

Good afternoon. I'm Commander Ibad Khan, and I'm representing the Clinician Outreach and Communication Activity, COCA, with the Emergency Risk Communication Branch at the Centers for Disease Control and Prevention. I'd like to welcome you to today's COCA Call: What Clinicians Need to Know about COVID-19 Safety and Effectiveness and How to Address Patient Questions and Concerns. Pardon me, that's COVID-19 Vaccine Safety and Effectiveness and How to Address Patient Questions and Concerns. Please note that continuing education is not offered for this webinar. All participants joining us 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 presentations. To ask a question using Zoom, click the Q&A button at the bottom of your screen. Type your question and hit enter.

The video recording of this COCA Call will be posted on COCA's web page and available to view on demand a few hours after the call ends. If you're a patient, please refer your questions to your healthcare provider. And for those who may have media questions, please contact CDC Media Relations at 404-639-3286 or send an email to media@CDC.gov.

I would now like to welcome our presenters for today's COCA Call. We are pleased to have with us today Captain Tom Shimabukuro, who's the vaccine safety team lead as part of CDC's COVID-19 response. Our second presenter is Dr. Kathleen Dooling, who is a co-lead for the Advisory Committee for Immunization Practices COVID-19 Vaccines Workgroup as part of CDC's COVID-19 response. And our final presenter is Lieutenant Stephen Perez, who is a clinical lead for the vaccine confidence team as part of CDC's COVID-19 response. It is my pleasure to now turn it over to Captain Shimabukuro.

Captain Shimabukuro, please proceed.

Thank you and good afternoon or good morning, wherever you may be. I'll be giving a vaccine safety update. Next slide.

Next slide.

So I'm going to briefly cover some of our monitoring systems and then I'll spend a little time on vaccine safety and pregnancy. Next slide.

And the first system I'm going to cover is the v-safe system. Next slide.

Just to remind you, v-safe is a new smartphone-based active surveillance program that CDC implemented just for COVID-19 vaccine. It's a voluntary self-enrollment process and we encourage all providers to offer it to patients, and patients can also go on the website and get the enrollment information. It involves a series of web surveys, where we check in on individuals during the post-vaccination period. If individuals do report a medically intended adverse health impact, we reach out and we'll contact them to take an adverse event report. And we also can assess pregnancy status for enrollment in a pregnancy registry, which I'll cover later. Next slide.

So at the time of the last analysis, which was mid-February, there were about 55 million people receiving dose one of any dose of COVID vaccine, about 3.9 million registrants in v-safe completing at least one health check in and just over 30,000 self-reported pregnancies to v-safe. Next slide.

So I want to focus on reactogenicity. And this is from a paper that was published fairly recently. And I think the take home message for both healthcare providers and for patients is that these messenger RNA vaccines are fairly reactogenic and patients can expect to experience and should be counseled that they can expect to have pain and systemic reactions like fatigue, headache, myalgia and chills. If you look at this comparison, the results for the Pfizer vaccine and the Moderna vaccine for dose one are pretty similar. Next slide.

So we did have some data for Pfizer dose two, and we do have now data for Moderna dose two which is similar. And I think the take home message here, again, for healthcare providers and for patients is that that patients can expect to experience significantly more systemic reactions like fatigue, headache, myalgia, chills, fever, joint pain, and nausea after dose two compared to dose one. Sometimes three to fourfold more. And these results are consistent with what was observed in the clinical trials and are essentially expected. We're confirming the basic reactogenicity profile of these vaccines. Next slide.

So moving on to the Vaccine Adverse Event Reporting System, which is the nation's early warning system, it's a spontaneous reporting system or passive surveillance system that's managed by CDC and FDA. Next slide.

The main limitation of VAERS is that as a passive surveillance system, it's not designed to assess causality or cause and effect with respect to a vaccination. It's a hypothesis generating or signal detection system designed to identify unusual or unexpected patterns, which might indicate a safety problem which can be further assessed in more robust data systems. Next slide.

So through mid-February, there are just over 104,000 reports for both of these vaccines combined, of which 94% were classified as nonserious and 6% as serious. And that's according to the regulatory definition of serious and nonserious. And that number 94% nonserious is similar to what we've observed with other vaccines that are administered to adults like flu vaccine, shingles vaccine, pneumonia vaccine. Next slide.

So here is a side by side comparison of the two vaccines looking at the most commonly reported adverse events. And so similar to what we observed in our v-safe monitoring system, and similar to what was observed in the clinical trials, systemic and local reactions are common. And again, I think this reinforces the point that healthcare providers should be aware that these symptoms are fairly common after these mRNA vaccines.

And it would be good if patients were counseled that they can expect to experience some of these symptoms to set expectations for the post-vaccination period. Next slide.

I just want to update you on anaphylaxis, because that's been an adverse event of concern. Our most recent data show 4.7 cases of anaphylaxis per million Pfizer doses administered, and 2.5

per million Moderna doses administered, and those rates have remained fairly stable since we conducted this last analysis. Next slide.

So moving on to another one of our CDC systems, the vaccine safety data link. This is a collaboration between nine integrated healthcare organizations, and we have data on about 12 million persons per year. Next slide.

