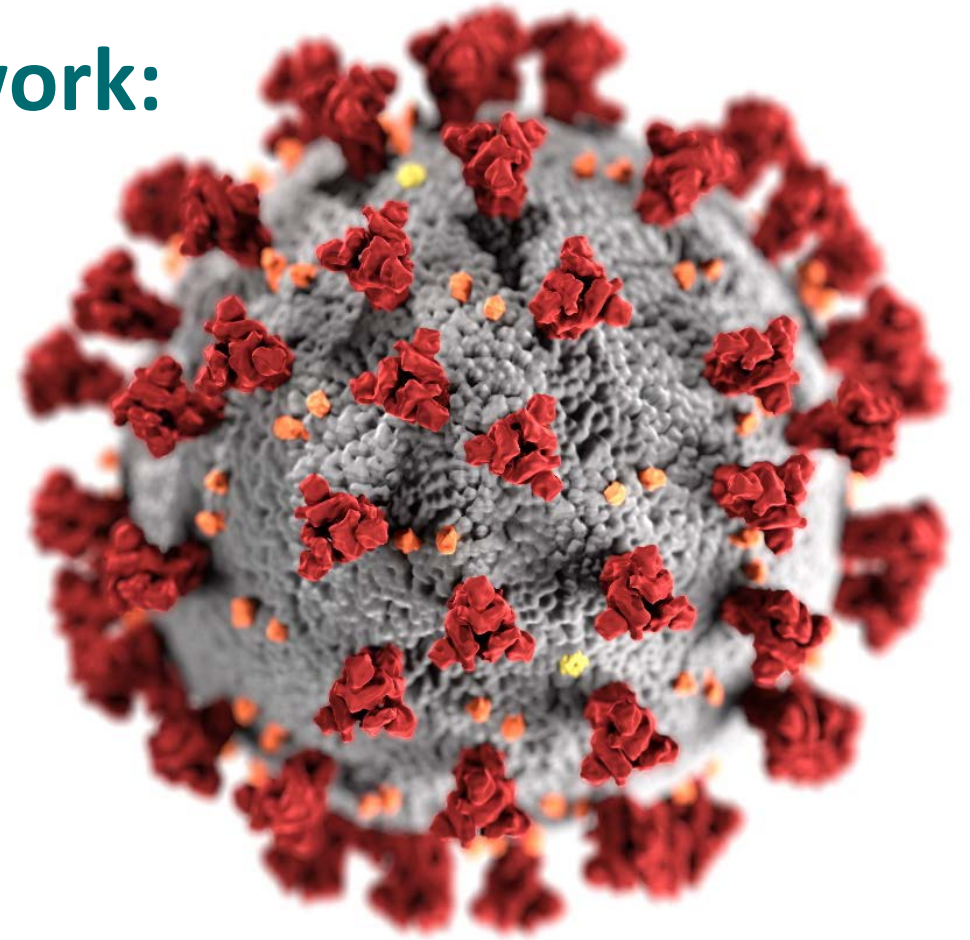


Evidence to Recommendation Framework: Moderna & Janssen COVID-19 Vaccine Booster Dose

Kathleen Dooling, MD, MPH
ACIP Meeting, Oct 21, 2021



cdc.gov/coronavirus

Evidence to Recommendations (EtR) Framework

EtR Domains
Public Health Problem
Benefits and Harms
Values
Acceptability
Feasibility
Resource Use
Equity

Booster doses of COVID-19 vaccines

- Policy on booster doses will be coordinated with **FDA** for regulatory allowance and **ACIP/CDC** for recommendations for use



CDC recommends the following groups for Pfizer-BioNTech COVID-19 vaccine boosters

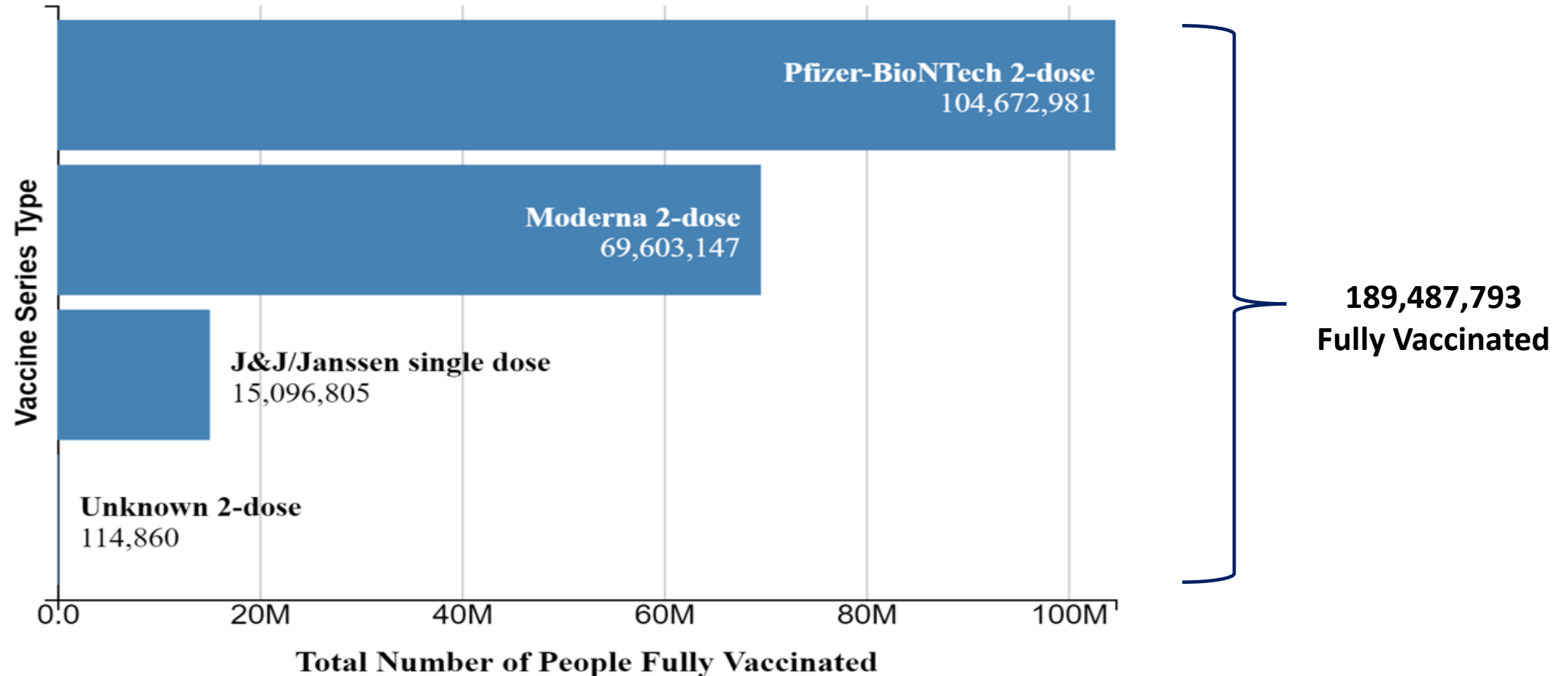
- The following recipients of Pfizer-BioNTech COVID-19 vaccine primary series **should receive** a single booster dose ≥ 6 months after completion of the primary series:
 - ≥ 65 years
 - ≥ 18 years and reside in long-term care settings
 - Aged 50-64 years with certain underlying medical conditions
- The following recipients of Pfizer-BioNTech 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:
 - 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

Evidence to Recommendations (EtR) Framework

Policy Questions

- 1) Among risk groups for whom CDC recommends a Pfizer-BioNTech booster dose, should those who received a Moderna COVID-19 vaccine primary series be recommended to receive a single Moderna COVID-19 booster dose (50 μ g) \geq 6 months after completion of the primary series?
- 2) Among people aged \geq 18 years who received Janssen COVID-19 vaccine for their primary COVID-19 vaccine, should a booster dose of Janssen COVID-19 be recommended \geq 2 months after receipt of the initial dose?

