



CDC and FDA Update: Interim Clinical Considerations for Monkeypox Vaccination

Clinician Outreach and Communication Activity (COCA) Call
Thursday, August 11, 2022

Continuing Education

- Continuing education is not offered for this webinar.

To Ask a Question

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 - Click on the “Q&A” button
 - Type your question in the “Q&A” box
 - Submit your question
- If you are a patient, please refer your question to your healthcare provider.
- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov

Today's Presenters

Jennifer McQuiston, DVM, MS (*no slides*)

CAPT, U.S. Public Health Service

Incident Manager

2022 Multinational Monkeypox Response
Centers for Disease Control and Prevention

Peter Marks, MD, PhD

Director, Center for Biologics

Evaluation and Research

U.S. Food & Drug Administration

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Monkeypox Vaccine (JYNNEOS)

- JYNNEOS is the only FDA-licensed vaccine in the US to prevent monkeypox disease in individuals 18 years of age and older
 - Also licensed to prevent smallpox disease in this age group
 - Requires two doses (days 1 and 28)
- Non-replicating viral vectored vaccine using Modified Vaccinia Ankara (MVA-BN) originally developed as alternative to ACAM2000 (live replicating vaccinia virus-based smallpox vaccine)
 - For use in the event of a bioterrorist attack in immunocompromised individuals in whom such a live replicating virus vaccine was relatively or absolutely contraindicated



Monkeypox Current Issues

- Concern regarding spread to other populations is increasing
- Approximately 1.6 to 1.7 million people at risk need vaccination
- Would require total of 3.2 to 3.4 million doses JYNNEOS; however, only about 1.6-1.8 million doses will be available by December
- Stockpile material being tested for suitability for use
- Technology transfer in process with doses expected early 2023
- Use of ACAM2000 considered; determined to have excessive risk
- Other potential vaccines not available: LC16m8

Intradermal Dosing Regimen

- Early on during its development in the 1970's, MVA was given intradermally in Germany to thousands of people
- Intradermal MVA has also sometimes been given as a boost in combination with other vaccines; redness at inoculation site noted
- Clinical trial conducted in accordance with GCP by NIAID indicates 1/5 of the dose (0.1 mL) given intradermally (ID) on the same schedule (day 1 and 28) produces similar efficacy to subcutaneous (SC) with more local redness and itching, less local pain
 - Frey SE et al, Vaccine 2015; 33: 5225-5234

Immunogenicity

Assay	SC peak titer	ID peak titer	Difference	97.5% CI
SLU PRNT	8.37	8.36	0.005	0.43, 0.44
BN PRNT	5.63	5.90	-0.27	-0.77, 0.23
SLU ELISA	9.66	9.52	0.14	-0.21, 0.49
BN ELISA	9.59	9.57	0.02	-0.31, 0.35

Reactogenicity

Reactogenicity event	SC (%) N=166	ID (%) N=190
Feeling Tired	49.7	51.3
Muscle Aches	41.3	30.4
Headache	43.1	41.4
Nausea	21.6	23.0
Change in Appetite	15.0	20.4
Chills	12.6	14.7
Joint Pain	9.0	17.8
Pain at injection site	91.0	65.4
Erythema at injection site	81.4	99.5
Induration at injection site	69.5	99.5
Itchiness	48.5	89.0
Underarm pain	18.0	20.9
Underarm swelling	6.0	10.5

Summary

- 1/5 of the dose (0.1 mL) given ID on the same schedule produces similar efficacy to SC, albeit with more local redness
- Could facilitate vaccination of entire current target population and allow for additional supply in the event of further spread
- Information on management issues
 - Education on administration by ID route
 - Use of single dose vial to draw up multiple doses within a few hours
 - Management of side effects

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CAPT, U.S. Public Health Service

Lead, Vaccine Team, Clinical Task Force

2022 Multinational Monkeypox Response

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CDC Interim Guidance

Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak

Updated August 9, 2022 [Print](#)

