

MONKEYPOX: WHAT NORTH DAKOTA HEALTH CARE WORKERS NEED TO KNOW

September 28, 2022 Presentation Updated September 2022 NORTH Dakota

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LUNCH AND LEARNS

The HIV/STD/TB/Hepatitis Program and the Dakotas AIDS Education and Training Center (DAETC) conduct monthly Lunch and Learn Webinars for health care professionals in North and South Dakota.

Each month a new topic will be held from 12:00 p.m. to 1:00 p.m. CST on the **fourth Wednesday of the month**.



TODAY'S PRESENTERS: ND DEPT OF HEALTH AND HUMAN SERVICES

- Danni Pinnick,
 MPH
 - Immunization
 Surveillance
 Coordinator
 - Disease Control Section

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

OUTLINE

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

MONKEYPOX SITUATIONAL UPDATE

N O R T H Dakota

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SITUATIONAL UPDATE

- Countries that typically do not see monkeypox began to see cases in Spring 2022.
- Most cases are among men who have sex with men (MSM)
- Five US commercial laboratories are fully operational and able to conduct monkeypox testing in addition to the LRN laboratories.
- Monkeypox does not spread easily between people without intimate close contact. The threat to the US population remains LOW

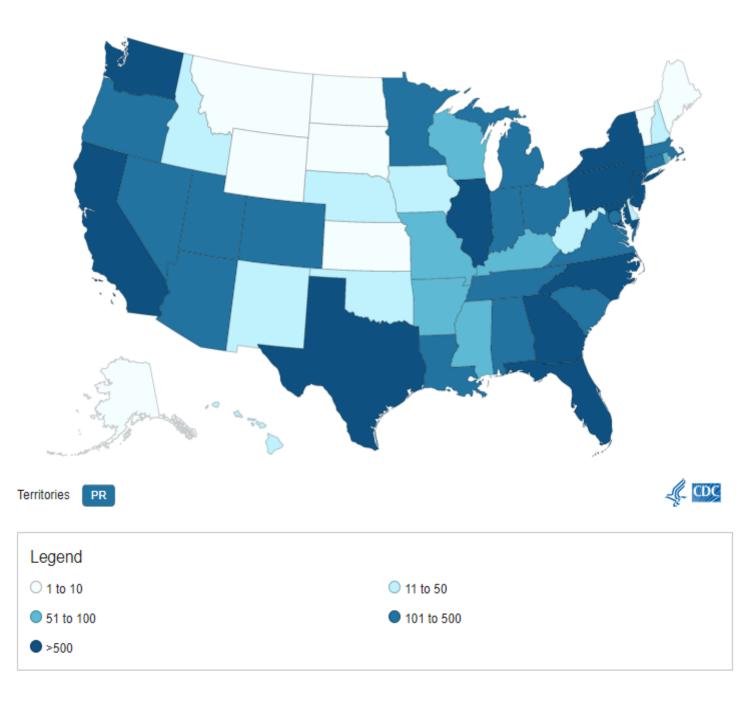
CASE DEFINITION

- Suspect Case
 - New characteristic rash* OR
 - Meets one of the epidemiologic criteria and has a high clinical suspicion⁺ for monkeypox
- Probable Case
 - No suspicion of other recent Orthopoxvirus exposure (e.g., Vaccinia virus in ACAM2000 vaccination) AND demonstration of the presence of
 - Orthopoxvirus DNA by polymerase chain reaction of a clinical specimen **OR**
 - Orthopoxvirus using immunohistochemical or electron microscopy testing methods **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

WORLD-WIDE CASES CURRENT AS OF SEPTEMBER 27, 2022



US CASES CURRENT AS OF SEPTEMBER 27, 2022



WORLDWIDE DEATHS CURRENT AS OF SEPTEMBER 27, 2022

Country	Cases	Deaths
Nigeria*	277	6
Ghana*	84	4
Spain	7,083	3
Central African Republic*	8	2
Cameroon*	8	2
Brazil	7,300	2
United States Of America	25,161	1
Sudan	7	1
India	12	1
Ecuador	93	1
Czechia	66	1
Cuba	2	1
Belgium	757	1