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



Evidence to Recommendations Framework

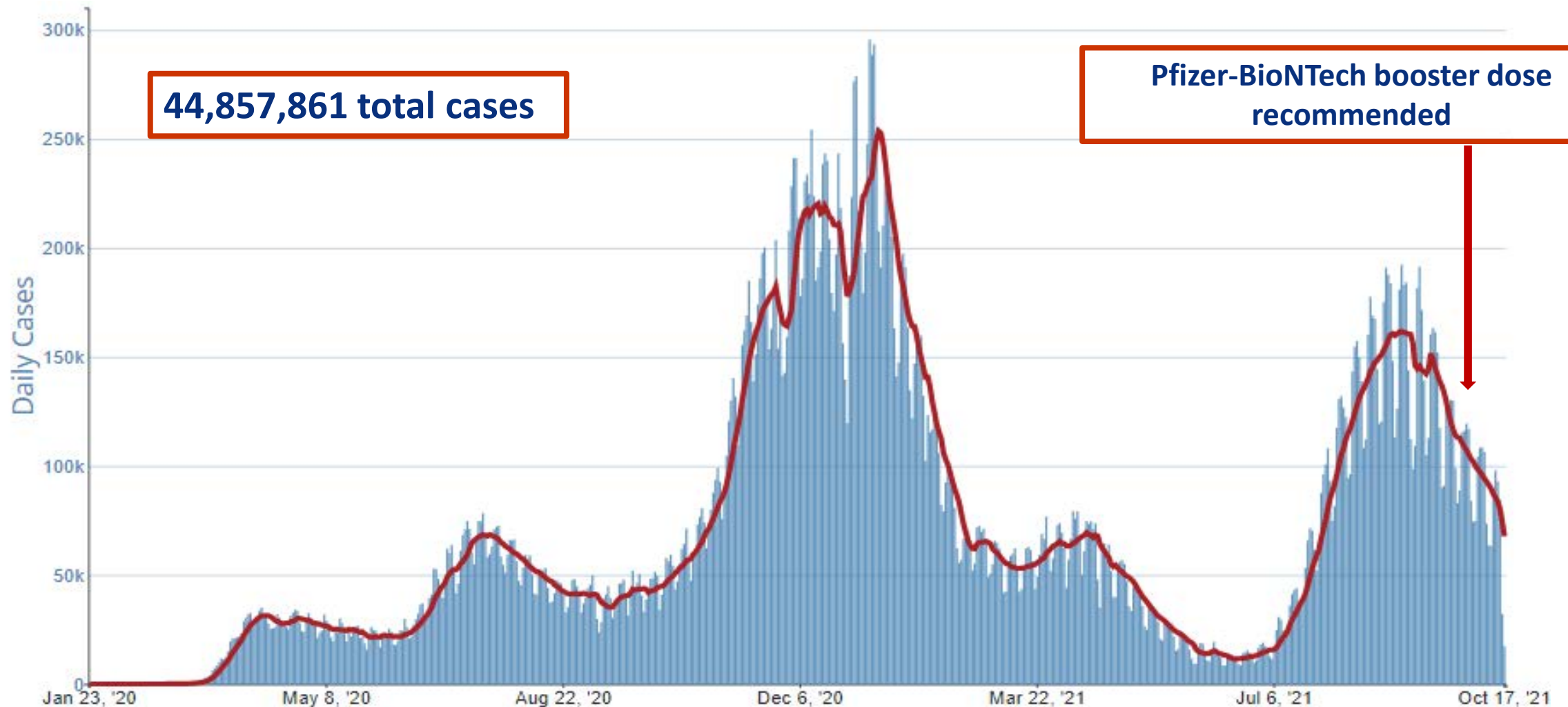
Booster doses of COVID-19 vaccines



Public
Health
Problem

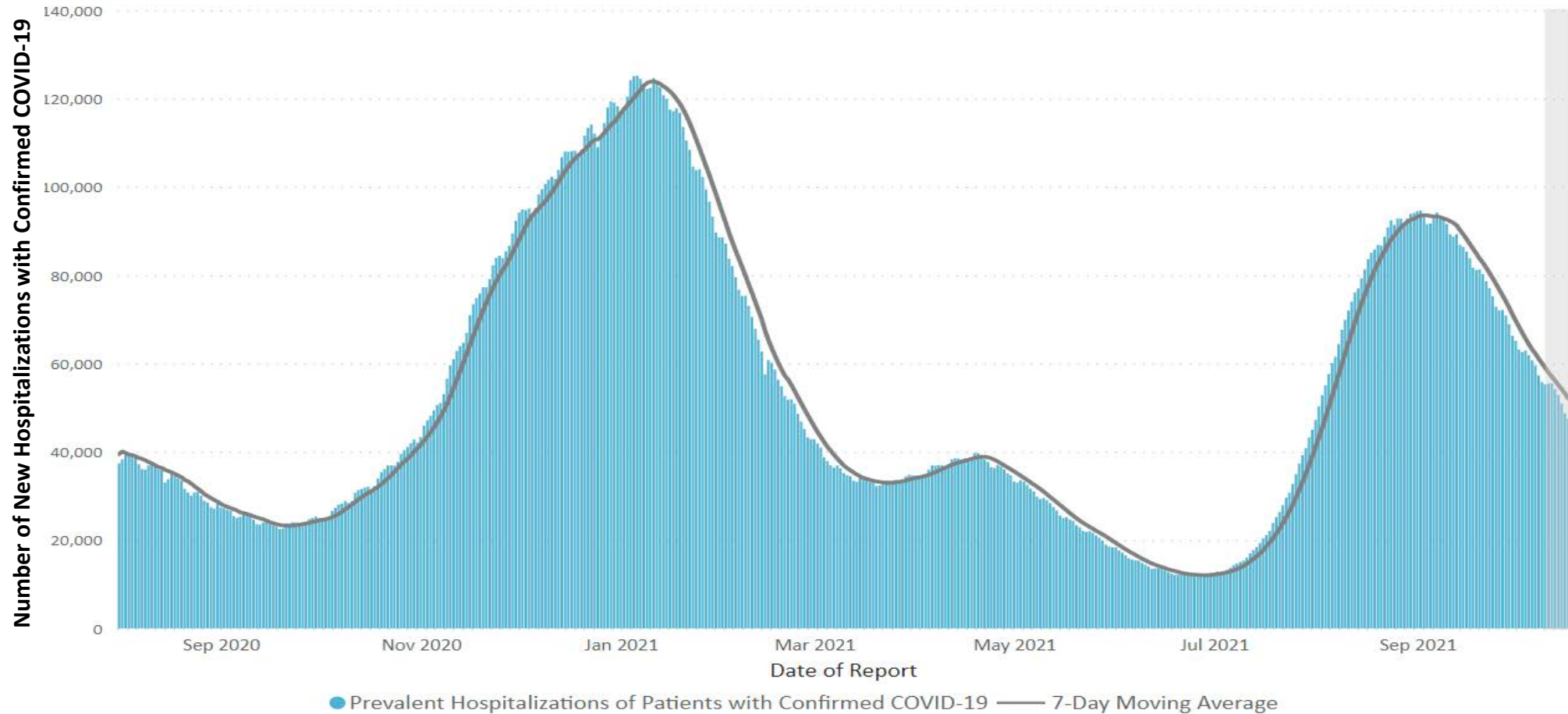
Daily trends in number of COVID-19 cases in the United States

January 23, 2020 – October 17, 2021

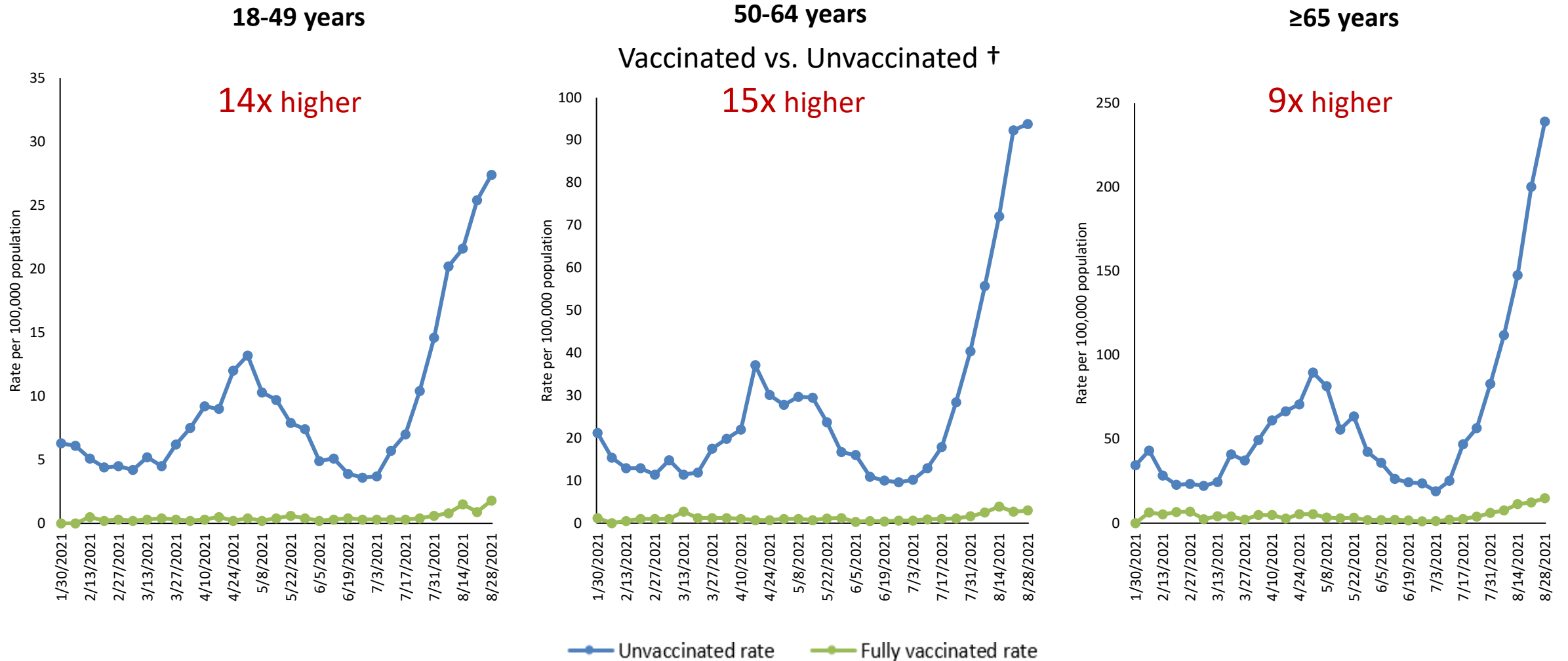


Daily trends in number of hospitalized COVID-19 cases in the United States

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.

COVID Data Tracker: <https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination>

Long COVID-19 and risk in vaccinated people

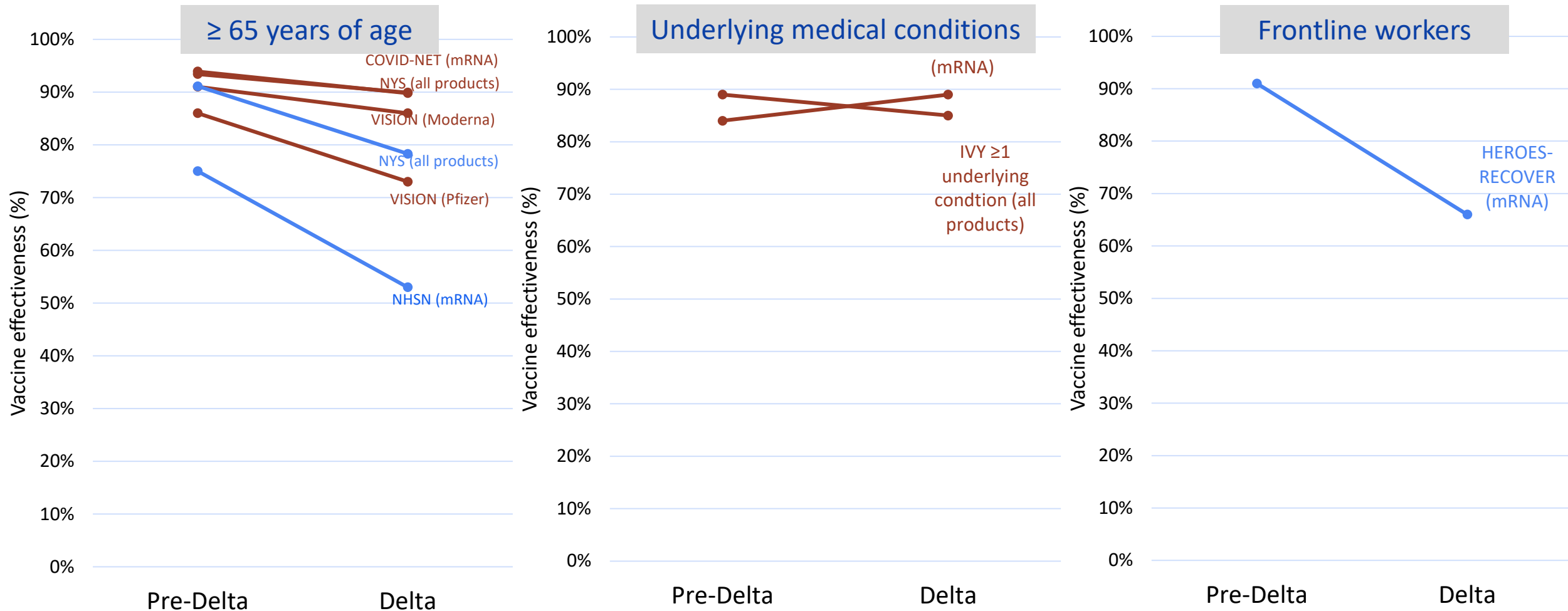
- Prevalence of post-COVID-19 conditions, among vaccinated and unvaccinated, reported from 5%–80%¹
- Prevalence of long COVID-19 among fully vaccinated persons who develop COVID-19 ranges from 5% (U.K. adults)² to 19% (Israeli healthcare workers)³
- Among COVID-19 cases in a U.K. study, odds of long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

