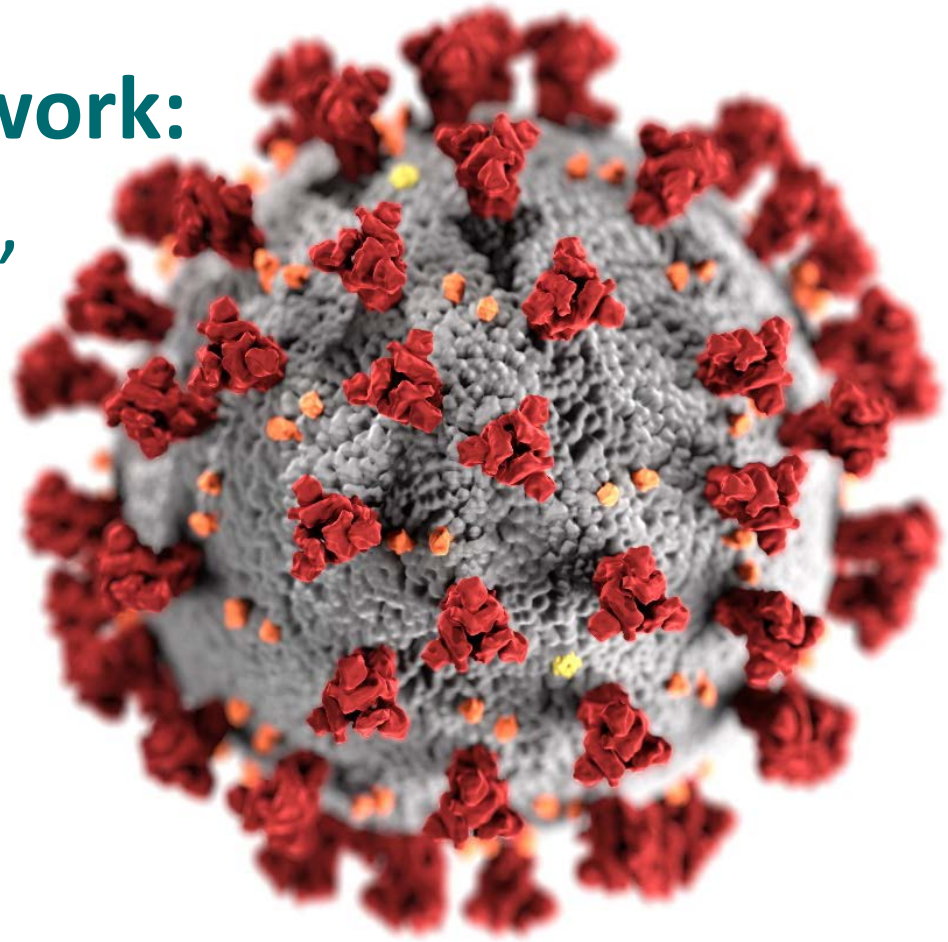
Evidence to Recommendation Framework:

Pfizer-BioNTech COVID-19 vaccine, Comirnaty



Kathleen Dooling, MD, MPH

ACIP Meeting

August 30, 2021

cdc.gov/coronavirus

Evidence to Recommendations Framework

Evidence to Recommendations (EtR) Framework

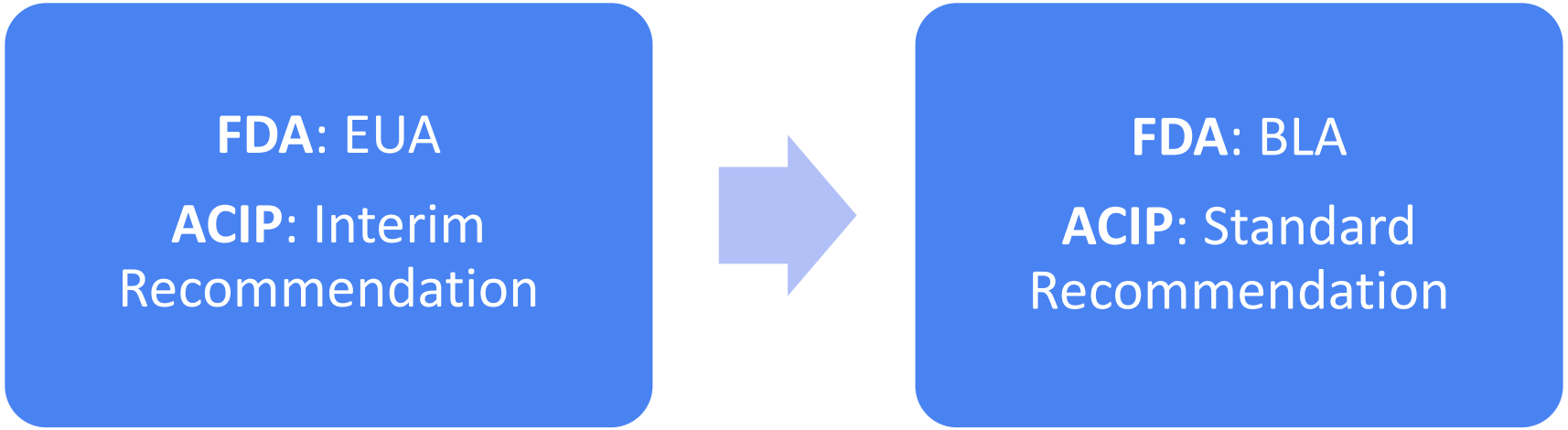
- Structure to describe information considered in moving from **evidence** to ACIP vaccine **recommendations**

- Provide **transparency** around the impact of additional factors on deliberations when considering a recommendation

Evidence to Recommendations (EtR) Framework

Policy Question

- Should vaccination with the Pfizer-BioNTech COVID-19 vaccine be recommended for people 16 years of age and older?



EUA= Emergency Use Authorization, BLA= Biologics License Application

Evidence to Recommendations (EtR) Framework:
PICO Question

Population	People aged ≥16 years
Intervention	Pfizer-BioNTech COVID-19 vaccine (BNT162b2) 30µg, 2 doses IM, 21 days apart
Comparison	No vaccine
Outcomes	Symptomatic COVID-19 (PCR confirmed) Hospitalization due to COVID-19 Death due to COVID-19 Asymptomatic SAR-CoV-2 infection (assessed using PCR) Serious adverse events (including death, myocarditis/pericarditis and anaphylaxis) Reactogenicity (≥grade 3 or worse reactions)

Evidence to Recommendations (EtR) Framework

EtR Domain	Question
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 outcomes?
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?

Evidence to Recommendations (EtR) Framework

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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 problem" = COVID-19

"The vaccine" or "The intervention" = Pfizer-BioNTech COVID-19 vaccine

EtR Domain: Public Health Problem

Public Health Problem

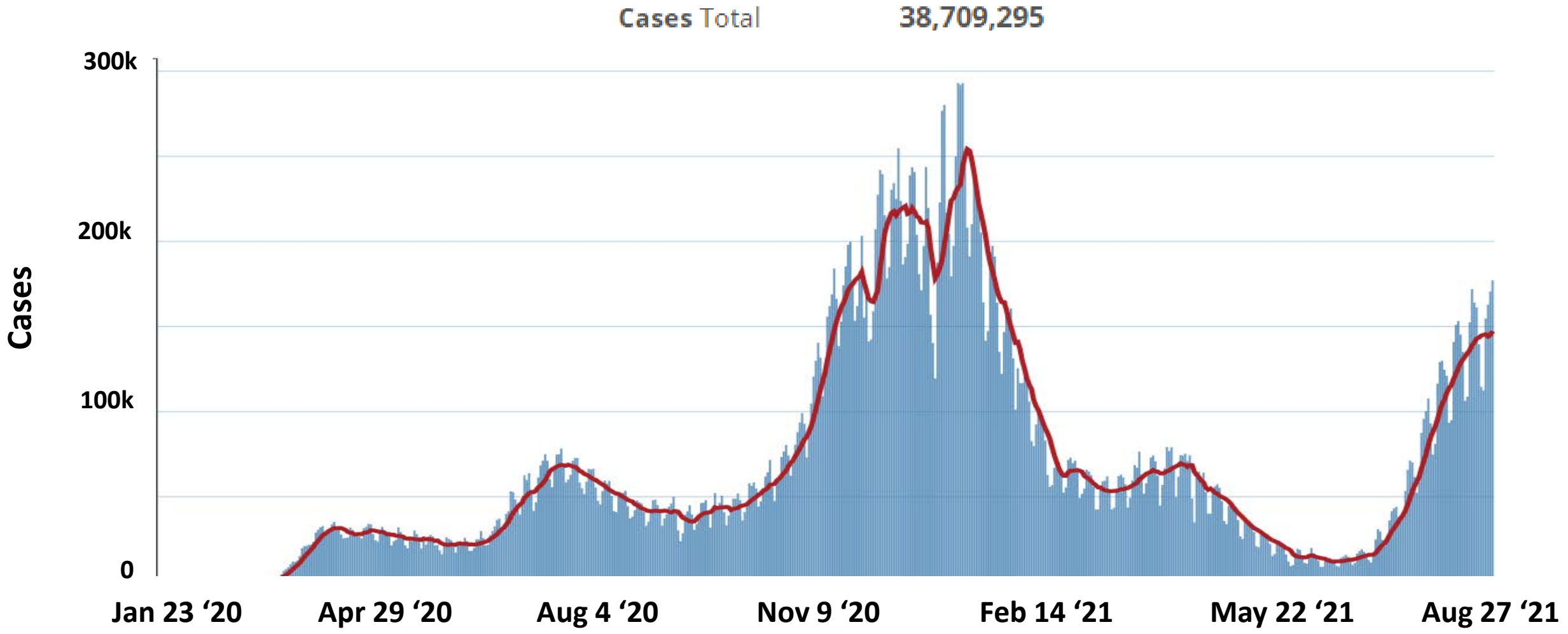
Is COVID-19 of public health importance?

- Are the consequences of COVID-19 serious?
- Is COVID-19 urgent?
- Are a large number of people affected by COVID-19?
- Are there populations disproportionately affected by COVID-19?

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

Daily Trends in Number of COVID-19 Cases in the U.S.

