Good afternoon. I'm Commander Ibad Khan, and I'm representing the Clinician Outreach Communication Activity, COCA, with the Emergency Risk Communication Branch at the Centers for Disease Control and Prevention. I'd like to welcome you to today's COCA Call: What Clinicians Need to Know about Johnson and Johnson's Janssen COVID-19 Vaccine. Continuing education is not offered for this webinar. All participants today are in listen only mode.

After the presentation, there will be a Q&A session. You may submit questions at any time during today's presentation. To ask a question using Zoom, click the Q&A button at the bottom of your screen. Type your question in the Q&A box. The video recording of this call will be posted on COCA's webpage and available to view on demand a few hours after the call ends.

If you're a patient, please refer your questions to your healthcare provider. For those who may have media questions, please contact CDC Media Relations at 404-639-3286 or send an email to media@cdc. gov.

Now I would like to welcome our presenters for today's COCA Call. We are pleased to have with us today Lieutenant Commander Sarah Oliver, the co-lead for the Advisory Committee for Immunization Practices, COVID-19 Vaccines Work Group as part of CDC's COVID-19 response. Commander Sarah Mbaeyi, Medical Officer in the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention. And Dr. Kathleen Dooling, Medical Officer and co-lead for the Advisory Committee for Immunization Practices COVID-19 Caccines Work Group as part of CDC's COVID-19 response. It is my pleasure now to turn it over to Lieutenant Commander Oliver. Lieutenant Commander Oliver, please proceed.

Thanks so much. Next slide.

So this is what the three of us will be talking about today. I'll go over the safety and efficacy of the Janssen COVID-19 vaccine. And then Dr. Mbaeyi will go over clinical considerations for the use of the vaccine, and Dr. Dooling will go over implementation considerations. Next slide.

So I'll just go over a quick summary of the available evidence from the phase three trials, first on vaccine efficacy, then on safety and reactogenicity. These slides will provide an overview. But for a deeper dive into the data, the slides from the ACIP meeting this weekend are up on the ACIP website. So the clinical trial demonstrated efficacy against symptomatic lab-confirmed COVID-19 with an efficacy of 66. 3% starting 14 days after vaccination. For hospitalization, 31 events occurred. 29 were in the placebo group and two in the vaccine group. Vaccine efficacy against hospitalization was 93%. And for all-cause mortality, five deaths occurred in the vaccine group and 20 in the placebo group for an estimate against all-cause mortality of 75%. Next slide.

Preliminary data were available to look at vaccine efficacy against seroconversion between days 29 and day 71, based on the first 7% of specimens tested. The analysis was based on detection of the N-binding antibody among persons who remained asymptomatic and did not have a positive SARS-CoV-2 PCR at any time in the study.

So between four and 10 weeks after vaccination, 10, or 0. 7%, of vaccine recipients seroconverted compared to 37 or 2. 8% of placebo recipients, for a vaccine efficacy against asymptomatic seroconversion of 74%. While this data is encouraging, it is a single time point only 10 weeks after vaccine receipt, and it's in less than 10% of the study population. So we look forward to more data on this as the trial progresses. Next slide.

So this one shows a similar efficacy was noted across age, sex, race, and ethnicity categories and those with underlying medical conditions 14 days or more post-vaccination. Each of the estimates are shown here on this graph and you can see that they all coalesce around that overall efficacy endpoint of 66%. Next slide. There was higher efficacy against severe outcomes than for symptomatic COVID with an efficacy against COVID-19 associated death of 100%.

Efficacy estimates for severe outcomes assessed at 28 days or more post-vaccination were even higher at 83% for severe disease, and 100% for hospitalization. Efficacy against severe illness remained high across world regions, suggesting protection against severe illness even with the variant strains. Next slide.

So next, I'll just provide a quick summary for the safety and reactogenicity data seen in the phase three trials. Serious adverse events were reported in a similar proportion among recipients of vaccine and placebo.

The reactogenicity outcome graded which was used for our evidence determination at ACIP was severe or grade three reactions. Overall, a grade three or higher reaction, which means those with symptoms that were severe enough to prevent daily activity, were reported by 2. 5% of those receiving the vaccine and 0. 7% of placebo. Next slide.

Local reactions occurring within seven days were common, with pain at the injection site as the most common. Systemic reaction within seven days were common as well. Headache, fatigue, and myalgias were the most common, but most symptoms resolved after one to two days. Next slide.

So this figure shows reactogenicity, including local and systemic adverse events by age group. The blue bars are those who received vaccine and the gray bars are the placebo recipients. In each color, the darker bars are adults 18 to 59 years, and the lighter bars are older adults. So this figure shows that the reactogenicity was higher among vaccine compared to placebo recipients and in younger compared to older adults. Next slide.

