A Medical Ethics Framework to Support Decision-Making in the Allocation and Distribution of Scarce Medical Resources During Pandemic Influenza

A Report to the Texas Department of State Health Services

On Behalf of The Texas Pandemic Influenza Medical Ethics Work Group

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About this Document

This document reports on the deliberations of the Texas Pandemic Medical Ethics Work Group that met in Austin, Texas from October 18 – 20, 2009. Jeffrey L. Levin, M.D., M.S.P.H., chaired this multidisciplinary work group of 17 subject matter experts from across Texas. Work group members are identified below. To assist in the completion of this document, the professional facilitation services of The Litaker Group were used.

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This report is based on discussion and feedback from the Pandemic Influenza Medical Ethics Work Group convened in October 2009. The report was written and revised after the work group met and was made available for public comment on April 27, 2010. The final report was released on August 31, 2010. Readers are advised to consider this report in light of the timing in which the work group was convened and in which the report was written and released for public comment.

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1 Executive Summary

The response by the Texas Department of State Health Services (DSHS) to the novel H1N1 outbreak was based on years of planning, preparation, training, and practice. The response tested many of the assumptions that had been built into planning activities. Following the spring 2009 outbreak, DSHS conducted a comprehensive after action process to identify areas of improvement to support future response activities. Some of the activities reviewed included internal agency response operations, continuity of operations needs, epidemiological surveillance and laboratory testing activities, non-pharmaceutical interventions, antiviral medication distribution, and vaccine distribution. Results from the after action process, as well as changes in plans and procedures, were communicated to state and local leaders through a series of conferences held statewide from August to September 2009.

DSHS also considered the impact that a pandemic would have on resource availability and on healthcare system surge capacity. DSHS recognized that resources could be scarce during a pandemic (e.g., if the supply chain is disrupted, manufacturing delays occur, or if the severity of disease increases). As such, DSHS outlined a process to develop an ethical framework to support decision-making in the allocation and distribution of scarce state-owned resources. This multi-step process included:

1. Convening a multidisciplinary work group of 17 members to deliberate and recommend a decision-making process to assist in the allocation and distribution of scarce health and medical resources owned by DSHS. The consensus of the work group was that these recommendations are predicated on a series of assumptions as outlined in this report.

2. Writing a draft report of the goals, framework, values, and recommendations based on the discussions from this work group.

3. Hosting public hearings in Austin and by videoconference statewide to obtain public feedback on the work group draft report.

4. Soliciting reviews and comment from additional stakeholders, partner groups, and interested organizations.

5. Summarizing all public comment for consideration by the multidisciplinary work group for inclusion in the final report.

6. Releasing the final report to the Commissioner of Health.

The outcome from this work group, called the Pandemic Influenza Medical Ethics Work Group, addressed the following topics: (1) Vaccine Allocation and Distribution; (2) Antiviral Medication Allocation and Distribution; (3) Medical Surge Resource Allocation and Distribution; and (4) Ventilator Allocation and Distribution. For each of these topics, four items were addressed.

- **Goal:** A desired outcome for the allocation and distribution of a specific resource
- **Framework:** A structure for considering ethical principles in the allocation and decision-making process
- **Values:** Principles or standards that reflect ethical considerations about the allocation and distribution of a specific resource
- **Recommendations:** A course of action that incorporates ethical considerations for the allocation and distribution of a specific resource

Table 1 identifies the goals and recommendations for each of the four topics.

Table 1: Goals and recommendations for the four topic areas considered by the Pandemic Influenza Medical Ethics Work Group

Vaccine Allocation and Distribution	
Goals	**Recommendations**
A. Minimize morbidity and mortality associated with novel H1N1 influenza **B.** Prevent the spread of novel H1N1 influenza	**A.** Communicate allocation decisions clearly and effectively (a) Information will be transparent, accurate, and straightforward (b) Internal communication to health and medical stakeholders and external communication to the public are both important **B.** Health care workers get vaccinated for both seasonal and novel H1N1 influenza, with a specific emphasis on those who have direct patient care **C.** Create an advisory group to provide advice to the DSHS Vaccine Allocation and Approval Committee (VAAC) on allocation and distribution issues related to novel H1N1 vaccine. Considerations for this committee should include: (a) Multidisciplinary membership from both the public and private sectors (b) A public member in the group (c) Regional representation (d) Representation from both urban and rural areas of the state **D.** Continue to make novel H1N1 vaccine allocation and distribution decisions based on available epidemiological evidence

Antiviral Medication Allocation and Distribution	
Goals	**Recommendations**
A. Reducing mortality by adhering to the most current treatment guidelines **B.** Reducing the need for hospitalization by adhering to the most current treatment guidelines	**A.** Discourage prophylaxis to preserve resources for when they are medically needed and indicated **B.** Communicate to clinicians the importance of properly prescribing medications and the impact of improper prescribing (e.g. resistance, medication shortages, etc.) **C.** Support the ability of the state to adapt to changing conditions with regard to allocation and distribution decisions **D.** Acknowledge and continue strong partnerships with pharmacies in the state **E.** Develop a prioritization system in the event of a significant shortage; prioritization may be based on severity of illness and likelihood of recovery (i.e., greatest benefit) and first-come, first served if need is equal **F.** Redistribution of medication would occur for purposes of treatment **G.** The prioritization system will change if a shortage of antiviral medication occurs; such prioritization may be targeted based on severity of illness and the likelihood of recovery
Medical Surge Resource Allocation and Distribution	
Goal	**Recommendations**
To maintain the healthcare systems' capacity to provide judicious and efficacious care to as many people as possible	**A.** Material resources should be disseminated to facilities that can effectively and appropriately utilize them in accordance with best practices **B.** Regional medical systems, comprised of representation from local hospitals, long-term care facilities, nursing homes, public health, etc. should coordinate the development of prioritization protocols, based on ethical and medical standards of care, to optimize effective use of scarce resources during a pandemic **C.** Information on available state-owned supplies, including product specifications, should be made available to eligible health care entities who may use these resources

Ventilator Allocation and Distribution	
Goal	**Recommendations**
To reduce mortality by the most judicious and efficacious use of available resources	**A.** There should be uniform and cooperative guidelines in place at the hospital level, as it pertains to the use of mechanical ventilators. The state should lead efforts in developing guidelines that can be applied statewide. Guideline development would include involvement from local and regional officials, professional organizations, and other stakeholders **B.** The ventilator distribution process should be optimized for rapid deployment so requesting hospitals receive such equipment in a timely manner **C.** Ventilator allocation decisions should be based on two related factors: (1) severity of illness; and (2) likelihood of recovery

The Department of State Health Services will use the information in this document when making decisions about the allocation and distribution of scarce state-owned health and medical resources. In particular, it will serve to inform the decision-making process and to provide officials with a framework from which to determine allocation decisions. It should be noted that the above goals and recommendations are intended to support decision-making in a mild to moderate pandemic. While this work group is intended to meet only to provide a framework and recommendations for the current outbreak, this framework could serve as a model for addressing future public health emergencies pertaining to influenza.

2 Introduction

2.1 Background

The Texas Department of State Health Services (DSHS) began preparing for an influenza pandemic in early 2000. Since that time, DSHS, local health departments, healthcare system partners, and hospitals have developed plans and procedures to guide response activities during a pandemic. Training and exercises have occurred at regular intervals at the local, regional, and state levels to support both preparedness activities and response efforts.

In April 2009, Texas was one of the first locations outside the country of origin to have individuals diagnosed with novel H1N1 influenza. At the time, little was known about this illness except that hundreds of persons in Mexico City had fallen ill since mid-March, with reported hospitalizations and deaths. The two index cases in Texas, both military dependents, resided between Austin and San Antonio, Texas.

When the initial cases of novel H1N1 infection occurred, few people, including most public health officials expected that this was going to be the first influenza pandemic of the 21st century. Eventually, an area of South Texas encompassed by DSHS Health Service Region 11, had more confirmed cases associated with novel H1N1 infection than 44 states. As such, Texas was at the epicenter of the worldwide spread of novel H1N1.

The ongoing impact of an influenza pandemic is uncertain, difficult to predict, and contingent upon numerous factors such as epidemiology and severity. None-the-less, it is prudent to anticipate and prepare for future peaks of disease activity in an effort to minimize the degree of impact when considering limited resources. Future waves may occur through 2010 and into 2011.

2.2 Ethical Dimension

During a pandemic, DSHS has access to limited resources that can be allocated and distributed across the state. These resources include antiviral medications, ventilators, personal protective equipment (PPE), and the recently developed H1N1 vaccine.

Seeking to make allocation decisions of these medical resources based on ethical principles, DSHS convened a multidisciplinary work group of professionals from across the state and charged them with developing an ethically based decision-making framework for this purpose.

Over a two and a half day meeting from October 18 – 20, 2009, this work group of 17 members met to address their charge. Prior to the meeting they reviewed appropriate background material. At the meeting they heard presentations from DSHS staff regarding the scope of the pandemic in Texas, as well as the available DSHS medical resources and how allocation decisions had been made to date. The work group

developed assumptions upon which their work was based. Those assumptions are outlined in Section 3.7. Following lengthy deliberations, the work group developed a framework for decision-making supported by goals, ethical values, and recommendations for each medical resource that was discussed.

2.3 Note from Work Group Members

Because of the complexities of pandemic influenza planning, uncertainties associated with the disease caused by a novel strain, dynamic circumstances surrounding the outbreak, and the dramatic and broad impact of the actual event, work group members emphasized that no one solution will work in all scenarios. Therefore, the approach developed by this work group has culminated in a living document that may need revision based on new information and specifics of response. Work group members identified assumptions (see Section 3.7) for preparing these recommendations. The members also recognized the precarious nature of pandemic influenza and have asked that the adoption of these recommendations consider the various factors that may influence available resources and affected populations during an actual response. This work group is ready to be reconvened to consider revisions of the ethical approaches outlined in this document when needed.

3 Methodology

3.1 Introduction

In the fall of 2009, DSHS embarked on a process to develop an ethical framework to support decision making for the allocation and distribution of state-owned assets in response to pandemic influenza. This process consists of the following major components:

1. **DSHS Medical Ethics Steering Committee:** A steering committee was formed to oversee the project, provide direction and advice, and to review timelines and deliverables. Led by the Assistant Commissioner for Prevention and Preparedness, this committee was composed of DSHS personnel from across the department.

2. **Pandemic Influenza Medical Ethics Work Group (PIMEWG):** A multidisciplinary work group of 17 experts was convened to review, consider, and make recommendations to DSHS regarding ethical considerations for the allocation and distribution of four assets: (1) novel H1N1 vaccine; (2) antiviral medications; (3) mechanical ventilators; and (4) medical surge resources (e.g., PPE).

3. **Public Comment Period:** A public comment period will seek input from partners, stakeholders, the general public, and other interested individuals on the outcome from the PIMEWG.

4. **Implementation of Findings:** The final report will be used by the Commissioner of Health to inform allocation and distribution decisions for scarce state-owned health and medical resources during a pandemic. Although the state health department initiated this process, a broad public health and medical audience may also use the findings to guide allocation and distribution decisions of scarce resources at the regional and local levels during a pandemic.

DSHS contracted with the Litaker Group to organize and facilitate the 2.5-day meeting of the PIMEWG along with follow-up activities.

3.2 Pandemic Influenza Medical Ethics Work Group Membership

Based on recommendations from the DSHS steering committee and input from state-level professional organizations, the PIMEWG was composed of a broad range of subject matter experts representing medicine, hospitals, medical ethics, law, faith-based organizations, local health departments, elected officials, and planning partners. Box 1 identifies disciplines represented in the work group.

