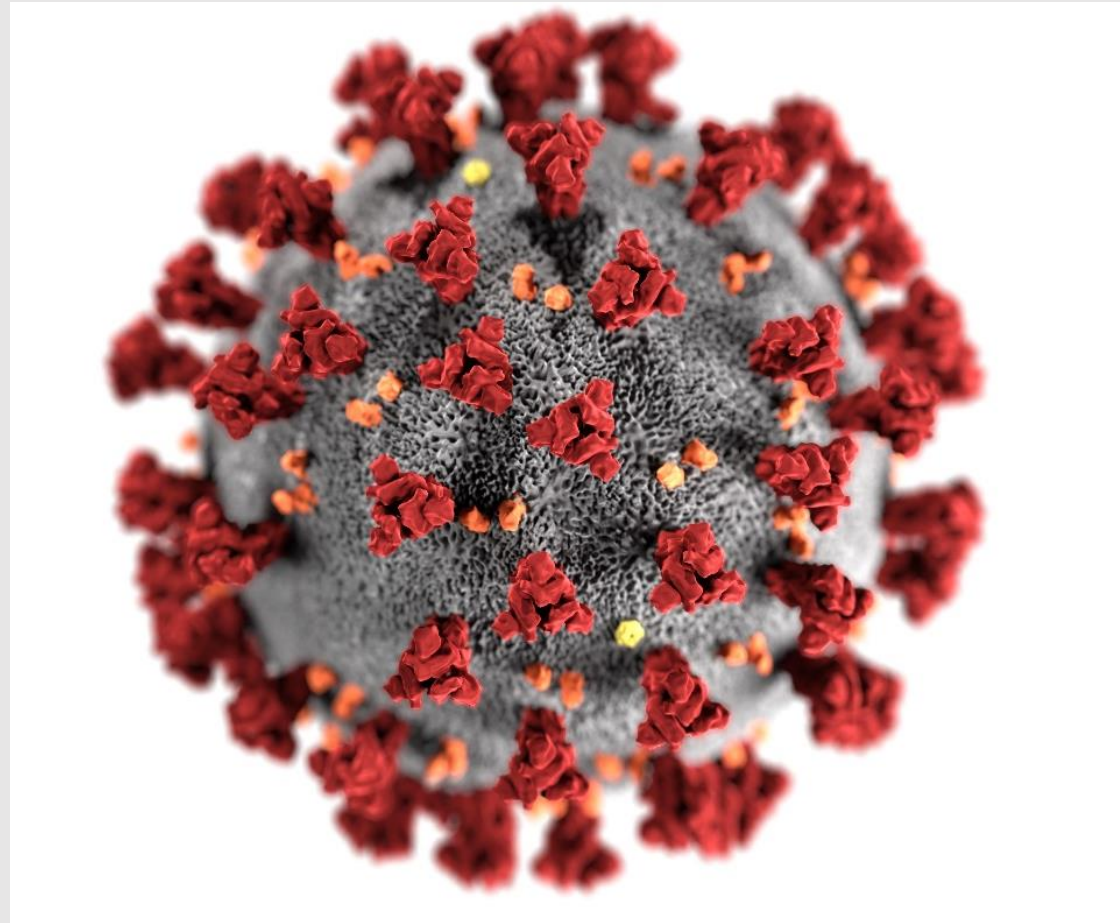


## COVID-19 vaccines: Policy Questions, Evidence to Recommendation Framework & Critical and Important Outcomes

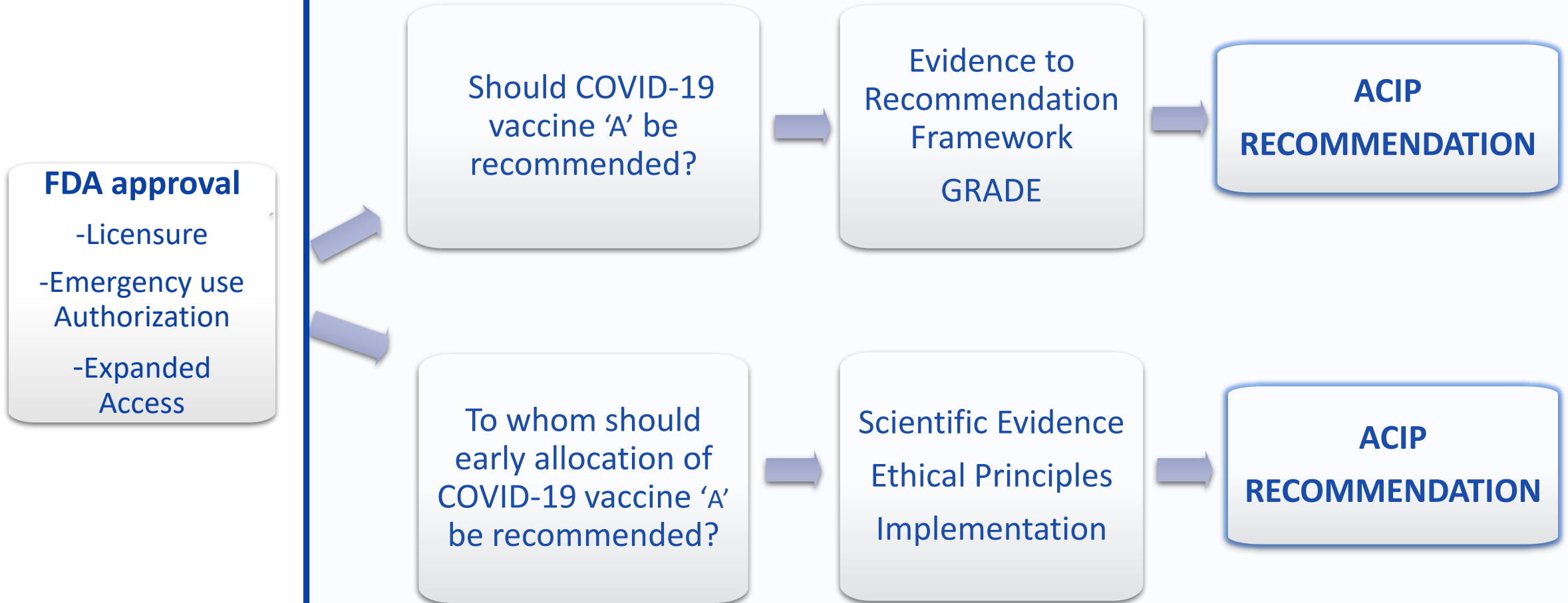
Kathleen Dooling, MD MPH  
October 30, 2020



