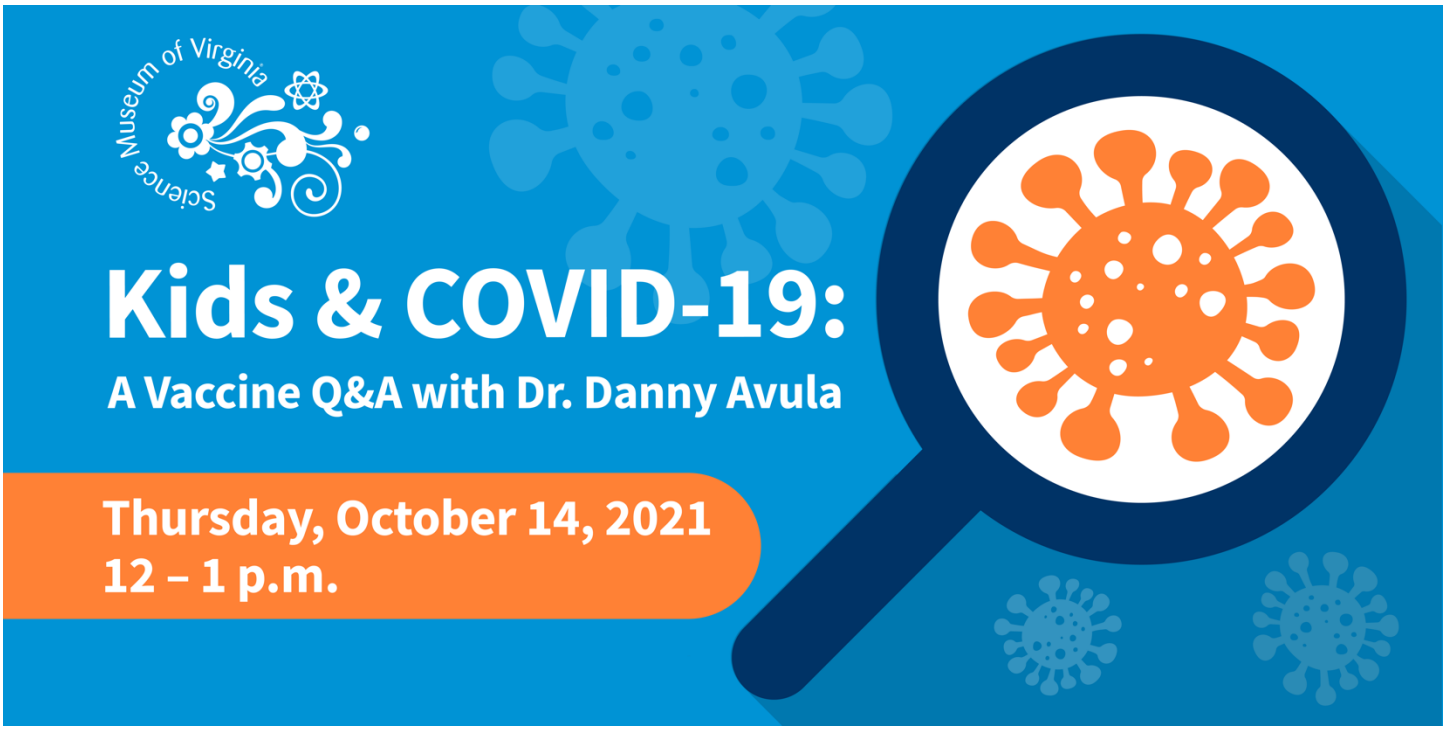

On Thursday, October 14, 2021, the Science Museum of Virginia's neuroscientist Dr. Catherine Franssen teamed up with board-certified physician Dr. Danny Avula, Director of the Richmond City and Henrico County Health Departments, for a question-and-answer session about kids and the COVID-19 vaccine. The experts explained the science behind the vaccine development, the way it works in the body and the impacts it will have on children in the future by answering pre-submitted and live questions from attendees.

The free, virtual event is part of the Communities for Immunity initiative. Communities for Immunity is made possible with funding from the Centers for Disease Control and Prevention and the Institute of Museum and Library Services. For more information, visit www.communitiesforimmunity.org. It was presented in English and Spanish, and included ASL interpretation. The following is the transcript from the event.

[DR. FRANSSEN] Thanks all of you for being here. I am Dr. Catherine Franssen. I am the life scientist here at the Science Museum of Virginia. I'm a neuroscientist by training, and I use the lens of neuroscience to explain and improve the human experience, touching on lots of different topics.

