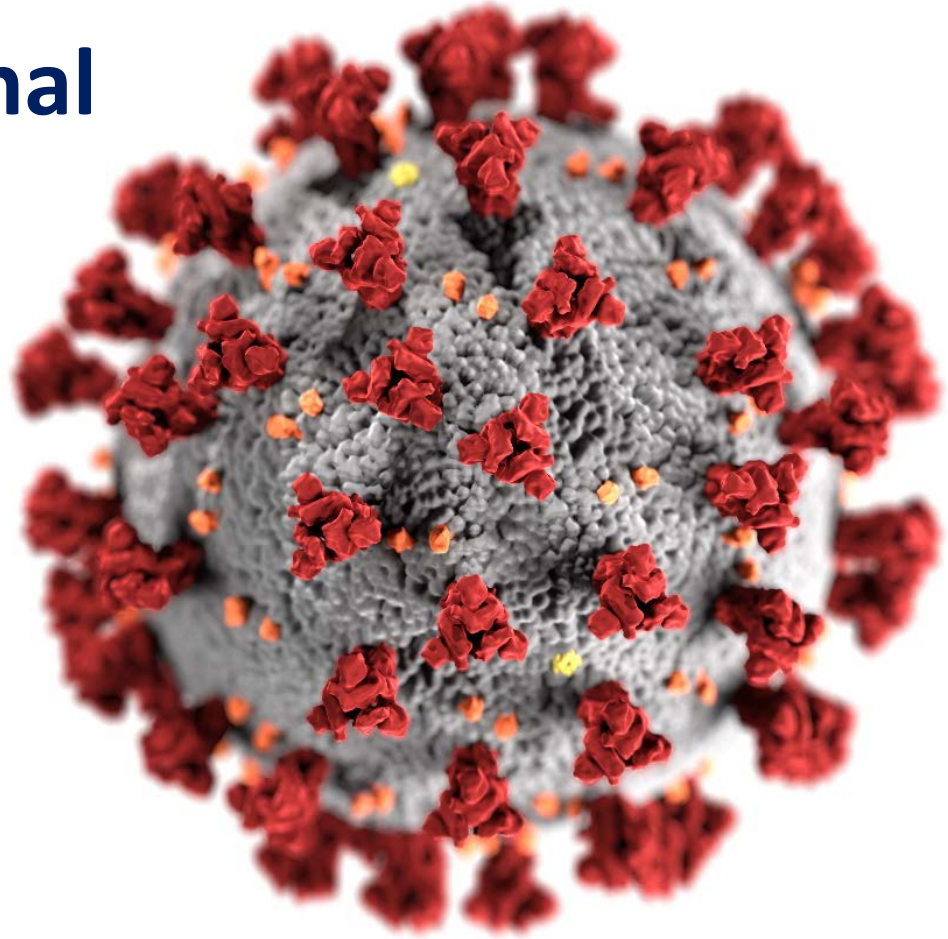
Early safety monitoring for additional COVID-19 vaccine doses: Reports to VAERS and v-safe



Advisory Committee on Immunization Practices

September 22, 2021

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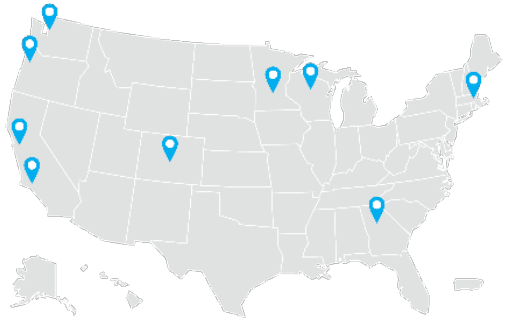
V-safe Team Co-Lead
COVID-19 Vaccine Task Force

