This Week in Virology

TWiV 1232 Clinical Update

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Guest: Daniel Griffin

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Vincent Racaniello: *This Week in Virology*, the podcast about viruses, the kind that make you sick.

[music]

VR: From *MicrobeTV*, this is *TWiV, This Week in Virology*, Episode 1232, recorded on July 3, 2024. I'm Vincent Racaniello, and you're listening to the podcast all about viruses. Joining me today from New York, Daniel Griffin.

Daniel Griffin: Hello, everyone.

VR: I really can't see anything on your tie, so you'll have to tell me or give me a clue. I just see blue and yellow.

DG: Yellow's good. There are these golden grape-like clusters of bacteria.

VR: Oh, *Streptococci.* Grape-like cluster -

DG: Say grapes in, what is it, Greek or Latin?

VR: It's not staph, is it?

DG: Yes, staph.

VR: I thought the streps were the grape-like clusters.

DG: The strep tends to be in strips. Think of it that way, strept and strips. They'll be either diplococci or they'll be chains.

VR: At least I was gram-positive, right?

DG: Yes, you got there.

VR: What was the *Diplococcus*? That was an old name for what?

DG: For strept pneumoniae.

VR: Oh, *Diplococcus*, and they changed it to strept pneumoniae.

DG: Yes, and also meningitis. *Neisseria meningitidis* also is a gram-negative diplococci, so yes.

VR: OK, so we have *Staphylococcus aureus* on your tie today.

DG: Yes. I was going in this morning to Columbia, and we're going to discuss this man who had methicillin-sensitive *Staph aureus* bacteremia. The terminology they like to use at Columbia is he eloped. [laughs] He did not go and find a bride and skip the church. He just skipped the church, skipped the hospital, and headed out into the world. Hopefully, he will make better decisions going forward.

VR: Did you say he is sensitive or resistant?

DG: Sensitive, yes. We have the methicillin-sensitive, the methicillin-resistant *Staph aureus.* He's sensitive.

VR: Sensitive is good, right?

DG: It's good, but if you don't get any antibiotics, then it's not good.

VR: Then it's not going to matter, right?

DG: Yes.

VR: OK.

DG: All right, let's jump in. We got a lot to cover today. I will start off with a quotation from Winston Churchill. It's been a little while, but, "A lie gets halfway around the world before the truth has a chance to put its pants on." I can sort of picture Winston saying this. We've had some issues recently, and I'm going to start off with that. I want to try to make sure when I'm covering things that people might consider political, I'm going to really focus on what is the science that people need to understand, what's the science that's out there. I'm not really being political. I think if you want to participate in a democracy, it's important to be informed, and I'm going to keep helping people.

Let's start with, should this continue to be an issue? I'm going to leave in a link to a CDC document. This document addresses something that people have been chatting about recently in the document, which was taken down, but I've got a link here for you. “Thimerosal-containing vaccines and neurodevelopmental outcomes: Review of the evidence.” This actually reviews the science on thimerosal and vaccines. Just a few quotations, but I'm going to leave in a link so people can go, they can peruse.

What is the story? Thimerosal is an ethyl mercury-containing compound that was used for decades in the United States as a preservative in multidose vials of vaccines and other products to prevent growth of harmful microbes such as bacteria and fungi. Under the FDA Modernization Act of 1997, the FDA conducted a comprehensive review of the use of thimerosal in childhood vaccines. This review found no evidence of harm from the use of thimerosal as a vaccine preservative other than local hypersensitivity reactions.

In 1999, with input from the Public Health Service and other partners, FDA requested all vaccine manufacturers for plans to remove thimerosal from vaccines. This was taken as a precautionary step, not due to evidence of harm, to reduce an infant's overall exposure to mercury, given that other environmental sources of mercury were challenging to eliminate.

Now, if people listen to the recent ACIP meeting, they're rehashing this same discussion 26

years later. So, 1999, they say, "Let's get a plan. Let's get this out of there." Since 2001, for 24 years, all childhood vaccines licensed and recommended in the United States have been thimerosal-free, with the exception of some multidose formulations of influenza vaccines. Several vaccines used in the United States, for example, MMR, varicella, inactivated polio, pneumococcal conjugate, which we're just talking about, have never contained thimerosal. When people bring up this argument, they think it's the thimerosal, the mercury, and an MMR that causes autism. What thimerosal? What mercury and MMR?

VR: What autism?

DG: Yes. During the 2024/2025 season, 96% of all the flu shots in the U.S. were thimerosal-free; 98% of federal vaccines procured through the Vaccines for Children, or 317 program, thimerosal-free. A recent analysis from CDC's Vaccine Datalink, because they're all worried about, oh, the pregnant women are getting this, only 0.3% of doses had thimerosal. Thimerosal was taken out of vaccines in the U.S. in 2001. MMR vaccines do not and never contained thimerosal in the U.S.

Recently, this whole discussion, they spent a whole bunch of our taxpayer dollars, chatting about revisiting this. Then they had these thimerosal vaccines not recommended. The WHO responded to the ACIP decisions, and they said, "Thimerosal has been reviewed multiple times by multiple agencies, including WHO, and it's clear from the evidence that there is no evidence of harm from the use of thimerosal," Dr. Katherine O'Brien from the WHO told reporters on Friday. All right.

