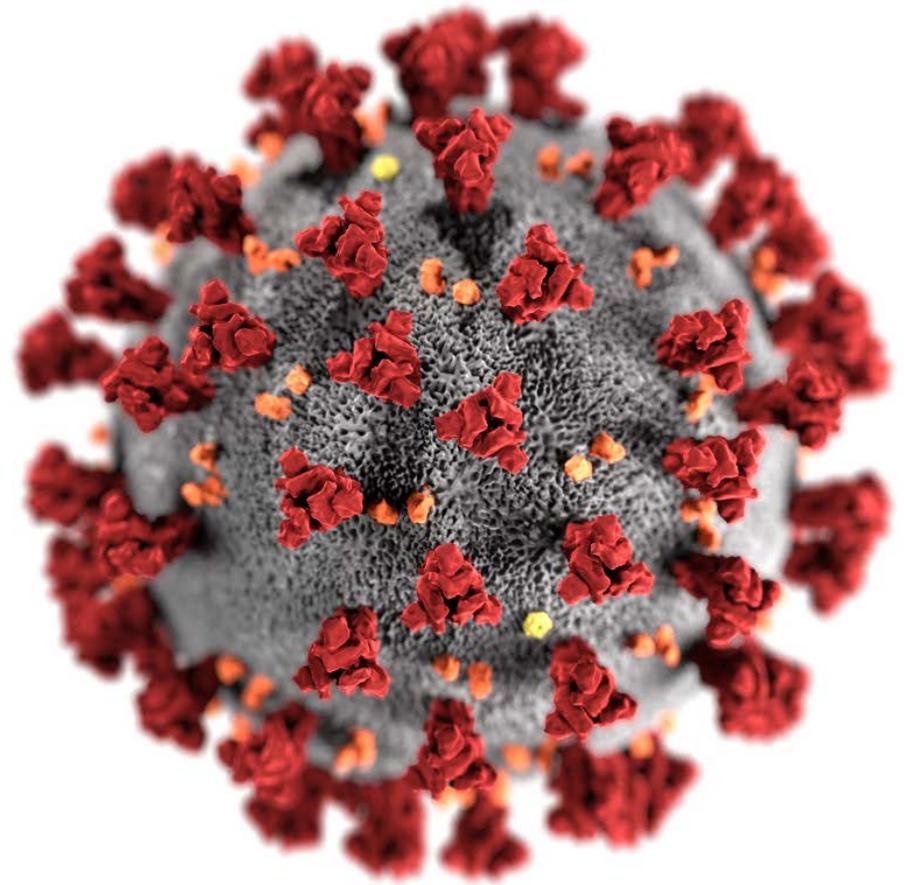


EtR Framework: Public Health Problem, Resource Use and Equity Domains



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ACIP Meeting
November 23, 2020



