

Good afternoon. I'm Nikki Grimsley, and I'm representing the Clinician Outreach and Communication Activity or COCA with the Emergency Risk Communication Branch at the Centers for Disease Control and Prevention. I'd like to welcome you to today's COCA Call, Recommendations for Pfizer BioNTech and Moderna COVID-19 Vaccine Primary Series in Children Six Months through Five Years Old. All participants joining us today are in listen-only mode.

Free continuing education is offered for this webinar, and instructions on how to earn continuing education will be provided at the end of the call. In compliance with continuing education requirements, all planners and presenters must disclose all financial relationships in any amount with ineligible companies over the previous 24 months, as well as any use of unlabeled products or products under investigational use. CDC, our planners and presenters wish to disclose they have no financial relationships with ineligible companies whose primary business is producing, marketing, selling, reselling, or distributing healthcare products used by or on patients.

Presentations will not include any discussion of the unlabeled use of a product or a product under investigational use, with the exception of Dr. Hall's and Dr. Oliver's discussion of vaccine use under emergency use authorization or emergency use instructions. CDC did not accept financial or in-kind support from ineligible companies for this continuing education activity.

At the conclusion of the session, participants will be able to accomplish the following: Review current COVID-19 vaccination recommendations for children ages six months through five years, including children who are moderately or severely immunocompromised. List key points for all healthcare providers to use when talking about COVID-19 vaccination with parents and caregivers of children ages six months through five years, including children who are moderately or severely immunocompromised. And discuss where to find online resources for clinicians about COVID-19 vaccination for children ages six months through five years old.

After the presentation, there will be a Q&A session. You may submit questions at any time during today's presentation. To ask a question using Zoom, click the Q&A button at the bottom of your screen, then type your question in the Q&A box. Please note that we receive many more questions than we are able to answer during our webinars. If you are a patient, please refer your questions to your healthcare provider. If you are a member of the media, please contact CDC Media Relations at 404-639-3286 or send an email to media@cdc.gov.

We have introduced self-knowledge checks throughout the presentation. We hope you enjoy these opportunities to assess your understanding of today's session. Please do not type your answers into the Q&A box, as this may disrupt the Q&A portion at the end of the session.

I would now like to welcome our presenters for today's COCA Call. We are pleased to have with us Dr. Sarah Oliver, who is the co-lead for the Advisory Committee for Immunization Practices COVID-19 Work Group and the Chief Medical Officer of the COVID-19 Vaccine Policy Unit for CDC's COVID-19 response.

Dr. Elisha Hall, who is the Clinical Guidelines Lead and Chief Medical Officer for the COVID-19 Vaccine Policy Unit for CDC's COVID-19 response. And Dr. Kevin Chatham-Stephens, who

is the Pediatric, Vaccine Planning and Implementation Lead for the Vaccine Coordination Unit also with CDC's COVID-19 response. And Dr. Anne Hause who is the V-safe team co-lead for the Immunization Safety Office in the National Center for Emerging and Zoonotic Infectious Diseases at CDC. I'll now turn it over to Dr. Sarah Oliver. Dr. Oliver, please proceed.

Thank you so much. I will note that we won't be able to walk through all of the information discussed during the ACIP meeting on today's COCA Call, but the slides and all of the information are posted publicly at the ACIP website. Next slide. Next slide.

And again, we talked about this in more detail at the meeting, but we do know that there is a pervasive myth that young children have no ill effects from COVID. We discussed that overall COVID has caused more than 2 million cases among children ages six months through four years. We know that children in this age group are at risk of severe illness. More than half of the hospitalized children in this age group had no underlying conditions.

COVID hospitalizations among children in this youngest age group have similar or increased severity compared to older children and adolescents. The burden of COVID-19 associated death is similar to or exceeds that of other pediatric vaccine preventable diseases. We also know that prior infection may not provide broad protection against newer SARS-CoV-2 variants, emphasizing the importance of children to get vaccinated even if they've been infected previously. And as we all know, the COVID pandemic continues to have a significant impact on families. Next slide.

So, I'll briefly walk-through information for the Moderna COVID-19 vaccine for children ages six months through five years. Next slide.

As a reminder, this trial was conducted from December of 2021 through February of 2022, with case accrual after a second dose at the height of the Omicron surge. Children ages six months to five years in the US were randomized three-to-one vaccine to saline placebo. Analyses were performed separately for six to 23 months and two to five years, and we have results pooled for a combined estimate for six months through five years. The Moderna schedule is two doses of 25 micrograms separated by 28 days, and the median follow up after the second dose in the trial was two and a half months. You can see here that there were over 6,000 children included in the trial for efficacy and safety populations as well. Next slide.

And this slide provides a bit more detail on the efficacy estimates from the trial. For those six through 23 months, the vaccine effect, the VE, was 50.9. And for two through five years, VE was 37% for an overall VE of six months through five years at 41.5%. We have higher confidence in this estimate, since it was based on 181 COVID cases in the vaccine group and 97 cases in the placebo group -- remember, they were randomized three-to-one.

So, for context, we put this efficacy with what we've seen in the post-authorization effectiveness for the Moderna vaccine in adults 18 to 64 during Omicron, where the VE against infection two months after dose two was 35%. Next slide.

