

Transcript for NC DHHS COVID-19 Vaccine Webinar

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Presenters:

Dr. Betsey Tilson
Dr. Charlene Wong
Dr. Kelly Kimple
Dr. Amanda Fuller Moore
Hugh Tilson

Hugh Tilson

All righty, let's go ahead and get started. Good evening everyone, and thank you for participating in today's webinar to update providers on North Carolina's COVID-19 vaccination plans. Its webinars put on by the North County Department of Health and Human Services and supported by North Carolina AHEC to provide relevant information timely information about the state's COVID-19 vaccine plans and will provide a forum for you to ask questions of DHHS leaders. My name is Hugh Tilson I'll be moderating this evening. There's a ton of great information coming your way so I'll be brief, want to start by thanking the DHHS team for all they're doing for making time in their crazy busy schedules to provide this information for us tonight, really, really appreciate it. I will make these slides available on the NC AHEC website as soon as possible. And when they are available, we'll put a link in the q&a so you can copy those. A couple other kind of quick adjustments as you can adjust the proportion of the speakers and the slides by dragging that double gray line between the slides and the speakers. And then you can also adjust your video settings to hide people who aren't speaking, click on the View button on the top of the screen and select side by side speaker. And that means you'll just have the slides in the speaker and that can minimize some distractions, we'll have time for questions at the end we hope so, two ways you can submit your questions. First, just know that everybody is muted so you can use the q&a feature on the black bar on the bottom of the screen to submit a question. The other is submitting an email to questionsCOVID19webinar@gmail.com. And if you've called in that's the only way you can you can submit a question. I'm gonna turn it over now or state's health director chief medical officer. Dr Betsey Tilson so she can introduce herself and the DHHS team.

Dr. Betsey Tilson

Wonderful. Thank you all very, very much for joining us for another evening webinar and we're also very grateful to our AHEC team for so beautifully helping to moderate this. And for all of our professional society to really you're able to get this out to many of our providers across the state. Very grateful for that partnership across the state. We have a lot of stuff for you tonight there's been a lot of movement a lot of things going on. And so we'll we'll jump right into it but first I just want to also introduce some of my fellow teammates who will be. Some will be presenting and some also available for questions as we

go through. We have Dr Amanda Fuller Moore who is our public health pharmacist and one of our operational leads for our vaccine distribution plan we have Dr Charlene Wong as well. Who is Chief for health policy. And then we also have Danielle Brady who is on our CVMS team as well. So I apologize that we also have Dr. Kelly Kimple, who is the section chief for our women's and children branch and also our children. Women's and Children's section and our immunization branch as well and so very instrumental in our vaccine work. So we'll be with you tonight tag teaming on different topics. We're going to do some quick hits to update some of things on our on where we are with distribution some of our prioritization on our equity on CVMS and some communication tools but spend the most chunk of time on really some nuts and bolts of providers and rolling activating and then once you're actually activated, how do you actually need to receive allocation because there's a fair amount of complexity there. And we also want to spend some good time on the new Johnson vaccine as it was just authorized to make sure you have up to date information on that.

Okay. And with that, please advance to the next slide. Okay, we'll just do a really quick, quick update on distribution, distribution and then some allocation updates. Next slide please. Alright, so a little bit of good news. Well, we actually have a lot of good news but I really love this slide a little bit of where we are in terms of our two monitors are fast and fair, we want to get the vaccines out fast and also fairly so this is the first fast piece. I hope many of you have bookmarked our, our dashboard where we have the status of our vaccine distribution on that dashboard. One of the things we look at very closely is the percent of first doses that have come into the state that have been actually administered we asked our providers to do that within five days. And that's the line that we look at. That's what you see as circled that percent of first doses, we call our vaccine week Wednesday through Tuesday that vaccines, in general, come into the state on Wednesday and we want them all administered by that following Monday or Tuesday. So you can see today then Tuesday at 99% of those first doses have been administered so we're very so grateful for our providers for for working so hard to make that happen. We have administered more than two and a half million doses so far in North Carolina. On the right hand side you'll see the CDC dashboard looking at states and the percent of first dose delivered and you'll see that we're in that top tier the dark purple, percent of first doses administered so we're very grateful for our providers that made that happen on the bottom right. The other thing I want to call out is this week. There was a report by the Kaiser foundation and highlighting that North Carolina is the top state in the percentage of folks 65 and over that have been vaccinated. So that's been a huge priority for us and our providers, really made that happen and we're leading the country and our people 65 and over being vaccinated, which is really important because 83% of our deaths have been in people 65 and over so this is a really important focus. For this first prioritization wave. So thank you all for being really instrumental to that success.

Next slide. And then what actually happened when you vaccinate people and our epidemiology team has brought this forward and it's so exciting to see this data but it actually matters. Yay. So on the left hand side will one I hope you all know that our overall case rates are coming down. Now we still have a high level of virus spread across the state. We can't let up on our three W's prevention we still are hardcore in prevention mode, but some really really nice trends, if you look at the case rates that kind of medium blue is our 65 year. 65 years and up, and you can see an even more steep decrease in the cases

in our 65 and up in that blue, and you can see it's actually now at the same level as our pediatric population has always been our lowest case, case rates, and now our 65 year old is on par with our pediatric population which is huge, so we can see that big movement in that 65 and up the other population that we've been very intentional about getting to is our long term care, especially at skilled nursing facilities and that was a huge source of outbreaks. And on the right, the top right on that you'll see that basically the cases linked with skilled nursing facilities have come down, incredibly quickly, as well as the number of outbreaks in our skilled nursing facilities really precipitous drop in those high risk settings so it's so exciting to actually see that that data and the effect of vaccination so thank you all for being part of that and wanted to share some of that really concrete good news. Go team. Okay. Next slide.

