Mayo Clinic Q & A - Dr. Gregory Poland 10 11 21

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SPEAKERS

Dr. Halena Gazelka, Dr. Gregory Poland

D **Dr. Gregory Poland** 00:01

Coming up on Mayo Clinic Q&A, October is going to be a very exciting month in the U.S. in regards to COVID vaccines. The FDA is going to look at boosters for Moderna, boosters for J&J vaccine. They're going to look at extending that EUA for Pfizer vaccine down to five years of age. So, five- to 11-year-olds. How soon they'll start immunizing kids after that EUA approval would probably be within a couple of weeks. Along with the prospect of vaccinating children, there are other signs of progress in the fight against COVID-19. We have a lot of reason for optimism here. We're going to see approval of an oral antiviral. We're going to see extensions, and I hope mix and match allowances, and we're already seeing the value of people getting immunized in the downturn in the pandemic.

D **Dr. Halena Gazelka** 01:00

Welcome, everyone to Mayo Clinic Q&A. I'm Dr. Halena Gazelka. We're recording this podcast on Monday, October the 11th, 2021. Well, the cold weather is looming, and experts are encouraging people to continue to get vaccinated as we're beginning to move back indoors because of the cold weather. Soon those eligible to be vaccinated may include children ages five to 11. Here with us to discuss today is our expert, Dr. Greg Poland from the Mayo Clinic. Welcome, Greg.

D **Dr. Gregory Poland** 01:30

Good morning.

D **Dr. Halena Gazelka** 01:31

Good morning. Happy Monday.

D **Dr. Gregory Poland** 01:33

Thank you. It was an early start to the day today.

D Dr. Halena Gazelka 01:38

Well, I'm glad that we just are continuing your day while you're in keeping going. Greg, can you tell us what's going on with kids and the EUA, or the emergency use authorization request by Pfizer to vaccinate them?

D Dr. Gregory Poland 01:52

October is going to be a very exciting month in the U.S. in regards to COVID vaccines. On the 14th of this month, the FDA is going to look at boosters for Moderna, on the 15th boosters for J&J vaccine, and on the 29th of October, they're going to look at extending that EUA for Pfizer vaccine down to five years of age. So, five- to 11-year-olds. This is coming a little faster than we thought, which is good. How soon they'll start immunizing kids after that EUA approval, and I'm guessing they'll get that approval, would probably be within a couple of weeks. Notably, the the recommendation is shaping up to look like for five to 11-year olds, they'll get a 10 microgram dose rather than a 30 microgram dose. So, they'll get a third of the dose that people 12 and older get.

D Dr. Halena Gazelka 02:56

Well, that is exciting news, Greg. I was thinking about before, how you told us how much paperwork goes into these meetings, where you review all of this data, and I thought, well, that's a lot for people to read in a month.

D Dr. Gregory Poland 03:07

It really is. And you know, and maybe not too surprising, these younger kids getting a third of the dose just have superior immune responses.

D Dr. Halena Gazelka 03:16

Oh, wonderful.

D Dr. Gregory Poland 03:17

Their young, healthy immune systems really rev up in response to the vaccine. So, they'll do very well, I think.

D Dr. Halena Gazelka 03:25

Oh, that's great. Such good news since we are more indoors at this time of year.

D Dr. Gregory Poland 03:30

Indeed. And you know, with school starting, we've certainly seen surges in different areas. Were concerned, you know, about this, this rough pattern that has occurred since the start of the pandemic of every two, three months a surge, then it lets up a while, everybody relaxes, and that sparks another surge. And school is one of those particularly with

the Delta variant. So, I'm really, really happy that we're going to be able to protect kids.

D **Dr. Halena Gazelka** 04:01

Greg, what do we know about the demand for booster shots? Are those who are eligible to get them getting them?

D **Dr. Gregory Poland** 04:07

Yeah, I mean, I think there's been a lot of movement in that direction. Where we're not seeing movement, and that's really the concerning part, is unlike other nations, we've got a really large segment of people who are hesitant or resistant to getting the vaccine. So, on the one hand, you've got a large percent of America that's now moving to their booster dose, kids that will get their primary series, and then this group of people that will continue to periodically have infection and drive these surges and these outbreaks. And it's an almost intractable problem unless you make mandates.

D **Dr. Halena Gazelka** 04:55

Greg, one of the most interesting things that I think I've heard is going on in research is this thought about mixing different COVID vaccines. Now currently, if you had Pfizer, you get another Pfizer, if you can get a booster, you'd get a Pfizer. What about people getting different brands of vaccines?