So this figure has similar colors and layout as the previous slide, but it's only showing numbers for those grade three reactions. Note that the scale for this figure is substantially different. Overall, grade three reactions were rare, in the range of 1 to 2% of participants, and again, more common in the younger age. As was done with other COVID-19 vaccines, we have a website summarizing reactogenicity data on the CDC and ACIP websites to help inform providers and patients about symptoms post-vaccination that were seen in the clinical trials. Next slide.

There were several adverse event imbalances of note from the clinical trials. This doesn't mean that there's a causal relationship, but that these events are highlighted and will be important for

future post-authorization safety monitoring. Urticaria events, which FDA determines could possibly be related to the vaccine. And then tinnitus and thromboembolic events where FDA stated that there was insufficient data to determine a causal relationship. In addition for thromboembolic events, many of the participants had predisposing conditions. But FDA recommends surveillance for further evaluation of thromboembolic events. Next slide.

This is the third COVID vaccine with an emergency use authorization. We just wanted to provide some thoughts as to how this vaccine fits into the overall program. There were no trials that compared efficacy between vaccines in the same study at the same time. All phase three trials differed by calendar time and geography.

This is important because it means the vaccines were tested against different circulating variants and in settings with different background incidence. So this limits the ability to draw specific comparisons with each of the phase three trials. All authorized COVID vaccines have demonstrated efficacy against symptomatic lab-confirmed COVID ranging from 65 to 95%. All authorized COVID vaccines have demonstrated high efficacy against COVID severe enough to require hospitalization at 89% or higher. And in the vaccine trials, no participants who received a COVID vaccine died from COVID. Both the Moderna and Janssen trials had COVID deaths in the placebo arm. Next slide.

And with that, I'll turn it over to Dr. Mbaeyi to go over clinical considerations for use of the Janssen COVID vaccine.

Great. Thank you so much, Dr. Oliver. Next slide.

CDC's clinical considerations for the use of mRNA COVID-19 vaccines are published on the CDC website. Today, I will present updates to these clinical considerations to include information on the newly authorized Janssen viral vector COVID-19 vaccine. I will also include other key updates that have been made to the clinical considerations since the December ACIP meetings. These considerations will continue to be updated as additional information becomes available, or if additional vaccine products are authorized. I also wanted to highlight that you can sign up to receive email updates when the clinical considerations are updated by scrolling to the very bottom of the webpage listed on this slide. Next slide.

Janssen COVID-19 vaccine is authorized for persons 18 years of age or older. It is administered through intramuscular injection with a dose volume of .5 mL. The vaccine is shipped and stored at refrigerator temperatures of two to eight degrees Celsius. It is administered as a single dose and there is no diluent required. Next slide.

Any of the currently authorized COVID-19 vaccines can be used when indicated. ACIP does not state a product preference. However, the COVID-19 vaccines are not interchangeable. And the safety and efficacy of a mixed product series has not been evaluated.

In exceptional situations where the first dose of an mRNA COVID-19 vaccine was received but the patient is unable to complete the series with either the same or different mRNA COVID-19 vaccine -- for example, due to a contraindication -- a single dose of Janssen COVID-19 vaccine

may be administered at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose. But I will come back to this a little bit more again when we talk about contraindications and precautions in this presentation. However, these patients should be considered to have received a valid single dose Janssen vaccination series, not a mixed series. Next slide.

The currently authorized COVID-19 vaccines are all non-replicating vaccines and they are not live vaccines. COVID-19 vaccines should be administered alone with a minimum interval of 14 days before after administration with any other vaccines. However, a shorter interval may be used in certain situations where the benefits of vaccination are deemed to outweigh the potential unknown risks for coadministration. For example, tetanus toxoid containing vaccination as part of wound management. Or to avoid barriers or delays to COVID-19 vaccination. For example, in long term care facility residents or healthcare personnel who received influenza or other vaccinations prior to or upon admission or onboarding. Next slide.

COVID-19 vaccines can be administered to persons with underlying medical conditions who have no contraindications to vaccination. The clinical considerations guidance includes information for vaccination of immunocompromised persons, those with autoimmune conditions and persons with a history of Guillain-Barre syndrome, Bell's palsy, and dermal filler use. Clinical trials have demonstrated similar safety and efficacy profiles in persons with underlying medical conditions, including those that place them at increased risk for severe COVID-19 compared to persons without comorbidities. Next slide.

Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19. Immunocompromised individuals may receive COVID-19 vaccination if they have no contraindications, but should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses and the need to continue to follow current guidance to protect themselves against COVID-19. Next slide.

