Q&A: COVID-19 Vaccine and Myocarditis - August 2021

This document serves to provide answers to questions recently (July 23, 2021) posed by individual Chapter members regarding the perceived risk of cardiac myocarditis in adolescents who have been immunized for COVID-19. The following is a compilation of responses by the state's pediatric cardiology and infectious disease community.

Unless otherwise noted, responses below from David Kimberlin, MD, FAAP, Professor of Pediatrics, Co-Director, Division of Pediatric Infectious Diseases, The University of Alabama at Birmingham and AAP liaison to the Advisory Committee on Immunization Practices:

How concerned should we be about the connection between the COVID vaccine and myocarditis?

As one of two AAP liaisons to the CDC Advisory Committee on Immunization Practices, I prepare the AAP minutes of the ACIP meetings. Here are the notes that I took on June 23 at the ACIP meeting on myocarditis and booster doses. In addition, I pulled out of this document the following key points:

Myocarditis/pericarditis per million doses administered in VSD and VAERS using a 21-day window (VSD) and no restriction (VAERS) are summarized as follows:

	All (chart confirmed in VSD)	Females (ICD10 in VSD)	Females (crude in VAERS)	Males (ICD10 in VSD)	Males (crude in VAERS)
Dose 1	4.4	1.9	0.8 -1.5	4.7	2.0 -9.8
Dose 2	12.6	4.7	1.8 -9.1	32.0	10.0 -66.7

Baseline rates of myocarditis are 1 to 10 cases per 100,000 persons per year. Data available to date suggest a likely association of myocarditis with mRNA vaccination in adolescents and young adults.

A summary of the clinical features of myocarditis following mRNA vaccines are that it occurs most commonly in males < 30 years of age, and symptom onset clusters in the week following vaccination. Early data of acute outcomes have been good. Many cases have been hospitalized, but usually for short durations of time. No long-term data available yet. COVID-19 incidence, hospitalization, and mortality rates are decreasing overall. Variants continue to spread, and scenarios exist in which cases increase in fall. Adolescents are a growing proportion of cases given vaccine coverage among adults. Post-COVID-19 conditions also impact adolescents and young adults, with 4,018 MIS-C cases have been reported to national surveillance. Myocarditis is a disease marked by inflammation of the heart muscle, risk factors for which include younger age and male sex. It can occur with SARS-CoV-2 infection. Myocarditis after mRNA vaccines has been noted with highest frequency in males aged 12–29 years following a second vaccine dose. Early outcomes have been encouraging, but no long-term data are available yet.

Multiple real-world effectiveness studies from the United States and other countries demonstrate that a two-dose mRNA COVID-19 vaccination series in age groups for which the vaccine is recommended is effective. Against SARS-CoV-2 infection, efficacy ranges from 64–99%, and against COVID-19-associated hospitalization it is 87–97%. With the current U.S. exposure risk calculated over 120 days, for every million doses of mRNA vaccine the hospitalizations prevented versus cases of myocarditis are graphed visually as follows:
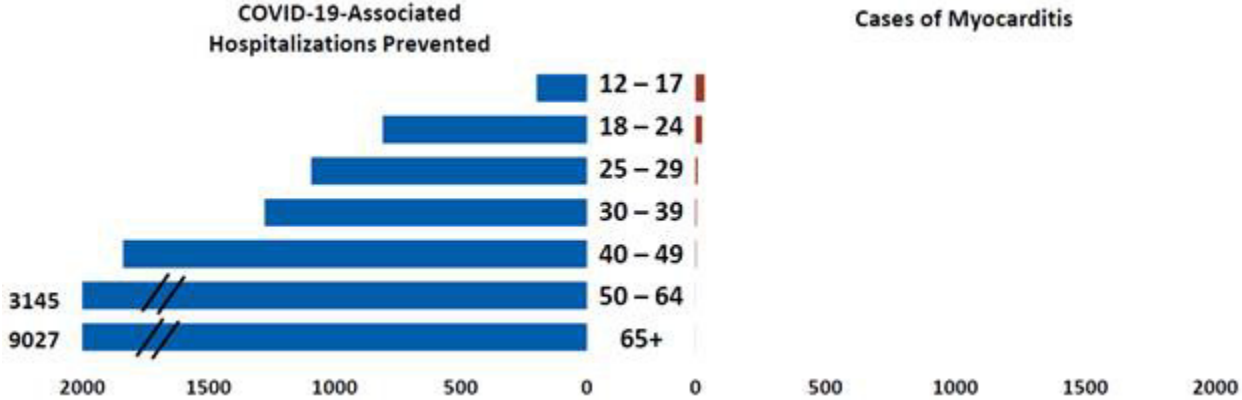
Predicted cases prevented versus myocarditis cases for every million second dose vaccinations over 120 days are as follows:

	COVID-19 cases prevented	Hospitalizations prevented	ICU admissions prevented	Deaths prevented	Myocarditis cases
Females 12-17 years of age	8,500	183	38	1	8-10
Males 12-17 years of age	5,700	215	71	2	56-69
Females 18-24 years of age	14,000	1,127	93	13	4-5
Males 18-24 years of age	12,000	530	127	3	45-56
Females 24-29 years of age	15,000	1,459	87	4	2
Males 24-29 years of age	15,000	936	215	13	15-18

Benefit-risk interpretations and limitations were discussed next. Direct benefit-risk assessment shows a positive balance for all age and sex groups. Benefits are likely an underestimate since the analysis was performed using reported rates of cases and hospitalizations but this likely represent only a fraction of the true cases that have occurred in the population. There is some uncertainty about the rates of myocarditis after mRNA vaccines; not all cases are verified, and crude rates were used. The balance of benefits and risks could change with increasing or decreasing incidence. There currently are limited data on the risk of myocarditis in the 12–15 year old population due to the timing of recommendations and the limited number of second doses given to date.

Given the rarity of the occurrence of myocarditis following COVID vaccination and the favorable outcomes when it occurs, the ACIP and the AAP both continue to strongly support COVID vaccination in eligible people. Here is the [AAP public statement](#) that was released on June 23. In addition, here is the [Advance Release MMWR](#), which came out three days ago.

Responses from pediatric cardiologists Cam Hebson, MD, (UAB) and Lynn Batten, MD, FAAP (USA):

The cases of vaccine-related myocarditis seen at UAB (n = 4, at time of writing) have all been mild. None of the patients have had cardiac dysfunction and all of them have had resolution of symptoms within a few weeks of presentation. One of the four had evidence of myocardial information on a cardiac MRI, but the others have had normal MRIs. We have also reported our data to a larger author group across the country and from the preliminary data I've seen back from that group that has been the typical presentation. COVID-associated myocarditis and MIS-C have been worse overall from a presentation standpoint and this is just cardiac disease, not even including the other manifestations. So we are still recommending vaccination for all of our eligible patients, even those who have significant congenital heart disease.

Cases of COVID myocarditis I've seen here at USA have all needed admission (many have shown up with GI complaints and have been worked up for appendicitis, etc., then dropped their blood pressures and subsequently were found to have myocardial dysfunction on ECHO, elevated troponin, etc.).   Most have recovered quickly, but some have needed intubation and/or inotropes. One 16-year-old patient who presented with COVID and cardiac arrest last year actually recovered slowly, wore a LifeVest for six months in case of ventricular arrhythmias, was doing great for four months, and then passed away suddenly. Her autopsy is pending. In my reading of the cases of myocarditis post-vaccine, the myocarditis has simply been chest pain, prompting a troponin which was elevated - and that's all you need for the diagnosis of myocarditis. I haven't seen that any of those patients needed inotropes or intubation, and their symptoms subsided quickly. That said, I did receive a Doximity update about an 18-year-old who died in his sleep shortly after getting his second vaccine, but his autopsy was also pending. That certainly gives me pause even though this is just one case, so I'm sharing what I've said above with parents and letting them make their decisions with no pressure from me.

How does the COVID vaccine cause myocarditis? This possibility alone can prevent my practice's parents from getting their children vaccinated for COVID.

We do not know at this point. This is expected, though, since the association with the vaccine was recognized only about seven weeks ago [at time of writing]. The thought is that it is really a manifestation of the inflammation from the vaccine, which is also why injection site pain, low-grade fever, etc., can happen. The degree of inflammation following vaccine administration is much, much less than during COVID disease, and in parallel, myocarditis is less common and less severe when following vaccine administration than it is during disease.

