

Speaker 1: Welcome to Conversations on Healthcare. This week we welcome Dr. Paul Offit, director of the Vaccine Education Center at Children's Hospital of Philadelphia, and member of the FDA Advisory Panel on COVID Vaccine Strategies. Now here are your host, Mark Masselli and Margaret Flinter.

Mark Masselli : Well first of all we want to thank you for joining us today, but the Biden Administration plans to end the COVID public health emergency in May. Is that the right decision, and what [00:00:30] big changes could be in the future for COVID vaccines?

Dr. Paul A. Off...: Right, so well we're certainly in a different place now than we were in 2020, in January, 2020 when this virus entered this country. At that time we didn't have monoclonal antibodies, we didn't have vaccines, we didn't have antivirals, and we had a blank slate in this country for people who were susceptible to the virus, there were 0% population immunity.

Fast forward more than two years and we have monoclonals, we have vaccines, and we have antivirals. [00:01:00] Monoclonals have sort of fallen by the wayside, and we have population immunity that approaches 96%. We're in a much better position than we were then. And so what now? I mean, are we going forward? And here's the way I would put this together.

I think it is fair to assume this virus is going to be with us for decades, if not longer. I mean, the two strains of human coronavirus that were first identified in 1960s, probably under the human population in the late 1700s and the late 1800s. Flu [00:01:30] has been with us since the mid 1300s. This virus is going to be with us for a long time.

Secondly, there will be vulnerable populations moving forward. So we need to identify those populations and make sure that we protect them as best as possible. So I think it's incumbent upon the CDC to look carefully at the people who are being hospitalized or being killed by this virus, and identify exactly who they are. How old are they, what vaccines have they received? When was their most recent vaccine? Did they receive antivirals? Did they have [00:02:00] comorbidities? If so which, so that we can really target our booster dosing strategy to those groups.

Mark Masselli : To the CDC, is it a little late to be giving them instructions like this? Is this something they should have been doing? Have they been keeping the right information? They've taken a lot of heat over this entire period. There's been a loss of trust in the public health system, and I think the CDC is at the lead of this, but is this a new formula for them or [00:02:30] are they already undertaking some of these?

Dr. Paul A. Off...: I think the hardest thing has been separating those who are admitted with COVID versus for COVID. I mean for example, at our hospital any child who comes into the emergency department that is then admitted to the hospital for

whatever reason will be tested to see whether or not they have COVID. If they have COVID, and even if they're admitted for something else, they're often counted as a COVID admission, and that's not helpful.

Recently a prominent epidemiology association [00:03:00] said don't test asymptomatic people who come into the hospital to see whether they had COVID, because those are often getting counted as admissions. So I think that's been the hardest thing, and I think we suffer from not having a national health system. That's why we often look to places like Israel or Canada which do have national health systems to kind of try and answer those questions, and that's not the way it should work because those countries aren't the same as ours in terms of ethnic population, age, et cetera. So we can do a better job. I think we should continue to hold the CDCs feet to the [00:03:30] fire to provide that information.

Margaret Flinte...: Well Dr. Offit, the advisory committee that you serve on supports a COVID vaccine consisting of a single composition for everyone, whether they're currently vaccinated or not. And as you know many of our audience know the current approach involves getting two shots of the original vaccine spread out weeks apart, and then one of the new bivalent omicron boosters at least two months later. Take us through the thinking on why the vote in favor [00:04:00] of the change.

Dr. Paul A. Off...: I think mostly for simplicity. So now you basically have the same vaccines that are given both as a primary series and a booster dose. I don't think there's any evidence that this bivalent vaccine is going to be dramatically better clinically than what we already had. And the reason for that is that we have to define what we want from these vaccines. The only reasonable, the only attainable goal for this vaccine, is prevention of severe illness. Keep people out of the hospital, keep them out of the intensive care unit, keep them [00:04:30] from dying.

