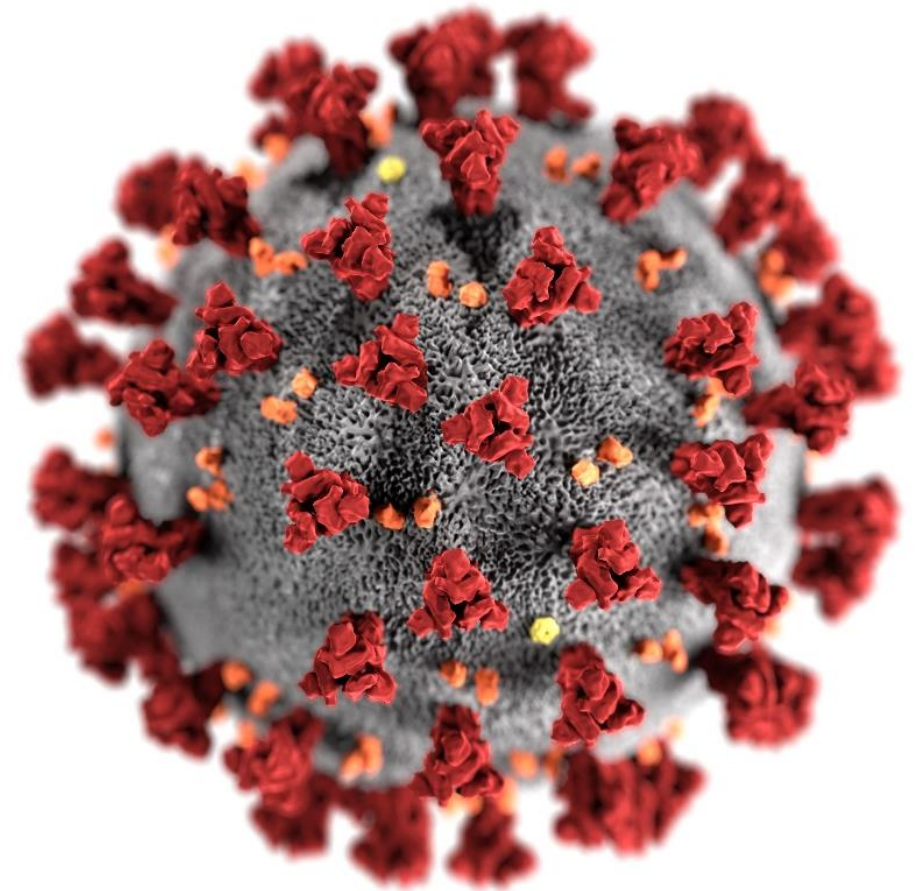