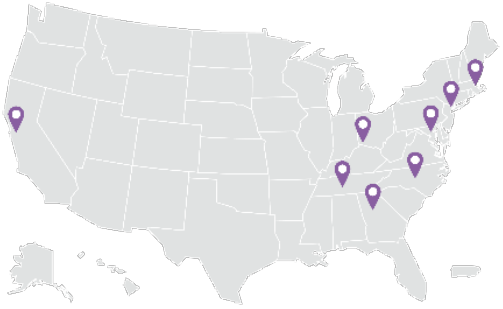
cdc.gov/coronavirus

CDC vaccine safety monitoring

- COVID-19 vaccines are being administered under **the most intensive vaccine safety monitoring effort in U.S. history**
- Strong, complementary systems are in place—both new and established

v-safe	VAERS	VSD	CISA Project





Full list of U.S. COVID-19 vaccine safety monitoring systems

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

CDC vaccine safety monitoring

- Authorized COVID-19 vaccines are being administered under **the most intensive vaccine safety monitoring effort in U.S. history**
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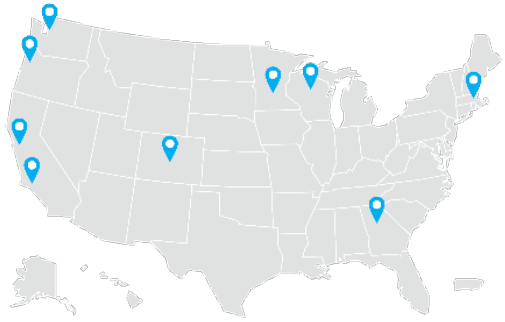
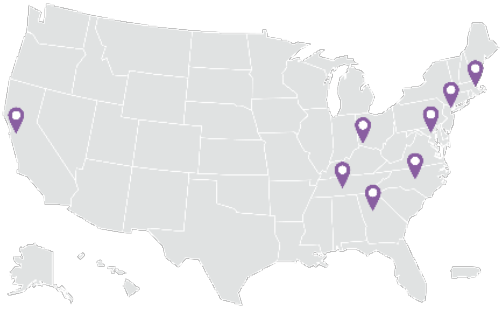
v-safe

VAERS

VSD



CISA Project



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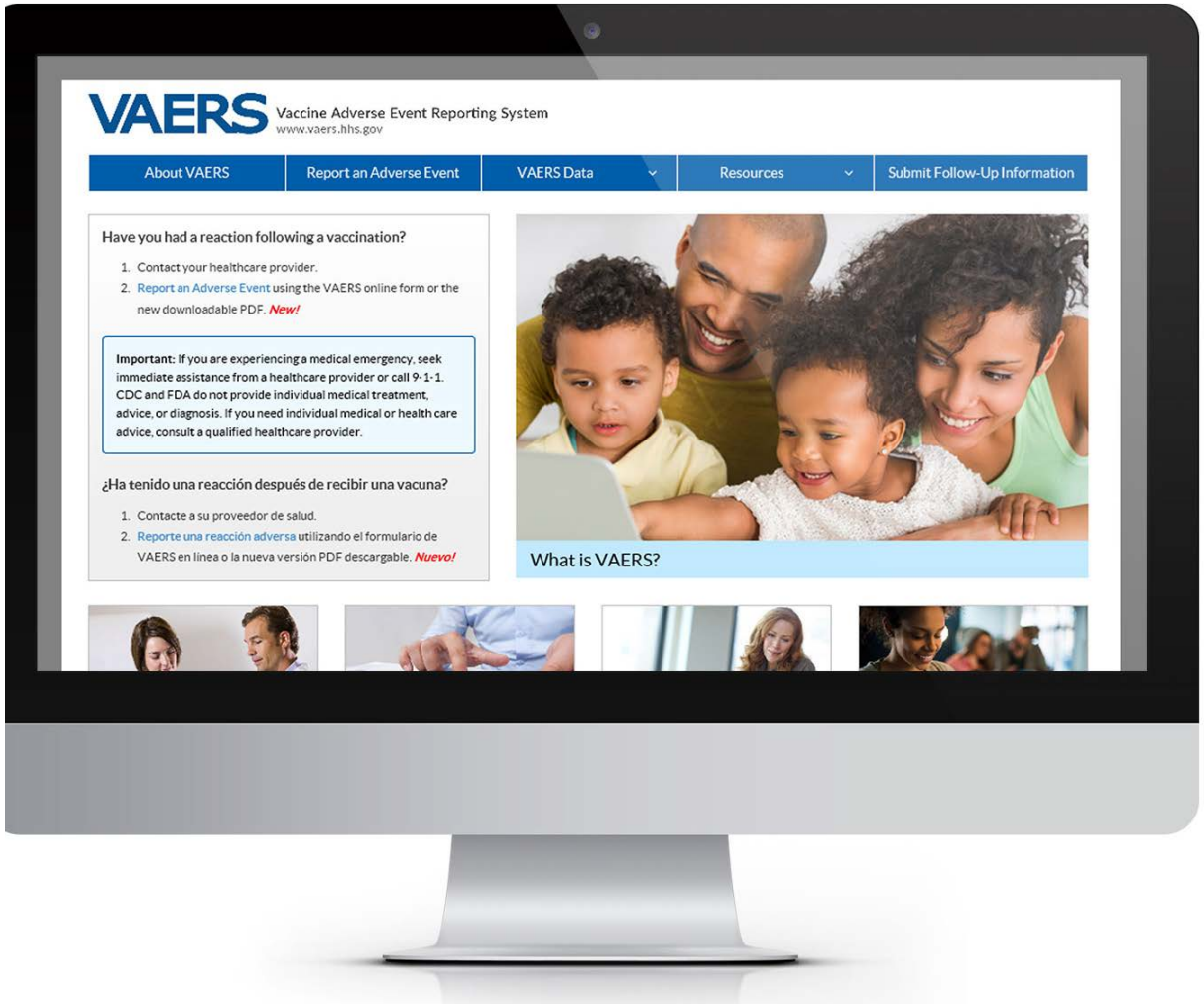
VAERS is the nation's early warning system for vaccine safety

