A Sigh of Relief: COVID Vaccines Approved for Kids

ABSTRACT: With the recent FDA approval of one CORONAVIRUS SARS-CoV-2 (COVID-19) vaccine for children aged 5 to 11, many UConn learners have asked for information about what to expect as they vaccinate children. This continuing education activity answers that request.

INTRODUCTION
Most Americans have hoped for and anticipated the Food and Drug Administration’s nod that it’s time to vaccinate children against CORONAVIRUS SARS-CoV-2 (COVID-19). In the first week of November 2021, the go-ahead arrived. Many pharmacists and pharmacy technicians will be vaccinating children for the first time!

To start, let’s look at a quote from Grey’s Anatomy, a lesson delivered to incoming residents by Arizona:

“This is not general surgery on a miniature scale. These are the tiny humans. These are children. They believe in magic. They play pretend. There is fairy dust in their IV bags. They hope, and they cross their fingers, and they make wishes, and that makes them more resilient than adults. They recover faster, survive worse. They believe.”

Pharmacy teams need to remember that information as we vaccinate America’s children. We’ll skip any further introduction and launch right into useful information for pharmacy teams.
**KIDS: NOT JUST SMALL ADULTS**

What should pharmacy teams expect when they encounter kids who need vaccinations? Pediatric patients obviously have smaller builds than adolescents and adults. They are substantially more likely to exhibit acute distress than most adults in the timeframe around vaccine administration. Pharmacy staff must consider several differences in how they administer vaccines to these children. They need to be familiar with the different packaging, the lower dose, and the need for a shorter needle to ensure proper injection site technique.

Pharmacy staff should also adjust their administration technique to reduce potential distress. When children are distressed, they may respond with crying, screaming, or kicking. A third of parents report that their child will flail during vaccine administration, this increases risk of administration errors. To reduce this risk, pharmacy staff should work with the child and the parents to make sure the child experiences the least amount of stress possible (we discuss this in more detail below). Vaccinating children may take longer than vaccinating adults, and pharmacy staff should prepare for that possibility. These patients may be more scared of needles and injections than adults are and may not comprehend why they need a shot. Pharmacy teams need to take steps to make them feel safe. The immunizer should be calm and reassuring to the patient and avoid using the words “pain,” “shot,” and “hurt,” which are distressing to children. Also, trying to reassure them by saying “it’ll all be okay” usually does not make children feel better.

As the vaccines for children roll out, pharmacy teams must ensure that pediatric patients have the best possible experience. The experience that we provide to patients and parents will impact whether the patient will come back to receive the second dose.

**Differences between Adult and Pediatric Dosing**

Most immunizers are familiar with immunization technique and potential problems when they provide care to adults. Reviewing the basics of vaccinating adolescents and adults for COVID-19 will make it easier to see how the process and products differ in children.

**Adults and Adolescents**

Adults and children older than age 12 are FDA-approved to receive the full primary series of the Pfizer-BioNTech COVID-19 vaccine. The primary series consists of two 0.3 mL (30 mcg) intramuscular doses separated by a minimum of 21 days.

Boosters are available for all individuals who are older than 18. As this continuing education activity goes to print, the Centers for Disease Control and Prevention (CDC) has recommended that everyone who is 18 years or older receive a booster shot at least six months after completing the primary COVID-19 vaccination series if they received the Pfizer-BioNTech or Moderna vaccines. People who received the Johnson & Johnson’s Janssen vaccine should receive a booster at least two months after their first COVID-19 vaccination. They can choose any of the authorized COVID-19 vaccines. Pharmacy staff may administer the appropriate booster intramuscular dose six months following completion of the primary series.

All individuals older than 12 years old with a history of solid organ transplantation or diagnosis with equivalent immunocompromise are also approved for a third 0.3 mL (30 mcg) intramuscular dose 28 days after their second dose.

Pharmacy staff must reconstitute the adult/adolescent vaccine with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use. Once reconstituted, each vial will contain six doses that are good for six hours at room temperature. Staff should record the date and time of first puncture and discard all unused vaccines beyond six hours.

