

SUPPLEMENTAL DOCUMENT A.

An Analysis of Theoretical Approaches to Rationing

Given the lack of an acceptable existing prioritization process, it is necessary to first select relevant vaccination strategies that will achieve the intervention goals. In order to do this, we identified all possible approaches toward allocating limited medical resources, translated them into relevant vaccine rationing strategies, and evaluated their appropriateness. The analysis presented in this supplemental document will inform the development of criteria to evaluate population groups.

A. Identifying approaches toward allocation of limited medical resources

Patients are frequently prioritized for treatment using limited medical resources. Such prioritization occurs during normal operations of the medical care system (e.g., allocation of organs, human blood, and artificial hearts) and during emergency situations (e.g., medical care on the battlefield, natural disasters, massive accidents, and terrorist attacks).¹ Pandemic influenza is an emergency situation and therefore only this type of resource allocation will be discussed.

There are two main theoretical approaches toward the rationing of limited medical resources: utilitarian approaches and egalitarian approaches.² Utilitarian principles aim to create the greatest good for the greatest number of people. These principles aim to raise the general welfare of society rather than prioritizing those in greatest need. Egalitarian principles, within this context, focus on maintaining or restoring equality for the persons in need of medical care. Though each of these theories will be described in detail below, it must be noted that the lines between these two theories are not clearly drawn. Nevertheless, this division between utilitarianism and egalitarianism is commonly accepted among bioethicists. Table 1 outlines these approaches and provides a brief definition of each.

TABLE 1: APPROACHES TO RATIONING LIMITED MEDICAL RESOURCES ³		
Utilitarian Approaches	Definition	Additional Characteristics of Approach
Principle of medical success	Priority is given to those for whom treatment has the highest probability of medical success.	Those who will probably live even without treatment and those who will probably die even if treated are left aside in order to treat those who will probably live <i>only</i> if they receive this resource.
Principle of immediate usefulness	Priority is given to the individuals who are most useful under the immediate circumstance.	This principle is not based on the individual's social worth, but rather on their ability to provide services, which are essential and can be utilized to respond to an emergency.

¹ Petrou, S. and J. Wolstenholme (2000). "A review of alternative approaches to healthcare resource allocation." *Pharmacoeconomics* **18**(1): 33-43.

² Winslow, Gerald. *Triage and Justice*. Berkeley: University of California Press, 1982.

³ Ibid.

TABLE 1: APPROACHES TO RATIONING LIMITED MEDICAL RESOURCES ³		
Utilitarian Approaches	Definition	Additional Characteristics of Approach
Principle of conservation	Priority is given to those who require proportionately smaller amounts of the resource.	The principle of conservation benefits those individuals who require a smaller portion of the available resource.
Parental role principle	Priority is given to those who have the largest responsibilities to dependents.	This principle is based on the idea that providing the resource to caregivers will benefit both the caregiver and the dependents.
Principle of general social value	Priority is given to those who are believed to have the greatest general social worth.	“Social worth” could be calculated based on the following characteristics: income, wealth, marital status, emotional stability, education level, IQ/aptitude, and/or professional role.
Egalitarian Approaches	Definition	Additional Characteristics of Approach
Principle of saving no one	This principle says that no one should be saved if not all can be saved.	Though this is the most egalitarian approach, it is more of a rejection of rationing than an application of it.
Principle of medically neediest	Resources are given to those with the greatest medical need.	This principle presumes that equality does not demand that each person <i>receive</i> the same physical treatment, rather that each person should be treated in such a way that he achieves the same level of <i>well being</i> as every other.
Principle of general neediness	Priority is given to the most helpless or generally neediest.	This principle advocates that those who are least able to fend for themselves should be helped first. General need may include a range of characteristics, including: lack of political power, social status, intelligence, physical strength, or financial power. This is relevant because having these characteristics/ conditions often limits one's <i>access</i> to medical resources.
Principle of queuing	Priority is given to those who arrive first (e.g., “first come, first served”).	Patients needing scarce resources would be treated in the order of their arrival for treatment, presumably some type of waiting list or queue would be established.
Principle of random selection	Priority is given to those selected by chance through a lottery.	Random selection gives each person an equal chance of being selected.

