2022 Monkeypox Outbreak

North Carolina's Response Plan



Update for North Carolina Providers September 8, 2022

Logistics for Today's Webinar

Question during the live webinar



Technical assistance

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Agenda and NC DHHS Members

OPENING REMARKS

COVID-19 UPDATE

OVERVIEW OF NORTH CAROLINA MONKEY POX RESPONSE

CLINICAL BACKGROUND AND EPIDEMIOLOGY

VACCINATION AND TREATMENT

EQUITY AND COMMUNICATIONS

QUESTION AND ANSWER

Elizabeth C. Tilson, MD, MPH State Health Director, Chief Medical Officer

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COVID Updates



COVID-19 TRENDS

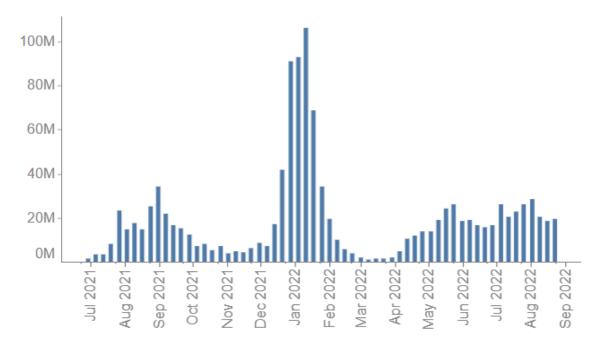
Early Warning Indicators

Rising levels of these can be an early sign of community spread and illness.

19.3 Million Previous Week 18.5 Million

COVID-19 Virus Particles Found in Wastewater

COVID-19 virus particles appearing in wastewater can signal how quickly the virus is spreading, even if people don't get tested or have symptoms.

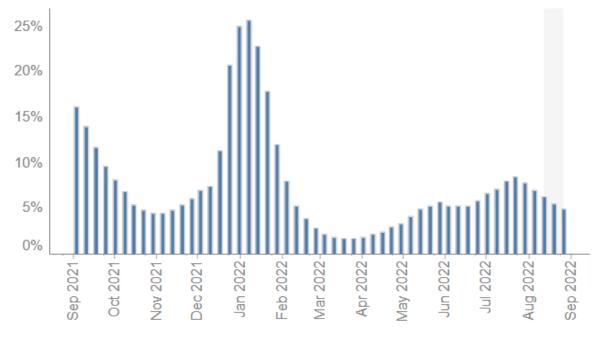


Average COVID-19 virus copies found per person per week from participating North Carolina wastewater treatment plants. <u>More Info</u>

5.0% Previous Week 5.5%

Emergency Room Visits for COVID Symptoms

The percentage of all emergency department visits that are for COVID-like symptoms can signal how much illness there is in a community.



Emergency department visits that are for COVID-like illnesses (CLI). More Inf..

COVID-19 TRENDS

Health System Capacity

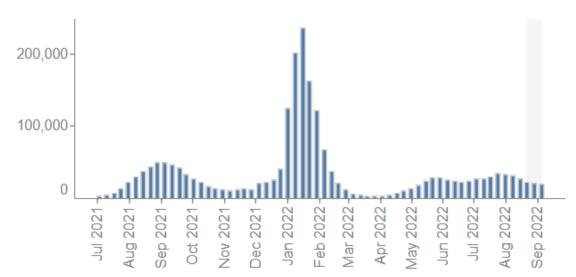
Rising levels of these can indicate strain on the health care system.

19,638

Pre

Previous Week 21,288

COVID-19 Reported Cases by Week of Specimen Collection



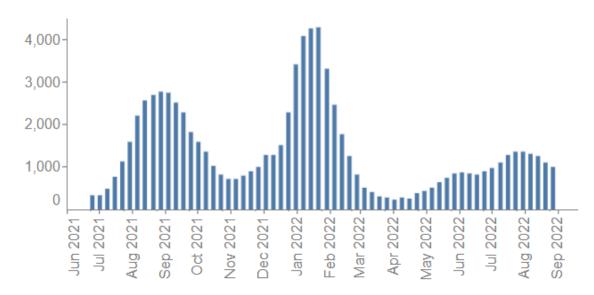
Number of new cases reported to the state each week, shown by the date specimen was collected. <u>More Info</u>

996



Previous Week 1,103

Hospital Admissions - COVID-19 Patients by Week



Number of confirmed COVID-19 patients admitted to hospitals each week. More info



FALL BIVALENT BOOSTER AUTHORIZATION

- The Centers for Disease Control and Prevention (CDC) has officially <u>recommended</u> Pfizer and Moderna bivalent booster doses following FDA <u>emergency use authorization.</u>
- Provides updated protection against original and Omicron strain
- The monovalent mRNA COVID-19 vaccines are no longer authorized as booster doses for individuals 12 years of age and older. Eligible children 5-11 years old can still receive the original Pfizer booster.

