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Guidance for the New York State COVID-19 Vaccination Program: Vaccination of Individuals Ages 6 Months to Adult

July 1, 2022

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Summary of Recent Changes

- Update as of June 18, 2022: Everyone ages 6 months and older in the United States should receive a COVID-19 primary series vaccination for the prevention of COVID-19. This NYS COVID-19 vaccination program provider guidance includes all age ranges accordingly.
- On June 23, 2022, the CDC authorized the Moderna COVID-19 vaccine for use as a 2 dose primary series in individuals aged 6–11 years and 12–17 years.
- Currently, children 6–11 years and 12–17 years who receive a Moderna primary series separated by 4-8 weeks, are not authorized to receive a booster dose. Children 5–11 years and 12–17 years who receive a Pfizer primary series separated by 3–8 weeks should receive 1 booster dose at least 5 months after the completion of the primary series.
- Additionally, on June 23, 2022, the CDC updated the COVID-19 vaccine schedule for those eligible to receive a COVID-19 vaccine, by age, immunocompetency status, and vaccine product. A summarized immunization schedule for individuals 6 months of age and older can be found here.
- There are special considerations for the immunocompetent population for an extended interval of up to 8 weeks between dose 1 & 2 of Pfizer or Moderna vaccine. An 8-week interval between the first and second doses of an mRNA COVID-19 vaccine primary series may be optimal for some people aged 6 months to 64 years, especially for males 12–39 years, as it might reduce the small risk of myocarditis/pericarditis associated with mRNA COVID-19 vaccines and might result in a better immune response. A shorter interval (3 weeks for Pfizer-BioNTech; 4 weeks for Moderna) between the first and second doses remains the recommended interval for people who are moderately & severely immunocompromised; adults ages 65 years and older; and in situations where there is increased concern about COVID-19 community levels or an individual's higher risk of sever disease.
- In general, the same mRNA vaccine product should be utilized for all doses in the primary series. The CDC's interim clinical considerations notes that children ages 6 months–4 years who inadvertently receive different mRNA products for the first 2 doses of an mRNA COVID-19 vaccine series should follow a 3-dose schedule. A third dose of either mRNA vaccine should be administered at least 8 weeks after the second dose to complete the 3-dose primary series. This is considered a vaccination administration error and should be reported to VAERS.
- Individuals should receive the recommended age-appropriate vaccine dosage based on their age on the day of vaccination. According to the CDC, if a child moves from a younger group to an older age group during the primary series or between primary series and receipt of a booster dose, they should receive the vaccine product and dosage for their older age group for all subsequent doses. However, FDA authorization allows for different dosing for certain age transitions; more information regarding transitions from a younger to older group can be found here for Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine.
- NYS Wastage Guidance has been updated to reflect updated guidance.
- Storage and Handling Guidance has been updated to reflect updated guidance inclusive of all age ranges.

Key points about COVID-19 Vaccine for Children Ages 6 months–11 years old

- All individuals ages 6 months and older are eligible to receive an age-appropriate COVID-19 primary series. The same mRNA vaccine product should be used for all doses of the primary series (see Interchangeability of COVID-19 vaccine products).
- Additionally, individuals 6 months and older with certain immunocompromising conditions are eligible for a third primary dose. Further information on this third primary dose for immunocompromised children aged 6 months to 11 years old can be found in CDC's Interim Clinical Considerations document, section entitled Guidance for COVID-19 vaccination for people who are moderately or severely immunocompromised. To note:
    - Immunocompromised children ages **6 months–5 years** old who received 2 doses of Moderna primary series, should receive a third primary dose of the Moderna vaccine.
    - Immunocompromised individuals ages **6–11 years** who received 2 doses of the Moderna vaccine should receive a third primary dose of the Moderna vaccine at least 4 weeks after the second dose.
    - Immunocompetent & immunocompromised children **6 months–4 years** old, should receive a 3-dose primary series of Pfizer-BioNTech COVID019 vaccine. Immunocompromised children ages 6 months–4 years old who receive the standard 3-dose Pfizer primary series are not authorized for an extra primary dose as for other immunocompromised age groups.
    - Immunocompromised children ages 5–11 who received a primary series of a non-FDA authorized or approved COVID-19 vaccine at least 28 days prior should receive an additional dose of an age-appropriate mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech or Moderna). More information can be found within the CDC Clinical Considerations.
    - An at-a-glance vaccination schedule for immunocompromised children can be found here.
- The Moderna vaccine for ages 6–11 years has a different pediatric formulation (50 µg), packaging, preparation, and NDC from the other Moderna vaccines and age groups. The Moderna vaccine formulations for adults and adolescents (red cap with light blue border; 100 µg) and for young children aged 6 months–5 years (dark blue cap with magenta border) CANNOT be used in children ages 6–11 years of age.
    - Children ages 6–11 years old should receive the age-appropriate vaccine formulation regardless of their size or weight. For more information regarding the dosing and pediatric formulation please visit the CDC's clinical considerations.
    - Note that the vial for this age group (dark blue cap with purple label border) may say "booster dose only" on the label, but it can be used for the primary series for children 6 years–11 years of age.
- As before, there is no minimum interval between COVID-19 vaccine and other vaccines. CDC states that "COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day." For more information, see CDC's Interim Clinical Considerations sections entitled Coadministration of COVID-19 vaccines with other vaccines and Time, Spacing, and Interchangeability of COVID-19 Vaccines.
- Regarding potential for local and systematic reactions among younger children, particularly younger than ages 3 years, systematic reactions can include irritability, crying, sleepiness, and loss of appetite in addition to common local reactions (i.e., pain, swelling, erythema at the injection site).

