CDC KEY MESSAGES

U.S. monkeypox outbreak 2022

Issue #8 – Aug. 18, 2022

This document summarizes key messages about the monkeypox outbreak and CDC's response. It is distributed weekly. Updated content is in blue. For the most current information, visit <u>http://www.cdc.gov/monkeypox</u>.

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OUTBREAK SUMMARY

Since mid-May 2022, CDC and its partners have been working to prevent the spread of monkeypox in a global outbreak in the United States and many other countries without a history of monkeypox.

- As of August 17, there have been 13,517 confirmed cases of probable or confirmed monkeypox in 49 U.S. states, the District of Columbia, and Puerto Rico.
- Worldwide, cases have been reported in 85 countries across all continents except Antarctica. Nearly 99% of cases in this outbreak have occurred in countries that did not historically report monkeypox.
 - While this level of monkeypox activity is unexpected, the risk to the general U.S. population remains low.
 - Current U.S. and global maps and case counts are available here.
 - o Trends in U.S. cases <u>are available here</u>.
 - In the 2022 global outbreak, the virus is spreading mostly through close, personal, often skin-to-skin contact with someone who has monkeypox.

- At this time, <u>data</u> suggest that gay, bisexual, and other men who have sex with men make up the majority of cases in the current monkeypox outbreak. However, anyone, regardless of sexual orientation or gender identity, who has been in <u>close</u>, <u>personal contact</u> with someone who has monkeypox is at risk.
- On June 28, CDC activated its Emergency Operations Center to support the agency's monkeypox response.
- Also on June 28, the U.S. Government <u>announced</u> a strategy to vaccinate and protect people at risk for monkeypox, prioritize vaccines for areas with the highest numbers of cases, and provide guidance to state, tribal, local, and territorial health officials to aid their planning and response efforts.
 - Since then, CDC and HHS have been working closely with partners to ensure there are enough doses available to vaccinate all people for whom vaccination is recommended. CDC is working with state and local health officials to identify people who may have been in contact with people who have tested positive, so those contacts can monitor their health, be counseled on post-exposure vaccine prophylaxis, if indicated, and seek care if they develop symptoms.
 - Many people who have been diagnosed with monkeypox are reporting anonymous contacts, or contacts with people who cannot be identified for contact monitoring and consideration for post-exposure prophylaxis (PEP). As a result, CDC and partner agencies have since expanded vaccine use to protect against virus transmission.
 - As of August 17, 2022, CDC and the Department of Health and Human Services (HHS) have <u>distributed more than 634,000 doses</u> of the JYNNEOS vaccine from the Strategic National Stockpile to states and jurisdictions nationwide.
- On July 23, the World Health Organization (WHO) declared monkeypox a Public Health Emergency of International Concern (PHEIC). This is WHO's highest level of global alert, and the decision recognizes the potential threat this virus poses to countries around the world.
- In late July, CDC learned of the first cases of monkeypox among children during this outbreak. Infections in children can be more severe, so it's vital to identify pediatric cases as quickly as possible so they can receive treatment if needed.
- On July 26, CDC published <u>Clinical Considerations for Monkeypox in Children and Adolescents</u> to help clinicians and health systems develop a plan for managing children and adolescents who may be affected by monkeypox.
- On July 27, CDC published <u>Isolation and Prevention Practices for People with Monkeypox</u> to help people affected by monkeypox protect others from getting it. The page has been since integrated into CDC's recommendations <u>for healthcare professionals</u>, which now include more than 20 webpages, plus downloadable and printable files.
- Since July, CDC has published and regularly updated consumer pages with emphasis on user-friendliness and mobile accessibility to help people who are concerned about or affected by monkeypox, including:
 - o About Monkeypox
 - o Signs and Symptoms
 - o How it Spreads
 - o <u>Prevention</u>
 - o If You Are Sick
- On July 28, CDC published its first <u>Technical Report on the outbreak</u>. The purpose of the report is to share preliminary results of new analyses with a technical audience to improve understanding of the outbreak and inform further scientific inquiry.
- Five major U.S. commercial laboratory companies -- Labcorp, Mayo Clinic Laboratories, Quest Diagnostics, Aegis Sciences, and Sonic Healthcare USA are now participating in the U.S. government's expanded orthopoxvirus testing effort. Four of these commercial labs are performing the CDC non-variola orthopoxvirus test, while Quest is running a monkeypox lab developed test (LDT) that adds another 30,000 tests per week.

- Combined with testing within the Laboratory Response Network, total U.S. testing capacity is at 80,000+ per week.
- On August 9, 2022, CDC published <u>Interim Clinical Considerations for Use of JYNNEOS and ACAM2000</u> <u>Vaccines during the 2022 U.S. Monkeypox Outbreak</u>. This CDC guidance includes information for clinicians about use of the alternative (intradermal) dosing regimen as well as the standard (subcutaneous) regimen for JYNNEOS vaccine.
- According to research, intradermal vaccination produces similar results to standard vaccination. This alternative route of administration uses much less vaccine and could help existing vaccine supplies reach more people.
- CDC also simplified the process for U.S. healthcare providers to request the antiviral drug tecovirimat (TPOXX) to treat patients with monkeypox. Forms and other documentation required for obtaining TPOXX can be submitted after clinicians receive the drug and begin patient treatment.
 - Earlier requirements to photograph lesions, collect specimens, and ship them to CDC are now optional. Healthcare providers can begin administering TPOXX as soon as they obtain informed consent from the patient. Additional modifications are being worked out with the U.S. Food and Drug Administration (FDA) and will be announced soon.
- On August 10, 2022, human-to-animal transmission of monkeypox was reported, the first ever, when a dog was confirmed to have the virus.
- On August 12, 2022, WHO <u>announced</u> new names for monkeypox virus clades—or types—which replace regional names with Roman numerals. The formerly named Congo Basin, or Central African, clade was renamed Clade I. The former West African clade was renamed Clade II, which is made up of two sub-clades, IIa and IIb. Clade IIb is the clade in the 2022 global outbreak.
- CDC and our U.S. health partners have past experience effectively responding to monkeypox cases in the United States. We dealt with two cases imported from Africa in 2021 and responded to an outbreak involving 47 cases in 2003.
- CDC urges health departments, clinicians, and the public to remain vigilant, institute appropriate infection prevention and control measures, and notify public health authorities of suspected cases to reduce disease spread.