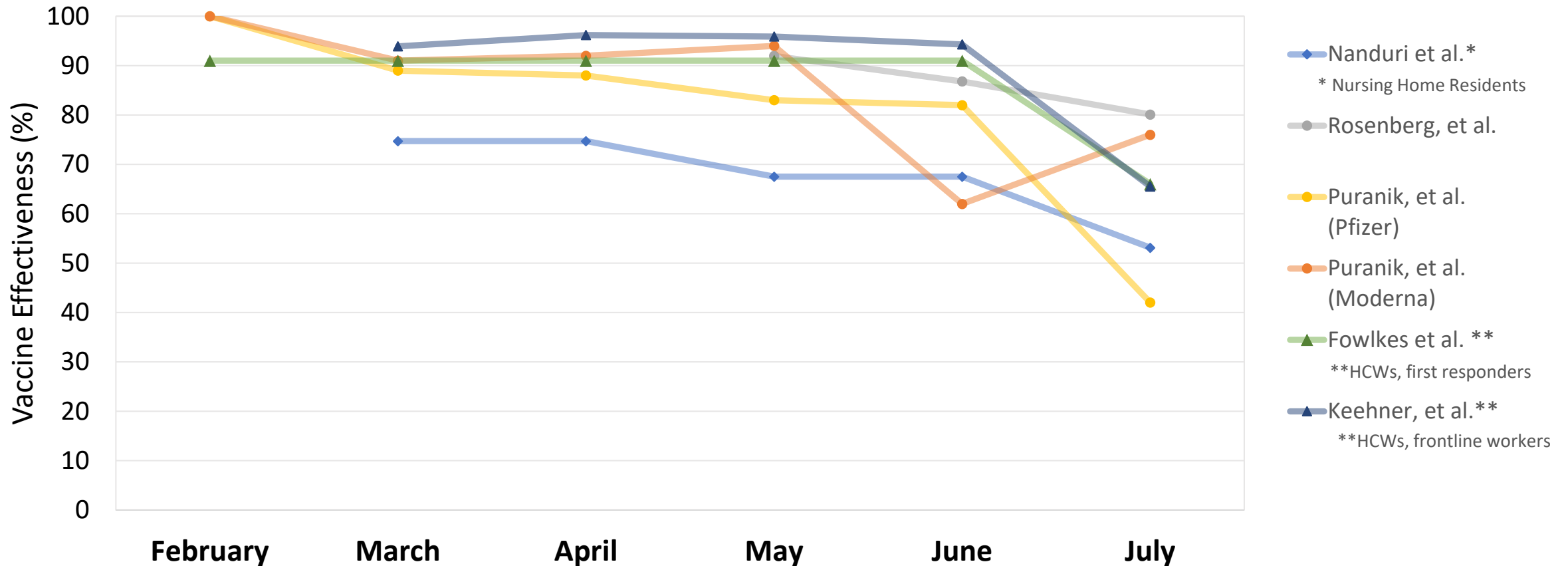


NHSN: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e3.htm>
 COVID-NET: CDC unpublished
 IVY: CDC unpublished data
 NYS: <https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e1.htm>

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.

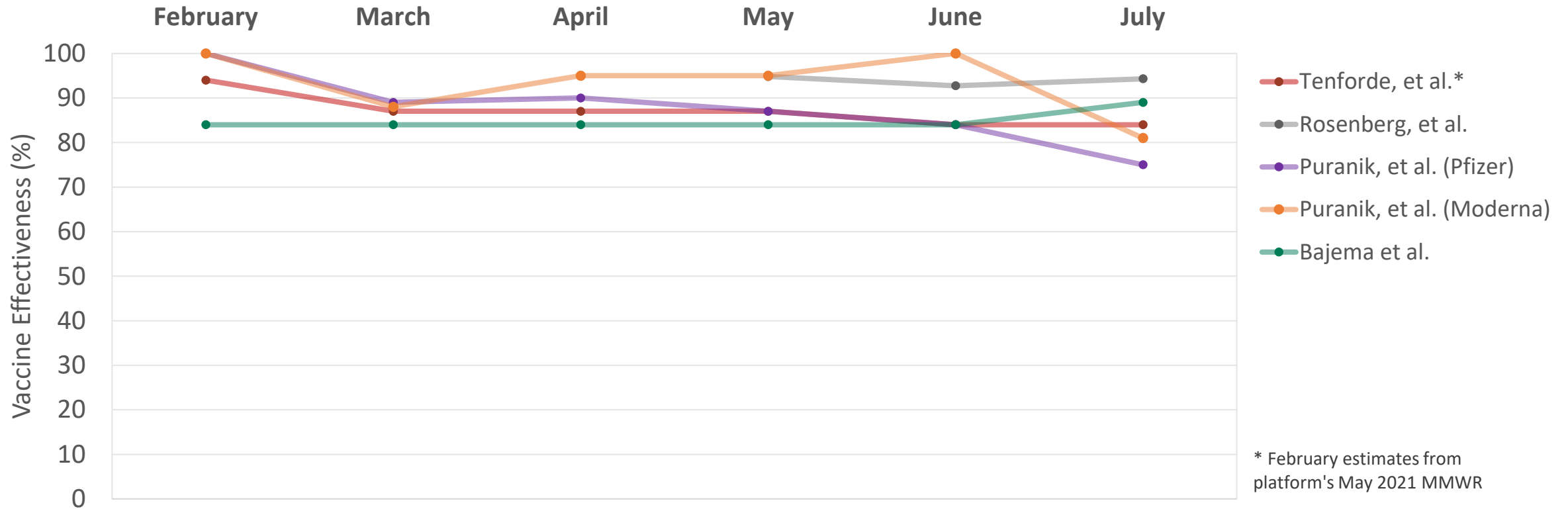
Fowlkes A, Gaglani M, Groover K, et al. Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021. MMWR Morb Mortal Wkly Rep. ePub: 24 August 2021.

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.

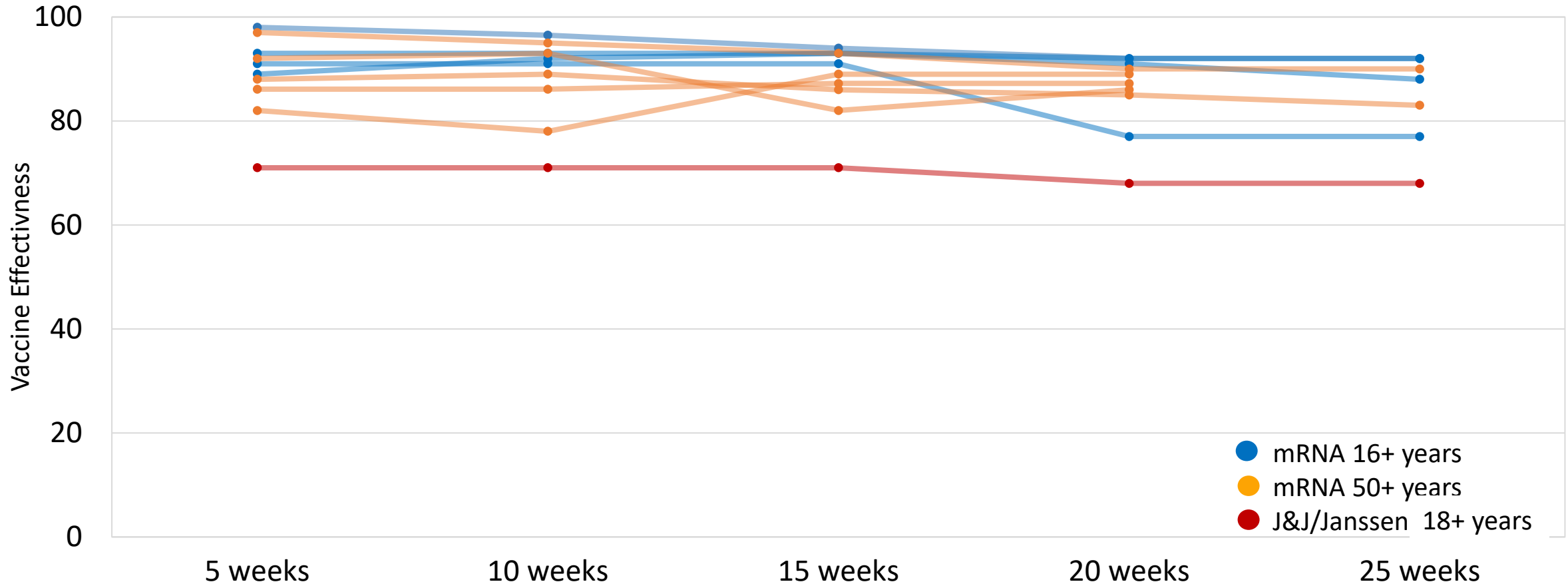
Rosenberg ES, Holtgrave DR, Dorabawila V, et al. New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3–July 25, 2021. *MMWR Morb Mortal Wkly Rep.* ePub: 18 August 2021.

