

Good afternoon. I'm Nikki Grimsley, and I'm representing the Clinician Outreach and Communication Activity or 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, Preparing for the Upcoming Respiratory Season: Recommendations for Influenza, COVID-19, and RSV Vaccines for Older Adults. 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 they have no financial relationship with any 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 product under investigational use with the exception of Dr. Lisa Grohskopf's discussion of FDA-approved package inserts for egg-based influenza vaccines that indicate that their use is contraindicated for people who have had a severe allergic reaction to any vaccine component which includes egg for egg-based vaccine. However, the ACIP and CDC recommend that people with egg allergy of any severity should receive influenza vaccine and that they may receive any influenza vaccine that is otherwise appropriate for age and health status (egg-based or non-egg based).

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. Describe the recommendations and clinical considerations for administering influenza, COVID-19, and RSV vaccines to older adults. List key points for clinicians to use when discussing influenza, COVID-19, and RSV vaccination with older adults. And describe where to find online resources for clinicians about vaccination of older adults against influenza, COVID-19, and RSV.

After the presentations today, there will be a Q&A session. You may submit your question at any time during today's presentation. 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 that we receive many more questions than we can answer during our webinars. If you are a patient, please refer your question to your healthcare provider. If you are a member of the media, please contact CDC Media Relations at 404-639-3286 or send an e-mail 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 Dr. JoEllen Wolicki, who is a nurse educator with the Immunization Services Division in the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention.

Dr. Lisa Grohskopf, who is a Medical officer with Influenza Division in the National Center for Immunization and Respiratory Diseases at CDC.

Dr. Megan Wallace, who is an epidemiologist with the Coronavirus and Other Respiratory Viruses Division also in CDC's National Center for Immunization and Respiratory Diseases.

And Dr. Amadea Britton, who is a medical officer with the Coronavirus and Other Respiratory Viruses Division in the National Center for Immunization and Respiratory Diseases at CDC.

I'll now turn it over to JoEllen. JoEllen, please proceed.

Thank you. Next slide, please.

This fall, we now have three vaccines to protect vulnerable adults from respiratory viruses, COVID-19, flu, and RSV vaccines. These vaccines may be administered during the same clinical visit. And now is the time to talk with your patients about vaccination with COVID and RSV cases rising and flu season just around the corner. Next slide, please.

As a healthcare provider, you are your patient's most trusted source of information on vaccines. For example, we know from research that even initially reluctant adults are likely to receive an influenza vaccination when the healthcare provider's opinion of the vaccine is positive. Next slide, please.

Here is a summary of the information we will be sharing during this webinar. You can use this slide as a reference for key updates. Now let's discuss the recommendations for each vaccine beginning with Dr. Grohskopf and influenza vaccines.

Thanks very much. Can we have the next slide? Thank you. Okay, next slide, please.

So this is going to be a brief overview of some issues related to influenza vaccination of older adults for the season. For the upcoming 23-24 flu season, influenza vaccination of all people aged six months and older who do not have contraindications continues to be recommended.

Overall, the recommendations specifically concerning older adults, here we specify those 65 years old and older, are similar to those of last season. The main updates to the ACIP recommendations for this season include the influenza vaccine composition for 23-24 and changes to the recommendations for people with egg allergy, neither of which are specific to older adults. However, we're going to go over some points related to egg allergy briefly later in this presentation. Next slide.

First, some background on influenza burden among older adults, specifically again those 65 years and older who bear the greatest burden of severe influenza illness each season. These data are from FluSurv-NET. This is a CDC influenza surveillance platform that collects data on laboratory confirmed influenza associated hospitalizations from a large network of U. S. hospitals each week during the flu season. Reporting for the 23-24 season will begin in the next few weeks.

This is data for the 2022-23 season, which is the latest season for which we have data available. The reason for focusing on hospitalization here is that it's a severe outcome, and this is also one of our surveillance systems that, again, collects data on laboratory confirmed outcomes. This graph shows cumulative influenza hospitalization for 100,000 population for the 2022-23 flu season. Calendar week is on the X axis and hospitalization rate on the Y axis. The black line represents all ages combined, whereas the other colors represent different age groups.

Examining these curves by age group, the highest rates are for the population 65 and older. This is what we typically see in most influenza seasons. For 2022-23, the cumulative hospitalization rate for those 65 and older by late April was 188 per 100,000. In most flu seasons, adults 65 and older bear the greatest burden of hospitalizations and deaths associated with influenza. In one multi season study, this age group accounted for 54 to 70% of hospitalizations and 71 to 85% of deaths. Next slide.

This slide summarizes the influenza vaccines expected to be available for this season, organized by the ages for which they are approved by FDA. That is their age indication. Like last season, we have a total of nine distinct brands of flu vaccines. All of these are quadrivalent, that is, they contain hemagglutinin and antigen from four different influenza viruses. Trivalent vaccines are not available.

The three main vaccine types are inactivated influenza vaccines or IIVs, which contain inactivated virus, recombinant influenza vaccine, or RIV, which contains only antigen and no viruses, and the live attenuated influenza vaccine LAIV, which is the nasal spray vaccine that contains live viruses. For those 65 and older, all vaccines other than the live attenuated influenza vaccine are approved. LAIV is licensed only for people two through 49 years of age. Among the remaining eight vaccines, the largest group are the inactivated vaccines, which has several subcategories.

