Ethics
Planning & Assessment Tool:
A Healthcare Guide for Pandemic Flu Planning

Planning Today For A Pandemic Tomorrow
Publication Series

Prepared by the New Jersey Hospital Association

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*NJ*HA's *Planning Today for a Pandemic Tomorrow* resource is supported by a grant from Roche Pharmaceuticals. The module is intended to serve as a planning tool and is not intended to constitute a standard of care. As such, a hospital's pandemic preparedness plan should be tailored to meet its specific needs.

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INTRODUCTION

Through the use of a detailed assessment and planning tool, hospitals can review existing policies and procedures, identify gaps, adopt new policies and procedures and generate a pandemic influenza plan that will facilitate a more effective response during a crisis. This tool will assist hospitals in developing and adopting new policies that will be required to protect employees, patients and the hospital itself. The planning and assessment tool identifies critical elements within each module related to hospital operations during an emergency situation. In addition, the tool provides a variety of sample policies and procedures that facilities may elect to use in their planning process.

Critical areas to address when planning for a pandemic include:

Clinical Care	Leadership
Communication	Legal/Regulatory
Ethics	Operations
Finance	Psycho-Social
Human Resources	Supplies/Logistics/Support Services

Hospitals should form multi-disciplinary work teams to develop policies and procedures relating to each of the critical areas identified above. Diverse perspectives will help ensure that all issues or concerns that may be raised during a pandemic can be brought to the table while in the planning process.

The modules are to be used as a guide to facilitate discussion and to ensure that key points related to a topic such as human resources are identified and addressed in the planning process. Sample policies and/or procedures are provided; these policies and procedures are by no means all inclusive, and hospitals should not interpret the sample policies as what *must* be adopted. Sample policies are provided to assist a hospital in developing a policy that is consistent with the culture and values of the organization. Hospitals are not required to adopt any of the sample policies and procedures; they are intended simply to serve as a resource and guide in the planning process. *They are not reflective of a standard of care.*

Upon completion of the 10 modules reflected in *Planning Today for a Pandemic Tomorrow,* a "cross-walk" will be developed. This cross-walk will provide guidance for other module areas that should be referenced when developing policies and procedures. For example, when examining a Human Resources policy, the Legal and Regulatory module may need to be reviewed.

And finally, the information reflected in the planning and assessment tool modules is intended to be used as a fluid and flexible resource in dealing with the problems associated with a pandemic influenza outbreak. It is based on existing information, therefore hospitals should routinely review their plan to ensure new information is incorporated into policies and procedures as necessary.

ETHICS MODULE

When the next influenza pandemic strikes, health care providers and leaders will face a wide range of difficult decisions that will affect how we, as a society, cope with the medical consequences of a pandemic. Individual health care workers will be forced to decide what level of personal risk they are willing to take, and employers will be forced to decide what protections they will provide for employees and their families. Insufficient or strained resources will have a significant impact on medical decisions and resource allocation. Ethics can provide a moral compass to guide the difficult decisions that must be made during a pandemic.

The need for a clearly understood and widely accepted ethical approach to dealing with serious communicable diseases was underscored during the outbreak of Severe Acute Respiratory Distress (SARS) in early 2003. The SARS outbreak highlighted that health care systems had generally not prepared themselves to deal with immediate and tough ethical choices. Research done in the aftermath of the outbreak showed that people are more likely to accept difficult and complex decisions if the decision making processes are reasonable; open and transparent; inclusive of all concerned parties; and responsive to the concerns of health care workers and the community[1]. This transparency extends to patients, caregivers and the general public. The results of not having an ethical framework in place included loss of trust, low morale, fear and misinformation. This module will help guide health care facilities with understanding and incorporating accepted ethical principles into pandemic planning. (See Glossary for a list of terms.)

As with all of the modules in the *Planning Today for a Pandemic Tomorrow* series, the sections that follow contain a series of planning/policy tasks broken down by essential ethics expertise areas. However, this module starts with a "primer" in order to lay the foundation for the *process* of making ethical decisions. As always, the planning/policy tasks are discretionary and are representative of the issues that *should* be considered. The module includes:

I. How to Use This Module
II. Core Values
III. The Decision Making Process

A. Multidisciplinary Ethics Committee
B. Ethical Values and Processes
C. Ethical Conflicts
D. Health Care Worker Issues
E. Patient Issues

Associated with each section are appendices and/or suggestions to refer to other toolkit modules that offer additional details, tips and/or further explanation of important considerations for each task. Careful planning in these areas will assure that ethical decisions run smoothly under the extreme conditions of a pandemic.

The following positions are recommended for the Ethics subcommittee:

- Administrator
- Community member
- Educator
- Ethicist
- Human resources representative
- Legal representative
- Risk manager
- Nurse
- Pastoral care representative
- Physicians representing various departments
- Patient advocate
- Social worker
- Selected, if not all, members of facility's current ethics committee (if applicable)

I. HOW TO USE THIS MODULE*

Regardless of whether a facility has a formal ethics committee, or simply convenes key staff when ethical issues arise, the reality is a pandemic will create ethical challenges that health care providers have not been faced with in any other crisis. The critical directive of this module is to think through anticipated ethical challenges/issues to determine how the facility will respond in advance of a pandemic.

When giving consideration to these ethical decisions, it can be easier to think in terms of "buckets" (see next page for illustration). A number and variety of decisions will fall within these buckets that are reflective of a facility's *core values* (the values of the facility that drive day to day operations). In other words, the buckets will include examples of specific values that are associated with:

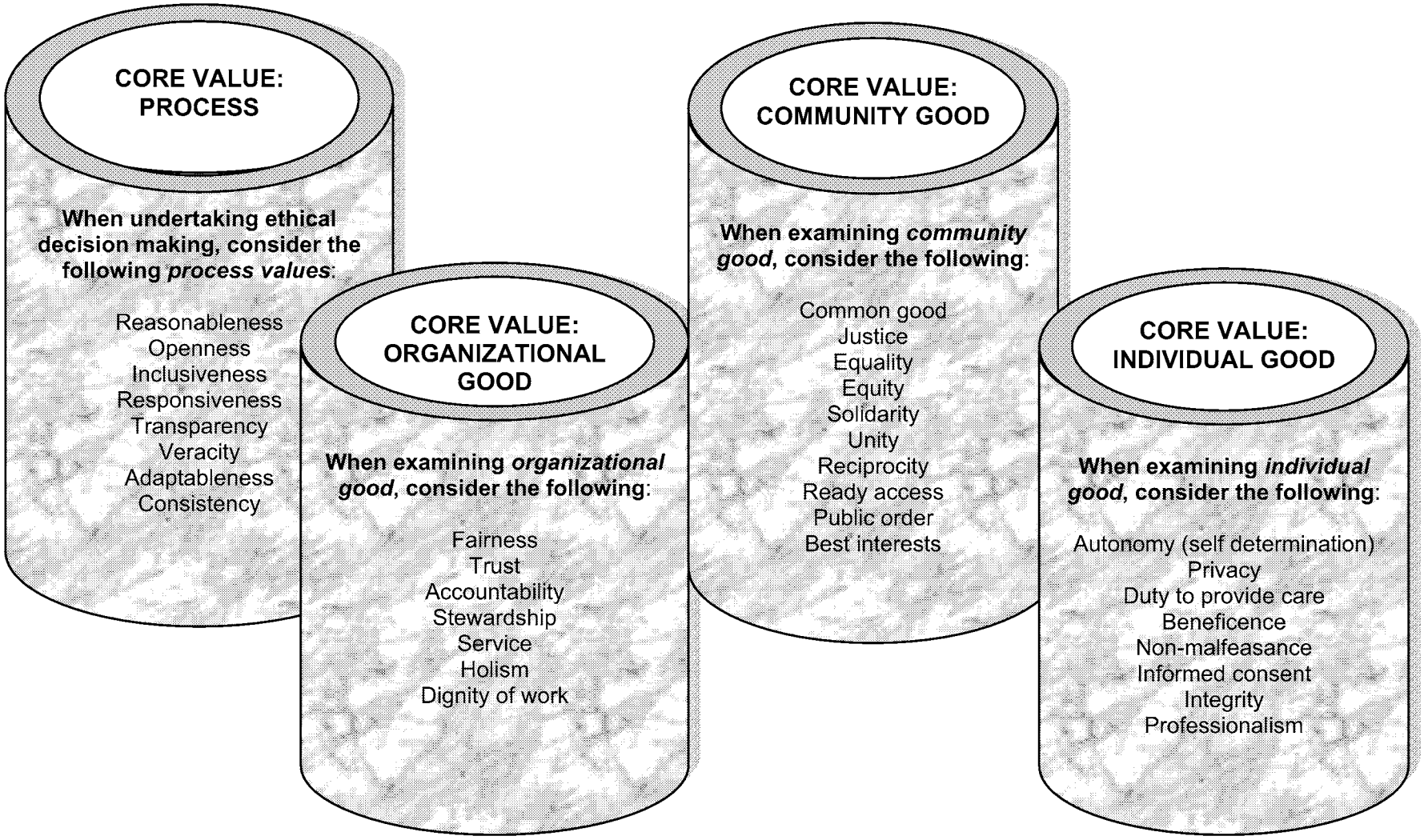
- The process by which decisions will be made;
- What is in the best interest of the organization/facility;
- What is in the best interest of the community; and
- What is in the best interest of the individual.

The core values reflected by the buckets are not reflective of any order of importance as it is up to each individual organization to determine the priority of one value over another. For example, one facility may determine that the good of the community should take priority over the good of the individual during a pandemic, while others may believe that focusing on the good of the facility should be the main concern. Since determining the priority of a facility's core values is of utmost importance, the process of determining these core values must always be transparent to those served by the facility (e.g., the community, employees, patients, caregivers), to avoid negative public perception or misunderstood intent.

Reflected within each bucket are examples of different values that may be considered when developing policies on behalf of the facility. They are by no means all-inclusive, but may be used to facilitate discussion and to ensure that the values are considered before determining if they will be reflected in policy (e.g., when developing policy regarding a health care worker's responsibility to provide care, should the decision be left to the individual worker, or should the worker be informed that the facility believes he/she has a duty to provide care?). Considering these values can assist in the decision making process, and should result in consensus-based, clearly understood agreements.

** The information reflected in this module is based in large part on the model developed by the Catholic Health Association; however, there are many and varied models that may serve as a guide to ethical decision-making. In addition, the ethical considerations discussed are in relation to a facility's scope of authority. Other entities, such as insurers, faith-based organizations, etc., should be engaged in their own ethical determinations since these organizations will be interrelated with the facility during a pandemic. Given that each organization will adopt their own values, conflicts that add complexity to the ethical decision-making process should be expected.*

II. Core Values



III. FRAMEWORK FOR DECISION MAKING

Providers and staff at every level of the facility must understand the ethical *decision making process* and comprehend the consequences of those decisions. There must also be an assurance that the facility is understanding and supportive of its employees when they are faced with ethical dilemmas. If these critical elements are not addressed, staff's ability to function effectively will be diminished.

This module provides a framework for decision making as well as the assessment tool. This resource will support the facility in evaluating its decision making process in advance of a pandemic. While the decisions may be challenging, the process can be more easily understood by following a structure that reflects the context of the situation being addressed – in this case, a pandemic. The determined and understood values of the facility are guides – not answers – to the challenges of concrete circumstances during a pandemic outbreak and should be considered when decision alternatives are identified. Of course, these values should also be an extension of the facility's clearly delineated goals.

- **STEP ONE**
  - Determine:
    - ✓ Who should be heard?
    - ✓ Who should be "at the table?"
    - ✓ Who makes the final decision?

      For example: *When resources become scarce, patients must be prioritized in terms of who will receive those resources. Physicians, nurses, patient advocates and general counsel should have input into the decision making process.*

- **STEP TWO**
  - Gather information, including:
    - ✓ Who, what, where, when, why and how
    - ✓ Key stakeholders
    - ✓ Relevant social, political, economic, legal and religious considerations

      For example: *Speak with community leaders, including clergy to solicit their feedback regarding how the hospital will function during a pandemic and the support it will need.*

III. FRAMEWORK FOR DECISION MAKING CONTINUED

- **STEP THREE**
  - Identify the specific issue and determine:
    - ✓ What are the values that may be in conflict (e.g., protecting the good of the community/public vs. protecting the rights of the individual patient, employee, etc.)?
    - ✓ What is creating a conflict with the facility's values?
      For example: *Quarantine for individuals with confirmed influenza in an effort to slow or prevent its spread to the larger community*.

- **STEP FOUR**
  - Review core commitments
    - ✓ What core values may need to change in the context of a pandemic?
    - ✓ Is there a clear and justifiable reason for modifying the facility's values?
    - ✓ Do values need to be reprioritized?
      For example: *Limiting ventilators to specific categories of patients.*

- **STEP FIVE**
  - Identify alternatives
    - ✓ Are there alternative options that can be utilized to address the situation/problem?
    - ✓ Have the negative and positive consequences (both short-term and long-term) been identified?
    - ✓ Do the facility's core values determine which alternatives, if any, are unacceptable?
    - ✓ Are the consequences of the decision(s) acceptable?
      For example: *Utilizing expired drugs and allowing patients to bring drugs in from home when supplies are diminished or depleted.*

- **STEP SIX**
  - Make a decision
    - ✓ Choose one of the alternatives
    - ✓ Ensure the ability to justify the chosen alternative, as well as the process used to eliminate other alternatives
    - ✓ Determine how the decision will be communicated; ensure a process is in place to allow for discussion of concerns
      For example: *Suspending key services such as outpatient oncology services, including clinical trials that patients are dependent upon for survival.*

III. FRAMEWORK FOR DECISION MAKING CONTINUED

- **STEP SEVEN**
  - Evaluate:
    - ✓ The impact the decision has had on the facility's core values
    - ✓ If the chosen alternative is not appropriate, determine if other alternatives exist.
      For example: *Offering only palliative care to critically ill patients while focusing on caring for the acutely ill.*

Through the assessment provided in this module, core values will be identified and defined, and specific questions asked to determine if these core values have been thoroughly examined. This assessment will allow a facility to identify strengths in its ethical decision making process, as well as areas that need further examination and resolution. Most critical is creating a process to ensure all facility employees understand these values and the process by which these decisions have been made (transparency). Employees must be empowered to have a voice in the process to ensure that their eventual actions are consistent with the facility's values.

*Process outline based on *A Process for Ethical Decision Making*, Catholic Health Association of the United States.

A

A. MULTIDISCIPLINARY ETHICS COMMITTEE

COMMITTEE PLANNING CONSIDERATIONS

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
1	Create ethics committee* that includes many or all of the following: ✓ Administrator ✓ Community representative ✓ Nurse ✓ Educator ✓ Ethicist ✓ Emergency coordination representative ✓ Risk manager ✓ Patient advocate ✓ Pastoral care (clergy/chaplain) ✓ Physicians ✓ Lawyer ✓ Social worker					
2	If no standing ethics committee is in place, confirm process to form an ad-hoc ethics committee as needed.					
3	Confirm that ethics committee has clearly defined scope of authority (i.e., will committee be advisory in nature, or will it make binding decisions).					
4	Create policy that governs which types of issues are brought to the ethics committee.					
5	Confirm capabilities to facilitate virtual meetings of the ethics committee during a pandemic (within the framework of Incident Command System).					

