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 would like to welcome you to today's COCA call, What Clinicians Need to Know About Pfizer-BioNTech COVID-19 Vaccination of Adolescents. All participants joining us today are in listen-only mode.

Closed captioning will not be available during today's webinar. A transcript and closed-captioned video will be posted to the COCA call web page located at emergency. cdc. gov/coca/calls/2021/callinfo_051421. asp.

As soon as possible after today's live session. This link can also be found at emergency. cdc. gov/coca. Continuing education is not offered for this webinar.

After the presentation, 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. Please note we receive many more questions than we can answer during our webinar and we may not be able to get to your question. If you're a patient, please refer your questions to your healthcare provider.

If you're a member of the media, please contact CDC Media Relations at (404) 639-3286 or send an e-mail to media@cdc. gov. I would now like to welcome our presenters for today's COCA call. We're pleased to have with us Lieutenant Commander Sara Oliver, who is a co-lead for the Advisory Committee for Immunization Practices COVID-19 Vaccines Work Group. As part of CDC's COVID-19 Response.

Next, will be Dr. Kate Woodworth, who is a medical officer on the Clinical Guidance Team as part of CDC's COVID-19 Response. And for today's third presenter, we have with us today Dr. Tanya Myers, who is CDC's v-safe Team co-lead. It is my pleasure now to turn it over to Lieutenant Commander Oliver.

Lieutenant Commander Oliver, please proceed.

Great. Thank you so much. So we're here to talk about what clinicians need to know about the Pfizer-BioNTech COVID-19 vaccination of adolescents. Next slide. So first, just to talk about COVID epidemiology among adolescents.

Next slide. To date, there have been over 32 million cases of COVID reported to CDC, with the most recent seven-day moving average of around 38,000 cases per day. Cases have declined in recent weeks after a slight uptick in March and early-April.

Next slide. So now really highlighting the adolescent population, much of our surveillance data in the U. S. uses a 12 to 17-year age group, so we're presenting cases within this age period. Through the end of April, there have been over 1. 5 million cases among adolescents 12 to 17 years of age. Next slide.

Then this slide shows the total - the proportion of total COVID cases by age group. You can see that early in the pandemic, the older adults shown in darker orange represented a larger proportion of cases. However, that proportion has decreased in recent weeks. As more adults are vaccinated, adolescents age 12 to 17 years of age make up a greater proportion of total cases. In April, 9% of cases were age 12 to 17 years, which actually represents a larger proportion than adults 65 years of age and older for this last month.

Next slide. So, this chart illustrates the cumulative rates of COVID-19-associated hospitalizations for age groups of children and young adults for March 2020 through the end of March 2021. From the COVID-NET surveillance, which is a population-based surveillance system that collects data on lab-confirmed COVID-associated hospitalizations among children and adults. Through a network of over 250 acute-care hospitals in 14 states. The red line illustrates the rates for persons aged 12 to 17 years, which was 51. 3 per 100,000 population. And rates for this group have consistently been higher than in those aged five to 11 years for most of the pandemic.

Next slide. So then to provide some additional context for these hospitalization rates. Here we're showing a cumulative COVID-19-associated hospitalization rates among adolescents age 12 to 17 years by MMWR week in yellow.

Compared to the cumulative influenza-associated hospitalization rate during the H1N1 pandemic year of 2009-2010 from our historic FluSurv-NET data in blue. Cumulative hospitalization rates for adolescents age 12 to 17 years is 51. 3 per 100,000 for COVID and 23. 9 for H1N1 influenza.

Next slide. So now moving to COVID-related deaths, there have been nearly 580,000 deaths in the U. S. with the most recent seven-day moving average of around 600 deaths per day.

Next slide. The major accounts of COVID-19 deaths among persons up to age 20 between January 1, 2020 and April 30, 2021, there have been 127 COVID-19 deaths among adolescents 12 to 17 years of age.

Which accounted for 1. 3% of all deaths among adolescents during this same time period. And while this sounds like a lower proportion, it's worth noting that this would still be in the top ten causes of death among children in 2019. Which is the last year that we have data for that comparison.

Next slide. So, the next, moving to multisystem inflammatory syndrome in children, or MIS-C. This is a severe hyper-inflammatory syndrome occurring two to six weeks after acute SARS-CoV-2 infection resulting in a wide range of manifestations and complications. Sixty to 70% of patients with MIS-C are admitted to intensive care and one to 2% die. There have been 3,742 MIS-C cases reported to national surveillance as of early-May. The median age was nine, with 21% of cases occurring in adolescents 12 to 17 years of age.

Sixty-three percent of those cases occurred in children who were Hispanic or non-Hispanic black. And MIS-C has an estimated incidence of one to 8. 5 MIS cases per million person-months.

Next slide. While adolescents may have a slightly lower incidence of MIS-C compared with younger 1children, they generally have more severe MIS-C.