Key Points About COVID-19 Vaccine for Ages 12 and Older

- All individuals 12 years and older are eligible to receive an age-appropriate COVID-19 primary vaccine series; an mRNA vaccine is preferred.

    - Individuals **12-17 years** old are currently only eligible to receive the Moderna Vaccine primary series (i.e., red cap with light blue border) or Pfizer-BioNTech COVID-19 vaccine primary series (i.e., purple and grey caps). Individuals 18 years and older can receive any COVID-19 primary vaccine series that is currently FDA approved or authorized in the United States (i.e., Pfizer, Moderna, or Janssen).
- Additionally, individuals **12 years and older** with certain immunocompromising conditions are eligible for a third primary dose. Further information on this third primary dose for immunocompromised individuals aged 12 and older can be found in CDC's Interim Clinical Considerations document, section entitled Guidance for COVID-19 vaccination for people who are moderately or severely immunocompromised. To note:
    - Immunocompromised individuals ages **12–17 years old** who received 2 doses of Moderna primary series, should receive a third primary dose of the Moderna vaccine at least 4 weeks after the second dose. Currently, a booster dose is not authorized for adolescents in this age group who receive a Moderna primary series.
- The CDC endorses and recommends a clinical preference for individuals aged 18 years and older to receive an mRNA COVID-19 vaccine over the Janssen (also known as Johnson & Johnson) COVID-19 vaccine.
- All individuals aged 5-17 years should receive a booster dose of an FDA-approved or -authorized COVID-19 mRNA vaccine. Individuals aged 18 years or older should receive any FDA-approved or -authorized COVID-19 vaccine as the booster dose; however, Janssen should only be used in limited situations and cannot be used as a second booster dose. Those who elect to receive the Janssen COVID-19 vaccine should be informed about the risk and symptoms of thrombosis with thrombocytopenia syndrome (TTS). For more information regarding booster dose eligibility, please visit the CDC's clinical considerations here.
- The time intervals between the COVID-19 primary series and COVID-19 booster doses differ based on type of COVID-19 vaccine, age group, current SARS-CoV-2 infection, and the vaccine recipients' level of immunocompetency. For more information, please visit the CDC's Clinical Considerations here.
- For information regarding the time interval between the primary series and booster doses for individuals:
    - Who are NOT moderately to severely immunocompromised, please visit the CDC's clinical considerations here.
    - Who ARE moderately to severely immunocompromised, please visit the CDC's clinical considerations here. Attempts should be made to match the additional dose type to the mRNA primary series, however if that is not feasible, a heterologous additional dose is permitted.
- As before, there is no minimum interval between COVID-19 vaccine and other vaccines. CDC states that "COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day." For more information, see CDC's Interim Clinical Considerations, section entitled "Coadministration of COVID-19 vaccines with other vaccines".

Scheduling the Second or Third COVID-19 Vaccine Dose

All providers should schedule the second (or third) dose appointment for recipients **at the time the first (or second) dose is administered**. If scheduling a second (or third) dose appointment is not possible at the time of the first (or second) dose, providers should supply information on how/where to obtain a subsequent dose(s) of vaccine.

Circumstances may arise where individuals need to receive their second (or third) dose at a different location than their first. Providers who have determined that the individual cannot return to the location where they received their first (or second) dose **should** either schedule a second (or third) dose for these individuals elsewhere or must supply information on how/where to obtain a second (or third) dose of vaccine. Vaccine availability can be located using the CDC's VaccineFinder. Please ensure all individuals are informed on how to locate second (or third) dose appointment.