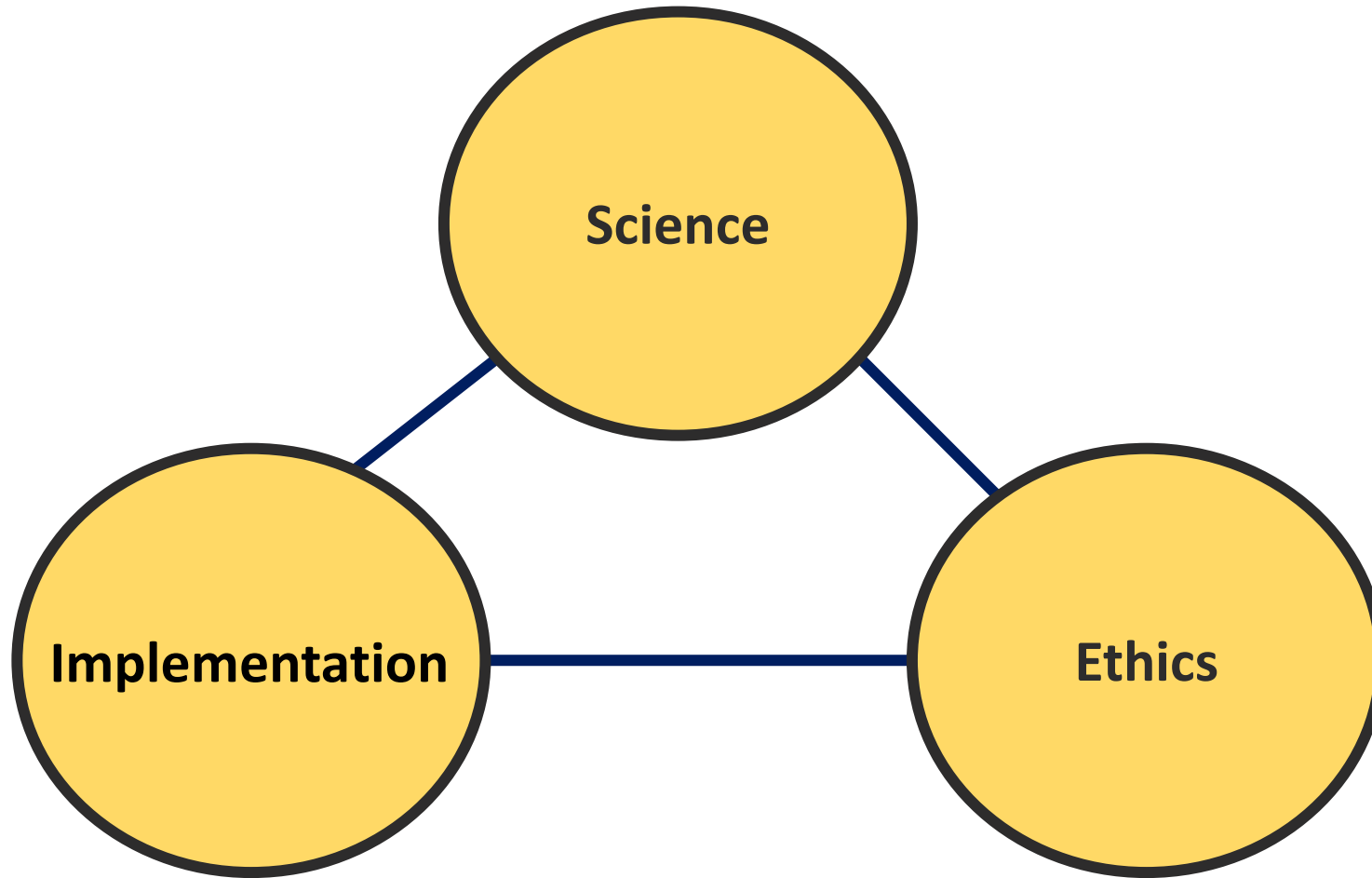