Compared with MIS-C patients aged zero to five years, both ICU admissions and decreased cardiac function were more likely in patients age 13 to 20 years hospitalized with MIS-C.

Next slide. Then for adolescents and transmission, some studies have observed similar infection rates between children and adults while others found lower infection rates among children compared to adults. Adolescents may be more likely to be infected than younger children. And this is supported by data from several different methods including contact tracing, test positivity, and population-based seroprevalance data.

Secondary transmission from adolescents can and does occur. While SARS-CoV-2 transmission among students is relatively rate, several studies suggest that transmission is more likely within high school than in elementary school settings. Multiple outbreak and contact tracing investigations have demonstrated efficient transmission among children, adolescents, and young adults, including transmission to older household members.

Next slide. So, in summary, adolescents 12 to 17 years of age are at risk for severe illness from COVID-19.

There have been over 1. 5 million reported cases and over 13,000 hospitalizations to date among adolescents 12 to 17 years. Overall, the hospitalization rate for COVID in this population is higher than the influenza-associated hospitalization rate for the same age group during the 2009 H1N1 flu pandemic. And the clinical presentation of MIS-C is more severe in adolescents and in young children. In addition, COVID in adolescents may also indirectly impact others' health.

Adolescents contribute to transmission in households and communities including older adults at higher risk of COVID-19. And finally, adolescents represent an increasing proportion of recent COVID cases. Next slide. So then to briefly discuss the safety, efficacy, and immunogenicity of the Pfizer-BioNTech COVID-19 vaccine in adolescents. Next slide.

The clinical trial from the Pfizer vaccine demonstrated efficacy against symptomatic lab-confirmed COVID with an estimate of 100%. As you can see in the table here, for the primary outcome, which was symptomatic COVID among those with no evidence of prior infection seven or more days after the second dose. There were 16 cases in the placebo group and no cases in the vaccine group.

Next slide. Then regarding the immunobridging data.

The immune response was measured in 12 to 15-year-olds and compared to what was seen in the 16 to 25-year-olds from the Phase III trial where high efficacy was demonstrated. The antibody response in adolescents was similar to and actually higher than the response seen in 16 to 25-year-olds. The geometric mean ratio was 1. 76, which met the predefined noninferiority criteria. In addition, there were no hospitalizations due to COVID and no cases of MIS-C were reported by any trial participants.

Next slide. So then moving to the safety data, serious adverse events, or SAEs, were reported in a higher proportion of recipients of the vaccine versus placebo. Based on five SAEs in the vaccine group and two in the placebo group. However, none of these events were determined to be associated with vaccination and there were no deaths among any trial participants.

Next slide. Local reactions within seven days were common, occurring in 91% of vaccine recipients, with pain at the injection site as the most common. Systemic reactions were common, as well, with fatigue and headache as the most common. And most symptoms resolved in one to two days. Severe reactions were more common in vaccine recipients. A grade three or higher reaction, which is defined as a symptom that could interfere with daily life, was reported by around 10% of vaccinated versus 1.

9% of the placebo group. Fatigue, fever, and headache were the most commonly reported for those type of reactions.

Next slide. Then regarding other events of interest that we've been following with Pfizer vaccines, no cases of anaphylaxis were reported in the adolescent study participants. No cases of Bell's palsy or facial paralysis were reported in adolescent participants.

There were seven study participants in the vaccine group that had lymphadenopathy compared to one participant in the placebo group. Mostly lymphadenopathy was local, either in the arm or the neck region, and occurred on the same side as vaccination and occurred within two to ten days after receiving the vaccine.

Next slide. So then briefly to talk about values regarding vaccination of adolescents and implementation.

Next slide. This figure shows the overall proportion regarding positive vaccination intentions by month of data collection with bubbles proportional to the survey sample size. Surveys were conducted among adults asking about their intent to receive the vaccine themselves. There has been a steady increase in the intent to be vaccinated among adults.

Next slide. So then when evaluating surveys of parents regarding their intent to have their child or adolescent vaccinated.

Among the surveys found 46 to 60% of parents surveyed planned to get their children vaccinated. The most common reasons for not planning to vaccinate their children include not being sure it's safe or that the vaccine was developed too quickly. Don't trust the information about vaccines or don't have enough information. Generally, parents reported a similar or slightly lower intent to vaccinate their children compared with the intent to vaccinate themselves.

Next slide. The intent to vaccinate their children differed by the parents' gender, age, and income status. Fathers were more willing than mothers to vaccinate their children and older mothers were more willing than younger mothers to vaccinate their children. Households with higher income were more likely to report intent to vaccinate. Whereas households with lower income

were twice as likely to say that they were not sure about vaccinating their children compared to higher-income households.