Great, and other news to share with you, and Dr. Fuller Moore we'll talk a little bit more about this, specifically around the j&j but the other good news is, although we still have a limited supply of vaccine, it is increasing, which we had talked about like right in the beginning this can be really tight, but then the supplies will be increasing so we're excited about that. We did have a really big week last week with our vaccines because some of you may be has remembered that with all that weather delay across the country. We had a week where we didn't get vaccine and then we got double amount in one week. So, our providers had a lot of work. This week and next and last week of getting a bunch of vaccines into arms about double amount but also we're getting increase allocations, and both on the Moderna and our Pfizer, which is really nice. So we're getting more state allocation. And we're also then going to get new allocation with our j&j vaccine so another 83,000 coming from j&j. So we're really, really excited about that. So not only are we getting, we're getting increased state allocation, but also and then a new vaccine on the way, but also we are getting increased federal allocation coming to the state as well and we're seeing that in a couple different places. One we're seeing increased federal allocation coming in to the federal retail pharmacy program so coming into Walgreens, and then starting to come into CVS, we are going to have a big FEMA site, set up in Greensboro that's going to run for eight weeks. 3000 doses a day for eight weeks. And that's directly from federal allocation and also we're going to get federal allocation directly to some of our federally qualified health centers. So we're seeing not only increased state allocation but also direct federal allocation coming to the state, and a new vaccine. So, although our supplies still are limited they are increasing and so we're very excited about that and we've really been able to speed up some of our work and moving through a part prioritization groups because of the increasing supply. We're really excited about it.

Next slide please. Okay so that gets us into some of the updates and maybe some of you would heard, though there was a press conference today the governor and the Secretary was reporting on our moves for our prioritization, but wanted to update you on that. So, next slide. Great. So some of you may have heard that we had already been, we had opened to our front our first group of frontline essential workers that was our folks in childcare, and in school settings. But instead of waiting till next week to open up to the rest of frontline essential workers that group will be opened up, as of tomorrow we're again seeing more vaccine. And some of the demand was decreasing. So we're able to open that up a week earlier so we're very, very excited about that. And you'll see all the updated information and deep dives on our on our website. Next slide please. And there's a couple other changes as well that I wanted

to call your attention to. So first, in group one if remember group one our health care workers those involved in vaccination plans and also those in long term care. One of the things I wanted to call your attention to is that we have expanded somewhat the definition of long term care. Originally it was restricted to settings that were considered long term care and we've expanded that definition to say. Also within long term care or people who are receiving long term home care, as defined by receiving services for more than 30 days or more. And those services are home or community based services for people with intellectual and developmental disability. Private duty nursing personal care services and home health and hospice for people who are receiving long term home care as defined by the services we offer them now are considered long term care and are eligible for vaccination. This will allow us to get some of our most medically fragile people vaccinated in that group one.

Second change as I mentioned is that we are opening up that second phase of frontline essential workers tomorrow. And then the third change is in terms of group four. So one, we, we did the math we looked at the allocations did the math, and are planning to open up to group four starting March 24, but we're going to open it up in two phases. The first phases will be people who have a high risk medical condition. And again this maps to that CDC list of high risk medical conditions, and also including people experiencing homelessness or living in a homeless shelter, and people in a correctional facility who have yet to be vaccinated that will be the first part of group four. And then the next part of group four will be people living in lower, lower risk people living in group settings so this will be our students and congregate housing like in dormitories. And then other essential workers, non frontline essential workers will be that next phase of group four since it's such a big group. And then finally we just did a little bit of adjustment for the definition of high risk medical conditions that we've included already included people with Down syndrome, but we also included people with IDD intellectual developmental disabilities including Down syndrome so opened up that category just a little bit. And then also made a little bit more intentionality, the CDC says neurologic conditions such as dementia, and we intentionally added schizophrenia also in that category as there is good data that people with schizophrenia, even if you correct for other confounding factors have high risk of morbidity and mortality. So, those are some of the adjustments that we did, kind of, or the expanded definition of long term care, increasing the pace of group three and then some slight adjustments on include for and when we're going to open.

Okay, great. So that's some quick hits on all of that, then I'm going to turn it over so we want to be fast, but we want to be fair, and so Dr. Wong will talk through some of our equity equity story and work.

Dr. Charlene Wong

Right. Thanks. Next slide. All right, we are doing a lot of work in the equity space and we can organize this in two areas and as you may know many of you all are that are vaccine providers and are really working alongside us in thinking about how we earn trust our historically marginalized communities as well as how we embed equity in our vaccine operations. So just a few things to highlight here in earning trust, so much around communications wanted to make you all aware we have a continued partnership with the ACORD group which is out of North Carolina Central University, because we understand that

the perspectives of our communities in particular historically marginalized populations will continue to evolve as our vaccine efforts continue. And so we're continuing to do that, particularly around things like our Johnson and Johnson vaccine we'll be discussing shortly. I think many of you all have likely attended one of our vaccine COVID vaccine 101 presentations, we are offering these weekly now to the general public as well as soliciting requests for presentations and we can offer these in English or Spanish. If you and your practice are interested in doing a presentation for your patient population, please do reach out and we'd be happy to accommodate those requests. You can see some of the types of groups that we've been presenting to listed there. We also have a growing library of really fantastic video PSAs featuring trusted messengers from our HMP populations. And one of the things we're developing that's new is a misinformation toolkit with our, we have a large advisory group for more historically marginalized population advisory group, something we're developing as we're hearing more from on the ground, and making sure people have the right accurate and up to date information.

