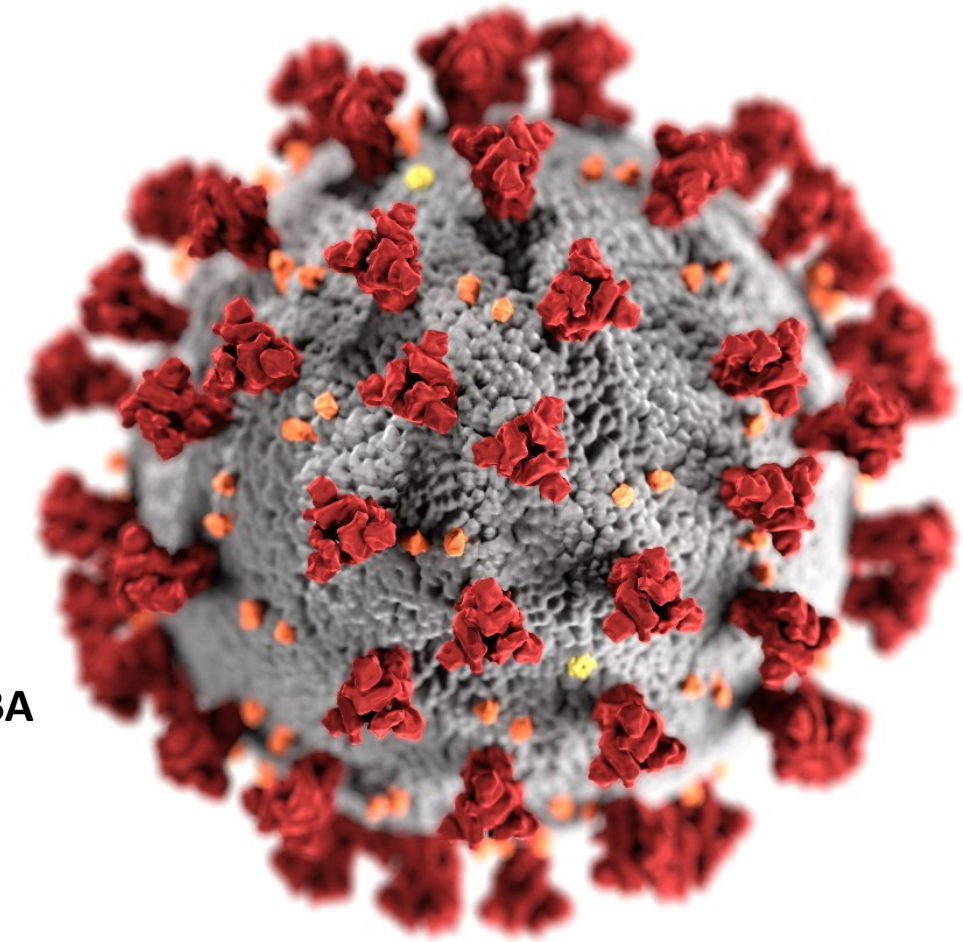
Safety update of 1st booster mRNA COVID-19 vaccination



Advisory Committee on Immunization Practices (ACIP)

April 20, 2022

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cdc.gov/coronavirus

Safety Surveillance of 1st Booster Doses in the Vaccine Safety Datalink

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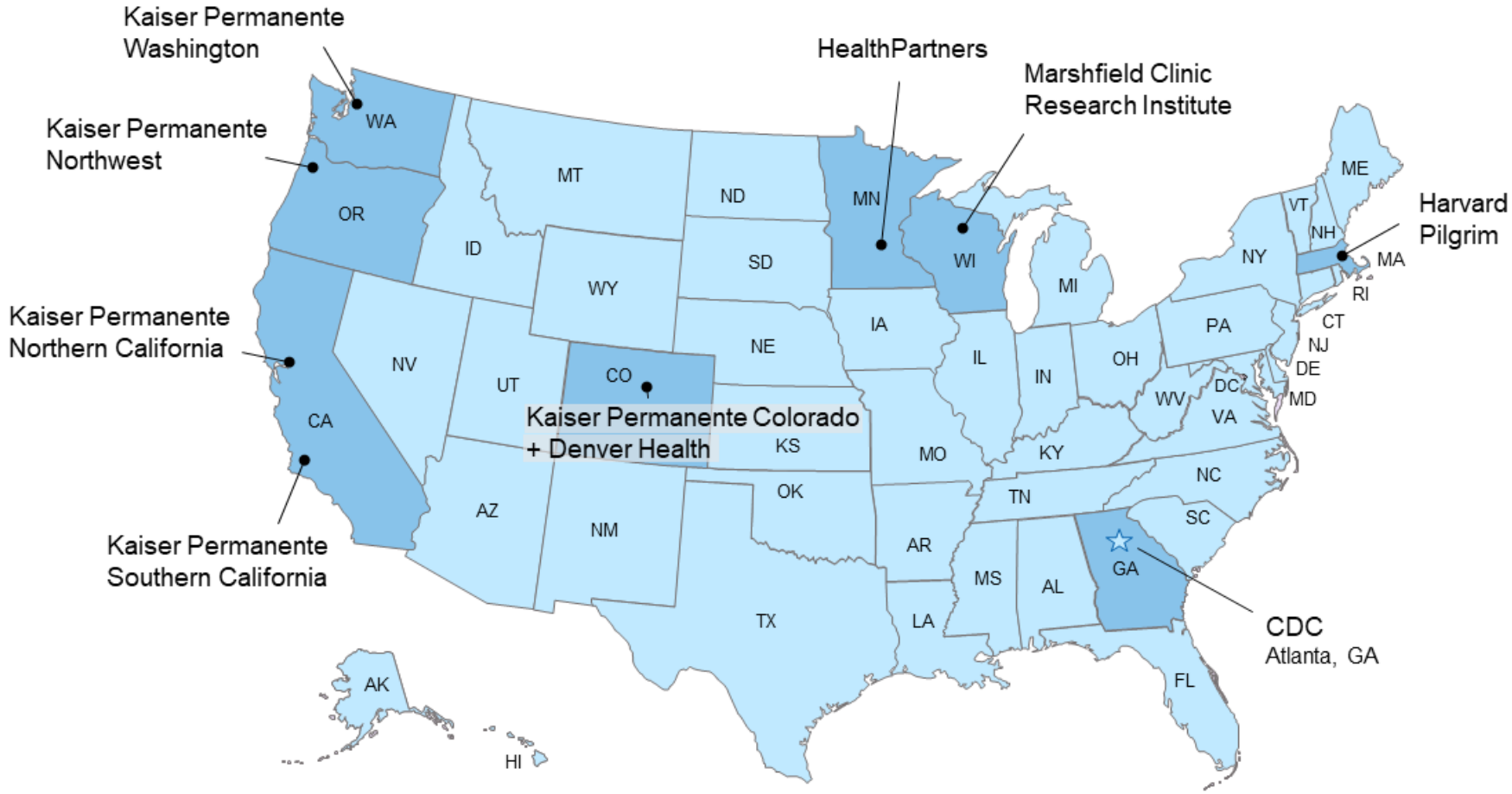
KAISER PERMANENTE®
VACCINE STUDY CENTER

CDC

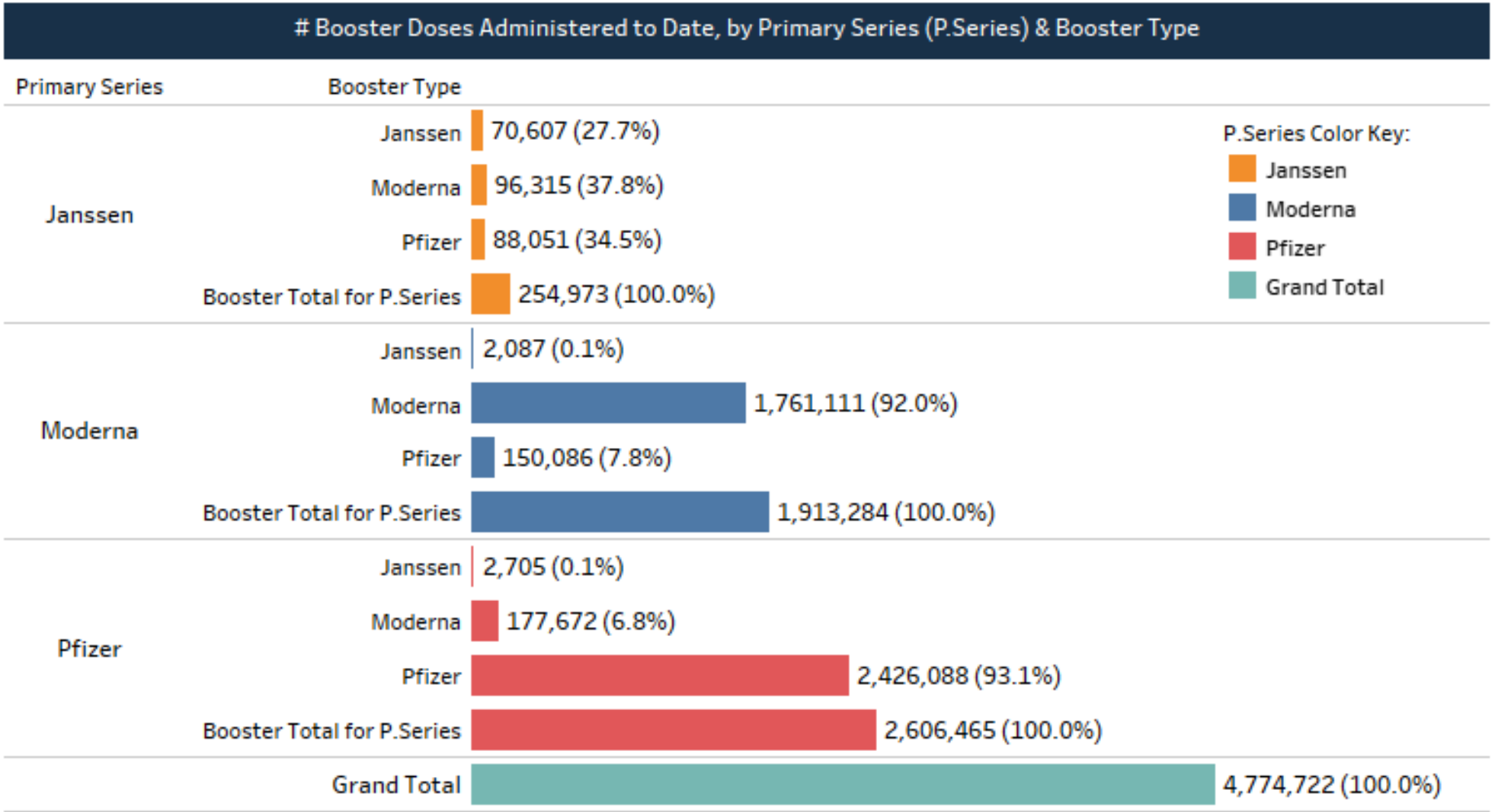
Marshfield Clinic®
Research Institute

Vaccine Safety Datalink (VSD)