**Children Aged 5 to 11**

Children aged 5 to 11 have been FDA-approved to receive the Pfizer-BioNTech COVID-19 vaccine following several clinical trials. However, the pediatric vaccine is different than the adult/adolescent vaccine in terms of dose. The primary series for children 5 to 11 consists of two 0.2 mL (10 mcg) intramuscular doses separated by at least 21 days. The child dose contains one-third the concentration of the adult and adolescent dose.

Pfizer packages the pediatric vaccine in orange-capped vials (as opposed to purple-capped vials for adult/adolescent vaccine). Similar to how healthcare providers store the adult/adolescent vaccine, Pfizer packages the pediatric vaccine in orange-capped vials (as opposed to purple-capped vials for adult/adolescent vaccine).
vials, health care providers should store pediatric vials in a freezer at -90ºC to -60ºC (-130ºF to -76ºF) until the expiration date printed on the label. Pharmacy staff can thaw frozen vials in the refrigerator at 2ºC to 8ºC (35ºF to 46ºF) for up to a month, or at room temperature for two hours maximum. Pharmacy staff must reconstitute the pediatric vaccine with 1.3 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use. Once reconstituted, each vial will contain 10 doses that are good for 12 hours at room temperature. Staff should record the date and time of first puncture and discard all unused vaccines beyond 12 hours.6

Table 2 summarizes the differences between the two vaccines.

<table>
<thead>
<tr>
<th>Age</th>
<th>Primary Series</th>
<th>Booster Dose</th>
<th>Dilution Information</th>
<th>Dose/vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric (5-11)</td>
<td>Two 0.2 mL (10mcg) IM doses separated by 21 days</td>
<td>Not approved</td>
<td>Reconstitute with 1.3 mL of sterile 0.9% Sodium Chloride Injection, USP</td>
<td>10 doses</td>
</tr>
<tr>
<td>Adolescent (12-15)</td>
<td>Two 0.3 mL (30mcg) IM doses separated by 21 days</td>
<td>Not approved</td>
<td>Reconstitute with 1.8 mL sterile 0.9% Sodium Chloride Injection, USP prior to use</td>
<td>6 doses</td>
</tr>
<tr>
<td>Adult (&gt;16)</td>
<td>Two 0.3 mL (30mcg) IM doses separated by 21 days</td>
<td>Booster: 0.3 mL (30mcg) IM dose at least 6 months after completion of primary series</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Eye on Technique Please!
Administering the COVID-19 vaccine correctly ensures maximum therapeutic benefit.

First: Select the Proper Syringe and Needle
It is important to choose proper needle length based on the patient’s age and size. The CDC’s general recommendation is to use a needle in the range of 22 to 25 gauge, with the higher gauge indicating a smaller needle diameter. For pediatric patients, staff should select needles that are shorter in length than those used for adults, but this also depends on the child’s muscle size. The needle needs to be long enough to penetrate past the subcutaneous tissue into deltoid muscle. If it is too long, it may hit the bone. While patients will not feel if you hit the bone, the muscle may not fully absorb the vaccine, leading to lower efficacy. Table 3 summarizes the CDC’s recommendations on needle length and gauge for intramuscular injections.

Second: Identify the Injection Site
Immunizers will need to expose the child’s entire upper arm and identify the “target triangle” that consists of the upper part of the deltoid muscle. Identifying the acromion process, the bony protrusion of the upper shoulder, defines the top of the upside-down triangle. Immunizers will give the injection below the acromion process and above the axillary fold (the armpit). It’s critical to inject in the lower two-thirds of the deltoid muscle, as injections given too high can result in shoulder injury related to vaccine administration. See Figure 1, next page.

