



Mayo Clinic Q & A - Dr. Gregory Poland 9 27 21

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SPEAKERS

Dr. Halena Gazelka, Dr. Gregory Poland, Narrator

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Narrator 00:00

Coming up on Mayo Clinic Q&A: This past week, millions of Americans became eligible to receive the Pfizer booster to help increase their protection against COVID-19. But just who is eligible? There's booster confusion.

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Dr. Gregory Poland 00:15

All we're talking about is Pfizer. If you're 65 and older, and it's been six months or more, you are eligible for a booster. If you're 50 to 64, and you have medical conditions that place you at high-risk, you are eligible for the booster. If you're 18 to 49, talk to your provider. Based on medical condition and your individual balance of risks and benefits, you may be able to get it.

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Narrator 00:47

But are boosters the answer to the COVID pandemic?

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Dr. Gregory Poland 00:50

We cannot boost our way out of this pandemic. This is a chasing our tail kind of scenario until we get the large proportion of Americans who are eligible for vaccines vaccinated.

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Dr. Halena Gazelka 01:07

Welcome everyone to Mayo Clinic Q&A, I'm Dr. Halena Gazelka. We're recording this podcast and Monday, September the 27th, 2021. There has been a lot of news around COVID, and boosters, and vaccines, and boy has the path to approval for boosters been confusing. And so, I'm so delighted that we have Greg Poland back today to help explain this to us. Welcome back, Greg.

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Dr. Gregory Poland 01:33

Thank you Halena. You know what I wore my viral tie again. I've only worn it one other time on this podcast.

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Dr. Halena Gazelka 01:40

Love the viral tie, the spirit. Great. Tell us Greg, about what was the path? How did all this come down? And what is the answer now about boosters?

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Dr. Gregory Poland 01:52

Yeah, it's led to a lot of booster confusion. But, let me start back with the FDA meeting. So, this occurred a week ago Friday, and the FDA advisory committee was confronted after hearing the data with the question, Do the safety and effectiveness data support approval of a dose, a booster dose, six months or more after the primary Pfizer series in people 16 and older?

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Dr. Halena Gazelka 02:26

Only Pfizer and we'll get to that again?

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Dr. Gregory Poland 02:28

Only Pfizer, so everything we're about to talk about is delimited to the narrow case of Pfizer, and they voted 16 No, 3 Yes. So, that was defeated. They then revised the voting question and said, Well, what about a booster dose at six or more months in people aged 65 and older and at high risk of severe disease? They voted 100% Yes on that. Then a third vote, which was, Should health care providers and others at high risk for occupational exposure be included? And the vote was 100% Yes. Now what happened is that this past Wednesday and Thursday, as per protocol, it went from the FDA Advisory Committee to the CDC's Advisory Committee called the ACIP, Advisory Committee on Immunization Practices. I have been a past member of both of these committees, so I know how they work well. So again, after hearing the data for a day and a half, they then voted. The first question was should there be booster doses? Again, this is only for Pfizer vaccine. Should there be booster doses for people aged 65 and older or in long-term care facilities, six months or more after the primary series? And it was a unanimous Yes. Now, that was a "should" recommendation. It should be offered. The second vote was in people 50 to 64. So, they've stepped it down one age range, who have medical conditions, and the vote there was 13 Yes, 2 No. And again, that was a "should" recommendation. It should be recommended. Now two more votes. The third vote was what about 18 to 49-year-olds, so now the third step down, 49-year-olds who have medical conditions and basing that on their individual risk and benefit, which we'll come back to, and that was 9 Yes, 6 No, very close vote. And that was a "may" be offered. And that one was difficult. Because now you're in the situation and CDC will have to do this very carefully, of defining what medical conditions, what would be the individual risk and benefit parameters that a clinician would take into effect. Then the final one, should 18 to 64-year-olds with occupational, you know, at high occupational risk or in an institutional setting that was high risk be offered the vaccine. It was 6 Yes, 9 No. So, that did not pass. Now what happened that vote took place last Thursday. On Monday, the CDC director, overruled that last vote and approved boosters for 18 to 64-year olds who are at risk of exposure and transmission because of their occupational or institutional setting. So, that now is being operationalized. The key thing here is that they're going to have to make clear to the public, to the providers, who is at risk. This is a confusing set of recommendations. Because there's been pro and con votes, one has been added or changed, we're looking at a total of four, so we can kind of make it easy. If you got as a primary series, the Pfizer vaccine, okay, that's all we're talking about is Pfizer. If you're 65 and older, and

