**Virginia Department of Health Tele-Press Conference
on Virginia's COVID-19 Vaccine Developments
Moderator: Logan Anderson
August 19, 2021, 1:00 p.m.**

Coordinator: Welcome and thank you all for standing by. At this time, all participants are in a listen only mode until the question and answer session of today's call. At that time, you can dial star 1 on your phone to ask a question. I would like to inform all parties that today's call is being recorded. If you have any objections, you may disconnect at this time. I would now like to get the call turned over to Logan Anderson. Thank you. You may begin.

Logan Anderson: Thank you. My name is Logan Anderson and I'm a public information officer for the Virginia Department of Health Office of Communications. Today we are joined by State Vaccine Coordinator, Dr. Danny Avula, who will give an update on the latest developments with the COVID-19 vaccine.

Today's call is being moderated by an operator. So when we get to the Q&A portion of the call, please follow their instructions to ask a question. And now I'd like to welcome Dr. Avula, to share a brief update with us.

Dr. Danny Avula: Thanks, Logan. And hello, everybody. Obviously yesterday there was some breaking news from the White House about a potential or upcoming recommendation for booster shots. And I wanted to kind of take a little bit of time just to summarize what came out of that and then to talk about what that means for us here in Virginia and then obviously, as always, to open up to questions.

So the crux of the message yesterday is that in the ongoing review of data around the effectiveness of the COVID vaccine, there were three emerging

trends. First, that the vaccine efficacy against infection with COVID begins to decrease over time. This idea that over time you have a lessened effect, a lessened protective effect of the vaccine.

Second, that the effectiveness against the severe consequences of COVID, so hospitalization and death, still remains very high. And then the third is that the effectiveness of these vaccines in general, in the context of this new Delta variant, in general, is showing some decrease. So kind of three major take-homes that the ongoing data is starting to signal.

And because of that, the federal government is really moving towards some more active planning about when we might need a booster shot to increase our protection against this virus. So in addition to that, they kind of pointed out three different studies that were published in the CDC's MMWR,. The study captured a number of different data points - one from over 10 million New Yorkers that showed a progressive decrease in vaccine effectiveness from 92% down to 80% in July.

The Mayo Clinic took a segment of their population. And then there was a third study that was looking at vaccine efficacy in nursing homes. And again, you know, a lot of details, a lot of slightly different numbers in different populations, different age groups, different context. But the takeaways were very consistent. And the takeaway is again, that over time, vaccine efficacy starts to decrease.

That vaccine efficacy is still very strong in the hospitalization - against hospitalization and death. And that we are seeing decreased effectiveness against the Delta variant. So, you know, that data in addition to the data sets that Israel is looking at, the United Kingdom is looking at, and the impact of

vaccination and now breakthrough infection and waning immunity in those other countries.

But the combination of that body of evidence has really led our government to say we can expect a decrease in vaccine efficacy over the next few months. And so we need to plan for that and we need to plan a rollout of booster shots. Now they stated that September 20th would be the day that we would move forward as a nation with booster vaccinations. That is contingent on a few different things happening.

One, you know, the regulatory processes that the vaccine goes through are not changing. So that September 20th date is a planning assumption, it's a target to shoot for, but it is contingent on FDA approval on the Advisory Committee of Immunization Practice doing its, you know, neutral third party data review. And then contingent upon the CDC accepting whatever recommendation comes out.

So if all of those things happen then we will be moving forward on September 20th with booster shots for all people. And the very kind of distilled simple directive is that you will be eligible for a booster shot eight months after your second dose of your mRNA vaccine. So that is a very specific directive to people who got either the Moderna or the Pfizer. That immediately raises questions about what about the millions of folks who got the Johnson and Johnson vaccine?

And right now, there's still not enough data to make a clear recommendation on a booster. The White House does anticipate that by September 20th they will have enough of that data and be able to release a booster recommendation at that time for Johnson and Johnson. But in general, the planning assumption

that we're going to be working with here in Virginia, is eight months after your second dose. And that would start on September 20th.

So how does that then relate to the planning work here in Virginia? I think there have been some very reassuring things in kind of the top line take-home messages. One, that the federal government has very much reassured us that supply is not an issue. That there is enough vaccine for a third dose for every American. And, you know, we just need to remember that that means this will be a very different scenario than what we were working with from December to March.

Because our biggest issue at that point was not having enough supply. And that led to a lot of confusion and concern on the part of the public. This will not be that. We will have enough supply, and whenever people become eligible they will have access to a vaccine. As we start the planning at the state level the capacity numbers are really reassuring. And we looked kind of week by week at who would be eligible based on the completion - eight months past the completion of their second dose.

And as you all remember, both because of supply constraints or primarily because of supply constraints, there was a narrowed funnel of who was eligible back in the middle of December. And therefore, would be eligible around that September 20th date. And that would really focus on our healthcare workers and our long term care facility residents and staff. And that bucket would probably last for two to three weeks.