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

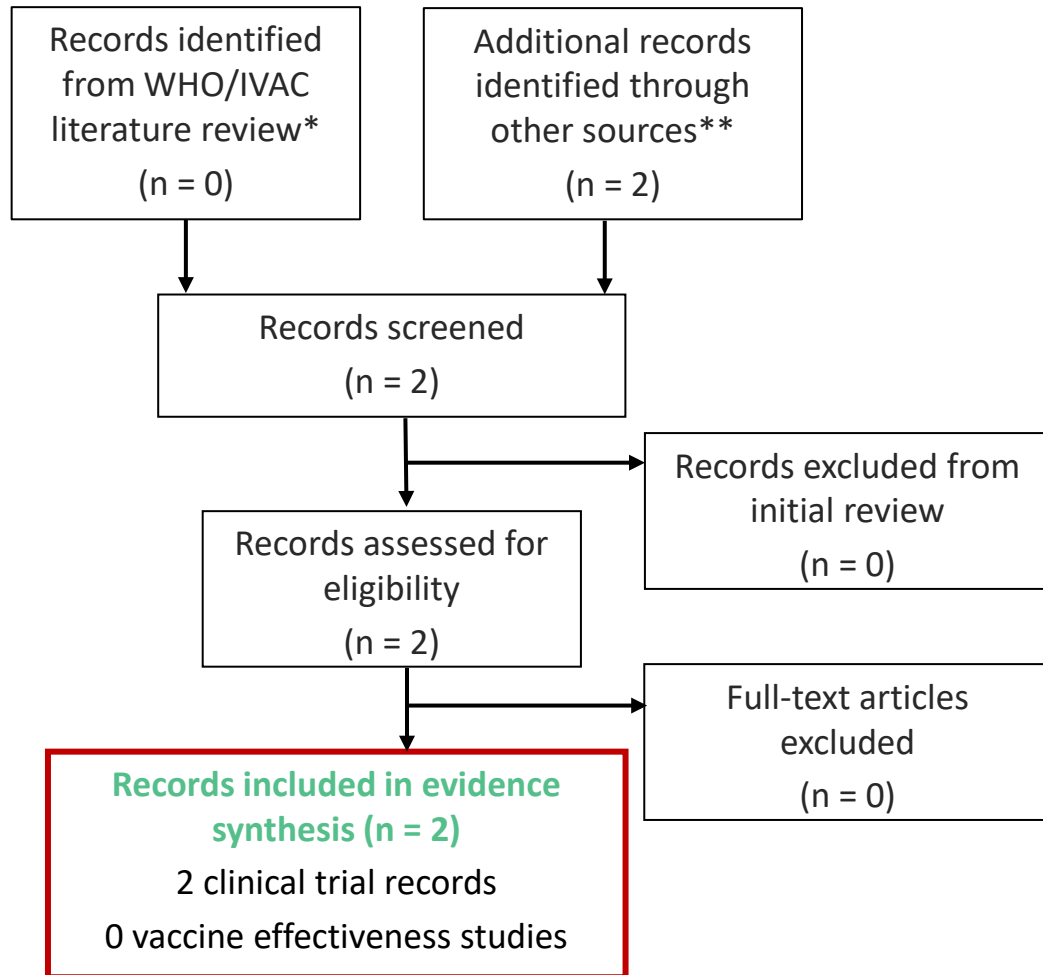
PICO Question

	Moderna	Janssen
Population	Persons aged ≥ 18 years who completed a COVID-19 vaccine primary series ≥ 6 months ago	Persons aged ≥ 18 years who completed a COVID-19 vaccine primary series ≥ 2 months ago
Intervention	Moderna COVID-19 Vaccine booster dose (mRNA-1273, 50 μ g, IM)	Janssen COVID-19 Vaccine booster dose (Ad26.CoV2.S, 5×10^{10} VP, IM)
Comparison	No booster dose	
Outcomes	Symptomatic laboratory-confirmed COVID-19* Hospitalization due to COVID-19* Death due to COVID-19 Transmission of SARS-CoV-2 infection Serious adverse events* Reactogenicity	

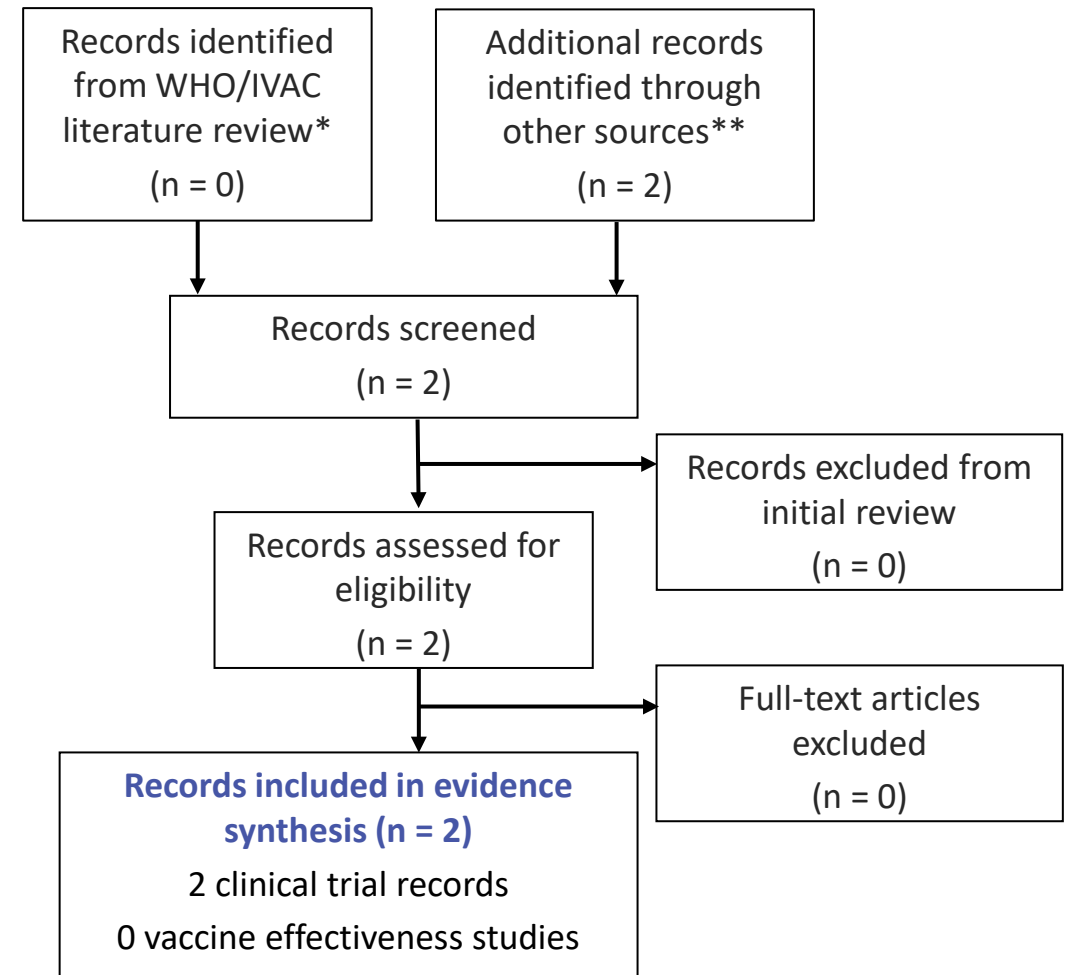
* Critical outcomes

Evidence Retrieval

Janssen booster



Moderna booster



*See <https://view-hub.org/resources>** clinicaltrials.gov and Sponsor

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 µg) induced immune response (GMR) noninferior to that following dose 2 of the 100 µg 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 µg) 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 µg) recipients vs 19.7% primary series (100ug)	4

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

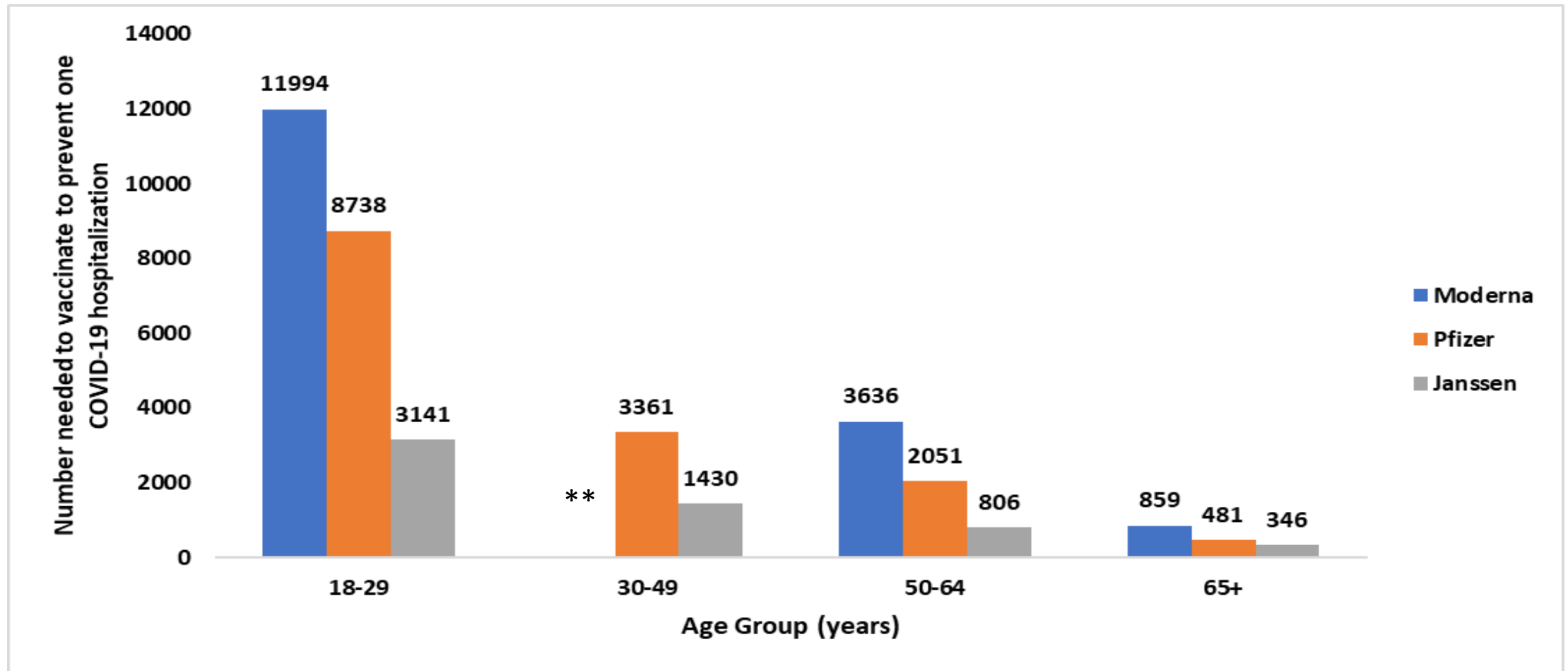
Janssen booster ≥ 2 months after primary dose

