COVID-19 Vaccine Webinar for Healthcare Providers
Topics: Pediatric Vaccine and Boosters

New York State Department of Health Staff
Thursday, November 4, 2021 | 7:30pm – 8:30pm
Webinar Agenda

• Opening Remarks
• COVID-19 and Vaccine General Information
• Additional Doses and Boosters
• ACIP Recommendations: Children 5-11 years
• Vaccine Administration: Children 5-11 years
• COVID Vaccine Operations – Key Points
  – Enrollment, Ordering, Storage, and Reporting
• Additional Resources
• Questions and Answers (time permitting)

The information in this document is current as of November 3, 2021 and is subject to change as guidance is updated!
Opening Remarks
Dr. Zucker
COVID-19 and Vaccine
General Information
Dr. Lutterloh
Updates

• Pediatrics
  – NYSDOH is excited to offer the Pfizer-BioNTech mRNA COVID-19 vaccine endorsed by the CDC and the Advisory Committee on Immunization Practices’ (ACIP) for children 5 to 11 years old
  – Expands vaccine recommendations to about 1.5 million children in NYS
    • Consideration of access for the most vulnerable and underserved pediatric populations
  – COVID-19 cases in pediatric patients can result in hospitalizations, deaths, MIS-C, and long-term complications, such as “long COVID,” affecting children's school performance, mental and physical health as well as overall community transmission

• Additional doses and boosters
New York State
Cases and Testing Timeline
Hospitalizations
Variants

Distribution of variants sequenced and uploaded to GISAID

- Alpha
- Beta
- Gamma
- Delta
- Eta
- Mu
- Iota
- Other

Total new cases
Cases and Vaccine Status

Cases, by vaccination status: All Adults Age 18+

Diagnoses per 100,000: Fully-vaccinated
Diagnoses per 100,000: Unvaccinated
Vaccine effectiveness

NEW YORK STATE Department of Health
Hospitalization and Vaccine Status

![Graph showing hospitalization rates and vaccine effectiveness for adults age 18+](image-url)
COVID-19 Vaccines Timeline

• 12/11/20: Pfizer-BioNTech authorized (ages 16+)
• 12/18/20: Moderna authorized (ages 18+)
• 2/27/21: Janssen authorized (ages 18+)
• 5/12/21: Pfizer-BioNTech authorized for ages 12-15
• 8/13/21: Pfizer-BioNTech and Moderna additional dose authorized for moderate/severely immunocompromised individuals
• 8/23/21: FDA grants full approval for Pfizer-BioNTech (16+)
• 9/23/21: Pfizer-BioNTech or Moderna boosters authorized for select populations
  • 6 months after primary; 65+, LTCF, 18-64 with underlying conditions or increased risk of exposure
• 10/20/21: Janssen booster and mix-and-matching of boosters authorized
  • Janssen booster: 2 months after primary, 18+
• 11/2/21: Pfizer authorized for children (ages 5-11)
COVID-19 Vaccination Program

- Providers enrolled (excluding NYC): 5,157
- Doses administered in NYS: 27,314,769
- Percent of those 18+ in NYS with at least 1 dose: 87.7%
- Percent of Total NYS population fully vaccinated: 66.8%

As of 11/2/2021
Percent of People with COMPLETE Vaccination Series by Age Group

Gender = 66.6% Female | 61.8% Male
Summary of Vaccines with FDA EUA and Full Authorization

### Additional primary dose

Moderately and severely immunocompromised persons aged ≥12 years (Pfizer-BioNTech recipients) or ≥18 years (Moderna recipients) should receive an additional primary dose of the same mRNA COVID-19 vaccine administered for the primary series, as follows:

- **Pfizer-BioNTech**: 30 µg in a volume of 0.3 ml (same as the primary series and booster doses) for persons aged ≥12 years.
- **Moderna**: 100 µg in a volume of 0.5 ml (same as the primary series dose) for persons aged ≥18 years.

<table>
<thead>
<tr>
<th>Primary and additional primary doses vaccine manufacturer</th>
<th>Age of recipient (years)</th>
<th>Vial cap color denoting formulation</th>
<th>Concentration of mRNA per primary dose</th>
<th>Primary dosage injection volume</th>
<th>Number of doses in primary series (interval between doses)</th>
<th>Additional primary dose in immunocompromised people (interval since 2nd dose)</th>
<th>Interval between last primary (including additional) to booster dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>5-11</td>
<td>Orange</td>
<td>10 µg</td>
<td>0.2 ml</td>
<td>2 (21 days)</td>
<td>Not recommended</td>
<td>Booster not recommended</td>
</tr>
<tr>
<td>Pfizer-BioNTech</td>
<td>12-17</td>
<td>Purple</td>
<td>30 µg</td>
<td>0.3 ml</td>
<td>2 (21 days)</td>
<td>1 (≥28 days)</td>
<td>Booster not recommended</td>
</tr>
<tr>
<td>Pfizer-BioNTech</td>
<td>≥18</td>
<td>Purple</td>
<td>30 µg</td>
<td>0.3 ml</td>
<td>2 (21 days)</td>
<td>1 (≥28 days)</td>
<td>≥ 6 months</td>
</tr>
<tr>
<td>Moderna</td>
<td>≥18</td>
<td>Not applicable</td>
<td>100 µg</td>
<td>0.5 ml</td>
<td>2 (28 days)</td>
<td>1 (≥28 days)</td>
<td>≥ 6 months</td>
</tr>
<tr>
<td>Janssen</td>
<td>≥18</td>
<td>Not applicable</td>
<td>5×10⁰³ viral particles</td>
<td>0.5 ml</td>
<td>1 (Not applicable)</td>
<td>Not applicable</td>
<td>≥ 2 months</td>
</tr>
</tbody>
</table>

