Monkeypox Multi-Country Outbreak Update for Virginia

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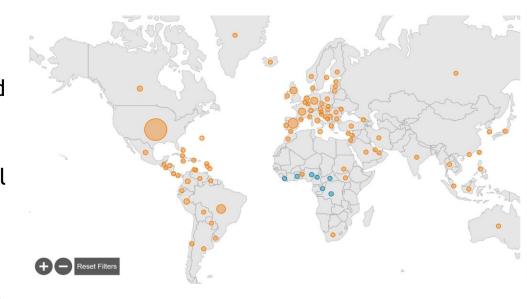


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Current Situation: Worldwide

- In 2022, cases identified in 102 countries
- 56,026* cases have been confirmed (for monkeypox or orthopoxvirus)
- 17 deaths have been reported
- Majority have no established travel link to endemic countries
- Many, but not all, cases have occurred in gay, bisexual, or other men who have sex with men (MSM)





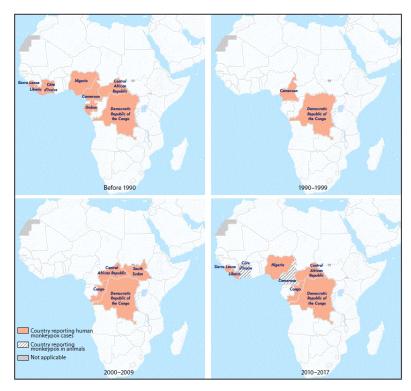
^{*}As of 9/7/22

Monkeypox - Endemic Countries

Monkeypox occurs naturally in these central and west African countries:

- Cameroon
- Central African Republic
- Democratic Republic of the Congo (DRC)
- Gabon
- Ghana (identified in animals only)
- Ivory Coast
- Liberia
- Nigeria
- Republic of the Congo
- Sierra Leone

Past importations: Benin and South Sudan



Emergence of Monkeypox — West and Central Africa, 1970–2017

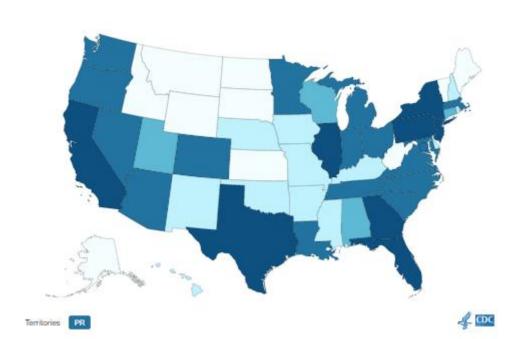


Monkeypox virus

- Uncertainty remains as to the animal reservoir of the monkeypox virus
 - Some African rodents and non-human primates are hosts
- Historically, monkeypox disease has been rare
 - First human case in DRC in 1970.
 - Sporadic exported cases outside of central and western African countries



United States



- In 2022, 21,274* monkeypox cases have been reported in the United States, including 389 cases in Virginia
- Texas reported first death in patient associated with monkeypox on August 30, but unknown if it caused the death

*As of 9/7/22



Data in Virginia

- VDH data dashboard summarizes case data
- As of 9/7/22:
 - 389 confirmed cases, 16 hospitalizations, 0 deaths
 - 98% male
 - Predominantly middle age groups (20-29, 30-39 years)
 - Majority of cases have reported race/ethnicity as Black, followed by white and Latino

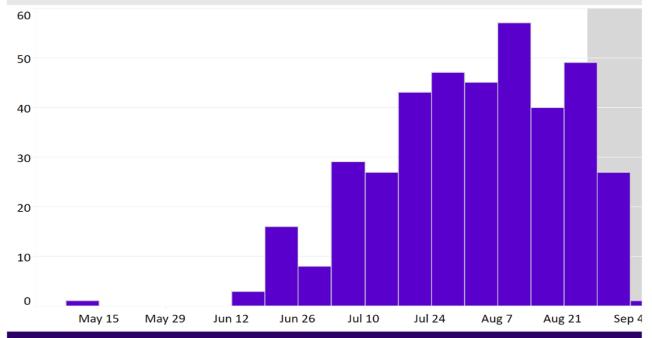




Virginia Epidemic Curve

Number of Cases by Week

The graph shows the number of monkeypox cases reported to VDH by the date closest to when the person became or got tested for the monkeypox virus.