We have five standard dose unadjuvanted inactivated vaccines, including four that are egg based and one that's cell culture based. All of these are approved for ages six months and older. Then there are two inactivated vaccines that are approved for 65 and older. The standard dose adjuvanted inactivated flu vaccines which contains an adjuvant called MF59 and the high dose inactivated influenza vaccine which contains four times the dose of antigen compared with the standard dose in activated vaccine.

Then the recombinant influenza vaccine which is approved for ages 18 years and older. This one also has a higher dose of antigen, in this case three times the dose of a standard dose in activated vaccine. While any influenza vaccine other than LAIV is acceptable for those 65 years and older purely on the basis of approved age indication, since the 2022-23 season, there's been a preferential recommendation for the use of higher dose, that is the high dose vaccine and the recombinant vaccine and adjuvanted, the adjuvanted vaccine for those 65 years of age and older. These are the three vaccines marked with an asterisk in the chart. Again, the high dose recombinant and adjuvanted vaccines. Next slide.

So a bit about the rationale for this. As we talked about earlier, older adults bear the greatest burden of flu hospitalizations and deaths every year. They're at higher risk for flu illness that is

severe compared with younger populations. Unfortunately, they also tend to have less efficacy with influenza vaccines compared with younger populations. However, in looking at these three vaccines, high dose recombinant, and adjuvanted data support greater potential effectiveness of high dose vaccine or HD-IIV, recombinant vaccine or RIV and adjuvanted vaccine or AIIV compared with standard dose unadjuvanted vaccines.

Of these vaccines, the most data are available for high dose vaccine, particularly the previously available trivalent formulation. Also of note, comparisons of these THRAG [phonetic] three vaccines with one another are limited. There are not many data on these as are data for the currently available quadrivalent formulation of HDIIV and IIV. Although one study was recently published that compared quadrivalent high dose with quadrivalent standard dose.

I'm no longer able to see the slides.

Host, can you please pull the slides up?

Daria, can you please take over as host and put the slides up?

We will take a brief pause in the presentation for about a minute until the slides come back up.

Thank you.

Please stand by. Host, please go back a few slides.

Dr. Grohskopf, will you please indicate when --.

Yes.

-- stop in the slide presentation.

Slide 18 I think would be fine. Sorry, maybe, maybe it was 17. Perfect. Oh, back by one. Okay.

So now just to go over the specifics of the preferential recommendation, which are that adults aged 65 years and older should preferentially receive anyone of the following higher dose or adjuvanted vaccines, quadrivalent high dose inactivated influenza vaccine, quadrivalent recombinant influenza vaccine, or quadrivalent adjuvanted inactivated influenza vaccine. If none of these three vaccines is available at an opportunity for vaccine administration, any other age appropriate influenza vaccine should be used. That would include any other influenza vaccine except for LAIV, the live attenuated vaccine.

Just as an aside, another point relative to older adults is timing of vaccination. Even though we're past July and August now, but vaccination of older adults in July and August should be avoided unless later vaccination might not be possible. This is due to the potential for waning of vaccine induced immunity over the course of the season. There are descriptions of her considerations of July and August vaccination for other groups in the ACIP influenza statement. Next slide.

Briefly a bit about the update for egg allergy. Now egg allergy affects approximately 1 to 3% of children by age three years, and it actually resolves for many in later childhood or adolescence.

So it's more commonly observed in the pediatric population. However, while it's more common among children, some adults might be concerned about receiving influenza vaccine due to a history of egg allergy or may decline vaccination because they know or perceive themselves to be egg allergic. You may also be aware that severe allergic reaction to any vaccine component which includes egg for the egg-based vaccines is listed as a contraindication in the package inserts for egg based flu vaccines. Previously, however, ACIP has recommended for several seasons now that all with egg allergies should receive any influenza vaccine appropriate for their age and health status. So all with egg allergy should be vaccinated, and an egg-based vaccine could be used.

So this is an area where for the past several seasons the ACIP recommendations have departed from the FDA labeling information. The one difference that was made in the recommendations, and this is what changed this season, was that those with a history of severe allergic reaction to egg were recommended to be vaccinated in a medical setting if an egg-based vaccine was selected. Next slide.

So for the upcoming season, similarly, all people age greater than or equal to 6 months with egg allergy should receive flu vaccine and still any influenza vaccine, egg-based or not, that's appropriate for the patient's age and health status can be used. However, what's changed this year is that no recommendations are made any longer for specific vaccination settings.

Egg allergy in and of itself necessitates no additional safety measures for flu vaccination beyond those recommended for any recipient of any vaccine, regardless of severity of previous reaction to egg. However, providers should be aware that all vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of an acute allergic reaction is available. And this is because, though serious allergic reactions are rare, they can sometimes occur in people who have never had an allergic reaction history. Next slide.

Very briefly to touch on influenza antiviral medications. Treatment with influenza antiviral medications is recommended as soon as possible for any patient with suspected or confirmed influenza who's hospitalized, has severe, complicated, or progressive illness or is at higher risk for flu related complications, including of course those 65 and older. Initiation of therapy should not wait for lab confirmation of influenza. Available drugs include oral oseltamivir, oral baloxavir, inhaled zanamivir and intravenous peramivir, all of which can be used for older adults.

