Good afternoon. I'm commander Ibad Khan and I am representing COCA, with the Emergency Risk Communication Branch at the Centers for Disease Control and Prevention. I would like to welcome you all to today's COCA call, Updated Guidance for Clinicians on COVID-19 Vaccines. All participants joining us today are in listen only mode. Free education is available for this webinar.

Instructions on how to earn continuing education will be provided at the end of the call. In compliance with continuing education requirements, all planners and presenters must disclose all financial relationships in any amount with ineligible companies over the previous 24 months, as well as any use of unlabeled products, or products under investigation of use. CDC, our planners and presenters wish to disclose they have no financial relationship to eligible companies whose primary business is producing, marketing, selling, reselling, or distributing health care products used by, or on patients. All of the relevant financial relationships listed for these individuals have been mitigated. Content will not include any discussion of the unlabeled use of product, or a product under investigation of use with the exception of Sarah Mbaeyi's discussion of vaccine use.

She will be discussing vaccine use under instruction. CDC did not accept financial or any kind of support from ineligible companies for this continuing education activity. At the conclusion of today's session, the participants will be able to accomplish the following. Discuss current recommendations related to COVID-19 vaccination for people who are moderately or severely immunocompromised. Describe the simplified recommendations for COVID-19 vaccination after a patient has received passive antibody therapy.

And list key points for health care providers to use when talking about COVID-19 vaccination for people who are moderately or severely immunocompromised, and people who have received passive antibody therapy. After today's presentation, there will be a Q&A session. You may submit questions at anytime during today's presentation. To ask a question using Zoom, click the Q&A button at the bottom of your screen and type of the question in the Q&A box. Please note, we received many more questions than we can often answer during our webinars.

If you are a patient, please refer your question to the health care provider. If you are a member of the media, please contact CDC media relations at 404-639-3286. Or send an email to media@cdc. gov. We have introduced self knowledge checks throughout our presentation.

We hope you enjoy these opportunities to assess your understanding of today's session. Please do not type your answers in the Q&A box, as this may disrupt the Q&A portion at the end of the session. I would now like to welcome our presenters for today's COCA Call. We are pleased to have with us Lieutenant Commander, Sara Oliver, Medical Officer and Lead for the Advisory Committee for Immunization Practices COVID-19 Vaccines Work Group. Dr.

Elisha Hall, the Clinical Guidelines Lead for CDC's COVID-19 Response. Dr. Evelyn Twentyman, Chief Medical Officer for the COVID-19 task force as part of CDC's COVID-19 Response. It is now my pleasure to turn it over to lieutenant commander Oliver. Lieutenant commander Oliver, please proceed.

Thank you so much. I will get started.

Next slide. So this is just a highlight of what we are going to discuss today. First, I will go through updates from the February 4th advisory committee on immunization practices, or ACIP meeting.

This will include a review of the evidence to support that extended interval between a first and second mRNA COVID-19 vaccine doses. Then I will turn it over to Dr. Hall for updates to CDC's interim clinical considerations, including guidance for people who are moderately to severely immunocompromised. And then finally, Dr. Twentyman will cover COVID-19 vaccination and a's summary of our current recommendations for recommendation by a group.

Next slide. This slide shows the daily trends in the COVID-19 cases in the U. S. This was the figure that was shown at the ACIP meeting in early February, when we had around 75 million COVID cases reported to CDC. Since then, with continued decline after the Omicron surge that peak in January.

Through today, there have been over 78 million cases reported to CDC. But the seven day moving average now is under 100,000 cases.

Next slide. This slide illustrates the rates of COVID-19 cases and deaths by vaccination status. People who are fully vaccinated with an additional or booster dose have a much lower risk of testing positive and dying from COVID-19, compared with those who are unvaccinated.

This slide shows that the largest gap in COVID cases and deaths are between those who are unvaccinated and those who are fully vaccinated. Then there is additional protection for those who are fully vaccinated and have also received a booster dose.

Next slide. This slide shows the percent of COVID-19 vaccination coverage by age, and date administered. The highest coverage is among the oldest, with 95% of those 65 and over having received at least one dose.

Then the lowest coverage is around 75%, among those 18 to 24 years of age.

Next slide. We know these COVID-19 vaccines have saved lives. Before the Omicron surge, it was estimated that COVID vaccines presented -- prevented up to 10 million hospitalizations and up to 1 million deaths through November of 2021.