Virginia

- VDH investigates all reported suspect cases and facilitates laboratory testing, if needed
- VDH asks healthcare providers to immediately report suspected cases to local health department (LHD), even if testing is being conducted at a commercial laboratory
- When cases are detected, VDH identifies close contacts and monitors them based on level of exposure
- VDH also monitors Virginia residents who are close contacts of case-patients in other states or jurisdictions



Risk Assessment

- Risk for most people in the U.S. is currently low. The highest risk is among MSM, especially those with multiple or anonymous sex partners.
- WHO assesses the global risk as Moderate.
 - On July 23, WHO Director-General declared this outbreak a public health emergency of international concern.
- On Aug 4, HHS Secretary Becerra declared monkeypox a **public health emergency**.

- Situation is rapidly evolving
- Healthcare providers should be on alert for patients with signs and symptoms (sometimes symptoms appear like sexually transmitted infections (STIs))



Clinical Features & Info, VDH Treatment and Vaccination Strategies



Monkeypox Virus Virology

- Orthopoxvirus genus
 - Genus includes variola virus (causes smallpox), vaccinia virus (used in smallpox vaccine), cowpox virus, and monkeypox
- Monkeypox virus clades renamed by WHO experts in August 2022
 - Clade two (II) is the former West Africa clade
 - Historically, caused less severe disease
 - Clade II has been identified in current outbreak
 - Consists of two subclades: Clade IIa and Clade IIb
 - Clade IIb is largely circulating in current outbreak
 - Clade one (I) is the former Central Africa clade (Congo Basin clade)
 - Causes more severe disease



Monkeypox Transmission in Current Outbreak

- Close contact with lesions, body fluids, contaminated materials (e.g., bedding, towels), or large respiratory droplets
 - While many cases have been in people who identify as MSM, <u>anyone</u> can get and spread monkeypox through close contact
- Incubation Period: 3-17 days
- Infectious Period: Symptom onset until skin lesions scabbed over and fallen off
- Scientists are researching
 - If the virus can spread when someone has no symptoms
 - How often monkeypox spread through respiratory secretions, or when a person with monkeypox symptoms might be more likely to spread the virus through respiratory secretions
 - Extent of spread through contaminated objects
 - If it can spread via semen, vaginal fluids, urine, or feces



Monkeypox: Overview of VDH Response

- Coordinating testing of potential cases
 - Case isolation and evaluation for treatment
- Identifying and monitoring contacts of cases
 - Evaluating exposure risk, monitoring symptoms for 21 days, and coordinating postexposure prophylaxis (PEP) when needed
- Clinician Outreach
 - Clinician letters, webinars, websites, social media
- General Public
 - Media interviews, websites, social media, information sharing to targeted audiences
- Coordinating with laboratory and federal partners
- Developing targeted enhanced surveillance strategies to actively identify cases



Clinical Features

- Prodrome = fever, chills, headache, back pain, fatigue, adenopathy
- Rash occurs 1-3 days after prodrome
 - Oral mucosal lesions
 - Cutaneous lesions progress through sequential stages macules, papules, vesicles, pustules, scabs
- Illness generally self-limited and lasts <u>2-4 weeks</u>
 - Lesions can be very painful and itchy
- Atypical presentations noted among some cases in current outbreak
 - Localized rash (oral, perigenital and/or perianal distribution) and painful lymphadenopathy
 - No prodrome
 - Lesions in an area can be in different stages
- Differential diagnoses = secondary syphilis, chancroid, herpes, chickenpox, shingles



