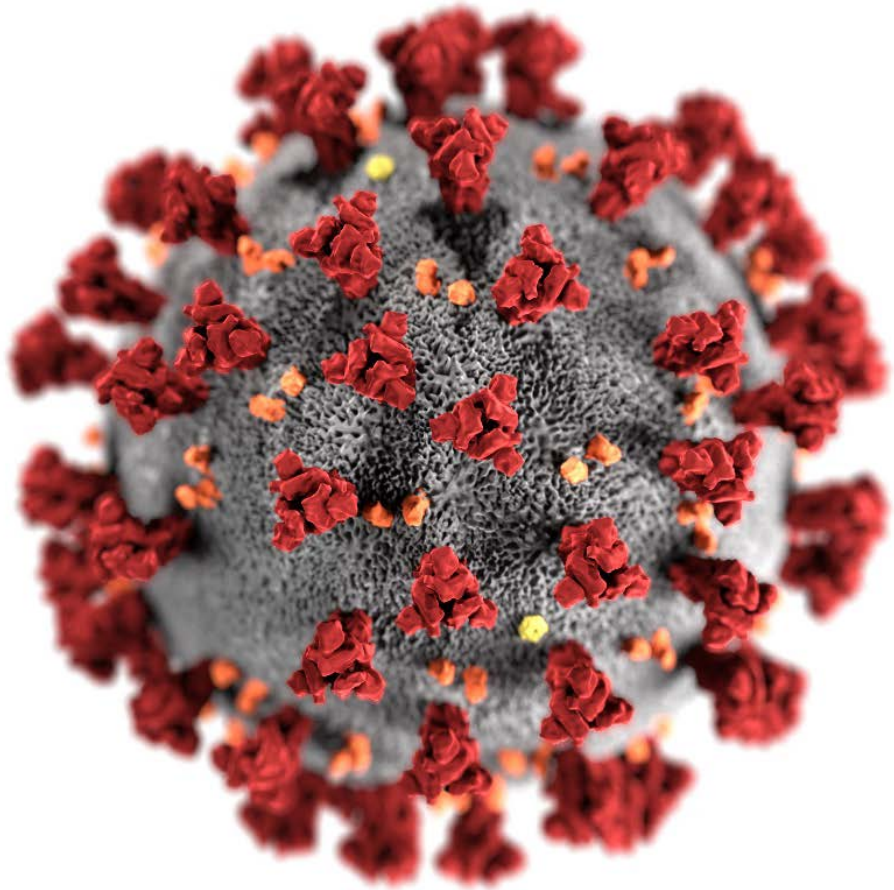
ACIP COVID-19 Vaccines



EtR Framework:

Janssen COVID-19 vaccine

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ACIP Meeting

February 28, 2021

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 Janssen COVID-19 vaccine (1 dose) be recommended for persons 18 years of age and older under an Emergency Use Authorization?

Evidence to Recommendations (EtR) Framework:
PICO Question

Population	Persons aged ≥18 years
Intervention	Janssen COVID-19 vaccine (Ad26.COV2.S) 5×10^{10} viral particles, 0.5 ml single dose IM
Comparison	No COVID-19 vaccine
Outcomes	Symptomatic laboratory-confirmed COVID-19 Hospitalization due to COVID-19 All-cause death SARS-CoV-2 seroconversion to a non-spike protein Asymptomatic SARS-CoV-2 infection Serious Adverse Events Reactogenicity grade ≥3

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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Equity	• What would be the impact of the intervention on health equity?

“The problem” = COVID-19 disease
“The vaccine” or “The intervention” = Janssen COVID-19 vaccine

EtR Domain: Public Health Problem

Public Health Problem

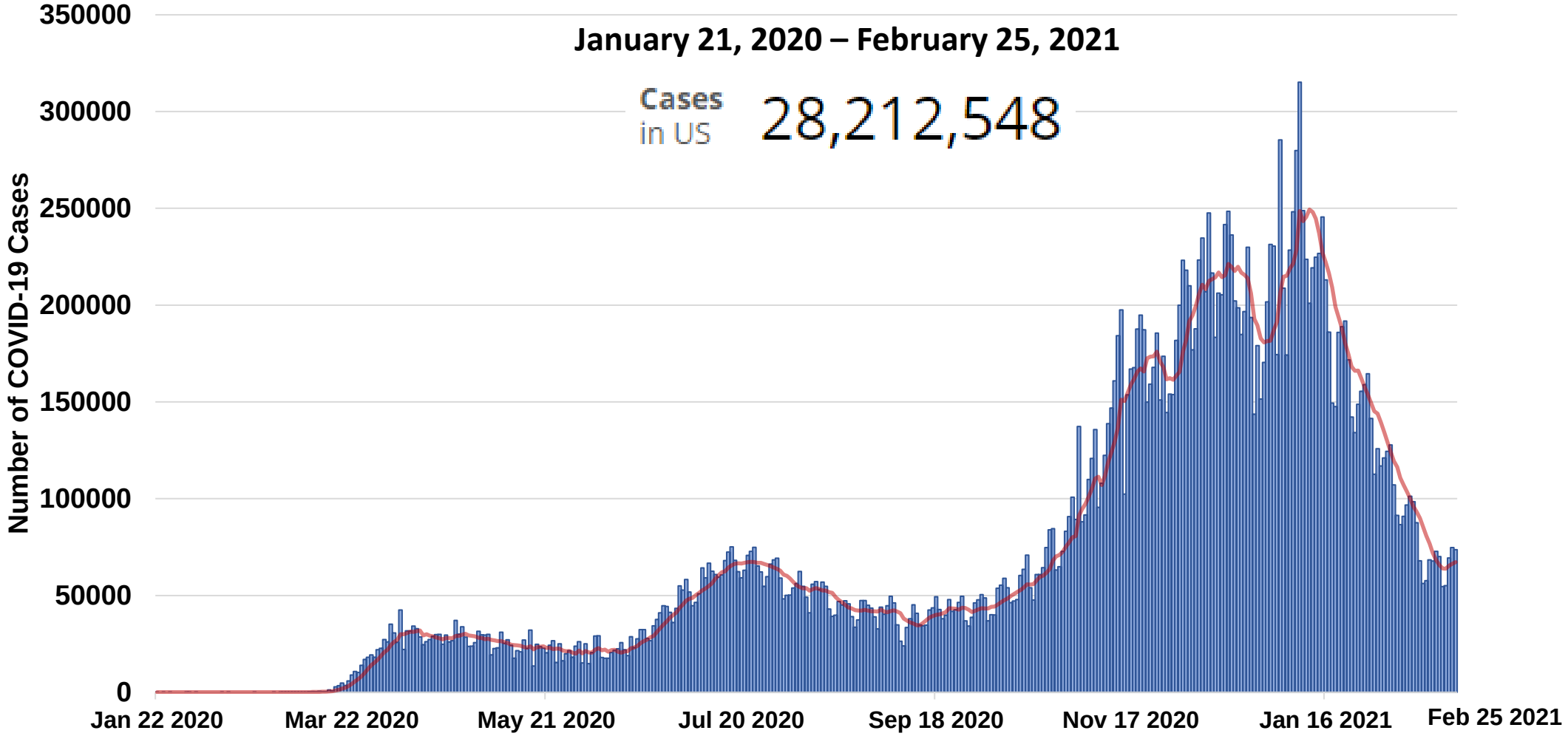
Is COVID-19 disease of public health importance?