The data are primarily electronic health record administrative data that are linked by unique study IDs. And we also have access to the electronic health record to look at charts and review cases. Next slide.

So the main analysis surveillance project we do in VSD is called rapid cycle analysis. And in rapid cycle analysis, the data are refreshed weekly.

So we're looking, taking weekly sequential looks at the data as it comes in to us. The outcomes we monitor are pre-specified so identified in advance. This is a surveillance activity. It's not the same as an epidemiologic study. It's designed to detect statistically significant associations and statistical signals, which do not necessarily indicate a safety problem.

And when we do detect these signals, we implement a series of checks and evaluations. One of the main things we do is chart review and chart confirmation of a diagnosis to confirm or exclude the cases of true incident case. Next slide.

And I'm going to move past -- these are just some of the analyses we use. Next slide.

So as of mid-February, there are roughly 630 dose one doses of any mRNA vaccine in the vaccine safety data link, and about 200,000 of individuals who had received dose two. Next slide.

So on the left hand side, there you see the 21 pre-specified outcomes that we are monitoring in VSD. And again, we do the analyses weekly as the data come in. So we know what is happening as the immunization program is rolling out and we can give our public health partners and healthcare providers near real-time information on these safety outcomes.

And as of mid-February, in both of the analyses that we've conducted so far, we've detected no statistically significant increased risks or no statistical signals for any of these pre-specified outcomes. Next slide.

So next step, we'll be looking at dose specific analyses. So dose one versus dose two, and product specific analyses by manufacturer and then looking at different risk intervals and then looking at historical comparisons. Next slide.

I just want to mention that we have a group at CDC called the Clinical Immunization Safety Assessment Project, which does clinical case reviews at the request of healthcare providers. And I'm going to go through these next two slides, move through them. But this information will be

available for individuals who are interested in requesting consults for their patients for complex adverse events. Next slide.

Next slide.

Next slide.

So now I'm going to move into vaccine safety and pregnancy. Next slide.

So this is the same slide as before. I just want to remind you that there are about 30,000 self-reported pregnancies to v-safe as of mid-February. Next slide.

So this is looking at reactogenicity in self-reported pregnant women compared to non-pregnant women. And on the top there, you have the Pfizer dose one compared to Moderna dose two. You can see that pregnant and nonpregnant women, the self-reported symptoms are pretty similar. In fact, for some of these, you can even argue that there's less local reactogenicity in pregnant women compared to non-pregnant.

And then on the left-hand side for the dose two, where we have dose two information -- again, pretty similar, and really nothing concerning when you're looking at pregnant compared to non-pregnant women as far as local reactions. Next slide.

So this slide looks -- it's the same setup, but it's looking at systemic reactions in pregnant women. And you can see things like fatigue, headache, myalgia, chills, nausea, and fever. If you look at the Pfizer vaccine compared to the Moderna vaccine, very similar reactogenicity profile.

And if you look at pregnant women compared to non-pregnant women, it looks like there may even be a little less reactogenicity reported in pregnant women compared to non-pregnant women. Then just focusing on the left-hand side, Pfizer dose one versus Pfizer dose two, you can see that similar to the general population, there's substantially more systemic reactogenicity reported after dose two, both in pregnant and nonpregnant women. So I think the take home message from these two slides is we don't see any substantial differences or any indication of a safety problem for pregnant women compared to non-pregnant women with respect to reactogenicity of these vaccines. Next slide.

So now I'm going to focus on the v-safe pregnancy registry. And remember, individuals self-report pregnancy status through v-safe safety monitoring. And then we have a separate process where we actively contact and enroll these women into a pregnancy registry. And these participants are contacted once per trimester after delivery and when the infant is three months old. And the outcomes of interest that we're looking at include miscarriage and stillbirth, pregnancy complications, maternal Intensive Care Unit admission, adverse birth outcomes, neonatal death, infant hospitalizations, and birth defects. Next slide.

So towards the end of February, we had enrolled roughly 1,800 individuals into the pregnancy registry. And of those we did have some information on outcomes. We had 275 completed

pregnancies, including 232 live births. Outcomes other than live births included miscarriage, stillbirth and ectopic and tubal pregnancies. Next slide.

So this table shows what we're seeing as far as pregnancy outcomes, pregnancy complications and neonatal outcomes in pregnant women enrolled in the v-safe pregnancy registry who actually had an outcome compared to background rates from the literature. So we're looking at miscarriage, stillbirth, gestational diabetes, preeclampsia or gestational hypertension, eclampsia, intrauterine growth restriction, and some other neonatal outcomes. And I think the take home message here is that the rates of these outcomes in the v-safe pregnancy registry are similar to background rates in general. So we're not seeing any safety problems with respect to these outcomes in these vaccinated pregnant women who have been enrolled in v-safe.

So to me, the take home message here is this should be reassuring information for pregnant women who have questions about getting vaccinated. And what does that mean for me? And what does it mean for my developing baby? I think the answer is the data we have right now indicate that we are not seeing any safety problems with respect to maternal vaccination for these mRNA vaccines. Next slide.

This is just a reference slide for the background rates. Next slide.