Special Considerations for Individuals Receiving Their Primary Series Doses Outside New York State

Individuals who received their primary series of COVID-19 vaccine (one, both, or all doses) outside of New York State will not have a record of this dose(s) in NYSIIS or CIR. Providers should either enter the dose(s) in NYSIIS/CIR as part of the historical record using data listed on the individual's COVID-19 Vaccination Record Card OR advise the parent/patient that they ask their primary care provider to enter their primary series doses into NYSIIS/CIR so the state has a full record of all doses of COVID-19 vaccine.

Special Considerations for Individuals Receiving COVID-19 Vaccine Outside the United States

The CDC guidance for fully vaccinated people states that "this [CDC] guidance can also be applied to COVID-19 vaccines that have been authorized for emergency use by the World Health Organization (WHO) (e.g., AstraZeneca/Oxford)."

Individuals who received only the first dose of a two-dose or three-dose mRNA COVID-19 vaccine are not considered fully vaccinated in the United States. They should be offered an age-appropriate second dose of an mRNA vaccine (i.e., Pfizer-BioNTech COVID-19 Vaccine or Moderna Vaccine formulation).

To determine if an individual who received COVID-19 vaccines outside the USA is "up-to-date" depends on which COVID-19 vaccine (and how many doses) they received. More information about when individuals vaccinated outside the USA are considered fully vaccinated and/or "up-to-date" can be found here.

For COVID-19 vaccines not authorized by the FDA but listed for emergency use by the WHO:

- Please visit the CDC's guidance on vaccines listed for emergency use by the WHO but not approved/authorized by the FDA.
- Individuals who have received all recommended doses of a COVID-19 vaccine that is listed for emergency use by the WHO **do not need** any additional doses with an FDA-authorized COVID-19 vaccine.

For COVID-19 vaccines neither authorized by FDA nor listed for emergency use by the WHO:

- For individuals who received all or some of the recommended doses of a COVID-19 vaccine that is neither authorized by FDA nor listed for emergency use by the WHO, the CDC does NOT consider these persons to be fully vaccinated. They should be offered an age-appropriate COVID-19 mRNA vaccine (i.e., Pfizer-BioNTech or Moderna COVID-19 Vaccine formulation). For more information, please visit the CDC's guidance on these vaccines.

COVID-19 Vaccines Listed for Emergency Use by the WHO

As of May 1, 2022, the WHO has listed several COVID-19 vaccines for emergency use. There are several vaccines on this list that are also authorized by the FDA for Emergency Use in the United States. These include:

- Pfizer-BioNTech COVID-19 vaccines (e.g., COMIRNATY, Tozinameran)*

- Janssen (Johnson & Johnson) COVID-19 vaccine*
- Moderna COVID-19 vaccine (Spikevax)*

For more information regarding other vaccines listed for emergency use by the WHO, please visit the WHO website.

Please note that the minimum interval between receipt of the non-FDA-approved/authorized vaccine and initiation of the FDA-approved/authorized COVID-19 vaccine primary series is at least 28 days.

Vaccine Safety

Post-vaccination monitoring is an essential part of the COVID-19 vaccination program. The CDC is promoting and encouraging all those being vaccinated to participate in V-Safe, a smart-phone based application that will allow those vaccinated to enter their symptoms in the days after vaccination using text messaging. V-Safe also provides reminders for the second dose and telephone follow up for anyone who reports medically significant adverse events. V-Safe materials can be found at http://www.cdc.gov/vsafe, including a V-Safe information sheet. Please print out the information sheet and hand to each person vaccinated.

You must report any adverse events that occur after vaccination to the Vaccine Adverse Events Reporting System (VAERS) at info@VAERS.org or by calling 1-800-822-7967. For a list of administration errors and deviations and what action to take after an error or deviation has occurred, please refer to this CDC resource: Appendix C. Vaccine Administration Errors and Deviations.

Information on COVID19 vaccine safety signals that have been assessed by one or more of these mechanisms can be found in CDC's Selected Adverse Events Reported after COVID-19 Vaccination. Additional information can be found in CDC's Interim Clinical Considerations:

- Section entitled Safety considerations for mRNA COVID-19 vaccines: Pfizer-BioNTech and Moderna (including considerations surrounding myocarditis and pericarditis), and
- Section entitled COVID-19 vaccination and SARS-CoV-2 infection including MIS-C and MIS-A (including considerations for vaccination after MIS-C).

Regarding vaccine demand and hesitancy—serious safety problems associated with COVID-19 vaccines are rare. Still, patient perception of COVID19 vaccine safety, often fueled by false reports on social media, can impact public trust in vaccination. Information on common myths about COVID-19 vaccine safety (including impact on fertility and DNA) can be found at the CDC's Facts webpage and New York State's webpage Combatting Misinformation about the COVID-19 Vaccines.

