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

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ACIP Meeting
February 4, 2022
Policy question

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

**EUA= Emergency Use Authorization, BLA= Biologics License Application**
Policy question

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

Regulatory action, GRADE, Evidence to Recommendation Framework, Vote

- Moderna COVID-19 vaccine
- Compared to
- No COVID-19 vaccine
Additional questions for discussion

Implementation;
Discussions around myocarditis and intervals

- Moderna COVID-19 vaccine
- And
- Pfizer-BioNTech COVID-19 vaccine
Evidence to Recommendations (EtR) Framework: PICO Question

<table>
<thead>
<tr>
<th>Population</th>
<th>People ages 18 years and older</th>
</tr>
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<tbody>
<tr>
<td>Intervention</td>
<td>Moderna COVID-19 vaccine mRNA-1273 (100µg, 2 doses IM, 28 days apart)</td>
</tr>
<tr>
<td>Comparison</td>
<td>No vaccine</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Symptomatic laboratory confirmed COVID-19</td>
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<tr>
<td></td>
<td>Hospitalization due to COVID-19</td>
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<td>Death due to COVID-19</td>
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<tr>
<td></td>
<td>Asymptomatic SARS-CoV-2 infection</td>
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<tr>
<td></td>
<td>Serious adverse events</td>
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<tr>
<td></td>
<td>Reactogenicity</td>
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</tbody>
</table>
## Evidence to Recommendations (EtR) Framework

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

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

“The problem” = COVID-19
EtR Domain: Public Health Problem
Trends in daily number of COVID-19 cases in the United States

January 23, 2020 – February 1, 2022

Cases Total 75,302,383

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

January 23, 2020 – February 1, 2022

Rates of COVID-19 cases by vaccination status

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

4X
Risk of Testing Positive for COVID-19

compared to fully vaccinated adults

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

- **15X** Risk of Dying from COVID-19

compared to fully vaccinated adults

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

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

- **13X** Risk of Testing Positive for COVID-19
- **68X** Risk of Dying from COVID-19

compared to fully vaccinated adults with booster dose

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

March 7, 2020 – January 29, 2022

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

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

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

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

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

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

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

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

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

ICU utilization by state as of February 3, 2022

3 states over 90% of ICU capacity
29 states over 80% of ICU capacity

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.

Omicron is the dominant circulating SARS-CoV-2 variant

Daily trends in doses of COVID-19 vaccine administered

December 14, 2020 – February 1, 2022

Daily trends in doses of COVID-19 vaccine administered

December 14, 2020 – February 1, 2022

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

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

- **Pfizer-BioNTech**: 317,292,439 doses
- **Moderna**: 204,662,169 doses
- **J & J**: 18,198,400 doses
- **Other**: 477,190 doses

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

- **Pfizer-BioNTech 2-dose**: 120,744,329
- **Moderna 2-dose**: 74,646,620
- **J&J/Janssen single dose**: 16,603,504
- **Other 2-dose**: 136,231

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

December 14, 2020 – February 2, 2022

Percent Receiving ≥1 dose

- 75+ years 95.0%
- 65-74 years 95.0%
- 50-64 years 91.5%
- 40-49 years 84.8%
- 25-39 years 77.6%
- 18-24 years 75.1%

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

CDC Data Analytics and Visualization Task Force; Data included through the end of January 2022
Percent of population fully vaccinated ≥18 years of age

The Omicron variant is the dominant circulating variant of SARS-CoV-2 in the United States.

As of January, COVID-19 cases, hospitalizations, and deaths have increased.
- In November 2021, unvaccinated adults ages 18 years and older had a 4X risk of testing positive and a 15X risk of dying from COVID-19 compared to fully vaccinated adults.

Increasing cases are taxing healthcare resources, with many states facing ICU bed shortages again.

