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ORIGINAL ARTICLE

Ethical allocation of COVID-19 vaccine in the United States: an evaluation of competing frameworks for the current pandemic and future events

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Abstract

The COVID-19 pandemic, caused by the SARS-CoV-2 virus, created the need for an effective vaccine. Questions arose about allocating the initial limited supplies in the United States. We present four allocation models and compare their characteristics for ethically meeting the health needs of the population. The literature shares broad agreement on guiding ethical principles with those of the four proposed models for vaccine allocation, featuring the concepts of utilitarianism, prioritarianism, equity, and reciprocity. We conclude that the "Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States" from the Johns Hopkins Bloomberg School of Public Health is the most comprehensive and ethically sound. We recommend government officials and policymakers at all levels consider the principles and objectives in this model as US COVID-19 vaccination distribution efforts continue. This model may serve as an effective framework for initial vaccine distribution efforts during future epidemic and pandemic events.

Keywords COVD-19 · Vaccine · Pandemic · Ethical allocation

Key messages

- The development of a COVID-19 vaccine raised questions about allocating initial limited vaccine supplies.
- The authors reviewed four proposed allocation models based on ethical concepts.

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- The Johns Hopkins "Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States" is felt to be the most comprehensive and ethically sound model.

Introduction

Coronavirus disease 2019 (COVID-19) is an illness caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [1]. First identified in China in late 2019, the outbreak quickly spread to 213 countries and territories around the world. On March 11, 2020, the World Health Organization (WHO) declared COVID-19 a pandemic and the United States (US) declared a national emergency on March 13, 2020 [2]. The effects of COVID-19 have been enormous: over 280 million cases globally with over 5.4 million deaths as of December 27, 2021. In the United States alone, reported cases exceeded 52 million with more than 816,000 deaths [3].

Devastating socioeconomic impacts resulted from reduced activity across every economic sector. Business capacity limits, curfews, mandatory quarantines, and travel restrictions catapulted the United States into a recession with a historically unprecedented spike in unemployment claims [4].

It quickly became apparent that development and widespread use of a vaccine could greatly mitigate the impact of COVID-19. Vaccine development typically takes 10 to 15 years [5]. To expedite this process, on March 30, 2020, the US Department of Health and Human Services announced a program, "Operation Warp Speed" (OWS) [6]. Research quickly led to clinical trials of several vaccines. Two messenger ribonucleic acid (mRNA) vaccines, one produced by Moderna and the other by Pfizer, proved effective. The US Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for the Pfizer vaccine on December 11, 2020, and for the Moderna vaccine on December 19, 2020 [7]. The FDA granted EUA approval to a third, adenovirus-based, vaccine produced by Johnson & Johnson on February 27, 2021 [8].

Limited availability of these agents initially hampered their distribution across the United States and affected allocation strategies. The US Centers for Disease Control and Prevention (CDC) recommended priorities for vaccine administration to local and state governments; each state developed its own plan [9].

Response planning to infectious disease outbreaks has been a priority for the CDC since the 1970s [10]. Previously, including during the 2009 influenza pandemic, the CDC allocated vaccine doses to states based on population [11]. More recent guidelines prioritize specific high-risk groups and frontline healthcare workers. Because a complex mass vaccination program requires balancing of countervailing priorities, decision-makers must weigh all factors in competing strategies for allocation, logistical distribution, access, and administration.

Limited vaccine supplies require a comprehensive framework for allocation based on ethical and practical considerations. Criteria considered for models proposed for early allocation of COVID-19 vaccine doses in the US include impact to public health, economic recovery, and equitable distribution among demographic groups.

We evaluated these criteria for vaccine allocation in the current COVID-19 pandemic and made recommendations based on current bioethical expert opinion. Allocation goals include (1) reduction of mortality and morbidity associated with COVID-19; (2) fair and equitable distribution of vaccine doses in a way that does not exacerbate social disparities; and (3) prioritization of those with the greatest medical need and those who serve the most vital societal functions in the ongoing pandemic response.

