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# **Pediatric Myocarditis and Pericarditis Complication after mRNA-based COVID-19 Vaccination**

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## **Author's contribution**

*The sole author designed, analysed, interpreted and prepared the manuscript.*

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## **ABSTRACT**

Oyster and co-authors (2022) have authored an article called *Myocarditis cases reported after mRNA-based COVID-19 vaccination in the United States from December 2020 to August 2021*, which studies and investigates the resulting number of cases of Myocarditis concerning the COVID-19 vaccination for pediatric patients older than 12 years of age but include individuals less than 30 years of age. From analyzing COVID 19 vaccination, there is more attribute towards the benefits associated with health matters as outlined by Bozkurt and co-authors (2021). However, from the research, the vaccination holds potential risks that would harm the population involved (Halushka & Vander Heide, 2021). The article investigates the different reports of Myocarditis and pericarditis rates after mRNA-based vaccination in the United States and globally. With the detailed information, the article has reviewed additional existing knowledge to support the study's objective. Public health Ontario 2022 also provides an overview of the event of Myocarditis and Pericarditis following mRNA COVID 19 vaccines. Data from other countries also reported Cases of Myocarditis/Pericarditis following immunization with mRNA vaccine in Ontario, Canada, and internationally. Reported cases have occurred more frequently in males under 30 years, following the second dose, usually within one week of vaccination, and have mild with quick recovery. Although they also mention that the benefit of vaccination continues to outweigh the risk of COVID-19 illness, the authority still recommends vaccination for all eligible individuals, including children and youth. Also, per the American college of cardiology, vaccine-associated Myocarditis is a rare but possible side effect after m-RNA based COVID-19 vaccine. The clinical course of this Myocarditis is generally mild, with most symptoms resolving quickly.

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## 1. INTRODUCTION

With the nationwide implementation of the COVID 19 vaccine campaign as per [1] starting in December 2020, CDC and FDA started noticing several adverse events, including Myocarditis and Pericarditis, in the vaccine adverse event reporting system (VAERS). Because of this concern, the aim was to find confirmed cases of Myocarditis after m-RNA-based COVID 19 vaccination and provide possible risk prediction based on the vaccine type, number of vaccine doses, age, and sex. As per [2] also, “the risk of Myocarditis after receiving m-RNA based COVID-19 vaccine was increased across multiple age and sex strata and was highest after the second dose of the vaccine, but this risk should be considered in the context of the benefit of COVID19 vaccination”. “Preventing the spread of COVID-19 remain extremely important, and the National Advisory Committee on immunization as per [3] in Canada continues to recommend the COVID-19 vaccine for all eligible individuals, including youth”. CDC also outweighs the risk of Myocarditis and Pericarditis after COVID-19 mRNA vaccination and continues to recommend the COVID vaccine to eligible individuals. From analyzing COVID 19 vaccination, there is more attribute towards the benefits associated with health matters as outlined by [4]. However, from the research, the vaccination holds some potential risks that would harm the population involved [5]

## 2. MYOCARDITIS

Myocarditis is a heart muscle inflammation that peaks during infancy and adolescence. Clinical presentation and course of the disease are variable, as some patients do not require any treatment while some get severe heart failure followed by heart transplantation or death. Myocarditis can be of unknown etiology or following viral infection. It concerns that vaccination can trigger Myocarditis, which generally happens one week after vaccination.

Case definition as per [6-7] mentioned international and national reports of myocarditis/Pericarditis following vaccination with COVID-19 mRNA vaccine have emerged. These reports indicate that:

- Cases have been observed after the first dose of the COVID-19 mRNA vaccine but

are more commonly reported after the second dose

- “Symptoms onset was typically within several days after vaccination, with most reported cases within seven days after vaccination” [8]
- Cases were in adolescence and young adults
- Cases were more often male compared to female
- Cases experienced mild illness, responded well to conservative treatment and rest, and their symptoms improved quickly

“Myocarditis and Pericarditis involve inflammation of the myocardium or the pericardium, respectively, in response to an infection or other trigger. Symptoms include shortness of breath, chest pain, or a feeling of rapid or abnormal heart rhythm. Myocarditis and Pericarditis may overlap in clinical practice. Cases of Pericarditis with an associated elevation of troponins in the absence of reduced left ventricular function may be designated as myopericarditis” [8-9].

## 3. COVID -19 VACCINE IN PEDIATRIC

The U.S. Food and Drug Administration (FDA) granted emergency use authorization for Pfizer -BioNTech’s mRNA vaccine for children 5-11 years of age on October 29, 2021 [10]. FDA also authorized COVID 91 mRNA vaccine for children for at least 6-month-old on June 20, 2022 [11]. As with all routine vaccination for children, these vaccines were tested and reviewed by the FDA, CDC, and their independent scientific committee to ensure they are safe for children.

