Myocarditis following mRNA COVID-19 vaccination

Advisory Committee on Immunization Practices (ACIP)
July 19, 2022

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CDC COVID-19 Vaccine Coordination Unit
Topics

- Background on classic myocarditis and myocarditis associated with mRNA COVID-19 vaccination
- Update on myocarditis following mRNA COVID-19 vaccination with a focus on people ages 18 years and older
  - Vaccine Adverse Event Reporting System (VAERS)
  - Vaccine Safety Datalink (VSD)
Epidemiology of classic myocarditis (excluding infants)

- Usually has an infectious cause, typically viral or presumed to be viral, although infection with a pathogen is frequently not identified (only ~40% of time a pathogen is identified)\(^1,2,3\)
- Can be due to direct microbial infection of myocardial cells and/or ongoing inflammatory response, with or without clearance of pathogen\(^4,5,6\)
  - Can also be toxin-mediated or in setting of systemic infection or infection of non-cardiac tissue
- Rarer causes include autoimmune, hypersensitivity, and giant cell myocarditis
- Incidence in males > females starting after age 5 years\(^7\)
- It is common to not identify a pathogen or possible infectious etiology for myocarditis
  - Based on case series, where autopsy tissues were examined and tissue-based infectious disease testing was performed, a specific infectious cause was only identified in 13%–36% of cases across age groups\(^6,8,9\)
  - For a case series where endomyocardial biopsy tissues were tested, viral nucleic acids were detected in heart tissues in ~38% (adults and children combined)\(^1\)

Epidemiology of myocarditis

- **Children**
  - Annual incidence 0.8 per 100,000
    - In 15-18yo, 1.8 per 100,000 in 2015-2016
  - 66% male
  - Median LOS 6.1 days

- **Adults**
  - Gradual decrease in incidence with age
  - 76% male

Previously presented: [https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/02-COVID-Oster-508.pdf](https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/02-COVID-Oster-508.pdf)

LOS = Length of hospital stay
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Myocarditis associated with mRNA COVID-19 vaccination*;†</th>
<th>Viral myocarditis‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inciting exposure</td>
<td>mRNA COVID-19 vaccination • Dose 2 &gt; Dose 1</td>
<td>Viral illness • 30–60% with asymptomatic viral course</td>
</tr>
<tr>
<td>Demographics</td>
<td>Most cases in adolescents and young adults, males &gt; females</td>
<td>Males &gt; females, male incidence peaks in adolescence and gradually declines</td>
</tr>
<tr>
<td>Symptom onset</td>
<td>A few days after vaccination, most within a week</td>
<td>1–4 weeks after viral illness</td>
</tr>
<tr>
<td>Fulminant course</td>
<td>Rare¶</td>
<td>23%</td>
</tr>
<tr>
<td>ICU level support</td>
<td>~2%</td>
<td>~50%</td>
</tr>
<tr>
<td>Mortality/transplant</td>
<td>Rare¶</td>
<td>11–22%</td>
</tr>
<tr>
<td>Cardiac dysfunction</td>
<td>12%</td>
<td>60%</td>
</tr>
<tr>
<td>Recovery of cardiac function</td>
<td>Nearly all</td>
<td>~75%</td>
</tr>
<tr>
<td>Time to recovery of cardiac function (ejection fraction on cardiac echo), if initially poor</td>
<td>Hours to days</td>
<td>Days to weeks to months</td>
</tr>
</tbody>
</table>

† Oster et al. JAMA. 2022;327:331-340
¶ There are rare reports in the literature, especially from other countries, but it is unclear to what extent such cases were investigated.
VAERS is the nation’s early warning system for vaccine safety

http://vaers.hhs.gov
VAERS

VAERS accepts reports from everyone (healthcare professionals, patients, parents, caregivers, manufacturers, etc.) regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event

Key strengths

▪ Rapidly detects potential safety problems
▪ Can detect rare adverse events

Key limitations

▪ Passive surveillance system
▪ Inconsistent quality and completeness of information
▪ Reporting biases
▪ Generally, cannot determine cause and effect
U.S. reports to VAERS of myocarditis after mRNA COVID-19 vaccination among people ages 18 years and older following primary series and 1st booster (as of May 26, 2022)

- Approximately **491.9 million** primary series and 1st booster mRNA COVID-19 vaccine doses administered in the United States among people ages 18 years and older
  - 213.3 million dose 1
  - 185.1 million dose 2
  - 93.4 million 1st booster dose

