Distribution of COVID-19 Vaccine: Ethics of Allocating Scarce Vaccine & Other Ethical Issues

Anne Barnhill, Ph.D. November 1, 2020





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This lecture:

1. Ethics of allocating of scarce medical resources, a very brief introduction

- 2. Ethics of allocating scarce COVID-19 vaccine
 - Focus on allocation in the United States
- 3. Other ethical issues in COVID-19 vaccine distribution

Scarce medical resources could include:

- Vaccines
- Organs
- Beds in an Intensive Care Unit
- Ventilators
- Medicines
- Medical tests
- Blood
- Personal protective equipment, e.g. medical-grade masks

Example: Allocation of scarce COVID vaccine in the United States

Which groups should get scarce COVID-19 vaccine first, in the United States?

- Offer COVID vaccine first to those at highest risk of dying?
- Offer COVID vaccine first to Black and Latino people?
- Offer vaccine first to health care workers and certain other essential workers?
- Prioritize groups of people in whatever way best enables important social and economic activity?

Save the most lives

Advance social justice

Recognize and reward sacrifice

Enable important social & economic activity

Principles for allocation of scarce medical interventions

Govind Persad, Alan Wertheimer, Ezekiel J Emanuel

Allocation of very scarce medical interventions such as organs and vaccines is a persistent ethical challenge. We evaluate eight simple allocation principles that can be classified into four categories: treating people equally, favouring the worst-off, maximising total benefits, and promoting and rewarding social usefulness. No single principle is sufficient to incorporate all morally relevant considerations and therefore individual principles must be combined into multiprinciple allocation systems. We evaluate three systems: the United Network for Organ Sharing points systems, quality-adjusted life-years, and disability-adjusted life-years. We recommend an alternative system—the complete lives system—which prioritises younger people who have not yet lived a complete life, and also incorporates prognosis, save the most lives, lottery, and instrumental value principles.

Lancet 2009; 373: 423-31

Department of Bioethics, The Clinical Center, National Institutes of Health, Bethesda, Maryland, USA (G Persad BS, A Wertheimer PhD, E J Emanuel MD)

Ezekiel J Emanuel,

Department of Bioethics,

	Advantages	Disadvantages	Examples of use	Recommendation
Treating people eq	ually			
Lottery	Hard to corrupt; little information about recipients needed	Ignores other relevant principles	Military draft; schools; vaccination	Include
First-come, first-served	Protects existing doctor-patient relationships; little information about recipients needed	Favours wealthy, powerful, and well-connected; ignores other relevant principles	ICU beds; part of organ allocation	Exclude
Favouring the wors	st-off: prioritarianism			
Sickest first	Aids those who are suffering to "rule of rescue"; makes sen scarcity; proxy for being wors Persa	d et al. (2009) identify	four broad	ethical
Youngest first	Benefits those who have had planners have an interest in line with the planners have a planner have a			
Maximising total b	enefits: utilitarianism			
Number of lives saved	Saves more lives, benefiting number; avoids need for comparative judgments about quality or other aspects of lives		vaccine policy; bioterrorism response policy; disaster triage	
Prognosis or life-years saved	Maximises life-years produced	Ignores other relevant principles, particularly distributive principles	Penicillin allocation; traditional military triage (prognosis) and disaster triage (life-years saved)	Include
Promoting and rev	varding social usefulness			
Instrumental value	Helps promote other important values; future oriented	Vulnerable to abuse through choice of prioritised occupations or activities; can direct health resources away from health needs	Past and current NVAC/ACIP pandemic flu vaccine policy	Include but only in som public health emergencies
Reciprocity	Rewards those who implemented important values; past oriented	Vulnerable to abuse; can direct health resources away from health needs; intrusive assessment process	Some organ donation policies	Include only irreplaceal people who have suffered serious losses

