

<http://i-base.info/order>



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 I would like to make a donation to i-Base - *Please see inside back page*• **HIV Treatment Bulletin (HTB) every two weeks** **by e-mail**• **Pocket leaflets** - *A7 small concertina-folded leaflets (2017)*

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

• **Booklets about HIV treatment****NEW: Guide to HIV testing and risks of sexual transmission** (*Jan 2020*): 32-page A5 booklet **quantity** _____**NEW: Introduction to ART** (*October 2019*): 48-page A5 booklet **quantity** _____**NEW: UK Guide To PrEP** (*November 2019*): 24-page A5 booklet **quantity** _____**ART in pictures: HIV treatment explained** (*June 2019*): 32-page A4 booklet **quantity** _____**Guide to HIV, pregnancy and women's health** (*April 2019*): 36-page A5 booklet **quantity** _____**Guide to changing treatment: what if viral load rebounds** (*Jan 2018*): 24-page A5 booklet **quantity** _____**HIV and quality of life: guide to side effects and long-term health** (*Sept 2016*): 96-page A5 **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