When we look at the week by week analysis we see that the highest number of eligible Virginians will happen in late December. And that'll be about 320,000 Virginians who would become eligible in a given week. Just as a point of

comparison, you know, that during the height of our vaccination effort, we had weeks where we delivered in excess of 500,000 doses per week.

And even when you start to take out those mass vaccination centers, we were able to deliver through various channels - through pharmacies, providers, health departments and health systems, about 520,000 doses at peak, when you take out those mass vaccination centers. So, you know, we can parse that in a lot of different ways. And that's the work that we're going to be doing over the next few days and weeks.

But at the state level that's really reassuring, that the peak of eligibility is far below our overall capacity to deliver vaccines. Now, the next step there is really to take that state analysis and work locally with the districts and localities, to ensure that that vaccination capacity does exist. And our role at the state level in preparation for that, is to really determine okay, how many pharmacies on the ground; what's their capacity; how many providers?

We have recruited about 2700 doctors' offices and other provider types, to become approved CDC vaccination sites. And so that will represent a tremendous channel that people will receive the vaccine through. But again, you know, when we - over the next few days we'll be doing this planning with our local partners and the local health districts to determine if any additional contracted support will be needed. So we'll have more of an update on that in the weeks to come. But in broad brushstrokes, very, very reassuring there.

I think the last thing that I'll say before we open up for questions, is that the sense that people will be eligible for boosters at the point, eight months past their final dose, the sense of urgency or emergency is very different than what we experienced when people had no protection against this virus. Your

protection through vaccination doesn't drop off overnight. It is a slowly waning decrease in effectiveness.

And so there does not need to be an urgent need to go out on the day that you hit eight months to get your vaccine. So if it happens at eight months and one week, eight months and three weeks know that you're going to have a window here you still have a fair amount of protection. So the reason for saying that is that I want Virginians to recognize that they still have a high degree of protection, a very high degree of protection against severe consequences.

And that when their turn comes up, they really can approach that in a more relaxed way and identify a provider in their community where they can go and get that booster dose. Okay. That's all I've got to start. But let's see where the questions go Logan.

Logan Anderson: Thank you for that update, Dr. Avula. Before we begin the question and answer portion of today's call, I'd like to remind everyone that our call today is focused on the latest developments with the COVID-19 vaccine. For questions regarding other topics, please email them to the VDH Communications Office. And contact information is available on our Web site at www.VDH.Virginia.gov/News.

And please remember to limit your inquiries to one question and one follow up per person, to allow time for everyone. And now we'll begin the Q&A portion of today's call. Operator?

Coordinator: Thank you very much, Logan. At this time we will begin the question and answer session. If you would like to ask a question you can dial star 1, unmute your line and record your name. And we'll be required to introduce you. And

if you would like to withdraw your question you can dial star 2. Again, it's star 1 to ask a question. And the first question that we have here today will come from Amie Knowles from The Dogwood. Thank you. Your line is now open.

Amie Knowles: Hey, Dr. Avula. Thanks so much for taking our questions. Last time you had mentioned that vaccines for kids 5 to 11 might come as early as September. I was wondering number one, if we could just get an update on that progress and then number two, where we can find information on that timeline as it progresses.

Dr. Danny Avula: Well I have not seen any new information about a 5 to 11 timeline, Amie. What I've consistently seen in public news reports is that Pfizer plans to submit its data to the FDA in September. Now if that happens in early to mid-September I think it is certainly possible that the FDA would review that data and approve vaccine for 5 to 11 year olds by the end of September.

If it doesn't - if that data submission doesn't happen until later in September, then that's going to push until October. So really, the second part of your question - where do we go to see that timeline, I mean if paying attention to the press releases that Pfizer is putting out about when they plan to submit their data.

Now the FDA review process can take anywhere from two to four, maybe even more, weeks. But I do think and here is where there is just a little bit of speculation on my part, that both in the face of the Delta variant, there's certainly been a lot of advocacy from the American Academy of Pediatrics, a lot of different groups urging the FDA to move quickly on 5 to 11. And the reality of what we're seeing right now in southern states where we're seeing

increased rates, the highest rates of pediatric hospitalization that we've ever seen due to this disease.

We're seeing a strain on healthcare infrastructure across the board, but also in pediatric hospital settings. And so I think they're just - there will be a huge sense of urgency on the part of the FDA to put everything they can on reviewing that data and getting an approval. So again, Pfizer submitting their data is the first step that will help determine the overall timeline there.

Amie Knowles: Thank you.

Coordinator: Thank you. The next question that we have here will come from Evan Watson with WVEC. Your line is now open.

Evan Watson: Hey, Dr. Avula. Thanks for talking today. Here in Norfolk at the Military Circle Mall Clinic, I talked to multiple people today who are in line for their third doses, many of which said they were immunocompromised and that's why they were here. And public health officials said that they are going ahead and providing those third doses to people who request it.

So my question being how will you determine eligibility based on whether it's immunocompromised or other factors or when people can show up for third doses and get them currently?

