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)



Opening Remarks Dr. Zucker



COVID-19 and Vaccine General Information Dr. Lutterloh



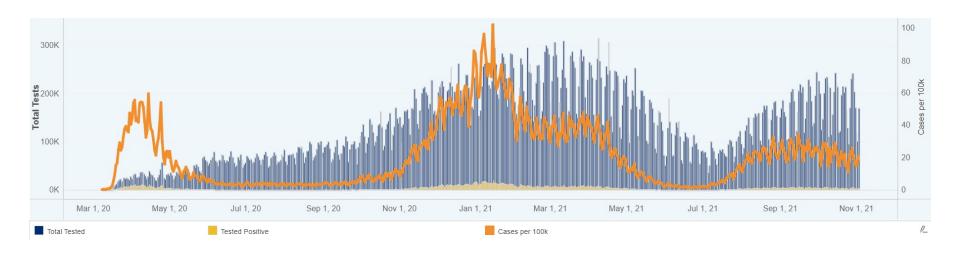
Updates

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

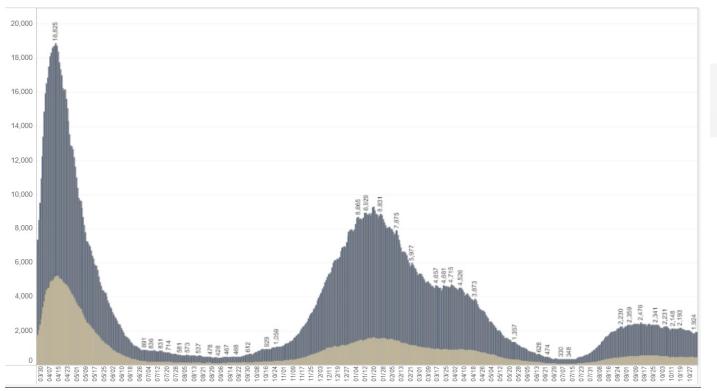


New York State Cases and Testing Timeline





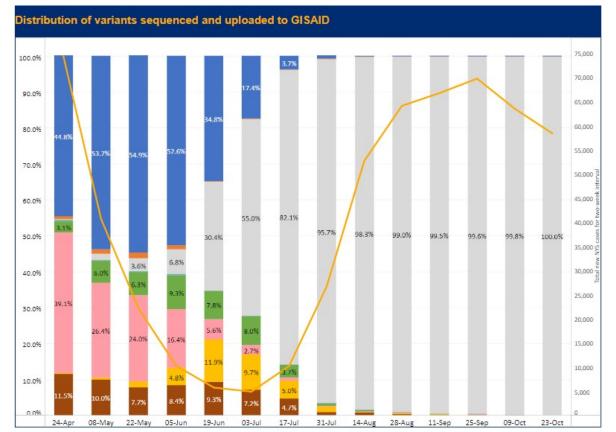
Hospitalizations

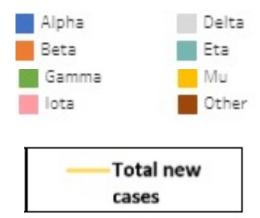


■ Total COVID-19 Patients Hospitalized

Total COVID-19 Patients in ICU

Variants

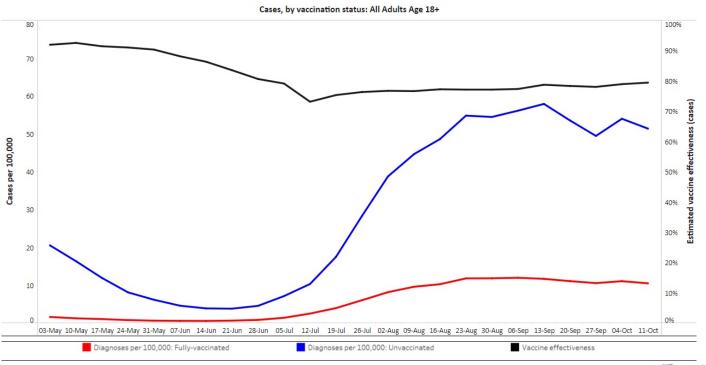






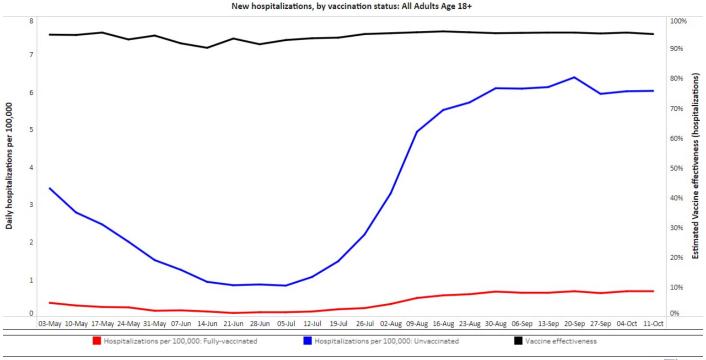
Collection date, two weeks ending

Cases and Vaccine Status





Hospitalization and Vaccine Status





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)