Observational data demonstrate that pregnant people with COVID-19 have an increased risk of severe illness, though the absolute risk is low. Additionally, they might be at increased risk of adverse pregnancy outcomes.

There are currently limited data on the safety of COVID-19 vaccines in pregnant people. No safety concerns were demonstrated in animals that received any of the three authorized COVID-19 vaccines. In addition, the adenovirus vector platform used in the Janssen COVID-19 vaccine has been used for other vaccine development programs that included pregnant people vaccinated during any trimester, including a large scale Ebola vaccination trial. And no adverse pregnancy related outcomes, including infant outcomes, were determined related to the vaccine in these trials. Based on current knowledge, experts believe that COVID-19 vaccines are unlikely to pose a risk to the pregnant person or her fetus, because none of the currently authorized COVID-19 vaccines are live vaccines.

All are non-replicating vaccines. However, the potential risks of COVID-19 vaccines to the pregnant person and the fetus are unknown because these vaccines have not been studied in pregnant people. Next slide.

Pregnant people may choose to receive a COVID-19 vaccine when eligible. A conversation between the patient and their clinical team may assist with decisions about the use of a COVID-19 vaccine, though a conversation with a healthcare provider is not required prior to vaccination.

When making a decision, pregnant people and their healthcare providers should consider the risk -- consider the level of COVID-19 community transmission, the patient's personal risk of contracting COVID-19, the risks of COVID-19 to the patient and potential risks to the fetus, the efficacy of the vaccine, the side effects of the vaccine, and the limited data about the vaccine during pregnancy. Next slide.

Recommendations for contraindications and precautions for the COVID-19 vaccines are summarized in this table. Beginning at the left in the red box are contraindications to vaccination. Contraindications include a history of severe allergic reaction after a previous dose, or to a component of a COVID-19 vaccine, or an immediate allergic reaction of any severity to a previous dose, or known diagnosed allergy to a component of the vaccine.

Individuals with a contraindication should not be vaccinated, and consideration should be given to referral to an allergist immunologist and providing another vaccine alternative. In the yellow box are precautions to vaccination. Precautions include persons without a contraindication who have a history of any immediate allergic reaction to other vaccines or injectable therapies. And we will be issuing more specific guidance around use of Janssen vaccine in persons with a contraindication to mRNA vaccines. So please stay tuned for that specific information when the guidance is released.

Individuals with the precaution should receive a risk assessment, and referral to an allergist immunologist should be considered. If vaccinated, these individuals should be observed for 30 minutes following vaccination. Finally, the green box summarizes people who can proceed with vaccination. Individuals without a contraindication or precaution, but with a history of allergy to oral medicines, foods, pets et cetera, or with a family history of allergies can be vaccinated. In these situations, a 30-minute observation period should be used with individuals with a history of anaphylaxis due to any cause, while a 15-minute observation period should be used for all other people. Next slide.

And with that, I will turn it over to Dr. Dooling.

Thank you very much, Dr. Mbaeyi. Next slide, please.

So in the unanimous vote to recommend the Janssen vaccine, the ACIP stated no preference for any of the three authorized vaccines. The vaccines were not studied in head to head trials, therefore the results of the Janssen phase three trials are not directly comparable with the mRNA vaccines.

The Janssen COVID-19 vaccine was studied at different calendar time and geography which led to different circulating strains of SARS-CoV-2 variants and a higher background of incidence during the time the vaccine was studied. The Janssen vaccine demonstrated strong protection against severe COVID with 93% vaccine efficacy against hospitalizations, with two cases in the vaccinated group compared to 29 cases in the placebo group. And moreover, there were no COVID associated deaths in the vaccinated group, versus seven in the placebo group. Next slide.

So given that the vaccine has been authorized for emergency use by the FDA, and recommended by the ACIP, how does this vaccine best fit into the national COVID-19 vaccination program? The characteristics of the vaccine are that it is a one dose regime and it may be transported and stored at two to eight degrees Celsius for up to three months.

It requires no diluent or reconstitution at the point of use. Next slide. With regard to where the Janssen COVID-19 vaccine may best fit into a vaccination program, jurisdictions may consider use in places such as mobile or popup clinics, newly established vaccine administration sites, or sites that do not have freezer capacity, which is the case for many adults healthcare provider offices. It should be noted that the type of vaccine available at any given appointment should be transparent to the consumer. In terms of who, people who want to be fully vaccinated quickly, people who don't want to return or can't return for a second dose and mobile populations or homebound populations. Next slide.

