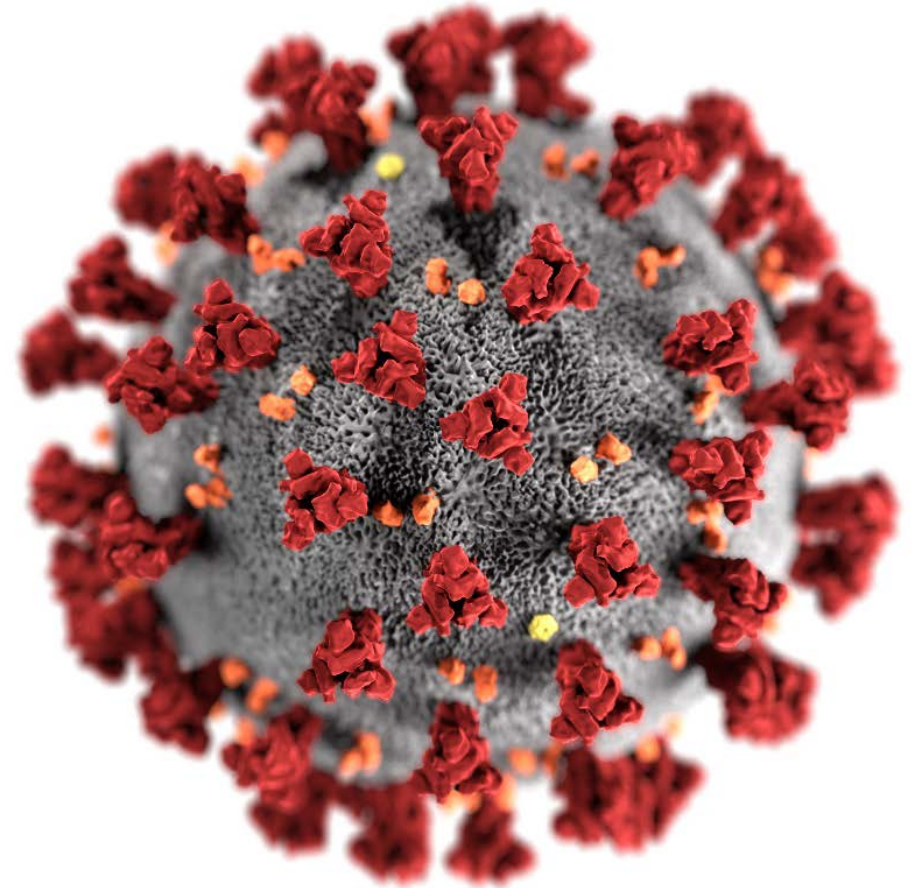


COVID-19 vaccine Work Group Considerations: Evidence to Recommendation Framework

Kathleen Dooling, MD MPH
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Work Group Considerations: Objectives 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

Evidence to Recommendation



Formulate question

Select outcomes

Rate importance

Outcomes across studies

Rate quality of evidence for each outcome

P
I
C
O

Outcome Critical

Outcome Critical

Outcome Important

Outcome Not important



Study	Outcome	Relative Risk (95% CI)	Quality
Study 1	Critical	1.2 (0.8, 1.8)	High
Study 2	Critical	1.1 (0.7, 1.7)	Moderate
Study 3	Important	1.0 (0.6, 1.6)	Low
Study 4	Not important	0.9 (0.5, 1.5)	Very low

Summary of findings & estimate of effect for each outcome

High
Moderate
Low
Very low

Systematic review

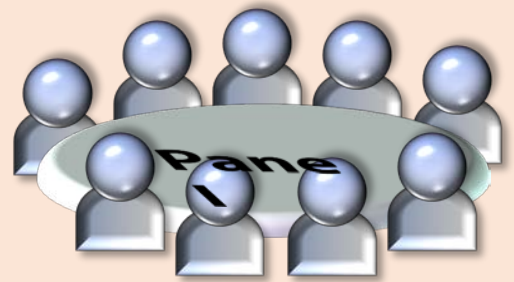
Guideline development

Formulate recommendations :
• For or against (direction)

By considering:



- Magnitude of PH problem
- Quality of evidence
- Balance benefits/harms
- Values and preferences
- Acceptability
- Resource use (cost)



GRADE
quality of evidence by outcomes

Formulating the Question: PICO



Work Group Conceptualization of Vaccine Policy Question

P opulation	Entire US population. Sub-populations TBD
I ntervention	
C omparison	
O utcomes	

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C omparison	Placebo (including saline or non-COVID-19 vaccine) No vaccine Future COVID-19 Vaccine?		
O utcomes		Benefits	Harms
	Important		
	Critical		

Work Group Conceptualization of Vaccine Policy Question

Outcomes		Possible Benefits (Prevention of...)	Possible Harms
	Important	SARS-CoV-2 Seroconversion COVID-19 hospitalization Mechanical ventilation Death	Reactogenicity
	Critical	Symptomatic COVID-19	Severe Adverse Events (includes VED)

COVID-19 Vaccine Recommendations:



Vaccine Recommendations

- stable (Δ if new data on harms/benefits)
- populations broad, likely consistent with FDA approval
- purpose: set standard + inform prioritization

Prioritization Recommendation

- dynamic (Δ if vax rec, Δ supply or demand)
- subset populations as required
- purpose: implementation

Equity



Work Group Considerations: Process for identifying proposed priority groups for COVID-19 vaccination

Pandemic influenza framework for vaccine allocation

- Burden of disease and severity
- Pandemic severity and impacts on society
- Vaccine supply

Principles of the Evidence to Recommendations (EtR) Framework

Criteria for prioritization

- Burden and severity of disease
- Benefits and possible harms
- Values of the target population
- Acceptability to stakeholders
- Feasibility of implementation

Ethics and equity principles

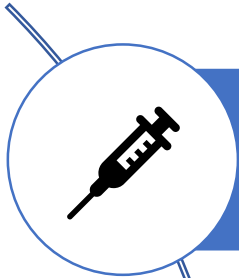
- Minimize death and serious disease
- Preserve functioning of society
- Reduce disproportionate burden on those with existing disparities

Consideration should be give to:

- Maximize benefits/minimize harms
- Transparent, fair process
- Just, fair stewardship of vaccines
- Removing barriers to vaccination

ACIP COVID-19 Vaccine Work Group: Proposed Guiding Principles

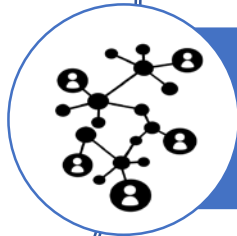
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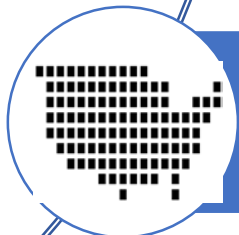
Safety is paramount. Vaccine safety standards will not be compromised in efforts to accelerate COVID-19 vaccine development or distribution



Inclusive clinical trials. Study participants should reflect groups at risk for COVID-19 to ensure safety and efficacy data are generalizable



Efficient Distribution. During a pandemic, efficient, expeditious and equitable distribution and administration of approved vaccine is critical



Flexibility. Within national guidelines, state and local jurisdictions should have flexibility to administer vaccine based on local epidemiology and demand

National Academies of Science Engineering and Medicine

Committee on Equitable Allocation of Vaccine for the Novel Coronavirus

Purpose: To develop a framework for planning for equitable allocation of vaccines which can inform decisions by ACIP

- What criteria should be used in setting priorities for equitable allocation of vaccine?
- How should the criteria be applied in determining the first tier of vaccine recipients?
- How can communities of color be assured access to vaccination?

Next Steps for the Work Group

Vaccine Recommendations:

- Complete definition of the policy question for inclusion in the EtR Framework
- Review clinical trial data for candidate vaccines, as they becomes available
- Build understanding of adverse event reporting and surveillance systems in clinical studies and post approval use— identify gaps and strengthen systems

Further refine Tier Groups for allocation of early vaccine, including persons at high risk:

- Review proposed vaccine implementation—understand needs of State/Local planners
- Review modelling analysis of vaccine implementation strategies
- Review results of focus groups and other public engagement as they become available