Coming up on Mayo Clinic Q&A,

The FDA did review the safety, the serious side-effects, the efficacy, and the conclusion was really clear that this is really worthwhile to really prevent the transmission of COVID in this age category and providing a safe vaccine, and a highly effective vaccine for this age group.

Kids between the ages of five and 11 could soon be getting their first dose of the Pfizer COVID vaccine. Under the emergency use authorization issued by the Food and Drug Administration, children will receive 1/3 of the adult dose with two injections given three weeks apart.

It’s important that we reach a very high level of vaccination rate to achieve kind of a wall of immunity that could prevent transmission and prevent us from dealing with these repeated peaks that we’ve been dealing with over the last year and a half during this pandemic.

Welcome everyone to Mayo Clinic Q&A. I’m Dr. Halena Gazelka. We’re recording this podcast on Monday, November the 1st, 2021. Can you believe that it’s November already? Across the US COVID-19 boosters are being administered to adults, and vaccines for kids could start later this week. Vaccinations for children ages five to 11 will be an exciting
step forward in the fight against COVID-19. With us to discuss the latest news on COVID-19 and vaccinations, we have a new face for our show today. Not new to Mayo Clinic though, Dr. Elie Berbari is the Division Chair of Infectious Disease. Welcome, Elie.

Dr. Elie Berbari 01:36
Thank you, Halena.

Dr. Halena Gazelka 01:38
Thanks for being here today. It is exciting to chat with you about vaccinations for kids.

Dr. Elie Berbari 01:44
Wonderful. Thank you.

Dr. Halena Gazelka 01:46
So, it’s the big news. We think that the COVID-19 vaccine might be authorized for kids ages five to 11. What should parents know as they’re considering whether or not to vaccinate their children?

Dr. Elie Berbari 01:58
Very good Halena, you’re absolutely right. The FDA did authorize the use of the vaccine, the Pfizer vaccine, for children who are between five and 11 years of age. This is welcome news and is going to give opportunities to almost 28 million children in this age category in the U.S. to get vaccinated. On the minds of many parents, is this safe? is this effective, and so forth. So, let’s start with the effectiveness piece. And this is really important as we’re trying to balance the safety versus the effectiveness of any vaccine. The vaccine is extremely effective, giving protection effectiveness around 90%. Very similar to the young adult age group.

Dr. Halena Gazelka 02:53
Is that two doses Elie?

Dr. Elie Berbari 02:55
That’s correct. So, two doses three weeks apart. It is to be noticed that the dose of the Pfizer vaccine is reduced for this age category. And that’s really keeping in mind, you know, the balance between the effectiveness and the safety. One major side-effect on many people’s mind is, is the vaccine safe. And the issue with safety is the myocarditis. That’s kind of a risk that has been rare, but highly publicized in the news, which is inflammation of the heart muscle. It does happen rarely, and it happens more in boys than girls. But it’s rare. It’s the magnitude of 20 or 30 cases or, you know, in that kind of category per a million administered patients. So, it’s extremely rare, but it does happen. When it does happen, it’s a temporary problem, it goes away. You know, for that the FDA is going to be monitoring
those cases. That’s one of the rationale for reducing the dose in the Pfizer vaccine. And you know, there are common side-effects, pain, and fever, and so forth, that tend to be, you know, short lived, and they go away after a few days like many other vaccines. So, the FDA did review the safety, the serious side-effects, the efficacy, and the conclusion was really clear that this is really worthwhile to really prevent the transmission of COVID in this age category and providing a safe vaccine and a highly effective vaccine to this age group.

**Dr. Halena Gazelka  04:46**

Elie, what would you say to parents who say, but I have heard that when children get COVID that it isn’t a very serious disease, sometimes they don’t even know they have it.

**Dr. Elie Berbari  04:56**

Yeah, that’s true for most kids, but not for all. You know, we have data to show the risks that could lead to hospitalization and occasional death in this age group. So, certainly still a risky proposition. Most kids do well, like most adults, but not all, and I think we’re trying to prevent that, and also we’re trying to prevent the chain of transmission. You know, it’s important that we reach a very high level of vaccination rate to achieve kind of a wall of immunity that could prevent transmission and prevent us from dealing with these repeated peaks that we’ve been dealing with over the last year and a half during this pandemic.

