I would now like to welcome our presenters. Our first presenter today is Captain Amanda Cohn. She is a medical officer in the lead for the vaccine planning unit as part of the CDC COVID-19 response. Our second presenter is commander Sarah Mbaeyi. Our third presenter is Lieutenant Commander Sara Oliver.

I would like to turn it over. Please proceed.

Good afternoon, everyone. Today we are going to provide an overview of what clinicians need to know about the Pfizer-BioNTech and Moderna. We will review new information as well as reviewing information we presented over the last couple of weeks on either COCA or other partner calls. Next slide. So both of these vaccines are mRNA.

The Pfizer-BioNTech vaccine was authorized on December 11th. It was voted to support authorization of the vaccine yesterday on December 17th. We anticipate if they authorize that product as well in the next couple of days. Both products demonstrate a vaccine effectiveness of greater than 90%. This was demonstrated across age groups and racial and ethnic groups.

The vaccine safety profile of both products are also accessible -- or acceptable. There was an imbalance of Bell's palsy cases for both products, but this is still within the expected range and what we continue to monitor. Local and systemic reaction, particularly after the second dose, occurred but was also expected and resolved relatively quickly in a couple of days. The take-home message about these two vaccine products is they should not be compared with each other at this time. They both appear effective and safe.

Looking at information such as whether or not one product causes more fever than the other or is more effective in certain groups than the other, you have to take into account the populations that were different for these two vaccine clinical trials as well as the way of the solicited adverse events and the adverse events that they solicited for. While there appears to be small differences in these two products, if you look just at the vaccinated group, if you look at the vaccinated compared to the placebo group for adverse events, they do appear quite comparable. Next slide. I am going to take a moment to explain messenger RNA vaccines. These next slides were presented at the meeting by Moderna yesterday but apply to both vaccines in general.

MRNA vaccines provide instructions directly to the immune system of the individual getting vaccinated. The spike protein is the protein that the messenger RNA codes for. This efficiently produces a specific immune a memory response in a natural context, so this is very similar to how the immune response would happen if you were exposed to the virus. However, there is no like virus in this vaccine, and it can either interact with nor integrate into the DNA. Next slide.

This goes into a little bit more detail. The spike protein encoded mRNA and the lipid nanoparticles that in case the mRNA are the only ingredients in these vaccines. The lipid nanoparticles allows these vaccines to travel to the lymph system and enter presenting cells. So the encoded mRNA is then read. The spike protein is produced and then presented on the surface of the cell.

Importantly, we know from studies that the company has done that the mRNA disintegrates or is broken down by the cell very quickly. I am next going to review the advisory committee for immunization practices. After FDA authorization on December 12, 2020, they recommended the use of the COVID-19 vaccine in person 16 years of age and older under the emergency use authorization. On December 19th, with just tomorrow, the use of the maternal vaccine in persons 18 years of age and older if the vaccine is

authorized by the FDA. The big difference between the two vaccine products are the age group for with the authorization goes down to.

It is 16 verses 18. The other big difference in these vaccines, while they are both too dose of vaccine series, the Pfizer product is 21 days apart and the Moderna product is given 28 days apart. They also made recommendations about prioritization. ACIP recommends that when a COVID vaccine is authorized by the FDA and is recommended by ACIP that healthcare personnel be offered vaccination in the initial phase. This is phase 1A.

To let everyone know, ACIP is considering phase 1A and 1B, and we anticipate them being completed by Sunday, where the next final group would be all adults. Next slide. To complement the ACIP recommendations, the CDC has also published on our website clinical considerations for the use of the Pfizer-BioNTech vaccine. These were presented last week and are available at this link on our website. These clinical considerations will be updated to include information on both authorized mRNA products.

We anticipate that the clinical considerations will be nearly identical at this time for both products other than the two differences that I've just mentioned. There may be some other small differences, but we are trying to align the clinical guidance as closely as possible, regardless of the product. That does not mean the products are interchangeable. These clinical guidance was informed by data submitted to FDA for the EUA of the vaccine, other data sources, and we relied heavily on the general best practices guidelines for immunization as well as expert opinion. We will continue to update the clinical guidance documents as we understand these vaccines more.

A couple of key highlights to make from these clinical considerations is that we want clinical providers to understand that these vaccines are reactive. Before a vaccination, you should question recipients about expected local and systemic postvaccination. This is particularly true. It is particularly true for the second dose. This is including things like redness, pain, and fevers after vaccination that resolved within 24 to 48 hours.

