Questions and Answers: COCA Call: Mpox Update: Clinical Management and Outbreaks

June 27, 2024

General questions

Q: Have there been possible reservoir hosts identified in the US such as wild rodents?
A: There haven't been any infections of monkeypox virus (MPXV) identified in animals from the United States. An upcoming CDC publication shows a study in which there were no MPXV infections among companion animals that lived with people with mpox in the U.S. Additionally, there are laboratory studies (some not yet published from CDC) that have found clade IIb is less pathogenic in rodents compared to clade IIa: Virulence differences of mpox (monkeypox) virus clades I, IIa, and IIb in a small animal model - PubMed (nih.gov)

Q: What BSL level should be used for mpox research for clade I and II?
A: Both are RG3 pathogens. According to the Biosafety in Microbiological and Biomedical Laboratories—6th Edition, ABSL-3 practices, containment equipment, and facilities are recommended for monkeypox work in experimentally or naturally infected animals. BSL-2 facilities with BSL-3 practices are advised if vaccinated personnel perform laboratory work with monkeypox virus. The same BSL should be used for both clades, but clade I is regulated a select agent.

Q: Is vaccine being used in DRC?
A: Although clade I is not a new viral strain and was first identified in DRC in the 1970s, vaccine has not been utilized in the country since eradication of smallpox, outside of two studies (one for TPOXX performed by NIH and one for JYNNEOS in healthcare workers in one province by CDC (Serological responses to the MVA-based JYNNEOS monkeypox vaccine in a cohort of participants from the Democratic Republic of Congo - PubMed (nih.gov)). However, the government of DRC recently approved the use of mpox vaccines for the country, and the process has begun for the US and other countries to supply them. CDC continues to work with other U.S. Government (USG) and non-USG partners including in-country health organizations to support the country in making vaccine available.

Q: Have there been mpox cases diagnosed in incarcerated populations, either federal, state, or local? If so, please give details.
A: An MMWR about an mpox investigation in a jail was published in 2022: Monkeypox Case Investigation — Cook County Jail, Chicago, Illinois, July–August 2022 | MMWR (cdc.gov)

Q: How feasible would it be to include HIV and other STI testing and PrEP guidance with mpox test kits, because we found that patients reported getting tested for mpox without other STI testing, and very few who were eligible were offered PrEP (across several types of testing sites)
A: Mpox vaccination, testing, and treatment activities should become a routine component of sexual health and HIV clinical care with public health monitoring. There is an expectation that comprehensive sexual health services include integrated screening of mpox, HIV and STIs. This would include treatment for any STIs identified, and if found to test positive for HIV. the patient should be referred for HIV care and treatment. People with HIV are at risk for more severe complications from mpox. Additionally, HIV prevention services should be offered for those who test negative for HIV, including HIV preexposure prophylaxis (PrEP) and HIV postexposure prophylaxis (PEP) as indicated. Doxycycline PEP for bacterial sexually transmitted infection prevention (aka DoxyPEP) should be offered if indicated. You can get more detailed information at the following links:

- Clinical Quick Reference | Mpox | Poxvirus | CDC
- The CDC Domestic Mpox Response — United States, 2022–2023: the association of mpox cases with HIV infection highlights the need for a syndemic approach to care for HIV, sexually transmitted infections, and mpox in the context of comprehensive sexual health care.
- HIV and Sexually Transmitted Infections Among Persons with Monkeypox — Eight U.S. Jurisdictions, May 17–July 22, 2022 | MMWR (cdc.gov): screening for HIV and other STIs and other preventive care should be considered for persons evaluated for mpox, with HIV care and HIV preexposure prophylaxis offered to eligible persons.
- CDC Clinical Guidelines on the Use of Doxycycline Postexposure Prophylaxis for Bacterial Sexually Transmitted Infection Prevention, United States, 2024 | MMWR