Methods

Ethical considerations for evaluating mass immunization campaigns must be at the forefront of a framework for vaccination allocation and distribution. We reviewed studies by bioethical experts who identified ethical principles related to allocation of scarce resources. Next, we considered vaccination allocation frameworks appropriate for using scarce resources to reduce risk and maximize benefit and to promote fairness and accountability with transparency for prioritization of at-risk groups. A framework must maximize patient and community benefit while allowing for mitigation of disparities among population groups. And it must ensure flexibility and responsiveness as new evidence comes to light. Using these guidelines, we evaluated current COVID-19 vaccine allocation and distribution models to select one that most closely adheres to these principles.

We identified four allocation frameworks focused on distribution of COVID-19 vaccine:

(1) The Johns Hopkins School of Public Health "Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States;"
(2) The National Academies of Science, Engineering, and Medicine "Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine;"
(3) The World Health Organization "A Global Framework to Ensure Equitable and Fair Allocation of COVID-19 Products;" and
(4) The Hastings Journal article "Vaccine Rationing and the Urgency of Social Justice in the COVID-19 Response."

Results

Ethical decision-making criteria for evaluation of immunization models

Laventhal et al. [12] studied ethical principles underlying allocation of scarce resource through the lens of the ongoing COVID-19 pandemic. They agreed upon principles appropriate to the situation:

(1) Allocate resources to those most likely to survive;
(2) Allocate resources to those with the greatest need;
(3) Maximize opportunities to benefit the most people;
(4) Prioritize those who perform the most vital functions; and
(5) If all other factors are equal, use random sampling to allocate resources.

The Nuffield Council on Bioethics [13] published a policy brief on ethical decision-making principles to ensure equal access to COVID-19 treatments and vaccines. They identified factors that impact equitable access and distribution, including prioritization and funding of research, disparities in structure and health that limit access, allocation of research effort burden and benefit among countries of high and low socioeconomic status, and challenges related to engaging and earning public trust with the introduction of any new treatment or vaccine. Their consensus: an ethically sound COVID-19 vaccination allocation framework must prioritize dignity and human rights, reduce suffering of those in most dire need, and maintain fairness through non-discriminatory and equitable distribution of benefits from any program.

Evaluation of proposed model frameworks

Johns Hopkins School of Public Health model

The Johns Hopkins Bloomberg School of Public Health published a comprehensive COVID-19 vaccination distribution framework in August 2020, "Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States" [14]. Its authors proposed it as a resource to inform public discussion of COVID-19 vaccine allocation strategies. They based it on broad ethical constructs of utilitarianism and equity to maximize overall health benefit to the country while remaining focused on fairness. This framework involves four ethical values: (1) public well-being, (2) societal justice, (3); liberty, and (4) legitimacy. The policy goals and objectives appear in Table 1.

The Johns Hopkins model divides prioritized groups of initial vaccine recipients between "Tier 1" and "Tier 2." Tier 1 (Table 2) prioritizes initial recipients as those most essential in sustaining the ongoing COVID-19 response, those at greatest risk of severe illness and death and their caregivers, and those most essential to maintaining core societal functions. The basis for group selection is ability to avert the greatest public harm through vaccination, thus promoting the greater common good. This aligns with the model's policy objectives of preventing COVID-19 related deaths, protecting existing health systems, and protecting the country's essential services. Inclusion of these groups supports availability of basic services during the ongoing pandemic. During the initial vaccination campaign, direct protection against COVID-19 related illness for the most vulnerable subset of the population and those in high-contact occupations offers the most effective way to minimize illness and mortality.

In addition to promoting the greater common good, other guiding ethical principles contribute to prioritization in Tier 1 allocation. The concept of 'prioritarianism',

Table 1 Johns Hopkins model: ethical principles and goals with vaccine objectives. (Johns Hopkins, 2020)

