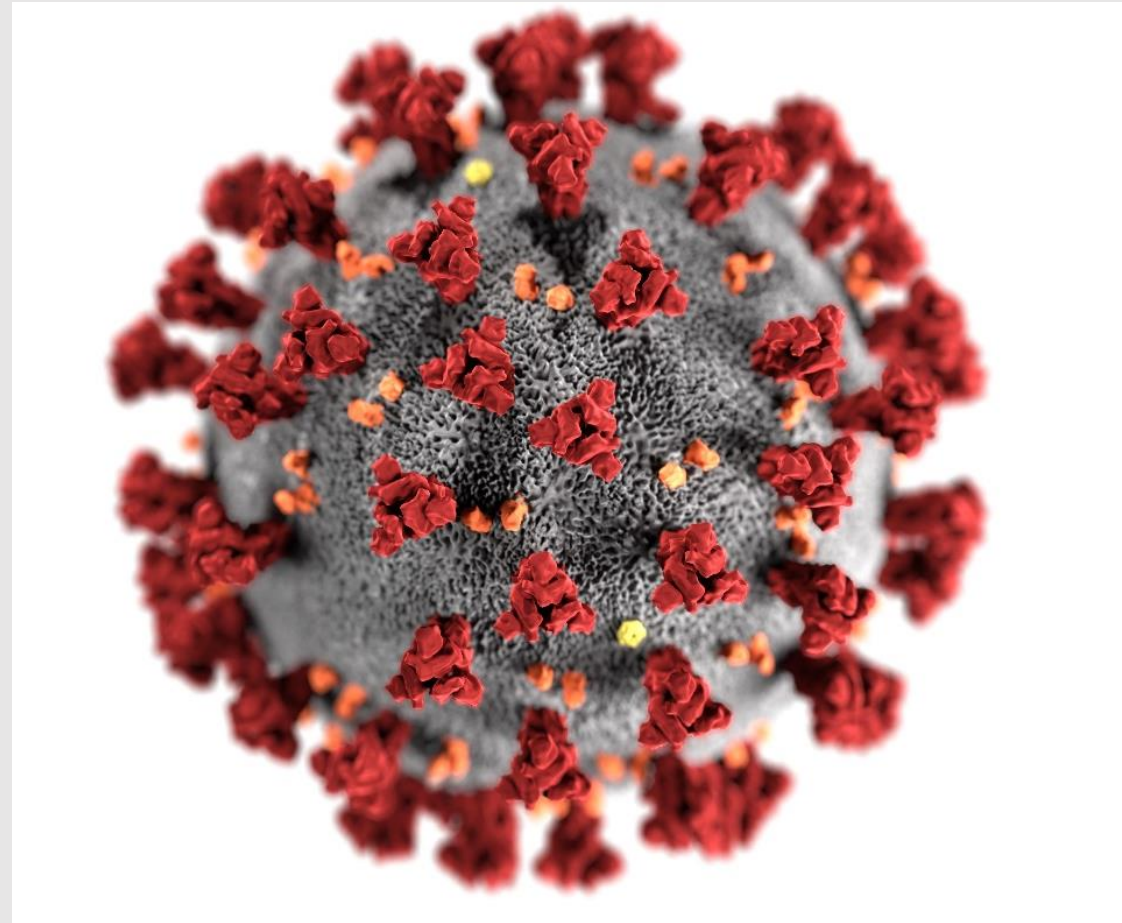


COVID-19 vaccines: Policy Questions, Evidence to Recommendation Framework & Critical and Important Outcomes

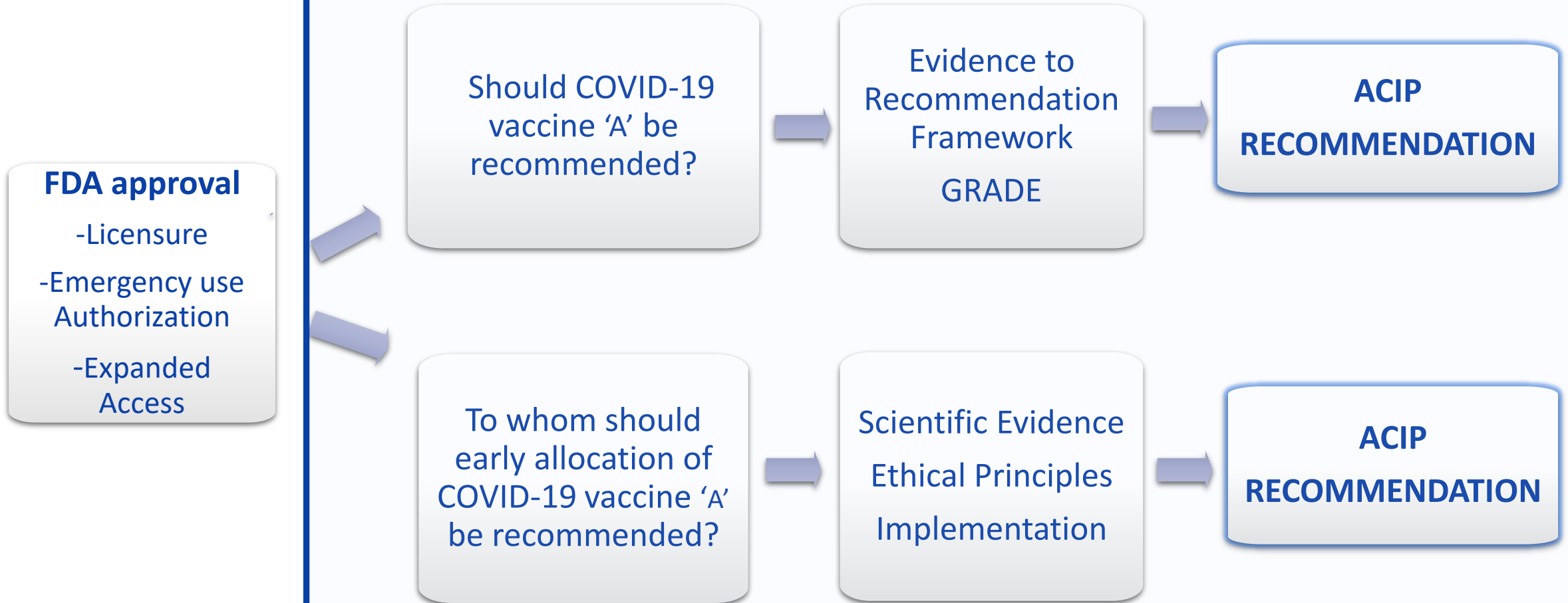
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Work Group Considerations: Goals of the COVID-19 Vaccine Program

- 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)

EtR Domain

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

Evidence to Recommendation Framework (EtR)

EtR Domain

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

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

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

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?