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**Booster dose**

<table>
<thead>
<tr>
<th>Booster dose vaccine manufacturer</th>
<th>Age of recipient (years)</th>
<th>Vial cap color denoting formulation</th>
<th>Booster dose injection volume</th>
<th>Booster dose</th>
<th>Number of doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>≥18</td>
<td>Purple</td>
<td>30 µg</td>
<td>0.3 ml</td>
<td>1</td>
</tr>
<tr>
<td>Moderna</td>
<td>≥18</td>
<td>Not applicable</td>
<td>50 µg*</td>
<td>0.25 ml</td>
<td>1</td>
</tr>
<tr>
<td>Janssen</td>
<td>≥18</td>
<td>Not applicable</td>
<td>5×10⁰³ viral particles</td>
<td>0.5 ml</td>
<td>1</td>
</tr>
</tbody>
</table>
You are a Trusted Source

- When asked who they trust to provide reliable information about the COVID-19 vaccines, personal doctors, including pediatricians, top the list, with 83% of adults saying they trust their own doctor a great deal or a fair amount and 85% of parents saying the same about their child’s pediatrician.

- Seven in ten each say they trust the CDC (71%), the FDA (69%), and their local public health department (69%).
Call to Action

• Trusted health care providers are uniquely situated to vaccinate and discuss COVID-19 vaccination with patients and families.
• We ask that you communicate with your patients and parents about the importance of getting vaccinated.
• **Ways you can do your part:**
  – Enroll in the NYS COVID-19 Vaccination Program
  – Discuss and strongly recommend vaccination to your patients and family members who have not yet been vaccinated
  – Facilitate vaccination appointment scheduling, if you cannot administer the vaccine directly
Additional Doses and Boosters
Dr. Rausch-Phung
Definition: Additional Dose

- An additional dose of vaccine may be needed when the immune response following a primary (initial) vaccine series was likely too weak.
  - e.g., most healthy preteens only need 1 initial dose of meningococcal vaccine, but immunocompromised children and teens need several doses to develop an immune response.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-additional-dose
Definition: Booster Dose

- A **booster** dose of vaccine may be needed when the initial sufficient immune response to a primary vaccine series is likely to have decreased or worn off over time.
  - e.g., healthy preteens’ initial strong immune response to meningococcal vaccine wears off within 3-5 years, and so they need a booster dose at age 16 years

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-additional-dose
mRNA vaccine effectiveness (VE) studies among immunocompromised populations

- **VE: 7-27 days after 2nd dose of Pfizer-BioNTech vaccine**
  - 71% (CI 37-87%) among immunosuppressed* people vs. 90% (CI 83-96%) overall: SARS-CoV-2 infection
  - 75% (CI 44-88%) among immunosuppressed people vs. 94% (CI 87-97%) overall: symptomatic COVID-19

- **VE: ≥7 days after 2nd dose of mRNA vaccine**
  - 80% among people with inflammatory bowel disease on immunosuppressive meds: SARS-CoV-2 infection
  - VE of 25% was noted after 1st dose of mRNA vaccine for SARS-CoV-2 infection

- **VE: ≥14 days after 2nd dose of mRNA vaccine**
  - 59% (CI 12-81%) among immunocompromised people vs. 91% (CI 86-95%) without immunocompromise: COVID-19 hospitalization

*Immunocompromised conditions (e.g., recipients of hematopoietic cell or solid organs transplant, patients under immunosuppressive therapy, asplenia, and chronic renal failure: advanced kidney disease, dialysis, or nephrotic syndrome)

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Additional Dose for Immunocompromised

• An additional dose of an mRNA COVID-19 vaccine, at least 28 days after an initial 2-dose mRNA COVID-19 primary vaccine series should be considered for people with moderate to severe immune compromise*
• To the extent possible, the additional dose should be the same mRNA vaccine as the primary series
  o Alternate mRNA product can be used if primary series product not available
• These individuals may receive a booster dose (4th dose) 6 months following the additional dose
• Currently additional doses are not recommended for immunocompromised persons who received Janssen vaccine, however they are eligible for a booster dose, as described later in this presentation

*Defined on next slide
Moderate to Severe Immunocompromise

- Active cancer treatment
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Within 2 years of stem cell transplant or chimeric antigen receptor (CAR)-T-cell therapy
- Moderate or severe primary immunodeficiency
- Advanced or untreated HIV infection
- Active treatment with certain high dose medications that suppress or change the immune system
- An individual’s treating healthcare provider is the best judge of their degree of immunocompromise
Importance of Infection Prevention Measures

• People who are immunocompromised (including those who receive an additional mRNA COVID-19 vaccine dose) should be counseled about the potential for a reduced immune response to COVID-19 vaccines and the need to continue to follow current prevention measures (including wearing a mask, staying 6 feet apart from others they don’t live with, and avoiding crowds and poorly ventilated indoor spaces) until advised otherwise by their healthcare professional.

