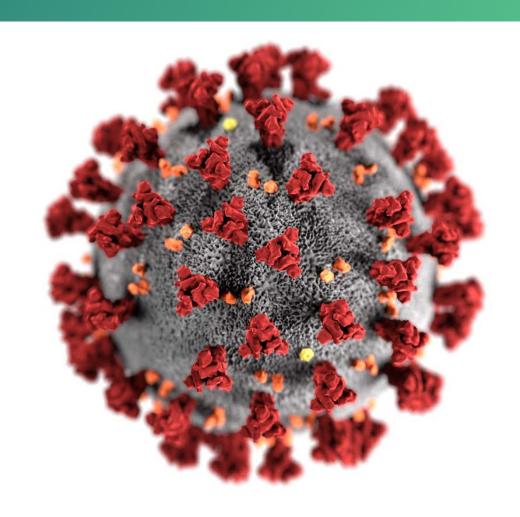


ACIP COVID-19 Vaccines Work Group

Phased Allocation of COVID-19 Vaccines

Kathleen Dooling, MD, MPH ACIP meeting December 20, 2020





Objective

Policy Question:

Which groups should be offered COVID-19 vaccination in Phase 1b & 1c?

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 the economy, including maintaining healthcare capacity
- Ensure equity in vaccine allocation and distribution

Prevention of Morbidity & Mortality



Preservation of Societal Functioning

Prevention of Morbidity & Mortality

1a LTCF residents



Preservation of Societal Functioning

Health care personnel

- Ensure safety and effectiveness of COVID vaccines
 - •Ensure equity in vaccine allocation and distribution

- 10 public ACIP meetings, 28 COVID-19 Work Group meetings
- Evidence: Scientific, Implementation, Ethical
- External Expert Advice
 - National Academies of Science Engineering Medicine
 - Academic Reports
 - International Recommendations
- Public Input
 - Focus groups
 - Population surveys
 - Pandemic preparedness
 - ACIP public comment and federal register

	Prevention of Morbidity & Mortality	Preservation of Societal Functioning
1a	LTCF residents	Health care personnel
1b	Persons 75 years and older	Frontline Essential Workers
1c	Persons 6574 years Persons 1664 with high-risk medical conditions	Other Essential Workers

- •Ensure safety and effectiveness of COVID9 vaccines•
 - •Ensure equity in vaccine allocation and distribution

Prevention of Preservation of Morbidity & Mortality Societal Functioning Health care personnel 1a LTCF residents 1b Persons 75 years and older Frontline Essential Workers Persons 6574 years Persons 1664 with high-risk 1c Other Essential Workers medical conditions

- •Ensure safety and effectiveness of COVID9 vaccines•
- •Ensure equity in vaccine allocation and distribution

NASEM Framework

Phase 1

Phase 1a "Jumpstart Phase"

High-risk health workers
 First responders

Phase 1b

- People of all ages with comorbid and underlying conditions that put them at significantly higher risk
- Older adults living in congregate or overcrowded settings

Phase 2

- K-12 teachers and school staff and child care workers
- Critical workers in high-risk settings—
 workers who are in industries essential to
 the functioning of society and substantially
 higher risk of exposure
- People of all ages with comorbid and underlying conditions that put them at moderately higher risk
- People in homeless shelters or group homes for individuals with disabilities, including serious mental illness, development and intellectual disabilities, and physical disabilities or in recovery, and staff who work in such settings
- People in prisons, jails, detention centers, and similar facilities, and staff who work in such settings
- All older adults not included in Phase 1

Phase 3

- Young adults
- Children
- Workers in industries and occupations important to the functioning of society and at increased risk of exposure not included in Phase 1 or 2

Essential Workers* (total ~87M)

Frontline Essential Workers (~30M)

- First Responders (Firefighters, Police)
- Education (teachers, support staff, daycare)
- Food & Agriculture
- Manufacturing
- Corrections workers
- U.S. Postal service workers
- Public transit workers
- Grocery store workers

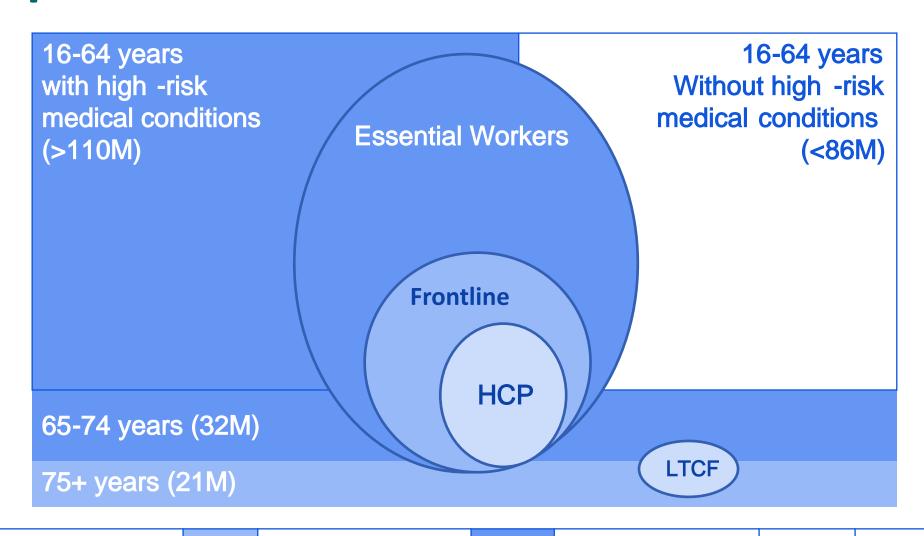
Other Essential Workers (~57M)

