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From:Emma Doran, MD, MPH, Medical EpidemiologistTo:North Carolina CliniciansSubject:Human-to-human transmission of Clade I Monkeypox virus in AfricaDate:August 15, 2024

The North Carolina Division of Public Health and the Centers for Disease Control and Prevention are alerting clinicians to <u>ongoing Clade I Monkeypox virus (MPXV) outbreaks</u> involving human-to-human transmission in the Democratic Republic of the Congo (DRC) with spread to neighboring countries. The World Health Organization (WHO) declared these outbreaks a <u>public health emergency of international concern (PHEIC)</u>.

Background

MPXV has two distinct genetic clades, I and II, endemic to central and west Africa respectively. A subclade of Clade II (Clade IIb) has been associated with <u>the 2022-23 mpox outbreak</u> that has predominantly affected gay, bisexual, or other men who have sex with men (MSM) in the United States and globally. Clade I has previously been observed to be more transmissible and cause more severe illness than Clade II.

Since January 1, 2023, DRC has reported more than 22,000 suspected cases and more than 1,200 suspected deaths, the largest number of yearly suspected clade I mpox cases on record. Human-to-human transmission via sexual contact <u>has also been reported</u>. The current outbreak is more widespread than any previous DRC outbreak and has resulted in clade I mpox transmission to some neighboring countries including Central African Republic, Republic of the Congo, Burundi, Rwanda, Kenya, and Uganda. Clade I MPXV is not known to be endemic in Burundi, Rwanda, Kenya or Uganda. A <u>Clade I MPXV case has also been reported in Sweden</u> in an individual with recent travel to a region in Africa with an ongoing outbreak.

Although it's important to note that mpox can affect anyone, the main route of transmission in the current global outbreak associated with Clade IIb has been through sexual contact. Consistent with national reports, North Carolina has seen coinfection with mpox, HIV, and other sexually transmitted infections. Additional information about mpox cases in North Carolina can be found <u>here</u>.

Testing and Reporting

For individuals with suspected MPXV infection and travel to DRC or neighboring countries in the 21 days preceding symptom onset or close contact with someone with such recent travel, clinicians should contact the Communicable Disease Branch epidemiologist on call at 919-733-3419 for consultation on clade-specific MPXV testing. Neighboring countries include Republic of the Congo, Angola, Zambia, Rwanda, Burundi, Uganda, South Sudan, Kenya, and Central African Republic. Affected countries may continue to expand, please check the <u>CDC mpox outbreak site</u> for the most up to date list of countries.

Testing for individuals without travel and suspected MPXV infection is widely available and can be performed through commercial laboratories or through the <u>NC State Laboratory of Public Health</u>. Personal protective equipment should be worn when <u>collecting specimens</u> from a person with suspected mpox. Unroofing or aspiration of lesions, or otherwise using sharp instruments for mpox testing, is not recommended due to the risk for sharps injury. Confirmed cases of mpox should be reported to your <u>local health department</u>.

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF PUBLIC HEALTH

LOCATION: 225 N. McDowell St., Raleigh, NC 27603 MAILING ADDRESS: 1902 Mail Service Center, Raleigh, NC 27699-1902 www.ncdhhs.gov • TEL: 919-733-7301 • FAX: 919-715-1020

Prevention and Control

No Clade I MPXV infections have been reported in the United States. However, the North Carolina Division of Public Health is urging clinicians to increase efforts to vaccinate those who might be at higher risk to mitigate against the potential for imported cases leading to local transmission.

JYNNEOS became available on the commercial market on April 1, 2024, at a cost between \$229.50 and \$270 per dose, but some supplies of free vaccine still remain in the state until they expire on October 31, 2024. Making a strong recommendation to encourage vaccination in populations at highest risk while supplies of free vaccine are available should be a high priority for providers.