WHAT CDC IS DOING

• CDC is working with state and local health officials to identify people who may have been in contact with the people who have tested positive, so those contacts can have the information they need to monitor their

health and seek care if symptoms appear. CDC has distributed detailed information on identifying and testing for potential infections to clinicians.

- CDC is providing guidance on risk assessment and public health management of monkeypox cases and contacts in travel settings.
- CDC has published a series of <u>Health Alert Network</u> updates to highlight emerging issues in the monkeypox response for healthcare providers.
- On July 28, a <u>HAN Health Update</u> shared recent information for clinicians about commercial testing, collecting clinical specimens for testing, and using the antiviral drug tecovirimat (TPOXX) for treating monkeypox.
- Another HAN Health Update <u>on July 30</u> alerted clinicians to considerations for preventing, diagnosing, and managing monkeypox in people with HIV, children, adolescents, and people who are pregnant or breastfeeding.
- CDC is working with community health organizations, including multiple partners in the LGBTQIA+ community, to raise awareness of the outbreak and share accurate information about what people can do to protect their health and the health of others.
- CDC is currently working to stop the spread of monkeypox by working with state, territorial, local and territorial health departments and partners to understand the epidemiology of the outbreak and to also learn about the populations most affected. We are using guidance from our work in HIV and STIs to ensure that we are not furthering stigma toward gay, bisexual, and other men who have sex with men. One of the biggest lessons learned from HIV is it is critical to have the community most affected involved and ideally leading response efforts. In this case, gay and bisexual men are at the forefront of this response due to the current epidemiology of the outbreak.
- Internally, response leadership is a mixture of subject matter experts in monkeypox, but also experts in HIV/STI Prevention and the gay/bisexual male community. Externally, CDC is conducting community listening sessions and working very closely with HIV, sexual health, and LGBTQIA+ advocacy organizations to create messaging that is sex positive and not stigmatizing. CDC is strongly committed to combating stigma and discrimination and encourage feedback from the community both internal and external.
- In addition to this focused messaging, CDC is also providing information to a wider U.S. audience about symptoms and the behaviors that can lead to the spread of monkeypox.
- CDC posted a <u>travel health notice (THN)</u> to inform travelers and clinicians about monkeypox-related health issues that could affect travelers' health.
- CDC recommends you do not travel if you have monkeypox.
 - Isolate at home or in another location until your symptoms are gone and your rash has healed; this means all scabs have fallen off and a fresh layer of skin has formed.
 - If you have monkeypox and must travel:
 - Make sure that you do not have fever or respiratory symptoms such as sore throat, nasal congestion, or cough.
 - Cover your rash and wear a well-fitting mask.
- CDC is supporting diagnostic testing at Laboratory Response Network (LRN) labs and 5 commercial labs, which conduct tests for orthopoxviruses like monkeypox virus; and at CDC itself, which conducts viral characterization testing specifically for monkeypox.
- GeoSentinel, a collaboration between the CDC and the International Society of Travel Medicine, is a global clinical-care-based surveillance system that monitors infectious diseases and other adverse health events that may impact international travelers and migrants. GeoSentinel deployed a data collection tool in May to

gather information on monkeypox cases internationally to improve our understanding of monkeypox epidemiology and clinical manifestations.

- CDC has been communicating information more broadly to clinical and lab audiences through interactive partner calls, including:
 - Hosting <u>Clinician Outreach and Communication Activity (COCA) calls</u> that have shared information with more than 32,000 participants.
 - Sending news of new commercial laboratory testing options to more than 64,000 subscribers of its <u>COCA Now email updates</u>.
 - Distributing <u>Health Alert Network</u> notices to inform thousands of clinicians about updated and expanded case definitions.
 - Sharing weekly updates with more than 90 partner organizations, including state, tribal, local, and territorial agencies, public health organizations, and clinical, community, and LGBTQ+ organizations that forward information to their members.
 - Conducting ongoing consultations through a Clinician Call Center that was quickly set up to respond to individual providers and state and local health officials.
 - Publishing more than 69 webpages to inform the public, healthcare providers, health departments, and partners about monkeypox.
- CDC researchers are working with our partners to learn how long the virus has been circulating; how the virus was introduced into some of the current clusters of cases; the clinical course of illness; and whether the virus is being spread through contact with semen or vaginal fluids.
- CDC continues to provide technical assistance and respond to inquiries and information requests from state, tribal, local, and territorial health departments and partner organizations.
- CDC is facilitating access to vaccines and therapeutics for people who may have been exposed to monkeypox.
- On August 9, 2022, CDC Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak. This CDC guidance includes information for clinicians about use of the alternative (intradermal) dosing regimen as well as the standard (subcutaneous) regimen for JYNNEOS vaccine.
- The interim clinical considerations document includes
 - an overview of available vaccines, vaccination strategies and post-exposure prophylaxis, and planning considerations for health departments including health equity.
 - interim guidance for use of JYNNEOS or ACAM2000, including the schedule and dosing regimens that can be considered, dosing intervals, vaccine administration, pre- and post-vaccination counseling, and contraindications and precautions.
 - Related resources include vaccine information statements and EUA fact sheets in English and Spanish, template standing orders, preparation and administration summaries, and teaching tools for intradermal injection.
- CDC is developing a portfolio of vaccine effectiveness projects that will identify data from various locations, populations, and timepoints. The proposed projects include some new studies and leverage existing platforms and relationships.

