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An Ethical Framework for Use in a Pandemic

Report of The Iowa Pandemic Influenza Ethics Committee

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Promoting and Protecting the Health of Iowans

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Local Public Health Officials

Dear Public Health Officials;

The Iowa Department of Public Health is pleased to announce the release of the guidance document "An Ethical Framework for Use during a Pandemic: Report of the Iowa Department of Public Health Ethics Committee". This document provides an ethical framework for decision making when preparing and responding to a pandemic influenza outbreak, and is intended for use by local public health officials.

The report combines the Iowa Pandemic Influenza Ethics Committee's framework for decision making and examples on how to make ethical decisions in public health disaster situations. In addition the guidance attempts to communicate the types of ethical issues that local public health officials may face during a public health disaster such as pandemic influenza outbreak. However the report is not a legal document and does not intend to address legal issues that may arise during such situations. The document goal is to guide public health officials around Iowa on how to make ethical decision. The document is not meant to replace the burden of ethical practice and decision making by physicians and other health care professionals. The decisions shown in the examples and scenarios are meant to demonstrate how these types of decisions could be reached ethically, not what decisions should be made.

Included within the document are four ethical points that public health and healthcare workers may use to address during a public health disaster; they include:

- **General Ethical Considerations**
- **Protection of Individual Rights**
- **Triage**
- **Duty to Care and Health Professional's Protection**

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TABLE OF CONTENTS

I. Introduction

This ethical framework document, compiled by the Iowa Pandemic Influenza Ethics Committee, provides ethical guidance to the Iowa Department of Public Health (IDPH) for a pandemic influenza situation. The ethics committee proposes the document as a foundation for decision making in preparing for and responding to pandemic influenza. The document addresses four ethical or moral focal points that public health and health care workers may need to address during a public health disaster; they include:

- **General Ethical Considerations** (do no harm, transparent decision making and for the common good of society),
- **Protection of Individual Rights** (the development of interventions that would limit individual freedom and social distancing – often referred to as non-pharmaceutical interventions),
- **Triage** (vaccine and anti-viral drug distribution prioritization, treatment prioritization of individual Iowans using limited available state or local pharmaceutical and other medical resources and the rationing of mechanical ventilation equipment),
- **Duty to Care and Health Professional's Protection** (the health professional's code of conduct, legal protection for health professionals' actions, during public health disaster and the suspension of restrictive licensure requirement for some health care workers).

The *Ethical Framework for Use in a Pandemic* document is to guide all health professionals in Iowa, to assist in ethical decision-making during a public health disaster such as pandemic influenza. This document, put forth by IDPH, is to be used by IDPH, our partners, health care professionals and other public health practitioners in a pandemic or other public health disaster situation. However, this document does not replace the burden of ethical practice and decision-making by physicians and other health care professionals as stipulated in the code of conduct in our Iowa laws (653 Iowa Administrative Code Chapter13) entitled, Standard Practice and Principles of Medical Ethics.

This document includes the recommendations of the Iowa Pandemic Influenza Ethics Committee appointed by the director of Iowa Department of Public Health (IDPH). The document only addresses ethical considerations for difficult decisions that could be made during a public health disaster. It is important to note that the document does not attempt to address legal issues during such disasters.

The committee intends the report to be used by the IDPH director, the IDPH medical director, and any decision makers they designate, in conjunction with the *Ethical Guidelines in Pandemic Influenza* document released by the Centers for Disease Control and Prevention (CDC) on Feb. 15, 2007. The two documents have much in common but are significantly different in approach. References are made to the CDC document in this report. No attempt has been made to combine the two documents or to reconcile any differences. Each can be helpful in a particular circumstance, and

the committee believes that their use in tandem will be the most beneficial to decision makers.

A. Historical and Pandemic Influenza Overview

Many Americans consider influenza a little more than a nuisance or a seasonal illness from which people easily recover. However, public health and health care practitioners are well aware of its threat. Every year, 30 – 60million Americans are affected by the seasonal flu from which nearly 36,000 die, including about 1,000 Iowans[1]. About three times per century, new strains of the influenza virus cause a pandemic, usually resulting in higher rates of illnesses and deaths than seasonal influenza. Pandemic influenza is not the same as seasonal influenza; depending on its virulence, pandemic influenza has the potential to kill far greater numbers of people across the world. For instance, in 1918, a deadly influenza virus strain H1N1 arose infecting millions worldwide and killing an estimated 50million people, about 500,000 of those in America; about 10,000 of them were Iowans.

Public health officials and scientists around the world believe another pandemic outbreak of influenza will occur. According to CDC, an estimated medium level case scenario of a pandemic influenza with no vaccine or drugs capable of protecting individuals against the influenza virus strain could cause about 90,000 – 200,000 deaths in the U.S.; 900 – 2,000 of those deaths could occur in Iowa.[2] It is further estimated that the same outbreak could cause some 300,000 – 700,000 hospitalizations nation wide 3,000 – 7,000 of those could be in Iowa. The CDC report went on to state that about 2million US residents would visit their health care providers; 20,000 of those could occur in Iowa.[3]

B. The Committee

Pandemic influenza in the US and Iowa may necessitate difficult decisions around health care, community strategies and the prioritization or rationing of scarce medical resources. These difficult decisions would arise from questions like:

- Who is most at risk?
- Who gets treated and who does not?
- What principles do we hold in common that would help answer those questions?
- How do we make such decisions fairly?
- How could we be sure decisions made are perceived as fair?
- How could we make decisions that would be in the interest of the greater good of our society?

[1] Center for Disease Prevention and Control (CDC); Ethical Guidelines in Pandemic Influenza, February, 2007. For the purpose of modeling, Iowa rates of morbidity and mortality are estimated to be 1% of that experienced nationally. Iowa's population is 1% of the total population of the U.S.