We are also doing a lot of work with our community based organizations as we know many of you all have as well. I think hopefully many of our vaccine providers are aware that we have a survey we launched for community based organizations to be able to fill out how it is that they would like to help with vaccination efforts. We have had over 200 of those who have expressed interest in hosting a vaccine event at their community based organization site. Those are being sent out regularly to our vaccine providers. If you're a provider and you feel like you haven't seen them and you can sort them so you can see by which county these community based organizations are in again please let us know we have a lot of folks are really interested in helping out and particularly reaching these equity goals. We're also very excited to announce in our older adult population. We have a partnership with a double AARP for reaching out to their members who are 50 and older and particularly working to look at their lists for folks who are from historically marginalized populations, for embedding equity and vaccine operations, we and we know you all as well are using equity data to drive action. I think as Dr Tilson just mentioned and Dr Fuller Moore will tell more about our allocation method as you all know, prioritizes based on historically marginalized population estimates wanted to give one really great example from Wake County that happened recently where wake med in the local health department partnered up with a bunch of churches and community centers and with 150 volunteers vaccinated almost 1800 people, and 91% of those folks identified as black African American. Quick reminder for our vaccine providers about the expectations that vaccines administered to individuals should match your local demographics, and that provider allocations could be at risk if not meeting these equity expectations for multiple weeks in a row.

Also when thinking about site selection. It's certainly something we're thinking about we're seeing great work by vaccine providers as well. For example, deploying our DHHS directed testing and vaccination vendors to zip codes with higher numbers of historically marginalized populations, particularly those over 65, Dr. Tilson was just mentioning our FEMA event where there will also be sort of spoke additional events in the surrounding community again looking at places that are have higher underserved historically marginalized populations are some of the sites that were really excited are really now up and running like NC A&T and UNC Pembroke which are open all semester we have more HBCUs that are being planned now. We've got lots of vaccine provider, different support including for example our

community health workers several 100 of whom are really dedicated fully to vaccine work right now. And then just a reminder that we're seeing also great work and making sure that folks have transportation to get there to their vaccine appointments, including a partnership with our local transportation agencies. Next slide please. Also of course as Dr Tilson showed as well we're really proud of the data and the dashboards and wanting to make sure that we can promote accountability for ourselves for everyone, through our data, a screenshot here a little bit different than what Dr Tilson showed shows the percent of first doses broken down by race, broken down ethnicity, age and gender. This is available both statewide and by county and we're really proud that Bloomberg news recently rated us as being the best in the nation for data quality. And as our vaccine providers know we have weekly reports sent off also each week so our providers know their own specific vaccination rates by race, ethnicity.

And finally, we're happy to see that we are making progress and certainly there's more work to do. For the past actually now it's four weeks, even updated since we finished these slides, more than 20% of first doses administered in the state have gone to our black African American population. And that's pretty close to our state's population at 22%, we're starting to see some progress in our Latinx, Hispanic population, but a little more work to do there as we were about 4% but really want to get closer to our state's population which is closer to 10%. Next slide. And I think I'm turning it over to Dr. Fuller Moore.

Amanda Fuller Moore

Thank you Dr Wong. Good evening everybody so just easily I'm going to hit several highlights on several things, quick rundown of our CVMS releases over the next couple of weeks. This week we will bring in our one dose vaccine for the j&j Yat Sen product as well as the ability to accept federal inventory. As you know, as Dr Tilson mentioned earlier, we have a number of sites that are accepting federal allocations which is great for us as the state and so we are going to make it possible in our system to separate those out. Also bringing in some Spanish information, as well as updating CVMS to remove the priority hearing and routing risk routing recipients to our find my group tool gives me. We also will have a release, then again this weekend, which will implement some of our scheduling capacity, as well as a couple of other increased capability things to do some data integration with our vaccine finder, and also allow the recipient to be able to use a single email address for multiple recipient recipient administrations. There are also going to be some provider enrollment enhancements to help those providers enrolling as well as our team going through this next slide. We also have an ongoing project with our HIE which will allow us through the health information exchange to be able to receive vaccine records into our COVID vaccine management system. We're hoping it will decrease our double documentation improve our cvms user experience, deduplicating patient records and also be an avenue for more timely and accurate patient timely and accurate recipient reporting so there are a few steps for providers to go through we went for provider pilot on this and so this is really going to be some time-saving enhancements for our providers in general. Next slide. Next slide.

So, we are continuing our onboarding process we continue to look for providers in all communities, there's a specific process for federal and non federal partners so for non federal partners who have not enrolled in any sort of program through the federal government. We have 686 provider organizations approved, those locations account for over 1400 providers sites. So those locations those sites are individual places where North Carolina resident can go to receive their vaccines so we started with our hospitals and our health department, and we are moved on to our FQHCs and rural health centers, we've got pharmacies primary care providers occupational health. We are really working to enroll providers in as many places as we can. Next Slide. Provider enrollment process starts with completing the provider agreement the provider agreement is a federal agreement, we have to meet very specific requirements that are set out in that. You start with registering and Organization Administrator, they complete Section A, which is basically information about the organization, then a vaccine coordinator complete Section B which is the information about the site, including the practicing providers as well as how to do storage and handling and the storage and handling equipment. And then finally, it is signatures by the responsible officer so the CEO and the CMO. Once that process is completed A is complete B is complete and the signatures are in place in our payment the immunization branch goes through and reviews the application and provides a response, which may be approved may be denied or maybe need some more information, next Slide.

