Good afternoon. I'm Commander Ibad Khan, and I'm representing the Clinician Outreach and Communication Activity 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, Pediatric COVID-19 Vaccines, CDC's Recommendations for Pfizer-BioNTech COVID-19 Vaccine Primary Series in Children 5-11 years old. All participants joining us today are in listen-only mode. Continuing education is not offered for this COCA Call.

After today's presentations, there will be a Q&A session. You may submit questions at any time during today's presentations. 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-- the video recording of this COCA Call, will be posted on COCA's web page and available to view on demand a few hours after the call ends. If you're a patient, please refer your questions to your healthcare provider. For those who may have media questions, please contact CDC Media Relations at 404-639-3286 or send an email to media@cdc.gov.

I would now like to welcome our presenters for today's COCA Call. We are pleased to have with us Lt. Cmdr. Sara Oliver, who's in the Vaccine Task Force as part of CDC's COVID-19 Response and serves as the Co-lead for the Advisory Committee for Immunization Practices. Dr. Kate Woodworth, who's on the Vaccine Task Force as part of CDC's COVID-19 response and serves on the Advisory Committee for Immunization Practices COVID-19 Vaccines Workgroup; and Cmdr. Kevin Chatham-Stephens, who's on the Vaccine Task Force as part of CDC's COVID-19 Response and serves as a Pediatric Vaccine Readiness and Implementation Lead.

It is my pleasure to now turn it over to Lt. Cmdr. Oliver. Please proceed.

[Sara Oliver:] Thank you so much. Next slide. So, briefly, what we'll be doing today is walking through the data that was presented at the ACIP meeting earlier this week and the discussion they had at the ACIP meeting that led to the vote. So, this slide shows the epi curve across the pandemic by age. Over 1.9 million cases among children 5 through 11 years of age had been reported to CDC. Next slide.

This slide shows the proportion of total cases by age group. You can see that children ages 5 through 11 years shown in the darker blue are making up a greater proportion of total cases, representing 10.6% of cases, the week of October 10, although they only represent 8.7% of the population. Next slide.

So, this slide shows the weighted infection-induced antibody seroprevalence estimates by age group for September of 2021 for 47 US jurisdictions. Seroprevalence in children aged 5 through 11 years is estimated to be 38%, which is higher than seroprevalence estimates among adults and similar to estimates in children aged 12 to 17 years. We know seroprevalence varies greatly by state and by jurisdiction with a range from 11 to 61%. And using seroprevalence to estimate the cumulative number of infections, the number of infections reported of cases by age was calculated. For the general population including adults, the jurisdiction level infection-to-case ratio was a median of 2. 4 with a range of 2 to 3.9. But, for children, the infection to case ratio was substantially higher with a median of 6. 2 and a range of 4. 7 to 8. 9. Next slide.

So, we compared COVID-19 and influenza associated hospitalization rates among children aged 5 through 11 years using data from COVID-NET and data from the Influenza Hospitalization Surveillance Network or FluSurv-NET. Both are population-based surveillance systems. FluSurv-NET looks at hospitalization rates from October 1st through April 30th of each year, the timeframe that's typical for the US influenza season. Then the gray box is the timing outside of the typical flu season. So, you can see in blue, green and red are the rates of influenza-associated hospitalizations during that flu season for the 2017-2018, 2018-2019 and then the 2019-2020 seasons. And then, for comparison, we extended the hospitalization rates out into the gray box.

So, influenza 2020-2021 rate is in black at the bottom of the graph, it was extremely low, with only nine hospitalizations being reported across all pediatric age groups. This is likely because, during this season, mitigation measures such as school closures and mask wearing were in place, decreasing influenza transmission. During the same time period shown here in yellow is the COVID-19 associated hospitalization rate for children in the same age group. It was calculated for a one-year period of October 2020 through September 2021 because COVID-19 transmission has been occurring throughout the year.

You can see that this in yellow was similar to the influenza associated hospitalization rates for the 2017-2018 and 2018-2019 seasons, the blue and green, but was lower than the 2019-2020 season shown in red. The low influenza hospitalization rate for this past season in black suggests that the annual rate of COVID hospitalizations may have even been much higher than the influenza hospitalization rates during typical flu seasons had the COVID mitigation measures not been in place. Next slide.

As of October 22, there have been over 730,000 COVID-19 deaths reported in the US. The vast majority are in adults. However, we know deaths in children have been reported. Here the counts of reported COVID-19 deaths by age between January 1, 2020, and October 16 of 2021, there were 94 COVID-19 deaths reported among children 5 through 11 years. Among deaths in this age group, COVID-19 associated deaths accounted for 1.7% of all deaths during the same time period. Next slide.

So, overall, as we think about the epi of SARS-CoV-2 in children aged 5 through 11 years, we know there have been 1. 9 million cases reported in this age group. Infections in children are less likely to be reported as cases than infections in adults. Children 5 through 11 years of age are at risk of severe illness from COVID. There have been over 8300 hospitalizations from COVID in this age group alone. The cumulative hospitalization rate for COVID is similar to pre-pandemic influenza seasons, and this is in the setting of the intense mitigation efforts in place over the course of the pandemic.

