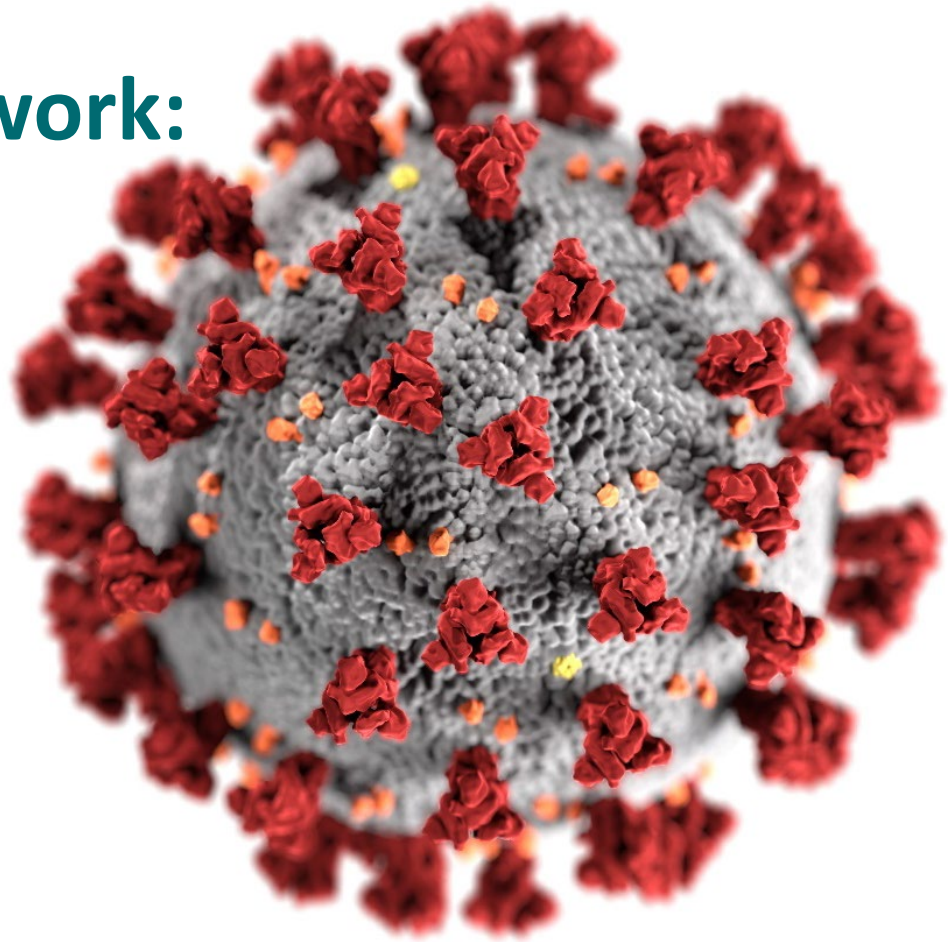
Evidence to Recommendation Framework:
Moderna COVID-19 vaccine, Spikevax

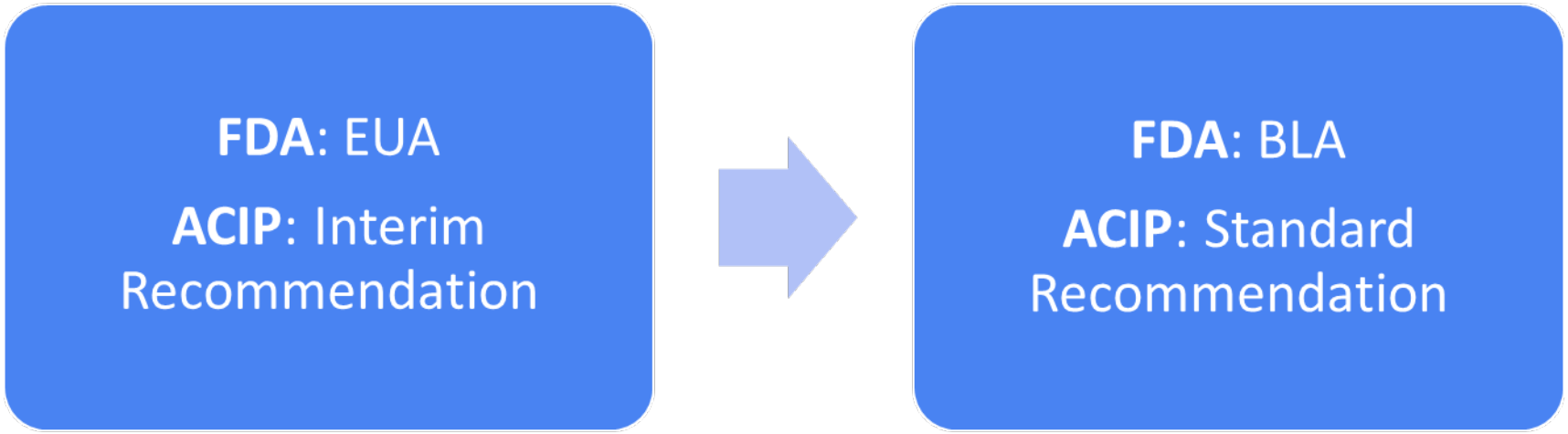


Sara Oliver, MD, MSPH
ACIP Meeting
February 4, 2022

cdc.gov/coronavirus

Policy question

- Should vaccination with the Moderna COVID-19 vaccine (Spikevax, 2-dose primary series) be recommended for persons 18 years of age and older?



EUA= Emergency Use Authorization, BLA= Biologics License Application

Policy question

- Should vaccination with the Moderna COVID-19 vaccine (Spikevax, 2-dose primary series) be recommended for persons 18 years of age and older?

Regulatory action, GRADE, Evidence to Recommendation Framework, Vote

Moderna COVID-19 vaccine	Compared to	**No COVID-19 vaccine**

Additional questions for discussion

Implementation;
Discussions around myocarditis and intervals

Moderna COVID-19 vaccine

And

Pfizer-BioNTech COVID-19 vaccine

Evidence to Recommendations (EtR) Framework:
PICO Question

Population	People ages 18 years and older
Intervention	Moderna COVID-19 vaccine mRNA-1273 (100µg, 2 doses IM, 28 days apart)
Comparison	No vaccine
Outcomes	Symptomatic laboratory confirmed COVID-19 Hospitalization due to COVID-19 Death due to COVID-19 Asymptomatic SARS-CoV-2 infection Serious adverse events Reactogenicity

Evidence to Recommendations (EtR) Framework

EtR Domain	Question(s)
Public Health Problem	• Is the problem of public health importance?
Benefits and Harms	• How substantial are the desirable anticipated effects? • How substantial are the undesirable anticipated effects? • Do the desirable effects outweigh the undesirable effects?
Values	• Does the target population feel the desirable effects are large relative to the undesirable effects? • Is there important variability in how patients value the outcome?
Acceptability	• Is the intervention acceptable to key stakeholders?
Feasibility	• Is the intervention feasible to implement?
Resource Use	• Is the intervention a reasonable and efficient allocation of resources?
Equity	• What would be the impact of the intervention on health equity?

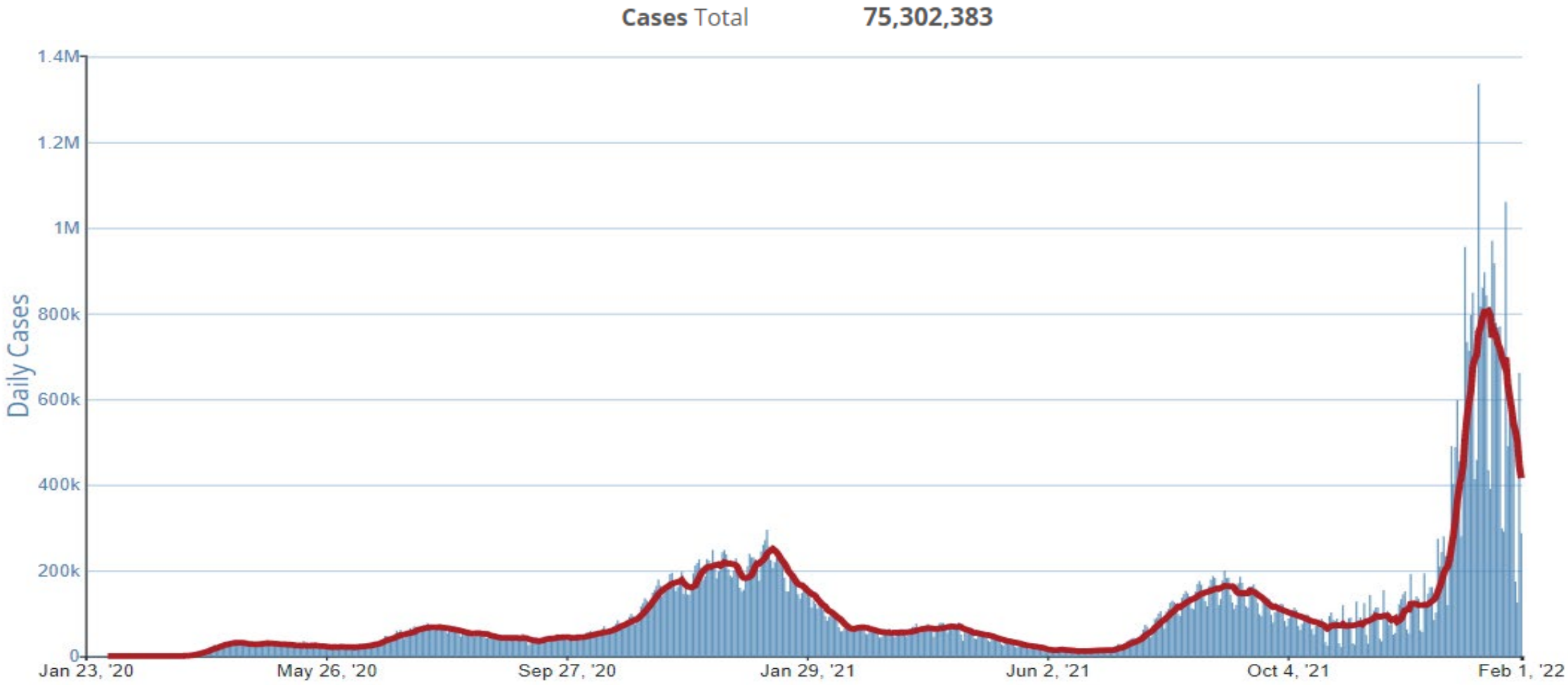
"The intervention" = Moderna COVID-19 vaccine, given to adults ages 18 years and older

"The problem" = COVID-19

EtR Domain: Public Health Problem

Trends in daily number of COVID-19 cases in the United States

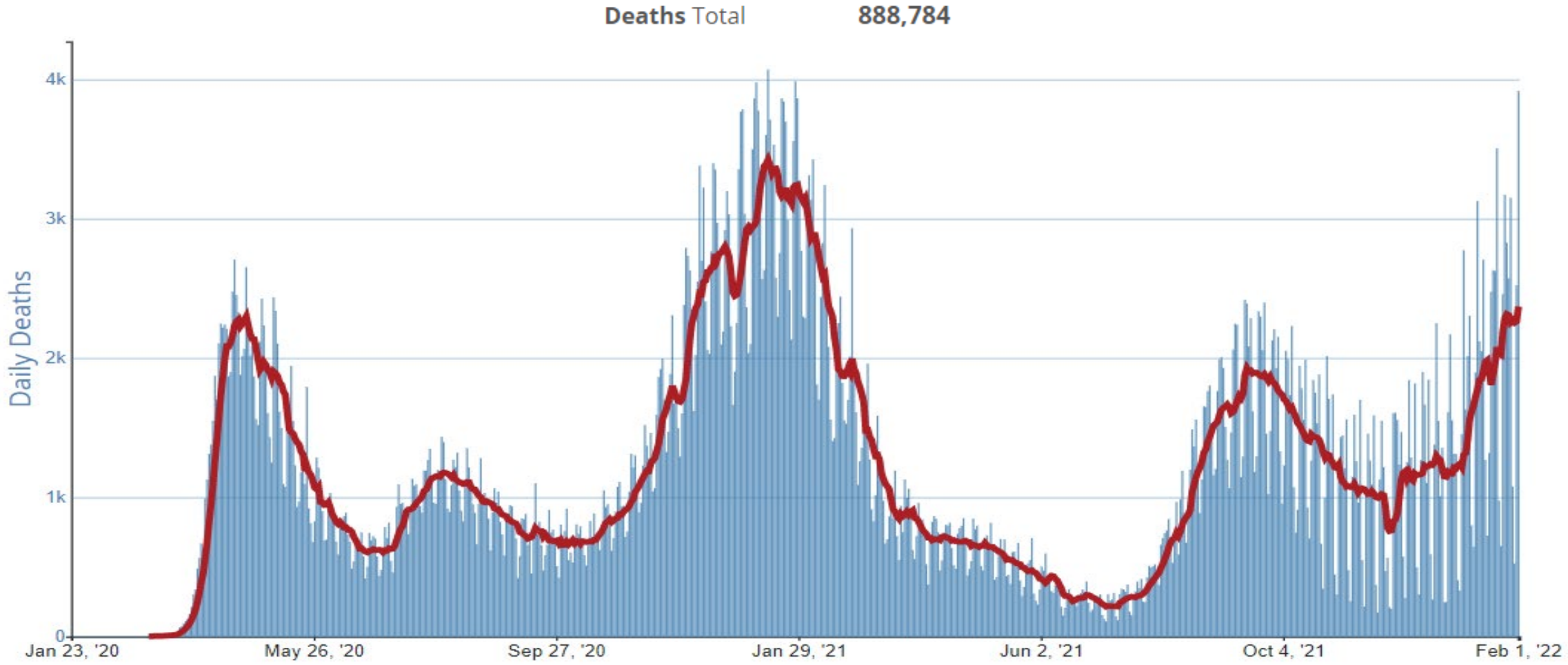
January 23, 2020 – February 1, 2022



CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#trends_dailycases Accessed February 3, 2022

Trends in daily number of COVID-19 deaths in the United States

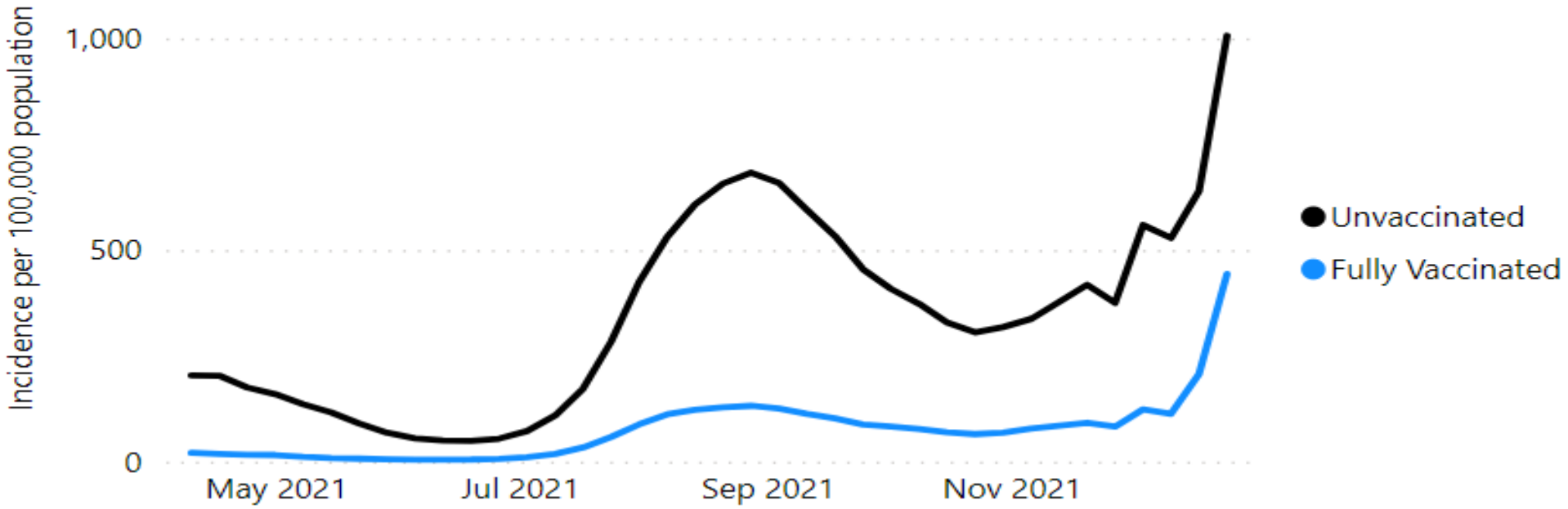
January 23, 2020 – February 1, 2022



CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#trends_dailydeaths Accessed February 3, 2022

Rates of COVID-19 cases by vaccination status

April 04 – December 25, 2021 (28 U.S. Jurisdictions)



In November, unvaccinated adults ages 18 years and older had:

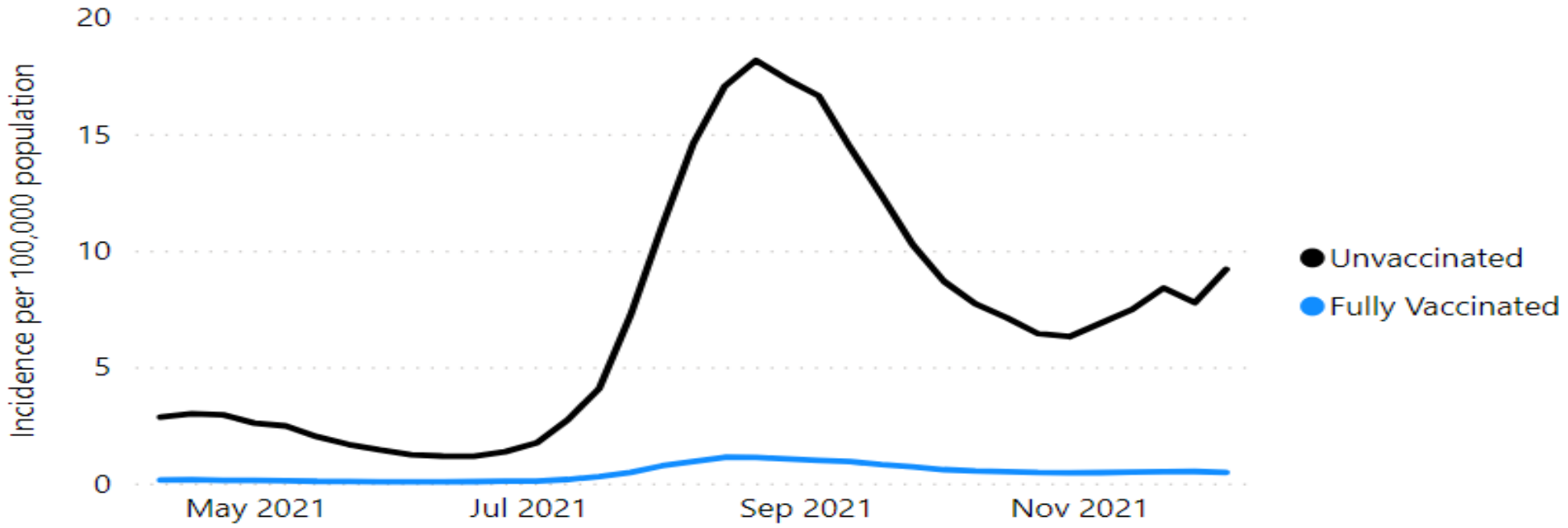
4X
Risk of Testing Positive for COVID-19

compared to fully vaccinated adults

CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status Accessed January 24, 2022

Rates of COVID-19 deaths by vaccination status

April 04 – December 25, 2021 (28 U.S. Jurisdictions)



In November, unvaccinated adults ages 18 years and older had:

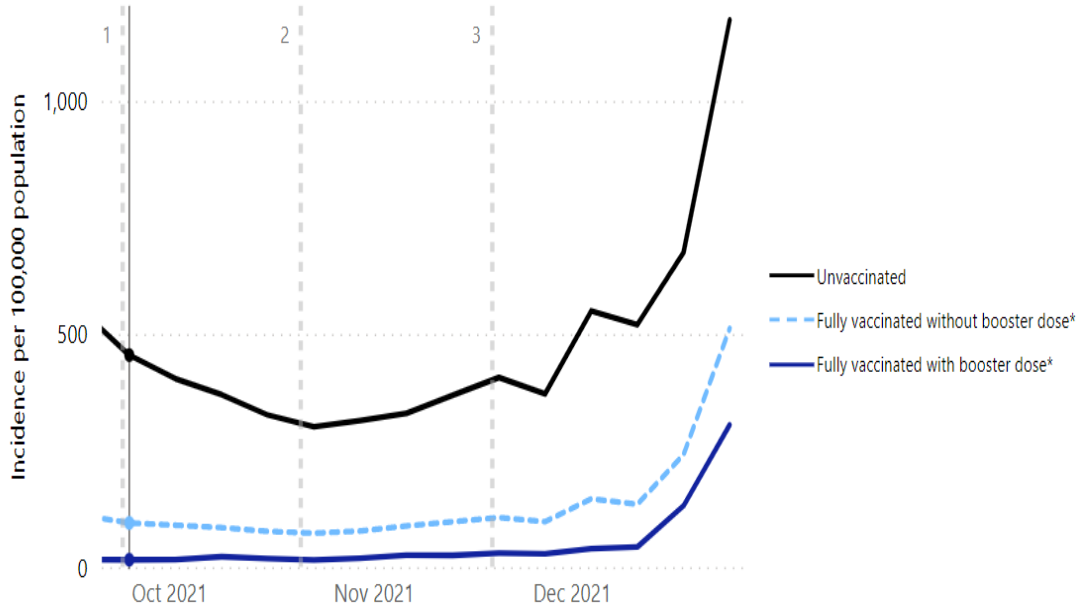
15X
Risk of Dying from COVID-19

compared to fully vaccinated adults

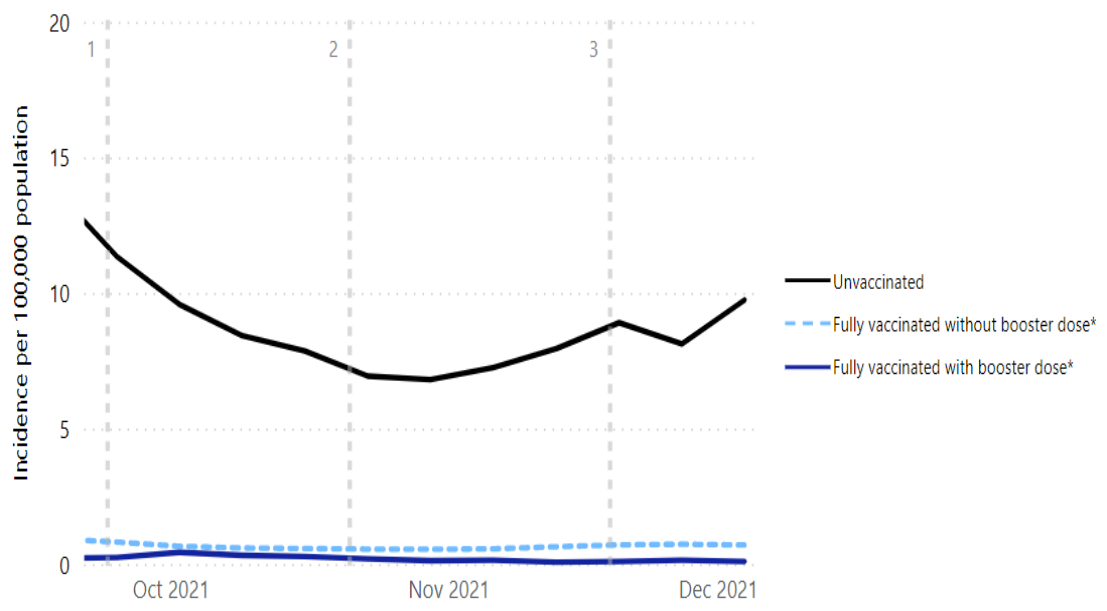
CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status Accessed January 24, 2022

Rates of COVID-19 cases and deaths by vaccination status, August 29 – December 25, 2021 (25 U.S. Jurisdictions)

Cases



Deaths



In November, unvaccinated adults ages 18 years and older had:

13X
Risk of Testing Positive for COVID-19

AND

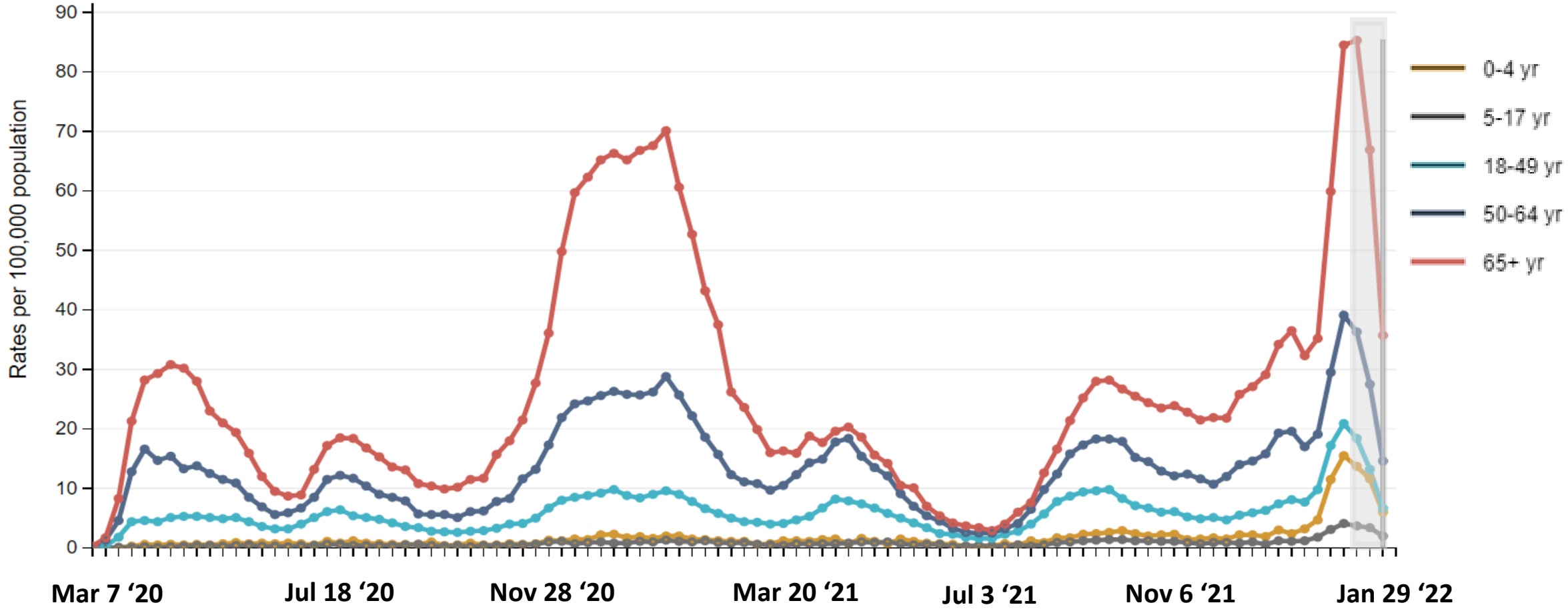
68X
Risk of Dying from COVID-19

compared to fully vaccinated adults with booster dose

CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status Accessed January 24, 2022

Weekly trends in COVID-19-associated hospitalization rates in the United States

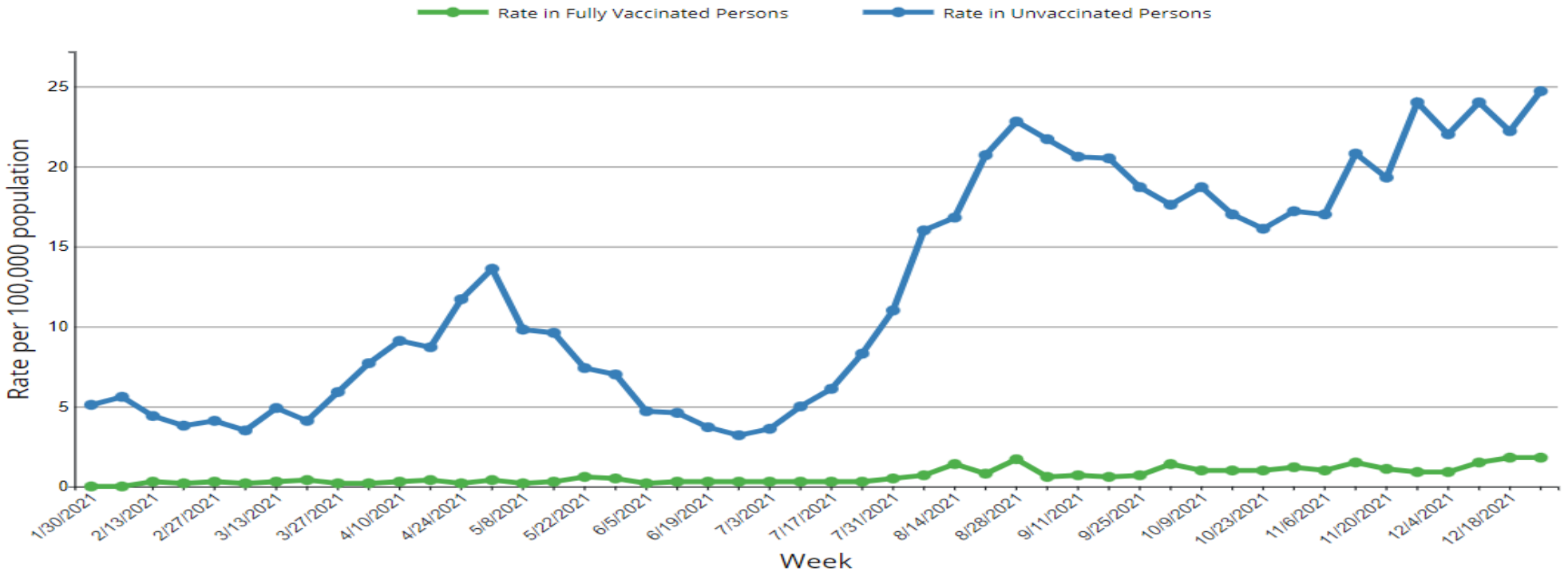
March 7, 2020 – January 29, 2022



CDC COVID-NET. https://gis.cdc.gov/grasp/covidnet/covid19_3.html Accessed February 3, 2022

Rates of COVID-19-associated hospitalizations by vaccination status in adults ages 18-49 years, January – December 2021

In December, compared to fully vaccinated adults ages 18-49 years, monthly rates of COVID-19-associated hospitalizations were **12X** higher in unvaccinated adults ages 18-49 years

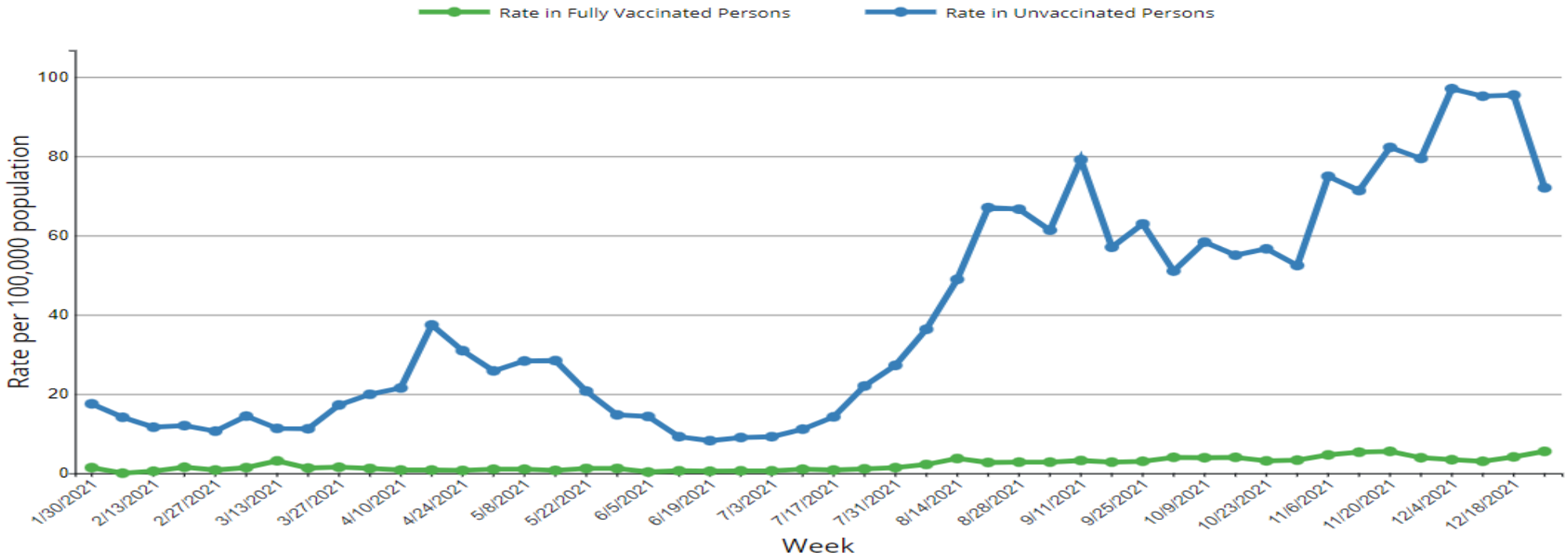


A population-based surveillance system (COVID-NET) collected data on laboratory-confirmed COVID-19-associated hospitalizations among adults through a network of over 250 acute-care hospitals in 14 states.

CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination Accessed January 31, 2022

Rates of COVID-19-associated hospitalizations by vaccination status in adults ages 50-64 years, January – December 2021

In December, compared to fully vaccinated adults ages 50-64 years, monthly rates of COVID-19-associated hospitalizations were **18X** higher in unvaccinated adults ages 50-64 years

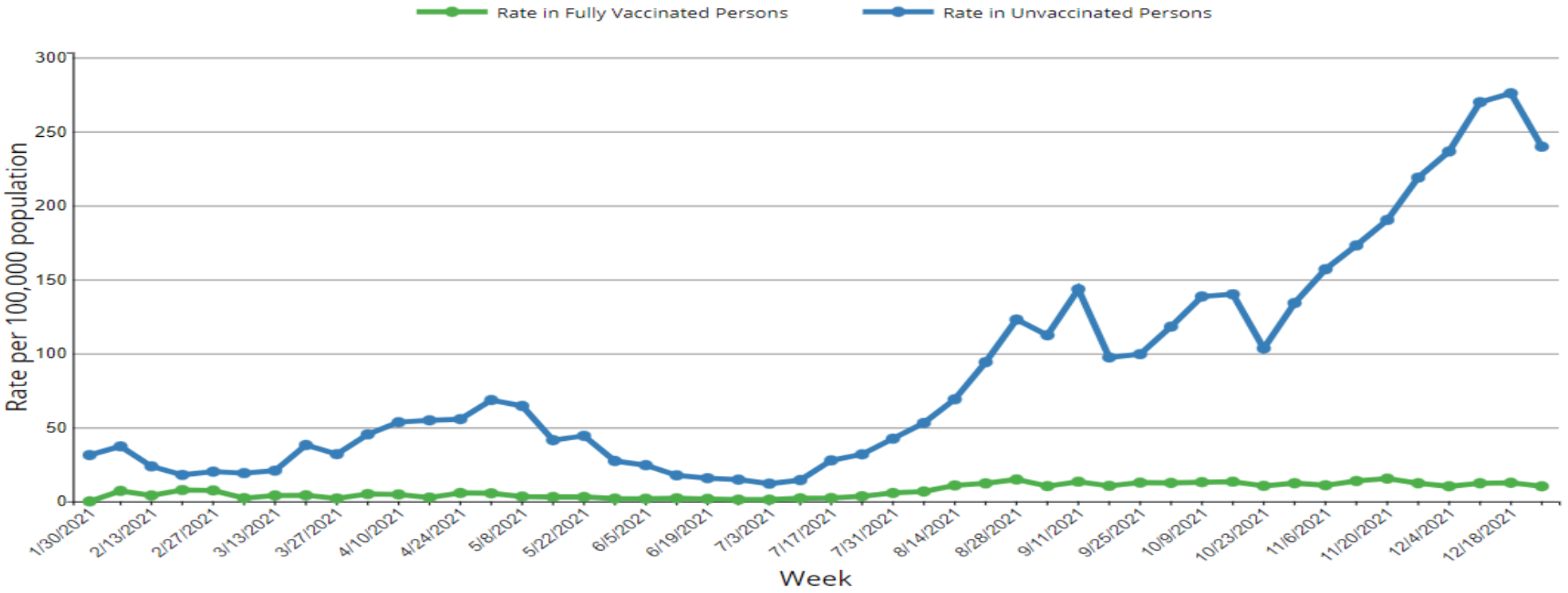


A population-based surveillance system (COVID-NET) collected data on laboratory-confirmed COVID-19-associated hospitalizations among adults through a network of over 250 acute-care hospitals in 14 states.

CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination Accessed January 31, 2022

Rates of COVID-19-associated hospitalizations by vaccination status in adults ages ≥65 years, January – December 2021

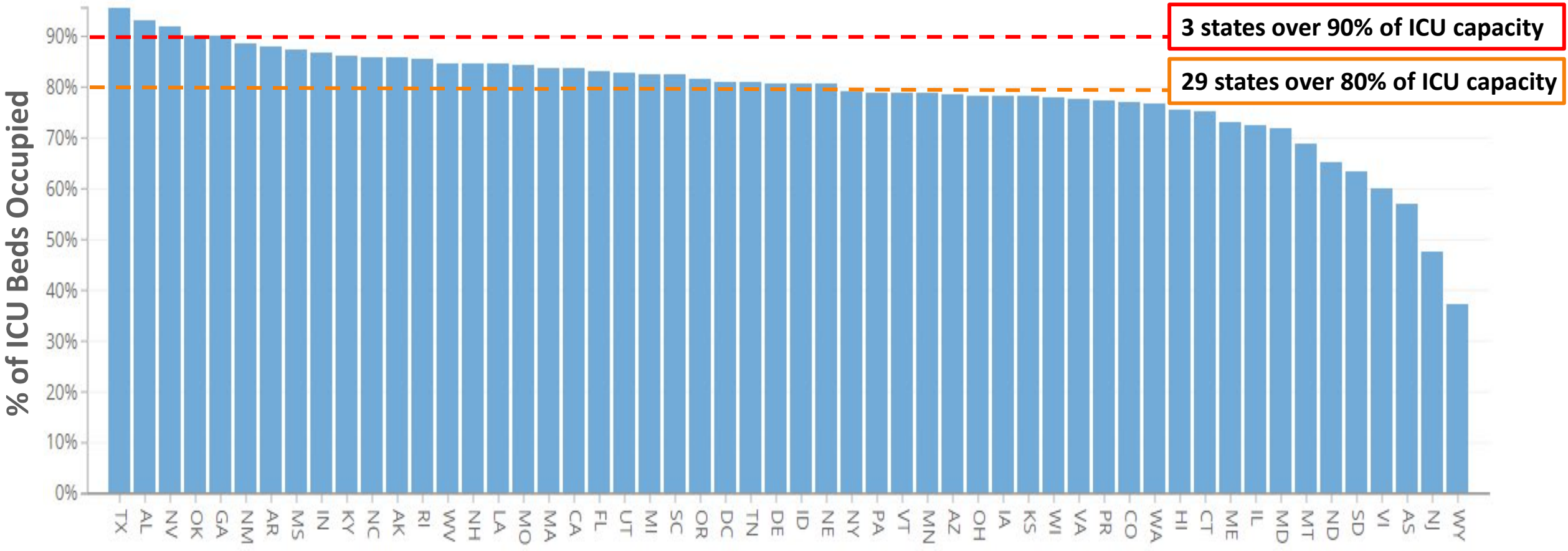
In December, compared to fully vaccinated adults ages ≥65 years, monthly rates of COVID-19-associated hospitalizations were **18X** higher in unvaccinated adults ages ≥65 years



A population-based surveillance system (COVID-NET) collected data on laboratory-confirmed COVID-19-associated hospitalizations among adults through a network of over 250 acute-care hospitals in 14 states.

CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination Accessed January 31, 2022

ICU utilization by state as of February 3, 2022

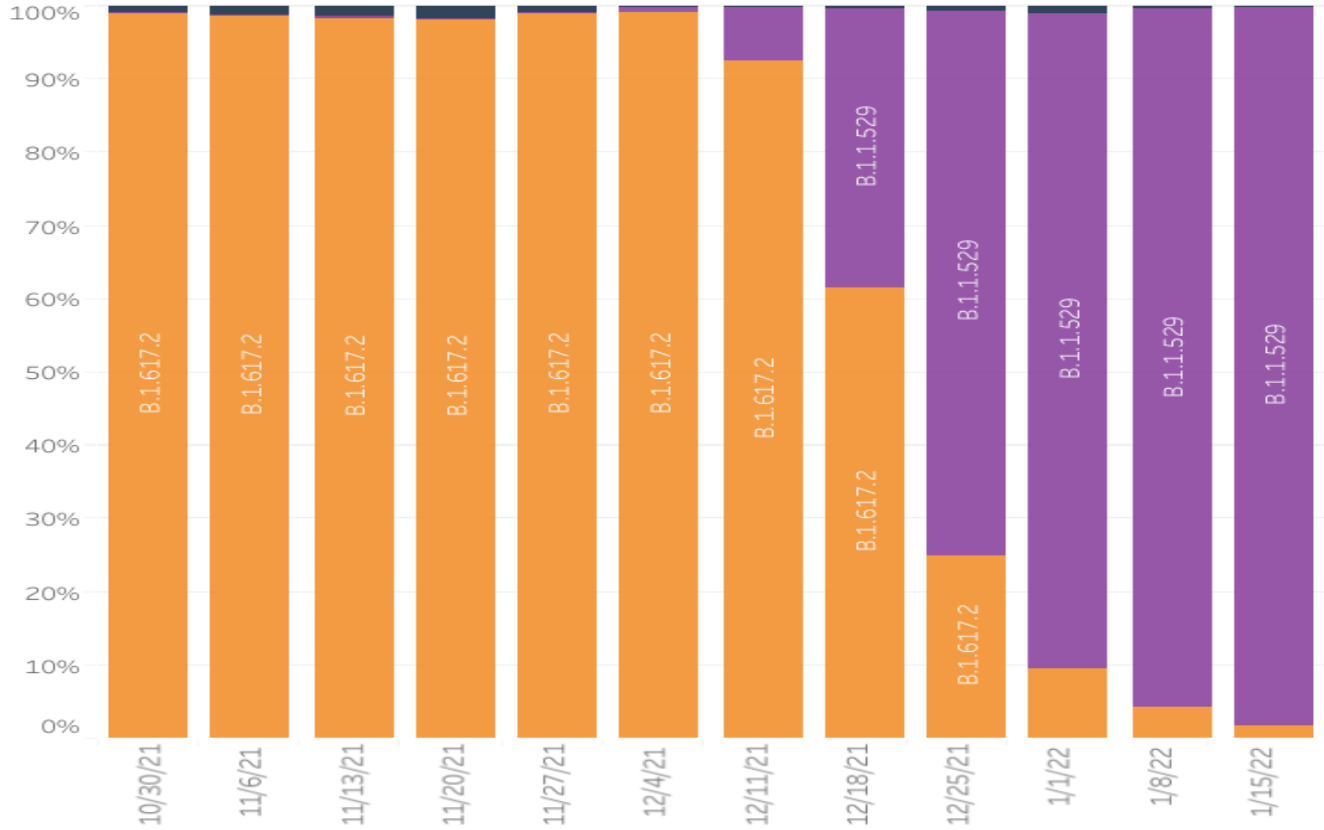


Data updated daily and provides the latest values reported by each facility within the last four days. No statistical analysis is applied to account for non-response and/or to account for missing data.

HHS Protect Public Data Hub. https://protect-public.hhs.gov/pages/hospital-utilization Accessed February 3, 2022

Omicron is the dominant circulating SARS-CoV-2 variant

United States: 10/24/2021 – 1/15/2022



United States: 1/9/2022 – 1/15/2022

USA

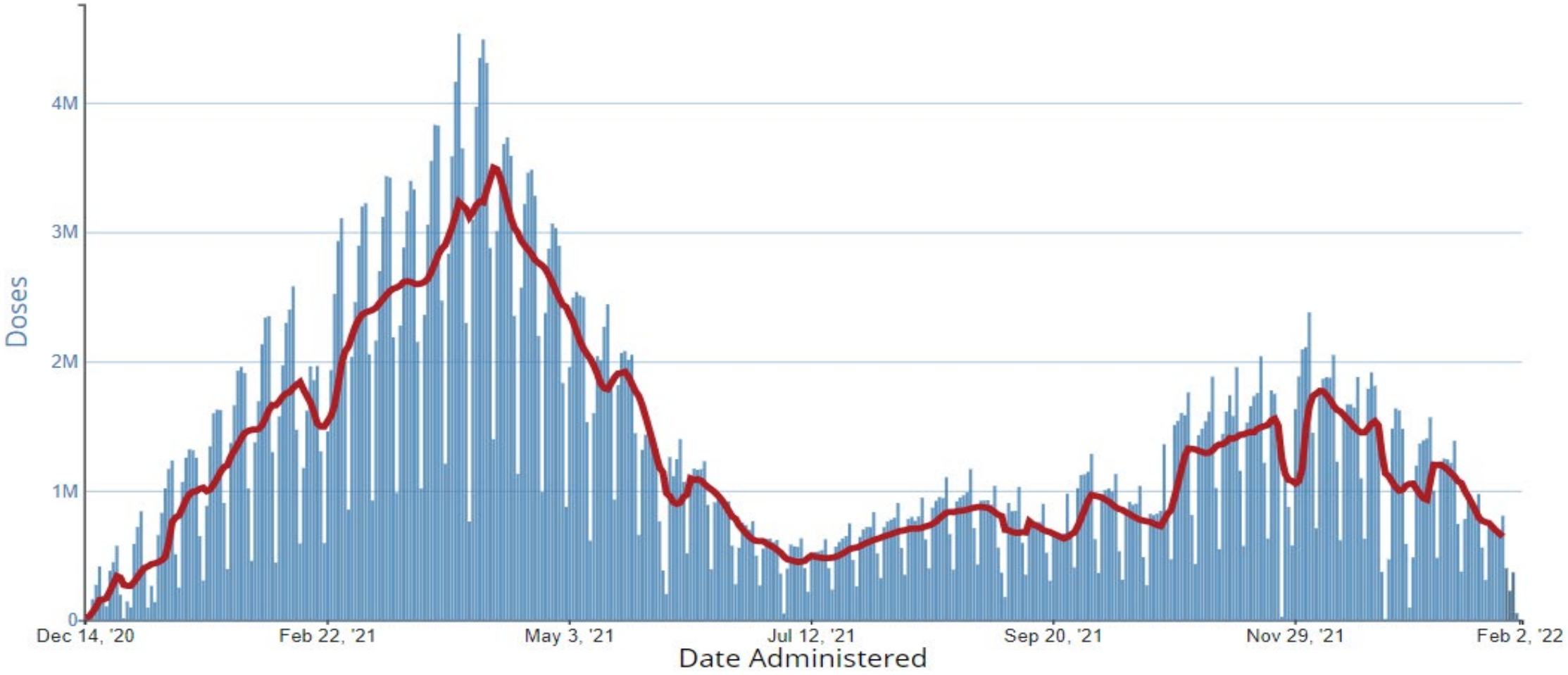
WHO label	Lineage #	US Class	%Total	95%CI
Omicron	B.1.1.529	VOC	97.8%	97.4-98.2%
Delta	B.1.617.2	VOC	1.9%	1.5-2.3%
Other	Other*		0.3%	0.2-0.5%

* Enumerated lineages are US VOC and lineages circulating above 1% nationally in at least one week period. "Other" represents the aggregation of lineages which are circulating <1% nationally during all weeks displayed.
# AY.1-AY.133 and their sublineages are aggregated with B.1.617.2. BA.1, BA.2 and BA.3 are aggregated with B.1.1.529.

CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#variant-proportions Accessed February 3, 2022

Daily trends in doses of COVID-19 vaccine administered

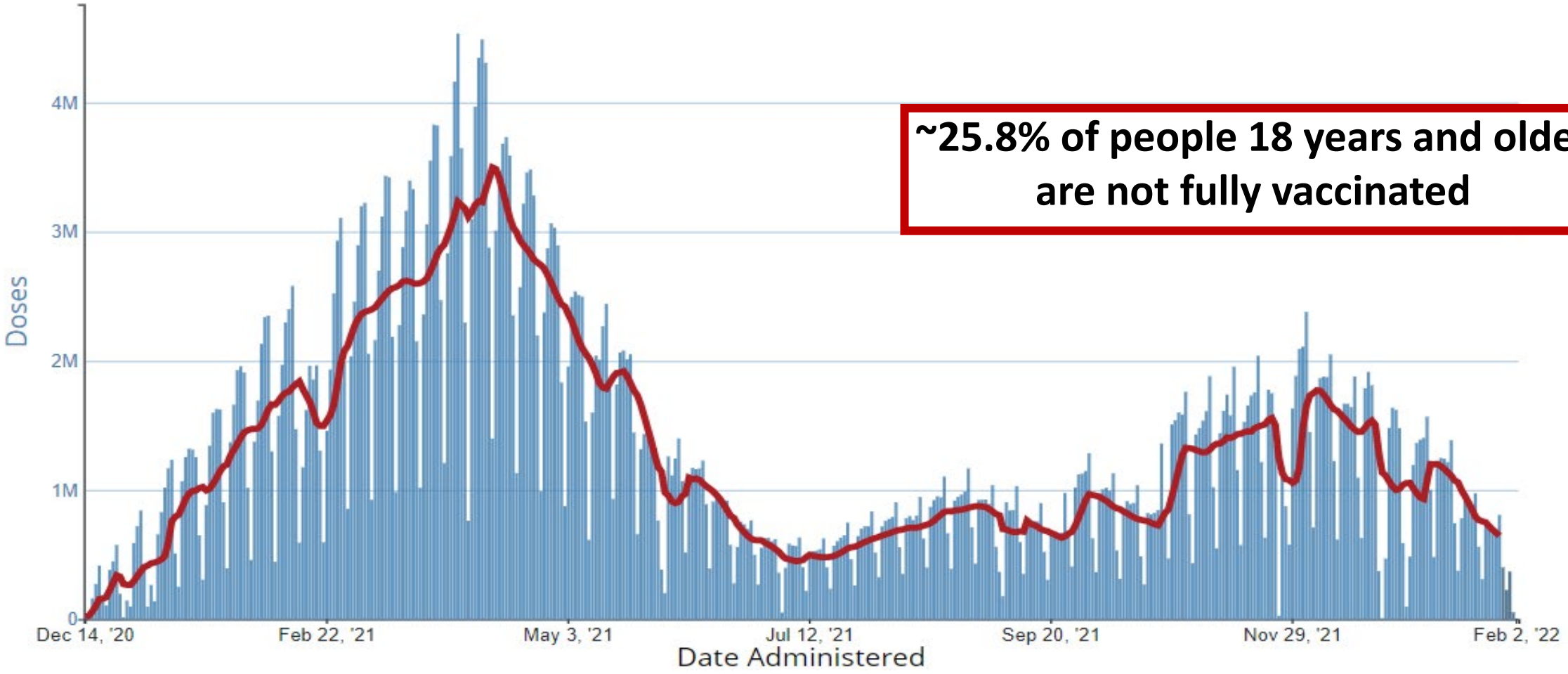
December 14, 2020 – February 1, 2022



CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#vaccination-trends Accessed February 3, 2022

Daily trends in doses of COVID-19 vaccine administered

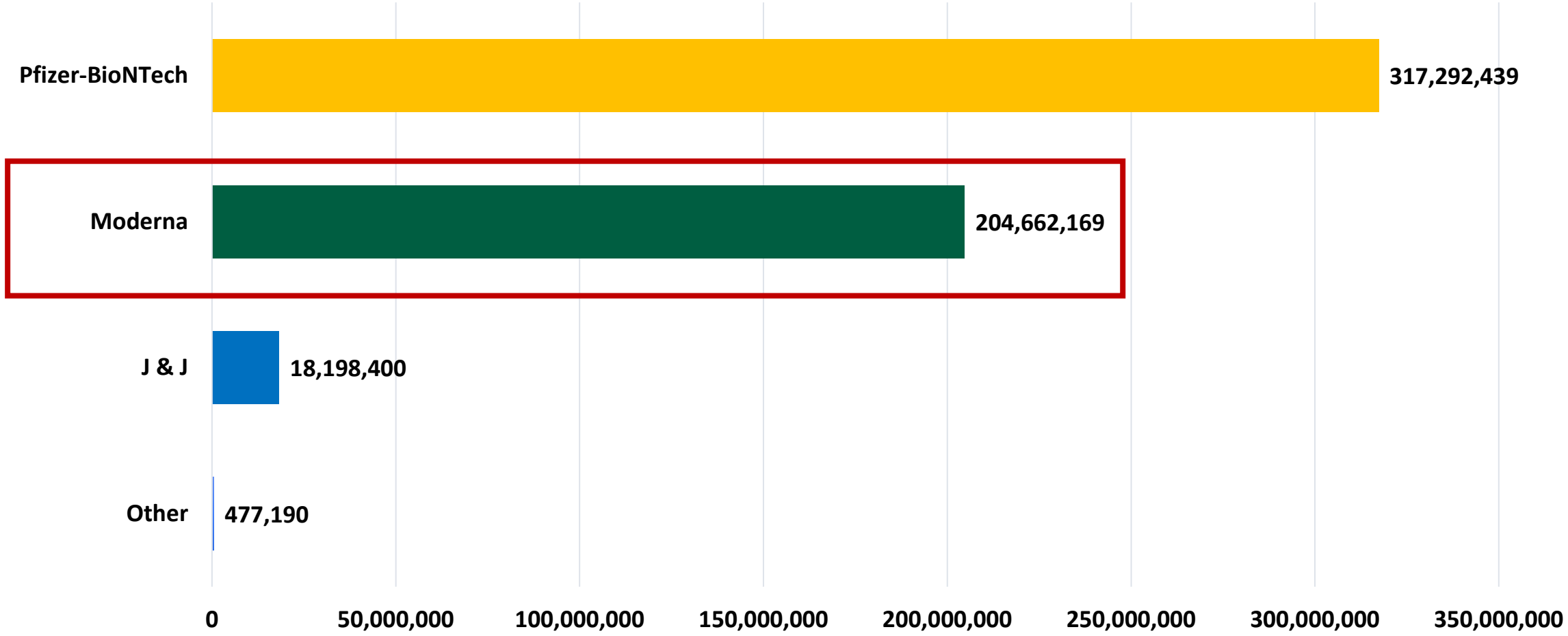
December 14, 2020 – February 1, 2022



~25.8% of people 18 years and older are not fully vaccinated

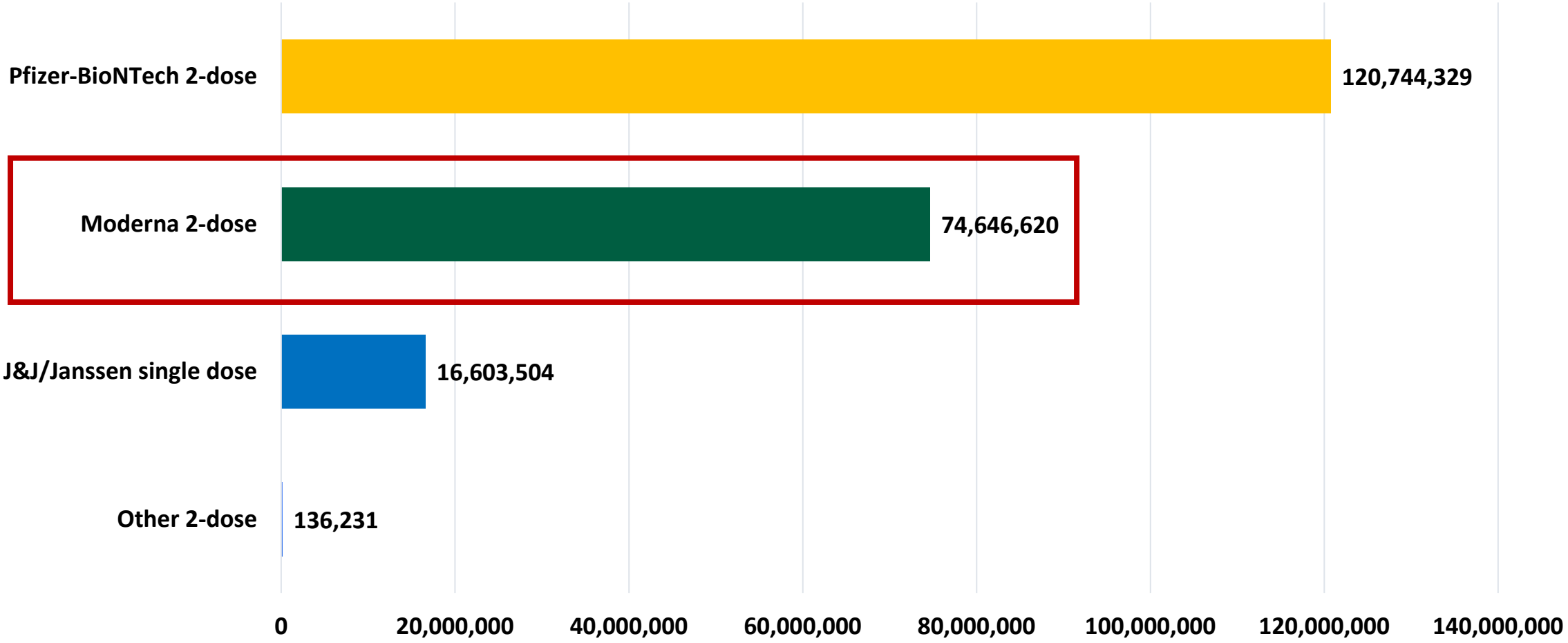
CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total Accessed February 3, 2022

