

MONKEYPOX

UPDATE



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DEPARTMENT OF COMMUNITY MEDICINE

SREE GOKULAM MEDICAL COLLEGE & RESEARCH FOUNDATION

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SYMPTOMATOLOGY OF MONKEYPOX: AN OVERVIEW

EDITORIAL: DR.BENNY PV, PROFESSOR & HOD, SREE GOKULAM MEDICAL COLLEGE

OVERVIEW

Monkeypox can cause a range of signs and symptoms. While some people have mild symptoms, others may develop more severe symptoms that require treatment in a medical facility. People at higher risk for serious illness or complications include pregnant women, children, and people with compromised immune systems.

The most common symptoms of monkeypox are fever, headache, muscle aches, back pain, lack of energy and swollen lymph nodes. This is followed or accompanied by the development of a rash that may last two to three weeks. The rash can appear on the face, palms, soles, eyes, mouth, throat, groin, and the genital and/or anal areas of the body. The number of lesions can vary from one to several thousand. The lesions start out flat, then fill with fluid before scabbing, drying, and shedding, creating a fresh layer of skin underneath.

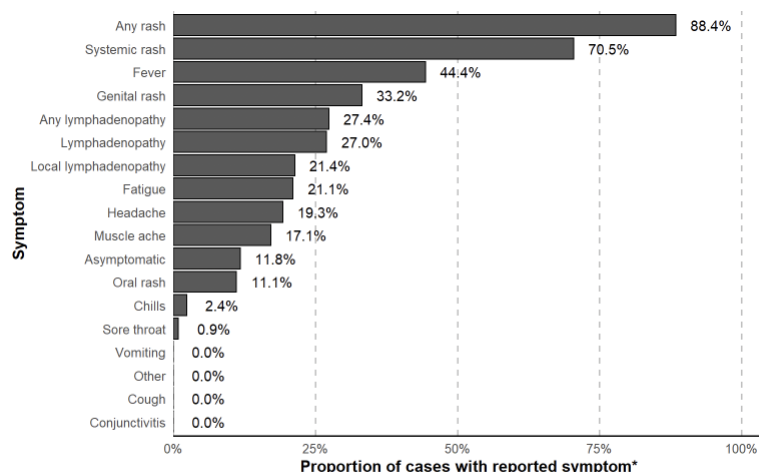
Symptoms typically last two to three weeks and usually go away on their own or with supportive care, such as medication for pain or fever. People

remain infectious until all of the lesions have crusted over, the scabs fallen off and a new layer of skin has formed underneath. Anyone who has symptoms that could be monkeypox or who has been in contact with someone who has monkeypox should call or visit a health care provider and seek their advice.

MOST COMMON SYMPTOM

Among the cases who reported at least one symptom, the most common symptom is **any rash** and is reported in **88%** of cases with at least one reported symptom. Note that identifying true denominators for symptomatology is difficult due to a general lack of negative reporting and symptom definitions that may vary between countries' reporting systems.

A bar chart and table showing symptoms is shown below. Here **ANY RASH** refers to one or more rash symptoms (systemic, oral, genital, or unknown location), and **ANY LYMPHADENOPATHY** refers to either general or local lymphadenopathy.



Source: WHO
 *6589 cases with at least one reported symptom from a country where at least two unique symptoms reported used as denominator

CURRENT SCENARIO OF MONKEYPOX IN INDIA

REVIEW ARTICLE: DR.DEVI VIDHYADHARAN, TUTOR, DEPARTMENT OF COMMUNITY MEDICINE

The first laboratory confirmed case of monkeypox in WHO South-East Asia Region has been reported from India, in a 35-year-old man who arrived from UAE on July 12. All his contacts were identified and 11 of his co-passengers, his family members, an auto-driver, a taxi driver and a dermatologist of a private hospital, where the infected person sought treatment first, are kept under observation. On July 18, Kerala govt informed about the second confirmed case of monkeypox in the state. The person landed at the Mangalore airport in coastal Karnataka from Dubai. He was admitted to a hospital after he exhibited symptoms of the disease. His samples were sent to NIV Pune and they tested positive for monkeypox. The central government has directed screening of all international travellers arriving in the country and a high-level central multi-disciplinary team of specialists was dispatched to help the health department of Kerala. India have been taking measures to rapidly detect and take appropriate measures to prevent spread of monkeypox. On 18th July, the Union Ministry of Health and Family Welfare had reviewed the functioning of health screening of international travellers arriving

