WELCOME to the

Just in Time: Testing, Vaccination, and Treatment for Monkeypox ECHO

Session 1, Efficient Effective Testing, 8/17/2022

Please let us know you are here: Type your name, email, organization into CHAT

Monkeypox Testing

Project ECHO, 8/17/2022

Graphic credit: WHO Monkeypox Outbreak 2022

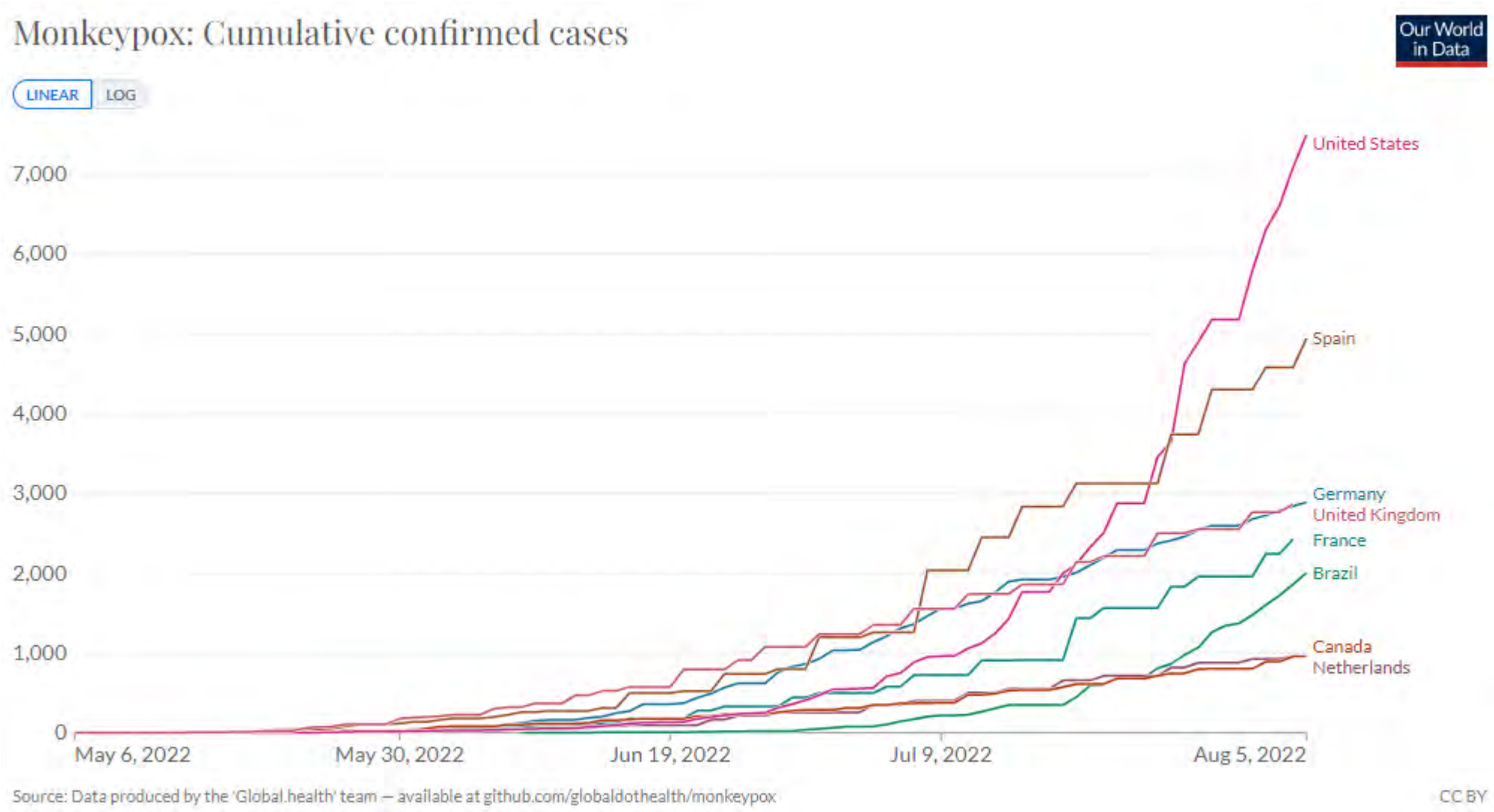
I have no conflicts of interest to disclose.

Graphic credit: CDC

Graphic credit: CDC

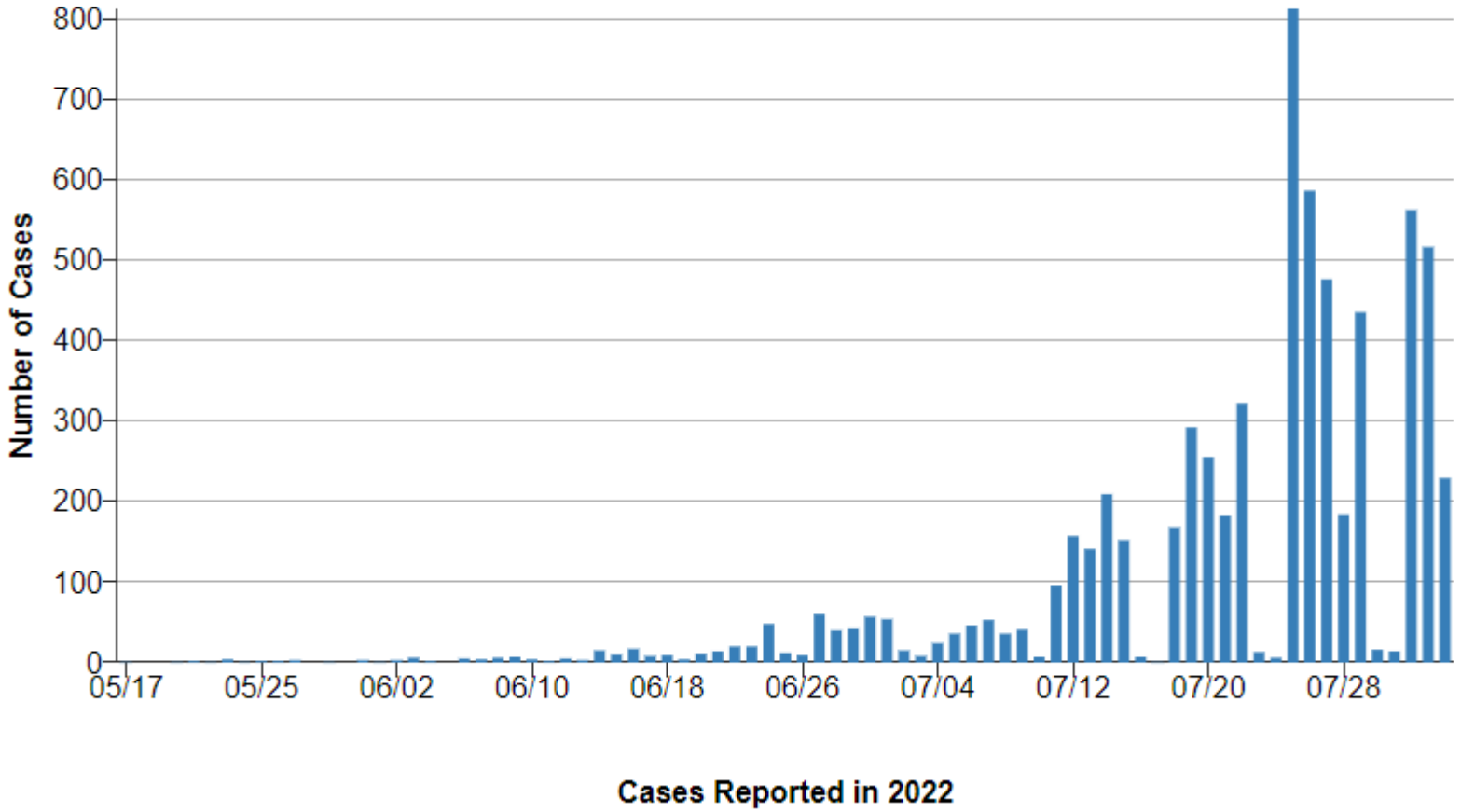
Key take aways:

- *Monkeypoxvirus* testing is widely available through New Hampshire Public Health Laboratories (PHL) or through five national commercial labs
- Any individual suspected of monkeypox should be immediately placed in a private room
  - Negative pressure room not necessary unless completing an aerosol producing procedure
- Providers seeing patient with suspicion for monkeypox should use gowns, gloves, eye protection, and an N95 or higher level respirator
- Concurrent testing for other sexually transmitted infections (STIs) is recommended in patients with lesions suspicious for monkeypox
- For testing at NH PHL, call Division of Public Health Services (DPHS) at 603-271-4496



https://ourworldindata.org/monkeypox

U.S. Monkeypox Case Trends Reported to CDC



https://www.cdc.gov/poxvirus/monkeypox/response/2022/mpx-trends.html

What are the demographics of currently identified cases?

Per Thornhill, et.al., NEJM April-June 2022:

- Men who identify as gay, bisexual, or other men who have sex with men: 98%
- Age median: 38 years
- Persons living with HIV: 41%, majority on ART and well controlled
- Mode of transmission through sexual activity: 95%
- Median time from exposure to first symptoms (prodrome or lesions): 7 days
- Found to have concomitant STI (chlamydia, gonorrhea, syphilis): 29%
- Admitted for inpatient management: 13%

*Seen in endemic disease

What features are most commonly seen on presentation?

- Initial presentation:
  - Skin lesions 95%: anogenital, trunk/arms/legs, face, palms and soles
    - Mucosal lesions 41%:
      - anorectal lesions 11.5% → Symptoms: anorectal pain, proctitis, tenesmus, diarrhea, penile edema
      - oropharyngeal 5% → Symptoms: pharyngitis, odynophagia, epiglottitis, oral/tonsillar lesions
    - 10% presented with one genital ulcer, could be mistaken for STI

    +/- Prodromal symptoms: fever, lymphadenopathy, myalgias, lethargy, headache

  - Reasons for hospital admission: pain control, inability to take PO, bacterial superinfections

Graphic credit: CDC

Can we test people without skin or mucosal lesions?