U.S. COVID-19 vaccine administration by vaccine type



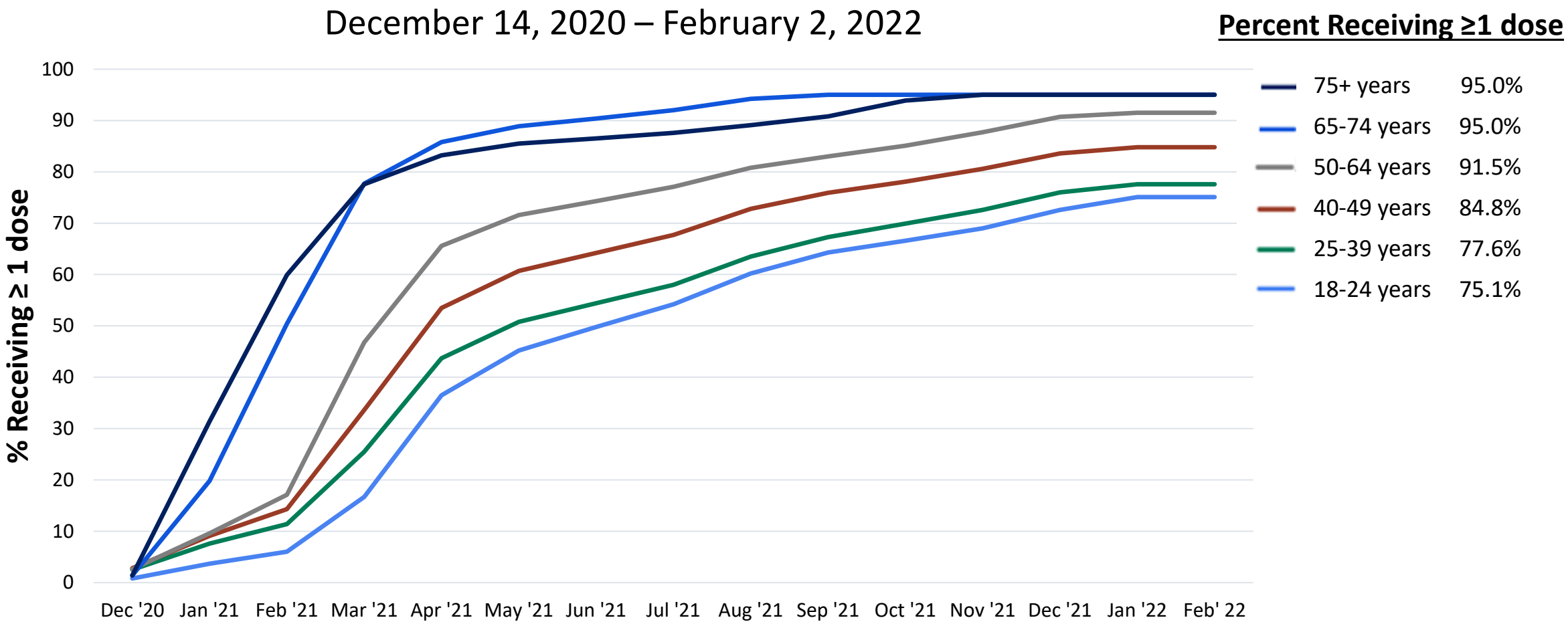
CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total Accessed February 3, 2022

Number of people fully vaccinated in the United States by COVID-19 vaccine series type



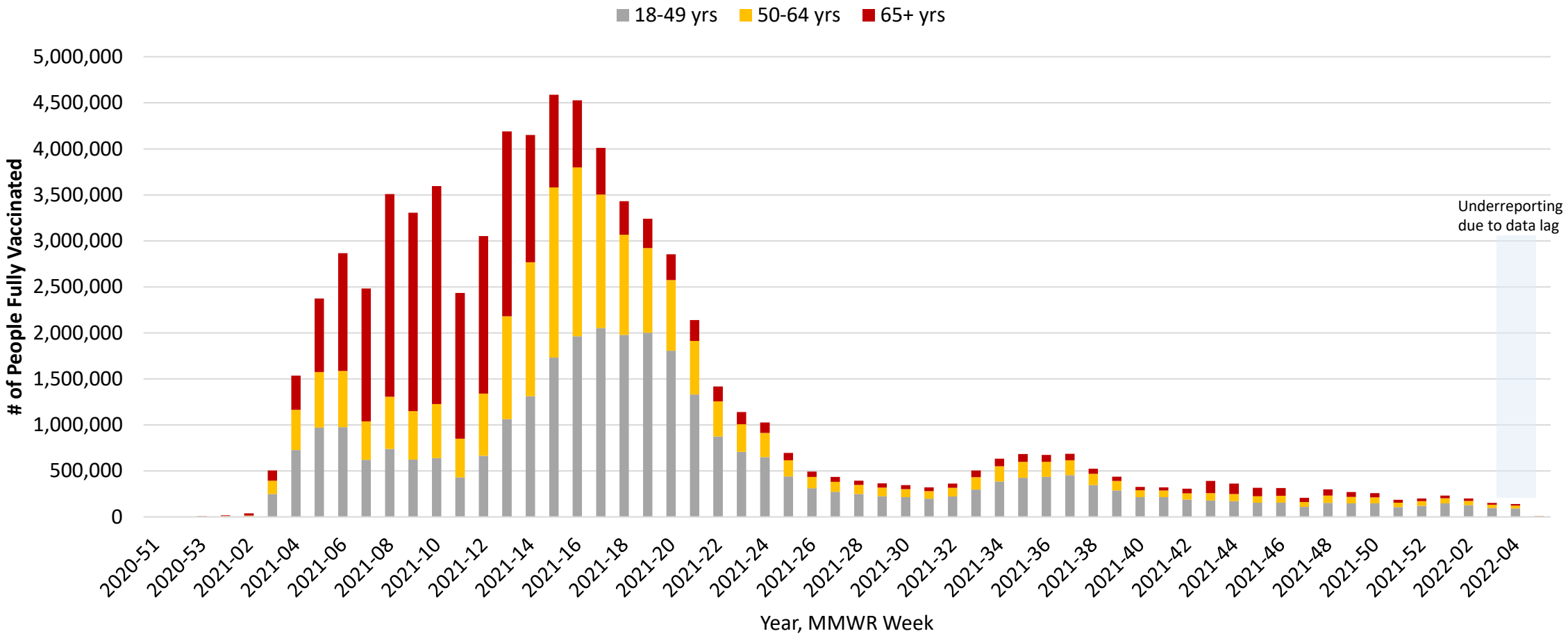
CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total Accessed February 3, 2022

Percent of COVID-19 vaccination coverage by age and date administered, United States



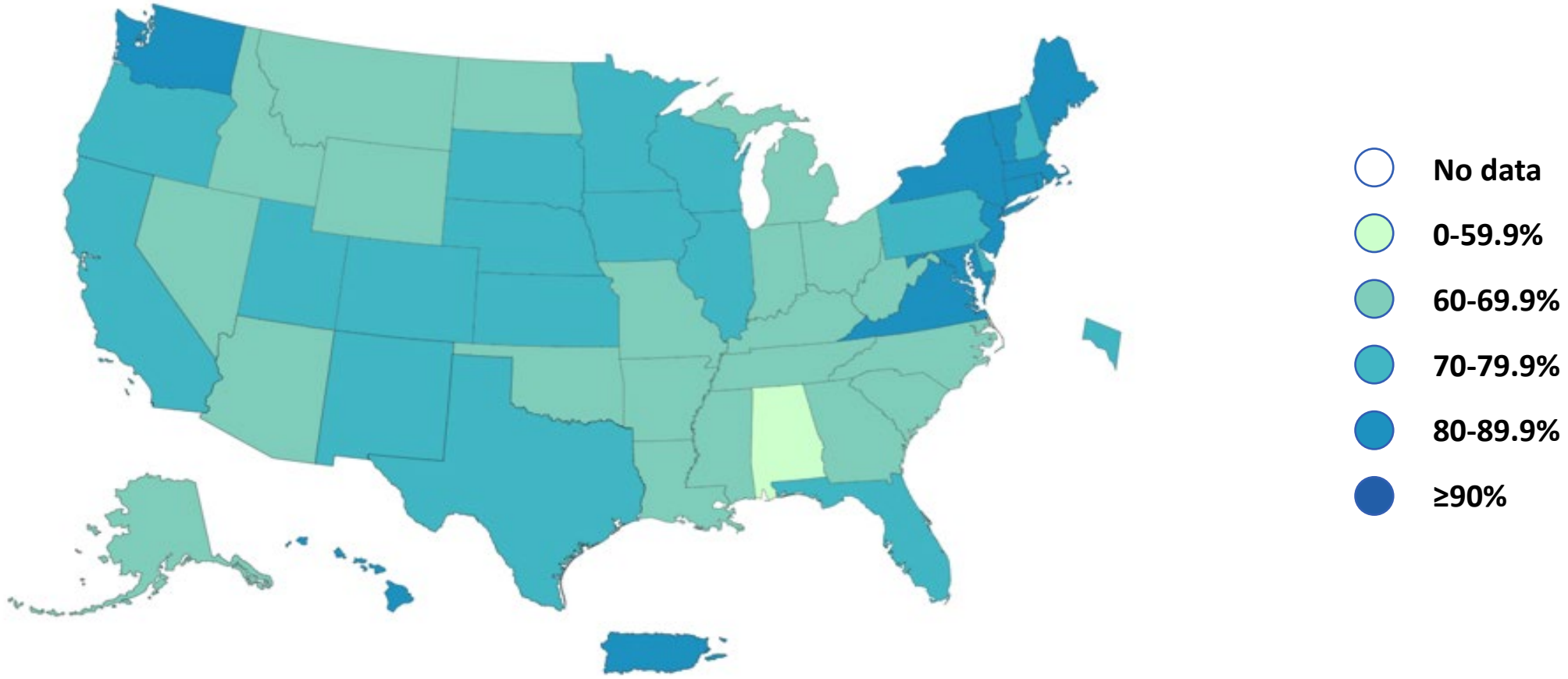
CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends Accessed February 3, 2022

People fully vaccinated with Moderna COVID-19 vaccine, by MMWR week and age group



CDC Data Analytics and Visualization Task Force; Data included through the end of January 2022

Percent of population fully vaccinated ≥18 years of age



CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-fully-percent-pop18 Accessed February 3, 2022

Summary

- The Omicron variant is the dominant circulating variant of SARS-CoV-2 in the United States
- As of January, COVID-19 cases, hospitalizations, and deaths have increased
  - In November 2021, unvaccinated adults ages 18 years and older had **4X** risk of testing positive and **15X** risk of dying from COVID-19 compared to fully vaccinated adults
- Increasing cases are taxing healthcare resources, with many states facing ICU bed shortages again
- Over 212 million people (63.9%) are fully vaccinated in the United States; however, vaccination coverage varies by age and geography

Public Health Problem

Work Group Interpretation

Is COVID-19 disease among adults aged 18 years and older of public health importance?

○ No	○ Probably no	○ Probably yes	○ Yes	○ Varies	○ Don't know

EtR Domain: Benefits and Harms

Benefits and harms assessments

- GRADE
- Potential risk of myocarditis
- Potential benefit and harm balance

GRADE= Grading of Recommendations, Assessment, Development and Evaluation

Benefits and Harms

Summary of the Available Evidence: Benefits

The clinical trial demonstrated efficacy against symptomatic, laboratory-confirmed COVID-19, which was further supported by observational data. The overall efficacy was 92.7% (95% CI: 90.4%, 94.4%).

High certainty of evidence

The clinical trial demonstrated efficacy against hospitalization due to COVID-19, which was further supported by observational data. The overall efficacy was 95.9% (95% CI: 69.5%, 99.4%).

Moderate certainty of evidence

Deaths were uncommon in the clinical trial, however observational data demonstrated effectiveness against death due to COVID-19. The pooled vaccine effectiveness was 93.8% (95% CI: 91.5%, 95.4%).

Moderate certainty of evidence

The clinical trial demonstrated efficacy against asymptomatic SARS-CoV-2 infection. The overall efficacy was 57.4% (95% CI: 50.1%, 63.6%).

High certainty of evidence

Benefits and Harms

Summary of the Available Evidence: Harms

Serious adverse events (SAEs) were reported in a similar proportion among recipients of vaccine and placebo (1.7% vs 1.9%). Two specific, rare SAEs have been associated with vaccination through safety surveillance.

Moderate certainty of evidence

Severe reactions were more common in vaccine recipients; any grade ≥3 reaction was reported by 21.3% of vaccinated versus 4.5% of placebo group.

High certainty of evidence

Conclusion

GRADE

Policy question: Focuses on recommendation following licensure of Moderna COVID-19 vaccine primary series that has been in use for a year under an emergency use authorization

Benefits: Supported by body of evidence from randomized controlled trials (RCTs) and observational studies

- RCT evidence demonstrated efficacy for all beneficial outcomes, including the 2 critical outcomes: symptomatic disease and hospitalization
- Efficacy data further supported by body of evidence from observational studies

Harms:

- Grade 3 reactions were more common in vaccine than placebo recipients
- SAEs occurred at a similar frequency in vaccine and placebo groups
- Two specific, rare SAEs have been associated with vaccination through safety surveillance

Benefits and harms assessments

- GRADE
- Potential risk of myocarditis
- Potential benefit and harm balance

GRADE= Grading of Recommendations, Assessment, Development and Evaluation

Summary

Myocarditis after Moderna COVID-19 vaccine: U.S. data

- VAERS demonstrates reporting rates of myocarditis greater than the background rates for males (18–49 years) and females (after dose 2, 18–29 years)
- At least 90 day after myocarditis diagnosis, most patients reported no impact on their quality of life, and most did not report missing school or work
  - Most (81%) healthcare providers indicated the patient was probably or fully recovered

Benefit and risk balance for Moderna COVID-19 vaccine in adults ages 18–39 years

Benefits

Moderna COVID-19 vaccine

Risks

Moderna COVID-19 vaccine

Methods for assessment of benefit-risk balance

Benefits — Calculated per 1 million people who are fully vaccinated

- Age group: 18 – 39 years
  - Selected because this age group has the highest rates of myocarditis and lowest hospitalization rates among adults, and would therefore have the closest benefit/risk margin
- Age/sex specific hospitalization rates: COVID-NET (average of rates from Dec 11-Jan 1, 2022)[1]
- Pooled vaccine-specific VE estimates from two platforms[2]
- Time Horizon: 150-day period

Harms — Calculated per 1 million people who are fully vaccinated

- Vaccine-specific myocarditis rates from Vaccine Safety Datalink (VSD)

VE: Vaccine Effectiveness

[1]https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html

[2]https://covid.cdc.gov/covid-data-tracker/#vaccine-effectiveness

Vaccine-specific estimates of effectiveness against COVID-19 hospitalization

VE against COVID-19 hospitalization[1]			
	IVY Network[2], Oct – Nov, 2021 % (95% CI)	VISION[2], Aug – Dec, 2021, % (95% CI)	Pooled VE Estimate
Moderna	91 (89-93)	92 (91-93)	92

VE= vaccine effectiveness; VE reported for 2 doses of mRNA COVID-19 vaccines

1. https://covid.cdc.gov/covid-data-tracker/#vaccine-effectiveness
2. VE estimate for 17-179 days after 2nd dose

Reporting rates of myocarditis following Moderna COVID-19 vaccination (per million 2nd doses administered) among persons ages 18-39 years[1]

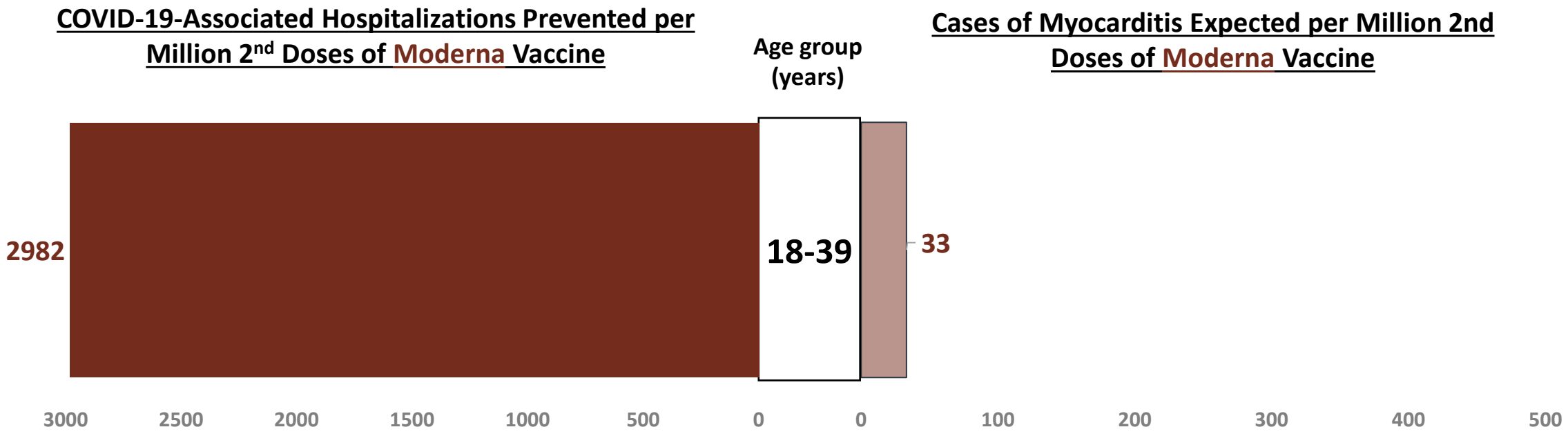
Vaccine	Sex	Rate per 1M 2nd Doses in 7-day risk period among persons ages 18–39 years[2]
Moderna	Males	67.5
	All	33.0

1. Data from the Vaccine Safety Datalink (VSD): https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html
2. Data through Jan 15, 2022

Benefits and risks after mRNA COVID-19 vaccines among persons ages 18-39 years

per million 2nd doses

- COVID-19-associated hospitalizations prevented by Moderna COVID-19 vaccine compared with myocarditis cases expected



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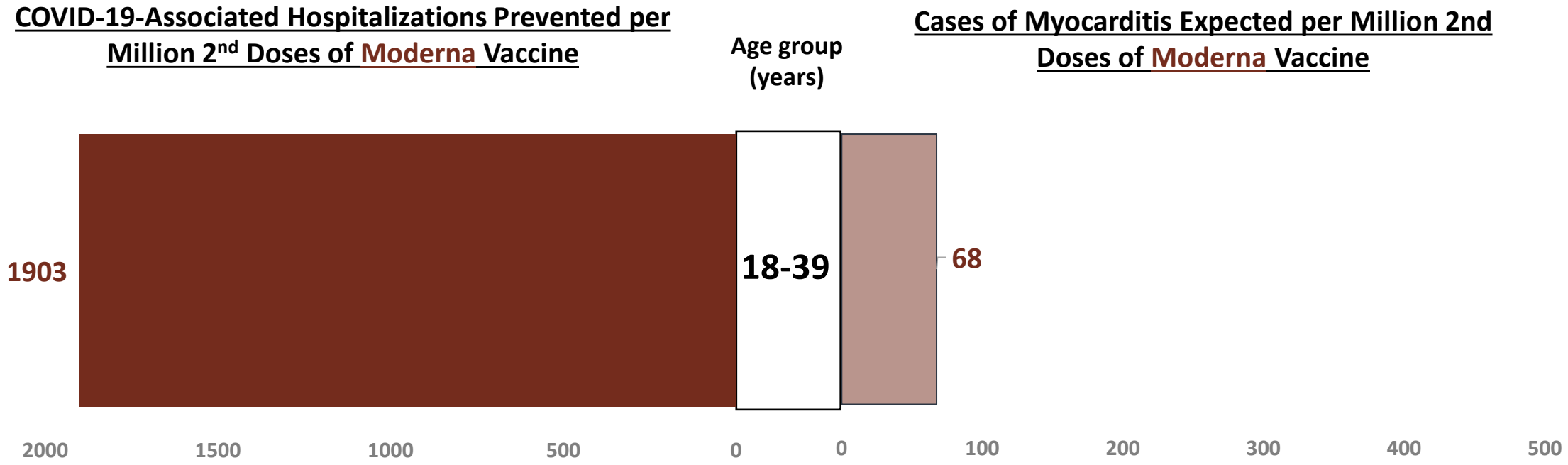
Benefits and risks after mRNA COVID-19 vaccines among males ages 18-39 years

per million 2nd doses

- COVID-19-associated hospitalizations prevented by Moderna COVID-19 vaccines compared with myocarditis cases expected



Limitations

- Benefit-risk analysis considers direct benefits and risk over a 180-day period comparing vaccine vs. no vaccine
- VE assumptions used in the model do not yet include Omicron-specific VE estimates
- The model assumes static hospitalization rate over 5 months
  - Benefit/risk profile might change as hospitalization rates change
- Model does not account for booster doses or prior infection

Benefits and Harms

Summary

- Clinical trial and observational studies demonstrated Moderna COVID-19 vaccine is effective in the prevention of COVID-19 in persons ages 18 years and older
- Risk of myocarditis/pericarditis noted after mRNA COVID-19 vaccines
  - The highest risk was seen after the second dose among younger males
- Benefits for the Moderna COVID-19 vaccine **far outweigh** any possible vaccine-associated risks

Benefits and Harms

How substantial are the desirable anticipated effects?