Next slide. When adolescents were asked about their intents to get vaccinated, you can see on the left that 51% reported that they would definitely or probably get vaccinated from the part of the chart in blue. Parents in the same survey, although not necessarily paired to the parents of the adolescents interviewed, reported that 55% would definitely or probably get their adolescent vaccinated.

Next slide. The parents were also asked about where they would prefer to get their adolescent to receive a COVID vaccine. You can see that at the far left in green, parents were the most comfortable being vaccinated at their regular doctor's office with a local pharmacy next.

Next slide. So the objective of adolescent vaccination is to promote vaccination among adolescents as quickly and equitably as possible, which will require a multi-pronged approach. Jurisdictions and providers already are vaccinating adolescents 16 to 17 years of age. Currently, implementation plans to expand down to 12 include leveraging current vaccination infrastructure and adapting over time. This would include an early summer sprint in May and June, followed by increasing access in June and July, and a back-to-school campaign later in the summer and at the start of the school year.

Next slide. All of this will require a stepwise approach to increasing vaccine access for adolescents. Phase 1, which includes augmenting existing infrastructure, includes all current COVID vaccine providers opening up to allow vaccination for children 12 and over. Then Phase 2 includes strategically adding providers serving adolescents including larger provider groups and children's hospitals. As well as smaller providers needed to increase access such as those in areas with a high social vulnerability index and rural areas.

And Phase 3 includes utilizing school-based vaccination program in partnership with public health, pharmacies, third parties, and through HRSA sites.

Next slide. So health equity is when everyone has the opportunity to be as healthy as possible and no one is disadvantaged from achieving this potential. Because of social position for otherly socially-determined circumstances. There are two characteristics of the Pfizer-BioNTech COVID-19 vaccine that have the potential to impact health equity.

Cold chain storage handling and administration requirements and the need for a two-dose series. New data recently submitted to FDA on stability may reduce the need for ultra-cold storage, thereby increasing access, particularly to smaller providers. Additional support to efficiently utilize doses as well as smaller tray size would improve access, as well. The requirements for a two-dose series could make follow up challenging for some disadvantaged groups such as those who are homeless, live in rural locations, and have limited to no access to healthcare. Within adult early in the vaccination program, only a very small proportion didn't receive the second dose of a two-dose series.

However, differences were seen by jurisdiction, race and ethnicity, and age. Overall, taking a multipronged approach to implementation will be needed to both improve access and to improve equity.

Next slide. So then to talk about the vaccine policy that was discussed at the ACIP meeting this week regarding the Pfizer-BioNTech vaccine. Next slide.

This was the policy question addressed by ACIP. Should vaccination with the Pfizer-BioNTech COVID-19 vaccine, two doses, IM, be recommended for persons 12 to 15 years of age under an Emergency Use Authorization?

Next slide. Then this is the language that ACIP voted on. The Pfizer-BioNTech COVID-19 vaccine is recommended for persons 12 to 15 years of age in the U. S. population under the FDA's Emergency Use Authorization. ACIP voted 14 to zero in favor of the interim recommendations for use of the Pfizer vaccine in adolescents. One ACIP member recused herself because of participation in clinical trials and other studies involving companies producing COVID vaccines.

Now next slide. And so now I'll turn it over to Dr. Woodworth, who will talk us through the updated clinical considerations.

Thank you.

Next slide. So clinical considerations for COVID-19 vaccines are available on CDC's website and apply to the use of all COVID-19 vaccines under FDA's Emergency Use Authorization. These clinical considerations are being updated to include guidance for adolescents and recommendations. Regarding vaccine coadministration and vaccination after multisystem inflammatory syndrome in children and adults.

I have seen a few questions in the chat already noting that the website that we point to is not yet up to date but these should be updated this afternoon. And we'll continue to update as additional information becomes available or additional vaccine products are authorized.

Next slide. I just wanted to note that the Pfizer-BioNTech COVID-19 vaccine is currently the only COVID-19 vaccine authorized by FDA for use under EOA for adolescents aged 12 to 17. The dosing and administration schedule is the same as that for adults.

Next slide. The federal government does not have specific requirements for medical consent for vaccination, including COVID-19 vaccines. However, states and jurisdictions have medical consent laws that address the circumstances requiring and the processes for obtaining consent. It's important to note that these laws vary across jurisdictions. Providers may also be subject to policy requirements for consent within their own organizations.

And all sites administering vaccines should follow current state or jurisdictional policies and practices for other routine immunizations in this age group.

Next slide. COVID-19 vaccines were previously recommended to be administered alone with a minimum interval of 14 days before or after administration of any other vaccines. This was out of an abundance of caution and not due to any known safety or immunogenicity concerns. However, substantial data have now been collected regarding the safety of COVID-19 vaccines currently authorized by FDA for use under EUA.

Although data are not available for COVID-19 vaccines administered simultaneously with other vaccines, there is extensive experience with non-COVID-19 vaccines. That has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they're administered alone.