Then regarding immunogenicity data, the antibody levels were measured 28 days after the second dose for participants without prior infection. And then the antibody responses after two 25 microgram doses in these young children were compared to two 100 microgram doses in individuals aged 18 to 25 years, and they were as high or higher, which was the criteria set by FDA for authorization. Next slide.

So, for the safety data, there were no deaths reported in any of the trial participants. Serious adverse events were rare overall, occurring in 5% of vaccine recipients and 2% of placebo recipients. No cases of myocarditis or anaphylaxis occurred in any trial participants. Local reactions such as pain at the injection site was common, and systemic reactions also occurred. In children ages two through five years, they most commonly reported fatigue and headache. And in children six to 23 months, their parents reported irritability or sleepiness as the most common. Symptoms typically started one to two days after the vaccine and resolved after a couple of days. Next slide.

Specifically looking at fevers, they were more common after vaccine than placebo, and more common after the second dose than the first. Most fevers were reported in the first few days after the vaccine and lasted for around a day. This table shows fever after the second dose occurring at about 16%. However, fevers after other routine vaccines given at this age can be around 30% of people who receive them. There was one febrile seizure in the trial that may have been related to the vaccine. Next slide.

The trial also had some imbalances with respiratory infections such as RSV. However, when taken for all respiratory infections including COVID, no imbalances were noted. The events were rare and occurred in less than 1% of trial participants. In addition, there was no pattern or clustering of the cases noted, and the clinical characteristics were typical and consistent with seasonal respiratory infections. And again, remember these trials were really conducted at the height of that cold and flu season.

For the Moderna trial, lymphadenopathy was a solicited adverse event, meaning that the trial asked everyone about lymph node swelling. So, lymphadenopathy either in the axillary region or the groin was noted in 9% of vaccine recipients compared to 2% of placebo recipients. Next slide.

Oh, back one, I think we skipped over one.

Yeah. So, the efficacy seen after two doses of the Moderna vaccine in children six months through five is consistent with the real-world vaccine effectiveness in other ages during Omicron. The antibody levels after two doses in children produced similar antibody levels after two doses seen in young adults, and the reactogenicity or symptoms seen after the vaccines is consistent with other recommended vaccines in this age group. Next slide.

Now moving on to quickly describe the Pfizer data. Next slide.

This clinical trial was conducted from June of 2021 through April of 2022. Children ages six months through four years in the US were randomized two-to-one vaccine to saline placebo. The

series is three doses at three micrograms each. Dose one and those two are separated by 21 days, and dose two and dose three are separated by at least eight weeks. However, note the interval between dose two and dose three in the trial was longer than the authorized interval.

For children in that younger age group, the six to 23 months, the interval was 16 weeks. And for children two to four, the interval was 11 weeks. In addition, the median follow-up time after the third dose was 1.3 months. Next slide.

Then we talked about this in more detail at ACIP. But according to the Pfizer protocol, they unblinded people six months after the second dose. And many of us know what happens. The trial was initially set to study two doses. And then after the analysis after two, they learned that a third dose would be needed. So, by the time participants were set to receive the third dose, many of the population had already been unblinded. So around 32% of the overall eligible population contributed the blinded person time to efficacy and safety populations for that third dose. Next slide.

So, this slide shows the efficacy estimates after the third dose. For those six to 23 months, it was 75%. For two to four years, it was 82%. And overall six months through four years, it was 80%. But note the very wide confidence intervals for many of these estimates. So overall, we have lower confidence in these estimates based on three COVID cases in the vaccine group and seven COVID cases in the placebo group.

Overall, by the time they gave the third dose and were accruing cases, we were into February, March and April when we were seeing the case counts from Omicron decline. So, for comparison in context, we know that the post-authorization vaccine effectiveness seen after the Pfizer vaccine in adolescents seen during Omicron two months after the second dose was 29%, and two months after the third dose was 43%. Next slide.

So, since we have lower confidence in the efficacy estimates, we rely a lot on the antibody studies that were done immunobridging data. So again, antibody levels were measured one month after the third dose for participants without prior infection. And again, the antibody responses after three 3 microgram doses in these young children was compared to two 30 microgram doses in individuals 16 to 25. Both age groups met the non-inferiority criteria, meaning that the antibody levels seen were as high or higher with the ratio shown here. Next slide.

Then we have a lot of questions with what was the data after the second dose. And so, it's shown here again for the younger population where the efficacy was minimal, again with the wide confidence interval, that the noninferiority criteria were met. And then in two to four years that had a little bit higher efficacy, but the noninferiority criteria were not met. It was after these data that the decision was made to study the third dose. Next slide.

From a safety standpoint, no deaths again were reported in the trial participants. And again, serious adverse events were rare overall, in 1% of vaccine recipients and 1.5% of placebo recipients. Again, no cases of myocarditis or anaphylaxis occurred.

Local reactions such as pain or tenderness occurred within seven days. And again, fatigue was the most common systemic symptom in children two to four, and irritability and drowsiness were the most common symptom reported by parents in children six to 23 months. Overall, the reactions were comparable after doses one, two and three. Most symptoms were mild and resolved after a day or two. Next slide.

But again, specifically highlighting fevers, they were reported with similar frequency after both the vaccine and placebo, and similar frequency after doses one, two and three. Most fevers were reported on days one and two after any of the doses and lasted for around a day. Next slide.