- Transportation and logistics
- Food Service
- Shelter & Housing (construction)
- Finance
- IT & Communication
- Energy
- Media
- Legal
- Public Safety (Engineers)
- Water & Wastewater

Frontline Essential Workers: workers who are in sectors essential to the functioning of society and are at substantially higher risk of exposure to SARS-CoV-2

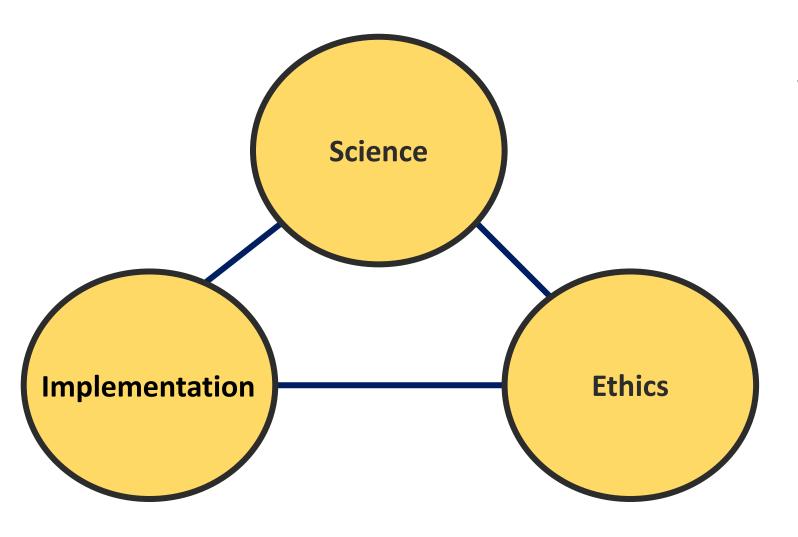
^{*}CISA: Essential Critical Infrastructure Workers: https://www.cisa.gov/news/2020/08/18/cisa-releases-updated-guidance-essential-critical-infrastructure-workers

Proposed Phases of COVID-19 Vaccination



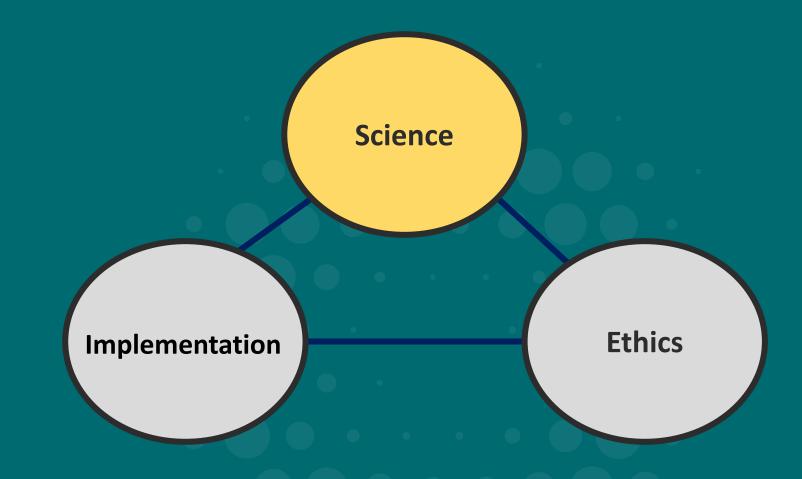
Phase 1a Phase 1b Phase 1c Phase 2

Allocation of COVID-19 vaccine



Which groups should be recommended to receive COVID-19 vaccines in Phase 1b & 1c?