The current chair of the Texas Medical Association, Council on Public Health, was invited to serve as chair for the work group. DSHS subject matter experts were also present to provide background information to the work group, to answer questions from the work group, and to discuss pandemic planning activities that have occurred at DSHS.

Box 1: Disciplines represented by the Pandemic Influenza Medical Ethics Work Group

- Pediatrics
- OB /GYN
- Occupational health
- Respiratory therapy
- Nurse
- Pharmacy
- Medical ethicist
- Health law
- Local health authority
- Local health departments
- Healthcare system preparedness contractor
- Faith-based representative
- Federal partners
- State elected officials

3.3 Work Group Charge

The work group was charged with creating an ethical approach to inform the DSHS decision-making process in allocating and distributing scarce state-owned medical resources. This approach will be used to support future resource planning and to refine plans currently in place as needed. As such, DSHS would like to utilize an ethical framework and process to inform the allocation and distribution of state-owned resources in cases of a shortage.

The medical ethics work group was charged with addressing the following components of the ethical approach and process as they relate to each of the four resource types identified in Section 1.1.

- **Goal:** A desired outcome for the allocation and distribution of a specific resource
- **Framework:** A structure for considering ethical principles in the allocation and decision-making process
- **Values:** Principles or standards that reflect ethical considerations about the allocation and distribution of a specific resource
- **Recommendations:** A course of action that incorporates ethical considerations for the allocation and distribution of a specific resource

3.4 Work Group Deliberation Process

3.4.1 Introduction

Prior to the meeting, background articles, including the DSHS antiviral tool kit, the novel H1N1 mass vaccination plan, pandemic influenza plans from other countries and states, and recent scholarly articles were provided to work group members (See Appendix 10.3). Additional materials in these categories became available during the meeting (some from panel members) and were circulated and considered. The meeting lasted for two and a half days. During this meeting, DSHS staff presented background information on five topics:

1. Ethical principles, processes, and values
2. H1N1 vaccine allocation and distribution
3. Antiviral medication allocation and distribution
4. Ventilators
5. Medical surge resources

3.4.2 Pandemic Influenza Medical Ethics Work Group Meeting in Austin, Texas

The PIMEWG met in Austin, Texas from October 18 – 20, 2009. During this time, a total of approximately 20 hours of contact time occurred. The contractor facilitated discussions and took detailed notes to assist with report writing. For each resource type, work group members provided comments in real time on the goals, framework, values, and recommendations. Specific outcomes for each day of the meeting are outlined in Table 2.

Table 2: Outcomes achieved for each day of the work group session

Day	Outcome
1	• Member introduction • Review of logistical and operational information • Review of the process • Overview of medical ethics and public health ethics
2	• Introduction by the Texas Commissioner of Health • Introduction by the Work Group Chair • Introduction by the Assistant Commissioner for Prevention and Preparedness • Provided summary of Day 1 to members • Clarification of the work group charge • Discussed vaccine allocation and distribution • Discussed antiviral medication allocation and distribution • Discussed ventilator allocation and distribution
3	• Revisited vaccine allocation and distribution discussion • Continued ventilator allocation and distribution discussion • Discussed medical surge resource allocation and distribution

During the deliberation process, the work group further clarified its charge and scope for the ethical framework.

- The framework will be based on the assumption of limited availability of resources relative to the pandemic level and severity, with the assumption that this would be a mild to moderate pandemic.
- The guiding principle for this framework is medical prioritization based on scientific evidence.
- The ethical framework will focus on state-owned or controlled resources only.
- The ethical principles will be determined from the public health perspective.
- There are certain conditions that the state cannot change or that are out of the scope of the current charge for the work group (e.g., health care professional shortage).

3.5 Public Comment Plan

DSHS has developed a public comment plan that provides broad dissemination of work group findings for input by partners, stakeholders, the general public, and other interested individuals. Specifics of the public comment plan include:

- Post the draft report on TexasFlu.org and in the Texas Register for a 15-business day comment period.
- Request review and comment on the draft report from a comprehensive list of partners and key stakeholders.
- Solicit input during a formal comment period.
- Summarize and consider public comment in the final report.
- Issue the final report.

3.6 The Final Report

After a comprehensive public comment and public hearing process, DSHS anticipates the release of the final Pandemic Influenza Medical Ethics Work Group Report in early 2010. The final report will be shared widely with public health and healthcare system partners. The Commissioner of Health and his executive team will use this report to inform decision-making around the allocation and distribution of scarce health and medical resources during an influenza pandemic. The report may also be used as a resource for allocating and distributing scarce resources at the regional and local levels.

3.7 Assumptions

Work group members identified and considered the following assumptions (see Table 3) during the deliberation process. It should be noted, however, that the Texas Department of State Health Services is subject to law. The legislature or Congress may impose, or designate an official to impose, priorities on the distribution of resources. The agency is bound to adhere to law. Certain types of priorities may be constrained by legal prohibitions against discrimination.

Table 3: Assumptions identified and considered by work group members

A. Communication is critical.
B. Communication will remain open and available to persons across the state using a variety of means.
C. Current state of health care / access will influence outcomes.
D. The Texas response to the pandemic is complex and will vary across the state.
E. Criteria should be evidenced-based and applied consistently across the state.
F. Time sensitive, critical decisions may be made likely without complete data.
G. The medical standards of care will not be altered until resource demands begin to exceed maximum capacity.
H. Guiding principles lead to accountability. Decisions will be made which reflect the highest levels of accountability, so ethical principles will be utilized.
I. Ethical decisions are not judged based on right or wrong.
J. Local healthcare facilities control their resources.
K. The standard supply chain (i.e., the normal channel of manufacturing and distributing resources), which is operational during non-disaster circumstances, may not remain intact during a disaster.
L. Limited federal supplies / support will be provided, but the federal government cannot meet all resource needs of the state.
M. The numbers of healthcare personnel may be limited based on severity of event, which may affect the ability to deliver care, regardless of resource availability.
N. The state currently does not have enough trained human resources to support treatment in a severe pandemic.
O. All entities involved in responding to pandemic influenza should participate in mutual aid relationships and practice good stewardship for their communities.
P. For-profit and not-for-profit hospitals and other health care entities may not respond in similar ways.
Q. Limitation on individual autonomy may benefit the greater good of the society. Public acceptance and understanding of this limitation will be necessary in order to be effective.
R. Social disparities are more evident during a crisis such as an influenza pandemic.
S. The federal government is engaged and will share their plan regarding related immigration factors during an influenza pandemic.
T. The state must have a plan that includes everyone in the state at the time of the event.
U. Current health care stressors (i.e., access to care) will continue to be operative during a pandemic.
V. Existing supplies and resources should be used and not rationed.

4 Ethical Decision-Making Framework

Making decisions regarding the allocation and distribution of limited resources can be complex. Such decisions hinge upon a variety of variables, including need, resource availability, and operational issues. By necessity, such decisions should also include an ethical component. In a pandemic influenza event, DSHS will make decisions regarding the allocation and distribution of scarce state-owned medical assets. As such, having a pre-determined ethical framework can assist in the decision-making process.

4.1 Definition of Ethics

Ethics is a branch of philosophy related to the study of morality, which deals with determining "standards of behavior that [inform] how human beings ought to act" in various situations.[1] These codes of conduct are often shaped by character traits, societal expectations/norms, religious beliefs, and values.[2]

4.2 Ethical Frameworks

The importance of ethics for pandemic planning is

> "In the application of value judgments to science. The use of ethical frameworks to guide decision-making may help to mitigate some of the unintended and unavoidable collateral damage from an influenza pandemic…[as well as] for building mutual trust and solidarity."[3]

Ethical frameworks can assist the decision-making process with regard to the allocation and distribution of scarce health and medical resources. Thompson, et al. noted that an ethical framework is intended to:[4]

- Inform decision-making, not replace it;
- Encourage reflection on important issues;
- Promote discussion and review of ethical concerns arising from a public health crisis; and
- Improve accountability for decision-making.

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[1] A framework for thinking ethically. Markkula Center for Applied Ethics. Santa Clara University. http://www.scu.edu/ethics/practicing/decision/framework.html. Accessed October 14, 2009. (Note: This ethical framework resulted from a dialogue and debate at the Markkula Center for Applied Ethics at Santa Clara University. Primary contributors include Manuel Velasquez, Dennis Moberg, Michael J. Meyer, Thomas Shanks, Margaret R. McLean, David DeCosse, Claire André, and Kirk O. Hanson. This article appeared originally in *Issues in Ethics*, Vol. 1, No. 2 (Winter 1988). It was last revised in May 2009.

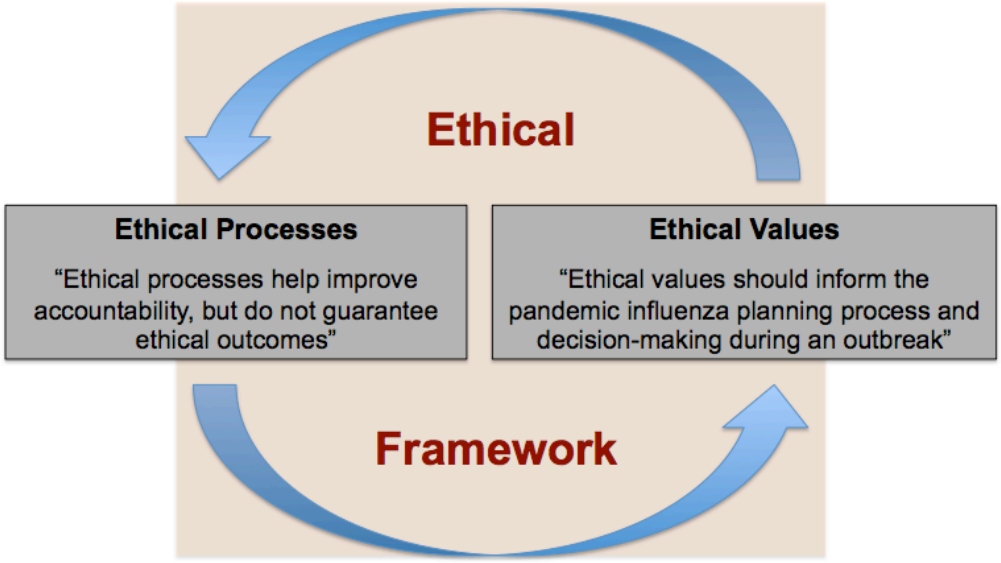
[2] Aristotle's *Ethics* (Stanford Encyclopedia of Philosophy). http://plato.stanford.edu/entries/aristotle-ethics/. Accessed October 14, 2009.

[3] *Ibid.*

[4] Thompson AK, Faith K, Gibson, JL, and Upshur REG. Pandemic influenza preparedness: an ethical framework to guide decision-making. *BMC Medical Ethics* 2006, 7:12.

In their framework, Thompson, et al. described it as consisting of two parts: (1) ethical processes and (2) ethical values.[5] Ethical processes are designed to support and improve accountability, ideally with a method to obtain feedback and incorporate lessons learned. Ethical values are designed to provide guidance, with acknowledgement that more than one value may be appropriate to a particular discussion. While ethical processes and ethical values were not defined in explicit terms, based on Thompson et al.'s description, the procedural elements seem to refer to characteristics or qualities of the method or way a decision (based on ethical principles) is made. Ethical values represent aspects of an action or behavior executed based on ethical principles (Figure 1 depicts the interaction of these two components).