Next slide.

For ACIP, we've walked through multiple different versions of this benefit risk assessment. We are not going to go through all of them today, but the slides are posted on the ACIP website, if you want to go into further detail. As we have done with our previous benefit risk assessments, we have calculated the benefits per million people who are fully vaccinated. And we have focused this time on the group 18 to 39 years. That was selected because this age group has the highest rates of myocarditis and the lowest hospitalization rates among adults.

Therefore, it has the closest benefit risk margin. We looked at the benefits calculated over 150 days or a five month period. The harms were calculated per 1 million persons who are fully vaccinated, using the vaccine specific myocarditis rates. This slide shows associated hospitalizations prevented by the vaccine, compared with myocarditis cases expected. On the left side of the figure, COVID hospitalizations prevented by the Moderna vaccine are in the dark red bars.

And hospitalizations prevented by the Pfizer vaccine are represented in the dark green bars. On the right side of the figure, expected myocarditis cases for the Moderna vaccine are in the light red bars. And myocarditis for the Pfizer vaccine are in the light green. And over the course of five months, the benefits of receiving either mRNA vaccine far outweigh the risk. We know that when we look across all vaccines, more myocarditis cases would be expected among the Moderna recipients than Pfizer, but also, more COVID hospitalizations would be expected among the Moderna recipients compared to Pfizer.

Next slide. In summary, we know that these COVID-19 vaccines are safe and effective. The vaccines have been a critical tool in this pandemic, preventing millions of COVID associated hospitalizations and deaths. To date, hundreds of millions of doses of mRNA COVID-19 vaccines have been given, with over a year of incredibly closely monitored, real world safety and effectiveness data. We know that vaccinating the unvaccinated with a primary series continues to be important.

An additional protection from all recommended COVID-19 vaccine doses are important in this evolving pandemic.

Next slide. So, as an overview of what has happened over the last month, at the very end of January, FDA approved the Moderna COVID-19 vaccine, which now has the formal name of spike vax for individuals 18 years of age or over. This full FDA approval is built on the data and information that supported the pre clinical and clinical data. As well as details of the manufacturing process, and sites where the vaccine is made.

Then we just want to highlight that the Moderna COVID vaccine remains under EUA for the other recommendations. The primary dose for age 18 and over who have certain kinds of immunocompromised, and a single booster for people 18 years of age and over after completing the primary series. Again, we will go through all of these details at the end of the presentation, as well. So on February 4th, ECAP reviewed this data and revised its interim recommendation to a standard recommendation, for use of the Moderna COVID-19 vaccine in person's 18 years of age or over.

Next slide.

So now, I will transition to evidence reviewed by ACIP, related to the extended interval between the first and second doses of mRNA vaccines. This was discussed at the ACIP meeting on the fourth, as well. Overall, some studies of adolescents and adults have shown that the small risk of myocarditis associated with mRNA COVID-19 vaccines might be reduced if antibody responses and vaccine effectiveness might be increased with an interval of longer than four weeks.

Next slide. At the ACIP meeting, we had a presentation from our colleagues in Canada that described their experience around these extended intervals.

I will provide a few updates and summary of the data that they showed here. So, this figure shows weights of myocarditis per million doses among males aged 18 to 24 years by vaccine schedule and by dosing interval. You can see that across the three schedules of the primary series, the rates of myocarditis decreased, as the interval between dose one and dose two lengthened. Within each schedule, the lowest rates of myocarditis were observed among those who had the longest time between dose one and dose two.

Next slide.

So this slide moves to data to look at vaccine effectiveness, seen with varying intervals between the doses. Adjusted vaccine effectiveness estimates against -- infection in green, and hospitalization in blue. By dosing interval and weeks, that is shown here. The results from British Columbia are shown on the left and Quebec on the right. MRNA vaccine effectiveness against -- was five to 10% higher with an extended interval of 7 to 8 weeks, compared to a standard interval of 3 to 4 weeks.

Increases in that teen effectiveness can appear to level off around that 7 to 8-week interval between the doses. Overall, the vaccine effectiveness against hospitalizations and infections compared to a two dose mRNA vaccine series, with an extended dosing interval of seven weeks or greater, was 94 to 97% for hospitalization. And 89 to 91% for infection.