Table 1: Simple principles and their core ethical values

	Advantages	Disadvantages	Examples of use	Recommendation		
Treating people equally						
Lottery	Hard to corrupt; little information about recipients needed	Ignores other relevant principles	Military draft; schools; vaccination	Include		
First-come, first-served	Protects existing doctor-patient relationships; little information about recipients needed	Favours wealthy, powerful, and well-connected; ignores other relevant principles	ICU beds; part of organ allocation	Exclude		
Favouring the wors	t-off: prioritarianism					
SICKEST IIISC	to "rule of rescue"; makes sense in temporary scarcity; proxy for being worst off overall	Surreptitious use of prognosis; ignores needs of those who will become sick in future; might falsely assume temporary scarcity; leads to people receiving interventions only after prognosis deteriorates; ignores other relevant principles	Emergency rooms; part of organ allocation	Exclude		
Youngest first	Benefits those who have had least life; prudent planners have an interest in living to old age	Undesirable priority to infants over adolescents and young adults; ignores other relevant principles	New NVAC/ACIP pandemic flu vaccine proposal	Include		
Maximising total b	enefits: utilitarianism					
saved	number; avoids need for comparative judgments about quality or other aspects of lives	Ignores other relevant principles	Past ACIP/NVAC pandemic flu vaccine policy; bioterrorism response policy; disaster triage	Include		
Prognosis or life-years saved	Maximises life-years produced	Ignores other relevant principles, particularly distributive principles	Penicillin allocation; traditional military triage (prognosis) and disaster triage (life-years saved)	Include		
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When we apply different allocation principles, we may reach different allocation decisions

First-come, first-served → give vaccine to those who show up first

Instrumental value \rightarrow *prioritize frontline healthcare workers and other essential workers*

Save the most lives \rightarrow prioritize those who are most likely to die from COVID-19 / those most likely to transmit the virus

When we're making an allocation scheme for a scarce medical resource, we should combine multiple allocation principles

"Although some [principles] are better than others, no single principle allocates interventions justly. Rather, morally relevant simple principles must be combined into multiprinciple allocation systems." (Persad et al. 2009, p.423)

Which allocation principles are appropriate, and how they should be balanced, may vary depending upon the scarce resource in question and the context

Example: Should people's "social usefulness" or instrumental value to society affect the allocation of scarce medical resources?

Allocation of scarce COVID vaccine: yes, we should prioritize health care workers and certain other essential workers because of their importance to COVID response

Allocation of scarce organs on an ongoing basis: no, we should not prioritize people seen as more "socially useful"

Ethics of allocating scarce COVID-19 vaccine in the United States

If there isn't enough vaccine available in the United States initially to offer vaccine to all who want it, who should be offered vaccine first?

Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States

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Center for Health Security

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- 1. Promote the common good
 - Promote public health
 - Prevent COVID-19-related illness and death
 - Prevent injury, illness, and death from other causes
 - Protect the health system
 - · Promote economic and social wellbeing
 - Protect (other) essential services
 - Enable economic activity more broadly
 - Enable children to return to school and childcare settings
- 2. Treat people fairly and promote equity
 - Address background and emerging inequities between groups
 - Reduce higher rates of severe COVID-19 illness and mortality being experienced by systematically disadvantaged social groups and marginalized populations
 - Address disproportionate economic and social impacts on some population groups, especially those that are marginalized or systematically disadvantaged
 - · Give priority to worst-off individuals
 - Protect those at highest risk of severe illness and death, especially those with the most years of life left to live
 - Reduce burdens on those individuals who are multiply burdened
 - Reciprocity
 - Protect those who face increased risk of COVID-19 disease in order to provide essential services for the benefit of others or advance the development of COVID-19 vaccines and therapeutics
- 3. Promote legitimacy, trust, and sense of ownership in a pluralistic society
 - Respect the diversity of views in a pluralistic society
 - Create allocation schemes with the input of a diverse set of experts and constituencies
 - Establish mechanisms for public engagement and input
 - Engage community members to improve vaccine program design and effectiveness
 - Develop and implement allocation schemes in a culturally competent way, including for improved communication and crisis leadership
 - Enable community ownership of decision making to strengthen desire to vaccinate and steward shared resources responsibly

We identified two broad ethical values that should guide vaccine allocation:

- Promote the common good
- Treat people fairly and promote equity

And a third ethical value to guide allocation decision-making & vaccine distribution:

 Promote legitimacy, trust, and sense of ownership in a pluralistic society

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Under each of the three broad **ethical values**, there are more specific **ethical principles**

We also identified more specific **policy goals** that follow from these values & principles

