

**Virginia Department of Health Tele-Press Conference on
Virginia's COVID-19 Vaccine Developments
Moderator: Melissa Gordon
April 13, 2021, 2:00 pm**

Coordinator: Welcome and thank you for standing by. Today's call is being recorded. If you have any objections, you may disconnect at this time. I would like to inform all participants; you will be in a listen-only mode until the question-and-answer sessions of today's conference. At which time, you may press Star 1 and speak your name and affiliation to ask a question. I would now like to turn the conference over to Ms. (Melissa Gordon). Thank you. You may begin.

(Melissa Gordon): Good afternoon and thank you for joining our call today. My name is (Melissa Gordon) and I'm a Public Information Office for the Virginia Department of Health Office of Communications. Today we're joined by state vaccine coordinator Dr. Danny Avula. He will give an update on the latest developments with the Johnson & Johnson COVID-19 vaccine.

Today's call is being moderated by an operator. So when we get to the Q&A part of the call, please follow their instructions to ask a question.

I'd like to welcome Dr. Avula to share a brief update.

Dr. Danny Avula: Thanks, (Melissa). Good afternoon, everybody. I, at this point, all of you have heard the news of both CDC and FDA issued a pause on the use of the Johnson & Johnson vaccine today. So we, in Virginia, are following that recommendation. We have made the decision and sent out messaging to our providers and partners this morning that we will hold off on administering the Johnson & Johnson vaccine in Virginia. That as, wherever possible that those clinics would be replacing their vaccine supply with Moderna and Pfizer and if not possible, then we would postpone until further notice.

We, I guess, I'll kind of recap some of the reasons for the pause and then talk a little bit more about how that affects us here in Virginia. Really the main cause of this was the recognition of a concerning pattern of medical conditions. So these stroke-like events that were associated with low platelet counts occurring in six women. Because of that pattern of disease that is pretty rare the have that kind of stroke in the context of a low platelet count, the CDC and FDA wanted to do a deeper dive. Look at the data.

And the real reason for the pause was not the frequency necessarily but really the establishment of the pattern. Because six cases out of (unintelligible) 8 million doses of J&J that have been administered is still exceeding rare, right, less than one in a million. But because the pattern emerged, the CDC surveillance systems is doing exactly what it's built to do. To recognize a pattern and then to make a decision to be able to dive more deeply into the data and then change the recommendations if needed.

So they've issued a recommendation for pausing the administration of J&J. The advisor committee on immunization practice will meet tomorrow and do a more thorough review of these six individual cases. And then any others that they turn out. So part of the reason for, you know, making this decision was, one, to identify if there are other cases that would fall into this category,

other individuals who had a similar stroke-like event in the context of low platelets. And then see if there's a higher incident of this scenario.

But also because of the uniqueness of treating this condition, the CDC and FDA felt like it was really important to alert healthcare providers to these instances. Because some of the normal treatments in the context of a stroke, Heparin namely, can actually make this condition worse.

And so they felt that it was important to bring this to the attention of healthcare providers to ensure that they ask about a vaccination history if they see this combination of a stroke-like event and low platelet count and to not use Heparin in the treatment of those cases.

So, we will find out more after the ACIP meets tomorrow. That is a public meeting for anyone who wants to join. I think they meet from 1:00 to 4:30 tomorrow afternoon. And what it means for us in Virginia is that we will hold off on administering Johnson & Johnson until we get more clarity and more guidance.

The impact of that here in Virginia is not insignificant. We had, as you all know, 14,800 doses coming into the state this week. Then in addition to that, about another 60-58,000 doses that were scheduled for clinics, you know, yesterday, today, tomorrow, I - that were carried over from last week. So, all-in-all we have about 30 events that amounted to about 72,000 doses of Johnson & Johnson that were scheduled for administration this week that we are now postponing.

Now in relation to our Moderna and Pfizer, you know, that accounts for less than 15% of the doses that we expected to administer this week. So, again, not insignificant, but there will still be lots of vaccination happening. In the

national context know that, you know, to date, Johnson & Johnson has accounted for about 5% of the total vaccine. So this will not impact our ability to move into Phase 2. We will still all, you know, most of the state, if you look at the map today, has moved into Phase 2 at this point. A few more districts that are planning to do that later this week. What it will do is just slow down the progress through Phase 2. We will not be able to have quite as many appointments available for first doses next week and beyond until we have more news about if we can start using Johnson & Johnson again.

I think that's probably - maybe the last thing I'll say by way of introduction and then open up to questions is what is the message to folks who have had their Johnson & Johnson vaccine? Uh, so far what the CDC is telling us is that in all six of these cases, they've identified the onset occurred within 6 to 13 days.