VR: It's just a show, Daniel. They just want to show that they're in charge.

DG: Yes. I'm trying to figure out, how is this a win when it wasn't a problem? The same arguments were 25 years ago. It's like, "You know what? Listen, it doesn't look like there's any issue here. Just to be on the safe side, let's get this out." There are just a few situations, like really in nursing homes, other areas, mostly overseas, where thimerosal might be used because there's a price point issue. We're seeing, what, 0.3% of pregnant women, so really not an issue there. Children, it's not part of the vaccine schedule.

It's sort of a problem for the - I think I like the analogy of when the dog catches the car. Like, thimerosal's gone. There's no mercury here, but you were telling us that it was causing all this autism. Autism, according to you guys, is rising 25 years of thimerosal out of the vaccines and never even in the vaccine that you claim is the big concern of yours. It's sort of a problem with the arguments here.

VR: RFK Jr. will crow that he helped Americans by taking dangerous mercury out of your vaccine. That's what he'll say, and people will be, "Oh, that's so lovely."

DG: It was already out. Basically, they were just like a tiny - A nice article in the *The Wall Street Journal*, "RFK Jr.'s Vaccine Panel Has a New Approach. Question Everything." ACIP is supposed to be a committee that looks at the evidence. That evidence-based mandate was repeated several times during the meeting. One of the members of the committee was not really on board with making evidence-based recommendations. This really is what had me sort of thrown. We heard from Retsef Levi, who voted against the new monoclonal antibody for RSV that, as a father, his outlook takes him beyond the science and data.

VR: What the hell is he talking about? First of all, why is he on there? That's all you have to

look at, the science and data. It makes no sense, Retsef.

DG: Yes. We're asking for evidence-based recommendations. As a father trying to keep kids safe, including yours, the science, the evidence, this is what we look to. We don't look to, I don't know, the impression that you get from social media and some, I don't know. Some, many who work to provide vaccines already review the ACIP as a lost cause. The University of Minnesota is now home to a group working to make alternative recommendations, the Vaccine Integrity Project.

I'm going to read a quote here from Michael Osterholm, the epidemiologist who helps direct this project. "The meeting served as further evidence that vaccine information and recommendations, at least temporarily, need a new independent home outside the U.S. government."

All right. Now, I've got a very disturbing but really good article. If you can only read one article, read this one. [laughs] “Top FDA Official Overrode Scientists on COVID Shots ” by Christina Jewett. This deals with another issue. I'll just give people some background, say, well, what is going on here?

The way it's supposed to work, and maybe this helps people with understanding, is that the FDA has these committees, these groups, and be a number of experts on these. They go through the data. They prepare these really well-edited, well-thought-out, basically, reports that then go to the head of the FDA. Recently, we had Novavax coming up for full licensing. You've got multiple pages, really well-written. Here's all the data on what's going on with COVID.

Really important to know, like how many people are dying, how many people are being hospitalized, how many people are ending up with issues after the fact. Then a lot of data on the vaccines. Does the vaccine work? Does the vaccine reduce deaths? Does it reduce hospitalizations? All the rest. You end up with dozens of staff experts. They put together this report. Then the FDA gets to make a decision. Are we going to make this product available to the public or not?

Now, there is one example where there was a particular product. It was felt to be a high-risk product. The previous head of the FDA said, "Listen, there's no other options. We realize that this particular therapy might have a high risk of issues. We want to give people a choice because, otherwise, this is a deadly disease." I forget which. It was a neurodegenerative disease. That was the only precedent we have in the past.

The FDA is there to make a decision, license or not. Not, "Oh, we're going to license it, but then I'm only going to decide who gets access. I'm going to make everyone else use it off-license." Vinay Prasad for Novavax and the new Moderna mRNA COVID vaccine is basically going to override. He's going to reject the recommendations of his staff. This article really outlines how Vinay Prasad, the appointed FDA administration's top vaccine official, rejected broad uses of two COVID vaccines, citing unknown risks or injuries despite assurances of safety from dozens of staff experts.

What was my reaction? My reaction was that it is a dark time in the history of public health when political appointees overrule expert recommendations, pick and choose data to support their ideology, and use their position to advance personal agendas. I read the reports by the experts. Then I read these really poorly put-together memos by Vinay Prasad.

I say poorly put together. At one point, you're trying to figure out, why does this sentence have these two footnotes that seem to be referencing Vinay Prasad's opinion piece twice?

The reason it's confusing is it's actually a cut-and-paste sentence from another memo. He's not even properly having his memos proofed on something as serious as restricting access to these vaccines and forcing those who may want to access those that have to do it off-label. One of the things I commented on is that the memos did not really acknowledge the fact that myocarditis is occurring at a rate, I say seven to 16, but really, basically to say, if you get vaccinated, you are going to reduce your risk of myocarditis tenfold.

Because people keep getting COVID, there's a very high rate of myocarditis, or I should say a tenfold higher rate of myocarditis if you get COVID without the protection of a vaccine than if you get the protection of the vaccine. If you really want to lower the risk of myocarditis, as I like to point out, in the population with ongoing COVID cases, vaccination is safer than not vaccinating.

