



Department of
Public Health

CITY OF PHILADELPHIA

Mpox Vaccine Distribution

January 2023



Objectives

By the end of this presentation, you will understand:

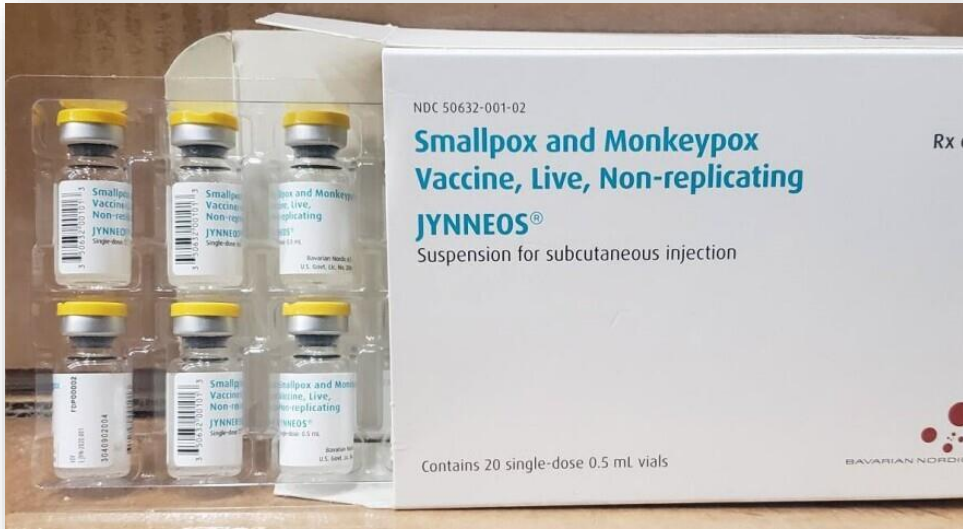
- How Monkeypox (Mpox) vaccine is packaged and shipped.
- Vaccination strategies and patient eligibility.
- How to place Monkeypox vaccine requests.
- How to report the temperature data for your site.
- How to administer Mpox using two different methods.
- How/when to differentiate and report administration deviations & errors.



Mpox Vaccination Overview



Mpox Vaccine: Jynneos



JYNNEOS

Freezer -25°C to -15°C (-13°F to 5°F) until expiration date.

Refrigerator 2°C to 8°C (36°F to 46°F) up to 8 weeks.

Email tempcheck@phila.gov for help.

NAME _____ TODAY DATE ____/____/____

EXP DATE ____/____/____ LOT# _____

USE BY

DATE ____/____/____ TIME _____

Manufacturer

Bavarian Nordic

Dosage & Administration

0.5 mL, subcutaneous (SC), OR
0.1mL, intradermal (ID)

Packaging

Twenty (20) 0.5mL vials per box (single dose for SC, up to five doses for ID¹)

NDC

50632-001-02

CPT

206

Storage Conditions

Freezer below -5° F
(-25°C to -15°C)

Through expiration date on box

Refrigerator 36° F - 46° F (2°C to 8°C)

8 weeks*

1. Most sites are getting 3 – 4 doses per vial.

*Vaccine will be delivered refrigerated from PDPH. DO NOT REFREEZE.



Dosage and Administration Guidance

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



Current Vaccination Strategies

- PEP – Vaccination of individuals with *known* Monkeypox exposure.
- PEP++ - Vaccination of individuals with *known or presumed* Monkeypox exposure.
- PreP - Vaccination of certain high-risk populations prior to exposure.

We are currently using these models to vaccinate patients with known and presumed Monkeypox exposure.



Patient Eligibility

Any patient who feels that they are at risk for coming into contact with mpox can be vaccinated. They do not need to meet any further eligibility criteria.

However, outreach should continue to those who are most at risk. This includes sex workers of any sex or gender, and gay, bisexual, transgender, or other men who have sex with men, or non-binary persons who meet the following criteria:


- Have had multiple or anonymous sex partners in the last 14 days
- Have had any newly diagnosed STI in the past 12 months, including gonorrhea, chlamydia, early syphilis, or HIV
- Have recently attended or plan to attend any venue where anonymous sex or sex with multiple partners will occur (e.g. saunas, bathhouses, sex clubs, sex parties) in the next 30 days
- Have met recent partners or plan to meet new partners in the next 30 days through social media platforms (such as Grindr, Tinder or Scruff), or at clubs, raves, sex parties, saunas



Ordering

- Orders are due by Monday's at 5:00 pm
- Three step process:
 - Submit temperature logs.
 - Complete reconciliation.
 - Submit order using monday.com form.
- Delivery days are Wednesday and Thursday (following your request)

<https://forms.monday.com/forms/e6f409409743eae9e4a220b55bbaac37?r=use1>

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MPX Vaccine Request Form

AS OF 8/16/2022, PROVIDERS ARE REQUIRED TO SWITCH TO INTRADERMAL VACCINATION AS SOON AS POSSIBLE.

Please use this form to request quantities of JYNNEOS vaccine for intradermal administration at your practice.

While JYNNEOS dose availability is currently limited, the recommendation is for providers to begin with a single shot. The vaccine requires two doses to be considered fully vaccinated, however, people won't be immediately scheduled for their second dose and may not

Site Name *

Site Address *

Site Pin Number *

Date of Request *

Planned Vaccination Start Date *



Reporting Requirements Quick View

A Monkeypox inventory has been set-up in PhilaVax to track Jynneos doses in sites' inventory.

