P0485

Temporal trends in myocarditis by recent COVID-19 vaccination status, United States, 2020–2025: a multi-source cohort study

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BACKGROUND

Rare cases of myocarditis have been observed following vaccination with mRNA vaccines targeting SARS-CoV-2, including mRNA-1273, more frequently after the second dose in the primary vaccination series and typically within 14 days post-vaccination.

We describe temporal trends of incident myocarditis diagnoses identified from structured healthcare data, comparing cases following mRNA-1273 vaccination with those without recent COVID-19 vaccination, overall and among males aged 12–24 years (the highest risk group).

METHODS

Data source: Veradigm Integrated Dataset (electronic health records, claims, and registry data sourced from all 50 US states)

Screening case identification: Incident myocarditis diagnoses between 18 Dec 2020 (mRNA-1273 Emergency Use Authorisation date) and 16 Sep 2025

- First recorded myocarditis diagnosis during this period = index date

Clinical criteria:

- ≥6 months medical history prior to index, and no myocarditis diagnosis in the 6 months prior to index
- Within ±30 days of the index, evidence of both a cardiac test and ≥1 myocarditis-related symptom
  - These data elements were a proxy for the US Center for Disease Control and Prevention (CDC) myocarditis case definition[1] using structured healthcare data in the absence of medical record adjudication.

Exposure classification (30-day window prior to index date):

- Post-Vaccine Myocarditis (PVM): Receipt of mRNA-1273 within 30 days prior to the index date
- Non-Post-Vaccine Myocarditis (NPVM): no COVID-19 vaccination documented within 30 days prior to the index date

RESULTS

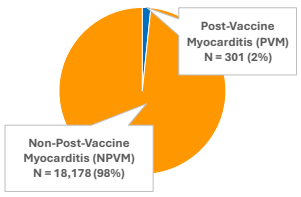
Study population

Individuals with a myocarditis diagnosis
18 Dec 2020 – 16 Sep 2025
N = 42,893

Met criteria for a screened incident case
N = 18,479

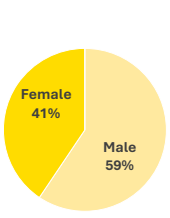
Exposure classification

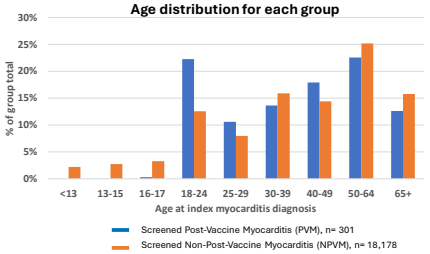
30-day window prior to index date



- Males 12–24 years of age comprised 13% (n=2,419) of all screened incident cases; 2.1% of this subgroup were PVM.

Demographics (all ages, sexes)





RESULTS (continued)

- 80% of all PVM cases across all ages and sexes, and 92% of PVM cases among males 12-24 years of age, were observed between Jan 2021 – Feb 2022, when a primary 2-dose vaccination series was predominant.

Figure 1. Percentage of Screened Myocarditis Cases Within Each Group, by Index Month *(All Ages, All Sexes; n=18,479)*

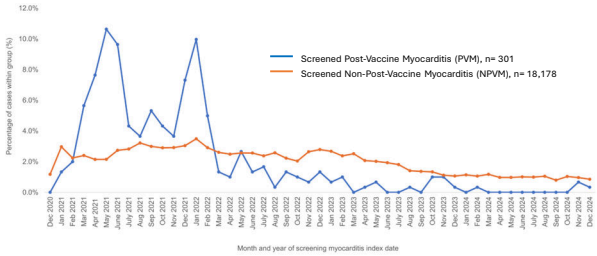
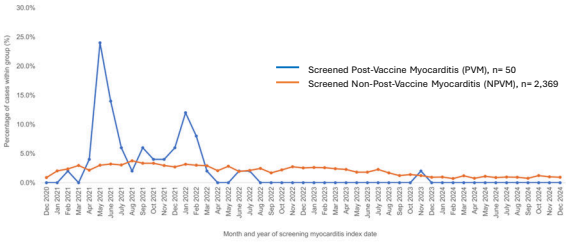


Figure 2. Percentage of Screened Myocarditis Cases Within Each Group, by Index Month
(Males, 12-24 years of age; n=2,419)



Footnote: Percentages are calculated within each group using the total group case count as the denominator and represent temporal distribution rather than incidence.

LIMITATIONS

No clinical adjudication was performed; cases are considered screened based on structured data.

CONCLUSIONS

In this US nationwide analysis of incident screening cases identified from structured healthcare data, most myocarditis cases were classified as NPVM. PVM was uncommon and largely concentrated through Feb 2022, with few cases observed thereafter. NPVM accounted for the majority of cases at all time points based on case counts; from Mar 2022 onwards, it also predominated in the monthly percentages of cases within each group. Similar temporal patterns were seen among males aged 12–24 years, with only one PVM case observed after Aug 2022.

References

[1] Gargano, J. W. *et al.* Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021. *Morbidity Mortal Wkly Rep* **70**, 977–982 (2021)

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Disclosures

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ADDITIONAL INFORMATION