Unless a person develops a contraindication to vaccination, they should be encouraged to complete the series even if they developed postvaccination symptoms in order to optimize protection against COVID-19. At this time, we do not have data to support use of a single dose of vaccine. Next is that it may be taken for treatment of postvaccination, but we do not recommend routine prophylactics due to lack of information on the impact of its use of antibody responses. The link for this is included below. Next slide.

The other really important thing to counsel your patience and for all of you to understand is that protection from vaccination is not immediate. The vaccine is a two dose series and will take one to two weeks following the second dose to be considered. Additionally, no vaccine is 100% effective, so given the current limited information on how well the vaccine works in the general population, how much it may reduce disease, severity, or transmission and how long protection lasts, we are recommending that vaccine persons continue to follow all current guidance to protect themselves and others, including all of these things you see below, which are normal social distancing guidance. We do recommend that an individual follow guidance after exposure to someone with COVID-19, even if vaccinated, and following workplace or school guidance. Next slide.

We will talk about this a little bit more in the question and answer, but we do have in our clinical guidance and algorithm to support triaging persons presenting for mRNA vaccines. The green column

indicates conditions in which you may proceed with vaccination. The second column is conditions which are considered caution to vaccination. The third column is contraindications to vaccination. This is split up into two rows.

The first row is conditions, so things like immunocompromised conditions, pregnancy, lactation. A person may proceed with vaccination, but additional information should be provided to those individuals. Additionally, any history of allergy to food, to pets, to insects or allergies not related to vaccines can proceed with vaccinations, but we recommend a 30 minute observation for person with a history of severe reaction due to any cause. Precautions include moderate to severe illness as well as history of severe allergic reactions to another vaccine or history of severe allergic reactions to any injectable therapy. That would require a risk assessment, considered differing vaccination, and if an individual does get vaccinated implementing a 30 minute observation.

Finally, there are no conditions which are contraindications to vaccination. So we do have an additional focus interim considerations for management of anaphylaxis, which includes information on early recognition, medication and supplies, management of anaphylaxis, and recommendation to immediately activate EMS if there is an anaphylactic reaction and patient counseling and reporting. Next slide. These are the recommended medications and supplies that sites should have available to manage anaphylaxis. Epinephrine, antihistamines, stethoscope, and timing device to assess a pulse should be available at all sites.

There is some additional sites recommendations to include where feasible. The most important thing to do is to administer epinephrine and call 911 if any individual is experiencing anaphylactic reaction. I want to highlight that we have multiple COVID-19 vaccine communication resources for healthcare providers, for medical centers, both how to engage in effective COVID-19 vaccine recommendations, a strong recommendation from a healthcare provider. We know that is one of the most important things to inform a person's decision to get vaccinated. Even if you are a healthcare provider who is not administering vaccine at this time, all of you see patients every day and can recommend vaccination when it is the right time for that individual to get vaccinated.

We also have a toolkit with multiple posters and stickers and slide presentations to talk to both healthcare personnel in your institution or medical practice as well as your patience. So we do have more toolkits that will be available soon, including one for long-term care facilities, for health departments, for community-based organizations, and for employers. Next slide. One other key set of documents we want to point out is we have developed infection prevention and control of accommodations for persons with postvaccination symptoms. This is really important both for healthcare personnel as well as long-term care facility residents.

It helps build out a framework for determining, you know, we do not want to unnecessarily exclude healthcare personnel who only have postvaccination signs and symptoms from work. We also do not want to inadvertently allow healthcare personnel with another transmissible infection to work. These are both available on our website as well. Next slide. So we will now move to the second part of our session where I will be asking questions and moderating a panel discussion with Dr.

Mbaeyi and Dr. Oliver. These questions have been taken from the multiple questions we've received from healthcare providers, including during our last COCA call over the last week to 10 days. We really want to hear your questions. It has helped us so much in understanding what clinical guidance we need to have available to healthcare providers, so please continue to put questions that you have in the Q&A as we go through these questions and have this discussion.

So I will begin with a question that I have asked and answered a couple of times, but I'm going to ask Dr. Oliver to talk about this. I think the answer is evolving. What do we know currently about the benefits of mRNA COVID-19 vaccines to prevent transmission?