January 23, 2020 – Aug 27, 2021



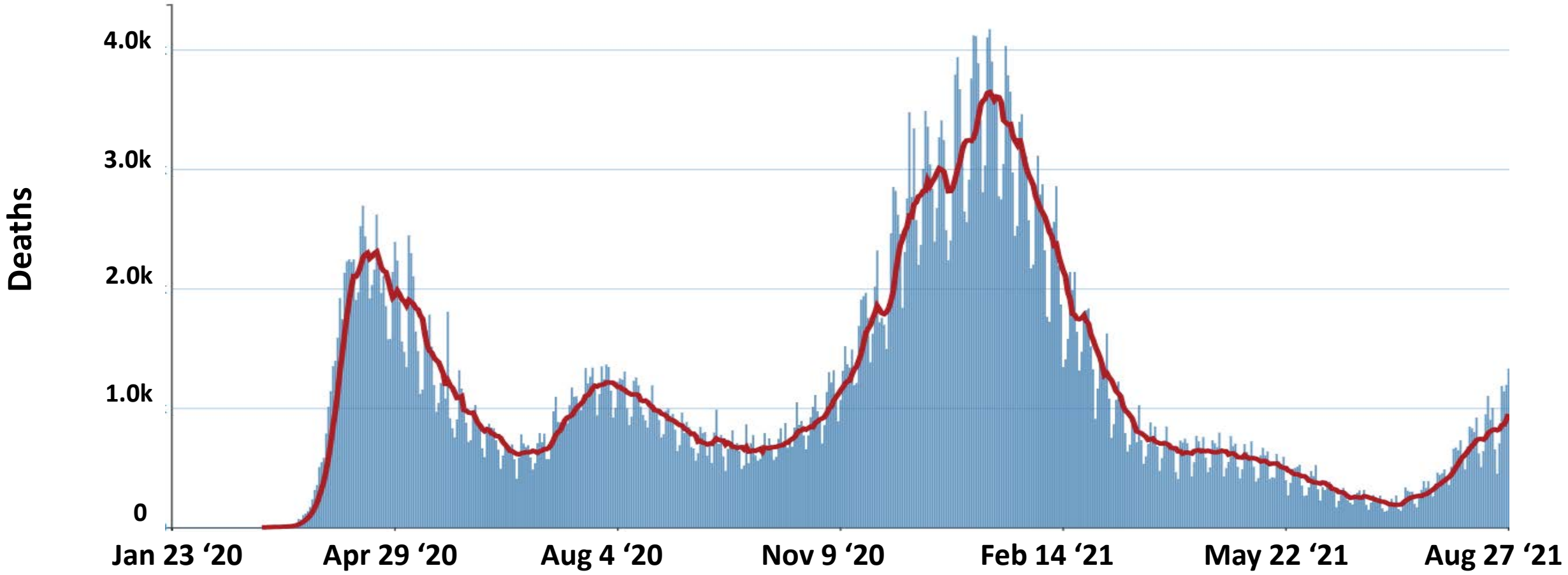
https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases

Aug 27 2021

Daily Trends in Number of COVID-19 Deaths in the U.S.

January 23, 2020 – Aug 27, 2021

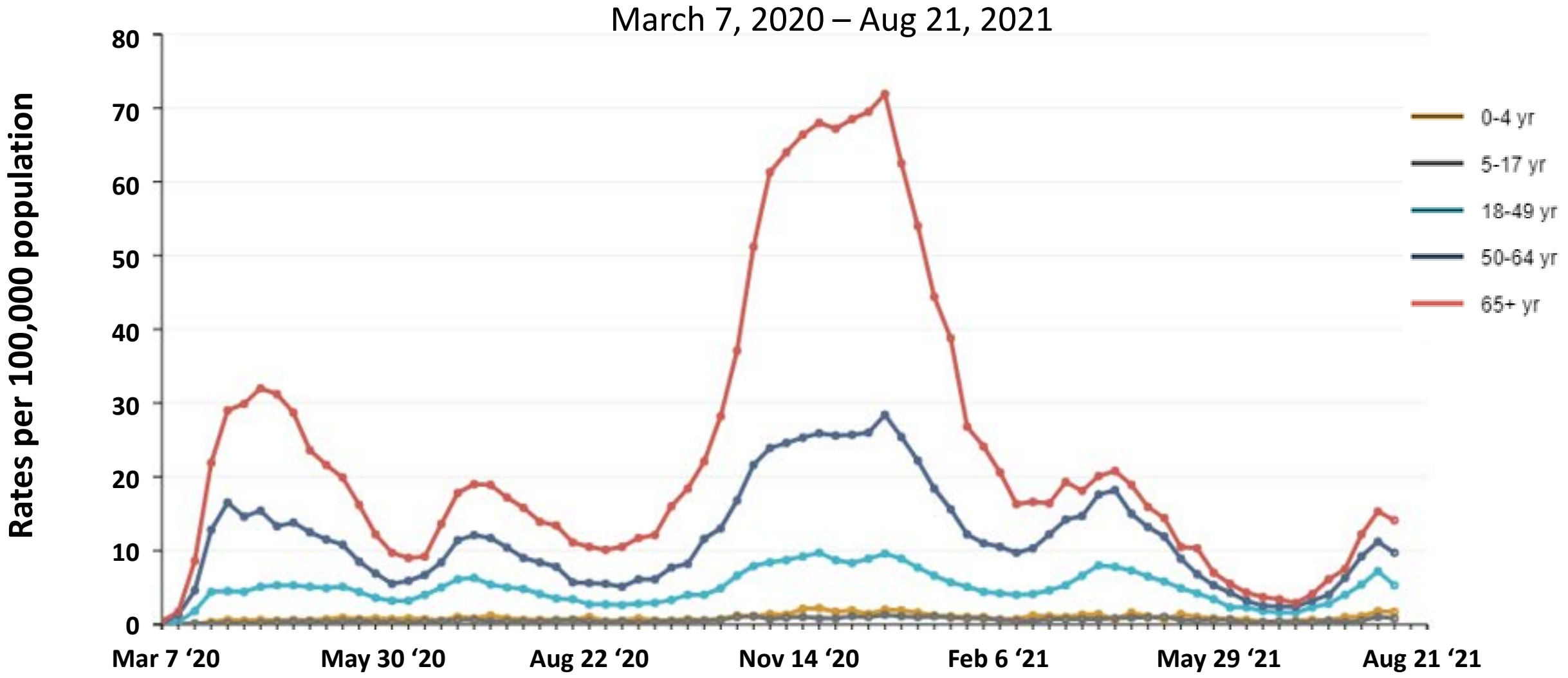
Deaths Total **634,157**



https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases

Aug 27 2021

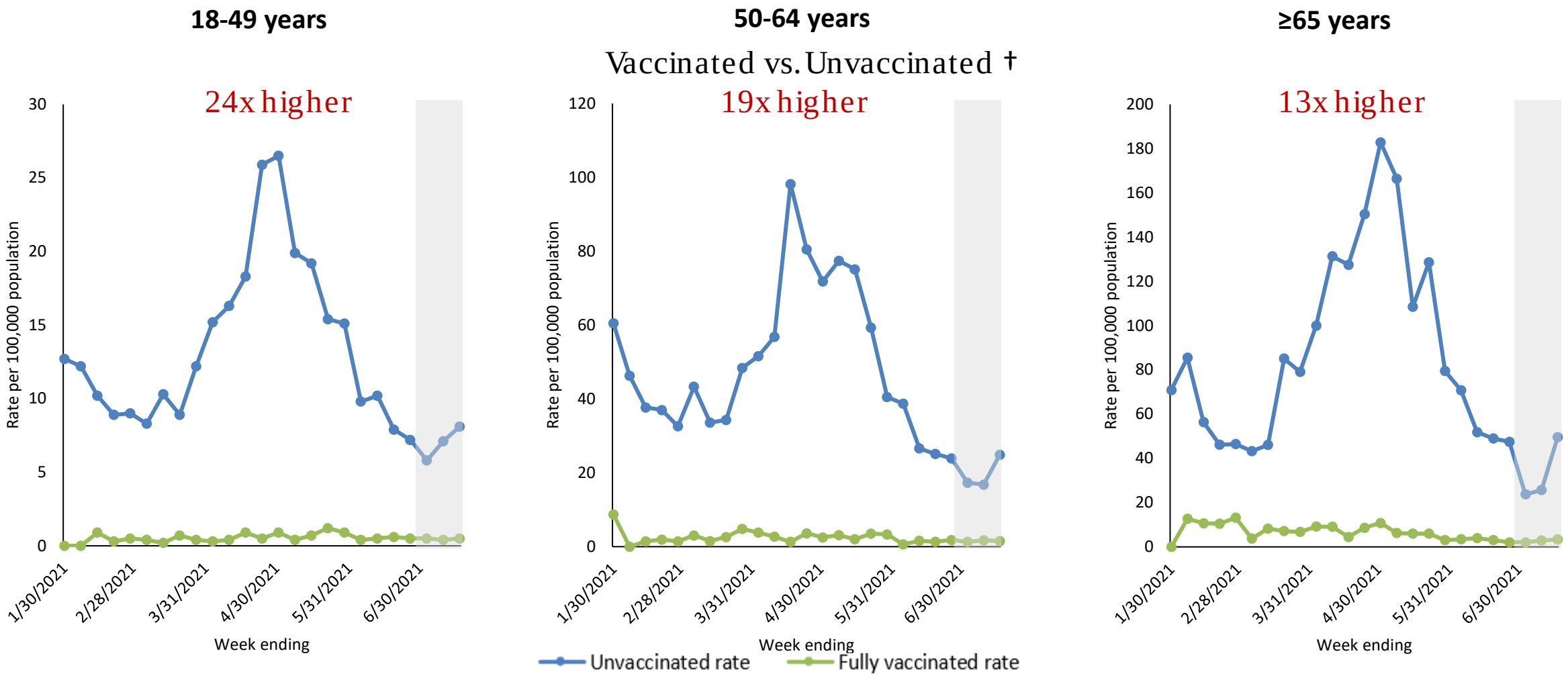
Weekly Trends in COVID-19 Associated Hospitalization Rates in the U.S.