D **Dr. Gregory Poland** 05:15

You know that so-called mix and match ideas also going to be reviewed by the FDA I think again on that on the 29th of October. I've been privy to those preliminary data, all I can say or am allowed to say, is that looking at those data, it works. You see really nice immunogenicity. You do not see any significant increase in reactogenicity, or safety issues. So, I suspect it will be approved. That will be very helpful for travelers, for clinicians. As you know, you and I are faced all the time by patients and often because of where we work, patients that have come from other countries using vaccines that for example, maybe AstraZeneca vaccine that we don't have here in the U.S. And I think it will be very, it's a very practical thing to be able to say you can mix and match these vaccines.

D **Dr. Halena Gazelka** 06:16

Yeah, that's really exciting news. Convenient, I would think.

D **Dr. Gregory Poland** 06:20

Indeed.

D **Dr. Halena Gazelka** 06:23

Another study I wanted to ask you about Greg, was in the New England Journal of Medicine, and they talked about how immunity in men may wane faster than it does in women after Pfizer vaccine. Tell me about that.

D Dr. Gregory Poland 06:36

I knew you were gonna bring this up.

D Dr. Halena Gazelka 06:41

I couldn't pass up an opportunity, Greg.

D Dr. Gregory Poland 06:44

I think you're referring to the Israeli healthcare worker study. It was just published in the New England Journal, as you mentioned, and it is interesting. You're exactly right. What they showed is that in men, antibody decayed or waned faster, significantly faster than in women. It also waned faster in people over the age of 65 and in people who were immunocompromised. None of that is a surprise. I have to admit to you Halena, I've studied vaccines for 40 years, and in every vaccine that I have studied, women have superior immune responses to men, they just do. We don't know precisely why that is. I know you and my wife have offered an explanation, but it's not a scientific one.

D Dr. Halena Gazelka 07:34

Sometimes no explanation is required, Greg.

D Dr. Gregory Poland 07:38

But you know, I think that the point is that, as I have written about for almost two decades now, in time we're going to move toward a more personalized or individualized vaccinology approach. It may well mean, for example, that men need a booster sooner than women, or maybe it's at least older men need a booster before older women do. Those are the kinds of things that having data like this would enable. It also fits with the clinical picture that we see. Men have suffered more in this pandemic than women in terms of hospitalization, deaths, etc. So, you know, it does fit with the clinical data, and then it's incumbent on us to design policy around that.

D Dr. Halena Gazelka 08:35

What's the status of the Merck antiviral pill?

D Dr. Gregory Poland 08:38

Well, this is another area that's exciting. I mean, it's going to turn out that the fall here is good news in terms of this pandemic. So, Molnupiravir is the name, it's a mouthful, of the antiviral, the dose is going to be two pills taken twice a day for I can't remember now, is it four or five days, I think four days. We don't know yet how low of an age you'll be able to use it in. So, I don't have that information yet. But the exciting thing is that it cuts the risk of hospitalization and death by 55 or 50%. So, you know, like all antivirals, it's not a miracle cure, but the earlier you get to that infection and treat it makes a significant difference. Now, why are we so excited about this over the antiviral we have or monoclonal antibodies? This is oral, all the rest have to be administered by injection or IV infusion.

D Dr. Halena Gazelka 09:40

So, you can take this is at home perhaps?

D Dr. Gregory Poland 09:42

You can take this at home, and then the nice part about this, is this kind of fits with the same paradigm that we already have in clinical medicine with treatment of influenza, with an antiviral. With influenza, in fact, we now have an option where you take one pill, one time We're not there yet with COVID-19. But who knows, as more research occurs. So, this is very exciting news to be able to treat people who develop COVID regardless of whether they got vaccine or not as an outpatient and decrease that, you know, surge demand that we have seen on the medical system.

D Dr. Halena Gazelka 10:23

Greg, is it known yet if that antiviral would be used in conjunction with monoclonal antibody, for instance?

D Dr. Gregory Poland 10:29

There probably wouldn't be a need to simultaneously do that. Now, potentially, you know, you could envision maybe some clinical scenarios where you're sort of throwing everything at the fire to see what would help, but the antivirals tend to work best, the earlier that they're used. So, you really don't want to wait until somebody is, you know, is on a ventilator in the ICU. And again, that's the value of this as an oral outpatient treatment.

D Dr. Halena Gazelka 11:06

So, the earlier, you know, the better?

