Provider Webinar

Monkeypox

Alex Millman, MD / Cherie Drenzek, DVM, MS / Ashlie Pullen, DNP, APRN, WHNP / September 19, 2022

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Objectives

Review:

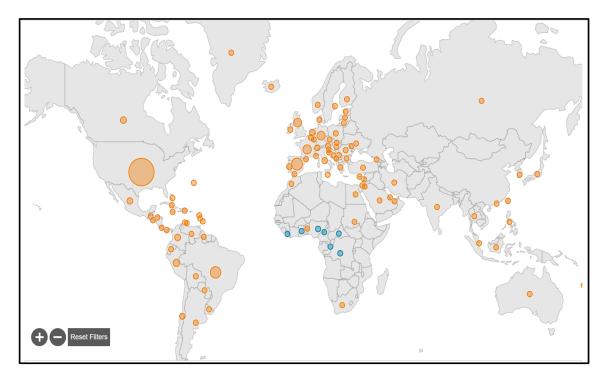
- Status of monkeypox in Georgia
- Clinical evaluation and management of monkeypox
- Testing of suspect monkeypox patients
- Reporting of monkeypox cases
- Vaccination requirements and access

Monkeypox in Georgia

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Situational Update as of September 16, 2022

- Globally, the MPX outbreak has impacted 104 countries with a total of 61,282 cases and 20deaths
- In the US, there have been 23,499 MPX cases reported in all states and territories with 1 confirmed death (in California).

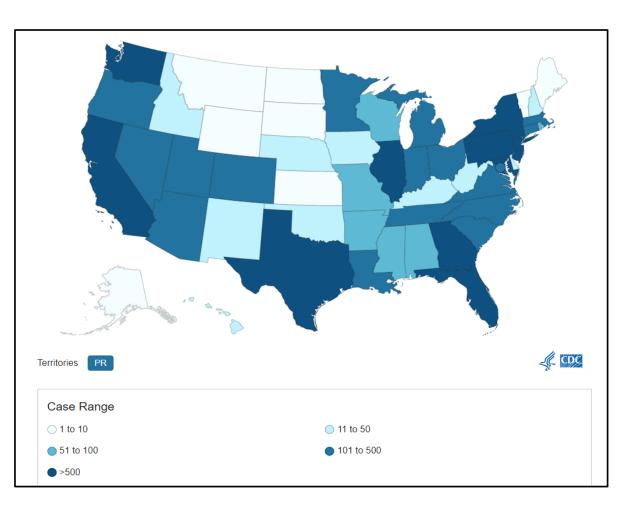


https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html

U.S. Situational Update

Top 5 states:

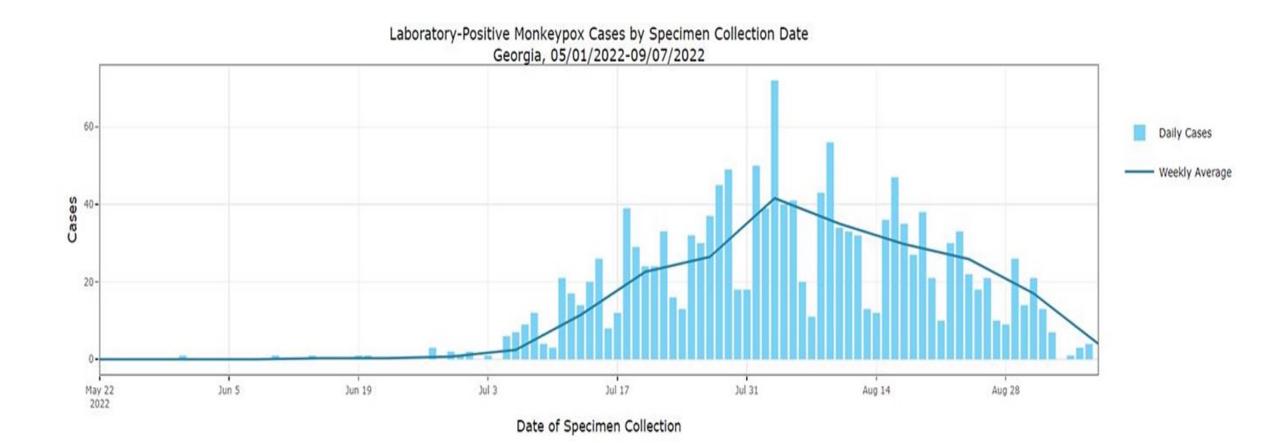
- 1. California
- 2. New York
- 3. Florida
- 4. Texas
- 5. Georgia