## Ethical Principles for Phased Allocation of COVID-19 Vaccines

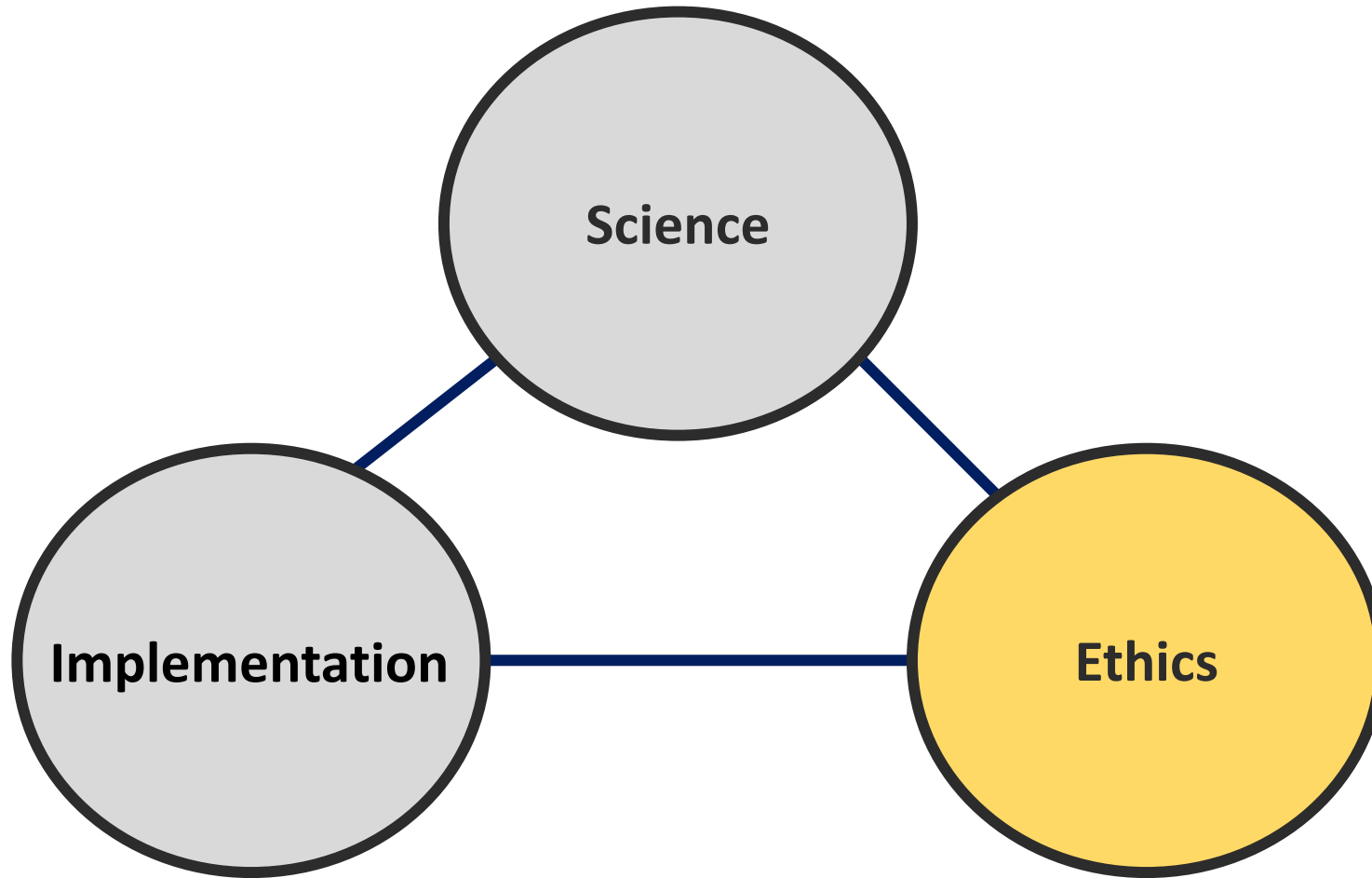
Mary E Chamberland, MD, MPH  
ACIP Meeting  
October 30, 2020



# Allocation of COVID-19 vaccine



# Allocation of COVID-19 vaccine



**Purpose:** Assist ACIP in the identification of groups for early allocation of COVID-19 vaccine in the setting of a constrained supply

# Ethical principles and potential groups for early phase COVID-19 vaccine allocation

- Endorsed five interim ethical principles (Sept ACIP meeting)
  - Maximizing benefits and minimizing harms, equity, justice, fairness, and transparency
- Explored possible groups for Phase 1 vaccination (July – Sept ACIP meetings)
  - Phase 1a: Healthcare personnel (HCP)
  - Phase 1b: Essential workers (non-HCP), persons with high-risk underlying medical conditions, adults aged  $\geq 65$  years

# Ethical principles: progression of work

- Reviewed COVID-19 vaccine allocation frameworks including Johns Hopkins University, National Academies, WHO
- Reviewed ethical literature
- Consulted with experts in health equity, ethics, and GRADE
- Updated interim ethical principles to guide phased allocation
- Drafted manuscript on ethical principles
  - Key questions to guide allocation planning
- Incorporation of a health equity domain into EtR Framework

# ACIP ethical principles for phased allocation of COVID-19 vaccines

- ACIP ethical principles
  - Maximize benefits and minimize harms
  - Promote justice
  - Mitigate health inequities
  - Promote transparency
- Updates to interim version
  - Fold fairness into justice
  - Style as action phrases

# From principles to practice

- A series of **Key Questions** developed to facilitate “translation” of the ethical principles
- Assist ACIP in developing its national recommendations for early phase COVID-19 vaccine allocation
- Serve as a tool for state, tribal, local, and territorial (STLT) health authorities as they develop vaccination implementation plans
- Although ethical principles fundamental for stewardship of a limited supply of vaccine, also applicable when COVID-19 vaccines are more widely available

