



MONKEYPOX: WHAT NORTH DAKOTA HEALTH CARE WORKERS NEED TO KNOW

Immunization Division Lunch and Learn
July 13, 2022
Presentation Updated July 2022

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**TODAY'S PRESENTERS:
ND DEPT OF HEALTH**

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- Disease Control Section
- Brenton Nesemeier, MS
- Director of Field Services
- Disease Control Section
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- Director of Biothreat
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OUTLINE

- US and Worldwide Situational Update
- Monkeypox 101
- Laboratory Collection
- Case Investigation/Contact Tracing
- Vaccine and Treatment

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SITUATIONAL UPDATE

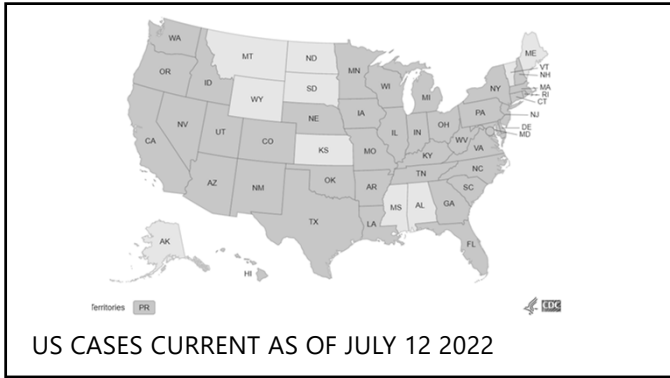
- Countries that typically do not see monkeypox began to see cases in Spring 2022.
- Most cases are among the MSM population
- CDC continuing to work with state, federal and international partners
- Five US commercial laboratories recently approved to conduct mpvx testing to increase nationwide testing capacity
- Monkeypox does not spread easily between people without close contact. The threat to the US population remains **LOW**

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CASE DEFINITION

- Suspect Case
 - New characteristic rash* **OR**
 - Meets one of the epidemiologic criteria and has a high clinical suspicion¹ 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 **OR**
 - 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

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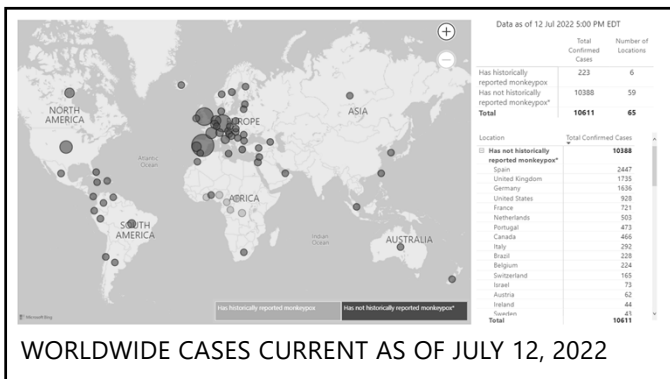


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NORTH DAKOTA CASES

- North Dakota has not identified any cases of monkeypox
- We are continuing to work with our healthcare providers to offer consultation and testing when indicated
- Subsequent diagnoses of those who were tested and negative for monkeypox in North Dakota include folliculitis and shingles

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MONKEYPOX

- Rare, sometimes life-threatening zoonotic infection
- Endemic in west and central Africa
 - West Clade, Central Clade
- Specific animal reservoir unknown but likely small mammals
- Caused by Monkeypox virus (which is an orthopoxvirus)
- Can spread from infected animals to humans and person-to-person
 - Respiratory secretions
 - Skin-to-skin contact with infected body fluids (e.g., fluid from vesicles and pustules)
 - Fomites (e.g., shared towels, contaminated bedding)

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MONKEYPOX

- How it Spreads
 - Direct contact with the infectious rash, scabs, or body fluids
 - Respiratory secretions during prolonged, face-to-face contact, or during intimate physical contact, such as kissing, cuddling, or sex
 - Touching items (such as clothing or linens) that previously touched the infectious rash or body fluids
 - Pregnant people can spread the virus to their fetus through the placenta