So we've also been monitoring pregnancy reports in the Vaccine Adverse Event Reporting System. Again, this is a passive surveillance system. So women or their healthcare providers are sending these reports into the VAERS system. And as of mid-February, we had 154 pregnancy reports to VAERS. The median maternal age was 33. Median gestational age was 13 weeks. Just over half of these reports involve pregnancy during the first trimester, about a third in the second. And you see the vaccines, the split of the vaccines there on the bottom. Next slide.

So here's some information specifically on the adverse events. I wanted for you to first focus on the bottom part of this table.

And it's notable that roughly three quarters of these adverse event reports to VAERS in pregnant women involve non-pregnancy specific adverse events. So things that anyone would experience and report into VAERS, like systemic and local reactions. Only about a quarter of these reports involve pregnancy or neonatal specific conditions. And you see there the most commonly reported pregnancy condition of these 42 reports was miscarriage -- 29 reports. It's important to note that the frequency of clinically recognized early pregnancy loss for women aged 20 to 30 years is nine to 17%. Age 30, it's 20%. Age 40 it's 40%. And then by age 45, that's up to 80%. And that's from an ACOG practice bulletin. Next slide.

I just want to mention we have other safety activities going on in the vaccine safety data link. And then the CISA project. We have a coverage assessment in VSD. We have a study looking at the risk of miscarriage and stillbirth, and then a general safety study. And then in the CISA project, we have a prospective observational cohort study to look at adverse pregnancy and birth outcomes, serious events, local and systemic reactogenicity and infant health outcomes. Next slide.

So just to sum up maternal vaccination safety, pregnant women were not specifically included in the preauthorization clinical trials. Post-authorization safety monitoring and research are the primary ways to obtain safety data on COVID vaccination during pregnancy. There are substantial numbers of self-reported pregnant persons registering in v-safe. The reactogenicity profile and adverse events observed among pregnant women in v-safe did not indicate a safety problem.

Most reports to VAERS involve non-pregnancy specific adverse events. And miscarriage was the most frequently reported pregnancy specific adverse event to VAERS, although the numbers are within known background rates based on presumed doses administered to pregnant women. I think the take home message for healthcare providers and for their patients who may be pregnant or considering becoming pregnant is that there is a lot of safety monitoring going on of the COVID-19 -- the authorized COVID-19 vaccines -- and pregnant women are a special population that CDC is paying a lot of attention to with respect to safety of maternal vaccination. The data we have so far are reassuring. We do not see any signs of a safety problem in pregnant women, both with respect to the pregnant women individually and with respect to the developing fetus. Or the infants. Again, reassuring data from our comprehensive maternal vaccination safety monitoring. Next slide.

So just to sum up, as of the end of February, there are about 75 million doses administered in the United States. The reactogenicity profiles in v-safe monitoring are consistent with what was observed in the clinical trials, and systemic and local reactions are commonly reported to VAERS.

Anaphylaxis following both vaccines has been reported to VAERS, though rarely. And there's guidance for recognizing, treating, and managing anaphylaxis on the CDC website. There's been no other safety signals for serious adverse events detected in VAERS. There have been no safety concerns identified among VSD rapid cycle pre-specified outcomes, and no unexpected pregnancy or infant outcomes have been observed. related to COVID-19 vaccination during pregnancy. However, safety monitoring in pregnant women is ongoing and planned, both in V-safe and VAERS and VSD and in CISA. Next slide.

I'd like to acknowledge the contributions of investigators from the following organizations. And with that, I'll turn it over to my colleague, Dr. Dooling.

Thanks very much for that, Dr. Shimabukuro. So now I'd like to go through some of the evidence that we have around COVID-19 vaccines. Next slide.

So it's important to say right at the beginning that COVID-19 vaccine phase three trial results are not directly comparable. ACIP now has recommended three different COVID-19 vaccines, and states no preference for any of these authorized vaccines. The vaccines, in fact, were not studied head to head and the results of the Janssen phase three trial are not comparable with the mRNA vaccines. And that's because the trial was conducted at a different calendar time, as well as different geography. And those both resulted in different circulating variants as well as higher background incidence of the virus. Next slide.

So let's go through one by one now and discuss the main outcomes that were assessed through the phase three trials for each of these vaccines, the first being Pfizer, BioNTech COVID-19. So for each of these, I'll discuss the when, who, where and what the main results were. So in terms of when, the interim results from this trial were observed between September and November of 2020. This vaccine was studied in persons 16 and older, and the trials were conducted in United States, Brazil, Argentina, South Africa, Turkey, and Germany. The primary outcome of symptomatic lab confirmed-COVID was observed in eight people in the vaccinated arm, 162 persons in the placebo arm, giving a vaccine efficacy of about 95%. Hospitalization was much more rare. There were no hospitalized cases in the vaccinated group. There were five in the placebo, giving an estimate of 100% with very wide confidence intervals. There were no deaths in either the vaccinated group or the placebo group of the Pfizer BioNTech trial. And again, those are hospitalizations and deaths that are COVID associated. Next slide.