Next slide. So COVID-19 vaccines and other vaccines may now be administered without regard to timing. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as coadministration within 14 days.

And just to note that this does apply for all persons who are eligible for COVID-19 vaccines currently under EUA and is not specific to adolescents. So it apply for anyone 12 years of age or older.

Next slide. It's unknown whether reactogenicity is increased with coadministration, including with other vaccines that are known to be reactogenic, such as adjuvanted or live vaccines. When deciding whether to coadminister with COVID-19 vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines.

Their risk of vaccine-preventable diseases, such as during an outbreak or after an occupational exposure. And the risk of - sorry. The reactogenicity profile of the vaccines being administered.

Next slide. If multiple vaccines are administered at a single visit, it's best practice to administer each injection in a different injection site.

For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection. Best practices for multiple injections include labeling each syringe to identify the vaccine it contains. Using separate injection sites or separating injection sites by one inch or more, if possible. And administering COVID-19 and other vaccines that may be more likely to cause a local reaction in different limbs, if possible.

Next slide. I just want to note that the updated coadministration recommendations may facilitate catch-up vaccinations of adolescents. That as of May 2, 2021, overall vaccine for children provider orders other than influenza are down by 11. 7 million doses compared with 2019. And that this gap is largest in the vaccines that are primarily given to adolescents, the Tdap, HPV, and meningococcal vaccines. And getting kids up to date on routine vaccines, as well as COVID-19 vaccines, will be important for increasing confidence in safe return to school this fall.

Next slide. Now regarding multisystem inflammatory syndrome in children, or MIS-C, and adults, or MIS-A. MIS-C and MIS-A are a severe hyperinflammatory syndrome that occur two to six weeks after acute SARS-CoV-2 infection and result in a wide range of manifestations and

complications. The mechanisms of MIS-C and MIS-A are not well understood, but include a dysregulated immune response to SARS-CoV-2. Next slide.

Children with MIS-C have high antibody titers to SARS-CoV-2. However, it's unknown if this correlates with protection against reinfection and for how long protected antibodies may persist. It's unclear if people with a history of MIS-C or MIS-A are at risk for recurrence of the same dysregulated immune response following reinfection of SARS-CoV-2 or in response to a COVID-19 vaccine.

Next slide. People with a history of MIS-C or MIS-A may choose to be vaccinated and considerations for vaccination may include clinical recovery from MIS-C or MIS-A, including return to normal cardiac function.

Personal risk of severe acute COVID-19, such as age or underlying conditions. The level of COVID-19 community transmission and a personal risk of reinfection. A lack of safety data on COVID-19 vaccines following these illnesses. And timing of any immunomodulatory therapies. A conversation between the patient, their guardians, and the clinical care team may assist with decisions about the use of COVID-19 vaccines.

Though a conversation with a healthcare provider is not required before vaccination. Next slide. Current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. Thus, people with a history of MIS-C or MIS-A should consider delaying vaccination until they have recovered from illness and for 90 days after the date of diagnosis of MIS-C or MIS-A. Recognizing that the risk of reinfection and, therefore, the benefit from vaccination, might increase with time following initial infection.

Next slide. Healthcare personnel or health departments can request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. If they have a complex COVID-19 vaccine safety question that's not readily addressed by CDC guidance.

Next slide. I just wanted to touch on the contraindications.

So, the following are considered to be contraindications to vaccination with the COVID-19 vaccine. And that includes severe allergic reaction or anaphylaxis after a previous dose or to a component of the COVID-19 vaccine. And immediate allergic reaction of any severity to a previous dose or known diagnosed allergy to a component of the vaccine. And of known polysorbate allergies no longer a contraindication to mRNA vaccines such as Pfizer. But is a contraindication to Janssen COVID-19 vaccine, and thus, a precaution to the mRNA COVID-19 vaccines.

Next slide. Syncope or fainting may occur in association with any injectable vaccine, especially in adolescents. Procedures should be in place to prevent falling injuries and manage syncopal reactions following vaccination. All people are recommended to be observed following vaccination for at least 15 minutes. And patients should be seated or lying down during the observation period to decrease their risk for injury should they faint.

And if syncope develops, patients should be observed until symptoms resolve.

Next slide. People with a history of immediate allergic reactions to a vaccine or injectable therapy with a contraindication to a different COVID-19 vaccine or a history of anaphylaxis due to any cause. Should be observed for 30 minutes. And all persons should be observed for 15 minutes after vaccination.

Next slide. And I just want to briefly mention some of the resources that CDC has developed around COVID-19 vaccines that will be relevant for providers, parents, and teens.

Next slide. So CDC has developed some additional tools that providers can use at vaccination sites to help identify persons with contraindications or precautions to vaccination. Including a pre-vaccine checklist and additional information in the form of a fact sheet.

Next slide. There's also information regarding preparing for the potential management of anaphylaxis at COVID-19 vaccination sites.