Preliminary reports of myocarditis (N=1836)

- Under review* (n=11)
- Did not meet definition† (n=504)
- Met CDC definition† (n=1321)

* Awaiting medical records and/or healthcare provider interview; some still processing
† Adjudicated after healthcare provider interview and/or medical record review, or vaccine received before authorized for use; CDC myocarditis case definition available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm

▪ Approximately **491.9 million** primary series and 1st booster mRNA COVID-19 vaccine doses administered in the United States among people ages 18 years and older
  - 213.3 million dose 1
  - 185.1 million dose 2
  - 93.4 million 1st booster dose
Verified* U.S. reports to VAERS of myocarditis after mRNA COVID-19 vaccination among people ages 18 years and older following primary series and 1st booster, by time to symptom onset† and dose number (N=1184; as of May 26, 2022)

Verified reports

Time to symptom onset, days

† 1184 of 1321 (90%) with known time to symptom onset; 183 (15%) reports with time to symptom onset >10 days

*Verified according to CDC myocarditis case definition available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm
Verified U.S. reports to VAERS of myocarditis after mRNA COVID-19 vaccination among people ages 18 years and older following primary series and 1st booster (as of May 26, 2022, 491.9 million primary series and 1st booster doses administered)

- 1321 reports verified using CDC case definition
  - Median age: 28 years (IQR: ages 21–42 years)
  - Median time to symptom onset after vaccination: 3 days (IQR: 2–5 days)
    - 229/1184 (19%) reports with known symptom onset >7 days after vaccination
  - After dose 2 (n=962), dose 1 (n=257), 1st booster dose (n=102)
  - Male cases (n=960), female cases (n=361)
VAERS reporting rates of myocarditis (per 1 million doses administered) after mRNA COVID-19 vaccination, days 0–7 and 8–21 post-vaccination*, †

<table>
<thead>
<tr>
<th>Age (yrs)</th>
<th>0–7 days</th>
<th>8–21 days</th>
<th>0–7 days</th>
<th>8–21 days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Males</td>
<td>Males</td>
<td>Females</td>
<td>Females</td>
</tr>
<tr>
<td></td>
<td>Dose 1</td>
<td>Dose 2</td>
<td>Booster</td>
<td>Dose 1</td>
</tr>
<tr>
<td>5–11</td>
<td>0.2</td>
<td>2.6</td>
<td>0.0</td>
<td>0.6</td>
</tr>
<tr>
<td>12–15</td>
<td>5.3</td>
<td>46.4</td>
<td>15.3</td>
<td>1.2</td>
</tr>
<tr>
<td>16–17</td>
<td>7.2</td>
<td>75.9</td>
<td>24.1</td>
<td>1.7</td>
</tr>
<tr>
<td>18–24</td>
<td>4.2</td>
<td>38.9</td>
<td>9.9</td>
<td>1.1</td>
</tr>
<tr>
<td>25–29</td>
<td>1.8</td>
<td>15.2</td>
<td>4.8</td>
<td>0.4</td>
</tr>
<tr>
<td>30–39</td>
<td>1.9</td>
<td>7.5</td>
<td>1.8</td>
<td>0.4</td>
</tr>
<tr>
<td>40–49</td>
<td>0.5</td>
<td>3.3</td>
<td>0.4</td>
<td>0.2</td>
</tr>
<tr>
<td>50–64</td>
<td>0.5</td>
<td>0.7</td>
<td>0.4</td>
<td>0.2</td>
</tr>
<tr>
<td>65+</td>
<td>0.2</td>
<td>0.3</td>
<td>0.6</td>
<td>0.3</td>
</tr>
</tbody>
</table>

* As of May 26, 2022; reports verified to meet case definition by provider interview or medical record review; primary series and 1st booster doses only
† An estimated 1–10 cases of myocarditis per 100,000 person years occurs among people in the United States, regardless of vaccination status; adjusted for days 0–7 and 8–21 risk intervals, this estimated background is 0.2 to 2.2 per 1 million person-day 0–7 risk interval and 0.4 to 3.8 per 1 million person-day 8–21 risk interval (peach shaded cells indicate that reporting rate exceeded estimated background incidence for the period)
CDC enhanced surveillance for myocarditis outcomes following mRNA COVID-19 vaccination in VAERS case reports among people ages 12–29 years*,†

- **Purpose**: Assess functional status and clinical outcomes among individuals reported to have developed myocarditis after mRNA COVID-19 vaccination