B. Converting approaches into relevant strategies

Before evaluating these approaches, it is important to first convert the theoretical strategies into strategies relevant to an influenza pandemic. At this point, no judgment will be made regarding whether the strategy is appropriate, legal, ethical, or feasible. This section only describes how the theoretical strategy could be applicable to an outbreak of pandemic influenza. Table 2 below briefly describes these conversions.

TABLE 2: CONVERTING APPROACHES INTO RELEVANT STRATEGIES

Theoretical Utilitarian Approach	Relevant Utilitarian Strategy	Description
Principle of medical success	Ration by probability of successful immunization	This strategy would favor those for whom vaccination has the highest probability of preventing severe influenza illness and/or death.
Principle of immediate usefulness	Ration to those who perform essential emergency response role	This strategy favors groups of individuals who are involved in the emergency response. Individuals will be identified by professional role.
Principle of conservation	Not applicable	Rationing to "conserve resources" does not apply to the vaccine situation because everyone will receive the same number of doses. Since there is no differentiation in amount of resources required by each person, this strategy can be eliminated from further analysis.
Parental role principle	Ration to those who perform a caretaker role	This strategy favors individuals who provide primary home care for children, elderly, and the unwell.
Principle of general social value	Ration to those who perform an essential community role	This strategy favors groups of individuals who are essential to maintaining social and economic continuity. Individuals will be identified by professional role.
Theoretical Egalitarian Approach	Relevant Egalitarian Strategy	Description
Principle of saving no one	Do not ration vaccine	This strategy means that no vaccine would be distributed.
Principle of medically neediest	Ration by medical and prevention needs	This strategy favors those groups who are most likely to transmit influenza virus to susceptible populations as well as those groups at high risk of developing severe illness and/or death.
Principle of general neediness	Ration to those with minimal access to medical care	This strategy favors those who have poor access to medical care services based on their income and employment levels.
Principle of queuing	Ration via queuing	This strategy gives priority to California residents who are first in line for the vaccine.
Principle of random selection	Ration via lottery	This strategy would give everyone within California who needs and wants the vaccine an equal chance of being selected for vaccination.

C. Designing the evaluation process

Though the above strategies provide a range of rationing options for influenza vaccination, not all of them meet the State's intervention goals of minimizing health consequences, economic consequences, and social disruption. In addition, the vaccination strategy chosen must meet ethical, legal, political feasibility, and implementation standards. Therefore, these nine strategies will be put through five tests to determine whether they should be included for further analysis. The five tests are as follows:

1. Does the strategy meet the intervention goals?

The California Department of Health Services has identified three primary goals of using a vaccine intervention to combat an influenza pandemic. The three goals along with their definitions are as follows:

- a. *Minimize health consequences*: The ability of the intervention to reduce the number of severe illnesses and deaths caused by pandemic influenza.
- b. *Minimize social disruption*: The ability of the intervention to reduce disruption in essential community services and to minimize social chaos and disorder caused by pandemic influenza.
- c. *Minimize economic consequences*: The ability of the intervention to reduce the extent of economic losses caused by disruption in essential financial services as well as by reductions in production and consumption of goods and services.

Since CDHS has established "minimizing health consequences" as the primary intervention goal, each strategy must reduce the number of illnesses and deaths in order to be included for further analysis. As described previously, focusing on reducing health consequences will also minimize social and economic consequences.

2. Is the strategy fair and just?

Assessments of "justice" will be based on bioethicist Gerald Winslow's assessment of the ten theoretical approaches toward the allocation of scarce medical resources detailed in his book *Triage and Justice*.⁴ Winslow evaluated each of the theoretical approaches toward triage using John Rawls' theory of justice.

