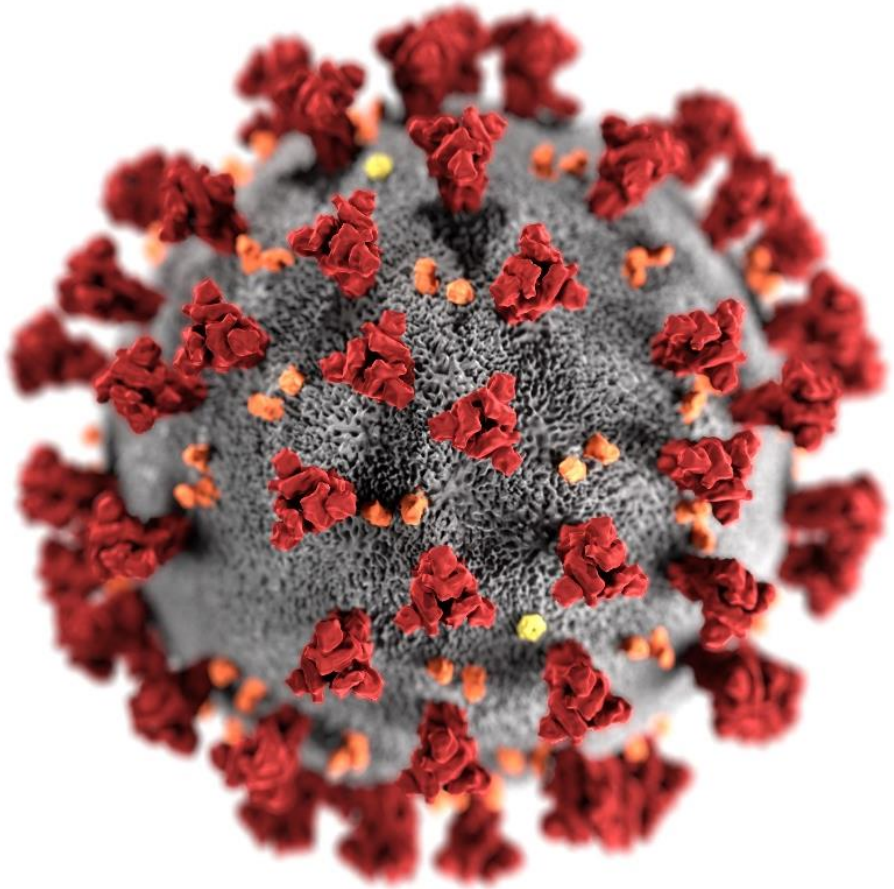
Ethical Principles for Phased Allocation of COVID-19 Vaccines



