

Texas Ethics Group Provides Recommendations on Allocation of Health Care Services During an Influenza Pandemic

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Last fall, a multidisciplinary work group consisting of medical ethicists, public health experts, and state agency officials met in Austin, Texas, to discuss and formulate an ethical framework for the allocation of health care services during a public health emergency—more specifically during an influenza pandemic. On May 14, 2010, this group issued its findings to the Texas Department of State Health Services (DSHS) in a draft report for public comment.¹ Once finalized, the DSHS will use the framework contained in the document as a guide when providing local health officials with information about making decisions regarding the allocation and distribution of state-owned health and medical resources during a mild to moderate pandemic.²

H1N1 Flu Outbreak

In April 2009, Texas was one of the first states to have individuals diagnosed with novel H1N1 influenza. At that time, little was known about the illness except that hundreds of individuals in Mexico City had become ill, with reported hospitalizations and deaths.³ By the end of April, then-Acting U.S. Department of Health and Human Services (HHS) Secretary, Charles E. Johnson, declared a public health emergency pursuant to section 319 of the Public Health Service Act (PSHA)⁴ – one of the major federal laws addressing protocol during public health emergencies. Since that time, current HHS Secretary Sebelius has renewed the declaration twice, on July 24, 2009, and on October 1, 2009.⁵ As the reported cases of H1N1 infections grew worldwide, the World Health Organization (WHO) raised the worldwide pandemic level to Phase 6 on June 11, 2009.⁶ A Phase 6 alert, the highest assigned by the WHO, is characterized as a global outbreak of the disease and an indication that a global pandemic is underway.⁷ Although the H1N1 pandemic did not reach such a critical point where limited supplies of antiviral medications and vaccines had to be widely rationed, the outbreak gave pause to many state health agencies on how best to distribute scarce medical resources.

¹ See Jeffrey L. Levin, *et al.*, *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*, May 14, 2010 (Draft for Public Comment), available at <http://www.dshs.state.tx.us/txflu/PIMEWG-Report-for-Public-Comment-051410.pdf>.

² *Id.* at p. 4.

³ *Id.*

⁴ 42 U.S.C. § 247d-6d (West 2009).

⁵ U.S. Dep't of Health & Human Servs., *HHS Pandemic Influenza Plan*, available at <http://www.hhs.gov/pandemicflu/plan/appendix.html> (last accessed May 22, 2010).

⁶ Centers for Disease Control & Prev., *A Pandemic Is Declared*, <http://www.cdc.gov/h1n1flu/updates/071709.htm> (last accessed May 22, 2010).

⁷ World Health Org., *Global Alert and Response, Current WHO Phase of Pandemic Alert*, http://www.who.int/csr/disease/avian_influenza/phase/en (last accessed May 22, 2010).

Biomedical Ethics Overview

During a public health emergency, such as the most recent bout of widespread H1N1 influenza, federal and state health agencies had a limited supply of medical resources and medical devices for distribution. These resources included antiviral medications, ventilators, personal protective equipment (PPE), and the recently-developed H1N1 vaccine. As a result, federal and state government officials were required to make decisions regarding which groups of individuals would receive those resources first. For example, it was well known that high-risk individuals such as pregnant women and the very young and elderly were in a priority position to receive vaccinations. Such decisions were made, in part, based on ethical principles.

Before the 1970s, there was no firm ground or framework on which a commitment to principles or ethical theory could take root in biomedical ethics and effectively guide health care practitioners in ethically making medical decisions.⁸ That isn't to say that physicians lacked ethical standards. They have been instructed to "do no harm" for over a century. For the most part, a physician's goal was to maximize medical benefits while minimizing risks of harm and disease. However, some aspects of medical ethics had not fully addressed issues such as truthfulness, privacy, justice, autonomy, and communal responsibility.⁹

Then, in early 1976, bioethicists Tom Beauchamp and James Childress drafted a set of four principles suitable for biomedical ethics.¹⁰ Those principles,¹¹ respect for autonomy, nonmaleficence, beneficence, and justice, continue to serve as the foundation upon which other problematic medical decisions can be analyzed and made.¹²

Respect for Autonomy

Serving as the basis for informed consent, respect for autonomy is a principle requiring respect for the decision-making capacity of an individual and is rooted in the tradition and importance of freedom and choice.¹³ This means that people should have control over their lives as much as possible and make decisions that best suit their own needs and lifestyle. However, such autonomous respect does not necessarily mean a wholly "hands off" approach by physicians. In fact, it often means that health care providers must supply the most information to the patient to allow him or her to make the best possible choice. Disrespect for autonomy often involves attitudes or actions which ignore or

⁸ Tom L. Beauchamp, *The 'Four Principles' Approach to Health Care Ethics* in RICHARD E. ASHCROFT, ANGUS DAWSON, ET AL., EDITORS, *PRINCIPLES OF HEALTH CARE ETHICS* 3 (2nd ed. 2007).

