



What Clinicians Need to Know about the Recent Updates to CDC's Recommendations for COVID-19 Boosters

Clinician Outreach and Communication Activity (COCA) Call

Tuesday, October 26, 2021

Continuing Education

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Today's Presenters

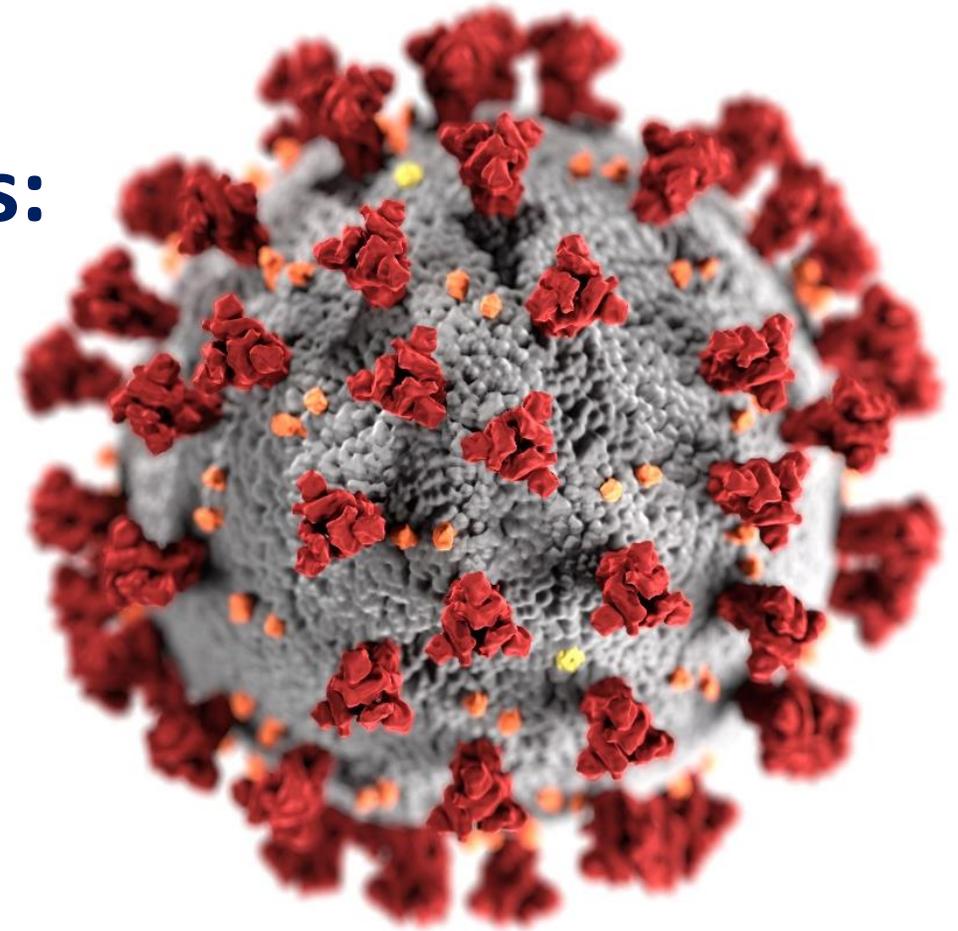
- **Anne Hause, PhD**
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Early Safety Monitoring for Additional COVID-19 Vaccine Doses: Reports to VAERS and v-safe

Clinician Outreach and Communication Activity
(COCA) Call

October 26, 2021

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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>



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- 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

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VAERS



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

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



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 ←



Reports to VAERS following dose 3 mRNA or dose 2 Janssen COVID-19 vaccination, by age group and sex

Age group, years	n (%)
12–17	34 (1)
18–49	1,225 (25)
50–64	1,304 (26)
≥65	2,427 (49)
Total	4,990

Sex	n (%)
Male	1,823 (37)
Female	3,153 (63)
Unknown	14 (<1)
Total	4,990

- Median age 64 years (interquartile range: 49-73)
- Majority (63%) among women

Includes data collected during August 12–October 10, 2021



Reports to VAERS following dose 3 mRNA or dose 2 Janssen COVID-19 vaccination, by race and ethnicity

- Most reports either
 - Unknown/not reported race or ethnicity (49%)
 - White, non-Hispanic race and ethnicity (41%)

Race or ethnicity	mRNA, dose 3 (%)	Janssen, dose 2 (%)
Hispanic or Latino	207 (4)	4 (10)
Non-Hispanic		
AI/AN	21 (<1)	0 (0)
Asian	101 (2)	1 (3)
Black or AA	115 (2)	4 (10)
NHPI	3 (<1)	1 (3)
White	2,011 (41)	12 (31)
Multiracial	28 (1)	1 (3)
Other	24 (<1)	0 (0)
Unknown/ not reported	2,441(49)	16 (41)
Total	4,951	39



Includes data collected during August 12–October 10, 2021 for persons aged 12 years and older. Hispanic also includes persons identified of Hispanic ethnicity of unknown race. Abbreviations: AI/AN = American Indian/Alaska Native; AA = African American; NHPI = Native Hawaiian or other Pacific Islander.

Reports to VAERS following dose 3 mRNA or dose 2 Janssen COVID-19 vaccination

Manufacturer	Non-serious reports	Serious reports*	Total reports
Pfizer-BioNTech	3,351 (95%)	160 (5%)	3,511
Moderna	1,325 (92%)	115 (8%)	1,440
Janssen	39 (100%)	0 (0%)	39
Total	4,715 (94%)	275 (6%)	4,990

- Regardless of manufacturer, $\geq 92\%$ of reports non-serious



Includes data collected during August 12–October 10, 2021 for persons aged 12 years and older.

* 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 mRNA or dose 2 Janssen COVID-19 vaccination, by seriousness

Serious* (n = 275)

Rank	Adverse event**	n (%)
1	Extra dose administered	40 (23)
2	Fever	38 (14)
3	Shortness of breath	37 (14)
4	Blood test	33 (12)
5	Fatigue	32 (12)

Non-serious (n= 4,715)

Rank	Adverse event**	n (%)
1	Interchange of vaccine products	1,110 (24)
2	Extra dose administered	969 (21)
3	Fever	764 (16)
4	Headache	697 (15)
5	Fatigue	665 (14)



Includes data collected during August 12–October 10, 2021 for persons aged 12 years and older. * 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 mRNA or dose 2 Janssen COVID-19 vaccination

Preliminary impression of cause of death*	mRNA, dose 3
No cause specified	8
Found dead	4
Respiratory and/or cardiac arrest	3
Stroke	3
COVID-19 disease	3
Pneumonia; sepsis	2
Pulmonary embolism	2
Miscellaneous other [†]	5
Total	30

- Median age = 79 years (IQR: 69 – 88)
- Median time from third dose to death = 2 days (IQR: 0 – 9)



Includes data collected during August 12–October 10, 2021. Abbreviations: IQR = interquartile range. * Based upon physician review of initial report and available documentation, including death certificates. † Cardiomyopathy, congestive heart failure, acute leukemia, renal failure/end stage renal disease, general decompensation/end stage disease.

Reports to VAERS of co-administration of COVID-19 and other vaccines

- Most common vaccines co-administered with COVID-19 vaccines*
 - Vaccine not specified (n = 442)
 - Influenza (total = 204; inactivated = 127)
 - Zoster (n = 61)
- Most commonly reported adverse events
 - Typically “extra dose” or “expired product” administered
 - Systemic symptoms: reflect known adverse events (headache, fatigue, fever, etc.)
 - Unique to zoster: “herpes zoster”, “vaccination failure”
- Surveillance for adverse events is ongoing



Includes data collected during December 14, 2020–October 10, 2021.

* 605,095 reports were of COVID-19 vaccine with no other vaccine administered

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)



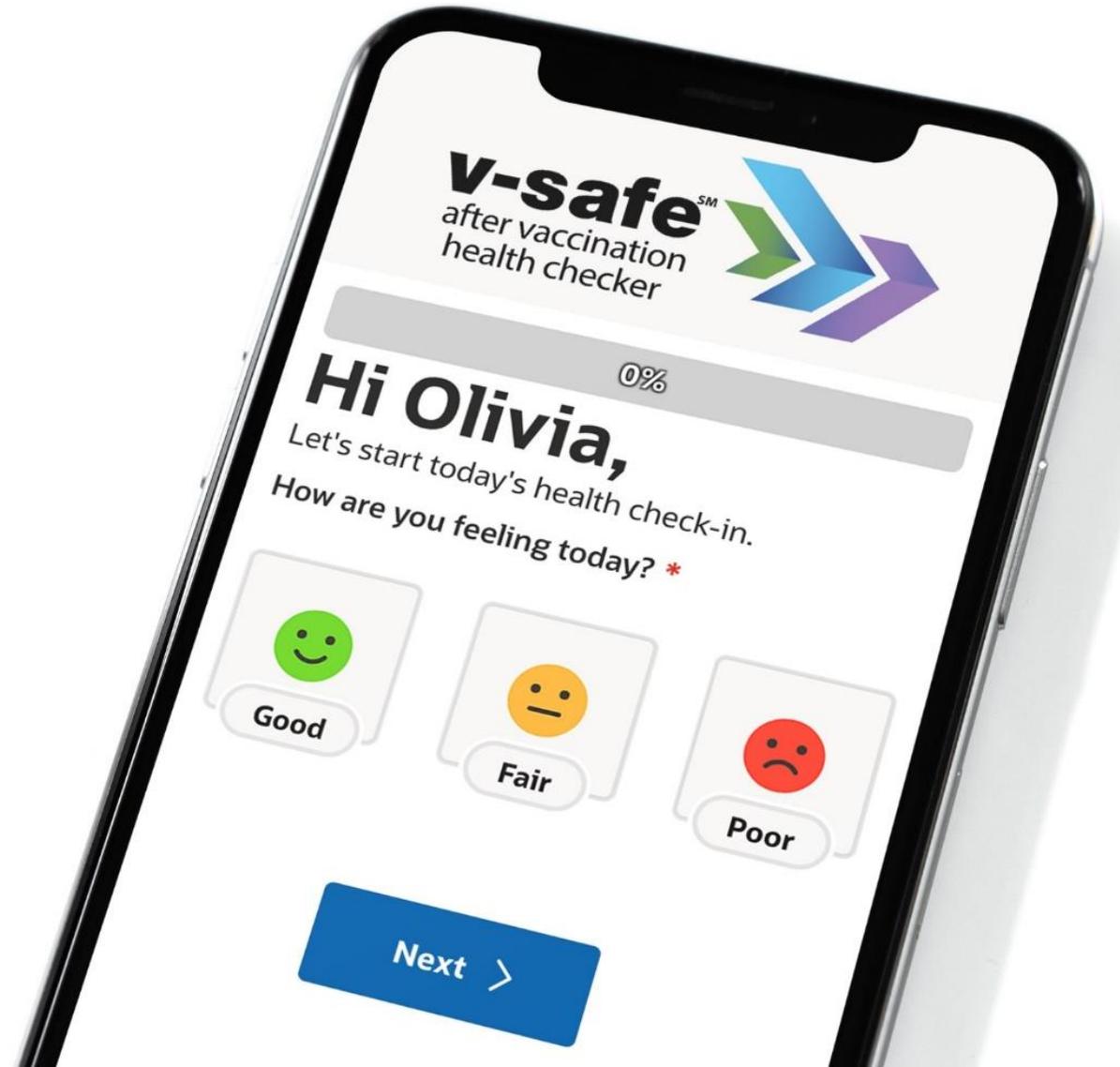
Smartphone-based active safety monitoring

Key strengths

- Easy and quick
- Active outreach
- Longitudinal data

Key limitations

- Voluntary enrollment
- Requires smartphone
- Generally, cannot determine cause and effect



Demographic summary of 274,167 v-safe participants who reported an additional dose

Characteristic	% of participants
Sex	
Female	61.8
Male	37.3
Unknown	0.9
Age group (years)	
0-17	0.05
18-49	26.6
50-64	23.0
65-74	38.9
75-84	10.5
≥85	0.9

Characteristic	% of participants
Ethnicity	
Hispanic or Latino	6.3
Not Hispanic/ Latino	90.1
Unknown	3.5
Race	
AI/AN	0.4
Asian	5.6
Black or AA	5.0
NHPI	0.3
White	83.7
Multiracial	1.4
Other	1.8
Unknown	1.9



Includes participants who completed at least one survey in the first week after additional dose, data collected during August 12–October 10, 2021
 Abbreviations: AI/AN = American Indian/Alaska Native; NHPI = Native Hawaiian or other Pacific Islander; AA=African American.