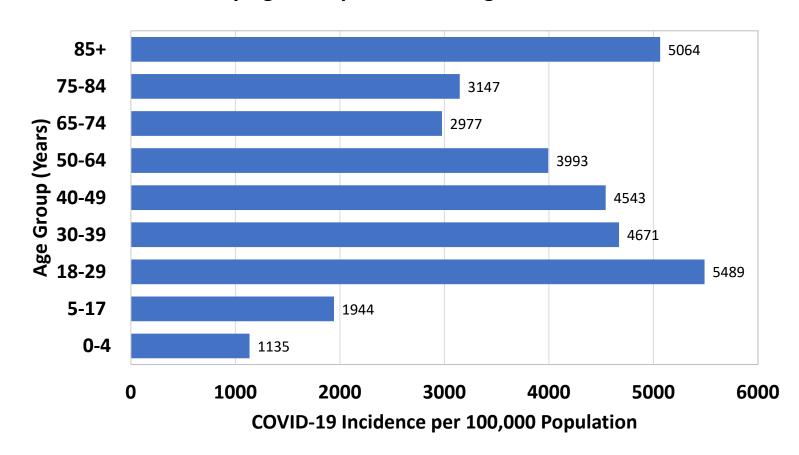
Science





COVID-19 incidence is highest in young adults

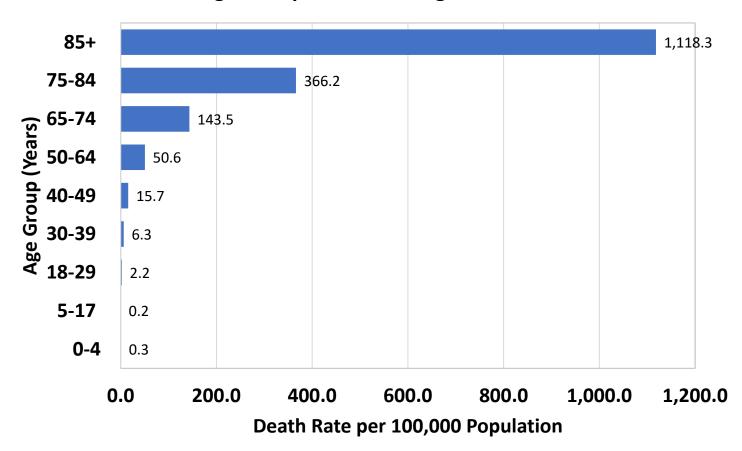
National Estimate of COVID-19 Incidence per 100,000 Population, by Age Group – Data through Dec 16, 2020



^{*}Data sources: CDC COVID-19 data tracker. Population estimates from 2019 US Census Bureau. Data provisional, subject to change.

COVID-19 mortality rates are highest in older adults

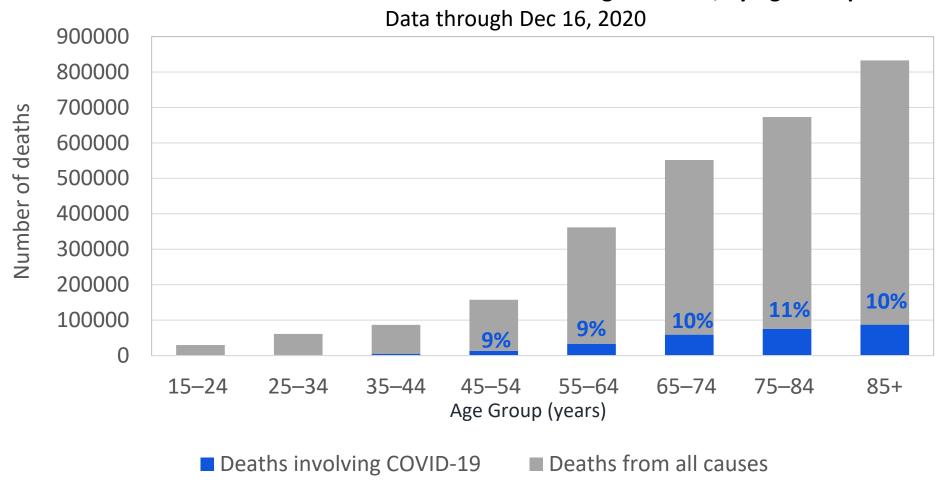
National Estimate of COVID-19 Deaths per 100,000 Population, by Age Group – Data through Dec 16, 2020



^{*}Data sources: CDC COVID-19 data tracker. Population estimates from 2019 US Census Bureau. Data provisional, subject to change.

Although overall mortality increases with age, the proportion of deaths associated with COVID-19 is similar across middle-age and older adults

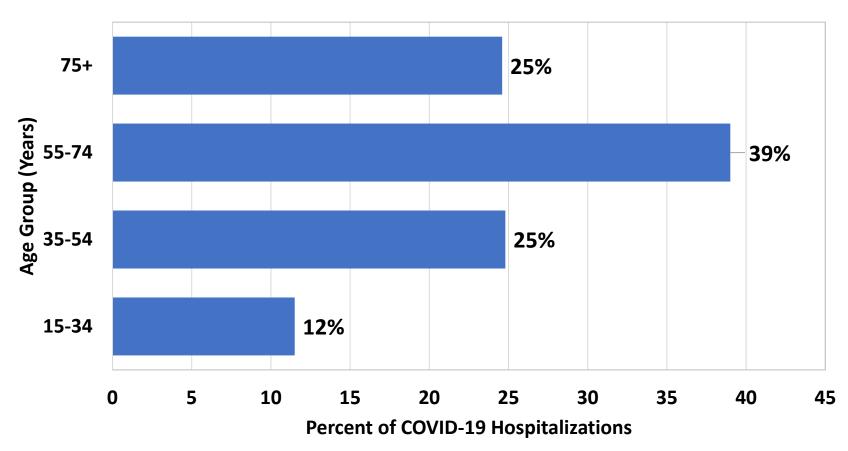




Adults 75 years and older account for 25% of COVID-19 associated hospitalizations

