Good afternoon. I'm Captain Ibad Khan I'm representing the Clinician Outreach and Communication Activity (COCA) with the Office of Emergency Risk Communication at the Centers for Disease Control and Prevention. I'd like to welcome you to today's COCA call, Protecting Infants from Respiratory Syncytial Virus (RSV). All participants Joining us today are in listen only mode. Free continuing education is offered for this webinar and instructions on how to earn continuing education will be provided at the end of the call.

In compliance with continuing education requirements, all planners and presenters must disclose all financial relationships in any amount with ineligible companies over the previous 24 months, as well as any use of unlabeled product or products under investigational use. CDC, our planners, and presenters wish to disclose to have no financial relationships with ineligible companies whose primary business is producing, marketing, selling, reselling, or distributing healthcare products used by or on patients. Content will not include any discussion of the unlabeled use of a product or a product under investigational use. CDC did not accept financial or in-kind support from ineligible companies for this continuing education activity.

At the conclusion of today's session, participants will be able to accomplish the following: review current RSV epidemiology in infants; describe the safety of nirsevimab and maternal RSV vaccine; discuss CDC's latest recommendations and clinical considerations for administering RSV immunizations in infants under eight months, toddlers at increased risk for severe illness due to RSV, and pregnant people; and list implementation considerations for nirsevimab and the maternal RSV vaccine, including updates for the Vaccines for Children (VFC) program.

After today's presentations, there will be a Q&A session. You may submit questions at any time during today's presentations. To ask a question using Zoom, click the Q&A button at the bottom of your screen then type your question in the Q&A box. Please note we often receive many more questions than we can answer during our webinars. If you're a patient, please refer your questions to your health care provider.

If you're a member of the media, please contact CDC Media Relations at 404-639-3286 or send an email to media@cdc.gov. It is now my pleasure to welcome our presenters for today's COCA. We're pleased have with us Commander Jefferson Jones, who's the co-lead for the ACIP RSV Maternal-Pediatric Work Group in the Coronavirus and Other Respiratory Viruses Division in the National Center for Immunization and Respiratory Diseases at CDC. And Captain Sarah Meyer, who's the Chief Medical Officer in the Immunization Services Division in the National Center for Immunization and Respiratory Diseases at CDC.

It is my pleasure to turn it over to Commander Jones. Commander Jones please proceed.

Hello, and thank you for having me. Next slide. Today, I will be reviewing RSV epidemiology in children; the efficacy and safety of the two products we have to protect infants from RSV disease, nirsevimab; and Pfizer's maternal RSV vaccine. And then, I'll review recommendations and clinical guidance. I will first discuss the initial release guidance that assumes sufficient nirsevimab availability.

I will then discuss the shortage of nirsevimab and interim guidance for health care facilities experiencing limited availability of nirsevimab as released in a recent health alert network or HAN health advisory. The next presentation will cover considerations for implementation of these products. Next slide. First, RSV Epidemiology in Children. Next slide.

RSV infection is the leading cause of hospitalization in US infants. Most infants are infected in the first year of life and nearly all by age two years. 2 to 3% of young infants will be hospitalized for RSV. RSV is a common cause lower respiratory tract infection in infants, which is what leads infants to be hospitalized. The highest RSV hospitalization rates occur in the first months of life and risk declines with increasing age in early childhood.

And although certain medical conditions are associated with increased risk of severe disease, recent studies have shown 79% of children hospitalized with RSV age less than two years had no underlying medical conditions. Next slide. CDC estimates that each year in the United States, among children younger than five years of age, RSV is associated with one to 300 deaths, 58 to 80,000 hospitalizations, about 520,000 emergency department visits, and approximately 1. 5 million outpatient visits. Next slide.

The New Vaccine Surveillance Network or NVSN, systematically tests children with acute respiratory illness and tests them for RSV among other pathogens to estimate population based rates. Displayed are RSV associated hospitalization rates by age group during 2000 to 2004 in red, during 2016 to 2020 in yellow, and during 2021 in gray. RSV associated hospitalization rates are highest in young infants aged zero to five months and decrease with increasing age and childhood. RSV associated hospitalization rates in infants aged zero to five months are more than double those among infants aged six to 11 months. Then, you can see that rates are even lower among toddlers 12 to 23 months and among children aged 24 to 59 months.

And this pattern of seeing the highest rates in infants ages zero to five months is true across different time periods in which NVSN has conducted surveillance. Next slide. Now, we can zoom in and take a closer look RSV hospitalization rates in children aged zero to 11 months, which demonstrates what passive immunization has been pursued for this age group. The red bars represent NVSN hospitalization rates for 2000 to 2005, while the yellow bars represent rates for the surveillance period 2016 to 2020. And the highest rates occur in the first few months of life, peaking at age one month, and then decrease with increasing age, indicating that the older an infant is when they get RSV, the less likely they are to be hospitalized for RSV.