Pfizer-BioNTech COVID-19 Bivalent Booster Dose (12+)

All individuals **12 and older** are recommended to receive a bivalent booster dose if it has been at least **two months** since they have completed primary vaccination or have received the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

EUA fact sheets:

- Pfizer 12+ Bivalent Booster Fact Sheet for Healthcare Providers
- Pfizer 12+ Bivalent Booster Fact Sheet Recipients and Caregivers

Pfizer Statewide Standing Order

Moderna COVID-19 Bivalent Booster Dose (18+)

All individuals **18 and older** are recommended to receive a bivalent booster dose if it has been at least **two months** since they have completed primary vaccination or have received the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

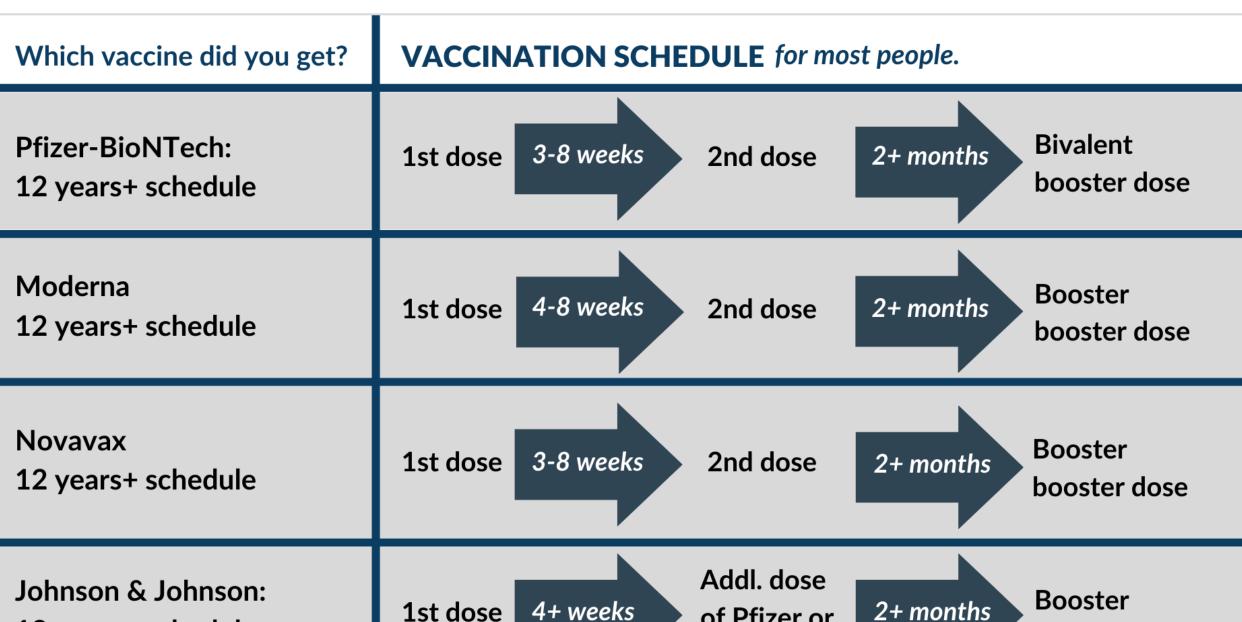
EUA fact sheets:

- Moderna 18+ Bivalent Booster Fact Sheet for Healthcare Providers
- Moderna 18+ Bivalent Booster Fact Sheet Recipients and Caregiver