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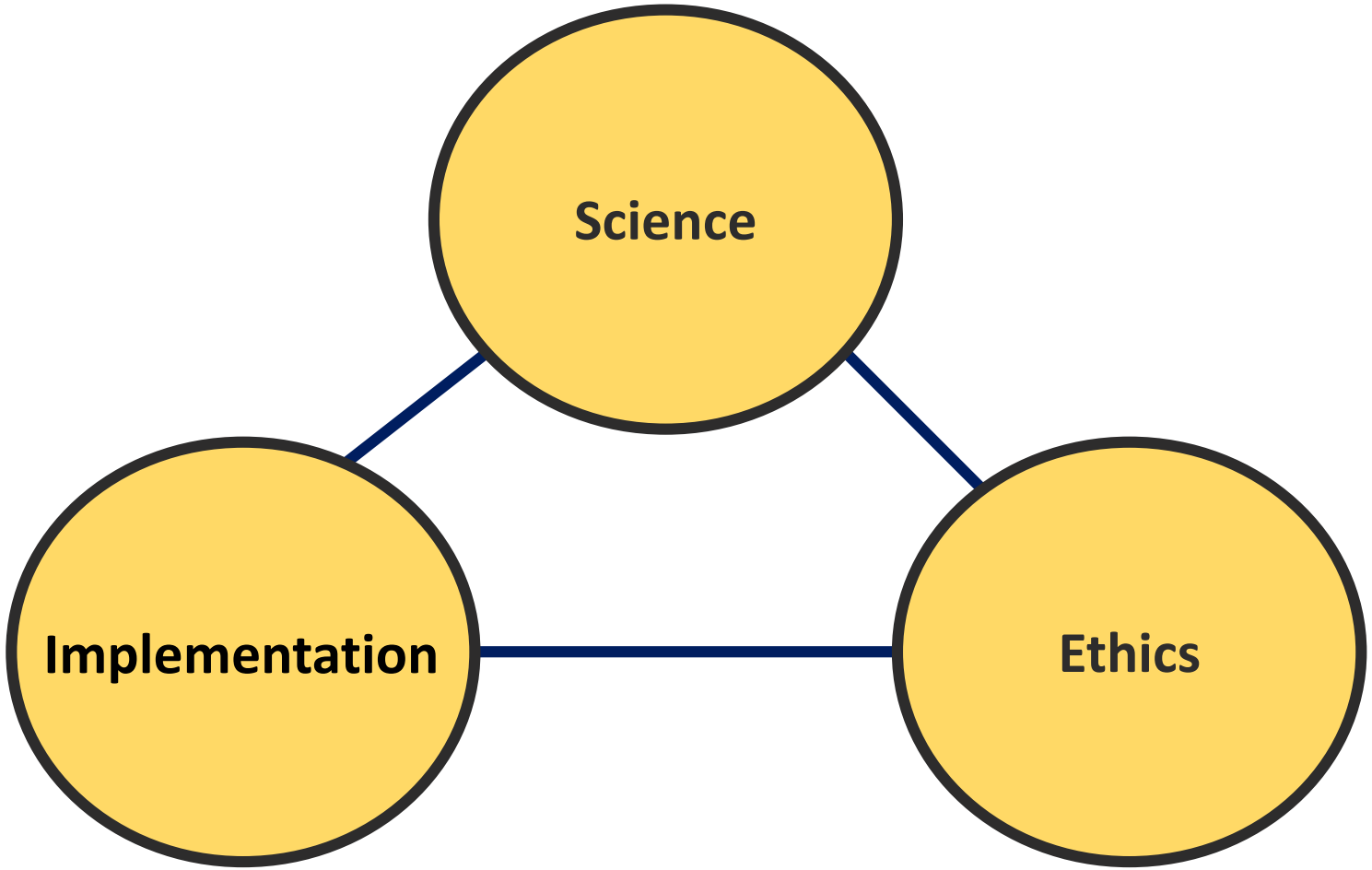
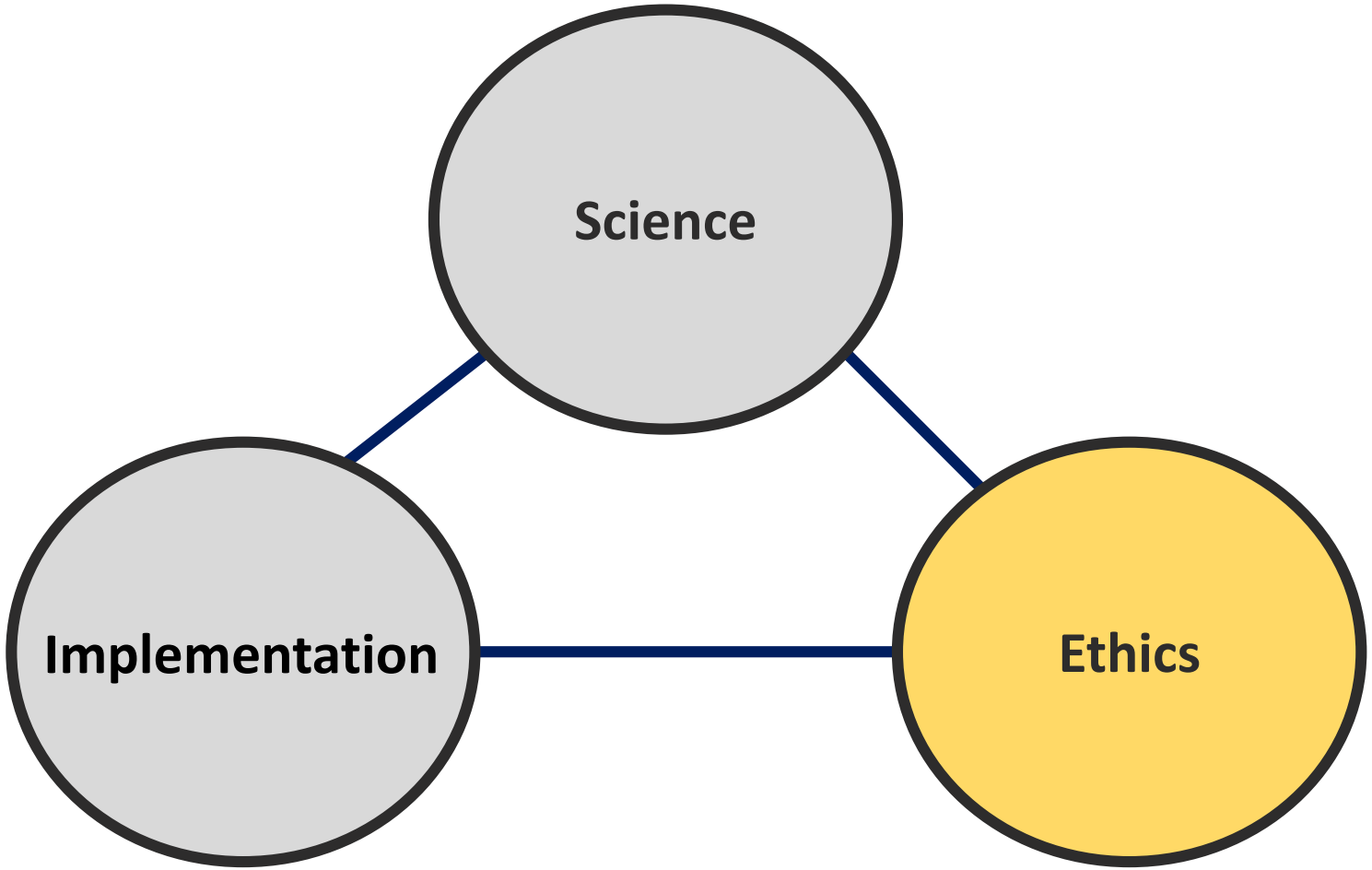
ACIP Meeting