- JYNNEOS vaccines are available through the Vaccines for Children (VFC) program for eligible 18-year-olds as of August 1, 2024.
- For assistance procuring non-commercial JYNNEOS vaccine, please complete the allocation request here.
- Providers can procure commercial vaccine by working with an authorized distributor to order JYNNEOS Vaccines <u>here</u>.
- Funding from HRSA's Ryan White HIV/AIDS Part C and D Programs may be used to purchase vaccines.
- Medicare and Medicaid should provide full coverage for all beneficiaries within the recommended populations. (Ryan White Part A funds could possibly be used; contact Part A Administrator at Mecklenburg County Health Department.)

Vaccination can protect against mpox infection from both Clades I and II and can reduce severity of illness if infection does occur. The 2-dose JYNNEOS vaccine series is recommended for persons aged 18 years and older at risk for mpox, including the following:

- Anyone who has or may have multiple or anonymous sex partners; or
- Anyone whose sex partner is eligible per the criteria above; or
- People who know or suspect they have been exposed to mpox in the last 14 days; or
- Anyone else who considers themselves to be at risk for mpox through sex or other intimate contact.

Vaccination is NOT recommended for travelers who do not meet at least one of these criteria. The <u>mpox</u> <u>vaccine locator</u> can be used to find local vaccine providers.

Treatment

Treatments that have been used during the ongoing Clade IIb outbreak, including tecovirimat, brincidofovir, and vaccinia immune globulin intravenous, are expected to be effective for Clade I MPXV infections.

Patients with mpox benefit from supportive care and pain control that is implemented early in the illness (<u>Clinical Considerations for Pain Management of Mpox</u>). For information about skin and wound care for individuals with mpox lesions, please visit <u>Mpox: Caring for the Skin</u> and <u>Mpox: Treating Severe Lesions</u>. For most patients with intact immune systems, only supportive care and pain control is needed. However, supportive care and pain control may not be enough for some patients, for example, those with weakened immune systems. In these cases, <u>treatment should be considered</u>.

Tecovirimat is available by enrolling patients in the STOMP <u>clinical trial</u> or through an investigational new drug (IND) protocol. Additional information on ordering and prescribing therapeutics is available under resources on the <u>North Carolina mpox website</u>.

Please contact the Communicable Disease Branch Epidemiologist on Call at 919-733-3419 for any questions regarding testing and reporting.

Additional Information <u>Mpox Communications Toolkit</u> <u>Mpox Frequently Asked Questions</u> Mpox: What You Need to Know

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Mpox Caused by Human-to-Human Transmission of *Monkeypox Virus* in the Democratic Republic of the Congo with Spread to Neighboring Countries

Summary

The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Update to provide additional information about the outbreak of monkeypox virus (MPXV) in the Democratic Republic of the Congo (DRC); the first <u>Health Advisory</u> about this outbreak was released in December 2023.

Since January 2023, the DRC has reported the largest number of yearly suspected clade I mpox cases on record. While <u>clade I MPXV</u> is endemic, or naturally occurring, in DRC, the current outbreak is more widespread than any previous DRC outbreak and has resulted in clade I mpox transmission to some neighboring countries. The Republic of the Congo (ROC), which borders DRC to the west, declared a clade I mpox outbreak in April 2024, and there have been confirmed cases in the Central African Republic (CAR). While clade I mpox is endemic in ROC and CAR, the epidemiologic pattern of recent cases suggests a possible link to DRC.

In late July 2024, Burundi, Rwanda, and Uganda, which sit on the eastern border of DRC, reported confirmed cases of mpox, with some cases having linkages to DRC. Rwanda and Uganda have confirmed these cases are due to clade I MPXV; in Burundi, clade-specific testing is underway, but cases are presumed to be clade I due to DRC's proximity. Mpox is not known to be endemic in these countries.

No cases of clade I mpox have been reported outside central and eastern Africa at this time. Because there is a risk of additional spread, CDC recommends clinicians and jurisdictions in the United States maintain a heightened index of suspicion for mpox in patients who have recently been in DRC or to any country <u>sharing a border</u> with DRC (ROC, Angola, Zambia, Rwanda, Burundi, Uganda, South Sudan, CAR) and present with <u>signs and symptoms consistent with mpox</u>. These can include: rash that may be located on the hands, feet, chest, face, mouth, or near the genitals; fever; chills; swollen lymph nodes; fatigue; myalgia (muscle aches and backache); headache; and respiratory symptoms like sore throat, nasal congestion, and cough.