Ethical principle	Policy goal	Objective	Priority group for vaccination
Promote public health	Prevent Covid-19 related illness and death	Protect those at greatest risk of poor outcome	Those 65 and older Those with comorbid conditions Those in close contact with high-risk groups
		Protect those at greatest risk of infection	Health system workers Workers with high-contact public jobs Workers in high-density workplaces Those in high-density housing
	Prevent injury, illness, and death from other causes Protect the health system	Protect workers needed to maintain public safety	EMS personnel Public health personnel Police and fire personnel
		Protect health system workers	Healthcare workers EMS workers Workers needed for vaccination effort
Promote economic and social well-being	Protect essential services	Protect workers needed to maintain infrastructure	Transportation workers Food system workers Warehouse workers Utility workers TSA and border security
	Enable economic activity	Protect workers to aid economic recovery	Those who cannot work remotely with high infection risk Those who cannot work remotely with high risk of poor outcome
	Enable school & childcare openings	Provide vaccination to enable rapid return to in-building school and childcare	Teachers Childcare workers Children living with high-risk adults Children with comorbid conditions

Table 1 (continued)

Ethical principle	Policy goal	Objective	Priority group for vaccination
Address inequity between social groups	Reduce higher rates of COVID-19 infection experienced by marginalized groups	Protect disproportionately affected disadvantaged groups	Essential workers Worker groups with high levels of Black and Latino staff Low-income workers Incarcerated individuals Those who face barriers to healthcare access
	Address economic and social impacts on historically disadvantaged groups	Protect workers who face elevated economic harm from not working	Group with high rates of low-income workers
Give priority to the worst-off	Protect those at highest risk for severe illness and death	Protect young people at high risk	Young people with comorbid conditions Young people with comorbid conditions who attend school in person
	Reduce burden for those with high health and economic risks	Protect people with both high health and economic risk from not working	Work groups with high rates of low-income workers
Reciprocity	Protect those at high risk who contribute to efforts against COVID-19	Protect essential workers and those in their households	High-risk essential workers Essential workers with high-risk individuals in their household Essential workers with comorbid conditions

Table 2 Tier 1 group examples. (Johns Hopkins, 2020)

Priority Groups	Examples
Essential in sustaining the ongoing COVID-19 response	Frontline health workers providing care for COVID-19 patients Frontline emergency medical services personnel 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 their caregivers	Adults aged 65 years and older and those living with them or otherwise providing care to them Other individuals and groups at elevated risk of serious COVID-19 disease, including people with health conditions putting 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 maintaining core societal functions	Frontline public transportation workers Food supply workers Teachers and school workers (pre-kindergarten through 12th grade)

giving priority to those in greatest medical need, means this group holds the strongest claim to initial COVID-19 vaccine doses [15]. The ethical concept of reciprocity prioritizes reward for sacrifice, thus justifying inclusion of healthcare workers and others whose occupations maintain essential societal functions.

Tier 2 priority groups appear in Table 3. They include workers involved in broader health provision (i.e., providing healthcare services to non-COVID-19 patients), people facing high barriers to care if seriously ill, individuals contributing to maintenance of core societal functions, and those whose living or working conditions pose elevated risk of infection, even if they have lesser or unknown risk of severe illness and death. Tier 2 designation expands the logic underlying Tier 1 by adding periphery workers essential to sustaining health systems and those whose occupations provide secondary services to maintain infrastructure function (i.e., utility operations, public safety, and delivery services) during the pandemic. It also includes those who may face barriers to care and those at elevated COVID-19 infection risk. The rationale is offering vaccination protection to those at high risk for transmission to prevent illness and death because those with higher personal infection risk would be more likely to spread the virus to others. Thus, prioritization of these groups would slow transmission and reduce emergent COVID-19 hotspots.

Table 3 Tier 2 group examples. (Johns Hopkins, 2020)

Priority Groups	Examples
Essential to broader health provision	Health workers and staff with direct patient contact (non-COVID-19 specific) Pharmacy staff
Least access to health care	Those living in remote locations with substandard infrastructure and healthcare access (Native American reservations, isolated rural communities)
Needed to maintain other essential services	Frontline workers involved in maintaining operation of electricity, water, sanitation, information, financial, fuel infrastructure (who cannot work remotely) Warehouse, delivery workers (including postal workers) Deployed military (including National Guard) involved in operations Police and fire personnel with frequent public contact Transportation Security Administration and border security personnel with direct public contact
Elevated risk of infection	Those unable to maintain safe physical distance within their living or work environments Those working in high-density or high-contact jobs where distancing may not be feasible Those living in shelters (e.g., homeless, domestic violence) Incarcerated individuals and prison workers Other groups yet to be identified who are shown to be at elevated risk of infection because of other working or living conditions

