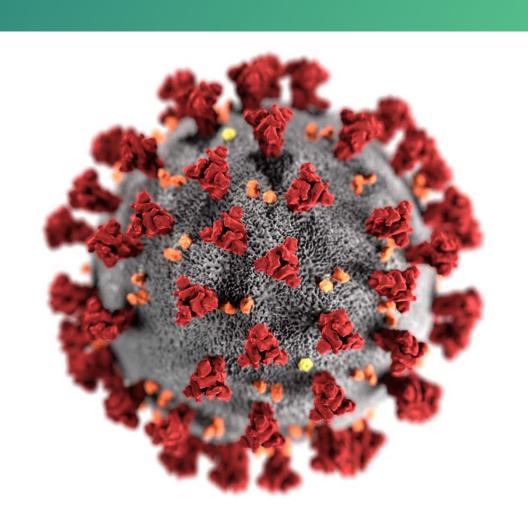


ACIP COVID-19 Vaccines Work Group

Considerations for COVID-19 Vaccine Prioritization

Sarah Mbaeyi, MD MPH June 24, 2020



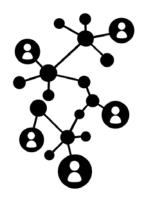


Identifying priority groups for COVID-19 vaccination

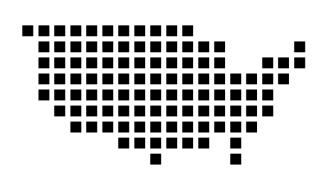
An essential roadmap for vaccine program planning and implementation

- Although the goal is to offer vaccine to the entire U.S. population, identifying priority groups for COVID-19 vaccination is essential to support vaccine planning
 - Necessary to begin planning prior to vaccine approval to avoid delays
- Vaccine prioritization is challenging due to incomplete information on COVID-19 epidemiology and vaccines, including characteristics, timing, and number of doses
- Identifying priority groups: essential to start now with the information available to date, with continuous reassessment as data become available

Importance of identifying COVID-19 vaccine priority groups for implementation planning



Strengthen vaccine distribution networks to reach target group



Develop state and local microplans for vaccine implementation



Create communications strategies to promote vaccination in priority groups



Plan evaluations to rapidly monitor vaccine safety, effectiveness, and coverage

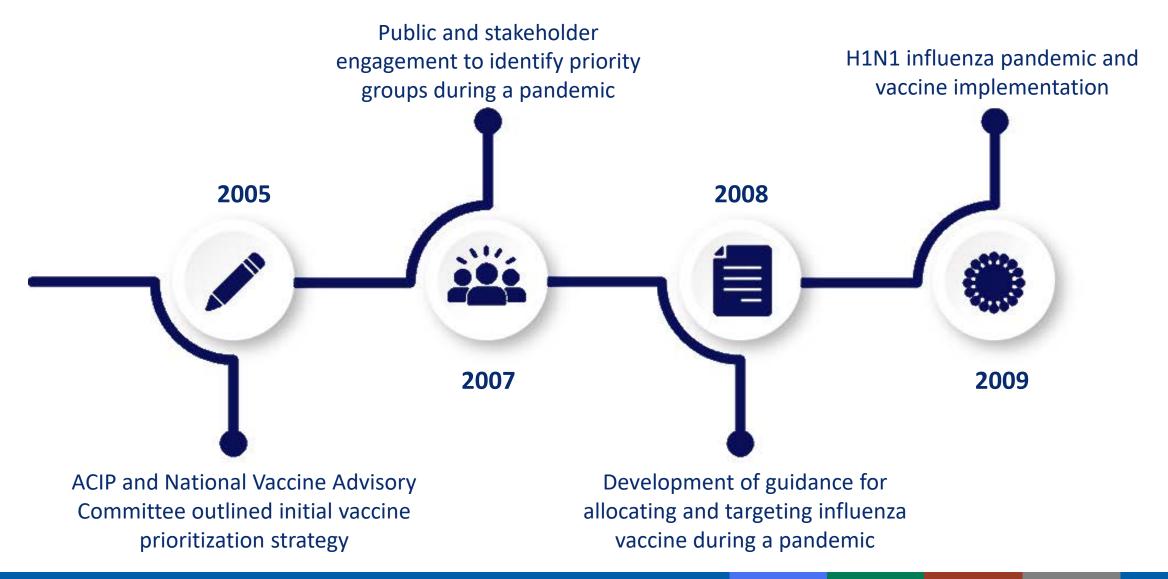
Lessons learned from pandemic influenza vaccination

