Coming up on Mayo Clinic Q&A: Recently there has been a steady uptick in COVID-19 infections due to the new and changing variants. These variants are highly contagious. So, it’s still important to take the precaution of masking in public areas, even if you have been immunized and have received your boosters.

I can't say it enough. This is so hyper contagious, that regardless of having had three or four doses of vaccine, or of having previous COVID, you still run an appreciable chance of getting COVID. The risk in that case is not of death or hospitalization, but of the complications and long-haul symptoms of COVID. And that’s what we’re trying to prevent in people who have been immunized.

Welcome everyone to Mayo Clinic Q&A. I'm your host, Dr. Halena Gazelka, and we're recording this podcast on Tuesday, June the 14th, 2022. As immunity for many wanes, and Omicron and its sub variants continue to circulate, just about everyone knows someone who has COVID or has had COVID. Is this the state of our new normal? And what’s the latest update on vaccines and boosters including for young children? Well, we have your answers today because our expert, Dr. Greg Poland, from the Mayo Clinic is here to talk to us just about those topics. Welcome back, Greg.

Thank you, Halena. Good to see you.
Dr. Halena Gazelka 01:30
Good to see you. It's been a couple of weeks hiatus.

Dr. Gregory Poland 01:33
I know.

Dr. Halena Gazelka 01:33
What a way to get together again.

Dr. Gregory Poland 01:34
A lot has happened since we last spoke.

Dr. Halena Gazelka 01:38
Oh, boy. So, let's jump right in. Tell me what is going on with COVID, Omicron, sub variants.

Dr. Gregory Poland 01:44
Yeah, we're in a kind of a sad situation right now that's a juxtaposition of so much of the general public wrongly thinking that COVID is over, and it is not. We're having around 100,000 known new cases a day.

Dr. Halena Gazelka 02:06
Wow.

Dr. Gregory Poland 02:07
And the real number, because of the amount of home testing, or lack of testing, is probably three times more than that. We have about 33,000 people in the hospital, and about 300 dying every day from this preventable disease. That in association with confusion about what's going on, new variants, and waning immunity, has really moved us backward rather than forward. And you asked about the variants. This is the biggest thing that's changed since you and I last spoke. Now about 20% of the circulating strains are the BA.4 and BA.5. About 60 plus percent are the BA2.12.1. And about 20% or less are the old, if you will, Omicron. The problem with that is we're having more and more variants. BA.4 and BA.5 likely will take off. And unfortunately,
because people keep getting infected, allowing the virus to mutate, it substantially escapes illness induced and vaccine induced immunity. So, it’s likely we could have a real problem this summer and going into the school year on our hands as people fail to take the basic mitigation measures.

Dr. Halena Gazelka  03:45
Greg, I have a couple questions about vaccines for you today. First of all, what is a bivalent vaccine? And will it be recommended for most of us this fall?

Dr. Gregory Poland  03:55
That's a great question Halena. Moderna has been working on a bivalent vaccine. Initially, it was the Wuhan and beta. But beta is essentially gone now. So, they've just traded that out, switched it out to include the Wuhan, that is the original strain, and the Omicron strain. It looks in very preliminary data to offer strong immunity. And so, the thought is that they will put that before the FDA, I believe it's scheduled for the 28th of June, and then vote, a discussion and a vote be taken on that. The problem of course is again with the incredible number. I was just on an airplane, and I bet three to 5% of us wore a mask, nobody else. So, you know what's gonna happen. When you go into the grocery store almost nobody is in a mask, so they're getting infected, one after another. Each time that happens there's the risk of new variants, and these new variants could come along and negate the value of a new bivalent vaccine. So, we're in this constant catch 22 because we can't get people to adopt evidence based public health and scientifically driven measures. So, you know, best guess is we will have a bivalent vaccine that we would be able to get some time this summer, toward the end of summer. One hopes that all of this can get sorted out before kids go back into school. Because with these newer variants, they are highly, they are super contagious. I may have mentioned before the most contagious virus known to humans is the measles virus. And this one, these new variants, are just below measles.

Dr. Halena Gazelka  05:55
Wow. Well, you brought up children, Greg. So, let's jump into the big news this week about vaccines for kids under five. I know there's a lot going on behind the scenes on this topic. Can you tell us about it?