There is no rank-ordering of the groups in either tier. Architects of the Johns Hopkins model acknowledged likelihood of insufficient supply of vaccine for all in Tier 1. They estimated availability initially only for adults aged 65 and older and those with comorbidities that increase risk of serious COVID-19 disease. These two Tier 1 groups include approximately 93 million people in the US. Thus, decision-makers would base priorities for subgroups on greater needs and maximum benefit. For example, individuals with comorbidities who work in residential care facilities are more at risk than other people with comorbid conditions. Prioritization within the essential worker candidate groups may be determined by relative essentialness and difficulty for replacing staff in the positions. Decision-makers could also consider equity by prioritizing groups that include people of nationalities or races at higher risk of infection.

The National Academies of Science, Engineering, and Medicine model

The National Academies of Science, Engineering, and Medicine published a report, "Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine," establishing a COVID-19 vaccination allocation model to assist policymakers in rationing COVID-19 vaccine doses [16]. It rests on six principles: Maximization of benefits, equal regard, mitigation of health inequities, fairness, utilization of evidence-based interventions, and transparency. The overarching

goal is to "maximize societal benefit by reducing morbidity and mortality caused by transmission of the novel coronavirus" [16]. The rationale is to achieve maximum benefit through the prevention of COVID-19 related death and to reduce overall COVID-19 transmission. Initially the model focuses on prevention of COVID-19 related illness and death and on protection of health systems and essential services, with increased focus on reducing transmission in later phases of the immunization program.

Risk-based criteria align with principles. These include immunization prioritization based on risk of acquiring infection, risk of severe morbidity and mortality, risk of negative societal impact, and risk of transmitting the disease to others. These form the basis of a four-phased COVID-19 vaccination framework with population group prioritization (Table 4).

The first phase (the "Jumpstart") is two-tiered. The first tier includes initial vaccine distribution to frontline healthcare workers and emergency responders whose jobs involve direct patient care. The model bases priorities on a worker's potential exposure to COVID-19 through respiratory and aerosolized droplets or bodily fluids from affected patients exhibiting COVID-19 symptoms, not professional titles. Not only would frontline healthcare workers be unable to complete their duties if they became ill with COVID-19, they may also serve as potent spreaders of the virus. This risk is exacerbated by living conditions. Many workers live in multigenerational households and belong to communities with systemic health inequities, especially home health aides and those employed at nursing facilities. The second tier includes people of any age with comorbid conditions putting them at high risk for developing COVID-19 related illness or death. This group includes elderly individuals living in communal settings such as nursing facilities. Phase 1 would provide immunization for 15% of the total US population.

Phase 2 includes essential workers at high risk of exposure: teachers for school children ages 5–18 and school staff, those living or working in homeless shelters or group homes, and those incarcerated or working in prisons, jails, and detention centers. Enclosed communal settings often ease transmission and become hotspots. Policymakers must assess ongoing risk of increased age and morbidity relative to COVID-19 as knowledge grows to allow more effective prioritization. Phase 1 and Phase 2 together would cover 45 to 50% of the US population.

Phase 3 would include healthy young adults and children as vaccine supply grows, plus workers whose occupations do not place them in a high-risk group for COVID-19 exposure. Phase 3 would reach approximately 85% of the US population. Phase 4 includes all not vaccinated in previous phases, including healthy adults. Vaccine distribution during this phase would take place using an egalitarian method such as a lottery based on regional supply.