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 ≥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

Maximize benefits and minimize harms	Does the allocation plan address: • What populations are at highest risk of infection, hospitalization, and death from COVID-19? • What populations are essential to the COVID-19 response? • What populations are essential to maintaining critical functions of society? • 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?

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

Promote justice	• Does allocation planning include input from groups who are disproportionately affected by COVID-19 or economically/socially marginalized? • Does the allocation plan result in fair and equitable access of the vaccine for all people? • Does the plan identify and address barriers to vaccination among groups who are disproportionately affected by COVID-19 or economically/socially marginalized? • How do characteristics of the vaccine and logistical considerations impact equitable access for all people?

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

Mitigate health inequities	• Does the plan identify and address any population groups who are disproportionately affected by COVID-19? • Does the allocation plan contribute to a reduction in health disparities in COVID-19 disease and death? • What health inequities may inadvertently result from the allocation plan, and what interventions could remove or reduce them?

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
Healthcare personnel (~21M) Paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials[a]	Preserves healthcare capacity essential to the COVID-19 response "Multiplier effect"[b]	Addresses elevated occupational risk of SARS-CoV-2 exposure for those unable to work from home Promotes access to vaccine across a spectrum of HCP job types and settings	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[c]
Transparency			

[a] 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.

[b] 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.

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

[a] 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.

[b] 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.

[c] 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/NIOSHPUB2012161.

[d] 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.

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

[a] 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.

[b] 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.

[c] 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.

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

[a] 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.
[b] 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?

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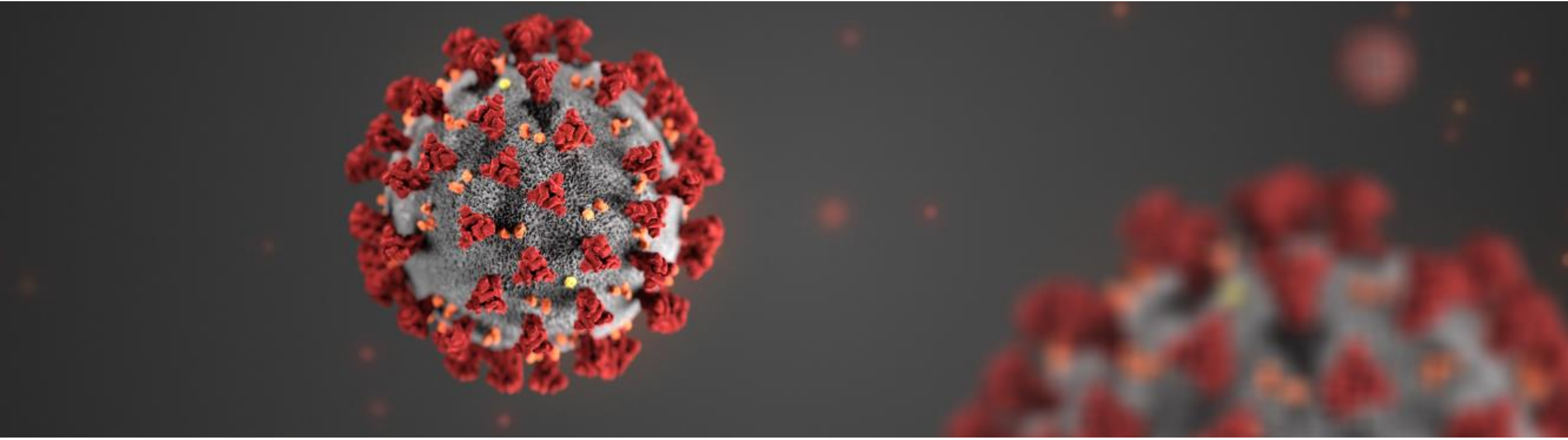

For more information, contact CDC
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TTY: 1-888-232-6348 www.cdc.gov

Thank you

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