Rawls' theory of justice sprung forth from a thought experiment in which rational and self-interested contractors who are unaware of their own economic and social status (e.g., behind the "veil of ignorance") negotiate a system of procedural justice that is as 'fair' as possible. Rawls argues that under this system, social goods would be distributed equally (aka "equality principle") unless an unequal distribution of any or all of these goods is to the advantage of the least favored (aka "difference principle").⁵

⁴ Winslow, Gerald. *Triage and Justice*. Berkeley: University of California Press, 1982.

⁵ "Least favored" is interpreted as those who have the least access to the limited resource.

Winslow interprets Rawls' theory specifically in the context of disaster triage. He argues that in this circumstance the social contractors would favor *equal access* to scarce life-saving resources amongst those who need medical treatment in order to continue life.

The contractors would also be mindful of *efficient* use of the limited resources in order to maximize the probability of saving the most lives. Using this interpretation of what is 'just', Winslow predicts which approaches the contractors would support and oppose.

3. Is the strategy legal?

Legality will be granted to those strategies that are legitimate exercises of public health power enumerated by the California Health and Safety code.

4. Is the strategy politically feasible?

Political feasibility will be determined by whether the strategy is likely to be accepted by the majority of the population, including both constituents and political representatives.

5. Can the strategy be practically implemented given the emergency circumstances?

Ease of implementation will be based on whether the relevant group can be easily identified. Other facets of implementation (such as administrative time and money required to implement the strategy) are discussed in *Annex H. An Analysis of Implementation Options* (p **Error! Bookmark not defined.**).

All of the tests were evaluated on a points scale. Each strategy was allocated between zero and two points, with zero points indicating that the strategy does not pass the test and two points indicating that the strategy is completely acceptable based on the given criteria. Receiving one point indicates that either there are some reservations about the strategy or that the acceptability of the strategy is uncertain.

To move on for further analysis, each strategy must pass all of the tests; in other words, each strategy must receive one or two points on all of the tests. Because minimizing health consequences is of utmost importance during an emergency, any strategy that receives zero points on the first test will not be passed on for subsequent tests.

D. Evaluating the strategies

Four of the nine strategies were deemed acceptable for further analysis. These strategies passed all five of the tests, though with varying final scores. These strategies include the following:

1. Rationing by probability of successful immunization (Score: 9/10)
2. Rationing to those who perform an essential emergency response role (Score: 10/10)
3. Rationing to those who perform an essential community role (Score: 7/10)
4. Rationing by medical and prevention needs (Score: 10/10)

Table 3 below summarizes the results of these tests.

TABLE 3: EVALUATING RATIONING STRATEGIES								
Strategy	Test 1: Minimizes illness/death	Test2: Fair/just strategy	Test 3: Legal	Test 4: Politically feasible / appropriateness	Test 5: Feasible to implement	Final Score	Pass or Fail	
Utilitarian Strategies								
<i>Utilitarian Strategies</i>								
Ration by probability of successful immunization	2	2	2	2	1	9	Pass	
Ration to those who perform essential emergency response role	2	2	2	2	2	10	Pass	
Ration to those in a caretaker role	1	0	2	0	0	3	Fail	
Ration to those who perform essential community role	1	1	2	1	2	7	Pass	
<i>Egalitarian Strategies</i>								
Do not ration vaccine	0	--	--	--	--	0	Fail	
Ration by medical and prevention needs	2	2	2	2	2	10	Pass	
Ration to those with limited access to medical care	1	2	2	0	0	5	Fail	
Ration via queuing	1	1	2	0	2	6	Fail	
Ration via lottery	1	2	2	0	2	7	Fail	

Below is a brief discussion of how the nine rationing strategies fared in this filtering process.

Test 1: Minimize health consequences

Three strategies—rationing by “probability of successful immunization,” to those who “perform essential emergency response roles,” and to those with the “greatest medical and prevention needs”—have the highest likelihood of saving and preserving lives and therefore received full points on this test.

Several strategies—rationing to those in a “caretaker role,” to those who “perform essential community roles,” to those with “limited access to medical care,” via “queuing,” and via “lottery”—will most likely be able to *reduce* the number of illnesses and deaths. However, since it is unknown whether vaccinating the people covered under these strategies will result in additional lives saved or preserved, it is unknown whether these strategies will actually *minimize* health consequences. Because of these unknowns, these methods received 1 point.