So, in conclusion, again, the antibody levels seen after these three doses produced similar antibody levels seen after two doses in the young adult population. The reactogenicity or the symptoms after a vaccine were similar after each of the three doses and similar to what was seen in placebo. However, the efficacy estimates after these three doses are difficult to interpret given small numbers and limited follow up time. And ACIP did talk about the impact of that longer interval in the trial between dose two and dose three, that we really don't know what the efficacy will look like when it's given at that eight-week interval as authorized. Next slide.

So, overall, in summary, with the data that we are able to review -- next slide.

Since the beginning of the pandemic, among children six months to four years of age, there have been over 2 million cases, over 20,000 hospitalizations, and tragically over 200 deaths. COVID can cause severe disease and death among children, including children without underlying medical conditions. We also know that future surges will continue to impact children, with unvaccinated children remaining at higher risk of severe outcomes. Next slide.

These were the first clinical trials for COVID conducted during the Omicron predominance, but at different months and incidence levels during Omicron. So, in addition to differences in the number of participants and the differences in follow up time, the incidence levels impacted the COVID-19 case accrual and uncertainty in our efficacy estimates. Because of that, we really can't compare the estimates for these two vaccines. However, we do know both vaccines met the noninferiority criteria for neutralizing antibody levels, again, which is what FDA had set as the criteria for authorization. Next slide.

But we do know a lot. So, in other age groups during Omicron, we've seen that the effectiveness was lower against infection, but was higher and more sustained against severe disease. While the clinical trials weren't powered to detect efficacy against severe disease in these younger children, we fully expect that similar patterns in this age group will be seen to what we've seen for everyone else ages five and over. Next slide.

So again, the current data are for a two-dose with Moderna or a three-dose Pfizer primary series. We will very closely monitor post-authorization effectiveness studies to help determine the subsequent timing and need for boosters. We acknowledge that immunocompromised children may also need additional doses for optimal protection. And Dr. Hall will get into those recommendations in just a minute. ACIP also talked about the two vaccine options in this

population may allow parents and providers a choice, which may increase uptake and acceptability. Next slide.

So ACIP voted unanimously to recommend both the two-dose Moderna series and the three-dose Pfizer series for use in young children. Next slide.

So, the self-knowledge check for my section is the current data for COVID vaccines for young children are for how many doses for Pfizer and how many doses for Moderna? Next slide. And again, as we've talked about, it's a three-dose Pfizer series and a two-dose Moderna series. Next slide.

So, at this I will hand it off to Dr. Hall who will walk through the clinical considerations for these vaccines. Thanks.

Thank you, Dr. Oliver. Next slide, please.

So, I'll start with updates for the pediatric vaccination schedule. Next slide.

The age ranges for the youngest group of children for Moderna and Pfizer are slightly different. Moderna includes ages six months through five years, while Pfizer includes ages six months through for years. To clarify, through means up to and including. This means the upper range includes the entire year through the last day before the next birth date. It is denoted by an N dash, and this applies to all the age ranges I'll be talking about today. Next slide.

First is the pediatric schedule for Moderna COVID-19 vaccine for this age group. Starting at the top in teal, for people who are not moderately or severely immunocompromised, all children ages six months through five years should receive two primary doses separated by four to eight weeks. Shown at the bottom in gold is the schedule for people who are moderately or severely immunocompromised. All children in this group should receive three primary doses each separated by for weeks.

Just like when other COVID-19 vaccines were first authorized for a specific age group, only primary doses are authorized at this time. Booster doses are not currently authorized for this age group. But we would expect this in the future. Next slide.

So next, we'll look at Pfizer BioNTech for ages six months to four years. Starting in teal, for those who are not moderately or severely immunocompromised, they are recommended to receive a three-dose primary series, the first two doses separated by three to eight weeks, and dose two and three separated by at least eight weeks. Now looking at the gold schedule for those who are immunocompromised, it is actually also a three-dose primary series. However, the interval is slightly different between dose one and two. It's three weeks. And between dose two and three it's at least eight weeks. Again, there are no booster doses currently authorized for this age group. Next slide, please.

So, this slide just brings together the new recommendations with all existing pediatric recommendations for those who are not immunocompromised.

Depending on the age and product, children and adolescents should receive either two or three total doses if they are not immunocompromised. Next slide.

This slide puts together all the recommendations for children who are immunocompromised. As you can see more doses in this population, depending on age and product, children and adolescents who are immunocompromised should receive between a total of three and five doses. Next slide.

So now I'll talk more about that three or four-to-eight-week interval between dose one and dose two, and when it's appropriate to use the shorter authorized three- or four-week interval, and when it's appropriate to use the longer eight-week interval. This eight-week extended interval can be used in anyone ages six months through 64 years. Benefits and risks can be weighed with individual patients based on their characteristics and situations. Next slide.

So, some considerations for the shorter interval, this is going to be most appropriate when protection needs to be achieved soonest. So, some situations include being immunocompromised. So, this is why we already had that three-or-four-week interval on those slides. Another underlying medical condition that puts a person at higher risk for severe disease, living with a household member who has an increased risk for severe disease or cannot be vaccinated due to contraindication. Or living and going to school in or traveling to an area with high COVID-19 community levels. Next slide.