And so at this point, they are thinking that anybody who's more than a month out of their vaccination is likely at very minimal risk for anything like these. And then if you have had your vaccine more recently. There are several symptoms that we should all be looking out for. Those are severe acute onset headaches, abdominal pain, leg pain or acute onset shortness of breath. So those are all signs and symptoms of what we call cerebral thrombotic events. Those are clots, blood clots that would lodge in different parts of our body, would lead to those symptoms.

So, if anyone who has received a Johnson vaccine in recent weeks, have developed onset of any of those systems. They should contact their healthcare provider and see medical attention immediately.

Okay, let's open it up to questions.

(Melissa Gordon): 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 is focused on the latest developments of the J&J COVID-19 vaccine. For questions regarding other topics, please email them to the VDH communications office. Contact information is available [ADH.virginia.gov/news](https://adh.virginia.gov/news).

Please remember to limit your inquiries to one question and one follow-up per person. Now we'll begin the Q&A portion of today's call. Operator?

Coordinator: To ask a question, press Star 2. Unmute your line and speak your name and affiliation when prompted as this is required to answer. Our first question comes from (Amy Knoll) with the Dogwood. Your line is open.

(Amy Knoll): Hey yes, Dr. Avula. Thanks for taking our questions. Why wasn't this something that was caught in the Johnson & Johnson clinical trials.

Dr. Danny Avula: Thanks, (Amy). I think really because of how rare it is, right? So when clinical trial is conducted, that's typically done on the scale of tens of thousands. I think the Johnson & Johnson trial was about 40,000 total participants. And again, this is six cases out of a total of 6.8 million doses administered nationally.

So really it didn't show up on the scale of tens of thousands and it may be that it's, you know, part of what happens at this stage of investigation is trying to determine is this happening at a rate higher than you would normally expect in the population. I think the rareness of this particular event, that stroke-like syndrome with low platelet count clearly establish a pattern that concerned the CDC and the FDA.

And what may come of this is some clarity on subsets of the population who may not be recommended to get the Johnson & Johnson vaccine. So we really will have to wait and see what additional data turns up and you know if any kind of reasoning can be determined. Right now, the leading hypothesis is that somehow this particular vaccine triggers an autoimmune response where your own immune system is attacking your platelets. And that perhaps explains why it's only happening in women who tend to have a higher baseline rate of autoimmune disease.

But, you know, all that to say it's happening on such a small frequency at this point. That's why it didn't show up in the clinical trials but I will also say this is the surveillance of them working, right? The whole reporting of adverse events is exactly for this kind of scenario. In fact, you know, I was on a call earlier today where some people were asking why are we stopping with these few cases? And the answer is that right now vaccine hesitancy or vaccine safety is of the utmost importance, right? If we can't confidently have the American public believe and trust in the safety and efficacy of vaccines, that could undermine the entire effort.

And so I think the federal government is going to be more - there's thresholds to make decisions like this will be lower than it might otherwise.

(Amy Knoll): Understood, and then as a follow up, how does the pulling of the Johnson & Johnson vaccine impact vaccine trust?

Dr. Danny Avula: I think we'll have to see. I mean depending on what this additional time to solicit data and then any other information the advisor committee on immunization practice and FDA come up with, I think, you know, it will all have to do with what additional data is found and then what messaging accompanies that, right? I think it's hard to speculate but clearly pausing on

the administration of vaccine certainly will raise question marks for the public and we got to make sure that with have good answers and clarity on who this vaccine is safe for and who is should be used for if we're going to restore that trust.

(Amy Knoll): Thank you.

Coordinator: (Jenna Portner) with the Washington Post, your line is open.

(Jenna Portner): Hi there. Dr. Avula, thanks for doing this. My question is about what you're seeing today, if you know at this point, do you know how many people have canceled or didn't show up to appointments either in Manassas or any other clinics happening?

Dr. Danny Avula: I don't know that (Jenna). All I know is that, you know, about 30 total events that we had scheduled for today and beyond that are having to be postponed. So, that, those (unintelligible) was about 72,000 doses that were scheduled to be administered between today and our next delivery next week. But I don't know anything else beyond that.

(Jenna Portner): Okay, I know you talked previously about how the J&J vaccine was good for people in the hospital or transient populations, homeless folks. For now, do you have additional concerns that those folks will not - will be less likely to show up for their second dose if they switch to Pfizer or Moderna?

Dr. Danny Avula: Yes, so the J&J is the one-dose vaccine, so there won't be a second dose that's required for them. So, you know, I think, again, we'll just really have to see if it affects future uptake of the J&J vaccine by some of those populations because, yes, it's still an incredibly rare occurrence and I think until there's

clarity established about causality I think it's hard to speculate how this will impact us moving forward.

(Jenna Portner): Just to be clear, so are you thinking that populations like that like hospitalized folks for example, will not be getting vaccinated right now or will they get the Pfizer or Moderna because people?