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

- Inconsistent quality and completeness of information
- Reporting biases
- Generally, cannot determine cause and effect

Reports to VAERS following dose 3 of mRNA COVID-19 vaccination, by age group and sex

Age group, years	n (%)
12–17	48 (2)
18–49	622 (24)
50–64	654 (26)
≥65	1,239 (48)
Total	**2,563**

Sex	n (%)
Male	979 (38)
Female	1,570 (61)
Unknown	14 (1)
Total	**2,563**

- Median age 64 years (range: 12–100)
- Most reports (61%) among women

Includes data collected during December 14, 2020–September 17, 2021

Reports to VAERS following dose 3 of mRNA COVID-19 vaccination, by race and ethnicity

- Most reports either
  - Unknown/not reported race or ethnicity (49%)
  - White, non-Hispanic race and ethnicity (39%)

Race or ethnicity	Reports (%)
Hispanic	143 (6)
Non-Hispanic	
AI/AN	11 (<1)
Asian	51 (2)
Black	89 (3)
NHPI	1 (<1)
White	998 (39)
Multiracial	14 (1)
Other	8 (<1)
Unknown/not reported	1,248 (49)
Total	**2,563**

Includes data collected during December 14, 2020–September 17, 2021 for persons 12+ years of age. Hispanic also includes persons identified of Hispanic ethnicity of unknown race.
Abbreviations: AI/AN = American Indian/Alaska Native; NHPI = Native Hawaiian or other Pacific Islander.

Reports to VAERS following dose 3 of mRNA COVID-19 vaccination

Manufacturer	Non-serious	Serious	Total
Pfizer-BioNTech	1,175 (95%)	68 (5%)	1,243
Moderna	1,257 (95%)	63 (5%)	1,320
Total	**2,432 (95%)**	**131 (5%)**	**2,563**

- Regardless of manufacturer, 95% of reports non-serious

Includes data collected during December 14, 2020–September 17, 2021 for persons 12+ years of age.
Per federal law, includes reports of hospitalization, prolongation of existing hospitalization, life threatening condition, permanent disability, congenital deformity or birth defect, or death

Most frequently reported adverse events to VAERS following dose 3 of mRNA COVID-19 vaccination, by seriousness

Serious (n = 131)

Rank	Adverse event*	n (%)
1	Extra dose administered	40 (31)
2	Fever	27 (21)
3	Dyspnea	23 (18)
4	Death	18 (14)
5	Fatigue	14 (11)

Non-serious (n= 2,432)

Rank	Adverse event*	n (%)
1	Extra dose administered	945 (39)
2	Fever	323 (13)
3	Headache	274 (11)
4	Fatigue	269 (11)
5	No adverse event	243 (10)

Includes data collected during December 14, 2020–September 17, 2021 for persons 12+ years of age. Per federal law, includes reports of hospitalization, prolongation of existing hospitalization, life threatening condition, permanent disability, congenital deformity or birth defect, or death.