# NEW: Key questions for COVID-19 vaccine allocation planning stratified by ethical principles

<b>Maximize benefits and minimize harms</b>	<p>Does the allocation plan address:</p> <ul style="list-style-type: none"><li>• What populations are at highest risk of infection, hospitalization, and death from COVID-19?</li><li>• What populations are essential to the COVID-19 response?</li><li>• What populations are essential to maintaining critical functions of society?</li><li>• What are the key characteristics of these populations, e.g., size or geographic distribution, that may inform the magnitude of benefit based on the amount of vaccine available or its characteristics?</li></ul>
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# NEW: Key questions for COVID-19 vaccine allocation planning stratified by ethical principles

<b>Promote justice</b>	<ul style="list-style-type: none"><li>• Does allocation planning include input from groups who are disproportionately affected by COVID-19 or economically/socially marginalized?</li><li>• Does the allocation plan result in fair and equitable access of the vaccine for all people?</li><li>• Does the plan identify and address barriers to vaccination among groups who are disproportionately affected by COVID-19 or economically/socially marginalized?</li><li>• How do characteristics of the vaccine and logistical considerations impact equitable access for all people?</li></ul>
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# NEW: Key questions for COVID-19 vaccine allocation planning stratified by ethical principles

<b>Mitigate health inequities</b>	<ul style="list-style-type: none"><li>• Does the plan identify and address any population groups who are disproportionately affected by COVID-19?</li><li>• Does the allocation plan contribute to a reduction in health disparities in COVID-19 disease and death?</li><li>• What health inequities may inadvertently result from the allocation plan, and what interventions could remove or reduce them?</li></ul>
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# NEW: Key questions for COVID-19 vaccine allocation planning stratified by ethical principles

## **Promote transparency**

- How does the development of the allocation plan include diverse input, and if possible, public engagement?
- Is the allocation plan and evidence-based method publicly available?
- Is the allocation plan clear about the knowns, unknowns, and certainty of evidence?
- What is the process for revision of allocation plans based on new information?

# Application of ethical principles



# Principle of transparency

- Applied across entirety of the allocation decision-making process
  - Essential for building public trust and confidence
  - Being clear about the level of certainty in available evidence
- Methods and data used for ACIP recommendations are publicly available
- Public participation
  - ACIP meetings open to public and available on-line
  - Comments to Federal Register and/or during ACIP meetings
  - Engagement with stakeholders/partners

# Updated application of ethical principles to potential early vaccine allocation groups

Group	Maximize benefits	Promote justice	Mitigate health inequities
<p><b>Healthcare personnel</b> (~21M)</p> <p>Paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials<sup>a</sup></p>	<p>Preserves healthcare capacity essential to the COVID-19 response</p> <p>“Multiplier effect”<sup>b</sup></p>	<p>Addresses elevated occupational risk of SARS-CoV-2 exposure for those unable to work from home</p> <p>Promotes access to vaccine across a spectrum of HCP job types and settings</p>	<p>Racial and ethnic minority groups are disproportionately represented in low-wage HCP, such as nursing aides and home-health aides, health services, or those working in long-term care<sup>c</sup></p>
<p><b>Transparency</b></p>			

<sup>a</sup> Essential workers during the COVID-19 response have been defined by U.S. Department of Homeland Security, Cybersecurity and Infrastructure Security Agency: [https://www.cisa.gov/sites/default/files/publications/Version\\_4.0\\_CISA\\_Guidance\\_on\\_Essential\\_Critical\\_Infrastructure\\_Workers\\_FINAL%20AUG%2018v2\\_0.pdf](https://www.cisa.gov/sites/default/files/publications/Version_4.0_CISA_Guidance_on_Essential_Critical_Infrastructure_Workers_FINAL%20AUG%2018v2_0.pdf).

<sup>b</sup> Defined as those whose ability to stay healthy helps to protect the health of others and/or to minimize disruption to society and the economy.