However, one caveat is that zanamivir, the inhaled agent, is not recommended for people with underlying respiratory disease. There is more information on this topic than can be covered today, but additional information on the use of antivirals for treatment and also chemoprophylaxis of flu is available at the link at the bottom of the slide. Next slide.

So finally, our self-knowledge check. Question is, which influenza vaccines are appropriate for people with egg allergy?

Choice A, egg-free cell-based inactivated influenza vaccine, ccIIV4 only. B, egg-based recombinant influenza vaccine, RIV4 only. Choice C, any flu vaccine egg-based or non-egg based. Choice, D, A and B, the egg-free vaccines only. And choice E, none, egg allergic people should not receive flu vaccine. I'll give it a couple of seconds. Okay, I think we can go to the next slide now.

And the correct answer is C, people with egg allergy can receive any flu vaccine, egg-based or non-egg based appropriate for age and health status.

Egg allergy in and of itself necessitates no additional safety measures for flu vaccination beyond those recommended for any recipient of any vaccine. And that ends my portion of this. I'd like to hand it over now to my colleague Dr. Megan Wallace.

Thank you. As Lisa said, I'm Megan Wallace, and I'll be presenting on the COVID-19 vaccine recommendations. Next slide.

I'm going to start with a brief update on the current epidemiology of COVID-19. This figure shows COVID-19 hospitalization rates by age group over time with more recent months pulled out in the figure on the right.

We see that hospitalization rates are highest in those 75 years and older, followed by infants and those 65 to 74 years. The hospitalization rates overall are lower than we've seen at previous points in the pandemic, but we've seen rates begin to increase in recent weeks. Next slide.

When we look at the number of COVID-19 new hospital admissions by week from NHSN, we see that even when rates are low, as they currently are, that corresponds to over 17,000 new hospital admissions a week. The same is true of COVID-19 deaths, with thousands already reported this year. Next slide.

Over the next couple of slides, I will summarize some of the data that informed this year's vaccine recommendations. We know that burden of COVID-19 varies by age and underlying condition status, with those ages 65 years and older and those with multiple underlying conditions having the highest risk of severe outcomes due to COVID-19. Despite the fact that COVID-19 burden is currently lower than at previous points in the pandemic, there are still thousands of hospitalizations and hundreds of deaths each week, many of which are in older adults. Children and adults ages 5 to 49 years had the lowest hospitalization rates overall.

However, severe outcomes still occur in this age group, including in people with no underlying medical conditions. And although hospitalization rates are currently low, we have seen rates increase in recent weeks and anticipate further increases as we enter respiratory virus season. As we all know, the majority of the U.S. population has some level of immunity due to infection, vaccination, or both.

However, vaccine and infection induced immunity wane and new variants have emerged suggesting that susceptibility remains and may increase over time. It's also important to note that

racial and ethnic minority groups have and continue to be disproportionately affected by COVID-19. Next slide.

When we look at the benefits and risks of vaccination, we saw that the monovalent XBB containing COVID-19 vaccines increase the immune response against the currently circulating variance. Last year's updated vaccine was effective at preventing medically attended COVID-19 and hospitalization and death due to COVID-19.

And the COVID-19 vaccines have a high degree of safety. Millions of COVID-19 vaccines have been given over the past couple of years under robust post safety, post authorization safety surveillance. So we know a lot about the safety of these vaccines, and it's unlikely that updating the formulation would increase adverse event rates. Benefits of vaccination are anticipated in all age groups, but the benefits of COVID-19 vaccines do vary by age, with older adults getting the most benefit from vaccination. And they vary, the benefits vary with incidence of the COVID-19 hospitalizations.

So when disease incidence increases, we expect that there will be higher benefit of vaccine. In our benefit risk assessment, we found that benefits of COVID-19 vaccination outweigh the risks in all age groups. And modeling projected that more hospitalizations and deaths would be averted when updated doses are universally recommended compared to no recommendation or recommended for only persons 65 years and older. Next slide.

This slide shows a visualization of what the bivalent COVID-19 mRNA vaccine recommendations were just for context. So under the bivalent recommendations, a multi dose initial series was recommended in unvaccinated children ages six months to four or five years depending on the manufacturer. With those ages five or six years and older and those that are previously vaccinated all receiving a single bivalent dose. Next slide.

The recommendations for the 2023-2024 COVID-19 vaccine are very similar to the bivalent recommendations, but with streamlining the multidose initial series to those six months to four years, with all those five years and older recommended for a single dose of vaccine. Next slide.

In this slide, we're highlighting the key changes in the recommendations compared to the bivalent recommendations. And the first two rows discuss simplifications for the pediatric schedule, which I won't go into much detail about. But on the bottom row, you see that we had an optional second bivalent dose for those ages 65 years and older. We do not have an additional dose recommendation for the updated 2023-2024 vaccine at this time. But we'll monitor the epidemiology and vaccine effectiveness to determine if additional doses are needed in the future. Next slide.

Now we'll go into more detail on the recommendations, including some graphics to help understand how the new recommendations correspond to the vaccine vials. Note that the additional details about clinical considerations can be found in CDC's online Interim Clinical Considerations for Use of COVID-19 Vaccines. So beginning with persons without immunocompromise, next slide.

I know we're focusing on older adults here, but I'll just say briefly that children in the youngest age group, six months to four years without immunocompromise are recommended to receive an initial series of mRNA vaccine with at least one dose of the 2023-2024 vaccine. Next slide.