For the Moderna COVID-19 vaccine phase three trials, the interim results came from a similar time period as to Pfizer -- September to November of 2020. This trial was conducted in persons 18 years of age and older and only in the United States. For the primary outcome of symptomatic confirmed, lab-confirmed COVID, there were only 11 cases in the vaccinated group versus 185 cases in the placebo group, yielding a vaccine efficacy of 94%. Once again, hospitalization was rare with just one case of hospitalized COVID in the vaccinated group, compared to nine in the placebo group, giving a VE estimate of 89% with wide confidence intervals. There were no COVID-associated deaths in the vaccinated group for the Moderna trial and one in the placebo. Next slide.

Now as for Janssen, the most recent trial which has yielded interim results, those came from an observed period between November 2020 and January 2021. The vaccine was studied in persons 18 years and older. And this trial was conducted in multiple countries including the United States, South Africa, Brazil, Chile, Colombia, Peru and Argentina.

As for the main outcome of symptomatic lab confirmed disease, this trial yielded a lot more outcomes than the earlier mRNA trials. There were 173 cases observed among the vaccinated group versus 509 observed amongst the placebo group yielding a vaccine efficacy of 66%. Still, hospitalizations were rare. Even with many cases in the trial, there were only two hospitalized persons in the vaccinated group versus 29 hospitalized people with COVID in the placebo group, yielding a vaccine efficacy against hospitalizations of 93%. There were no COVID-associated deaths in the vaccinated group versus seven in the placebo group in this trial. Next slide.

So in summary, all the authorized and recommended vaccines have demonstrated high efficacy against severe COVID-19. And with respect to COVID-associated hospitalization that was an efficacy of more than 89% for all three vaccines. It's important to note that no vaccinated person has died due to COVID-19 for the interim study results, versus eight COVID-19 associated deaths among placebo recipients. Next slide.

So, therefore, with respect to Janssen COVID-19 vaccination implementation, the ACIP supported that during a pandemic and under an emergency use authorization, that offering Janssen COVID-19 vaccine to persons 18 years of age and older according to established allocation and eligibility recommendations in a given jurisdiction is an effective implementation

strategy. And that allows for jurisdictional flexibility. It supports rapid vaccination and increases in population immunity. It doesn't single out any particular group and it allows individuals to be vaccinated with the earliest vaccine available. Next slide.

So that concludes my brief overview of vaccine efficacy. And I'll pass it on now to Lieutenant Stephen Perez.

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

As more people in the United States become eligible to receive COVID-19 vaccines, clinicians are likely to hear increasing questions and concerns from patients who want more information about their safety and efficacy. To address these questions today, I'll be speaking about elements of vaccine confidence as well as some strategies for building vaccine confidence and for talking with patients and answering their common questions about COVID-19 vaccines. Next slide.

First, I'll begin by discussing some core elements of vaccine confidence. Next slide, please.

Among our patients, we can address vaccine hesitancy by building vaccine confidence, which is a multifaceted concept based largely on trust. It includes the trust that patients, parents, or providers have in the recommended vaccines, and providers who administer vaccines, and processes and policies that lead to vaccine development, licensure, manufacturing, and recommendations for use.

A person must have trust in all three of these facets to feel fully confident in their decision to get vaccinated. This foundation is critical, and sometimes it must be built over time. As healthcare providers, your impact is often centered in helping patients trust in you and your role as vaccine administrators. But you can also help build trust in the processes and policies by helping your patients to understand new vaccine technologies, what to expect in terms of vaccine side effects, and how these vaccines are being continuously monitored for safety. Being honest about what you don't know is also important for building trust. Next slide, please.

This slide shows how the willingness to accept a vaccine falls on a continuum. The vaccine demand continuum illustrates behaviors, whereas confidence is both a feeling and can be acted on. Some people might fall in the middle of the spectrum, adopting a wait and see approach. We want to move people toward the right.

The closer you get to active demand on the right side of the continuum, the increasing confidence the person likely feels in the vaccine, in the vaccinator and the health system because they actively chose vaccination. If there's sufficient confidence and trust in ability, then people will seek out vaccines, overcoming barriers to do so. People with less confidence or motivation or ability may be less willing to overcome real or perceived barriers such as transportation or getting time off work. Next slide, please.

Recently released data from the Kaiser Family Foundation COVID-19 Monitor show promising gains in vaccine confidence and acceptance. A higher percentage of respondents in February of 2021 reported acceptance or a willingness to accept the vaccine as soon as available when

compared to December 2020. A smaller percentage of respondents in February 2021 reported adopting a wait and see approach when compared to previous months. Next slide, please.

These promising trends are seen when data are stratified across racial and ethnic groups as well. Next slide, please.

But despite these gains, hesitance remains an issue. Of those respondents who remain in the wait and see group, 80% cited the possibility of serious side effects as a significant concern, as well as the possibility of getting COVID-19 from the vaccine, indicating that a critical means of confidence in this group -- of increasing confidence in this group might lie in both basic patient education and addressing potential misinformation about these vaccines. Next slide, please.

Some recent work from the vaccine confidence team at CDC has shown similar trends. Our most recent state of vaccine confidence report synthesizes trends and findings from multiple sources of qualitative and quantitative data to find major themes and possible threats to confidence in the COVID-19 vaccines.