*Facility should determine if it will utilize its existing/standing ethics committee, or establish a separate, pandemic-focused committee.

B

B. PROCESS FOR ETHICAL DECISION MAKING (SEE APPENDICES B1, B2, B3)

The goals of creating and implementing a formalized standard process for ethical thinking are to provide a consistent set of guidelines and directions for leaders who will be forced to make difficult decisions during a pandemic and to provide an organized way of presenting situations and cases for discussion.

The process for ethical decision making includes the following three broad phases: **Preparation, Decision Making and Follow Through**. While there are several processes used in ethical decision making, we present the basic elements below:

PREPARATION PHASE PROCESS CONSIDERATIONS

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
1	Create a formal ethical decision making process that is clearly delineated in layperson language.					
2	Create process by which an issue or question is brought forward in a succinct written statement.					
3	Create process to identify those who will be affected by the decision (stakeholders). Agreement should be reached by those developing policies to acknowledge stakeholders' interests when reaching a decision.					

B. PROCESS FOR ETHICAL DECISION MAKING continued

PREPARATION Phase Process Considerations

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
4	Create process to gather relevant key facts about the issue or question: ✓ Identify legal and regulatory issues. ✓ Identify system-wide regulations (i.e. ethical and/or religious directives). ✓ Clarify the patient's perspective by examining religious beliefs and cultural or philosophical values. ✓ Determine if a patient-based model is appropriate vs. another model (e.g., community-based decision-making model). ✓ Identify financial constraints. ✓ Determine essential ethical principles. ✓ Identify treatment alternatives.					
5	Confirm formal medical staff process to assign patients to different treatment groups: ✓ Treat aggressively ✓ Treat non-aggressively ✓ Palliative care only ✓ Withdraw care to reassign resources					

B. PROCESS FOR ETHICAL DECISION MAKING CONTINUED

DECISION MAKING PHASE PROCESS CONSIDERATIONS

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
6	Determine what is in the best interest of all involved parties: ✓ Allow input and/or acknowledge all perspectives. ✓ Integrate public health policies into the decision making process. ✓ Bring stakeholder groups into the decision making process.					
7	Create process to make timely decisions when the decision is a difficult morally or ethically.					
8	Train several people in the ethical decision making process and empower them to guide others in making difficult decisions.					
9	Confirm committee has process to document deliberative process used to reach decision points.					
10	Create plan to communicate how decisions are made; what values played a role in the decision; and how stakeholder impact was factored into the decision.					
11	Create policies based on the final decision, as well as process to implement the new policies.					
12	Collect data on changes introduced by the decision for later analysis.					

B. PROCESS FOR ETHICAL DECISION MAKING CONTINUED

FOLLOW-THROUGH Phase Process Considerations

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
13	Ensure flexibility to change decisions when new information becomes available or unanticipated results occur.					
14	Create complaints/appeals process.					
15	Review the implementation of the decision and the new policy using collected data.					
16	Monitor and report measurable outcomes.					

C

C. ETHICAL VALUES AND PROCESSES (SEE APPENDICES C1, C2)

The following are examples of values that can apply to issues and decisions that will be encountered during a pandemic. Some of these values relate to the decision making process outlined in Section III. The remainder are core values that drive a facility's mission and can be further subdivided into:

- Community good
- Common good
- Organizational values
- Individual rights (include employees, patients and caregivers)

Some core values may apply to more than one category (e.g., it can be both an individual right and an institutional value). Facilities should determine which of these values are applicable and implement the associated policies.

PRIVACY PLANNING CONSIDERATIONS

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
1	Consider individual right-to-privacy issues. During a pandemic or patient surge, it may be necessary to override this right to protect the public from harm. When examining individual good issues, consider the following: ✓ Autonomy (self determination) ✓ Privacy ✓ Duty to provide care ✓ Beneficence ✓ Non-malfeasance ✓ Informed consent ✓ Integrity ✓ Professionalism (see glossary for definitions)					
2	Determine how, when, to whom and what medical information will be released to protect the public good.					

C. ETHICAL VALUES AND PROCESSES continued

Duty to Provide Care Considerations

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
3	Weigh duty to provide care against competing obligations to staff's own health, family/friends' needs, etc.					
4	Confirm medical, nursing and human resources staff (and other professional groups) have devised and ratified a code of ethical behavior that will govern professional duties during a pandemic. Include language on: ✓ Difficult decisions related to resource allocation ✓ Scope of practice ✓ Professional liability ✓ Workplace conditions					

C. ETHICAL VALUES AND PROCESSES continued

Equity Considerations

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
5	During a pandemic, equal claims to clinical services may be curtailed or suspended. Create process to determine which services may be suspended and how patients requiring these services will be handled.					
6	When examining community good issues, consider the following: ✓ Common good ✓ Justice ✓ Equality ✓ Equity ✓ Solidarity ✓ Unity ✓ Reciprocity ✓ Ready access ✓ Public order ✓ Best interests.					
7	Tier suspension of services and tie to resource availability.					
8	Decide which life sustaining services may be suspended during a pandemic and make accommodations for patients (e.g., how will dialysis patients receive care?)					
9	Determine how staff impacted by suspension of services should be supported through reassignment and/or retraining. See HR module.					

C. ETHICAL VALUES AND PROCESSES continued

Fairness

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
10	Create policy reflecting that people in similar circumstances should be treated similarly regardless of age, gender, race, creed, mental ability, social status or financial resources. When examining organization good issues, consider the following: ✓ Fairness ✓ Trust ✓ Accountability ✓ Stewardship ✓ Service ✓ Holism ✓ Dignity of work					
11	Design processes and procedures to deliver compassionate care to all to the best of facility's ability.					
12	Design processes and procedures to deliver palliative care to those who cannot receive life saving measures (e.g., lack of sufficient anti-viral medications, lack of ventilators, etc.).					

C. Ethical Values and Processes continued

Trust

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
13	Recognize that, during a pandemic, facility leaders will have the difficult challenge of maintaining stakeholder trust while simultaneously implementing unpopular or unproven measures.					
14	Create open, transparent process when making difficult decisions that have moral implications.					
15	Include various stakeholder groups in the decision making process.					

C. ETHICAL VALUES AND PROCESSES CONTINUED

SOLIDARITY

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
16	Prepare services and professional staff to set aside traditional values of self-interest and territoriality in order to present solidarity to stakeholders.					
17	Reach out to surrounding health care facilities to work collaboratively on community planning efforts.					
18	Foster a culture of cooperation and collaboration among competing medical groups for the purpose of pandemic planning. Include representatives from the various groups to develop policies.					
19	Implement policies for facility departments and services that will eliminate conflict during a public health crisis (e.g., which departments must maintain operations/services within the facility vs. which departments can function with employees working remotely).					

C. ETHICAL VALUES AND PROCESSES continued

Reasonableness

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
20	Ensure that decisions made during a pandemic are based on evidence, principles and values (i.e., reasons) that stakeholder groups agree are relevant to the crisis health needs. When undertaking ethical decision making, consider the following process values: ✓ Reasonableness ✓ Openness ✓ Inclusiveness ✓ Responsiveness ✓ Transparency ✓ Veracity ✓ Adaptiveness ✓ Consistency					
21	Ensure that decisions are rational, not arbitrary, and can be justified and applied consistently.					
22	Ensure that decisions are based on appropriate evidence available at the time of the decision (e.g., effectiveness of ventilators for specific age groups).					

C. ETHICAL VALUES AND PROCESSES continued

Policy Decision/Information

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
24	Ensure decisions are result of appropriate process that takes into account how quickly a decision must be made (e.g., two people with same health status each requiring a ventilator when only one is available).					

Openness and Transparency

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
25	Confirm that ethics decisions are open to scrutiny by various stakeholders, well documented, and the basis upon which these decisions are made are publicly accessible.					
26	Confirm decision making process follows a pre-established pathway and uses a pre-established framework.					

C. ETHICAL VALUES AND PROCESSES CONTINUED

Inclusiveness

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
27	Engage as many stakeholder groups as possible in decision making process to confirm final decisions are made with stakeholder views in mind.					
28	Consider process to assure unrepresented stakeholder groups have their views represented during the decision making process.					

Responsiveness

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
29	Create opportunities to revisit and revise decisions as new information emerges and/or as complaints/disputes arise.					
30	Create mechanism to address disputes/complaints.					
31	Plan to revisit and revise decisions based on new information, clinical data, or epidemiological knowledge.					

C. Ethical Values and Processes continued

Accountability

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
32	Ensure process for accountability related to ethical actions and inactions.					
33	Formally document decision making process for all morally and ethically challenging decisions to provide for legal defense, and to create "lessons learned" document for future pandemics.					

Beneficence and Non-Malfeasance

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
34	Remind health care providers of their duty to promote and engage in positive effect activities with patients while refraining from any activity that may cause harm.					
35	Ensure decisions are made with the goal of promoting the best public health outcome during a pandemic (e.g., employees work from home to reduce risk of exposure).					

C. ETHICAL VALUES AND PROCESSES CONTINUED

UNITY/RECIPROCITY

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
36	Create crossover to work together both internally and with external community groups to limit disease spread and minimize amount of suffering and death (e.g., restrict access to facilities to reduce risk of public infection).					
37	Support staff pandemic needs and plan to show generosity towards workers who assume a higher risk during a pandemic.					
38	Create process to minimize or evenly distribute burdens placed on employees who choose to take on increased pandemic risk.					

STEWARDSHIP

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
39	Ensure facility leaders are guided by trust and ethical behavior in making their decisions to achieve the best possible public health outcomes.					
40	Provide education/training program for staff that may be called upon to assume leadership roles in the ethical decision making process. Ensure they are able and willing to provide appropriate information to all employees upon request. See Leadership Module.					

D

D. ETHICAL CONFLICTS

Duty to Provide Care Planning Considerations

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
1	Establish explicit pandemic work expectations.					
2	Develop codes or statements of ethical conduct in high risk situations for all staff (e.g., physicians, nurses, clinical staff, non-clinical staff).					
3	Address reciprocity and solidarity issues (see Section C): ✓ Acknowledge that work is dangerous ✓ Help workers cope with high stress of pandemic care ✓ Provide for health and safety of workers ✓ Care for those who become ill at work or as a result of work ✓ Provide health and disability insurance and/or death benefits for those who become ill or die					

D. Ethical Conflicts continued

Restriction of Personal Liberties in the interest of Public Health

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
4	Create policy to implement work quarantine if directed to do so by public health authorities.					
5	Create policy to handle workers who ignore work quarantine guidelines.					
6	Create policy to handle staff that refuse mandatory vaccination.					
7	Create policy to handle staff who are arrested or imprisoned for failing to follow public health requirements during a pandemic (e.g., if someone is arrested and/or quarantined for refusing mandatory vaccination, will they be fired).					

D. Ethical Conflicts continued

Priority Setting – Allocation of Scarce Resources

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
8	Guarantee that scarce resources allocations are reasonable, open and transparent, inclusive, responsive, accountable and fair.					
9	Create policy regarding how scarce resources will be distributed and utilized, taking into account (D1): ✓ The greatest good for the greatest number may not be the right decision. The overarching goal is to preserve a functioning society. ✓ Who will decide how resources are prioritized and distributed? ✓ Who will be eligible recipients of various goods and services?					
10	Create effective communication strategy with stakeholder groups (including community members) to explain the process that will be used to allocate scarce resources. ✓ Engage stakeholder groups to determine what criteria should be used to allocate scarce resources. ✓ The community should know in advance the clear rationale for giving priority to certain groups for certain resources. ✓ What morally relevant criteria will be employed to assign higher or lower priorities to groups or individuals within the community?					

D. ETHICAL CONFLICTS CONTINUED

Priority Setting – Allocation of Scarce Resources Continued

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
11	Create process to bring forward new information, appeal previous decisions, raise new concerns, and resolve disputes.					
12	Allocate available health care professionals to answer the following questions: ✓ How will procedures and interventions be delegated (e.g., physician tasks done by nurses; nursing tasks done by aides, etc.)? ✓ What percentage of health care professional time will be allocated to pandemic care, non-pandemic care, time-sensitive critical research, animal care, etc.?					

Suspension of Ordinary Moral Rules

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
13	Determine procedure to suspend ordinary moral rules that are commonly used to guide behavior, disciplinary committees/actions, and decision making processes. ✓ Under what conditions would such suspensions occur? ✓ Who is authorized to suspend such rule?					

E

E. HEALTH CARE WORKER ISSUES

Employer Obligations to Health Care Workers

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
1	Recognize duty to minimize workers' risk of exposure to pandemic influenza by providing some or all of the following: ✓ Ethical decision framework training. ✓ Infection control equipment supply and training. ✓ Antiviral medications and vaccines supply (if available). ✓ Access to health insurance, disability insurance, death benefits with waived waiting periods (to be negotiated with insurance companies, if possible). ✓ Liability protection that provides care beyond facility's scope of practice (if within limits of the law). ✓ Institutional or community guidelines that could be cited as legal standard of care.					

E. HEALTH CARE WORKER ISSUES continued

Obligations of Health Care Workers to Employer

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
2	Establish minimum obligations of health care workers expected during a pandemic: ✓ Language should be written into collective bargaining agreements. ✓ Minimum obligations should take into account workers' family responsibilities, for example a single parent that has sole responsibility for their family.					
3	Establish guidelines for sanctions and incentives: ✓ If sanctions are applied, application must be consistent across similar situations/contexts; they should be limited to usual sanctions; and a formal appeals process must be in place. ✓ Consider incentives to encourage workers to assume increased risk.					

E. HEALTH CARE WORKER ISSUES continued

Other Issues

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
4	Establish procedure to handle moral dilemmas when a staff member is asked to do something with which they disagree.					
5	Establish procedure to handle situation where a physician recommends an appropriate course of treatment, but the patient requests a different, non-conventional (but approved) treatment or therapy.					
6	Determine what sanctions, if any, will be implemented if a physician refuses to abide by the adopted decision-making process (e.g., a population-based triage decision-making policy rather than individual-based).					

