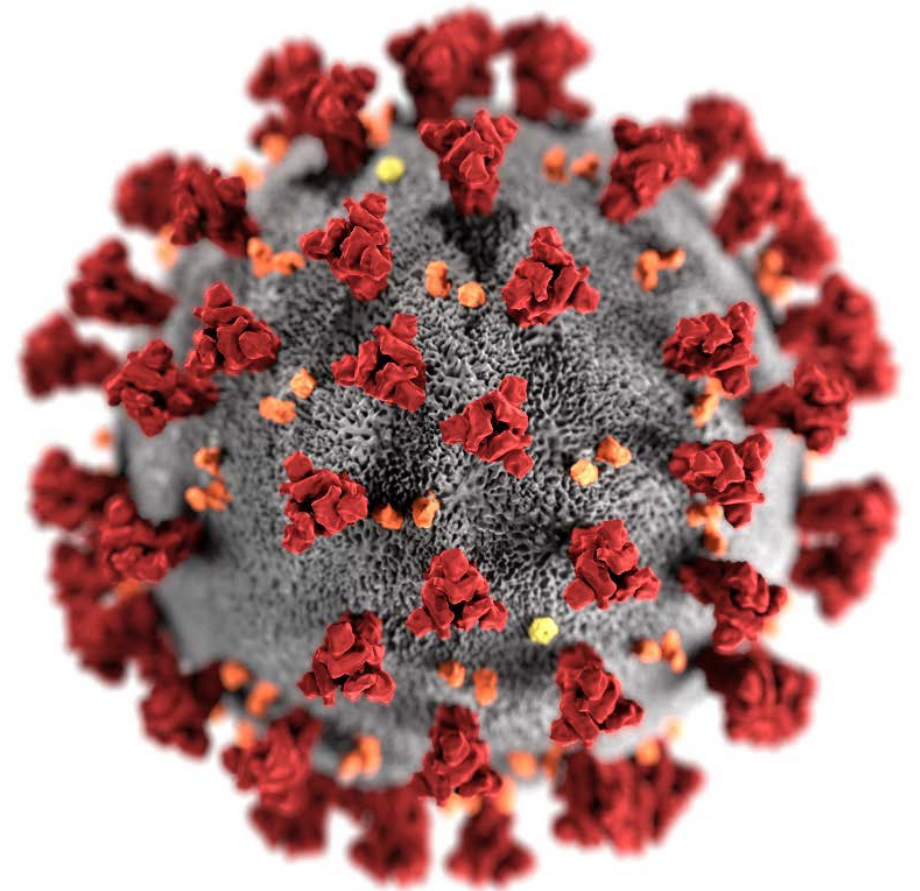


EtR Framework: Values, Acceptability and Feasibility Domains



Sara Oliver MD, MSPH
ACIP Meeting
November 23, 2020

Evidence to Recommendations (EtR) Framework

EtR Domain	
Public Health Problem	
Benefits and Harms	
Values	Impacted by individual vaccine characteristics
Acceptability	Impacted by individual vaccine characteristics
Feasibility	Impacted by individual vaccine characteristics
Resource Use	
Equity	

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 COVID-19 vaccine 'X'?

☐ 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
 - 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
 - Last search date: November 17, 2020
- Inclusion criteria
 - Data collection in 2020 related to COVID-19 vaccine beliefs, attitudes, and intentions
- Review of scientific articles: 272 results, 14 papers included
- Review of news media and reports (Google): 10 sources included
- Preliminary findings from CDC vaccine intent survey and focus group discussions

Values:

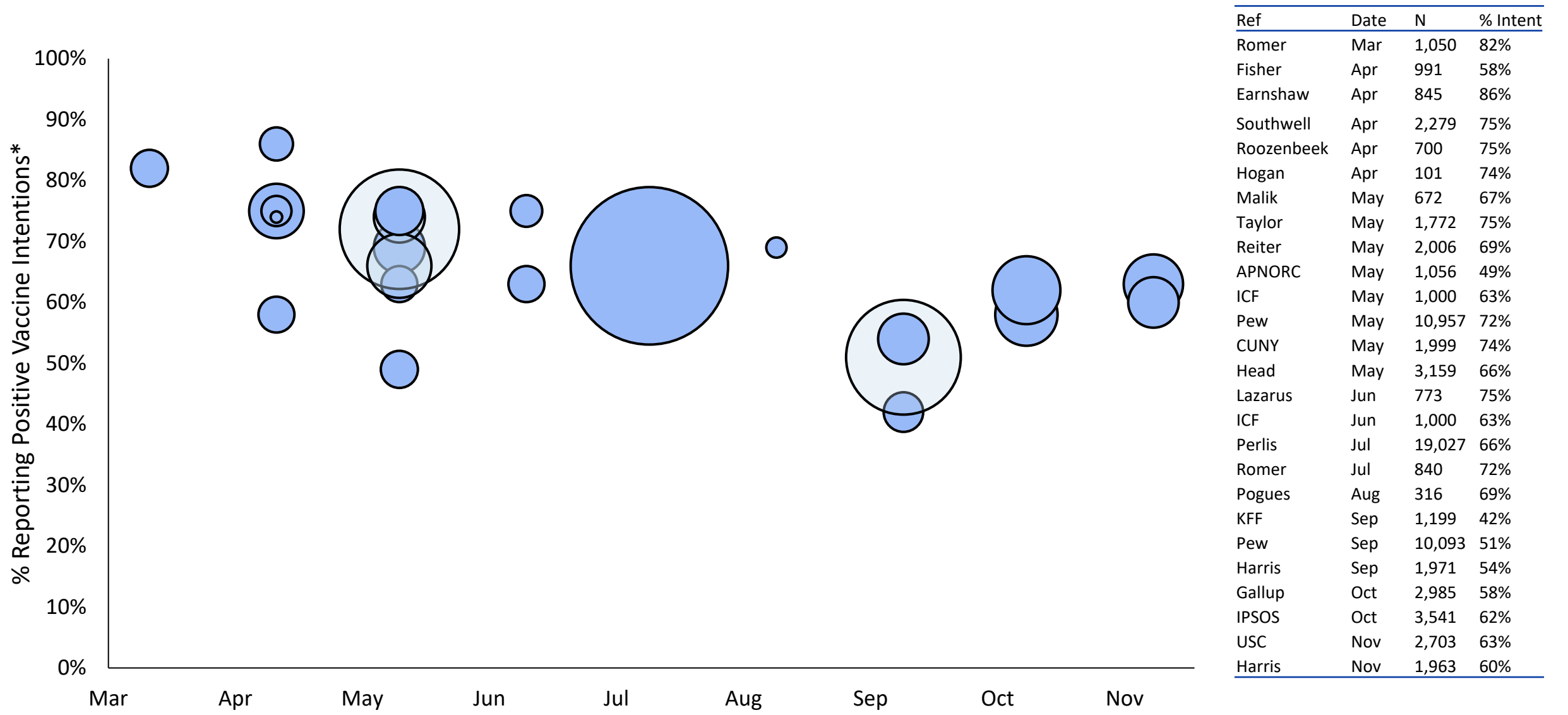
Summary of the available evidence

- Overall acceptability of a COVID-19 vaccine was **moderate**¹
 - Proportion intending to receive vaccine ranged across surveys: **42-86%**
 - Attitudes towards Pfizer vaccine with news reports of 90% efficacy: 71% believed effective, 68% safe
- Many reported anticipated benefits of vaccination¹
 - Protect self, family, and community
 - Prevent SARS-CoV-2 infection and severe illness
 - Return to normalcy
- Vaccination intentions varied by time, population, and vaccine characteristics¹
 - Large national survey found decline from **72%** in May to **51%** in September²
 - Acceptance lowest among Black respondents, highest among Asian respondents
 - Acceptance greater with higher socioeconomic status
 - Acceptance greater with history of influenza vaccination and higher COVID-19 risk perception
 - Acceptance greater with higher vaccine efficacy and healthcare provider recommendation

1. APNORC; Harris; Fisher *Ann Intern Med.*; ICF; Kreps *JAMA Netw Open.*; Lazarus *Nature Med.*; Malik *EClinicalMedicine.*; Pogue *Vaccines.*; Reiter *Vaccine.*; Thunstrom *SSRN.*