And this is important for considering which infants benefit the most from passive immunization protects against severe RSV illness. Next slide. The National Respiratory and Enteric Virus Surveillance System or NREVSS, is a system CDC uses to monitor RSV seasonality using the percent positive of RSV tests submitted by over 300 participating labs from across the country. And prior to the COVID-19 pandemic, in most regions the United States, RSV season started in the fall and peaked in the winter, as shown in the gray shaded area, which has a range of values for the pre pandemic years during 2009 to 2019. The COVID-19 pandemic influenced RSV seasonality.

RSV was mostly absent 2020. And as shown in the blue line, there was a summer peak and 2021; and as shown in the black line, there was a slightly early peak in the 2022 to 23 season. Now, as shown in red, the current RSV season. It's slightly earlier than pre-pandemic RSV season trends. Importantly, RSV transmission has increased to seasonal epidemic levels in the southern regions in the United States, and is expected to increase to the rest of the continental United States within the next one to two months.

Next slide. To review. So, among infants hospitalized due to RSV, most are born premature or have chronic medical conditions. Is this true or false? Next slide. The answer is false.

A national study showed 79% of children hospitalized with RSV each less than two years had no underlying medical conditions. Next slide. So, there are two products that can protect infants in the first RSV season. We'll review the efficacy and safety. Next slide.

So, there is a maternal vaccine for pregnant persons from Pfizer, brand name Abrysvo, and a monoclonal antibody, nirsevimab, brand name Beyfortus, given to the infant after birth. Please note that there is an additional RSV vaccine by GSK, brand name Arexvy. This vaccine is not approved or recommended for use in pregnant people. So, to protect eligible children at increased risk in their second RSV season, there's only one option and that is nirsevimab. Next slide.

So, the efficacy for nirsevimab was initially evaluated through two multicountry trials that included preterm and term infants. And efficacy was evaluated through 150 days after injection and the pooled efficacy from the trials was 79% and preventing medically attended RSV lower respiratory tract infection or LRTI and 80. 6% in preventing RSV, LRTI, with hospitalization. Next slide. Nirsevimab is an acceptable safety profile and it's what has been generally well tolerated.

The most common reported adverse reactions in the trial were injection site reactions and rash, which were present in less than 1% of recipients. In trials, the incidence of serious adverse events was not significantly different between the nirsevimab and placebo arms. Next slide. The efficacy of Pfizer's maternal RSV vaccine was evaluated in a multi-country trial with the vaccine administered during 24 through 36 weeks gestation. And the efficacy was evaluated through 180 days of birth and results displayed here.

And it was 51. 3% in preventing medically attended RSV associated LRTI and was 56. 8% in preventing hospitalization for RSV associated LRTI or lower respiratory tract infection. Next slide. The side effects of the maternal RSV vaccine tended to be mild or moderate, temporary, and like those experienced after either vaccinations, but the most common local and systemic adverse reactions during trials were pain at the injection site, headache, muscle pain, and nausea.

More preterm births and reports of hypertension during pregnancy, including preeclampsia, were seen in the vaccine group than the placebo group in clinical trials. But these differences were not statistically significant. And it is not known if this was related to the vaccine or simply due to chance. Restricting vaccination to 32 through 36 weeks gestation reduces any potential risk of preterm birth. And ACIP judged that the benefits of maternal RSV prevaccination at 32 to 36

weeks gestation, to outweigh the potential risks for preterm birth and hypertensive disorders of pregnancy.

Next slide. So, next we'll talk about the recommendations for Pfizer's maternal RSV vaccine. Next slide. Maternal vaccine or RSV is recommended for pregnant people during 32 weeks and zero days through 36 weeks and six days gestation with seasonal administration. This means administering during September through January in most of the continental United States.

However, in jurisdictions with seasonality that differs from most of the continental United States, for example, Alaska and jurisdictions with tropical climates, providers should follow state, local, or territorial guidance on timing of administration. The maternal RSV vaccine can be simultaneously administered with other indicated vaccinations. Next slide. So, either of the two options: maternal vaccination or use of your nirsevimab in the infant is recommended to prevent RSV low risk for tract infection. But administration of both products is not needed for most infants.