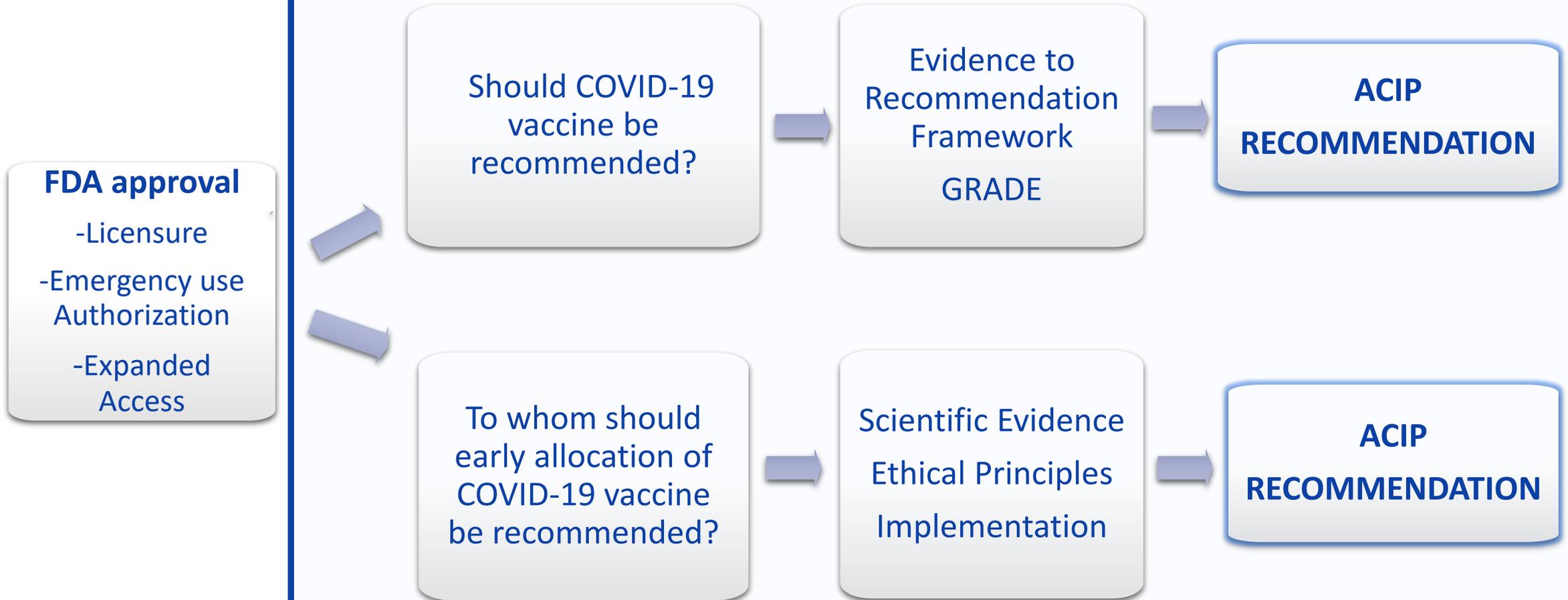
Evidence to Recommendations Framework



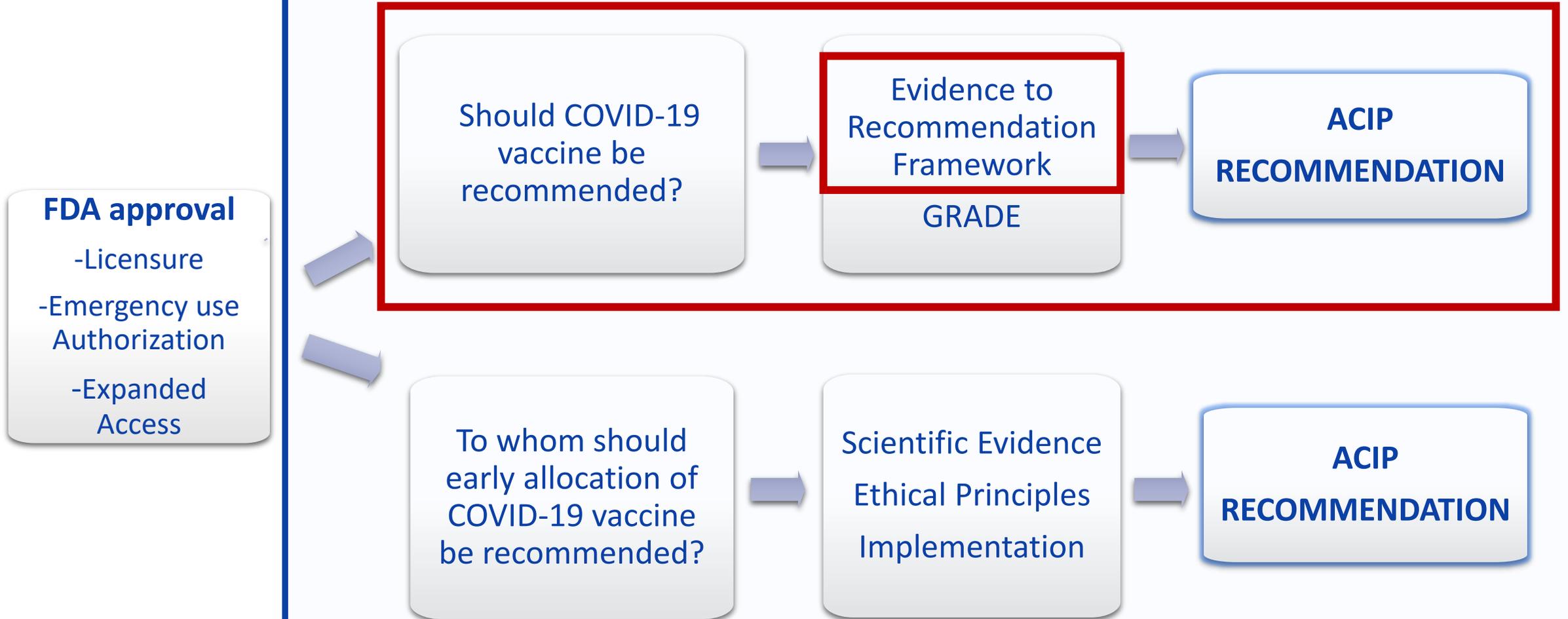
Evidence to Recommendations (EtR) Framework