Dr. Danny Avula: Thanks, Evan. So let's clarify real quick, between the FDA announcement and CDC move last week, which was the addition of a third dose to the primary immunization series for immunosuppressed individuals. And differentiate that from the recommendation that we anticipate in mid-September for a booster dose for those who were previously fully vaccinated.

So the real difference there is that the - what is - what people are now eligible for as of this past Saturday in Virginia, is if they self-attest as immunosuppressed and there are guidelines that are posted on both the CDC and VDH Web sites about what that definition is - people who are actively undergoing cancer treatments; people who have had an organ transplant; people who are on chronic immunosuppressive therapy, if they're HIV positive, and untreated.

So there are a few different kind of guidelines about what is defined as immunosuppressed. And if you meet that definition then you can self-attest and say hey, I'm immunosuppressed, I need a third dose. We are trusting people at their word. We are asking them to self-attest to that. We are not requiring any kind of documentation per the CDC guidance. I think CDC's really trying to ensure as much access and not create barriers for people, to get access to that third dose.

So that is the category of folks who should get a third dose right now. People who are not immunosuppressed really should wait and, you know, again the anticipated guidance that will come out in September, is that a booster dose will be approved eight months after your final dose. So people who are not immunosuppressed and are just fully vaccinated and want that booster dose, should wait until we see the clear guidance from the FDA and we start offering booster doses to the rest of the population September 20th and beyond.

Evan Watson: Great. That answered my question about the self-attesting that you're putting kind of the trust in their word when it comes to it. And so then as my one quick follow up, will VDH be sending out any kind of messages or reminders

past September 20th of like hey, it's getting close to your eight months, you might look at this? Or is this on individuals to check when they got their last, second shot and then to sign up or enroll for eight months? Or do you even know yet?

Dr. Danny Avula: Yes. We were actually just talking through that this morning on our vaccine unit call. I mean I think there certainly is a role that we can play in looking at our database and proactively alerting when they hit that eight month mark past their second dose. And so we'll look at the feasibility of that on a large scale. I know that the private sector is already doing it.

I was talking to a friend yesterday who got an email from Walgreens that said hey, if you're immunosuppressed you would qualify for a third dose. So I think it will be a combination where different providers are probably proactively messaging. And then we'll look at - we'll continue to plan our ability to do that at the state level.

But, you know, all three of those things are probably true - that VDH will take a part of that; private sector will take a part of that. And people should just, you know, pull their record, figure out what eight months past their second dose is and then schedule an appointment or go to a walk-in clinic at that time.

Coordinator: Okay. And the next question that we have here will come from Jackie Defusco with 8 News. Your line is now open.

Jackie Defusco: Hey, Dr. Avula. I wanted to ask is - first of all, I presume that the state has the ability to verify that somebody is eight months away from their shot in the record. Obviously we talked about in the past, some people are already going ahead and getting their third dose despite not being officially recommended.

So will the state turn people away who try to come in sooner, even people who got Johnson and Johnson or anything like that?

Dr. Danny Avula: Yes. I mean I think the guidance that we're going to give all providers Jackie, is to follow the FDA and CDC recommendations. And so, you know, let's presume that those come out and those recommendations clearly state you're eligible for your booster dose after - eight months after your last dose. Like that's what we will tell providers is the guidance and then we'll ask them to follow it.

There are a couple of different ways that they could confirm that, either by people bringing in their vaccination card and verifying the date that way; by bringing in a printout of their verification from the VDH Web site; and some places will actually just check because many of our providers, their electronic medical records sync with the state database and so they'll be able to query the database that way, to confirm.

So that's going to be our stance. And we'll encourage all providers to follow that guidance. The reality is that some providers won't and some providers will actually have the leeway likely, I mean I'm guessing that by September 20th we will also see the FDA fully approve this vaccine, which then gives providers a little bit more flexibility in how they apply the guidance. So I think we'll see some variation, but probably not too much.

Jackie Defusco: And do you expect that booster doses will be part of the state employee mandate or, you know, private sector mandates?

Dr. Danny Avula: Yes. Still working through that. I think it was interesting, yesterday on a CDC call, that question was asked. And the CDC said at this time we anticipate being fully vaccinated as just the two doses, not including the booster dose. But then on the White House press conference when they asked the question, there was a little bit more leeway to say yes, we likely will consider boosted - the booster dose as part of full vaccination.

So I don't know. Jury's still out. We'll see how the recommendation comes together and I expect that there won't be any changes in the definition certainly before September 20th. But probably it'll take a little time after that to actually allow for that third dose to be administered.

Jackie Defusco: Okay. Thanks.

Coordinator: And the next question that we have here will come from Rachel Hersheimer with NBC 29. Your line is now open.

Rachel Hersheimer: Hi, Dr. Avula. My question is how is VDH going to track who's getting a third dose, so the public sees online how many people have received this extra dose.