*Countries that have historically reported monkeypox cases

NORTH DAKOTA CASES

- North Dakota has identified six cases of monkeypox in North Dakota (5 – Eastern, 1 – Western)
- We continue to work with our healthcare providers to offer consultation, testing and PEP/PEP++ for those that it is indicated for
- Upon suspicion of MPXV provider can reach out to the NDDHHS at 701.328.2378 for further consultation
- Subsequent diagnoses of those who were tested and negative for monkeypox in North Dakota include folliculitis, shingles, syphilis, hand foot and mouth



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- Rare, sometimes life-threatening zoonotic infection
- Endemic in west and central Africa
 - Clade I, Clade IIa and Clade IIb
 - Clade IIb referring to the currently circulating strain
- Specific animal reservoir unknown but likely small mammals
- Caused by Monkeypox virus (which is an orthopoxvirus)
 - A less severe cousin of the virus that causes smallpox
- Can spread from infected animals to humans and person-to-person

- 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

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

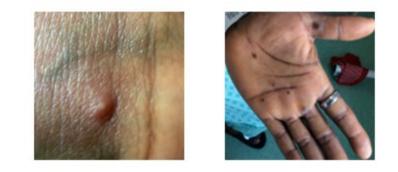
- 2022 Outbreak
 - First cases reported May 17 in the US
 - Most cases are among the MSM population
 - Co-Infection with STIs has occurred.
 - Atypical presentation
 - Genital/perianal lesions
 - Proctitis
 - Hospitalizations=low
 - Deaths = 1 in the United States (Texas), 6 additional deaths in countries that have not historically reported monkeypox cases

Most common symptoms include

- Fever (63.3%)
- Mylagia (55%)
- Swollen lymph nodes (58.5%)
- Chills (59.1%)
- Malaise (57.1%)







- 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
 - ~100% of cases report having a rash
 - Many cases are reporting anorectal (~31%) or genital (~46%) lesions
 - The rash goes through different stages before healing completely. The illness typically lasts 2-4 weeks.

Progression of Symptoms – Rash Phase

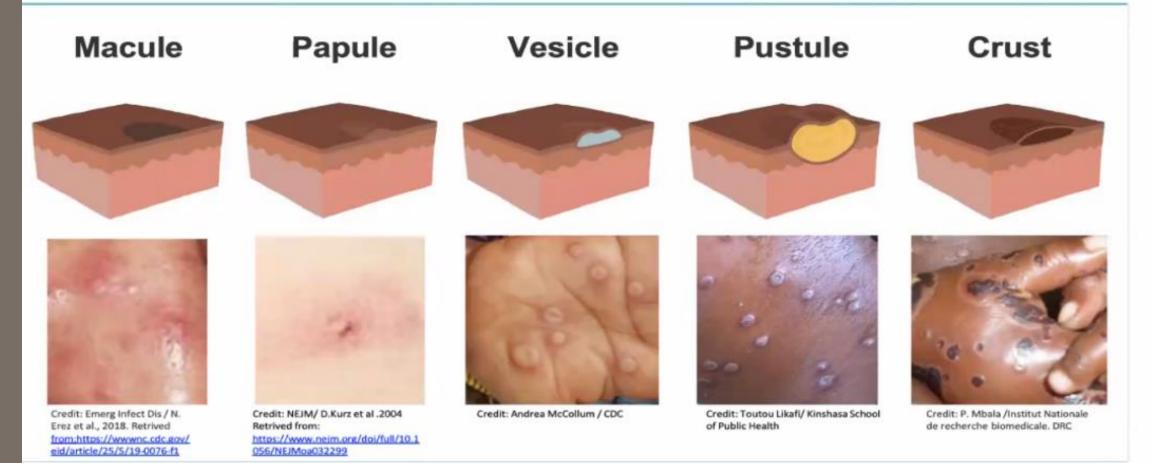




Photo Credit: NHS England High Consequence Infectious Disease Network

- 2022 atypical signs and symptoms
 - Rash or enathem in all patients
 - Firm, deep-seated, well-circumscribed and sometimes umbilicated
 - Small lesions
 - May rapidly progress through stages (papules, vesicles, pustules, and scabs)
 - Papulovesicular and pustular lesions may be seen on same body site
 - Prodromal symptoms mild or not occurring

- 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

- 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



REDUCING STIGMA IN MONKEYPOX COMMUNICATIONS

- Focus on larger general messaging with key points that anyone can get monkeypox
- When we say that people who identify as gay, bisexual, and other MSM are at high-risk, we are combining someone's identity/sexual orientation with a risk factor, making messaging without stigma complicated.