Some of the findings indicate that confusion about how the vaccines work and their benefits continue to be an increasing threat to confidence. Some other threats include that those with high-risk medical conditions or allergies, being unsure of vaccines are safe for them, as well as continuing themes noted in previous reports indicating concerns about side effects, fertility and pregnancy and adverse events. Next slide, please.

Now that we've discussed the general issues around confidence in COVID-19 vaccines and some drivers of hesitancy, we'll shift the discussion to building confidence among your patients. This is CDC's vaccinate with confidence strategy.

It's a framework for thinking about interventions to increase vaccine confidence. The three components of the framework are building trust, empowering healthcare personnel, and engaging communities and individuals. And while much of our discussion today is aimed at helping providers feel prepared and empowered, so that they in turn can empower their patients towards vaccine acceptance, we understand that you play a critical role in each of these strategies. Next slide, please.

There are multiple tactics we suggest to implement this strategy, and today we're focusing on strengthening the capacity of healthcare professionals to have empathetic vaccine conversations, to address myths and common questions and to provide tailored vaccine information to their patients. Next slide, please.

And this is because you as healthcare providers remain a trusted source of information about COVID-19 vaccines. This is supported by multiple data sources and is illustrated here in data from the Kaiser Family Foundation. These data show that your patients who have not been vaccinated will likely turn to you for information and guidance, and that these findings extend across multiple racial and ethnic groups. Next slide, please.

So as a trusted messenger, remember that vaccine confidence begins with you. It's important to get a COVID-19 vaccine if you haven't already done so. The example you model in choosing to receive the vaccine is critical, as is your willingness to share and celebrate that experience. And the importance of your role in this cannot be overemphasized. Next slide, please.

So now we'll spend some of the remaining time discussing specific strategies and some language that you as providers can use to build confidence and address patient questions about COVID-19 vaccines. As with most things in the healthcare space, preparation is key. This slide includes some important considerations when preparing for COVID-19 vaccine conversations. As I just mentioned, confidence starts with you. Patients will likely ask you if you've been vaccinated yourself.

If you have not, they might ask you why. And your response might have an impact on their own decision making. It's also important to start vaccine conversations early even before your patients may be eligible. Remind them that it will be available to them in the future and ask what they've heard from friends, family, or the media. And then use this as an opportunity to debunk any myths or misconceptions. Learn how to engage in effective conversations and then be prepared for questions, and we'll talk more about this in the coming slides. Next slide, please.

When discussing COVID-19 vaccines, it's important to remember that brief and consistent messaging is key. This slide includes some strategic messaging that you can use to discuss the vaccine with your patients, even when your time is limited. Many of these messages address some of the major concerns or questions that patients might have, including reiterating that the vaccines are safe and effective, they're offered at no cost, and that there's the possibility that they might experience some side effects. Next slide, please.

When having these conversations, there are important evidence-based strategies you can use to make them more effective. And these includes starting from a place of empathy and understanding. This pandemic has been stressful for many people, and the first step is to acknowledge the disruption COVID-19 has caused in all of our lives. Additionally, hesitancy may stem from feelings of mistrust in the medical establishment or the government as a result of mistreatment and collective or individual trauma.

These are very real concerns for many, and listening with empathy and validating these concerns might help make patients feel trust in you and in your message. It's important to assume patients will want to be vaccinated, but still be prepared for questions, including questions about common side effects. Remember to also give a clear and strong recommendation and include any relevant reason why a vaccination might be particularly important for a specific patient, for example, because of their possible exposure at work, or an underlying health condition. After your recommendation, let your patients know that you are available to share key facts, to listen to their questions and to provide them additional information if requested. Next slide, please.

Use the conversation as a chance to address misinformation by sharing key facts. Ask what your patients have heard from friends and family or on social media. Let them know that it's easy to be confused by all the information that's circulating, some of which may be conflicting. CDC has

facts and messaging to counteract some common myths. Some of these key messages are shared here, and they include that COVID-19 vaccines will not give you COVID-19.

People who have gotten sick with COVID-19 may still benefit from getting vaccinated. Getting vaccinated will help prevent you from getting sick with COVID-19. And COVID-19 vaccines will not cause you to test positive on COVID-19 viral tests. The CDC page with this information and more can be accessed here on the link through this slide. Next slide, please.

It's also important to remember that when addressing misinformation for patients, the focus should remain on building confidence. Help your patients navigate to accurate resources, including patient focused material from your own trusted sources of information on COVID-19 vaccines. Some language that you could use during your patient interaction might be, "I trust this website for accurate medical information. They also have some great resources for patients that can be found here. " When addressing misinformation from the patient's community or family, focus less on the source of the information and more on the information itself.

If a patient's family member gave them incorrect information, you can counter by saying something like, "I'm sure that when your brother gave you that information, it was with good intentions for you. But the information is incorrect. Here's some accurate information on that same question that I've shared with many other patients who have the same concern. " It's also important to build on the trust that you've already earned in your patient provider relationship. Some language that can emphasize this could be, "My priority for you has always been and will continue to be your health and wellness. I know there's a huge amount of information out there about these vaccines. Just as with everything I recommend to keep you healthy, you can trust I strongly recommend these COVID-19 vaccines to help protect you from getting sick. "

And finally, build a trusted space by seeking permission from your patients to share your knowledge with them. Returning to the family member example, use language like, "Your brother gave you a lot of information. And I appreciate you bringing that in and sharing it with me. I have some information that I think will help address your question. May I share it with you?" Next slide, please.

