Myocarditis Outcomes Following mRNA COVID-19 Vaccination

Preliminary Data: data are subject to change

Advisory Committee on Immunization Practices
February 4, 2022

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Disclaimer

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Myocarditis following mRNA COVID-19 vaccination

- Evidence from safety monitoring systems in multiple countries supports the finding of an increased, but still rare, risk of myocarditis following mRNA COVID-19 vaccination*

  - **Risk:**
    - Highest in adolescents and young adults
    - Males > females
    - Following dose 2 > dose 1
  
  - Onset within a few days of vaccination, mostly within a week
  
  - Severity of cases varies; most who presented to medical care have responded well to medications and rest

Assessment of myocarditis health effects after COVID-19 vaccination in progress

CDC enhanced surveillance for myocarditis outcomes after mRNA COVID-19 vaccination in Vaccine Adverse Event Reporting System (VAERS) case reports*

- **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 12–29 years of age, ascertain 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

- **Timeline:** Data collection August 2021–January 2022

Preliminary data from surveys of patients at least 90 days post myocarditis diagnosis
Outreach focusing on myocarditis patients 12–29 years of age

- As of November 2021, VAERS had received ~989 reports of myocarditis or myopericarditis after COVID-19 vaccination that met CDC case definition*
- Of these, ~850 patient ages 12–29 years had reached 90 days post-myocarditis diagnosis

  - Of ~850 patients 90 days post diagnosis, 648 (81%) had a phone number listed
    - Of the ~648 patients who were called, ~360 (56%) completed the survey; ~270 (42%) were unreachable and 18 (3%) declined to participate
    - For the 360 patients interviewed, time from myocarditis onset to interview was 143 days (IQR: 131, 162)

* [https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm](https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm)
Most patients diagnosed with myocarditis were young males

- Median patient age was 18 years (IQR: 15–22);
- Of the 360 patients 90 days post myocarditis diagnosis, 86% (308) were male.

### Sex and Age Group

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Male Patients</th>
<th>Female Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 to 14</td>
<td>17%</td>
<td>2%</td>
</tr>
<tr>
<td>15 to 19</td>
<td>38%</td>
<td>6%</td>
</tr>
<tr>
<td>20 to 24</td>
<td>21%</td>
<td>3%</td>
</tr>
<tr>
<td>25 to 29</td>
<td>11%</td>
<td>2%</td>
</tr>
</tbody>
</table>
Race and ethnicity of myocarditis patients (N=360)

- White, non-Hispanic: 62%
- Hispanic: 20%
- Asian, non-Hispanic: 5%
- Black, non-Hispanic: 4%
- Multi-racial, non-Hispanic: 4%
- Other, non Hispanic: 3%
- American Indian or Alaskan Native, non-Hispanic: <1%

*4 patients did not provide a response
Prior to their myocarditis diagnosis, most patients received two doses of a COVID-19 vaccine

- 87% (314/360) received two doses of a COVID-19 vaccine
  - Of those who received two doses, 98% (307/314) reported receiving both doses before they were diagnosed with myocarditis
  - 9% (31/360) had a positive COVID-19 test before their myocarditis diagnosis
Self reported previous medical history among patients with myocarditis after mRNA COVID-19 vaccination (N=360)

- 60 (17%) had any condition
  - 11 (3%) had an arrhythmia
  - 6 (2%) had congenital heart disease
  - 6 (2%) had a history of myocarditis
  - 2 (<1%) had Kawasaki disease
  - 1 (<1%) had previous heart failure
  - 32 (9%) had a history of asthma
  - 7 (2%) had an autoimmune disorder
  - 5 (1%) genetic or chromosomal condition
  - 4 (1%) were immunosuppressed
  - 1 (<1%) had a history of Leukemia
  - 1 (<1%) had type 1 diabetes
Most patients with myocarditis after vaccination reported being hospitalized at the time of myocarditis diagnosis (n=360)

- 92% (324) were hospitalized
  - 4% (13) were readmitted following myocarditis; 8 of 13 (62%) were readmitted because of a concern with the heart
  - 20% (71) were prescribed medication for their heart as of their last appointment with the provider
Missed school or work within the 2 weeks prior to the date of the interview reported among patients with myocarditis after vaccination (N=360)

- **46 (8%)** reported missing school
  - Of these, **10 (37%)** believed it was due to their myocarditis

- **19 (5%)** missed work
  - Of these, **7 (37%)** believed it was due to their myocarditis
Self-reported symptoms within 2 weeks prior to the date of the interview among myocarditis patients (n=360)

- About half (49%) reported experiencing at least 1 symptom in the prior two weeks.