VR: Dr. Prasad, the expert, of course, says there's no COVID anymore, so it doesn't matter. We don't need to do this. Is that true, Daniel?

DG: It's interesting. He acknowledges that COVID is out there. Then there's going to be a piece, and I'm going to return back to myocarditis next time, because he does go through it. He says, "We were seeing myocarditis," and he actually gives the rates as sort of this 22 to 65 per million when we first rolled out the mRNA vaccines, and particularly in this population, 15 to 25.

When this was first seen, the response was to space out the vaccine so that the doses, instead of given three to four weeks, were given three months apart. He does acknowledge, and a thing he's trying to get published, that we're really not seeing post-vaccination myocarditis anymore. That's interesting. He points out, he goes, "We're not really seeing it anymore. It's not really an issue, but I'm still worried about it."

Now, we're certainly still seeing post-COVID myocarditis. Here's a safe, effective vaccine, which we're not really seeing the myocarditis anymore now that we've spaced out the vaccines. Yet, he wants to not let us have access. I'm going to return to this weird myocarditis thing that they keep returning to.

VR: The access, you're talking about people under 65 and pregnant women no longer have access. Is that correct?

DG: With Novavax, for instance, so Novavax has been the vaccine that I've actually chosen to go with and my family's gone with for the last several cycles, and now we hear it's going to be licensed. That's great. I'm a healthcare worker, constantly exposed. If I want to get a Novavax shot in the fall, that will actually have to be off-label. He basically said, "We're going to license Novavax, but we're not going to license it for Dr. Griffin, who's under 65." Remember I told you this, I went out and I bought cigarettes and I inhaled a couple of times, so now I can claim to be a former smoker and get access.

VR: [laughs]

DG: We were actually a number of healthcare workers. We were talking about this today, the fact that, if we want to use Novavax because we want to have less reactogenicity or

whatever, no. Then the new Moderna vaccine, which there are some evidence suggesting that it might actually be a little more effective than the old Moderna COVID vaccine. Again, if we want to do that to protect ourselves, it will be off-label.

VR: I don't understand his motivation there at all. Makes no sense.

DG: It does make no sense. Unfortunately, this is probably the trope that got him in this position. He's got all these interesting ideas, epidemiology ideas about this healthy vaccine bias, and why he can't trust any of the data. He's an oncologist. He's not a vaccine expert. As I said, it's a dark time when you've got this political appointee, he's got his own ideology, his own agenda. Then even when you present him with really, here's all the evidence, here's the science, you try to explain it to him, he's like, "I don't care. I've already made up my mind. I made up my mind four years ago when we first saw the myocarditis, and it ain't changing."

VR: Unbelievable.

DG: What's going to be a challenge here is they're trying to get things up ahead, because what had happened in response to the recent ACIP meeting is a lot of the professional societies, like the American Academy of Pediatrics, American Academy of Family Physicians, American College of Obstetricians and Gynecologists, they actually posted, "Hey, here are our recommendations." The AAP, for instance, has been doing this for decades upon decades, but now it's going to create a problem because how do you create guidance if you've got the head of the FDA not fully licensing these vaccines?

All right. Fortunately, vaccine-preventable illnesses are not a problem in the U.S., turning to measles. I say that with tongue-in-cheek because, ouch, the article, “Assessing the Transmissibility and Outbreak Risk of Measles in the United States, 2024 to 2030,” was published in *JID*. Here, these authors are really asking this question, like, "Do we have to worry? Is there potentially going to be a measles outbreak in the U.S.?" Interesting question.

Here, the investigators assess the local transmissibility and outbreak risk at present and in future years under various vaccination scenarios in the United States. They looked at the, I love this, spatio-temporal outbreak risk pattern. We've got projections through 2030, and really some nice figures here. You can see, based where we are, and then with a 10% or a more significant drop in the vaccination coverage, what's going to happen within five or two years based upon that. If it declines by 10%, you can see, basically, you're really starting to go up 25%, and then 50%. Not looking good. Not looking good if this vaccination erodes even further.

It's gotten to the point now, Vincent, where if you are a U.S. traveler, and you go to, for instance, Honduras, you have to actually bring your proof of measles vaccination before entry.

VR: Gosh, I got mine in the '60s.

DG: Where are people going to find this? Now, I think there will be some - you're old enough that you're before a certain date, so that will count for someone like you. A young pup like myself, I have to somehow get my vaccine records if I want to go visit Honduras. According to the Secretary of State at the Ministry of Foreign Affairs and International Cooperation, Honduran authorities are requiring documentation to show proof of a measles

vaccine for travelers coming from various countries, including the United States.

VR: Wonderful.

DG: Isn't this crazy? We're now a threat. Now, what's going on here in the U.S.? Why is the rest of the world concerned? As of June 24, so it was a little bit a week behind, 1,227 confirmed measles cases. We're now up to 37 jurisdictions. A week ago, so we're probably already there. We're just reporting we're now only eight cases away from the most cases since measles was eliminated from the U.S. in 2000. We have had a 29-fold increase in cases in the Americas from last year.

