Rationing of civilian COVID-19 vaccines while supplies are limited

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Summary (39 of 40 allowed words): Allocation of the initial doses of COVID-19 vaccines should account for epidemiology, vaccinology, bioethics, and racial disparities. Our priority tiers for vaccination are critical infrastructure, those at highest medical benefit, and those chosen by a weighted Area-Deprivation Index lottery.

Globally, the COVID-19 pandemic has infected millions and killed hundreds of thousands. All anticipate the development of vaccines to protect individuals, assist in providing herd immunity, and interrupt transmission. Multiple candidate vaccines are in clinical or preclinical evaluation. With one exception, none of the vaccines in advanced development utilize platforms that have been licensed for human use, including the so-called “genetic” vaccines (e.g., mRNA or DNA) and live adenovirus vectored vaccines. In addition to the usual concerns over vaccine safety and efficacy, other concerns arise, including equitable access [1]. Furthermore, a critical concern—and our topic here—is how to allocate limited initial doses in the United States.

Consensus is lacking on principles for allocation, which raises concerns about equity and justice. These concerns are substantial because, historically, disadvantaged and minority groups have had lower vaccination rates and less access to health care (including newer vaccines) [2, 3]. Vaccine-distribution policies must address the distrust felt by racial/ethnic minority communities toward organized health care systems. This distrust is based upon historical unethical treatment, including, for example, the Tuskegee syphilis study and studies that deceived Latinas and African-American women regarding scope and reversibility of contraceptive methods [4, 5]. Consequently, this history influences future decisions that require trust in the medical system. The disproportionate COVID-19 mortality rate for blacks [6] and contemporaneous concerns for racial injustice emphasize the need to minimize systemic inequities while establishing national protections.

A classic work on the just rationing of scarce medical resources contrasts the strengths and weaknesses of the theories of utilitarianism and egalitarianism [7]. Utilitarianism has been used in wartime triage and weighs perceived benefits in order

to rank options; however, it has the potential to justify injustice to minorities to satisfy the majority and therefore has significant limitations for public health decisions [8]. Egalitarianism proposes that all persons have equal rights and distributes resources according to need. An alleged weakness is that it does not address difficult choices during scarcity. Using the strengths of these two theories, we propose consideration of allocating COVID-19 vaccines in three (or four) tiers (Table 1) and *a priori* allocating vaccine supplies to each tier, given concerns about distortion of equity. These tiers must be informed by evolving understandings of COVID-19 epidemiology and vaccine clinical trial findings.

Both theories support our first tier: those with the critical skills needed for society during a pandemic, such as health care providers (HCPs), police, firefighters, and makers of vaccines and therapeutics required for treatment of COVID-19 [9-11]. During influenza vaccine shortages, the Society for Healthcare Epidemiology of America argued for prioritizing HCPs due to transmission risk, burden of absenteeism during outbreaks, and protecting household contacts of HCPs [12]. Consideration should also be given to military service members who anchor rapid-response teams, but these decisions are made outside the civilian prioritization system.

The second tier includes individuals who experience the highest medical benefit, which combines medical need with the likelihood of protective responses to vaccination. Egalitarianism supports priority for the medically neediest. For COVID-19, those most likely to die are the oldest and those with complex comorbidities. Many individuals in these groups respond poorly to vaccines; for this reason, for example, high-dose influenza vaccines were developed for the elderly. Although such vaccines provide more benefit, they require more antigen and thus might

reduce the overall number of doses available. Therefore, a utilitarian approach suggests balancing medical need with likelihood of protective vaccine response in order to protect the largest number of people. Given that vaccines are still in development, it is unknown who among the medically needy will respond well. Although medical benefit is theoretically more equitable, it could be unintentionally distorted or intentionally manipulated. The second tier combines aspects of both egalitarian and utilitarian thought to achieve highest medical benefit.

The third tier, based on egalitarianism, is selection by random chance and is likely the largest group. Lotteries for allocation of scarce COVID-19 treatments have been advocated [13]. Although thought to avoid overt discrimination, access to benefits from lotteries may have hidden inequalities that can even reduce the fairness of chance [14]. Given this history and the epidemiology of COVID-19 with a higher impact on disadvantaged groups, Schmidt proposed that the lottery be weighted by the Area Deprivation Index (ADI) so that disadvantaged groups have more access to vaccine [11]. The ADI ranks neighborhoods by their disadvantage in socioeconomic status (SES) and has been correlated with COVID-19 hotspots [15]. Over-weighting the disadvantaged makes epidemiologic sense because those in low SES areas experience more crowding, more often have multi-generational households that include the elderly, and are more reliant on public transportation for employment (and therefore have less opportunity for social distancing) [11]. Further rationale for this is the the fact that racial disparities occurred in the uptake of the 2009 H1N1 influenza pandemic vaccine in the US [16], and survey data suggest that this might occur again [17].