- **Methods**: A two-component survey conducted at least 90 days after the onset of myocarditis symptoms
  - Patient survey: Focused on ascertaining functional status, clinical symptoms, quality of life, and need for medication or other medical treatment
  - Healthcare provider (e.g., cardiologist): Gather data on cardiac health and functional status


CDC enhanced surveillance for myocarditis outcomes following mRNA COVID-19 vaccination in VAERS case reports among people ages 12–29 years

Results of cardiologist/healthcare provider survey

- Based on the cardiologists or healthcare provider assessment, most patients appear to have fully or probably fully recovered from their myocarditis
  - 398 patients received a follow-up assessment by a cardiologist or other healthcare provider regarding their myocarditis recovery
    - 265 (66.6%) fully recovered
    - 60 (15.1%) probably fully recovered but awaiting more information
    - 61 (15.3%) improved but not fully recovered
    - 8 (2.0%) recovery status unsure
    - 4 (1.0%) same cardiac status as at initial myocarditis diagnosis

81.7% fully recovered or probably fully recovered
CDC enhanced surveillance for myocarditis outcomes following mRNA COVID-19 vaccination in VAERS case reports among people ages 12–29 years

Key findings

- At least 90 days after myocarditis diagnosis, most patients who were reached reported no impact on their quality of life, and most did not report missing school or work
- Most (81.7%) healthcare providers who completed surveys indicated the patient was fully recovered or probably fully recovered
  - There was substantial heterogeneity in initial and follow-up treatment and testing
  - There did not appear to be a single test that was indicative of recovery

Next steps

- Additional follow-up with patients who were not yet recovered at time of the 90+ day survey (and their healthcare providers) to further assess recovery status at 12+ months
- Follow-up and evaluation of myocarditis cases in children ages 5–11 years is ongoing
Vaccine Safety Datalink (VSD)

- Established in 1990
- Collaborative project between CDC and 9 integrated healthcare organizations
VSD Rapid Cycle Analysis (RCA)

Aims

- To monitor the safety of COVID-19 vaccines weekly using pre-specified outcomes of interest among VSD members
- To describe the uptake of COVID-19 vaccines over time among eligible VSD members overall and in strata by age, site, and race/ethnicity
<table>
<thead>
<tr>
<th>Prespecified outcomes</th>
<th>Settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute disseminated encephalomyelitis</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Acute myocardial infarction – First ever in EHR in ICD-10 era</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Acute respiratory distress syndrome</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Anaphylaxis – First in 7 days in EHR in ICD-10 era</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Appendicitis</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Bell’s palsy – First ever in EHR in ICD-10 era</td>
<td>Emergency dept, Inpatient, Outpatient</td>
</tr>
<tr>
<td>Cerebral venous sinus thrombosis</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Disseminated intravascular coagulation</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Encephalitis / myelitis / encephalomyelitis</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Guillain-Barré syndrome</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Immune thrombocytopenia</td>
<td>Emergency dept, Inpatient, Outpatient</td>
</tr>
<tr>
<td>Kawasaki disease</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Multisystem inflammatory syndrome in children/adults (MIS-C/MIS-A)</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Myocarditis / pericarditis – First in 60 days in EHR in ICD-10 era</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Narcolepsy / cataplexy</td>
<td>Emergency dept, Inpatient, Outpatient</td>
</tr>
<tr>
<td>Pulmonary embolism – First ever in EHR in ICD-10 era</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Seizures</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Stroke, hemorrhagic</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Stroke, ischemic</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Thrombosis with thrombocytopenia syndrome – First ever in EHR in ICD-10 era</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Thrombotic thrombocytopenic purpura</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Transverse myelitis</td>
<td>Emergency dept, Inpatient</td>
</tr>
<tr>
<td>Venous thromboembolism – First ever in EHR in ICD-10 era</td>
<td>Emergency dept, Inpatient, Outpatient</td>
</tr>
</tbody>
</table>
For the primary analysis, the number of outcomes observed in the risk interval after COVID-19 vaccination were compared to the number expected

The expected was derived from “vaccinated concurrent comparators” who were in a comparison interval after COVID-19 vaccination

On each day that an outcome occurred, vaccinees who were in their risk interval were compared with similar vaccinees who were concurrently in their comparison interval

• Comparisons were adjusted for age group, sex, race/ethnicity, VSD site, as well as calendar date