* Not mutually exclusive

Reports of death to VAERS following dose 3 of mRNA COVID-19 vaccination

- Median age = 76 years (range: 47–93)
- Median time from 3rd dose to death = 1 day (range: day of vaccination – 12)

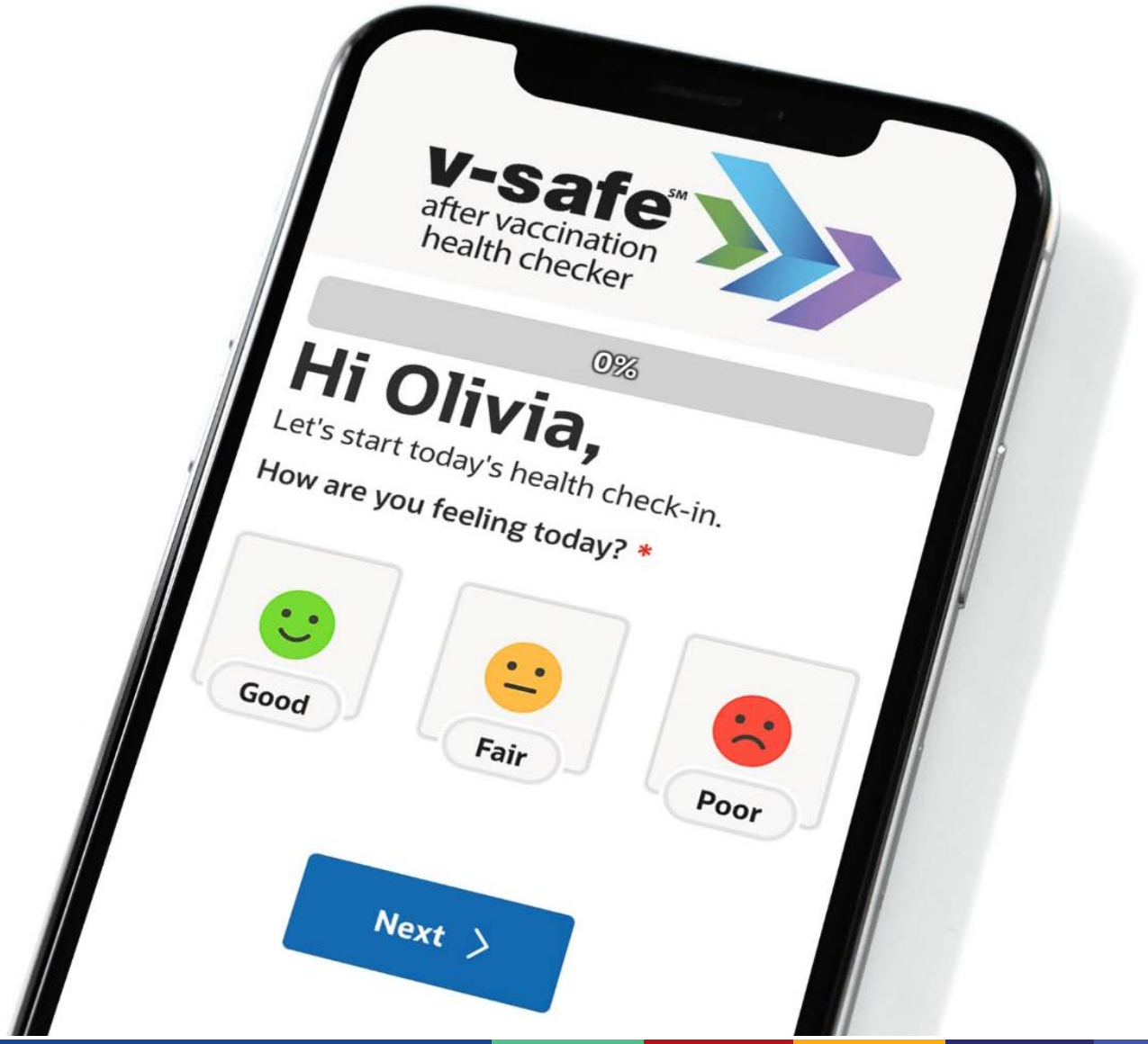
Preliminary impression of cause of death*	Reports
Respiratory and/or cardiac arrest	7
Unable to assess	4
Pulmonary embolism	2
Sepsis	1
Accident/trauma	1
Cancer	1
COVID-19 pneumonia	1
Total	**18**

Includes data collected during December 14, 2020–September 17, 2021

* Based upon physician review of initial report and available documentation, including death certificates