F

F. PATIENT ISSUES

Informed Consent Issues

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
1	Create process to handle informed consent in administering alternate levels of care (e.g., ignoring informed consent under pandemic circumstances; or deferring informed consent for minor changes to standard of care, etc.)					
2	Create process to handle informed consent in using unproven or uncertified technology.					
3	Ensure patients are aware of proposed medical interventions and available alternatives during a pandemic.					
4	Create process to document the informed consent process.					
5	Create consent process for when there is no ability to obtain informed consent in these populations: ✓ Unaccompanied child ✓ Unconscious adult ✓ Adult with altered mental status ✓ Language barrier ✓ Insufficient mental ability to understand					

F. PATIENT ISSUES CONTINUED

Intervention Issues

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
6	Follow public health policy to address mandated interventions when a patient refuses treatment (e.g., mandated flu vaccine).					
7	Create policy to address medically futile treatment issues, if requested by patient or family.					
8	Create policy that addresses giving treatments to individuals in a priority group while withholding treatment from others (e.g., treating a teenager and denying their parents if young people are prioritized).					
9	Create policy that addresses withdrawing treatment from one group to give it to another group (e.g., removing an elderly person from a ventilator to provide service to a 20-year-old).					
10	Create policy that addresses brain death (utilizing same definitions utilized during "normal" times) in order to redeploy scarce resources: ✓ Whole brain ✓ Neocortical death ✓ Brain-stem death					

F. PATIENT ISSUES CONTINUED

Intervention Issues Continued

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
11	Create policy that addresses patients in persistent vegetative states that are using scarce resources (e.g., ventilators).					
12	Confirm decisions on how medical staff will respond to codes (cardio-pulmonary arrests)..					

Right to Die Issues

	ASSIGNMENT	COMPLETED	IN PROGRESS	NOT STARTED	DATE TO BE COMPLETED	LEAD STAFF MEMBER
	Create policy that addresses a patient's request to withhold treatment.					
	Create policy that addresses how to handle DO NOT RESUSCITATE (DNR) requests.					
	Create policy that addresses withholding treatment in special circumstances such as: ✓ If the patient is 20-years-old and was previously healthy. ✓ If the patient is elderly and does not want to use a ventilator that could benefit someone else.					

G

Appendix B - I

A Matrix For Ethical Decision Making in a Pandemic

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Health Progress

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A Matrix for Ethical Decision Making in a Pandemic

The Oregon Tool for Emergency Preparedness

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In recent years, there has been a great deal of interest in emergency preparedness. This is especially true in light of concerns about a pandemic of the H5N1 virus, the "bird flu."* Ethical concerns include ensuring access to basic resources such as health care, and the duties of professionals to perform their task in the face of such events.[1†] Like other states, Oregon set out to establish an emergency preparedness plan to address these issues. A part of this planning included the establishment of a Medical Advisory Group (MAG), whose charge it was in part to describe the role ethics would play in decision making during a pandemic.[§] In this article, I intend to describe why and how we in Oregon took an approach that differed in some ways from other plans.

* This concern is also fueled by memories of the SARS event in 2002, which had a 9.6 percent mortality rate worldwide; a continued increase in the number of West Nile cases each year; and the infrastructure failures resulting from events such as Hurricane Katrina in 2005.

† These expectations have been called into question by the behavior of some professionals after Katrina. For example, Anna Pou, MD, and two nurses were alleged to have euthanized four patients at Memorial Medical Center in New Orleans after three days without electricity or water. On July 25, 2007, a Louisiana grand jury refused to return an indictment against the three.

§ The Medical Advisory Group was established by the director of Oregon's Department of Health Services (DHS), Susan Allan, MD, JD, MPH, as an interdisciplinary group. The group's membership includes county health departments, health professional organizations, health insurors, local governments and tribal organizations, a researcher with expertise in mass communications, and an ethicist (the author of this article). In a DHS news release of February 2007, Allan said, "This group is helping establish guidelines and frameworks that will be instrumental for making complex decisions quickly in a time of crisis. Members of this group also may be asked to review proposed recommendations by the state during a crisis. Many of them represent professionals who will be at the forefront in carrying out those decisions. It is far better to build an understanding of what is at stake now, while we have time to discuss potential issues and identify the critical factors that would have to be balanced."

A Critique of the Ethical Basis of Preparedness Plans

It is beyond the scope of this article to provide a thorough analysis of the relevant literature, or of state and local emergency preparedness plans themselves. It can be said that such plans generally contain a reference to the ethical principles that should inform decision making during a pandemic. At the same time, there is a wide variety as to what principles are listed and how they are defined.

For example, *Stand on Guard for Thee*, the plan of the University of Toronto's Joint Centre for Bioethics, offers 15 different ethical values; 10 of which are described as "substantive" values (intended to inform decision making) and five are described as "procedural values" (to guide implementation).[2] In contrast, the plan offered by the Minnesota Center for Health Care Ethics has only six ethical principles in its recommendations, of which four are really outcomes measures.3 These principles are intended to achieve the primary goal of "maximizing Minnesotans' chances of surviving," with a secondary goal of protecting "against the loss of any single generation when *reasonable measures* to do so are available" [emphasis added].[¥]

¥ Another secondary goal is to promote social cohesiveness and collaboration in the population.

For all these plans' strengths, these two examples illustrate the common absence of a decision-making matrix in emergency preparedness plans. *Stand on Guard for Thee* does state that decisions should be reasonable, transparent, and inclusive—but these procedural values do not, by themselves, provide insight into what is "reasonable" in a particular situation or who should be included in the process. Because the Minnesota model appears more oriented toward outcomes, one cannot but wonder how it might be possible to demonstrate that protecting against the loss of any single generation might be "unreasonable."

To ensure consistency and accountability in responding to a catastrophic event like a pandemic, preparedness plans need more than a commitment to acting reasonably and with transparency in the pursuit of principles or outcomes. A commitment to acting ethically requires a definition of what it means in a crisis to act "reasonably." Moreover, if we are to avoid utilitarianism, we cannot make achieving objective outcomes a primary goal. The measure of acting ethically is the measure of the quality of the relationships in a particular situation.* The way to ensure quality relationships is through a defined and tested decision-making matrix that can demonstrate consistency and accountability in the honesty, reliability, and fairness with which decisions are made.† For that reason, the Oregon MAG decided that in its own preparedness plan ethical grounding would be assured through a decision-making matrix to be used in all aspects of the implementation of a preparedness response.

* Because, as will be seen, acting ethically is so vital, the Minnesota plan's secondary goal of social cohesiveness is for us a primary concern.

† I am indebted for some of this language, especially in the organizational sphere, to Laura Nash, Good Intentions Aside: A Manager's Guide to Resolving Ethical Problems, Harvard University Press, Cambridge, Mass., 1993.

Beginning with Context

Decision making is always contextual. Decisions are made not in the abstract but, rather, in the context of concrete circumstances and situations. A decision-making matrix, therefore, must be adequate to the context in which it will be used. Changes in context can make a once robust and appropriate decision-making matrix feeble or dangerous.

For example, one challenge in a pandemic found in another context is the allocation of limited resources. One typical scenario is the allocation of vital organs to people needing organ transplants. Looking at this issue from her vast experience in the transplant field, Margaret Riggs Allee has articulated the ethical concerns that should inform allocation decisions in this context.[4] Although Allee does not offer a decision-making matrix per se, her discussion of benefit, quality of life, duration of benefit, and the urgency of patient need are specific enough to allow a community to know that organs are being allocated in a way that is consistently honest, reliable, and fair.

Three years ago, the allocation question emerged in an entirely new context. On October 5, 2004, the Centers for Disease Control and Prevention (CDC) was notified by the Chiron Corporation that, because of contamination during production at the firm's plant in Great Britain, none of its influenza vaccine Fluvirin would be available for distribution in the United States. In this case, the context was not about allocating scarce resources among the people who needed them but, rather, about allocating resources to prevent the outbreak of an infectious disease. With a prophylaxis, the concern is not who gets the vaccine, but who should get the vaccine *in order to reduce the risk of an outbreak among the general populace*. Public health, not personal health, is the value at risk.

In this new context, Allee's considerations concerning who should receive an organ will not lead to honest, reliable, and fair decisions when applied to questions about who should receive the flu vaccine. The clinical difference between the vaccine's benefit for the elderly, on one hand, and the young, on the other, is insufficient to favor one age group over the other. The flu vaccine's prophylactic benefit is the same for all, regardless of age. If there is not enough for all those who will equally benefit clinically, but there is not enough of it to go around, by what criteria should the vaccine be allocated? Because the context here is public health, allocation decision-making criteria should be applied toward public health and public order concerns, such as vaccinating health care workers—in some cases before vaccinating at-risk patients.

The point here is that context is ethically significant. Emergency preparedness plans must have context-specific ethical approaches if they are to be applied consistently and held accountable as being honest, reliable, and fair.

Context for a Pandemic

The context within which decision making will likely be made for current emergency preparedness plans is that of an infectious agent, namely H5N1.* An infectious-agent context is one that refers to the presence of one or more pathogens, with various degrees of infectivity, in a community for an indefinite period of time. If infectivity is low, as it is with Norovirus, which causes gastrointestinal disorders, it is common to speak of an "outbreak" that directly and indirectly impacts a limited number of people.

* Noninfectious contexts include radiation, anthrax, and catastrophic events such as hurricanes or conventional bombings.

Where there is an increase in infectivity or in the number of pathogens, a dramatic change in context results. As the infection rate from a pathogen moves beyond a localized area to involve the general population within a large geographic area, the term *epidemic* is applied. An example cited often of an epidemic is the "Spanish flu" that occurred in the United States between 1918 and 1920. The direct impact of that epidemic was the approximately 550,000 deaths attributed to it.† There was also a dramatic increase in the indirect impact. One study of the epidemic notes that it was "a large shock that had substantial macroeconomic effects," causing the post-World War I recession to extend into 1921.[5] The study shows that states that sustained the highest *direct* impact of the epidemic, large numbers of deaths, also sustained the greatest *indirect* impact, such as business failures.

† There were 675,000 U.S. deaths from all causes during this period.

The fear with H5N1 is that it will be so highly infectious and spread so easily in today's global economy that there will be no natural geographic boundaries or geopolitical populations capable of isolating the virus. This is a *pandemic*. Other pathogens theoretically capable of causing a pandemic include Ebola virus, antibiotic resistant strains such as vancomycin-resistant staphylococcus aureus (VRSA), and sudden acute respiratory syndrome (SARS). The virulent nature of such a pathogen, and the ease with which it can spread due to global travel will cause its direct and indirect impacts to grow exponentially.

In the context of a pandemic, the values at risk are clearly astounding. Certainly among them is the value of the life and health of each affected person. But if H5N1 should develop a subtype that allows human-to-human transmission, the likely result in mortality, which will be far higher than that of the 1918-1920 flu pandemic, these will not be the only values at risk. With an event of that size, the values related to the social, psychological, political, economic spheres of life will also be put at extreme risk.[§] Just as it is not possible to make decisions regarding the allocation of a prophylaxis according to the ethical considerations used in allocating kidneys, so this new pandemic context also requires a specific approach to decision making. The principles involved may be the same, but the context shapes the way those principles are brought to bear. This particular ethical discussion, with its epidemiological, social, political, psychological, and economic dimensions, cannot be adequately managed in a way that ensures consistency and accountability for honesty, reliability, and fairness unless it is done with a robust decision-making matrix within which ethical principles are applied specifically to the context.

§ A study done for the CDC estimates that the effects of the next influenza pandemic in the United States will result in 89,000 to 207,000 deaths and an economic loss of $71.3 billion to $166.5 billion, excluding disruptions to commerce and society. See M. I. Meltzer, N. J. Cox, and K. Fukuda, "The Economic Impact of Pandemic Influenza in the United States: Priorities for Intervention," Emerging Infectious Diseases, vol. 5, no. 5, September-October 1999, pp. 659-671.

Constructing an Ethical Decision-Making Matrix

For Oregon's MAG, constructing the matrix involved several full days and numerous meetings in which we sought a thorough understanding of the context of the course of a pandemic, defined by the World Health Organization as having inter-pandemic, pandemic alert, and pandemic stages[6], in order to identify the key values most at risk in this context. These we came to describe as "social solidarity," "adherence to the standards of one's profession," and "justice." We then went on to describe the characteristics of those three values, a process that helped us clarify both what was at risk and the goods we hoped to pursue. Lastly, we sought to articulate the principles we believed were most relevant to those values. The same ethical principles can fit in different value spheres. Still, we felt that if our decision making was to be dynamic, flexible, and robust enough to respond in real time to predicted and unseen challenges, we needed to work with ethical principles within a specific value, not with principles "in general."

Most challenging perhaps was developing a diagram to illustrate the interchange between the different values, characteristics, and principles. What is key here is that the measure of the matrix's usefulness is the quality of the relationships in the community before, during, and after the pandemic event. If the community is inclined to agree that decisions are made consistently and with accountability, and that they reflect honesty, reliability, and fairness in accounting for the values of social solidarity, adherence to standards, and justice are brought to bear on the question at hand, then we will be acting ethically.

The three circles represent the three key values. The words in bold type indicate the value's characteristics, whereas those in italic type indicate the principles involved. Real-time decision making takes place within the overlapping areas of the matrix. A decision is never, for example, simply about clinical infectivity; such a decision might suggest that closing schools is a good idea. A decision on school closing must also account for the impact of that decision on social solidarity, as well as the justice obligation to the children who will not get a meal because they are not in school. A decision to keep open or close schools must be accountable to all facets of the matrix, even though the decision makers can ultimately choose only one. This is what distinguishes this model for preparedness from some others. The matrix makes decision making explicit, and therefore more readily consistent and accountable.

Describing the Decision-Making Matrix

As stated above, this matrix has three values: social solidarity, professionalism, and justice. Each value has its own characteristics and ethical principles most relevant to it.

Social Solidarity
This value refers to the bonds that unify a community, as well as to the structures, such as schools and organizations, that support and maintain those bonds. Characteristics of social solidarity include a person's *interdependence* with and among others, *attachment* to or interest in others and their concerns, *commitment* to or support for the social structures that make social life possible, and personal *involvement* or engagement in the community's social life. Social solidarity is also characterized by *shared beliefs* and convictions, which contribute to the community's ability to achieve consensus on important issues. These characteristics will be at risk in a pandemic, and must be explicitly accounted for in all decisions.

- With this understanding of solidarity, the MAG identified those ethical principles most relevant to it. Among these were:
- *Subsidiarity,* the moral requirement that decisions be made at the most local level possible to promote the common good.
- The *common good*, those conditions such as health care, housing, and food, that each person and groups of persons need to live a full and productive life.
- *Public order*, the minimal structures needed to maintain a well-functioning society.
- *Safety*, the ability to move about and engage with others and in social life without fear of harm.
- *Ready access* to public services, so as to be able to receive health care and basic necessities such as food, shelter, clean water, with relative ease, or at least without bureaucratic obstacles.

These principles must explicitly inform ethical decision making, and do so in a dynamic interplay with other principles that reflect the other values.

Adherence to the Standards of One's Profession
This value, also referred to as " professionalism," although it truly denotes much more than "being a professional," refers to the importance of maintaining the competence, performance measures, and social contribution of groups, organizations, and professions upon which society depends. First responders and health care providers are obviously included in this category. But it also includes people whose work may be related more to a pandemic's indirect impact, such as sanitation engineers, who must maintain a level of professionalism if the overall effects of the pandemic are to be mitigated.