Hospitalization rates for COVID likely would have been much higher without these mitigation efforts. Then severity is comparable among children hospitalized with fluid COVID with approximately one-third of hospitalized children 5 through 11 years requiring ICU admission. In addition, MIS-C is the most frequently -- is most frequently reported among children in this 5 through 11-year age group, and over 2300 cases of MIS-C have been reported in this age group.

Additional post-COVID conditions have been reported in children, and secondary transmission from these young school-aged children can and does occur in household and school settings. We didn't have time for this COCA Call to go through all of this data, the epi data. But the slides are posted on the ACIP website if anybody wants to go deeper into that data. Next slide. Then, as we put this epi for COVID in other context, here we have the annual hospitalizations per year for other diseases prior to when they had a recommended pediatric vaccine. You can see that it varies by disease, but COVID in this 5-to-11 year old population is in line with many of these diseases that we recommend routine vaccination for. Next slide.

And this slide shows the average deaths per year prior to recommended pediatric vaccines. Overall, again, it varies by disease. But COVID in just this 5 through 11-year-old age group only is among the highest deaths across these now vaccine preventable diseases. Next slide.

Through collaborations with the CDC Modeling Team and the COVID-19 Scenario Modeling Hub Consortium, there were multi-model projections that were created to evaluate the impact of vaccination of children 5 through 11 years of age on COVID cases and hospitalizations in this population. The models assumed vaccination started in early November and would have had uptake rates similar to what we see in 12-to-17-year old's. The scenarios project cases prevented in the absence or presence of pediatric vaccination and in the absence or presence of a more transmissible variant. The pool projections show that vaccination in this age group is expected to accelerate the decline in cases we're currently experiencing, reducing the cumulative incidence nationally by an expected 8% from November of 2021 through March of 2022 and estimated to be a reduction of around 600,000 cases. Obviously, the emergence of a more transmissible variant would impact future COVID-19 epi and projected impact, and the models estimate that vaccination of 5-to11 year old's would dampen but not prevent a resulting resurgence. Next slide.

In addition to the severe outcomes of hospitalization, ICU admission and death, missed school is another potential adverse outcome of COVID illness and exposure among children. Numerous reports have described the negative impact on social, emotional and physical health of children with disproportionate impacts on children of color. Here we're showing data from the school dismissal monitoring system, which performs daily systematic searches of Google, Google News and Google Alerts to assess information on unplanned school closures, including the number of districts and individual schools as well as students and teachers impacted. In this school year to date, 2351 schools had unplanned closures, impacting nearly 1. 2 million students. You can see from the map on the right the range of school closures by states. And we also know for the 2020-2021 school year at least 19,000 school closures occurred in all 50 US states, affecting at least 12 million students. Next slide.

And a larger and growing body of literature describes the numerous indirect impacts of the COVID pandemic on children. While a few are highlighted here, it's by no means an exhaustive list. And we also know for all of these listed, children of color have been disproportionately impacted in these areas as well. Children have experienced worsening of mental and emotional health, widening of already existing education gaps. Children have experienced decreased physical activity and increased BMI, doubling in hospitalizations for new onset type 2 diabetes; decrease in healthcare utilization and routine immunizations; and an overall increase in adverse

childhood experiences, including an estimated 140,000 children that have lost a caregiver to COVID-19 with, again, significant disparities by race and ethnicity. Next slide.

So, in summary, we know children 5 through 11 years of age are at increased risk from severe illness from COVID. This includes hospitalization as well as MIS-C. We know we can see post-COVID conditions in children, and COVID in children leads to missed school for themselves and their communities. Wide use of an effective vaccine would reduce the public health burden of COVID in children 5 through 11 years of age. Next slide.

So now we'll walk through the data from the clinical trials as well as the potential benefits and risks discussed at ACIP. Next slide.

We have data from the Phase 2/3 clinical trial from the Pfizer-BioNTech COVID-19 vaccine. As we look at the ability to prevent lab confirmed symptomatic COVID. There was a 2:1 randomization of vaccine to placebo with a median follow-up time of 3. 3 months in the trial. We chose a primary efficacy endpoint to use the estimate among children with or without prior infection of SARS-CoV-2, as it best reflects what we may see in a real-world estimate. There were three COVID cases occurring at least seven days after dose 2 among 1400 children in the vaccine arm and 16 cases among over 700 children in the placebo arm, which resulted in a vaccine efficacy estimate of 90. 9.

The Phase -- the Phase 2/3 trial was designed in parallel to use immunobridging to evaluate efficacy. The immunobridging studies compare immunogenicity in a group of interest -- so, for example, those 5 through 11 years -- with a comparison group in which efficacy has been demonstrated in a clinical trial so, for example, those 16 to 25 years. The immune response to the vaccine in children 5 through 11 years was at least as strong as the immune response in young adults 16 through 25 years. Based on SARS-CoV-2 neutralizing titers measured one month after dose 2 in participants without evidence of prior infection. Next slide.

On serious adverse events from the initial enrollment group reviewed for all participants who received at least one dose. Serious adverse events on a safety expansion group, which is shown in the box, is also shown with an additional 1500 children in the vaccine arm and over 700 children in the placebo arm. The median follow-up time for the safety expansion group was two weeks. And you can see that none of the serious adverse events were deemed related to the vaccine in this -- in either group. Next slide.