A reconciliation must be completed weekly (every 7 calendar days)

You must track the number of wasted doses for each lot number.

Wastage should be reported to PhilaVax at least weekly.

Use either an HL7 connection or SFTP the website to report patient administration data. NEVER SEND PHI VIA EMAIL.

Patient data must be reported within 24 hrs of vaccine administration.



Wastage

Please avoid wasting doses by keeping the vaccine stored properly and not pre-drawing doses.

- Only wastage of a whole vial should be reported for Mpox. Vaccine is considered wastage in the following situations:
 - The vial is broken or damaged or the rubber stopper is compromised and unusable.
 - Vaccine is drawn into syringe, but no vaccine was administered from an open vial (ie. contamination, patient refusal, beyond use date/time (BUD) reached).
 - Closed vials of vaccine that are not used before the expiration date or BUD.
 - PDPH has instructed you to discard the vials due to improper storage and handling.



Reporting Wastage to PhilaVax

- Wastage should be reported weekly.
- Because the vaccine is licensed for one dose per vial, wastage will be considered as any wastage of a full vial of vaccine for any reason.
- If you administer at least one dose, using either ID or subQ administration, you do not need to report wastage on that vial.
- Please review the following wastage guidance:
 - [Vaccine Wastage Guide](#)
 - [Vaccine Wastage Video](#)



Accounting for Vials and Doses

Reporting Inventory
in PhilaVax:



1 vial



Report the number of vials when
completing your reconciliation

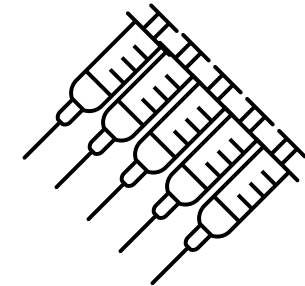
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Reporting administration data:

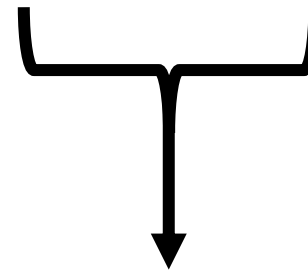


1 dose subQ

or



Up to 3 - 4 doses ID



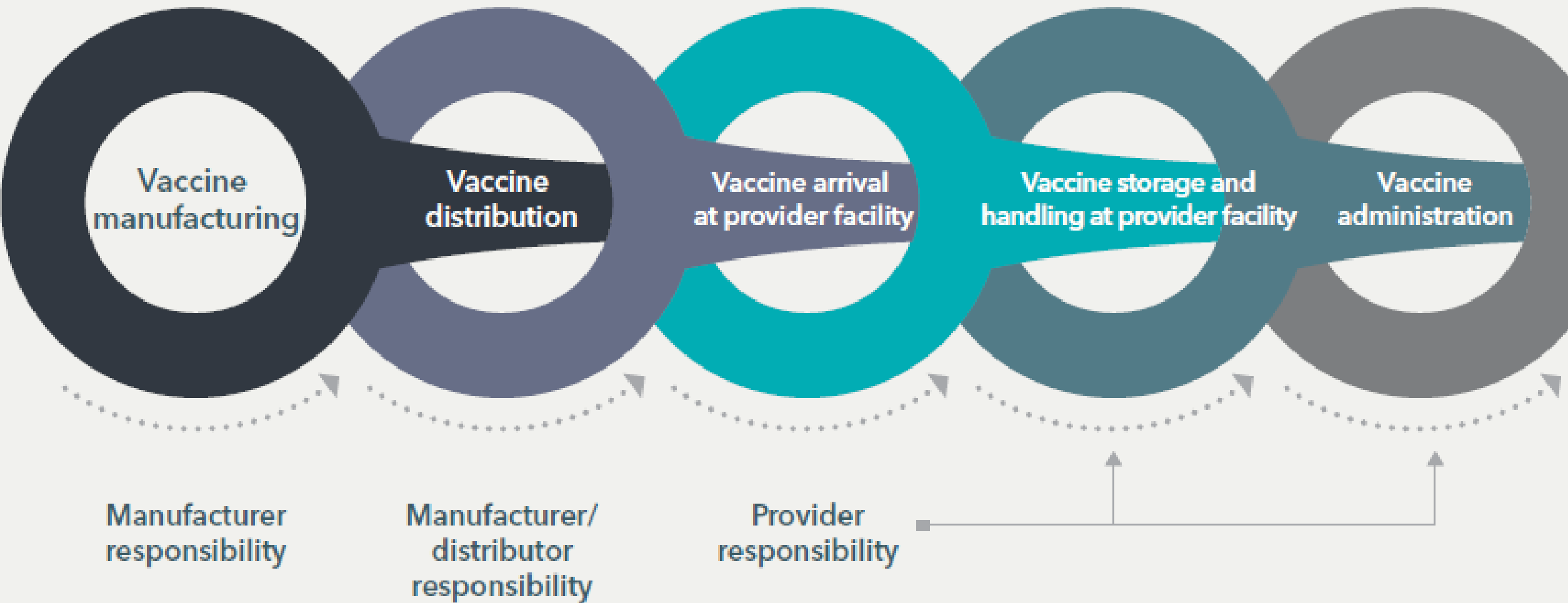
Report all administration data for every dose
administered via HL7 connection
or STFP flat file.