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MONKEYPOX

- Pre-2022 Outbreak in the United States
 - 2003 – Outbreak linked to small mammals imported from Ghana
 - 2021 – Two unlinked cases with travel to Nigeria

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MONKEYPOX

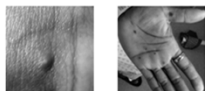
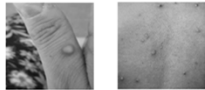
- 2022 Outbreak
 - First cases reported May 17 in the US
 - Massachusetts resident with travel to Canada
 - Most cases are among the MSM population
 - Co-Infection with STIs has occurred.
 - Atypical presentation
 - Genital/perianal lesions
 - Proctitis
 - Hospitalizations=low
 - Deaths=0

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MONKEYPOX

▪ Symptoms can include

- Fever
- Headache
- Muscle aches and backache
- Swollen lymph nodes
- Chills
- 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.

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MONKEYPOX

- Isolation
 - Most cases will be able to self-isolate at home
 - Cases should isolate in a separate room away from other members (including pets) of the same household
 - Cases will be asked to remain isolated until the last scab falls off
 - Typically within 2-4 weeks from onset
 - People who do not have symptoms of monkeypox cannot spread the virus
 - Unknown if monkeypox is spread through semen/vaginal fluid at this time

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MONKEYPOX

- Prevention
 - Avoid skin-to-skin contact with anyone with the monkeypox rash
 - Do not handle clothes, bedding, or towels of a sick person
 - Wash your hands often or use hand sanitizer, especially after contact with a sick person
 - Vaccination



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LABORATORY COLLECTION

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COLLECTION OF SPECIMEN

- Two swabs from each lesion should be collected for testing.
 - Using two sterile, dry synthetic swabs (including, but not limited to polyester, nylon, or Dacron) with a plastic, wood, or thin aluminum shaft, swab the lesion vigorously to collect adequate DNA.
 - Do not use cotton or rayon swabs.
 - It is not necessary to de-roof the lesion before swabbing.
 - Break off the end of each swab's applicator into a 1.5- or 2-mL screw-capped tube with O-ring or place the entire swab in a sterile container that has a gasket seal like a 15 mL conical tube.
- Two swabs from each lesion should be collected, preferably from different locations on the body or from lesions which differ in appearance.
 - Swabs and other specimens should each be placed in different containers
- Dry Swabs are Preferred for testing
- Swabs in Viral Transport Media (VTM) are also acceptable.
 - Universal Transport Media (UTM) is **not acceptable** and any samples submitted in UTM will be rejected.



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SAMPLE STORAGE AND SHIPPING

- Specimens being sent for testing should be stored
 - Refrigerated (2-8°C) for up to 7 days shipped on ice packs OR
 - Frozen (-20°C or lower) for up to 60 days and shipped on dry ice
- Complete a Laboratory Services Test Request form found on the Microbiology website and select : "Bioterrorism Rule Out-Agent Suspected: Monkeypox"
- Specimens can be shipped Category B

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TURNAROUND TIME

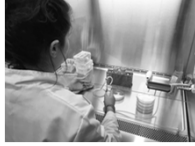
- Testing at the ND Lab is performed M-F
- Typically performed day of receipt if received in the morning
- Turnaround time for CDC confirmatory testing is 1-2 days after receipt in their lab.



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LABORATORY BIOSAFETY CONSIDERATIONS

- BSL-2 facilities with standard BSL-2 work practices
 - Routine chemistry, hematology and urinalysis
 - Molecular analysis of extracted nucleic acid preparations
 - Routine examination of bacterial and mycotic cultures
- BSL-2 facilities with more stringent BSL-3 work practices
 - All other testing that may be done on specimens



<https://www.cdc.gov/poxvirus/monkeypox/lab-personnel/lab-procedures.html>

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SELECT AGENT REGULATIONS

- Laboratory testing has indicated that the current outbreak is associated with the West African clade of monkeypox virus. The West African clade of the monkeypox virus is not subject to select agent regulations.