in India at airports and seaports. The Kerala government had started testing for monkeypox infection at the Alappuzha NIV with testing kits brought from NIV, Pune from 19th July 2022.

On 20th July 2022 the Kerala state government issued Standard Operating Procedures (SOP) for isolation, sample collection and treatment of those infected or showing signs of monkeypox disease. In the state assembly, the Health Minister said that there was no need to be concerned about monkeypox, but the people should take precautionary measures like wearing masks and using sanitisers to prevent spread of the disease, suspected and probable cases of monkeypox are to be treated separately and in isolation and the District Surveillance Officer (DSO) should be informed immediately. Samples should be collected as per the protocols laid down for the same by the National Institute of Virology (NIV) and the DSO would be responsible for sending the same to the lab. Referrals from private hospitals to government facilities should be on patient request and only critically ill patients from state-run hospitals with isolation facilities should be referred to medical

colleges. While transporting infected persons from to a hospital or from one medical institution to another, PPE kit, N95 masks, gloves and goggles should be worn by the health professionals and the patients too should wear an N95 or triple layered mask and any wounds on their bodies should be covered. After patient delivery, the ambulance and equipment therein should be disinfected and the patient's items like clothing, should be disposed of. Confirmed cases of monkeypox should be managed as per the Centre's guidelines.

India's third monkeypox was confirmed on 22nd July 2022 in a 35-year-old man who returned to Malappuram from UAE who was admitted with fever at Manjeri Medical College Hospital. His family and close contacts under observation.

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EPIDEMIOLOGY OF MONKEYPOX

REVIEW ARTICLE: DR.DIVIJA, ASSOCIATE PROFESSOR, DEPARTMENT OF COMMUNITY MEDICINE

INTRODUCTION

Monkey pox is a viral zoonotic disease that is endemic to western and central Africa and occurs in proximity to tropical rainforests. It is a self-limiting disease lasting 2 to 4 weeks and has symptoms that are similar to small pox; fever, lymphadenopathy and rash. Smallpox is another Orthopoxvirus infection eradicated in 1980. With the cessation of smallpox vaccine in post eradication, monkeypox has emerged as the most important orthopoxvirus for public health. However, monkeypox is less contagious than smallpox and causes less severe illness. The case fatality ratio is approximately 3 to 6 %.

OUTBREAKS

Monkeypox was first identified among humans in 1970s in the Democratic Republic of Congo in a 9 month old boy. Smallpox had been eliminated here in 1968. Ever since several outbreaks have been reported rural rainforests of the Congo Basin, and across central and west Africa. Human cases of monkeypox have been reported from 11 African countries: Benin, Cameroon, Central Africa Republic, Democratic Republic of Congo, Gabon, Cote d'Ivoire, Liberia, Sierra Leone, South Sudan and Nigeria and the Republic of Congo. In 2003 the first monkeypox outside Africa was in the USA, which was linked to contact with infected pet prairie dogs which had been housed with Gambusian rats and dormice imported from Ghana.

In May 2022, multiple cases of monkeypox were identified in several non-endemic countries (Figure1).

Epidemic curve shown for cases reported up to 18 Jul 2022 to avoid showing incomplete weeks of data.