### Table 3. CDC Intramuscular Injection Guidelines on Needle Gauge and Length

<table>
<thead>
<tr>
<th>Age</th>
<th>Weight</th>
<th>Length</th>
<th>Injection Site</th>
<th>Gauge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children (3-10 years)</td>
<td>N/A</td>
<td>1-1.25 inches</td>
<td>Vastus lateralis muscle (anterolateral thigh)</td>
<td>22-25</td>
</tr>
<tr>
<td></td>
<td></td>
<td>⅞ - 1 inch</td>
<td>Deltoid muscle (arm)</td>
<td></td>
</tr>
<tr>
<td>Children (11-18)</td>
<td>N/A</td>
<td>⅞ - 1 inch</td>
<td>Deltoid muscle (arm)</td>
<td></td>
</tr>
<tr>
<td>Adults ≥ 19 years</td>
<td>≤ 130 lbs</td>
<td>1 inch**</td>
<td>Deltoid muscle (arm)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>130-152 lbs</td>
<td>1 inch</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Men: 152-260 lbs</td>
<td>1-1.5 inches</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Women: 152-200 lbs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Men: ≥ 260 lbs</td>
<td>1.5 inches</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Women: ≥ 200 lbs</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*If the skin is stretched tightly and subcutaneous tissues are not bunched
**Some experts recommend a 5/8-inch needle for men and women weighing less than 60 kg, if used, skin must be stretched tightly and subcutaneous tissue must not be bunched.
Third: Administer the Vaccine Correctly
To administer the vaccine, patients should be seated with relaxed arms and ideally, the immunizer should also be seated. Immunizers should:

- Hold the syringe with the dominant hand and remove the needle cover.
- Place the syringe between the thumb and first finger (like a dart).
- Stretch the patient’s skin taut with the non-dominant hand, ensuring that the subcutaneous tissue is not bunched to aid in the needle’s entry.
- Insert the needle firmly and quickly at a 90-degree angle.
- Depress the plunger at a rate of 0.1 mL per second.
- After injecting the vaccination, remove the needle at the same 90-degree angle (see Figure 2).
- Activate the needle’s safety device and dispose of the syringe and needle in the sharps container (which should be located on the side of the immunizer’s dominant hand).
- Cover the injection site with a bandage, but do not massage the area as this may cause vaccine to leak.

When Fairy Dust is Unavailable
Having fairy dust available to make vaccinations fun would be ideal, but it seems like fairy dust is in short supply. There’s no need to despair. Parents and immunizers can help children feel more comfortable during the pediatric immunization process. Parents can promote a relaxing environment for young children by making them feel safe and distracting them with toys, sweets, and more.

Parents will be key to the process, and preparation can be especially helpful. Before the visit, parents can “rehearse” with the child. Letting children give a pretend vaccination to a favorite doll or stuffed animal can reduce anxiety. Parents may also choose to reward children following a successful vaccination as a way to reinforce the positive experience. Parents need to avoid suggesting how children will feel; let children determine on their own how they feel. In addition, parents can ask immunizers to use a pain-relieving or numbing ointment or spray prior to the appointment so that it can be applied beforehand. Immunizers should note that holding a child in an upright position is fine; physically restraining a child or pinning a child down is not. Restraints are frightening for children and in some places, it is illegal. Restraining children contributes to development of needle phobia.

Although not typically necessary, parents can ask immunizers to use a pain-relieving or numbing ointment or spray prior to the appointment so that it can be applied beforehand. At Children’s Minnesota, clinicians offer a numbing topical to every single child every time they need an injection. It takes planning and coordination, as parents or staff need to apply the medication 30 minutes before a scheduled shot. 

Young children are most likely to need parents and immunizers to alleviate their fear and worry. Immunizers can offer children (older than two years of age) a lollipop or some other source of glucose or sucrose to distract them. Frequently, pediatricians’ offices have toys and books on hand for children to play with while the process occurs. Pharmacies who see a large number of children might consider doing the same. An online discussion board included a tip from a pharmacist who keeps a picture of her dog with its head stuck in a pizza box to stimulate some discussion. Another said that telling kids to keep their arms loose like spaghetti noodles and having them jiggle their arms can calm them down.

