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hiv treatment bulletin (e)

AIDS 2022 reports and monkeypox crisis (1 September 2022)

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Introduction to ART: i-Base guide (June 2022)

The widely used i-Base guide to ART has been updated to include recommendations in the 2022 BHIVA guidelines.

Both online and print versions are now updated.

This guide covers information for people newly diagnosed, those about to start ART, and also those who have been living with HIV for many years and who want to learn more about treatment.

https://i-base.info/guides/starting

PrEP for women (June 2022)

A new leaflet about PrEP produced by and for women (with the Sophia Forum).

These small 16-page A7 leaflets were produced to raise awareness of access to PrEP.

Translations into key European and African languages are online and will be included on this page when available.

https://i-base.info/htb/43453

EDITORIAL

This issue of HTB includes further reports from the 24th International AIDS Conference (AIDS 2022) held in Montreal from 29 July to 2 August 2022.

This includes further data to support the use of dolutegravir during pregnancy, a move already supported by WHO.

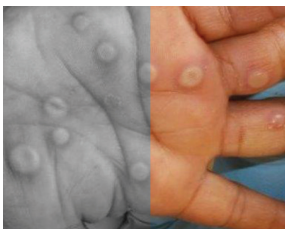
We also report that longer follow-up in the ADVANCE studies continues to report weight gain associated with dolutegravir and tenofovir alafenamide, especially in Black women.

And this caution might also exend to long-acting injectable ART which shows a similar weight and lipid profile to dolutegravir-based ART.

Other studies report that oral PrEP during pregnancy does not have any negative impact on exposed children.

The IAS cure workshop is now available to watch online.

Other reports from AIDS 2022 include a presentation on monkeypox cases diagosed at the three London clinics and a talk about the public health response in Montreal.



And our reporting on this outbreak in the UK continues with another dozen reports.

These are outlined in the special report on monkeypox that leads this issue of HTB.

The good news is that cases are starting to fall, but this might mainly be due to behavioural changes by gay and bisexual men who now believe that monkeypox is real and they know they want to avoid it.

But the range of reports includes a BHIVA update on vaccine efficacy, the potential for asymptomatic transmission, heterosexual transmission in Nigeria, a case of transmission to pets and several severe and difficult cases.

We cover the vaccine shortage in the UK and the potential to extend doses by using intradermal delivery. Also that a tecovirimat study has opened in the UK.

These have been particularly difficult months, especially coming after (and during) covid, which is still ongoing.

The response from sexual health clinics to manage this crisis has been remarkable.

Thank you.

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Supporting Ukraine

Simon Collins, HIV i-Base

The significant challenges to support people who remain in Ukraine or who migrated involves both international and community-based organisations.

HTB includes the following two online resources: one to donate unused medicines and the other to highlight organisations that can benefit from direct financial support.

Sending unused meds to Ukraine: emergency appeal

https://i-base.info/htb/42694

The call for HIV and other meds, and medical supplies is still important, even though International agencies and drug manufacturers are also organising to meet this demand.

This project is led by EACS and BHIVA and supported by the UK-CAB.

Medicines need to be in original packaging, ideally in unopened packs. All HIV and related meds are acceptable, ***even if they are past the use-by date.***

All donations will be screened beforehand to make sure they are suitable.

The link page includes further details, including postal addresses in the UK, Europe and the US.

Organisations to help support Ukraine

https://i-base.info/htb/42633

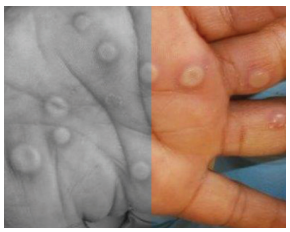
This page including 14 organisations that are helping people affected by the crisis in Ukraine.

This includes organisations that are supporting people living with HIV that are still in Ukraine or who have migrated to other countries.

SPECIAL REPORT: MONKEYPOX IN THE UK

Update on monkeypox in the UK: reduced cases, vaccine access, transmission and treatment...

Simon Collins, HIV i-Base



This issue of HTB continues to report on the current monkeypox (MPX) crisis and range of responses.

The following news has particular relevance to the UK.

- Most importantly, latest figures show that the number of new cases has been dropping in all areas of the UK, including London. [1]

  This is linked to several factors. One is the impact from vaccinating more than 33,000 people at high risk of MPX and the advice to wait 2 to 4 weeks after vaccination for protection to develop. Approximately 30,000 of these vaccines were given to gay and bisexual men, mainly in London, which is the centre of the UK crisis.

  Another factor is significant behavioural changes by men to reduce their risk of exposure to MPX by limiting situations where it is easy to have multiple anonymous partners. This lessens the chance that any single social event will result in many new cases.

  A US survey has reported that up to 50% of gay men have made similar changes and a study published in MMWR predicts this should reduce overall cases. Both are reported in this issue of HTB. [2, 3]

  Behaviour change is a short-term strategy that some community organisations, including i-Base, have been encouraging, especially until new vaccine supplies become available. [4]

- An update to the BHIVA statement on MPX includes a summary of vaccine efficacy results, including in people living with HIV.

  This recognises that it might take up to four weeks to generate a maximum response to a single shot. It also recommends a second vaccine shot for people living with HIV in order to achieve the maximum overall response to >95% (two weeks after the second shot). [5]

- The three clinics run by the Chelsea and Westminster Foundation in London, including 56 Dean Street, had diagnosed 620 MPX cases by mid July. Results from this cohort were presented at AIDS 2022, and are also reported in this issue of HTB. [6]

- The UK now has very limited supplies of monkeypox vaccine until the next shipment is delivered, hopefully later in September. [7]

- The potential to use intradermal rather than subcutaneous administration for the MPX vaccine, might allow up to five doses from a single vial. The convincing pharmacokinetic and immunogenicity data from a 2015 study has also led to intradermal use in the US. Practical concerns include the need for training for health workers, inadvertent subcutaneous injection with the low dose, using syringes with minimal waste and stability of the vial to allow multiple use. These will hopefully be quickly understood from use at the UK sites chosen to pilot this approach. [8, 9, 10, 11]

- UK use of tecovirimat for people with mild MPX should increase with the launch of the PLATINUM study. This study plans to randomise 500 non-hospitalised people with MPX to either tecovirimat or placebo. Participants can join while self-isolating as it does not involve clinic visits. However, the protocol and participant information refers to potential drug interactions between tecovirimat and several antiretrovirals (darunavir, rilpivirine and maraviroc) being an exclusion criteria. This is disappointing as these interactions should not be a clinical concern over the short two-week duration of the study. The study researchers are working with the MHRA to reverse this decision. [12]

- We report several cases that should inform future prevention and care. These include:
  - That people without symptoms might also be infectious. [13]
  - That non-sexual transmission has been reported. [14]
  - That MPX can pass to pets. [15]
  - That routine sexual health checks are important: one man was diagnosed with syphilis and advanced HIV at the same time as MPX. [16]

- Finally, although the decision to rename MPX is unlikely to be made until 2023 and might still include the word monkeypox, the different subtypes have been renamed as Clades 1 and 2 for Central and West Africa clades, respectively. [18]

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CONFERENCE REPORTS

24th International AIDS Conference (AIDS 2022)

29 July to 2 August 2022, Montreal, Canada

Simon Collins, HIV i-Base

Introduction

This year the IAS conference was held in Montreal and also as an impressive fully hybrid conference online.

