

Paul Offit, MD, on parent concerns for vaccinating 12-15 year-olds

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Featured topic and speakers

In today's COVID-19 Update, noted children's vaccine expert Paul Offit, MD, discusses the recent authorization of the Pfizer vaccine for 12 to 15-year-olds and shares advice for physicians on addressing parent's concerns about vaccinating this age group.

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Speaker

- Paul Offit, MD, director, Vaccine Education Center, Children's Hospital of Philadelphia

Transcript

Unger: Hello, this is the American Medical Association's COVID-19 Update. Today, we're discussing the recent authorization of the Pfizer vaccine for 12 to 15-year-olds with Dr. Paul. Offit, the director of the Vaccine Education Center and an attending physician in the Division of Infectious Diseases at Children's Hospital of Philadelphia. I'm Todd Unger, AMA's chief experience officer in Chicago.

Thanks again for joining us today, Dr. Offit. Good news about the Pfizer vaccine, which was recently authorized for 12 to 15-year-olds. Looking at the data provided, what do we know about the effectiveness of the vaccine in this group?

Dr. Offit: There was a study of 2,300 children between 12 and 15 years of age. Those children were divided into two groups, half received vaccine, half received placebo. The half to receive vaccine, got it at the same dose as the 16 to 17 and 18-year-old in the previous trial, which is to say 30

micrograms per dose divided by three weeks. They then followed those children for several months and over that period of time, they were 18 cases of COVID, all in the placebo group. The vaccine induced high titers of virus-specific neutralizing antibodies. The vaccine was safe. So I think this answers the question, "Did this vaccine work and was it safe in the 12 to 15-year-old?" So hence, the Pfizer then submitted an application to extend their use through Emergency Use Authorization down to 12 years of age, which the FDA approved. And then just a couple of days ago, the CDC also agreed to recommend this vaccine for 12 to 15-year-olds.

Unger: You mentioned the dosage in there. Is that different than what adults get?

Dr. Offit: No. It's the exact same dose. I mean, because that's why this was, I think, so much more easily and quickly done, was you had a lot of data on the 16 and 17-year-old. More than a million 16 to 17-year-olds have already received this vaccine. So it was easy to just extrapolate to this to use the same dose. It may be a little more difficult as we get to much younger children, but at least for the 12 to 15-year-old, these were relatively easy studies to do.

Unger: Did you see any difference in the data in terms of side effects? Or are they pretty much the same as what you see in the adult population?

Dr. Offit: Yeah, I've just seen what everybody else has seen, which is comp line data. These data were not submitted for approval through the FDA's Vaccine Advisory Committee. The FDA decided that they didn't need to go to that committee to ask for advice. So I haven't seen that as either a published study or as data that were submitted to the FDA. We, the FDA Vaccine Advisory Committee, haven't seen that. So I don't know the answer to that question. I would suspect that the side effect profile would at least be similar to the 16, 17, 18-year-old because it's really, biologically, a virtually identical population.

Unger: Okay. It's been a good news this week. We had announcement from the CDC about, for those who were vaccinating not needing to wear masks necessarily. And at the same time, we're running into a population here that somewhat more hesitant at getting the vaccine. How does enrolling, let's say this 12 to 15-year-old group, helped with our overall vaccine efforts and kind of keep the positive trend rolling?

Dr. Offit: Right. I would think this would be a welcome relief for parents of now children who are over 12 years of age. I mean, that finally, they get a Get out of Jail Free card. I mean, these children have been basically imprisoned either because they don't get to go to school. They don't get to participate in activities, group activities like sports or other activities. They don't get to spend as much time with their friends. This then allows them to do that. I mean, while I understand that I think parents should be skeptical of anything they put into either their or their children's bodies, at this point, you have enough information to clearly say that this vaccine is safe and effective, and to immunize the 12 to 15-year-old. I mean, and now they can go back to school without worrying about it. I think we'll see how this plays out.

Unger: I mean, those are huge benefits. We know that psychologically being captive in a house and not being in school, not seeing your friends, not being able to play sports has had a tremendous impact on young people. But there's still parents out there that don't feel like there's a need to vaccinate children in this group because they feel like the incidence or the complications of COVID-19 in this age group are relatively low. How do you respond to that?

Dr. Offit: Well, first of all, when the virus first came into this country and started killing people in March of 2020, about 3% of those cases were in children. Now, today it's about 24%. So children represent a significant percentage of current cases, number one. Number two, it's estimated that at least 3.8 million children have been tested and found to be infected. I think you can assume that that number therefore is much higher than that. We know that at least 300 children have died from this infection. And we know that this so-called multi-system inflammatory disease is also a phenomenon, which has clearly occurs, albeit not commonly, but clearly occurs in children who usually have mild or fairly asymptomatic infections. So, it is a disease of children.