- Do not test individuals who do not have skin/mucosal lesions
- Conduct detailed history and careful physical exam, including perirectal or anal symptoms or lesions
- These individuals should isolate and practice proper infection prevention precautions
  - Avoid close contact with others/pets, use a separate bathroom from others or disinfect common surfaces with EPA-registered household cleaning product, handle own linens, do not share glasses or utensils
- Instruct patients with prodromal symptoms to monitor for worsening of systemic symptoms or development of rash and notify provider immediately, especially those with risk factors of severe disease
  - under 8 years of age, pregnant, immunocompromised, history of atopic dermatitis/eczema
- Will need to bring patient back in for formal testing if they develop rash

Can we test people with skin or mucosal lesions?

- Consider testing any person with lesions (skin/mucosal) consistent with monkeypox:
  - macules, papules, vesicles, pustules, scabs, enanthem
  - most commonly presenting in anorectal region
  - can see multiples stages simultaneously and increase in number over time

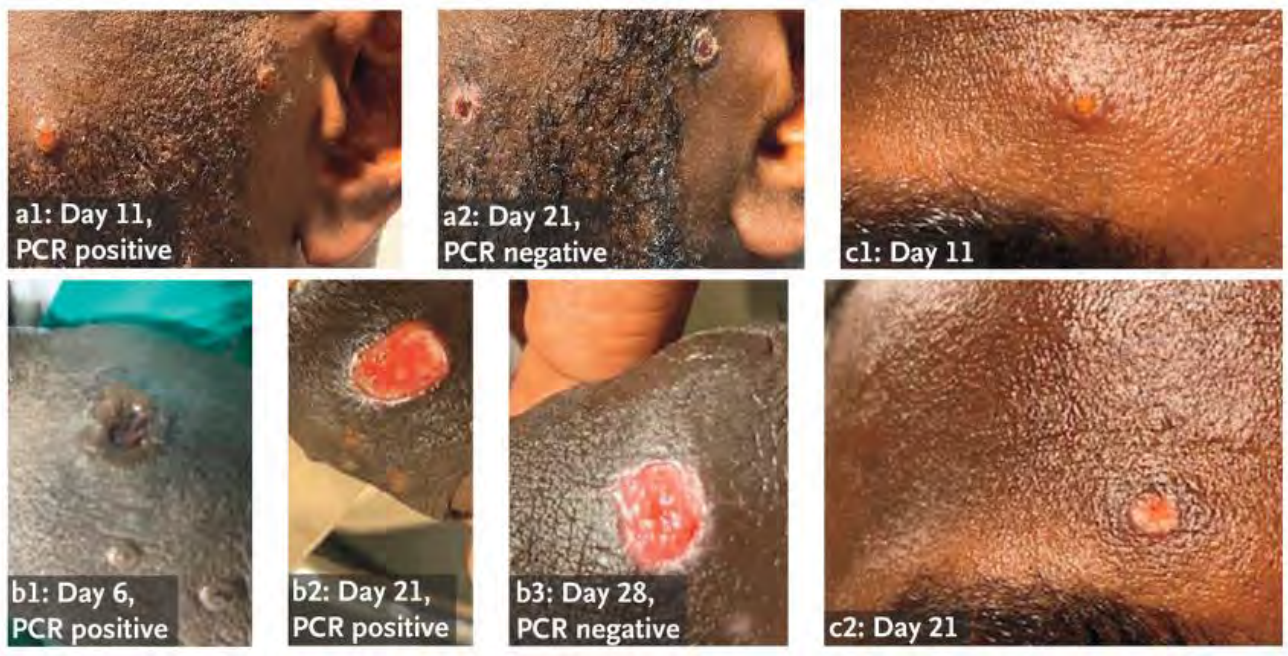
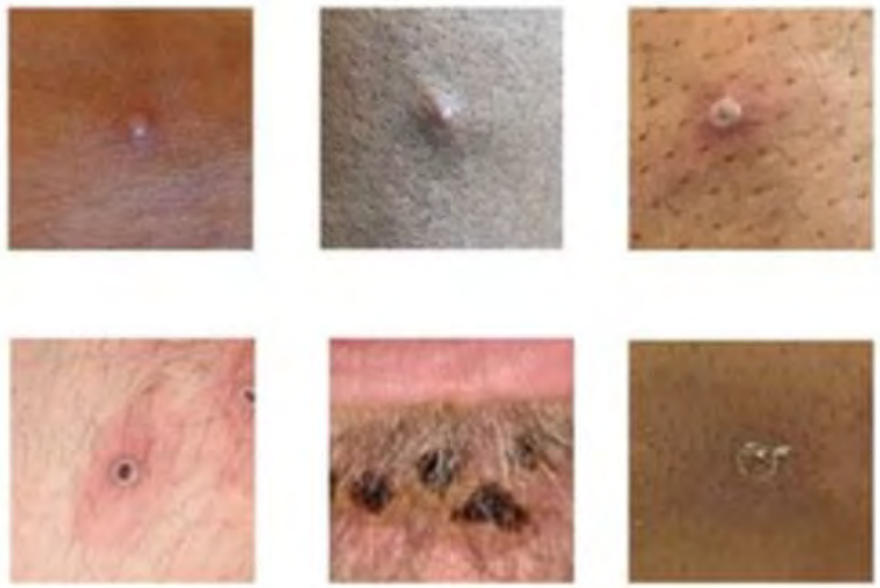


Photo courtesy: Thornhill, et.al.

What type of sample is collected?

- Swabbing of lesion material:
  - Skin Vesicle
  - Skin Ulcer
  - Mucosal ulceration (oral, perianal, vaginal)
  - Dry scraping of scab

Photo courtesy: UK Health Security Agency (UKHSA)



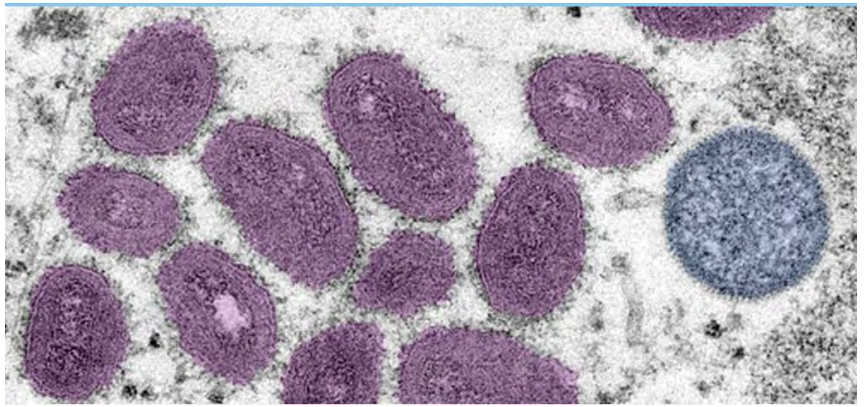
***Recommended to additionally test for other sexually transmitted infections (gonorrhea, chlamydia, syphilis) due to high rate of concomitant infection

How do we examine a patient with possible monkeypox?

- Patient should be brought out of the waiting room and moved to a private room
  - If inpatient, patient should be in single-person room with dedicated bathroom
  - Negative pressure room is not necessary unless conducting an aerosol generating procedure
- Provider should don proper PPE: gown, gloves, eye protection (goggles or face shield covering front and sides of face), N95 or higher level respirator
- Patient should wear a well fitting mask and cover rash (gloves, long sleeves, etc)
- Standard disinfection precautions with EPA-registered hospital-grade disinfectant according to manufacturer's directions
- Wet cleaning methods preferred to prevent aerosolizing virus

Graphic credit: WHO

Graphic credit: CDC



How do we safely test for monkeypox?

- Provider should don appropriate PPE
- Vigorously swab a single lesion with two swabs (at PHL limited to 2 lesions)
- Break off applicator of each swab in a separate sterile tube to fit without bending
  - Check with lab whether the sample can/should be media in transport as it varies by lab (PHL requires dry specimens)
- Proper patient labeling and indicate location of lesion
- Wrap Parafilm square around the top of each closed tube
- Refrigerate (2-8°C) within one hour of collection

Where do we send samples for testing in NH?

- Testing is widely available at the NH PHL and at five national commercial laboratories
  - If sending to PHL, must first contact NH DPHS to speak to public health professional

    603-271-4496 or 603-271-5300 (after hours)

  - Five commercial reference laboratories conducting testing nationwide:
    – Aegis Science, Labcorp, Mayo Clinic Laboratories, Quest Diagnostics, Sonic Healthcare

What happens after we submit the sample to NH PHL?

- *Orthopoxvirus* PCR performed at NH PHL
  - Expected turn-around time: within 12-24 hours of specimen receipt
    Monday through Friday during regular business hours

Anyone who tests positive at PHL or commercial lab should be considered to have monkeypox

New Hampshire Public Health Laboratories
Helping Protect the Community Through Service & Education

When and how should we report cases to NH DPHS?

- NH DPHS should be notified of any person who tests positive for monkeypox: 603-271-4496
  - Important information: individual's risk factors, date of suspected exposure, date of prodrome onset (if any), date of rash onset and location, exposures since onset of symptoms

Suspected cases being tested through commercial labs do not need to be reported to NH DHPS unless:

- high suspicion for disease and
- potentially large group of people exposed that may need PEP or preemptive treatment

Key take aways:

Graphic credit: CDC

- *Monkeypoxvirus* testing is widely available through New Hampshire Public Health Laboratories (PHL) or through five national commercial labs
- Any individual suspected of monkeypox should be immediately placed in a private room
  - Negative pressure room not necessary unless completing an aerosol producing procedure
- Providers seeing patient with suspicion for monkeypox should use gowns, gloves, eye protection, and an N95 or higher level respirator
- Concurrent testing for other sexually transmitted infections (STIs) is recommended in patients with lesions suspicious for monkeypox
- For testing at NH PHL, call Division of Public Health Services (DPHS) at 603-271-4496

Key Resources:

- To discuss testing at NH PHL or report a confirmed case, call DPHS at:
  603-271-4496 or 603-271-5300 (after hours)

- NH DPHS website: https://www.dhhs.nh.gov/programs-services/disease-prevention/infectious-disease-control/monkeypox
- NH PHL test requisition: https://www.dhhs.nh.gov/sites/g/files/ehbemt476/files/documents/2021-11/phl-lab-requisition.pdf

- CDC Information for Healthcare Providers: https://www.cdc.gov/poxvirus/monkeypox/clinicians/index.html

Questions?