Moderna Statewide Standing Order

NON-IMMUNOCOMPROMISED VACCINE SCHEDULE

18 years+ schedule

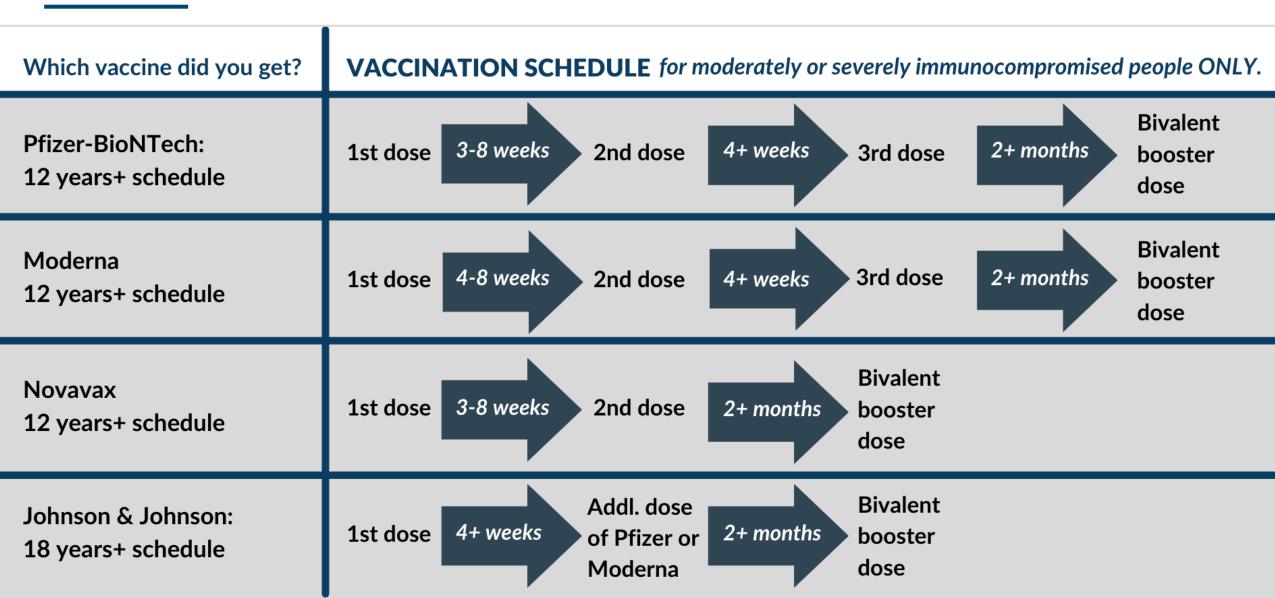


of Pfizer or

Moderna

booster dose

IMMUNOCOMPROMISED VACCINE SCHEDULE





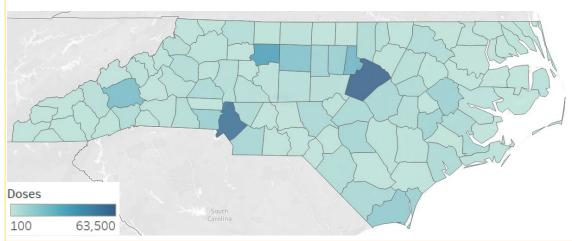
PFIZER AND MODERNA BIVALENT BOOSTER – WAVE 1 / WAVE 2 / FED PHARMACIES

500K Doses are being delivered to 1,033 providers across all 100 counties

Booster Recap

- All counties are set to receive the new booster products
- Geographic breakdown with an emphasis on equitable distribution for counties with large HMPs and providers serving long-term care facilities
- It will take at least 3 months for everyone who wants a booster to receive it

Where the Doses are Going



Provider Type	Provider #	Moderna	Pfizer	Total	
Pharmacy - Federal	604	42,900 189,000		231,900	
Pharmacy - State	147	25,600	68,400	94,000	
LHD	92	27,000	32,400	59,400	
Hospital	40	3,900	37,200	41,100	
PCP	92	3,300	33,900	37,200	
Other	28	6,800	13,200	20,000	
FQHC/RHC	13	1,900	2,400	4,300	
Student Health	4	300	2,700	3,000	
LTC	8	2,500	300	2,800	
Correctional Facility	4	2,000	0	2,000	
Commercial Vax	Commercial Vax 1		1,200	1,200	
Total	1,033	116,200	380,700	496,900	

Overview of North Carolina Monkey Pox Response



Monkeypox: Evolving Public Health Response

- Raising public and clinician awareness
- Testing
 - Wide availability of testing
 - State Laboratory of Public Health, several commercial laboratories, and some academic medical centers
 - Working to increase awareness in the public and among providers
- Case investigation and response
 - All <u>cases required to be reported</u> to your Local Health Department or NCDPH (919-733-3419) within 24 hours per state law and NC State Administrative Code.
 - Local and state public health investigate each case to identify contacts and facilitate access to care and vaccines
- Treatment
 - Medications developed for similar viruses can be used to treat severe cases
 - Tecovirimat (TPOXX) available through Strategic National Stockpile under EA-IND protocol
 - NCDHHS working to streamline access, including pre-positioning doses with providers
- Vaccination
 - JYNNEOS vaccine FDA approved for prevention of monkeypox
 - Can prevent or reduce severity of symptoms if given within 14 days after exposure (post-exposure, PEP)
 - Can be given before exposure to those at higher risk (pre-exposure, PrEP)

Clinical Background



CLINICAL PRESENTATION

- Typically, but not always, begins with flu-like symptoms, lymphadenopathy
- Rash appears within 5 days after prodrome. Lesions may be all over or localized.
- Rash from bumps to vesicles and then pustules before scabbing over and resolving over a period of 2-4 weeks.
- Lesions are usually firm, well circumscribed, and deep seated
- Atypical presentations common in current outbreak



