Episode 24 – Safety & Approval Process of Vaccines

With Dr. Evelyn Twentyman

Diane (00:00):

How quickly can vaccines safely move through the approval process? We'll find out on today's Vax Matters.

Diane (00:14):

Hi, and welcome to Vax Matters. Today we'll get a full understanding of the most important piece of immunization, vaccine safety and the approval process. Dr. Evelyn Twentyman, medical epidemiologist for the Center for Disease Control and Prevention give us the details on this long discussed subject.

Diane (00:37):

Thank you so much, Doctor, for joining us today.

Dr. Twentyman (00:41):

Thanks for having me. It's such a pleasure to be here.

Diane (00:43):

Well, you know, let's just go ahead and jump right in. How does the research and development for a vaccine begin?

Dr. Twentyman (00:52):

Sure. Thank you so much for the great question. So the research and discovery stage is how a vaccine development process begins. In this stage scientists develop a rationale for a vaccine based on how an infectious organism, sometimes called an infectious agent, causes disease.

Dr. Twentyman (01:13):

Scientist then conduct laboratory research to test their idea for a vaccine candidate. Uh, sometimes this testing occurs in animals, sometimes it's in vitro, meaning in blood samples, and this is considered the research and development stage. Sometimes, and this is kind of exciting, sometimes scientists can use ongoing work in a different field to make advancements toward an idea for a vaccine candidate.

Dr. Twentyman (01:42):

For example, the mRNA vaccine platform was studied for decades actually, by numerous scientists before being used in our current mRNA COVID-19 vaccines. And many of these scientists were actually in oncology, that is to say cancer research, not even thinking of coronaviruses at that time at all. And then once a scientific finding or, or, or once, um, a platform is thought to have really practical applications in that it might be feasible to develop a vaccine candidate, based on that finding or these findings or findings from another field borrowed into this, um, vaccine platform idea, then the research can move forward out of that research and development stage.

Diane (02:31):

And sometimes, a- as you said, it's just one of those things you're really not looking for as in the oncology, but it lays the groundwork for something fabulous and to be able to have that when again, with the all the COVID-19 that we've heard so much about for, for a long time.

Dr. Twentyman (02:51):

Exactly. And that's one of the one of the principles that makes basic science and laboratory research so beautiful.

Diane (03:00):

Mm-hmm.

Dr. Twentyman (03:00):

I would encourage everyone to follow their curiosity wherever it leads you and you know because all of these scientists that have been following their curiosity for decades have led us to one of the fastest, uh, developments of vaccine in U.S. history, and so it's very exciting.

Diane (03:16):

Well, it is incredible too and we were talking about that when you... W- 'cause we heard a lot about the pl- the preclinical trials. Can you... not only for COVID, but for other vaccines, so can you explain what goes into the assessment or th- the preclinical trials, Doctor?

Dr. Twentyman (03:34):

Absolutely. So first, researchers use computers to predict how the vaccine will interact with the human immune system. After that prediction, uh, sometimes called modeling is done, the researchers test the vaccine on animals with similarity to human physiology. In other words, animals whose immune systems work pretty similarly to humans. So some of those animals include mice, guinea pigs, rabbits, monkeys.

Dr. Twentyman (04:09):

Before a vaccine can be tested in people in any case, um, an individual research group or, or a company producing a vaccine performs a lot of laboratory research and testing to obtain information about how the vaccine works and whether it's likely to be safe and work well in humans. And these tests overall are known as the preclinical phase.

Diane (04:35):

And how many phases are there? You have the preclinical and then you have the different phases or the different stages after that. Pretty intense each stage, correct?

Dr. Twentyman (04:46):

Correct. And I'll walk through, um, the most common phases which-

Diane (04:51):

Okay.

Dr. Twentyman (04:52):

... which, which are three.

Diane (04:52):

Okay.