The World Health Organization model

Policy briefings by the World Health Organization's Group on Ethics and COVID-19 provide guidance on principles of scarce resource allocation during the ongoing pandemic. The briefings, "A Global Framework to Ensure Equitable and Fair Allocation of COVID-19 Products" and "Fair Allocation Mechanism for COVID-19

Table 4 Allocation Criteria Applied to Population Groups (National Academies of Science, Engineering, and Medicine, 2020)

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 healthcare workers	H	M	H	H	Adequate access to PPE[1]. Workplace management of exposure
1a	First responders	H	M	H	H	Adequate access to PPE. Workplace management of exposure
1b	People with significant comorbid conditions	M	H	M	M	Ability to socially distance and isolate
1b	Older adults in congregate or overcrowded settings	H	H	L	M	Institutional management of exposure
2	Teachers and school staff (K-12), childcare workers	H	M	H	H	Online schooling, especially for lower grades
2	Critical workers in high-risk settings	H	M	H	M	Adequate access to PPE. Workplace management of exposure
2	People with moderate comorbid conditions	M	M	M	M	Ability to socially distance and isolate
2	People in homeless shelters or group homes and staff	H	H	L	H	Adequate access to PPE. Institutional / workplace management of exposure
2	Incarcerated/detained people and staff	H	M	L	H	Adequate access to PPE. Institutional / workplace management of exposure
2	All older adults	M	H	L	L	Ability to socially distance and isolate

Table 4 (continued)

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
3	Young adults	H	L	M	H	Ability to socially distance and isolate. Closure of congregate settings
3	Children	M	L	M	H	Ability to participate in online schooling
3	Workers in industries important to societal functions	M	M	M	M	Adequate access to PPE. Institutional / workplace management of exposure

PPE personal protective equipment, *H* high risk, *M* medium risk, *L* low risk

Vaccines Through the COVAX Facility," prioritize transparency and inclusiveness of at-risk population groups in the decision-making process and accountability for policymakers [17].

The WHO acknowledged limited vaccine supply and noted that reducing deaths related to COVID-19 and protecting health systems will be key factors for improving population well-being and reducing negative impact on economy and society overall. To achieve this, countries should target groups to make maximum benefit of the vaccine, classify them into tiers, and distribute vaccine in descending priority. Although still in development at the time of this writing, the WHO model suggested Tier 1 could include: (1) individuals 65 and older, (2) frontline healthcare and social care workers, and (3) high-risk adults under age 65, such as those with known comorbidities.

The targeting of populations and structuring of tiers takes on greatest significance for countries that receive vaccine supplies through the WHO's COVID-19 Vaccines Global Access (COVAX) Facility**.** For most of these, Phase 1 allocation of vaccine equals 20% of the population. Model architects estimated this would cover most individuals in Tier 1 target groups. Phase 2 distribution would begin for each country as it completed Phase 1. WHO acknowledged that the percentage of at-risk populations varies among countries, thus, 20% represents a baseline. WHO also recognized that initial vaccine supplies might not be sufficient to cover all Tier 1 target groups. The WHO recommended a gradual allocation scheme of identifying Tier 1 subgroup targets and vaccinating them before approving more groups for allocation.

This model's global allocation of vaccines combines the ethical principles of fairness through proportional allocation to all countries with equity by adjusting for risk profile variation among countries. The rationale for prioritizing target groups rests on the ethical principle of utility to maximize benefit and minimize societal harm. The model dictates balancing maximization of utility with the ethical concept of prioritizing the worst-off, thus reaching those with greatest medical urgency first. Also essential to this model is prioritizing those in occupations helping others, such as frontline healthcare workers.

Schmidt model

Harald Schmidt, in his Hastings Journal article, "Vaccine Rationing and the Urgency of Social Justice in the Covid-19 Response," provided a unique supplement to the other models by taking greater account of social justice and health disparities in communities of lower socioeconomic status [18]. His model emphasizes socially equitable COVID-19 vaccine allocation using New York City as a case-study. At the onset of the pandemic, New York City quickly became the nation's COVID-19 hotspot, with the highest case rates and concomitant deaths in the country. Many affluent New Yorkers moved to secondary homes outside of the city, while individuals in lower resource communities remained. A study on subway ridership at the end of March 2020 showed that for Manhattan, the wealthiest borough, public transit ridership fell by 75%.; for the Bronx (the lowest resourced of the five major boroughs) ridership fell only 20% [18]. This disparity may illustrate differences in individuals' ability to trade-off health and income, with lower income workers staying in the city

and facing risk of exposure by using mass transit. COVID-19 mortality data support these disparity findings, with the Bronx having shown more than 1.7 times the rate of COVID-19 related deaths than Manhattan (372 deaths per 100,000 residents versus 217 deaths per 100,000 residents, respectively) by the end of April 2020 [19].