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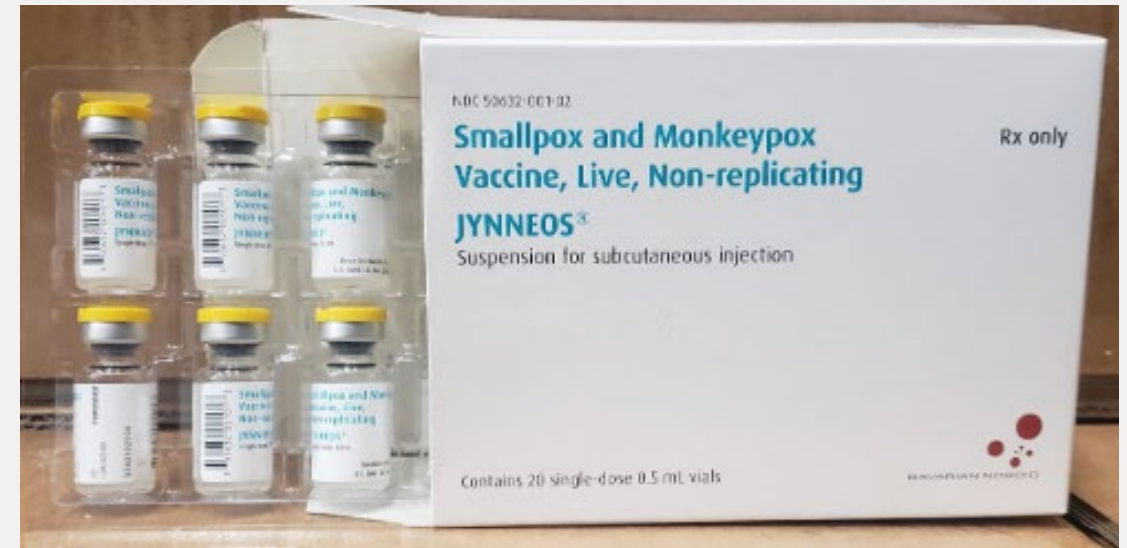
› What You Need to Know	Interim Guidance
Vaccination Strategies	ACAM2000
Health Equity	Special Populations
JYNNEOS	Errors and Deviations

Vaccination Strategies

Strategy	Definition
Post-Exposure Prophylaxis (PEP)	Vaccination after known exposure to monkeypox
Expanded Post-Exposure Prophylaxis (PEP++)	Vaccination after known or presumed exposure to monkeypox
Pre-Exposure Prophylaxis (PrEP)	Vaccination before exposure to monkeypox

JYNNEOS vaccine

- Vaccination with JYNNEOS **can be considered** for people who are at high risk for infection to prevent monkeypox disease
- Third-generation smallpox vaccine based on a live attenuated **non-replicating** orthopoxvirus, Modified Vaccinia Ankara (MVA)
- Licensed for prevention of smallpox and monkeypox disease
- Distributed to jurisdictions from the Strategic National Stockpile
- Global supply is currently limited
- Mild side effect profile compared with ACAM2000 vaccine



JYNNEOS vaccine

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Vaccination Schedule

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

Interchangeability

- 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 to complete the vaccination series.
- For example, a person who received only one dose of the standard regimen before August 9 may receive one dose with the alternative regimen to complete the series.
- Also, a person whose 18th birthday occurs between their first and second dose may complete the series with the alternative regimen.

Duration of Immunity and Dosing Intervals

- Peak immunity is expected 14 days after the second dose
- Duration of immunity after two doses of JYNNEOS is unknown
- *Recommended interval: 28 days (or up to 35 days)*
 - If the second dose is not administered during the recommended interval, it should be administered as soon as possible.
 - There is no need to restart or add doses to the series if there is an extended interval between doses.
- *Minimum interval: 24 days*
 - 4-day grace period applies

Safe Injection Practices

- Every year, unsafe injection practices by U.S. healthcare providers—like syringe reuse and misuse of medications vials—can cause outbreaks.
- It is the responsibility of every provider who prepares and administers injections, or supervises those that prepare and administer injections, to make sure that patients receive the correct medication and are not exposed to life-threatening infections.
- Providers should adhere to Standard Precautions and the principles of Safe Injection Practices, including the use of a sterile, single-use, disposable needle and syringe for each injection given, and prevention of contamination of injection equipment and medication.



