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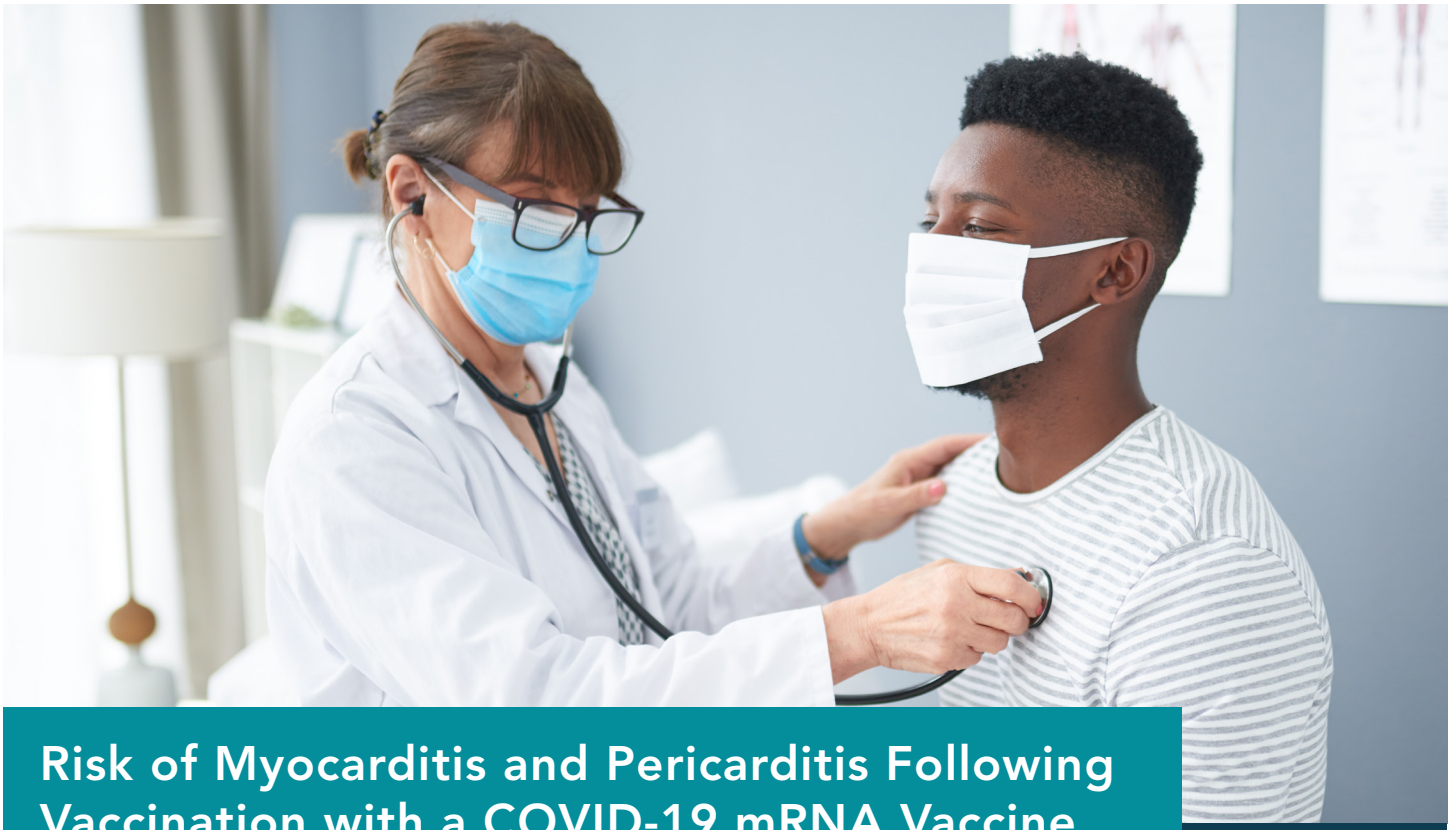

Risk of Myocarditis and Pericarditis Following Vaccination with a COVID-19 mRNA Vaccine

Myocarditis and pericarditis are rare side effects that have been reported after receipt of the covid mRNA vaccine.

International cases are consistently reported to have occurred:

- **More often after the second dose**
- **Usually within a week after vaccination**
- **More often in adolescents and young adults (12 to 30 years of age)**
- **More often in males than females**

Data from Ontario suggests a product specific difference in the risk of myocarditis/pericarditis following mRNA vaccines with both side effects occurring more often following Moderna than Pfizer-BioNTech among 18 – 24-year-old males.

Most cases were mild and resolved quickly. Until more evidence is available, the National Advisory Committee on Immunization (NACI) recommends that individuals who experienced myocarditis or pericarditis following their first does of an mRNA covid vaccine **defer receipt of a second dose.** NACI continues to monitor the situation.

continued...

Public Health Ontario published the following information about **Ontario's reports of myocarditis or pericarditis: "Based on 455 reports of myocarditis or pericarditis, the overall crude reporting rate is 21.6 per million doses of mRNA vaccines administered. The highest reporting rates were observed in younger age groups (12-17 and 18-24 years) and among males. The highest reporting rate was observed for males aged 18-24 years of age following dose 2, at 173.9 events per million doses administered."**

WHAT TO BE AWARE OF:

The study **SARS-CoV-2 mRNA Vaccination Associated Myocarditis in Children Ages 12-17: A Stratified National Database Analysis** was recently run as a preprint. Based on their review, the authors of the study drew the following conclusions: **"12-15 year old healthy boys are 4 times more likely to experience a cardiac event such as myocarditis after their second dose of Pfizer BioNTech vaccine than be admitted to hospital as a result of covid infection."**

However, another article was published cautioning against this study and its credibility. The subsequent article highlights the following key elements that need to be considered when evaluating the original preprint:

- The study has not been peer reviewed.
- The data source for the study was the US vaccine adverse reporting system (known as VAERS) which is a passive monitoring system that members of the public can use to report suspected vaccine side effects. Consequently, the reports in this system require validation through a more active surveillance to account for reporting and re-call bias.
- Professor Trish Greenhalgh, University of Oxford, was consulted during the subsequent article and reiterated that the CDC states the VAERS system should not be used to alone imply the existence of vaccine side effects, their frequency, or rates.
- The authors of the original study felt the reporting system was a way to access timely information about the events occurring after immunization and claimed their review of the system looked for objective information to support reports of cardiac events post vaccine receipt.
- However, critics of the article further note that the reported cases of myocarditis may have had a completely different etiology.
- **https://www.bmj.com/content/374/bmj.n2251**

BOTTOM LINE:

- Cases of myocarditis and pericarditis are potential side effects that need to be reported to assist in continued monitoring of vaccine safety.
- In addition to NACI, regulatory health bodies, including the US Centers for Disease Control and Prevention's safety committee, and the UK's Medicines and Healthcare Products Regulatory Agency, continue to emphasise the occurrence of such cases in association with the vaccine are rare and the cases that occur are mild in nature and respond well to treatment.