Monkeypox Outbreak: Epidemiology

- "Monkeypox is transmitted through close, sustained physical contact, almost exclusively associated with sexual contact in the current outbreak"
- Georgia has 1658 cases in 61 counties, but nearly 90% of cases are in the metro Atlanta area.
- Case rates have been consistently slowing over the last few weeks nationally and in Georgia ("cautiously optimistic").

Monkeypox Epi Curve, Georgia



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Monkeypox Case Characteristics: Georgia

- Gender: 1623 (98%) are male; 35 (2%) are female
- Age range: 4-68 years, median: 34 years; 3 pediatric cases
- Race (known for 97% of cases): Of these, 80% are Black, 14%
 White
- Ethnicity (known for 95% of cases): For these, 92% are non-Hispanic and 8% Hispanic.
- HIV Status: (known for 98% of cases): 60% HIV-positive and 93% in care
- 50% of cases had a STI in last 12 months
- 5% were hospitalized

Clinical Evaluation and Management

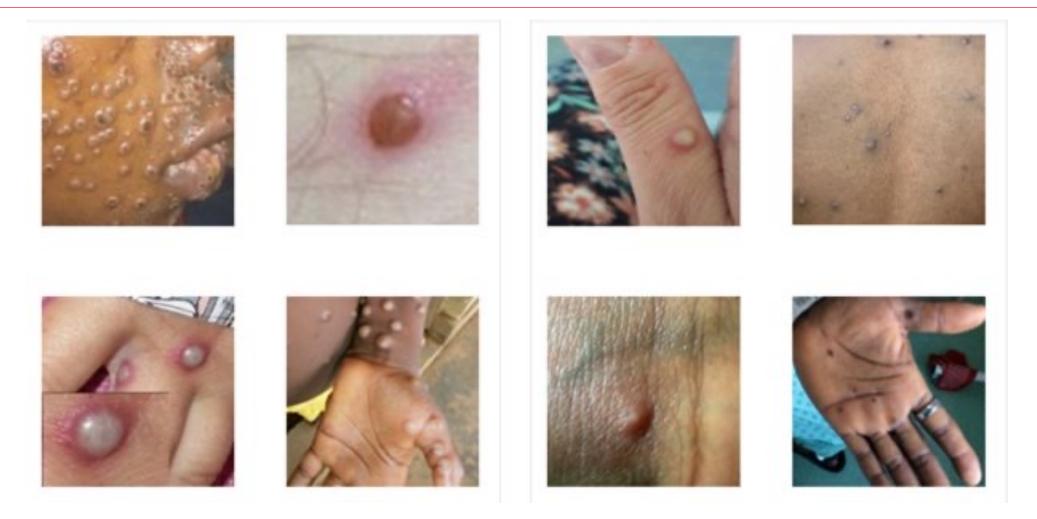
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Signs and Symptoms

- Symptoms of monkeypox can include:
 - \circ Fever
 - \circ Headache
 - Muscle aches and backache
 - Swollen lymph nodes
 - o Chills
 - o Exhaustion
- A rash that can look like pimples or blisters that appears on the face, inside the mouth, and on other parts of the body, like the hands, feet, chest, genitals, or anus.
 - The rash goes through different stages before healing completely. The illness typically lasts 2-4 weeks.
 - Sometimes, people get a rash first, followed by other symptoms. Others only experience a rash.

