

1 **Determinants of COVID-19 Vaccine-Induced Myocarditis Requiring Hospitalization**

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3 **Jessica Rose\***, PhD, MSc, BSc and **Peter A. McCullough<sup>1</sup>**, MD, MPH

4 <sup>1</sup>Truth for Health Foundation, Tucson, AZ, USA

5 \*Correspondence: jessicarose1974@protonmail.com

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7 **Word Count: 8952**

8 **Funding source(s): none related**

9 **Conflict of interest:** Nothing to disclose. Author had access to data and wrote the manuscript.

10 **Author's contributions:** Dr. Jessica Rose completed the data analysis and wrote and edited the  
11 manuscript. Dr. McCullough provided critical edits and content.

12

13

14 **Abstract**

15 Objective: To characterize determinants of COVID-19 vaccine-induced myocarditis requiring  
16 hospitalization in Vaccine Adverse Event Reporting System (VAERS) domestic data.

17

18 Design: Cross sectional, descriptive analysis of VAERS reports of COVID-19 vaccine-induced myocarditis  
19 requiring hospitalization in individuals aged 3 months to 98 years of age.

20

21 Participants: All individuals who submitted an adverse event (AE) report to VAERS associated with a  
22 diagnosis of myocarditis from December 14, 2020 through March 18, 2022.

23

24 Results: 3569/3594 (**99.3%**) cases of COVID-19 vaccine-induced myocarditis requiring hospitalization  
25 reports analyzed in the VAERS domestic data set were **not** co-associated with COVID-19 respiratory  
26 illness in accordance with either 'negative' polymerase chain reactions (PCR) to detect SARS-CoV-2,  
27 COVID-19 diagnosis, or both. Rates of hospitalization were high with 84% of all myocarditis reports  
28 associated with hospitalization in the 0-19 age group and 70.9, in general. Myocarditis in the context  
29 of co-presentation of elevated cardiac troponin (cTn), chest pain (CP), abnormal cardiac imaging ,  
30 electrocardiogram ST segment elevation (STE) and abnormal C-reactive protein levels (CRP) was  
31 reported in the context of hospitalization in 92.2%, 85.5%, 93.5%, 93.9% and 90.3%, respectively, in  
32 children ages 0-19. 79% of all myocarditis requiring hospitalization reports were made within 7 days  
33 of injection and 48% were reported within 48 hours of injection. **90%** of all myocarditis requiring  
34 hospitalization reports and 58% of reports were filed within 7 days and 48 hours, respectively in  
35 children ages 0-19. Higher reporting rates of troponin elevation, ST segment elevation and CRP  
36 abnormalities were found in 12-18-year-olds when compared to the next highest rates found in 19-29-  
37 year-olds (chi-sq; p = 0.00000000; p = 0.00000000; p = 0.00000006). The independent predictors of  
38 hospitalization were as follows: male gender, OR=1.81, 95% CI 1.68-1.95, p<0.005; age (0-19 vs. 19+)  
39 OR=2.32, 95% CI 2-2.69, p<0.005; elevated troponin (12-18 vs. all other age groups), OR=4.63, 95% CI  
40 3.59-5.99, p<0.005; an ST elevation (12-18 vs. all other age groups), OR=4.62, 95% CI 2.99-7.13,  
41 p<0.005.

42

43 Conclusions: Among those with COVID-19 vaccine-induced myocarditis, the majority were  
44 hospitalized, and the independent predictors of hospitalization were age, male gender, positive  
45 troponin, and ST-segment elevation on the ECG. Temporal proximity of reporting to injection date and  
46 significantly higher reporting rates of cardiac troponin, electrocardiogram ST segment elevation and  
47 abnormal C-reactive proteins in young individuals (12-18) in the context of myocarditis requiring

48 hospitalization indicate that these particular pathognomonic markers may be linked to incipient heart  
49 failure whereby the injury due to the injection is the reason for the hospitalization, and should always  
50 be measured and used as diagnostic markers for COVID-19 vaccine-induced myocarditis.

51

52 Keywords

53 SARS-CoV-2; C-reactive protein (CRP); electrocardiogram ST segment elevation (STE); cardiac imaging  
54 procedure abnormal (CI); Chest pain (CP); cardiac troponin elevation (cTnE); Adverse Events (AEs);  
55 Vaccine Adverse Event Reporting System (VAERS); COVID-19; myocarditis

56

57        1. **Background**

58

59        1.1 COVID-19 vaccine-induced myocarditis

60

61 COVID-19 injectable biological product use is prompting above-background reporting of myocarditis  
62 into many adverse event data collection systems including the Vaccine Adverse Events Reports System  
63 of the United States, and many case reports of COVID-19 vaccine-induced myocarditis have been  
64 reported. [1-33] Myocarditis is inflammation of the myocardium, or musculature, of the heart in the  
65 absence of ischemia (reduced blood flow and oxygen). [34-40]<sup>1</sup> Although the etiology associated with  
66 myocarditis is typically viral, it can be the result of exposure to toxic substances or immune-mediated.  
67 [36] Damaged muscle is prone to lethal cardiac arrhythmias as well as having the potential to develop  
68 both right and left ventricular dysfunction (cardiomyopathy), thus it is vital to diagnose early and  
69 medically intervene, if necessary. Diagnosis is commonly done by an assessment of cardiac markers  
70 and tests. [37-55]

71

72 Pre-COVID-19, background rates indicated that 1 in 100,000 children per year were affected by  
73 myocarditis and it has been reported that 0.05% of all pediatric hospitalizations are for myocarditis.  
74 [43,46,47] Aroliya and colleagues found in that the rate of myocarditis pre-COVID-19 was 4  
75 cases/million/year among children and adolescents. Between 0.5 and 3.5% of heart failure  
76 hospitalizations are due to myocarditis. Most cases of myocarditis are identified in young adults with  
77 males affected more often than females. [41] “Data on all NHS England hospital admissions due to  
78 myocarditis between 1998 and 2017 showed that over the 19-year period there were 12,927  
79 admissions with a primary diagnosis of myocarditis accounting for 0.04% (36.5 per 100,000) of all NHS  
80 admissions (although this condition is likely underdiagnosed).” [41]

81

82 Since the mass administration of the Pfizer Inc./BioNTech BNT162b2, Moderna mRNA-1273 and  
83 Janssen Ad26.COV2.S COVID-19 injectable biological products, only two have received biological  
84 licensing agreements but are not fully approved: COMIRNATY product (Pfizer Inc./BioNTech) and the  
85 Moderna product. FDA Biological licensing agreement letters call for more studies on COVID-19  
86 vaccine-induced myocarditis (August 23<sup>rd</sup>, 2021) [56,57,58]. It is vital to actively monitor potential

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<sup>1</sup> Myocarditis can manifest as sudden death, chest pain or heart failure. The symptoms of heart failure from myocarditis include effort intolerance, dyspnea, fatigue, and ankle swelling.

87 cases of COVID-19 vaccine-induced myocarditis, especially in children, and to investigate the  
88 determinants and outcomes.<sup>2,3</sup> [59-88]

89

## 90 1.2 Vaccine Adverse Event Reporting System (VAERS)

91

92 VAERS was created in 1990 by the Food and Drug Administration (FDA) and Centers for Disease Control  
93 and Prevention (CDC) to receive reports of AEs that may be associated with vaccines. [89,90,91,92]

94 The primary purpose for maintaining the database is to serve as an early warning or signaling system  
95 for adverse events not detected during pre-market testing and clinical trials. In spite of the fact that  
96 the National Childhood Vaccine Injury Act of 1986 (NCVIA) requires health care providers and vaccine  
97 manufacturers to report to the DHHS specific AEs following the administration of vaccines outlined in  
98 the Act,<sup>4</sup> under-reporting is a known imperfection of the VAERS system. [93,94,95,96,97]

99

100 A serious or severe adverse event (SAE) is defined an adverse event that can result in a life-threatening  
101 illness, death or prolonged hospitalization or incapacity.<sup>5</sup> [91] Myocarditis qualifies as an SAE as it is  
102 often associated with hospitalization in young individuals [98] and can be life threatening. Myocarditis  
103 requiring hospitalization is the focus of this descriptive analysis.