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LABORATORY QUESTIONS?

- Contact Stacey Alexander or Maggie Kuklok at the North Dakota Department of Health Laboratory at 701-328-6272

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CASE INVESTIGATION

- Case and contact investigation will be managed by the North Dakota Department of Health
- Questions/Interview will be documented in the MAVEN system using questions generated from the CDC case report form.
- The NDDoH will provide updates on case counts on a regular basis. Field epidemiologists will reach out to LPHU to notify them of cases in their region.

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CASE INVESTIGATION

- Upon suspicion of MPXV provider should reach out to the NDDoH at 701.328.2378 for further consultation
- If MPXV is suspected provider should ensure proper PPE is worn including; gown, gloves, eye protection, mask (N95 preferred)
- Samples must be collected per previously described laboratory process or by process defined by commercial laboratory in which you are submitting specimens
- NDDoH will facilitate transport of the sample through our courier service for samples submitted to the NDDoH

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CASE INVESTIGATION

- Upon suspicion of MPXV provider should do a full sexual health and travel history . This should be documented in the medical chart. Providers should also inquire about known exposures to person(s) that have similar type illness.
- Providers should also test for other infectious diseases such as syphilis at the time of testing

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CASE INVESTIGATION

- After confirmation of Orthopoxvirus, field epis will reach out patient to identify risk, elicit contacts and provide guidance
- Many countries and states are reporting difficulty in obtaining contacts or the patient reporting only anonymous contacts
- If provider is able to obtain contact information or identifying information for close contacts, report that the North Dakota Department of Health
 - This will be important for determination of Post-Exposure Prophylaxis (PEP) for exposed individuals

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CASE INVESTIGATION

- Cases will be investigated same day that our lab confirms orthopoxvirus
- Cases will be assigned to the field epidemiologist assigned to your region
- Field epis will also reach out to LPHU to notify them of the positive case (no identifying information)

Fargo – Luke Unger	Grand Forks – Rachel Goebel
Jamestown – Deanna VanBruggen	Devils Lake – Crystal Duncan
Bismarck – Gino Jose	Minot – Linda Larson
Dickinson – Heather Kontz	Williston – Sarah Favorite

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CASE INVESTIGATION

- Field Epidemiologist will gather the following information
 - Intimate contacts
 - Other close contacts that may have had skin-to-skin contact
 - Exposure History
 - Travel History
 - Future Travel Plans (if traveling while infectious)
- Field epidemiologist will also begin the monitoring process, which may include daily text/phone check ins. Cases will be monitored until they are no longer considered infectious

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CASE INVESTIGATION

- Field Epidemiologist will ensure that individuals tested for monkeypox are also screened for other infections they may be at risk of based on their investigation. Epis will advise about prevention (HIV PrEP) and treatment of other diseases.



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CONTACT TRACING

- The NDDoH plans to do active surveillance of contacts. We will reach out 1x every 24 hours via phone call, text or email. If no response within 48 hours, they will be instructed to call.
- Contacts will be asked to monitor for the following symptoms:
 - Fever > 100.4
 - Chills
 - New lymphadenopathy
 - Skin Rash
- Contacts who develop symptoms will be instructed to report to their healthcare provider for assessment

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CONTACT TRACING

- Contacts who meet criteria for Post-Exposure Prophylaxis (PEP) will be referred to appropriate facility to begin initiation of PEP
 - PEP Initiation should begin with 4 days from last exposure, it is important that all facilities are ready to administer vaccine for those who are eligible
- Initiation of PEP will be determined based on the levels of contacts as described in subsequent slides
 - High, Medium, Low, No Risk