Next slide. This slide has further information on the Pfizer vaccine by primary series interval in England.

In the figure, you can see how age group across the type and interval between dose one and dose two and weeks across the bottom. Across all ages, these age groups show that Pfizer vaccine effectiveness against the infection is higher with the extended interval. Those greater than six weeks, compared to distant three or four-week interval.

Next slide. So now when we think about immunogenicity or the antibody response to the vaccines, with an extended primary series interval.

In a study by pain and colleagues out of the UK, they examined SARS-CoV-2 infection and naive persons, the responses were higher after an extended dosing interval of 6 to 14 weeks, compared to the standard interval of 3 to 4 weeks. Among persons with an extended interval, there were higher antibodies and be cell responses, as well as sustained D. C. and T cell responses compared to a standard interval. The extended interval may promote efficient T cell expansion and long term memory cell persistence.

There were three additional studies that found neutralizing anti by the Tigers were higher following an extended dosing interval with a vaccine compared to the standard interval of 3 to 4 weeks. Backslide. So in summary, the rates of myocarditis and pericarditis were lower with the

extended interval between the first and second dose of mRNA vaccine primary series. This extended interval may improve immunogenicity and vaccine effectiveness.

Next slide.

So all go over our first self knowledge check here, again, you don't need to put the answers in the Q&A. This is just for you to think about, extending the interval between the first and second mRNA COVID-19 vaccine dose may help to, a, reduce the small risk of myocarditis, be increase vaccine effectiveness, and see, both A and B. The correct answer is C. Studies in adolescents and adults have shown that the small risk of myocarditis maybe reduced and that the peak antibody response in vaccine effectiveness may be increased with an interval longer than four weeks. So this point I'll turn it over to Dr.

Hall, who can walk us over updates to people who are moderately to severely immunocompromised.

Thank you, next slide please.

Next slide. So recommendations for people who are immunocompromised at the time a vaccination are different then recommendations for most people. This is because, this group is at increased risk for severe COVID-19, they're more likely to have serious breakthrough infections. They may not mount a protective immune response after two dose primary series and in general have lower vaccine effectiveness than people who are not immunocompromised and have waning protection overtime.

Next slide. Moderate and severe immunocompromising conditions and treatment include but are not limited to, active treatment for solid tumor and hematologic malignancies, receipt of solid organ transplant or taking immunosuppressive therapy, receipt of car T cell or hepatic poetic stem cell transplant, moderate or severe primary immunodeficiency, advanced or untreated HIV infection, active treatment with high dose -- you can find more information on resources to consult for additional information about the degree of immune suppression associated with different medical conditions and treatments at the link listed on the slide.

Next slide please. As a reminder, individuals can self-'s test to their moderately or -- wherever vaccines are offered. Ppatients do not need to provide ddocumentation.

VVaccinators should not deny CCOVID-19 vaccination to a person ddue to a lack of documentation. People -- this helps to prevent barriers to access for this population. If individuals have questions about their health conditions, they should discuss with their health care provider about what is appropriate for them. To help with self at a station, CDC provides a pre-vaccination checklist, this provides a checklist on if they're moderately or severely immunocompromised.

The next slide please.

So the first update all cover is clarification of existing guidance. There is been recent confusion about the recommendation for this population. Therefore, we've clarify that this population should receive a primary series of three mRNA COVID-19 vaccine doses for people five years and older, followed by one booster dose or a fourth dose for those aged 12 and older. Those 5 to 11 are not eligible for a booster dose. There are no changes in the number of doses here, it is simply clarification to address the challenges we are hearing, and to emphasize that a total of four doses is recommended.

Next slide. The next few things I want to discuss are allowed through regulatory provision known as emergency use instructions or EUI, this was an acted under the pandemic and all hazards preparedness reauthorization act of 2013. What this did was allowed creating an issuing EUI for FDA approved, or FDA licensed in the case of vaccines, products regarding their approved indications with instructions that go beyong the FDA approved labeling more package insert. This authority was delegated to the CDC director. The CDC director may issue EUI for emergency use of FDA medical products that go beyond the approved labeling or patch cage insert based on available supported information and circumstances of the emergency.