- 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

Public Health Problem:

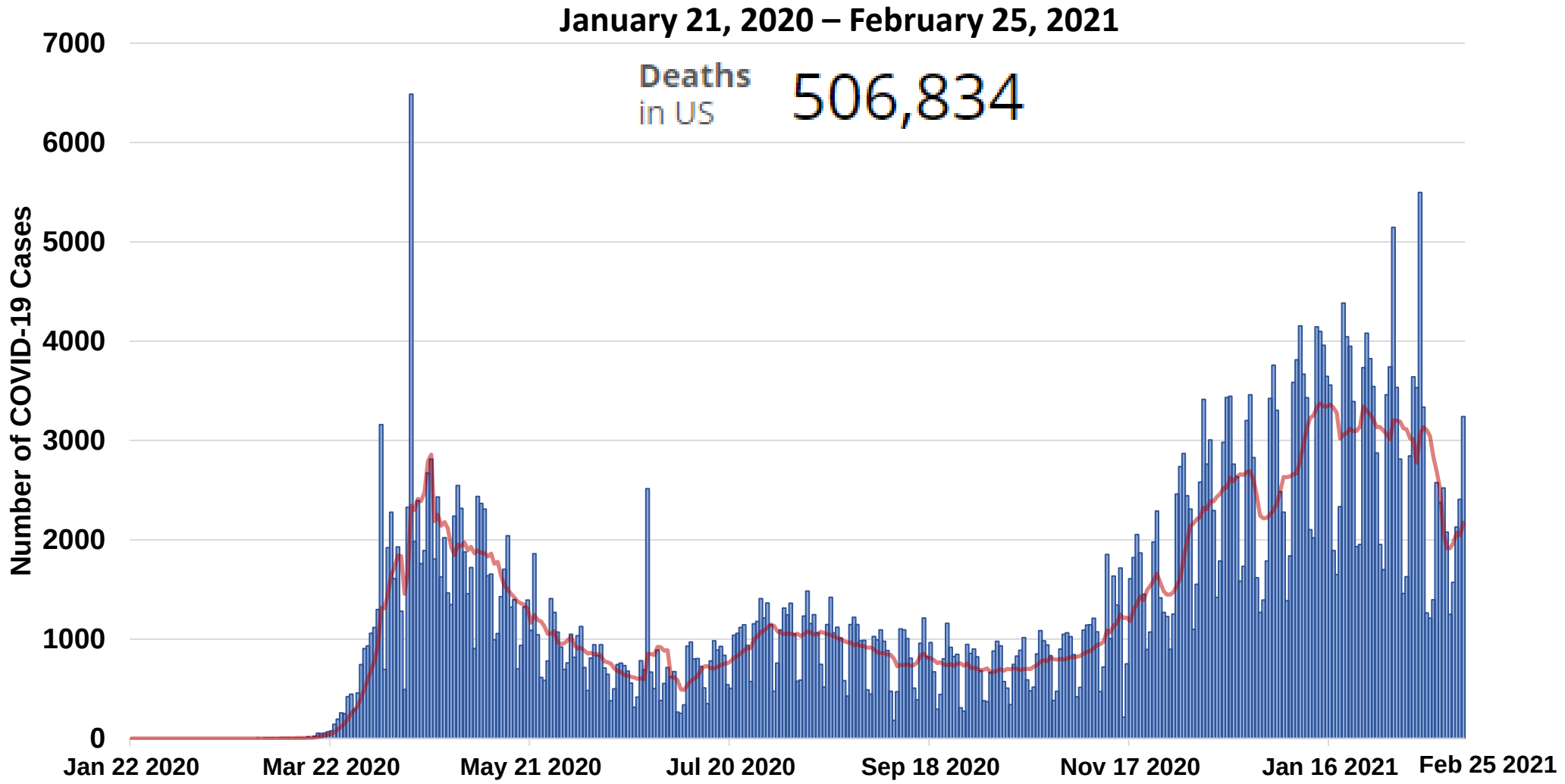
Review of the Available Evidence



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

Public Health Problem:

Review of the Available Evidence



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

Public Health Problem:
Summary of the Available Evidence

- **Hospitalization**
  - Cumulative hospitalization rate between March 1 and February 20, 2021 was **452.2** per 100,000 population
  - Among those hospitalized, **25**% required care in an intensive care unit and **11**% died
- **Mortality**
  - Cumulative mortality rate between January 22, 2020 and February 25, 2021 was **153** per 100,000 population
- **Life expectancy**
  - Dropped full year for U.S. population overall in first half of 2020
  - Black population declined 2.7 years, Hispanic population declined 1.9 years

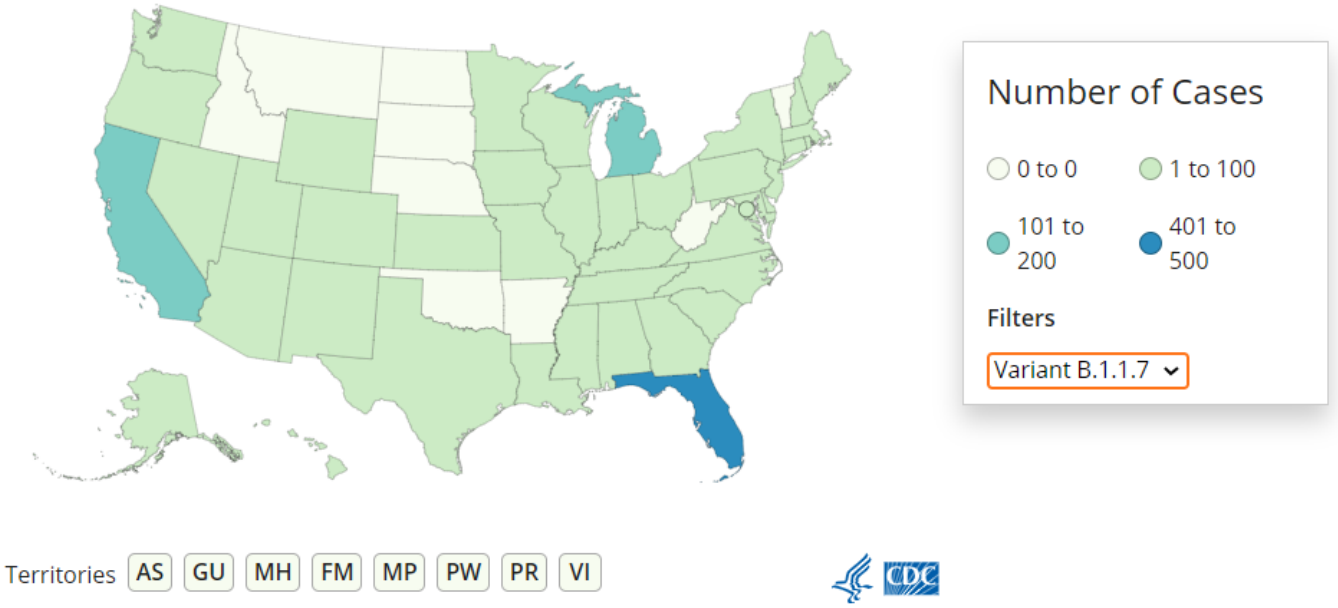
https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html . https://gis.cdc.gov/grasp/COVIDNet/COVID19_5.html .
https://www.cdc.gov/nchs/data/vsrr/VSRR10-508.pdf

Emerging Landscape of SARS-CoV-2 variants

- Requires urgency with vaccination to build population immunity

Variant	Reported Cases in US	Number of States Reporting
B.1.1.7	1523	42
B.1.351	21	10
P.1	5	4

Emerging Variant Cases in the United States*†



https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html ; As of Feb 17, 2021

Public Health Problem:

Work Group Interpretation

Is COVID-19 disease 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 (Janssen COVID-19 vaccine)
- Favors comparison (no vaccine)
- Favors both
- Favors neither
- Unclear

Benefits and Harms:

Summary of the Available Evidence: Benefits

- The clinical trial demonstrated efficacy against symptomatic, laboratory-confirmed COVID-19. The overall efficacy was **66.3%** (95% CI: 59.9%, 71.8%).

  Moderate certainty of evidence

- For COVID-19 associated hospitalization, 31 events occurred, 29 in the placebo group, 2 in the vaccine group. Vaccine efficacy against hospitalization was **93%** (95% CI: 71%, 98%).

  Moderate certainty of evidence

- For all-cause deaths, 5 occurred in the vaccine group and 20 in the placebo group. Vaccine efficacy against all-cause death was **75%** (95% CI: 33%, 91%)

  Moderate certainty of evidence

Benefits and Harms:

Summary of the Available Evidence: Benefits

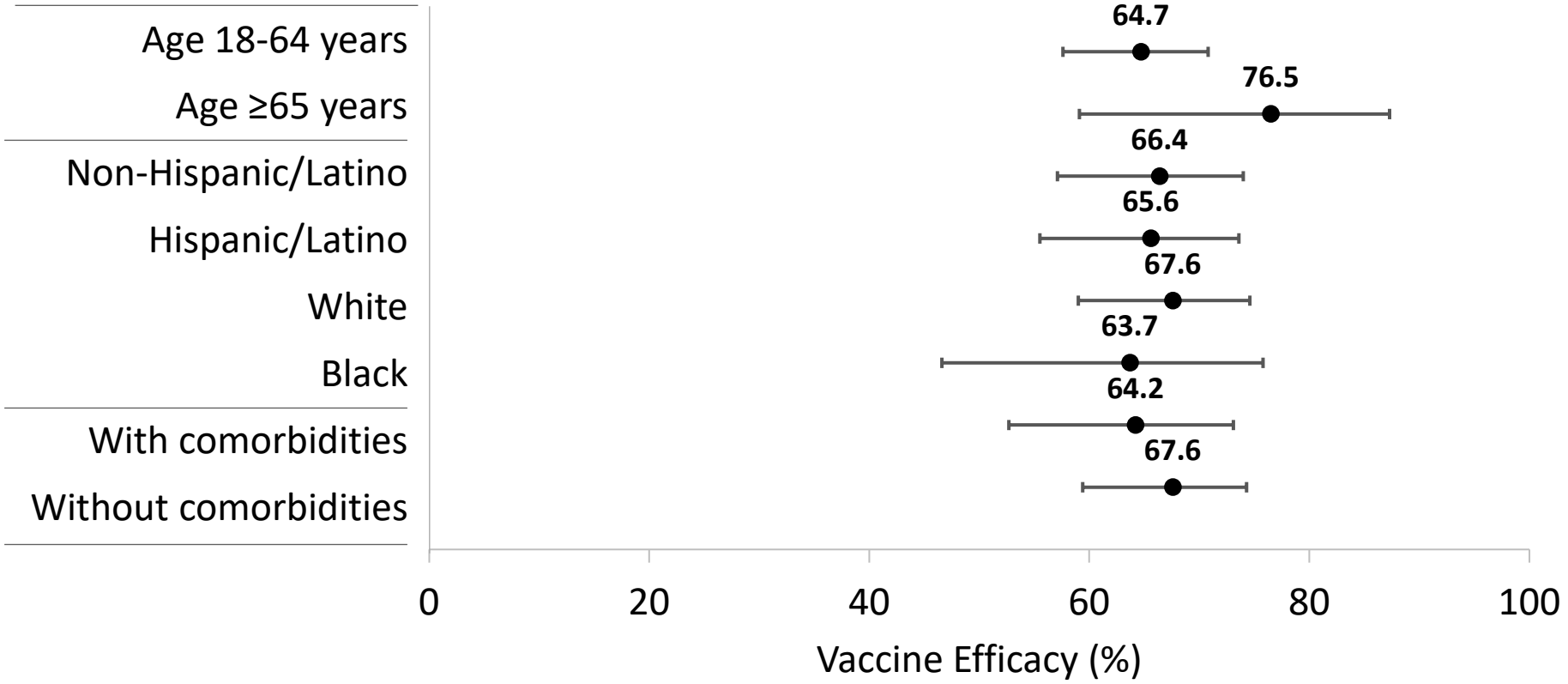
- Preliminary data were available to assess vaccine efficacy against seroconversion between days 29 and 71, based on the first 7% of specimens tested.
- Analysis was based on detection of N-binding antibody among persons who remained asymptomatic and did not have a positive SARS-CoV-2 PCR at any time in the study.
- Between four and ten weeks after vaccination with the Janssen COVID-19 vaccine, 10/1346 participants (**0.7**%) seroconverted, compared to 37/1304 (**2.8**%) of those receiving placebo. Vaccine efficacy against seroconversion was **74**% (95% CI: 48%, 87%).

Low certainty of evidence

Benefits and Harms:

Summary of the Available Evidence: Benefits

- **Similar** efficacy for across age, sex, race, and ethnicity categories, and those with underlying medical conditions at ≥14 days post-vaccination



Benefits and Harms:
Summary of the Available Evidence: Benefits

- **Higher** efficacy against **severe** outcomes than for any symptomatic COVID-19*
  - VE against **deaths** due to COVID-19**: 100%**
- Efficacy estimates for severe outcomes **assessed ≥28 days** post vaccination were **higher**: **83.5%** for severe disease†, **100%** for hospitalization
- Efficacy against severe disease† remained high across world regions (**73-82%***), suggesting protection against severe illness with variant strains

†**Definition** :Respiratory Rate ≥ 30, Heart Rate ≥125, SpO2≤ 93% on room air at sea level or PaO2/FIO2< 300 mm Hg; OR respiratory failure or Acute Respiratory Distress Syndrome (ARDS), defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO; OR evidence of shock (systolic blood pressure <90mmHg, diastolic BP<60mmHg or requiring vasopressors); OR significant acute renal, hepatic or neurologic dysfunction; OR admission to an intensive care unit or death

*Assessed ≥ 14 days post vaccination

Benefits and Harms:

Summary of the Available Evidence: Harms

- Serious adverse events were reported in a similar proportion among recipients of vaccine and placebo (0.4% vs 0.4%).

Moderate certainty of evidence

- Severe reactions were more common in vaccine recipients; any grade ≥3 reaction was reported by 2.5% of vaccinated versus 0.7% of placebo group.

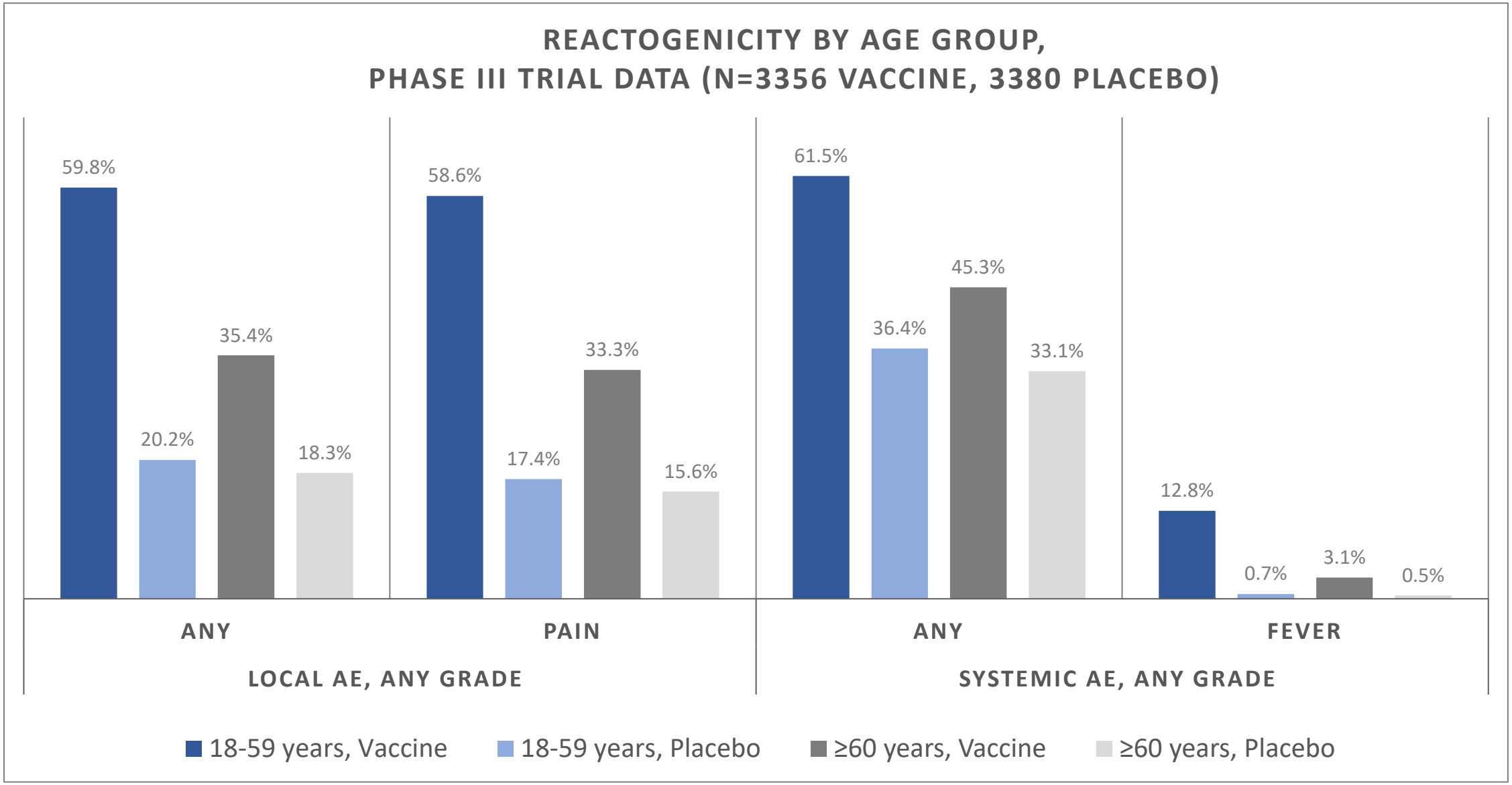
High certainty of evidence

Benefits and Harms:

Summary of the Available Evidence: Harms

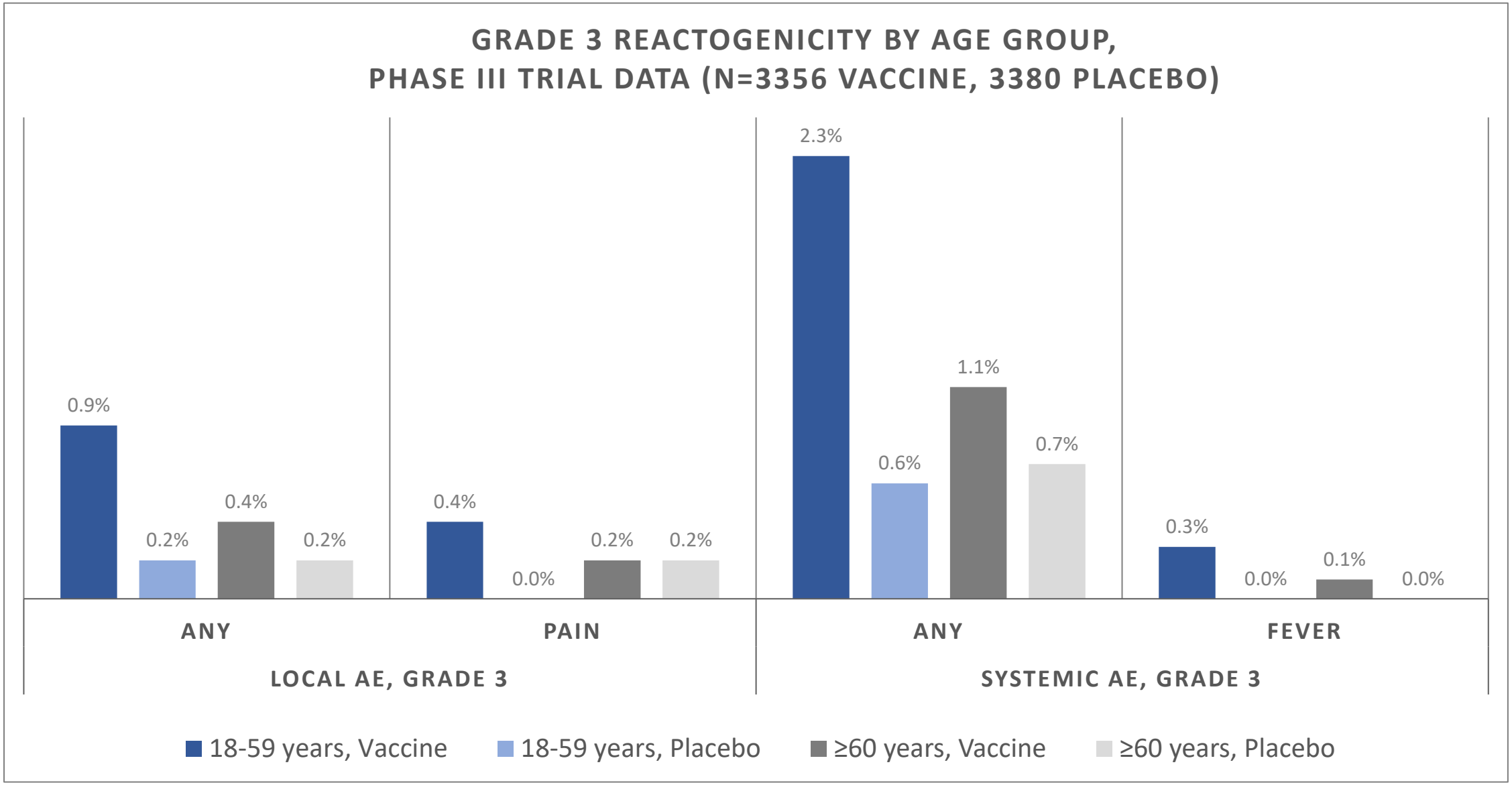
- **Local** reactions within 7 days occurred in ~50% vaccine recipients
  - Pain at the injection site most common
- **Systemic** reactions within 7 days occurred in ~55% vaccine recipients
  - Headache, fatigue, and myalgia most common
- Most symptoms resolved after 1-2 days

Benefits and Harms: Reactogenicity



Abbreviations, AE= Adverse Events

Benefits and Harms: Reactogenicity



Abbreviations, AE= Adverse Events

Benefits and Harms:
Summary of the Available Evidence: Harms

Adverse event imbalances of note:

- **Urticaria** events: vaccine n=5; placebo n=1
  - Possibly related to the vaccine*
- **Tinnitus**: vaccine n=6; placebo n=0
  - Insufficient data to determine causal relationship*
- **Thromboembolic** events: vaccine n=15; placebo n=10
  - Many of the participants had predisposing conditions. FDA determined contributory effect of vaccine not excluded, insufficient data to determine causal relationship*
  - FDA recommends surveillance for further evaluation of thromboembolic events

*Causal determination per FDA

Benefits and Harms:
Summary of the Evidence: All authorized COVID-19 vaccines

- No trials compared efficacy between vaccines in the **same** study at the **same** time
  - All Phase 3 trials differed by calendar time and geography
  - Vaccines were tested against different circulating variants and in settings with different background incidence
- All authorized COVID-19 vaccines demonstrated efficacy (range 65 to 95%) against symptomatic lab-confirmed COVID-19
- All authorized COVID-19 vaccines demonstrated **high** efficacy (≥89%) against COVID-19 severe enough to require **hospitalization**
- In the vaccine trials, **no** participants who received a COVID-19 vaccine **died** from COVID-19
  - The Moderna and Janssen trials each had COVID-19 deaths in the placebo arm

Summary of GRADE

Outcome	Importance	Design (# of studies)	Findings	Evidence type
Benefits				
Symptomatic laboratory-confirmed COVID-19	Critical	RCT (1)	Janssen COVID-19 vaccine is effective in preventing symptomatic COVID-19	**2**
Hospitalization due to COVID-19	Critical	RCT (1)	Janssen COVID-19 vaccine prevents COVID-19-resulting in hospitalization	**2**
All-cause Death	Important	RCT (1)	Janssen COVID-19 vaccine is associated with a lower risk of both all-cause death and death due to COVID-19	**2**
SARS-CoV-2 seroconversion	Important	RCT (1)	Data from day 71 serology indicates that Janssen COVID-19 vaccine prevents seroconversion during the available follow-up period; data support an effect on prevention of asymptomatic infection	**3**
Asymptomatic SARS-CoV-2 infection	Important	No Studies	No systematically collected PCR data are available to develop an estimate for this outcome	**ND**
Harms				
Serious adverse events	Critical	RCT (3)	SAEs were balanced between vaccine and placebo arms. 3 participants had SAEs judged by FDA as likely related to vaccination	**2**
Reactogenicity	Important	RCT (3)	Severe reactions were about 3 times more common in vaccinated vs. placebo; any grade ≥3 reaction was reported by 2.5% of vaccinated	**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

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?

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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 (Janssen 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 the Janssen 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