So, on the other hand, that longer eight-week interval might be more appropriate in situations when the priority is to reduce myocarditis risk. Some studies in adolescents and adults have shown the small risk of myocarditis associated with mRNA COVID-19 vaccines might be reduced with a longer interval. Use of this longer interval would be especially important in adolescents and young adult males will receive a higher risk. And another instance would be to optimize vaccine effectiveness, which may be increased with a longer interval, keeping in mind that this is going to be balanced with the risk of remaining not fully protected for a longer period of time. Next slide.

So now I'll move on to the new products. Next slide.

So, we'll start with the three Pfizer BioNTech vaccine products. Next slide.

The new product for ages six months through four years has a maroon cap. Each dose has an mRNA concentration of three micrograms. The product requires dilution with 2.2 milliliters of diluent, and the injection volume is .2 milliliters after dilution. There are 10 doses per vial. Next slide.

As a reminder, there are two other products currently available -- the product for ages five through 11 years with an orange cap, and the product for ages 12 years and older with a gray cap. These products should not be used in children ages six months through four years. Next slide.

Here's a sample of what the label of the maroon cap product will look like. There's a couple inaccuracies I'd like to note on this label for your awareness. So maroon cap via labels and

cartons may state a vial should be discarded six hours after dilution. Stability studies supersede the vial label and support discarding the vaccine after 12 hours from the time of dilution. Additionally, the label may state age two years to less than five years, but it can be used in children ages six months through four years. Next slide.

So now we'll take a look at the Moderna products. Next slide.

The new product labeled for ages six months through five years has a dark blue cap and a magenta label border color. Each dose has an mRNA concentration of 25 micrograms. The product should not be diluted and has an injection volume of 0.5 milliliters, and there are 10 doses per vial. Next slide.

The currently available product has a red cap and a light blue label. Although we are not discussing the older age group today because ACIP has not yet meant on recommendations for Moderna's six through 17, I'll mention the EUA for this product was amended last week from ages 18 years and older to include ages 12 years and older. So that's why you see 12 years on this slide. Primary series dose continues to be 100 micrograms or 0.5 milliliters, so a different concentration than this new product. Next slide, please.

Here's a look at the label for six months through five-year formulation with the magenta border. There's nothing particular to note on this label, however. Next slide.

So, in deciding what to give for those who age up during their series, children should receive the age-appropriate vaccine product and follow the schedule based on their age on the day of vaccination, regardless of their size or weight. Because of how vaccines work, they typically require low quantities of active ingredients. Different dosages are evaluated during vaccine development to determine the lowest effective dose for the target group. Clinical trials evaluate various dosing regimens and determine the best dosage and schedule that produces an adequate immune response which is both safe and effective.

So, we commonly get the question about weight and age. So, this is some of the reasoning behind the dose on the day of vaccination. So, if a person moves from a younger age group to an older age group during the primary series, or between the primary series and receipt of booster doses, which does not apply to this age group, they should receive the vaccine dosage for the older age group for all subsequent doses. And we'll walk through some examples. I'll also note FDA authorization allows for different dosing for certain age transitions. And that's what I'll walk through on the next few slides. Next slide.

So, this first scenario is a bit confusing, and I know I've already seen questions in the Q&A about this. So, the big question is on children who turn from age four to five between any dose in the primary series who are receiving Pfizer BioNTech. Because the younger age group has a three-dose primary series, and that older one has a two-dose primary series. So, it is extra confusing. So essentially, there are two different scenarios that you could go down.

For children who age from four to five during any dose in the primary series. The first scenario is that they receive a two-dose series with both of those being the orange cap formulation for

people ages five to 11 years. So, this does mean that a four-year-old who would age up to five years during that transition period can go ahead and start a two-dose orange cap series. That is one of their options. Next slide, please.

So, the second option has options within the option. So, the second option is a three-dose primary series. And that would be initiated with the product for ages six months to four years, or the maroon cap. In this scenario where you've chosen a three-dose series, dose two and three may be with either the product for ages six months through four years, or the product for ages five through 11 years.

And I apologize, there is a typo on the slide for that second formulation there. So, in other words, either the orange cap or the maroon cap. So, it would be dose one maroon cap, dose two orange or maroon cap, and dose three also can be orange or maroon cap. Next slide, please.

So, for interchangeability COVID-19 vaccines continue to not be interchangeable, including for this new age group. The same mRNA vaccine product should be used for all doses in the primary series. In exceptional situations in which the mRNA vaccine product administered for a previous dose of the primary series cannot be determined or is not available, either age-appropriate mRNA COVID-19 vaccine products may be administered at a minimum interval of 28 days between doses to complete the vaccination series. Next slide.

So, if this exceptional situation occurs, or if a child receives a different mRNA product for the first two doses in error, they should receive a third dose of either mRNA vaccine eight weeks after the second dose to complete a three-dose primary series. So, let's look at that visually. Next slide.

So, say the child started with Pfizer. This is essentially what it would look like. Pfizer would be dose one, dose two Moderna either because of that exceptional situation or by error. So, you have them at dose three, you can give either Pfizer the maroon cap, or Moderna the dark blue cap and magenta label border. Next slide.