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

Number of people needed to vaccinate with a booster dose to prevent one hospitalization over 6 months



** Not estimable due to pre-booster efficacy estimated at >95%
Methods for calculations included in backup slides

Myocarditis/pericarditis following Moderna

■ Myocarditis and Pericarditis

- Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae.¹
- Highest reporting rate in 18-24yo males (0-7 days post dose 2)= **39 cases/1M doses administered**²

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

2. VAERS

TTS following Janssen

- **Thrombosis with thrombocytopenia syndrome (TTS)**
 - Blood clots involving blood vessels in the brain, lungs, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two weeks after vaccination. Reporting of these blood clots and low levels of platelets has been highest in females ages 18 through 49 years. The chance of having this occur is remote.¹
 - Highest reporting rate in 30-39 year old females (0-21 days post dose)= **10 cases/1M doses administered²**

1. [Janssen COVID-19 Vaccine Fact Sheet for Recipients and Caregivers \(fda.gov\)](#)

2. VAERS

GBS following Janssen

- **Guillain Barré syndrome (GBS)**

- ...has occurred in some people who have received the Janssen COVID-19 Vaccine. In most of these people, symptoms began within 42 days following receipt of the Janssen COVID-19 Vaccine. The chance of having this occur is very low. ¹
- Highest reporting rate in 50-64 year old males (1-42d post dose)= **16 cases/1M doses administered** ²

1. [Janssen COVID-19 Vaccine Fact Sheet for Recipients and Caregivers \(fda.gov\)](#)

2. 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 dose of COVID-19 vaccines



Values and
Acceptability

Values and Acceptability

- In published surveys completed in August (n=5), **76%-87%** of vaccinated adults reported they would get a booster dose, if available¹⁻⁵
 - In one survey, this increased to 93% of surveyed adults if it was recommended by their primary care provider

1. Axios Ipsos Poll. August 2, 2021.

2. Axios Ipsos Poll. August 30, 2021.

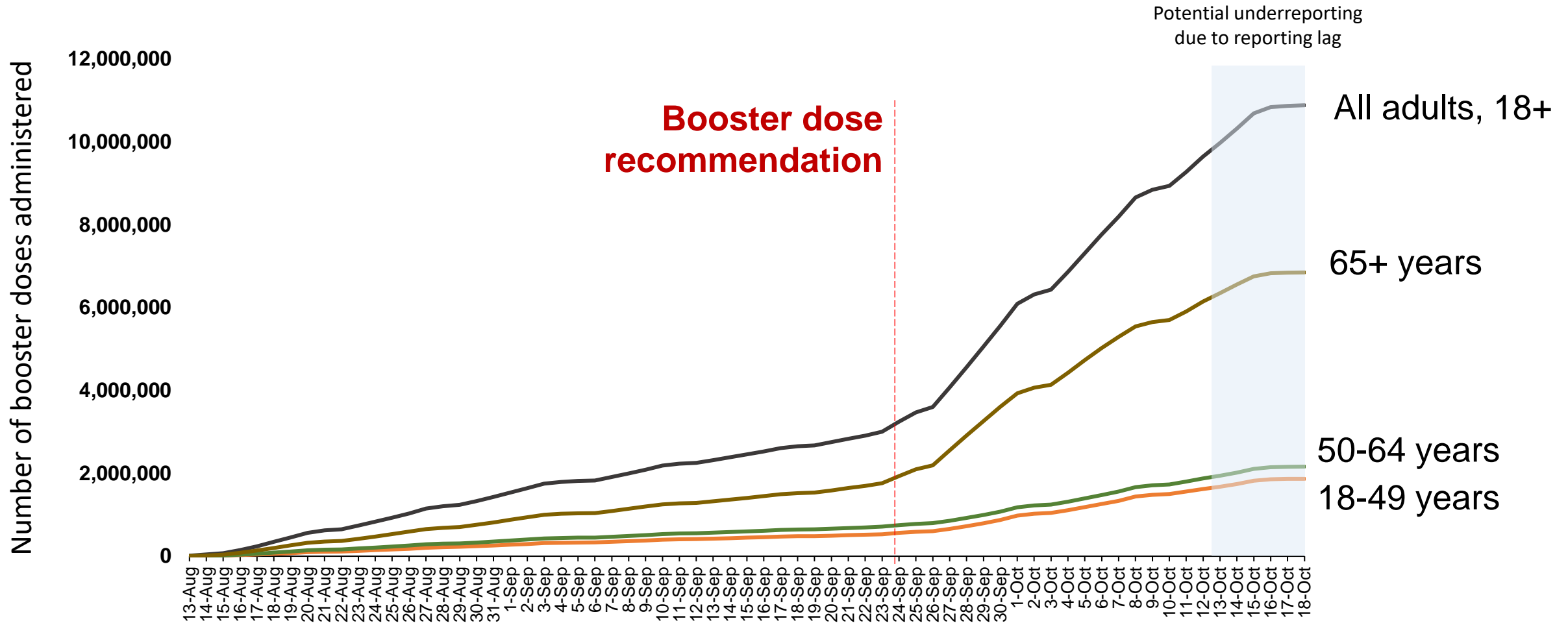
3. Marist Poll. September 3, 2021. <https://maristpoll.marist.edu/polls/npr-pbs-newshour-marist-national-poll-covid-september-3-2021/>

4. Morning Consult Poll. August 25, 2021. <https://morningconsult.com/2021/08/25/covid-booster-shot-poll/>

5. Reuters/Ipsos Poll. September 1, 2021. <https://www.reuters.com/business/healthcare-pharmaceuticals/most-vaccinated-americans-want-covid-19-booster-shots-reutersipsos-poll-2021-09-01/>

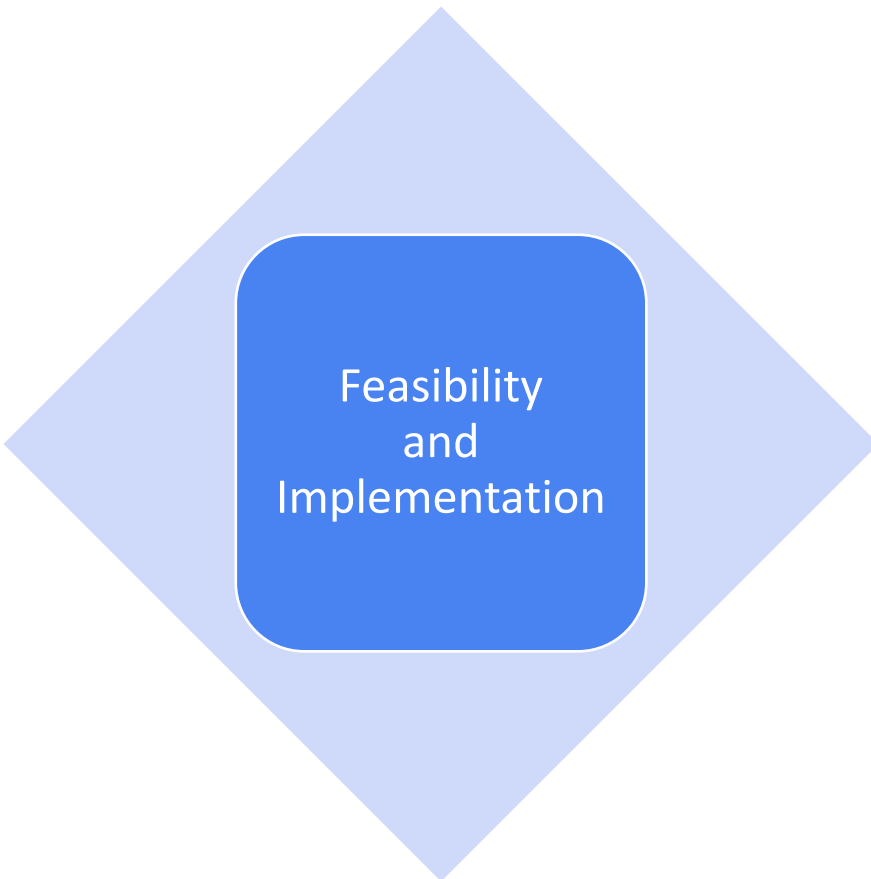
Cumulative Number of COVID-19 Vaccine Booster/Additional Doses