Over 212 million people (63.9%) are fully vaccinated in the United States; however, vaccination coverage varies by age and geography.
Public Health Problem

Work Group Interpretation

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

- No
- Probably no
- Probably yes
- Yes
- Varies
- Don’t know
EtR Domain: Benefits and Harms
Benefits and harms assessments

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

GRADE= Grading of Recommendations, Assessment, Development and Evaluation
Benefits and Harms
Summary of the Available Evidence: Benefits

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

*High certainty of evidence*

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

*Moderate certainty of evidence*

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

*Moderate certainty of evidence*

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

*High certainty of evidence*
Benefits and Harms
Summary of the Available Evidence: Harms

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

*Moderate certainty of evidence*

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

*High certainty of evidence*
Conclusion
GRADE

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

**Benefits:** Supported by body of evidence from randomized controlled trials (RCTs) and observational studies
- RCT evidence demonstrated efficacy for all beneficial outcomes, including the 2 critical outcomes: symptomatic disease and hospitalization
- Efficacy data further supported by body of evidence from observational studies

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

- GRADE

- Potential risk of myocarditis
- Potential benefit and harm balance

GRADE= Grading of Recommendations, Assessment, Development and Evaluation
Summary
Myocarditis after Moderna COVID-19 vaccine: U.S. data

- VAERS demonstrates reporting rates of myocarditis greater than the background rates for males (18–49 years) and females (after dose 2, 18–29 years)

- At least 90 day after myocarditis diagnosis, most patients reported no impact on their quality of life, and most did not report missing school or work
  - Most (81%) healthcare providers indicated the patient was probably or fully recovered
Benefit and risk balance for Moderna COVID-19 vaccine in adults ages 18–39 years

**Benefits**
Moderna COVID-19 vaccine

**Risks**
Moderna COVID-19 vaccine
Methods for assessment of benefit-risk balance

**Benefits** — Calculated per 1 million people who are fully vaccinated

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

**Harms** — Calculated per 1 million people who are fully vaccinated

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

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VE: Vaccine Effectiveness

\(^1\)https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html

\(^2\)https://covid.cdc.gov/covid-data-tracker/#vaccine-effectiveness
# Vaccine-specific estimates of effectiveness against COVID-19 hospitalization

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>IVY Network&lt;sup&gt;2&lt;/sup&gt;, Oct – Nov, 2021 % (95% CI)</th>
<th>VISION&lt;sup&gt;2&lt;/sup&gt;, Aug – Dec, 2021, % (95% CI)</th>
<th>Pooled VE Estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderna</td>
<td>91 (89-93)</td>
<td>92 (91-93)</td>
<td>92</td>
</tr>
</tbody>
</table>

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

2. VE estimate for 17-179 days after 2nd dose
Reporting rates of myocarditis following Moderna COVID-19 vaccination (per million 2\textsuperscript{nd} doses administered) among persons ages 18-39 years\textsuperscript{1}

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Sex</th>
<th>Rate per 1M 2\textsuperscript{nd} Doses in 7-day risk period among persons ages 18–39 years\textsuperscript{2}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderna</td>
<td>Males</td>
<td>67.5</td>
</tr>
<tr>
<td></td>
<td>All</td>
<td>33.0</td>
</tr>
</tbody>
</table>

\textsuperscript{1} Data from the Vaccine Safety Datalink (VSD): [https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html](https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html)

\textsuperscript{2} Data through Jan 15, 2022
Benefits and risks after mRNA COVID-19 vaccines among persons ages 18-39 years

*per million 2nd doses*

- COVID-19-associated hospitalizations prevented by Moderna COVID-19 vaccine compared with myocarditis cases expected
Benefits and risks after mRNA COVID-19 vaccines among **males** ages 18-39 years

*per million 2nd doses*

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

<table>
<thead>
<tr>
<th>Age group (years)</th>
<th>Cases of Myocarditis Expected per Million 2nd Doses of Moderna Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-39</td>
<td>68</td>
</tr>
</tbody>
</table>

COVID-19-Associated Hospitalizations Prevented per Million 2nd Doses of Moderna Vaccine
Limitations

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

Summary

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

How substantial are the desirable anticipated effects?

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

- Minimal
- Small
- Moderate
- Large
- Varies
- Don’t know
Benefits and Harms

How substantial are the undesirable anticipated effects?

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

  - Minimal
  - Small
  - Moderate
  - Large
  - Varies
  - Don’t know
Benefits and Harms

Do the desirable effects outweigh the undesirable effects?