a) early vesicle, 3mm diameter

d) ulcerated lesion,

5mm diameter



b) small pustule, 2mm diameter



c) umbilicated pustule, 3-4mm diameter





lesion









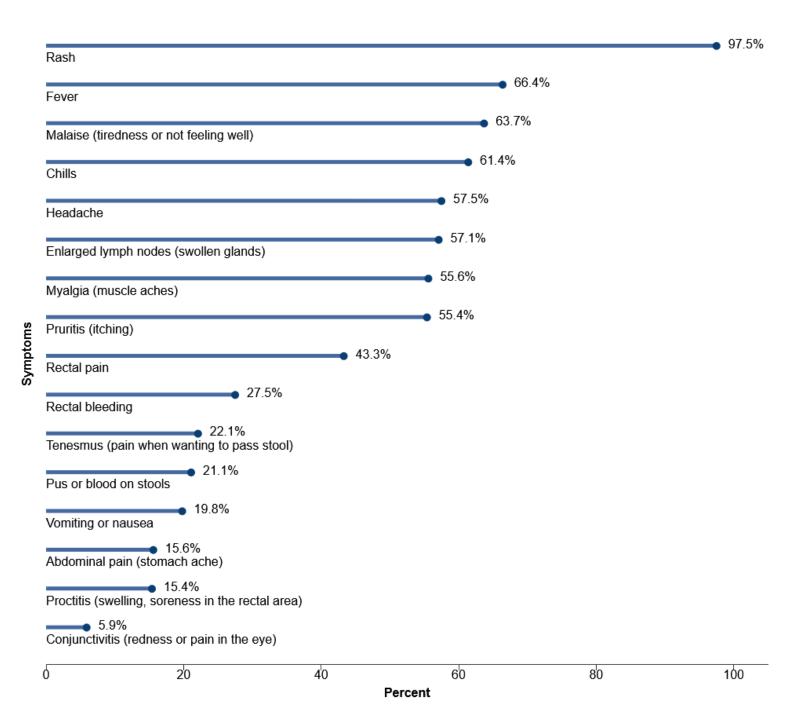








Symptoms of Monkeypox Cases Reported to CDC



How it Spreads

Monkeypox spread through close contact, including:

- Direct skin-to-skin contact with the monkeypox rash, sores, or scabs
- Contact with objects that have been used by someone with monkeypox (e.g., clothes, linens)
- Exposure to respiratory droplets or oral fluids during prolonged faceto-face contact with someone with monkeypox
- From pregnant people to the fetus through the placenta

Individuals are infectious until all scabs have fallen off and a fresh layer of skin has formed

Infection Prevention

- When monkeypox is suspected, healthcare workers should implement contact and enhanced droplet precautions, including wearing gloves, a protective gown, eye protection, and a NIOSH-approved N95 or higher-level respirator.
- Respirators should not be re-used between patients because fomite transmission is possible.
- Cleaning processes for testing facilities are similar to standard cleaning after a patient visit. See: <u>CDC</u>
 <u>Infection Control in Healthcare Settings</u>.
- For people with monkeypox who do not require hospitalization, home isolation is required during the infectious period. People are contagious until lesions have scabbed over and a fresh layer of skin has formed underneath.
- People who have had close contact should be monitored and offered post-exposure prophylaxis based on <u>level of exposure</u>.

Epidemiology of Outbreak



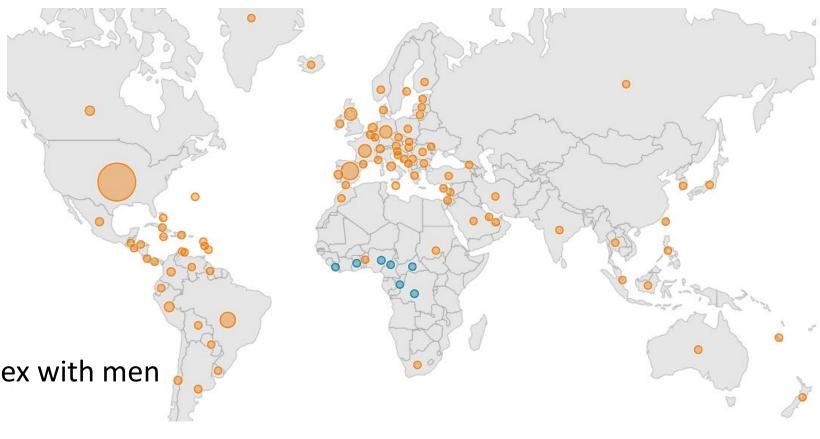
Current Outbreak — Global and National

Globally

 54,400 cases in countries that have not historically reported monkeypox



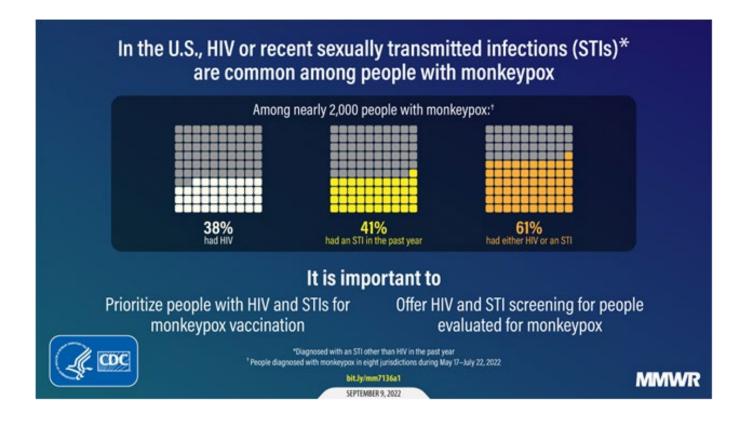
- 20,733 cases
 - 79% in men who report sex with men
 - 33% White non-Hispanic
 - 31% Hispanic
 - 31% Black non-Hispanic
 - 4% Asian



