Coming up on Mayo Clinic Q&A:

Dr. Gregory Poland  00:03
After 15 months of this, this is the first week we have not had an increase in COVID cases in any US state, and in 33 of those states, there was a decrease last week. This has not happened on any consistent basis for every US state since the start of this pandemic.

Narrator  00:30
Even though there has been a decrease in adult cases, more children and teens are getting COVID due to varying strains. So, it's crucial that parents get their children immunized when the vaccine is available for their age groups.

Dr. Gregory Poland  00:43
My advice to parents would be get your kids immunized as soon as you can. Let them go to summer camp. Let them get together with friends that socialization is so important, and let them get back to in person school as safely as possible.
Welcome, everyone to Mayo Clinic Q&A. I’m Dr. Halena Gazelka. We’re recording this podcast on Monday, May the 10th, 2021. There was big news on the COVID-19 vaccination front last week. Pfizer requested emergency use authorization of their vaccine to be extended to include 12- to 15-year-olds. Well, here to discuss this and other COVID News with us today is our favorite expert, Dr. Greg Poland, who’s an infectious disease vaccine expert and virology expert at the Mayo Clinic. Thanks for being here, Greg.

Now I hope that you missed me last week.

I did.

I missed our conversation.

Yes, absolutely.

Well, we have a lot to get to Greg, I want to ask you about vaccines. And I have several listener questions for you. But first, I heard that you have some really good news for us today. So, let’s go with the good news first.

News gets out, good news especially gets out fast. Well, the good news is this after 15 months of this, this is the first week, we have not had an increase in COVID cases in any US state, and in 33 of those states, there was a decrease last week. This has not happened
on any consistent basis for every US state since the start of this pandemic.

Dr. Halena Gazelka 02:29
Woo-hoo!

Dr. Gregory Poland 02:31
I know woo-hoo, America.

Dr. Halena Gazelka 02:33
Good COVID news. We can use good COVID news. That's great, Greg. Now, tell us about vaccines. Where are we with teenagers and with vaccines overall?

Dr. Gregory Poland 02:45
Yeah. Well, you know, the flip side of the good news is where we are seeing infections is in people who are not yet vaccinated, and that includes younger adults and kids. That's a concern. A good quarter of the cases that are occurring, are in kids, something we did not expect.

Dr. Halena Gazelka 03:05
Oh, that's a lot.

Dr. Gregory Poland 03:06
Yeah, earlier in this pandemic, when you look at the US now, it's hard to even imagine these numbers. 262 million doses we're given by the end of this weekend. Which means 46% of the population has gotten at least one dose, and 35, so let's just call it a third, of the nation is fully vaccinated.

Dr. Halena Gazelka 03:32
Wow, that's amazing.

Dr. Gregory Poland 03:33
So, the big push now is we got to get, you know, I think none of us want to go back. None of us want to go back. I think what’s going to happen is that through the spring, and summer we’ll continue I hope, I hope to see a decrease in cases. The concern will be as summer travel starts and travel is a risk factor where you have people who are not vaccinated, and then with kids going back to school in the fall, are we going to see surges again, and part of that will be determined by what variants circulate. But the good news, follow on to the good news is that Pfizer is coming forward to extend their EUA down to 12 years old.

Dr. Halena Gazelka 04:24
Wonderful.

Dr. Gregory Poland 04:25
What that means is that we will be able to start immunizing every American age 12 and older, and they’re working their way down. Moderna will do the same thing. Johnson & Johnson will probably do the same thing. So, if we do this well America, if we do this well and all do our part and get a vaccine, we are going to have a normal life again and not constantly be thinking about COVID.

Dr. Halena Gazelka 04:54
That deserves another Woo-hoo.

Dr. Gregory Poland 04:56
Yes.

Dr. Halena Gazelka 04:58
So, a lot of the obstacles to receiving vaccines are being removed. Greg here in Minnesota, the centers even here at Mayo Clinic, and many of the state vaccine centers are opening up for walk-ins, a great convenience.

Dr. Gregory Poland 05:14
Yeah.
Yeah, so in a lot of states, I think that’s true.

