

Good afternoon, I'm Commander Ibad Khan, and I'm representing the Clinician Outreach and Communication Activity, COCA, with the Emergency Risk Communication Branch at the Centers for Disease Control and Prevention. I'd like to welcome you to today's COCA call, COVID-19 Update: Clinical Guidance and Patient Education for Bivalent COVID-19 Vaccines. All participants joining us today are in listen-only mode.

Free continuing education is offered for this webinar. 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 products or products under investigational use. CDC, our planners and presenters, wish to disclose they have no financial relationships with ineligible companies whose primary business is producing, marketing, selling, reselling, or distributing healthcare products used by or on patients. Content will not include any discussion of the unlabeled use of a product or a product under investigational use. CDC did not accept financial or in-kind support from ineligible companies for this continuing education activity.

At the conclusion of the presentation, participants will be able to accomplish the following. Discuss current data on effectiveness of COVID-19 vaccines. Review current recommendations for bivalent COVID-19 vaccines. And describe strategies for communicating with patients about COVID-19 vaccination.

After the presentations, there will be a Q&A session. You may submit questions at any time during today's presentations. To ask a question using Zoom, click the Q&A button at the bottom of your screen, then type your question in the Q&A box. Please note, we often receive many more questions than we can answer during our live webinars. If you're a patient, please refer your questions to your healthcare provider. If you're a member of the media, please contact CDC Media Relations at 404-639-3286 or send an email to media@cdc.gov. We have introduced self-knowledge checks throughout the presentations. We hope you enjoy these opportunities to assess your understanding of today's session. Please do not type your answers into the Q&A box, as this may disrupt the Q&A portion at the end of the session.

I would now like to welcome our presenters for today's COCA Call. We are pleased to have with us from CDC's National Center for Immunization and Respiratory Diseases, Lieutenant Commander Ruth Link-Gelles, the Program Lead for COVID-19 Vaccine Effectiveness. Dr. Alicia Hall, the Lead for the Clinical Guidelines Vaccine Policy Unit, and Mr. Richard Quartarone, Acting Communication Team Lead in the Immunization Services Division. I will now turn it over to Lieutenant Commander Link-Gelles. Lieutenant Commander Link-Gelles, please proceed.

Hi. Good afternoon. I'll be presenting today on some updates on COVID-19 mRNA vaccine effectiveness. The data that I'll present were published in CDC's Morbidity and Mortality Weekly Report the week before Thanksgiving, so if you're interested in more information on the methods or how the study was conducted, you'll see the link to the study itself down at the bottom of my slides. Next slide, please.

So, this study was conducted using data from the Increasing Community Access to Testing, or ICAT, partnership. This is a national community-based drive-through COVID-19 testing platform that uses pharmacy-based testing, so if you've gone to get a COVID test at a CVS or Walgreens or one of a number of other national and regional pharmacy chains, your data may have appeared in this data set, all de-identified, of course. These data -- sorry, these patients, when they go for their COVID-19 or their SARS-CoV-2 test, they do self-report a vaccine history at the time of registration, and we exclude from the study anybody who does not report a vaccination status. This study used what's called a test-negative case control design, and essentially, what that means is that we take people with COVID-like illness, so persons with one or more COVID-like symptom, including cough, respiratory disease, fever, and so on, and if they've tested positive for SARS-CoV-2, they're considered a case in our study. If they test negative for SARS-CoV-2, they're considered a control.

So essentially, we're comparing people that showed up for testing because they had respiratory virus symptoms, and then looking at people that did and did not test positive for COVID-19. In this case, we've excluded anyone who reported having an immunocompromised condition, and we've adjusted for the demographics and other variables shown here on the slide, including basic demographics, race, ethnicity, and age, social vulnerability index, which is a measure of the sort of socioeconomic status of the area where the test took place, underlying conditions, so the presence or absence of an underlying condition that was not immunocompromising, state of residence of the person tested, pharmacy chain conducting the test, local virus incidence, so we looked at cases per 100,000 by zip code, and date of the testing.

We also excluded individuals from this study if they reported a positive test within the last 90 days before their current test, and that was just done to ensure that we weren't counting the same episode of COVID-19 twice in our dataset. Down at the bottom of the slide, you'll see the period for analysis. In this case, we were looking at the era of bivalent vaccinations, so we were looking at people who showed up at a pharmacy for testing between September 14th and November 11th, 2022. And it's important to note that this represented a time where VA5 was the predominant circulating variant, but we did include some weeks where we are sort of in this variant soup, if you will, of BQ1, BQ1. 1, and BF7, and other circulating viruses. Next slide.

So, moving on to the results of our analysis, so we were looking here at vaccine effectiveness of a bivalent booster against symptomatic infection with SARS-CoV-2, and this slide shows absolute vaccine effectiveness, which means the comparison group here is individuals who have never received a single dose of COVID-19 vaccine. So, we were looking here at complete schedules, including a bivalent booster, so that's people who received two, three, or four monovalent doses, and a bivalent booster, compared to people who had received no doses of vaccine.

