Trish Kritek:

Welcome to UW Medicine Town Hall, I'm Trish Kritek Associate Dean for Faculty Affairs. And it's my pleasure to welcome all of you to UW Medicine Town Hall. This is a special vaccine edition and because of that I have with us some special guests who I'm really appreciative of their time and contributions. We have outstanding experts across UW Medicine on the topics of vaccine, and we're lucky to have several of them with us today. So I'm going to go around the screen and say who's here. I will reiterate that as I ask questions.

Trish Kritek:

So it's my pleasure to welcome Shireesha Dhanireddy who is a professor in the Division of Allergy and Infectious Diseases. She's the chair of UW Medicine Pharmacy and Therapeutics Committee and is leading the efforts on a distribution of vaccine. Timothy Dellit our Chief Medical Officer for UW Medicine. Santiago Neme Chief Medical Director at UWMC Northwest and Infectious Disease doctor. Anna Wald, the Chief of the Division of Allergy and Infectious Disease. And one of the PIs for our vaccine evaluation unit leading the trials on vaccines. Anne Browning, our Assistant Dean for Well-Being. Deb Fuller professor in the Department of Microbiology and basic scientist expert on vaccines and mRNA vaccine. John Lynch, another infectious disease doctor and the head of our infection prevention group at Harborview's and leading our medical response for COVID.

Trish Kritek:

And I have given our chief nursing officers and other chief medical officers the day off. I feel surrounded by infectious disease doctors which makes me a little bit nervous as a pulmonary critical care doctor. And with that I want to do a really quick framing. We're going to try to answer as many questions as we can today. I read more than 400 questions that were submitted through different portals for today. Thank you so much for your outstanding questions. We will not possibly get through all of them. We already have an FAQ posted, we will add to that FAQ and we're going to have a “I'm a science person who's read a lot about mRNAs” special FAQ's for those really nuanced questions as well. So we are going to get more answers to you and we're going to try to cover as much as we can today.

Trish Kritek:

So know that those of you who have been reading everything there is about mRNA vaccines won't have every question to answered today, our goal hope is to get the most information to the most people. So I appreciate your grace as we start. And with that, I do want to hold true to one thing that we do every Town Hall and that is turn to Anne Browning for a well-being message before we kick it off.

Anne Browning:

Hello, Happy Hanukkah. It feels good to celebrate light as we move towards the darkest day of the year. Last week, I talked a little bit about mirror neurons and how we unconsciously mirror the emotions of folks around us and how important it is to realize that calm is just as contagious as fear. This week I want to continue the theme of emotions in neuroscience. And reading a lot about wellbeing of healthcare teams during COVID-19 I keep seeing folks use the phrase compassion fatigue. What would folks really mean is empathy fatigue. Compassion and empathy are two very distinct emotions that activate different parts of our brains. We experience empathy, we feel the suffering of folks around us and that activates pain centers in our brains. And it depletes us over time. However, something very different happens when we feel compassion.

Anne Browning:

Rather than feeling the suffering around us we hold that suffering and in some small ways and big ways we do what we can to alleviate some of that suffering in ourselves and others through the care we provide and the love we share. And compassion ends up activating these pro-social parts of our brains which makes compassion a positive and restorative emotion rather than one that fatigues us. And as the weeks and the months tick by and we see a lot of suffering around us, sticking with compassion will help us stay sustained in the work we have ahead of us. And we'll hope the folks around us who are suffering mirror some of that sense of connection. Thanks.

Trish Kritek:

Thank you. And I think that's a very powerful message to start the day. Okay. Deep breath, vaccines. Tim, I'm going to start with you and I wondered if you could just start with a bit of an overview about where we stand with the vaccine on a national level and then locally, and then I have follow-up questions.

Timothy Dellit:

Right. Thanks Trish. Thank you everyone for joining us again here this week. Thank you again for all the care you're providing for our patients and particularly the support you're providing for one another. We really are reaching a milestone now. Really on the forefront of going forward with the vaccine and if you think now that it's really been less than 12 months from the time that SARS-CoV-2 was actually identified and sequenced to now having a vaccine that is 95% efficacious that is phenomenal. So I'm very excited about today's Town Hall and really sharing this information with you. Where we are with respect to our timeline is on December 1st, the advisory committee on immunization practices for the CDC forward recommendations on who should be that first phase of vaccinations. And they recommended healthcare personnel as well as residents of long-term care facilities.

Timothy Dellit:

The next stage then is that both of the companies Pfizer, BioNTech with their vaccine submitted an emergency use authorization request to the FDA. A special advisory committee to the FDA yesterday reviewed the ethics to safety data from that trial and that's also published in the New England Journal of Medicine yesterday as well. Based on their review they recommended that the emergency use authorization be approved by the FDA and then we anticipate either later today or tomorrow the FDA will grant that approval. Assuming they do that then vaccine will start to be allocated. We anticipate initially roughly 62,000 doses of the Pfizer vaccine would come to Washington State, more vaccine will come then subsequently each week. The Moderna vaccine which has also an mRNA vaccine, now both of these required two doses, right? The Pfizer 21 days apart, the Moderna 28 days apart. Moderna is going to go before the FDA next week on the 17th for evaluation of their emergency use authorization.

Timothy Dellit:

The state as a whole is anticipating that we will have roughly 400,000 doses of vaccine by the end of the month. Therefore, the department of health is really pushing for us to try to get through that first phase 1a healthcare personnel and residents of long-term facilities by the end of this month. Now that's an ambitious goal but I do think over the next two to four weeks we will get through that group. Now in order to operationalize that we have been working hard with our planning and operations team and dividing into groups. And think of those groups of individuals as who is most likely to care for someone with known COVID-19 or handle infectious material. But ultimately all of our clinical healthcare workers

within that clinical environment will be offered the chance to be vaccinated within those next two to four weeks.