[2] Pandemic Influenza Annex Executive Summary, Iowa Department of Public Health, Revised July 26, 2006.

[3] Pandemic Influenza Annex Executive Summary, Iowa Department of Public Health, Revised July 26, 2006.

- What guidance do we have in place to make ethical and scientific decisions in allocating scarce medical resources?

These types of difficult questions require leadership on the part of the state health department in relation to the health and safety of all Iowans. To set guidelines to answer these questions, the Iowa Department of Public Health in 2006 commissioned the Iowa Pandemic Influenza Ethics Committee to help develop a Pandemic Influenza Ethics Guideline Report. Ten Iowans from various works of life with expertise in ethics, public health, health care and other related scientific disciplines were asked and agreed to be members of the committee. (Please see list in Appendix C.) This committee will remain in existence as an ad hoc committee to be consulted for ethical opinions as needed by the state health department.

C. Methodology

The committee conducted most of the work for this document via e-mail and conference calls. There was an initial meeting between committee members and some health department staff. The project coordinator provided documents and other resources to assist the committee members in compiling this ethics document.

D. The Report

Given the level of uncertainty a pandemic or similar public health disaster may bring, no attempt was made to determine which ethical or moral principles should have priority over others in any given situation or to harmonize the principles with each other. In the event of a public health disaster, as in many life situations, decision makers will need to use their best judgment in prioritizing and applying the appropriate principles to assist in making sound, ethical and informed decisions.

E. Legal Authorities

The law of Iowa, Iowa Code sections 29C.6 and 135.140, gives authority to the governor and the Iowa Department of Public Health to proclaim a public health disaster. These disasters may include, but are not limited to, imminent threat from a novel or other previously controlled infectious disease, the acts of bio-terrorism, natural disasters, and biologic or chemical accidents capable of causing widespread illness and deaths in Iowa.

Also, Iowa Code section 135.142(1) states: “IDPH is authorized to ‘purchase and distribute antitoxins, serums, vaccines, immunizing agents, antibiotics, and other pharmaceutical agents or medical supplies as deemed advisable in the interest of preparing for or controlling a public health disaster’”. This law authorizes the Iowa Department of Public Health to purchase, distribute, control and procure necessary pharmaceutical and medical supplies using public tax money. During a public health disaster, such as pandemic influenza, the law (Iowa Code 135.142(2)) states IDPH may “control, restrict, and regulate by rationing and the use of quotas, prohibitions on shipments, allocation, or other means, the use, sale, dispensing, distribution, or transportation of the relevant product necessary to protect the public health, safety, and welfare of the people of this state”, and further authorizes the state health department to control and ration medical resources purchased by the state.

Specifically, in the event of a vaccine shortage, the law states that the Iowa Department of Public Health "may issue an order controlling, restricting, or otherwise regulating the distribution and administration of the vaccine. The order may designate groups of persons which shall receive priority in administration of the vaccine and may prohibit vaccination of persons who are not included in a priority designation. The order shall include an effective date, which may be amended or rescinded only through a written order of the department. The order shall be applicable to health-care providers, hospitals, clinics, pharmacies, health-care facilities, local boards of health, public health agencies, and other persons or entities that distribute or administer vaccines." (Iowa Code section 139A – 8A)

F. The Director's Charge

Part of the public health disaster declaration law, (Iowa Code sections 135.144 & 139A.4), authorizes the Iowa Department of Public Health in general, and both the health department's director and medical director or their designee in particular, to issue quarantine or isolation orders during public health disasters. Such public health disasters may range from bio-agent attack to pandemic influenza. Making such decisions would require both scientific facts and ethical reasoning. For this reason, the director charged the ethics committee to develop this document to provide an ethical framework.

II. The Four Focal Principles, Rationales and Examples

The following principles, rationales, and examples assume a pandemic or public health disaster in which ethical decisions must be made, especially in situations where the need exceeds resources, and public health professionals, elected officials and community leaders must decide priorities for restrictive measures, treatment, care, use of medical equipment, and risk communications. These principles include:

- **General Ethical Considerations**,
- **Protection of Individual Rights**,
- **Triage,** and
- **Duty to Care and Health Professional's Protection.**

The principles are further expanded in this document with examples. The committee believes these ethical principles could be relevant to pandemic planning and response, as well as difficult decision-making situations. However, it is important to note that not all of these principles will be relevant in every particular decision-making process. Decision-makers must decide in a particular situation which principles might be relevant and which ones should take precedence over the others.

A. General Ethical Considerations – These three principles, do no harm, transparent decision-making (perceived to be fair by the public) and for the common good of society, are amongst the general ethical maxims that could apply to a pandemic or similar public health disaster. They should, therefore, constitute the fundamental basis in any decision-making during a pandemic planning and response strategy.

1. Do no harm. This is a fundamental ethical principle for physicians and other health care practitioners. Typically, possible side effect(s) of medications, vaccines or other pharmaceutical therapies are discussed and revealed to patients before being administered. Therefore, even during a pandemic influenza situation or other public health disaster, this basic health principle should not be compromised.

However, there are situations where health care workers may not have all necessary required information about specific side effects of certain medical interventions at the time of treatment. In such situation(s), as it might be during a pandemic, health professionals should use the best scientific information available to them at that time, to the benefit of their patients and the community at large.