Consent for Vaccination of Minors

Entities operating vaccination sites may use the following verification methods as a model for securing consent for vaccination of minors, in consultation with counsel as needed. It is important to verify the age of any individual who appears to be a minor to ensure consent is obtained, confirm eligibility, and ensure the administration of the proper COVID-19 vaccine.

Proof of age should be requested but is not required where the parent or guardian is available to attest to the minor's age. Documentary proof may include (but is not limited to):

- Driver's license or non-driver ID
- Birth certificate issued by a state or local government

- Consulate ID
- Current US passport or valid foreign passport
- Permanent resident card
- Certificate of Naturalization or Citizenship
- Life insurance policy with birthdate
- Parent/guardian attestation

For all minors, a parent or legal guardian must provide consent for vaccination.

6 months–5-year-olds:
For minors who are 6 months through 5 years of age, additionally, an adult caregiver should accompany the minor. If the adult caregiver is not the parent/guardian, the adult caregiver should be designated by the parent/guardian. The parent/guardian must still provide consent to the vaccination.

16 and 17-year-olds:
For minors 16 or 17 years of age, consent should be provided either in person or by phone, at the time of vaccine appointment. Providers may elect to accept a written statement of consent from the parent or guardian, where the parent or guardian is not available by phone to provide consent to vaccinate an unaccompanied minor.

EUAs, FDA Vaccine Approval Status, and Appropriate Use of Vaccines in New York State

Providers must administer COVID-19 vaccines in accordance with all program requirements and recommendations of NYSDOH and the CDC, the Advisory Committee on Immunization Practices, and the U.S Food and Drug Administration (FDA). This applies to vaccines administered in accordance with an EUA or Emergency Use Instruction (EUI), as well as FDA approved COVID-19 vaccines. Accordingly, use of these products outside of those that have been approved and authorized by FDA or in accordance with a CDC EUI (often referred to as **"off-label use") is not recommended**. It would violate the provider agreement and could expose providers to the following risks:

- Administration of the product off label may not be covered under the Public Readiness and Emergency Preparedness (PREP) Act or the PREP Act declaration; therefore, providers may not have immunity from claims.
- Individuals who receive an off-label dose may not be eligible for compensation under the Countermeasures Injury Compensation Program after a possible adverse event.
- CDC has defined the scope of the CDC COVID-19 Vaccination Program in terms of how the USG-provided vaccines may be used in the program. Providers giving off-label doses would be in violation of the CDC Program provider agreement potentially impacting their ability to remain a provider in the CDC program.
- Administration fees may not be reimbursable by payers.

Accurate and timely reporting to NYSIIS/CIR is critical, as this information can be used to allow individuals to display proof of vaccination, such as the Excelsior Pass or Excelsior Pass Plus.

Ordering Instructions

Please see the NYSDOH COVID-19 Vaccine Information for Providers page for more information on ordering pediatric Pfizer-BioNTech and Moderna COVID-19 vaccine in NYSIIS. Providers in New York City should follow instructions from NYC DOHMH and CIR.

All facilities or practices are required to track vaccine uptake among their staff and must furnish uptake data to the NYSDOH via HERDS survey upon request, or as directed by your agency or organization.

Storage and Handling Requirements

Vaccines must be stored and handled properly from the time they are manufactured until they are administered to maintain the cold chain, thus protecting the potency and effectiveness of the vaccine and ensuring vaccine recipients are fully and safely protected from vaccine-preventable diseases. Detailed information regarding COVID-19 vaccine storage and handling requirements is available at CDC Vaccine Storage and Handling Toolkit.

CDC storage and handling summaries for the COVID-19 vaccines by age for each product can be found here:

- Pfizer COVID-19 Vaccine Storage and Handling
- Moderna COVID-19 Vaccine Storage and Handling
- Janssen Vaccine Storage and Handling

As part of the COVID-19 Vaccination Provider Agreement, providers are required to:

- Store and handle vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with an EUA or vaccine package insert, manufacturer guidance, and CDC guidance in the Vaccine Storage and Handling Toolkit.
- Monitor storage unit temperatures at all times, using equipment and practices that comply with guidance in the toolkit. Every storage unit that holds COVID-19 vaccines must have a digital data logger (DDL). Staff must check and record temperatures each workday and regularly check the DDL temperature data.
- If the temperature of the storage unit goes outside of the recommended temperature range, the temperature excursion must be reported immediately. Providers located outside NYC must complete the COVID-19 Vaccination Program Temperature Excursion Report.
- Monitor and comply with COVID-19 vaccine expiration and beyond use dates.
- Preserve all records related to COVID-19 vaccine management, including temperature records, for a minimum of three years.
- Comply with CDC instructions and timelines for disposing of COVID-19 vaccine and diluent, including used doses.

