Dec. 23, 2020, Weekly Briefing Transcript

Dr. Daniel Podolsky:

Good morning. I'm Dr. Daniel Podolsky, President of UT Southwestern Medical Center. And I thank you for joining this special live edition of our bi-weekly campus briefing session for the UT Southwestern community. Unlike past sessions, we will be joined by a number of our colleagues to address what certainly is a timely issue that I know is on many members of the campus community's minds. That is the recently available vaccines and their deployment here at UT Southwestern. So my plan this morning is to take about 15 minutes to do as I have on prior briefings to provide an update to the campus on developments since our last briefing. And then I'll introduce and turn to our panelists to address the questions that you forwarded regarding the COVID-19 vaccines. As we are meeting in this last briefing of the calendar year 2021, I wish the news of the status of the pandemic was better than it is this morning.

Dr. Daniel Podolsky:

As of this morning, there are 83 patients we are caring for at Clements University Hospital with COVID-19. And although I haven't seen today's number from Parkland yet, no doubt, they're about the same as yesterday, 140, which is less than at the scene at the peak of the surge in July in Parkland, but still well above the number of patients we were caring for there in September. Coming to University Hospital, that 83 figure is a high to date by a fair margin. I think speaks volumes about what is going on around us in the region, in terms of transmission of the pandemic. I had the opportunity to see very early this morning, the latest update from our UT Southwestern modeling group. That update will be posted on our website as we have done for prior updates in the next day or so. And the picture it paints is one of a continued acceleration of the pandemic, certainly across Dallas County and Tarrant County for at least the next two weeks.

Dr. Daniel Podolsky:

And I'm afraid that, given the reliability that that model has provided over the months of the pandemic, we can be pretty sure that the picture that it depicts is the experience that we will be confronting. It's not surprising we continue to see a very high rate of positivity in the region in terms of positive COVID-19 tests for those being evaluated at hospitals at about 22 percent. And it's another reflection of just how active COVID-19 transmission is in our community. And along with it, we are seeing some evolution in the demographics, if you will, of those who are being affected. And also the demographics of the patients we're caring for in the hospital. And that shift is to an older age group, which has the further implication of the possibility of requiring increasing health care resources. And a look regionally suggest that the health care resources are broadly speaking, being stretched and approaching some of their limits. About 96 percent of ICU capacity reported for the North Texas region is occupied, of which about 45 percent of those patients are COVID-19 patients.

Dr. Daniel Podolsky:

So we're at a very different part of the pandemic curve than we've ever been before. And so I would just extrapolate to the most obvious statement that follows from that is it was never more important for us to do our part for ourselves and in setting an example for others, of adhering to the things that we know have worked in the past to bring down surges. And that's rigorous attention to masking, maintaining physical distancing, hand hygiene, and the other nonpharmacologic interventions. I'm going to come in a few moments to a brief update of that broad Prevalence Study that UT Southwestern has launched in partnership with Texas Health Resources to share some insights, to say indeed, as a broad community, we are at least in some of our segments falling short of the kind of adherence that is able to take the oxygen out of a pandemic surge.

Dr. Daniel Podolsky:

Before coming to that, though, let me stay close to home here on the campus. I know it's of interest to the campus community for each of these briefings about the number of colleagues who have been affected, and also the experience of transmission on the campus. From the start of the pandemic to present day, 750 of the 22,000 or so members of the UT Southwestern community have been diagnosed with COVID-19. As I have reported in each of these updates, the vast majority of that COVID-19 has been acquired through exposure in the community. And that continues to be the case in the time since the last briefing. Of the new instances, they comprise 62 community-acquired infections amongst UT Southwestern community members. And if you will, only one, still one to many, of transmission on the campus, which happened to be from employee to employee in a nonclinical setting.

Dr. Daniel Podolsky:

As was the case, when I last reported two weeks ago, again, in every instance where we have seen transmission on the campus, it is associated with some gap in complying with our usual measure. Whether that's sitting too close in a break room without masks, lack of eye protection in the clinical setting, it is the exception which continues to prove the rule. And so as much as in thinking about our topic later this morning, vaccines may be and will be, in my view, the way out of this pandemic. In the meantime, before you get the true collective benefit of what vaccines can deliver, we have the means to keep ourselves safe, to keep those around us safe, and hopefully to get the growth of this pandemic under control. We can see the consequences of failing to do the last, as I've mentioned already straining the capacity of many parts of the North Texas care-providing capacity.

Dr. Daniel Podolsky:

Let me come to that Prevalence Study that I touched on very briefly a few moments ago. Again, this was launched in the late summer, under the leadership of Dr. Amit Singal and Dr. Jasmin Tiro in collaboration with colleagues at THR and has made great progress now. I believe there's close to 15,000 participants and already some important insights that are being generated from that. They will be sharing those more broadly, publicly and I'm going to not, in the interest of time management here, go into details. But I did want to touch on a couple of findings that really caught my eye to come back to the theme about compliance with nonpharmacologic interventions. In addition to participants having both a COVID-19 virus test, a PCR test, and an antibody test, participants also answer a number of questions.

And what we learned from answering those questions are that 10 percent of people within the age group of 18 to 24 are still not choosing to wear masks most of the time.