Some researchers suggest that having the child blow bubbles is an excellent distraction if it isn’t the child’s first exposure to bubble-blowing and they enjoy it. Having a short children’s video...
playing is also a good distraction, and in this day and age of ubiquitous cellphones and tablets, this is an easy intervention. An other way to de-escalate the stress of the immunization process for children is to provide kid-friendly bandages to show them with popular characters from television and movies.

Verbal communication is critical to create a seamless vaccination experience with children. Immunizers should never inform a child that vaccination will not hurt. Although it may seem harmless to tell children that the vaccine they are about to receive will be relatively painless, from children’s perspective, it may be painful, and this may cause distrust in providers. Children respect honesty over trickery, so it is vital to establish trust and understanding between the immunizer and the child. One way to go about the pain aspect is to have the immunizer describe what the child is about to feel as “a quick pinch” while simultaneously injecting the vaccination. Children often respond with “it is already over?” which is the patient response goal when administering vaccines.

When it comes to older children, parents can prepare them for immunizations by reinforcing relaxation techniques, such as deep breathing or looking away and thinking of something they enjoy. Some older children find comfort in having their parents hold their hands or holding a conversation with a trusted adult to distract them. Adolescents may also require special care during immunizations, so parents and immunizers must treat them with patience and understanding.

As children age, having a parent present in the room during an immunization may not be helpful. The parent’s behavior is the key contributor to children being riled up and uneasy before receiving a vaccination. If parents themselves are afraid of needles, their fear and behavior alone can instill anxiety in the child. In these instances, having someone else who can stay calm and is familiar with the child might be wise. Even better, if children are comfortable, they can inform the immunizer they can receive their immunization without their parents’ presence.

Dealing with Side Effects
Every vaccine has side-effects, but with this vaccine newly approved for ages 5 to 11, pharmacy staff can expect parents to have questions and concerns. Overall, immunizers can expect children to have side effects similar to those that adults have reported with the COVID-19 vaccines. According to the CDC, common side effects are pain, redness, and swelling at the injection site. Additionally, children may experience fatigue, headache, muscle aches, chills, fever, and nausea. Pharmacy staff should alert all parents of these potential side effects. Children should experience fewer side effects than adults due to the lower dosage of mRNA, but should still be monitored for 15 minutes after vaccination to monitor for an allergic reaction. Side effects usually last 24 to 48 hours and can be managed with acetaminophen or ibuprofen as needed. Pharmacy staff should also advise guardians that redness, swelling, and even fever are all positive indicators that the body is building immunity; however, if the redness or tenderness at the injection site worsens after 24 hours, guardians should contact a primary care provider.

Non-pharmacologic therapies such as staying hydrated for fever management and placing a cool, damp cloth over the injection site for pain are helpful. Pharmacy staff should advise all guardians to avoid giving their children aspirin after receiving the COVID-19 vaccine. Aspirin is only recommended for those over 18 years of age and never for anyone who has or is recovering from chickenpox or flu symptoms (due to association with Reye syndrome); pharmacy staff should recommend non-aspirin products such as ibuprofen or acetaminophen for pain.

Similarly, the CDC recommends against use of over-the-counter medications before the vaccine for the purpose of preventing side effects. We currently do not understand how analgesics influence the vaccine’s effectiveness. Pharmacy staff should caution guardians against administering prophylactic over-the-counter medications. It is critical, however, that pharmacy staff distinguish between taking medications to prevent side-effects and taking medications to treat a current condition. Pharmacy staff should counsel patients not to discontinue medications in preparation for vaccines unless indicated by a healthcare provider.
DEALING WITH COMMON QUESTIONS

Is it really necessary to vaccinate my child?
Parents may feel unwilling or believe it’s unnecessary to vaccinate their children due to the relatively low risk of COVID-19 causing harm to them. Since the spread of the Delta variant, pediatric COVID-19 cases have risen 5-fold. Although the relative risk of serious illness or hospitalization is low, approximately one-third of children who are hospitalized due to COVID-19 have no underlying risk factors. This makes it hard to predict which children will become sicker or recover quicker from COVID-19. Explaining this calmly to parents and guardians can help them accept the vaccine.

