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CROI 2023, mpox vaccines, statins (6 April 2023)

CONTENTS

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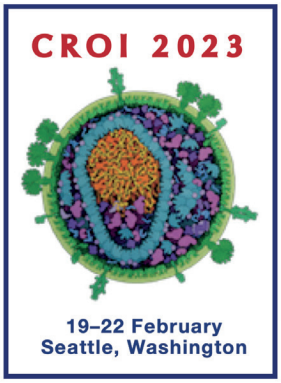
EDITORIAL

This issue of HTB includes reports from CROI 2023 on the safety of the dapivirine ring during pregnancy and on the impact of recent US legislation on the reproductive health of women in the US.



Also that several generic companies have signed licenses to be able to manufacture cabotegravir-LA for use as PrEP in selected low- and middle-income countries, though the timeline for this has not been announced.

Although cases of mpox have almost disappeared in the UK and many other countries, we include three reports that caution against reliance on current vaccine coverage to prevent new outbreaks. One looks at efficacy data based on observational studies, another summarises latest US research, including plans for a new mRNA-based vaccine, and the third reports cases of mpox reinfection, including after receiving a course of the current MVA-BN vaccine, also noting other currently approved drugs that might have mpox activity.

Although many UK clinics are still providing vaccine services, this will apparently only be for a short period. Anyone who has not yet had a first dose will have to do this by 16 June 2023. The last day to complete the second dose is 31 July 2023. It is unclear whether this will provide sufficient cover on a population level to prevent a future outbreak. [1]

The large international REPRIEVE study looking at statin use in people living with HIV at low-to-moderate cardiovascular risk has reported a significant and early benefit in reducing heart attacks and stroke, with all participants now offered open-label pitavastatin for the remaining follow-up.

And a small study reports that penile Botox injections might overcome erectile dysfunction in people who are unresponsive to other treatments.

Richard Jefferys reports a consensus on the order of HIV cure cases and a new documentary about the artist David Wojnarowicz is now streaming free online. Recommended watching.

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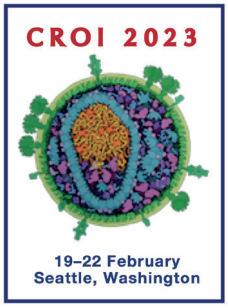
CONFERENCE REPORTS

30th Conference on Retroviruses and Opportunistic Infection (CROI 2023)

19–23 February 2022, Seattle and virtual

Simon Collins, HIV i-Base

Introduction



This year the annual Conference on Retroviruses and Opportunistic Infections (CROI) was held in Seattle from 19–22 February, and also virtually.

The programme was dynamic and exciting with much to report.

Open access to all other material including most webcasts and will be available online one month after the conference.

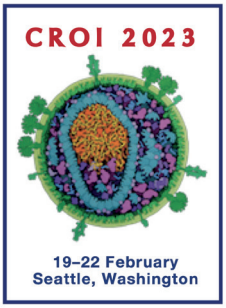
https://www.croiconference.org/search-abstracts

New reports included in this issue of HTB are:

- Dapivirine ring safe in late pregnancy and during breastfeeding
- Implications of restrictions on reproductive rights for HIV care in the USA and beyond

Dapivirine ring safe in late pregnancy and during breastfeeding

Polly Clayden, HIV i-Base



The dapivirine vaginal ring appears safe when used in the third trimester of pregnancy and during breastfeeding – according to data presented at CROI 2023.

Pregnancy

Adverse pregnancy outcomes were uncommon when the dapivirine ring was used in the third trimester – in the first study of the monthly ring in pregnancy. [1] Rates were also similar to those seen in the comparator arm – oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) – and in the communities where the study is being conducted. These data support plans for subsequent investigation of safety earlier in pregnancy.

Microbicide Trials Network (MTN)-042/DELIVER is a phase 3b, randomised, open-label safety trial of the dapivirine ring and oral TDF/FTC. The trial has a stepwise design working backwards from the third trimester. This includes an IRB review before moving to the next cohort:

- Cohort 1 – 36+ weeks (gestation); 2:1 randomisation/4–6 weeks
- Cohort 2 – 30–35 weeks; 2:1 randomisation/7–12 weeks
- Cohort 3 – 12 to 29 weeks; 4:1 randomisation/up to 30 weeks

The findings reported at the conference were safety data from the first two cohorts of pregnant participants.

Eligible pregnant women aged 18–40 in Malawi, South Africa, Uganda and Zimbabwe were randomised 2:1 to monthly dapivirine ring or daily TDF/FTC.

The evaluation assessed pregnancy outcomes and complications up to six weeks after delivery and summarised the findings using descriptive statistics. These were compared to local background rates from a systematic chart review: MTN-042B. This review included 10,138 records across four sites.

The trial started in January 2020 but was paused briefly March to May 2020, to ensure COVID-19 safety

measures were in place.

The study enrolled 150 participants into cohort 1 (101 randomised to dapivirine ring and 49 to TDF/FTC) and 157 participants into cohort 2 (106 randomised to dapivirine and 51 to TDF/FTC).

Demographic and clinical characteristics were similar by study arm for each cohort.