Professionalism is characterized by *adherence to evidence-/experience-based standards* that are, like the prognostic scales used in critical care,[7] sufficiently verifiable or accepted by the professional community to be used in life and death situations or for limiting access to critical services. *Competence*, entailing both knowledge and skill sets, also characterizes this sphere, as does *consensus-driven* rather than individual-based protocols and practices. *Consistency* is that characteristic that speaks to the ability to perform according to professional standards on a regular and ongoing basis, especially in times of stress. Finally, this value is characterized by the *ability to adapt* competencies, standards, and practices to challenges. This value is also referred to as "alternative standards," meaning adaptive responses that nevertheless reflect the other characteristics needed to better achieve the ends of social solidarity and the demands of justice. It is important not to confuse "alternative standards" with a utilitarian "whatever-it-takes" approach to achieving some desired outcome.*

> * This understanding, with its narrow focus on what is needed to perform professionally, is slightly but significantly different from that offered in Stand on Guard for Thee, which speaks of the requirement to "support" health care workers and their families. This broader understanding could be problematic in light of some literature that suggests only a slim majority of physicians see a professional duty to treat patients in epidemics. See G. C. Alexander and M. K. Wynia, "Ready and Willing? Physicians' Sense of Preparedness for Bioterrorism," Health Affairs, vol. 22, no.5, September-October 2003, pp. 189-197.

We suggest that the ethical principles most relevant in this sphere include:

- *Duty to act*, which refers to a person's obligation to fulfill his or her professional role without inducements.[8]
- *Transparency*, openness and accountability for how one performs his or her work.

- *Reciprocity*, the need to make available to the individuals and groups whose work supports the life of the community the things they need in order to perform those tasks, such as vaccinations for health care professionals as they seek to manage the risks inherent upon them in providing health care.†

- Integrity is important here, reflecting the need to act with honesty, reliability, and fairness, and a willingness to be held accountable to explain one's actions, especially when they depart from the consensus in one's field.

†Mayor Schmitz's "shoot to kill" order, intended to restore public order after the 1906 San Francisco earthquake, is an example of a "whatever-it-takes" attitude.

Justice

This value involves the fundamental commitment that individuals have toward one another, a commitment that makes social solidarity possible and drives professional decisions regarding the provision of services. Justice, as its biblical grounding in righteousness suggests, requires that we strive to ensure that "right relationships" exist between and among individuals and groups in society.

Justice is characterized by *equality*, with its avoidance of bias. To say people are equal, however, does not suggest that all have equal access or receive equal treatment. *Equity* is that characteristic of justice which understands access not as equal access by all groups but, rather, access by specific groups in light of a particular risk, disease or need in a particular situation.[9] With Rawls, we see the *difference principle* as a characteristic of justice.[10] This idea is similar to the Catholic social teaching related to a *preferential option for the poor* in that both concepts characterize justice as allowing society to show some preference to its most vulnerable members. In a strict sense, preference may be seen as related to the role a person plays, not to the person himself or herself, or even to the position that person holds.

Justice is also characterized by *liberty*, the individual and civil freedoms that are inherent in human dignity and necessary to the pursuit of the goods of social solidarity and professionalism. These are balanced by *due process*, in the event it becomes necessary, in light of social solidarity or professionalism, to impose limits on liberty.

Finally, justice is characterized by *proportionality*. Proportionality is what makes the "right" possible in "right relationships," in that it speaks of the due relationship between tensions that can arise between the liberty of the individual, the needs of society, and the standards of a profession. Proportionality is the measure, for example, that ensures the justice of either closing a school during a pandemic or keeping it open, as we balance the need of children in general to associate, the need of poor children in particular to have access to school for the lunch it provides them, and the community's epidemiological need to contain an infectious pathogen.

In the context of a pandemic, the ethical principles most relevant to justice are:

- *Autonomy*, with its respect for the individual and his or her claims and aspirations.
- *Confidentiality* and the protection of individual privacy.
- *Disclosure* and *truth-telling*, which ensure access to complete, accurate, and timely information, along with the related principle of *informed consent/refusal*.
- *Beneficence* and its obligation to provide for the good of others (not just in health care).
- *Nonmaleficence* and its prima facie but not absolute duty to protect oneself from harm, whether inflicted by another or by oneself.
- *Stewardship*, the right use of resources, which itself is a measure of proportionality in a given situation, is an ethical principle related to justice as well.

Decision Making and the Matrix

The Oregon MAG's goal was to articulate a firm ethical underpinning for its emergency preparedness plan. We wanted, first, to explicitly acknowledge the ethical significance of the pandemic context and, second, to provide a dynamic and robust matrix that could be applied in real time and in a way that offered consistency and accountability in the honesty, reliability, and fairness with which decisions are made.

In ways and in degrees that make it different from other crises, a pandemic places the values of social solidarity, adherence to professional standards, and justice at great risk. Each of these values has characteristics that help one understand what is at risk, as well as ethical principles that help one account for these values in difficult decisions.

The matrix described in this article is meant to capture those dynamics. The members of Oregon's MAG believe that if the decisions made during a pandemic are made according to our matrix, the decision makers will be able to say in the midst of tragic loss of life and the catastrophic loss of social, political, and economic opportunity that they acted justly, with professional competence, and preserved social solidarity.

NOTES

- See K. Morin, D. Higginson, and M. Goldrich, "Physician Obligation in Disaster Preparedness and Response," *Cambridge Quarterly of Healthcare Ethics*, vol. 15, no. 4, Fall 2006, pp. 417-421; in the same issue, see R. Rhodes, "Commentary: The Professional Obligation of Physicians in Times of Hazard and Need," pp. 424-428; and A. B. Zwi, P. M. McNeill, and N. J. Grove, "Commentary: Responding More Broadly and Ethically," pp 428-431. See also C. Ruderman, et al., "On Pandemics and the Duty to Care: Whose duty? Who cares?" *British Medical Ethics*, vol. 7, no. E5, April 20, 2006 (www.biomedcentral.com/1472-6939/7/5).
- University of Toronto Joint Centre for Bioethics Pandemic Influenza Working Group, *Stand on Guard for Thee: Ethical Considerations in Preparedness Planning for Pandemic Influenza*, Toronto, Ontario, Canada, 2005.
- The six principles include: "Contain and limit serious harm to Minnesota's public health," and "Reduce significant difference in influenza-related mortality." See "Allocating Pandemic Influenza Vaccines in Minnesota: Recommendations

of the Pandemic Influenza Ethics Work Group," Minnesota Center for Health Care Ethics, Minneapolis, Minn., September 2006.

- Margaret Riggs Allee, "Ethical Considerations in the Allocation of Scarce Resources," *Transplant Trends*, vol. 6, no. 5, 2004, pp. 82-83.
- E. Brainerd and M.V. Siegler, "The Economic Effects of the 1918 Influenza Epidemic," Centre for Economic Policy Research Discussion Papers, Centre for Economic Policy Research, London, England, February 2002 (www.cepr.org/pubs/dps/DP3791.asp).
- See www.who.int.
- See F. L. Ferreira, et al., "Serial Evaluation of the SOFA Score to Predict Outcome in Critically Ill Patients," *JAMA*, vol. 286, no. 14, October 10, 2001, pp. 1,754-1,758.
- M. I. Meltzer, N. J. Cox, and K. Fukuda, "The Economic Impact of Pandemic Influenza in the United States: Priorities for Intervention," *Emerging Infectious Diseases*, vol. 5, no. 5, September-October 1999, pp. 659-671.
- See President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Screening and Counseling for Genetic Conditions*, Washington, DC, 1983, especially p. 84.
- John Rawls, *A Theory of Justice*, Harvard University Press, Cambridge, Mass., 1971.

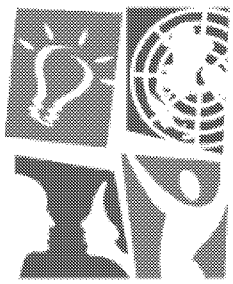
Appendix B - 2

Stand On Guard For Thee

STAND ON GUARD FOR THEE

Ethical considerations in preparedness planning for pandemic influenza

November 2005



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University of Toronto Joint Centre for Bioethics
Pandemic Influenza Working Group

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Key Points

- Plans to deal with an influenza pandemic need to be founded on widely held ethical values, so that people understand in advance the kinds of choices that will have to be made. Decision makers and the public need to be engaged in the discussions about ethical choices, so plans reflect what most people will accept as fair, and good for public health.

- The Pandemic Influenza Working Group at the University of Toronto Joint Centre for Bioethics (JCB) has developed a 15-point ethical guide for planning and decision-making for a pandemic.

- The JCB Working Group has identified four key ethical issues that need to be addressed in pandemic planning, and made specific recommendations for each. The four major issues are:
    1. health workers' duty to provide care during a communicable disease outbreak;
    2. restricting liberty in the interest of public health by measures such as quarantine;
    3. priority setting, including the allocation of scarce resources such as vaccines and antiviral medicines; and
    4. global governance implications, such as travel advisories.

- The JCB Working Group recommends that all pandemic plans have an ethical component, and offers the ethical guide contained in this paper for use in

developing such a component.

A. INTRODUCTION

When an influenza pandemic strikes the world many people, ranging from government and medical leaders to health care workers, will face a host of difficult decisions that will affect people's freedoms and their chances of survival. There will be choices about the level of risk health care workers should face while caring for the sick, the imposition of restrictive measures such as quarantines, the allocation of limited resources such as medicines, and the use of travel restrictions and other measures to contain the spread of disease.

Governments and health care leaders have been working on pandemic plans in many parts of the world. However, most of their communication to the public has focussed on technical issues, such how to obtain, stockpile and distribute medicines, and the assignment of duties.

Planners have not generally communicated the ethical underpinnings of their choices in a clear manner. But ethical issues have surfaced in public debates, often in the news media. Should people purchase their own stockpiles of antiviral drugs such as Tamiflu, or should they accept governments' decisions on how to allocate such medications? When medications are distributed, should children come before or after health care and emergency services workers, or decision makers such politicians?

Government and health care leaders need to make the values behind their decisions public. They should discuss the values with people who could be affected, ranging from health care workers, who will find themselves on the front lines, to government officials, who are making decisions about the allocation of limited resources, to the public at large, because people will be affected in many ways. They need to do this in advance of a health crisis, not when people are lining up at emergency ward doors.

Openly discussing the choices and confirming that they are based on ethical values that are shared by members of a society brings important benefits. If ethics are clearly built into pandemic plans in an open and transparent manner, and with buy-in from multiple sectors of society, the plans carry greater trust, authority and legitimacy. Advance discussions of such issues can help to address fears of the unknown. People will be more likely to cooperate, and accept difficult decisions made by their leaders for the common good. It is a goal of this paper to provide guidance and to spur a broad public discussion of the often difficult ethical issues underlying decisions.

This fall the World Health Organization (WHO) issued a checklist for influenza pandemic preparedness planning, calling on planners to deal with ethical issues, and to use an ethical framework. The WHO said a framework might deal with such issues as quarantines, the allocation of scarce resources and compulsory vaccinations. The Province of Ontario in Canada built a significant ethics

component into its *Ontario Health Plan for an Influenza Pandemic* of June 2005. The Toronto Academic Health Science Network, made up of all the teaching hospitals in Toronto, is working on a collaborative pandemic plan that will include references to using an ethical framework. Although the JCB Working Group is aware of ethics sections in other plans, we are unaware of any that address the ethical issues in a clear and comprehensive fashion and that articulate the underlying principles and values.

The need for a clearly understood and widely accepted ethics approach to dealing with serious communicable disease outbreaks was underscored during the outbreak of Severe Acute Respiratory Syndrome (SARS) in early 2003. SARS showed the universal vulnerability of humans to communicable diseases, and the need for coordinated and cooperative responses across national borders. It also found that health care systems had generally not prepared themselves to deal with the hard ethical choices that rapidly arose.

Immediately after that outbreak, the JCB produced the report *Ethics and SARS: Learning Lessons from the Toronto Experience*. Since then the JCB has conducted much more detailed research, which is summarized in this paper, and will be published in more detail in separate papers.

Research found that as the SARS crisis became more severe, and restrictions were imposed, there were concerns over access to care and the allocation of medicines, access to safety equipment, who had to work and under what protections, and the sharing of vital information. People started raising the issues of whose values should prevail during a public health emergency.

Leaders in governments and health care systems had not previously developed an ethical framework or held prior consultations on to deal with the suite of ethical issues forced on them by SARS. Decision makers had to balance individual freedoms against the common good, fear for personal safety against the duty to treat the sick, and economic losses against the need to contain the spread of a deadly disease. Decisions had to be rapid, and were as transparent as possible given the limitations of the time. Therefore the lesson learned is to establish the ethical framework in advance, and to do it in a transparent manner.

One major finding of the JCB research was that people are more likely to accept such decisions if the decision-making processes are reasonable, open and transparent, inclusive, responsive and accountable, and if reciprocal obligations are respected. Although these principles can sometimes be difficult to implement during a crisis, SARS showed there are costs from not having an agreed-upon ethical framework, including loss of trust, low morale, fear and misinformation. SARS taught the world that if ethical frameworks had been more widely used to guide decision-making, this would have increased trust and solidarity within and between health care organizations.

SARS gave the world an advance warning of the need for ethical frameworks for decision-making during other communicable disease outbreaks, such as a flu pandemic. JCB research has identified critical issues and ethical principles that can be applied to pandemic planning. The Working Group recommends using these principles to develop a preventive ethics approach. This will have many benefits, including the reduction of conflicts during a crisis.

While much of the research was done in Canada, the lessons are generally applicable around the world. They should be part of the democratic process of making decisions that affect a society.

Following is a comprehensive ethical guide for planning for and dealing with major communicable disease outbreaks, such as pandemic influenza. The guide was developed with expertise from clinical, organizational and public health ethics, and validated through a stakeholder engagement process. It includes both substantive and procedural elements for ethical pandemic influenza planning. This can form the basis for applying the framework that the WHO has recommended. It can be a key planning tool for pandemic readiness.

Next comes a section exploring four key ethical issues that will arise during a flu pandemic. Drawing from the ethical framework, the group identified the applicable key ethical values for each issue, and provides recommendations for dealing with each. The recommendations are particularly addressed to governments and decision-making bodies, mainly in the health care sector, around the world. The key issues are:

1. health workers' duty to provide care during a communicable disease outbreak;

2. restricting liberty in the interest of public health by measures such as quarantine;

3. priority setting, including the allocation of scarce resources, such as vaccines and antiviral medicines; and

4. global governance implications, such as travel advisories.

These may not be the only ethical issues that the world will face in an influenza pandemic, but they are critically important issues that the Working Group has identified. Planners and decision-makers need to be vigilant for other ethical challenges that will need to be managed.

B. AN ETHICAL GUIDE FOR PANDEMIC PLANNING

Based on the SARS experience, the JCB Working Group has assembled an ethical guide for planning and decision-making that can be used both in advance of and during an influenza pandemic. This guide is composed of 15 ethical values, of which 10 are substantive values and five are procedural values. They should be seen as a package of interdependent values that are important in any democratic society.

