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SPEAKERS

Dr. Halena Gazelka, Dr. Gregory Poland, Narrator

Narrator 00:00

Coming up on Mayo Clinic Q&A: This past Friday an FDA advisory panel rejected a proposal to give COVID-19 vaccine boosters to the general public.

Dr. Gregory Poland 00:11

Now I'm arguing caution before we proceed into boosters, and the reason for that is because we do our best to follow the science. There is no recommendation for a third dose for anybody other than those who are moderately or severely immunocompromised.

Narrator 00:31

With vaccine boosters on hold for the general public, are the current vaccines still viable and recommended to those who are unvaccinated?

Dr. Gregory Poland 00:38

At this point, what I see, my read of the data is that the vaccines, two dose mRNA vaccines in particular, maintain very high efficacy against death, hospitalization and severe disease.

Dr. Halena Gazelka 00:54

Welcome, everyone to Mayo Clinic Q&A. I'm Dr. Halena Gazelka. We're recording this podcast on Monday, September the 20th, 2021. Well, we are going to hop right to it today because we have more COVID updates for you, and I have Dr. Greg Poland with me again today. Dr. Poland is a virology, vaccine, and infectious disease expert at Mayo Clinic. Good morning, Greg

- Dr. Gregory Poland 01:19
 Good morning Halena.
- Dr. Halena Gazelka 01:20 Wonderful to see you today.
- Dr. Gregory Poland 01:22

 And you. I've recovered over the weekend after sitting all day long Friday for this FDA meeting.
- Dr. Halena Gazelka 01:29

 Well, how wonderful you are just the person to tell us then what is going on with boosters?
- Dr. Gregory Poland 01:34

Yeah, well, you know, the FDA heard information from a number of interesting people from CDC from some vaccine trial experts over in the UK, and then from Pfizer scientists themselves around this idea of should we give a universal immunization or booster immunization to everybody five months or more after, or sorry, six months or more after their series. And the vote was 16 No, 3 Yes. That was followed by a very impromptu vote. I'm actually a little surprised at this, a vote about whether a booster dose should be given at six months or more after the second dose in people 65 and older, and "those at high risk of severe disease" and that vote was unanimous Yes. Again, I'm very surprised at that. That was followed by an informal poll. They made it a point not to call it a vote, a poll, should health care providers be included as those at high risk of occupational exposure. That was unanimously voted Yes. So, what happens, and this is really important for our listeners, this recommendation is a recommendation to the FDA. The FDA will take this under advisement, and then this, is it Tuesday and Wednesday? No Wednesday and Thursday. This Wednesday and Thursday, there will be a two day meeting, any of our listeners can tune in and listen to it at the CDC through a committee called the ACIP, the Advisory Committee on Immunization Practices. And they will make an advisory decision that goes to CDC who makes the final decision. So, it's a bit of a complicated path. But I outline that because as you and I are aware, people are already going out and getting boosters and there is no recommendation for a third dose for anybody other than those who are moderately or severely immunocompromised.

Dr. Halena Gazelka 04:00

Well, that is interesting, and I appreciate that offer to listen in, Greg, but I think I'm going to leave that to you. And I bet many of our listeners will as well.

Dr. Gregory Poland 04:08
Thank you.

- Dr. Halena Gazelka 04:12
 All right.
- Dr. Gregory Poland 04:14

Maybe one of the things to emphasize, Halena because again, I know what happens, you and I talk about it, where listeners, patients, the lay public, they see a headline right of a third dose, and then they rush out and get it, which is kind of ironic, because after the very large well conducted studies, people weren't convinced that they should get the primary series we still have about 40% of adults who have not been immunized. But one of the things that was pointed out and it may seem odd that earlier in the year I'm arguing for the primary series. Now I'm arguing caution before we proceed into boosters. And the reason for that is because we do our best to follow the science, not what we want to have happen. And they had a couple of people from the UK, as I mentioned, who went very carefully through the studies that were presented to support the request of a third dose. And they pointed out that these studies had very small numbers of people, for people aged 65 and older, there were only 12 people included. So, small numbers, exploratory analyses, they used what we call non-validated assays, they had only very short-term follow-up, and it didn't reflect the U.S. population. So, when you're reading these headlines, you've got to be very careful, very discerning about what are the actual data that support or don't support a recommendation?

Dr. Halena Gazelka 05:59

So, Greg I'm kind of seeing two questions that could come up from our listeners here, because they're popping into my head. One is that there might be two issues. One might be that perhaps there isn't enough evidence yet for boosters. So, we may be needing more evidence. But the second is, is it dangerous to get them because there may be people who feel more comfortable getting a booster, the health care workers are going to get a booster, people over the age of 65 are going to get a booster?