Dr. Twentyman (04:53):

So during Phase 1, uh, small groups of people receive a trial vaccine. This is usually, um, like a pretty tiny number of generally healthy folks to assess the safety of the vaccine at increasing doses and to gain some early information about how well the vaccine works just to induce an immune response in people. So that's, that's Phase 1.

Diane (05:17):

Okay.

Dr. Twentyman (05:18):

And in the absence of any safety concerns coming from Phase 1, then Phase 2 studies include more people where various dosages are tested on hundreds of people with typically varying health status and from different demographic groups in randomized control trials, and these studies provide additional safety information on common short term side effects and risks. They examine the relationship between the dose administered and the immune response to really hone that optimally as possible. And they can even sometimes provide initial information regarding the effectiveness of the vaccine.

Dr. Twentyman (06:00):

And then in Phase 3, the vaccine is generally administered to thousands of people in randomized controlled trials involving very broad demographic groups, that is to say, the, the population intended for use of the vaccine ultimately and these Phase 3 trials gener- generate very critical information on effectiveness and additional important safety data. This phase provides additional information about the immune response in people who receive the vaccine compared to those who receive a control, uh, sometimes called a placebo.

Diane (06:39):

Mm-hmm, right, right.

Dr. Twentyman (06:39):

And then I'll, I'll mention too, Phase 4. Sometimes people talk about Phase 4 of development and, uh, that involves formal ongoing studies after the vaccine is approved and licensed, um, and many vaccines undergo Phase 4 as well.

Dr. Twentyman (06:57):

So those the, the three phases that always happen, uh, and then the fourth phase, which often happens as well.

Diane (07:02):

So with Phase 4, it doesn't always happen, sometimes happens or you, you said the first three are more common and you don't hear or at least I don't think you hear as much about a Phase 4, you know, fo- in my brain it's 1, 2 and 3, but is that, is it, uh, an anomaly instead of the, the rule for a Phase 4 or no?

Dr. Twentyman (07:21):

Uh, well, I would say that depends on the context. So in many vaccine, uh, trials previously there have been Phase 4 components, um, and I wanna talk about something different that's happened in COVID-19, um, vaccines in particular that's, uh, partially formal, so partially Phase 4-

Diane (07:45):

Okay.

Dr. Twentyman (07:46):

... and partially, um, learning everything that we can after a vaccine is released. So the difference between Phase 1, 2 and 3 and Phase 4 is that Phase 1, 2 and 3 happen before emergency use, authorization or approval and Phase 4 happens after that. So Phase 4 is always what's happening after the vaccine is out there and in use.

Diane (08:10):

I see. I see.

Dr. Twentyman (08:11):

That, that what we formally call Phase 4 are the formal trials that are ongoing after that point and that is certainly happening with the COVID-19 vaccines, but the other neat thing that is happening quite intensively with the COVID-19 vaccines is called post marketing surveillance. And this is to say that we at CDC and other groups are doing this as well, are observing very closely how the vaccine is working, um, and looking very aggressively for any safety signals, uh, after these vaccines are, are in use.

Dr. Twentyman (08:46):

So in other words we've looked super intensively before all these vaccines were released and we're looking super intensively after. The before always involves formal trials, um, and in the stage 2 and 3, like these placebo controls. In the after we don't get that because we're looking at what's happening in the population, but we get to look at what's happening in the population like at the millions of persons level. So we get to observe the actual efficacy, uh, in the actual world (laughs) and we get to observe any, any safety side effects, anything that happens with the vaccine after it's being used as well.

Dr. Twentyman (09:27):

And so that's, that's really cool, and one thing that really reassures in me, as someone with a big family and children myself-

Diane (09:35):

Hmm.

Dr. Twentyman (09:35):

... I just love how intensive, how intensively, rather, these vaccines are being studies, uh, in an ongoing way, uh, both preauthorization and post.

Diane (09:47):

And post. So the follow-up is just as critical or just as important as the pre. Of course, the pre, you have to have that before you can have the post, obviously, but it is, as you said, reassuring to know it doesn't, just doesn't stop there. You're always following up and you're always looking and tweaking and seeing what could happen and what is happening.