Framework for COVID-19 prioritization and implementation planning



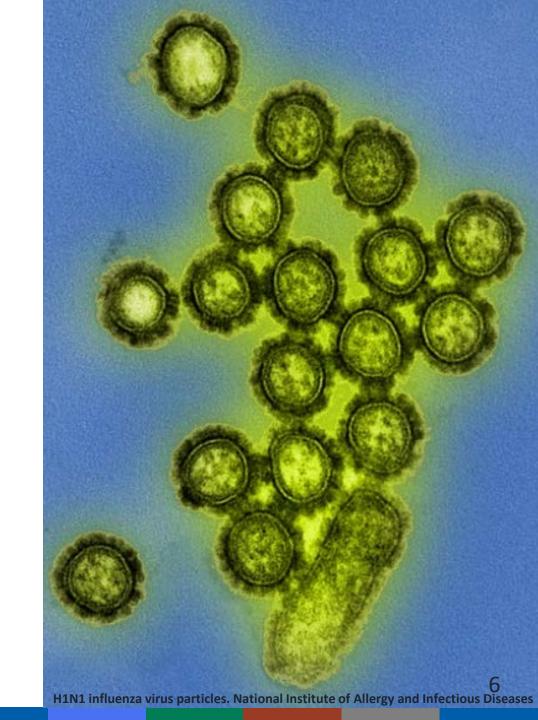
Pandemic influenza vaccine prioritization planning

Principles of pandemic vaccine planning to be adapted for COVID-19 vaccination



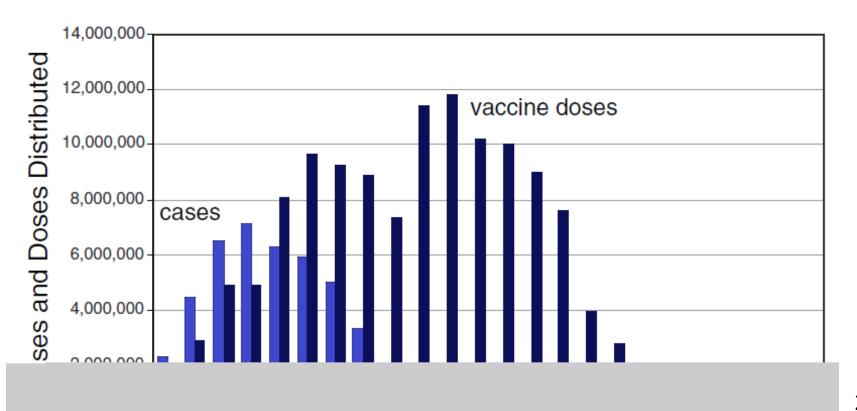
H1N1 influenza pandemic

- Novel influenza A virus (H1N1) emerged in April 2009, leading to a global pandemic
- H1N1 vaccine became available in October 2009 during second wave of disease
- ACIP recommended priority groups for initial vaccination:
 - Persons at increased risk for severe disease
 - Healthcare personnel



H1N1 vaccine supply and demand

Estimated number of H1N1 cases and vaccine doses distributed – October 2009 to March 2010