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

  - Favors intervention (Moderna COVID-19 vaccine)
  - Favors comparison (no vaccine)
  - Favors both
  - Favors neither
  - Unclear
EtR Domain: Values
Positive COVID-19 vaccination intent† among adults ages 18 years and older

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

*Surveys with multiple time points are shown with the same color bubble for each time point. Surveys with only one time point are shown in gray.
Vaccination status and intent among all adults ages 18 years and older, United States

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

A survey of the American general population (N = 1,094) was conducted on individuals ≥ 18 years between January 7 – 10, 2022

Unvaccinated survey respondents were asked, “Does the discovery of the Omicron variant make you more likely or less likely to get the COVID-19 vaccine?"

- Makes no difference: 72%
- Less likely: 13%
- More likely: 13%

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

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

- Nothing: 48%
- More research/transparency: 12%
- If it were required for work/if it were mandatory: 6%
- Money/large sum of money: 5%
- If a doctor recommended it: 3%
- If it prevented 100% of infections: 3%

Rise in COVID-19 vaccinations following full FDA approval

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

Survey of vaccination intent among unvaccinated adults

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

<table>
<thead>
<tr>
<th>Partial or Unvaccinated Sample</th>
<th>GENDER</th>
<th>AGE</th>
<th>ETHNICITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>58% Female</td>
<td>41% 18-39 Years</td>
<td>40% Non-Hispanic White</td>
<td></td>
</tr>
<tr>
<td>42% Male or Other Gender Identity</td>
<td>34% 40-59 Years</td>
<td>41% Non-Hispanic Black</td>
<td></td>
</tr>
<tr>
<td></td>
<td>25% 60+ Years</td>
<td>19% Hispanic</td>
<td></td>
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</tbody>
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Data collection is ongoing until sample target is reached, consisting of 1200 partial or unvaccinated US adults

CDC and University of Iowa/RAND survey, unpublished
Concerns about vaccine side effects or general mistrust of COVID-19 vaccines were the top reasons given for continuing to be unvaccinated.

<table>
<thead>
<tr>
<th>Reason</th>
<th>% of non-vaccinated respondents (n=507)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concerned about long-term side effects</td>
<td>43.6%</td>
</tr>
<tr>
<td>I don’t trust COVID-19 vaccines</td>
<td>41.4%</td>
</tr>
<tr>
<td>Concerned about short-term side effects</td>
<td>33.1%</td>
</tr>
<tr>
<td>Don’t know if COVID-19 vaccines work</td>
<td>20.7%</td>
</tr>
<tr>
<td>Concerned about allergic reaction</td>
<td>18.9%</td>
</tr>
<tr>
<td>Wait to see if vaccine is safe</td>
<td>18.3%</td>
</tr>
<tr>
<td>Don’t trust healthcare system</td>
<td>15.0%</td>
</tr>
<tr>
<td>Not worried about COVID-19</td>
<td>13.0%</td>
</tr>
<tr>
<td>Fear of needles</td>
<td>10.8%</td>
</tr>
<tr>
<td>I already had COVID-19</td>
<td>10.1%</td>
</tr>
<tr>
<td>Not mandated</td>
<td>8.5%</td>
</tr>
<tr>
<td>Against religious beliefs</td>
<td>8.5%</td>
</tr>
<tr>
<td>Other</td>
<td>5.3%</td>
</tr>
<tr>
<td>HCP said not to get vaccinated</td>
<td>4.7%</td>
</tr>
<tr>
<td>None of these</td>
<td>4.5%</td>
</tr>
<tr>
<td>Obstacles (lack of transportation, no time off work)</td>
<td>3.9%</td>
</tr>
<tr>
<td>Community not getting vaccinated</td>
<td>3.0%</td>
</tr>
<tr>
<td>Cost concerns</td>
<td>3.0%</td>
</tr>
</tbody>
</table>

CDC and University of Iowa/RAND survey, unpublished
Awareness of FDA status of Moderna COVID-19 vaccine

29% of unvaccinated respondents thought the Moderna COVID-19 vaccine had already received full approval from the FDA.
Vaccination intentions in response to a Moderna FDA BLA