104

## 105 1.3 Background myocarditis rates and VAERS-reported myocarditis rates

106

107 Recent published findings provide clinical evidence of COVID-19 vaccine-induced myocarditis. A study  
108 published online in the Journal of American Medical Association (JAMA) reviewed 2,000,287 electronic  
109 medical records (EMR) from 40 hospitals in the U.S. of people who received at least one dose of the  
110 COVID-19 biological products. [12] They report 20 individuals succumbed to myocarditis (1/100,000)  
111 and 37 to pericarditis (1.8/100,000) and this was linked to age: the elderly were reported to succumb  
112 to pericarditis more frequently. Importantly, they examined myocarditis and pericarditis rates for a  
113 pre-injection period spanning ~1 year starting January 2019 and they found a 62% increase in

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<sup>2</sup> mRNA injectable products (biologicals) are not true vaccines. True vaccines are a preparation of a weakened or killed pathogen, such as a bacterium or virus, or of a portion of the pathogen's structure that upon administration to an individual stimulates antibody production or cellular immunity against the pathogen but is incapable of causing severe infection. Vaccines undergo an extremely rigorous testing time-dependent protocol to ensure safety and efficacy typically enduring between 10 and 15 years. The mRNA biologicals do not satisfy either these requirements and are thus more akin to experimental gene therapy.

<sup>3</sup> The COVID-19 vaccines administered in the U.S. have not been approved or licensed by the U.S. Food and Drug Administration (FDA), having been authorized instead for emergency use by FDA under an Emergency Use Authorization (EUA), originally designed to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older.

<sup>4</sup> It must be noted that the reported AEs as part of the VAERS represent a fraction of the actual number of incidents. Studies have shown that the percentage of incidents reported can be quite low (1-10%) but, for the purposes of this report, in order to do the necessary calculations, VAERS numbers were used, and the results should be considered to reveal trends.

<sup>5</sup> These classifications are based on the Code of Federal Regulations. The VAERS handbook states that approximately 15% of reported AEs are classified as severe.

114 myocarditis reports and 60% increase in pericarditis reports. A COVID-19 vaccine safety update by the  
115 Advisory Committee on Immunization Practices (ACIP) (June 23<sup>rd</sup>, 2021) by Tom Shimabukuro  
116 (Supplementary Table 1), showed increased myocarditis and pericarditis reporting rates in VAERS. [97]  
117 To be clear, they reported that 66.7/1,000,000 children between the ages of 12 to 17 succumbed to  
118 myocarditis and reported to VAERS. This is up to and including June 11<sup>th</sup>, 2021 - the roll out for children  
119 aged 12-15 began on May 18<sup>th</sup>, 2021: 24 days. Thus, since administration of the COVID-19 vaccines to  
120 children aged 16 and 17 began slightly earlier, these products had been administered to children aged  
121 12-17 for approximately 6 weeks. This means that one would expect 580/1,000,000 children per year  
122 between the ages of 12 to 17 to succumb to myocarditis as a result of the injections. 1/100,000  
123 children are thought to suffer myocarditis each year thus 10 per million would be expected to occur  
124 in any average per year.<sup>6</sup> This means that the reports (ie: the reports we know of made by the CDC for  
125 the ~6-week period of roll out in to 12-17-year-olds) are 58x higher than the expected baseline rate.  
126 These estimates are likely gross underestimates since not all recipients are screened with re-exam,  
127 ECG and troponin. Supplementary Table 1 (right) also reveals a discrepancy between Dose and Dose  
128 2 rates in both females and males. This will be addressed in the section on Cumulative Dose Effect.

129

130 VAERS reports following the first or second dose of the COVID-19 vaccines have previously revealed  
131 that myocarditis rates are significantly higher in youths between the ages of 13 to 23 ( $p < 0.0001$ ) with  
132 86% occurring in males. [97] VAERS data also revealed 19 times the expected number of myocarditis  
133 cases in the vaccination volunteers aged 12-15 years over background myocarditis rates for this age  
134 group. [96]

135

136 More recent evidence (Supplementary Table 2) of above background reporting rates of myocarditis in  
137 VAERS is from ACIP in 2 reports presented on August 30<sup>th</sup> and October 21<sup>st</sup>, 2021 by CDC's John R. Su  
138 both entitled "Myopericarditis following COVID-19 vaccination: Updates from the Vaccine Adverse  
139 Event Reporting System (VAERS)". It is striking that both reports reveal more than 100 times above-  
140 background reporting rate for males in the 12-15 age group.<sup>7</sup> Considering these data, and the clear  
141 above-background safety signals projected, the continuance of the COVID-19 injectable product roll-  
142 out into young children and the push to inject even younger age groups is, questionable.

143

144 1.1 Pathognomonic markers associated with myocarditis requiring hospitalization

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<sup>6</sup> Dr. Rochelle Walensky, director of the Centers for Disease Control and Prevention

<sup>7</sup> John R. Su, MD, PhD, MPH, Vaccine Safety Team, CDC COVID-19 Vaccine Task Force. ACIP presentation October 21, 2021.

146 Correct and early diagnosis is vital to minimize damage induced from COVID-19 vaccine-induced  
147 myocarditis and to maximize the medical management of myocarditis regardless of the etiology.  
148 [36,39] The clinical picture of cardiac injuries associated with the COVID-19 injections are  
149 characterized by extreme elevations in cardiac troponin levels (with cutoff 0.04 ng/mL) [42,76,77,82],  
150 chest pain and abnormal cardiac imaging, electrocardiogram readings, echocardiogram readings<sup>8</sup>, C-  
151 reactive protein levels and cardiac magnetic resonance imaging. In addition to atypical profiles with  
152 regard to these markers, in many cases, individuals report their injuries in temporal proximity to  
153 injection. For example, both can be defined in terms of subclinical possible myocarditis (no cardiac  
154 symptoms with abnormal ECG, echocardiogram, or troponin findings consistent with myocarditis) or  
155 probable myocarditis (no cardiac symptoms without abnormal ECG, echocardiogram, or troponin  
156 findings and only abnormal CMR imaging findings) or clinical (cardiac symptoms present before or at  
157 the time of cardiac testing).<sup>9</sup> But, COVID-19 vaccine-induced myocarditis will be associated with an  
158 additional temporal association with COVID-19 mRNA or adenoviral DNA injections and massive  
159 troponin elevations in the absence of another known cause, for example. COVID-19 vaccine-induced  
160 myocarditis has been reported to present with clinical symptoms such as chest pain (and effort  
161 intolerance), excessively elevated cardiac troponin levels, electrocardiogram ST segment elevation,  
162 and in some cases, left and right ventricular dysfunction on echocardiography (cardiac imaging) and  
163 C-reactive protein abnormalities.<sup>10</sup> The emergence of COVID-19 vaccine-induced myocarditis clinical  
164 symptoms is also supported by preclinical studies and CMRI studies that recently reported myocardial  
165 damage suggestive of ‘autoimmune’ myocarditis that further distinguishes between acute  
166 inflammatory processes.

167

## 168 2. Methods

169

170 To analyse the VAERS data, the Language and Environment for Statistical Computing, R was used.  
171 VAERS data is available for download<sup>11</sup> in three separate comma-separated values (csv) files  
172 representing i) general data for each report; ii) the reported AEs or ‘symptoms’, and iii) vaccine data  
173 including vaccine manufacturer and lot number, for each report. VAERS data is updated weekly. Upon  
174 report of (an) adverse event(s), a VAERS ID number is provided to preserve confidentiality, and a  
175 detailed description of the AEs are transcribed along with the individual’s age, residence by state, past

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<sup>8</sup> The cardinal signs of myocarditis determined by an echocardiogram include an elevated wall thickness, dilation, pericardial effusion, and ventricular systolic dysfunction. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8270733/>

<sup>9</sup> Daniels CJ, Rajpal S, Greenshields JT, et al. Prevalence of Clinical and Subclinical Myocarditis in Competitive Athletes With Recent SARS-CoV-2 Infection: Results From the Big Ten COVID-19 Cardiac Registry. *JAMA Cardiol.* 2021;6(9):1078-1087. doi:10.1001/jamacardio.2021.2065.

<sup>10</sup> In cases where the echocardiogram is unrevealing, cardiac Magnetic Resonance Imaging (MRI) can detect changes in tissue characterization consistent with myocardial inflammation.

<sup>11</sup> <https://vaers.hhs.gov/data/datasets>

176 medical history, allergies and gender and many other demographic details. In addition, the vaccine lot  
177 number, place of vaccination and manufacturer details are meant to be included in the report.

178

179 In order to optimize the input variables for analysis, the three files were merged according to VAERS  
180 ID: a linking variable present in all three files. The merged data set comprises data collected pertaining  
181 to all VAERS reported AEs associated with BNT162b2, mRNA-1273, and Ad26.COVS products.

182

183 The merged data set was sorted according to vaccine type (data reported only in the context of COVID-  
184 19 products) and relevant variables were sorted according to ascending VAERS ID. A data subset  
185 including only reports of myocarditis was created by keyword search according to MedDRA  
186 nomenclature.<sup>12,13</sup> Supplementary Table 1 shows the MedDRA codes used as key words.<sup>14</sup> [92] The  
187 myocarditis data subset was filtered to only include hospital-associated cases (myocarditis requiring  
188 hospitalization includes only reports where hospitalization was indicated (HOSPITAL == "Y").  
189 Diagnostic markers for clinical (as opposed to subclinical) myocarditis including troponin Increases  
190 (cTnE), chest pain (CP), cardiac imaging procedure abnormal (CI), electrocardiogram ST segment  
191 elevation (STE) and abnormal C-reactive protein (CRP) levels were isolated and compared in the  
192 context of the myocarditis reports using age and gender stratification.