And here is an infographic for additional information in that age group. Next slide.

So moving on to those that are aged five years and older. Next.

All people aged five years and older including adults are recommended to receive one dose of updated 2023-2024 vaccine regardless of prior vaccination history. This updated dose is recommended to be received at least two months after the last COVID-19 vaccine dose. Next slide.

And this is the visual for the recommendations for those aged 5 to 11 years. Next slide.

And on this slide, we'll focus on those age 12 years and older including older adults. Both the unvaccinated and those with one or more of any COVID-19 vaccine dose are recommended to receive one dose of mRNA vaccine. The 2023-2024 Moderna vaccine for this age group is a dark blue cap with a dark blue label at 0.5 milliliters per 50 microgram dose. And the Pfizer BioNTech vaccine is a gray vial with a gray label at 0.3 milliliters per 30 micrograms. Next slide.

Now we'll discuss the updated recommendation for people who are moderately or severely immunocompromised. Next.

For all age groups, persons who are moderately or severely immunocompromised are recommended to receive an initial series of COVID-19 vaccine and then at least one updated 2023-2024 COVID-19 vaccine dose. They may also receive one or more additional updated mRNA COVID-19 vaccine doses informed by the clinical judgment of their healthcare provider and patient personal preference and circumstance. Next slide.

We've built corresponding infographics for each age group for persons who are moderately or severely immunocompromised. This slide shows the recommendations for those age six months to four years. Next slide.

And this is the infographic for those 5 to 11 years. Next slide.

And this is the infographic for those ages 12 years and older who are moderately or severely immunocompromised, which I'll use to walk through this a bit more. So on your left, you can see that anyone who is unvaccinated is recommended to receive three doses. On the right, under the gray vaccinated box, you can determine how many doses are recommended now based on how many doses they received by manufacturer on the second row. Again, additional information can be found in the interim Clinical Considerations for Use of COVID-19 Vaccines. Next slide.

We are frequently asked about simultaneous administration of COVID-19 and other vaccines, which is increasingly important with RSV products now available. In accordance with general

best practice guidelines for immunization, routine administration of all age appropriate doses of vaccines is recommended for children, adolescents, and adults if there are no contraindications at the time of the healthcare visit. In other words, providers may simultaneously administer COVID-19, influenza, and RSV vaccines to eligible patients.

The HAN published by CDC on September 5 has more information. Note that there are additional considerations of administering orthopox vaccine and COVID-19 vaccine, so please consult the links below in that scenario. Next slide.

This year's vaccine will be the first COVID-19 vaccines to be available directly from the manufacturers as part of the commercial market rather than through the United States Government. So while providers will no longer be required to report inventory to [vaccines.gov](https://www.vaccines.gov) after vaccine transition to being available in the commercial market, we do encourage voluntary reporting. The public will continue to be directed to [vaccines.gov](https://www.vaccines.gov) to find providers offering COVID-19 vaccines. And CDC will continue its efforts to make sure that all people have access to COVID-19 medical countermeasures and know where to find product now and in the future. Next slide.

There are several important changes which will make vaccine implementation more feasible. There will be single dose vial presentations and smaller minimum order quantities. And this directly addresses concerns raised by healthcare providers and is likely to reduce wastage and ease logistics and helps the storage capacity limitations. So I won't read them all, but you can see the presentations and order quantities for each vaccine listed below. And finally, the preparation is the same or simpler than it was before. Next slide.

Storage and handling will be the same as it is now. Moderna is frozen until expiration in 30 days at refrigerator storage. Novavax is stable at refrigerator storage within nine months shelf life. And Pfizer has ultra cold storage until expiration in 10 weeks at refrigerator storage. And we know that the ultra cold storage continues to be a challenge. The dose volume Pfizer is simplified. Now all doses are the same. And Moderna now only has two presentations reducing the chance for errors. Next slide.

Treatment is an important intervention and secondary prevention of morbidity and mortality due to COVID-19. This slide summarizes the recommendations for mild to moderate COVID-19 from the NIH Treatment Guidelines panel. The recommended first line therapies are Ritonavir-boosted, Nirmatrelvir, or Remdesivir. The second line therapy is Molnupiravir, which is authorized for use only when other approved or authorized treatments are not appropriate or accessible. People with mild or moderate symptoms of COVID-19 who are at risk for severe COVID-19 outcomes, namely those who are aged 50 years and older or have an underlying condition including moderate or severe immunosuppression or are unvaccinated or eligible for treatment regardless of their vaccination status.

All of these groups of people should be tested for SARS-CoV-2 as soon as possible after symptom onset and receive treatment within five to seven days of symptom onset with one of several treatment options. Next slide.

And this slide gives some additional treatment resources. Next slide.

And now we are at our self-knowledge check.

What are the current COVID-19 vaccine recommendations for people aged five years and older without immunocompromise?

A, no recommendation. B, one dose of 2023-2024 COVID-19 vaccine under shared clinical decision making. C, one dose of 2023-2024 COVID-19 vaccine regardless of prior vaccination history. Or D, multiple doses of 2023-2024 COVID-19 vaccine. Okay, next slide.

And the correct answer is C. People aged five years and older are recommended for one dose of 2023-2024 COVID-19 vaccine regardless of their prior vaccination history. Next.

