STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
OFFICE OF PUBLIC HEALTH PREPAREDNESS

Ethical Guidelines for Allocation of Scarce Medical Resources and Services During Public Health Emergencies in Michigan

Version 1.0

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Record of Changes

Change Number	Description of the change and/or the affected part of the EOP	Date of Change	Person Responsible
1		8/26/2010	

Ethical Guidelines for Allocation of Scarce Medical Resources and Services During Public Health Emergencies in Michigan

Executive Summary

The Ethical Guidelines for Allocation of Scarce Medical Resources and Services during Public Health Emergencies in Michigan (Guidelines) presented in this report provide guidance to decision-makers throughout the state of Michigan to assist in making choices about resource and service allocation and prioritization during situations of scarcity that may arise during public health emergencies. These Guidelines do not present a formalized series of instructions but rather a set of criteria that can be employed by decision-makers in various circumstances during a public health emergency using their best professional discretion.

Assumptions

The Guidelines incorporate eight assumptions that help define their scope and purpose:

1. Public health emergencies give rise to unique public health challenges that can lead to, and be exacerbated by, scarcity of medical resources and services.
2. The likely conditions during public health emergencies may be anticipated even in emergency circumstances that arise from sudden, extraordinary, or temporary events.
3. Emergency planners have an ethical duty to provide guidance related to the ethical allocation of scarce medical resources and services during public health emergencies.
4. The Guidelines apply to public health emergencies, not everyday scarcity of medical resources and services.
5. The Guidelines apply to allocation decisions made by decision-makers at different levels of government and as well as the private and nonprofit sectors.
6. The Guidelines apply to allocation decisions affecting all medical resources and services that may become scarce during a public health emergency.
7. The Guidelines employ ethical principles that take into account both individual health and population health.
8. The Guidelines should be implemented in ways that comply with all relevant laws at the federal, state, and local levels.

Goals

The Guidelines recognize three salient goals in determining the allocation of scarce medical resources and services during public health emergencies. First, efforts should be made to protect and maintain the public's health through *minimizing morbidity and mortality*. Second, we should strive to *sustain a functioning society* through actions

to preserve the capacity to deliver health care, public health, public safety, and other social services and critical infrastructure. Efforts to promote trust, transparency, and understanding among the public regarding allocation decisions also support this goal. Third, decisions about how scarce medical resources and services are allocated should *ensure fairness* and endeavor to achieve equality. These goals are listed in no order of hierarchy – all are equally important to achieve.

Ethical Considerations

The committee identified numerous underlying ethical considerations that guide the structure, procedures, and recommendations outlined in these Guidelines. These ethical considerations include **beneficence** (preserving the welfare of others through affirmative acts to promote well-being and save lives); **utility** (achieving the greatest good for the greatest number); **fairness** (applying consistent, equitable, and non-discriminatory policies); **transparency** (providing open access to information and decision-making processes); **accountability** (holding decision-makers responsible for their actions); **veracity (**truth-telling); **respect for persons** (upholding individual autonomy, privacy, dignity, and bodily integrity); **proportionality** (demanding policies necessary and proportional to the scope and severity of the circumstances); **solidarity** (shared obligations and social cohesion); **reciprocity** (compensating someone for past actions or deeds); **stewardship** (preserve the effectiveness and impact of these resources and services as best as possible).

Allocation Criteria

Green light: Acceptable Allocation Criteria

The Committee identified two general criteria considered acceptable for guiding allocation decisions: *medical prognosis* and *essential social functions*. These criteria should be considered in conjunction with each other when evaluating allocation decisions.

1. Medical prognosis. Medical prognosis should be used to determine priority of access to scarce medical resources and services during public health emergencies. Decision-makers should consider the patient's medical condition, the likelihood of a positive medical response, the relative risk of harm posed by not treating the patient, and other indicia of survivability and favorable medical outcomes.
2. Essential social functions. Workers who perform essential social functions, i.e., those deemed critical for the ongoing functioning of society should receive priority access to scarce medical resources and services. Essential personnel may include:
    - health care workers who are directly treating patients affected by the public health emergency (doctors, nurses, etc.);

- personnel key to responding to the public health emergency (first responders, public health scientists, etc);
- personnel key to public safety (police, fire, military, etc.); and
- personnel key to critical infrastructure (energy grid, telecommunications etc.).

3. Applying the Acceptable Allocation Criteria. The acceptable allocation criteria of medical prognosis and essential social functions may apply to a number of different groups of people, requiring additional decisions to be made regarding the prioritization of scarce medical resources and services. The Committee reached the following conclusions regarding the ordering of priority among people who meet one or both of the two acceptable allocation criteria described above:

    Tier 1 (highest priority):
    - Essential personnel with high risk of severe morbidity or mortality and favorable medical prognosis
    - Essential personnel that are irreplaceable with a favorable medical prognosis
    - Essential personnel that have high occupational exposure with a favorable medical prognosis
    - Groups with high risk of severe morbidity or mortality with a favorable medical prognosis

    Tier 2 (elevated priority):
    - Essential personnel with a favorable medical prognosis
    - Groups with elevated risk of severe morbidity and mortality with a favorable medical prognosis
    - Groups with moderate risk of severe morbidity and mortality that have a high risk of exposing others (may not apply in some public health emergencies)

    Tier 3 (lowest priority):
    - All eligible groups

Yellow light: Situation-Dependant Allocation Criteria

The Committee identified three criteria—*age*, *lottery*, and *first-come, first-served*—that could be considered for medical resource and service allocation under limited circumstances due to their controversial nature. The Committee acknowledges that reasonable decision-makers may disagree on whether these criteria are appropriate to use. Yet, these criteria may be useful if scarcity requires prioritization between people who would be indistinguishable on the basis of the acceptable criteria of medical prognosis and essential social functions.

1. Age: Granting priority to access scarce medical resources or services based on numerical age, quality-adjusted life-years, disability-adjusted life-years, or some

other measurement based upon longevity or functioning raises several difficult issues. It may be fair to allow a younger person to have the chance to live to an older age, given that older people have already had the opportunity to experience those phases of life. But this approach goes against equality in the sense that it is making an explicit differentiation between people on the basis of numerical age.

2. Lottery: A lottery approach gives each eligible person an equal random chance to be selected to receive scarce medical resources or services. Advantages include: truly random, and therefore fair, allocation across the population. But a lottery does not allow targeting of resources for maximum population health benefit and could be complicated to administer. The Committee considered the use of a lottery approach as a tie-breaker between potential recipients of scarce medical resources and services in the event that all other criteria are equivalent and scarcity persists.
3. First come/First served: This approach favors those with existing informational, social, and economic advantages. However, it is the easiest to administer and generally accepted in non-emergency situations.

Red light: Unacceptable Allocation Criteria

The Committee identified several criteria that are unacceptable to consider when making allocation decisions, due to their inherent lack of fairness, potential for abuse or discrimination, or irrelevance to achieving the goals set out in these Guidelines.

