

# Cardiovascular safety signals in Israeli adolescents following COVID-19 Vaccination: Evidence from an unprocessed FOIA dataset

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## ABSTRACT

**Background:** During the first year of the COVID-19 vaccination campaign, vaccine-associated cardiac risk was largely portrayed as rare, mild, and transient. However, according to the State Comptroller of Israel – a country often regarded as the world's vaccination laboratory – most adverse event reports submitted during the campaign by Clalit Health Services, Israel's largest health provider, were not processed. This study discloses and analyzes the majority of these previously unexamined reports, obtained through Freedom of Information Act (FOIA) requests.

**Methods and Findings:** A large anonymized dataset comprising 294,877 mild and severe adverse event reports (e.g., seizures, Guillain-Barré syndrome), documented by healthcare personnel between December 2020 and December 2024 was made publicly available on the Open Science Framework. Using a deliberately conservative analytical strategy, 277 unique cardiovascular events were identified among underage vaccinees, including acute cardiovascular injury, myocarditis, and pericarditis. Events were broadly distributed across genders (145 girls) and timeframes (133 after the first dose, 84 within 21 days of the second dose, and 60 more than 21 days after the second dose). Notably, 271 of these cases (98%) occurred among adolescents aged 12–16 within a narrow six-week window, temporally coinciding with the expansion of vaccine eligibility to this age group.

**Conclusions:** The findings indicate a substantial and previously unrecognized cardiovascular safety signal. Even under deliberately conservative assumptions, the observed age- and time-specific clustering reflects a magnitude well beyond background expectations. Earlier disclosure and analysis of these data could have enabled age-sensitive risk-benefit assessments and more adaptive vaccination policies.

## KEY WORDS

COVID-19 vaccination; Myocarditis; Pericarditis; Adolescents; Post-marketing surveillance

## ARTICLE HISTORY

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## Introduction

As of early 2026, adverse cardiovascular events are widely recognized as one of the most salient and broadly accepted safety concerns associated with mRNA COVID-19 vaccination [1-5]. However, this recognition emerged gradually and only after substantial delays in evidence dissemination.

Despite early warnings issued on February 28, 2021, by the Israeli Ministry of Health (IMOH) regarding “a large number of myocarditis and pericarditis cases in young individuals,” relevant studies appeared in the peer-reviewed literature only from August–September 2021 onward [6]. These early publications largely framed vaccine-associated cardiac risk as rare, transient, and confined to a specific subgroup – predominantly adolescent and young adult males, most often following the second mRNA dose and within a short, predefined post-vaccination interval [7-10].

Within this emerging scientific framing, public messaging during the first year of the vaccination campaign remained largely unidimensional and reassuring across all age groups. On

May 10, 2021, the U.S. Food and Drug Administration (FDA) expanded the vaccine's Emergency Use Authorization to adolescents aged 12–15 years [11], and on June 23, 2021, the Advisory Committee on Immunization Practices (ACIP) determined that “the benefits of using mRNA COVID-19 vaccines... outweigh the risks in all populations [12].” This explicit reassurance was published in the weekly report of the U.S. Centers for Disease Control and Prevention (CDC) titled “Use of mRNA COVID-19 Vaccine after Reports of Myocarditis.”

## The Present Research

This brief research report uncovers real-time safety data from Israel (often described as the “world's laboratory” due to its early and extensive vaccination campaign) that were not disclosed to the public during the critical decision-making period of mid-2021 [13]. These data could have materially informed contemporaneous risk-benefit assessments, particularly with respect to adolescents, and may have warranted age-stratified reconsideration of vaccination policy.

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Notably, the absence of these data from public and scientific discourse was not incidental. Several years later, the Israeli State Comptroller revealed that the IMOH had failed to process approximately 279,300 adverse event reports submitted by Clalit Health Services – the largest of Israel's four state-mandated health organizations, serving more than five million members [14]. Following this disclosure, the Community NGO of Givat Mordechai (Jerusalem) submitted repeated Freedom of Information Act (FOIA) requests. On September 17, 2025, Clalit released the dataset, which has since been made publicly available in anonymized form on the Open Science Framework [15]. These newly disclosed data allow, for the first time, an independent examination of the cardiovascular safety reports recorded during Israel's vaccination campaign.