Figure 1: The interplay between ethical processes and ethical values[6]



[5] *Ibid.*
[6] Figure created by The Litaker Group based on: Thompson AK, Faith K, Gibson, JL, and Upshur REG. Pandemic influenza preparedness: an ethical framework to guide decision-making. *BMC Medical Ethics* 2006, 7:12.

4.3 DSHS Charge

In September 2009, DSHS outlined a multi-step process designed to develop a decision-making framework to assist the state in the allocation and distribution of scarce state-owned or controlled health and medical resources during an influenza pandemic. The major steps included:

- Convene a multi-disciplined Pandemic Influenza Medical Ethics Work Group (PIMEWG) to deliberate and recommend a decision-making process to allocate and distribute scarce health and medical resources.
- Once a draft report from the PIMEWG is developed, DSHS posts the draft report on TexasFlu.org and in the Texas Register for a public comment period.
- DSHS hosts one public hearing in Austin and several regional public hearings via videoconference during the public comment period.
- DSHS solicits review and comment on the draft report from a comprehensive group of partners and key stakeholder organizations.
- DSHS will review and summarize public comment and send to the PIMEWG for consideration / amendment of the final report.
- DSHS issues the final report.

4.4 Ethical Framework Developed by the PIMEWG

In early October 2009, DSHS contracted with the Litaker Group to convene a multidisciplinary medical ethics work group to recommend a decision-making process to allocate and distribute scarce resources as the first step in this process. A group of 17 health and medical subject matter experts were identified from across Texas and came together for a two and a half day deliberation meeting in Austin, Texas on October 18-20, 2009. The group was asked to review, consider and make recommendations for the ethical allocation of scarce or potentially scarce state-owned or controlled resources including novel H1N1 vaccines, antiviral medications, medical surge personal protective equipment (PPE) and supplies, and mechanical ventilators. The work group was charged with addressing the following considerations for each topic:

- **Goal:** A desired outcome for the allocation and distribution of a specific resource.
- **Framework:** A structure for considering ethical principles in the allocation and decision-making process.
- **Values:** Principles or standards that reflect ethical considerations about the allocation and distribution of a specific resource.
- **Recommendations:** A recommended course of action that incorporates ethical considerations for the allocation and distribution of a specific resource.

5 Vaccine Allocation and Distribution

The Medical Ethics Work Group discussed both practical and ethical issues related to the allocation and distribution of novel H1N1 vaccine. Summary findings are identified in Box 2. The remaining parts of this section provide context for discussions and observations by the work group.

Box 2: Summary of work group recommendations related to vaccine allocation and distribution

GOALS

A. Minimize morbidity and mortality associated with novel H1N1 influenza
B. Prevent the spread of novel H1N1 influenza

FRAMEWORK

Medical prioritization based upon best evidence, epidemiological data, and greatest risk of vulnerability to serious illness, complications, and death

VALUES

- Efficacy
- Equity
- Inclusivity
- Justice
- Reciprocity
- Solidarity
- Stewardship
- Transparency
- Trust

RECOMMENDATIONS

A. Communicate allocation decisions clearly and effectively
(a) Information will be transparent, accurate, and straightforward
(b) Internal communication to health and medical stakeholders and external communication to the public are both important

B. Health care workers get vaccinated for both seasonal and novel H1N1 influenza, with a specific emphasis on those who have direct patient care

A. Create an advisory group to provide advice to the DSHS Vaccine Allocation and Approval Committee (VAAC) on allocation and distribution issues related to novel H1N1 vaccine. Considerations for this committee should include:

(a) Multidisciplinary membership from both the public and private sectors
(b) A public member in the group
(c) Regional representation
(d) Representation from both urban and rural areas of the state

C. Continue to make novel H1N1 vaccine allocation and distribution decisions based on available epidemiological evidence

5.1 Background

Based on the projected availability of a novel H1N1 vaccine from the federal government in the fall of 2009, DSHS staff created a mass vaccination plan. With only three months lead-time before the expected availability of the vaccine, DSHS was charged with developing a plan that addressed the allocation and distribution of up to 15 million doses. It should be noted that this is the first time that DSHS has been charged with a program of this magnitude and scope (e.g., developing a system in which providers across the state could register online regarding their anticipated vaccine supply needs). Below is a summary of major components of the *DSHS Mass Vaccination Plan*, which is available for download at www.TexasFlu.org. Box 3 outlines specifics addressed in the plan.

Box 3: Components addressed by the DSHS Mass Vaccination Plan

- Goals
- Objectives
- Assumptions
- Facts
- Procedures
- Operational activities related to vaccine distribution

5.1.1 Novel H1N1 Vaccine Allocation

Allocation decisions are based on a multitude of variables at the weekly meeting of the DSHS Vaccine Allocation Approval Committee (VAAC). Using guidelines from the Advisory Committee on Immunization Practices (ACIP), this multidisciplinary committee makes allocation decisions for the novel H1N1 vaccine based on the following.

- Amount and type of vaccine shipped to Texas each week
- Quantity of vaccine made available by the federal government
- Dosage forms available by indication (e.g., for children 2 to 5, pregnant women, etc.)
- Vaccine formulation available (e.g., preservative free, thimerosal based, or live attenuated virus)
- Vaccine packaging available (e.g., single or multi-dose)
- Suitability of available vaccines for target populations

The VAAC is composed of DSHS subject matter experts in medicine, epidemiology, infectious disease, immunization, maternal and child health, law, and governmental affairs.

5.1.2 Vaccine Distribution

Both a national distributor and a state distributor support distribution efforts. The national distributor can provide quantities in 100 dose increments, while the state distributor provides quantities in less than 100 dose increments. Both distributors are in the private sector and take direction from DSHS on where and when to ship orders.

A key component of this vaccination campaign is to enroll as many providers as possible to provide vaccinations. Such providers may include private physician offices, hospitals, school systems, universities, and public health departments. Local and state public health departments will provide vaccines to those without access to another provider. As of October 2009 there are nearly 13,000 providers registered in Texas to receive allocations of the vaccine using the designated DSHS web site (www.texasflu.org).

5.1.3 Adverse Event Reporting

Texas participates in the national Vaccine Adverse Event Reporting System (VAERS). This system, maintained by the U.S. Centers for Disease Control and Prevention (CDC) monitors all adverse events reported. The CDC also conducts statistical analyses of reported adverse event data.

5.2 High-Level Discussion Points

The Medical Ethics Work Group considered several issues related to vaccine allocation and distribution.

- DSHS is adhering to priority groupings identified by the Advisory Committee on Immunization Practices (ACIP) when allocating novel H1N1 vaccine to providers. These priority groupings are based on epidemiological evidence that indicates specific populations are more susceptible to morbidity and mortality if infected with the novel H1N1 influenza virus.

- The amount of vaccine allocated and distributed each week is directly related to the quantity, types, packaging, and formulation received by the federal government (see Section 5.1.1). It is also related to the ACIP priority groups. Providers and the public should be informed on how allocation decisions are made and the complexities of the decision-making process.

- All novel H1N1 vaccinations are reported using the Texas immunization registry tool, ImmTrac. Data is provided to ImmTrac by manual submission (e.g., faxed forms), individual online submission, or by batch processing. However, there is a time lag between actual dose administered and submission to the ImmTrac registry. Improved timeliness of such data input could inform and support the vaccine allocation decision-making process.

- The DSHS Vaccine Allocation and Approval Committee (VAAC) is composed of a multidisciplinary team of DSHS subject matter experts. To support transparency of the decision-making process, some form of outside representation – either on the committee or in an advisory capacity – should be considered. Similarly, a summary of the weekly report outlining the decisions of this committee could be published.

- Seasonal and novel H1N1 influenza cause considerable infection, morbidity, and mortality for both the general population and for healthcare workers. However, the percentage of healthcare workers who are vaccinated for seasonal influenza on an annual basis remains low; there are concerns that a similar trend will occur for novel H1N1 vaccination. Each healthcare system can identify actions most appropriate to optimize patient and employee safety. These actions may include influenza vaccination, use of masks by all unvaccinated staff, or limiting direct patient care responsibilities for unvaccinated staff.

- Once novel H1N1 vaccine is allocated to a provider, it is the provider's responsibility to adhere to ACIP guidelines when providing vaccinations to individual patients when resources are scarce.

5.3 Goal

The goal for the allocation and distribution of vaccine during pandemic influenza is

To minimize morbidity and mortality associated with novel H1N1 influenza and to prevent the spread of novel H1N1 influenza

5.4 Framework

An ethical framework can assist in the decision-making process. Such a framework is intended to:[7]

- Inform the decision-making process
- Encourage reflection on important issues
- Promote discussion and review of ethical concerns
- Improve accountability of decision-making

The framework developed by the Medical Ethics Work Group is noted in Table 4 with an explanation for the rationale for the framework.

[7] Thompson AK, Faith K, Gibson, JL, Upshur REG. Pandemic influenza preparedness: an ethical framework to guide decision-making. *BMC Medical Ethics* 2006, 7:12.

Table 4: The framework and rationale related to vaccine allocation and distribution decisions

FRAMEWORK	RATIONALE
A. Medical prioritization based upon best evidence, epidemiological data, and greatest risk of vulnerability to serious illness, complications, and death	• Texas continues to request its full allotment of novel H1N1 vaccine from the federal government. • However, as in most states, Texas is receiving less than its total allotment due to manufacturing and distribution challenges. • For doses received in Texas, DSHS considers a multitude of variables when making allocation decisions. • Allocation variables include quantity, dosage, formulation, and packaging of vaccine received. • Early vaccine allocation is targeted to vulnerable populations based on ACIP guidelines. • As Texas continues to receive its full allotment, allocation of the vaccine will be expanded to more and more of the population.

5.5 Values

The Medical Ethics Work Group identified values to inform the decision-making process related to vaccine allocation and distribution. Table 5 identifies these nine values, along with definitions and appropriate examples.

Table 5: Values ascribed to vaccine allocation and distribution

Efficacy	*Definition* "Efficacy is the idea that a program should be scientifically sound and have a significant chance of being successful in achieving its goals of improving a community's health and wellness. An efficacious program is one that is feasible in regard to social, political, and cultural climates."[8] *Examples* • The novel H1N1 vaccine was rigorously tested during clinical trials, before its release to the public, to evaluate the effectiveness and safety (efficacy) of the vaccine by monitoring the effects on large groups of people. • Every person in Texas, who chooses to be vaccinated, should be able to recieve the novel H1N1 vaccine once vaccine quantities are sufficient.

[8] Klugman CM. Public Health Principlism 2007. *Online Journal of Health Care Ethics* 1 (1):1-13.