COVID-19 Vaccine Expiration Dates

Determining when a vaccine expires is a critical step in proper storage and handling. The expiration date should always be checked prior to preparing or administering vaccine. Expired vaccine or diluent should NEVER be used. As additional stability data become available, the expiration dates for some products may change.

1) **Pfizer-BioNTech COVID-19 Tris Sucrose vaccine products: ages 6 months–4 years old (vials have maroon caps), ages 5–11 (vials have orange caps), and ages 12+ (vials have gray caps):** Expiration dates for Pfizer-BioNTech products can be found here.
    - The date printed on the maroon cap, orange cap, and gray cap Pfizer-BioNTech COVID-19 vaccines indicate the manufacture date and **NOT** the expiration date. **The expiration date for all Tris Sucrose formulations is 12 months from manufacture date (while held at ULT frozen).**
    - Vials may also be stored up to 10 weeks in the refrigerator at 2-8° C (see beyond use dates, below). Once thawed, vials CANNOT be refrozen.

- **No standard freezer storage is approved for the Pfizer-BioNTech Tris Sucrose formulations**.
- Regardless of storage conditions, Pfizer-BioNTech maroon cap, orange cap, and gray cap vaccines should not be used after 12 months from the date of manufacture printed on the vial and cartons. Therefore, vaccine must be used by the expiration date, or the 10-week beyond use date for refrigerator storage, whichever comes first. The updated expiry dates for the maroon cap, orange cap, and gray cap vials based on 12 months from the date of manufacture are provided below.

Printed Manufacturing Date	12-Month Expiry Date*
06/2021	31-May-2022
07/2021	30-Jun-2022
08/2021	31-Jul-2022
09/2021	31-Aug-2022
10/2021	30-Sep-2022
11/2021	31-Oct-2022
12/2021	30-Nov-2022
01/2022	31-Dec-2022
02/2022	31-Jan-2023

*Date of expiration always falls on the last day of the month.

2) **Pfizer-BioNTech COVID-19 vaccine for ages 12 and older (vials have purple caps)**: FDA approved an amendment to the EUA for Pfizer-BioNTech COVID-19 vaccine extending the expiration dates of purple cap vials to 12 months. Cartons and vials of Pfizer-BioNTech COVID-19 vaccine with an expiry date of November 2021 through March 2022 printed on the label may remain in use for 6 months beyond the printed date as long as authorized storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained. Frozen vials stored at -25°C to -15°C and refrigerated vials (2°C to 8°C) are NOT eligible for extension. Updated expiry dates for vaccine maintained in ultra-cold storage are shown below. The extended expiration date is effective immediately for all currently available batches that have not yet expired. Vaccine cannot be used after the new expiration date, even if the storage-determined beyond-use date would be after the updated expiration date.

Printed Expiry Date	Updated Expiry Date
December 2021	June 30, 2022
January 2022	July 31, 2022
February 2022	August 31, 2022
March 2022	September 30, 2022

3) **Moderna COVID-19 vaccines (all formulations):** The expiration date is NOT printed on the vaccine vial or carton.
   - To obtain the expiration date of the lot number received, providers can scan the QR code located on the vial or carton or access the manufacturer's website directly, enter the lot number and the expiration date will be displayed.
   - Moderna vaccines may be stored in standard freezer at temperatures between -50°C and -15°C (-58°F and 5°F) until expiration date. If vaccine is stored in a refrigerator, beyond use dates must be tracked.

4) **Janssen/Johnson & Johnson COVID-19 vaccine**: The expiration date is NOT printed on the vaccine vial or carton.

- On April 27, 2022, the FDA announced the approval of another shelf-life extension for refrigerated Janssen vaccine. This decision is based on data from ongoing stability assessment studies, which have demonstrated that the vaccine is now stable at 11 months when refrigerated at temperatures of 36º–46º Fahrenheit (2º–8º Celsius).
- To determine the most current expiration date:
  - Scan the QR code located on the outer carton, or
  - Call 1-800-565-4008, or
  - Go to https://vaxcheck.jnj/, enter the lot number and the expiration date will be displayed.