• Close contacts of immunocompromised people should also be strongly encouraged to be vaccinated against COVID-19 to protect these people.
Vaccine effectiveness against **infection** over time

Adults ≥18 years of age

[Rose...0-20-80-90-100
February March April May June July

Vaccine effectiveness against **hospitalization** by month
Adults ≥18 years of age

![Graph showing vaccine effectiveness against hospitalization by month](image)

- Tenforde, et al.*
- Rosenberg, et al.
- Puranik, et al. (Pfizer)
- Puranik, et al. (Moderna)
- Bajema et al.

* February estimates from platform’s May 2021 MMWR

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Current age-specific VE estimates for hospitalization

<table>
<thead>
<tr>
<th>Age Group</th>
<th>COVID-NET, April – August 2021&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Scobie et al., June – July 2021&lt;sup&gt;2&lt;/sup&gt;</th>
<th>VISION, June – August 2021&lt;sup&gt;3&lt;/sup&gt;</th>
<th>IVY Network, July – August 2021&lt;sup&gt;4&lt;/sup&gt;</th>
<th>Average VE for base case</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 – 29 years</td>
<td>94.7%</td>
<td>93%</td>
<td>85%</td>
<td>90%</td>
<td>90.7%</td>
</tr>
<tr>
<td>30 – 49 years</td>
<td>95.6%</td>
<td>93%</td>
<td>82%</td>
<td>90%</td>
<td>90.2%</td>
</tr>
<tr>
<td>50 – 64 years</td>
<td>95.5%</td>
<td>91%</td>
<td>84%</td>
<td>94%</td>
<td>91.1%</td>
</tr>
<tr>
<td>≥65 years</td>
<td>95.2%</td>
<td>87%</td>
<td>73%</td>
<td>85%</td>
<td>85.1%</td>
</tr>
</tbody>
</table>

VE = vaccine effectiveness;
<sup>1</sup>https://www.medrxiv.org/content/10.1101/2021.08.27.21262356v1
<sup>2</sup>https://www.cdc.gov/mmwr/volumes/70/rr/mm7037e1.htm?ss_digits_from_title
<sup>3</sup>https://www.cdc.gov/mmwr/volumes/70/rr/mm7037e2.htm. Using Pfizer specific estimate.
<sup>4</sup>https://www.cdc.gov/mmwr/volumes/70/rr/mm7034e2.htm
Recommendation: Booster Doses (1 of 3)

- People in one or more of the following groups **should** receive a booster dose of COVID-19 vaccine at least 6 months after their 2\textsuperscript{nd} dose of a primary series of mRNA COVID-19 vaccine (Pfizer or Moderna):
  - People aged 65 years or older
  - People aged 18 years or older in long-term care settings
  - People aged 50-64 years with underlying medical conditions*

- May receive any FDA-approved or –authorized COVID-19 vaccine for the booster

Recommendation: Booster Doses (2 of 3)

- People in one or more of the following groups may receive a booster dose of Pfizer-BioNTech or Moderna COVID-19 vaccine at least 6 months after their 2\textsuperscript{nd} dose of a primary series of an mRNA vaccine (Pfizer or Moderna), based on their individual benefits and risks:
  - People aged 18-49 years with underlying medical conditions*
  - People aged 18-64 years at increased risk of SARS-CoV-2 exposure and transmission because of occupational or institutional setting
- May receive any FDA-approved or –authorized COVID-19 vaccine for the booster

Recommendation: Booster Doses (3 of 3)

- People age ≥ 18 years who received a Janssen COVID-19 vaccine as the primary series should receive a booster dose at least 2 months after their Janssen primary dose.
- May receive any FDA-approved or -authorized COVID-19 vaccine for the booster.
  - People who developed thrombosis with thrombocytopenia syndrome (TTS) following a dose of Janssen COVID-19 vaccine should not receive a second dose of Janssen COVID-19 vaccine. These people may receive a booster dose of mRNA COVID-19 vaccine at least 2 months after the Janssen primary dose and after their clinical condition has stabilized.
## Dosing

### Primary series

<table>
<thead>
<tr>
<th>Vaccine manufacturer</th>
<th>Primary dose</th>
<th>Primary dose volume</th>
<th>Number doses/series</th>
<th>Interval between primary doses</th>
<th>Interval between primary and booster doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech</td>
<td>30 µg</td>
<td>0.3 ml</td>
<td>2</td>
<td>3 weeks (21 days)</td>
<td>≥ 6 months</td>
</tr>
<tr>
<td>Moderna</td>
<td>100 µg</td>
<td>0.5 ml</td>
<td>2</td>
<td>1 month (28 days)</td>
<td>≥ 6 months</td>
</tr>
<tr>
<td>Janssen</td>
<td>$5 \times 10^{10}$ viral particles</td>
<td>0.5 ml</td>
<td>1</td>
<td>Not Applicable</td>
<td>≥ 2 months</td>
</tr>
</tbody>
</table>