1. Social characteristics: Social characteristics, including but not limited to race, ethnicity, gender, national origin, sexual orientation, religious affiliation, and disability unrelated to immediate medical prognosis, should not be used as criteria in making resource or service allocation decisions during public health emergencies. These characteristics serve no meaningful purpose in differentiating between people in the context of allocation decisions. Moreover, categorization of people according to these types of characteristics is often used as pretext for favoritism, discrimination, and reduced access for minority groups. Therefore, use of social characteristics as allocation criteria is unacceptable.
2. Social worth: The discussion of acceptable allocation criteria (in section V.A. above) recognizes that limited categories of people who provide specific social functions, namely groups of identified essential personnel, may be granted priority access to scarce resources and services during a public health emergency. However, beyond these limited categories, factors that take into account a person's social worth are not acceptable to consider for allocation decisions. Social worth criteria are generally unacceptable because they can lead to unfair decisions based on subjective determinations of a person's background or characteristics, which can in turn lead to stigma, bias, greed, or nepotism in allocation decisions. Unacceptable factors under this category would include but are not limited to job status, training or education, social standing, personal or familial relationships, belief systems, political affiliations, or any other

measurement of a person's social value. In particular, the Committee found unacceptable any sort of decision-making process that considered a person's ability to pay for medical resources or services as relevant to prioritizing resources or services. Similarly, it would be inappropriate for providers of medical resources and services to take into account the financial or economic consequences of a person's ability to pay in making allocation decisions for scarce medical resources or services.

Implementation

1. Efforts should be made to eliminate scarcity prior to having to implement allocation guidelines. At all levels of planning, from the state government to individual health care institutions, efforts should be made to acquire sufficient levels of medical resources and services to alleviate the need for rationing these resources and services whenever possible through coordinated plans to share, stockpile, and estimate needed resources in advance of a predictable public health emergency scenario. The implementation of these Guidelines should only occur after all reasonable efforts to avoid scarcity have been explored.

2. The probability of scarcity occurring should be assessed and planning should occur to prepare for scarcity.

3. Criteria should be offered to determine when scarcity exists and when prioritization guidelines should be used. The Guidelines should only go into effect after conditions of scarcity have developed using the following factors:

- Nature of scarcity
- Duration of scarcity
- Severity of scarcity

4. Fair and transparent processes. Allocation decisions made under conditions of scarcity should adhere to clear and specific processes to ensure that these decisions are not being made in an unjust or discriminatory manner.

5. Prioritization guidelines and decisions should be reviewed continuously and periodically assessed. The policies and practices that emerge from these Guidelines should receive ongoing scrutiny to assure their relevance to the circumstances at hand. Periodic reassessment of an individual patient's qualifications to receive, or be excluded from receiving, scarce medical resources and services pursuant to these Guidelines also should be undertaken.

6. Prioritization guidelines should be used consistently across the state. Consistency in implementation of the Guidelines will promote fairness in access to scarce resources and services and will defuse allegations of favoritism and efforts to "venue-shop" for medical resources and services. However, local conditions may require

allocation decisions to deviate from statewide guidance under some circumstances. Decision-makers who are departing from common guidance should only do so after careful deliberation and documentation.

7. Decisions to implement prioritization should be made by persons removed from the clinical context. To minimize conflicts of interest and difficult interactions at the clinical care level between health care providers and patients, decisions regarding when to apply these Guidelines should be made by decision-makers removed from the clinical context whenever possible. Health care professionals should not be required to determine which patients qualify as essential personnel. This determination should be made by decision-makers removed from the direct clinical relationship.

8. Palliative care resources should be provided consistently throughout a public health emergency. Access to palliative care resources and services should be provided to individuals who will not have access to some scarce medical resources and services based on allocation decisions.

I. Introduction

Effective public health emergency preparedness requires thoughtful planning and proactive anticipation of the likely needs of various sectors of the population during a public health emergency. Decision-makers must consider carefully the development and implementation of practical, logistical, and scientific methods that will be necessary for effective response and recovery initiatives. The state of Michigan, through the efforts of the Michigan Department of Community Health (MDCH) Office of Public Health Preparedness (OPHP), has made extensive progress in developing health-focused preparedness planning within the state. A number of ongoing initiatives around the state seek to supplement the planning process by examining key ethical issues that may arise during public health emergency preparedness and response.

Public health preparedness efforts raise numerous challenging questions. One set of particularly difficult questions asks what we should do when necessary medical resources and services are in short supply during a public health emergency? How can we ethically allocate scarce medical resources and services during emergencies? How can we ensure that our decisions about allocation are effective, humane, fair, and consistent with our ethical values and goals? Answering these questions presents a difficult task, which we undertake in this report.

The Ethical Guidelines for Allocation of Scarce Medical Resources and Services during Public Health Emergencies in Michigan (Guidelines) presented in this report seek to respond to these questions and to provide insight into how decision-makers throughout the state of Michigan can make tough choices about resource and service allocation and prioritization if such decisions become necessary. These Guidelines will provide a template from which health care practitioners, partners and institutions in the health sector, and local and state officials can plan for situations involving an acute scarcity of medical resources and services. The Guidelines also will serve as a tool that will assist decision-makers at all levels in making difficult decisions related to allocation of medical resources and services in times of emergency-induced scarcity.

The Guidelines build upon the already extensive emergency preparedness and planning efforts undertaken by the state of Michigan, and will complement the existing plans through addressing complex issues related to allocation.

The Guidelines have been developed as a part of an ongoing project to gain consensus on ethical issues relating to allocation of scarce medical resources and services during emergencies. The primary objectives of this project are: 1) to engage in a collaborative process to address ethical issues related to allocating scarce medical resources and services that may arise during public health emergencies; and 2) to develop ethical guidelines and other support materials that meet the needs of state, regional, and local partners who may be faced with making difficult decisions during an acute emergency or incident that leads to scarcity of needed medical resources and services.

The Guidelines and all other materials produced through this project are the result of a state level, multi-disciplinary committee. The consensus views of this Ethics Advisory Committee do not necessarily represent the views of the state of Michigan or its departments.

The approach adopted by these Guidelines reflects similar concerns as other recent reports on the ethical and practical aspects of allocating scarce medical resources and services during public health emergencies. However, the Guidelines can be distinguished from similar guidance drafted by other jurisdictions in three notable ways.

1. The Guidelines take a broad approach to addressing scarcity of resources and services during public health emergencies. They are structured to be applicable to public health emergencies of varying types and to assist in allocation decisions affecting multiple types of resources. This approach contrasts with many similar efforts in other states and at the national and international levels addressing more targeted allocation questions.[1] For example, several other states have addressed the ethics of scarce resource allocation with regard to specific types of emergencies (e.g., pandemic flu)[2] or specific types of resources (e.g., ventilators or vaccines).[3] While these other existing models provide useful frameworks in their respective contexts, the Guidelines outlined in this report will provide a model that can be applied in numerous different circumstances to address the ethical allocation of a wide range of potentially scarce resources.

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[1] A notable exception is the recent report on crisis standards of care produced by the Institute of Medicine, which does take a more generalized approach to the ethics of scarce resources allocation in disaster situations. INSTITUTE OF MEDICINE, GUIDANCE FOR ESTABLISHING CRISIS STANDARDS OF CARE FOR USE IN DISASTER SITUATIONS: A LETTER REPORT (2009). Further referred to as "IOM Report".

[2] Ethics reports produced by authors in Canada as well as the states of Minnesota and Indiana, all of which focus on pandemic influenza. Dorothy W. Vawter et al., "For the Good of Us All: Ethically Rationing Health Resources in Minnesota in a Severe Influenza Pandemic" (2009). Available at: http://www.ahc.umn.edu/mnpanflu/preliminary/rationing/home.html. Indiana State Department of Health. 2008. *Confronting the Ethics of Pandemic Influenza Planning: Communique from the 2008 Summit of the States*. Available at:
http://www.bioethics.iu.edu/communique_2008_summit_of_the_states.pdf
University of Toronto Joint Centre for Bioethics. (2005). *Pandemic influenza and ethics – stand on guard for thee: Ethical considerations in preparedness planning for pandemic influenza.* Available at: http://www.utoronto.ca/jcb/home/documents/ pandemic.pdf.