### Methods

The dataset comprises 294,877 adverse event reports following COVID-19 vaccination, all submitted by healthcare professionals between December 21, 2020, and December 27, 2024 (excluding two entries without specified adverse events). Each report includes structured fields such as report date, sex, year of birth,

vaccine dose number, batch number, and adverse event code and description, as recorded in the official adverse event reporting system of the Israeli Ministry of Health (IMOH), known as the "Nachlieli" system [16].

Specifically, the date fields, year of birth, batch numbers, vaccine identifiers, and adverse event codes are recorded using numerical values and alphanumeric (English) characters. Gender is coded using Hebrew letters, with "ז" denoting male and "נ" denoting female. The adverse event description itself appears in Hebrew, reflecting the original terminology used by healthcare personnel within the *Nachlieli* reporting system. The English translations of these descriptions (presented in this article) were taken from the official MOH documentation the *Nachlieli* reporting system.

Table 1 summarizes the distribution of the reports, which consists mainly of mild local or systemic reactions but also severe outcomes, such as seizures, Guillain-Barré syndrome, anaphylaxis, thrombocytopenia, arthritis, thromboembolism, acute cardiovascular injury, and other significant vascular, respiratory, and metabolic events.

**Table 1.** Distribution of adverse event reports by the Israel Ministry of Health Categories.

Category	Code Range	Number of Reports	Examples and Notes
Local reactions	101-113	2,33,015	Pain, redness, swelling at injection site
General reactions	201-238	59,086	Fever, headache, dizziness, weakness, cyanosis, chest pain, menstrual changes, chills, muscle pain
Allergic reactions & anaphylaxis	301-302	151	Anaphylaxis, allergic response
Neurological reactions	401-414	855	Seizures, sudden loss of consciousness, paresthesia, meningitis, Guillain-Barré, Bell's palsy
Significant events	503-506	17	Parotitis, orchitis, thrombocytopenia, arthritis
Other significant categories	601-607	427	Vascular, musculoskeletal, cardiac, respiratory, metabolic events
COVID-specific follow-up events	701-724	725	Vaccine-associated enhanced disease, myocarditis, pericarditis, stroke, thromboembolism
Physician discretion	998	9	Reported without further description
"Other" (free-text entries)	999	591	Miscellaneous descriptions not otherwise coded
<b>Total</b>		<b>2,94,877</b>	

A more detailed breakdown of the designated category "COVID-specific follow-up events" (codes 701-724) is presented in Table 2. The total number of reports in this category was 725, the vast majority of which involved adverse cardiovascular events. The most frequently reported event was Acute Cardiovascular Injury (646 cases, code 704), followed by Myocarditis/Pericarditis (23 cases, code 719), Myocarditis (13 cases, code 724), and Pericarditis (9 cases, code 723).

It should be noted that the most frequently used code, "Acute

Cardiovascular Injury" (code 704), appears in the dataset in Hebrew as "אוטם חרוף בשריר הלב", which translates literally to Acute Myocardial Infarction (AMI). We did not identify an explanation in the official documentation for the discrepancy between the Hebrew term denoting AMI and the broader, less diagnostically specific English label "Acute Cardiovascular Injury" used in the *Nachlieli* reporting system. Nevertheless, in the present report we adhere to the official English terminology provided by the official documentation.

**Table 2.** Distribution of adverse event reports with COVID-specific follow-up codes.

Code	Event Description	Cases
701	Vaccine-associated enhanced disease	1
703	Acute respiratory distress syndrome	8
704	Acute cardiovascular injury	646
705	Acute disseminated encephalomyelitis	1
706	Coagulation disorder	2
708	Acute liver injury	3
709	Acute demyelinating disease	2

710	Anosmia and/or ageusia	3
714	Thromboembolism	2
715	Disseminated intravascular coagulation	1
717	Stroke	7
718	Narcolepsy and cataplexy	1
719	Myocarditis/Pericarditis	23
720	Pregnancy and birth outcomes	3
723	Pericarditis	9
724	Myocarditis	13
<b>Total</b>		<b>725</b>

## Results

To quantify cardiovascular adverse events among adolescents, we conducted a manual count of all reports categorized as *Acute cardiovascular injury* (code 704), *Myocarditis/Pericarditis* (code 719), *Pericarditis* (code 723), and *Myocarditis* (code 724). The analysis was restricted to patients born in 2004 or later (i.e., under 18 years old in 2021).