Dr. Daniel Podolsky:

And 47 percent of that same age group are engaging what in a COVID era, is risky behavior, dining inside, gathering in large gatherings. And so I share that as more than just an assumption, but that's a documentation of the room we have to improve how we collectively as a community, respond to try to keep safe while the transmission is growing here in North Texas. I'm going to wrap up before turning to our panelists with just a couple of non-COVID updates. And in particular to take note that within just a few weeks, the Texas Legislature will gather for its 87th session. This is extremely important for the state of Texas, of course, more broadly, but certainly important for UT Southwestern as a state agency. The legislature, we know will have a challenge in front of it to arrive at the balanced budget, which our Constitution requires while meeting all the needs of the state.

Dr. Daniel Podolsky:

And that means we can expect pressure on the budgets of every state agency. And we're obviously alert to the fact that would include UT Southwestern. We have no specifics on that yet, but we are busy being sure that our legislators understand the value that you, the UT Southwestern community, bring to the State of Texas. And if there ever was a silver lining, and I'm not suggesting there really is for the pandemic, it has stressed just how important academic medical centers and the work that goes on here are for the state of Texas. And you can all, I hope, take collective pride and satisfaction in how much we are supporting our community, providing guidance to the state, and of course, support for patients in need of care. And finally, before turning to our panel in the topic for this morning, I want to take this opportunity as the last of these briefings in 2020 to thank each and every one of you for the exceptional work that's been done over the course of these months.

Dr. Daniel Podolsky:

I've come to realize in the 12-plus years I've been President that year after year, there's exceptional work and commitment that goes out on the campus. And so in that sense, there's nothing exceptional about being exceptional this year, except this was extraordinary. And extraordinary and how you all have learned to adapt, to find the resilience, to carry on the work of the university – whether that's caring for our patients, continuing to see their students and other learners get the training and the foundations they need to be the caregivers of tomorrow – and of course, really impactful research, much of it this year focused on the problem at hand, COVID-19. But in parallel with that, really important discoveries across the many areas of unmet medical need. And I'm enormously proud of that and I'm incredibly grateful. And in taking satisfaction, you will also take a moment of time to reflect on that, to find time for your family and for your friends in this holiday season.

Dr. Daniel Podolsky:

And for those that will be celebrating, a Merry Christmas this week, and I hope a productive and healthy year for all of us in 2021. So, with that update for the campus generally, I'm really, really very pleased to welcome three colleagues to provide their expertise and guidance to us as a committee on the topic of,

in my view, great excitement and importance for the potential it has to return us to a healthy society we all want to be in terms of being pandemic-free. I'm joined here by a Dr. Reuben Arasaratnam, who is Assistant Professor in the Department of Internal Medicine and Infectious Diseases, and whose own work is in particular, focused on the care of immunocompromised patients. Also Health System Chief Medical Officer Seth Toomay, also a member of our Department of Radiology. And Associate Vice President of Ambulatory Quality Outcomes, Dr. Sonja Bartolome, also a member of our Division of Pulmonary and Critical Care Medicine.

Dr. Daniel Podolsky:

Before turning to our panel and your questions, I did want to frame it in both an institutional context and in frankly, a personal one. I wanted you, the campus community to know that there's been many people hard at work now for what now is months of preparing for the time when vaccines might be available. And there were three groups which have done really important work on behalf of all of us. One, convening back in October, was to develop a principled approach to how we would prioritize vaccination. Anticipating that if a vaccine were approved, inevitably, there would be limited supplies to begin with. And we wanted to be sure that we had a plan, which was both impactful in terms of getting that vaccine to those most in need and equitable. And so, that was really one important foundational group.

Dr. Daniel Podolsky:

Second, a group of scientific experts coming from multiple departments, poised to review the data on the vaccines when they were becoming available. And that group really focused the last few weeks as the data from the two now-approved vaccines, from Pfizer and Moderna shared their data with the public, with the FDA. I felt that for the campus, it was really important that even if we have confidence in the process of the FDA has for us evaluating candidate vaccines, that if we were going to recommend it to our c community or to our patients, that they knew we also looked as carefully as possible, our experts did, before giving that stamp of approval as it were and recommendation.

Dr. Daniel Podolsky:

And finally, there were many, many people in the Health System who were working, they develop an effective, efficient, operational plan to deploy the vaccine. And I want to thank all the people involved in all three of those work groups. Unfortunately, too many to name all individually this morning, but they've done exceptional works on behalf of the entire UT Southwestern community. And any of those who have by now received your vaccine, can see just how well-organized it was as a process. And that if you did get a vaccine or you will take the vaccine, can know from our own experts that this is safe and effective, and that we're doing it as an institution in a way we can be proud of in terms of fairness.

Dr. Daniel Podolsky:

And so the personal side of this is to say why I took the vaccine. I received the vaccine in turn at the end of last week. When it became my turn, I didn't hesitate to do that for a number of reasons. First, because I did have confidence from what I had read, but also from our own experts, that this was a safe and effective vaccine. Second, and in some ways you might say the most obvious, obviously I was hoping

it would be protection. But it isn't just protection for me. It's protection from everybody around me here on the campus. And over the course of time, being part of the solution that is only possible when enough of us have vaccine to get to the point where, to be somewhat selfish, I will be able to travel to other parts of the country to see my children and grandchildren in a way that's safe.