Patterns of vaccination for 274,167 v-safe participants who reported an additional dose

Primary series

Additional dose

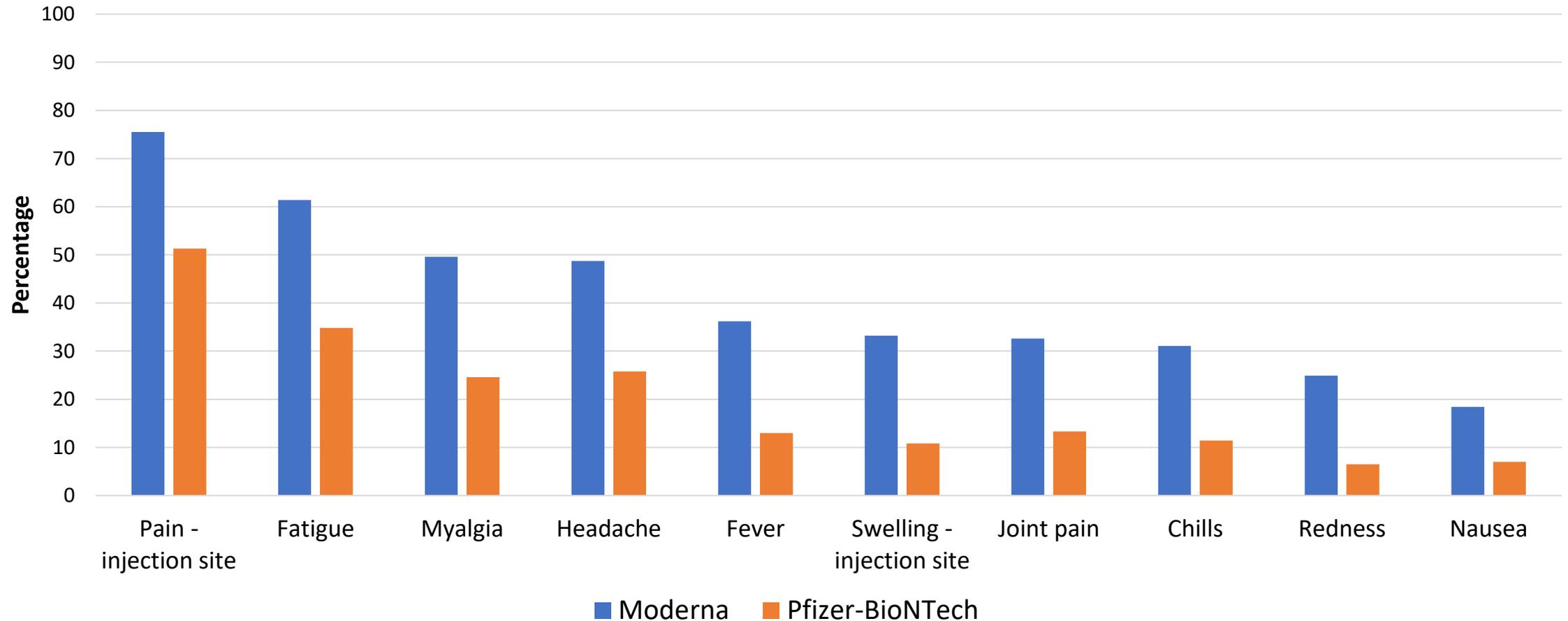
	Moderna (%)	Pfizer-BioNTech (%)	Janssen (%)*	Total
Moderna	13,719 (98.5)	583	89	14,391
Pfizer-BioNTech	207	259,327 (>99.9)	83	259,617
Janssen	7	70	82 (32.3)	159
Total	13,933	259,980	254	274,167



Includes participants who completed at least one survey in the first week after additional dose, data collected during August 12–October 10, 2021

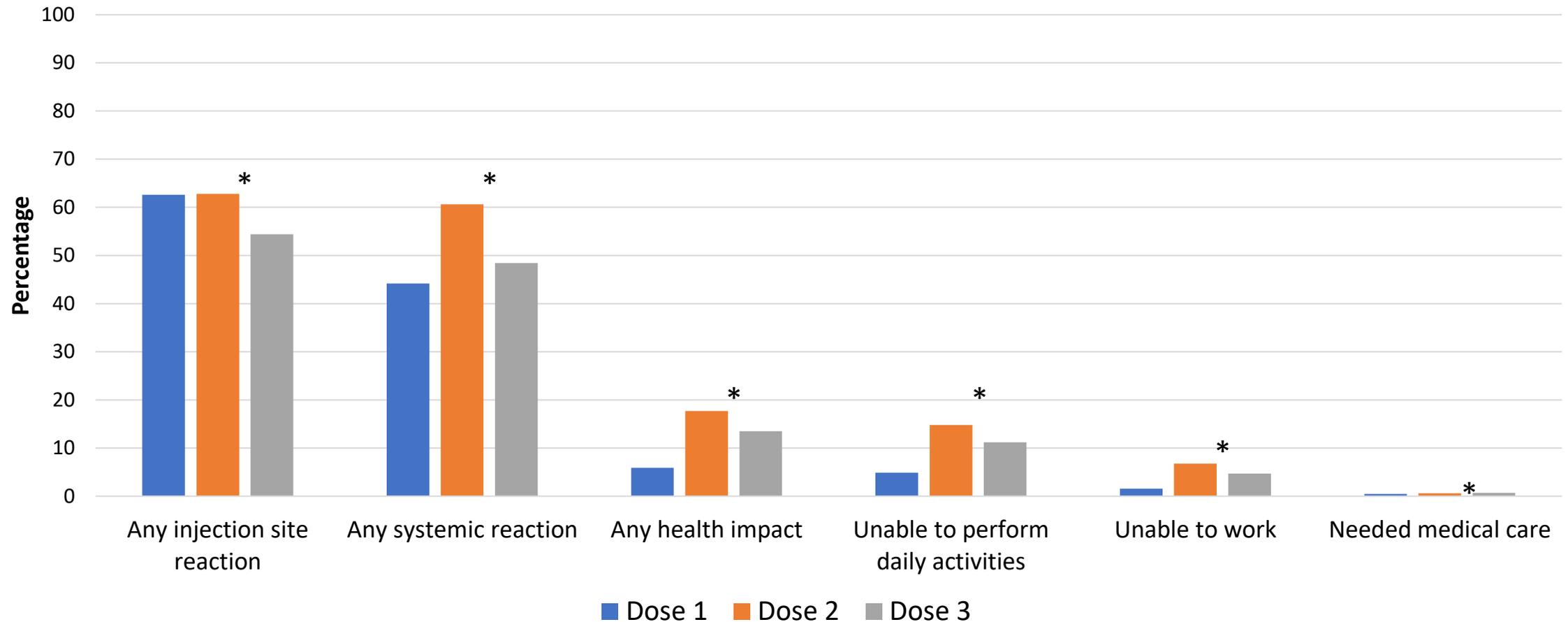
* Includes persons who received Janssen as their primary series and one additional dose of vaccine from the listed manufacturers

Top 10 solicited reactions reported at least once 0-7 days after dose 3 of Moderna or Pfizer-BioNTech vaccine



Includes 273,046 participants who completed at least one survey in the first week after additional dose, data collected during August 12–October 10, 2021

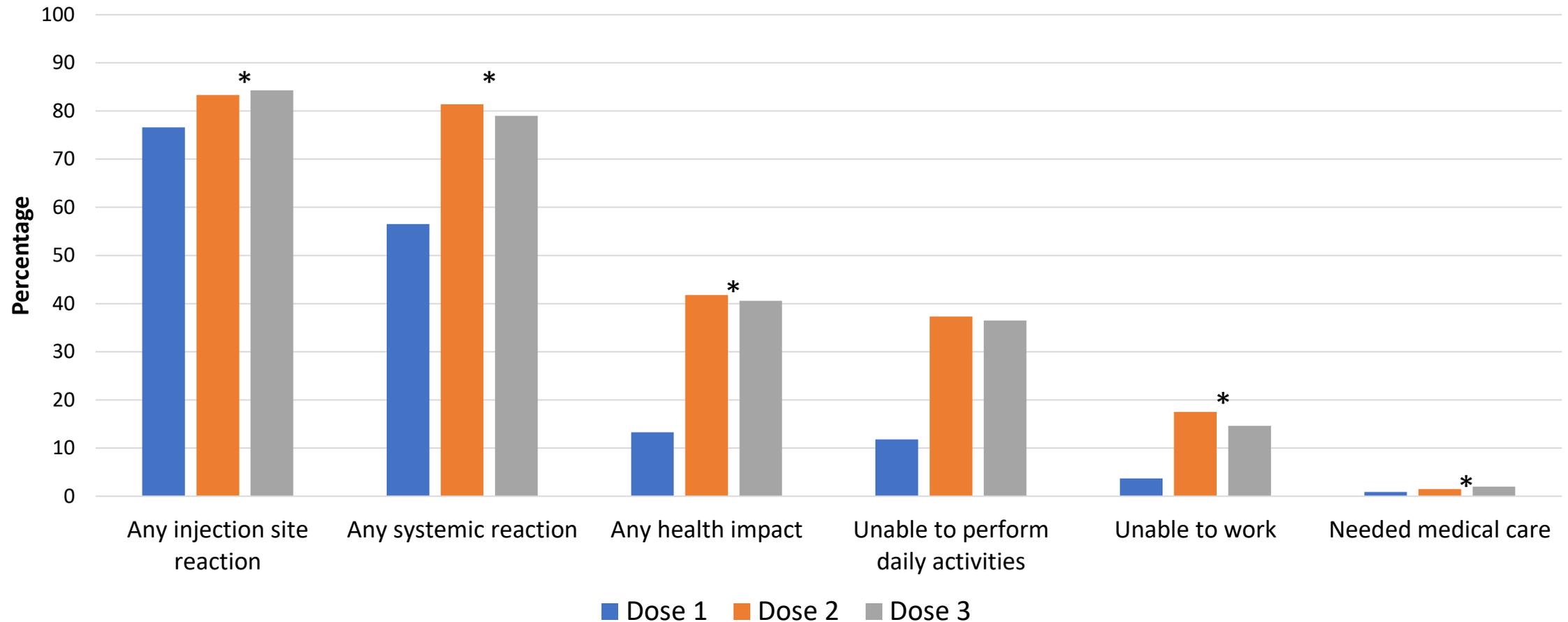
Reactions and health impact events reported at least once in days 0-7 after Pfizer-BioNTech vaccination, by dose



Includes 188,514 participants who completed at least one survey in the first week after each dose, data collected during August 12–October 10, 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.



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



Includes 8,153 participants who completed at least one survey in the first week after each dose, data collected during August 12–October 10, 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.



Summary of v-safe 65,247 v-safe participants who reported co-administration of COVID-19 and other vaccines

- Most (89.9%) participants were aged 18-74 years
- 89.8% of co-administration occurred with dose 3 COVID-19 vaccine
- Surveillance is ongoing

Age group	% of participants
0-17	1.4
18-49	31.8
50-64	23.9
65-74	34.2
75-84	8.0
≥85	0.8

Dose number	% of participants
1	6.3
2	3.8
3	89.8



Includes 65,247 participants who completed at least one survey in the first week after each dose, data collected during June 19–October 10, 2021. Collection of co-administration data in v-safe began June 19, 2021.

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
- Approximately half of mRNA third doses are among persons aged ≥ 65 years
- At this time, data are limited to:
 - Determine patterns of adverse events after dose 2 Janssen or an additional dose from a manufacturer different from the primary series
 - 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
- ≥92% of VAERS reports following dose 3 of COVID-19 vaccination were non-serious
 - Vaccination errors and systemic symptoms were most commonly reported
- Over 270,000 v-safe registrants reported an additional dose
 - Most reported a primary mRNA vaccine series followed by dose 3 from the same manufacturer
 - For Pfizer-BioNTech, local and systemic reactions were reported less frequently following dose 3 than dose 2
 - For Moderna, local reactions were reported slightly more frequently and systemic reactions slightly less frequently following dose 3 than dose 2



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 its ongoing safety 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 the Advisory Committee on Immunization Practices (ACIP) as additional data become available



What can you do for vaccine safety?