Next slide. There are numerous CDC resources available regarding COVID-19 vaccines, administration, storage, reporting, patient education, and more on CDC's website.

Next slide. And CDC has general toolkits for medical centers, clinics, and clinicians. And I also just wanted to point out that we've developed a toolkit for pediatric healthcare providers that's listed here on the second bullet.

Next slide. And finally, I just wanted to point out that your patients really need to hear from you. So, patients consistently rank healthcare providers as their most trusted source of vaccine information and so your recommendation to get a COVID-19 vaccine is critical for vaccine acceptance.

I wanted to highlight the Engaging in Effective COVID-19 Vaccine Conversations link, which can be seen here on the screen. It has concrete examples on how to answer your patients' question about COVID-19 vaccines in clear language. And how you can share important information with them to help build their confidence in vaccines.

Next slide. And here are some tips for making strong recommendations to get a COVID-19 vaccine.

It's important to make clear to your patients that you recommend COVID-19 vaccination for them. Tell your patients how important COVID-19 vaccines are to protect their health, as well as the health of their family and friends. Acknowledging that COVID-19 vaccines are new and that it's understandable that your patients may have questions. Your answers can help them make informed decisions about getting vaccinated. Make it clear that you understand they may have questions and that you want to answer them so that they feel confident in choosing to get vaccinated.

And finally, if you are not currently offering COVID-19 vaccinations in your practice, please send your patients to www. vaccines. gov to help them find a location to receive vaccination.

And next slide. That's the end and I can turn it over to Tanya Myers.

Thank you, Dr. Woodworth. This is Tanya Myers. I'm the current co-lead for the v-safe after vaccination health checker program and happy to be with you today. I don't have any slides, so if you're still seeing the last slide that Kate presented, that is correct.

It's not that your computer has frozen. But I - what I want to do today is just reiterate some key points that were mentioned by Dr. Tom Shimabukuro from the Immunization Safety Office at Wednesday's ACIP meeting. And let you know that the v-safe after vaccination checker is open for parents and guardians to enroll their vaccinated adolescents in v-safe. So, we are encouraging parents and guardians after their adolescents have been vaccinated to register their child and complete those health surveys on the parents' phone.

And one of the things that's nice about this after vaccination health checker is that there you're able to report not only adverse events. But also when vaccinated persons are feeling well and have no side effects. So we're encouraging reporting even when folks are feeling well. Participation in v-safe is going to help us continue to monitor the safety of COVID-19 vaccines as use has expanded into these younger populations. And we're asking for your help in continuing to promote v-safe at your vaccination sites in your practices.

So, let me thank you for all that you have already done to promote v-safe. Whether that's from handing information sheets out to your vaccines' recipients thus far or from mounting posters in the waiting area. That 15-minute, 15 to 30-minute observation period that Dr. Woodworth mentioned is an ideal time for people to lay eyes on those posters. And even if you happen to have a nurse or other staff person that's monitoring that waiting area.

It can be a very powerful recommendation for them even to point the poster out to people or point them towards those information sheets. So that's what I wanted to share with you today. The system - the survey is the same as many of you have probably already taken and we're just asking that parents do this for this younger cohort of vaccinees that are coming in. So, thank you. I'll turn it back over to Dr. Khan.

Thank you very much.

Next slide, please. Presenters, thank you for providing our audience with this timely information. We will now go into our Q&A session. Please remember to ask a question using Zoom.

Click the Q&A button at the bottom of your screen and type your question. Please note we receive many more questions than we can answer during our webinars. However, I encourage you to seek the resources that our presenters shared with you today. For additional information, please continue checking CDC's COVID-19 page as it will be updated shortly and continuously. Links to all of that can be found on emergency.

cdc. gov/COCA. So let's start with our Q&A session.

Our first questions asks did the trial data for adolescents show any different adverse events that were encountered during the trial data for adults.

This is Dr. Oliver. So overall, the adolescents' population is healthier than the adult population. The adult studies over-recruited or really tried to kind of enrich their study with older adults and adults with underlying medical conditions. So, when you compare just the medical events that occurred in the two months after vaccine for an older adult population versus an adolescent population.

There were far fewer serious adverse events, even those that were deemed unrelated to vaccination. There were far fewer of those seen in an adolescent population just because, in general, they were overall healthier. But there was nothing kind of consistent that would be concerning across the entire age spectrum that was seen either in adolescence or adults.

Thank you very much.

Next question is asking specifically about female adolescent patients. Is there any data on COVID vaccine and its effects on menstrual periods, especially with heavier bleeding?

Hi. This is Dr. Woodworth. I can answer this question. So, at this time, there haven't been any studies published on changes to a person's menstrual cycle as a result of COVID-19 vaccinations in adolescents or otherwise.