# Work Group Considerations: Goals of the COVID-19 Vaccine Program

- Ensure safety and effectiveness of COVID-19 vaccines
- Reduce transmission, morbidity, mortality of COVID-19 disease
- Help minimize disruption to society and economy, including maintaining healthcare capacity
- Ensure equity in vaccine allocation and distribution

# ACIP Pathway to Recommendation



# Two ACIP Policy Questions

**#1. Should COVID-19 Vaccine “A” be recommended for adults in the U.S.?**

**#2. Who should be recommended to receive COVID-19 Vaccine “A” during Phase 1?**

# Evidence to Recommendation Framework (EtR)

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## EtR Domain

<b>Public Health Problem</b>	<ul style="list-style-type: none"><li>•Is the problem of public health importance?</li></ul>
<b>Benefits and Harms</b>	<ul style="list-style-type: none"><li>•How substantial are the expected benefits?</li><li>•Are there harms? How substantial?</li></ul>
<b>Values</b>	<ul style="list-style-type: none"><li>•Does the target population value the vaccination?</li></ul>
<b>Acceptability</b>	<ul style="list-style-type: none"><li>•Is the vaccine program acceptable to key stakeholders?</li></ul>
<b>Feasibility</b>	<ul style="list-style-type: none"><li>•Is the vaccine program feasible to implement?</li></ul>
<b>Resource Use</b>	<ul style="list-style-type: none"><li>•Is the vaccine program a reasonable and efficient allocation of resources?</li></ul>
<b>Equity</b>	<ul style="list-style-type: none"><li>•What would be the impact of the vaccine program on health equity?</li></ul>

# Evidence to Recommendation Framework (EtR)

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## EtR Domain

<b>Public Health Problem</b>	<ul style="list-style-type: none"><li>•Is the problem of public health importance?</li></ul>
<b>Benefits and Harms</b>	<ul style="list-style-type: none"><li>•How substantial are the expected benefits?</li><li>•Are there harms? How substantial?</li></ul>
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<b>Equity</b>	<ul style="list-style-type: none"><li>•What would be the impact of the vaccine program on health equity?</li></ul>

# EtR: Health Equity Domain

## **Criterion question: What would be the impact on health equity?**

- Are there any groups or settings that might be disadvantaged in relation to the problem or options that are considered?
- Are there plausible reasons for anticipating differences in the relative effectiveness of the option for disadvantaged groups or settings?
- Are there different baseline conditions across groups or settings that affect the absolute effectiveness of the option or the importance of the problem for disadvantaged groups or settings?
- Are there important considerations that should be made when implementing the intervention (option) in order to ensure that inequities are reduced, if possible, and that they are not increased?

# PICO for Vaccine Policy Question #1

<b>P</b> opulation	Adults		
<b>I</b> ntervention	COVID-19 vaccine “A”		
<b>C</b> omparison	No vaccine (Placebo, including saline or non-COVID-19 vaccine)		
<b>O</b> utcomes		Benefits ( <i>prevention of</i> )	Harms ( <i>possible risks</i> )
	Critical	<ul style="list-style-type: none"> <li>Symptomatic COVID-19 (PCR* conf)</li> <li>Hospitalization due to COVID-19</li> </ul>	<ul style="list-style-type: none"> <li>Serious Adverse Events (including vaccine-associated enhanced disease)</li> </ul>
	Important	<ul style="list-style-type: none"> <li>Death (all cause)</li> <li>SARS-CoV-2 Seroconversion (non-spike)</li> <li>Serial PCRs for asymptomatic infection</li> </ul>	<ul style="list-style-type: none"> <li>Reactogenicity</li> </ul>

PCR= Polymerase chain reaction



# Outcomes under study in clinical trials

Outcome	In clinical Protocols?	Comments
Symptomatic COVID-19 (PCR+)	✓	Primary outcome, consistent definition
Hospitalization due to COVID-19	✓	Exploratory aim (or as adverse event)
Serious Adverse Events	✓	Unsolicited, consistent definition
Death (all cause)	✓	Exploratory aim (or as adverse event)
Reactogenicity	✓	Solicited symptoms 7d
SARS-CoV-2 Seroconversion (non-spike)	✓	Differences in timing & assay
Serial PCRs for asymptomatic infection	X	? Outside U.S.

# COVID-19 Vaccine Work Group next steps

## Policy Question #1: **Vaccine Recommendations**

- Populate the Evidence to Recommendation Framework
- Start GRADEing vaccine evidence and incorporate Phase III data when available
- Discuss clinical guidance (special populations/concomitant administration/scheduling)

## Policy Question #2: **Allocation Recommendations**

- Publish ethical principles manuscript
- Incorporate latest information regarding science, implementation, and ethics to further refine Phase 1 allocation

# Questions for ACIP

- Do ACIP members agree with the proposed policy questions and outcomes?