NOTE: In this outbreak we are also seeing proctitis, hematochezia, and tenesmus

Rash



Transmission and Duration

- Spread from person-to-person through direct contact with the infectious rash, scabs, or body fluids
- Spread by respiratory secretions during prolonged, face-to-face contact, or during intimate physical contact, such as kissing, cuddling, or sex
- Monkeypox can spread from the time symptoms start until the rash has fully healed, all scabs have fallen off, and a fresh layer of skin has formed
- The illness typically lasts 2-4 weeks

Isolation Guidance for Persons with Monkeypox

- Current data suggests that people can spread monkeypox from the time symptoms start until all symptoms are resolved.
- People with monkeypox should ideally isolate until the rash has fully resolved, the scabs have fallen off, and a fresh layer of intact skin has formed.
- Key points to discuss for isolation:
 - Stay home except to get medical care
 - Separate yourself from other people in your home as much as possible
 - Provide guidance for household cleaning and disinfection
- DPH monkeypox home isolation guidance can be found here: <u>https://dph.georgia.gov/monkeypox</u>

Infection Prevention in Healthcare Settings

- A patient with suspected monkeypox infection should be placed in a single-person room; **special air handling is not required.** The door should be kept closed (if safe to do so).
- If the patient is transported outside of their room, they should use wellfitting source control (e.g., medical mask) and have any exposed skin lesions covered with a sheet or gown.
- PPE used by healthcare personnel should include gown, gloves, eye protection that covers the front and sides of the face, NIOSH-approved particulate respirator equipped with N95 filters or higher
- CDC guidance environmental infection control : <u>https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-healthcare.html#anchor_1653508909869</u>

Treatment

- Many people infected with monkeypox virus have a self-limiting disease course in the absence of specific therapy.
- Although the illness is described as mild, some people particularly those with anogenital and mucosal lesions have experienced severe pain.
- CDC recommends the following:
 - Assess pain in all persons with monkeypox
 - Use topical and systemic strategies including sitz baths, saltwater gargles, topical steroids and lidocaine, OTC pain relivers, and prescription pain relivers such as gabapentin and opioids, and stool softeners for proctitis if indicated
 - Tecovirimat (TPOXX) may indicated for pain control

Treatment

- TPOXX was developed to fight smallpox, but the U.S. Food and Drug Administration allows its use to treat monkeypox during the current outbreak
- TPOXX can be considered for treatment for people with monkeypox with
 - Severe disease (e.g. sepsis, encephalitis, conditions leading to hospitalization)
 - Risks for severe disease including immunocompromising conditions
 - Lesions involving eyes, mouth, or other anatomic areas the genitals or anus
 - For more information visit: <u>https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html#</u> <u>anchor_1654624161405</u>
- TPOXX must be administered under an Investigational New Drug (IND) protocol

Required Documents for TPOXX

3 documents must be completed during the TPOXX treatment process, 2 must be returned to the CDC:

- <u>FDA Form 1572 [1MB, 2 pages]</u> Required to be completed by a physician and submitted to CDC. One Per facility within 3 days of starting treatment.
- <u>Informed Consent Form [214KB, 5 pages]</u> Informed Consent Form must be completed and retained by the client and the treating facility. A copy does not have to be returned to the CDC.
- <u>Patient Intake Form [321KB, 3 pages]</u> complete and submit to CDC within 3 days of TPOXX initiation.
- <u>Clinical Outcome Form [279KB, 4 pages]</u> during treatment at one in-person or telemedicine follow up visit, and at a visit 7-10 days after treatment during the last follow-up in-person or telemedicine visit, document information on the same Clinical Outcome Form and submit to CDC within 3 working days of the last follow-up visit.