The Vaccine Adverse Event Reporting System, or VARS, which is a national vaccine safety system managed by CDC and FDA has received reports of menstrual cycle changes including heavier periods. But also early or later onset and painful menstrual cramps. But it's important to remember that many things can affect a woman's or a person's menstrual cycle. Including stress-related hormones, changes in schedule, problems with sleep, infections, changes in diet and exercise, etc. So, I would encourage folks if they're worried about menstrual cycles or experience any unusual menstrual cycle related side effects after receiving the COVID-19 vaccine.

To talk to their healthcare providers and share their concerns.

Thank you very much.

Our next question asks about adolescents that may be developmentally delayed. Would they receive the same dosage or does the dosage need to be adjusted for their size?

This is Dr. Woodworth, again. I can answer that one. So, the dose is the same for all adolescents. It's not a weight-based dose and is really just the same across the board for anyone who's 12 years of age or younger, so tied to that age and not tied to anything else.

Thank you very much. We have quite a few questions asking about COVID-19 vaccines and coadministration with other routine vaccinations.

Can you address if there are any specific guidance for how long the separation? Are we still sticking with the 14-day, two-week separation between vaccinations, or is coadministration guidance a little bit different?

Sure. This is Dr. Woodworth, again. I can answer that. So, in terms of the coadministration recommendations, it's really sort of a across the board for COVID-19 vaccine and any other vaccine can be administered without regard to timing.

So, there's not the need to wait those 14 days anymore. And just to clarify, too, so this would be either direction, right? So, if you were - if you had received, you know, a tetanus vaccine two days ago, you could still receive a COVID-19 vaccine two days later, and vice versa. So, if you received a COVID-19 vaccine two days ago and needed that tetanus vaccine today, you could still get it. So, it does sort of work both directions there, if that helped to clarify those answers.

Yes, thank you.

Along the same lines, do you have any guidance or recommendations for preference in IM injection deltoid versus thigh?

So, there are some best practices and I can pull up that website about where vaccines should be administered and I can put that in the chat. But it's typically the deltoid muscle for adolescents and adults, so anybody who's eligible for the COVID-19 vaccines.

Thank you very much.

Our next question asks do you have an understanding of the timeline or an expectation for the other COVID-19 vaccines that are authorized for adult population to be authorized for adolescents. Such as the Moderna or the Johnson & Johnson vaccines.

Yeah, this is Dr. Oliver. I think we've - based on kind of enrollment, and study numbers, and how things have gone. Moderna has stated that they have completed enrollment of their Teen COVE is what they've called their 12 to 15 - or 12 to 17-year-old, sorry, study. And so they are analyzing the data and ACIP and CDC will be happy to review that data as soon as it is submitted to FDA.

I think we're hopeful that information will be available sometime in the early summer, so within the next one to two months.

Thank you very much.

Our next question's also similarly related to vaccinations. Is there any updates on when the Pfizer vaccine will be authorized for the next group younger than adolescents, so whether it's two to 11 or other group?

This is Dr. Oliver, as well. So one of the reasons that we were able to get the two to 15 or two to 17 that for both Pfizer and Moderna. That this has been able to happen relatively soon after the

authorization for the adult population, is because they - they're using the same dose and the same interval. As we go younger, so that's kind of less than 12 years of age, both Pfizer and Moderna are doing what's called dose finding first.

So, making sure that they're actually testing the right dose in a kind of younger and obviously physically smaller population. So those studies are going to take a little bit longer. They're in the process of conducting those studies right now. So, they will do dose finding first, and then once they believe that they've found the right dose for a younger age group. Then they do the safety and, you know, bridging studies like the data that we reviewed today.

So, I know both studies are ongoing. It's harder really to pinpoint an exact time on that. Just because it depends on how, you know, how the results of the study kind of pan out over the time couple of weeks to months. So, we're hopeful that we'll have that potentially by the end of the year or, you know, into early-2022. But we've just got to see, you know, how the data evolves over the next weeks to months.

Thank you very much. Next, we have a few questions about v-safe. The first question asks are adolescents that have cell phones and things like that, are they able to register themselves for v-safe, and monitor themselves, and respond themselves. Or do they have to have a parent or guardian who is 18 or older?

This is Dr. Myers. I'll be happy to take that question. So we're - for this younger cohort, in particular, we're encouraging parents and guardians to register those adolescents. We do have some 16 and 17-year olds that have completed the registration process for Pfizer's vaccine because they were already able to get access to that vaccine and enrolled in the system.

But for 12 to 15-year-olds, we're encouraging that to be parents and guardians that are registering their children so that any call outreach goes to the parent or guardian.

Thank you very much.

And this is a follow-up question to that about v-safe and you may have also already answered it, but perhaps it bears repeating. Can school teachers or school personnel enroll their students in v-safe?

