COMMENTARY

Vaccine-Induced Myocarditis Concerns Demand Respect, Not Absolutism

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Editor's note: Find the latest COVID-19 news and guidance in Medscape's Coronavirus Resource Center.

For the first half of 2021, the mRNA vaccines looked to be near perfect. The trials reported more than 90% efficacy for the Pfizer and Moderna vaccines. Both provided near 100% prevention of *severe* COVID-19 and after hundreds of millions of adults received the shots, no signal of harm emerged.

I, like any rational person, see a positive benefit-harm ratio from the vaccines for adults.

Younger People?

After a "positive" trial in which just over 1100 kids aged 12 to 15 years received an mRNA vaccine, a movement arose to vaccinate young and old alike. I put "positive" in quotes for two reasons: The first is that this trial measured noninferiority of the immune response, not clinical outcomes. That was necessary because so few kids get sick with COVID-19. The other reason is that the authors claimed a favorable safety profile, but 1100 kids is not enough to inform the safety of a vaccine that will be given to many millions.

Then came a signal of myocarditis in young people, then another, and another, and now one in slightly older (median age, 25 years) military recruits. These reports complicate matters because young people have the lowest risk from COVID-19.

A debate arose: some argued to slow the deployment of vaccines for children, while the CDC noted that the benefit-harm profile is favorable.

The aim of this column is to argue that when it comes to vaccinating young people at low risk from the virus, parents and younger people should be allowed to weigh the vaccine decision with their clinicians without anyone being tarred as an antivaxxer.

What About the Myocarditis?

Medicine is full of euphemisms that hide reality: we say "cardioversion" instead of "shock"; "ablate" instead of "burn"; "fibrosis" instead of "scar." The term "myocarditis" sterilizes and obscures heart injury due to excess inflammation.

Emergency medicine doctor and frequent contributor to the *New York Times*, Jeremy Faust, MD, called postvaccine myocarditis "self-limited troponinemia." CDC director Rochelle Walensky, MD, recently described postvaccine myocarditis in young people as "mild."

I disagree; calling myocarditis mild reminds me of the saying about minor surgery. Minor surgery is surgery on someone else; mild myocarditis is something that happens to other folks' kids.

Humans have only one heart; inflaming it at a young age is not a small thing.

University of Michigan cardiologist Venk Murthy, MD, a specialist in imaging, rebutted the "mild" framing with comments on Twitter: "people with myocarditis are usually counseled to limit activity, placed on 1 or more meds and are at lifetime increased risk of cardiac complications. This can have profound consequences."

As an electrophysiologist, I see the complications of myocarditis: heart failure and ventricular arrythmia due to scar. Availability bias notwithstanding, heart rhythm doctors feel the asymmetry of myocarditis risk. Although it is true that most myocarditis resolves without issue, it is also true that sometimes it does not.

A radiologist who reads cardiac magnetic resonance scans might oppose this framing by saying myocarditis occurs on a spectrum and even patients with severe myocarditis mostly recover. Pediatricians might counter my framing by saying that most of the affected kids recovered and were discharged *from the hospital*. Public health experts could argue that 300-plus kids died of COVID-19 and no one as yet has died from the vaccine, so the benefit-harm ratio favors the vaccine.

These are all true statements, but that's not how people make medical decisions. Regular people are not emotionless robots who decide using odds ratios. Most people do not *calculate* risk, they *feel* risk. People have special circumstances and

make judgments relative to *their* benefit-harm situation. To persuade people with charts and statistics belies an understanding of clinical practice.

For example, let's say the parents (or grandparents) of a teenager have pre-existing conditions. These special circumstances tip the balance, and the parents decide to vaccinate the adolescent. Contrast that with, say, young parents who have no risk factors. This family feels less risk from the virus, and they might feel more regret if their child developed myocarditis. They want to see more data before making the decision.

Both scenarios depict rational decision-making. It's how medical decisions should be made: with judgment and benefit-harm balances and considerations of special circumstances.