As usual, the conference had a strong programme that covered all aspects of HIV treatment, prevention, activism and policy. Many specialist workshops were also held in the few days before the main conference.

The programme for the meeting is available online:

https://programme.aids2022.org

This issue of HTB includes the following reports from the conference.

- Dolutegravir no longer linked to higher risk of neural tube defects: latest update from the Tsepamo study
- Weight gain with dolutegravir and TAF in ADVANCE study continues out to week 192
- VRC01 added to early ART in infants no better than early ART alone
- Using PrEP during pregnancy is safe for children
- Long-acting CAB/RPV injections have a similar weight and lipid profile to dolutegravir-based oral ART
- Summary of 620 cases of monkeypox seen at three London clinics
- Advances in HIV cure-related research: IAS workshop now online

Dolutegravir no longer linked to higher risk of neural tube defects: latest update from the Tsepamo study

Polly Clayden, HIV i-Base

The prevalence of neural tube defects (NTDs) among infants born to women receiving dolutegravir (DTG) at conception has declined slightly to 0.11% and is not substantially different from those exposed to other antiretrovirals. [1]

These reassuring findings from the Tsepamo study, Botswana were presented at AIDS 2020.

Botswana started using DTG-based first-line ART in 2016. In May 2018 the Tsepamo study first reported a possible association between NTDs and exposure to DTG from conception. Since then, yearly updates from the study have shown a steady decline in risk with additional documented exposures.

We have covered Tsepamo and this potential safety signal extensively in HTB – including study methodology and commentary. [2, 3, 4] As a quick recap:

- Original signal, May 2018: 0.94 NTDs with conception DTG exposure (n=426) vs 0.12% with other ART exposure groups (n=11,300)
- Last update, March 2021: 0.15% with conception DTG exposure (n=5,860) vs 0.1% with other ART exposure groups (n=22, 475)
- Data presented at AIDS 2020, as a late breaker poster described here, were collected through March 2022.

Overall, between 15 August 2014 and 31 March 2022, there were 224,251 deliveries at study sites and 223,797 (99.8%) had an evaluable infant surface exam.

Of these, 9,460 were exposed to DTG from conception; 23,664 were exposed to non-DTG ART (14,432 efavirenz); 6,551 started DTG in pregnancy and 170,723 were among women without HIV.

Since March 2021, 32,819 additional births were recorded, including 3,600 more DTG conception exposures. The authors identified 16 additional NTDs: 1 with DTG conception exposure; 3 with non-DTG conception exposure; 1 with DTG started in pregnancy and 11 among women without HIV.

The additional NTD with DTG conception exposure was anencephaly (the authors noted that there was no available photo).

Across the entire study, since August 2014, there were 156 (0.7%, 95% CI 0.6% to 0.8%) NTDs identified (100 with photo and 56 description only). With DTG conception exposure there were 10 NTDs among 9,460 exposures (0.11%, 95% CI 0.06 to 0.19%).

This compared with non-DTG ART from conception, where there were 25 NTDs among 23,664 exposures (0.11%, 95% CI 0.07 to 0.16%). And with efavirenz from conception, there were 11 NTDs among 14,432 exposures (0.08%; 95% CI 0.04 to 0.14%).

For women who started DTG in pregnancy there were 4 NTDs among 6,551 exposures (0.06%; 95% CI 0.02 to 0.16%). And 108 NTDs out of 170,723 exposures (0.07%; 95% CI 0.05 to 0.08%) among women without HIV.

Table 1. Prevalence difference of neural tube defects by ARV and HIV exposure categories

Exposure group vs comparison group	Prevalence difference (95%CI)
DTG at conception vs non-DTG at conception	0.00% (–0.07 to +0.10%)
DTG at conception vs. EFV at conception	0.03% (–0.05 to +0.12%)
DTG at conception vs DTG started in pregnancy	0.04% (–0.06 to +0.14%)
DTG at conception vs non-DTG started in pregnancy	0.04% (–0.07 to +0.13%)
DTG at conception vs women without HIV	0.04% (–0.01 to +0.13%)

The authors concluded that these data support existing WHO guidelines that recommend DTG-based first-line ART for all adults, regardless of reproductive potential.

C O M M E N T

Following the previous update two years ago, for which the prevalence estimates suggested about one excess NTD per 1000 births with exposure to DTG at conception (with the lower bound of the 95% confidence interval just below or just about zero) we wrote: "Good news that we can finally 'lay this to rest' (as remarked at the AIDS 2020 press conference)".

This further slight decline to 0.11% reported here should surely finally, finally do so.

DTG must now be the most scrutinised antiretroviral for use in pregnancy. The updated Tsepamo data needs to be widely publicised as unfortunately concern about the original safety signal has remained in some settings despite evidence to dispute this.

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Weight gain with dolutegravir and TAF in ADVANCE study continues out to week 192

Polly Clayden, HIV i-Base

Participants in the ADVANCE trial, taking tenofovir alafenamide, emtricitabine and dolutegravir (TAF/FTC/DTG) had greater weight gain, risk of metabolic syndrome and clinical obesity than tenofovir disoproxil fumarate (TDF)/FTC/DTG with longer term follow up. This was particularly notable in women.

These findings were presented at AIDS 2022.

There were no significant differences in viral load suppression or renal or bone-related adverse events between the two DTG-based regimens. But both TAF/FTC/DTG and TDF/FTC/DTG had significantly higher rates of viral load suppression than TDF/FTC/efavirenz (EFV) at week 192 in the main ITT analysis.

WHO guidelines recommend first-line HIV treatment with TDF/lamivudine (3TC) or FTC/DTG. TAF is recommended only as an alternative to TDF for people with osteoporosis or impaired renal function.

ADVANCE compared the two DTG regimens to EFV-based ART (previous first-line standard of care). The study showed non-inferiority at 48, 96 and 144 weeks but greater weight gain in the DTG arms, which was most pronounced among those taking TAF/FTC/DTG.

ADVANCE was extended to 192 weeks to assess the weight gain – as well as safety and efficacy – longer term. Participants were reconsented for the study extension.

A total of 1,053 treatment-naive participants in South Africa were randomised to one of the three regimens. The study assessed viral load, vital signs and renal and bone adverse events prospectively. BMI was similar in the three arms at baseline.

At 192 weeks, 218/351 (62.3%) in the TAF/FTC/DTG arm, 204/351 (58.1%) in the TDF/FTC/DTG arm, and 177/351 (50.4%) in the TDF/FTC/EFV arm had viral load <50 copies/mL. In the on treatment analysis, these respective proportions were: 218/226 (96%), 204/209 (98%) and 177/179 (99%).