Dr. Danny Avula: I got you.

(Jenna Portner): Previously you were thinking this is great. We have one dose. Now they're going to have to come back for a second.

Dr. Danny Avula: Yes, I think we will shift. This could be just a couple of days, right? So I think, you know, in the meantime, wherever possible, we're going to shift to Pfizer and Moderna. And then for those specific subpopulations, you know, obviously for whatever period of time we're not using the Johnson & Johnson we'll have to figure out how to coordinate to this vaccine to vaccinate as many people as possible.

So I don't think we hold off on it. I think it just requires additional administrative effort to ensure that people are getting their second dose.

(Jenna Portner): Okay, thanks.

Coordinator: (Kate Nasdus) with the Virginia Mercury. Your line is open.

(Kate Nasdus): Thank you. So actually both myself and multiple other journalists were having technical issues getting onto the call. So we missed a lot of the opening remarks. So I guess I was wondering if you can repeat those, you know, what was said before you answered the questions. And I'm specifically

interested in how this is going to affect the state planning in terms of rolling out Phase 2 because I know that last week you said, you know, you were able to move into Phase 2 with confidence because of the previous week's large shipment of Johnson & Johnson vaccine.

Dr. Danny Avula: Yes, so I'll try to recap that as best I can which is that, you know, last week received and administered large amounts of Johnson & Johnson. You know, we received about 124,000 and then another 90 plus thousand through the federal pharmacy partnership. And some of that was carried over into this week for events that were planned for today and beyond.

And then that in addition to the 15 or so thousand doses that were being delivered into Virginia this week, we had about 70,000 doses that we were planning to administer this week. So, that, those in some cases will be replaced with Moderna and Pfizer. We've already talked to a number of health directors this morning who actually have enough Moderna and Pfizer on hand to be able to replace their clinics for today. But in some cases that means they're going to have to cancel or postpone clinics late this week depending on you know, Moderna and Pfizer availability.

It won't impact our ability to go into Phase 2. If you look at the Phase 2 map, you'll see that almost every district in Virginia has already opened up to general eligibility in Phase 2. There's a small handful that we're planning to, you know, today or tomorrow and a couple that were slated to go the end of this week. The amount of Johnson & Johnson that factored into this week's vaccination is less than 15% of the overall vaccine that we were administering. So I don't think it will impact anyone's ability to go into Phase 2.

What it will do is limit the total number of appointments for Phase 2 individuals, you know, Sunday and beyond. So obviously we will max out our Pfizer and Moderna first doses for appointments and for as long as the federal government recommends, we will hold off on delivering any Johnson & Johnson.

(Kate Nasdus): Okay, and following up on that, you know, I think back in January, there's a lot of confusion among people across the state when, you know, Virginia opened the Phase 1B and at the same time our actually shares of shots really plummeted. So, you know, people were wondering well, if I'm in 1B, why am I not able to get an appointment? So what is the state's messaging on that? I mean when do you expect that Virginians across the state will, you know, be able to get a dose if they want one?

Dr. Danny Avula: Yes, I may have to do a little bit more math on that (Kate). I mean so one of the things, interestingly that we're seeing is that in many communities that have moved into Phase 2 this past week, we're actually not seeing the demand that with expected to thinking that most of the demand was likely in people who are higher risk because of their worker status or because of their age and underlying conditions.

And so, you know, we're already, if you go to vaccinefinder.org or get my vaccine, there's a couple of other platforms that have been built to look for vaccine availability. You know, there are a number of places around the state where you can go to a pharmacy today and get vaccinated. And then anecdotally what we're also hearing from our health directors is that as they made the switch into Phase 2, they're not seeing a flood of interesting.

And it's yet to be seen whether that is simply like marketing and public awareness like our people in communities not aware that they are now

eligible. And it's just going to take, you know, some more socialization word of mouth for that to get out. Or is it that the, truly, the demand is dropping off?

So I think that's true in almost every part of the state outside of Northern Virginia and perhaps the Richmond area, but otherwise we're really seeing demand drop off.

So I think it's a pretty different scenario than when we went from 1A to 1B in that the supply-demand numbers just look different. We do relative to where we were in the middle of January have much more supply even with just counting the Moderna and Pfizer. And then relatively less demand since it seems like a lot of folks who want to be vaccinated have already been able to be vaccinated.

So, I still think the end of May is a very reasonable goal for everybody who wants a vaccine. It might even be sooner than that, but that's not necessarily good news through the lens of herd immunity. I really think it just means there's less low-hanging fruit than we otherwise thought and getting more people vaccinated is going to take, you know, a much more kind of, much more of a ground game, right? Much more work out in communities doing satellite clinics, going into neighborhoods, all of that type of work which we've been doing some of and we'll very likely need to do much more of for the large part of our population who are not coming to mass vaccination sites.