And one final self-knowledge check. People aged six months and older who are moderately or severely immunocompromised may receive one or more additional 2023-2024 mRNA COVID-19 vaccine doses.

And this one is true or false. Next slide.

The correct answer is A, which is true. Further additional doses may be administered informed by the clinical judgment of the healthcare provider and personal preference and circumstances. And further additional doses should be administered at least two months after the last 2023-2024 COVID-19 vaccine dose. Next slide. Thank you. And now I'll hand it off to Dr. Britton to talk about RSV.

Good afternoon, everyone. We will be switching over to RSV as Dr. Wallace just said. And we're going to be talking about the new RSV vaccines for older adults. Next slide, please.

First, I'll go over a bit about RSV infection among adults. Next slide.

Although RSV is a familiar viral infection to providers who take care of infants and young children, RSV is also an important cause of respiratory illness in adults. Most adults recover within one to two weeks, but RSV infection can be serious for some adults, especially older adults and those with chronic medical conditions. In the U.S., RSV causes annual outbreaks of respiratory illness in all age groups in the fall and winter. It's spread through respiratory droplets when an infected person coughs, for example, through direct contact, and through fomites. Next slide, please.

Prior to the COVID-19 pandemic, the RSV season started in the fall and peaked midwinter. But the COVID-19 pandemic interrupted this typical pattern and has made RSV seasonality more difficult to predict. Next slide.

These are data from a recent report showing the impact of the COVID-19 pandemic on RSV transmission. The blue lines show the percentage positive of RSV PCR tests reported to CDC's National Respiratory and Enteric Virus Surveillance System over three pre-COVID RSV seasons

from 2017 to 2020. You can see there's a consistent pattern with peaks in December and January. The pandemic era RSV seasons are shown in dashed orange for 2020-21, which is mostly a flat line with virtually no RSV transmission. Yellow for the 21-22 season. And red for the 2022-23 season. We can see the impact the COVID-19 pandemic had on disrupting RSV seasonality. Last fall in red, although the RSV season started early, it was closer to the pre-COVID norm. This suggests a gradual return to pre-pandemic seasonality. And this year some states, particularly in the Southwest, are already starting to see RSV cases. Next slide.

Now moving on to talk about the clinical presentation in adults. Healthy adults who get infected with RSV may have mild or no symptoms. Symptoms are usually consistent with an upper respiratory tract illness, which can include runny nose, sore throat, cough, headache, fatigue, and fever. However, older adults have an increased risk of becoming seriously ill from RSV infection.

Some adults may develop lower respiratory tract disease like pneumonia. Others may experience exacerbation of existing serious medical conditions like asthma, COPD, and congestive heart failure. Next slide.

Older adults account for most of the burden of severe RSV disease in adults. Among adults 65 and up each season, RSV has been estimated to cause 900,000 to 1.4 million medical encounters, 60 to 160,000 hospitalizations, and 6 to 10,000 deaths. These incidents estimates vary widely and are affected by limited RSV testing in adults and by lower test sensitivity in adults compared with that in children. Next slide.

Not all adults are at equal risk of severe RSV disease. There are several chronic medical conditions that have been associated with increased risk, including lung disease like COPD and asthma, cardiovascular disease like congestive heart failure and coronary artery disease, moderate or severe immune compromised, diabetes, neurologic or neuromuscular conditions, kidney and liver disorders, hematologic disorders, and others. Next slide.

In addition to chronic medical conditions, there are other factors associated with increased risk. These include residents in a nursing home or other long-term care facility, frailty, and advanced age. Next slide.

So we'll pause briefly now for our quick self-knowledge check.

Which of the following statements about RSV clinical symptoms in older adults is false?

A, RSV only causes upper respiratory symptoms like runny nose and sore throat. B, RSV can cause lower respiratory tract infection, e. g. pneumonia. C, RSV infection can cause exacerbations, i.e. flare of existing chronic conditions. And D, clinical symptoms are nonspecific and overlap with symptoms of other respiratory infections. So next slide.

The correct answer is A. Although RSV infection in most adults typically causes mild upper respiratory symptoms, older adults are at increased risk of serious illness compared with younger adults. And serious illness from RSV can include lower respiratory tract infection like

pneumonia or an exacerbation that exists in chronic conditions like congestive heart failure or chronic obstructive pulmonary disease. Next slide.

Now I'd like to talk about the efficacy and safety of the new RSV vaccines for use in older adults. Next slide.

In June of this year, ACIP recommended the first two RSV vaccines for prevention of symptomatic lower respiratory tract disease in older adults. They're both recombinant protein vaccines based on the same RSV antigen. The first vaccine, RSVPreF3 or Arexvy is made by GSK and is combined with GSK's AS01 adjuvant system. This is the same adjuvant that's in GSK's recombinant shingles vaccine, Shingrix. The other RSV vaccine is RSVpreF or Abrysvo made by Pfizer. It does not contain an adjuvant. This is the formulation that was also recently FDA approved for use in pregnant persons to prevent RSV disease and infants after birth. And this will be discussed in an upcoming ACIP meeting this Friday on September 22. Next slide, please.

