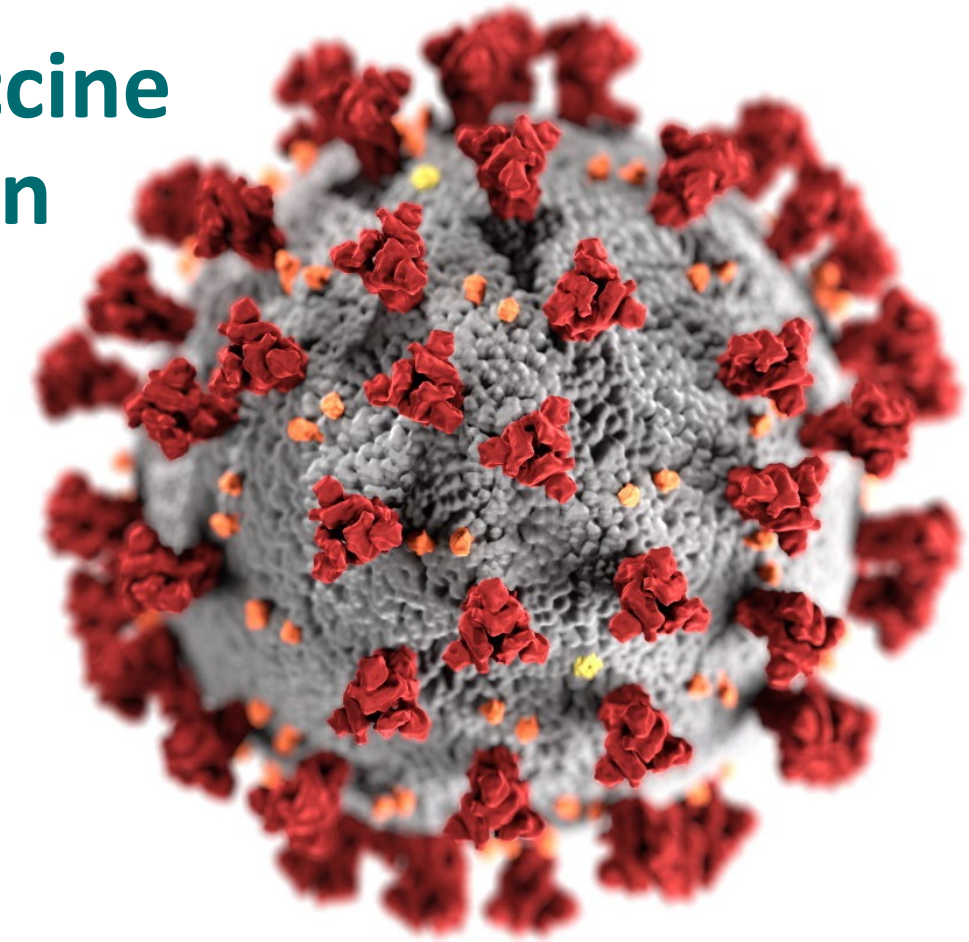
Safety monitoring of COVID-19 vaccine among children and young adults in v-safe



Advisory Committee on Immunization Practices

January 5, 2021

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COVID-19 Vaccine Task Force

cdc.gov/coronavirus

Active safety monitoring for COVID-19 vaccines

v-safe is a voluntary CDC smart phone-based monitoring program for COVID-19 vaccine safety in the United States

- Uses text messaging and web surveys to check in with vaccine recipients after vaccination
- Can register at any time: after first, second, or booster 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