For example, EUI for FDA license COVID vaccines may resuscitate modified dosing interval, schedule, or regiment from the FDA approved label dosing. The scope of the EUI authority is limited only to those medical products that are FDA approved, and pertain to their FDA approved indications. Therefore, the COVID-19 vaccines that are EUI eligible currently, are the two mRNA vaccines that have received FDA licensure for prevention of SARS-CoV-2. Those would be spike vax or Moderna the, this would apply to people 18 years or older. We guidance would apply to 12 years and older for biotech.

Next slide please. EUI materials including EUI factions for health care providers include this information, fact sheets recipients and caregivers, can be found on the website listed on the slide. Next slide. So there are three updates utilizing that EUI mechanism for people who are moderately or severely immunocompromised. These are all gonna apply to Pfizer and Moderna as I mentioned previously.

So the first update is a shortened interval between completion of an mRNA COVID-19 vaccine primary series, and a booster dose. People who are moderately or severely immunocompromised should now receive a booster at least three months after the last or third dose of an mRNA COVID-19 vaccine primary series. So previously this interval was five months, the rationale for this decision was out of an abundance of caution to help this population that may not be as well protected get their booster dose sooner. Particularly with concerns about initial immune response, loss of protection overtime, high community transmission.

Next slide.

The next update is for people who are moderately or severely immunocompromised that received a Janssen COVID 19 primary series. These people are now recommended to receive one second additional mRNA COVID-19 vaccine dose, at least 28 days after the primary Janssen COVID-19 vaccination dose, and a booster dose at least two months after completion of the additional dose. This will give a total of three doses. We realize many people may have already received two

doses, one primary dose and one booster dose. So our updated clinical consideration includes an appendix that provides guidance for people who have already received a booster dose prior to the recommendation for the second additional dose using an mRNA COVID-19 vaccine.

Next slide. So finally with the updates, guidance has been added that on a case by case basis, providers who care for moderately or severely immunocompromised patients may administer mRNA COVID-19 vaccines outside of the FDA and CDC dosing intervals based on clinical judgment when the benefits of a different vaccination with a different schedule or dosage are deemed to outweigh the potential unknown risks. One note, provider should not routinely administer additional voices of COVID-19 vaccine beyond those recommended in this guidance. They can consult treatment guidelines for use of monocryl antibodies, for moderately or severely immunocompromised people who may not mount an immune response to COVID-19 vaccination.

Next slide.

Let's through view with our next knowledge check. At this time how many total doses of COVID-19 vaccine should a moderately or severely immunocompromised person receive? A, too. B, three. C, for. Or D, it depends on their age and which vaccine they received for their primary series.

Next slide. So the correct answer is, the. For mRNA COVID vaccine recipients a three dose primary series is recommended for peoples aged five and older who are moderately or severely immunocompromised. People 12 and older should receive a booster dose for a total of four doses. Then for Janssen COVID-19 vaccine recipients, a primary Janssen vaccine dose is recommended for people ages 18 and older who are moderately or severely immunocompromised, followed by a second additional dose using an mRNA COVID-19 vaccine and a booster dose, for a total of three doses.

And now I will go ahead and pass it over to my colleague Dr. 20 men.

A thank you so much. I will be covering additional updates recently made to our COCA considerations as well as providing a summary of our current recommendations for COVID-19 by age group.

Next slide please. As you will see, our newest recommendations for COVID-19 vaccination by age group incorporates all of the updated guidance for clinicians on COVID-19 vaccines, that you've heard here today.

Next slide please first I will summarize our new and simplified guidance for COVID-19 vaccination for people who receive passive antibody products.

Whether those passive antibodies were used from prophylaxis or for treatment. Our previous guidance recommended deferred vaccination for 30 days if a passive and a body was used for post exposure prophylaxis. 90 days if that passive anybody product was used for treatment, we had no guidance for -- we now recommend no deferral period following receipt of any passive

anybody product and subsequent vaccination. This simplifies a recommendation here regardless of product receive, patients do not need to wait to initiate vaccination. We do have one consideration.

In other words, we see a passive anybody product after vaccination, it's administered for pre exposure prophylaxis in people aged 12 and up who are unable to receive COVID-19 vaccination all due to a severe adverse reaction. Or for those with moderate or severe immunocompromised who may not mount an adequate immune response. Among those in this group who can receive COVID-19 vaccination this pre exposure prophylaxis should be administered at least two weeks after that COVID-19 vaccination.

Next slide please. I'll now summarize our new recommendations for the interval between the first and second mRNA COVID-19 vaccine doses.