Once a provider has completed provider enrollment, we still have to go through the onboarding process so the onboarding process is what allows you to go from an enrolled provider to a provider that is eligible to receive vaccines. So it's completing a readiness checklist, giving getting NC IDS for all of this folks in an agency and a site that will be using cvms, and then having each of those providers uploaded having accounts created for them within cvms. Once we do that, they get an email and then they log in to the portal and register themselves as a provider enrollment process is running so you've submitted your application. That is the point at which once that has been complete the vaccine coordinator should start working through that COVID-19 readiness checklist to start doing the things to get ready to go through this onboarding process. There is some specific information link at the bottom on our immunization branch website so that once you have submitted your provider enrollment application, you can be actively doing the things that will be needed for cvms in the time that you are waiting for that final provider enrollment appointment. Next slide.

So, there are some steps, you've enrolled, you've activated but now you're waiting on that screen. So once your cvms activation is complete. We ask that you go in and turn on the allocation buttons. Once you are then selected for an allocation, you would be added to our case manager list in our case manager, this was done to you would reach out and introduce themselves and give you an avenue for added support, and also let you know that an allocation is being, you have been selected for an allocation and the steps that you need to take from that which the primary step the first step after that is that on Thursdays we send our allocation, emails, providers must accept by noon on Fridays any allocations that are not accepted, either all or in part are assumed to be declined and are reallocated to other providers. Next slide. So, all providers that have cvms accounts should ensure that their allocation button is set how they would like it set, so you're going to click on the vaccine inventory, and then you click on your change allocation availability and then you set that value all providers, start at no value so

you're not set at yes or no, we ask that you set that we check that value on Mondays. If you set that value at yes, that means your location is able to receive vaccine if it's allocated to you and you are ready to receive vaccine but it is not a guarantee that you will receive vaccine. If you have that value set it No, that means that we know that is telling us that you are not ready for a vaccine or you do not wish to receive any more vaccine. And so you would not fall on that next week's Allocation Plan.

So, we have a couple of surveys that happen every week on Thursday, they go out in the same email they go out from our vaccine and so mailbox sometime on Thursday afternoon. The first part of that is accepting or declining your allocation that has to happen by noon on the following Friday so the very next day. That is the key to making sure that your allocation actually makes it to the order spreadsheet. And that same email is where we have our events survey and so we do open our, a portion of our allocation each week for events and so providers can request, they submit to us some information about an event that they would like to do, how many vaccines they need what their target audience is going to be and who their partners are and submit that and then we have a team that reviews, those event requests and select based on the amount of vaccine that we have in our event set aside, each week. Next slide. So a couple of things that related to that our Johnson and Johnson allocation in particular it. We got our first allocation this week, and we allow providers to volunteer or volunteer events for that so they let us know hey, in addition to my current allocations I can take on additional doses of vaccine. So, 83,700 doses of that J&J vaccine will arrive this week, either Wednesday or Thursday to providers that raise their hand to be considered for an event, specifically using the j&j vaccine. We do not expect any additional vaccine in the next three weeks of that of the j&j vaccine we we have been under the impression from the beginning that we would receive an amount at very shortly after the authorization of their EUA but then there would be a several weeks period where there would not be j&jvaccine. So, most likely the next allocation of that vaccine will become will come to us the very end of March, very beginning of April. Again, just for ease that link is there for our allocation of events and so people can submit their additional event allocations. The current deadline is by Monday March 8 at noon and then we will be looking through those events to try to give people some advance notice of events that we plan to support in the weeks of March 15 22nd and 29th for those are the Mondays, we run our events our allocations in general on a Tuesday to Monday week. And so we always named the week by the Monday that starts week when the allocation would be arriving next month. So with that, I am going to turn it back to Dr. Tilson.

Hugh Tilson

Right. Can I just, Dr. Tilson before you get started. There's a link to these slides in the q&a. There's a lot of really good information on there, I just want to make sure everybody had access to that. Sorry to interrupt you.

Dr. Betsey Tilson

Not at all. It's great yeah and then really thinking through that this kind of like case management strategy like these nuts and bolts that what we're learning is that once we get providers enrolled and

onboarding and activated, these really nuts and bolts of how do I receive an allocation and when and what's that email and I need to respond to those details are really really really important and so I also know that we're going to rely on our professional societies and our AHEC to also take this deck, and to be able to work through and provide support for providers, especially the new providers those first couple of weeks when you're getting application. A we are learning it takes a fair amount of hand holding to really make sure providers are successful so really want this deck to be a great resource for, for, not just the participants but also our great professional societies who are going to help us help their practices. Okay, so the last tranche is really diving deep into Johnson and Johnson, and then we'll see at this end if we all have a little bit of time for some more of the communication materials. One thing just want to say is that you're going to see it two ways Janssen and Johnson and Johnson don't get confused, it's the same. It's the same vaccine it's just the name of the company, and where it's being manufactured. And those of you who are receiving allocations. You'll see it come in as Janssen. So just want to make sure that people know it is the same vaccine but most people know it is Johnson and Johnson or j&j so we're trying to keep those two together.