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Promote the common good (ethical value)

- Promote public health (ethical principle)
- Promote economic and social wellbeing (ethical principle)

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Two elements of our framework that are responsive to important features of the COVID-19 pandemic as it's playing out in the United States:

- Promoting the common good requires promoting public health and also promoting economic and social well-being
 - Protect essential services
 - Enable economic activity more broadly
 - Enable children to return to school & childcare

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Two elements of our framework that are responsive to important features of the COVID-19 pandemic as it's playing out in the United States:

2. Under the broad ethical value of treating people fairly and promoting equity, one important policy goal is reducing higher rates of COVID-19 related severe illness and mortality being experienced by systematically disadvantaged social groups (e.g. Black and Latino people)

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Similarities between our framework & Persad et al (2009) include:

- Both include a broad value about promoting or maximizing benefits: "maximizing total benefits" vs. "promote the common good"
- Both have principles concerned with treating people fairly and/or equally
- Both include a prioritarian principle (prioritize the worst off)
- Both include principles that support prioritizing important workers

How do we get from an ethics framework – with ethical values, principles and goals-- to actual groups of people who should be prioritized for COVID-19 vaccine?

Table 2. Linking Ethical Principles and Goals with Vaccine Objectives and Example Priority Groups

Ethical Principle	Policy Goal During COVID-19 Pandemic	Objective for COVID-19 Vaccine Allocation	Example Priority Groups for Vaccination
Promote public health	Prevent COVID-19-related illness and death	Protect those at greatest risk of poor outcome from infection	 Those older than 65 years of age Those with comorbid conditions (eg, hypertension, diabetes, cardiovascular disease, chronic kidney disease, immunosuppression, obesity, chronic obstructive pulmonary disease, pregnancy) Those in close contact with people at very high risk of poor outcomes (eg, nursing home and long-term care facility workers, home health aides, household contacts of those at very high risk of poor outcomes)
		Protect those at greatest risk of infection and further transmission	Health system workers in contact with COVID-19 patients (eg, nursing home and long-term care facility residents and workers; healthcare workers assigned to care for COVID-19 patients; frontline healthcare workers doing direct patient care; emergency medical services personnel)
			Workers in high public contact jobs (eg, grocery workers; transportation workers, including bus drivers, train conductors, flight attendants and Transportation Security Administration agents)
			 Workers in high density workplaces (eg, food-processing workers) People residing or working in high-density housing (eg, incarcerated individuals and prison workers, homeless residing in shelters, migrant workers in congregate housing) Others in contact with high numbers of other people
	Prevent injury, illness, and death from other causes (non-COVID-19)	Protect workers needed to maintain public safety	Emergency medical services personnelPublic health personnelPolice and fire personnel

Broad ethical values



Ethical **principles** falling under those values



Policy goals during the COVID-19 pandemic



Policy **objectives** for COVID-19 vaccine allocation



Priority **groups** for vaccination

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			People residing or working in high- density housing (eg, incarcerated individuals and prison workers, homeless residing in shelters, migrant workers in congregate housing)
			Others in contact with high numbers of other people
	Prevent injury, illness, and death from other causes	Protect workers needed to maintain	Emergency medical services personnel Public health personnel
	(non-COVID-19)	public safety	Police and fire personnel

Balance policy goals

Are there trade-offs between different policy goals?

 Trade-off between protecting those at greatest risk of poor outcomes from infection & protecting those at greatest risk of transmission to other?

If so, how should those two goals be balanced?

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		Protect those at greatest risk of infection and further transmission	Health system workers in contact with COVID-19 patients (eg, nursing home and long-term care facility residents and workers; healthcare workers assigned to care for COVID-19 patients; frontline healthcare workers doing direct patient care; emergency medical services personnel)
			Workers in high public contact jobs (eg, grocery workers; transportation workers, including bus drivers, train conductors, flight attendants and Transportation Security Administration agents)
			 (eg, food-processing workers) People residing or working in high-density housing (eg, incarcerated individuals and prison workers, homeless residing in shelters, migrant workers in congregate housing) Others in contact with high numbers of other people
	Prevent injury, illness, and death from other causes (non-COVID-19)	Protect workers needed to maintain public safety	 Emergency medical services personnel Public health personnel Police and fire personnel