Storage and Handling

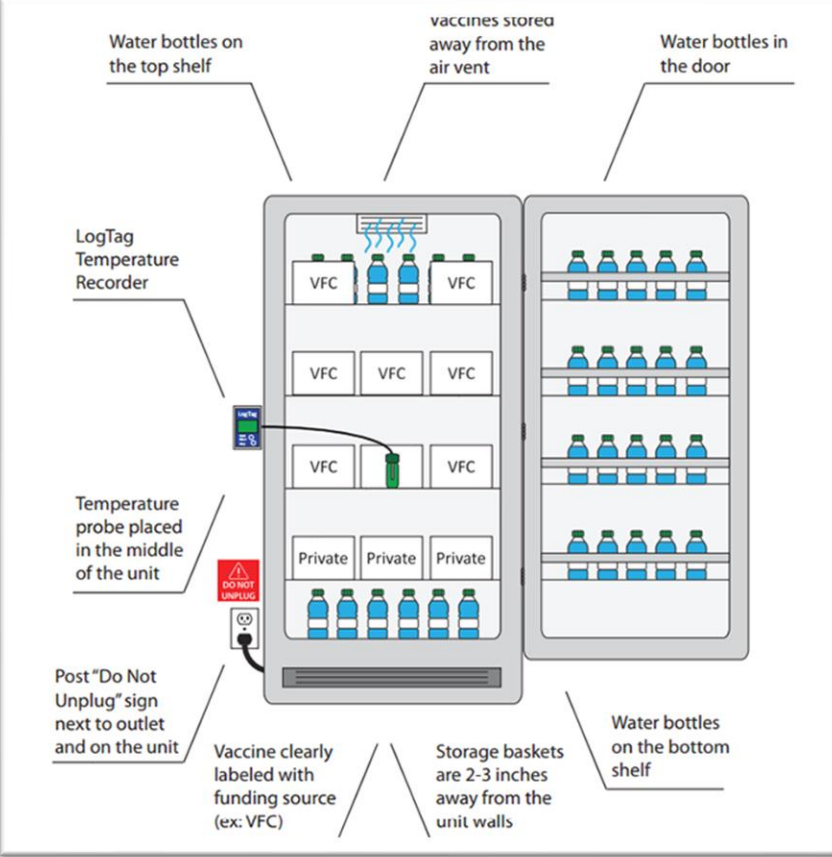


Cold Chain Flowchart

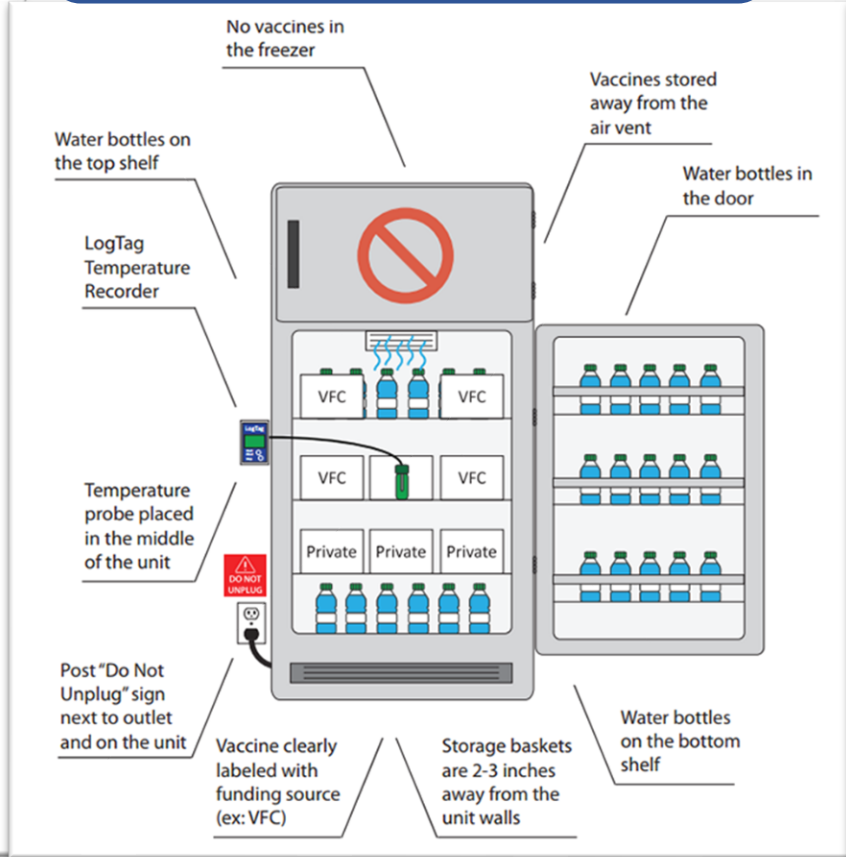


Vaccine Storage

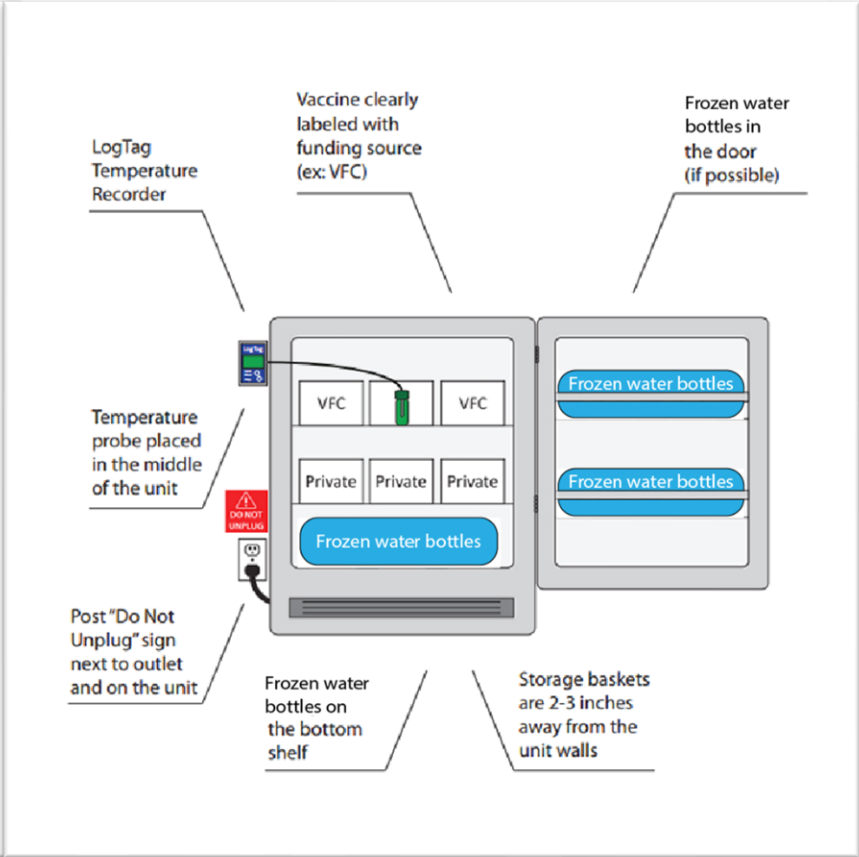
Pharmaceutical Grade Unit (Recommended)



Traditional Household Unit, Fridge section only (Acceptable)



Stand Alone Unit (Acceptable)