I mean, if you look at the number of children who've died of this virus over the past year, roughly 300 plus, some estimates are as high as 500, that compares as to the same, or if not greater, as cases that's caused by influenza or chicken pox or measles, for which we also have vaccines for children. There's every reason to vaccinate your child to protect against disease.

If I were to convince a parent, the thing that's most compelling to me have been these children with multi-system inflammatory disease. I mean, they have a very similar story. Usually, it's the 6 to 14-year-old child. Usually they have an asymptomatic infection that just happened to be picked up because a friend was infected or a family member was infected. Then they come back a month later, they're not PCR positive anymore. They have antibodies in their circulation and they have evidence of damage to heart, liver, kidney. And although most obviously recover, I fully believed that like the disease, Kawasaki's disease, which is another multi-system inflammatory disease of children, there may be some children who suffer longer-term consequences.

This is not a virus to be fooled around with. I mean, when this virus left China, it was built as a winter respiratory virus like pneumonia, which could cause severe and occasionally fatal lung infections. It is

far more than that. This virus can cause vasculitis. This virus can cause you to make an immune response against the endothelial cells that line your blood vessels. And because every organ system in your body has a blood supply, every organ system is at risk. That's why you really need to vaccinate children.

Unger: Dr. Offit, I wanted to just clarify something you said earlier that's interesting. It's really about kind of a comparable, like parents are sometimes maybe comparing this just to adult versions of COVID versus the range of other kinds of vaccine preventable diseases that are measles, influenza, things like that. Is that something that needs to be clarified with parents?

Dr. Offit: No, I think it's a good point so people can understand relative risk a little better. I mean, I think people are scared of meningococcus, scared of meningococcal meningitis because it can overwhelm you. You can be fine one minute and dead four hours later. And so, people want to get meningococcal vaccine. Meningococcal has probably affects fewer than 300 people a year in the United States. I mean, here's a virus that is still spreading wildly in this country, that still is causing tens of thousands of cases a day. And those are just people who've been tested and found to be infected, that it's still causing hundreds of people to die every day. I mean, that is still a far more of a challenge for children than the viruses that we typically deal with like influenza or measles or a pneumococcus or haemophilus influenza type B, for which people are much more willing to get a vaccine.

While I understand that this is a new virus, while I understand that this is a novel technology, we've never used messenger RNA vaccines commercially before ever, so I get that, but we now have a lot of information about this. The guy who is the father of modern vaccines to me, Maurice Hilleman, who did the primary research or development on nine of the 14 vaccines that we give to children said it best. He said, "I never breathe a sigh of relief until the first 3 million doses are out there." Okay. Well, 200 million doses are out there through these mRNA vaccines and it don't even appear to cause a rare, serious side effect. I mean, already more than a million teenagers have been immunized because the Pfizer vaccine was approved down to 16 years of age. So, we're jumping with a net here. This vaccine is the Get out of Jail Free card for children.

Unger: I like that it just ... This isn't something to fool around with, and yet, we see a lot of misinformation out there that kind of clouds judgment. What are kinds of things that you're coming across in your own practice in terms of that kind of misinformation stream that you'd like to correct here?

Dr. Offit: Well, I would say having written about the anti-vaccine movement for the last 20 years, that nothing they would ever do would surprise me. I was wrong. They can still surprise me here in the midst of the pandemic that has brought us to our knees, that has caused mess of joblessness and homelessness and food insecurity, and depression and other psychological issues and an increase in child abuse and domestic violence, which has caused us to economically just stop doing everything

we were doing. And within a year, you have a vaccine that is remarkably safe and remarkably effective. Still, they find a way to try and tarnish that vaccine with bad information.

I think the big ones I get are, one, that the vaccine can affect fertility, which it can't. Two, that it will somehow alter your DNA, which it can't. Or three, that it itself can cause SARS-CoV-2, which obviously it can't. Or then, my favorite is that when you get this vaccine, that would cause you to somehow cause other people to get SARS-CoV-2. I mean, they continue to make it up with outlandish claims. And so, we just keep playing whack-a-mole with each of these claims.

Unger: That's absolutely right. We're finding out at the point we're at right now where we need to really enroll kind of local pediatricians and family medicine physicians because they are trusted sources for folks. Can you speak to the importance of state health departments getting the vaccine supply to these offices? And how do we do a better job in getting vaccines to smaller practices?