Bibliography

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Laboratory testing for the monkeypox virus: Interim guidance. Accessed August 8, 2022. https://www.who.int/publications-detail-redirect/WHO-MPX-laboratory-2022.1

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Thornhill, J. P., Barkati, S., Walmsley, S., Rockstroh, J., Antinori, A., Harrison, L. B., ... & Orkin, C. M. (2022). Monkeypox virus infection in humans across 16 countries—April–June 2022. New England Journal of Medicine.

WELCOME to the

Just in Time: Testing, Vaccination, and Treatment for Monkeypox ECHO

Session 2, Vaccine: PEP and PrEP, 8/24/2022

Please let us know you are here: Type your name, email, organization into CHAT

Monkeypox: PEP and PrEP Vaccination

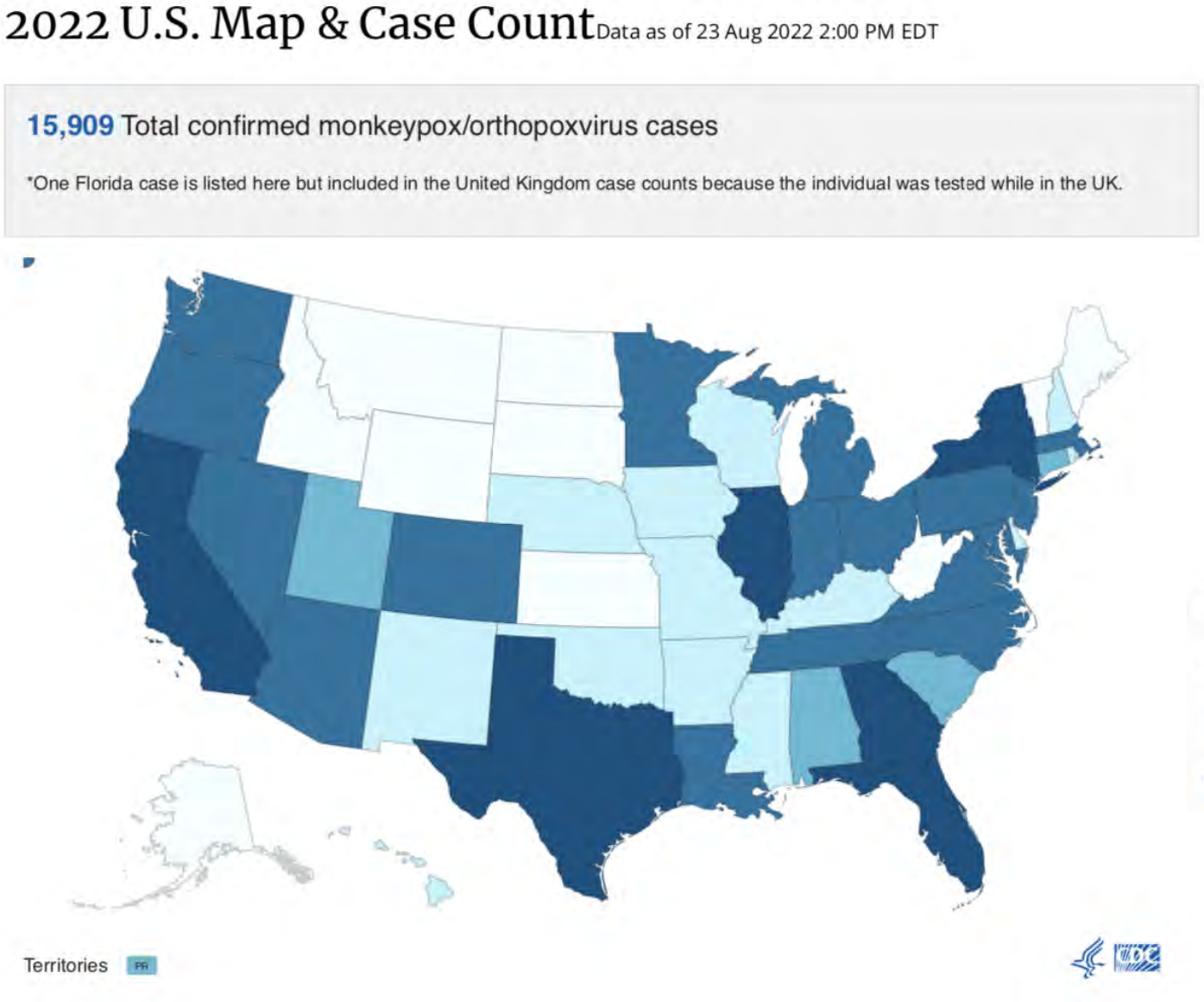
Mona Yazdi, DO

8/24/2022

Disclosure Statement

No Conflicts of Interest to Disclose

Epidemiology of the Current Outbreak



- More than 44,503 cases of monkeypox have now been reported from 96 countries and territories, with 12 deaths.
- 15,909 (~37.7%) of cases in the current outbreak are in the US.
- No deaths have occurred in the US.

Centers for Disease Control and Prevention (CDC, updated August 23, 2022)

Key Messages

- People who should get vaccinated against monkeypox include those who:
  - Are at high risk of contracting monkeypox
  - Have had high risk contact to a person with monkeypox within the last 14 days

- JYNNEOS is the only vaccine against monkeypox available in New Hampshire and should be administered intradermally in eligible recipients age 18 years or older
  - If providers administering vaccines are not familiar with intradermal injections, they should be trained.

- JYNNEOS vaccine is available now throughout New Hampshire.

- JYNNEOS vaccine is safe and effective against monkeypox disease and has very few contraindications.

PrEP vs. PEP Terminology

- In the context of this presentation, PrEP vs PEP refers to:
  - Vaccination before exposure to monkeypox = Pre-exposure prophylaxis (PrEP)
  - Vaccination after exposure to monkeypox = Post-exposure prophylaxis (PEP)

What vaccines are available?

- ACAM2000 and JYNNEOS (also known as Imvamune or Imvanex) are the two currently licensed vaccines in the United States to prevent smallpox, which are also effective against monkeypox.

- JYNNEOS is the preferred vaccine nationwide because it is safer, operationally easier, and has fewer side effects and adverse events than ACAM2000.

- Currently, New Hampshire is administering JYNNEOS vaccine to patients who are candidates for PrEP or PEP.

Centers for Disease Control and Prevention (CDC, updated June 2, 2022)

Pre-Exposure Prophylaxis (PrEP) Recommendations

- NH DHHS recommends JYNNEOS vaccine PrEP for men who identify as gay, bisexual, or other men who have sex with men and report any of the following high risk sexual activities:
  - 3 or more new sex partners in the last month
  - Engaging in group or anonymous sex
  - Engaging in sex with others at sex-on-site venues or events
  - Exchanging sex for money, drugs, or other services; or
  - Taking medications for HIV prevention (i.e., HIV PrEP) because of high-risk sexual activity
- Other at risk groups that qualify for PrEP include people whose job may expose them to monkeypox, such as :
  - Laboratory workers who handle specimens for testing of orthopoxvirues
  - Some designated healthcare or public health workers

Post-Exposure Prophylaxis (PEP) Recommendations

- NH DHHS recommends JYNNEOS vaccine PEP should be offered to people who have been exposed to monkeypox within the prior 14 days, including any of the following:
  - Prolonged (i.e., hours of) face-to-face contact with another person with monkeypox.
  - Direct skin-to-skin contact of any duration with another person with monkeypox.
  - Any physical contact with contaminated items (e.g. clothing or linens that have touched a rash or body fluids of a person with monkeypox).

Timing of PEP Vaccination Following Monkeypox Exposure

Day 0-4
Vaccinate to **prevent onset of disease**

Day 5-14
Vaccinate to **reduce symptoms** but not prevent disease

Day 15 and onward
Do **not** vaccinate

Centers for Disease Control and Prevention (CDC, updated June 2, 2022)
CDC MMWR August 12,2022

Centers for Disease Control and Prevention (CDC, updated August 10, 2022)
Frey et.al.*Vaccine*. 2015;33(39)
CDC MMWR August 12,2022

JYNNEOS vaccine administration

Population receiving vaccine	Route of administration	Injection volume	Recommended number of doses	Recommended interval between 1st and 2nd dose
INTRADERMAL DOSING REGIMEN				
People age ≥18 years	Intradermal	0.1mL	2	28 days
SUBCUTANEOUS DOSING REGIMEN				
People <18 years	Subcutaneous	0.5mL	2	28 days
People of any age who have a history of developing keloid scars	Subcutaneous	0.5mL	2	28 days

Note: Dosing regimens can be interchangeable for the 2nd dose

Centers for Disease Control and Prevention (CDC, updated August 15, 2022)

Vaccine Administration Errors: When to Not Repeat Dose

Type of Error	Example	What to do next
Vaccine given at incorrect site	If you give SQ dose at site other than triceps or ID dose at site other than volar forearm	Do not repeat dose. Inform the recipient of potential for local and systemic adverse effects
SQ 0.5mL dose given via unapproved route*	Intramuscular injection	
Incorrect dosage administered resulting in higher than authorized dose	>0.1mL dose is administered ID	

SQ= Subcutaneous
ID= Intradermal
*wording has been modified from CDC website to clarify the intent behind guidance