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

CDC and University of Iowa/RAND survey, unpublished
Vaccination intentions in response to a Moderna FDA BLA

20% of unvaccinated respondents said they would continue waiting to see if COVID vaccines were effective or safe
Vaccination intentions in response to a Moderna FDA BLA

52% of unvaccinated respondents said they would **definitely not** get vaccinated or would only do so if it were **required**.
11% of unvaccinated respondents who were open or unsure about getting vaccinated (n=236) said they would **wait a few more weeks** to get a COVID vaccine after the Moderna vaccine received full FDA approval.
**Time to vaccination in response to a Moderna FDA BLA**

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

[CDC and University of Iowa/RAND survey, unpublished]
Criteria 1:
Does the target population feel that the desirable effects are large relative to undesirable effects?

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

- Minimal
- Small
- Moderate
- Large
- Varies
- Don’t know
Values

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

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

- Important uncertainty or variability
- Probably important uncertainty or variability
- Probably not important uncertainty or variability
- No important uncertainty or variability
- No known undesirable outcomes
EtR Domain: Acceptability
Vaccine administration

- As of February 2, 2022, >204 million doses of Moderna COVID-19 vaccine have been administered¹

- 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

Vaccine acceptability among stakeholders

- Vaccination with Moderna COVID-19 vaccine was already highly acceptable to stakeholders under FDA emergency use authorization and ACIP interim recommendation.

- Vaccination may be more acceptable to stakeholders under full FDA approval and standard ACIP recommendation.
Acceptability

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

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

○ No  ○ Probably no  ○ Probably yes  ○ Yes  ○ Varies  ○ Don’t know
EtR Domain: Feasibility
Feasibility of vaccine implementation

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

- The Moderna COVID-19 vaccine will be the second COVID-19 vaccine with a BLA
- BLA only been issued for some indications, which may add complexity
  - BLA:
    - Primary series for those ages 18 years and older
  - EUA:
    - Additional dose in immunocompromised people for those ages 18 years and older
    - Booster dose in persons ≥18 years who completed a primary series ≥5 months ago

- Recommendations made under EUI only allowed for vaccines with a BLA
  - Will allow these recommendations to extend to Moderna COVID-19 vaccine as well
  - Include recommendations for additional/booster vaccination of people who received their primary series overseas or as a part of a clinical trial
Vaccine storage and handling requirements

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

Financial barriers

- All COVID-19 vaccines will be provided to U.S. population **free of charge**

- Health systems or health departments incur costs for vaccine implementation, clinics, outreach, and education

- Financial hardship may arise if vaccine recipients need to take time off to receive the vaccine or experience post-vaccination reactogenicity that prevents them from working
Supply barriers

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

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

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

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

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

○ No  ○ Probably no  ○ Probably yes  ○ Yes  ○ Varies  ○ Don’t know
EtR Domain: Resource Use
Estimated cost of preventable COVID-19 hospitalizations among unvaccinated adults in the United States, June – November 2021

June to November total: $13.9 Billion

[Bar chart showing estimated costs for each month from June to November 2021.]

Costs & benefits associated with COVID-19 vaccines

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

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Resource Use

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

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

○ No  ○ Probably no  ○ Probably yes  ○ Yes  ○ Varies  ○ Don’t know
EtR Domain: Equity

- American Indian/Alaska Native: 1736.8
- Black: 1289.3
- Hispanic: 1013
- Overall: 878.5
- White: 691.1
- Asian/Pacific Islander: 423.3

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

- AI/AN: 69.3%
- Asian: 64.4%
- NH/PI: 63.1%
- Hispanic: 59.3%
- White: 52.4%
- Black: 45.9%

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

COVID-19 vaccination coverage varies by geography

Percent of population ages 18 years and older fully vaccinated

<table>
<thead>
<tr>
<th>% of population ≥18 years of age fully vaccinated</th>
<th>% of U.S. counties at this level</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-29.9%</td>
<td>1%</td>
</tr>
<tr>
<td>30-39.9%</td>
<td>4%</td>
</tr>
<tr>
<td>40-49.9%</td>
<td>18%</td>
</tr>
<tr>
<td>50-69.9%</td>
<td>58%</td>
</tr>
<tr>
<td>70%+</td>
<td>20%</td>
</tr>
<tr>
<td>No Data</td>
<td>--</td>
</tr>
</tbody>
</table>
Disparities in vaccine intent by geographic location