[3] New York, for example, has produced an allocation planning document dealing specifically with ventilators. See New York State Workgroup on Ventilator Allocation in an Influenza Pandemic (2007). *Allocation of ventilators in an influenza pandemic: Planning document draft*. Available at;
http://www.health.state.ny.us/diseases/communicable/influenza/pandemic/ventilators/docs/ventiltaor_guidance.pdf

Creating an ethical allocation framework that can be applied to multiple emergency situations and varying types of medical resource and service scarcity presents a daunting challenge. To achieve this standard, the Guidelines must simultaneously be flexible enough to provide useful guidance in a variety of circumstances and also sufficiently concrete to provide meaningful support in specific situations. We have approached this quandary by providing both general goals and ethical criteria in the body of the Guidelines as well as more specific information in the appendices applying these ethical criteria in various situations.

2. The Guidelines focus on the state of Michigan and are designed to provide targeted guidance to practitioners and officials in the state. From its inception, this project has endeavored to ensure that ethical discussions reflect the values and decisions of the residents of Michigan. Consistent with this goal, these Guidelines have been developed with extensive input from representatives from a variety of constituencies across the state, reflecting a diversity of expertise, geography, and knowledge.[4]

3. The Guidelines consider the ethical implications of allocating scarce medical services as well as scarce medical resources. While the availability of medical resources (such as medication, medical equipment, ICU beds, health care personnel) and medical services (such as routine wellness care, elective surgery) is often closely connected, the factors in making these allocation decisions may raise different ethical and practical considerations.

These Guidelines are not envisioned as a formalized series of instructions but rather a set of criteria that can be employed by decision-makers in various circumstances during a public health emergency using their best professional discretion. It is expected that these Guidelines will be utilized to develop more detailed allocation plans at various levels throughout the state. Thus, the criteria offered within these Guidelines are meant to be malleable, adaptable, and functional. However, extreme or unforeseeable circumstances may challenge the foundations of the framework. In those situations, decision-makers will be expected to use their professional training and prudence to guide allocation decisions. The criteria offered here may have to be amended to address unforeseen circumstances and should be periodically reviewed and updated to incorporate

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[4] There have been several other efforts to address the ethical issues that may arise during an influenza pandemic at the regional and hospital levels in Michigan. Two reports in particular have been helpful in our drafting of these Guidelines: 1) Spectrum Health, Caring for the Community: Preparing for an Influenza Pandemic, Ethics Committee Report (2009) further referred to as "Spectrum Ethics Report"; and University of Michigan Hospitals and Health Centers Pandemic Planning Committee Ethics Team, Guidelines for Allocating Life-Saving or Critical Resources During a Pandemic (working draft, August 28, 2009) further referred to as "University of Michigan Ethics Guidelines."

new information gained from practical experience. Successful implementation of the Guidelines will demand ongoing deliberation, transparency, public education and input, and careful evaluation and oversight.

II. Assumptions

There are many relevant ethical and practical considerations to be taken into account in developing appropriate guidelines for allocation of scarce medical resources and services during a public health emergency. The sections below outline some of the assumptions being used to inform our discussion of the Guidelines.

1. Public health emergencies give rise to unique public health challenges that can lead to, and be exacerbated by, scarcity of medical resources and services. During a public health emergency, health conditions could be dire and may require health workers and government officials to make difficult decisions regarding allocation and prioritization that would not be acceptable under normal conditions. Hospitals and other providers of health services may have to resort to triage techniques and supplies may have to be rationed due to scarcity. Emergency preparedness laws and policies recognize that the legal and operational environment changes during a public health emergency.[5]

2. The likely conditions during public health emergencies may be anticipated even in emergency circumstances that arise from sudden, extraordinary, or temporary events. Some types of public health emergencies present scenarios that are likely to give rise to predictable scarcity in medical resources and services. In other cases, public health emergencies may occur without advance warning, pose unanticipated and extraordinary threats to health, and last for a limited or uncertain duration. Regardless, many of the consequences that may arise during public health emergencies are foreseeable and therefore planning and preparedness efforts, along with proper implementation and response, can mitigate some of the negative impacts of the emergency.

3. Emergency planners have an ethical duty to provide guidance related to the ethical allocation of scarce medical resources and services during public health emergencies. Given that conditions of medical resource and service scarcity are often predictable during public health emergency situations; emergency planners have an obligation to provide guidance to aid decision-makers in navigating the difficult ethical issues that pertain to prioritizing scarce resources and services during public health emergencies. Since allocation decisions impact health across the population and may greatly affect the ability to achieve important public health goals, public health officials at the state level should take a leading role in promulgating this guidance to ensure consistency, visibility, and accountability for the Guidelines. Beyond the state-level guidelines provided in this document, other persons and organizations engaged in emergency planning also should prospectively consider providing targeted ethical

[5] The Michigan Public Health Code (MCL §§ 333.1101 et seq.) and the Michigan Emergency Management Act (MCL §§ 30.401 et seq.) both have detailed provisions for authorizing legal powers during public health emergencies.

guidance to their respective constituencies regarding the ethical allocation of scarce medical resources and services during public health emergencies.

4. The Guidelines apply to public health emergencies, not everyday scarcity of medical resources and services. These Guidelines are drafted to deal with allocation decisions that may occur during the extraordinary circumstances created by a public health emergency, when these circumstances give rise to medical resource scarcity. In so doing, the Guidelines consider, and are based on, the atypical circumstances of public health emergencies and the heightened risks to morbidity and mortality that may arise in these situations. Therefore, the Guidelines should only apply to public health emergencies as defined in attachment 2, which are severe events with the potential for widespread morbidity and mortality. The Guidelines are not meant to be applied to decision-making related to allocation of scarce medical resources in other situations.

5. The Guidelines apply to allocation decisions made by decision-makers at different levels of government and as well as the private and nonprofit sectors. One complexity of making ethical decisions regarding allocation of scarce medical resources and services during public health emergencies is that decisions will, by necessity, be made on multiple levels: 1) at the individual level between patients and health care practitioners in both clinical and non-clinical settings; 2) at an institutional level within a hospital, clinic, or other health care site; 3) at a local/regional level; 4) at the state level; and 5) at the national level. These Guidelines therefore consider who will be making the decisions at these respective levels and the effects of decisions from one level on the others. In addition, the Guidelines are designed to be useful to decision-makers at all levels. The Guidelines strive to complement and be consistent with other ethical guidance promulgated throughout the state of Michigan and nationally.

6. The Guidelines apply to allocation decisions affecting all medical resources and services that may become scarce during a public health emergency. During a public health emergency, a variety of medical resources and services may become scarce. The Guidelines view medical resources broadly to include medications, medical devices, medical supplies, and medical professionals. Medical services include the administration of medical care in a variety of settings by a variety of health care practitioners. While the ethical considerations relevant to allocating these various resources and services in differing situations may vary in application, the principles, goals, and strategies suggested by the Guidelines should apply to the full range of decisions. Therefore, the Guidelines should inform both public health-level resource and service allocation decisions and medical-level resource and service allocation decisions during public health emergencies.

7. The Guidelines employ ethical principles that take into account both individual health and population health. Scarce medical resource and service allocation decisions have substantial population-level health effects as well as individual-level health effects. Therefore, decision-makers may need to consider the impact of their allocation decisions

on population health. The Guidelines recognize this consideration by incorporating ethical principles derived from individual bioethics and public health ethics.[6]

8. The Guidelines should be implemented in ways that comply with all relevant laws at the federal, state, and local levels.