Centers for Disease Control and Prevention (CDC, updated August 15, 2022)

Vaccine Administration Errors: When to Repeat Dose

Type of Error	Example	What to do next
ID 0.1mL dose given via incorrect route*	ID dose given as SQ i.e. no “wheal” formed	Repeat dose via intended route (no waiting period needed) at least 2 inches away from the inadvertent site placement
Incorrect dosage administered resulting in lower than authorized dose	Recipient pulled away, vaccine leaked out of a syringe, 0.1mL administered SQ	

SQ= Subcutaneous
ID= Intradermal
*wording has been modified from CDC website to clarify the intent behind guidance

Centers for Disease Control and Prevention (CDC, updated August 15, 2022)

Vaccine Administration Errors: Timing and Storage

Type of Error	Example	What to do next
Second dose given too early	Interval between first and second dose is less than 24 days	Repeat dose after the dose given in error by at least 28 days if the patient is severely immunosuppressed. Otherwise do not repeat dose.
Second dose given too late	Interval between first and second dose is greater than 28 days	Administer the second dose as soon as possible. Do not restart series.
Dose administered after improper storage and handling	Not stored at recommended temperature	Contact the manufacturer regarding stability of the vaccine. If manufacturer does not have data to support the stability of the vaccine, repeat the dose immediately.
Dose administered past the expiration date/beyond-use date		

CDC Intradermal Administration Video

https://www.youtube.com/watch?v=TLv1mR6mECQ

CDC Subcutaneous Administration Video

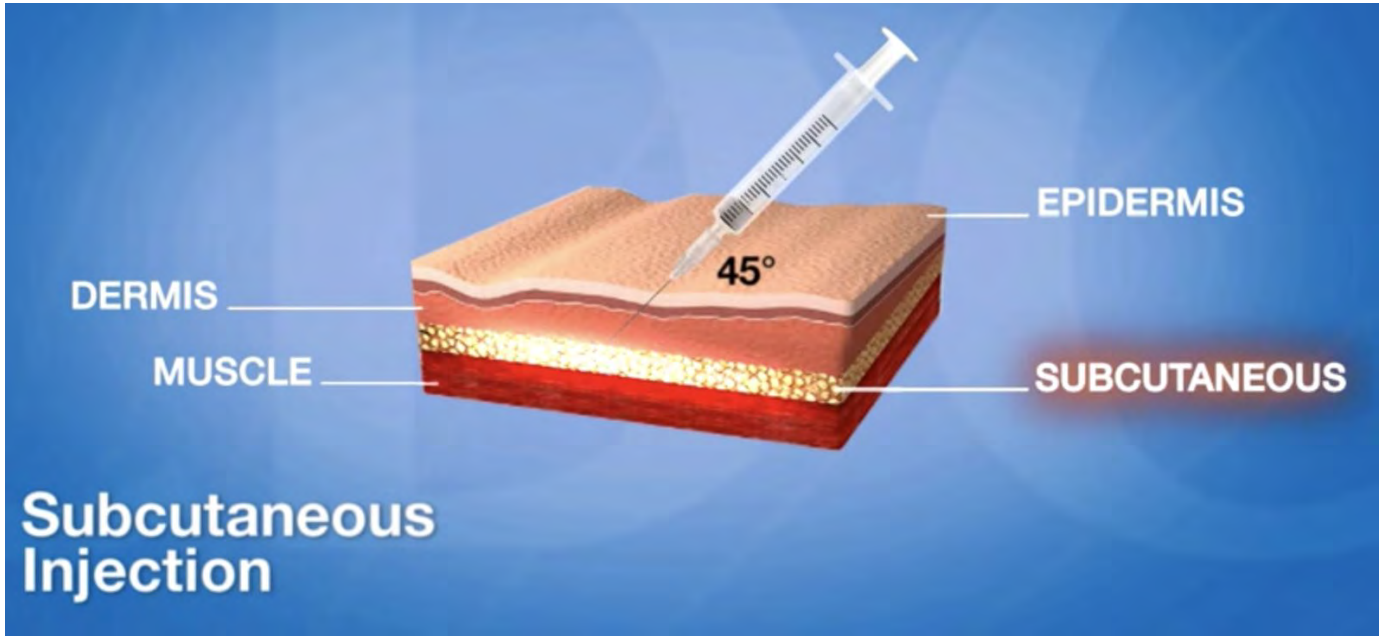
https://www.youtube.com/watch?v=R5jd4SDEcsA

Centers for Disease Control and Prevention (CDC, updated June 2, 2022)

Intradermal vs Subcutaneous Vaccination

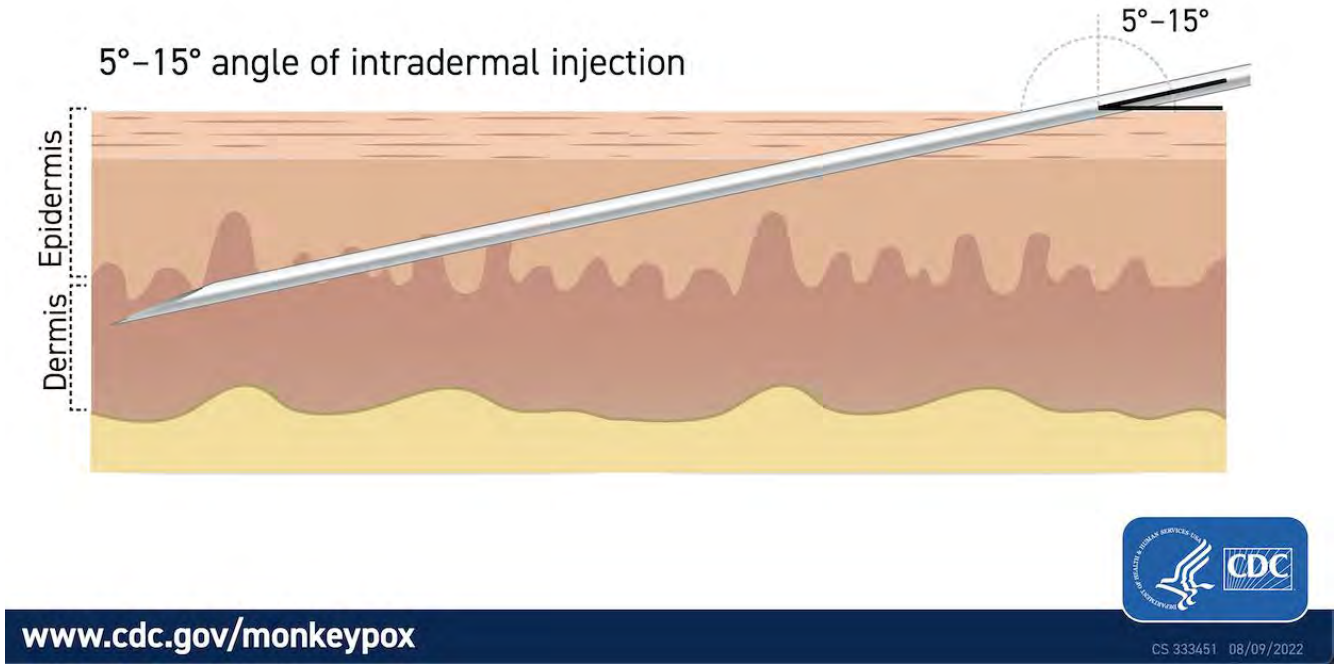
	Intradermal	Subcutaneous
Dose/volume	0.1mL	0.5mL
Needle length (inches)	¼ to ½” needle w/ short bevel	5/8’’ needle
Needle Gauge (G)	Tuberculin syringe: 26-28 G	23-25 G
Location of administration	Volar surface of forearm	Fatty tissue over triceps
Needle angle/depth	5-15º angle into the dermis	45º angle into subcutaneous fatty tissue
Presence of wheal	Yes	No

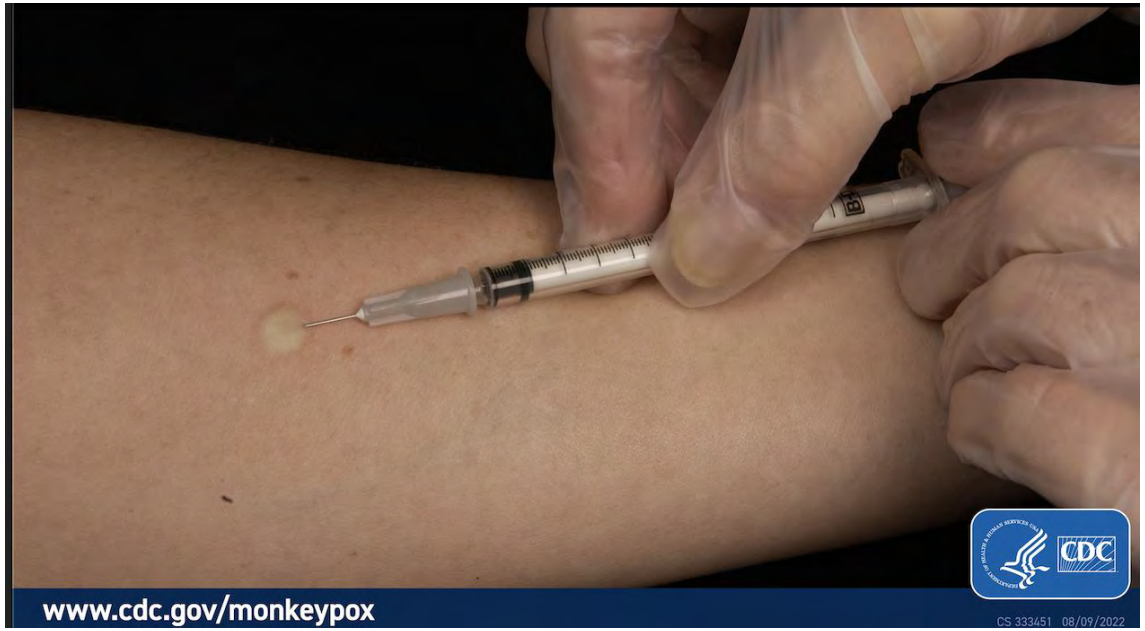
Subcutaneous Injection



Centers for Disease Control and Prevention (CDC, updated August 10 2022)