ABOUT MONKEYPOX

- Monkeypox is a rare but potentially serious disease that typically begins with a flu-like illness and swelling of the lymph nodes and progresses to include a widespread rash on the face and body.
 - However, in recent cases, patients have developed rashes without having flu-like symptoms first.
- Monkeypox is caused by a virus that is in the same family as the virus that causes smallpox, but it typically results in a less severe infection.

- Symptoms of monkeypox may include intense pain, itching, or other debilitating issues that make simple things like walking or going to the bathroom difficult. The rash may also leave scars once it heals.
- CDC recommends that clinicians assess pain in all patients with monkeypox.
- Most infections last 2-4 weeks and resolve without specific treatment.
- The type of monkeypox seen in this outbreak is rarely fatal, and more than 99% of people who get this form of the disease are likely to survive. However, some groups are likely at higher risk of severe illness, including children under age 8, people who have weakened immune systems or are pregnant, and people with history of atopic dermatitis or eczema.
- Monkeypox is endemic in parts of Africa, with more than 1,000 cases reported annually in the Democratic Republic of the Congo in recent years. Nigeria has reported ongoing spread of monkeypox since 2017, when the virus re-emerged after nearly 40 years with no reported cases.
- Analysis by CDC experts has found that there are at least two genetically distinct variants of monkeypox virus circulating in the current outbreak, both of which share common ancestors of strains present in Nigeria since 2017. This shows it's likely that there were at least two separate instances where the monkeypox virus spread from animals to people in Nigeria, then began to spread person-to-person through close contact.
- Prior to the current outbreak, there were at least eight reported monkeypox cases in travelers who visited Nigeria and returned home with monkeypox infections (including cases in the United States, United Kingdom, Israel, and Singapore). In the United Kingdom, several additional monkeypox cases occurred in people who had contact with travelers who had monkeypox.
- Experts have yet to identify where monkeypox virus is found in nature, but it's thought that small mammals in some parts of Africa play a role in spreading the virus to people and other forest animals, like monkeys.

TRANSMISSION

- Monkeypox is caused by a virus that can spread from animals to people. It can spread between people when someone has contact with someone who is infected with monkeypox or touches materials that are contaminated with the virus.
- Monkeypox can spread to anyone through:
 - Direct contact with monkeypox rash or scabs on a person's skin.
 - Contact with objects, fabrics (clothing, bedding, or towels), and surfaces that have been used by someone with monkeypox.
 - Contact with respiratory secretions during prolonged, face-to-face contact.
- Monkeypox can be spread during intimate contact, including:
 - Oral, anal, and vaginal sex, or touching the genitals or anus of a person with monkeypox.
 - Hugging, massage, kissing, or talking closely.
 - Touching fabrics, shared surfaces, and objects that were used by a person with monkeypox, such as bedding, towels, fetish gear and sex toys.
- The current outbreak has led to questions about whether monkeypox is a sexually transmitted infection (STI). Monkeypox can more accurately be described as "sexually transmissible." In other words, sex is just one of the ways that monkeypox can be spread.
- In the past, monkeypox outbreaks have been linked to direct exposure to infected animals and animal products, with limited person-to-person spread. In the current monkeypox outbreak, the virus is spreading primarily through close personal contact. This may include contact with infectious lesions or respiratory secretions via close, sustained skin-to-skin contact that occurs during sex.
- On August 10, 2022, a report in *The Lancet* described a monkeypox infection in a dog that had close contact with two people with monkeypox. This is the first known human-to-animal transmission of monkeypox and the first confirmed dog with the virus.
- However, any close, sustained skin-to-skin contact with someone who has monkeypox can spread the virus; the contact does not have to be exclusively intimate or sexual.

• To learn more about how monkeypox can spread, visit CDC's <u>How it Spreads</u> page.

SYMPTOMS

People with monkeypox may first develop a flu-like illness with fever, headache, muscle aches, exhaustion, and enlarged lymph nodes. A characteristic rash, which can appear like blisters or pimples, occurs a few days later. However, in recent cases, patients have developed localized rashes around the genitals or anus without having flu-like symptoms first.

- Early flu-like symptoms of monkeypox can include:
 - o Fever
 - o Headache
 - Muscle aches and backache
 - Swollen lymph nodes
 - o Chills
 - Exhaustion
- The rash sometimes is located on or near the genitals or anus, but may be in other areas like the hands, feet, chest, neck or face.
 - The sores can look like pimples or blisters and may be painful or itchy.
 - The sores typically go through several stages, including scabs, before healing.
 - Sores may be inside the body, including the mouth, vagina, or anus.
- A <u>Health Alert Network update</u> published June 14 highlighted two emerging issues in the monkeypox response:
 - Some aspects of the clinical presentation are different from what has been seen historically in countries where most previous monkeypox outbreaks have occurred.
 - A number of monkeypox cases were reported in people who had no obvious link to international travel (often called "community cases").
- These two issues raised concerns that some monkeypox infections in the United States were not being recognized and tested. As a result, CDC updated and expanded its case definition to encourage testing for monkeypox in people with a rash and who may be at risk for developing monkeypox.
- Monkeypox can be spread from the time symptoms start until all sores have healed and a fresh layer of skin has formed.
- The illness may last for up to 2–4 weeks and usually resolves without specific treatment.
- For more information on symptoms, see <u>www.cdc.gov/poxvirus/monkeypox/symptoms.html</u>.
- If you're a healthcare worker looking for more information on how to recognize monkeypox, please see www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html

TESTING

- In June, CDC began distributing its orthopoxvirus test to five commercial laboratory companies Labcorp, Mayo Clinic Laboratories, Quest Diagnostics, Aegis Sciences, and Sonic Healthcare USA – to increase monkeypox testing capacity and access.
- As of July 18, all five commercial laboratory companies taking part in the U.S. government's expanded orthopoxvirus testing effort – Labcorp, Mayo Clinic Laboratories, Quest Diagnostics, Aegis Sciences, and Sonic Healthcare USA – have begun testing. Four of these commercial labs are performing the CDC nonvariola orthopoxvirus test, while Quest is running a monkeypox lab-developed test (LDT) that adds another 30,000 tests per week.