### Booster dose

<table>
<thead>
<tr>
<th>Vaccine manufacturer</th>
<th>Booster dose</th>
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<tr>
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<tr>
<td>Janssen</td>
<td>$5 \times 10^{10}$ viral particles</td>
<td>0.5 ml</td>
</tr>
</tbody>
</table>

Janssen Booster Safety

- No new safety signals identified during Phase 3 clinical trial
- Limited post-authorization safety data to date on persons who received 2 doses of Janssen vaccine
  - 39 adverse events reported to VAERS after 2 doses of Janssen vaccine; all were non-serious
- Limited safety data to date on individuals who received a mixed Janssen-mRNA COVID-19 vaccine study
- CDC will continue to monitor
ACIP
Recommendations: Children 5-11 years
Dr. Rausch-Phung
ACIP Recommendation (CDC Endorsed)

- A two-dose series of Pfizer-BioNTech COVID-19 vaccine (10 µg, 0.2 mL), separated by 21 days, is recommended for children 5-11 years of age, under the Emergency Use Authorization
<table>
<thead>
<tr>
<th></th>
<th>Formulation for ≥12-year-olds (purple cap)</th>
<th>Formulation for 5–11-year-olds (orange cap)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age group</td>
<td>12 years and older</td>
<td>5-11 years</td>
</tr>
<tr>
<td>Vial cap color</td>
<td>![Purple Cap Image]</td>
<td>![Orange Cap Image]</td>
</tr>
<tr>
<td>Dose (mRNA concentration)</td>
<td>30 ug</td>
<td>10 ug</td>
</tr>
<tr>
<td>Injection volume</td>
<td><strong>0.3 mL</strong></td>
<td><strong>0.2 mL</strong></td>
</tr>
<tr>
<td>Fill Volume (before dilution)</td>
<td>0.45 mL</td>
<td>1.3 mL</td>
</tr>
<tr>
<td>Amount of Diluent*</td>
<td><strong>1.8 mL</strong></td>
<td><strong>1.3 mL</strong></td>
</tr>
<tr>
<td>Needed per vial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doses per Vial</td>
<td><strong>6 (after dilution)</strong></td>
<td><strong>10 (after dilution)</strong></td>
</tr>
<tr>
<td>Number of doses</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Interval</td>
<td>3 weeks (21 days)</td>
<td>3 weeks (21 days)</td>
</tr>
<tr>
<td>Additional primary dose</td>
<td>Moderate and severe immunocompromise</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Booster dose</td>
<td>Not recommended 12–17 years</td>
<td>Not recommended</td>
</tr>
<tr>
<td></td>
<td>Recommended for certain groups ≥18 years*</td>
<td></td>
</tr>
</tbody>
</table>
Benefits: COVID-19 vaccine for ages 5-11

- Estimated vaccine efficacy 90.9% against symptomatic lab-confirmed COVID-19 (95% confidence interval 68.3% - 98.3%)
- Children 5-11 years of age are at risk of severe COVID-19, including multisystem inflammatory syndrome in children (MIS-C)
  - >8300 COVID-19 hospitalizations in this age group from March 2020 – mid-October 2021
  - Severity among children hospitalized with COVID-19 comparable to children hospitalized with influenza
  - MIS-C occurs most frequently in ages 5-11 years
  - Post-COVID conditions have been reported in children
  - COVID-19 is the 8th leading cause of death in this age group
- Secondary transmission from children in this age group occurs in household and school settings
  - Leads to missed school for themselves and classmates
### Other vaccine preventable diseases: Deaths per year prior to recommended vaccines

<table>
<thead>
<tr>
<th></th>
<th>Hepatitis A&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Meningococcal (ACWY)&lt;sup&gt;2&lt;/sup&gt;</th>
<th>Varicella&lt;sup&gt;3&lt;/sup&gt;</th>
<th>Rubella&lt;sup&gt;4&lt;/sup&gt;</th>
<th>Rotavirus&lt;sup&gt;5&lt;/sup&gt;</th>
<th>COVID-19</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>&lt;20 years</td>
<td>11–18 years</td>
<td>5–9 years</td>
<td>All ages</td>
<td>&lt;5 years</td>
<td>5–11 years</td>
</tr>
<tr>
<td><strong>Average deaths per year</strong></td>
<td>3</td>
<td>8</td>
<td>16</td>
<td>17</td>
<td>20</td>
<td>66</td>
</tr>
</tbody>
</table>


