

TPWKY

This is Exactly Right.

Ashley

Hi everyone, my name is Ashley Pleasant, I work as a paralegal in Tyler, Texas but I live about an hour away in Wood County with my mom and stepdad. Tyler is a college town but the surrounding area including my county is very rural. I think people have had a false sense of security that COVID wouldn't come here but in reality our low population density could only delay its arrival. My family and I have been taking all the precautions we can since the nationwide lockdowns began happening in March and April. We only leave the house to go to work and the store, we wear multilayer cloth masks every time we leave the house, we wash our hands, use hand sanitizer frequently, and we stopped seeing anyone in person socially. But at the beginning of October, COVID still found us.

It started off like a mild cold. My mom started experiencing mild fatigue and a cough. We were slightly worried but trying not to read too much into it. I mean, we were being careful after all. Within three days though, I started having the same symptoms, my stepdad the day after me, and my 87-year-old grandmother the day after him. We were still trying to not worry too much, I mean colds are common and still happen even during a pandemic. That all changed though the night my mom decided to grill hamburgers. I realized we had a serious problem when I couldn't smell the charcoal grill or cooking burgers.

After that, we couldn't keep telling ourselves it was just a cold. Over the course of the next week, all four of us were tested and all four of our tests came back positive for COVID. The second week of symptoms felt more severe with more extreme fatigue and coughing as well as headaches, body aches, and a loss of appetite. None of us really ran a fever with the exception of my grandmother for just one morning. She was struggling with dementia and wasn't eating or drinking enough, my mom and I had to get her to drink fluids every hour to keep her hydrated and keep her fever down and we had to make sure she was eating so she didn't get too weak.

We muddled through well enough for a few weeks, feeling pretty crummy but managing. Around the end of October, we felt like we made it through the worst of things and were starting a slow recovery process. My grandmother had even gotten a mostly clean bill of health from her doctor and was getting up and walking around more. We really thought we were in the clear.

Then at four o'clock in the morning on October 24th, I heard my grandmother call out for my mom while I was on my way to bring her a drink of water. When I got to her she was having difficulty breathing. She was still aware and talking but she couldn't take air in properly. I ran to get my mom, called an ambulance, and within 15 minutes she was gone.

My mom, stepdad, and I are still experiencing mild symptoms from COVID two and a half months later. I personally still have shortness of breath, fatigue, trouble concentrating, and a reduced appetite. We're all still struggling with the fact that my grandmother isn't here this year for the holidays. This is something no family should have to go through but this pandemic only ends if we all do our part.

So please, everyone. Wear your masks, wash your hands, stay safe, and save a life. Thank you.

Rhiannon

My name is Rhiannon. I live in Central Florida, I work as a paralegal for a small family law firm, and I am a volunteer participant in the phase 3 trial of the COVID-19 vaccine produced by Pfizer.

Before my first visit I had a pre-screening eligibility phone call with someone from the study. She mentioned that it was \$150 per visit, and I was like, 'Ooh, well I guess it's worth it to be able to participate.' Then she mentioned that they would add the money to a debit card starting at my first visit. It took a minute to register that they would pay me. In late August I went to my first appointment. They took a blood sample, gave me a pregnancy and a COVID test, had me complete and sign an informed consent form, I gave them my complete medical history, and finally they injected me with the vaccine or placebo.

They sent me home a thermometer, a copy of the informed consent form, an emergency information card in case I have to go to the ER during the study, and a swab test kit that I can administer myself and mail in if I develop symptoms and can't get tested right away. Three weeks later at my second visit, they gave me another pregnancy test, COVID nasal swab, and a second injection which was the same as the first. They administer either vaccine/vaccine or placebo/placebo.

About a month after that, I returned for my third visit during which they drew blood to check antibody levels. My fourth visit will be in March of 2021 and then I'll return for at least a fifth and a sixth visit over the next 20 months. This is an observer-blind study so they will not tell me whether I received the vaccine or placebo until it's over. They also don't share with me the results of my blood tests.

Once a week I'm asked to complete an illness diary through an app on my phone. I simply answer yes or no to the question of whether I have developed any symptoms of COVID-19. So far I've been able to answer 'no' every week. After my first injection I felt nothing. No pain at the injection site, no indication of any side effects at all. After the second injection though, my arm was sore for days, it was itchy, and there was a raised bruise at the injection site. I was cautiously optimistic that I had received the vaccine. Actually, I was pretty thrilled.

I work from home most of the time but I had worked in the office one Thursday in late October and by the following Monday, two of my four coworkers had symptoms and tested positive. By the next week, a third coworker was also positive and symptomatic. Knowing that I had been exposed, I got tested and was negative. At that point I was pretty sure that the vaccine had made me, well, immune is the right word but invincible is how I felt.

So in November I asked my primary care physician for an order for an antibody test. It came back negative. I was so disappointed. I don't know what will happen when the vaccine is approved and available. The study doctor said that I would not be at a disadvantage for having participated in the trial. He sent a letter a couple weeks ago that said they were, quote: "Exploring potential ways to change the study to create a process that would allow interested participants in the placebo group who meet the eligibility criteria for early access in their country to cross over to the vaccine group in the study." End quote.

At my first visit, the doctor in charge of the research facility asked me why I decided to take part in the study. I was speechless for a moment, thinking, 'You see there's this podcast. Erin and Erin got me all excited about vaccines and medical research even before the pandemic, and I was really excited for this opportunity to not only take part in an important study but to see for myself how informed consent forms look these days, because you know they haven't always been like this.' But before I found words, he said that most people tell him they're just so tired of all this and want to help things get back to normal as fast as possible.

I nodded and said that yes, I just wanted to help. Our conversation was over pretty quickly, so I never got to tell him the rest. That I don't believe things are ever going to get back to normal because some things have changed forever, that this could be my one chance as a paralegal to help save lives through medical science, that I feel like it's my duty to do what others can't do, and that I'm incredibly grateful to live in 2020 when so many medical professionals have worked tirelessly so that there is already a vaccine.

TPWKY

(This Podcast Will Kill You intro theme)

Erin Welsh

Thank you so much Ashley and Rhiannon for sharing your stories with us. We really appreciate it. And thank you to everyone else who has sent in their firsthand accounts of how COVID-19 has impacted their lives. I think it's so important that we tell these stories and hear these stories to know that we're not in this alone and to remind ourselves of the far-reaching effects of this pandemic.

Erin Allmann Updyke

Yeah, absolutely.

Erin Welsh

Hi, I'm Erin Welsh.

Erin Allmann Updyke

And I'm Erin Allmann Updyke.

Erin Welsh

And this is This Podcast Will Kill You.

Erin Allmann Updyke

Yeah. In this episode of our Anatomy of a Pandemic series on COVID-19, we're revisiting the topic on everyone's minds: vaccines!

Erin Welsh

Yes. How do these COVID-19 vaccines work? How do we know that they're safe to take? And when will they become widely available?

Erin Allmann Updyke

Great questions, Erin.

Erin Welsh

Great questions, and these questions are just the tiniest sampling of what we covered in this super duper info-packed episode.

Erin Allmann Updyke

Really truly. I don't think we've ever packed more information into one episode.

Erin Welsh

Oh my gosh.