Q: I work in infection control in congregate living settings, and I have been wondering if there is a significant risk of airborne mpox transmission between non-intimate partners, i.e., two people who share beds a few feet apart in a dorm.
A: It's important to note that the resident with mpox should be isolated from the others. There is additional information regarding mpox in congregate living settings here: Congregate Living Settings | Mpox | Poxvirus | CDC
With that said, for the scenario described, the level of transmission risk would depend most upon the degree of separation and whether or not other objects are shared/touched in the room. The risk of mpox spread via aerosolization continues to be an area of inquiry, and while there are certain rare scenarios where such transmission may be possible (e.g., shaking of soiled linens), they are typically not considered to carry a high level of risk. Practically speaking, we have not seen spread of mpox via this mode of transmission in congregate living facilities. Please see Monitoring and Risk Assessment for Persons Exposed in the Community for more information.

Q: For the N95 recommendation, are there known respiratory transmission? Are there other mechanisms of transmission than contact with lesion/fluids/secretions?
A: The risk of mpox spread via aerosolization continues to be an area of inquiry, and while there are certain rare scenarios where such transmission may be possible (e.g., shaking of soiled linens), they are typically not considered to carry a high level of risk. Please see Monitoring and Risk Assessment for Persons Exposed in the Community for more information. Both types of the virus can spread through close contact (including intimate or sexual contact) with a person with mpox; direct contact with contaminated materials; direct contact with infected animals.

Q: Will people travelling to the US from DRC and surrounding countries be required to be vaccinated or be screened prior to US entry?
A: Mpox vaccination and public health entry screening are neither required nor recommended for travelers entering the United States from DRC or any other countries. Vaccination against mpox is recommended for U.S. residents traveling to the DRC if they have certain risk factors. The screening of travelers will not be effective in preventing the introduction and spread of mpox given the longer incubation period and because, in most cases, the rash may not be visible (other than through medical examination which is not feasible in an airport setting). Public health mechanisms are in place to detect, assess, and manage overtly ill travelers arriving in the United States, including those with fever and rash.

Q: Can your speakers address ventilation considerations in terms of IPC practices in clinical settings? RE: use of HEPA filters not recommended during patient exam and after discharge from isolation room. Is active air circulation (e.g., HEPA filtration) post wet mopping/disinfection of fomites in these rooms discouraged or recommended?
A: In general, we usually defer to infectious disease physicians to make the determination on whether there is a risk of infectious aerosols based on the patient care/treatment occurring in the space. If there is a risk of infectious aerosols, then the use of HEPA air cleaning seems warranted and will generally provide benefit over normal ventilation alone. Even if we set that determination aside, the use of auxiliary air cleaning devices is always permissible if it does not introduce additional hazards on its own. Some examples of that might be that the device interferes with the desired pressure relationship between two adjacent spaces (e.g., negative pressure being maintained inside an airborne infection isolation room) or that it results in undesirable airflow patterns where it pushes (or pulls) potentially contaminated air over room occupants that otherwise wouldn't be exposed (or would be exposed to a lesser extent). In typical exam and patient rooms, smart placement of the air cleaning device usually alleviates the issues. For instance, place the device so it pulls infectious aerosols away from the patient and then discharges clean air up into the space and over the healthcare providers. When properly sized and strategically placed, the use of portable air cleaners can greatly enhance air cleaning and reduce aerosol exposure potential within clinical settings.
For more information on portable air cleaners, please see the information on the Ventilation in Buildings | CDC webpage, including the examples in FAQs #3 and #5.