As you might recall from the earlier presentation, the advisory committee and our immunization practices have had the opportunity to review events related to an extended interval between first and second doses of vaccines. This evidence as you saw presented here today, it suggests that extending this interval between the first and second mRNA COVID-19 vaccine doses may help both to reduce the small risk of marrow keratitis and increase vaccine effectiveness. We observed in our clinical considerations that some people, ages 12 through 64 years, especially males ages 12 through 29 years, may benefit from getting their second vaccine dose eight weeks after receiving their first dose. Providers should continue, however, to recommend the three or four-week interval, depending on whether that is Pfizer or Moderna, respectively. For patients who are at higher risk of having and inadequate response to the first mRNA dose, such as those who are moderately or severely immunocompromised.

Those who are at higher risk of severe COVID-19 disease, such as adults ages 65 years and older, those who need rapid protection, such a during high levels of community transmission. And among children ages five through 11 years old, among whom these extended intervals have not yet -- next slide, please. We will now transition to presenting the new COVID-19 vaccination schedules. Before we present them, we wanted to reiterate that COVID-19 primary series vaccination is recommended for everyone, ages five years and older in the United States for the prevention of COVID-19. This recommendation includes people both with and without underlying medical conditions.

As you've seen here today, people with moderate or severe immunocompromised have additional consideration and need more doses than others. To echo what Dr. Oliver and Dr. Hall stated earlier, vaccinating the unvaccinated with a primary series is extremely important. Vaccines remain our best public health measure for reducing the spread of COVID-19 and preventing the emergence of new variants.

Additionally here, we would like to underscore that in most situations, Pfizer BioNTech, or Moderna vaccines, in other words, the mRNA vaccines, are preferred over the home Janssen vaccine for both primary and booster vaccination.

Next slide on this slide, we are sharing with you our new COVID-19 vaccination schedule for people ages five years and older, who do not have moderate or severe immunocompromised. To briefly summarize these recommendations, by age group and going down this chart by row, children ages 5 to 11 years are eligible only for the Pfizer BioNTech COVID-19 vaccine. Those ages 5 to 11 should receive their doses three weeks apart. People in this age group are not eligible for a booster doses.

That's why you don't see a green box after the second dose for those in this range. People ages 12 years and older who receive the Pfizer BioNTech COVID-19 vaccine, including adolescents ages 12 to 17 years, who are eligible only for the floors were BioNTech vaccine, should receive two doses in their primary series. And a booster dose at least five months after. People ages 18 years and older are eligible for the Pfizer BioNTech, Moderna, and Johnson COVID-19 vaccine. Those who received Moderna should receive two doses in their primary series, and a booster dose at least five months after completing that primary series.

In terms of the timing between the first and second doses for both mRNA vaccines, meaning for both Pfizer BioNTech, and Moderna vaccines, an eight-week interval may be optimal for some people ages 12 years and older, especially from ages ages 12 to 29 years. A shorter interval, three weeks, between the first and second doses, remains the recommended interval for people who are moderately or severely immunocompromised. For adults, ages 65 years and older. And others who need rapid protection due to increased concern about community transmission or risk of severe COVID-19. The last row in this chart includes are used for Janssen COVID-19 vaccine, although mRNA COVID-19 vaccines are preferred over the Janssen vaccine for both.

Those who receive Janssen should receive a single dose and a booster dose, at least two months later.

Next slide, please. On this slide, we are sharing with you our new designation schedule for people ages five years and older, who have moderate or severe immunocompromised. You will note that recipients of mRNA vaccines are recommended to receive three doses in the primary series. For Pfizer, the first and Dennis -- a second doses should be given three weeks apart.

The third dose in the primary series should be given for weeks after. For Moderna, in contrast, the second doses should be given four weeks apart and the third dose in the primary series should be given for weeks after that. All people with moderate or severe immunocompromised who receive mRNA vaccines and our ages 12 years or older are also eligible for a booster dose. Now recommended to be given three months after completion of the three dose primary series. Therefore, people with moderate or severe immunocompromised who receive mRNA vaccines under 12 years or older or recommended to receive four total vaccine doses.

And thanks to everyone on this call for helping us continue to spread the word to that end. On this last row in this revised schedule for COVID-19 vaccination, you will see a revised recommendation for the with moderate or severe immunocompromised, who receive the Janssen COVID-19 vaccination. These individuals should receive a second additional dose using an mRNA vaccine, at least four weeks after their Jansen dose.