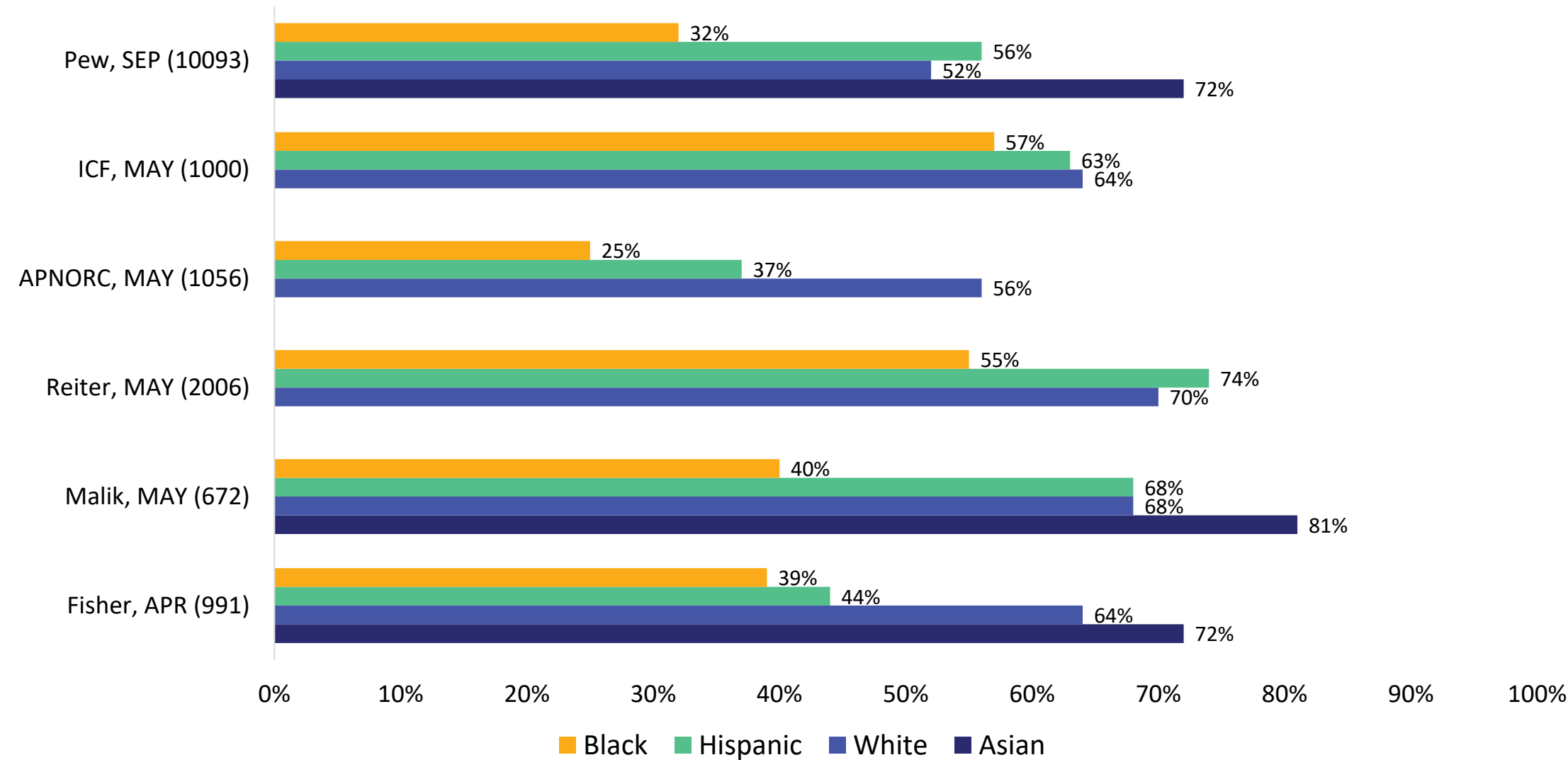
2. Pew Research Center, 17 Sep 2020: https://www.pewresearch.org/science/wp-content/uploads/sites/16/2020/09/PS_2020.09.17_COVID-19-Vaccine_FINAL.pdf

COVID-19 Vaccination Intentions Varied by Survey Month



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

COVID-19 Vaccination Intentions Varied by Race/ethnicity



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

Values:

Summary of the available evidence

- Common reasons for not intending to get vaccinated included¹:
 - Concern for vaccine side effects
 - Uncertainty of vaccine efficacy
 - Low risk perception of COVID-19 or severe disease
- Vaccine efficacy (90% or 70%) associated with preferred choice of hypothetical vaccine²
- Focus groups (49, n=239): most are open to vaccine, but many prefer not to be first³
- Many reported concerns that COVID-19 vaccine approval process was too fast¹
- Limitations
 - Surveys conducted prior to vaccine available
 - Convenience samples may not be representative

1. Pew Research Center, 17 Sep 2020: https://www.pewresearch.org/science/wp-content/uploads/sites/16/2020/09/PS_2020.09.17_COVID-19-Vaccine_FINAL.pdf

2. Kreps et al. *JAMA Netw Open*. 20 Oct 2020. 3. Jorgenson C. *CDC Presentation to ACIP Working Group*. 3 Sep 2020.

Values:

Summary of the available evidence

- Across national surveys, many adults reported intentions to receive COVID-19 vaccine.
 - Common desirable effects included protecting self, family, community from SARS-CoV-2 infection and severe illness and return to normalcy.
 - Common concerns included vaccine side effects, uncertainty of vaccine efficacy, and speed of vaccine approval process.
- Vaccination intentions varied substantially by race or ethnicity and socioeconomic status of respondents.