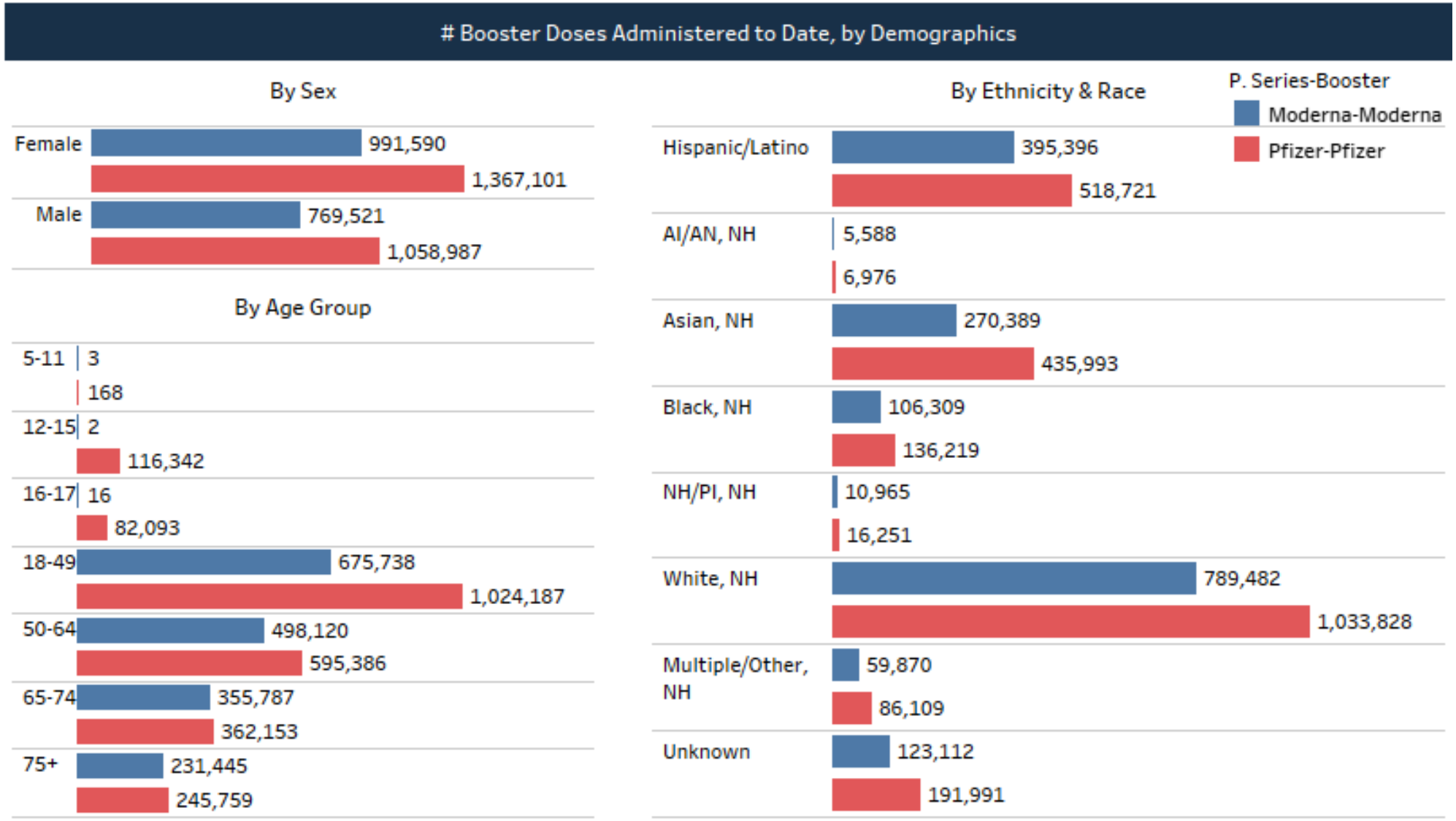


- Established in 1990
- Collaborative project between CDC and 9 integrated healthcare organizations
- Includes ~ 12 million individuals across all sites

VSD 1st Boosters by Primary Series Vaccination Data Through April 9th, 2022



VSD 1st Booster Dose by Demographics

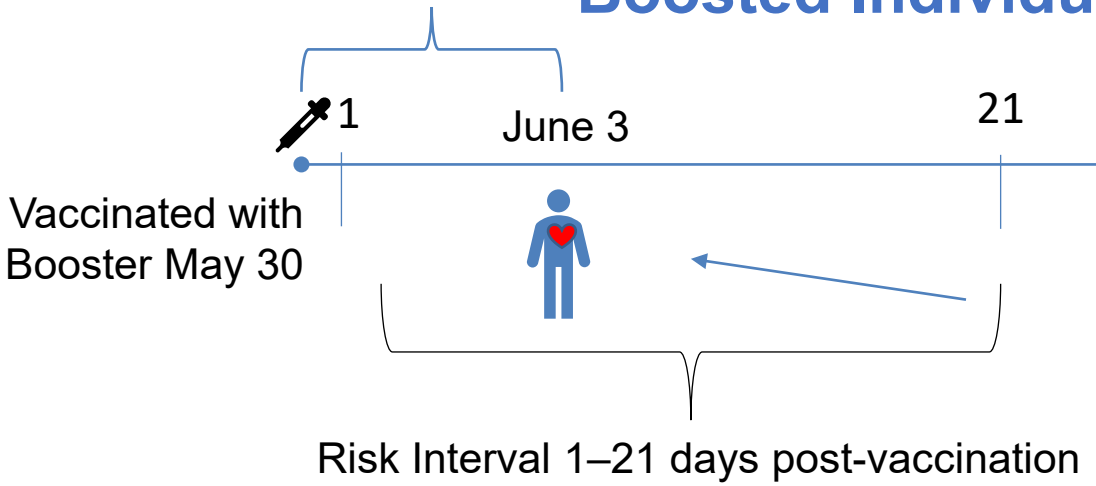


VSD Rapid Cycle Analysis (RCA) for Boosters

- Pre-specified surveillance outcomes were assessed during weekly sequential monitoring after 1st COVID-19 booster vaccination*
  - Analyses assess the risk of pre-specified outcomes within 1–21 days following a booster vaccination compared with boosted individuals who are within 22–42 days following the booster dose, adjusting for age, sex, race/ethnicity, VSD site, time since primary series, and calendar time.
  - Weekly sequential analyses will continue through 2022, with a one-sided p-value threshold for signaling of 0.01.
  - Due to the association of myocarditis/pericarditis with primary mRNA vaccination, myocarditis/pericarditis cases after the 1st booster were also chart reviewed and adjudicated using the CDC case definitions.

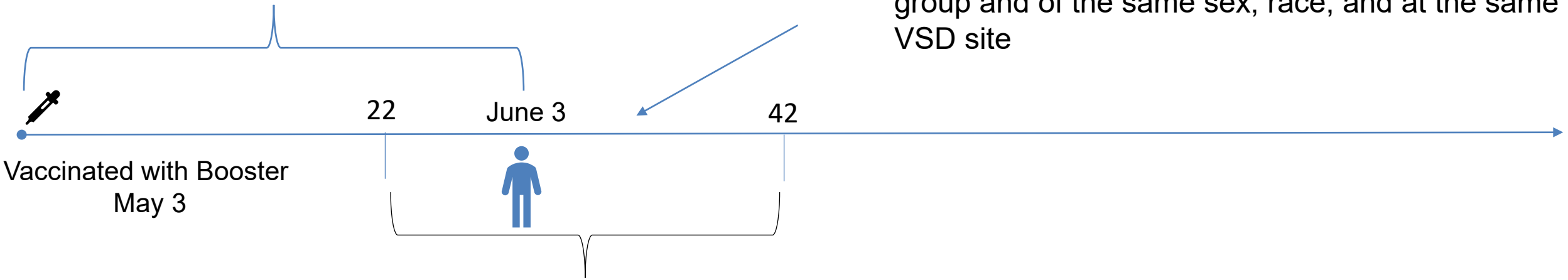
*Rapid Cycle Analysis (RCA) to monitor the safety of COVID-19 vaccines in near real-time within the Vaccine Safety Datalink.
Available at https://www.cdc.gov/vaccinesafety/pdf/COVID19-RCA-Protocol-1342-508.pdf

Vaccinee with Outcome in the Risk Interval and a Concurrent Comparator "Boosted Individuals Only"



On each calendar day that an outcome occurred in a vaccinee (e.g., June 3), we compared vaccinees in their risk interval (day 1–21) with similar vaccinees in their comparison interval (day 22–42)

By similar, we mean they were in the same age group and of the same sex, race, and at the same VSD site



Signals for Pre-specified Outcomes in 21-day Risk Interval Through 4/12/22

Primary series with	*Pfizer - Pfizer OR Moderna - Moderna*	*Pfizer - Pfizer*	*Moderna - Moderna*	*Janssen*		
Signal after 1st Booster	**Pfizer OR Moderna**	**Pfizer**	**Moderna**	**Pfizer**	**Moderna**	**Janssen**
Outcome Event	**Signal?**					
Acute myocardial infarction	No	No	No	No	No	No
Appendicitis	No	No	No	No	No	No
Bell's palsy	No	No	No	No	No	No
Cerebral venous sinus thrombosis	No	No	No	-	-	No
Disseminated intravascular coagulation	No	No	No	No	-	No
Encephalitis / myelitis / encephalomyelitis	No	No	No	-	-	-
Guillain-Barre syndrome	No	No	No	No	-	No
Stroke, hemorrhagic	No	No	No	No	No	No
Stroke, ischemic	No	No	No	No	No	No
Immune thrombocytopenia	No	No	No	No	No	-
Myocarditis / pericarditis	**Yes**	No	No	No	No	No
Seizures	No	No	No	No	No	No
Transverse myelitis	No	No	No	-	-	-
Thrombotic thrombocytopenic purpura	No	No	No	-	-	No
Thrombosis with thrombocytopenia syndrome	No	No	No	-	No	-
Venous thromboembolism	No	No	No	No	No	No
Pulmonary embolism	No	No	No	No	No	No

"-" indicates that analyses are not yet possible.

VSD COVID-19 RCA
1st Booster Dose
Myocarditis and Pericarditis – Preliminary Chart Review Analysis

Myocarditis and Pericarditis: Electronic Case Identification using ICD-10 Codes[1]

Code List (based on consultation with cardiologist)
• B33.22 Viral myocarditis • B33.23 Viral pericarditis • I30.* Acute pericarditis • I40.* Acute myocarditis • I51.4 Myocarditis, unspecified • I31.9 Disease of the pericardium, unspecified

[1]Case definition excludes individuals with COVID-19 infection <30 days before myocarditis/pericarditis diagnosis.

* Includes all subcodes.

Chart Review Summary: Myocarditis and Pericarditis after a 1st mRNA COVID-19 Booster Vaccine

- All electronically-identified cases among all ages up to 98 days post vaccination are being chart-reviewed.