I hope people take advantage of that. I hope we very quickly get this EUA, by the way, followed on the Pfizer and Moderna will do the same thing, and two other companies are filing for what’s called a BLA, so a full approval license, and what that’ll mean is that anybody can walk in and get a vaccine. There will be no excuse, no reason to not protect yourself, your family and your community.

Greg, can you remind us again, what an EUA is?

Sure, so an EUA is an emergency use authorization. And what that says is that the known and potential benefits and risks are outweighed, in other words, more benefits than risks that are known. Now what happens with a BLA or biologic license application, full licensure, is now you’re not looking at potential risks, you’re looking at known benefits, known risk. We have more data for these vaccines than any vaccines we’ve ever had at this stage. I mean, America needs to hear that. This is a stunning amount of data with stunning efficacy and safety associated with it. So, when you move to a BLA, now you know the risks, you know the benefits, you know what’s called the real-world effectiveness, and the last part of it is that the FDA does all of the lot-to-lot consistency testing. They examine, they’ve already done it, but they examine normally under normal conditions, they wouldn’t normally do the facilities inspection until this stage, they’ve already done that. So, it’s going to be what’s called a rolling BLA. They’ll put the part that FDA wants, FDA will have more questions, they’ll put that next part forward, and that should accelerate full licensure.

Oh, wonderful. That’s great. Oh, and Greg, you mentioned more and more people getting the vaccine and here in Minnesota, and I’ve seen this in many states as well, but governor Walz has started sort of a rollback of the mandates on social distancing on how many can gather in a group, on hours that restaurants etc., can be open. And it’s sort of in a staged process, as more Minnesotans get vaccinated. And I think the hope is for 70% by July 1, to
be able to open up even more.

Dr. Gregory Poland 08:01
Yeah, you know, what a great thing. Take it to July 4th, a day of freedom, right? And it really, really centers on people getting vaccine, I cannot stress this enough. This virus will continue to mutate, we’ve seen excellent efficacy against these mutant viruses. But once they get ahold in a community where you have a high number of unvaccinated people, as we just saw in Michigan, then we start all over again. And I just dearly hope that doesn’t happen. And that people have the confidence that they are warranted to have in these vaccines.

Dr. Halena Gazelka 08:45
I wanted to go over that one more time with you because that was going to be my next question, Greg is about the variants. So, you’re saying that each of these vaccines seems to be efficacious against the variants?

Dr. Gregory Poland 08:55
Yeah, we have some really excellent what’s called real world effectiveness. So, not in a special kind of study, but what actually happens out in the world. And they’ve published studies now, actually last week, so your question is a very timely one in Qatar and Israel, looking at Pfizer vaccine. Other studies have looked at Moderna vaccine. They are just shy by a percentage or two of 100% efficacy against death, severe illness, critical illness, hospitalization. About 85% effective against asymptomatic infection, and that’s the key. That’s why we all get the vaccine, so that we’re all protected and protecting those that can’t get the vaccine. So, this is really important. And it’s really good news if we do this well.

Dr. Halena Gazelka 09:56
And Greg yet, there are still those who are concerned about receiving a vaccinee, that it was just rushed, that the vaccines were brought forward too early. Can you just again for our listeners, and for me, because I like to learn something every day, go through a little bit of the history and why we’ve been able to do this within the 15 months. And why do we know they’re safe?
Dr. Gregory Poland 10:20

Yeah, a really good question, and everybody deserves an answer to that question. So, the mRNA vaccines started being developed in the 1960s. By 1990, they figured out how do you stabilize that mRNA molecule and decrease the reactogenicity. So, that started in 1990-1991. They worked and worked and worked on those vaccines, along comes SARS-CoV-1, in 2003. They started doing all the studies for the development of that mRNA vaccine. Thankfully SARS-CoV-1, through containment procedures, a much more lethal disease went away. We were able to control that and it disappeared. They put the vaccine on the shelf. 2012 comes along, MERS another Coronavirus. They take it back off the shelf, start developing it. MERS did not thankfully become a pandemic, put it back on shelf. And then of course in 2019-2020, we learn about this. So, Coronavirus vaccines using mRNA technology were already developed. They had already had, depending on how you want to count it, 15 to 30 years of development. So, all that operation warp speed does was figure out how do you cut out the administrative bureaucracy? How do we get contracts out? How do we incentivize manufacturers to make hundreds of millions to billions of doses? How do we get countries around the world to cooperate, it can be a multi-year process to cooperate in getting all the ethical approvals for the phase III clinical trials? And the drug companies pitched in, and they did it beautifully. I will say. I can sometimes be very critical of them. They did this beautifully. And we ended up with really large phase III clinical trials. And at this point, when somebody says Well, I'm not sure that they've used it enough for that we know enough. Hundreds of millions of doses have been given at this point, and no safety signal with the mRNA vaccines other than anaphylaxis. And with the adenovirus vectored vaccines, no safety signal at all other than this very rare coagulation syndrome that can occur.