One rationing strategy—“do not ration vaccine”—failed this test. Withholding available vaccine from the public will not reduce or minimize the number of illnesses and deaths and therefore will not be able to reduce economic or social consequences. This strategy was therefore excluded from further analysis.

Test 2: Justice

Five strategies received full points on the justice test. Two strategies—rationing by “medical and prevention needs” and via “lottery”—are direct applications of the ‘fair equality of access’ principle. Rationing by “medical and prevention needs” is at the essence of egalitarian thought and justice. Equality demands that each person achieves the same level of well being as every other; it does not demand that people receive the same physical treatment. Therefore, treating those with the greatest medical need will ensure that these individuals achieve the same health status as those that are less needy. Rationing by “lottery” is a “pure” way to achieve equal access to the resource amongst those of medical need. This approach gives everyone whose life is in jeopardy an equal opportunity for treatment.

Three strategies received full points (because they would be accepted by the social contractors in Rawls’ theory of justice) but were understood as limitations on the principle of equal access. First, rationing by “probability of immunization success” is an example of efficiency trumping the desire to strictly support equality of access. This strategy does not ensure equal access based on need, but by providing the vaccine to those who are most likely to live if treated, this strategy would save the largest possible number of lives.

Second, rationing to those with “minimal access to medical care” is an application of the “difference” principle. This principle advocates for the *unequal* distribution of resources so that the greatest benefit for the least favored can be achieved.⁶

Finally, rationing by “essential emergency role” is another instance in which efficiency would trump equal access. In a disaster context, contractors would depart from equality of access in order to give priority to those most likely to *save more lives* under the immediate circumstances. In other words, rationing to essential emergency workers is a means of securing the delivery of life-saving treatment, which would in turn help maximize the number of lives saved.

Two strategies—rationing to those who perform “essential community roles” and via “queuing”—were given one point on this test in order to reflect the uncertainty on the justice test. Rationing to those who perform “essential community roles” is an example of an unequal distribution of resources so that *all of society* can receive some benefit (such as functioning transportation, electrical, and food production systems). Winslow speculates that the contractors would be unwilling to sacrifice equal access to a *life-saving* resource in order to receive these other benefits. However, those who perform essential community roles do indirectly support those who perform essential emergency

⁶ The contractors would be unlikely to support rationing to those who are in “general need” because this would require a form of restorative justice, meaning that inequalities in other areas are being compensated with life-saving goods. The only circumstance in which this would be acceptable is if the disadvantage the needy group experiences have somehow led to their medical need. Because we have redefined “general need” into “limited access,” the approach more clearly aligns with the tenets of the “difference principle” and is acceptable to contractors.

response roles. If the basic community infrastructure (e.g., transportation, communication, power) ceased to function properly, the efforts of emergency responders to perform life saving/life preserving duties would be significantly hindered. By interpreting the “difference” principle in this way, rationing to those who perform “essential community roles” would be deemed “just”.

Similarly, it is uncertain that contractors would support “queuing” as the primary means of achieving equal access to limited resources. This is due to facets of human behavior, social structures, and health limitations. In terms of human behavior, it is likely that individuals will try to “cut in line” in order to improve their chances of receiving the life-saving resources. In terms of social structures, individuals with increased wealth, power, information, and contacts will likely circumvent the queue in order to gain a competitive advantage. In terms of health limitations, individuals who are too ill and/or handicapped to wait in line will lose their access to the limited resource. If contractors were certain that these inequities would be sufficiently addressed, they may support this strategy. Otherwise, they would likely reject this strategy in favor of another.

The final strategy—rationing to “caretakers”—received zero points on this test. Rationing by “parental role” is unjust because the strategy is biased against single and dependent-free individuals and systemically denies them equal access to needed medical resources.