Ultimately, the workgroup and the ACIP felt that during a pandemic and under an emergency use authorization, offering Janssen COVID-19 vaccine to persons 18 and older according to established allocation and eligibility recommendations in a given jurisdiction is an effective implementation strategy. This approach allows for jurisdictional flexibility, supports rapid vaccination, and increases in population immunity, does not single out any group, and finally allows for individuals to be vaccinated with the earliest vaccine available. Thank you. That concludes my portion of the presentation and I will turn the microphone back to Dr. Khan.

Thank you so much, presenters. Thank you for providing our audience with such useful information. We will now go into our Q&A session. Our first question asks, are pregnant women recommended to get one COVID-19 vaccine over another?

Hi, this is Sarah Mbaeyi. I will answer that question. So no, pregnant women can receive any of the authorized vaccines, BioNTech, Moderna or Janssen. And so there's no product preference. ACIP states that they can receive any of those vaccines.

And you know, that's because these vaccines, you know, none of them are live vaccines, none of them are replicating. So experts believe that they're unlikely to pose a risk to the unborn child. But of course, further data collection is ongoing. There is data for all three of these types of vaccines. There have been women enrolled through VSAFE, which is our kind of active safety surveillance system where people can kind of opt in and self-declare themselves as being pregnant.

There are women who have received Pfizer, BioNTech and Moderna who are pregnant. And so safety data is being collected and reviewed on them. But as I mentioned in the talk, using the

exact same platform, the adenovirus viral vector platform that is used for the Janssen vaccine -- that has been used in other clinical trials in which pregnant women have been enrolled and monitored. So we also have safety data for pregnant women who have received a vaccine that uses the same vector platform. So ACIP has not stated any product preference.

Again, pregnant women can choose to be vaccinated. It could be helpful to have a conversation with their provider, but there is no preferential recommendation for one COVID-19 vaccine over another.

Thank you for that. Our next question is specific to the Janssen vaccine. And our inquirer asks that they've heard of a trial of Janssen vaccine going on as a two-dose series. And they want to know if you think people that get one dose now will eventually need to go back to get that second dose, depending on the study.

Hi, this is Dr. Dooling. So that is correct. There is a phase three trial that's currently studying a two-dose Janssen series. The doses are separated by 56 days in that trial.

And the interim results have not been announced for that. So we don't know if there will be a difference in efficacy. We also don't know if the duration of protection would be different between one dose and two doses. So those two things we'll be eagerly awaiting when the data are available. And at that point I think the workgroups and the ACIP will weigh in to see if the benefits, you know, are sufficient to suggest that two doses would be better than one.

Thank you. Our next question asks, can you compare the results from the phase three trial of the Janssen vaccine to the phase three trial results for both the Pfizer and Moderna vaccines? And how do they compare?

Thanks, this is Sarah Oliver, I'm happy to take that one. So each of the phase three trials were conducted at different times in the pandemic, which really impacts not only kind of the background incidence that was seen, but also the circulating variants that were seen at the time. In addition, the trials were conducted in different locations and in different countries. So we really can't draw direct comparisons from one phase three trial conducted in one country in kind of one setting to a phase three trial conducted globally, potentially, and in a different time period. What we do know is that all three of the authorized vaccines are effective at the prevention of symptomatic COVID.

And all had high efficacy against COVID-19 associated hospitalizations and deaths. So what we do know is that people are recommended to receive any recommended COVID-19 vaccine and are really encouraged to receive the earliest available vaccine to them. And the use of all of the authorized vaccines is really going to be critical in controlling the pandemic.

Thank you very much. Our next question asks, are there any groups for whom the Janssen vaccine is a better fit than the other two vaccines?

Hi, thanks for that question. This is Dr. Dooling. So people who may be particularly drawn to this vaccine are people who need to achieve completion of the vaccine series quickly, either

because they're going to travel or they have some other need. Or perhaps people who find it very difficult to come back for a second dose for whatever reason.

But beyond that, this is really a vaccine for everybody. And I'd like to pick up on the what Dr. Oliver just said. And really, in terms of what's the best vaccine, the best vaccine is the first vaccine that you have access to. So this is a vaccine for everybody.

Thank you very much. Next, we have a question that says, how do you think this vaccine, the Janssen vaccine -- how do you think this vaccine will work against the new variants? And if there's any data on that information, please.

Hey, this is Sarah Oliver. So this is actually the first vaccine that's been authorized in the US where we have information on the variance as a part of the phase three trials. So both South Africa and Brazil and several other countries in South America were study sites in this trial. So we have information on how well this vaccine works against variants from both of those locations. So the overall efficacy endpoint was slightly lower in countries where we know that those variants have wide circulation.