**Dr. Halena Gazelka  05:35**

Now on to boosters Elie. We have been talking about kids, but now let’s get back to adults. We keep hearing that they’re going to expand the indication to give boosters and one of the groups last week was those with mental or mood disorders. What does that include?

**Dr. Elie Berbari  05:57**

So, Halena you’re absolutely right. The CDC is really keen on fine tuning the list of indication for booster shots. And there’s a long list on the CDC website that includes, you know, cardiovascular diseases, immunocompromised conditions and so on. And the most recent addition is mood disorders. That’s mostly depression, some schizophrenia but some others. This is really stemming from a large meta-analysis that was performed that showed that patients with these health conditions are at higher risk for complications from COVID. Some with having immunocompromised conditions or under underlying cardiovascular conditions, and therefore would benefit more from a booster. And these conditions were included as of late on the CDC list.

**Dr. Halena Gazelka  06:55**

Okay. Anything further from the CDC on immunocompromised individuals?

**Dr. Elie Berbari  07:00**

I think this is an important topic and it keeps getting refined. One of the things that we have been doing, and we all know that immunocompromised patients do benefit from a booster. And you know, there’s a little bit of a distinction between a third dose and a fourth dose for this category of patients. You know, there’s support from the CDC saying
that an immunocompromised patient, especially in the kind of moderate or severe immunocompromised categories, they might benefit more from a third dose, that’s not a booster, just a third dose, in addition to the first two dosages. A booster is typically one that’s given six months later or more that can also boost that immunity and the level of neutralizing antibodies, and those patients would benefit from that booster. So, in total, some of those patients may get four dosages as opposed to two or three dosages in the rest of the population.

Dr. Halena Gazelka 08:00
Elie, I think there's still a lot of confusion in the public about why should we still mask and socially distance. Some stores require it. Some don't. Some buildings do, some don't. And what's the scoop on that?

Dr. Elie Berbari 08:15
Yeah, and you know, the public is right to be confused. And a lot of it is because of the understanding of the pandemic is evolving, and the knowledge is evolving. We've known all the way that any intervention alone is not enough to stop this pandemic, including the vaccination, our best strategy right now that we can deploy. Even if we rely solely on vaccination, we can't stop this pandemic totally. So, we have to rely on a multi-layered approach. And you know, if I put those kind of in the list, vaccine is certainly on top, masking would come second. So, we really need to rely on multi-layered strategies to prevent the spread and really get over these kind of, you know, surges that we're seeing over the last two years or so. So, masking does add to the vaccine because the vaccine is not 100% effective. And in high-risk situations, especially in an indoor environment and healthcare situation, school situation and so forth, the risk of transmission is higher despite a relatively high level of vaccination. And we need to add another intervention and masking is our next best thing.

Dr. Halena Gazelka 09:34
And Elie, is it true that those who have been vaccinated can still carry the virus even though they may not exhibit any signs or symptoms of it, but pass it to someone else?

Dr. Elie Berbari 09:45
Yeah, absolutely. And that's really something that we've seen more of with the Delta strain. That's called the breakthrough cases. So, a fully vaccinated individual could still acquire COVID and transmit it to others. What the vaccine does, it's to prevent those individuals from developing a more severe illness. So, now the vaccine is still effective at preventing an individual from getting COVID. But it's much more effective from preventing that individual if they were to get COVID from developing a more serious COVID, needing hospitalization or worse an intensive care unit stay. So, breakthrough cases do occur. And they do occur, you know, especially later on, month and month after the initial you know, vaccination series, and that's where boosters may come into play.

Dr. Halena Gazelka 10:43
Elie, I saw a really interesting article, it intrigued me at least, about using an antidepressant to treat COVID-19. Is that effective? And why? Why would it work?
Dr. Elie Berbari 10:55
Sure. It’s intriguing, and we’ve seen a number of drugs that we don’t associate, typically as being antiviral in this field. And Fluvoxamine is an anti-depressant used in obsessive compulsive disorder. There’s a study that you’re alluding to from Brazil that has compared patients who received the Fluvoxamine to not receiving it and show that there’s a reduction in the risk of progression to severe disease. And it’s a little bit unclear why that’s the case, but possibly related to some immunomodulation that may occur as a result of taking this antidepressant or antipsychotic. And I think, you know, I wouldn’t recommend that we use that as our primary agent, we have a lot more effective drugs that have been studied in larger studies. But it’s certainly intriguing, and it’s certainly something that would warrant further studies and analysis.