All right, so 101 of this new vaccine and what you need to know and then what you need to be able to share with your providers. Excuse me with your patients. So, one thing, just like the Pfizer and Moderna vaccines were the mRNA technology was not new. Same thing with this, this, this is a vector viral viral vector vaccine. This is not a new technology, and has been used already with Ebola and HIV and Zika. And so this is different than the mRNA if you remember the mRNA it's a little bit of RNA encoded in lipid envelope. This is different. This has a DNA that codes for a SARS spike protein for SARS and it's inserted in this is really important in a Replication-incompetent adenoviral vectors, but that adenovirus cannot replicate until it's inactive virus. So you have a little bit of a DNA at that spike protein in an adenovirus receptor and so what happens then is that with that vaccination of that DNA is allowed to make the meant to make that that that spike protein, and that triggers the immune response, really really really important piece that when you telling your patients, it is not a live virus we'll get into that about there's no contraindication for people with immunosuppression. It is not a live virus it's an inactivated just like the mRNA vaccine. You can't get an adenovirus virus infection and you can't get COVID-19 from the vaccine, really, really important. Also we get asked a lot, what is in the vaccine want to make sure that you have a list of all the other ingredients. Those are all inactive ingredients. But they're in there I will call note to the polysorbate, which was also a little bit of a concern for some of the allergies may be in the other vaccines. There's no preservatives in that we get that question a lot there's no preservative and there's no animal derived protein, so it's basically just so that DNA in a non replicating adenovirus. And it's salt and sugars. And the beauty of the Janssen is that the ones affecting. Okay. Next slide. Just a little bit about the clinical trial so again just like the other ones big clinical trial more than 40,000 folks, you can see a breakdown of demographics wide range of age, but the age minimum was 18, and so spoiler alert this vaccine has been authorized and recommended for people, 18 and up, unlike the Pfizer that went down to 16. There were pretty good representation of people with comorbidities in the trial and a pretty good breakdown in terms of race, ethnicity, as well. And this was an international trial so you can see breakdown in several other states, several other countries, excuse me, and again a fair amount of race, ethnicity demographics in there. And then there were people had had evidence of SARS COVID 2 infections, as well that were entered into the trial with no concerns about safety.

Next slide. Alright, let's just talk a little bit about effectiveness. So, again, it's one dose protection starts at, at day 14, and so some of the preliminary data was looking at effectiveness after day 14, but really that that protection really continues to increase, and especially after day 28. So the trial did look at both after 14 days and after 28 days. I'm highlighting the effectiveness after 28 days as we see that protection going up. So overall 66% effective in preventing moderate to severe illness, and they actually went back and looked in preventing any symptomatic disease, and so about 66% in that you'll see on the right, though, that that effectiveness varied across the world, depending on what the strains were circulating in the United States, 72% in preventing moderate to severe illness. The really important pieces though is that also looking at the effectiveness of preventing severe disease, hospitalization and death and those are the data we're really interested in so 85% effective in preventing severe disease. And in the trial 100% effective in preventing the need for medical intervention so innovation ECMO hospitalization ICU and death. So really, really, really good vaccine and preventing severe illness and death which has been the main focus and really similar across age, race, ethnicity, comorbid chronic conditions. There's actually some promising data from this trial looking at preventing asymptomatic infection, and they're continuing to look at that data may have be up to like 72% effectiveness in preventing asymptomatic infection, but we're going to keep learning at that because that's obviously a really important piece as well but really focusing in on the protection of the severe disease hospitalization and death and this is a really good vaccine for that. Next slide.

Okay and then let's talk about them the flip side looking at safety and side effects. First of all, say no serious safety concerns in this trial. Yes, the temporary reaction similar to what we see with Pfizer and Moderna. Some local reaction, pain, swelling at the site and then some systemic reactions. Fatigue headache muscle pain. I'm pretty similar to what we see in the other vaccine, and also very similar to what we see with the other vaccines that the temporary reactions tend to be more prominent in the younger group, 59 and under, as opposed to over 60 over 60 years old. Same thing with the other vaccines you expect that these temporary reactions will occur within a couple days of vaccination and then last a couple days. Next slide. Then looking at broader. So these were events that had a numerical imbalance so it didn't, didn't come to any statistical significance, but just a numerical imbalance that they are going to continue to look at one from urticaria, so five in the vaccine group one in the placebo that analysis was possibly related to vaccine possibly part of an allergic reaction. Then there was some cases of --, which sick from the vaccine manual placebo, but the analysis ran insufficient data to determine causal relationship to the vaccine. And then there was some thrombotic from both thrombo embolic events. 15 in the, in the vaccine group 10, the placebo group that relates to about 0.05% versus 0.06%. And so the there is sufficient data to really see that this is causal for the vaccine but this was one of the events that will have continuous surveillance once a vaccine is being used in more people as well so this will be one of the intentional surveillance, post marketing surveillance exercise. All right, and so now I'm going to turn it over to Dr. Kimple who talks more through some of the nuts and bolts of administration and some of the special population recommendations.