When considering strategies for building confidence, healthcare providers must be sensitive to the longstanding health and social inequities faced by racial and ethnic minority groups and other groups experiencing health disparities. Many people from these groups may also have a mistrust or fear in healthcare institutions or the government after experiencing very real trauma or mistreatment from these same institutions. Providers must show compassion and empathy in the space.

Messaging should be tailored and culturally appropriate for the populations you serve. Establish partnerships with community groups, faith-based organizations and leaders who serve and who are representative of the patients you see in your program, and leverage those partnerships to develop effective messages around vaccine confidence. Don't make assumptions about a person's desire to accept the vaccine based on demographics. Always avoid stigmatizing language and ensure that you and your staff are trained to identify and interrupt all forms of discrimination. Next slide, please.

So patients will likely have many questions about COVID-19 vaccines which can be challenging to address in a busy clinic setting. It's important to remember that having many questions doesn't necessarily mean they won't accept a COVID-19 vaccine. And questions don't necessarily equal concerns. Sometimes patients simply want your answers to their questions. In these last few slides, we'll review some common questions you might hear and critical messages you can provide when responding to them. Next slide, please.

One question you're likely to get is, how do we know if COVID-19 vaccines are safe? Explain that the Food and Drug Administration carefully reviews all safety data from clinical trials and authorizes emergency vaccine use only when the expected benefits outweigh potential risks. The Advisory Committee on Immunization Practices reviews safety data before recommending any COVID-19 vaccine for use. And explain that FDA and CDC continue to monitor the safety of COVID-19 vaccines to make sure even very rare side effects are identified. So for example, you can say to your patients, "COVID-19 vaccines are safe and effective, and were tested in large clinical trials to make sure they meet safety standards. Many people were recruited to participate in these trials to see how the vaccines offer protection to people of different ages, races, and ethnicities, as well as those with different medical conditions." Next slide, please.

Another question that many people have is that they can get the COVID-19 vaccines if they have allergies. It's important to ask what allergies the patient may be concerned about, and explain that people should not receive a COVID-19 vaccine if they're allergic to any specific ingredient in that COVID-19 vaccine. But that people with other types of allergies, including oral medications, foods, pets, latex or environmental irritants like pollen or dust may still be vaccinated. Reiterate that you or a specialist such as an allergist or an immunologist can help them make the decision. Next slide, please.

Many people have questions about pregnancy, breastfeeding and fertility. Explain that there are limited data about the safety of COVID-19 vaccines during pregnancy and breastfeeding, but that experts do not believe it poses a risk and that there is no evidence that fertility problems are a side effect of any vaccine, including COVID-19 vaccines. Emphasize the importance of personal decision making, and remind your patient that you're available to discuss this more in depth.

For example, you can say something like, "There's limited information about COVID-19 vaccines during pregnancy. However, based on what we know about how these vaccines work, experts believe they're unlikely to pose a risk for pregnant people. You may choose to get vaccinated if you're part of a group that is recommended for COVID-19 vaccination, and we can walk through this decision together." Next slide, please.

People might also have concerns that the vaccines have not been tested in people who are similar to themselves. Explain that the clinical trials recruited a diverse mix of participants. Share any information you have about the percentages of people of color, people with underlying health conditions and older adults included in the trials. And reiterate that no serious safety concerns were identified in these groups. Next slide, please.

Some patients may ask, is it better to get natural immunity rather than immunity from vaccines? Explain the potential serious risks COVID-19 poses to them and to their loved ones if they get

the illness or spread it to others, adding that the disease can be serious, even if they're not in a high risk group.

Also explain that scientists are still learning more about the virus that causes COVID-19. And it's not known whether getting COVID-19 disease will protect everyone against getting it again, or if it does, how long that protection might last, and that the risks of severe illness or death from COVID-19 far outweigh any benefits of natural immunity. So for example, you can say, "Both this disease and the vaccine are new. We don't know for how long protection lasts for those who get infected or those who are vaccinated. What we do know is that COVID-19 has caused very serious illness and death in many people. If you get COVID-19 you also risk giving it to loved ones who might get sick. Getting a COVID-19 vaccine is a safer choice. " Next slide, please.

Some people might ask if the shot will hurt, if it will make them sick or if they'll have any side effects. Explain that they cannot get COVID-19 from the vaccines. Explain what the most common side effects from the vaccination are, how severe they might be, and that they will typically go away on their own within a few days. Provide a comparison if it's appropriate for the patient. For example, similar side effects from other vaccines. And make sure patients know that a fever is a potential side effect. You can say, "These side effects are signs your immune system is doing exactly what it's supposed to do. It is working and building up protection to disease. "

Then provide more detail on specific side effects by saying, some people report getting tiredness, headache, muscle pain, chills, fever or nausea after getting a COVID-19 vaccine, but that these typically go away on their own within a few days. Remember also that even if a patient doesn't ask, proactively explaining these side effects can help manage expectations and build trust. Next slide, please.