- **Fatigue**: 25% reported yes, 75% reported no.
- **Chest pain**: 32% reported yes, 68% reported no.
- **Shortness of breath**: 22% reported yes, 78% reported no.
- **Palpitations**: 22% reported yes, 78% reported no.
EuroQol-5D-5L measurement of health status among patients who developed myocarditis after vaccination (n=242)
Preliminary data from completed cardiologist or other healthcare provider surveys
Outreach to cardiologists or other healthcare providers

- Of the 360/648 patients interviewed, ~346 (96%) listed contact information for a cardiologist or other healthcare provider
  - Of the 346 providers with contact information listed, 229 completed a survey
  - An additional 151 providers completed surveys they had submitted for multiple patients in VAERS or provided contact information via the VAERS report
  - We were unable to contact 268 providers
  - In total, 380 providers completed the survey with a median of 191 days (IQR: 170, 216) from patient myocarditis onset to date of provider survey
The proportion of myocarditis patients cleared for physical activity by their cardiologist or healthcare provider has increased (n=380)

At time of myocarditis diagnosis, 83% of patients had restrictions on their physical activity

83%
Restricted

At time of provider survey, at least 90 days post diagnosis, only 39% had restrictions

39%
Restricted

*25 (7%) were unsure
Based on the cardiologists/healthcare provider assessment, most patients appear to have fully or probably recovered from their myocarditis (n=380)

- 81% (309) of cardiologists or healthcare providers indicated the patient was fully or probably recovered

*8 providers were unsure*
Proportion of myocarditis patients deemed to be fully or probably recovered by their healthcare provider (n=309)
Results of the most recent cardiac function test (n=380)

- **Troponin**: 53% Normal or baseline, 46% Abnormal or elevated
- **Cardiac MRI**: 36% Normal or baseline, 64% Abnormal or elevated
- **Echocardiogram**: 7% Abnormal or elevated
- **Electrocardiogram**: 77% Normal or baseline, 23% Abnormal or elevated
- **Exercise stress test**: 90% Normal or baseline, 10% Abnormal or elevated
- **Ambulatory rhythm monitoring**: 89% Normal or baseline, 11% Abnormal or elevated

Number of patients
Abnormal findings from most recent cardiac function test

- Late gadolinium enhancement
- Inflammation or edema
- Wall motion abnormalities
- ST segment elevation
- T wave abnormalities
- Arrhythmia
- Conduction delays or blocks
- Ectopic rhythm
- Arrhythmia
- Other cardiac concern
- Other non-cardiac concern
- Arrhythmia
- Other non-cardiac concern
- Conduction delays or blocks
- Ectopic rhythm

<table>
<thead>
<tr>
<th></th>
<th>All patients</th>
<th>Patients fully or probably recovered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Late gadolinium enhancement</td>
<td>121</td>
<td>92</td>
</tr>
<tr>
<td>Inflammation or edema</td>
<td>68</td>
<td>53</td>
</tr>
<tr>
<td>Wall motion abnormalities</td>
<td>23</td>
<td>17</td>
</tr>
<tr>
<td>ST segment elevation</td>
<td>18</td>
<td>9</td>
</tr>
<tr>
<td>T wave abnormalities</td>
<td>32</td>
<td>20</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Conduction delays or blocks</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Ectopic rhythm</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Other cardiac concern</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Other non-cardiac concern</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>Other non-cardiac concern</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
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<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Ectopic rhythm</td>
<td>5</td>
<td>4</td>
</tr>
</tbody>
</table>

Cardiac MRI
Electrocardiogram
Exercise stress test
Ambulatory rhythm monitoring
Overlap of abnormal findings among most recent cardiac function tests

<table>
<thead>
<tr>
<th>Test</th>
<th>0–20%</th>
<th>20–40%</th>
<th>40–60%</th>
<th>60–80%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Troponin</td>
<td></td>
<td></td>
<td>51</td>
<td></td>
</tr>
<tr>
<td>EKG</td>
<td>26</td>
<td>22</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ambulatory rhythm</td>
<td>3</td>
<td>2</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Exercise stress test</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>ECHO</td>
<td>9</td>
<td>7</td>
<td>31</td>
<td>20</td>
</tr>
</tbody>
</table>