[6] A detailed explanation of the relevant ethical considerations utilized in this Report is included in Section IV of this report.

III. Goals

The Guidelines recognize three salient goals in determining the allocation of scarce medical resources and services during public health emergencies.[7] First, efforts should be made to protect and maintain the public's health through *minimizing morbidity and mortality*. Second, we should strive to *sustain a functioning society* through actions to preserve the capacity to deliver health care, public health, public safety, and other social services and critical infrastructure. Efforts to promote trust, transparency, and understanding among the public regarding allocation decisions also support this goal. Third, decisions about how scarce medical resources and services are allocated should *ensure fairness* and endeavor to achieve equality.

These goals are not listed in any particular order of priority and should be pursued concurrently. Several participants in the Committee discussions suggested that these three goals may have different priorities at the clinical level versus the state level and that guidance should be directed accordingly to help at both levels. For instance, the hospital level decision-makers are looking for guidance to help with situation management, while the state level may be focused on minimizing morbidity and mortality levels.

The specific ethical justifications underlying these goals and the principles designed to achieve them are outlined in more detail below.

Minimizing morbidity and mortality: The Ethics Advisory Committee had a general consensus that protecting the public's health was an important goal. Some committee members suggested that this goal should be the primary factor in making allocation decisions. However, a focus on reducing morbidity and mortality alone is not a sufficiently robust goal to direct allocation decision-making. First, achieving this goal faces some inherent difficulties related to the uncertainties of assessing risk and predicting patient outcomes at the population level. Moreover, public health emergencies create risks to population health that go beyond the direct health impacts of the emergency. If critical services become unavailable and there is a fraying of the social order, health consequences may be exacerbated.[8]

Suggestions to minimize morbidity and mortality include:

- employ evidence-based, scientific criteria for decision-making regarding resource and service allocation;
- make allocation decisions based on medical prognosis of a good health outcome rather than by which patient is worst off at the time.

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[7] These goals are adapted from the approach proposed by the state of Minnesota. See Dorothy W. Vawter et al., "For the Good of Us All: Ethically Rationing Health Resources in Minnesota in a Severe Influenza Pandemic" (2009). Available at: http://www.ahc.umn.edu/mnpanflu/preliminary/rationing/home.html.

[8] See "For the Good of Us All" at 14.

Maintaining the social fabric: The Committee determined that several considerations supported the goal of maintaining the social fabric. Targeting scarce medical resources and services to support the ongoing functioning of important social institutions alleviates pressure on systems critical to societal functioning, including health care, public health, critical infrastructure, and public safety. These systems provide needed services to the community, protect against civil disorder, and facilitate efforts to respond effectively to the public health emergency. Committee members also pointed out that the complexity of maintaining a functioning society may be too much to ask of these Guidelines.

There was a robust debate on the issue of which categories of people with which vital skill sets to perform necessary societal functions should receive priority, particularly since granting prioritization based on profession was generally objected to by the Committee. Some groups identified as essential to societal functioning included health care workers, emergency responders, energy workers, police, military personnel, sanitation workers, supply distribution workers, and manufacturers of medical supplies. Maintenance of the health care infrastructure itself was deemed a particularly high priority to the Committee.

An additional consideration for maintaining the social fabric centers on public acceptance of allocation decisions and the ethical justifications for those decisions. Members of the public should have access to information about allocation priorities and the methods by which allocation decisions will be made in public health emergency circumstances. The public should also have an ample opportunity to comment on and provide input to emergency planners regarding these allocation priorities. Fostering transparency, accountability, and an informed populace will increase public support and confidence in the way that scarce medical resources and services will be allocated and will thereby enhance the stability of the social fabric during potentially difficult times.

Suggestions to maintain the social fabric include:

- identify specific groups that are essential to maintaining a functioning society and granting members of these groups some level of priority in accessing scarce medical resources and services;
- provide a process for members of essential groups to be quickly and clearly identified;
- provide a process for members of essential groups to receive access to medical resource and services that minimizes the need for individual health care professionals to have to make judgment calls about whether a person qualifies for priority access;
- solicit public feedback on allocation and prioritization plans;
- provide access to allocation guidance to members of the public through many forms of media;

- alert the public promptly to any changes to prioritization plans.

Ensuring fairness: The Committee included fairness as a core goal based upon the fundamental role that fairness plays in both ethical and legal discourse in our country. Fairness recognizes the moral equality of all people and the inappropriateness of treating people disparately in allocation decisions. The Committee recognized the difference between fair access and equal access. Adopting criteria and procedures that fairly allocate resources and services based on pre-determined decision criteria was favored strongly by the Committee, but many acknowledged that equal access (or some measures of equality) would not be feasible under the circumstances of a serious emergency. Moreover, it was noted that the public would understand that equal access is not always possible or appropriate. Many people will be willing to accept a fair process even if they are not fortunate to be at the top of the list for access and some will want to give up their right to access (choose a risk of illness or death) in order to save others. The Committee also acknowledged that tension may exist between what is fair and what is the best overall health outcome during an emergency situation.

Suggestions to ensure fairness include:

- outline fair procedures for decision-making related to allocation decisions;
- endeavor to reduce significant health outcome disparities across demographic categories in the population and across geographic regions of the jurisdiction;
- develop a fair process for allocating resources and services between individuals with equal priority;
- provide the highest level of medical care possible under the circumstances, including palliative care services.

IV. Ethical Considerations

The committee recognizes several underlying ethical considerations that guide the structure, procedures, and recommendations outlined in these Guidelines. These ethical considerations are not listed in any particular order of importance or priority. Rather, any or all of these considerations should be taken into account by those responsible for making allocation decisions during a public health emergency.

Beneficence is the duty to preserve the welfare of others through affirmative acts to promote well-being and save lives. In the context of public health emergencies, beneficence requires that decisions regarding the allocation of scarce medical resources and services strive to protect the welfare of individuals and the community as a whole. The duty of health care professionals and health institutions to provide the best possible care and services to patients is grounded in beneficence as well as notions of professional competence. The related ethical consideration of **utility** suggests that decisions should be made in order to achieve the greatest good for the greatest number.

Fairness demands that the process and the criteria used for allocation of scarce medical resources and services during public health emergencies be consistent, equitable, and non-discriminatory. In the event of a public health emergency, **procedural justice** requires that fair and clear processes be used to make allocation decisions, and that members of society are afforded a fair chance of access based on non-discriminatory criteria. **Distributive justice** in this setting requires that the scarce medical resources and services are fairly and equitably distributed across society. This may require making specific provisions to ensure that access to scarce resources and services is available to vulnerable populations and groups in society affected by disparities in access to health care. Allocation criteria based on fair and equitable factors will promote predictable and consistent decision-making. Fairness does not require that all people have equal access to scarce medical resources and services, but it does require that if certain groups receive priority access to these resources and services, this priority is granted according to appropriate factors such as increased medical risk or susceptibility.

Transparency, accountability, veracity, and **trust** are cornerstones to implementing a plan to allocate scarce medical resources and services during a public health emergency. Transparency refers to providing open access to information and decision-making processes. This allows the public to be aware of the content of and the rationale for allocation decisions and fosters both accountability and trust. In addition, transparency promotes understanding and the opportunity for comment and participation by interested members of the population. Accountability of those making allocation decisions also promotes thoughtful, fair, and consistent decisions. The ethical principle of **veracity**, or truth-telling, similarly bolsters trust and accountability. Transparency, accountability, veracity, and fairness are necessary to create trust in the allocation processes and criteria. Generating trust helps to encourage compliance with and understanding of allocation decisions.