Dr. Daniel Podolsky:

And so for all those reasons, for me it was a straightforward decision. I understand that many have concerns and hopefully we're going to get to those momentarily now. But I really hope everyone at the very least will think very seriously about the opportunity the vaccine provides to them and to those that they care about. And I certainly hope every one of you will decide it is the right thing for all of those reasons.

Dr. Daniel Podolsky:

Be assured though, this is absolutely your decision. There is no obligation if, for whatever reason, an individual decides that it's not right for them. I've told you what I've done and why. You make your own decision. And I'm just hopeful that what we're about to hear from the panel will be helpful to you in that regard.

Dr. Daniel Podolsky:

So with that, I'm going to turn to our panelists, thank them for joining us this morning and begin with the questions which some of you had forwarded ahead of this briefing. We're going to cover as many as we can. Also, you can submit your questions live here by chat. If we don't get to them, we will then follow up, answer all those questions. So let me start with the first question to you, Dr. Bartolome. A frequently asked question coming from those who have already had COVID-19. And the question is, is it safe to get the COVID-19 vaccine if you've had the virus or recently tested positive or including those who may be asymptomatic?

Dr. Bartolome:

Yes, that's a really good question. It is safe to get the vaccine. In fact, some of the later phases of the trials included people who had had COVID-19 already. Importantly, what we've been learning over the last few months is that after a natural infection, especially a milder one, the natural immunity wanes after approximately 90 days. And we have had, although rare, some cases of reinfection. When looking at the antibody levels of patients who receive the vaccine, the vaccine actually gives us a much more robust antibody response to COVID, the virus itself. And so we do recommend getting that to protect you and your family in the future.

Dr. Daniel Podolsky:

Thank you. The next question is for Dr. Arasaratnam. Can we still transmit the virus after being vaccinated? What impact does vaccination have on the need to wear masks and social distance and our ability to interact with vulnerable family members?

Dr. Arasaratnam:

I think it's very exciting that in the past couple of weeks, we've had emergency use authorization of these two vaccines. And that excitement is justified, but it really doesn't take away from our ability and our need to actually continue to use those nonpharmacologic measures to prevent infection, masking, hand hygiene, and social distancing. And the reason is for a couple of reasons. These phase three trials that led to approval of both of these vaccines were really designed to look at prevention of symptomatic COVID-19 disease. They weren't really designed to look at asymptomatic infection and the ability to transmit the virus. There are going to be ongoing studies to look at this, but for the foreseeable future, we should assume that we, even though being vaccinated, may still have the ability to carry the virus and transmit it to others. And that just really underscores the importance of mask wearing and the measures that we've talked about.

Dr. Arasaratnam:

Secondly, it's also really important to understand that even though we've done a terrific job of rolling out these vaccines, there is still a large amount of our campus that still remains unvaccinated waiting their turn. And so we need to be respectful and think about them as well. And our hope really is that over the coming year, we will be able to achieve that estimated 70 percent uptake of vaccinations in order to achieve herd immunity. And at that point, we can start to think about relaxing some of those restrictions.

Dr. Daniel Podolsky:

Thank you. Another question for you, Dr. Bartolome. Is it possible to still contract COVID-19 if you get the vaccine?

Dr. Bartolome:

It is. It's significantly less likely. In studies, around 94 to 95 percent of people did not get COVID-19 as compared to the people who did not receive the vaccine, but that still leaves a few who did develop the disease after receiving the vaccine. Importantly, the vaccine, even if you were the rare patient who got the disease after getting the vaccine, it did seem to protect against severe disease. And so even if you were to contract it after getting the vaccine, staying out of my intensive care unit and off of the ventilator is still considered a win.

Dr. Daniel Podolsky:

Thank you. Now, Dr. Toomay, this is a multipart question and it's coming in multiple forms just as we've been in this panel discussion. As of yesterday, we have now received two shipments of the Pfizer-BioNTech vaccine. Even if the Moderna vaccine was also given FDA emergency use authorization, is it possible for UT Southwestern to distribute Moderna too? When and which vaccine will be shipped next? And what do we know about how much vaccine we'll receive and at what kind of intervals?

Dr. Toomay:

Sure. Thanks, Dr. Podolsky. That's a good question. As many people are aware, a lot of hospital systems and pharmacies will be receiving the Moderna vaccine this week. Because of UT Southwestern's excellent minus-80 freezer capacity, we are likely to continue to receive the Pfizer vaccine while the Moderna vaccine will go to other systems and pharmacy locations. As you may have read, the Moderna vaccine does not require to be kept as a cold a temperature, so it's easier to handle it at some of the more geographic dispersed locations. As far as which vaccine to get, both are very similar and both have been shown to be safe and effective. And really if you desire to be vaccinated, I would suggest getting the one you have access to first.

Dr. Daniel Podolsky:

Staying with you, Dr. Toomay, an additional question that lot of people are asking who have had the opportunity to receive the vaccine. And that is what's the plan for being scheduled for your second dose?

Dr. Toomay:

Sure. It's a good question. And the process for being scheduled for the second dose will be very similar to the first dose. So the second doses will be shipped from Pfizer three weeks after they ship the first dose. When we receive notice of shipment, we'll create slots to be scheduled and you will receive a MyChart notification and an email that the slots are available, at which time you can schedule a time that's convenient for you to come get your second dose.