Scenario:

An outbreak of a novel influenza virus strain occurred in Southeast Asia causing severe illness and mortality in humans. In a few months, the outbreak quickly spread to different parts of the world causing a pandemic. Scientists and health officials quickly realized that previously manufactured flu vaccines are not capable of protecting people against this new virus strain, and the strain seems more deadly than other influenza strains. As scientists and health officials worldwide are struggling to find an effective vaccine or anti-viral medication against the virus strain, a non Food and Drug Administration (FDA) regulated pharmaceutical company in Africa has manufactured a new anti-viral drug. The drug is known to be effective in helping relieve patients' worst symptoms, but not completely curing them, thus delaying or lowering mortality rates. Other industrialized nations have turned to this drug company and are using this new drug to help their citizens. However, FDA is warning American consumers that the drug has not been fully tested for efficacy and side effects. As FDA struggles to go through difficult federal drug testing standards for this new drug, the influenza pandemic is widely spreading and fatality continues to grow in the US.

Ethical & Scientific Considerations:

- Physicians and other health care professionals are under oath never to knowingly harm their patients.
- Scientifically, this new drug is not fully proven to be safe for patients.
- The drug is, however, helpful to patients and it is the only drug currently available.
- The new drug relieves worst symptoms but does not completely cure the patient.
- The drug manufacturing company does not have any standardized safety data for the new drug.

- Should health professionals use data from other countries prescribing this drug for their patient's safety?
- Is it permissible to prescribe this new drug?
- If a physician refuses to prescribe the new drug for the patient and the patient dies, would this be an ethical violation?

Ethically, based on the maxim "Do no harm", physicians might consider prescribing this new drug with caution after reviewing data from across the globe for any side effects. In this situation, the possible side effect(s) of the new medication could not be revealed to recipients because they are not available. In the event scientists or health officials learn of any serious health risks to patients, this information should be made public and the drug usage discontinued. Also, during the course of the pandemic, if a new and more effective drug is manufactured and with fewer side effects, the initial drug use should be discontinued. Cost and availability of the new drug should not outweigh patients' safety.

2. Decision-making must be transparent and perceived to be fair by the public. Public acceptance of, and cooperation with any plan to use scarce resources or community interventions depends on the public understanding and perception that the plan is fair. For instance, pandemic plans and procedural frameworks, including this ethical framework, should be publicized, **to the extent possible**, and public feedback encouraged.

There should be commitment to transparency, **to the extent possible,** during the pandemic influenza planning and response process**.** Reasons why choices are made, and who stands to benefit from those choices or who might be harmed by those choices, should be fully articulated; the values and principles justifying those decisions should be clearly identified and open for examination. Commitment to transparency will help individual citizens to understand how those decisions were made. Also important during pandemic influenza planning and response process is public engagement and involvement. This will further help build public will and trust before a situation arises. The public should be seen as a partner in the planning process with particular attention to vulnerable or historically marginalized members of society.

3. For the common good of society. This category of principle focuses on the rights of, and duties toward, society as a whole. Its principal goal is the securing and maintenance of the common good. Protecting individual rights during a pandemic influenza situation are important, but balancing those acts with the common good of society in mind is more important. In a society, individuals are responsible for their own good, but everyone within the community is responsible for the good of that society. Although emphasis might be placed on the respect for individual autonomy in a pandemic planning, precedence should be given to the preservation of society for the good of all in that community.

Moreover, implicit in membership in society is an obligation to abide by certain ethical and legal constraints to enjoy the benefits. These constraints actually provide the conditions under which personal freedom and flourishing are possible. Thus, restrictions essential for the common good, including the public health, of a society, may be imposed on each member of society or on a community during a public health disaster, like pandemic situation.

Scenario:

An old farming community in the southwest corner of Iowa along the Missouri River, with population of 20,000 residents, starts experiencing an unusual illness in young healthy individuals early in the fall season. The source and cause of the illness are determined to be similar to a highly contagious and fatal influenza strain virus causing outbreaks in some parts of Europe. There is a century-old tradition in this community to celebrate the fall harvest season, and the gathering has never been interrupted as far back as any living person could remember. There is denial in the community of the seriousness of this situation; thus, community leaders are very reluctant to cancel this gathering. The potential for an outbreak of a deadly influenza virus in the community and beyond is possible if the three-day festivity takes place. State health officials have estimated that, with such close contact and the estimated 30,000 – 40,000 expected to attend the festival, it is possible that thousands of people could become infected and hundreds of people could die within a few weeks.

Ethical consideration with the common good of society in mind. In the scenario described above, it could be an ethical obligation on state and local health and elected officials – for the common good of society to ignore the individual community autonomy and implement social distancing strategy by canceling the annual fall festival. It would be most efficient if local community leaders cooperated with public health officials to help implement public health prevention and control strategies that could prevent or slow the spread of the deadly infectious disease within and beyond their community. However, even if this cooperation is lacking, the common good of society might take precedence over individual community right.

4. Preserve society's critical infrastructure and minimize social disruption. The common good consists of certain general conditions that are equally to everyone's advantage.[4] It also consists in the functioning of society in a manner that benefits everyone – the social systems, institutions, and environments on which we all depend.[5]

[4] Velasquez, Manuel, and Claire Andre, Thomas Shanks, Michael J. Meyer. "The Common Good," paper prepared for the Markkula Center for Applied Ethics, University of Santa Clara, 2005. (Available at www.scu.edu)

[5]Velasquez, Manuel, and Claire Andre, Thomas Shanks, Michael J. Meyer. "The Common Good," paper prepared for the Markkula Center for Applied Ethics, University of Santa Clara, 2005. (Available at www.scu.edu)

B. Protection of Individual Rights – This principle addresses protection of individual rights, the procedural conditions in restricting personal freedom, restrictive measures of personal freedoms that are ethically justified (social distancing and restrictions on mass gatherings) and ability to care and support for those under restrictive orders. The U.S. Constitution is primarily based on the idea of the protection of individual rights. Any planning and response program for a public health disaster should always address the protection of citizens' rights. However, as important as individual rights are, there are limitations. Ethically, the recognition of limitations of individual rights means that individuals also have responsibility to society in which they live and to their fellow humans in that society. Because there might be restrictions on certain individual rights during a pandemic influenza, this report addresses the protection of individual rights during a pandemic and that of the common good of the society in which these individuals live. The principle will deal with proportionality, equity, sensitivity and ability to provide justly for those whose rights are restricted.