https://gis.cdc.gov/grasp/covidnet/covid19_3.html

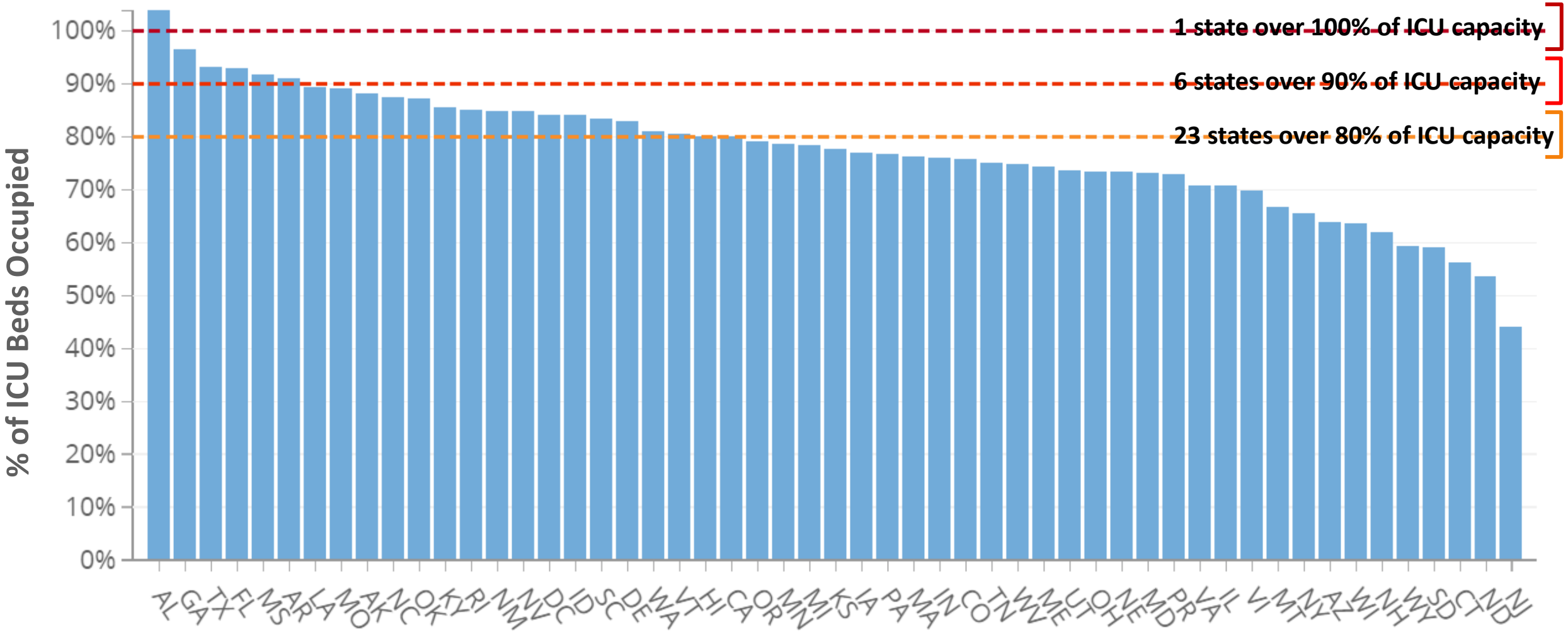
Aug 23 2021

Age-adjusted weekly COVID-19-associated hospitalization rates among adults by week of admission and age group*—COVID-NET, January 24–July 17, 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 – July 17, 2021. Shaded area indicates preliminary July data that does not include one site.
Havers et al. https://medrxiv.org/cgi/content/short/2021.08.27.21262356v1. COVID-19-associated hospitalizations among vaccinated and unvaccinated adults ≥18 years - COVID-NET, 13 states, January 1-July 24, 2021

ICU Utilization by State

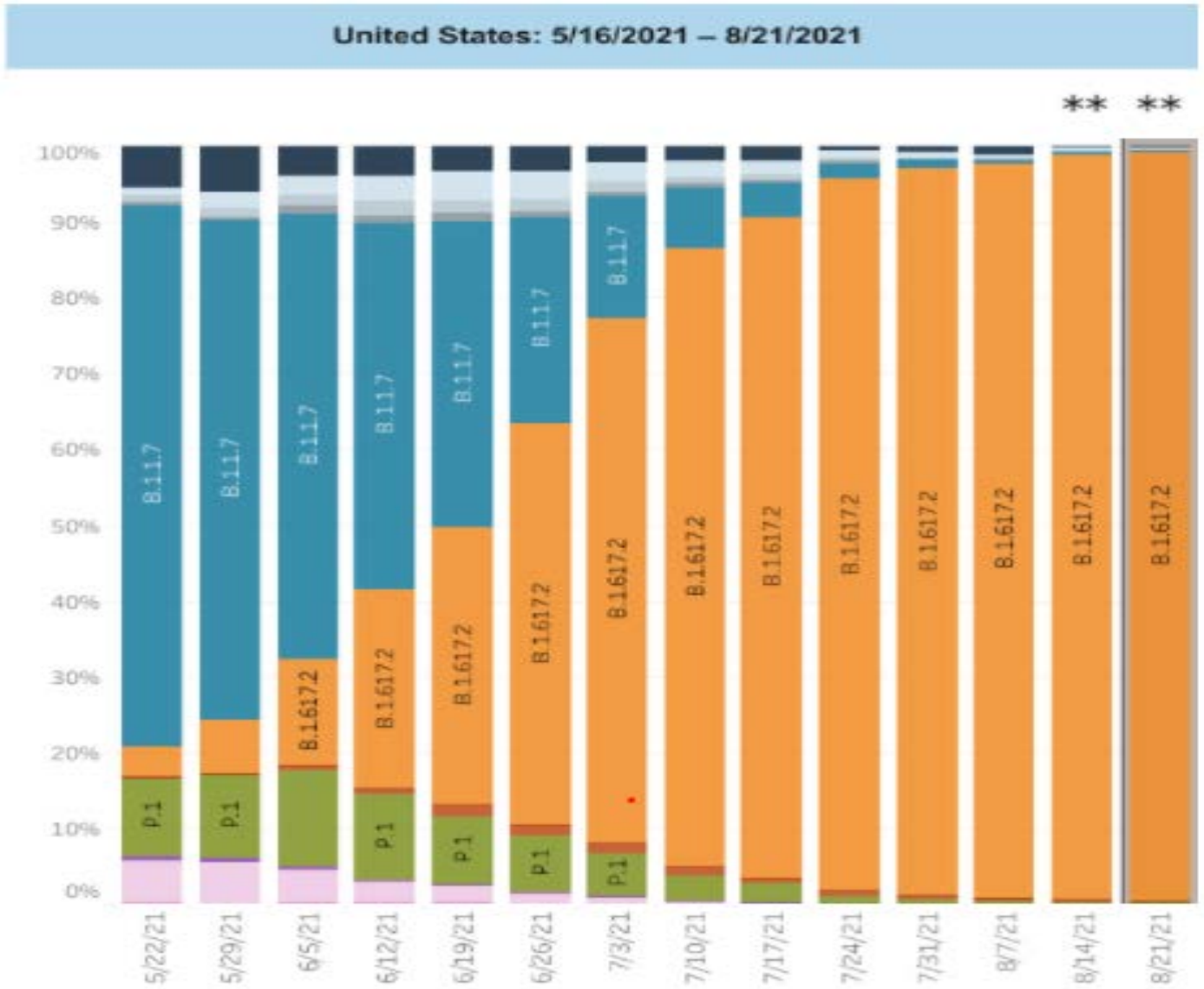


Data updated daily and provides the latest values reported by each facility within the last four days. No statistical analysis is applied to account for non-response and/or to account for missing data.

https://protect-public.hhs.gov/pages/hospital-utilization

Aug 29, 2021

Delta Is the Dominant Circulating SARS-CoV-2 Variant



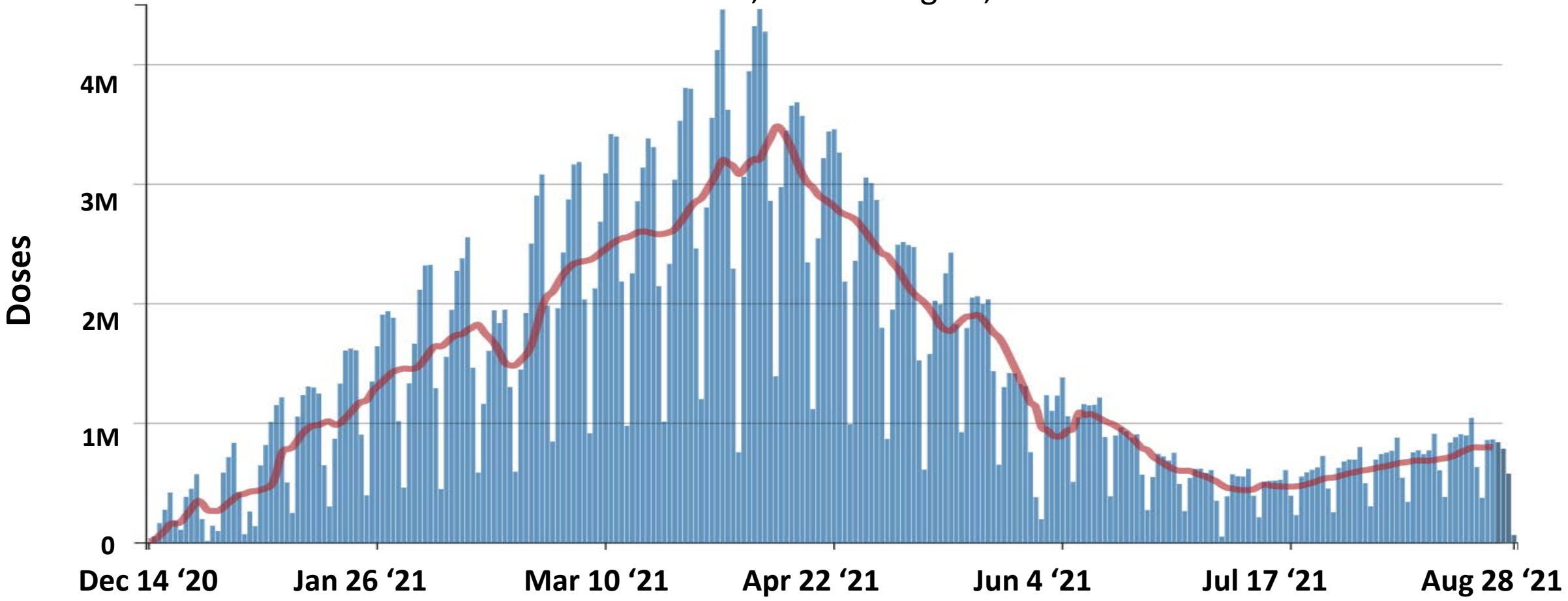
- Delta is more than 2x as contagious as alpha variant

https://covid.cdc.gov/covid-data-tracker/#variant-proportions; https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html