Stats and Data

At the June 23 FDA meeting, Tom Shimabukuro, MD, gave a vaccine safety update, and two CDC doctors (Megan Wallace, DrPh, and Sara Oliver, MD) gave a benefit-risk discussion of mRNA vaccines in young people.

They both used many slides. Yet I need only two data points to support my argument that parents and adolescents should be allowed to make judgments based on their unique situation.

The first is slide 13 of the benefit-risk presentation, which shows the risk for hospitalization in a young person *in the last 3 months* from COVID-19 as less than 1 in 100,000. The other comes from slide 27 of the Shimabukuro talk, which shows the rate of myocarditis in 12- to 17-year-old boys after the second dose of mRNA as 132/2,039,871, or about 6/100,000.

Suffice it to say that rates that low allow for consideration of special circumstances and judgment. But that's not what has happened. The CDC concluded "the benefits still clearly outweigh the risks for COVID-19 vaccination in adolescents and young adults," and in a tweet with 500 retweets, Faust listed the stats and concluded: "#vaccinate," with a peace sign emoji.

What About Societal Good?

Some might argue that shared decisions don't apply to communicable disease prevention. Vaccination of an individual helps others by reducing transmission and promoting herd immunity. For example, human papillomavirus vaccine in boys reduces the future risk for cervical cancer in women.

I see two problems with this argument in the case of SARS-CoV2.

The mRNA vaccines are so effective at preventing severe COVID-19 disease that US citizens need not depend on others for protection. If someone wants to be protected, they can simply get the shots. Recent reports from Israel on the rise of cases due to the Delta variant support my point: these were *cases*, not hospitalizations.

The second problem with the societal-good argument is that the signal of myocarditis from the vaccine is strong enough to be more than correlation. I am not an ethicist, but it seems dubious to force young people to expose themselves to a risk for an unknown benefit to society. Once again, data from Israel are instructive: cases and hospitalizations plummeted earlier in the year without mandating vaccinations in the young.

Other countries see the need for nuance in vaccinating the young: advisors in the United Kingdom have decided not to support vaccination for kids under 18. In Germany, the Standing Vaccination Commission advised that only children with pre-existing conditions receive the vaccine. And the Dutch health counsel has invited kids with pre-existing conditions or those living in a household with a family member who cannot be vaccinated to receive the mRNA vaccine.

Benefits of Waiting

The recent FDA presentation on myocarditis provided three clear signals. There were many more cases after the second shot; males were more often affected; and the age groups with the highest incidence were 16- to 24-year-olds.

Given the extremely low levels of circulating SARS-CoV2 in the United States, public health experts have time to consider different options for young people: would one shot (especially in younger males) offer a better benefit-harm calculus? Should we study lower doses in children? Should we test young adults for signs of recovered infection and delay vaccination in those with natural immunity?

Conclusion: The Danger of Absolutism

In the United States, rates of vaccine uptake among vulnerable adults remain less than ideal. This is not from lack of knowledge. Americans can now observe the vaccine efficacy directly from the evidence in the digital space but also in their communities where cases have plummeted.

In my clinic, I occasionally see at-risk adults who refuse the vaccine. This makes me intensely curious. These are folks taking preventive cardiac medications with a fraction of the efficacy of the (free) mRNA vaccines.

I could be wrong, but I can't help thinking that absolutism about vaccine decisions in the young, or the minimization of harm from myocarditis, might reduce trust in messaging.

Consider that earlier in the pandemic there was intense coverage of a flawed paper on myocarditis after SARS-CoV2 infection. Hundreds of news outlets wrote scary headlines, and college sports were almost canceled. Subsequent studies found no evidence that the virus had any special proclivity for heart inflammation.

A neutral observer might wonder: well, if folks were that excited about myocarditis in young people after the infection, why are they not equally worried about this early signal of harm from the vaccine?

As I write this column, many major universities will mandate vaccines for college-age kids. Some hospitals will require the mRNA vaccines for *all* employees—including the 18-year-old who works in engineering, has no patient contact, and who recovered from COVID-19 a few months ago.

Maybe, just maybe, a more humble and nuanced approach to vaccination in low-risk young people would improve trust and vaccine uptake?

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