Next slide, please. Let's move now to our last knowledge check.

Which people are among groups who should continue to receive their second mRNA COVID-19 dose at three or four weeks after their first mRNA COVID-19 dose? Is it a, people who are moderately or severely immunocompromised? Be, adults aged 65 years and older? See, people in areas of high levels of community transmission? De, children ages 5 to 11 years? Or E, all of the above? And drumroll, please. And move to the next slide, please.

Correct answer is B. A three or four-week interval is still recommended for people who are at higher risk of having an inadequate response to the first mRNA vaccine dose. They are at higher risk of receiving complications of COVID-19.

Or they need rapid protection. That three-week interval and the four-week interval for Moderna.

Next slide, please. Concluding this presentation, we did want to stop to sincerely thank you. Not only for your attendance and your attention here today, but also for the excellent care you are providing to your patients and your communities.

And the dedication to preventing COVID-19 that your presence here today only serves to further underscore. So sincere thanks to you for your time and for your efforts in this pandemic. This concludes our remarks and we really welcome your questions. Thank you.

Profit centers, thank you so much for providing our audience with this timely information. We will now go into our Q&A session. Joining us for the Q&A session is commander Sarah Bay, senior adviser for the vaccine task force as part of CDC's COVID-19 response. Audience, please remember that you ask a question using Zoom, click the Q&A button at the bottom of your screen and type your question. Please do note that we often receive many more questions than we can answer during our session.

For our first question to the presenters, this is a question we are seeing quite a lot in the Q&A box. That is regarding the information that we shared about the Canadian studies as well as the study from England.

First question regarding that data asks, based on the vaccine effectiveness against hospitalization, the vaccine effectiveness against infection, it seemed like there was quite a similarity between the seven week mark and the 11 week mark and can you share a little bit more on what led to the conclusion of choosing eight-week interval as the one, and not, say, nine weeks or ten weeks?

Hi. This is Dr. Oliver. I am happy to get started with a question. So absolutely, wanting to highlight that if we think back to those figures, we really saw that the benefits of extending the interval seem to level off at about eight weeks.

The added benefit but, as was mentioned, was minimal once you got beyond eight weeks. We do know that recommendations for extending an interval, especially while we remain within a pandemic, really need to be balanced. So you've got a long term benefits of improving longer term -- and lowering the myocarditis risk. You also have a longer time where you are only

protected with the first mRNA vaccine dose. And so, I've also seen many questions in the chat where people are asking, what about this situation are that situation? When it comes to the extended a week interval.

This is why we wanted to go through and explain the data so people are aware. We went with eight weeks because that really seems to be the best balance of that trade-off of benefits and risk. You get the benefits of lowering the myocarditis, having the improved longer term a vaccine effectiveness, but minimizing the length of time with which you are only protected with the first dose. For individuals who are thinking through what should they remain with a three or four-week interval, obviously provided what ACIP and other experts felt. Obviously, individuals who are immunocompromised or remain at high risk, they would want to get that second dose earlier.

But I think that is also something that can go into those discussions of that trade-off. But that is why we felt that the balance of that benefit and risk supported the eight week interval.

Thank you very much for that.

As a follow-up question to some of the seams lines we were discussing earlier, regarding both the studies from Canada and England, day do you find that the risk for myocarditis and pericarditis very based on sex?

This is Dr. Oliver. As we have seen really, across the studies when we look at mRNA, and when we've looked at myocarditis with these vaccines. We tend to see that the highest rates of myocarditis are in males. And in that younger, I believe we should 12 to 49 in this print cetacean several times.

But in that age group. In many of the instances, with Canada, it's difficult. As you start to look at each individual week cut down by vaccines, they are not always able to provide figures that look at females and males for all of the different permutations of the intervals. But we do know that the risks of myocarditis appear to be higher in a young males. But we know that that's the population that benefited the most if the reduced myocarditis rates were for a longer interval.

We know that females can experience myocarditis and would also potentially benefit from the extended interval, as well.

Great. Thank you very much.

The next question asks them that you did address the hospitalization and vaccine effectiveness against infection. Did you also see a similar promising data for vaccine effectiveness against death? Or was that not captured as part of the study?