So, across the top of the slide, you'll see the number of prior monovalent doses that a person had received, two doses, three doses, four doses, and then on the far-right column, you'll see we've lumped all of those individuals together, so two, three, or four doses of monovalent vaccine together, and then on the left-hand column, you'll see age group. And generally, what I would say here is that we see, depending on the number of doses that you had previously received and your age group, we see vaccine effectiveness of between about 20 and 50%, which means you

have a 20 to 50% reduction in the likelihood that you'll test positive for SARS-CoV-2 if you had a full monovalent series and a bivalent dose, compared to someone who had received no doses of vaccine. Next slide.

This slide is quite a bit more complicated, so please bear with me. I'll explain it kind of step by step. So here, we're looking at relative vaccine effectiveness, which is, I think, a more complicated concept, but probably more applicable to most patients that you'll see. So here, we were looking at people who had received two, three, or four monovalent doses and a bivalent booster, and we compared those people to people who had received two, three, or four monovalent doses and no bivalent booster. So, you can think of these estimates as sort of the incremental benefit that you would get if you had already been vaccinated with the monovalent vaccines, the original vaccines, and went on to get a bivalent booster this fall. So similar to the last slide, across the top of the table, you'll see the number of previous monovalent doses that an individual received, two, three, or four doses. We've, again, pooled all of those people together in the far-right column, two or more doses.

And then, along the left-hand side, you'll again see age groups. And here, we've also added a time since your most recent monovalent dose. So here, we were looking at, for example, if someone got a monovalent booster over the summer and then went on to get a bivalent booster, they would be in that top row, the two to three months since the most recent monovalent dose. If they had received, for example, two primary series doses and had never come back for another dose, they're likely to be in the bottom row in each age category, where it's been eight or more months since their last monovalent dose, and they went ahead and got a bivalent booster. So if you come all the way over to the right-hand column, this is the column where we have the most statistical power to look at our analyses, and that's because we've pooled everybody together that has two, three, or four doses of monovalent vaccine. And so this is the most easily interpretable column.

And what you see here is a very clear gradient. The more time it's been since your last monovalent dose, the higher incremental benefit you get from that bivalent dose. And this makes a lot of sense. This is what we expected to see, because we know that, over time, your protection from your monovalent vaccine series wanes quite a bit, especially against symptomatic infection. So the people that did not get any booster doses, that waited a very long time, got their primary series, or even maybe got a booster dose last fall, and then a long period of time had elapsed, and they went ahead and got their bivalent dose, their protection from their monovalent doses had waned quite a bit. And so, they get the most extra protection.

That being said, even the group that was only a few months out from their last monovalent dose did get some added protection from getting that bivalent booster. And with the holiday season coming up, I think what's important to keep in mind here is that, you know, a bivalent booster is not going to protect you if you get it in April. It'll protect you from the winter wave of COVID if you get it now, regardless of how long it's been since your last dose. But those people that are the most out, the most distance out from their last monovalent dose are the ones that'll get really the best added protection. And most Americans actually fit in that category.

Most Americans are more than a year out from their last monovalent dose. So overall here, we know that relative vaccine effectiveness increases with the longer time since your last monovalent dose. That was expected. That's what we saw previously. And given that we know that monovalent doses wane quite a bit, we did expect to see that and the data confirm it. Generally, what we see is that vaccine effectiveness is similar regardless of the number of monovalent doses received.

So, a patient who got two primary series doses and a patient who got three or four primary series doses, they should get pretty similar added benefit from the bivalent vaccine. And so overall here, what we learned is that time since the last monovalent dose in the comparison group matters more than the total number of doses. And so I would say the message here to patients is really that regardless of when you got your last dose or how many doses you got, you're going to get a boost. But for those patients that it's been a year or eight months or more in this case since you got your last dose, and again, that's most Americans, for those patients, you're going to get the most added benefit. And it's really important to get that bivalent booster before seeing friends and family over the winter holidays. Next slide.

So we have here just a quick self-knowledge check. The question is true or false. Number of doses matters more than time since the last dose for vaccine effectiveness. And if you go to the next slide,

That is B, false. The relative vaccine effectiveness of a bivalent booster dose after two, three or four monovalent doses against symptomatic infection increases with longer time since the last monovalent dose in the comparison group. Generally, vaccine effectiveness is similar regardless of the number of doses received. And overall, time since the last monovalent dose matters more than the number of doses. And with that, I will pass it off to Dr. Alicia Hall. Thank you so much.

Thank you. Today, I'll be discussing the clinical recommendations as well as vaccination coverage for bivalent vaccines. Next slide, please.

I'll start with the overarching COVID-19 vaccine recommendations. People ages six months and older are recommended to complete a primary series. Monovalent vaccines should be used for the primary series with one exception. That exception is that children ages six months through four years who received two doses of a monovalent Pfizer-BioNTech vaccine are authorized to receive a bivalent Pfizer-BioNTech vaccine as their third primary series dose. This was just authorized last week, so we'll go into more detail on this in a few slides when we go through the schedule by age group. Next slide.

Now, for booster recommendations, people ages six months and older are recommended to receive a bivalent booster with one exception. It's going to be the same group here. Children six months through four years who receive a three-dose Pfizer-BioNTech primary series are not authorized to receive a booster dose at this time, regardless of which Pfizer vaccine, whether it's monovalent or bivalent, was administered for the third primary dose. And once we get to the schedule portion, we'll go into a bit of what this means for the booster when aging up, as that's a bit different. Next slide.