Values

- Strategies to consider for overcoming barriers to vaccine acceptance:
 - **Engage trusted sources** (e.g., social workers, faith leaders, community leaders, advocacy groups, facility administrators, union representatives)
 - **Develop communication materials** that are ADA-compliant and culturally, linguistically, and literacy appropriate
 - **Ensure providers have information** on vaccine recommendations to counsel patients
 - **Educate throughout jurisdiction** about vaccination recommendations and where to refer patients for free COVID-19 vaccination
 - **Educate non-clinical facility administrators**

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 COVID-19 vaccine 'X' 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)
 - Focus group discussions with nurses (7 focus groups)
 - National online survey: sub-group analysis for healthcare providers (n=216)
- Review of news media, professional society and workers' unions websites
 - AAFP, AFT, AFSCME, AGS, ANA, AMA, IDSA, SEIU
 - American Nurses Foundation (ANF) survey (n=12,939)
- 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
- CDC evaluations
 - State health officers, Oct: concerns with rollout included vaccine hesitancy (53%), vaccine safety (32%), and communications (26%)¹
 - Focus groups with nurses (n=7), Jun-Aug: most supported prioritizing nurses, some reluctant to get vaccinated, and many do not want to get it right away²
 - Vaccine intent survey, Sep-Oct: **63%** healthcare providers would get COVID-19 vaccine³
- ANF nurses survey, Oct: moderate acceptability of COVID-19 vaccine⁴
 - **63%** somewhat or very confident vaccine will be safe and effective
 - **34%** would voluntarily receive COVID-19 vaccine
 - 57% comfortable discussing COVID-19 vaccines with patients

1. CDC COVID-19 Response Team. 2. Jorgenson. *CDC Presentation to ACIP Working Group*. 3 Sep 2020. 3. Lindley *et al*, CDC COVID-19 Response Team: Report in progress.

4. ANF, 16 Nov 2020. <https://www.nursingworld.org/practice-policy/work-environment/health-safety/disaster-preparedness/coronavirus/what-you-need-to-know/covid-19-vaccine-survey/> **18**

Acceptability:

Summary of the available evidence

- All jurisdictions have submitted COVID-19 vaccine implementation plans
- Large and small pharmacy chains have committed to participate in COVID-19 vaccination program
- In a CDC survey of 34 state health officers in October, common concerns about vaccine administration included vaccine hesitancy, vaccine safety, and communications
- A survey of nurses, most were confident the vaccine will be safe and effective, while less would voluntarily receive COVID-19 vaccine if not required

Acceptability:

Work Group Interpretation

Is COVID-19 vaccine 'X' acceptable to key stakeholders?

☐ No ☐ Probably no ☒ Probably yes ☐ Yes ☒ Varies ☐ Don't know



EtR Domain: Feasibility



Feasibility

Is COVID-19 vaccine 'X' feasible to implement?

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

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



Feasibility:

Summary of the available evidence

- Barriers to implementation may include:
 - 1) Financial barriers
 - 2) Complexity of recommendations
 - 3) Access to healthcare or vaccine providers
 - 4) Vaccine storage and handling requirements

Feasibility:

Summary of the available evidence

1) Financial barriers

- All COVID-19 vaccines will be provided to U.S. population **free of charge**
- Health systems or health departments could incur costs for vaccine implementation, clinics

Feasibility:

Summary of the available evidence

2) Complexity of recommendations

- Multiple vaccines under an EUA could make overall COVID-19 vaccine recommendations more complex
- Individual vaccine recommendations may also contribute to complexity
 - Variations in number of doses, schedule

Feasibility:

Summary of the available evidence

3) Access to healthcare or vaccine providers

- Population access to healthcare could be limited in rural or other hard-to-reach areas
- Range of providers providing vaccine could be impacted by:
 - Cold storage requirements
 - Population(s) with proven safety/efficacy
 - Population(s) recommended to receive vaccine

Feasibility:

Summary of the available evidence

4) Vaccine storage and handling requirements

- Vaccine with **ultra-cold** requirements unable to be integrated into providers' practices
 - Vaccines with refrigerator (2-8°C) temperature requirements easier to integrate
- Minimum size of orders
- Requirements for two-dose series for some vaccines

Feasibility:

Summary of the available evidence

- **Innovative** solutions to overcome barriers:
 - Expanded funding opportunities
 - Pharmacy partnerships
 - Technology, including second dose reminders
 - Unique packing containers to maintain ultra-cold temperatures without freezer
 - Detailed state micro-planning

Feasibility:

Work Group Interpretation

Is COVID-19 vaccine 'X' feasible to implement?