For the pre-specified outcome myocarditis/pericarditis, cases were verified using the CDC case definition (https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm)
mRNA COVID-19 vaccine doses administered in VSD in people ages 18–39 years by week

Note: Data shown on slide are from December 14, 2020 – May 21, 2022
Day of onset of verified myocarditis/pericarditis among people ages 18–39 years after either primary series dose of a mRNA COVID-19 vaccine

Two overlapping clusters identified
Days 0-3 (P<0.001)
Days 0-4 (P<0.001)
Verified myocarditis and pericarditis in the 0–7-day Risk Interval among 18–39-year-old MALES by product and dose
(compared with outcome events in vaccinated comparators on the same calendar days)

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Dose</th>
<th>Events in Risk Interval</th>
<th>Events in Comparison Interval*</th>
<th>Adjusted Rate Ratio†</th>
<th>95% Confidence Interval</th>
<th>2-sided P-value</th>
<th>Excess cases in Risk Period per million doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Either mRNA COVID-19 Vaccine**</td>
<td>Dose 1</td>
<td>11</td>
<td>18</td>
<td>2.10</td>
<td>0.86 – 4.97</td>
<td>0.101</td>
<td>5.1</td>
</tr>
<tr>
<td></td>
<td>Dose 2</td>
<td>59</td>
<td>11</td>
<td>14.51</td>
<td>7.54 – 29.88</td>
<td>&lt;0.001</td>
<td>50.6</td>
</tr>
<tr>
<td></td>
<td>Booster</td>
<td>18</td>
<td>5</td>
<td>7.53</td>
<td>2.66 – 24.53</td>
<td>&lt;0.001</td>
<td>29.5</td>
</tr>
<tr>
<td>Pfizer-BioNTech (primary)</td>
<td>Dose 1</td>
<td>5</td>
<td>12</td>
<td>1.91</td>
<td>0.56 – 5.87</td>
<td>0.279</td>
<td>3.4</td>
</tr>
<tr>
<td></td>
<td>Dose 2</td>
<td>32</td>
<td>7</td>
<td>13.98</td>
<td>6.01 – 36.14</td>
<td>&lt;0.001</td>
<td>44.1</td>
</tr>
<tr>
<td></td>
<td>Booster</td>
<td>10</td>
<td>2</td>
<td>13.72</td>
<td>2.86 – 104.20</td>
<td>&lt;0.001</td>
<td>32.3</td>
</tr>
<tr>
<td>Pfizer-BioNTech (booster)</td>
<td>Dose 1</td>
<td>6</td>
<td>6</td>
<td>2.41</td>
<td>0.63 – 9.24</td>
<td>0.193</td>
<td>8.2</td>
</tr>
<tr>
<td></td>
<td>Dose 2</td>
<td>27</td>
<td>3</td>
<td>23.46</td>
<td>7.49 – 100.76</td>
<td>&lt;0.001</td>
<td>62.7</td>
</tr>
<tr>
<td></td>
<td>Booster</td>
<td>5</td>
<td>2</td>
<td>4.56</td>
<td>0.82 – 36.56</td>
<td>0.085</td>
<td>21.5</td>
</tr>
<tr>
<td>Moderna (primary)</td>
<td>Dose 1</td>
<td>6</td>
<td>6</td>
<td>2.41</td>
<td>0.63 – 9.24</td>
<td>0.193</td>
<td>8.2</td>
</tr>
<tr>
<td></td>
<td>Dose 2</td>
<td>27</td>
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<td>Dose 1</td>
<td>6</td>
<td>6</td>
<td>2.41</td>
<td>0.63 – 9.24</td>
<td>0.193</td>
<td>8.2</td>
</tr>
<tr>
<td></td>
<td>Dose 2</td>
<td>27</td>
<td>3</td>
<td>23.46</td>
<td>7.49 – 100.76</td>
<td>&lt;0.001</td>
<td>62.7</td>
</tr>
<tr>
<td></td>
<td>Booster</td>
<td>5</td>
<td>2</td>
<td>4.56</td>
<td>0.82 – 36.56</td>
<td>0.085</td>
<td>21.5</td>
</tr>
</tbody>
</table>

* Comparison interval is 22–42 days after either primary series or booster dose
† Adjusted for VSD site, 5-year age group, sex, race/ethnicity, and calendar date
** Individual product events may not sum to “Either mRNA COVID-19 Vaccine” total due to heterologous series and/or noninformative events.
Verified myocarditis and pericarditis in the 0–7-day Risk Interval among 18–39-year-old FEMALES by product and dose (compared with outcome events in vaccinated comparators on the same calendar days)