Today, I am thrilled to be joined by Dr. Danny Avula, who is a public health physician board certified in pediatrics and preventative medicine and he practices clinically as a pediatric hospitalist.

In January, Governor Northam appointed Dr. Avula to lead the Commonwealth of Virginia's unprecedented COVID-19 vaccine effort. After graduating from the University of Virginia, he attended the Virginia Commonwealth University School of Medicine and completed residencies at VCU and Johns Hopkins University where he also received a master's in public health. He's an affiliate faculty member at VCU where he regularly serves as an advisor and preceptor to graduate and medical students. Governor McAuliffe appointed Dr. Avula to the state board of social services in 2013 and he served as board chair from 2017-2019. He's an immediate past chair of the Richmond Memorial Health Foundation and serves in several other community boards.

He has been named one of Richmond's top docs every year from 2013-2019. He's a recipient of the Virginia Center for Inclusive Communities humanitarian award, was a Richmond Times-Dispatch person of the year honoree in 2019, and was named Style Weekly's Richmonder of the Year in 2020. Dr. Avula's work has been featured nationally by the CDC, MSNBC, The New York Times, NPR, and PBS Newshour. I am absolutely thrilled to get to talk with him today about COVID vaccinations.

[DR. AVULA]

Thank you, Dr. Franssen. Great to be here with you all. Thanks so much for having me.

[DR. FRANSSEN] Yeah, thank you. Well, we have a number of questions that have come in from a variety of people so I'm going to get us get us started. We have some questions, let's see here … I've got a whole humongous list that have to do with lots of different things and I thought we'd start out with a couple of questions about the development of the vaccine. So, as we know, there's a lot of testing processes for the COVID-19 vaccine for children. Did the vaccine go through the same testing processes for children as it did for adults? It was a question that one of our people brought to us.

[DR. AVULA] Sure, and you know this concern has been raised throughout the vaccine roll out. Let me first say that in addition to being a public health doc and a pediatrician and so having kind of clinical and public health expertise, I'm also a parent. My wife and I have five children and so this experience of thinking about COVID, thinking about how it's going to impact our kids, school decision making—my wife is an elementary school teacher, teaching kindergarten here in Richmond Public Schools—and so there's also a very personal lens to all of this that has to come together as we make decisions about whether we should get our kids vaccinated or not, what it's like to send our kids back to school, and kind of constantly doing that risk-benefit calculation that we'll talk a lot about.

So, let me jump into the clinical trial process and we are coming to the end of that. These clinical trials for kids have been going on for the better part of a year now and typically the way that this works—whether it's a vaccine or a new medication—is that we always start in laboratory testing first, and then in animals, and then in human beings—adults and then, when we've seen a track record of safety and efficacy at each stage, that's typically when we open it up to children. That has been the case with the COVID vaccine. It's why we've had an approved vaccine since December for adults, but it's taken the better part of a year now to be on the cusp of an approved vaccine for children, or at least younger children. We've had approved vaccine for 12 and up since May, but that process of ensuring that a new medication or a new vaccine is safe in those other segments of the population before we go to kids has been followed here.

Companies started recruiting for clinical trials a little over a year ago, typically or initially at the upper end of that age range, so the 12 and ups, and then progressively you saw that open up to five to 11 year olds, and then even clinical trials that have been going on for kids down to the age of six months. Those were staggered and it's why we have seen different types of data emerge at different points, and why in May we had an approved Pfizer vaccine for 12 and up because there was sufficient data to show that it was effective and safe. Now, Pfizer has submitted that data for five to 11 year olds. They did that just the very last week of September. We know that the advisory committee for the FDA is meeting to discuss this data the week of October 25th, and then the CDC's advisory committee is meeting to presumably vote on a direction November 2nd and 3rd. Now, there may be some flexibility in that timeline; they may decide to move it up based on how the process is unfolding, but the take-home is that we should have an answer and some clarity about five to 11 year olds by the first week of November.

Now, to get into the background of those clinical trials: I mentioned that they've been recruiting for over a year. They've staged these trials at different points. With the five to 11 year olds, Pfizer's clinical trials enrolled a little over 2,200 kids ages five to 11. They have been amassing data, really looking at what dose needs to be administered, and for the Pfizer product it looks like it is going to be a different dose than with adults.