In cohort 1, there was one stillbirth and one neonatal death, both in the TDF/FTC arm. One stillbirth and one neonatal death also occurred in cohort 2, both in the dapivirine ring arm. The prevalence of preterm delivery was 2% in cohort 1 and 6% in cohort 2.

In both cohorts, the most common outcome (93%) was a full-term, live birth. Pregnancy complications were rare, with hypertensive disorders being the most commonly reported (10.5%) and generally similar to local background rates.

There were no cases of fever of unclear etiology or preterm premature rupture of membranes. In cohort 2, there was 1 (1%) case of chorioamnionitis in the dapivirine ring arm and 1 (1%) of postpartum endometritis in the TDF/FTC arm, and 2 (4%) of puerperal sepsis in the TDF/FTC arm.

There were no seroconversions or maternal deaths during the reporting period. There was one infant death in each arm, neither were deemed to be associated to the study product.

Breastfeeding

Few adverse events were reported among mothers and infants in a related presentation showing the first evaluation of dapvirine ring safety and drug detection during breastfeeding. All infant adverse events were judged unrelated to study product. And although dapivirine appears to concentrate in breastmilk, detection in infant plasma was low.

A previous study, MTN-029/IPM 039, found a positive safety profile in lactating women and low likelihood of significant drug transfer to infants. Dapivirine was safe and well-tolerated among those who had weaned infants but were still able to produce milk. Median dapivirine concentrations were 676 pg/mL in breast milk, 327 pg/mL in plasma (milk/plasma ratio approximately 2.0). This study estimated extremely low infant exposure (74.3 ng/kg/day).

Following that study, additional research was recommended to evaluate safety of dapivirine use during breastfeeding.

MTN-043 was a phase 3b, randomised, open-label trial, with 12 weeks of exposure to monthly dapivirine ring or daily oral TDF/FTC. From September 2020 to July 2021, exclusively breastfeeding, mother-infant pairs were enrolled 6–12 weeks after delivery at sites in Malawi, South Africa, Uganda, and Zimbabwe.

Mother-infant pairs were randomised to 3:1 to the dapivirine ring or TDF/FTC. Adverse event data were collected for mothers and infants throughout product exposure and at two weeks after the end of product use.

Drug concentrations were measured in maternal plasma, maternal dried blood spots (DBS), breast milk, infant plasma, and infant DBS.

The study enrolled 197 mother-infant pairs. Infants were a median age of 9 weeks at enrollment.

Mean dapivirine concentrations in breast milk ranged from 698.3 pg/mL at week 1 to 596.1 pg/mL at month 3 (50.1pg/mL 2 weeks post-use). Extremely low concentrations of dapivirine were detected in infant plasma samples: 0 pg/mL week 1, 14.5 pg/mL week 2 and 10.7 pg/mL month 3 (BLQ 2 weeks post-use).

No serious adverse events or grade 3 and higher events in mothers or infants were considered to be related to study product.

In the TDF/FTC arm, tenofovir diphosphate concentrations from infant DBS were all below the lower limit of quantitation.

C O M M E N T

The risk of acquiring HIV increases during pregnancy and is highest during the postpartum period.

These studies are excellent and provide important data from a new product to guide use in pregnant and lactating women that is usually absent (or very slow to obtain) in both treatment and prevention of HIV.

As the authors pointed out, typically development programmes rely on phase 3 trial results or post market surveillance.

Phase 3 studies usually include contraception requirements, so few pregnancies occur and participants who do get pregnant either discontinue the study or the study product. For example in MTN-020/IPM 027 (2629 women) there were 86 pregnancies in the dapivirine arm and in HPTN-084 (3224 women) 29 pregnancies in the cabotegravir long-acting arm.

Post-market surveillance depends on adequate reporting systems, results in substantial delay and shifts the risk-benefit to the user and clinician – pregnant women receive a new product in an uncontrolled and unconsented fashion.

A safety study, designed for a pregnant population, is the most efficient and rigorous way to collect safety data for an investigational product in pregnancy, so very welcome. These studies can be difficult and require support from the community, developers and donors.

MTN-042 is an example of good participatory practice. The study included a stakeholder meeting, with key opinion leaders from each trial site country, researchers and WHO after which recommendations were incorporated into the protocol (for example standardised definitions, background pregnancy outcome data and longer infant follow up). In-country meetings were also conducted with community groups and NGOs in each participating country.

Since early 2021, WHO recommends the dapivirine vaginal ring as part of combination prevention. [3] The guidance states: "The dapivirine vaginal ring may be offered as an additional prevention choice for women at substantial risk of HIV infection as part of combination prevention approaches". This is a conditional recommendation with moderate-certainty evidence. It defines substantial risk of HIV infection as "HIV incidence greater than 3 per 100 person-years in the absence of PrEP."

The ring is now approved by several national agencies including the Medicines Control Authority of Zimbabwe, Uganda National Drug Authority, and South African Health Products Regulatory Authority (as well as European Medicines Agency).

But there are substantial questions concerning the ring's efficacy in reducing the risk of acquiring HIV. Although the WHO guideline summary of its review findings notes that a systematic review and meta-analysis of the ring trials demonstrated it to be effective, the two key randomised controlled trials, the Ring Study (IPM-027) and ASPIRE (MTN-020), showed only 33% and 27% relative reduction in HIV risk versus placebo.

