



## Talking Points About the Pfizer and Moderna COVID-19 Vaccines and Reports of Myocarditis

May 26, 2021

**Background:** Rare cases of myocarditis (swelling of the heart muscle) reported by an ACIP work group on May 17, 2021, are raising new concerns about the Pfizer and Moderna (mRNA) vaccines.

The cases of myocarditis, or swelling of the heart muscle, reported by people who received the Pfizer or Moderna vaccine have been rare and are not known to be related to the vaccines.

About 285 million doses of COVID-19 vaccines have been given in the U.S. and only several cases of myocarditis were reported.

- It is not known if these rare cases of myocarditis are connected to the vaccines.
- Since the cases are rare and mostly mild, the benefits of the COVID-19 vaccines still far outweigh the rare, possible risk of heart complications.
- As with other reported adverse events, the few cases of myocarditis that have been reported after COVID-19 vaccination are being investigated.

Myocarditis is swelling of the heart muscle and usually results from a viral infection, such as the flu, Lyme disease, and also COVID-19 disease.

- Myocarditis can affect the heart's electrical system, reducing its ability to pump blood to the rest of the body.
- This causes rapid or abnormal heart rhythms, called arrhythmias, or clots that may lead to a stroke or heart attack.
- Myocarditis may also develop in children and adolescents who have <u>multisystem</u> <u>inflammatory syndrome (MIS-C)</u>, a reaction to medicine, or it may be part of a general inflammatory condition in the body.
- About 10 to 20 people out of every 100,000 people in the U.S. are diagnosed with myocarditis each year.
- Myocarditis is treatable, and many get better on their own or with treatment and fully recover.

The cases of myocarditis that were reported are mostly in male adolescents and young adults.

- In reported cases, symptoms showed up more often following the second dose of the Moderna or Pfizer vaccines than the first dose.
- Symptoms also typically appeared within four days after receiving a second dose in reported cases.
- Most of the reported cases were mild.

## Anyone who has signs or symptoms of myocarditis, especially chest pain or shortness of breath, should call their doctor.

- If symptoms are severe, go to the emergency room or call 911.
- Other symptoms are tiredness; rapid or abnormal heart rhythms (arrhythmias); fluid retention; and swelling of legs, ankles, and feet.
- Some symptoms are the same as a viral infection: headache, body aches, joint pains, fever, sore throat, or diarrhea.
- Early in the illness, or if it is a mild case, there can be little to no symptoms.
- In children, symptoms may include fever, fainting, fast breathing, difficulty breathing, and rapid or abnormal heart rhythms.

## These cases <u>were reported</u> by the COVID-19 Vaccines Safety Technical Work Group (VaST), so healthcare providers would be aware and could begin appropriate treatment when needed.

- VaST conducts independent and rapid reviews of safety information for the U.S. COVID-19 vaccination program and then provides summaries of their findings to the Advisory Committee on Immunization Practices (ACIP).
- Ten independent expert consultants make up this work group along with members from other federal agencies and organizations.
- The ACIP is a committee comprised of medical and public health experts, doctors, and scientists who develop recommendations on the use of new and existing vaccines for the U.S. population.

## **More Information**

The American Heart Association released the following <u>statement</u> on May 23, 2021: The benefits of COVID-19 vaccination enormously outweigh the rare, possible risk of heart-related complications, including inflammation of the heart muscle, or myocarditis. The American Heart Association/American Stroke Association, a global force for longer, healthier lives, urges all adults and children ages 12 and older in the U.S. to receive a COVID vaccine as soon as they can.

We strongly urge all adults and children ages 12 and older in the U.S. to receive a COVID vaccine as soon as they can receive it, as recently approved by the U.S. Food and Drug Administration and the CDC. The evidence continues to indicate that the COVID-19 vaccines are nearly 100% effective at preventing death and hospitalization due to COVID-19 infection. According to the CDC as of May 22, 2021, over 283 million doses of COVID-19

vaccines have been administered in the U.S. since December 14, 2020, and more than 129 million Americans are fully vaccinated (i.e., they have received either two doses of the Pfizer-BioNTech or Moderna COVID-19 vaccine, or the single-dose Johnson & Johnson/Janssen COVID-19 vaccine).

We commend the CDC's continual monitoring for adverse events related to the COVID-19 vaccines through VAERS and VSD, and the consistent meetings of ACIP's VaST Work Group, demonstrating transparent and robust attention to any and all health events possibly related to a COVID-19 vaccine. The few cases of myocarditis that have been reported after COVID-19 vaccination are being investigated. However, myocarditis is usually the result of a viral infection, and it is yet to be determined if these cases have any correlation to receiving a COVID-19 vaccine, especially since the COVID-19 vaccines authorized in the U.S. do not contain any live virus.

We remain confident that the benefits of vaccination far exceed the very small, rare risks. The risks of vaccination are also far smaller than the risks of COVID-19 infection itself, including its potentially fatal consequences and the potential long-term health effects that are still revealing themselves, including myocarditis. The recommendation for vaccination specifically includes people with cardiovascular risk factors such as high blood pressure, obesity and type 2 diabetes, those with heart disease, and heart attack and stroke survivors, because they are at much greater risk of an adverse outcome from the COVID-19 virus than they are from the vaccine.

We also encourage everyone to keep in touch with their primary care professionals and seek care immediately if they have any of these symptoms in the weeks after receiving the COVID-19 vaccine:

- chest pain including sudden, sharp, stabbing pains;
- difficulty breathing/shortness of breath;
- abnormal heartbeat;
- severe headache;
- blurry vision;
- fainting or loss of consciousness;
- weakness or sensory changes;
- confusion or trouble speaking;
- seizures;
- unexplained abdominal pain; or
- new leg pain or swelling.

We will stay up to date with the CDC's recommendations regarding all potential complications related to COVID-19 vaccines, including myocarditis, pericarditis, central venous sinus thrombosis (CVST) and other blood clotting events, thrombosis thrombocytopenia syndrome (TTS), and vaccine-induced immune thrombosis thrombocytopenia (VITT).

The American Heart Association recommends all health care professionals be aware of these very rare adverse events that may be related to a COVID-19 vaccine, including myocarditis, blood clots, low platelets, or symptoms of severe inflammation. Health care professionals should strongly consider inquiring about the timing of any recent COVID vaccination among patients presenting with these conditions, as needed, in order to provide appropriate treatment quickly. As detailed in last month's AHA/ASA statement, all suspected CVST or blood clots associated with the COVID-19 vaccine should be treated initially using non-heparin anticoagulants. Heparin products should not be administered in any dose if TTS/VITT is suspected, until appropriate testing can be done to exclude heparin-induced antibodies. In addition, health care professionals are required to report suspected vaccine-related adverse events to the Vaccine Adverse Event Reporting System, in accordance with federal regulations.

Individuals should refer to their local and state health departments for specific information about when and where they can get vaccinated. We implore everyone ages 12 and older to get vaccinated so we can return to being together, in person – enjoying life with little to no risk of severe COVID-19 infection, hospitalization or death.