Health care providers of pregnant people should provide information on both products and consider patient preferences when determining whether to vaccinate the pregnant patient or to not vaccinate and rely on administration of nirsevimab to the infant after birth. And the next presentation by Dr. Meyer will go into more detail on vaccine counseling and the importance of discussing the potential lack of nirsevimab availability as part of this conversation. Next slide. To review, when a pregnancy is Pfizer's RSVpreF maternal vaccine recommended? a) any time during pregnancy, b) 24 through 36 weeks gestation, or c) 32 through 36 weeks gestation.

Next slide. The answer is C. The maternal RSV vaccine from Pfizer is recommended to be given only during 32 weeks and zero days through 36 weeks and six days gestation. Next slide. Now, we'll talk about nirsevimab recommendations.

So, I'm first, again, I'm going to discuss the general recommendations that have been given in ACIP and printed in the MMWR. And these apply to healthcare settings currently where there's a sufficient supply of 100 milligram doses. And then later, I will talk about those with that insufficient supply. Next slide. So, in most of the United States, as discussed, the RSV season has started or is expected to start in the next one to two months.

Therefore, nirsevimab administration to eligible children should begin as soon as nirsevimab is available. To repeat, nirsevimab administration should begin as soon as it is available. And nirsevimab should continue to be offered through March to eligible infants and children. And this is mainly important for those born during October 2023 through March 2024. Next slide.

So, for infants born in October 2023 through March 2024, they should be immunized with nirsevimab within one week of birth. Nirsevimab administration can occur during the birth hospitalization or in the outpatient setting. Providers immunizing infants with nirsevimab with prolonged birth hospitalizations shortly before or promptly after discharge. Next slide. For all other infants younger than age eight months, providers should administer as soon as nirsevimab is available if the age of the infant is younger than eight months at the time of immunization.

And this is, again, is assuming sufficient nirsevimab availability. And I'll discuss how this is different for healthcare that lacks sufficient nirsevimab shortly? Next slide. So, because the maternal RSV vaccine is effective if the mother was vaccinated 14 or more days prior to birth, nirsevimab is not needed for most infants. Next slide. However, there are rare circumstances for which nirsevimab can be considered when the mother has received RSV vaccine 14 or more days prior to birth when for the clinical judgment of the healthcare provider, the potential incremental benefit of administration is warranted.

So, these include, but are not limited to, infants born to pregnant people who may not mount an adequate immune response to vaccination. For example, people with immunocompromising conditions or who have conditions associated with reduced transplacental antibody transfer, for example, people living with HIV infection. Also, infants who might have experienced loss of maternal antibodies, such as those who have undergone cardiopulmonary bypass or ECMO. And if it's with substantial increased risk for severe RSV disease, for example, hemodynamically significant congenital heart disease or infants with Intensive Care Unit admission and requiring oxygen at the time of discharge. Next slide.

So, for high-risk children aged 8 to 19 months entering their second RSV season, providers should administer nirsevimab as soon as it is available if the age is 8 through 19 months at the time of immunization and the child is at increased risk for severe disease. Again, this is assuming sufficient nirsevimab availability, and I'll discuss the differences shortly for those without sufficient nirsevimab. Now, the group that's considered an increased risk for severe disease includes children with chronic lung disease of prematurity, require medical support anytime during the six month period prior to the start of the second RSV season; children with cystic fibrosis who either have manifestations of severe lung disease or wait for length that's less than the 10th percentile; children with severe immunocompromise and American Indian or Alaska Native children. Next slide. Next, I would like to address interim recommendations for healthcare settings with a lack of nirsevimab availability.

Next slide. So, for the current 2023 to 24 RSV season, the manufacturers reported a limited supply of nirsevimab, particularly the 100-milligram dose prefilled syringes that are used for infants weighing five kilograms or more. And based on manufacturing capacity and the current available stock, there is not sufficient 100-milligram dose prefilled syringes of nirsevimab to protect all eligible infants weighing five kilograms or more during the current RSV season. Additionally, the supply of 50-milligram dose prefilled syringes may be limited during this current RSV season. Next slide.

So, on October 23, 2023, CDC released a health advisory describing interim recommendations to provide options for clinicians to protect infants from RSV in the context of a limited supply of nirsevimab. Next slide. The recommendations for the 50-milligram doses remain unchanged at this time. But to help preserve 50-milligram doses, providers should encourage pregnant people to receive Pfizer's RSV maternal RSV vaccine during the 32 to 36 weeks gestation to prevent RSV associated lower respiratory tract infection and the potential for this limited nirsevimab availability should be considered when deciding on maternal RSV vaccination versus nirsevimab. Next slide.