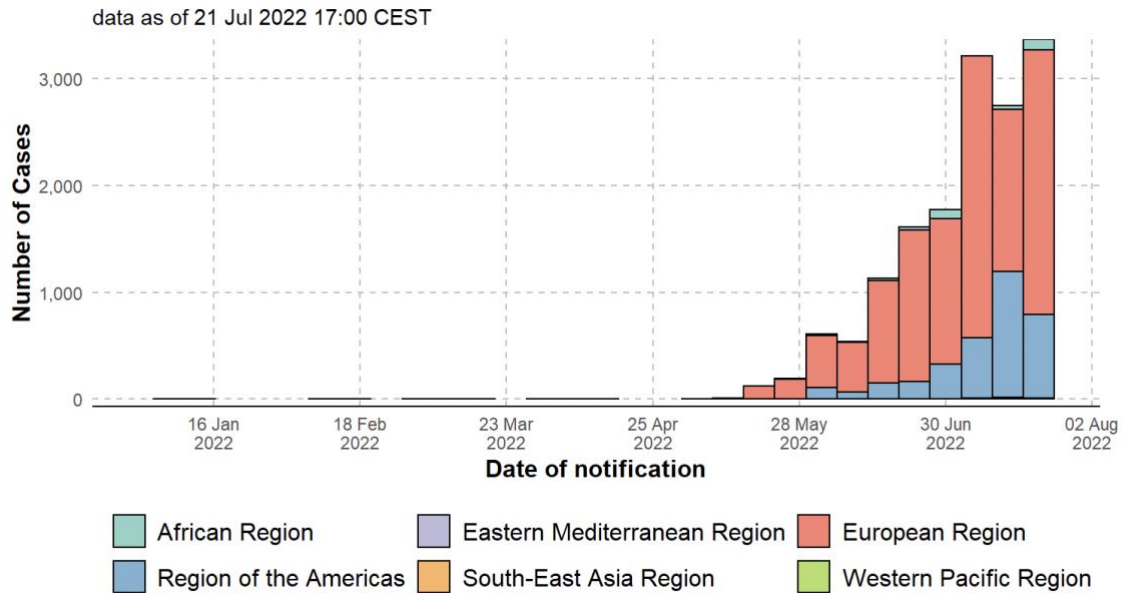


Figure 1: Weekly update of Monkeypox cases

AGENT FACTORS

Monkeypox virus (MPXV) is a double stranded DNA virus, belonging to *Orthopoxvirus* genus and *Poxviridae* family. There are 2 distinct genetic clades: the central African (Congo Basin) clade and the west African clade. The Congo Basin clade is more severe (Figure 2).



Figure 2: Monkeypox virus (MPXV)

HOST FACTORS

Rope squirrels ,Tree squirrels, Gambian pouched rats, dormice and non-human primates are identified as susceptible to monkey pox virus. There is uncertainty regarding the natural history of monkey pox virus and further studies are needed to identify the reservoir and virus circulation in nature (Figure 3).

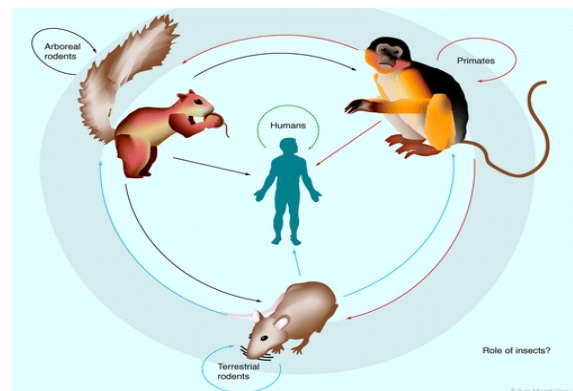


Figure 3: primates susceptible to monkey pox virus

MODE OF TRANSMISSION

Monkeypox is transmitted through close contact with infected individuals or animals, or materials contaminated with the virus.

Person to person transmission occurs through close contact with body fluids, skin lesions, respiratory droplets and contaminated materials of an infected person (Figure 4). Droplet transmission requires prolonged face to face contact and therefore health workers, household members and other contacts are at risk.

Transmission can also occur from infected mother to foetus through the placenta (congenital monkey pox) or close contact during and after birth. While transmission can occur via close contact, there is lack of clarity regarding sexual transmission.