Dr. Kelly Kimple

Okay, thank you Dr Tilson. So, the Janssen vaccine How do you store there's been a lot of conversation about storage and handling but this is the first vaccine that actually can be stored and handled with

refrigerated temperatures. So it is initially frozen by the manufacturer but then shipped refrigerated. And then, not to be refrozen once a person receives it and it should be protected from light and stored in a refrigerator and for up to three months, and then may also be stored at room temperature for up to 12 hours. Next slide. So each dose is 0.5 ml is given again at that single dose intramuscular injection, each vial contains five doses. And again, a reminder not to pull that I subtracting from multiple vials. And then those vials. The minimum shipment for the anti vaccine is also comes in two cartons of 50, so 100 doses, in one shipment. There's no diluent required and, and they provide some instructions on what the vaccine looks like to make sure that people visually inspect the vials and the dose, and the dosing syringe prior to giving it to make sure that nothing looks abnormal. And this does not contain preservatives, so it's important to record the date and time of the first use of the vial and then after that first dose has been withdrawn so that vial has been punctured. And that needs to be used within six hours if it put back in the refrigerator or two hours if it's kept at room temperature, and beyond those times, it would be discarded and not use. Next slide.

Next slide. There we go. So, any COVID vaccine can be used when indicated so there's no product preference. And really, the ACIP recommended COVID vaccine that is available. The earliest available to a person should be the one that they are able to receive. If it's indicated. the Janssen COVID vaccine is not interchangeable with the other ones. And like the other mRNA mRNA COVID vaccine, there's no data on the coadministration of those vaccines with other vaccines. So it should be administered alone with minimum interval of 14 days before or after other vaccine. There, there was some information released about considering a shorter interval in situations where that benefit might outweigh the potential risks. For example, if they need to get a tetanus booster, or to avoid errors or delays to vaccination, and especially you know in populations that need that are going seeking care and need to be caught up on other vaccines, this is an important consideration. And there may be more information coming out as time goes by. Next slide. So, we know that limited data suggests individuals can be re infected with COVID-19, and and vaccination should be offered regardless of history of prior symptomatic or asymptomatic infection. And as part of that it is not recommended to do any kind of viral testing whether for current infection or serologic testing as part of decision making for vaccinations. The one the limitation should be that vaccination should be deferred until recovery from acute illness, if that person has symptoms, and you want that person to have met the criteria to discontinue isolation, so they're not potentially exposing others, but there's no minimum interval between infection and vaccination. So the other thing is that persons with documented infection may choose to temporarily delay vaccination given some of the current evidence that suggests reinfections uncommon really in the months after initial infection, but that risk of reinfection and the need of vaccination may increase with time calling that initial infection. Next slide.

Alright, so a little bit more about some special populations or other considerations so those that have received passive antibody therapy for COVID-19. There's not much data or safety on safety or efficacy in these people but vaccination as a precaution vaccination should be deferred for at least 90 days to avoid interference of the treatment with vaccine induced immune response. Also, any currently authorized COVID-19 vaccine can be administered to persons with underlying medical conditions that don't have another contraindication. So that includes immunocompromised persons people with autoimmune

conditions, history of Guillain-Barre, Bell's Palsy from affiliates and others and clinical trials have demonstrated similar safety and efficacy profiles, and people with underlying medical conditions, compared to those without comorbidity because the next slide. So in immunocompromised persons. Again, they, if there's not another contraindication. They can receive COVID-19 vaccines all of these unauthorized vaccines are inactivated vaccines, the mRNA as well as the Janssen, but individuals should be counseled, study, and also important to note that for the j&j vaccine adenovirus vector was previously used for other clinical programs that had pregnant people as part of that so that included a large scale vaccine trial that has been, and that mechanism has been used in pregnant women. So, currently authorized. We mentioned are all inactivated vaccines or no live virus vaccine and pregnant people may choose to receive when eligible that vaccine. Now it may be helpful. Although not required to have that conversation between the patient and the clinical team with that decision, thinking about the risk and benefits. So the community transmission that person's personal risk of contracting COVID-19, and the efficacy and side effects of a vaccine and other considerations. But with time, and also other clinical trials to evaluate the safety and efficacy of COVID-19 being planned and underway.

So there's not much out yet, and again acfe I think will continue to release information about the clinical guidance specifically on the Johnson & Johnson vaccine. And so far with the EUA, that there's not much data around the breastfed infant or milk production. Next slide please. So this is just a summary chart that provides some information around the contraindications, and precautions for COVID 19 vaccine. So this includes all authorized vaccines including j&j and an mRNA vaccine. So right now the contraindications to vaccine includes a severe allergic reaction after a previous previous dose, or to a component of the vaccine. And again, that is the same contraindication for the Janssen vaccine. If there's a allergic severe allergic reaction to a component of that vaccine. Then there's precaution is may include people without a contraindication but may have a history of any immediate allergic reactions to other vaccines or injectable therapies. And then those that may have no contraindication or precaution but a history of a type of allergy, which may require longer observation period after vaccination so 30 minutes. Whereas everyone should be observed for 15 minutes following vaccination. But I do believe that ACIP will be coming out with additional information around the clinical diagnosis and publishing more information be available to the Janssen vaccine.

Okay. And so, with what our vaccination providers are supposed to do, under the emergency use authorization so providers have to communicate with the recipient or their caregiver information from consistent with the fact sheet for recipients and caregivers and provide that copy or direct the person to the website to find a copy. Prior to the individual receiving that vaccine. So, the main points to include are that this vaccine has been authorized by the FDA for emergency use. And it's not an FDA approved vaccine that recipient or the caregiver can accept or refuse that vaccine, and then going over the known potential risks and benefits of the Janssen COVID vaccine, as well as information about available alternative vaccines and risk and benefits of both alternatives. Like with all vaccinations we want to make sure it's documented and that person has the information that they need to know what, when they got vaccinated with which vaccine so they have those CDC vaccination cards that should be provided to the recipient. And this is of course especially important for those that are receiving mRNA vaccine that needs to get that second dose. There's also v safe information sheet, which can be provided

and this is some more active surveillance from CDC. So in addition to and I'll get to the adverse event reporting. In addition to those reports. This is a active follow up with the recipient to see how they're feeling after they receive vaccines. And then with all medical treatments to obtain consent but again it does not have to be written consent that consent can be verbal.