- Structure to describe information considered in moving from **evidence** to ACIP vaccine **recommendations**
- Provide **transparency** around the impact of additional factors on deliberations when considering a recommendation

ACIP Pathway to Recommendation



ACIP Pathway to Recommendation



Evidence to Recommendations (EtR) Framework

EtR Domain	Question
Public Health Problem	<ul style="list-style-type: none">• Is the problem of public health importance?
Benefits and Harms	<ul style="list-style-type: none">• How substantial are the desirable anticipated effects?• How substantial are the undesirable anticipated effects?• Do the desirable effects outweigh the undesirable effects?
Values	<ul style="list-style-type: none">• Does the target population feel the desirable effects are large relative to the undesirable effects?• Is there important variability in how patients value the outcomes?
Acceptability	<ul style="list-style-type: none">• Is the intervention acceptable to key stakeholders?
Feasibility	<ul style="list-style-type: none">• Is the intervention feasible to implement?
Resource Use	<ul style="list-style-type: none">• Is the intervention a reasonable and efficient allocation of resources?
Equity	<ul style="list-style-type: none">• What would be the impact of the intervention on health equity?

Evidence to Recommendations (EtR) Framework

EtR Domain	Question
Public Health Problem	<ul style="list-style-type: none">• Is the problem of public health importance?
Benefits and Harms	<ul style="list-style-type: none">• How substantial are the desirable anticipated effects?• How substantial are the undesirable anticipated effects?• Do the desirable effects outweigh the undesirable effects?
Values	<ul style="list-style-type: none">• Does the target population feel the desirable effects are large relative to the undesirable effects?• Is there important variability in how patients value the outcomes?
Acceptability	<ul style="list-style-type: none">• Is the intervention acceptable to key stakeholders?
Feasibility	<ul style="list-style-type: none">• Is the intervention feasible to implement?
Resource Use	<ul style="list-style-type: none">• Is the intervention a reasonable and efficient allocation of resources?
Equity	<ul style="list-style-type: none">• What would be the impact of the intervention on health equity?

“The vaccine” or “The intervention” = COVID-19 vaccine ‘X’
“The problem” = COVID-19 disease

Evidence to Recommendations (EtR) Framework

EtR Domain	
Public Health Problem	
Benefits and Harms	Await Phase III clinical trial data
Values	
Acceptability	
Feasibility	
Resource Use	
Equity	

Evidence to Recommendations (EtR) Framework

EtR Domain	
Public Health Problem	
Benefits and Harms	
Values	
Acceptability	
Feasibility	
Resource Use	
Equity	New addition to EtR Framework

Evidence to Recommendations (EtR) Framework

EtR Domain	
Public Health Problem	Not impacted by individual vaccine characteristics
Benefits and Harms	
Values	
Acceptability	
Feasibility	
Resource Use	Minimal impact currently by individual vaccine characteristics
Equity	New addition to EtR Framework Impacted by individual vaccine characteristics

Evidence to Recommendations (EtR) Framework

EtR Domain	
Public Health Problem	
Benefits and Harms	
Values	Impacted by individual vaccine characteristics
Acceptability	Impacted by individual vaccine characteristics
Feasibility	Impacted by individual vaccine characteristics
Resource Use	
Equity	

Evidence to Recommendations (EtR) Framework

- Presentations today will focus on current evidence and Work Group discussions around each EtR Domain for future COVID-19 vaccines
 - Areas where EtR Domain judgment may vary by individual vaccine characteristics will be identified
- No vote today: Once Phase III clinical trial data and an FDA decision are available, EtR framework for **specific** vaccine will be presented
- It is expected that information will continue to evolve: EtR Framework and Recommendations continually evaluated, updated as needed

EtR Domain: Public Health Problem



Public Health Problem

Is COVID-19 disease of public health importance?