Q: Are there any updates on the outbreak of mpox in Republic of the Congo (not DRC)? Are there any clade I cases in this outbreak?(https://www.reuters.com/world/africa/congo-republic-declares-mpox-epidemic-2024-04-24/)
A: Clade I mpox is endemic in Republic of Congo (RoC), and this outbreak is associated with clade I mpox. WHO has recent information on mpox around the world, including ROC:
https://cdn.who.int/media/docs/default-source/health-emergency-information-risk-assessment/20240628_mpox_external-sitrep_34.pdf?sfvrsn=7a4abfce_1&download=true

Mpox vaccine

Q: I am seeing other jurisdictions providing mpox booster shots for those who completed the original series 2 years prior. What guidance can you provide regarding boosters?
A: At this time, CDC does not recommend booster doses for any of the patients impacted by the 2022 outbreak. Breakthrough infections (i.e., infections after 2 JYNNEOS doses) are rare as described in this manuscript: https://pubmed.ncbi.nlm.nih.gov/38781111/.
Although studies have indicated that vaccine titers decrease a few months after vaccination, the clinical significance of this finding is uncertain, particularly given the real-world findings that breakthrough infections are rare. The level of circulating titers is not the only marker of protection conferred by mpox vaccinations; innate and cell-mediated immunity are likely important.

Q: Should mpox field staff in DRC receive only 2 doses of JYNNEOS?
A: JYNNEOS was licensed as a 2-dose series. DRC public health authorities will determine what vaccination schedule should be used for people who work there. For people in the United States, the 2022 ACIP recommendations are to use JYNNEOS (as an alternate to ACAM2000) for certain healthcare

worker response teams designated by appropriate public health authorities. This would include clinicians caring for mpox patients in DRC with various humanitarian groups. For these individuals, the ACIP recommendation is 2 vaccine doses. For any specific questions about a particular patient, please reach out to poxvirus@cdc.gov for information.

Q: For those traveling to the rural DRC South Kivu province for extended family or work reasons would vaccination be recommended?
A: Not specifically. Person-to-person transmission has occurred during this outbreak, including through sexual contact, household contact, and within the healthcare setting.
Vaccination against mpox is recommended for people with certain risk factors (https://www.cdc.gov/poxvirus/mpox/vaccines/index.html. Travelers should:
- Avoid close contact with sick people, including those with skin lesions or genital lesions.
- Avoid contact with contaminated materials used by sick people (such as clothing, bedding, or materials used in healthcare settings) or that came into contact with infected animals.
- Avoid contact with dead or live wild animals, such as small mammals including rodents (rats, squirrels) and non-human primates (monkeys, apes).
- Avoid eating or preparing meat from wild game (bushmeat) or using products derived from wild animals from endemic countries throughout Central and West Africa (creams, lotions, powders).
- Seek medical care immediately if you develop new, unexplained skin rash (lesions on any part of the body), with or without fever and chills, and avoid contact with others.
- Tell your doctor if you traveled to the DRC within the last 21 days before developing symptoms.
- If you are sick and could have mpox, follow isolation and infection control measures at home and during travel. See additional information about what to do if you are sick with mpox. More information is available here: https://wwwnc.cdc.gov/travel/notices/level2/monkeypox-democratic-republic-of-congo

Q: If a high-risk patient was exposed to a diagnosed patient 5 days ago and now is developing some malaise, low grade fever, but no rash lesions, is it worth giving the first dose of the vaccine?
A: If a patient has symptoms of mpox (including prodromal symptoms), vaccine will not prevent or ameliorate mpox. It takes time for a vaccine to be helpful; the body's own immune system will respond faster.

Q: Any guidance re: off label use for a 17-year-old at high risk? AND **How is JYNNEOS vaccine provided to teens < 18 years old who are at risk?**
A: The Emergency Use Authorization is still in effect and allows for children to be administered JYNNEOS vaccine. CDC recommends vaccination of adolescents at risk for mpox before an exposure as outlined here: https://www.cdc.gov/poxvirus/mpox/clinicians/pediatric.html

Q: For those under 18 who need JYNNEOS vaccination and could get it under EUA, would the vaccine come from CDC/National Stockpile or still need to be obtained commercially?
A: After August 1, there will be no additional JYNNEOS supply distributed from the Strategic National Stockpile. JYNNEOS is now readily available commercially, including through the Federal Supply Schedule (FSS), 340B Prime Vendor Programs, and other mechanisms. As an FDA-approved vaccine and with an active EUA, clinicians can prescribe JYNNEOS for any at-risk individual as clinically appropriate. It is advised individuals, especially those not specifically included on the approved label, confirm insurance coverage with their specific plan before receiving the vaccine.