☐ No ☐ Probably no ☒ Probably yes ☐ Yes ☐ Varies ☐ Don't know



Summary



Summary:

EtR Domain	Question	Work Group Judgments
Values	Does the target population feel the desirable effects are large relative to the undesirable effects?	Probably Yes; Varies
	Is there important variability in how patients value the outcomes?	Important/ probably important uncertainty
Acceptability	Is COVID-19 vaccine 'X' acceptable to key stakeholders?	Probably Yes; Varies
Feasibility	Is COVID-19 vaccine 'X' feasible to implement?	Probably Yes

Summary:

EtR Domain	Question	Work Group Judgments
Public Health Problem	Is COVID-19 disease of public health importance?	Yes
Values	Does the target population feel the desirable effects are large relative to the undesirable effects?	Probably Yes/ Varies
	Is there important variability in how patients value the outcomes?	Important/ probably important uncertainty
Acceptability	Is the intervention acceptable to key stakeholders?	Probably Yes/ Varies
Feasibility	Is the intervention feasible to implement?	Probably Yes/ Varies
Resource Use	Is COVID-19 vaccine X a reasonable and efficient allocation of resources?	Yes
Equity	Does COVID-19 vaccine X have the potential to increase health equity?	Probably reduced/ Probably increased*

*Judgment differed by COVID-19 vaccine

Proposed Clinical Considerations:

- **Pregnancy/Breastfeeding:**
 - Pregnancy/breastfeeding is not a contraindication to receiving a COVID-19 vaccine
 - For those recommended to receive vaccine in an early allocation phase
- **Prior SARS-CoV-2 infection:**
 - Vaccination is recommended regardless of prior infection
 - Testing for SARS-CoV-2 antibodies is not recommended prior to vaccination
 - While vaccine supplies are constrained, vaccination of persons with recent prior infection may be delayed. However, duration of protection after infection is unknown.
- **Other topics for future presentations to ACIP:**
 - Coadministration with other vaccines
 - Vaccine dosing schedules, intervals
 - Impact of vaccine reactogenicity for healthcare providers

Questions for ACIP:

- **Values:**

- What does ACIP think about the values of the target population?
- Any additional information that ACIP needs to see before a vote?

Questions for ACIP:

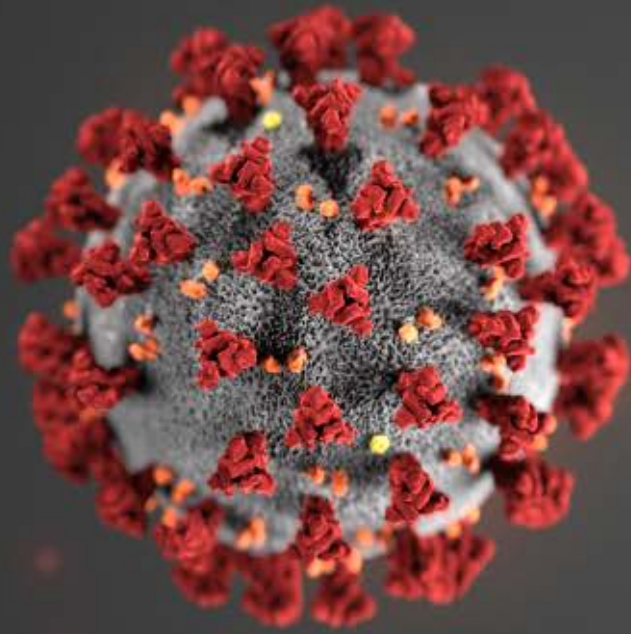
- **Acceptability:**

- What does ACIP think about the acceptability of COVID-19 vaccines from stakeholders (providers, health departments, health systems)?
- Can ACIP members, liaison organizations provide additional insight into acceptability of stakeholders?

Questions for ACIP:

- **Feasibility:**

- What does ACIP think about the feasibility of implementation?
- Any additional information that ACIP needs to see before a vote?



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.