it's been six months or more, you are eligible for a booster. If you're 50 to 64, and you have medical conditions that place you at high risk, you are eligible for the booster. If you're 18 to 49, talk to your provider. Based on medical condition, and your individual balance of risks and benefits, you may be able to get it. And then lastly for people 18 to 64-years-old, who are healthcare providers, who are in, for example, congregate living situations, or who are, who have occupations that place them at high risk for transmission such as school teachers, for example, they also may be eligible. And that should happen now very soon. I know a lot of people are going, they call it freelancing, going and getting their booster. So, I think we have solved the booster issue. Implementation is going to be a bit of a challenge. One note, we do not know how long durability of the booster dose will be, by definition, we've just started doing it. We also don't know what would happen with a new variant. And many people think that the need for the booster has been based primarily on time since completion of the primary series with some effect due to the Delta variant.

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Dr. Halena Gazelka 08:17

Okay, so that's fine for people who had the Pfizer vaccine. But what about people who had Moderna and J&J? What happens to them if they want a booster?

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Dr. Gregory Poland 08:27

A little more complicated of a situation? So, the reason that they could approve, or if you will, expand the Pfizer EUA is because they were the first ones out of the gate, had collected data on this. Both Moderna and J&J are doing the same thing but are a bit behind. So, what do we know about the J&J vaccine? Well, we don't have a peer reviewed publication yet, we only have a press release from the company showing that vaccine efficacy went up to 94% after a second dose. Globally, that same vaccine efficacy after a second dose was only 75%. Unclear why? The follow-up for that was only between one month and two months. So again, not a long amount of durability data. For Merck, it's interesting, that vaccine. I'm sorry, I was thinking about antivirals. For Moderna, that's interesting, both because the dose is almost a little more than three times higher, and there was a week longer between doses and probably some minor differences in the lipid nanoparticle. Efficacy for the Moderna vaccine has been and persists being higher than J&J or Pfizer. What will be the long-term meaning of that? Again, by definition, we don't know yet. What we can say is, there was just released this morning, a paper in JAMA looking at a Pfizer booster in those who had gotten the Moderna vaccine, and those who had gotten the Pfizer vaccine. If you look in people over the age of 50, who got a Moderna primary, a Pfizer boost, their antibody level was almost 72 in the way this was measured. If you look at people who got a Pfizer primary series, and a Pfizer boost, and again, were over the age of 50, their antibody level was still less than half that of Moderna, only 31. Now, what is the clinical meaning of that? It's hard to know, at this point, but and I've just given you a very quick run over the data, it's led to a lot of confusion.

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Dr. Halena Gazelka 11:05

Its very confusing.

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Dr. Gregory Poland 11:06

Yeah, I mean, more is not necessarily better. Might more mean efficacy for a longer period of time? Yes, maybe. But our way out of this, and as Dr. Walensky at the CDC said, and I agree with it, we cannot boost our way out of this pandemic. I mean, this is a chasing our tail kind of scenario, until we get the large proportion of Americans who are eligible for vaccines vaccinated. The biggest fear we have is that we're going to continue to generate variants,

mutants that will increasingly learn how to escape immunity. We've seen that with the Delta variant. We are concerned about the mu variant. There's another variant called the R1 variant that has kind of disappeared from the U.S, interestingly enough, but all of these are possibilities.

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Dr. Halena Gazelka 12:15

So Greg, one thing I wish you would clear up for me is I have difficulty with what is the difference between a third dose and a booster? Are you getting the same medication, the same vaccine? Or is the third dose different than what you get in a booster?