So, the authorized bivalent booster product varies by age and primary series, and this is due to what the FDA authorization allows. So, for ages six months through four years who completed the Moderna primary series, one bivalent Moderna booster dose is recommended. For the same age group but completed the Pfizer-BioNTech primary series, as I just mentioned, no booster dose is recommended at this time. Age five is a little unusual because the Pfizer and Moderna age groups don't overlap completely. One is six months through four years and one is six through five years. So age five years is kind of a little odd.

So age five and completed Moderna primary series, these children should receive one bivalent mRNA booster, can be either Moderna or Pfizer. Age five years but completed the Pfizer primary series, they should only receive one bivalent Pfizer booster. Moderna is not allowed in this case because for six months through five years, that Moderna booster dose is only authorized as a homologous booster dose. So it can't be given after Pfizer for that age. Then, ages six years and older, we get simple, this is for any primary series, one bivalent mRNA booster dose, either Moderna or Pfizer should be given.

Next slide.

So now we'll get into what this actually looks like on the schedule, and I'm going to start with ages six months through four years. And I want to emphasize these age groups are just to explain the schedule. This doesn't necessarily align with the products and formulations because, as we know, and as I just mentioned, Moderna has that six months through five years age grouping. So this is just, again, for the schedule and not for the products. So, starting with six months through four years, either Moderna or Pfizer BioNTech primary series is recommended.

I'll start with the top row. That's Moderna. This is a two-dose primary series separated by four to eight weeks, and then only a Moderna bivalent booster is recommended at least two months after the primary series. Moving to the bottom line, we have Pfizer. This is the Pfizer three-dose primary series. The first two doses are monovalent and separated by three to eight weeks. The new piece is that the third dose is bivalent, and this is administered at least eight weeks after the second dose, same interval as it was before. And a couple things to note here, for children who have already received a three-dose monovalent series, the series is complete and they are not authorized to get a bivalent primary dose. They are done.

And no booster dose is authorized for children in this age group that receive a three-dose Pfizer primary series, regardless of whether they already received a monovalent product or if they get this bivalent third primary dose. Next slide.

So, this is age five. Again, I sat this alone because it's a little different on the schedule. Again, either Moderna or Pfizer primary series is recommended. Starting on the top with Moderna, same two-dose primary series separated by four to eight weeks. For this age and for the Moderna primary series, either Moderna or Pfizer bivalent booster is recommended two months after the primary series. Then on the second line, for Pfizer, this is a two-dose primary series separated by three to eight weeks. As I mentioned, only a Pfizer bivalent booster is recommended at least two months later. The Moderna booster cannot be used in age five who received a primary Pfizer series.

One question we're already receiving a lot is that there's this bivalent booster on the schedule for children age five who received a Pfizer primary series. Can a child who completes their primary series at the younger age group, six months through four years, and then ages up to five -- can they get that bivalent booster when they turn five years? The answer is, yes. A child in the six months through four years age group who completes their three-dose Pfizer series but then ages up to five years, they can get this one bivalent Pfizer booster as long as it's been at least two months since their last dose. Next slide, please.

Next is age six through 11, either Moderna or Pfizer two-dose primary series is recommended. This is at the same intervals as just discussed on the last slide. And then a Pfizer or Moderna bivalent booster is recommended at least two months after the primary series or last booster dose. Next slide.

Next is age 12 through 17. This has not changed in this last update. So, the primary series is recommended to be Moderna, Novavax, or Pfizer. The only thing new here from the previous slide I just went over is that Novavax is now an option, and that primary series is separated by three to eight weeks, just like Pfizer. Moderna continues to be four to eight weeks. And then a Pfizer or Moderna bivalent booster is recommended at least two months after the primary series or last monovalent booster dose. Next slide.

And then finally, finishing this up is adults ages 18 years and older. So, the top line here is the same as what was just covered on the 12 through 17 slide. Primary series can be Moderna, Novavax, or Pfizer, and then a Pfizer or Moderna bivalent booster is recommended. And then on the second line here, this is different. Janssen can be used in limited situations in adults. This is just one dose followed by a bivalent booster at least two months later. Next slide, please.

And one addition for the adult recommendations is that if a person ages 18 years or older who has not received any previous booster dose is unable or unwilling to get a bivalent mRNA booster, they can get a monovalent Novavax booster dose instead at least six months after completion of the primary series. And one thing I want to emphasize here is that that piece I mentioned about they have not received any previous booster dose, this is because of the FDA authorization. FDA has only authorized the Novavax booster as a first booster dose. Next slide.

I won't go through the schedule for people who are moderately or severely immunocompromised in detail, because a lot of it is a repeat of what I just covered except with an extra dose. So, in most cases, a third primary dose is recommended. The only exceptions are for ages 12 years and older who receive Novavax primary series. This is just a two-dose primary series across the board. There's no third primary dose. And ages 18 years and older who receive Janssen, this is a one-dose primary series followed by one additional mRNA dose. If you do want the visuals, I've put those at the very end of the presentation, so those will be included in the slides. Next slide, please.

The purpose of this slide is just to highlight with the added products in the under six years age group, there are now a total of 13 COVID-19 vaccine products, two manufacturers have multiple products, Moderna and Pfizer. There's a lot of complexity here and more opportunity for errors. So at the bottom of this slide, you'll find two links. The first one links CDC's vaccine materials

for healthcare providers, which provides information on each of these products. And the second is a job aid on errors, which includes strategies to put in place to prevent errors before they happen. Next slide.