I'll leave in a link where you can look at just the number of cases in all these different countries: 7,132 measles confirmed cases, including 13 deaths. Cases in Argentina, Belize, Bolivia, Brazil. Canada's, we're going to go up to there, over 3,000, 3,526. That number is actually higher. You get in Costa Rica, Mexico, 2,597 cases, nine deaths. Peru. The United States, as I mentioned, we have 1,227 confirmed, already three deaths. More bad news, New Mexico announces measles outbreak in a county detention facility. They got 400 incarcerated people there, 100 staff members. So far, five people have been diagnosed with measles. They're trying to get this under control.

Canada, another 145 new measles cases this past reporting week, up to June 21 there, 3,526. I'll leave in links to all the information about the vaccines and how this can be prevented.

Maybe this is a number I want people to remember as we talk about flu. A total of 253 flu-associated pediatric deaths occurred during 2024/2025. We don't even have the final tally. This is the highest number, 253 kids, children, died from flu in this last season. The highest number of pediatric deaths reported in any non-pandemic flu season since this became reportable in 2004.

Just a few comments that we keep repeatedly making. Ninety percent of these kids, not vaccinated. The majority of these kids, no known health risks. These are healthy kids in general who end up dying. They often die pretty quickly because people, they say, "Oh, maybe they died with the flu." No, these are healthy kids. They got the flu often within 48, 72 hours. They're dead. These are mostly preventable deaths - 253 children dead from the flu.

All right. The article, “Influenza Vaccination During Pregnancy and Infant Influenza in the First Six Months of Life,” was published in the journal *OBGYN*. This is a cohort study among pregnant individuals enrolled in Kaiser Permanente's Northern California, KPNC, and their infants. They followed all infants from birth until the first occurrence of a PCR result positive for flu, or the infants reach six months. We're looking at little kids, first six months. They're not eligible for flu vaccination yet. This is where if mom gets vaccinated, she might protect the little kids.

They compared the hazard of getting flu in infants whose mothers were vaccinated during pregnancy compared to those mothers who did not get vaccinated and did not potentially provide this protection to their children. So, 245,498 infants included in the study, 46% were born to vaccinated moms, about half there. The incidence of influenza was lower among infants of vaccinated mothers than unvaccinated mothers, about a threefold difference.

Vaccination during pregnancy was associated with a reduction in infant influenza in any clinical setting by 44.4%. We're going to see here vaccination during the first trimester, reduction in infant influenza by 11%. If we move up to the second trimester, now we're at 51.5%. Third trimester, 59.3% reduction in infant influenza. Pretty significant. If you want to reduce influenza in your little kids, you can actually reduce. You can get rid of the majority of infant influenza by getting a flu shot during that third trimester.

The article, "Influenza Vaccination in Japanese Children, 2024/25: Effectiveness of Inactivated Vaccine and Limited Use of Newly Introduced Live-Attenuated Vaccine," published in *Vaccine*. Lots of limitations here. Basically, this is not a lot of vaccine uptake in the Japanese children. The researchers concluded that during this last season, flu vaccine was 57% effective against outpatient flu, 73% effective against flu-related hospitalization among Japanese children.

If you want to protect those children, those over 250 children that died this last year in the U.S., mom can get vaccinated, particularly during that last trimester. We're going to get about a 60% reduction in kids getting the flu. Then once the children get up to 6 months, we can actually vaccinate them at about a 73% reduction in the kids ending up in the hospital.

VR: Daniel, the flu vaccine in the U.S. is licensed for everyone, right?

DG: This is actually interesting. It's licensed for everyone. The most recent recommendations from ACIP, from the CDC, are universal and now approved by the CDC, is recommendation for everyone 6 months of age, all the way up, including pregnant women, to get vaccinated, so yes.

VR: COVID restriction doesn't make any sense because I view COVID and flu equal numbers, more or less, and equal risk for everyone. I guess the myocarditis thing is the only differentiator, right?

DG: Yes. I know there's this whole, "Oh, what about mRNA? Why are they going after Novavax? That's traditional. It's protein-based. As they pointed out, now that we're spacing vaccine doses apart, we're not seeing the myocarditis. It's a traditional vaccine. Why would you limit the licensing?" There's no good science there. It's agenda. It's ideology. It is unfortunate because there were these really well-prepared briefs. "Here's all the science, Vinay Prasad." He says, "Yes," just like that member of the ACIP meeting, "I just got my own ideas."

All right, COVID. This is interesting. We're going to leave in links to two different sources. Where do you get the data on the wastewater? There's data.wastewaterscan.org. Interesting enough, there, they're actually reporting upward trend in the last 21 days, moving SARS-CoV-2 high. According to the CDC, though, nationally, wastewater viral activity level is low. A little subtle difference there between where's the level and where's the trajectory. The data that we look at in our multicolored chart is a little old. It looks flat to me. Doesn't it look flat to you?

VR: I don't know, Daniel. We're in the 21st of June. If you look at last year, it was already up by then.

DG: We were already actually -

VR: It could be that we don't have a summer peak. That would be great, wouldn't it?

DG: I'm hoping. I was doing an interview for *The Washington Post* today. I was saying, listen, right now, let's say you're going to go out and enjoy the day. They say, "Oh, the chance of rain is really low." Yes, your chance of getting COVID right now is really low. I'm hoping it stays that way. I'm hoping July 4th, people can enjoy it. They can have a great time. Those of you around the world, we have a big celebration on July 4th, where we celebrate, what, taking away Medicaid from people and raising taxes on the poor and lowering on the rich, something like that. Isn't that what July 4th is all about, at least this year?