Total booster/additional doses administered: 10.9M



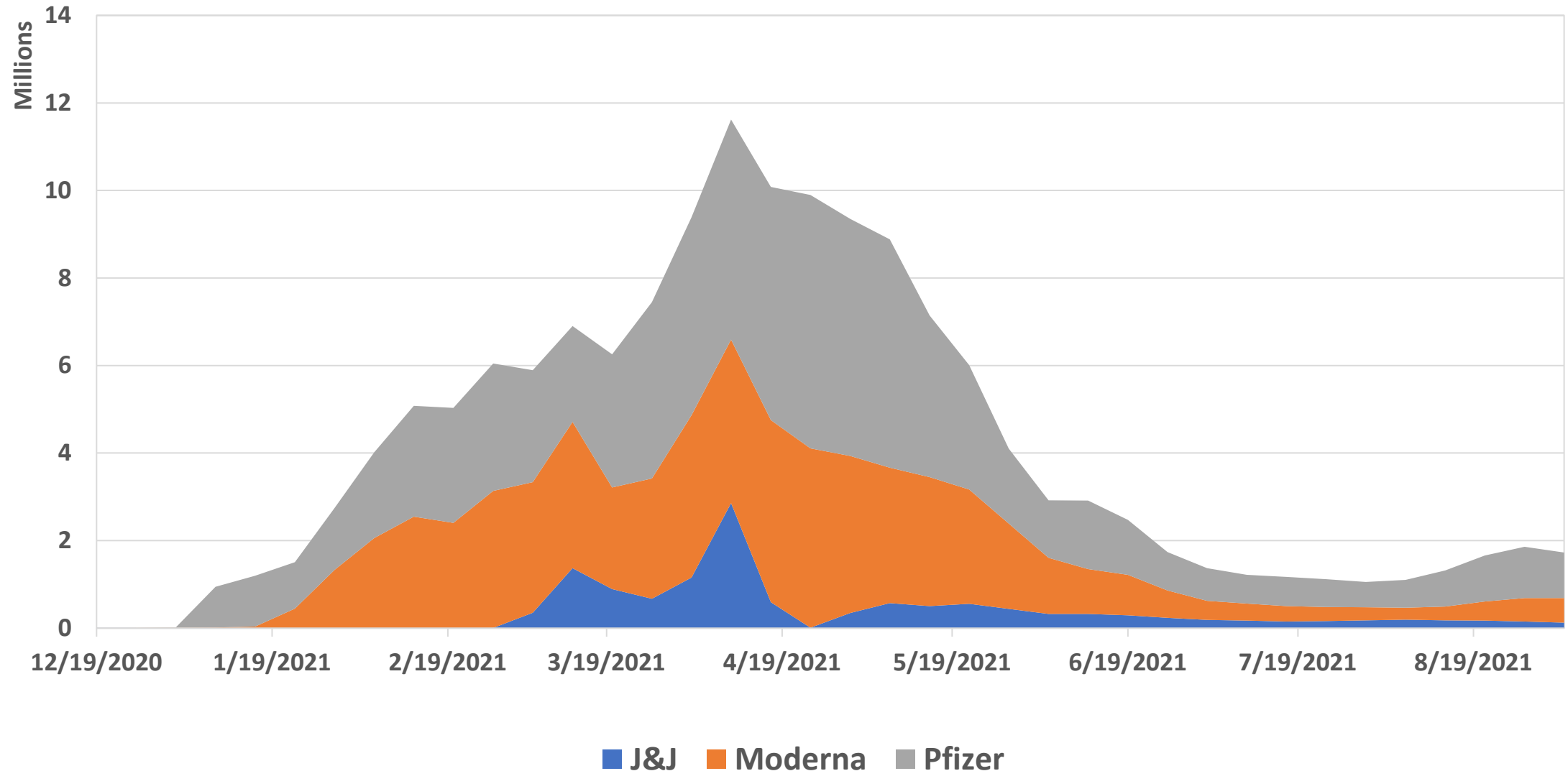
Evidence to Recommendations Framework

Booster doses of COVID-19 vaccines

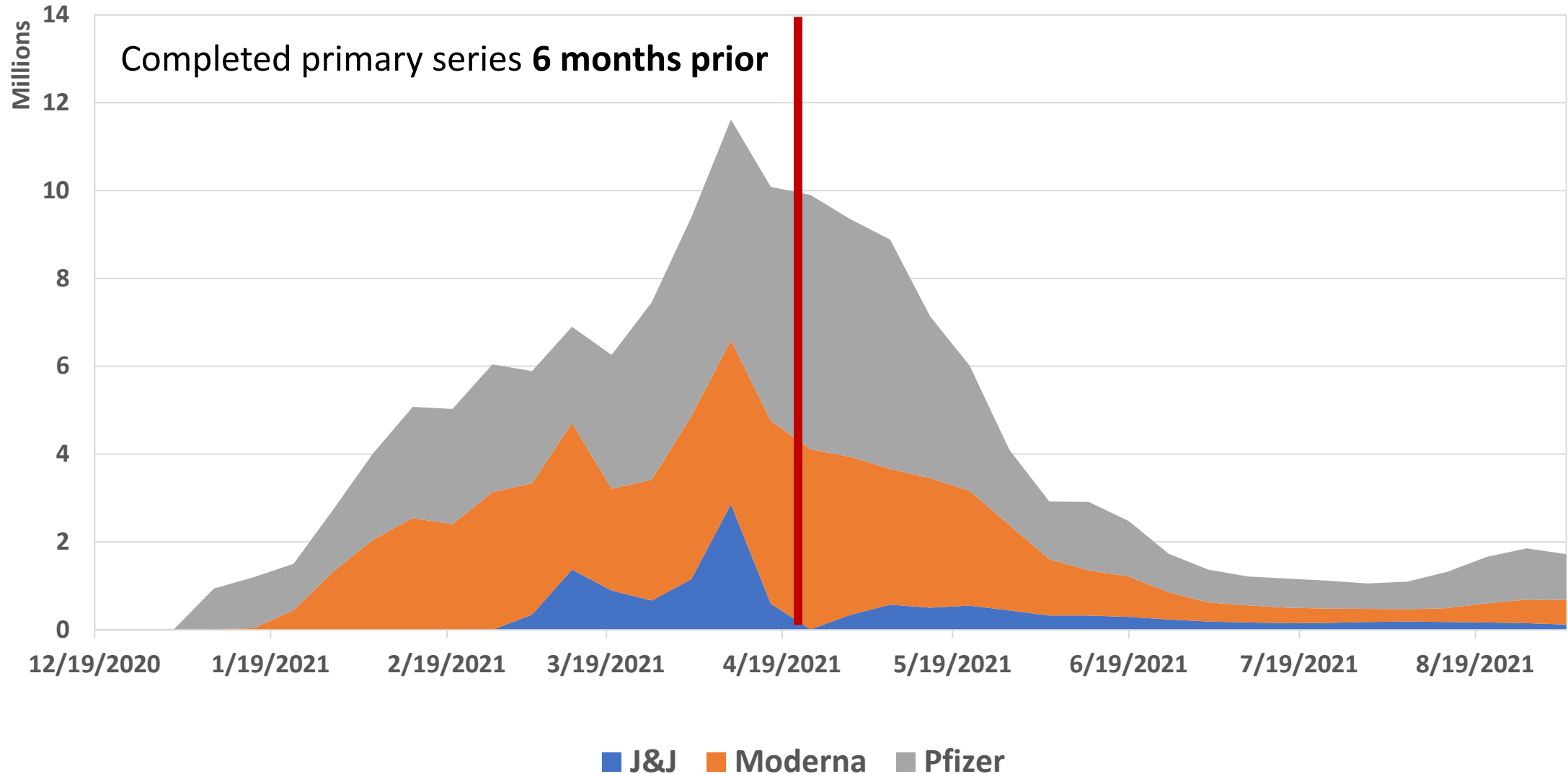


Feasibility
and
Implementation

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

Implementation

Long-term care (LTC) facility residents

- CDC's federal pharmacy program provides vaccination support to LTC settings, including on-site vaccination clinics where needed, to help residents access vaccine in local community
- 8.1 million doses administered during original LTC program (December 2020-March 2021): 6.2M (**76%**) were Pfizer-BioNTech, 1.9M (**24%**) were Moderna
- Thus far, the support for booster doses has been restricted to Pfizer-BioNTech recipients based on current FDA and CDC guidance

Evidence to Recommendations Framework

Booster doses of COVID-19 vaccines



Resource
Use

Summary - Resource Use

- All COVID-19 vaccines, including booster doses, will be provided **free of charge** to the U.S. population
 - Health systems or health departments incur costs for vaccination program planning and implementation
 - Fees for administration of COVID-19 vaccines recommended by ACIP/CDC are reimbursable by insurance or other federal programs
- Cost effectiveness analyses will take on increased importance in the future, when public health emergency is over

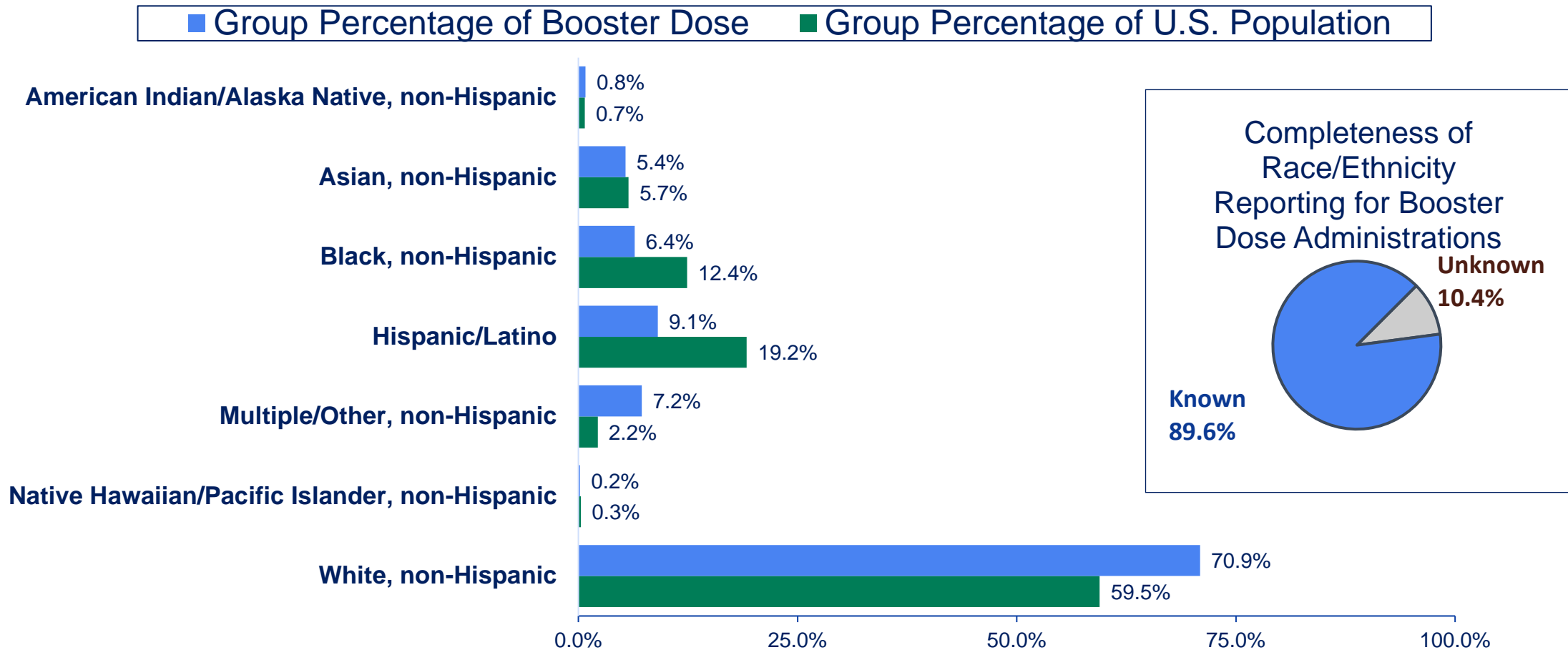
Evidence to Recommendations Framework

Booster doses of COVID-19 vaccines



Equity

Percentage of Booster Dose Administrations by Race/Ethnicity



Data shown for 9.8M people with a booster/additional dose administration and known race/ethnicity, vaccinated since August 13, 2021

Source: Immunization Data Lake Aggregate Dataset (includes TX). Data reported as of 19OCT2021 0600.