The results from two open-label extension studies – DREAM and HOPE – found better efficacy (62% and 39% versus simulated control), compared to the randomised controlled trials. And a subgroup analysis by age did not demonstrate efficacy among women 18–24 years old, who had very low adherence.

Of note, in December 2021, The International Partnership for Microbicides (IPM) – who developed the ring – voluntarily withdrew its New Drug Application (NDA) from the US Food and Drug Administration (FDA), following feedback that current data are unlikely to support the ring's approval by the agency. [4]

WHO followed this announcement with one saying it continues to support its conditional recommendation for the ring as an additional prevention option for women at substantial risk of HIV. [5]

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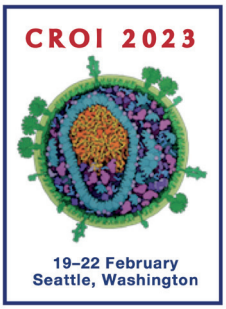
Implications of restrictions on reproductive rights for HIV care in the USA and beyond

Kirk Taylor, HIV i-Base



The impact of recent changes to reproductive rights legislation in the US, following last year's Supreme Court decision, was the topic of an important plenary at CROI 2023 . [1] Abortion legislation changes have direct implications for HIV care and research.

In June 2022 the US Supreme Court voted to overturn Roe vs Wade, ending the constitutional right to abortion and allowing states to implement, or reinstate existing anti-abortion law. Dr Denise Jamieson, an obstetrician/gynaecologist and head of department at Emory University examined the implications of the Dobbs vs Jackson judgement for people living with HIV in the US. The university is based in Atlanta, a southern state with restrictive abortion legislation.

She used four hypothetical scenarios to illustrate the impact of the recent changes:

Scenario 1: 17 year old woman living with HIV is five weeks pregnant and lives in Georgia

The pregnancy is unplanned and the woman wants an abortion. State law dictates that abortion can only occur after she signs consent and waits 24 hours, her parent or guardian is informed and in the absence of a detectable heartbeat (approximately 6 weeks gestation). The abortion is scheduled and cancelled due to detection of cardiac activity. The next closest clinic is 134 miles away in South Carolina, but the woman has no resources to travel.

With many states imposing restrictive abortion bans, pressure is growing on states that allow procedures as people travel to seek out of state care. Georgia only grants exemptions for medical emergencies, if the pregnancy is medically futile or is the result of rape or incest and it is less than 22 weeks since last the period.

Scenario 2: ART-naive woman living with HIV is six weeks pregnant and lives in Oklahoma

A woman living with HIV and not on ART has a viral load of 150,000 copies/mL and her CD4 count is 50 cells/mm^3. She is six weeks pregnant and presents with cryptococcal meningitis. Recommended treatment includes flucytosine which is contraindicated in the first trimester. Both vertical transmission of HIV and potential teratogenic effects are of concern.

State law only allows abortion in medical emergencies to save the life of the pregnant woman. Most drugs have not been tested in pregnancy and safety data are lacking. Without abortion the optimal treatment will be delayed.

It is not clear if this case meets the criteria for medical emergency under Oklahoma abortion law. Should the doctor perform the procedure it is unlikely to be covered by malpractice insurance and could result in criminal sanctions.

Scenario 3: Woman living with HIV is 17 weeks pregnant, experiences PROM and lives in Texas

Woman experiences PROM (preterm premature rupture of membranes) at 17 weeks' gestation (pre-neonatal viability). Standard of care recommended by ACOG (American College of OB/GYN) is to offer expectant management or abortion due to high risk of adverse outcomes for both the mother and foetus.

Under Texas state law, it is illegal to perform abortion with doctors risking up to two years in jail and a $10,000 fine. The only exception is to save the life of a pregnant woman.

ACOG guidance states that without abortion maternal morbidity may increase. A case series of 28 pregnant people with PROM at <22 weeks pregnancy showed that maternal morbidity was twice as high for those that received expectant management vs those receiving terminations.

Scenario 4: Woman living with HIV diagnosed with liver cancer aged 35 and lives in Alabama

A woman living with HIV is diagnosed with cancer and starts on sorafenib, which is both teratogenic and embryotoxic. Having missed her period she returns and discovers she is five weeks pregnant and wants an abortion.

Alabama state law prevents abortion after conception, except to save the life of the pregnant woman. There are no exceptions for rape or incest and providing an abortion is a crime. The woman travels 128 miles to Georgia but the procedure is cancelled after detection of a foetal heartbeat. Now at seven weeks gestation, her next option is a clinic 250 miles away in Tallahassee Florida.

Cancer care is a big issue after the Dobbs decision. Cancer affects 0.1% of pregnancies and is likely rising due to increasing age of pregnant people. Delaying treatment raises mortality risk and most cancer therapies are not safe during pregnancy. Abortion rates for pregnant women with cancer are between 9 to 28%. State laws prohibiting abortion for pregnant women may lead to increased mortality.

What can be done?

WHO guidelines are clear that access to sexual and reproductive services should be non-coercive and not affected by HIV status. Abortions should be offered in a respectful and non-judgemental manner.