⁹ *Id.*

¹⁰ TOM L. BEAUCHAMP AND JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* (1st ed. 1979).

¹¹ Beauchamp defines a principle as "an essential norm in a system of moral thought, forming the basis of moral reasoning. More specific rules for health care ethics can be formulated *by reference* to these four principles, but neither rules nor practical judgments can be straightforwardly *deduced* from the principles." *See id.*

¹² *See* Beauchamp, *supra* note 8 at p. 3.

¹³ *Id.* at p. 4.

demean another's right of autonomy.¹⁴ In other words, if a patient has the capacity to act intentionally, with understanding and without influences that would negate a free and voluntary act, then those discussions should be respected by physicians.¹⁵

Nonmaleficence

Primum non nocere: "above all, do no harm." British physician Thomas Percival relied on this philosophy when he furnished the first-developed modern account of health care ethics in 1803, which was later relied upon by the *American Medical Association* in establishing its first code of ethics in 1847. Percival maintained that a principle of nonmaleficence held by a physician would trump even an individual's right to autonomy in some circumstances when an individual's decision posed a risk of self-harm. He said:

[t]o a patient...who makes inquiries which, if faithfully answered, might prove fatal to him, it would be a gross and unfeeling wrong to reveal the truth. His right to it is suspended, and even annihilated; because...it would be deeply injurious to himself, to his family, and to the public. And he has the strongest claim, from the trust reposed in his physician, as well as from the common principles of humanity, to be guarded against whatever would be detrimental to him.¹⁶

A number of issues involving nonmaleficence arise in the health care arena. For example, medications are often a modality of choice used to calm a mentally ill patient. While, in theory, such medications do not harm the patient and may, in fact, be somewhat beneficial, the choice made by some physicians does not take into account the patient's wishes and may not actually get to the root of the illness.

Beneficence

Similar in some ways to nonmaleficence, the principle of beneficence actually guides physicians to not only "do no harm," but to "do good." It includes all forms of action intended to benefit other persons and often requires physicians to do what is necessary to prevent or remove possible harms to the patient such as pain, suffering, and disability.¹⁷ The principle includes rules such as (1) maximize possible benefits and minimize possible harms and (2) balance benefits against risks.¹⁸ Sometimes this benefit is for the patient, and other times for society. In his article, Beauchamp notes:

[s]ome writers in health care ethics suggest that certain duties such as not to injure others are more compelling than duties to benefit them. They

¹⁴ *Id.*

¹⁵ See Univ. of Washington School of Medicine, Ethics in Medicine, *Principles of Bioethics*, <http://depts.washington.edu/bioethx/tools/princpl.html> (last accessed May 22, 2010).

¹⁶ Beauchamp, *supra* note 8 at pp. 4-5, *citing* THOMAS PERCIVAL, MEDICAL ETHICS; OR A CODE OF INSTITUTES AND PRECEPT, ADAPTED TO THE PROFESSIONAL CONDUCT OF PHYSICIANS AND SURGEONS 165-66 (1803).

¹⁷ See Beauchamp, *supra* note 8 at p. 5.

¹⁸ *Id.*

point out that we do not consider it justifiable to kill a dying patient in order to use the patient's organs to save two others, even though benefits would be maximized, all things considered. The obligation not to injure a patient by abandonment has been said to be stronger than the obligation to prevent injury to a patient who has been abandoned by another...¹⁹

Some philosophers argue that the principle of beneficence is a moral ideal, but not an obligation worthy of a place in an ethical framework. Beauchamp disagrees, noting that while the line between what is required and what is not required by the principle may be difficult to draw, there are obligations of beneficence.²⁰ Those obligations are dependant on the physician's ability to weigh, judge, and sometime rank order the beneficence principle with the other principles.

Justice

The principle of justice denotes a quality of "fairness" in medical decision making, i.e., that a patient has been treated justly if medically treated according to what is fair, due, or owed.²¹ Even more simply, the principle guides health care providers that "equals ought to be treated equally, and unequals unequally."²² A prime example is the application of Medicare which is available to all persons over the age of 65 years. The one thing all Medicare recipients have in common is being 65 years or older; however, they may not be equal on other levels. That is the same problem arising with the justice principle. There are no definitions to guide someone regarding what "equal" means or the proportion of equality.

Some ethicists and philosophers claim that many of the inequalities that we face are the result of a "social lottery," for which the individual is not to blame. Thus, members of society ought to even the playing field by distributing resources more consistently to maximize the benefit to more individuals.²³

The Ethical Principles in a Public Health Emergency

Making decisions regarding the distribution of limited resources in a public health emergency such as an influenza pandemic can be complex. Such decisions must not only reflect ethical considerations, but also take into account a number of other variables including need, resource availability, and operational issues.²⁴ Using a variation of the four ethical principles for pandemic planning may help to mitigate "some of the unintended and unavoidable collateral damage from an influenza pandemic."²⁵

¹⁹ *Id.*

²⁰ *Id.* at p. 6.