In terms of efficacy of the vaccines, both were studied in large clinical trials. GSK's phase three clinical trial enrolled almost 25,000 older adult participants in 17 countries. Efficacy analysis here represent a single dose. Over the first RSV season, the efficacy against RSV associated lower respiratory tract disease was 82.6%, declining to 56.1% during the second RSV season with an aggregate of 74.5% efficacy over both seasons. Next slide, please.

Pfizer's phase three clinical trial enrolled almost 37,000 older adults in seven countries. Over the first RSV season, the efficacy estimate was 88.9% declining to 78.6% during the second RSV season with an aggregate of 84.4% over both seasons. Of note, both products demonstrated significant efficacy against lower respiratory tract disease. However, the trials were underpowered to show efficacy in older adult subpopulations including adults 75 and older. The trials were also underpowered to show efficacy against RSV hospitalization, though the good efficacy against symptomatic illness likely indicates efficacy against more severe disease such as hospitalization. Next slide.

In terms of safety overall, both vaccines were generally well tolerated with an acceptable safety profile. The most common side effects after both vaccines and clinical trials were similar to those of other vaccines that included pain at the injection site, fatigue, headache, muscle pain, and joint pain. Next slide.

As was presented at ACIP, six cases of inflammatory neurologic events including Guillain-Barre syndrome were observed in the trials. Due to the very small number of events, it's unknown at this time whether these occurred by chance or whether RSV vaccination increases the risk of these events.

Additionally, there was an imbalance in a small number of atrial fibrillation events recorded within one month post-vaccination. Until additional evidence from post marketing surveillance clarifying the existence of any potential risks becomes available, RSV vaccination in older adults should be targeted to those who are at highest risk for severe RSV disease and therefore most likely to benefit from vaccination. Next slide.

As with all new vaccines, CDC will monitor adverse events, including cases of Guillain-Barre syndrome following RSV vaccination through its existing vaccine safety surveillance networks VAERS and the Vaccine Safety Datalink.

CDC will also prioritize estimating vaccine effectiveness against RSV hospitalization and other outcomes of interest. These data will be evaluated and shared by CDC as soon as they're available. Next slide, please.

Now let's examine the recommendation itself. ACIP voted that adults age 60 and older may receive a single dose of RSV vaccine using shared clinical decision making.

To unpack that a bit further, notice that this recommendation does not specify either of the two RSV vaccines because there is no preferential recommendation for one or the other. Providers should administer whichever vaccine is available. In addition, the recommendation is currently for a one time dose only. Studies are ongoing to determine whether older adults might benefit from receiving additional doses in the future. Next slide.

So what exactly is shared clinical decision-making? Shared clinical decision-making, which has been previously used for other ACIP recommendations including that for PCV13 and HPV, means that there is no default decision to vaccinate. This is unlike for routine and risk-based vaccine recommendations which by default target all persons in a particular age group or an identifiable risk group. By contrast, under shared clinical decision making, the decision whether to vaccinate an individual is based on a decision process between the patient and clinician or provider and may be informed by the best available evidence of who might benefit an individual patient's characteristics, values of preferences, the healthcare provider's clinical discretion, and the characteristics of the vaccine. Next slide, please.

For RSV vaccination the patient's risk of severe RSV disease is an important consideration as those at increased risk are most likely to benefit from vaccination.

As previously mentioned, there are several chronic medical conditions that have been associated with increased risk listed again here. This list is not meant to be prescriptive, but rather to highlight for providers and patients conditions which increase risk while still allowing individual flexibility. Next slide.

In addition to chronic medical conditions, here's a reminder again of other factors associated with increased risk of severe RSV disease and which may inform the decision to vaccinate against RSV. These include residents in a nursing home or other long-term care facility, frailty, and advanced age. Next slide.

Regarding advanced age, there is no specific age cut off, but incidence of RSV hospitalization increases with increasing age even within those over 60. And clinicians can consider a patient's age in determining their overall risk of severe RSV disease. In particular, we see the highest rates of RSV associated hospitalization in adults 75 and older. Next slide, please.

As for timing, optimally, vaccination should occur before the onset of the RSV season. However, because as we previously discussed, typical RSV seasonality has not returned entirely to pre-pandemic patterns, and as mentioned, some states are already starting to see RSV cases this year. Providers should offer RSV vaccination now and should continue to offer vaccination throughout the season to eligible older adults who remain unvaccinated. Next slide.

Lastly, I'd like to speak briefly again about coadministration.

Same day administration of RSV vaccine with other adult vaccines is acceptable. This includes giving RSV vaccine at the same visit with seasonal influenza vaccine, COVID-19 vaccine, pneumococcal vaccine, Tdap, and recombinant zoster vaccine. If vaccines are not administered on the same day, there is no minimal interval required between vaccines. Next slide.

To date, for RSV vaccines, coadministration has only been studied with influenza vaccines. In general, coadministration of RSV and influenza vaccines met noninferiority criteria for immunogenicity in trials. That means RSV and influenza antibody titers were considered equivalent. RSV and influenza antibody titers were generally somewhat lower when both RSV and influenza vaccines were given on the same day compared with different days. However, the clinical significance of that difference is unclear, meaning that there's no evidence to show it reduces efficacy in preventing illness against either disease. There are additional studies underway on coadministration of RSV vaccines with other adult vaccines.

We do know that administering RSV vaccine with one or more other vaccines at the same visit might increase local or systemic adverse events like headache, muscle pain, or fatigue. However, receiving multiple vaccines on the same day provides a better opportunity for patients to get up to date with important recommended vaccines. Next slide.