- Report adverse events following vaccination to VAERS even if you aren't sure if the vaccination caused the adverse event
- Enroll yourself in v-safe
- Healthcare providers, encourage your patients to enroll in v-safe
- Parents and guardians, you can enroll your children in v-safe



VAERS

Vaccine Adverse Event Reporting System

<http://vaers.hhs.gov>



vsafe.cdc.gov/en/

Please get involved, your participation matters

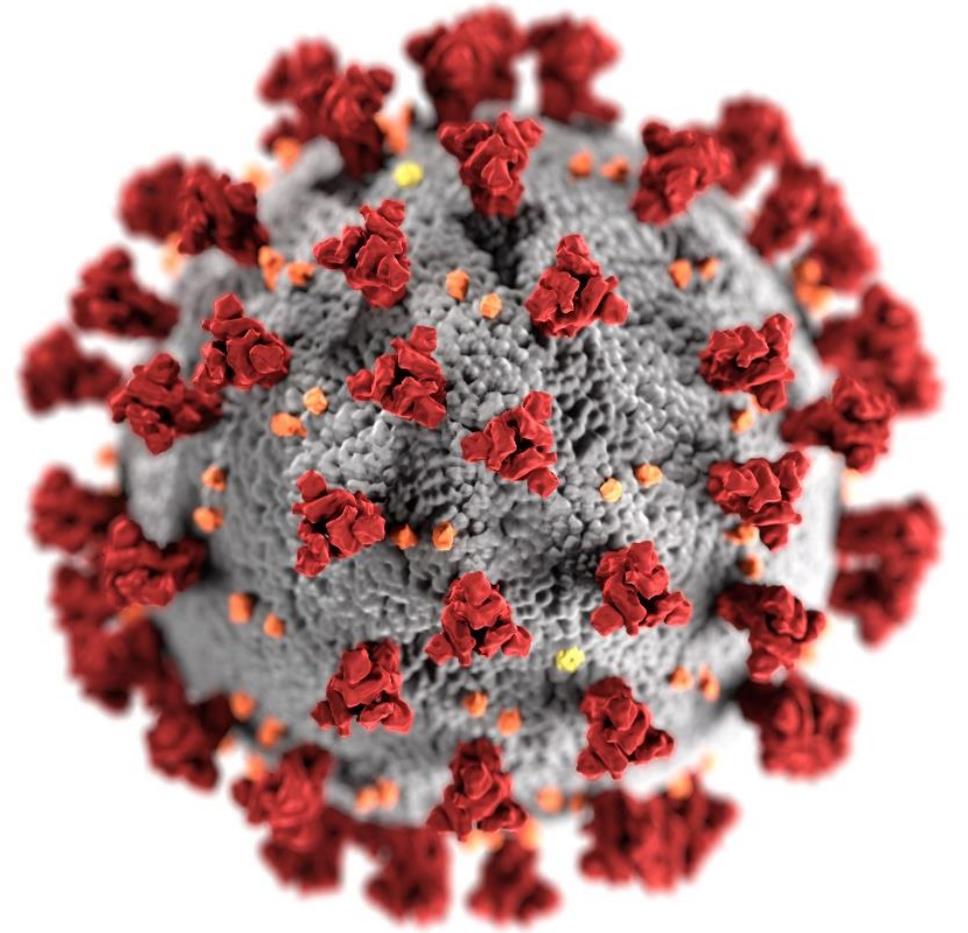


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- Tom Shimabukuro
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Thank you!



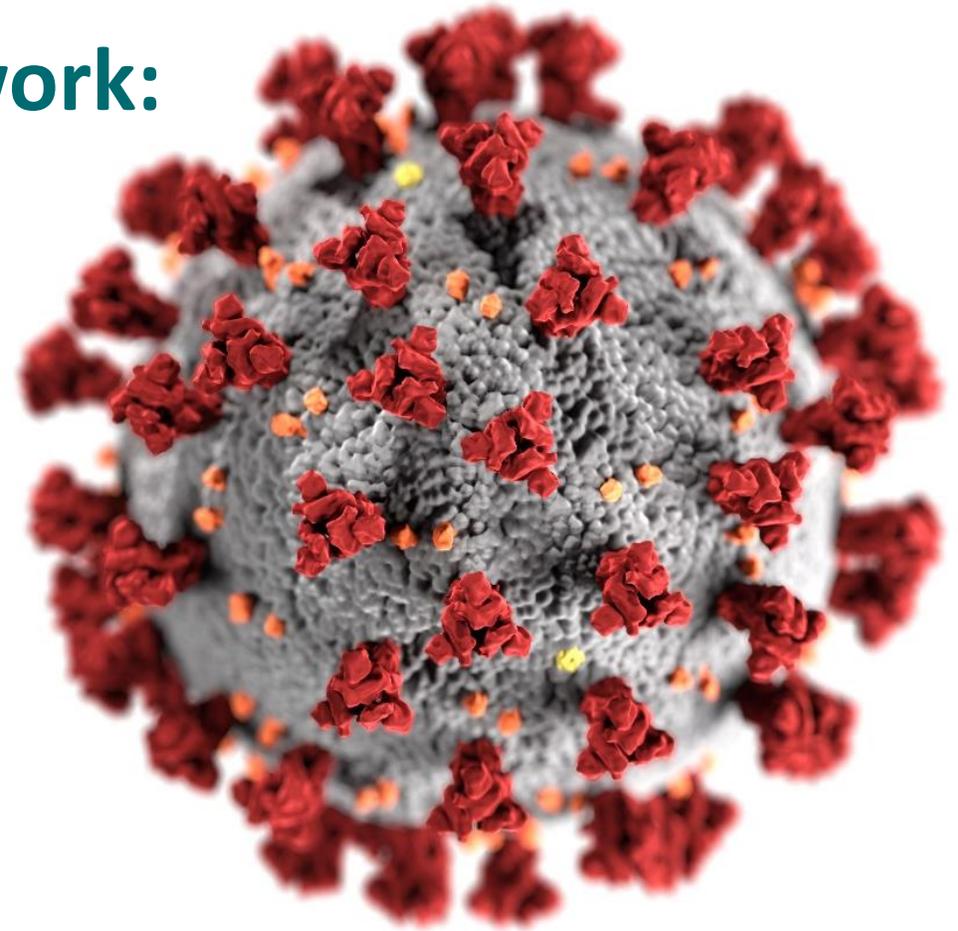
For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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.



Evidence to Recommendation Framework: Moderna & Janssen COVID-19 Vaccine Booster Dose

Kathleen Dooling, MD, MPH
COCA Call, October 26, 2021



cdc.gov/coronavirus

#1) CDC recommends the following groups receive a booster dose following Pfizer-BioNTech and Moderna COVID-19 vaccine primary series

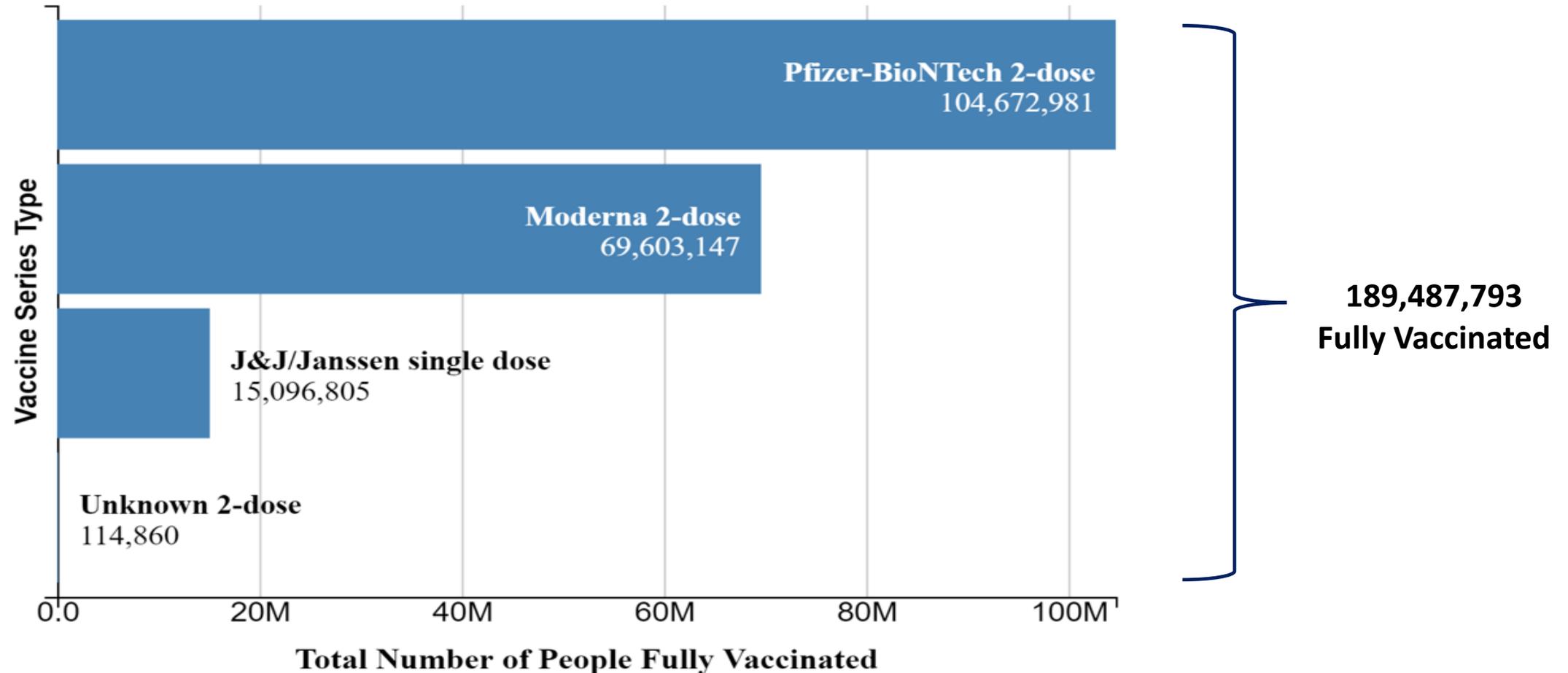
- The following recipients of mRNA COVID-19 vaccine primary series **should receive** a single booster dose ≥ 6 months after completion of the primary series:
 - ≥ 65 years
 - ≥ 18 years and reside in long-term care settings
 - 50-64 years with certain underlying medical conditions
- The following recipients of mRNA COVID-19 vaccine primary series **may receive** a single booster dose ≥ 6 months after completion of the primary series based on their individual risks and benefits:
 - 18-49 years with certain underlying medical conditions
 - 18-64 years at increased risk for SARS-CoV-2 exposure and transmission because of occupational or institutional setting

#2) CDC recommends the following population receive a booster dose following Janssen COVID-19 primary vaccination