Now, in health care settings with a limited availability of 100-milligram doses, providers should prioritize infants at the highest risk of severe RSV disease for receipt of 100-milligram nirsevimab doses. This includes young infants aged less than six months, American Indian or Alaska Native infants aged less than eight months, infants aged six to less than eight months, they have conditions that placed them at high risk for severe RSV disease. And this includes infants who were born in premature birth at less than 29 weeks gestation, chronic lung disease of prematurity, hemodynamically significant congenital heart disease, severe immune compromised, severe cystic fibrosis, and neuromuscular disease, or congenital pulmonary abnormalities that impair the ability to clear secretions. Next slide. Additionally, now 50-milligram doses should be reserved only for infants weighing less than five kilograms.

Providers should avoid using two 50-milligram doses in place of 100-milligram dose for those infants weighing five kilograms or more. And providers should follow AAP recommendations for palivizumab- eligible infants that are aged less than eight months when the appropriate dose nirsevimab is not available. Next slide. Now, in healthcare facilities with limited availability of 100-milligram doses for palivizumab eligible children aged 8 through 19 months, providers should suspend the use of nirsevimab for the current 2023 to 24 season. These children should receive palivizumab per AAP recommendations.

Providers should continue offering nirsevimab to American Indian or Alaska Native children are aged 8 through 19 months who were not palivizumab eligible, and who live in remote regions where transporting children with severe RSV for escalation of medical care may be challenging, or live in communities with known high rates of severe RSV disease among older infants and toddlers. I now I'd like to pass it on to Dr. Meyer will discuss some considerations for implementing RSV immunization.

Thank you, Dr. Jones. So, I will be talking a little bit more about how to implement RSV immunizations in your practice. Next slide. So, I know Dr. Jones, provided a lot of information about recommendations and the background behind the recommendations and I just want to quickly review some of that information before we get more into implementing in your practice. So, just to summarize, there are two options to protect infants and young children from RSV. Maternal immunization or through administering nirsevimab to the infant or young child. Next slide. But as just mentioned, you know, pregnant patients and providers should take into account the limited availability of nirsevimab during the 2023/2024 season when making decisions about maternal RSV immunization.

Next slide. So, just quickly to recap what we just learned, this is a little bit more about the who, what, when, where, and why of immunizations to prevent RSV infection. So, starting with maternal RSV immunization, just to review, we are talking about the Pfizer or Abrysvo RSV vaccine for pregnant people administered from 32 through the end of the 36 week of gestation seasonally or through September through January. This vaccine is primarily available in outpatient clinics and pharmacies and we give the vaccine to the pregnant mom to protect infants from severe RSV from birth through the first month of life. Next slide.

For nirsevimab, this involves immunization of infants aged less than eight months whose mother did not receive the RSV vaccine, and children 8 to 19 months at increased risk. Using

nirsevimab, which is a monoclonal antibody, given in the first week of life for those babies born during the season, or for those born outside of the season, or who are, you know, beyond the newborn period, essentially, as they are entering the RSV season from October through March. So, as Dr. Jones mentioned, now is really the time to be administering nirsevimab. And this vaccine is given primarily in the birthing hospital and outpatient clinics.

And the goal here is really to protect infants and young children from severe RSV in the months after immunization. Next slide. But as Dr. Jones just mentioned, we do have some priority groups in the setting of limited nirsevimab availability during this season. And the link at the bottom is where you can find even more information.

Next slide. All right. So now, let's move a little bit more into the implementation of RSV immunizations in your practice. We'll talk a little bit more about ordering, costs and insurance coverage, storage handling and administration, patient education and counseling, documentation, as well as some special considerations for VFC or Vaccines for Children program providers. Next slide.

So, let's start with ordering of RSV immunizations. Ordering of RSV immunizations is very similar to how other immunizations are ordered. So essentially, through routine mechanisms. For example, directly from the manufacturer, or wholesaler, or distributor for vaccines. For children's providers, these immunizations are ordered through the state or local immunization program.

Again, very similar to how this occurs with other routine immunizations. And as Dr. Jones mentioned, the ability to order nirsevimab doses may be limited at this time, particularly for the 100-milligram dose. And just to also point out, you know, we would recommend inquiring with the manufacturer directly for any information around return or refund policies for expired or unused doses. Next slide.

Let's talk a little bit more about costs and insurance considerations. We'll talk first about maternal RSV vaccine. This vaccine is priced at about $295 per dose and it is covered through insurance. So, for Medicaid, which think about 40% of pregnant people get their care covered under Medicaid. Medicaid covers without cost sharing for nearly all full benefit adult beneficiaries who have traditional Medicaid.

This vaccine is also included in the VFC program for any pregnant teens, those aged less than 19 years. And most private insurance plans are required to cover but they do have one year to do so. For nirsevimab, this is priced at about $495 per dose using the private sector costs. There are some payment flexibilities this season. So, the manufacturer has stated that there is 150 days for payment when ordering directly from the manufacturer.