The principle immunological component associated with protection against severe disease is really T-cells, T helper cells, and especially cytotoxic T-cells. The good news about this virus, if there's any good news that can come of a pandemic virus, is if you look at the original strain, the SARS-CoV-2 strain that first came into this country, the Wuhan-1 strain and that original variant, D614G, if you look at that original strain, Wuhan-1, and compared to the current strains like XBBB15, there's still 80 to 85% [00:05:00] conservation between those two strains in terms of T-cell recognition, that's why you're still protected against severe disease. I mean, when Omicron for example first raised its head in southern Africa it clearly swept across that region and caused a lot of illness, but there was a disproportion rise in hospitalizations, which you didn't see, or deaths, because people were still largely protected against severe disease.

Mark Masselli : One troubling figure in all of this is only 15% [00:05:30] of people eligible for the COVID booster shot that targets the Omicron variant that you described have

gotten it. I really wonder if this is an indictment on the public health community. Where have we gone wrong in our message, and how much of an increase in Americans receiving the COVID vaccine can we expect with the new single shot makeup?

Dr. Paul A. Offit...: Not much more would be my prediction. See, I just think that the... I'm not sure this is a failure of public [00:06:00] health messaging as much as it's a perception by the public that this pandemic is largely over. I mean I rode the subway yesterday to see the Eagles 49ers game and that subway was packed, and no one was wearing a mask. Think about where we were two years ago, no one would have done that. We were scared to death of human contact. That's not true anymore.

So I think the reason that you're not seeing an uptake in booster dosing, I think is because there's booster fatigue at this point, or vaccine fatigue, and I just don't think people [00:06:30] perceive this as a risk. Or at least I'd like to think that those who perceive it as a risk or those who are most likely at risk, which are those high risk populations, people over 75, people who have multiple comorbidities, and people who are immune compromised, those are the risk groups moving forward.

Margaret Flinte...: It's interesting, maybe those folks are sitting out the Eagles game and watching it from home and saying yep, nobody else is going to be wearing a mask on that subway so I'll sit it out too.

But in all seriousness Dr. Offit, as we talk with you [00:07:00] the Committee recommendations still needs CDC approval for the single composition of the vaccine, and that single shot will be the updated bivalent version. Over these last couple of years we've certainly often seen there can be disagreements between different of the body's charged with making these decisions. Is there any reason to think that the CDC will not see things as you do?

Dr. Paul A. Offit...: No, no. I think the CDC will approve this vaccine [00:07:30] as both the priming series to go along with, to harmonize it with the booster dosing. I think that that will happen.

I'm optimistic about where we are actually, I think we're in a much better place than where we were before. And I'm telling you if I rode the subway yesterday and didn't get COVID then I think we're pretty good because I don't know if you've ever been on subways in Japan where they kind of push people in to pack them in so that everybody can fit, it was like that yesterday on the subway, or Sunday.

Mark Masselli : Yeah. Speaking of Japan, [00:08:00] pandemic's global, what are you hearing from your colleagues around the globe in terms of their efforts? Are we seeing anything that might be considered a best practice and how countries are handling it? What do you hear? What do you see?

Dr. Paul A. Off...: Right now I think if there's a failure, I think it's the failure to really make sure that a hundred percent of people on this globe have gotten vaccinated. I mean, because that will definitely lessen the risk of severe disease.

This is a short incubation period of mucosal [00:08:30] infection. Even if 100% of the world were vaccinated, and even if this virus never created variants, it would still circulate. It would still cause asymptomatic infection. It would still cause mild disease. But such as the nature of a short incubation period virus.

I mean, look at rotavirus. Rotavirus is an intestinal pathogen, but it like SARS-CoV-2 is a mucosal infection that has a short incubation period. We instituted a vaccine in this country in 200, in babies the uptake is probably 90 to 95%, and we've virtually eliminated [00:09:00] hospitalizations from that virus, and that's a virus that is stable, that doesn't create variants.

Nonetheless, the virus still circulates in the community, still causes mild disease in the community. So I think we have to have a reasonable expectation for this vaccine in terms of what it can and can't do. But globally, I do think we have maybe 70% of people in this world who've been vaccinated, but 30% haven't, and we need to make sure they're vaccinated. And I think every year three and a half to 4 million children are born in this country who are going to be susceptible to this virus, and we need [00:09:30] to make sure I think they get vaccinated.