Equity	*Definition* In terms of public health, the fair and equitable distribution of benefits and burdens within a community. In economics, ensuring an equal opportunity for access to benefits. *Examples* • Every person in Texas, without restriction, should have equal access to the novel H1N1 vaccine, using appropriate prioritization (e.g., guidelines from the Advisory Committee on Immunization Practices). • Local public health officials and healthcare partners should work together at the community level to provide access to all who seek to be immunized against novel H1N1 influenza once vaccine supplies are plentiful.
Inclusivity	*Definition* Comprehensive, including everyone. *Example* • Any person who seeks the novel H1N1 immunization should be able to access the vaccine through the local healthcare or public health system, regardless of their ability to pay. • Every person in Texas who wishes to receive novel H1N1 vaccine should have the opportunity to be immunized.
Justice	*Definition* (1) To treat likes alike and different differently; and (2) The distribution of scarce resources. In general, a scare resource can be distributed using one of six criteria: need, merit, contribution, egalitarian, desert, free market. *Example* • All people in Texas can expect to be treated justly, impartially and fairly in regard to access to novel H1N1 vaccine once vaccine quantities are sufficient and high-risk groups have been immunized.
Reciprocity	*Deinition* "The act or practice of making an appropriate and often proportional return—for example, returning benefit with proportional benefit…"[9] *Example* • Persons in a community who have received the novel H1N1 vaccine can expect not only individual immunity for that influenza virus, but can also expect that the overall community will benefit. This should ultimately decrease the disease burden in that community.
Solidarity	*Definition* "The notion of solidarity holds that as a result of common needs and interests, a community comes together to improve its aggregate health by reducing morbidity and mortality."[10] *Example* • The more persons who receive an influenza vaccine, the more the overall community and state benefit by reduced illness, hospitalization, and resource overutilization.

[9] Beauchamp TL and Childress JM. 2009. *Principles of Biomedical Ethics*. New York: Oxford.
[10] Klugman CM. Public Health Principlism 2007. *Online Journal of Health Care Ethics* 1 (1):1-13.

Stewardship	*Definition* Responsibly administering or managing a service, good, or resource on behalf of others. *Example* • Local providers, both public and private, will take proper care in the handling, storing, transporting and dispensing of influenza vaccine to assure that those people who are at greatest risk to serious illness, complications and death are immunized as soon as vaccine is available in the community.
Transparency	*Definition* Candid, frank, open *Example* • An individual seeking an influenza vaccine will be fully informed of any risk and potential adverse events of receiving the vaccine. • Local communities will fully understand the quantities, formulations and packaging of the vaccine being distributed and how those allocation decisions were made.
Trust	*Definition* "A confident belief in and reliance on the moral character of another person…entails a confidence that another will act with the right motives and in accordance with appropriate moral norms."[11] *Example* • Every person in Texas should expect that local and state public health authorities will distribute the influenza vaccine equitably and vaccinate persons using policies and standards based on science (ACIP guidelines), ethics, and timely disease data / trends.

[11] Beauchamp TL and Childress JM. 2009. *Principles of Biomedical Ethics*. New York: Oxford.

5.6 Recommendations

In developing recommendations, the PIMEWG considered the values, goals, and framework discussed above. Each recommendation is outlined in Table 6, with context on how it was developed.

Table 6: Recommendations and rationale related to vaccine allocation and distribution decisions

RECOMMENDATION	RATIONALE
A. Communicate allocation decisions clearly and effectively (a) Information will be transparent, accurate, and straightforward (c) Internal communication to health and medical stakeholders and external communication to the public are both important (b) Provide allocation, shipping, delivery, and administration updates on the DSHS website. (c) Send vaccine supply and administration updates to emails in the VORS system.	• Providers and the public need to be aware of how novel H1N1 vaccine allocation and distribution decisions are made and constraints associated with making these decisions (e.g., less quantities received than ordered and the variables that must be considered for allocation). • Timely communication is critical so that people who are willing to be immunized for novel H1N1 do not get discouraged because of lack of vaccine availability. • Public education should focus on how and why allocation decisions are made, including the rationale behind using the ACIP prioritization model (e.g., it is based on epidemiological evidence). • There may be a role with the current media contractor to educate the public, providers, key partners, and stakeholders on the vaccine allocation and distribution system.
B. Health care workers get vaccinated for both seasonal and novel H1N1 influenza, with a specific emphasis on those who have direct patient care	• Patient and healthcare worker safety is paramount. • Not only do unvaccinated healthcare workers pose a risk to patients, but patients suffering from influenza pose a risk to unvaccinated healthcare workers. The latter, in turn, could have significant impact on the availability of, and access to, health care personnel resources during a pandemic. • DSHS does not have the statutory authority to mandate healthcare worker influenza vaccination. • However, DSHS can strongly recommend that healthcare workers be vaccinated for both seasonal influenza and novel H1N1 influenza in order to protect the health and welfare of patients and workers. • In lieu of statutory guidance, employers may make appropriate decisions to protect patients and healthcare workers from employees who are not vaccinated against seasonal and novel H1N1 influenza. • These actions may include requirements that unvaccinated workers use masks or have limitations on direct patient contact.

RECOMMENDATION	RATIONALE
C. Create an advisory group to provide advice to the DSHS Vaccine Allocation and Approval Committee (VAAC) on allocation and distribution issues related to novel H1N1 vaccine. Considerations for this committee should include: (a) Multidisciplinary membership from both the public and private sectors (b) A public member in the group (c) Regional representation (d) Representation from both urban and rural areas of the state	• The DSHS VAAC is currently comprised of a multi-disciplinary team of DSHS subject matter experts. • Local public health officials and healthcare providers need to understand the complexities and variables that impact vaccine allocation and distribution decisions. • Local public health officials and healthcare providers need to understand and be able to communicate how VAAC decisions impact their communities and areas of responsibility. • To make sure that vaccine allocation and distribution decisions are transparent, DSHS should create an advisory committee to advise the VAAC. • The advisory committee should be multi-disciplinary and have wide geographic representation.
D. Continue to make novel H1N1 vaccine allocation and distribution decisions based on available scientific evidence	• DSHS should continue to use epidemiological disease trends as a basis for vaccine allocation and distribution. • Priority for novel H1N1 vaccine should be based on medical need and potential greatest benefit rather than first come, first served. • Limited vaccine availability, formulation type, and packaging issues, currently contribute to the complexity of how the vaccine is allotted and to whom. • When novel H1N1 vaccine is limited, allocation and distribution decisions should be based on reaching populations that are likely to have the greatest benefit. Allocation decisions should consider the population more broadly when vaccine availability increases.

6 Antiviral Medication Allocation and Distribution

The Medical Ethics Work Group discussed both practical and ethical issues related to the allocation and distribution of antiviral medications. Summary findings are identified in Box 4. The remaining parts of this section provide context for discussions and observations by the work group.

Box 4: Summary of work group findings related to antiviral allocation and distribution.

GOAL

A. Reduce mortality by adhering to the most current treatment guidelines

B. Reduce the need for hospitalization by adhering to the most current treatment guidelines

FRAMEWORK

A. Medical need initially, followed on a first come, first served basis

B. Opportunity to review allocation distribution if changing conditions warrant (e.g., the pandemic worsens or if manufacturing / distribution problems occur)

VALUES

- Efficacy
- Equity
- Inclusivity
- Justice
- Reciprocity
- Solidarity
- Stewardship
- Transparency
- Trust

RECOMMENDATIONS

A. Discourage prophylaxis to preserve resources for when they are medically needed and indicated

B. Communicate to clinicians the importance of properly prescribing medications and the impact of improper prescribing (e.g.. resistance, medication shortages, etc.)

C. Support the ability of the state to adapt to changing conditions with regard to allocation and distribution decisions

D. Acknowledge and continue strong partnerships with pharmacies in the state

E. Develop a prioritization system in the event of a significant shortage; prioritization may be based on severity of illness and likelihood of recovery (i.e., greatest benefit) and first-come, first served if need is equal

F. Redistribution of medication would occur for purposes of treatment

G. The prioritization system will change if a shortage of antiviral medication occurs; such prioritization may be targeted based on severity of illness and the likelihood of recovery

6.1 Background

Antivirals are prescription medications that inhibit the growth and reproduction of influenza viruses. If given within 48 hours of exposure, antiviral medications may reduce the natural course of the disease by one or two days and prevent serious complications from occurring. The use of these medications as a prophylactic measure can confer protection from infection, but this benefit ceases once the medication has been discontinued. Antiviral medications are not the same as a vaccine and do not provide immunity to influenza. Table 7 compares properties of both antiviral medications and the influenza vaccine.

Table 7: Comparison of properties between antiviral medications and influenza vaccine

Property	Antiviral Medication	Influenza Vaccine
Treatment or Prevention	Used to treat influenza	Used to prevent influenza
Immunity	Does not provide immunity to influenza	Helps your body build immunity to influenza
Length of Protection	When taken as a prophylactic measure, protection is provided only as long as a person takes the medication	Once the body develops immunity, there is lasting protection
Availability	There is a finite amount of medication available in the United States but not enough to provide to everyone	Novel H1N1 vaccine is being produced in sufficient quantities to allow vaccination by all who request it

Source: Texas Department of State Health Services

Currently, enough antiviral medication is available in the retail marketplace to meet the needs of individuals who are prescribed these medicines. Guidelines are available to assist providers when making treatment decisions and are available at www.TexaFlu.org.

In addition to the retail marketplace, DSHS has a stockpile of antiviral medications available. This stockpile is a compilation of purchases made with state funds, federal preparedness funds, and from stock received from the United States Strategic National Stockpile. Medications in the state stockpile are designated for use:

- By uninsured or underinsured persons who cannot afford to purchase antiviral medications
- By public health officials for outbreak control
- In the event of disruptions to the normal supply channel

To provide access to uninsured or underinsured persons, Texas has implemented a retail pharmacy distribution network by contracting with chain and independent pharmacies. DSHS is also working with Federally Qualified Health Center (FQHC) clients to provide

access to antiviral medications directly through FQHC pharmacies. Table 8 outlines the number and types of pharmacies participating in this initiative.

Table 8: Participating pharmacies as of October 29, 2009 in the Texas antiviral medication distribution system

Pharmacy Type	Number of Pharmacy Type	Number of Retail Stores	Counties Covered[1]
Chain Pharmacies[2]	8	1,337	160
Independent Pharmacies	47	47	36
FQHC Pharmacies	69	69	53
Total Current Pharmacies[3]	**-**	**1,453**	**199 (With no overlap)**
Total Potential Pharmacies	**-**	**1,520**	**227**

1. Independent pharmacies participate if there is not a chain pharmacy in that county; FQHC pharmacies are for their clients only and may be used in counties that have coverage by either a chain or independent pharmacy or neither
2. Chain pharmacies examples include: HEB, Walgreen's, CVS, Wal-Mart etc.
3. There are 35 counties in Texas that do not have a pharmacy

DSHS Health Service Regions (HSR) have also been allocated antiviral medications to meet needs related to outbreak control and supply chain disruptions.

6.2 High-Level Discussion Points

The Medical Ethics Work Group considered several issues related to antiviral allocation and distribution.

- The potential for novel H1N1 influenza to become resistant to antiviral medications is a concern. Therefore, antiviral medications should be used judiciously – regardless of whether it is dispensed from state or private stock. Clinical presentation should be a key factor in the decision making process on whether or not to prescribe an antiviral.

- Currently there are no plans to monitor appropriateness of prescribed antivirals dispensed from state stock or to require prior authorization before dispensing. However, this decision may be revisited if conditions change.

- Texas has both pharmacy chains and independent pharmacies participating in the DSHS antiviral distribution network. All counties, except the 35 without pharmacies, are included. To promote access to counties without pharmacies, neighboring counties will have increased pharmacy participation. The goal is to have one participating pharmacy for every 25,000 persons in Texas.

- Individuals who are underinsured or who lack health insurance must present a valid prescription from a licensed, United States provider in order to obtain antiviral medication from state stock. No other requirements are placed on uninsured / underinsured individuals to obtain antiviral medication from state stock.

- Redistribution of allocated antiviral medications among participating pharmacies would be encouraged if a medical need is demonstrated.