Has not historically reported monkeypox Has historically reported monkeypox

North Carolina Case Demographics and Coinfection

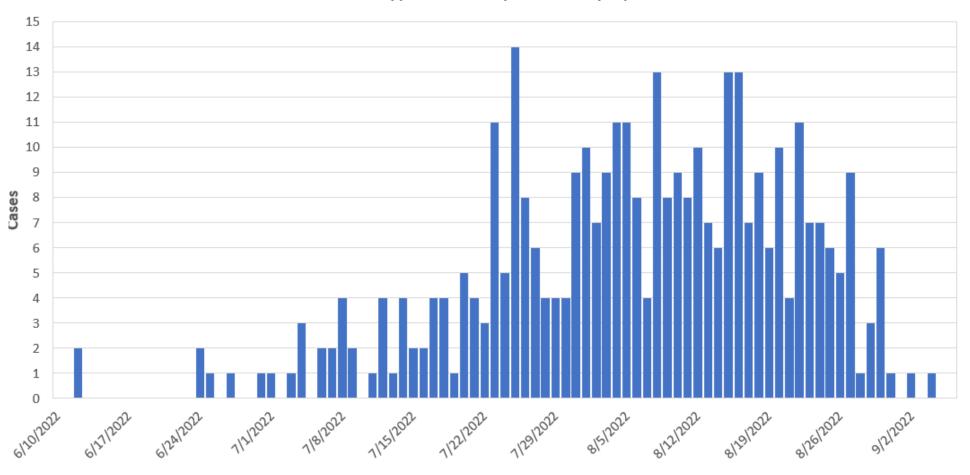
North Carolina Monkeypox Case Demographic Data	Number of Cases (%)
Total	387
Sex/Gender	
Male	380 (98)
Female	7 (2)
Other than sex assigned at birth	0
Age	
0-17	2 (1)
18-29	146 (38)
30-49	211 (55)
50+	28 (7)
Race	
American Indian/Alaskan Native	3 (1)
Asian	1 (<1)
Black or African American	261 (67)
Native Hawaiian or Pacific Islander	0
White	93 (24)
Multi-racial	14 (4)
Other	13 (3)
Unknown	2 (1)
Ethnicity	
Hispanic	43 (11)
Non-Hispanic	336 (87)
Unknown	8 (2)
Coinfection	
Known to be living with HIV	209 (54)





North Carolina Case Trends

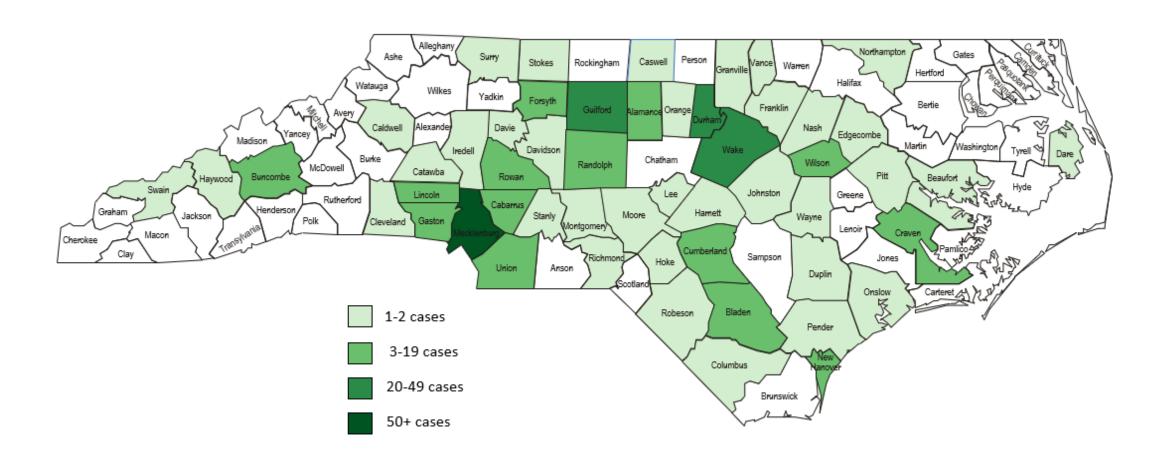
North Carolina Monkeypox Cases by Date of Symptom Onset*, 2022



Date of Symptom Onset



North Carolina Cases Geographic Trends





Testing



Testing is Widely Available

- Testing available at NC SLPH and many commercial and hospital labs
- Prior approval is not needed for monkeypox testing
- Test any patients with clinical symptoms consistent with monkeypox
- Carefully consider testing in patients with no plausible risk of exposure and low suspicion for monkeypox disease. False positive results have been reported and the likelihood is higher when pre-test probability is low

Specimen Collection Guidance

PCR testing of swabs from skin lesions

- Two <u>vigorous</u> swabs from base of each lesion (3 per patient different body parts or different appearance) using sterile synthetic swabs.
- Place swabs in sterile containers that have a gasket seal and able to be shipped under the required conditions*
- Store refrigerated (2-8°C) or frozen (-20°C or lower) within an hour of collection
- Use of tubes with transport media varies by laboratory*