Local and systemic events were solicited from participants in their -- from their parents or legal guardian via electronic diaries for seven days following each dose. Grade 3 or higher local or systemic reactions were reported in 2. 7% of children in the vaccine arm and 1% of children in the placebo arm. Most of these events were grade 3 with one grade 4 event of pyrexia in a vaccine recipient. Events were more common after dose 2. Pain at the injection site, fatigue and headache were the most common events. Next slide.

So that was the data from the clinical trial. ACIP also put this in context with what we know we would be experiencing in the real-world settings so thinking through what we know around COVID-19 vaccines and seropositivity with a focus on children. Specific data on this from the

clinical trial showed that around 9% of children in the trial were baseline SARS-CoV-2 seropositive. Post-vaccination antibodies were higher in children who were seropositive, and rates of local and systemic reactions as well as adverse events were lower in children who were seropositive. Then from the broader US studies, we heard previously that approximately 38% of children 5 through 11 have evidence of prior infection based on those seroprevalence estimates from the residual commercial lab sera.

Prior infection can result in some protection against infection. But it's not 100%, and it likely decreases over time. We know children have a greater proportion of asymptomatic infection relative to adults. An asymptomatic infection can result in lower antibody levels compared to severe disease. Next slide.

So, when we think through that balance of benefits and risks by seropositive status, we know that the Delta waves -- wave surges of pediatric COVID hospitalizations occurred, even with the known seroprevalence, suggesting that this alone is not sufficient to provide broad protection for children. We have limited data on rates of reinfection in children. Protection against asymptomatic or mild infection is still an important outcome in children. MIS-C typically occurs after asymptomatic or mild infection, and additional post-COVID conditions can also occur after mild infection.

We've administered over 400 million doses of COVID-19 vaccines to those 12 years of age and over, and no concerns have been identified in post-authorization safety surveillance with seropositive adolescents and adults. Individuals 12 through 64 years have seropositivity over 30%. Vaccine recommendations that require serologic testing would place unnecessary barriers to vaccination and would be quite difficult to implement. And while we may have limited data to estimate the impact of vaccination of seropositive children, the risks are minimal. Based on that, the balance of benefits and risks is favorable for vaccination of all children 5 through 11 years. Next slide.

So, we also walked through what those estimated benefits would be. This is the estimated benefits for every million Pfizer vaccine in children 5 through 11 years of age using recent incidents. We're projecting out over six months and using epi from mid-September. You can see for each million vaccinations given, we'd be preventing over 50,000 cases and hundreds of hospitalization and MIS cases in children. Next slide.

We do acknowledge that the recent epi estimate pulls from epi close to the peak of the recent Delta surge. So, we wanted to include other epi estimates for context. We know we're not always great at predicting COVID epi in the future, so we looked back at the pandemic average, smoothing out all the previous peaks and troughs. Those are the rates that are shown on the right with that pandemic average. But using this epi we would even be prevented -- predicted to prevent nearly 20,000 cases of COVID, 80 hospitalizations and 40 NIS cases. Next slide.

So, we balance those benefits when thinking through the potential risks of a vaccine-associated myocarditis. Identified rates of myocarditis are based on data for adolescents and adults receiving a 30-microgram dose of the Pfizer vaccine, which is different than the dose proposed for this age group, which is 10 micrograms. We'll hear more about that in the future

presentations. It's a rare event, the myocarditis, but it most commonly occurs in males 12 through 29 years of age; and no cases of myocarditis occurred in the clinical trials in this pediatric population. Next slide.

So, when we think about what the possible risks for myocarditis would be for children 5 through 11 years of age, the rates of myocarditis after vaccination in children this age are unknown. No cases occurred in the trials. And the underlying epi of viral myocarditis varies greatly between children 5 through 11 and children 12 through 17. Myocarditis is substantially lower in children 5 through 11 years of age. In addition, the dose in those 5 through 11 is a third of the dose used in adolescents. Both of these factors predicts that, if seen, any rates of myocarditis after vaccination in the 5-through-11-year-old population would likely be lower than anything that was seen in the 12 to 15 year old's. Next slide.

There was an entire talk on myocarditis at the ACIP meeting. So, for kind of a thorough review of that, I'll defer to that talk. And, again, we can provide the link for the ACIP slides on the ACIP website. But this was a slide from Dr. Oster, the cardiologist's talk. And if you look at this graph on the right, this is rates of myocarditis in the pre-COVID era. And you notice that just the underlying myocarditis in children 5 through 11 really is kind of the lowest rates of myocarditis that we see in a pediatric population. Next slide. So, this shows the rates of myocarditis after vaccination in what we see in the 12-to-15-year-old population per million second doses and could be acknowledging that this is likely an overestimate of anything we would see in the 5 to 11 year old's. Next slide.

So, when we think through the overall benefit risk balance, we include not only the known benefit for the prevention of COVID cases documented in the clinical trial but the broader benefits: prevention of hospitalizations, MIS-c and deaths, as well as the prevention of additional post-COVID conditions. There could be possible prevention of transmission in greater confidence in a safer return to schools and social interactions. Then, for the risks, we have data on the short-term reactogenicity and also the possible risks of myocarditis or other rare events that may be seen after mRNA vaccines. Next slide.