Dr. Halena Gazelka 12:04
Well, speaking of research, I know that you keep your finger on the pulse of COVID-19 research. What are you most excited about right now?

Dr. Elie Berbari 12:12
There’s a lot of excitement, Halena. If you look at the last year and a half, where we started, where we didn’t have anything in the management, and where we are today in not only in prevention, but vaccination which is really a remarkable, remarkable disruption to the COVID. But also, implementation of a number of drugs that didn’t exist before COVID, and now we know are very effective. Several of those drugs have been proven in large scale clinical trials and are very effective. Monoclonal antibodies in the way they work is an extremely effective intervention, either from preventing one from getting COVID if they were to be exposed or preventing the transition to severe COVID early in the treatment. And Mayo Clinic has had really great success in implementing, you know, administration of the monoclonal antibodies. There are a lot of newer drugs on the market. There’s an oral drug from Merck that’s extremely effective, and I think will be a game changer that’s easy to use in the outpatient and seems to be safe and highly effective. And if available on a large scale, I think can be also another agent that we can use. More and more studies combining these strategies and how to combine them and what we have been done at this moment. And I think this will add more clarity to the management of this disease. So, think about this, we started with a disease that’s potentially deadly in 3 to 4% of individuals, it would put 10 to 15% of individuals in the hospital requiring months or weeks of prolonged stay, and 30 to 40% of individuals with long COVID. You know, this is really how we started, mortality has decreased, we’re preventing more than ever people from getting admitted, and even better than that, preventing them from getting COVID, and if they do get COVID, preventing them from going to the hospital. And we transformed a relatively deadly disease to a disease that can be managed where we have strategies and effective strategies of prevention as well as effective treatment. And that’s really remarkable. And if you think about how we deployed that, why can’t we deploy that for other serious infection or other serious illnesses such as cancer and others and really disrupt research and how we do research in these conditions. So, this is exciting. It’s a roadmap of how we can accelerate the discovery and even better than that, the implementation of discovery. And understanding that there’s hesitancy in many of those interventions too and how we deal with it.

Dr. Halena Gazelka 14:58
It really is amazing, Elie. Sorry, I didn’t mean to interrupt you. I was just excited. I think that what we have seen with COVID is akin to decades that it has taken to make progress in other disease states.

Dr. Elie Berbari 15:12
You're absolutely right, Halena. What we used to do in years or decades, we're now doing in weeks and months. And the vaccine story is a remarkable story. It typically takes 10 or 15 years, from the conception to the implementation, it took us few months. And that's just a remarkable discovery, not only discovering the vaccine, but administering the vaccine. I mean, if you think about the scale of administration, which is akin to the delivery of care, right? It doesn't help if you have the best management and we can't deliver it, or the best prevention strategy, and we can't deliver it. So, the execution of the delivery is so important in the space. And we learned as a nation, as a world how to do that. We're still learning. We're still not there yet where we want to be. There's still a lot of barriers and hesitancy. But I think we're learning as we go on how to do that, and how to implement a disruptive intervention, and implement that intervention in real life. And that's remarkable. And again, those learning is going to allow our society, our healthcare institutions to translate that into other fields in the future.

Dr. Halena Gazelka  

16:24

Well, Elie, we always have questions from our savvy listeners that we like to get to. So, the first one is, if an individual has had COVID-19, is the immunity that they gain from actually having the infection different from what they would get from a vaccination?

Dr. Elie Berbari  

16:43

You know, that's been a hot topic, Halena for quite some time. And, you know, there's been quite a bit of studies. And, you know, one of the things about COVID is, you know, our knowledge is evolving, right? What we knew a month or two or three ago is changing today. And so, there was a little bit of discrepancy and contradictory data. Is immunity from natural infection better than, say, the immunity from the vaccine or vice versa. What we knew is that having both is better than either that kind of we knew. There are large studies that supported this. There's a CDC study that was recently published that looked at trying to answer what you just said is, what's better? Is it the vaccine or the natural immunity? And from that CDC study, it seems like the immunity from the vaccine is superior at preventing COVID. And they did a large study and looked at the risk, and it's about five-fold more protective. So, in essence, a vaccine affords five, you know, times more protection against having COVID than a natural infection. Natural infection does afford immunity and protection, but not as good as the vaccine. So, we still recommend that folks who have gone through a natural infection, you know, after they symptom free to get the vaccine. And I think that really affords the best scenario for those individuals.