TPOXX Request Process

- Providers can email <u>TPOXXorders@dph.ga.gov</u> to request TPOXX
- Include the provider's phone number and email address
- Dedicated DPH TPOXX on-call staff work with providers to collect required information
- Dedicated DPH TPOXX on-call staff will collect:
 - Patient information
 - Formulation requested
 - \circ Doses needed
 - Shipping information
- TPOXX on-call staff will place order for PO or IV TPOXX

Information Needed for all TPOXX Orders

- Relevant clinical summary and clinical eligibility for TPOXX (e.g., suspected monkeypox infection, HIV infected, unable to take oral medication)
- Patient weight (kg)
- Formulation requested (IV or Oral)
- Number of days of therapy requested
- Name of receiving facility
- Shipping address
- Point-of-contact name, phone, and email
- Days/times facility can receive shipment

Additional Guidance

- Positive monkeypox test results are NOT required for patients to receive treatment.
- 3 patient visits are required and can be provided via telemedicine: baseline, during treatment, and after completion of treatment.
- IV TPOXX orders take 2-3 days to arrive; Oral TPOXX orders typically take 24 hours to ship when requested on weekdays



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Testing Availability

- The Georgia Department of Public Health (DPH) will continue to support testing at the state public health laboratory but understands that commercial testing provides an expansion of laboratory testing capacity to assist with identifying new cases of monkeypox and stop the spread of disease.
- We know that commercial testing may also fit into the workflow of a facility and facilitate more access to testing in settings like emergency departments, urgent care clinics, and primary care clinics.
- We encourage providers to utilize commercial testing and the best testing option for their patient.

Commercial Laboratory Testing

Commercial Testing is available at the following five labs:

- Labcorp
- Quest
- Mayo
- Aegis
- Sonic

DPH commercial testing guidance for Georgia providers can be found: <u>https://dph.georgia.gov/document/document/monkeypox-commercial-</u> <u>testing-guidance-georgia-providers/download</u>

It is critical to work with commercial laboratories directly to determine:

- Ordering codes
- Specimen requirements
- How results will be returned to you
- To set expectations like turn-around time, billing, etc.

Testing for all Labs

 Use CDC recommended PPE (gown, NIOSH-approved N-95 mask, goggles or face shield, and gloves) during assessment and collection of specimens.

Testing at GPHL

- For testing at Georgia Public Health Laboratory: Providers should contact 1-866-PUB-HLTH (866-782-4584) and then proceed with recommendations.
- Collect specimens for monkeypox molecular testing to send to GPHL.
 - For the most up to date information on the types of swabs to use, and how to collect, handle, & transport specimens please visit: <u>https://dph.georgia.gov/monkeypox/information-providers</u>

Who to Test

- Persons with a characteristic rash for monkeypox regardless of exposure history AND/OR
- Persons with a new rash (even if not characteristic for MPXV) and who within 21 days of illness onset:
 - Reports contact with a person with a similar rash or who received a diagnosis monkeypox OR
 - Had close contact with individuals in a social network experiencing monkeypox activity (men who have sex with men (MSM) who meet partners online, or at a social event like a bar or party)

Testing and Isolation

- Anyone under suspicion of monkeypox should be counseled to isolate while awaiting results
- Any patient being tested should be given isolation guidance to prevent additional exposures and secondary cases. Test results may take 1-2 business days to receive, they should isolate during that time:

https://dph.georgia.gov/document/document/home-isolationguidance-monkeypox/download

Reporting

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Epidemiology Investigation

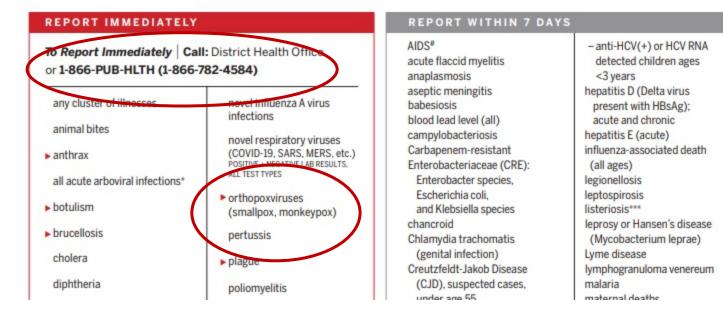
Monkeypox cases should be reported to DPH through the traditional notifiable disease reporting system.