A tier that could potentially become a priority are those critical to transmission dynamics for SARS-CoV-2 (e.g., super-spreaders). Indeed, two major barriers to the

control of SARS-CoV-2 are viral shedding prior to symptom onset (presymptomatic) and asymptomatic shedding. For example, the epidemiology of influenza is well-known: school-aged children play a substantial role and are thus considered a priority group. The role of children in transmitting SARS-CoV-2 is still being investigated, and quantitative estimates remain unclear. Transmission may vary according to community structure and cultural practices, among other factors. If this became possible to identify, individuals critical to transmission dynamics would be a high priority for vaccination under both theories.

Given the concerns about subjective allocation guidelines that could distort equity, we propose *a priori* allocating a percentage of available vaccines to each tier. Thus, some vaccine would be allocated by chance while at the same time allowing decisions based on critical infrastructure needs, epidemiology, and perceived medical benefit.

Several alternative approaches might be proposed but have potential shortcomings. Some might propose priority based on social worth—valuations that are typically subjective and supportive of institutional discrimination. Prioritizing quality of life may be well-intentioned but can result in arbitrary metrics and definitions of "quality." Unintentional discrimination against groups (e.g., the disabled) can ensue. Some might propose an age criterion for the eldest seniors, but that may miss the degree of suffering that afflicts the oldest due to COVID-19 and therefore may not be equitable if the calculus includes burden of suffering. Additional concerns regarding equitable access arise, given that those of higher socioeconomic status have better access to information, transportation, and new interventions [10].

The World Health Organization (WHO) has proposed a framework for

equitable allocation of COVID-19 products, including vaccines [18]. Based on epidemiology, WHO proposes the following priority populations with their estimated proportion of the population: healthcare system workers (1%); adults >65 years of age (8%); and high-risk adults due to comorbidities (15%). WHO notes that transparency, evolving epidemiologic risk, vaccine-specific information (e.g., number of required doses), and availability of vaccine are key considerations.

The Advisory Committee on Immunization Practices (ACIP) (chartered by Congress to develop civilian immunization policy) has not yet published recommendations on prioritization, but the Centers for Disease Control and Prevention (CDC) has discussed the issue [19]. The ACIP's COVID vaccine-prioritization framework uses its 2009 H1N1 pandemic prioritization framework based on epidemiologic risk, adds ethical and equity considerations, and bases its approach on burden of disease, impact on healthcare capacity, and vaccine characteristics. Notably, the ACIP Work Group decided not to include concerns about reduced efficacy in certain populations (e.g., the elderly or immunocomprised) because such data are largely unavailable. The ACIP also expressed the desire to reduce the disproportionate burden on those with existing disparities. The ACIP preliminarily proposed the following priority groups: (1) healthcare personnel; (2) essential workers; (3) adults aged ≥65; (4) long-term care facility residents; and (5) persons with high-risk medical conditions. The ACIP noted that state and local microplans for vaccine implementation would be needed.

Our proposal is similar to those of WHO and ACIP but differs in several ways, including consideration of potential super-spreaders, use of medical benefit instead of just medical risk, use of an ADI-weighted lottery, and allocation of doses to each tier. We also hold different views about local and state implementation of microplans;

we are concerned about the historic and recent racial, SES, ageist, and disability-related injustices, calling on the need for national guidelines that are less subject to the whims of local interpretation. This concern may be heightened by state differences in child and adolescent vaccination coverage [20, 21].

As COVID-19 vaccine development progresses, considerable forethought and debate are needed to prioritize vaccine distribution, allow for citizen input, and to widely communicate allocation plans. The CDC established a prioritization plan for pandemic influenza vaccine [22], but this was based primarily on a utilitarian ethic. Recent evidence of unequal risk and treatment of underrepresented citizens in multiple arenas highlights the need for a national policy that diminishes subjective decision making, represents all affected communities, and is guided by epidemiology, science, and bioethics.

Priority groups for pandemic rationing of a COVID vaccine when supplies are limited, by rationale and ethical basis

Priority	Priority Group	Rationale	Comment	Ethical Theory Support	
				Utilitarianism	Egalitarianism
1	Health care providers (HCP), therapeutics and vaccine makers, military	Critical need in pandemic	HCP needed to treat disease and support the ill. These groups help and protect others, valuing lives beyond their own.	X	X
2	Groups at highest benefit	Medical benefit	Medical benefit incorporates both ability to respond well to a particular vaccine and medical need (i.e., underlying health conditions or age).	X	X
3	Persons selected by lottery	Random chance	Values each person equally but even chance may not overcome historic inequities given problems with follow-through on opportunities. Weight by Area Deprivation Index.		X
Potentially high if identified	Persons highly involved in transmitting SARS-CoV2 (e.g., super-spreaders)	Reducing transmission	Key to reducing transmission by the asymptomatic or mildly symptomatic. Historically, live vaccines often have the most potential for this (e.g., the community benefits of live attenuated influenza vaccine).	X	X

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