There is not enough data on medical and surgical abortions for women living HIV to identify outcome differences that are linked to HIV status. However, the data does not suggest that abortions are less safe for women living with HIV.

Dr Jamieson discussed five areas to focus on to monitor and mitigate the impact of changes to reproductive rights.

1. Establish robust national surveillance systems: While the CDC and Guttmacher Institute have collated several decades worth of abortion data, there are many gaps. The impact of changes in reproductive rights legislation should be tracked through the number of medical and surgical abortions performed and the frequency of self-induced abortions changes.
2. Promote and protect research for pregnant women and people of childbearing potential: abortion research must continue and include implementation studies to improve acceptability (ie reduce pain), improve access to safe abortion and document the impact of legislative change. It is also important to identify funding sources – relatively few donors fund abortion research.

   Removal of legal abortions will likely reduce the number of people of childbearing potential that are eligible for all clinical studies. For example, clinical trials of new antiretrovirals could be more likely to exclude women of child-bearing potential if abortion is not an option. Selection of clinical trial sites may also be determined by access to abortion services. This will further widen the knowledge gap for the use of medicines for HIV treatment and prevention by people of childbearing potential and pregnant women.
3. Ensure clinical training for reproductive care that includes abortion: changes to reproductive rights legislation risks creating "maternity care deserts" where there is not sufficient access to OB/GYN trained doctors – particularly trained to perform abortions in an emergency. Increased efforts are required to train and retain doctors in OB/GYN roles.
4. Promote and engage in reproductive rights advocacy and education through medical training programmes. Currently many students worry about where to train as states implement restrictive policies and deprive them of essential abortion training. Dr Jamieson described the impressive mobilisation of medical students to addressing these social justice issues as a "bright light".
5. Promote health equity and reduce disparities: half of people accessing abortion services are below the poverty line and are unlikely to have the resources required for out of state care. These legislative changes are also predicted to further widen racial disparities in healthcare and increase maternal mortality in the US.

Dr Jamieson concluded by saying that the right to abortion is a critical component of HIV care, not just in the US, but globally. This resonated with the comments of the former IAS president Adeeba Kamarulzaman who said that the "US Supreme Court's ruling on abortion rights will be felt across the world".

C O M M E N T

In no uncertain terms, this excellent talk outlined the dreadful repercussions brought about by overturning women's right to access safe abortion care and, in many states, returning their options to those available before 1973.

This talk focused on people living with HIV but it goes without saying that this legislation disproportionally affects people who are already marginalised in terms of health and social justice in the US.

Although the talk highlights the domestic situation, Dr Jamieson's closing remarks acknowledged the likely global implications of this legislation.

Global funding by US donors for abortion and reproductive health services is already shaky and blighted by the global gag rule. This bans NGOs who receive US funding from providing abortion services or referrals, and even advocacy for legal abortion. The global gag has been implemented and revoked by successive US governments since President Reagan. A substantial proportion of global HIV funding is provided by the US government.

Ref: Jamieson DJ. Restrictions on reproductive rights and their impact on people living with HIV. CROI 2023, 19-22 February 2023, Seattle. Plenary presentation 2.
https://www.croiwebcasts.org/console/player/51663 (webcast)

ANTIRETROVIRALS

Generic versions of injectable PrEP could enable access to CAB-LA in low-income countries

Simon Collins, HIV i-Base

On 30 March 2023, the Medicines Patent Pool (MPP) announced that three Indian generic companies have signed licenses to be able to manufacture lower-priced versions of ViiV Healthcare's long-acting PrEP drug cabotegravir (CAB-LA). [1]

This is an essential step before injectable PrEP could become widely available globally to low-income countries where rates of new HIV infections are still highest.

CAB-LA was approved as PrEP by the US FDA in December 2021 where it had already been approved as a component in long-acting HIV treatment. It was developed by ViiV Healthcare who markets the PrEP formulation under the trade name Apretude.

Even in the US, access to PrEP has so far been very limited because of the high price.

Last year, ViiV Healthcare signed a voluntary licensing agreement to make CAB-LA available to MPP after community pressure for the need for generic versions, notably from the AfroCAB. Previously, ViiV had announced that they would produce CAB-LA globally. [2, 3, 4]

The three generic companies included in today's announcement are Aurobindo, Viatris (through its subsidiary Mylan) and Cipla who will all manufacture CAB-LA in India. Cipla also plans to manufacture CAB-LA in South Africa.

The press statement makes no reference to the timelines that will be needed before generic CAB-LA becomes available, or the likely generic prices.

However, research from the Clinton Health Access Initiative (CHAI) reported that generic formulations of CAB-LA injections could be produced at around $15-23 for a year's course of six injections. [5]

CAB-LA for PrEP is also approved in Australia and Zimbabwe and was submitted to the EMA in Europe in December 2022. It has also been submitted in South Africa, Malawi, Botswana, Brazil, Kenya, Uganda, Vietnam, Malaysia, Myanmar, Philippines and China. [6]

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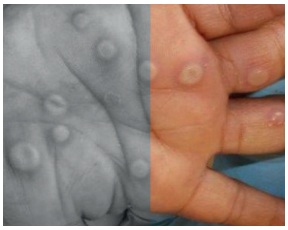
MPOX (MONKEYPOX)

UK data on efficacy of mpox vaccine: caution needed in observational analyses

Simon Collins, HIV i-Base

New data from the UK on the efficacy of mpox MVA-BN vaccine have been published in Lancet Infectious Diseases, together with an editorial comment that highlights major limitations in this and similar studies. [1, 2]



Estimating efficacy of this vaccine is complicated by a lack of prospective data, that the decline in mpox cases predated widespread access to the vaccine, and the significant differences in mpox risk factors between vaccinated and unvaccinated groups.