And just a couple things I want to draw your attention toward with the products. The new Moderna product for children ages six months through five years of age is supplied in a two-dose vial. These are not single-dose vials. This could cause confusion as no other vaccine is supplied in a two-dose vial. So, we recommend including the message that this is a two-dose vial containing two, 2 milliliter doses in any provider trainings, emails, newsletters that you have for your site or facility. Next slide.

And the second thing I'll highlight is that the monovalent and bivalent Pfizer products for each age group look almost identical. There are two maroon, two orange, and two gray cap and label products. The only differentiating feature is the name at the top of the label. Next slide.

And with bivalent vaccines, co-administration guidance continues to be the same. Providers should offer all vaccines for which a person is eligible. We recommend routine administration of all age-appropriate doses of vaccines simultaneously as best practice. We know from extensive experience with routine vaccines that immunogenicity and adverse event profiles are generally similar when administered together as when administered alone. And I'll just note that orthopoxvirus vaccine does not follow the same routine guidance. So you can click the link on the slide to find information on that vaccine and COVID-19 vaccine co-administration. Next slide.

And just last note, I'll say on co-administration, because we receive a lot of questions, this does apply to influenza. Providers should offer influenza and COVID-19 vaccines at the same visit if the person is eligible. With both flu and SARS-CoV-2 circulating, it is important to get both vaccines. And we know from studies specifically on the flu and COVID vaccines that co-administration has shown a similar immune response and similar or only slightly higher reactogenicity with no safety concerns identified. Next slide.

And this just lists some resources. The top one is our main interim clinical consideration, which has an infographic of the schedule, especially with these new recommendations. The younger age group is a bit confusing, so we have an infographic to help visualize this. The next one is a scheduled job aid. And finally, all the product job aids for healthcare providers. Next slide.

And now I'll just briefly talk about COVID-19 vaccination coverage. We'll start by looking at the primary vaccination by age. And I'll mention these data are from CDC's COVID-19 data tracker last updated November 23rd. Here we see that complete primary series vaccination coverage increases with increasing age. Next slide.

Primary vaccination coverage is lowest in the youngest age groups, particularly those at less than two years where coverage is only 3%, and those age two through four years where coverage is only 5%. Next slide.

Shown on this slide is primary vaccination coverage by race and ethnicity. Primary vaccination coverage disparities are observed by race and ethnicity. Next slide.

Coverage is lowest among Black non-Hispanic persons at 44%, compared with a range of 51 to 64% for other groups. Next slide.

Now transition to booster coverage, specifically looking at the bivalent booster. In general, bivalent booster vaccination coverage is low, ranging from 6 to 33%, depending on the age group. Next slide.

Bivalent booster vaccination coverage is lowest among those younger than age 65 years. Next slide.

Despite higher coverage among those 65 years and older, rates are still relatively low, and a booster is critical for older adults who are at higher risk for severe disease, hospitalization, and death. Next slide.

This slide shows the percentage of nursing home residents who are up-to-date with COVID-19 vaccination using facility-level data. The National Healthcare Safety Network collects data on nursing home residents and staff who are up-to-date with COVID-19 vaccines. For the purpose of surveillance, as of the week ending October 2nd, individuals are considered up-to-date if they received a bivalent booster or completed a primary series in the last two months or received their last monovalent booster in the last two months. These vaccination data can be reported at the person level or at the facility level. Among the subset of facilities submitting person-level data, over 99% of individuals classified as up-to-date received a bivalent booster dose. Therefore, up-to-date can be used to estimate bivalent booster coverage. So, the take-home on this slide is that as of the week ending 11-27-2022, an estimated 45% of nursing home residents have received a bivalent booster dose. Next slide.

Now we're going to flip back to COVID data tracker data. Finally, this slide shows the bivalent booster vaccination coverage by race and ethnicity, where again we observe disparities. Next slide.

Coverage is lowest among Black, non-Hispanic, Hispanic, Latino, and Native Hawaiian or other Pacific Islander with rates ranging from 5% to 8% compared to 10% to 18% in other groups. Next slide.

And now we'll finish out with a self-knowledge check. Can the bivalent booster be heterologous or mix-and-match, in other words, a different manufacturer for the primary series and booster dose? Yes, no, or it depends on the person's age and primary series. Next slide.

So, the correct answer is that it depends on the person's age and primary series. Bivalent booster recommendations do vary based on the person's age at the time of vaccination and the primary series received. Next slide.

And now I'll hand it over to Richard.

Great. Thank you, Alicia.

Now that we've talked about the recommendations and the current status of vaccination and of the illness, I'd like to talk a little bit about talking to patients and increasing vaccination, increasing prevention. Next slide, please.

So, I always like to start out with this slide just to kind of frame where we are and how we build vaccine demand and vaccine confidence. Really, a lot of this comes down to very much a building process. We start with the vaccine being accessible. We want to have enough supply. We want to have enough vaccinators. And we want it just easy to get, physically in proximity.

But from there, you know, you can have something, but it really has to be beneficial. People need to understand the health risks of the disease and the benefits of getting the vaccine. And, of course, it has to be convenient. And this means not only reducing any sort of out-of-pocket or financial costs, but social and opportunity costs as well. So easy to get to.