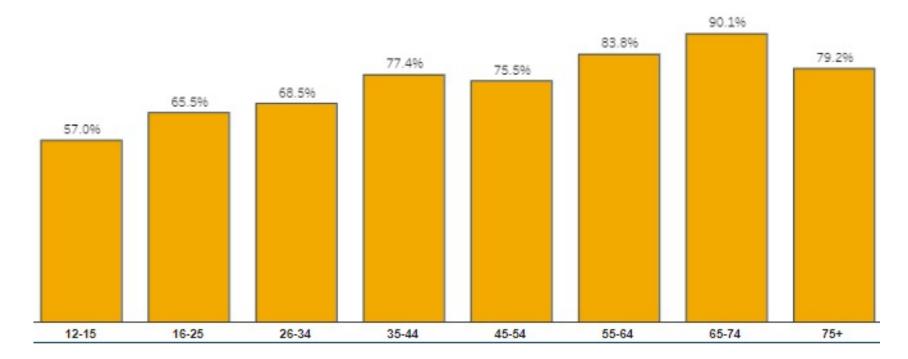
COVID-19 Vaccination Program

- 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

Primary series

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

Booster dose

Booster dose vaccine manufacturer	Age of recipient (years)	Vial cap color denoting formulation	Booster dose	Booster dose injection volume	Number of doses
Pfizer-BioNTech	≥18	Purple	30 µg	0.3 ml	1
Moderna	≥18	Not applicable	50 μg*	0.25 ml	1
Janssen	≥18	Not applicable	5×10 ¹⁰ viral particles	0.5 ml	1

Additional primary dose

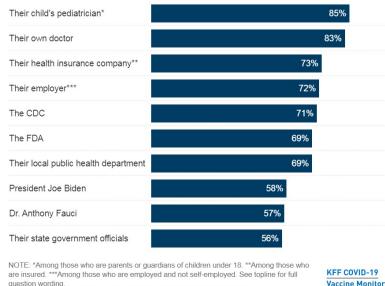
Moderately and severely immunocompromised persons aged ≥12 years (Pfizer-BioNTech recipients) or ≥18 years (Moderna recipients) should receive an additional primary dose of the same mRNA COVID-19 vaccine administered for the primary series, as follows:

- •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. Department of Health

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%)

Percent who say they have a great deal or a fair amount of trust in each of the following to provide reliable information about the COVID-19 vaccines:



SOURCE: KFF COVID-19 Vaccine Monitor (June 8-21, 2021) • Download PNG



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 <u>additional</u> 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 <u>booster</u> 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 vaccine¹
 - 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 vaccine²
 - 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 vaccine³
 - 59% (CI 12-81%) among immunocompromised people vs. 91% (CI 86-95%) without immunocompromise: COVID-19 hospitalization³

^{*}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)

^{1.} Chodick et al. Clinical Infectious Diseases, ciab438, https://doi.org/10.1093/cid/ciab438; 2. Khan et al. Gastroenterology (2021). https://www.gastrojournal.org/article/S0016-5085(21)03066-3/pdf; 3. Tenforde et al. medRxiv preprint: https://doi.org/10.1101/2021.07.08.21259776

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
 - 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

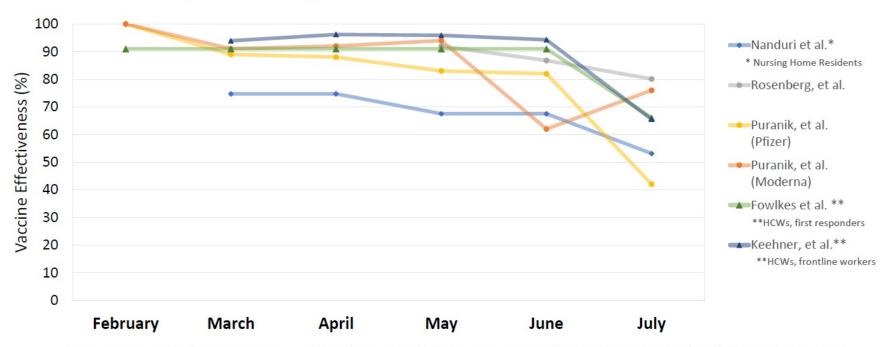


Importance of Infection Prevention Measures

- 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 <u>infection</u> over time Adults ≥18 years of age