1. Protect the rights of individuals. The common good of society should not be protected by ignoring individual rights. For example, patient confidentiality should be protected, **to the extent possible**, even during a public health crisis such as pandemic influenza. It should be waived only in cases in which the needs for the common good of society outweigh those of the individual. It is also important to be sensitive to the needs of minorities, marginalized individuals, and those with disabilities.

2. Restrictive and permissive measures should be proportional and part of a well developed plan. The principle of proportionality, in this ethical document mandates that actions should be commensurate to achievable objectives. In this regard, measures to curtail morbidity and mortality in a community during a pandemic should be only as restrictive as necessary. If restrictions are not producing desired public health outcome, they should be quickly reexamined and modified.

Scenario:

The harvest festival in the old farming community was cancelled by state and local health officials and the community was put under a quarantine order. Residents with symptoms were isolated earlier during the investigation. However, because people were infectious before developing symptoms, the virus had spread throughout the community and the entire population may now be infected with the virus. Thus, isolation of patients will no longer prevent the spread of the disease and the needs of those in isolation are overwhelming local resources.

Ethical and logical considerations – Based on the above scenario, it appears that the basic public health intervention of isolation did not prevent the spread of the virus in the community. In this case, it might be logical for

health and community leaders to allow residents of this community to have their personal freedom, thus suspending the isolation order. However, if the virus has not widely spread into neighboring communities, then the community's quarantine order might remain in effect.

There should be a well thought-out criteria detailing an acceptable system regarding restrictions on personal freedom. The restriction process should be determined in advance, detailing who the decision-makers could be and the criteria that could be used to determine when restrictions will be implemented and when they will be removed. It will be important that decision-makers be seen by all stakeholders as appropriate representatives of the community. A reasonably diverse group that includes voices across racial, cultural, community, providers and patients' advocate groups should be involved in planning for that community.

According to recommendations from the CDC pandemic influenza ethics subcommittee, in a pandemic influenza the centralization of decision-making may be important in creating fair and equitable restrictions that will apply across communities. As in other areas of pandemic influenza management, transparency about the process is essential, and communication about restrictions should be communicated early in the planning process. The public should be clearly informed that restrictions on personal freedom are anticipated and the benefits clearly explained.[6] This is best done prior to the need for restrictions.

3. Restrictions on personal freedom and community gathering should be ethically justified. Reducing transmission of a pandemic influenza will require non-pharmaceutical interventions as well as traditional public health strategies such as social distancing, quarantine and isolation. These actions are often considered first line of defense in public health when dealing with infectious disease outbreaks and they often prove to be very important strategies for controlling and/or limiting the spread of infectious diseases.

When enacting measures where personal freedom could be limited, it is important to employ the least restrictive, effective measure. Enactment of these measures should be based on the best available scientific evidence that shows restricting personal freedoms will achieve its intended goal, that limitation is proportional to the effect, and that no less restrictive measure is likely to be as effective. Some of the social distancing interventions may include but are not limited to:

- School closings
- Cancellation of public events (sports, concerts)
- Closing shopping malls, restaurants, museums, theaters

[6] Center for Disease Prevention and Control (CDC); Ethical Guidelines in Pandemic Influenza, February, 2007.

- Other measures may be restricting access to public places deemed more essential like grocery stores, public transportation, or gasoline stations
- Flexible work scheduling that may decrease potential for exposure
- Limiting travel within or between cities, counties or regions.

4. Ensuring essential needs of those restricted are addressed. There is an ethical obligation to ensure that the basic needs are addressed for those members of society whose personal freedoms are restricted. It is very important during pandemic planning to identify strategies to care for those members of society who may be quarantined or isolated voluntarily or involuntarily. Compliance might be easier if the public understands there is a plan to address their needs and are requested by health officials to stay in their home for an extended period of time.

C. Triage – Triage refers to a process for sorting injured or ill people into groups based on their need for, or likely benefit from, treatment. It is typically used when resources are limited or needs are great. The following components are required for designing a critical care triage system: Clinicians need a method that accurately differentiates those patients who will survive without use of critical resources, those who will survive only with use of critical resources, and those who will die even with use of critical resources.

There are a number of proposed systems for medical triage, but none is specifically designed to demonstrate the most efficient use of scarce resources. Some systems require resource-intensive tests that might be scarce during a pandemic; others focus on trauma patients and so are less applicable for a pandemic[7]. When rationing scarce medical resources during a public health disaster, it is ethically appropriate to **save the most lives.**

As stated in the CDC pandemic influenza ethics document, in ordinary circumstances, the distribution criterion, 'to each according to his or her social worth,' is not morally acceptable[8]. However, in planning for a pandemic where the primary objective is to preserve the function of society, it is necessary to identify certain individuals and groups of persons as essential to the preservation of society and to accord to them a high priority for the distribution of certain goods such as vaccines and antiviral drugs. To be efficient, however, identification of essential individuals for this purpose must be recognized for what it is and be reflected in advanced planning. Care must be taken to avoid extension of the evaluation of social worth to other attributes that are not morally relevant.

[7] New York State Department of Health; Allocation of Ventilators in an Influenza Pandemic: Planning Document, March 15th, 2007.

[8] Center for Disease Prevention and Control (CDC); Ethical Guidelines in Pandemic Influenza, February 15th, 2007.