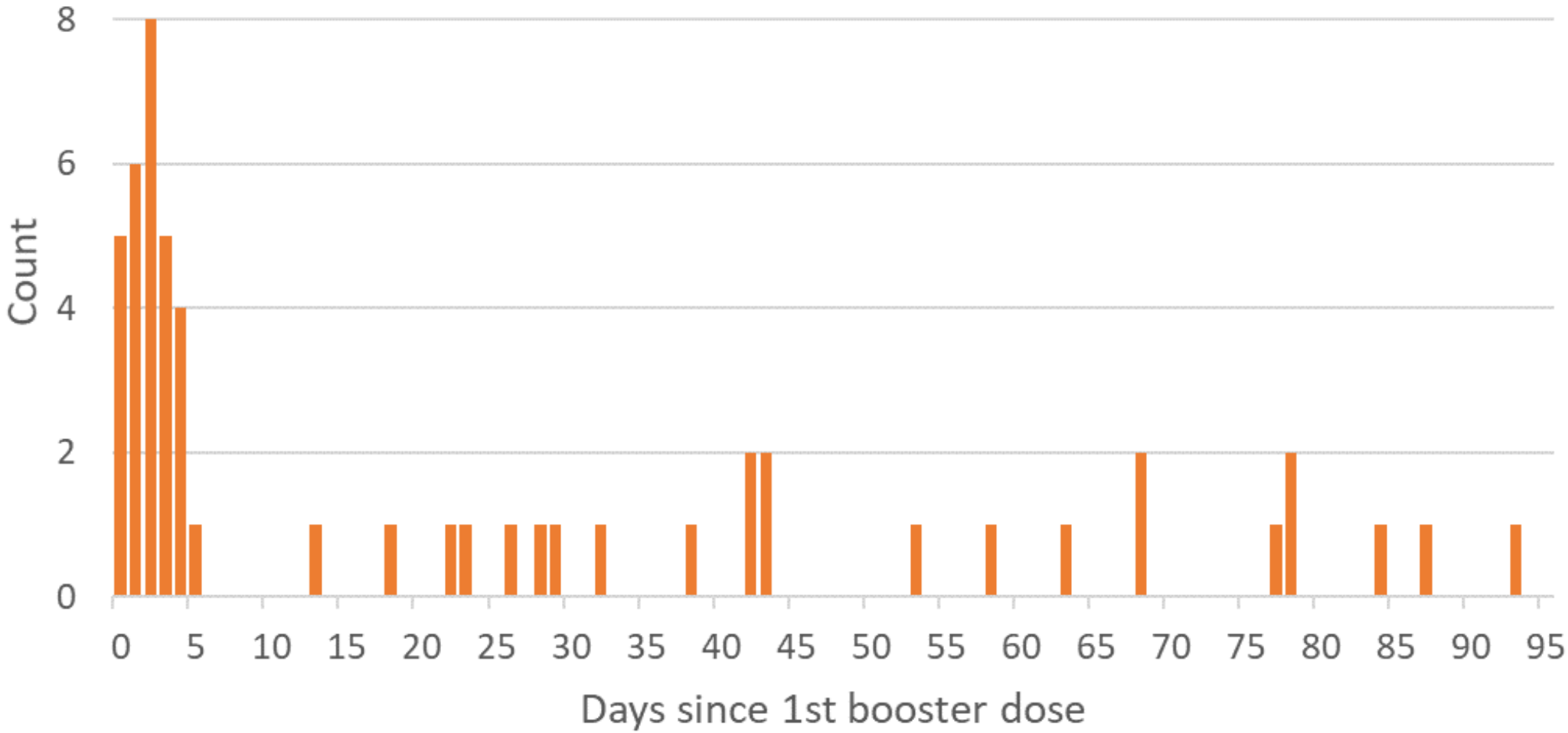
- Chart review is completed for 271 cases through March (25 potential cases pending).

- **Adjudicators verified 139/271 (51%) myocarditis/pericarditis cases.**
  - 12–39 years old: 53/68 (78%)
  - 40+ years old: 86/203 (42%)

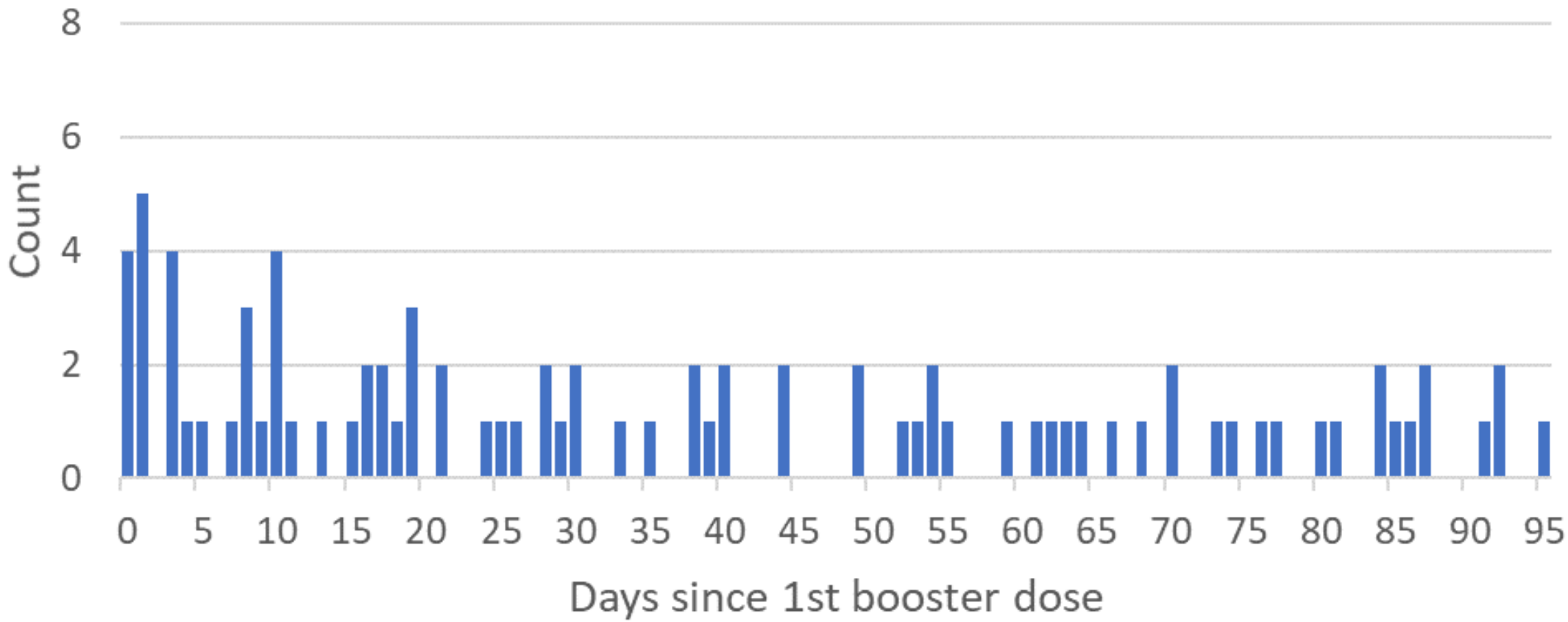
Chart Review Summary: Verified Myocarditis and Pericarditis cases after a 1st Booster Vaccine

	12–39 year olds	40+ year olds
Case verification (anytime after vaccination)	**53/68 (78%)**	**86/203 (42%)**
Male sex	38/53 (72%)	51/86 (59%)
History of COVID (>30 days prior to diagnosis)	10/53 (19%)	11/86 (13%)
History of myocarditis/pericarditis	2/53 (4%)	4/86 (5%)
Median age	25 years	68.5 years
Median time from vaccination to symptom onset	**4 days**	**29.5 days**
Adjudication diagnosis		
Myocarditis	12/53 (23%)	12/86 (14%)
Pericarditis	12/53 (23%)	**57/86 (66%)**
Myopericarditis	**29/53 (55%)**	17/86 (20%)

Timing of Symptom Onset after 1st Booster: 53 Verified Myocarditis and Pericarditis Cases in 12–39-Year-Olds



Timing of Symptom Onset after 1st Booster: 86 Verified Myocarditis and Pericarditis Cases in 40+ year-olds



Verified Myocarditis and Pericarditis in the 0–7 Day Risk Interval

Compared with Events on the Same Calendar Days Among Primary Series and Boosted Comparators

					Analysis			
	Ages	Vaccine	Events in Risk Interval	Events in Comparison Interval[1]	Adjusted Rate Ratio[2]	95% Confidence Interval	2-Sided P-value	Events/Million Doses
1st Booster[3]	12–39	Either	28	10	4.89	2.24 – 11.31	<0.001	20.3 (13.5 – 29.3)
	12–39	Pfizer	18	6	5.14	1.86 – 15.90	0.001	21.4 (12.7 – 33.8)
	12–39	Moderna[4]	5	3	3.64	0.79 – 19.45	0.097	17.0 (6.8 – 35.0)

[1]Comparison interval is 22–42 days after booster dose.
[2]Adjusted for VSD site, 5-year age group, sex, race/ethnicity, calendar date, and time since primary series.
[3]"Either" includes heterologous and homologous primary -> booster doses. Product specific analyses include only homologous primary->booster doses.
[4]Two additional cases were in the risk interval but were not included because there were no appropriate comparators. These cases are included in the events/million dose calculation.

Verified Myocarditis and Pericarditis in the 0–7 Day Risk Interval

Compared with Events on the Same Calendar Days Among Primary Series and Boosted Comparators

					Analysis			
	Ages	Vaccine	Events in Risk Interval	Events in Comparison Interval[1]	Adjusted Rate Ratio[2]	95% Confidence Interval	2-Sided P-value	Events/Million Doses
Primary, Dose 2	12–39	Either	112	14	24.38	14.00 – 44.96	<0.001	38.2 (31.5 – 45.9)
	12–39	Pfizer	83	10	28.07	14.63 – 58.50	<0.001	41.4 (33.1 – 51.1)
	12–39	Moderna	28	3	24.49	7.82 – 105.14	<0.001	30.8 (20.5 – 44.5)
1st Booster[3]								
	12–39	Either	28	10	4.89	2.24 – 11.31	<0.001	20.3 (13.5 – 29.3)
	12–39	Pfizer	18	6	5.14	1.86 – 15.90	0.001	21.4 (12.7 – 33.8)
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[4]Two additional cases were in the risk interval but were not included because there were no appropriate comparators. These cases are included in the events/million dose calculation.
[5]One additional case was in the risk interval but not included because there were no appropriate comparators. This case is included in the events/million dose calculation.

Verified Myocarditis and Pericarditis in the 0–7 Day Risk Interval

Compared with Events on the Same Calendar Days Among Primary Series and Boosted Comparators

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	12–39	Pfizer	18	6	5.14	1.86 – 15.90	0.001	21.4 (12.7 – 33.8)
	12–39	Moderna[4]	5	3	3.64	0.79 – 19.45	0.097	17.0 (6.8 – 35.0)
	40+	Either[5]	11	15	2.30	0.95 – 5.43	0.063	4.0 (2.1 – 7.0)
	40+	Pfizer[5]	4	5	1.65	0.34 – 7.31	0.509	3.3 (1.1 – 7.6)
	40+	Moderna[4]	4	8	1.85	0.43 – 6.85	0.373	4.6 (1.7 – 10.1)

[1]Comparison interval is 22–42 days after booster dose.
[2]Adjusted for VSD site, 5-year age group, sex, race/ethnicity, calendar date, and time since primary series.
[3]"Either" includes heterologous and homologous primary -> booster doses. Product specific analyses include only homologous primary->booster doses.
[4]Two additional cases were in the risk interval but were not included because there were no appropriate comparators. These cases are included in the events/million dose calculation.
[5]One additional case was in the risk interval but not included because there were no appropriate comparators. This case is included in the events/million dose calculation.