District epidemiology staff conduct initial interview with patient to:

- Review and reiterate isolation guidance (to support information already shared up front by testing provider!)
- Identify high risk contacts that could be provided PEP
- Collect information on risk factors
- Complete CDC case report form

NOTIFIABLE DISEASE CONDITION REPORTING

All Georgia physicians, laboratories, and other health care providers are required by law to report patients with the following conditions.



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Exposure Risk Categories

Degree of Exposure: Higher

Recommendations

- Monitoring: Yes
 PEP¹: Recommended
- 1.44 COMPACT NO. 24 (CD2) (CD2)

Exposure Characteristics

- Contact between an exposed individual's broken skin or mucous membranes with the skin lesions or bodily fluids from a person with monkeypox -OR-
- Any sexual or intimate contact involving mucous membranes (e.g., kissing, oral-genital, oral-anal, vaginal, or anal sex (insertive or receptive)) with a person with monkeypox -OR-
- Contact between an exposed individual's broken skin or mucous membranes with materials (e.g., linens, dothing, objects, sex togs) that have contacted the skin lealons or bodily fluids of a person with monkeypox (e.g., sharing food, handling or sharing of linens used by a person with monkeypox without having been disinfected or laundered)

Degree of Exposure: Intermediate

Recommendations

- Monitoring: Yes
- PEP*: Informed clinical decision making recommended on an individual basis to determine if the benefits of PEP outweigh the risks

Exposure Characteristics

- Being within 6 feet for a total of 3 hours or more (cumulative) of an unmasked person with monkeypox without wearing a surgical mask or respirator -OR-
- Contact between an exposed individual's intact skin with the skin lesions or bodily fluids from a person with monkeypox -OR-
- Contact between an exposed individual's intact skin with materials (e.g., linens, dothing sex toys) that have contacted the skin lesions or bodily fluids from a person with monkeypox without having been disinfected' or laundered. OR-
- Contact between an exposed individual's clothing with the person with monkeypox's skin lesions or bodily fluids, or their soliad linens or dressings (e.g., during turning, bathing, or assisting with transfer)

Degree of Exposure: Lower

Recommendations

- Monitoring: Yes
- PEP⁴: None

Exposure Characteristics

Entry into the living space of a person with monkeypox (regardless of whether the person with monkeypox is
present), and in the absence of any exposures above

Degree of Exposure: No Risk

Recommendations

- Monitoring: No
- PEP⁴: None

Exposure Characteristics

 No contact with the person with monkeypox, their potentially infectious contaminated materials, nor entry into their living space

Abbreviations: PEP=postexposure prophylaxis

https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html

Degree of Exposure: Healthcare settings

- Most healthcare provider interactions will fall into Low/Uncertain risk or possibly No Risk
- Recommend awareness, but not daily checks
- Expect CDC updates shortly moving situations where providers are wearing appropriate PPE out of Low/Uncertain Risk category



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Vaccine

- Jynneos is an attenuated, live, non-replicating vaccine for use in the prevention of smallpox or monkeypox
- People who receive Jynneos are considered to reach maximum immunity 14 days after their second dose (~ 6 weeks from first dose)

Jynneos Overview

Vaccine Virus	Replication-deficient Modified Vaccinia Ankara
Administration	Subcutaneously in 2 doses, 28 days apart
"Take"	No "take" after vaccination
Inadvertent Inoculation and Autoinoculation	No risk
Cardiac Adverse Events	Considered low
Contraindications	Allergy to vaccine component
Effectiveness	Unknown in current outbreak