Percent of COVID-19-Associated Hospitalizations, by Age Group

Data through Dec 5, 2020

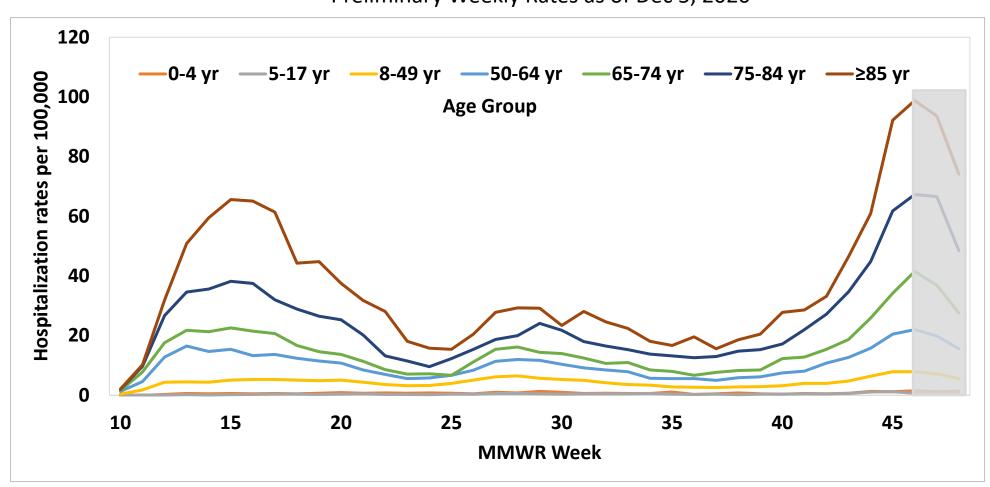


Data Source: COVID-19 associated hospitalizations reported to Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET) surveillance system. COVID-NET is a population-based surveillance system that collects data on laboratory-confirmed COVID-19-associated hospitalizations among children and adults through a network of over 250 acute-care hospitals in 14 states.

COVID-19-associated hospitalization rates are highest in older adults

COVID-19-Associated Hospitalization Rates per 100,000 population

Preliminary Weekly Rates as of Dec 5, 2020



Risk for COVID-19 associated hospitalization increased with the number of underlying medical conditions

Unadjusted and Adjusted Rate Ratios for Number of Underlying Medical Conditions and COVID-19-Associated Hospitalization, COVID-NET March 1- June 23, 2020

	Unadjusted Rate Ratio (95%CI)	Adjusted Rate Ratio ^a (95%CI)	
Number of conditions ^b			
1	2.8 (2.7, 3.1)	2.5 (2.1, 3.0)	
2	5.6 (5.2, 6.1)	4.5 (3.7, 5.5)	
3+	7.2 (6.6, 7.9)	5.0 (3.9, 6.3)	
Age 45-64 years ^c		1.8 (1.5, 2.2)	
Age 65+ years ^c		2.6 (2.1, 3.1)	
Male sex ^d		1.2 (1.1, 1.4)	
Non-Hispanic black ^e		3.9 (3.3, 4.7)	
Other race/ethnicity ^e		3.3 (2.8, 3.9)	

CI: Confidence Interval; COVID-NET: Coronavirus Disease 2019-Associated Hospitalization Surveillance Network

^aModel for number of conditions (variable) is adjusted for age, sex, and race/ethnicity

^bReference group is no underlying medical condition; Number of conditions is a sum of underlying medical conditions excluding hypertension; the most recent year of available BRFSS data for hypertension was 2017.