- People aged ≥ 18 years, ≥ 2 months after receipt of the initial Janssen dose

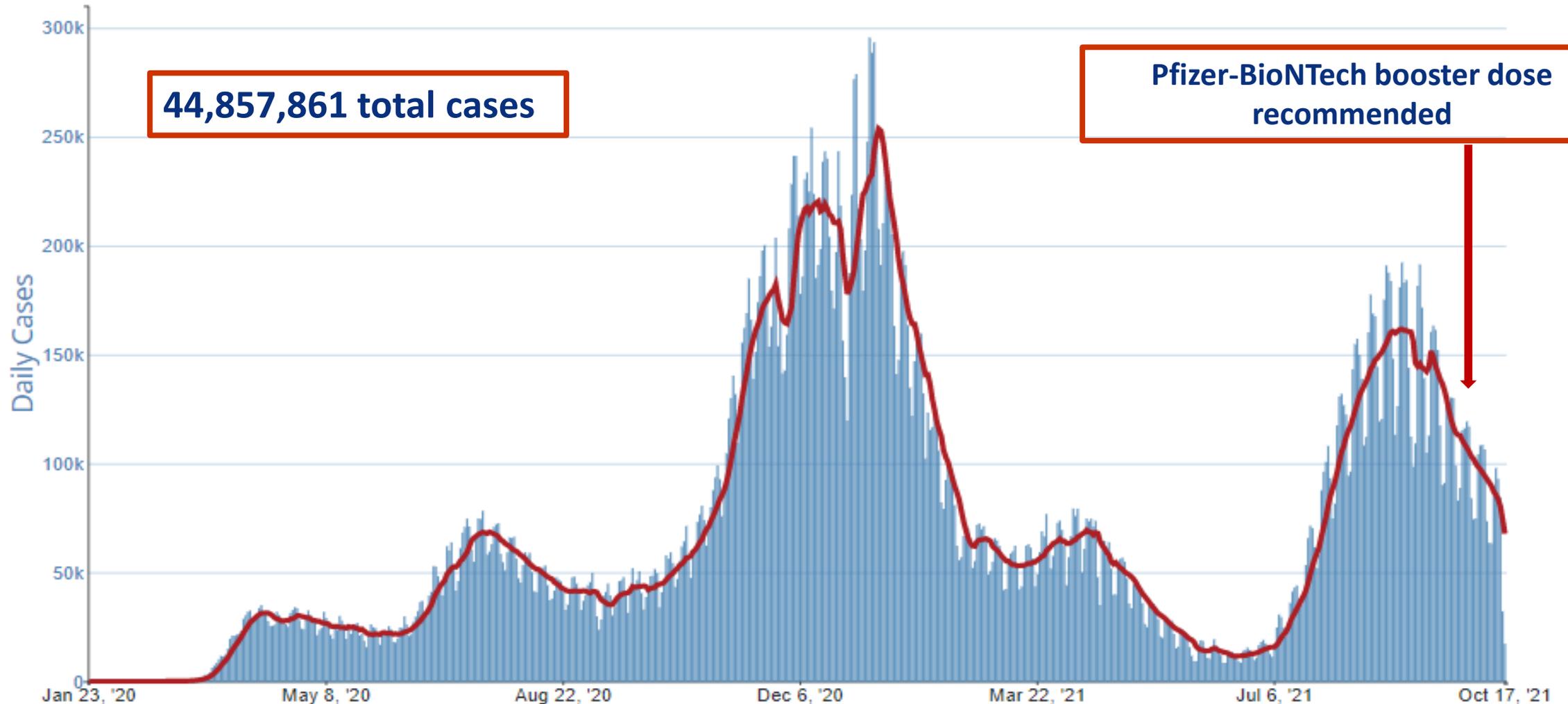
Any of the authorized COVID-19 vaccine boosters (Pfizer-BioNTech, Moderna, Janssen)
can be used following any of the primary series vaccination
“Heterologous boosting”
a.k.a **“Mix and Match”**

Number of people fully vaccinated in the U.S. by COVID-19 vaccine series type



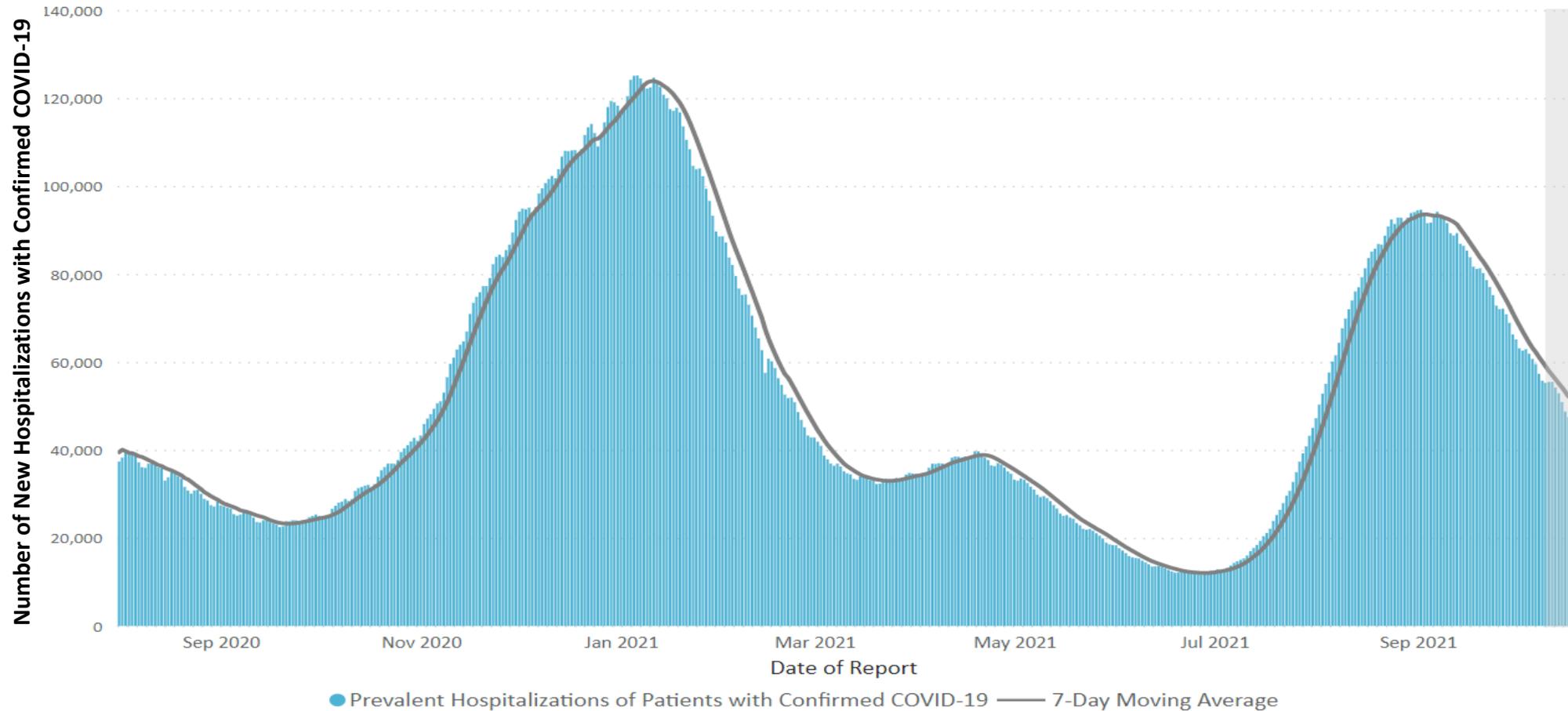
Daily trends in number of COVID-19 cases in the United States

January 23, 2020 – October 17, 2021

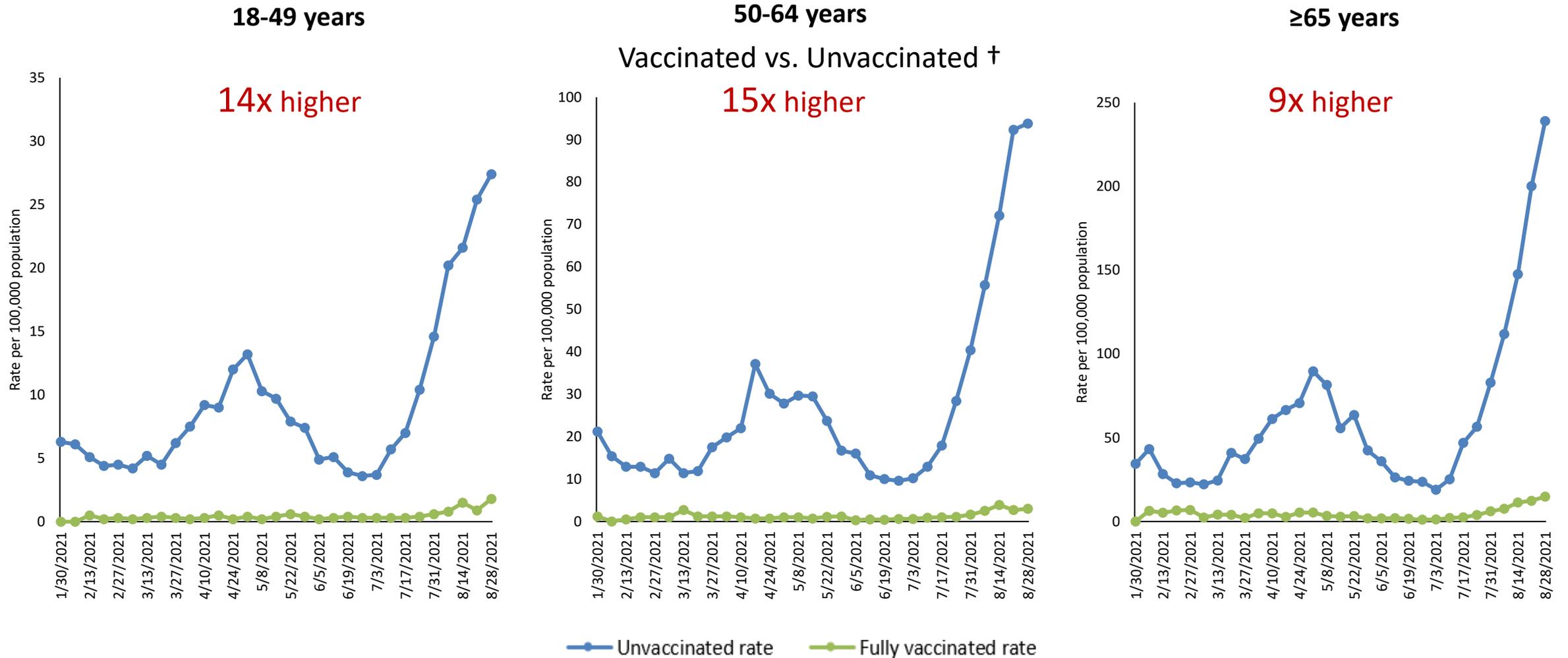


Daily trends in number of hospitalized COVID-19 cases in the United States

New Hospitalizations for COVID-19 with a 7-Day Moving Average, August 2020-October 2021



Age-adjusted weekly COVID-19-associated hospitalization rates among adults by week of admission and age group*—COVID-NET, January 24–August 28, 2021



*Data are preliminary and case counts and rates for recent hospital admissions are subject to lag. As data are received each week, prior case counts and rates are updated accordingly.

†Cumulative rate ratio from January 24 – August 28, 2021.

Long COVID-19 and risk in vaccinated people

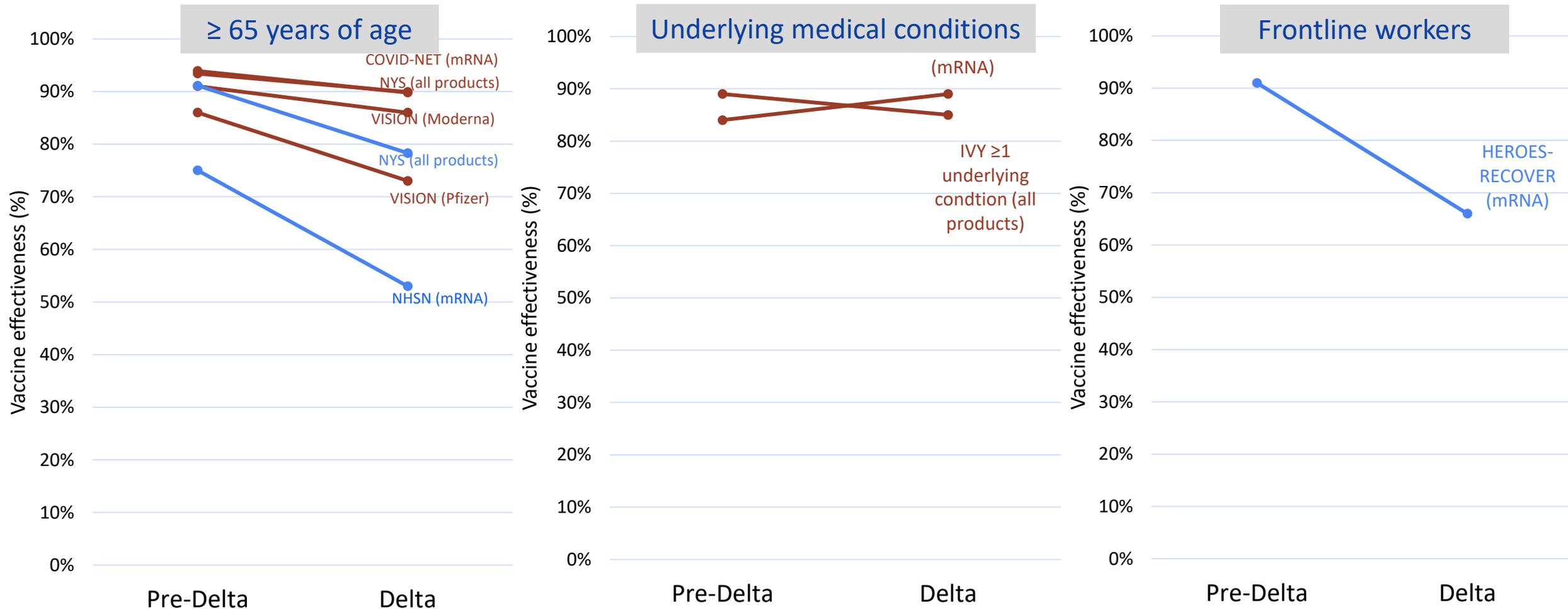
- Prevalence of post-COVID-19 conditions, among vaccinated and unvaccinated, reported from 5%–80%¹
- Prevalence of long COVID-19 among fully vaccinated persons who develop COVID-19 ranges from 5% (U.K. adults)² to 19% (Israeli healthcare workers)³
- Among COVID-19 cases in a U.K. study, odds of long COVID-19 were reduced by half among fully vaccinated compared to unvaccinated²

¹Cabrera Martimbianco AL, Pacheco RL, Bagattini ÂM, Riera R. Frequency, signs and symptoms, and criteria adopted for long COVID-19: a systematic review. *Int J Clin Pract* 2021;e14357. Epub May 11, 2021. [PMID:33977626](https://pubmed.ncbi.nlm.nih.gov/33977626/)

²Antonelli, M et al. "Risk factors and disease profile of post-vaccination SARS-CoV-2 infection in UK users of the COVID Symptom Study app: a prospective, community-based, nested, case-control study." *The Lancet Infectious Diseases* (2021).