Dr. Halena Gazelka 13:00

So, to say that these mRNA vaccines were developed in the past year would be erroneous....

Dr. Gregory Poland 13:08

It’s frankly wrong, and you know, I don’t expect that lay people would know that right? To them, they just heard about this. To us in the field, this has been being developed my entire career. This is just the first application in a widespread manner.

Dr. Halena Gazelka 13:29

Well, Greg, it’s time to turn to the mailbag. Our brilliant listeners have some great
questions for you today.

Dr. Gregory Poland  13:35
I always wonder what am I going to get?

Dr. Halena Gazelka  13:39
We like to test you and keep you on your toes. Our first question is from an individual with a penicillin allergy, who is questioning whether the COVID vaccines are indeed safe for someone with a penicillin allergy, and is there a preference for one vaccine over another?

Dr. Gregory Poland  13:54
That's fortunately a very easy one. They do not contain preservatives, antibiotics, nothing that would cause any other sort of allergic reaction than the one we've seen, in about two to four out of a million doses, about the same as other vaccines. So, the advantage of these vaccines, no antibiotics in them, no preservatives in them.

Dr. Halena Gazelka  14:19
Perfect. I'm going to read the next question to you, Dr. Poland. I'm wondering if you could comment on whether or not the post vaccination symptoms of Bell's Palsy after an initial dose are of sufficient concern to delay the second dose as a general recommendation. So, maybe start with what is Bell's Palsy and what is this listener talking about.

Dr. Gregory Poland  14:41
Yeah, so Bell's Palsy is a condition when this the cranial nerve that causes us to move our face, allow us to smile or frown or blink our eyes, whatever it would be, when those nerves in this case, the seventh nerve, actually is damaged in some way either from an inflammatory process, shingles is one of the more common causes of it, and in the clinical trials, there was a very slight imbalance. So, remember, we give some people a placebo, some people the vaccine. That's been hundreds of 1000's of people now, and we look for any differences. In the initial study, there was a slight imbalance toward the vaccine. So, in other words, a little red flag of here is something we have to look for. So, now after 10's of millions of doses, they looked again, no imbalance. They have not seen anything that they can say is vaccine associated. So, you're really looking to say, in a group of people that get the vaccine, do we find that side effect any more frequently than two years ago, before there was any COVID or COVID vaccine, or among people who never got the
vaccine, and there’s no imbalance. So, while there was a hint of a concern, that particular concern has not shown up to be true.

Dr. Halena Gazelka  15:32
All right. Another concern. Our next listener has a teenage daughter, and is wondering whether it is safe for their daughter to receive the Johnson & Johnson vaccine out of concern for potential blood clots. And if not blood clots, is it possible that the researchers will later find there are other complications and that we should have waited to receive vaccines?