Others may be more worried about vaccine safety and long-term side effects, given that the vaccines are new. You can remind them that most vaccine side effects occur soon after the injection. And as with similar questions, explain the extensive monitoring that's in place to detect and report safety problems. Compare the potential serious risk of COVID-19 illness with what is currently known about the safety of COVID-19 vaccines. So for example, you can say, "COVID-19 vaccines are being tested in large clinical trials to assess their safety and effectiveness. However, it does take time and more people getting vaccinated before we learn about very rare or long-term side effects.

That's why safety monitoring will continue. CDC has an independent group of experts that reviews all safety data as they come in and provides regular safety updates. Any possible problems will be quickly investigated to determine if the issue is related to COVID-19 vaccines and determine the best course of action. " Next slide, please.

And finally, some patients might have concerns about one vaccine being better than another. Remind them that the best vaccine is the first vaccine that's available to them. Explain that all vaccine recommendations were based on reviews of data from ongoing clinical trials that found them all to be safe and effective in preventing severe COVID-19 illness, hospitalization and death. Consider adding that there may be other patient considerations for specific vaccines, including the convenience of only needing one dose if applicable, eliminating the need to find a

time to return for the second dose. It's also critical to remind patients that they still need to take precautions to protect themselves and their families, including wearing a mask, washing hands often and maintaining social distancing. So some language that you could use with patients could be, "If you do get exposed to COVID-19, all available vaccines can prevent you from getting sick, missing work or ending up in the hospital.

It's important to remember that even after you're vaccinated, you will need to keep wearing a mask that covers your nose and mouth, wash your hands often and stay at least six feet away from other people you do not live with. This gives you and others the best protection from catching the virus. " Next slide, please.

Once you've answered questions and explained side effects, encourage your patients to take at least one action such as if required, scheduling the second dose appointment right away if they were vaccinated that same day, or sharing their experience with others if they received a vaccination. Or reading additional information you provide them about COVID-19 vaccines if they declined vaccination.

And if they do decline, continue to remind them about the importance of getting a COVID-19 vaccine during future visits, and wrap up the conversation by letting them know that you're open to continuing the discussion and answering any additional questions they might have. Next slide, please.

As the COVID-19 landscape continues to change, be sure to find trusted sources of information that are constantly updated. These can include sources from CDC, from FDA, from your professional association, a state and local health department or your facilities immunization coordinator. Next slide, please.

And you can find more information within this suite of resources that CDC has created to help providers with COVID-19 vaccine conversations. These resources include guidance on addressing health equity and how to begin the conversation around COVID-19 vaccination with your patients. This also includes a very valuable list of frequently asked questions. And this page includes a link to FAQs designed specifically for healthcare providers that addresses common clinical questions, including additional information on pregnancy and breastfeeding, reporting of safety events and vaccine administration. So next slide, please.

I'd like to thank you all for your time today and for all you've done and all you continue to do for your patients. And with that, I'll turn it back over to Commander Khan.

Thank you very much, and presenters, thank you for providing our audience with such useful information. We will now go into our Q&A session. For our audience, please remember, you may submit questions through the webinar system by clicking the Q&A button at the bottom of your screen and then typing your question. And please understand that we receive hundreds if not more than a 1,000 questions during Q&A sessions often so we may not be able to answer every question. We will answer as many questions as we can, during this part of our call.

So our first question that we have for our presenters is, how do the adverse events experienced by patients after the Johnson and Johnson vaccine compared to Pfizer and Moderna?

This is Tom. I think if Kathleen -- I don't know, that's more of a clinical trials questions since we don't have a whole lot of post-authorization J&J data.

Sure, this is Kathleen Dooling. And so this vaccine was established to be safe in the clinical trials. The proportion of vaccine recipients versus placebo recipients who had any observed serious adverse events was similar between those two arms of the study at 4% each. And in terms of the expected reactogenicity that occurred after the vaccine, that was observed more commonly in the vaccinated group, with about 2.2% of vaccine recipients experiencing some type of adverse event -- adverse reaction that kept them from doing some of the regular activities of daily living, versus 7 in the placebo group. And the most common reactions were the same ones you'd expect -- pain, redness, swelling at the injection site, and then more generally, fatigue, myalgia, headache, systemically.

Thank you very much. Our next question comes from a clinician who's asking, can you please share any info available for breastfeeding mothers?

This is Kathleen again. So the vaccine certainly -- none of the vaccines in fact were studied in pregnant or breastfeeding women. Although there are no concerns that the vaccine would be in the breast milk or be dangerous to a breastfeeding infant.

Thank you very much. We received quite a few compliments on the vaccine safety data that was shared in the presentation. And one of the questions we received is, is the agency preparing to update this vaccine safety data? And if so, what is the best way for providers to get those updates?

This is Tom. So we give safety updates on ACIP meetings. So certainly folks can tune into the ACIP meetings and see our routine updates. We are also in the process of drafting papers for the MMWR and for other journals on updated safety data and also on new safety data that hasn't been published yet. So that information should be coming out in the MMWR and in other journals.

So we definitely want to be transparent and be timely in the way we communicate this information and make it as publicly available as possible.