Dr. Daniel Podolsky:

Thanks. Back to you, Dr. Arasaratnam. We've been hearing reports about allergic reactions to COVID-19 vaccines. Initially, I think they seem to be mostly coming out of the U.K., but some here in the U.S. How are we advising individuals with a history of allergy? What is meaningful versus not meaningful in terms of risks for this vaccine?

Dr. Arasaratnam:

I think it's important to frame that question with the background that true severe allergic reactions to vaccines historically are very, very, very rare. One in a million to 1 in 2 million. And as of the 18th of December, the CDC had looked at, at that point, the 270,000 vaccinations that had been given and recognized six cases of severe reactions. And these are undergoing intense scrutiny discussion with immunologists as to potential mechanisms. In light of that, there's been very clear recommendations that have come out from the CDC as to how to proceed with this, which UT Southwestern is following. One of those is a 15-minute observation period after getting the vaccine and that is being done. And then the other question comes as to who should get vaccines if they've got allergy histories and the CDC is very clear about this.

Dr. Arasaratnam:

The only true absolute contraindication to getting the vaccine is if you've had a severe allergic reaction to the COVID-19 vaccine itself or one of its components. For routine allergies, such as hay fever, latex allergy, even or medication allergies, you're actually fine to proceed with getting the vaccine.

Dr. Arasaratnam:

Now, for those who have had a severe reaction to an intravenous medication or injectable, it's recommended that you actually discuss with your provider before getting the vaccine. But in the vast, vast majority of cases, you can still get this vaccine, but with an extended 30-minute observation period. Regardless, I would also really recommend that people do participate in the CDC smartphone-based app called V-Safe, which you will be given details once you get the vaccine. Essentially it is a daily or weekly check-in that you get sent to your cellphone to see any potential reactions that you're having. And I really want to reassure that these reports that we've heard should not detract us from getting vaccinated. Overwhelmingly, there are significant benefits to getting vaccinated and be rest assured that there are very clear and strict monitoring protocols and investigations going into these reactions.

Dr. Daniel Podolsky:

Just to make the comment, this V-Safe app, if that's the right kind of descriptor for it, is something that's voluntary. Am I right? [crosstalk 00:27:19] It's not an obligation. Is that correct?

Speaker 1:

That's correct. It's purely voluntary. And all information is stored incredibly securely. And what it is is essentially is just a daily text reminder to check in to see how you're feeling. And if there are any concerning features, it actually prompts you to get a call to actually investigate those symptoms.

Dr. Daniel Podolsky:

In parallel with that Dr. Toomay, is there a local source to turn to if somebody believes they're having a reaction to the vaccine? What should somebody do if they feel they're having a reaction?

Dr. Toomay:

That's a good question. So a lot of the reactions to the vaccine are local, and this vaccine is no different. So people can typically experience redness or arm soreness, very similar to the flu shot. And if you have that, most of those reactions typically respond or go away in about a day or two. If you're concerned that your symptoms may be worsening or progressing, definitely reach out to Occupational Health. The number's on the website, I believe it's (214) 645-5300. And we can post that in other materials. But there are definitely people around to help evaluate any symptoms that you might find concerning.

Dr. Daniel Podolsky:

And staying with the theme of side effects and then we're going to get on to the effects, what about the second dose? What do we know about the first dose versus second dose? What should people receiving the vaccine anticipate when they get to that second dose? Dr. Bartolome, you want to respond to that?

Dr. Bartolome:

Sure. As Dr. Toomay mentioned, severe side effects were really rare, less than a half a percent of patients who have severe side effects. But the milder side effects are pretty common. About 84 percent of people will have some pain at the injection site. I had it myself after my vaccine for a couple of days. Just took some Tylenol for it. But some other things have been reported such as headache, fatigue, muscle pain, chills, joint pain, and fever, all tend to be mild and resolved within a couple of days.

Dr. Bartolome:

The side effects, as you mentioned, Dr. Podolsky, are more significant after the second dose. And we expect that because the second dose is that booster that really gets your immune system revving up. And so the side effects are a sign that is what is occurring, and that's what we want to occur in the body.

Dr. Bartolome:

There are a couple of rarer side effects I did want to mention that have been [inaudible 00:30:05] times the lymph nodes will swell, especially in the arm, or under the arm that had the vaccine. Again, common. The lymph nodes are where our immune system is reacting. And so it's showing us the vaccine is working. And then there were some rare reports of a nerve condition in the face called Bell's palsy. Looking at the vaccine studies, both Moderna and Pfizer, it was numerically more common, although really rare, in both those studies, but at the same level we see in the general population. Bell's palsy is a pretty common condition and tends to resolve over time.

Dr. Bartolome:

So just to recap, the vaccines were safe and effective and certainly safer than the side effects we're seeing long term even of COVID-19 infection. And that effectiveness was across all groups, all ages, ethnicities. And so really had great safety profiles.