Aug 28 2021

Daily Trends in Doses of COVID-19 Vaccine Administered

December 23, 2020 – Aug 28, 2021

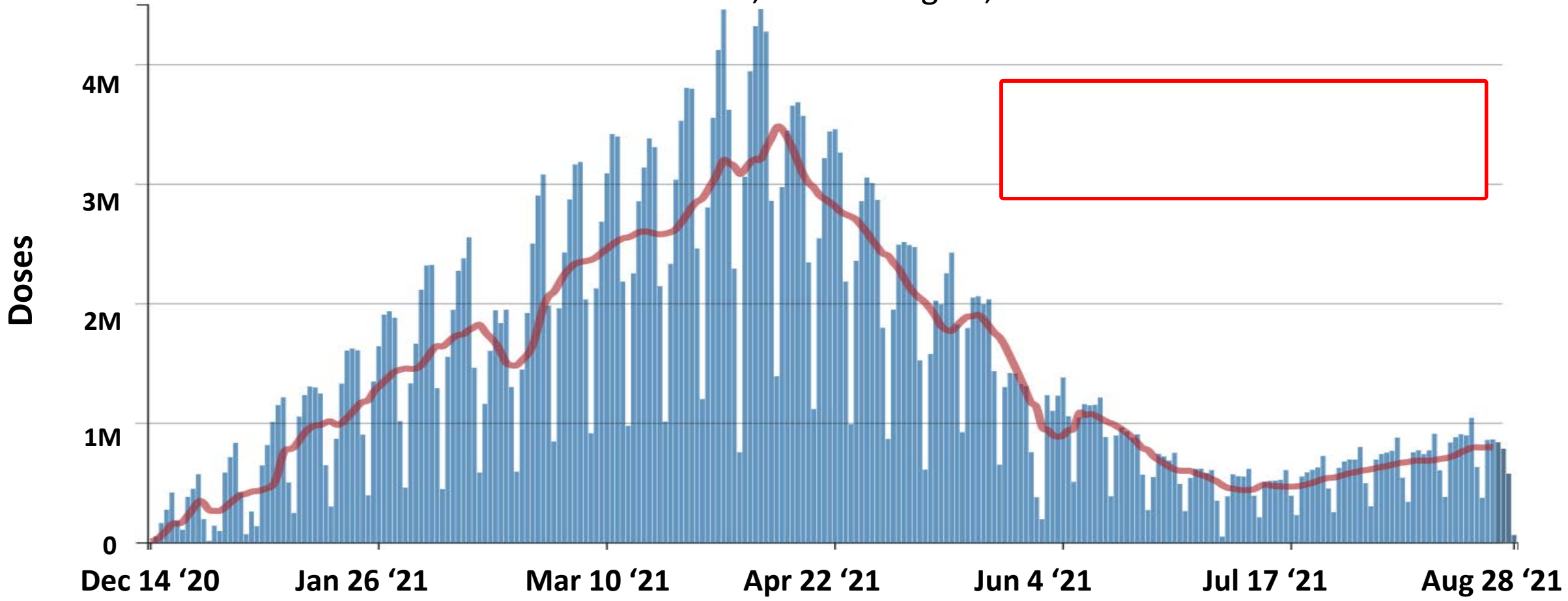


https://covid.cdc.gov/covid-data-tracker/#vaccination-trends

Aug 28 2021

Daily Trends in Doses of COVID-19 Vaccine Administered

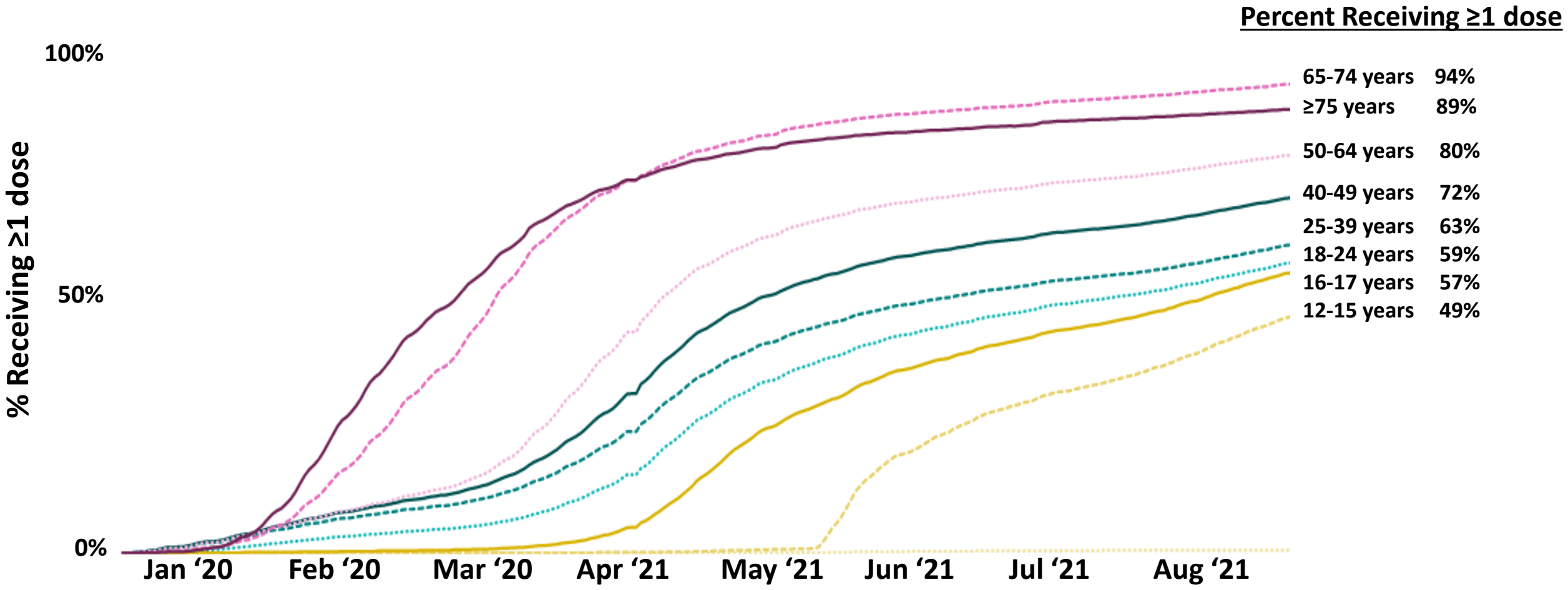
December 23, 2020 – Aug 28, 2021



https://covid.cdc.gov/covid-data-tracker/#vaccination-trends

Aug 28 2021

COVID-19 Vaccination Coverage by Age

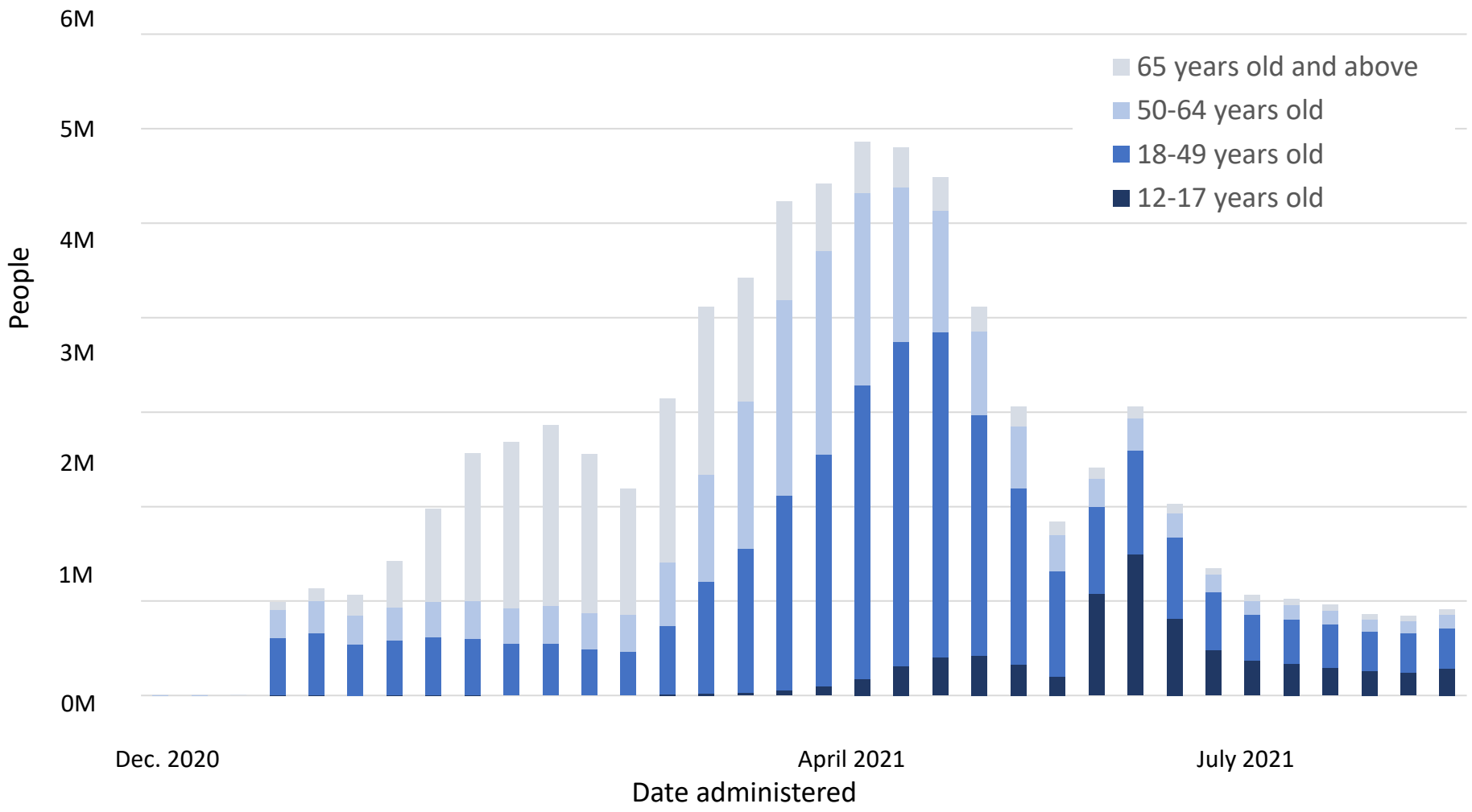


https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic

Aug 28, 2021

People Fully Vaccinated with Pfizer-BioNTech COVID-19 Vaccine, by Week and Age Group

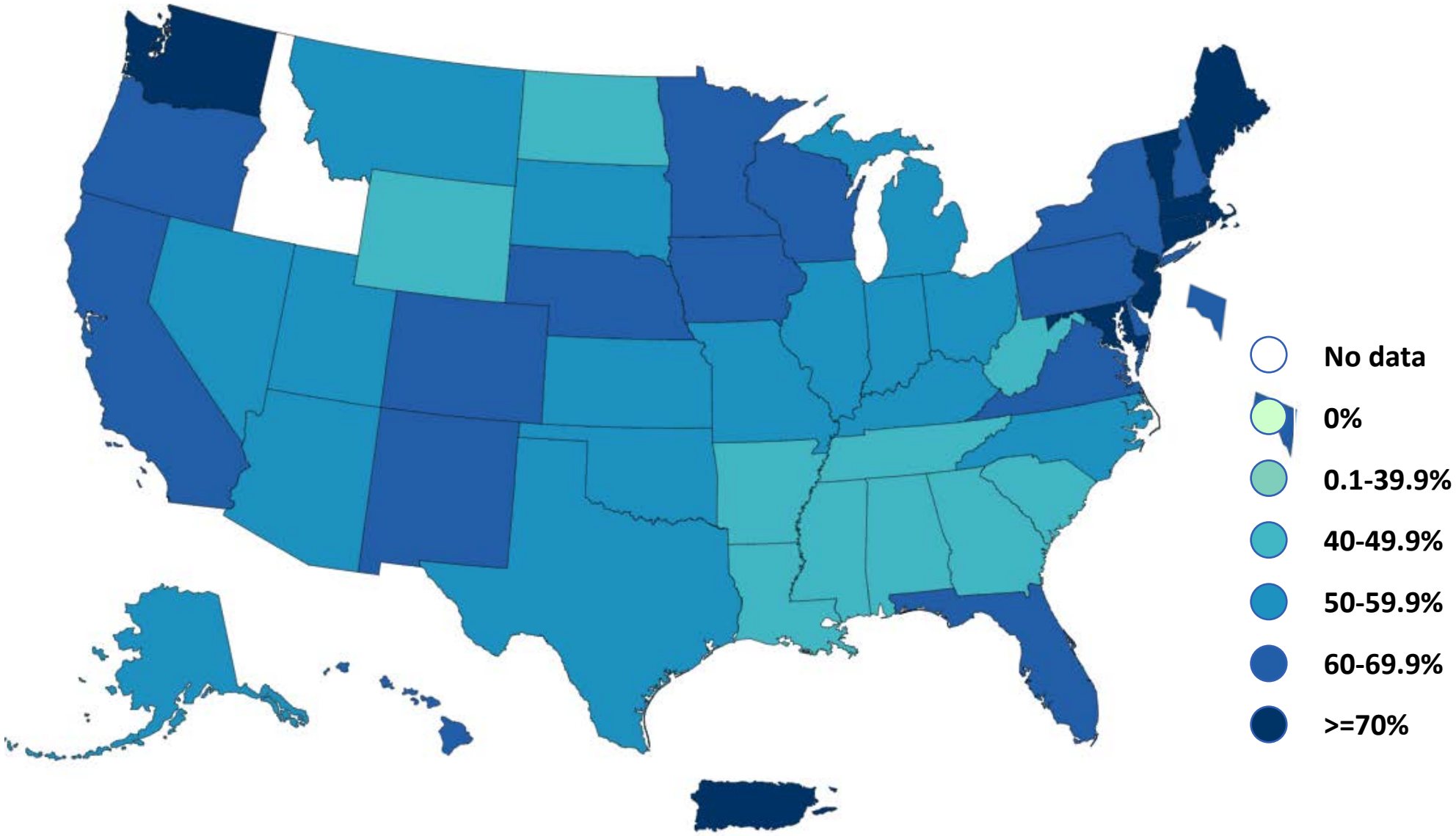
Since April, most people achieving full vaccination are younger than 50 years old