Background

MPXV has two distinct genetic clades (subtypes of MPXV), I and II, which are endemic to central and west Africa, respectively. Clade I MPXV has previously been observed to be more transmissible and to cause a higher proportion of severe infections than clade II MPXV. The <u>ongoing global mpox outbreak</u> that began in 2022 is caused by clade II MPXV, and cases continue to be reported worldwide.

Clade I MPXV is endemic in DRC and several other Central African countries, and cases are reported annually. More than 22,000 suspect cases, with more than 1,200 suspected deaths, have been reported in DRC since January 1, 2023, a substantial increase from the median 3,767 suspect <u>clade I mpox cases</u> reported annually in DRC during 2016–2021. Clade I mpox cases have been reported from every DRC province, including areas where clade I mpox does not normally occur, such as the capital city Kinshasa. Outbreaks of clade I MPXV associated with sexual contact among men who have sex with men

and female sex workers and their contacts have been reported in some provinces. In other provinces, patients have acquired infection through contact with infected dead or live wild animals, household transmission, or patient care (transmitted in the absence of appropriate personal protective equipment); a high proportion of cases have been reported in children younger than 15 years of age. Mpox vaccine, which is expected to be effective against both clades, is not generally available in DRC at this time. However, the country is actively working on a plan to vaccinate.

Confirmed clade I mpox cases were reported in April in CAR and ROC. In late July 2024, clade I cases were confirmed in Rwanda and Uganda. Cases were also confirmed in Burundi; due to Burundi's proximity to DRC and Rwanda, these cases are presumed to be clade I while clade-specific testing is conducted. Clade I MPXV is not known to be endemic in Burundi, Rwanda, and Uganda.

Due to the limited number of travelers and lack of direct commercial flights from DRC or its neighboring countries to the United States, the <u>risk of clade I mpox importation</u> to the United States is considered to be very low.

The United States has robust mpox testing capacity in state public health laboratories and several commercial laboratories, including clade-specific testing, sequencing, and/or flagging high-likelihood clade I MPXV samples (i.e., negative for clade II MPXV but positive for orthopoxvirus). In addition, CDC continues to receive a subset of MPXV samples from across the United States that were not differentiated during the initial diagnosis to test for MPXV clade and to look for mutations using genetic sequencing. CDC is helping communities monitor the presence of both clades of <u>MPXV in wastewater samples</u>, including from select airports. Data from samples can provide an early warning of mpox activity and spread in communities.

Recommendations for Clinicians

Evaluation and Diagnosis

- Follow CDC guidance on <u>infection prevention and control</u> for mpox to minimize transmission risk when evaluating and providing care to patients with suspected mpox.
- Consider mpox as a possible diagnosis in patients with <u>epidemiologic characteristics</u> and <u>lesions</u> <u>or other clinical signs and symptoms</u> consistent with mpox. This includes persons who have been in DRC or, due to the demonstrated risks of regional spread, any of its neighboring countries (ROC, CAR, Rwanda, Burundi, Uganda, Zambia, Angola, Tanzania, and South Sudan) in the previous 21 days.
- Ask patients with signs and symptoms of mpox but no recent travel whether they have had contact with people who had recently been in any of the above countries and who were symptomatic for mpox.
- Consider mpox as a possible diagnosis if a clinically consistent presentation occurs, even in people vaccinated for or previously diagnosed with mpox.
- Advise all patients suspected of having mpox to isolate themselves from others.
- Evaluate all suspected cases related to DRC or its neighboring countries with laboratory testing (rather than clinical diagnosis alone). In most situations, specimens should be sent to the appropriate state public health laboratory or a commercial laboratory for initial testing. If you are authorized by your health department to send specimens directly to CDC for testing, contact CDC at poxviruslab@cdc.gov for information regarding specimen types accepted, labeling, specimen storage, and shipping timeframes.
- Follow <u>specimen collection guidelines</u> (including collecting two swabs per ~2-3 lesions) to ensure specimen availability for clade-specfic testing. This testing will help distinguish between cases that are part of the ongoing clade II mpox global outbreak and those associated with this clade I outbreak.
- Avoid unroofing or aspiration of lesions or otherwise using sharp instruments for mpox testing to minimize the risk of a sharps injury.