The new dataset is based on self-completed questionnaires from roughly one-third of the cases reported in the UK from July to October 2022. Overall, only 508/1545 people with confirmed cases returned the questionnaire and the final analysis only included 363/508 cases in gay and bisexual men who provided the required information.

Of these replies, 322/363 (89%) were unvaccinated, 8/363 (2.2%) occurred at least 14 days after vaccination and 32 (8.8%) occurred within 13 days after vaccination. However, by October 2023, actual vaccine coverage was only 47%, so this would have been significantly lower for much of the study period.

Vaccine effectiveness using this case-coverage design was based on coverage at 50% of an estimated 89,000 gay and bisexual men at risk. This compared vaccine coverage among cases with coverage in the eligible population. Rates were also calculated for higher and lower coverage.

Based on these data, three key results were reported.

- The estimated effectiveness at least 14 days after a single dose of MVA-BN was 78% (95% CI: 54 to 89).
- When excluding people older than age 50 (due to likely childhood smallpox vaccination), effectiveness was 74% (95% CI: 43 to 88).
- No early protection was reported within 13 days of the vaccine: –4% (95%CI: –50 to 29).

In sensitivity analyses vaccine effectiveness was 85% (95% CI: 69 to 93) for high-coverage (63% coverage) and 71% (40 to 86) for low-coverage (42% coverage) scenarios.

Breakthrough infections more than 14 days after a vaccine occurred in 8./363 cases, with 4/8 in men living with HIV.

The researchers concluded that a single dose of the MVA-BN vaccine was significantly protective of symptomatic mpox.

The linked editorial notes that major limitations of this study include:

- The low questionnaire return rate.
- The inability to systematically adjust for potential confounders of vaccine effectiveness including age, underlying clinical conditions (such as HIV), previous childhood smallpox vaccination, and behavioural practices related to mpox exposure.
- No data on the likely duration of protection.

Not adjusting for relevant confounders of vaccine effectiveness are significant limitations of two other frequently quoted studies looking at vaccine efficacy. [3, 4]

This is despite numerous studies at CROI 2023 that reported significant differences in both risk and related demographics in people who accessed mpox vaccines. [5, 6, 7, 8, 9, 10]

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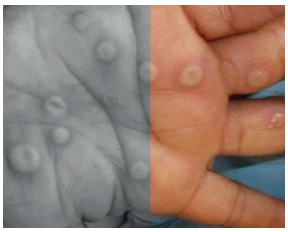
https://www.croiconference.org/abstract/characteristics-of-patients-hospitalized-with-mpox-during-the-2022-us-outbreak

Updates on US mpox research: surveillance, testing, vaccines and research

Simon Collins, HIV i-Base

Four talks covering the current understanding about mpox and plans for future research are now available online.



These form part of a virtual meeting to be held on 31 March 2023 to discuss the US government's approaches to mpox.

The studies include selected reports covering vaccine efficacy and also early research by Moderna to develop an mRNA vaccine against mpox. Treatment studies include using tecovirimat both in the US and the Democratic Republic of Congo (DRC) and a programme to look for new drugs.

The talks also provide an update on international studies with multiple partners. This includes studies using tecovirimat to treat mpox, both in the US and the Democratic Republic of Congo (DRC) and other research looking at mpox in Nigeria, Cameroon and DRC countries.

Research also covers genomic surveillance looking at the development of mpox viruses and susceptibility in various animal populations.

Registration for the meeting is at this link.

https://pitc.zoomgov.com/meeting/register/vJItdu6hqz0vHWiYuDEPdCCAaPi34rGGsFs

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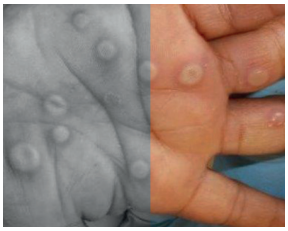
https://www.hiv.gov/hiv-basics/staying-in-hiv-care/other-related-health-issues/monkeypox/mpox-research-gathering

Cases of mpox reinfection in HIV negative men on PrEP: atovaquone, mefloquine and molnupiravir as potential treatments

Simon Collins, HIV i-Base



A case of mpox reinfection in an HIV negative gay man without immunosuppression, has just been reported in CID, occurring six months after the first infection. [1]

A similar case was also reported in the BMJ earlier this year, with only four months between infections, during which time the man had also received two doses of the Jynneos vaccine. [2]

The first case was a 31-year-old man on PrEP living in Switzerland who was first diagnosed with mpox in May 2022, at the outset of the epidemic last year. Presenting symptoms included four umbilicated penile lesions. Skin lesions and pharyngeal swabs tested PCR-positive for mpox with a cycle threshold (Ct) of 16.5 and 35.3 respectively. He also tested positive for chlamydia. Within two weeks skin lesions spontaneously resolved without complications.