So, this just literally flips the doses, and I see we got another typo on this slide. I apologize for that. So, the point here is that it doesn't matter what order the mixed series is in. It can be Pfizer and then Moderna or it can be like this slide shows, Moderna and then Pfizer. Regardless of the order, the third dose can be either Pfizer or Moderna. Next slide, please.

Now I'll walk through a few administration topics. Next slide.

So, for administration for children six months through two years, the injection site is the vastus lateralis in the anterior lateral thigh. For children ages three years and older, the site is the deltoid muscle which is going to be familiar. Job aids on injection site by age can be found on this slide. Next slide, please.

So, we get a lot of questions about comfort and restraint techniques in this younger age group. So, I wanted to call out this great training video. So, for both children and adults, the best

position and type of comforting technique should be determined by considering the patient's age, activity level, safety, comfort, and administration route and site.

Parents play an important role when infants and children receive vaccines. Parent participation has been shown to increase the child's comfort and reduce the child's perception of pain. Holding infants during vaccination reduces acute distress. So, I've linked this training video as I mentioned, and this demonstrates comfort and restraint techniques with three groups of children - infants younger than age 12 months, children 12 through 35 months, and children three years and older. Next slide.

Another common question we get is on coadministration. COVID-19 vaccines may be administered without regard to timing of other vaccines. So, this includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day, and at any time before or after another vaccine. So, there's no required interval.

Extensive experience with non-COVID-19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone. However, data assessing the outcomes of simultaneous administration of COVID-19 vaccines with other vaccines are limited currently, including any potential increase in reactogenicity when they are administered at the same visit. Next slide.

So, in accordance with general best practices, routine administration of all age-appropriate doses of vaccines simultaneously is recommended for children for whom no specific contraindications exist at the time of the healthcare visit. So, when deciding whether to administer another vaccine with COVID-19 vaccine, providers and parents or guardians may consider whether a child is behind or at risk of becoming behind on recommended vaccines.

During COVID-19, children may have gotten behind on their routine vaccines. The likelihood of the child returning for another vaccination and avoiding that missed opportunity. The risk of vaccine preventable diseases, and the risk of severe disease if infected. And the reactogenicity profile. Next slide.

So best practices for multiple injections include labeling a syringe with the name and dosage of the vaccine, lot number, initials of the preparer and exact beyond use time if applicable. As a reminder, COVID-19 vaccines are a little unusual with those short beyond use times. Administer each injection in a different injection site. Recommended sites have multiple injection sites, and separate those by one inch or more if possible. And administer COVID-19 vaccine and vaccines that may be more likely to cause a local reaction in different limbs if possible. Next slide.

So finally, in this section with more products available, its important providers continue to put practices in place to avoid errors. So, this first link on the slide is the clinical guidance if errors do occur. And the second link on this slide is strategies to prevent errors, which is categorized by the type of error. Next slide.

So finally, I'll cover adverse events and patient counseling. Next slide.

In clinical trials, children tended to experience similar but fewer side effects compared with adolescent or young adults. Providers should counsel parents and guardians on potential side effects. Local side effects may include pain, swelling and redness at the injection site, along with lymph nodes swelling in the armpit or groin area on the same side as the vaccinated limb. Systemic side effects may include fever, fatigue, headache, chills, myalgia, arthralgia, as well as irritability, crying, sleepiness, and loss of appetite in infants and younger children. Next slide.

Febrile seizures were rare in COVID-19 vaccine clinical trials for young children. In most cases, simultaneous vaccination in general does not lead to higher rates of febrile seizures, although administering more than one vaccine at the same clinic visit has been associated with increased risk for febrile seizures in some studies. The impact of coadministration of COVID-19 and routine vaccines on the risk of febrile seizures have not been specifically studied.

Febrile seizures are not uncommon in general and can occur in infants and young children with any condition that causes the fever. Up to 5% of children younger than five years will have at least one febrile seizure. These can occur after vaccination, but are uncommon. CDC will closely monitor for febrile seizures following COVID-19 vaccination in young children. Next slide.

And finally, I just want to point out some resources. Next slide.

So first are CDC's Interim Clinical Considerations and associated supplemental material. So the first link leads you directly to the clinical considerations. The second is commonly asked questions about the clinical considerations. And finally, is an at-a-glance schedule for COVID-19 vaccination. Next slide.

Next are clinical resources and job aids by vaccine product, which can be found on the link listed at this slide. These webpages have actually been recently redesigned and they are super easy to use. This is going to include things like standing orders, prep and admin summary, storage and handling summary. And they also have added a new at-a-glance resource for both Pfizer and Moderna vaccines. Next slide.

Finally, there's some resources for educating vaccine recipients and parents and caregivers, including social media graphics, posters, videos, customizable vaccination letter template for parents, factsheet for parents, and more, which can be found on the links on this slide. Next slide. So I'll just wrap this up with a knowledge check. So the question is, what is the interval between the second and third primary doses for children ages six months through four years that receive Pfizer BioNTech COVID-19 vaccine? Is it at least four weeks, at least eight weeks, at least four months, or at least five months? Next slide.

So, the answer is at least eight weeks. And this applies to both the schedule for people who are not immunocompromised and people who are immunocompromised. I wanted to specifically call out this interval, because if you are familiar with COVID-19 vaccination, if you're not a new provider and you've been doing it for a while, for the schedule for people who are immunocompromised for our older age groups, we're used to that being a four-week interval. So I wanted to specifically call out that this is going to be different with this younger age group for Pfizer. It is an eight-week interval. Next slide.