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Dr. Gregory Poland 12:31

No, they are identical. And again, that terminology I agree has led to some confusion. So, a late dose, a late third dose is a terminology restricted to those who are moderately to severely immunocompromised. They need a three dose, if you will, primary series, whereas you and I got a two-dose series. A booster dose is something that occurs after the primary series, it is a true boost. So, it may well turn out that the moderately to severely immunocompromised who got three doses will also have to get what in essence is a fourth dose, their booster, whereas you and I would get a third dose, one booster. And it's the same dose. It's the same vaccine.

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Dr. Halena Gazelka 13:29

Okay. Okay. Make sense? Greg, tell us about the latest and with kids and vaccines.

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Dr. Gregory Poland 13:36

Yeah, this is good news. And I'm pleased to share this. It turns out that the manufacturers have been able to enroll children faster than they thought and collect the data, even though they expanded the size of the study. So, there is thinking that prior to Halloween, we will see an EUA approval for children down to the age of five. So, five to 11-years-old, we already have the EUA for 12 and above. Now, it will be a dose of Pfizer vaccine that is 10 micrograms, rather than the 30 micrograms that many of us would have gotten. So, a third the dose. Now what they're working on is people six months to four-years-old who will get a 10th of the dose instead of 30 micrograms, they'll get three micrograms. And the studies show it's safe, it's effective. And those younger kids, no surprise, at those much lower doses, generate antibody responses equal to people in that 12 to 18-year-old age group. So, I think the good news is that we're going to see that become available. Now, here's my prediction. Okay, this is moving into prediction.

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Dr. Halena Gazelka 15:00

You heard it here first.

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Dr. Gregory Poland 15:01

Yeah, we're going to see, and we are already starting to see a trend I've been able to follow for over a week or two now, of declining, slowly declining cases. If people use masks and responsible distancing, if there's no new variant, I expect that trend to continue. What I'm afraid is going to happen is just like last year, we'll get to mid winter and

have another surge. But that decline is going to fool people into thinking there's no more risk that will be happening just as the vaccine for kids will be coming out and people say, well we don't need it, and that will fuel a midwinter surge.

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Dr. Halena Gazelka 15:56

Greg, continuing on the theme of kids and vaccines, we have had a number of listeners ask us the very same question. And that is this, they have understood that the Moderna vaccine might be more effective against some of the variants. And they're wondering even though Pfizer is likely to get an emergency use authorization for children the fastest, should they have their child get the Pfizer vaccine, or should they wait?

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Dr. Gregory Poland 16:24

You know, I'm going to continue what we said from the very beginning, the best vaccine to get is the vaccine available to you. And I say that particularly in the case of kids. Why are we even immunizing children is a valid question, because they tend not to die. Now there have been in fact over 500 deaths. They tend not to be hospitalized, though with Delta, we've seen over 20,000 hospitalizations, but at the population level for kids, that's still at least an uncommon event. So, we're trying to prevent that uncommon event. We're trying to prevent them from spreading it to other people and keep them in school and social activities. That's the reason, that conglomeration of reasons is why we would immunize kids. So, if I had a child that was, you know, five, eight-years-old, you know, whatever, as soon as that EUA was available, I would have them immunized with Pfizer vaccine rather than waiting an unknown amount of time until Moderna presented data to FDA and got an EUA. I might have a slightly different feeling if I had a highly immunocompromised child, or if it was an older adult. But for the younger children, we're not as worried about whether they're going to have severe disease or be hospitalized. We're trying to prevent them from having any disease, spread it, and we want to keep them in school.

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Dr. Halena Gazelka 18:07

Makes sense. Greg, there is ongoing research for an antiviral medication to help treat COVID. Do you think that sometime we're going to have a pill that people could take to treat COVID?