As of August 15, 2021

A person is considered fully vaccinated against COVID-19 ≥2 weeks after receipt of the second dose in a two-dose series (Pfizer-BioNTech) CDC. https://covid.cdc.gov/covid-data-tracker; *Does not include vaccine data from Idaho for persons under 18; Excludes vaccines administered by DoS (Department of State). Excludes vaccines administrations reported by Texas. Includes U.S. territories.

Percent of Population >= 12 Years of Age that is Fully Vaccinated



https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-fully-percent-pop12

Aug 28, 2021

Summary

- COVID-19 cases, hospitalizations and deaths have been increasing
- The Delta variant is the dominant circulating variant of SARS-CoV-2 in the U.S., and is estimated to be more than 2x as transmissible as previous variants
- Over 173 million people are fully vaccinated in the U.S., however vaccination coverage varies by age and geography
- Increasing cases are taxing healthcare resources, with many States facing ICU bed shortages

Public Health Problem:

Work Group Interpretation

Is COVID-19 of public health importance?

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

EtR Domain: Benefits and Harms

Benefits and Harms

How substantial are the desirable anticipated effects?

- How substantial is 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 is 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 (Pfizer-BioNTech COVID-19 vaccine)
- ○ Favors comparison (no vaccine)
- ○ Favors both
- ○ Favors neither
- ○ Unclear

Summary of GRADE

Outcome	Importance	Design (# of studies)	Findings	Evidence type
Benefits				
Symptomatic lab-confirmed COVID-19	Critical	RCT (1) OBS (9)	Pfizer-BioNTech COVID-19 vaccine is effective in preventing symptomatic COVID-19	**1**
Hospitalization due to COVID-19	Critical	RCT (1) OBS (8)	Pfizer-BioNTech COVID-19 vaccine prevents COVID-19-resulting in hospitalization	**2**
Death due to COVID-19	Important	RCT (1) OBS (4)	Pfizer-BioNTech COVID-19 vaccine prevents death due to COVID-19	**2**
Asymptomatic SARS-CoV-2 infection	Important	OBS (2)	Two cohort studies show benefit of vaccination for preventing asymptomatic infections, but magnitude inconsistent	**4**
Harms				
Serious adverse events	Critical	RCT (2)	In the RCT, SAEs were balanced between vaccine and placebo arms. In post-authorization safety monitoring, myocarditis and anaphylaxis were rare but more common following vaccination.	**2**
Reactogenicity	Important	RCT (2)	Severe reactions within 7 days were more common in vaccinated; any grade ≥3 reaction was reported by 10.7% of vaccinated vs. 2.3% of placebo group	**1**

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

Benefits and Harms

How substantial are the desirable anticipated effects?

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

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

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- Favors intervention (Pfizer-BioNTech COVID-19 vaccine)
- Favors comparison (no vaccine)
- Favors both
- Favors neither
- Unclear

EtR Domain: Values

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 feel that the benefits outweigh the harms and burden?
-Does the population appreciate and value **Pfizer-BioNTech COVID-19 vaccine**?

○ No ○ Probably no ○ Probably yes ○ Yes ○ 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 outcomes in relation to the other outcomes?
-Is there evidence to support those value judgments?
-Is there evidence that the variability is large enough to lead to different decisions?

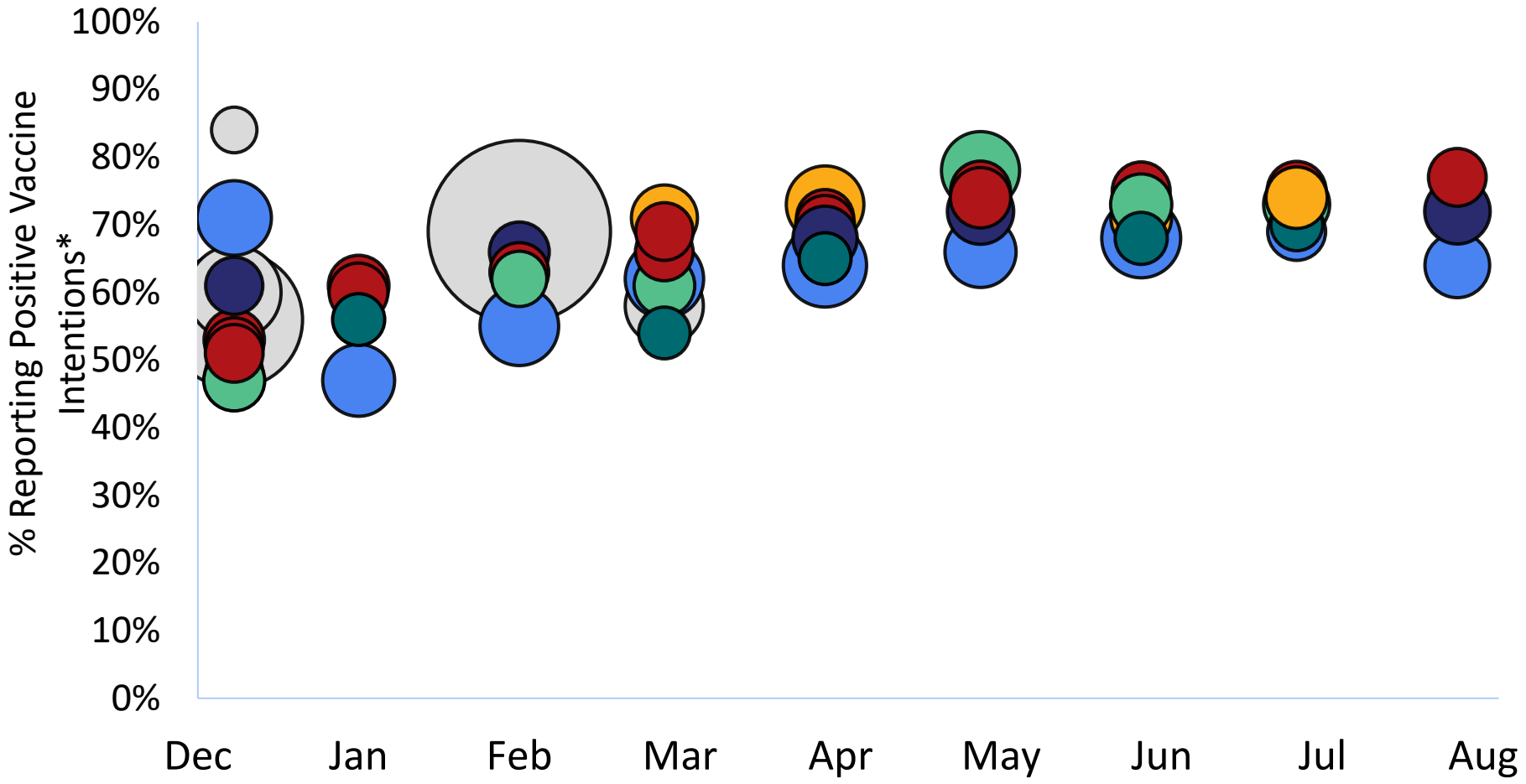
- Important uncertainty or variability
- Probably important uncertainty or variability
- Probably not important uncertainty or variability
- No important uncertainty or variability
- No known undesirable outcomes

Values:
Review of the Available Evidence

- Review of scientific literature, news media, and reports
- Surveys were limited to those conducted since authorization of COVID-19 vaccines (December 2020)

Search strategy: Pubmed: (COVID-19 OR coronavirus OR SARS-CoV-2) AND (vaccin* OR immunization) AND (survey OR questionnaire OR poll) AND (adolescent OR child* OR parent*)
Google: “COVID-19,” “coronavirus,” “vaccine,” “survey,” “poll,” “hesitancy,” “intent,” “willingness”
Societal Experts Action Network COVID-19 Survey Archive

Positive COVID-19 Vaccination Intent†



Reference	Date	N	% Intent
Szilagyi	Dec	5,660	56%
Savoia	Dec	2,650	60%
KFF	Dec	1,676	71%
APNORC	Dec	1,117	47%
Axios-Ipsos	Dec	1,101	53%
Axios-Ipsos	Dec	1,009	48%
Axios-Ipsos	Dec	1,003	52%
Axios-Ipsos	Dec	1,002	51%
Quinnipiac	Dec	978	61%
ABC/IPSOS	Dec	621	84%
Axios-Ipsos	Jan	1,112	61%
KFF	Jan	1,563	51%
Axios-Ipsos	Jan	1,038	60%
Monmouth	Jan	809	50%
Pew	Feb	10,121	69%
KFF	Feb	1,874	55%
Quinnipiac	Feb	1,075	66%
Axios-Ipsos	Feb	1,038	63%
APNORC	Feb	914	62%
COVID Collab	Mar	1,845	58%
NPR/Marist Poll	Mar	1,309	71%
KFF	Mar	1,862	62%
APNORC	Mar	1,103	61%
Axios-Ipsos	Mar	1,001	66%
Axios-Ipsos	Mar	995	69%
Monmouth	Mar	802	54%
NPR/Marist Poll	Apr	1,809	73%
Axios-Ipsos	Apr	979	71%
Axios-Ipsos	Apr	1,033	70%
Quinnipiac	Apr	1,237	68%
Monmouth	Apr	800	65%
KFF	Apr	2,097	64%
APNORC	May	1,842	78%
KFF	May	1,526	66%
Quinnipiac	May	1,316	72%
Axios-Ipsos	May	1,078	75%
Axios-Ipsos	May	1,102	74%
KFF	Jun	1,888	68%
NPR/Marist Poll	Jun	1,115	71%
Axios-Ipsos	Jun	1,016	75%
Axios-Ipsos	Jun	1,027	73%
APNORC	Jun	1,125	73%
Monmouth	Jun	810	68%
APNORC	Jul	1,308	73%
KFF	Jul	1,009	69%
Axios-Ipsos	Jul	1,048	75%
Monmouth	Jul	804	70%
NPR/Marist Poll	Jul	1,132	74%
KFF	Aug	1,259	64%
Quinnipiac	Aug	1,290	72%
Axios-Ipsos	Aug	999	77%

† **Positive vaccination 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.