Verified Myocarditis and Pericarditis in the 0–21 Day Risk Interval

Compared with Events on the Same Calendar Days Among Primary Series and Boosted Comparators

					Analysis			
	Ages	Vaccine	Events in Risk Interval	Events in Comparison Interval[1]	Adjusted Rate Ratio[2]	95% Confidence Interval	2-Sided P-value	Events/Million Doses
1st Booster[3]	12–39	Either	30	10	1.90	0.91 – 4.25	0.092	21.9 (14.8 – 31.2)
	12–39	Pfizer	19	6	2.07	0.79 – 6.05	0.146	22.8 (13.7 – 35.6)
	12–39	Moderna[4]	6	3	1.36	0.33 – 6.87	0.697	19.5 (8.4 – 38.5)

[1]Comparison interval is 22–42 days after booster dose.
[2]Adjusted for VSD site, 5-year age group, sex, race/ethnicity, calendar date, and time since primary series.
[3]"Either" includes heterologous and homologous primary -> booster doses. Product specific analyses include only homologous primary-> booster doses.
[4]Two additional cases were in the risk interval but were not included because there were no appropriate comparators. These cases are included in the events/million dose calculation.

Verified Myocarditis and Pericarditis in the 0–21 Day Risk Interval

Compared with Events on the Same Calendar Days Among Primary Series and Boosted Comparators

					Analysis			
	Ages	Vaccine	Events in Risk Interval	Events in Comparison Interval[1]	Adjusted Rate Ratio[2]	95% Confidence Interval	2-Sided P-value	Events/Million Doses
1st Booster[3]	12–39	Either	30	10	1.90	0.91 – 4.25	0.092	21.9 (14.8 – 31.2)
	12–39	Pfizer	19	6	2.07	0.79 – 6.05	0.146	22.8 (13.7 – 35.6)
	12–39	Moderna[4]	6	3	1.36	0.33 – 6.87	0.697	19.5 (8.4 – 38.5)
	40+	Either[5]	29	15	1.96	1.02 – 3.88	0.044	11.0 (7.5 – 15.4)
	40+	Pfizer[5]	15	5	3.01	1.06 – 9.68	0.038	12.5 (7.5 – 19.5)
	40+	Moderna[6]	9	8	1.28	0.42 – 3.80	0.650	9.3 (4.8 – 16.3)

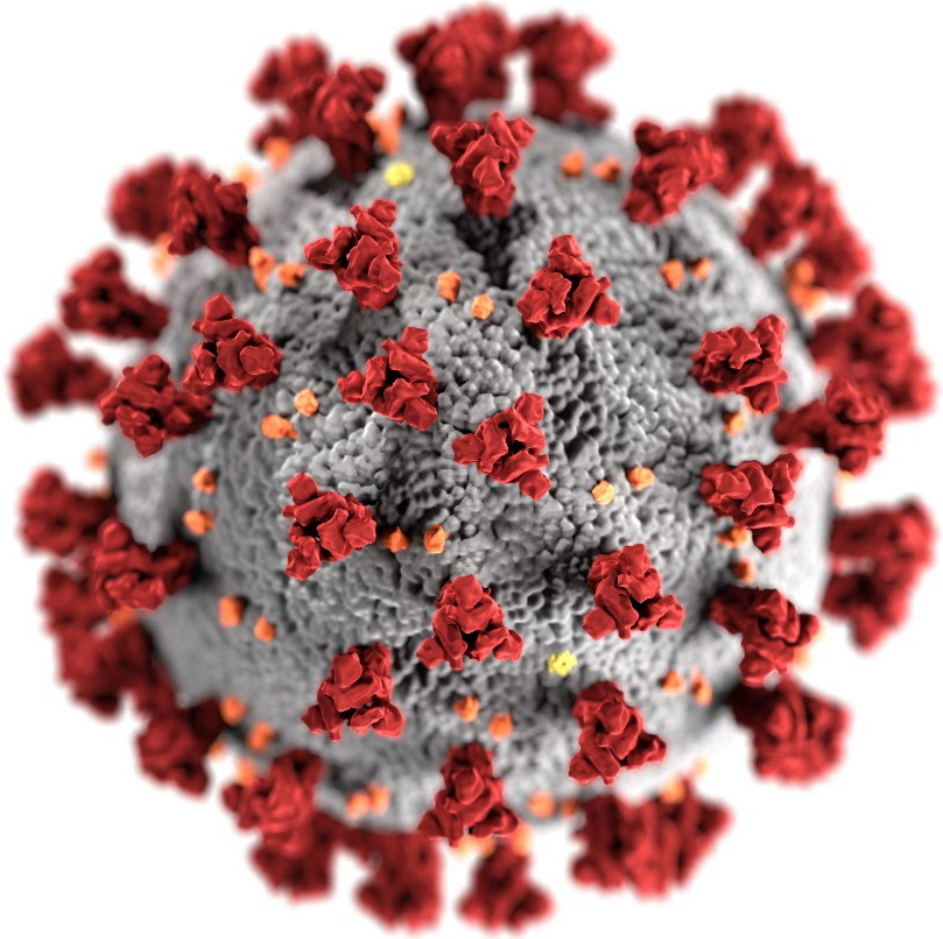
[1]Comparison interval is 22–42 days after booster dose.
[2]Adjusted for VSD site, 5-year age group, sex, race/ethnicity, calendar date, and time since primary series.
[3]"Either" includes heterologous and homologous primary -> booster doses. Product specific analyses include only homologous primary-> booster doses.
[4]Two additional cases were in the risk interval but were not included because there were no appropriate comparators. These cases are included in the events/million dose calculation.
[5]Four additional cases were in the risk interval but not included because there were no appropriate comparators. These cases are included in the events/million dose calculation.
[6]Three additional cases were in the risk interval but not included because there were no appropriate comparators. These cases are included in the events/million dose calculation.

Summary: Preliminary Findings of RCA Monitoring for 1st Boosters

- In weekly surveillance, the only safety signal has been for myocarditis/pericarditis in the 21 days after a 1st booster dose.
  - No other safety signals in weekly monitoring of pre-specified outcomes.
- Myocarditis/pericarditis differed between persons ages 12–39 and 40+ years.
  - 12–39 years: mostly myocarditis and myopericarditis with onset <7 days after 1st booster.
  - 40+ years: mostly pericarditis; cases more spread out in the 3 weeks after 1st booster.
- For persons ages 12–39 years, rate ratios for myocarditis/pericarditis 0–7 days after 1st booster dose were elevated.
  - Rate per million 1st booster doses administered was not higher than after primary series dose 2 mRNA COVID-19 vaccination.
- For persons ages 40 years and older, rate ratios for myocarditis/pericarditis were elevated, but less so, in the 0–7 and 0–21 days after the 1st booster dose compared with persons ages 12–39 years.
- Surveillance is ongoing.

Safety update of 1st booster mRNA COVID-19 vaccination

Vaccine Adverse Event Reporting System (VAERS)
&
V-safe



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CDC COVID-19 Vaccine Task Force

cdc.gov/coronavirus

VAERS is the nation's early warning system for vaccine safety

CDC + FDA

VAERS

Vaccine Adverse Event Reporting System

http://vaers.hhs.gov

VAERS accepts reports from everyone

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 following 1st booster mRNA COVID-19 vaccination* (as of April 11, 2022)

Doses admin†	Total reports	Median age	Male‡ n (%)	Female‡ n (%)	Non-serious n (%)	Serious n (%)
93,118,318	52,063	53 years	17,281 (33)	33,692 (65)	47,014 (90)	5,049 (10)

- Proportions by seriousness and sex were comparable to primary series
  - Most reports (90%) were non-serious
  - Most reports (65%) were among females

* Among persons receiving Pfizer-BioNTech dose 3: children and adolescents ages 12–15 years vaccinated during Jan 3 – April 11, 2022, and ages 16–17 years vaccinated during Dec 9, 2021 – April 11, 2022; adults ages ≥18 years vaccinated during September 22, 2021 – April 11, 2022. Among persons receiving Moderna booster doses, adults ages ≥18 years vaccinated during October 20, 2021 – April 11, 2022. All reports received and processed as of April 11, 2022.

† Doses of Pfizer-BioNTech dose 3 administered among children and adolescents ages 12–15 years during January 6 – Apr 14, 2022; adolescents ages 16–17 years during Dec 9, 2021 – April 14, 2022; adults ages ≥18 years during September 22, 2021 – April 14, 2022. Doses of Moderna dose 3 administered among adults ages ≥18 years during October 28, 2021 – April 14, 2022

‡ Sex was not reported in approximately 2% of reports.

U.S. reports to VAERS following 1st booster mRNA COVID-19 vaccination, by race and ethnicity* (as of April 11, 2021)

Race and ethnicity	n (%)
Non-Hispanic White	25,508 (49)
Unknown or not reported	14,787 (28)
Hispanic†	3,616 (7)
Non-Hispanic Other	2,987 (6)
Non-Hispanic Black	2,264 (4)
Non-Hispanic Asian	1,764 (3)
Non-Hispanic multiracial	561 (1)
Non-Hispanic American Indian/Alaskan Native	520 (<1)
Non-Hispanic Native Hawaiian or Other Pacific Islander	56 (<1)
Total	**52,063**

* Among persons receiving Pfizer-BioNTech dose 3: children and adolescents ages 12–15 years vaccinated during Jan 3 – April 11, 2022, and ages 16–17 years vaccinated during Dec 9, 2021 – April 11, 2022; adults ages ≥18 years vaccinated during September 22, 2021 – April 11, 2022. Among persons receiving Moderna booster doses, adults ages ≥18 years vaccinated during October 20, 2021 – April 11, 2022. All reports received and processed as of April 11, 2022.

† Includes persons reported as of Hispanic ethnicity, but of unreported or unknown race.

Most frequently reported non-serious adverse events to VAERS following 1st booster mRNA COVID-19 vaccination (47,014 total non-serious reports)* (as of April 11, 2022)

Non-serious reports (all reports)

Rank	Adverse event (not mutually exclusive)	n (%)
1	Headache	6,119 (13)
2	Pyrexia	5,840 (12)
3	Pain	5,783 (12)
4	Fatigue	5,420 (12)
5	**Expired Product Administered**	**5,082 (11)**
6	Chills	4,836 (10)
7	**Product Storage Error**	**4,030 (9)**
8	Pain In Extremity	3,813 (8)
9	Nausea	3,209 (7)
10	Dizziness	2,982 (6)

Non-serious reports (clinical outcomes)†

Rank	Adverse event (not mutually exclusive)	n (%)
1	Headache	6,119 (13)
2	Pyrexia	5,840 (12)
3	Pain	5,783 (12)
4	Fatigue	5,420 (12)
5	Chills	4,836 (10)
6	Pain In Extremity	3,813 (8)
7	Nausea	3,209 (7)
8	Dizziness	2,982 (6)
9	Urticaria	2,966 (6)
10	Lymphadenopathy	2,896 (6)

* Among persons receiving Pfizer-BioNTech dose 3: children and adolescents ages 12–15 years vaccinated during Jan 3 – April 11, 2022, and ages 16–17 years vaccinated during Dec 9, 2021 – April 11, 2022; adults ages ≥18 years vaccinated during September 22, 2021 – April 11, 2022. Among persons receiving Moderna booster doses, adults ages ≥18 years vaccinated during October 20, 2021 – April 11, 2022. All reports received and processed as of April 11, 2022.