Body weight increased by +8.9 kg for participants in the TAF/FTC/DTG arm, +5.8 kg for TDF/FTC/DTG, and +3.3 kg for TDF/FTC/EFV.

Twenty nine per cent of participants taking TAF/FTC/DTG, 21% TDF/FTC+DTG and 15% TDF/FTC/EFV had developed clinical obesity.

The risk of clinical obesity was significantly higher among participants taking TAF/FTC/DTG, women and those with higher baseline BMI (all $p<0.001$).

Among the women in the study, 43% taking TAF/FTC/DTG developed clinical obesity by week 192 compared to 27% TDF/FTC/DTG and 20% TDF/FTC/EFV ($p<0.001$).

The risk of metabolic syndrome, as defined by the International Diabetes Foundation, was significantly higher in the TAF/FTC/DTG arm compared with the TDF/FTC/DTG and TDF/FTC/EFV arms ($p<0.001$). The investigators noted that this is associated with increased risk of diabetes, stroke and heart disease.

Bone fracture and Grade 3 or 4 renal adverse events were rarely seen in ADVANCE and similar across arms.

C O M M E N T

DTG and TAF continue to be associated with weight gain in ADVANCE. Particularly among women: 43% developed clinical obesity by week 192.

At 96 weeks, 27% of women in ADVANCE had developed clinical obesity so there appears to be no sign of a plateau in weight gain. [2]

As previously noted, according to QDIABETES algorithm, if weight rises by 10 kg, the risk of diabetes rises by 3 cases per 1000 people treated. This might not sound much, but in countries like South Africa, where millions of people need ART, the absolute numbers could be very substantial and create a huge extra burden on health services.

The ADVANCE investigators are looking into potential strategies to mitigate ART-associated weight gain, including weight loss drugs and alternative newer antiretrovirals.

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VRC01 added to early ART in infants did not reduce viral reservoir

Polly Clayden, HIV i-Base

VRC01 made no difference to HIV-1 DNA or RNA when added to early ART in infants compared with ART alone. These results from IMPAACT 2008 – a 60-infant study conducted in Africa and Brazil – were presented at AIDS 2022. [1]

Presenting author Alka Khaitan started the presentation with a reminder that in 2021, more than 160,000 infants acquired HIV.

Rapid formation of latent viral reservoirs is a barrier to ART-free remission. Early ART reduces viral reservoirs in infants. Broadly neutralising antibodies (bNAbs) have the potential to also do so.

VRC01 is a bNAb that targets the CD4 binding site of gp120. In the Tatelo Study, dual bNAb treatment maintained 24 weeks of viral suppression without ART in 44% of children who received early ART. [2]

VRC01 combined with early ART in infants may further reduce viral reservoirs.

The objectives of IMPAACT 2008 were to evaluate the safety of multi dose VRC01, given to infants with HIV combined with early ART and to compare the effect of VRC01 with early ART to early ART only on HIV DNA concentrations.

It was a randomised phase 1/2 multisite, open-label study in which infants age 72 hours to 84 days started ART up to 14 days before study entry. Infants were randomised 1:1 to VRC01 plus early ART (VRC01) vs early ART alone (no VCR01). VRC01 was given 40 mg/kg subcutaneous doses at weeks 0, 2, 6 and 10. ART was local standard of care.

Infants were followed for 48 weeks and the primary analysis (presented) was at week 14.

Sixty one infants were randomised: 30 in each arm completed week 14 and 28 in each arm completed week 48.

Enrollment was between April 2019 and March 2020 in Malawi, Botswana, Zimbabwe, and Brazil. Infants were 84% black non-Hispanic and 57% female.

Baseline characteristics were (VRC01 vs no VRC01): median age (72 vs 73 days), log10 plasma viral load (4.1 vs 4.4 copies/mL), viral load >100, 000 copies/mL (13 vs 11).

Median days on ART before entry (8 vs 6), receiving nevirapine-based ART (16 vs 9), receiving lopinavir/ritonavir-based ART (14 vs 21), baseline ART resistance (44% vs 33%). ART resistance was mostly to NNRTI.

Ninety per cent of infants experienced local injection reactions (all grade ≤2). Most resolved within a day and there was no increase with subsequent doses.

Adverse events grade ≥3 (none attributed to VRC01) to week 14 occurred in 40% of VRC01 and 47% of no VRC01. Most were anaemia, neutropenia and gastrointestinal disorders.

Twenty eight days after VRC01 dose median levels were 83 mcg/mL but 31% of infants had <50 mcg/mL (target). These levels were lower than predicted from earlier studies but no anti-drug antibodies were detected.

Baseline resistance to VRC01 (IC50 >50 mcg/mL) was detected in 5 of 17 (29%) infants with available results receiving VRC01.

Plasma viral load declined in both groups, with no apparent difference at week 14.

HIV DNA changes were measured by droplet digital PCR. In the primary efficacy analysis there was no difference in the decline of HIV DNA at week 14 minus week 0: (VCR01 vs no VCR01) –0.41 vs –0.53 log copies/million PBMCs, p=0.42.

A post hoc analysis revealed higher VCR01 concentrations correlated with larger reductions in HIV DNA: –0.42 (Spearman correlation), p=0.03.

Dr Khaitan noted that the limitations of this study included: high baseline NNRTI resistance, more nevirapine in the VRC01 group and small sample size.

She added that more potent ART regimens with combination bNAbs are likely needed to facilitate early clearance of infected cells in infants and that additional studies are required to define how to optimally dose bNAbs.

C O M M E N T

These results are not unexpected given VRC01 was only given after the viral reservoir was already well established.

It would be interesting to know whether bNAbs are likely to produce different results if used much earlier.

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Using PrEP during pregnancy is safe for children

Polly Clayden, HIV i-Base

No differences in growth or neurodevelopmental outcomes were seen in young children with and without maternal PrEP exposure. These results were from an ongoing evaluation of prenatal PrEP in Western Kenya presented at AIDS 2022.

WHO recommends PrEP during pregnancy to those at risk – including women in high-prevalence settings. Several high burden countries are considering rolling out or have already launched PrEP. Kenya was one of the first countries to include this population in national guidelines in 2017.

Safety data to date are reassuring, with studies showing no adverse pregnancy outcomes following prenatal PrEP use. But numbers are small as some analyses are from PrEP efficacy trials that typically exclude pregnant women or discontinue PrEP use with pregnancy. Evaluations have less than one year of follow-up and have not assessed neurodevelopmental outcomes among PrEP-exposed infants.

PRIMA was a cluster randomised trial conducted in 20 mother and child health clinics in Kenya. Participants (n=4447) were followed for nine months post-partum.

The data presented were from the PRIMA extension study that is following a subset of four facilities until 60 months post-partum. Data were collected between October 2020 and June 2022 at six month intervals and represented 24 to 36 months follow up.

Trained study nurses conducted anthropometric measurements and evaluated neurodevelopment using the Ages and Stages Questionnaire (ASQ), an early developmental screener.

There were 664 mother-child pairs included in the analysis and 17% (119) had any PrEP exposure during pregnancy.