- Are the consequences of COVID-19 serious?
- Is COVID-19 urgent?
- Are a large number of people affected by COVID-19?
- Are there populations disproportionately affected by COVID-19?

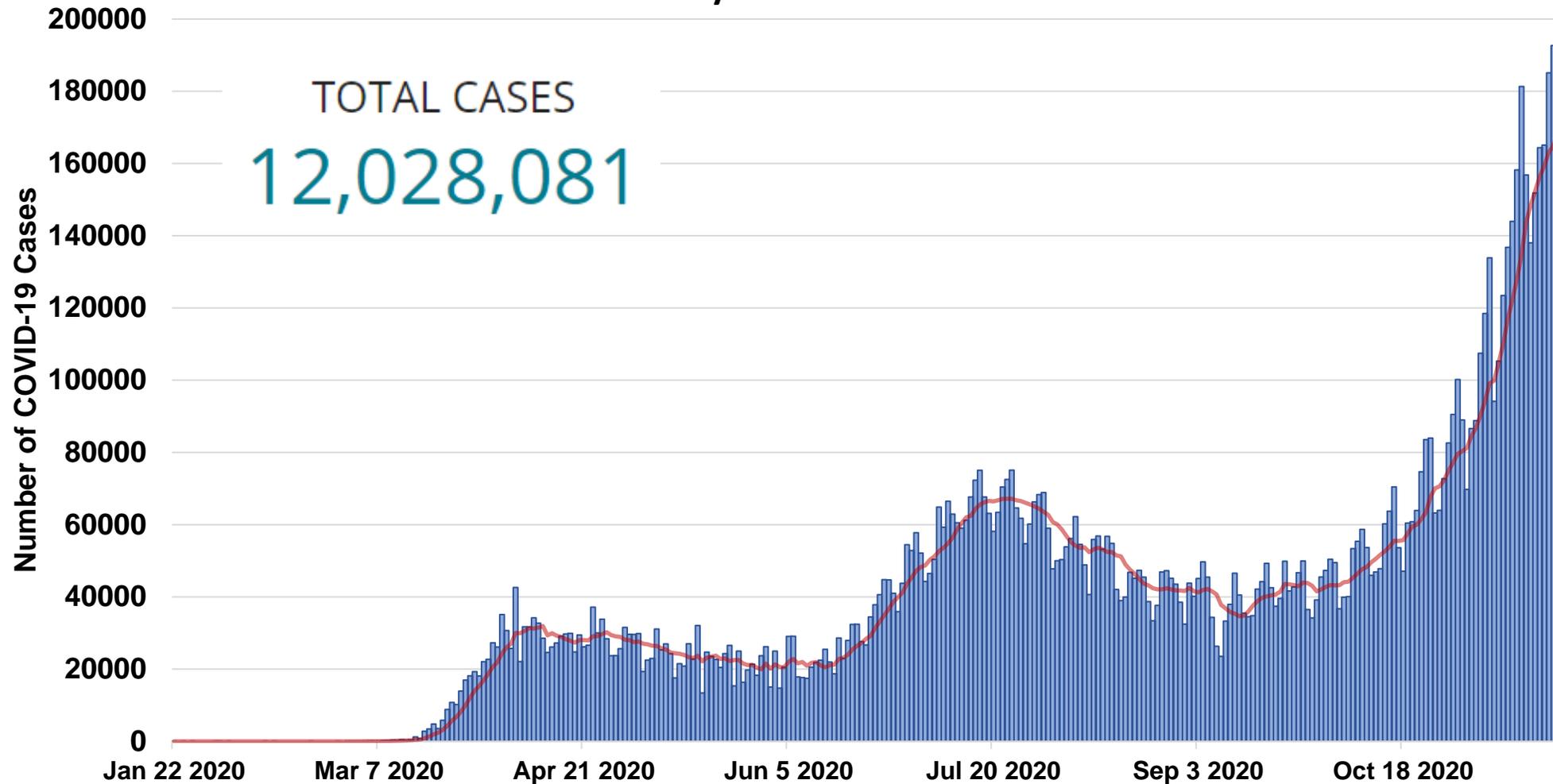
No Probably no Probably yes Yes Varies Don't know