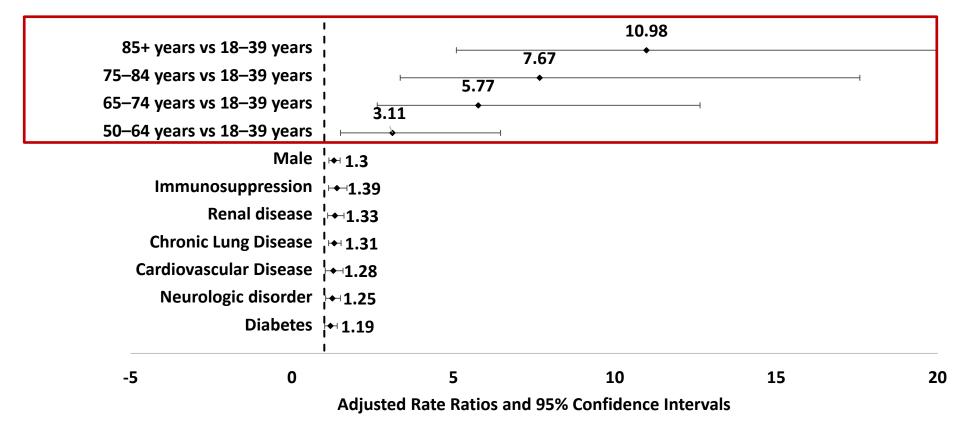
^cReference group is 18-44 years

dReference group is female

^eReference group is non-Hispanic white

Risk of in-hospital death among persons hospitalized for COVID-19 increased with age

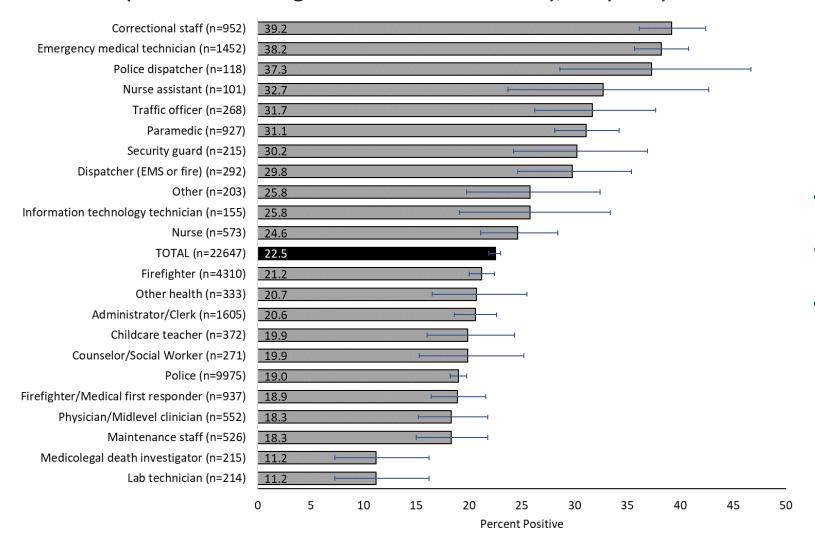
Risk of in-hospital death among patients with COVID-19 associated hospitalization, COVID-NET March 1 - May 2, 2020





*COVID-NET Surveillance; Final model adjusted for age, sex, race/ethnicity, smoker, hypertension, obesity, diabetes, chronic lung disease, cardiovascular disease, neurologic disease, renal disease, immunosuppression, hematologic disorders, and rheumatologic or autoimmune disease. Kim *et al*, 2020, https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1012/5872581

Percent seropositive for SARS-CoV-2 IgG antibody, by occupation among workers in public service agencies — New York City, May–July 2020

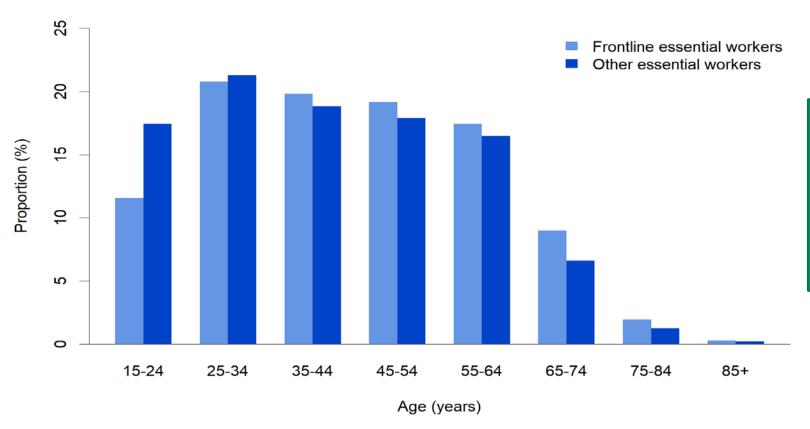


High seroprevalence among many frontline essential workers groups following first wave of pandemic in NYC

Other includes Dietary Service Staff, Environmental Service Staff and participants who selected Other and were not reassigted existing category

Other Health includes Student/Trainee, Respiratory Therapist, Occupational/Speech/Physical Therapist, Therapy Aide/Assistant, Pharmacist, Diagnostic Imaging Technician, Phlebotomist, Medical Registrar, Orderly, Dietician, Dentist, Clinical Technician, Medical Assistant. Sami et al. Manuscript in preparation.