On 1 December, he was diagnosed with mpox a second time and proctitis after reporting anal pain without bleeding that starting two weeks earlier, four weeks after a visit to Brazil – where a very high number of daily infections were still being reported. Rectal swabs tested PCR-positive for mpox with a Ct of 27. He also tested positive for chlamydia again. Four weeks after exposure he had an anal fissure but no typical mpox lesions.

On 13 December, orthopoxvirus PCR was negative in the blood and urine.

Unfortunately, viral isolates were only available for the first infection. The study authors discussed the potential that the second infection was due to immune escape mutations or that the high viraemia associated with anal lesions might have outweighed any earlier immune response. However, the median time for mpox PRC-positivity in rectal swabs is about 8 days with a 95th upper percentile of 14 days and no cases reporting persistent viral shedding over months.

The second infection was described as mild and resolved completely.

Another case of mpox reinfection in an HIV negative man on PrEP was reported in the BMJ earlier this year.

In this case, there was only four months between the two infections, during which time this person had also received two doses of the Jynneos vaccine.

One dose was given a week after the first infection in July 2022 and the second was given 10 weeks later in October (5 weeks before the second infection and 9 weeks before painful anal lesions).

Both mpox infections resolved without complications.

C O M M E N T

These cases show that the hoped-for sterilising immunity after an initial systemic infection is not sufficiently protective to prevent subsequent infections, even after less than six months.

Even though this is only a single case, the lack of protection more than four weeks after the second vaccine shot is also worrying. Although several reports claim high efficacy for the vaccine, protection has not been properly tested as mpox cases were already falling before significant protections would have been established.

Early studies reporting high levels of efficacy are also observational datasets, where the people receiving vaccinations were at lower risk of mpox compared to the unvaccinated groups where higher mpox rates were reported. [3, 4, 5]

This was supported by numerous studies at CROI 2023 reporting that people at highest need for mpox vaccinations in the US were least likely to be able to access them. [6, 7, 8, 9, 10, 11]

It was also interesting to see a recent CID paper suggesting that atovaquone, mefloquine, and molnupiravir might have activity against mpox and with greater potency than cidofovir. [12]

As this issue of HTB went to press, two further cases of mpox reinfection were publihed in Lancet Infectious Diseases. [13]

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COMPLICATIONS

Statins reduce heart disease by 35% in the international HIV REPRIEVE study

Simon Collins, HIV i-Base

The largest randomised controlled study of statin therapy in people living with HIV has proved benefits earlier than expected, with all participants now being offered statins. [1, 2]

This international US-funded REPRIEVE study (NCT02344290) randomised just over 7,750 participants to either oral pitavastatin calcium (4 mg daily) or matched placebo. Entry criteria included HIV positive adults aged 40 to 75, on ART with CD4 counts >100 cells/mm3. Participants also could only have with low-to-moderate cardiovascular risk, when statins would not be routinely used. This definition included having a 10-year risk of serious cardiovascular events that was less than 10%. Pitavastatin was used because it has fewer drug interactions than other statins.

The study started in 2015 and included more than 100 sites in the US, Canada, Thailand, South Africa, Brazil, Peru, Haiti, Zimbabwe, Botswana, Uganda and India.

A planned early interim analysis showed that people in the statin group had 35% fewer cardiovascular events including heart attacks and strokes, and the placebo arm has now closed early. All participants will be offered open-label pitavastatin and will continue to be followed until the planned end of the study.

Important sub-studies in REPRIEVE include an analysis presented at CROI 2023 reporting that integrase inhibitors were associated with modestly higher BMI increases over two years, and that these were significantly higher in women and Black African/American participants. [3]

Pitavastatin is approved and available in the UK. [4]

C O M M E N T

Notably important in the context of HIV, a recent meta-analysis of three large RCTs in the general population and a related editorial comment, reported on the role of immune inflammation (measured as CRP) as a risk factor for cardiovascular disease in people taking statins. [5, 6]

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Penile BOTOX injections improve blood flow and other outcomes in men with moderate to severe erectile dysfunction

Kirk Taylor, HIV i-Base

A double-blind randomised controlled trial evaluated BOTOX injections as therapeutic intervention for men with moderate to severe erectile dysfunction (ED). [1]

BOTOX injections improved penile blood flow and participants reported improved ability to maintain erections during penetrative sex. High dose BOTOX (100 units) was most durable with effects observed out to 24 weeks. Longer follow-up periods are required to establish minimum treatment intervals.

Botox injections helped 40% of participants restart sexual activities but others continued to report being unable to complete intercourse.

Erectile dysfunction (ED) is a global problem and is associated with co-morbidities, such as cardiovascular disease, neuropsychological disorders, HIV and depression. The efficacy of pharmaceutical interventions (e.g. PDE-5 inhibitors) are short-lived and there is demand for alternatives.

BOTOX is widely used in cosmetic and medical procedures and can improve blood flow, which would be of benefit to people with ED.

Males (n=176) who had not responded to pharmaceutical interventions were enrolled onto the study, median age was 55 years (IQR: 49 to 64) and median time since diagnosis was 6 months (IQR: 6 to 12 months). Co-morbidities were common and were evenly distributed between groups.

