

NV COVID-19 PLAYBOOK BRIEF: Vaccinating Children ages 5-11 years

Nevada's COVID-19 Vaccination Playbook Brief is being updated to incorporate recommendations regarding authorization of the Pfizer-BioNTech 10mcg COVID-19 vaccine for children ages 5-11 years. This Playbook Brief is designed to inform parents, health care providers, community partners, and all Nevadans about implementation of childhood (e.g., 5-11 years) COVID-19 vaccines in Nevada and the key differences between the adult/adolescent rollout and this rollout for younger ages. This guidance will include details about the authorization and recommendations for the Pfizer-BioNTech 10mcg COVID-19 vaccine and will be updated if other manufacturers receive authorization for COVID-19 vaccines for children.

Background

On November 2, 2021, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) <u>recommended</u> use of the Pfizer-BioNTech 10mcg COVID-19 vaccine in children ages 5-11 years in the United States. This comes after the <u>U.S. Food and Drug Administration</u> (FDA) expanded its Emergency Use Authorization (EUA) for the Pfizer-BioNTech 10mcg COVID-19 vaccine to include this age group on Friday, October 29, 2021. Previously the Pfizer vaccine was authorized for those ages 12 years and older in a higher dosage.

Additionally, the American Academy of Pediatrics (AAP) issued a <u>policy statement</u> recommending COVID-19 vaccination for "all children and adolescents 5 years of age and older who do not have contraindications using a COVID-19 vaccine authorized for use for their age," including children with previous COVID-19 infection and those with underlying health conditions. The AAP's statement, coupled with the recommendations from CDC, support administration of the Pfizer-BioNTech 10mcg two-dose series in children ages 5-11 years.

The AAP and CDC also support coadministration of routine childhood immunizations, including seasonal influenza vaccine, with the COVID-19 vaccine to help children catch up on any missed vaccinations (based on the CDC/AAP Recommended Child and Adolescent Immunization Schedule) caused by the ongoing pandemic. The Nevada State Immunization Program encourages all vaccinating providers to use patient visits as an opportunity to promote and provide all vaccines and not miss an opportunity to protect children from all vaccine-preventable diseases.

Why Vaccinate Children Against COVID-19?

With the recent increase in childhood COVID-19 incidence and hospitalizations and the risk of serious but rare complications such as <u>multisystem inflammatory syndrome in children (MIS-C)</u>, vaccination is the best route to protect children from COVID-19. All age groups can transmit COVID-19 and vaccinating children helps protect vulnerable family members including siblings too young to get the COVID-19 vaccine and the community at large, as well as prevent COVID-19 spread in children, including children and youth with special health care needs. Vaccination will help children safely engage in group activities which support needed socialization to enhance resilience and mental health.

Where can I find a Pfizer-BioNTech Childhood COVID-19 Vaccine?

There are approximately 277,000 children ages 5-11 years in Nevada, and the federal government has procured enough of the Pfizer-BioNTech childhood vaccine product to serve 28 million children in the United States.

Nevada received an initial allocation of 95,100 doses of the Pfizer-BioNTech 10mcg COVID-19 vaccine which will allow approximately one-third of children ages 5-11 years in the state to receive one dose. Incoming supply allocations are expected to be sufficient to ensure children can receive their second dose three weeks later and that unvaccinated children can continuously receive primary doses.

To offer COVID-19 vaccines to Nevadans, providers must be enrolled with the Nevada State Immunization Program. All interested providers are encouraged to click <u>here</u> to begin the enrollment process.

Currently, more than 230 providers across Nevada are enrolled to receive COVID-19 vaccines and can vaccinate children ages 5 years and older. Additionally, many pharmacies and Federally Qualified Health Centers are receiving direct allocations from the CDC to locations across the state.