High demand when supply limited and prioritized



Low demand when supply adequate 20% vaccine coverage by late January

Lessons learned from H1N1 vaccine prioritization

- Overly optimistic vaccine supply projections
- Restrictive enforcement of priority groups can lead to vaccine surpluses
- Challenges in expanding vaccination outside of the priority groups to the general public
- Importance of population values
- Need for state and local flexibility in implementation
- H1N1 experience: valuable lessons learned, though complexity of COVID-19 pandemic will lead to new challenges

Guidance for allocating and targeting pandemic influenza vaccine

 Updated in 2018 based on lessons learned from H1N1 pandemic

 Occupational and high risk populations grouped into tiers for prioritization

 Provides framework for adaptation to COVID-19 vaccine prioritization

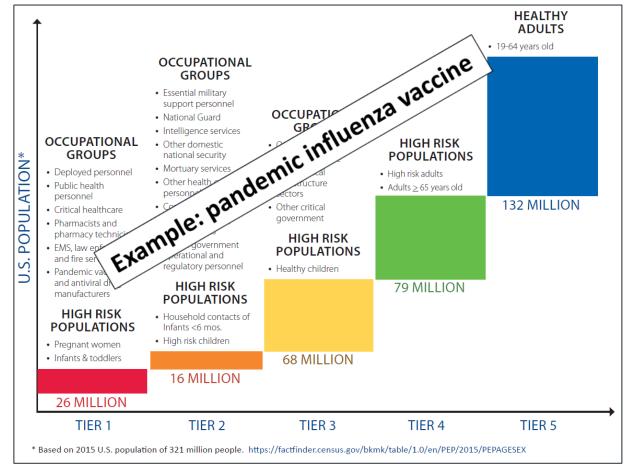


2018 guidance and associated support documents

Tiered approach to defining priority groups for vaccination

- Prioritization framework: roadmap for vaccine program planning
- Tiered priority groups to be adapted for COVID-19 based on:
 - Burden of disease and severity in risk groups
 - Impacts on society and critical infrastructure
 - Characteristics of vaccines
 - Number and timing of doses available

Allocating and targeting pandemic influenza vaccine during an influenza pandemic



ACIP COVID-19 Vaccine Work Group

Considerations for identifying COVID-19 vaccine priority groups



Role of ACIP in identifying COVID-19 vaccine priority groups

- ACIP provides advice to the CDC director and HHS secretary on use of vaccines in the U.S. civilian population in a transparent, evidence-based process
- To help inform ACIP deliberations around use of COVID-19 vaccines, the work group is reviewing:
 - Epidemiology of COVID-19
 - Characteristics of vaccine candidates under development
 - Evidence-based vaccine recommendation, ethics, and equity frameworks

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

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

Identifying vaccine priority groups: Current challenges and preliminary Work Group assumptions

Challenges

Work Group assumptions for prioritization

Evolving understanding of COVID-19 epidemiology and immunology

- Prioritization should occur based on the information available to date and be continually refined based on data
- A substantial proportion of the U.S. population, regardless of age, location, or occupation, remains susceptible to COVID-19.

Current absence of data on safety and efficacy of COVID-19 vaccines

- Vaccines will not be administered until safety and efficacy have been demonstrated.
- Concerns for reduced efficacy in certain populations (e.g., older adults, immunocompromised individuals) should not preclude their inclusion as priority groups while data are pending.

Unknown timing and number of vaccine doses

- Number of initial doses may not be sufficient to vaccinate everyone in the priority groups, necessitating sub-prioritization.
- Vaccine doses will become available in incremental quantities over several months.