Next slide. So that's just a little reminder about the vaccine adverse event reporting system, and this is our national early warning system to detect any safety problems with vaccine has been around for a while and, and the EUA does require providers to report certain events so there's a vaccine administration error, whether or not it was associated with an adverse event or not. Serious adverse event, again, whether or not it can be attributed to that vaccine cases of multi system inflammatory syndrome in adults and children or cases of COVID-19 that result in hospitalization or death, and here also I just provided, there's a link for the state's information that you can provide for for patients to self enroll and they can report adverse events that way as well. And how to submit a Vaers report so again you can either go online and submit that report or you can call that phone number and do it that way. Next slide.

And this is just a summary of the FDA emergency use authorization, with some of the helpful links that may come in handy when we get these available to you but again it has been authorized for use in people that are 18 years and older. And this is some of the preliminary clinical guidance that we've received, and we expect that additional guidance will be coming in the next day or so. Alright, I'm going to hand it over to Dr. Wong.

Dr. Charlene Wong

Okay. Thanks Dr. Kimple, this is the last slide. Next slide. You know we're getting already a lot of questions about Johnson & Johnson which you guys now have so much more information on and we really want to highlight for this group that our key message on all of the COVID vaccines are that the COVID-19 vaccines help prevent COVID-19, and are extremely effective in preventing hospitalization and death, with no serious safety concerns. I think these are again some bullet talking points, feel free to use Johnson and Johnson is given a one shot doesn't require the extreme cold storage which means it can more easily be shipped stored and administered providing opportunities to increase the number of vaccination sites and make them more convenient. We're really highlighting that we want to get as many North Carolinians vaccinated as quickly as possible, and also meet our equity goals, and then we have one message here also about the variants because as you all know, getting as many people vaccinated as quickly as possible will help us also stop the spread of any current or new COVID-19 variants. And with that, thank you. We're ready for questions.

Hugh Tilson

That's great. So you guys have access to the questions Is there any one in particular that you want to get started with or can we just start throwing some out.

Dr. Charlene Wong

Whew, I think we can answer several of them to save some of that we don't know like if there's going to need to be two doses, you know a booster for the j&j vaccine. I think there was another question about single dose for the Pfizer, Moderna you know right now we're really following the guidance that's coming out of the FDA and the CDC, and we'll update our providers as we get more information.

Hugh Tilson

And there was a kind of other related question would a person taking the j&j vaccine be considered fully vaccinated at 14 days, or 28 days after the vaccine is administered

Dr. Charlene Wong

28 days for that vaccine, two weeks for the other two.

Hugh Tilson

Gotcha.

Dr. Charlene Wong

Well, actually, that's the end count. Are we officially saying that we I heard someone CDC that that's that was a little bit, I couldn't tell if they were saying still two weeks or not. Yeah. Okay.

Amanda Fuller Moore

So on the CDC call again today I think someone had stated two weeks, 14 days following and so I think we'll have to. We've heard different things so I think that some clarity is needed there.

Dr. Betsey Tilson

And I would say that you are, I mean you're fully vaccinated with the Johnson & Johnson after the one dose. It's just that at the end of the clinical guidances. We do know that protection really starts at 14 but continues on till 28, so I think it would just be a good counseling for your patients to say, you know, you might want to wait until that full 28 days to get that full protection. I think it's more of a counseling than a definitional thing.

Hugh Tilson

This may be one of those we don't know the answers to as well but with very low rates of reaction even compared to other vaccines, is there any point in the future to remove the 15 minute waiting period that would improve throughput, especially in primary care clinics.

Dr. Betsey Tilson

Yeah, I think we're gonna wait on CDC guidance on that one on that piece, and what to see with, with the J and J more circulation What is that, what does that look like. But we do know there is that risk of it and it is low, but there is still that risk of anaphylaxis with the mRNA. Very little. There was no anaphylaxis in this vaccine in the clinical trials again they become urticaria there, but no true anaphylaxis with this vaccine during the clinical trials, but again, what we learn with mRNA is that once you have it in more populations and you might start seeing some other things that were in a really low frequency that you didn't pick up in the clinical trials.

Hugh Tilson

Will supplies be sent with a j&j vaccine like with the other two vaccines.

Amanda Fuller Moore

No, I was just gonna say they are. There's been in increments of 100, they come in about a shoe box size box, and all of them have around a 10% overage in those ancillary kits.

Hugh Tilson

Will the CDC guidance to longer require quarantine after an exposure be true for the single dose of j&j vaccine.

Dr. Betsey Tilson

Oh, that's a really great question. Um, I haven't seen that. But what let's um, we'll keep looking at that for I haven't haven't seen that specific language, but I anticipate as, as Dr. Wong was saying or maybe you have to Kimple that we haven't seen the full clinical information on the j&j yet but my, my guess is that will extend as well, but I don't want to go ahead and CDC.

Hugh Tilson

Primary Care offices have the ability to request the j&j vaccine specifically for any vaccine.