Half of essential workers are older than 40 years



- 8-11% are ≥65 years old¹
- >56% of adults 18-64 years have ≥1 high-risk medical condition²

1. Data Source: American Community Survey, 2019 2. Data source: 2019 Behavioral Risk Factor Surveillance System

Summary of Work Group interpretation: Modeling

- In the scenarios considered, differences between strategies is minimal
 - Vaccinating older adults first averts slightly more deaths, vaccinating younger adults first (essential workers or younger adults with high-risk conditions) averts slightly more infections
 - Ethical principles and implementation considerations also contribute to selecting the optimal sequence in Phase 1b and 1c
- Largest driver of impact in averted deaths and infections is the timing of vaccine introduction in relation to increases in COVID-19 cases
 - Emphasizes the need to continue non-pharmaceutical interventions (e.g. wearing a mask, social distancing to prevent cases so vaccine can have maximum impact)
- Vaccine's ability to prevent transmission will further inform future modeling analysis and interpretation

Impacts of COVID-19 not represented in models: Late Sequelae of COVID-19

Most commonly reported symptoms include:

fatigue, dyspnea, cough, arthralgia, and chest pain

More serious complications appear to be less common but have been reported:

- Cardiovascular: myocardial inflammation, ventricular dysfunction
- Respiratory: pulmonary function abnormalities
- Renal: acute kidney injury
- Dermatologic: rash, alopecia
- Neurological: olfactory and gustatory dysfunction, sleep dysregulation, altered cognition, memory impairment
- Psychiatric: depression, anxiety, changes in mood

CDC, Late Sequelae of COVID https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/late-sequelae.html

Science **Ethics Implementation**

Implementation



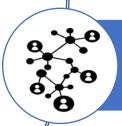
ACIP COVID-19 Vaccine Work Group: Proposed Guiding Principles



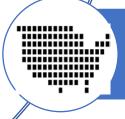
Safety is paramount. Vaccine safety standards will not be compromised in efforts to accelerate COVID-19 vaccine development or distribution



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

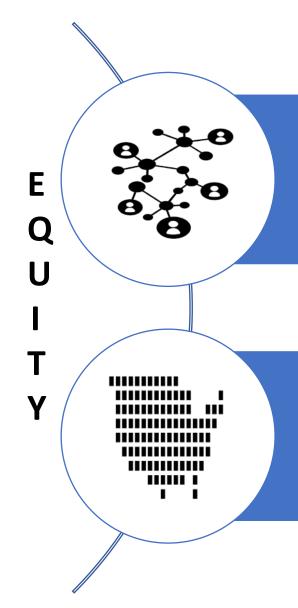


Efficient Distribution. During a pandemic, efficient, expeditious and equitable distribution and administration of approved vaccine is critical



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

ACIP COVID-19 Vaccine Work Group: Proposed Guiding Principles



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

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

Feasibility

Adults ≥65 years

- Challenge: long distances to central clinics and high throughput of clinics
- Older adults report high intent to receive COVID-19 vaccine
- Physician offices, pharmacies and public health clinics are established providers of adult vaccination
- Population surveys report 73% 82% of respondents supported priority vaccination of persons aged ≥65 years/elderly in polls conducted in December 2020 ^{2,3}

Feasibility

Essential workers

- Challenge: reaching workers in rural locations, shift workers, those working multiple jobs or working in small cohorts
- Jurisdiction approaches include on site occupational clinics/pharmacies/Health Dept POD strike teams
- Population surveys report 68% 87% of respondents supported prioritization of early allocation of COVID-19 vaccine supply to essential workers (eg. police/fire/rescue and teachers)¹⁻³

^{1.} The Harris Polhttps://www.axios.com/who-gets-coronavirus-vaccine-first-4ff87ff8-39d7-49d6-8d25-fa2307119235.html. 2. AP-NORC Center for Public Affairs Research. Many remain doubtful about getting COVID-19 vaccine. December 2020. https://apnorc.org/projects/many-remain-doubtful-about-getting-covid-19-vaccine. 3. ABC/IPSOS poll. December 14, 2020. https://www.ipsos.com/en-us/news-polls/abc-news-coronavirus-poll.

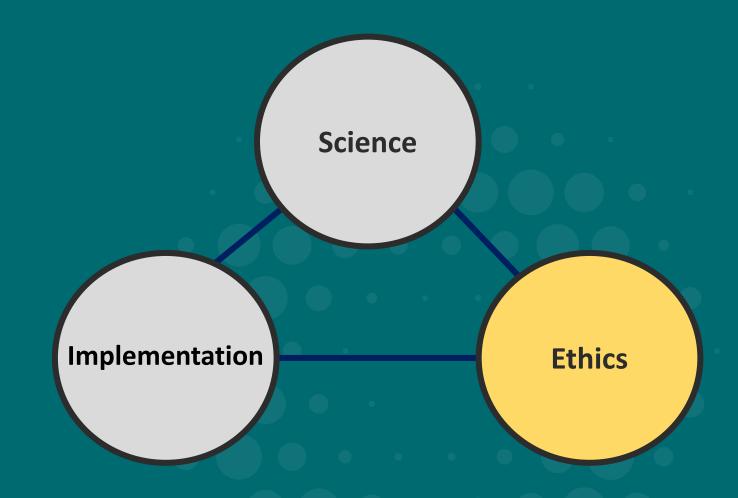
Feasibility

Adults with high-risk medical conditions

- Challenges: determining eligibility & very large group
- Healthcare homes, such as physician offices or pharmacies, could be better suited to verifying underlying medical conditions
- Population surveys report 68% 84% of respondents supported prioritization of early allocation
 of COVID-19 vaccine supply to persons who are high risk because of medical problems¹⁻³