VR: I thought it was No Kings, Daniel.

DG: [chuckles] No Kings. That's actually what it was. Independence from authoritarian kings. Anyway. Right now, I think we're in good shape. We'll see what happens. I would love if your prediction, Vincent, is that it stays low. What is that? There's this wonderful story where this guy says that he served under the British government for his whole career. His career started 1910, and it was 50 years till 1960, and every day, he would report to his superior, "There will not be a world war today." I can say, after 40 years, I was only wrong twice.

[laughter]

VR: Wonderful.

DG: We'll keep predicting that we're not going to see a rise, but we'll see what happens. Let's get people more upset here, Vincent, with the - This week, we have the, "WHO Independent Assessment of the Origins of SARS-CoV-2 Developed by the Scientific Advisory Group for the Origins of Novel Pathogens, SAGO. You got to have your four-letter acronym.

SAGO, the Scientific Advisory Group for the Origins of Novel Pathogens, provided initial findings and recommendations to better understand the origins of SARS-CoV-2 in a report published on June 9, 2022. Now we've got an update, and the current review is an independent assessment of the origins of SARS-CoV-2 developed by the SAGO for WHO, provides an evaluation of the information from published scientific papers reports, available intelligence statements and reports, scientific presentations provided to SAGO, expert discussions held by SAGO during closed meetings between November 2021 and June 2025.

I know if you've already formed your opinion ahead of time, I'm sorry, but they're looking into it. They're trying to see. The WHO appointed this group of 27 international experts, the Scientific Advisory Group for the Origins of Novel Pathogens in November 2021. There are four hypotheses that they're considering. Here are the four hypotheses. One, introduction from a natural zoonotic source, spillover event either directly to humans from wild animals or through an intermediate host, what we call the zoonotic theory hypothesis. Two, accidental lab-related event, which may have involved exposure to the virus during field research or a breach in laboratory biosafety procedures.

Three, introduction of SARS-CoV-2 into animal markets via cold chain processes and subsequent infection in humans through contact with products sold at markets. Number four, this is the big one, deliberate manipulation of the virus in a lab followed by a lab biosafety breach. Two and four are like the lab leak hypotheses. Two is it was an accident. It leaked out of the lab. Four is they deliberately leaked it out of the lab. They're looking at all the data here.

This is one of those, I think, where like if you're, "It was a lab leak," and I don't say that, you're like, "I'm never listening to Dr. Griffin again. I'm unsubscribing." In this full report, we read: “Most available and accessible public scientific evidence supports hypothesis number one, zoonotic transmission from animals, possibly from bats or an intermediate host to humans.”

VR: People just don't seem to understand. There are no data for a lab leak. Zero, zero, zero. It's all innuendo.

DG: Yes. You know what? As a conspiracy theorist, that just means they did a really good job of covering it up, Vincent.

VR: Of course.

DG: [laughs]

VR: There's always a response, right?

DG: That's the response is that if you can't find any evidence, that's really suspicious. They must have done a great cover-up job. All right, SARS-CoV-2 variants. There's now a disclaimer when you go here, and I think this is important because one of the questions I got today is, how reliable is this wastewater, these variants, what's going on? Before you can even look at the data, you got to close this box that says, due to low numbers of sequences being reported to CDC, precision in the most recent reporting period is low. CDC is moving to longer reporting periods to gather the number of sequences required to provide reliable Nowcast estimates.

We're seeing out-competition and out-competing by Nimbus NB.1.8.1 compared to LP8.1. We're also seeing this XFG variant rising as the proportion of these variants that we're seeing. Is there a catchy name for the XFG?

VR: I don't know, Daniel. I don't follow any of this.

DG: OK. I'm sure our Canadian colleague has given it a catchy name, just to keep people - I think the big message here is that the variants are changing. They're all now still in the JN.1 lineage. This is an important issue, Vincent.

VR: Stratus.

DG: Yes. Why do I care? Why do I care? The reason I care is, remember that last meeting, and this was actually at the VRBPAC, at the FDA level, where they said, "It's all still JN.1. We think the old vaccines are probably just fine. Maybe the new ones might be a little bit better." By the way, if we stick with the old ones, it seems like everything's good. If we recommend updating them, are you guys going to restrict access?

VR: Right.

DG: Crickets. Crickets. "We're thinking about that. We're not going to tell you." [laughs]

VR: The name for this is Stratus.

DG: Stratus. OK. XFG, I don't know where they got Stratus.

VR: You know what's interesting? Nobody talks about the variants of flu that displace each other every year. Nobody bothers to make a catchy name. They just go ahead and everyone ignores it pretty much because you make a flu vaccine every year, which is what we're doing here.

DG: Yes. It is interesting because that's Moderna's argument for their mRNA flu vaccines. Like, "We can respond so much quicker." Instead of you making a decision six months ahead and saying like, "OK, this year we'll use Victoria, Croatia, Austria," you'll be able to jump in really quickly and say, "Oh no, we're switching to Wisconsin, District of Columbia, Austria version, Victoria, Thailand, Austria." That's their whole idea.