Public Health Problem:

Review of the available evidence

January 21 – November 22



Public Health Problem:

Summary of the available evidence

■ Hospitalization

- Cumulative hospitalization rate between March 1 and November 14, 2020 was **228.7** per 100,000 population
- Among those hospitalized, **32%** required care in an intensive care unit and **15%** died

■ Mortality

- As of November 22, 2020, there were **255,076** COVID-19-associated deaths reported in the United States
- Estimates of the SARS-CoV-2 infection fatality ratio range from 0.5% to 1.4%

https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html .

https://gis.cdc.gov/grasp/COVIDNet/COVID19_5.html .

Hauser, A. et al. Estimation of SARS-CoV-2 mortality during the early stages of an epidemic: a modeling study in Hubei, China, and six regions in Europe. PLoS medicine, 17(7), p.e1003189

Yang, W. et al. Estimating the infection-fatality risk of SARS-CoV-2 in New York City during the spring 2020 pandemic wave: a model-based analysis. Lancet Infect Dis. 2020

DOI:[https://doi.org/10.1016/S1473-3099\(20\)30769-6](https://doi.org/10.1016/S1473-3099(20)30769-6)

Public Health Problem:

Work Group Interpretation

Is COVID-19 disease of public health importance?

- No Probably no Probably yes Yes Varies Don't know



EtR Domain: Resource Use



Resource Use

Is COVID-19 vaccine 'X' a reasonable and efficient allocation of resources?

- What is the cost-effectiveness of COVID-19 vaccine 'X'?
- How does the cost-effectiveness of COVID-19 vaccine 'X' change in response to changes in context, assumptions, etc?

No Probably no Probably yes Yes Varies Don't know



Resource Use:

Review of the available evidence

- Work Group reviewed estimates of economic costs related to COVID-19 vaccinations, disease outcomes and disease mitigation activities

Resource Use:

Summary of the available evidence

Costs associated with COVID-19 disease

- If 20% of the U.S. population is infected with COVID-19, the direct medical costs could be **\$163 billion**¹
- Health-related costs (including premature deaths, long-term health impairment and mental health impairment) have been estimated at **\$8.5 trillion**²

1. Bartsch et al. 2020. Health Affairs “The Potential Health Care Costs And Resource Use Associated With COVID-19 In The United States”.

2. Cutler and Summers. 2020. JAMA. “The COVID-19 pandemic and the \$16 trillion virus.”

Resource Use:

Summary of the available evidence

Costs associated with COVID-19 disease

- If 20% of the U.S. population is infected with COVID-19, the direct medical costs could be **\$163 billion**
- Health-related costs (including premature deaths, long-term health impairment and mental health impairment) have been estimated at **\$8.5 trillion**

Costs associated with COVID-19 vaccines

- U.S. Government has committed **\$10 billion** to Operation Warp Speed for the provision of vaccines¹
- Vaccine doses purchased with U.S. taxpayer dollars will be given to the American people at **no cost**²

1. <https://www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html>

2. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>

Resource Use:

Work Group Interpretation

- No published cost-effectiveness analyses currently available
- Precise cost-effectiveness analysis and economic impact of vaccination depend on number of factors that are currently unknown:
 - Duration of vaccine protection
 - Vaccination coverage levels
 - Implementation costs associated with large vaccination program
- The Work Group concluded that cost-effectiveness may not be a primary driver for decision-making during a pandemic and for vaccine used under EUA
 - Will need to be reassessed for future recommendations

Resource Use:

Work Group Interpretation

Is COVID-19 vaccine 'X' a reasonable and efficient allocation of resources?

- No Probably no Probably yes Yes Varies Don't know



EtR Domain: Equity



Equity

What would be the impact of COVID-19 vaccine 'X' on health equity?

- Are there groups or settings that might be disadvantaged in relation to COVID-19 disease burden or receipt of COVID-19 vaccine 'X'?
- Are there considerations that should be made when implementing the COVID-19 vaccine 'X' program to ensure that inequities are reduced whenever possible, and that they are not increased?

