COVID-19 BIVALENT BOOSTER VACCINE SAFETY & ADMINISTRATION WEBINAR TRANSCRIPT

Washington State Department of Health
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[Phil Wiltzius]: Okay, good afternoon everybody. We're just waiting for everybody to file in. I've turned on the auto transcript here in case people can't hear very well. I know we're running a couple minutes late so I think we'll probably just get into it. We're already close to 250 folks.

So welcome to our Covid-19 Bivalent Booster Safety and Vaccine Administration webinar. I'm Phil Wiltzius, I'm a School and Childcare Immunization Health Educator from Health and I'll be facilitating today.

So before we start, just some ground rules. We generally have everybody muted for the presentation. If you do have any questions, you can type them in the questions and answer box. We will have time at the end of the presentation to hopefully get through a variety of questions. Just ask that you ask questions that are pertinent to the webinar otherwise we will probably not answer them.

We are offering continuing education for this training for nurses and pharmacists and pharmacy techs. So and that applies to if you're watching live or if you watch our recording, which we'll be probably posting in the next week we'll have more information at the end of the webinar. And then we do have a webpage for this training which you can find on our DOH website. If you search for immunization training, you can find this web or the training webpage.

Okay, so the learning objectives today, discuss the safety studies for Covid 19 bivalent vaccines, describe updated Covid 19 bivalent vaccine schedule, identify ways to address Covid 19 Bivalent vaccine administration errors. Our presenters today are Kathy Bay, she's our Clinical, Quality, and School Section Manager at the Office of Immunization in the Department of Health, and Heidi Kelly who is our Public Health Nurse Consultant, also with Office of Immunizations at the Department of Health.

And before we jump in, just a couple of small things. This is our continuing education slide that we had to share. Basically saying for our nursing and pharmacy credit, they're approved by a couple different folks. Some quick disclosures. None of the planners or speakers of this activity have any relevant financial relationships with any commercial interests pertaining to this activity. And as I mentioned before, I'll cover a little bit more about continuing education credit at the end of the webinar. Okay, so with that I'm gonna turn it over to Kathy Bay.

[Kathy Bay]: Thank you Phil, so much. I think I've been having a little bit of IT problems with bandwidth and stuff so I'm turning on my camera to say hello. I'm gonna turn it off and we'll just keep moving through the slide. So next slide please. So next slide. So I think you know, as we consider, again we've talked about the pandemic in the United States and that we really maybe are no longer in the pandemic but really are continuing to see the endemic impact of the Covid virus and so really, the SARS Co-V 2 virus technically, but causing the Covid 19 infections. So this actually is kind of a current slide to think

about. I pulled it earlier this week, technically I guess last week on the fourth, looking at the daily trackers. You can see across this the kind of the caseloads in the United States and we've had multiple little surges from an epi standpoint when we first started talking about the epi curve and thinking about where we were going and where we were, and you can see our huge numbers that have spiked depending on which variant we were in at that point in time. But I think the key piece for everybody for awareness is we need to continue to focus on really ensuring that individuals can get vaccinated and are vaccinated. And that's where we're gonna really talk about that a little bit today, next slide.

So this actually looks at a report across the United States thinking again, downloaded from CDC, it's public data, we have Washington state data as well. But looking across the United States, the number of individuals that have been impacted by Covid and have actually died because of Covid. And you can see that we started with, you know, a huge number of people back in 2020 and then had another surge in the winter of 2021. And we're gonna talk a little bit about waning immunities and why a bivalent vaccine is important, next slide.

I wanna start with some positive information thinking about vaccines in general. So the global impact, this is actually a report that was published in the Lancet Infectious Diseases, an article that was posted that looked at the world basically and the impact of vaccinations and the reduction in the number of cases. It really, the reduction in the number of deaths and looking at the impact of vaccination. And so according to this article and these researchers, they really felt that the number of deaths that were averted based on vaccination was a 63% reduction in the global deaths related to the SARS Co-V 2 virus. So I think if we think about the idea of the impact of the vaccine, and again it could be any of the vaccines, but thinking across 185 countries and the world and the impact of the vaccines have had, it really does make a difference when we think about the need to continue to provide booster doses to get people's immunities that are waning back up. And a couple of really important things to consider is, you know, countries with higher socioeconomic benefits had reduced deaths. We find the same thing when we look kind of across the United States and internationally. When you look at communities where individuals may not have as many benefits or higher SVI communities, you could have more deaths in those communities due to lack of access to vaccines. So continuing to think about how we impact that and although we've had over a 97 million cases and over a million deaths in the United States, again we continue to see the impact of vaccines and how much worse it could have been if we had not had them available, next slide.

This is actually an article from the Commonwealth Fund where they're reporting looking at, they looked at a year in synopsis and so this is actually a year old now, but I have a little bit of updated information and from their perspective what they looked at is the number of hospitalizations that would've occurred in the United States per 100,000 people if with and without vaccines. So you can see this graphic actually shows you what they would've seen based on this profile or this look if we had not had vaccines available in the United States. And when we think of how significantly our health system has been and continues to be impacted by the SARS Co-V 2 virus itself as well as the sequelae from it, for individuals and other health conditions, it really does make sense, again, that the vaccine really did impact safety and health across the US and continues to do so today, next slide.