193

194 Statistical analysis was done using the Student's t-Test to determine statistically significant differences  
195 between mean ages and the Chi-square test for independence was used to determine significance  
196 between categorical variables (male/female, for example).

197

### 198 3. Results

#### 199 3.1 General information

200

201 To date (March 18, 2022), approximately 5.1 billion people worldwide have received at least one dose  
202 of the COVID-19 products, including the Pfizer Inc./BioNTech BNT162b2, Moderna mRNA-1273 and  
203 Janssen Ad26.COVS products, with 77% of the total population of the United States having received  
204 at least one dose.<sup>15,16</sup> As of March 18<sup>th</sup>, 2022, 1,099,183 AEs have been reported to the VAERS system

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<sup>12</sup> Medical Dictionary for Regulatory Activities <https://www.meddra.org/>

<sup>13</sup> Since VAERS reports of AEs related to cardiac inflammation can span a variety of MedDRA code classifications such as 'Myopericarditis', 'Myocarditis' and 'Autoimmune myocarditis' as prominent examples, for the purposes of this study so as not to exclude potential myocarditis cases, a function was created to select specific key words to capture these cases.

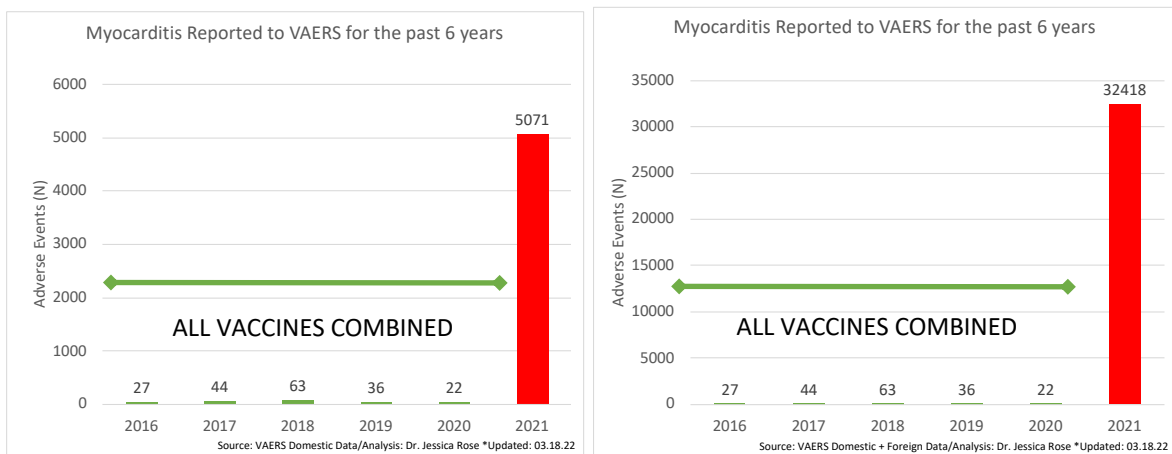
<sup>14</sup> MYOCARDITIS STRING - according to ACIP October 21,2021 report (<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/07-COVID-Su-508.pdf>)

<sup>15</sup> Hannah Ritchie, Edouard Mathieu, Lucas Rodés-Guirao, Cameron Appel, Charlie Giattino, Esteban Ortiz-Ospina, Joe Hasell, Bobbie Macdonald, Diana Beltekian and Max Roser (2020) - "Coronavirus Pandemic (COVID-19)". Published online at OurWorldInData.org.

<sup>16</sup> <https://usafacts.org/visualizations/covid-vaccine-tracker-states/>



205 in the context of the COVID-19 products where 753,460 AEs are from the VAERS Domestic data set.  
 206 These numbers are extraordinarily atypical in comparison to total AE reports to VAERS for the past 10  
 207 years for all vaccines combined: the increase in total reports for 2021 is more than 1800%. Even more  
 208 atypical, are the numbers of myocarditis reports in the context of the COVID-19 products with a more  
 209 than 13,000% increase in reports as compared to the past 5 years of death data in VAERS. Figure 1  
 210 shows the total AE counts and total VAERS-reported myocarditis counts per year for the past 5 years  
 211 up to and including the VAERS update on March 18<sup>th</sup>, 2021. Both the absolute numbers of total AEs  
 212 and those of myocarditis per year dramatically outnumber the absolute numbers recorded in previous  
 213 years. To date, there are 5,071 (<1% of all AEs) reports of myocarditis in the VAERS Domestic database  
 214 and 32,418 (3%) myocarditis reports in total including the reports from the Foreign data set.  
 215



216  
 217 Figure 1: Bar plots – all Domestic VAERS reports of myocarditis in association with all vaccines  
 218 administered to the U.S. population from 2016-2020 shown with COVID-19 products  
 219 (Moderna/Spikevax, Pfizer/BioNTech/Comirnaty and Janssen) administered in the U.S. in (2021)  
 220 (left). The right plot is the same except includes Foreign VAERS reports for 2021.  
 221

222 The number of cases of myocarditis reported to the VAERS database dramatically outnumber case  
 223 counts seen in previous years with a 13,105% increase in reporting in the domestic data set when  
 224 compared to the average number of myocarditis reports over the past 5 years. Remarkably, 5,039  
 225 (99.4%) and 10,862 (99.3%) of the reports of myocarditis to VAERS domestic and foreign data sets,  
 226 respectively, are in the context of a negative PCR test for SARS-nCoV-2 and absence of COVID-19  
 227 diagnosis. (This statistic is maintained in the myocarditis requiring hospitalization group with 99.3% of  
 228 reports made in the presence of negative PCR test and absence of COVID-19 diagnosis.<sup>17</sup>) In spite of  
 229 the low COVID-19-associated rates in the context of myocarditis reports in VAERS, the COVID-19 and

<sup>17</sup>A COVID Case is defined by the keywords: "Pneumonia viral", "COVID-19", "Suspected COVID-19", "SARS-CoV-2 test positive", "COVID-19 pneumonia", "Asymptomatic COVID-19", "Vaccine breakthrough infection"

230 non-COVID-19-associated subsets of myocarditis will be compared thus creating an evidence set for  
231 characteristics of the markers specific for COVID-associated myocarditis and COVID-19 vaccine-  
232 induced myocarditis. Since myocarditis baseline rates from the United States will be compared, from  
233 this point on, only the numbers from the VAERS domestic data set will be reported.

234

### 235 3.2 General descriptive analysis of myocarditis reports in VAERS

236

237 When the myocarditis dataset is age-stratified, it becomes evident that a large proportion of  
238 myocarditis reports are being made for young individuals ages 12-29 (44%) (Supplementary Figure 1).  
239 It is being repeated by public health policy members that myocarditis in young individuals is primarily  
240 'mild' and 'transient'. [10,97] However, rates of hospitalization (and emergency room visits) occur at  
241 high rates among the myocarditis reports in VAERS (70.9%) and can thus be used to rule out claims of  
242 'mild' myocarditis. Interestingly, 49% of individuals hospitalized with myocarditis experienced chest  
243 pain. This and other pathognomonic markers will be discussed in the upcoming sections.

244

245 When the reports of myocarditis associated with hospitalization are stratified by age group, it  
246 becomes more obvious that young individuals are suffering at higher rates. The majority of  
247 myocarditis reports associated with death (2%) are occurring in the elderly age group 60-69.  
248 Supplementary Figure 1 also shows that half of the hospitalizations (49%) were reported in the cases  
249 of young individuals aged 12-29. One quarter (23%) of the reports were made for children aged 12-  
250 18. Subdivision by age group follows in the upcoming section.