FDA Dose Sparing Strategy

- On August 9, FDA issued an emergency use authorization (EUA) allowing an alternative dosing regimen for individuals ≥18 years.
- The alternative dosing regimen is 0.1mL administered intradermally given in two doses four weeks (28 days) apart.
- Results from a clinical study showed that the lower intradermal dose was immunologically non-inferior to the standard subcutaneous dose.
- Administration by the intradermal route resulted in more redness, firmness, itchiness and swelling at the injection site compared to subcutaneous administration.

https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#interim

Vaccine Supply and Availability

- As part of an effort to control MPV in the United States, the federal government has allocated the limited supply of Jynneos vaccine to jurisdictions
- Vaccines are being offered by appointments in all health districts
 - o <u>https://gta-vras.powerappsportals.us/en-US/</u>
 - Vaccine Scheduling Resource Line at (888) 457-0186
- Given the currently limited available supply, vaccine is being prioritized for specific indications

Current Vaccine Priorities

- Postexposure Prophylaxis (PEP)
 - For high-risk exposure to a confirmed monkeypox case
 - Most beneficial when within 4 days of exposure but some may benefit up to 14 days following exposure
 - If given between 4–14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease.
- Expanded Postexposure Prophylaxis (PEP++)
 - For people with certain risk factors that might make them likely to have had high-risk exposure to monkeypox
 - Used for response to outbreaks in areas where spread is occurring

Vaccine for Pre-exposure Prophylaxis (PreP)

- Indicated for people with certain occupations that may place them at high risk for potential exposure such as laboratory staff working with monkeypox specimens
- Due to the limited vaccine supply, vaccine is being prioritized for PEP and PEP++ at this time
- Laboratorians should use appropriate BSL precautions when working with specimens sent for monkeypox evaluation
- Healthcare providers should use standard and recommended isolation precautions when caring for patients with suspected or confirmed monkeypox

Vaccine Outreach Activities

- DPH has partnered with local health departments and the communitybased organizations to conduct outreach activities to increase MPX vaccination in highly affected populations
- Ongoing vaccination efforts include routine vaccination clinics at health departments, mass vaccination events, and pop up vaccination events
- Social media advertisements about prevention and vaccination have been purchased on social media apps frequently used by MSM
- DPH participated in federal government initiative, which provided additional vaccine for use prior and during Atlanta Black Pride

Ongoing DPH Vaccine Efforts

- Broadened vaccine eligibility criteria to increase access tovpopulations that may have higher likelihood of exposure to MPX
- Working with local health departments and community-based organizations to arrange second dose vaccine activities for those who were vaccinated through outreach activities
- Continuing to work with community-based organizations that work with heavily affected populations
- Preparing to offer first and second dose vaccinations during Atlanta Pride in October
- Being ready to respond to changes in outbreak epidemiology that may require re-evaluating vaccination priorities in the context of the currently limited supply of vaccine

CPT Codes

The American Medical Association (AMA) has released coding guidance for laboratory testing and vaccine administration (available immediately)

- <u>Laboratory test code 87593</u>: Infectious agent detection by nucleic acid (DNA or RNA); orthopoxvirus (eg, monkeypox virus, cowpox virus, vaccinia virus), amplified probe technique, each
- <u>Vaccine code 90611</u>: Smallpox and monkeypox vaccine, attenuated vaccinia virus, live, non-replicating, preservative free, 0.5 mL dosage, suspension, for subcutaneous use

Questions

For more information, please contact:

Alex Millman, M.D. Chief Medical Officer Georgia Department of Public Health alexander.millman@dph.ga.gov

Cherie Drenzek DVM, MS

State Epidemiologist Georgia Department of Public Health <u>cherie.drenzek@dph.ga.gov</u>

Ashlie Pullen DNP, APRN, WHNP

Deputy Chief Nurse-Emergency Preparedness Georgia Department of Public Health <u>Ashlie.Pullen1@dph.ga.gov</u>