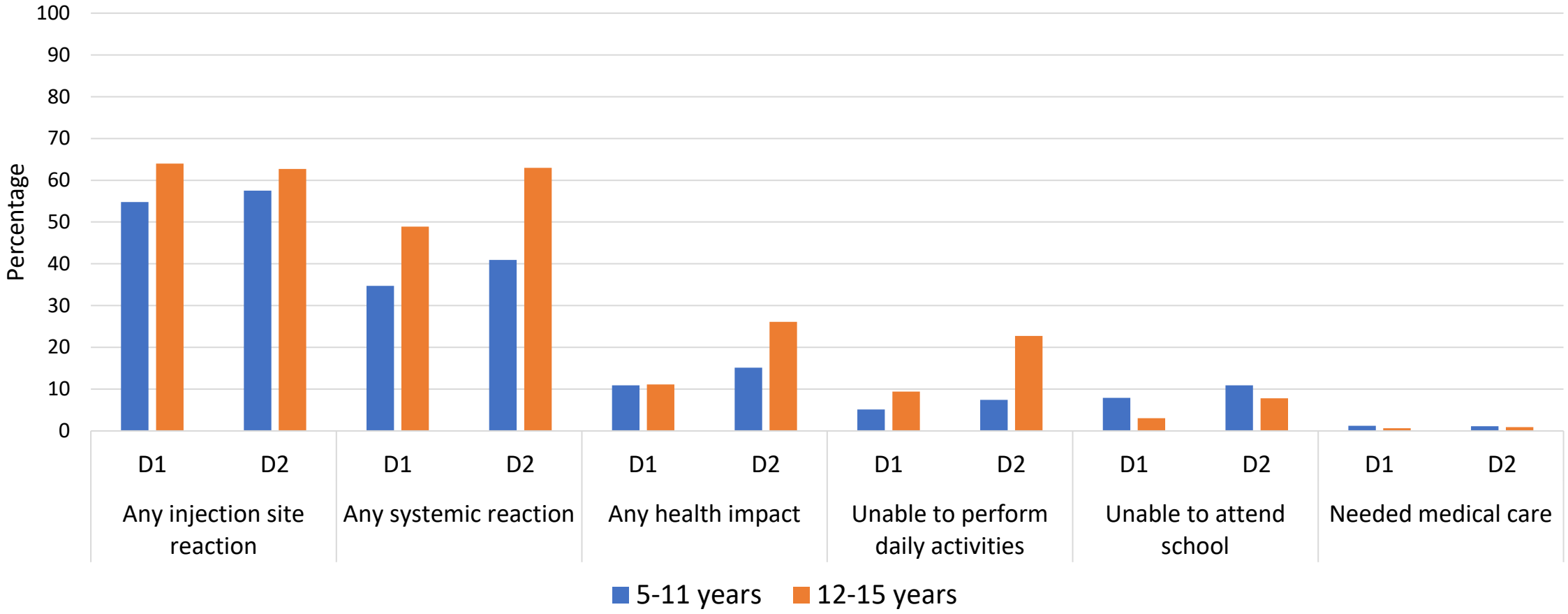
Demographic summary of 115,208 v-safe participants ages 5-15 years who reported Pfizer-BioNTech vaccination

Characteristic	% of participants
Sex	
Female	50.6
Male	48.4
Unknown	1.0
Age	
5-11 years	36.9
12-15 years	63.1

Characteristic	% of participants
Ethnicity	
Hispanic or Latino	17.0
Not Hispanic/ Latino	78.1
Unknown	4.7
Race	
AI/AN	0.8
Asian	8.3
Black or AA	7.3
NHPI	0.4
White	67.9
Multiracial	7.3
Other	4.8
Unknown	3.0