Due to the structure of the released dataset, which did not include personal identifiers (to preserve confidentiality) or clinical vignettes, it was not possible to determine with certainty whether some reports represented duplicate entries. We formally requested access to the clinical comment fields required by the IMOH reporting guidelines for significant adverse events; however, the health service responded that such information was not available. In response, we adopted a highly conservative approach. To avoid overestimation due to potential duplication, we included only cases with at least one distinguishing feature (e.g., sex, year of birth, or vaccine dose number), thereby yielding the lowest possible estimate of unique cases based on the available information. For example, two records describing an acute cardiovascular injury (code 704) in a male born in 2006, following the first vaccine dose on the same date, were counted as a single case.

Using this deliberately conservative approach, the focused analysis identified 277 unique cardiovascular cases among adolescents under 18 years of age in 2021, of which 271 (98%) were aged 16 years or younger. Importantly, this figure represents a lower-bound estimate of affected individuals; the total number of cardiovascular-related reports among individuals under 18 years of age in the dataset could reach up to 564 cases. Notably, all cardiovascular cases except one were reported within a six-week window, between June 28 and August 8, 2021 (with one additional case reported on October 13, 2021).

Table 3 presents the breakdown of cardiovascular events by gender, vaccine dose, and timing relative to vaccination. Contrary to the commonly described risk profile (see the introduction), cardiovascular events in the present dataset were distributed across both genders and across vaccine doses, without a clear concentration among males or in close temporal proximity to the second dose. As shown in Table 3, reports were nearly evenly distributed between girls (145 cases) and boys (132 cases). Events were observed following the first dose (133 cases), within 21 days of the second dose (84 cases), and beyond 21 days after the second dose (60 cases), with similar patterns across genders.

**Table 3.** Distribution of reported cardiovascular events by gender and vaccine dose.

	After the 1st dose	Within 21 days from the 2nd dose	More than 21 days post-vaccination	Total
Boys	62	40	30	132
Girls	71	44	30	145
Total	133	84	60	277

## Discussion

The findings of the present research report provide a retrospective window into previously undisclosed cardiovascular safety signals that emerged during the critical early phase of the COVID-19 vaccination campaign. Using newly disclosed surveillance data from Israel – often described as the “world’s laboratory” – this analysis documents a marked concentration of cardiovascular adverse events among adolescents in mid-2021, coinciding with the expansion of vaccination eligibility to younger age groups [13].

Within the designated COVID-specific follow-up category (Table 2), cardiovascular events constituted the overwhelming majority of reports, representing a pronounced disproportionate safety signal [17,18]. Furthermore, the clustering of 271 cardiovascular events among adolescents aged 12–16 within a narrow six-week interval – shortly after the IMOH expanded vaccination eligibility to adolescents under 16 (on June 21, 2021) [19] – represents an order-of-magnitude excess compared with background expectations [20,21].

## The magnitude of the risk

To contextualize the magnitude of the observed clustering of 271 cardiovascular cases among adolescents aged 12–16 years, several simplifying assumptions are required (to approximate population-level rates and to compare them with established background estimates). These assumptions are stated explicitly and are intended to provide general orientation rather than precise risk quantification:

- According to estimates from the Israeli Central Bureau of Statistics, the population of adolescents aged 12–16 years in Israel at the end of 2020 comprised approximately 776,251 individuals [22].
- The dataset analyzed in the present study was obtained from Clalit Health Services, the largest health organization in Israel, which covered approximately 51.6% of the national population at the time [23]. Accordingly, the relevant denominator for rate estimation is approximately 400,546 adolescents aged 12–16 years.

- According to the IMOH public dashboard, approximately 63.5% of adolescents aged 12–15 years received at least one dose of the Pfizer mRNA vaccine during the study period (Figure 1). Applying this proportion yields an estimated vaccinated population of approximately 254,347 adolescents within the age group relevant to the present analysis, representing the pool of individuals at risk against which cardiovascular events were assessed.