Risks: COVID-19 Vaccine for ages 5-11

- The most common adverse events were similar to or milder than those in adolescents and adults
  - Pain, swelling and redness at injection site, fever, fatigue, headache, chills, myalgia, arthralgia, lymphadenopathy
- Myocarditis and pericarditis
  - Has been reported following receipt of mRNA COVID-19 vaccine
  - Observed risk is highest following dose 2 and in males 12-29 years of age
  - The risk of myocarditis and pericarditis after receipt of an mRNA COVID-19 vaccine is lower than the risk associated with COVID-19
  - The baseline (pre-COVID-19) risk of myocarditis in age 5-11 years was lower than in adolescents 12-17 years
Clinical Considerations for ages 5-11

- Children should receive the age-appropriate dosing regardless of their weight
- Dosage should depend on the child’s age at the day of vaccination, for each dose
  - If a child is 11 at the time of dose 1 then turns 12 before dose 2, they should receive the pediatric dosage for dose 1 and adult dosage for dose 2
- COVID-19 vaccine may be administered at any time before, after or at the same visit as other vaccines
  - If given at the same visit as other vaccines, administer each vaccine in separate limbs if possible
  - If administering 2 vaccines in same limb, separate by at least 1 inch
Prior COVID-19 infection

- COVID-19 vaccination should be given regardless of history of prior COVID-19 infection
  - Vaccination should be deferred in people currently ill with COVID-19 until they have recovered and met criteria to end isolation
  - Clinical trials and the COVID-19 vaccine experience to date have demonstrated the safety of mRNA COVID-19 vaccines in people with a history of prior COVID-19 infection
  - Serologic testing for prior COVID-19 infection is not recommended prior to vaccination
  - At this time, there is no FDA-authorized or approved test that providers or the public can use to reliably determine whether a person is protected from COVID-19 infection
History of MIS-C

• The benefits of COVID-19 vaccination are likely to outweigh the potential and known risks for children and adolescents with a history of MIS-C who meet the following criteria
  o Clinical recovery has been achieved, including a return to normal cardiac function;
  o It has been ≥ 90 days since their diagnosis of MIS-C;
  o They are in an area of high or substantial community transmission of SARS-CoV-2, or otherwise have an increased risk for SARS-CoV-2 exposure and transmission;
  o Onset of MIS-C occurred before COVID-19 vaccination.

• In the rare event of MIS-C following COVID-19 vaccination, referral to a specialist should be considered, and report to VAERS at https://vaers.hhs.gov/reportevent.html
Administration Errors

- If a child age 5-11 years receives a 30 µg dose for their first dose, then they should receive a 10 µg dose for their second dose and then be considered fully vaccinated.
  - If they receive the 30 µg dose for their second dose, then they should be considered fully vaccinated.
- If an adolescent age 12-17 years receives a 10 µg dose for their first dose, then it will count toward their 2-dose schedule but they should receive the 30 µg dose for their second dose.
  - If they receive the 10 µg dose for their second dose, then in general it does not need to be repeated. However, based on clinical judgment (e.g., if an adolescent received 2 doses of incorrect formulation), an additional 30 µg dose can be given at an interval of 21 days after the dose given in error.
- If someone age ≥ 18 years receives a 10 µg dose, then the dose should be repeated immediately (no minimum interval) with a 30 µg dose. The 10 µg dose will not count toward their 2-dose schedule.
  - Due to the rare risk of myocarditis, males age < 30 may consider waiting 21 days following the erroneous dose before repeating it.
- Report administration errors to VAERS at [https://vaers.hhs.gov/reportevent.html](https://vaers.hhs.gov/reportevent.html)
Resources

• FDA EUA approval for 5-11 year olds
  https://www.fda.gov/media/153717/download

• Updated clinical considerations for vaccinating the 5-11 year olds
Vaccine Administration: Children 5-11 years
Dr. Cook

Materials by Tim Kuhmann, MSEd, RN-BC
Understanding School-Aged Kids (5-11)

• Learning rules for appropriate behavior and cooperation in social settings.
  – “Children want to be good.”
• Fears of body mutilation & pain.
• Like to talk about themselves and their personal interests.
• Praise and positive encouragement lead to a sense of competence.
• Failure leads to a sense of inferiority.
Blueprint For a Positive Vaccine Experience

• **Don’t call it a shot.**
  – Use ‘poke’ or ‘injection’ instead. Shot has negative connotations (gunshot).

• **Offer the child choices.** **Gives them some control over the situation.**
  – “Do you want to try to sit on your own or on someone’s lap”?
  – “Do you want to watch or look at something else”?
  – “Do you want me to count to 3, or should we count together”?
  – “Do you think you can hold your body still on your own or do you need help”? 
Blueprint For a Positive Vaccine Experience

• **Positioning.**
  – Never lay the child down. Their instinct is to sit back up which causes more difficulty. Have the child sit chest-to-chest or back-to-chest with parent/other staff member.

• **Distraction.**
  – If the child does not want to watch, block their view with I Spy book. Visual distraction reduces the brain's ability to process as much pain stimuli.

• **Never offer bribes.**
  – “If you sit still, I’ll get you a prize.” **This does not encourage coping** and negatively affects the child’s ability to cope in the future.