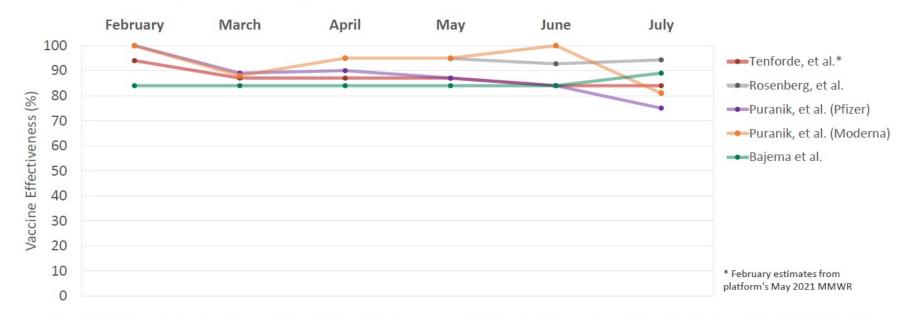
Rosenberg ES, Holtgrave DR, Dorabawila V, et al. New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3—July 25, 2021. MMWR Morb Mortal Wkly Rep. ePub: 18 August 2021.

Nanduri S. Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — National Healthcare Safety Network, March 1—August 1, 2021. MMWR Morbidity and Mortality Weekly Report. 2021 2021;70.

Fowlkes A, Gaglani M, Groover K, et al. Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020—August 2021. MMWR Morb Mortal Wkly Rep. ePub: 24 August 2021.

Puranik A, Lenehan PJ, Silvert E, et al. Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence. medRxiv 2021.08.06.21261707. Keehner J, Horton LE, Binkin NJ et al. Resurgence of SARS-CoV-2 Infection in a Highly Vaccinated Health System Workforce. NEJM, September 1, 2021. DOI: 10.1056/NEJMc2112981

Vaccine effectiveness against <u>hospitalization</u> by month Adults ≥18 years of age



Tenforde MW, Self WH, Naioti EA, et al. Sustained Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Associated Hospitalizations Among Adults — United States, March—July 2021. MMWR Morb Mortal Wkly Rep. ePub: 18 August 2021.

Tenforde MW, Olson SM, Self WH, et al. Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Among Hospitalized Adults Aged ≥65 Years — United States, January—March 2021. MMWR Morb Mortal Wkly Rep 2021;70:674–679.

Rosenberg ES, Holtgrave DR, Dorabawila V, et al. New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3-July 25, 2021. MMWR Morb Mortal Wkly Rep. ePub: 18 August 2021. Puranik A, Lenehan PJ, Silvert E, et al. Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence, medRxiv 2021.08.06.21261707.

Bajema KL, Dahl RM, Prill MM, et al. Effectiveness of COVID-19 mRNA Vaccines Against COVID-19—Associated Hospitalization — Five Veterans Affairs Medical Centers, United States, February 1—August 6, 2021. MMWR Morb Mortal Wkly Rep.

Current age-specific VE estimates for hospitalization

	VE for hospitalization					
Age Group	COVID-NET, April – August 2021 ¹	Scobie <i>et al.,</i> June – July 2021 ²	VISION, June – August 2021 ³	IVY Network, July – August 2021 ⁴	Average VE for base case	
18 – 29 years	94.7%	93%	85%	00%	90.7%	
30 – 49 years	95.6%	93%	82%	90%	90.2%	
50 – 64 years	95.5%	91%	84%	94%	91.1%	
≥65 years	95.2%	87%	73%	85%	85.1%	

VE = vaccine effectiveness;

¹https://www.medrxiv.org/content/10.1101/2021.08.27.21262356v1

²https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm?s_cid=mm7037e1_w

³https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e2.htm. Using Pfizer specific estimate.

⁴https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e2.htm

Recommendation: Booster Doses (1 of 3)

- People in one or more of the following groups <u>should</u> receive a booster dose of COVID-19 vaccine at least 6 months after their 2nd 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 <u>may</u> receive a booster dose of Pfizer-BioNTech or Moderna COVID-19 vaccine at least 6 months after their 2nd dose of a primary series of an mRNA vaccine (Pfizer or Moderna), <u>based on their individual benefits and risks:</u>
 - 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 <u>should</u> 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.