Under these assumptions, even if all 254,347 adolescents were vaccinated within the same narrow six-week window, and even if all cardiovascular events occurring shortly after vaccination were captured and reported (two clearly conservative and unlikely assumptions), the observed clustering corresponds to a minimum risk of approximately 1 cardiovascular event per 939 vaccinated adolescents.

Following identification of this unusually large clustering, we contacted Clalit Health Services to seek verification. We reported the higher, unfiltered count of cardiovascular reports (including potential duplicates) and specifically inquired whether the number of adolescents reported with “אִוּטָם חֲרִירָה” (acute myocardial infarction, per the original Hebrew terminology used in the reporting system) differed from our findings, or whether reporting errors had been identified. In response, Clalit Health Services stated that “the data do not exist”.

In the absence of additional clarifying information from the reporting health organization, the magnitude of this finding

can be contextualized by comparison with established background rates of severe cardiac events in adolescents. Even without annualizing the observed approximated risk ratio (1:939), it substantially exceeds known background rates of acute myocardial infarction (AMI) from the U.S. In the U.S., a country with a population approximately 35 times larger than that of Israel, only about 157 cases of AMI are expected annually among adolescents across a broader age range (13–18 years), corresponding to approximately 6.6 cases per million person-years [21].

It is possible, of course, that the unique cardiovascular cases identified in the present analysis encompass a spectrum of outcomes, including myocarditis and pericarditis. Moreover, the dominant adverse event code – translated in the *Nachlieli* system as “Acute Cardiovascular Injury” and rendered literally in Hebrew as “Acute Myocardial Infarction” – may reflect a broader category of unspecified cardiac injuries or suspected ischemic or inflammatory events recorded prior to definitive clinical adjudication (see Methods). Nevertheless, even under this broader interpretation, the magnitude of cardiovascular safety signals observed in the present dataset exceeds the highest vaccine-associated myocarditis incidence estimates reported in the literature (e.g., the rate of 1 in 2,679 among adolescent boys in Hong Kong following the second vaccine dose, which ultimately led local health authorities to recommend a single-dose vaccination regimen for this age group) [10].

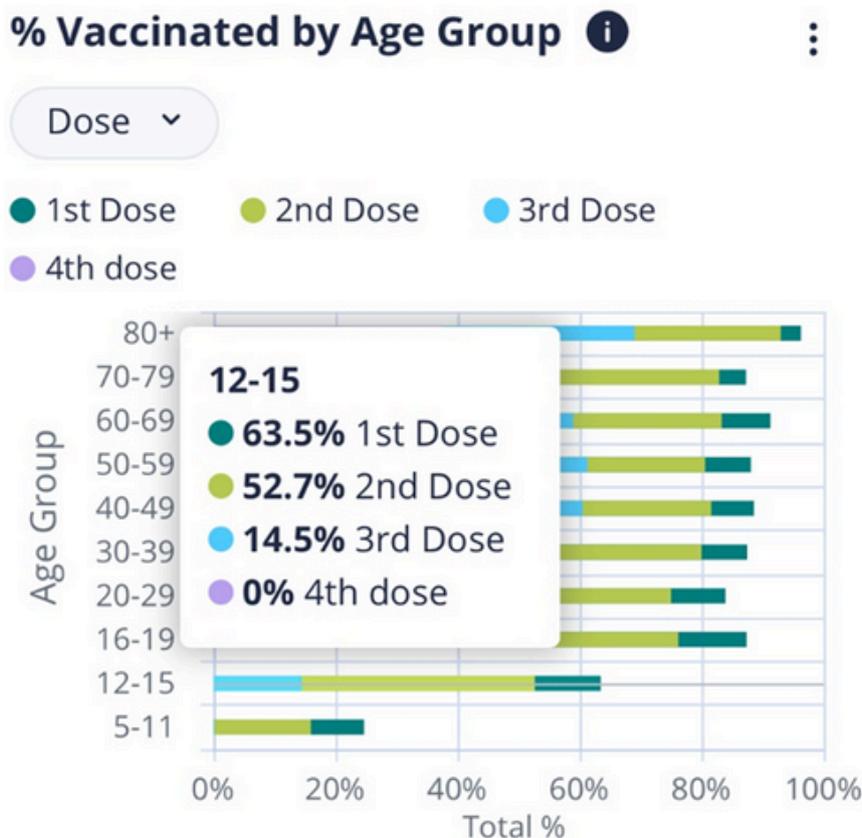


Figure 1. Vaccine uptake by age and dose, according to the MOH public dashboard.