Erin Allmann Updyke

At my first visit, the doctor in charge of the research facility asked me why I decided to take part in the study. I was speechless for a moment, thinking, 'You see there's this podcast. Erin and Erin got me all excited about vaccines and medical research even before the pandemic, and I was really excited for this opportunity to not only take part in an important study but to see for myself how informed consent forms look these days, because you know they haven't always been like this.' But before I found words, he said that most people tell him they're just so tired of all this and want to help things get back to normal as fast as possible.

Erin Welsh

It is quarantini time. What are we drinking this week?

Erin Allmann Updyke

Well of course, Quarantini 13! (laughs)

Erin Welsh (laughs) Naturally. And in the Quarantini 13 is bourbon, ginger ale, rosemary simple syrup, lime juice, and muddled blackberries.

Erin Allmann Updyke Delicious.

Erin Welsh It really, really is. And also we want to give a shout-out to Abby and Jessie who are the daughters of one of our guests for this episode, Dr. Orin Levine, and who sent along a placeborita version of this recipe which they called the Sweet Lady Levine.

Erin Allmann Updyke I love it so much! (laughs)

Erin Welsh It's amazing. (laughs)

Erin Allmann Updyke Thank you both so much for the suggestion, it made our lives easier coming up with this quarantini and it's delicious.

Erin Welsh (laughs) Yeah, really, I was like, 'Oh my gosh, a recipe? Just here? Just gifted? This is amazing.' We will post the full recipe for the Quarantini 13 along with the nonalcoholic placeborita on our website thispodcastwillkillyou.com as well as on all of our social media channels. So make sure you follow us there.

Erin Allmann Updyke Okay, what else? We are, of course, still soliciting firsthand accounts for this COVID-19 series, so if you haven't yet and you'd like to submit your firsthand account, you can go to our website thispodcastwillkillyou.com, click on the COVID-19 tab and that'll send you to a Google Form that you can fill out. And thank you again so much to everyone who has submitted their firsthand account so far.

Erin Welsh Absolutely. And we are also in the process of getting transcripts done for all of our episodes! And we are so excited about this.

Erin Allmann Updyke Yeah, really. And we will announce on our social media when the transcripts are ready for current or past episodes, so make sure that you follow us on there. And we'll also be posting links to the transcripts on our website under the TRANSCRIPTS tab so you can also check back in there periodically if you are curious.

Erin Welsh Yeah.

Erin Allmann Updyke Other than that we have kind of usual business things really quick. We have a Goodreads list, check that out, a Bookshop affiliate account, really phenomenal, and amazing TPWKY merch. You can find links to all of these on our website thispodcastwillkillyou.com.

Erin Welsh Okay. Erin.

Erin Allmann Updyke (laughs) Yeah.

Erin Welsh I think it's finally time to get to the meat of this episode.

Erin Allmann Updyke I think so too.

Erin Welsh I mean, this is what everyone has been waiting for.

Erin Allmann Updyke	Really truly, myself included.
Erin Welsh	Oh my gosh. At the time of recording this, which is December 15th 2020, according to the New York Times coronavirus vaccine tracker, there are currently 41 vaccines in phase 1 trials, 16 in phase 2, 16 also in phase 3, 5 vaccines approved for early or limited use, and 2 approved for full use.
Erin Allmann Updyke	That is huge! Amazing! Truly phenomenal!
Erin Welsh	Absolutely remarkable, I can't stop smiling thinking about it, it's amazing. It just feels like such a relief. And it's really hard to take in good news and so it sort of feels like...
Erin Allmann Updyke	(laughs) It's true. The news that there are multiple vaccines that have been shown to be effective against this virus that causes COVID-19 is some of the best news that we've had in a very long time. And it really does finally feel like the light at the end of that very, very long pandemic tunnel we're living in is finally visible.
Erin Welsh	Yes, it really does feel that way. But there are many questions that remain.
Erin Allmann Updyke	Oh yeah.
Erin Welsh	There has been a lot of concern about the safety of these vaccines and possible side effects in addition to questions of access and vaccine distribution. And to help us address these concerns we were fortunate enough to talk to two amazing scientists.
Erin Allmann Updyke	Two!
Erin Welsh	Two. Two, how cool. Dr. Maria Sundaram, postdoctoral fellow at the University of Toronto Center for Vaccine Preventable Diseases and fellow at ICES, a nonprofit health research organization. And also Dr. Orin Levine, Director of Vaccine Delivery at the Bill and Melinda Gates Foundation.
Erin Allmann Updyke	Both are phenomenal interviews, we can't wait for you to hear them. We're gonna start with Dr. Sundaram who answered our many, many, many questions about the vaccines themselves. Questions like what are the ingredients and how do they actually work? We recorded this interview on December 14th, 2020. So we'll let her introduce herself right after this break.
TPWKY	(transition theme)
Maria Sundaram	So my name is Maria Sundaram, I'm an infectious disease epidemiologist, and I'm a postdoctoral fellow at the University of Toronto Center for Vaccine Preventable Diseases and I'm also a fellow at ICES which is a not-for-profit research institute in Toronto.
Erin Allmann Updyke	Excellent, thank you. We're very excited to have you here. Over the last month or so there have been some very optimistic and exciting headlines with the emergence of what appears to be at least three potentially successful vaccines for SARS-CoV-2. Could you kind of break down what those vaccines are and how maybe each of them work?

Maria Sundaram

Yes, definitely. So I think the three vaccines that we're talking about are the Pfizer BioNTech vaccine, the Moderna vaccine, and then this vaccine that's being developed by Oxford and AstraZeneca. And it's worth noting there's a couple other vaccines that have been approved for use in other countries but I can just talk about these three, I think they've been at the top of our national conversation, at least. So the Pfizer BioNTech and the Moderna vaccines are both mRNA vaccines and the Oxford AstraZeneca vaccine is a non-replicating viral vector vaccine.

Your listeners may know that when we're talking about kind of a traditional vaccine, a normal vaccine like your seasonal flu shot, what we're doing is we're showing our immune systems a dead virus, a killed virus that can't infect us but it's the whole thing. So our immune systems are seeing this complete virus that's dead and saying, 'Okay, this is really helpful, now I know what this looks like I'm gonna be prepared for next time I see this one that looks like this, but it's alive.'

So we're starting at an earlier point in the process with the mRNA vaccines. And what we're actually doing there is we're giving our cells like the IKEA instructions to make one part of the virus and in this case it's the spike protein, which is this protein on the outside of the coronavirus. So our cells are able to produce this protein only, not the whole virus but just this protein, and then they say, 'Okay, we're gonna protect specifically against this protein, which is the protein that we really need to protect against. And then we're prepared when we see the whole virus.' So that's really helpful because it allows us to understand how to protect against this virus without the risk of actually getting ill.

And the non-replicating viral vector that's in the Oxford AstraZeneca vaccine works kind of in a similar way but instead of us making that protein, we're asking a different virus to make that protein. In this case it's an adenovirus. So this is another respiratory virus that in this case, it's usually among chimpanzees, it doesn't really cause us any physical discomfort or anything, we probably don't even notice that it's there. But we've given this adenovirus the information to also make this spike protein. So it's on its little membrane, it's showing all of its sort of normal adenovirus stuff and then it's also got the spike protein. So our immune system is like, 'Oh okay, there's that thing that I need to protect against, now I know.' So that's kind of how those vaccines work.