VR: How much time do they actually need to make -

DG: It's about a six-month lead because they got all these eggs, and then you got to put it in the eggs.

VR: I mean the mRNA vaccine. How much does that take?

DG: They say they only need 60 days.

VR: OK.

DG: The cell and recombinant vaccines, actually also, they don't need six months. It's really just the egg-based vaccines that need the lead time. We're still up in the high, majority of the vaccines are egg-based, so they want that extra lead time.

VR: They need egg-xtra time.

DG: Egg-xtra time. I like that. COVID active vaccination immunity. Are those vaccines still working? We know that we've had tens of thousands of people die, hundreds of thousands of people in the hospital, still about 1% of folks with Long COVID. Millions of people still suffering. You try to go to these Long COVID clinics like Mount Sinai, Columbia, talking to Lawrence Purpura yesterday, months and months of waiting lists, because so many people are still suffering with Long COVID.

It's a problem. Can we do anything about it? We have the article, “Estimated 2023-2024 COVID-19 Vaccine Effectiveness in Adults,” published in *JAMA Network Open*. Test-negative design, vaccine efficacy case-control study conducted using data from September 21, 2023, to August 22, 2024. From emergency departments, urgent care centers, hospitals, six U.S. healthcare systems. Very robust. They're using this case patients with those with a positive molecular antigen test, control patients with a negative molecular test. This is that case-negative approach that certain people seem unable to understand.

Main outcomes were COVID-19-associated ED, urgent care encounters, hospitalizations, critical illness, ending up in the ICU or in the hospital, death. We've talked about the fact that doesn't even capture all that post-discharge mortality. Basically, what do we get? 345,639 eligible encounters, median age 53. The vaccine efficacy against COVID-19-associated emergency department and urgent care encounters was 24%. Among 111,931 eligible hospitalizations, we're seeing that during the seven to 290 days after vaccine efficacy was 29% against hospitalization, 48% against COVID-19-associated critical illness.

There's a really nice chart where you can actually look at the vaccine efficacy. Really what's

interesting, I thought, was particularly looking at the high-risk folks received two in-season COVID-19 doses. You follow that recommendation, you get your first dose, you get your second dose, and you're actually seeing this adjusted vaccine efficacy really favoring getting that second dose in these high-risk folks.

VR: We don't know what variants these people have. We don't know what vaccines they're getting, except for the ones that get two a year. It must have gotten the latest ones, right?

DG: Yes. All right. We also have the article, "RECOVID," I thought that was catchy, "Retrospective Observational Study of Renal Outcomes and Long-Term Mortality in Patients with COVID-19-Associated AKI," acute kidney injury, "A Comparison Between Vaccinated and Unvaccinated Patients." Vinay Prasad wasn't talking about this. What about protecting kids and adults and everyone from kidney issues? Here we have a cohort study. 972 adult patients admitted with COVID-19 infection, acute kidney infections at a large urban academic medical center.

They found that unvaccinated patients had a higher rate of requiring continuous renal replacement therapy during their hospitalization compared with vaccinated patients. You can see that was 15.8 versus 10.9. The continuous renal replacement therapy during hospitalization was significantly associated with in-hospital death, basically tripling it. Long-term follow-up death also adjusted hazard ratio of 2.4. In an adjusted multivariable analysis, those who were unvaccinated had significantly increased hospital mortality, increased by more than fivefold, and the long-term follow-up mortality also increased fivefold.

VR: Daniel, what's the mechanism of kidney injury in COVID?

DG: There's a couple different things, but the biggest thing we're thinking is this inflammatory response. You get the cytokine, you get all the damage that follows.

VR: What's the incidence roughly?

DG: What is the incidence? It's a good number. I don't know off the top.

VR: Is it considered a Long COVID, or is it resolved?

DG: Sometimes it can be long. It can actually turn into Long COVID.

VR: All right.

DG: Here we're seeing acute issues, acute renal replacement, and actually, acute mortality. No, these are good questions. It's really important to have a sense of number needed to treat to protect these folks. All right, COVID early viral phase. We still have the guidelines. Number one, still recommended Paxlovid, but as we keep hearing issues with access, issues with pricing there. Number two, remdesivir. Number three, molnupiravir or convalescent plasma. Still, unfortunately, seeing folks end up in that early inflammatory phase where folks end up either being eligible for steroids or anticoagulation, pulmonary support, remdesivir, immune modulation.

I will move us into Long COVID, late phase, PASC. The article, "COVID-19 and Cognitive Change in a Community-Based Cohort," published in *JAMA Network Open*. These results are from a multicenter prospective cohort study from 2016 to 2022. 3,525 participants alive on March 1, 2020, enrolled in the ARIC study, the Atherosclerosis Risk in Communities study,

and the Collaborative Cohort of Cohorts for COVID-19 Research study.

Basically, they took these cohorts and they're going to use them to make this assessment. You end up with 3,525 eligible participants. You get 307 that end up with SARS-CoV-2. You end up with 33.6, so 103 of those folks end up hospitalized. They're actually going to report to us that the decrease in cognitive function was faster among patients hospitalized for infection, but not different from participants who were infected but not hospitalized. The association among participants hospitalized for infection was evident in cognitive domains of memory and executive function.