<sup>c</sup> HRSA estimates from American Community Survey 2011-2015

# Updated application of ethical principles to potential early vaccine allocation groups

Group	Maximize benefits	Promote justice	Mitigate health inequities
<p><b>Other essential workers (~87M)</b></p> <p>Person who conduct operations vital for continuing critical infrastructure, such as food, agriculture, transportation, education, and law enforcement<sup>a</sup></p>	<p>Preserves services essential to the COVID-19 response and overall functioning of society</p> <p>“Multiplier effect”<sup>b</sup></p>	<p>Addresses elevated occupational risk of SARS-CoV-2 exposure for those unable to work from home</p> <p>Promotes access to vaccine and reduces barriers to vaccination in occupations with low vaccine uptake<sup>c</sup></p>	<p>Racial and ethnic minority groups are disproportionately represented in many essential industries<sup>d</sup></p> <p>Almost one-quarter of essential workers live in low-income families<sup>e</sup></p>
<h2>Transparency</h2>			

<sup>a</sup> Essential workers during the COVID-19 response have been defined by U.S. Department of Homeland Security, Cybersecurity and Infrastructure Security Agency: [https://www.cisa.gov/sites/default/files/publications/Version\\_4.0\\_CISA\\_Guidance\\_on\\_Essential\\_Critical\\_Infrastructure\\_Workers\\_FINAL%20AUG%2018v2\\_0.pdf](https://www.cisa.gov/sites/default/files/publications/Version_4.0_CISA_Guidance_on_Essential_Critical_Infrastructure_Workers_FINAL%20AUG%2018v2_0.pdf).

<sup>b</sup> Defined as those whose ability to stay healthy helps to protect the health of others and/or to minimize disruption to society and the economy.

<sup>c</sup> Influenza vaccination coverage is low among many non-healthcare essential workers; lowest among construction workers (10.7%): <https://www.cdc.gov/niosh/docs/2012-161/pdfs/2012-161.pdf?id=10.26616/NIOSH-PUB2012161>.

<sup>d</sup> Among 742 food and agriculture workplaces in 30 states, 73% of workers were Hispanic or Latino and 83% of COVID-19 cases occurred in racial or ethnic minority workers: [https://wwwnc.cdc.gov/eid/article/27/1/20-3821\\_article](https://wwwnc.cdc.gov/eid/article/27/1/20-3821_article).

<sup>e</sup> American Community Survey, 2011-2015: <https://cepr.net/a-basic-demographic-profile-of-workers-in-frontline-industries>.

# Updated application of ethical principles to potential early vaccine allocation groups

Group	Maximize benefits	Promote justice	Mitigate health inequities
<p><b>Adults with high-risk medical conditions</b></p> <p>(&gt;100M)</p> <p>Adults who have ≥1 high-risk medical condition, such as obesity, diabetes, and cardiovascular disease<sup>a</sup></p>	<p>Reduces morbidity and mortality in persons with high burden of COVID-19 disease<sup>b</sup></p>	<p>Will require focused outreach to vaccinate persons in this group who have no or limited access to healthcare</p>	<p>Increased prevalence of obesity and diabetes (most prevalent conditions in this group) among some racial/ethnic minority groups;<sup>c</sup> prevalence of some medical conditions higher for persons in rural areas<sup>d</sup></p> <p>Could <i>increase</i> health inequities because diagnosis of high-risk medical conditions requires access to healthcare</p>
<h2>Transparency</h2>			

<sup>a</sup> Medical conditions considered high-risk are updated routinely based on the best available scientific data: [https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fneed-extra-precautions%2Fgroups-at-higher-risk.html](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fneed-extra-precautions%2Fgroups-at-higher-risk.html).

<sup>b</sup> As of October 15, 2020, nearly 90% of persons with COVID-19 associated hospitalizations have at least one high-risk condition. Data is routinely updated through Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET): [https://gis.cdc.gov/grasp/COVIDNet/COVID19\\_5.html](https://gis.cdc.gov/grasp/COVIDNet/COVID19_5.html).

<sup>c</sup> National Center for Health Statistics, National Health Interview Survey, 2018. Estimates not available for Hawaiian/other Pacific Islanders or for chronic kidney disease among American Indian/Alaska Native.