Do they have to make a lot of effort to make appointments and go into the office or somewhere to get vaccinated? Or is it really easy for them to get to and they're really not spending a lot of time, energy, money to get vaccinated? And, of course, it has to be desirable. This really goes along with the beneficial aspects of it. But there's sort of a setting, and this kind of blends into normative. So, this idea that it is the social norm, the common, really kind of becomes the way that we think about this. So, if it is something that you just do, something that's very comfortable, something that your friends, your peers and your social group sees as a normal thing to do, it's a social default.

Then again, that's another really key thing in getting vaccinated. And the final thing is really what's the necessity? Is the vaccine indispensable for accessing things we want to do? When we sort of take a look and compare sort of where we were a year or so ago, two years ago, the necessity sort of and the calculations that people face are a little bit different.

So, when we're talking about COVID vaccine, the necessity really drove a lot of the demand that we saw in late 2020, early 2021 with vaccination because people had to get vaccinated to get back on with their lives. And so now we're living our lives and the perception of necessity is a little bit different. So, we have to kind of reframe a lot of these discussions and a lot of how we understand COVID-19 vaccination going forward. And thinking about it, even as we begin to think about -- and not only COVID vaccine, but routine vaccines as well. Next slide, please.

So just again, to level set a little bit, when we talk about vaccination and willingness to accept vaccination or vaccine demand, we really do think of it as a continuum. And the continuum, get more demand, more acceptance, more interest in the vaccine with increasing confidence, support and desirability around the vaccine, the vaccinator and all the systems that surround the vaccine itself. So, when we look at, say, routine vaccination, particularly for children in the United States, it tends to fall in the passive acceptance, high demand range because it is very much a social norm.

It is something that people incorporate into their regular daily lives. There's very little social cost in it.

And so people just -- many people either really want it or they understand sort of the necessity of it or they just sort of do it because it's part of the process. Every time a child goes in and a young child goes in and gets a checkup to get a vaccine, it becomes part of that process. So that's kind of where, again, these behaviors and these structures fit into this continuum. Next slide.

I mentioned this idea of vaccine competence and it being built on trust and that it really comes down to not only the trust in the vaccines, but you, the providers who administer the vaccines, recommend the vaccines, discuss the vaccines, as well as all the processes and policies lead to vaccine development, licensure, authorization, recommendations for use, all the practice, everything that goes into what happens in the vaccine process. Next slide.

So, this is pretty commonly understood, commonly known that you as health care providers, your patients, parents, most trusted source of information on vaccines and many other health issues. So even initially reluctant adults who are likely to receive influenza vaccination when we study this, when they get their health providers opinion, when they get their health providers recommendation, getting that point of view across is very important.

And patients who receive recommendations from their children's health care provider are easily four or five times more likely to get their HPV vaccine for their child. And so these are data that we've gotten on specific vaccines. And so we know how important provider recommendations, provider conversations are to vaccination. Next slide.

When we're talking about building and sustaining trust, when we're talking about building that confidence, having those conversations, every conversation impacts vaccine confidence in both routine and COVID-19 vaccines. So, this includes flu vaccine, and it reinforces not only the point of view of vaccinations as prevention tools, but it reinforces that opportunity to create and build trust and support and understanding of prevention with your patients. And these conversations really happen in the personal and professional settings.

So, what you say to family members, how you frame things with friends, family -- there's a lot of social engagements happening right now. And presenting your point of view, reframing that point of view has an impact in both, say, a clinical professional setting and in your personal setting as well. Next slide.

So, I want to go through a few approaches to recommending vaccination that we found to be very effective and that we highly recommend as part of building your vaccination program. And we really talk about it in terms of not one approach, but it's really a combination of approaches. And the presumptive approach, the motivational approach, and taking a restorative approach as you go into those conversations really interconnect and support each other and give you more tools to be able to have these conversations with your patients and build vaccination into your clinical practice more effectively and in a more integrated way. Next slide.

So, with all vaccines, CDC recommends giving a strong recommendation for vaccination and using the presumptive approach. A strong and direct recommendation level sets the point of view, level sets the value of prevention, and reiterates all the value of vaccination as part of a safe, effective, trusted, routine medical system. And while this may be the end of the conversation for most, because the default really is getting vaccinated in most cases, it may be the start of the conversation for some. So, taking this presumptive approach assumes that patients will be vaccinated, it opens that conversation, sets the point of view, and it is the most important part of the vaccine conversation.

And when we're talking about the vaccine conversation, and this can be in a hospital setting, this can be in a telemedicine setting, it can be in a consultancy, consultant setting, or it can be in a pharmacy setting. Or, again, there's ways of doing this in a personal setting, just, again, framing your point of view and ensuring that people are clear about what you're recommending and why you're recommending it. Next slide.

So, the best way to understand a presumptive approach versus, say, a participatory approach is that a presumptive approach assumes that the patient will get vaccinated, whereas the participatory approach doesn't assume, and it really kind of shifts all the responsibility to the patient or the parent. The difference can be, hey, you're due for the COVID-19 vaccine today, versus have you thought about the COVID-19 vaccine? Again, this sets the point of view of what you believe, what you know, and what is represented in the medical, health care, and public health system as well. Next slide.