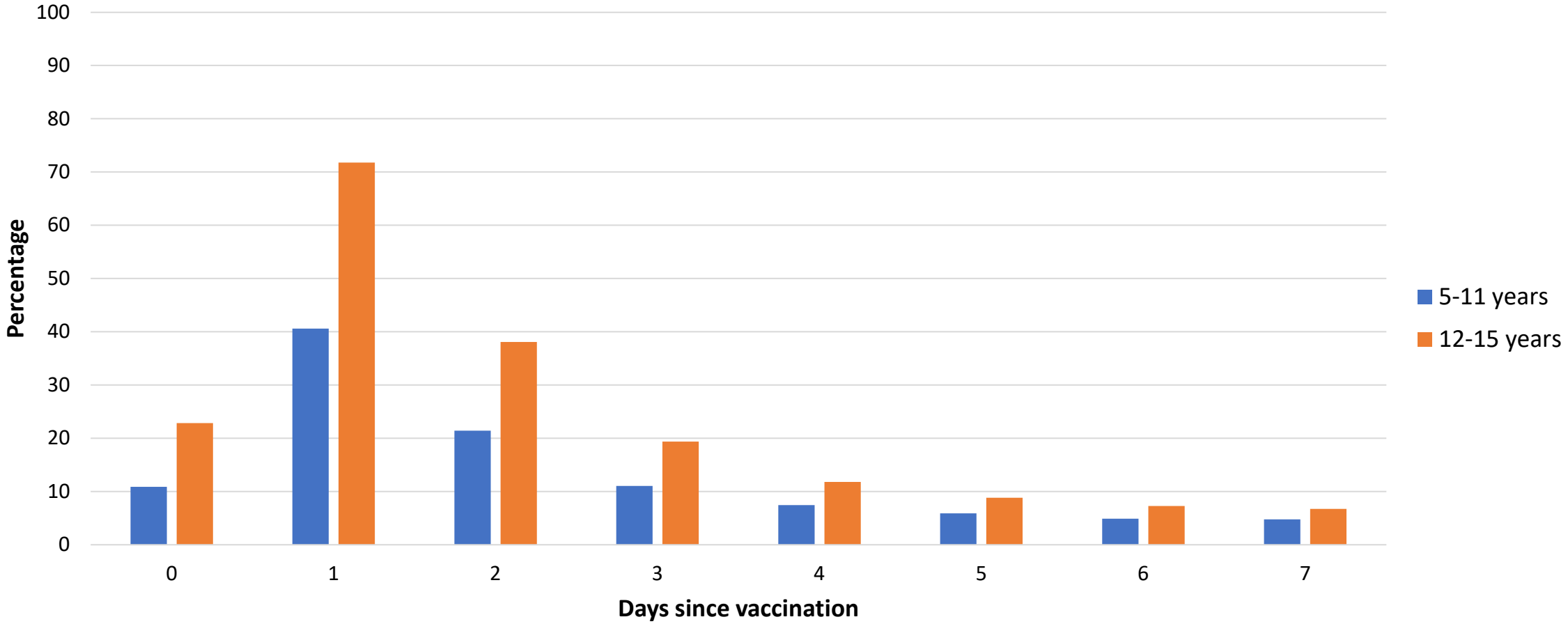
Data as of December 19, 2021. Includes participants who completed at least one survey in the first week after booster dose. Abbreviations: AI/AN = American Indian/Alaska Native; NHPI = Native Hawaiian or other Pacific Islander; AA=African American.

Reactions and health impact events reported at least once in days 0-7 after Pfizer-BioNTech vaccination for children and adolescents ages 5-11 and 12-15 years,* by dose



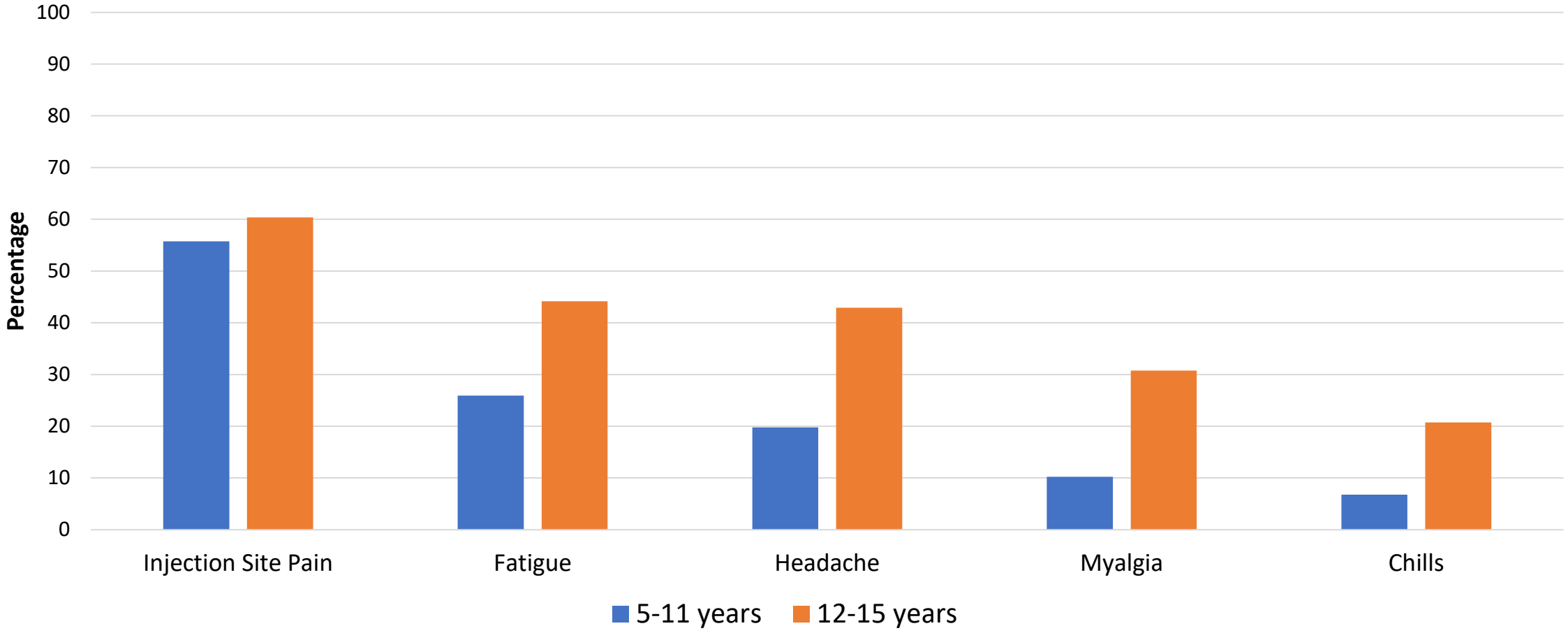
* The dosage for children ages 5-11 years (10 µg) is smaller than that recommended for persons ages ≥12 years (30 µg).
Includes 77,747 participants who completed at least one survey in the first week after dose 2, data as of December 19, 2021