^{1.} The Harris Polhttps://www.axios.com/who-gets-coronavirus-vaccine-first-4ff87ff8-39d7-49d6-8d25-fa2307119235.html. 2. AP-NORC Center for Public Affairs Research. Many remain doubtful about getting COVID-19 vaccine. December 2020. https://apnorc.org/projects/many-remain-doubtful-about-getting-covid-19-vaccine. 3. ABC/IPSOS poll. December 14, 2020. https://www.ipsos.com/en-us/news-polls/abc-news-coronavirus-poll.

Ethics





Older Adults

Ethical Principle	Age 75+ years (21M)	Age 65-74 Years (32M)	
Maximize benefits and minimize harms	Reduces morbidity and mortality in persons with highest burden of COVID-19 hospitalization and death	Reduces morbidity and mortality in persons with high burden of COVID-19 hospitalization and death	
Promote justice	-Will require focused outreach to those who experience barriers to access healthcare -Persons living in multi-generational households may have greater risk of exposure		
Mitigate Health inequities	- Racial and ethnic minority groups under-represented among adults <u>></u> 65 - Racial and ethnic minority persons <u>></u> 65 disproportionate COVID-19 related hospitalization and death rates		

Essential	MOR	LOKE
ESSEIILIGI	VVUI	VEI 2

Ethical Principle	Frontline essential workers (~30 M)	/ Other essential workers (~57M)	
Maximize benefits and minimize harms	-Essential Workers are at high risk of exposure. Prevention of disease will reduce transmission -Preserves services essential to the COVID-19 response and overall functioning of society. "Multiplier effect"		
Promote justice	-Workers unable to work from home -High level of interaction with public or others in the workplace -May be unable to control social distancing	-Frequently interact with others in the workplace	
Mitigate Health inequities	-Racial and ethnic minority groups disproportionately represented in many essential industries -~1/4 of essential workers live in low-income families		

Ethical Principle	Persons 16-64 with high-risk medical conditions (>110 Million)	
Maximize benefits and minimize harms	Reduces morbidity and mortality in persons with moderate to high burden of COVID-19 associated hospitalization and death	
Promote justice	Will require focused outreach to those with limited or no access to healthcare	
Mitigate Health inequities	-Increased prevalence of some medical conditions in race/ethnic minority groups & persons in rural areas -Diagnosis of medical conditions requires access to healthcare	

Summary of Work Group Considerations



Summary: Work Group considerations

- Scientific, implementation and ethical considerations support inclusion of groups in Phase 1b and
 1c as a balance of prevention of morbidity and mortality and preservation of societal functions
- This represents an interim Phase 1 sequence— allocation policy will need to be dynamic and adapt
 as new information such as vaccine performance and supply and demand become clear
- Gating criteria will be necessary to move expeditiously from one Phase to the next, if supply exceeds demand
- Following vaccination, measures to stop the possible spread of SARS-CoV-2, such as masks and social distancing, will still be needed
- The U.S. government is committed to making COVID-19 vaccines available to all residents, as soon as possible

Proposed Phase 1 & 2 allocation, December 2020

Phase	Groups recommended for vaccination	Number of persons in each group (millions)	Number of unique* persons in each group (millions)	Total* (millions)
1a	Health care personnel Long-term care facility residents	21 3	21 3	24
1b	Frontline essential workers Persons aged 75 years and older	30 21	30 19	49
1c	Persons aged 6574 years Persons aged 1664 years with high-risk conditions Essential workers not recommended in Phase 1b	32 110 57	28 81 20	129
2	All people aged 16 years and older not in Phase 1, who are recommended for vaccination			

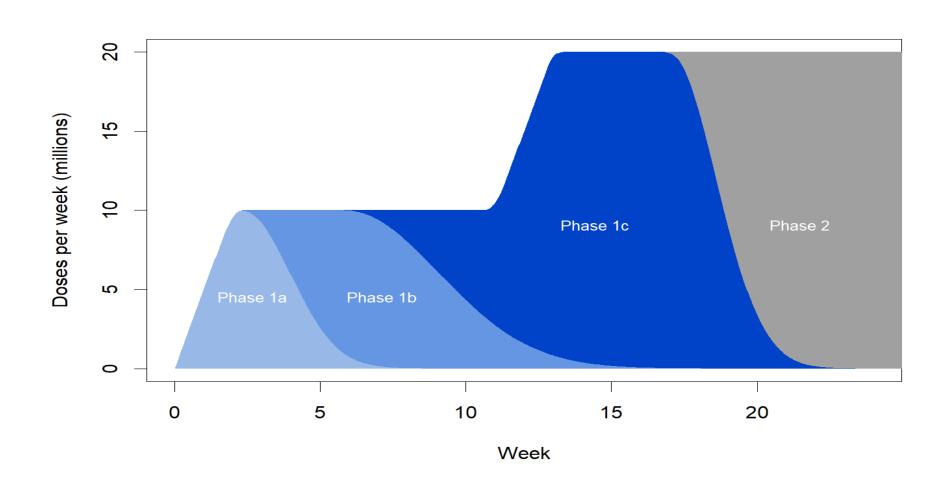
^{*}Accounts for persons recommended in prior phases or overlap within a phase