NO DORM-STYLE UNITS PERMITTED

<https://vax.phila.gov/index.php/storage-handling/#MonitoringEquipment>



Digital Data Logger (DDL) Requirements

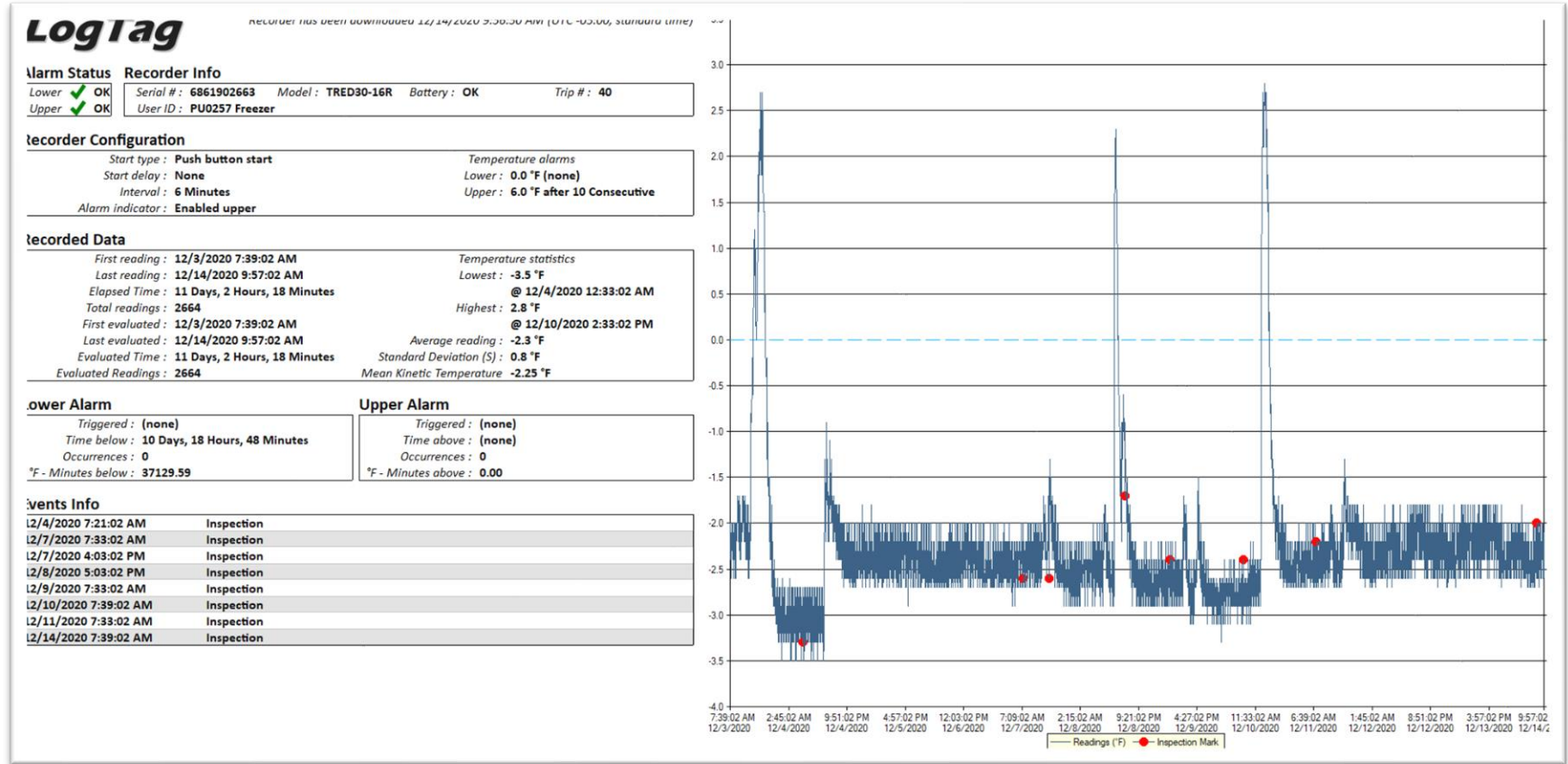
To meet the CDC's definition of a DDL, a thermometer must be accurate within $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$) and have:

- A current and valid Certificate of Calibration (also known as a Report of Calibration).
- A probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon[®]) placed in the center of the storage unit close to the vaccine.
- A digital display that shows current, minimum, and maximum temperatures
- A low battery indicator.
- A logging interval (or reading rate) that can be programmed by the user to measure and record temperatures no less frequently than every 10 minutes.
- An audible alarm.
- For more information, see the [CDC's Storage and Handling Toolkit](#)



DDL Temperature Data Example

Index	Date	Time	Readings (°F)	Type	
1	12/16/2020	2:09:24 PM	-3.6		
2	12/16/2020	2:15:24 PM	-3.8		
3	12/16/2020	2:21:24 PM	-3.6		
4	12/16/2020	2:27:24 PM	-3.5		
5	12/16/2020	2:33:24 PM	-2.9		
6	12/16/2020	2:39:24 PM	-2.6		
7	12/16/2020	2:45:24 PM	-2.4		
8	12/16/2020	2:51:24 PM	-2.6		
9	12/16/2020	2:57:24 PM	-3.1		
10	12/16/2020	3:03:24 PM	-3.5		
11	12/16/2020	3:09:24 PM	-3.8		
12	12/16/2020	3:15:24 PM	-3.8		
13	12/16/2020	3:21:24 PM	-3.6		
14	12/16/2020	3:27:24 PM	-3.5		
15	12/16/2020	3:33:24 PM	-2.9		
16	12/16/2020	3:39:24 PM	-2.4		
17	12/16/2020	3:45:24 PM	-2.6		
18	12/16/2020	3:51:24 PM	-2.7		
19	12/16/2020	3:57:24 PM	-3.3		
20	12/16/2020	4:03:24 PM	-3.6		
21	12/16/2020	4:09:24 PM	-3.8		
22	12/16/2020	4:15:24 PM	-3.8		
23	12/16/2020	4:21:24 PM	-3.6		
24	12/16/2020	4:27:24 PM	-3.3		
25	12/16/2020	4:33:24 PM	-2.7		
26	12/16/2020	4:39:24 PM	-2.6		
27	12/16/2020	4:45:24 PM	-2.6		
28	12/16/2020	4:51:24 PM	-3.1		
29	12/16/2020	4:57:24 PM	-3.6		
30	12/16/2020	5:03:24 PM	-3.8		
31	12/16/2020	5:09:24 PM	-4		
32	12/16/2020	5:15:24 PM	-4		
33	12/16/2020	5:21:24 PM	-3.5		
34	12/16/2020	5:27:24 PM	-3.1		
35	12/16/2020	5:33:24 PM	-2.6		
36	12/16/2020	5:39:24 PM	-2.7		
37	12/16/2020	5:45:24 PM	-2.9		
38	12/16/2020	5:51:24 PM	-3.5		
39	12/16/2020	5:57:24 PM	-3.8		