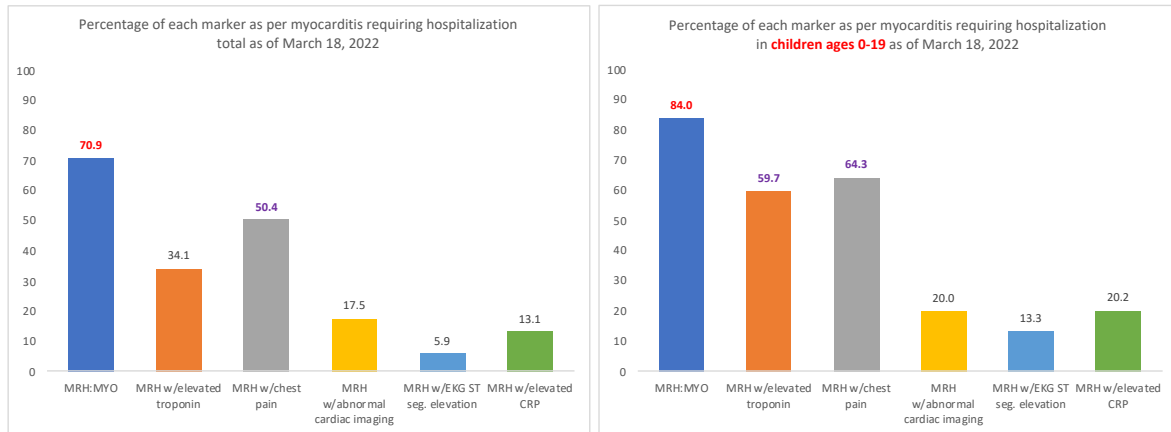
251

### 252 3.3 Characterizing pathognomonic markers for COVID-19 vaccine-induced myocarditis

253

254 Selected clinical features of myocarditis were filtered out of the total myocarditis requiring  
255 hospitalization cases by MedDRA code. As shown in Figure 2, 70.9% of reports of myocarditis are  
256 hospital-associated. Of these, 34.1% are associated with cTnE, 50.4% are associated with CP, 17.5%  
257 are associated with abnormal CI, 5.9% are associated with STE and 13.1% are associated with  
258 abnormal CRP levels.

259



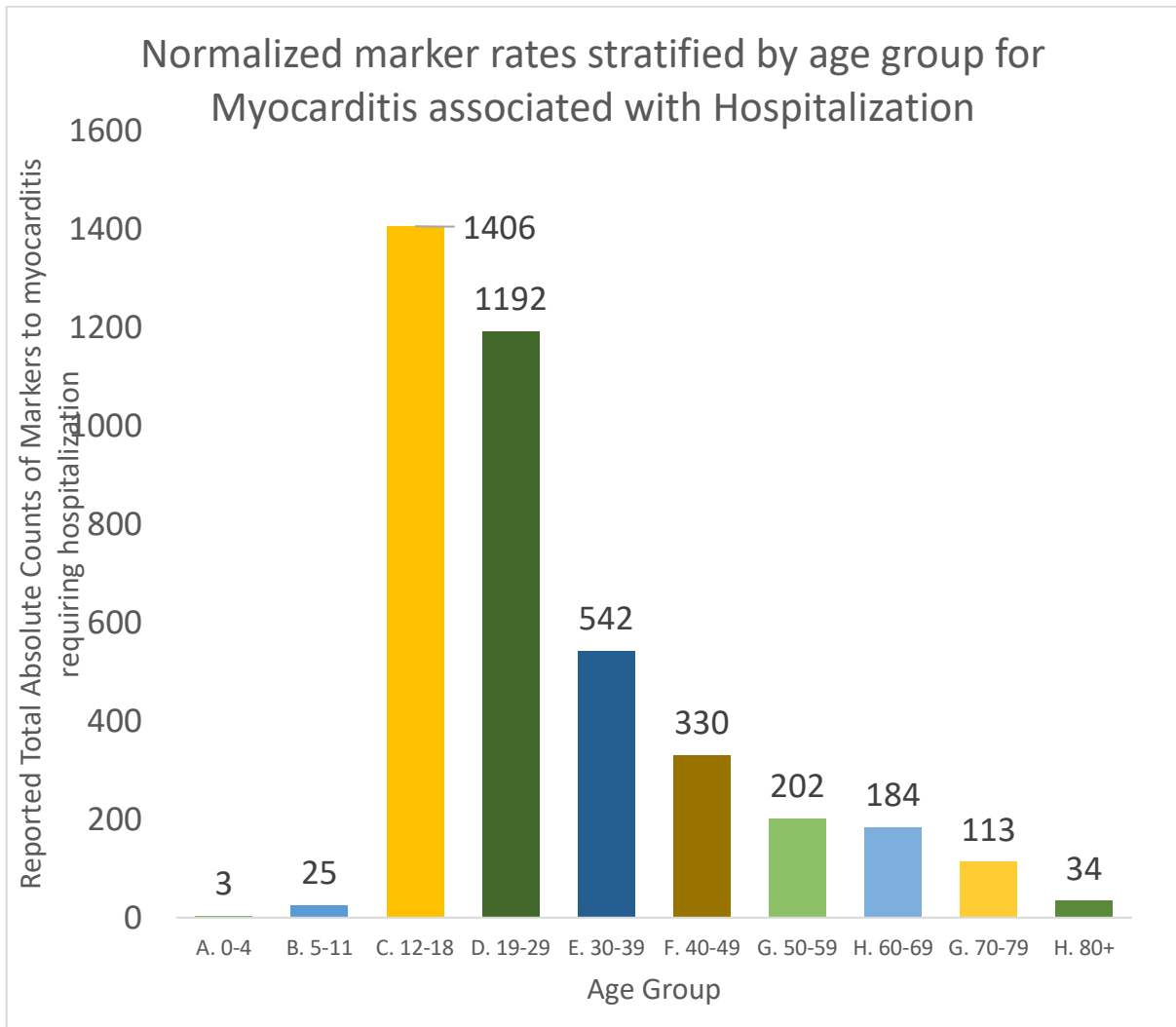
260  
 261 Figure 2: Bar graphs showing the percentage of myocarditis requiring hospitalization to myocarditis  
 262 reports and the percentages of pathognomonic markers associated with myocarditis requiring  
 263 hospitalization cases co-associated with Troponin elevation, Chest pain, abnormal cardiac imaging,  
 264 electrocardiogram ST segment elevation and abnormal C-reactive protein levels for all ages (left) and  
 265 children ages 0-19 (right).

266  
 267 As previously reported, 70.9% percent of myocarditis reports are associated with hospitalization and  
 268 1.99% are associated with death (not shown). For children ages 0-19, 84% of myocarditis cases are  
 269 hospital-associated with 59.7%, 64.3%, 20.0%, 13.3% and 20.2% co-associated with cTnE, CP, CI, STE  
 270 and CRP, respectively. This means that there is a high preponderance of elevated troponin and chest  
 271 pain with myocarditis requiring hospitalization, in general, and this preponderance is higher in  
 272 younger ages. These myocarditis requiring hospitalization cases are *not* associated with COVID-19.

273  
 274 The markers in the context of the myocarditis reports were age-stratified and plotted to determine if  
 275 there are preponderances of these markers in young people (Figure 2). As previously reported, 47%  
 276 of myocarditis requiring hospitalization cases are made in the context of young individuals ages 12-29  
 277 (Figure 3). Of these reports, 50% were associated with troponin elevation, 62% chest pain, 14%  
 278 abnormal cardiac imaging, 10% electrocardiogram ST segment elevation 17% C-reactive protein  
 279 (Supplementary Figure 2).<sup>18</sup>

280

<sup>18</sup> It is important to note that this might mean that more youths were tested with higher frequency for these markers in association with myocarditis. It is highly unlikely that this is the case, but it warrants mentioning. It is not possible to know with certainty.



281  
 282 Figure 3: Absolute counts of markers co-associated with myocarditis requiring hospitalization by age  
 283 group.  
 284

285 If only the younger age group 12-18 is considered (this group represents 22% of all of the myocarditis  
 286 requiring hospitalization reports), these percentages become 62%, 65%, 14%, 15% and 21%, for cTnE,  
 287 CP, CI, STE and CRP, respectively. Thus, even in the small range of ages in the 12-18 age group,  
 288 approximately half of the reports are associated with elevated troponin and ECG ST segment elevations  
 289 and one-third to one-quarter are associated with abnormal CRP levels, chest pain and abnormal  
 290 cardiac imaging. It is interesting to note that STE is most prevalent in the 12-18-year-olds – significantly  
 291 so ( $p = 0.00000006$ ) - and more prevalent than any other marker (31% higher than for the 19-29-year-  
 292 olds). Troponin elevation is highest in 12-18-year-olds and is 20% higher than in the 19-29-year-old  
 293 age group ( $p = 0.000000$ ). CRP abnormalities are also statistically-significantly higher in 12-18-year-  
 294 olds than for 19-29-year-olds ( $p = 0.000045$ ) (Supplementary Table 2).

296 Table 1 shows a summary of the total counts for each marker in co-association with myocarditis and  
 297 the percentages of the total respective variable in the context of death, hospitalization and children  
 298 ages 0-19.

300 Table 1: Table showing myocarditis absolute counts and rates (N (%)) of reports made to VAERS  
 301 domestic data co-associated with death, hospitalization and children (0-19).