This actually looks again at the idea, this is that retrospective look by them, and considering the idea of, you know, from the one year of vaccination availability from December of 2020 through November of 2021, what they would've anticipated we would've seen if we hadn't had the vaccine. And I want you to

consider again how significant that curve was last year that continued to loop up. But again, we know we have waning immunity and we have to continue to think about what we can do for the future, next slide.

This actually looks at the ongoing, so this is an updated sort of look at that process. And so it's also from the Commonwealth Fund and this is all published and the data is here with the references to it, but this looked at the data from December of 2020 through March of 20, end of March, 2022. Looked at the number of deaths, hospitalizations, infections and then again, even the healthcare cost. And so what they looked at was they looked at a range of high to low and so those are those that like last column over but then they looked at that kind of middle of the road number, the credible intervals are there on the far side but in the middle or what they think really from an impact of the number of deaths that were averted, the hospitalizations, infections, and then the healthcare cost, next slide.

Again, putting it in perspective, this is actually an article that CDC posted or referenced, but it pulls off of a different source, as far as information it pulls off the Commonwealth Fund. Again looking at the idea that we, by starting vaccinations early, we actually avoided a significant number of deaths in the United States and then continuing to do that over time, next slide.

So this looks at data through for those ages 50 and older from April till July of 2022. And again, thinking about the need for bivalent boosters, which is really what we're talking about today, looks at that idea that if an individual had not, you know, the three tiers if you or four tiers if you wanna think about it, the completely unvaccinated, those who received a primary series only, those who received a primary and one booster and those who had a primary and two boosters. Again, if you're 50 and older, that would've been the recommendation unless you had other, and if we think of primary in this case, we're thinking of those who are an immunocompromised, would've had a recommendation for an additional dose in that series probably so. So you can look at this as a process as you're considering the idea of the risk of death in an individual based on the number of vaccine doses that they'd received. And again, when we think about the ongoing impact of receiving booster doses, it's an important piece for us to consider. We actually can ensure or reduce the number of deaths in the United States and for our cases in Washington state with residents by ensuring that people stay up to date on their vaccination status, which Heidi's gonna talk about in a few minutes, next slide.

So one more slide, kind of looking at history, looking at the idea of the severe outcomes of Covid 19. And again, the vaccine doesn't completely stop people from spreading disease and it may not stop individuals from getting sick, but what it does do is it helps reduce the severity of disease and helps reduce deaths in individuals. So maybe decreasing the risk of need for hospitalization, severity of disease and how important that is for those particularly as we think about those with chronic diseases, whether it's, you know, again the 65 and older population or other populations with chronic disease. So we can make a difference when we think about managing and helping support those individuals. Okay, one more slide that's kind of in this history piece and then we're gonna talk a little bit more about efficacy and safety. So this actually is another kind of projected piece looking at kind of the impact of the fall booster campaign, thinking about bivalent and I love to be able to use pictures to help share information. And for me when you look at this, when we think about how low the uptake has been, although it's starting to trend up a little bit as numbers of both influenza and Covid are surging again a little bit across the US, and so you can see the purple line in this on the projected hospitalization looks at vaccination based on its current daily rate. So thinking about where we have been in the US, if we don't

increase the number of people who are vaccinated with a primary series and a bivalent rate, if they have never received a vaccine, that primary series is important but a bivalent, so it looks at the current daily rate and then the blue line in this actually shows you if we think about flu-like vaccination coverage as we consider what normally we see each year for influenza vaccines, the blue line shows you how much you would've seen a reduction of hospitalization because again, it does help to decrease severity of symptoms. And then the green line is if we could get up to that 80% booster eligibility, what a difference that would make as we think about this oncoming winter season where people are gonna be inside more, at risk for more spread of disease, and at higher risk again of hospitalization. The other graphic that's here is the same information as far as the color coding but looks at the number of projected deaths. And again, Commonwealth Fund looks at that process piece and kind of takes that data and assesses overall where the impact could be and so we can make a difference to reduce those purples and those are people when we think about it and look at reducing hospitalization and death by assisting with vaccination, next slide.

I'm gonna switch in, we're gonna talk a little bit more generally about vaccine safety, next slide.

So I have, I wanna think about the idea again of the vaccines that we're using in the United States and they have been literally utilized in millions of individuals and initially were evaluated in tens of thousands of individuals during the clinical trials. Both Pfizer and Moderna are fully licensed for adults. There's ongoing safety monitoring that happens even with full licensing and then ongoing monitoring that happens as part of, you know, EUA status for younger children. More than 63 million doses of the vaccine had been administered from December of 14, 2020 through October 27th of 2022. And again, I pulled data recently so you know, I think the numbers would've gone up since the 27th of October. In addition to the idea of how many doses at 63 million doses in the United States, these same vaccines that we're using in the US have been used in other countries and kind of in that international picture that we've looked at. And so again, there have been significant kind of clinical trials that have been done internationally and definitely again use of vaccines. So 63 million doses administered in the US at that point in time, next slide.