And now I'll pass it over to Dr. Chatham-Stephens.

Great, thanks so much. I'm just going to take a few minutes to chat about some of our planning efforts that have gone into making sure that this vaccine program is a success. So, our goal in this vaccine rollout for children under five years old really mimics our overarching goal in the five to 11 and adolescent vaccine programs. That is to really try to ensure that all children have access to the vaccine. Next slide, please.

And similar to the vaccine rollout for children five to 11 years old, we're planning for an all of the above approach, which you can see on this slide. Working to ensure vaccine is widely available in different locations throughout communities, trying to meet families and children where they are as much as possible. But we do understand that there will be some key differences between the five to 11 vaccine program and the vaccine program for children under five years.

For example, for five- to 11-year-olds, approximately one-third were vaccinated in pharmacies, and just under 10% in school located vaccination clinics. We anticipate that these two settings in particular will be less prominent in the under five vaccine program, in that primary care physicians such as pediatricians and family practice doctors in the medical home such as private pediatric clinics, federally qualified health centers, local health departments, et cetera, will play a much larger role, especially for the younger children.

We do still anticipate that pharmacies will play a critical role, for example, perhaps in having vaccine available at night, on weekends and holidays when those clinics may be closed. And local health departments especially in rural areas and federal entities such as IHS and HRSA's federally qualified health centers and rural health clinics will continue to serve critical roles in contributing to vaccine equity.

In addition, we anticipate that early care and education programs like Headstart and other support programs such as WIC will play more prominent roles in this vaccine program given their roles as trusted messengers for families of children in this age group. Next slide, please.

So, to estimate how well a network of likely pediatric vaccine providers would cover children under five years of age, a mapping analysis was conducted to assess the proportion of children under five years that reside within five miles of a likely vaccine provider. We considered as likely vaccine providers approximately 18,000 non-pharmacy providers that have ever administered vaccines to children five to 11 years of age, assuming they will administer a vaccine to children under five as well, and approximately 4,000 pharmacies that expressed interest in offering vaccines to children under five.

The analysis found that when these two sets of providers are mapped and combined, overall approximately 85% of children under five years reside within five miles of a likely vaccine provider, and approximately 94% reside within 10 miles of a vaccine provider. Next slide, please.

We know that vaccinating in the medical home is incredibly important as the medical home provides comprehensive primary care that facilitates partnerships between children, families and clinicians. Routine immunizations typically occur in the medical home, as we all know. As an example, for the 2020 to 2021 flu season, approximately 80% of children six months to four years of age received their flu vaccine in their doctor's office. This is compared to pretty low percentages of children this age who are vaccinated in a pharmacy. So, under 1% of children six to 23 months old, and approximately 4% of children two to four years old.

And in addition to getting COVID-19 vaccination and other routine childhood immunizations, medical homes are obviously great places for children to get recommended screenings for a variety of issues, including developmental and vision screening, and anticipatory guidance that helps them thrive in a safe environment. Next slide, please.

So, to try to get at the COVID-19 vaccine practices and intention to vaccinate children aged under five years among some of these pediatric clinicians and medical homes, we surveyed several thousand vaccines for children providers back in March. We've included some of these preliminary unpublished results for all providers, as well as results by urban or rural location. And just please note that on this slide, the results are limited to those who are enrolled in the COVID-19 vaccination program.

Most VFC providers have administered a COVID-19 vaccine to children aged five to 17 years at 85%. And almost three-quarters of all providers intend to offer COVID-19 vaccination with children aged less than five years. The percentage is higher for urban providers at 76% compared with rural providers at 67%. And since not all clinics will have the vaccine and not all children have a medical home, we also asked whether the practice intends to offer COVID-19 vaccination to children who are not currently patients of the practice, with approximately half of all providers saying that they would do so. The percentage is higher for rural providers at 58% compared with urban providers at 49%. Next slide, please.

And here are just some of the select activities we've conducted to support health departments, clinicians and others. During the past several months, we disseminated operational planning guides that included characteristics of the vaccines, some key planning assumptions, and a planning checklist. We're currently working on a Dear Colleague letter for VFC providers, emphasizing the importance of their role in this vaccination program and providing some tips and resources. Our vaccine competence colleagues have also engaged in a variety of vaccine competence boot camps, which are these really great interactive trainings to provide partners and participants with strategies for building vaccine competence in their communities.

Some examples that are particularly relevant to this discussion include boot camps with the National Association of School Nurses, Early Care and Education Partners, and YMCA. We've also shared some jurisdiction-specific maps of likely vaccine providers for children under five years. Jurisdictions can use these maps to identify and then address any gaps in provider availability. Next slide, please.

We just wanted to highlight on this slide some of the communication resources that are available for vaccine providers. We recently posted a website for providers on vaccinating children with

disabilities, which lists some strategies providers can implement to make vaccination settings as welcoming as possible to children with disabilities. We also have an updated quick conversation guide that helps empower clinicians to answer questions that parents and caregivers may have about the vaccines. You know, we just wanted to highlight our thanks to AAP for their input on this most recent update.

And we're also working on a Medscape commentary for late summer that will remind clinicians to incorporate COVID-19 vaccines and routine childhood immunizations into any back to school visits. Next slide, please.