I think the answer to that is no. Our advice is that we prefer that the enrollment be completed by a parent, or a guardian, or someone in the best position to be able to answer some of the questions in the survey. That would be related to whether that vaccinated child has received medical care. So I think it - we would say it should really be the parent or the guardian.

Thank you very much for that distinction.

We have some questions about post-vaccination. First question asks are there any recommendations for use of over-the-counter pain relievers or fever reducers in adolescents?

So, this is Dr. Woodworth and it is fine for adolescents to take over-the-counter pain relievers if they develop any symptoms after vaccination. So NSAIDs, or acetaminophen, or over-the-counter pain relievers.

Thank you very much.

Next question asked do you have any guidance regarding changing the timing or delaying PPD or TB testing?

This is Dr. Oliver and I'm just trying to make sure that I get it. This - I will say that this is on our clinical considerations website. I'm just trying to make sure that I pull it up.

I have it.

Okay, do you have it, Dr. Woodworth? Okay.

Yeah, sorry. So COVID-19 vaccines should not be delayed because of testing for TB infection and testing for TB infection can be done before or even during the same encounter as the COVID-19 vaccine. With the tuberculin skin test, the TSD, or the interferon release assay. So when - but when you're testing with TSD, the tuberculin skin test or the interferon release gamma assay. When it can't be done at the same time as COVID-19 vaccination, then these tests should be delayed for four weeks after the completion of COVID-19 vaccination, but generally should not be cancelled.

And, again, like Dr. Oliver mentioned, that is on our clinical considerations website. And I'll just take this time to let you know I know when I started my talk, I said that we would be updating the website this afternoon. And I did refresh it and it is updated now so that coadministration language is up on that clinical considerations website now, as well.

Thank you very much. I appreciate that.

Next question we have is any concern about childhood allergies that may be different, and may manifest only at the childhood age, and might not have been a consideration for the adults. Would that be a consideration for this patient population when considering COVID-19 vaccination?

So, this is Dr. Woodworth and our sort of contraindication regarding anaphylaxis, the contraindications and precautions would be the same for adolescents as they are for adults. And so, again, those contraindications are really just pointed to severe allergic reactions or anaphylaxis after a previous dose or to a component of the COVID-19 vaccine. Or an immediate allergic reaction of any severity to a previous dose or known allergies to a component of the vaccine. So those are not specific to adolescents or adults.

Thank you. We have one more question about v-safe. And the question asks if a parent has multiple children, will they be able to register them on v-safe using their same cell phone, one cell phone, multiple children.

Yes. This is Dr. Myers. Thank you for that question. Yes, parents are able to register multiple children on the same phone.

And in addition to that, not just the children, but they might also have an existing account for themselves if they have been vaccinated. So multiple registrations are allowed.

Thank you very much.

Our next question asks you talked about dosage. What about needle size? Do you have any recommendations for needle size for this patient group of adolescents?

Sure. This is Dr. Woodworth, again. So, for this age group for eligibility, they can still use the same needle size, so the one-inch needles would still be used for adolescents as per adults.

Thank you.

Next question asks we talked about MIS-C. Is there any data that you're aware of for long COVID, in general, in adolescents similar to what we have available on adults?

This is Dr. Oliver. I'm happy to kind of start that and then we can - I'll see if Dr. Woodworth has anything else to add. I will say, you know, that we recognize that looking at long COVID or kind of the prolonged symptoms after acute COVID infection is important.

And understanding the impact of vaccination on that is important. I think as we work through developing kind of what a case definition is for that and surveillance moving forward. We'll be able to have, you know, a better understanding both in the adult population, as well as in this adolescent population, as for the impact of vaccination on these longer symptoms. We don't have any information from the clinical trials on that per se. But we, you know, we'll forward to continuing to collect information on this as we move forward.

Dr. Woodworth, anything else to add?

No, no. That was great.

Okay, thanks.

The following question I think applies, I think, generally to any patients in various age groups. And the question asks is there any guidance on patients that would - that might be planning a pregnancy as far as counseling and recommendation.

So this is Dr. Woodworth and I can answer that, too. We do have information for vaccination of pregnant people on that same clinical considerations page. But do just want to point out that pregnant persons and people who are planning for pregnancies are eligible for and can receive the COVID-19 vaccine. But you can find more information on that on the website.

Thank you very much.

Next question asks is the COVID vaccine okay for children that are suffering from various symptoms of MIS-C.

Sure, so this is Dr. Woodworth, again. So we don't have safety data currently specifically on the safety of COVID-19 vaccines after patients who've had MIS-C. And right now, what we're recommending is that, you know, individuals who have had MIS-C, of course, can choose to be vaccinated. And just wanted to list out some considerations that they can take into account when making that decision.

And, you know, it's really we do want to point out that it's unclear if people with a history of MIS-C or MIS-A are at risk for that, you know, recurrence of that same dysregulated immune response. Following either a natural reinfection or in response to the COVID-19 vaccine. And so really weighing those theoretical risks and known benefits is important. And so we laid out a couple of considerations in this document, things like making sure they have recovered from MIS-C or MIS-A. Thinking about their personal risk of severe acute COVID-19 and risk of reinfection.