AVOID STIGMATIZING OTHERS

- Frame monkeypox as an issue that affects everyone by using "us" and "we."
- Educate about monkeypox. State the facts.
- Use "person first," inclusive, non-stigmatizing language.
- Communicate with a health equity lens.
- Use culturally responsive and culturally appropriate language.
- Consider unique barriers and challenges the community may face and how they may receive your messaging.



TAKING A SEXUAL HISTORY

THE 5 "P"s OF SEXUAL HEALTH



Partners

Number, sex and gender identity of partners



Practices

Types of sex — oral, vaginal, anal and risk behaviors such as injecting drugs, having sex while intoxicated or having anonymous sex partners



Protection from STIs, including HIV

Use of condoms, other barrier methods, HIV PrEP or PEP



Past History of STIs, including HIV

Previous STI diagnoses, history of STI and HIV testing and partners history of STI diagnoses

Pregnancy Intention

Desire for pregnancy and/or use of prevention methods

Best Practices for Taking a Sexual History

- Ensure a safe patient environment
- Assure confidentiality
- Be nonjudgmental
- Be sensitive, and matter-of-fact
- Avoid assumptions
- Use normalizing language
- Utilize open-ended questions
- 6th 'P': Prevention

"It Is Important We Discuss Your Sexual Practices. I Speak With All Of My Patients About Many Different Aspects Of Their Lives."



LABORATORY COLLECTION

NORTH Dakota

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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 multiple lesions should be collected, preferably from different locations on the body or from lesions which differ in appearance. Label each set of tubes with the collection site, when collecting from multiple sites.
 - 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.



ENSURING A WELL COLLECTED SAMPLE

- Ensuring that a sample is well collected is essential
 - Do **NOT** clean the site prior to collection!
 - Our laboratory can detect if human material is present
 - Several samples have been reported as "inconclusive" because this target isn't detected
- Excellent video on sample collection:
 - <u>https://www.youtube.com/watch?v=kEYfW9rVmRI</u>

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
- Starting September 1st you can order a Monkey pox test by logging into your Laboratory Web Portal. On the requisition page under the Viruses section, you will find Orthopox panel (Monekypox) PCR.
- Specimens can be shipped Category B

MYCOBACTERIOLOGY	
O Mycobacteria Culture (TB) & Smear	O Mycobacteria Reference ID
Quantiferon (TB)	
MYCOLOGY	
O Fungal Culture	O Fungal Reference ID
OTHER	
O Other	
PANELS	
O Measles/Mumps, IgG Immune Screen	O Measles/Mumps/Rubella, IgG Immune Scree
O Measles/Mumps/Rubella/Varicella, IgG Immune Screen	O HIV/HBsAg
HIV/HBsAg/RPR	O HIV/HBsAg/Syphilis Testing Panel
O HIV/HCV	O HIV/HCV/HBsAg
O HIV/RPR	O HIV/Syphilis Testing Panel
PARASITOLOGY	
Giernsa Thick & Thin Blood Smears	O Ova and Parasites
STD/SCREENING	
O Chlamydia trachomatis/N gonorrhoeae	O Fluorescent Treponemal Antibody
HIV-1, 2 Antibody/HIV-1 p24 Antigen Combo	O Mycoplasma genitalium
RPR Syphilis	○ Syphilis Testing Panel ⊙
O TP-PA: Treponema pallidum Particle Agglutination	O VDRL (CSF)
SURVEILLANCE	
SARS-CoV-2 WGS (Whole Genome Sequencing)	

VIROLOGY

Enterovirus PCR
 Hepatitis A Antibody, IgM
 Hepatitis B Core Antibody, IgM
 Hepatitis B Surface Antigen (HBsAg)
 Hepatitis C Virus Genotyping
 Influenza Virus PCR

- O Mumps Virus PCR
- O multipa virua rok
- O Respiratory Panel (RP2) PCR O
- O Trioplex (Zika, Dengue, Chikungunya) Virus PCR
- Herpes Simplex/Varicella Zoster Virus HDA
 Hepatitis B Core Antibody (Anti-HBC), Total
 Hepatitis B Surface Antibody (Anti-HBS)
 Hepatitis C Antibody (Anti-HCV)
 Hepatitis C Virus RNA (Quantitative)
 Measles (Rubeola) Virus PCR
 Prenatal Hepatitis B Surface Antigen
 SARS-CoV-2 PCR (COVID19)