1. Implementation of prioritization plans must be practical, workable and efficient in allocating scarce resources where they do the most good. Efficient implementation of prioritization will result in the correct individuals and groups receiving priority. Transparency will encourage acceptance and cooperation by collaborators and the public. It is important to note that prioritization may mean excluding groups such as those with natural immunity against the disease, low probability of successful treatment, low risk of acquiring the disease, those having available alternative protection, or those with compromised immune systems (who may not respond to vaccines).

Prioritization can and must occur based on a rational and understandable plan that is seen to respect all people. For example, distribution of vaccine first to health professionals could be seen as equitable, since they would be asked to put themselves at increased risk when caring for ill patients.

Ethical Considerations –Typically, society should treat all people equal when considering use of scarce resources such as anti-viral medications during influenza pandemic. However, it may be scientifically sound and ethically justifiable to give priority to some members of a community, such as health care professionals. Not only are they asked by the community to put themselves at higher risk of being exposed, by caring for ill people in a pandemic situation and becoming infected, they could more easily spread the disease in the community if not protected by vaccination. Therefore, for the common good of society and to help control the spread of a potential deadly disease in a community, it could be appropriate to vaccinate or offer drugs to certain people before others.

2. Health care and essential workers as priority. Reduction of mortality and morbidity may depend on the continued functioning of health care and other essential workers. As stated in the Iowa law, Statute 135.14213, the principle of reciprocity would warrant such priority, especially for those whose work would increase their personal risk. An example is the distribution of vaccines and anti-viral medications to groups like health care workers and police officers. At the same time, the distribution of information on how to avoid infection should be given to those not receiving medications or those refusing treatment for medical reasons.

Affirming this principle (preserving the functioning of society) raises important conceptual questions about who is needed for functioning and how particular services and functions are determined to be essential. These questions are set in important historical and social contexts involving individuals' ability to attain certain positions given societal barriers and obstacles. These types of essential service providers should be identified during the planning process.

3. Hospital ventilator rationing. Rationing hospitals' ventilators follow from the principle of beneficience. Triage is an efficient way to avoid providing futile medical care and assuring the provision of humanitarian care and comfort. Triage also helps assure that scarce resources are allocated according to

known benefit. Each medical intervention has a spectrum of efficacy: some will be aided greatly, some will receive some benefit, and some will not be helped at all.

An ethical framework must serve as the starting point for a plan that proposes to allocate ventilators fairly. A just rationing plan cannot evolve from technical considerations alone, such as survival probabilities and resource estimates. Ethics applied as an afterthought to such consideration may not withstand ethical scrutiny. Usually, when dealing with medical resource rationing, the key ethical concepts are the duty to care for patients and the duty to use the scarce resources wisely. Maintaining a balance between these two sometimes competing ethical obligations represents the core challenge in designing a just system for allocating ventilators.

In a disaster on the scale of the 1918 influenza pandemic, stockpiles of ventilators would not be sufficient to meet need. Even if the vast number of ventilators needed for a disaster of that scale were purchased, a sufficient number of trained staff may not be available to operate them. If the most severe forecast becomes a reality, Iowa may need to confront the rationing of ventilators.

Situations may arise where a ventilator might be pulled from someone who needs it to survive to use it on a patient who would have more value or survivability. Another possibility could occur when there are more patients needing ventilators than are available or that have available staff to run them. It may become necessary for physicians and other health professionals to consider scoring protocols such as the **Sequential Organ Failure Assessment (SOFA)**[9] **system,** when rationing ventilators.

Scenario:

*The State of Iowa has implemented a SOFA scoring system to be included in assessments of ventilator need during the influenza pandemic. Hospital B in XP County has 10 ventilators and all are in use in the ICU. The pandemic has caused all nearby hospitals to be at capacity as well, so no ventilators are available to borrow. Two patients are brought in with severe respiratory failure and clearly in need of ventilators for survival. When assessed by ICU staff, it becomes apparent that both patients have been healthy individuals who will recover from their ailments if placed on ventilators**…** One of the patients is a 19 year-old local high school athlete; the other, a 29 year-old elementary school teacher with a 6 month-old son. The ICU staff review and score all patients*

[9] There are numerous publications on the SOFA system. The system could be used to score patient's survivability based on important organ failures while in an intensive care unit (ICU). The system might help health professionals in rationing scarce medical resources during a pandemic flu. The NYS – DOH gave detailed description of the SOFA system in their "Allocation of Ventilators in an Influenza Pandemic: Planning Document".

currently using the 10 ventilators. The review reveals that a 78 year-old patient who is failing and has a SOFA score indicating the patient's survivability with the ventilator is low. In this case, the decision-maker should not consider factors such as gender, race, sex, or color. It might be ethically appropriate, for the common good of society, to remove the ventilator from the person using, but not benefiting, from its use and apply the ventilator to the new patient.

Ethical considerations:

- Based on the above scenario, difficult decisions may be made, but if made with ethical considerations and openness, the general public would perceive the decision appropriate.
- The decision-maker may rely on determinations such as young and healthy people who have better survivability from respiratory distress than aged or immuno-compromised patients.
- It might be in the interest of the common good of society, and proper use of scarce resource in a health emergency situation, to make the decision that might reflect the best use of the scarce medical ventilator for that community.
- Distribution of scarce resources should not depend on recipients' ability to pay. This follows from the principles of fairness and the equality of human life.

D. Duty to Care and Health Professional's Protection – Health care professional organizations traditionally recognize the obligation of licensed health practitioners to provide care when a patient is ill. Such care may take many forms. During a public health disaster, especially in infectious disease outbreak situations, it may become challenging for practitioners to provide care that may put their own lives at risk.