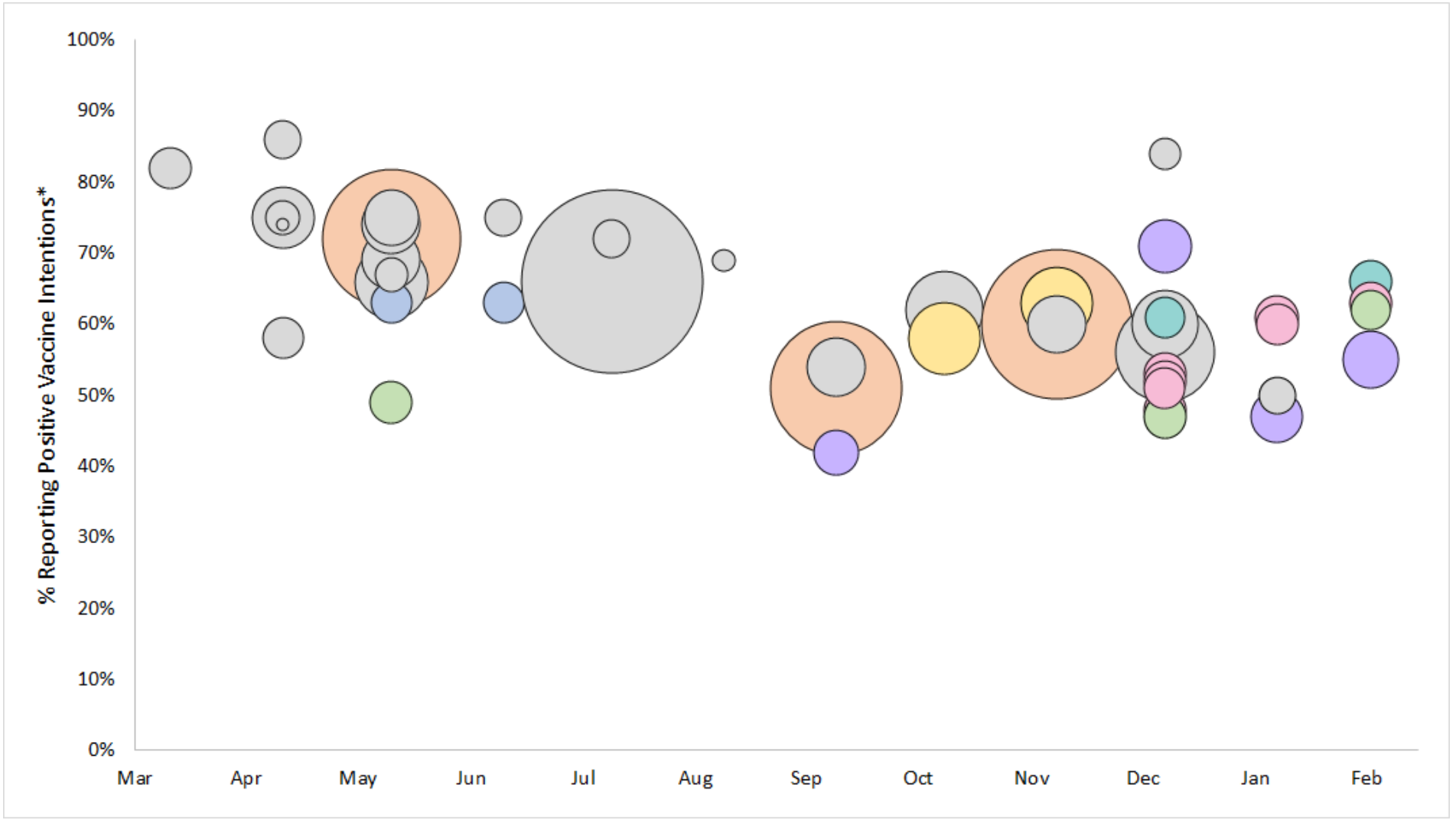
- Review of scientific literature, news media, and reports
  - Databases: Medline, Embase, Psycinfo, Global Health Ovid, CINAHL, ProQuest Coronavirus Research, Scopus, WHO COVID-19
  - Search terms: SARS-CoV-2/COVID-19 string; vaccine string; intent, confidence, hesitancy, attitude, belief, accept, choice, decision, refusal
  - News media and reports: Societal Experts Action Network COVID-19 Survey Archive, Google
  - Last search date: **February 26, 2021**
- Inclusion criteria
  - Data collection in 2020 and 2021 related to COVID-19 vaccine beliefs, attitudes, and intentions
  - Population: Adults in the U.S.

Values:
Summary of the Available Evidence

- Overall acceptability of a COVID-19 vaccine was **moderate**[1]
  - Proportion intending to receive vaccine ranged across surveys: **42-86**%
  - February 2021: 46% get as soon as available, 27% wait and see, 18% definitely not get[2]
- Highest estimates of non-intent to receive COVID-19 vaccination[3]:
  - Younger adults
  - Women
  - Non-Hispanic Black adults
  - Adults living in nonmetropolitan areas
  - Adults with less education and income, and without health insurance

1. APNORC; Harris; Fisher *Ann Intern Med*.; ICF; Kreps *JAMA Netw Open*.; Lazarus *Nature Med*.; Malik *EClinicalMedicine*.; Pogue *Vaccines*.; Reiter *Vaccine*.; Thunstrom *SSRN.* Szilagyi *JAMA.* Axios-IPSOS. Pew. KFF. ABC News-IPSOS. Quinnipiac. Monmouth.
2. KFF COVID-19 Vaccine Monitor: February 2021. February 26, 2021. https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-february-2021/
3. Nguyen KH, Srivastav A, Razzaghi H, et al. COVID-19 Vaccination Intent, Perceptions, and Reasons for Not Vaccinating Among Groups Prioritized for Early Vaccination — United States, September and December 2020. MMWR Morb Mortal Wkly Rep 2021;70:217–222. DOI: http://dx.doi.org/10.15585/mmwr.mm7006e3

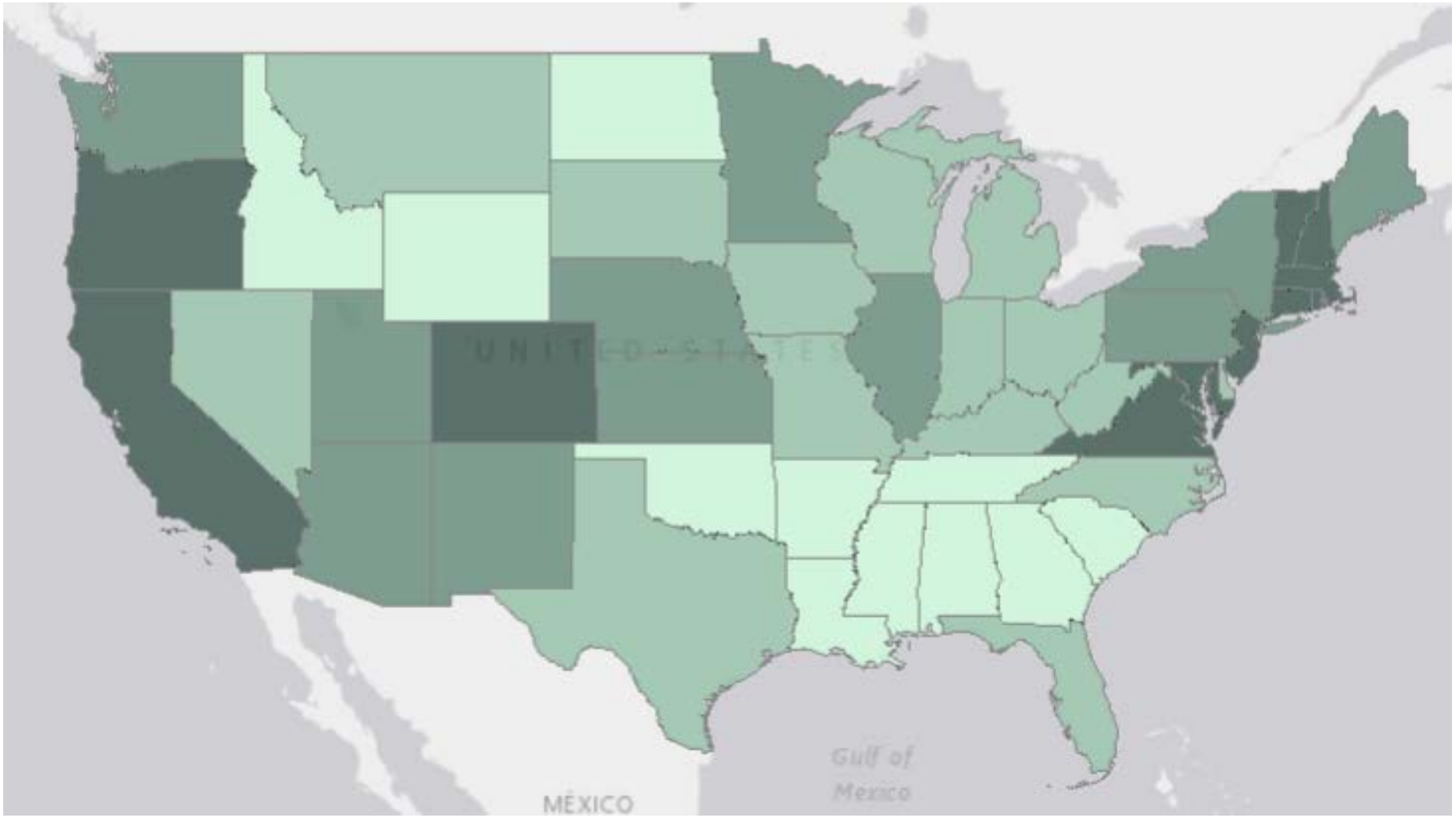
COVID-19 Vaccination Intentions Vary by Survey Month†