Dr. Daniel Podolsky:

And we're going to get to some questions here in just a moment that have been coming in that have to do with, in one instance, the plan for additional cohorts of folks to get the vaccine. And also what we know about the vaccine in some special populations like women who are pregnant. But I want to go back to something basic as a question that comes here is that you do have a common understanding, and that is to understand what is a mRNA vaccine. Dr. Arasaratnam, do you want to take that on and understanding that we've got our campus communities, some of whom are working with RNA every day and others who that's not part of their common discussion.

Dr. Arasaratnam:

Yeah. I'm happy to explain it. It's a very important question. So vaccines are essentially teachers of the immune system, and by administering a vaccine, you prime your immune system to defend yourself against the infection, should it come along in the future.

Dr. Arasaratnam:

Now, there are traditional approaches to teaching that immune system. You can administer a virus that has been inactivated or modified, or you could actually administer a critical part of the virus, maybe a protein within its code that actually stimulates the immune system. Now, what messenger RNA vaccines are is a different approach. Essentially, what we're doing is providing the genetic code or blueprint to create a very important protein called spike protein, and by creating that protein, your body can produce antibodies towards spike protein. So essentially, it's actually allowing your body to make the vaccine itself.

Dr. Arasaratnam:

Now, it's very important to know two things about these mRNA vaccines. The first thing is that they're not made from live virus. They're not made with live viral particles. So there's no risk of actually getting the infection itself. The second thing is that the mRNA vaccine is rapidly degraded, and doesn't mess with, or alter your genes in any way.

Dr. Daniel Podolsky:

Thank you. Let me pick up on the questions. There are many of them about when, how, if UT Southwestern will be expanding its ability to provide vaccine beyond those who have been in the several tiers. And I guess I'll remind those who are joining us this morning, or if not reminding them, letting people know who may not be aware that we have posted that prioritization grid, that working group I mentioned that in framing the UT Southwestern response developed ahead of the vaccine's [inaudible 00:33:55] and you can go and look at that on the website.

Dr. Daniel Podolsky:

So one question that has certainly come up this morning, and I've certainly received it over the course of the past week, Dr. Toomay, when will we be providing vaccine to other groups? And I'm going to ask you about two. One, for those who are working off campus, members of UT Southwestern community, and secondly, to patients.

Dr. Toomay:

Sure. That's a good question. Certainly one that I've been hearing a lot, and right now, the initial phases of the vaccine deployment are focused on people who are providing front-line health care, or those supporting them. And then those who are living or working in nursing homes. And as more and more vaccine becomes available, the distribution effort will broaden to basically patients that either are elderly or have high-risk medical conditions. And so, we expect that to happen in conjunction with the state and federal guidelines.

Dr. Toomay:

The piece that you mentioned about folks working from home as part of UT Southwestern, that'll likely fall in the middle. So after we transition from front-line health care workers to the phase two, where it's a broader distribution, so we'll have more guidance about that, as we move through the vaccine distribution.

Dr. Daniel Podolsky:

Dr. Arasaratnam, you work with immunocompromised patients. We've got a number of questions about, if you will, special category. So I'm going to ask you, immunocompromised patients, is there a reason for them to be ... What do we know? Risks of side effects, efficacy? Are there any different ... What's your advice to your patients?

Dr. Arasaratnam:

Yeah. This is a very, very important question. So as part of the phase three trials that led to authorization of both vaccines, there were some groups of patients that were excluded from these phase three trials, and one of those includes immunocompromised recipients, solid organ transplant recipients, allogenic stem cell transplant recipients, and those with some auto-immune conditions who are on immunosuppression.

Dr. Arasaratnam:

Now, despite their exclusion, they are still recognized of being of risk of COVID-19, and actually severe disease. And indeed, these groups should still be considered for vaccination. The CDC has actually designated immunocompromised patients as a high-risk population, as part of phase 1C of their rollout plan.

Dr. Arasaratnam:

So what is my advice to providers as they interact with patients? Well, the first thing to say is about safety. As I iterated before, these mRNA vaccines are not live, they don't have live viral particles. They showed excellent safety profile in the trials. And so, there's no reason to really suspect that there's going to be new safety concerns that come up in those populations. And what needs to happen is a very careful discussion with the patient to really understand that, in the vast majority of patients, the benefits of vaccination are going to override any theoretical risks.

Dr. Arasaratnam:

The other thing I would say, though, is that provider and shared decision making is important because, in these immunocompromised patients, we don't yet know what type of immune responses they're going to mount to the vaccine, and how that will translate into efficacy. And so, a necessary part of that discussion is the reminder to use those nonpharmaceutical measures of prevention. But also, there may be cases in which vaccination timing may need to be altered depending on what types of chemotherapy or immunosuppression that you're getting, because you want to try and improve the immune response as much as you can.

Dr. Arasaratnam:

To assist providers with this, there are several disease societies coming out with guidelines pertaining to immunocompromised patients, as to how to apply these vaccines. Already, the American Society of Transplantation and the National Psoriasis Foundation released initial guidance, and there'll be far more societies releasing guidance in the coming weeks.

Dr. Daniel Podolsky:

So Dr. Bartolome, could I ask you to speak to another important, distinct group of a potential vaccinees. Women who are pregnant, women who are breastfeeding, women who are trying to become pregnant. What are we advising them? What do we know also, kind of a bonus question here, about pediatric populations?