Timothy Dellit:

And so I really also ask for patience as we go through this process, this is going to go very quickly. We're going to be able to offer this to particularly all of our healthcare personnel following those CDC recommendations, but it's going to take us just a few weeks to get through everyone. But rest assure you will be offered that vaccine. Then subsequently there'll be more long-term planning.

Trish Kritek:

Okay. I have a bunch of follow-up questions some of which I'll ask now, some I'm going to ask later. For everyone who's wondering we'll go into some more nuances on the tiers in a little bit. But my first question for you Tim is, presuming this is FDA approved today or tomorrow, the Pfizer vaccine. When will we start vaccinating at UW Medicine?

Timothy Dellit:

Our anticipation is December 17th. We hope to receive vaccine on the 15th and then start on the 17th right now.

Trish Kritek:

Okay. And then my second question to you is, where will those vaccinations occur?

Timothy Dellit:

So the vaccine will initially come to the Montlake Campus but it is for all of UW Medicine. So there will be sites on the Northwest Campus, the Montlake Campus, Harborview Medical Center as well as Valley Medical Center.

Trish Kritek:

So all four hospitals will have a site for vaccination. And if you aren't at one of those sites you'll come into those sites to get vaccinated, correct?

Timothy Dellit:

Correct.

Trish Kritek:

I see Shireesha nodding too so thank you. And then last two for you before I pivot. Does everyone have to get vaccinated if they're offered the vaccine?

Timothy Dellit:

No. We expect everyone to participate in the program just like our influenza vaccination campaign. So people when they're contacted will be offered the option to either schedule to be able to receive the vaccine, they can postpone if they wish or they can decline. Again, we strongly encourage everyone to be vaccinated. I personally after reviewing the data and watching this very closely feel very comfortable with being vaccinated and plan to do so when it's my turn. I'm not in that first group because I'm not

caring directly from COVID-19 patients, but I fully plan to be vaccinated and encourage all of our healthcare workers to do this.

Trish Kritek:

And I'll just say it now that I am in that first tier and I am planning to get vaccinated as well. I do want to follow that last thing that you said which is, if someone says I don't want to get vaccinated right now, can they get vaccinated later? Because there are people who are worried about the early data aspects of this and want to see how things go.

Timothy Dellit:

Yes. If people wait or if they change their mind we will always then be able to put them in and be able to get them vaccinated later on. So if you do change your mind later on, absolutely we want to get you vaccinated as well.

Trish Kritek:

Okay. Last one, do we have to pay to be vaccinated?

Timothy Dellit:

No.

Trish Kritek:

Okay. Thank you. More to come on all of that. And I can see Shireesha has the answers to the things I'm already thinking about asking us all. But I'm going to take a step back and I'm going to turn to Deb Fuller. And Deb I wonder if you can... And I think we could probably spend the whole hour on this so this will be a challenge for you, walk us through for people who haven't worked in the world of mRNA and vaccines, how an mRNA and a vaccine works and why this was an attractive strategy that was tried?

Deb Fuller:

Right. Well, let me first say that research and mRNA vaccines has been going on for nearly 30 years. So I've been involved in it for actually that long of time. And so this particular vaccine is a culmination of literally decades of research to develop this technology. So what is an mRNA vaccine? Well, let me take you to the basics of something you already know. Most of us would have received a hepatitis B vaccine. Hepatitis B vaccine falls in a category of vaccines called recombinant protein vaccines, and the way they are made, you actually just get a genetic sequence for a particular antigen on the virus. Often it's going to be the antigen that is on the viruses surface that it uses to infect the cell. And you take the genetic code for that and you actually have cells in the lab end up that protein, you go through a process of purifying that protein, and then you inject that into people, you make immune responses against that protein usually antibody and that's going to be able to block the infection.

Deb Fuller:

Well, mRNA vaccines are very similar to that except what we end up doing is we take the genetic code for a particular protein. In this case it would be the spike protein on the SARS-CoV-2 and instead of putting that in cells in the lab and having the cells in the lab produce that, we put that directly into your cells and your own cells end up becoming essentially a factory for your own vaccine. And so by actually having the vaccine produce the protein in your own host cells you end up generating an immune

response that is very specific for the SARS-CoV-2 and it's very effective. And so one of the things that mRNA vaccines do as you can see is it really shortcuts the whole process. You don't have to go through this long process of producing and purifying protein, and then injecting that into your body. Those types of recombinant protein vaccines they take months and months to develop.

Deb Fuller:

An mRNA vaccine literally only takes weeks to be able to design an initial vaccine and start to test it. So that's one of the reasons why mRNA vaccines are our first vaccines across the finish line for this virus.

Trish Kritek:

So one of the really attractive things is the speed because you're using the cells in the person's body to make that protein to which the body's going to have their immune response. So that's unique. And I think it's what makes people a little nervous. So I'm going to ask a couple followup questions on that. So you said there's been 30 years of experience looking at mRNA vaccines, have we had any experience with rolling out an mRNA vaccine in other clinical settings before?

Deb Fuller:

So mRNA vaccines have for the last five years especially been in advanced stages of clinical trials including phase II clinical trials for other infectious diseases. One of the reasons why the mRNA vaccines were able to pivot so quickly to COVID-19 is because Moderna as an example already had a vaccine for MERS, which is another coronavirus in a phase II human clinical trial. So the minute COVID-19 emerged they were able to quickly pivot their technology. They basically swapped out the sequence for the MERS surface antigen and replaced that with spike protein for SARS-CoV-2. And that's why they were able to very quickly accelerate this forward into human trials.

Trish Kritek:

So we were already testing it and getting ready to do it for other diseases MERS specifically?