† Determined by subject matter expert consensus

Most frequently reported serious adverse events to VAERS following 1st booster mRNA COVID-19 vaccination (5,049 total serious reports) (as of April 11, 2022)

Serious reports (all reports)

Rank	Adverse event (not mutually exclusive)	n (%)
1	Covid-19	1,196 (24)
2	Sars-Cov-2 Test Positive	997 (20)
3	Dyspnoea	817 (16)
4	Death	549 (11)
5	Chest Pain	440 (9)
6	Pyrexia	436 (9)
7	Asthenia	435 (9)
8	**Condition Aggravated**	**396 (8)**
9	Fatigue	386 (8)
10	Pain	369 (7)

Serious reports (clinical outcomes)†

Rank	Adverse event (not mutually exclusive)	n (%)
1	Covid-19	1,196 (24)
2	Sars-Cov-2 Test Positive	997 (20)
3	Dyspnoea	817 (16)
4	Death	549 (11)
5	Chest Pain	440 (9)
6	Pyrexia	436 (9)
7	Asthenia	435 (9)
8	Fatigue	386 (8)
9	Pain	369 (7)
10	Cough	328 (7)

* Among persons receiving Pfizer-BioNTech dose 3: children and adolescents ages 12–15 years vaccinated during Jan 3 – April 11, 2022, and ages 16–17 years vaccinated during Dec 9, 2021 – April 11, 2022; adults ages ≥18 years vaccinated during September 22, 2021 – April 11, 2022. Among persons receiving Moderna booster doses, adults ages ≥18 years vaccinated during October 20, 2021 – April 11, 2022. All reports received and processed as of April 11, 2022.

† Determined by subject matter expert consensus

U.S. reports to VAERS of myocarditis and pericarditis following 1st booster mRNA COVID-19 vaccination, by age, time to symptom onset, and sex*

(as of April 11, 2022)

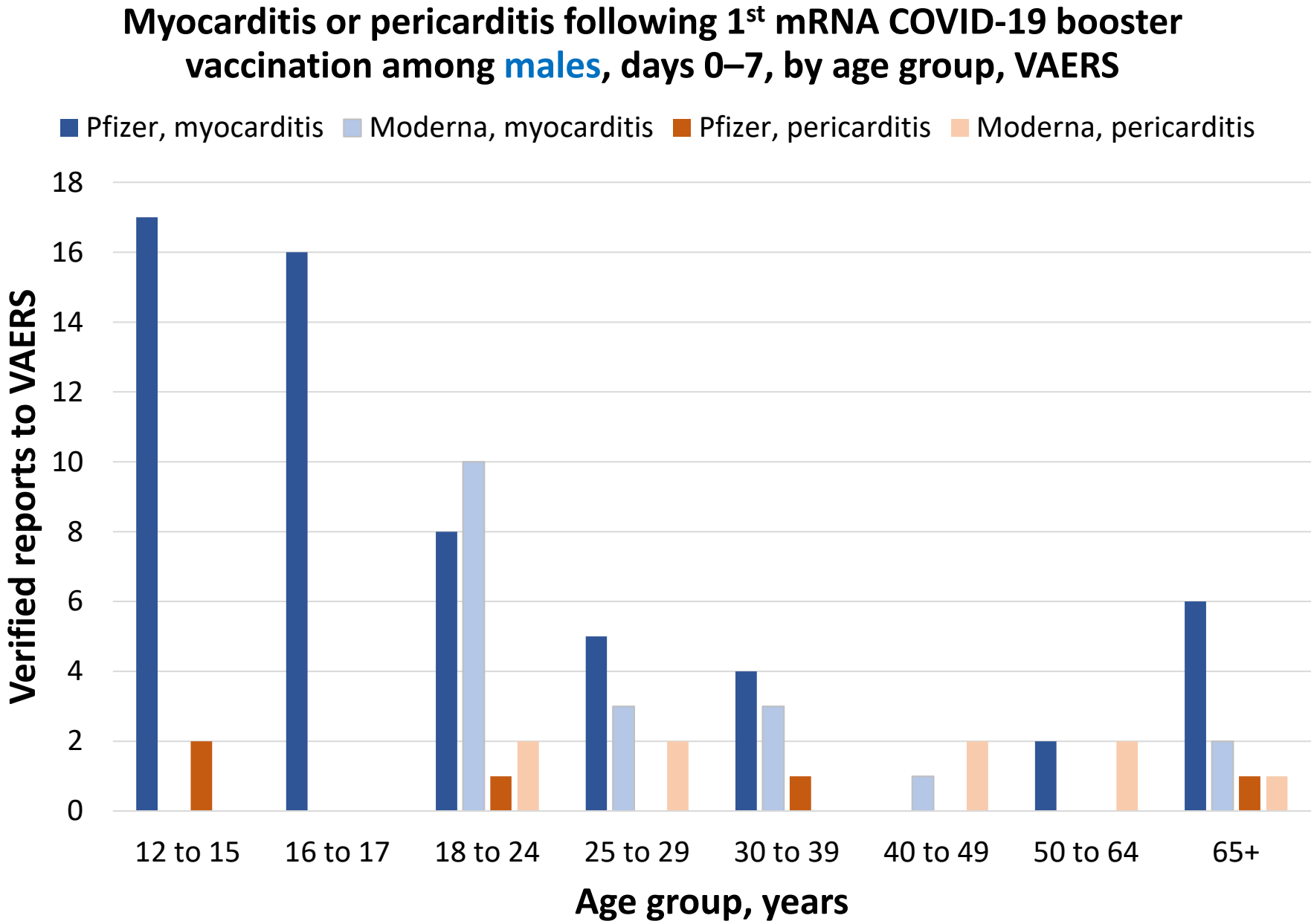
	Myocarditis (n=110)	Pericarditis (n=38)
Median age (IQR†)	23 (16–36)	46 (25–62)
Median time to symptom onset (IQR†)	3 (2–4)	3 (1–7)
Male, n (%) / Female, n (%)	89 (81%) / 21 (19%)	18 (47%) / 20 (53%)

- Median age in myocarditis case reports is younger vs. pericarditis
- Male predominance observed for myocarditis case reports but not for pericarditis

* Among persons receiving Pfizer-BioNTech dose 3: children and adolescents ages 12–15 years vaccinated during Jan 3 – April 11, 2022, and ages 16–17 years vaccinated during Dec 9, 2021 – April 11, 2022; adults ages ≥18 years vaccinated during September 22, 2021 – April 11, 2022. Among persons receiving Moderna booster doses, adults ages ≥18 years vaccinated during October 20, 2021 – April 11, 2022. All reports received and processed as of April 11, 2022.

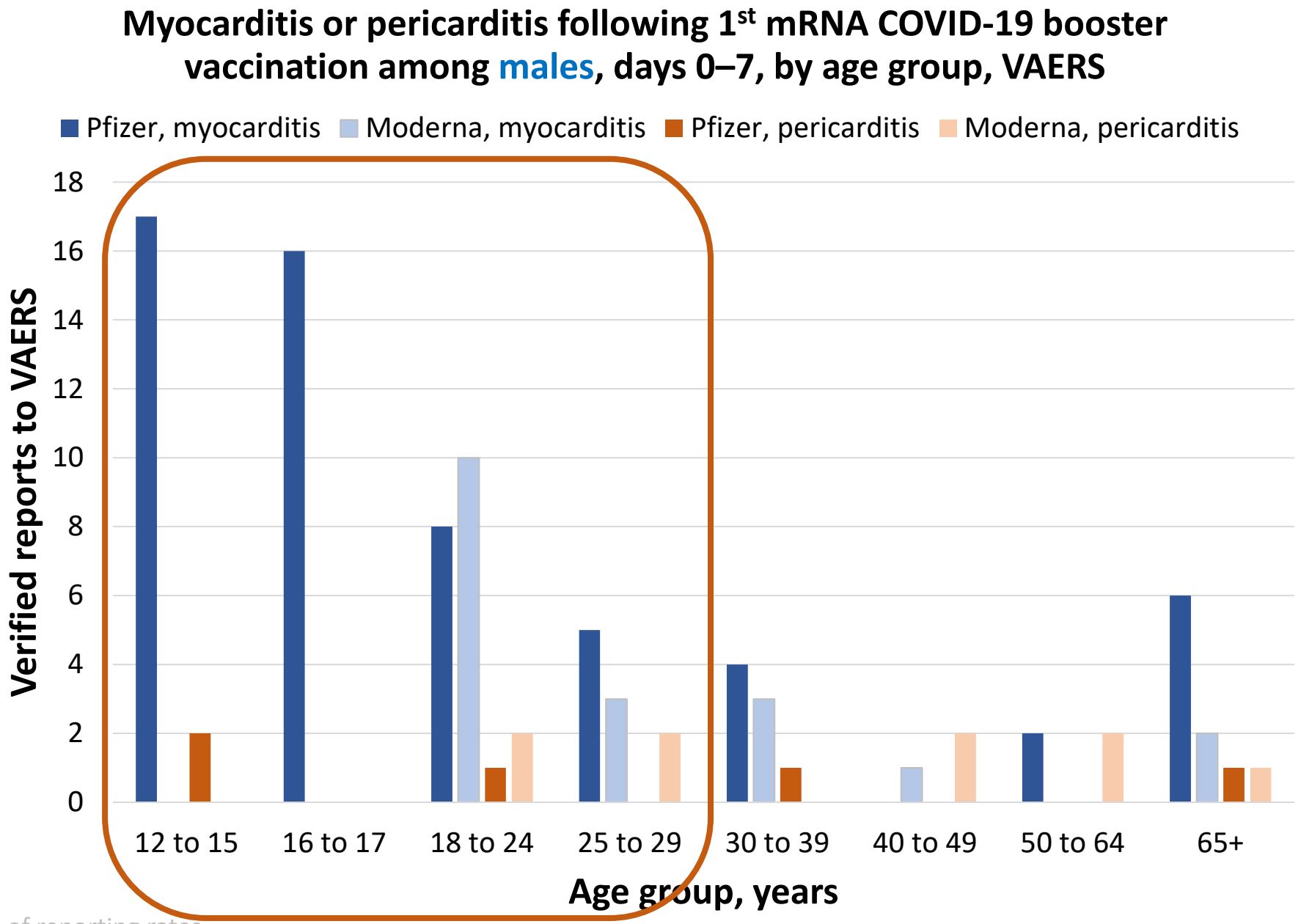
† Interquartile range.