Erin Welsh

Awesome. So let's start at the very beginning, and this might be sort of a more general question, but what are in these vaccines? What are the ingredients and what do each of them do?

Maria Sundaram

Yeah, so I did talk a little bit about this already, kind of how the mRNA vaccines work and then how this adenovirus vector vaccine works. The other things that are in these vaccines, so for example the Pfizer vaccine has lipids, salts, and sugar. This is pretty similar to what's in the Moderna vaccine as well. So the lipids are these tiny little fat globules and they are there because we want to be able to protect this mRNA before it can be absorbed into our cells.

And I said before that the mRNA is kinda like IKEA instructions and it very much is but it's not in the book that you get from IKEA. (laughs) It's like it was written on ticker tape or on a super long CVS receipt. So it's kind of like, you know, flapping in the wind a little bit, it's bobbing around and it can be really fragile. And so we wanna make sure that when we're giving it to people that it really stays intact enough so when it gets to our cells it really has something meaningful to say and our cells can read it instead of being confused. So they've charged these little fat globs and the charge allows the mRNA to stick inside them. So it's almost like a little sphere that surrounds the mRNA and protects it.

The salts are the buffer that's in the Pfizer BioNTech and the Moderna vaccines respectively allow all of the stuff that's in the vaccine including the antigen and everything else to be the same pH and the same solidity as our bodies, and that's really helpful so that we can only react to the antigen.

And then there's sugar in both vaccines as well. And this can help, for example, if the vaccine has to be stored at very cold temperatures, it can help with the vaccine antigen not being damaged in that process.

And then the Moderna vaccine also has something called sodium acetate and this can be something that kind of holds all of this other stuff together, kind of stabilizing everything that's in the vaccine. Because there's polar items and then there's nonpolar items, which would be the lipids, it can sort of wind up... You know how salad dressing separates? (laughs) And you've got the oil and the vinegar and you have to shake it up in order to have it be palatable? So we obviously don't want our vaccines to be like salad dressing that has separated, so some of these things, sodium acetate for example, can help kind of stabilize that and the buffer can help with that as well. And both of those vaccines are preservative-free.

Erin Welsh

Gotcha.

Erin Allmann Updyke

So there has been some misunderstanding, I think, that we've heard a lot that these vaccines have the potential to give somebody COVID-19. And I think you kind of touched on this already but could you kind of explain more specifically why that isn't possible in this case?

Maria Sundaram

Yes, I can. So I understand why this is a concern and there are, way in the beginning when we were making vaccines we used attenuated versions of viruses and that means kind of, it was alive but it was kind of limping along, not as effective as the sort of natural infections against some of these different pathogens. And that's still the case for some of the immunizations that we receive today. For example, there's a live-attenuated version of the flu vaccine that you can get in a nasal spray. So this is an example of a virus that really can't cause illness but is still sort of limping along enough for our immune system to really take notice.

These vaccines that I've just mentioned, they don't contain a whole virus, much less one that's alive. As I mentioned, they only contain one part of the virus which is the spike protein. And so there's really, there's no virus in any of these vaccines that I've mentioned and so it's really just not possible, it's just not there.

Erin Welsh

So that being said, there is this advisory that people who receive the vaccine are still told you should still wear a mask. So can you explain why people should wear a mask even after getting vaccinated?

Maria Sundaram

Yeah this is a great question. Why should you wear a mask even after you've been vaccinated? So one really important thing to remember is that after you get the first shot, you're gonna have to wait three weeks and you're gonna have to go back for another shot, and then you're gonna have to wait a little bit after that to build the maximum amount of antibodies that we would consider for you to be fully vaccinated. And this is actually the case for a lot of vaccines, for example, when you get your flu shot you're not considered to be truly vaccinated until two weeks later because that's when your body has made sort of the maximum amount of antibody that's gonna really protect you throughout the flu season.

So first of all, you're not sort of immune like superhero-style right after you get the first shot, unfortunately. It's gonna take a while, at least five weeks. And you have to go back for the second shot (laughs) which is gonna be challenging, I know, for some people.

The other thing is that part of this is about humoral vs. mucosal immunity. So when we get these shots, we're going to have these antibodies in our blood. And you and I know that's not where COVID-19 goes first. It doesn't sort of get injected directly into our skin, it comes into our body through our respiratory pathways. And so there are these mucosal surfaces in our nose and our nasal pharynx, kind of the back of our nose and throat area, that also have their own sort of unique mucosal defense mechanisms and there can be cells waiting at that mucosal surface for different pathogens.

It's not clear yet what kind of immunity we might be developing from the vaccine at those mucosal surfaces. And so if that's not as robust as the immunity that's in our blood, we could wind up sort of hosting COVID-19 in our nasal mucosa and then inadvertently sort of wiping our nose and then exposing someone else to that. It's possible that it could happen. Even though we wouldn't experience physical discomfort from any sort of colonization, it's still possible that we could spread that on to someone else and it's always possible for us to touch a surface and then touch something else that someone else may touch and then touch their face.

So it's not as though we're completely cutting off all modes of transmission, we're reducing them quite a lot but it still may be possible to transmit that virus even if you don't feel unwell. So that's why it's a really good reason to continue wearing a mask and continue taking those other precautions as well, including washing your hands.

Erin Allmann Updyke

That makes so much sense. So kind of looking big picture, what does the timeline look like for these vaccines until we could just go to our doctor or the pharmacy and actually get one? What kind of steps are still remaining in the process?

Maria Sundaram

So I will start by saying I wish I could give you a date. (laughs)

Erin Welsh

(laughs)

Maria Sundaram

I wish I could give myself a date and be like, 'Oh, on this date, that's when I'm gonna go and get vaccinated.' I don't have that date yet because so much of this process is moving so fast and there are so many different moving components, and all of those moving components are happening sort of simultaneously. So a couple of things that I'm keeping in mind, and certainly it's gonna be longer for you and for me than it would be for healthcare workers, older adults, and essential workers, those people have the greatest risk and they need to be prioritized, we need to protect them.

The additional steps include the manufacturing, the delivery, rollout campaigns, and establishment of systems that help people remember to come back for their second dose - again, that can be really challenging. So those are all of the steps for vaccines that have obtained this emergency use authorization. For vaccines that aren't quite there yet, that's another step. So it's really hard to say exactly what all of that means. I'm hopeful for the fall but I have to be honest and tell you I'm not exactly sure what date.

Erin Allmann Updyke

(laughs) That's fair.

Erin Welsh

So even before this pandemic there was a great deal of vaccine hesitancy and now many people are expressing concerns about receiving a vaccine that was developed so rapidly. And, you know, is that actually a valid concern? And maybe by way of answering that could you walk us through some of the steps being taken to ensure safety and efficacy of a vaccine and these vaccines in particular?

Maria Sundaram

Yeah, this is a great question. So I completely understand that when you're not part of these steps, when you're not sort of living and breathing them everyday, this can be incredibly confusing. It's happened so fast and so many other things have been happening this year that it's just really, really hard to sort of put all of this in context. And even people like myself who are infectious disease epidemiologists by training and by trade, we often struggle to keep up with the incredible amount of information that's being circulated every day.