- Combined with the existing capability of the facilities in the Laboratory Response Network, this will bring the total U.S. testing capacity to at least 80,000 per week.
- Healthcare providers can order the orthopoxvirus test from these companies just as they normally would order other tests. As of July 25, there was not a specific CPT ordering code for monkeypox testing at the commercial labs. This code varies by commercial lab.
- The companies will use electronic laboratory reporting (ELR) to report results to jurisdictions, as outlined in <u>CDC reporting guidance</u>. Test results will be reported to the health department in the patient's state or territory of residence.
- The addition of these commercial laboratories will greatly expand the current capacity provided through CDC's Laboratory Response Network (LRN), which has the capacity to test about 10,000 specimens per week.
- Previously, all initial testing for monkeypox was being performed at LRN labs, located at most state health departments.
- If samples are positive for orthopoxvirus (the genus of viruses that includes monkeypox virus), the labs send some of the samples to CDC to perform viral characterization testing, including a PCR assay and potential sequencing. Since there are no other circulating orthopoxviruses within the United States detected with the non-variola orthopoxvirus test, a positive test is probable for monkeypox infection.
- As of Aug. 2, Laboratory Response Network (LRN) laboratories that conduct the CDC non-variola orthopoxvirus test are no longer required to send all positive specimens to CDC for monkeypox characterization testing. Laboratories only need to send 10% of their positive specimens each month.
- All orthopoxvirus positive specimens submitted to CDC have been characterized as the West African clade. However, collecting the genetic sequences and related data from a selection of positive specimens can help CDC track any changes to the virus and identify potential variants that might be spread more easily or respond differently to treatments.
- Routine testing of specimens will also ensure that CDC's orthopoxvirus test remains effective.
- A similar change for the commercial labs running the CDC non-variola orthopoxvirus test is planned in the near future.
- A positive orthopoxvirus test result is enough for public health authorities to take the actions necessary to care for the patient and help prevent additional spread the same actions they would take for a positive monkeypox test result. They can start treatment if needed, begin contact tracing, and offer post-exposure vaccination to contacts.
- The LRN consists of approximately 120 laboratories, including state and local public health laboratories, and 84% of the U.S. population lives within 100 miles of one of these laboratories. Currently, 75 of these laboratories can test for orthopoxviruses.

IF YOU FEEL SICK

If you have a new or unexplained rash or other symptoms, see your healthcare provider for medical attention and evaluation.

- If you do not have a provider or health insurance, you can visit a public health clinic.
- If you seek medical evaluation for possible monkeypox, cover all parts of the rash with clothing, gloves or bandages, wear a well-fitting mask, and remind the healthcare provider that this virus is circulating.
- Avoid close contact, including sexual or intimate contact, with anyone until you have been evaluated by a healthcare provider.
- See CDC's <u>Social Gatherings, Safer Sex, and Monkeypox</u> page for additional information on how to reduce your risk of monkeypox.

If you have received a monkeypox diagnosis, avoid having close contact with others until your symptoms have gone away and the rash has healed completely.

- Avoid sex or being intimate with anyone until all your sores have healed and you have a fresh layer of skin formed.
- Isolate until your rash has fully healed and a fresh layer of skin has formed. People with monkeypox can spread the illness to others from the beginning of symptoms until the rash has formed a fresh layer of skin.
 - Under some circumstances, if you have monkeypox, you may have to leave isolation before you have fully healed. If so, you should cover the rash and wear a well-fitting mask to protect others from getting monkeypox.
 - It is very important to isolate if you have a fever or respiratory symptoms, including sore throat, nasal congestion, or cough. When experiencing these symptoms, you should leave isolation only to see a healthcare provider or for an emergency.
 - If you have an active rash or other symptoms, stay in a separate room or area away from people or pets you live with, when possible.
- Avoiding contact with animals including pets, domestic animals, and wildlife. For more information, see CDC's <u>Pets in the Home</u> page.
- Cover rashes on the body with clothing, gloves, or bandages.
- Wash your hands often with soap and water. Use hand sanitizer if soap and water aren't available.
- Clean and disinfect surfaces and materials that you have touched while you had symptoms, including bedding, towels, clothing, sex toys, and surfaces such as door handles or counter tops.
 - Standard household cleaning/disinfectants may be used in accordance with the manufacturer's instructions.
- For more details, see CDC's <u>If You Are Sick</u> page.

TREATMENT

There is no treatment specifically for monkeypox. However, because the monkeypox and smallpox viruses are closely related, drugs and vaccines developed to protect against smallpox may be used to prevent and treat monkeypox virus infections.

- Treatment will depend on how sick someone gets or whether they're likely to get severely ill, such as if they have a weakened immune system. Most people with monkeypox recover fully within 2 to 4 weeks without the need for treatment.
- Antiviral drugs used to treat smallpox and monkeypox require a prescription and must be released from the U.S. Strategic National Stockpile at the request of a patient's local or state health department.
- State and territorial health authorities can call the CDC Emergency Operations Center (770-488-7100) to ask for medical countermeasures for the treatment of monkeypox.
- The antiviral drug tecovirimat (also known as TPOXX) was developed to fight smallpox but the U.S. Food and Drug Administration (FDA) allows CDC to use it to treat monkeypox during an outbreak.
- In addition, other drugs may be useful against monkeypox, but have not yet been tested:
 - Vaccinia Immune Globulin Intravenous (VIGIV) is licensed by FDA for treating complications from smallpox vaccination. CDC has permission to use of VIGIV for the treatment of orthopoxviruses, including monkeypox, during an outbreak.
 - Cidofovir (also known as Vistide) is an antiviral medication approved by the FDA for the treatment of cytomegalovirus (CMV) retinitis in patients with Acquired Immunodeficiency Syndrome (AIDS).