DO NOT unroof lesions using needles, scalpels, or other sharp instruments

*Adhere closely to the specimen collection and shipping guidance for the specific testing laboratory

Vaccination



Expanded Vaccine Eligibility - JYNNEOS

- Anyone who had close contact in the past two weeks with someone who has been diagnosed with monkeypox; or
- Gay, bisexual, or other men who have sex with men, or transgender individuals, who are sexually active; or
- People who have had sexual contact with gay, bisexual, or other men who have sex with men, or transgender individuals in the past 90 days; or
- People living with HIV, or taking medication to prevent HIV (PrEP), or who were diagnosed with syphilis in the past 90 days; or
- Certain health care, laboratory, and public health response team members

At this time, most clinicians in the United States and laboratorians not performing the orthopoxvirus generic test to diagnose orthopoxviruses, including monkeypox, are not advised to receive orthopoxvirus PrEP

VACCINE ADMINISTRATION DATA

Sex	Percentage:
Female	6%
Male	85%
Unknown	9%
Race	Percentage:
American Indian or Alaska Native	1%
Asian	3%
Black or African-American	27%
Native Hawaiian or Other Pacific Islander	0%
Other Race	4%
Prefer not to answer	3%
White	62%
Ethnicity	Percentage:
Hispanic or Latino	9%
Not Hispanic or Latino	87%
Prefer not to answer	3%
Unknown	0%
Age Breakdown	Percentage:
0-17	0%
18-29	26%
30-49	50%
50+	24%
Deceded an data was subsided as of	

- As of Aug. 31, 11,420 vaccine doses have been administered across the state, and more doses are expected in the coming weeks.
- Over 2,300 North Carolinians have been fully vaccinated against Monkeypox during the current vaccine rollout
- As of 8/29/22 all vaccine providers are required to administer JYNNEOS vaccine via intradermal route, barring contraindications
- 5,000 vials of JYNNEOS currently on hand in North Carolina



NC VACCINATION RESPONSE - DISTRIBUTION

Hub and Spoke Distribution Model

- Nine local health departments serving as hubs:
 - Buncombe, Cumberland, Durham, Forsyth, Guilford, Mecklenburg, New Hanover, Pitt, Wake
- Providing vaccine regardless of county of residence; transferring to other health departments and vaccine providers as needed
- 61 additional sites identified to pair with LHD hubs to receive vaccine to expand access
 - Vaccines administered in 41 counties across NC
- Monkeypox vaccine hubs and additional provider locations available at
 - https://www.ncdhhs.gov/divisions/public-health/monkeypox/monkeypox-vaccine-locations

Going Forward

- NC currently has ~2,500 additional vials available in our next order when we have used 85% of our current allocation
- White House and CDC announced special allocations process for equity-focused community events
 - Up to 100 vials for 5 events
 - Details expected mid-September



HOW TO ACCESS VACCINE

- 1. Patient in need of PEP/PEP++
 - Refer to LHD or clinic with current vaccine supply
- 2. All providers interested in receiving vaccine supply in the future must complete: NC DHHS Monkeypox Vaccine Enrollment and Capacity Survey
 - Submission of enrollment survey does not guarantee an allocation of vaccine Current supply very limited
 - Purpose of enrollment
 - Validate vaccine storage capabilities
 - Ensure vaccine accountability
 - Confirm NCIR access for proper documentation
 - Set up HPOP account (federal system used for vaccine ordering)
- 3. All enrolled providers placed on waitlist until vaccine availability improves
- 4. Difficulty locating LHD/clinic with vaccine, submit NC DHHS Monkeypox MCM Request Form
 - NC DHHS will review and assist in locating vaccine for transfer



NC VACCINATION RESPONSE - OPERATIONAL CONSIDERATIONS

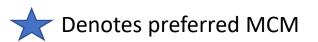
- Cross functional collaboration
 - We need all providers, local health departments, and community partners working together
- Equity
 - Ensuring our limited resources reach those at highest risk, regardless of their race, ethnicity, or socioeconomic status
 - Collecting the proper data to inform equitable decision making
 - Community-focused events in Mecklenburg County and Durham County have demonstrated ability to close racial gap in vaccine administrations
- Information Sharing
 - Leveraging community partners to help get the word out and support initiatives focused on equity
- Billing and reimbursement
 - Vaccines and therapeutics are provided free from the strategic national stockpile
 - Providers must administer vaccine at no cost to the recipient and regardless of the vaccine recipient's ability to pay administration fees
 - Providers may seek appropriate reimbursement from a program or plan that covers vaccine administration fees
- Use of the North Carolina Immunization Registry (NCIR)
 - Providers must have NCIR access to be able to receive and administer monkeypox vaccine
 - Provider sites are expected to maintain vaccine inventory and document administrations in NCIR



Treatment



MEDICAL COUNTERMEASURES: TREATMENT OPTIONS



Currently no proven, safe, and effective treatments for Monkeypox. Animal data suggests smallpox treatments could be used in severe cases.