B1. Ten substantive values to guide ethical decision-making for a pandemic influenza outbreak

Substantive value	Description
Individual liberty	In a public health crisis, restrictions to individual liberty may be necessary to protect the public from serious harm. Restrictions to individual liberty should: • be proportional, necessary, and relevant; • employ the least restrictive means; and • be applied equitably.
Protection of the public from harm	To protect the public from harm, health care organizations and public health authorities may be required to take actions that impinge on individual liberty. Decision makers should: • weigh the imperative for compliance; • provide reasons for public health measures to encourage compliance; and • establish mechanisms to review decisions.
Proportionality	Proportionality requires that restrictions to individual liberty and measures taken to protect the public from harm should not exceed what is necessary to address the actual level of risk to or critical needs of the community.
Privacy	Individuals have a right to privacy in health care. In a public health crisis, it may be necessary to override this right to protect the public from serious harm.
Duty to provide	Inherent to all codes of ethics for health care professionals is the duty to provide care and to respond to suffering. Health care

care	providers will have to weigh demands of their professional roles against other competing obligations to their own health, and to family and friends. Moreover, health care workers will face significant challenges related to resource allocation, scope of practice, professional liability, and workplace conditions.
Reciprocity	Reciprocity requires that society support those who face a disproportionate burden in protecting the public good, and take steps to minimize burdens as much as possible. Measures to protect the public good are likely to impose a disproportionate burden on health care workers, patients, and their families.
Equity	All patients have an equal claim to receive the health care they need under normal conditions. During a pandemic, difficult decisions will need to be made about which health services to maintain and which to defer. Depending on the severity of the health crisis, this could curtail not only elective surgeries, but could also limit the provision of emergency or necessary services.
Trust	Trust is an essential component of the relationships among clinicians and patients, staff and their organizations, the public and health care providers or organizations, and among organizations within a health system. Decision makers will be confronted with the challenge of maintaining stakeholder trust while simultaneously implementing various control measures during an evolving health crisis. Trust is enhanced by upholding such process values as transparency.
Solidarity	As the world learned from SARS, a pandemic influenza outbreak, will require a new vision of global solidarity and a vision of solidarity among nations. A pandemic can challenge conventional ideas of national sovereignty, security or territoriality. It also requires solidarity within and among health care institutions. It calls for collaborative approaches that set aside traditional values of self-interest or territoriality among health care professionals, services, or institutions.
Stewardship	Those entrusted with governance roles should be guided by the notion of stewardship. Inherent in stewardship are the notions of trust, ethical behaviour, and good decision-making. This implies that decisions regarding resources are intended to achieve the best patient health and public health outcomes given the unique circumstances of the influenza crisis.

B2. Five procedural values to guide ethical decision-making for a pandemic influenza outbreak

Procedural value	Description
Reasonable	Decisions should be based on reasons (i.e., evidence, principles, and values) that stakeholders can agree are relevant to meeting health needs in a pandemic influenza crisis. The decisions should be made by people who are credible and accountable.
Open and transparent	The process by which decisions are made must be open to scrutiny, and the basis upon which decisions are made should be publicly accessible.
Inclusive	Decisions should be made explicitly with stakeholder views in mind, and there should be opportunities to engage stakeholders in the decision-making process.
Responsive	There should be opportunities to revisit and revise decisions as new information emerges throughout the crisis. There should be mechanisms to address disputes and complaints.
Accountable	There should be mechanisms in place to ensure that decision makers are answerable for their actions and inactions. Defence of actions and inactions should be grounded in the 14 other ethical values proposed above.

Recommendations

1. National, provincial/state/territorial, and municipal governments, as well as the health care sector, should ensure that their pandemic plans include an ethical component.

2. National, provincial/state/territorial, and municipal governments, as well as the health care sector, should consider incorporating both substantive and procedural values in the ethical component of their pandemic plans.

C. FOUR KEY ETHICAL ISSUES

As a result of analyses of the SARS crisis, the JCB Working Group identified four key ethical issues that are expected to be very important during a pandemic flu outbreak. Below, each of these issues is described in turn to illustrate how this ethical guide can be used. Specific recommendations are included for each issue.

C1. Health workers' duty to provide care during a communicable disease outbreak

During SARS, some medical workers were afraid that they would be infected while caring for SARS patients, and that they would infect their families, friends and co-workers. The workers were torn between these fears and a sense of duty to their patients and solidarity with fellow workers. A flu pandemic will mean virtually all health care workers will face such difficult choices.

Overview

The duty to care for the sick is a primary ethical obligation for health care workers for a number of reasons, including:

1. the ability of physicians and health care workers to provide care is greater than that of the public, thus increasing their obligation to provide care.

2. by freely choosing a profession devoted to care for the ill, they assume risks.

3. the profession has a social contract that calls on members to be available in times of emergency. (In addition, they largely work in publicly supported systems in many countries.)

When SARS broke out, health care workers in a number of countries were on the firing line, and had to make decisions for which they were not always prepared. They faced an unknown and deadly communicable disease, a coronavirus for which there was no known effective treatment. They were rapidly forced to weigh serious and imminent health risks to themselves and their families against their duty to care for the sick. A significant number of health care workers were infected with SARS because of their work, and some died. Many workers were placed under work quarantine.

Workers generally showed heroism and altruism in the face of danger during the SARS outbreak, but some balked at caring for people infected with SARS, and a few were dismissed for failing to report for duty. Post-SARS, many health care workers raised concerns about the level of protection to themselves and their families. Some even left the profession.

A flu pandemic would put far greater pressures on health care systems around the world. Faced with a very serious disease for which there may be no absolute protection or cure, health care workers will find themselves facing overwhelming demands. They will be forced to weigh their duty to provide care against competing obligations, such as their duty to protect their own health and that of families and friends. Initially the primary care and emergency services workers will take the full brunt of responding to the flu, and therefore bear a disproportionate risk compared to more specialized care providers. There will likely be pressure on other health care providers to come to the front lines.

Some believe that under dire circumstances, professionals should have minimal self-regard and pursue their duties at potential cost to their own lives. By analogy, firefighters do not have the freedom to choose whether or not they have to face a particularly bad fire, and police do not get to select which dark alleys they walk down. Others claim that it is unreasonable to demand extreme heroism from health care workers as the norm, and even more unreasonable to demand that workers put the lives of their families at high risk or make themselves unavailable to care for them should they become ill.

At times like this, health care workers' ethical codes should provide important guidance on such issues as professional rights and responsibilities. It is important for health care professionals, from doctors to nurses to hospital and ambulance staff, to articulate codes or statements of ethical conduct in high-risk situations, so that everyone knows what to expect during times of communicable disease crises. These codes or statements should cover such issues as:

- how much risk should health care workers be required to take;
- their duty to care for the sick, and to care for themselves so they can continue to provide care; and
- their duty not to harm others by transmitting diseases.

There is currently a vacuum in this field. For example, the 2004 Canadian Medical Association (CMA) revised *Code of Ethics*, released a year after SARS, provides no clear guidance on the key ethical issues raised by communicable disease outbreaks, including the duty to care. The JCB Working Group has looked at a number of medical codes of ethics in other countries and found a similar lack of specific guidance on these issues.

In the past, particularly after the 1919 influenza pandemic, such issues were explicitly addressed by some codes. For example, the 1922 *CMA Code of Ethics* said: "When pestilence prevails, it is their (physicians') duty to face the danger, and to continue their labours for the alleviation of suffering, even at the jeopardy of their own lives." The American Medical Association used similar language in its code of ethics from 1846 until the 1950s. The disappearance of this stringent demand from medical codes of ethics is unexplained, perhaps related to belief in recent decades that dangerous communicable diseases had been vanquished. The resurgence of communicable diseases for which there are no ready defences raises the need for clarity from the professions.

While much of the discussion post SARS has been about the duties of health care workers, there are other important ethical issues that need to be addressed, including reciprocity and solidarity. If workers are to take high risks, there is a duty upon society, in particular on their institutions, to support them. The institutions need to plan to help workers cope with the high stress of a pandemic, to acknowledge that their work is dangerous. For example, they need to provide for the health and safety of workers, and for the care of those who fall ill on duty. This might include an insurance fund for life and disability to cover health care workers who become sick or die as they place themselves in harm's way. Also, there is a need for fair and workable human resource plans for emergency situations. Limitations imposed during SARS resulted in a loss of work for some health care workers. The imposition of employment restrictions should not result in financial hardship or job loss and should not unduly affect part-time staff.

The risk to care providers is not only physical, but also psychological. Senior decision makers and physicians will have to make many hard choices about care and the assignment of staff. They need to feel that they have the support of the highest levels of administration, including boards of directors.

Just after the SARS crisis, a JCB paper recommended a review of professional codes to help clarify professional duties and define the acceptable extent of professional obligation. That paper recommended that health care institutions develop ethical frameworks in collaboration with their workforce, establish explicit work expectations in times of communicable disease, and make them available to their staffs.

Ethical values and processes

Based on the guide of substantive values and process for ethical decision-making, the substantive values most applicable to this issue are: duty to provide care, reciprocity, trust, and solidarity.

All five procedural values apply: reasonable, open and transparent, inclusive, responsive, and accountable.

Recommendations

1. Professional colleges and associations should provide, by way of their codes of ethics, clear guidance to members in advance of a major communicable disease outbreak, such as pandemic flu. Existing mechanisms should be identified, or means should be developed, to inform college members as to expectations and obligations regarding the duty to provide care during a communicable disease outbreak.

2. Governments and the health care sector should ensure that:

    a. care providers' safety is protected at all times, and providers are able to discharge duties and receive sufficient support throughout a period of extraordinary demands; and

    b. disability insurance and death benefits are available to staff and their families adversely affected while performing their duties.

3. Governments and the health care sector should develop human resource strategies for communicable disease outbreaks that cover the diverse occupational roles, that are transparent in how individuals are assigned to roles in the management of an outbreak, and that are equitable with respect to the distribution of risk among individuals and occupational categories.

C2. Restricting liberty in the interest of public health by measures such as quarantine

During the SARS outbreak, a number of people, including health care staff, were ordered to remain at home to prevent spreading the disease. People faced the loss of income and possibly their jobs. The number of people affected could be far higher during a global flu pandemic, and people subject to restrictive measures will need to have their basic needs met, including some protection for their income and jobs.

Overview

Until a new flu vaccine is developed or other medications are found to control pandemic flu, restrictive measures may be one of the important public health tools to reduce spread of this communicable disease. Governments may need to limit three basic personal freedoms that we take from granted: mobility, freedom of assembly and privacy. They may close schools, cancel public gatherings and

sporting events, and impose quarantine, isolation and even detention, where needed.

During SARS, a significant number of people were placed in quarantine to control the spread of this disease, making it one of the largest quarantines in modern times. A major flu pandemic could result in very large numbers being subjected to such measures. These restrictions impose a heavy burden on those affected. People may be cut off from family, friends, work, shopping, entertainment, travel, and most other activities, including some forms of medical care. People may feel stigmatized if they are put into quarantine or identified as being affected by pandemic flu.

JCB research in the aftermath of SARS showed that people understood and accepted the need for restrictive measures for the control of communicable diseases. Most saw it as a form of civic duty, and were willing to make a sacrifice. However, our data also indicate that if decision makers expect full compliance with restrictive measures, the decisions need to be made in a fair manner, and people affected by such measures need support. Reciprocity requires society in turn to ensure that those affected receive adequate care, and do not suffer unfair economic penalties. If leaders expect people exposed to or suffering from communicable diseases to act in a manner that does not put others at risk, it is important that they create a social environment that does not leave people without supports.

For example, if quarantine is implemented, governments should ensure that people have adequate food supplies and are able to carry out essential functions. Their jobs should be protected, and they should not suffer an undue financial burden. Volunteer organizations will have a vital role to play, but since they are voluntary, they do not have the same ethical obligations as governments.

There will be related issues, including the privacy of personal information and the public needs to know about high risks of disease. In SARS, the outbreak in Canada was linked to a traveller from China, leading to some people boycotting Chinese businesses elsewhere.

The state has the right to override an individual's right to privacy in cases of serious public health risks if revealing private medical information helps to protect public health. Governments also have an obligation to reduce stigmatization by respecting the value of privacy as much as possible, and by providing accurate information, and only the information that will give the public a realistic view of such key public health issues as the spreading of disease.

The world could face the possibility of other measures that could be used to contain the disease, including mandatory vaccination, surveillance cameras, monitoring devices, and even imprisonment for people who failed to comply with quarantine orders.

Restrictive measures are a reminder of the legitimate limits to our highly prized individual liberties. When making such decisions, leaders will need to balance individual freedoms against the common good of society, fear for personal safety against the duty to treat the sick, and economic losses against the need to contain the spread of a deadly disease. Authorities exercising public health powers should do so in a way that is relevant, legitimate, legal, proportional, and necessary. They should use the least restrictive methods that are reasonably available to limit individual liberties, and should apply restrictions without discrimination. People need to be fully informed about issues, including risks and benefits of public health measures.

Decision makers need to turn for guidance to documents such as charters of rights and freedoms and human rights legislation. They can look to the United Nations' Siracusa Principles, which are based upon human rights documents. The principles stipulate the extent to which state powers should be exercised in times of public health emergencies. The principles hold that public health may be invoked as grounds for limiting certain rights in order to manage a serious threat to the health of individuals or a population. These measures must be specifically aimed at preventing disease or injury, or providing care for the sick and injured. The actions taken must be legal, necessary, and proportional to the threat.

In November 2005, the American Medical Association issued guidelines for protecting patient rights if they have to be quarantined during an epidemic. An AMA spokesperson said: "…Physicians must do everything they can to protect the rights and privacy of patients without compromising the health of the public."

Ethical values and processes

Based on our guide of substantive values and process for ethical decision-making, the substantive values most applicable to this issue are: liberty, protection of public from harm, proportionality, privacy, and reciprocity.

All five procedural values apply: reasonable, open and transparent, inclusive, responsive, and accountable.

Recommendations

1. Governments and the health care sector should ensure that pandemic influenza response plans include a comprehensive and transparent protocol for the implementation of restrictive measures. The protocol should be founded upon the principles of proportionality and least restrictive means, should balance individual liberties with protection of public from harm, and should build in safeguards such as the right of appeal.

2. Governments and the health care sector should ensure that the public is aware of:

    a. the rationale for restrictive measures;
    b. the benefits of compliance; and
    c. the consequences of non-compliance.

3. Governments and the health care sector should include measures in their pandemic influenza preparedness plans to protect against stigmatization and to safeguard the privacy of individuals and/or communities affected by quarantine or other restrictive measures.

4. Governments and the health care sector should institute measures and processes to guarantee provisions and support services to individuals and/or communities affected by restrictive measures, such as quarantine orders, implemented during a pandemic influenza emergency. Plans should state in advance what backup support will be available to help those who are quarantined (e.g., who will do their shopping, pay the bills, and provide financial support in lieu of lost income). Governments should have public discussions of appropriate levels of compensation in advance, including who is responsible for compensation.