- How substantial are the anticipated effect for each main outcome for which there is a desirable effect?

○ Minimal	○ Small	○ Moderate	○ Large	○ Varies	○ Don't know

Benefits and Harms

How substantial are the undesirable anticipated effects?

- How substantial are the anticipated effect for each main outcome for which there is an undesirable effect?

○ Minimal	○ Small	○ Moderate	○ Large	○ Varies	○ Don't know

Benefits and Harms

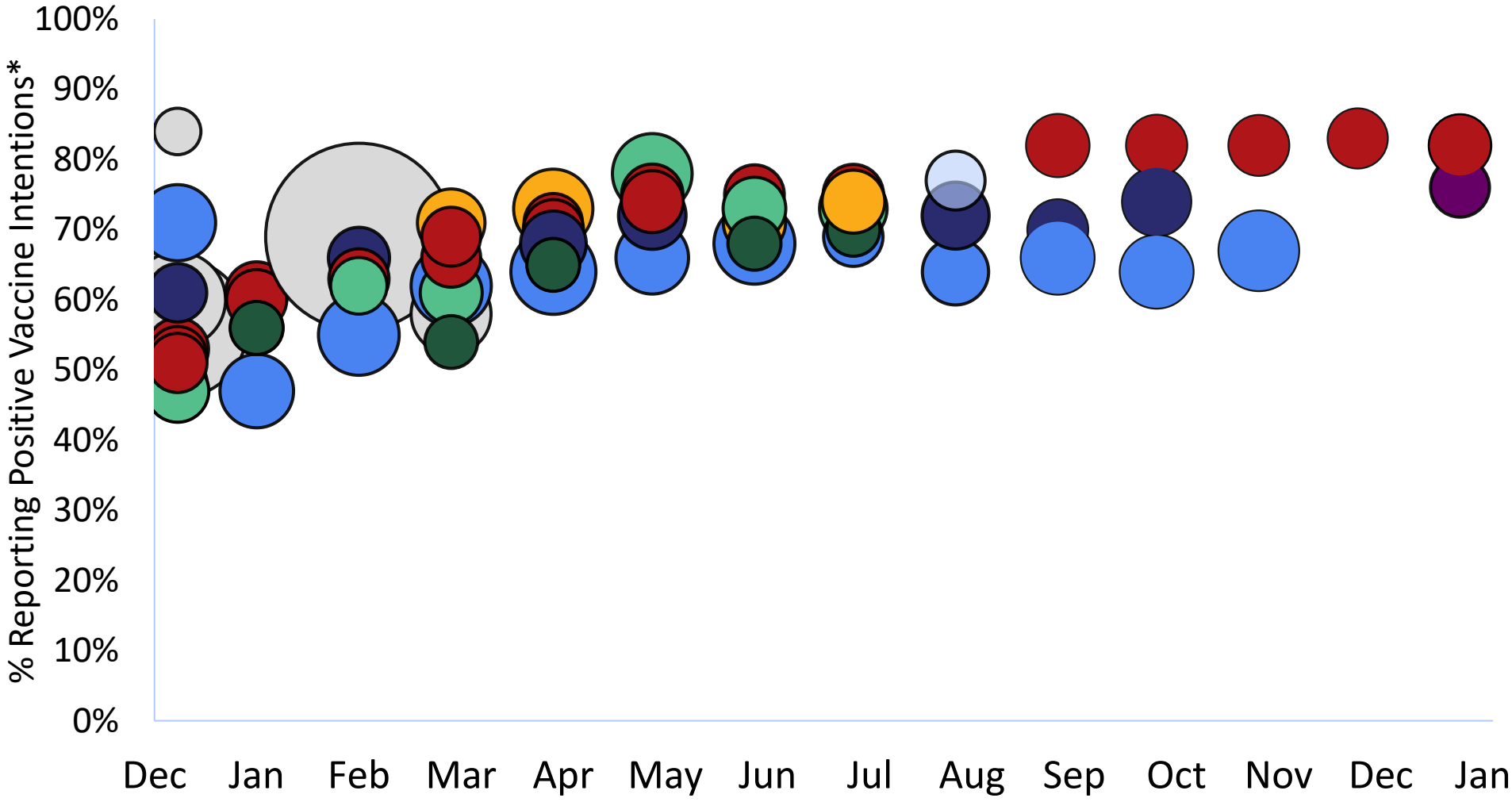
Do the desirable effects outweigh the undesirable effects?

- What is the balance between the desirable effects relative to the undesirable effects?

- ○ Favors intervention (Moderna COVID-19 vaccine)
- ○ Favors comparison (no vaccine)
- ○ Favors both
- ○ Favors neither
- ○ Unclear

EtR Domain: Values

Positive COVID-19 vaccination intent† among adults ages 18 years and older



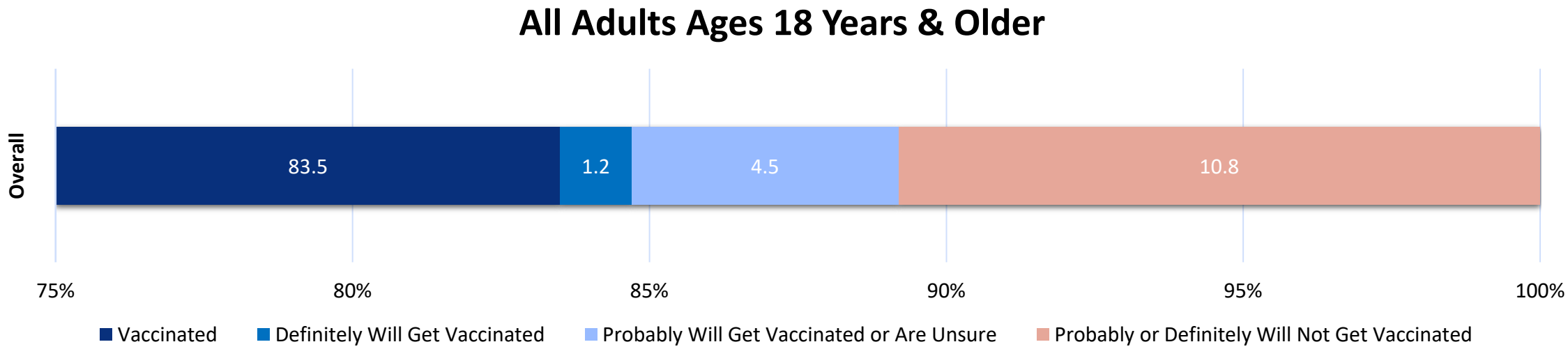
Reference	Date	N	% Intent
Szilagyi	Dec 20'	5,660	56%
Savoia	Dec 20'	2,650	60%
KFF	Dec 20'	1,676	71%
Axios-Ipsos	Dec 20'	1,009	48%
APNORC	Dec 20'	1,117	47%
Axios-Ipsos	Dec 20'	1,101	53%
Axios-Ipsos	Dec 20'	1,003	52%
Axios-Ipsos	Dec 20'	1,002	51%
Quinnipiac	Dec 20'	978	61%
ABC/IPSOS	Dec 20'	621	84%
Axios-Ipsos	Jan 21'	1,112	61%
KFF	Jan 21'	1,563	47%
Axios-Ipsos	Jan 21'	1,038	60%
Monmouth	Jan 21'	809	56%
Pew	Feb 21'	10,121	69%
KFF	Feb 21'	1,874	55%
Quinnipiac	Feb 21'	1,075	66%
Axios-Ipsos	Feb 21'	1,038	63%
APNORC	Feb 21'	914	62%
COVID Collab	Mar 21'	1,845	58%
NPR/Marist Poll	Mar 21'	1,309	71%
KFF	Mar 21'	1,862	62%
APNORC	Mar 21'	1,103	61%
Axios-Ipsos	Mar 21'	1,001	66%
Axios-Ipsos	Mar 21'	995	69%
Monmouth	Mar 21'	802	54%
NPR/Marist Poll	Apr 21'	1,809	73%
KFF	Apr 21'	2,097	64%
Axios-Ipsos	Apr 21'	979	71%
Axios-Ipsos	Apr 21'	1,033	70%
Quinnipiac	Apr 21'	1,237	68%
Monmouth	Apr 21'	800	65%
APNORC	May 21'	1,842	78%
KFF	May 21'	1,526	66%
Quinnipiac	May 21'	1,316	72%
Axios-Ipsos	May 21'	1,078	75%
Axios-Ipsos	May 21'	1,102	74%
KFF	Jun 21'	1,888	68%
NPR/Marist Poll	Jun 21'	1,115	71%
Axios-Ipsos	Jun 21'	1,016	75%
Axios-Ipsos	Jun 21'	1,027	73%
APNORC	Jun 21'	1,125	73%
Monmouth	Jun 21'	810	68%
APNORC	Jul 21'	1,308	73%
KFF	Jul 21'	1,009	69%
Axios-Ipsos	Jul 21'	1,048	75%
Monmouth	Jul 21'	804	70%
NPR/Marist Poll	Jul 21'	1,132	74%
KFF	Aug 21'	1,259	64%
Quinnipiac	Aug 21'	1,290	72%
Axios-Ipsos	Aug 21'	999	77%
Axios-Ipsos	Sept 21'	1,105	82%
Quinnipiac	Sept 21'	1,020	70%
KFF	Sept 21'	1,519	66%
Axios-Ipsos	Oct 21'	1,038	82%
KFF	Oct 21'	1,519	64%
Quinnipiac	Oct 21'	1,326	74%
Axios-Ipsos	Nov 21'	1,023	82%
KFF	Nov 21'	1,820	67%
Axios-Ipsos	Dec 21'	993	83%
Axios-Ipsos	Jan 22'	1,054	82%
Axios-Ipsos	Jan 22'	1,085	82%
NBC News	Jan 22'	1,000	76%

† **Positive vaccine intent** includes persons already vaccinated or reporting definitely, probably, or somewhat likely to get vaccinated

*Surveys with multiple time points are shown with the same color bubble for each time point. Surveys with only one time point are shown in gray.

Vaccination status and intent among all adults ages 18 years and older, United States

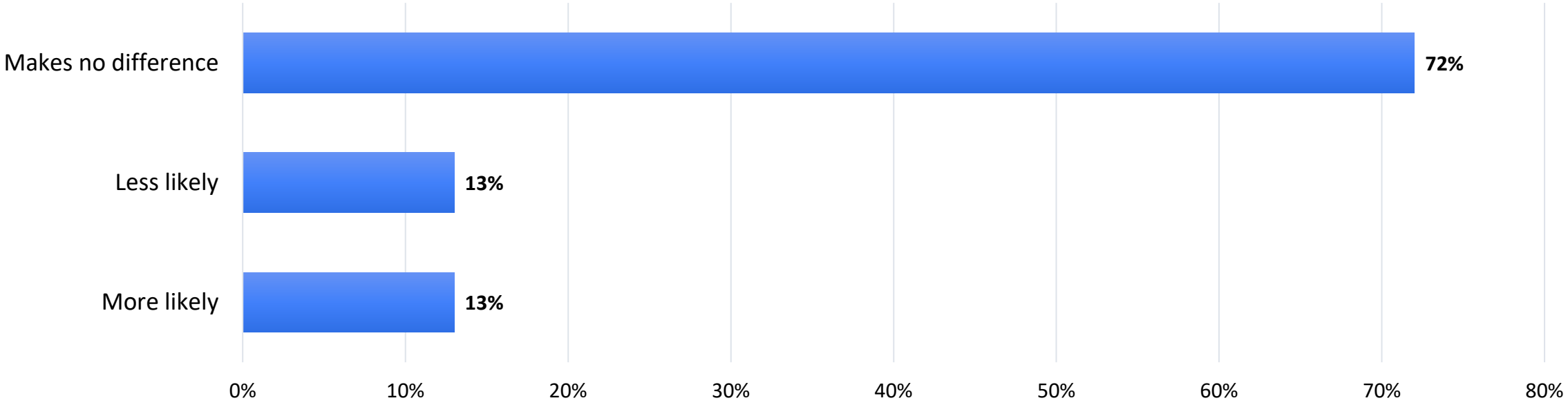
- Data collection period: January 2 – January 8, 2022 (N = 19,115)
  - **84.7%** are **Vaccinated (83.5%)** or **Definitely Will Get Vaccinated (1.2%)**
  - **4.5%** **Probably Will Get Vaccinated or Are Unsure**
  - **10.8%** **Probably or Definitely Will Not Get Vaccinated**



CDC COVID Data Tracker. Trends in COVID-19 Vaccine Confidence in the US. https://covid.cdc.gov/covid-data-tracker/#vaccine-confidence. Accessed January 21, 2022

Vaccination intent among unvaccinated adults ages 18 years and older

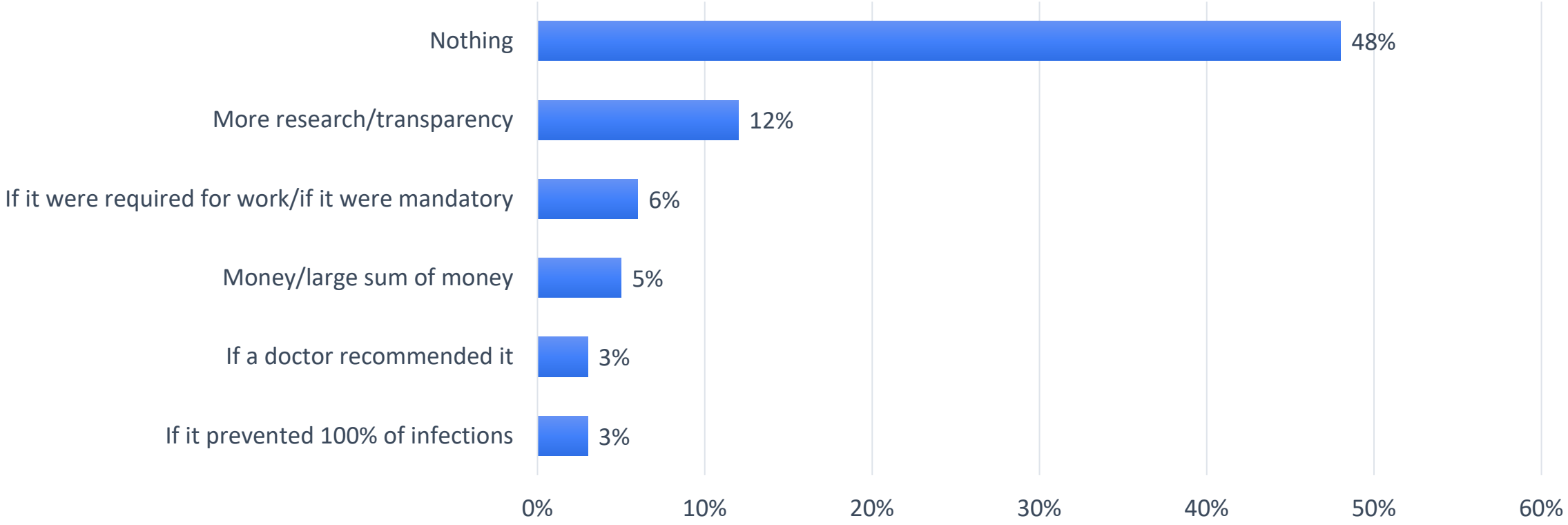
- A survey of the American general population (N = 1,094) was conducted on individuals ≥ 18 years between January 7 – 10, 2022
  - Unvaccinated survey respondents were asked, *"Does the discovery of the Omicron variant make you more likely or less likely to get the COVID-19 vaccine?*



Axios/Ipsos Poll. January 2022. https://www.ipsos.com/en-us/news-polls/axios-ipsos-coronavirus-index Accessed January 19, 2022

About half of unvaccinated adults say nothing will convince them to get a COVID-19 vaccine

- Among unvaccinated adults: *"What, if anything, will convince you to get vaccinated for COVID-19?"*



KFF COVID-19 Vaccine Monitor: Early Omicron Update (Dec 15 – 20, 2021). https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-early-omicron-update/. Accessed January 19, 2022

Rise in COVID-19 vaccinations following full FDA approval

- Initial data indicated that following the FDA's full approval of the Pfizer-BioNTech COVID-19 vaccine, the United States saw a slight uptick (17%) in the average number of Americans getting their first COVID-19 vaccine dose
  - In the week prior to full approval, an average of about 404,000 Americans were initiating vaccination each day
  - Following approval, approximately 473,000 Americans were getting their first dose each day
- Although not a rapid surge in vaccinations in the days immediately following approval, full approval may have been enough to convince some to finally get immunized

ABC news. August 31, 2021. More Americans getting vaccinated following full FDA approval of Pfizer COVID vaccine. https://abcnews.go.com/Health/americans-vaccinated-full-fda-approval-pfizer-covid-vaccine/story?id=79750505.