Additional input was requested by DSHS of the Medical Ethics Work Group. This input is summarized in Table 9.

Table 9: Issues raised by DSHS for input from the Medical Ethics Work Group regarding antiviral medication allocation and distribution

Issue	Requested Input
Compounding	The role of the state in paying for compounding when pediatric suspension formulation is unavailable
Redistribution	A framework to assist with redistributing state stock if data indicates a need for redistribution
Shortages	A framework for allocating state stock in case of shortages
Prioritization	Priority use of antivirals if supplies are scarce
Target Groups	Considerations of other potential target groups for antiviral use (e.g., teachers)
Rural Counties	Considerations for including rural or frontier counties as part of the Texas antiviral distribution system

6.3 Goals

The goal for the allocation and distribution of antiviral medications during pandemic influenza is

A. To reduce mortality by adhering to the most current treatment guidelines

B. To reduce the need for hospitalization by adhering to the most current treatment guidelines

6.4 Framework

An ethical framework can assist in the decision-making process. Such a framework is intended to:[12]

- Inform the decision-making process
- Encourage reflection on important issues
- Promote discussion and review of ethical concerns
- Improve accountability of decision-making

The framework developed by the Medical Ethics Work Group is noted in Table 10 with an explanation for the rationale for the framework.

Table 10: The framework and rationale related to antiviral medication allocation and distribution decisions

FRAMEWORK	RATIONALE
A. Medical need initially, followed on a first come, first served basis **B.** Opportunity to review allocation distribution if changing conditions warrant (e.g., the pandemic worsens or if manufacturing / distribution problems occur)	• Antiviral medications are known to shorten the clinical duration of influenza infection. They are also known to lessen symptom severity. • However, antiviral medications must be used judiciously (1) so that patients who can most benefit will receive them; and (2) to guard against development of antiviral medication resistance. • Currently there are no shortages of antivirals in the retail marketplace; however, this could change if the pandemic worsens or if manufacturing or distribution problems occur. • As conditions change (e.g., epidemiological data suggest increased virulence in a particular part of the state, supply disruptions occur, or increased illness occurs), DSHS will have the ability and flexibility to adapt accordingly.

6.5 Values

The Medical Ethics Work Group identified values to inform the decision-making process related to antiviral medication allocation and distribution. Table 11 identifies these nine values, along with definitions and appropriate examples.

[12] Thompson AK, Faith K, Gibson, JL, Upshur REG. Pandemic influenza preparedness: an ethical framework to guide decision-making. *BMC Medical Ethics* 2006, 7:12.

Table 11: Values ascribed to antiviral medication allocation and distribution

Efficacy	*Definition* "Efficacy is the idea that a program should be scientifically sound and have a significant chance of being successful in achieving its goals of improving a community's health and wellness. An efficacious program is one that is feasible in regard to social, political, and cultural climates." *Example* • Antiviral medications are most efficacious if used within 48 hours of exposure and onset of symptoms of influenza-like illness and may help both reduce the duration of the disease by 1 to 2 days and the severity of illness. • The state cache antiviral medication program is efficacious if it contributes to the reduction of the severity of illness and the need for hospitalization in the community. • Utilizing pharmacies allow for the wide distribution of antiviral medications across Texas in a relatively short period of time.
Equity	*Definition* In terms of public health, the fair and equitable distribution of benefits and burdens within a community. In economics, ensuring an equal opportunity for access to benefits. *Example* • Persons who are uninsured or underinsured should have equal access to the healthcare system in order to be evaluated and prescribed antiviral medications if clinically needed regardless of their ability to pay. • Community public health officials, working with private healthcare systems, should establish local opportunities for persons who are uninsured or underinsured to have access to medical evaluation and care (including prescribed antiviral medications if clinically warranted) regardless of their ability to pay.
Inclusivity	*Definition* Comprehensive, including everyone. *Example* • Any person who has been prescribed antiviral medications by a licensed healthcare professional should have access to those medications through the retail pharmacy system or from primary health care clinic pharmacies. • Every person in Texas, if prescribed antiviral medications by a licensed healthcare professional, should be able to have those prescriptions filled in the community through the retail marketplace or through state stock.
Justice	*Definition* (1) To treat likes alike and differents differently and (2) the distribution of scarce resources. In general, a scare resource can be distributed using one of six criteria: need, merit, contribution, egalitarian, desert, free market. *Example* • All people in Texas can expect to be treated justly, impartially and fairly in regard to access to antiviral medications, if prescribed by a licensed health care professional, through contracted retail pharmacy market place or a primary healthcare clinic pharmacy if there are sufficient quantities of the medications in the system.

Reciprocity	*Definition* "The act or practice of making an appropriate and often proportional return—for example, returning benefit with proportional benefit…" *Example* • A person should not misrepresent their uninsured status to gain access to state cache antiviral prescriptions if they have the ability to pay for the medication. • Licensed healthcare providers will only issue prescriptions for state stock antiviral medications when warranted clinically and based on the patient's uninsured/underinsured status or lack of ability to pay. • Persons in a community who have received and take antiviral medications based on clinical need and prescription directions can expect the duration of the influenza disease to be shorter and the symptoms less severe.
Solidarity	*Definition* "The notion of solidarity holds that as a result of common needs and interests, a community comes together to improve its aggregate health by reducing morbidity and mortality." *Example* • Licensed healthcare workers will prescribe antiviral medications only when clinically warranted to minimize the development of resistence to the virus. • In a shortage situation, licensed healthcare providers will not issue prescriptions for antiviral medications unless warranted to reduce the severity of disease and minimize hospitalizations.
Stewardship	*Definition* Responsibly administering or managing a service, good, or resource on behalf of others. *Example* • Local contracted pharmacies will take proper care in the handling, storage and transporting of state cache antiviral medications and administer the medications in accordance with state guidelines. • DSHS will allocate antiviral medications based guidance from the federal government and the state antiviral medication toolkit.
Transparency	*Definition* Candid, frank, and open *Example* • Licensed health care providers across Texas will be appropriately informed on how to access state cache antiviral medications, when clinically necessary, for persons who are uninsured and underinsured. • The public health and medical community will be informed on the appropriate use of and access to state cache antiviral medications.

Trust	*Definition* "A confident belief in and reliance on the moral character of another person…entails a confidence that another will act with the right motives and in accordance with appropriate moral norms." *Example* • Healthcare providers and facilities will use state cache antiviral medications for the purposes outlined in the state's antiviral medication toolkit and not for personal or professional gain. • Every person in Texas should expect that licensed healthcare professionals will only prescribe antiviral medications when clinically indicated based on science and timely disease data / trends.

6.6 Recommendations

In developing a set of recommendations, the Medical Ethics Work Group considered the goal, framework, and values discussed above. Each recommendation is outlined in Table 12, with an explanation for the rationale of each recommendation.

Table 12: Recommendations and rationale related to antiviral medication allocation and distribution decisions

RECOMMENDATION	RATIONALE
A. Encourage prescribing for appropriate use in accordance with CDC and DSHS guidelines (e.g., those with severe disease, patients in high-risk categories, and hospitalized patients)	• Prophylactic treatment with an antiviral medication may not prevent influenza infection, although it may delay infection. • Prophylactic treatment runs the risk of: (1) creating resistance to antiviral medications; (2) causing adverse events in patients receiving prophylaxis; (3) creating supply chain disruptions; and (4) putting a strain on state stock due to high demand. • Therefore, providers should be discouraged from providing prophylactic treatment and instead should be encouraged to use antiviral medications for high-risk patients (e.g., those with severe disease, patients in high-risk categories, and hospitalized patients). • However, as a pandemic unfolds, it may be appropriate to consider the need for prophylactic treatment.

RECOMMENDATION	RATIONALE
B. Communicate to clinicians the importance of properly prescribing medications and the impact of improper prescribing (e.g. resistance, medication shortages, etc.)	• Antiviral medications are one of several options available for treatment of patients with influenza. • The need to prescribe these medications in a judicious manner cannot be overstated. • Providers should be educated on clinical guidelines to promote appropriate prescribing. • The decision to prescribe will include consideration of not only the drug and dose but also the clinical indication. A proper written prescription will include the drug, dose and other information required by state law. • With regard to state stock, pre-authorization is not currently required, but could be required if limited supplies dictate. • The sphere of influence on the appropriate use of antiviral medications should go beyond use of the state cache.
C. Support the ability of the state to adapt to changing conditions with regard to allocation and distribution decisions	• The state should be able to quickly adapt should the situation warrant. • Allocation and distribution priorities may change if the pandemic worsens.
D. Acknowledge strong partnerships with pharmacies in the state	• Private retail pharmacies are strong partners at the state and local level and play a key role in distributing state stock to those in need. • Private pharmacies are working with the state to monitor availability of private stock.
E. Develop a prioritization system in the event of a significant shortage; prioritization may be based on severity of illness and likelihood of recovery (i.e., greatest benefit) and first-come, first served if need is equal	• In a severe pandemic or a critical supply shortage, providers should focus on reducing mortality. • If a severe shortage occurs, providers might have to change from a medical need / first-come, first-serve model to another appropriate model.
F. Redistribution would occur for purposes of treatment	• Influenza infection rates may change over time. • Such changes may require the state to reevaluate allocation and distribution decisions. • For example, some areas of the state may not meet hospital demand due to supply chain shortages. • The state should develop recall and redistribution systems that could be deployed quickly if redistribution becomes necessary to target severity of illness and to maximize benefit.

RECOMMENDATION	RATIONALE
G. The prioritization system will change if a shortage of antiviral medication occurs; such prioritization may be targeted based on severity of illness and the likelihood of recovery	• In a true shortage, some sort of prioritization system based on medical need would be required. • One prioritization factor might be the number of days of illness before treatment while another factor might be severity of illness.

7 Medical Surge Resource Allocation and Distribution

The Medical Ethics Work Group discussed both practical and ethical issues related to the allocation and distribution of medical surge resources. Summary findings are identified in Box 5. The remaining parts of this section provide context for discussions and observations by the work group.