Any systemic reaction reported for children ages 5–11 and 12-15 years* at least once in 0–7 days after dose 2 of Pfizer-BioNTech vaccine, by days since vaccination



* The dosage for children ages 5-11 years (10 µg) is smaller than that recommended for persons ages ≥12 years (30 µg).
Includes 77,747 participants who completed at least one survey in the first week after dose 2, data as of December 19, 2021

Top 5 reactions reported at least once in 0–7 days after dose 2 of Pfizer-BioNTech vaccine for children ages 5-11 and 12-15 years*



* The dosage for children ages 5-11 years (10 µg) is smaller than that recommended for persons ages ≥12 years (30 µg).
Includes 77,747 participants who completed at least one survey in the first week after dose 2, data as of December 19, 2021

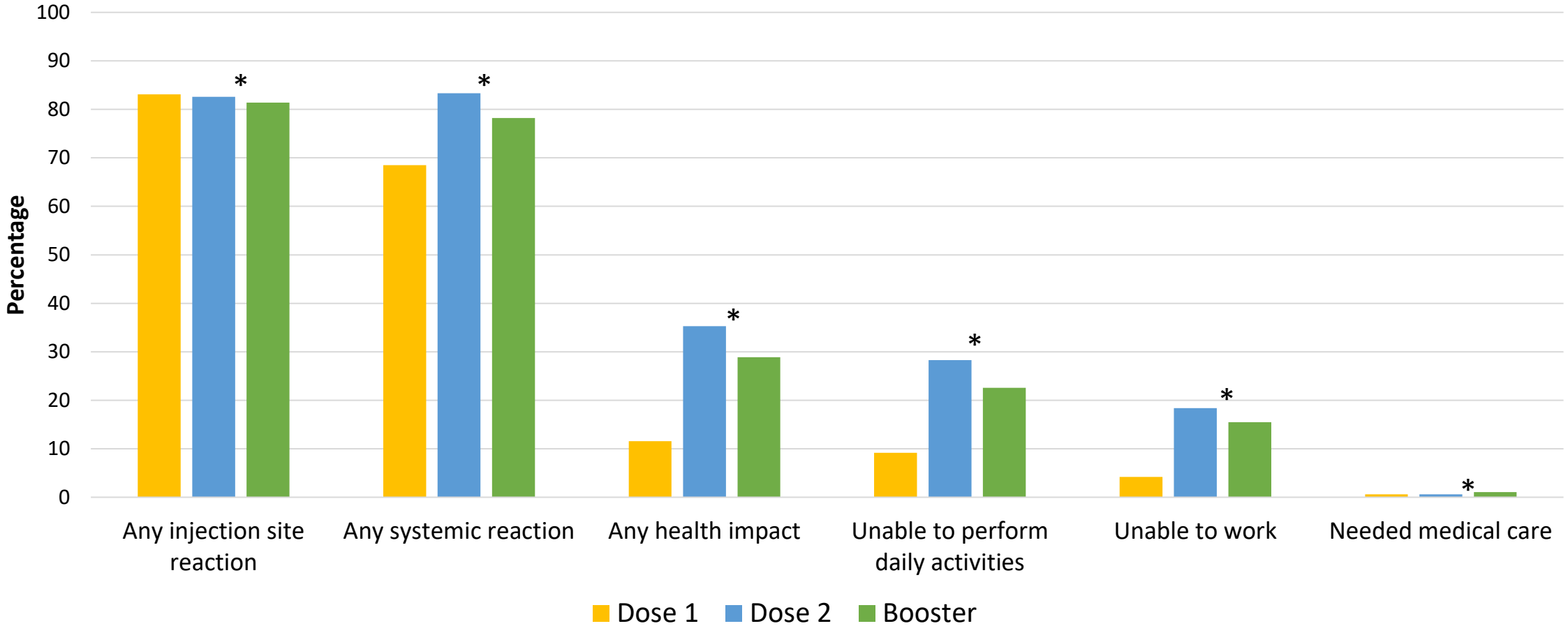
Demographic summary of 7,088 v-safe participants ages 16-24 years who reported homologous Pfizer-BioNTech booster dose