As per [9], “Clinical trials of BNT162b2 produced a significant immune response in children but had fewer participants than in adult COVID-19 vaccine trials. The trial of the BNT162b2 vaccine was initially limited to 2268 children 5 to 11 years of age, 1518 of whom received two doses of 10 micrograms of mRNA three weeks apart. The other 750 children got a placebo vaccine. The study assessed safety, levels of neutralizing antibodies, and vaccine efficacy for at least two months after the second dose. After FDA’s proposal, an additional 1591 vaccinated children were followed up for 2.5 weeks after their second dose to expand surveillance for adverse events. Pfizer-BioNTech reported an efficacy rate of 91% against symptomatic COVID-19 in the age group

of 5- 11". Also, as per [10], the COVID 19 vaccine was reported safe in kids from 6 months to 5 years of age.

According to CDC [11], younger children may experience fewer side effects than teens or young adults after COVID -19 vaccination. The Side effect most commonly reported were pain and swelling at the site of injection, Fever, tiredness, headache, chills, muscular or joint pain, and swollen lymph node [12-13].

#### 4. METHODOLOGY

The article [2] discusses several cases related to the wide range of evidence regarding vaccination among the USA population. The data collected for the study was between December 2020 and August 2021 among individuals older than 12 years. In addition, the data processing was through VAERS on September 30, 2021. The data samples used for the study were dependable as they were randomly selected to prevent biases [2]. The median age for the sample collected for the analysis was twenty-one. The authors identified an existing Myocarditis occurrence and a secondary pericarditis result. The medical dictionary was used to outline the details of the reports on VAERS for the findings. From the analysis of the collected data, it was clear that severe and rare cases of adverse events occurred among the mRNA-based COVID-19 vaccination.

In this study [2], "1626 cases of Myocarditis were reported in the national passive reporting system. The rate of myocarditis cases was highest after the second vaccination dose in adolescent males aged 12 to 15 years (70.7 per million doses of the BNT162b2 vaccine). In adolescent males aged 16 to 17 years (105.9 per million doses of the BNT1626b vaccine).and in young men aged 18 to 24 years (52.4 and 56.3 per million doses of the BNT1626b vaccine and the m-RNA-1273 vaccine, respectively)".

inclusion criteria included reports of Myocarditis or Pericarditis after COVID-19 vaccination that met CDC's case definition and were received by VAERS between December 14, 2020, and August 31, 2021, by age, sex, race, ethnicity, and vaccine type. Race and ethnicity were included to provide the complete baseline description possible for the individual but were not stratified by race and ethnicity because of the high percentage of missing data. In addition, reports of Pericarditis with evidence of potential

myocardial involvement were included in the review of the report of Myocarditis.

Cases that did not meet the CDC cases definition and were reported after seven days were excluded from the study. Individuals with any diagnosis of Myocarditis prior to that year were also not included in the study.

Analysis was conducted only for Myocarditis as the preponderance of reports to VAERS, in clinical immunization safety assessment project consultation, and the published article. The Crude reporting rate for Myocarditis during the 7-day risk interval was calculated using the number of reports of Myocarditis to VAERS per million doses of COVID -19 vaccine administered during the analytic period and stratified by age, sex, vaccination dose (first, second, unknown). And vaccine type. The Expected rate of Myocarditis by age and sex was calculated using 2017-2019 data from IBM Market scan commercial research database.

As per [1], "Between December 14, 2020, and August 31, 2021, 192 405 448 individuals older than 12 years of age received a total of 354 100 845 mRNA-based COVID-19 vaccines. VAERS received 1991 reports of Myocarditis (391 had reported having Pericarditis) after getting at least one dose of mRNA-based COVID-19 vaccine and 684 reports of Pericarditis without the presence of Myocarditis. Of the 1991 reports of Myocarditis, 1626 met the CDC's case definition for possible or confirmed Myocarditis". "Two hundred eight reports did not meet the CDC's case definition for Myocarditis, and 157 reports required more information to validate data. Of the 1626 reports that met the CDC's case definition for Myocarditis, 1195 (73%) were younger than 30 years of age, 543 (33%) were younger than 18 years of age, and the median age was 21 years[1]". Of the reports of Myocarditis with dose information, 82% (1265/1538) occurred after the second vaccination dose. Of those with a noted dose and time to symptom beginning, the median time from vaccination to symptom onset was three days after the first vaccination dose, and 74% (187/254) of Myocarditis occurred within seven days. After the second vaccination dose, the median time to symptom onset was two days, and 90% (1081/1199) of myocarditis events occurred within seven days. Male who suffered from Myocarditis reported 82%.

Also, among people younger than 30 years of age, there were no confirmed cases of

Myocarditis in those who died after mRNA vaccination without any other cause, and there was one probable case of myocarditis death but was insufficient information.