Dr. Bartolome:

Okay. So as a mother of three myself, I understand that these decisions, when you're pregnant or breastfeeding or planning to become pregnant, are difficult and complex. And so, when we're thinking about making these decisions for ourselves and our family, I think we just go back to the data.

Dr. Bartolome:

Available data currently says that pregnant women are more at risk for severe disease from contracting COVID-19 than their nonpregnant peers. And if you have one of the high-risk conditions, most commonly obesity or diabetes, those patients are even more at risk from developing severe disease, meaning having to come to the hospital, needing oxygen, that sort of thing, if they contract the virus. Pregnant individuals were not included in these clinical trials, and that's very common. When we're trying out new things, we often don't include pregnant women at the beginning, but there were a handful of women in both trials who became pregnant after the start of the trial.

Dr. Bartolome:

There were no safety signals with those pregnancies, if there were any problems after. The American College of Obstetrics and Gynecology convened an expert group to look at all the science, and all of the things that they know about the virus and women who are pregnant, when you become pregnant or breastfeeding, and the results of that task force were that they think the benefits of the vaccine outweigh the risk given in their own science, and they do recommend that all three of those categories, pregnant, wanting to become pregnant, or breastfeeding, that women do have the vaccine.

Dr. Bartolome:

Our Scientific Review Committee also talked about this quite a bit, including immunologists and pediatricians around campus, and agreed with that recommendation. In fact, there is an idea that if you're breastfeeding, you could then give immunity to your child. And so it may be beneficial. However, it's a personal choice, and UT Southwestern is not going to require that you would receive the vaccination. You should talk about it with your doctor and your family, and pick the right choice for you.

Dr. Bartolome:

Regarding pediatrics, these vaccines and their emergency use authorizations currently only go to down to age 16 for Pfizer, and 18 for Moderna, but there are trials ongoing right now in the pediatric population, and we expect to have more concrete data for those groups coming out shortly.

Dr. Daniel Podolsky:

Thanks. To you, Dr. Toomay, one question, which I know has been in the minds of many, in hearing how many doses of vaccine UT Southwestern received last week, 5,850, does that include also the second dose for those individuals? How many people are actually getting vaccinated?

Dr. Toomay:

Sure. So that's a good question. So the 5,850 just represents the first dose. And so Pfizer is going to ship us a second box, if you will, of 5,850 three weeks from now, to account for that second dose. And as some of you may have read in the media accounts, there was some overfill in the first box that allows us to get extra doses out of that. So it was actually a fortuitous event that we were allowed to vaccinate more people in the early phases than we'd initially planned.

Dr. Daniel Podolsky:

So can I also ask a follow-up to an earlier question, and it's about the sequencing of access to the vaccine, as more is received here. A question that's come in, in the meantime, is what about people here on the UT Southwestern campus working in laboratories, not in clinical settings, who have not yet received a My Chart notice, where will they sit in that orderly progression of access?

Dr. Daniel Podolsky:

And the second, I'll ask it to begin with, is I'm coming back to the matter of when we will be able to provide access to patient, how is that going to work? Patients are asking, "Will I be notified?" Can you tell us about that process? We know how it works for our campus community.

Dr. Toomay:

Sure. So the first piece, the folks who are working at UT Southwestern writ large, but not in a role supporting the clinical enterprise are currently phased at 1a.6 tranche, and those decisions on when to release to the different phases are basically considered as more vaccine comes in, in discussions with the top leadership of the organization. And so, we would expect to move to those phases as more vaccine arrives. And we just received another shipment of vaccine yesterday, and released scheduling appointments to phase 1a.5 last night.

Dr. Toomay:

In response to the second part of the question, how are we going to approach the offering the vaccine to patients? There's been a lot of excellent work by many, many folks on campus, really to develop the infrastructure, to identify patients who are at high risk of contracting COVID. And so some of this was done around how to administer belimumab and Regeneron monoclonal antibody therapies to people. And so, what will likely occur is we will use the same tools to identify high-risk patients, and offer them the vaccine, probably in a similar format as we're offering it to our employees, through a My Chart scheduling invite and email communications, and other ways to reach out.

Dr. Daniel Podolsky:

It does occur to me, as I'm seeing many questions here that have expanded on this general theme, when will we perhaps make it available to retirees or to family members of the campus, that this will be an evolving landscape in terms of many, many other distribution channels, as more vaccine comes available, right? In terms of you being able to order a pharmacy at a certain point, just like one can go to a pharmacy for a flu shot. So that will also kind of be in dynamic evolution with the vaccine we will get for our deployment.

Dr. Toomay:

Yeah, that's a really good point. So a lot of the Moderna vaccine that is being shipped this week is going to pharmacy chains, and the state and federal government have contracted with CVS and Walgreens to vaccinate folks in nursing homes, but we also anticipate that a lot of the vaccination of the general public will be done through these retail pharmacy chains. So this is not just a hospital effort, it's going to be a societal effort.

Dr. Daniel Podolsky:

Thank you. Back to you, Dr. Arasaratnam. Lots of questions, not surprisingly, about the mutant SARS-CoV-2 virus that has emerged in the U.K. And the question is obviously, primarily in this session, about what efficacy can we expect for the vaccine, but I certainly welcome you to comment more broadly about what the potential impact of that variant may be.