Thank you very much. Next question asks, how soon after completing a COVID-19 vaccination course can a patient receive steroid injections? And the provider gives an example intra-articular injections.

This is Tom. That's more of a clinical practice, clinical recommendations issue. I'm not sure if we have the right people on the call to answer that, but maybe I'd defer to Kathleen to see if she has any thoughts.

I also would say we don't have really much data from the clinical trials to answer that question.

Thank you very much. Our next question asks, is it okay to recommend NSAIDs and/or Tylenol post-vaccination to patients?

Yes, following vaccination, we know that usually self-limited, mild to moderate symptoms are expected and patients can take over the counter pain medications to relieve these symptoms.

Thank you. Our next question asks, are you aware of any data of age as a factor on determining systemic reactions? And the inquirer mentions that anecdotally, they have seen older patients seem to tolerate the dose, especially the second mRNA vaccine dose, better than their younger patients.

And this is Kathleen again, that's exactly what we saw on the clinical trials. Persons 18 to 55 or 60, tended to have more frequent and more intense reactogenicity symptoms than patients who are older.

Thank you. Our next question is regarding deaths being reported following COVID-19 vaccine. And we have received a couple of questions on that. So if you can address deaths being reported following COVID-19 vaccine and any information you have on that.

So we do receive reports of deaths following COVID-19 vaccine. Most of our monitoring of deaths occurs through the Vaccine Adverse Event Reporting System, which again, is a spontaneous or passive reporting system. And it's just important to kind of understand what exactly is in there. So these are situations where a vaccination is given. And then at some point in the future, there's an adverse health event of which death is an adverse health event.

And then there is a decision made to report that to VAERS. Those death reports get processed at VAERS. Those are classified as serious reports. We reach out to the reporter, and we request medical records, death certificates, and autopsy reports if autopsies are done. The primary purpose of that is to verify the cause of death.

We do intense monitoring of deaths. And one of the ways -- one of the ways we monitor is to put the number of deaths that we're observing in VAERS into the context of what we would expect for background rates of death, so deaths for natural causes or deaths due to chance alone. And when we look at both the numbers and the causes of death, we're not seeing any concerning patterns or any unexpected patterns with both the numbers of deaths and the causes of death with respect to what we would expect, just by way of background. We also do monitoring and some special monitoring in the Genesis Healthcare data through a partnership with the National Institutes of Health and Brown University, where they're monitoring in long-term care electronic health records. And death is one of the outcomes, and what we've observed in that data is that actually the rate of death is lower in vaccinated persons compared to unvaccinated persons.

And this may be the result of what we call the healthy vaccinee effect, that healthy individuals are more likely to get vaccinated. But at least we are not seeing an excess of deaths in the period following vaccination of vaccinated individuals compared to unvaccinated individuals. So I think overall, we are not seeing any safety signals or any concerning patterns with respect to deaths

after COVID-19 vaccination. The causes of death are consistent with what we would expect to see based on vital statistics records.

Thank you very much. Our next question asks, do you have any guidance or recommendations for reporting to VAERS if the common adverse reactions that you talked about last longer than 48 to 72 hours?

So there are mandatory reporting requirements for COVID-19 vaccines that are specified in the emergency use authorization and that's specified by the FDA. CDC encourages the reporting of any clinically important or medically significant adverse event following immunization, regardless about whether the healthcare provider knows or suspects that it's caused by the vaccine. So with respect to the situation you describe there, I think if a healthcare provider thinks that their patient is having an unusual or unexpected reactogenicity event, certainly we would encourage that reporting. We're not going to discourage that reporting. And we will accept any report, regardless of the seriousness or regardless of whether it's biologically plausible that the event -- that the vaccine is causing the event. We basically accept all these reports, and we'll analyze them.

Thank you very much. And we have time for one last question. And it's a question that's shown up multiple times. And it essentially boils down to this, what is your guidance for patients counseling wise that are either hoping to get pregnant after being vaccinated and are concerned about that, or are concerned about effects on fertility after getting vaccinated?

This is Tom, I'll give you my opinion. And then I'll let others weigh in. I think one of the messages is that there is evidence that pregnant women are at increased risk for complications from COVID infection and/or increased risk for more severe disease. There is also some evidence that COVID infection may increase the risk of certain pregnancy and birth outcomes. So I think in order to protect both the mother and the developing baby, I think it's important that women get vaccinated.

And if they have specific concerns or general concerns, I think the healthcare provider should be the first person that they speak to, to get advice about vaccination.

Yeah. Thank you very much. And with that, I'd like to thank everyone for joining us today, with a special thanks to our presenters. 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. You'll also be able to find today's slides there as there are a lot of resources that I'm sure you're interested in. And that address is emergency.CDC.gov/COCA.

Please join us this Thursday, March 11. We will have our next COCA Call on COVID-19 titled The Role of Telehealth in Expanding Access to Healthcare during the COVID-19 Pandemic: Considerations for Vaccine Uptake and Monitoring for Adverse Events. Again, this COVID-19 COCA Call will take place this 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. COCA Call announcements for upcoming COCA Calls and other COCA products are sent via email. In addition to visiting our web page, please remember to subscribe to COCA

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