Balance policy goals

In some cases, multiple policy goals or ethical principles will align behind a particular priority group Our report did not make firm recommendations about priority groups

Allocation decisions should emerge from a process of public deliberation

And may depend upon features of the vaccines that ultimately get approved & used first

Table 4. Provisional Examples of Tier 1 Groups (each supported by multiple ethical principles/policy goals)

Priority Groups	Examples				
Essential in	Frontline health workers providing care for COVID-19 patients				
sustaining the	Frontline emergency medical services personnel				
ongoing COVID-19 response	Pandemic vaccine manufacturing and supply chain personnel				
	COVID-19 diagnostic and immunization teams				
	• Public health workers carrying out critical, frontline interventions in the community				
Greatest risk of severe illness and death, and	Adults aged 65 years and older and those living with them or otherwise providing care to them				
their caregivers	• Other individuals and groups at elevated risk of serious COVID-19 disease, including people with health conditions that put them at significant increased risk of serious COVID-19 disease, potentially including those who are pregnant (as evidence warrants) or are members of social groups experiencing disproportionately high fatality rates.				
	Frontline long-term care providers				
	Healthcare workers providing direct care to patients with high-risk conditions				
	Other groups yet to be identified who are shown to be at significant risk of severe illness and death				
Most essential to	Frontline public transportation workers				
maintaining core	Food supply workers				
societal functions	Teachers and school workers (pre-kindergarten through 12th grade)				

What is the basis for choosing these priority groups?

Primary reason: Prioritizing these groups would prevent harm and promote the common good, specifically by:

- preventing COVID-19related illness and death
- protecting the health system
- protecting essential services

Table 4. Provisional Examples of Tier 1 Groups (each supported by multiple ethical principles/policy goals)

Priority Groups	Examples				
Essential in	Frontline health workers providing care for COVID-19 patients				
sustaining the	Frontline emergency medical services personnel				
ongoing COVID-19 response	Pandemic vaccine manufacturing and supply chain personnel				
	COVID-19 diagnostic and immunization teams				
	• Public health workers carrying out critical, frontline interventions in the community				
Greatest risk of severe illness and death, and	Adults aged 65 years and older and those living with them or otherwise providing care to them				
their caregivers	• Other individuals and groups at elevated risk of serious COVID-19 disease, including people with health conditions that put them at significant increased risk of serious COVID-19 disease, potentially including those who are pregnant (as evidence warrants) or are members of social groups experiencing disproportionately high fatality rates.				
	Frontline long-term care providers				
	Healthcare workers providing direct care to patients with high-risk conditions				
	Other groups yet to be identified who are shown to be at significant risk of severe illness and death				
Most essential to	Frontline public transportation workers				
maintaining core	Food supply workers				
societal functions	Teachers and school workers (pre-kindergarten through 12th grade)				

What is the basis for choosing these priority groups?

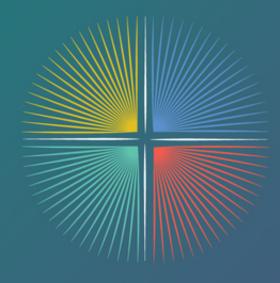
But also: Prioritizing some of these groups advances other goals and values

- Prioritizing frontline workers
 - shows reciprocity
 - may help to address higher
 COVID burden among
 Black and Latino people,
 given overrepresentation
 among essential workers

The National Academies of SCIENCES • ENGINEERING • MEDICINE

CONSENSUS STUDY REPORT

EQUITABLE ALLOCATION OF COVID-19 VACCINE



NATIONAL ACADEMY OF MEDICINE

Another framework for allocation of COVID-19 vaccine in the United States

National Academies of Sciences, Engineering, and Medicine 2020. *Framework for Equitable Allocation of COVID-19 Vaccine*. Washington, DC: The National Academies Press.

https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus

EQUITABLE ALLOCATION OF COVID-19 VACCINE

The goal of the committee's framework is to **reduce severe morbidity and mortality and negative societal impact due to the transmission of SARS-CoV-2.** The framework is intended to assist and guide the federal government and decision-making bodies, including the Advisory Committee on Immunization Practices, as well as state, tribal, local, and territorial (STLT) authorities in their COVID-19 vaccine allocation planning.