Adverse Event Reporting

- Vaccination providers who are administering JYNNEOS under the EUA are required to report the following adverse events that occur after JYNNEOS vaccination:
 - Vaccine administration errors
 - Serious adverse events
 - Cases of cardiac events, including myocarditis and pericarditis
 - Cases of thromboembolic events and neurovascular events
- Information on how to submit a report to the Vaccine Adverse Event Reporting System (VAERS) is available at <https://vaers.hhs.gov> or by calling 1-800-822-7967.



Evidence Quality

- **Interim guidance may change as new evidence is considered**
- Benefits and harms
- Values
- Acceptability
- Resource use
- Equity
- Feasibility
- Certainty of the evidence
- **Balance of consequences favors the intervention to vaccinate**

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JYNNEOS Intradermal Vaccination Preparation

- With the vial upright, gently swirl the vaccine for 30 seconds before withdrawing the dose.
- 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.
- Using a new, sterile alcohol prep pad, cleanse the stopper of the vaccine vial.

JYNNEOS Intradermal Vaccination Preparation

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

JYNNEOS Intradermal Vaccination Preparation

- Withdraw correct dosage (0.1 mL) of vaccine into a tuberculin syringe
- Do NOT combine residual vaccine from multiple vials to obtain a dose
- 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.
- Immediately replace the vaccine vial in the refrigerator.
- Bring the dose of vaccine from the designated preparation area directly to the patient treatment area for administration.

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How to administer a JYNNEOS vaccine intradermally



STEP 1

Locate and clean a site for injection in the inner (volar) surface of the forearm.

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How to administer a JYNNEOS vaccine intradermally