<sup>d</sup> <https://www.cdc.gov/chronicdisease/resources/publications/factsheets/reach.htm>; <https://www.cdc.gov/mmwr/volumes/69/wr/mm6929a1.htm>



# Updated application of ethical principles to potential early vaccine allocation groups

Group	Maximize benefits	Promote justice	Mitigate health inequities
<p><b>Adults ≥65 years of age</b></p> <p>(~53M)</p> <p>Includes adults living at home and adults living in long-term care facilities (3 million)</p>	<p>Reduces morbidity and mortality in persons with high burden of COVID-19 disease<sup>a</sup></p>	<p>Will require focused outreach to vaccinate persons in this group who experience inequities in social determinants of health</p>	<p>Although racial and ethnic minority groups under-represented among adults ≥ 65 yrs. of age, they have increased rate of hospitalization for COVID-19 disease<sup>b</sup></p> <p>Strict age-based criterion could <i>increase</i> disparities due to racial and social inequities, such as occupation, income, access to healthcare</p>
<p><b>Transparency</b></p>			

<sup>a</sup> As of October 15, 2020, 80% of COVID-19 deaths were among adults aged ≥ 65 Years. Data is routinely updated through CDC case-based surveillance: <https://covid.cdc.gov/covid-data-tracker/#demographics>.

<sup>b</sup> As of October 15, 2020, for adults ≥65 years of age, compared to persons who were non-Hispanic White, persons who were non-Hispanic Black (rate ratio [RR] 3.6), Hispanic or Latino (RR 2.7), and non-Hispanic American Indian or Alaska Native (RR 2.4) had higher COVID-19 hospitalization rates. Data is routinely updated Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET): <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>.

# Application of ethical principles to early phase COVID-19 vaccine allocation groups

- Allocation of limited supply of vaccine is complicated by efforts to address multiple goals, most notably
  - Reduce morbidity and mortality
  - Minimize disruption to society, the economy, and healthcare capacity
- If the goals of a vaccination program are not clearly prioritized, difficult to draw distinctions between groups for early phase allocation
- Increasing consensus among allocation frameworks for early vaccination of HCP, suggesting maintenance of healthcare capacity as the highest priority
- If vaccine supply remains constrained, ethical principles can help guide identification of subsets of other groups for subsequent early phase allocation

## Next steps

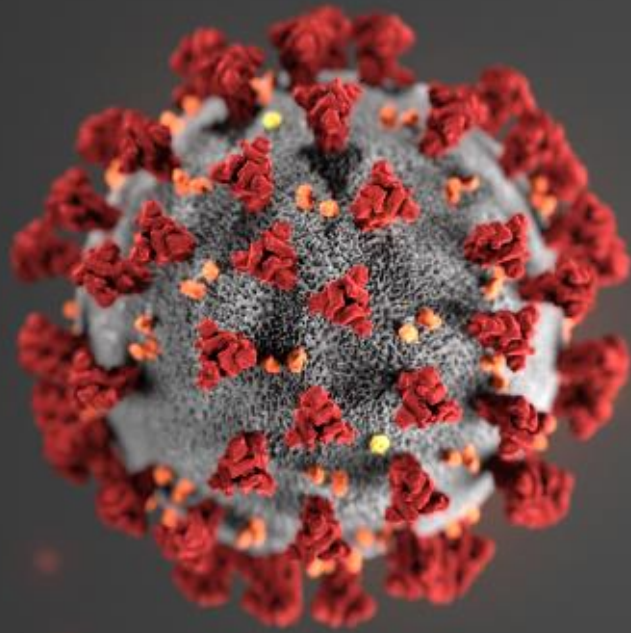
- Seek ACIP's views on updated ethical principles and key questions
- Publication of ACIP's ethical principles
- Further Work Group discussion about application of ethical principles to help inform Phase 1 allocation recommendations

# Discussion: Ethical Principles

- How could application of these principles and key questions be made more useful to STLT health authorities for COVID-19 vaccine allocation planning?

# Acknowledgements

- Nancy McClung
- Kathy Kinlaw
- Dayna Bowen Matthew
- Beth Bell
- VTF ACIP WG Team



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