So, when you're using the presumptive approach, one of the things that is really important in this is understanding that it's useful and important at every stage of the clinical experience. So, this starts with making an initial appointment. When somebody may be calling in, say, I'm just scheduling my regular checkup and having that conversation and ensuring that they know that they are due for certain vaccines at that regular appointment. And making sure that staff, everybody that is connecting with a patient, every system that is connecting with a patient, is using that same consistent messaging around vaccination.

So, the doctor or nurse may recommend a vaccine and may have a very clear, strong recommendation about it, but the person who took the call to schedule the appointment, they might have said, well, you don't have to get the vaccine today. That's fine. But really, again, reiterating and putting that into your clinical flow is incredibly important. And taking that presumptive approach throughout the clinical process is absolutely critical. Next slide.

So, when we talk about the benefits of the presumptive approach and in presuming that people are going to get vaccinated, again, this is not an aggressive or forceful approach to things. It really just creates the opportunity to have that conversation with a clear point of view. And when you do it, people are more likely to accept vaccines with a presumptive approach versus participatory approach. And this is even true among individuals or groups that we might consider vaccine hesitant or first-time patients. And when we talk about hesitancy, one of the things we like to say is that assuming hesitancy reinforces hesitancy.

So, the last thing that we want to do is create a situation where we are opening up mistrust or distrust of the system, whether it be the vaccine component or another component of the health system. When you set your point of view, you're more likely to get those questions, those concerns. It's in a calm, direct way. And typically, you get a reciprocal response. So, if somebody does express concerns or have questions, they appreciate the point of view, appreciate the openness, and you create an opportunity to build and strengthen trust. Next slide, please.

So when we're talking about giving a strong recommendation, some of the skills and one of the tools that we have for delivering that recommendation is the share tool, where we share the reasons why the vaccines are right for the patient, highlight positive experiences, address patient questions and concerns, remind the patient that the vaccine helps to protect them and their loved ones, and explain the potential costs of getting the vaccine-preventable disease. We have a lot of resources on this related to adult flu and COVID vaccination, but these work pretty much across the board. And now, next slide.

Let's blend into motivational interviewing. So, this really builds on a presumptive approach. And it's an evidence-based and culturally sensitive way of speaking with unvaccinated patients about getting vaccinated. So, you never know what exactly somebody is going to come into a situation or setting with, and these tools will really kind of help frame that so that you're expressing empathy and building on and opening up that conversation with your patients to understand their point of view and give them that space to share that.

And the goal is to help people manage any mixed feelings or concerns that they have around vaccination or any other kind of healthy behavior, and help them work through the process of showing that prevention and vaccination are consistent with their values and needs. It's ideal for situations where you have concerned parents and patients, where they have a lot of questions, and studies using MI with vaccination demonstrate really increasing the intent to vaccinate and improves vaccination rates. Next slide, please.

So, the motivational interviewing is just a really quick way to build trust. And again, there's trust in the system and in our health care professionals as the conduit, as the connection, the personal connection to the health system and the public health system. This becomes really critical to that understanding and that long-term trust and the long-term habits of vaccination, in addition to the short-term. So, we really want to take four basic steps and this can be done in just a few minutes. So, we really want to be empathetic.

We want to ask permission, make sure that even though we're making a presumptive recommendation, we have a point of view, but we want to make sure that they're empowered to access information and really take control of their health, and that you're there working them through that process. We're going to apply some additional interviewing techniques and we're going to respond to questions throughout this process as well. Next slide.

So, empathy, and when we say sort of express empathy or act empathetic, it's really about being an empathetic partner through the process. It's about being compassionate, showing empathy, being sensitive to the culture, to the family dynamics, the circumstances that a patient might be in and what those effects might -- what those things might have in terms of affecting their views

on vaccination. This is not an argument or debate. It's really giving them that space and that opportunity, knowing that they are there talking to you. And if they're there talking to you, there is an inherent level of trust. And if your point of view is different than their point of view, this creates that opportunity for them to explore and open up and perhaps change or expand their point of view. Next slide.

So, as we get into this, one of the things that that is incredibly important about motivational interviewing is asking permission to share more information about vaccines. So, this could be -- well, we'll go through some scenarios in a minute. But an example is as simple as, if it's okay with you, let's spend a few minutes talking about COVID-19 vaccines, other vaccines and protecting your family. So, this again, is it okay with you? Let's talk about this for a little bit, or can I share this flyer? Those types of things really kind of create a decision-making process that kind of gets the ball rolling for them to move toward a positive decision about vaccination. Next slide.

So, if the patient indicates they don't want to talk about vaccines, I think it becomes very important to understand why, because they may not even understand all the reasons why. They just don't want to deal with it. So, you know, taking that little extra time to ask why, you know, can you tell me more about why you don't want to talk about vaccines today? They're recommended, good for you, prevent disease. And, you know, if they push back, you know, you've got to respect the patient's decision. If you're not ready to talk about vaccines today, that's okay. We'll talk about it on your next visit.

You know, we'll make sure that you have information of accurate sources to get information about vaccines for you and your family when you leave. And if they are willing to talk about vaccines at their next visit, make sure to frame it. You know, this this is about their health, about your caring for their health and helping them navigate through really what has been two years of being bombarded with all kinds of information, making it very difficult to make decisions. So next slide.

So, this is just, we're going to walk through with Judy, a primary care provider and Anna the patient through some of these steps. So again, hey, if it's okay with you, I'd like to spend a few minutes talking about COVID-19 vaccines in your family. Oh, that sounds okay. Next slide.