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Dose</th>
<th>Events in Risk Interval</th>
<th>Events in Comparison Interval*</th>
<th>Adjusted Rate Ratio†</th>
<th>95% Confidence Interval</th>
<th>2-sided P-value</th>
<th>Excess cases in Risk Period per million doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Either mRNA COVID-19 Vaccine**</td>
<td>Dose 1</td>
<td>3</td>
<td>2</td>
<td>5.36</td>
<td>0.70 – 50.71</td>
<td>0.105</td>
<td>1.8</td>
</tr>
<tr>
<td></td>
<td>Dose 2</td>
<td>6</td>
<td>1</td>
<td>22.08</td>
<td>3.10 – 530.11</td>
<td>&lt;0.001</td>
<td>4.4</td>
</tr>
<tr>
<td></td>
<td>Booster</td>
<td>4</td>
<td>3</td>
<td>2.68</td>
<td>0.54 – 14.85</td>
<td>0.227</td>
<td>3.4</td>
</tr>
<tr>
<td>Pfizer-BioNTech (primary)</td>
<td>Dose 1</td>
<td>1</td>
<td>1</td>
<td>5.44</td>
<td>0.14 – 213.88</td>
<td>0.312</td>
<td>1.0</td>
</tr>
<tr>
<td>Pfizer-BioNTech (booster)</td>
<td>Dose 2</td>
<td>5</td>
<td>1</td>
<td>19.85</td>
<td>2.59 – 495.35</td>
<td>0.002</td>
<td>5.9</td>
</tr>
<tr>
<td></td>
<td>Booster</td>
<td>1</td>
<td>2</td>
<td>0.98</td>
<td>0.03 – 12.91</td>
<td>0.976</td>
<td>-0.05</td>
</tr>
<tr>
<td>Moderna (primary)</td>
<td>Dose 1</td>
<td>2</td>
<td>1</td>
<td>3.86</td>
<td>0.27 – 120.68</td>
<td>0.325</td>
<td>2.9</td>
</tr>
<tr>
<td></td>
<td>Dose 2</td>
<td>1</td>
<td>0</td>
<td>NE</td>
<td>0.33 – ∞</td>
<td>0.136</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>Booster</td>
<td>1</td>
<td>1</td>
<td>2.48</td>
<td>0.06 – 105.24</td>
<td>0.591</td>
<td>6.9</td>
</tr>
</tbody>
</table>

NE= not estimable

* Comparison interval is 22–42 days after either primary series or booster dose

** Individual product events may not sum to “Either mRNA COVID-19 Vaccine” total due to heterologous series and/or noninformative events.

† Adjusted for VSD site, 5-year age group, sex, race/ethnicity, and calendar date
### VSD Incidence Rates of Verified Myocarditis/Pericarditis 0–7 Days Following mRNA COVID-19 Vaccination – December 14, 2020–March 31, 2022

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Pfizer-BioNTech</th>
<th>Moderna</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cases, 0–7 days</td>
<td>Doses</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18–29 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males – Dose 1</td>
<td>4</td>
<td>348,080</td>
</tr>
<tr>
<td>Males – Dose 2</td>
<td>27</td>
<td>330,594</td>
</tr>
<tr>
<td>Males – 1st Booster</td>
<td>7</td>
<td>146,979</td>
</tr>
<tr>
<td>Females – Dose 1</td>
<td>1</td>
<td>414,730</td>
</tr>
<tr>
<td>Females – Dose 2</td>
<td>2</td>
<td>398,678</td>
</tr>
<tr>
<td>Females - 1st Booster</td>
<td>1</td>
<td>212,299</td>
</tr>
<tr>
<td>30–39 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males – Dose 1</td>
<td>1</td>
<td>352,403</td>
</tr>
<tr>
<td>Males – Dose 2</td>
<td>5</td>
<td>340,819</td>
</tr>
<tr>
<td>Males – 1st Booster</td>
<td>3</td>
<td>182,162</td>
</tr>
<tr>
<td>Females – Dose 1</td>
<td>0</td>
<td>420,934</td>
</tr>
<tr>
<td>Females – Dose 2</td>
<td>3</td>
<td>409,651</td>
</tr>
<tr>
<td>Females - 1st Booster</td>
<td>1</td>
<td>247,245</td>
</tr>
</tbody>
</table>
**Verified myocarditis and pericarditis 0–7 days after any **primary series** dose of mRNA COVID-19 vaccine: Level of care and status by age group/product**