The committee also developed foundational principles that form the basis of its framework:

Ethical Principles: Maximum Benefit, Equal Concern, and Mitigation of Health Inequities

Procedural Principles: Fairness, Transparency, and Evidence-Based

To put these principles into practice, the committee used four risk-based criteria to set general priorities among various population groups: (1) risk of acquiring infection, (2) risk of severe morbidity and mortality, (3) risk of negative societal impact, and (4) risk of transmitting infection to others.

BOX 3-3 Risk-Based Criteria

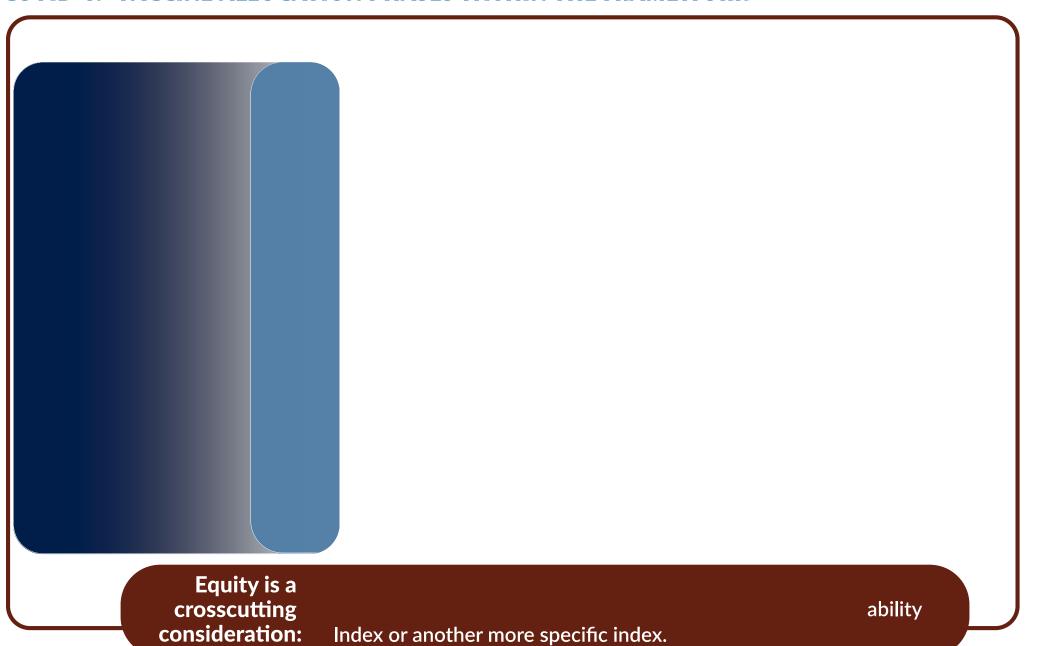
- Risk of acquiring infection: Individuals have higher priority to the extent that they
 have a greater probability of being in settings where SARS-CoV-2 is circulating and of
 being exposed to a sufficient dose of the virus.
- Risk of severe morbidity and mortality: Individuals have higher priority to the extent that they have a greater probability of severe disease or death if they acquire infection.
- **Risk of negative societal impact:** Individuals have higher priority to the extent that societal function and other individuals' lives and livelihood depend on them directly and would be imperiled if they fell ill.
- Risk of transmitting infection to others: Individuals have higher priority to the extent that there is a higher probability of their transmitting the infection to others.