Reference	Date	N	% Intent
Romer	Mar	1,050	82%
Southwell	Apr	2,279	75%
Fisher	Apr	991	58%
Earnshaw	Apr	845	86%
Roozenbeek	Apr	700	75%
Hogan	Apr	101	74%
Pew	May	10,957	72%
Head	May	3,159	66%
Reiter	May	2,006	69%
CUNY	May	1,999	74%
Taylor	May	1,772	75%
APNORC	May	1,056	49%
ICF	May	1,000	63%
Malik	May	672	67%
ICF	Jun	1,000	63%
Lazarus	Jun	773	75%
Perlis	Jul	19,027	66%
Romer	Jul	840	72%
Pogues	Aug	316	69%
Pew	Sep	10,093	51%
Harris	Sep	1,971	54%
KFF	Sep	1,199	42%
IPSOS	Oct	3,541	62%
Gallup	Oct	2,985	58%
Pew	Nov	12,948	60%
Gallup	Nov	2,968	63%
USC	Nov	2,703	63%
Harris	Nov	1,963	60%
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%
KFF	Feb	1,874	55%
Quinnipiac	Feb	1,075	66%
Axios-Ipsos	Feb	1,038	63%
APNORC	Feb	914	62%

†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.
*Positive vaccine intentions includes persons reporting definitely, probably, or somewhat likely to get vaccinated. Some surveys also included persons who already received vaccine.

Likelihood of Receiving a COVID-19 Vaccine Varies by State

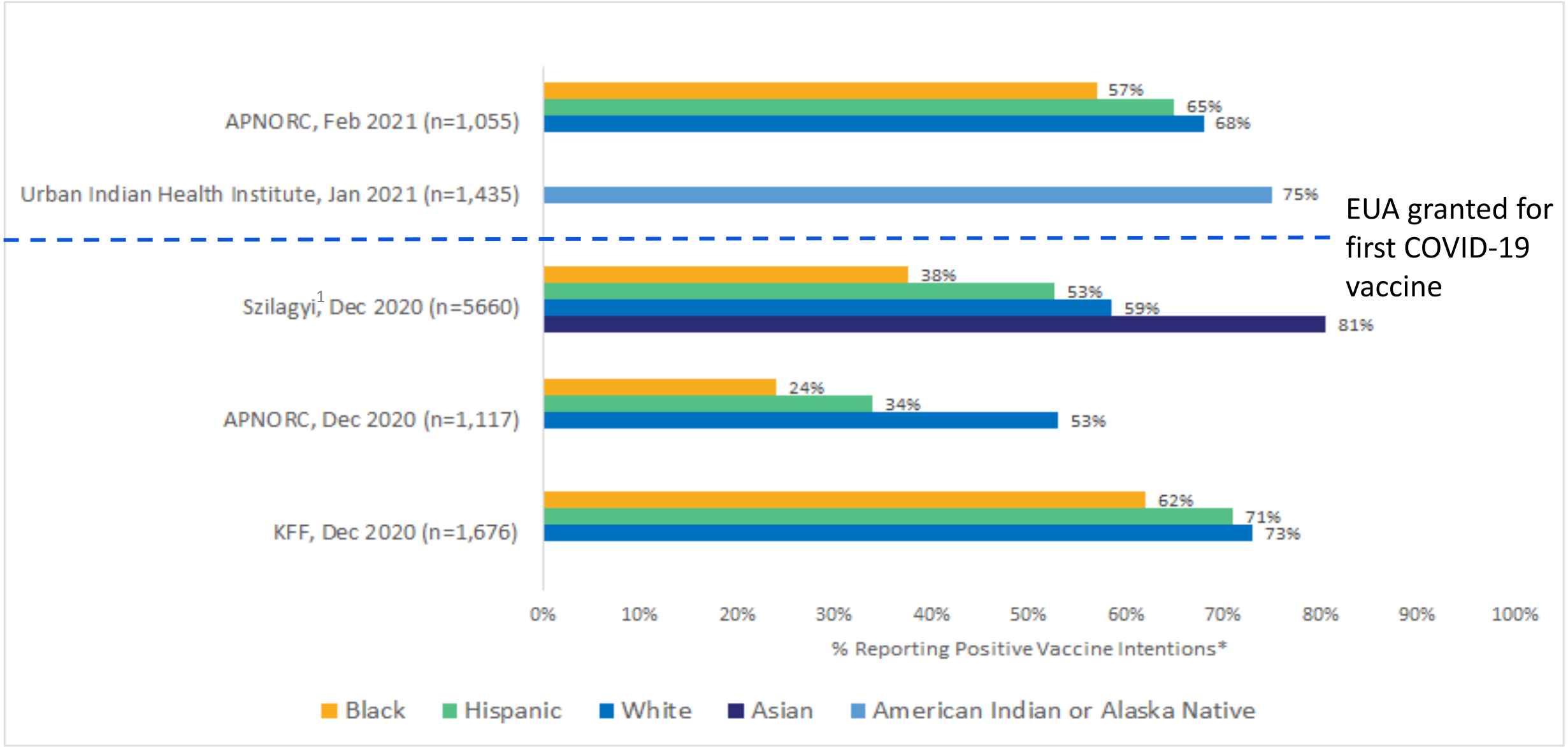


Percentage of adults who have not received a COVID-19 vaccine but definitely will once available

- > 61.0% - 69.9%
- > 53.6% - 61.0%
- > 45.7% - 53.6%
- 35.9% - 45.7%

U.S. Census Bureau, Household Pulse Survey, Week 24 Data, February 3-15

COVID-19 Vaccination Intentions Vary by Race/ethnicity



*Positive vaccine intentions includes persons reporting definitely, probably, or somewhat likely to get vaccinated.

1. Szilagyi PG, Thomas K, Shah MD, et al. National Trends in the US Public's Likelihood of Getting a COVID-19 Vaccine—April 1 to December 8, 2020. JAMA. 2021;325(4):396–398. doi:10.1001/jama.2020.26419

Values:
Summary of the Available Evidence

- Vaccination intentions varied substantially by race/ethnicity and socioeconomic status
- Common reasons for positive intentions: protecting self, family, and community from COVID-19, belief that COVID-19 vaccines are safe, and ability to resume social activities
- Common concerns included vaccine side effects and uncertainty about vaccine safety

- Feb 2021 survey of 2-dose vs. 1-dose vaccines*: 58% would choose 2-dose vaccine, 7% would choose 1-dose vaccine, 21% would take either[1]
  - Of those that chose 2-dose, 28% would get the 1-dose vaccine now rather than wait a month to get 2-dose
- Limitations:
  - Most surveys conducted prior to availability of information on Janssen COVID-19 vaccine
  - Convenience samples may not be representative

*Comparing a 2-dose vaccine that is 94% effective against getting COVID-19 and 97% effective against getting severe disease to a 1-dose vaccine that is 72% effective against getting COVID-19 and 85% effective against getting severe disease

1. NORC AmeriSpeak, Feb 11-15, 2021. CDC unpublished data.

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 the Janssen 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:
Review of the Available Evidence

- Review of scientific literature
- Preliminary findings from CDC evaluations of COVID-19 vaccine attitudes
  - Survey with State Health Officers (n=34)
- Review of news media, professional society and workers' unions websites
  - AAFP, AFT, AFSCME, AGS, ANA, AMA, IDSA, SEIU
- Consideration of programmatic, financial, and ethical aspects
  - State/jurisdiction and partner planning for vaccine implementation
  - Anticipated out-of-pocket costs

Acceptability:
Summary of the Available Evidence

- No published provider knowledge, attitudes, and practices surveys
- State health officers, Oct 2020: concerns with rollout included vaccine hesitancy (53%), vaccine safety (32%), and communications (26%)[1]
- Concern from jurisdictions regarding vaccine supply and unmet demand
  - National Governors Association Executive Committee Letter to the President[2]

1. CDC COVID-19 Response Team.
2. National Governors Association. Executive Committee Letter To President Regarding Vaccine Distribution Process. https://www.nga.org/advocacy-communications/executive-committee-letter-to-president-regarding-vaccine-distribution-process/

Acceptability:
Summary of the Available Evidence

- Logistics regarding implementation may be more accessible to a wide variety of stakeholders
  - Single dose
  - More convenient storage (3 months at 2-8^{o}C)
  - Does not require dilution

Acceptability:
Summary of the Available Evidence

- 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

- As of February 27th, 2021, >72 million doses have been administered[1]
  - >48 million people have initiated a series
  - >7 million doses administered in LTCFs

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

Acceptability:

Work Group Interpretation

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

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

EtR Domain: Feasibility

Feasibility

Is the Janssen COVID-19 vaccine feasible to implement?