Median maternal age was 28 years and median child age was 26 months at enrollment into the extension cohort. There was no difference in marital status, maternal education, number of living children and preterm birth between participants with and without PrEP exposure. But those who took PrEP during pregnancy more frequently reported a partner with HIV: 13 vs 3%.

PrEP was started at a median of 27 weeks gestation and exposure during pregnancy was for a median of 2.4 months; 54% of 119 participants continued PrEP 9 months post-partum.

At 24-months follow up, there was no difference in median weight between children with any or no PrEP exposure during pregnancy: adjusted coefficient: -0.07 kg (95% CI -0.83 to 0.69), p=0.783. There was also no difference in length between the two groups: -0.61 (95% CI -1.85 to 0.63), p=0.217.

Differences in child growth indicators between the two groups remained non-significant at 30 and 36 months follow up.

Prenatal PrEP exposure was also not associated with any adverse growth outcomes (underweight or stunting) at 24–36 months. Nor was it associated with adverse developmental outcomes (overall ASQ scores) at 30 and 36 months.

C O M M E N T

These data support previous small studies showing safety of PrEP during pregnancy and add to the (scant) data available on antiretroviral exposure without HIV exposure on children's outcomes.

The PRIMA extension will continue to follow this subset through 60 months of age and the investigators are evaluating growth and bone mineral density (DEXA). They are also quantifying PrEP exposure with TDF levels measured in hair samples and dried blood spots and evaluating neurocognition with the Malawi Development Assessment tool.

This information will be very welcome.

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Long-acting CAB/RPV injections have a similar weight and lipid profile to dolutegravir-based oral ART

Kirk Taylor, HIV i-Base

A new pooled analysis from ATLAS-2M and FLAIR report that long-acting cabotegravir (CAB) and rlpivirine (RPV) injections have a similar weight gain and lipid profile to oral dolutegravir-based ART. [1]

Approximately 30% of participants on each regimen moved up a BMI category at week 96 compared to baseline. Lipid profiles were similar between groups.

Data were pooled from participants that received LA CAB+RPV (Q4W/Q8W; n=937) or ABC/DTG/3TC (QD; n=283). Median age was 37 years (range: 18 to 83) and baseline BMI was 24.7 (IQR: 21.8 to 28.6). At baseline 49% of those receiving LA and 40% on daily therapy were obese.

Other demographics included being female (23%), trans women (n=6), 17% were Black or African American and 5% were Asian. Median CD4 counts were 607 cells/mm^3 (IQR: 411 to 849) and 453 cells/mm^3 (IQR: 323 to 604) for the CAB/RPV and ABC/DTG/3TC groups, respectively. Co-medications included anti-hypertensives (n=22), anti-diabetes (n=23), statins (n=92) and SSRIs (n=47).

Between weeks 48 and 96 median BMI increased for those on Q8W (from +0.4 to +0.6 kg/m^2), Q4W (from 0.4 to 0.5 kg/m^2) and QD regimens (from 0.5 to 0.6 kg/m^2) that contained DTG. Across the same period, median weight increased by 0.5 kg (+1.3 to 1.8 kg), 0.6 kg (+1.0 to +1.6 kg) and 0.5 kg (+1.5 to 2.0 kg) for Q8W, Q4W and QD regimens, respectively. Weight gain of ≥10% was reported for 12% of participants on LA therapy and 13% of those on daily therapy.

Disaggregated data indicated that being Black, female or aged >50 was associated with weight gain. Lipid parameters were not significantly altered at week 96. Overall, there was little difference between the weight gain and lipid profiles for daily vs LA therapy.

C O M M E N T

The most important information about this presentation is that dolutegravir is included in the comparison arm which was associated with increased weight in the ADVANCE and other studies.

As in those studies, this is related to race and gender and is highest in Black women.

This means that people using long-acting injectable ART also need to be carefully monitored for weight gain.

Research into the management options to reduce or reverse this are urgently needed.

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Montreal's response to monkeypox: rapid vaccine rollout, 39 breakthrough infections

Simon Collins, HIV i-Base

The main session at AIDS 2022 on monkeypox also included a presentation by Geneiviève Bergeron on the rapid public health response to monkeypox (MPX) in Montreal including launching the first prophylaxis vaccine programme.

On 12 May 2022, five cases of unusual cancroid had been seen at one of the sexual health clinics in the city, and after the announcement of UK cases on 16 May, the connection to MPX was confirmed in Montreal. The city initiated an emergency response on 19 May that included involving community organisations.

This led to a rapid and sustained community response that included sharing medical and scientific information, promoting the vaccine and supporting self-isolation.

Early on this included recognising that contact tracing would not contain an outbreak as more than 80% of contacts were not traceable because their details were not available.

Canada was also lucky in having stockpiled vaccines as part of the national strategic reserve and this was part of a strategy to quickly limit further infections.

From 3 June 2022, Montreal offered free vaccination in open-access clinics to anyone at recent risk of MPX, including at sexual health and mobile clinics. This was expanded from 14 June to include pre-exposure prophylaxis for all gay men at risk. Single doses were given to as many people as possible but a second shot will be availble for people living with HIV. By 31 July, more than 15,000 people had received the vaccine.

This limited the number of cases to 317 (confirmed or probable) by 1 August, all men except 4 women (3 trans, 1 cis). Nearly all cases involved likely sexual contact and only one household transmission. Most were managed at home, although seven cases were hospitalised (none fatal) and five cases were in people who were homeless.

The first data were also presented on 39 cases of MPX in people who had recieved the vaccine, including 20/39 where this had occured more than two weeks after the shot. However, timing of exposure is unknown, as is the denominator of people that were at risk post-vaccine.

Reference

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Summary of 620 cases of monkeypox seen at three London clinics

Kirk Taylor, HIV i-Base

IAS 2022 included a special satellite session on monkeypox (MPX) covering epidemiology, clinical pathology, and ongoing challenges.

This included an oral presentation by Nicolo Girometti from the Chelsea and Westminster Foundation in London on 620 confirmed cases seen up until 17 July 2022 in three clinics, including 56 Dean Street in Soho. [1]

At the time, this huge caseload accounted for more than 40% of the total cases in London, 29% of the cases in the UK and 4% of global MPX cases.

Similar to other national and international cohorts, 99% were gay and bisexual men. Median age was 39 years (IQR: 33 to 43) and 70% were white, of which 38% were born in the UK. Nearly all reported a new sexual partner in the previous three months (94%), with a median of five partners over this time. Although none had travelled to endemic countries, 43% had travelled outside the UK within the past 60 days.

Nearly a third (31%) were living with HIV, all with a CD4 count >350 cells/mm^3 and 90% with viral load <50 copies/mL on ART.

Clinical results were summarised for the first 101 of these cases.

The mean incubation time was 8 days (95%CI: 6 to 11) with mild symptoms in the prodromal phase, including: fever (66%), asthenia (64%), myalgia (36%), headache (32%), sore throat (14%) and concomitant rash (64%). However, 17% remained asymptomatic.