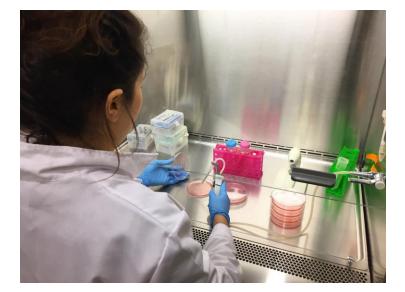
TURNAROUND TIME

- Testing at the ND Lab is performed M-F
- Typically performed day of receipt if received in the morning
- Turnaround time for CDC testing is 5-7 days after receipt in their lab.



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



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

SELECT AGENT REGULATIONS

Laboratory testing has indicated that the current outbreak is associated with Clade IIb of monkeypox virus. Clade IIb of the monkeypox virus is not subject to select agent regulations.



LABORATORY QUESTIONS?

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



CASE INVESTIGATION

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CASE INVESTIGATION

- Case and contact investigation will be managed by the North Dakota Department of Health and Human Services
 - Division of Field Services will complete most case interviews and contact referrals
- Questions/Interview will be documented in the MAVEN system using questions generated from the CDC
- The NDDHHS will provide updates on case counts on our monkeypox dashboard Monday - Friday.
 - <u>https://www.health.nd.gov/monkeypox</u>

CASE INVESTIGATION

- Upon suspicion of MPXV provider can reach out to the NDDHHS 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 NDDHHS

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 ensure that individuals tested for monkeypox are also screened for other infections they may be at risk of based on their investigation.
- Providers should also consider prescribing HIV PrEP to patients that may be at risk

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

CONTACT TRACING

- The NDDHHS plans to do <u>active</u> 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

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

Degree of Exposure: High

Recommendations

- Monitoring[§]
- PEP[¶] 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)

Degree of Exposure: Intermediate

Recommendations

- Monitoring[§]
- PEP[¶] Informed clinical decision making recommended on an individual basis to determine whether benefits of PEP outweigh risks ^{¶¶}

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)

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)

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



VACCINE/TREATMENT

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VACCINE

- 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
- EUA administration (requires EUA fact sheet)
 - ID administration for adults
 - SC admin for patients under 18

Table 2. Vaccination Schedule and Dosing Regimens for JYNNEOS Vaccine

JYNNEOS vaccine regimen	Route of administration	Injection volume	Recommended number of doses	Recommended interval between 1st and 2nd dose
Alternative regimen				
People age ≥18 years	ID	0.1 mL	2	28 days
Standard regimen				
<u>People age <18 years</u>	Subcut	0.5 mL	2	28 days
People of any age who have a history of developing keloid scars	Subcut	0.5 mL	2	28 days

M O N K E Y **P O X**

How to administer a JYNNEOS vaccine intradermally.

How to administer a vaccine intradermally.

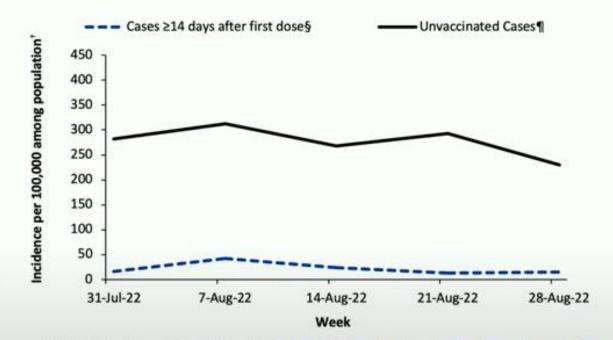
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*

0:02 / 0:55

Rates of Monkeypox Cases* by Vaccination Status

July 31, 2022 - September 3, 2022



People eligible for a monkeypox vaccination who were **not vaccinated** were **14X** more likely to become infected than those who received **one dose of** JYNNEOS vaccine.