Dr. Gregory Poland  16:34
So, the latter question is a really good question, right? I mean, people want to know and deserve to know, is what I’m about to take, say, what are the risks, and what are the benefits? Now, wisdom resides in knowing the risks and benefits of getting a vaccine, and the risks of not getting a vaccine. There are few, if any benefits, to not getting a vaccine unless you’re allergic to a component in that. And that’s this idea of trying to balance risk.
So, let’s just say that with the Johnson & Johnson vaccine, we’re looking at a risk of about two people out of a million developing this very new, very rare syndrome called DTS, what it basically means is blood clots associated strangely enough, with a decrease in the cells that circulate in our blood that cause clotting, called platelets. Almost all those cases have occurred in women, and almost all in women under the age of 50. So, the concern, as teeny as it is, is a concern limited almost entirely to younger women. So, you have a choice. In the US, you can go ahead and get J&J, a big advantage, single dose, or you can get the mRNA vaccines, and later this month, there’ll be a fourth new vaccine available for people. So, what would I do, I would get the vaccine that’s available to me. And you know, it depends on circumstances, if you’re a young woman living at home, and she’s got good access, she could pick any of them. If it’s college, and I’ve got one choice, and I could get it done in one dose, I would have no problem with that either. The main thing is that we would just monitor somebody, these are not hard to pick up. This is the worst headache I’ve ever had in my life, a swollen blue limb, or severe abdominal pain; these are not subtle things. And one of the reasons for the J&J pause was to educate the public about that, but also for you and I, as physicians to be educated because you treat that blood clot very differently than we treat all other blood clots. So, even within that minor safety issue, there’s enhanced safety in knowing what to do.

Dr. Halena Gazelka  19:12
Okay. I’m not aware of who is in the household of our next listener, but this individual is
wondering, is it enough just to vaccinate adults within the household, even as vaccines become available for the younger individuals in the household?

**Dr. Gregory Poland  19:28**
The answer to that is also pretty clear. No. And you and I were talking a little bit before the show that where we are seeing cases is in younger people and teenagers who are you know, in school, who are in congregate settings. In Colorado, a fourth or more of the cases are occurring in the younger kids. So, the sooner we get them immunized, the better. Right now, with Pfizer vaccine, we can start at age 60. May 12, so this later this week, the ACIP will be meeting and almost certainly will extend this down to age 12, after seeing the safety data in the studies. And my advice to parents would be, get your kids immunized as soon as you can. Let them go to summer camp. Let them get together with friends, that socialization is so important. And let them get back to in person school as safely as possible. You know, this is so important, it’s really, really interesting to me to see who’s picking up on this. Colleges and universities by the droves are making it mandatory, so that they can safely have in person classes. All the state universities in New York, this fall will be mandatory.

**Dr. Halena Gazelka  20:52**
So, it’s interesting. I’ve seen that in some health systems that are considering making it mandatory.

**Dr. Gregory Poland  20:56**
And I hope they all do. I mean, our job is to be safe ourselves, but to keep our patients safe. So, I always say, you know, do your kids a favor, they want to live a normal life, get them immunized as soon as you can. And that reminds me to say, get them caught up on any vaccines they missed over this past year because of COVID.

**Dr. Halena Gazelka  21:22**
Yeah, that was a real issue. Initially, I remember that little children weren’t necessarily getting into have their normal vaccine schedule. That’s a good reminder. The next question is kind of interesting, Greg, and I wouldn’t have thought of it, but this individual is wondering, because their adolescent is a smaller sized individual than an adult? Do they need two doses of the two dose vaccines? Or does it have anything to do with the size of the individual what the response is?
Dr. Gregory Poland 21:53
All I can say is, wow. That is a research question that my group is studying. Whoever that listener is, we make them an honorary member of the Mayo Clinic vaccine research group. We have that same concern. In fact, we have that concern in males versus females. Because women produce better antibody responses by men, now no smiling Halena.

Dr. Halena Gazelka 22:25
Just one of many things.

Dr. Gregory Poland 22:29
But they also have tend to have more in the way of vaccine side effects, fever, not feeling well, red swollen arms, etc. So, in the studies that they did down to age 12, they saw no safety issues any different than adults. When you get down below age 12, Pfizer is studying and Moderna are studying half doses, and sometimes a third the dose for exactly that reason. So, our listener is very sharp, as they all have been, I’ve got to stay on my toes with our listener questions. But our listener is very sharp. And, we’ll know the question to that for people below the age of 12 as we do those studies.

Dr. Halena Gazelka 23:15
Well, that’s all of our listener questions. And they were great questions. I saw the most fascinating article in The New York Times that I wanted to ask you about, is that people are showering less during COVID. Why?

Dr. Gregory Poland 23:30
Umm, it's true for me too.

Dr. Halena Gazelka 23:36
True confession.