That's another thing that kind of stretches out the process, to figure out what is the right dosing that achieves the immunologic effect, gets your immune system to do what we need it to do, but also balances against side effects because if a vaccine has a lot of really heavy side effects—which we've seen some with COVID vaccine for adults—that can discourage a lot of people from

getting it. What these companies have done in their trials is really try to find what's the sweet spot where you get the immune response you need and minimize the symptoms. For Pfizer, that was at a third of the dose strength. The adult dose is 30 micrograms the kid dose for five to 11 year olds is 10 micrograms. So, they've used that 10 microgram dose in these clinical trials with about 2,200 people.

As we've talked with a lot of different stakeholders about this people say, "but wait, there were 30,000 people that were in the initial adult trials," and I think it's really important to remember that 30,000 spanned 16 to, you know, 90 or so in terms of the age ranges that were covered. So, when you look at the sliver of the population that was 5 to 11—that 2,200 people enrolled in this study—is actually more than any similar age range of six or seven years. Hopefully that will reassure people that this is a really sizable study that showed really good effects and we have not seen that data. That data has been reported publicly. A couple weeks ago, Pfizer put out a press release saying that in their five to 11 year old clinical trials, their vaccine showed really good safety profiles as well as antibody responses that mirror what we see we've seen in adults.

Now, that's their press release and the way this process works is that they send all of that data to the Food and Drug Administration—the FDA—and the FDA's scientists comb through it, page by page, and really do a super thorough analysis. So, really, what we wait for to talk about this publicly and to say this is what the safety looks like is really the FDA's stamp of approval. That's where we are right now: we're waiting for the FDA to finish their data review, but that's what we know about the Pfizer clinical trials.

Now, Moderna has also been engaging in clinical trials. Those have been a little of a larger age range and closer to 7,000 participants for 5 to 18, I think. They have not yet submitted their data for pediatric vaccine and so we'll know more about that when they ultimately do release that data to the FDA and the FDA reports out on what they're seeing there.

[DR. FRANSSEN] Thank you, that was really -

[OFFSCREEN] Dr. Franssen and Dr. Avula: I'm sorry to interrupt. We've had a request to slow down just a tad so we can keep up with you.

[DR. AVULA] Sounds good. We're learning how to do the interpretation. That's great!

[DR. FRANSSEN] That's right, that's right. We're learning how to how to be accessible, which is wonderful. Thank you for such a great comprehensive answer. I feel like I'm going to have to re-watch the recording of this to pull out every single element of that, which is wonderful.

I gave a comment and a question based on what you just said. The comment is you did a great job of reviewing the different steps of the process. I wanted to point out to our audience that we actually have been publishing vaccine information on our blogs and social information through the Museum, including an Instagram swipe through as well as a blog that detailed all of the steps that Dr. Avula just outlined that came out relatively recently, so I want to encourage everyone to look for our resources both before and after this event to detail some of these great points.

Then, I had a question for you, and actually, this was the most frequently asked question ahead of this event. A lot of people are really struggling to understand what to do with their 11 year olds because there's this big difference, like you said, the 10 micrograms for the 5 to 11 year olds versus the 30 milligram is essentially 12 and up. Several people asked about what to do with an 11 year old who maybe they'd like to get vaccinated. Should they wait until their 12th birthday or how do we approach that?

[DR. AVULA] Yeah, I think this will become more and more of an issue with all those 11 year olds who are on the cusp, and there's a part of this that I don't have a great answer to in terms of why the 11 to 12 year old cut off.

In pediatrics, typically what we do is dose by weight. Now, with a vaccine that's much more challenging. When you think logistically about how that would happen when we're setting up vaccination sites vaccinating, you know 3,000 people a day, having to dose out each of those based on weight just is not practical. That's one of the reasons why we really look to the

companies to give a clear dosing guidelines by age and sometimes by weight. For example, with EpiPen's that's dosed by weight, so I'm not sure how they ended up on age with this, but it is where we're at and that does mean there's going to be some gray area in these 11 year olds who may have hit that growth spurt a little bit earlier and may actually benefit from a larger dose.

I think what happens in this process, we talked about the fact that the companies do their trials, they submit the data to the FDA, the FDA scientists review that. The CDC, a separate agency with an independent panel of experts called the Advisory Committee on Immunization Practice (ACIP), they will do their independent review and in that process they come up with what are called clinical considerations and kind of give you ways to handle those gray areas. I think we will see some clinical considerations that come from the CDC that will answer that question. We likely won't see that until about the first week of November.