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LEVELS OF CONTACTS

Degree of Exposure: High

Recommendations

- Monitoring¹
- PEP² - Recommended

Exposure Characteristics

- Unprotected contact between a person's skin or mucous membranes and the skin, lesions, or bodily fluids from a patient (e.g., any sexual contact, inadvertent splashes of patient saliva to the eyes or oral cavity of a person, ungloved contact with patient), or contaminated materials (e.g., linens, clothing) -OR-
- Being inside the patient's room or within 6 feet of a patient during any procedures that may create aerosols from oral secretions, skin lesions, or resuspension of dried exudates (e.g., shaking of soiled linens), without wearing an N95 or equivalent respirator (or higher) and eye protection -OR-
- Exposure that, at the discretion of public health authorities, was recategorized to this risk level (i.e., exposure that ordinarily would be considered a lower risk exposure, raised to this risk level because of unique circumstances)

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LEVELS OF CONTACTS

Degree of Exposure: Intermediate

Recommendations

- Monitoring³
- PEP⁴ - Informed clinical decision making recommended on an individual basis to determine whether benefits of PEP outweigh risks ^{5,6}

Exposure Characteristics

- Being within 6 feet for 3 hours or more of an unmasked patient without wearing, at a minimum, a surgical mask - OR-
- Activities resulting in contact between sleeves and other parts of an individual's clothing and the patient's skin lesions or bodily fluids, or their soiled linens or dressings (e.g., turning, bathing, or assisting with transfer) while wearing gloves but not wearing a gown -OR-
- Exposure that, at the discretion of public health authorities, was recategorized to this risk level because of unique circumstances (e.g., if the potential for an aerosol exposure is uncertain, public health authorities may choose to decrease risk level from high to intermediate)

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LEVELS OF CONTACTS

Degree of Exposure: Low/Uncertain

Recommendations

- Monitoring[†]
- PEP[†] - None

Exposure Characteristics

- Entered the patient room without wearing eye protection on one or more occasions, regardless of duration of exposure -OR-
- During all entries in the patient care area or room (except for during any procedures listed above in the high-risk category), wore gown, gloves, eye protection, and at minimum, a surgical mask -OR-
- Being within 6 feet of an unmasked patient for less than 3 hours without wearing at minimum, a surgical mask -OR-
- Exposure that, at the discretion of public health authorities, was recategorized to this risk level based on unique circumstances (e.g., uncertainty about whether Monkeypox virus was present on a surface and/or whether a person touched that surface)

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LEVELS OF CONTACTS

Degree of Exposure: No Risk

Recommendations

- Monitoring[†] - None
- PEP[†] - None

Exposure Characteristics

- Exposure that public health authorities deemed did not meet criteria for other risk categories

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VACCINES

- JYNNEOS
- live vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, nonreplicating orthopoxvirus
 - Also known as IMVAMUNE, IMVANEX, MVA
 - Licensed by FDA in September 2019
 - Indicated for prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection
- ACAM2000
 - ACAM2000 is a live vaccinia virus vaccine • Licensed by FDA in August 2007 • Replaced Dryvax - license withdrawn by manufacturer and remaining vaccine destroyed • Indication • ACAM2000 is indicated for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection • CDC-held Emergency Access Investigational New Drug Protocol allows use for Non-Variola Orthopoxvirus Infection (e.g., monkeypox) during an outbreak

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	ACAM2000	JYNNEOS
Vaccine virus	Replication-competent vaccinia virus	Replication-deficient Modified vaccinia Ankara
"Take"	"Take" occurs	No "take" after vaccination
Inadvertent inoculation and autoinoculation	Risk exists	No risk
Serious adverse event	Risk exists	Fewer expected
Cardiac adverse events	Myopericarditis in 5.7 per 1,000 primary vaccinees	Risk believed to be lower than that for ACAM2000
Effectiveness	FDA assessed by comparing immunologic response and "take" rates to Dryvax*	FDA assessed by comparing immunologic response to ACAM2000 & animal studies
Administration	Percutaneously by multiple puncture technique in single dose	Subcutaneously in 2 doses, 28 days apart
<small>*Both ACAM2000 and Dryvax are derived from the NYC Board of Health strain of vaccinia; ACAM2000 is a "second generation" smallpox vaccine derived from a clone of Dryvax, purified, and produced using modern cell culture technology.</small>		