And, you know, encouraging if they have questions to talk to their healthcare providers. And then just did add that one additional consideration that, you know, given that there's a really low risk of reinfection in the months after initial infection. People with a history of MIS-C or MIS-A should consider delaying vaccination until they have reached 90 days after their date of diagnosis.

Thank you very much.

Next question asks that there is some talk about Pfizer intending to apply for full approval from the Food and Drug Administration. Are you aware that would it be full approval for adults or would it include adolescents in, as well?

This is Dr. Oliver. So, yeah, I mean Pfizer announced in a press release last week, maybe, that they had begun the submission process for BLA, the biologic license approval to - or application to FDA. It is what's called kind of a rolling application is how they're doing it. So they started the process but they have not kind of submitted all of the data that's needed and that will kind of occur in an ongoing manner over the next several weeks until the application is complete.

Details on that I will really defer to FDA. I will say it's our understanding that, you know, the kind of initial BLA, because it requires six months of data from vaccination, really will be that adult population. And then eventually, they will submit data to support the BLA for the younger populations.

Thank you very much.

Next question asks is there any data available on the efficacy of the Pfizer COVID-19 vaccine for variants with adolescents or is it similar to what was observed with the adult population.

This is Dr. Oliver. So we don't have data on efficacy specific for the variants in adolescence in this kind of 12 to 15 population because it's really only been studied at this point within the clinic trial. We expect that it would be similar. The immune response, as I mentioned earlier in the talk was as good if not better.

The antibody titers were actually higher in the adolescent population. So we expect that, you know, where the Pfizer vaccine has been shown to work against the variants in adults, we would expect that similar level of efficacy in adolescents. I will say that we'll continue to monitor this moving forward, so we're already working - CDC has many platforms by which we're looking at kind of this real-world effectiveness. So once the vaccine is rolled out, continuing to monitor. I think in the MMWR, today, another vaccine effectiveness study result was released.

So, we're continuing to get this in, this information in, and our platforms are already kind of adapting to include these younger ages. So, we can continue to monitor what vaccine effectiveness looks like in kind of a real-world setting as we move forward.

Great, thank you. We have time for one last question and the question asks do you have any special or specific recommendations for vaccinating adolescents with primary immune disorders. And somebody also asked about Kawasaki syndrome.

So this is Dr. Woodworth. So, for Kawasaki syndrome, we don't have any specific guidance for that syndrome. But in general, there are some recommendations regarding individuals who are immunosuppressed, or on immunosuppressive therapy, or immunomodulatory therapies. On that clinical considerations website, so I'd encourage you to go there and check out that website.

Thank you very much.

This concludes our COCA call for today. I want to thank everyone for joining us today with a special thanks to our presenters for sharing this urgent and timely information. As was mentioned throughout this COCA call, you can find a lot of these resources by visiting CDC's COVID-19 page. Links for that are also available on the COCA web page at emergency. cdc. gov/coca. I'll share that link, again.

Today's COCA call will be available to view on demand a few hours after the live call and you can find the video recording of today's COCA call at emergency. cdc.gov/coca.

Next, please join us for three upcoming COCA calls where free continuing education will be offered. Our next scheduled COCA call, Lyme Disease Updates and New Educational Tools for Clinicians, will be on Thursday, May 20th, at 2:00 PM Eastern. One week later, on Thursday, May 27th, will be a COVID-19-related COCA call. Where our presenters will discuss updated evidence-based information for healthcare providers about Underlying Medical Conditions and Severe COVID-19.

Then one week later, on Thursday, June 3, we will hold another COVID-19-related COCA call where the topic will be Evaluating and Caring for Patients with Suspected Long COVID. All three COCA calls will be at 2:00 PM Eastern time and more information and call announcements

will be available soon. Please share those call announcements with your clinical colleagues. You can also sign up to receive weekly COVID-19 Science Updates by visiting the link provided here. These slides, of course, are available at emergency. cdc. gov/coca.

COCA Call announcements for upcoming COCA calls and other COCA products are sent via e-mail. In addition to visiting our web page, please remember to subscribe to COCA to receive notifications about upcoming COCA calls or other COCA products and services. Be sure to subscribe to receive notifications by going to emergency. cdc. gov/COCA. Again, that's emergency. cdc. gov/COCA.

We invite you to join the COCA e-mail list by visiting the COCA web page at emergency. cdc. gov/COCA, clicking on Get E-mail Updates and entering your e-mail address where indicated. To stay connected to the latest news from COCA, be sure to like and follow us on Facebook at facebook. com/CDCClinicianOutreach AndCommunicationActivity.

Again, thank you for joining us for today's call and have a great day.