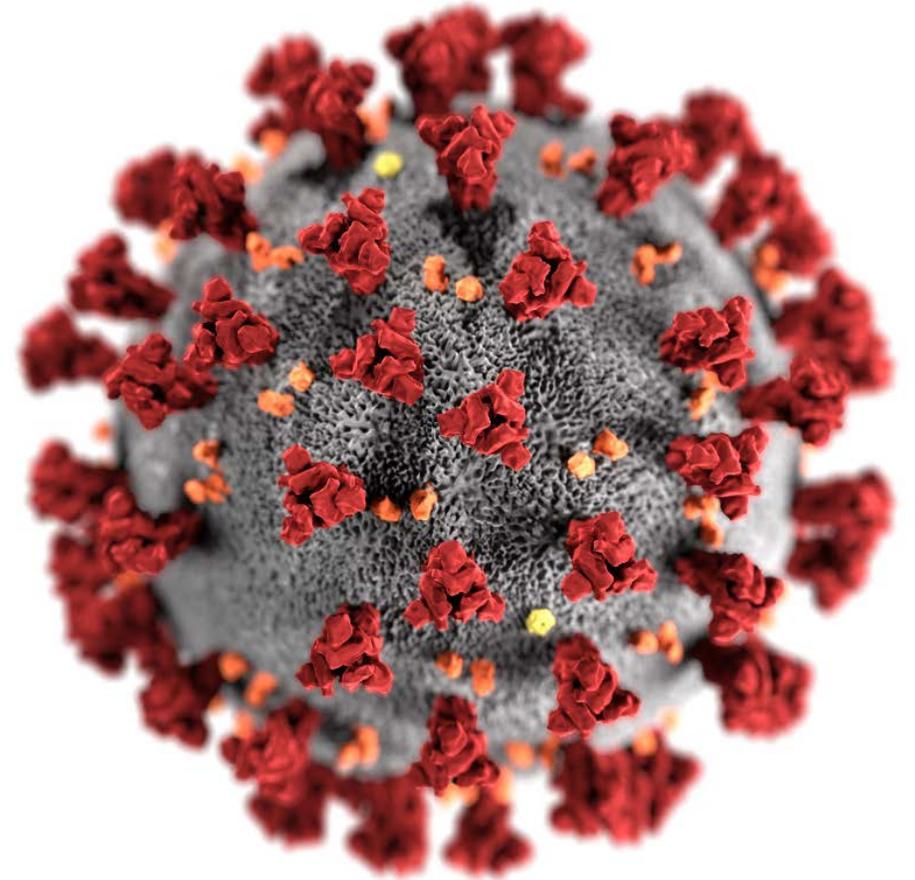


Work Group Considerations and Next Steps

Kathleen Dooling, MD MPH
June 24, 2020



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

Summary- COVID-19 Immune response

What we know

- Most people with SARS-CoV-2 develop antibodies, usually within 2 weeks
- Most people with SARS-CoV-2 mount neutralizing antibody responses

Key unknowns for vaccine policy

- What is the duration of immunity following SARS-CoV-2 infection?
- Will neutralizing antibodies protect against viral infection?
- Are there immunologic correlates of protection?

Summary- COVID-19 Epidemiology in the U.S.

What we know

- Multiple populations with evidence of high risk of COVID-19 disease or severity
- Occupation
 - healthcare, agricultural
- Individual characteristics
 - Older adults, underlying medical conditions
- Social determinants
 - Belonging to American Indian, Black or Hispanic race/ethnic groups
 - Long-term care, Correctional facilities, homeless

Key unknowns for vaccine policy

- Proportion of viral transmission contributed by children
- Risk of disease and severity in pregnant women
- Incidence of MIS-C*, and long term sequelae
- Current level of population immunity and heterogeneity by factors such as geography/occupation/race/ethnicity

Summary- Development of COVID-19 Vaccines

What we know

- Multiple platforms are being utilized to develop COVID-19 vaccines
- Multiple approaches increase the chances of developing safe and effective vaccines to meet national and global needs
- Vaccines must meet stringent safety standards in clinical trials. Otherwise, the vaccine will not be used in the population

Key unknowns for vaccine policy

- Vaccine characteristics
 - # doses
 - Route of administration (SQ*/IM^/electroporation)
 - Storage temperature
- Vaccine performance
 - Immunogenicity and efficacy by age and risk groups
 - Interval from vaccination to protection
 - Vaccine effect on acquisition of infection and transmission
 - Adverse event profile by age and risk groups
 - FDA approved populations

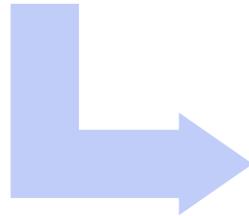
SQ*- subcutaneous

IM^- Intramuscular

Path from clinical development to recommendation

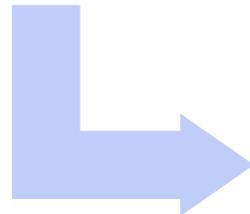
Clinical Development

- Generates safety, immunogenicity, and efficacy data
- Close coordination within OWS (DHHS [CDC,NIH,ASPR], DoD)
- Manufacturing of vaccine- could save months of time post-approval



FDA

- Licensure
- Emergency Use Authorization (AVA Anthrax for PEP)
- Expanded Access IND (MenB vaccine during college outbreaks)