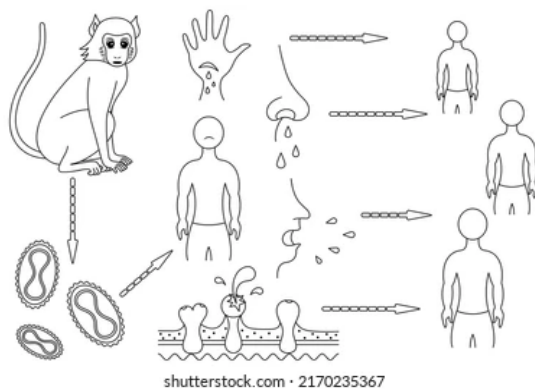


Figure 4: Monkeypox transmission

Animal to human contact (zoonoses) can occur from direct contact with the blood, body fluids, or mucosal/cutaneous lesions of infected animals. Eating inadequately cooked meat and other animal products of infected animals is a possible risk factor and people living near forest areas may have risk of indirect or low level exposure to infected animals.

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CLINICAL PRESENTATION OF MONKEYPOX

REVIEW ARTICLE: DR.HARSHA LAIS, ASSISTANT PROFESSOR, DEPARTMENT OF COMMUNITY MEDICINE

Clinical presentation resembles smallpox but is less severe. Symptoms can vary depending on different factors, including exposure characteristics, age, presence of conditions that alter immune response, previous immunity for smallpox and viral strain.

MONKEYPOX INFECTION HAS TWO CLINICAL PHASES

A prodromal illness that lasts between 1 to 5 days characterized by fever, intense headache, lymphadenopathy, back pain, myalgia, fatigue. Other symptoms have been also described, such as sore throat, cough and less frequently, vomiting or diarrhoea. In some cases, no prodromal symptoms were reported or these symptoms occurred after the beginning of the rash.

A SKIN RASH THAT BEGINS 1-5 DAYS AFTER FEVER

The rash evolves from macules, papules, vesicles then pustules, before crusting, which then scale off. Lesions are frequently painful and can be pruritic. Lesions of different clinical stages can be present at the same moment (Figure 1).

The number of lesions and affected regions can vary, Lesion can be found on all parts of the body, including palmar and plantar areas. In the current outbreak, lesions frequently begin and affect the genital, anal and oral areas. Some cases developed proctitis (for ex. rectal pain, bloody stools, diarrhea). Facial lesions can potentially lead to ocular involvement, affecting the conjunctivae and cornea.

SYMPTOMS LAST 2 TO 4 WEEKS

Children, pregnant women and some immunocompromised individuals are considered at higher risk for severe disease. Recent cases in Canada and western countries have been described as mild. Since May 2022, no deaths have been reported in western countries. Long-term skin effects, such as prolonged ulcer healing and scarring, have been described in the literature. Complications can include secondary infections (for example, cellulitis), and less frequently pneumonia, sepsis, encephalitis and keratitis leading to vision loss.



Figure 1 : Skin lesions at various stages



DIFFERENTIAL DIAGNOSIS

Given the epidemiology of the cases confirmed thus far in Europe and North America, clinicians should be aware of the differential diagnosis as lesions associated with monkeypox can resemble several other infections, including:

- Herpesviruses (e.g. herpes simplex virus, varicella zoster virus [i.e. shingles and chicken pox])
- Syphilis (*Treponema pallidum*)
- Chancroid (*Haemophilus ducreyi*)
- Other poxviruses (e.g. molluscum contagiosum)
- Lymphogranuloma venereum (LGV)

Features of monkeypox virus infection may overlap with sexually transmitted infections (STI), and co-infections are possible. For each individual, consider risk-informed STI testing.

TRANSMISSION

PERIOD OF COMMUNICABILITY

During the symptomatic period, including the prodrome. Lesions are considered infectious until the scabs fall off and new skin can be seen.

MODES OF TRANSMISSION

Monkeypox doesn't generally spread easily between people. Most historical transmissions occurred through close contact with infected animals (bite, scratch or ingesting meat). The current global outbreak, however, is facilitated by human to human transmission.