- Brincidofovir (also known as Tembexa) is an antiviral medication that was approved by the FDA in 2021 for the treatment of human smallpox disease.
- For more information, see <u>https://www.cdc.gov/poxvirus/monkeypox/treatment.html</u>.

VACCINES

CDC believes that making vaccines available now is one important strategy to mitigate the spread of monkeypox. On June 28, 2022, the federal government announced an enhanced nationwide strategy to vaccinate and protect people at risk for monkeypox, prioritize vaccines for areas with the highest numbers of cases, and provide guidance to state, tribal, local, and territorial health officials to aid their planning and response efforts.

- A substantial number of people diagnosed with monkeypox have reported anonymous contacts (sex partners), or people who cannot be identified for contact monitoring and consideration for post-exposure prophylaxis (PEP). As a result, CDC and partner agencies have been revising their strategy and expanding vaccine use as a priority to stop virus transmission.
- Two smallpox vaccines licensed by the FDA may be used to prevent monkeypox: JYNNEOS, also known as Imvamune or Imvanex, and ACAM2000. CDC and HHS are working closely with partners to ensure there are enough vaccine doses available to vaccinate all people for whom vaccination is recommended.
- The National Strategy has several phases.
 - In Phase 1 (June 2022), vaccine was distributed to jurisdictions using a tiered allocation system based on case rates, to give to people who have had close contact with people known to have monkeypox, and to people who may have had high-risk exposures in venues or areas where monkeypox is actively spreading. This approach is called post-exposure prophylaxis (PEP).
 - In Phase 2a and 2b (July 2022), additional vaccine doses were distributed based on a weighted algorithm to determine an equitable threshold based on population sizes, to continue to support PEP and to administer to more people as expanded post-exposure prophylaxis (PEP++):
 - In Phase 3a and 3b/c (July-August 2022), additional vaccine doses were allocated based on a weighted algorithm using population at risk and cases reported to establish thresholds for jurisdictions that would continue to support prioritizing PEP and PEP++.
 - A Phase 4 is anticipated as soon as late August.

Available vaccines

- This plan allocates the two-dose <u>JYNNEOS</u> vaccine, which the FDA approved for prevention of smallpox and monkeypox in people ages 18 years and older who are at high risk for monkeypox infection.
- On August 9, 2022, FDA announced an emergency use authorization (or EUA) for JYNNEOS vaccine to allow healthcare providers to use the vaccine by intradermal injection for people ages 18 years and older who may be at high risk for monkeypox infection. This action enables providers to receive up to five times the number of doses out of a single vial.
 - The FDA-licensed standard regimen for JYNNEOS vaccine is for subcutaneous administration (in the fatty layer under the skin). The alternative regimen allows for intradermal administration (directly into the skin's top layer). The intradermal route of administration requires a smaller amount of vaccine to produce a similar effect.
 - Because the dermis layer houses a large amount of immune cells, vaccinating in that area of the skin can create a robust response to protect against infection.
- Also on August 9, CDC published <u>Interim Clinical Considerations for Use of JYNNEOS and ACAM2000</u>
 <u>Vaccines during the 2022 U.S. Monkeypox Outbreak</u>, which provides guidance for use of JYNNEOS vaccine

including the intradermal regimen. Linked related resources for health departments and healthcare providers include vaccine information statements (VIS) and EUA fact sheets in both English and Spanish, template standing orders, preparation and administration summaries, and teaching tools about intradermal injections, including a video.

- The EUA allows people under age 18 years to receive JYNNEOS vaccine using the standard (subcutaneous) route. It also allows use of the standard subcutaneous regimen (injection of a whole 0.5mL vial) in children and adolescents under 18 years, and in people of any age with a history of keloids.
- Intradermal vaccination has been studied for other vaccines including rabies, influenza, and hepatitis B vaccines.
- A randomized, independent study published in the peer-reviewed journal *Vaccine* in 2015 found that JYNNEOS vaccine administered intradermally produced a similar antibody level (immunogenicity) as the vaccine administered into the subcutaneous tissue (the fatty layer just under the skin).
- Overall, there was no difference in the proportion of people with adverse events who received the vaccine into the skin (intradermally) or under the skin (subcutaneously). However the reaction around the injection site may be last longer than when administered under the skin.
- Real-world vaccine effectiveness of JYNNEOS vaccine is unknown in the context of the current outbreak. Licensure was supported by animal studies as well as clinical studies demonstrating a comparable immune response to ACAM2000.
- Because JYNNEOS is licensed as a two-dose series, CDC continues to recommend two doses of JYNNEOS vaccine to prevent monkeypox disease. The two doses should be given 28 days apart.
- See CDC's <u>Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S.</u> <u>Monkeypox Outbreak</u> for detailed recommendations, including how healthcare providers should handle dosing or administration errors and what to do if the vaccine is given in the wrong site, route, dose, or interval.
- To supplement the supply of JYNNEOS, state and local jurisdictions, tribal nations, and territories may also
 request <u>ACAM2000</u> vaccine. ACAM2000 is given as a single dose. However, ACAM2000 carries greater risk of
 certain serious side effects than JYNNEOS and should not be given to some people, including people with
 weakened immune systems, certain skin conditions such as eczema, heart disease, or who are pregnant or
 lactating.
- CDC will work with state, territorial, tribal, and local health departments requesting ACAM2000 vaccine to ensure that people who are considering getting the vaccine are fully informed on the benefits and the risks before they receive it.
- What is CDC doing to study vaccine effectiveness of monkeypox vaccines?
- CDC is developing a portfolio of vaccine effectiveness projects that will identify data from various locales, populations, and timepoints. The proposed projects include some new studies and leverage existing platforms and relationships.
- Initial estimates of vaccine effectiveness will take some time. However, some initial projects are underway. For example, a CDC field team is currently supporting an investigation in Washington, D.C., to prospectively evaluate infections among persons seeking vaccination. Additionally, CDC is conducting a data call to U.S. jurisdictions to assess population-level vaccination trends in high-burden jurisdictions.
- While additional vaccine effectiveness studies are underway, CDC is recommending that people who get vaccinated continue to take steps to protect themselves from infection by avoiding close skin-to-skin contact, including intimate contact, with someone who has monkeypox.