C3. Priority setting, including the allocation of scarce resources, such as vaccines and antiviral medicines

One of the side effects of SARS was that people scheduled for important treatments, such as cancer surgery, had their care postponed. A number of hospital beds, staff and equipment were redirected to the public health emergency. These kinds of decisions will be even more prevalent during a flu pandemic.

Overview

If the flu pandemic is as severe as some fear, there will be an extraordinarily high number of sick people around the world, all requiring care at the same time. This will be on top of the "normal" health care needs, which strain medical systems at the best of times. During a pandemic, the human and material resources of health care will be rapidly overwhelmed. There will be scarcities of medicines, equipment and health care workers in all countries, with less-developed nations facing some of the greatest scarcities. There will be cases of people who will have to forego medical care for other ailments, such as cancer and heart disease.

Decision makers will seek to maximize benefits for society while balancing obligations to individuals and individual needs. They will have to decide who gets access to vaccines, antiviral drugs, such as Tamiflu, ventilators, and other forms of care. They will use priority-setting processes, also known as rationing or resource allocation. This means that current societal expectations about access to health care will have to change in light of a public health crisis of major proportions.

Already there are signs of a public debate over choices. Some jurisdictions are stockpiling Tamiflu rather than allowing unlimited private sales. Most pandemic plans give priority for the use of antivirals and vaccines to health care workers and people in emergency services. Some plans state that once a vaccine is developed, children would be among the last to be immunized. This is based on experience with flu in the past, showing that after age 2, children are most likely to survive the virus. While these choices are justifiable, it would help to build public support by discussing them in a public manner.

People expect decisions to be reasonable, open and transparent, inclusive, responsive, and accountable. In the midst of a pandemic, when guidance will be incomplete, consequences uncertain, and information constantly changing, and where hour-by-hour decisions involve life and death, fairness is crucial. Experience shows that there is often disagreement on what principles should be used to make fair allocation decisions. This means that decision makers may have also to rely on a fair process to establish the legitimacy of priority setting decisions.

There is still time for many decisions to be made in consultation with stakeholders and the public. Although the organizational leaders would ultimately be accountable for making the priority setting decisions, a broader range of stakeholders should be engaged particularly as key informants through expert and broader stakeholder consultation. The stakeholders can range from employees and patient groups to institutional partners, community groups, and government officials.

People need to know in advance what to expect. An effective communications strategy should be developed to ensure a transparent priority setting process. The purpose of the communication strategy should be to ensure that stakeholders know and understand the scope and necessity of priority setting decision-making, the degrees of freedom within which priority setting would take place and the roles of various people. In addition, the rationales for priority setting decisions should be communicated to stakeholders, and should clearly demonstrate how these decisions are defensible in light of the priority setting criteria and available data and information.

Among the benefits of open communications about priority-setting:

- stakeholders feel engaged and understand the decision-making process;

- priorities can be justified and seen to be reasonable; and
- the process is perceived to be fair.

Ethical values and processes

Based on our guide of substantive values and process for ethical decision-making, the substantive values most applicable to this issue are: equity, trust, solidarity, and stewardship.

All five procedural values apply: reasonable, open and transparent, inclusive, responsive, and accountable.

Recommendations

1. Governments and the health care sector should publicize a clear rationale for giving priority access to health care services, including antivirals and vaccines, to particular groups, such as front line health workers and those in emergency services. The decision makers should initiate and facilitate constructive public discussion about these choices.

2. Governments and the health care sector should engage stakeholders (including staff, the public, and other partners) in determining what criteria should be used to make resource allocation decisions (e.g., access to ventilators during the crisis, and access to health services for other illnesses), should ensure that clear rationales for allocation decisions are publicly accessible and should provide a justification for any deviation from the pre-determined criteria.

3. Governments and the health care sector should ensure that there are formal mechanisms in place for stakeholders to bring forward new information, to appeal or raise concerns about particular allocation decisions, and to resolve disputes.

C4. Global governance implications, such as travel advisories

In rural China, a farmer developed a chest infection, and then family travels began a chain of events that would take the SARS virus to the other side of the world. In Geneva, officials of the World Health Organization (WHO) weighed the risk of the spread of SARS, and issued travel warnings that would affect a number of countries, sometimes causing severe economic impacts.

The current avian flu virus is moving across vast distances, carried by wild birds.

If this virus mutates to become transmissible among humans, the WHO has warned that it could reach all continents in less than three months. The WHO will have to carefully consider when it will institute travel measures to protect the global community from spread of the disease.

Overview

The SARS outbreak showed our global interdependence, and the increasing risk to global human security from the emergence and rapid spread of communicable diseases. It showed the need for global solidarity, involving highly coordinated public health responses that involve the cooperation of local, regional, national, and supra-national governments.

One way that governments and the WHO seek to control the spread of communicable diseases is through restrictions on travel. Especially during the early stages of what looks like a pandemic, travel advisories can help to slow the spread of the virus. These restrictions can impose severe penalties not only on individuals, but also on entire regions. The ethical challenges of global public health decision-making are well illustrated by the issuance of travel advisories.

During the 2003 SARS crisis, the WHO advised international travelers against all non-essential travel to a number of regions, including parts of China, including Hong Kong, as well as Taiwan and Toronto. There were many side effects of those public health decisions. The reduction in travel and tourism cost Canada, particularly Toronto and the province of Ontario, many millions of dollars in economic losses.

Analysis of the SARS case showed that federal states, where powers are shared among national and provincial or state governments, can face problems in organizing themselves to respond to public health crises. During SARS, the Canadian federal government's ability to obtain data from the Province of Ontario was dependent on voluntary transfer since the management of communicable disease outbreaks falls under provincial jurisdiction. Problems with communication among governments may have led to a delay in providing information on SARS to the WHO. This in turn could have undermined the WHO's confidence in the Canadian response, which perhaps contributed to the imposition of the travel advisory on Toronto.

While it was the duty of the WHO to do everything it could to prevent the spread of SARS to other countries, and in particular developing countries that have limited resources to combat the spread of the disease, it had to do so in a manner that was respectful of national sovereignty. Conversely, nations such as Canada had a responsibility as members of the global community to cooperate fully in the international pandemic response.

The Working Group's examination of global governance has centered on the issue of travel advisories as well as national and international responsibilities related to pandemic response. In particular, any decision by the WHO that can infringe upon the sovereignty of a nation needs to be clearly justified and the process must be transparent. There were concerns about the issuance of travel advisories during SARS. These issues have been addressed in the revised International Health Regulations (IHR), which have formalized the process by which the WHO can take such measures. The WHO must carefully consider how and when it issues travel recommendations. The issuing of recommendations that are perceived by nations to be inappropriate could lead to their lack of confidence in the WHO's leadership, and also undermine their support for the IHR. Conversely, the failure of the WHO to institute travel advisories in a timely manner, perhaps due to political pressure, could lead to the otherwise preventable spread of the pandemic.

Individual countries have a responsibility to the international community to communicate information on the emergency of public health threats. The revised international health regulations have outlined these responsibilities primarily as they relate to surveillance. However, countries with federal systems of government may not be able to comply with these responsibilities due to the allocation of powers within the country. This is potentially true for such countries as Canada, the United States, and Australia. Ultimately, it is the responsibility of these countries to utilize whatever policy instruments the federal governments have available to ensure that they can comply with the requirements of the new IHR.

The surveillance responsibilities of individual countries may be beyond the capacity of many developing countries. These countries are being pressured to improve their existing surveillance infrastructure. However, doing so may divert resources from areas in which needs are much greater in order to achieve goals that are more in the interest of developed countries. Developed countries must be aware of this trade-off and take measures, most suitably in the form of increased investment, to ensure that enhanced surveillance does not occur at the expense of managing the multitude of ongoing public health threats many developing countries face.

To sum up, protecting global health requires governments around the world to show solidarity and to be open and transparent in the way they carry out health protection responsibilities.

Ethical values and processes

Based on our guide of substantive values and process for ethical decision-making, the substantive values most applicable to this issue are: protection of the public from harm, proportionality, trust, and solidarity.

All five procedural values apply: reasonable, open and transparent, inclusive, responsive, and accountable.

Recommendations

1. The World Health Organization should remain aware of the impact of travel recommendations on affected countries, and should make every effort to be as transparent and equitable as possible when issuing such recommendations.

2. Federal countries should utilize whatever mechanisms are available within their system of government to ensure that relationships within the country are adequate to ensure compliance with the new International Health Regulations.

3. The developed world should continue to invest in the surveillance capacity of developing countries, and should also make investments to further improve the overall public health infrastructure of developing countries.

C5. Other ethical issues

In addition to the four key ethical issues explored by the JCB Working Group, there may be other important issues that people feel should be discussed in advance of a pandemic. These might include, for example:

- research ethics during a public health emergency;
- the ethical treatment of animals, such as the culling of poultry flocks, during a public health emergency; and
- compensation for farmers put out of business and loss of food supply and income resulting from mass culls.

This paper should be seen as fostering a public debate and providing guidance on issues that have been carefully studied.

D. NEXT STEPS

The JCB Working Group strongly encourages all governments and health care systems around the world to assess their pandemic plan against the ethical framework and recommendations presented in this discussion paper.

Looking ahead, we can say that if the pandemic strikes it will cause great hardship, but societies will struggle through. They will be better able to do so if they have prepared in all possible ways, including having general agreement on an ethical approach. Afterwards, history will judge today's leaders on how well they prepared for and acted during the crisis and if they treated people in an ethical manner.

The Working Group looks forward to receiving comments on this discussion paper, and encourages an open dialogue on its key points and recommendations.

E. END MATERIALS

Consolidated list of recommendations:

An ethical guide for pandemic planning

1. National, provincial/state/territorial, and municipal governments, as well as the health care sector, should ensure that their pandemic plans include an ethical component.

2. National, provincial/state/territorial, and municipal governments, as well as the health care sector, should consider incorporating both substantive and procedural values in the ethical component of their pandemic plans.

Recommendations from Issue 1

Health workers' duty to provide care during a communicable disease outbreak

1. Professional colleges and associations should provide, by way of their codes of ethics, clear guidance to members in advance of a major communicable disease outbreak, such as pandemic flu. Existing mechanisms should be identified, or means should be developed, to inform college members as to expectations and obligations regarding the duty to provide care during a communicable disease outbreak.

2. Governments and the health care sector should ensure that:

    a. care providers' safety is protected at all times, and providers are able to discharge duties and receive sufficient support throughout a period of extraordinary demands; and

b. disability insurance and death benefits are available to staff and their families adversely affected while performing their duties.

3. Governments, hospitals and health regions should develop human resource strategies for communicable disease outbreaks that cover the diverse occupational roles, that are transparent in how individuals are assigned to roles in the management of an outbreak, and that are equitable with respect to the distribution of risk among individuals and occupational categories.

Recommendations from Issue 2

Restricting liberty in the interest of public health by measures such as quarantine

1. Governments and the health care sector should ensure that pandemic influenza response plans include a comprehensive and transparent protocol for the implementation of restrictive measures. The protocol should be founded upon the principles of proportionality and least restrictive means, should balance individual liberties with protection of public from harm and should build in safeguards such as the right of appeal.

2. Governments and the health care sector should ensure that the public is aware of:

    a. the rationale for restrictive measures;
    b. the benefits of compliance; and
    c. the consequences of non-compliance.

3. Governments and the health care sector should include measures in their pandemic influenza preparedness plans to protect against stigmatization and to safeguard the privacy of individuals and/or communities affected by quarantine or other restrictive measures.

4. Governments and the health care sector should institute measures and processes to guarantee provisions and support services to individuals and/or communities affected by restrictive measures, such as quarantine orders, implemented during a pandemic influenza emergency. Plans should state in advance what backup support will be available to help those who are quarantined (e.g., who will do their shopping, pay the bills and provide financial support in lieu of lost income). Governments should have public discussions of appropriate levels of compensation in advance, including who is responsible for compensation.

Recommendations from Issue 3

Priority setting, including the allocation of scarce resources, such as vaccines and antiviral medicines

1. Governments and the health care sector should publicize a clear rationale for giving priority access to health care services, including antivirals and vaccines, to particular groups, such as front line health workers and those in emergency services. The decision makers should initiate and facilitate constructive public discussion about these choices.

2. Governments and the health care sector should engage stakeholders (including staff, the public and partners) in determining what criteria should be used to make resource allocation decisions (e.g., access to ventilators during the crisis, and access to health services for other illnesses), should ensure that clear rationales for allocation decisions are publicly accessible and should provide a justification for any deviation from the pre-determined criteria.

3. Governments and the health care sector should ensure that there are formal mechanisms in place for stakeholders to bring forward new information, to appeal or raise concerns about particular allocation decisions and to resolve disputes.

Recommendations from Issue 4

Global governance implications, such as travel advisories

1. The World Health Organization should remain aware of the impact of travel recommendations on affected countries, and should make every effort to be as transparent and equitable as possible when issuing such recommendations.

2. Federal countries should utilize whatever mechanisms are available within their system of government to ensure that relationships within the country are adequate to ensure compliance with the new International Health Regulations.

3. The developed world should continue to invest in the surveillance capacity of developing countries, and should also make investments to further improve the overall public health infrastructure of developing countries.

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-END-

Appendix B - 3

Ethical Guidelines in Pandemic Influenza

ETHICAL GUIDELINES in PANDEMIC INFLUENZA

Prepared by

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Disclaimer: This document represents the recommendations of the Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention and does not necessarily represent Centers for Disease Control and Prevention policy. The document was reviewed and approved by the Advisory Committee to the Director on December 12, 2006 and approved for release by the Director of the Centers for Disease Control and Prevention, Dr. Julie Louise Gerberding, on February 15, 2007.

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ETHICAL GUIDELINES in PANDEMIC INFLUENZA

This document provides ethical guidance that the Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC) proposes as a foundation for decision making in preparing for and responding to pandemic influenza. The document was developed in response to a request from CDC that the Ethics Subcommittee address ethical considerations (1) in vaccine and anti-viral drug distribution prioritization and (2) in the development of interventions that would limit individual freedom and create social distancing[2] (in discourse on pandemic influenza, often referred to as non-pharmaceutical interventions). Although the issue of the duty of health care professionals to provide care during a pandemic was outside the scope of the request, the Ethics Subcommittee believes that this issue is of central importance in pandemic planning and response and should be addressed in a subsequent document. An equally relevant issue, but also beyond the scope of this document, is the importance of providing legal protections for health care providers who, during a declared public health emergency, may be asked to perform services outside of their usual realm of responsibilities or to administer interventions which are not yet scientifically validated. As with many other areas of community or public decision making, ethical issues are frequently encountered in the decision making process. And though difficult decisions are made on a regular basis, the process for decision making, including the framework and reasoning that support ethical choice, may not be clearly articulated. We are acutely aware of the need to have ethical perspectives provide practical assistance and to have these proposed guidelines fully vetted by those involved in the pandemic influenza planning and response process. We offer the following document with both commitments in mind and attempt to articulate the boundaries and underlying ethical premises that can serve as a marker against which to test implementation decisions. In utilizing these guidelines, decision makers at all levels – federal, local, state, tribal, etc. – should continue to exercise their best judgment in particular situations.