So it's absolutely true that people can have side effects after they've been vaccinated. We know that our immune system responds, and I love this graphic from the Children's Hospital of Philadelphia 'cause I think it looks at that perspective thing, it makes it easier. And so this is a little bit dated when it looks at the one and two doses of the mRNA vaccine and it only has mRNAs in Janssen. It doesn't have Novavax on it but I like it because of the simplicity of thinking about, you know, it's not unusual, it's common for individuals to have those minor side effects or those effects of their immune system actually, you know, creating immunity. So when I got my vaccine I had pain in my arm,. I didn't really have a headache. I had a low grade fever, I had fatigue, I had swelling in that area and general muscle aches and that was pretty much me. And again, I get that I'm, you know, at that upper wedge of that triangle which to me is a really unfortunate to be there with the idea of my immune system responding and those are the side effects that I get. It is rare to have more severe and some of the more severe symptoms that you can have are, you know, swelling under the arm which is you know, the lymph system actually reacting as the immune system and responding. And then there are some more very rare side effects that can occur in individuals and we're gonna talk about those just a little bit more. But again, I think for me, thinking about that idea of this inverted triangle and thinking about if I can help protect those people at the top and I can help protect myself to reduce hospitalization and help reduce burden on the healthcare

system while we're very overwhelmed and continuing to stay that way, then there it's important for us to continue to consider it from that perspective, next slide.

So we've already talked about this, there's embedded in the slide deck, I'm not gonna play this video but it actually kind of talks through, it's on a CDC website, and it really goes through that idea of that rigorous testing that's been done. There's a slide very similar on the FDA website that looks at that kind of process. So we're gonna step back just a second and look at that in just a minute. But again, the slide is there, next slide.

Two things to think about as we think about, again, the adverse events, I've already said that there could be in that inverted triangle individuals, so right now what the data shows that about five cases per 1 million vaccine doses administered, individuals will have anaphylactic reaction. So again, a pretty small number when you think about the risk stratification but again, something for individuals to be aware of. The thrombosis with the thrombocytopenia syndrome that we know is associated with the Janssen, J and J vaccine, again it's four cases per 1 million doses and this is data from CDC off of their website. But again a smaller number but we do wanna make sure that people are screened and that they actually have the information to make the right decision about which vaccine is safe for them or which one is best for them based on their age and their other health risk. And then the Guillain-Barre Syndrome or GBS, again it's a very rare disorder and it's not, it's really more thought again as you kind of walk through the process with it, it does seem like there are some cases, I'm not absolutely certain about that true association but it is something that is visible and can happen after vaccination, next slide.

We're gonna talk more specifically about the myocarditis and the pericarditis 'cause I know there are questions about that. And so this is actually data, this was actually discussed at the ACIP meeting recently looking at the process for the vaccines and where we are from a safety standpoint. And so as of the 27th of October, there had been about a little over 1000 preliminary reports in VAERS and VAERS is that emergency, you know that real national reporting system and we'll talk more about that in a second, but looking at those under the age of 18 in the five to 11 year old population, there were 22 verified reports after over 21 million doses administered. In the 12 to 15 year old population, 358 verified reports, after over 24 million doses administered. And in the 16 to 17 age population, 310 verified reports, with over 13 million doses administered. So I think again, most commonly individuals, the myocarditis, excuse me, or pericarditis, is it has been really reported. Just for clarity, again, myocarditis is an inflammation of the heart muscle itself and pericarditis is an inflammation of the outer lining of the heart or that pericardial sac as we think about it sometimes.

The thing that is important to remember as we consider the impact, next slide, is that the cases of myo and pericarditis are much higher in individuals who develop disease versus those who have been vaccinated. So when I'm vaccinating whether in that population, I continue to share with parents, you know, when we know that primary series could be, reduction risk could be to reduce the, to spread out the distance between dose one and dose two in that primary series. But again, individuals who are not vaccinated do develop and develop disease are at higher risk for SARS Co-V 2, myo and pericarditis. And what we typically see with that population is when they do get sick or have complications from it, from disease state, they tend to be sicker. It'll last for longer and could have more scarring tissue. Individuals who are vaccinated, it's kind of the reverse. When we do see it, they tend to be less ill, have really more just medical observation management as a general rule. And again it's an important piece for parents to

be aware of, for individuals to be aware of. But again, we know that as numbers continue to surge it can make a difference for individuals to be vaccinated. Next slide.

I'm gonna speed up a hair so I can make sure there's time for Heidi to talk and give more details. But this is actually a picture of what the life cycle of a vaccine looks like. And again from vaccine development through the safety, it's an ongoing process and that safety in that continued monitoring by CDC and FDA for safety monitoring, even after licensing in that phase four, the vaccines actually have gone through that full continuum. We think about the ones that are available here in the United States, next slide.