Proposed Phase 1 & 2 allocation, December 2020

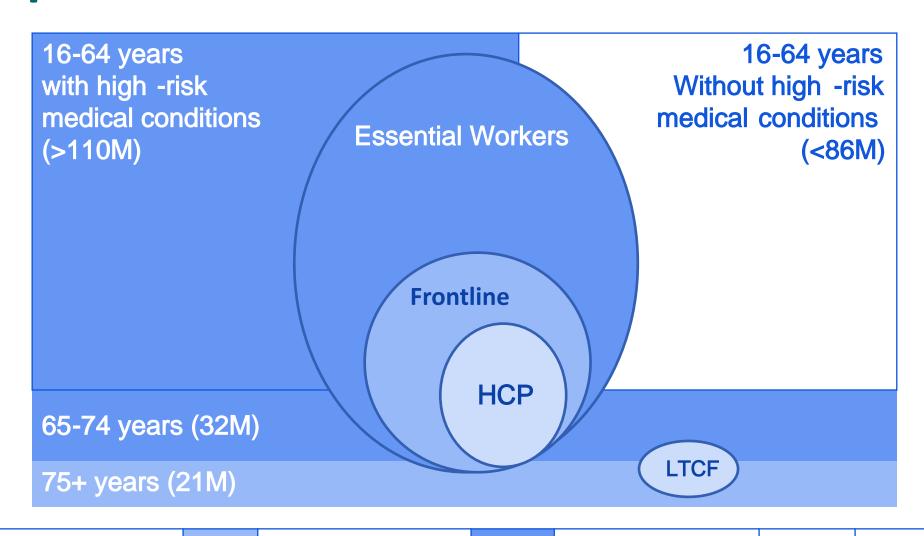
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2	All people aged 16 years and older not in Phase 1, who are recommended for vaccination			

^{*}Accounts for persons recommended in prior phases or overlap within a phase

Example of Phase 1 & Phase 2 COVID-19 vaccination roll-out



Proposed Phases of COVID-19 Vaccination



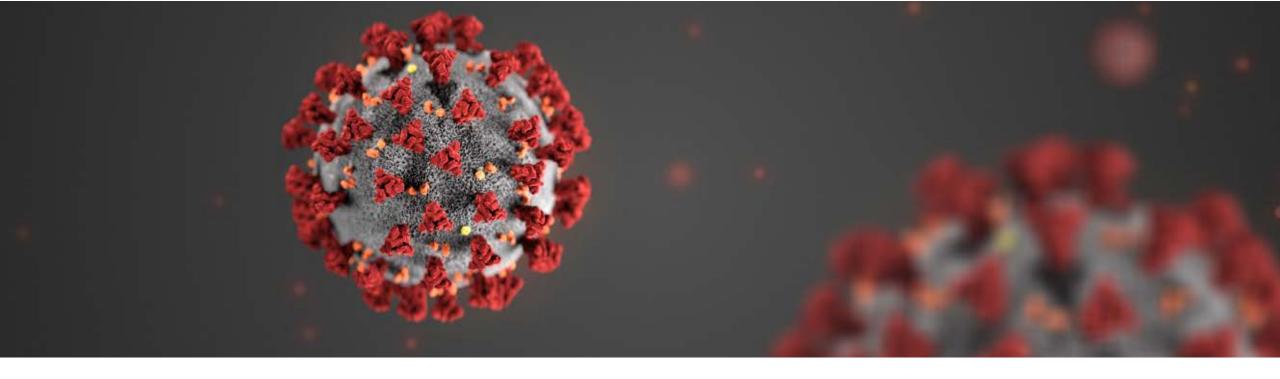
Phase 1a Phase 1b Phase 1c Phase 2

ACIP Vote – Interim Recommendation

As an update to ACIP recommendations for vaccination in Phase 1a (health care personnel, and long-term care facility residents), if COVID-19 vaccine supply is limited, the following groups should be offered vaccination:

Phase 1b: persons aged ≥75 years and frontline essential workers

Phase 1c: persons aged 65–74 years, persons aged 16–64 years with high-risk medical conditions, and other essential workers



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.