D Dr. Gregory Poland 11:10

Right. So, we don't know quite yet when this drug will come up before the FDA for review, I imagine pretty quickly since we already have the high-level efficacy and safety data. And almost certainly, unless there are any surprises, it would end up getting approved.

D Dr. Halena Gazelka 11:29

Say, Greg, this is a little off topic from COVID. But I wanted to get your take on the first ever malaria vaccine that the World Health Organization is endorsing. Tell us about that. That sounds like amazing,

D Dr. Gregory Poland 11:43

We will finally be able to eliminate malaria in Minnesota. We have a cure for that in Minnesota. It's called winter.

D Dr. Halena Gazelka 11:53

Right and it's coming soon.

D Dr. Gregory Poland 11:55

We don't have mosquitoes then. But you're exactly right. There's a vaccine called the RTS,S Mosquirix is what it's going to be called, made by GSK. And this is very interesting. Looks like it's going to be a four-dose series, again, significantly decreases the risk of severe disease. We don't know about death, but presumably it will cut the risk of death. You know, let's take Africa, you have Sub-Saharan Africa, you have 400-500,000 kids a year who die of malaria. Now, this vaccine is probably only about 50% effective. So, it's a start. One study showed 30% efficacy, so it's a start. And it probably only lasts about four years. So, it's not a panacea. But a very exciting new paradigm for a vaccine against a parasite. Parasites are very complex organisms. So, this will be a vaccine against a parasite, a pathogen that has ravaged the human population for centuries and centuries. So, this is very exciting news in the field of vaccines.

D Dr. Halena Gazelka 13:17

Great. Any other thoughts you'd like to share with our listeners today?

D Dr. Gregory Poland 13:22

You know, I want to push a little bit Halena, just because we have seen some very, very sad cases nationally. And that is the importance of immunizing women who want to get pregnant or who are pregnant with COVID vaccine. And again, this has a double benefit. It protects the mom, and it protects the child both unborn and immediately after birth. In fact, I know this is going to sound almost unbelievable. The risk of death in a pregnant woman with COVID is 70% higher than in a non-pregnant woman of the same age. And, you know, by the way, we see similar kinds of statistics for pregnant women who develop influenza. So, particularly that second to third trimester, it's really important that a woman be updated with pertussis vaccine, COVID vaccine, and influenza vaccine. So, it's also a reminder that in the midst of all the COVID information, there are important things you can do to protect your well-being, your health, and your life above and beyond COVID, and that's pertussis, shingles, pneumonia, influenza vaccines.

D Dr. Halena Gazelka 14:46

Wow. I had no idea, Greg, that the risk of flu was so high in pregnant women.

D Dr. Gregory Poland 14:53

And you know, we talked about a twin-demic last year, and I think I've mentioned before now the concern is over a tri or even quad-demic. What has happened is last year we saw almost no influenza, right? I personally did not see a single flu case. That has never happened in my career, never. But we were wearing masks. We were distanced at that time. By pretending that the pandemic is over, we've already seen more cases of influenza than we did all of last year. And we've seen surges in RSV, respiratory syncytial virus, which, you know, makes people sick, but it can kill

young kids and elderly adults when we don't have a vaccine against it. So, we really do want to urge people be careful here, you're going to hear news. And I think it's true that the COVID-19 pandemic is going to wane, and it has waned quite a bit already in the last few weeks, it will wane further. But many predictive models concern. It's speculation. But based on what we had, the pattern we have seen over the last 19-20 months, concern that as we get deeper into winter, with travel, the holidays, etc., that we'll see another surge, both because of the large number of unvaccinated people and waning immunity where you see breakthrough cases.

D Dr. Halena Gazelka 16:32

So, in summary, Greg, what are you thinking and feeling this month about the trajectory of COVID-19?

D Dr. Gregory Poland 16:37

Well, I'm really pleased as you can tell, I mean, there's some serious things to attend to. But we have a lot of reason for optimism here. I think we're gonna see approval of a vaccine for kids down to age five. We're going to see approval of an oral antiviral. We're going to see extensions, and I hope mix and match allowances for vaccines, and we're already seeing the value of people getting immunized and the downturn in the pandemic. I still have concerns about the people who are not immunized. But I think we can be very positive here, particularly as we get to the holidays if people will remember what we said all along hands, face, space and vaccinate, and it will serve them well.

D Dr. Halena Gazelka 17:27

Our thanks to Dr. Greg Poland for being here today to be our virology and vaccine expert, and to give us our COVID-19 updates. I hope that you learned something. I know that I did. We wish each of you a very wonderful day.

D Dr. Gregory Poland 17:41

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