But I think the key thing to note is that the protection against severe disease was high in all countries, including countries where the circulating variant is really high, which suggests protection against severe illness, even with these variant strains. So we'll continue to monitor variants in the US and the impact of all authorized variants, what they have on the vaccine effectiveness. But it's encouraging to know that this vaccine has been studied in locations where we've seen high circulating variance.

Thank you. Our next question asks, if someone has received the Pfizer or the Moderna vaccine, can they also receive the Janssen vaccine for extra protection?

Hi, this is Sarah Mbaeyi. I can take that one. So, no at this time, we are recommending if somebody has completed a series -- so you know, they've gotten their Pfizer or Moderna series -- they are considered vaccinated. They do not need any additional, you know, Janssen vaccine to kind of boost their protection. And we're recommending against that.

You know, I did mention in my part of the talk around, you know, there might be some very rare situations where somebody's got an mRNA vaccine, and they just absolutely cannot get the next dose of that. We do have some considerations and our guidance around that. But that's kind of a different matter. In terms of somebody who has completed a Pfizer or Moderna series, they shouldn't get an extra dose of Janssen just to kind of boost it, and vice versa. Somebody who gets a single dose of Janssen doesn't need any more vaccine doses. They shouldn't get any Pfizer or Moderna doses.

Thank you very much. We have a question about the recovery time at vaccination site or location for the Janssen vaccine. Is it similar to the Pfizer and Moderna vaccine of observation for either 15 or 30 minutes?

Yes, this is Sarah Mbaeyi. I can take that one again, too. So yes, we have kind of harmonized our recommendations around this to apply to all COVID-19 vaccines. So anybody with a precaution to vaccination, so people with a history of an immediate allergic reaction to other vaccines or injectable therapies, or anybody that has had anaphylaxis due to any reason, they would get a 30-minute observation period. Everybody else would get a 15-minute observation period. So these are unchanged recommendations from those that we previously issued for mRNA vaccines.

Thank you very much. Our next question asks about any contraindications. Are the contraindications different than the Pfizer and Moderna vaccines? Or are they similar? And if they are different, are there additional contraindications that prescribers and clinicians should be aware of?

This is Sarah Mbaeyi. I'll take that one again, as well. So the contraindications and precautions for all of the COVID-19 vaccine -- so Pfizer, Moderna and Janssen -- all include people with a history of a severe allergic reaction such as anaphylaxis to a previous dose, or to any component of the vaccine. That's part of the EUA, the authorization for emergency use. That's the contraindication listed there.

CDC also has, you know, an additional kind of contraindication that we consider to be an immediate allergic reaction of any severity to a previous dose of that vaccine, or a known allergy to component of that vaccine. So for the mRNA vaccines, you know, I think we've presented on previous calls and discussed this -- mRNA vaccines contain polyethylene glycol, or PEG. And Janssen vaccines contain polysorbate amongst other ingredients. But you know, PEG right now is an ingredient -- in terms of vaccines, there are no other currently licensed vaccines in the United States that use PEG as an ingredient. It's very common in other medications though.

Polysorbate is a common ingredient in vaccines that we use in the United States. PEG and polysorbate are structurally similar. So cross-reactive hypersensitivity is possible between them. So as I mentioned in my talk, we will have some additional guidance that we will be issuing around what to do if somebody is contraindicated to receive an mRNA vaccine -- can they receive Janssen and vice versa? So we're still finalizing those. So but that will be released when we post our guidance.

So it's kind of just to summarize the question. You know, they're the same contraindications for all the vaccines, but the vaccines have different ingredients. So it's just important to kind of pay attention to that. And the most the most, I would say, important ingredients to be aware of for these vaccines are PEG in the mRNA vaccines and polysorbate in the Janssen vaccine.

Thank you very much. And we have received multiple questions along the lines of immunocompromised patient population. Can you speak about the safety profile of this vaccine when used in immunocompromised population?

Sure, sorry. This is Sarah Mbaeyi. I'll take that one again as well. So yes, I see multiple questions in the chat box related to this. So I think I'll just start with kind of repeating what I said earlier, that none of these vaccines, none -- Janssen, Moderna, or Pfizer -- are live vaccines, they're all non-live vaccines, and they're all non-replicating vaccines.

So for that reason, there is no safety risk. You know, they can be given safely to people who are immunocompromised. So whether that's somebody who is immunocompromised due to HIV, or a, you know, bone marrow transplant or solid organ transplant, or who takes, you know, corticosteroids or kind of any reason why somebody might be immunocompromised, we recommend that they can get the vaccine. And these people are, you know, also at increased risk for severe COVID. You know, I think, people with immunocompromised conditions were included -- people with stable HIV were included in the clinical trials for the three vaccines, but we do not have data for them yet.