I think given what we're living through right now which is still a pretty significant surge of the Delta variant—and maybe it's worth us taking a quick side step to talk about the current context with COVID—but given the fact that we are seeing this very contagious variant impacting kids more significantly than we've seen at any point during the pandemic, I would really encourage people to go and get vaccinated as quickly as possible.

Now, if they're in that age range where within the next couple of weeks they would get that full dose maybe it's worth waiting, or maybe it's fine to just get the 10 microgram strength dose and then on the second shot that they would get the adult dose because they'll span that age group. I think we have to wait and see what the CDC comes up with clinical considerations, but I imagine at the end of the day talking to your healthcare provider and trying to navigate that together is going to be the best option.

Catherine, is it worth talking about Delta now, or do you want to kind of go a different direction now?

[DR. FRANSSEN] Sure, well, what you just mentioned—the second dose—we've had several questions about that. Will the children's dose need two doses the same as the adults?

[DR. AVULA] That is what Pfizer's application was around: it was around a one-third strength dose, so 10 micrograms instead of the 30 micrograms for 12 and up, but it's the same timeline. So it's two doses separated by three weeks. Now, that's what we've seen and heard from the company. Remember that the FDA needs to review all that data and ultimately they'll come up with a recommendation next week and then that will ideally be adopted by the CDC the first week of November, so it could move, but that's what we know right now.

[DR. FRANSSEN] Great, great, thanks. Would you like to talk a little bit about the Delta variant?

[DR. AVULA] Yeah, so you know this has been the headline since August, really, and hopefully people have heard that and have a sense of what's been going on across the country. This is what we're calling the fourth wave of disease. We had the initial climb up the hill back in April of 2020. Things got better for a while and then we saw another spike in August, and then we had a relatively quiet summer and fall. Then December, January, February we saw just an incredible spike of disease, and it's where certainly here in Virginia, but really throughout the United States, we saw the highest death toll, the highest number of cases and hospitalizations. But all the while, through all of that, kids were pretty well spared, right. This was really a disease that was significantly impacting adults. We had incredibly low rates of pediatric infection, but more importantly pediatric hospitalization and death. Those were extremely, extremely rare occurrences.

Then what happened at the end of this past summer—kind of July of 2021—we saw this Delta variant, which emerged months before in India. We saw it kind of tear through the rest of the world, and as has been the case at every stage, we see these spikes in the eastern hemisphere—or you know, whether it's Africa or Israel, United Kingdom—and we point to them a lot because they have really incredibly effective data collection capacity. So they're about two months ahead of us and so we were really able to see what that curve looked like in the UK and Israel, and then about two months later that hit the United States.

What has been different about Delta is that because it is so much more contagious than the previous strains of this virus. It has impacted kids at a scale that we just haven't seen, so the overall toll of Delta has been significant. It's not quite as high as we saw in December and January, but much higher, about two to three times higher than the first two waves.

But in kids it's been a totally different story. We've seen the highest rates of pediatric cases and the highest rates of pediatric hospitalizations that we saw at any point during the pandemic. Now, we don't really think that's because this is a more virulent or severe version of the virus. It's definitely more contagious, but I think the contagiousness combined with a really different context, right. Last year, schools were closed, parents were keeping kids at home, all youth sports were cancelled and in many of those ways we've gotten back to not business as usual, but at least some increased level of interaction. So the opportunity for kids to contract this virus in the context of a much more contagious disease means we see a lot more cases. And when we see a lot more cases, even if it's a really small percentage—a 0.01 percent chance of really severe illness—0.01 of a bigger number is a bigger number. So what we saw in July, August and September was a huge impact on pediatric hospitals.

There were reports out of Florida, Arkansas, Missouri and Alabama of their pediatric hospitals being full of kids with COVID. This was our experience, not to the same degree in Virginia, but Dr. Franssen mentioned that I still work as a pediatric hospitalist and so about once or twice a month, I'll do an overnight shift at one of our local hospitals here in Richmond. All of last year we would have kids who had COVID, but they were incidental positives, right. This was a kid who maybe had appendicitis and then on their screening ended up having COVID, but it was mild disease and it wasn't really why they were being hospitalized. But this past October or so, maybe September, was really the first time that we started to see kids who were having severe lung disease. They were in the hospital with pneumonia, they were requiring oxygen, and so that was different. So even in a much smaller scale than some of our southern state counterparts have seen, we saw that here in Virginia as well.