The vaccine is safe, with no serious concerns or common long-term side effects identified for children. It is effective with a two-dose series being 90.7% effective in preventing symptomatic COVID-19 in children aged 5 to 11. Vaccinating children will help protect the child, the child’s family, and others.

What about the risk for myocarditis?
Myocarditis (inflammation of the middle muscular layer of the heart wall) and pericarditis (inflammation of the conical sac of serous membrane that encloses the heart and the roots of the great blood vessels) are rare side effects of the Pfizer/BioNTech vaccine. During clinical trials, no children developed myocarditis or dangerous allergic reactions, but the CDC expects some cases may occur as the vaccines are administered across the U.S. The CDC recommends all children should receive the COVID-19 vaccine, as the risk for myocarditis or pericarditis from a vaccine is lower than the risk of myocarditis associated with COVID-19 infection in adolescents and adults. Additionally, the baseline risk of myocarditis is much higher in adolescents ages 12 to 27 compared to children aged 5 to 11, making it less risky for children.

Should I wait for my child’s 12th birthday so he or she can get the adult series?
The Pfizer COVID-19 vaccine dosage for children aged 5 to 11 is 10 mcg, a third of the normal adult dosage. The CDC recommends children receive the appropriate vaccine dose based on age on the day of vaccination. It is not recommended or necessary for children to wait to turn 12 to receive the adult vaccine series, as children can remain susceptible to COVID-19 during this time. Additionally, immune response to the vaccine is independent of weight; vaccines do not need to be sized-up for larger bodies.

My child will turn 12 in three months. Do we start with the pediatric dose and then transition to the adult dose? Or just stick with the pediatric dose? Or something else entirely?
For children who will turn 12 soon, starting with the lower dose is fine—the clinical trials indicate that children’s immune responses with that lower dose are robust. If they turn 12 in between the doses, parents will have the option of staying with the lower dose or changing to the adolescent dose. Children’s immune systems are more responsive than adults’, but their response begins to decrease as they enter puberty and reach adulthood.
Good Vaccination Practices & Preparation
As our COVID-19 vaccination patient demographics change, we have a unique opportunity to review our site set-up, preparation, and documentation practices and make changes if necessary. Included below are some tips and tricks to ensure that immunizers are ready for success when vaccinating.

Before starting to vaccinate, immunizers should stock each station with enough supplies. Table 4 lists items that are always needed in a well-stocked station and patient-specific items. Immunizers need to ensure their own safety with personal protective equipment, and practice good hygiene by keeping hands away from your face and washing your hands often.

Next, the “clean as you go” approach is optimal when vaccinating many people. Three main points are crucial regarding cleaning:

- Throw paper and miscellaneous trash away immediately! This includes the cap of the needle, which you won’t need later – we never recap needles after injections.
- Activate the safety device on the needle using a hands-free method immediately after use. If in some situation you absolutely must recap the needle, use the scoop method: with the syringe in one hand and the cap on the table of your work area, use a ‘scooping’ motion to push the needle deep inside the cap, and press the tip of the needle against an inanimate object to secure the cap in place.
- Place used needles or sharps into sharps container as soon as you finish using them. Never place a used syringe on your work area. Monitor your sharps container and know where the ‘full’ line is. If it is close to full, retrieve a back-up container before it’s needed.

PAUSE AND PONDER: What data do you need to collect and record each time you vaccinate a person?

Table 4. Necessary Supplies for Immunization

<table>
<thead>
<tr>
<th>Always at Your Station</th>
<th>Have Ready for Each Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>A sharps container</td>
<td>One alcohol wipe</td>
</tr>
<tr>
<td>A handy trash can</td>
<td>One sterile 2 x 2 gauze pad or cotton ball</td>
</tr>
<tr>
<td>Ample supply of bandages</td>
<td>A new needle and syringe that are the correct size</td>
</tr>
<tr>
<td>Cleaning solution for the station</td>
<td>A clean pair of disposable gloves (for you to wear)</td>
</tr>
<tr>
<td>Your personal protective equipment (e.g., mask, face shield, gloves)</td>
<td>A bandage, partially open</td>
</tr>
<tr>
<td>A box of tissues</td>
<td></td>
</tr>
</tbody>
</table>