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

Pandemic influenza framework for vaccine allocation

Principles of the Evidence to Recommendations (EtR) Framework

Ethics and equity principles

Criteria for prioritization

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

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

- 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

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

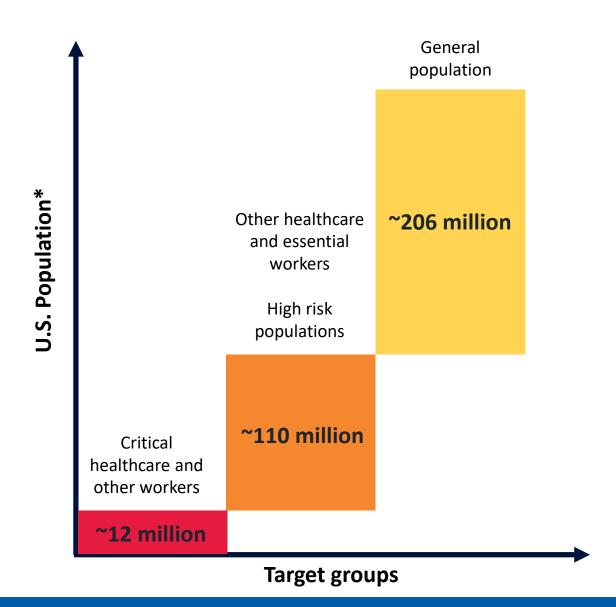
Pandemic influenza framework **Ethics and equity principles EtR** framework

Proposed prioritization scheme:

- General approach for prioritization to help with operational planning for vaccine implementation
- Iterative process with priority groups to be refined as more information becomes available



Work Group considerations: Among target groups, subset of critical healthcare and other workers should receive initial doses

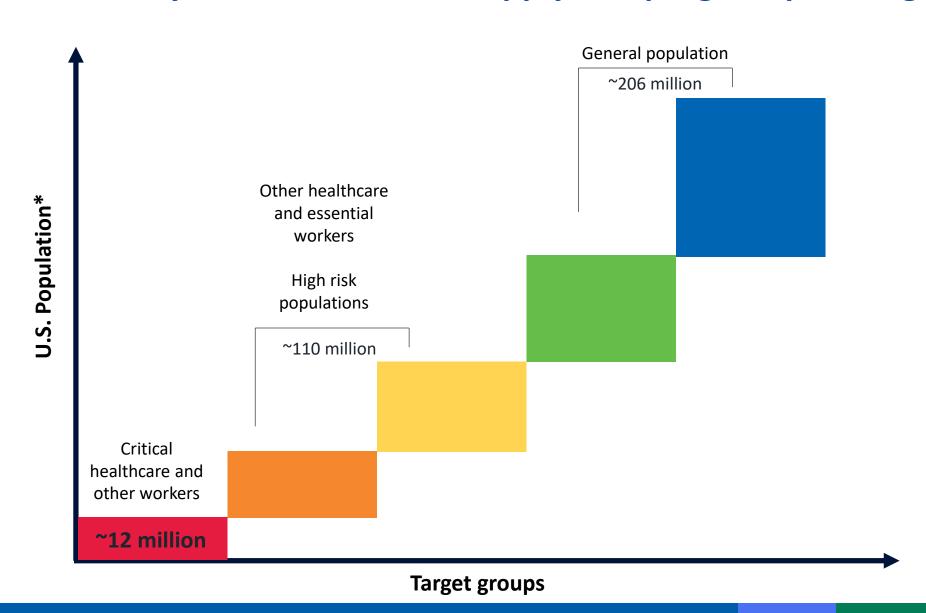


Highest priority target group includes:

- Highest risk medical, national security, and other essential workers
- Rationale: protect healthcare infrastructure and other critical societal functions

^{*} Based on 2019 U.S. population of 328 million and information from Department of Defense, Department of Homeland Security, Department of Health and Human Services, and U.S. Census Bureau

Work Group considerations: Further tiering of target groups may be necessary based on vaccine supply and program planning



^{*} Based on 2019 U.S. population of 328 million and information from Department of Defense, Department of Homeland Security, Department of Health and Human Services, and U.S. Census Bureau