Dr. Danny Avula: Well our - I mean the way that our system collects this information now does differentiate between first and second doses. And so, you know, we're right now putting, and maybe it's already been done actually, the fields for the third dose. So we will be able to pull down that data and report who's getting third doses. And yes, I imagine there'll be some part of our dashboard that's looking at booster dose uptake.

Rachel Hersheimer: And then just quickly, what is the difference between a booster shot and a third dose? A lot of our viewers have been confused with this wording.

Dr. Danny Avula: Yes. So that really comes back to I think the conversation with (Evan) earlier, about the FDA approval for third doses for immunosuppressed individuals, and booster doses for the rest of the population who have been fully vaccinated. So I'll just talk a little bit more about that. So, you know, different vaccines require different types of series to reach full vaccination.

So for example, the HPV vaccine requires three separate doses at a certain timeline. So what the FDA did at this review of the data in immunosuppressed individuals, so folks who met those categories that I just reviewed - cancer therapy; organ transplant; etc., is that people with suppressed immune systems didn't ever fully mount a robust immune response, and the third dose is now a part of the recommendation of the primary series.

So if you're immunosuppressed, to get fully vaccinated you should get three doses. That's what that boils down to. And that's why we use the third dose language in that context. The booster dose implies that you did mount a full immune response of full vaccination, and over time that immune response starts to decrease in strength and you need a booster dose to rev it back up.

So that's really how we're - and I probably slipped up a couple of times on this call between booster and third dose, but that's the crux of the language we're trying to parse out there.

Coordinator: And the next question that we have here will come from Anne Stewart with VPM. Your line is now open.

Anne Stewart: Thanks, Dr. Avula. My question goes back to the effectiveness - the three trends that you were talking about at the beginning. You mentioned hospitalization is still high and the Delta variant is showing a decrease or something. Can you kind of go over that one more time? You were just kind of explaining I think what the CDC or the FDA was kind of looking at in terms of...

Dr. Danny Avula: Yes.

Anne Stewart: ...when to get a booster shot. So if you could explain that slowly for someone like me who's typing it out, I'd appreciate it.

Dr. Danny Avula: No problem. So I guess the impetus for these new booster shot recommendations came from a review of a body of data that included a number of studies here in the United States. And the following of longitudinal studies here in the US, in Israel, and in the United Kingdom. And the common themes that emerged from the review of all of that data, were that vaccine protection against inception with COVID, so actually getting the disease, that protection begins to decrease over time; the idea of waning immunity.

The second conclusion was that effectiveness of the vaccine against the severe consequences of COVID, against hospitalization and death, still remains very high. So even in these studies, even as immunity wanes against infection, we were still seeing really high levels of protection against hospitalization and death.

And third, that the effectiveness of the vaccine against the Delta variant is less. We are seeing decreased effectiveness against the Delta variant. So we're seeing more infections with Delta. And if you look at the MMWRs, if you go

to the CDC Web site these were posted yesterday afternoon, you know, you can kind of read in the abstract kind of the big takeaways there.

As I said, there were different studies done in different populations and so the numbers look different. So for example, the New York studies showed that it went from 92% effective in May to 80% effective in July. So they noted a pretty marked decrease in vaccine efficacy against infection in a two month time period.

Similarly, in that same New York study, they showed that in that same timeline, they - the vaccine still offered between 92% and 95% protection against hospitalization. So that's one example. There's a number of examples in those three MMWR articles that strengthened the recommendation. But hopefully that clarifies it for you. I mean I think the takeaway really is that over time the vaccine is going to become less effective. Right now the vaccine is still very effective against hospitalization and death.

Anne Stewart: Great. Thank you.

Coordinator: And just one moment while we collect the next name.

Dr. Danny Avula: Are you still there?

Woman: We're still here. We're waiting on the operator.

Dr. Danny Avula: Okay. Okay. I didn't know if anyone could even hear me though. I thought I was on hold or mute. No more fancy piano music though.

Woman: Operator, are you still there? Okay. I'm going to ask everyone to hold just until the operator returns. We're going to look into this.

Man : Cool. Anyone there?

Logan Anderson: We're experiencing some issues. We ask that you please continue to hold on the line, and we will be back with you shortly.

Coordinator: Leanna Scachetti, your mic is open.

Leanna Scachetti: Hello. Can you hear me?

Coordinator: Yes, we can.

Leanna Scachetti: Okay, great. Hi, Dr. Avula. My first question for you is, I was just wondering if you could - you had said that September 20 was the target date for this booster vaccine shot. You had mentioned there are some regulatory processes involved. Can you just explain a little bit more in depth about what needs to happen to make September 20th work?

Dr. Danny Avula: Yes, absolutely. So, what is happening right now is that the FDA is reviewing the data around the need and effectiveness and safety of a booster dose. So, you know, they're going to look at these studies. They're going to look at the longitudinal clinical trials.

And based on what our other experts, you know, what the CDC reported yesterday, if they come to the same conclusions that, yes, vaccines are waning in effectiveness, yes, our overall immunity as measured by circulating antibodies is decreasing, we're at higher risk, and that a third dose actually

increases your immune protection, so if their data reveals all of those things, then they will make their recommendation or update their authorization.