Participants were randomised to receive placebo (n=55), 50 Units BOTOX (n=59) or 100 Units BOTOX (n=62) injections at four sites at the base of the penis.

Median SHIM (sexual health inventory for men) scores at baseline were 8 (IQR: 7 to 9) indicative of moderate to severe ED. BOTOX injections significantly improved SHIM scores at weeks 2 and 12 ($p>0.05$). Week 24 show a decrease of SHIM scores from 13 (IQR: 12 to 15) to 8 (8 to 10) in the 50 unit BOTOX group. The higher dose group (100 units) maintained SHIM scores across the study period.

BOTOX treatment improved blood flow and modestly increased stretched penile length with no change to penile girth.

Some adverse events (4%) were reported as follows: penile pain that was managed with analgesics (n=1), injection site hematoma (n=1) and prolonged erection during doppler flow assessment (n=4). No systemic adverse events were reported.

C O M M E N T

This study is included in HTB as a potential option for people who have not responded to other available treatment. The data should be interpreted cautious until confirmed in other studies.

A linked editorial congratulates the authors on their study, but also raises questions about the relatively short follow-up period and failure to stratify participants by vascular complications.

Further information is also required to determine the long-term impact of BOTOX therapy and which people with ED are most likely to benefit. [2]

Further information on sexual health and well-being is included in the recently updated i-Base guide to HIV and quality of life. [3]

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CURE-RELATED RESEARCH

HIV cures 3, 4 and 5: Düsseldorf case published, City of Hope patient gives public interview, New York case published

Richard Jefferys. TAG

The news on 20 February 2023 was awash with stories about the Düsseldorf Patient, one of five people considered likely cured of HIV after receipt of a stem cell transplant to treat a life-threatening cancer diagnosis.

As with all five reported cases to date, the stem cell donor was homozygous for the CCR5 delta-32 mutation, which renders immune cells resistant to most HIV variants. The media coverage has been prompted by the publication of a detailed report in the journal Nature Medicine by Björn-Erik Ole Jensen and colleagues. [1]

The individual, who identified himself as Marc in an interview with a Dutch news outlet in 2021, has now been off antiretroviral therapy (ART) for four years with no sign of HIV viral load rebound. [2]

His current health is reported to be good, although the paper makes clear his journey has been difficult having experienced two relapses of acute myeloid leukemia and reactivation of multiple chronic viral infections (cytomegalovirus, herpes simplex virus 2, human herpesvirus 8 and Epstein–Barr virus). Mild chronic graft-versus-host disease of the eyes with bilateral keratoconjunctivitis sicca (dry eye syndrome) developed after the stem cell transplant and is still present.

The news headlines are potentially confusing because some state Marc is the third case [3] to reflect the chronological sequence (after Timothy Ray Brown and Adam Castillejo) while others designate him the fifth [4] to reflect the total number of cases described to date, which include two more recent examples in New York City [5] and at the City of Hope in Los Angeles [6].

The first scientific description of the Düsseldorf Patient was in a poster presentation at the 2016 Conference on Retroviruses and Opportunistic Infections (CROI), prior to interruption of ART. Two post-interruption follow up posters were presented at CROI in 2019 and 2020. [7]

The HIV cure research field has thus been aware of the case for a long time, and there was frustration and confusion last year when the announcement of a fifth similar possible HIV cure at the City of Hope mistakenly referred to it as the fourth based on the unnecessarily prim rationale that information on the Düsseldorf Patient hadn't yet been published in a journal. [8]

Today's publication will hopefully put any uncertainty to rest.

C O M M E N T

The City of Hope patient has since been interviewed on US television giving his name as Paul. [9]

The New York case has also since been published. [10]

Source

Jefferies R. The Düsseldorf Patient HIV Cure Case Published in Nature Medicine. TAG Basic Science Blog. (20 February 2023).

https://tagbasicscienceproject.typepad.com/tags_basic_science_vaccin/2023/02/the-d%C3%BCsseldorf-patient-hiv-cure-case-published-in-nature-medicine.html

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DRUG RESISTANCE

IAS-USA update HIV drug resistance tables

Simon Collins, HIV i-Base

On 5 April 2023, the US International Antiviral Society IAS-USA publicised their latest updated to the list of mutations associated with clinical resistance to HIV drugs and the accompanying user notes.

This edition covers the following drugs.

- Cabotegravir, fostemsavir and ibalizumab are all now included. The capsid inhibitor lenacapavir (GS 6207) has been added to Figure 2.
- A new section on recently approved drugs.
- Several changes were made to the bars of the integrase strand transfer inhibitors (InSTIs) cabotegravir and dolutegravir, the protease inhibitors atazanavir and lopinavir, and the nonnucleoside analogue reverse transcriptase (NNRTI) inhibitor doravirine.
- The user notes for tenofovir have been modified as recent clinical data suggest that the K65R plus M184V mutational profile is of less clinical relevance if tenofovir with either lamivudine or emtricitabine is prescribed in combination with a boosted protease inhibitor or one of the second generation InSTIs bictegravir or dolutegravir.

Antiretroviral drugs that are no longer recommended are listed at the bottom of the drug class and are shaded in gray. Their user notes are retained for historical significance.