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

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

Feasibility:
Summary of the Available Evidence

1) Janssen vaccine characteristics

- Vaccine shipment and storage (3 months) at refrigerator temperatures (2-8^{o}C)*
- Single-dose series

* Long-term storage at standard freezer temperatures (-20^{o}C)

Feasibility:
Summary of the Available Evidence

2) Financial barriers

- All COVID-19 vaccines are provided to U.S. population **free of charge**
- Health systems or health departments could incur costs for vaccine implementation or clinics
- Personal investments in time and travel to obtain vaccine may be a barrier for some groups
  - Janssen: Cost related to one dose presumably less than for two vaccine doses

Feasibility:
Summary of the Available Evidence

3) Complexity of recommendations

- One adenoviral vector vaccine and two mRNA vaccines under an EUA with different numbers of doses, dosing intervals, storage and handling requirements may make vaccine recommendations more complex
- Potential for emerging challenges related to managing choice/preferences of providers and consumers for different products

Feasibility:
Summary of the Available Evidence

4) Access to vaccines

- Adding a third vaccine will increase access, in terms of vaccine doses available
- Access to vaccine could be limited for people who are underserved or live in rural or other hard-to-reach areas
  - Consider differential access when planning vaccination locations, communicating vaccine information, and scheduling appointments[4]
- Federal Retail Pharmacy Program[1], Federally Qualified Health Center Program[2], and FEMA Community Vaccination Centers[3] should further expand access
- Vaccine without freezer requirements could be used in individual provider offices, once supply allows

[1] CDC. Understanding the Federal Retail Pharmacy Program for COVID-19 Vaccination. https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html

2 CDC. Ensuring Equity in COVID-19 Vaccine Distribution. https://www.cdc.gov/vaccines/covid-19/planning/health-center-program.html

[3] FEMA. https://www.fema.gov/press-release/20210216/fema-supports-vaccine-distribution-amid-winter-weather-response

[4] COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations. October 29, 2020: https://www.cdc.gov/vaccines/covid-19/covid19-vaccination-guidance.html

Feasibility:

Work Group Interpretation

Is the Janssen COVID-19 vaccine feasible to implement?

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

EtR Domain: Resource Use

Resource Use

Is the Janssen COVID-19 vaccine a reasonable and efficient allocation of resources?

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

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

Resource Use:
Summary of the Available Evidence

- Health-related costs (including premature deaths, long-term health impairment and mental health impairment) have been estimated at $**8.5 trillion**[1]
- U.S. Government has committed over $**10 billion** to provision of vaccines[2]
- A recent study estimated COVID-19 vaccinations to range between "cost-saving" and $94,000 per quality-adjusted life-year (QALY), depending on target population[3]
  - Hypothetical vaccine; vaccine not provided free of charge
  - Did not consider societal costs, e.g., productivity, individual costs associated with pandemic
- Modeling study concluded only limited situations favor foregoing currently available vaccine(s) for substantially higher efficacy vaccines available later in pandemic[4]

[1] Cutler and Summers. 2020. JAMA. "The COVID-19 pandemic and the $16 trillion virus."

[2] Source: https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html

[3] Kohli M, Maschio M, Becker D, Weinstein M. "The Potential Public Health and Economic Value of a Hypothetical COVID-19 Vaccine in the United States: Use of Cost-Effectiveness Modeling to Inform Vaccination Prioritization." *Vaccine* 2021 Feb 12; 39(7): 1157–1164.

[4] Bartsch SM, O'Shea KJ, Wedlock PT, et al. The Benefits of Vaccinating With the First Available COVID-19 Coronavirus Vaccine. American Journal of Preventive Medicine. 2021 Jan 19.

Resource Use:
Work Group Interpretation

- Precise cost-effectiveness analysis and economic impact of vaccination depend on number of factors that are currently unknown:
  - Real-world vaccine effectiveness and duration of vaccine protection
  - Vaccination coverage levels and speed of vaccination
  - Implementation costs associated with large vaccination program
- Work Group concluded that cost-effectiveness may not be a primary driver for decision-making during a pandemic and for vaccine used under EUA
  - Will need to be reassessed for future recommendations, including post BLA
- During pandemic, best utilization of resources is to employ all vaccines with acceptable VE – save cost and lives

Resource Use:

Work Group Interpretation

Is the Janssen 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 Janssen 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 Janssen COVID-19 vaccine?
- Are there considerations that should be made when implementing the Janssen 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: Groups that have experienced disproportionate COVID-19 morbidity and mortality or decreased uptake of COVID-19 vaccines

- Racial and ethnic minority populations and tribal communities
- People living in poverty or with high social vulnerability
- Essential workers
  - Some racial/ethnic minority populations disproportionately represented in subsets of essential workers, e.g., public transit, building cleaning services, construction, food and agriculture[1-3]
  - Almost one quarter live in low-income families[1]
- Residents in congregate settings, such as long-term care facilities, correctional/detention facilities, homeless shelters, and group homes
- People with disabilities
- People with substance abuse disorders
- Sexual and gender minorities (social or structural inequities leading to health disparities)

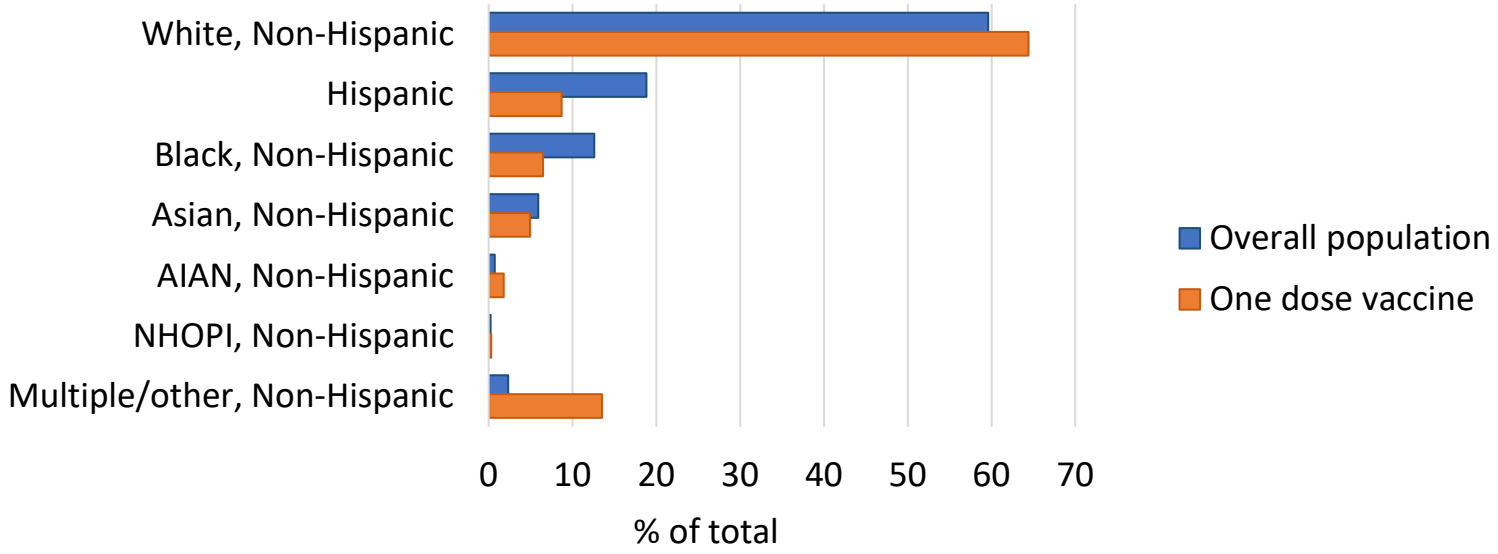
[1]Rho HJ, Brown H, Fremstad S. A basic demographic profile of workers in frontline industries. April 2020. Washington, DC: Center for Economic and Policy Research;2020. https://cepr.net/a-basic-demographic-profile-of-workers-in-frontline-industries

[2]Bui DP, McCaffrey K, Friedrichs M, et al. Racial and ethnic disparities among COVID-19 Cases in workplace outbreaks by industry sector — Utah, March 6–June 5, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1133–8. DOI: http://dx.doi.org/10.15585/mmwr.mm6933e3

[3]Waltenburg MA, Rose CE, Victoroff T, et al. Coronavirus disease among workers in food processing, food manufacturing, and agriculture workplaces Emerg Infect Dis. 2021 Jan. https://wwwnc.cdc.gov/eid/article/27/1/20-3821_article