Who should get vaccinated?

- People can be vaccinated after known or presumed exposure to someone with monkeypox as post-exposure prophylaxis (PEP).
- In the context of this outbreak the following people can be vaccinated under the strategy of PEP:
 - People who are known contacts to someone with monkeypox who are identified by public health authorities, for example via case investigation, contact tracing or risk exposure assessment
- In addition to those who can be vaccinated under the PEP strategy, people with certain risk factors and recent experiences that might make them more likely to have been exposed to monkeypox can be considered for vaccination in a strategy known as expanded post-exposure prophylaxis (PEP++). This includes
 - People who are aware that a recent sex partner within the past 14 days was diagnosed with monkeypox
 - Certain gay, bisexual, other men who have sex with men, or transgender people who report any of the following in the past 14 days:
 - Group sex or sex with multiple partners.
 - Sex at a commercial sex venue or in association with an event, venue, or defined geographic area where monkeypox transmission is occurring
- Vaccination of people before exposure to monkeypox, or pre-exposure prophylaxis (PrEP) is recommended only for people in certain occupational risk groups (e.g. research laboratory workers performing diagnostic testing for Monkeypox virus, and members of healthcare worker response teams designated by appropriate public health and antiterror authorities) based on long-standing recommendations from the Advisory Commitee of Immunization Practices (ACIP) that predate the outbreak.
- Currently, CDC is not encouraging mass vaccination for the general public or for all sexually active people while JYNNEOS vaccine supplies remain limited.
- JYNNEOS doses should be prioritized for people who are at risk for severe adverse events with ACAM2000 or severe disease from monkeypox, such as people living with HIV infection or other immunocompromising conditions, or those who are taking medications that weaken the immune system.

Distribution

- States and other jurisdictions are being offered equitable allocations of JYNNEOS vaccine doses based on current cases as well as the proportion of the population at risk for severe disease from monkeypox.
- The federal government is partnering with state, tribal, local, and territorial governments in deploying the vaccines.
- As of August 17, more than 634,000 vials of JYNNEOS vaccine have been distributed.
- On July 1, 2022, the Biomedical Advanced Research and Development Agency (BARDA) <u>ordered an</u> additional 2.5 million vials of JYNNEOS for use in responding to current or future monkeypox outbreaks and as part of U.S. smallpox preparedness. Deliveries from this latest order will begin arriving at the SNS later this year and will continue through early 2023. Altogether, HHS anticipates making approximately 1.9 million vials of JYNNEOS available in 2022, with an additional 2.2 million available during the first half of 2023.
- In some areas, there may be more people with known or presumed exposures than supplies of JYNNEOS. States are encouraged to prioritize JYNNEOS for use in people who are at risk for severe adverse events with ACAM2000 (see below).
- When states have considered the complexities and elect to use ACAM2000 as part of their strategy, it can be offered to people who have been adequately screened and counseled.

• This may include ensuring vaccinees clearly understand possible health risks, have signed informed consent, have ensured they are not HIV positive through rapid testing, and are able to avoid close contact with people – including household members – at risk of severe disease until the vaccine site is fully healed.

What approaches to vaccination can states or other jurisdictions take?

- In the context of this outbreak vaccine strategies include:
 - Monkeypox vaccine post-exposure prophylaxis (PEP) refers to vaccination of a person following known exposure to monkeypox. These are known contacts to someone with monkeypox who are identified by public health authorities, for example via case investigation, contact tracing or risk exposure assessment. This is intended to help prevent illness from the monkeypox virus.
 - **Monkeypox vaccine expanded post-exposure prophylaxis (PEP++)** refers to vaccination of people with certain risk factors that might make them more likely to have been recently exposed to monkeypox. The PEP++ approach aims to reach these individuals for vaccination even if they have not had a known exposure to monkeypox.
 - Monkeypox vaccine pre-exposure prophylaxis (PrEP) refers to vaccination given to people at high risk for monkeypox, and is currently recommended only for people in certain occupational risk groups (e.g. research laboratory workers performing diagnostic testing for Monkeypox virus, and members of healthcare worker response teams designated by appropriate public health and antiterror authorities). These are long-standing recommendations from the Advisory Commitee of Immunization Practices that predate the outbreak.
- PEP and PEP++ should be primarily employed, with PEP being prioritized before other vaccination strategies.
- Currently, CDC is not encouraging mass vaccination for the general public or for all sexually active people (PrEP) while JYNNEOS vaccine supplies remain limited.
- To better understand the protective benefits and the risks associated with these vaccines in the current outbreak, CDC will collect data on any side effects, infections of vaccinated people, and whether the way the person was infected makes any difference in how well the vaccine protects them.

Pre-Exposure Prophylaxis (PrEP) and protection from previous vaccination:

- ACIP recommends that people whose jobs may expose them to orthopoxviruses, such as monkeypox, should be vaccinated with either ACAM2000 or JYNNEOS to protect them if they are exposed to one of these viruses.
- Most people in this category work in laboratories that handle monkeypox and other related viruses.
- Other people, such as healthcare workers who may be caring for people with monkeypox, also may be vaccinated.
- CDC does not currently recommend pre-exposure vaccination <u>for most U.S. healthcare workers</u>. Monkeypox primarily spreads through close contact and does not spread as easily as diseases like COVID-19. Proper use

of personal protective equipment and <u>infection control practices</u> are effective at reducing the risk of spread of the monkeypox virus when examining a patient or handling contaminated materials.