And then, terms of insurance coverage, this immunization is covered under the Vaccines for Children, or VFC, program. And similar to the maternal RSV vaccine, most insurance plans are required to cover this product but do you have one year to do so. Next slide. So, next I'll review of storage handling and administration of RSV immunizations. Next slide.

So, we'll start with the Pfizer maternal RSV vaccine. This vaccine is supplied as a three-component kit that has a vial of lyophilized antigen component, a syringe of sterile water delay component, as well as the vial adapter, and this vaccine does require reconstitution. And the storage and handling procedures depend on whether you reconstitute it or not yet. So, before reconstitution, this vaccine is stored between two to eight degrees Celsius. So, normal kind of vaccine storage conditions, but it should not be frozen.

And then, after reconstitution it can be stored at room temperature, but it should not go back in the refrigerator, or be frozen, and it should be used within four hours. Next slide. In terms of administration, this vaccine is administered through intramuscular injection at the deltoid muscle in the upper arm. Alternatively, the vastus lateralis muscle of the upper thigh can also be used. And this is a 0.

5 mL dose. And as Dr. Jones mentioned, only the Pfizer vaccine or (Abrysvo) should be given to pregnant people. Do not administer or the GSK vaccine, or Arexvy, to pregnant people because it is not at this time licensed, or approved, or recommended in this population. So, for those providers that carry both of these vaccines in their office or, let's say for example, you are a family practice provider, or a pharmacy provider, and you only have the Arexvy vaccine by GSK, you should refer that patient elsewhere where they can get the Pfizer RSV vaccine.

So, they should not be given the GSK vaccine. Next slide. Let's move on to nirsevimab now in terms of storage and handling. This immunization is supplied either as a 50-milligram or point five mL prefilled syringe with a purple plunger rod or a one mil or 100-milligram prefilled syringe with a light blue plunger rod. And we will go through a little bit more the dosing and who should get which product.

But for both of these presentations, they are stored refrigerated. So, just like any other most other vaccines between two to eight degrees Celsius, but it should be used within eight hours from removing from the refrigerator. It can be stored at room temperature for a maximum of eight hours and it should not be frozen, or shaken, and it should be protected from light. Next slide. This immunization is administered through intramuscular injection and the vastus lateralis muscle of the upper thigh.

And the dosage does depend on the weight. So, for those infants who are in their first season and who weighed less than five kilograms, which, you know is a, you know, about the age at which the average infant transitions from under five kilos to five kilos and over is about two months of age. So, this dosage is really for your younger infants and newborns. So, for those that are less than five kilos, it is 150-milligram prefilled syringe or 0. 5 mLs.

And then, for those infants in their first RSV season, who weigh five kilos or more, they are given 100-milligram prefilled syringe or one mLs. And for those infants who are in their second RSV season, so those infants and toddlers in their second season, they would get two 100-milligram prefilled syringes or two mLs. But again, the ability to vaccinate, you know, children with the 100-milligram prefilled syringes would really depend on the availability this season. Next slide. So, in terms of coadministration, both the maternal RSV vaccine or nirsevimab can be administered with other recommended vaccines.

So, this includes, for example, for the maternal RSV vaccine. This means you can get this vaccine along with Tdap, or flu, or COVID, or any of the other vaccines that a pregnant person may get during their pregnancy if timing aligns. And then, for nirsevimab, this can be administered with any other routine child childhood vaccine that's recommended. So, for example, you can give nirsevimab along with the hepatitis B birth dose in the hospital, or at any of their well child checks with any other routine vaccines that they're recommended for at that time. Next slide.

But I do want to highlight one point. You are your patients most trusted source of information on vaccines. So, I am going to spend a little bit of time talking about how you can counsel your patients about these two products. Next slide. So first, we'll start with patient education and counseling for the Pfizer maternal RSV vaccine.

So, as mentioned, either maternal RSV vaccine or infant nirsevimab is recommended for all infants, but administration of both products is not needed for most infants. I have seen a couple of messages in the chat or a couple of questions in the Q&A so I'm just going to take a minute to address it here. Regardless if somebody has had RSV infection in the past, whether that's the mom, whether she's had it in the past, or the baby has ever had an RSV infection, they're still recommended to get RSV immunization. Somebody having had prior infection in the past does not change the recommendations and there is no waiting period in between infection and when they should get immunized as long as they are not moderately to severely ill or have kind of recovered from that acute phase of their infection. But we do advise, where possible, that prenatal providers discuss both products with pregnant people to aid in their decision-making about which product to get either the maternal immunization or the infant nirsevimab.