Survey of vaccination intent among unvaccinated adults

- Ongoing survey designed to assess vaccination intention of unvaccinated Americans in response to FDA BLA for Moderna COVID-19 vaccine
- Data collection period: January 27 – January 31, 2022
- Current unvaccinated sample (N = 507)

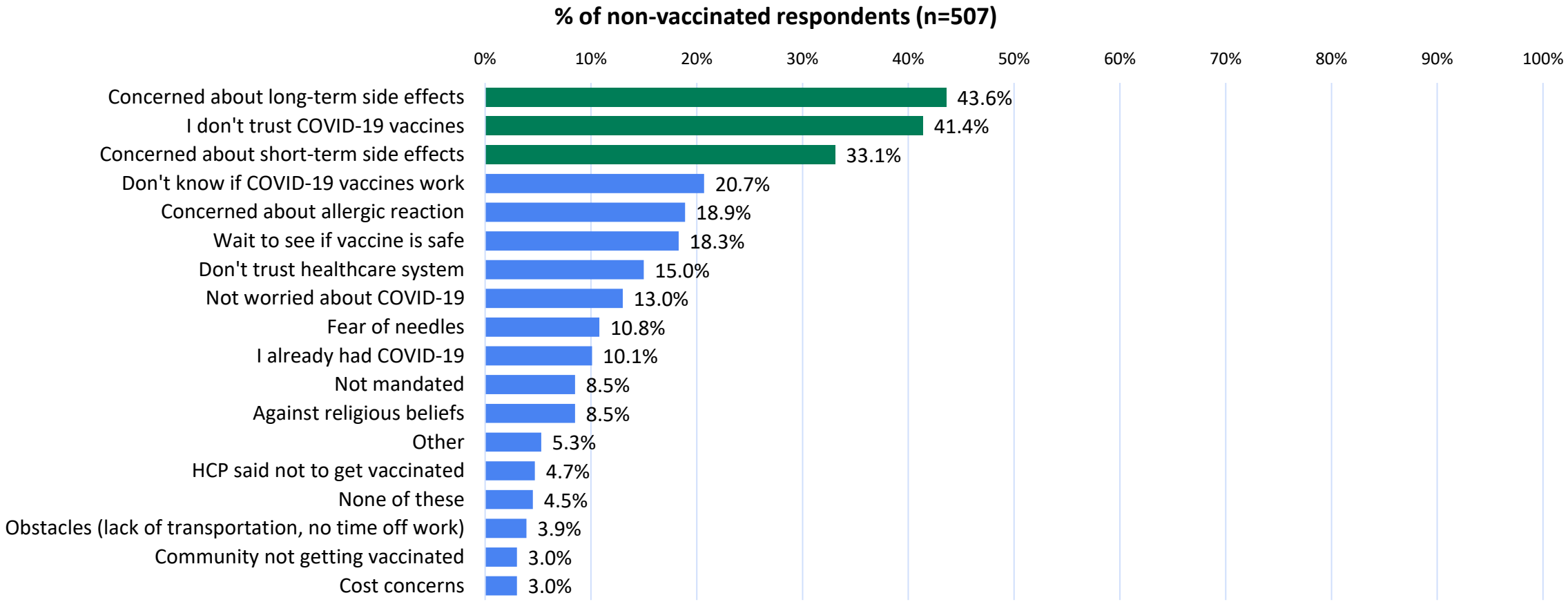
	GENDER	AGE	ETHNICITY
Partial or Unvaccinated Sample	58% Female 42% Male or Other Gender Identity	41% 18-39 Years 34% 40-59 Years 25% 60+ Years	40% Non-Hispanic White 41% Non-Hispanic Black 19% Hispanic

Data collection is ongoing until sample target is reached, consisting of 1200 partial or unvaccinated US adults

CDC and University of Iowa/RAND survey, unpublished

Reasons for remaining unvaccinated

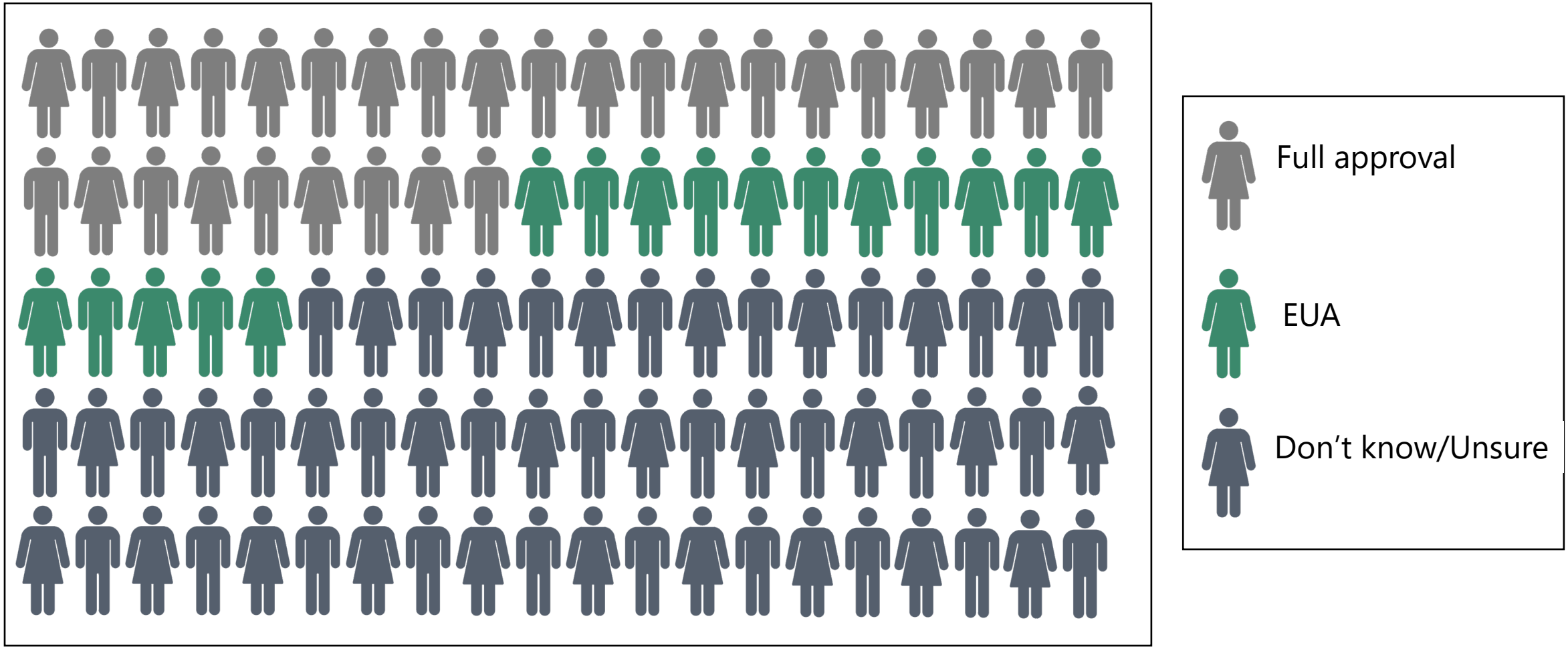
Concerns about **vaccine side effects** or **general mistrust** of COVID-19 vaccines were the top reasons given for continuing to be unvaccinated



CDC and University of Iowa/RAND survey, unpublished

Awareness of FDA status of Moderna COVID-19 vaccine

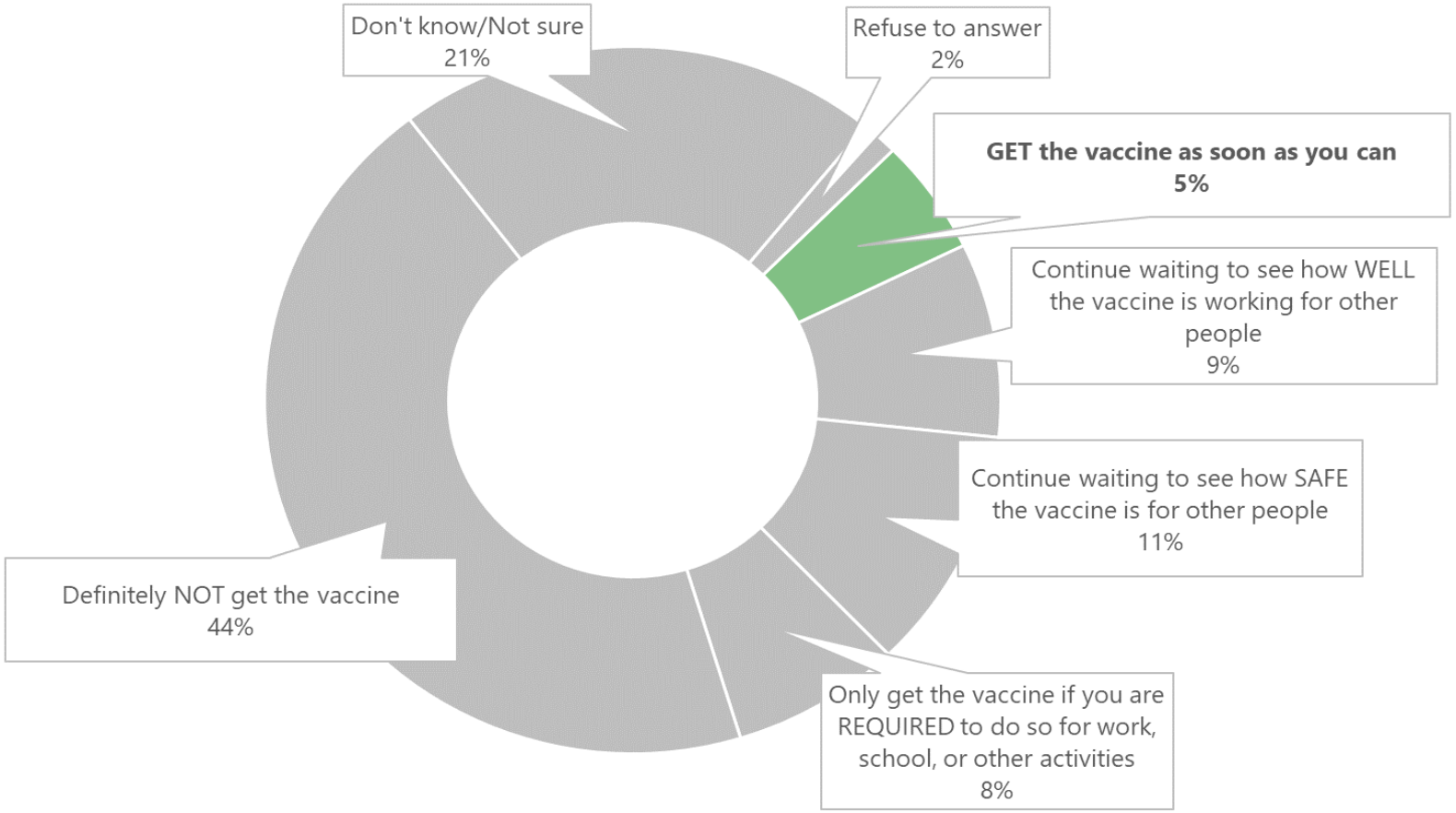
29% of unvaccinated respondents thought the Moderna COVID-19 vaccine had already received full approval from the FDA



CDC and University of Iowa/RAND survey, unpublished

Vaccination intentions in response to a Moderna FDA BLA

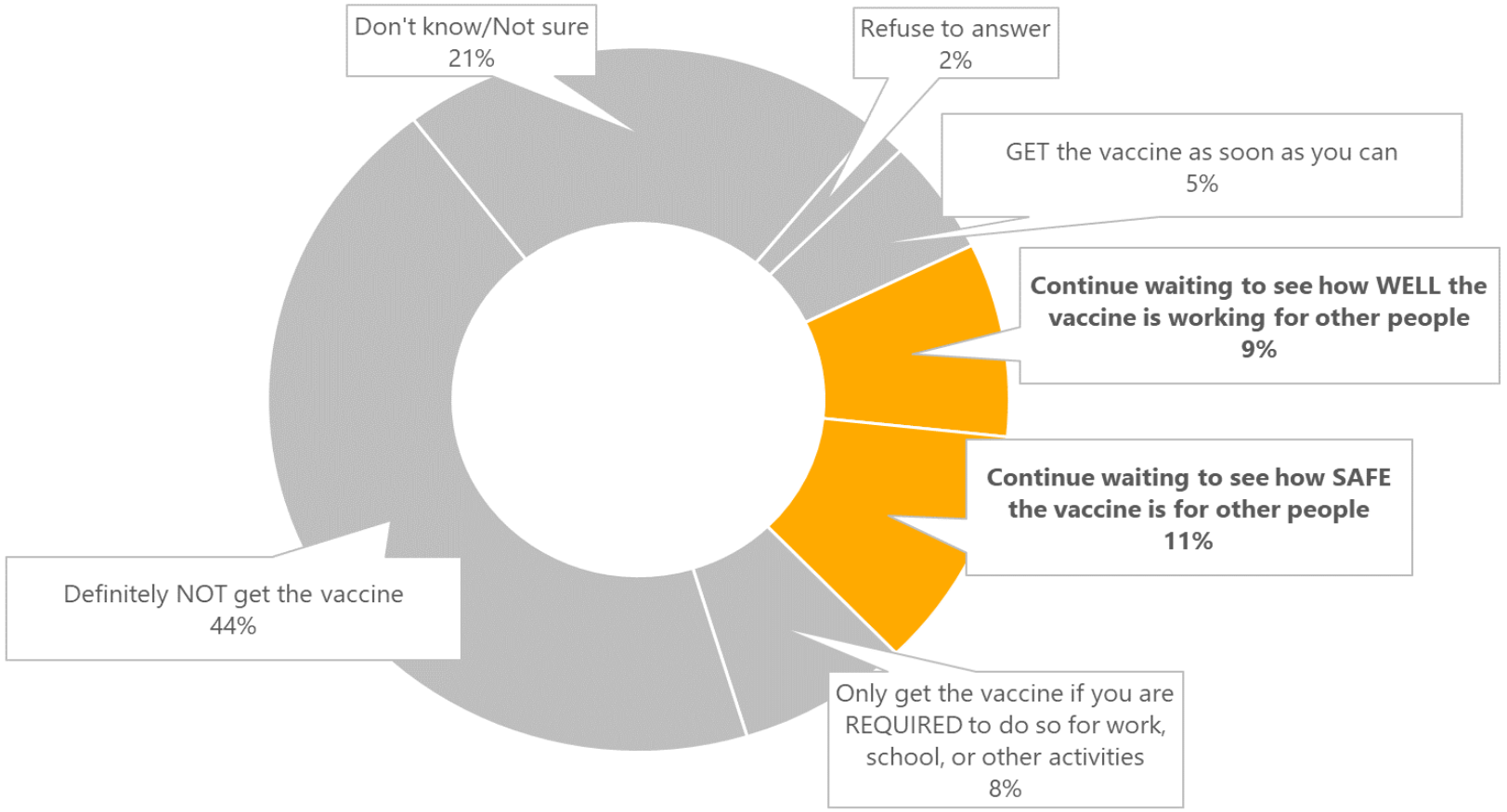
Only **5%** of unvaccinated respondents said they would get a COVID vaccine as soon as they could if the Moderna vaccine received full approval from the FDA



CDC and University of Iowa/RAND survey, unpublished

Vaccination intentions in response to a Moderna FDA BLA

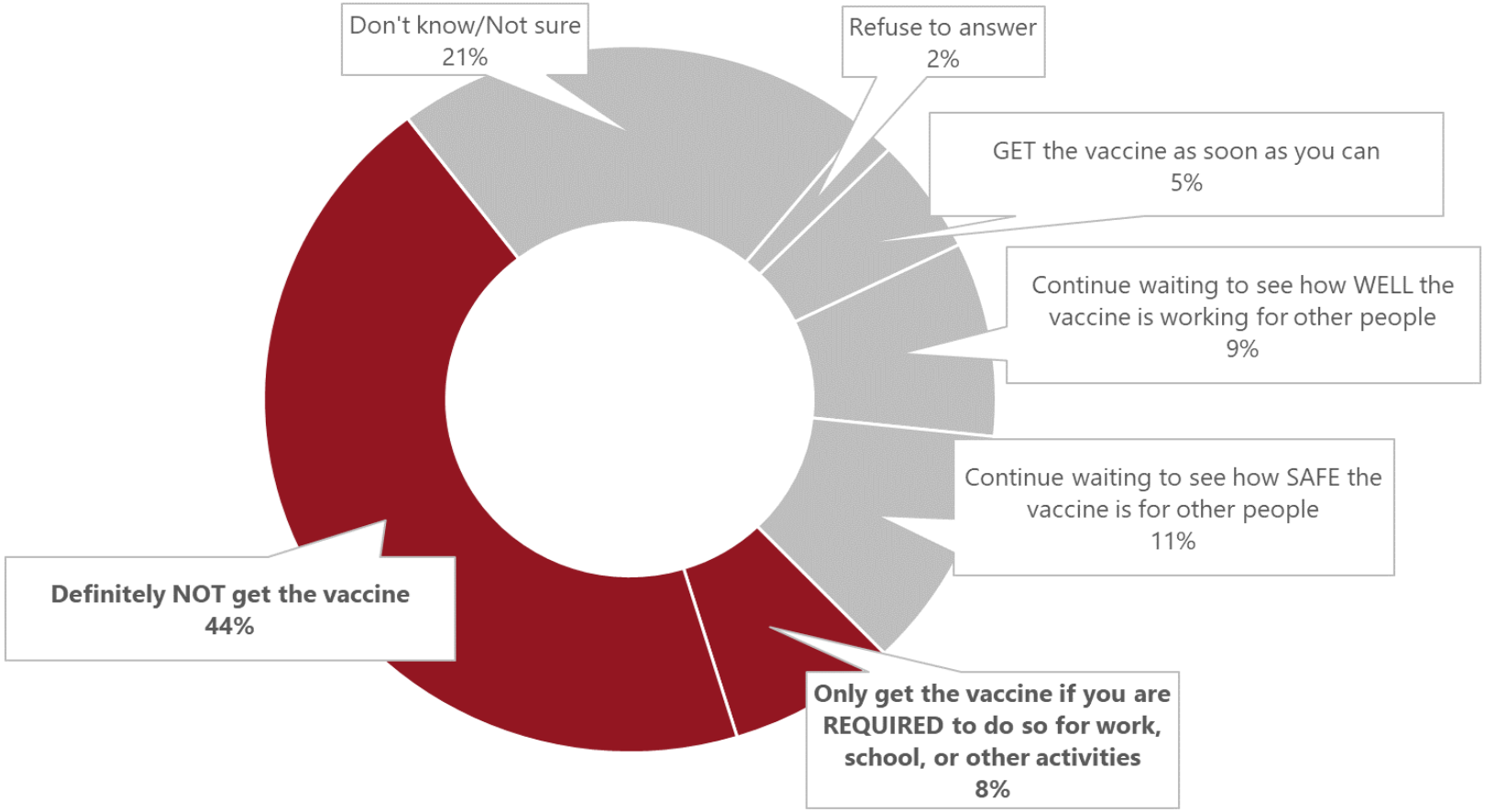
20% of unvaccinated respondents said they would continue waiting to see if COVID vaccines were effective or safe



CDC and University of Iowa/RAND survey, unpublished

Vaccination intentions in response to a Moderna FDA BLA

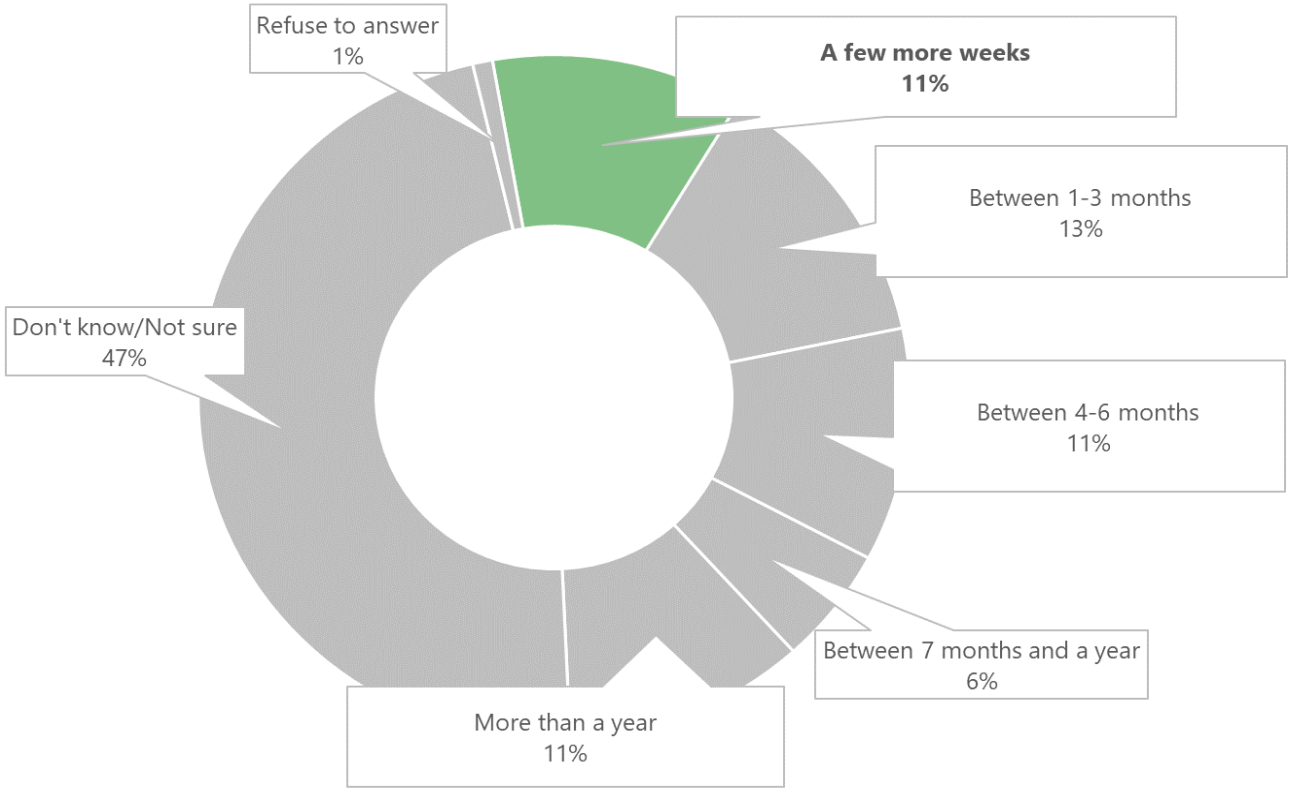
52% of unvaccinated respondents said they would **definitely not** get vaccinated or would only do so if it were **required**