So I'll walk you through some of the steps that have been taken to ensure the safety and the effectiveness of these vaccines. So this is why we do phase 1 and phase 2 and phase 3 studies, different phases of clinical trials. So in phase 1 studies and preclinical studies, what we're trying to do is identify is this something that could help people, but more specifically is this something that could potentially be harmful to people? And we're continuing to ask that question about safety in each subsequent phase of clinical trials. And in each subsequent phase we're asking more and more people, 'Hey, are you feeling okay? How was that for you? Are you feeling discomfort?' Even, you know, 'Do you have a mild headache?' We want to know that as well. And that doesn't stop after the emergency use authorization or even after full approval from FDA.

So the U.S. for example, and this is true in other countries too, but specifically in the U.S. there are several different mechanisms for the reporting and sort of identification of different safety outcomes for vaccines. One of those is called a Vaccine Safety Datalink and another one is called VARS or the Vaccine Adverse Event Reporting System. So these are super fast mechanisms where we're constantly looking to see, hey, is there anyone who received this vaccine that maybe a week later they had like a headache still? Or they had some fatigue, or they had some other sort of safety outcome. We wanna know about that. Even though this vaccine has been approved by FDA, we're gonna continue to ask these questions and continue to make sure that there isn't, for example, some really super rare one in a million type of event that could make us reassess the risk/benefit ratio of this vaccine.

Erin Welsh

And so along these same lines, can you talk about what emergency use authorization means and whether we've seen this before, and if we have, under what circumstances?

Maria Sundaram

Yes. I will say we have seen emergency use authorization before and maybe one of the best examples is during the 2009 swine flu pandemic. During that time we had an EUA to use Tamiflu, which is a flu antiviral, for children less than a year old. At the time it was already approved for children over a year old but we knew during that swine flu pandemic, very young children were having really severe outcomes. And we were really concerned specifically for that age group and so we said, okay, the available safety data indicates that this is probably a good risk/benefit ratio for children under one year old. And then that became part of our pandemic response. So it's certainly not the first time that we've used this mechanism and I think it's really important that we do use it when we really need it, such as during a global pandemic.

EUAs can only be given based on phase 3 results or interim results from phase 3 studies and those interim results are sort of decided upon by this independent data safety and monitoring board. And then there's this expectation that those applications for EUAs that companies have to make formally to FDA. When they apply for the EUA, they include all of the safety information from their phase 1 and phase 2 studies and then ideally their phase 3 study with a median of two months of follow-up. So that means that not only are they assessing safety outcomes, but they're making sure that they're identifying safety outcomes on the kind of timeframe that we really think is relevant as well. So they're not just looking for the data after and then like two days after they forget about it. No, they really are looking for quite a long time after people do receive this shot.

Erin Allmann Updyke

Yeah, that makes sense. So I feel like you've explained a lot about how, you know, we've tried to make sure that this is a very safe vaccine. But for people who are maybe still a bit nervous or a bit scared, could you explain why someone maybe doesn't need to be any more afraid of this vaccine than any of our usual vaccines like MMR or even the seasonal influenza vaccine?

Maria Sundaram

So I do think it's understandable why people might be more hesitant or cautious about this vaccine development process because the mRNA and the viral vector vaccines are relatively new to us and the development process has been really quick. So it is definitely understandable. I think the main thing to remember is that all of these vaccines have gone through the same vaccine evaluation process as all the other vaccines that we've had. So we took the same amount of steps and asked the same amount of questions that we would have if this vaccine development process had taken 10-15 years, we just did it in a much shorter time frame. And that was possible because we all decided sort of as a society that these vaccines would be incredibly important to all of us. So there was a great amount of monetary support, political will, and then also tens of thousands of people agreed to be participants in these studies as well. And we wouldn't have had a vaccine so quickly if people were slower to say, 'Okay, I'm gonna participate in this study.'

So they've all gone through the same evaluation process and they all continue to be assessed with the same safety reporting mechanisms. So we're not just skipping steps just because, you know, this one time it's convenient for us. No. We're still adhering to all of those rules, we're not cutting any corners there. And again, I kind mentioned this a little earlier but the vaccines also cannot... These mRNA vaccines and the viral vector vaccines, they can't give you COVID-19 because they don't contain the virus.

Erin Welsh

Yeah. I also keep thinking about how this is just such a high stakes situation for the companies producing these vaccines, like if there's a misstep, if something happens, there's a lot on the line and not only that but just like public faith or acceptance or whatever of vaccines, that's also hugely on the line at this point. And so it really does seem like there's so much to risk, so why would there be steps skipped or something like that? Like there's just so much on the line.

Maria Sundaram

Oh yes, absolutely. And you know they have to still get the go ahead from FDA. So if they were to skip steps and then apply for this EUA... If they skip the steps FDA has to say, 'You know what, sorry. We can't award you this emergency use authorization, we can't do it.' And that really, just like you said, it represents a huge loss of investment for those companies. There's really no reason for them to skip steps and there's a lot of reasons for them to not skip those steps.

Erin Welsh

Right, exactly, yeah. So much of this concern, also, that I've seen around seems to be centered around potential side effects of the vaccines. And you know we expect to see things or it's not unusual to see things like mild side effects like you mentioned a slight headache or maybe some fatigue. And this happens for many vaccines including potentially the vaccines for SARS-CoV-2. And these side effects are not really something to worry about because they do seem to be short and mild.

But how likely is it that additional side effects, severe or not, that we haven't yet seen or even long-term side effects may emerge later on months from now as more people take the vaccine?

Maria Sundaram

So some of these outcomes as you mentioned like headache, fatigue, what my mom calls just feeling junky, feeling cruddy, feeling tired, maybe even having a low-grade fever for a day, they're unpleasant but they mean your immune system is working. And so that's a really good sign for us. And it's a possibility, however small, that rare side effects that may be more serious could happen. And that's why we continue to monitor vaccines for safety well after they're approved. We still are doing safety assessments for flu vaccines, for example. So we take that so seriously and especially, you know you mention with COVID-19 vaccines, there's so much on the line with keeping people safe and then proving to people that we've made sure that these vaccines are safe and okay for them to get. We really take that so, so seriously.

Erin Allmann Updyke

Yeah, definitely. So speaking of kind of long-term side effects, there's been some discussion lately of a fear of antibody-dependent enhancement which is something that we've only touched very briefly on in this podcast, I think in our dengue episode. So what do we know... Maybe you could explain for people who don't remember kind of what antibody-dependent enhancement is and what do we know about the risk of vaccine-induced ADE with this COVID vaccine or, I don't know, maybe with vaccines in general?

Maria Sundaram

Yeah, this is a great question. So antibody-dependent enhancement of disease is kind of this phenomenon where, for example, a vaccine might not work in the way that you intended it to work. And for dengue we know that for example if you get infected with dengue serotype 1, you may recover and ideally it won't be that bad of an infection, it's gonna be uncomfortable but maybe not terrible. But then your risk of more severe disease including dengue hemorrhagic fever is really increased if you then get infected with a different serotype like 2, 3, 4. And that's because your body has created these antibodies but those antibodies don't neutralize the virus.