CDC 2022 Monkeypox Outbreak Cases & Data: https://www.cdc.gov/poxvirus/monkeypox/cases-data/mpx-vaccine-effectiveness.html

*A probable or confirmed case entered into DCIPHER. Confirmed (presence of Monkeypox virus DNA by polymerase chain reaction (PCR) testing or Next-Generation sequencing of a clinical specimen OR isolation of Monkeypox virus in culture from a clinical specimen) and probable (presence of orthopoxvirus DNA by PCR, or orthopoxvirus using immunohistochemical or electron microscopy or detectable levels of anti-orthopoxvirus IgM antibody) monkeypox cases. 'Vaccinated population determined based on cumulative number that received first dose of vaccine 2 weeks prior to week. Unvaccinated population determined based on population eligible for vaccinated population per jurisdiction of men who have sex with men (MSM) who are living with HIV (as of 2020) or MSM who are eligible for HIV pre-exposure prophylaxis (as of 2021)] minus number vaccinated.

¹MPX case ≥14 days after first dose: A probable or confirmed case entered into DCIPHER with positive orthopox test for monkeypox date, illness onset date, or specimen collection date (earliest available date) ≥14 days after receiving the first dose of JYNNEOS vaccine.





VACCINE

- Monkeypox Vaccine Post-Exposure Prophylaxis (PEP)
 - People can be vaccinated following exposure to mpxv 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 mpxv. 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 mpxv cases.
- Monkeypox Vaccine Pre-Exposure Prophylaxis (PrEP)
 - This approach refers to administering vaccine to someone at high risk for mpxv (ex. lab workers who handle specimens). At this time, most clinicians not performing the orthopoxvirus generic test are not advised to receive mpxv vaccine PrEP.

UPDATED MPV VACCINE ELIGIBILITY

- PEP++ vaccination is indicated for anyone ages 18 and older who is a:
 - Man who has sex with other men
 - Woman who has sex with a man who has sex with other men
 - Person who engages in sex work or exchanges sex for food, money, substances, shelter, etc.
 - Person experiencing homelessness
- People who are identified as close contacts to monkeypox cases will also continue to be a high priority for vaccination.

MPV ORDERING

- Due to limited supplies of Jynneos[™], the North Dakota Department of Health and Human Services (NDHHS) has been allocating doses to providers. Starting Thursday, September 22, enrolled monkeypox vaccine providers began ordering Jynneos[™].
- The ordering process is similar to COVID-19 vaccine ordering. Jynneos[™] may be ordered <u>online</u> for administration to <u>eligible</u> <u>patients</u>.

MPV ORDERING

- Please note that ordering is in vials, not doses. About 5 intradermal doses can be obtained from one vial.
- Facilities will receive an email confirmation from the NDHHS Immunization Unit within one business day of Monkeypox vaccine request. The NDHHS Warehouse is unable to accommodate last minute orders.
- Providers are responsible for ordering second doses.
- Please allow up to 48 hours after delivery for lot numbers to appear in NDIIS.

TRACKING MONKEYPOX VACCINE INVENTORY

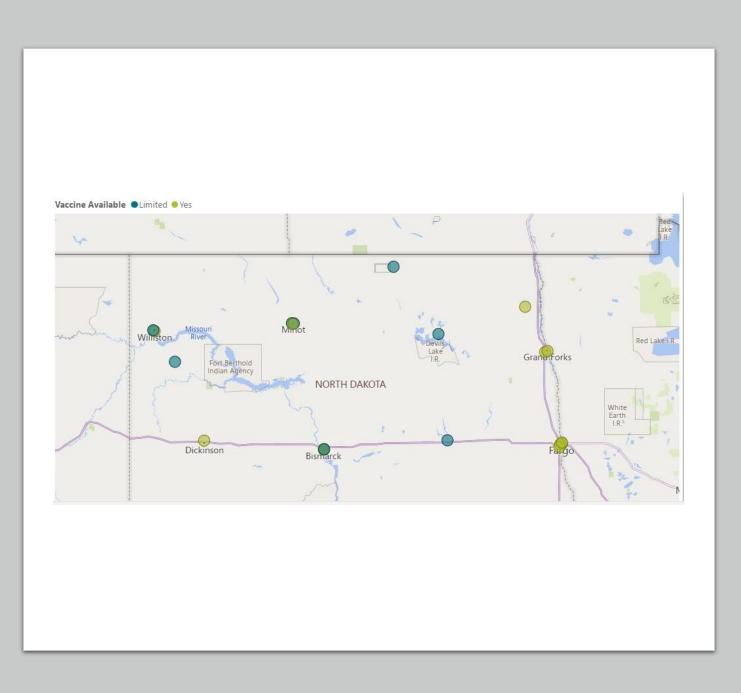
- Vaccine inventory will be allocated and/or ordered based on vials, not doses as the number of doses per vial varies depending on the administration.
- Inventory on hand in the NDIIS1 must be regularly updated to reflect the number of vials currently on hand. Doses administered will decrement inventory, which means providers who are able to administer more than one dose from a single vial will end up with a negative balance of inventory on hand.
- Inventory in the NDIIS should be reviewed and adjusted daily but MUST be reviewed and adjusted by end of business every Monday and Wednesday, at a minimum.