Thank you, Dr. Cohn. The vaccine manufacturers of the Pfizer biotech has stated they are doing additional studies to better understand the impact for you we look forward to being able to review that data when it's available. Yesterday information was presented at the meeting for the Moderna vaccine. Among people who received one dose of the vaccine, there was a reduction in the number of participants who were asymptomatic but had a positive PCR compared to those participants who received placebo.

The screening was done when the participants came back into receive their second dose of vaccine. It's early data, and we still need to know more around how these mRNA vaccines will prevent transmission, but overall it is encouraging from the clinical trials. We look forward to additional information around how these vaccines may prevent transmission. Until they have that additional information, and until there is high vaccination coverage for the general population, we do want to continue to encourage and recommend that vaccinated people continue to use all of the tools available for preventing COVID-19, including mask use, social distancing, and hand hygiene. Hygiene even after vaccination.

Great. Thanks so much. I do think -- I am really looking forward to this information, and I'm really excited about the small amount of encouraging data that was presented yesterday. So, Dr. Oliver, I will also -- since I have two cigarettes, I am using doctor.

So Dr. Oliver, should people who have had COVID-19 B vaccinated, and should they be vaccinated now?

Thanks. COVID-19 vaccination should be offered to persons regardless of prior COVID-19 infection. People should wait to get vaccinated until after their acute illness is resolved and after they've met the criteria to discontinue isolation. There is current evidence that reinfection is uncommon in at least 90 days after initial infection. Because of that, persons with a recent COVID infection may defer vaccination until the end of the 90 days if desired.

Great. I am going to take this question one step further. What if, for example, I get dose one and then when I am do for dose number 2, what if, a, I have symptomatic COVID and I am ill, and what if I have a positive PCR test showing I have asymptomatic COVID.

We really want to protect the healthcare personnel people who would be providing the vaccine and not expose them to risk. There are certain circumstances that are detailed in the clinical considerations, especially around quarantining individuals were people residing in congregate care settings, when they are under quarantine, may still receive vaccine. Overall individuals who are positive should wait to receive vaccine until they have met the criteria and discontinue isolation.

Great. Thanks so much. So it's not for concern about us being -- it's not about concern for vaccine safety forgetting that vaccine, it's really about maintaining our quarantining recommendations.

Exactly.

Okay. Moving on to what I know is a question that is at the top of everyone's minds and has been really challenging. Dr. Mbaeyi, can you talk a little bit about the contraindications to components of the Pfizer-BioNTech and Moderna vaccine? What does it mean in terms of -- what kinds of things we do think

about in terms of being concerned about whether or not you have had a severe allergic reaction to one of those components in either vaccine. What should people be thinking about in terms of severe versus less severe allergic reactions and anaphylaxis?

Sure, thank you, Dr. Cohn, for that question. As you mentioned a little bit earlier, there are some people that should absolutely not get this vaccine. Those are people that have had a severe allergic reaction to any component of the vaccine. I just wanted to point out, one of the components that Dr.

Cohn showed, you know, contains polyethylene glycol. That something clinicians are used to using for things like laxatives or chronic bowel prep. If someone had an anaphylactic reaction to that medication, you know, that's a component of the vaccine. That's kind of the main one of concern. But people who have had a reaction to any component of the vaccine should not get it.

If somebody gets the first dose of the vaccine and experiences anaphylaxis, they should not get a second dose of the vaccine. In terms of, you know, how people can decide, was this a serious reaction, like anaphylaxis or not, when they are talking to their patient, you know, some things like listening. Did it require use of an EpiPen customer did it require hospitalization or visit to the emergency room? Really trying to elicit those symptoms to see how severe an allergic reaction it might have been. So there is those people that should not get vaccine but there's also that group of people who there is precautions around the vaccine there should really be a history of little bit more. Somebody who has had a severe allergic reaction to any vaccine or any injectable medication at this time we are recommending those are precautions that are on the vaccine.

Somebody can still get the vaccine, but there needs to be that discussion to better understand what happened and take into account, you know, kind of various factors to determine whether that person should get the vaccine. As Dr. Cohn mentioned, people with things like food allergies, insect allergies, latex allergies, those kinds of things, those people we do not have any sort of contraindication or precaution to people with other types of allergies. Having said that, everybody who gets the vaccine we are recommending an observation. For anyone with history of anaphylaxis due to any reason at all, we are recommending a 30 minute observation.

For everybody else who's never had anaphylaxis in their life, we are recommending a 15 minute observation.