TABLE 3-2 Applying the Allocation Criteria to Specific Population Groups

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Phases	Population Group	Criterion 1: Risk of Acquiring Infection	Criterion 2: Risk of Severe Morbidity and Mortality	Criterion 3: Risk of Negative Societal Impact	Criterion 4: Risk of Transmitting Infection to Others	Mitigating Factors for Consideration
1a	High-risk health workers	Н	M	Н	Н	Adequate access to personal protective equipment. Workplace management of exposure.
1a	First responders	Н	M	Н	Н	Adequate access to personal protective equipment. Workplace management of exposure.
1b	People with significant comorbid conditions (defined as having two or more)	М	Н	М	M	Ability to maintain social distance and isolate.
1b	Older adults in congregate or overcrowded settings	Н	Н	L	М	Effective institutional management of exposure.
2	K–12 teachers and school staff and child care workers	Н	M	Н	Н	Online schooling, especially for lower grades, recognizing educational and social impacts.
2	Critical workers in high-risk settings	Н	M	Н	M	Adequate access to personal protective equipment. Workplace management of exposure.
2	People with moderate comorbid conditions	M	M	M	M	Ability to maintain social distance and isolate.
2	People in homeless shelters or group homes and staff	Н	Н	L	Н	Adequate access to personal protective equipment. Effective institutional/workplace management of exposure.
2	Incarcerated/detained people and staff	Н	M	L	Н	Adequate access to personal protective equipment. Effective

National Academies of Sciences,
Engineering, and
Medicine 2020.
Framework for
Equitable Allocation
of COVID-19
Vaccine.
Washington, DC:
The National
Academies Press.
Page 3-16.

COVID-19 VACCINE ALLOCATION PHASES WITHIN THE FRAMEWORK



Consensus Report
Highlights. National
Academies of
Sciences,
Engineering, and
Medicine 2020.
https://www.nap.edu
/resource/25917/Fra
mework%20for%20E
quitable%20Allocatio
n%20of%20COVID19%20Vaccine_Highli
ghts.pdf

Decisions about how to allocate scarce COVID-19 vaccine may vary in different countries

- Which vaccines are first available in a given country, and what are the features of those vaccines?
- Which groups of people (for example, workers, students, incarcerated people, others) are at highest risk of infection, and of those, which can't be adequately protected through other means?
- Which essential workforces are most critical, and at the highest threat of being depleted?
- Different value judgments when weighing competing ethical values and goals

Other ethical issues in COVID-19 vaccine distribution

The process of making vaccine allocation decisions



- The process of making vaccine allocation decisions
 - People will disagree about vaccine allocation.
 - When people disagree about high-stakes decisions, providing opportunities for input and voice is important.

"First, different individuals and communities will disagree about who is entitled to a vaccine. This disagreement will arise because people have different opinions about the implications of the values discussed, such as what best promotes the common good. Another source of disagreement relates to the perceived importance of the different values. For example, some people may think that when considerations of fairness conflict with promoting the common good, priority should be given to fairness, whereas others may think the common good should be maximized. Moreover, as with other decisions about how to allocate scarce medical resources, whatever is decided will have significant impact on people's lives. There will inevitably be "winners" and "losers"; some people who would like to receive a vaccine will have to wait until the supply significantly increases, while others will have more immediate access. Ordinarily, when reasonable people disagree about difficult, high-stakes moral questions like these, additional important considerations come into play. In particular, some argue that to respect each person involved, the decision reached about allocation must be acceptable to different affected parties, even when the parties disagree that the decision is the right one. Furthermore, in the face of reasonable moral disagreements about questions like these, affected parties should get a say, so trying to provide opportunities for voice and engagement is important. Accordingly, policymakers should try to provide opportunities for citizen input into decisions about allocation." (Toner et al., p.13)

- The process of making vaccine allocation decisions
- Access to vaccines

- The process of making vaccine allocation decisions
- Access to vaccines
 - Make vaccines available in safe, familiar, convenient locations?
 - Make vaccines are affordable for all / free of charge?

Schoch-Spana M, Brunson E, Long R, Ravi S, Ruth A, Trotochaud M on behalf of the Working Group on Readying Populations for COVID-19 Vaccine. *The Public's Role in COVID-19 Vaccination: Planning Recommendations Informed by Design Thinking and the Social, Behavioral, and Communication Sciences*. Baltimore, MD: Johns Hopkins Center for Health Security; 2020.

- The process of making vaccine allocation decisions
- Access to vaccines
- Advancing public understanding of and acceptance of vaccines

- The process of making vaccine allocation decisions
- Access to vaccines
- Advancing public understanding of and acceptance of vaccines
- Mandatory vaccination for some groups?

- The process of making vaccine allocation decisions
- Access to vaccines
- Advancing public understanding of and acceptance of vaccines
- Mandatory vaccination for some groups?
- Allocation of vaccines between countries
 - Equitable and effective distribution vs. Vaccine nationalism