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

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

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

Equity

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

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

- Reduced
- Probably reduced
- Probably no impact
- Probably increased
- Increased
- Varies
- Don’t know
<table>
<thead>
<tr>
<th>EtR Domain</th>
<th>Question</th>
<th>Work Group Judgments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Public Health</strong></td>
<td>Is COVID-19 of public health importance?</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Problem</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Benefits and</strong></td>
<td>How substantial are the desirable anticipated effects?</td>
<td>Large</td>
</tr>
<tr>
<td><strong>Harms</strong></td>
<td>How substantial are the undesirable anticipated effects?</td>
<td>Small</td>
</tr>
<tr>
<td></td>
<td>Do the desirable effects outweigh the undesirable effects?</td>
<td>Favors intervention</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Moderna COVID-19 vaccine)</td>
</tr>
<tr>
<td></td>
<td>What is the overall certainty of the evidence for the critical</td>
<td>High to Moderate</td>
</tr>
<tr>
<td></td>
<td>outcomes?</td>
<td></td>
</tr>
<tr>
<td><strong>Values</strong></td>
<td>Does the target population feel the desirable effects are large</td>
<td>Large</td>
</tr>
<tr>
<td></td>
<td>relative to the undesirable effects?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is there important variability in how patients value the outcomes?</td>
<td>Probably important uncertainty or variability</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acceptability</strong></td>
<td>Is the Moderna COVID-19 vaccine acceptable to key stakeholders?</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Feasibility</strong></td>
<td>Is the Moderna COVID-19 vaccine feasible to implement?</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Resource Use</strong></td>
<td>Is Moderna COVID-19 vaccine a reasonable and efficient allocation of</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>resources?</td>
<td></td>
</tr>
<tr>
<td><strong>Equity</strong></td>
<td>What would be the impact of the intervention on health equity?</td>
<td>Probably no impact</td>
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</table>
EUA ≥16 years of age

Pfizer-BioNTech COVID-19 vaccine

BLA ≥16 years of age

EUA ≥16 years of age

EUA 5-15 years of age

EUA ≥18 years of age

Modernova COVID-19 vaccine

BLA ≥18 years of age

EUA ≥18 years of age

EUA ≥18 years of age

Additional/Booster doses

Additional dose EUA ≥5 years of age

Booster dose EUA ≥12 years of age

EUA ≥12 years of age

Janssen COVID-19 vaccine

EUA ≥18 years of age

EUA ≥18 years of age
Work Group Interpretation

- COVID-19 vaccines have been a critical tool in this pandemic, preventing millions of COVID-19 associated hospitalizations and deaths.

- To date, hundreds of millions of doses of the Moderna COVID-19 vaccine have been given with over a year of closely monitored real-world safety and effectiveness data.

- Vaccinating the unvaccinated with a primary series continues to be important:
  - Additional protection from all recommended COVID-19 vaccine doses important in evolving pandemic.
### Evidence to Recommendations Framework

#### Summary: Work Group Interpretations

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<th>Balance of consequences</th>
<th>Undesirable consequences clearly outweigh desirable consequences in most settings</th>
<th>Undesirable consequences probably outweigh desirable consequences in most settings</th>
<th>The balance between desirable and undesirable consequences is <em>closely balanced or uncertain</em></th>
<th>Desirable consequences probably outweigh undesirable consequences in most settings</th>
<th>Desirable consequences clearly outweigh undesirable consequences in most settings</th>
<th>There is insufficient evidence to determine the balance of consequences</th>
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# Evidence to Recommendations Framework

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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**

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<th>We recommend the intervention for individuals based on shared clinical decision-making</th>
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- ACIP COVID-19 Vaccines Work Group
- Vaccine Task Force
- Epi Task Force
- Data Analytics and Visualization Task Force
- Respiratory Viruses Branch
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.

For more information, contact CDC
1-800-CDC-INFO (232-4636)