And so unfortunately one of two things can happen. One of those things is that those antibodies then promote the uptake of the virus into, for example macrophages, other cells in your immune system, and instead of destroying the virus, the virus then infects the macrophage and then produces more copies of itself. So that's one sort of way in which that can make the disease more severe. And the other way that's kind of generally seen is that we're reacting to this infection in a much more severe way than we might have during the first time around. And so our bodies are forming these immune complexes that are viruses plus a bunch of antibodies glommed on and they're promoting these kind of really severe, inflammatory chains that really cause a lot of discomfort and maybe some really bad side effects.

So that's kind of the two main avenues where this could happen and where we've seen it potentially happen for stuff like dengue. I will say for SARS-CoV-2, the studies that have been done in animals, the results are really variable about which if any of these things could be happening. But what does seem consistent is that neutralizing antibodies, so antibodies that can sort of take out the virus, those do protect animals from subsequent challenge, so subsequent exposure to that virus on purpose.

And we do see neutralizing antibodies for these vaccines, the Pfizer and Moderna vaccines that have been reported. So that's a really good sign that this is not a major concern for these vaccines. And I will say as well this hasn't been a focus of the primary efficacy or safety outcomes of the vaccines but it's certainly the case that people in both the Pfizer and the Moderna clinical trials will have been seropositive at baseline. So that means some people, whether they know it or not, will have had a SARS-CoV-2 infection before they get vaccinated.

And we see very favorable safety profiles for both of these vaccines and so that's an additional sort of notch that can help us feel comfortable about this. But we're obviously gonna still be assessing that particular question.

Erin Welsh

Okay. That is good, good news though. We haven't seen anything yet, that's pretty promising. (laughs) So speaking of efficacy, what do we know so far about the efficacy of these vaccines? Can you walk us through, also, what efficacy vs. effectiveness means in terms of vaccines and how that translates into protection under real world conditions?

Maria Sundaram

Yeah. So efficacy vs. effectiveness, this is something that is totally inside baseball I think for infectious disease epidemiologists and other epidemiologists. (laughs)

Erin Welsh

(laughs)

Erin Allmann Updyke

(laughs)

Maria Sundaram

They're very similar actually. So efficacy really refers to how something works, either a drug or a vaccine or something else in a clinical trial setting under ideal conditions where we're asking people to keep a diary and set a reminder, 7pm, think about if you have a headache and if you do, write that down. So we're really, very closely following everyone that are in these clinical trials. Now in the real world I'm sure you can imagine a lot of differences. For example, I don't check a timer at 7pm every night to see if I have a headache. (laughs)

So the really world is a little bit messier and things might sort of float away from us. We might forget, for example, that we're feeling just a little junky today if something really good is on TV or something. So there's a little bit of a difference in terms of how well we know it works in the ideal scenario where we're absolutely assessing every possible thing we can assess and we're making sure everyone's coming back for their second dose at the right time. In the real world, you know, maybe it doesn't happen exactly that way. And so we wanna make sure that it's also as effective and as safe in the real world setting. And so that's what effectiveness is.

So when we say the Pfizer and Moderna vaccines are about 95% effective, that means we're saying, 'Okay, we gave people these shots, we tried to get them in at the time that they were supposed to for their second shot, but you know they weren't living in a lab, they were also kind of at home living their own normal lives.' So when we say that they're about 95% effective, that kind of relates to this understanding that we think of this as more mirroring like a real world scenario than a very regimented clinical trial. Of course they're still in a clinical trial.

So we do, after vaccines become available for use by for example you and me, we do something called a phase 4 study. And that's kind of to assess in truly real world conditions where people are not participants in a clinical trial, how well is this vaccine working? So we're gonna continue to update that number.

Erin Allmann Updyke

What do we know, at least so far, about how long immunity is expected to last from the various vaccines that we have?

Maria Sundaram

I will say that the existing evidence suggests that immunity is what we call 'durable' up until a certain point. So we have this kind of durable immune response that seems to last for at least a few months. And of course we do not know exactly how long it lasts because we'd need a crystal ball into the future to know that for sure. The existing evidence based on the follow-up that we've been able to have so far suggests that it does last for at least a few months and that is really great news.

Erin Welsh

Mm-hmm, mm-hmm. So what are some of the issues with clinical trials and vaccine development in terms of getting, you know, a representative subsection of the population? And what does this mean for who may be able to get a vaccine once they're ready or once they're all available, particularly in terms of age group or immune status?

Maria Sundaram

So yeah, so I already mentioned a little bit how clinical trials are not quite like real life. And you've touched on something that I think is so important. The people who are willing to participate in clinical trials are often a little bit different than the people who are just in our population in general. So they represent a subsection of the general, for example the general U. S. population but maybe not every single person.

For example, frequently clinical trials for vaccines don't include pregnant women and they don't include people with underlying immunosuppressive conditions, like people that have MS or myasthenia gravis. And that's because we want to know is this vaccine gonna work in people that it absolutely definitely should work in? People whose immune systems are functioning in a way that we expect and unfortunately this can exclude people who are at really high risk sometimes, and so this is a really challenging sort of push and pull with vaccine development.

And the other really important component here - I think a lot of the clinical trials have really tried to address this but it's still very challenging - is that there's probably not enough outreach to folks who are not white in clinical trials. So that makes it hard to understand exactly, is this vaccine gonna be better in this community or is it gonna be exactly the same? Or is it gonna underperform? So we need to make sure that we're getting a really representative sample. And that's sometimes age too. I mentioned the EUA for Tamiflu was then applied to children under one year of age. A lot of things are not tested for children unless the disease is specifically mostly in children because we have this different sort of risk/benefit calculus for children, we really wanna keep them safe from any possible thing that they could experience that's unpleasant.

So what this all means is that we have a vaccine, for example the Pfizer BioNTech vaccine, that we feel really confident about for adults and there's some inclusion in their clinical trials of children a little bit younger. And we need to follow that data a little bit more before we can expand those recommendations to children who are, for example, younger than 16. And we'll probably have to do separate studies about the safety and effectiveness of these vaccines for example in pregnant women or people with underlying immunosuppressive conditions.

Erin Allmann Updyke

Interesting. I've seen a misconception kind of floating around that if you've already had COVID-19 you don't have to get vaccinated. This immunity passport kind of idea. Can you explain please why that is not the case?

Maria Sundaram

Yes. So I will say for many folks who do have an actual COVID-19 infection, it does appear that neutralizing anybody does last, again, at least a few months. So that's a good sort of first step. But I will say again it's not clear the difference between humoral antibody and mucosal antibody, kind of this thing I was talking about earlier where those cells in your nasal pharynx or your nasal mucosa are kind of lying in wait for that virus at that respiratory epithelial interface.

It's also not clear, for example if you actually truly have a COVID-19 infection, how long you may shed that virus. So that's another really important difference between COVID-19 infection and receiving a vaccine against COVID-19. There are reports of people shedding virus for quite a long time. You know, even if you are recovered physically and you are feeling great and you have antibodies, you could still be exposing other people. And that's certainly not something that you wanna do.

And then finally it's not really clear from the available data exactly how long you're neutralizing antibody's gonna last. And so it's really tough to say, 'Oh, I had a COVID-19 infection in March so I'm good, I'm superman. I can do whatever.' It's really hard to know based on the epidemiological data what's your antibody level, how much of that antibody is neutralizing antibody, are you gonna be able to protect other people as well from transmission, all of that is unclear. So I think maybe the last and possibly the last obvious thing to mention here is that it's better to get vaccinated. It's not as uncomfortable as getting the actual illness and that's why we have vaccines. They're much safer.