I. General Ethical Considerations

- **Identification of clear overall goals for pandemic planning** is essential to making difficult choices. Historically, the organizing principle for resource (antiviral and vaccine) distribution in inter-pandemic years has been the minimization of serious influenza-associated complications, including hospitalization and death. Individuals most at risk of experiencing the serious negative health consequences of hospitalization or death if infected are given priority in receiving influenza vaccinations. The recommendations of two federal advisory committees, the Advisory Committee on Immunization Practices (ACIP)

[2] Social distancing refers to methods for reducing frequency and closeness of contact between people in order to decrease the risk of transmission of disease. Examples of social distancing include cancellation of public events such as concerts, sports events, or movies, closure of office buildings, schools, and other public places, and restriction of access to public places such as shopping malls or other places where people gather.

and the National Vaccine Advisory Committee (NVAC) reflect this principle.[3]

However, in pandemic influenza management a second principle – that of preserving the functioning of society – should receive greater priority in decision making than preventing serious complications. Those individuals who are essential to the provision of health care, public safety and the functioning of key aspects of society should receive priority in the distribution of vaccine, antivirals and other scarce resources. Engagement of diverse stakeholders will be essential in affirming this priority, determining who is considered key to the functioning of society, and establishing a distribution strategy that allows for decisions to be made when resources are limited. In any prioritization proposal, it must be clearly acknowledged that maintaining the functioning of society may result in a lack of resource availability to those at high risk of severe medical complications due to pre-existing medical conditions or advanced age.

Affirming this second principle (preserving the functioning of society) raises important conceptual questions about who is valued and how particular services and functions are determined to be "key." These questions are set in important historical and social contexts involving individuals' ability to attain "essential" positions given societal barriers and obstacles. Discussion of these questions, while very important in ordinary times, takes on a lower priority when confronted with the urgent demands of preserving society.

- There is a **commitment to transparency** throughout the pandemic influenza planning and response process. The reasoning behind choices made is fully articulated (in language appropriate to particular audiences) and the values and principles justifying those decisions are clearly identified and open for examination. This commitment to clarity and openness, which is based on a deep respect for all individuals and communities involved, exists in balance with the understanding that those with the authority and responsibility of making decisions must often make decisions in a timely manner.

- **Public engagement and involvement** are essential to build public will and trust and should be evidenced throughout the planning and response process. The public is seen as a partner with other experts, with particular attention to vulnerable or historically marginalized members of society. Clear mechanisms must be created for public involvement in planning and for feedback throughout the process.

- Public health officials have **a responsibility to maximize preparedness** in order to minimize the need to make allocation decisions later. (Examples of maximizing preparedness include shortening the time for virus recognition or

[3] The NVAC/ACIP recommendations for prioritization of pandemic influenza vaccine are described in the HHS Pandemic Influenza Plan available at http://www.hhs.gov/pandemicflu/plan/appendixd.html. Vaccine and antiviral manufacturers, medical and public health workers, and persons at highest risk of influenza complication are identified as priority groups for receipt of pandemic influenza vaccine.

vaccine production, increasing the capacity to produce vaccines or antivirals and increasing the supplies of antivirals.) Proactive planning of response strategies for a pandemic, including the training of staff, is required. This necessarily entails consideration of the full context in which choices are made. Enhancing the available range of prophylaxis and treatment options should decrease the need to focus on scarcity of resources and allocation during a pandemic. Preparedness also includes determining and articulating what rules will govern public health decision making in advance of the time that decision making must commence. Though every specific choice or contingency cannot be foreseen, comprehensible foundational guidelines and procedural action plans provide coherence and direction and build trust.

- **Sound guidelines should be based on the best available scientific evidence**. There is no need to establish rules for the equitable distribution of goods that will not work or to implement public health interventions that are ineffective. This is equally true for vaccines and antivirals as it is for 'social distancing' measures. Because the scientific basis for efficacy of particular interventions continues to be studied and models projecting the course of a pandemic are being investigated, sound scientific evidence for proposed interventions may not currently exist. The current knowledge basis should serve as a foundation for ethical guidelines and a commitment to ongoing scientific and ethical evaluation of interventions should be made.

- The United States recognizes its membership in the global community, and the pandemic planning process acknowledges the **importance of working with and learning from preparedness efforts globally**. This recognition is not based simply on the potential of global involvement to benefit U.S. citizens (an "instrumental" reason), but on a deep recognition of the common good[4] and our interdependence globally. Mechanisms for global involvement and criteria for determining the scope of impact of U.S. decisions should be explicit.

- **Balancing of Individual Liberty and Community Interests**
  Pandemic influenza planning, like other public and community health activities, is a cooperative and shared responsibility that balances community and individual interests. During the course of a pandemic, the functioning of society may be threatened. Our moral tradition embodies an understanding that it may be ethically acceptable (or perhaps even ethically mandatory) to suspend some (but not all) ordinary moral rules in such circumstances. For example, limits on individual freedom or choice may be necessary to protect individuals as well as entire communities during pandemic influenza. Yet, individual liberty should be restricted with great care and only when alternative approaches to realizing the goal of weathering the pandemic are not likely to be effective. Suspensions of

[4] The "common good" refers to the interests of a group or collective that is defined by having in common certain attributes (e.g., location in a geographically-defined community, risk of a specific disease) that create a commonality of interests. Its use in this context reflects an understanding that in the case of an influenza pandemic, all human beings are part of a single collective that has a 'common good'.

ordinary moral rules should be anticipated and the conditions calling for such suspensions should be specified.

Guiding principles in determining these restrictions include:

- Adopting the least restrictive practices that will allow the common good to be protected.
- Ensuring that restrictions are necessary and proportional to the need for protection.
- Attempting to ensure that those impacted by restrictions receive support from the community (e.g., job security, financial support for individuals and their families, provision of food and other necessities to those who are isolated or placed under quarantine, and/or protection against stigmatization or unwarranted disclosure of private information).

- **Diversity in Ethical Decision Making**
  Given numerous historical examples of abuse of individuals, particularly those who are considered vulnerable, in the name of the public good (e.g., involuntary sterilization of the mentally retarded, the U.S. Public Health Service Syphilis Study at Tuskegee, the internment of Japanese-Americans during World War II), public health officials must adequately acknowledge and respond to strong currents of suspicion and distrust of the healthcare system. This acknowledgement is, of course, a part of a much larger healthcare dialogue. Addressing this distrust should be a strong and enduring commitment and not viewed as merely instrumental to inducing individuals to comply with recommendations. Diverse public voices should be involved in determining the need for restrictions and in articulating the ethical justification for these restrictions.

- **Fair Process Approach (Procedural Justice)**
  We recommend an approach to justice that focuses on the procedures to be followed with the hope that good procedures will lead to fair outcomes. Following are the elements of an ideal procedural justice approach:
  - Consistency in applying standards across people and time (treating like cases alike).
  - Decision makers who are impartial and neutral.
  - Ensuring that those affected by the decisions have a voice in decision making and agree in advance to the proposed process.
  - Treating those affected with dignity and respect.
  - Ensuring that decisions are adequately reasoned and based on accurate information.
  - Communications and processes that are clear, transparent and without hidden agendas.
  - Inclusion of processes to revise or correct approaches to address new information, including a process for appeals and procedures that are sustainable and enforceable.

The involvement of diverse voices in pandemic influenza planning and in creating a transparent procedure for decision making is essential. In addition to engaging citizens in general, this process would involve those who are primarily responsible for implementing the pandemic influenza plans (e.g., direct health care providers who would be asked to commit to providing care even in the face of personal risk or the competing needs of their own families.)

A balance between centralized, federal control and state and local community implementation of central guidelines must be effectively struck (see Section II-B, page 10, paragraph 1 for more discussion about the strong presumption in favor of centralized decision making during a pandemic). This process should be especially attentive to historically marginalized communities and those where sensitivity to cultural, racial, religious or other values must be incorporated.

Thoughtful preparation and attention to process will not provide guidance in all specific circumstances. The practice of attending to fair process may provide support for local decision makers addressing unanticipated questions. In addition, these decision makers must be authorized to utilize their best judgment in addressing and resolving particular issues.

II. Addressing Particular Ethical Issues in Pandemic Influenza Planning

A. Allocation of Resources

The distribution of goods should be guided by criteria specified well in advance of any need to apply them. As indicated earlier, the primary goals of the distribution system should be clearly specified. Further distribution criteria should be evaluated according to their ability to contribute to the realization of the primary goals. These further criteria should be directed at maximizing fairness (or equity) in the distribution process.

We have concluded that a classic utilitarian approach to defining priorities, 'the greatest good for the greatest number,' is not a morally adequate platform for pandemic influenza planning. We recommend an approach to ethical justification, that, like utilitarianism, evaluates the rightness or wrongness of actions or policies primarily by their consequences, but, we further recommend that planning should take into account other checks ('side constraints') grounded in the ethical principles of respect for persons, non-maleficence, and justice. For example, a classic utilitarian approach, which might accept imposing suffering on the few for the greater benefit of all, would be tempered by such principles as:

- Refrain from harming or injuring individuals and communities.
- Equal opportunity to access resources should be assured to those within agreed upon priority groups.
- Respect for individual autonomy by, for example, employment of the least restrictive interventions that are likely to be effective.

Distribution plans should further specify:

- What scarce goods are involved in the distribution plan? The names of the individual vaccines or classes of goods (e.g., antivirals for the purpose of treating or preventing influenza) should be publicly communicated. It would also help to specify what will not be covered by the distribution plan and why (e.g., drugs that treat or prevent certain disorders or conditions that make one more susceptible to contracting influenza.)
- Who (or what agency) will decide about prioritization and distribution? A mechanism for authoritative interpretations of the rules in the case of a dispute or an appeal is needed.
- Who is eligible to be a recipient? (e.g., Will all individuals present in the local community be eligible, regardless of visitor status? Will the local community encourage travelers to return to home communities to receive the scarce resource? Will exceptions be made? If so, why?)
- What morally relevant criteria will be employed to assign higher or lower priorities to groups of individuals or individuals within the determined goal (preserving the functioning of society)? For example, are certain key services more essential than others? Within the organization or group of individuals who provide an essential service, are there justified criteria for determining a further order of priority (e.g., those with more years of experience or those who have dealt with crises in the past)?

Some theoretical distribution criteria that would generally **not** be ethically supported in pandemic influenza planning include:

- To each according to purchasing power.
- To each according to what he or she deserves.
- First come, first served. (Superficially, this may appear to be fair but, de facto, this puts certain groups – such as those who are less likely to be informed or those who have inadequate transportation - at a disadvantage.)
- Criteria, such as race, ethnicity, religious belief, gender, sexual orientation, or IQ, when used to make discriminations that are only invidious and not morally relevant.

In ordinary circumstances, the distribution criterion, 'to each according to his or her social worth,' is not morally acceptable. 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 'key' 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. Identification of key individuals for this purpose must be recognized for what it is: it is a social worth criterion and its use is justified in these limited circumstances. Care must be taken to avoid extension of the evaluation of social worth to other attributes that are not morally relevant.

Among the goods that must be allocated is the time of health care professionals. It may be necessary to delegate the responsibility and authority to perform procedures and interventions customarily carried out by certain professionals to other individuals. For example, physicians may need to delegate duties to nurses, physicians' trained assistants,

and other personnel (e.g. retired health care professionals) who may not be part of the customary health care team. Similarly, procedures customarily carried out by nurse practitioners and other health care professionals may also be delegated. Such delegations of authority and responsibility should be carefully planned and suitable training programs should be activated in advance of the pandemic.

B. Ethical Guidelines Regarding Social Distancing and Restrictions on Personal Freedom for Managing Pandemic Influenza

In the management of a pandemic, it will often be prudent to employ procedures and interventions that will limit the freedom of movement of individuals or create conditions of social distancing. In general, the proposed use of such interventions and procedures should be in the form of recommendations for voluntary action. Requirements for mandatory liberty-limiting and social distancing interventions should be imposed only in cases in which voluntary actions seem unlikely to be effective. This point notwithstanding, the remainder of this section is concerned primarily with circumstances in which mandatory liberty-limiting and social distancing interventions are being considered.

As noted earlier, sound guidelines should be based on the best available scientific evidence. Ideally, the validity of liberty-limiting and social distancing interventions would be established in a manner similar to that employed for pharmacological interventions, through carefully controlled research. However, in most cases this will not be possible, particularly in the circumstances of a pandemic. Indeed, in the course of a pandemic, it may be necessary to employ some interventions which have little or no scientific support. The model we recommend is that of 'evidence-informed' decision-making, a model that is somewhat less rigorous than 'evidence-based' decision making but something that has to do until more satisfactory validation becomes available.

Liberty-limiting and social distancing interventions include the following:

- Isolation of individuals infected with or ill with influenza.
- Quarantine of those thought to have already been exposed, including family members and others in close contact.
- Closing schools, cancellation of public events (e.g. sports events, concerts), and closing public venues such as shopping malls, restaurants, museums, theaters, etc. as mechanisms to decrease social contact that may lead to the spread of influenza.
- Restricting access to public venues deemed more "essential" such as grocery stores, public transportation, and gasoline stations.
- Providing guidance on office practices and/or flexible work scheduling that decreases potential for exposure.
- Limiting travel within or between cities/local regions.

Is Restricting Personal Freedom in Managing Pandemic Influenza Justified?
Implementing any of these interventions involves restricting personal freedoms that are strongly held and highly valued in U.S. society. The ethical concept of individual autonomy, or the freedom to make one's own decisions, is deeply embedded in U.S.

culture. Respect for individual autonomy is founded on the inherent dignity and worth of the individual and the understanding of each individual's general right to non-interference. Therefore justification for any restrictions on individual freedom must be carefully considered.

Legitimate restrictions on individual freedom may occur if, in exercising one's freedom, one places others at risk. An individual does not have the right to injure another or to take someone's property merely because she or he wishes to exercise her or his freedom. Additionally, implicit in membership in society, is an obligation to abide by certain ethical and legal constraints in order to enjoy the benefits of membership in that society (e.g., security, health-care, general welfare). These "constraints" actually provide the conditions under which personal freedom and flourishing are possible. Thus restrictions essential to the common good, including the public health, of society may be imposed on each member of society. Even so, these restrictions on personal freedom must always be carefully considered and justified.

Procedural Conditions in Restricting Personal Freedom

In Section II-A, we set forth criteria for an acceptable system for allocation of resources, including some characteristics of satisfactory distribution plans and unacceptable distribution criteria. These allocation considerations are equally applicable to developing guidelines regarding restrictions on personal freedom and other non-pharmaceutical interventions for managing pandemic influenza.