Dr. Gregory Poland  06:08
Yeah, you're right, Halena. In fact, as we talk right now, the first of a two-day FDA discussion and meeting is taking place. We have results from both Moderna and Pfizer. They've been shown to be generally safe. There are side-effects, of course, and to offer protection. The difficulty is that these are being studied while new variants are arising. So, there is no clinical data on the efficacy of these against BA.4 and BA.5, because BA.4 and BA.5 didn't exist when they started this study. That's how fast it's happening. In fact, BA.4 and BA.5, their prevalence in the U.S. has doubled in the last week. As of early May, it was only 1% of sequences, now almost 20%. Nonetheless, so Moderna is a two-dose vaccine for children. In their top line
results it offered between 37 and 50% protection against symptomatic disease. The Pfizer vaccine is a really small dose. It is a 10th of the dose that we use in adults. So, they had to move to three doses. You may remember, they started with two doses, and that's what has delayed this. And their efficacy in children six months to two-years-old, was 75%. And in two to five-year-olds, it was 82 or 83%, somewhere in there. So, you know, it makes it confusing to parents as to which vaccines should be used, a two dose, a three dose, a difference in efficacy, a potential difference in side-effects. All of that is being sorted out over these next two days. If they vote positively, then on Friday, this would go to the CDC expert committee for discussion, and then a recommendation made. If those are both approved, the Biden administration has signaled that they will release these vaccines very quickly after that, by the end of the second to third week of June.

Dr. Halena Gazelka 08:30
I think that will probably be a relief to a lot of parents. But there is more news to come on this, so we know you'll be watching. Greg, what is the significance of Novavax? I saw that it was, I believe, released last week, or put into use last week. Why does that matter when we already have multiple vaccines?

Dr. Gregory Poland 08:51
Yeah, so just full disclosure, I give consultative advice to all the vaccine manufacturers. But for the FDA meeting, I actually presented the clinical case for Novavax vaccine. Listeners should just be aware of that. The importance, so the FDA approved it unanimously with one abstention, it now goes to CDC. So, we don't actually have it released and available yet. The advantage of it, I would say, is that it causes less in the way of reactogenicity with immunogenicity and efficacy equal to the other mRNA vaccines. So, I think for some people who don't want to get an mRNA vaccine, or who had a side-effect due to an mRNA vaccine, this will be a good option for them. And I think the more options we have, the better for the public.

Dr. Halena Gazelka 09:52
Greg, I'm gonna open the listener mailbag to our brilliant listeners. But I want to ask you one question because it's been in the news so much recently. Tell us about monkeypox and the significance of this.

Dr. Gregory Poland 10:04
You know, this is really interesting. The media hasn't quite reported it this way, but monkeypox now fulfills the technical definition of a pandemic. In that regard, we have two pandemics happening simultaneously. Outside of Africa we now have almost 1300 documented cases across 28 different countries, and a huge outbreak within certain countries over these last months in Africa. So, the concern is that it will continue to spread. What happened is that initially, there were very large rave parties for men who have sex with men in Spain and Belgium. This occurred over 10 days, just, you know, all kinds of anonymous sexual activity. Some of those individuals had been to Africa, had contracted monkeypox, and then spread it
because of the close skin-to-skin contact with other people. And then 1000's of those people went back to their home countries, and that's why it has spread into these 28 different countries in the U.S., Canada, Australia and multiple countries in Europe and Asia. Now, fortunately it's what's called the West African clade or strain, which normally has a less than 1% fatality rate. But it's all the other complications that can occur, including scarring of the eye with subsequent blindness, inflammation of the brain, skin scarring, pneumonia, and the transmissibility of it. Now fortunately, it's not as transmissible as something like measles, or COVID, or even smallpox. It really takes pretty close and prolonged contact in order to spread. But it's a concern if this were to get established in the population, and spill over into the animal population. You might remember in 2003, in our own Midwest region we had 71 cases of monkeypox related to imported rodents from pet rodents. I don't know why anybody would want one, but from Africa that were infected, and we were gravely concerned that if one of those had escaped and gotten into, for example, the prairie dog population, we would never be rid of this, and the population would always be at risk for monkeypox. So, that's the concern that's happening.

Dr. Halena Gazelka 12:57
Is it true that they use the same smallpox vaccine that we received as children to prevent monkeypox?

Dr. Gregory Poland 13:05
Well, we actually have two vaccines now. We have the smallpox vaccine, and you're exactly right that it does protect against monkeypox. But there's also a monkeypox vaccine, which is safer, but more limited in availability. So, both can be used. In fact, you can use, ideally you use the vaccine before exposure, we're not going to immunize the population. If somebody has had exposure, we try to get them the vaccine within four days to prevent the disease, or as long as 14 days to decrease the severity of disease. In addition, we've got two antivirals that can be used. So, in the United States we're well prepared, we're in good shape. That is not the case for other nations. So, you know, for the general listening public, I would say your risk is if you're having close contact with somebody who has skin lesions, and the vast majority of cases have been in men who have sex with other men. So, contact in those sorts of circumstances are higher risk, as well as a health care worker taking care of somebody with monkeypox.

Dr. Halena Gazelka 14:22
Greg, you said earlier that monkeypox would fit the criteria of a pandemic or that definition. What is the criteria for something to be a pandemic?

