EtR Framework:
Values, Acceptability and Feasibility Domains

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ACIP Meeting
November 23, 2020
# Evidence to Recommendations (EtR) Framework

<table>
<thead>
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<th>EtR Domain</th>
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<tr>
<td>Public Health Problem</td>
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<tr>
<td>Benefits and Harms</td>
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<tr>
<td>Values</td>
<td>Impacted by individual vaccine characteristics</td>
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<td>Acceptability</td>
<td>Impacted by individual vaccine characteristics</td>
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<td>Feasibility</td>
<td>Impacted by individual vaccine characteristics</td>
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<tr>
<td>Resource Use</td>
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<tr>
<td>Equity</td>
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</tbody>
</table>
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%\(^{1}\)
  - Attitudes towards Pfizer vaccine with news reports of 90% efficacy: 71% believed effective, 68% safe\(^{1}\)

- Many reported anticipated benefits of vaccination\(^1\)
  - Protect self, family, and community
  - Prevent SARS-CoV-2 infection and severe illness
  - Return to normalcy

- Vaccination intentions varied by time, population, and vaccine characteristics\(^1\)
  - Large national survey found decline from 72% in May to 51% in September\(^2\)
  - 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.
COVID-19 Vaccination Intentions Varied by Survey Month

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

<table>
<thead>
<tr>
<th>Ref</th>
<th>Date</th>
<th>N</th>
<th>% Intent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Romer</td>
<td>Mar</td>
<td>1,050</td>
<td>82%</td>
</tr>
<tr>
<td>Fisher</td>
<td>Apr</td>
<td>991</td>
<td>58%</td>
</tr>
<tr>
<td>Earnshaw</td>
<td>Apr</td>
<td>845</td>
<td>86%</td>
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<td>Southwell</td>
<td>Apr</td>
<td>2,279</td>
<td>75%</td>
</tr>
<tr>
<td>Roozenbeek</td>
<td>Apr</td>
<td>700</td>
<td>75%</td>
</tr>
<tr>
<td>Hogan</td>
<td>Apr</td>
<td>101</td>
<td>74%</td>
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<tr>
<td>Malik</td>
<td>May</td>
<td>672</td>
<td>67%</td>
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<tr>
<td>Taylor</td>
<td>May</td>
<td>1,772</td>
<td>75%</td>
</tr>
<tr>
<td>Reiter</td>
<td>May</td>
<td>2,006</td>
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</tr>
<tr>
<td>APNORC</td>
<td>May</td>
<td>1,056</td>
<td>49%</td>
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<tr>
<td>ICF</td>
<td>May</td>
<td>1,000</td>
<td>63%</td>
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<tr>
<td>Pew</td>
<td>May</td>
<td>10,957</td>
<td>72%</td>
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<tr>
<td>CUNY</td>
<td>May</td>
<td>1,999</td>
<td>74%</td>
</tr>
<tr>
<td>Head</td>
<td>May</td>
<td>3,159</td>
<td>66%</td>
</tr>
<tr>
<td>Lazarus</td>
<td>Jun</td>
<td>773</td>
<td>75%</td>
</tr>
<tr>
<td>ICF</td>
<td>Jun</td>
<td>1,000</td>
<td>63%</td>
</tr>
<tr>
<td>Perlis</td>
<td>Jul</td>
<td>19,027</td>
<td>66%</td>
</tr>
<tr>
<td>Romer</td>
<td>Jul</td>
<td>840</td>
<td>72%</td>
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<tr>
<td>Pogues</td>
<td>Aug</td>
<td>316</td>
<td>69%</td>
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<tr>
<td>KFF</td>
<td>Sep</td>
<td>1,199</td>
<td>42%</td>
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<tr>
<td>Pew</td>
<td>Sep</td>
<td>10,093</td>
<td>51%</td>
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<tr>
<td>Harris</td>
<td>Sep</td>
<td>1,971</td>
<td>54%</td>
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<tr>
<td>Gallup</td>
<td>Oct</td>
<td>2,985</td>
<td>58%</td>
</tr>
<tr>
<td>IPSOS</td>
<td>Oct</td>
<td>3,541</td>
<td>62%</td>
</tr>
<tr>
<td>USC</td>
<td>Nov</td>
<td>2,703</td>
<td>63%</td>
</tr>
<tr>
<td>Harris</td>
<td>Nov</td>
<td>1,963</td>
<td>60%</td>
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</tbody>
</table>
COVID-19 Vaccination Intentions Varied by Race/ethnicity

*Positive vaccine intentions includes persons reporting definitely, probably, or somewhat likely to get vaccinated.
Common reasons for not intending to get vaccinated included:
- 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 vaccine

Focus groups (49, n=239): most are open to vaccine, but many prefer not to be first

Many reported concerns that COVID-19 vaccine approval process was too fast

Limitations
- Surveys conducted prior to vaccine available
- Convenience samples may not be representative

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 away\(^2\)
  - Vaccine intent survey, Sep-Oct: **63%** healthcare providers would get COVID-19 vaccine\(^3\)
- ANF nurses survey, Oct: moderate acceptability of COVID-19 vaccine\(^4\)
  - **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

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

*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?
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.