Deb Fuller:

That's right. Yeah. mRNA vaccines were already on the cusp of becoming the next generation vaccines. It was going to be a matter of maybe a year or two and then we would probably have our first license mRNA vaccine anyway. COVID 19 just accelerated that because of the essential need that this pandemic had to quickly develop a vaccine to stop it.

Trish Kritek:

Okay. But none of that's been rolled out before it's just that we were on the cusp and now this pushed us over.

Deb Fuller:

This will be the first in class that will be licensed for human use. Yes.

Trish Kritek:

Okay. Okay. Thank you for clarifying that. Couple of three followup questions. One is, for the folks who've been reading about this, the word spike protein came up in many questions. What types of cells are being used in this to make the protein? Where does the mRNA incorporate itself into cells?

Deb Fuller:

So the mRNA actually gets injected intramuscularly. So the first cells that actually would start to produce the protein would be just essentially your muscle cells, but the mRNA vaccine can actually be delivered into multiple different types of cells including what we call antigen-presenting cells. And these are really the first cells that help to instruct our immune system to start to make antibody responses against the virus. So even if our muscle cells are producing the protein, the protein gets picked up by these antigen presenting cells and starts to make antibody.

Trish Kritek:

So it starts with muscle cells, then antigen presenting cells. Thank you for clarifying. There are lots of curious healthcare providers out there about this. I think that whole thing where it's taking over cells or in being part of cells makes people worried about future auto-immune disease. So I wonder if you could speak to the risks that are known or concerned about future auto-immune disease.

Deb Fuller:

One of the things early in the development of the messenger RNA vaccines what was achieved was actually eliminating sequences within mRNA vaccines that could actually potentially cause that. So there was a major modification in terms of how our body actually reads those sequences so that we are unable to generate the types of inflammatory immune responses that could lead down a pathway of auto-immunity. Instead, the mRNA vaccines are more specific for inducing adaptive immunity which is the immunity the antibody responses that we need for protection.

Trish Kritek:

So we think it's unlikely because of these two different types of immunity it's doing the one that's less likely to cause or doesn't cause auto-immune disease.

Deb Fuller:

That's right. The type of innate immune pathways that typically lead down the path to auto-immunity is called a type I interferon pathway the RNA is modified so it doesn't go down that pathway.

Trish Kritek:

Thank you for clarifying that. And for those of you who are like, I don't know what you just said. That's okay. I think there are a bunch of people who are very curious about that because these are very real worries that people have in something that's new. So thank you. Are there any types of patients that should avoid in general, not this vaccine but mRNA vaccines?

Deb Fuller:

That's the question for me?

Trish Kritek:

Yeah.

Deb Fuller:

So one more-

Trish Kritek:

Last one.

Deb Fuller:

So we don't know yet, this is early phase clinical trials. I think some people had read probably the news about a few people in the U.K. that had developed allergies. One of the concerns generally with vaccines is whether or not you might have allergic reactions for example, our flu vaccines produced in eggs and so people who have egg allergies are recommended not to take that. And so with the tens of thousands of people that have been in phase III clinical trials there hasn't been any real evidence that is going to be a major safety issue. But these particular two allergies then raises a question. Is there a particular rare groups of people who may be recommended not to take that particular vaccine? So they're going to look at that and what might cause that? Well, the RNA vaccine is formulated with something called lipid nanoparticle and there are chemical compositions in there that they need to look at and study whether or not there are potential rare cases of inducing allergic reactions.

Trish Kritek:

Okay. So that's the general side effects, which I'll actually give you a break and say thank you. Those are wonderful responses to being peppered with questions. I'm going to look to you Shireesha and ask you. Maybe you could walk through what are the side effects that we know about that we're going to be concerned about as we roll out this vaccine?

Shireesha Dhanireddy:

Yeah. I think we're all looking to the U.K. that just started vaccinating their healthcare workers in their first phase and looking at their reports as well as the preliminary data that's been presented so far and the data that was presented to the FDA just yesterday. I think Debra brings up the point of allergy and there were there's two anaphylax reactions that have been reported so far in the U.K.. Leading them to have advisory for people who have had anaphylaxis or anaphylactoid reactions, for instance, those who carry up enepinephrin or have been told to carry up an epinephrin or received epinephrin to hold off on getting vaccinated as they sort that out. And as Debra mentioned, whether there are some components of that in that vaccine that may be contributing to that. And so further work is going into figuring that out but for the meantime, maybe holding off on those individuals. We've actually already reached out to our allergy colleagues Anna and I, to talk about how we would potentially deal with that for our staff and our patients.

Shireesha Dhanireddy:

There's also a signal of four cases of Bell's palsy that had been reported in the vaccinated group versus none in the placebo group. So Anna is probably better to speak to about that because as a herpes virus expert and also our vaccine clinical trials lead here for COVID vaccine I think she can speak to that a little bit more. So just four cases in those thousands of patients that have received vaccines. So something to look for in terms of another signal for that. But other than that unlike the flu vaccine egg allergy is not something that we would use as a reason to not get this vaccine. It is a different type of vaccine as Deborah explained. So I think it looks pretty good and the efficacy as Tim said is really looking good.

Trish Kritek:

So I'll ask Anna in a second about the Bell's palsy, but I think can you just hit the ones that are pretty common side effects which I think are the ones that I think we're hearing about.

Shireesha Dhanireddy:

Yeah, sure. So I think people have heard about the reactogenicity issues with the vaccine. So things that happen within the first few days, most likely within the first two days of receiving vaccines. So local suture pain, low-grade fever, body aches, those are the main symptoms that people may experience after vaccination. And as you can tell those can be indistinguishable from COVID infection itself. So I know we're in the process of coming up with a protocol for that to deal with-

Trish Kritek:

I will ask Anna about that in a minute.