Mark Masselli : Yeah.

Margaret Flinte...: Well Dr. Offit, here we are in January, we're still in flu season, but it began months ago I guess in terms of people getting their vaccines. What do you think about the advice for Americans to get the flu shot and the COVID vaccine at the same time? I'm sure quite a bit happened this past fall, but we know the FDA is starting a study to look at potential safety concerns that could result from giving the COVID, Omicron shots at the same time as the flu shots. [00:10:00] What are your thoughts on that?

Dr. Paul A. Off...: Well, we certainly need to have this studied thoroughly before we recommend it to be given at the same time. I think many people are giving it at the same time. What worries me about then, this isn't exactly your question, but the flu analogy has been sort of made with this vaccine, meaning that every year now we, the FDA Vaccine Advisory Committee, like we do in March to pick flu strains for a September rollout, will be meeting in June to pick strains for a September rollout for [00:10:30] SARS-CoV-2 virus vaccines.

I mean, these two viruses are very different. I mean when we pick flu strains we look at countries that have winters that precede ours, Australia, South America, to predict what strains come into this country, and we better be right. Because if we miss, if we're wrong on picking the strain, a miss is a mile, and that's happened. If you look in the last 10 years for example, if you pick the wrong

H3N2 strain, which we've done, and you get a vaccine that does not match the circulating strain, you have [00:11:00] pretty much 0% protection, including against severe disease. That's not this virus. I mean this virus, you are still largely protected against severe disease if you've been naturally infected or vaccinated or both, because of the conservation of those T-cell regions. So this isn't flu. Flu is a strange specific phenomenon, that doesn't seem to be true here. So I think I don't see the flu analogy for this virus.

Margaret Flinte...: I think that's a very important point for people to hear, haven't heard it stated so clearly, so thank you, Dr. Offit.

Mark Masselli : But I do [00:11:30] want to challenge it a little because I thought the mRNA vaccination process really allowed us much shorter time. That in fact the old model would have been if we missed it by a mile we were in big trouble, but isn't the development of the mRNA an opportunity to have a second chance here, or is it still so clunky and cumbersome that we can't make mid-course correction? I thought this was one of the advantages of [00:12:00] seeing the new process that got developed?

Dr. Paul A. Off...: You're right. I mean, the mRNA process is quicker I think than say the flu vaccine process, and the flu vaccine remember, there's a variety of different flu vaccines. There's this sort of inactivated vaccine, which is enhanced for hemagglutinate. There's flu block, there's high dose vaccines, there's squalene adjuvanted vaccines. There's a variety of different flu vaccines.

But look how hard it is to pick strains. I mean so for example, in January, [00:12:30] February when Omicron BA.1 rolled into the United States both companies, Moderna and Pfizer, made a BA.1 bivalent vaccine. We, the FDA Vaccine Advisor Committee, sat down in June '20 to consider the data from that bivalent BA.1 containing vaccine, which and the other part of that was the Wuhan-1 strain. Well by the time we sat down BA.1 was gone. So the thing was okay, well let's make a BA.4, BA.5 containing vaccine and move forward with that. Well now here we are starting in November, December, BA. [00:13:00] 4 was gone, BA.5 is virtually gone. So this isn't flu. And I think that oh, do we really want to try and chase these variants given that you still are largely protected against severe disease no matter what you got really.

Margaret Flinte...: Well Dr. Offit pivoting just a little bit, you're an author of a new research article in JAMA Pediatrics with a headline COVID-19 Vaccines and Young Children, Reassuring Evidence for Parents, which I think will be reassuring just that you have that headline. [00:13:30] But tell us what was the basis for your being able to offer reassuring evidence, and maybe specifically since parents heard so much about myocarditis as a possible complication of the vaccine, what did you find?