Further assessment revealed twice as many Black residents died of COVID-19 related illness compared to white residents in New York City [20]. Disenfranchised neighborhoods of color have comprised a disproportionate amount of morbidity and mortality related to COVID-19 while suffering most from associated financial burdens. Due to inherent socioeconomic disparities as outlined above, Schmidt argued against a vaccine allocation lottery system because it implies baseline equality among the US population, although data show this has not always been historically accurate [18]. He stated that lotteries, if used, should be adjusted to reflect underlying levels of disadvantage among population groups; use of the Area Deprivation Index (ADI) is one way to accomplish this.

The ADI, created by the US Health Resources and Services Administration (HRSA), uses data on income, education, employment, and housing quality to rank neighborhoods by socioeconomic status. The US Centers for Medicare and Medicaid Services (CMS) previously used the ADI to identify diabetes interventions. The ADI may serve as a helpful proxy for determining priority allocation for COVID-19 vaccine, ensuring that those groups worst off from an economic and epidemiologic standpoint and, therefore, more likely to be impacted by COVID-19 are among the first to receive the vaccine. [18].

Schmidt's model proposed two priority groups for initial allocation of vaccine. The first group includes health care workers and other essential workers with greater likelihood of spreading infection based on their employment and living conditions. Examples include garbage haulers, transportation workers, and core manufacturing and service employees. The second priority group includes those who, based on epidemiological, ethical, and economic considerations, the ADI or other methods would identify as more disadvantaged.

There are ethical arguments for using the ADI to guide distribution of initial COVID-19 vaccine doses. This measure prioritizes the most disadvantaged in society and may help reduce associated disparities. Its use may also promote the greater common good, leading to overall reduction in virus transmission as low-income workers are likely to live in crowded homes or in multigenerational ones. Reduction of virus transmission in mass transit systems may also help achieve the utilitarian goal of reducing harm and maximizing health benefit to the population.

Policy analysis

We seek to provide an ethical evaluation of the four competing frameworks as a basis for recommendations based on their ability to satisfy these goals: (1) reduction of mortality and morbidity associated with COVID-19, (2) fair and equitable distribution of vaccine doses in a way that does not exacerbate social disparities, and (3) prioritization of those with the greatest medical need and those who serve the most vital functions in the ongoing pandemic response.

The models share many characteristics. Three models focus on maximizing public well-being through reducing mortality and morbidity related to COVID-19, with specific emphasis on protecting those with the greatest medical need and those serving vital functions in society. Each also seeks to promote equity by alleviating socioeconomic disparity and factors limiting access to healthcare. All rely on ethical bases of utilitarianism, reciprocity, and prioritarianism – evidenced by prioritization of frontline healthcare workers and emergency responders, individuals with underlying comorbidities and health risks, and those essential to maintaining core societal functions during the ongoing pandemic. All base allocation on reducing societal disparities, perhaps most clearly in the ADI model outlined by Schmidt [18]. All share values in the guiding principles of transparency and use of evidence-based decision-making. And each aligns well with the bioethical decision-making publications discussed above.

There are differences among them. The Johns Hopkins and National Academies models describe division and prioritization by population groups for vaccine in greater detail than the other two. The National Academies and Schmidt models place healthcare workers at the top of their respective priority groups. The WHO framework places frontline healthcare workers in the second target group of its first tier. Although the Johns Hopkins model includes healthcare workers as a Tier 1 priority, it does not rank groups within that Tier.

The Johns Hopkins and WHO models define the older adult population as "65 and older"; the National Academies framework refers to "older adults" and Schmidt did not specifically address the elderly. The WHO model emphasizes prioritizing individuals 65 and older for initial vaccination; the National Academies prioritizes only those elders also residing in communal settings such as nursing facilities—because such settings pose high risks for viral transmission. The Johns Hopkins framework allocates first-round vaccination to individuals 65 and older regardless of living situation, *and* to their caregivers. These differences illustrate varied approaches to satisfy the common goal of reducing morbidity and mortality associated with COVID-19.