The take home is that there's a lot more kids getting infected with Delta. That's leading to more hospitalizations and thankfully now, we are on the downside of that curve, so things aren't where they were this past summer, but they are still we're still seeing a lot more disease than we were really at any point in kids.

[DR. FRANSSEN] Thank you very much for that sort of overview of how Delta has changed the landscape of pediatric cases of COVID. What effect do you think that the availability of the COVID vaccines for the five to 11 year olds will have on communities, hospitals, schools?

[DR. AVULA] Well, I think they would have had a much bigger effect if they were available to us this past summer. I think that was one of the really hard things about the timing of Delta is that we were still doing these clinical trials and just weren't far enough along in the process to be able to protect against the impact of Delta and so you see what we've seen around the country these past few months.

As things get better—but they're not going to get totally better as COVID's not going to disappear overnight and we're going to continue to see outbreaks—we're going to continue to see spikes of disease in communities likely through the winter. What we saw with COVID the first year, what we anticipate with all diseases that are primarily spread through respiratory droplets, is that we have a seasonal variation and when we have seasons when people are spending more time indoors, more time in close contact, that gives more opportunity for the virus to spread. I think we will still have kind of sporadic outbreaks and a baseline level of disease through the winter and then likely in the spring because of access to vaccination, natural immunity that happens just through a lot of people getting infected, and then the seasonal variation. I think we'll start to really see things open up in the spring. So, I'm not downplaying the importance of the vaccine. I think the vaccine is -

[OFFSCREEN SPANISH INTERPRETER SPEAKS BRIEFLY]

[DR. AVULA] So I want to just reset that getting kids 5 to 11 vaccinated is going to, in the long run, is going to be an incredibly important part of our journey beyond COVID. I say that with some hesitancy because we're not going to get over COVID. COVID is going to become a part of the mix of viruses that we deal with every year for a long, long time. We, every winter, see outbreaks of

flu, adenovirus and rhinovirus, and COVID will just be part of that mix. Unfortunately, it's a more severe part of that mix, so we are going to have to learn how to live with it, how to identify it, how to contain it, and vaccination is an incredibly—probably the most—important part of that mix. But it would have been really nice if we had access to it a couple months ago.

[DR. FRANSSEN] Yeah, absolutely. As a mom of one kid who's over 12 and vaccinated, but another kid who is younger, I'm deeply wishing and looking forward to the time when I can feel a little bit safer. What role will masking continue to play after both vaccines are more widely available for the younger children?

[DR. AVULA] Well, I think it's important first to note what an important role it has played in preventing the transmission in kids, but really in all of us. I mean, I think part of what's been confusing about the last 18 months is how that knowledge, and subsequently those guidelines, rolled out. Because remember at the beginning of this—back in March and April of 2020—the messaging that we were hearing from public health, from the CDC, was we don't need to mask, that masking without having N95 masks or professional-grade masks and other masks, aren't really going to help. It turns out that that was absolutely wrong. It was the wrong message and many other parts of the world, even from the beginning, were saying masking is what we need to do to prevent the spread of a primarily respiratory-driven disease.

Getting that wrong I think confused a lot of people, but it also eroded a lot of trust in the government because people then asked, "Okay, if the government's first telling me don't mask. Two months later they're saying, 'oh wait, everybody has to wear masks,' how do I make any sense of that?" I think part of the answer is that we are learning as we go. Every week we learn more and more about this virus, and so we as a community need to understand that with a new novel coronavirus that we've got to understand that guidelines are going to change as we gather more information. At the same time, I think there's a really important learning for our federal public health leadership about how to message things. We'll spend a lot of time hot washing this for the next few years for sure, but that reality around masking, I think, has really confused the picture.

That said, at this point we know that masking is incredibly effective in reducing the transmission of this disease and especially when you have multiple people masking. When everybody's masking, it reduces the risk for everyone. So, what's the future of that because right now in Virginia we have a universal K-12 mask mandate and a lot of other kind of mask guidance in other settings. I think in times like right now where we still see a lot of circulating disease, masking is still a really important part of us minimizing spread. As we get to lower community rates, as we get to higher rates of overall vaccination, I think there are other things that will help with this. For example, two weeks ago, Merck applied for FDA authorization on a new oral pill that will actually help treat the symptoms of COVID.

The combination of all of those things—of vaccination, of lower circulating rates, of better therapeutics—will lead us to a place where masking is no longer as necessary because we have effective treatments and we have effective ways to identify disease. We'll have a lot more access to rapid testing. I don't think masking is a permanent part of our future. I do think that we will probably see a lot more seasonal masking. In other parts of the world, when you get to the winter months, people just wear it as a course of habit, and I think we'll probably see some more of that here in the US because we've seen how effective it is. But I don't think it's going to be a requirement much past the spring. It was a really long answer, sorry about that.