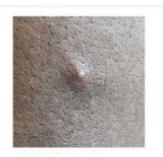
Key Characteristics of Rash

Well circumscribed, firm, deep-seated lesions that often develop umbilication

During the current global outbreak:

- Lesions often occur in genital and anorectal areas or in the mouth
- Rash is not always disseminated across many sites on the body
- Rash may be confined to only a few lesions or only a single lesion
- Rash does not always appear on palms and soles















Patient Evaluation & Diagnosis

- History CDC Epidemiologic Criteria
 - Close contact with someone with a similar rash or who received a diagnosis of confirmed or probable monkeypox
 - Sexual contact with individuals in a social network experiencing monkeypox activity.
 - Travel outside the US to a country with confirmed cases of monkeypox or where
 Monkeypox virus is endemic
 - Animal exposures with a dead or live wild animal or exotic pet that is an African endemic species or used a product derived from such animals (e.g., game meat, creams, lotions, powders, etc.)
- <u>Isolate patient</u> standard and transmission-based precautions
- Contact LHD immediately to report suspected case
 - LHD Locator: vdh.virginia.gov/health-department-locator/



Testing

- VDH encourages providers to use commercial labs (Aegis, LabCorp, Mayo Medical Labs, Quest, and Sonic Healthcare)
 - Testing is not free and out-of-pocket costs will vary
 - Refer to lab for test ordering and specimen collection information
 - Labs may send positive specimens to CDC for additional characterization
- Public health testing at DCLS is available at no cost for patients who meet clinical and epidemiologic criteria
 - Preapproval by LHD is required at this time
 - Consider testing for other concurrent infections
- Regardless of lab, providers should immediately report any suspected case to LHD so LHD can prepare for treatment and PEP



Supportive Care for All Patients

- Assess and provide supportive care for management of pain, skin and oral lesions, proctitis, gastrointestinal symptoms
- Examples include:
 - Over-the-counter or prescription pain medications for discomfort
 - Oral antihistamines for pruritic skin lesions
 - Rehydration for fluid losses
 - Anti-emetics for nausea and vomiting
 - Sitz baths for proctitis or painful lesions in the genital and anal areas



Treatment Options

- No specific treatment approved in the U.S. but there are treatment options that may prove beneficial for people who are more likely to get severely ill (e.g. weakened immune systems)
- Can be accessed through the federal government and LHDs under an expanded access investigational (EA-IND) protocol
- Providers should make requests for medications and vaccines through their local health department as part of case investigation process

Treatment Option	Indication	Formulations Available
Tecovirimat (TPOXX or ST-246) *antiviral	FDA approved for the treatment of smallpox in adults and children >3 kg	Oral (200 mg capsule)* Injection for intravenous administration *ability to mix with semi-solid food for pediatrics < 13 kg
Cidofovir (Vistide) *antiviral	FDA approved for treatment of cytomegalovirus retinitis in patients with AIDS	Intravenous infusion single-unit vial
Vaccinia Immune Globulin Intravenous (VIGIV)	FDA licensed for treatment of complications due to vaccinia vaccination	Intravenous infusion single-dose vial

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To protect the health and promote the
well-being of all people in Virginia.

Treatment Options

- CDC is currently developing an expanded access investigational new drug (EA-IND) protocol to help facilitate use of brincidofovir as a treatment option for monkeypox
- However, brincidofovir is not currently available from the Strategic National Stockpile (SNS)

Treatment Option	Indication	Formulations Available
Brincidofovir (Tembexa) *antiviral	FDA approved for the treatment of smallpox in adults and pediatrics, including neonates	Oral (100 mg tablet or 10 mg/mL suspension)



Treatment Options: TPOXX

Tecovirimat may be considered for treatment in people infected with monkeypox virus:

- With **severe disease** (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalization)
- Who are at high risk of severe disease:
 - People with immunocompromising conditions
 - Pediatric populations, particularly patients younger than 8 years of age
 - Pregnant or breastfeeding women
 - People with a history or presence of atopic dermatitis or people with other active exfoliative skin conditions
 - People with one or more complication
- With aberrant infections involving accidental implantation in eyes, mouth, or other anatomic areas where monkeypox virus infection might constitute a special hazard (e.g., genitals or anus)

VDH Medication Strategy

Providers can request TPOXX using the TPOXX Provider Treatment Initiation Interest Form

- All providers may request TPOXX for an identified patient
- Local Health Districts, Health Systems and local Infectious Disease providers may additionally request prepositioned inventory of TPOXX
 - These requests are not guaranteed as they are dependent on VDH supply
- Providers attest to complete the required documentation
- Prescribers must complete the <u>TPOXX Inventory and Patient Initiation Survey</u> for all patients who are started on TPOXX
- TPOXX is provided at no cost

Resources:

CDC Guidance for Tecovirimat

Healthcare Providers Obtaining and Using TPOXX for the Treatment of Monkeypox

<u>VDH - Treatment of Monkeypox - Information for Healthcare Providers</u>



VDH Vaccine Strategy

- Monkeypox vaccine is not routinely recommended for general public, and is intended to be used in specific groups that have higher risk of exposure
- VDH has developed recommended prioritization in context of limited vaccine supply
 - Priority 1: Traditional PEP
 - Priority 2: Expanded PEP (or PEP++)
 - Priority 3: PrEP
- Limiting vaccination to traditional PEP may not be effective for controlling current monkeypox outbreak
 - Cases with large number of contacts, who are hard to locate/identify
- Expanded PEP (or PEP++) may be more effective



Available Vaccines

Either vaccine can be used for Preexposure Prophylaxis (PrEP), Postexposure Prophylaxis (PEP), and Expanded PEP (PEP++)

JYNNEOS

- Replication-deficient attenuated live vaccinia virus vaccine
- Licensed in the US in 2019 to prevent both smallpox and monkeypox
- Manufacturer: Bavarian Nordic A/S
- Administered by subcutaneous injection as a 2-dose series, separated by 4 weeks
 - Considered vaccinated 2 weeks after receipt of 2nd dose
 - Booster doses may be recommended for ongoing occupational exposure
- Recommended by CDC for people age 18 or older who are at high risk for monkeypox illness due to occupational exposure, or exposure to the virus by other means

ACAM2000

- Proper Name: Smallpox (Vaccinia) Vaccine, Live
- Manufacturer: Emergent Product Development Gaithersburg, Inc.
- Requires 1 dose
 - Considered vaccinated after 28 days
 - Booster doses may be recommended for ongoing occupational exposure
- Administered using a droplet by the percutaneous route (scarification) using 15 jabs of a bifurcated needle; verify evidence of 'take' at days 6-8
- Approved in 2007 for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection



Vaccine Risks and Contraindications

JYNNEOS

- Newer vaccine, clinical trials have not indicated specific safety risks at this time
- There is no visible "take" and as a result, no risk for spread to other parts of the body or other people
- Vaccination prior to vaccine administration NOT required
- Contraindications: severe allergy to any component of the vaccine (gentamicin, ciprofloxacin, egg protein) should not receive this vaccine

ACAM2000

- Has many precautions and risk for serious adverse effects associated with vaccination
- Infection control measures required; contact with the vaccination site can result in auto-inoculation or infection to others
- Patients should be counseled that ACAM2000 may cause serious heart problems, including myocarditis and pericarditis.
- Contraindications: Atopic dermatitis*, other active exfoliative skin conditions*, immunocompromised*, pregnancy*, age < 1 year*, breastfeeding, known underlying heart condition, >3 known cardiac risk factors, allergy to vaccine component
 - *Vaccinee OR household contact

Currently, JYNNEOS is the primary vaccine being used in Virginia.