Another difference among frameworks is inclusion of teachers and those working in the frontline education sector as first-round immunization recipients, as in the Johns Hopkins model. This difference may reflect a higher priority on re-opening schools and childcare programs to facilitate educational and social development of the nation's children, as well as their parents' continued employment. The authors for each model emphasized that their prioritization of population groups places some objectives ahead of others; this may lead to differing conclusions about which groups to afford the earliest opportunities for vaccination.

We also recognize the limitations of the various models. Success will hinge on effective communication, compliance, and widespread adoption during implementation. Community outreach and engagement will be key elements. Implementation must allow for input and transparent consensus decision-making by public and community stakeholders, with an emphasis on clear communication and respect of cultural concerns. Success will also rely on flexibility. Adjustments will be needed to respond to new data emerging from clinical vaccine trials and other sources; group prioritization will also need to remain malleable.

Recommendation

Based on this review and analysis, we recommend to policymakers at every level of government the "Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States" model developed by the Johns Hopkins Bloomberg School of Public Health for COVID-19 vaccine distribution. It provides more detail about links between priority groups and ethical principles and very effectively ties these principles to tangible policy goals and objectives to satisfy the comprehensive health needs of the US public. Priority groups in this framework are better defined and examples of the priority group constituents are more comprehensive than in other models. The model involves aggregation of priority groups into two tiers, with Tier 1 groups selected on ability to sustain the response to COVID-19, avert harm to those at great risk of illness, and maintain essential services in society, creating larger societal benefit. Because this model does not mandate a particular rank-ordering among priority groups in each Tier, it allows communities greater flexibility to achieve the greatest benefits for their populations given constrained vaccine resources. This model's plans for distributing limited vaccine doses align closely with expert recommendations. It provides an effective process for reducing COVID-19 transmission and deaths and for protecting essential workers, historically marginalized groups, high-risk individuals, and those sacrificing their well-being in the efforts to quell the pandemic. The model's two-tier plan will enable the US to effectively mitigate societal and economic hardships. Policymakers at every level of government should consider implementing the Johns Hopkins model to create comprehensive immunization campaigns well tailored to individual and community needs. A well-formulated distribution plan will help decision-makers evaluate which population groups have the strongest claim to limited doses based on new evidence of greatest need and potential benefit.

This study has several limitations. First, the study was designed to evaluate currently proposed COVID-19 vaccine distribution models in the context of specific ethical principles. We did not evaluate other vaccine allocation frameworks, such as those that have been implemented previously to combat other infectious diseases. A comparison of existing applied frameworks to those we considered may be relevant and worthwhile. Also, our search yielded the four models we described, but there may be other COVID-19-related vaccine allocation models of which we are unaware.

Second, it is difficult to validate our recommendations a priori for using the Johns Hopkins model for COVID-19 vaccine allocation. This is a pandemic involving a novel coronavirus for which we have limited experience. There is much still to be learned about the role vaccines play in mitigating the illness. Consequently, it is important to make the best decision possible with the information we currently have to select an appropriate vaccine allocation model. Validation may only occur through implementation of the Johns Hopkins model and analysis of the results.

Third, three of the four models we analyzed focus on vaccine distribution in the United States; only the WHO model addresses vaccine allocation on a global

basis. It is unclear how generalizable the Johns Hopkins model will be for vaccine distribution to other nations. Politics, demographics, and differing socioeconomic determinants of health may render this model unsuitable in other countries.

Finally, we did not identify specific criteria for success in deploying the Johns Hopkins model. It will be important to define and monitor metrics to determine whether this allocation framework is being implemented appropriately and achieving the desired result of vaccinating and protecting members of the defined priority groups with the initially limited amounts of vaccine.

Conclusions

SARS-CoV-2 is only one of several novel pathogens causing new infectious diseases in the last few decades. There will be more requiring development, production, and distribution of vaccines. Given its potential for success during the current pandemic, the Johns Hopkins model offers a blueprint for managing scarce supplies in future epidemics and pandemics. By reviewing health expert opinion and implementation of the Johns Hopkins model, policymakers will be empowered to develop effective immunization campaigns, providing initially limited vaccine doses to the people who need them most.

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Declarations

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

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