So, once the FDA does that, then the Advisory Committee on Immunization Practices, which is a voluntary group of experts around the country, who review data and make recommendations, they will review the data. They will make their independent recommendation, and then the CDC will endorse or not endorse that recommendation.

So, those three steps, the FDA step is generally, as we've looked at the different stages of this vaccine rollout, that's the one that's taking the longest. But what we have seen is that those three things typically happen in fairly quick succession. So, for example, with this third dose for the immunosuppressed last week, the FDA had been reviewing data for some time.

They made a decision on Thursday afternoon. No, sorry, on Wednesday. We - no, that's right, on Thursday. The Advisory Committee on Immunization Practice then pulled together an emergency meeting. They met, had a vote on Friday, and within about an hour of that vote, the CDC adopted the advisory committee's recommendations.

So, it's hard to know, but I think our recent experience shows us that those things can happen pretty quickly once the initial stage of the very thorough data review that the FDA has done is completed. So, I think the White House, looking at that timeline for those three different steps, they have kind of put September 20th in the sand and said, hey, here's what we're shooting for. Now, obviously, if the FDA doesn't complete its review by then, then that data is going to get pushed back.

Leanna Scachetti: And so, my follow-up question is also, you know, thinking about the flu vaccine, there's like a new one every year that can adjust to the different strains of the flu. Are these third doses and the booster shots, have they or are they able to be altered in any way to meet the additional stress that the Delta variant is pushing? And if those changes are made, does that still make the vaccine eligible under an EUA or even a full FDA approval? Does that make sense?

Dr. Danny Avula: Yes. So, right now, these booster doses are just a third shot of the same formulation of vaccine. That's all we have currently. Manufacturers are continuing to develop new formulations of the vaccine that incorporate the Delta variant, and probably the alpha, beta, and gamma variants as well.

I don't anticipate one of those new formulations of a booster shot being ready before next year. So, we've heard very little about it. I know there are some that are currently being formulated. I don't know if they've actually started trials yet on those, but right now, it will just be an approval for a booster shot of the same formulation of vaccine.

That does open up another question that others have asked, which is, if you got the Johnson & Johnson - sorry, the Pfizer vaccine, can you get a booster dose of the Moderna vaccine and vice versa? When the guidance for third doses in immunosuppressed individuals came out last week, the CDC was very clear to say, we encourage people to get the same brand for their third dose, but if your provider only carries the other mRNA vaccine, that is fine to do that.

And so, I suspect that the guidance will be very similar on booster doses,

which will allow for, you know, some cross-dosing between the two mRNA vaccines. It will be interesting to see what the data shows for J&J, because there's two different options. Either J&J gets boosted with another dose of the Johnson & Johnson vaccine.

Or I guess the other thing we could anticipate, whether it happens in September or later, is that more data from some of what are called the cross - the mix and match studies that have been going on in other countries. So, in the United Kingdom, for example, a lot of their early dosing was done with the AstraZeneca vaccine, which was similar to J&J, in that it was an adenovirus vaccine, the same type of platform.

They started to look at immunity when you cross over from AstraZeneca to Pfizer or to Moderna, and saw some pretty good results. And so, I think we'll continue to watch those. And I do think it's possible that J&J ends up with a recommendation, either for a second J&J vaccination, or the medical term is heterozygous boosting, or heterozygous - shoot, I forgot it, but yes, heterozygous boosting, where you're crossing over to a different type of vaccine.

Leanna Scachetti: Got it. Thank you.

Coordinator: Thank you. And the next question that we have here will come from Kate Masters with Virginia Mercury. Kate, your line is now open.

Kate Masters: Thanks so much, and hi, Dr. Avula. I had one question about the availability and sort of inventory assurances that you mentioned earlier in the call. I guess, what I'm wondering is, I mean, where those assurances come from? And I'm wondering, are we now at the point where that inventory is kind of stockpiled

and will be immediately available to States? Or do you have the sense that it will be more of a manufacturing ramp up as more and more people become eligible for their third doses, the way it was earlier in the campaign?

Dr. Danny Avula: Good question, Kate. I mean, all I can really point to right now is the reassurance from the White House, where Jeff Zients, who is the task force lead, has said in multiple venues that supply is not an issue, that we have enough supply for three doses for every American.

What I don't know is how much of that is actually produced and in holding, versus how much we're relying on ongoing production for. My sense from his comments yesterday is that a lot of the ongoing production will go to serve - donate vaccine to other countries. They announced that they would be sending a total of half a billion, 500 million Pfizer vaccines to other countries. So far, they've already shipped out 115 million.

So, I don't have a clear answer to the question. I do know that right now in Virginia, we have over a million doses kind of on hand, in circulation among different providers, and we have the ability to draw down another two plus, 2.5 million doses. And, you know, looking at, at least the runway for the next two months, that's more than enough to meet that demand. But we will await further clarification from the White House about - on what schedule we can start to order down more.