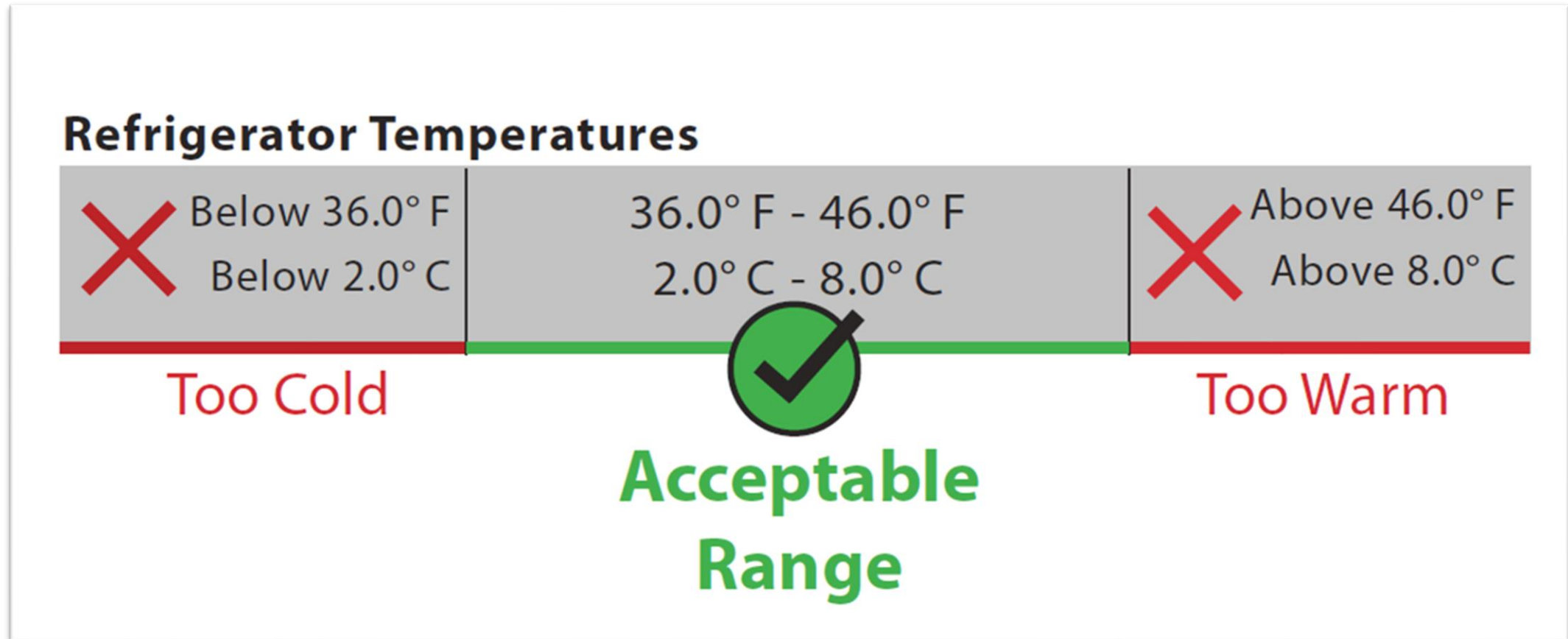


Temperature Data Reporting

- Temperature data must be reported to the Immunization Program:
- Every time you place an order.
- Whenever there is an out-of-range temperature alarm (aka temperature excursion).
 - Label vaccine “**DO NOT USE**” if temperature excursion occurs.
- Every 28 days (if you have not placed an order or had a temperature excursion).
- New Units: at least 48 hours (2 days) of temperature logs before storing vaccine.



Refrigerator Temperature Range



If DDL alarm sounds, contact tempcheck@phila.gov immediately.





Storage for Jynneos



- **THAWED** Jynneos vaccine **should not be refrozen.**
- Jynneos vaccine **cannot be stored at room temperature at any time.**
 - Immediately replace the punctured vial in the refrigerator.
 - Once the vial is punctured, you must discard it after 8 hours.

Contact tempcheck@phila.gov and kenya.mack@phila.gov with any questions or for additional guidance.



Temperature Excursions

Any temperature outside the recommended ranges for a vaccine are considered an excursion. In the event of an out-range temperature, refer to your **Emergency Management Plan**, posted on your unit. It provides guidance on:

- Protecting the viability of the vaccine.
- Documenting the resolution of the excursion.
- Transporting the vaccine if the temperature can't be stabilized.

Contact tempcheck@phila.gov with any questions or for additional guidance.



Emergency Vaccine Transport

Sites need to be prepared and not wait for an emergency!
Make sure they have all the needed supplies on hand in case vaccine needs to be moved.

Wherever the vaccines go, the DDL goes!

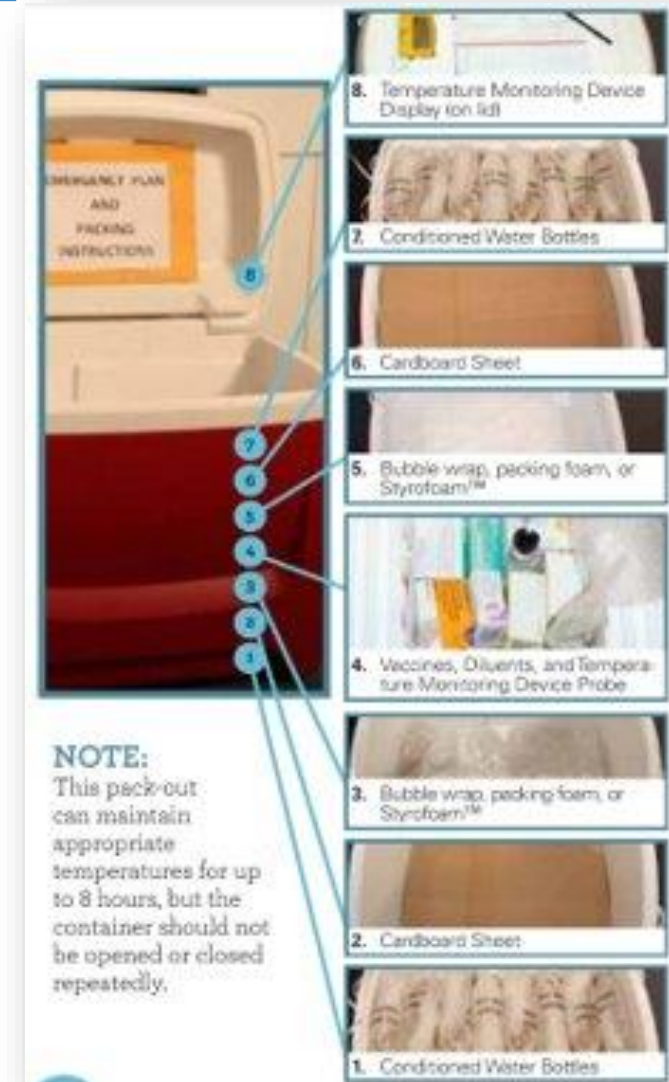
1. Purpose Built Cooler.