HUMAN-TO-HUMAN TRANSMISSION OCCURS VIA:

- Direct contact with cutaneous or mucosal lesions;
- Fomites, i.e. contaminated material such as linens or clothing;
- Respiratory droplets from prolonged face-to-face contact.

Monkeypox has been detected in many body sites, including semen. However, the significance of this finding on the potential for sexual transmission through semen is not yet known. Transmissions in the context of sexual activity are likely related to close contact as described above.

Monkeypox virus can cross the placental barrier. No case of vertical transmission has been reported in non-endemic countries. However, a case of fatal infection with pathological signs of monkeypox has been described from an endemic country, indicating the potential for vertical transmission.

CASE DEFINITIONS FOR MONKEYPOX

SUSPECT CASE

New characteristic rash* OR meets one of the epidemiologic criteria and has a high clinical suspicion† for monkeypox.

PROBABLE CASE

- No suspicion of other recent Orthopoxvirus exposure (e.g., Vaccinia virus in ACAM2000 vaccination) AND
- Demonstration of the presence of Orthopoxvirus DNA by polymerase chain reaction of a clinical specimen OR Orthopoxvirus using immunohistochemical or electron microscopy testing methods.
- Demonstration of detectable levels of anti-orthopoxvirus IgM antibody during the period of 4 to 56 days after rash onset.

CONFIRMED CASE

Demonstration of the presence of Monkeypox virus DNA by polymerase chain reaction testing or Next-Generation sequencing of a clinical specimen OR isolation of Monkeypox virus in culture from a clinical specimen.

PUBLIC HEALTH RESPONSE TO MONKEYPOX OUTBREAK

REVIEW ARTICLE: DR. MARIYAM ALEX, ASSISTANT PROFESSOR, DEPARTMENT OF COMMUNITY MEDICINE

INTERNATIONAL RESPONSE

WORLD HEALTH ORGANIZATION (WHO)

17 May 2022 onwards: Disease Outbreak News on the Multi-country outbreak of Monkeypox issued by the WHO. Monkeypox endemic countries are: Benin, Cameroon, the Central African Republic, the Democratic Republic of the Congo, Gabon, Ghana (identified in animals only), Côte d'Ivoire, Liberia, Nigeria, the Republic of the Congo, and Sierra Leone. Benin and South Sudan have documented importations in the past. Countries currently reporting cases of the West African clade are Cameroon and Nigeria. With this case definition, all countries except these four should report new cases of monkeypox as part of the current multi-country outbreak.

23 June 2022: The first meeting of IHR Emergency Committee on the multi-country outbreak of monkeypox held its first meeting on 23 June 2022

24 June 2022: Interim guidance on vaccination, surveillance, case investigation and contact tracing were issued on 24th June

21 July 2022: The second meeting of IHR Emergency Committee on the multi-country outbreak of monkeypox was held. In a press conference that followed on 23 July 2022, the WHO Director-General determined the event to constitute a Public Health Emergency of International Concern (PHEIC) and issued Temporary Recommendations to States Parties. Temporary recommendations include health measures to be implemented by the State Party experiencing the PHEIC, or by other States Parties, to prevent or reduce the international spread of disease and avoid unnecessary

interference with international traffic. The recommendations require reviews every 3 months. Public Health Emergency of International Concern (PHEIC):

A PHEIC is defined in the IHR (2005) as, “an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response”.

The IHR decision algorithm assists WHO Member States in deciding whether a potential PHEIC exists and the WHO should be notified. The WHO should be notified if any two of the four following questions are affirmed:

1. Is the public health impact of the event serious?
2. Is the event unusual or unexpected?
3. Is there a significant risk for international spread?
4. Is there a significant risk for international travel or trade restrictions?