Dr. Twentyman (10:11):

That is absolutely correct. The, the follow-up is really critical, and you know with COVID-19 vaccines, I'll just, I'll just add this because it's true, COVID-19 vaccines are undergoing the most intensive vaccine safety surveillance in U.S. history. So that is-

Diane (10:31):

In history.

Dr. Twentyman (10:33):

... to add what we've already been saying-

Diane (10:34):

Oh, sh- yeah.

Dr. Twentyman (10:34):

... um, not only is follow-up after authorization or approval important, we're actually doing it more aggressively now than we ever have before.

Diane (10:44):

Mm-hmm.

Dr. Twentyman (10:44):

... and I think that's a really reassuring fact.

Diane (10:46):

It should be, absolutely. So let's just talk just a moment about how vaccines actually get approved. How does that process happen?

Dr. Twentyman (10:58):

Sure. So we'll walk through, um, authorization or approval.

Diane (11:03):

Okay.

Dr. Twentyman (11:03):

Uh, so the people that are in charge of approving or authorizing vaccines are the U.S. Food and Drug Administration, sometimes known as FDA. Their Center for Biologics Evaluation and Research, sometimes known as CBER, they are responsible for regulating vaccines in the United States, meaning authorizing or approving vaccines.

Dr. Twentyman (11:30):

The sponsor of a new vaccine, in other words the research group or the company that has developed the vaccine follows a multi-step process to this end in, uh, coordination with the Food and Drug Administration, which typically includes, one, an investigational new drug application, two, pre licensure of vaccine clinical trials, three, an emergency use authorization request, also known as an EUA request-

Diane (12:00):

Mm-hmm.

Dr. Twentyman (12:00):

... or a Biologics License Application, which is also known as a BLA, inspection of the manufacturing facility, presentation of findings to FDA's Vaccines and Related Biological Products Advisory Committee, also known as VRBPAC, and usability testing of product labeling. So making sure that however the vaccine vials are labeled, that they can be used correctly every time. And that's the, that's the process of vaccine authorization, um, and/or approval.

Diane (12:40):

So there is definitely then a specific protocol that is used no matter what the vaccine is, not just COVID-19, but-

Dr. Twentyman (12:50):

Yep.

Diane (12:50):

Okay.

Dr. Twentyman (12:51):

That is correct. This is a, it's a tried-and-true process that, that we had the opportunity to use with COVID-19 vaccines, but you know it's been really well established and we've gotten to hone this process over decades for greater, uh, safety and greater protection of the American public.

Diane (13:11):

And after a vaccine is approved, is it, as you were talking about, you know, the post check and all of this, i- is it continually checked for safety no matter the vaccine?

Dr. Twentyman (13:23):

Yes, absolutely. Uh, like I (laughs) like I said before, COVID-19 vaccines are undergoing the most intensive vaccine safety surveillance in U.S. history.

Dr. Twentyman (13:33):

So let's speak first to all vaccines.

Diane (13:36):

Okay. Yes, yes.

Dr. Twentyman (13:36):

In other words, what all vaccines get in terms of safety surveillance and then I'm gonna add just a few things about, um, COVID-19 vaccine safety surveillance as well.

Dr. Twentyman (13:46):

So for all vaccines, after vaccines are licensed they're monitored really closely, as people begin using them. And the purpose of this monitoring is to watch for adverse events or possible side effects. Monitoring a vaccine after it's licensed helps to ensure that the benefits of the vaccine continue to outweigh any of the risks of the vaccine for people who receive the vaccine. And if any link is ever found between a possible side effect of the vaccine and, and the vaccine, public health official take appropriate action by first weighing the benefits of the vaccine against the risks of the vaccine to determine if recommendations for use of the vaccine should change.

Dr. Twentyman (14:30):

CDC uses, uh, four systems to monitor vaccine safety. Three of them, uh, have been ongoing for a long time, and then I wanna add a fourth one, um, that has been established in the era of COVID-19 and has worked really well to help us understand COVID-19 vaccine safety.