Variable	Myocarditis N (% total)	Myocarditis w/TROP ↑ N (% total)	Myocarditis w/CP N (% total)	Myocarditis w/CI N (% total)	Myocarditis w/EST ↑ N (% total)	Myocarditis w/CRP ↑ N (% total)
Myocarditis	5071 (100)	1362 (26.8)	2367 (46.6)	731 (14.4)	230 (4.5)	549 (10.8)
Death	101 (2)	12 (0.9)	8 (0.3)	10 (1.4)	1 (0.4)	6 (1.1)
Hospital	3594 (70.9)	1224 (89.9)	1812 (76.6)	629 (86)	212 (92.2)	471 (85.8)
Kids (0-19)	1105 (21.8)	601 (44.1)	698 (29.5)	199 (27)	131 (57)	207 (37.7)

302  
 303  
 304 If one suffers myocarditis and is hospitalized, then in 89.9% of cases, troponins are elevated and in  
 305 92.2% of cases the individual has ST segment elevation. Also of note, 86% of the cases involve  
 306 abnormal cardiac MRI. Children ages 0-19 represent approximately half of all cases involving elevations  
 307 in troponins and EST. Boxes shaded cyan are rates that exceed 70%, boxes shaded green are rates that  
 308 exceed 85% and red boxes show rates that exceed 90% meaning that 92.2% of reports of  
 309 electrocardiogram ST segment elevations measured in the context of myocarditis involved  
 310 hospitalization.

311  
 312 The rate of the vaccine-induced myocarditis requiring hospitalization becomes even clearer if the data  
 313 is organized according to ambulatory versus non-ambulatory reports. The following bar plot shows the  
 314 number of myocarditis-associated non-ambulatory reports versus ambulatory reports. The non-  
 315 ambulatory reports comprise a mere 27% of all reports.

316

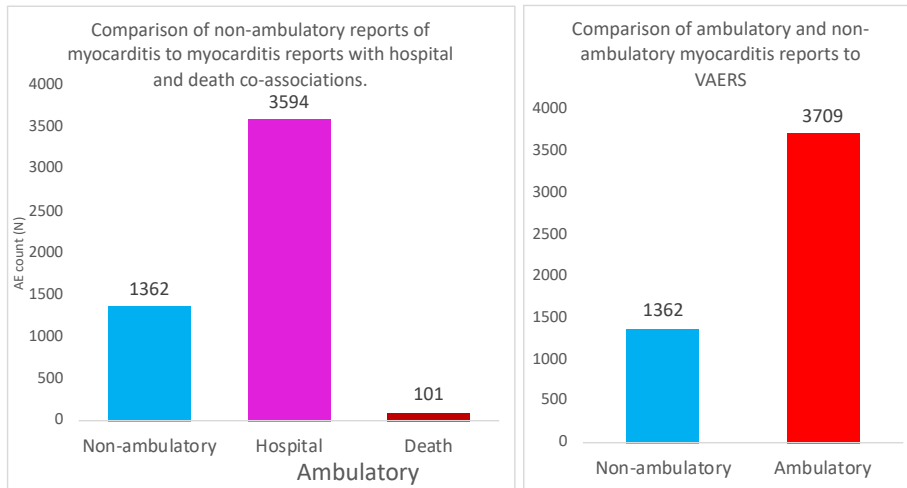


Figure 4: Comparison of myocarditis in the context of non-ambulatory reports and ambulatory reports filed to VAERS Domestic dataset as of March 18, 2022.

Non-ambulatory reports in the context of myocarditis (these are the reports that did not involve hospitalization), are less prominent than ambulatory reports made in this context (chi-sq. -> p=0.000). In fact, when myocarditis ensues, one is 12X more likely to be hospitalized (OR=11.89; CI=10.2-13.9; p=0.000).

Table 2 is the same as Table 1, conceptually, but includes the data for only children ages 0-19. Except for the CP clinical marker, the pathognomonic markers are reported at extremely high rates – almost exclusively in the context of hospitalization. This means that half (54.4%) of the children aged 0-19 are reported to have elevated troponin and of those children 92.2% are hospitalized. In general, half (46.6%) of all myocarditis cases were associated with chest pain of those, 76.6% involved hospitalization.

Table 2: Table showing myocarditis absolute counts and rates (N (%)) of reports made to VAERS domestic data for children ages 0-19 co-associated with death and hospitalization.

Variable KIDS 0-19	Myocarditis N (% total)	Myocarditis w/TROP ↑ N (% total)	Myocarditis w/CP N (% total)	Myocarditis w/CI N (% total)	Myocarditis w/ESTSE ↑ N (% total)	Myocarditis w/CRP ↑ N (% total)
Myocarditis	1105 (100)	601 (54.4)	698 (63.1)	199 (18)	131 (11.9)	207 (18.7)
Death	2 (0.2)	1 (0.2)	0 (0)	0 (0)	0 (0)	1 (0.5)
Hospital	928 (84)	554 (92.2)	597 (85.5)	186 (93.5)	123 (93.9)	187 (90.3)

### 3.4 Comparison of myocarditis requiring hospitalization in the presence and absence of COVID reporting

339 If negative PCR tests are used as confirmation of the absence COVID-19 in the presence of myocarditis,  
340 then the resulting clinical manifestation of myocarditis must be either from a previous injury to the  
341 heart, or from the injections. When the COVID-19-associated cases are separated and compared to  
342 the non-COVID-19 cases, there is no significant difference in the deaths between the myocarditis cases  
343 associated with COVID-19, 2% vs. 3.1% for no COVID versus COVID, respectively. There is also no  
344 significant difference between hospitalizations in COVID-associated myocarditis reports, 70.8% vs.  
345 78.1% for no COVID versus COVID, respectively. Interestingly, for myocarditis cases in children ages 0-  
346 19 without COVID-19 association, 84% involve hospitalization versus 66.7% in the case where there is  
347 a COVID association. Although this difference is not statistically significant ( $p=0.4$ ), this data indicates  
348 that COVID-19-associated myocarditis in children is less associated with hospitalization than COVID-19  
349 vaccine-induced myocarditis and thus it appears as though the injections induce worse outcome with  
350 regard to myocarditis if we measure outcome by hospitalization.

351  
352 Among all cases of myocarditis all ages, 32 (0.6%) had co-incident COVID-19 respiratory illness and  
353 among those 1 died and 25 (78.1) were hospitalized. Of these cases, there were 3 (9.4%) children ages  
354 0-19 and among those none died and 2 (6.3%) were hospitalized. Among all cases of myocarditis all  
355 ages, 5039 (99.4%) had no co-incident COVID-19 respiratory illness and among those 100 (2%) died  
356 and 3069 (70.8%) were hospitalized. Of the non-co-incident COVID-19 respiratory illness cases, 1102  
357 (22%) were 0-19 years of age. Of these children, 2 (0.2%) died and 926 (84%) were hospitalized.

358  
359 When the COVID versus non-COVID cases of myocarditis requiring hospitalization are compared in the  
360 context of the markers, although the differences are not statistically significant except in the case of  
361 CRP ( $p=0.28$ ;  $p=0.79$ ;  $p=0.46$ ;  $p=0.2$ ;  $p=0.05$ , respectively), they are higher in all cases in the absence of  
362 COVID as shown in Supplementary Table 2.

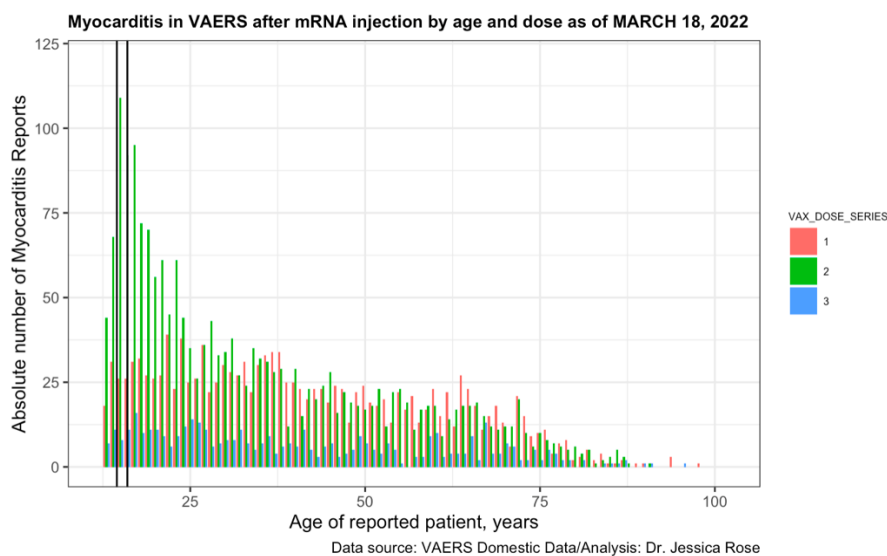
363  
364 Another way to examine the COVID-19/non-COVID-19-associated data from VAERS is to superimpose  
365 the myocarditis cases for each by age group to determine if there is an observable difference in COVID-  
366 19-association within each age group. Among all cases of myocarditis ages >19 years, 28 had co-  
367 incident COVID-19 respiratory illness and among those 23 were hospitalized and 1 died. Similarly,  
368 among all cases of myocarditis ages 0-19 years, 3 had co-incident COVID-19 respiratory illness and  
369 among those 2 were hospitalized and 0 died.