Beyond Use Dates (BUDs)

All vaccines have expiration dates, and some routinely recommended vaccines have a beyond use date (BUD), which is calculated based on the date the vial is first punctured and the storage information in the package insert. Whenever a vial of COVID-19 vaccine is moved to storage conditions that affect BUD or a multidose vial is punctured, label the vial(s) with the beyond use date/time. **The BUD must never exceed the labeled expiration date.** Once the vaccine has reached its expiration or beyond use date/time, unused doses must be disposed of as medical waste and reported as wastage in NYSIIS or CIR. A summary of COVID-19 vaccine beyond use dates and resources are listed below.

1) Pfizer Pediatric (Maroon Cap): Beyond-Use Date (BUD) Tracking Labels for Vaccine During Refrigerator Storage
   - Refrigerator (2° C to 8° C): 10 weeks
   - **NOTE: NO standard freezer (-25° C to -15° C) storage allowed**
   - Room temperature (8 ° C to 25° C): 12 hours prior to first puncture
   - After Puncture: 2° C to 25° C for up to 12 hours. Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in the EUA Fact Sheet (12 hours) supersedes the number of hours printed on vial labels and cartons.

2) Pfizer Pediatric Tris (Orange Cap): Beyond-Use Date (BUD) Tracking Labels for Vaccine During Refrigerator Storage
   - Refrigerator (2° C to 8° C): 10 weeks
   - **NOTE: NO standard freezer (-25° C to -15° C) storage allowed**
   - Room temperature (8 ° C to 25° C): 12 hours prior to first puncture
   - After Puncture: 2° C to 25° C for up to 12 hours. Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in the EUA Fact Sheet (12 hours) supersedes the number of hours printed on vial labels and cartons.

3) Pfizer age 12 and older (vials have purple caps): Pfizer-BioNTech COVID-19 Vaccine Beyond-Use Date (BUD) Tracking Labels for Vaccine During Freezer or Refrigerator Storage
   - Freezer (-25° C to -15° C): Two weeks
   - Refrigerator (2° C to 8° C): 31 days
   - After Puncture: 2° C to 25° C for up to 6 hours

4) Pfizer Adult/Adolescent Tris (Gray Cap, age 12+, no diluent): Beyond-Use Date (BUD) Tracking Labels for Vaccine During Refrigerator Storage
   - Refrigerator (2° C to 8° C): 10 weeks
   - **NOTE: NO standard freezer (-25° C to -15° C) storage allowed**
   - Room temperature (8 ° C to 25° C): 12 hours prior to first puncture

- After Puncture: 2° C to 25° C for up to 12 hours. Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in the EUA Fact Sheet (12 hours) supersedes the number of hours printed on vial labels and cartons.

5) Moderna: Moderna COVID-19 Vaccine Beyond-Use Date (BUD) Tracking Label for Vaccine During Refrigerator Storage
   - Refrigerator (2° C to 8° C): 30 days
   - After Puncture: 2° C to 25° C for up to 12 hours

6) Janssen/J&J: Janssen COVID-19 Vaccine Preparation and Administration Summary
   - ONLY store in refrigerator up to expiration date.
   - After Puncture: 2° C to 8° C up to 6 hours OR 9° C to 25° C for up to 2 hours. These times are NOT cumulative (i.e., you cannot store a punctured vial for 6 hours at refrigerated temperatures and then another 2 hours at room temperature).

Each provider that receives vaccine:

- Must make best efforts to use all vaccine doses before expiration or reaching beyond use dates based on temperature storage requirements by assessing the COVID-19 vaccination status of each patient and offering the vaccine to all eligible individuals.
- Providers should continue to report all doses administered to NYSIIS and CIR, including third vaccine doses and booster doses as appropriate based on ACIP recommendations. It is critical that providers follow the appropriate intervals and product combinations in order for these doses to be considered valid. Providers should fully utilize both NYSIIS and CIR to confirm patients' previous dose dates and vaccine type. Full contact information for the parent/guardian of the child receiving the vaccination, including phone number, email and zip code, should be entered as well.

In addition, to ensure all New Yorkers can find vaccination locations close to them, **vaccine providers are strongly encouraged to have their facility/facilities opt-in to the CDC's online VaccineFinder tool** (Vaccines.gov)**.** To do so, providers should set the display field in the COVID-19 Locating Health Portal to "display" if the facility is currently providing vaccinations to the general public. This will allow patients in the local area to see in real-time whether the facility has doses of each brand available, enabling vaccination access for a broader population.

- NYSDOH reports inventory to the CDC every Monday through Friday for each organization. Therefore, organizations do not need to report inventory to VaccineFinder (despite having access). Providers must maintain accurate inventory in NYSIIS or CIR. Additional information on the VaccineFinder tool can be found here.

