

## Paul Offit, MD, talks about vaccine authorization for kids

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### Featured topic and speakers

In today's COVID-19 Update, a discussion with Paul Offit, MD, the director of the Vaccine Education Center and an attending physician in the Division of Infectious Diseases at Children's Hospital of Philadelphia, about the importance of getting vaccinated and what physicians need to know about COVID-19 and kids.

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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 vaccines and other pediatric issues 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 so much for joining us today, Dr. Offit. I'm seeing you all over the place in the news and in the press and so thanks for making time for us. We received some good news with full approval of the Pfizer vaccine for those 16 and older but there are a lot of questions about children, namely the timeline for vaccine authorization for kids under 12. Can you offer any insight there, both for the five to 11-year-old set and for children under five?

**Dr. Offit:** Well, my understanding is that the companies have not yet submitted data to the FDA for review for these five to 12-year-olds. Hopefully that will happen soon, my sense is we may not have a vaccine until winter for children, which is too bad because what's about to happen is that you're about to have a group of fully susceptible people all in one place with a highly contagious virus, transmissible

virus, like the Delta virus. And in some communities where disease rates are high, I really do worry that that's a recipe for a problem as we come into the school year. Plus, as we move to winter, this is a winter virus, it's spread much more easily in cooler, dryer climates. So that's not a good confluence of events.

**Unger:** I know it's on the minds of a lot of parents as their kids head back to school. How is the vaccine authorization different for younger children and why does it feel like the timeline is so much longer? Are there additional considerations, especially when we're dealing with a relatively new platform, like the mRNA vaccine?

**Dr. Offit:** Right, so I think it was fairly easy to extend that out to the 12-year-old because you had a lot of data on the 16- to 17- year-old, not a huge difference between that and the 12- to 15-year-old. So it was the same dose, in the case of the Pfizer vaccine, 30 micrograms, it was same dosing interval, which is three weeks. So you could do a 2,300 child study fairly quickly and get information. And in that case, you knew that there were 18 cases of COVID in the placebo group and none in the vaccine group—the vaccine worked, it was safe, it was highly immunogenic.

When you start to get down to children five years of age, you need to dose ranging studies, so-called phase one studies. Is it a 30 microgram dose or is it a 10 microgram dose, 20 microgram dose? Is it a 30 microgram dose, is it the same dosing interval? So you have to do those studies to look at the immune response with different dosing to see whether you have the right dose. Then you move to phase two studies where now you have the dose, you have the dosing interval, you do more children—say a few hundred children—and then you go to the phase three studies. And you're giving the vaccine probably to what will be 4,000 children, 10,000, 7,000 children. But you want to make sure it's safe because you're about give it to millions of children. So I know it's really frustrating, I'm frustrated, you'd like to have a vaccine as soon as possible but, most importantly, you want to make sure that it's safe before you put it out there into the arms of millions of children.

**Unger:** Absolutely. And we know that the FDA recently asked Pfizer and Moderna to expand their clinical trials for kids. Is there anything beyond what you just laid out in terms of backgrounds about why that's needed?

**Dr. Offit:** So they're looking at what's going on in those trials. So they know more than I know about those trials. Obviously, they saw something that made them want to do more children. I think that in terms of safety issues, historically, there has never been a serious adverse event from a vaccine that occurred more than six weeks after a dose. So extending the vaccine safety until two months afterwards makes sense. Whether they want to extend it further, that wouldn't make as much sense but I'm not sure that's what's going on. I think the issue is just what you described, which is they just want more children, and they may want more children because they don't have enough children, say, in the placebo group who've gotten ill that have made it clear whether or not this is effective or not.

**Unger:** Can you just repeat something you just said, which is about, are there any examples that occurred outside that six-week window? I just want to emphasize that.

**Dr. Offit:** Any medical product that has a positive effect will have a negative effect. That's always true. I think that if something doesn't have any negative effects, it probably never had a positive effect, sort of the way dietary supplements are often sold. So I think that what happens, if you look historically at serious adverse events like polio, which was a consequence of the oral polio vaccine—it was very rare, one per 2.4 million doses, but it was a real phenomenon. It happened within a month of a dose. If you look at thrombocytopenia, which is a lowering of the platelet count that was associated with measles vaccine that occurred in roughly one per 25,000 to 30,000 children. It was rare but it too was real. If you look at Guillain-Barré syndrome, which is a consequence of the influenza vaccine, that too occurred usually within a month of getting the dose. Or narcolepsy, which was a permanent disorder of wakefulness, it was associated with the squalene adjuvanted flu vaccine given in Europe, also all occur within a month of the dose.