Notes: Census populations used to calculate Group Percentage of U.S. Population are from the Census 2019 Vintage files. The Multiple/Other category includes vaccine recipients that were identified as Multiple Race or Other Race. The Census populations used to calculate the Group Percentage of U.S. Population for this group represent the non-Hispanic Two or More Race population only, since Other is not a Census-recognized group.

Summary - Equity

- COVID-19 disease and COVID-19 vaccination varies by socioeconomic and sociodemographic groups
 - However, vaccine effectiveness does not vary by race and ethnicity
- At present, only recipients of Pfizer-BioNTech COVID-19 vaccine have been recommended to receive a booster, thus creating inequity for recipients of Moderna or Janssen COVID-19 vaccine
 - Janssen COVID-19 vaccine may have been used more commonly for outreach to homeless or medically underserved communities because it is a single dose regime

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

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- Heather Scobie
- Ian Plumb
- Amy Blain
- Neela Goswami
- 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



Evidence to Recommendations Framework

Summary: Work Group Interpretations

<p>Type of recommendation</p>	<p>We do not recommend the intervention</p>	<p>We recommend the intervention for individuals based on assessment of benefits and risks</p>	<p>We recommend the intervention</p>
--------------------------------------	---------------------------------------------	--------------------------------------------------------------------------------------------------------------	--------------------------------------



Used when the **risks** clearly outweigh the **benefits** in a population

Used when there is diversity of the **benefits** and **risks** in a population

Can allow flexibility across a population

Used when the **benefits** clearly outweigh the **risks** in a population

Policy question #1

Among risk groups for whom CDC recommends a Pfizer-BioNTech booster dose, should those who received a Moderna COVID-19 vaccine primary series be recommended to receive a single Moderna COVID-19 booster dose (50ug) ≥ 6 months after completion of the primary series?

Policy question #2

Among people aged ≥ 18 years who received Janssen COVID-19 vaccine for their primary COVID-19 vaccine, should a booster dose of Janssen COVID-19 be recommended ≥ 2 months after receipt of the initial dose?

ACIP Vote #1

Interim Recommendation

A single Moderna COVID-19 vaccine booster dose (50ug) is recommended at least 6 months after completion of the Moderna primary series, in the same risk groups for whom CDC recommended a booster dose of Pfizer-BioNTech, under the FDA's Emergency Use Authorization

ACIP Vote #2

Interim Recommendation

A single Janssen COVID-19 vaccine booster dose is recommended for persons aged ≥ 18 years, at least 2 months after receipt of the initial Janssen dose, under the FDA's Emergency Use Authorization

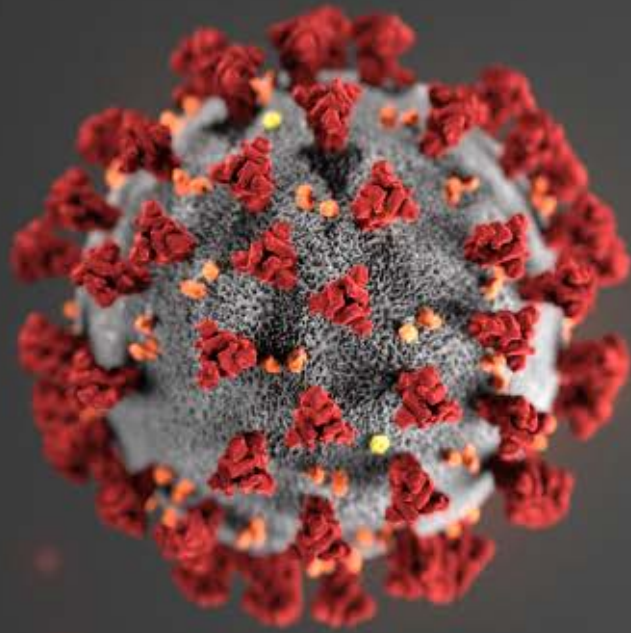
CDC recommends the following groups for Pfizer-BioNTech COVID-19 vaccine boosters

- The following recipients of Pfizer-BioNTech 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
 - Aged 50-64 years with certain underlying medical conditions
- The following recipients of Pfizer-BioNTech 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:
 - 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

ACIP Vote #3

Interim Recommendation

Among groups recommended to receive booster vaccination after a Pfizer-BioNTech, Moderna, or Janssen COVID-19 vaccine primary series, a single booster dose of any of the authorized or approved COVID-19 vaccines may be administered as a heterologous booster dose, under FDA's Emergency Use Authorization.



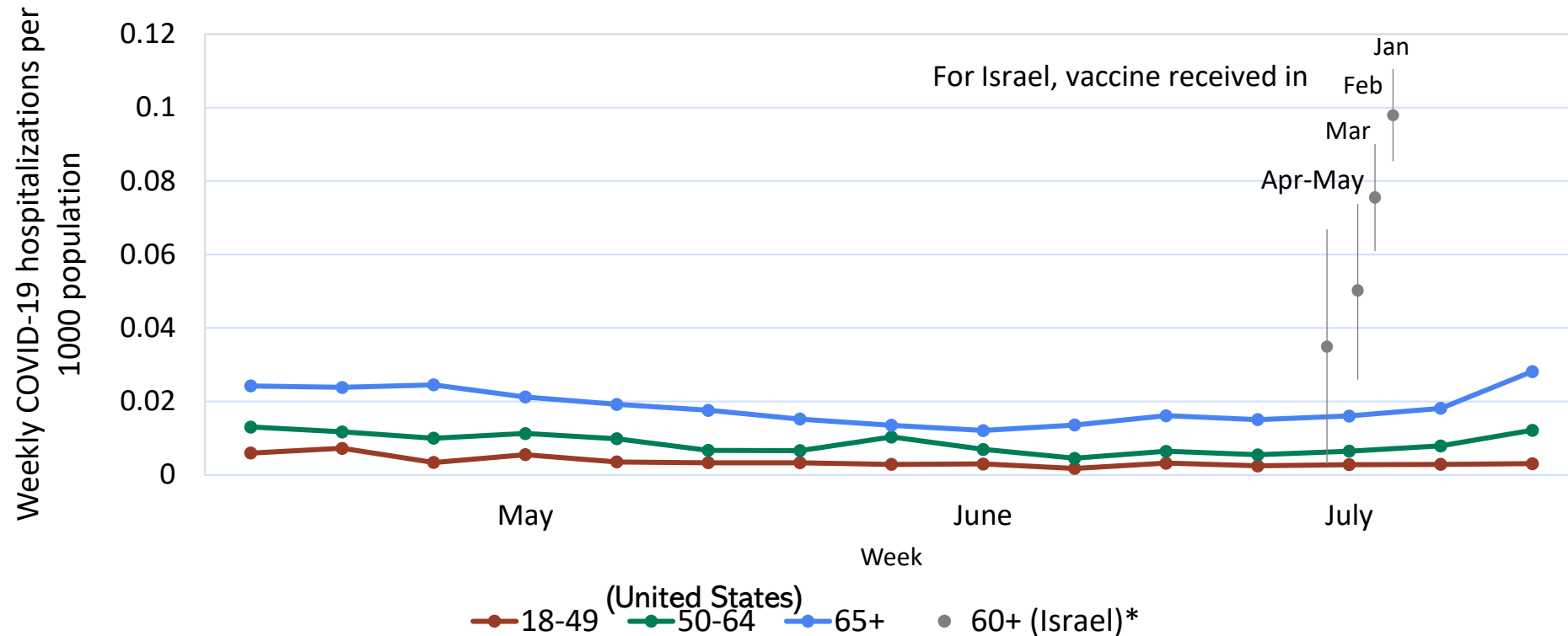
For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Thank you

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.



Incidence among vaccinated people, for hospitalization by month in United States and for severe disease by time since 2nd dose in Israel



*Israel estimates were derived from rate of severe COVID-19 (per 1,000 persons) from July 11, 2021 to July 31, 2021. Each data point represents all person stratified by when second dose of COVID-19 vaccine received.

Summary of GRADE- Pfizer-BioNTech

Outcome	Importance	Design (# of studies)	Findings	Evidence type
Benefits				
Symptomatic laboratory-confirmed COVID-19	Critical	RCT (2) OBS (1)	Pfizer-BioNTech COVID-19 booster dose induced immune responses (GMR, seroresponse) noninferior to those following dose 2. Observational data suggest increased protective effect against any SARS-CoV-2 infection.	4
Hospitalization due to COVID-19	Critical	RCT (0) OBS (1)	Observational data suggest increased protective effect against severe COVID-19.	4
Death due to COVID-19	Important	RCT (0) OBS (0)	No data available.	ND
Transmission of SARS-CoV-2 infection	Important	OBS (0)	No data available.	ND
Harms				
Serious adverse events	Critical	RCT (1)	No SAEs were attributed to booster dose.	4
Reactogenicity	Important	RCT (1)	Grade ≥ 3 reactogenicity was reported by 6.6% of booster dose recipients.	4

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

Methods for number needed to vaccinate

Calculated per 1 million booster doses using current COVID-19 vaccine and disease data to estimate number of cases and hospitalizations occurring among vaccinated

- Age groups: 18 – 29 years, 30 – 49 years, 50 – 64 years, ≥65 years
- Time Horizon: 180-day period, with stable incidence and VE

Input	Source
Number fully vaccinated	CDC Data Tracker (Sept 10, 2021) ¹
Case Incidence	CDC Data Tracker (Sept 9, 2021) ²
Hospitalization Incidence	COVID-NET (Aug 21, 2021) ³
Vaccine Effectiveness (primary series)	Averaged VE estimates from four platforms
Vaccine Effectiveness booster	Assumption (VE post-booster is unknown) 95% VE for hospitalization