Great. So I have a daughter who carries an EpiPen. I've never had to use it before, but she is allergic to certain Trina's. You would recommend that she go ahead and get vaccinated when she is old enough. She's 18.

Would you recommend that she go ahead and get vaccinated when she is recommended based on prioritization but you watch her for 15 minutes to 30 minutes, is that the advice for what we know are many, many people who are concerned about anaphylaxis but have not had to use that EpiPen before?

Yeah, that's right. People of other types of allergies who've experienced allergic reactions but have never had, you know, a severe reaction such as anaphylaxis, you know, a lot of people get EpiPen. They are given that. Unless someone has had an anaphylactic reaction in the past to a vaccine or injectable medication, they can get vaccine, they just need to be observed afterwards.

Great. Thank you. [barking] I apologize. Those are, unfortunately, my dogs. Someone rang the doorbell.

Let's move onto the next question. Can you go into a little bit more detail about what is needed on-site vaccination clinics? I know I talked about this a little bit, but do you have anything else to add to talk about what is prepared in case there is anaphylaxis.

I think the key things they need to do is make sure they are at the vaccination site, whoever is administering the vaccines are involved and should be able to, you know, rapidly recognize the signs and symptoms of anaphylaxis, to give epinephrine. Epinephrine is first-line treatment. There are no contraindications to getting epinephrine credit if somebody has anaphylaxis, you want to give that immediately and then call for emergency services, call for 911. And so I think those are kind of I think the main take-home messages. We did prepare kind of some recommendations of the minimum that people need to have on site.

I think the minimum, like I mentioned, is epinephrine. We do recommend that people have antihistamines on site. That does not treat anaphylaxis. That does not treat, you know, respiratory obstruction and things like that, but it can provide symptomatically relief for people that need it. We do recommend some equipment to help monitor vital signs or assess vital signs.

Blood pressure cuffs, stethoscope, something to time someone's pulse. Then there is the other things that, you know, are used for treatment of anaphylaxis that if you have it or if you're able to get it, you know, the more you can be prepared, the better. I think what I've mentioned are really kind of minimum requirements. Again, being able to recognize anaphylaxis, administer epinephrine appropriately, and call for emergency services are kind of the ABC for vaccination sites to do.

Great. Thank you. Dr. Mbaeyi, I know and some types of settings it can be really challenging to recognize anaphylaxis. For example, if an individual who is living in a long-term care facility setting who may have some dementia and cannot report symptoms, if you are sort of on the fence about whether or not that individual is having an anaphylactic reaction, you are saying you would go ahead and give epinephrine regardless, right? And then call 911.

Yes. If anaphylaxis is suspected, epinephrine delays -- you know, delays in administering can create bad outcomes. I do want to mention, as you mentioned, it can be hard and some patients to tell. Hindsight is always 2020. I do want to mention that some older adults, especially those who have certain cardiac issues like hypertension, they are more at risk for kind of cardiac side effects from epinephrine itself, so you, certainly, do not want to give unnecessary doses when people do not need it.

Like I mentioned, because of how life-threatening anaphylaxis can be an drafted prompt attention is necessary, if anaphylaxis is expected, you should administer it and then call 911.

Great. Thank you. I guess to close out the question on anaphylaxis, I just like to make the comment that, you know, we are not saying that -- anaphylaxis still is rare, but if these reports do end up turning out to have been real anaphylaxis and it is occurring at the more than regular rate, we -- usually anaphylaxis to vaccines is more than one in a million. It's one in about 1. 3 million persons vaccinated.

We are vaccinating a lot of people over the next couple of months, and if it is lower than that, you know, one and 100,000 or one in 500,000, the benefits of vaccination are really important, but we will be doing whatever we can to understand what is causing anaphylaxis and supporting continuing vaccination unless there is a real need to shift. I will say the cases that have been reported have all been reported from Pfizer vaccine. You know, it is still really a handful. We do not know if this will happen with

Moderna texting, but we are maintaining the same clinical guidance for both vaccines until we know otherwise. So moving on to vaccination.

We are going to talk about some special populations. I know a lot of this information is in that document, but as you know, the vaccine clinical trials did not include unknown pregnant women. Dr. Oliver, can you talk a little bit about whether or not pregnant persons can get before vaccines and if there are special considerations for pregnant women?