(Kate Nasdus): Great, thank you.

Coordinator: (Sabrina Morino) with the Richmond Times and Dispatch. Your line is open.

(Sabrina Morino): Thank you so much. I was wondering kind of what will Virginia's next steps be in, you know, assuring that vaccine trust? Are there any plans to kind of ramp up that? Just to make sure that trust doesn't creep into, you know, feelings about Pfizer and Moderna and just, you know, what that will look like for Virginia especially as on the federal level, they're grappling with messaging challenges?

Dr. Danny Avula: Yes, we will clearly need to be really clearly state that this is specific to Johnson & Johnson. That, you know, nationwide we've had over 180 million doses of Moderna and Pfizer delivered and have not seen this pattern so far in the federal government surveillance. That Moderna and Pfizer work on a different platform. So you know, the way that Johnson & Johnson works it's called an adenovirus specter. It uses a shell of another common cold virus and that is the same platform that the Astra Zeneca product is built on. And so, some of what we've seen globally and the reason that you're also paused on the administration of Astra Zeneca, were because of similar patterns.

And so, there may be something about the adenovirus vector that we'll need to look more into and learn more about. But hopefully what we'll be reassuring to people who are receiving the Moderna and Pfizer vaccine is that it's a different vaccine on a different platform and we've not seen those patterns yet.

(Sabrina Morino): Just a quick follow-up-

Dr. Danny Avula: One other thing to put on that. I think that a big part of the reason the federal government took this step really early on, right? Like I can't state enough six cases out of 6.8 million is an exceedingly rare number of a serious side effects, right? So I think the reason they did it with such low incidents, is because everybody recognizes how important public trust is in the process in the government.

So, you know, I think they were very conservative about the decision to pause administration because they needed to - they know we need to maintain public trust.

(Sabrina Morino): Thank you so much for that and a quick follow-up. Earlier today, the CDC and FDA kind of emphasized that this is recommendation and not a mandate. And mentioned kind of you know, if a healthcare provider speaks to someone and their - and that person is still comfortable proceeding with Johnson & Johnson, they still technically can do that. I was wondering how much of a concern is that and how the state is kind of tracking that with so much Johnson and Johnson still distributed across the state?

Dr. Danny Avula: Yes, that's right. It is a recommendation and not a mandate. I think clinicians will have the choice. I think it would be hard for anybody in this current context, right? I mean this is such significant news. Again though in relative terms, these are really low rates of incidents and I think all of this is like a big risk-benefit calculation, right? So, let me just put this in relative terms.

So about 10% of the American population has contracted COVID. And out of the people, the 31 million folks who have actually contracted COVID, one out of every 585 of those have died. So, I think thinking about those odds of contracting COVID and having the severe consequence like death from contracting COVID six out of 6.8 million is really rare.

And so I think a clinical might look at that and say, you know, for your situation, your underlying conditions, your age, it's still worth it. But I think for the next few days as the federal government is testing this out, they would likely offer modern or Pfizer instead.

(Sabrina Morino): Thank you.

Coordinator: (Benton Lee) with the AP. Your line is open.

(Benton Lee): Thank you. I just want to circle back to how many Johnson & Johnson vaccines were administered in the state. Do we have a firm number on how many have been given so far?

Dr. Danny Avula: Yes, so far 184,000 doses administered.

(Benton Lee): Okay, great. Thank you.

Coordinator: As a reminder, to ask a question, press Star 1. Unmute your line and speak your name and organization or affiliation when prompted. To remove your question, you'll press Star 2. Our next question comes from (Alan Rodriguez Esperanza) with VPN News. Your line is open.

(Alan Rodriguez Esperanza): Hey, doctor. Thanks so much. I just want to be clear. You told someone just now that you still expect Virginia to meet President Biden's May 1 deadline to make the vaccine available to everyone. Are we still on track to meet Governor Northam's mid-April deadline? I believe it's April 18 for Phase 2.

Dr. Danny Avula: Yes, we are, (Alan). I and President Biden actually moved that up to April 19 as well. I think, you know, the vast majority of the state has already done that. We have about four or five districts that are planning on doing that this week. Their ability to do that not that I've heard so far. I don't think that Johnson & Johnson will significantly impact their ability to at least invite Phase 1 individuals to appointments.

So we're still on track to be all in April in Phase 2 by April 18. But, as I said, it will slow down appointment availability for the general public once we've all moved into Phase 2.

(Alan Rodriguez Esperanza): Got it, thank you.

Coordinator: (Alexander Chen) with CBS. Your line is open.

(Alexander Chen): Hi, thanks for taking my question. Can you confirm anymore details on the woman who passed away with these rare clotting side effects here in Virginia? You know, where it happened, what role the state is playing on probing that case, any details you can share on that? Thanks.