Dr. Twentyman (14:49):

So, um, the first three are firstly the Vaccine Adverse Event Reporting System, which is sometimes called VAERS. This is an early warning system for vaccine safety. This is co-managed by CDC and FDA to monitor for potential vaccine and safety problems. Anyone can report a possible vaccine side effect to VAERS and by anyone, I mean anyone. Um, you know, vaccine clinics, physicians, nurses that give vaccines, patients that receive vaccines, parents of patients who receive vaccines, um, you know, other caretakers, anyone. We really wanna capture any possible safety event. The two-

Diane (15:33):

So someone, if they did have a problem... Excuse me, I'm sorry-

Dr. Twentyman (15:35):

All right. All right.

Diane (15:35):

... but just to clarify that, anyone who did have a problem they need to speak to their family physician, is that how that would be reported? That just the average person s-, you know, speak to their doctor and say, "Man, this just no, it's not working out at least well for me." It could for 1,000 other people, but there's that one person that you also wanna know about.

Dr. Twentyman (15:55):

Yeah.

Diane (15:55):

So that one voice is equally as important as 1,000 voices?

Dr. Twentyman (15:59):

Absolutely. Every single voice is important. Every single possible safety effect, no matter how small, is important. CDC and FDA wanna know about all of them. Um, and you know you mentioned family practice physician or a person's individual physician. That is a really good way of getting a report about a possible vaccine safety event to CDC and FDA and then I'll also say you can actually just go directly... people can go directly to the VAERS system through the internet if they would like by searching the Vaccine Adverse Event Reporting System and then, uh, just entering a por- report themselves. So you don't have to be a physician to get a report to us. You certainly can get a report to us through your physician, but you don't, you don't even have to if, if the more direct route works well for you. And just like you said, even if it works, even if the vaccine is perfectly safe for millions of people, if you think that you had like a side effect, we totally wanna hear from you.

Diane (17:04):

Absolutely.

Dr. Twentyman (17:05):

An individual voice is extremely important.

Diane (17:07):

Yes.

Dr. Twentyman (17:08):

And then I wanna talk about two other vaccine safety platforms, uh, and then a third one that we've developed in the era of COVID-19. So, um, next the Vaccine Safety Datalink, this is called VSD. This is a collaboration between CDC and nine major health care organizations that conducts vaccine safety monitoring and research. Uh, and then third, we have the Clinical Immunization Safety Assessment, otherwise known as CISA project. This is a partnership between CDC and several medical research centers that provide the expert consultation, uh, and conducts clinical research on vaccine associated health risks.

Dr. Twentyman (17:53):

And then in the era of COVID-19 we've also developed a platform called V-safe. This is really cool because this is active surveillance. V-safe uses text messaging and web surveys to check in with vaccine recipients after a vaccination. So after any dose of a vaccine, um, any, any... by the way, any simultaneously administered vaccine can be entered at the same time. So if you are a person going to get your COVID-19 booster and your flu shot at the same time, which you certainly should (laughing), uh, if you haven't done so... so already, you can enter both of those. Um, and V-safe is a, is a platform that you can opt into through your cellphone at the time that you get vaccine or any other time that you wish. Um, and surveys solicit our participants' responses on how they feel after a COVID-19 vaccination at regular intervals and just do a lot of checking in to, to make sure that people are staying safe and well after their vaccines.

Dr. Twentyman (18:55):

Um, and then I'll just say, FDA continues, um, to monitor safety really carefully. They require all manufacturers to submit, uh, samples from each vaccine lot prior to its release. So I mentioned manufacturing, um, investigation before release, uh, but that actually happens on a regular basis. So whenever a new lot is released, FDA says that manufacturers have to submit, uh, samples from those lots before they go out. Um, and then manufacturers also need to provide FDA with their test

results for vaccine safety potency and puris- purity. Each lot gets tested, um, because vaccines are sensitive to environmental factors like temperature, uh, and we just wanna be really, really sure that every lot is exactly the same and is super safe.