Box 5: Summary of work group recommendations related to medical surge resource allocation and distribution

GOAL

To maintain the healthcare systems' capacity to provide judicious and efficacious care to as many people as possible

FRAMEWORK

A. Prioritization will be directed to healthcare facilities that are providing direct care to patients with influenza

B. That there will be an initial allocation of material resources based on population

C. If necessary, based on operating needs, resources can be allocated or reallocated, depending on availability, demand, and epidemiology

VALUES

- Accountability
- Efficacy
- Individual Liberty
- Integrity
- Justice
- Reciprocity
- Solidarity
- Stewardship
- Transparency
- Trust

RECOMMENDATIONS

A. Material resources should be disseminated to facilities that can effectively and appropriately utilize them in accordance with best practices

B. Regional medical systems, comprised of representation from local hospitals, long-term care facilities, nursing homes, public health, etc. should coordinate the development of prioritization protocols, based on ethical and medical standards of care, to optimize effective use of scarce resources during a pandemic

C. Information on available state-owned supplies, including product specifications, should be made available to eligible health care entities who may use these resources

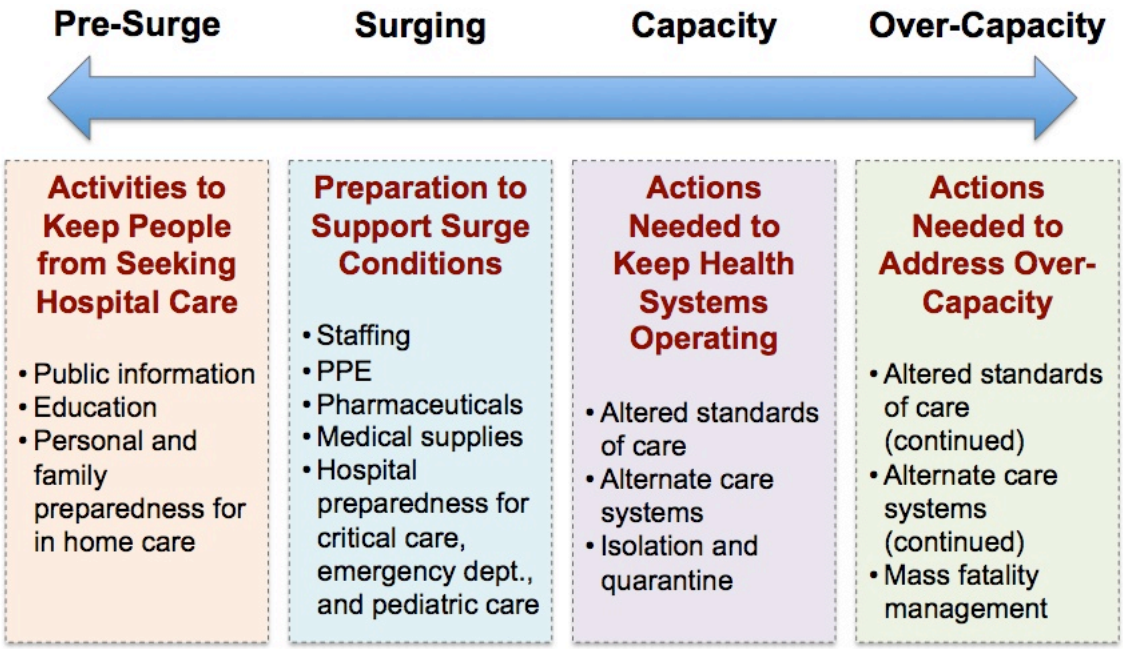
7.1 Background

The U.S. Department of Health and Human Services defines medical surge as the ability to provide adequate medical evaluation and care during events that exceed the limits of the normal medical infrastructure of an affected community.[13] This would include issues like:

- How will all points of entry to the healthcare system cope with an increase in visits (e.g., clinics, private physician offices, and hospitals)?
- How will hospitals cope with admission demand that exceeds availability?
- How will the healthcare system cope with workforce shortages due to illness among healthcare worker employees?
- How will physician offices, clinics, and hospitals deal with supply shortages?

Figure 2 identifies four stages of planning to address increased demand during surge conditions.

Figure 2: Four stages of planning to meet surge capacity demands placed on healthcare systems[14]



[13] U.S. Department of Health and Human Services. *A Management System for Integrating Medical and Health Resources During Large-Scale Emergencies*. September 2007.
[14] Figure created by The Litaker Group, October 2009.

1. **Pre-Surge:** At this stage, people are beginning to become ill with influenza-like illnesses, but are not yet accessing the healthcare system. Medical surge planning in this stage would use a combination of public information using multiple media sources to inform patients when to seek access to healthcare and how to provide treatment at home. This will enable more people to receive care at home and to utilize the healthcare system when warranted.

2. **Healthcare System Surge:** At this stage, there is an increase in the number of people seeking treatment at all levels of the healthcare system (e.g., physician's office, clinics, and hospital emergency departments). Medical surge planning in this stage would include increasing availability of supplies, medications, and other treatment resources. As additional demands are placed on the healthcare system, providers may begin to defer non-essential services (e.g., postponing elective surgeries).

3. **Healthcare System at Capacity:** At this stage, the healthcare system is exceeding the normal number of patients treated. Physician offices may experience overwhelming demand and hospitals may be at or above full census. Medical surge planning during this stage may include increased hours of service, alternate treatment sites, and triage. Healthcare staff may be assigned to care for a greater number of clients and augmentation of staff may occur by using retired healthcare professionals or students in healthcare programs. Healthcare systems may also be seeking assistance from nearby communities.

4. **Healthcare System Over Capacity:** At this stage, the healthcare system is exceeding its capacity to provide care in the usual and customary manner. Hospitals may be unable to admit persons who require care. Alternate care systems will continue to be used and altered standards of care may be required. All elective procedures will be canceled. An ethical decision framework will be needed to assist in making some decisions about the allocation of scarce resources.

Currently, DSHS and communities throughout Texas are addressing surge capacity demand issues related to PPE, antiviral medication availability, augmentation of medical staff, and availability of medical equipment such as medical tents, cots, and ventilators. Some of these assets have been purchased locally and at the state level, while the federal Strategic National Stockpile (SNS) may be another source of assets.

7.2 High-Level Discussion Points

The Medical Ethics Work Group considered several issues related to medical surge resource allocation and distribution.

- Workforce availability during a pandemic is a key concern. DSHS clarified that even with medical staffing contracts for immunization efforts, it is unlikely that it will be able to augment medical staff during a pandemic. Augmentation options include

working with professional schools (e.g., medicine, nursing, pharmacy, and veterinary medicine) to provide additional workers during a pandemic. Regardless, staffing surge may realistically only represent redistribution of staffing resources in a community, not increased staffing to a community.

- Hospital employees, and their families, have a specific vulnerability that can be addressed by vaccines, antiviral medications, and PPE. Consideration for prioritizing employees and their families should be considered.

- Hospitals have a responsibility to take care of employees and their families particularly with regard to providing vaccines, antiviral medications and PPE.

- Surge conditions may warrant discharge of non-critical care patients and delays of non-emergent surgeries. A uniform standard would be helpful to hospitals to be able to prepare for such an event.

- There is concern that some allocated resources may not be the same as resources currently used by hospitals (e.g., surgical masks versus N-95 respirators; certified respirators [by the National Institute for Occupational Safety and Health or NIOSH] versus uncertified respirators).

- Allocation decisions may be influenced by whether hospitals provide essential services and critical care services to influenza patients, as compared to hospitals who might not treat such patients.

- Local communities should consider creating local groups to review allocation requests at the local level before forwarding such requests through the state's emergency management process. This would allow a community to vet specific requests with available resources, before requesting assistance from the state.

- Hospitals are strongly encouraged to provide vaccine, antivirals and/or appropriate PPE to health care workers to prevent health care workers from becoming disease vectors. All available measures should be taken to prevent spread of disease from health care workers to patients.

7.3 Goal

The goal for the allocation and distribution of medical surge resources during pandemic influenza is

To maintain the healthcare system's capacity to provide judicious and efficacious care to as many people as possible

7.4 Framework

An ethical framework can assist in the decision-making process. Such a framework is intended to:[15]

- Inform the decision-making process
- Encourage reflection on important issues
- Promote discussion and review of ethical concerns
- Improve accountability of decision-making

The framework developed by the Medical Ethics Work Group is noted in Table 13 with an explanation for the rationale for the framework.

Table 13: The framework and rationale related to medical surge resource allocation and distribution decisions

FRAMEWORK	RATIONALE
A. That prioritization will be directed to healthcare facilities that are providing direct care to patients with influenza	• There are likely to be resource shortages during pandemic influenza as increased numbers of patients and admissions occur. • To meet demands placed on healthcare systems due to a surge in patients, healthcare systems may need to defer some types of care (e.g., elective or non-acute procedures or admissions). • Therefore, healthcare systems that treat patients suffering from influenza or influenza-like illnesses and that request resources to support medical surge conditions will have priority on receiving such resources.
B. That there will be an initial allocation of material resources based on population	• Surge conditions will vary across Texas in terms of timing and intensity. • Regardless, once surge conditions occur, communities are likely to witness surge conditions relative to the population (e.g., a large city could be expected to see a larger number of surge patients than a small town). • It is important for a community to be ready to respond to potential surge conditions. • Therefore, initial allocation to communities will be based geographically on population service area / population size served.
C. If necessary, based on operating needs, resources can be allocated or reallocated, depending on availability, demand, and epidemiology	• As surge conditions change, one community may have a greater need than another community for resources. • This is particularly likely in pandemic influenza, where infection intensity may peak at different times. • Therefore, resources may be reallocated, as appropriate, based on actual need and supporting science.

[15] Thompson AK, Faith K, Gibson, JL, Upshur REG. Pandemic influenza preparedness: an ethical framework to guide decision-making. *BMC Medical Ethics* 2006, 7:12.

7.5 Values

The Medical Ethics Work Group identified values to inform the decision-making process related to medical surge resource allocation and distribution. Table 14 identifies these ten values, along with definitions and appropriate examples.

Table 14: Values ascribed to medical surge resource allocation and distribution

Accountability	*Definition* "Fulfilling the implied contract governing the patient/provider [government/citizen] relationship through self-regulation, standard setting, managing conflicts of interest, acceptance of service, and responsibility." *Example* • Healthcare facilities are obligated to use personal protective equipment responsibly. • The system developed to allocate state cache medical surge PPE and supplies should outline appropriate use and accountability guidelines for healthcare facilities, local public health and communities.
Efficacy	*Definition* "Efficacy is the idea that a program should be scientifically sound and have a significant chance of being successful in achieving its goals of improving a community's health and wellness. An efficacious program is one that is feasible in regard to social, political, and cultural climates."[16] *Example* • Local healthcare facilities requesting and using state cache N-95 respirators will properly fit test such equipment for maximum efficacy. • The system developed to allocate state cache medical surge PPE and supplies should include proper use and fit testing instructions to provide for the efficacious use of the materials.
Individual Liberty	*Definition* The notion that persons should be able to exercise their own free will with as little restriction as possible. *Example* • A healthcare worker should be able to exercise free will with as little restriction as possible in the use of PPE and supplies from the state stockpile as long patient safety is not impacted. • The system developed to allocate and distribute PPE and other medical surge supplies should allow for individual free will in the usage of the material when it does not pose a health risk to patient safety, themselves, or others.

[16] Klugman CM. Public Health Principlism 2007. *Online Journal of Health Care Ethics* 1 (1):1-13.

Integrity	*Definition* (1) A characteristic of a person or organization related to purity and wholeness; and (2) a commitment to acting morally. *Example* • The system developed to allocate and distribute state cache medical surge PPE and supplies should be based on the expectation that the material will be used for the intended purpose of providing direct healthcare to as many people as possible and not for personal or facility gain. • Every person in Texas should expect that healthcare providers and facilities will use every precaution and protection available to minimize the spread of influenza.
Justice	*Definition* (1) To treat likes alike and differents differently and (2) the distribution of scarce resources. In general, a scare resource can be distributed using one of six criteria: need, merit, contribution, egalitarian, desert, free market. *Example* • A healthcare facility would request state cache PPE and supplies to supplement facility supplies only during a supply chain breakdown or other emergency / medical surge situation. • The system developed to allocate and distribute state cache medical surge PPE and supplies should be based on the expectation that local facilities will attempt to maintain adequate stocks of supplies and use the state assets to increase surge capacity during a public health emergency.
Reciprocity	*Definition* "The act or practice of making an appropriate and often proportional return—for example, returning benefit with proportional benefit…"[17] *Example* • A healthcare facility requesting state cache PPE and supplies might return an equivalent stock of material to the state or local public health supplier once supply chain breakdowns are restored. • Realizing the potential shortage of medical equipment and supplies during in influenza pandemic, a healthcare facility will not request more PPE and medical supplies than they need or can realistically use during an influenza pandemic response.
Solidarity	*Definition* "The notion of solidarity holds that as a result of common needs and interests, a community comes together to improve its aggregate health by reducing morbidity and mortality."[18] *Example* • A healthcare worker, who is provided appropriate PPE, and is not ill, will come to work during an influenza pandemic. • The local community, including both public and private providers, will work together to plan for medical surge and minimize the impact on the healthcare system during an influenza pandemic.