Values

- The most common reasons for not getting vaccinated included[1-2]
  - Concern about side effects
  - Belief that the vaccines are too new
  - Belief that vaccination is not necessary

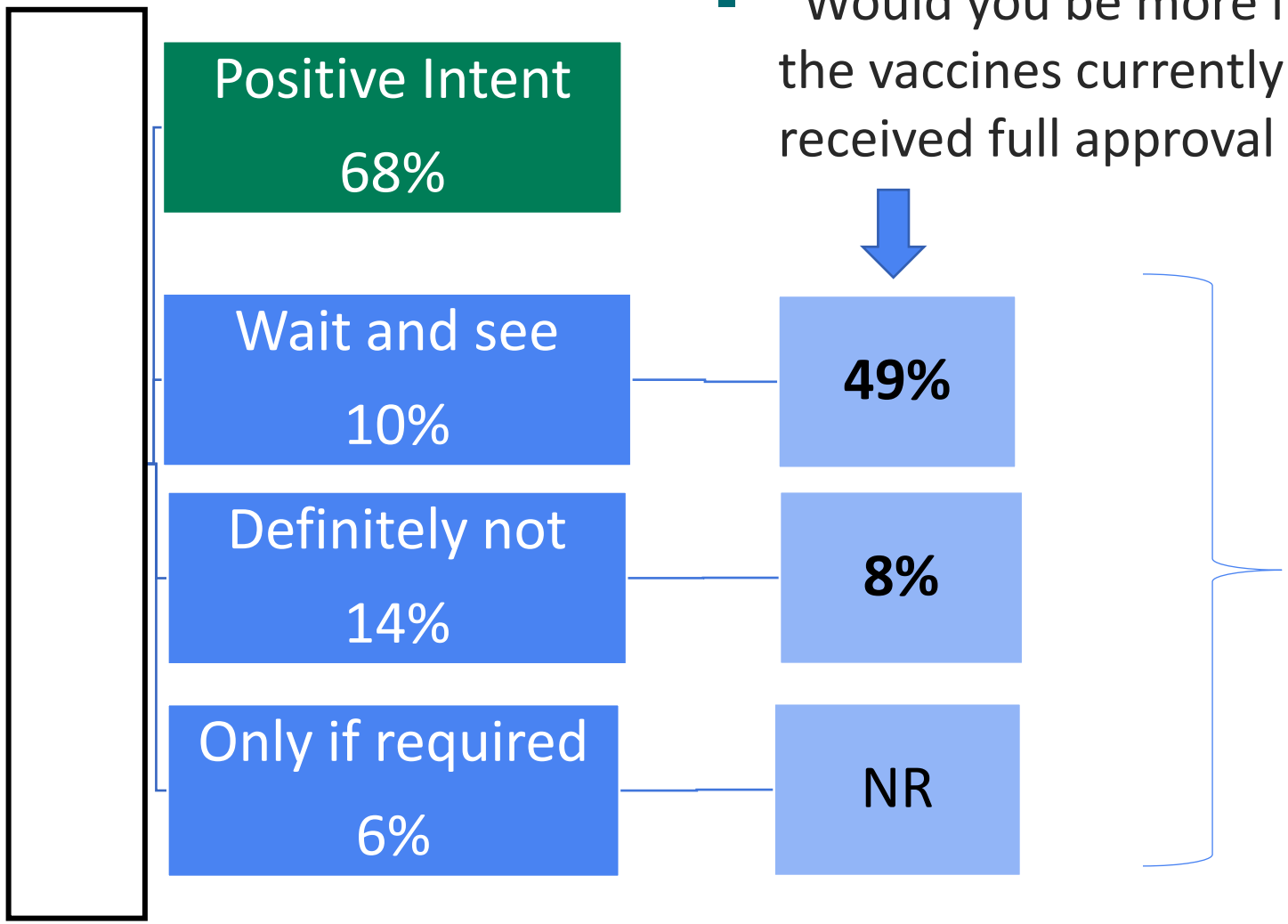
- Of those not vaccinated[3]
  - 20% said they would only get vaccinated if required
  - 36% said they would definitely not get vaccinated

1. KFF COVID-19 Vaccine Monitor: June 2021. June 30, 2021. https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-june-2021/
2. Quinnipiac Poll. August, 2021. https://poll.qu.edu/poll -release?releaseid=3815
3. KFF COVID-19 Vaccine Monitor: May 2021. May 28, 2021. https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-may-2021

Values

Unvaccinated people were asked:

- "Would you be more likely to get vaccinated if one of the vaccines currently authorized for emergency use received full approval from the FDA"



31% of unvaccinated respondents said they would be more likely to get vaccinated after full FDA vaccine approval

KFF COVID-19 Vaccine Monitor: June 2021. June 30, 2021. https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-june-2021/

Values: Work Group Interpretation

Criteria 1:
Does the target population feel that the desirable effects are large relative to undesirable effects?

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

Values: Work Group Interpretation

Criteria 2:
Is there important uncertainty about, or variability in, how much people value the main outcomes?

- 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

Acceptability

Is Pfizer-BioNTech 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

Acceptability

- 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
  - Healthcare Provider offices
- As of August 29th, 2021, >207 million doses of Pfizer-BioNTech COVID-19 vaccine have been administered[1]

1. COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#vaccinations.

Acceptability

- Vaccination with Pfizer-BioNTech 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:

Work Group Interpretation

Is the Pfizer/BioNTech COVID-19 vaccine acceptable to key stakeholders?

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

EtR Domain: Feasibility

Feasibility

Is the Pfizer/BioNTech COVID-19 vaccine feasible to implement?

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

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

Feasibility

- Barriers to implementation may include:
  1. Complexity of recommendations
  2. Vaccine storage and handling requirements
  3. Financial barriers
  4. Supply barriers

Feasibility

1) Complexity of recommendations

- The Pfizer-BioNTech COVID-19 vaccine is currently the only COVID-19 vaccine that has an FDA approved BLA
- BLA has only been issued for some indications, which may add complexity to current recommendations

  BLA: Ages 16 years and older

  EUA: Ages 12-15 years

  Additional dose in immunocompromised people

Feasibility

2) Vaccine storage and handling requirements

- Ultra-cold storage requirements (-90°C to -60°C) impacts where vaccine can be stored
  - Ultra cold storage maximum extended from 6 to 9 months
  - Freezer storage (-25°C to -15°C) for up to 2 weeks
  - Refrigerator (2°C to 8°C) temperatures for up to 1 month (31 days)

- Minimum size of orders (currently 450 doses)

Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary (cdc.gov)
Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (fda.gov)

Feasibility

3) 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

Feasibility

4) Supply barriers

- Vaccine supply in the US is sufficient for implementation of the intervention
- As of August 29, 2021, >209 million doses of Pfizer-BioNTech Covid-19 vaccine have been administered in the U.S., demonstrating that the vaccine is feasible to implement[1]

1. CDC COVID Data Tracker

Feasibility:

Work Group Interpretation

Is Pfizer-BioNTech COVID-19 vaccine feasible to implement?

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

EtR Domain: Resource Use

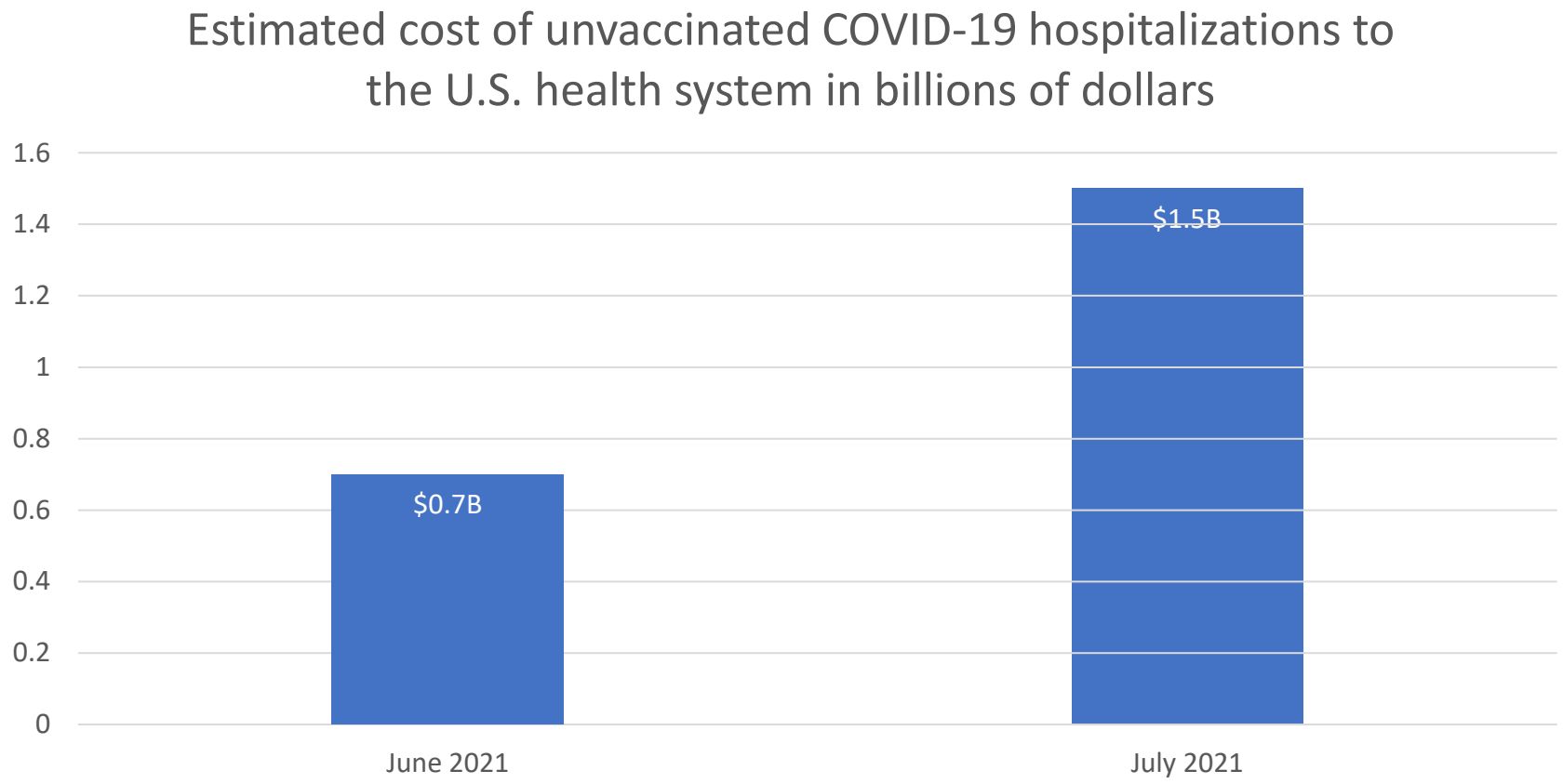
Resource Use

Is Pfizer-BioNTech COVID-19 vaccine a reasonable and efficient allocation of resources?