Dr. Gregory Poland 14:32
So, we really want to see elevated case rates across multiple countries at the same or concurrent time. And that's definitely the case here. More than one case is considered an outbreak. And we have that, as I mentioned, across 28 countries, and those cases have been rapidly climbing. So, we've got to keep a sharp eye out for the physicians who might be
listening, as well as our general public. What's different, you tend to see pictures of somebody covered with pustules, or skin lesions. What has generally been different and aberrant about this outbreak is it has generally been one to a handful of lesions. And those can be easily confused with other kinds of lesions including chickenpox. So, somebody who has a fever or rash who's had contact with a high-risk person, even though you may not feel sick, it would be wise to see your healthcare provider with a question being could this represent monkeypox? That's how we're going to find cases and prevent new transmission to other people.

Dr. Halena Gazelka  15:49
All right, Greg, let's see what our listeners have in store for you to challenge you today.

Dr. Gregory Poland  15:54
Okay, here we go.

Dr. Halena Gazelka  15:55
All right. Our first listener asks, with so many people having recent COVID infections due to Omicron, how do people know when they should get their first booster? I've had three mRNA shots, and now I've had COVID. Should I get a second booster? If so, when?

Dr. Gregory Poland  16:12
Yeah, I probably, in that case, if that individual were not immunocompromised, I probably would not rush to get a second booster, since they've in essence had three doses of vaccine and a case of COVID, which we would count as similar to a booster and in that case, I would probably hold for the handful or two of weeks, i.e., during the summer when we may have a bivalent vaccine, and that would be the better booster then for this individual.

Dr. Halena Gazelka  16:50
But wear a mask, you would say that.

Dr. Gregory Poland  16:52
And you need to wear a mask. I mean, this is just so, I can't say it enough. This is so hyper contagious, that regardless of having had three or four doses of vaccine, or of having previous COVID, you still run an appreciable chance of getting COVID. The risk in that case is not of death or hospitalization, but of the complications and long haul symptoms of COVID. And that's what we're trying to prevent in people who have been immunized.
Dr. Halena Gazelka 17:28
All right Greg, our second listener says, I'm immune compromised, and my doctor talked about a COVID preventative drug called Evusheld. I'd love to hear what you know about this.

Dr. Gregory Poland 17:40
Yeah, that's a great question. Actually, all of our listeners, every single question we've had have been great questions. Some of them cause me to scratch my head and go back into the lab, I'm not kidding, to try to figure out the answer. In this case, though, what the listener is referring to is a combination of two monoclonal antibodies that are given in two different ways. One of them is to prevent infection. So, prophylactically, you get two intramuscular immunizations or injections, I should say, protects you for about six months at a level of about 85 to 90%. So, very effective.

Dr. Halena Gazelka 18:24
Wow.

Dr. Gregory Poland 18:24
We also use it in people who are for valid medical reasons unable to get vaccine or who are immunocompromised and may not respond to a vaccine. The other thing though, and it's interesting, this question came up, because these are pretty much hot off the press data. There was a phase III study called TACKLE, which was an outpatient trial of giving one dose of the vaccine in people who had mild COVID to see if you could prevent progression in high-risk people. If you gave it within three days, it had almost 90% effectiveness in preventing progression, in five days, 67% efficacy, and within seven days about a 50% reduction in going on to more severe disease. So, this is a very valuable prophylactic, and in a sense, therapeutic that we have in our armamentarium. So, certainly people who are immunocompromised or who can't get the vaccines for some reason, this is a great option for them. As a matter of fact, in that outpatient trial, one of the interesting things is that the side-effect rate in the placebo group was higher than in the group that got the combination monoclonal antibodies.

Dr. Halena Gazelka 19:53
Oh, interesting.

Dr. Gregory Poland 19:54
That rarely happens.

Dr. Halena Gazelka 19:56
Rarely. Well, anything else to share with our listeners today, Greg?
Dr. Gregory Poland  20:01
I think we've talked quite a bit about it. I just would plead that, we, you know, we're in year three now of this pandemic. And I was stopped on the streets yesterday by somebody who knew me. And his opening comment was, nobody's afraid of COVID anymore, right? It's over. And I marvel that people have that idea. Where did they get that idea? It's true, that before Christmas, after Delta, we had reached quite a low point that all those gains had been totally reversed, totally reversed. We had more people die in the U.S. in four months of Omicron than six months of Delta. And people don't realize this, even if they don't die, the risk of myocarditis from the disease, the risk of diabetes and cardiovascular complications, fatigue to the point where they can't work. These are real and ever-present risks if you get infected. So, we're really trying to tell people preserve your health and the health of those around you. Get fully immunized, and wear a mask when you're indoors with people not in your family.

Dr. Halena Gazelka  21:22
Thank you, Greg for being here today.

Dr. Gregory Poland  21:24
My pleasure.

Dr. Halena Gazelka  21:26
Our thanks to Dr. Greg Poland, virologist and vaccine expert for being here with us today to share the latest on COVID variants, vaccines and monkeypox. I hope that you learned something. I know that I did. And we wish each of you a very wonderful day.

Narrator  21:45
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