Dr. Paul A. Off...: Right. So when we sit down to make decisions at the FDA Vaccine Advisory Committee, we always base it on only the data that we have. And for the five to

11 year old, you had studies of a few thousand children, but then you've made a recommendation for millions and millions of children. So you don't [00:14:00] know whether or not that few thousand children ends up being predictive of what happens in a larger group.

With this Watanabe Study done that was published in JAMA Pediatrics is it looked at millions of children who've received this vaccine. And so there were two things that were reassuring there. One is we didn't know whether this vaccine would prevent this multi-system inflammatory disease of children, this post-infectious inflammatory disease, but it appears to according to these data. And also you didn't really know the instance of myocarditis, you knew that it was highest in that 16 to 17 year old [00:14:30] male, primarily within a few days of that second dose, as high as one in 6,600. But you didn't know for the five to 11 year old, and you were worried because you knew that for that younger male it was higher than it was say for an older male. So what happens when you get younger and younger? Well the answer here was the incidence was one per 500,000, which is extraordinarily rare, and roughly in the same category for your chance of being struck by lightning every year in the United States.

Mark Masselli : I want to [00:15:00] ask about President Biden and his declaration, or at least the administration has let the public know that they plan to end the public health emergency hopefully in May, though there's some battling going on for extending that. But what are your thoughts? Are we past this point now where we can move on from the public health emergency, and what do you worry about if the May date [00:15:30] holds?

Dr. Paul A. Off...: Right. We should probably never make predictions about this virus because you're always wrong, but I'll try anyway.

Mark Masselli : Go ahead.

Dr. Paul A. Off...: I think my prediction is that this virus is going to enter the pantheon of winter respiratory viruses, which also caused severe suffering and hospitalizations and death. I mean, two years before SARS-CoV-2 entered this country, which was in January, 2020, influenza caused 800,000 hospitalizations and 60,000 deaths. I mean, RSV [00:16:00] typically kills between 6,000 to 10,000 elderly Americans every year. Parainfluenza causes tens of thousands of hospitalizations and thousands of deaths. So they're all killers, they're all bad.

And what I see is I see sort of SARS-CoV-2 sort of entering that route, which is interesting in terms of how we move forward because you could argue... I have friends for example, who have children and they're trying to decide whether to send them to school. So if they have upper respiratory tract symptoms and they test to see whether they have COVID, and if they don't they go [00:16:30] great, I can send them to school. But there are other viruses out there like RSV, flu and para flu, that also are a problem.

And so I think maybe moving forward the smartest thing to do is for people who are at risk, who clearly would benefit from an antiviral, they should test. And if they're positive treat with an antiviral. But for everybody else assume you have a virus which can be severe for other people and stay home if you can. And if you can't stay home then wear a mask when you go into work. Which is it's sort of done in many countries, say in Southeast Asia, [00:17:00] it's just not our culture.

Mark Masselli : So good to go with the public health emergency just with some more detailed instructions for people?

Dr. Paul A. Off...: I think that's right. I mean, you could argue every year flu is a public health emergency. We don't treat it that way, but it certainly kills tens of thousands of people every year.

Margaret Flinte...: Well Dr. Offit, I wonder if you could take us inside your practice and that of your colleagues at Children's Hospital of Philadelphia. You're seeing parents, you have the recommendation for vaccine against [00:17:30] COVID for children's six months and older, and those five and older to get the boosters. What happens when a parent says no maybe today, take us inside those conversations. Do you have a strategy to encourage people, motivational interviewing, just more information, what happens when you get the no?

Dr. Paul A. Off...: Well you can sort of understand at some level. I mean, we're talking about COVID. If you look at who dies from COVID, [00:18:00] it's primarily the over 75 year old nursing home resident. I think 93% of all deaths are in people over 55. But you can die as a child. I mean, if you're less than 18, the number of deaths is in sort of 1,500 range, so it's about a thousand. You're a thousandth fold less likely to die as a child than an older adult, but that doesn't mean that it can't happen. And so that's what we try and talk about is that a choice not to get a vaccine, it's not a riskier choice, it's just a choice to take a different risk, and this is what that risk looks like.