So, the overall summary of benefits and harms, the clinical trial demonstrated that the Pfizer-BioNTech COVID-19 vaccine is safe, immunogenic and efficacious in children 5 through 11 years of age. The trial wasn't powered to assess the rate of rare adverse events, but no cases of myocarditis were seen in over 3000 vaccinated children. As with all analyses we've done previously, the balance of benefits and risks varies by COVID incidents with the largest benefits in a higher incidence setting. But the balance of benefits and risks is favorable, regardless of the seropositivity rates. While many children 5 through 11 may be seropositive, there's an unknown duration of protection for asymptomatic infection in children. And we know that safety data is reassuring in the seropositive population. Next slide.

So, we also looked at several other factors that could go into a pediatric vaccination program and one of the factors being parental intent to have their child vaccinated. Among parents that have been surveyed, 34 to 57% say they plan to get their child vaccinated. This intent varied by several factors. Ninety percent of parents who were worried their child would get COVID reported an intent to vaccinate their child, compared to 7% of parents who weren't worried at all.

In addition, 82% of fully vaccinated parents reported intent to vaccinate their child compared to 1% of parents who were unvaccinated and don't plan to get vaccinated. And we know a recommendation from a child's healthcare provider is so important. Among parents of teens who discussed vaccination with their pediatrician, three-quarters of those whose pediatrician recommended the vaccination say that their child received at least one dose. Next slide.

So, we know that around half of parents say that they're likely to get their child vaccinated. Parents cited concerns for shorter long-term side effects such as fever, anaphylaxis, or myocarditis in their decision to vaccinate their child. And other factors were included in that like their parents own vaccination status or a provider recommendation. Next slide.

So, the ACIP workgroup and ACIP as a whole overall discussed that vaccine policy decisions are made on the balance of known benefits and risks to the individual. But we consider other benefits such as the prevention of transmission, greater confidence in a return to school or social interactions and risks such as extrapolation of myocarditis risk from other ages, as a part of a broader picture. We've experience with over 400 million doses of mRNA vaccines administered to people 12 years of age and over with a reassuring safety profile. And, overall, the benefits outweigh the risk, regardless of seropositivity rates. Next slide.

So, as we think through the direct impact of vaccination on a child 5 through 11, we know we have over 90% efficacy in the prevention of COVID cases. We likely have prevention of COVID-19 related post-COVID conditions, MIS, hospitalization, ICU and death and the possibility for more social interactions and uninterrupted -- uninterrupted school. Next slide.

But we also know that this child is a part of a family. Vaccination of this child could possibly prevent transmission to vulnerable family members. And if children aren't getting sick, parental participation on workforce may be more stable and predictable. Next slide.

And then the child was also within a community. Vaccination of the child could result in lower transmission within schools in the community and could have a more -- help all have a more confident return to in-person learning. Next slide.

So, since the beginning of the pandemic among US children 5 through 11 years of age, there have been 1. 9 million cases, over 8300 hospitalizations, over 2000 MIS cases and at least 94 deaths. Next slide.

COVID-19 is now vaccine preventable, so we have the ability to prevent this burden of disease, future hospitalizations and deaths from COVID-19 in children 5 through 11 years of age. Next slide.

So, the ACIP vote that occurred earlier this week was they recommended the Pfizer-BioNTech COVID-19 vaccine for children 5 through 11 years of age in the US under the FDA's emergency use authorization. Next slide.

So, I'll turn it over to Dr. Woodworth who'll walk through the interim clinical considerations for vaccines in this population.

[Kate Woodworth:] Thanks so much, Dr. Oliver. So, these interim clinical considerations provide additional information to healthcare professionals and public health officials on the use of COVID-19 vaccines and are informed by the ACIP and CDC's recommendation, data submitted to the FDA and other data sources such as the general best practice guidelines for immunizations and expert opinions. Next slide.

I'll start by reviewing -- reviewing the Pfizer-BioNTech COVID-19 vaccine formulation and dosages. And then I'll go into considerations for vaccine recipients, patients and parent or guardian counseling and end with vaccine formulation -- administration. Next slide.

And next slide. So, the Pfizer-BioNTech COVID-19 vaccine for children ages 5 through 11 years is a new and different formulation than the current formulation for those 12 years of age and older. The 5-through-11-year formulation comes in an orange capped and labeled vial as opposed to the purple vial for those 12 years of age and older. The dose is 10 micrograms, a third of the concentration in the mRNA -- of the mRNA in the purple-capped 12-year-and-older formulation. This formulation also requires a different injection volume and amount of Diluent. The orange 5 through 11 formulation contains 10 doses per vial. Next slide.

The 5-through-11-year orange-cap formulation is stable at ultra-low temperatures for up to six months and can be stored at routine refrigerator temperatures for 10 weeks. Next slide.

Similar to the 12-year-old and older population, children 5 through 11 years of age would receive two doses based three weeks apart. Currently, children ages 5 through 11 with moderate and severe immunocompromised are not recommended to receive an additional or third primary dose. But ACIP and CDC will continue to evaluate data to update these recommendations if needed. Booster doses are not recommended for anyone under eight years of age. Next slide -- 18 years of age. Sorry. Next slide.