Response from UAB pediatric cardiologist Cam Hebson, MD:

I'm not completely sure, but I have told families so far that I think it is due to the inflammation the vaccine induces that somehow is specific for the heart in a few patients.

How do you diagnose and treat myocarditis? I wasn't trained for that. I've never seen it. How will I know if one my patients gets it? And if I can learn how to diagnose it when it happens, what do I do next?

The following was presented at the June 23, 2021, ACIP meeting. Symptoms and diagnostic findings of preliminary myocarditis/pericarditis reports after mRNA COVID-19 vaccination under review and limited to ≤ 29 year olds (N=484) (data through June 11, 2021), are as follows:
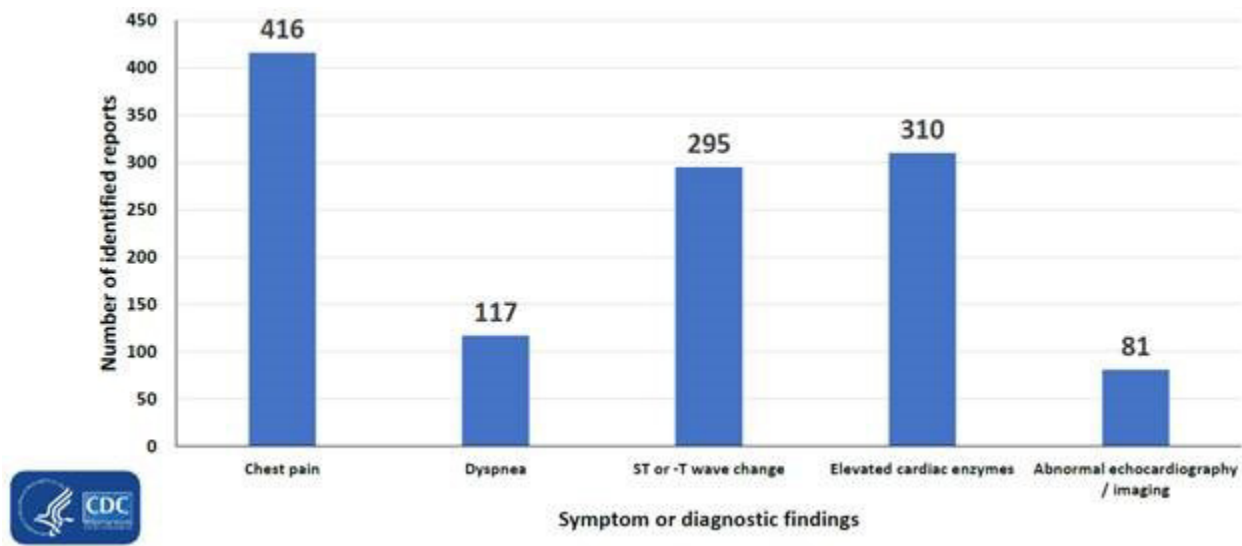
Response from UAB pediatric cardiologist Cam Hebson, MD:

Diagnosis is based on clinical presentation (chest pain, fever, nausea, vomiting, sometimes respiratory difficulty), blood tests (elevated troponin), and abnormalities in cardiac testing (EKG, echo, MRI). Viral testing to designate the cause is also performed. All of the patients I have seen with vaccine-myocarditis so far have presented with a majority of these symptoms ~2 days after the 2nd Pfizer vaccine. These patients should be seen if they seem "mild" or just sent to the ER if more than this for evaluation. Treatment includes IVIG to help treat the inflammation (or virus itself, if present), symptom relief with NSAIDs, and sports restriction.

Why are we vaccinating teens anyway? From what I have gathered, the only ones under the age of 18 who have had complications or died from COVID infections were immuno-compromised.

Please see the attached meeting minutes of the May 12, 2021, Advisory Committee on Immunization Practices (ACIP) meeting taken by David Kimberlin, MD, FAAP, for the AAP Committee on Infectious Diseases (the Red Book Committee). Rather than summarize this data, we are including these minutes, which are comprehensive.

Response from UAB pediatric cardiologist Cam Hebson, MD:

We have had two cases of COVID-related myocarditis in the last two weeks. One patients was fairly mild and similar to the vaccine-related patients. The other was EXTREMELY sick and required ECMO. I think she is going to pull through but she definitely would have died without extreme measures being taken and some luck.