3 OUT OF 4 CRITERIA WERE MET FOR MONKEYPOX

PUBLIC HEALTH MEASURES

ISOLATION AND MANAGEMENT OF CASES



Figure 1: Isolation of Monkeypox

SURVEILLANCE

Surveillance case definitions have been published for suspect, probable and confirmed cases of monkeypox. Identified cases are to be notified to national public authorities and to WHO through IHR focal points

CONTACT TRACING

Based on current epidemiology and monitoring of contacts for minimum of 21 days for symptom onset

RING IMMUNISATION

Ring immunisation of close contacts wherever vaccines are available. For contacts of cases, post-exposure prophylaxis (PEP) is recommended with an appropriate second- or third-generation vaccine, ideally within four days of first exposure to prevent onset of disease. Mass vaccination is not required nor recommended for monkeypox at this time.

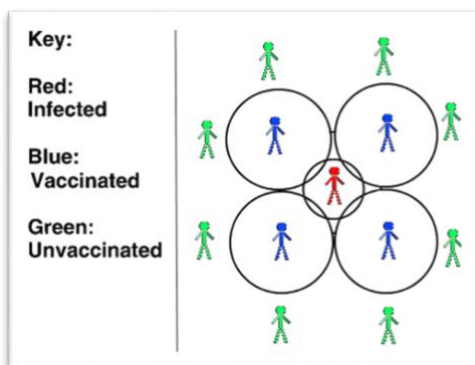


Figure 5: Concept of Ring Immunization

Vaccination programmes must be backed by thorough surveillance and contact-tracing, and accompanied by a strong information campaign, robust pharmacovigilance, ideally in the context of collaborative vaccine effectiveness studies with standardized protocols and data collection tools. Decisions on use of smallpox or monkeypox vaccines should be based on a full assessment of risks and benefits on a case-by-case basis

HEALTH WORKERS CARING

Health workers caring for patients with suspected or confirmed monkeypox should implement standard, contact and droplet infection control precautions. Pre-exposure prophylaxis (PrEP) is recommended for health workers at risk, laboratory personnel working with orthopox viruses, clinical laboratory staff performing diagnostic testing for monkeypox, and others who may be at risk as per national policy.

GENOMIC SEQUENCING

Wherever available, have been undertaken to determine the monkeypox virus clade(s) in this outbreak. No international trade and travel restrictions have been imposed thus far for monkeypox

NATIONAL LEVEL RESPONSE (INDIA)

India had issued guidelines for Monkeypox management even before the first infection was detected. The Union government and several state governments have stepped up their measures against Monkeypox in the light of infections in India and abroad. Designated hospitals have been identified for isolation management of monkey pox cases.

In May, the Union Health Ministry had directed the National Centre for Disease Control and the Indian Council of Medical Research to keep a close watch on the situation. Airport and port health officers were also asked to be vigilant. Any sick passenger with a travel history to Monkeypox-affected countries be isolated and samples sent to the BSL-

4 facility of the National Institute of Virology in Pune for an investigation

The Union Health Ministry has also published detailed guidelines that cover various aspects of Monkeypox management, such as collection of samples, isolation and treatment of patients, and contact tracing.

The monkeypox virus strain has been isolated by Indian Council of Medical Research-National Institute of Virology, Pune. The institution has invited an Expression of Interest (EOI), proposing to handover the strain to industry partners for development of indigenous vaccine and diagnostic kits for the disease. Isolation of virus strains is the first step towards expediting the development of drugs, vaccines and rapid diagnostic kits in the country.

STATE LEVEL RESPONSE (KERALA)

Kerala reported India's first three cases of monkeypox in persons who had travelled from overseas. Help desks have been set up in all the four international airports in Kerala. They are manned by trained personnel, and would help detect symptoms of monkeypox in those coming from abroad, provide them with expert care and resolution of queries

Extensive training has been provided for doctors and officials of local bodies regarding surveillance, reporting, management and care of monkeypox cases in Kerala based on the national guidelines. Facilities for isolation and Treatment have been set up in each district

Testing and surveillance have been intensified across the state. The Alappuzha unit of the National Institute of Virology (NIV) has started running the

diagnostic tests for distinguishing monkeypox virus from clinical specimens. All 28 State laboratories with RT-PCR testing facilities are equipped to conduct monkeypox testing. However, as a first step, test kits were given to the NIV lab at Alappuzha. Random samples of cases with symptoms similar to chickenpox from districts are also being sent to Alappuzha lab now. As the disease is a newly reported one in the State, utmost biosafety-level precautions are being maintained in conducting the tests. Primary contacts of the three infected persons in the state have tested negative.