But I think, you know, what we would advise people is, you know, people still need to continue their precautions like wearing a mask, hand washing, things like that. Because we don't have data yet on, you know, how effective the vaccine is. There might be some slightly reduced or reduced effectiveness in people with immunocompromised conditions. So, again, you know, the kind of concern is more along the line of how well the vaccine will work in these people. We do have some additional information that we're including in our guidance for this version around timing of vaccination in immunocompromised people.

We've gotten a lot of questions of, you know, when should I get it, if somebody's planning to, you know, undergo a treatment or medication that will make them immune compromised? So we're essentially following, you know, ACIP's general best practices for immunization, which recommends, you know, if possible, you know, complete vaccination two weeks before, you know, undertaking any sort of immunocompromising treatment or medication. You know, in terms of any questions about, should we delay their treatment or medication so they can get the vaccine -- those are I think discussions and decisions that would need to be had with the individual provider. And kind of in balancing kind of the risks of delaying treatment in those patients.

Thank you very much. Another question we have is providers asking if there's a lapse for any reason, or an absence of a patient being able to get their second dose of Moderna or Pfizer, can they get Janssen?

This is Sarah Mbaeyi. I will take that one as well. So no, we are not recommending, you know, that people substitute in Janssen if there's some, you know, temporary unavailability of Pfizer or Moderna. So in our updated guidance, you know, we still are recommending that people stick with, you know -- stick to the recommended schedule. So 21-day interval between doses for Pfizer, and 28-day minimum, one month interval between two doses for Moderna.

We do have updated guidance that extends that period up to six weeks or 42 days between doses if it is not possible to get the doses, you know, according to the recommended schedule. You know, I think it would be extremely unlikely that somebody wouldn't, you know, be able to in some way or another get their dose, you know, within that time period, or, you know, close to that time period. And we don't want people to just start mixing and matching with whatever is the easiest to get. So, if somebody, you know -- if somebody was due for their second dose, and they showed up that day, and they're giving, you know, a different, you know, vaccine out that day, we wouldn't say just go ahead and give them Janssen because they're there. We would want

them to be scheduled to come back to get their second mRNA dose, according to the schedule and, you know, in that kind of time period that CDC recommends.

Thank you. Along the same lines, another question we have is, will there be an opportunity for patients to know what vaccine they're getting before they arrive at their appointments?

Hi, this is Kathleen Dooling. I'll take that one. So CDC is recommending that patients do have knowledge of what vaccine is being offered at the time that they -- certainly preferably before they arrive for their appointment, and certainly at the time before they are offered the vaccine. And we understand that that will roll out in in different states in slightly different ways. I've seen in the chat box several people asked about allocations.

Allocation of Janssen COVID-19 vaccine is available to jurisdictions right now. So that will likely start arriving within today and the next several days. And different jurisdictions are going to be utilizing it in different ways. Some are focused on large vaccination centers, whereas others may put it more preferably into pharmacies or smaller provider venues. So I think you will see it in many different locations, but important of course for people to have full informed consent and know what product they're getting.

Thank you very much. Another question asks about patients who have had recent receipt of either monoclonal antibodies or convalescent plasma, is there a time duration when considering vaccination?

Hey, this is Sarah Mbaeyi. So our recommendation is the same as the recommendations we made for mRNA COVID-19 vaccines. And that's to defer the receipt of Janssen and all COVID-19 vaccines for at least 90 days after they receive the monoclonal antibodies or convalescent plasma. And this is really more of a precaution until we have more data. We just, you know, want to avoid this theoretical risk of immune interference if the monoclonal antibodies and vaccine are given, you know, close together.

You know, we do often get the question of, well, what happens if they got their -- you know, I'm reverting back now to the mRNA vaccines. But what happens if they get their first dose and then get COVID and get treated with monoclonal antibodies? When should they get their second dose? And we do say to -- even if they've gotten a dose already, to defer their second dose until 90 days after receipt of their monoclonal antibody. We also get the question a lot of okay, they got sick, they got their monoclonal antibody, and then they got vaccinated because nobody realized at the time that they got their monoclonal antibody. So what should we do? And again, we say just defer 90 days until after receipt of the monoclonal. So those are kind of, I think, the nuanced recommendations about mRNA vaccines that I wanted to pass along, just because we do get questions about that all the time.

But again, for the Janssen vaccine, it's the same recommendation -- defer for 90 days until we have more information.

Thank you very much. And thank you for the nuance and the delineation between the types of vaccines. Along the same lines, we've had this question come up a couple of times. So it might

be worth explaining. What is a viral vector vaccine and how is it different from the so far authorized vaccines, the mRNA vaccines?