## **5. FINDINGS AND DISCUSSION**

### **5.1 Strength**

The most important part of the article is that the literature review includes proper inclusions of other people's research to support the topic and the details outlined by the authors. The medical decision includes understanding the factors and attributes required and outlining evidence-based samples [14]. In addition, the random samples used for the analysis formed a significant part of giving precise incision and indication about the topic in question [15]. Therefore, statistical analysis was a vital analysis procedure for the study. The authors characterized the reports of Pericarditis and Myocarditis after the COVID-19 vaccination that met the case retrieved by VAERS; the analysis was conducted uniformly by sex, race, age, vaccine type, and ethnicity.

### **5.2 Weaknesses**

However, there were several weaknesses of the study; VAERS is a passive reporting system; therefore, the information used for the survey was unreliable. The quality information used for the analysis remains variable due to the incomplete cases of Myocarditis. Also, the data used for the study does not produce the history of the prior SARS-Cov-2 cases among the individuals. The data administration for the vaccination was only limited to the reports of the CDC and was incomplete regarding the demographics.

## **6. GLOBAL MYOCARDITIS/ PERICARDITIS REPORTING RATE**

### **6.1 Reporting Rate of Myocarditis/ Pericarditis in Israel**

As per [16] "analysis of observational data of myocarditis/pericarditis after mRNA-based vaccine from the largest health care organization in Israel compared matched individuals 42 days after being vaccinated with two doses of Pfizer to unvaccinated individuals. Vaccination was most strongly associated with an elevated risk of

Myocarditis". The risk of Myocarditis increases after three vaccinations, translating to approximately three excess events per 1 million people. Further analysis of adverse events stratification by age and sex found that among males between 16 and 39 years, there was an excess of 8.62 events of Myocarditis per 1 million people. In comparison, the excess risk for the same group following actual SARS CoV-2 infection was 11.54 events of Myocarditis per 1 million people. Similarly, there was an increased risk of Pericarditis following the mRNA vaccine in young males aged 16-39.

### **6.2 Reporting Rate of Myocarditis/ Pericarditis in Canada**

As per [17], "Up to and including March 4, 2022, there are 1886 reports of myocarditis /pericarditis to the public health agency of Canada. Of these reported cases, 1,192 occurred following Pfizer - BioNTech COVID-19 vaccine for reporting rate of 2.18 events per 100,000 administered doses. In addition, there were 656 events following the Moderna Spikevax COVID-19 vaccine reporting rate of 2.88 per 100,000 administered doses".

### **6.3 Reporting Rate of Myocarditis/ Pericarditis in the U.K.**

As per [18] "study from the U.K. on more than 42 million vaccinated people, including over 10 million receiving the third dose in the general population, two excess cases of Myocarditis per million for each dose of Pfizer-BioNTech, including booster doses was noted, the Moderna vaccine was associated with 36 excess myocarditis cases per million after the second dose. Furthermore, In males younger than 40 years, 28 cases per million across three doses of Pfizer-BioNTech and 113 cases across two doses of Moderna were noted".

### **6.4 Reporting Rate of Myocarditis/ Pericarditis in Denmark**

A comprehensive study of VAM in Denmark suggested similar rates of VAM in the general population, with 1.4 cases per 100,000 for Pfizer-BioNTech and 4.2 cases per 100,000 for Moderna; interestingly, in the male population between 12 and 39 years of age, the rate was only 1.8 per 100,000 which was different from reported cases in other countries [19].

## 6.5 Reporting Rate of Myocarditis/ Pericarditis in Hong Kong

As per [20], “A small, published abstract found much higher VAM rates in Hong Kong among all 12-17-year-old adolescents at 18.5 per 100,000, rising to 37.2 per 100,000 for males of the same age; it should be noted that this study only includes 33 cases of confirmed Myocarditis”.

## 7. CONCLUSION

In conclusion, the article has analyzed the main idea toward the analysis of myocarditis cases based on the mRNA COVID-19 vaccination. There is an increased case of vaccination across sex and age strata which is the highest vaccination dose among young men and adolescent males. The varied results from the study show the existing relationship between individuals with Myocarditis and COVID-19 vaccination. The risks of the study include the beneficial contexts of the vaccination processes. As per [21] “Vaccine, associated Myocarditis is a rare but possible side effect of mRNA vaccination against COVID-19. Large-scale observational studies on hundreds of millions of vaccine recipients across three continents have identified the highest risk of VAM in adolescent males, with rates as high as 107 cases per million in the teenage years. Across the general population, in comparison, COVID-associated Myocarditis is higher than VAM, though VAM exceeds COVID-associated Myocarditis for adolescent males. The clinical course of VAM is mild, with most symptoms resolving before hospital discharge. Even in the adolescent male population, the entirety of the protective effect of COVID vaccination, particularly in preventing severe COVID, hospitalization, MIS-C, and death, continues to outweigh the risk of VAM”.

## FINANCIAL DISCLOSURE

The authors declare that they do not have a financial relationship with any commercial entity that has an interest in the subject of this manuscript.

## CONSENT AND ETHICAL APPROVAL

It is not applicable.

## DATA AVAILABILITY

The authors declare that data supporting the findings of this study are available within the article.

## COMPETING INTERESTS

Author has declared that no competing interests exist.

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