Respect for persons, the ethical notion that encompasses individual autonomy, privacy, dignity, and bodily integrity, must also be upheld, even during public health emergencies. The decision to provide palliative care resources throughout a public health crisis even if treatment resources and services are not available comports with the ideal of preserving dignity and promoting comfort and care even in the face of resource scarcity.

Proportionality demands that any allocation decisions made be necessary and proportional to the scope and severity of the circumstances.[9] Allocation decisions made under conditions of resource or service scarcity will necessarily create burdens on those providing and receiving care. These burdens should be minimized as much as possible, and the level of health care provided should only be adjusted as little as necessary to address the immediacy of the situation.

Solidarity, the concept that we are all in this circumstance together, binds the community in a sense of shared sacrifice and social cohesion. Solidarity encourages members of the community to accept the validity of allocation decisions so long as they are made transparently and fairly. This notion supports community collaboration and cooperation. This sense of community also promotes the duty of health care workers to continue to provide care and services despite the difficulties created by the situation. As a result of such dedication, the community may reward health care workers for their efforts. The principle of **reciprocity**—compensating someone for past actions or deeds—sustains such actions. Providing priority access to specific essential workers may serve ethical goals of efficiency and utility, but also comports with reciprocity.

Finally, the principle of **stewardship** requires decision-makers at all levels to allocate scarce resources and services to preserve the effectiveness and impact of these resources and services as best as possible. This can be a challenge since it requires decision-makers to weigh competing duties to care for individual patients and to preserve adequate resources for the community and for future needs.[10]

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[9] See IOM report (2009) p. 32.
[10] See IOM report (2009) p. 30.

V. Allocation Criteria

A. Green light: Acceptable Allocation Criteria[11]

The Committee identified two general criteria considered acceptable for guiding allocation decisions: *medical prognosis* and *essential social functions*. These criteria should be considered in conjunction with each other when evaluating allocation decisions. The sections that follow explain the substance of these two criteria and delineate how prioritization decisions regarding the allocation of scarce medical resources and services should be made when people meet one or both of these criteria.

1. Medical prognosis. Medical prognosis should be used to determine priority of access to scarce medical resources and services during public health emergencies. Decision-makers should consider the patient's medical condition, the likelihood of a positive medical response, the relative risk of harm posed by not treating the patient, and other indicia of survivability and favorable medical outcomes. Treating patients according to their medical prognosis directly supports the goal of reducing morbidity and mortality. It is consistent with ethical principles of beneficence, utility, and stewardship.

2. Essential social functions. Workers who perform essential social functions, i.e., those deemed critical for the ongoing functioning of society should receive priority access to scarce medical resources and services. The Committee agreed that workers who fall into these categories of people would be given priority because preserving their socially-useful functions will facilitate two of our overall goals: maintaining the social fabric and reducing morbidity and mortality. Essential personnel may include:

- health care workers who are directly treating patients affected by the public health emergency (doctors, nurses, behavioral and mental health professionals, etc.);
- personnel key to responding to the public health emergency (first responders, public health scientists, etc);
- personnel key to public safety (police, fire, military, etc.); and
- personnel key to critical infrastructure (energy grid, telecommunications etc.).

Giving priority to health care workers involved in treating and caring for the victims of a public health emergency serves the purpose of maintaining social functioning and the goal of minimizing morbidity and mortality. With respect to this second goal, prioritizing health care workers has an aggregative effect on reducing morbidity and mortality: not only does providing health care workers priority access mitigate risks to the health and well-being of these critical workers; it allows them to continue to assist

[11] The model of green, yellow, and red lights to indicate the appropriateness of allocation criteria was adopted from the Spectrum health pandemic influenza ethics report (2009).

other sick individuals. Prioritization in this way is grounded on ethical notions of utility, reciprocity, beneficence, and efficiency. Many of these same justifications apply to the other categories of essential workers listed above. The Committee stressed however that the use of essential social functions as defined above is the only acceptable measure of social worth to be used in allocation decision-making. Other considerations of social worth are inappropriate to use as decision-making criteria.

3. Applying the Acceptable Allocation Criteria. The acceptable allocation criteria of medical prognosis and essential social functions may apply to a number of different groups of people, requiring additional decisions to be made regarding the prioritization of scarce medical resources and services. The Committee reached the following conclusions regarding the ordering of priority among people who meet one or both of the two acceptable allocation criteria described above:[12]

Tier 1 (highest priority):

- Essential personnel with high risk of severe morbidity or mortality and favorable medical prognosis
- Essential personnel that are irreplaceable with a favorable medical prognosis
- Essential personnel that have high occupational exposure with a favorable medical prognosis
- Groups with high risk of severe morbidity or mortality with a favorable medical prognosis

Tier 2 (elevated priority):

- Essential personnel with a favorable medical prognosis
- Groups with elevated risk of severe morbidity and mortality with a favorable medical prognosis
- Groups with moderate risk of severe morbidity and mortality that have a high risk of exposing others (may not apply in some public health emergencies)[13]

Tier 3 (lowest priority):

- All eligible groups

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[12] These categories are adapted from models put forward by the state of Minnesota and the Department of Health and Human Services in their influenza pandemic allocation plans.

[13] This category will only apply in situations where the causative agent of the public health emergency is an infectious disease or otherwise transmissible agent that can spread from affected persons to others with whom they come into contact. For example, if the scarce resources is medication to treat an infectious agent that can be transmitted respiratorily, then health workers likely to come into contact with this agent through their occupational exposure may receive priority access to the treatment. In some cases, this group may include the close family members of essential personnel as well, due to their heightened risk of exposure.

B. Yellow light: Situation-Dependant Allocation Criteria

The Committee identified three criteria—*age*, *lottery*, and *first-come, first-served*—that could be considered for medical resource and service allocation under limited circumstances due to their controversial nature. The Committee acknowledges that reasonable decision-makers may disagree on whether these criteria are appropriate to use. Yet, these criteria may be useful if scarcity requires prioritization between people who would be indistinguishable on the basis of the acceptable criteria of medical prognosis and essential social functions. Criteria based on longevity or functioning, such as age or quality-adjusted life years could provide additional stratification among the population to assist with allocation decision-making. Alternatively, a random sorting process such as a lottery or a first-come, first-served model could be used. These criteria should only be used as secondary allocation criteria to medical prognosis and essential social functions. Further, these criteria should only be used with appropriate procedural protections, including advanced notice to the public that they will be used, to ensure that they are implemented fairly and transparently. This guarantee of adequate process comports with ethical notions of fairness, transparency, accountability, veracity, and trust.

1. Age: Granting priority to access scarce medical resources or services based on numerical age, quality-adjusted life-years, disability-adjusted life-years, or some other measurement based upon longevity or functioning raises several difficult issues. The "fair innings" argument states that everyone should have the opportunity to live a full life, and those therefore younger individuals should receive preference over older individuals. This approach comports with notions of equality in one sense and cuts against equality in another sense. It may be fair to allow a younger person to have the chance to live to an older age, given that older people have already had the opportunity to experience those phases of life. But this approach goes against equality in the sense that it is making an explicit differentiation between people on the basis of numerical age. It also undermines attempts to achieve intergenerational equity in allocation decisions.