Moderna Booster Dose Inventory Considerations when using Moderna Red Cap Vials

It is important to note that the volume of a Moderna booster dose from the Moderna red cap vial is **0.25 mL** (half the volume of a primary dose). The Moderna COVID-19 vaccine was previously supplied in two multiple-dose vial presentations. The 14-dose vials (NDC 80777-0273-98) have all expired and should no longer be in use. Booster doses may now be administered from either multiple-dose vials containing 5.5 mL with red cap (i.e., Moderna 10-dose) or the multiple-dose vials containing 2.5 mL with blue cap and purple label border (i.e., Moderna 5-dose). The instructions below relate to the use of the Moderna red cap (Moderna 10-dose) vials for booster doses.

Reporting: Despite the volume of the booster dose from red cap vials being **0.25 mL**, providers must still **report a full dose as administered in NYSIIS**. Reporting of half doses is not allowed and **inventory must only be reported in whole doses**. Half doses in NYSIIS inventory will prevent a provider from entering new vaccine orders.

Maximum vial puncture: Providers may extract both primary series doses (0.5mL) and booster doses (0.25 mL) from the same Moderna red cap vial. When extracting only booster doses or a combination of primary series and booster doses, **the maximum number of doses that may be extracted from either vial presentation should not exceed 20 doses. Do not puncture the vial stopper more than 20 times.**

- After the vial has been punctured 20 times, the vial must be discarded, even if there is vaccine remaining in the vial and the beyond use date/time has not been reached (see more info below on when to report wastage in NYSIIS).
- The use of vial adapters, dispensing pins, or strategies where a needle is inserted into the vial septum for multiple medication withdraws is not allowed due to contamination risk.

NYSIIS inventory: Due to the reporting of full doses for boosters and the maximum of 20 punctures for each Moderna red cap vial, the number of doses reported may exceed the number of doses recorded in NYSIIS inventory (i.e., 100 dose order = up to 200 booster doses). This means NYSIIS inventory may be depleted before physical inventory. Best practice would be to modify inventory to add doses to the lot number BEFORE ADMINISTRATION. Do a vial count of physical inventory at the end of the day and multiply your full, unopened vials times the number of labeled doses in the vial (10 doses) and manually modify your NYSIIS inventory to reflect this count. If you report vaccine administration data via data exchange, additional doses beyond the NYSIIS doses on hand will go to the Inventory Not Deducted module. If this happens, manually add doses to the lot number and then update non-deducted inventory.

NYSIIS inventory is used to populate Vaccine Finder product availability through a daily data upload. If you have physical inventory and you do not modify inventory to add doses once it is depleted in NYSIIS, your location will not show as having Moderna vaccine available on Vaccine Finder.

Wastage: Continue to maintain reporting of wastage in whole doses. Wastage should only be reported if the total doses administered from a vial, regardless of volume or series, is less than the vial dose count (i.e., 1 primary and 5 booster doses from a 10-dose vial would be reported as 6 doses used and 2 doses wasted). Once 10 doses are given from a 10-dose vial, regardless of whether primary or booster doses, no wastage needs to be reported even if there is vaccine remaining in the vial. Post-puncture times must still be tracked and remaining doses discarded as medical waste.

Vaccine Redistribution

As the ordering quantities and the storage conditions have become more practical, providers are encouraged to place direct orders in NYSIIS and avoid redistribution whenever possible, even if all doses cannot be used. Vaccine may be redistributed to another facility, provider, practice, or local health department that is enrolled in the COVID-19 vaccination program, with proper notice to the NYSDOH. Prior to redistributing vaccine, facilities must submit a completed redistribution form to COVIDVaccineRedistribution@health.ny.gov and can proceed with the redistribution once submitted. Redistributions must follow the New York State COVID-19 Vaccine Program Guidance for Vaccine Transport, including use of a digital data logger to monitor temperatures during transport. Direct orders are the preferred and safest way to receive vaccine.

A provider may transport vaccine to another location for the purpose of holding a limited duration vaccination clinic without notifying the NYSDOH. If the provider is administering the doses and reporting doses administered against their own inventory in NYSIIS, all unused vaccine must be transported back to the original location at the conclusion of the clinic that day. The provider must retain possession and control of the vaccine for the duration of the transport and administration.

Responsible Wastage

The CDC released guidance on May 11, 2021, regarding wastage along with a critical message to "take every opportunity to vaccinate every eligible person." As more vaccination opportunities are created, the likelihood of leaving unused doses in a vial may increase. While enrolled providers must continue to follow clinical best practices to use every dose possible, it should not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated.