Over the course of infection, 99% had at least one skin lesion, with 93% having at least one lesion in the anogenital region. Approximately one-third of cases had lesions on only one body site and one-third had lesions on at least three sites. The online presentation includes photographs showing the range of rash.

Complications included proctitis (17%), antibiotic treatment for co-infection (25%) in addition to pharyngeal/conjunctival lesions, and 35% tested positive for a further STI (22% gonorrhoea, 14% chlamydia and 6% with syphilis).

Treatment was primarily to relieve pain and included paracetamol, codeine, morphine and lidocaine depending on severity, with complex cases also using laxatives, hydration, catheters, mesalamine enemas for proctitis, antibiotics and surgically draining abscesses.

Antivirals including tecovirimat were only used in more severe cases. Vaccination as post-exposure prophylaxis was also effective in some people.

C O M M E N T

In the UK, London is the epicentre of the UK MPX outbreak, accounting for 70% (n=2,257) of all cases in England. [2]

This additional work has not been supported by additional funding to manage the MPX response, including running the vaccine programme.

Without additional support other essential sexual health services are being put at risk.

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https://programme.aids2022.org/Programme/Session/860 (symposium listing)
https://conference.aids2022.org/media-2315-monkeypox-outbreak-and-response-in-non-endemic-countries (webcast)

Advances in HIV cure-related research: IAS workshop now online

Simon Collins, HIV i-Base

As in recent years, the IAS organised a satellite workshop before the main conference on cure-related research.

These meetings bring together a wide range of expert researchers, doctors and community representatives to focus on the latest advances and to highlight new areas of interest.

This year, almost 200 delegates attended the workshop which took place on 28 July at the Centre hospitalier de l'Université de Montréal (CHUM), in Canada and a further 200 attended online.

The programme covered the most recent research developments and connected science with community presentations.

All materials from the meeting including webcasts and slides are linked here.

https://www.iasociety.org/events/pathways-hiv-cure-research-and-advocacy-priorities

Reference
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https://www.iasociety.org/events/pathways-hiv-cure-research-and-advocacy-priorities

ANTIRETROVIRALS

Lenacapavir approved in the EU and UK to treat multidrug resistant HIV

Simon Collins, HIV i-Base

On 22 August 2022, the EMA approved lenacapavir in Europe as a treatment for multi drug HIV resistance. [1]

This was also approved by the MHRA in the UK a few days later. [2]

Lenacapavir is the first capsid inhibitor to be approved as an HIV treatment. It is an extremely long-acting formulation and is given as a single subcutaneous injection, every six months.

However, it is essential to only use lenacapavir as part of a combination that includes other active HIV drugs.

If lenacapavir is used as virtual monotherapy, resistance can quickly develop. This shows the importance of good adherence to other drugs in the combinations.

Earlier reports in HTB have reported on the development of this exciting compound. Most recently this included 52-week results in both treatment-experienced and -naive studies, at CROI earlier this year. [3, 4]

Although the current approval is only for multidrug resistant cases, it is also being studied in other populations, including as first-line ART.

C O M M E N T

Lenacapavir is a remarkable new drug with an exciting PK profile that allows 6-monthly dosing.

Until other compounds with similar long-acting properties are available, it will still need to be used with other HIV drugs that require more frequent dosing. However, Gilead are also developing long-acting monoclonal antibodies and other compounds to use in combination with lenacapavir.

The current indication is for multidrug resistance, which has been prioritised due to the greater need in this group. Additional support for adherence to the oral drugs used to treat MDR HIV is vital.

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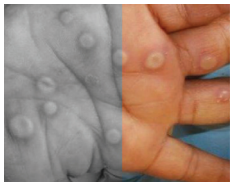
   https://i-base.info/htb/42128

COMPLICATIONS: MONKEYPOX

US survey reports 50% of gay men changed sexual behaviour to avoid monkeypox

Simon Collins, HIV i-Base



A national US internet survey conducted in early August, and reported in MMWR, showed that roughly half of 824 gay men were worried enough about monkeypox (MPX) to reduce their risks, at least in the short-term. [1]

The survey invited participants of the larger annual AMIS convenience sampled survey (n=10,000) to participate in a short MPX survey. [2]

Even though participants in the MPX survey were older (26% were >55) and less racially diverse (70% white) than the main survey, the results showed high interest in vaccination, and greater access in those at higher risk.

In the previous two weeks, approximately half of respondents reported:

- Reducing the number of partners,
- Reducing one-time partners (anonymous hook-ups).
- Reducing partners met on dating apps or at sex venues.
- Reducing participation in group sex.

Of the 22% who had received an MPX vaccine, this included 30% of those with two or more recent partners compared to only 13% in those with one or fewer partners. Similarly, vaccination was reported by 31% vs 12% in those who had vs had not participated in group sex. HIV status was not linked to likelihood of vaccination but PrEP use was (30% vs 7% in those on vs not on PrEP).

Approximately 28% of those who had not been vaccinated had tried to access the vaccine.

Only three participants (1.7%) had been diagnosed with MPX but 11% knew someone who had had MPX.

COMMENT

Although this small survey has limitation of a self-selected population and has limited diversity, it shows that that many men have already made changes to reduce their risk of MPX.

Behaviour change is an acceptable short-term strategy in the context of limited access to vaccines.

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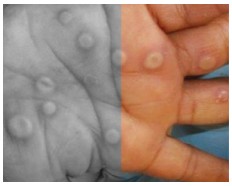
US model limits monkeypox infections by one-third from having fewer one-time partners: short-term strategy until next vaccine supply

Simon Collins, HIV i-Base



A modelling paper, published in the MMWR, supports the importance of reducing the number of one-time sexual partners as a strategy to manage the current monkeypox (MPX) crisis. [1]

In addition to significantly reducing the risk of new infections, perhaps by up to one-third, this would buy time until new vaccine supplies become available – expected in the next month.

The model projected that among a population of 10,000 gay men, ten highly active individuals could lead to 1,500 to 2,500 infections (15-25%), depending on different transmission scenarios.

In this setting, approximately 50% of all monkeypox (MPX) cases are linked to one-time sexual partnerships, even though they only account for 16% of daily sex acts and 3% of daily sex partnerships.

The model predicted that reducing one-time partnerships by 40% could reduce new cases by approximately 20-30%, and that these gains would be increased if combined with other changes in risk.

Importantly, this level of risk reduction has already been reported in at least one US survey. [2, 3]

C O M M E N T

Behavioural changes now to reduce the number of MPX cases is a short-term strategy to block the current outbreak and enable the vaccine programme to be more effective. [4]

MPX vaccine supplies are already exhausted in the UK, with the next shipment of 100,000 vials expected by late September. [5]

The move to intradermal vaccination, pending results from a UK pilot study, might also enable up to five doses from each vial that is currently approved to give a single subcutaneous shot. [6]

Although divided dosing is being used in the US, initial practical difficulties have also been reported. These include retraining nurses, needing different syringes, contraindication with hisotry of keloids, and community information. [7]

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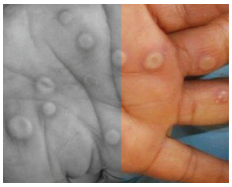
BHIVA include efficacy data on HIV and monkeypox vaccine: updated statement (August 2022)

Simon Collins, HIV i-Base



On 17 August 2022, BHIVA issued an updated statement on monkeypox (MPX) that includes information about vaccine efficacy, including in people living with HIV. [1]

The statement summarises information about the time to develop antibody responses and how these continue to increase over four weeks after a single shot.