   Other commentators have long tried to develop more sophisticated approaches and justifications for criteria based on longevity and functioning through the use of measurements such as quality-adjusted life years (QALYs) and disability-adjusted life years (DALYs). These measurements attempt to place a value on future life-years as opposed to just using numerical age as the relevant criteria. These approaches therefore adopt a different set of considerations, not just who will live the longest life, but also who will live the "best quality" life whether that is measured by health, self-satisfaction, or contributions to society. These approaches are problematic for some of the same reasons as the fair innings model, and in some ways they raise even more concern because they may introduce subjective evaluations of quality of life in the calculation.

2. Lottery: A lottery approach gives each eligible person an equal random chance to be selected to receive scarce medical resources or services. A lottery has two inherent advantages: 1) if conducted correctly it will lead to a truly random allocation across the population and 2) therefore it provides an allocation strategy that strongly upholds the goal of fairness. On the other hand, the random allocation approach advanced by a lottery is not conducive to minimizing negative health consequences and resource stewardship since it does not allow for resources to be targeted. In addition, a lottery requires top-down coordination and consistent application for it to be equitable. The Committee considered the use of a lottery approach as a tie-breaker between potential recipients of scarce medical resources and services in the event that all other criteria are equivalent and scarcity persists. While the Committee generally supported the idea of using a lottery under these limited circumstances, the Committee did not come to a consensus on how such a lottery provision would be structured or implemented.

3. First come/First served: Another alternative allocation approach—first-come, first-served—presents several challenges from ethical and practical perspectives. This approach is potentially problematic as a sorting mechanism because it favors those with existing informational, social, and economic advantages. Nevertheless, it is the easiest to administer and generally accepted in non-emergency situations. Other states have endorsed the use of a first-come, first-served approach in their allocation plans for scarce medical resources during public health emergencies.

Table: Random sorting approaches – Pro and Con

	Pro	Con
Lottery	• Truly fair and completely random	• Not conducive to minimizing morbidity and mortality or stewarding resources • Complex to administer
First come, first served	• Easy to administer • Widely accepted	• Not truly fair since those with information and resource advantages will gain priority over those who do not

C. Red light: Unacceptable Allocation Criteria

The Committee identified several criteria that are unacceptable to consider when making allocation decisions. These criteria have been rejected due to their inherent lack of fairness, potential for abuse or discrimination, or irrelevance to achieving the goals set out in these Guidelines.

1. Social characteristics: Social characteristics, including but not limited to race, ethnicity, gender, national origin, sexual orientation, religious affiliation, and disability unrelated to immediate medical prognosis, should not be used as criteria in making resource or service allocation decisions during public health emergencies. These characteristics serve no meaningful purpose in differentiating between people in the context of allocation decisions. Moreover, categorization of people according to these types of characteristics is often used as pretext for favoritism, discrimination, and reduced access for minority groups. Therefore, use of social characteristics as allocation criteria is unacceptable.

2. Social worth: The discussion of acceptable allocation criteria (in section V.A. above) recognizes that limited categories of people who provide specific social functions, namely groups of identified essential personnel, may be granted priority access to scarce resources and services during a public health emergency. However, beyond these limited categories, factors that take into account a person's social worth are not acceptable to consider for allocation decisions. Social worth criteria are generally unacceptable because they can lead to unfair decisions based on subjective determinations of a person's background or characteristics, which can in turn lead to stigma, bias, greed, or nepotism in allocation decisions. Unacceptable factors under this category would include but are not limited to job status, training or education, social standing, personal or familial relationships, belief systems, political affiliations, or any other measurement of a person's social value. In particular, the Committee found unacceptable any sort of decision-making process that considered a person's ability to pay for medical resources or services as relevant to prioritizing resources or services. Similarly, it would be inappropriate for providers of medical resources and services to take into account the financial or economic consequences of a person's ability to pay in making allocation decisions for scarce medical resources or services.

VI. Implementation

1. Efforts should be made to eliminate scarcity prior to having to implement allocation guidelines. At all levels of planning, from the state government to individual health care institutions, efforts should be made to acquire sufficient levels of medical resources and services to alleviate the need for rationing these resources and services. Public health emergency preparedness planning can foster efforts to eliminate scarcity through the implementation of consistent and coordinated plans to share, stockpile, and estimate needed resources in advance of a predictable public health emergency scenario. Additional strategies may include sharing resources with other entities and possibly transferring patients to other settings that will have access to adequate resources.[14]

Despite the best efforts to avoid scarcity of medical resources and services during public health emergencies, it is inevitable that in some situations medical resources or services will become scarce, either due to unanticipated emergency circumstances, scientific limitations, or political and economic constraints on access to resources and services. The implementation of these Guidelines should only occur after all reasonable efforts to avoid scarcity have been explored.

2. The probability of scarcity occurring should be assessed and planning should occur to prepare for scarcity. Scarcity of medical resource and services may emerge through various mechanisms during a public health emergency. The process of public health emergency preparedness planning should include assessing the likelihood of medical resource or service scarcity to materialize. Admittedly, in some situations this probability will be quite difficult to determine. Nevertheless, closely evaluating the potential for scarcity can assist with preparedness and allow for increased readiness should the Guidelines have to be put into place.

3. Criteria should be offered to determine when scarcity exists and when prioritization guidelines should be used. The Guidelines should only go into effect after conditions of scarcity have developed. What is scarcity and when is it sufficiently problematic to resort to prioritization approaches? Scarcity of medical resources and services during a public health emergency may take many forms. Whether sufficient scarcity exists to merit the use of prioritization guidelines with respect to a specific medical resource or service can be evaluated using the following factors:

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[14] The Task Force on Mass Critical Care agrees with this provision. See Devereaux et al., Definitive Care for the Critically Ill During a Disaster: A Framework for Allocation of Scarce Resources in Mass Critical Care 133 Chest 51-66 (2008). Suggestion 4.2 states: "All attempts should be made by the health-care facility to acquire scarce critical resources or infrastructure, or to transfer patients to other health care facilities that have the appropriate ability to provide care (state, national, and even international). Critical care will be rationed only after all efforts at augmentation have been exceeded."

- Nature of scarcity
- Duration of scarcity
- Severity of scarcity

a. Nature of scarcity: What type of resource or service is in short supply? Is this a resource or service that can be adequately replaced by an alternative resource? In order to evaluate the intersection of complementary resources, decision-makers should weigh different allocation strategies to maximize all resources and services. Should, for example, staff forgo prophylaxis with oseltimivir during an influenza outbreak and use protective personal equipment instead in order to preserve the supply for sick patients?[15]

b. Duration of scarcity: What is the likely length of time that the scarcity will persist? If the scarcity is only likely to be of short duration (a few hours or days), then the use of prioritization strategies may not be appropriate. Scarcity of specific medical resources or services may rise and fall over time. For example, during an influenza pandemic vaccines may become more available over time as the production of a vaccine to combat a new flu strain is successfully produced, while antivirals may become more scarce as initial stockpiles are used up.[16]

c. Severity of scarcity: How significant is the shortage of the medical resource or service? How widespread is this shortfall? How significant are the consequences of not being able to provide access to that resource or service? The severity of scarcity of a particular resource or service not only informs decision-makers of the relative restrictions that may be imposed on their access to the scarce resource or service, it may also dictate the appropriate allocation strategy for the resource or service.

These criteria can be assessed on a continuum. The greater the duration and severity of scarcity, the more likely that using the prioritization criteria will be warranted.