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

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

Resource Use:
Costs Associated with Hospitalization due to COVID-19



Peterson-KFF Health System Tracker;

Resource Use:
Costs & Benefits Associated with COVID-19 Vaccines

- Vaccine doses purchased with U.S. taxpayer funds will be given to people living U.S. 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]

COVID-19 Vaccines Are Free to the Public | CDC

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:
Work Group Interpretation

- The Work Group concluded that cost-effectiveness may not be a primary driver for decision-making during a pandemic
  - Will need to be reassessed for future recommendations

Resource Use:

Work Group Interpretation

Is Pfizer-BioNTech COVID-19 vaccine a reasonable and efficient allocation of resources?

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

EtR Domain: Equity

Equity

What would be the impact of the Pfizer-BioNTech COVID-19 vaccine on health equity?

- Are there groups or settings that might be disadvantaged in relation to COVID-19 disease burden or receipt of the Pfizer-BioNTech COVID-19 vaccine?
- Are there considerations that should be made when implementing the Pfizer-BioNTech 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

Equity:
Review of the Available Evidence

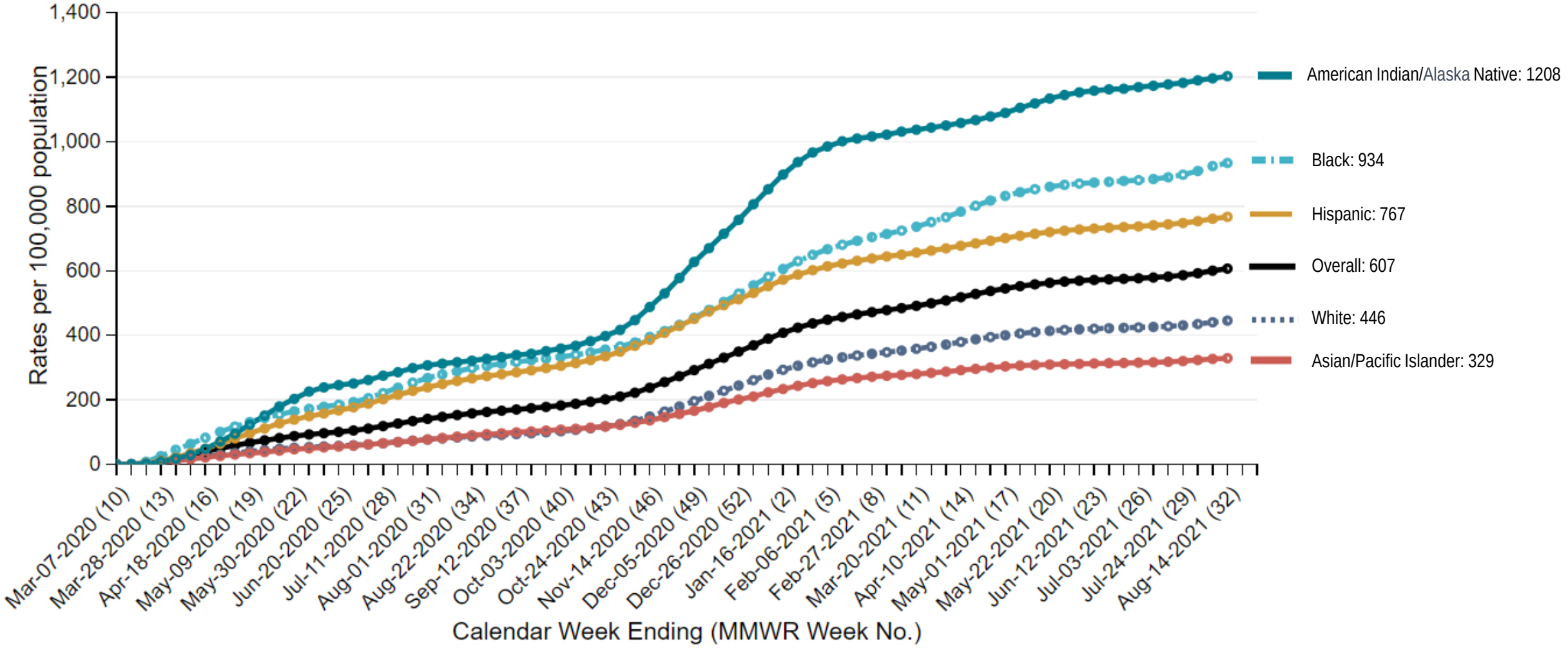
- Identification of groups that might be disadvantaged in relation to COVID-19 disease burden or receipt of the Pfizer-BioNTech COVID-19 vaccine
  - PROGRESS-Plus Framework:[1] Place of residence, race or ethnicity, gender or sex, socioeconomic status, disability, other
- Review of the scientific and gray literature
- Review of CDC COVID-19 response data and resources

1 PROGRESS-Plus is an acronym to identify factors associated with unfair differences in disease burden and the potential for interventions to reduce these differential effects. See O'Neill J, Tabish H, Welch V, et al. Applying an equity lens to interventions: using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. J Clin Epi. 2014;67: 56-64; Welch VA, Akl EA, Guyatt G, et al. GRADE equity guidelines 1: considering health equity in GRADE guideline development: introduction and rationale. J Clin Epidemiol. 2017;90:59-67.

Equity: Which Groups in the United States Could be Disadvantaged in Relation to Standard Recommendation for the Pfizer-BioNTech COVID-19 Vaccine?

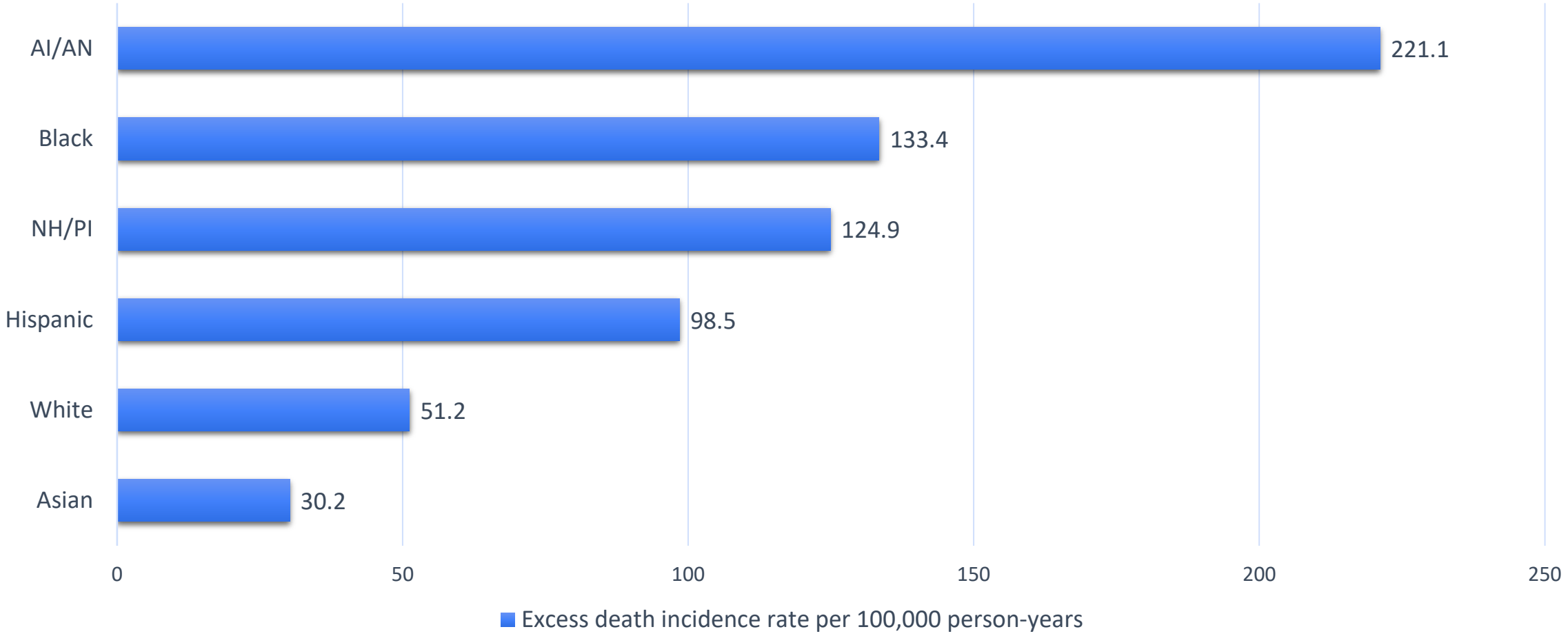
- **Place of residence**
  - Living in rural/frontier areas
  - Justice-involved (incarcerated persons)
  - Living in congregate settings (long-term care facilities)
  - Experiencing homelessness
- **Racial and ethnic minority populations**
  - Black, Hispanic or Latino, and Alaskan Native/American Indian
  - No- U.S. -born persons
- **Socioeconomic status**
  - Poverty
  - High social vulnerability
- **Personal characteristics associated with discrimination**
  - With disabilities
  - Substance use

Equity: Cumulative COVID-19 Associated Hospitalizations in the United States by Race/Ethnicity, March 7, 2020 – August 14, 2021



CDC. https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network as of August 22, 2021

Equity: Annual Excess Death Incidence Rates for Persons aged 25-64 years by Race/Ethnicity – United States, 2020