Intradermal Administration of JYNNEOS Vaccine

- August 9, FDA issued an Emergency Use Authorization (EUA) for JYNNEOS vaccine, which allows it to be administered by intradermal route (ID or in between layers of the skin) instead of standard subcutaneous route (SQ or under the skin) for people 18 years of age and older who are at high risk for monkeypox infection
- 0.1 mL of JYNNEOS vaccine is given ID instead of FDA-approved dose of 0.5 mL given SQ.
 - This increases total number of available doses by up to five-fold
- Similar immune responses with ID and SQ administration but local reactions more likely with ID route
- EUA allows standard SQ administration in anyone with history of keloids
- LHDs began ID administration on August 29



Vaccine Strategies to Prevent Monkeypox

1. Postexposure Prophylaxis (PEP) "Traditional"

- Vaccination of an individual following exposure to a known case
- 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

2. Expanded Postexposure Prophylaxis (Expanded PEP or PEP++)

- This approach aims to reach people for postexposure prophylaxis, even if they have not had documented exposure to someone with confirmed monkeypox (e.g., attended an event with known monkeypox cases)
- Broadened eligibility on August 25

3. Preexposure Prophylaxis (PrEP)

- Vaccination of those at higher-risk for monkeypox
- Applies to: lab workers handling monkeypox virus specimens, those with multiple sexual partners, sexual facility staff
- At this time, most clinicians and laboratorians are not advised to receive vaccine PrEP



Accessing Vaccines

- U.S. Government working to increase vaccine supply to respond to current outbreak
 - Majority of vaccines will be available at LHDs and select community partners
- States have access to treatment and vaccines for cases, known close contacts, likely close contacts
 - At this time, VDH Central Pharmacy has only ordered JYNNEOS vaccine
 - VDH Central Pharmacy has a small stock of TPOXX readily available and has opportunity to order more when needed
- Providers should make requests for vaccines through their LHD as part of case investigation process
- VDH requires proof of Virginia residency to receive monkeypox vaccination



Health Equity

- Monkeypox outbreak has disproportionately affected gay, bisexual and other MSM community, also people of color
 - Critical to ensure equity in treatment and vaccination
 - Recent publication and available data suggest racial and ethnic disparities in vaccination rates, especially among Black and Latino men



Infection Control, Collaboration With Public Health, and Risk Communication



Infection Prevention and Control

- Isolate patient in a single room with a dedicated bathroom
 - Limit patient transport; mask patient & cover lesions during transport
- Use standard and transmission-based precautions
 - PPE: gown, gloves, N95 respirator, eye protection
 - Any procedures likely to spread oral secretions should be performed in an airborne infection isolation room
- Avoid activities that may spread material from lesions
 - Soiled laundry should be gently and promptly contained; avoid shaking or handling in a manner that may disperse infectious material

Prevention During Current Outbreak

- Avoid skin-to-skin contact with people who have a rash that looks like a monkeypox virus rash.
 - Do not cuddle, have sex, kiss, or hug someone with monkeypox.
 - Do not touch the rash or scabs of a person with monkeypox.
- If you are planning to attend a gathering where you might be in close proximity to others, consider the risk.
 - Seek out information from trusted sources like health departments.
 - Consider how much close, personal, skin-to-skin contact is likely to occur at event you plan to attend.
- Having multiple or anonymous sex partners may increase your chances of getting monkeypox. Limiting number of sex partners may reduce exposure.
- Wash hands frequently or use alcohol-based hand sanitizer
- Vaccine for postexposure or preexposure prophylaxis