Parents and caregivers can call 1-800-401-0946 to speak with a call center representative (English/Spanish) who can help locate and schedule COVID-19 vaccine appointments for children ages 5-11 years or visit <u>NVCOVIDFighter.org</u>. Additionally, please visit the local health district websites in <u>Carson City</u>, <u>Clark</u> and <u>Washoe Counties</u> for scheduling availability and help finding other providers who vaccinate children, if needed.

Dosing for the Pfizer-BioNTech Childhood COVID-19 Vaccine

	Formulation for ≥12-year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)
Number of doses	2	2
Interval	3 weeks (21 days)	3 weeks (21 days)
Additional primary dose	Moderate and severe immunocompromise	Not recommended
Booster dose	Not recommended 12–17 years	Not recommended
	Recommended for certain groups ≥18 years*	

- 2 10mcg doses each (0.2mL), administered intramuscularly, 21 days apart.
- Formulations of the adult/adolescent and childhood Pfizer-BioNTech COVID-19 vaccines are NOT interchangeable.
 - If a child ages 5-11 years inadvertently receives 30mcg for their first dose, then they should receive a single age-appropriate 10mcg dose for their second dose 21 days later and should be considered as having completed a primary series.
 - If a child ages 5-11 years inadvertently receives 30mcg for their second dose, then they should be considered as having completed a primary series.
- The dose a child receives should be based on the child's age on the day of vaccination, regardless of their size or weight (i.e., a child on their 12th birthday would receive the adult dosage of the Pfizer-BioNTech COVID-19 vaccine).
 - If a child turns from age 11 to age 12 years in-between their first and second dose and receives the childhood (10mcg) formulation for their second dose, then they do not need to repeat the dose, and this is not considered an administration error per the FDA EUA.
- Serologic testing to assess for prior infection is not recommended for the purpose of vaccine decision-making.
- Children with known current COVID-19 infection should defer vaccination at least until they have recovered from acute illness (if symptomatic) AND they have met the criteria to discontinue isolation.
 - Isolation can typically be discontinued 10 days after a positive test if asymptomatic or 10 days after symptom onset, and after resolution of fever for at least 24 hours.

Coadministration of the Pfizer-BioNTech Childhood COVID-19 Vaccine

COVID-19 vaccines may be administered without regard to timing of other age-appropriate recommended vaccines; this includes simultaneous administration of a COVID-19 vaccine dose and other recommended vaccine(s) on the same day. The Nevada State Immunization Program encourages providers to stock influenza and routine childhood vaccines along with the childhood Updated: November 23, 2021

COVID-19 vaccine to not miss an opportunity to give a needed vaccine to a patient.

If multiple vaccines are administered at a single visit, then administer each vaccination in a different injection site, according to recommendations by age:

- Separate injection sites by at least 1 inch
- For children ages 11 years and older, the deltoid muscle can be used
- For children ages 5-10 years, if more than two vaccines are being injected into a single limb, the vastus lateralis muscle of the anterolateral thigh is the preferred site due to greater muscle mass.

Expected Side Effects from the Pfizer-BioNTech Childhood COVID-19 Vaccine

- <u>Local and systemic reactions</u> following COVID-19 vaccination are less frequent for children ages 5-11 years compared with young adults ages 16-25 years.
- Local reactions include pain, swelling, and erythema at the injection site.
- Systemic reactions include fever, fatigue, headache, chills, muscle aches, joint stiffness, and lymphadenopathy.
- Routine fever reducers, such as Ibuprofen, can be provided to a child post-vaccination to treat local or systemic symptoms, if medically appropriate.
- In general, aspirin is NOT recommended for use in children or adolescents ages 18 years and younger following receipt of the COVID-19 vaccine.