Intradermal Injection





Centers for Disease Control and Prevention (CDC, updated August 10 2022)

FDA Fact Sheet, August 16, 2022
Clinical Trial NCT00316602

Most Common Side Effects of JYNNEOS Vaccine

Intradermal (ID) Vaccine

- Erythema at injection site (99.5%)
- Induration at injection site (99.5%)
- Itchiness (89.0%)
- Pain at injection site (65.4%)
- Feeling tired (51.3%)
- Headache (41.4%)
- Muscle aches (30.4%)
- Nausea (23.0%)
- Underarm pain (20.9%)
- Change in appetite (20.4%)
- Joint pain (17.8%)
- Chills (14.7%)
- Underarm swelling (10.5%)

Subcutaneous (SQ) Vaccine

- Pain at injection site (84.9%)
- Redness at injection site(60.8%)
- Swelling at injection site (51.6%)
- Induration at injection site (45.4%)
- Itching at injection site (43.1%)
- Muscle pain (42.8%)
- Headache (34.8%)
- Fatigue (30.4%)
- Nausea (17.3%)
- Chills (10.4%)

Serious Adverse Events of JYNNEOS Vaccine

- Serious adverse events (SAEs) are very rare
- Review of pooled safety data across 22 studies for SQ vaccination showed:
  - SAEs were reported for 1.5% of JYNNEOS recipients who never previously had the vaccine and 1.1% of placebo recipients.
  - No serious cardiac adverse events were related to study vaccination

- Based on limited data, we expect ID administration to be similarly safe with rare SAEs. A clinical study of ID vaccination by Frey et. al. noted serious adverse events reported were not associated with the vaccine.

JYNNEOS package insert, revised June, 2021
Frey et.al.*Vaccine*. 2015;33(39)

Contraindications and Precautions to JYNNEOS Vaccine

Guidance	Medical condition or history	Suggested action(s)
Contraindication	History of severe allergic reaction (e.g. anaphylaxis) after previous dose of JYNNEOS.	Do not vaccinate.
Precaution	History of severe allergic reaction (e.g. anaphylaxis) to ciprofloxacin or gentamicin.	Discuss risks and benefits with the patient. They can be vaccinated with a 30-minute observation period.
Precaution	History of severe allergic reaction to chicken or egg protein AND are currently avoiding exposure to all chicken or egg products	
Precaution	Moderate or severe acute illness with or without fever.	Consider deferring vaccination until the acute illness has improved.

Centers for Disease Control and Prevention (CDC, updated June 2, 2022)
Thompson et.al *Clinical Infectious Diseases*, 2022
Thornhill et.al. *N Engl J Med*. 2022

Risks of Vaccination vs Monkeypox disease

Risk of Vaccine

- Most people have only minor reactions: mild fever, tiredness, swollen glands, and redness and itching at the place where the vaccine is given

Risk of Monkeypox disease

- Symptoms include: fever, lethargy, headache, muscle aches, backache, swollen lymph nodes, a general feeling of discomfort, exhaustion, and severe rash that can leave scars.
- Complications can be severe including phimosis, anorectal pain, proctitis, tenesmus, diarrhea, pharyngitis, odynophagia, epiglottitis, and oral or tonsillar lesions that have required hospitalization for management

For most people who have been exposed to monkeypox, risks of disease are greater than risks from vaccination.

Dartmouth Health | Project ECHO

Where can my patient get vaccinated?

Dartmouth-Hitchcock monkeypox hotline: (603) 650-1818

NH MONKEYPOX VACCINE CLINIC SITES

NH residents who have a primary care provider can contact their provider and ask if the vaccine is right for them. If yes, residents can ask their provider to make a referral to one of the listed clinic sites to schedule an appointment. NH residents who do not have a primary care provider can contact one of the clinics directly to be assessed for vaccine eligibility and scheduling.

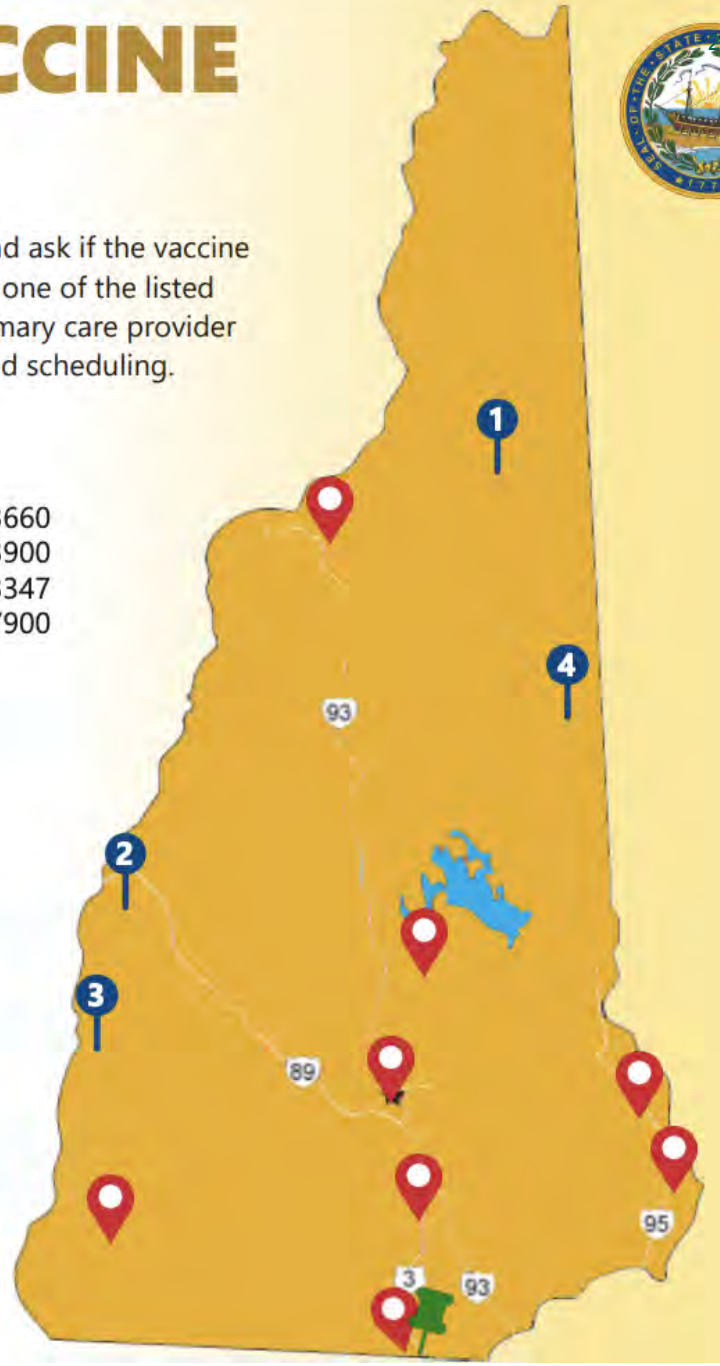
ConvenientMD Urgent Care - COMING SOON

BELMONT	603-737-0550	LITTLETON	603-761-3660
CONCORD	603-226-9000	MANCHESTER	603-384-3900
DOVER	603-742-7900	NASHUA	603-578-3347
KEENE	603-352-3406	PORTSMOUTH	603-942-7900

1. **Coos Family Health**
   BERLIN 603-752-2040
2. **Dartmouth Health - COMING SOON**
   LEBANON 603-650-5000
3. **Keady Family Practice**
   CLAREMONT 603-863-7777
4. **White Mountain Community Health**
   CONWAY 603-447-8900

Nashua Health Department - Clients who are under/uninsured in the Greater Nashua Region

NASHUA 603-589-4500 option 2



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  - If providers administering vaccines are not familiar with intradermal injections, they should be trained.

- JYNNEOS vaccine is available now throughout New Hampshire.

- JYNNEOS vaccine is safe and effective against monkeypox disease and has very few contraindications.

Key Resources

- CDC website with more resources and information on JYNNEOS vaccine: https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html
- CDC website on vaccine administration error: https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/errors-deviations.html
- FDA Fact Sheet on JYNNEOS vaccine: https://www.fda.gov/media/160774/download
- **Manufacturer contact information** for JYNNEOS vaccine:
  - Email: medical.information_US@bavarian-nordic.com
  - U.S. phone number: 1-844-422-8274
  - U.S. fax number: 1-843-422-8274
- Vaccine Adverse Event Reporting System (VAERS): Information on how to **submit a report to VAERS is available at vaers.hhs.gov or by calling 1-800-822-7967.**
- Frey SE, Wald A, Edupuganti S, et al. Comparison of lyophilized versus liquid modified vaccinia Ankara (MVA) formulations and subcutaneous versus intradermal routes of administration in healthy vaccinia-naïve subjects. *Vaccine*. 2015;33(39):5225-5234. doi:10.1016/j.vaccine.2015.06.075

JYNNEOS: Intradermal Vaccine Administration

Morgan Kuhnly MSN, RN, CIC: Infection Preventionist, Infection Prevention, DHMC

Highlights

- Standard dosing: 0.5ml JYNNEOS Subcutaneously **HOWEVER:**

- In the context of the current national Public Health Emergency (PHE), an **alternative regimen should be used** for people age ≥18 years under an Emergency Use Authorization beginning August 9, 2022
  - Intradermal route; injection volume of 0.1ml
  - Increase number of available JYNNEOS vaccine five-fold

- Comparison subcutaneous vs intradermal route:
  - Lower intradermal dose immunologically non-inferior to the standard subcutaneous dose (Frey SE et al, Vaccine, 2015; 33(39):5225-5234).