[17] Beauchamp TL and Childress JM. 2009. *Principles of Biomedical Ethics*. New York: Oxford.
[18] Klugman CM. Public Health Principlism 2007. *Online Journal of Health Care Ethics* 1 (1):1-13.

Stewardship	*Definition* Responsibly for administering or managing a service, good, or resource on behalf of others. *Example* • The state will allocate state cache PPE and medical supplies based on guidance from the federal government or other authoritative body and will supply proper use instructions if available. • The local community or receiving facility will take proper care of state cache PPE and supplies received, use according to federal and/or state guidance and reduce waste as much as possible.
Transparency	*Definition* Candid, frank, open *Example* • Healthcare workers using state cache PPE, such as N-95 respirators, will be provided information on the proper use of the resources and be individually fit tested if indicated. Patients will be advised on the rationale for health care workers using the respirators. • Local communities and healthcare facilities receiving state cache PPE and supplies will be fully informed on product specifications and use / fit requirements.
Trust	*Definition* "A confident belief in and reliance on the moral character of another person…entails a confidence that another will act with the right motives and in accordance with appropriate moral norms."[19] *Example* • A healthcare worker can expect to be provided guidance or training on the appropriate use of PPE and medical supplies and that some protection from the spread of influenza-like illness will result from the proper use of the equipment / supplies. • Healthcare providers and facilities will use state cache PPE and medical supplies to supplement surge capacity due to pandemic influenza and not for personal or professional gain. • Every person in Texas should expect that every precaution and protection available to healthcare workers and facilities is being used to minimize the spread of influenza.

[19] Beauchamp TL and Childress JM. 2009. *Principles of Biomedical Ethics*. New York: Oxford.

7.6 Recommendations

In developing recommendations, the PIMEWG considered the values, goals, and framework discussed above. Each recommendation is outlined in Table 15, with context on how it was developed.

Table 15: Recommendations and rationale related to medical surge resource allocation and distribution decisions

RECOMMENDATION	RATIONALE
A. Disseminate material resources to places that can effectively and appropriately utilize them in accordance with best practices	• The dissemination of state resources, such as N-95 respirators, should be based on need, as identified by epidemiological data. • Local stocks of personal protective equipment (PPE) such as respirators should be used before requesting limited state cache items. • Priority for allocating scarce state medical surge resources should be given to medical surge hospitals that are providing direct care to patients with influenza.
B. Regional medical systems, comprised of representation from local hospitals, long-term care facilities, nursing homes, public health, etc. should coordinate the development of prioritization protocols, based on ethical and medical standards of care, to optimize effective use of scarce resources during a pandemic	• Optimizing asset allocation and use at the local level is important to the efficient use of resources. • Such optimization could be enhanced by the use of prioritization protocols at the local level. • Such protocols should consider the needs of the local healthcare community. • Based on these protocols, local providers should be better able to promote the optimal use of assets before requesting additional assets from the state. • It was also recognized that some systems have been proactive in planning needs (e.g., purchasing ventilators and PPE) while others will continue to require additional support in a pandemic. • However, the work group recognized that patients and staff in areas that require additional support in a pandemic should not be refused such support.
C. Information on available state-owned supplies, including product specifications, should be made available to eligible health care entities who may use these resources	• There are multiple manufacturers of surgical masks and certified N-95 respirators. Fit-testing requirements should be followed where applicable. • Since some healthcare systems may use a manufacturer or model that is not available from the state cache, it is important that information be shared up front regarding the product types and specifications that are available. • Healthcare system employees may then be able to plan for fit testing and other tasks that might be required to use different brands of equipment or supplies.

8 Ventilator Allocation and Distribution

The Medical Ethics Work Group discussed both practical and ethical issues related to the allocation and distribution of mechanical ventilators. Summary findings are identified in Box 6. The remaining parts of this section provide context for discussions and observations by the work group.

Box 6: Summary of work group recommendations related to ventilator allocation and distribution

GOAL

To reduce mortality by the most judicious and efficacious use of available resources

FRAMEWORK

Ventilators obtained from the state cache should be distributed or redistributed based upon:

A. The availability of professional staff who are trained, experienced, and proficient in ventilator use for patient care
B. Recognition of either (1) a medical need based on number influenza cases; (2) or a public health outbreak in a region
C. Initial, pre-event proportional allocation to a DSHS Trauma Service Area (TSA) based on population percentage
D. Reallocation of ventilators based on medical and epidemiological need

VALUES

- Accountability
- Duty to Provide Care
- Efficacy
- Egalitarianism
- Integrity
- Proportionality
- Stewardship
- Trust

RECOMMENDATIONS

A. There should be uniform and cooperative guidelines in place at the hospital level, as it pertains to the use of mechanical ventilators. The state should lead efforts in developing guidelines that can be applied statewide. Guideline development would include involvement from local and regional officials, professional organizations, and other stakeholders

B. The ventilator distribution process should be optimized for rapid deployment so requesting hospitals will receive such equipment in a timely manner

C. Ventilator allocation decisions should be based on two related factors: (1) severity of illness; and (2) likelihood of recovery.

8.1 Background

In a severe influenza pandemic, it is estimated that the number of hospitalized patients requiring ventilator care will exceed available resources in Texas and in the United States. While the exact number of ventilators available in the U.S. is not known, it is estimated that hospitals have at least 85% of ventilators in use on a daily basis.[20] During a pandemic, there may not be enough ventilators available to meet projected demand in Texas.

The state of Texas has ventilators available in the Texas allotment of the Strategic National Stockpile (SNS). Additional ventilators have been purchased on a regional basis using hospital preparedness funding. As of October 2009, Texas received funding from the Public Health Emergency Response grant from the U.S. Department of Health and Human Services to purchase an additional cache of ventilators. Current quantities of available ventilator stock from DSHS are highlighted in Table 16.[21]

Table 16: Ventilator assets available for allocation by the Texas Department of State Health Services

Source	Quantity Available
Texas Strategic National Stockpile Allotment	291
DSHS Public Health Emergency Response Grant Purchase	≈ 300
Total Ventilators Available from DSHS	≈ 600

Note: There are approximately 174 mechanical ventilators in regional caches, but these are maintained and allocated by Healthcare System Preparedness Contractors.

Requests for ventilators from DSHS will follow the Texas emergency management resource request process. Allocated ventilators remain either state or federal assets, depending on the source of funding. State cache ventilators will be returned to the state after use and maintained for redistribution purposes.

8.2 High-Level Discussion Points

The Medical Ethics Work Group considered several issues related to ventilator allocation and distribution.

- Most patients who receive ventilator care are hospitalized in an intensive care unit (ICU). In the period from late fall to early spring, ICU bed availability in Texas is at or near 100% census capacity because of an increase in seasonal-type illnesses (e.g., respiratory syncytial virus (RSV) and seasonal influenza). The ability to provide additional ventilator care is, therefore, directly related to ICU bed availability.

[20] Texas Department of State Health Services Public Health Emergency Preparedness Branch, October 20, 2009
[21] *Ibid*.

- Ventilator care requires a skilled, expert workforce to operate the ventilator in a safe, effective manner. This includes physicians and nurses trained, experienced, credentialed, and proficient in critical care medicine, respiratory therapists, and other ancillary staff to support patient care needs.

- A critical care infrastructure is needed to support patients who require ventilator care. Hospitals able to support this type of care are typically located in a metropolitan area, meet certain designations by accrediting organizations, provide a mix of services, and have a minimum number of licensed beds. In Texas, 25% of hospitals have greater than 127 beds; with 50% of hospitals having less than 48 beds.[22]

- The decision to provide ventilator care to a patient is a clinical decision made at the local level. However, such decisions impact the use of locally available ventilators and may ultimately impact how available statewide ventilator assets are allocated and distributed. To assist in the decision-making process, consistent guidelines related to a clinical framework for ventilator care for individual patients should be developed with input from partners and stakeholders at the local and state levels. The guidelines would be applied at the state level.

8.3 Goals

The goal for the allocation and distribution of ventilators during pandemic influenza is

To reduce mortality by the most judicious and efficacious use of available resources

[22] Litaker JR and Morrill JB. Results of the 2005 Hospital Bioterrorism Preparedness Survey: Final Report to the Texas Department of State Health Services. November 2005.

8.4 Framework

An ethical framework can assist in the decision-making process. Such a framework is intended to:[23]

- Inform the decision-making process
- Encourage reflection on important issues
- Promote discussion and review of ethical concerns
- Improve accountability of decision-making

The framework developed by the Medical Ethics Work Group is noted in Table 17 with an explanation for the rationale for the framework.

Table 17: The framework and rationale related to ventilator allocation and distribution decisions

FRAMEWORK	RATIONALE
Ventilators obtained from the state cache should be distributed or redistributed based upon: **A.** The availability of professional staff who are trained, experienced, and proficient in ventilator use for patient care **B.** Recognition of either (1) a medical need based on number influenza cases; (2) or a public health outbreak in a region **C.** Initial, pre-event proportional allocation to a DSHS Trauma Service Area (TSA) based on population percentage **D.** Reallocation of ventilators based on medical and epidemiological need	• Ventilators are sophisticated pieces of medical equipment that require trained, professional staff and appropriate support services to operate. • Ventilators may be in short supply during pandemic influenza. • DSHS will have a limited supply cache of ventilators to allocate and distribute to medical facilities. • Allocation and distribution decisions will be based on the ability of a medical facility to properly use an allocated ventilator. • Other allocation and distribution factors will include population and demonstrated need. • Allocation decisions will not be based on demographic characteristics, socioeconomic status, or any other non-clinical measure.

[23] Thompson AK, Faith K, Gibson, JL, Upshur REG. Pandemic influenza preparedness: an ethical framework to guide decision-making. *BMC Medical Ethics* 2006, 7:12.

8.5 Values

The Medical Ethics Work Group identified values to inform the decision-making process related to ventilator allocation and distribution. Table 18 identifies these eight values, along with definitions and appropriate examples.

Table 18: Values ascribed to ventilator allocation and distribution

Accountability	*Definition* "Fulfilling the implied contract governing the patient/provider [government/citizen] relationship through self-regulation, standard setting, managing conflicts of interest, acceptance of service, and responsibility." *Example* • The requesting facility should request state cache ventilators during an influenza pandemic only if their ventilator usage exceeds historical usage patterns and if they have the trained workforce and capacity to properly use the equipment. • State cache ventilators should only be allocated after determining that the requesting facility has a valid need and has the trained workforce and capacity to properly use the equipment.
Duty to Care	*Definition* A duty is an obligation to take action in order to fulfill a responsibility. Thus, a "duty to provide care" is one in which a healthcare worker must takes steps in order to provide a physiological or psychological beneficial action to help patients. *Example* • The requesting facility should only request state cache ventilators if they intend to use the equipment in the immediate future to provide life-saving care for a patient(s) with influenza. • State cache ventilators should only be allocated after assessing: (1) that the requesting facility has a valid need that cannot be met locally or regionally; (2) the capacity to operate the machine; (3), the intention to use the equipment in the immediate future to provide life-saving care for a patient(s) with influenza.