So the point being that vaccines can cause serious adverse events but when they occur, they occur usually within six weeks of a dose. So you don't really need to extend the safety time. People will often say that, they'll say, "The vaccine hasn't been out there for 10 years or 20 years, for 30 years," but I know of no example, at least with vaccines, where that's become an issue where a serious side effect was noted much later. Sometimes it's noted only after the vaccine is out there in the real world because it's a very, very rare phenomenon, say clotting associated with J&J's vaccine, which would occur in say one per 500,000 people, you're not going to find that out preapproval. You're only going to find that out if it's into the general population but it's not because it took longer for that side effect to occur. It's just because you needed to vaccinate more people to see that it had occurred.

**Unger:** Yeah, that is one of the reasons, you mentioned, that concern that you hear out there about the longer-term impact. And so it's so important how you clarified that. On the topic of misinformation that's been circulating about the vaccines, there are a lot of parents obviously who were eager to get the vaccine themselves, and for whatever reason, some are less willing to get it for their children. I'm sure you hear a lot of the misconceptions about vaccinating kids. Can you talk about some of those top ones and how you address them?

**Dr. Offit:** Well, I think people are generally always sort of hesitant to vaccinate their children. I mean, they reasonably put safety first and it's a little scary, right? You're taking a needle and syringe, you're injecting into the muscle a biological agent, which generally most people don't understand particularly well. So it's easy to see how they would be somewhat scared. And you see it now. I mean, we've had a vaccine now for many weeks for the 12- to 17-year-old, yet only about 30% are vaccinated. I was just on service last week and we had a number of kids in the hospital who were adolescents that could have been vaccinated that weren't. What was even more concerning or which was equally concerning was we had a number of children in the hospital who were less than 12, who couldn't be vaccinated

and their parents also weren't vaccinated, which just also put those children at risk.

So it is hard. I mean, vaccines won't work as a concept, you actually have to give them to people in order to get them to work. So that is frustrating. But the kinds of things that you hear are, "I don't want to get the vaccine because it's not fully licensed yet." Well, now it's fully licensed, so that's off the table. Or people say, "I don't want to get this genetic vaccine because it's going to alter my DNA or it's going to affect my fertility or it's going to make me magnetic." I mean, you hear all these sort of things and none of them are true but I think the reason that people attach themselves to those kinds of misperceptions is because they're scared and they really don't want to get the vaccine, and they're looking for reasons not to get it, and the internet is able to provide those reasons. I mean, really, there is no good reason not to get a vaccine, just a lot of bad reasons.

**Unger:** We're going to return to that topic of protecting kids in a minute. But I think clearly the Delta variant has kind of changed the calculation here. Any additional science that you're seeing about the variant's impact on children? Is this just more transmissible or are you seeing more serious disease?

**Dr. Offit:** So it's clearly more transmissible. That's not an issue. The Delta variant is more transmissible than the previous variant, which was the Alpha variant, which was more transmissible than the variant before that, which was the so-called D614G variant. So that's three variants in a period of a year and a half. Do I think that there's going to be more variants in our future? No doubt about it. So we need to stop this pandemic as quickly as we can. When I think in terms of children, certainly I've seen anywhere from 14% to 18% of all cases now are in children because we vaccinated the older population or the older population has got infected already or those who were going to die have already died from that infection.

So we're seeing more disease in children, certainly. And the numbers I've seen most recently is that 2% of those children, meaning less than 18 years of age, who are infected, are hospitalized. That is higher than the previous rate, which was closer to 0.5%. So it may well be more virulent, meaning more likely to cause serious disease. The CDC did present at the last ACIP meeting, Advisory Committee for Immunization Practices meeting, three studies that also claimed that this virus was more virulent in addition to being more transmissible.