Characteristic	% of participants
Sex	
Female	72.0
Male	26.2
Unknown	1.9
Age	
16-17 years	6.7
18-24 years	93.3

Characteristic	% of participants
Ethnicity	
Hispanic or Latino	14.6
Not Hispanic/ Latino	83.7
Unknown	1.7
Race	
AI/AN	0.4
Asian	10.5
Black or AA	4.1
NHPI	0.1
White	74.3
Multiracial	4.9
Other	3.2
Unknown	2.5

Data as of December 19, 2021. Includes participants who completed at least one survey in the first week after booster dose. Abbreviations: AI/AN = American Indian/Alaska Native; NHPI = Native Hawaiian or other Pacific Islander; AA=African American.

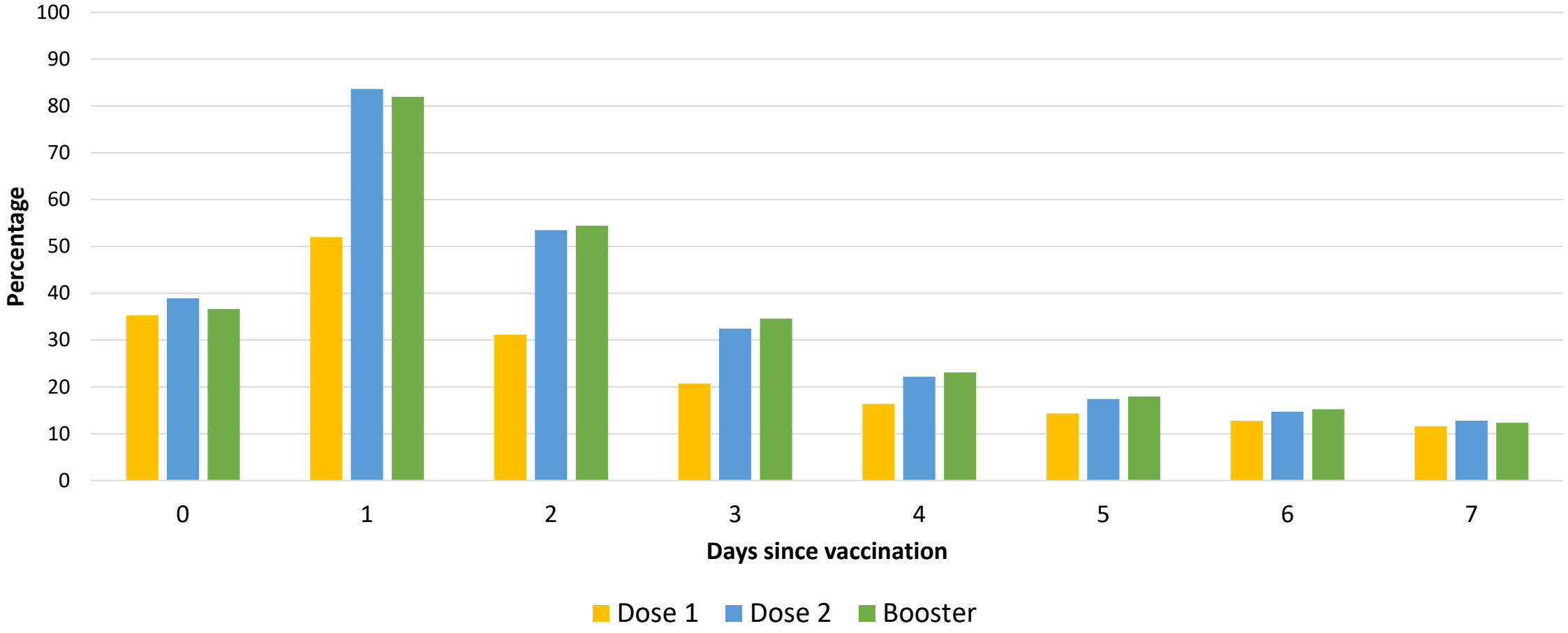
Reactions and health impact events reported by v-safe participants ages 16-24 years at least once in days 0-7 after Pfizer-BioNTech vaccination, by dose