I mean, [00:18:30] our hospital now has about 10 children in the hospital with suffering from COVID, and it's hard to watch, especially when they've made the choice not to get the vaccine, or the family has also made the choice not to get the vaccine for parents and siblings because this is preventable. And it's hard to watch a child come in, struggle for breath, being put on face mask oxygen, and then having to be sedated, brought up to the intensive care unit, intubated because of pneumonia, when it's a preventable disease. So you try and make that case [00:19:00] of what it looks like to take this different risk, and without being too heavy handed.

The most dramatic thing to me in 2020 when we didn't have anything to specifically prevent this virus infection was missing. I'd never seen anything like that before. I mean, here were children who usually had either an asymptomatic infection or a mild infection that was only picked up because they'd had a friend

or family member who had contracted COVID, and then they're fine, the symptoms go away, they're running and playing, and one month later [00:19:30] they come back to the hospital with high fever, pneumonia, liver involvement, kidney involvement, heart involvement, occasionally going to the intensive care unit with severe myocarditis. I've never seen something that dramatic before, and it was primarily the five to 13 year old sort of peeking at the nine year old. And so prevent it, if you can prevent it, safely prevent it.

Mark Masselli : I was thinking about back in 2020 when we didn't have a vaccine and then we thought maybe it was the traditional development. We all learned about [00:20:00] something called the mRNA vaccine, which was 20 years old but nonetheless it reemerged. And tell me past COVID what benefits are we seeing from technology coming up? What's out there that you're excited about in the research that's going on?

Dr. Paul A. Off...: Right. Certainly the mRNA vaccines for SARS-CoV-2 was a perfect fit. I mean, I can tell you this to [00:20:30] me is the greatest single medical advance in my lifetime. And as you can tell since you see me on the screen I'm old, so my lifetime includes the development of the polio vaccine.

It's remarkable, and it's held up. I mean now two plus years into this mRNA technology you still have excellent protection against severe disease assuming you're not in a high risk group. So that's amazing.

Will it be as applicable to in other infections? So actually when people are worried about the [00:21:00] mRNA technology because they think it's new, it's not as you know, it's not new. I mean starting in 2005 researchers working on mRNA vaccines for example, to try and prevent a human immunodeficiency virus. Now people are looking at it as a universal flu vaccine, as a better malaria vaccine, so we'll see.

I mean, I trained in an influenza lab many decades ago, and the guy who was the head of the lab, Walter Gerhard, said to me something I'll never forget, which is if you want a research career that lasts for the rest of your life study influenza. So [00:21:30] although we talk about trying to make universal influenza vaccines or an HIV vaccine that works, those two viruses have really been resistant to that. And I don't think this is going to be the magical answer, but it would be great if it was. So we'll see. I mean, certainly we'll see how it goes moving forward.

Margaret Flinte...: Absolutely. Well Dr. Offit, we were looking back to when you joined us in 2021, and you called yourself at the time a vaccine skeptic and said it's fine to be skeptical of anything that [00:22:00] you put in your body, but skepticism can go overboard. And we note that you also made the contribution through your book over a decade ago called Deadly Choices, How The Anti-Vaccine Movement Threatens Us All. What's your take on where we are with that movement at this point. That preceded COVID for sure, certainly mandatory vaccines and

immunizations have brought out a lot from that community, but what's your status of what the public health community has done [00:22:30] and can do about the anti-VAX movement in terms of trying to really protect the public's health going forward, not just from COVID, but from all the things that we have vaccines against?

Dr. Paul A. Off...:

Yeah. I can safely say I was dead wrong in predicting what would happen with the anti-vaccine movement as this virus entered the country. Because really the anti-vaccine movement, to some extent on its heels. I mean, it sort of thrived in the early 1980s with the airing of a show called DPT Vaccine Roulette claiming that [00:23:00] the pertussis vaccine caused permanent harm, and it really took off then. And then it went further with the notion that MMR vaccine, the measles, mumps, rubella vaccine caused autism. Also untrue. And then it really started to take its hits.