Shireesha Dhanireddy:

Yeah. And also there's going to be the guidance forthcoming from the CDC as well about management of potential systemic reactions or systemic reactogenicity from low-fever body aches from the vaccine.

Trish Kritek:

Okay. So fever, headache, aching-

Shireesha Dhanireddy:

Body ache.

Trish Kritek:

Body ache-

Shireesha Dhanireddy:

... local suture reaction.

Trish Kritek:

... issues at first place where you got it for maybe two days after you get it. Otherwise we've heard about the anaphylaxis. Sounds like we're talking to our experts about that and then Anna I'll look to you, there's I guess four reports of Bell's palsy, is that something that we should be worried about? Where do we stand with that?

Anna Wald:

Well, I do think it was interesting that there were four cases of Bell's palsy and that they were all in the vaccine. We think that most cases of Bell's palsy are caused by herpes-simplex virus, but that's the virus that you feel cold sores or fever blisters. And that occurs when a person has a fever or just general inflammation, because these vaccines do cause reactions that include fever that may result in herpes virus being more active and therefore causing Bell's palsy-

Trish Kritek:

I see.

Anna Wald:

Bell's palsy is unpleasant but most people resolve it completely. So I think even if somebody does develop it the prognosis is very good for it.

Trish Kritek:

That's great. So prognosis is good, has to do with activating the herpes virus that somebody already has in their system and that inflammatory immune response. I appreciate that. Okay.

Anna Wald:

Which is response of the virus which we want because that's what keeps you from getting COVID.

Trish Kritek:

Excellent. John Lynch, Shireesha alluded to this. Many people ask this question, the concern is that someone who gets immunized will have these symptoms like fever and feeling crappy that are also consistent with having COVID. So how are we going to manage that in terms of our workforce?

John Lynch:

Yeah. So it's a couple of things and I appreciate the technical term you use there.

Trish Kritek:

Thank you.

John Lynch:

And quick apologies I know I usually do a lot of Q&A's here but there's a lot of questions that I can't keep up. So Santiago and I are doing our best but hopefully I can tackle them as we talk. So what are we doing? Some of them are administrative and that's the things that Shireesha already mentioned around, we're going to try to focus vaccinations prior to, for instance, a day off, right? That gives us if you have some muscle pain, maybe some fatigue, some headache that comes on. And by that night it goes away, you're feeling back to normal, right? That's a way to mitigate that. We're going to be providing guidance on this. Every person that gets vaccine is going to get a form called a VIS or Vaccination Information Statement or something like that. And I think that we're going to try to include some guidance on that document for people and how to manage those symptoms. So you have something there.

John Lynch:

In addition, should you develop symptoms next day we're looking at possibly setting up a hotline so that people can call and get some information. We know that people just have questions and we want to be able to provide answers to those questions. And when in that call both online or in-person we're going to have a flow chart that what symptoms. Because as Shireesha mentioned, you have just a sore arm you can come back to work, right? If you have a sore arm and fatigue that comes on and gets better or is getting better, potentially you can come back to work. But if you have a vaccine and then get a cough or shortness of breath or lose your taste or smell, right? Those are much more typical for COVID and we're going to allot or reserve a certain number of COVID testing spots for those folks.

John Lynch:

So we're going to just really ask people to move very quickly if you have any concerns they're getting tested right away. And if that test is negative, especially if your symptoms are getting better then you'd

be able to go back to work. So we've got a few different pieces. They're all still getting hammered out right now but that's the approach.

Trish Kritek:

Putting out the details, but a piece of paper informs you about the side effects, potentially a phone line and then depending on what symptoms you have could come back to work, but if it sounds a lot more like COVID, that won't be the case.

John Lynch:

Right.

Trish Kritek:

Okay.

John Lynch:

And testing.

Trish Kritek:

And testing. Thank you for adding that. I appreciate that. Before I leave you if you don't mind, since you and I always talk about testing one of the questions that's come up is... And you just alluded to testing, if I get vaccinated, will it affect if I get tested in the future? Will it affect antibody test in the future and would it affect actually... The other question is, my PCR test in the future.

John Lynch:

Yeah. So I'll tackle the first question which is... Oh, the second question, which was around the PCR testing. So it should not change your PCR testing, right? Dr. Fuller can speak to this even way better than I can, but we don't think that that spike protein that the muscle cells and the APCs, the antigen-presenting cells are going up to your nose and are presenting spike protein that we're going back there and sampling and then testing for, right? That's the protein because most of the tests we're doing are genetic tests, which this doesn't pick up. So that's one. I am going to defer I think the answer I know the antibody question is yes, but there's experts. So I'm going to actually go to and make sure that that's actually true.

Trish Kritek:

I'll ask Deb, do you know if people's antibody tests will be positive after they get the vaccine?

Deb Fuller:

Your antibodies has to definitely be positive. The antibodies against spike protein are what are going to protect you. With that said, there are already tests being developed in the laboratory to distinguish between antibody responses induced by the vaccine versus antibody responses that would be induced by the pathogen. That is really looking at different protein on the virus that is not encoded by the vaccine.

Trish Kritek:

Okay. So antibodies-

Anna Wald:

Can I just add here?

Trish Kritek:

Yes, please.

Anna Wald:

The virology lab actually the test they're using looks for nucleoprotein antibodies and not spike. So our internal test that we use will not be positive after this vaccination.

Trish Kritek:

Okay. So thank you for clarifying. So the antibody tests that we use right now is not to that specific protein that we're creating an antibody response to. So if got the vaccine our antibody tests will not be positive based on that, is that right? Okay. You will make antibodies to the spike protein but that's not what we're measuring. Thank you for clarifying that, that's really helpful. Before we leave these contra-indications... I mean complications or side effects Tim, I'm actually going to ask this question of you because I know you've had some conversations with Barbara Goff and others in the department of OBGYN. There are many, many questions that came in beforehand today focused on getting vaccinated if you're pregnant or breastfeeding. So I wondered at first the question is, are we offering it to people in this first year who are pregnant and, or breastfeeding?