Dr. Twentyman (19:43):

FDA has very rarely recalled vaccine lots for concerns like mislabeling, minor contamination during protec- production or like any potential manufacturing problems at a production plant. They just are really aggressive in safety assurance for, uh, our vaccine recipients.

Dr. Twentyman (20:04):

And then ACIP the Advisory Committee on Immunization Practices, continues to monitor vaccine safety and effectiveness data after vaccines routine use and has the ability to change or update recommendations for use based on that data.

Diane (20:20):

Your checklist is, it's a good... it's a good checklist and, and the beauty of that too, uh, Dr. Twentyman, is the fact that you have a lot of eyes looking at this and you have a lot of brains and a lot of people from not just one area, but all over, the CDC, the FDA and what have you. You, you all are brainiacs. You, you know what you're doing, you're looking for specifics and you have the experience. You know what you're doing, that's the bottom line.

Dr. Twentyman (20:53):

We do and we're working together.

Diane (20:55):

Yes.

Dr. Twentyman (20:55):

I mean this, this vaccine safety surveillance is the effort of not just FDA, not just CDC, uh, but all of these research groups, all of these health care organizations and by the way, the American public. The reason we have these platforms that we're soliciting feedback from the American public through like VAERS, like V-safe, is so that everyone, listening to this podcast, for example, everyone who receives a vaccine can help us understand really thoroughly how well these vaccines work and how safe they are.

Diane (21:34):

And that again is what we're all striving for, the information, information and correct information 'cause we hear a lot about the misinformation, we still do in this day and age it seems like, so the correct, the approval. Yo- let's, let's talk about the difference between approval and the emergency use authorization. I- that was something I believe that a lot of folks, uh, heard about during the early days of, of COVID-19. What is that difference, Doctor?

Dr. Twentyman (22:07):

Absolutely. So an emergency use authorization, also known as EUA, is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines during public health emergencies, like for example, the current COVID-19 pandemic. Under EUA, FDA can allow the use of, uh, not yet approved medical product or approve uses of not yet approved medical products in an

emergency to diagnosis or to treat or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate approved available alternatives.

Dr. Twentyman (22:56):

So what FDA does there is evaluate a manufacturer's EUA request, and determine whether the relevant statutory criteria are met, taking into account the totality of the scientific evidence about the vaccine that is available to FDA and then when they do that, all that same information comes to the Advisory Committee on Immun- Immunization Practices or ACIP, as well.

Diane (23:22):

There was a lot of concern from many people about how quickly, with COVID in particular, it was approved. Um, was there less safety testing? I, I think I know the answer to this, but I would like for you to elaborate on that for our listeners today.

Dr. Twentyman (23:41):

Absolutely, and I, I am aware of concerns from the American public and, and you know it makes sense that since we manage to release vaccines in record time, I'm glad people are asking questions, are we sure this is safe, because that gives me the opportunity to say, "Yes, it absolutely was safe, but thank you for the question."

Diane (24:02):

Yeah.

Dr. Twentyman (24:02):

So vaccine clinical trials are always conducted according to very rigorous standards set forth by the FDA and ACIP, Advisory Committee on Immunization Practices and CDC are looking at all the data coming out of those rigorous standards when they recommend vaccines for use.

Dr. Twentyman (24:22):

So how did this get faster? So one thing is researchers can sometimes combine either Phase 1 and Phase 2, like I previously described or Phase 2 and Phase 3, to speed up the development and testing processes of a vaccine and this helps scientists learn much more quickly whether a vaccine will continue being studied if it appears safe and effective or it needs to be stopped because it's not showing in those combined phases to help, uh, prevent an illness or help prevent severe symptoms of it.

Dr. Twentyman (24:55):

If and when study phases are combined, the same safety protocols, and the same standards are used in traditional trials and all safety requirements must be met, even at a more rapid testing speed. Ultimately for an EUA to be issued for a vaccine, FDA has to know that the known and potential benefits outweigh the known and potential risks of vaccine. Um, an EUA request for a vaccine, like a COVID-19 vaccine can be submitted to FDA based on a final analysis of a Phase 3 clinical trial or an interim analysis of the trial.