VR: It's interesting. The severity of illness, it doesn't matter apparently, right?

DG: I guess the issue, the severity relative to hospitalization. If you end up sick enough to go to the hospital, then we're going to see cognitive impacts of that.

VR: If you're sick and you don't go to the hospital, the same amount of cognitive impact as well?

DG: You see the normal age-appropriate, or age-appropriate is what I call it, but the age-expected cognitive decline is the same, but the people that end up in the hospital, they have more of a drop in cognitive. That's another thing that people don't consider. If I can get vaccinated, if I can end up not getting COVID, if I can end up not getting COVID and hospitalized, if folks can do that, then have some impact on cognitive function. I'm happy with my cognitive function. I don't want to lose any more of it.

VR: With the reduced accessibility of vaccines, we're going to see this increase, unfortunately.

DG: Unfortunately, I think that's true. Yes. All right. Our last article, "SARS-CoV-2 Infection and New-Onset Type 1 Diabetes in the Post-Acute Period Among Children and Young People in England," published in *Diabetic Medicine*. Here they looked at a population cohort of over a million, so we've got 1,087,604. They found that the hazard of developing type 1 diabetes was significantly higher among those exposed, basically those that got SARS-CoV-2 infection, those with COVID-19.

It was actually a range depending upon the comparison cohort. More than double, actually, in looking up to even a sevenfold increase, depending upon the comparison cohort, but really a significant increase in the development of type 1 diabetes, getting a SARS-CoV-2 infection.

VR: Again, this is probably an inflammatory disease, right?

DG: Yes, that's what we're thinking, because the diabetes type 1 is actually targeting the beta islet cells, the production of insulin, destroying those, ending up with diabetes. These are pretty significant. I know this isn't something that people at FDA and the CDC, the current CDC ACIP group look at, but this is important stuff. You've got all these kids who, for the rest of their lives, are going to be living with type 1 diabetes. As we know, these vaccines can reduce your risk of getting COVID and they certainly can reduce the severity.

I used to have this last section, low and middle-income countries, but now I'm just going to basically be like all of us, including the U.S., no one is safe until everyone is safe. We're

speaking up, we're sharing the science, we're trying to communicate, fill this vacuum, but we need your support. This is all about you. This is all about the *MicrobeTV* and Parasites Without Borders family. Pause what you're doing, go to parasiteswithoutborders.com, click Donate. Even a small amount helps.

May, June, and July, we're doing our Foundation International Medical Relief of Children fundraiser. Again, hoping to double your donations, hoping to send that maximum donation of $20,000 to help support the great work of FIMRC.

VR: It's time for your questions for Daniel. You can send yours to daniel@microbe.tv. Jonathan writes, "A doctor friend recommended I reach out to you with my question. I had chickenpox as an adult in '91. I received Zostavax November 2015. I received Shingrix twice, January 2020, June 2020. My doctor friend told me I needed to have the two Shingrix shots within three months of one another. We read up online, and it was a three- to six-month window. I'm about a week outside the window. Should I worry about this? Am I covered for shingles, or do I need to schedule another round of vaccines? Please advise."

DG: Looking at the science, Jonathan, I really don't see there's a problem here. Looking strictly at the recommendations, yes, you're just really in trouble here. No, Jonathan, I don't think those seven days are a game-changer. We were talking today about this sepsis criteria. It's one number above or below a cut off and you get the point or not. I think you're OK.

VR: Christine writes, "Thanks for all you do and for being a reliable source of truthful scientific information. I'm writing because I'm very concerned about the price of Paxlovid for myself and the other seniors in my community. I'm a retired physician, so I'm not a stranger to insurance coverage problems. Are you aware that in recent months, a Paxlovid prescription is costing even well-insured seniors on Medicare with Part D prescription drug plans thousands of dollars for a single five-day course?

I currently have a friend who decided to suffer through her case of acute COVID without Paxlovid because it would have cost her $2,000. I'm in my late 60s, as are most of my friends. We're in Northern California. We're all insured with Medicare, a Medicare supplemental and Part D drug coverage. I also know some people with Kaiser Medicine Advantage plans.

In the last few months, many of us have been prescribed Paxlovid, either to have on hand for travel or for an active case of COVID. We have various Part D Medicare prescription drug plans, including Cigna, Aetna, Wellcare, Kaiser. Everyone I've talked to has been told it will cost at least $2,000 to $2,500 to pick up the prescription at the pharmacy. This seems like a disaster for higher-risk seniors without limitless means seeking appropriate care. I spent hours on the phone with my insurance company and the pharmacy trying to understand why Paxlovid isn't better covered for people who need it most. Any ideas?"

DG: This is terrible. I think we've talked about, in the past, this program called PAXCESS. I'm going to make sure that's still available, and if it is, leave in links where you can go and hopefully help you access it. Just checking now in real time as we're chatting. There still is this patient support program, the PAXCESS. I'm going to leave in a link, paxlovid.pfizerpro.com/access-resources/access. This will just make that really hard on people, but I'll keep leaving that in the notes.