Children should receive the age-appropriate vaccine formulation regardless of their size or weight. As opposed to many medications, vaccine dosages are based on age, not weight or body size. And, in general, the formulation and dosage should be based on the child's age on the day of vaccination. However, currently if a child turns from age 11 to 12, in between their first and second dose and received the 5 to 11 10 microgram orange-capped formulation for their second dose, they do not need to repeat the dose; and this is not considered an error under the EUA. Next slide.

So, moving on to some considerations for vaccine recipients, next slide, children with underlying medical conditions may be at increased risk for severe illness from COVID-19. However, as Dr. Oliver mentioned, severe COVID-19 can occur in children with and without underlying medical conditions. COVID-19 primary vaccination is recommended for everyone ages 5 years of age and older, regardless of underlying medical conditions. Next slide.

People with known current SARS-CoV-2 infection should defer vaccination at least until they have recovered from their acute illness, if they have symptoms, and have met criteria to discontinue isolation. Serologic testing to assess for prior infection is not recommended for the purpose of vaccine decision-making. Next slide.

COVID-19 primary vaccination is recommended for everyone ages 5 years of age and older, regardless of the history of symptomatic or asymptomatic SARS-CoV-2 infection or seropositivity. More than 7 million adolescents ages 12 through 15 have been fully vaccinated with Pfizer-BioNTech COVID-19 vaccine in the United States. In the general population, there have been no safety concerns associated with vaccination of those who had prior infection. Next slide.

Just to note, there are limitations to antibody testing. Antibody tests cannot determine when a person was infected. Antibody tests greatly vary in their sensitivity, particularly more than three months after infection. People can test positive on commercial antibody tests, even after markers of immunologic response such as neutralizing antibodies have waned. At this time, there is no FDA-authorized or approved tests that providers and the public can use to reliably determine whether a person is protected from infection. Next slide.

And now some considerations for counseling patients and parents or guardians. So based on the clinical trial data that Sara -- Dr. Oliver presented, children may experience fewer side effects than adolescents or young adults, and children with evidence of prior infection may have fewer side effects than those without evidence of prior infection. The expected side effects are similar to those seen in adolescence and include local reactions such as pain, swelling or erythema at the injection site; or systemic reactions such as fever, fatigue, headache, chills, myalgias, arthralgia and lymphadenopathy. The most common side effects were pain at the injection site and fatigue. While preemptive medication prior to vaccination is not recommended, routine antipyretic or analgesic medications can be taken for the treatment of post-vaccination local or systemic reactions if medically appropriate. Next slide.

As Dr. Oliver mentioned, myocarditis and/or pericarditis have occurred rarely in some people following receipt of mRNA COVID-19 vaccines, typically within a few days following receipt of the second dose. The observed risk is highest in males 12 through 29 years of age. The risk of myocarditis or pericarditis after receipt of an mRNA COVID-19 vaccine in adolescents and adults is lower than the risk of myocarditis associated with SARS-CoV-2 infection in adolescents and adults. Next slide. FDA has authorized and ACIP has recommended the Pfizer-BioNTech COVID-19 vaccine in children ages 5 through 11.

Based on the determination that the benefits of COVID-19 vaccination outweigh risks in this population, people receiving mRNA COVID-19 vaccine, especially males aged less than 30 years, should be made aware of the possibility of myocarditis or pericarditis on receipt of mRNA vaccines and should seek care for symptoms of chest pain; shortness of breath; feelings of having a fast beating, fluttering or pounding heart; and any cases of myocarditis or pericarditis after vaccination should be reported to the Vaccine Adverse Event Reporting System. Next slide.

And some considerations about administration, so COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day. This is all the more important as we begin influenza season to ensure that children are protected against both influenza and COVID-19 vaccines. If multiple vaccines are administered at a single visit, they should be administered at different injection sites separated by one inch or more. For younger children ages 5 through

10, if more than two vaccines are injected into a single limb, the vastus lateralis muscle of the anterior lateral thigh is the preferred site because of greater muscle mass. Next slide.

With the new formulation, there are additional possible administration errors. The clinical considerations website listed here and provided on the website for the COCA Call provides a table of possible administration errors as well as actions to take after an error has occurred. Next slide. We are updating many current tools to help providers get the information they need to provide these vaccines safely. And, as a reminder, all of the information discussed here can be found on the Interim Clinical Considerations For Use of COVID-19 Vaccines website, which has been updated to include information on children ages 5 through 11. Next slide.

The safety monitoring processes for COVID-19 vaccines are very robust, and healthcare providers play an important role. Here are ways that you can help. First is to report any adverse events to the Vaccine Adverse Event Reporting System or VAERS, even if you aren't sure if the vaccination caused the adverse event. Information on VAERS is included in the additional resources on the COCA website for this event. Additionally, encourage your patients' parent/guardians to enroll them in v-safe. Next slide.

I'd like to thank the many individuals who worked on these considerations. Next slide. And next slide. And I'll turn it over to Dr. Chatham-Stephens. [Kevin Chatham-Stephens:] Great.

Thanks so much, Dr. Woodworth. Can we go on to the next slide, please. We're going to pivot a bit and talk a bit about the planning that went into the launch of this vaccine because we know there's been a lot of work done at the federal level as well as at the jurisdictional level by our clinical partners, etc., to make sure that everyone is prepared for this vaccine. So, we just wanted to talk through some of those activities.