- Most myocarditis reports among ages 12–29 years
- Pericarditis reports distributed fairly evenly among age groups*



* Complicates estimation of reporting rates

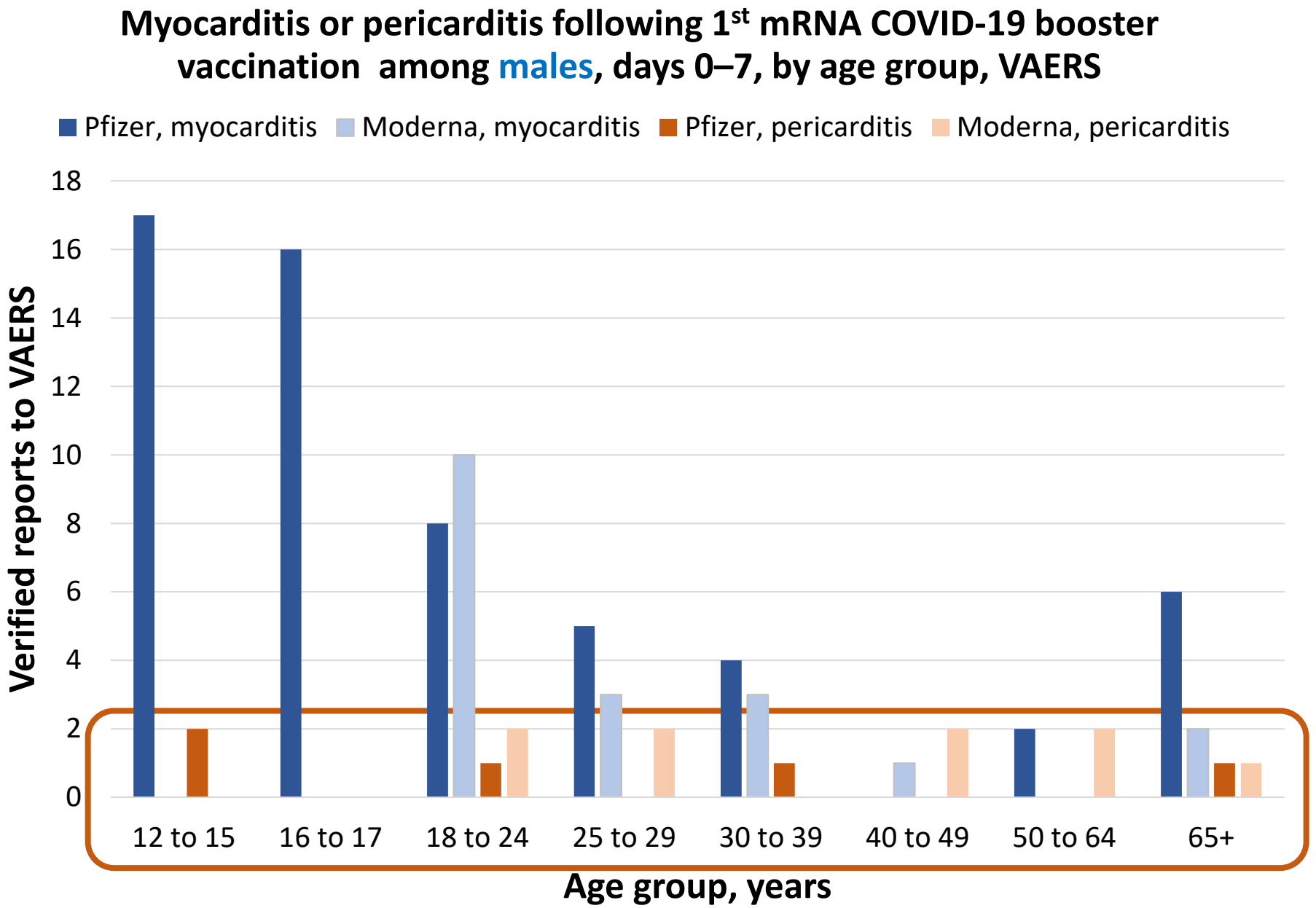
- **Most myocarditis reports among ages 12–29 years**
- Pericarditis reports distributed fairly evenly among age groups*



* Complicates estimation of reporting rates

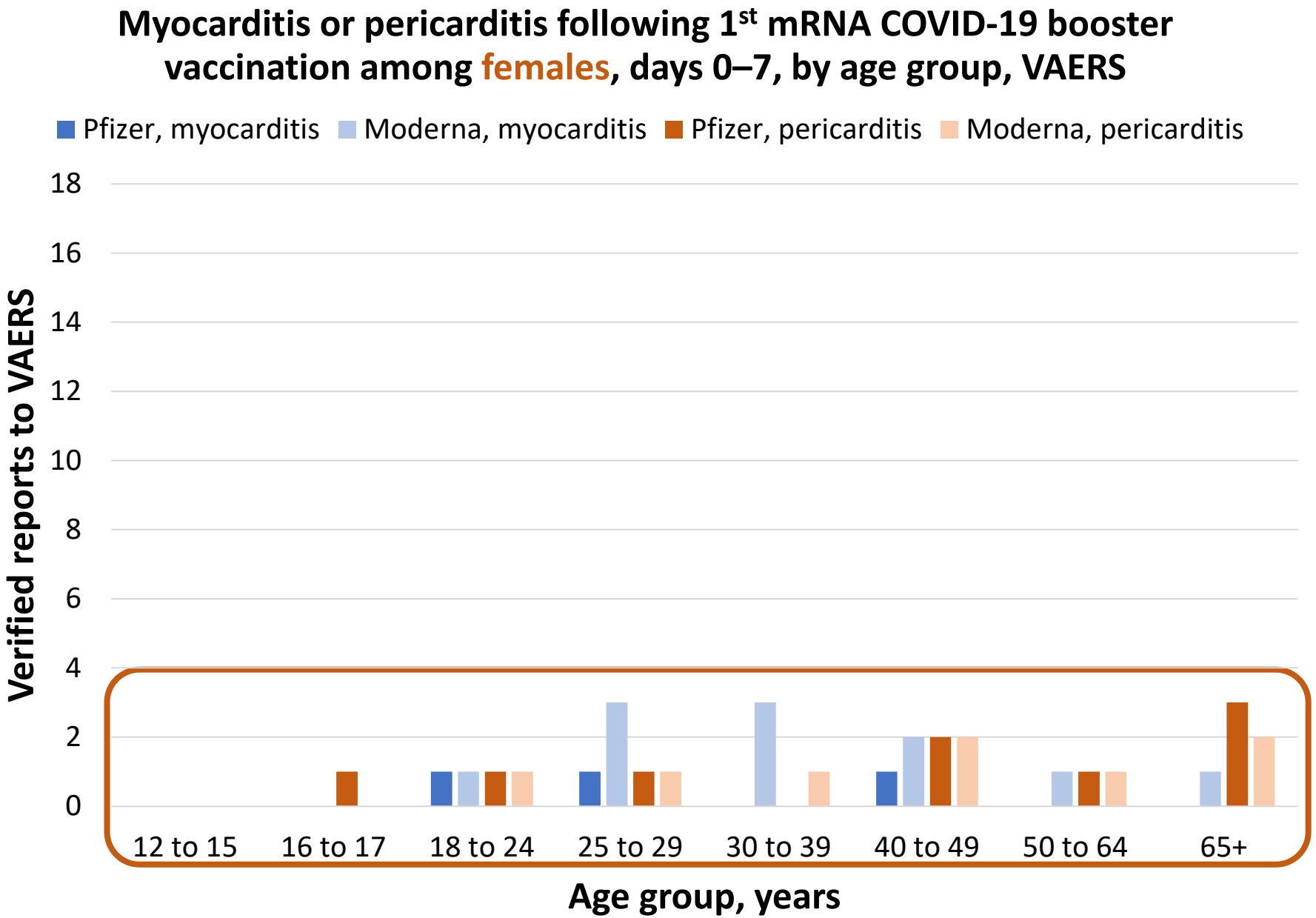
- Most myocarditis reports among ages 12–29 years

- **Pericarditis reports distributed fairly evenly among age groups***



* Complicates estimation of reporting rates

- Few reports among females of either condition
- Both myocarditis and pericarditis reports distributed fairly evenly among age groups



Reporting rates of myocarditis (per 1 million doses administered) among males following 1st mRNA COVID-19 booster vaccination, by risk interval*

- **41,670,922** 1st mRNA COVID-19 booster vaccinations administered in males*
- Reporting rates exceed background incidence in ages 12–29 years
- Reporting rates highest in males ages 16–17 years, followed by 12–15 years

	Pfizer-BioNTech	Moderna
age group	Days 0–7	Days 0–7
12 to 15	17.2	N/A
16 to 17	23.2	N/A
18 to 24	5.4	12.1
25 to 29	4.8	4.0
30 to 39	1.5	1.5
40 to 49	0.0	<1.0
50 to 64	<1.0	0.0
65+	<1.0	<1.0

* Among persons receiving Pfizer-BioNTech dose 3: children and adolescents ages 12–15 years vaccinated during Jan 3 – April 11, 2022, and ages 16–17 years vaccinated during Dec 9, 2021 – April 11, 2022; adults ages ≥18 years vaccinated during September 22, 2021 – April 11, 2022. Among persons receiving Moderna booster doses, adults ages ≥18 years vaccinated during October 20, 2021 – April 11, 2022. All reports received and processed as of April 11, 2022. Doses administered as of April 14, 2022. 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 day 0–7 and 0–21 risk periods, this estimated background is 0.2 to 2.2 per 1 million person risk period.

Clinical outcomes of myocarditis and pericarditis following 1st mRNA COVID-19 booster vaccination*