And I'll actually have you go one more. In summary, RSV can cause serious illness in older adults including hospitalization and death. Chronic medical conditions and other factors are associated with increased risk of severe RSV disease. For the first time, RSV vaccines are licensed in the U.S. for the prevention of RSV associated lower respiratory tract disease. CDC recommends that adults 60 and older may receive a single dose of RSV vaccine using shared clinical decision making.

Shared clinical decision making is informed by the patient's risk of disease, their characteristics, values and preferences, providers, clinical discretion, and characteristics of the vaccine. Coadministration with RSV and other adult vaccines is acceptable. Next slide.

And this is a link to a number of resources on CDC's website. And next slide.

And I'll hand it off now to our final presenter, JoEllen Wolicki. Thank you.

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

Talking about vaccines can be a challenge for all the reasons outlined on this slide. Next slide, please.

The biggest challenge is knowledge does not equal behavior. It certainly contributes, but simply giving information doesn't mean the person will change their behavior. It's easy to think that providing knowledge will lead to action, but a broad range of sociopsychological determinants have been identified. These may range from attitudes, past experiences, and cognitive biases to trust social norms and even moral values and worldview. And it matters who the message is coming from and how it's communicated.

So what do we do? How do we communicate with patients? Next slide, please.

Today, I'll be discussing two approaches which you will need in your tool belt for communicating about vaccination with patients. We start first with the presumptive approach, which assumes the patient will vaccinate and involves a strong recommendation. Next, if the decision requires more discussion, we move to the motivational approach, which is a collaborative communication approach to guide people toward behavior change. Next slide, please.

CDC recommends giving a strong recommendation for vaccination using the presumptive approach for routinely recommended vaccines. The presumptive approach assumes a patient will choose to vaccinate. A strong recommendation is the most important part of the vaccine conversation. Whether you discuss vaccines with your patients during an in person office or hospital encounter, do messages on your patient portal or at a telemedicine visit or during consultation in the pharmacy. While this may be the end of the conversation for most as they choose to get vaccinated, it may be the start of conversation for some. Next slide, please.

Which leads us to discuss motivational interviewing. Next slide, please.

Some vaccination decisions require a conversation between the provider and patients, which is where a motivational interviewing framework can be used. This is an evidence-based and culturally sensitive way to speak with patients about getting vaccinated. It is a client-centered and guided communication style for enforcing a person's own motivation for change or behavioral action. MI is effective. It has been used for behavior change with many health decisions such as smoking cessation. There are fewer studies using MI with vaccination. However, initial studies demonstrate increased intent to vaccinate and improved vaccination rates. Next slide, please.

Let's walk through how to apply motivational interviewing rapidly. This involves four steps. Be empathetic, ask permission, motivational interviewing techniques, responding to questions. Next slide, please.

The first step is to embrace an attitude of empathy and collaboration. Be compassionate, show empathy, and be generally curious about the reasons why the patient feels the way they do. Be sensitive to culture, family dynamics, and circumstances that may influence how the patient views vaccine. Remember that arguing and debating do not work. Next slide, please.

Next ask permission to share more information about the vaccines, and you can see an example of this on that slide. Next slide, please.

If the patient says no, probe about why they don't want to talk about vaccines. For example, you could ask can you tell me more about the reasons you don't want to discuss vaccination today? Respect the patient's decision. If they are unwilling to talk about vaccine and probing is not effective, accept that. But leave the door open for further discussions by asking if they would be willing to talk about vaccines at their next visit. Next slide, please.

When discussing vaccines with patients using motivational interviewing key techniques, open the conversation using open-ended starters. Avoid yes/no questions which stop the conversation. Affirm positive behaviors.

For example, this can help build a person's confidence for change. Listen and reflect back what you hear. This lets the patient know that you hear them and are trying to understand their point of view. It also allows the opportunity for the patient to correct and elaborate. You can do simple reflection, such as it sounds like you have questions. Summarize the conversation. A summary is just a type of reflection. It brings the whole conversation together and shows the patient your understanding. Next slide, please.

Openers can be tough. One way to open the conversation is with a scaled question shown here on the slide. Once the patient gives you a number, explore that number with probes. You want them to talk about this out loud, because talking actually changes how they process their choices and can develop forward momentum. People hesitant about vaccines usually have more practice explaining why they haven't gotten vaccinated, so it's good to reverse that. Get them to verbalize the benefits.

Be compassionate and curious about the patient's mixed feelings, both the part of them that wants to trust that getting a vaccine is important and safe, and the other part that feels resistant. It is important to show support for the patient to incorporate their personal values and health needs of their family and community as they make their decision. The goal is to help the patient become more open to moving toward a higher number, i.e., getting vaccinated. Next slide, please.

Questions are an opportunity to build trust, not hesitancy or concern. Answering those questions will result in long-term dividends in the person's health and your ability to maintain a trusted relationship with that individual. If you feel competent and aware of how to answer the patient's question, respond with empathy, and provide information as needed. Refer the patient to resources on the CDC website.

If the patient's question is outside your competence or awareness, recommend that they speak with their medical or mental health provider or a knowledgeable expert as needed. Next slide, please.

So now we've come to our self-knowledge check. Who is the patient's most trusted source of information on vaccine? Healthcare staff, Dr. Google, neighbors, family and friends. Next slide, please.