Dr. Danny Avula: So all I know thus far is that there's six cases nationally and only one of them has passed away and one is in critical condition currently. They're hospitalized. So, the six cases of cerebral venous sinus thrombosis which is the medical term for the stroke-like syndrome. And they were ages 18 to 48 and in each of these cases, this event occurred somewhere between 6 and 13 days after the vaccination.

So that's what is being reported nationally. That's all we know thus far. Again, part of the reason for this pause is the opportunity for more reporting, more information collection that happened. And so we may find in the coming days that number is higher, but we'll have to wait and see what turns up.

(Alexander Chen): And just a quick follow-up to clarify. So you're saying that you don't know of any cases right now in Virginia, but are collecting information to figure out if there are any cases?

Dr. Danny Avula: That's right, yes. On the CDC reporting Web site, there is one case of an individual who passed away within a couple of weeks of getting vaccinated. That does match up to this. We have a call into the CDC to A, confirm if that's the individual who's been counted as a death here. And if not, then should it be counted as an additional case.

Coordinator: (Heidi) (unintelligible), your line is one. Excuse, (Heidi Prazila) with NBC.

(Heidi Prazila): Hi, thank you. You said that the Johnson & Johnson only kind of just for about 5% of overall vaccinations so far but then 17% this week. So I'm assuming that we were in a ramp-up phase. And I'm curious what portion of your distribution were you expecting Johnson & Johnson to account for in vaccinating the general population?

Dr. Danny Avula: The Johnson & Johnson production has been so sporadic it's hard to know. I don't have an answer for what that number is going to look like moving forward. Johnson & Johnson said that they would have 100 million doses delivered by June. They have been off of that pace. And so for example, the first week that J&J was made available, we received 69,000 doses. That number has dropped significantly to under 10,000 doses a week up until last week when we received 124,000 doses. That number dropped to 15,000 this week.

So it's kind of been all over the map. I think, you know, the bulk of our vaccine coming in is Moderna and Pfizer. Our hope was that starting in, you know, the latest information we have is starting the last week of April or the first week of May, we would consistently be getting over 100,000 doses of Johnson & Johnson per week. So it was going to be a significant portion, probably 20 to 25% of the vaccination that we were doing was going to be J&J. And it may still be, right? Again, we'll have to wait and see what this

pause turns up. But that's probably the best ballpark answer I can give for May and beyond.

(Heidi Prazila): That's good. Thank you. And to that point, so given that was kind of a rough back of the envelope estimate there, at what point do you kind of max out? Like how long can you just be rebooking with Pfizer and Moderna without being, you know, materially affected in terms of the number of appointments, available appointments?

Dr. Danny Avula: Yes, I don't know the answer to that yet. I mean I think Northern Virginia is probably the one place where we're still seeing demand that exceeds supply. Perhaps the Richmond area. We'll see they just moved into Phase 2 and so we'll see what demand looks like this week? But almost every other and Blue Ridge (unintelligible) surrounding areas would be one other are where that is true. But almost every other part of the state at this point has plenty of supply. They're opening up appointments. They've got availability.

So, I don't know. I mean the supply/demand dynamics have changed so much, almost on a daily or every other day basis. That based on what I know today, I think we're still looking at, you know, the middle to end of May for when we saturate the existing demand. And then as I was saying earlier like the strategies we use to have people vaccinated are changing and will continue to change.

So once specific example, we know that private providers, nurse, you know, where you go for your primary care, those healthcare providers have the most influence on people who are perhaps on the fence about getting vaccinated. And so as we see the demand slowing through these max vaccination clinics, our strategy will continue to shift to getting vaccine out to those providers

where the vaccine hesitancy will have the opportunity to ask questions and to talk through this with their provider.

So, you know, that's one example of where the strategy is already changing and will happen even more as demand wanes in the mass setting.

(Heidi Prazila): Thank you.

Coordinator: (Dana Smith) with DBEC. Your line is open.

(Dana Smith): Thanks so much. Dr. Avula, side effects happen with just about every medication, vaccine. And there are other medications out there that do have blood clot risks and they're still in use. So, you know, this is affecting women. Birth control is one example. So why is there such a big concern with this Johnson & Johnson vaccine considering the rarity of side effects? Is it because they're not fully understood? They need more time to research this. Is this just the heightened awareness around vaccines right now?

Dr. Danny Avula: That's a really good question, (Dana). And I think, you know, that's some of what has been churning in social media is that this rate of side effect is actually far lower than you might expect with birth control pills as an example. But I'll come back to what I was saying earlier about the importance of the public's faith in process and in transparency. And so I think you're right. The numbers are not compelling on their own, six cases out of 6.8 million doses administered.

But the establishment of a unique pattern certainly warrants more investigation. And I think it's in both those public and the government's best interest to really thoroughly research that and be able to make a more definitive statement while, you know, there's been so much yes, concern

around the vaccine process to begin with. And so I think this is the government being both incredibly transparent and also very conservative because it needs to retain the public's trust in the process.