Q: Does the mpox vaccine have a Grade A recommendation under USPSTF?
A: We are not aware of any current USPSTF rating for the mpox vaccine. You may want to reach out to USPSTF to understand whether a rating is under consideration.

Q: Will the EUA extend to commercialized doses past August 1?
A: Like all FDA approved vaccines, clinicians can prescribe use of JYNNEOS as appropriate for at risk individuals. The EUA also remains active and can serve as an additional source for providers to assess the appropriate use for individuals less than 18 years of age.
(https://www.fda.gov/media/160774/download)

Q: To clarify, JYNNEOS will come from 317 funds, not from VFA ordering? is that correct? Will local health departments order from state DHHS?
A: Currently, there is no Vaccines for Adults (VFA) program. Local health departments should reach out to their state or territorial health officials with any questions about available supply through 317 funding and/or through the Vaccines for Children (VFC) program. As a reminder, the VFC program supply is only available for children 18 years of age that fall within the ACIP recommended population for JYNNEOS.

Q: There were outbreaks of mpox have happened in homeless shelters; will mpox vaccines still be provided for people who are homeless and/or incarcerated?
A: As with other routine vaccinations, JYNNEOS will be available to those individuals through existing programs for commercially available routine vaccinations.

Q: Can HRSA EHE Funds (20-078) be used for vaccines?
A: Please refer to the HRSA Mpox FAQs webpage for information on the use of Ryan White HIV/AIDS Program (RWHAP) funds to support mpox vaccination, including the purchase of vaccine All RWHAP recipients should follow the HHS Guidelines for Immunizations for Preventable Diseases in Adults and Adolescents with HIV.

Q: When would the mpox vaccine be available to the general population?
A: The risk for mpox among the general population in the United States is very, very low. Unless that risk changes, it will not be recommended for the general population. People for whom JYNNEOS vaccine is recommended are listed here: https://www.cdc.gov/poxvirus/mpox/interim-considerations/overview.html

STOMP trial/TPOXX

Q: What is the typical timeframe from remote enrollment to receipt of assigned study drug for STOMP?
A: STOMP remote enrollment is available Monday through Friday only. In general, remote enrollments that complete by 1 pm ET will have the study drug be shipped out on the same day as the enrollment. Depending on the delivery location, the delivery time is generally about 24 hours after enrollment completion. For question or additional information on NIH's STOMP clinical trial, contact the STOMP call center at (855) 876-9997 or see STOMP (stomptpoxx.org)

Q: When a local health jurisdiction tried to send patients to the closest STOMP site, the stomp replied that while mpox treatment was available and would include some help with transportation to and

from the site, concurrent STI treatment if needed and PrEP were not available at the STOMP site. Has that changed since 2023?
A: STI treatment is not part of the STOMP trial. Many, but not all, STOMP study sites have ready access to STI preventive and treatment services that may be offered to STOMP participants. Otherwise, the STOMP study sites would refer enrolled participants to appropriate facilities that can provide ongoing comprehensive sexual health services.

Q: For patients with lesions in potentially sensitive areas (foreskin, anorectal) would not be eligible for TPOXX under the updated EA-IND now?
A: The lesions in the sensitive anatomic area or pain alone in non-pregnant or non-lactating adults who do not have severe immunocompromise or active skin conditions wouldn't meet the EA-IND eligibility criteria for tecovirimat treatment. Patients with severe immunocompromise (e.g., HIV with DC4 <200) or active skin conditions (e.g., atopic dermatitis), or protracted or life-threatening manifestations of mpox (e.g., lesions affecting ≥ 25% of body surface that may be confluent, necrotic, and/or hemorrhagic in appearance) and pregnant and/or breastfeeding persons and children (< 18 years) irrespective of illness severity or underlying conditions are eligible for tecovirimat under the EA-IND protocol. Please refer to the current version of tecovirimat EA-IND protocol (v6.4 dated June 5. 2024) for full listing of immunocompromising conditions and active skin conditions, and additional details.