Absolutely. If a pregnant person is a part of a group that is recommended to receive it COVID-19 vaccine, such as a healthcare personnel, they may choose to be vaccinated. While we think a conversation with a healthcare provider may be helpful in helping the pregnant individual make that decision, it is not required prior to vaccination. I think from the clinician standpoint, when thinking through talking with a pregnant patient, providers need to think through what we know and don't know about vaccines during pregnancy. Based on our current knowledge, and leading up to these recommendations, we really pulled together some of kind of the country's experts in this technology and in pregnancy and in pregnant women.

The experts believe that mRNA vaccines are unlikely to pose a risk for people who are pregnant just based on the biology of how these vaccines work. The vaccines are not life. The mRNA degrades quickly after vaccination. There has not been any safety threats that have been identified. Observational data demonstrate that while the absolute risk is low, pregnant people with COVID-19 have an increased risk of severe illness.

by including illness that resulted in an ICU ventilation or death. They also may be at increased risk for adverse outcomes such as preterm birth. While there is no data on the safety of these vaccines in pregnant people, studies are ongoing. So there were some inadvertent pregnancies in the clinical trials. In both the Pfizer and Moderna trials, the manufacturers and FDA and CDC are going to follow it to see how those pregnancies progress and the outcomes.

There have not been any safety issues identified to date. And then the animal studies. We call those the developmental and reproductive toxicity studies. Those are ongoing, and we expect to have those results very soon. Hopefully, the studies in pregnant people specifically are planned and will be beginning soon as well.

The clinician also needs to consider some other factors when discussing this with pregnant patients, including the patient risk of exposure to COVID based on their occupation such as the exposure in a healthcare setting. If they are a healthcare personnel and a level of COVID in the person community. Risk of COVID to the baby, the benefits of the vaccine and the known side effects and a lack of data around mRNA vaccine and during pregnancy, balancing that with what we do know.

Great. You just reminded me. I am going to give a plug for the safe, which is the active safety monitoring system that we are asking people to get vaccinated to enroll in. It is a text message-based system where we are collecting information on people's adverse events, if they have a significant health impact after vaccination, we are following up with phone calls to understand that health impact better. We are reminding people.

We are asking people to let us know how they are doing up to two weeks after vaccination and then a couple of additional time points. We have really had incredible uptake of persons enrolling in this first week of vaccination. I've been so happy because it is really going to give us the most timely -- it's going

to really help inform how to use these vaccines effectively and safely. I will also say that this is following individuals who are being vaccinated who are pregnant, and so if a patient or if any of you are pregnant and get vaccinated, we really want to understand vaccine safety in pregnant individuals, so we already have more pregnant women enrolled than we had in the clinical trials or that were vaccinated not knowing they were pregnant in the clinical trials, so be really excited about that.

Dr. Oliver, can I ask you then about lactating women? Does the same hold true?

Yes, absolutely. There is no data, again, on the safety of the COVID vaccines in lactating people or in the effects of mRNA on a breast-fed infant or on milk production or excretion. However, mRNA vaccines are not thought to be a risk to a breast-feeding infant, so a lactating person who is a part of a group that's otherwise recommended to receive COVID-19 vaccine -- for example, in phase 1A, the healthcare personnel may choose to be vaccinated as well.

Great. Before we leave this topic, can you just give us an update about other provider organizations and clinical guidance that they have released as well?

Yes. When CDC was developing these clinical considerations, we did it in close collaboration with ACOG and AAP. There is a practice advisory available online and the pregnancy webpage on the COVID vaccines site, specifically linking to that practice advisory as well. So I think recognizing that some of the burden of walking through the risks and the benefits is going to fall to these OB/GYN's and providers that people may turn to for questions. ACOG has provided that information and support in addition to what is available from the CDC website.

Great. Thanks. Now moving to the topic of immuno compromised persons. We are going to turn back to Dr. Mbaeyi.

I know in the triage slide that persons who are immunocompromised are not considered a contraindication for vaccination, but there is a lot of questions. You know, there's a wide range of immunocompromised persons and persons receiving medications like Biologics. So what are the current -- what is the guidance for individuals who have -- who are immuno compromised and around receiving a mRNA COVID vaccine?

Yes. As he mentioned, people who are immune compromise can receive the vaccine, unless they have any other contraindications that were already mentioned. People with stable HIV were included in the clinical trials. Other people with other types of immunosuppression were not included, so we really don't know right now kind of the benefits and risks of the vaccine for them or the safety and efficacy, but these people we believe to be might be at risk of severe COVID disease. There is really kind of that risk that needs to be taken into account.