So we talked about the idea of FDA and CDC but I just wanna put a plug in for the ACIP meeting and make sure that people are aware that the ACIP, an Advisory Committee on Immunization Practices, is it's a group of healthcare experts. They are, as a general rule, there are 15 voting members who are responsible for making vaccine recommendations to CDC, which includes the Covid vaccines. 14 of those members have expertise in vaccinology and immunology and other clinical practice areas. And in addition to that there are what they call eight ex officio members who represent other federal agencies with responsibilities and there are 30 non-voting representatives of liaison organizations, which includes your, really your kind of across the spectrum clinical scope. That 14th member, that 15th member sorry, of the group, I see that I made a typo on this and it says the hundred and 15th member, but it is the 15th member is a consumer representative who provides community and social aspects of vaccinations. So across that 15 voting member group and then of course all of those other people that are involved to make sure that there's perspectives from pediatricians, from family practice, from midwives, from OB GYN providers, from regular, you know, internal medicine physicians. Really looking at the spectrum of care provided in healthcare in the United States to ensure that we're thinking about that. So there is a strong group of people from a clinical knowledge and expertise standpoint that are involved in these ACIP meetings and involved in the recommendations to CDC. ACIP was established in 1965 and again, they give recommendations to CDC on both childhood and adult vaccination series. And they have fully, they have have been full advocates for the vaccine series, both the primary and the new bivalent from a safety and an approach standpoint, next slide.

So this actually says, and this is actually from the ACIP meeting that happened recently and you can find this information on the ACIP website. That meeting was the 19th. This was Dr. Oliver who said really since the SARS Co-V 2 with really focusing on the Covid vaccines, typically the group meets, you know, four times a year or so, they've actually had 22 meetings and they have looked at vaccine effectiveness data in 11 of those meetings and they've looked at safety data in 21 of those meetings. So thinking again, all of those are public meetings, they're all recorded, they're all visible, you can look at all of their slides, you can listen to them talk either in the current moment or otherwise. So to me that brings that transparency of awareness about vaccine safety and looking at it, next slide.

Looking specifically at some of the tools that are available, these are all the monitoring systems for vaccine safety in the United States. V-Safe has been used as an active surveillance tool that really came about as part of our work for the SARS C0-V 2 virus but since then, we've also used V-Safe for Jynneos vaccine in relation to the Monkeypox virus that we are currently dealing with in the United States. And so there is a discussion about would we wanna use V-Safe for future pieces to have individuals who are actively, you know, being vaccinated, actually report their side effects and symptoms. We're gonna spend just a moment talking more specifically about the VAERS system, but I just wanna say again this is a large number of different kind of process pieces and we think about the different groups of individuals

that are covered and monitored through these systems. Some of them active systems, some of them you know, passive systems, but there is a large spectrum of vaccine safety work that goes on on a routine basis, next slide.

We're gonna look specifically at VAERS and VAERS is considered the nation's early warning system for vaccine safety. It's a warning system under the idea it actually was used and helped to identify that there could be a risk with the Janssen vaccine, with the TTS. And actually because of that sort of alert of the system in that process there was a pause on administration of the vaccine both in Washington and across the United States Resumption and then again, changes in the recommendations of who should receive and how providers should screen and ensure that individuals receive the vaccine that are appropriately screened and managed for it as well as if someone did have side effects after the vaccine, how you could best manage the care of the patient. So the VAERS system is a good system but I think the things that you have to make sure you're considering is that the VAERS system is not, because something is reported in VAERS does not mean that there's a causal relationship with the vaccine. It means that the information was reported and we really wanna make sure that VAERS reports are filed.

Next slide, and reports come in through VAERS by individuals who are involved. You know, if I got vaccinated and I had a fever the day after or I had another symptom, I could report that into VAERS. And so they come from patients, from patients family members, caregivers, those who administer vaccines like myself, I've written reports into VAERS, and then healthcare providers and then vaccine manufacturers. So there can be duplicates reports in the system when you think about it, and again, it doesn't create a cause and effect situation in the system because it's there, next slide.

So the VAERS system is actually used to assess the safety of newly licensed vaccines but then also to look for ongoing trends or any concerns. Again, the nice thing is because it is a national database and we're using it across the entire US, it does help us to be able to know again, side effects that are there and if they're more minor like that arm soreness that I described earlier when I talked about the Covid vaccine. But in particular, are there other concerns or is there that risk? And because there is that national database of information, it gets us to be able to identify those things more quickly than if it were just a more unique community area or a smaller population overall. So again, limitations in the VAERS system, they can't be used to determine a cause and effect but can look at that idea of is there an association from a temporal standpoint or a time-based standpoint? And so that's the key piece, that's the benefit of the VAERS system, next slide.

There are legal requirements for reporting and again, specifically for the Vaccine for Children Injury Prevention Act, there are specific pieces.

