



The occurrence of myocarditis after the first series of mRNA vaccine for COVID-19 is rare and typically mild; however, the occurrence after booster doses and in children <12 years, and whether there are long-term effects, are unknown.

Hartling L, Pillay J, Bialy L, Gaudet L, Wingert A, Mackie A, Paterson I, Wilhelm L, Trehan N, Skidmore B. Rapid review of incidence, associated risk factors, and clinical course of myocarditis and pericarditis following COVID-19 vaccination. SPOR Evidence Alliance and COVID-END in Canada, 9 November 2021.

Why is all the evidence on this topic being summarized?

- Vaccines for COVID-19 are highly effective for preventing symptomatic infection and hospitalization; however, the safety of the vaccines especially for serious, rare events has been uncertain.
- As early as April 2021, cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the two-layered sac surrounding the heart) were reported after COVID-19 vaccination.
- It is unclear:
 - how frequently myocarditis and pericarditis are occurring
 - who is most often affected
 - what happens to the individuals who get these complications.

What questions did we want to answer?

- What is the incidence of myocarditis and pericarditis after COVID-19 vaccination and does the incidence vary by patient characteristics (e.g., age, sex) or vaccine factors (e.g., type of vaccine, dose)?
- What are the characteristics and short-term clinical course in patients with myocarditis and pericarditis after COVID-19 vaccination?

How have we done this rapid review?

- We searched several electronic databases to find scientific studies. We also searched key national websites (e.g., active or passive surveillance systems or registries) for unpublished data.
- We focused on vaccines that had been approved by Health Canada. We limited studies to those published in English, but did not limit by setting or country.

How up to date is this rapid review?

- The review included studies published up to October 6, 2021 and publicly available data from key national websites up to October 21, 2021.





What are the main results of our rapid review?

- We included 34 studies/data sources in this review.
- The incidence of myocarditis after an mRNA vaccine is low (<1 in 10,000) but probably highest in males 12-29 years, with lower incidences in older ages. In females, the incidence may be very low (12-29 years) or not exist (≥ 30 years).
- Among adult males under 40, the Moderna compared with Pfizer vaccine may be associated with a small increase in risk for myocarditis or (one of) myocarditis or pericarditis. The evidence does not strongly support preference for Pfizer, even in young males.
- Based on studies that provided more details, symptoms of myocarditis typically occur within 2 to 4 days after a second dose. Most cases experience chest pain or pressure. Most cases are hospitalized for a short time (average 2 to 4 days). The vast majority of affected individuals appear to make a complete recovery in the short-term.
- Most cases of pericarditis were unconfirmed and there appears to be more variation in age, sex, time when symptoms begin and rate of hospitalization compared to the cases of myocarditis.

What are the gaps in what we know?

- There is no information currently available about the incidence and course of myocarditis or pericarditis after booster doses and the possibility of long-term effects.
- There is a need for more information about incidence and long-term effects of myocarditis and pericarditis particularly for new groups (children < 12 years old as they start to receive vaccines), after third and subsequent doses, and for those who have already been affected and are receiving a subsequent dose.
- More research on what personal risk factors may put someone at higher risk would be very useful.

What are take-away messages from patient partners?

- A small risk for myocarditis after COVID-19 vaccination seems to exist for young males (<29 years), occurrences appear to be quite mild with full recovery.
- Clear and effective communication of the risks (rates of myocarditis and likely clinical course), benefits from vaccination, and the availability of good alternatives will be critical for individuals and, for young males and their parents. This will help increase their confidence and ability to make decisions about vaccination.
- Getting vaccinated is important for young males (for their contacts and themselves) and recommendations against vaccines, even if cautionary or against a single vaccine, may lead to unnecessary harm from increasing hesitancy. Recommendations could focus on positive guidance about awareness and identification of symptoms for these rare and relatively mild risks.
- Individuals should discuss their concerns about the possibility of adverse events and personal risk factors of vaccination with their doctor.

How confident are we in the results?

- The literature and data on this topic are evolving very quickly, so the findings from this review could change. We have moderate certainty of increased risk of myocarditis in males between 12 and 29 years; however, overall the incidence is low. The description of cases in the literature indicates a fairly consistent mild course of illness, but may not be generalizable to all cases.