Test 3: Legality

The California Department of Health Services (CDHS) can legally implement all of the rationing strategies and the strategies were therefore given full points. California Health and Safety Code grants very broad powers to CDHS and to local health officers during a declared state of emergency. Specifically, the California Health and Safety Code section 121045 gives health officers the authority to “quarantine, isolate, and *disinfect persons*, animals, houses, rooms, or other property, places, cities, localities, whenever in its judgment the action is necessary to protect and preserve public health” [emphasis added]. Furthermore, the California Emergency Services Act (ESA) allows the governor to declare a state of emergency and exercise the entire police power of the State. When a state of emergency is declared, which is a certainty in the event of an influenza pandemic, city and county health officers retain the authority to “take any preventive measure that may be necessary to protect and preserve the public health from any public health hazard” (Government Code sec code 101040, 101475). As such, all of the remaining strategies are within CDHS’ legal powers to implement.

Test 4: Political Feasibility

Three strategies received full points on this test—rationing by “probability of successful immunization,” by “medical and prevention needs,” and to those who “perform an essential emergency response role.” These three strategies are already standard emergency medical practices. No literature was found that disputed the legitimacy or appropriateness of these strategies.

One approach—rationing to those who “perform essential community roles”—received 1 point on this test. Though these roles are critical to the basic functioning of society, not all will be in a life-saving/life-preserving capacity. Some constituents may dispute this rationing method because it is difficult to determine which community roles are the most essential. This could lead to favoring professionals whose jobs require advanced

training over other workers. This can add an educational bias occupations against individuals who may not have been able to pursue these professions due to social injustices (e.g., class, race, and/or gender). Since this strategy could come under scrutiny by both politicians and their constituents, it receives one point on this test.

Four strategies received zero points on the political feasibility test. Allocating to those with “limited access to medical care” is often used because those people who would qualify for vaccination under this strategy often have health conditions that increase their risk of complication from disease; in other words, “limited access” is often used as a proxy for elevated medical need. Since we have already captured medical need within another strategy, this strategy is redundant and unnecessary. Therefore, this strategy would not be politically acceptable.

Neither “queuing” nor “lottery” would be acceptable as a primary rationing strategy. In terms of “queuing,” it is unlikely that constituents would be supportive of a policy that required all needy California residents to wait in line for immunization day after day. Furthermore, those constituents that are unwilling or unable to wait in line (elderly, pregnant women, some professionals) would not accept this approach. Similarly, it is unlikely that California residents would accept a policy that required all needy California residents to monitor a weekly or monthly lottery for the available doses.

Finally, rationing to “caretakers” as a primary strategy would inevitably come under scrutiny due to its lack of basis in clinical reasoning and its disregard for equality between people of different lifestyles and statuses.

Test 5: Feasible to Implement

Five strategies received full points on Test 5. Neither rationing by “queuing” nor “lottery” requires target groups to be pre-identified. The entire California population needs the vaccine and therefore they will be combined into a single target group. Because of this ease in identifying group members, both of these strategies receive full points.

Given that “medical need” is largely based on an individual’s health status, this group can be fairly easily identified. Individuals with “prevention needs” are largely defined by their professional roles as are individuals who perform an “essential emergency response” and/or “community role”. Once it is determined who qualifies for vaccine under these strategies, which poses a surmountable challenge to the State, it should not be difficult to identify and communicate with the organizations that employ these professionals.

One strategy—rationing by “probability of successful immunization”—received fewer points but can be implemented. Rationing by “probability of successful immunization” may be a challenging strategy to implement because the State will not know precisely which groups are experiencing the highest levels of vaccine effectiveness until data from the pandemic are collected and analyzed. As a proxy, the State can assume that rates of effectiveness will be similar to those observed during interpandemic years.

Finally, two strategies—rationing by “general neediness” and by “parental role”—received zero points on Test 5. Allocating by “general neediness” and “parental role” are challenging due to the process of identifying who falls within these categories. Meaning, what is the cutoff on “need” and “number of dependents?” Furthermore, creating a

verification system (to ensure that potential vaccine recipients are actually qualified for vaccination under the given system) would probably be burdensome and wasteful.