Dr. Gregory Poland 06:28

Yeah. Excellent, excellent questions, and I have wrestled with this for several months and examined the data. I will say that data come in literally every couple of days. There were just three new studies published in the New England Journal, one of them quite large, the other two quite small. And so, what's happened is we've seen kind of a divergence in the data that honestly makes it hard to interpret. The data from Israel is very concerning, showing significant drops in efficacy of the vaccine. The data from Scotland, England, Canada, the UK, do not show data that concerning. And so, what I would say is, overall, at this point, subject to change because we keep seeing new data. At this point, what I see, my read of the data is that the vaccines, two dose mRNA vaccines in particular, maintain very high efficacy against death, hospitalization and severe disease. Where we do see a drop in efficacy is against mild, asymptomatic, and sometimes moderate infection. And so, do you embark on a massive public health immunization program to prevent infection? Maybe. We certainly can demonstrate with a third dose that you boost antibody levels very high. But what does that mean when we don't know what's the minimum level you need to protect? And the second question about safety is not well known. Do I think it's likely that there's going to be a problem? No, there's not been any real red flags or hint that way, but notice I'm being cautious in my language. It's not like we've got, you know, 40,000 people in a trial that have gotten a third dose across ages across medical conditions where we can look. As an example, let's just pick myocarditis in younger people. That's likely to be what we call an off-target inflammatory side-effect. Well, what does giving a third dose do in an age group like that? And the answer is, we don't know. We just don't know yet.

Dr. Halena Gazelka 06:50

So, in other words, could there be more of those complications that we've seen at an exceedingly low level with the first two vaccinations if people start getting more vaccinations?

Dr. Gregory Poland 09:08

Yeah, I think the answer to that has to remain potentially. And that's why we need carefully controlled studies to know those data as definitively as we can. I don't want to recommend anything to a patient that I think has more risk than benefit. And right now we're sort of in a situation of equipoise, where we really don't know, are we tipping over into needing boosters or is that going to cause more in the way of sideOeffects? And as I say, I think the answer to that question is not yet entirely clear. Different situation for immunocompromised people. I think that recommendation for 65 and older was probably a little too soon in my mind. And we'll see if CDC signs off on that. I think for much older, more frail people, it does make sense. But for the rest of us, I'm still a little bit cautious.

Dr. Halena Gazelka 10:13

So, Greg what's the latest on those who received an original Johnson & Johnson vaccine? They had one vaccine. What is the thinking on whether they should get another J&J vaccine or a follow-up mRNA vaccine?

Dr. Gregory Poland 10:29

Yeah. So, you know, I get this question a lot. And I understand it. People who have gotten one dose of a vaccine are concerned. The news makes them more concerned because honestly, the data suggests a a larger drop in efficacy over time. And in the face of Delta, we don't know if it's one or both of those variables that's causing a drop in efficacy. So, what to do? Well, the company themselves have announced that they've done a second study called Ensemble two. We have not yet seen those results peer reviewed and published. So, we don't know really what to say about it. Their press release suggests a dramatic increase in antibody level. But again, what does antibody level by itself meet? So, again we're in a situation where this this is real-time happening. And there has been no request by Johnson & Johnson to the FDA to allow a recommendation of a second dose, I think probably pending these data. So, right now, there is no recommendation and yet a growing concern, and that's a problem. We need data.

Dr. Halena Gazelka 11:50

But Greg, I would imagine that one of the most important things that not get lost in all this discussion of third doses and boosters is that we still have people in the United States who have not had their first vaccine, and they need to get vaccinated.

Dr. Gregory Poland 12:05

You know, this is so true Halena. I mentioned that to the press on Friday. You know, we're sort of spending a lot of time, and we need to, about kind of smallish affects, right, when we have a major segment of the U.S. population eligible for a vaccine with more in the way of safety data than we have for literally any other vaccine, who have to this point, decided not to get immunized. And I don't think they're going to unless they are in some way compelled by

their employer, or you know, whatever it might be. And that is a very dangerous, dangerous situation. You and I did a podcast that has probably been a couple of months ago, where we pointed out that we are in the most dangerous phase of the pandemic for those that have not been vaccinated. All it takes is even a cursory look at the news to see the number of people who have died or had serious illnesses and complications, who were not vaccinated, who then seek to tell everybody we were wrong, please go out and get vaccinated. And yet, people harden into a position, are not willing to see the data, or discuss the data and remain unvaccinated.

Dr. Halena Gazelka 13:32

Greg, something you said there was a great segue to my next question for you because I have found the news reports to be a little bit conflicting. I have seen news reports that the virus surge seems to be declining in some states, but also the death rates still remain fairly high. Where are we with the Delta variant surge? And how do you make sense of that?

Dr. Gregory Poland 13:51

Yeah, when you look in the US, in fact, I had recorded some numbers, where are they, here they are. Just glancing down here, new cases over the last 14 days have been estimated to drop by about 8%. And that's what we've seen with each surge, right? We see a surge, we see it drop, then we see a next surge and after each one, people have pretended or maybe it's emotionally want the pandemic to be over. They don't take precautions, then we have another surge and that has gone on through four cycles now. The death rate however, has increased while cases dropped 8% over the last 14 days, the death rate has increased. The number of death cases has increased 30% and that again is typical. There is a lag period between infections, then hospitalization, then ICU, then death. And it's easy to think, oh, cases are down 8%. I'm home free. That's not the case at all. The other thing is that, you know, we're not a homogeneous geographic location. That's overall. And yet we certainly have a tremendous hotspots and areas were super local, hyper local, super spreader events have occurred. So, that's again a need for data to know what's happening in your community.