So what we are saying is that, you know, people with immunosuppression can get the vaccine. They should just be aware that we don't really have that much data in the vaccine may not work as well and they have some diminished immune responses. It makes it important for them to continue with the health measures that are recommended for everybody like social distancing, masking, all of those kind of things to help keep themselves safe.

Great. Is this similar for persons with autoimmune disease? I know there is a lot of concerns about autoimmune disease and these vaccines. What are the current recommendations are guidance around that?

Yes. It's a similar recommendation. We really don't have much data in this particular group. People with autoimmune disease, they were eligible to it be enrolled in the clinical trials, so they were able to take part in the clinical trials. There were not any -- you know, there was no data available specifically in this group, but when FDA reviewed the data, they did not find any kind of imbalances between the vaccinated group and the unvaccinated -- and the placebo group in terms of, you know, occurrence of symptoms consistent with autoimmune diseases.

We recommend people with autoimmune diseases or persons on biologic treatment, they can get the vaccine unless they have a medical contraindications such as the anaphylaxis issues we were talking about earlier.

Great. And then final question in this grouping. So what if -- I know we are saying people who have had COVID-19 should be vaccinated but they can -- if you are trying to prioritize, you could defer vaccination for 90 days in those individuals. Have the recommendations changed if a person received convalescent serum when they were treated for COVID-19?

Yes, it's a great question. Again, we don't have data on this in terms of how soon after somebody gets a treatment or convalescent serum. The safety, efficacy, all of those parameters. But we do know some things about the half-life of how long the antibodies would last in the system. Based on that information, we are saying that people who have received convalescent serum or monochrome, they should delay vaccination for at least 90 days.

This is a precautionary measure until we have additional information available. This is to help avoid interference of the antibody treatment with vaccine -induced immuno responses. So it's kind of based on what we know about these therapies but also knowing that people who have been recently infected with this are unlikely to have reinfection in those 90 days, so we are saying wait 90 days to get the vaccine if you have had antibodies or convalescent plasma.

Thank you. A couple of questions about dosing administration of these vaccines. As you know, it is next to impossible to make sure that everybody gets back to get their second dose right at 21 days or right at 28 days. Can you talk a little bit about what happens if a person comes in before 21 days or 28 days, depending on the product or after. What are the recommendations to manage differences in time intervals between doses?

Sure. So the Pfizer is recommended at 21 days. The Moderna is 28 days. The reason is simply the way the studies were designed. Pfizer gave there is at 21 days and Moderna did 28 days.

Not based on any specific concerns around how the vaccines work, but well aware that it is difficult especially if the products are different to know exactly when everybody should come back in the second dose scheduling. We have had some kind of intervals where things are okay based on data from the clinical trials. They said that a four day grace period should be fine. In addition, there is no maximum interval between the first dose and a second dose. If there is a delay in receiving the second dose, they should receive the second dose as soon as possible after that kind of 21 or 28 day interval.

You do not have to start the series over again. At this point, there's no recommendation where we restart the series or need to repeat doses. A person receives two doses of these vaccines, especially in the setting of limited supply. That is what is recommended right now.

Great. Thank you. That makes a lot of sense. We do have lots of systems in place. You know, electronic systems and at the state and the health department to support people having reminders to get back for their second doses.

Hopefully, a lot of people are getting their second dose is scheduled at this time when they come in. Certainly, as vaccination expands, I think that is going to be a challenge. Hopefully, we will have more data to inform effectiveness with differences in administration dates. One more question for you, Dr. Oliver, that we have also gotten a ton of questions about.

Can influenza or any other vaccine be administered at the same time as other COVID-19 vaccines?

So right now we are recommending that the mRNA vaccines be given alone with a minimum interval of 14 days before or after administration. If a vaccine -- if a mRNA vaccine is inadvertently administered within 14 days, providers do not need to repeat the dose or restart the series of the mRNA vaccine. Again, this is mostly in this time where we are trying to learn about, you know, monitoring these vaccines. We just want to have a very clear picture of what is happening specifically with related to the mRNA vaccines. If an individual receives multiple vaccines at the same time, it can be hard to figure out kind of what's going on in that picture.

So for right now, we are saying vaccine given alone with an interval of 14 days before and after with the knowledge that as this expands and as we learn more, we will update that recommendation.