TRACKING MONKEYPOX VACCINE WASTAGE

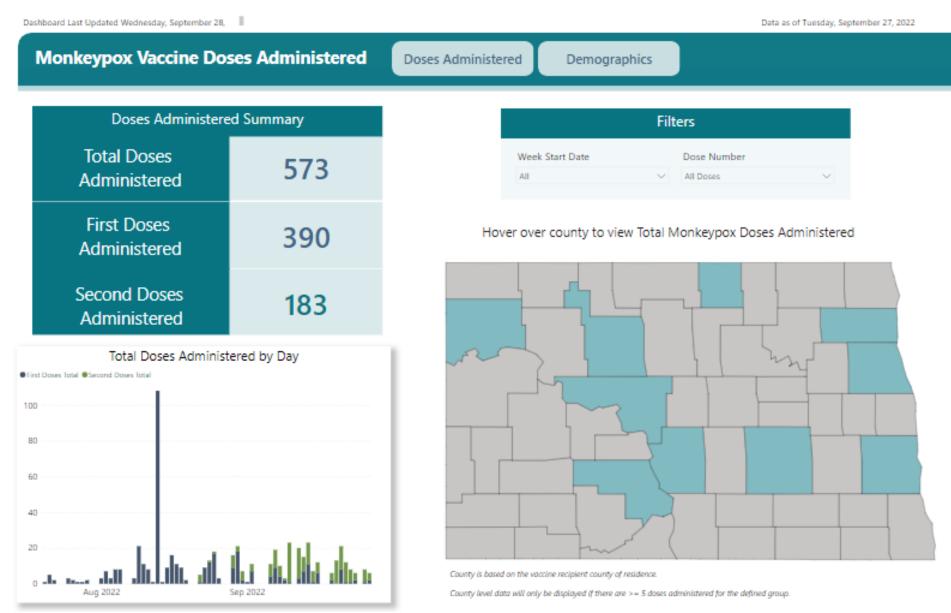
- Immunization Unit Staff must be notified via email (vaccine@nd.gov) when vaccine needs to be wasted.
- Vaccine vials wasted must be entered into the NDIIS Vaccine Ordering, Returns, and Wastages module.
- Vaccine wastage should only be reported if a whole vial will be wasted. If one or more doses have been administered but the whole vial was not used, the remaining vaccine should be discarded and no wastage should be reported.

MONKEYPOX VACCINE IN ND

- Any male age 18 or older who identifies as having sex with other men
- North Dakota Monkeypox Vaccine Locator | Department of Health (nd.gov)



Vaccine Doses Administered Data



VACCINE DOSAGE AND SCHEDULE

- Administered as two intradermal injections 28 days apart in adults 18 years and older.
 - Doses can be given up to four days early.
 - It is recommended to schedule second doses at the time of first doses.
 - Vaccine delivery updated in order to ensure better access to limited supplies of vaccines. Providers can get 3-5 doses from a vial versus a single dose.
- Booster doses are recommended every 2 to 10 years if a person remains at continued risk for exposure to smallpox, monkeypox or other orthopoxviruses.

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 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

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: <u>Monkeypox (hhs.gov)</u>
- 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 <u>manufacturer</u> (this differs from the package insert).
- DO NOT REFREEZE VACCINE VIALS
- DO NOT STORE IN DORM-STYLE REFRIGERATORS

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.