Yeah, so this is Sarah Oliver. I'm happy to take that one. So the Janssen vaccine is a replication incompetent adenovirus 26, or AD-26 viral vector vaccine. It's kind of the full long title of it. So it's not an mRNA vaccine.

It's a viral vector vaccine. This means that the virus, that AD-26 virus, is used as a way to deliver the gene that instructs our bodies to make the SARS CoV-2 antigen called the spike protein. This then triggers the production of antibodies and an immune response. But there are a few important things to note with these replication incompetent viral vectors. So the adenovirus that's used in this vaccine cannot cause illness in humans.

It has important parts of the virus removed, so it's unable to replicate in the human body. Another important thing to note is that the gene that's used in these vaccines cannot incorporate into human DNA. So that's not a concern as well for these viral vector vaccines. And finally, we actually have experience with this specific AD-26 vector platform. There's an Ebola vaccine that uses the same vector that's been studied and authorized for use in Africa for Ebola outbreaks.

In these studies, it's been safely given to a variety of populations, including pregnant women and children. So you know, the technology between the viral vectors and the mRNA vaccines are both a little bit different, but hopefully that's a little bit of an explanation around kind of what this replication incompetent viral vector is.

Thank you very much. Our next question asks about the adverse event of tinnitus. Do you have any data on how much on average the tinnitus lasted?

Sorry, delayed mute. So this is Sarah Oliver. Details for the cases are available in the FDA VRBPAC briefing document. I actually don't have that pulled up right in front of me to go over kind of how long they lasted. I know that most of them did not involve any form of hearing loss.

And most of the people recovered relatively quickly. And like I said, the FDA said that they didn't have enough information to determine that this was causally linked to the receipt of the vaccine. Sometimes there just happens to be an imbalance. But we do plan on, you know -- we take these information that we see from clinical trials and really use that to help inform -- we have a multitude of safety surveillance platforms that are employed to look at these COVID vaccines in this kind of post-authorization phase. And so we take information that we get from the clinical trials, where these imbalances are, and that allows us to have kind of a deep dive and extra look when we get this post-authorization data.

So it's definitely one of the things that we'll keep an eye on as we look through VSAFE and VAERS and the variety of other safety surveillance platforms.

Thank you very much. Our next question asks, do you have any recommendations for timing vaccinations for individuals who may receive steroids via IV, IM, intra-articular or epidural routes?

Hi, this is Sarah Mbaeyi again. So I mentioned this a little bit when I was discussing vaccination for immunocompromised people. But we would currently just recommend that for people wondering about timing of vaccination relative to either steroid use or other, you know, treatments, you know, that would be initiated that could make somebody immunocompromised, to follow what we have in our general best practices for immunization that kind of applies across vaccines. And that would be to, if possible, complete, either, you know, a series or vaccination at least two weeks prior to initiating that kind of treatment.

Thank you very much. Next question asks, how soon after a COVID infection can the Janssen vaccine be administered to an individual?

This is Sarah Mbaeyi. I'll take that one again. So our recommendations for Janssen are the same as what we currently recommend for mRNA vaccines, which is, you know, we do recommend that people who have had COVID, you know, are vaccinated, but we just recommend that they wait until they have recovered from the acute phase of their illness, and that they've met criteria to discontinue isolation because of their illness. We also do say, though, that, you know, people who have a history of COVID could temporarily delay their vaccination during the setting where supply is limited. And that's primarily to help, you know, people who are still susceptible to COVID to have the opportunity to receive vaccine.

You know, we know that the risk of reinfection after somebody has had COVID is, you know -- the risk of reinfection is low for at least three months after they've had COVID. But we also know that it's a spectrum and that, you know, the risk of reinfection likely increases with time since illness. So we do say that people could temporarily delay vaccination. But we don't have any firm interval. We just say they have to have recovered from the acute phase of their illness and they should be out of isolation by the time they get their vaccine.

Thank you very much. Next question asks about, are there any considerations or concerns about patients who may have undergone a splenectomy?

This is Sarah Mbaeyi again. It's really -- this group of individuals would really fall into the same kind of considerations we have for, for example, people with immunocompromised conditions. Since, you know, splenectomy can increase risk for certain illnesses and certain infections. But we don't have any specific recommendations for people with splenectomy. But again as a best practice, if possible to complete their COVID-19 vaccination at least two weeks prior to their splenectomy.

I do want to add, because I forgot to mention this kind of in earlier kind of iterations of this question. We do have some recommendations for, you know, timing before, you know, undergoing these procedures or medications. But unlike what's in our general best practices for immunization for immunocompromised people, we currently do not recommend people get revaccinated after their immune competence is restored. So we don't recommend any sort of testing after somebody regains immune competence to say, you know -- testing to see if they have antibodies. We don't recommend that right now.