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Vaccine manufacturer	Primary dose	Primary dose volume	Number doses/series	Interval between primary doses	Interval between primary and booster doses	https://www.cdc.gov/vaccines/covid-19/clinical-
Pfizer-	30 µg	0.3 ml	2	3 weeks (21	≥ 6 months	considerations/covid-19-

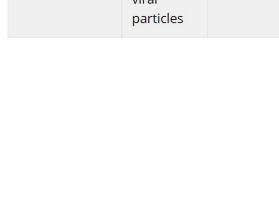
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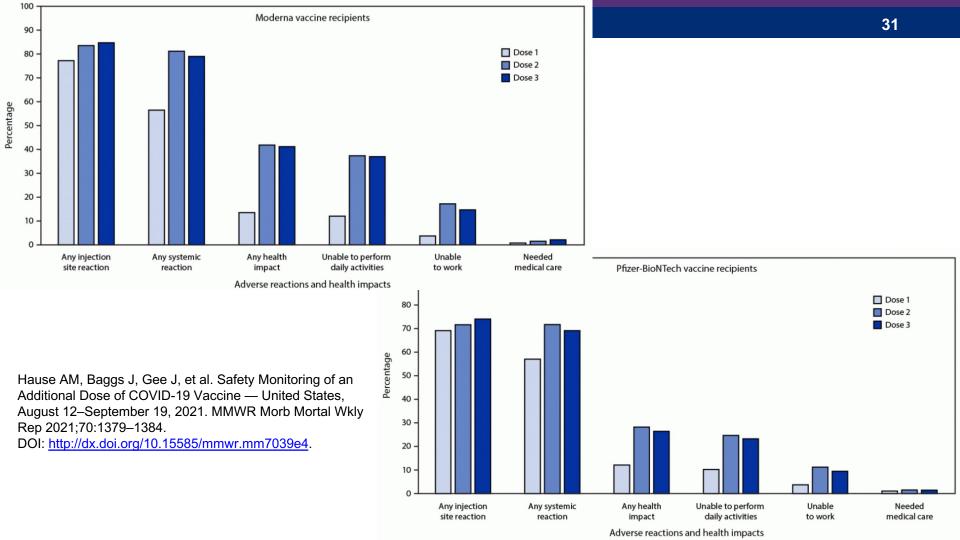
BioNTech days) <u>schedule</u> Moderna 100 µg 0.5 ml 2 1 month (28 ≥ 6 months days)

considerations/covid-19vaccines-us.html#dosing-5×10¹⁰ 0.5 ml Not Applicable ≥ 2 months Janssen viral

particles Vaccine manufacturer **Booster dose Booster volume** Pfizer-BioNTech 30 µg 0.3 ml 0.25 ml Moderna 50 µg 5×10¹⁰ viral particles 0.5 ml

Janssen





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



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

	Hepatitis A ¹	Meningococcal (ACWY) ²	Varicella ³	Rubella ⁴	Rotavirus ⁵	COVID-19
Age	<20 years	11–18 years	5–9 years	All ages	<5 years	5–11 years
Time period	1990–1995	2000–2004	1990–1994	1966–1968	1985–1991	Oct 2020– Oct 2021
Average deaths per year	3	8	16	17	20	66

¹Vogt TM, Wise ME, Bell BP, Finelli L. Declining hepatitis A mortality in the United States during the era of hepatitis A vaccination. J Infect Dis2008; 197:1282–8.

²National Notifiable Diseases Surveillance System with additional serogroup and outcome data from Enhanced Meningococcal Disease Surveillance for 2015-2019.

³Meyer PA, Seward JF, Jumaan AO, Wharton M. Varicella mortality: trends before vaccine licensure in the United States, 1970-1994. J Infect Dis. 2000;182(2):383-390. doi:10.1086/315714

⁴Roush SW, Murphy TV; Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States. JAMA2007; 298:2155-63.

⁵ Glass RI, Kilgore PE, Holman RC, et al. The epidemiology of rotavirus diarrhea in the United States: surveillance and estimates of disease burden. J Infect Dis. 1996 Sep;174 Suppl 1:S5-11.

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 <u>currently</u> 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 <u>not</u> 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
 - Clinical recovery has been achieved, including a return to normal cardiac function;
 - It has been ≥ 90 days since their diagnosis of MIS-C;
 - 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;
 - 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.
 - o 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



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

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html



Vaccine Administration: Children 5-11 years Dr. Cook





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"

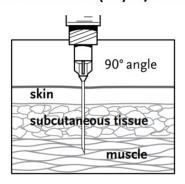
Special thanks to Tim Kuhmann, MSEd, RN-BC





Vaccination Administration

Intramuscular (IM) injection



Age	Needle length	Injection site	
	5/8-1"1	Deltoid muscle of arm (preferred)	
3-10 years	1-1¼"	Vastus lateralis muscle of anterolateral thigh (alternative	
	5/s-1"¹	Deltoid muscle of arm (preferred)	
11-18 years	1-1½"	Vastus lateralis muscle of anterolateral thigh (alternative	

Note: The ancillary supplies include 1" needles.

https://www.immunize.org/catg.d/p3085.pdf

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 <u>resource documents</u> 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 <a href="https://www.nysiis.