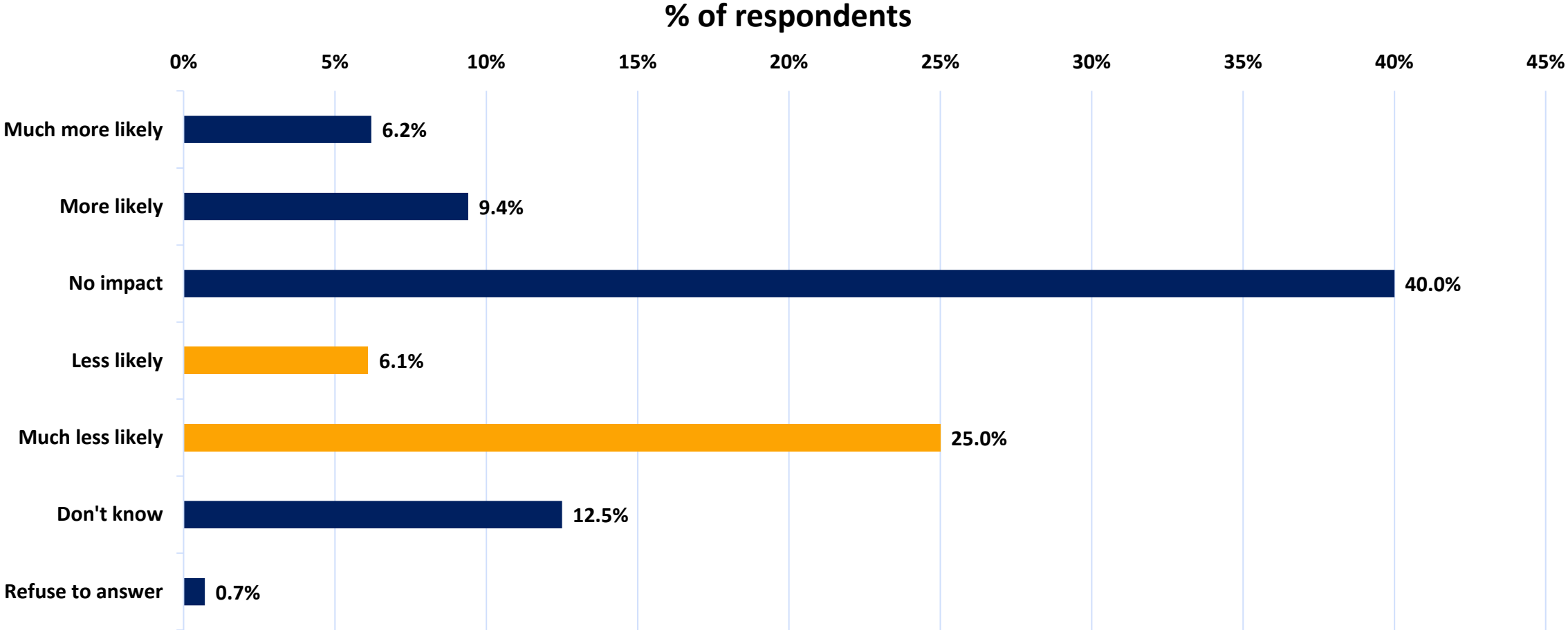
VE: Vaccine Effectiveness

¹<https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic>

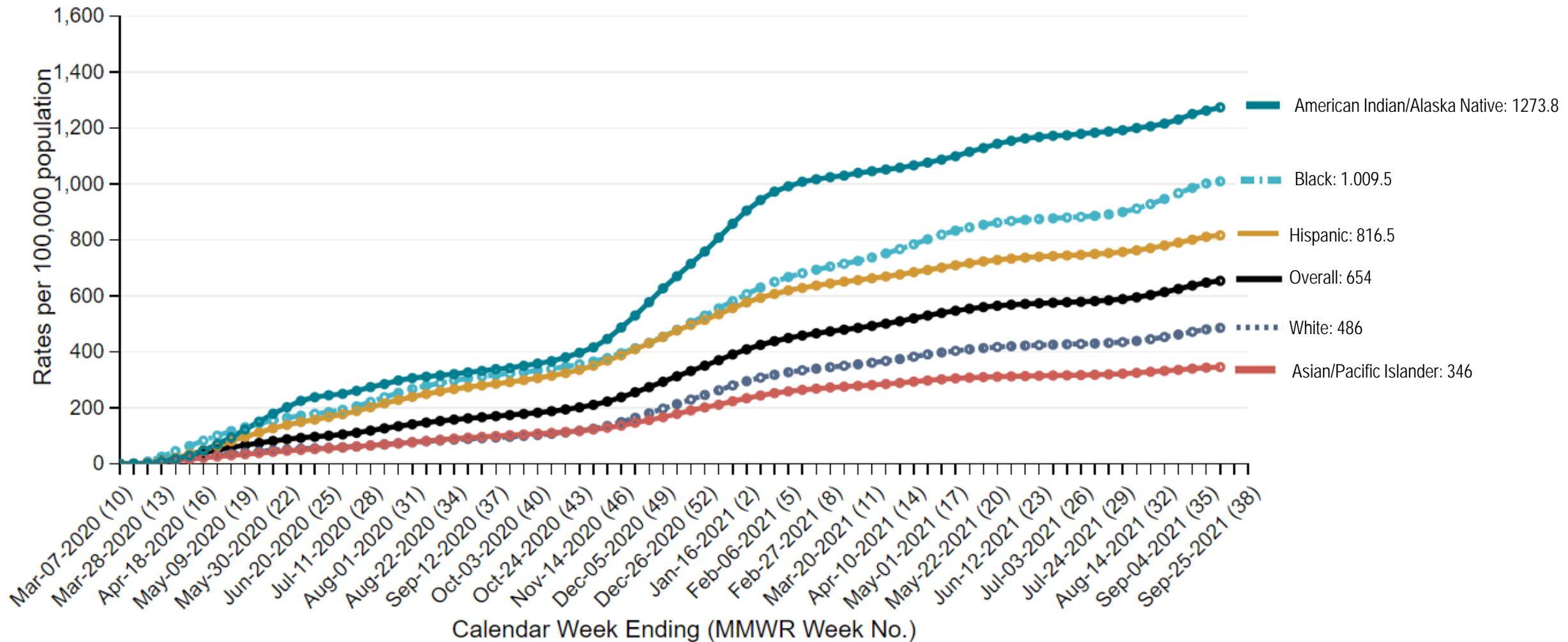
²https://covid.cdc.gov/covid-data-tracker/#trends_dailycases

³https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html

Around 1/3 of unvaccinated respondents said that COVID-19 booster vaccines would make them less likely to get vaccinated at all



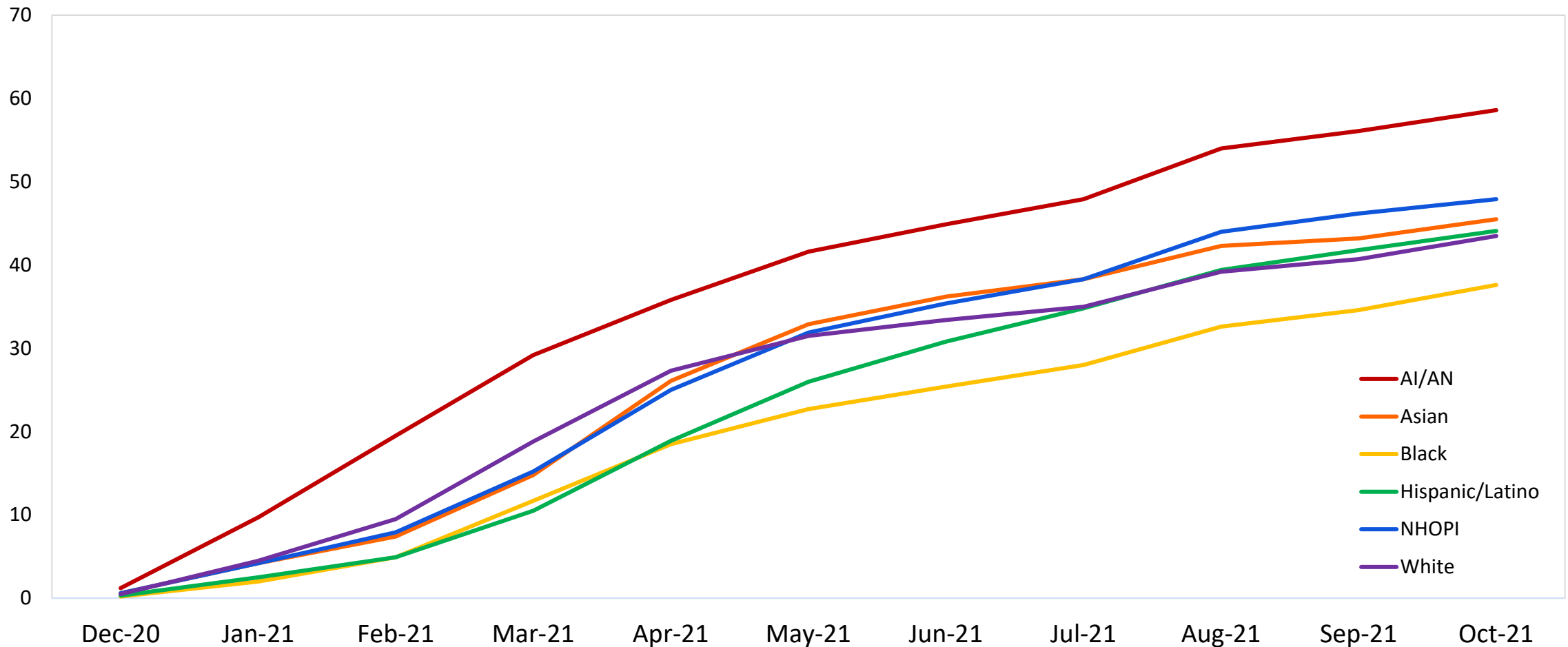
Cumulative COVID-19 associated hospitalizations in the United States by race/ethnicity, March 7, 2020 – September 11, 2021



Vaccine effectiveness by race and ethnicity

- Among VE platforms able to provide specific estimates for vaccine effectiveness by race or ethnicity, **no differences** noted
- VE against hospitalization among adults ≥ 50 years of age:
 - Overall: 89% (95% CI: 87-91%)
 - Black individuals: 86% (95% CI: 75-92%)
 - Hispanic individuals: 90% (95% CI: 85-93%)
- VE against hospitalization among VA centers:
 - Black individuals: 86% (95% CI: 77-93%)
 - White individuals: 88% (95% CI: 77-94%)

Percentage of people who have received at least one dose of the COVID-19 vaccine by race/ethnicity over time



Implications for public health recommendations

Definition of 'fully vaccinated'

- For public health purposes, 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
- The above definition applies to all people including those recommended to receive an additional single dose due to moderate to severe immunocompromise and those recommended to receive a booster dose
- People who have received a booster dose should continue to follow guidance for fully vaccinated persons to minimize spread of SARS-CoV-2