³Bergwerk, M et al. "Covid-19 breakthrough infections in vaccinated health care workers." *New England Journal of Medicine* (2021).

Magnitude of vaccine effectiveness (VE) against infection or hospitalization by Delta predominance and study, by risk group

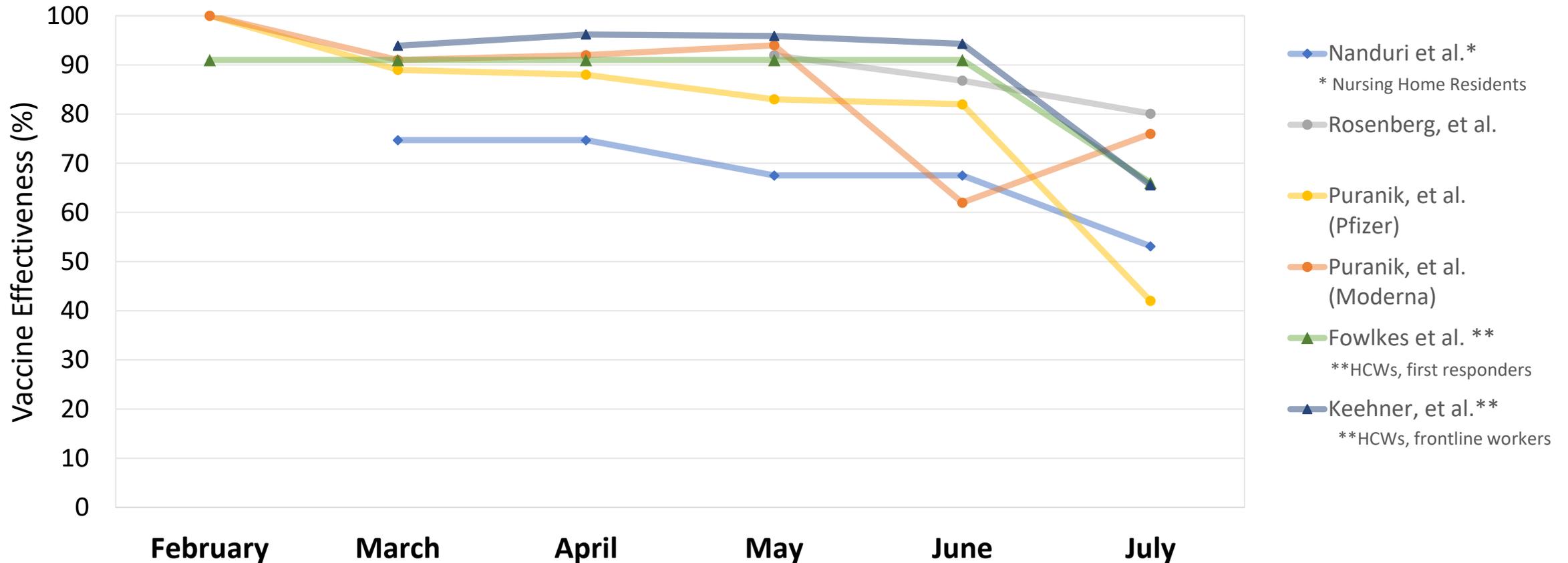


NHSN: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e3.htm>
 COVID-NET: CDC unpublished
 IVY: CDC unpublished data
 NYS: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e1.htm>

VISION: <https://www.nejm.org/doi/10.1056/NEJMoa2110362> <https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e2.htm>
 SUPERNOVA: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e3.htm>
 HEROES-RECOVER: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm>

Vaccine effectiveness against infection over time

Adults ≥ 18 years of age



Rosenberg ES, Holtgrave DR, Dorabawila V, et al. New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3–July 25, 2021. *MMWR Morb Mortal Wkly Rep.* ePub: 18 August 2021.

Nanduri S. Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — National Healthcare Safety Network, March 1–August 1, 2021. *MMWR Morbidity and Mortality Weekly Report.* 2021 2021;70.

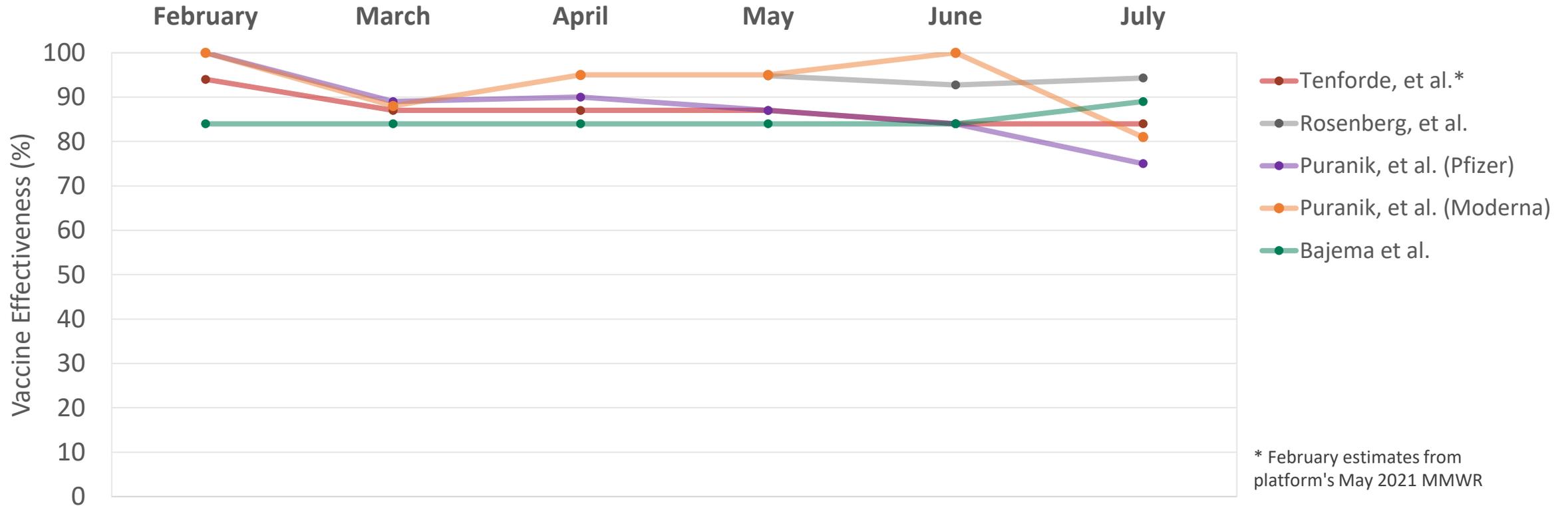
Fowlkes A, Gaglani M, Groover K, et al. Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021. *MMWR Morb Mortal Wkly Rep.* ePub: 24 August 2021.

Puranik A, Lenehan PJ, Silvert E, et al. Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence. *medRxiv* 2021.08.06.21261707.

Keehner J, Horton LE, Binkin NJ et al. Resurgence of SARS-CoV-2 Infection in a Highly Vaccinated Health System Workforce. *NEJM*, September 1, 2021. DOI: 10.1056/NEJMc2112981

Vaccine effectiveness against hospitalization by month

Adults ≥ 18 years of age



Tenforde MW, Self WH, Naioti EA, et al. Sustained Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Associated Hospitalizations Among Adults — United States, March–July 2021. *MMWR Morb Mortal Wkly Rep.* ePub: 18 August 2021.

Tenforde MW, Olson SM, Self WH, et al. Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Among Hospitalized Adults Aged ≥ 65 Years — United States, January–March 2021. *MMWR Morb Mortal Wkly Rep* 2021;70:674–679.

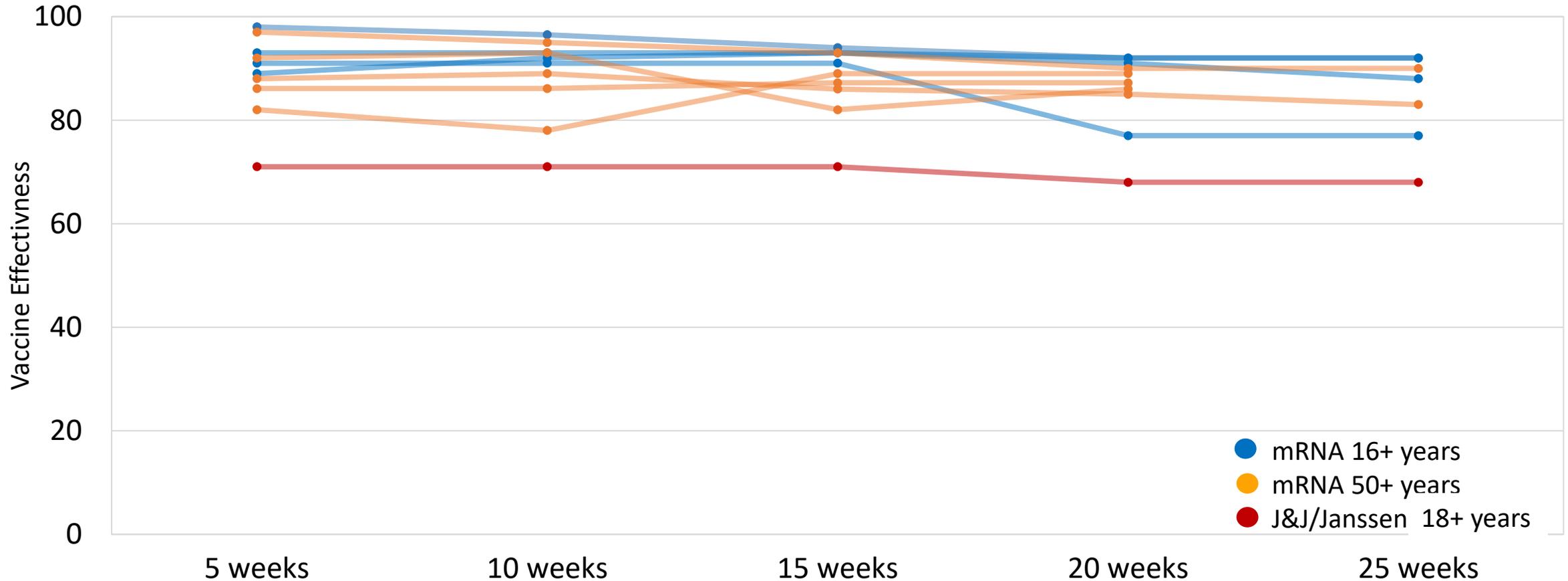
Rosenberg ES, Holtgrave DR, Dorabawila V, et al. New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3–July 25, 2021. *MMWR Morb Mortal Wkly Rep.* ePub: 18 August 2021.

Puranik A, Lenehan PJ, Silvert E, et al. Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence. *medRxiv* 2021.08.06.21261707.

Bajema KL, Dahl RM, Prill MM, et al. Effectiveness of COVID-19 mRNA Vaccines Against COVID-19–Associated Hospitalization — Five Veterans Affairs Medical Centers, United States, February 1–August 6, 2021. *MMWR Morb Mortal Wkly Rep.*

Vaccine effectiveness against hospitalization over time

Adults ≥ 16 years of age



Bajema KL, Dahl RM, Prill MM, et al. Effectiveness of COVID-19 mRNA Vaccines Against COVID-19–Associated Hospitalization — Five Veterans Affairs Medical Centers, United States, February 1–August 6, 2021. *MMWR Morb Mortal Wkly Rep.*

Thompson MG, Burgess JL, Naleway AL, et al. Prevention and attenuation of Covid-19 with the BNT162b2 and mRNA-1273 vaccines. *N Engl J Med* 2021;385:320–9.