370  
371 Interestingly, in children ages 12-18, there is a difference in reporting rate whereby children in this age  
372 group report higher rates of myocarditis requiring hospitalization in the absence of COVID-19. In

373 individuals 80 years of age or older, the opposite is observed whereby the reporting rate of myocarditis  
374 requiring hospitalization is much higher in the presence of COVID-19. It should be noted that the rates  
375 of reporting on the context of COVID-19 are very low so these results are simply notable observations.  
376

### 377 3.5 Cumulative Dose Effect

378  
379 When the myocarditis reports are plotted according to age and dose (1, 2 and 3), it becomes apparent  
380 that the reporting rate has a 4-fold difference in the young following dose 2. 15-year-olds (outlined by  
381 black lines in Figure 5) are the highest reporters of myocarditis in VAERS following dose 2 and represent  
382 11% of the total myocarditis requiring hospitalization cases. Dose 3 reporting is dramatically lower in  
383 comparison to both dose 1 and dose 2 and this is likely due to fewer individuals getting dosed a third  
384 time. There are 2.65 fewer 3<sup>rd</sup> doses than 1<sup>st</sup> doses administered as of March 18<sup>th</sup>, 2022 in the United  
385 States. This is confirmed by the CDC’s U.S. Coronavirus vaccine tracker statistics.<sup>19</sup> This dose response  
386 provides evidence of a causal effect of the COVID-19 vaccines and myocarditis in children.  
387



388  
389 Figure 5: Myocarditis in VAERS Domestic data according to age and dose.

390  
391 It was reported in October 2021 as part of a case study entitled “COVID-19 vaccine-induced  
392 myocarditis: Case report with literature review”, that ‘patients reported myocarditis symptoms within  
393 three days of receiving the first/second dose; however, most presentations correlated with the second

<sup>19</sup> At least 254,599,776 people or 77% of the population have received at least one dose. Overall, 216,690,804 people or 65% of the population are considered fully vaccinated. Additionally, 96,035,748 people or 29% of the population have received a booster dose. <https://usafacts.org/visualizations/covid-vaccine-tracker-states/>



394 *dose of the COVID-19 vaccine*.<sup>20</sup> It is notable that 34% and 50% of total myocarditis reports (including  
395 reports of myocarditis requiring hospitalization) were filed to VAERS within 24 and 48 hours. 79% were  
396 filed within 7 days of injection. It is also notable that 30% and 48% of myocarditis requiring  
397 hospitalization reports were filed to VAERS within 24 and 48 hours. This means that within 2 days, half  
398 of all individuals had not only succumbed to myocarditis but had been diagnosed as such and  
399 successfully filed a VAERS report. 79% of myocarditis reports were filed to VAERS within the 7 days of  
400 the injections. (See Supplementary Figure 3)

401

402 Discussion

403

404 We found that COVID-19 vaccine-induced myocarditis was common and frequently required  
405 hospitalization. The determinants of hospitalization were older age, male gender, troponin elevation  
406 and ST-segment elevation. While rare, concurrent COVID-19 respiratory illness was more frequently  
407 related to COVID-19 vaccine-induced myocarditis in older age groups.

408

409 There is an historically unprecedented absolute number of reports of AEs in the VAERS  
410 database in the context of general AE reports. The rate of SAEs is typically 15% of the total number  
411 and has consistently (from week to week) remained at 18% for the entirety of the COVID-19 vaccine  
412 roll-out in the United States. There are also an unprecedented number of types of AEs (over 10,000  
413 types<sup>21</sup>, as of March 18, 2022) reported to VAERS in the context of the COVID-19 injectable biological  
414 products. Specifically, myocarditis reporting rates in VAERS are also entirely atypical with an over  
415 13,000% increase in the reporting frequency when compared to the past 5 years of reports. This is not  
416 due to the excess number of doses administered in the United States in the context of COVID-19  
417 vaccines. According to the CDC, 193.8 million doses of flu vaccine have been distributed in the United  
418 States as of February 26, 2021 (for the 2020-2021 flu season): “the highest number of doses in a single  
419 flu season”.<sup>22</sup> 558 million doses of COVID-19 vaccines were administered in the United States from  
420 December 14, 2020, through March 21, 2022. This is 462 days. A flu season is a year (365 days), thus  
421 it would be fair to assume that if 193.8 doses of flu vaccine were administered in 365 days then ~245  
422 million doses would be administered in 462 days. Assuming that there were 2.3 times more doses of  
423 COVID product administered than for the flu for the same time period of 462 days, it would make  
424 sense then, that the rate of reporting in VAERS (for the same range of adverse events as reported for

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<sup>20</sup> Nassar M, Nso N, Gonzalez C, et al. COVID-19 vaccine-induced myocarditis: Case report with literature review [published correction appears in *Diabetes Metab Syndr*. 2021 Sep-Oct;15(5):102277]. *Diabetes Metab Syndr*. 2021;15(5):102205. doi:10.1016/j.dsx.2021.102205

<sup>21</sup> <https://wonder.cdc.gov/vaers.html>

<sup>22</sup> <https://www.cdc.gov/flu/season/faq-flu-season-2020-2021.htm>

425 the flu) would be about twice for COVID than for flu. Twice as many doses - a proportional number of  
426 reporting - twice as many reports.

427

428 As of March 25, 2022, according to the WONDER/CDC system, there were 1,696 different types of  
429 adverse events and 45,650 total adverse events reported to VAERS in the context of the 14 variations  
430 of flu vaccines. Also according to the WONDER/CDC system, there were 10,526 different types of  
431 adverse events and 5,368,444 total adverse events reported to VAERS in the context of the 3 variations  
432 of the COVID-19 products used in the United States.<sup>23</sup> Thus, there are twice as many COVID shots than  
433 flu shots, 6.2 times as many types of adverse event types reported in the context of the COVID shots  
434 and 117.6 times as many reports of adverse events in the context on the COVID shots. Therefore, even  
435 though all the other vaccines were not considered in this comparison (there are 82 other types), there  
436 is no contest in this case with regard to the number of shots and the relationship to the number of  
437 AEs occurring and being reported, and the 'anticipated' doubling of the reports is certainly not seen  
438 as would be expected if the injection to AE ratio was proportional for flu and COVID products.

439

440 Almost half (44%) of the reports of myocarditis in VAERS are for young individuals ages 12-29 and of  
441 these, 62% were hospitalized. Children ages 0-19 comprise 22% of the myocarditis reports and of  
442 those, 69% were hospitalized. The CDC<sup>24</sup>, FDA and other health care organizations refer to myocarditis  
443 as 'mild' and 'transient' and do not consider this serious ailment to be so in children enough to warrant  
444 a stop gap in the roll-out to prevent cases of injection-associated childhood myocarditis. "CDC  
445 continues to recommend that everyone ages 5 years and older get vaccinated for COVID-19. The  
446 known risks of COVID-19 illness and its related, possibly severe complications, such as long-term  
447 health problems, hospitalization, and even death, far outweigh the potential risks of having a rare  
448 adverse reaction to vaccination, including the possible risk of myocarditis or pericarditis." The data  
449 from where they draw these comparisons should be made transparent. Childhood death from COVID-  
450 19 is far rarer than childhood rates of myocarditis leading to lifelong health problems according to  
451 data.

452

453 Our study has all the limitations of reports from spontaneous reported safety event databases that  
454 rely on the entry of information by the end-user, most commonly a healthcare professional (Meisner  
455 et. al Pediatrics 2022) and later confirmation by the CDC. VAERS has inherent limitations, one being  
456 human error where column vector field entries are incomplete in the case of many VAERS ID entries.

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<sup>23</sup> N.B. These counts do not represent the individuals who experienced an AE but the total number of events reported.

<sup>24</sup> <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html>

457 Cases (individuals) in this report may have been biased towards hospital-associated diagnoses of  
458 myocarditis, since ambulatory cases may have gone unreported. It is assumed that individuals (and  
459 their data) used in this analysis *were* treated equally upon hospitalization and that upon presentation  
460 of myocarditis-like symptoms, the specific markers (cTnE, CP, CI, STE, CRP) were assessed or tested, in  
461 addition to others, and a diagnosis made based on the results of these tests. Finally, we did not have  
462 external adjudication of myocarditis beyond the CDC officers who routinely call and validate cases  
463 with the reporting physician.

464

465 Unlike the majority of reports of myocarditis that follow SARS-CoV-2 respiratory infection which rely  
466 upon ICD-10 codes, our study found that COVID-19 vaccine-induced myocarditis is well characterized  
467 by clinical data supporting the actual diagnosis and that its ramifications including hospitalization of a  
468 previously well individual are serious and concerning.