Dr. Gregory Poland 23:38
As I said, I believe in radical transparency when we're talking to patients. It's not true after I've gone running or biking or anything like that, but...
Dr. Halena Gazelka  23:47
Thanks for clarifying that.

Dr. Gregory Poland  23:51
The reason for it is probably complex, but the idea behind it is important. What dermatologists will tell you is that daily bathing and showering with the harsh chemicals and soaps and shampoos that we use are actually not healthy for your skin. So, you know, unless you got a manual job or you’ve been outside or working out, there really is no reason for that every day. Now, you know, we would say wash the parts that need to be washed and under your arms. But you know, the rest, your skin is actually healthier without doing that every day. So, maybe you’re doing it every other or every third day. I know some people have moved to a routine, especially in the colder states, of once or at most twice a week. And there is no ill effect from that. And interestingly, we have to remember that humankind never did this before. This is a modern-day invention, basically of the marketers who are selling deodorants and scented shampoos and soaps and things like these. For me, for one thing, I mean the volumizing shampoo didn’t work I’m done with it.

Dr. Halena Gazelka  25:15
No more selling that to you. It’s interesting it is sort of a luxury to be able to turn on your shower and have a shower every day.

Dr. Gregory Poland  25:22
Indoor plumbing with clean water, and that’s the only reason it ever worked.

Dr. Halena Gazelka  25:27
And I do think about the skin living in Minnesota, you know gets so cold, you notice in the winter, that your hands get much drier because we’re constantly washing them obviously in healthcare, and then during COVID everybody’s constantly washing.

Dr. Gregory Poland  25:41
Any of our patients that we have sent to dermatology, always hear this: Moisturize, moisturize, moisturize. And there actually is a company that kind of spun off a Mayo invention. I think it’s called Vanicream that they actually use and the dermatologists think
is a great skin cream for exactly that reason. They see rashes, they see cracks in the skin with infections and cellulitis. So, we can probably cool it a little bit.

Dr. Halena Gazelka 26:14
There may be something to this idea.

Dr. Gregory Poland 26:16
Yeah.

Dr. Halena Gazelka 26:18
Well, any last thoughts for our listeners today? Greg?

Dr. Gregory Poland 26:21
You know, I think kind of what we often do. You know, I'm about at the point as dangerous as this is going to be, is if you really have information-based needs and hesitancy on the vaccine, contact us. I will personally do everything I can to try to give you an answer or direct you to an answer. I'll probably be overwhelmed. But truly, I mean, I have spent 40 years as a vaccinologist. I would not put my reputation on the line, or at stake here, if I had not seen the data myself and did not believe these data. These are out of the ballpark superior vaccines. They are safe and effective vaccines. And we have come through in the United States, as we've often talked about, it breaks my heart one out of every 550 Americans died of COVID or its complications, and it need not have been. So, please get your vaccines, please get your kids immunized. If I can help you or Mayo Clinic can help you with any information needs, we will do that. It's that important.

Dr. Halena Gazelka 27:46
We want to see that positive trend you talked about in the beginning continue, don't we Greg?

Dr. Gregory Poland 27:51
You know, wouldn't it be great if we are on summer vacations with our families, and kids are in summer camps and doing all the things kids should do. And as parents, us not worrying at all. We have had somewhere around 600 children die in the US of COVID. I don't want to see even one more. It is heartbreaking. I'll tell you this transparently. I didn't
go into pediatrics, because I can't emotionally divorce myself from that with kids. I don't want to see anybody die needlessly. But kids and young adults, when we know we can prevent it.

Dr. Halena Gazelka 28:34
Keep doing the work.

Dr. Gregory Poland 28:36
Hands, face, space and vaccinate.

Dr. Halena Gazelka 28:39
Perfect. Thanks for being here, Greg.

Dr. Gregory Poland 28:41
Thank you.

Dr. Halena Gazelka 28:42
I look forward to seeing you next week.

Dr. Gregory Poland 28:44
Yes, indeed. Thank you.

Dr. Halena Gazelka 28:45
Our thanks to Dr. Greg Poland for being here today to give us our COVID-19 updates and to answer some of your questions. I hope that you learned something, I know that I did. We wish each of you a wonderful day.

Narrator 28:58
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