(Dana Smith): Very quickly, we missed the beginning because of some issues getting into the meeting. So I'm not sure if you answered this. But how long do you expect this pause to last? Have you been given any indication from federal authority?

Dr. Danny Avula: Yes, Dr. Schuchat, he's the Deputy Director of the CDC said, you know, we're probably looking at days to weeks. So, you know, I think we will have a much clearer answer on, you know, whether this is going to be an extended process by the end of tomorrow when the advisory committee on immunization practice meets tomorrow afternoon.

So it could be that they do a deep dive on the data and really don't see an increased incidents. And then say okay, it's fine to use J&J again, but it could be that they need more information and this could last several days or longer.

Coordinator: (Alexis Powers) with the Virginia (unintelligible). Your line is open.

(Alexis Powers): Hi, Dr. Avula.

Dr. Danny Avula: Hi (Alexis).

(Alexis Powers): It sounded like you just said earlier that the adverse event case and the surveillance system where someone appeared to have died from this stroke-like syndrome with a person in Virginia. Am I understanding that correctly?

Dr. Danny Avula: That is correct, yes. There was, and this is all publicly available on the CDC VEAR's Web site. The VEAR's vaccine adverse event registry. So or reporting system is what it's called. So you can go to the CDC and you can see the list of adverse events that get reported either by individuals or by healthcare providers. And that's system is what the CDC uses to identify patterns like this. But one of the cases does appear to match up with what is being described by the CDC. We just have not heard confirmation of that particular Virginia woman is who they are referenced.

So we've asked the CDC and just haven't heard back yet.

(Alexis Powers): And you weren't particularly aware of that case before this?

Dr. Danny Avula: No, not by itself. You know, there are lots of adverse events that occur around the time of fractionation and they get reported to VEARS. Sometimes depending on the timing and the circumstance around them, they get investigated by the medical examiner and then an autopsy is done. But yes, I mean I think with all of these what the investigation process is trying to reveal is, is there something that could be tied specifically to vaccinations that leads to an event? And is that event happening at an increased rate when you would otherwise expect it to?

So, you know, one case of a woman having a stroke doesn't by itself, you know, trigger a full investigation. Or even and that in local public health or state public health surveillance. Because it's happening, because it's so rare, it really does require the national surveillance infrastructure to identify those.

(Alexi Powers): Thank you.

Coordinator: (Rick Massemo) with WTOP. Your line is open.

(Rick Massemo): Hi, Dr. Azula, thanks. So yes, can you walk me through the process?

Because it just seems as a layperson these cases are something to keep an eye on, but is it in the purview of the FDA and CDC when making this decision? Is it within their purview to say well, okay on one hand we have this pattern and we have these cases. On the other, we have, you know, in jest in Virginia, we have 72,000 doses that are being delayed at least a week, 72,000 people who are not being immunized. What, how do we, you know, how do they weigh that?

Dr. Danny Avula: That's a fascinating question. I mean, I think and this is where it comes back to the risk-benefit analysis of vaccination, right? We do know that vaccines carry some risk of side effects. Those were certainly outlined at the scale they were able to be identified during the clinical trials and now, I mean I think it's trying to determine whether this particular side effect A, is actually linked to the vaccination. Is it happening at higher rates in a vaccinated population than it would at baseline?

And then does the risk of that outweigh the actual risk of contracting COVID and being hospitalized or dying from it. And I think these are all the questions that the federal government seeks to answer in the next few days and doing the data gathering and doing the deeper dive with that.

And then in the meantime, because of the context around vaccine hesitancy and the need for public trust, they felt the more conservative course of action was to issue the recommendation. So we'll see. I do think there probably will be cases where, you know, local providers may opt to continue using the Johnson & Johnson vaccine particularly in higher-risk individuals. And we wouldn't necessarily bar them from doing that, but we will extend the same recommendation as we seek to figure this out.

(Rick Massemo): Okay, thanks. And one other thing, so if somebody's Johnson & Johnson appointment is rescheduled, do they go maybe not to the back of the line but like are people, let's say for example, Johnson & Johnson shots resume on Monday. If you had an appointment for tomorrow or Wednesday, are you getting a report on Monday or the people who had appointments Monday going to keep them? And you have to wait longer than that.

Dr. Danny Avula: I don't know that I have a great answer to that yet. I mean I do think again in almost every part of the state there is plenty of capacity and so that's not really going to be an issue outside of Northern Virginia and a couple of other places. I think one thing we can look at if we do get an answer that quickly is how do we - like we'll have the vaccine on hand. And so then it's just a matter of growing capacity to be able to reschedule those with other providers.