JYNNEOS Specifics

- Licensed for use as two doses administered 28 days (4 weeks) apart
  - 2nd dose may be administered up to 4 days before the minimum interval of 28 days (grace period): **should NOT be administered before minimum interval**
  - 2nd dose may be given up to 7 days later than the minimum interval of 28 days

- Peak immunity is expected to be reached 14 days after the second dose of JYNNEOS vaccine. The duration of immunity after two doses of JYNNEOS is unknown.

Administration

- Intradermal administration: vaccine injected between epidermis and hypodermis; typical volar aspect (inner side) of forearm. **Should produce a noticeable elevation (wheal)**

- A person who presents for their second JYNNEOS vaccine dose who is still experiencing erythema or induration at site of 1st dose:
  - may have the second dose administered intradermally in the contralateral forearm (opposite arm)

- When necessary, a person aged 18 years or older who received one JYNNEOS vaccine dose with the standard subcutaneous regimen may receive a second dose with the alternative intradermal regimen at the recommended interval (i.e., 28 days) to complete the vaccination series.

Supplies

- JYNNEOS vaccine
- JYNNEOS vaccine information statement (VIS) or FDA JYNNEOS EUA Fact Sheet
- PPE: Gloves, face-mask (per DH masking guidance)
- Sterile alcohol prep pad
- Band-Aid
- Gauze
- Tuberculin syringe: 27 gauge, ¼ to ½” needle w/ short bevel
- Sharpie/pen (to date & time puncture of vial)
- Emergency medical equipment nearby (in case of emergency)

General Information

Vaccine: JYNNEOS Smallpox and Monkeypox vaccine

Multi-dose vial: maximum of 5 doses

Diluent: None

Dosage: 0.1 mL

Age Indications

Persons 18 years of age and older who do not have a history of keloid scars

Vaccination Schedule

Administer two doses of JYNNEOS (0.1 mL each)

28 days apart

- For more details on the dosing interval, refer to www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html.

Administration

Intradermal (ID) injection into the volar surface of the forearm

Thawing Frozen Vaccine

- Use vials in the refrigerator before removing more vials from the freezer. Frozen vaccine must be thawed before using. Once thawed, store in:
  - **Refrigerator:** Between 2°C and 8°C (36°F and 46°F). Unpunctured vials may be stored in the refrigerator for up to 8 weeks. Punctured vials may be stored continuously in the refrigerator for up to 8 hours.
  - **Room temperature:** Between 8°C and 25°C (46°F and 77°F). Unpunctured vials may be held at room temperature for up to 6 cumulative hours.
- Do NOT refreeze thawed vaccine.
- Use beyond-use date labels for this vaccine to track storage times.

Expiration Date

When thawing directly from the freezer, use vaccine before date marked on the carton. For unpunctured vials stored in the refrigerator, use before beyond-use date (BUD) of 8 weeks from thawing. Punctured vials must be discarded 8 hours after puncture.

Prepare and Administer the Vaccine

1. Assess recipient status:
   - » Screen for contraindications and precautions.
   - » Review vaccination history.
   - » Review medical considerations.

2. Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves, and any time hands become soiled.

3. Frozen vaccine must be thawed before using. If removing the vial from the refrigerator, let it stand at room temperature for 15 minutes.

4. **Unpunctured vials:** Check the expiration date and/or beyond-use date. Never use expired vaccine. **Punctured vials:** Check the beyond-use date and time. Never use vaccine past the beyond-use date or time.

5. With the vial upright, gently swirl the vaccine for 30 seconds before withdrawing the dose.

6. Examine the vaccine. It should be a milky, light yellow to pale white colored suspension. Do not use if liquid contains other particulate matter or is discolored.

7. Using a new, sterile alcohol prep pad, cleanse the stopper of the multidose vaccine vial.

8. Choose the correct equipment for intradermal injection: use a tuberculin syringe with a 27 gauge, 1/4 to 1/2" needle with a short bevel. **Always use a new, sterile needle and syringe for each injection.**

9. Ensure the needle and syringe are secured tightly together to prevent the vaccine from inadvertently leaking during preparation and administration.

Prepare and Administer the Vaccine (continued)

10. Withdraw the correct dosage (0.1 mL) of vaccine into a tuberculin syringe
    - » Do NOT combine residual vaccine from multiple vials to obtain a dose
11. For new vials: note the date and time the vial was first punctured. Once the vial is punctured, you must discard it after 8 hours.
12. Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.
13. Ensure staff has the correct personal protective equipment (PPE), including gloves, before administering vaccine. Ask vaccine recipients to wear a face covering, if tolerated.
14. Select and cleanse vaccination site two to four inches below the antecubital fossa (elbow) on the volar surface of the forearm.
15. Administer the vaccine immediately by intradermal (ID) injection into the volar surface of the forearm. Refer to this video for guidance.
16. While pulling the skin taut, position the needle bevel facing upward and insert the needle at a 5-to 15-degree angle into the dermis. Slowly inject 0.1mL intradermally. This should produce a noticeable pale elevation of the skin (wheal).
17. A bandage may be placed over the injection site as needed.
18. Observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
    - » **30 minutes:** persons with a history of anaphylaxis to gentamicin, ciprofloxacin, chicken or egg protein (AND are currently avoid exposure to all chicken or egg products)
    - » **15 minutes:** Can consider for all other persons

Sample Screening Questionnaire

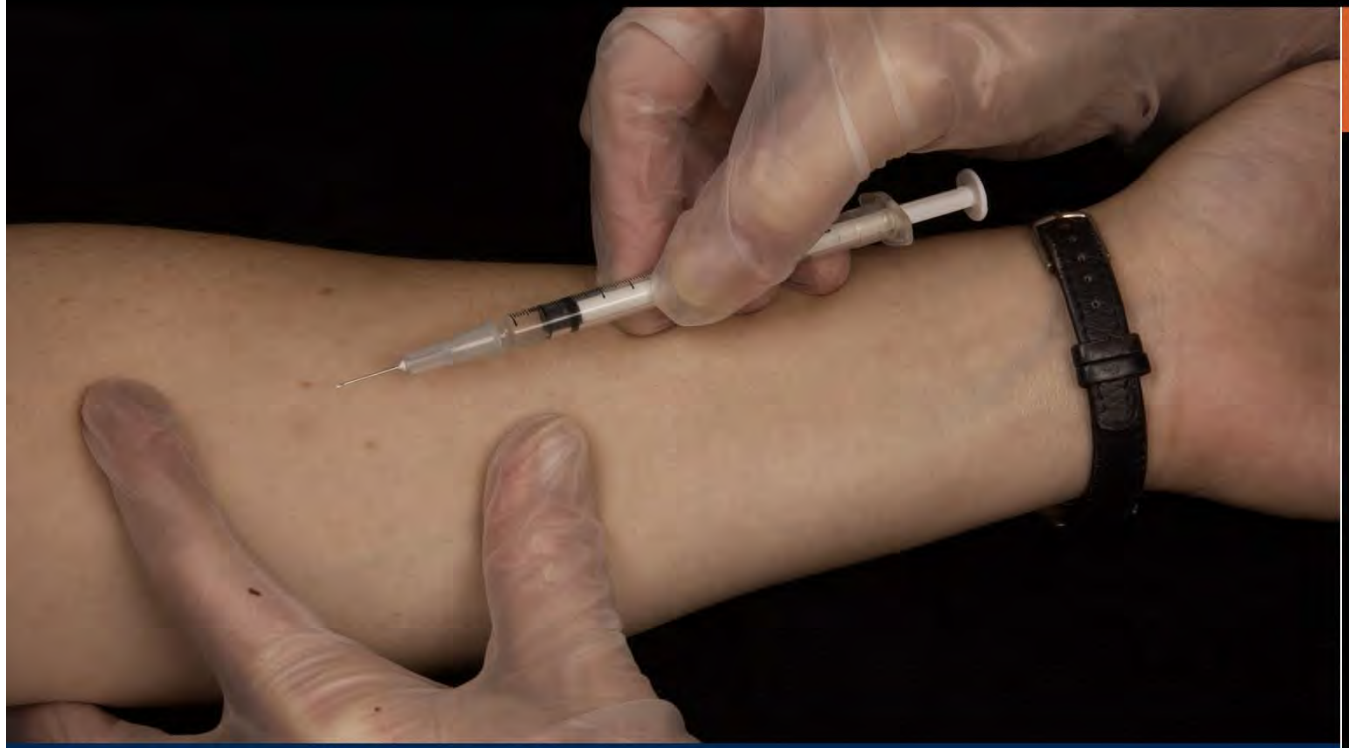
SECTION 1: VACCINE RECIPIENT INFORMATION			
Last Name:	First and Middle Initial:	Date of Birth:	Age (Years):

SECTION 2: JYNNEOS™ VACCINE SCREENING QUESTIONS		
Please answer the following questions.	**YES**	**NO**
1. Are you feeling sick today?		
2. Have you had a serious allergic reaction (e.g., anaphylaxis) after a previous dose of the JYNNEOS vaccine?		
3. Do you have a history of a severe allergic reaction to aminoglycoside antibiotics (such as gentamicin, amikacin, or tobramycin)?		
4. Do you have a history of a severe allergic reaction to fluoroquinolone antibiotics (such as ciprofloxacin, levofloxacin, or moxifloxacin)?		
5. Do you have a history of a severe allergic reaction to chick or egg protein AND are you currently avoiding exposure to all chicken or egg products?		
6. Have you been diagnosed with confirmed monkeypox virus infection during the 2022 outbreak?		
7. Do you have a history of developing keloid scars on your skin?		


MONKEYPOX
How to administer a JYNNEOS vaccine intradermally
STEP 1
Locate and clean a site for injection in the inner (volar) surface of the forearm.
www.cdc.gov/monkeypox
CDC
CS 333451 08/09/2022

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally



STEP 2

While pulling the skin taut, position the needle with the bevel facing up and insert the needle at a 5- to 15-degree angle into the dermis.