Self WH, Tenforde MW, Rhoads JP, et al. Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID-19 Hospitalizations Among Adults Without Immunocompromising Conditions — United States, March–August 2021. *MMWR Morb Mortal Wkly Rep.* ePub: 17 September 2021.

Nunes et al. mRNA vaccines effectiveness against COVID-19 hospitalizations and deaths in older adults: a cohort study based on data-linkage of national health registries in Portugal. *MedRxiv preprint.*

Andrews et al. Vaccine effectiveness and duration of protection of Comirnaty, Vaxzevria and Spikevax against mild and severe COVID-19 in the UK. *Preprint.*

Tartof SY, Slezak JM, Fischer H, Hong V, Ackerson BK, Ranasinghe ON, et al. Six-month effectiveness of BNT162b2 mRNA COVID-19 vaccine in a large US integrated health system: a retrospective cohort study. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3909743

Summary

- More than 189 million people in the U.S. are fully vaccinated (~57% total population)
- Hospitalization rates are ~9X-15X higher in unvaccinated as compared to vaccinated adults
- Moderna COVID-19 Vaccine (37% of fully vaccinated people)
 - Infection: Declines in VE against infection over time and during Delta period
 - Hospitalization: Minimal to no declines in VE against hospitalization in younger adults and mild declines observed in some for platforms among older adults
- Janssen COVID-19 Vaccine (8% of fully vaccinated people)
 - Lower VE compared to mRNA vaccines, but most study platforms show persistent VE over time against infection and hospitalization, even among older adults

Evidence to Recommendations Framework

Booster doses of COVID-19 vaccines



Benefits
and
Harms

Moderna booster ≥ 6 months after primary series

Summary of GRADE

Outcome	Importance	Design (# of studies)	Findings	Evidence type
Benefits (prevention of outcome)				
Symptomatic laboratory-confirmed COVID-19	Critical	RCT (0) OBS (2)	Moderna COVID-19 booster dose (50 μ g) induced immune response (GMR) noninferior to that following dose 2 of the 100 μ g primary series	4
Hospitalization due to COVID-19	Critical	RCT (0) OBS (0)	No data available	ND
Death due to COVID-19	Important	RCT (0) OBS (0)	No data available	ND
Transmission of SARS-CoV-2 infection	Important	RCT (0) OBS (0)	No data available	ND
Harms				
Serious adverse events	Critical	RCT (0) OBS (2)	No SAEs were attributed to Moderna COVID-19 booster dose (50 μ g) during follow-up. No imbalance between booster and comparison group	4
Reactogenicity	Important	RCT (0) OBS (2)	Grade ≥ 3 reactogenicity occurred in 10.8% of Moderna COVID-19 booster dose (50 μ g) recipients vs 19.7% primary series (100ug)	4

Evidence type: 1=high; 2=moderate; 3=low; 4=very low; ND= no data

Janssen booster ≥ 2 months after primary dose

Summary of GRADE

Outcome	Importance	Design (# of studies)	Findings	Evidence type
Benefits (prevention of outcome)				
Symptomatic laboratory-confirmed COVID-19	Critical	RCT (0) OBS (2)	Janssen COVID-19 booster dose is more effective at preventing symptomatic laboratory-confirmed COVID-19 than the primary dose	4
Hospitalization due to COVID-19	Critical	RCT (0) OBS (2)	Janssen COVID-19 booster dose may be more effective at preventing hospitalization due to COVID-19 (severe COVID-19) than the primary dose	4
Death due to COVID-19	Important	RCT (0) OBS (2)	Janssen COVID-19 booster dose may be more effective at preventing death due to COVID-19 than the primary dose	4
Transmission of SARS-CoV-2 infection	Important	RCT (0) OBS (0)	No data available	ND
Harms				
Serious adverse events	Critical	RCT (1) OBS (0)	3 SAEs were attributed to Janssen COVID-19 booster dose (facial paresis, pulmonary embolism, and cerebrovascular accident). SAE were balanced between booster and placebo arms	4
Reactogenicity	Important	RCT (1) OBS (0)	Grade ≥ 3 systemic adverse events occurred in 2.1% of Janssen COVID-19 booster dose recipients- similar or less than after the primary dose	4

Evidence type: 1=high; 2=moderate; 3=low; 4=very low; ND=no data

Post-authorization safety surveillance

- Myocarditis/pericarditis following Moderna
 - Highest reporting rate in 18-24yo males (0-7 days post dose 2)= **39 cases/1M doses administered**²
- Thrombosis with thrombocytopenia syndrome (TTS) following Janssen
 - Highest reporting rate in 30-39 year old females (0-21 days post dose)= **10 cases/1M doses administered**²
- Guillain Barré syndrome (GBS) following Janssen
 - Highest reporting rate in 50-64 year old males (1-42d post dose)= **16 cases/1M doses administered**³

1. [Moderna COVID-19 Vaccine Fact Sheet for Health Care Providers \(fda.gov\)](#)

2. VAERS

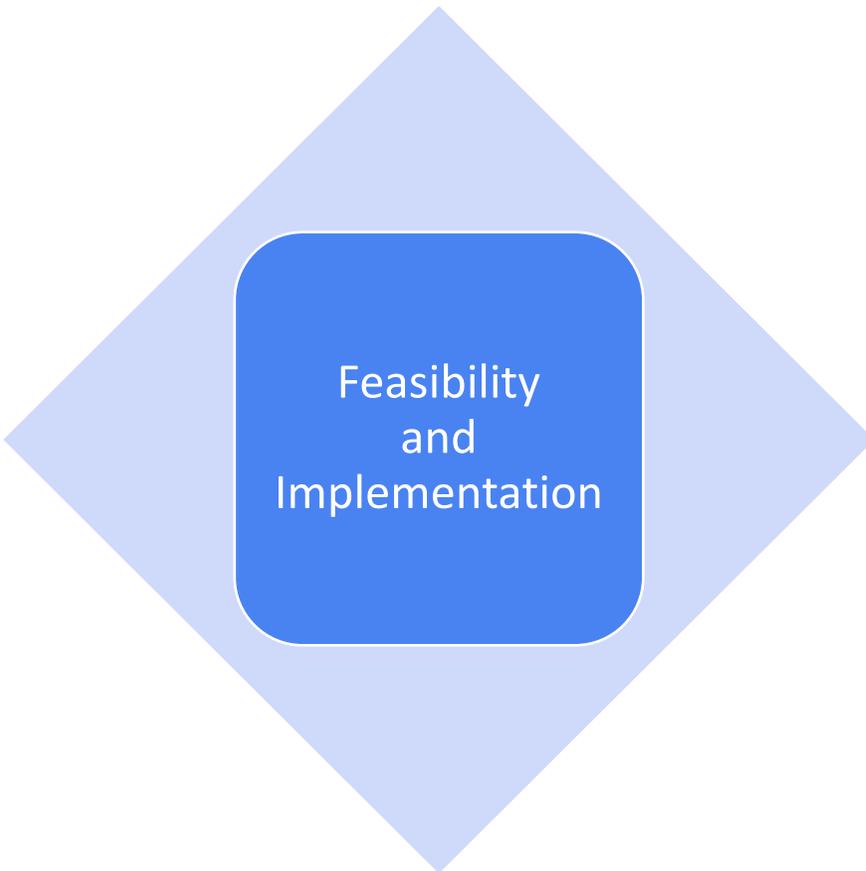
3. Rosenblum et al. [MMWR, Volume 70, Issue 32 — August 13, 2021 \(cdc.gov\)](#)

Heterologous Boosting (Mix and Match)

- Use of Moderna, Janssen, and Pfizer-BioNTech COVID-19 vaccines as boosters led to strong serologic responses in groups primed by all three vaccines
- For a given primary COVID-19 vaccine, heterologous boosts elicited similar or higher serologic responses as compared to their respective homologous booster responses
- mRNA vaccines resulted in higher antibody titers in the first 28 days after the boost
- The study arms were small (n=49-53), but no safety concerns were identified