Rare Potential Side Effects from the Pfizer-BioNTech Childhood COVID-19 Vaccine

- A <u>severe allergic reaction</u>, like anaphylaxis, may happen after any vaccine, including COVID-19 vaccines, but this is rare.
- <u>Myocarditis</u> (inflammation of the heart muscle) and pericarditis (inflammation of the outer lining of the heart) are rare, serious adverse events which have been reported after receiving the second dose of mRNA COVID-19 vaccines, with the highest risk currently observed in males ages 12-29 years.
 - The FDA and CDC have recommended the Pfizer-BioNTech COVID-19 vaccine for children ages 5-11 years and adolescents ages 12-17 years <u>based on a determination</u> that the benefits of COVID-19 vaccination in these age groups outweigh the risks of a rare event occurring after vaccination.

Storage and Handling for the Pfizer-BioNTech Childhood COVID-19 Vaccine

The Pediatric (10mcg) formulation of the Pfizer-BioNTech COVID-19 vaccine contains 10 doses per vial, has an orange vial cap, orange banding on the vial, and orange outer packaging.

- The pediatric vaccine formulation is available in minimum order sizes of 100 doses.
- The pediatric vaccine formulation does NOT have an expiration date printed on the vial or carton.
- Instead, each vial has the lot number and date of manufacture printed on the label.
- The QR code on the pediatric Pfizer-BioNTech COVID-19 vaccine carton links to the EUA for ages 5-11 years but does not provide information on expiration dates.

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	Formulation for ≥12-year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)
Age group	12 years and older	5-11 years
Vial cap color		
Dose (mRNA concentration)	30 ug	10 ug
Injection volume	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	1.3 mL
Amount of Diluent* Needed per vial	1.8 mL	1.3 mL
Doses per Vial	6 (after dilution)	10 (after dilution)

Storage of the Pediatric Formulation

- Ultra-low temperature freezer for up to 6 months
- Refrigerator for up to 10 weeks
- Do NOT store in a standard freezer
- The vial can be used for <u>12 hours</u> after initial puncture

	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

Expiration of the Pediatric Formulation

- Pfizer does not have an expiration date look-up tool.
- The pediatric formulation has a 6-month expiration if held frozen at ultra-low temperatures:
 - Manufacturing date + 6 months (inclusive of the month of manufacture) = expiration date
 - $\circ~$ Ex: An 08/2021 manufacture date has a vial expiration date (if stored in ultra-low temperatures the entire time) of 01/2022

CHILDREN AND YOUTH WITH SPECIAL HEALTH CARE NEEDS

Current evidence suggests children with medical complexity, with genetic, neurologic, or metabolic conditions, or with congenital heart disease can be at increased risk for severe illness from COVID-19. Like adults, children with obesity, diabetes, asthma or chronic lung disease, sickle cell disease, or immunosuppression can also be at increased risk for severe illness from COVID-19. Widespread vaccination for COVID-19 is a critical tool to best protect everyone, especially people at highest risk from severe illness and death should they contract COVID-19.

People of any age with the <u>medical conditions</u> listed below are more likely to get severely ill with COVID-19 and should be protected with initial and booster doses of COVID-19 vaccines. This list **does not** include all medical conditions that place a person at higher risk of severe illness from COVID-19. Rare medical conditions, including many conditions that primarily affect children, may not be included below. A person with a condition that is not listed may still be at greater risk of severe illness from COVID-19 than people of similar age who do not have the condition and **should talk with their health care provider**. Resources and considerations for children with <u>developmental disabilities</u> are also available.

- Asthma
- Blood disorders such as Sickle Cell Disease (SCD) and Thalassemia
- Cerebrovascular disease including Stroke (CVA)
- Chronic kidney disease (CKD)
- Chronic Obstructive Pulmonary Disease (COPD)
- Cystic Fibrosis (CF)
- Diabetes mellitus, type 1 and 2
- Down Syndrome
- Heart conditions (heart failure, coronary artery disease (CAD), or cardiomyopathies)
- HIV/AIDS
- Immune deficiencies
- Liver disease, including Cirrhosis, Hepatitis, and nonalcoholic fatty liver disease
- Morbid obesity (BMI=/>40kg/m2)