- Reduced
- Probably reduced
- Probably no impact
- Probably increased
- Increased
- Varies
- Don't know



Equity:

Review of the available evidence

- Identification of groups that might be disadvantaged in relation to COVID-19 disease burden or receipt of COVID-19 vaccine 'X'
 - PROGRESS-Plus¹: Place of residence, race or ethnicity, occupation, gender or sex, religion, education, socioeconomic status, social capital, disability, other
- Review of the scientific and gray literature
- Review of CDC COVID-19 response data and resources
 - CDC COVID Data Tracker & COVID-19-Associated Hospitalization Surveillance Network (COVID-NET)
 - National Center for Health Statistics
 - COVID-19 Disproportionately Affected Populations Team critical populations review

¹ PROGRESS-Plus is an acronym to identify factors associated with unfair differences in disease burden and the potential for interventions to reduce these differential effects. O'Neill J, et al. Applying an equity lens to interventions: using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. J Clin Epi. 2014;67: 56-64; Cochrane methods. Equity. <https://methods.cochrane.org/equity/projects/evidence-equity/progress-plus>

Equity:

Summary of the available evidence

■ People from racial and ethnic minority populations

- Represent 40% of U.S. population, but 50% of COVID-19 cases and 45% of COVID-19 deaths¹
- Age-adjusted COVID-19 hospitalization rates approximately **4** times higher among racial and ethnic minority groups, compared to non-Hispanic White persons²
- Inequities in social determinants of health put racial and ethnic minority groups at increased risk of COVID-19 disease, including discrimination, lack of healthcare access, overrepresentation among essential workers, low-income, and crowded housing³

■ People living in poverty or with high social vulnerability

- COVID-19 cumulative case rate per 100,000 population is **1.5** times higher in high versus low poverty counties and **1.3** times higher in counties with high versus low social vulnerability⁴

¹<https://www.cdc.gov/covid-data-tracker/index.html#demographics> , as of Nov 17, 2020

²<https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html> and COVID-NET Surveillance, as of Nov 13, 2020

³CDC Health Equity: <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html>

⁴<https://covid.cdc.gov/covid-data-tracker/> , as of Nov 17, 2020

Equity: summary of the available evidence

■ Essential workers

- Large COVID-19 outbreaks have been reported in multiple essential industries (food and agriculture, manufacturing, construction, wholesale trade)¹
- Racial and ethnic minority populations disproportionately represented in subsets of essential industries² and almost one quarter live in low-income families³

■ Persons from other disadvantaged groups

- Justice-involved: COVID-19 case rate for persons in federal/state correctional facilities **5.5** times higher than U.S. population⁴
- Homelessness: Shelters associated with rapid spread/outbreaks of SARS-CoV-2⁵
- Disabilities: COVID-19 case and mortality rates ~4 and ~8 times higher, respectively, for NY group home residents with intellectual/developmental disabilities compared to NY State residents⁶
- Substance use disorder (SUD): Analysis of e-health records found patients diagnosed with SUD in past year had 8-fold increased risk of COVID-19 diagnosis compared with non-SUD patients⁷
- Sexual and gender minorities: Face social or structural inequities that can lead to health disparities⁸

¹Bui DP, et al. MMWR 2020;69:1133–1138. DOI: [http://dx.doi.org/10.15585/mmwr.mm6933e3external icon](http://dx.doi.org/10.15585/mmwr.mm6933e3external%20icon).

²Waltenburg MA, et al. Emerg Infect Dis. 2021 Jan. <https://doi.org/10.3201/eid2701.203821>https://wwwnc.cdc.gov/eid/article/27/1/20-3821_article

³American Community Survey, 2011–2015: <https://cepr.net/a-basic-demographic-profile-of-workers-in-frontline-industries>

⁴Saloner B, et al. JAMA. 2020;324(6):602–603. doi:10.1001/jama.2020.12528

⁵Tobolowsky FA, et al. MMWR 2020;69:523–526. DOI: <http://dx.doi.org/10.15585/mmwr.mm6917e2>;

⁶Landes SD, et al. Disabil Health J 2020;13:1–5. <https://doi.org/10.1016/j.dhjo.2020.100969>

⁷Wang QQ, et al. Mol Psychiatry. 2020 Sep 14:1–10. doi: 10.1038/s41380-020-00880-7.