- Previous smallpox vaccination does provide protection, but it may not be lifelong. During the 2003 monkeypox outbreak and during the current outbreak, several people who were infected with monkeypox had previously been vaccinated against smallpox decades prior.
- In response to an outbreak, vaccines and other medical measures would also be given to eligible people who were previously vaccinated against smallpox. To date, ACIP has only considered vaccine recommendations for people at risk of exposure to orthopoxviruses, including monkeypox virus, as part of their jobs. As such, booster vaccination recommendations are also only applicable to these populations.

Vaccine safety:

- Vaccination providers who are administering JYNNEOS under the EUA are required to report certain adverse events that occur after JYNNEOS vaccination.
- The Vaccine Adverse Reporting System (VAERS) is the nation's passive vaccine safety surveillance program that serves as a national early warning system by helping to detect unusual or unexpected reporting patterns of adverse events for vaccines.
- VAERS is co-managed by CDC and the U.S. Food and Drug Administration (FDA). It can receive reports from anyone, including patients, parents, caregivers, and healthcare providers. Healthcare providers are required to report certain adverse events that occur after vaccination. VAERS is not designed to identify cause and effect. If an adverse event is reported to VAERS, that doesn't mean that the vaccine caused the adverse event. Instead, the system allows detection of potential safety concerns that might need further investigation.
- These adverse event reports are studied by vaccine safety experts who look for previously unobserved adverse events, or changes in patterns of reporting of adverse events after people receive a particular vaccine.
- When VAERS staff members investigate a report of a serious adverse event, they ask for the patient's medical records related to the serious adverse event to learn more about what happened.
- If vaccine safety experts find an association between a serious adverse event and a vaccine, FDA and the vaccine manufacturer will work to find an appropriate solution to address the specific safety concern, and the public will be alerted.
- VAERS reports are available to the public but do not include any information that could identify the person.

PREVENTION

There are a number of measures that can be taken to prevent infection with monkeypox virus:

- Avoid close contact with people with symptoms consistent with monkeypox infection and items (such as clothing or linens) with which they have been in contact.
- Avoid contact with animals that could harbor the virus, including animals that are sick or that have been found dead in areas where monkeypox occurs.
- Avoid contact with any materials, such as bedding, that has been in contact with an animal that has been infected with monkeypox.
- Wash your hands with soap and water or use an alcohol-based hand sanitizer after contact with animals or people known or suspected to have monkeypox infection or items they handled or used while ill.
- CDC has posted additional considerations for infection prevention and control in non-healthcare settings, including:
 - o <u>Homes</u>
 - o <u>Congregate living settings</u>, such as dormitories, homeless shelters, or correctional facilities

- <u>Disinfection instructions</u> for non-healthcare settings, such as homes and cars
- People should consult their local public health department for help implementing the recommended steps.
- Healthcare providers should use <u>standard and recommended isolation precautions</u> when caring for patients with suspected or confirmed monkeypox infection.
- Healthcare providers (HCP) should <u>understand recommendations</u> for assessing the risk of HCP with monkeypox virus exposures, including how to monitor HCP and when to apply work restrictions.
- We don't know whether condoms prevent the transmission of monkeypox. If rashes are confined to the genitals or anus, condoms may help. However, since infectious respiratory secretions may be present, condoms alone are probably not enough to prevent monkeypox.
- Condoms may help to prevent transmission of monkeypox by preventing contact with infectious rash and potentially infectious fluids. However, condom use for prevention of monkeypox has not been evaluated.
- Condoms are effective at preventing the transmission of some infections, such as chlamydia, gonorrhea, and HIV.
- Be aware that not all monkeypox rashes occur in areas that a condom can cover. Even when condoms are used, direct skin-to-skin contact with infectious rash, scabs, or body fluids not covered by a condom and face-to-face monkeypox transmission can occur.
- As public health experts learn more about monkeypox transmission, this information will be updated. Having multiple or anonymous sex partners may increase your chances of getting monkeypox. Limiting your number of sex partners may reduce the possibility of exposure.

REDUCING STIGMA AND MISINFORMATION

Reducing Stigma in Monkeypox Communication and Community Engagement: How CDC is Framing Communication Around Monkeypox

- Helping people make the best-informed decisions to protect their health and the health of their community from monkeypox requires a combination of providing key prevention information to the public and working with partners and trusted messengers to ensure information reaches affected communities.
- Anyone can get monkeypox, and <u>CDC is carefully monitoring for monkeypox</u> in the United States. We are working to provide frontline healthcare providers and public health officials with information about what monkeypox looks like and how to manage the illness. Many—though not all—of the reported cases have been among gay, bisexual, or other men who have sex with men. Given this, we have put added emphasis on identifying and using specific channels that will directly reach gay and bisexual men across racial, ethnic, socioeconomic, and geographic backgrounds with messages. In addition to these focused messaging activities, we are also messaging to a wider audience using broad language that focuses on the symptoms and the behaviors that can lead to transmission of monkeypox.
- How Partners can Help Message about Monkeypox
 - Partners can help by messaging to different communities and channels to increase awareness of monkeypox, while reducing the chances of stigmatizing those who may have contact with the virus or marginalizing groups who may be assumed to be at increased risk for monkeypox. Keeping messages fact-based can help reduce stigmatizing disproportionately affected populations.
 - As you're developing resources and messages, use <u>CDC's Health Equity Guiding Principles for</u> <u>Inclusive Communication</u>.
 - O For Messages to General Audiences:
 - Promote messaging that provides information on what monkeypox is and how it is spread and that encourages seeking health care if experiencing symptoms related to monkeypox.
 - Emphasize that *anyone* can get it and promote it as a public health concern for all. Focusing
 on cases among gay, bisexual, or other men who have sex with men when messaging to a

broader audience may inadvertently stigmatize this population and create a false sense of safety among those who are not gay and bisexual men.