Just as health professionals have a duty to care for their patients, so it is for society to consider those professionals who, in a disaster situation, would put themselves at risk to care for the sick and dying. In a public health disaster, especially a highly contagious disease with no immediate, known treatment, medical professionals could take great risk in caring for their patients. Some might opt not to place themselves and their families at risk of becoming infected, while others would feel obligated to serve their patients because they have a duty to care. It could be ethical and logical to protect the interest of those who would serve patients during a public health disaster. If health professionals know their interests are protected during a pandemic, most should care for the sick and dying. It would be necessary to have a well thought-out plan in advance for health professionals' protection for their patient care duties.

According to the Iowa Code Section 29C.6, when a public health disaster declaration is made by the governor, both health officials and the Governor's Office have the authority to waive other authorities that could help control the disease outbreak and prevent widespread illnesses and death. One such provision could be reduction of

health care standards for the greater good of the public. Also, the governor and the director of the state health department could consider easing restrictive licensure requirements for health professionals. For instance, recently retired health professionals could be requested to return to duty without first having to reactivate their licenses (which would take time).

No one can be asked to do the impossible. Health care workers may not be required to provide care if harm to the practitioner outweighs the benefits to the patient. Therefore, pregnancy, age or physical condition might preclude provisions of care. Ethical protocols for duty to care during a pandemic situation might include an opt out option, a mechanism for fair adjudication and compensatory public service.

1. Health care workers have a duty to care for victims of a pandemic. Most professional health care organizations have policies recognizing the duty to care, even at risk of harm to practitioners and their families. In a pandemic, state professional organizations, for instance, should be asked to issue confirmation of their ethical policies. Employers, such as hospitals and doctors' offices, should be asked to do so, too, as well as to establish how workers are to be compensated for longer hours and higher risk. Hospital and professional groups should help determine when risks to workers outweigh benefits of their continued care for patients.

2. Health care workers must provide care that benefits their patients. This is another interpretation of the principle of beneficience. During a public health disaster, for instance, practitioners should not, without a compelling reason, attempt to provide treatment for which they are unqualified. Hospitals should not allow regulations on licensing and/or supervision to be waived if not absolutely needed. Hospitals should allow practitioners to operate outside their scope of practice only temporarily and only when necessary for the common good.

3. Protect the safety and financial future of essential workers. Health care workers will be more likely to risk their own safety if their health and financial future and those of their families are protected. Government, for instance, might provide incentives, such as death and/or disability insurance, hazard pay, child care and medical care, to essential workers. Protection from future lawsuits should also be considered, similar to the Good Samaritan laws.

4. Consideration to ease restrictive licensure requirements – During an extensive pandemic influenza situation, it would be ethically justifiable for the common good of society and protection and preservation of human lives for a temporary suspension of licensure requirement for health professionals. Generally, it is illegal for retired health professionals with inactive licenses or out-of-state licensed health professionals to practice medicine in Iowa. However, in a public health disaster situation, it might be ethical to allow health professionals with inactive or out-of-state licenses to practice medicine when need surpasses availability of licensed professionals.

Scenario:

During an outbreak of a fatal contagious disease in a rural Iowa community, three of the seven physicians at the county hospital contracted the disease and are too ill to care for patients. The 200- bed health care facility is then left to be operated by less than the needed number of physicians. Two recently retired physicians, husband and wife, live nearby, but have let their Iowa medical licenses expire. As the situation worsened in the community, it became apparent that other communities around the state are overwhelmed too. The hospital felt it could not handle the situation and, therefore, requested help from the two retired physicians. The physicians are willing to work at the hospital, but are concerned about being sued if they practice without a valid license.

Ethical considerations:

- There are issues that have to be taken into consideration when thinking of asking health professionals with inactivated or out of state licenses to help during a disaster.
- Implicit in Iowa code 29C.6, when public health disaster is declared, the governor and/or the state health department might lower the standard care for patients
- Society must be willing to accept a different standard during disasters.

In a situation like this, the legal implications could be difficult to deal with. However, it might be ethically justifiable for less-qualified individuals to use basic medical methods to save people when licensed professionals are not readily available. It is important to note that situations might lead to a waiver of restrictive licensure requirement to relieve overwhelmed health care agency during a disaster.

III. Closing remarks

This document seeks to provide a framework and examples of ethical considerations which could be used as a guide in preparing for and responding to a pandemic. This ethics guideline document is not meant to be narrowly prescriptive; it recognizes the need to assist decision-makers to address ethical and moral decisions that may arise in public health disasters.

In ethical decision-making, it is assumed that judgments will be based on best available scientific knowledge, that effectiveness of interventions will be carefully assessed, and that transparency of the process will be evident. As ethical decisions are considered, processes should be in place for identifying which ethical issues were addressed, how guidelines were utilized, how decisions impacted the affected individuals and the community, and what lessons can be shared with other decision-

makers. While decision-makers will always have the responsibility of assessing and addressing their particular situations, it is hoped the principles, rationales and exemplars discussed in this document may provide helpful guidance for the decision- making process**.**

Appendix A: Executive Summary

This report includes principles, rationales and exemplars that assume a pandemic in which need exceeds resources and public health officials must decide priorities for restrictive measures, treatment, care, use of medical equipment and risk communication.

Entries are grouped into sections on general principles; protecting rights; use of triage; the duty of health care workers to provide care; society as priority; and health-care and essential workers as priority.

The report includes ethical principles the committee believes could be relevant to pandemic decisions, but not all principles will be relevant in every circumstance. Decision-makers must decide in the situations in which they find themselves which principles are relevant and which take precedence over others.