As the ordering quantities and the storage conditions have become more practical, we are encouraging providers to place direct orders whenever possible, even if you cannot use all doses. This is the safest way for providers to receive vaccine and reduces the risk of temperature excursions and the burden of continued redistribution.

- Currently available COVID-19 vaccine products are all multidose vials. Vaccine vials must often be punctured without using the full number of doses printed on the label. Do not turn anyone away because you do not have additional people to vaccinate with remaining doses in a vial. Discarding the remaining doses is acceptable wastage (and needs to be reported as wastage in NYSIIS). Doses not administered within the limits below post-puncture must be wasted:
    - 12 hours: Pfizer Adult/Adolescent Tris (gray cap, age 12+, no diluent), Pfizer ages 5-11 (orange cap), Pfizer ages 6 months through 4 years (maroon cap)
    - 6 hours: Pfizer-BioNTech 12+ purple cap vials
    - 12 hours: Moderna (all formulations)
    - 6 hours (refrigerated) or up to 2 hours at room temperature: J&J/Janssen. These times are NOT cumulative (i.e., you cannot store a punctured vial for 6 hours at refrigerated temperatures and then another 2 hours at room temperature).

Please note: **Any vial of vaccine that exceeds the shelf life indicated by the manufacturer (expiration date OR beyond use date) must be disposed of as regulated medical waste and reported as wastage** in consultation with the manufacturer.

Equity and Access

Efforts must be made to conduct outreach to families in all communities and settings. Children and families in areas that have a high social vulnerability index are particularly vulnerable to COVID-19 and should be notified about how they can receive vaccine. Every effort should be made to increase their access to vaccination opportunities. Encourage families to look for the vaccine through https://www.vaccines.gov/ or call 1-800-232-0233 (TTY 1-888-720-7489). Locations, types of vaccine available, age range for vaccination and appointment scheduling information can be found here.

Communicating the Plan

Please be sure to clearly communicate this critical guidance to all staff involved in the vaccination program. Even front desk staff can be champions to promote the vaccine.

This guidance is in effect from the date of issuance until it is updated, or additional guidance is issued by NYSDOH. For questions, please contact the New York State Department of Health, Bureau of Immunization at COVID19vaccine@health.ny.gov.

Resources

1) Resources for Individuals 6 months–11 years of Age

- Moderna EUA for 6 months through 5 years of age
- Pfizer EUA for 6mo through 4 years of age
- Pfizer fact Sheet for instructions for preparation and administration
- Communication resourcse for pediatrics
- Vaccine Administration Resource Library for Healthcare Professionals (CDC)
- Epidemiology and Prevention of Vaccine-Preventable Diseases: Vaccine Administration (CDC)
- COVID-19 Vaccine Webinar Series (CDC)
- COVID-19 Vaccination Clinical and Professional Resources (CDC)
- How to Administer Intramuscular and Subcutaneous Vaccine Injections (Immunization Action Coalition)
- Medical Management of Vaccine Reactions in Children and Teens in a Community Setting (Immunization Action Coalition)
- Updated toolkit for pediatirc COVID vaccines

2) Resources for Individuals 12 and Older

- Pfizer-BioNTech COVID-19 Vaccine (Purple Cap, Must Dilute) FDA EUA for 12 Years of Age and Older for Healthcare Providers
- Pfizer-BioNTech COVID-19 Vaccine (Grey Cap, No Dilution) FDA EUA for 12 Years of Age and Older for Healthcare Providers
- Pfizer-BioNTech COVID-19 Vaccine FDA EUA (12 Years of Age and Older) for Caregivers and Recipients
- Moderna COVID-19 Vaccine FDA EUA for Caregivers and Recipients
- Moderna COVID-19 Vaccine FDA EUA for Vaccination Providers for Primary Series and Booster Dose 12 and up
- Janssen COVID-19 Vaccine FDA EUA for Caregivers and Recipients
- Janssen COVID-19 Vaccine FDA EUA for Vaccination Providers
- Interim recommendations for COVID-19 vaccine administration errors and deviations

3) General Resources

- Patient friendly vaccine chart
- Protective Measures for Vaccinating During the COVID-19 Pandemic (Immunization Action Coalition)
- Skills Checklist for Vaccine Administration (Immunization Action Coalition)
- Supplies You May Need at an Immunization Clinic (Immunization Action Coalition)
- Ask the Experts: COVID-19 Specific Information (Immunization Action Coalition)
- Ask the Experts: Administering Vaccines (Immunization Action Coalition)
- Additional information about the level of immune suppression associated with a range of medical conditions and treatments can be found in general best practices for vaccination of people with altered immunocompetence, the CDC Yellow Book, and the Infectious Diseases Society of America policy statement, 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host.