Smallpox/Monkeypox Vaccine Considerations

**General Actions**

☐ Review and implement all storage and handling recommendations in [CDC’s Vaccine Storage and Handling Toolkit](https://www.cdc.gov/vaccines/), which is available on [CDC’s Vaccine Storage and Handling Resources](https://www.cdc.gov/vaccines) webpage.

☐ Review additional [CDC Vaccine Storage & Handling training video](https://www.cdc.gov/vaccines/trainings/vaccine-storage-handling/index.html).
  - Additional CDC Vaccination training videos are available [here](https://www.cdc.gov/vaccines/trainings/vaccine-storage-handling/index.html).

☐ Review [JYNNEOS FDA package insert](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/301523s0020lbl.pdf).

☐ Review Smallpox/Monkeypox Standing Order.

☐ Review Smallpox/Monkeypox Vaccine Information Sheet (VIS).

☐ Prepare to submit vaccine administration data into the New Jersey Immunization Information System (NJIIS).
  - Options: HL7 interface with NJIIS or direct (manual) data entry.
  - The [interface enrollment form](https://www.nj.gov/health/immunization/clinicians/other-clinicians.html) will need to be submitted for HL7 interface.

**Smallpox/Monkeypox Vaccine Storage Information**

☐ Ensure vaccine storage units meet CDC specifications and temperatures are monitored using digital data loggers (DDL) at all times.
  - Storage units must be:
    - Pharmaceutical grade or purpose built
    - Household grade refrigerator with separate, stand-alone freezer
  - Do not use the freezer section of a combination household unit to store vaccines.
  - NEVER use a dormitory-style refrigerator to store vaccines, even temporarily!

☐ Ensure plans are in place for appropriate handling of vaccines during a disaster or power outage.

- JYNNEOS™ is shipped at -20°C and requires cold chain management.
- JYNNEOS™ should be stored frozen at -25°C to -15°C (-13°F to +5°F) - please refer to the package [insert](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/301523s001lbl.pdf) for more detailed storage requirements for this vaccine.
  - For immediate administration, JYNNEOS™ vials can be thawed at ambient temperature - thawing a vial at ambient temperature should take less than 10 minutes when the vial is taken from -20°C.
  - If not for immediate administration, the frozen vials can also be removed from the -20°C storage to 2-8°C storage to maintain until use.
    - Unopened vials of JYNNEOS™ may be stored at 2-8°C up to 8 weeks from thawing (please be aware that this differs from the package insert – see [Provider Letter](https://www.bavarian-nordic.com/)).
- If vaccine is being transported to another facility, it must be done so ONLY using a [qualified container/packout](https://www.bavarian-nordic.com/) for transfers and DDLs; transporting vaccines in a cooler is unacceptable.
  - [Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations](https://www.bavarian-nordic.com/).
  - [Bavarian Nordic A/S](https://www.bavarian-nordic.com/)
  - Phone: 1-800-675-9596
  - Email: info@bavarian-nordic.com

**Temperature Monitoring – Digital Data Loggers (DDL)**

☐ Ensure that DDLs meet CDC specifications. A DDL is required for each permanent and temporary storage unit.

☐ DDLs must have current and valid Certificates of Calibration.

☐ Learn how to access and download your DDL data. It must be checked at least weekly and temperature data must be kept for a minimum of 3 years.
- Place DDLs in each storage unit. Review/download data at least weekly, whenever an alarm sounds, and whenever an out-of-range current or min/max temperature is noted
  - Ensure alarms are set correctly. DDLs should alarm before a temperature excursion would occur, so you can correct the issue before the vaccines are exposed to an out-of-range temperature (for example set minimum at 2.5°C and maximum at 7.5°C, so you can take action to keep the refrigerator in 2-8°C range)
  - Set device to record at least every 30 minutes
  - Ensure a backup DDL is available

- Keep min/max temperature logs up to date and available

- Post “Do Not Disconnect” signs on outlets and circuit breakers

- Immediately address and report all temperature excursions to the vaccine manufacturer

### Every Vaccination Visit

- Provide Smallpox/Monkeypox Vaccine Information Sheet (VIS) to the patient
  - No consent form is required

- Provide patient with Smallpox/Monkeypox vaccination record
  - For example: copy of facility vaccination record, print out of dose information from NJIIS, NJDOH yellow card

- Report Smallpox/Monkeypox vaccine administration into NJIIS
  - Be sure all information entered is accurate and complete. This includes all patient demographic information.
  - Collect and enter race/ethnicity information for each patient
  - Complete charting includes the date a VIS was given to patient and the date that document was published

- Evaluate NJIIS Consent from patient if appropriate (English or Spanish)
  - Consent is required for individuals who are born before 1998 and/or are not already in NJIIS
  - For those who refuse to sign the consent form, enter doses as “administered to person not in NJIIS” to allow dose to deduct from inventory

### Reminders

- Download, review, and save DDL data. If you find any out-of-range temperatures, notify the manufacturer

- Check vaccine expiration dates and rotate stock
  - Expiration dates are found on the carton but not on the vial itself. Expiration dates may also be found at: Monkeypox (hhs.gov)

- If an Adverse Event occurs, submit a VAERS report
  - Healthcare providers are required to report:
    - Vaccine administration errors (whether associated with an adverse event or not)
    - Serious adverse events (irrespective of attribution to vaccination)
  - Healthcare providers are encouraged to report any clinically significant adverse events that occur after vaccination

### Appendix

*DDL requirements as outlined in CDC Storage and Handling Toolkit:*
  - Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon)
  - Air probes are only permitted for ultra-low freezers, otherwise, probes should be buffered.
  - Alarm for out-of-range temperatures
  - Low battery indicator
  - Current, minimum, and maximum temperature display outside of storage unit
  - Recommended uncertainty of +/-0.5°C (+/-1°F)
• Memory for storing at least 4,000 readings
• Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes

DDL(s) must have at least enough probes to cover the total storage unit compartments at your site. At minimum, your site must have at least 1 back-up DDL, which is self-sustaining and portable for transport and off-site clinic use.

Certificate of Calibration requirements as outlined in the CDC Storage and Handling Toolkit:
• Model/device name or number
• Serial number
• Date of calibration (report or issue date)
• Expiration date/Recalibration date
• Confirmation that the instrument passed testing
• Documented accuracy of +/-0.5°C (+/-1°F)
• Must be issued by an appropriate entity, which is indicated by one or more of the following:
  o Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 Tolerance Class F (<+-0.5°C or <+/-1°F)
  o Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body
  o Traceable to the standards maintained by the National Institute of Standards and Technology (NIST)