Smartphone-based active safety monitoring

v-safe[SM]
after vaccination
health checker



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

- Uses text messaging and web surveys to check in with vaccine recipients after vaccination
- Can register at any time: after 1st, 2nd, or 3rd dose
- Solicits participants' reports on how they feel after COVID-19 vaccination
  - Local injection site reactions
  - Systemic reaction
  - Health impacts (unable to perform normal daily activities, missed school or work, or received care)

v-safe after vaccination health checker

Demographic summary of 21,935 v-safe participants who reported an additional dose

Characteristic	% of participants
Sex	
Female	63.4
Male	35.7
Unknown	1.0
Age group (years)	
0-17	0.3
18-49	29.2
50-64	29.8
65-74	30.5
75-84	9.5
≥85	0.8

Characteristic	% of participants
Ethnicity	
Hispanic/Latino	8.2
Not Hispanic/ Latino	87.7
Unknown	4.2
Race	
AI/AN	0.4
Asian	5.2
Black	5.6
NHPI	0.3
White	82.4
Multiracial	1.9
Other	2.0
Unknown	2.2

Includes participants who completed at least one survey in the first week after additional dose, data collected during August 12–September 19, 2021
Abbreviations: AI/AN = American Indian/Alaska Native; NHPI = Native Hawaiian or other Pacific Islander.

Patterns of vaccination for 21,935 v-safe participants who reported an additional dose

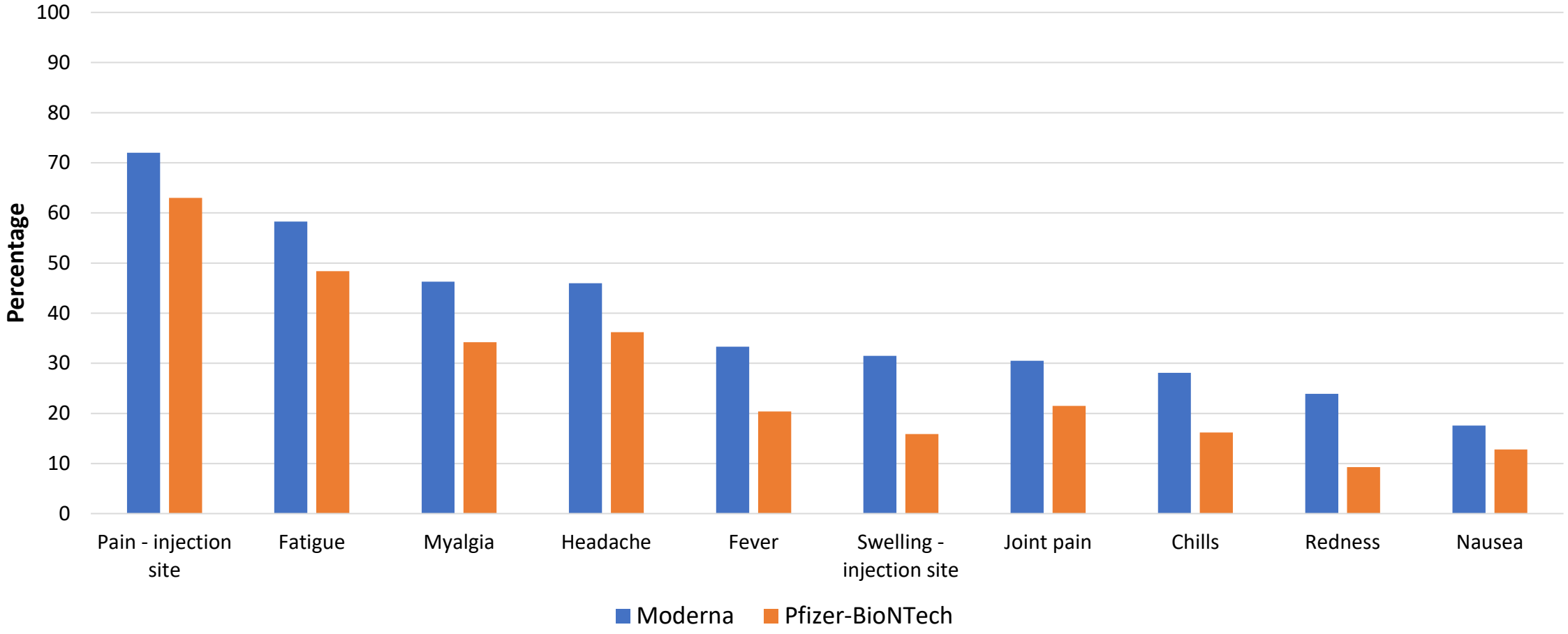
Primary series

Additional dose	Moderna (%)	Pfizer-BioNTech (%)	Janssen (%)*	Total
Moderna	**10,331 (98.6)**	196	63	6,903
Pfizer-BioNTech	142	**11,082 (98.2)**	64	11,288
Janssen	4	6	**47 (27.0)**	57
Total	10,477	11,284	174	**21,935**