Dr. Twentyman (25:37):

So for example, an ana- an analysis performed before the end of the trial even, once the data have met pre specified success criteria, um, and have met the study's, uh, primary safety and efficacy end points. So this is to say, um, if we get to the point or if a sponsor gets to the point that they know a vaccine is working, especially against COVID-19, we don't want them to wait, we want their study to keep going, but we want that data, uh, to go to FDA.

Dr. Twentyman (26:11):

If FDA approves that, it goes to ACIP, and then ACIP reviews safety and effectiveness of the vaccine, um, compares that to the severity of the disease that we're looking at. Uh, we look at the number of people who will get the disease if that vaccine is not out there for the American public. We look at how well that vaccine is working for people of different ages and different demographic groups, and then we also look at how practical those recommendations for a vaccine, whether under emergency use authorization or approval are to put into practice. Uh, so we can consider all of these factors when moving forward to authorization, approval and recommendation of a vaccine, even on an emergency basis.

Diane (27:00):

So definite, very definite checks and balances that you all go through. I, I believe another question would be or a thought or maybe a concern, before COVID-19 was there any other vaccine that received that emergency use authorization prior to COVID-19?

Dr. Twentyman (27:20):

Yes, there was. Um, some of your listeners to this podcast might recall, uh, the anthrax concerns, uh, in the, the decade of the 2000s.

Diane (27:30):

Yes.

Dr. Twentyman (27:30):

And, and indeed the anthrax vaccine in 2005 went through exactly this process and received emergency use authorization by these, uh, aggressive, uh, safety and efficacy protocols. So we're not, we're not the first to use these, but these vaccines and these processes to authorize or approve these vaccines and then recommend these vaccines, have been extremely helpful and have been critical to reducing the number of Americans affected by COVID-19 and by protecting our population, our communities.

Diane (28:09):

I'd venture to say that a number of people listening today had kind of forgotten about anthrax. You know, when you said that, you, you, yes, that there was. I thought, "Which one could it be? What would it be?" And, uh, anthrax, I gotta tell you, didn't, it wasn't the top of my list. I didn't realize that.

Dr. Twentyman (28:25):

Well, let's hope there's a day far in the future where we can say-

Diane (28:29):

Oh-

Dr. Twentyman (28:30):

... "Oh, we almost forgot about COVID-19."

Diane (28:31):

Oh, God (laughing). Oh, dear Lord, wouldn't that be lovely. Amen to that, Doctor. So I, I think before we close today, one thing I didn't ask you that I'm, I'm curious about is h- how does a vaccine, just a- any vaccine, get added to the recommended list of routine vaccines and who gets added to that list?

Dr. Twentyman (28:53):

Thank you so much for the question. So CDC set's the U.S. immunization schedules based on recommendations from the Advisory Committee on Immunization Practices or ACIP and ACIP is a group of medical and public health experts that develop recommendations for use of vaccines to control diseases in the United States. Um, and I, I mentioned earlier that ACIP reviews safety and effectiveness, severity of disease, the number of people who get the disease without the vaccine, how well a vaccine works for people of different ages and, and demographic groups, how practical those recommendations are to put into practice, and then I'll also just walk through the evidence to recommendations framework that ACIP uses every time to publicly and transparently weight all the evidence around a vaccine, um, and then I'll also mention that we have reframed... in the COVID-19 space, we've reframed our evidence to recommendations framework to spotlight health equity specifically.

Dr. Twentyman (29:58):

And so I'll walk through the domains that we're currently using. Um, those domains are, one, the public health problem. We, um, as ourselves is the, is the problem that this vaccine is trying to prevent of public health importance? And in the equity vein, we ask does this problem affect all populations equally? Might it be affecting some populations more than others? Two, we look very rigorously (laughs) at the benefits and harms of any given vaccine. Um, whether the desirable and undesirable anticipated effects, uh, are clearly demonstrated across all populations equally and whether those desirable ou- effects outweigh those undesirable effects.