**Unger:** That is scary. And in addition to what you're talking about, there is also the concern, which I think some people don't factor in here, about long COVID. We've seen studies in prior segments that we've done here on the COVID-19 Update which say a very significant amount of people, almost one in five, that had even moderate symptoms are experiencing some kind of long term effect. What are you seeing in children? Is that a concern there as well?

**Dr. Offit:** It's pretty frightening. I mean, children have usually an asymptomatic infection, they just happen to be picked up serendipitously as having a shedding virus because they were exposed to someone, a friend or family member. And then a month goes by, they're no longer shedding virus

anymore, they have antibodies in their bloodstream, and they come in with high fever, evidence of lung disease, heart disease, liver disease, kidney disease, a subset of these children go on to become sort of long haulers. You really can tell when you walk into the room, they have this sort of brain fog that is unique. This is a scary virus.

And in addition, about 400 children plus have died from this virus already. So we clearly need a vaccine for children and what worries me is when we get a vaccine—we will get a vaccine, hopefully by no later than the beginning of next year—that people won't give it, for the same reason they're not giving vaccines to the older child. I just worry about this. We're not going to get on top of this pandemic until we vaccinate this population and children less than 18 represent about 20% of the population.

**Unger:** We talked about return to school and the risks associated with that for unvaccinated kids. There's a lot of controversy around that, obviously you're paying attention. I saw a sign in someone's yard that said, "Follow the science, unmask the kids." I mean, it's just pretty discouraging when you see stuff like that. When you are advising parents and talking with them about concerns about returning to school, what are you saying in terms of risk and benefits? How are you addressing protocols around masking and things like that?

**Dr. Offit:** Well, in a better world, a world in which we don't currently live, what you would see is that every child would wear a mask because that's their only mechanism of protection right now for the less than 12-year-old child, they can't get a vaccine. So their only mechanism for protection is to wear a mask. Masks do work. It is a respiratory disease that is spread by small droplets that emanate from the nose and throat. And therefore, if you're wearing a mask, it lessens the capacity of those small droplets to leave. This isn't rocket science, you don't have to be like a particle physicist to understand this. I mean, it's small droplets that can't get through. And you want all the teachers to be vaccinated because, again, they should be. There's no good reason not to be. So in a better world, all the teachers would be vaccinated, all the children would be masked.

But what do you do when that's not true? I mean, I got a call from a woman in Florida the other day who said, "I'm nervous, my child is," whatever, nine years of age, "he's going to be going to school where they're not allowing a mask mandate, where a number of teachers aren't going to be vaccinated. What can I do?" And I don't know the answer to that. I mean, all you can do is put a mask on your child, ask your child to do their best to physically distance themselves from people that aren't wearing masks and hope for the best. What else can you do? Move to Vermont would be the other things you could do. It's just really frustrating.

I mean, I'm an older person, as you can probably see from this video. So I mean, I'm a child of the '50s. I grew up with polio. I remember polio as a child and polio was the enemy. I mean, polio was what we were trying to defeat. And so there was the March of Dimes, which put forward money to create the vaccine and distribute the vaccine. And polio had no friends. This virus has a great many friends. It does. I mean, vaccine denialists, conspiracy theorists, science denialists, people who ban

mask mandates, people who ban vaccine mandates—these are all friends of the virus. Really, I would like to see ... No, I won't say that because it's political and I'll get in trouble with my hospital. So I'm not going to say the next thing.

**Unger:** Yes, I'm sure it's a big concern for like the woman that you were talking to. I mean, kids are not very good at avoiding viruses in school, so that's probably pretty scary. I mean, the subject that you brought up was about mandates and a lot of talk about that. And you've been really vocal about vaccine mandates. And most recently you co-authored a really compelling opinion piece for CNN about how we don't have the constitutional right to refuse a vaccine. Can you give us a little background on your argument and what you think we should be doing with mandates?