CDC and University of Iowa/RAND survey, unpublished

Time to vaccination in response to a Moderna FDA BLA

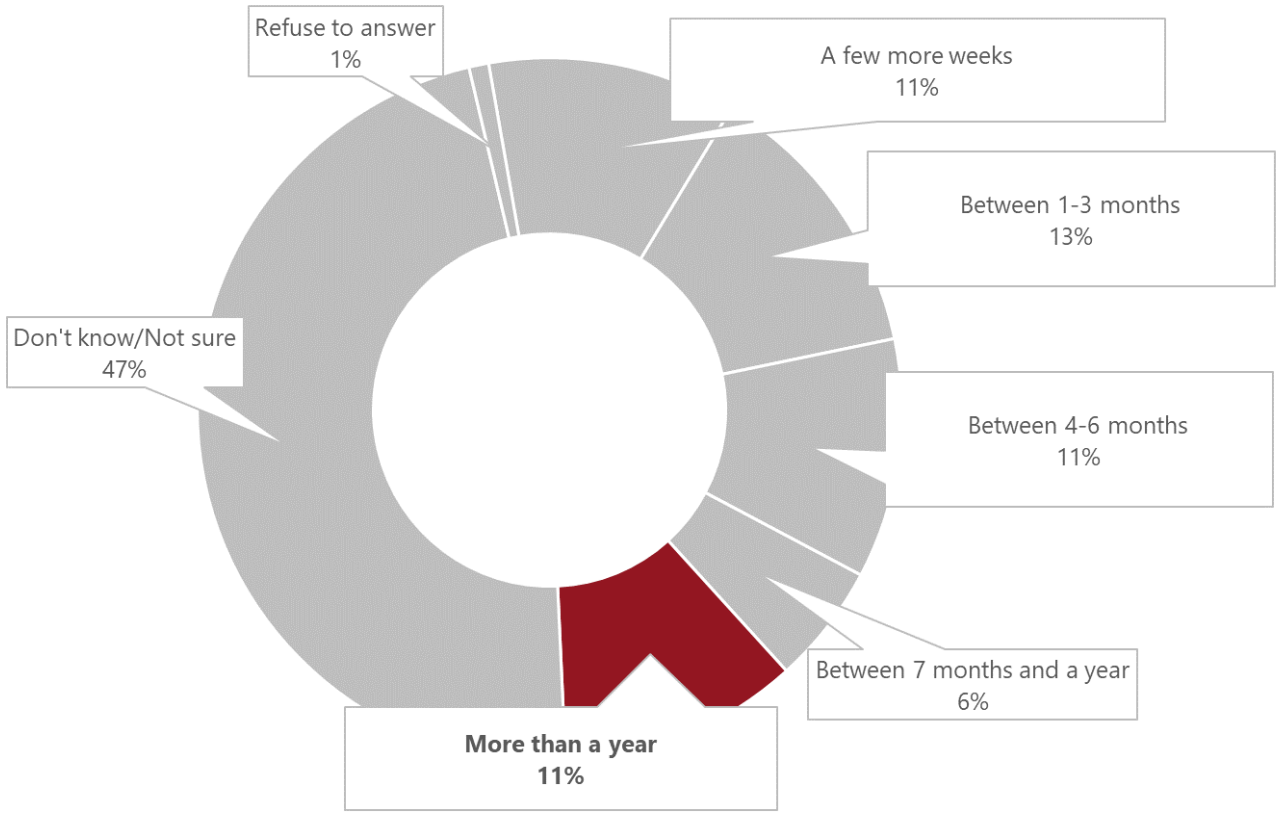
11% of unvaccinated respondents who were open or unsure about getting vaccinated (n=236) said they would **wait a few more weeks** to get a COVID vaccine after the Moderna vaccine received full FDA approval



CDC and University of Iowa/RAND survey, unpublished

Time to vaccination in response to a Moderna FDA BLA

11% of unvaccinated respondents who were open or unsure about getting vaccinated (n=236) said they would **wait more than a year** to get a COVID vaccine after the Moderna vaccine received full FDA approval



CDC and University of Iowa/RAND survey, unpublished

Values

Criteria 1:

Does the target population feel that the desirable effects are large relative to undesirable effects?

- How does the target population view the balance of desirable versus undesirable effects?
- Would patients/caregivers feel that the benefits outweigh the harms and burden?
- Does the population appreciate and value the Moderna COVID-19 vaccine?

○ Minimal	○ Small	○ Moderate	○ Large	○ Varies	○ Don't know

Values

Criteria 2:

Is there important uncertainty about, or variability in, how much people value the main outcomes?

- How much do individuals value each outcome in relation to the other outcomes?
- Is there evidence to support those value judgements?
- Is there evidence that the variability is large enough to lead to different decisions?

- ○ Important uncertainty or variability
- ○ Probably important uncertainty or variability
- ○ Probably not important uncertainty or variability
- ○ No important uncertainty or variability
- ○ No known undesirable outcomes

EtR Domain: Acceptability

Vaccine administration

- As of February 2, 2022, >204 million doses of Moderna COVID-19 vaccine have been administered[1]

- COVID-19 vaccination has been implemented in a variety of settings
  - State and local health departments
  - Healthcare sites/hospitals
  - Mass vaccination clinics
  - Long Term Care Facilities (LTCF)
  - Retail pharmacies

1. CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total Accessed February 3, 2022.

Vaccine acceptability among stakeholders

- Vaccination with Moderna COVID-19 vaccine was already highly acceptable to stakeholders under FDA emergency use authorization and ACIP interim recommendation
- Vaccination may be more acceptable to stakeholders under full FDA approval and standard ACIP recommendation

Acceptability

Is the Moderna COVID-19 vaccine acceptable to key stakeholders?

- Are there key stakeholders that would not accept the distribution of benefits and harms?
- Are there key stakeholders that would not accept the undesirable effects in the short term for the desirable effects (benefits) in the future?

○ No	○ Probably no	○ Probably yes	○ Yes	○ Varies	○ Don't know

EtR Domain: Feasibility

Feasibility of vaccine implementation

- Barriers to implementation may include:
  - Complexity of recommendations
  - Vaccine storage and handling requirements
  - Financial barriers
  - Supply barriers

Complexity of recommendations

- The Moderna COVID-19 vaccine will be the second COVID-19 vaccine with a BLA
- BLA only been issued for some indications, which may add complexity
  - BLA:
    - Primary series for those ages 18 years and older
  - EUA:
    - Additional dose in immunocompromised people for those ages 18 years and older
    - Booster dose in persons ≥18 years who completed a primary series ≥5 months ago
- Recommendations made under EUI only allowed for vaccines with a BLA
  - Will allow these recommendations to extend to Moderna COVID-19 vaccine as well
  - Include recommendations for additional/booster vaccination of people who received their primary series overseas or as a part of a clinical trial

Vaccine storage and handling requirements

- Moderna COVID-19 vaccine multiple-dose vials are stored frozen: -50°C to -15°C (-58° to 5°F)
  - The vaccine should not be stored on dry ice or below -50°C (-58°F)
  - The vaccine must be stored in the original carton to protect from light
- Vials can be refrigerated between 2° to 8°C (36° to 46°F) for **up to 30 days** prior to first use
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F)
  - Vials should be discarded 12 hours after the first puncture

Moderna. Storage & Handling. Storage & Handling | Moderna COVID-19 Vaccine (EUA) (modernatx.com). Accessed January 18, 2022

Financial barriers

- All COVID-19 vaccines will be provided to U.S. population **free of charge**
- Health systems or health departments incur costs for vaccine implementation, clinics, outreach, and education
- Financial hardship may arise if vaccine recipients need to take time off to receive the vaccine or experience post-vaccination reactogenicity that prevents them from working

Supply barriers

- Vaccine supply in the United States is sufficient for implementation of the intervention

- As of February 2, 2022, over 204 million doses of Moderna COVID-19 vaccine have been administered in the United States, demonstrating that the vaccine is feasible to implement broadly[1]

1. CDC COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total Accessed February 3, 2022.

Feasibility

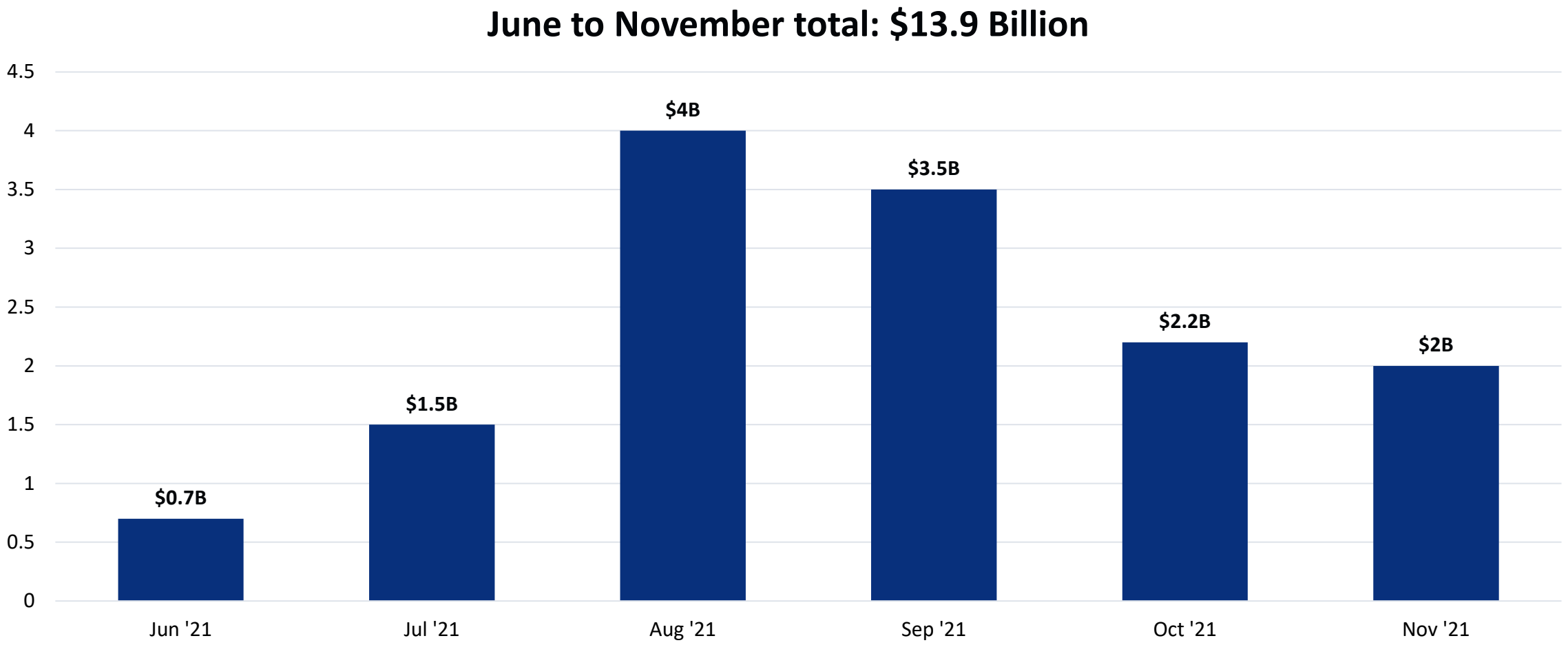
Is the Moderna COVID-19 vaccine feasible to implement among people ≥18 years?

- Is the Moderna COVID-19 vaccine program sustainable?
- Are there barriers that are likely to limit the feasibility of implementing the Moderna COVID-19 vaccine or require considerations when implementing it?
- Is access to Moderna COVID-19 vaccine an important concern?

○ No	○ Probably no	○ Probably yes	○ Yes	○ Varies	○ Don't know

EtR Domain: Resource Use

Estimated cost of preventable COVID-19 hospitalizations among unvaccinated adults in the United States, June – November 2021



Peterson-KFF Health System Tracker. https://www.healthsystemtracker.org/brief/unvaccinated-covid-patients-cost-the-u-s-health-system-billions-of-dollars/ Accessed January 25, 2022

Costs & benefits associated with COVID-19 vaccines

- Vaccine doses purchased with U.S. taxpayer funds will be given to people living in the United States at **no cost**[1]
- Several published modeling studies have found that COVID-19 vaccinations are likely to be of a reasonable economic value and may also be cost-saving under many circumstances[2-5]

1. CDC COVID-19. COVID-19 Vaccines Are Free to the Public. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/no-cost.html
2. Padula et al. 2021. J Med Econ; 3. Bartsch et al. 2021 J Inf Dis; 4. Gupta et al. 2021 Health Aff; 5. Kohli et al 2021 Vaccine

Resource Use

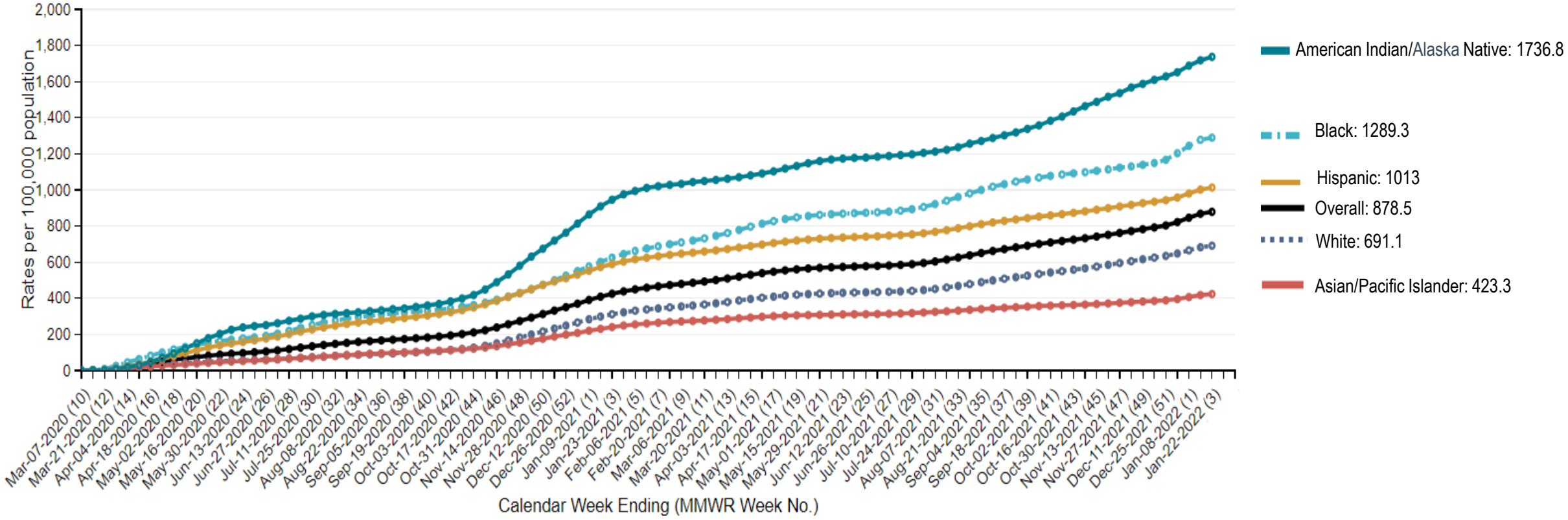
Is the Moderna COVID-19 vaccine among adults 18 years and older a reasonable and efficient allocation of resources?

- What is the cost-effectiveness of the Moderna COVID-19 vaccine?
- How does the cost-effectiveness of the Moderna COVID-19 vaccine change in response to changes in context, assumptions, etc.?

○ No	○ Probably no	○ Probably yes	○ Yes	○ Varies	○ Don't know

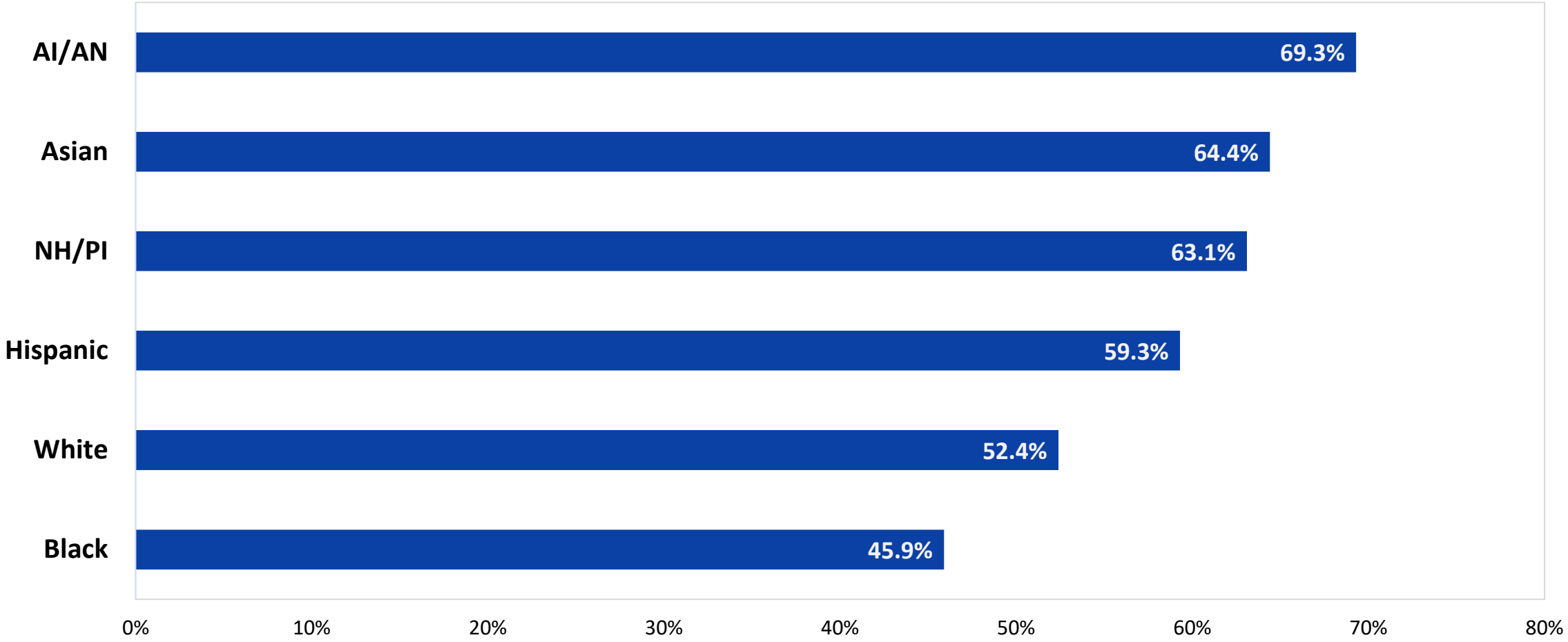
EtR Domain: Equity

Cumulative COVID-19 associated hospitalizations in the United States by race/ethnicity, March 7, 2020 – January 22, 2022