469

#### 470 4. Conclusion

471

472 COVID-19 vaccine use is prompting above-background reporting of myocarditis and pericarditis into  
473 VAERS. Recent published findings provide evidence of COVID-19 vaccine-induced myocarditis that is  
474 disparate from COVID-19-associated myocarditis. Of the 5,071 total clinically-related myocarditis AE  
475 reports in VAERS made as of March 18<sup>th</sup>, 2021, 101 individuals have died, which comprises 2% of the  
476 total myocarditis reports, 70.9% involve hospitalization and 21.8% of all cases are children aged 0-19.

477

478 COVID-19 injectable products are novel and have a genetic, pathogenic mechanism of action causing  
479 uncontrolled expression and production of SARS-CoV-2 spike protein within human cells. When you  
480 combine this fact with the temporal relationship of AE occurrence and reporting, biological plausibility  
481 of cause and effect, and the fact that these data are internally and externally consistent with emerging  
482 sources of clinical data, it supports a conclusion that the COVID-19 biological products are  
483 deterministic for the myocarditis cases observed after injection.

484

485 It would be prudent to stop all further roll-out of these product and to maintain a strict protocol for  
486 measuring the pathognomonic markers for myocarditis requiring hospitalization in individuals  
487 reporting to VAERS. [99-101]

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781 Supplementary Materials

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783 Supplementary Table 1: Myocarditis/pericarditis reports per million mRNA vaccine doses

784 administered by gender and dose number with no restrictions on post-vaccination observation time

785 as reported by CDC in ACIP report by Tom Shimabukuro. June 23, 2021. Pages 28 and 29.

**Preliminary myocarditis/pericarditis reports to VAERS following dose 2 mRNA vaccination, Exp. vs. Obs. using 7-day risk window (data thru Jun 11, 2021)**

Age groups	Females			Males		
	Doses admin	Expected <sup>a,1</sup>	Observed <sup>a</sup>	Doses admin	Expected <sup>a,1</sup>	Observed <sup>a</sup>
12-17 yrs	2,189,726	0-2	19	2,039,871	0-4	128
18-24 yrs	5,237,262	1-6	23	4,337,287	1-8	219
25-29 yrs	4,151,975	0-5	7	3,625,574	1-7	59
30-39 yrs	9,356,296	2-18	11	8,311,301	2-16	61
40-49 yrs	9,927,773	2-19	18	8,577,766	2-16	34
50-64 yrs	18,696,450	4-36	18	16,255,927	3-31	18
65+ yrs	21,708,975	4-42	10	18,041,547	3-35	11
Not reported	—	—	1	—	—	8



<sup>a</sup> Assumes a 7-day post-vaccination observation window (i.e., symptom onset from day of vaccination through Day 6 after vaccination)  
<sup>1</sup> Based on Gidycz et al. U.S. Population-based background incidence rates of medical conditions for use in safety assessment of COVID-19 vaccines. Vaccine. 2021 May 14;39(20):4202-4205. doi:10.1016/j.vaccine.2021.05.024. Expected counts among females 12-29 years adjusted for lower prevalence relative to males by factor of 1.7 (Fairweather, D. et al. Curr Probl Cardiol. 2013;38(1):7-40).

**Preliminary myocarditis/pericarditis crude reporting rates to VAERS following mRNA COVID-19 vaccination (data thru Jun 11, 2021)**

Age groups	Overall reporting rate per million doses			Reporting rate in females per million doses			Reporting rate in males per million doses		
	All doses	Dose 1	Dose 2	All doses	Dose 1	Dose 2	All doses	Dose 1	Dose 2
12-17 yrs	18.1	5.3	37.0	4.2	1.1	9.1	32.4	9.8	66.7
18-24 yrs	15.9	4.8	28.4	3.6	1.5	5.5	30.7	8.7	56.3
25-29 yrs	6.7	2.5	10.8	2.0	0.8	2.6	12.2	4.5	20.4
30-39 yrs	4.2	1.7	5.6	1.8	1.4	1.8	6.9	2.0	10.0
40-49 yrs	2.7	0.9	3.8	2.0	0.9	2.8	3.5	1.0	5.1
50-64 yrs	1.7	1.0	2.0	1.6	1.0	1.8	1.9	1.0	2.3
65+ yrs	1.1	0.7	1.3	1.1	0.6	1.2	1.2	0.7	1.4



Myocarditis/pericarditis reports per million mRNA vaccine doses administered by sex and dose number with no restrictions on post-vaccination observation time

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788 Supplementary Table 2: 'Myopericarditis' reports per million mRNA vaccine doses administered by

789 gender and dose number with a 7-day observation window as reported by CDC in ACIP report by

790 John R. Su. (left -> August 30, 2021 ; right -> October 21, 2021.)

**Expected vs. Observed reports after Pfizer-BioNTech dose 2, 7-day risk period (N=549)\***

Age group, years	Females		Males	
	Cases of myopericarditis, expected	Cases of myopericarditis, observed	Cases of myopericarditis, expected	Cases of myopericarditis, observed
12-15*	0-3	12	1-5	116
16-17*	0-2	15	0-3	120
18-24*	0-5	11	1-7	134
25-29*	0-4	4	1-5	30
30-39	1-13	7	1-11	40
40-49	1-13	12	1-11	26
50-64	2-22	9	2-19	5
65+	2-22	4	2-18	4



\* As of Aug 18, 2021, assumes a 7-day observation window, with 149 of 162 reports after mRNA vaccines occurring during Days 0-6 after vaccination; counts among 12-29 years from reports meeting case definition for myopericarditis; expected estimates for females 12-29 years adjusted to reflect reduced incidence in this age group

**Expected vs. Observed cases of myocarditis reported to VAERS after Pfizer-BioNTech dose 2, 7-day risk period (N=518)\***

Age group, years	Females		Males	
	Cases of myopericarditis, expected	Cases of myopericarditis, observed	Cases of myopericarditis, expected	Cases of myopericarditis, observed
12-15	0-4	14	1-7	143
16-17	0-2	17	0-4	139
18-24	1-5	12	1-8	152
25-29	0-4	4	1-6	33
30-39	1-14	5	1-13	34
40-49	1-14	8	1-12	13
50-64	2-24	6	2-21	3
65+	2-23	3	2-18	1



\* As of Oct 6, 2021, assumes a 7-day observation window, with 138 of 162 reports after Pfizer-BioNTech dose 2 occurring during Days 0-6 after vaccination; counts from reports meeting case definition for myopericarditis; expected estimates for females 12-29 years adjusted to reflect reduced incidence in this age group

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794 Supplementary Table 3: List of VAERS IDs with clear pathognomonic markers for COVID-19 vaccine-  
795 induced myocarditis

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VAERS ID: 1486983; 13 years old; 1 day after 2<sup>nd</sup> shot. "Troponin I 5.23 (7/19@1936), 5.08 (7/19@2014), 3.63 (7/20@0215). C-Reactive Protein 10.2 (7/20@0806), BNP 24 (7/19@1936). [Chest pain.] *COVID Negative.*"

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VAERS\_ID: 1693372. 31 years old. myocarditis developed 2 days after the 2nd shot. *troponin almost 22K*. No history. No illnesses. No meds.

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VAERS\_ID: 1533287. 12 years old. Chest pain. hs troponin peak at >25,000 ng/L Echo normal

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VAERS\_ID: 1539671. 15 years old. CHEST PAIN, ELEVATED TROPONIN >22,000 WITH EKG CHANGES, SUSPECTED MYOCARDITIS

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VAERS\_ID: 1974116. 17 years old. Troponin 9,986.9, then 15,943.8

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VAERS\_ID: 2019971. 33 years old. high sensitivity troponin 28k (elevated) EKG with diffuse ST elevation and PR depression

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VAERS\_ID: 1327111. 19 years old. CRP increased. Troponin 10.804 CRP 32 Echocardiogram ordered for LV function.

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VAERS\_ID: 1962935. 26 years old. high-sensitivity troponin 1,387 (myocarditis) EKG with diffuse ST elevations and PR depressions (pericarditis).

---

VAERS\_ID: 1334092. 23 years old. Chest pain. Troponin peak of 6 CRP >100 MRI showed subepicardial gadolinium enhancement in the basal inferolateral wall.