And when we go into motivational interviewing, it can be difficult to open the conversation, and in this process opening that conversation with open ended questions, not a yes or no. So you're not forcing them into a dichotomy.

You're really asking them to explore or give a little bit of background. So asking those open ended questions is really important. And then you want to affirm positive behavior. So if you've got in front of your chart, this person doesn't want to get the COVID-19 vaccine, but they got their flu vaccine or their children got their vaccines, really affirming that behavior and how positive that is. And then reflecting and repeating back what you hear.

Sounds like you're feeling some concerns. Can we talk about them? And then summarizing and making sure that you are understanding what they're saying, repeating it back to them and that

they're hearing it again. It is not unusual for people to say something and not fully appreciate everything that they're saying. So this process allows them to understand kind of what they're saying. Next slide.

So one way of asking these open ended questions and giving you something to kind of build on so that you can navigate through the other parts of the process is asking, you know, hey, we ask a lot of things in medicine on a one to 10 scale. On a scale of one to 10, how likely are you to get the COVID vaccine today? And then after you hear the numbers, navigate through why they chose that number, why it wasn't higher. And if it was higher and they're not getting vaccinated, you know, why aren't they getting vaccinated? The goal really is to help the patient become more comfortable and move toward higher numbers in this process. And higher numbers means more likelihood of getting vaccinated. Next slide.

So, on a scale of one to 10, how likely are you to get vaccinated? four, tell me more about why you said four. Next slide.

So, this is a situation where I think looking at the numbers on primary vaccination coverage, the vast majority of people have been vaccinated with their first two doses. I got the first two doses. I just don't feel like getting another shot.

I don't think my immune system can handle it. You know, I'm just tired of getting this. And we are hearing this kind of fatigue. I think you guys are, too. And, you know, I'm hearing that you're not seeing much benefit to the booster, and reinterpreting that back to them, because really they're kind of writing it off.

It doesn't seem like a high priority. And then this this idea of now that you've framed it and then giving this other opportunity to move to a higher number, because they're not fundamentally against vaccines, framing it. And again, we're hearing this, too. Vaccinations are a population-based tool, but there is an individual choice that has to happen. So knowing what's in it for you, explaining the benefits of vaccination, again, going back to that ladder becomes a very simple way to navigate through that. Next slide.

And then, you know, again, having that opportunity to go through and identify those issues, those things that really kind of frame the benefit for the individual and the family. Next slide.

So, responding to questions, I think this is really tough with kind of where we are right now. A lot of clinics, a lot of hospitals are seeing a lot of patients right now because of the respiratory illnesses going around. And also getting caught up on routine vaccinations and other things that have maybe not been as routinely addressed over the last couple of years. And so responding to these questions is really critical because questions are opportunities to build trust. And one of the things that is difficult, I know from my personal experience, is answering the same questions again and again. But knowing that this may be the first time that the patient has had a chance to really talk to somebody with expertise who they trust. And so they're going to have all kinds of questions.

And using that opportunity to dispel misinformation, really get people on the right track, is critical to not only building trust long term with the patient, but getting them vaccinated in the short term. Next slide.

So, the benefits you explain make sense. But what about risks? We have to really present everything, you know, framing that, you know, acknowledging. Yeah, some people have talked about these issues, but it's really not true.

This is what we know. And information that's been shared today and information on CDC website can help you navigate through those questions. Next slide.

So, the third piece of this is an area that we're beginning to really dig into a little bit more. We've really gone through, I think, collectively a lot of different types of trauma over the last couple of years, whether it be individual, community, family and friends dying, getting sick, the disruptions. And so taking the motivational interviewing, the empathetic approach one step further and taking a restorative, almost trauma-informed approach is something that we're beginning to encourage and see some value in. Next slide.

So, resources that we got have come from places like SAMHSA, where we're where we kind of go through some of the things that you can do to build a system, a restorative system within your practice. So we're talking about safety, building a safe environment. That includes sort of offering training to staff, being trustworthy and transparent.

So talking about positives and then acknowledging that there might be some risks, no matter how small. And then making the process collaborative. We saw that with that back and forth about asking permission in the motivational interviewing section. And peer support. So creating this way to find shared experiences and opportunities to improve, and then being thoughtful and understanding, recognizing any sort of historical trauma or individual trauma that might have come from any historical, cultural or gender related aspects, from consistent policies or execution of certain policies and acknowledging and affirming those realities. Those go a long way in diffusing situations and really opening people up to conversation. Next slide.

So, when we talk about communication strategies, it comes down to sort of speaking with a controlled, normal voice, creating a sense of calm, expressing kindness, patience, acceptance, engaging eye contact and positive body language and asking open ended questions and then respecting people's personal space. And again, this goes to, can I share information with you? And so, it's physical as well as mental. And we're talking about personal space. Next slide.

So now that we've kind of gone through some of those strategies, I do want to highlight some of the things that we're seeing from our various social listening tools. And so we reach out, look at news, look at social media, get information on the ground of what people are hearing. And just a couple of these themes. So, theme one, we are hearing continued concerns about availability and eligibility requirements.