- Neurologic conditions, including dementia
- Other lung diseases including interstitial lung disease, pulmonary fibrosis, pulmonary hypertension
- Overweight (BMI>25kg/m2 30kg/m2)
- Pregnancy and postpartum
- Severe obesity (BMI>30kg/m2 <40kg/m2)
- Smoking, current and former
- Solid organ or blood stem cell transplantation
- Substance use disorders, e.g., alcohol, opioids, etc.
- Tuberculosis
- Use of corticosteroids or other immunosuppressive medications

SCHOOL-LOCATED VACCINATION CLINICS

With COVID-19 vaccination now recommended for all children ages 5 years and older, K-12 schools play an essential role in COVID-19 prevention by ensuring their students have access to the vaccine. The Department of Education recently distributed the following toolkit to school districts and partnering agencies: <u>School-Located Vaccination Clinics: Best Practices for School Districts</u>.

It is recommended that school district administrators work directly with local health departments and other vaccine providers (e.g., pharmacies) to set up vaccination clinics in places that K-12 students and their parents know and trust.

The toolkit provides a three-tiered approach for school districts to follow to partner with an appropriate vaccine provider to host school-located vaccination clinics:

- Partner with a vaccine provider previously used for school-located flu or adolescent COVID-19 vaccination clinics or seek state/local health department guidance regarding appropriate partners.
- 2) Visit <u>vaccines.gov</u> to identify nearby vaccine providers or <u>contact pharmacies</u> directly to request if they can support a vaccination clinic at your school.
- 3) If unable to find a vaccine provider using the steps above, school districts may request to be matched to a pharmacy partner in their area, if a nearby pharmacy partner can support a vaccination clinic.
 - a. The CDC created this program for school districts at a district level. The pharmacy partners will work directly with the *school district* to arrange vaccination clinics.
 - b. During the week of November 8, 2021, the CDC sent pertinent information to school district superintendents regarding the process for requesting these vaccination clinics.
 - c. The Nevada State Immunization Program can also request vaccination clinics on behalf of their school districts and will be able to monitor school/pharmacy partnerships using the Tiberius system developed by the Federal Government.

The Nevada State Immunization Program is working with the Nevada Department of Education to ensure information regarding school-located vaccination clinic opportunities is shared with the chief school nurses and superintendents across Nevada's school districts.

FREQUENTLY ASKED QUESTIONS - PEDIATRICS

1. Why do children younger than 12-years-old need to get a COVID-19 vaccine? Are they at increased risk of getting sick from COVID-19?

With children back to in-person schooling and participating again in extracurricular activities, COVID-19 vaccination among children ages 5 to 11 years is critical to preventing infections and possible severe disease, as well as generally reducing the spread of COVID-19 within a community. While fewer children have been sick with COVID-19 compared to adults, <u>children can be infected with the virus</u>, and there is no way to tell in advance if a child will get a severe or mild case. Some children have developed a rare but serious disease that is linked to COVID-19 called <u>multisystem inflammatory syndrome (MIS-C)</u>.

2. Are COVID-19 vaccines safe for children in this age group?

Based on data from the clinical trial, children may have some <u>side effects</u> from COVID-19 vaccination, which are normal signs that their body is building protection. These side effects may affect your child's ability to do daily activities, but they should go away in a few days. <u>Serious side effects</u> are rare but may occur.

3. Where are vaccines available for younger children?

Finding available COVID-19 vaccines in Nevada for anyone 5 years and older is convenient. Pediatricians and Family Medicine providers, Pharmacies, Federally Qualified Health Centers (FQHCs), Rural Health Clinics (RHCs), and Community Health Nurses across the state are administering COVID-19 vaccines to children.

FQHCs, pharmacies, public health, and pediatric provider networks can partner with individual schools, school districts, and communities to host pediatric vaccination clinics. These vaccine providers can encourage school-based and extracurricular vaccination for younger school-aged children to hold targeted programs to ensure equity and broad coverage and access.