And here we have some communication resources that are aimed at parents and caregivers. We've updated various webpages including an FAQ page and six things to know about COVID vaccination for children page. You can see those highlighted to the right on this slide. And just like for clinicians, we posted a page aimed at parents on vaccinating children with disabilities. That's on the bottom right of the slide here. In addition, we have fact sheets available in a variety of languages that folks can use. These and other resources are available at the link on the bottom of the slide. Next slide, please.

And finally, just a reminder about vaccines.gov, which really serves two major purposes. It, one, enables the public to identify nearby providers with vaccine and stock, and learn how to make an appointment. And two, enables providers to report their COVID-19 vaccine inventory. The search function for under five vaccines went live on vaccines.gov yesterday. A new function will also be added potentially later this week that will enable the minimum age that can be vaccinated at a location in months and years to be displayed. You can see an example screenshot of this function on the right of the slide.

In addition to vaccines.gov, we continue to encourage parents and caregivers to reach out to their child's pediatrician or family practice doctor, their local health department, pharmacy, et cetera, to ask if they have the vaccine, understanding that not every vaccine or pharmacy has gotten their vaccine yet. We know that some vaccine providers are waiting for the emergency use authorizations and CDC recommendations before ordering their vaccine. They wanted to see the data to help them decide which of the two vaccines to order.

So, we really expect the vaccine provider network to expand as these providers order their vaccine post-EUA or post-ACIP receive their vaccine. We also wanted to highlight that some vaccine providers may not begin notifying their patient population or opening up vaccine appointments until they have vaccine in stock. So just to finish, we do anticipate that the vaccination program is going to ramp up in the following days and weeks, with more and more doses and more and more appointments becoming available. Next slide, please.

All right. So, here's our self-knowledge check. How is CDC supporting health department's clinicians and other partners in vaccine planning for children six months through four years of age? Next slide, please.

And the answer here is E, all of the above. Our goal once again is really to ensure that all eligible children under five years of age have access to this particular vaccine. Thanks so much.

Hi, so I am excited to share some updates that we've recently made to V-safe. Next slide.

As a reminder, V-safe is a voluntary smartphone-based safety surveillance system that allows anyone to register after any dose of COVID-19 vaccine. Children 15 years of age or younger must be registered by a parent or guardian. Parents can add a child to their own account and complete surveys on their behalf even if they didn't participate in V-safe themselves. Pictured on the slide is our landing page, which we've updated to make this process easier for parents. Next slide.

V-safe health surveys are sent daily during the week following each dose of vaccine and include questions about local injection site and systemic reactions and health impacts. We've recently added new surveys that were specifically designed with young preverbal children in mind. Next slide.

V-safe relies on vaccine providers to promote registration in V-safe. There are a few ways to promote V-safe to parents and patients. You can verbally direct parents and patients to go to vsafe.cdc.gov, or provide a V-safe information sheet. Ideally, for young children, this should occur before vaccination. There are also informational V-safe posters that can be displayed. These printouts have recently been updated to make the registration process easier for parents to understand. The printouts and additional information are available at the link listed at the bottom of the slide and are available in five languages. Next slide.

So, a quick self-knowledge check. True or false, a parent or guardian must be registered with V-safe in order to add a child to their account? Next slide.

The answer is true. Children 15 years of age or younger must be registered by a parent or guardian. Parents can add a child with their own account and complete surveys on their behalf even if they didn't participate in V-safe themselves. Next slide.

Now I'm briefly going to describe VAERS, or the Vaccine Adverse Event Reporting System. VAERS serves as an early warning system for vaccine safety. It's comanaged by CDC and FDA. Anyone can submit a VAERS report regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event. Next slide.

This is a screenshot of the various websites. Highlighted in the red box is the link for the VAERS form. Next slide. And this is a screenshot of the VAERS form. Next slide.

Another quick self-knowledge check. A VAERS report may be submitted by A, a healthcare provider. B, a vaccine manufacturer. C, a member of the public like a patient or a parent. D, all of the above. Next slide.

The answer is D, all of the above. Anyone can submit a VAERS report, regardless of the plausibility of the vaccine causing the event or the critical seriousness of the event. And this is my final slide. So back to the moderator for Q&A.

Presenters, thank you so much for providing our audience with this very timely information. We will now go into our Q&A session. Joining us for the Q&A session are Dr. Sarah Meyer, Chief Medical Officer. Dr. Evelyn Twentiman, a Medical Officer, and Chris Dugar, a Senior Public Health Advisor. And they are all with CDC's National Center for Immunization and Respiratory Diseases.

Please remember that to ask a question using Zoom, click the Q&A button at the bottom of your screen and then you can type your question. Please remember that we receive many more questions than we can answer during our webinar sessions.

Our first question, can you please review co-administering COVID-19 vaccine and routine vaccines, and include whether any vaccines cannot be co-administered?

I can jump in on that one. COVID-19 vaccines may be administered without regard to timing. So they can be co-administered at the same clinic visit and any time before or after. So, if you don't catch them at the same clinic visit, you don't have to wait a certain period. You have not missed that opportunity. And this applies to all routine vaccines. There's a weird exception with the monkey pox vaccine, but that's not going to apply to this age range of kiddos. But for adults, that would be my only call out.