Evidence to Recommendations Framework

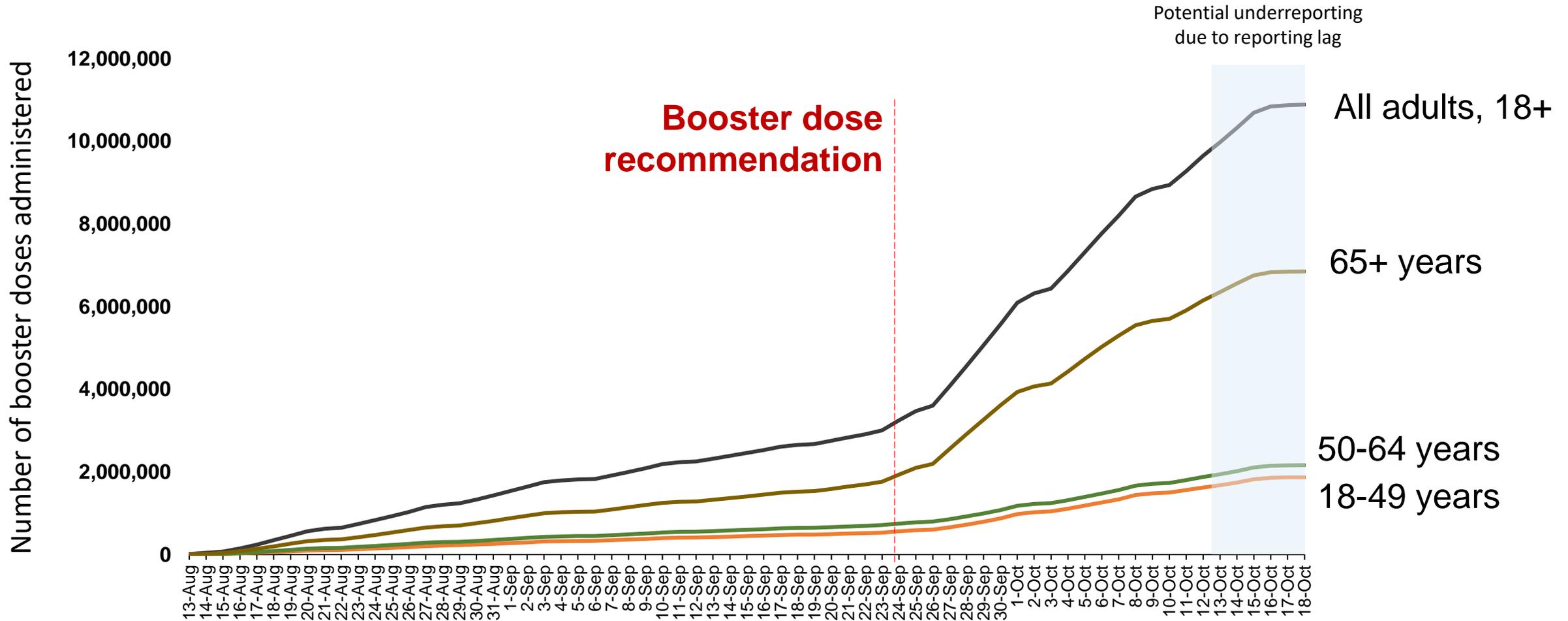
Booster doses of COVID-19 vaccines



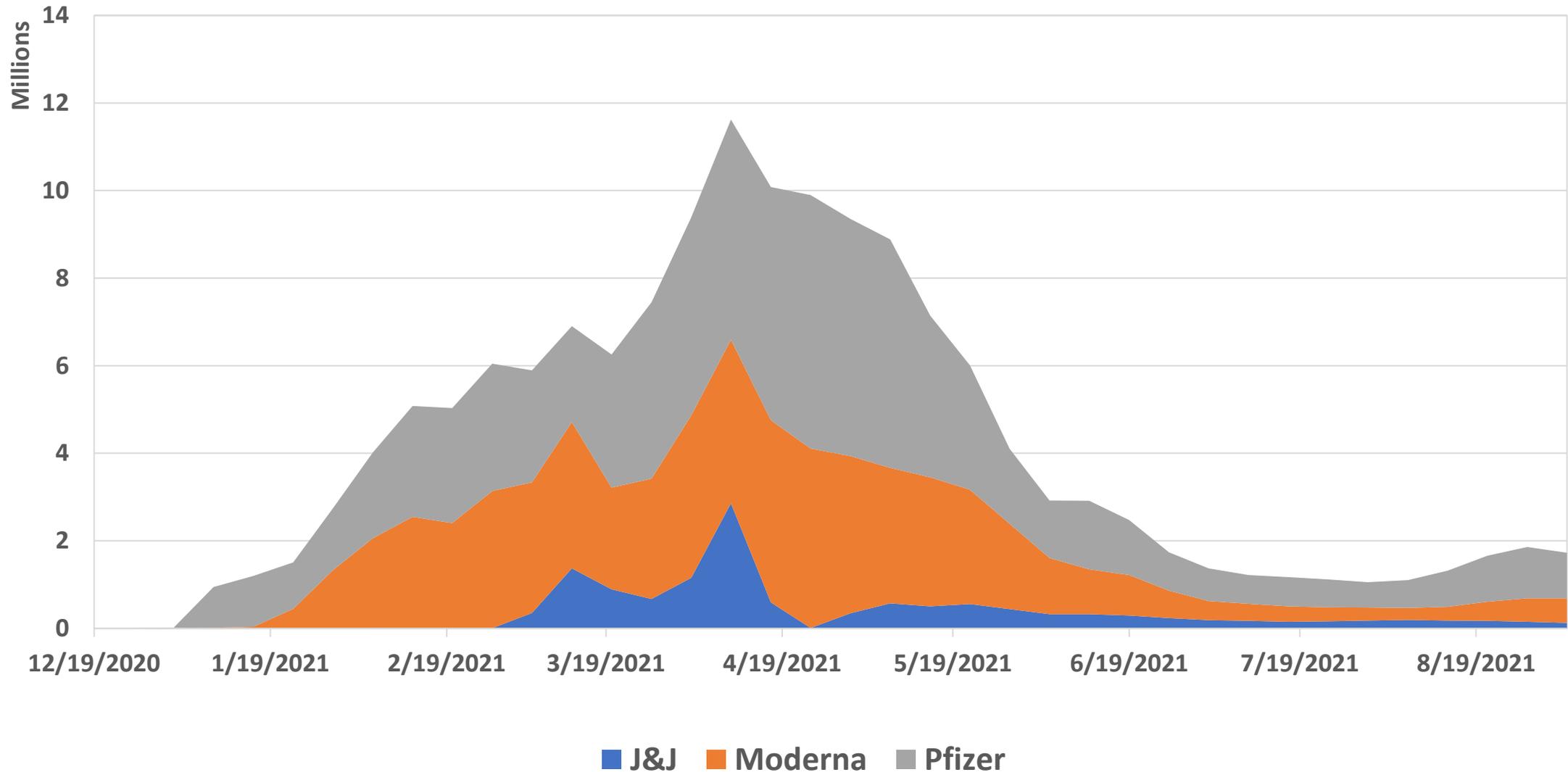
Feasibility
and
Implementation

Cumulative Number of COVID-19 Vaccine Booster/Additional Doses

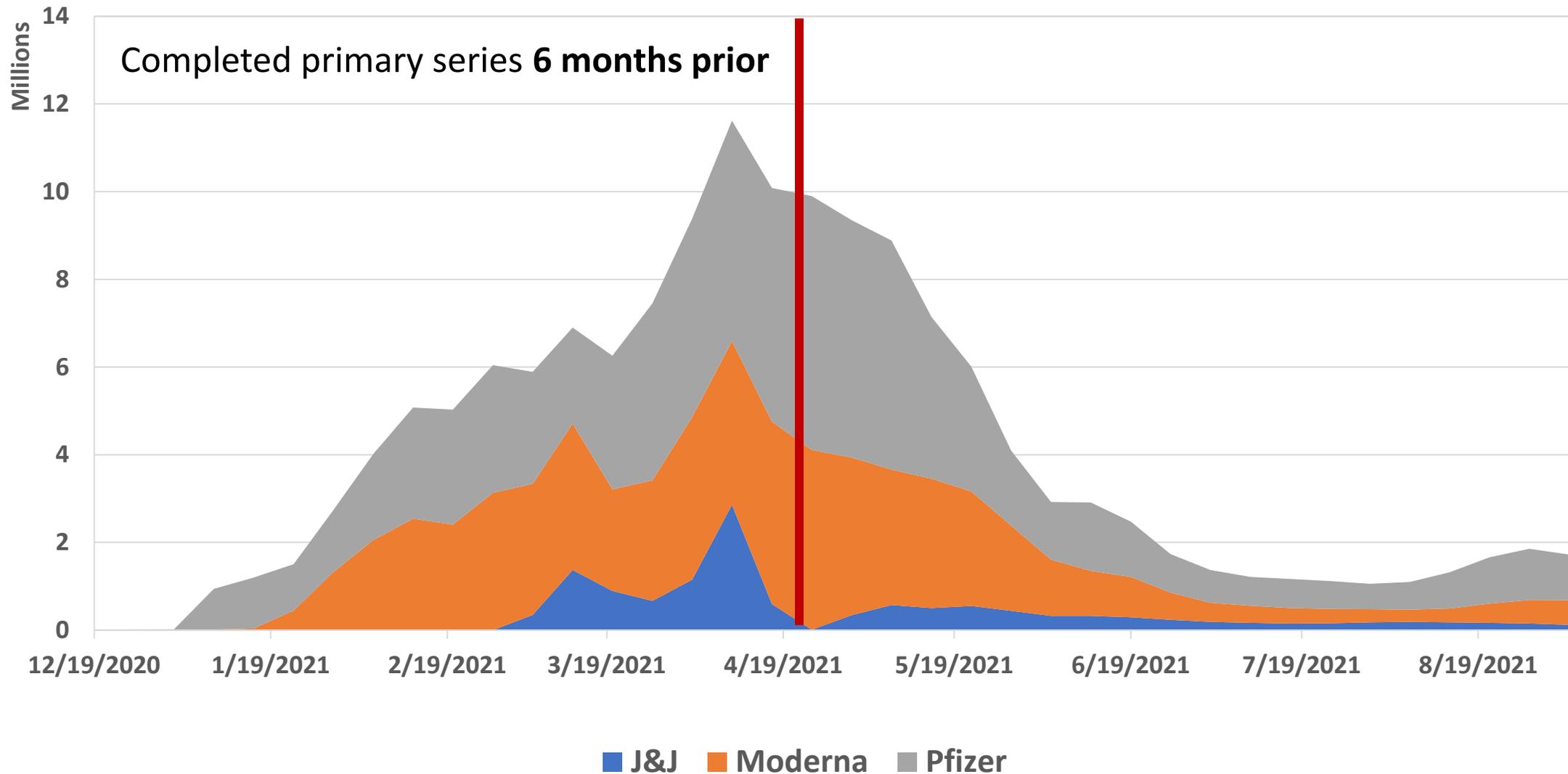
Total booster/additional doses administered: 10.9M



Completed primary vaccination regime, by week



Completed primary vaccination regime, by week



Number of U.S. persons potentially eligible (in millions) for a booster dose on October 22, 2021

Age group	Pfizer-BioNTech ≥6m	Moderna ≥6m	Janssen ≥2m	Total
18-29 years old	4.7	3.0	2.4	10.1
30-49 years old	11.9	8.3	4.5	24.7
50-64 years old	13.2	10.1	4.0	27.3
65+ years old	17.3	17.7	1.9	36.9
Total	47.1	39.1	12.9	99.1

Summary



Work Group interpretation

- **Top priority** should be **continued vaccination of unvaccinated individuals**
- Goals of booster program:
 - Prevention of **severe disease**, including hospitalization and death
 - Other considerations are important, such as maintaining workforce and healthcare capacity, prevention of transmission, individual benefit/risk balance
- Balance of benefits and risks **varies by age**
 - Adults ≥ 65 years have the clearest benefit > risk
 - Moderna: Benefits are incrementally smaller with decreasing age, given high effectiveness maintained from primary series. Myocarditis risk higher in young adults.
 - Janssen: Benefits may be smaller across age groups compared with mRNA vaccines. TTS risk higher in young females.

Work Group interpretation

- For people who received Moderna COVID-19 vaccine as a primary series, the Work Group supports using a single booster dose ≥ 6 months following the primary series in certain populations (consistent with CDC recommended populations for Pfizer-BioNTech COVID-19 booster)
- For people who received Janssen COVID-19 vaccine as primary vaccination, the Work Group supports using a single booster ≥ 2 months following the initial dose in all people aged ≥ 18 years and older
- A single dose of Janssen COVID-19 vaccine results in lower VE and antibody levels compared to mRNA vaccine primary series- data demonstrate that a single dose of Janssen or mRNA COVID-19 vaccines boost immune response in these individuals

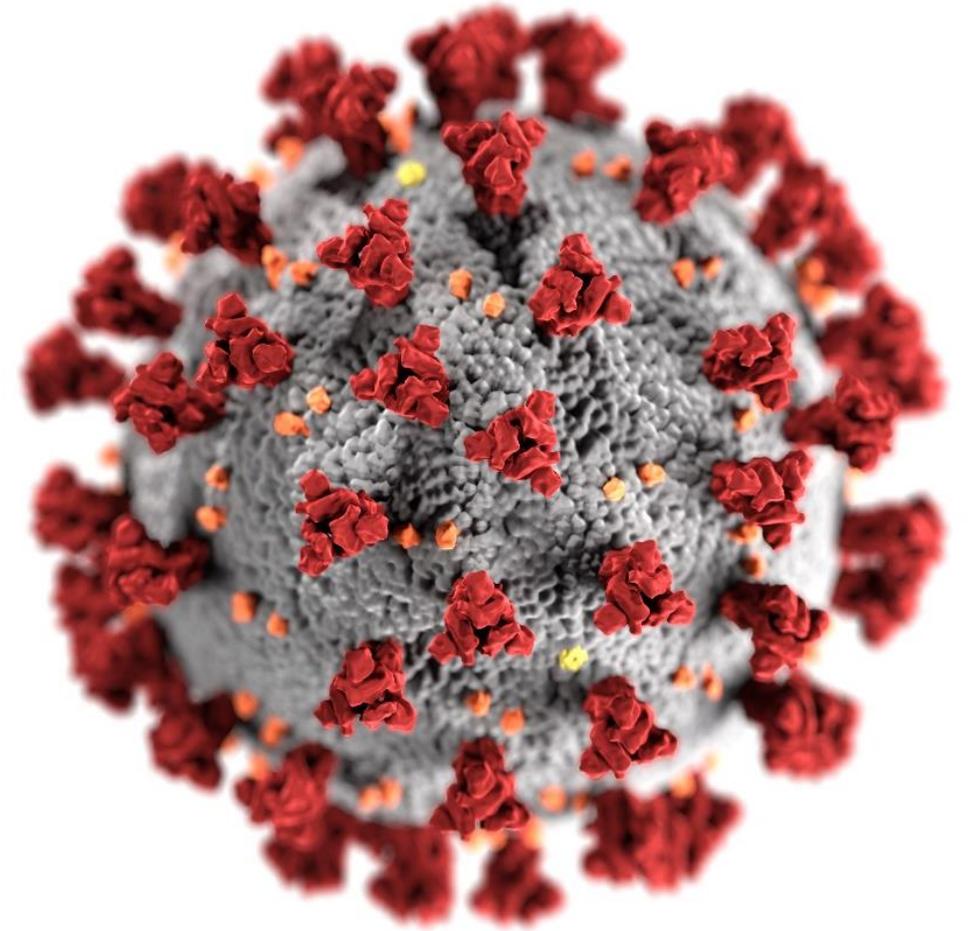
Acknowledgments

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- Mary Chamberland
- CDC/University of Iowa
- VTF ACIP WG Team
- ACIP COVID-19 Vaccines Work Group
- Vaccine Task Force
- Epi Task Force
- Respiratory Viruses Branch

Clinical Considerations for COVID-19 Vaccine Booster Doses

Sujan Reddy, MD, MSc

October 26, 2021



cdc.gov/coronavirus

Key clinical considerations regarding booster doses

- Indication for and timing of booster dose depends on which primary series was administered
- Booster product can be the same as or different than the primary series product
 - Any FDA-approved or authorized COVID-19 vaccine can be used for booster dose, regardless of vaccine received for primary series
- Moderna booster dose is half (50 µg in 0.25ml) of the primary series dose (100 µg in 0.5ml)
- Special considerations for moderately and severely immunocompromised people



<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>

COVID-19 vaccine booster dose in persons who completed an mRNA primary series

Persons who should receive a COVID-19 booster dose

- Aged ≥ 65 years
- Aged ≥ 18 years and reside in long-term care settings
- Aged 50-64 years with certain underlying medical conditions