• **Never lie.**
  – If the child asks if it will hurt, you can say, “It does have a feeling, but the feeling goes away very quickly. Here’s what we can do to help with the feeling.”
Setting Up The Room For Success

Remember, the provider “runs” the room.

- Set up the patient & parent position of comfort how you want it!
  - You are the expert giving the injection, not the parent.

- Set equipment up for quick vaccine administration.
  - Lay equipment out for easy/quick access.
  - Set equipment up on administrators' dominant hand side.
  - Out-of-sight of patient.
  - Needle protective cap loose, alcohol swab, gauze, and band aid ready to apply.

- Focus child on planned distraction technique. Examples:
  - Looking at a book, phone.
  - Child “in charge” of counting, blowing out “birthday” candles, etc.
Patient Positions of Comfort

**Tips for injections:**
- Holder places child’s legs between theirs
- Inside arm tucked under parent’s armpit
- Arm closest to holder is wrapped around child’s body

Arms are held at shoulder and forearm/wrist, depending on location of injection

Holder’s hand restrains outside arm close to chest, positioned sideways on lap with child
Patient Positions of Comfort

Tips for injections:

- Holder holds patient’s arms tight under their arms.
- Injection is done on arm out of view of patient.
- Chest-to-chest can also be done from a standing position with an older-aged child.
After Vaccine Administration

✓ The goal is to build a positive experience for the child.
✓ The power of praise is an important step to end with.
  ✓ We want the child to know how great they did!
  ✓ Praise them for a good job holding still or being so great at helping you count.
  ✓ This is an experience the child will build on. Do all you can to make it a positive experience!
Side Effects and Co-administration

• On the arm where they received the shot:
  – Pain, Redness, Swelling

• Throughout the rest of their body:
  – Tiredness, Headache, Muscle pain, Chills, Fever, Nausea

• COVID-19 vaccines may be administered without regard to timing of other vaccines including simultaneous administration of COVID-19 vaccine and other vaccines on the same day.

• If co-administering vaccines like the flu shot or regular childhood immunizations administer each injection in a different injection site

• For people ≥11 years, the deltoid muscle can be used for more than one intramuscular injection administered at different sites in the muscle

• For children (5–10 years), if more than 2 vaccines are injected in a single limb, the vastus lateralis muscle of the anterolateral thigh is the preferred site because of greater muscle mass.
Video Reference

- **Comfort Position** (https://www.youtube.com/watch?v=r1dGpTCgerE)
  Start at the 2:27 minute mark for techniques specific to the 5-11 year old group.

- “Comfort and Restraint Techniques”

- “Intramuscular (IM) Injection: Supplies (Children Birth Through 18 years of Age)”

- “Intramuscular (IM) Injection: Sites”

Special thanks to Tim Kuhmann, MSEd, RN-BC
Vaccination Administration

Note: The ancillary supplies include 1" needles.

https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html
COVID Vaccine Operations – Key Points
Robin Suitor
COVID-19 Vaccination Program Enrollment

• Locations in New York State outside of the 5 New York City boroughs enroll in the NYS COVID-19 Vaccination Program via an application tool in the Health Commerce System (HCS).

• Requests for vaccine and reporting of doses administered is done through the New York State Immunization Information System (NYSIIS).

• New York City locations enroll via the New York City Department of Health and Mental Hygiene’s Citywide Immunization Registry (CIR).
Enrollment Process For Locations Outside NYC

**Step 1:** Complete the online COVID-19 Vaccine Program Provider Enrollment application located in the Health Commerce System (HCS). There are a set of resource documents to assist you.

The application includes two sections:
- Section A: Provider Requirements and Legal Agreement specifies the conditions of participation and must be filled out for the organization (i.e., network, health system, or medical group).
- Section B: Program Provider Profile Form must be filled out for every vaccination provider location receiving and administering COVID-19 vaccine.

**Step 2:** Ensure the appropriate individuals have access to the New York State Immunization Information System (NYSIIS). New users must complete two NYSIIS Trainings in order to obtain NYSIIS accounts.
- Standard User Training, approximately 45 minutes
- Administrative User Training, approximately 20 minutes

NYSIIS is used to submit requests for vaccine, manage vaccine inventory and report doses administered.

**Step 3:** Sign and return a “Memorandum of Understanding (MOU) for the COVID-19 Vaccination Program” to demonstrate commitment to complying with New York State’s directives regarding the COVID-19 Vaccination Program. The MOU will be emailed to you after you submit an application in the HCS. The MOU is required in addition to the online enrollment application.
Enrollment Process For Locations In NYC

Step 1: Register your facility in the CIR to obtain a CIR facility code. Go to the online registration page to register your facility for the first time or to update an existing registration if your facility has not reported to the CIR in over a year. You will need the National Provider Identifier (NPI) number and NYS medical license number of the provider-in-charge to complete the registration.