Okay, thank you. Our next question asks -- and we actually received a handful of questions about this topic. But can you discuss whether pharmacists can give this vaccine to this age group?

Hey, this is Kevin Chatham-Stephens. So yes, the Prep Act allows pharmacists and other related pharmacy clinicians to vaccinate down to the age of three years. And that's across the country -- does not vary by state. For a child to get vaccinated under three years in a pharmacy, it would need to be in one of those pharmacies that has a clinic within it, such as a Minute Clinic or Little Clinic, something that has a nurse, nurse practitioner or another type of healthcare provider other than a pharmacist that can administer the vaccine.

Okay, thank you very much. We received quite a few questions on this topic. So, if you could address this kind of both generally and specifically, where possible. But what do I do if a child ages from four years old and then to five years old during their Pfizer primary series?

Okay, I can address that. And I see I've caused some confusion by mentioning a typo. The typo was not in any of the doses or the intervals on that slide. In the intro, I had called the product six through 11 years instead of five through 11. So, I want to clarify that first. Now I'll dive in.

So, if a child ages from four to five and is receiving the Pfizer series, there are two scenarios. They can either receive a two-dose series of the orange cap product for people ages five through 11 years. And yes, they can start it at age four, provided that they would age to five before completing the series. I know that's a bit of confusion.

And then the second scenario is a three-dose primary series initiated with the maroon cap for ages six months through four years. So, if initiated with the maroon cap and they'll age to five

some time before completing that series for the second dose, they can receive the maroon cap or the orange cap.

And for the third dose, they can also receive the maroon cap or the orange cap. So, a lot of possibilities. If you can dream it, you can do it--situation, within reason, with these vaccines.

Thank you. Our next question asks if there is an observation period recommended or required after administering these vaccines.

Okay, I can jump in for that one as well. So, there is a recommended observation period after COVID-19 vaccination. It's going to be the same observation period that we have for all other age groups. So, it's a 30-minute period if the person has a contraindication to a different type of COVID-19 vaccine.

So that's not really going to apply to these little kids, because they can't get Janssen which would be the other type of vaccine. If they have a history of a non-severe immediate allergic reaction after a previous dose. So, if they're getting their first dose, it wouldn't apply. History of immediate allergic reaction of any severity to non-COVID-19 vaccines or injectable therapies, or a history of anaphylaxis due to any cause. If they don't fall in any of those groups, the recommendation is 15 minutes.

Thank you. Our next question asks about vaccine site injection. Referring to the slide where that was laid out, are the vaccine site injection locations -- is that more of a suggestion or a requirement?

So as for the site, it is recommended that six months through two years be the vastus lateralis in the anterior lateral thigh. That is the primary recommended site. And three years and older, the deltoid muscle. So, there are exceptions.

If you're using a five-eighths to one-inch length needle with the deltoid muscle, a five-inch needle may be used only the skin is stretched tightly and the subcutaneous tissue is not bunched. That would be an alternate site if there's any reason, they can't be vaccinated in the vastus lateralis. And it's sort of the opposite with the deltoid muscle. The vastus lateralis would be the alternate site if they cannot be vaccinated in the deltoid muscle for any reason.

Thank you. Our next question, should we screen for a history of febrile seizure?

No, there is no requirement to screen for a history of febrile seizures.

And our last question, for infants with documented prior infection, what is the recommended time interval before administering the first dose?

I am so sorry. The end of the question sounded like it was me, but it cut out at the beginning of the question for me. Could you say that one more time?

Of course. So, if anyone in this age group has documented prior COVID-19 infection, how quickly can they get the first dose of the series administered?

Okay, perfect. Yes, three months -- three months after positive test if asymptomatic, or three months after symptom onset.

Thank you very much for answering the question. And thank you to all of our presenters and those who participated in the Q&A session. Thank you for sharing your expertise with us today. All continuing education for COCA Calls are issued through the CDC training and continuing education online system at <https://tceols.cdc.gov>.

Those who participate in today's live COCA Call and wish to receive continuing education, please complete the online evaluation and post-test before July 25th, 2022 with the course code WC4520-062222, the access code is COCA 062222. Those who will participate in the on-demand activity and wish to receive continuing education should complete the online evaluation and post-test between July 26th, 2022, and July 26th, 2024 and use course code WB 4520-062222. The access code is COCA 062222.

Continuing education certificates can be printed immediately upon completing your online evaluation. Accumulate transcripts of all CDC ATSDRCEs obtained through the CDC training and continuing education online system are maintained for each user. Today's COCA Call will be available to view on demand a few hours after the live recording ends at emergency.cdc.gov/COCA.

A transcript and closed caption video will also be available on demand on the COCA call web page shortly after that. Continuing to visit emergency.cdc.gov/COCA to get more details about upcoming COCA Calls, as we intend to host more COCA Calls to keep you informed of the latest guidance and updates on COVID-19. We also invite you to subscribe to receive announcements for future calls by visiting emergency.cdc.gov/COCA/subscribe/asp.

You will also receive other COCA products to help keep you informed about emerging and existing public health topics. We also invite you to stay connected with COCA by liking and following us on Facebook at facebook.com/CDC Clinician Outreach and Communication Activity.

Again, thank you for joining us for today's COCA Call. Have a great day.