The <u>NVCOVIDFighter.org</u> website and <u>vaccines.gov</u> will list doctor's offices, local pharmacies, health care clinics, and local health departments where vaccine is available. These resources help provide accurate and up-to-date information about vaccination services in your area. You can also call the Nevada Vaccine Call Center at 1-800-401-0946 to speak with a call center representative (English/Spanish) who can help locate and schedule COVID-19 vaccine appointments for children, adolescents, and adults.

4. How does dosage work for children? What should a parent do if a child turns 12 after they get their first dose of the pediatric vaccine but before the second dose is due?

As opposed to many medications, vaccine dosages are based on age and not size or weight. A child of 12 years should receive the adult dosage for their vaccine. However, if a child turns from 11 to 12 years of age in between their first and second dose and receives the pediatric Pfizer-BioNTech COVID-19 vaccine for their second dose, they do not need to repeat the dose and are considered fully vaccinated.

5. Is the pediatric formulation of the Pfizer-BioNTech COVID-19 vaccine the same as the adult formulation?

The Pfizer-BioNTech vaccine for children ages 5 through 11 years has the same active ingredients as the vaccine given to adults and adolescents. However, the vaccine for children comes in a different vial with a different color cap. The Pfizer-BioNTech COVID-19 vaccine that is given to adults and adolescents cannot be used for children ages 5 through 11 years.

Children ages 5 through 11 years will receive an age-appropriate dose that is one-third of what adolescents and adults receive. Smaller needles, designed specifically for children, are used for children ages 5 through 11 years. COVID-19 vaccine dosage does not vary by patient weight but by age on the day of vaccination. Children are still required to get two doses three weeks apart to be considered fully vaccinated.

6. How will vaccine safety be monitored in this age group?

COVID-19 vaccines have undergone – and will continue to undergo – the most intensive safety monitoring in U.S. history. CDC and FDA will continue to monitor safety using established and new safety monitoring systems. Parents/caregivers can enroll their child in <u>v-safe</u>, a free and easy-to-use smartphone-based

app, where they can complete health check-ins after COVID-19 vaccination and report how their child is feeling after vaccination. Additionally, patients, caregivers, and vaccine providers are also asked to report adverse events after vaccination to the <u>Vaccine Adverse Event Reporting System (VAERS)</u>, even if it is not clear that the vaccine caused the adverse event. CDC reviews all the information and reports any serious adverse reactions.

7. Are medical experts worried about myocarditis or pericarditis after vaccination in children?

Cases of <u>myocarditis</u> (inflammation of the heart muscle) and pericarditis (inflammation of the outer lining of the heart) have been reported after Pfizer-BioNTech COVID-19 vaccination of children ages 12–17 years. These reactions are rare; in one study, the risk of myocarditis after the second dose of Pfizer-BioNTech in the week following vaccination was around 54 cases per million doses administered to males ages 12–17 years.

8. Is it safe to co-administer COVID-19 vaccines with other vaccines, like flu?

Yes, if a patient is eligible, both flu and COVID-19 vaccines can be administered at the same visit, as <u>recommended by CDC and ACIP</u>. In addition to flu vaccine, COVID-19 vaccine can be given with other routine childhood vaccines as well.

9. Will COVID-19 vaccines continue to be free for children in this new age group?

Yes, COVID-19 vaccines are available for everyone at no cost, including the Pfizer-BioNTech vaccine for children ages 5 through 11 years. COVID-19 vaccines will continue to be given to all eligible people living in the United States, regardless of insurance or immigration status.

10. Will children younger than 12 receive a CDC COVID-19 Vaccine Card?

Yes, all vaccine recipients, including children ages 5 through 11 years, will receive a CDC COVID-19 vaccination card upon initial vaccination.

For more information go to NVCOVIDFighter.org