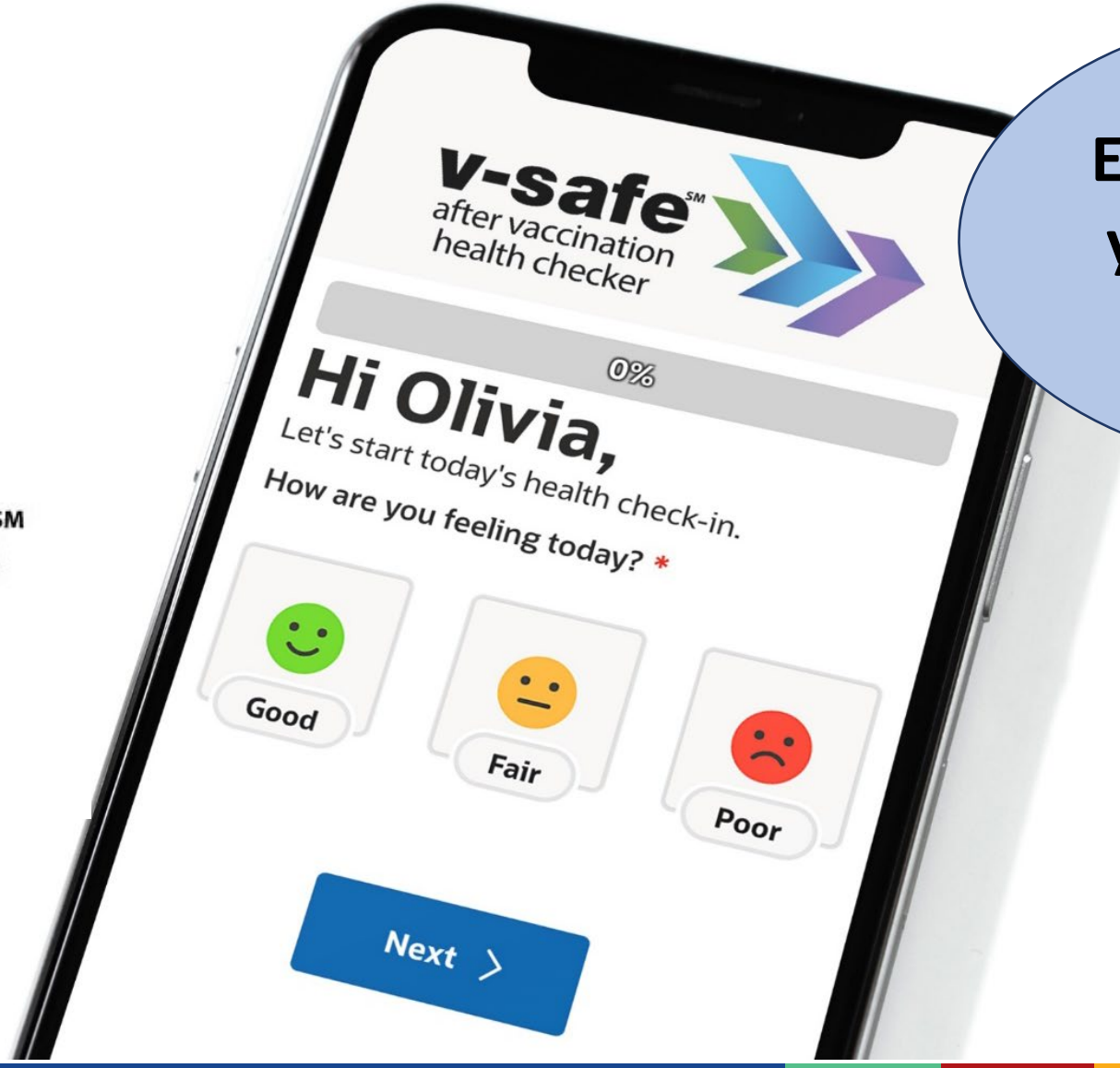
- **93,118,318** total booster doses administered*
- Patients not hospitalized received outpatient care
- Patients still recovering are stable or improving

	Myocarditis (N=110)	Pericarditis (N=38)
Hospitalized	90/110 (82%)	15/38 (39%)
Discharged	90/90 (100%)	15/15 (100%)
Known outcomes	86/90 (96%)	14/15 (93%)
Recovered from symptoms at last follow up	51/86 (59%)	10/14 (71%)

* Doses of Pfizer-BioNTech dose 3 administered among children and adolescents ages 12–15 years during January 6 – Apr 14, 2022; adolescents ages 16–17 years during Dec 9, 2021 – April 14, 2022; adults ages ≥18 years during September 22, 2021 – April 14, 2022. Doses of Moderna dose 3 administered among adults ages ≥18 years during October 28, 2021 – April 14, 2022

Smartphone-based active safety monitoring

v-safe[SM]
after vaccination
health checker



Enroll yourself or your dependent after any dose!

http://cdc.gov/vsafe

Active safety monitoring for COVID-19 vaccines

v-safe is a CDC smart phone-based monitoring program for COVID-19 vaccine safety in the U.S.

- Uses text messaging and web surveys to check in with vaccine recipients after vaccination
- Can register at any time: after first, second, or third dose
- Solicits participants' reports on how they feel after COVID-19 vaccination
  - Local injection site reactions (i.e., pain, redness, swelling)
  - Systemic reactions (i.e., fatigue, headache, joint pain)
  - Health impacts (unable to perform normal daily activities, missed school or work, or received care)

v-safe after vaccination health checker

Patterns of vaccination for 729,720 v-safe participants aged ≥18 years who reported a booster dose

Primary series

Booster dose	Moderna (%)	Pfizer-BioNTech (%)	Janssen (%)	Total
Moderna	**311,374 (94)**	17,034	23,211	351,619
Pfizer-BioNTech	19,538	**336,618 (95)**	13,685	369,841
Janssen	247	238	**7,775 (17)**	8,260
Total	331,159	353,890	44,671	**729,720**

Data as of April 10, 2022. Includes participants who completed at least one survey in the first week after each dose (administered beginning September 22, 2021 for Pfizer-BioNTech and October 20,2021 for Moderna and Janssen).

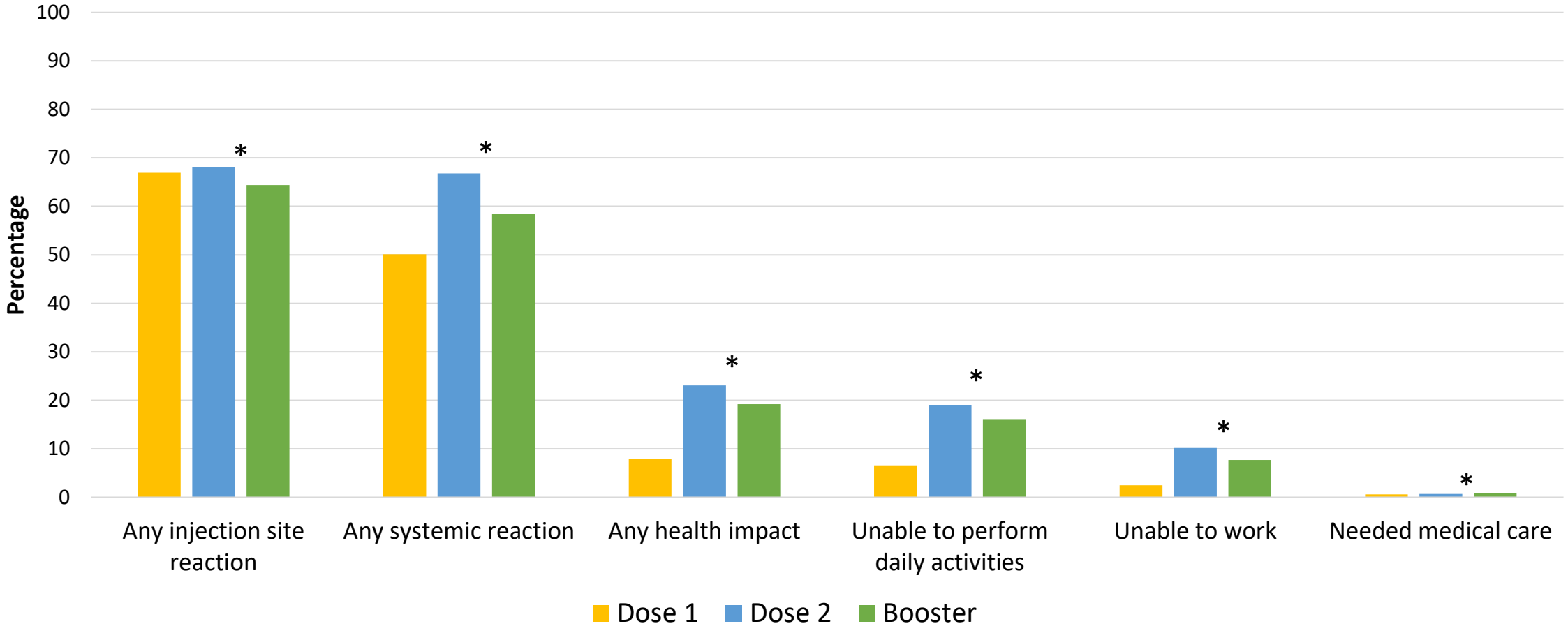
Demographic summary of 729,720 v-safe participants aged ≥18 years who reported a booster dose

Characteristic	% of participants
Sex	
Female	62.8
Male	36.4
Unknown	0.8
Age group (years)	
18–49	268,632
50–64	189,735
65–74	210,566
75–84	56,051
≥85	4,736

Characteristic	% of participants
Ethnicity	
Hispanic or Latino	6.7
Not Hispanic/ Latino	90.2
Unknown	3.1
Race	
AI/AN	0.4
Asian	5.4
Black or AA	5.6
NHPI	0.2
White	82.9
Multiracial	1.8
Other	1.9
Unknown	1.8

Data as of April 10, 2022. Includes participants who completed at least one survey in the first week after each dose (administered beginning September 22, 2021 for Pfizer-BioNTech and October 20,2021 for Moderna and Janssen).
Abbreviations: AI/AN = American Indian/Alaska Native; NHPI = Native Hawaiian or other Pacific Islander; AA=African American.

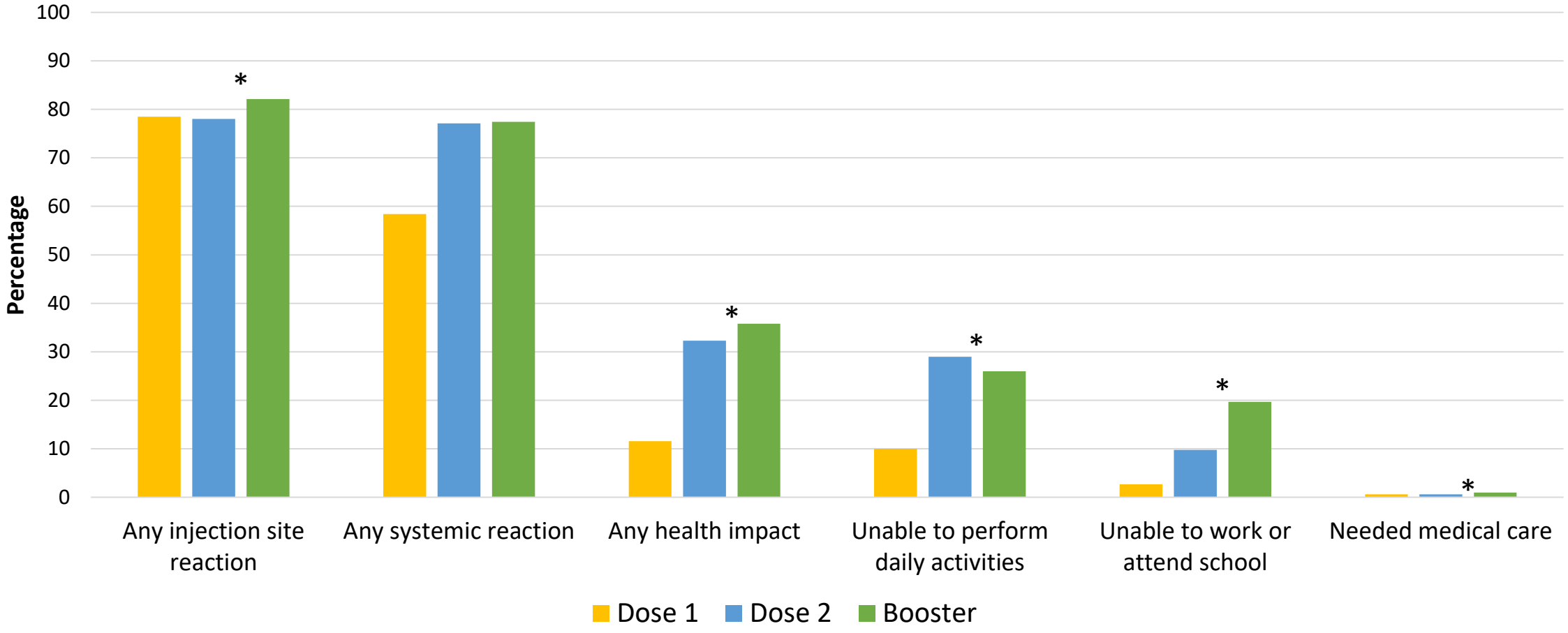
Reactions and health impact events reported by v-safe participants aged ≥18 years at least once in days 0–7 after homologous Pfizer-BioNTech vaccination, by dose