And we also don't recommend that people get revaccinated right now. We are waiting for more data to help inform those kinds of recommendations.

Thank you very much. And along the same lines, and this is a bit repetitive. But how about injections like Prolea? Would they fall under the similar considerations as you shared with other immunocompromised situations or steroids?

To be honest, I am not as familiar with Prolea. So I don't want to comment on specific medications. But I will say that our recommendations are the same kind of across the board. There aren't any medications for which we have any different recommendations for what I've already mentioned.

Thank you. We also have questions that providers have asked related to patient education. For example, what is the best response in plain language for patients if they show any concerns about getting a vaccine that they deemed to be, say in their words 66% effective compared to others that they've heard off that are around 95%? effective? What are some strategies that you would inform clinicians with that they can use when providing patient education?

Oh, this is Sarah. We can probably both take a stab at that, because it's a really important question. So this is Sarah Oliver. I think we've been really emphasizing that ultimately what most people say that they want to prevent is the severe outcomes from COVID. They want to prevent severe hospitalization and death.

And this vaccine really appears to have high efficacy against the severe outcome. So I would say in kind of plain language, that's a great point to emphasize. We continue to kind of emphasize the fact that it's not really comparable to be able to say, you know, this study looks at this, and this study had that number. We'll get data over time kind of in similar populations, but we don't have that data right now. And then again, the best vaccine is the vaccine that you have access to.

So I think if you have access to any one of the vaccines, you know, that's the vaccine that you should get. Dr. Dooling, anything else to add?

I agree with all of those points, Sarah. And I would add this potentially telling your patients, it's a bit of an apples to orange comparison, putting the two side by side because they weren't studied head to head. And that's the only way to truly know, a direct comparison between the two. We are still in the midst of a pandemic and we are going to need every vaccine at our disposal to get ahead of this. So I would recommend my patients again, the best vaccine is the first vaccine that you're offered.

Thank you very much. We have time for one more question. And it's sort of like a two-part question. The first part is, can you speak about what the sort of inflammatory or immune response is that patients experience after getting this vaccine compared to say, the mRNA vaccines like Pfizer and Moderna, specifically some of the discomfort people have shared after their second doses? That's part one. And part two is, what is the time response recommended for consideration for full efficacy for the Janssen vaccine, compared to say two to three weeks for the mRNA vaccines?

Yeah, maybe I'll take the first part and then Dr. Mbaeyi, if you want to take the second part. So I think as unfortunately we keep we keep reiterating, but really even comparing reactogenicity numbers across the clinical trials is difficult. Each of the three clinical trials asked different questions. They asked them in different ways.

And they measured different things so when it comes to symptoms that we're seeing afterwards. So it's really difficult to kind of pick out and say this one particular -- using the data from this one trial, this looks better, this looks worse. We do know that overall, the Janssen vaccine is one dose. And so for people who, you know, potentially are worried about needles for two doses, this is one dose so that's an option. And then again, as I mentioned, there's, you know, through VSAFE and through other ways, we'll be able to look at all of the vaccines and kind of have numbers in a more comparable environment.

So we'll report on those as soon as we have them. Dr. Mbaeyi, you want to take the fully vaccinated question?

Sure, sure. So we consider somebody to be fully vaccinated two weeks after they've received their Janssen dose, if that's what they get. If somebody gets an mRNA vaccine, we consider somebody to be fully vaccinated at least two weeks after they complete their second dose. So that you know, the data from the different trials -- there was some assessment at various time points across different studies. But what we have seen consistently is that, you know, two weeks after completion of the dose for Janssen or the series for mRNA vaccines, we're seeing, you know, good efficacy and immune responses. And so that is what we are considering as someone being fully vaccinated.

Thank you very much. I would like to thank everyone for joining us today with a special thank you to our presenters, Lieutenant Commander Oliver, Commander Mbaeyi and Dr. Dooling. Today's COCA call will be available on demand a few hours after the live call. You can find the video recording of today's call at emergency.CDC.gov/COCA. Again, that's emergency.CDC.gov/COCA.

Next Thursday, March 11, we will have our next COVID-19 COCA Call -- the Role of Telehealth in Expanding Access to Healthcare During the COVID-19 Pandemic: Considerations for Vaccine Uptake and Monitoring for Adverse Events. This COCA Call will take place on Thursday, March 11 at 2:00 PM Eastern. Continue to visit emergency.CDC.gov/COCA to get more details about this COCA Call and other upcoming COCA Calls.

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