[DR. FRANSSEN] No, but you covered several different topics related to masking and I think all of those were really useful as we're thinking about what role masks have played in protecting us so far.

I really appreciate how you've touched on that science is always changing. We're always learning new things and that's an incredibly important part of being a scientist and to digest science. But it's really, really hard because a lot of us are just, "tell me what the answer is so I can understand how to shape my life." And people, I think, have a hard time making those shifts and staying updated and informed.

I also appreciate that you mentioned the trust issues. I think one of the things that has happened is because a lot of misinformation and disinformation has spread around the virus because information is changing rapidly, and then people don't know exactly who to believe or what to believe. For example, there's some disinformation going on around how COVID vaccines

might negatively affect fertility or reproductive issues, and that spread from a couple of people that spread some incorrect information a year ago and it still persists today because people are worried about that. What would you say to parents who are worried about fertility issues, and then more generally about how disinformation and misinformation is spreading, and how we can help find the right answers?

[DR. AVULA] Let me start with the second part of that first because this has been one of the biggest challenges of trying to communicate with the public at every stage, from discovering what COVID is and trying to explain who it affects, how it's transmitted, to testing and how testing needs to be conducted, to vaccination where it's really come to a head.

I think it's important for people to understand how deliberate in many cases the spreading of bad information has been and there's lots of reasons for that. In some cases, it's completely honest mistake: it's like you read something and you're like, "oh, this sounds right, maybe I should get this out there," and you're just trying to be helpful. In other cases, there are people who, with intentionality, are putting bad information out to seed distrust or to seed anti-vaccination sentiments in many cases. They're either doing that because they have a strong ideological position or they're financially benefiting from this and we've seen that a lot. We've seen a lot of people who are really pushing natural remedies or other things, even gaining a platform and making millions of dollars off of it. We've seen a handful of cases where that has been true.

There's actually a really interesting analysis done by a national or an international think tank called The Center on Countering Digital Hate. In the month of May, just a few months ago, they did a survey of information related to COVID on three platforms—on Facebook, Twitter and Instagram—and what they did was they looked at all of that information on social media that was related to COVID and they deemed, they kind of defined, what was misinformation (wrong information that was being spread unknowingly) and disinformation (wrong information that was being spread with mal-intent). Of all of that information, 65 percent of the misinformation and disinformation emanated from 12 user accounts. So that's thousands and thousands of messages out there being tweeted and retweeted, shared and re-shared, that came initially from 12 specific users.

I share that because what I think is important for the public to know is that mix of info that exists in social media, and on the internet really, has strategy and intention around it to build distrust. In addition to that, they also use strategies like paying social media influencers, so people who have big followings would get paid thousands of dollars to share some of that messaging. Or they would write programs—they would write algorithms and bots that would tweet and retweet to really just populate misinformation.

I think that reality is a really different place than we have ever been in terms of like rallying the country around trying to do something positive for health or trying to get behind something. I think the combination of that distrust—general distrust with government, kind of a political division that we've seen over the last few years—has made this a very, very challenging response to this pandemic.

Okay, so that's the broad-brush strokes around social media. I think the succinct answer is that you really do need to go to credible sources that are looking at data, that are translating data, that have experts who are doing this—scientists that are doing this—so the CDC, the FDA, there's a few other national bodies, and certainly the state health department.

Can you repeat the first part of that question, Catherine?

[DR. FRANSSEN] Yes, well, I had asked you about fertility and reproduction.

[DR. AVULA] Right, yes.

[DR. FRANSSEN] So sir, we had several people write in that they themselves were comfortable with vaccination, but they had seen a lot of things that scared them, so I really appreciate you addressing some of that misinformation.

[DR. AVULA] Absolutely. So with the fertility issue and I would say on national surveys the question of fertility and other potential unknown long-term impacts is the most popular reason that people choose not to get vaccinated, so it is a real challenge because

of that unknown. I think that the questions that people raise really get at "how do we make decisions now about things we don't know about down the road?" We see that with every vaccine, with every therapeutic, and the particular issue of fertility is a specific hot button. We certainly saw it with polio vaccine, with the HPV vaccine—sort of the same questions that are being raised and sometimes that's done in, like I said, a harmless, trying-to-help way and sometimes it's done very intentionally and I think that continues to be the case here.