Persons who may receive a COVID-19 booster dose, based on individual benefits and risks

- Aged 18-49 years with certain underlying medical conditions*
- Aged 18-64 years at increased risk for SARS-CoV-2 exposure and transmission because of occupational or institutional setting

- Booster dose administered at least 6 months after completion of mRNA primary series
- Any FDA-approved or authorized COVID-19 vaccine (Pfizer-BioNTech, Moderna, or Janssen) can be used for booster dose, regardless of vaccine received for primary series



* Includes pregnant people

Individual risk-benefit assessment for people who “may receive” mRNA booster dose

- Individual risk factors for SARS-CoV-2 infection
 - Risk of exposure (occupational and institutional settings)
 - Risk for infection (time since completion of primary series)
- Potential impact of SARS-CoV-2 infection
 - Risk for severe infection (underlying conditions)
 - Risk associated with a person’s circumstances (living with/caring for at-risk individuals or consequences of inability to meet obligations due to infection)
- Potential benefits of booster
 - Reduced risk of infection, including severe infection
- Potential risks of booster
 - Common risks of transient local and systemic symptoms
 - Rare risks of serious adverse events



COVID-19 vaccine booster dose in persons who received a dose of Janssen vaccine

- Persons aged ≥ 18 years who received primary vaccination with Janssen COVID-19 vaccine **should** receive a single COVID-19 vaccine booster dose at least 2 months later
- Any FDA-approved or authorized COVID-19 vaccine (Pfizer-BioNTech, Moderna, or Janssen) can be used as the booster dose, at an interval of at least 2 months since the primary Janssen vaccine dose



FDA-authorized or approved COVID-19 vaccines for primary or booster vaccination

Vaccine	Primary series/dose				Booster dose	
	Dose (volume)	No. doses (interval)	Age (yrs)	Interval from primary to booster dose	Dose (volume)	Age (yrs)
Pfizer-BioNTech	30 µg (0.3 ml)	2 (21 days)	≥12	≥6 months	30 µg (0.3 ml)	≥18
Moderna	100 µg (0.5 ml)	2 (28 days)	≥18	≥6 months	50 µg (0.25 ml)	≥18
Janssen	5 × 10 ¹⁰ VP (0.5 ml)	1 (N/A)	≥18	≥2 months	5 × 10 ¹⁰ VP (0.5 ml)	≥18

- Any of the COVID-19 vaccines (Pfizer-BioNTech, Moderna, Janssen) can be used for booster vaccination, regardless of the vaccine product used for primary vaccination
 - When a heterologous (mix-and-match) booster dose is administered, the booster dose eligibility criteria and interval for receiving a booster dose are those of the vaccine used for primary vaccination



Heterologous (mix-and-match) booster dose

- Heterologous dosing may be considered for the **booster dose** only
 - Primary series doses and additional dose should utilize the same vaccine product with limited exceptions
 - Additional dose only indicated for moderately to severely immunocompromised people who received 2 doses of mRNA vaccine
- Interval from the primary series should follow the interval recommended by the primary series
 - People who received a single dose Janssen primary series can receive a mRNA COVID-19 booster dose at least 2 months after completing primary series
- Individual risk-benefit assessment may inform which booster product to use
 - Availability of booster product
 - Risk profile of vaccine boosters, including rare events



Potential risks of COVID-19 vaccine booster doses, based on rare events observed after primary vaccination

- Janssen:

- Thrombosis with thrombocytopenia syndrome (TTS): highest risk in women aged 18-49 years
- Guillain-Barré Syndrome (GBS): highest risk in men aged 50-64 years

- mRNA:

- Myocarditis and pericarditis: highest risk in males aged 12-30 years

Moderately and severely immunocompromised people



Definitions

- **Additional dose:** a subsequent vaccine dose to people who likely did not mount a protective immune response after primary vaccination in order to optimize vaccine-induced protection
- **Booster dose:** a subsequent dose of vaccine administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time



<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>

Additional dose of mRNA COVID-19 vaccine in immunocompromised persons

- Moderately-to-severely immunocompromised persons aged ≥ 12 years (Pfizer-BioNTech) or ≥ 18 years (Moderna) who completed an mRNA COVID-19 vaccine primary series **should** receive an additional mRNA vaccine dose at least 28 days after their second dose
- Recommendation does not apply to immunocompromised recipients of Janssen COVID-19 vaccine; these persons should follow the booster dose recommendations

Moderately and severely immunocompromised people

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥ 20 mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers, and other biologic agents that are immunosuppressive or immunomodulatory

Recommendation for moderately and severely immunocompromised people

- If received mRNA primary series
 - Administer mRNA additional dose ≥ 28 days after second dose
 - If received Moderna primary, Moderna additional dose is 100 μg (0.5ml)
 - Administer any COVID-19 vaccine booster dose ≥ 6 months after the additional dose (after third mRNA vaccine dose)
 - If Moderna booster dose is used, dose is 50 μg (0.25ml)
 - Pfizer-BioNTech dose is the same for primary series, additional and booster dose
- If received Janssen primary dose
 - Administer any COVID-19 vaccine booster dose ≥ 2 months after the initial Janssen dose
 - If Moderna booster dose is used, dose is 50 μg (0.25ml)

Additional considerations



Definition of ‘fully vaccinated’

- People who have completed a primary vaccine series (i.e., 2-dose mRNA vaccine series or a single dose of the Janssen vaccine) are considered fully vaccinated ≥ 2 weeks after completion of the primary series
- Receipt of an additional or booster dose is not required to be considered fully vaccinated
- People who have received a booster dose should continue to follow guidance for fully vaccinated persons to minimize spread of SARS-CoV-2



Coadministration with other vaccines

- COVID-19 vaccines (Pfizer-BioNTech, Moderna, or Janssen) may be given with other vaccines, without regard to timing.
- This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day.
- If multiple vaccines are administered at a single visit, administer each injection in a different injection site.



<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Coadministration>

Additional updates to clinical considerations of COVID-19 vaccines

- Recipients of hematopoietic cell transplant or CAR-T-cell therapy should be revaccinated with a primary vaccine series at least 3 months after transplant or therapy
- Further considerations for risks and benefits of vaccination in people with history of multisystem inflammatory syndrome in children/adolescents (MIS-C) or adults (MIS-A)
- Updated recommendations for administration errors and deviations

Updates to additional clinical resources

Updates will be posted at:
<https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html>

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States

CDC now recommends that certain people are now eligible to receive a COVID-19 booster shot, including those who received Moderna and Johnson & Johnson/Janssen COVID-19 vaccines. Get more information and read [CDC's media statement](#).

Reference Materials

- Summary Document for Interim Clinical Considerations
- Summary Document for Interim Clinical Considerations poster
- COVID-19 Vaccine Administration Errors and Deviations
- COVID-19 Vaccine Administration Errors and Deviations Poster
- Presentation: Clinical Care Consideration Slides for Healthcare Providers

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Summary of recent changes (last updated September 27, 2021):

- New section on [Considerations](#) for use of a Pfizer-BioNTech COVID-19 vaccine booster dose after completion of a Pfizer-BioNTech primary vaccine series

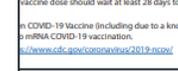
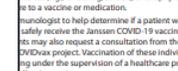
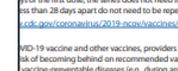
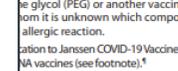
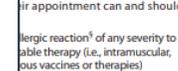
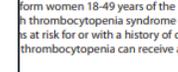
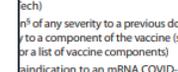
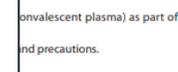
Key points

- COVID-19 vaccination is recommended for everyone aged 12 years and older in the United States for the prevention of coronavirus disease 2019 (COVID-19).
- COVID-19 vaccines currently approved or authorized by FDA are [highly effective](#) in preventing serious outcomes of COVID-19, including severe disease, hospitalization, and death.
- Available evidence suggests vaccines offer protection against known variants, including the Delta variant (B.1.617.2), particularly against hospitalization and death. The Delta variant, currently the predominant SARS-CoV-2 variant in the United States, is associated with increased transmissibility.
- Efforts to maximize the proportion of people in the United States who are fully vaccinated against COVID-19 remain critical to ending the COVID-19 pandemic.
- ACIP has recommended the [FDA-approved Pfizer-BioNTech](#) (COMIRNATY) COVID-19 Vaccine for use in persons aged ≥16 years.
- ACIP has issued interim recommendations under Emergency Use Authorization (EUA) for the use of:
 - Pfizer-BioNTech COVID-19 vaccine in persons [aged 12–15 years](#)
 - [Moderna](#) COVID-19 vaccine in persons aged ≥18 years
 - [Janssen \(Johnson & Johnson\)](#) COVID-19 vaccine in persons aged ≥18 years
- These clinical considerations provide additional information to healthcare professionals and public health officials on use of COVID-19 vaccines.

Moderna COVID-19 Vaccine Standing Orders for Administering Vaccine

Janssen COVID-19 Vaccine (Johnson & Johnson) Standing Orders for Administering Vaccine

Pfizer-BioNTech COVID-19 Vaccine Standing Orders for Administering Vaccine



Prevaccination Checklist for COVID-19 Vaccines



with Pfizer-BioNTech COVID-19 Vaccine for at least 90 days prior to administration of the mRNA COVID-19 vaccine (monoclonal convalescent plasma) as part of COVID-19 treatment, rindications and precautions.

allergic reaction³ of any severity to a previous dose or to a component of the vaccine (see footnote¹).

to have a contraindication to the mRNA COVID-19 Vaccine (see footnote¹).

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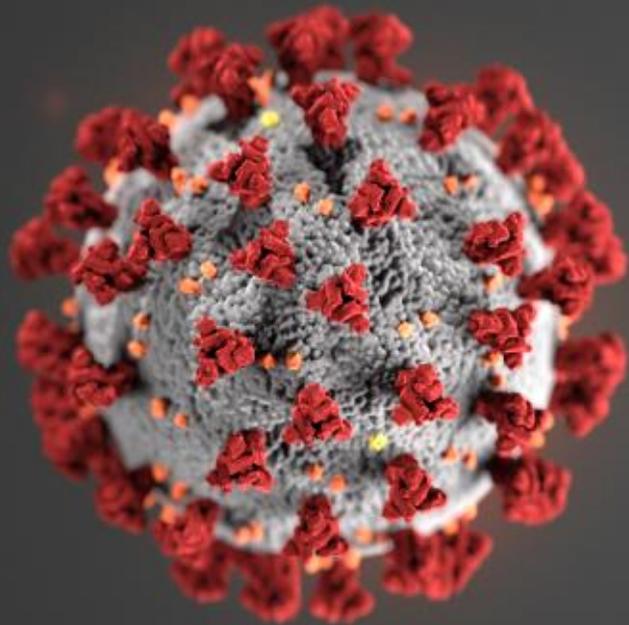
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9 infection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Date			
NC) screening checklists			



For more information, contact CDC
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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.



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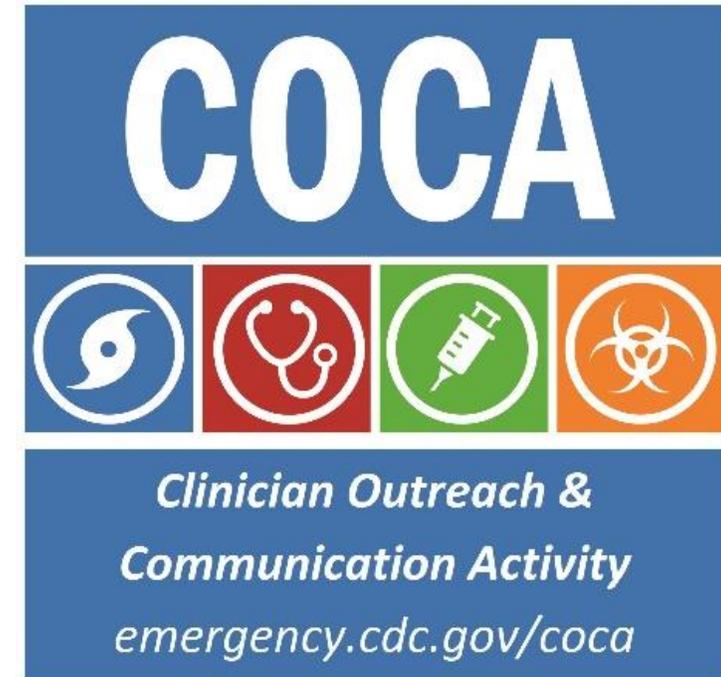
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