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MONKEY POX PREVENTION AND TREATMENT

Review Article: Dr. Jithu SJ Nath, Assistant Professor, Department of Community Medicine

PREVENTION STEPS

TAKE THE FOLLOWING STEPS TO PREVENT GETTING MONKEYPOX:

- Avoid close, skin-to-skin contact with people who have a rash that looks like monkeypox.
- Do not touch the rash or scabs of a person with monkeypox.
- Do not kiss, hug, cuddle or have sex with someone with monkeypox.
- Do not share eating utensils or cups with a person with monkeypox.
- Do not handle or touch the bedding, towels, or clothing of a person with monkeypox.
- Wash your hands often with soap and water or use an alcohol-based hand sanitizer.
- Also, avoid sick or dead animals, as well as bedding or other materials they have touched.

IF YOU HAVE AN ACTIVE RASH OR OTHER SYMPTOMS,

- Isolate at home
- Stay in a separate room or area away from people or pets you live with, when possible.

TREATMENT

There are no treatments specifically for monkeypox virus infections. However, monkeypox and smallpox viruses are genetically similar, which means that antiviral drugs and vaccines developed to protect against smallpox may be used to prevent and treat monkeypox virus infections. Antivirals,

such as tecovirimat (TPOXX), may be recommended for people who are more likely to get severely ill, like patients with weakened immune systems. If you have symptoms of monkeypox, you should talk to your healthcare provider, even if you don't think you had contact with someone who has monkeypox.

VACCINATION



CDC recommends vaccination for people who have been exposed to monkeypox and people who are at higher risk of being exposed to monkeypox, including:

- People who have been identified by public health officials as a contact of someone with monkeypox.
- People who may have been exposed to monkeypox, such as: 1) People who are aware that one of their sexual partners in the past 2 weeks has been diagnosed with monkeypox If you are sick with monkey pox 2) People who had multiple sexual partners in the past 2 weeks in an area with known monkeypox

- People whose jobs may expose them to orthopoxviruses, such as: 1) Laboratory workers who perform testing for orthopoxviruses 2) Laboratory workers who handle cultures or animals with orthopoxviruses to some designated healthcare or public health workers.

Vaccination against smallpox was demonstrated through several observational studies to be about 85% effective in preventing monkeypox. Thus, prior smallpox vaccination may result in milder illness. Evidence of prior vaccination against smallpox can usually be found as a scar on the upper arm. At the present time, the original (first-generation) smallpox vaccines are no longer available to the general public. Some laboratory personnel or health workers may have received a more recent smallpox vaccine to protect them in the event of exposure to orthopoxviruses in the workplace. A still newer vaccine based on a modified attenuated vaccinia virus (Ankara strain) was approved for the prevention of monkeypox in 2019. This is a two-dose vaccine for which availability remains limited. Smallpox and monkeypox vaccines are developed in formulations based on the vaccinia virus due to cross-protection afforded for the immune response to orthopoxviruses.

AVAILABLE VACCINES

Two vaccines licensed by the U.S. Food and Drug Administration (FDA) are available for preventing monkeypox infection:

- JYNNEOS (also known as Imvamune or Imvanex) and
- ACAM2000

There is currently a limited supply of JYNNEOS, although more is expected in coming weeks and months, but, there is an ample supply of ACAM2000. However, this vaccine should not be used in people who have some health conditions, including a weakened immune system, skin conditions like atopic dermatitis/eczema, or pregnancy.