- When using imagery, show realistic images when depicting symptoms, not extreme cases. Include pictures of people from diverse backgrounds and racial/ethnic groups.
- O For Messages to Gay & Bisexual Men:
 - It's important to reach the gay and bisexual community, or any disproportionately affected community, with non-alarmist, fact-based messaging about monkeypox that provides people with tools they can use to protect themselves and others.
 - When focusing messages to gay, bisexual, and other men who have sex with men, use targeted channels that directly reach these audiences such as specific websites, dating apps or media programs.
 - If trying to increase perceived relevance among specific groups, use relatable/personal stories that depict people "like me" (intended audience).
 - Messaging and dissemination tactics may need to be adapted to reach the communities who need the information as we learn more about the current monkeypox outbreak.
- How Partners Can Disseminate Messages to Events
 - We encourage partners to reach out to organizers of upcoming local events to provide a situational awareness of monkeypox and offer information and messages to share. The following are some tips:
 - Conduct an environmental scan of upcoming, large-scale events in your community. Consider festivals where there may be spin-off or side events like dances and gatherings where people may have close, skin-to-skin contact with others.
 - Take an inventory of other venues where close, skin-to-skin contact can occur, such as massage parlors, spas, saunas, and sex clubs.
 - Engage trusted community-based organizations, community leaders, and community healthcare workers to connect with event organizers and affected communities.
 - Have a clear call to action. This can include raising awareness by sharing information, asking people to seek healthcare if they experience a rash, or directing community members to local healthcare providers who can coordinate testing.
 - Provide event organizers with information and materials such as:
 - Messages that can be used on websites and social media sites
 - Talking points that event organizers can use when talking with their customers or attendees
 - This letter, which organizers can download, adapt, and send to their attendees/customers
 - o <u>Download Event Organizer Letter Template</u>
 - <u>Printed materials</u> that can be passed out at events and in venues
 - A point of contact if they have more questions or need information
- It will take partnerships between healthcare providers, affected individuals, and public health officials to ensure people who need care can access it and know how to protect their loved ones.
- For further information on communicating prevention information while reducing stigma, see CDC's <u>Reducing Stigma in Monkeypox Communication and Community Engagement page</u>.

Harm reduction approaches to prevent spread through intimate contact:

• When thinking about what to do, seek information from trusted sources like the local health department. Second, consider how much close, personal, skin-to-skin contact is likely to occur at the event you plan to attend. If you feel sick or have any rashes or sores, do not attend any gathering, and see a healthcare provider.

- Festivals, events, and concerts where attendees are fully clothed and unlikely to share skin-to-skin contact are safer. However, attendees should be mindful of activities (like kissing) that might spread monkeypox.
- A rave, party, or club where there is minimal clothing and where there is direct, personal, often skin-to-skin contact has some risk. Avoid any rashes or sores you see on others and consider minimizing skin-to-skin contact when possible.
- Enclosed spaces, such as back rooms, saunas, or sex clubs, where there is minimal or no clothing and where intimate, often anonymous sexual contact occurs have a higher likelihood of spreading monkeypox.
- Vaccination is an important tool in preventing the spread of monkeypox. But given the current limited supply of vaccine, <u>consider temporarily changing some behaviors</u> that may increase your risk of being exposed. These temporary changes will help slow the spread of monkeypox until vaccine supply is adequate.
- Reducing or avoiding behaviors that increase risk of monkeypox exposure is also important when you are between your first and second shots of vaccine. Your protection will be highest two weeks after your second dose of vaccine.
- Make a habit of exchanging contact information with any new partner to allow for sexual health follow-up, if needed.
- Talk with your partner about any monkeypox symptoms and be aware of any new or unexplained rash or lesion on either of your bodies, including the mouth, genitals (penis, testicles, vulva, or vagina), or anus (butthole). If you or your partner has or recently had monkeypox symptoms, or you have a new or unexplained rash anywhere on your body, do not have sex and see a healthcare provider. In some cases, symptoms may be mild, and some people may not even know they have monkeypox.
- If you or a partner has monkeypox or think you may have monkeypox, the best way to protect yourself and others is to avoid sex of any kind (oral, anal, vaginal) and kissing or touching each other's bodies—while you are sick. Especially avoid touching any rash. Do not share things like towels, fetish gear, sex toys, and toothbrushes.
- Even if you feel well, here are some ways to reduce your chances of being exposed to monkeypox if you are sexually active:
 - Take a temporary break from activities that increase exposure to monkeypox until you are two weeks after your second dose. This will greatly reduce your risk.
 - Limit your number of sex partners to reduce your likelihood of exposure.
 - Spaces like back rooms, saunas, sex clubs, or private and public sex parties, where intimate, often anonymous sexual contact with multiple partners occurs—are more likely to spread monkeypox.
 - Condoms (latex or polyurethane) may protect your anus (butthole), mouth, penis, or vagina from exposure to monkeypox. However, condoms alone may not prevent all exposures to monkeypox since the rash can occur on other parts of the body.
 - Gloves (latex, polyurethane, or nitrile) might also reduce the possibility of exposure if inserting fingers or hands into the vagina or the anus. The gloves must cover all exposed skin and be removed carefully to avoid touching the outer surface.
 - Avoid kissing or exchanging spit since monkeypox can spread this way.
 - Masturbate together at a distance without touching each other and without touching any rash.
 - Have virtual sex with no in-person contact.
 - Consider having sex with your clothes on or covering areas where rash is present, reducing as much skin-to-skin contact as possible. Leather or latex gear also provides a barrier to skin-to-skin contact; just be sure to change or clean clothes/gear between partners and after use.

- Be aware that monkeypox can also spread through respiratory secretions with close, face-to-face contact.
- Remember to wash your hands, fetish gear, sex toys, and any fabrics (bedding, towels, clothes) after having sex.