Efficacy	*Definition* "Efficacy is the idea that a program should be scientifically sound and have a significant chance of being successful in achieving its goals of improving a community's health and wellness. An efficacious program is one that is feasible in regard to social, political, and cultural climates."[24] *Example* • There should be uniform guidelines in place at the hospital level, as it pertains to the use of mechanical ventilators. Ventilators should be used in accordance with hospital policy based on the patient's medical need including the severity of illness and likelihood of recovery. • Due to the expected limited availability of this equipment, state cache ventilators should only be allocated after determining that the requesting facility has the ability to properly the use the equipment as well as the resources / capacity to utilize the equipment in the near future.
Egalitarianism	*Definition* "Emphasizes equal access to the goods in life that every rational person values." All people are valued equally and have an equal chance at access to a good or service. *Example* • The use of state cache ventilators should be based on medical need including the severity of illness and likelihood of recovery and not based on demographics, citizenship or any other socio-economic factors. • State cache ventilators should only be allocated to the requesting facility after determining that the requesting facility has uniform guidelines in place. These guidelines should provide for the ventilator usage based on severity of illness and likelihood of recovery and not be discriminatory to any person.
Integrity	*Definition* (1) A characteristic of a person or organization related to purity and wholeness; and (2) a commitment to acting morally. *Example* • The use of the limited state cache ventilators should be based on uniform guidelines at the hospital and state level. State cache ventilators should only be requested when the healthcare facility exceed historical usage patterns. • Healthcare facilities that have received state cache ventilators will use the equipment on a first come, first service basis to aid in the treatment of critically ill patients based on their medical need including the severity of illness and the likelihood of recovery. Ventilator allocation decisions will not be based on reasons such as the patient's citizenship status or ability to pay.

[24] Klugman CM. Public Health Principlism 2007. *Online Journal of Health Care Ethics* 1 (1):1-13.

Proportionality	*Definition* "An intervention must confer greater benefits than burdens. An estimate that a promised benefit outweighs a potential burden." *Example* • The data needed to justify a request for a state cache ventilator should be straightforward, requests should be processed quickly and the ventilators available for delivery in a matter of hours or facilities may conclude that the effort is not worth the benefit. • The DSHS process for allocation and distribution of state cache ventilators should be as simple as possible and not be burdensome on the healthcare system or the benefit of receiving the equipment may not be worth the effort to justify the request.
Stewardship	*Definition* Responsibly administering or managing a service, good, or resource on behalf of others. *Example* • The healthcare facility ultimately receiving the state cache ventilator should responsibly manage the use and maintenance of the equipment as the equipment will be returned to the state for reallocation purposes when it is no longer needed by the receiving facility. • The state system designed to allocate and distribute state cache ventilators should include guidelines for the transport, receipt, use, care, maintenance and return of the equipment when no longer needed so it can be reallocated to other parts of the state as needed.
Trust	*Definition* "A confident belief in and reliance on the moral character of another person…entails a confidence that another will act with the right motives and in accordance with appropriate moral norms."[25] *Example* • A patient placed on a state cache ventilator can expect that the healthcare facility has both the trained personnel and adequate resources available to properly manage the equipment. • A patient and their family can expect that the healthcare facility will make appropriate decisions on the use of existing ventilators based on medical need including severity of illness and likelihood of recovery. Ventilator use decisions will not be based on demographic, socio-economic, citizenship or ability to pay factors.

[25] Beauchamp TL and Childress JM. 2009. *Principles of Biomedical Ethics*. New York: Oxford.

8.6 Recommendations

In developing a set of recommendations, the Medical Ethics Work Group considered the goal, framework, and values discussed above. Each recommendation is outlined in Table 19, with an explanation for the rationale of each recommendation.

Table 19: Recommendations and rationale related to ventilator allocation and distribution decisions

RECOMMENDATION	RATIONALE
A. There should be uniform and cooperative guidelines in place at the hospital level, as it pertains to the use of mechanical ventilators. The state should lead efforts in developing guidelines that can be applied statewide. Guideline development would include involvement from local and regional officials, professional organizations, and other stakeholders	• The decision to provide ventilator care is a clinical decision made at the local level. • However, clinical decision-making at the local level can affect decisions at the state level. • For example, if two localities request the same state asset (e.g., a ventilator) it is important to consider whether clinical decisions are made consistently in locales across the state. • If such consistency in decision-making is not in place, a person may seek care in a locale that favors providing the type of care he or she seeks. • Therefore, a clinical-decision guideline with regard to ventilator care that can be applied statewide is needed. • The state is not in a position to develop such guidance; however, the state can support a process to bring experts, partners, and stakeholders together to develop such guidance.
B. The ventilator distribution process should be optimized for rapid deployment so requesting hospitals will receive such equipment in a timely manner	• Mechanical ventilators are used to provide life-sustaining treatment, the absence of which can lead to death. • Therefore, it is necessary that such equipment be made available in a timely manner. • As requested through the Texas emergency management process, assets are provided when they are no longer available locally. • For ventilators, a process needs to consider how long it will take for a state supplied asset to be made available locally and then to create procedures that optimize the request, allocation, and distribution of this equipment. • Such a system could consider historical supply and demand, with a request for state-owned assets when current demand reaches a pre-determined threshold level (e.g., a specific hospital is utilizing 95% of it's ventilators when historical usage patterns suggest an 80% usage rate should be occurring at a particular time).

RECOMMENDATION	RATIONALE
C. Ventilator allocation decisions should be based on two related factors: (1) severity of illness; and (2) likelihood of recovery	• Ventilators are a sophisticated type of medical equipment that require an appropriate infrastructure and supporting workforce to be in place. • Locations that have experience in using ventilators on a sustained basis and who have a workforce to appropriately care for patients who require ventilator care are likely candidates to be allocated a ventilator if requested. • Hospitals that do not support an appropriate infrastructure or staff, or that do not indicate a high likelihood of recovery for a patient, may not be likely candidates to receive a ventilator if requested. • Instead such hospitals should work with appropriate referral hospitals for patient transfer, as appropriate.

9 Conclusion

The Texas Department of State Health Services sought the creation of an ethical framework to assist in the decision-making process regarding the allocation and distribution of scarce resources. A first step in this effort was to convene a multi-disciplinary work group to identify goals, frameworks, values, and recommendations associated with four potentially scarce resources: (1) novel H1N1 vaccine; (2) antiviral medications; (3) medical surge capacity resources; and (4) ventilators. This work group, called the Pandemic Influenza Medical Ethics Work Group, met for 2.5 days in October 2009 to be informed about current DSHS activities related to these topics and to deliberate and provide specific feedback and recommendations. This report contains this feedback and recommendations.

10 Appendices

10.1 Abbreviations

ACIP	Advisory Committee on Immunization Practices
CDC	Centers for Disease Control and Prevention, U.S.
DSHS	Department of State Health Services, Texas
FQHC	Federally Qualified Health Center
HHS	Department of Health and Human Services, U.S.
PIMEWG	Pandemic Influenza Medical Ethics Work Group, Texas
PPE	Personal Protective Equipment
VAAC	Vaccine Allocation Approval Committee, DSHS
VAERS	Vaccine Adverse Event Reporting System, U.S.
VORS	Vaccine Ordering and Reporting System, DSHS

10.2 Glossary of Terms

Accountability: Fulfilling the implied contract governing the patient/provider [government / citizen] relationship through self-regulation, standard setting, managing conflicts of interest, acceptance of service, and responsibility.

Duty to Provide Care: A duty is an obligation to take action in order to fulfill a responsibility. Thus, a duty to provide care is one in which a healthcare worker must takes steps in order to provide a physiological or psychological beneficial action to help patients.

Efficacy: "Efficacy is the idea that a program should be scientifically sound and have a significant chance of being successful in achieving its goals of improving a community's health and wellness. An efficacious program is one that is feasible in regard to social, political, and cultural climates." (Klugman 2007).

Egalitarianism: "Emphasizes equal access to the goods in life that every rational person values." (Beauchamp & Childress 2009, p. 244). All people are valued equally and have an equal chance at access to a good or service.

Equity: In terms of public health, the fair and equitable distribution of benefits and burdens within a community. In economics, ensuring an equal opportunity for access to benefits.

Flexibility: "Susceptible of modification or adaptation" (Random House Websters 2001).

First come, first served: A type of egalitarian distribution of resources. All people are treated as equal no matter any demographic characteristic, socioeconomic status, or need. The first person to get in line receives the good or service. Those who arrive later may not receive the service or good.

Framework: A structure for considering ethical principles in the allocation and decision-making process.

Geographic Need: Distributing resources to a demarcated land area that requires certain services or supplies. For example, if there is an H1N1 outbreak in Houston but not El Paso, then the resources should go to Houston, where they could provide the greatest benefit.

Goal: A desired outcome for the allocation and distribution of a specific resource.

Inclusivity: Comprehensive, including everyone.

Individual Liberty: The notion that persons should be able to exercise their own free will with as little restriction as possible. (Stanford Encyclopedia 2008)

Integrity: (1) A characteristic of a person or organization related to purity and wholeness. (2) A commitment to acting morally.

Justice: According to Aristotle in the *Nichomachean Ethics*, (1) to treat likes alike and different differently and (2) the distribution of scarce resources. In general, a scare resource can be distributed using one of six criteria: need, merit, contribution, egalitarian, desert, free market.

Medical Need: Resources should be distributed based on the greatest urgency as defined by medical criterion. Thus, the sickest and most vulnerable people should have priority in receiving the resource. Also, the place with the most critical patients should get the resource.

Medical Prioritization: A rational method for ranking the importance or urgency of necessary welfare of a group, organization, or individual. For example, in standard ethics, the sickest people are those in greatest need and thus usually receive the most resources. However, in an emergency disaster or battle situation, the sickest may not receive care (since they require the most resources—thus impacting the care available to others—and have the least likelihood of survival), but rather those in great need who have a high likelihood of survival. This system is known as *triage.*

Population Based: Means looking at health care not from the perspective of the individual, but rather from the perspective of the community. The health of the group takes priority over the individual but since the individual is a member of the group, the individual also benefits.

Prioritization: A preferential rating to distribute goods in short supply. To rank according to importance or need.

Professional Capacity: Tasks and responsibilities specified as part of a person's job function.

Proportionality: An intervention must confer greater benefits than burdens. An estimate that a promised benefit outweighs a potential burden (Jonsen, Siegler & Winslade 2002). Distribution of a resource based on a numerical constant. For example, if a city has 12 percent of the total population, then they should receive 12 percent of all resources.

Reciprocity: "The act or practice of making an appropriate and often proportional return—for example, returning benefit with proportional benefit…" (Beauchamp & Childress 2009, p. 205).

Recommendations: A recommended course of action that incorporates ethical considerations for the allocation and distribution of a specific resource.

Solidarity: "The notion of solidarity holds that as a result of common needs and interests, a community comes together to improve its aggregate health by reducing morbidity and mortality." (Klugman 2007).

Stewardship: Responsibly administering or managing a service, good, or resource on behalf of others.

Transparency: "candid, frank, open" (Random House 2001).

Trust: "A confident belief in and reliance on the moral character of another person…entails a confidence that another will act with the right motives and in accordance with appropriate moral norms." (Beauchamp & Childress 2009, p. 41).

Values: Principles or standards that reflect ethical considerations about the allocation and distribution of a specific resource.

10.3 References

Prior to the October 2009 meeting, work group members were provided with a comprehensive set of reference documents and reference materials that represented current thinking on public health ethics.

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