Next slide, with the Covid vaccines, there were also additional requirements for vaccines for providers that are reporting or utilizing and vaccinating. And so FDA put requirements and again that system is actually a co-managed or co-monitored system through FDA and CDC. And so these are some of the things but I think we continue to think about that idea of how we can continue to increase safety and ensure that people are aware and look for side effects and monitoring. So next slide.

It's pretty easy to follow a report in the VAERS system and reports should be filed if you are aware of an event. But there are reasons again to think about it. You know, if you've given it in the wrong site or the wrong route. You give it subcutaneous instead of IM, when we're thinking about the Covid vaccine, you know you gave it in a location, the age of the individual, you gave a dose that was intended for a child to

an adult or vice versa, any formulation of dosage issues, storage and handling, you had temperature excursions. It's important to note those things 'cause it's a, it helps give perspective, it helps us know that there could be a risk of a scenario where we think about how we can reduce the potential risk to an individual of getting a vaccine that doesn't have effectiveness or efficacy. So it's important to do that. Also the dilution and non dilution, if you diluted something that shouldn't or vice versa, next slide.

So what are you gonna need to fill out the report? So this is a checklist and it's gonna be really easy. Next slide.

You can actually report directly into the CDCs VAERS reporting system, and again, there's, it's on a public page, there'll be a a link to it at the back of the slideshow. There are some things that are required, the individual's name is not required, but you can see the things that are required from this for you to make sure, the more information you can give, the better accuracy of the information is and you'll get an opportunity when you finish and you file the report to be able to give your email address and your name for them to follow up with you, not follow up with you to say this is what happened, but follow up to get more information, next slide.

This is the rest of the required stuff that's highlighted on this. What's really important and we think about sort of that process of looking at VAERS data is really, understanding again, were there criteria, was it that arm soreness that went away after a couple of days, which could be reported into VAERS? Or are there more concerns where there's a temporal association of an individual getting more acutely ill after being vaccinated? So important for individuals to know to report to VAERS. Next slide.

Other things that are happening with vaccine safety is the Vaccine Safety Datalink. And so the nice thing about the Vaccine Safety Datalink is I love, you know, we think about it's one of those national systems where we're looking at the vaccine and what kind of potential safety risks are there with it as we continue to think forward. And so the Kaiser Permanente system here in Washington actually contributes into this Vaccine Safety Datalink. Next slide.

And across their system as we're thinking about not just Kaiser but across those different organizations at the US level, they look for what they call the Vaccine Safety Datalink signals. So they're tracking or looking at all of these diseases and health conditions that could occur in individuals. And so these are the focused ones that were identified either because of higher risk of complication or because of higher risk of, you know, a potential thing that might have been looked at under something that might have occurred, right where we're looking at higher risk for the individual. And so as you're walking through this assessing, you can see that they're looking for what they call a signal, which means when they compare the information of individuals who received their booster doses and this case is what we're looking at and looking at the outcome pieces and they compare that to individuals who didn't and look at the comparison across. The only disease piece that, or a risk piece that actually sort of signals is the myocarditis pericarditis. So as they continue to look at all of these other diseases, there are no signals. And so you can see the myo pericarditis is actually, you know, reddened on this and this was a, you know, data that was looked at for the idea of, and this was first booster dose, but the key piece is these are the types of things that are done as part of that sort of assessment of ongoing vaccine safety in the US so that VSD system is actually utilized for this. Next slide.

This is the V-SAFE system. And I do encourage providers that are actually vaccinating to ensure that individuals are aware of the V-Safe system. It's an auto enrollment or a self-enrollment by the person

and then it continues to track and ask you, so how are you feeling for the first week after you've been vaccinated? It's a daily and then it goes to once a week and then it goes on from there. It actually, once you've enrolled yourself, you can dis-enroll. But the nice thing about it is it may also prompt you to say, hey, you may be due for a booster dose now, which is a good process from an awareness standpoint. So to me, I think the things that are important, you do have to be an adult actually using a smartphone and a parent can enroll their child, but it does require an adult or an emancipated minor from an enrollment standpoint. So the key pieces as we think about it, I'm gonna hand off to Heidi to be able to talk more about the vaccine schedule, is really considering where we are from a vaccine safety standpoint. Again, in the United States we've done well over, you know, 600 million doses, I think it was 636 million doses at some point late in October, And as we continue to track and monitor the vaccines and vaccine safety, we know that people can have side effects. But when we think about the risk of individuals not receiving their booster dose or not receiving this bivalent vaccine as time is continuing and the concerns about the fall of a surge of the virus, again, we wanna make sure that we're considering and thinking forward into how we can help people be vaccinated and with what. So with that, I'm gonna hand off, I have references there or some additional information there and I'm gonna hand back to Phil.

[Phil]: Thank you very much and I'm gonna hand back over to Heidi who's going to present next.

[Heidi Kelly]: Good afternoon everyone, Heidi here. I'm gonna be going over the bivalent booster schedule and addressing errors, what to do when you have an error occur. Next slide. Next slide.