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.
- Return vial to fridge between draws
- 3-5 0.1mL ID doses can be drawn, One 0.5mL SC dose
- Vial must be discarded 8 hours after first draw/puncture

OTHER CONSIDERATIONS

- REPORT ALL DOSES TO NDIIS W/IN 24 HRS
- Try to use all doses in vial. May give leftover doses to HCWs rather than waste.
- Work with local agencies to vaccinate target population
 - Pride organizations
- Consider vaccination of:
 - Homeless
 - Sex workers
 - Incarcerated
- TB needles/syringes for ID administration can be used
- DO NOT need to save 2nd doses or PEP doses.
- Consider walk-in MPV vaccination days
- Report adverse events to VAERS

DOSE REPORTING

- Doses will be entered into providers NDIIS inventory as a single dose vial.
- When administering more than 1 dose from the vial a providers inventory may be negative.
- Providers can either adjust to current vial count or leave as a negative number.
- As long as a provider can administer at least one dose out of a vial no wastage will need to be reported regardless of the number of doses that can be drawn.
- Only report wastage if an entire vial must be discarded (e.g. temperature excursion). Report all excursions to the NDDoH.

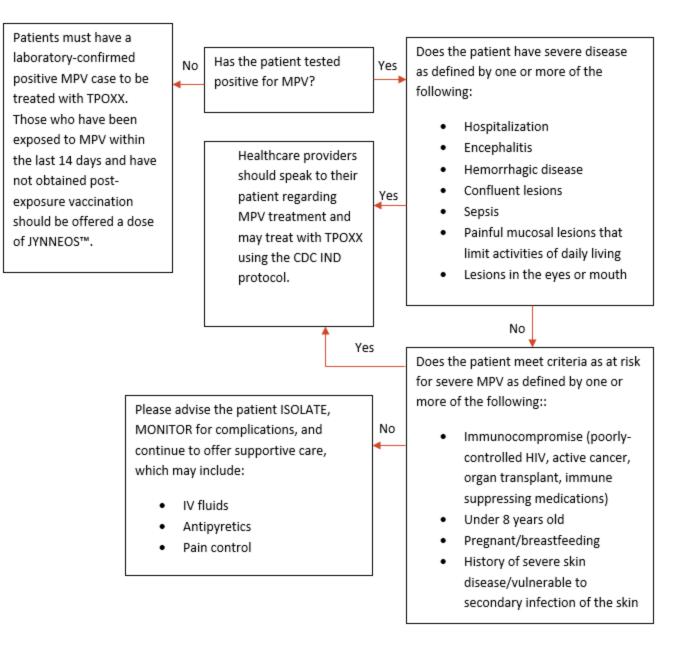
SPECIAL CONSIDERATIONS

- JYNNEOS[™] may be administered at the same time as other vaccines
 - Due to an increased risk of myocarditis, patients/providers may choose to separate doses of JYNNEOS and COVID-19 vaccines by 4 weeks, but should use clinical judgement to weigh risks and benefits
- 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.

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

Who should receive TPOXX?



ANTIVIRALS

- Providers treating MPV patients should contact the NDDOH to procure medication
- ND has pre-positioned PO courses of treatment for quick deployment to regions with MPV cases

OTHER RESOURCES

- Monkeypox (MPV/MPX/MPXV) | Department of Health (nd.gov)
- https://www.cdc.gov/poxvirus/monkeypox/index.html
- COCA https://emergency.cdc.gov/coca/calls/index.asp
- https://www.cdc.gov/vaccines/acip/meetings/downloads/slide s-2022-06-22-23/01-OPX-Rao-508.pdf

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CONTINUING EDUCATION CREDITS

Please complete the post-test to receive CEUs for this presentation. You must score at least 70% to receive credit. You may take the post-test up to two weeks after the presentation. Post-test, along with the slides and the recording of this presentation can be found at:

https://www.health.nd.gov/HIV/Education

For questions or comments contact: Sarah Weninger 701.328.2366 sweninger@nd.gov



Thank You to Our Speakers!

- CEU: www.health.nd.gov/HIV/Education
- Next Lunch and Learn: October 26, 2022
 - Topic: Patient Navigation and the Marketplace
 - Questions: Sarah Weninger, sweninger@nd.gov





Educational Opportunities - Events & Trainings

The North Dakota Department of Health (NDDOH) offers ongoing educational opportunities for healthcare providers on a variety of subjects. The Division of Sexually Transmitted and Bloodborne Diseases also offers on-site education such as agency presentations as requested. Contact the HIV.STI.Viral Hepatitis Prevention Coordinator, Sarah Weninger at sweninger@nd.gova, today with your training needs.





QUESTIONS? THANK YOU!