The committee intends the report to be used by the IDPH director, the IDPH medical director and any decision makers they designate, in conjunction with "Ethical Guidelines in Pandemic Influenza" released by the Centers for Disease Control and Prevention (CDC) on Feb. 15, 2007. The two documents have much in common but are significantly different in approach. The CDC document is referenced in this report. No attempt has been made to combine the two documents or to reconcile any differences. Each can be helpful in a particular circumstance, and the committee believes that their use in tandem will be the most beneficial to decision makers.

The IDPH ethical framework includes the following principles, arranged by section:

General principles

- Do no harm.
- Make decision-making transparent and perceived by the public to be so.

Protecting rights

- Protect the rights of individuals.
- Restrictive and permissive measures must be proportional to need.
- Any prioritization of treatment, care and distribution of medical supplies, as well as any restrictive measures, must be equitable.
- Be sensitive to the needs of people with disabilities and of minorities and marginalized individuals and groups.
- Distribution of scarce resources should not depend on recipients' ability to pay.

Triage

- Use triage in distributing scarce resources.
- Save the most lives.
- Save the most vulnerable.

Duty to Care

- Health care workers have a duty to care for victims of a pandemic.
- Health care workers must provide care that benefits their patients.
- Not all individuals who provide essential services have the interior resources, or are in appropriate circumstances, to be able to risk themselves for others. In those cases, they may serve the common good in other ways.

Society as Priority

- Protect the public from harm.
- Preserve society's critical infrastructure and minimize social disruption.
- Implementation of prioritization plans must be practical, workable and efficient, allocating scarce resources where they do the most good.

Health-care and Essential Workers as Priority

- Give priority to health care workers and others who provide essential services.
- Protect the safety and financial future of essential workers.
- Give priority to those caring for the dying, the dead, and their families.

Appendix B: Chart of Principles, Rationales and Exemplars

The following principles, rationales and exemplars assume a pandemic in which need exceeds resources and public health officials must decide priorities for restrictive measures, treatment, care, use of medical equipment and risk communication. Entries are grouped in sections on general principles; protecting rights; use of triage; the duty of health-care workers to care for people needing their help; society as priority; and health-care and essential workers as priority. The list includes ethical principles the committee believes could be relevant to pandemic decisions, but not all principles will be relevant in any particular decision. Decision makers must decide if the situation in which they find themselves are relevant and which principles take precedence over others.

i. General principles

These two principles are the most general of ethical maxims that could apply to a pandemic or practically any health care situation. They would be fundamental in any decision making during a pandemic.

Principle	Rationale	Example
1. Do no harm.	This is a fundamental ethical principle for physicians and other health-care practitioners.	Side-effect risks of any anti-virals and vaccines (If available to health providers) must be fully revealed to recipients, who should be required to give their informed consent before treatment. Health care workers should not on their own rule out treatment for any individuals or groups.
2. Decision-making must be transparent and perceived to be so by the public.	Public acceptance of, and cooperation with any plan depends on the public understanding and perceiving that the plan is fair.	For instance, plans, including this ethical framework, should be publicized, **to the extent possible,** and public feedback encouraged.

ii. Protecting Rights

This is another area that applies in many, if not all, health care situations, but must be the focus of pandemic decision making in particular. The principles focus on proportionality, equity, sensitivity and ability to pay. Here, the points on this subject made in the CDC's Ethical Guidelines in Pandemic Influenza, p. 10, are especially recommended.

Principle	Rationale	Example
1. Protect the rights of individuals.	The common good should not be protected by ignoring individual rights, whose existence is confirmed in the bills of rights of the U.S. and other countries.	Patient confidentiality, for instance, should be protected, to the extent possible, even during a health crisis such as a pandemic. It should be waived only in cases in which the needs of society outweigh those of the individual.
2. Restrictive and permissive measures should be proportional to need.	This follows from the principle of proportionality, that actions should be commensurate to the objective to be achieved.	Measures to curtail morbidity and mortality, such as quarantine and isolation, should be only as restrictive as necessary, and health-care workers temporarily practicing outside their normal scope of practice should be limited to what is necessary.
3. Any prioritization of treatment, care and distribution of medical supplies, as well as any restrictive measures, must be equitable.	The fundamental equality of all people is a widely accepted principle in the U.S. The extent to which people are treated equitably, and are perceived to be so treated, may determine whether the public accepts a plan and cooperates with it.	Any prioritization must value all human life equally. However, some individuals or groups, for reasons having to do with vulnerability, survivability or the common good, may get priority over others. Prioritization can and must occur based on a rational and understandable plan that is seen to respect all life. Thus, for example, distribution of vaccine first to health-care workers can be, and be seen to be, equitable.
4. Be sensitive to the needs of people with disabilities and of minorities and marginalized individuals and groups.	Disabled, minority and marginalized individuals and groups may be among the most at-risk, both from physical consequences of the pandemic and lack of attention from decision makers. The fundamental equality of all people is a widely accepted principle in the U.S.	Determine the communication needs of the population, e.g., Spanish, Bosnian, American Sign Language, etc., and establish the best delivery method for each.
5. Distribution of scarce resources should not depend on recipients' ability to pay.	This follows from the principles of fairness and the equality of human life.	A system needs to be in place to determine recipients' ability to pay. And, distribution sites may need to be set up at places like homeless shelters.

iii. Triage

A commonly used term in health care, triage refers to a process for sorting injured or ill people into groups based on their need for, or likely benefit from, treatment. It is typically used when limited resources are available.