This could take into account the relative advantages and disadvantages of each product, patient preferences, as well as local availability of nirsevimab. And prenatal providers who do not offer the maternal RSV vaccine in their practice should refer patients elsewhere for vaccination. So, if you don't have it in your office, we advise, you know, try to send them somewhere where you know they can get it like a pharmacy or elsewhere. But if a prescription is required by state law for vaccination in a pharmacy, we recommend proactively providing a prescription when you see that patient during one of their visits so that when it's time they can go get their vaccine from a pharmacy without having additional barriers and having to call, and request it, and all those things that can impede a pregnant person from getting the vaccine. Next slide.

So, I mentioned the discussion of relative advantages and disadvantages of each part but I first wanted to just point out that both products are safe and efficacious for protecting against RSV. There's no preference for one or the other from a recommendation standpoint, but there might be some patients who do have preferences, or situations, or other factors that they want to take into account for which one to get. So, some advantages of maternal RSV vaccine could be immediate protection after birth. It may also be more resistant to potential mutations in the F protein of the virus, which is the target for the vaccine. In terms of potential disadvantages, there could be some situations where the pregnant person might have some potentially reduced protection passed on.

So, for example, if a pregnant person is immunocompromised, or if the infant is born too soon after vaccination, that antibody may not have sufficiently transferred at that time. And then, other disadvantages could be the potential risks for preterm birth and hypertensive disorders of pregnancy. Next slide. So then, speaking of nirsevimab, some advantages may include that protection from nirsevimab may wane more slowly than that for maternal RSV vaccine, and that we are directly providing those antibodies. So, the infant directly receives those antibodies, rather than relied on transplacental transfer of his antibodies.

And there are, you know, of course, no risk for adverse pregnancy outcomes since this product is administered to the infants. Some potential disadvantages is what we really highlighted so far in this talk is that there is some potentially limited availability of this product during the 2023/2024 RSV season. And then, it does require an injection, which is not necessarily a disadvantage, but their patients may have some preferences around this. Next slide. So, in terms of how to have this conversation, so we know that this is a lot to put on the prenatal provider to discuss, you know, recommendations for both products, but it is really important so that the pregnant person can make the best decision for themselves and their baby.

So, here's an example of how you could approach the conversation. At this point in your pregnancy, you're eligible to get the RSV vaccine to protect your infant from severe respiratory illness. RSV is a common seasonal viral infection that can cause pneumonia requiring hospitalization of babies. It can become very severe and make it hard for babies to get the oxygen they need. It is the most common cause of infant hospitalization in the US, but we actually have two options for preventing severe RSV illness in babies.

Next slide. One option is a new vaccine that we give you during pregnancy, which allows your immune system to protect the baby. The vaccine causes you to make antibodies that you pass to your baby through the placenta. The other option is called nirsevimab. And this can be given to your baby after birth and work similarly to protect your baby from RSV illness after delivery.

One or the other is recommended, but both are not needed for most babies. Keep in mind, though, that there may be limited availability of nirsevimab this season once your baby is born. Next slide. All right. So, I've talked a little bit about how, you know, the prenatal provider might approach counseling of their patient.

But now, we'll talk a little bit about for that pediatric provider who is counseling the parents about use of nirsevimab. And, I guess the bottom line is that you should really counsel your patients about nirsevimab the same way you would for any immunization. They might have specific questions, just because this type of immunization is a little bit different than what they're used to. But in general, you know, you should approach it the same way you would for any other immunization. So, a good example of this is using the presumptive approach, which is essentially, you know, approaching the conversation such as, "Johnny is due for his nirsenivab dose today," instead of the participatory approach where you say something like, "What do you want to do about Johnny's nirsevimab dose today.

" And the reason for this is, you know, study after study really shows that when you approach immunization conversations using the presumptive approach, parents are much more likely to

feel confident in these decisions, confident that you're making a strong recommendation, and they're much more likely to accept immunization at that visit. So again, bottom line, approach it the same way you would for other immunizations using those kind of best practices for immunization counseling. If your practice did not carry or has insufficient supplies of nirsevimab, we suggest referring patients elsewhere in the community when feasible. Of course, we understand that if there are supply constraints. Elsewhere in the community, this may not always be possible, or it may be challenging.

But when there are those opportunities, we do encourage you to do that. And also, just wanted to make people aware, because this is a relatively new update, as of earlier this month there are two new CPT codes available for administration and counseling for nirsevimab. Next slide. All right. And then, two additional pieces of information I wanted to point out is the Vaccine Information Sheet, or VIS, for RSV vaccine has been updated to include information on maternal immunization.