Step 2: Create a CIR Online Registry (OR) account. To do so, you must complete the two forms listed below, then scan and email them to cir-reset@health.nyc.gov.
- Security Administrator (User Manager) Confidentiality Statement for Online Access and Acceptable Use Protocol (PDF)
- Security Administrator (User Manager) User ID/Password Request Form (Facilities) (PDF)

Step 3: After you have a facility code and OR account set up, you will be able to access the Vaccination Provider Agreement System (VPAS) from inside the OR. Paper forms are not accepted. NYC is accepting only online enrollments. This agreement is for enrollment in the COVID-19 Vaccination Program; it is not a vaccine order.

Once your VPAS agreement has been approved, you will be notified to order vaccine. Please be sure to complete both Parts A and B in VPAS. Part B will appear as a link in the upper left of the screen after completing Part A. Instructions are attached. For assistance with VPAS, email nycimmunize@health.nyc.gov.

For full instructions, please visit:
COVID-19 Vaccine Ordering

• Providers enrolled in New York State (outside New York City) place orders in NYSIIS (NYC providers order through CIR following NYCDOHMH instructions)
  – COVID-19 vaccine orders should always be placed separately from Vaccines for Children (VFC), Vaccines for Adults (VFA) and flu orders
  – Can be placed any day of the week
  – There is no limit to frequency of COVID-19 vaccine orders. NYSDOH recommends ordering enough doses for a 3-week supply (considering administration and current inventory) to reduce the risk of wastage due to expiration
  – Orders that are approved in NYSIIS ship from Pfizer or McKesson (Moderna and J&J vaccine) and typically deliver within 2-5 business days. Shipment notification emails are sent from Pfizer or McKesson to the primary vaccine coordinator.
Redistribution

• Currently, the minimum order size and increment for Pfizer Pediatric COVID-19 Vaccine is 300 doses but this expected to go down to 100 doses (1 carton of 10 multidose vials, 10 doses per vial) on or about Nov. 9th.

• Practices needing less than the minimum order size can partner with other local COVID enrolled providers (LHD, hospital, other large community practices, etc.) to obtain smaller quantities through redistribution.

• Practices without a redistribution partner can ADD A NOTE to their NYSIIS order and the ordering team will contact you to facilitate a redistribution option.
Responsible Wastage

- Providers should “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.
  - Pediatric Pfizer COVID-19 vaccine comes in a 10-dose multi-dose vial
  - Once a vial is diluted it must be used within 12 hours per the EUA. Any doses not administered within that time period must be reported as Wastage (see Wastage Reporting Guidance).
  - While enrolled providers must continue to follow 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.
Pediatric Pfizer-BioNTech COVID-19 Vaccine Shipments

• Cartons of Pediatric Pfizer-BioNTech COVID-19 Vaccine (orange caps and labels with orange borders) ship in a single-use thermal shipping container with dry ice along with a Controlant DDL (temperature monitoring device). The product is intended to arrive frozen at ultra-cold conditions.

• Evaluate the condition of the product (Is it frozen solid? Has it thawed?) and check the temperature data recorded by the DDL (via a website noted in the shipment email).

• Pediatric thermal shippers cannot be used for temporary or long-term storage (including transport). The Controlant DDL must be turned off upon receipt and returned in the box provided.
Pediatric Pfizer-BioNTech COVID-19 Vaccine
Storage after Shipment Arrival

• If vials are received ultra-frozen vaccine can be stored:
  – In an ultra-low temperature freezer at -90°C to -60°C (-130°F to -76°F) for up to 6 months; or
  – In a refrigerator [2°C to 8°C (35°F to 46°F)], thawed and stored for up to 10 weeks. The 10-week beyond use date should be recorded on the carton at the time of transfer.
  – If vials are received thawed, they must be stored at 2°C to 8°C. Update the carton to reflect the 10-week refrigerated expiry date. Once vials are thawed, they CANNOT be refrozen.

• Do not store vials at standard freezer temperatures -25°C to -15°C (-13°F to 5°F)

• Regardless of storage condition, vaccines should not be used after 6 months from the date of manufacture printed on the vial and cartons. (Note: The expiration date is NOT printed on the vial and cartons.)
## COVID-19 Vaccine Storage

<table>
<thead>
<tr>
<th>Storage conditions</th>
<th>Formulation for ≥12-year-olds (purple cap)</th>
<th>Formulation for 5–11-year-olds (orange cap)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultralow temperature freezer (-90°C to -60°C)</td>
<td>9 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Freezer (-25°C to -15°C)</td>
<td>2 weeks</td>
<td>N/A</td>
</tr>
<tr>
<td>Refrigerator (2°C to 8°C)</td>
<td>1 month</td>
<td>10 weeks</td>
</tr>
</tbody>
</table>

[https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf](https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf)
Pediatric Pfizer-BioNTech COVID-19 Vaccine
Vial Storage During Use

• If not previously thawed at 2°C to 8°C (35°F to 46°F), allow vials to thaw at room temperature [up to 25°C (77°F)] for 30 minutes.

• Pediatric Pfizer-BioNTech COVID-19 Vaccine may be stored at 8°C to 25°C (46°F to 77°F) for a total of 12 hours prior to dilution.

• After dilution, the vial should be held between 2°C to 25°C (35°F to 77°F). Vials should be discarded 12 hours after dilution.