One of the two HIV studies includes that responses might be slightly lower and take longer to develop in people who are HIV positive compared to HIV negative.

Importantly, it recommends that people living with HIV should receive two shots of the vaccine, even though it might take several months before the second dose.

When available, people who currently have a CD4 count <200 cells/mm^3 should be prioritised for the second dose.

Having had a smallpox vaccination as a child will increase MPX antibodies after a single shot of the vaccine now. However, there is no evidence that the residual antibodies will prevent MPX infection now. fo example, 10% of 528 cases in the recent NEJM paper had received the smallpox vaccine as a child. [2]

C O M M E N T

This update provides information that people can use when deciding their own levels of risk when returning to regular life.

This is especially important given the limited access to vaccines and that further supplies in the UK are not expected for 1–2 months.

Many people have already reduced their risk of exposure to MPX by changing how and when they have sex, given that this is only likely to be for a limited time, until vaccines become more widely available.

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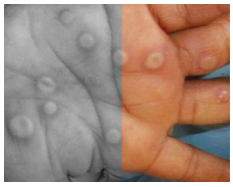
Monkeypox DNA detected in anal samples of asymptomatic men in Paris and Belgium



Simon Collins, HIV i-Base

Testing from sexual health screening in Paris from 5 June to 11 July 2022, reported high levels of monkeypox (MPX) in participants with symptoms but also identified MPX in anal samples of men who were asymptomatic.

The cohort included 706 men who were either HIV positive and on ART or HIV negative and on PrEP. Out of 383/706 men who had symptoms suggestive of MPX (40% had anal lesions), MPX infection was confirmed in 271/383 cases.

Anal swabs for gonorrhoea and chlamydia were analysed in men without MPX symptoms and only those that were negative were then tested retrospectively for MPX. Of these, 13/200 samples (6.5%) were PCR-positive for MPX, despite the men having no symptoms; 8/13 were HIV positive, all on ART with undetectable viral load.

All were advised to not have sex for the next three weeks and 2/13 later developed symptoms of MPX.

Although PCR-positive results do not show whether this represents infectious MPX, it indicates cases of asymptomatic infections that are not currently being recorded.

Positive monkeypox PCR results were also reported in 3/244 retrospectively-tested from anal swabs from a sexual health clinic in Belgium. Follow-up samples tested negative after 21 to 37 days. [2]

However, in 2/3 cases, the virus isolated from the swabs was replication competent, adding to evidence that onward transmission could be possible during asymptomatic MPX.

This early concern is also discussed in a new commentary article in JAMA. This review suggests asymptomatic transmission may be underestimated, not least because by the time someone has symptoms, they are unlikely to want to spend time in social situations where MPX is easily spread. [3]

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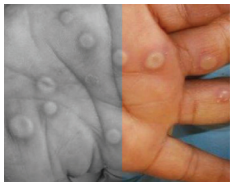
Unusual case reports: non-sexual acquisition, severe MPX and advanced HIV, human-to-dog transmission



Simon Collins, HIV i-Base

Although the overwhelming majority of cases in the current monkeypox (MPX) outbreak are linked to sexual networks of gay men, other unusual cases are worth noting.

Non-sexual acquisition

This case includes an American man in his 20s diagnosed with MPX after returning to the US and presenting on day 7 of a diffuse vesicular rash. [1]

The rash had started 14 days after attending several large crowded outdoor events in the UK, that lasted several hours and included close but clothed dancing. The man was taking PrEP and had a recent history of STIs but reported no sexual contact during the previous three months. He did not have typical symptoms, with no fevers, chills, headache, lymph node swelling, cough, fatigue, or anorectal pain.

His symptoms included “multiple nondraining skin lesions at different stages of appearance, including a centrally umbilicated vesicle on his left palm (testing PCR positive), a crusting flat lesion on his lip, and pustules on his right and left knuckles and on his lateral torso and back”. There were no penile, testicular, or anal lesions.

Although MPX DNA was also detected in self-sampled nasopharyngeal, saliva and rectal samples, the authors commented that contamination of the sample could not be ruled out. All lesions resolved by day 28.

Coinfection with severe MPX, advanced HIV and syphilis

A difficult case of severe monkeypox was reported in a 40-year old man who presented to his GP with a red spot on the tip of his nose that was misdiagnosed as sunburn. [2]

Within three days, this rapidly progressed to necrosis and typical MPX lesions appeared on the whole body, with serious infection of the penis and oral mucosa. The man had no history of STI testing and tested positive for long-standing syphilis (TPPA 1:2560, VDRL 1:8) and advanced HIV (CD4 count 126 cells/mm^3).

Treatment was with 600 mg tecovirimat, twice-daily for seven days.

The limited details reported on this case included that lesions resolved and swelling on the man’s nose was reduced. The necrosis has now completely resolved, without the need for surgery.

Human to dog transmission

MPX transmission from a human to a dog was reported in a recent letter to the Lancet. [3]

This case, the first of it’s kind, included a gay male couple in Paris. They lived together and both also had other sexual partners and both presented with PCR-confirmed MPX lesions. Symptoms including anal ulcers and wider body rash. Oropharynx samples tested positive.

Fourteen days after onset of initial symptoms, their four year old dog presented with skin lesions that were MPX PCR-positive and that phylogenetically matched one of the partners.

Although the couple had isolated their pet from contact with other animals since their first symptoms, the dog regularly slept in the same bed as the men.

As the dog's lesions, together with oral and anal swabs tested positive, the researchers believe this showed a new systemic canine infection, rather than viral transfer from either human lesions or airborne transmission. However, the animal has tested negative for MPX antibodies. All lesions have since resolved.

This is the first time that MPX transmission to a dog has been reported and this was an early concern when UK guidelines for self-isolation included separation from pets.

In countries where MPX is endemic the infection is generally thought to be maintained due to infections in rodents.

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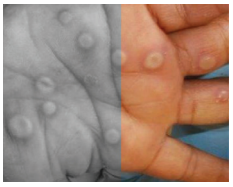
Tecovirimat for treating mild monkeypox: new studies open in the UK and US

Simon Collins, HIV i-Base

On 23 August 2022, the PLATIMUM study was launched in the UK to look at using tecovirimat (Tpoxx) to treat monkeypox (MPX). [1]



This study plans to randomise 500 people with mild MPX to either tecovirimat or matching placebo. Follow-up is for 28 days.

Participants need a referral from their doctor, but no further clinic visits are needed. This means that anyone who is self-isolating can still take part.

Although tecovirimat interacts with some HIV medications (darunavir, rilpivirine and maraviroc) these are either not clinicly important or can be easily managed.