- 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 applied to you after you submit an application in the HCS.

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 <u>online registration page</u> 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:

https://www1.nyc.gov/assets/doh/downloads/pdf/covid/providers/covid-19-vaccine-enroll-order-report.pdf NEW YORK PARTY OF THE PARTY OF T

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.

NEW YORK Department of Health

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.
- <u>Do not</u> 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
 <u>manufacture</u> printed on the vial and cartons. (Note: The <u>expiration</u> date is NOT printed on the
 vial and cartons.)

COVID-19 Vaccine Storage

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

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 <u>New York State COVID-19</u>
 <u>Vaccination Program Temperature Excursion Report</u> and submitted to <u>vaccinetempexcursion@health.ny.gov</u>
 - Send data logs with tables and graphs with the Excursion Report



COVID-19 Vaccine Storage and Handling Resources

Pfizer Age 12+ vaccine

Storage summary: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf

BUD labels: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/bud-tracking-labels.pdf

Excursion contact: 800-438-1985

Moderna

Storage summary: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/storage-summary.pdf

BUD labels: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/bud-tracking-labels.pdf

Excursion contact: 866-MODERNA or excursions@modernatx.com; Excursion web tool: https://tools.modernamedinfo.com/excursion/

<u>Janssen</u>

Storage summary: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/storage-summary.pdf

Excursion contact: 800-JANSSEN; Excursion web tool: https://www.janssenmd.com/janssen-covid19-vaccine/interactive-

content/stability-information

COVID-19 Vaccine Transport Guidance and Tracking Sheet:

https://coronavirus.health.ny.gov/system/files/documents/2021/05/covid-19-vaccine-transport-guidance-and-tracking-sheet_052621.pdf



^{*}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

<u>Frequently Asked Questions</u> - Answers to common questions about the COVID-19 vaccine.

Get the Vax Facts - Campaign to counter misinformation and disinformation with downloadable toolkits

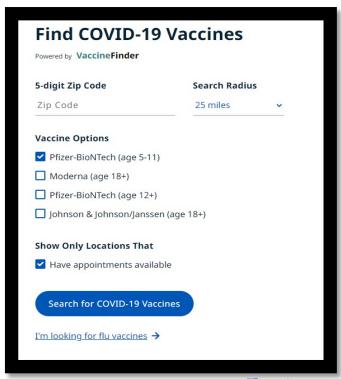


To schedule an appointment

CDC Vaccine Finder

Vaccines.gov

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:
 - https://coronavirus.health.ny.gov/covid-19-vaccine-information-providers
- 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
 https://www.kidshealth.org.nz/resources-help-explain-covid-19-children
- 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 https://www.unicef.org/coronavirus/how-to-talk-to-children-covid-vaccines
- 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
 https://www.nejm.org/doi/full/10.1056/NEJMoa2104983?query=featured_home
- COVID Vaccine Hesitancy: Boston Doctors Address Concerns Around Fertility, Pregnancy

https://www.nbcboston.com/news/local/covid-vaccine-hesitancy-boston-doctors-address-concerns-around-fertility-pregnancy/2330291/

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

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html

 CDC: COVID-19 Factsheet | Pregnancy https://www.cdc.gov/coronavirus/2019-ncov/downloads/communication/COVID-19 Pregnancy.pdf



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)
 - https://debeaumont.org/wp-content/uploads/2021/04/doctors-vaccines.pdf
- Webinar: Successful COVID-19 Messaging in Rural Communities (Public Health Communications Collaborative)
 - https://publichealthcollaborative.org/resources/webinar-successful-covid-19-messaging-in-rural-communities/
- An Uncertain Public Encouraging Acceptance of COVID-19 Vaccines (NEJM Perspective)
 - https://www.nejm.org/doi/full/10.1056/NEJMp2100351



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)
 https://www.ama-assn.org/delivering-care/public-health/covid-19-vaccine-hesitancy-10-tips-talking-patients
- 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:
 https://www.kff.org/coronavirus-covid-19/dashboard/kff-covid-19-vaccine-monitor-dashboard/



Questions and Answers

Covid19Vaccine@health.ny.gov