Timothy Dellit:

Yes, we will be offering it. So pregnant women and women who are breastfeeding were excluded from the study. However, the recommendations from the Society for Maternal-Fetal Medicine as well as our internal experts recommend that if you are in a high risk group such as healthcare workers and are pregnant or breastfeeding that you should still be offered the vaccine. When you look at that potential risk of mRNA vaccination it's thought that the harm whether it be maternal or fetal is very low relative to the known risk if a pregnant woman actually gets infected with COVID-19. So they should be offered to receive the vaccine based on their status as a healthcare worker.

Trish Kritek:

And then I think that the question is, do we have some guidance about whether or not to receive the vaccine? So we're going to offer it to everybody which I think I just heard you say.

Timothy Dellit:

Yeah, I think the recommendation is that they should receive and if you look at the Society for Maternal-Fetal Medicine, again, that's an individual choice, but that society of experts recommends that they are offered and receive the vaccine.

Trish Kritek:

Okay. I think that's helpful. And that goes for people who are breastfeeding as well?

Timothy Dellit:

Yes.

Trish Kritek:

Okay. Shireesha, did you want to add to that I saw you nodding. I didn't know if you had something else to add.

Shireesha Dhanireddy:

No. That's it that's exactly right. As we get more data the pregnant women will be included but right now we don't have any data. There was some data just of women who did get pregnant during the trials. And so there were 12 women who did get pregnant. There's just too early data to know from that. So we'll have more dedicated studies to evaluate that, but again, I want to emphasize what Tim said that, the Society for Maternal-Fetal Medicine and I think the American College of Obstetrics and Gynecology will also put forth a statement similarly that if you're a healthcare worker that as at risk for COVID-19 infection that you should be offered vaccine similar to other healthcare workers.

Trish Kritek:

Okay. Thank you. I think that is a super common question and I appreciate both of you, and I think we'll update our FAQ's with the nuances of the answer from today. So thank you. I'm going to turn to you Anna. I have a bunch of questions about what happens as you get vaccinated, but before I do that, we've alluded to this trial a couple of times. And since you are our trials expert I wondered if you could... We could spend the whole day on this, but give us a little short version of the trial that was just published yesterday in the New England Journal of Medicine which is leading to this probable approval for the vaccine.

Anna Wald:

The trial was conducted globally. So it was not only sites in the United States, but in other countries as well. It enrolled very rapidly and it followed people until certain number of COVID cases was documented. This trial randomized people one-to-one. So like randomly tossing a coin to either receive a vaccine or placebo just basically salt water and then follow up people for development of COVID. And they stopped because they were accruing cases and when they looked at the results it turned out that over 160 cases were in the placebo arm and there were less than 10 in the vaccine arm. So that shows incredibly high efficacy. I think it's important to note that after the vaccination people are followed very carefully for any safety signals and there are both followed very close right after the injections which in this study everybody got two shots, but they're actually followed up to two years.

Anna Wald:

So even though we now have these early results that have been published, the trial is not over because it is really important these trials to continue to follow people for longterm safety events. I see there was some questions in the chat about how do we know long term it's safe. And we can't really know about something that hasn't been yet given more than six months ago. So it is very important to put in place systems to monitor the safety, and those systems exist both within the clinical trials as well as now when we will roll out this vaccine the CDC has several different mechanisms for monitoring safety in the population.

Trish Kritek:

So we have the data for up to six months time from when people first got vaccinated and we'll continue to follow those people, but we don't have longer-term data obviously right now. And we will study the

people who are subsequently vaccinated not as part of the trial, through the CDC keeping track of other issues that might come up that we learn about as more people are vaccinated.

Anna Wald:

Right. I think what's really reassuring that in general vaccines are considered to be the safest interventions that we have because we give them to healthy people. And most of the side effects that were concerning about actually emerged pretty early. So the longer we follow people of course the better but I think those systems are in place.

Trish Kritek:

So I think the other question relevant to the duration of time that we've given these is, do we have a sense of how long immunity will last? Many people have asked, do I need to get it every month? Do I have to get it annually like the flu vaccine? Is it like MMR, I do it and then once again or do... And I think the answer maybe we don't know, but maybe you can tell us what we think.

Anna Wald:

Yeah. I think we don't know but I actually think that immunity from vaccines can be better than immunity from natural infection. We know that for the other coronaviruses that normally circulate in the community, immunity is not lasting and we can get infected with the same strains over again, but it might be that for the vaccines actually we can create long term immunity and we will not have to get revaccinated. We don't obviously know but I don't think there's a reason to be pessimistic about it.

Trish Kritek:

Okay. So maybe that we have longer-term immunity and we'll learn over time. I think the last two questions for you before I give you a break. One is this trial and the other one that Tim said is going to be discussed and we are both two doses. Do you need both doses? People have asked that question repeatedly and when did we start to see people being immune relative to those two doses?

Anna Wald:

Well, that's an excellent question. The data fully has not been analyzed. It does look like you have about 50% protection from the disease immediately after the first shot. But the number of people that have been looked at with only one shot is very small because 98% of the participants in the trial went on to have both shots. So we actually don't have a lot of data on a single dose, but it does look like it kicks in a very early after the shot. It is really important now to get high levels of immunity because we not only want to protect the person from getting ill, but we actually want protect them from getting infected and from spreading the infection to others. So that's why I think two dose is going to be what's recommended in our system by the CDC.

Trish Kritek:

Okay. So we don't know for sure if there's some immunity after the first dose and maybe more we just don't know. We think you have really good immunity after the second dose. And how many days after the second dose do we think people are probably feeling that response?