So, first, I'd really like to start off with some of the high-level implementation goals that we've had for the 5-to-11-year-old vaccine program during the past several months. You know, the first goal was really to reach the most and to meet families and children where they are as much as possible by enabling access to an availability of vaccine providers where populations are most likely to seek vaccination. Second, we wanted to ensure vaccine access for vulnerable and underserved pediatric populations. The third goal was to minimize any potential delays between FDA authorization of the vaccine and the initial rollout. And, finally, the fourth goal was to disseminate timely clinical guidance to jurisdictions and providers, and that's one of the reasons why we're here today. But to really achieve each of these, we're harnessing the existing robust pediatric vaccination network in the US, complementing that network with additional sites and building on successes and lessons learned from the adult and adolescent vaccine programs. Next slide, please.

Now we'll walk through our approach for reaching children through a variety of different clinicians and settings. In that first row, we have pediatricians and other pediatric providers such as family practice docs and nurse practitioners caring for patients in a medical home, which is the optimal location for many children to be vaccinated. Clinical settings such as federally qualified health centers or FQHCs, rural health clinics, health departments, Indian health service clinics among others can help ensure vaccine equity and broad coverage. We know,

unfortunately, that not every 5-to-11 year old has a medical home, so the medical home will be complemented by other vaccine providers. For example, in the second row, pharmacies will be leveraged to administer vaccines to children who may not seek or have access to care in a pediatric practice.

In addition, in that last row, schools can partner with vaccine providers such as health departments, pediatric clinics, FQHCs and pharmacies to host vaccination clinics at school. These school-located vaccination clinics can provide a convenient option for parents and caregivers who may experience challenges taking their child to a clinic. Next slide, please.

And, as announced recently by the White House as part of several key initiatives, more than 100 children's hospitals will also set up vaccination sites. These will be a critical part of efforts to provide vaccine access for all children but especially those with underlying medical conditions. And to really complement all the previous settings, jurisdictions may also use temporary community clinics, leveraging experience with these clinics from the adult and adolescent vaccination programs. Next slide, please.

So now we'll dive into a couple of slides about how jurisdictions have been planning for the 5-to-11-year-old vaccine. In late September, we surveyed jurisdictions to learn more about how they planned to use different types of vaccine providers and settings. Fifty-eight jurisdictions responded to this question regarding which providers they planned on using to deliver the vaccine. Please note that these options were not mutually exclusive. As you can see on the slide, jurisdictions seem to be using an all-the-above approach with most jurisdictions planning on using large pediatric providers, VFC providers, pharmacies, temporary community vaccine clinics and school-located vaccine clinics. Next slide, please.

In a follow-up survey, we asked jurisdictions to rank the settings in which they anticipated most children 5 to 11 years old would be vaccinated. Here we're showing the settings that were ranked either number one or number two by jurisdictions out of eight different options. Pediatric providers were the most highly ranked, followed by FQHCs and rural health centers, health departments and pharmacies. Next slide, please.

Next, I just want to show some data from a parental survey conducted by the University of Iowa, RAND and CDC in late September, early October. Among just over 1000 parents of children 5 to 11 years old, almost two-thirds felt comfortable having their child vaccinated in their regular doctor's office or clinic, followed by the pharmacy in another doctor's office or clinic. Approximately a quarter of parents felt comfortable having their child vaccinated at school with a parent present, and about 15% without the parent present. So surveys of both jurisdictions and parents do indicate that, you know, 5-to-11-year-old children will most likely be vaccinated across a variety of different settings. Next slide, please.

And I'll finish up with just a couple slides describing some of the support that we at CDC have provided to jurisdictions. As mentioned previously, we've conducted a couple jurisdictional surveys to help guide outreach and planning and identify key issues. We've also disseminated an Operational Planning Guide and some preliminary information about the Pfizer-BioNTech vaccine. The Operational Planning Guide included some key information about the vaccine,

assumptions to inform planning and strategies for jurisdictions to consider implementing as they roll out the vaccine.

For example, a checklist in that document included various tasks, such as jurisdictions routinely evaluating the adequacy of the provider network, identifying gaps and whether additional vaccination locations such as FQHCs, pharmacies, school-located vaccination clinics or rural health clinics may be needed to further increased equitable access and ensure vaccine equity. This particular document is available on the CDC webpage pictured on the right. And the document about the vaccine included a side-by-side comparison of the adult adolescent formulation and the formulation of 5 to 11 year olds'. Next slide, please.

CDC is also working to provide guidance on in support of school districts partnering with pharmacies to conduct school-located vaccine clinics. Some of our many resources for schools are available on the webpage pictured on the right. We've also conducted numerous listening sessions with a variety of public health, clinical and other partners to hear about potential challenges in the rollout of the vaccine and what resources CDC or others could provide to help facilitate the rollout. Next slide, please.

And, with that, I wanted to thank you all for your attention. And I'll turn it back to Cmdr. Khan. Thanks so much.