Includes participants who completed at least one survey in the first week after additional dose, data collected during August 12–September 19, 2021

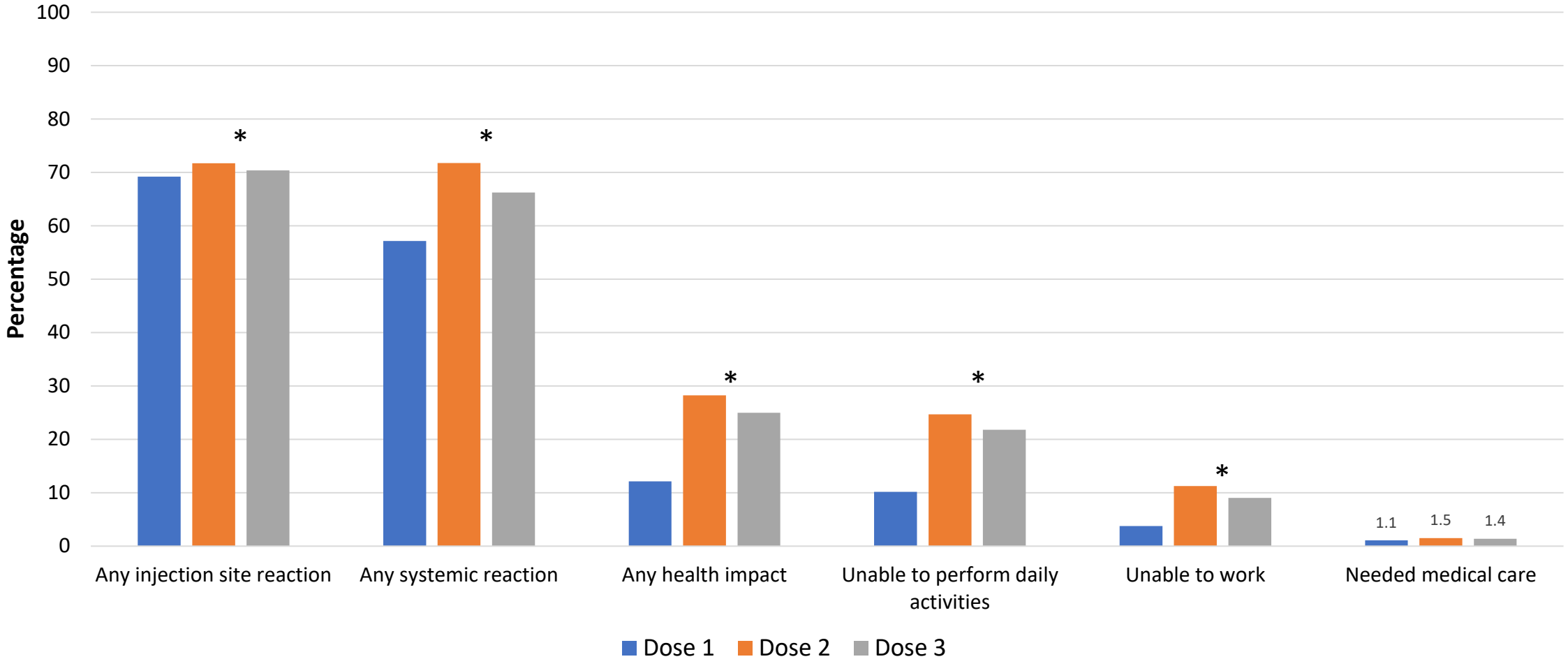
* Includes persons who received Janssen as their primary series and one additional dose of vaccine from the listed manufacturers

Most common solicited reactions reported at least once 0-7 days after dose 3 of Moderna or Pfizer-BioNTech vaccine



Includes 21,413 participants who completed at least one survey in the first week after additional dose, data collected during August 12–September 19, 2021