Again, Doctor Oliver. I'm happy to take that one. It's mostly that if we are looking at shorter term studies, thankfully, death due to COVID-19 is a rare rare outcome than if you are looking -- it's more difficult to get larger estimates, especially if you are looking relatively shortly after the vaccine. So we assume that if it's improving vaccine effectiveness against both infection and

severe disease in forms of hospitalization, that we would also see increased protection against death. So it is mostly just that COVID deaths are a rare outcome.

Sometimes it is harm, in some studies, to get estimates for that. Thank you very much.

Another question that we have received is, this is also another one that has shown up in a couple of different ways in the Q&A box, the new guidance, in light of this new guidance, are there any changes to reporting or documenting things that folks should know about? Mueller.

Sorry, go ahead.

I was just gonna chime in, I think we're all gonna see who's gonna take this question. There are no changes to reporting requirements other than those that are currently listed in the fact sheets, as well as what's listed in our considerations, those have remain the same. There are no new or additional requirements.

Thank you very much.

Our next question asks, the dose series that you discussed, can you please go over that one more time? I think because this is new for some of our audience, there is a few questions regarding, trying to understand the 5 to 12 year old range and then the 12 and older, three dose versus four dose. I believe those one of the knowledge check questions as well that said it depended on the patient age group. So if you don't mind revisiting that, we would appreciate it.

This is Dr. Hall, I can jump in for that when. The number of doses depends on age and the type of vaccine shows and for the primary series. Starting with the 5 to 11 year age group, for those that are moderately or severely immunocompromised, I think this might be at the question is getting out, so I'll get to that first. They should receive three doses, they should all be primary doses.

5 to 11 is not eligible for a booster at this time. Then moving up to the next age group, 12 and older, so, excuse me, 12 to 17 can only receive Pfizer. They'll receive a total of four doses if immunocompromised, they have a three dose primary series, just like five through 11, but they also get a booster dose. Then 18 and over, they're eligible for Pfizer, Moderna and Janssen. We'll start with Pfizer and Moderna cause they're going to be the same number of doses.

In either series there's going to be three primary doses for Pfizer or Moderna followed by a booster dose, so total of four doses. Finally, if Janssen is selected, that's going to be one primary dose, followed by a second additional dose, followed by a booster dose, a total of three doses there. I'm not sure if the question is also asking about those who are not immunocompromised, would you like me to go over that as well? Or is this move --.

That would be helpful, the way delineated it was very helpful. I've tried to compile several questions I think if you cover that patient population, I think that would be appreciated.

In that case, for most people, those who are not moderately or severely immunocompromised, this is also going to vary by age and by the vaccine selected for the primary series. Starting again with five through 11, these kids are only eligible for Pfizer. Same situation, they do not get a booster, these kids would only have two doses and they're going to be be primary series doses, no booster. For those aged 12 to 17, again, Pfizer only, the difference here being that this group also gets a booster dose. So to primary series doses and a booster dose, you have a total of three doses.

Then those 18 years and older are eligible for Pfizer, Moderna or Janssen. Again, starting with Pfizer Moderna because they're going to be the same total number of doses. They're going to be three total doses, you have two primary series followed by one booster dose, for a total of three. Then if Janssen is selected, that's one primary series dose, followed by one booster dose for a total of two doses. Hopefully that visual schedule that we've added to the interim clinical considerations web page will help out, because I know that was a lot to follow.

The visual schedule really helps to lay out the number of doses. Thank you very much for that. For our audience if you're looking to find those resources go to this COCA calls page and you can find links to that as well, as well as the slides, the audio as well.

A follow-up question for you on that. When you are referring to a booster, in those cases is that a full dose or a half dose, or is that a reduced dose?

Oh I can answer this one again it's going to depend on the vaccine that is used. We'll take Pfizer, 5 to 11, out of this, they don't get a booster. Looking at those 12 years and older. Pfizer is the 0. 3 millilitre dose, no matter if it's primary or a booster dose.

Janssen we, I'll skip to that one, this one is straightforward, it's a 0. 5 millilitre dose whether it's primary or booster. Moderna is the one that is different. So for a primary dose, this is a point to five millilitre or 50 microgram dose, excuse me, for a booster dose it is point 25 milliliters or 50 micrograms, for a primary dose it is 0. 5 milliliters or 100 micrograms.

It is a larger dose for the primary dose and a smaller dose for the booster dose.