Other drugs with potential interactions include: bupropion. repaglinide, voriconazole, midazolam, atorvastatin, tacrolimus, methadone, flurbiprofen, erectile drugs (sildenafil, tadalafil, vardenafil) and proton pump inhibitors (lansoprazole, omeprazole, rabeprazole).

Anyone with severe MPX, especially if hospitalised, should have named-patient access to tecovirimat without needing to join a placebo-controlled study.

Further participant information and the study protocol are available online.

In the US, the phase 3 STOMP study is randomising 530 adults and children with MPX (2:1) to either tecovirimat or placebo. It asks people to send photographs of their symptoms as part of the ongoing monitoring. [2, 3]

C O M M E N T

Several studies have already reported anecdotal evidence on potential benefits of tecovirimat to treat MPX, also supported in animal studies for smallpox. [4, 5, 6, 7, 8, 9]

This includes, as we went to press, a review of open-label use of tecovirimat in 549 participants in the US, reported in MMWR. Data is included for about 350 people. [9]

This makes results from a randomised study essential in order to be able to inform future access and use.

Results should similarly be compiled from open-label use.

The PLATINUM study is also linked to a similar study in Canada. [10]

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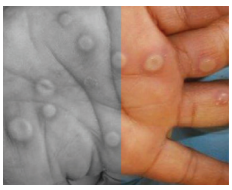
US cases: MMWR report on 1891 cases to 22 July 2022

Simon Collins, HIV i-Base



On 12 August 2022, the weekly MMWR reported on the monkeypox outbreak in the US which had been declared a national emergency eight days earlier.

Although 2,891 people had MPX up to 27 July, the MMWR report only summarises reports from the 1,195 (41%) cases with data on gender and age.

This included cases in 43 states, Puerto Rico, and the District of Columbia (DC). Among these, 99% of cases were in men; and in those with information, 94% reported male-to-male sexual or close intimate contact during the 3 weeks before symptom onset.

Among the 88% of cases with data, 41% were non-Hispanic White, 28% Hispanic or Latino, and 26% non-Hispanic Black or African American.

Further details though are more limited especially on other demographics, clinical presentation and outcomes where fewer than 400 cases have these details.

- 337/358 (94%) reported close contact with a man in the previous three weeks.
- 80/291 (27%) reported one partner, 40% reported 2 to 4 partners, 14% reported 5 to 9 partners, and 19% reported 10 or more partners.
- 136/334 (41%) had HIV infection.

By 31 August 2022, more than 18,000 people had been diagnosed in the US, approximately one-third of the global total.

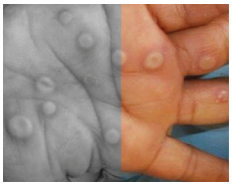
Reference

Philpott D et al. Epidemiologic and Clinical Characteristics of Monkeypox Cases — United States, May 17–July 22, 2022. MMWR Morb Mortal Wkly Rep 2022;71:1018-1022. DOI: 10.15585/mmwr.mm7132e3. (12 August 2022).

https://www.cdc.gov/mmwr/volumes/71/wr/mm7132e3.htm

Monkeypox transmission in heterosexual couples in Nigeria

Simon Collins, HIV i-Base



Although the current global monkeypox (MPX) outbreak is overwhelmingly linked to sexual networks of gay and bisexual men, the possibility of heterosexual transmission was suspected in at least some African countries where MPX is endemic.

Such transmission is now reported in a small series of cases seen at a single clinic in Nigeria, published ahead of peer review, by Dr Dimie Ogoina, who was the lead

researcher in the earlier reports. [1, 2]

The paper describes seven adult cases (aged 21 to 42) seen at the Niger Delta University Teaching Hospital (NDUTH), Okolobiri, between June and August 2022. No cases were seen earlier this year.

All cases had 3-6 recent partners and no recent non-sexual exposure risks. Detailed histories connected several cases as couples and contact tracing included at least one partner who had not sought formal medical care. Others initially used unspecified injections from 'patent medical stores' rather than seeking care from a sexual health clinic.

Genital lesions were reported in all cases, often with other sites reported. The number of lesions ranged from <10 (n=2) to 80–100 (n=2).

None of the household contacts of these cases reported MPX symptoms.

The authors concluded that sexual transmission could have accounted for MPX cases reported in earlier outbreaks and also that cases are likely to still be underreported.

The paper also highlighted the lack of access to testing, vaccines and treatment in African countries where MPX is endemic, despite cases having a higher risk of complications, including fatalities.

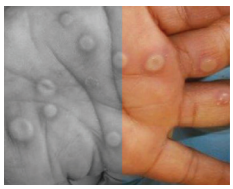
Reference

1. Ogoina D et al. Monkeypox among linked heterosexual casual partners in Bayelsa, Nigeria. Qeios. doi:10.32388/2Z4ZH4.2. (24 August 2022).

   https://www.qeios.com/read/2Z4ZH4.2
2. Ogoina D et al. Clinical Course and Outcome of Human Monkeypox in Nigeria. Clin Infect Dis 2020; 71: e210–e214. https://pubmed.ncbi.nlm.nih.gov/32052029

Access to vaccines and treatment for pregnant women at risk of monkeypox

Kirk Taylor, HIV i-Base



A commentary article in the September 2022 edition of Lancet Public Health, from Asma Khalil and colleagues from the Royal College of Obstetricians, reviews the limited data on management of monkeypox (MPX) during pregnancy. [1]

This includes data from 300 pregnant women who received MVA-BN and showed no increase in adverse events. Pre-clinical models did not report any birth defects following vaccination.

Unless there are other complications, the benefits and safety of the MVA-BN vaccine currently outweigh the risk of MPX transmission, where outcomes can include an increased risk of miscarriage and stillbirth.

The authors advise vaccinating contacts of confirmed cases, including health workers for up to 14 days post-exposure. Even if transmission occurs the vaccine might reduce the severity of symptoms. It could also limit the risk of transmission to the baby.

Given that MPX vaccination can reduce transmission and alleviate symptoms, consideration should be given to vaccinating pregnant women at risk.

With numbers likely to be low globally, the paper stresses the importance of learning from COVID-19 so that pregnant women are not again excluded from experimental vaccines and treatment.

It also recommends setting up an international registry to prospectively collect data on use during pregnancy and in other high-risk populations.

MVA-BN is a non-replicating vaccine and has been deemed safe for breastfeeding mothers.

C O M M E N T

The UKHSA recommends that pregnant women in the UK at risk of MPX should talk to their doctor about the benefits of vaccination. [2]

An international registry is important as many women at risk live in countries where MPX is already endemic and where access to both vaccines and treatment is extremely limited.