**Dr. Offit:** Right. So, I mean I'm not a lawyer but my coauthor was a lawyer, so that was good. But I mean, this sort of dates back to 1905, the so-called Jacobson vs. Massachusetts case. Henning Jacobson was a Lutheran minister in Cambridge, Massachusetts, during a smallpox outbreak. The Cambridge board of public health asked everyone in Cambridge to get a vaccine, they mandated a vaccine. He refused. If you chose not to get a vaccine, you had to pay a fine. So there's a difference between mandatory vaccination and compulsory vaccination. In mandatory vaccination, you are asked to get a vaccine or you will pay a fine or you won't get to work at the place where you're working or you won't be able to go to ... at a university or college or you won't be able to work in a hospital. That's what a mandatory vaccination is. Compulsory vaccination is you are vaccinated, period. Essentially the military has compulsory vaccination but, again, you don't have to be a member of the military.

So in any case, in that Jacobson case, that went all the way up to the United States Supreme Court where basically they ruled that they interpreted the Constitution to mean that a public health agency could mandate a vaccine. So then this was reaffirmed again 17 years later, with a girl who went to high school in Brackenridge, south San Antonio. There wasn't a smallpox outbreak but they did insist that she be vaccinated or she couldn't come to school. That ruling also reiterated the Jacobson vs. Massachusetts one.

So it's not your right to catch and transmit a potentially fatal infection. When people say, "This is my personal freedom, this is my body's autonomy, this is my civil liberty," that's just wrong. I mean, if I choose not to get a tetanus vaccine and get tetanus, that doesn't affect anybody else, tetanus isn't a contagious disease, no one's going to catch tetanus from me. But this is a virus which is transmitted to others. How do people think other people are getting this virus? And it's not your right to do that, any more than it's your right to run a stop sign because you feel that it's impinging on your civil liberties to have to stop at an intersection.

**Unger:** Yes. And in your opinion, too, you talk about there's a duty to protect children in this. Can you speak to that and vaccines?



**Dr. Offit:** That's exactly right. I mean, Marci Hamilton, who's a lawyer at the University of Pennsylvania, basically made a 14th amendment argument that everybody deserves equal protection under the law, including children and including children whose parents have misconceptions about vaccines. That doesn't make them less protectable. And so I think that that was the thinking here. It's just so frustrating because basically you have a large percentage of people in this country who are saying to you, "I don't want to get vaccinated. I am going to continue to allow this virus to be able to spread. I'm going to continue to allow this virus to harm people. I'm going to continue to allow this virus to mutate and create variants that may become more and more resistant to vaccine-induced immunity."

And what are you going to do about it? So you can do two things. You can do nothing. You can say that is your right as an American citizen to catch and transmit a potentially fatal infection or you can do what we are doing, which is to mandate this vaccine, and to say that if you want to work in this place of employment—no one is guaranteed employment, by the way, so private companies can say, "If you want to work here, fine, but you have to be vaccinated." And universities can do it, colleges are doing it, obviously the Penn health care system has done it, Children's Hospital of Philadelphia where I work is about to do it. If you don't want to get a vaccine, then don't work here.

**Unger:** Yeah, we're seeing that supported all the way up through the Supreme Court, whether it's a health system or Indiana University. So there is definitely support for that. And the implications of not getting people vaccinated, they're obvious, but one of the things we were talking about before we started the recording today, I was just reacting about Dr. Fauci's comment about spring of 2022 as being hopefully a period at which we would be on top of this. What's your outlook there and what happens if we don't make progress here on the vaccination front?

**Dr. Offit:** Right. Well, he had a caveat. He said that we can get there in the spring of 2022 if we can get the people who are unvaccinated vaccinated. I agree with that. I mean, look at Canada. Canada has vaccination rates much greater than ours and where they have sort of two cases per 100,000 we have about 27 cases per 100,000. So you can get on top of this pandemic, look at Vermont, states that have very high vaccination rates have much lower rates of transmission of this virus. So it is possible. Again, you don't have to be a molecular biologist to understand that vaccines work and that the more people that are vaccinated the less ability this virus is going to have to spread. We can do this. We have the power in our hands to do this. It is remarkable to me that a significant percentage of the population is choosing not to do it.

**Unger:** Indeed. That's a big asterisk and one that's so important, just protecting each other, our economy and so much more. Dr. Offit, always a pleasure to have you here on the COVID-19 Update. Thanks for being here. We'll be back soon with another segment. In the meantime, for resources on COVID-19, visit [ama-assn.org/COVID-19](https://www.ama-assn.org/COVID-19). Thanks for joining us. Please take care.



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