Great, thank you very much.

Our next question asks, are there any changes to vaccine recommendations for health care workers regardless of immunocompromised that is or not?

This is Dr. Oliver, I also see lots of questions on what does the future look like for the COVID vaccine program? I'm happy to just kind of provide some comments on health care workers, as well as the overall we don't have recommendations for. Additional doses beyond what has been described so far in this presentation. We will very closely, we vary continuously work with a vaccine effectiveness vaccine, our colleagues at CDC are continuously monitoring. We work very closely with colleagues FDA. If it appears that we need additional doses, either in a specific population or in the population at large, we will very closely evaluates the data for the safety and effectiveness of the vaccine.

We would discuss those recommendations publicly at a meeting. We would then be happy to come back and have a COCA call to talk about with the updated recommendations are. I can say right now, we don't have any updated recommendations, we're not anticipating in the imminent future there being additional booster doses for any particular population. We are continuing to monitor the data very closely. If there is a need for that, we will absolutely evaluate the data and discuss it publicly.

We will make sure that you guys are aware as soon as those recommendations are made.

Thank you very much.

Our next question asks, in the studies that you shared did you find the risk of myocarditis and pericarditis to be cumulative with each successive dose or not?

This is doctor all over me. This is a great question mark, this has been discussed, I don't have the slide or figures to show right now. The data that we review today, as well as data that we've seen as we look at both the U. S. and the global experience with boosters, it's that it's not a cumulative thing you're at risk of.

Myocarditis goes up after those two and gets higher after those three. We do know me that we have a lot to do with that interval. So we push the second dose out, that lowers the risk of myocarditis but if we skip ahead to the boosters, we know that the rate of myocarditis that we've seen after boosters, which are given in the five months, we had data for six months later. We see the rates myocarditis considerably fall me. There is somewhere between the rates that we see for those one and dose two, but closer to the rates that we see near dose one.

It's not a cumulative effect for the risk of myocarditis going up for every subsequent dose. There's a lot more that goes into it, we're learning how the interval between doses plays a role. The longer interval between the primary series lowers that risk. The prolonged interval, the months in between what we've seen with the primary series in the booster doses, definitely lowers the risk of myocarditis as well.

Thank you.

Our next question asks you to discuss the benefits of increasing the interval on vaccine effectiveness and decreasing the risk of myocarditis me. Is there is similar data available that either validates or affirms the need to increase the interval, regarding -- with the Janssen vaccine?

That's an interesting question mark. We have seen that most of the rates of PTS that we've seen, that we've reported in the U. S. have occurred after one dose. So it's not bend that we're seeing it after multiple doses.

The rates, the last time that they publicly reviewed the rates on this was in December. If you look then those rates for both TTS as well as deaths associated with TTS, where after the first dose. We know that globally other countries have seen that there is still a risk of TTS with his second

dose, many instances they're using AstraZeneca, this is a similar platform as what the Johnson & Johnson vaccine is. So I think it's less likely to be an interval thing there, the rates of what we've seen, at least in the U. S., have been after the first dose.

Great, thank you. We have time for one more question.

Our last question asks, in light of the new guidance and information that you have shared, would you consider the definition of fully vaccinated to be changed based on the patients immunocompromised at us? Me.

I can take that one. I'll start by saying CDC has not changed the definition of fully vaccinated. We have this useful new term of being up to date with your vaccines. Being fully vaccinated means having completed your primary series, being up to date means having completed your primary series and all doses for which you are eligible. Whatever your age category is.

So for a five year old, that would only be two RNA doses. Whereas a 65 year old would be eligible, if we hold the example of Pfizer, they would be eligible for two primary doses, plus a booster dose, unless they were immunocompromised, when they would be eligible for three primary series doses and a booster dose. We, to my knowledge, we do not have plans to change the definition of fully vaccinated. So that contrast, I hope that's helpful. It means you completed your primary series, being up to date means you've completed all doses for which you are currently eligible.

I think that was a great explanation. Thank you for the distinction, it is helpful. I want to thank everyone for joining us today with a special thanks to our presenters and our experts. While continuing education for coca calls are issued online through this CDC training and continuing education system at https://tceols.cdc.gov/.

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Facebook at Facebook dot com forward slash CDC combination outreach and communication activity. I want to thank you for joining us for today's COCA Call.

Have a great day.