And in many places, you know, they were operating under capacity. I'll just give the example of the Richmond Raceway here in the Richmond area. You know, they're doing somewhere around 10,000 a week, but have the ability to do 25,000 a week. And so I think it's very likely in most of the parts of the state where this has been an issue that they'll still be able to - we'll just increase capacity because we'll have the additional doses on hand.

(Rick Massemo): Sure, but Northern Virginia, that's a lot of people.

Dr. Danny Avula: Yes, I know. That's true. So we, I mean we are looking at increasing capacity there anyway. I mean I think we've been in the, well we have been planning community vaccination site up there over the last couple of weeks and are just really working out the allocation to make sure that we can commit to a 45-day operation there which is what (unintelligible) FEMA, (unintelligible) contract requires.

So we are slated, I'm hoping two weeks from now. We may be able to ramp that up particularly if the allocation comes in soon.

(Rick Massemo): Okay, great. Thanks.

Coordinator: (Cameron Thompson) with WTVR (unintelligible). Your line is open.

(Cameron Thompson): Thank you Dr. Avula. Just to circle back to this one case that you're trying to determine. I'm just as you were speaking pulling up the VEAR's information. Can you say roughly more circumstances, dates of the vaccine administration that you're looking into and just sort of where in this state this occurred? How long after vaccine (unintelligible) this death occurred?

Dr. Danny Avula: I don't know details of where the person was. All I know is what and I don't even... I don't actually even know what was listed in the report there. It was flagged by somebody on our team earlier today which is why we then solicit a question. But I think it was a woman in her 30s and who had, you know, similar thrombus embolic event that was listed on eh VEAR's site.

And so because both the gender and age range and the actual symptom matched up with the CDC reporting, that's what led us to say, to send it up to the CDC and say, hey, is this one of the ones you're looking at?

(Cameron Thompson): Got you. And just because this recommendation came down so, you know, quickly and I know there were some events this morning regarding, again, I know you said roughly 72,000 vaccines were earmarked. Were any already drawn and ready to grow and then ae being lost because of this

decision to put pause on this because they can't be salvaged for lack of a better term?

Dr. Danny Avula: I don't know for sure. Johnson & Johnson is a refrigerated vaccine. So unless the vials were actually opened, that would be pretty unlikely. And we made the decision very early on. I mean the news broke at what, 7:20 and within 20 minutes, we had issued a directive to the local health departments and to the pharmacy providers. So I think, you know, it's possible. Like I just said I don't know the granularity of what's happening around the state, but we made a pretty rapid decision. So I'd be surprised if people were already into their clinics at that point.

(Cameron Thompson): Got you. Thank you.

Coordinator: (Carol Vonn) with (Eastern Shore Post). Your line is open.

(Carol Vonn): Yes, well I was going to ask you if you could give data on, you know, major adverse reactions reported. I'm trying to make my way through this vaccine adverse event reporting system that, I mean I'm specifically interested in whether any major adverse reactions for any of the three vaccines were reported on the Eastern Shore and the local health departments said ask you. So I don't know if you can give that or not.

Dr. Danny Avula: I don't know it off the top of my head. So I think, you know, I'd have to defer to our Epi team who's doing that surveillance. And then ultimately, really to the federal government because the CDC is the one who'd looking for those trends at the national level. The, I mean I think there's a number. Because it's either self-report or a family report or a health provider report, there's a number of instances on there where there was a death that happened within a few weeks or shorter of vaccine.

In many cases those were, you know, elderly folks who may have died anyway. And I think that's where you really need the broader lens of a national surveillance system to look for and identify those patterns. But I mean it is ultimately this is the work that the CDC does in monitoring adverse events. So yes, I think we'd have to ask the CDC (unintelligible).

(Carol Vonn): Okay, thanks.

Coordinator: (Tom Alapa) with (unintelligible). Your line is open.

(Tom Alapa): Thank you. Just wondering if the pause continues into next week will Virginia continue to get shipment from J&J or would those also be halted? And also how long can they exist in vaccine doses remain viable before we need to get rid of them?

Dr. Danny Avula: They are good until their expiration date which I think is a couple years out. I actually pass that question to a member of the team and still waiting on an answer for that. So I don't think there's any short terms expiration that we need to be concerned about unless this is a, you know, a - yes, I think - in any scenario where Johnson & Johnson comes back online, we'll be able to use what has been distributed.

The first question (Tom) about whether we will still receive vaccine, I'm not 100% sure. Did not sound like it. I was on a call earlier today and it sounds like they're going to hold back on the Johnson & Johnson distributions at least for today until they have more information. That might change. There's a call later this evening with the White House. So I'm not exactly sure yet, but so far it sounds like they're going to hold off on distributing J&J this week.