Erin Allmann Updyke

(laughs) Absolutely.

Erin Welsh

(laughs) Oh yes. So for our listeners who may know someone who is hesitant to receive this vaccine, what advice or reassurance can you give them that choosing to get one of these vaccines is a better option than taking your chances with COVID-19?

Maria Sundaram

I think it's important to consider your risk-benefit measurement. And I'll tell you guys what I'm thinking about when I think about my risk-benefit measurement. So my risk as cases rise in the U.S. and Canada where I am, my personal risk for infection is increasing every day and the risk doesn't just represent a respiratory illness of like a common cold, it's a respiratory illness that could be quite severe for me and could give me really unpleasant long-term effects. And it's also about the risk of me spreading it to others that I really love and care about.

And on the flip side, the benefit from this potential vaccine is that I could be protected against an illness that could cause very severe and/or long-term illness but it would also give me peace of mind. And it wouldn't just benefit me, it would likely also benefit my community. So for me that's more than enough, to say this is a really good thing that I'm doing for myself and also for all of the people that I care about around me.

If you're working on a conversation with someone (laughs) who you maybe don't see eye to eye with in terms of your risk-benefit or maybe they just have questions and they're not totally sure, I think it's really important to start from a place of common ground and kind of lead with empathy. I know that can be challenging sometimes, especially if you don't see eye to eye but if you can see kind of common ground in terms of you care about the people around you or you don't want to be out of work for two or three weeks or potentially longer. Or thinking about what is important to them, that is really important. And then as much as you can just being patient and empathetic with the reasons that they might be concerned or the way that they're thinking about risk-benefit I think is also really important.

It can be challenging sometimes (laughs) and so I also recommend that you take breaks. If you get really frustrated be like, 'You know what, I'm so sorry, I have to go right now. I gotta go to the bathroom.' Or like, 'I'm just sitting down at dinner,' or 'Oh, someone just called me, can I call you back?' I think it's really helpful and important to take breaks and then maybe revisit it when you're feeling like you have more emotional equipment to have that conversation.

I've been thinking about this a lot and how great it is that we have a vaccine that can be delivered to people in the U.S. now. And I was really thinking about my mom who was born before the polio vaccine existed. So she was six when the polio vaccine became a thing and at the time there was just huge amounts of celebration, there were literal ticker tape parades for this vaccine because it was just this terrifying childhood illness that could just be so challenging and so terrible for so many people. And it was a huge relief to know that we would be able to protect children against that. And I have been thinking about like it's kind of a shame that we can't have a ticker tape parade for these vaccines because they represent an incredible amount of effort and sacrifice and hard work on so many people including the trial participants who've given their time and their energy for us to know that these vaccines are safe and effective.

And I really hope, as silly as it might seem, I hope that everyone gets a chance to set aside some time and truly celebrate the fact that this work has been done and it continues to happen and that people are working so, so hard to help us bring an end to this pandemic, it is truly amazing and just a feat. Specifically the contributions of the people who have been study participants I think is so amazing. And when I think about it, it kind of gets me choked up because literally these people are heroes for us. They have helped save so many lives and we're very lucky, I think, to live in a world where people are gonna work this hard to keep us safe.

TPWKY

(transition theme)

Erin Welsh

Thank you so, so much Dr. Sundaram. That was such a great interview.

Erin Allmann Updyke

It was so fun, too. I learned so much.

Erin Welsh

So much good information there and I feel like, yeah. I feel just a lot more knowledgeable about the COVID-19 vaccines. It's been so hard to keep up with all of this news so it was great to have it in like a digestible, 'here you go' way.

Erin Allmann Updyke

Yeah. Exactly. Exactly, I agree. It's been, even as someone who's into this kinda thing, it's really hard to keep up, so.

Erin Welsh

(laughs) Right. But Erin, we're not done yet.

Erin Allmann Updyke

No we're not! We're never done! Just kidding.

Erin Welsh

Never.

Erin Allmann Updyke

We also wanted to learn more about the logistical challenges that we know are huge in trying to get this vaccine distributed both in the U.S. and across the globe. And luckily we were able to chat with someone whose actual job title has 'vaccine delivery' in the name, Dr. Orin Levine. This interview was recorded on November 24th, 2020. So we'll let him introduce himself right after this break.

TPWKY

(transition theme)

Orin Levine

Hi, I'm Orin Levine, I'm the Director of the Global Delivery Programs at the Bill and Melinda Gates Foundation. In this role at the foundation I lead a series of teams that help to both introduce and scale new life-saving vaccines and improve primary healthcare systems around the world. One of the roles that I play externally for the foundation is that I sit on the board of GAVI, the Vaccine Alliance which is one of the central players in global immunizations and more recently in COVAX, the international collaborative effort to vaccinate everybody around the world.

Erin Welsh

Awesome, great. So the first question has to do with some of the biggest hurdles to vaccine distribution here in the U.S. and just like big picture, what are the kind of things that we might see at a national level that might make vaccine deployment a little bit more challenging?

So preparing for the rollout of vaccines in the U.S. or anywhere is gonna be an effort of unprecedented scale. The number of people that we wanna try and vaccinate, the speed with which we want to vaccinate them, and the fact that we need to vaccinate them with not one but two doses of vaccines make the rollout of COVID-19 vaccines kind of a scale and complexity that's really gonna challenge every system around the world.

And the challenges can be bucketed, if you will, into both supply challenges, right. So there's a volume of materials, logistics that need to be sorted out to make sure the right vaccines end up in the right place with the right supplies and the right people to deliver them at the right time. And demand issues. And we're seeing the emergence of demand issues around the world, in the U.S. and elsewhere.

Ironically, COVID vaccines had an anti-vaccine movement even before they had vaccines and that complicates things in terms of the acceptance and demand for the vaccine. So I think one of the things I worry about interesting the U.S. and elsewhere is we can't take for granted the vaccine demand. We're really gonna have to engage with people and listen to them and then answer their questions so that they can feel the confidence they need to accept the vaccine and get the immunity and protection that comes from those and help us all to get back to an increased comfort of interacting with each other.

Erin Allmann Updyke

Are there any hurdles that might be different in terms of global distribution of the vaccine compared to the hurdles in distribution in the U.S.?

Orin Levine

There are some challenges, obviously, for different places that differ. I tend to focus on what brings us together and what's more common but there are some unique characteristics. One is access to the supply. As you may know, there's a global effort called COVAX which is trying to bring together high income countries and low income countries to jointly fund a portfolio of vaccines that can then help to kind of vaccinate the world evenly that is operating in an environment where there's been a lot of bilateral deals, individual countries kind of locking up vaccine supply for themselves. So one of the things that is different is the kind of power dynamic and who's laying claim to different doses at different points in time.

There's a financing element to that as well. Wealthier countries are typically able to pay more and that sometimes put them at the front of the line in those negotiations. It's a big reason why COVAX was created because it's, I think, a shared value of many of us that in the middle of a pandemic, vaccine allocation should be equitable, not just driven by the lottery of whether you happen to live in a country that's wealthier than another one.