Q: Any estimate on time until TPOXX will be available commercially?
A: CDC is currently not aware of any specific plans by the manufacturer to pursue commercial marketing of tecovirimat.

Q: What is early read on tecovirimat success in trials then?
A: There are ongoing clinical trials evaluating tecovirimat and their study status vary. Refer to Search for: tecovirimat | Card Results | ClinicalTrials.gov. CDC will update information accordingly when clinical trial data on efficacy of tecovirimat become available.

Q: If a patient has severe pain from mpox requiring narcotic medication, are they eligible for tecovirimat treatment via EA-IND protocol?
A: Pain alone in non-pregnant or non-lactating adults who do not have severe immunocompromise or active skin conditions wouldn't meet the EA-IND eligibility criteria for tecovirimat treatment. Please refer to Clinical Considerations for Pain Management of Mpox | Mpox | Poxvirus | CDC. Patients with severe immunocompromise (e.g., HIV with DC4 <200) or active skin conditions (e.g., atopic dermatitis), or protracted or life-threatening manifestations of mpox (e.g., lesions affecting ≥ 25% of body surface that may be confluent, necrotic, and/or hemorrhagic in appearance) and pregnant and/or breastfeeding persons and children (< 18 years) irrespective of illness severity or underlying conditions are eligible for tecovirimat under the EA-IND protocol. Please refer to the current version of tecovirimat EA-IND protocol (v6.4 dated June 5. 2024) for full listing of immunocompromising conditions and active skin conditions, and additional details.

Q: How is it determined that a STOMP study subject received placebo vs real tecovirimat, in case there is no improvement after a specific time under treatment? Will that person once singled out, receive the actual treatment with the non-placebo medication?
A: Non-pregnant or non-lactating adults (≥ 18 years) within illness onset < 14 days with at least 1 active lesion (i.e., no scabbed) or proctitis and no prior or concomitant tecovirimat receipt AND who do not have severe immunocompromise or active skin conditions or severe mpox will be randomized 2:1 to tecovirimat (arm A) and placebo (arm B) arms, which are blinded. If participants in either arm A or B

develop severe disease or have persistent, severe pain, they are evaluated to confirm severe mpox or pain, stop blinded study treatment, and will switch to the open label 14-day tecovirimat treatment (arm C). They are not unblinded and so it's possible that some could receive greater than 14-day course of tecovirimat (e.g., a participant randomized to arm A who subsequently are switched to arm C).

Q: Are public health officials in relevant states being notified of TPOXX resistance results in residents of their state?
A: Although this testing is done under surveillance and therefore cannot inform patient care, CDC does share the results back with relevant jurisdictions to inform outbreak response.

Q: I may have missed this, but do we know anything about the prevalence of TPOXX resistance?
A: CDC published a report (https://wwwnc.cdc.gov/eid/article/29/12/23-1146_article) detailing that resistance occurred in less than 1% of patients treated and for which data was available. Because this data set does not include every patient for which TPOXX weas administered, this is likely an underrepresentation. It is important that clinicians are aware that resistance can occur, and that treated patients know that it is possible to spread TPOXX resistant virus to others. To prevent development and spread of resistant MPXV, tecovirimat use outside of clinical trials should be consistent with the CDC Investigational New Drug protocol for tecovirimat use.

Q: If resistance is in over 50 patients, what is the total number of patients dosed?
A: At least 8,001 patients have been prescribed tecovirimat based on returned IND forms as of 7/1/2024.