Includes 336,618 participants who completed at least one survey in the first week after each dose, data collected during September 22–April 10, 2022

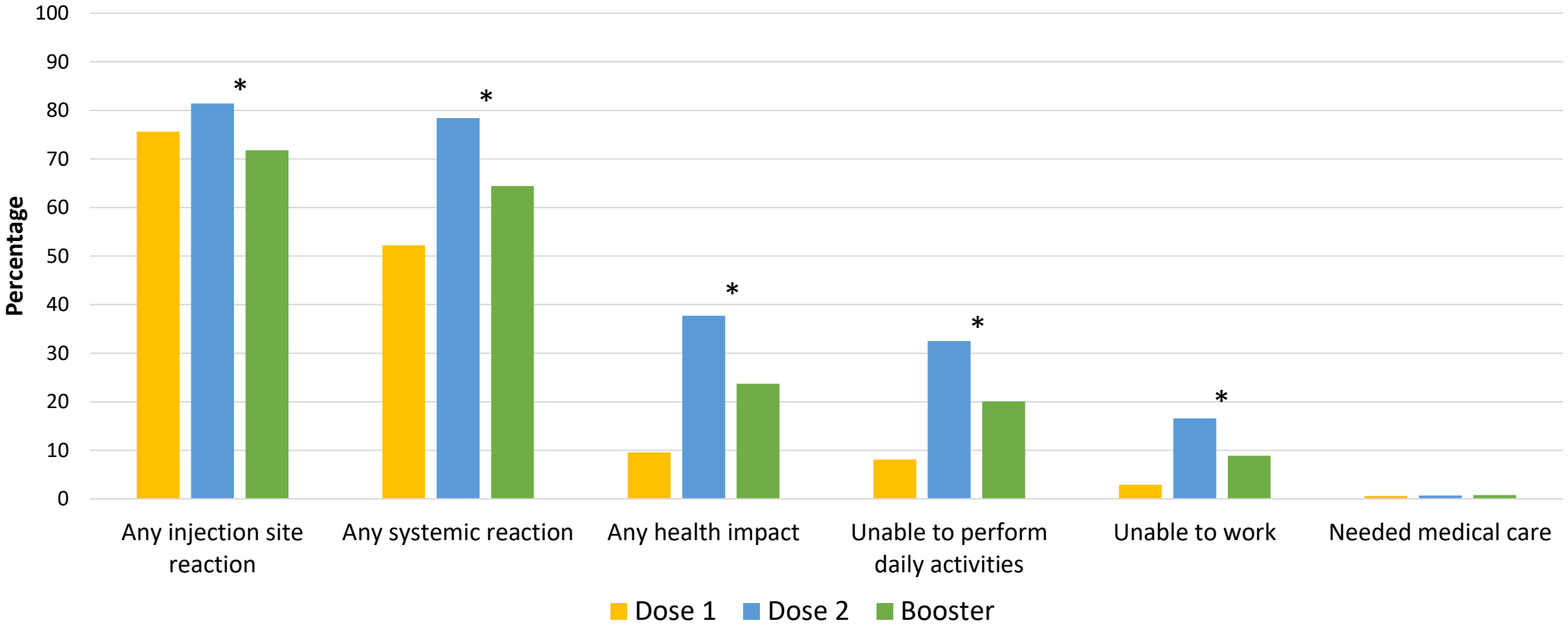
* Dose 2 compared to dose 3: statistically significant difference (p-value <0.05) using multivariable generalized estimating equations model that accounted for the correlation between registrants and adjusted for demographic variables.

Reactions and health impact events reported by v-safe participants aged 12–17 years at least once in days 0–7 after homologous Pfizer-BioNTech vaccination, by dose



Includes 3,694 participants who completed at least one survey in the first week after each dose, data collected during December 9, 2021–April 10, 2022
* Dose 2 compared to dose 3: statistically significant difference (p-value <0.05) using multivariable generalized estimating equations model that accounted for the correlation between registrants and adjusted for demographic variables.

Reactions and health impact events reported by v-safe participants aged ≥18 years at least once in days 0–7 after homologous Moderna vaccination, by dose



Includes 311,374 participants who completed at least one survey in the first week after each dose, data collected during October 20–April 10, 2022
* Dose 2 compared to dose 3: statistically significant difference (p-value <0.05) using multivariable generalized estimating equations model that accounted for the correlation between registrants and adjusted for demographic variables.

Summary of the safety of 1st booster mRNA COVID-19 vaccination

Summary

VSD Rapid Cycle Analysis (RCA) monitoring

- The only safety signal detected for any pre-specified outcome following 1st booster dose has been for myocarditis/pericarditis in the 21 days after mRNA COVID-19 vaccination
- Myocarditis/pericarditis differed between persons ages 12–39 and 40+ years
  - 12–39 years: mostly myocarditis and myopericarditis with onset <7 days after vaccination
  - 40+ years: mostly pericarditis; cases more spread out in the 3 weeks after vaccination
- For persons ages 12–39 years, rate ratios for myocarditis/pericarditis 0–7 days after 1st booster dose were elevated
  - Rate per million 1st booster doses administered was not higher than after dose 2 mRNA COVID-19 vaccination
- For persons ages 40 years and older, rate ratios for myocarditis/pericarditis were elevated, but less so in the 0–7 and 0–21 days after the 1st booster dose compared to persons ages 12–39 years

Summary (cont.)

VAERS monitoring (after 93 million 1st mRNA COVID-19 booster vaccinations in the United Sates)

- Local and systemic reactions are most commonly reported following 1st booster dose
- 110 verified reports of myocarditis and 38 of pericarditis
  - Myocarditis reporting rates were highest among young males (ages 12–29 years)
    - Reporting rates for persons ages 12–29 years following 1st booster exceeded background, but were lower compared to post-dose 2 rates with primary series
  - Pericarditis reports were relatively rare, and distributed evenly among males and females and among the varied age groups
  - More myocarditis (82%) than pericarditis (39%) case patients were hospitalized
    - Most hospitalized patients recovered from symptoms at time of follow up*

V-safe monitoring

- No unusual or unexpected findings or new safety concerns identified

*Follow up varies based on timing of the report and healthcare records availability

Summary (cont.)

- Active surveillance in VSD and passive surveillance in VAERS suggests an increased risk of myocarditis/pericarditis following the 1st mRNA COVID-19 booster vaccination
  - For myocarditis, the findings are consistent with those observed with primary series vaccination, but the risk appears to be lower following the 1st booster dose compared to dose 2 of primary series
    - Risk of myocarditis is highest in younger males with onset clustering within 0–7 days of 1st booster vaccination
    - Pericarditis is less common, more evenly distributed between males and females, and more evenly distributed across age groups
- Local and systemic reactogenicity and health impacts appear similar or attenuated for 1st mRNA COVID-19 booster vaccination compared to dose 2 of primary series
- Monitoring is ongoing

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- **CDC Immunization Safety Office**
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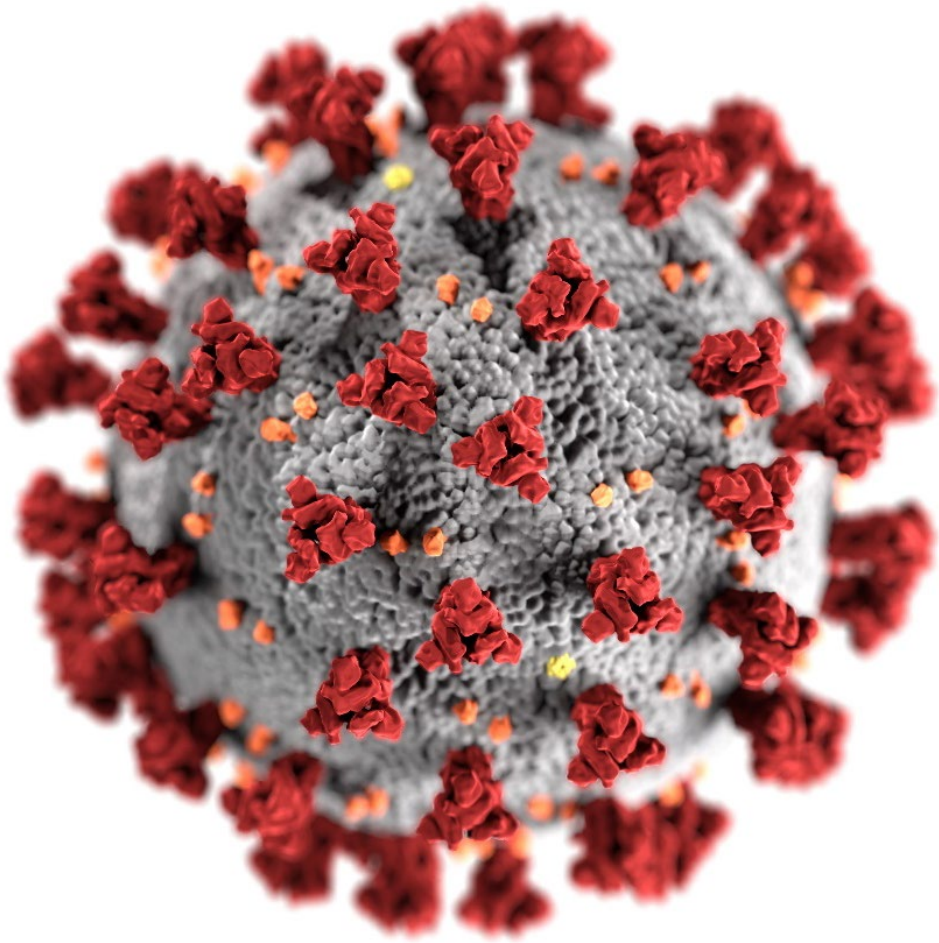
- **VSD Sites**
  - HealthPartners Institute, Minneapolis, Minnesota
  - Kaiser Permanente Colorado, Denver, Colorado
  - Kaiser Permanente Northwest, Portland, Oregon
  - Kaiser Permanente Southern California, Los Angeles, California
  - Kaiser Permanente Washington, Seattle, Washington
  - Denver Health, Denver, Colorado

- VAERS team
- CISA team
- VSD team
- COVID-19 Vaccine Task Force Data Monitoring and Reporting Group
- CDC Immunization Safety Office
- FDA/Center for Biologics Evaluation and Research
- State and local health departments
- Healthcare providers and other stakeholders reporting to VAERS

- V-safe team
- V-safe participants
- Anne Hause
- James Baggs
- Paige Marquez
- Isaac McCullum
- Bicheng Zhang
- Tanya Myers

Thank you!



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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.