So first we're gonna go over the vaccination schedule review. As you all know, everyone six months and older should complete a primary series of Covid 19 vaccinations. And then in order to be up to date, they would have to receive complete their primary series and then if they're eligible, so those five years old and up, should receive at least, well should receive, one bivalent booster dose. That's the current recommendation, but the way that they've written up the up to date definition is so that they can use it in future obviously. So you've got the primary series and then whatever's recommended for the most recent booster dose by CDC. And then I've included a little picture of the card, just as a, it's just a reminder of the doses that come up. Some, as I'll say later on, some people are filling these cards up. So we've gotten very, very creative in how to get it down, but this is a card that's been filled out with the primary series and then a monovalent booster and then a bivalent booster at some point. So just showing that I know you've all seen it one time or another as well. Next slide.

So with the booster doses you've got Pfizer, which is now available bivalent booster starting at five years and up and then you've got Moderna that's six years and up. So people five years and older are recommended to receive one bivalent mRNA booster dose after they've completed an FDA approved or authorized monovalent primary series or previously received monovalent booster dose. So, and as as you know, it's two months after their last dose of either, right? So they do have to have their primary series completed and then if they've had monovalent booster doses, it's gotta be at least two months after their last dose. And then I wanted to touch on the monovalent Novavax booster dose that was just recently authorized for use. It's being used instead of a bivalent mRNA booster dose and it's only for limited situations. So it's for those situations where intervals have not received a booster dose at all. So they've completed a primary series and let's say they completed it back in when we started vaccinations

and now they are, they have not received any booster doses at all, then they would qualify for a NOVAVAX vaccine, a Novavax booster dose. They have to be 18 years old and older again, not receive any other booster dose and usually that has to do with them not being able to receive an mRNA vaccine for whatever reason. Maybe they had a reaction after their second dose to the primary series or maybe they've never even received any mRNA at all. They received a Janssen one dose and then that was it. And now they're wanting to try Novavax or maybe they received Novavax just recently, the two Novavax doses and now they're ready to get their booster. And so now they can have a Novavax booster, but at this point Novavax is only for those special situations. And a reminder that there is no monovalent mRNA booster doses authorized at this point. And that does cause challenge as you're probably already aware, the vials look very similar so it's really important to pay attention to those vials and look at those labels to ensure that you're pulling the right vial because they do look similar. Next slide.

This is a picture of the schedule. This is for the, basically the healthy individual. You can see the primary series and then you see the booster, mRNA booster dose on there. Now the monovalent is on here, it's just under the footnotes. So this is a document that is available on the clinical considerations for use of Covid 19 vaccines in the US. It's on that web, on that webpage and it, and if you, it's basically the at a glance and if you pull up the full document, at the bottom, there's like a paragraph of footnotes that kind of addresses all the if thens, if then that, if this, then that kind of stuff. So that would be the Novavax would be discussed down there. And yeah, so I think we've got that. So you can see there, it's got a five years and up gets an mRNA booster dose and you can see also that they've simplified this. They've basically taken all the monovalent 'cause we're starting from scratch again, all the monovalent off the schedule. So if no one, if someone comes into your clinic and never received a monovalent, that's cool, a monovalent booster dose, but they've completed their series, primary series, they are eligible for a bivalent booster dose at this point. Okay, next slide.

This is the schedule for the immunocompromised. Again, you can see the added doses for that additional doses to talk about now that their primary, the part of the primary series for the immunocompromised. I'd like to note that, again, just keep in mind with those cards as I showed earlier, there could in theory have, you could have someone that actually received up to six doses because they got their primary series of three doses. They got their monovalent booster doses that were two and then they waited two months after the last monovalent and now they're getting their bivalent so they could have up to six doses. That is not unheard of. They could also just have four doses, let's say they stayed indoors and kept their mask on and decided not, decided to wait until they had a bivalent booster 'cause they kept hearing about it and then they went out and got their bivalent booster once it was available. So that's a possibility. The the other thing I wanna draw your eyes to is the bottom. They've added the Evusheld monoclonal antibody to the schedule and just be aware that it's there, it's another layer of protection that CDCs talked about during one of the most recent ASIP meetings. Just make you aware that that is something's out there for those that are truly immunocompromised and it's being underutilized. So if you know of or you have an immunocompromised patient and they received all their doses, look at the schedule down there to see when it would best time to get started on Evusheld. The plan is to give Evusheld every six months. Just keep in mind if they have any more booster doses in the future so you get it timed out just right with that. Okay, next slide.