Treatment and Prevention

- Recommend mpox vaccine to people exposed to MPXV to help prevent the spread of mpox.
- Offer mpox vaccination to people ≥18 years of age with risk factors for mpox, following <u>the Advisory Committee on Immunization Practices (ACIP) recommendation</u> for vaccination before an exposure with two doses of the JYNNEOS vaccine 28 days apart.
 - Two doses of JYNNEOS vaccine <u>offer substantial protection against mpox</u>, and is expected to offer protection regardless of clade.
 - Additional JYNNEOS vaccine doses ("boosters," more than two doses) are not currently recommended.
- Consider vaccinating patients <u>eligible for mpox vaccination</u> and planning travel to affected countries, with two doses of JYNNEOS vaccine. Eligible patients who received one dose of the JYNNEOS vaccine more than 28 days ago should receive the second dose as soon as possible.
- There is no vaccination recommendation for travelers who do not meet current vaccine eligibility.
- Consult your health department or CDC (<u>poxvirus@cdc.gov</u>) promptly about any mpox cases for which severe manifestations might occur (e.g., those with advanced HIV infection). <u>Medical</u> <u>countermeasures</u> (e.g., tecovirimat, brincidofovir, and vaccinia immune globulin intravenous) used during the ongoing clade II mpox outbreak are expected to be effective for clade I MPXV infections.
- Inform all patients with mpox, including those with mild disease, about the <u>STOMP Trial</u> and recommend that they enroll. Oral tecovirimat (TPOXX) is available through the STOMP Trial. To enroll in STOMP, call 1-855-876-9997.
- Contact your state, local, or territorial health departments to see if oral TPOXX remains available from prior prepositioned supplies for patients who are ineligible for STOMP's open-label arm (e.g., illness ≥ 14 days or prior TPOXX receipt) but <u>meet expanded use Investigational New Drug</u> (EA-IND) eligibility for tecovirimat treatment for mpox.
- Clinicians should counsel patients about <u>what to do if they are sick</u> to prevent household transmission, if they have mpox symptoms; staying away from other people and not sharing things they have touched with others; and cleaning and disinfecting the spaces they occupy regularly to limit household contamination.

Recommendations for Health Departments

- Promote mpox vaccination in your community to protect as many <u>eligible people</u> as possible from mpox.
- Report mpox cases to CDC within 24 hours. Initial reports can be submitted with only the minimum required data elements of a local record ID and case jurisdiction of residence.
 - Enter the necessary sCRF data directly in the CDC DCIPHER platform. Data can also be entered into an existing jurisdictional case surveillance system configured for mpox reporting, with data uploaded to the CDC DCIPHER platform as a CSV file.
- Collect the data listed in the <u>2022/2023 U.S. Mpox Outbreak Short Case Report Form (sCRF)</u> for patients who meet the probable or confirmed mpox case definition. Local health departments should check with state or territorial health authorities to verify their jurisdiction's preferred case reporting process.

Recommendations for Laboratories

- Follow CDC guidance on <u>infection prevention and control</u> for mpox to minimize transmission risk when working with suspected mpox specimens.
- Send clinical specimens collected from patients who traveled from DRC or its neighboring countries, or had close or intimate contact with symptomatic people from these countries, to a laboratory that can perform clade-specific testing **as quickly as possible**.
- If clade-specific testing is warranted based on epidemiologic criteria but is not available in a
 jurisdiction, <u>specimen submission</u> to a public health laboratory with this capability or to CDC is

encouraged; specimen submission to CDC can be coordinated through your state or local health department. Specimens that cannot be accepted at CDC for clinical testing under <u>Clinical</u> <u>Laboratory Improvement Amendments (CLIA)</u> will be redirected for surveillance purposes and tested, providing critical data on MPXV clade(s) circulating in the United States.