Anna Wald:

For the data in the clinical trial they started looking seven days after the second shot and it looks really good. So it looks like it kicks in a very quickly after the vaccine.

Trish Kritek:

Great. And I don't know if this is your Deb but a really common question is relevant to what you just said Anna, which is, I think people are wondering if I get the vaccine since they tested whether or not people were symptomatic they didn't actually test if they were COVID positive. Could I still be infectious? Could I be an asymptomatic carrier even if I am not getting sick. You want to answer that?

Anna Wald:

We don't know yet whether it is true or not. I think there are studies that are planned. You will know eventually how many people in each group that antibody to COVID. So could they have some seroconverted acquired immunity but we're not symptomatic. We don't know that yet and I think that's a really important point because that means we cannot abandon masks and physical distancing even though people may feel vaccinated. And I'm getting a lot of questions like that, can I stop wearing a mask with my patients if I'm vaccinated? And the answer is no.

Trish Kritek:

Okay. So I think we're going to actually pause on this one, because I think this is a really important one and it came up a bunch in the questions. I'm going to give Santiago a chance to answer too because he's talked to me so much about masks when I gave him an opportunity. But I think to go to the first question, we don't know if you could still get infected after you're vaccinated, that is unknown at this point in time. And thus, we're going to encourage people to continue to do all the things we're doing. Santiago, do you want to talk more about that?

Santiago Neme:

Yeah. No, absolutely. Because we don't know we really need to continue to do this just to make sure that everyone's protected. So since I have the mic I wanted to make sure that also... Last night I participated in a forum for Spanish speakers and that was the question that everybody wanted to know is whether they can stop wearing masks. And the answer is no, at least with information we have now.

Trish Kritek:

So still wearing masks, still physically distancing, still washing our hands, still doing all those things, which is really hard to hear because everyone wants life to go back to normal. And I think we still need to hold true to all of those behaviors that we've been reinforcing over and over again. That's great. I'm going to switch gears and talk a little bit about us rolling it out here at UW Medicine for a little bit. I may come back to the vaccine trials and those details in a little bit if we have time, but I want to make sure I talk a little bit about what we're going to do here. So Shireesha, Tim gave us a little bit of broad strokes about rollout here. He alluded to these tier ones. So can you go in a little bit more detail of who the first group of people are?

Shireesha Dhanireddy:

Yeah. So we really we're looking at that CDC guidance as Tim mentioned to really vaccinate workers in a healthcare setting who are working in contact with either people with COVID-19 or their laboratory specimens. So that's a broad group including many different types of staff that are working particularly on our COVID units. So we're thinking about people in a high-risk setting exposed to many people with

COVID. So units where that's predominantly COVID units. So that's our first push and this is really to maintain our COVID surge operations. Right now we all know in our community we have really high numbers. Our projections are that these numbers are going to rise and we want to maintain our workforce. And so making sure that the people that work in these critical areas are first who are going to get protected.

Shireesha Dhanireddy:

That being said, we have a large group of people who are in the clinical setting, who are workers in our hospitals and our clinics that are going to be in contact with people that are positive for COVID and at various stages of their disease and illness. So we want to make sure that that entire group is also protected. So those individuals will also be invited to be vaccinated not in the first week. We want to focus on our COVID units to maintain that capacity and then to quickly roll out to the other group of individuals that are also patient facing. And again, I want to reiterate this as a broad range of staff that will fit into these groups. And the time difference is really weeks like Tim said, not months so that we can get everyone in this phase 1a vaccinated.

Trish Kritek:

Okay.

Timothy Dellit:

I'll just make one other comment. We're also working with public health to define these subgroups more and alignment with other healthcare providers in our community. So for instance, when we receive those doses, over 20% of the doses we receive are reserved for other partners in the community. Seattle Fire Department, EMS, other healthcare providers and other organizations that logistically can't offer the vaccine. And so we need as a community to move forward at the same pace to ensure all healthcare personnel at all of our sites are vaccinated before we go into the nonclinical areas. And so there's a lot of coordination, not just our own prioritization but it's really an alignment with public health and other health care facilities.

Trish Kritek:

So trying to have a community view and be equitable, starting with the people who are taking care of a lot of patients who are COVID positive. But we're talking in weeks, people who are interacting with patients and then I think even downstream from there after all of those folks, and we're talking about all employees across UW Medicine as the third tier, is that right?

Shireesha Dhanireddy:

Sure. Sure.

Trish Kritek:

Okay. I'm going to ask you-

Shireesha Dhanireddy:

Yeah. We really want to focus on phase 1a and so those employees who are really in that CDC phase 1a are who we're going to target in this first rollout that's what we really want to emphasize. I know there's a lot of questions about non patient facing staff as Tim mentioned, but we really want to make sure that

we the vaccine goes to these intended groups in phase 1a and also looking at the community of first responders and other organizations that are also have healthcare workers or workers in a healthcare setting that are not able to utilize or store the mRNA vaccines that are also critical responders and need it earlier in the pandemic.

Trish Kritek:

Okay. I got it. Patient facing that's our priority and being equitable. I'm going to come back to you in a second. I'm going to ask you a couple of quick ones Shireesha that kept coming up. Residents and fellows, are they in this category.

Shireesha Dhanireddy:

Yes they are.

Trish Kritek:

Keep your cell phone muted. Medical students, are they in this category?

Shireesha Dhanireddy:

They are in this category.

Trish Kritek:

People who are travelers, like nurses who are traveling and working in our institution, are they in this category?

Shireesha Dhanireddy:

They are.

Trish Kritek:

Okay. Family members.

Shireesha Dhanireddy:

No, they are not.