[Ibad Khan:] Presenters, thank you so much for providing our audience with such timely information. We will now go into our Q&A session. In addition to our presenters, we would also like to welcome Capt. Tom Shimabukuro, Mr. Chris Duggar and Dr. Sujan Reddy to our Q&A session. For our audience, please remember to ask a question using Zoom. Click the Q&A button at the bottom of your screen. Then type your question. And please note: We receive many more questions than we can answer during our COCA Call.

So, our first question for presenters is, are there any different vaccine contraindications for this patient population than either the adults or the adolescents that we should be aware of?

[Kate Woodworth:] Hi. This is Kate Woodworth, and I can take that question.

So, the contraindications are really the same, regardless of age. And so, the contraindications are really around the severe allergic reactions such as anaphylaxis. And so, history of severe anaphylactic reaction at their previous dose or a component of the COVID-19 vaccine or a known diagnosed allergy to a component of the COVID-19 vaccine. And, again, that information can be found on the clinical consideration's website.

[Ibad Khan:] Thank you very much. And we have received multiple questions about what to do when a patient receives their first dose as an 11-year-old and in between the interval waiting for the second dose, the patient turns 12. You mentioned about that -- the dosages and how it would not be an EUA error. However, we have audience members that are asking would it be -- can you say if it's okay for that child and as a 12-year-old to receive the adolescent dose?

[Kate Woodworth:] Yeah, sure. Happy to clarify this. But I do think it's important, and we are getting a lot of questions about this. So, generally, we are recommending that the child received the vaccine based on their age the day of vaccination. And so, if you have a child who is, you know, 12 years and one month of age and is starting their vaccine series, we would recommend they receive the age appropriate 12 and older vaccine formulation. In the scenario that a child starts their vaccine series when they're 11 years of age and will be getting their second dose when they're 12, we still have that same general recommendation that they should receive the vaccine based on their age the date of vaccination.

However, the UA does allow some flexibility here. And so, what the UA actually says is that they may receive for either dose, either the formulation for children ages 5 through 11 or the formulation for children 12 years of -- or individuals 12 years of age and older, so that's really where there's some flexibility. However, if the child is starting their series and they're 12 years of age, regardless of their, you know, weight or their size, we would recommend they receive the age appropriate 12 year and older formulation. I hope that answers some questions. But, again -- and we will have this information on the clinical considerations website. I know a lot of providers and parents will be asking this question as well.

[Ibad Khan:] Thank you very much for that. And, again, to reiterate, if you're looking for some of these additional resources, please visit this COCA Calls landing page at emergency.cdc.gov/coca. And you'll be able to find a lot of these resources as well as links to CDC's COVID-19 page.

Our next question is also something we're seeing multiple questions on, and that's just to revisit and explain a little bit about the differences or changes in the formulation between the adult and adolescent dose as well as for this patient population and any guidance that you have for providers to be able to effectively counsel their patients' parents regarding these changes or differences.

[Kate Woodworth:] Yeah. So, this is Dr. Woodworth, and I can start. But, other panelists, please feel free to jump in. So, the difference in the formulation has to come -- comes down to a difference in the buffer that was used, which I've seen pop up in a few questions and as well. And so, this buffer allows for greater stability and also greater certainty in the concentration of mRNA in this vaccine. So that was really one of the drivers behind the change in the formulation. But the active ingredient remains the same. And so, we can actually find the full list of ingredients on this clinical considerations website if you have questions to find out exactly what ingredients are in which formulation.

But that's one of the reasons that we're saying that the two formulations are not interchangeable, and children should get the age appropriate vaccine rather than just drawing up a third of the dose. We're not recommending that. We are recommending they receive the age appropriate vaccine. I don't know if any other panelists want to add to that, but I hope that answers the questions.

[Sara Oliver:] This is Dr. Oliver. I'll just add and, again, see if others -- because I know that this has been a question. But I would just point that both of these, the PBS buffer and the Tris buffer,

which are the two buffers used in the mRNA vaccines, are very safe, well-studied, you know, buffers that are used in a variety of medications. So, it's not a novel, new never-used-before buffer. It's just a slightly different one, as they adjusted the dose down they needed again to a slightly different buffer to ensure the exact dose to make sure that you are getting exactly 10 micrograms. But a traditional buffer that is used in other kind of ingest -- injectable formulations.

[Sujan Reddy:] And just to add to this, this is Sujan Reddy. And the excellent question about the tromethamine specifically, and that is the same buffer that's actually in the Moderna vaccine as well. And so, like Dr. Oliver was saying, it's used in a lot of other vaccines, including the Moderna one. Thanks.

[Ibad Khan:] Thank you very much. That's very helpful information. Along similar lines regarding administration, storage, etc. , can you revisit how long the pediatric -- this new pediatric formulation can be kept at room temperature if undiluted or unreconstituted? Or how long can it be kept if the diluent has been added at room temperature, that is?

[Kate Woodworth:] Yeah. So you -- I don't know if you are able to go back to the slides, but I think on slide 40 I did have this, the pediatric -- or, sorry, slide 41. But this new formulation is stable at the ultra-low temperatures for up to six months and can be stored at the routine refrigerator temperature so 2 to 8 degrees Celsius for 10 weeks. And I don't know if Chris Duggar wants to say anything about the differences between diluted versus not diluted.