I'm just gonna talk about vaccination errors. We get a lot of questions in the mailbox about this. First I would like to say if you ever have questions, please contact us. We're more than happy to help you out. We also kind of have a back door quick pass to CDC. They usually back to us pretty quickly for those very

weird different issues that may come up with the vaccination process and they come up. So now, if you have a vaccination error, it's not that it, it usually happens just in oversight for whatever reason or maybe the child, we thought the child was eight and it was, you know, four, I don't know. But things like that happen. So, or maybe you pulled the wrong vaccine and gave a 18 year old a five to 11 year old vaccine. Those are all things that need to be reported. Also, something else that would come up is a storage and a handling issue. Let's say you pull a vaccine, this just happened recently, it happens more often than I, more often than expected, but it does happen. You label the vaccine, you do all the right stuff and the third party comes in and pulls it and gives it and didn't realize that it was outside of the basic use time or basic use date. So you would, beyond use date or beyond use time. So what you would do is you do have to report it. And that's something that we talked, that's something that Kathy went over a little bit. I would like to note in there that if it is a storage and handling issue and not a response, an adverse reaction to the vaccine itself, the actual event of the storage handling, that is the event. So when it says adverse event or other, you're gonna put, you know, the vaccine was given and it was expired or whatever. That's the event. I have a lot of confusion that questions regarding that. So that's what that is. So what would happen is you do need to let the person that received the vaccine know what happened and then if you have questions or anything, consult us, we can help you out with that. Follow the revaccination guidance that's in the appendix D of the Interim Clinical Practice Guidelines found on CDC website for Covid 19. It's again under appendix D and then you need to report all the vaccine administration errors even though it's not associated with an adverse reaction, to VAERS like I talked about. And then determine how the error occurred and implement strategies to prevent it from happening again. And I think all of us as providers overall tend to do that anyways because we wanna make sure it doesn't happen again but it's always go good to go back and review the processes with staff and coworkers just to make sure to do our best to try to keep that from happening again. Okay, next slide.

This is just a clip of the appendix D and it's just a clip of the actual table where you can go on there and look at what do I do if, and the most common things we're seeing right now is they grab the wrong vial and they give the bivalent for primary series or they give a monovalent for a booster dose. So I would take, I would go down to the bottom two blocks on the right and those blocks actually talk about those errors. And in the instance, for instance, if you received a monovalent booster dose, this happened a lot, especially in the beginning because CDC turned or FDA turned off the monovalent overnight literally. So it took time to get the message out. So it did happen. And in general, as you can see in the the last row at the very bottom, in general, you do not repeat the dose, but they also open it up as you can give a bivalent booster dose if the provider recommends it and or if the patient is asking for it, you just give it two months after the last dose, after the last monovalent booster dose you give, two months after that you give the bivalent. So it answers a lot of the main basic questions but there's always, there is always an exception. And on occasion we tend to contact CDC for clarification. So it does happen but this and this also has like three or four paragraphs after the graphic that is in a footnote format that answers a lot of questions that you may be asking as well. So I would highly recommend looking at the full document at whole. So next slide.

I'm gonna go over this case study real quick. Cali is a 22 year old immunocompromised person who has received two doses of Pfizer monovalent vaccine. She is in the clinic to receive her next dose, has been two months since her last dose. She receives one dose of bivalent Pfizer Covid 19 vaccine. What should happen next? A, nothing she's up to date. B, she should receive a monovalent Covid 19 vaccine dose

immediately. C, she needs to be told of the error, given the correct vaccine and it needs to be reported in VAERS. D, she needs to be told the error, no further vaccine is recommended at this time and the error needs reported in VAERS. Next slide.

So this question is tricky, I get it a lot. The answer is D, she needs to be told the error, no further vaccine is recommended at this time and I would say, so I pulled up this specific block but there, because she's immunocompromised, she could qualify or is eligible for another monovalent booster in two months after that bivalent booster to complete or bivalent dose to complete her series. So this is one that we had to talk to CDC about to verify the specific 'cause it is a little bit wonky 'cause she's immunocompromised. If she wasn't immunocompromised she would be done completely and up to date. Next slide.

Now for kiddos, there's those bridge ages I call them, where they're four years old when they start their vaccine series and then they turn five or maybe they received the five year old vaccine at four. So these pages deal with all that. Like the 11 to 12 years old, things like that, or the mixed dosing. These pages deal with all of that and this document is actually one document on the first page of the CDC Clinical Practice Guidelines. Okay, so we'll go over that next page, next slide.

Okay, so June is a four year old child that has just received their second dose of Covid 19 vaccine Pfizer five to 11 formulation. After giving the vaccine, the vaccinator noted June had received the six to four year old formulation for their first dose of their Covid 19 series. What is the next step in providing the recommended care according to CDC? So you've got, she's completed her primary series, no further doses needed at this time. B, parents should be made aware she received Covid 19 five to 11 years old formation, then schedule their third dose in eight weeks. And then C, parents should be made aware as she received Covid 19 five to 11 years old formulation, immediately revaccinate with Pfizer Covid 19, six months to four years old and once revaccinated report in VAERS, next slide.