The correct answer is A. Multiple studies have demonstrated that healthcare providers and their staff are the patient's most trusted source for healthcare information, including information about vaccines. Now I'll hand it back to the COCA staff for the Q&A.

Presenters, thank you for providing this timely information to our audience. We will now go into our Q&A session. Please remember that to ask a question using Zoom, click the Q&A button at the bottom of your screen, then type your question.

Our first question. Is there any reason not to administer or co-administer vaccines together, such as decreased immune response or an increase in side effects?

This is Dr. Britton. I can start to answer that question and happy to have Dr. Grohskopf or Dr. Wallace jump in as well.

So coadministration is obviously incredibly important. As I mentioned in my presentation, there is good data that RSV vaccines and influenza vaccines can be co-administered safely and that they generate non-inferior immune responses when they're given together. Just as, you know, with administration of any two vaccines that may have some reactogenicity that there can be additional side effects if you give two vaccines together. And so if you have a patient for whatever reason, you know, you're very concerned about having side effects that could be something to discuss with them about whether they would want to space. But there's no requirement to space, and it is acceptable to administer both RSV and influenza and COVID vaccines at the same visit. Especially in patients that you think might have a difficult time coming back for additional visits or at very high risk of vaccine preventable disease. So I will let Dr. Grohskopf and Dr. Wallace add if they have anything to add.

This is Lisa Grohskopf. I don't have much to add to that. There are also, for example, there's guidance concerning if you're giving, for example, two vaccines that might be more likely to cause a local reaction. Some vaccines, for example, the flu vaccines, the high dose and the adjuvated, might be more likely to cause a local reaction at the site to administer in general, in general, give injectable vaccines at separate sites if they're given at the same time. But sometimes people will choose to say if they have two vaccines, they're concerned about local reactions with giving them in two separate limbs.

And this is Dr. Wallace. Nothing to add for me. As I said in the presentation, you know, coadministration of vaccines sort of remains best practice, and so that's what we're recommending for COVID-19 vaccines. But if you're planning to administer with an orthopox vaccine, we have some additional considerations that are in our clinical considerations guide.

Thank you. Our next question, and there are actually quite a few questions on this topic, but can you please discuss recommendations about vaccination administration following an active case of influenza, COVID-19, or RSV? And specifically wait times between being diagnosed with one of those diseases and then receiving the vaccination?

This is Lisa Grohskopf. I can take that with regard to flu. There isn't a specific wait time that's recommended. In general, for somebody who has a moderate to severe acute illness with or

without fever, it's generally recommended that they've recovered from that illness. And that that's something that's common across most vaccines and is in the general best practices guidelines for recommendation. There isn't a specific wait period beyond that. But in general, you'd want to wait, particularly if it was a moderate to severe acute illness until recovery.

And this is Dr. Wallace. I will add to that. So COVID is the same, you know, we recommend that everyone wait until they're feeling better and sort of they meet the criteria for discontinuing isolation. But in addition, if they've recently had a SARS-CoV-2 infection, you know, they can consider delaying their COVID vaccine by three months from its symptom onset. And that's just, you know, we think that there's probably some protection still from the infection up to that point. So you can do that if you'd like.

Thank you. Again a few, quite a few questions on this topic. Will there be an updated vaccine information statement available for the new COVID-19 vaccine?

Hi, this is Dr. Wallace. I think there is some conversations going on right now about that. I think that there's going to be an updated EUI-BLA fact sheet being put up by FDA, but I don't want to speak for them. But that is sort of the last that I've heard. I think things are in the works.

Thank you, our next question. Is the RSV vaccine only for people 60 years and older? What if someone is immunocompromised and would like to receive the RSV vaccine, and they are less than 60 years old?

Hi, this is Dr. Britton. That's a great question. Right now the vaccines are only licensed by FDA and recommended in adults 60 and older. That includes people that may have immunocompromising conditions or other high risk conditions. However, there are ongoing clinical trials studying the use of RSV vaccines in these other groups. And as soon as that data is available, that will also be something that ACIP and FDA consider. And if we need an updated recommendation, there will be one in the future. So thanks.

Thank you. And then our last question is asking when vaccines are co-administered, can you discuss site administration? Can they all be administered in the same arm, or do you need to switch vaccination sites?

This is Lisa. I can take that because there have been some specific recommendations regarding that. In general, injectable vaccines should be administered in separate sites that could be in the same limb. I'd invite Dr. Wallace or Dr. Britton if they have other comments on that to please make them. And again if administering two vaccines at the same day that you think might be more likely to cause a local reaction. And again for flu vaccines, that's generally the high dose and the adjuvanted influenza vaccines. You can consider administering in separate limbs.

No, nothing to add. Those are, yeah, best practices stand for the RSV vaccines as well.

Thank you. Thank you for answering these questions and again for sharing your expertise with us today. All continuing education for COCA Calls is issued online through the CDC Training and Continuing Education Online System at tceols.cdc.gov.

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We invite you to join us this Thursday, September 21 at 2:00 PM Eastern Time for our next COCA Call. The topic will be about algorithms for diagnosing endemic mycosis. You can visit emergency.cdc.gov/COCA for more details about this COCA Call and other upcoming calls.

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Again, thank you for joining us for today's call. Have a great day.