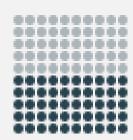


Behavior Changes during Current Outbreak



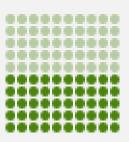
48%

reduced number of sex partners



50%

reduced one-time sexual encounters

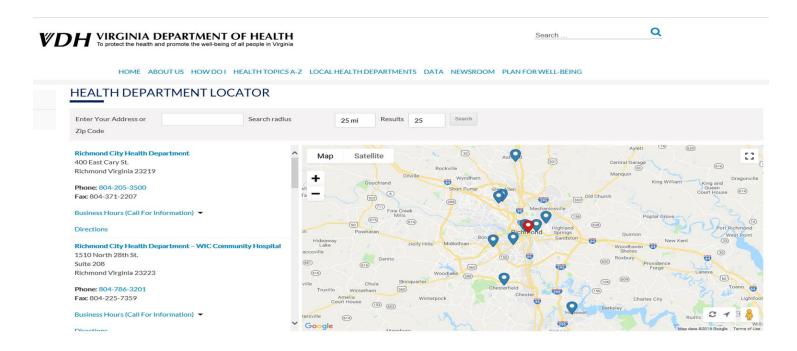


50%

reported reducing sex with partners met on dating apps or at sex venues



Notify the Local Health Department





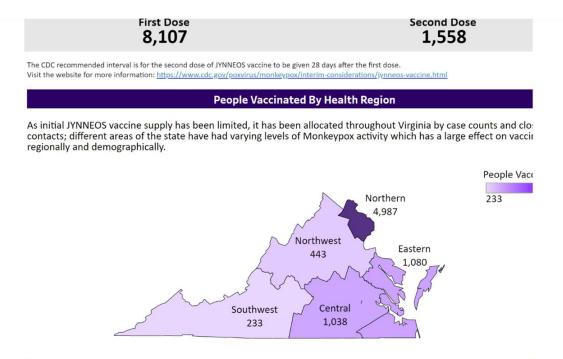
Public Health Response to Control Outbreak

- Intensify surveillance
- Identify cases early
- Conduct laboratory investigation
- Implement infection control measures
- Isolate cases
- Conduct contact tracing and monitor contacts
- Provide guidance and education
- Conduct outreach to social networks of MSM and their contacts, to public, and to HCP



VDH Vaccines Administered Dashboard

- Launched August 22
- 8,107 first doses and 1,558 second doses given so far*





^{*}data as of 9/7

Communication about Risk

- Anyone can get and spread the monkeypox virus
 - o To date, most cases in gay, bisexual, or men who have sex with men
- Contagious diseases do not affect or stay within one population
- It is important to educate the entire population about the symptoms and behaviors that can lead to the spread of monkeypox
- Certain behaviors, rather than a specific group event, put people at increased risk of getting monkeypox.
 - It is important to emphasize that close and prolonged contact, including sexual contact, increases risk of getting monkeypox, rather than just attendance at an event.
- You can combat stigma by providing fact-based information and emphasizing that monkeypox is a public health concern for everyone



Take Home Messages

- Risk to most people is considered low
 - People with monkeypox in the current outbreak generally report having close, sustained physical contact, including sexual contact, with other people who have monkeypox. Household contacts may also be at increased risk of monkeypox infection.
- When evaluating patients, have a high index of suspicion for monkeypox if characteristic rash is present
- Consult and collaborate with the Local Health District
- Stay updated on the latest information and recommendations regarding monkeypox via <u>CDC</u> and <u>VDH</u> websites.



Resources

- CDC Monkeypox <u>website</u>
 - Case definition
 - Information for clinicians
 - Clinician FAQs
 - Infection prevention
- CDC Health Alert Network health advisory 5/20/2022, 6/14/22, 7/28/22, 7/30/22
- COCA call 5/24/2022, 6/29/22, 7/26/22, 8/11/22
- VDH Monkeypox <u>Information for Healthcare Professionals</u>
 - VDH Monkeypox website
 - VDH Case and Vaccine Dashboards
 - VDH Communications Resources
 - Assessing and Managing Exposed Healthcare Personnel
 - Monkeypox Preparedness Checklist for Healthcare Facilities
 - DCLS Monkeypox testing and shipping instructions
- WHO Monkeypox <u>website</u>
- MMWR Epidemiologic and Clinical Characteristics of Monkeypox Cases United States, May 17-July 22, 2022



Thank You!

Q&A