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VAERS\_ID: 1357884. 16 years old. CBC - nl, d-dimer elevated at 0.60, troponin 6,389, CRP 9.50, ESR 22, BNP 479 EKG Sinus rhythm , ST elevation II, III, aVF, V4-V6 and ST depression with T wave inversions

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VAERS\_ID: 1394876. 14 years old. *normal Echocardiogram 6/13/2021--elevated highly sensitive troponin at over 1000 ng/L*

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VAERS\_ID: 1487493. 22 years old. B-Natriuretic Peptide: 12 CK: 163 CK MB: 3.3 CRP hs Cardiac: 0.92 Troponin I:1554 (!) Myoglobin: 46. *COVID-19 vaccine induced myopericarditis.*

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VAERS\_ID: 1493763. 15 years old. Troponin 20,987 at 1450 and CRP 79.4. 7/17 Troponin 28,338 at 2336. 7/18 Troponin 23376, CRP 53. 7/19 Troponin 19,463, CRP 29. 7/20 Troponin 4,658, CRP 16.6.

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800 Supplementary Table 4: MedDRA coded AEs reported to VAERS related to myocarditis according  
 801 to ACIP October 21, 2021 report  
 802 ([https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/07-COVID-Su-](https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/07-COVID-Su-508.pdf)  
 803 [508.pdf](https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/07-COVID-Su-508.pdf)).

- [1] "Myocardial necrosis marker increased" "Myocardial rupture"
- [3] "Myocardial ischaemia" "Viral endocarditis"
- [5] "Atypical mycobacterium pericarditis" "Myocarditis"
- [7] "Autoimmune myocarditis" "Myocarditis bacterial"
- [9] "Autoimmune pericarditis" "Myocarditis helminthic"
- [11] "Bacterial pericarditis" "Endocarditis"
- [13] "Endocarditis bacterial" "Myocarditis infectious "
- [15] "Coxsackie myocarditis" "Myocarditis meningococcal"
- [17] "Coxsackie pericarditis" "Myocarditis mycotic"
- [19] "Carditis" "Cytomegalovirus myocarditis"
- [21] "Myocarditis post infection " "Cytomegalovirus pericarditis"
- [23] "Myocarditis septic" "Endocarditis noninfective"
- [25] "Enterovirus myocarditis Pericarditis" "Eosinophilic myocarditis"
- [27] "Pericarditis" "Pericarditis adhesive"
- [29] "Hypersensitivity myocarditis" "Pericarditis constrictive"
- [31] "Immune-mediated myocarditis" "Pericarditis helminthic"
- [33] "Pericarditis infective" "Pericarditis mycoplasmal"
- [35] "Pleuropericarditis" "Purulent pericarditis"
- [37] "Viral myocarditis" "Viral pericarditis"

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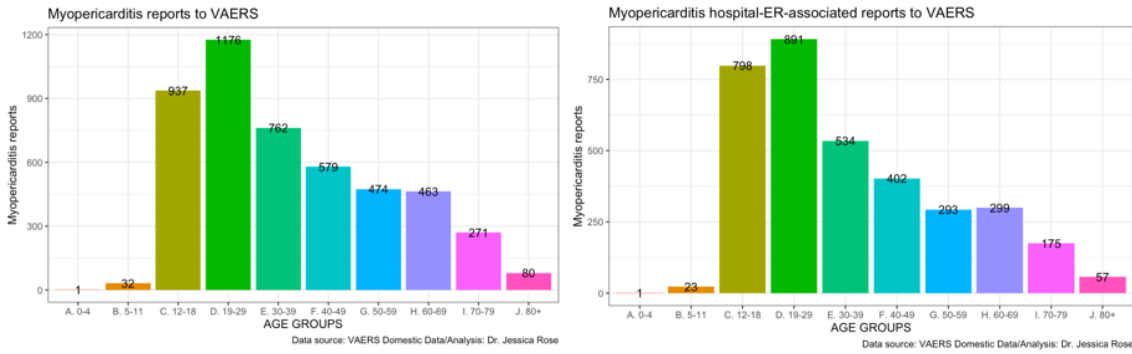
Supplementary Table 5: Comparison of COVID versus non-COVID myocarditis requiring hospitalization cases in VAERS domestic data with respect to 5 markers with chi-square table showing Relative Risk (RR), Odds Ratio (OR) and p-value associated with chi-square test.

COVID (ALL AGES)	MRH N (% total)	no COVID	MRH N (% total)	COVID (0-19)	MRH N (% total)	no COVID	MRH N (% total)
<b>Total</b>	25 (0.7)	<b>Total</b>	3569 (99.3)	<b>Total</b>	2 (0.06)	<b>Total</b>	926 (26)
<b>Troponin</b>	6 (24)	<b>Troponin</b>	1218 (34)	<b>Troponin</b>	2 (100)	<b>Troponin</b>	552 (60)
<b>CP</b>	7 (28)	<b>CP</b>	1085 (51)	<b>CP</b>	2 (100)	<b>CP</b>	595 (64)
<b>CI</b>	3 (12)	<b>CI</b>	626 (18)	<b>CI</b>	0 (0)	<b>CI</b>	186 (20)
<b>ESTSE</b>	0 (0)	<b>ESTSE</b>	212 (6)	<b>ESTSE</b>	0 (0)	<b>ESTSE</b>	123 (13)
<b>CRP</b>	0 (0)	<b>CRP</b>	471 (13)	<b>CRP</b>	0 (0)	<b>CRP</b>	187 (20)

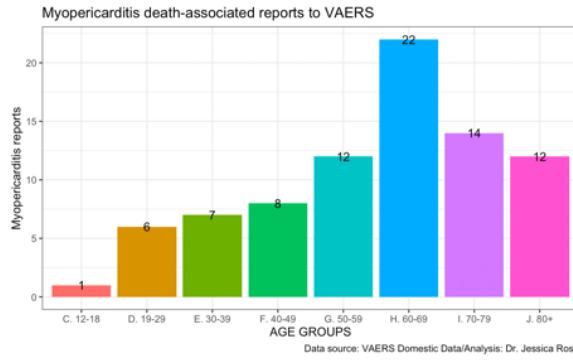
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CHI-SQ	RR	OR	p
<b>Troponin</b>	1.42	1.64	0.28
<b>CP</b>	1.09	1.12	0.79
<b>CI</b>	1.46	1.56	0.46
<b>ESTSE</b>	n/a	n/a	0.2
<b>CRP</b>	n/a	n/a	0.05

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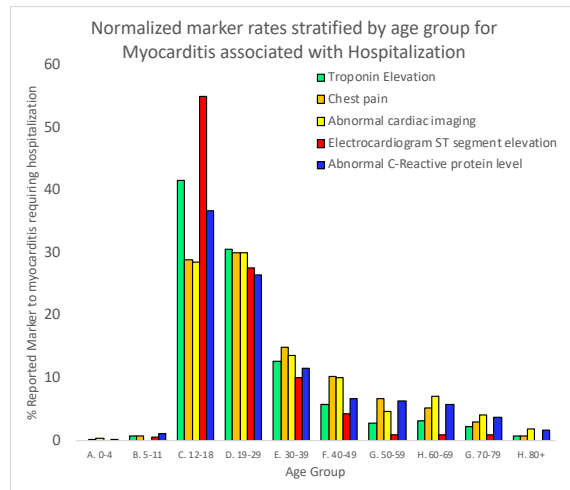
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Supplementary Figure 1: Histograms showing the absolute counts of total myocarditis, hospital-associated and death-associated myocarditis adverse events stratified by age group.

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Supplementary Figure 2: Percentages of markers co-associated with myocarditis requiring hospitalization by age group.

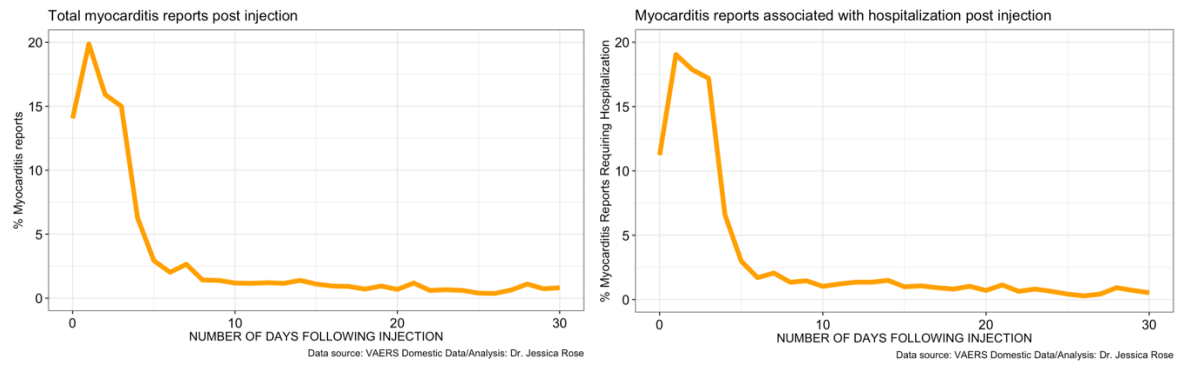
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Supplementary Figure 3: Time series plots showing  $\Delta$  injection date and onset date against percentage of myocarditis reports (left) and myocarditis reports requiring hospitalization (right).