Name	Indication	Dosing & Administration	Availability	Storage and Handling	Notes
TPOXX tecovirimat	FDA approved for treatment of smallpox in adults and pediatric patients weighing at least 3kg. Expanded access protocol for monkeypox	Oral and IV formulations Weight based dosing 14 day course of therapy	SNS request	Oral: 200mg capsules; 42 caps/bottle Stored at controlled room temp (>13kg) IV: 200mg/20mL vial Store refrigerated @ 2-8°C (>3kg)	TPOXX IV contraindicated in those with serve renal impairment TPOXX oral must be taken within 30 minutes after moderate/high fat meal No human data on use in pregnancy; no toxicity in animal reproductive studies
<u>Vistide</u> cidofovir	FDA approved for treatment of CMV retinitis in AIDS patients Expanded access protocol for monkeypox	5mg/kg IV once weekly x 2 weeks Must be administered with fluids and probenecid	Commercially & SNS Request	75 mg/mL in clear glass, single use vial Store at controlled room temperature 20-25°C	Causes severe nephrotoxicity Renal function monitored within 48 hours prior to administration No human data on use in pregnancy; embryotoxic in rats
Vaccinia Immune Globulin VIGIV CNJ-016	FDA approved for the treatment of complications associated with vaccinia vaccination Expanded access protocol for Monkeypox	6,000 U/kg IV x 1 dose Higher doses can be given if patient does not respond	SNS Request	15mL vial containing > 50,000 U/vial Product may be stored frozen at or below 5°F (≤ -15°C) or refrigerated at 36 to 46°F (2 to 8°C)	No animal or human pregnancy data; Other immune globulins used in pregnancy w/o negative effects



Note: CDC is currently developing a expanded access protocol for a fourth treatment; **Tembexa (brincidovofir)**. However, it is currently not available commercially or through SNS request. **Viroptic (trifluridine)** is a commercially available ophthalmic solution that can be considered for monkeypox treatment in patients with ocular lesions.

TPOXX EXPANDED ACCESS INVESTIGATIONAL NEW DRUG PROTOCOL

CDC Recently Revised TPOXX EA-IND Protocol

- Streamlined to make treatment easier, reduce patient visits, and required forms
- All visits can be conducted via telemedicine
- All laboratory testing is optional
- Required adverse event reporting on serious adverse events only
- No pre-registration is required to begin providing tecovirimat treatment
- Forms required for EA-IND can all be returned to CDC after treatment begins

Required As part of EA-IND Process:

- Obtain informed consent prior to treatment
- Conduct a baseline assessment and complete patient intake form
- Document progress once during and once after treatment on the Clinical Outcome Form
- Report life-threatening or serious adverse events with tecovirimat by completing a PDF MedWatch Form and returning to CDC
- Complete FDA Form 1572: One signed per facility

For more information: https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html



HOW TO OBTAIN ACCESS TO TPOXX

Providers interested in TPOXX can place a request using our NC DHHS Monkeypox Medical Countermeasures Request Form

Oral TPOXX Distribution

- To date more than 747 courses have been shipped to 40 locations in NC for utilization/pre-positioning.
- Current threshold available from CDC has 294 courses remaining
- CDC currently limiting states to 5 ship to sites per week and need to show 80% utilization to refill threshold
- Requests are filled based on need utilizing transfers from pre-positioned locations

Oral TPOXX Reporting

- All providers utilizing TPOXX must have a Health Partner Ordering Portal (HPOP) Account
 - This is created as part of the initial request process
- On-Hand inventory and administrations are required to be reported weekly every Tuesday by 5pm.
 - Inventory on hand should be reported in bottles
 - Administrations should be reported in patient courses administered since your last report

Provider Attestation

- Recently provided by CDC, required to attest with each request for TPOXX
- Attestation includes:
 - Providers utilize TPOXX in accordance with EA-IND and submit all required EA-IND regulatory documentation
 - Report adverse events via FDA MedWatch within 72 hours
 - Report inventory and administrations weekly via HPOP
 - Organization must provide TPOXX to recipients regardless of their ability to pay
 - Organization must preserve all TPOXX related documents/records for minimum of 3 years



Equity, Communications, Outreach



Monkeypox Vaccine: Equity Considerations

- Tracking case and vaccination data (including race and ethnicity)
- In North Carolina, 68% of cases were in Black or African American individuals, yet this group has received 27% of vaccines. Nationally, about 10% of vaccine doses have gone to Black or African American individuals.
- Considerations for access to testing, vaccination and treatment:
 - Access to healthcare
 - Transportation
 - Cost
 - Stigma / Anonymity
- NCDHHS is working with all levels of government together in partnership with community organizations to remove disparities in monkeypox cases and vaccinations.
- Extensive communication, town halls and coordination with LGBTQ+ focused CBOs, HBCUs, HIV and other STI care providers, other community partners to ensure awareness, low-barrier access.
- Local events
 - Mecklenburg Public Health and Charlotte Pride events.
 - Triangle Empowerment Center MPX vaccine event in Durham (8/30)
 - NCCU Community Health Fair (9/8)

Communications and Outreach

LEARN the facts. Anyone can get monkeypox. It spreads mostly through close skin-to-skin contact.