Dr. Twentyman (30:43):

Three, we look at values, whether the population, in this case, the American public, feels that the desirable effects are large relative to the undesirable effects, um, and if there's any variability there. Uh, acceptability. If the intervention is acceptable to key partners. Um, and then in the equity vein, is the intervention acceptable across all populations and all key partners. And then feasibility. I mentioned how practice the recommendations are. Are these vaccines feasible to implement and are they equally feasible to implement across all populations?

Dr. Twentyman (31:17):

And then lastly, are these vaccines a reasonable and efficient allocation of resources, um, and is that true across all the population. And so by doing that, and you know I mentioned publicly, so I'll just give a, give a plug here, ACIP meetings are public. Anyone in the U.S., around the world can attend them if they would like. Um, we also open a public comment period every single, every single one of these meetings, so you can actually weigh in on what you think about these vaccines, um, and let you guys see the future.

Diane (31:48):

And this is online? Excuse me, I'm sorry.

Dr. Twentyman (31:49):

No.

Diane (31:50):

It's online, that they can do this?

Dr. Twentyman (31:52):

Yes, it's online.

Diane (31:53):

Okay. Okay. Thank you.

Dr. Twentyman (31:53):

So if you search... um, actually if you just Google ACIP it, it's the, it's the first thing that will, that will come up and you can go to, uh, the meeting register, uh, and see what meetings are coming up and you are welcome to attend.

Diane (32:09):

Okay. Thank you. Thank you, I just wanted to clarify that, so, I didn't mean to interrupt. Go ahead, I'm sorry (laughs).

Dr. Twentyman (32:13):

Oh, no, no, no. I, I just wanted to invite all of your listeners and everyone else to (laughs)-

Diane (32:18):

Indeed.

Dr. Twentyman (32:19):

... to, uh, come attend our, um, public review of all of this vaccine data, uh, and to weigh in if you would like.

Diane (32:27):

Yo- as we are closing our podcast today, Dr. Twentyman, is there anything you've giving us just a whole vault, vault load of (laughs) very valuable information, is there anything that you can think that possibly we haven't touched on that, uh, the listeners should be aware of or should give, uh, further thought to? I, I just want you in the, in the closing minutes to be able to say if there's anything that, that you think that we should, uh, um, make sure that listeners are aware of?

Dr. Twentyman (32:59):

Sure. I think I'll mention safety, especially in pediatric populations, that is to say our children. We are seeing at CDC that these vaccines are effective in children and super safe in children. At the same time, we are a little saddened to see that use of these vaccines in children, especially kiddos under the age of 5 has been really limited. And so I want to speak a moment just to speak as a mother of

children myself to say that like many other mothers out there, I care so much about the safety and wellbeing of my children and on an individual basis, you know, I, I care about my children more than anything else in the universe, and I got my children vaccinated against COVID-19 because I am grateful to have the opportunity to provide them with this protection and I am confident that these vaccines are not only effective, they are very safe.

Dr. Twentyman (34:16):

And so I just encourage any of your listeners with children or who are, uh, aunts or uncles of children, um, to look into how to get those kiddos vaccinated and how to protect our whole population, not just our adult population, but our whole population, against COVID-19.

Diane (34:36):

Dr. Twentyman, you've been amazing. Thank you. Thank you so much for your insight, for clarifying a lot of the specifics about the vaccines and about the safety and the approval process. Uh, a- again, just a wealth of information. You broke it down so our listeners can understand it because that's... you know, that's the big part of this. People, they want to know, they want to know the right information and we've been able to speak to you this morning specifically about the approval process and the safety. So, again, uh, please be careful, be safe and, and hug your children for us. We're so happy that they're doing well and we do appreciate your time. And thank you all for joining us today for this very highly relevant segment of Vax Matters.