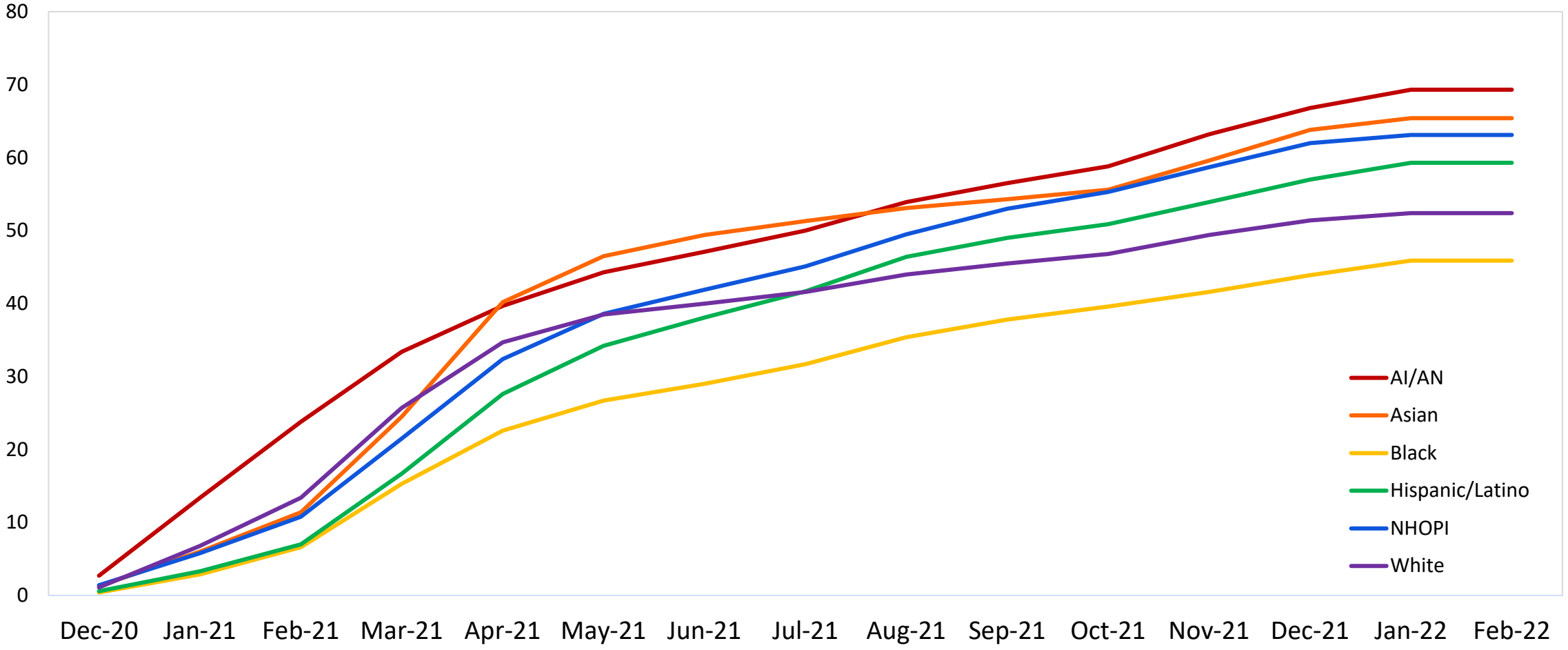
CDC. https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network Accessed February 3, 2022

What percentage of people ages 18 years and older in each race or ethnic group received at least one dose of COVID-19 vaccine?



CDC. https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends Accessed February 3, 2022

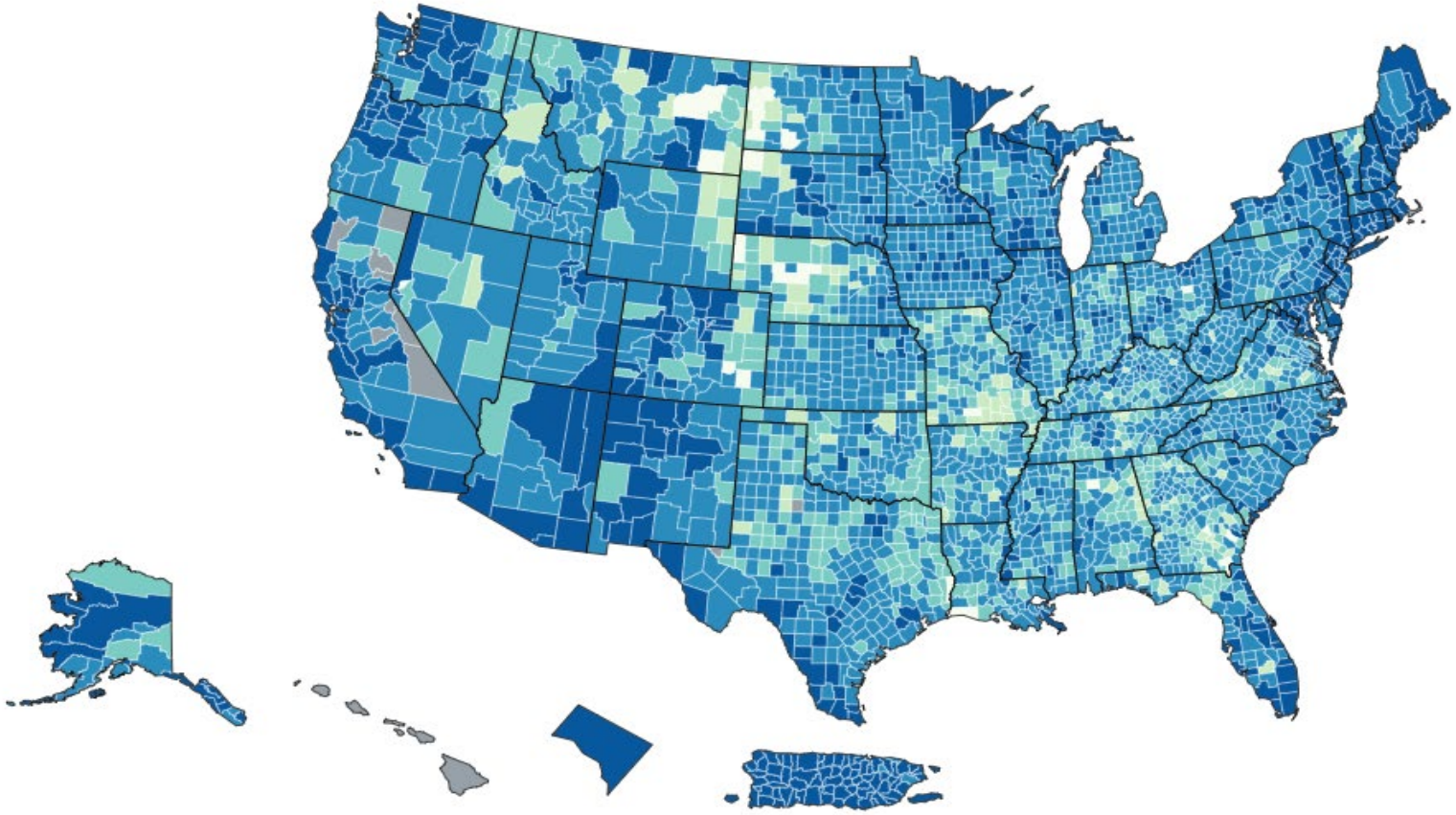
Percentage of people ages 18 years and older who have received at least one dose of the COVID-19 vaccine by race/ethnicity over time



CDC. https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends as of February 2, 2022, and US Census Bureau National Population Estimates

COVID-19 vaccination coverage varies by geography

Percent of population ages 18 years and older fully vaccinated



% of population ≥18 years of age fully vaccinated	% of U.S. counties at this level
0-29.9%	1%
30-39.9%	4%
40-49.9%	18%
50-69.9%	58%
70%+	20%
No Data	--

CDC COVID-19 County Integrated County View. https://covid.cdc.gov/covid-data-tracker/#vaccinations-county-view Accessed January 20, 2022

Disparities in vaccine intent by geographic location

- Vaccine uptake lags in adults living in rural and suburban areas compared with urban
- As of November 2021, **eight** in **ten** urban residents **(79%)** say they have received at least one dose of a COVID-19 vaccine, compared to **seven** in **ten** suburban adults and **67%** of rural adults
- **One** in **five (21%)** of those living in rural areas and **one** in **six (16%)** of those living in suburban areas say they will "definitely not" get a COVID-19 vaccine, at least twice the share of urban residents who say the same **(8%)**

KFF COVID-19 Vaccine Monitor: Differences in Vaccine Attitudes Between Rural, Suburban and Urban Areas. https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-vaccine-attitudes-rural-suburban-urban/. Accessed January 18, 2022

COVID-19 vaccination coverage by sexual orientation and gender identity – United States, August 29-October 30, 2021

- During August 29-October 30, 2021, data from the National Immunization Survey Adult COVID Module (NIS-ACM) were analyzed to assess COVID-19 vaccination coverage in COVID-19 vaccines among lesbian, gay, bisexual, and transgender (LGBT) adults ages 18 years and older
- By sexual orientation, gay or lesbian adults reported higher vaccination coverage overall (85.4%) than heterosexual adults (76.3%)
  - Among gay or lesbian adults and bisexual adults, vaccination coverage was lower among women (80.5% and 74.2%, respectively) than among men (88.9% and 81.7%, respectively)
- There were no significant differences in vaccination coverage among persons based on gender identity
- Vaccination coverage was lowest among non-Hispanic Black LGBT persons across all categories of sexual orientation and gender identity

McNaghten A, Brewer NT, Hung M, et al. COVID-19 Vaccination Coverage and Vaccine Confidence by Sexual Orientation and Gender Identity — United States, August 29–October 30, 2021. MMWR Morb Mortal Wkly Rep 2022;71:171–176. DOI: http://dx.doi.org/10.15585/mmwr.mm7105a3

Equity

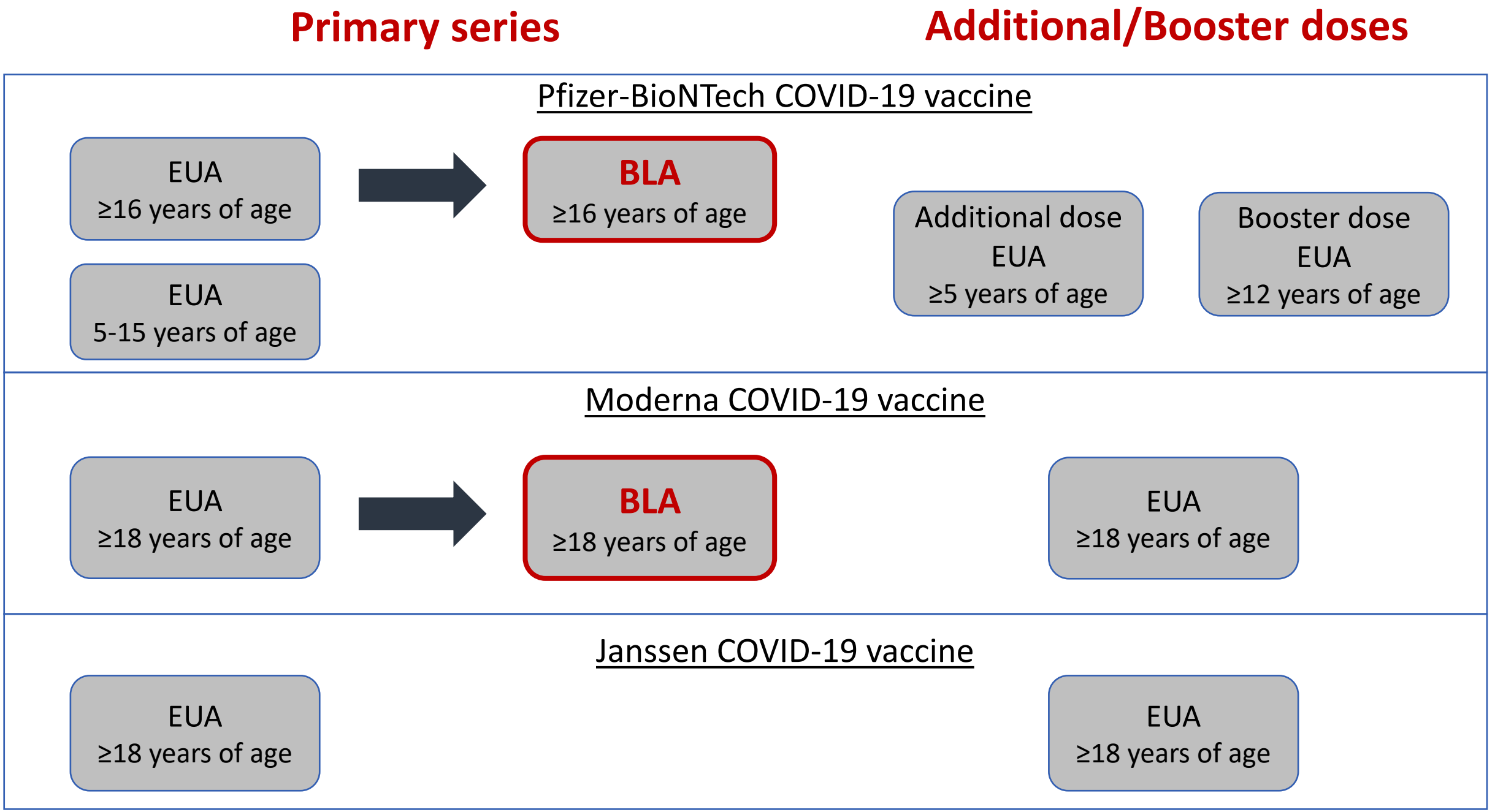
What would be the impact of the Moderna COVID-19 vaccine among people ages 18 years and older on health equity?

- Are there groups or settings that might be disadvantaged in relation to COVID-19 disease burden or receipt of the Moderna COVID-19 vaccine?
- Are there considerations that should be made when implementing the Moderna COVID-19 vaccine program to ensure that inequities are reduced whenever possible, and that they are not increased?

○ Reduced	○ Probably reduced	○ Probably no impact	
○ Probably increased	○ Increased	○ Varies	○ Don’t know

Summary

EtR Domain	Question	Work Group Judgments
Public Health Problem	Is COVID-19 of public health importance?	Yes
Benefits and Harms	How substantial are the desirable anticipated effects?	Large
	How substantial are the undesirable anticipated effects?	Small
	Do the desirable effects outweigh the undesirable effects?	Favors intervention (Moderna COVID-19 vaccine)
	What is the overall certainty of the evidence for the critical outcomes?	High to Moderate
Values	Does the target population feel the desirable effects are large relative to the undesirable effects?	Large
	Is there important variability in how patients value the outcomes?	Probably important uncertainty or variability
Acceptability	Is the Moderna COVID-19 vaccine acceptable to key stakeholders?	Yes
Feasibility	Is the Moderna COVID-19 vaccine feasible to implement?	Yes
Resource Use	Is Moderna COVID-19 vaccine a reasonable and efficient allocation of resources?	Yes
Equity	What would be the impact of the intervention on health equity?	Probably no impact


Primary series
Additional/Booster doses
Pfizer-BioNTech COVID-19 vaccine
EUA
≥16 years of age
EUA
5-15 years of age
BLA
≥16 years of age
Additional dose
EUA
≥5 years of age
Booster dose
EUA
≥12 years of age
Moderna COVID-19 vaccine
EUA
≥18 years of age
BLA
≥18 years of age
EUA
≥18 years of age
Janssen COVID-19 vaccine
EUA
≥18 years of age
EUA
≥18 years of age

Work Group Interpretation

- COVID-19 vaccines have been a critical tool in this pandemic, preventing **millions** of COVID-19 associated **hospitalizations** and **deaths**
- To date, **hundreds of millions** of doses of the Moderna COVID-19 vaccine have been given with over a year of closely monitored real-world safety and effectiveness data
- Vaccinating the unvaccinated with a **primary series** continues to be important
  - Additional protection from all recommended COVID-19 vaccine doses important in evolving pandemic

Evidence to Recommendations Framework

Summary: Work Group Interpretations

Balance of consequences	Undesirable consequences *clearly outweigh* desirable consequences in most settings	Undesirable consequences *probably outweigh* desirable consequences in most settings	The balance between desirable and undesirable consequences is *closely balanced* or *uncertain*	Desirable consequences *probably outweigh* undesirable consequences in most settings	Desirable consequences *clearly outweigh* undesirable consequences in most settings	There is insufficient evidence to determine the balance of consequences

Evidence to Recommendations Framework

Summary: Work Group Interpretations

Balance of consequences	Undesirable consequences *clearly outweigh* desirable consequences in most settings	Undesirable consequences *probably outweigh* desirable consequences in most settings	The balance between desirable and undesirable consequences is *closely balanced* or *uncertain*	Desirable consequences *probably outweigh* undesirable consequences in most settings	Desirable consequences *clearly outweigh* undesirable consequences in most settings	There is insufficient evidence to determine the balance of consequences

Evidence to Recommendations Framework

Summary: Work Group Interpretations

Type of recommendation	We do not recommend the intervention	We recommend the intervention for individuals based on shared clinical decision-making	We recommend the intervention

Evidence to Recommendations Framework

Summary: Work Group Interpretations

Type of recommendation	We do not recommend the intervention	We recommend the intervention for individuals based on shared clinical decision-making	We recommend the intervention

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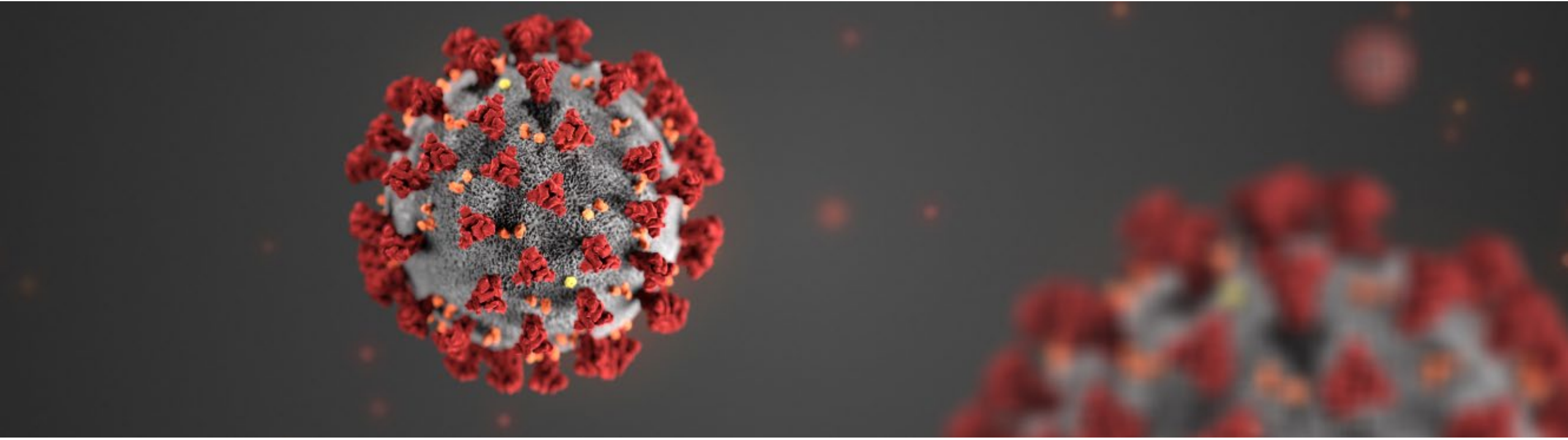
- Anthony Fiore
- Stephen Hadler
- Valerie Morelli
- JoEllen Wolicki
- Elisha Hall
- Erin Ricketts
- Faisal Minhaj
- Heather Scobie
- VTF ACIP WG Team
- ACIP COVID-19 Vaccines Work Group
- Vaccine Task Force
- Epi Task Force
- Data Analytics and Visualization Task Force
- Respiratory Viruses Branch



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.