Erin Welsh

Yeah, absolutely. We've heard a lot about different countries pre-purchasing, as you mentioned, these large stocks of vaccines. So in effect, we might have several different vaccines available. Which vaccine will a different country choose and will that be determined by what might be available in terms of just the sheer number of vaccine stocks that are already pre-purchased?

Orin Levine

Yeah. I think, Erin, that's gonna be one of the complex parts of this rollout. As different vaccines emerge with different characteristics and different efficacy and different price, you'll have preferences by different countries for these pieces. So for example many of us will probably remember where we were when we first heard that there was a COVID vaccine that worked.

The first one that we heard about was the Pfizer vaccine and that vaccine reportedly has over 90% efficacy which is really, really good. It's also a complicated vaccine to deliver in terms of some of its characteristics. It requires what's called ultra low temperatures, it's required to be stored at -70 celsius. Most vaccines are stored between 2 and 8 degrees celsius, which is like your kitchen refrigerator. Some vaccines are stored at -20 celsius, which is more like your freezer of your kitchen refrigerator or your downstairs freezer. -70 is dry ice, you gotta wear oven mitts when you handle it, you gotta have a special supply chain for it. It also is administered in a 0.3ml dose. Every other vaccine is administered as 0.5ml dose and so it requires a little bit of special training, a little bit of special handling, an ultra-cold chain delivery system, it's gonna be more complicated.

On the other hand it's gonna deliver 95% efficacy and have a differential price point from other vaccines. So that complex mixture of can I afford it, can I get it, when can I get it, how much can I get it, can I manage the complexity of the ultra-cold chain pieces, those are all gonna figure into the decisions that countries make and the plans that countries make in order to roll those vaccines out to everyone.

If we think about low and low-middle income countries, ironically they have some of the most experience working with ultra-cold chain vaccines. The early Ebola vaccines required -70 as well and so countries like the Democratic Republic of Congo and Rwanda, Uganda, Guinea, Sierra Leone, Liberia, these are actually countries that have experience using, in small volumes, ultra-cold chain-requiring vaccines. But that complex set of factors is what I think will go into the decisions that countries make and the rollout plans that they make with the vaccines.

Erin Welsh

That's interesting, that hadn't really occurred to me before but that completely makes sense. And so it seems like on the surface it's great to have different options for a successful COVID-19 vaccine but then you start to think about the logistics and how if the vaccine requirements are different both in terms of the number of doses required or storage requirements, then you have to just like bulldoze forward with one of those options. Is that what we might end up seeing for some of these countries? Or do you think it might be oh well, we'll just have to create a different supply chain or a different deployment chain for each one of these in case one ends up working better than the others or one is cheaper than the others or one is going to be more available than the others?

Orin Levine

I think early on, Erin, there's probably gonna be an intention wherever possible to supply a country with a vaccine rather than to have multiple vaccines flowing through countries. Now if it's a big enough country and each subgeography is large enough you might think about that but ideally, because these vaccines aren't gonna be interchangeable with one another, you're gonna want to simplify that part of the supply chain. And then from there forward say everybody in this country is getting either this mRNA vaccine or this live vaccine or this inactivated vaccine. Those decisions to kind of supply a country with a single vaccine simplify some of the logistics that would become way more complex if there are multiple vaccines flowing around at a subnational level.

Erin Welsh

Yeah. So earlier you touched on how there was an anti-vaccine movement or an anti-COVID vaccine movement even before there was a COVID vaccine. And of course a lot of this mistrust or skepticism that surrounds vaccines has been growing in general in the past few decades and especially from some communities that might already be rightly distrustful or mistrustful of the medical system. So could you talk about how that plays into not only vaccine development but administration and also what are some of the things that could be done to rebuild trust in those communities?

Orin Levine

Honestly, one of the things that keeps me up at night is the demand side of this. As a person who spent my career working in vaccines, I literally think vaccines have an opportunity to save the world, right. Like the thing that is keeping us from interacting is that we have a virus for which all of humanity lacks immunity. And vaccines have the potential to confer that immunity to all of humanity but only if people are willing to accept them, only if people are ready to be immunized. And to do that, people have to trust their health system. They have to trust their medical providers. They have to trust the process by which the vaccines were carefully manufactured, carefully regulated to make sure that they're safe and potent when they come out.

Any of us who's a human knows that trust is slow to build and quick to erode and in the most recent era we've had an erosion of trust on many levels, some of it related to vaccines specifically and some of it more generally in institutions and science and in many other things. So I hope we can use vaccines actually as an opportunity to restore trust. And that restoration probably starts with listening to people. There's been too much, in my view, polarizing, yelling at each other, and not enough listening to one another. So I'm really hopeful that one of the things that will - a side effect if you will of a COVID vaccine - will be to get people to listen to one another.

Erin Allmann Updyke

Yeah. That would be the dream. (laughs)

Erin Welsh

That would be fantastic. (laughs) In terms of vaccines specifically and maybe vaccine deployment or administration on a global scale, what do you think are the major lessons we've learned? Or how will this have changed the way that we view either emerging infectious diseases or vaccines in the future?

Orin Levine

I think there's a lot of opportunity. I keep trying to look for silver linings in all of this and I think there is some opportunity going forward. Let me give you one of the examples of the opportunity I think the rollout of COVID vaccines offers us. In many communities where we work, young adults may not be very engaged in their health system, they may not be regularly getting preventative care, they may not be getting screened for some of the concerns that they have or getting access to family planning or other preventative services.

I wonder if in the execution of our rollout of COVID vaccines if we integrate COVID vaccination with a package of services that they want and value. If we won't, if you will, draw into the health system, a large set of people who've been needing or potentially benefiting from health interventions but who've not been accessing the system in the past. And so if we can use the act of engaging with them around COVID vaccination to engage with them around a broader set of health prevention or health conditions, it could be that the rollout of COVID vaccines helps impact people's health well beyond conferring immunity.

I personally can't wait for us to get to the point where we're successful rolling out vaccines. I haven't seen my mom and dad in nearly a year and I wanna be able to hug my mom and dad without worrying about sharing a deadly virus with them. So my interests are both global and equity and, you know, partly personal as well. And thanks for sharing these kinds of stories and this information with your listeners cause I think that they're a big part of making this a success.

TPWKY

(transition theme)

Erin Welsh

Thank you so, so much again Dr. Sundaram and Dr. Levine, it was so great to talk with you and we really appreciate you taking the time out of your incredibly busy schedules to help us all get some more info about vaccines.

Erin Allmann Updyke

Yes. We learned so much.

Erin Welsh

So much.

Erin Allmann Updyke

So as always in these COVID-19 episodes, we want to summarize with five key points that we want you to take away from this episode. So number one. We learned that there are at least three different vaccines that are very close to approval or, in some cases, have been approved already in the U.S. and the U.K. and a few other countries. So these are the ones that we focused on for this episode. These are the Pfizer vaccine, the Moderna vaccine, and the AstraZeneca vaccine. And importantly, none of these vaccines contain the entire SARS-CoV-2 virus. They all contain what are essentially instructions of one kind or another to make one protein or antigen that is specific to SARS-CoV-2 that our body can then recognize and respond to in the case of a future exposure or infection.