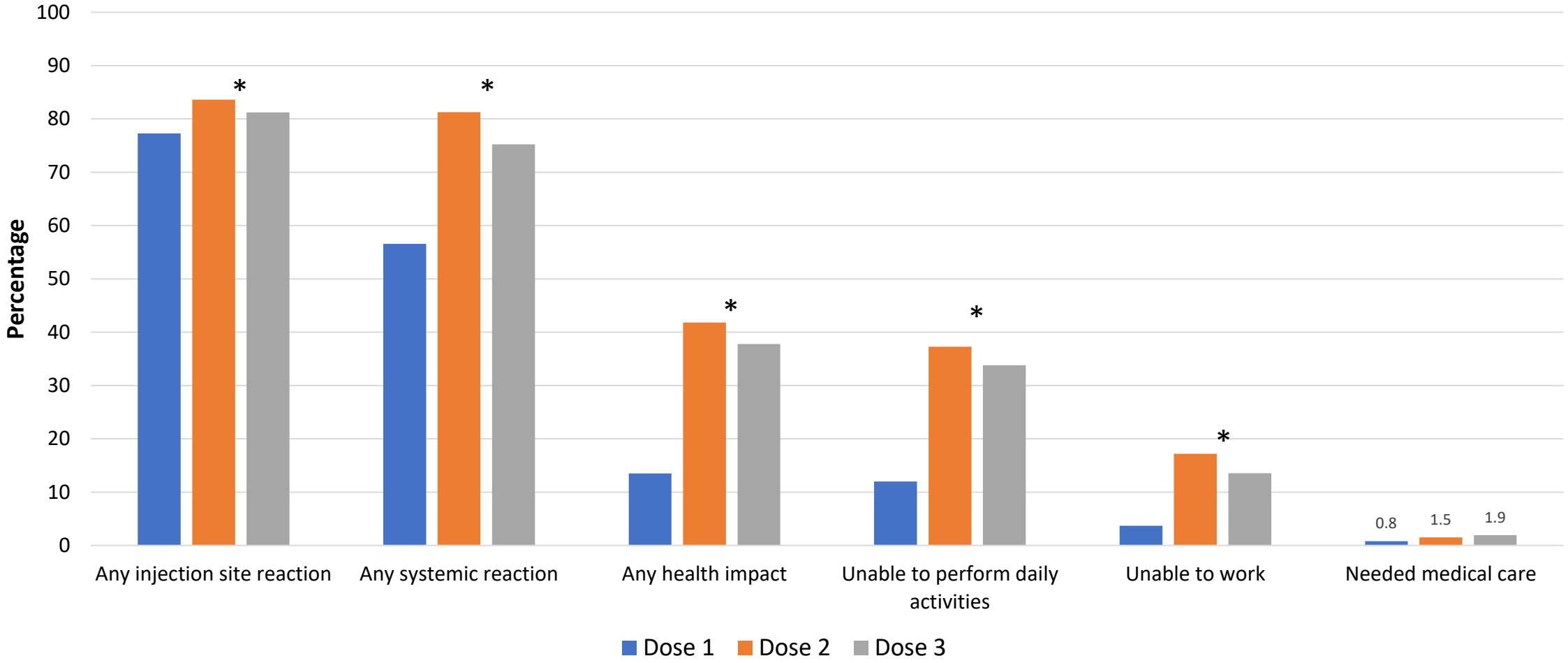
Comparison of reactions and health impact events reported at least once in days 0-7 after Pfizer-BioNTech vaccination, by dose



Includes 6,267 participants who completed at least one survey in the first week after each dose, data collected during August 12–September 19, 2021

* Odds of reporting an event following dose 2 and 3 compared using multivariable generalized estimating equations model that accounted for the correlation between registrants and adjusted for demographic variables; p-values less than 0.05 were considered statistically significant

Comparison of reactions and health impact events reported at least once in days 0-7 after Moderna vaccination, by dose



Includes 6,242 participants who completed at least one survey in the first week after each dose, data collected during August 12–September 19, 2021
* Odds of reporting an event following dose 2 and 3 compared using multivariable generalized estimating equations model that accounted for the correlation between registrants and adjusted for demographic variables; p-values less than 0.05 were considered statistically significant