Trish Kritek:

Okay. So that's an important one because I think a lot of people are asking about family members. Our priority is people who are facing patients and we understand the worry about family. We all completely understand that, but that is not part of our first tier. Yes?

Shireesha Dhanireddy:

Yes. And phase 1b of the CDC rollout per vaccine will start to address high risk patient population. So persons who are at high risk for morbidity and mortality from COVID disease and that anticipated rollout is really end of January or early February. So this is all going to happen pretty quickly.

Trish Kritek:

So high-risk end of January early February, because I think people were also worried about that. Older folks with other conditions, so we're thinking in the next few months that will be-

Shireesha Dhanireddy:

And I will say as phase 1a another important group is long-term care facility residents and staff are going to be in this grouping as well to make sure that they're vaccinated early.

Trish Kritek:

Okay. I want to ask you Santiago, because I know you've had some conversations about this. Shireesha alluded to the fact that we want to make sure that it's not just doctors and nurses but it's our environmental services team, it's nutrition team, it's folks who are interacting with patients on the units in the hospital or in the outpatient setting. I know you've had some conversations about trying to mitigate disparities in distribution of the vaccine. I wondered if you could comment on what we're doing to try to address that.

Santiago Neme:

Absolutely. Like Tim and everyone on this call had said, the success of our campaign really has to do with everyone participating. And we want to make sure that we get the right information to everyone who is either unsure, has doubts or feels they need more information. So we're coordinating with the [Paul Houston's 00:46:35] Office to make sure that we have discussion forums or folks can ask about their concerns or their safety concerns. They need more information because we want to help everyone to achieve and to make an informed decision because we're only going to succeed if the whole globe really participates. Otherwise we will not succeed and this will not be a robust and intervention as it should be.

Trish Kritek:

I appreciate your efforts on that. And I appreciate there's understandable confusion and fear about this. So I think everybody on this panel wants to help answer questions, which is why this won't be the end of our answering questions. We want to answer your question. So people feel okay about this.

Santiago Neme:

We'll have several sessions coming up.

Trish Kritek:

I think that's great. And I think we want to keep answering. Tim sorry?

Timothy Dellit:

We've received some questions around the basic science departments within the school of medicine and our research environment. Again, our goal is to get all of our community vaccinated. It's just a matter of how we go through the process starting with the CDC recommendations around the health care personnel, but ultimately yes, all members of our community will eventually be offered the vaccine as we go forward over the next several months. And we've also had a lot of questions around research coordinators. After we get through the healthcare personnel then we will start to look at those and we'll look at those that are specifically involved in COVID-19 trials and then sort them out. But again,

everyone will have access to the vaccine and that's where we just really ask everyone's patience as we go through this. It's going to go amazingly quickly but we just ask for your patience.

Trish Kritek:

Okay. I got the message asking for patience. I think the other part of that message was, we're going to get more granular in the tiers as we go. And we're starting with the highest tier and being granular as we need to be there first. And then we'll start sorting through everybody else. So it's not just like it's one, two, and then everybody else. It's one, two, and then we're going to keep making different groups, is that right? I see Shireesha nodding at me.

Timothy Dellit:

I met with the rest of the healthcare community, right? We got to stay in alignment with our overall community.

Shireesha Dhanireddy:

That's absolutely correct. And I communicated with Jeff Otjen and others too. There's guidance that's forthcoming to further sub prioritize these later groups amongst people who work in healthcare settings. So we'll want to be in alignment with that.

Trish Kritek:

So, Shireesha I want to ask you. Thank you. I think everybody here has repeatedly asked about taking care of the whole community. And I think this is the same spirit of taking care of the whole community. There are some people who are worried that they're going to get the first dose and then are we going to make sure that we have the second dose for them? How do we know that we'll have the second dose and is the timing of getting the second dose super important?

Shireesha Dhanireddy:

Yeah. Actually that's a great question. So when the invitations go out for our employees to get scheduled for vaccine, they will be able to schedule the first dose and the second dose at the same time. So it's 21 days, but there's a little wiggle room of a day or two before in a day or two after and so they will be able to schedule that second dose. Our allotments that we are getting are based on the fact that we will get that same allotment for the second dose. So we should be giving as much as we can to everyone and not saving for later because they're doing that at the state and federal level for holding vaccine for that second dose.

Trish Kritek:

So we're using what we have and we have a plan and we have a communication from the state that we're going to keep getting it. So then we'll know that. And then when you schedule the first dose you will schedule your second dose at the same time. Thank you for that. Anna, I'm going to ask you this question. There were a lot of people who asked about I've had COVID should I get vaccinated? And I would say there was a very humanitarian aspect to that because many of them said, should I not get vaccinated right now because other people might need it more?

Anna Wald:

I think it's a wonderful question. We think that if you've had COVID you're partially protected from getting another episode, but we also know that it's not 100%. So right now the recommendation is to get vaccinated if you have not had some traumatic COVID in the last three months. So I think if your train comes and you fall into this category I would say that people should line up and get the vaccine. I also should add that there were definitely people in the clinical trial who had COVID and then go vaccinated. And there's no concern about any safety issue in that group.

Trish Kritek:

There is no concern about safety.

Anna Wald:

There's no concern.

Trish Kritek:

Okay. So-

Shireesha Dhanireddy:

Yeah. I do want to add that when you sign up for scheduling, it will ask you, have you had COVID in the last 90 days, because that is one of the ACIP recommendations to defer vaccine if you've already had COVID in the past 90 days. So there will be an option to defer if you say yes.

Trish Kritek:

Okay. So you can defer, maybe the recommendation is go ahead and get vaccinated, you have some degree of immunity, it probably isn't forever and so we're still going to recommend getting vaccinated-

Timothy Dellit:

Yeah. And the deferring is not a safety issue, it's just to allow others who don't have any protection to go ahead.

