

IPCRG practice driven answers on COVID-19 and respiratory questions



What is the risk and impact of myocarditis for young adults aged 16 to 18 years following a COVID vaccination?

What the research says

As of November 2021, the Pfizer-BioNTech and Moderna vaccines have been authorised for use in young adults aged 16 to 18 years. Many countries have now initiated vaccination programmes that include those aged 16–18 years.

The Pfizer-BioNTech vaccine has been evaluated as suitable for use by the World Health Organization and has Emergency Use Authorization^a from the FDA in this age group. The Pfizer-BioNTech vaccine is already being used in a number of EU and non-EU countries to vaccinate children >12 years of age. The Moderna vaccine is approved for use in those >12 years old in Canada. In the US, the FDA have delayed a decision on the use of the Moderna vaccine in those aged 16–18 years until at least January 2022 in order to undertake a detailed review of the safety data.

An increased risk for myocarditis in adolescents (particularly males) following vaccination with the Pfizer-BioNTech and Moderna vaccines (both of which are mRNA-based vaccines) have been reported. These events appear to be rare and are estimated to affect 70 boys aged 12 to 17 years out of 1 million vaccinations (CDC June 2021).

This compares with a rate of diagnosis of myocarditis of approximately 10 to 20 cases per 100,000 people per year in the US and these cases are usually associated with viral infection (American Heart Association/American Stroke Association 2021). In fact, COVID-19 illness is associated with a higher rate of myocarditis than is observed following vaccination (American Heart Association/American Stroke Association 2021). The events, presenting as chest pain and changes in heart rhythm, are generally mild and temporary, with complete recovery following a period of rest (CDC November 2021). These events occur more often following the second vaccine dose and usually within a week of vaccination.

A number of vaccines are under investigation for use in the 16–18-year-old age group. The results of the CoronaVac (an inactivated SARS-CoV-2-based vaccine) study in a Chinese population indicates that vaccination is safe and induces immune responses in children and adolescents aged 3–17 years (Han et al 2021).

^aAn Emergency Use Authorization permits the use of a medical product that has either not yet received regulatory approval or has not received regulatory approval for a specific indication, to be used in an emergency situation to diagnose, treat, or prevent serious or life-threatening diseases or conditions

What this means for your clinical practice

- Adolescents and their parents/guardians with concerns can be advised that the data suggest the vaccines available for use in those aged 16–18 years of age are safe and effective
- Vaccination should be encouraged in those aged 16–18 years given the potential acute and long-term risks associated with COVID-19 illness and the likelihood that any side effects following vaccination, including myocarditis, are likely to be mild and temporary
- The evidence suggests the risk of serious side effects is small, but more data will emerge on this as the pandemic evolves and vaccination continues
- SARS-CoV-2 vaccine programs should be initiated and delivered according to National guidelines, with vaccines used according to their licenses

Useful links and supporting references

American Heart Association/American Stroke Association. CDC investigating rare myocarditis in teens, young adults; COVID-19 vaccine still advised for all who are eligible.

Available at:

<https://newsroom.heart.org/news/cdc-investigating-rare-myocarditis-in-teens-young-adults-covid-19-vaccine-still-advised-for-all-who-are-eligible>. Accessed December 2021.

CDC COVID-19 mRNA vaccine in adolescents and young adults: Benefit-risk discussion.

June 2021. Available at:

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/05-COVID-Wallace-508.pdf>. Accessed December 2021.

CDC. Myocarditis and pericarditis after mRNA COVID-19 vaccination. November 2021.

Available at:

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html>.

Accessed December 2021.

As of November 2021, a number of phase 1 to 3 studies of various SARS-CoV-2 vaccines are listed in the www.clinicaltrials.gov database in children and adolescents with completion dates ranging from 2021 to 2025. Available at: <https://www.clinicaltrials.gov/ct2/results?cond=COVID-19>. Accessed December 2021.

Han B, et al. Safety, tolerability, and immunogenicity of an inactivated SARS-CoV-2 vaccine (CoronaVac) in healthy children and adolescents: a randomised, double-blind, and placebo-controlled, phase 1/2 clinical trials. *Lancet Infect Dis* 2021;S1473-3099(21)00319-4. Available at:

[https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(21\)00319-4/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00319-4/fulltext).

Accessed December 2021.

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