The specific claim of fertility with the COVID vaccine: it probably came from a lot of places, but most notably there was a German physician and a former employee of Pfizer who raised this particular issue to Europe's version of the FDA, it's called the EMA. What they said was that this vaccine, which basically has been designed to grab onto the spike protein—so hopefully everybody has seen kind of the model of the coronavirus. It's the sphere with all these little spikes coming off of it. The vaccine trains your immune system to grab on to that spike protein—so this German doctor said that spike protein seems to have a lot of genetic overlap with proteins that are on the placenta, and this is just in December, so just like a month before vaccines were really approved and out there. They said, "EMA, we really need you to look at this and rule out the long-term potential here before we approve a vaccine now."

It turns out that multiple geneticists and immunologists have looked at the specific issue, have looked at the genetic code of the spike protein and the genetic code of syncytin (which is the protein on the placenta) and there's only about a seven percent overlap. It was really kind of a misappropriated idea, just sort of a brainstorm idea, that really took hold on social media because, again, it gets at that deep fear of the future and of the unknown and social media ran with it. It's presented really complicated decision-making processes for people, but what we've seen in every study around fertility or birth outcomes and pregnancy that has been done so far is that there is absolutely no negative effect of the vaccine and, in fact, particularly in pregnant women who are at much higher risk for severe consequences of COVID hospitalization and death, that it's even more important that pregnant women get vaccinated to protect against that.

[DR. FRANSSEN] Thank you, that's so important. As a neuroscientist, I certainly have heard many people thinking about how afraid they are of things and I know that our brains are wired to pay attention to things that are scary. It is very difficult to make those complex decisions, like you were saying, about things that are far in the future or that are not right there in front of us. I think that's a really, really good point.

I am just looking at some of the questions coming in as well as questions that we have from the people wrote in ahead of time. A few people are asking some questions about side effects of the vaccinations, and in particular in children, and if we know anything about what reactions and side effects that the vaccine might be delivering for kids. Do you have information about that?

[DR. AVULA] Yeah, let me reiterate that the Pfizer data has not been released publicly yet so I haven't seen it, the public at large have not seen it, and that won't happen until the FDA completes its review, but when Pfizer released their data, what they said about it, so two things I'll say: One is the …

[OFFSCREEN SPANISH INTERPRETER SPEAKS BRIEFLY]

[DR. AVULA] Oh okay, I think they just switched again. Yeah, where was I? Okay so, two thoughts that I want to share. One: the reason that Pfizer ended up on that one-third dosing was because they were looking for what dose led to the increase of circulating antibodies, sort of the immune response that we know we need, and minimize the side effects. We often see more side effects in kids than adults just because kids have more robust immune systems.

Remember, with vaccination, what we're trying to do is train your immune system to fight this potential invader and so when a vaccine is administered, your immune system is getting revved up against those proteins so that they can build your body's defenses. So we do expect some degree of side effect. What Pfizer has reported so far with that 10-microgram dose is that the side effects related to the vaccine compare pretty closely to what they're seeing in adults with a little bit shorter time span for those symptoms but a little bit higher frequency of fevers. So I think, again, we'll hear a lot …

[OFFSCREEN SPANISH INTERPRETER SPEAKS BRIEFLY]

[DR. FRANSSEN] Well, thank you, it's great to know about that. And we got our Spanish language back in. I think it was turned off for a few minutes.

There were several questions about, in particular with side effects, but also reactions. Some parents are concerned about their children who may be on other medications or have particular health concerns. What would you recommend for those parents? Should they reach out to their health care providers?

[DR. AVULA] Yeah, that is definitely always the best answer because everybody's situation is so different and having your provider that knows your child, that knows kind of the history and unique interactions they may have had, are going to be in the best position to make a recommendation there.

I would say that these vaccines have really been pared down, and from an ingredient standpoint, they're very simple. There are a few, kind of the only contraindications really, are if your child has had an allergic reaction to one of the ingredients of the vaccine and those are all listed on the CDC website. I can try to put something in the chat here in a minute where you can go to that link, but that's the main contraindication for the vaccine. I know that some parents have had kids who just have a lot of sensitivities and so it makes it a little more complicated. Usually if they don't have a direct allergy to one of the ingredients, the recommendation is that they just do a longer observation period after having that dose administered. So instead of the 15 minutes, it's recommended for everybody they do a 30-minute observation period under the observation of a health care provider. That's the main recommendation at this point.