Amanda Fuller Moore

No, we do not currently allow vaccine requests, we allocate based on the amount that we received, and currently that j&j vaccine is going to be provided via that event process so providers. As we get additional allocations we will announce that and allow people to make event requests through that even if it was for regular administration in a practice and then we will allocate through that process. That's our current plan with that j&j vaccine.

Hugh Tilson

Is there CDC training for the j&j vaccine dispensing administration like there is for Moderna and Pfizer is this training required before giving the j&j vaccine.

Dr. Kelly Kimple

So, there is. I have not seen a specific training on the Janssen vaccine yet although I have been looking and yes providers should be enrolled providers really should be ready and available to take any of the vaccines. But, but more, we're working on provider guidance and hoping to incorporate a lot of those additional in that additional information which continues to come out and hopefully some additional training, specifically from the manufacturer or CDC related to the new Johnson and Johnson or Janssen vaccine.

Hugh Tilson

So we're at seven. Just want to be respectful of everybody's time. I'm getting a lot of comments about thank you and these are very, very helpful and everybody's really really grateful. I did get one request for you, Dr. Wong to go speak to somebody, so I'll relay that information to you directly. Right. Do y'all have y'all see any other questions in here that are urgent, or that you want to respond to or do you want to call it a night.

Dr. Charlene Wong

Documentation that patients might need not that we know what they're going to need but just to say that all anyone who's vaccinated like you all know there is a portal that anyone who's been vaccinated, if they have email can sign into in addition to some of the things mentioned earlier about like the card and other things.

Dr. Betsey Tilson

And I'll just, just kind of put them through some of the questions. One, there's a lot of questions about freezers So one thing I believe Dr. Kimple covered this but but just in case because there's a lot of attentions about freezer. So, this vaccine comes will come frozen but then it is meant to be stored at refrigerated temperature you shouldn't store it frozen, it should be stored at refrigerator and that once you shouldn't refreeze one so. So, this is really refrigerated not freezer that's that's important and different than the other ones. And then there were several questions I saw about if I have an underlying comorbidity or immunosuppression so just really want to emphasize that information that Dr. Kimple said that there, other than having a known allergy to the ingredients in the vaccine and we gave you that there is no contraindication is the underlying comorbidity or immunosuppression just again, especially with the immunosuppression The biggest thing is just to counsel your patient that there may be a less robust response to the vaccine really any vaccine because of that immunosuppression so just a little counseling that the effectiveness may not be as great, because of the immunosuppressed state but there is not a contraindication for comorbidity including immunocompromised or immunocompromised conditions. Yeah.

Oh, and then there was a couple other questions just about enrollment in the timeline for enrolled provider enrollment. And just to say that we've, I think we had like 6000 providers who initiated enrollment so and and think as Dr Fuller Moore expressed, we are, we're bringing on and activating providers more and more but we do have a prioritization prioritization framework and we want to be sure that we're having good provider representation across all of our counties so we have about 23 counties where we don't have enough provider capacity. So we definitely are prioritizing those providers that are in counties that we don't have capacity. And then we also think about providers can get to historically marginalized population and have high capacity so can do 100 vaccines in a week so we are looking at prioritizing our providers so it's hard to say exactly what will be the timeframe because we are doing that prioritization but I will say, we are moving along with speed is increasing and we are definitely working on getting more and more people on board and Dr. Kimple and her team have been doing a lot of that work so we appreciate that but know some of you all are may be frustrated if you haven't gotten through that quickly but we are moving along. Moving along, much more quickly now and again prioritizing who we're bringing on to be sure we have good coverage across the whole state.

Hugh Tilson

Speaking of priorities is a question as North Carolina considered giving the j&j vaccine to 18 to 40 year olds and reserving the mRNA vaccines for higher risk populations.

Dr. Betsey Tilson

We discussed it but no, because this is a really really good vaccine in preventing severe illness and hospitalization and death. So we want to be sure that we're getting it out to those people at high risk for hospitalization and death. So, no we want to use this vaccine to get out of vaccine to people at high risk for hospitalization severe disease and death as quickly as we can.

Hugh Tilson

Somebody did comment that they were part of the j&j Research Group when they had minimal side effects. So, just want to make sure that got out there. All right, Dr Tilson I think we're just about out of time.

Dr. Betsey Tilson

Alright Esquire Tilson.

Hugh Tilson

I appreciate you to come home.

Dr. Betsey Tilson

Alright thank you all we knew that we had chock full of information tonight just was so many moving parts we knew this was going to be jam packed didn't actually surprise we had time for any questions at all, because it was so jam packed, but there was just so much going on we wanted to be sure we got it to you, you will have access to this deck. And again we will also rely on our great professional societies to also be able to continue to push this out. And you know how to find us. And we can again plan to do these, you know, with some periodicity to be sure that you have that up to date information. And then, we will look at all these questions that we did get in. And that will help inform for further webinars, but if you have real pressing concerns. Then, oh one other thing, forgive me I will say in the appendix of this deck. So we, we knew we were content heavy we do have a lot of slides in the appendix of this deck so if you get the deck. Look at that. It has a lot of our help desk. It has deeper dive into some prioritization that has deeper dives into different, different phases but for sure it has the Help Desk numbers so if you need questions asked, lots and lots of different ways that you can get support so look at that slide and no you can find as many different ways.

Hugh Tilson

Thank you all so much for all you're doing to look at the comments, everybody is grateful. So, please listen to them and know how much you're appreciated. Talk to you in a couple weeks. Take care everybody.