4. Fair and transparent processes. Allocation decisions made under conditions of scarcity should adhere to clear and specific processes to ensure that these decisions are not being made in an unjust or discriminatory manner. Members of the public should be forewarned of the possibility of medical resource and service scarcity, the means by which decisions will be made in those eventualities, and who will be accountable for making such decisions. These defined processes should be followed by both public- and private-sector decision-makers. Appropriate procedural protections also include designated mechanisms to appeal allocation decisions. These and other process

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[15] See Harvard School of Public Health case study.
[16] Marcel Verweij, Moral Principles for Allocating Scarce Medical Resources in an Influenza Pandemic, 6 Journal of Bioethical Inquiry 159-169, at 161 (2009).

guarantees will foster fairness, transparency, accountability, trust, and consistency in the application of these Guidelines.

5. Prioritization guidelines and decisions should be reviewed continuously and periodically assessed. The policies and practices that emerge from these Guidelines should receive ongoing scrutiny to assure their relevance to the circumstances at hand. If scarcity abates, then measures to control access to medical resources and services pursuant to these Guidelines shall be discontinued. Once the Guidelines have been implemented, resource scarcity should be periodically reassessed (the timeline for which will be determined by the resource and the situation) to ensure continual allocation and reallocation in keeping with the tenants of these Guidelines.

6. Prioritization guidelines should be used consistently across the state. Consistency in implementation of the Guidelines will promote fairness in access to scarce resources and services and will defuse allegations of favoritism and efforts to "venue-shop" for medical resources and services. Also, consistent application of the Guidelines can promote the goal of minimizing morbidity and mortality by fostering a coordinated public health response. However, local conditions may require allocation decisions to deviate from statewide guidance under some circumstances. Decision-makers who are departing from common guidance should only do so after careful deliberation and documentation.[17]

7. Decisions to implement prioritization should be made by persons removed from the clinical context. To minimize conflicts of interest and difficult interactions at the clinical care level between health care providers and patients, decisions regarding when to apply these Guidelines should be made by decision-makers removed from the clinical context whenever possible. These decision-makers should take into account the broader systemic, community, and population-level resource needs in determining whether implementation of these Guidelines is necessary to address the medical resource and service shortages created by the specific public health emergency at hand. In addition, health care professionals should not be required to determine which patients qualify as essential personnel. This determination should be made by decision-makers removed from the direct clinical relationship. While health care professionals have a great deal of expertise in assessing a patients medical prognosis, these professionals may be placed in a difficult position if they have to determine whether a patient requesting resources qualifies as a member of a prioritized essential worker.

8. Palliative care resources should be provided consistently throughout a public health emergency. When the guidelines are activated, it is possible that some individuals will not have access to some scarce medical resources and services based on allocation decisions. As a result, access to palliative care resources and services should be provided

[17] IOM report (2009), p. 32.

to these persons in order to minimize pain and suffering. It is critical that palliative care professionals be available to care for patients who may not receive scarce medical resources and services. The overall management of the public health emergency will be strengthened by providing persons in need with compassionate pain management and means to alleviate their symptoms, as well as offering emotional support and grief and bereavement services to patients, family members, and the community.

APPENDIX 1: SELECTING AN ETHICAL FRAMEWORK FOR THE GUIDELINES

There are many possible approaches to creating an ethical framework for the allocation of scarce medical resources and services during emergencies. As a preliminary step, the Committee evaluated several structural models for ethical guidelines. One model (Option 1, below) articulated a detailed, multi-level framework based on defined categories for prioritization. A second option (Option 2, below) set forth a more generalized set of ethical principles. Ultimately, the Committee chose a third option (Option 3, below) that combines aspects of the other two models, establishing a general ethical framework and specific categories.

A. Option 1: Multi-level categorical models

One approach favored by some proposals is a multi-level categorical model.[18] Typically, these models create defined categories of individuals and proceed to prioritize these categories on the basis of practical or ethical considerations. The HHS Guidance on Allocating and Targeting Pandemic Influenza Vaccine (HHS Guidance) provides an exemplary illustration of this approach.[19] While the HHS approach is targeted at decisions related to pandemic influenza vaccination, this approach could potentially be modified to work as a model for allocating scarce medical resources and services for other types of public health emergencies as well. This approach offers several advantages. The multi-level system, while sophisticated, is also clear and easy to follow. The explicit category system does not require much interpretation on the part of practitioners. Since decision-makers can readily follow its categories, implementation is likely to be fairly consistent.

The multi-level categorical approach has several shortcomings. First, the categorical nature of the framework may be too inflexible to work across multiple types of emergencies and for multiple types of scarce medical resources and services. The categories may remain essentially the same, but the prioritization for each target group may differ according to the details of the emergency and the type of resource and service being allocated. While certain target group may continue to receive top priority during virtually all types of emergencies (e.g., critical health care workers, fire, and police), other groups, particularly those defined by age and medical vulnerability, may receive

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[18] See e.g., U.S. Department of Health and Human Services, Guidance on Allocating and Targeting Pandemic Influenza Vaccine (2006); Ezekiel J. Emanuel & Alan Wertheimer, "Who Should Get Influenza Vaccine When Not All Can?" 312 Science 854 (2006).

[19] U.S. Department of Health and Human Services, Guidance on Allocating and Targeting Pandemic Influenza Vaccine (2006). The HHS Guidance creates four distinct categories: homeland and national security; health care and community support services; critical infrastructure; and general population. Within each category, target groups are identified and then ranked according to priority from Tier 1 through Tier 5, with some groups not targeted at all. Groups designated as Tier 1 groups will have the first priority in accessing vaccine, Tier 2 will be next in line, and so on. Tier 1 groups include essential personnel (critical health care professionals, deployed military forces, EMS, fire, and police) and the populations most medically vulnerable to influenza (pregnant women, infants, and toddlers).

greater or lesser priority depending on the salient health threat, the levels of scarcity, and the risk of medical harm posed by the threat to health. Therefore, the multi-level approach will only succeed in providing workable guidance in multiple emergency settings if the guidance builds in flexibility to adapt to changing medical and public health circumstances. The levels and even the breakdowns of target groups may need to be altered to comport with changed circumstances and to incorporate different ethical goals if necessary. A second problem with this approach is that it may not take into account the medical prognosis of individual members of the target groups and also may not ensure fairness in all circumstances. Treating all members of a particular group with identical priority may make sense for allocation of vaccine, but may not suffice for other resources and services, particularly when a patient is already sick.

A third deficiency in the multi-level approach, at least as it is employed in some of the available models, is that it is not sufficiently transparent about the ethical underpinnings that are implicitly guiding the prioritization. Since many of the ethical principles underlying how the categories are prioritized are not explicitly stated, efforts would need to be made to increase the transparency of the system. The table below sets out as an example some the underlying ethical justifications for prioritizing "tier 1" groups under the HHS Guidance and also some of the ethical critiques that could be raised for such an approach. The table entries address whether giving first priority to these groups supports the three goals stated for our Guidelines:

Table 1: HHS Priority Groups and Allocation Goals

"Tier 1": Target groups	**Reducing morbidity and mortality**	**Fostering social stability**	**Ensuring fairness**
Health care and public health personnel	**Yes**. Health care services are needed to treat people and will reduce morbidity and mortality	**Yes.** Functioning health systems are necessary for social stability	**No**. Prioritizing based on profession may be seen as unfair – criteria must be strict regarding who qualifies
Critical infrastructure personnel	**Maybe**. Maintenance of critical infrastructure may indirectly reduce morbidity and mortality	**Yes**. Functioning infrastructure are necessary for social stability and public safety	**No**. Prioritizing based on profession may be seen as unfair – criteria must be strict regarding who qualifies
Pregnant women, infants and toddlers	**Probably**. These groups are often the most vulnerable	**Maybe**. Prioritizing adults who are already trained and working may be	**Maybe**. Does not take into account prognosis of group members, but it may

		more conducive to social stability	be fair to give infants and toddlers a chance to live