As data sort of generated showing that these fears about vaccines weren't true, the anti-vaccine people were more and more marginalized, but they had been included on committees like the Advisory Committee For Immunization Practice, or the FDA Vaccine Advisory Committee. They had moved into [00:23:30] the mainstream and then they were pushed farther and farther away.

To me, I thought the death knell was the elimination of a philosophical exemption against vaccines to allow for a vaccine opt-out in California. I thought that really marked the end. But then what happened was, and it was never a politics to this, on the left it was kind of all things natural, don't put anything into my body that's unnatural, the sort of gluten free, casing free, vistenale free, dolphin free crowd. [00:24:00] And you saw that with the sort of measles outbreak in Southern California in 2010, that was a liberal community in the Disneyland area that allowed for that. And on the right, it was always libertarian government off my back, don't tell me what to do thing. It's become solely that. I think the anti-vaccine movement hooked in to the Republican right really on this, with this don't tell me what to do, don't mandate anything, and a lot of the support came from that.

And this is the first infectious disease [00:24:30] in human history where your political affiliation determines whether to some extent you're going to live or die. I mean, hence the name Red COVID. I've never seen anything like that. They really hooked into that. And during the insurrection in January 6th, there were the anti-vaccine activists a couple blocks down the road with their platform and their folks, and so that's what surprised me. That it's really hooked in to that government off my back notion that is prevalent at least among some in this country.

Mark Masselli :

[00:25:00] Yeah, though most of those leaders in the House and the Senate who might espouse that, as soon as they're sick they're off to their Reed Medical Center getting great care and listening to the providers who they would listen to on this issue. But that's another matter.

I want to... One final question, Dr. Lena Wen stated in the Washington Post that the medical community is "over counting the amount of COVID deaths and hospitalizations," and she cited sources claiming that most patients diagnosed with COVID are actually in the hospital for [00:25:30] some other illness, obviously set off a firestorm. What do you think of her point of view?

Dr. Paul A. Off...: Yeah, so the only data I've really seen on this, at least in published form, was a study by Klann Kale, ANN, out of Massachusetts General Hospital. Well what that group did was they evaluated medical records, they went through medical records one by one to try and answer the question if they were diagnosed with COVID were they receiving steroids like dexamethasone? Were they receiving supplemental oxygen for their pneumonia? And [00:26:00] they found that roughly 26% of those case reports, and they were looking at in Massachusetts, Pennsylvania, and Illinois, that there were misclassified as being admitted for COVID, and it could vary anywhere from 0% to 75%. So I think there is some element of that. It's unclear to me how common that is. I mean, now you've had sort of pushback on the other side saying if anything, COVID hospitalizations and deaths are underrated.

But it's really hard to evaluate in some ways because let's suppose you have a severe heart disease or [00:26:30] a lung disease, and then COVID sort of puts you over the top, is that a COVID death? I mean much in the same way that flu did that, or RSV did that, and so it's defining that has been difficult. But I guess just looking at what goes on in our hospital I can tell you things are a lot better from where they were.

Margaret Flinte...: And that's the good news. Dr. Offit, we know you and the Committee will meet again in a few months to select a strain for the vaccines that will be rolled out this fall, and we hope that you'll join us again once that decision [00:27:00] is made. Thank you for being with us today. And to our audience you can learn more about conversations on healthcare and can sign up for our updates at chcradio.com. Dr. Offit, thank you so much again.

Dr. Paul A. Off...: My pleasure.

Mark Masselli : All righty. Are you going to go out to the Super Bowl or what?

Dr. Paul A. Off...: I don't think so.

Mark Masselli : Oh come on.

Dr. Paul A. Off...: It's a tough one. I'm a season ticket holder, so when you're a season ticket holder you get into this lottery automatically to see whether you happen to win a Super Bowl ticket, but I didn't win, so [00:27:30] I don't know. I think probably not. Maybe the owner will invite me.

Mark Masselli : Good, thank you for taking this time, really appreciate it.

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Margaret Flinte...: Thanks for all your wonderful work, appreciate it.

Dr. Paul A. Off...: Thank you. Thanks for saying that. Take care.