Trish Kritek:

Thank you for clarifying that Tim. John, I'm going to ask you this question. People ask, will you still need to quarantine if you're exposed, if you've been vaccinated?

John Lynch:

We haven't actually tackled that question but the current status is all policies that are occurring place will continue to be in place and followed for the foreseeable future. As things go forward if we learn more as Dr. Fuller, Dr. Wallace, Dr. Dan already provide us more information we're always open to more information.

Trish Kritek:

Where'd you go?

John Lynch:

Can you still hear me?

Trish Kritek:

I can hear you. Yeah.

John Lynch:

I can't hear you. Okay. Anyway, I will just finish. What I'm saying is that we were always open to changing our policies but for the foreseeable future, we're going to stick with what we have in place.

Trish Kritek:

I know you can't hear this, but he's probably better off not being able to hear me. So we'll let him continue. John has been feverously answering questions in the Q&A which I really, really appreciate. I don't know, maybe it's you Shireesha I'm not sure who can answer this. People want to know how they can volunteer to help vaccinate. I think there were emails that went out about that, is there someplace that people can go to to volunteer?

Shireesha Dhanireddy:

Tim might have some more information about this but last I heard there were hundreds and hundreds of people who have volunteered already.

Timothy Dellit:

We have over 700 volunteers.

Trish Kritek:

Oh my gosh. That's wonderful.

Timothy Dellit:

Yeah. So it's been amazing to watch. So that is really, really exciting to see.

Trish Kritek:

I just want to say thank you to this community that is really heartwarming. And actually this other question has come up I think in the Q&A today, and it came up earlier. People want to know can they take a picture of themselves getting vaccinated and share it on social media? So Tim, I'm asking you, because you're rule enforcer.

John Lynch:

I'm in charge of employee health and I say yes.

Trish Kritek:

Oh, okay. And you have a Twitter account. I don't think Tim has a Twitter account.

Timothy Dellit:

They can take a picture of themselves, right, not someone else, yeah? Then they can get-

John Lynch:

Selfies are allowed.

Trish Kritek:

Okay. John is enthusiastically co-found his ability to hear us and says, yes, you can take a selfie and share it. And I love that people want to do that because part of our job is to get people to feel like it's okay to do this and it's understandable why people are anxious. This is an anxious time and this is a gray space. Some anxiety about it is really understandable. Okay. I'm going to try to fit in a couple last questions. Anna, I'm going to look to you. People have asked there's these other vaccines, what if there's better vaccines coming? Does that mean I can't get those other vaccines? Do you think there's something else better on the horizon? Can you comment on that?

Anna Wald:

I don't know. We know results of three trials right now. Two of them use the mRNA construct, Pfizer's the one we'll be getting next week hopefully. The next one is Moderna and that could come and then month or so. The other study that we know works but not nearly as well as the AstraZeneca, that might be vaccine construct that's useful in other places as it does not require the refrigeration that the Pfizer vaccine. But I don't know that we will have it here and when we will have it here. Since you asked the question we are starting a new clinical trial next week with Novavax which is a protein and antigen vaccine for a very traditional vaccine format. So if people are not getting vaccinated with Pfizer because they're not necessarily patient facing but they want to participate and potentially get a vaccine earlier, they can enroll in the clinical trial to do that. And they have two out of three chances of getting the real product in that trial.

Anna Wald:

I think all of the trials are dealing with what is going to happen once we know that people who are enrolled that they are eligible to get the vaccine outside of the clinical trial and it's recommended for them. And there's a lot of work being done to figure out both ethically how to do it and to make sure that we protect people as quickly as possible and as well as possible.

Trish Kritek:

Yeah. That question has come up in the chat. And I think it's come up before, which is like, are we then vaccinating people who got placebo and how do we continue to study this one, we want to protect as many people as possible.

Anna Wald:

And we need all sorts of vaccines because there's not going to be enough one type of vaccine to vaccinate everybody. So we need to continue to look for new products.

Trish Kritek:

So we're going to keep doing trials. We're doing one now if people want to enroll in that trial they can. It's more of the traditional vaccine that Deb talked about earlier where we make the protein outside and then expose the person to that. Do we know if... Anyone can answer, it might be maybe Anna you, think Shireesha alluded to the fact that we're going to enroll pregnant patients in some trials moving forward, is that true?

Anna Wald:

There are trials starting specifically for pregnant women as well as for children in the next few months.

Trish Kritek:

Okay. Many people asked about children getting vaccinated-

Anna Wald:

Mm-hmm (affirmative). The other question that has come up is what happens if you get one dose and then the second dose is no longer available, can you go to a different manufacturer? We don't have data on that yet, but we hope to have it soon as well. Those trials are starting as well, a mix and match study.

Trish Kritek:

Okay. So there's going to be many million or more vaccines. We have a globe to vaccinate. And so we're going to continue to work on these different vaccines and different trials. I have to say, you all did an amazing job of answering so many questions. And I know that there's all these other questions out there. I see still 159 questions in the Q&A and we will save these questions. We will incorporate them into the Q&A's that we post. We will continue to respond to. I know that there are some physicians, other clinicians who have really nuanced questions we'll try to answer all of those as well. So this is a start, not an end to answering questions. I want to do a special thanks to Deb Fuller, Anna Wald and Shireesha Dhanireddy for coming today. Thanks. I really appreciate your wisdom and your grace and joining us.

Trish Kritek:

I want to thank Santiago, John and Tim for being here as always. And the engagement today has been outstanding. I am so inspired by our community coming together to learn about this. I want to end by thanking all of you like I do every Town Hall for engaging and learning about vaccines, engaging in this process with us, for taking care of our patients, their families and most importantly... That's what this is about, taking care of each other. We'll see you back next week. Thank you so much. Bye.