Dr. Halena Gazelka 15:32

Greg, I have an interesting question from a listener that seems to fit right here. They had a question about if a fully vaccinated individual is exposed to the virus. Sometimes people who are fully vaccinated can even have the virus but be asymptomatic. Will they get a boost to their immunity just from the exposure?

Dr. Gregory Poland 15:54

In general, yes. If the reason that they got infected is that they are immunocompromised, and maybe severely so, outside of those kind of rare exceptions, but otherwise healthy people, even though they're vaccinated, if they get exposed, if they survive it, then they will have a boost in that immune response to the virus.

Dr. Halena Gazelka 16:20

And Greg, what's the latest on vaccines for those younger than 12?

Dr. Gregory Poland 16:26

Yeah, that date has kind of gotten pushed back. We had heard some information saying that by the end of September, now they're saying more like the end of October. That's still good news, because about six months ago, they were saying likely into 2022. So, I think we will see the data and likely a recommendation for those school aged kids in particular, yet I hope during this fall time period, which would be a great thing.

Dr. Halena Gazelka 16:57

That would be some exciting news, considering all those kids together in classrooms right now.

- Dr. Gregory Poland 17:03 Yes.
- Dr. Halena Gazelka 17:05

I have another listen listener question for you, Greg. This individual was wondering if you could talk about whether the symptoms when someone develops the Delta variant are different than from the original virus? And also, that got me to thinking about comparisons with flu, and you've talked about how RSV is kind of running rampant. How would, is there a difference really, in the symptoms?

Dr. Gregory Poland 17:36

Well, people make a lot of that, and that has not been my experience. So, you know, can there be subtle shifts, for example, with Delta variant, people have proposed that there's a little less in the way of sore throat and fever, a little more in the way of nasal drip, sinusitis, gastrointestinal side-effects. And while some of that may be true, I always liken it to, you know, like the overlapping Olympic rings. Only, there's a lot of overlap. And so, you really can't distinguish on the basis of symptoms. If somebody called me with symptoms that normally, I would say, well, it's just an upper respiratory infection. Now I'm telling them, they need to go in and get swabbed because it makes a difference for those around them, and for them. In regards to influenza, pertussis, para-influenza, RSV, COVID, and other upper respiratory and lower respiratory tract infections, they are impossible to tease apart. And so, the situation that we're going to be in this fall and winter, particularly with people not wearing masks is the amount of testing that we're going to have to do will significantly increase. Whereas we had been primarily testing for COVID in somebody who has symptoms that are compatible. Now we're going to have to look for a whole panel of respiratory viruses and possibly even bacteria in order to distinguish them. And we're starting to see with the onset of flu season, people co-infected. And that makes a difference because they may have a more severe course, if we knew you had influenza, we have a treatment for that. Depending on your particular clinical circumstance, if we knew you had COVID there's a treatment for that. If you're an infant with RSV, there's a treatment for that. So, we need to know and distinguish what are people infected and co-infected with in order to appropriately treat them.

Dr. Halena Gazelka 19:50

And are we starting to see flu and going to see more of it this year?

Dr. Gregory Poland 19:54

Yes, no question. We have started flu season in a few locations. As to how bad it will be this year, it is complete speculation. Many of us think that it likely will be a more severe year, simply because people are not taking precautions. They have emotionally decided that the pandemic is over, they have real misconceptions about the idea that well, I'm fully vaccinated, or I'm a healthy person, so I don't need to take precautions. And that's just not true. And unfortunately, we will likely pay the price for that, again, as a society.

Dr. Halena Gazelka 20:38

Anything else you'd like to share today, Greg.

Dr. Gregory Poland 20:41

Maybe just to push a little bit on the points that I just made. If you are fully vaccinated, the data are clear, where a mask. Masks, proper masks work. And you need to wear those indoors, even though you're fully vaccinated. If you're in a crowded situation, even though other people say they're fully vaccinated, they can be asymptomatically infected, pass it to you, and you might not have an asymptomatic infection. Similarly, with crowded outdoor situations, here's the most common question I get. I "had COVID" it may or may not have been documented, let's assume it was, and so I don't need to be concerned. Wrong. The data show that there is a breakthrough rate, which we know because we see it with seasonal Corona viruses. So, we do see breakthrough with vaccinees, with people who were previously infected, and that's why the recommendation to continue wearing a mask and responsible distancing. It doesn't mean you can't enjoy activities. It means doing so responsibly.

Dr. Halena Gazelka 21:57

I don't know if I've ever been called a vaccinee before.

Dr. Gregory Poland 22:02

You are so much more than that, Halena.

Dr. Halena Gazelka 22:05

Thank you, Greg. Leave it to a vaccine expert to know that I'm a vaccinee. Well, so good to discuss with you again today, Greg. Very informative. Thanks for being here.

Dr. Gregory Poland 22:17
Thank you.

Dr. Halena Gazelka 22:18

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

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Narrator 22:29

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