OR

2. Hard-sided cooler with...

- Conditioned water bottles.
 - Ice packs (for frozen vaccine).
 - Bubble wrap and 2 layers of corrugated cardboard.
 - DDL (in an emergency, sites should remove the one monitoring their unit to go with the vaccine and request a back-up DDL from our office.
- NEVER use icepacks or dry ice with refrigerated vaccines.

The Vaccine's original Styrofoam packaging can be used as a last resort.



Planned Transport

- Qualified pack outs and purpose-built coolers.
- DDL monitoring temps.
- Contact tempcheck@phila.gov to borrow.



Administration & Clinical Considerations



Precautions & Contraindications

- Jynneos vaccine contains small amounts of gentamicin and ciprofloxacin and is produced using chicken embryo fibroblast cells.
 - Discuss risks and benefits with potential recipients who have a history of severe allergic reaction (e.g., anaphylaxis) following gentamicin, ciprofloxacin, chicken, or egg protein.
 - These recipients may be vaccinated with a 30-minute observation period. Alternatively, vaccination can be delayed until an allergist-immunologist is consulted, but the impact of delaying vaccination should be considered.
- Do not vaccinate patients with a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of Jynneos.



Precautions & Contraindications (cont.)

- Do not vaccinate patients with a history of Monkeypox disease.
 - Additionally, if a patient is diagnosed with Monkeypox after receiving the first dose, do not complete the series (do not provide a second dose).
- Do not use intradermal (ID) administration for patients with a history of keloid scars.



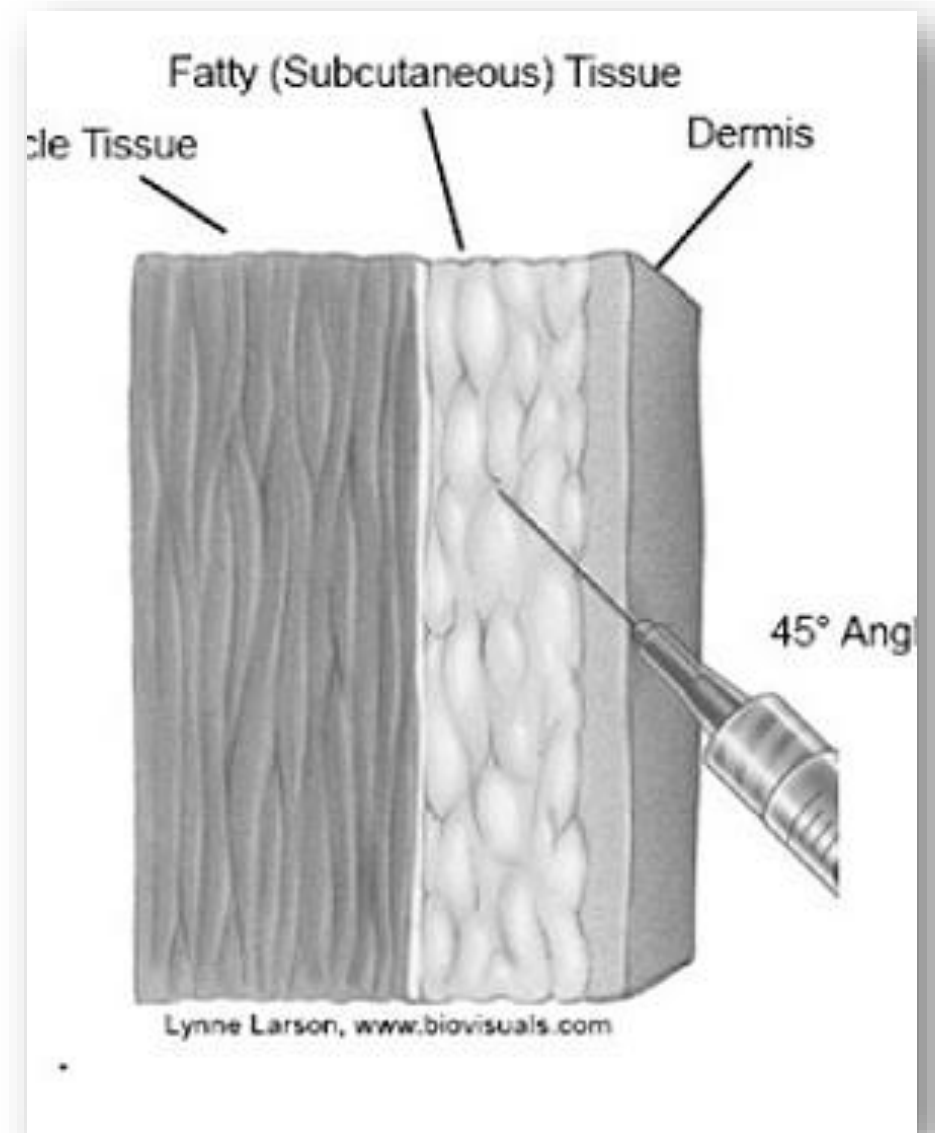
Jynneos Subcutaneous (SubQ) Vaccine Preparation

- Remove vaccine from refrigerator withdraw dose volume of 0.5mL.
 - **There is one SubQ dose available per vial.**
- Do NOT combine residual vaccine from multiple vials to obtain a dose.
- Use a 5/8", 23 – 25-gauge needle for administration.
- Dose should be administered at a 45-degree angle to the skin.
- Bring the dose of vaccine from the designated preparation area directly to the patient treatment area for administration.
- Use a new sterile needle each time.
- Discard vial, syringe and needle in sharps container after administration.