Dr. Halena Gazelka  

18:18

The next question is from our Mayo Clinic Connect Transplant Group. They have heard an expert physician on national news discuss that those who have are immune compromised, such as have had transplants may not gain antibodies or develop antibodies after having the vaccine. So, perhaps they should be treated with monoclonal antibodies prophylactically or preventatively. What does Mayo Clinic say about this?

Dr. Elie Berbari  

18:44

Yeah, you know, we do know that individuals who are immunocompromised, and certainly transplant patients are in that category, are at higher risk. And if they do get COVID are at higher risk for severe disease. So, that's the reason why a third dose is recommended for those individuals from a vaccine standpoint. So, if those individuals have received the initial series of two shots of the Moderna or the Pfizer vaccine, they are to get a third dose, and eventually a booster. So, in total they would get four dosages to compensate for the fact that their immune response
to the vaccine is not as robust as if they were not immunocompromised. Monoclonal antibodies are an interesting adjuvant, and let’s say an individual who has received a series of two shots are exposed to somebody who has COVID, they may be considered for monoclonal antibodies because of the fact that they may not have received or may not have developed antibodies from the vaccine itself. So, they will be considered like they have not received a full vaccination and therefore would be eligible potentially for monoclonal antibodies. Those discussions are done on one-on-one cases and not any kind of an open fashion that everybody would fit in that category. It depends on the level of immunosuppression, where they are at in their transplant journey. Are there other mitigating agents or drugs that they are taking that could make them more immunocompromised than they otherwise would be, and therefore might be considered for a shot of monoclonal antibody in case they’re exposed to somebody, and that exposure is deemed high risk.

Dr. Halena Gazelka 20:29
Okay, on another topic Elie, flu shots. It seems that we are lagging in giving flu shots this year. Not as many people have had them at this point. Why is it still important to get the flu shot?

Dr. Elie Berbari 20:42
Well, I mean, the last thing we want as a twin-demic is an ongoing COVID pandemic and another influenza on top of that. So, I think it’s important that we get both the COVID vaccine and the influenza vaccine. We are watching what’s happening on the southern hemisphere as a prelude to what might happen in the northern hemisphere. Halena, last year we didn’t see much of influenza cases across the globe, it’s really, there were few 100 cases, which is remarkable. This has never happened, you know, in modern history. And so, I think we’re watching what’s happening, what we’re seeing is that there are more influenza cases in the southern hemisphere than there were last year. And we are seeing a bit more cases in the U.S. already. Still very early to tell. It may end up that this is going to be another mild, you know, season for the flu. But it’s important that we get the influenza shots because influenza is still serious, and influenza could still lead to hospitalization. And many of the conditions that could make COVID more serious would make influenza more serious. So, really very important to get both the COVID series as well as the influenza shots.

Dr. Halena Gazelka 22:06
Great information. Thanks Elie. Any last words to share today?

Dr. Elie Berbari 22:12
No, I just want to kind of re-emphasize the fact that no drugs, and no vaccine is effective without being utilized. And that’s intuitive to think but it’s very challenging to implement large scale drug administration or large scale, you know, vaccination across the world. There are logistical challenges, there are financial, socioeconomic challenges, and we’re witnessing that unfold in the U.S. And I think unless we really can understand those challenges and find solutions for those we will not be able to really get on top of this pandemic. You know, this is a virus that can mutate, that can transform, that can kind of reinvent itself. And we have to really continue to be vigilant and implement the tools that we’ve created and the science we’ve created effectively, so we can really put this at bay where we could control it to a point where we can go back completely to a normal life, semi-normal life.
Dr. Halena Gazelka  23:11
Words of wisdom, and we all want that. Thank you, Elie.

Dr. Elie Berbari  23:14
Thanks for having me take care.

Dr. Halena Gazelka  23:16
Our thanks to doctor, Dr. Elie Berbari, Division Chair of Infectious Disease at Mayo Clinic for being here today to give us our COVID updates. I hope that you learned something. I know that I have. We wish each of you a wonderful day.

Narrator  23:30
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