References
1. Khalil A et al. Monkeypox vaccines in pregnancy: lessons must be learned from COVID-19. The Lancet Global Health. DOI: 10.1016/S2214-109x(22)00284-4. (27 June 2022).
https://www.sciencedirect.com/science/article/pii/S2214109X22002844?via%3Dihub
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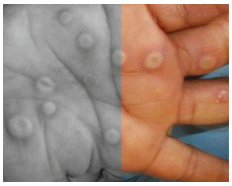
https://www.gov.uk/government/publications/monkeypox-vaccination-resources/protecting-you-from-monkeypox-information-on-the-smallpox-vaccination#if-you-are-pregnant

MPX DNA easily detected on surfaces in hospital after cleaning

Kirk Taylor, HIV i-Base

A case study from Toronto published in CID assessed the spread and persistence of MPX on surfaces in an airborne isolation room.



All surfaces, including bedlinen, hardwood furniture, door handles, toilet and a windowsill tested positive for MPX DNA before cleaning with disinfectant. The room was occupied by someone with >25-99 lesions and these were positive for MPX on days 1, 2, 3 and 7.

After standard daily hospital cleaning using cloths soaked with 0.175% accelerated hydrogen peroxide, two thirds of surfaces still remained positive for MPX DNA. Only the couch and windowsill did not test positive on follow up swabs.

The CT for DNA analysis – an inverse marker for viral load – was <38 with results up to 40 considered intermediate. Median CT values were 40.5 (range: 36.9 to 42.2), 36.7 (range: 33.8 to 40.8) and 36.2 (range: 32.9 to 37.6) for orthopoxvirus, pan-MPX and the MPX clade 2 (Western African clade), respectively.

CT values for surfaces that remained positive were not significantly lower after cleaning.

The authors caution that their study was limited to a single room and the MPX testing did not evaluate the viability of detected MPX virus.

C O M M E N T

Although these results show the persistence of MPX on many surfaces, the CT values were high (indicating low viral load) and the study had no minimum threshold - a single viral counted as a positive result. Future studies should really report on viability of virus before being submitted fro publiction.

So far, however, very few cases in the current MPX outbreak of more than 50,000 cases globally have been attributed to household or close contact linked to fomites.

Until results are verified, current guidelines for cleaning have been issued in the UK, and the US CDC has produced a particularly useful and easy to use resource. [2, 3]

References
1. Muller MP et al., Environmental testing of surfaces in room of a patient with monkey pox. Clinical Infectious Diseases, ciac654. (19 August 2022).
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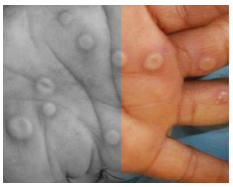
https://www.cdc.gov/poxvirus/monkeypox/pdf/Monkeypox-Interim-Guidance-for-Household-Disinfection-508.pdf (PDF)

Understanding HIV and monkeypox coinfection: NEAT/EACS dashboard

Simon Collins, HIV i-Base

The NEAT ID Foundation, in partnership with the European AIDS Clinical Society (EACS), has developed a real-time Dashboard to monitor monkeypox coinfection in people living with HIV.



This data will help understand impact of HIV on morbidity and mortality associated with monkeypox.

For example, it is likely that persons with advanced and uncontrolled HIV may be at a higher risk of severe disease and prolonged viral shedding. This will include some people who are only diagnosed with HIV because of MPX.

This Dashboard will publish cases by country and region, hospitalisations and outcomes, including death.

www.NEAT-ID.org.

Individual clinic data will only be seen by the submitting site and will be password and security protected.

This project is asking for data to be recorded for the months of April, May and June 2022 and then to input retrospectively on a weekly basis.

For further information please email: dashboard@neat-id.org

Please include your name, email, site name, city, and country. The group will respond with your site login details within 24 hours.

C O M M E N T

This important project depends on active support from HIV clinics with MPX cases.

Given that time is limited in all setting the Dashboard has been designed to easily add minimal data.

HIV PREVENTION

HIV seroconversions on PrEP in Australian study are linked to low adherence

Kirk Taylor, HIV i-Base

A large Australian PrEP implementation study involving 9,596 participants over two years only reported 30 people becoming HIV positive (0.31%) and these cases were linked to low adherence. Only one seroconversion was attributed to ART resistance (FTC: M184V mutation).

Seroconversions were all men that identified as gay/bisexual (97%) and reported condomless sex in the previous three months (90%). Median age was 31 years (IQR: 25 to 38). Median time from starting PrEP to diagnosis was 409 days (IQR: 347 to 656) and median viral load was 61,000 copies/mL. Two-thirds of participants were diagnosed with an additional STI, similar to rates for the overall group.

Adherence was tracked through dispensing logs, with perfect adherence defined as taking five or more doses/week with <4 doses/week considered insufficient.

Reasons for low adherence included recent change in sexual activity/entering monogamous relationships (n=5), renal impairment (n=1), affordability of PrEP (n=1) and not packing PrEP for vacation (n=1).

C O M M E N T

These results show that oral PrEP continues to be highly effective when taken as prescribed but that the difficulties of adherence still leads to HIV seroconversions.

It is notable that this large cohort only identified low adherence as a factor involved in the new cases.

Recent experience at the London clinic at 56 Dean Street, where more than 25,000 people have been prescribed oral PrEP, included 7 out of 52 seroconversions (13%) which occurred despite good adherence. Only one of these was linked to drug resistance. [2]

References

1. Dharan NJ et al. Characteristics of HIV seroconversions in a large prospective implementation cohort study of oral HIV pre-exposure prophylaxis in men who have sex with men (EPIC-NSW). Clinical Infectious Diseases, ciac660. (19 August 2022). https://doi.org/10.1093/cid/ciac660
2. 56 Dean Street reports M184V common with recent low adherence to PrEP and seven transmissions with good adherence. HTB (20 December 2021). https://i-base.info/htb/41912

Future meetings and webinars 2022/23

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)

Webcasts from meetings (YouTube listing)

2022

BHIVA webinar - ANCHOR Study: results and their implications

28 September 2022, 16:30 – 18:00, virtual

https://www.bhiva.org/HIVEventDiary

13th International Workshop on HIV & Aging

13 – 14 October 2022, USA (tbc)

https://academicmedicaleducation.com

HIV Glasgow 2022

23 – 26 October 2022, Glasgow and hybrid

https://www.hivglasgow.org

BHIVA Autumn Conference 2022

Friday 25 November 2022, London

https://www.bhiva.org/HIVEventDiary

2023

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

19–22 February, 2023, Seattle

https://www.croiconference.org

12th IAS Conference on HIV Science (IAS 2023)

23–26 July 2023, Brisbane, Australia and virtually

https://www.iasociety.org

19th European AIDS Conference (EACS 2023)

18-21 October 2023, Warsaw, Poland

https://www.eacsociety.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:

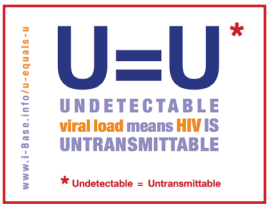
http://www.i-base.info/qa

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 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:

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Editor: Simon Collins

Contributing Editor: Polly Clayden

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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 HIV, pregnancy and women's health: *36-page A5 booklet* **quantity** _____

  Guide to changing treatment*: 16-p A5 booklet* **quantity** _____

  HIV and quality of life: side effects and long-term health*: 96-page A5* **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** _____

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