So what that means is that none, I repeat, none of these vaccines is capable of giving somebody COVID-19, which I think is so important. While it is normal to have some mild side effects after a vaccine like a headache or maybe pain where you got the vaccine shot or even a mild fever or just feeling kind of cruddy, these kind of symptoms don't mean that you have COVID-19 and they don't mean that you're infectious to others either. They just mean that your immune system is doing its job and responding to the vaccine which is awesome and what we want your immune system to do.

Erin Welsh

Yes. Number two. These vaccines have gone through the same exact safety and evaluation steps that other vaccines like the seasonal influenza vaccine or the measles, mumps, and rubella vaccines also had to go through. All of the same regulatory and safety questions were asked about the COVID-19 vaccines as they were for these other vaccines that we're more familiar with. The difference is that with these COVID-19 vaccines, we were able to ask and answer these questions in a much shorter time frame, which was made possible by the sheer amount of people and resources committed to this project. And like those other vaccines, we will continue to monitor the safety of these COVID-19 vaccines both in the people who were involved in the clinical trials as well as everyone else who takes them.

Tens of thousands of people were involved in these COVID-19 vaccine clinical trials and the results have been very encouraging, not just in terms of efficacy but also in terms of safety. Some mild side effects such as headache and fatigue may be expected, as you mentioned in point one Erin, but so far it doesn't appear that there are major adverse events associated with the vaccine. And our incredibly robust vaccine adverse event reporting system means that any and all side effects of these vaccines will be cataloged and closely examined, and if there do emerge more severe side effects later on, we will catch them very quickly.

Erin Allmann Updyke

Really early. Yeah, absolutely.

Erin Welsh

Like immediately. And one thing I keep coming back to is just how much is at stake with these vaccines.

Erin Allmann Updyke

Yeah.

Erin Welsh

The companies and the governments that have invested so much time and resources into vaccine development, public support for vaccines, there's a lot to lose here and so very, very much to gain. A misstep could be incredibly costly in many ways and for that reason there are many, many, many people ensuring the safety and efficacy of these vaccines.

Erin Allmann Updyke

Absolutely. And speaking of efficacy, point number three. Just how effective are these vaccines? It turns out very. So we learned from Maria that effectiveness is looking at how much protection these vaccines are going to provide in the real world, not just in a clinical trial or a very controlled setting. And in the case of these trials that have been conducted already, it seems like the vaccine candidates we have appear to be 90% or 95% effective which is amazing.

Erin Welsh

Truly amazing.

Erin Allmann Updyke

Really. We also know from these studies that immunity seems to be durable, at least for a few months which is great that we know that it lasts for at least a little while, although we still don't know how long immunity will last. And this is also true for infection. We know that immunity after infection lasts for at least a few months as well. But especially in the case of these vaccines, immunity isn't immediate. Because all the vaccines that we have that are close to approval are two-dose series, meaning you have to get one dose and then another three weeks later, full immunity isn't expected until at least five weeks or longer after the first vaccine or two weeks after you get that second dose. And because these are not live virus vaccines and they're given in our arms rather than through our nose like some of the live flu vaccine nasal sprays, we're not positive about the amount of mucosal immunity that they provide. So it's at least theoretically possible that even after vaccination, somebody could harbor the SARS-CoV-2 virus in their mucous membranes. And even after a real infection with SARS-CoV-2, people can shed virus for a really long time after infection. And that is why it's so important that even after vaccination or infection, we continue to practice all the same control strategies we've discussed at length, like wearing a mask, social distancing, etc.

Erin Welsh

Yeah, it's just one more layer of that Swiss cheese situation.

Erin Allmann Updyke

Yeah! (laughs)

Erin Welsh

Point four. Developing effective vaccines against the virus that causes COVID-19 was just the first necessary step.

Erin Allmann Updyke

Right.

Erin Welsh

It was hugely important. But it's still just the first step because we still need to get these vaccines to the people who need them. If you've been keeping up with the news, we've already started the rollout of vaccines here in the U.S. and in the U.K. as well as some other places to the highest priority recipients, like frontline healthcare workers and those residing in long-term care facilities. But the logistics of vaccine rollout are enormously complex and will require the construction of a lot of different moving parts. For instance, all of these vaccines that are close to approval or have been approved are two-dose series which does make their rollout a bit more challenging to make sure everyone gets both doses in the proper time frame.

Fortunately, some countries have these supply and deployment chains already in working order from past vaccine campaigns. But the existence of three different vaccines that may vary in their storage and administration requirements could lead some countries to build up a system around one of the types of vaccines. I mean, all in all it's kind of a good problem to have, like we'd rather be choosing among several effective vaccines rather than none at all.

Erin Allmann Updyke

Definitely.

Erin Welsh

But it does mean that some places will have to put their resources towards one of these vaccines over the other.

Erin Allmann Updyke

And finally point number five which I think is one of the biggest take home points for me especially. Vaccine hesitancy is an important issue, especially for these new COVID vaccines. But hesitancy in the face of something as new as this vaccine, it's really understandable and it's important for us, you know, as educators or even if you're just talking with friends and family, to address people who may be hesitant or have questions about this new vaccine with empathy. Maria Sundaram had, I think, some really good advice which was to start any conversation by trying to find a place of common ground, whether that be concerns about getting sick yourself or concerns about spreading disease to loved ones, whatever it might be. But by starting from a place of common ground, it's at least possible to have a conversation whether about vaccines or honestly this is just good advice for life. (laughs)

And from Orin's interview, and this is important especially on a community and kind of larger scale, we can't just assume that there's going to be a demand for this vaccine or any of these vaccines. We have to have good, honest, open communication surrounding these vaccines and the development process and everything surrounding them. And encourage that people get it and make it really easily available rather than just assuming that people are going to want a vaccine or will seek it out on their own.

Erin Welsh

Yeah, that's definitely true. I feel like now it's more important than ever to maybe have these conversations and, you know, practice this empathy. It's crucial right now to do that.

Erin Allmann Updyke

Yeah.

Erin Welsh

A huge thank you again to Dr. Sundaram and Dr. Levine for taking the time to chat with us about these amazing COVID-19 vaccines.

Erin Allmann Updyke

We learned so much.

Erin Welsh

We did.

Erin Allmann Updyke

Also a huge thank you to Diane Scott and Amber Zeddies for helping to set us up to chat with Dr. Levine.

Erin Welsh

Yes. And if you want to learn even more about these COVID-19 vaccines and other vaccines in development against the SARS-CoV-2 virus, there's an amazing, amazing vaccine tracker that was developed by a huge team of people including Dr. Sundaram at McGill University and also at the University of Minnesota among other places. It's an incredible resource with tons of great information and you can find it at covid19.trackvaccines.org and we will also post a link to it in our show notes as well as on our website.

Erin Allmann Updyke

Yeah. I this is a great resource either for you or maybe to send to friends and family that might be asking questions, it's just a really comprehensive resource.

Erin Welsh

Mm-hmm.

Erin Allmann Updyke

Thank you so much to Bloodmobile who provides the music for this episode and all of our episodes.

Erin Welsh

And thank you to the Exactly Right network which we are a very proud member of and without whom this podcast would not be possible.

Erin Allmann Updyke

This podcast would also not be possible without you, dear listeners. Thank you so much for listening to it all.

Erin Welsh

Thank you, thank you, thank you. Until next time, wash your hands.

Erin Allmann Updyke

You filthy animals.