You know, there's a number of vaccines and the recommendations are slightly different for each vaccine, each booster and with 13 products that can get very confusing. So, reaffirming that

vaccines are available, boosters available, it's something that we have to do quite a bit at the community level, at the individual level with our patients. Consumers are going to have questions about the safety of the booster. And again, you know, we saw a lot of questions with this new vaccine to start with. So, you have a new vaccine, a new product.

And then now we're making it new again. We're improving it. We're changing it. So obviously we're going to have questions about the bivalent booster. Even the term bivalent is not always great when talking to patients and the public. So being able to talk to and navigate through some of those concerns. And of course, consumers have questions about the effectiveness of the booster. And this goes from, you know, hey, the immunity of the vaccine wanes over a certain period of time we've seen with the monovalent booster and we also see that new variants come along.

So that really framing it from that point of view of this is to help you now, this is to reduce cases now, is an important way to navigate through those questions. And this idea that health experts are suggesting that combining messages around bivalent booster, annual flu dose might not be effective for all people. So again, you've got some data that shows the immunogenicity of both of these vaccines together to help you through that. Next slide.

So, I'll quickly go through some resources that we have. We do have a lot of these resources available. Lots of information for health care providers walking through all aspects of it, not all the way through. Storage and handling administration through the clinical encounter. Next slide.

And we have also a lot of information for vaccine education recipient. And a lot of those resources, and I encourage you to really kind of dig into this, because I know that I've noticed even on my side when I've gone in that there are new resources all the time. There are resources that maybe I've forgotten about when I'm going through and pulling stuff together as well. Next slide. We have lots of information on motivational interviewing in terms of COVID-19 vaccine as well as other vaccines. Next slide.

And information on routine vaccination as well as COVID vaccination, children and thinking through promotion of that. Next slide.

And a lot of the information on the restorative trauma informed approach came from our colleagues at SAMHSA. They have a great deal of experience in this area. And so if you're interested in that or really kind of looking at how to incorporate that into your practice, please check out their site. Next slide.

And just a reminder, this is not really sort of CDC space, but we do want to remind you that there's information, new codes, new opportunities related to billing around vaccine counseling as well as screening and diagnostics. So be sure to check those out if you're not aware of them and talk to the appropriate people to answer questions about those. Next slide.

So, a quick self-knowledge check. Which of the following is not a recommended approach for communicating with patients about vaccination -- presumptive, motivational, participatory or restorative? And next slide.

The participatory approach is the one that we don't use because it sort of puts all the burden of the decision making on the patient without any context and without the sort of the clear point of view. And we've seen through research that this approach is significantly less effective than a presumptive approach. Next slide.

Thank you.

Presenters, thank you very much for sharing this timely information with our audience. We will now go into our Q&A session. Joining us for the Q&A session is Dr. Evelyn Twentyman, who's the lead for the COVID-19 Vaccine Policy Unit. And in the interest of time, I'd like to sort of generally ask a question to our presenters, a question that we are seeing in many variations in the Q&A box, which is regarding vaccines for younger children. We're looking for a lot of answers to a lot of questions that refer to mixed primary series, kids aging up, the role of bivalent vaccination and all of that. So I'd like to sort of have the presenters please speak generally to this sort of wealth of questions we've received.

This is Alicia. I can jump in on that. So, on the COCA Call webpage for this webinar, under the additional resources, I want to point out that the second resource is a PDF that walks through with icons, how to address these different aging up scenarios, especially the new Pfizer ones, as well as a mixed primary series. So, you'll find all of those there, and additionally, I've laid those out at the end of the slides, which I do think are online at this point. So, all of those can be found in there. I'm not sure if I have time to go through in more detail.

Thank you, Dr. Hall. The resources Dr. Hall is talking about can be found on this COCA Call's webpage at emergency.cdc.gov/coca and when you click on this COCA Call's landing page, you can click on additional resources, and you'll find a lot of those resources that are being referred to posted there.

So, I want to thank everyone for joining us today, with a special thanks to our presenters. All continuing education for COCA Calls is issued online through the CDC training and continuing education online system at dceols.cdc.gov.

Those who participate in today's live COCA Call and wish to receive continuing education, please complete the online evaluation and post-test before January 16th, 2023, with the course code WC4520-121322. The access code is COCA121322. Those who will participate in the on-demand activity and wish to receive continuing education should complete the online evaluation and post-test between January 17th, 2023, and January 17th, 2025, and use course code WD4520-121322. Again, the access code is COCA121322.

Continuing education certificates can be printed immediately upon completing your in-line evaluation. A cumulative transcript of all CDC CE obtained through the CDC training and continuing education online system are maintained for each user. Today's COCA Call will be available to view on-demand a few hours after the live call at emergency.cdc.gov/coca.

A transcript and closed captioned video will be available on-demand on the COCA Call's webpage later this week. We invite you to join us next Tuesday, December 20th, at 2:00 PM

Eastern for our next COCA Call. The topic will be Ebola: Clinical Presentation, Evaluation, and Infection Prevention. Continue to visit emergency.cdc.gov/coca to get more details about upcoming COCA Calls. We invite you to subscribe to receive announcements for future COCA Calls by visiting emergency.cdc.gov/coca/subscribe.asp.

You will also receive other COCA products to help keep you informed about emerging and existing public health topics. You can also stay connected with COCA by liking and following us on Facebook at facebook.com/CDC Clinician Outreach and Communication Activity.

Again, thank you for joining us for today's COCA Call and have a great day.