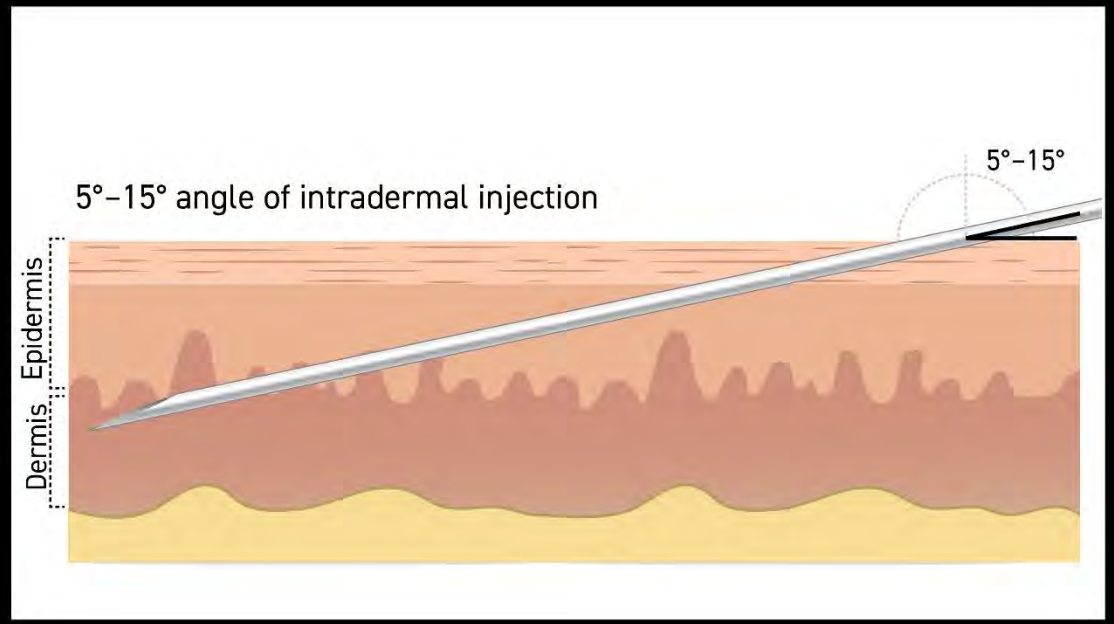
www.cdc.gov/monkeypox

CDC

CS 333451 08/09/2022

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally



STEP 2

While pulling the skin taut, position the needle with the bevel facing up and insert the needle at a 5- to 15-degree angle into the dermis.

www.cdc.gov/monkeypox

CS 333451 08/09/2022

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally

STEP 3

Slowly inject 0.1mL intradermally.
This should produce a noticeable pale elevation of the skin (wheal).

www.cdc.gov/monkeypox

CDC

CS 333451 08/09/2022

MONKEYPOX

How to administer a JYNNEOS vaccine intradermally

www.cdc.gov/monkeypox

STEP 4

Observe patients for 15 minutes after vaccination or 30 minutes if they have a history of anaphylaxis to gentamicin, ciprofloxacin, chicken or egg protein.

CDC

CS 333451 08/09/2022

Intradermal JYNNEOS Administration Video

How to administer a JYNNEOS vaccine intradermally - YouTube

Adverse Events

- Anyone (including patients) can submit a VAERS

- Vaccination providers who are administering JYNNEOS under the EUA are **required** to report the following adverse events that occur after JYNNEOS vaccination NO later than 72 hours after administration:
  - Vaccine administration errors whether or not associated with an adverse event
  - Serious adverse events (irrespective of attribution to vaccination)
  - Cases of cardiac events including myocarditis and pericarditis
  - Cases of thromboembolic events and neurovascular events

Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

References

- JYNNEOS Vaccine | Monkeypox | Poxvirus | CDC
- JYNNEOS Smallpox and Monkeypox Vaccine Intradermal Vaccine Preparation and Administration Summary: ALTERNATIVE DOSING REGIMEN (cdc.gov)
- For reference, DH Monkeypox Intranet Site: Monkeypox (hitchcock.org)

WELCOME to the

Just in Time: Testing, Vaccination, and Treatment for Monkeypox ECHO

Session 3, Treatment: TPOXX and beyond, *8/31/2022*

Please let us know you are here: Type your name, email, organization into CHAT

Monkeypox: Treatment with Tecovirimat (TPOXX)

Toey Mahatanan, MD

Infectious Disease Fellow and Leadership Preventive Medicine Resident

Dartmouth-Hitchcock Medical Center

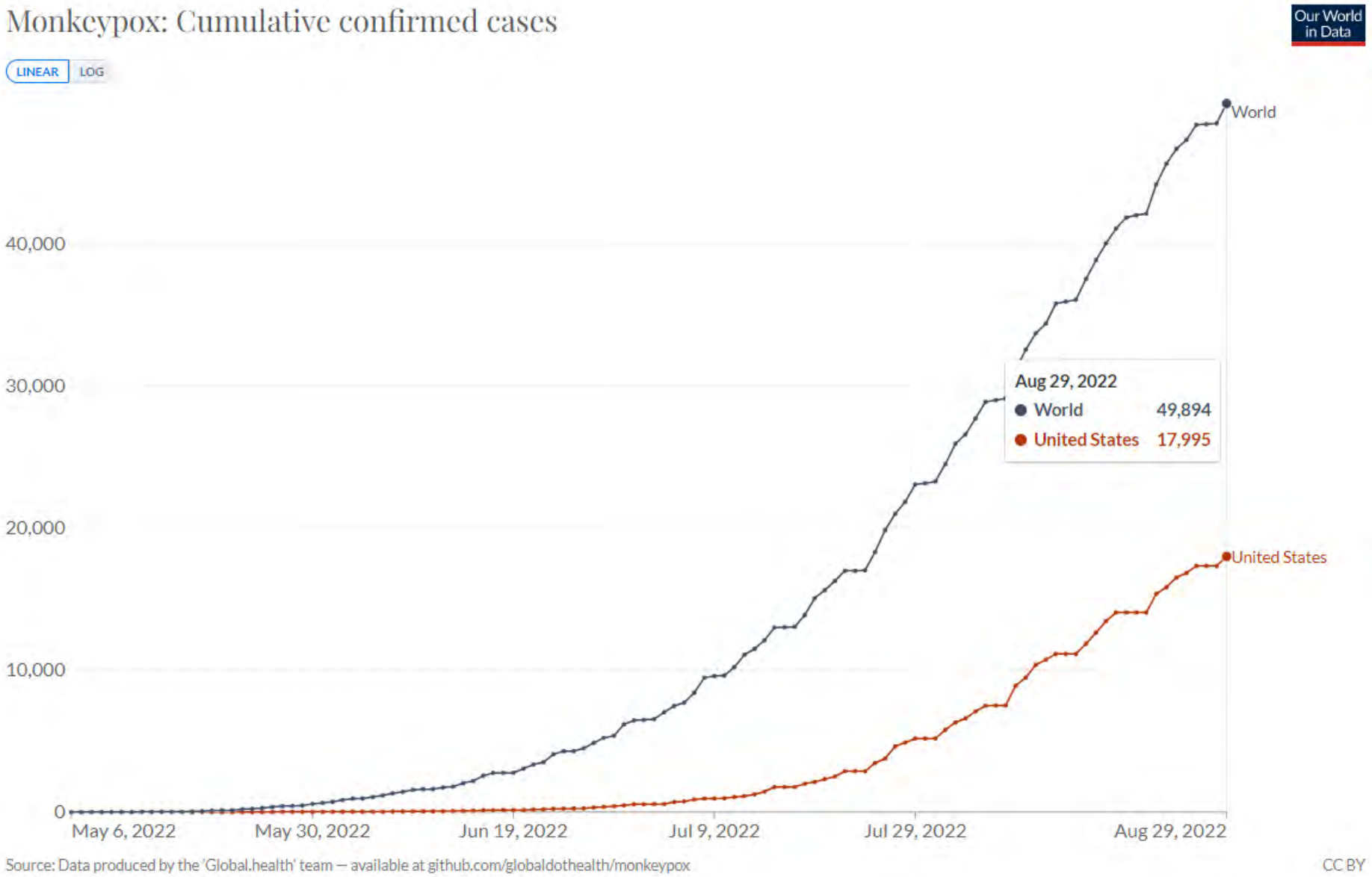
Disclosure Statement

No financial relationships to disclose

Takeaway Messages

- The majority of patients infected with monkeypox have a mild, self-limiting course and will not require treatment
- Persons who should be considered for the treatment include persons with severe disease, and persons who are at high risk for severe disease or who have complications from infection
- Currently, Tecovirimat (TPOXX) is the primary therapeutic agent used to treat monkeypox. The oral formulation is preferred.
- TPOXX can be accessed by calling NH DHHS at 603-271-4496 (after hours 603-271-5300)

Current Situation of 2022 Global Outbreak



As of August 29, 2022:

- 13 deaths reported among 49,894 confirmed cases

https://ourworldindata.org/monkeypox

What did we know before the 2022 global outbreak?

THE LANCET
Infectious Diseases
Volume 19, Issue 8, August 2019, Pages 872-879

Articles

Outbreak of human monkeypox in Nigeria in 2017–18: a clinical and epidemiological report

Adesola Yinka-Ogunleye MPH [a], Olusola Aruna FFPH [a, b], Mahmood Dalhat MBBS [c], Prof Dimie Ogoina FMCP [d], Andrea McCollum PhD [e], Yahyah Disu MPH [a], Ibrahim Mamadu MPH [f], Afolabi Akinpelu BSc [a], Adama Ahmad MPH [a], Joel Burga BSc [a], Adolphe Ndoreraho BSc [g], Edouard Nkunzimana BSc [g], Lamin Manneh BSc [g], Amina Mohammed BSc [a], Olawunmi Adeoye MBBS [a], Daniel Tom-Aba MSc [h, i], Bernard Silenou MSc [h, i], Oladipupo Ipadeola MPH [e] … Satheshkumar, Panayampalli S.