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Dr. Gregory Poland 18:23

I think the odds that we will have it are very, very high. Merck in particular is quite advanced in the development of an oral antiviral called molnupiravir, they always have these long names. Yes, Roche and Pfizer are also engaged in Phase 2-3 studies of an antiviral, and the thought is, much like we treat influenza with an oral medication, in fact, for influenza, that has advanced to the point where you take one pill once to treat influenza infection, that's an amazing feat of science. And I think we will begin to see that. And so, the landscape going forward with COVID, I would say is rosey if this large number of unvaccinated people will get on board. Otherwise, my concern is we will continue to see the development of new variants and mutants, some of which have already learned how to evade monoclonal antibodies. So, it's a serious issue, but if we can solve that issue, what I see is that we'll give a Coronavirus vaccine, let's say annually with the flu vaccine. If somebody didn't get it at breakthrough disease, whatever. I think we'll probably be treating it with an oral antiviral, and I think as time goes on, we're gonna see second and third generation Coronavirus vaccines in particular, the potential for an oral vaccine, take a pill for your vaccine or a nasal spray or a bandaid like patch to administer the vaccine. So, I'm very enthusiastic about that. I think the science is heading in that direction, and maybe that will prove to be more acceptable to people who are otherwise hesitant.



Dr. Halena Gazelka 20:35

Greg, I'm smiling because you used the word rosey, and I think that's the first time I've heard you say that in a very, very long time. So, I felt like we should just stop there while we were ahead.



Dr. Gregory Poland 20:49

Celebrate that word choice.



Dr. Halena Gazelka 20:51

That's right. Tell us, have you got anything else to share with us today?



Dr. Gregory Poland 20:54

I do. You know, we were talking about school. So, I thought I would do a little bit of show and tell.



Dr. Halena Gazelka 21:01

How wonderful, I love show and tell.



Dr. Gregory Poland 21:03

So, what works and what doesn't work? We're seeing all kinds of things. People using hydrogen peroxide, including young kids, nebulizing it, swallowing it, gargling it? No, no. We're seeing, people send me this stuff. We're seeing people taking high doses of vitamin D and a variety of other repurposed drugs. No. No data for that. Home remedies that people are using. This is cedar shavings in a bottle that you open and sniff and somehow it wards COVID away, no.



Dr. Halena Gazelka 21:47

That's for moths I think.



Dr. Gregory Poland 21:49

All kinds of pastes, including Ivermectin. No. So, what does work? Well, what does work is vaccines, we've clearly seen the data in multiple studies across multiple countries over time, and masks. So, the data are clear, if you want to prevent getting COVID, this is what we do. Once you get COVID, these other things that I've shown you are not treatments. They're magical thinking. They're not treatments. There are valid treatments for COVID, monoclonal antibodies, antivirals that are readily available. But as we always say in medicine, prevention is much easier than trying to cure. I would much rather have you suffer an hour or two of arm discomfort and maybe a headache and

low-grade fever for a couple of hours and be protected, than to see you every day in the hospital, struggling, whether you need to go on oxygen or not, treating you with a variety of medications, you losing school/work time, maybe suffering a complication, maybe having long COVID, when all of that is unnecessary.

D Dr. Halena Gazelka 23:15

Well, those are some true words of wisdom. Thank you, Greg.

D Dr. Gregory Poland 23:19

My pleasure.

D Dr. Halena Gazelka 23:20

I have never cease to be amazed by the willingness that some individuals have to use what they read about on the internet or about otherwise might be unproven or even unsafe.

D Dr. Gregory Poland 23:34

People are still, I mean, this started early on, people are still gargling and even swallowing bleach. I didn't have a bottle of that to show, please do not do that. Please don't do that. The irony that I face that keeps me up at night, because I get emails from people from all over the world. They will reject a vaccine that has been studied this intensely, and then begin to use treatments for which there are no scientific data. I mean, it boggles the mind to understand what tips you into an unregulated treatment where we have no safety or efficacy data. On the other hand, we have a vaccine with abundant efficacy and safety data, and one is hesitant or rejects it. It doesn't make any real sense.

D Dr. Halena Gazelka 24:33

Thanks for being here today. Greg. Those are some great words of wisdom.

D Dr. Gregory Poland 24:37

My pleasure.

D Dr. Halena Gazelka 24:39

Our thanks to infectious disease, virology and vaccine expert, Dr. Greg Poland, for being with us here again today to give us our COVID updates, and there were quite a few of them today. I hope that you learned something. I know that I did. We wish each of you a wonderful day.

N Narrator 24:57



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