⁸<https://www.cdc.gov/lgbthealth/about.htm>

Equity:

Additional considerations

- Although COVID-19 vaccines will be provided at no cost, personal investments in time and travel to obtain vaccine may be a barrier for some groups
- Characteristics of specific vaccines (e.g. storage and handling requirements) have potential to impact equitable distribution of COVID-19 vaccines
 - The Work Group had **different** assessments for the impact on health equity for different vaccines

Equity:

Additional information questions

- Are there **considerations** that should be made when implementing the COVID-19 vaccine 'X' program to ensure inequities are reduced whenever possible, and that they are not increased?
 - Identify groups disproportionately affected by COVID-19 or who face health inequities
 - Undertake focused outreach and education
 - Identify and address barriers to vaccination
 - Conduct active follow-up of disadvantaged groups to ensure completion of a 2-dose series; consider one-dose COVID-19 vaccines for groups where follow-up may be difficult

Equity: Summary

- Successful implementation of the COVID-19 vaccination program and confidence in COVID-19 vaccines are **pivotal** to reducing health inequities

“...increasing the availability of an effective intervention within a country or region is not necessarily enough to reduce inequities. The intervention has to be accessible, acceptable, effective in, and used by the most disadvantaged groups within that population to be truly effective at reducing inequities in health”.¹

¹O'Neill J, Tabish H, Welch V, et al. Applying an equity lens to interventions: using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. J Clin Epidemiol. 2014; 67: 56-64.

Equity:

Work Group Interpretation

What would be the impact of COVID-19 vaccine 'X' on health equity?

- Reduced
- Probably reduced
- Probably no impact
- Probably increased
- Increased
- Varies
- Don't know



Summary



Summary:

EtR Domain	Question	Work Group Judgments
Public Health Problem	Is COVID-19 disease of public health importance?	Yes
Resource Use	Is COVID-19 vaccine 'X' a reasonable and efficient allocation of resources?	Yes
Equity	What would be the impact of COVID-19 vaccine 'X' on health equity?	Probably reduced/ Probably increased*

* Judgment differed by COVID-19 vaccine

Questions for ACIP:

- **Public Health Problem:**

- Does ACIP agree that COVID-19 disease is a public health problem?
- Any additional information that ACIP needs to see before a vote?

Questions for ACIP:

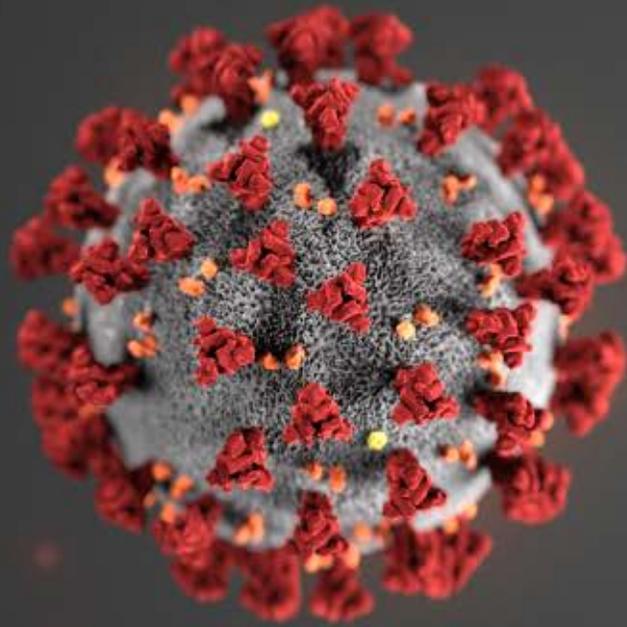
- **Resource Use:**

- Does ACIP agree that COVID-19 vaccines are a reasonable/efficient allocation of resources?
- Any additional information that ACIP needs to see before a vote?

Questions for ACIP:

- **Equity:**

- Does ACIP agree with the WG conclusions for the Equity domain (acknowledging the conclusions depend on the individual vaccine characteristics)?
- Any additional information that ACIP needs to see before a vote?



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.