No data are available yet on the effectiveness of these vaccines in the current outbreak. People are

considered fully vaccinated about 2 weeks after their second shot of JYNNEOS and 4 weeks after receiving ACAM2000. However, people who get vaccinated should continue to take steps to protect themselves from infection by avoiding close, skin-to-skin contact, including intimate contact, with someone who has monkeypox. Vaccine Strategies to Prevent Monkeypox When properly administered before or after a recent exposure, vaccines can be effective tools at protecting people against monkeypox illness.

The following vaccination strategies are being used in the United States: Monkeypox Vaccine Post-Exposure Prophylaxis (PEP)

- For the current outbreak, this approach can be considered as “standard PEP” for monkeypox. People can be vaccinated following exposure to monkeypox to help prevent illness from monkeypox virus. It is important that states and other jurisdictions identify contacts of confirmed or probable monkeypox cases to offer vaccine for PEP and to monitor for any early signs of illness.
- CDC recommends that the vaccine be given within 4 days from the date of exposure for the best chance to prevent onset of the disease.
- If given between 4 and 14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease. However, when coupled with self-isolation and other prevention measures when symptoms first occur, PEP is important for controlling outbreaks and preventing further transmission of monkeypox. Outbreak Response Monkeypox Vaccine Post-Exposure Prophylaxis (PEP)++
- For the current outbreak, this expanded approach can be considered as “individual-directed PEP” for monkeypox; public health officials refer to it as “expanded PEP” or “PEP plus-plus” or “PEP++”.
- People with certain risk factors are more likely to have been recently exposed to monkeypox. The PEP++ approach aims to reach these people for post-exposure prophylaxis, even if they have not had documented exposure to someone with confirmed monkeypox.

- When coupled with self-isolation and other prevention measures when symptoms first occur, PEP++ may help slow the spread of the disease in areas with large numbers of monkeypox cases—which would suggest a higher level of monkeypox virus transmission. Monkeypox Vaccine Pre-Exposure Prophylaxis (PrEP)
- This approach refers to administering vaccine to someone at high risk for monkeypox (for example, laboratory workers who handle specimens that might contain monkeypox virus).
- At this time, most clinicians in the United States and laboratorians not performing the orthopoxvirus generic test to diagnose orthopoxviruses, including monkeypox virus, are not advised to receive monkeypox vaccine PrEP.

JYNNEOS

- JYNNEOS contains a live virus that does not replicate efficiently in human cells. Administered as two subcutaneous injections four weeks apart. The immune response takes 2 weeks after the second dose for maximal development. Licensed by the FDA for use in the prevention of smallpox or monkeypox in people ages 18 years and older. Use in younger populations requires submission of a single patient Expanded Access Investigational New Drug (IND) application.

ACAM2000

- ACAM2000 is a live Vaccinia virus vaccine that is replication competent.
- Administered as one percutaneous dose via multiple puncture technique with a bifurcated needle.

- The immune response takes 4 weeks for maximum development.
- Following a successful inoculation, a lesion (known as a “take”) will develop at the site of the vaccination; the lesion may take up to 6 weeks or more to heal.
- Licensed by the FDA for use against smallpox; allowed for use against monkeypox under an Expanded Access IND, which requires informed consent along with submission of additional forms.
- The effectiveness of ACAM2000 is supported by human clinical trials and animal studies.
- There are no data on the efficacy of ACAM2000 for PEP or PrEP from the current outbreak.
- Adverse reactions include injection site pain, swelling, and redness; fever; rash; lymph node swelling; and complications from inadvertent inoculation.
- People with severe allergy to any component of the vaccine should not receive it. In addition, people with severely weakened immune systems should not receive this vaccine.

ACAM2000 SHOULD NOT BE GIVEN TO PEOPLE WITH THE FOLLOWING CONDITIONS:

- Cardiac disease
- Eye disease treated with topical steroids
- Congenital or acquired immune deficiency disorders, including those taking immunosuppressive medications and people living with HIV (regardless of immune status)
- Atopic dermatitis/eczema and persons with a history of atopic dermatitis/eczema or other acute or exfoliative skin conditions
- Infants less than 12 months of age
- Pregnancy