Kate Masters: Okay, thank you. And a follow up, I know obviously all of this is nascent, but can you go into at all any more of the logistics around the rollout? I mean, I'm wondering if we're going to see the same like type of mass vaccination events at local health departments that we saw before.

Are we at the point now where everyone can just go into their local pharmacy, you know, or to their doctor, and get a vaccine that way? Can you explain a little bit more what those logistics will actually look like?

Dr. Danny Avula: Yes. So, maybe to reiterate what I said at the top of the hour in terms of overall vaccination capacity. When we look at eligibility based on that eight months planning assumption, eight months first or second dose, our peak of vaccination is going to be about 320,000 eligible people for a booster shot, and that'll come the week of December 26.

So, over the course of the last seven months, we have had multiple weeks where we've vaccinated over 500,000 individuals and - in a particular week. And that is largely through the pharmacy infrastructure, the footprint of pharmacies, and the work of the health departments, in conjunction often with health systems, to do large-scale vaccination events.

So, what our next step is, and let me just summarize where that leads me to, is that we certainly have a footprint that can get to the kind of volume we would need for eligible booster doses in any given week. Now, our next step of planning is to get more granular at the locality level, because there obviously is going to be some variation of capacity region by region or district by district.

So, our next step is to work with our localities and our local health departments to look at that same week by week runway of eligibles for a booster shot, and then to say, hey, where does the capacity currently exist in your community, and where might we need to augment that?

So, one of the big things that's different is that the pharmacy footprint is just massive. We've really seen over the last few months, the capacity through the federal retail pharmacy program, has really taken on. And when you look at the distribution of vaccines overall in the State, pharmacies have done the most.

We also have augmented capacity through the recruitment of providers. And so, early on, when supply was pretty constrained, there wasn't a lot that could go out to providers. But at this point, we have 2,700 plus providers who are approved vaccinators. And so, they will be a huge part, and that's different than the initial rollout.

So, between pharmacies and providers, I really do think that gets to the vast majority of the need in any given community. We've got to do a little more planning to say that with (assuredness), but that's what's going to happen in the next few days. And then again, it's our job at the State level to ensure that each community has what it needs.

And so, if we see that there's a gap in capacity or an anticipated gap, then that's when we would marshal resources to bring in contracted entities. We would talk about, do we need to set up a temporary mass vaccination structure? What's the ability of a local health department to do that for a defined timeframe? These are all of the specifics of planning that will unfold in the next week or so.

Kate Masters: Okay, thank you very much.

Coordinator: And the next question that we have here will come from Jenna Portnoy with The Washington Post. Your line is now open.

Jenna Portnoy: Hi there. Dr. Avula, you know, there are still people who obviously have not gotten vaccinated. Do you worry at all that the need for a booster will discourage people who maybe were on the fence and now will say, oh, you know, we've already had two, and now we're getting asked to get a third one down the line?

Dr. Danny Avula: Hi, Jenna. Yes, that is a really interesting question. And it reminds me of something I meant to say at the front end of this, that even though the current news is all about boosters and what planning we're going to do for the next couple of months, I don't want to lose the importance of the fact that people getting that first dose is actually way more important in the long run to progressing beyond this pandemic, that we really need people who have not yet been vaccinated, to get there.

And, you know, some of that is going to happen, right? It's going to happen because Delta is real and it is causing more infection, and as we see cases surge, that's driving vaccination. We're already seeing that in terms of our day in, day out vaccination numbers.

I think the other thing that will drive that will be as we move to a fully licensed vaccine, and again, the FDA anticipates that will be sometime in September, that full licensure will, you know, get a few people that were on the fence that they'll now feel more comfortable, but it will also lead to a number of like employer requirements and other institutions that feel much more comfortable requiring the vaccine, because it is now fully licensed.

So, that is going to drive first vaccination for a lot of people. I am sure there will be a segment of the population who does exactly what you said, where the inclusion of now a booster dose starts to, I don't know, lessen confidence in the effectiveness of this. And I think that's where we just have to keep going back to what is happening in real life, which is that we're seeing cases skyrocket. We're seeing hospitalizations increase, and the vast majority of that is happening in unvaccinated people.

And so, I think when you look at those numbers, somewhere between 97 and 99% of people who are currently hospitalized, are unvaccinated. And I think the numbers around deaths are even more stark. It just - like it's going to become more and more clear to people that this works, and that this is what is needed to protect yourself, and ultimately to protect our community. And we're just going to have to find ways to reassure around that.

I think it's also important to say to people that no vaccine is 100% effective, and no vaccine lasts forever. And so, this idea that the effectiveness of the vaccine starts to wane over time, is inherent to vaccine science. We know that from lots of different types of vaccines.

I mean, it's part of why we get a new flu vaccine every year. Obviously, some vaccines produce longer-lasting immunity, and the numbers start to look a little different when a disease isn't that prevalent. But in the face of an extremely prevalent virus that continues to change, I think it's reasonable that we adopt boosters to make sure that our protection stays strong.