Limitations of early safety monitoring for an additional COVID-19 vaccine dose

- V-safe population likely not representative of the vaccinated U.S. population
- Additional dose recipients likely included immunocompromised and non-immunocompromised persons
  - V-safe does not include information about immune status
  - Immunocompromised persons might have different reactogenicity than immunocompetent persons
- Data available now are insufficient
  - To determine patterns of adverse events after receipt of an additional dose from a manufacturer different from the primary series
  - To identify rare adverse events
- Complete medical review of deaths following vaccination reported to VAERS is dependent on availability of medical records, death certificates, and autopsy reports, which may be delayed or not available

Summary

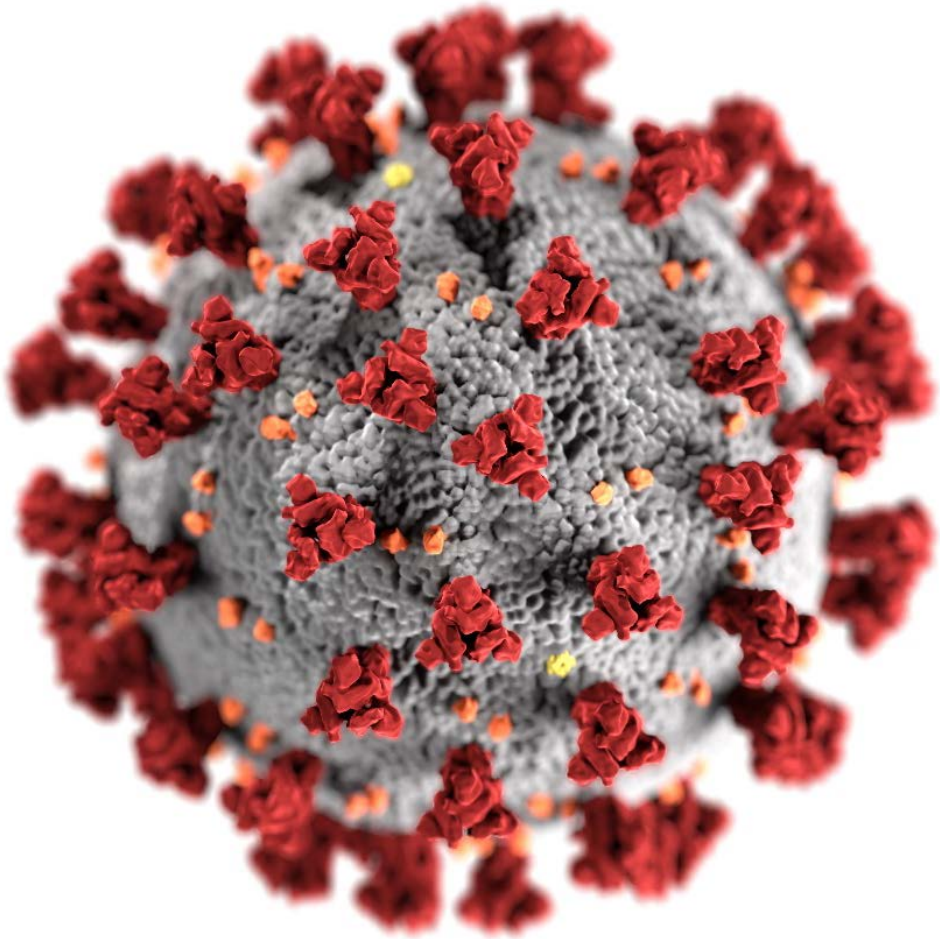
- No unexpected patterns of adverse events were identified
- 95% of VAERS reports following dose 3 of COVID-19 vaccination were non-serious
- Over 21,000 v-safe registrants reported an additional dose
  - Most reported a primary mRNA vaccine series followed by dose 3 from the same manufacturer
  - Local and systemic reactions were reported slightly less frequently following dose 3 than dose 2
    - Similar to Pfizer-BioNTech phase 3 clinical trial (included 306 persons)[1]

[1] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-initiate-rolling-submission

Next steps

- VAERS and v-safe will continue to monitor safety of additional doses of COVID-19 vaccination
- The Vaccine Safety Datalink (VSD) will incorporate additional doses of COVID-19 vaccination into weekly near real-time sequential monitoring
- The Clinical Immunization Safety Assessment (CISA) Project will continue to be available to consult on clinically complex adverse events following additional dose of COVID-19 vaccination
- CDC will update ACIP as additional data become available

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.