(Tom Alapa): Thanks, and then any thought to the possibility of going just to the first dose of Pfizer or Moderna for as many people as possible and worry about the second doses later? I know that's something that's been raised from time to time is this (unintelligible)? Are you any close to considering that or is that not really an option?

Dr. Danny Avula: I mean the recommendation around both (unintelligible), you know, were really around where are you getting optimal efficacy from the vaccine. I think, again, I don't see that recommendation changing unless there's, you know, FDA or CDC guidance that would support it.

I mean theoretically extending it out. So the CDC has already offered, you know, a six-week window, a 42-day window for that second dose above or beyond the three or four-week recommendation. You can extend that out.

So that's a possibility. I mean I think we'll just have to look at the demand numbers and see if that would even be warranted, right? Because Moderna and Pfizer do account for the vast majority of our vaccines coming in. And with demand dropping the way that it is, that may not even be necessary. So we'll await federal guidance on that.

Coordinator: (Kate Nasdus) with the Virginia Mercury. Your line is open.

(Kate Nasdus): Thank you. I just wanted to circle back with a couple of follow-up questions. And one is just trying to understand. I know you've gotten a lot of questions about the gas or adverse event that was reported. But is that - so that's something that is believed to be, you know, a similar side effect that the CDC and FDA are currently investigating. And then do we know the timeframe in which that happened or when it occurred?

Dr. Danny Avula: Yes, she passed in the middle of March and the specific thing that's listed in theirs is like, I'm not looking at it, but I think it says something like a thrombo embolic event. So it doesn't match you with the CDC is flagging as the symptom of concern. But we really don't have any details beyond what was reported in VEARS.

(Kate Nasdus): Okay, and are we sure that it was a woman in her 30s?

(Melissa Gordon): I think that's, I know it was a woman. I'm not 100% on the age, but this is listed in VEARS. But I don't know.

(Kate Nasdus): Okay and a follow-up more related to distribution efforts, I'm wondering, you know, you mentioned that in areas other than Northern Virginia and maybe who (unintelligible). It looks at, you know, demand is declining. So I'm wondering if VDH, you know, is going to issue a statewide policy around walk-in clinics and whether district can, you know, begin district pharmacies, hospitals, whatever can begin offering vaccines on a walk-up basis for folks who want them.

Dr. Danny Avula: Yes, are considering that. I mean I think what has been happening in (unintelligible) this past week where they have piloted that, right. So the FEMA site there we used walk-up registration. So if there was availability for somebody to be vaccinated with, at the time that they walked up, we would vaccinate them. And if not, they would just make an appointment for a future day and come back.

So I think that scenario is certainly worth expanding. We've done that in a couple of other locations. And then places where you're not seeing much demand, but there are, you know, there is vaccine, then that makes a lot of sense. I think what we - so the short answer is yes, we will move more and

more in that direction and what we want to just avoid is situations where people come and then have to wait incredibly long periods of time or were not able to plan the (unintelligible) of vaccine that needs to happen before it's ready to go.

So there are some logistical situations, but I do think for multiple reasons certainly demean the issue, but also the fact that, you know, walk-up just may be a better option for some segments of our population that we will expand the use of that.

(Kate Nasdus): Great, thank you.

Coordinator: (Jenna Portner) with the Washington Post. Your line is open.

Dr. Danny Avula: (Jenna), you there?

Coordinator: Ms. (Portner), you may need to check the mute button on your device.

(Jenna Portner): I'm actually all set now, thank you.

Coordinator: (Desire Montia) with WWBT. Your line is open.

(Desire Montia): Thank you. Hi, Dr. Avula. I apologize for the questions in advance. We did have a lot of technical difficulties trying to log into this call, so we missed the first half an hour. Can you walk me through, again, I guess the number of doses that are lost because of this pause and little bit about the number of Johnson & Johnson vaccines distributed in Virginia?

Dr. Danny Avula: Yes, (Desire). Just so this will be recorded and sent out in about an hour so you can catch what you missed. But the J&J allocation that we were

expecting this week or that was delivered this week was 14,800 doses. That, in addition, to some of the J&J that was distributed last week was being held for about 30 different clinics this week and 72,000 appointments. Now some portion of those will be, the J&J will be replaced by Moderna and Pfizer. So we won't lose all of that. Like we'll still be able to vaccinate at many of those sites.

But I don't quite yet have a rate on how many doses can be replaced with Moderna and Pfizer. And then depending on what the federal government offers after the advisory committee on immunization practice is meets tomorrow, we may just be able to kind of swap those out and push the J&J vaccine to later, vaccination to later in this week. Or we may have to hold off for longer.

(Desire Montia): Perfect, thank you.

(Melissa Gordon): Hello, everyone. We have reached all of our questions for this conference call. I'd like 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. You'll be able to access these documents at (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. Thank you.

Coordinator: Thank you for your participation in today's conference. You may disconnect at this time.

END