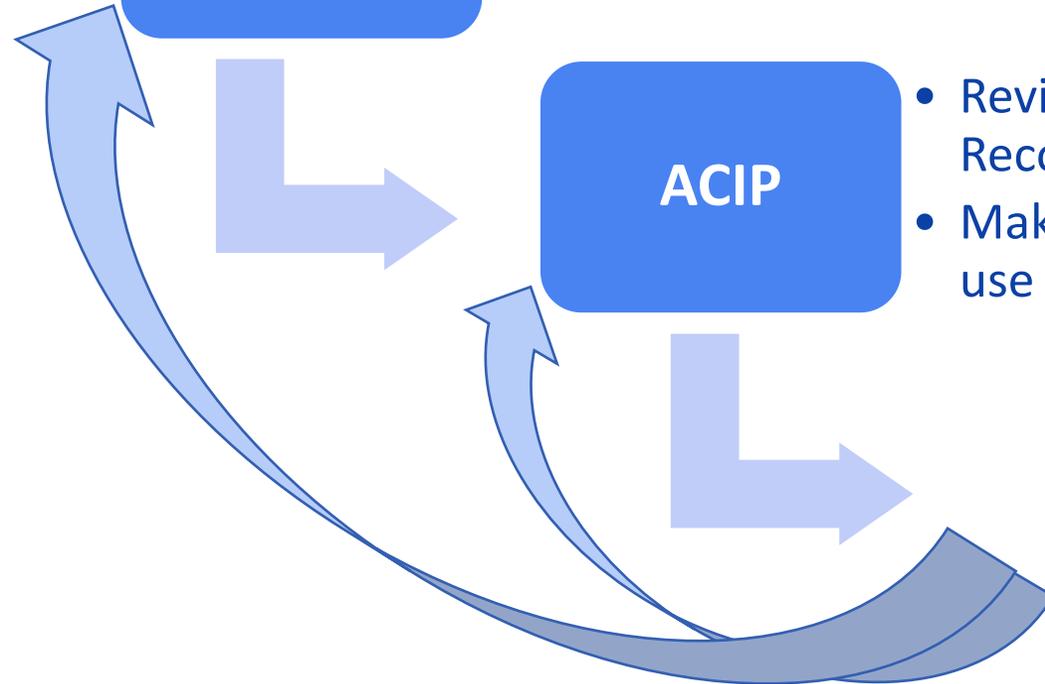


ACIP

- Review Evidence, utilize Evidence to Recommendation Framework
- Make recommendations regarding the use of vaccines to the CDC Director



**CDC Recommendation
Post-approval monitoring**



Evidence to Recommendation Framework

PROBLEM

- Is the disease of public health importance?

BENEFITS & HARMS

- How substantial are the expected benefits?
- Are there harms? How substantial?

Evidence to Recommendation Framework

VALUES

- Does the target population value the vaccination?

ACCEPTABILITY

- Is the vaccine program acceptable to key stakeholders?

FEASIBILITY

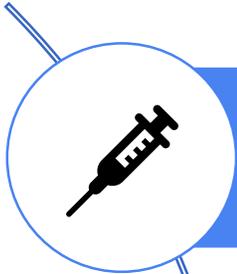
- Is the vaccine program feasible to implement?

Guiding Principles for COVID-19 Vaccines



ACIP COVID-19 Vaccine Work Group: Proposed Guiding Principles

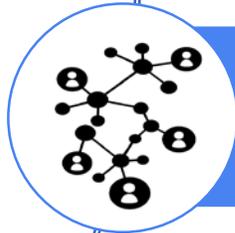
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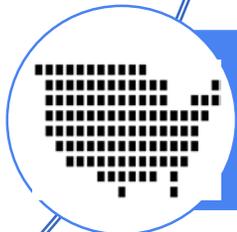
Safety is paramount. Vaccine safety standards will not be compromised in efforts to accelerate COVID-19 vaccine development



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



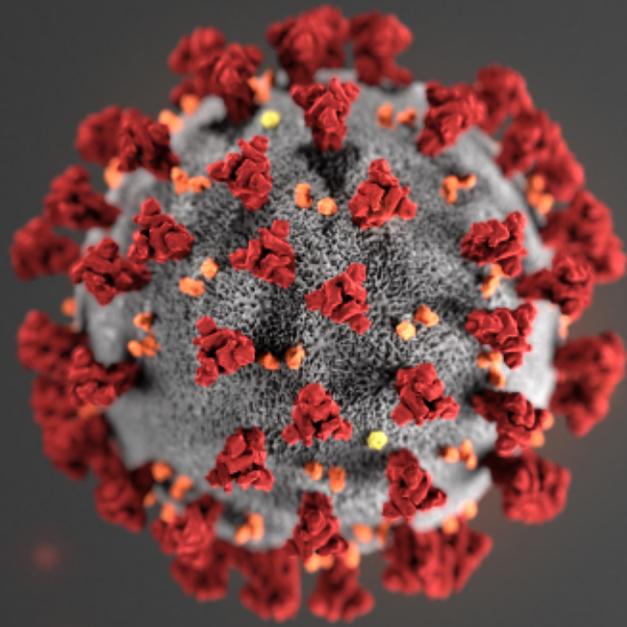
Flexibility. Within national guidelines, state and local jurisdictions should have flexibility to administer vaccine based on local epidemiology and demand

Next Steps for the Work Group

- Define the critical and important outcomes (benefits and risks for EtR)
- Review clinical trial data for candidate vaccines, as it becomes available
- Advance understanding of safety issues with each vaccine platform and safety studies in Phase III & IV
- Further refine Tier Groups for allocation of early vaccine, based on ACIP feedback
- Review proposed implementation strategies

Questions for ACIP

- Do you agree with the proposed guiding principles?
- Do you agree with the next steps?
- What topics would you like to see presented at the next ACIP meeting?



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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.