I'm sorry, Pfizer, this is excessive, $2,000. I don't know if it's Pfizer charging that much as

some kind of markup at the pharmacy. Why have a product? Why do it this way where you're restricting access with the financial burden? Chris, right here in your section, we'll try to get this up, this Paxlovid PAXCESS program, to help people, because it sounds like people are doing the right thing. They're trying to follow the guidance. They're trying to reduce their risk of bad outcomes, and now there's this - That's huge, $2,000. $2,500. That's just way too much.

VR: Jeff writes, "This article is making the rounds, and I would be grateful to hear your thoughts and analysis. I find both the authors and the conclusions a little concerning, and this is a *medRxiv* article, "Twelve-Month All-Cause Mortality after Initial COVID-19 Vaccination with Pfizer-BioNTech or mRNA-1273 among Adults Living in Florida." The senior author is Joseph Ladapo, the surgeon general of Florida, Daniel. "They conclude that Florida adults who received BNT162b2 had significantly higher risk of 12-month all-cause for cardiovascular COVID and non-COVID mortality compared to matched mRNA-1273 recipients."

DG: I'm looking at this now, but it's disturbing. Vinay Prasad will tell you that there's a healthy vaccinee bias, that more healthy people are more likely to get vaccinated, but we actually know as clinicians that you're going to encourage your higher-risk patients to go get vaccinated. If you have a discussion, you say, "All right, listen, you're 35, you don't want to do it, you have no health issues." I'm not going to spend a huge amount of resources trying to go through the science, but if you're 82 and you've got heart disease and other things.

There's really an unhealthy vaccinee bias. If you look at the people, you say, "Oh, but we tried to correct for everything." Again, this is you start off with your ideology, you start off with your conclusion, and then you rig a study. Yes, that's hopefully why it's still just sitting here as a preprint. If this ever gets through any kind of peer review, then all those limitations can be addressed, but that's really a concern. Science is the arena where we investigate and then we find truth. We don't invent our own truth and then invent science to support it.

VR: This is a classic example of confounding issues in a real-world study where you don't have the ability to select populations. You're just looking at the data and you don't know, as you say, one population has a lot of issues unrelated to vaccination and they don't control for that at all. You can't. It's very difficult to do that, and so you cannot make these kinds of conclusions.

DG: Yes, it's really - These will be the things, this will be out there tweeting them about.

VR: Yes. The problem is that these are preprints. They may never see the light of day, but they get tweeted. Ladapo is the guy who famously said these are deadly vaccines we shouldn't be using. He has a bias, as you say, and is trying to find something to support that.

DG: Yes, and he's not only trying to find it, he's trying to create it.

VR: Linnea writes, "Longtime *TWiV* listener from Alberta, Canada. Really appreciate your work explaining the lies about vaccines being spread by the current administration because they have spread to Canada. The Alberta provincial government has decided to become inspired by the RFK Jr. recommendations for COVID vaccines, and now COVID vaccines are no longer going to be free for most people, including healthcare workers, as of August. In their press release, they included some quick facts to defend their decision."

Listen to this, recently, the Federal Drug Administration in the U.S. - There's no such thing as the federal drug. It's the Food and Drug Administration. Even Canadian officials can't get it right. Stop recommending COVID vaccines for pregnant women and healthy children.

Back to Linnea, "It's horrifying, and appreciate your work dismantling the lies more than ever right now. Not sure how to manage the situation, but along with an alarming amount of measles outbreaks, it's arrived here in Alberta and isn't going away anytime soon with our current anti-science provincial government."

DG: No, it's really disturbing, and it is challenging. We're going to keep communicating. We're going to keep walking through this. We're going to keep providing the facts. There are the people out there that they know that these things are untrue, but you can make a lot of money off getting someone to buy your nutraceuticals. You can get a lot of money getting that person selling nutraceuticals to pay you to get up on stage and say anti-science, anti-vaccine things. Unfortunately, there's a multi-billion-dollar industry driving this. We're not a multi-billion dollar industry. We're going to continue to stand firm to our oaths and our principles and keep communicating the actual information.

VR: Finally, John writes. "Been listening to you and the crew since mid-2019. Love it all. Question: When I started college, I had no vaccination records. I received a measles shot on December 9 and then again on December 12 from the health clinic." Same year. "Based on everything I've heard, three days later," right, Daniel?

DG: Yes, I'm trying to figure, was it the same one? What's the story here?

VR: This doesn't follow any kind of recommended cadence. "Since no beta cells had a chance to mature between shots -" I don't know what the beta cells are. The B cells.

DG: Maybe B cells, yes.

VR: "It seems like I should get another one, but it has been 11 years. Already missing Dickson. Going back to listen to all his jazz recommendations again. Would love a compiled document of all his recommendations if anyone has the time out there to spend." John puts the CDC recommendations here with two-dose series at least four weeks apart.

DG: Not three days, not three days.

VR: Should he get another series?

DG: You should actually figure out what that vaccine was. It's the measles, and three days apart. Yes, you need to get that second shot. Get that second shot, it's been more than four weeks. [laughs]

VR: That's *TWiV* weekly clinical update with Dr. Daniel Griffin. Thank you, Daniel.

DG: Oh, thank you, and everyone, be safe.

[music]

[00:57:36] [END OF AUDIO]