Legend:
- Green: 40–60%
- Medium Blue: 20–40%
- Light Blue: 0–20%
Comparison of cardiac function tests at time of diagnosis and follow-up

At time of initial diagnosis

- Initial cardiac MRI normal: 14
- Initial cardiac MRI abnormal: 127
- No initial cardiac MRI or result not available: 239

At time of follow-Up

- Follow-up cardiac MRI normal: 68
- Follow-up cardiac MRI abnormal: 79
- No follow-up cardiac MRI or results not available: 233

Number of myocardiitis patients:

- Initial echocardiogram normal: 248
- Initial echocardiogram abnormal: 57
- No initial echocardiogram or result not available: 75

- Initial troponin normal: 36
- Initial troponin elevated: 340
- No initial troponin or result not available: 4

- Follow-up echocardiogram normal: 253
- Follow-up echocardiogram abnormal: 17
- No follow-up echocardiogram or results not available: 110

- Follow-up troponin normal: 174
- Follow-up troponin elevated: 20
- No follow-up troponin or results not available: 186
Comparison of cardiac function tests at time of diagnosis and follow-up

At time of initial diagnosis

- 14 Initial cardiac MRI normal
- 127 Initial cardiac MRI abnormal
- 239 No initial cardiac MRI or result not available

At time of follow-Up

- 68 Follow-up cardiac MRI normal
- 79 Follow-up cardiac MRI abnormal
- 233 No follow-up cardiac MRI or results not available

Number of myocarditis patients
Comparison of cardiac function tests at time of diagnosis and follow-up

At time of initial diagnosis
- Initial echocardiogram normal: 248 patients
- Initial echocardiogram abnormal: 57 patients
- No initial echocardiogram or result not available: 75 patients

At time of follow-up
- Follow-up echocardiogram normal: 253 patients
- Follow-up echocardiogram abnormal: 17 patients
- No follow-up echocardiogram or results not available: 110 patients
Comparison of cardiac function tests at time of diagnosis and follow-up

At time of initial diagnosis
- Initial troponin normal: 36 patients
- Initial troponin elevated: 340 patients
- No initial troponin or result not available: 4 patients

At time of follow-up
- Follow-up troponin normal: 174 patients
- Follow-up troponin elevated: 20 patients
- No follow-up troponin or results not available: 186 patients
Cardiac assessment and symptoms among patients deemed to be recovered and not recovered from their myocarditis

Patients deemed not recovered

- Shortness of breath
- Chest pain
- Daily medication
- Physical activity
- Troponin
- ECHO
- EKG
- cMRI

- Normal/Baseline function or absence of symptoms
- Abnormal function or presence of symptoms
- Unknown or no test results available

Patients deemed fully or probably fully recovered
Cardiac assessment and symptoms among patients deemed to be recovered and not recovered from their myocarditis

Patients deemed not recovered

- Shortness of breath
- Chest pain
- Daily medication
- Physical activity
- Troponin
- ECHO
- EKG
- cMRI

Normal/Baseline function or absence of symptoms
Abnormal function or presence of symptoms
Unknown or no test results available

Patients deemed fully or probably fully recovered
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Patients deemed fully or probably fully recovered

- Shortness of breath
- Chest pain
- Daily medication
- Physical activity
- Troponin
- ECHO
- EKG
- cMRI
Summary

- At least 90 days after myocarditis diagnosis, most patients reported no impact on their quality of life, and most did not report missing school or work
- Only 13 (4%) were readmitted to the hospital
- Most (81%) healthcare providers indicated the patient was probably fully or fully recovered
- There did not appear to be a single test that was indicative of recovery
- To our knowledge, there were no vaccine-associated myocarditis deaths in this group
- Ongoing efforts to continue patient follow-up and contact myocarditis patients who were not yet recovered at time of survey
- Surveys are being modified for children aged 5-11 and follow-up to start in February 2022
Acknowledgments

Thanks to the many people who made analysis of these data possible:

- **VAERS Team**
  - VAERS TTS abstraction team
  - VAERS Myopericarditis abstraction team
  - VAERS data team

- Clinical Immunization Safety Assessment Project

- COVID-19 Vaccine Task Force Data Monitoring and Reporting Group
Thank you!

For more information, contact CDC
1-800-CDC-INFO (232-4636)

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