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VACCINE

- Monkeypox Vaccine Post-Exposure Prophylaxis (PEP)
 - People can be vaccinated following exposure to mpvx to help prevent illness. Recommended to be given within 4 days from the date of exposure. If given between 4-14 days, may reduce severity of illness but not prevent disease. This is helpful in controlling outbreaks and preventing further transmission of disease.
 - All providers in North Dakota should be prepared now to administer PEP if seeing close contacts.
- Outbreak Response Monkeypox Vaccine Post-Exposure (PEP)++
 - Can be considered "Individual-directed PEP" for mpvx. People with certain risk factors are more likely to have been exposed. This approach aims to reach these people, even if they have not had documented exposure. May help to slow the progression of disease in areas with large numbers of mpvx cases.
- Monkeypox Vaccine Pre-Exposure Prophylaxis (PrEP)
 - This approach refers to administering vaccine to someone at high risk for mpvx (ex. lab workers who handle specimens). At this time, most clinicians not performing the orthopoxvirus generic test are not advised to receive mpvx vaccine PrEP.

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PEP++ IN NORTH DAKOTA

- The current ND recommendations are for gay, bisexual or other cisgender men who have sex with men or transgender persons who meet at least one of the following criteria:
 - Has had multiple sex partners in the last 14 days
 - Attended venues or events where monkeypox spread has been identified
 - Has had a sexually transmitted infection in the past year
- **Note: Persons living with HIV or other immune-compromising conditions** may be at higher risk for severe outcomes and should be a high priority for vaccination if they have exposure as listed above.** **Immune-compromising conditions: leukemia, lymphoma, generalized malignancy, solid organ transplantation, therapy with alkylating agents, antimetabolites, radiation, tumor necrosis factor inhibitors, high-dose corticosteroids, being a recipient with hematopoietic stem cell transplant <24 months

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VACCINE DOSAGE AND SCHEDULE

- Administered as two subcutaneous (SC) injections 28 days apart in adults 18 years and older.
 - There is a seven-day grace period for monkeypox doses.
 - It is recommended to schedule second doses at the time of first doses.
- Booster doses are recommended every 2 to 10 years if a person remains at continued risk for exposure to smallpox, monkeypox or other orthopoxviruses.

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VACCINE SHIPMENTS

- Vaccine will be distributed on an allocation system based on the doses allocated to North Dakota.
 - Accordingly to CDC's operational planning document Tribes and IHS will receive their own allocations.
- Full packages contain 20 single-dose 0.5mL vials.
 - Packages may be broken down by the Strategic National Stockpile or NDDoH warehouse in order to accommodate smaller allocations.
 - All doses not in the original packaging will need to be stored in amber bags to protect the vaccine from light.
- Vaccine may be shipped either frozen at -20°C or refrigerated at 2-8°C.
- Vaccines are NOT shipped with ancillary kits

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ALLOCATION PLANNING ASSUMPTIONS

- Phase 1: 56,000 doses
 - ND did not receive doses
 - Phase 2a: 144,000 doses
 - ND: 65 doses (ordered)
 - Some doses saved for PEP, others being distributed to 5 providers who see high-risk patients
 - Phase 2B: 96,000 doses
 - ND estimate*: 43 doses
 - Phase 3: 800,000 doses
 - ND estimate*: 361 doses
- *estimates may change based on vaccine availability and epidemiology*

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VACCINE STORAGE

- JYNNEOS™ is shipped to the NDDoH at -20°C and requires cold chain management.
- When stored at -20°C, labeled expiration date applies.
 - Expiration dates are found on the carton, but not on the vial itself. Expiration dates may also be found at: [Monkeypox \(hhs.gov\)](https://www.hhs.gov/monkeypox)
- Allow the vaccine to thaw and reach room temperature before administration.
- When thawed and refrigerated at 2-8°C temperature, unopened vials can be used for up to 8 weeks based on information provided directly by the manufacturer (this differs from the package insert).
- **DO NOT REFREEZE VACCINE VIALS**
- **DO NOT STORE IN DORM-STYLE REFRIGERATORS**

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VACCINE THAWING

- Vaccine thawing prior to administration:
- When taken from -20°C the vaccine will thaw in less than 10 minutes.
- Vaccine should be stored in the original packaging and protected from light.
- Vaccine should be left in the freezer and only the vials intended for use should be removed at that time. The vaccine package should not be taken in and out of the freezer to remove vials.