### The distribution of the risk

Aside from the magnitude of the observed risk, the gender and dose distributions of cardiovascular cases in the present dataset diverge from the risk profile that later became dominant in the literature. Most observational studies published during the first year of the vaccination campaign (2021) characterized vaccine-associated myocarditis as a predominantly male phenomenon [8,10], occurring more frequently after the second mRNA dose and typically within a narrow post-vaccination window of several days (as defined a priori by the investigators) [8,10].

In contrast, the current analysis indicates a broader distribution of cardiovascular events across genders, doses, and post-vaccination timeframes. As detailed in Table 3, reports were nearly evenly distributed between girls (145 cases) and boys (132 cases), and events were observed following the first dose, within 21 days of the second dose, and beyond the immediate post-second-dose period, with broadly similar patterns across genders. This pattern suggests that early peer-reviewed studies may have captured only a subset of the cardiovascular safety signal, while real-time surveillance data reveal a more diffuse and heterogeneous risk distribution.

Specifically, the observation that a substantial proportion of cardiovascular events occurred more than 21 days after the second vaccine dose carries important implications. Time-restricted observational studies are likely to have missed delayed-onset events, thereby producing systematic underestimation of risk. It is also plausible that the present analysis itself under-captures the true burden, as clinicians may be less inclined to attribute cardiovascular events occurring weeks or months after vaccination to the vaccine exposure. This attribution gap is particularly relevant given accumulating evidence that vaccine-related components, including mRNA molecules and spike protein expressed following vaccination, can persist in the human body for extended periods, in some cases months or longer [24-26]. Taken together, these considerations suggest that even the elevated risk observed in the current dataset should be regarded as a conservative estimate, and that cardiovascular risk following mRNA vaccination warrants more comprehensive and systematic long-term evaluation.

### Limitations

Several limitations should be acknowledged. The dataset analyzed in this study is highly anonymized and does not include personal identifiers or clinical vignettes. As a result, it was not possible to clinically adjudicate individual cases, assess symptom severity, confirm diagnoses, or evaluate clinical outcomes such as hospitalization or recovery. In addition, the absence of individual-level identifiers precluded definitive verification of duplicate reports, necessitating a deliberately conservative analytical strategy. These constraints limit case-level inference but do not undermine the detection of population-level safety signals, particularly when pronounced temporal clustering and disproportionate reporting patterns emerge across a large surveillance dataset.

### Conclusions

Without minimizing the limitations discussed above, the present study identifies an exceptionally serious cardiovascular safety signal that emerged during mid-2021 and had the potential to materially alter contemporaneous vaccination policy. The FOIA-released dataset, made public only in 2025,

documents at least 277 unique cardiovascular events following vaccination among underage adolescents, 271 of which occurred among youths aged 12-16 within a concentrated six-week period.

Even under highly conservative assumptions, the findings correspond to a minimum estimated risk of approximately one cardiovascular event per 939 vaccinated adolescents – a magnitude that stands in stark contrast to expected background rates as well as the common risk profile later emphasized in the literature (which largely portrayed vaccine-associated cardiac events as rare, male-predominant, and confined to a narrow post-second-dose window).

The scale, timing, and demographic breadth of these events, together with the prolonged failure to process and disclose the underlying reports, raise serious concerns regarding whether cardiovascular risks in adolescents were adequately recognized and communicated during a critical decision-making period. Earlier analysis and transparent reporting of these data could have enabled age-sensitive risk-benefit assessments and more adaptive vaccination strategies, better aligned with emerging real-world safety signals.

### Disclosure Statement

No potential conflict of interest was reported by the author.

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