Equity: Data on equitable provision of COVID-19 vaccine

- Only 19 (38%) states used a social vulnerability index to deliver vaccines more equitably in initial vaccine allocation plans [1]
- National survey (n=67,000) in first half of Jan. 2021, showed Black persons 52% less likely than White persons to be vaccinated or definitely plan to get vaccinated [2]
- As of February 26, lower % of Black & Hispanic persons received ≥1 vaccine dose vs % of overall population [3]



[1] Schmidt et al. Equitable Allocation of COVID-19 Vaccines. 2020: https://scholarship.law.georgetown.edu/facpub/2333/

2 Kim et al. https://www.medrxiv.org/content/10.1101/2021.02.16.21251769v1

[3] CDC. https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic as of Feb 17 2021 , and US Census Bureau 10-year July 2019 National Population Estimates

Equity: Characteristics of the Janssen COVID-19 vaccine that could impact health equity

- Storage, handling and administration requirements
  - Refrigerator-stable vaccine will facilitate the availability of the Janssen COVID-19 vaccine in most community settings and mobile sites, once supply allows
- Single dose schedule; increased vaccine options and more doses available
- Easier to reach some disproportionately affected groups such as: homeless, rural residents, justice-involved, disabled, homebound, or with no/limited access to healthcare
- Community engagement and education will be important as new vaccines are utilized

Equity:
Additional Considerations

- Equity and vaccination program implementation are closely linked
- Advancing health equity, particularly in populations who experience disproportionate COVID-19-related morbidity and mortality, requires community engagement and focused efforts to **identify** and **remove** barriers for COVID-19 vaccines, including issues related to access or vaccine hesitancy[1]
- Whenever possible, consider extending choice for COVID-19 vaccines

[1] CDC. COVID-19 Vaccination Program Interim Playbook for Jurisdictions Operations Annex: Considerations for Increasing COVID-19 Vaccination, Reaching and Increasing Uptake in Priority Populations (January 2021 Version 1.0). https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-vaccination-program-playbook-annex.pdf

Equity:

Work Group Interpretation

What would be the impact of the Janssen 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 disease 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 Janssen COVID-19 vaccine
	What is the overall certainty of the evidence for the critical outcomes?	2 (moderate) for prevention of symptomatic COVID-19 2 (moderate) for hospitalization 2 (moderate) for safety
Values	Does the target population feel the desirable effects are large relative to the undesirable effects?	Yes
	Is there important variability in how patients value the outcomes?	Probably important variability
Acceptability	Is the Janssen COVID-19 vaccine acceptable to key stakeholders?	Yes
Feasibility	Is the Janssen COVID-19 vaccine feasible to implement?	Yes
Resource Use	Is the Janssen COVID-19 vaccine a reasonable and efficient allocation of resources?	Yes
Equity	What would be the impact of the intervention on health equity?	Increased

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

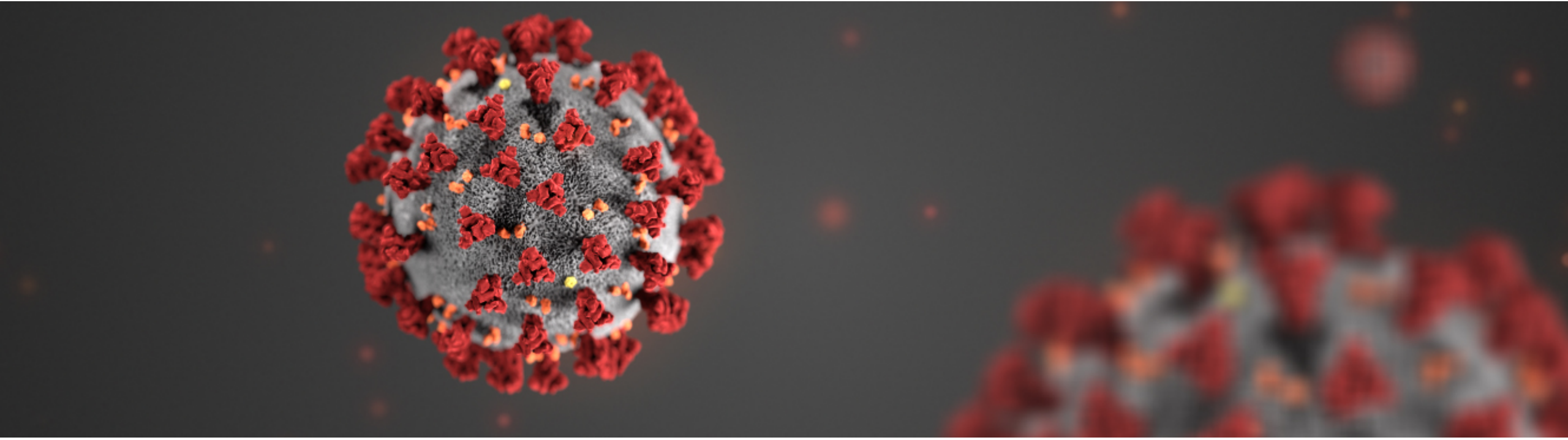
Summary: Work Group Interpretations

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

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.

Old extra slides

Benefits and Harms:

Summary of the Available Evidence: Benefits

- Primary efficacy endpoint: subjects without evidence of prior infection
  - Efficacy: **66.3**% (59.9%, 71.8%)

- Variable efficacy by **world region**, possibly reflecting impact of variants
  - United States: **74.4**% (65.0%, 81.6%)
  - South Africa: **52.0**% (30.3%, 67.4%)
  - Brazil: **66.2**% (51.0%, 77.1%)

Benefits and Harms:

Summary of the Available Evidence: Benefits

- **Higher** efficacy against **severe** outcomes than for any symptomatic COVID-19*
  - VE against **hospitalization** due to COVID-19**: 90%** (95% CI: 66%, 97%)
  - VE against **all-cause death: 81%** (95% CI: 36%, 95%)
  - VE against **deaths due to COVID-19: 100%**
- Efficacy estimates for severe outcomes **assessed ≥28 days** post vaccination were **higher**: **83.5%** for severe disease†, **100%** for hospitalization
- Efficacy against severe illness* remained high across world regions (**78-82%**), suggesting protection against severe illness with variant strains

*Assessed ≥ 14 days post vaccination

Benefits and Harms: Reactogenicity (Local)*

Select local reactions in persons aged 18-59 years

	Janssen vaccine N=2036	**Placebo** N=2049
Local Reaction		
Any	1218 (59.8)	413 (20.2)
Severe (Grade 3)	18 (0.9)	4 (0.2)
Pain at the injection site		
Any	1193 (58.6)	357 (17.4)
Severe (Grade 3)	8 (0.4)	0 (0.0)

Select local reactions in persons aged ≥60 years

	Janssen Vaccine N=1320	**Placebo** N=1331
Local Reaction		
Any	467 (35.4)	244 (18.3)
Severe (Grade 3)	5 (0.4)	2 (0.2)
Pain at the injection site		
Any	439 (33.3)	207 (15.6)
Severe (Grade 3)	3 (0.2)	2 (0.2)

*Based on phase III trial data

Benefits and Harms: Reactogenicity (Systemic)*

Select systemic reactions in persons aged 18-64 years

	Janssen vaccine N=2593	Placebo N=2594
Systemic Reaction		
Any		
Grade 3 or 4	52 (2.0)	12 (0.5)
Fever		
Any	284 (11.0)	16 (0.6)
Grade 3	7 (0.3)	0 (0.0)

Select systemic reactions in persons aged ≥65 years

	Janssen vaccine N=763	Placebo N=786
Systemic Reaction		
Any		
Grade 3 or 4	9 (1.2)	9 (1.1)
Fever		
Any	18 (2.4)	4 (0.5)
Grade 3	1 (0.1)	0 (0.0)

Grade 3 fever: 102.1–104.0°F
Grade 4 fever: >104.0°F

*Based on phase III trial data

Benefits and Harms:

Summary of the Available Evidence: Benefits

- Primary efficacy endpoint: subjects without evidence of prior infection
  - Efficacy: **66.3**% (59.9%, 71.8%)

- **Similar** efficacy analysis across age, sex, race*, and ethnicity categories, and those with underlying medical conditions
  - Efficacy among adults 18-64 years of age: **64.7**% (57.6%, 70.8%)
  - Efficacy among adults ≥65 years of age: **76.5**% (59.1%, 87.3%)

*Defined as White or Black race; other racial groups had numbers too small for analysis.