Speaker 1:

Yes. Well, perhaps it's worth framing that this is something that is rapidly at work, and what is said now, there'll be more information in a couple of days, and certainly in the next coming weeks. Viruses do evolve. Mutations do occur. We see this with RNA viruses, because the enzyme that copies the RNA is prone to error. And the vast majority of those mutations are what we call neutral. They don't really have an impact on the fitness of the virus, the ability to infect. We have, since the beginning of this pandemic, characterized several mutations, and while a few of them in the lab setting have shown the ability to infect cells at a greater level, this hasn't translated into any meaningful impact on the ability to evade vaccine immunity.

Dr. Arasaratnam:

Now, what happened in the United Kingdom is that there is an entity, the COVID-19 genomics consortium in the U.K. that sequences these viruses on a regular basis and looks for mutations. And at the time that there was a seasonal surge of the virus in Southern England, they picked up a new lineage, which had 17 mutations. Now, what drew biological interest into this is that there were several mutations within that spike protein, and that spike protein is the key protein the virus uses binding to the host ACE-2 receptor to enter the cell.

Dr. Arasaratnam:

Now while there's biological interest in this, we don't yet know the clinical significance of that, and that is going to be the focus of study for the next couple of days and weeks. What I would say is two things:

One, vaccine-induced immunity to the spike protein through the vaccines that we have will generate antibody responses that are to several parts of the spike protein, not just a few amino acids. And so in reality, it would take a series of cumulative mutations over a long period of time to start to impact vaccine immunity.

Dr. Arasaratnam:

The other thing I would say is that, regardless or not of whether we find out this variant lineage to have a higher transmutability, for me it just underscores the importance of all those nonpharmaceutical measures that we should be doing, wearing masks, preventing transmission, social distancing, and hygiene. And that's something that we can do right now.

Dr. Arasaratnam:

So, the bottom line is this should not distract us from getting vaccinated. We should continue to get vaccinated, and we should continue to use those nonpharmaceutical measures.

Dr. Daniel Podolsky:

Back to you, Dr. Toomay. Questions have come in. When we decide to opt in to be vaccinated, will we be given an option between Pfizer or the Moderna vaccine? Are there many differences? And others may want to comment as well.

Dr. Toomay:

Sure. So as far as the opt in and opt out, we have the ability to offer multiple vaccines should they be allocated to us, but at the current time, we have no Moderna vaccine that has been allocated to UT Southwestern. And so, we will continue to offer Pfizer vaccine as it gets shipped to us.

Dr. Daniel Podolsky:

And you touched on it, I believe, Dr. Bartolome, but maybe you could just amplify it because the question's come up, the differences between them I think in terms of efficacy and side effects, I think to the extent that we won't have a choice, should we feel we may be advantaged or disadvantaged because we happen to get Pfizer being at UT Southwestern, but what about Moderna if we were perhaps somewhere else?

Dr. Bartolome:

Right. Our Scientific Review Committee here at UT Southwestern took a look at these studies specifically for that. Are there differences? Are there groups who should receive one over another? And these trials were very similar, both in efficacy and side effects. And so, the 100 percent unanimous vote of the Scientific Review Committee is to get whichever vaccine you have access to first. They are both safe and efficacious, and take which one you can get.

Dr. Daniel Podolsky:

So, I think there's been a lot of comment in media that there's a threshold of 70 percent immunity that gets you to so-called herd immunity. And the question comes in, is that, if you will, an aggregate of immunity from the vaccine plus those that have had an infection, or is the goal we've got to have 70 percent of a community, hopefully the country as a whole, who are vaccinated and immune? I don't know. Dr. Arasaratnam, do you want to take that one?

Dr. Arasaratnam:

Yes. I would first begin by saying that's a very dynamic estimate, and one of the challenges we have is that, as is usual with many viruses, we don't have that immune correlate of protection. That is, what measure of the immune system correlates to protection. I will say that natural infection is not the way that we want to induce herd immunity. We've seen the disastrous consequences and toll of this for several months.

Dr. Arasaratnam:

And so, vaccine-induced herd immunity is the way forward. Now, how this will take shape, as we understand, the impact of vaccines on asymptomatic infection transmission of virus is going to be an evolving question in the next several months, but I think what that underscores is that 70 percent is a great target. It's based on the distribution and how long it will take to get vaccines, but also I want to underscore, like any of these public health interventions that we're looking to do which are to curb the pandemic, it's dependent upon population uptake.

Dr. Arasaratnam:

And so, we just need to consider carefully what we can do right now with all the tools at our disposal to prevent every single infection we can.

Dr. Daniel Podolsky:

A very basic question here that I think is important to be sure everybody is on the same page. Dr. Toomay, do both shots have to be the same vaccine?

Dr. Toomay:

It's a good question. And in both of the studies, they're very explicit about it being the same shot. There's uncertainty and unknowns around what would happen if you mixed up the shots. So, it's our intent to provide the same shot on both doses and comply with the instructions for use.

Dr. Daniel Podolsky:

Dr. Bartolome, I'm going to slightly generalize a question that's come in, which started about someone asking about their allergy symptoms. The question more generally is, if I'm not feeling 100 percent, is it okay to get my vaccine, if I feel I have a cold?

Dr. Bartolome:

It is. You have-

Dr. Daniel Podolsky:

It's assuming you've excluded COVID.