• 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.
Beyond Use Dates (BUD)

• Definition: The date or time after which a vaccine should not be administered, stored, or transported.

• If the vaccine has no BUD, use the expiration date provided by the manufacturer. BUD may shorten an expiration date, never extend it.

• If the BUD is less than the expiration date, it should be noted on the label along with the initials of the person making the calculation.

• Examples of conditions that change the BUD:
  – Time a vaccine is mixed with a diluent
  – Time a multidose vial (MDV) has been punctured
  – Limited storage conditions (i.e., time in freezer or refrigerator)

• Expiration dates and beyond use dates may change as additional stability data becomes available
Temperature Excursions

• Any time outside of recommended storage and handling conditions is considered a temperature excursion
• Label vaccines DO NOT USE and call manufacturer for determination on viability
• All excursions must be reported on the New York State COVID-19 Vaccination Program Temperature Excursion Report and submitted to vaccinetempexcursion@health.ny.gov
  – Send data logs with tables and graphs with the Excursion Report
COVID-19 Vaccine Storage and Handling Resources

**Pfizer Age 12+ vaccine**
Excursion contact: 800-438-1985

**Moderna**
Excursion contact: 866-MODERNA or [excursions@modernatx.com](mailto:excursions@modernatx.com);
Excursion web tool: [https://tools.modernamedinfo.com/excursion/](https://tools.modernamedinfo.com/excursion/)

**Janssen**

**COVID-19 Vaccine Transport Guidance and Tracking Sheet:**

*Excursion web tools are for single excursions only. Must call for any subsequent excursions.*
Reporting

• Entering vaccination data into NYSIIS or CIR (NYC) in an accurate and timely fashion is critical and required per the Provider Agreement.
• Providers are responsible for fixing any data entry errors identified.
• The Excelsior Pass verifies requests for passes against information entered into NYSIIS and CIR.
  – If data entered into NYSIIS or CIR is incorrect or incomplete – because identity cannot be confirmed, fields are missing, or dates do not show they are fully vaccinated – the person cannot get a pass.

• The New York State Vaccine Form collects demographic information.
  
  It is mandatory for all individuals receiving COVID-19 vaccine.
Additional Resources
Loretta (Lora) Santilli
Public Education (links to many educational resources)

Dedicated communications effort to promote vaccine confidence and quickly address misinformation that may spread on social media and in other media forms.

Frequently Asked Questions - Answers to common questions about the COVID-19 vaccine.

Get the Vax Facts - Campaign to counter misinformation and disinformation with downloadable toolkits.
To schedule an appointment

• CDC Vaccine Finder  
  [Vaccines.gov](https://vaccines.gov)

Search Tool for determining vaccine provider locations by ZIP and type of vaccine
New York State Resources

• For FAQs, NYS Vaccine Tracker, and more information:
  – Covid19Vaccine.health.ny.gov

• For all New York State guidance regarding COVID-19 vaccination:

• New York State COVID-19 Vaccine Hotline
  – 1-833-NYS-4-VAX (1-833-697-4829)
  – The COVID-19 Vaccine Hotline is open 7AM – 10PM, 7 days/week
Resources for kids

• General resources for kids and COVID

• Explaining covid to kids
  https://news.umich.edu/new-video-website-explain-coronavirus-for-kids/

• UNICEF video on talking to kids about the COVID vaccine

• From Boston’s Children’s Hospital
  https://www.youtube.com/watch?v=p7fDNWwWyBE
Resources for addressing vaccine hesitancy relating to pregnancy and/or fertility

- Preliminary Findings of mRNA COVID-19 Vaccine Safety in Pregnant Persons

- COVID Vaccine Hesitancy: Boston Doctors Address Concerns Around Fertility, Pregnancy

- CDC: Information about COVID-19 Vaccines for People who are Pregnant or Breastfeeding

- CDC: COVID-19 Factsheet | Pregnancy
Resources for addressing vaccine hesitancy

• COVID-19 Vaccine Recipient Education (CDC)
  – https://www.cdc.gov/vaccines/covid-19/hcp/index.html

• From Concern to Confidence: How physicians can build trust in COVID-19 vaccines (De Beaumont Foundation)

• Webinar: Successful COVID-19 Messaging in Rural Communities (Public Health Communications Collaborative)

• An Uncertain Public – Encouraging Acceptance of COVID-19 Vaccines (NEJM Perspective)
Resources for addressing vaccine hesitancy (continued)

- Physicians will play key role building trust in COVID-19 vaccine (American Medical Association)
  https://www.ama-assn.org/about/leadership/physicians-will-play-key-role-building-trust-covid-19-vaccine

- COVID-19 vaccine hesitancy: 10 tips for talking with patients (American Medical Association)

- Vaccine Hesitancy: An Evolving Public Health Threat (Commissioner’s Medical Grand Rounds: June 13, 2019)
  https://www.health.ny.gov/commissioner/grand_rounds/vaccine_hesitancy/

- Kaiser Family Foundation Vaccine Monitoring Dashboard:
Questions and Answers

Covid19Vaccine@health.ny.gov