SubQ Administration

- Subcutaneous (SubQ or SC) administration involves injecting the vaccine into the fatty tissue, typically over the triceps.
- Approved for adults and children.
- Recommended for individuals who have a history of keloids.
- All patients should be supplied a Vaccine Information Statement (VIS) prior to SubQ administration.



Intradermal (ID) Administration

- ID administration involves injecting the vaccine superficially between the epidermis and the hypodermis layers of the skin.
- Should produce a noticeable pale elevation of the skin (wheal).
- For patients 18+ years old.
- Not recommended for patients with a history of keloids.
- Provide an EUA to all patients prior to ID administration.



Jynneos ID Vaccine Preparation

- Remove Jynneos vial from refrigeration.
- Withdraw correct dosage (0.1mL) of vaccine into a tuberculin syringe.
 - There are **three to four*** ID doses available per vial.
- 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.

**Clinicians are getting 3 – 4 doses per vial. You are not expected to get more than that.*



Jynneos ID Vaccine Preparation, cont'd

- Use TB syringes with $\frac{1}{4}$ to $\frac{1}{2}$ inch, 27-gauge needles with short bevel for vaccine administration.
- While holding the skin taut, position the bevel facing up and insert the needle at an angle of 5-15 degrees. The bevel should be visible just under the skin.
- Discard syringe and needle in sharps container after administration.
- Monitor patient for 15 minutes (30 minutes if history of anaphylaxis) .
- Use a clean alcohol swab to cleanse the rubber stopper before drawing the next dose of vaccine.
- Use a new sterile needle each time.



Vaccine Administration Deviations & Errors

- Providers who are administering JYNNEOS are **required** to report vaccine administration ***deviations & errors***, even when not associated with an adverse event, to the VAERS (Vaccine Adverse Event Reporting System).
- Information on how to submit a report to VAERS is available at <https://vaers.hhs.gov> or by calling 1-800-822-7967.



Vaccine Administration Deviations & Errors (con't)

- A **deviation** is when the vaccine is administered, and the dose must be repeated.
 - For example, an ID injection does not result in a visible wheal. In this case, a repeat dose should be administered.
- An **error** is when the vaccine is administered, and the dose should **not** be repeated.
 - For example, if the incorrect dosage is administered, resulting in a higher-than-authorized dose (e.g., >0.1 mL administered ID), **do not** repeat the dose. You will need to inform the patient of the possibility of increased side effects.
- Detailed interim recommendations related to administration deviations & errors are posted here on the CDC website:
<https://www.cdc.gov/poxvirus/Monkeypox/interim-considerations/errors-deviations.html>.



Tips on the Vials

- Be careful with the vial, as it is easy to disrupt the rubber stopper.
- The yellow cap is connected to the metal ring. You can either carefully peel the cap or you can pop the cap cleanly off.
- If some metal sticks up, **do not touch the metal**. Rotate the vial then draw up the dose.



Do Not Remove The Metal Ring Around The Vial

- Peeling the metal around the vial stopper can compromise the vaccine seal.
- This can cause the stopper to come off the vaccine and for vaccine to leak.
- If this occurs and the vial is no longer usable, the vaccine vial must be discarded, and vaccine marked as wastage.



Resources



PDPH Resources

- [Mpox Wastage Reporting](#)
- [Mpox Vaccine Wastage Guide](#)
- [Reconciliation Quick Guide](#)
- [Mpox Vaccine Request Form](#)
- [Mpox Vaccine Dose Tracker](#)
- [Online Ordering: Accepting Shipments in PhilaVax](#)
- [Vaccine Management Plan](#)
- [Paper Temperature Logs \(Fahrenheit\)](#)
- [Paper Temperature Logs \(Celsius\)](#)



CDC Resources

- [Information for Healthcare Professionals](#)
- [Monkeypox and Smallpox Vaccine Guidance](#)
- [CDC Interim Guidance](#)
- [Video: Intradermal Vaccine Administration](#)
- [Clinical FAQs](#)
- [2022 U.S. Monkeypox Outbreak](#)
- [Considerations for Pregnancy](#)



Manufacturer Data – Bavarian Nordic

- [Jynneos VIS](#) (English)
- [Jynneos VIS](#) (Spanish)
- [Jynneos EUA](#) (English)
- [Jynneos EUA](#) (Spanish)
- Phone Number: 1-800-675-9596
- Email: BavarianNordicUS@medcomminc.com



PDPH Contact List

- Enrollment Questions:
 - Kenya.Mack@phila.gov (Adult Vaccine Coordinator)
 - Jillian.Brown@phila.gov (Pediatric & Adult Vaccine Manager)
- Storage and Handling or Temperature excursion:
 - Tempcheck@phila.gov
- General questions about PhilaVax or locked out of your account:
 - Philavax@phila.gov
- Help with reconciliations, wastage, or inventory adjustments:
 - DPHProviderhelp@phila.gov