Principle	Rationale	Example
1. Use triage in distributing scarce resources.	This follows from the principle of beneficience. Triage is an efficient way to avoid providing futile medical care and assure the provision of humanitarian care and comfort. It helps assure that scarce resources are allocated according to known criteria of benefit. Each medical intervention has a spectrum of efficacy: Some will be aided greatly, some will receive some benefit, and some will not be helped at all.	Some people, such as those with compromised immune systems, may not respond to anti-virals or vaccines. They should be given care and comfort but not resources that would be effective for others.
2. Save the most lives.	This follows from the goal of minimizing mortality and morbidity.	In some situations, closing schools and businesses in a broad geographical area may save more lives than providing vaccines or anti-virals.
3. Save the most vulnerable.	Society has an obligation to care for its most vulnerable citizens. This follows from the principle of "distributive justice," an extension of the egalitarian principle of equal distribution. This principle does not conflict with the principle of equality because it assumes that the basic needs of everyone will be met, though the proportion of resources they receive may not be the same.	If anti-virals are known to be effective for the entire population, including the frail elderly, and no alternative effective methods to protect the frail elderly have been identified, anti-viral medications should be provided to the most vulnerable among the frail elderly.

iv. Duty to Care

Health care provider organizations have traditionally recognized the obligation of health-care practitioners, who are licensed by the state and thus privileged, to provide care when the public health is at risk. This care may take many forms and though it may challenge practitioners to provide heroic care, it is limited ethically and legally.

Principle	Rationale	Example
1. Health care workers have a duty to care for victims of a pandemic.	Most professional health-care organizations have policies recognizing duty to care, even at risk of harm to practitioners and their families.	State professional organizations should be asked to issue confirmation of their ethical policies. Employers, such as hospitals and doctors' offices, should be asked to do so, too, as well as to establish how workers are to be compensated for longer hours and higher risk. Hospital and professional groups should help determine when risks to workers outweigh benefits of their continued care for patients.
2. Health-care workers must provide care that benefits their patients.	This is another interpretation of the principle of beneficience.	During a public health emergency, practitioners should not, without compelling reason, attempt to provide treatment for which they are unqualified. Hospitals should not allow regulations on licensing and/or supervision to be waived and should allow practitioners to operate outside their scope of practice only temporarily and if necessary for the common good.
	No one can be asked to do the impossible. Care may not be required if harm to the practitioner outweighs the benefits to the patient.	Pregnancy, age, or physical condition may preclude provision of care. Care protocols should include an opt out option, a mechanism for fair adjudication and compensatory public service.

v. Society as Priority

This category of principles focuses on the rights of, and duties toward, society as a whole. Its principal goal is the securing and maintenance of the common good.

Principle	Rationale	Example
1. Protect the public from harm.	This principle follows from public health's obligation to protect the public by minimizing mortality and morbidity.	A priority system for distribution of scarce resources should, among other groups, give priority to those most likely to spread the disease.
2. Preserve society's critical infrastructure and minimize social disruption.	The common good consists of conditions that are equally to everyone's advantage. It also consists in the functioning in a manner that benefits everyone – the social systems, institutions, and environments on which we all depend.	Any distribution plan must determine who provides society's essential services and who assures those services are not interrupted.
3. Implementation of prioritization plans must be practical, workable and efficient, allocating scarce resources where they will do the most good.	Inefficient implementation of prioritization may result in the wrong individuals and groups receiving priority. It may also discourage acceptance and cooperation by collaborators and the public.	To maximize efficiency in distribution, a partnership with physician, nursing and hospital associations may be necessary. Also, prioritization necessarily means excluding groups such as those with natural immunity, low probability of successful treatment, low risk and having available alternative protection.

vi. Health-care and Essential Workers as Priority

This group of principles focuses on health care and essential workers but has as its goal the securing and maintenance of the common good.

Principle	Rationale	Example
1. Give priority to health-care workers and others who provide essential services.	Reduction of mortality and morbidity may depend on the continued functioning of health care and other essential workers. The principle of reciprocity would warrant such priority, especially for practitioners willing to care for pandemic victims despite personal risk. This priority does not reflect any judgment about social worth.	Distribution of vaccines and anti-virals to groups such as health care workers and police officers should occur through joint plans with their organizations, which should be provided with criteria for determining who in their organizations should receive vaccines and/or anti-virals and who should not, and information on how to avoid infection.
2. Protect the safety and financial future of essential workers.	Such workers will be more likely to risk their own safety if their health and financial future, and those of their families, are protected.	Government could provide incentives, such as death and/or disability insurance, hazard pay, child care and medical care, to essential workers.
3. Give priority to those caring for the dying, the dead, and their families.	Such care is a hallmark of a compassionate society, and to assure such care, priority must be given to caregivers. It may reduce feelings of abandonment, and even panic among those receiving such care and help insure reporting of mortality during a pandemic.	Mortuary workers, mental health providers and spiritual caregivers could be among those receiving priority for scarce resources.

Appendix C: The Committee

1. Frank Agnoli, M.D., MDiv, deacon, director of Liturgy, St. Ambrose University & the Diocese of Davenport, Davenport

2. James Arthur, PhD, poultry geneticist, director of research, Hy-Line International, retired, Johnston

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4. Denise Coder, Community Health coordinator, Cass County Memorial Hospital Home Care/Hospice, Atlantic

5. Jill Fulitano Avery, administrator, Iowa Division of Persons with Disabilities, Des Moines

6. Charles Helms, M.D., Ph.D., chief of staff, University of Iowa Hospitals and Clinics; associate dean, University of Iowa College of Medicine and Infectious Diseases faculty; past president, Iowa Medical Society, Iowa City

7. Janine Idziak, Ph.D., professor of philosophy and director of the Bioethics Resource Center, Loras College, Dubuque

8. Vickie McCambridge, director, Home Care Services of Boone County Hospital, Boone

9. Larry McGuire, president, Inter-Religious Council of Linn County; president, Cedar Valley-Nauvoo Mission Center, Community of Christ Church, Marion