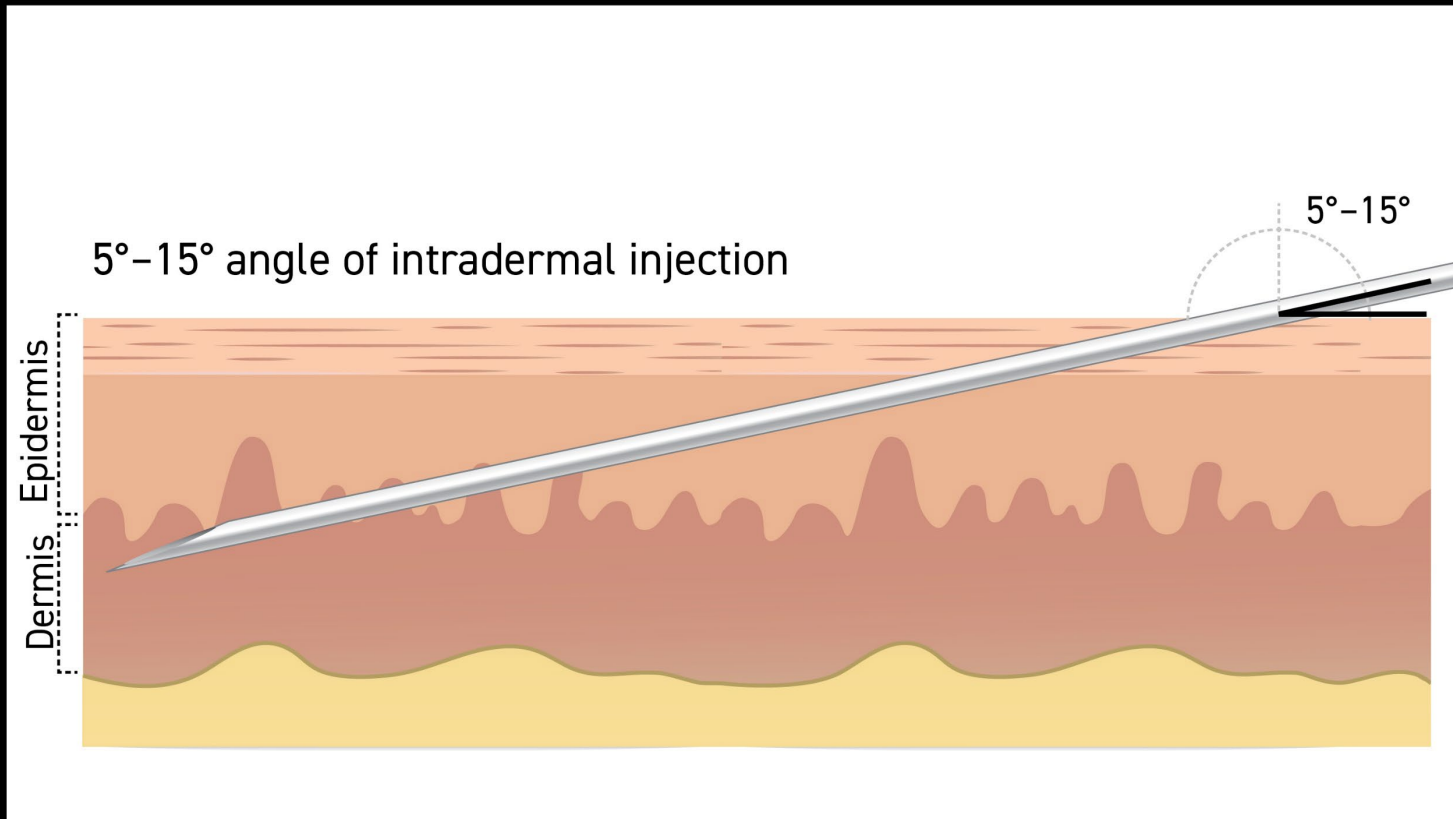


STEP 2

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.

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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.

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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).



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How to administer a JYNNEOS vaccine intradermally

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.

Demonstration Video




<https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination/jynneos-vaccine.html>

Educational Resources

- See CDC's website for educational resources on JYNNEOS intradermal administration: bit.ly/MPXVax

Video on Administering JYNNEOS Intradermally



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How to administer a JYNNEOS vaccine intradermally.


VIDEO

How to administer a JYNNEOS vaccine intradermally

Video Length: 00:00:55

Watch Video

Images on Administering JYNNEOS Intradermally



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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

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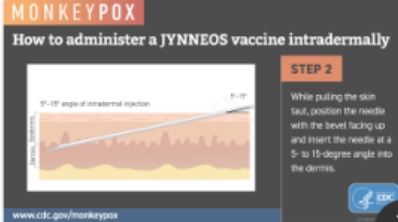
How to administer a JYNNEOS vaccine intradermally

STEP 2

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www.cdc.gov/monkeypox

Step 2a: 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.



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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

Step 2b: 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.



1-800-CDC-INFO (232-4636)

TTY: 1-888-232-6348 www.cdc.gov

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Today's COCA Call Will Be Available to View On-Demand

- **When:** A few hours after the live call ends*
- **What:** Video recording
- **Where:** On the COCA Call webpage
https://emergency.cdc.gov/coca/calls/2022/callinfo_081122.asp
- **Sign up to receive future COCA Call Announcements and other timely information:**
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**A transcript and closed-captioned video will be available shortly after the original video recording posts at the above link.*

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The screenshot shows the Facebook profile for COCA (CDC Clinician Outreach and Communication Activity). The profile picture features a group of diverse healthcare professionals. The cover photo shows a group of six healthcare workers, including nurses and doctors, smiling. The page includes a navigation menu on the left with options like Home, About, Posts, Photos, Events, and Community, along with a 'Create a Page' button. The main content area shows the page name, a bio, and a recent post from October 31, 2017, announcing a free CE event on November 7, 2017. The right sidebar displays the location (Atlanta, Georgia), the number of likes (21,420) and followers (21,217), and a map of the location.

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COCA CDC Clinician Outreach and Communication Activity - COCA shared their event.
October 31 at 1:18pm · 🌐
Clinicians, you can earn FREE CE with this COCA Call! Join us for this COCA Call November 7, 2017 at 2:00PM.

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Thank you for joining us today!



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