Includes 7,088 participants who completed at least one survey in the first week after each dose, data collected during September 22–December 19, 2021

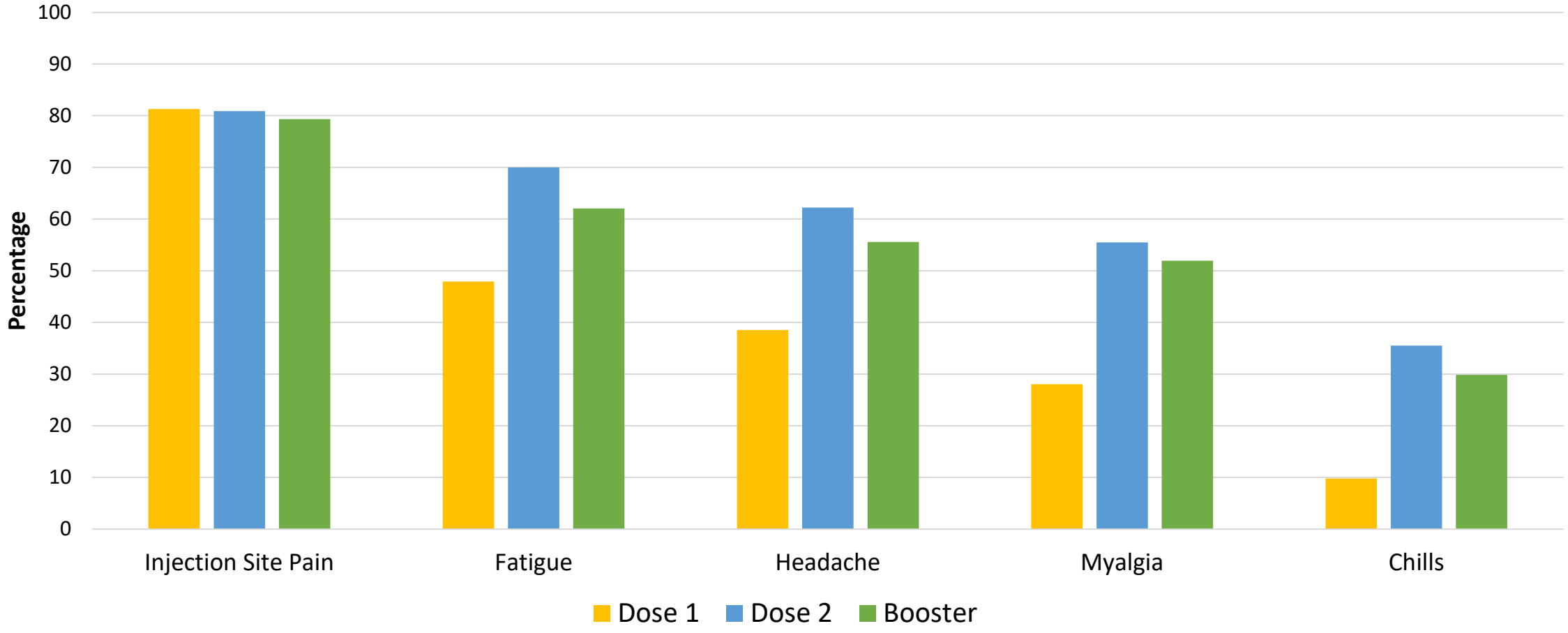
* Dose 2 compared to dose 3: statistically significant difference (p-value <0.05) using multivariable generalized estimating equations model that accounted for the correlation between registrants and adjusted for demographic variables. All differences were reported less frequently following booster dose than dose 2, except "needed medical care" which was more frequently reported.