B. Option 2: Generalized ethical framework

A second alternative approach to providing ethical guidance uses the ethical principles themselves as the framework rather than predetermined target groups. Many commentators have suggested various approaches to apply ethical principles to allocation decisions. Some commentators seek to identify ethical principles and rank the principles in order of priority,[20] while others merely provide additional criteria that will allow others to prioritize among the principles themselves.[21] A recent article by Persad et al. provides a sophisticated effort to identify ethical principles for allocation of scarce medical resources through an examination of four types of allocation principles and the advantages and disadvantages of these principles.[22]

This approach has several advantages from a structural perspective. Structurally, the approach provides an explicit discussion of the contours of each ethical principle, analyzes why it should or should not be used to make allocation decisions, and then provides a framework within which it may be applied. The framework can then be adapted to apply to multiple types of allocation decisions. This flexibility allows this ethical framework to be more malleable than the HHS multi-level categorical approach as well as more clearly justified from an ethics perspective.

This approach has some disadvantages as well. First, since it is structured as a set of ethical principles, it may be difficult to apply during an emergency when time for deliberation and interpretation is constrained. In addition, the principles may be interpreted and applied differently by different decision-makers, leading to inequitable results. Whether this is problematic or not is a matter of debate.

C. Option 3: Combined approach: General ethical framework and multi-level categorical model

The Committee preferred a third option for creating ethical guidelines, which combined the best features of the approaches offered in options 1 and 2. This strategy, which is similar to the approach adopted by the state of Minnesota in their pandemic influenza rationing strategy, sets out general ethical principles and then provides more

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[20] See, e.g., Govind Persad et al., "Principles for Allocation of Scarce Medical Interventions," 373 Lancet 423-431 (2009); Nancy E. Kass, "An Ethics Framework for Public Health and Avian Influenza Pandemic Preparedness," 78 Yale Journal of Biology and Medicine 235-250 (2005).

[21] See, e.g., James F. Childress et al., "Public Health Ethics: Mapping the Terrain," 20 Journal of Law, Medicine and Ethics 170-178 (2002).

[22] The principles are 1) treating people equally; 2) favoring the worst off (prioritarianism); 3) maximizing total benefit (utilitarianism); and 4) promoting and rewarding social usefulness. Persad et al., at p. 424.

detailed guidance on how these ethical principles could be applied in a range of specific circumstances.[23]

The combined approach has the advantage of providing both the substantive ethical principles and the justification for these principles (which helps with public trust and transparency) as well as the specific guidance (which will facilitate rapid education and implementation of the guidance among decision-makers at different levels). There remains sufficient flexibility to maintain provider discretion, but detailed enough criteria to achieve consistency in implementation. The challenge of this approach is the complexity of drafting the specific guidance for the broader range of resources and emergency situations that these Guidelines are meant to cover.

[23] The Minnesota plan provides specific guidance for antivirals, ventilators, N95 respirators, masks, and vaccine in the context of an influenza pandemic. Dorothy W. Vawter et al., "For the Good of Us All: Ethically Rationing Health Resources in Minnesota in a Severe Influenza Pandemic" (2009). Available at: http://www.ahc.umn.edu/mnpanflu/preliminary/rationing/home.html.

APPENDIX 2: DEFINITIONS

The following definitions are used throughout this document:

Essential Personnel: those whose functions are critical to limiting deaths and degradation of health care, public health, public safety and other critical infrastructures, including volunteers.

Public Health Emergency: an occurrence or imminent threat of an illness or health condition that:

> (1) is believed to be caused by any of the following: (i) bioterrorism; (ii) the appearance of a novel or previously controlled or eradicated etiological agent or toxin; (iii) a natural disaster; (iv) a chemical attack or accidental release; or (v) a nuclear attack or accident; and
>
> (2) poses a high probability of any of the following harms: (i) a large number of deaths in the affected population; (ii) a large number of serious or long-term disabilities in the affected population, including disabilities that occur from physical, psychological, or emotional injuries; or (iii) widespread exposure to an infectious or toxic agent that poses a significant risk of substantial future harm to a large number of people in the affected population.[24]

Scarce Medical Resource: a medical resource that is unavailable in sufficient quantity to provide to all patients who need the resource during a public health emergency. The specific resources identified as scarce medical resources will vary according to the type and scope of the public health emergency, but will include supplies (medicine, machines, other medical and support materials), space (available beds and treatment areas), and staff (adequately trained health care professionals). In the event of an influenza pandemic, for example, ventilators, masks, ICU beds, antivirals, and health care personnel are some of the types of medical resources that may be insufficient in quantity to treat all who are in need of them for the duration of the outbreak.

Scarce Medical Service: a medical service that is unavailable during a public health emergency due to insufficient quantity to provide to all patients who need the service or due to concerns that providing the services will impact the ability to adequately respond to the public health emergency. The scarcity of medical services will be closely linked to scarcity in medical resources. For example, in a public health emergency where ICU beds or health care personnel are scarce, the medical services provided in these beds or by these personnel may be similarly limited. Even if a resource is physically available, the exigencies of a public health emergency may cause a decision-maker to choose not to

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[24] This definition is adapted from the Model State Emergency Health Powers Act (2001), which was drafted by the Center for Law and the Public's Health. The full text of this Model Act is available at: www.publichelathlaw.net/modelacts.

provide a service in order to steward resources for anticipated future needs, thus creating a scarcity of medical services. Protocols for use of ambulances or the availability of elective surgical procedures, for instance, may be limited during a public health emergency.

APPENDIX 3: ETHICS ADVISORY COMMITTEE PARTICIPANTS

Beginning in Fall 2008, Professor Lance Gable, Principal Investigator, began to develop these Guidelines along with expert guidance from the Ethics Advisory Committee (EAC). These Guidelines were drafted by Professor Gable along with substantial input from the EAC. Representing a wide range of subject matter expertise and professional training, the EAC met over the course of several years to debate and discuss the vital ethical and practical issues surrounding allocation of scarce medical resources and services during public health emergencies.

The following individuals served as members of the EAC and attended one or more advisory committee meetings: Lance Gable (Wayne State University, chair); Nancy Baum (University of Michigan); Denise Chrysler (MDCH); Don Edwards (District 1 Regional Medical Response Coalition); Leonard Fleck (Michigan State University); Sheri Greehoe (Michigan State Medical Society); Charles Guernsey (Michigan Osteopathic Association); Peter Hammer (Wayne State University); Gregory Holzman (MDCH); Mark Kielhorn (MDCH); Marie Lozon (University of Michigan); Harry McGee (MDCH); Jeff Nigl (Region 3 Health Care Preparedness Network); Shelley Norris-Chapman (MDCH); Robert Piccinini (Michigan Osteopathic Association); Greg Roberts (Michigan Dept of Human Services); Thomas Sands (Michigan State Police); Peter Schonfeld (Michigan Hospital Association); Jacqueline Scott (MDCH); Linda Scott (MDCH); Dean Sienko (Ingham County Health Dept); Ashley Vandekopple (MDCH); Eden Wells (MDCH); John Wernet (Office of the Governor); Pamela Yager (Office of the Governor). Participation in the EAC does not necessarily represent the agreement or endorsement of all aspects of the Guidelines by these individuals or their organization.