I think a lot of people have also asked, "what about other vaccines?" because kids, especially right now, because COVID took such a toll on kids keeping up with their vaccine schedules. We have so many kids who are still getting caught up. Can COVID be administered in that mix?

There's a little bit of a confusion around this because initially, when the CDC made their recommendations with the COVID vaccine, they recommended that it be done at least two weeks apart from the administration of other vaccines, but as they've watched this and as they've studied more and gathered more data, they say that's not necessary. It’s completely fine to give the COVID vaccine at the same time as other vaccines. They would just ask the health care provider to administer it in different parts of the body. So if you go in and get your flu shot and your COVID shot, do one in one arm and the other in the other. That's the state of the recommendations right now. There's no reason that there hasn't been any science to show that it's less effective or that it gives you higher side effects to do them simultaneously.

[DR. FRANSSEN] Thank you. You just answered like three more questions that I had seen from people. That's wonderful. Several people have asked about heart inflammation—pericarditis and myocarditis. What the risks are in certain groups, in particular children. I think parents are trying to decide the risk/benefit analysis of a vaccination. What recommendations do you have there?

[DR. AVULA] Absolutely. So this issue of pericarditis and myocarditis—which is inflammation of the heart tissue or the sac that surrounds the heart—this came up a few months ago because when the Pfizer and Moderna vaccines had been given for a few months, there was a small safety signal of a slightly increased number of typically young adult males ages 18 to 30 who had a higher incidence of that side effect of myocarditis and pericarditis. That led the CDC to really do kind of an all-call and do a much deeper dive on that data. What they ultimately came out with was that, yes, we are seeing an increased incidence of myocarditis and pericarditis; however, we also see a much higher risk of that inflammation of the heart in people who actually get COVID and so what they did was the risk/benefit analysis. They looked at all the data and they said, “if we were to give—and remember this is specifically with the two dose mRNA vaccines, Pfizer and Moderna—if we were to give a million people a two-dose course of the mRNA vaccine, we would see about 60 or so cases of myocarditis or pericarditis, so it's a pretty rare occurrence, but not zero. At the same time, we would prevent about 11,000 cases of COVID, about 500 in total hospital admissions, 120 intensive care admissions, and somewhere between six and nine deaths.” So when you look at the population level at the benefit of avoiding deaths, intensive care unit, hospitalizations, hospitalization cases, versus the risk of what has been a very mild though serious—I

mean, the inflammation of the heart is something that needs to be observed and reported, but the vast majority of those cases resolved on their own—the scales clearly tipped in the benefit category. So that's when we talk about risk/benefit analysis. That's what we're doing from the public health perspective and so I think we will want to see that kind of analysis with the pediatric, with the five to 11 data as well. Clearly, the FDA and CDC are very attuned to that possibility and it's why even during the clinical trials, they really wanted to get that dosing right so that they weren't seeing an increased rate of some of those more serious side effects.

[DR. FRANSSEN] Dr. Avula, thank you so much for all of this. I want to be respectful of your time and everyone in our audience as well. I want to encourage everyone to seek answers. We at the Science Museum—please follow us on social, look for our blogs and other information—we will be doing a follow-up with on this event, trying to answer some additional questions for our audience. We really look forward to seeing you all on our interactions and in the museum. Thank you so much for being with us, Dr. Avula. This was really very educational. I really appreciate it.

[DR. AVULA] My pleasure, Dr. Franssen. Maybe I'll just end with this quick thought, which is that for all of us parents, it's okay to have questions, it's okay to be concerned. These are our kids. We should absolutely be sure about administering a vaccine or a new medication or whatever the case is so please be affirmed that you are doing your job as parents.

At the same time, I will say that we also need to know where to ask those questions and direct those concerns to. And when we've had the opportunity to see the data, to have scientists really weigh in on that. If they say that the benefits outweigh the risks, then we should get our kids vaccinated as quickly as possible because at the end of the day, once it's deemed safe, this is the thing that's going to help all of us collectively move on from COVID. Do your homework, wait for the recommendations, and then once they come out, if it's safe, let's all move in that direction.

[DR. FRANSSEN] Thanks, that's great advice and a relief to me as a mom as well as a scientist.

[DR. AVULA] Absolutely, great to be with you. Thanks, Dr. Franssen.

[DR. FRANSSEN] Great, thank you Dr. Avula. Take care.

[OFFSCREEN] To learn more, visit smv.org/vaccines.