And we also do have an immunization information statement for the RSV preventative antibody or nirsevimab, which provides very similar information as what you would see any traditional VIS. Next slide. And then, I will just mention a few points about documentation of immunizations administered. It is really critically important that administration of the maternal RSV vaccine is documented, because as we mentioned before, infants are recommended to either be protected through maternal RSV vaccine or nirsevimab but, in general, not both. So, it's very important that the pediatric provider taking care of the infant knows whether the mom, the pregnant person received maternal RSV while they were pregnant, so that they can make sure that if they didn't that they give them the nirsevimab dose.

So, this vaccine should be or can be recorded in the immunization information systems, or IAS; electronic health records. And then, also one good best practice would be to provide written documentation to the patient that they can bring, or have on them at the birthing hospital and pediatric provider visits so that, you know, just to kind of, you know, cross all our t's and dot our i's around making sure that the pediatric provider can know whether the mom received that vaccine or not. And then, for nirsevimab, we recommend reporting nirsevimab to the state IAS in accordance with state policies or laws for reporting a vaccine like you would for any other immunization administration. Next slide. And then, I'll just briefly mention a few special nirsevimab considerations for our VFC providers.

We did recently publish an addendum to our Operations Guide, which is now also published online, that provides some additional flexibilities or considerations for nirsevimab, particularly for this season. We do have a ramp up period for private inventory requirements. And although VFC eligible patients remain the priority for VFC doses, we do have some flexibilities around bi-directional borrowing between private and public stock allowed in certain situations and were allowed by the jurisdictional policies. One point I will just make, though, in the setting of supply constraints, it could be difficult to implement borrowing. So, this is really a flexibility meant for those practices that do have sufficient private and public stock to be able to do borrowing.

Next slide. And we have some resources which are included here. Next slide. So, we'll close with a question. Which of the following products are approved for use in pregnant people? Next slide.

So, the answer is only the RSV vaccine or Abrysvo is recommended and approved, approved and recommended for use in pregnant people. Next slide. And really brief, although the content of this presentation is really focused around RSV, we do have a few late breaking updates to pediatric COVID-19 vaccine policy that we thought would be of interest to this audience. Next slide. So, just to recap really quickly, the recommendations for COVID-19 vaccination for children aged six months through four years who are not immunocompromised include an initial series of two Moderna vaccine doses or three Pfizer vaccine doses, including at least one dose of the 2023/2024 COVID-19 vaccine.

Next slide. But what I really wanted to highlight is that there is some increased flexibility for interchangeability of COVID-19 vaccines. We have heard the feedback that, you know, strict homologous dosing for these vaccine products is a barrier for pediatric practices, especially for those who are only able to carry one of the vaccine products and not all of them. So, we do have some increased flexibility around mix and match for those pediatric doses that require, you know, more than one dose in the series. So, the previous language around this was that in the following exceptional situations, a different age appropriate COVID-19 vaccine may be administered under, you know, the following conditions which are listed there.

So, very pretty strict language around when it's permissible to give a different vaccine. So, for example, if somebody got Moderna for this first dose, very strict language about them needing Moderna for the next dose, except for, you know exceptional situations. The language now is more flexible, and we say in the following circumstances and age appropriate COVID-19 vaccine from a different manufacturer may be administered when the same vaccine is not available at the vaccination site at the time of the clinic visit, the previous dose is unknown, person would otherwise not receive the recommended vaccine, or the person starts but is unable to complete a vaccination series with the same COVID-19 vaccine due to a complication. So, we hope that this increased flexibility makes it a little bit easier for our pediatric providers to get COVID-19 vaccines to this youngest age group. Next slide.

Some additional updates that I'll just highlight very quickly in the interest of time, but this is all in our interim clinical considerations. We do have updated guidance for children who transitioned during the initial COVID-19 vaccination series from age four to age five years, and children who are moderately or severely immunocompromised and transition from age 11 to 12 years to receive the age appropriate dosage based on their day, their age on the day of expiration. So, this is a little bit of a change from our previous guidance for those children who cross age groups for different vaccine recommendations. Next slide. And I think that's it.

Thank you.

Presenters, thank you very much for providing this timely information to our audience. We will now go into our Q&A session. And for our audience, please remember to ask a question using Zoom, click the Q&A button at the bottom of your screen, and then type your question. And we have additional CDC subject matter experts joining our presenters for the Q&A session, so I'd like to take a moment to also thank them. Any CDC subject matter experts or presenters that answer a question, please I ask kindly, identify yourself so that it helps with our transcription purposes.