[Chris Duggar:] Sure. This may be buried in the UA fact sheet. So sorry if it's been difficult to find. We'll make sure you can see it easily. But it can be held up to 12 hours after dilution reconstitution. We do know that the fact sheet tells you to give it 30 minutes to thaw, and that does not cut away from your 12 hours of use once you've diluted it.

[Ibad Khan:] Thank you very much, all. Next question is regarding v-safe. The question is, if parents have been vaccinated themselves and they signed up for v-safe, are they still able to register their children for v-safe, and can they use their same contact information if they're registering multiple children for v-safe upon immunization?

[Tom Shimabukuro:] Hi. This is Tom Shimabukuro with the Immunization Safety Office. I may not able -- may not be able to provide specific details on the registration process. That information is available online. And, also, when you attempt to register, it'll walk you through the process. But a parent can register a child, can register on behalf of the child through their own smartphone. And you can -- there is the capability to register multiple individuals on the same smartphone number. So, each individual person does not have to have a separate smartphone. You're allowed multiple registrants on the same smartphone. And, again, parents can register on behalf of their children.

[Ibad Khan:] That's great. Thank you for that information. Our next question asks, What guidance can you provide -- give providers when it comes to counseling parents and addressing the concerns regarding cardiac adverse events?

[Sara Oliver:] This is Dr. Oliver. I'm happy to walk through that and then maybe somebody else can talk about kind of the communications materials that we are working on or will have around this. So, you know, I think, as we've learned with the mRNA vaccines, this is, you know, something that I think parents are -- have been hearing about and are used to being concerned about. Ultimately, I think there's two aspects of this. The first is, you know, we don't know what we're going to see after the 5-to-11-year-olds. We have every expectation that we're actually -- if we see it at all, it will be lower in the rates of myocarditis, both the fact that it's a lower dose, as well as the fact that just the underlying epidemiology of myocarditis is very different in this population. It really tends to be, if you look at it kind of driven by a, you know, adolescent puberty boy thing, which, you know, would be less of a concern in this 5-to-11-year-old population.

The other thing is we know that COVID infection can cause MIS-C, can cause heart inflammation, can cause myocarditis. And so, protection against, you know, COVID associated heart conditions would be important as well. Again, in Dr. Oster's slides at ACIP, he talks about -- really walks through, if we look at the vaccine-associated myocarditis is mild and tends to resolve quickly. They're doing some long-term follow-up. And Dr. Shimabukuro, let you -- you go through that. But the outcomes, you know, cardiologists, over 90% of these kids when they were followed with their cardiologist at three months were completely resolved, the ones that had any myocarditis associated with vaccination. And that's compared to what they're seeing with MIS where many of those kids are having kind of long-term consequences related to other forms of myocarditis.

So, Dr. Shimabukuro, if you want to say anything else about kind of the fantastic work you guys are doing with myocarditis.

[Tom Shimabukuro:] So from our monitoring of reports of myocarditis to VAERS and monitoring for myocarditis in other safety monitoring systems, the -- most of these patients symptomatically recover fairly after their myocarditis event. Hospitalizations tend to be short, and patients respond well to conservative and supportive treatment and are discharged quickly and do well. But you really need to follow these patients out at least three months after their myocarditis event to assess recovery status of the heart. And we are in the process of implementing an enhanced surveillance project to follow these individuals out. We're doing that both through following up on VAERS reports and also following up on cases in another electronic health record system called the Vaccine Safety Data Link.

Those -- that process is ongoing. But the preliminary information we have, both from serving the patients and from serving the doctors and checking on tests, imaging tests and lab tests and medication use and from checking electronic health records are reassuring that, you know, most -- in general, most of these patients are doing well and reported that they have recovered and are not experiencing any residual symptoms. And of the healthcare providers that we've been able to recover, most report that their patients have recovered or have probably recovered pending some further information. And the test results and laboratory tests, the laboratory results have generally normalized; and so, these patients do appear to be doing well. We're continuing to follow up and should have more information in the coming months.

[Ibad Khan:] Thank you very much for that. In the remaining time we have, we have one last question and that is; What are -- what is the time frame for children under 5 years old? We've gotten questions that parents are asking because they have children of younger age, as well, and they're concerned about their vaccinating as well. So, do you have a time frame for children in a group that are younger than 5 years old?

[Sara Oliver:] This is Dr. Oliver. It's a great question. We know the trials are ongoing right now. So they are looking at that as they've done with the others. They look at what's the best dose in that age and then look at what the, you know, immune responses are. So the trials are ongoing. We'll follow closely, and when the companies submit data to FDA, you know, FDA will review it and CDC will review it. I don't have an exact timeline for when the companies will submit, but we know the trials are ongoing.

[Ibad Khan:] Thank you very much.

I want to thank everyone for joining us today with a special thanks to our presenters and our subject matter experts. Today's COCA Call will be available on demand a few hours after the live COCA Call. You can find the video recording of today's call at emergency.cdc.gov/coca. Please join us for our next COCA Call on Thursday, November 18, from 2 to 3pm Eastern where the topic will be, What Clinicians, Pharmacists and Public Health Partners Need to Know About Antibiotic Prescribing and COVID-19.

Continuing Education will be offered. Continue 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 regarding COVID-19. Please share these call announcements with your clinical colleagues. You may also sign up to receive weekly COVID-19 Science Updates by visiting the link on these slides.

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