Jenna Portnoy: Okay. And just to follow up on that, is - I'm sorry if you said it and I missed it, but is the third shot and the booster like the same formulation, like actually the same amount of vaccine?

Dr. Danny Avula: Yep. Same dose, same vaccine. That will likely change sometime next year. The manufacturers are currently working on new formulations of a booster shot that would incorporate new variants, but we don't have one as of yet.

Jenna Portnoy: Okay, got it.

Coordinator: And the next question that we have here will come from Sierra Jenkins with the Virginian-Pilot. Your line is now open.

Sierra Jenkins: Hi, Dr. Avula. Thank you for speaking with us today. My question is about vaccine for people who are immunocompromised. I understand it's recommended for people to get their third dose 28 days after their second dose. What if they're past that threshold? How effective is that additional dose going to be for them?

Dr. Danny Avula: Yes. Let me kind of recap that just so everybody understands, Sarah. So, the recommendation for third doses for the immunosuppressed, which is what the FDA and CDC adopted last week, is that you get that third dose at least 28 days after your last dose.

And I just want to make it super clear and differentiate that from the booster dose recommendation, which is eight months after your second dose. So, your question of if somebody is beyond that 28-day window, who is immunosuppressed, is it too late? Does it diminish the effectiveness, et cetera?

What we've seen in sort of the boosting function of vaccines is that sometimes waiting longer actually is more helpful or produces more of a robust response. It was interesting, a lot of the - there were kind of cross studies with the original recommendation of Pfizer, which was separated at three weeks, and Moderna that was separated at four weeks.

There were a number of studies that showed if you actually waited a longer period of time, like six to eight weeks, that would increase your circulating antibodies even more, so much so that the United Kingdom actually adopted a different dosing interval for those two-dose mRNA vaccines.

So, I don't know that there is clear data. There's sort of conflicting studies. But I think the takeaway is it certainly still helps, that even if you wait beyond 28 days, there's still absolutely a boosting effect of your immune system. Sorry, I should really work on my language there. There's an immune system strengthening effect of that third dose that people absolutely need to take advantage of, especially when they're immunosuppressed.

Sierra Jenkins: Okay, thank you. And I just have one basic question for my follow-up. Well, not a follow-up to my last question, but can you remind me or what is the percentage of new cases that are attributed to the Delta variant? Do you know?

Dr. Danny Avula: So, right now in Virginia, we have a somewhat limited dataset here. And the reason it's limited is because any sample that comes through the State lab, so if providers contract with the State lab or they're part of our public health investigations, all of those samples are getting genetically sequenced.

And so, close to 100% of what comes through the State lab, we are able to subtype, is this the Delta variant or not? I would need to check. We have a variant dashboard, and last I checked, there was about 80%. That may have been updated this past week. The numbers at the national level look higher. It's probably more than 90% of all the new infections are the Delta variants. And I imagine we would reflect that pretty closely.

The reason that that is not a comprehensive answer is because there's a lot of people who get tested in different places, right? They get tested at Walgreens or they get tested at their doctor's office, and not all of those samples get genetically sequenced. There is a program with the CDC where some of the bigger labs do send those samples.

So, our best guess is that we're somewhere in that 80 to 90% range, but I haven't looked at that dashboard in the last few days. So, I'll see if I can find it while I'm on the phone with you.

Sierra Jenkins: Okay. Thanks so much.

Coordinator: All right. And the next question that we have here will come from Sabrina Moreno with the Richmond Times-Dispatch. Your line is now open.

Sabrina Moreno: Hi. Thank you so much, Dr. Avula. Hope you're hanging in there. My first question, I was wondering if you can kind of speak to how much the rush for the third shot among folks who are hyper vigilant about this, might complicate efforts to get to unvaccinated people, and the anticipated challenges to avoiding the racial and ethnic disparities that we saw at the start of the rollout.

Dr. Danny Avula: Hi, Sabrina, I do think it will - well, let me first say, I do think there will be a rush of people who are ready, they're waiting. They will try to get vaccinated either as soon as they're eligible, or maybe even beforehand. And I think we just recognize that that's going to happen.

We reiterate the guidance, and really it goes back to reassuring the public at large that your immunity doesn't disappear overnight, that there is no burning emergency for you to go get vaccinated the day you get - the day you hit that eight-month mark, but that it is a slow and progressive decline in immunity.

So, you know, we're just going to have to continue to say that and to repeat that and then encourage providers to reassure their patients as well. Will that rush, which invariably will come, will that actually make it more difficult for first doses for our unvaccinated population?

And, you know, we've been at a point really since the end of May, where the demand for that first dose has really, really slowed. And we've seen an uptick recently. Again, I think that's due to the Delta variant and the increased contagiousness, and the increased concern that people have.

And so, that's driving more and more people to get vaccinated. And then I think there will be a round, and we'll probably - we're already seeing it, but there'll be a round of employer-required vaccines that will drive some of our minority populations to get vaccinated when they weren't previously considering it.