These were published online in Topics in Antiviral Medicine.
https://www.iasusa.org/tam/october-november-2022

The figures are also available as downloadable PDF and are now available as PowerPoint Slides.

The mutations list is designed to help doctors make clinical decisions about the choice of ART.

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https://www.iasusa.org/tam/october-november-2022

ON THE WEB

David Wojnarowicz: F**k You F*ggot F**ker - now online

Simon Collins, HIV i-Base

A moving documentary about the artist David Wojnarowicz, also an early HIV activist with ACT-UP New York is now available to watch online.

Free access is available as part of the Vice YouTube documentary series.

The 2020 film, ***Wojnarowicz: F**k You F*ggot F**ker***, is told through Wojnarowicz's own works and recordings and other archive material from the 1980s and 90s.

The film includes an additional introduction and interview with the director, Chris McKim.

David Wojnarowicz died in 1992 from AIDS, aged 37.

*Wojnarowicz: F**k You F*ggot F**ker* (1h 43m)

https://youtu.be/18X5dBp06Qs

David Wojnarowicz

https://en.wikipedia.org/wiki/David_Wojnarowicz

Vice YouTube channel

https://video.vice.com/en_us/topic/documentary

Making PrEP accessible: Updates on long-acting injectable options

International AIDS Society (IAS) on 30 March 2023,

The latest updates on long-acting injectable PrEP, including science and research emerging from recent conferences and the results from HPTN 083 and 084 and the announcement of sublicenses from the Medicines Patent Pool to three generic manufacturers. Participants also heard a civil society perspective on the evolving PrEP landscape, as well as on-the-ground approaches to increase access to long-acting PrEP.

Results from HPTN 083 and 084 – Beatriz Grinsztejn

Long-Acting PrEP: What we learned from CROI and what we still need to know – Sunil S Solomon

The evolving PrEP landscape – Shakirah Namwanje

Accelerating access to Long-Acting PrEP: oral PrEP progress and planning for the future – Mitchell Warren

https://www.iasociety.org/webinars-and-recordings

MEETINGS & WORKSHOPS 2023/4

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.

Some meetings are in person, some are virtual and others offer both options.

Academic Medical Education (AME) meetings and workshops

Several AME workshops (previously Virology Education) are highlighted below but 35 meetings are planned each year. Many virtual meetings include free registrations for health workers, researchers and community.

https://academicmedicaleducation.com (meetings listings)

2023

BHIVA Annual Conference 2023

24 – 26 April 2023, Gateshead, UK

www.bhiva.org

15th AIDS Impact Conference

12 – 14 June 2023, Stockholm, Sweden

www.aidsimpact2023.com

HIV Cure & Immunotherapy Forum

22 July 2023, Brisbane, Australia

www.iasociety.org/conferences/ias2023/take-part/pre-meetings

12th IAS Conference on HIV Science

23 – 26 July 2023, Brisbane, Australia

iasociety.org

30th Intl Workshop on HIV Drug Resistance and Treatment Strategies

20–22 September 2023, Cape Town, South Africa

www.hivresistance.co.za

19th European AIDS Conference (EACS 2023)

18 – 21 October 2023, Warsaw, Poland

www.eacsociety.org

6th Southern African HIV Clinicians Society Conference (SAHCS 2023)

8 – 10 November 2023, Cape Town, South Africa

www.sahcsconference.co.za

2024

5th HIV Research for Prevention Conference (R4P 2023)

6 – 10 October 2023, Lima, Peru, and virtual.

www.iasociety.org/conferences/HIVR4P2023

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

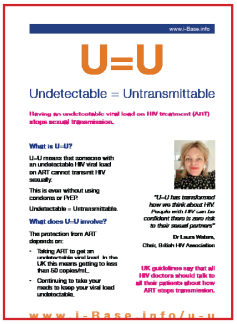
- Introduction to ART (May 2022)
- HIV & quality of life: side effects & long-term health (Sept 2016)
- Guide to PrEP in the UK (February 2022)
- HIV testing and risks of sexual transmission (June 2021)
- Guide to changing treatment and drug resistance (August 2021)
- Guide to HIV, pregnancy & women's health (April 2019)

Pocket guides

A series of pocket-size concertina folding leaflets that are 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 has 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 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 email: subscriptions@i-Base.org.uk

h-tb

HIV TREATMENT BULLETIN

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

http://www.i-Base.info

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

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

- **Booklets about HIV treatment**

Introduction to ART: *44-page A5 booklet* **quantity** _____

UK Guide To PrEP: *24-page A5 booklet* **quantity** _____

ART in pictures: HIV treatment explained: *32-page A4 booklet* **quantity** _____

Guide to changing treatment: *8-page A5 leaflet* **quantity** _____

Guide to side effects and quality of life: *8-page A5 leaflet* **quantity** _____

Guide to HIV testing and risks of sexual transmission *52-page A5 booklet* **quantity** _____

- **Other resources**

U=U resources:

A3 posters quantity _____ **A5 leaflets quantity** _____ **A6 postcards quantity** _____

HIV treatment passports - Booklets to record your HIV medical history **quantity** _____

Phoneline *posters (A4)* **quantity** _____

Please post to the above address, or email a request to HIV i-Base:

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