- <u>Laboratory Response Network</u> laboratories and commercial laboratories using CDC's non-variola orthopoxvirus (NVO) polymerase chain reaction (PCR) test should continue submitting duplicate specimens to CDC from all patients with positive NVO PCR test results for routine MPXV cladespecific testing. This testing will assist with national surveillance.
- Some non-CDC laboratories may also have other options available for clade-specific testing, (e.g., molecular testing or genetic sequencing). These laboratories should alert their <u>state health</u> <u>department</u> and CDC (<u>poxvirus@cdc.gov</u>) if results from such tests indicate detection of clade I MPXV.

Recommendations for the Public

- The risk of clade I mpox spreading to the United States is very low at this time.
- Seek medical care immediately and avoid contact with others if you have been in the DRC or its neighboring countries in the last 21 days and develop a new, <u>unexplained skin rash (lesions on any part of the body)</u>, with or without fever and chills.
- Consider getting vaccinated against mpox if you have <u>risk factors and are eligible for vaccination</u>. CDC continues to recommend that people who are eligible for vaccination receive two doses of the JYNNEOS vaccine for the best protection. People at risk for mpox who have only received one dose more than 28 days prior should receive a second dose as soon as possible. JYNNEOS vaccine is believed to protect against both mpox clades.
- Review <u>CDC Travel Health Notices for the DRC and neighboring countries</u> before traveling. People with risk factors for MPXV infection who are not able to be vaccinated or (e.g., pregnant people, infants less than 1 year, people with eczema or active skin conditions, and people who are immunocompromised) should avoid situations <u>that might increase their risk</u> for mpox.
- All travelers to areas with mpox cases should <u>protect themselves</u> by avoiding close contact with people who have skin or genital lesions; avoiding contact with dead or live wild animals; avoiding contact with materials used by sick people like clothing, bedding, or in health care; avoiding materials that came into contact with wild animals; and avoiding eating or preparing meat from wild animals (bushmeat), or using products made from wild animals in countries where mpox occurs in animals.

For More Information

For clinicians and laboratory staff

- Mpox Clinical Recognition and Vaccine Information for Healthcare Providers: Information For Healthcare Professionals | Mpox | Poxvirus | CDC
- Biosafety and Select Agent Considerations: <u>Laboratory Procedures | Mpox | Poxvirus | CDC</u>
- Diagnostic Specimen Packaging and Shipping: <u>Transporting Infectious Substances Safely.pdf</u> (dot.gov)
- CDC Poxvirus and Rabies Branch: <u>poxvirus@cdc.gov</u> or for emergencies, CDC's 24/7 Emergency Operations Center (EOC): 770-488-7100.
- State and Local Health Department Contacts: <u>After Hours/Epi-on-Call Contact Lists Council of</u> <u>State and Territorial Epidemiologists (cste.org)</u>

For the public

- General inquiries: CDC-INFO (1-800-232-4636)
- About Mpox: Discover, History, and Virus Types: <u>About Mpox | Mpox | Poxvirus | CDC</u>
- Mpox Information for the Public: <u>Your Health | Mpox | Poxvirus | CDC</u>

August 2024 Travel Health Notice: Mpox in DRC and Neighboring Countries •

References

- Dalton AF, Diallo AO, Chard AN, et al. Estimated Effectiveness of JYNNEOS Vaccine in • Preventing Mpox: A Multijurisdictional Case-Control Study — United States, August 19, 2022– March 31, 2023. MMWR Morb Mortal Wkly Rep. 2023;72:553-558. DOI: http://dx.doi.org/10.15585/mmwr.mm7220a3
- Kibungu EM, Vakaniaki EH, Kinganda-Lusamaki E, et al. Clade I-Associated Mpox Cases Associated with Sexual Contact, the Democratic Republic of the Congo. Emerg Infect Dis. Published online November 29, 2023. doi:10.3201/eid3001.231164

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