I don't - we've got a pretty long runway before we get to the high volume booster doses. So, I don't anticipate that being in conflict until probably

December. And my hope is that by December, we've reached the vast majority of our hold-outs for first doses, but we'll need to keep an eye on it.

Sabrina Moreno: Yes, and as a follow-up, across the country, health department in early summer kind of scaled back contact tracing efforts when cases began to decrease and testing numbers also dropped, but not every positive testing sample is tested for variants. And I was wondering how that might influence Virginia's ability to gauge risk and control spread, and what changes are underway to kind of address that.

Dr. Danny Avula: I think we should just assume that most of what we're seeing right now is the Delta variant. Certainly, the data we do have reinforces that. The national data reinforces that. And even in the, you know, sort of the details of our cluster investigations and case investigations, I think we - yes, we're seeing that Delta is very present. It's leading to more spread, even among fully vaccinated people.

So, how does that change things? I think we all really need to assume that the Delta variant is the dominant strain because it is, and that the recommendations that have been updated by the CDC in light of that are - like need to be followed. So, three weeks ago, when the CDC looked at the data, you know, the study they published was the one out of Massachusetts, but there were a number of other studies that showed that even fully vaccinated people could contract COVID, could contract the Delta variant and spread the Delta variant.

And therefore, we need to go back to mask-wearing in indoor setting. But that's got to be the - yes, that's got to be what we follow. That's got to be what we hold on to, that that new evidence-based recommendation is there for a

reason. Similarly, the K through 12 mask mandate. In the face of a much more contagious Delta variant, we really need staff and students to wear masks at all times indoors.

And then similarly, in light of this new evidence that the vaccine is not as effective against the Delta variant, that a booster dose will help increase your circulating antibody levels, increase your protection against the Delta variant. So, I guess the short answer to the question is, we should assume everything is Delta, and we should do the things that we know how to do to protect against Delta.

Logan Anderson: Hello, everyone. This is our five-minute warning before the end of the call. We have time for one final question. Operator?

Coordinator: Great. Thank you very much. And our next question will come from Darío López-Capera with Telemundo 44.

Darío López-Capera: Hi, Dr. Avula. Thanks very much for this briefing. My first question is, for those immunodeficient people, what are the criteria for this third dose? It will be the same as in the previous vaccination by age group, or is working in for everyone at this moment?

Dr. Danny Avula: Hi, Dario. So, for the immunosuppressed who are eligible for a third dose now, they can go anywhere. They can contact their healthcare provider if they have one, or they can go to any pharmacy Web site. There's really wide availability, or they can go to their health department's immunization clinic. But really you can go anywhere and self-attest, say, hey, I fall into one of these categories, and you'll be offered a third dose.

And the same holds true we anticipate for when booster doses get approved in September, that people will go to their outlet of choice, and won't have to go into one place or another. I think your question also had to do with like the order of who would qualify at different points.

So, no matter what, no matter when you were vaccinated, if you fall into the immunosuppressed category, so again, cancer treatment, HIV, organ transplant, all those bullets that are listed on our Web site, you are eligible now and should go get a third dose now. If you are not immunosuppressed, then you will be eligible for a booster come September 28th, if it everything goes the way we're expecting.

Darío López-Capera: Thank you, doctor. And I have another question. Doing this story today, I found a couple of cases for immigrants who have arrived in the country in recent weeks, were vaccinated with manufacturers that are not in the country, such as Sinovac, which also has two doses. Can they apply this third doses - third dose?

Dr. Danny Avula: Yes. The Sinovac has been used a lot and some of our surrounding countries. And I'm trying to - there has been guidance. I know - I'll need to get back to you on that, Dario. And I think, we don't have any clarity yet on booster doses for that. So, there is also - in addition to the approved vaccines we have here in the United States, there is a list of World Health Organization-approved vaccines.

And so, we do consider those as legitimate in certain circumstances. So, if you - like let's say we have an international student coming to a college, if they've

been fully vaccinated with one of the WHO-approved vaccines, we let that stand. I can't remember if Sinovac is on that list.

So, let me do some digging, and I will shoot you an email. But I think the answer to the part of your question is that we just don't know yet because we've not been given the guidance on what the specifics of boosters will be. So, we won't have an answer to that for a month or longer.

Darío López-Capera: Okay. Thank you, doctor. Thank you, everybody, for that email. Thank you very much.

Logan Anderson: I want to thank everyone for joining our call today. There will be an audio recording posted on the VDH Web site, as well as a written transcript, and you will be able to access those documents at www.Virginia - I'm sorry. www.vdh.virginia.gov/coronavirus/media-room.

Once again, if we were unable to answer your question today, please email them to the VDH communications office, and myself at Logan.Anderson@VDH.Virginia.gov. Thank you and have a good rest of the day.

Coordinator: And that concludes today's conference. Thank you all for participating. You may disconnect at this time.

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