Dr. Offit: Yeah, I think that some of these vaccines can be a challenge in that manner. The good news is Pfizer is working on a new formulation, but the current Pfizer formulation, which is now at this moment, which is May 14, 2021, that is approved down to 12 years of age. But that vaccine has to be shipped and stored at negative 60 to negative 80 degrees-centigrade, which means dry ice. It means you have to store it in dry ice. It means you have to constantly maintain it on dry ice. Once thought it has a five day life in the refrigerator and it comes into multidose vial. And once that vial is entered, you have to give those five doses within six hours because the vaccine doesn't contain a preservative. So that's not easy for a pediatrician's office. And also, there's a minimum order, which I think would also be challenging for the pediatrician's office.

I think with the formulations get a little easier to use, the Moderna vaccine is somewhat easier. It can be shift and stored at a freezer temperature. Once thawed, it has a one month life in the refrigerator, but it too has to be given within six hours of first of violating that rubber stopper.

Unger: Yeah. Those are some big challenges and hopefully we will be able to overcome them. We're just winding down the school year now. What are we looking at in terms of summer activities like camp and school in the fall?

Dr. Offit: Right. Well, the good news is for children down to 12 years of age, they can get vaccinated and be protected. I think that if people are now going to be congregating outside, a fewer than 1% of the disease is occurring outside. This is generally a winter virus. I mean, it's not spread as well during hot and humid months. It's much spread much easier in cooler and less humid months, so you have that working for you. When you're indoors, however, with a lot of people, the CDC has recently said that if you're vaccinated, you don't have to wear a mask. I think that's an important first step, but I would offer this caveat. I think that for myself, for example, I vaccinated. Not surprisingly, I'm fully vaccinated. And so, when we invite people over the house who were vaccinated, I have no problem not wearing a mask. When I'm in my office and the residents and interns and medical students were in my office and they're all vaccinated, I have no problem not wearing a mask.

But if I walk into a grocery store and I see people who are masked and unmasked, I'm going to have to assume that all those people who were unmasked are vaccinated, which I think is a big assumption because I'm sure there are many people out there who work on a lot of denialism, who are not masking and not vaccinating. And I think that if you come in contact with them in an indoor setting, there is some risk even if you're vaccinated. So I still wear a mask in those situations.

I think in terms of kids, you know, going out to, let's say to come work in summer camps for whatever that summer camp is whether it's a sport camp or other activity camp, if they're going to be large numbers indoors, I think that for those children who are vaccinated, they don't have to wear a mask, but for children who aren't vaccinated, which is pretty much going to be everybody under 12 years of age, I think they should still wear a mask.

Unger: Yeah. I'm excited to be vaccinated fully. I don't think I'd sleep in a cabin with 10 other people. That would scare me. So I can understand. I think that's good advice. Well the last question for you, the CDC has also updated its guidance last week to say that it's now fine to give more than one vaccine at a time as the COVID shot. And I know that's been an obstacle and concern for some folks. Can you tell us more about what it would mean for this age group?

Dr. Offit: Right. Let me take a step back for a second. When a vaccine is licensed, typically, it will not be licensed unless you do something called concomitant use studies, which means you have to prove before you can get that vaccine off to the schedule, that your vaccine doesn't interfere with the safety profile or the immunogenicity profile with vaccines that can be given at the same time. And vice versa, that those vaccines don't interfere with the safety profile or immunogenicity profile of your vaccine. That hasn't been done for these vaccines.

I think the CDC and the American Academy of Pediatrics have been weighing sort of two things. On the one hand, we have an under vaccinated childhood population. The immunization rates against measles, against polio and other vaccines has dropped dramatically in this pandemic. So they're thinking, "While you have the child, let's give them all the vaccines from which they could benefit," knowing that we don't have these concomitant use studies and knowing that when you give more than

one vaccine at once, when there are side effects that occur after many vaccines like headache or fatigue or fever or muscle ache or joint pain, then it's hard to know which vaccine is doing that. Because the benefits of getting children vaccinated, while you can, outweigh the theoretical risk that there may be interactions that you haven't defined.

On the other hand, there are a number of pediatricians who have called me in the last 24 hours, or emailed me saying, "I trust my population. I know that they're going to come back so I want to give this vaccine two weeks before or two weeks after they're getting their other vaccines. Is that okay?" And the answer is yes, that's okay. And so that's the competing interests now. On the one hand, you don't have data looking at concomitant use. On the other hand, you know that there are children who are massively under vaccinated and you want to vaccinate them as much as you can, and that if you only give them one vaccine and then wait two weeks, then you're going to lose them. So it's been a difficult road to hoe, I think, for the CDC and AAP in to figuring how best to navigate that.

Unger: Well, thank you so much Dr. Offit for your perspective. It's great to have you again on the COVID-19 Update. That's it for today's segment. We'll be back soon with another. In the meantime, for more information on COVID-19, visit ama-assn.org/COVID-19. Thanks for joining us today. Please take care.

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