- Largest documented outbreak due to West African clade of monkeypox
- 122 confirmed or probable cases
- **7 deaths (6%)**
  - **4/7 deaths occurred among those with untreated advanced HIV**

The NEW ENGLAND JOURNAL of MEDICINE

RESEARCH SUMMARY

Monkeypox Virus Infection in Humans across 16 Countries — April–June 2022

Thornhill JP et al. DOI: 10.1056/NEJMoa2207323

- 528 persons with PCR confirmed monkeypox in 16 countries on 5 continents

- Results
  - 98% were gay or bisexual men
  - 41% had HIV infection
  - Skin lesions noted in 95%; most common were anogenital lesions
  - Mucosal lesions reported in 41%; anorectal, oropharyngeal, conjunctival
  - Median incubation period 7 days
  - **13% were hospitalized; most often for pain management**
  - No deaths were reported

Who Should Be Treated?

- Those with severe disease: hemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalization
- Those at risk for severe disease
  - Immunocompromised patients
  - Children, particularly younger than 8 years old
  - H/o or current atopic dermatitis or other active exfoliative skin conditions
  - Persons who are pregnant or breastfeeding: risk/benefit consideration
  - Patients with complications of infection
    - secondary bacterial skin infection; gastroenteritis with severe N/V, diarrhea, or dehydration; bronchopneumonia
- Those with lesions in the areas that might constitute a special hazard (e.g., eye inoculation)

CDC Website

Treatment for Monkeypox

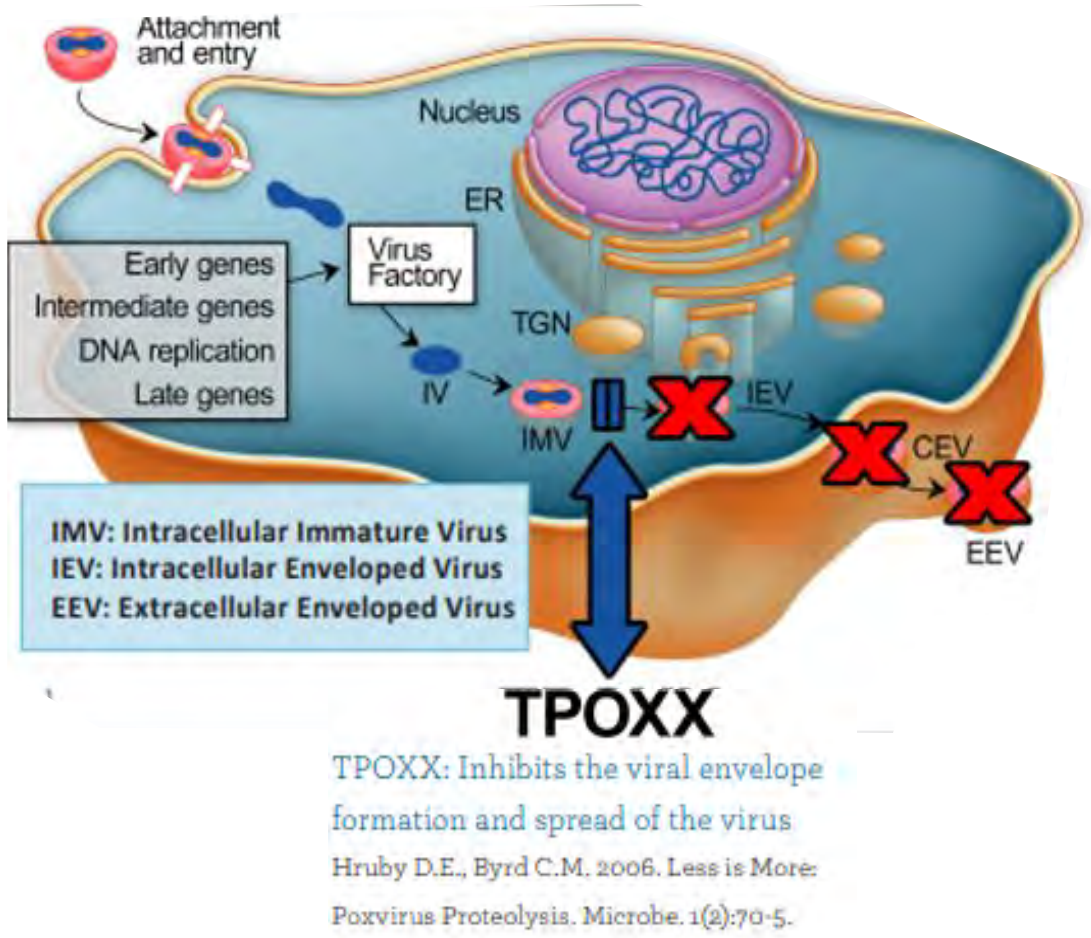
- No Food and Drug Administration (FDA)–approved treatments for monkeypox
- Antivirals developed for smallpox are expected to also be effective against monkeypox
- Medical countermeasures for treatment of monkeypox
  - Tecovirimat (TPOXX)
  - Vaccinia intravenous immune globulin (VIVIG)
  - Cidofovir (Vistide)
  - Brincidofovir (CMX001 or Tembexa)

Currently, Tecovirimat (TPOXX) is the primary therapeutic drug that being used to treat monkeypox infection for inpatient and outpatient therapy

CDC Website

Tecovirimat (TPOXX)

- The first drug approved by FDA in 2018 for the treatment of smallpox for adults and children (weight >13 kg)
- Expanded safety trial in humans showed the drug was safe and caused only mild side effects
- CDC holds expanded access Investigational New Drug (EA-IND) protocol that allows for the treatment of monkeypox in adults and children of all ages



https://www.siga.com/wp-content/themes/sigahba/TPOXX-Fact-Sheet.pdf

Grosenbach et al. N Engl J Med 2018;379:44–53

Tecovirimat (TPOXX): Formulary and Dosing

Oral (one capsule = 200 mg): Taken by mouth within 30 minutes of a moderate or high fat meal.

IV: 200 mg in 20 mL
Should NOT be administered if severe renal impairment (CrCl <30 mL/min)

*****Oral regimen is preferred over IV*****

Adult:

- 40-120 kg: 600 mg PO every 12 hours for 14 days
- 120 kg or more: 600 mg PO every 8 hours for 14 days

Children:

> 13 kg to < 25 kg : 200 mg PO every 12 hours for 14 days

25 kg to < 40 kg: 400 mg PO every 12 hours for 14 days

https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208627s007lbl.pdf

Tecovirimat (TPOXX): Precautions

- Adverse Reaction
  - Oral: headache (12%), nausea (5%), abdominal pain (2%), and vomiting (2%).
  - IV: infusion site pain (73%), infusion site swelling (39%), infusion site erythema (23%), infusion site extravasation (19%), and headache (15%).

- Drug-Drug Interactions
  - Hypoglycemia if co-administration with repaglinide
  - Decreases effectiveness of midazolam
  - Dose adjustment of certain HIV antiretroviral drugs may be considered

Grosenbach et al. N Engl J Med 2018;379:44–53.
O'Shea et al. MMWR Morb Mortal Wkly Rep 2022;71:1023-1028.

Tecovirimat (TPOXX): Special Populations

- Pregnancy/Lactation
  - No clinical studies done in pregnant and nursing women
  - Risk and benefit discussion
  - No fetotoxicity in animal studies, but tecovirimat was detected in trace amounts in milk
  - Avoid breastfeeding while on TPOXX

- Pediatric patients
  - No clinical studies done in pediatric populations
  - A report of use in a 28-month-old child with no adverse effects
  - Recommend monitoring renal function in children < 2 years of age; renal immaturity may result in higher exposure to an ingredient in IV tecovirimat

CDC Website

Dartmouth Health | Project ECHO

2022 Outbreak Data of Tecovirimat (TPOXX)

Research Letter

August 22, 2022

Compassionate Use of Tecovirimat for the Treatment of Monkeypox Infection

Angel N. Desai, MD, MPH[1]; George R. Thompson III, MD[1]; Sonja M. Neumeister, MPH[1]; et al

Author Affiliations | Article Information

JAMA. Published online August 22, 2022. doi:10.1001/jama.2022.15336

- UC Davis, Sacramento County (June 2022 – August 2022)
- 25 confirmed cases with monkeypox received Tecovirimat
  - All were self-reported males; 9 HIV patients
  - Symptoms present for a mean of 12 days (range 6-24) at time of treatment
  - 92% had genital and/or perianal lesions; all patients had painful lesions
  - All except one patient received 14 days of treatment
  - 40% reported complete resolution of lesions on D7, while 92% had resolution of lesions and pain by D21
  - Treatment well tolerated, and all patients completed the full treatment course
  - Reported adverse effects: fatigue 28%, headache 20%, nausea 16%, itching 8%, diarrhea 8%

How to Obtain TPOXX

DHHS

- Call 603-271-4496
- After hours or weekend call 603-271-5300, ask for public health professional on-call

Patient

- Obtain informed consent from the patient prior to treatment
- Treatment with TPOXX can begin upon receipt of medication once Informed Consent Form has been completed

CDC

- https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html
- Submit required EA-IND paperwork to CDC
- Can be submitted through encrypted email or ShareFile

Takeaway Messages

- The majority of patients infected with monkeypox have a mild, self-limiting course and will not require treatment
- Persons who should be considered for the treatment include persons with severe disease, and persons who are at high risk for severe disease or who have complications from infection
- Currently, Tecovirimat (TPOXX) is the primary therapeutic agent used to treat monkeypox. The oral formulation is preferred.
- TPOXX can be accessed by calling NH DHHS at 603-271-4496 (after hours 603-271-5300)

Resources

- DHHS
  - https://www.dhhs.nh.gov/programs-services/disease-prevention/infectious-disease-control/monkeypox
  - https://www.dhhs.nh.gov/sites/g/files/ehbemt476/files/documents2/han-mpv-outbreak-update3.pdf
- CDC
  - https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html
  - https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html
  - https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html
- FDA
  - https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208627s007lbl.pdf