SIDEBAR: Things to Know about Mass Vaccinations Sites
Experts highly recommend using mass vaccination sites when large numbers of people need to be immunized because they have a large impact on vaccination campaign effectiveness. Mass vaccination sites increase the number of lives saved and increase the maximum number of people who can be vaccinated because they create efficient high-throughput times. During a pandemic, normal vaccination sites such as pharmacies may not be able to maintain their vaccine supply or schedule a sufficient number of patients.

Setting up mass vaccination sites requires consultation with local or state public health offices and making sure all participating immunizers are licensed and have signed the CDC COVID-19 Vaccination Program Provider Agreement.

When choosing a mass vaccination site, its best to evaluate potential sites for vaccine distribution and resource consolidation. Generally, providers have two options: a walk-in or drive-through site. Walk-in vaccination sites have shorter wait times compared to drive-through vaccination sites but drive-through vaccination sites are more cost effective and allow better social distancing.

Population targeting is also very important. Locating mass sites near vulnerable populations such as low-income communities increases convenience and reduces mortality rates. Now that children 5 years and older are able to be vaccinated, mass vaccination sites to vaccinate children in an effective, rapid, and efficient manner are popping up. Convenient locations include stadiums near schools or school gymnasiums or cafeterias. Drive-through vaccination sites in school parking lots or other empty lots are also helpful.

Immunizers who work at mass vaccination sites should come prepared to stand for a significant amount of time (wear comfortable shoes) and to dress properly in layers (many of these sites have poor temperature control). Also, each site’s processes and technology might differ. If immunizers experience any confusion, they should contact the site coordinator for help or additional training.
Finally, all immunizers should review documentation procedures. As with all vaccines, immunizers must document the patient’s name, date of birth, vaccine lot number and expiration date, and the site of administration of the vaccine (i.e., left deltoid, right deltoid, etc.).

In addition to updating the Vaccine Administration Management System, sites might require additional documentation in their own electronic medical records or pharmacy system. Be certain to know local policies and procedures.

A final tip: even the most knowledgeable clinician sometimes needs to ask questions. Immunizers who feel unsure or uncomfortable at the immunization clinic should ask for help from a more experienced immunizer. Especially as we move into vaccinating more children at COVID-19 clinics, finding someone with more expertise and planning an approach is smart!

CONCLUSION

With approval of COVID-19 vaccines for children aged 5 to 11 years old, pharmacists and technicians have many new opportunities to improve their communities’ health. Pharmacy teams are able to make a difference by educating children and their caregivers on the vaccine and providing a positive, safe vaccination experience. Pharmacists should communicate the advantages of the vaccine and possible side effects to their patients. When vaccinating children, it’s important to appreciate this age group’s unique characteristics and cater to them as best as possible. Keep in mind that there are mass COVID-19 vaccination sites currently open. View the SIDEBAR for a list of tips about mass vaccination sites. Figure 3 summarizes key points.

Figure 3. Vaccinating Kids!

**Best**

1. **BE COMMUNITY CHAMPIONS.** Be an advocate for COVID immunizations in the youngest of children!
2. **Anticipate parents’ (and children’s) questions!** Be prepared to provide accurate, encouraging information.
3. **Share successful techniques with other immunizers,** especially if you have an ample supply of fairy dust!

**Better**

1. **Choose words carefully** when talking to children about vaccinations—or any medicine.
2. **Encourage parents to prepare children** in a calm, measured manner.
3. **Use distraction techniques** that have been proven to help kids deal with immunization.

**Good**

1. **Know the difference** between children and adults—it’s not just age!
2. **Stay up to date** with CDC and FDA recommendations.
3. **Constantly work on good injection technique.** Don’t get sloppy!
REFERENCES
1. Grey's Anatomy, Season 6, Episode 8. Accessed November 27, 2021. This is not general surgery on a miniature scale. These are the ... - TV Fanatic