²¹ See Beauchamp, *supra* note 8 at p. 6.

²² *Id.*

²³ Univ. of Washington School of Medicine, *supra* note 15.

²⁴ Jeffrey L. Levin, *et al.*, *supra* note 1 at p. 12.

²⁵ *Id.* citing Aristotle's Ethics from the Stanford Encyclopedia of Philosophy, <http://plato.stanford.edu/entries/aristotle-ethics/> (last updated Mar. 29, 2010).

As noted in the draft document submitted to the Texas DSHS, making determinations and decisions utilizing an ethical framework during a pandemic is intended to:

- 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.²⁶

In October 2009, the 17-member panel was asked to review, consider and make recommendations for the allocation of state resources including H1N1 vaccines, antiviral medications, medical surge personal protective equipment and mechanical ventilators.²⁷ It was also charged with addressing the following considerations for each topic: (1) a desired outcome for the allocation and distribution of a specific resource; (2) a structure for considering ethical principles in the allocation and decision-making process; (3) principles or standards that reflect ethical considerations about the allocation and distribution of a specific resource; and (4) a recommended course of action that incorporates ethical considerations for the allocation and distribution of a specific resource.²⁸

Recommendations of the Ethics Group

Following lengthy deliberations over a nearly three-day period, the work group developed a framework for decision-making supported by goals, ethical values, and recommendations for each medical resource that was discussed. The following are abbreviated summaries of their recommendations for each medical resource.

Vaccine Allocation and Distribution

The panel concluded that the goals for this resource were two-fold. First, and most importantly, the goal was to minimize mortality and morbidity associated with the H1N1 influenza. Second, the goal was to prevent the spread of the disease. To best meet these goals, the panel concluded that all allocation decisions would need to be communicated clearly and effectively in a transparent, accurate, and straightforward manner.²⁹ Also, they believed it to be important that health care workers get vaccinated for both seasonal and novel H1N1 influenza. The panel recommended that an advisory group made up of urban, rural, and regional health care officials and providers be created to provide advice to the DSHS Vaccine Allocation and Approval Committee on allocation and distribution issues related to the H1N1 vaccine.³⁰ Finally, the panel recommended that any vaccine

²⁶ Jeffrey L. Levin, *et al.*, *supra* note 1 at p. 12 *citing* A. Thomson, *et al.*, *Pandemic Influenza Preparedness: An Ethical Framework to Guide Decision-Making*, 7:12 BMC MEDICAL ETHICS (2006).

²⁷ Jeffrey L. Levin, *et al.*, *supra* note 1 at pp. 1, 13.

²⁸ *Id.* at p. 14.

²⁹ *Id.* at p. 2.

³⁰ *Id.*

distribution decisions be based on available epidemiological evidence in an ongoing manner.

Antiviral Medication Allocation and Distribution

The panel concluded that the goals for this resource were to reduce mortality and the need for hospitalization by adhering to the most current treatment guidelines.³¹ To accomplish these goals, the panel recommended that clinicians preserve antiviral medications for when they are medically needed and indicated. Additionally, they recommended that a prioritization system be developed in the event of a significant shortage of medication with those for whom it will provide the most good (i.e., the severity of illness and the likelihood of recovery) to receive priority and a first-come, first served system if the need is equal.³²

Medical Surge Resource Allocation and Distribution

The panel logically concluded that in order to maintain the health care systems' capacity to provide judicious and efficacious care to as many people as possible, resources will need to be disseminated to those facilities that can effectively utilize them.³³ Regional medical systems, long-term care facilities, nursing homes, and public health agencies are recommended to develop prioritization protocols, based on ethical and medical standards of care, to optimize the effective use of scarce resources during a pandemic.

Ventilator Allocation and Distribution

Again, the goal submitted by the panel in this resource category is to reduce mortality by the best possible use of available resources. To achieve that end, the panel recommended that uniform and cooperative guidelines be in place at the hospital level regarding the distribution of mechanical ventilators.³⁴ Those guidelines should be, in part, developed at the state health agency level and applied across Texas. Additionally, ventilator allocation decisions should be based on two related factors: (1) the severity of the illness; and (2) the likelihood of recovery.³⁵

Conclusion

The panel included a note in its report that stated:

[b]ecause 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

³¹ *Id.* at p. 3.

³² *Id.*

³³ *Id.*

³⁴ *Id.* at p. 4.

³⁵ *Id.*

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.³⁶

Undoubtedly, any form of public health emergency will likely present novel or unanticipated issues that must be dealt with by health care officials and practitioners. However, it is encouraging that the state is being proactive to develop a living document—an ethical framework to guide those with decision-making capacity to best handle the next pandemic or other public health emergency.

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³⁶ Jeffrey L. Levin, *et al.*, *supra* note 1 at p. 6.