Any systemic reaction reported for v-safe participants ages 16-24 years at least once in 0–7 days after Pfizer-BioNTech vaccine, by dose and days since vaccination



Includes 7,088 participants who completed at least one survey in the first week after each dose, data collected during September 22–December 19, 2021

Top 5 reactions reported by v-safe participants ages 16-24 years at least once 0-7 days following Pfizer-BioNTech vaccination, by dose



Includes 7,088 participants who completed at least one survey in the first week after each dose, data collected during September 22–December 19, 2021

Limitations

- v-safe is a voluntary safety monitoring system and the population likely not representative of the vaccinated U.S. population

- Data currently available are limited to determine patterns of adverse events after receipt of a booster dose for adolescents ages 16-17 years

Summary

- Over 115,208 v-safe participants ages 5-15 years have reported Pfizer-BioNTech vaccination
  - Reactions were generally mild to moderate and most frequently reported the day after vaccination
  - Reactions were more frequently reported after dose 2 than dose 1
  - Participants ages 5-11 years reported reactions less frequently than participants ages 12-15 years

- Over 7,088 v-safe participants ages 16-24 years reported a homologous Pfizer-BioNTech booster dose
  - Reactions were generally mild to moderate and most frequently reported the day after vaccination
  - Reactions were less frequently reported after booster dose than dose 2

Acknowledgments

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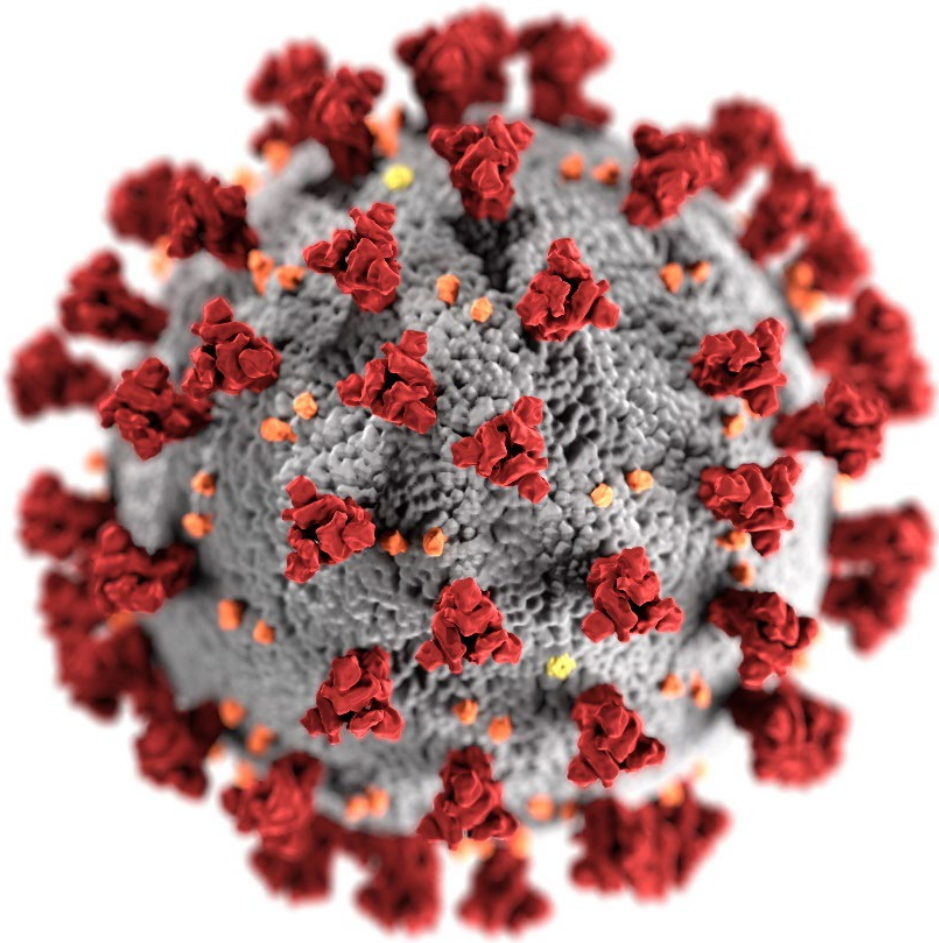
- James Baggs
- Paige Marquez
- Isaac McCullum
- Bicheng Zhang
- Tanya Myers
- v-safe team members
- v-safe participants

Disclaimer

- The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC)
- Mention of a product or company name is for identification purposes only and does not constitute endorsement by CDC

Thank you!



For more information, contact CDC
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