Dr. Bartolome:

Yeah. It's excluding active COVID. Yes. It is recommended if you have a moderate to severe acute illness, that you maybe postpone your vaccine until after that is over. But, mild illness, it's okay. Go ahead and receive your vaccine.

Dr. Daniel Podolsky:

Okay. I'm going to now ask a question, kind of a jump ball. There's the news just in the last day or two that the Pfizer is apparently able to expand production, or at least the country is contracting for additional doses, and the question is, should they be concerned about the quality control in rapidly expanding production? Any reason any of you would have worry about getting your vaccine if you hadn't already gotten it, hearing that there was such a rapid escalation?

Dr. Toomay:

Well, I'll take a first stab at it. I personally wouldn't have any concerns about that. One of the technological advantages of the mRNA vaccine is that it can be made quicker and easier than some of the other traditional technologies for vaccine production. So again, it wouldn't bother me.

Dr. Daniel Podolsky:

Anybody want to add?

Dr. Arasaratnam:

Yes. So what I'd also like to add is that when we think of the FDA emergency use authorization, there's a lot of focus given on efficacy and safety of the vaccines, and that is absolutely the most important thing. But, what also people don't realize is that a huge amount of consideration is given into making sure the manufacturing quality is absolutely on par and appropriate and safe.

Dr. Arasaratnam:

And so, when we think of approval, or sorry, authorization of this vaccine, we need to think that actually a lot of safety and oversight has gone into the manufacturing quality, not just the clinical trials.

Dr. Daniel Podolsky:

So, I'm going to make an editorial comment as context for the next question. In bringing together that working group to think about prioritizing vaccine deployment whenever we would be receiving it, and then posting it on our website, the intent was, as I said in my initial comments for this panel, to be sure we use the vaccine to its greatest initial impact, and to do it equitably. I'll add a third dimension, which is

to do it in a transparent way. So, the questions have to do with a little further understanding of the 1a.1-.5 and .6, two parts, and I'm looking at Dr. Bartolome, but if you, Dr. Toomay should answer this, you'll jump in. Is each of those tiers a larger number of individuals? Is that kind of a ... I'll put it this way, kind of a top down ... not top down, a pyramid which is getting a wider and wider base?

Dr. Daniel Podolsky:

And then, clarification in the 1a.5 of administrative, because I think we did recognize that needed a little more elaboration in the last couple of days because it was kind of not sufficiently specific. So, who wants to ... Sonja you headed that work. Maybe I'll turn to you for this.

Dr. Bartolome:

Yeah. I'm happy to take that. There was a working group, as Dr. Podolsky mentioned, emphasis and disease experts and a lot of reading that went into deciding how we were going to do these phases of rolling out vaccine, because we knew we wouldn't have enough for everybody at the beginning. And so, ultimately it was decided it would be equitable and fair that the way we would do it was based on your exposure to patients with COVID-19, the amount of people you were interacting with on a daily basis with COVID-19, our Occupational Health data on who was contracting COVID-19 in our workforce, and also taking into account our responsibility to our community, meaning that we needed to preserve hospital resources first, not because they're more important than outpatient resources or research, but rather so that we have a full complement of staff to take care of our community when they come in with COVID-19.

Dr. Bartolome:

And so, that's how those groups were made. It was not done in these phases by number, although when you get to the later stages, of course when we're including everyone, in the end stage that's going to be a larger number. But rather, those things that I mentioned before.

Dr. Bartolome:

Administration was specifically put in that group and was vague and required some clarification. And so, we have provided that. Administration was meant to be administration that's supporting that clinical enterprise, for the same reason so that we can make sure we have the ability to support our community when they do become ill.

Dr. Bartolome:

And so, hospital administration, Health System administration, and then also people who have critical jobs that support the clinical enterprise or the university enterprise take care of [inaudible 00:59:52] are included in that administrative group. And then, of course everyone is included in that sixth group, so that we can maintain a full complement of our campus and take care of our community.

Dr. Daniel Podolsky:

Well, thank you all. We have really come to the end of the hour, really grateful for your participation, the great insights that you've provided, and all the work you've done as being part of our way of responding to COVID-19 on behalf of our broad communities, but also UT Southwestern. Really delighted to see that many, many of our campus colleagues have joined us, and there's still lots of questions, even if we've already covered a lot of territory. And for those who uploaded questions that we didn't get to, we will be following up afterwards to see that those questions are addressed.

Dr. Daniel Podolsky:

So as we come to the end of the hour, also in addition to thanking our panelists, I want to thank all the members of the UT Southwestern community, as I did in the conclusion of my update to thank you for the extraordinary work that you have done throughout these very, very trying months of the pandemic in advancing our mission. I do hope you all have a very safe and wonderful Christmas and holiday and New Year season, and do everything you can to be an ambassador to our community and those around you to help us navigate through the near term challenge of a surge unlike any we've seen before, and until we get to the eventual other side of this through vaccines.

Dr. Daniel Podolsky:

I'll end by, again, encouraging all of you to take the opportunity when it's your turn to get the vaccine for your well-being and for the well-being of everybody around you, but know we respect your decision as uniquely yours. So with that, we'll say goodbye for this briefing session. I will be back in two weeks with a more usual update. And with that, we'll adjourn.