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Highest level of care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency department</td>
<td>5 (12%)</td>
<td>6 (17%)</td>
</tr>
<tr>
<td>Admitted to hospital</td>
<td>37 (86%)</td>
<td>29 (83%)</td>
</tr>
<tr>
<td>Admitted to ICU</td>
<td>1 (2%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Length of hospital stay, median (range)</td>
<td>1 day (0–2 days)</td>
<td>1 day (0–13 days)</td>
</tr>
<tr>
<td>0–1 days</td>
<td>24 (56%)</td>
<td>23 (66%)</td>
</tr>
<tr>
<td>2–3 days</td>
<td>19 (44%)</td>
<td>11 (31%)</td>
</tr>
<tr>
<td>4+ days</td>
<td>0 (0%)</td>
<td>1 (3%)</td>
</tr>
<tr>
<td>Discharged to home</td>
<td>43 (100%)</td>
<td>35 (100%)</td>
</tr>
</tbody>
</table>
Verified myocarditis and pericarditis 0-7 days after 1st booster dose of mRNA COVID-19 vaccine: Level of care and status by age group/product

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Highest level of care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency department</td>
<td>4 (17%)</td>
<td>2 (17%)</td>
</tr>
<tr>
<td>Admitted to hospital</td>
<td>18 (78%)</td>
<td>9 (75%)</td>
</tr>
<tr>
<td>Admitted to ICU</td>
<td>1 (4%)</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>Length of hospital stay, median (range)</td>
<td>1 day (0–3 days)</td>
<td>1 days (0–2 days)</td>
</tr>
<tr>
<td>0–1 days</td>
<td>17 (74%)</td>
<td>9 (75%)</td>
</tr>
<tr>
<td>2–3 days</td>
<td>6 (26%)</td>
<td>3 (25%)</td>
</tr>
<tr>
<td>4+ days</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Discharged to home</td>
<td>23 (100%)</td>
<td>12 (100%)</td>
</tr>
</tbody>
</table>
Summary: Myocarditis and pericarditis following mRNA COVID-19 vaccination

- Current evidence supports a causal association between mRNA COVID-19 vaccination and myocarditis and pericarditis
- Myocarditis is a rare event following mRNA COVID-19 vaccination
  - CDC verified 1321 myocarditis case reports in people ages 18 years and older after 491.9 million mRNA COVID-19 primary series and booster vaccinations administered in this age group in the United States
- Cases following mRNA COVID-19 vaccination cluster within the first week of vaccination
- Risk is greatest in adolescents and young adults, higher after dose 2 compared to dose 1 of the primary series, and higher in males compared to females
  - Some risk estimates for females in VSD are comparable to males but case counts are small and excess risk in females is substantially lower than for males
- Risk appears to decrease with age and the male to female predominance of cases attenuates with age
- Reporting rates in VAERS are highest following dose 2; reporting rates following dose 1 and 1st booster dose tend to be lower
- Incidence rates in VSD of verified myocarditis/pericarditis 0–7 days following mRNA COVID-19 vaccination are generally highest following dose 2
- Available information suggests that most persons with myocarditis after mRNA COVID-19 vaccination recover from myocarditis by 3–8 months after diagnosis
Acknowledgments

- VAERS Team
- Clinical Immunization Safety Assessment (CISA) Project
- Vaccine Safety Datalink (VSD) Team
- CDC MOVING Team
- CDC Immunization Safety Office
- CDC Infectious Diseases Pathology Branch
- COVID-19 Vaccine Task Force Data Monitoring and Reporting Group
- FDA/Center for Biologics Evaluation and Research
- Kaiser Permanente Northern California (VSD)
- Marshfield Clinic Research Institute (VSD)
- VSD sites
  - HealthPartners Institute, Minneapolis, MN
  - Kaiser Permanente Colorado, Denver, CO
  - Kaiser Permanente Northwest, Portland, OR
  - Kaiser Permanente Southern California, Los Angeles, CA
  - Kaiser Permanente Washington, Seattle, WA
  - Denver Health, Denver, CO
Disclaimer

- The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC) or the U.S. Food and Drug Administration (FDA)

- Mention of a product or company name is for identification purposes only and does not constitute endorsement by CDC or FDA
Thank you!

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