LOOK for a rash. Get new rashes, lesions or sores checked by a health care provider. Talk with your partner about any monkeypox symptoms.

LOCATE testing and vaccines for yourself or your community.

- There is no limit on testing. Talk to your doctor or local health department.
- Limited vaccine supply is prioritized for those currently most at risk, and the communities where the virus is spreading.



For more info, testing and vaccine locations: ncdhhs.gov/monkeypox



NC Department of Health and Human Services • Division of Public Health • Communicable Disease Branch • NCDHHS is an equal opportunity employer and provider. • 8/2022

Cover Photos: Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of High-Consequence Pathogens and Pathology (DHCPP), www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html

NHS England High Consequence Infectious Diseases Network, www.gov.uk/government/

NHS England High Consequence Infectious Diseases Network, www.gov.uk/government/news/ukhsa-latest-findings-into-monkeypox-outbreak, The National Archives, contains public sector information licensed under the Open Government Licence v3.0.



Monkeypox: Get Checked.
Get Tested. Get Vaccinated, if eligible.









Everyone can do their part to control the spread: We are in this together.

Communications and Outreach

LEARN the facts: Anyone can get monkeypox. It spreads mostly through close skin-to-skin contact.

Examples of Monkeypox Exposure by contact with someone who has the virus

HIGHEST EXPOSURE:

- · Bare skin-to-skin contact with infectious rash, scabs or bodily fluids
- Sexual contact
- Other intimate skin-to-skin contact; such as kissing, massage or cuddling

SOME EXPOSURE:

- Crowds where people aren't wearing much clothing with a lot of skin-to-skin contact
- Sharing drinks, utensils, cigarettes, vapes, pipes, etc.
- Sharing towels, bed linens, or other personal items
- Exposure to respiratory droplets through prolonged face-to-face contact with no mask use

UNLIKELY EXPOSURE:

- Crowds where people are mostly clothed, not much skin-to-skin contact
- Shaking hands with someone with no visible rash
- . Shopping at the grocery store or mall
- Traveling by bus, train or plane or using public restrooms
- Trying on clothing at a store

LOOK for a rash: Get new rashes, lesions or sores checked by a health care provider. 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 and anus.



LOCATE testing and vaccines for yourself, or your community: There is no limit on testing. Talk to your doctor or local health department: ncdhhs.gov/monkeypox

Vaccine is available at local health departments and clinics. Find out if you are eligible: ncdhhs.gov/monkeypox



Everyone can do their part to control the spread: We are in this together. Learn more: ncdhhs.gov/monkeypox

*Photos used with permission.

MONKEYPOX VACCINE AND TREATMENT RESOURCES

CDC:

U.S. Monkeypox Outbreak 2022: Situation Summary

Monkeypox and Smallpox Vaccine Guidance

Interim Clinical Guidance for the Treatment of Monkeypox

NC DHHS:

NC DHHS Monkeypox Website: Vaccine Locations

Monkeypox Communication Toolkit

Provider Memo (July 14th)

Vaccine Toolkit

Interim Guidance for NC Healthcare Providers: Tecovirimat in Treatment of Monkeypox Communicable Disease Manual for LHDs



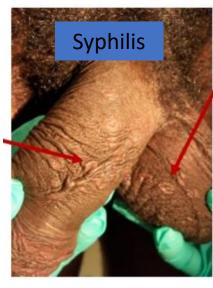
Questions



Additional information

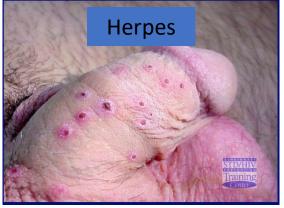


MANY RASHES CAN HAVE SIMILAR APPEARANCES

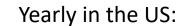












- 7-10,000 chickenpox cases
- 39,000 syphilis cases
- 572,000 genital herpes infections
- 1,000,000 shingles cases
- Unknown number of arthropod bites/stings, molluscum, handfoot-mouth disease, and more







Typical Characteristics of Rash Illnesses

Disease	Prodrome	Rash Appearance		Direction of Rash Spread	P/S		
		Macular	Papular	Vesicular	Pustular		
Monkeypox	YES	X	X	X	Χ	Face→body esp limbs	YES
Molluscum contagiosum	NO		X			Variable	RARE
Syphilis	+/-	X	X			Variable	YES
Chickenpox	+/-	X		X		Chest/back/face→rest of body	NO
Shingles	+/-			X		Dermatomal and unilateral	NO
Measles	YES	X				Face->body and limbs	YES
Herpes	NO			Χ		Localized (oral or genital)	NO
Hand-foot mouth	YES	X		X		Mouth→limbs, buttock or genitals	YES
RMSF	YES	Χ	Χ			Wrist/forearms/ankles → trunk	YES

Webinar May 24, 2022 - What Clinicians Need to Know about Monkeypox in the United States and Other Countries (cdc.gov)