Our first question asks, "Is the maternal RSV vaccination a one and done for future pregnancies or is vaccination indicated during every pregnancy?".

Hi, this is Dr. Jones. I'll handle this one. So, at this time, there is no data that we have to make the recommendations. So, at this time we're not recommending for a future pregnancy that you get at once.

But we do hope to have additional data and be able to provide updates on recommendations prior to the next RSV season. So, stay tuned.

Thank you very much. Our next question asks, "Are there any contraindications or drug drug interactions for nirsevimab that we should know about?".

Dr. Jones again. So, contraindications are fairly similar to routine vaccinations, as if they've had any severe allergic reactions such as anaphylaxis to nirsevimab or any of its components previously? There are no known drug drug interactions. It's a monoclonal antibody targeted to RSV.

Thank you very much. Our next question asks, "If maternal vaccine was received greater than 14 days prior to delivery, but the pregnancy is a twin/triplet gestation, is the multiple gestation rationale enough to give nurse overlap to the newborns, assuming they're otherwise healthy infants?".

Dr. Jones again. We don't have data on this specifically that I know of, in general. Multiple gestation pregnancies were excluded from the clinical trials along with other risk factors for preterm birth. So, we don't have data on that.

But assuming the infants are not preterm and otherwise healthy, or there are no recommendations to act any differently, for example, if they've received, as you said, if they received the maternal RSV vaccine 14 or more days prior to birth, the infants are otherwise healthy, then nirsevimab would not be recommended.

Thank you very much. Next question asks, "If a mother was not administered vaccine and nirsevimab is not available, what other options do we have?".

Dr. Jones again. So, if there's no nirsevimab available, if they're palivizumab eligible, as in their a high risk infant per AAP's recommendation to receive palivizumab, palivizumab is eligible. If they're not eligible for that, unfortunately, nirsevimab particularly, there may be, you know, we're suggesting using available doses for those at the highest risk for others. There's every day preventive measures that can limit such as trying to have a house with contacts, you know, wash your hands and avoid touching a face, avoiding close contact with sick people, covering cough and sneeze, et cetera, those every day preventive measures are something that that can be tried, but there's no other specific immunizations available.

Thank you very much. Our next question asks, "What do you attribute the recent increase in RSV hospitalization among children too?".

Dr. Jones. So, I mean, referring I guess, I'd have to ask a little about which increase? If we're talking specifically about the slides shown in 2021, I don't think we've proven there's actually a statistical increase. So, possible explanations include that there are changes in testing practices that can lead to differences, particularly when looking at certain hospital hospitals, not the data I showed, but other data, where there may be more testing of RSV recently, particularly when people are doing multi-pathogen testing with COVID-19. Other hypotheses include that this immune debt hypothesis that during 2020, there was very little RSV.

And so, infection induced immunity was less during then, leading to more at risk children in subsequent years. And CDC continues to look at the epidemiology of RSV and hope to gain more insights in the near future.

Thank you very much. That is very helpful. And our next question asks, "Is it possible to be co-infected by RSV and influenza?".

Dr. Jones. Yes, we have seen co-infections and I've had publications on this. Influenza and RSV is not as common as some other co-infections we've seen, such as with a rhinovirus or enterovirus, but co-infections are possible with RSV and sometimes the clinical symptoms and severity can change depending on the co-infection. And that is an active area of investigation that we have published and we'll continue to look at.

Thank you very much. And we have time for one last question. And the question asks, "If availability is not an issue, what is your recommendation for choosing between maternal RSV vaccine versus nirsevimab based on efficacy or would there be other factors to consider?

Dr. Jones again. So, I think Dr. Meyer did a good job of going through several potential things to consider. I mean, for this season, in particular, I think that there may be a lack of nirsevimab availability and to forego maternal vaccination.

And then, not have nirsevimab available after birth would be quite unfortunate. So, unless you know that nirsevimab is available, that is something to strongly consider. Efficacy trials comparing the two products head to head have not been conducted. And although the point estimates differ, the trials have different definitions of endpoints and are difficult to compare. The antibody data suggests the nirsevimab efficacy may last longer with a longer half-life than the maternal vaccine.

But for the many people, you know, for these infants being born during the season, we expect that protection will last through the season for either of the products or for at least the majority of the season. So, it can be, you know, patient preferences, avoiding an injection in the infant, it might be any concerns of -- some people are more concerned about being vaccinated during pregnancy than others. So, I think it'd be a lot of individual patient preferences to consider.

Thank you, Dr. Jones. Well said. Again, I want to thank everyone for joining us today with a special thanks to our presenters. Commander Jefferson Jones and Captain Sarah Meyer.

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