That's great. But if a person comes in and cannot remember if they got their flu vaccine a couple weeks ago, you do not have to track that down. You can go ahead and administer it and not have to repeat it. The goal is to be 14 days apart. I really understand and all of our other routine immunization guidance, we recommend coadministration of vaccines, because we want to use every opportunity.

I think this vaccine is still under an emergency use authorization and clinical trials were not done that included coadministration. We will shift our guidance when we feel we have the data to support that, but for right now try to administer this alone and within 14 days before or after another vaccine. So, Dr. Mbaeyi, could you talk a little bit -- I think this is going to be our last question. I know myself as long as -- and I am guessing most of the providers on this call have never actually administered a vaccine or potentially anything other than a diagnostic test under an EUA.

Could you talk a little bit about what providers need to report, but they need to do, and what are the requirements around administering COVID-19 vaccines under an EUA?

Sure, yes. It is a great question that I know probably a lot of people need more information on. I think, first, all COVID-19 vaccine providers should really carefully review these requirements that are in the COVID-19 vaccine provider agreement. This includes following CDC, AC IP, and manufacturer recommendations for the storage, handling, and administration of COVID-19 vaccines. They also should be familiar with the information in the EU a sheet for healthcare providers administering the vaccine.

As we talked about before, be prepared to medically manage any severe reactions that may occur. And then all patients must be provided with the fact sheet for recipients. They should be given this prior to vaccination. There is also a vaccination record card or a shop card that comes in ancillary kit. That completed vaccination record card should be given to each patient so that they know what they got, what vaccine they got, and when they need to contact to get their second shot.

And then vaccines administered should be documented in the patient's medical records within 24 hours of administration. We suggest vaccine providers should use their -- you know, make their best efforts to report the administration data to their jurisdiction either through their jurisdictions IIS or CDC vaccine administration management system as soon as it is practical but ideally no later than 72 hours after administration. Providers are also required to report their vaccine inventory to vaccine finder daily. They must report to the vaccine adverse event reporting system for any vaccine administration errors, even if there was no associated adverse event. All serious adverse events, regardless of whether they think it's vaccine related or not, multisystem inflammatory system in children and adults as well as cases of COVID-19 that result in hospitalization or death following vaccination.

In addition to these, any clinically significant adverse events may also be reported even if the provider is not sure whether or not vaccination caused that. There is also additional requirements in the FDA conditions of use that are kind of on the FDA website. Again, like Amanda mentioned, we are also encouraging providers to ask their vaccinated patients to participate in the be safe program, which is the voluntary monitoring system that would help us kind of understand the safety outside of clinical trials. So I know that was a lot of information, but that information is found in the vaccine provider agreement. That information is also available on our website as well.

Great. Thank you so much. I know that a primary reason to report is to make sure that patients do get the same vaccine, but I will also tell you that all of this data that is coming in and being reported by all of you is incredibly helpful as we assess potential adverse events. It gives us a denominator that's really quite critical. We appreciate it.

Dr. Mbaeyi, Dr. Oliver, I also appreciate you doing this today with us. I will hand it back over.

Thank you. Next slide, please. Here are some resources. Would you like to remark on these?

Sure. We did just put some general information, but this is with the Pfizer EUA and information about COVID vaccines from the FDA website. There will be -- once Moderna EUA is authorized, similar information will be authorized for the Moderna product. I did peruse the FDA website this morning, and the patient fact sheets have been translated into multiple languages already, which is incredible. Always, you know, if you need anything like that related to the EUA specifically, go to any of these links on the FDA website.

Thank you very much. I want to thank everyone for joining us today with a special thank you to our presenters. Thank you so much for providing our audience with such critical information. Today's COCA call will be available on demand a few hours after the live call. You can find a video recording of today's call.

Please continue to visit to get more details about this call and others as we intend to host COCA call to keep you informed on the latest guidance and updates of COVID-19. Be sure to subscribe to receive notifications. COCA call announcements for other announcements are sent via e-mail. In addition to sent visiting our webpage, please subscribe to COCA to receive notifications about calls and other COCA calls and services. Please share the call announcement with your clinical colleagues.

You can join the mailing list by visiting the COCA webpage. Click on get e-mail updates and enter your e-mail address. To stay connected to the latest news from COCA, be sure to like and follow us on Facebook. Again, thank you for joining us for today's COCA call, and have a great day.