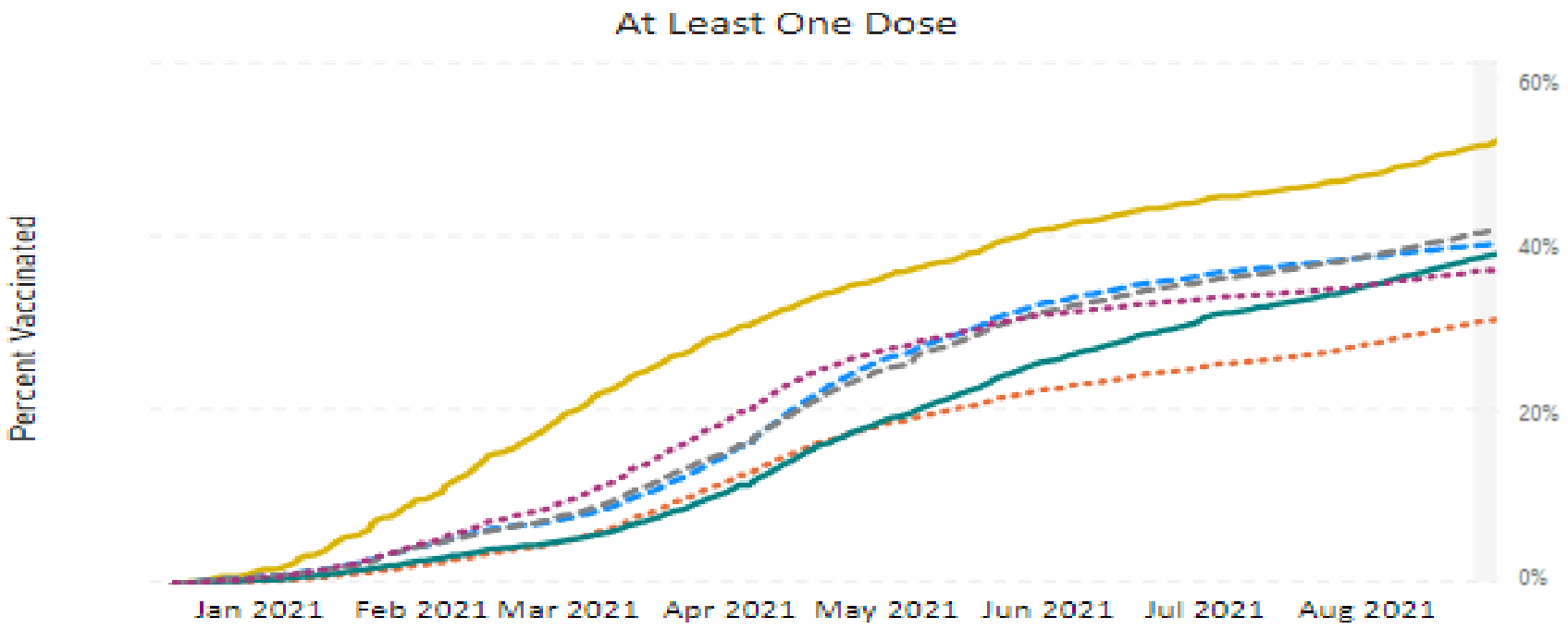


Rossen LM, Ahmad FB, Anderson RN, et al. Disparities in Excess Mortality Associated with COVID-19 — United States, 2020. MMWR Morb Mortal Wkly Rep 2021;70:1114–1119. DOI: http://dx.doi.org/10.15585/mmwr.mm7033a2

Equity: Percent of People Receiving COVID-19 Vaccine by Race/Ethnicity

December 14, 2020 – August 23, 2021

	AI/AN, NH	Asian, NH	Black, NH	Hispanic/Latino	NHOPI, NH	White, NH
At Least One Dose	51.5%	39.8%	30.8%	38.3%	41.2%	36.7%
Fully Vaccinated	43.6%	38.2%	26.6%	33.3%	35.3%	34.5%



CDC. https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends as of August 24, 2021, and US Census Bureau National Population Estimates

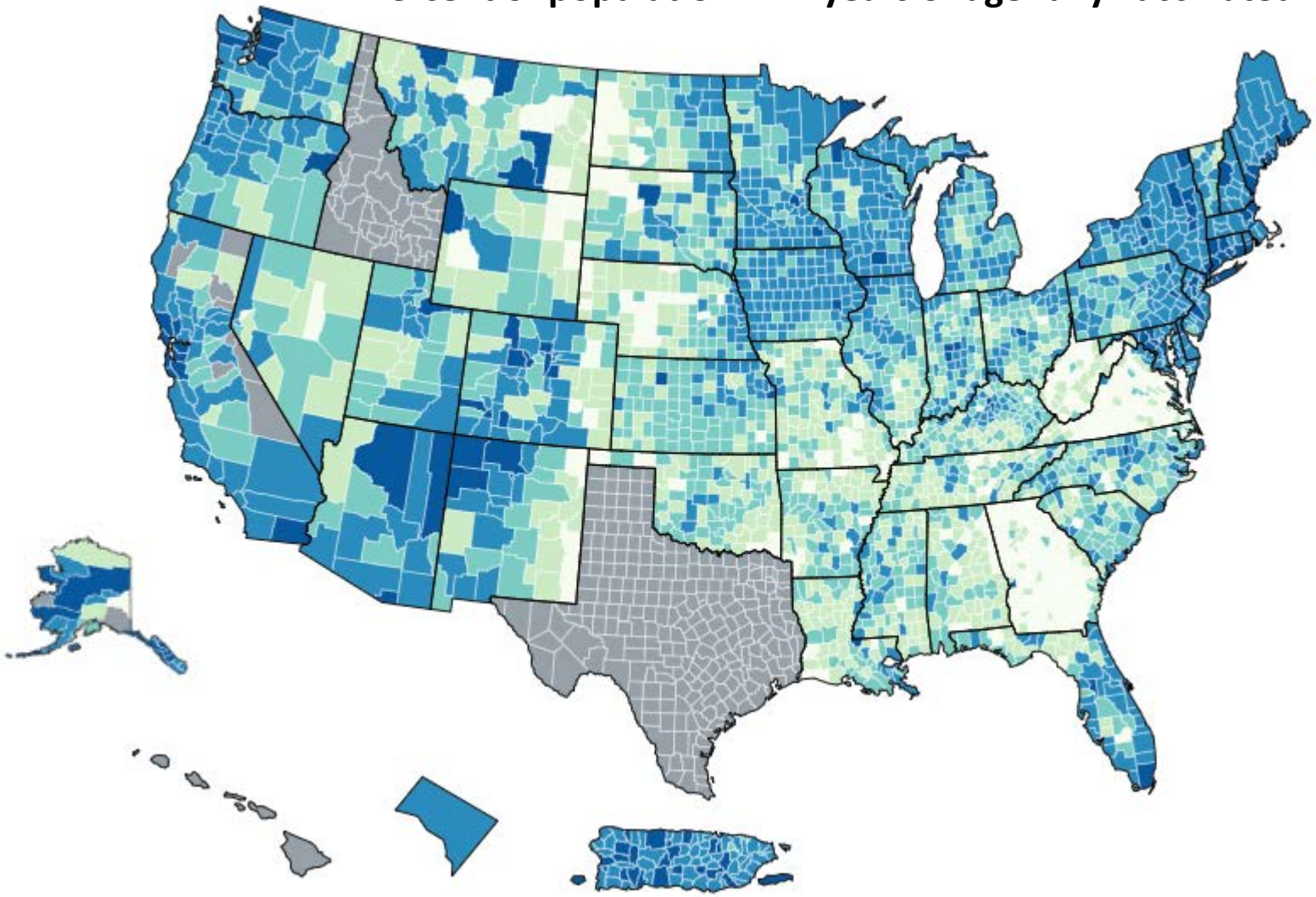
Equity: Reasons Why Some Adults Remain Unvaccinated

- Unvaccinated Hispanic and Black adults are more likely than White adults to cite worries about missing work and having to pay for the vaccine as major reasons for not being vaccinated.
- In addition, unvaccinated Hispanic adults are more likely than unvaccinated White adults to say they are too busy, would have difficulty traveling to a vaccination site, or are not sure how or where to get the vaccine.

KFF COVID-19 Vaccine Monitor (June 8-21, 2021) KFF COVID-19 Vaccine Monitor: June 2021 | KFF

COVID-19 Vaccination Coverage Varies by Geography

Percent of population ≥ 12 years of age fully vaccinated



% of population ≥12 years of age fully vaccinated	% of U.S. counties at this level
0-29.9%	14%
20-39.9%	21%
40-49.9%	28%
50-69.9%	32%
70%+	5%
No Data	--

https://covid.cdc.gov/covid-data-tracker/#vaccinations-county-view

Aug 29, 2021

Equity: Work Group interpretation

- COVID-19 has resulted in disproportionate hospitalization and mortality in minority populations
- Equitable uptake of COVID-19 vaccine has improved over time– we need to strive to continue to improve vaccine confidence and vaccine access for all
- The Work Group had varying opinions on the impact a standard ACIP recommendation for Pfizer-BioNTech COVID-19 vaccine would have on equity– it is likely that the impact will vary by community

Equity:

Work Group Interpretation

What would be the impact of Pfizer-BioNTech COVID-19 vaccine on health equity?

○ 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 the intervention
	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?	Probably yes
	Is there important variability in how patients value the outcomes?	Probably important uncertainty or variability
Acceptability	Is the Pfizer-BioNTech COVID-19 vaccine acceptable to key stakeholders?	Yes
Feasibility	Is the Pfizer-BioNTech COVID-19 vaccine feasible to implement?	Yes
Resource Use	Is Pfizer-BioNTech COVID-19 vaccine a reasonable and efficient allocation of resources?	Yes
Equity	What would be the impact of the intervention on health equity?	Varies/Don’t know

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

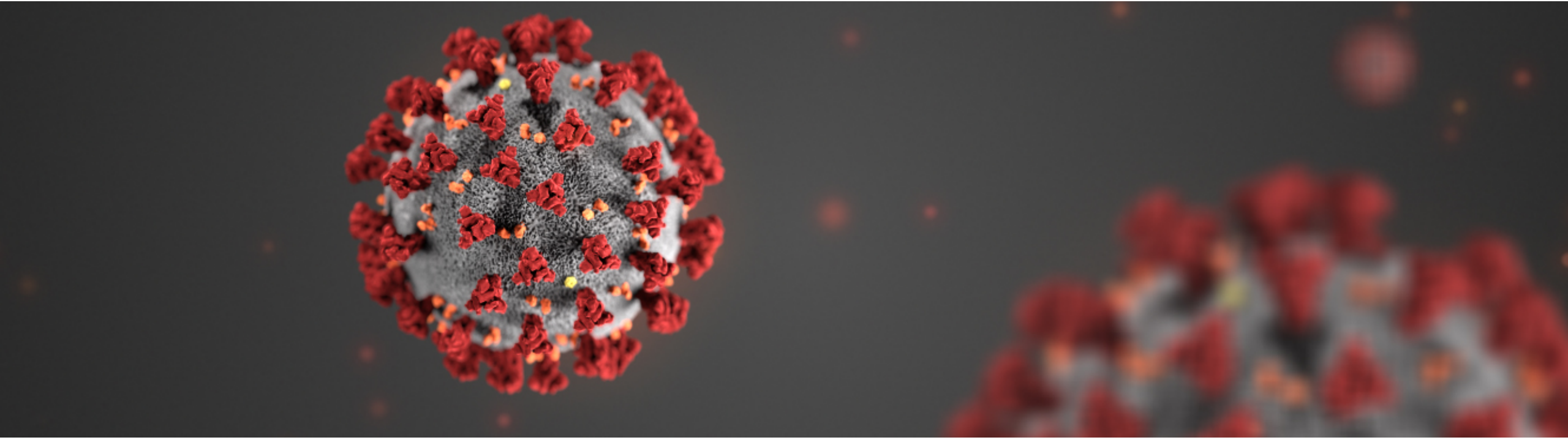
Summary: Work Group Interpretations

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**



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

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- Epi Task Force:
  - COVID-NET
  - DVD Enhanced Surveillance
  - Community Surveillance
- Data, Analytics and Visualization Task Force
- Respiratory Viruses Branch
- Immunization Safety Office