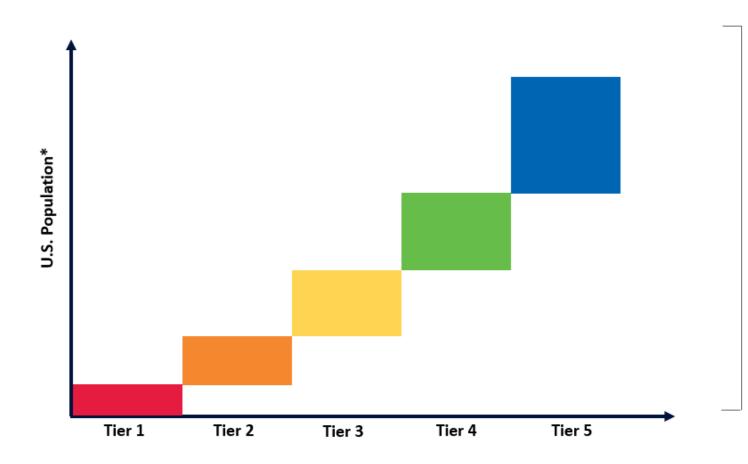
Additional data to inform prioritization

- Remaining information gaps in certain population subgroups:
 - Risk of disease and severe outcomes
 - Vaccine safety and efficacy
 - Transmission dynamics and level of population immunity
- Additional data to inform prioritization will be helpful, though may need to make decisions in the setting of unknowns for vaccine implementation planning

Summary

- Identifying priority groups for initial COVID-19 vaccination prior to approval of a vaccine is critical for implementation planning
- Lessons learned from the H1N1 influenza pandemic highlight importance of national guidance while allowing for state/local flexibility in implementation
- Work Group proposes priority groups for COVID-19 vaccination, including healthcare/ essential workers and persons at increased risk for severe disease
- Prioritization will need to be refined as more information becomes available.

Discussion: Key population groups where ACIP feedback needed to support vaccination program planning



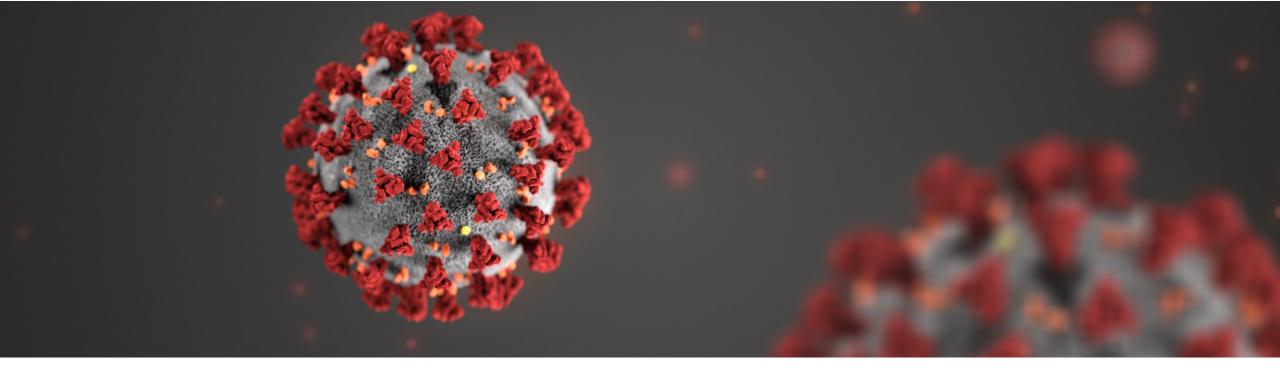
Which tier for key populations?

- Critical healthcare/other workers
- Long-term care facility residents
- Other congregate settings
- Children
- Pregnant women
- Racial/ethnic groups at high risk

Are there other data that ACIP would like to review?

Next steps

- Proposed priority groups to be further refined based on ACIP feedback
- Goal for next ACIP meeting: Completed prioritization framework



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.