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VACCINE PREPARATION AND ADMINISTRATION

- When thawed, JYNNEOS™ is a milky, light yellow to pale white colored suspension. The vials should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.
- Swirl the vial gently before use for at least 30 seconds. Withdraw a dose of 0.5 mL into a sterile syringe for injection.
- Administer JYNNEOS™ by subcutaneous injection, preferably into the upper arm (deltoid).

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SPECIAL CONSIDERATIONS

- JYNNEOS™ may be administered at the same time as other vaccines, with the exception of COVID-19 vaccine.
 - Cannot be administered at the same time as COVID-19 vaccine, must wait 4 weeks after JYNNEOS™ vaccination before getting an mRNA COVID-19 vaccine.
- It is highly recommended that hepatitis A and meningococcal conjugate vaccines be offered at the same time, if not previously vaccinated.
- The immune response takes two weeks after the second dose for maximal development.
- People with a severe allergy to any component of the vaccine (gentamicin, ciprofloxacin, egg protein) should not receive this vaccine.
- Consider offering or referring for other services the patient may need, including STI testing and HIV PrEP.

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ANTIVIRALS

- Tecovirimat
 - Tecovirimat is an antiviral medication that is approved by the FDA for the treatment of human smallpox disease in adults and pediatric patients weighing at least 3 kg
 - Also known as TPOXX or ST-246
- Oral capsule and IV formulations approved by FDA in July 2018 and May 2022, respectively - Indication
 - Tecovirimat is indicated for the treatment of human smallpox disease in adults and pediatric patients weighing at least 3 kg
 - CDC-held Emergency Access Investigational New Drug Protocol allows use of Tecovirimat for Non-Variola Orthopoxvirus Infection (e.g., monkeypox)
 - Includes allowance for opening an oral capsule and mixing its content with liquid or soft food for pediatric patients weighing less than 13 kg
- Available from the Strategic National Stockpile as an oral capsule formulation or an intravenous vial
https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/208627s000lbl.pdf

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VACCINIA IMMUNE GLOBULIN INTRAVENOUS

- **VIGIV is licensed by FDA for the treatment of complications due to vaccinia vaccination, including:**
 - Eczema vaccinatum
 - Progressive vaccinia
 - Severe generalized vaccinia
 - Vaccinia infections in individuals who have skin conditions
 - Aberrant infections induced by vaccinia virus (except in cases of isolated keratitis)
- CDC-held Emergency Access Investigational New Drug Protocol allows use of VIGIV for NonVariola Orthopoxvirus Infection (e.g., monkeypox)

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OTHER RESOURCES

- [Monkeypox \(MPV/MPX/MPXV\) | Department of Health \(nd.gov\)](https://www.nd.gov/health/monkeypox/)
- <https://www.cdc.gov/poxvirus/monkeypox/index.html>
- COCA
 - https://emergency.cdc.gov/coca/calls/2022/callinfo_052422.asp
 - https://emergency.cdc.gov/coca/ppt/2022/052422_slides.pdf
 - <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-22-23/01-OPX-Rao-508.pdf>

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POST-TEST

- Post-test
 - Nurses interested in continuing education credit, visit
 - https://ndhealth.co1.qualtrics.com/jfe/form/SV_41LBI3KGOYqvn4G
 - Successfully complete the five-question post-test to receive your certificate
 - Credit for this session will be available until Sept 13, 2022
 - This presentation will be posted to our website www.health.nd.gov/immunize

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QUESTIONS?
THANK YOU!

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