So the answer is B. If you look at the top of these documents it says for these age bridging ages, you don't have to report them in VAERS per se. So she would need another, a third dose because she received that four, that six month to four year old and the amount of antigen in the four, the six month to four year old, it requires three doses total. So, and then the other thing to keep in mind too, it's based off her age. So if she's still four at eight weeks after all this, she should be receiving that six month to four year old dosing. So this page is actually, has that as the next part on next part below this picture. But I wanted to show you and she could get the orange cap as well. So at the end of the day these pages are very helpful, very informative, and I highly recommend having them in your clinic because a lot of questions get answered by going through these pages. Okay, next slide. And that's all I have.

[Phil]: Thank you very much. So we're gonna go over the continuing education stuff right now and then we will have time for a couple of questions. So if you do have any questions, please type them in the questions and answers panel. So like I said before, continuing education contact hours are available for both nurses and pharmacists and pharmacy techs. Specifically what you need to do is you need to watch this webinar or the webinar recording and then complete the evaluation which is available after the webinar. I believe you will receive a email, a follow up email from Zoom that should have the evaluation link. It's also on the webpage so make sure to fill that out and if you can't find it, you're definitely welcome to email me or Trang and we can send you those links. So something to note when you

complete the evaluation, you don't automatically get your continuing education certificate. We do go through each of the evaluations and basically hand make all of the certificates. So it does take a little bit of time for us to do so, but when we finish we will email you those. So just know that it takes a little bit of time. Okay, so I think we have some questions here. So somebody wanted to ask if this information that we've shared today, if people can share it publicly. And Kathy, I don't know if you want to answer that but my thing is right, we're Department of Health, all of our stuff is technically public for the most part. I mean it's a public webinar.

[Kathy]: Yeah, the slides will be posted. Yeah, I think the slides will be posted and the webinar itself will be posted as far as a link and the information is all cited and resourced from the idea of the, within the slideshow itself, as far as where to find all of the info. So yes you can share and we encourage you to share the information so.

[Phil]: Thank you. Let's see, we have a kinda a more clinical question here. Somebody asked, just to clarify, if someone has received the primary series, two vaccines and a booster, are they now eligible for a bivalent vaccine? And then it says, although they should be two months post booster before receiving a bivalent vaccine. Is this correct?

[Heidi]: Hi, this is Heidi. I can answer that. Yeah, so for the most part, if they're healthy and they receive two doses, the primary series and then they ended up getting a booster, if it's been at least two months since their last dose, they are eligible for bivalent.

[Phil]: Okay, thank you. This is a packaging question. I'm not sure if we have the input to answer this but I'll ask it. Do we have any idea why the Pfizer bivalent vaccine in the maroon and in the orange are still packaged and needing dilution? Do you know if there are any plans to change the packaging? I find the different dilutant required for maroon versus orange and no dilution needed for the gray vial caps to be a situation setting vaccine administrators up for error. Heidi or Kathy, do we know if there's gonna be any changes to that or.

[Kathy]: This is Kathy, I can't speak to it specifically. I know that one thing that is coming soon, but I've seen some early information coming out this week about is a unit dose size. So I think of unit dose as a single vial that's coming with one of the vaccines that'll be, you know, you open the top, you're able to draw directly that one vaccine and then throw away the vial. So we've been asking, it's been a really, how can we move toward that process more? So I think that's something, and I know that as they thought about the bivalence and thought about future work that's happening, trying to think about bivalent work to keep the colors as coded as possible to make it consistent from a kind of a safety standpoint for future around the possibility of additional boosters in the future similar to an influenza vaccine. So I think those are the things that I'm aware of right now. But we are, we perpetually are giving feedback directly to CDC, directly to manufacturers through FDA and otherwise. So if you do have

suggestions or ideas, you know, please make sure we hear about them from DOH to be able to share so thank you.

[Phil]: Yep, thank you Kathy. Question maybe for you Heidi, there was a situation the other day this person experienced where a patient came in and had already received a primary series and a booster dose and they were coming in for their bivalent vaccine and they were accidentally given another primary dose of Pfizer. What should be done in this situation?

[Heidi]: Yeah, this is actually right on with the example that I gave earlier and it does continue to happen because the vials look so similar. I'm hoping that they come out with something a little bit better, but what happens then is they just have to wait two months from the last dose and then they'll be able to get their bivalent booster if that's what they want.

[Phil]: Okay, I think we have time for one more question that Trang marked for me. Why are we continuing to administer monovalent vaccines with the availability of the bivalent vaccine?

[Heidi]: That question was posed during the ASIP meeting and they're still working on the safety efficacy and also really more importantly, the monovalence work, they're working right now. So it's good to have that primary series. That's basically what ASIP was saying is they're working right now, they wanna continue with that and then adding on the bivalent creates a better coverage is what they were explaining.

[Phil]: Okay, thank you very much everybody. That's about all the time we have for today's webinar, but we appreciate it. Like I said, make sure you go to our our DOH website and you can search for vaccine training and you can find the links to this webinar webpage. We've got the PowerPoint available for download and everything else on there. So if you do have any questions, especially about continuing education, make sure to email Trang, her emails listed down there and you'll also have access to my email from Zoom so you can also email me as well with any questions you have. So thank you everybody and I hope you have a great day.

[End of webinar transcript]