The process for decision making about restrictions should be well thought out in advance. Both the decision makers and the criteria that will be used to determine when restrictions will be implemented should be specified. The group that specifies the decision makers and the criteria should be seen by all types of stakeholders as representative or otherwise acceptable. The group that is involved in implementing the policies, educating the public and hearing objections should also be seen as representative or otherwise acceptable. A reasonably diverse infrastructure that includes voices across racial, cultural, community, providers and recipients of care, etc. should be involved in planning, understanding the process, and conveying the process throughout the community. In pandemic influenza, centralization of decision making may be important in creating fair and equitable restrictions that will apply across communities. A process should be in place for objections to be heard, restrictions appealed, and for new procedures to be considered prior to implementation.

As in other areas of pandemic influenza management, transparency about the process is essential and communication about restrictions should begin early in the planning process. The public should be clearly informed that restrictions on personal freedom are anticipated, that these limitations may be important to the individual's own protection, and that they are also necessary to limit the spread of disease throughout the community. Communication should encourage individuals to partner with their communities and society at large in controlling influenza transmission. Information should be provided thoughtfully, balancing when information should be shared with protection of privacy and public trust.

In pandemic influenza there is a strong justification for centralization of decision making. This is a departure from the customary mode of public health decision making which occurs at the local, state, or tribal level by standards of their own choosing. General maxims and criteria for restrictions on personal freedom would be supported by (1) equity and by (2) the need to preserve the functioning of society across communities, including the tracking of disease. Local autonomy in decision making should be honored where there is no evidence to support a belief that centralization of decision making will contribute substantially to preservation of the functioning of society and where the easing of restrictions is proportional and reasonable in particular communities (e.g., uniform duration of school closing may not be reasonable in communities where the influenza wave has already ended). Local decision makers should be prepared to make their reasoning transparent in these situations; they must be authorized to use their best judgment and supported in their efforts to do so.

When are restrictions on personal freedom ethically justified?
In enacting any measure where personal freedom is limited, the least restrictive, effective measure should be taken. Enactment of these measures should be based on the best available scientific evidence that:

- The liberty-limiting measure will achieve its intended goal.
- The limitation is proportional and no less restrictive measure is likely to be as effective. An exception to this criterion may be justified if the less restrictive measure would be unduly burdensome (e.g., either too expensive or the agency responsible for implementation lacks the resources or expertise to implement).
- Failure to implement the measure is likely to result in grave harm to the functioning of society or to the well-being of the public. For example, if quarantine is enacted, the duration of the quarantine should be clearly informed by transmission characteristics and should be as short as is medically justifiable. Home quarantine should be honored where reasonable and desired, and monitoring/surveillance should be as non-intrusive as is reasonable. We should continually be asking what justifies one further restrictive step.

Restrictions on personal freedom should be equitably applied. It should be exceedingly clear why particular individuals or communities are being restricted and that the criteria that justify a restriction would be equally applied to any and all individuals meeting these same criteria. Care must be taken to avoid stigmatization of individuals or groups. Additionally, a process for questioning, appealing, and revising liberty-limiting measures should be in place and accessible when the level of urgency during a crisis makes this realistic.

When closure of public venues is being considered, determination must be made of which public venues are more essential in maintaining the functioning of society and may need to remain open with some constraints on level of access (e.g., grocery stores may need to remain open with some new mechanism for distribution that safeguards both fair access and decreased potential dissemination of disease, such as maximum order amounts or a delivery service). Other examples of possible "essential services" are public

transportation systems and gasoline stations.

Agencies responsible for imposing restrictions such as quarantine, isolation or other limitations must take into consideration the fact that the impacted population, their family members, and other dependents will require adequate access to food, water and other essential services. Such agencies should attempt to secure access to these requirements for the affected parties. Similarly, they should attempt to provide protection of the restricted individuals' jobs and their ability to meet economic obligations such as mortgage, rent, paying utilities, etc.[5]

There should be no unwarranted invasions of privacy and the mechanisms for maintaining confidentiality of private information should be secure. Where information sharing is important to protecting the public health, measures that safeguard personal, private information should be in place and support should be given to ill individuals, family members, and others potentially stigmatized by real or potential illness.

Throughout this process, respect for individual freedom must continue to be an extremely high priority. Translating this respect also involves serious acknowledgement of a past history of neglect and abuse of personal freedom in multiple U.S. health care programs – all with the best of public health intentions. This history is not taken lightly; the ability to restrict individual freedom to protect the common good requires careful reflection and examination throughout the management of an influenza pandemic.

Closing Statement

This document seeks to provide a framework of ethical considerations to guide decision makers at all levels in preparing for and responding to pandemic influenza. As such, these guidelines are not narrowly prescriptive, but recognize the need of decision makers in particular communities or regions to transform this guidance into specific decisions. Ethical decision making assumes that such judgments will be based on current scientific knowledge, that effectiveness of interventions is carefully assessed, and that transparency of the process is evident. As specific decisions in particular communities are considered, processes should be in place for identifying which ethical issues were addressed, how guidelines were utilized, how decisions impacted the affected community, and what lessons can be shared with other decision makers. In this way these guidelines will continue to be an interactive, working document.

[5] It is beyond the scope of our mandate to specify which agencies should have decision-making authority regarding liberty-restricting measures. We do not mean to suggest that such agencies are responsible for the provision of necessary goods and services. Rather, they should attempt to ensure that some agency stands prepared to provide such goods and services. In some cases they may be unable to do so. This should not be seen as an absolute barrier to implementation of the liberty-restricting measure. Rather, this should be treated as a serious cost in the analysis of the balance of costs and anticipated benefits necessary to determining whether implementation of the liberty-restricting measure is justified.

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Appendix C- I

A Process for Ethical Decision Making

A PROCESS FOR ETHICAL DECISION MAKING

Decisions that affect an organization's identity and character should be thoughtful and disciplined and made against the background of the organization's core commitments, the *Ethical and Religious Directives for Catholic Health Care Services* (ERDs), Catholic moral teaching, and other relevant moral principles. Ethical dilemmas arise when there is a conflict between and among values, rights, duties, or responsibilities. In some situations, the choice is clearly between good and evil. In those situations, we are called to choose the good. In many, if not most, situations, however, the choice is not between something good and something bad, but rather between two or more goods. It is usually not possible to achieve all potential goods in a given situation. Choosing one good means that other goods will not be realized. Deciding which good to choose can be difficult. It is often helpful to use a structured process (like the one presented here) in such decision-making, but even this will not guarantee an "answer." Sometimes, the "right" choice will be evident, but often it is arrived at only through discernment. The decision-making process that follows is similar to those that have been adopted by many Catholic health care organizations.

Prior to making ethical decisions, it is important to be clear about 1) who should be heard, 2) who should be at the table, and 3) who makes the final decision.

Gather information

- What are the facts of the situation (who, what, where, when, why, and how)? Is there need for any further information?
- Who are the relevant stakeholders? Are all of their views known?
- Are relevant social, political, economic, legal, and other factors known?

Carefully identify the issue

- What values are behind the various positions?
- What is the value conflict? What values are clashing?
- What is the conflict, if any, with the organization's core values? The ERDs? Catholic moral teaching? Other moral principles?

Review core commitments

- What values does the organization claim to espouse? If the organization is truly committed to these values, they should guide the entire decision-making process, in particular the consideration of options/alternatives for addressing the problem.
- What guidance is provided by the ERDs, the church's moral teaching, and other moral principles?

Identify alternatives

- What are potential alternatives for dealing with the situation?
- Are there any unacceptable alternatives (given guiding values and commitments, the ERDs, the church's moral teaching, and other moral principles)? What are the consequences of rejecting these alternatives? Are the consequences acceptable? Can the effect of negative consequences be lessened in some way?
- Of the remaining alternatives, what are likely significant positive and negative, short- and long-term consequences of each alternative, especially for those who will be affected by the decision and the organization?
- Which of the remaining alternatives are most likely to resolve the conflict and be consistent with the organization's values, the ERDs, the church's moral teaching, and other moral principles? What are the pros and cons of each alternative?

Make a decision

- Choose one of the alternatives.
- Be able to defend your choice of option(s) as well as why you decided against the other options. Being able to *justify* choices is extremely important.
- What is the *motivation* behind the choice of option?
- Decide how the decision will be communicated and how concerns will be addressed.
- Establish a time frame for communicating and implementing this decision.
- Determine a process of evaluation and commit to its implementation.

Evaluate the decision

- What has been the impact of this decision upon the organization's core values and identity as well as its key constituencies?
- If the outcome of the decision has not been as positive as expected, why is that the case? Is there another alternative that might have been better?

VALUES FOR GUIDING ORGANIZATIONAL DECISION MAKING

Every decision reflects and embodies a choice of values. In order for organizations to maintain their integrity, there must be a consistency between the values they espouse and the values that shape their decisions. The values they espouse are likely to be their core organizational values as well as the basic values that are associated with Catholic theology and the Catholic moral tradition. Other, secular, values also can and should guide decision making, provided they are not inconsistent with identity values and religious values and norms. The following are examples of values that might guide a Catholic health care organization's decisions. This list is not meant to be exhaustive. It needs to be expanded by at least the organization's core values. In addition, decision makers should consider guidance from the *Ethical and Religious Directives for Catholic Health Care Services* (ERDs), the church's moral teaching, and secular moral principles.

Human Dignity: respect for the inestimable and inalienable value of every individual; respect for fundamental human rights, including life, food, shelter, education, employment, and health care. Respect for dignity also underscores the fundamental equality of all persons (*Ethical and Religious Directives,* Part One, Introduction).

The dignity of each and every person gives rise to other important values and norms, such as:

- **Beneficence.** Our decisions and actions should contribute to the well-being of others.
- **Non-maleficence.** Our decisions and actions should not harm others.
- **Equality of all.** As human beings created in the image and likeness of God, all are created equal and, hence, should be treated equally. Conversely, no one should be treated unequally on the basis of irrelevant differences (cf., Directives 1 and 23).
- **Self-determination.** Essential to respecting human dignity is respect for all persons' rights to make their own decisions in accordance with their own values and life goals, while always taking account of their responsibilities to others (cf., Directive 28).
- **Informed consent.** Self-determination implies free and informed consent on the part of individuals who are able to make decisions for themselves. When making decisions about possible diagnostic, preventive, therapeutic, or palliative measures, individuals should have adequate *information* about their medical condition and the nature of the various alternatives and their likely risks and benefits (including choosing none of the alternatives). They should be able to *comprehend* the significance of the risks and benefits in light of their personal values and beliefs, and have the capacity to make this decision. Finally, their decision should be *voluntary,* i.e., there should be as much freedom as possible from coercion, manipulation, and undue influence. Seeking informed consent is usually a process and not a one-time event (cf., Directives 26 and 27).
- **Best interests.** When individuals are not able to make treatment decisions for themselves and have never had an opportunity to express values and preferences, those making decisions by proxy should base decisions on the person's "best interests," that is, what will most likely contribute to his or her well-being considering the individual as a whole (cf., Directive 35).
- **Privacy.** Respect for human dignity entails an obligation to refrain from unwarranted and unwanted intrusions into spheres that an individual has designated as his or her personal life. Respect for personal privacy is not an absolute requirement, though the burden of proof is on those who would breach it (cf., Directive 34).
- **Confidentiality.** Respect for privacy gives rise to an obligation to respect an individual's right to retain control over private information about himself or herself. Such information should not be disclosed to others without the individual's consent. Maintaining confidentiality is not an absolute requirement, but the burden of proof in breaching it is on those who would do so. Confidentiality may sometimes be breached in order to prevent serious harm from occurring to another (cf., Directive 34).
- **Professionalism.** The provider-patient relationship is professional in nature and therefore implies a fiduciary responsibility to those being served, that is, the well-being of those being served takes precedence over the interests of health professionals and health organizations. The professional responsibility of clinicians and health care organizations also requires that patients are provided only with that care which is needed and beneficial (cf., *Ethical and Religious Directives,* Part Three, Introduction).

Community: recognition that we are inherently social beings and, because of this, we have responsibilities to others and to the larger community/society; contributing to the common good.

Common good: ensuring that the fundamental dimensions of social life—political, economic, religious, etc.—contribute to the flourishing of individuals and communities; contributing to the well-being and flourishing of the larger community.

Service: response to the needs of others—individuals and communities—promoting their good and well-being to the degree possible. This is sometimes also called **solidarity** in the Catholic social justice tradition.

Subsidiarity: decisions should be made at the lowest, most appropriate level.

Justice: contributing to the realization of people's basic human needs; ensuring their participation in the human community; operating out of a sense of equity (not equality); fairness in agreements and exchanges; advocating for those for whom justice is not being done; and advocating for the change of structures that inflict injustice.

Wholism: responding to the whole person—body, mind, and spirit—in the context of his or her relationships; promoting personal development; creating a workplace supportive of all dimensions of the person.

Preference for the poor: giving priority to the marginalized, the vulnerable, and the disadvantaged, especially with regard to basic human needs and social structures and systems that exclude them from full participation in the community.

Stewardship: recognition that the goods of the earth are gifts of God, given and held in trust for the good of all; caring and prudent use of resources—human and material; recognizing limits in the use of resources; fairness in the use/consumption of resources; and care for the environment.

Veracity: honest and truthful communication and behavior.

Dignity of work: recognition that work is a sharing in God's work of creation as well as a contribution to humanity; that work is the distinctive human capacity for self-expression and self-realization, that it is the ordinary way for human beings to fulfill their material needs, and enables people to contribute to the well-being of the larger community; creating a workplace that reflects and fosters this view of work—that promotes mutual respect, participation, equitable compensation, growth, and effective use of talents.

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Appendix C-2

A Process for Decision Making

A PROCESS FOR DECISION MAKING

Decisions that could significantly impact persons' lives and affect an organization's identity and character must be approached with discipline and discernment. There are numerous tools for making such important decisions. The process here is but one model for identifying issues, considering options, and making decisions that can be confidently implemented. The final decision may not please everyone, but this process will help participants determine that the decision they make is the best one possible.

STEP 1: GATHER INFORMATION AND IDENTIFY THE ISSUE

Identify relevant decision makers and work toward consensus on defining the conflict/issue to be resolved.

Gather information to clearly define the conflict/issue.

- What are the facts of the situation (who, what, when, where, why, and how)?
  - Pay particular attention to *who* will be affected by a decision and *how* they will be affected.
- What are the pertinent factors (medical, social, organizational, financial, political, legal, religious, etc.)?

Discuss other factors that might influence decisions.

- Have each decision maker share his/her own perspective regarding the conflict/issue.
- Consider the organization's mission, vision, values, and core commitments.
- Are there any special concerns that arise because we are a Catholic health care organization?

STEP 2: IDENTIFY AND DISCUSS THE OPTIONS

Having identified the conflict/issue and discussed the factors that will influence a decision, list all the possible options/alternatives.

Develop a range of possible options/alternatives and discuss them.

- Discuss all possible arguments for and against these alternatives.
  - What are the pros and cons of each option, including doing nothing?
- Consider how people and organizations are affected under each option.

Before making a decision, spend some time in silent reflection. New insights or ideas may surface if decision makers can step away from the table for a day or two.

- Discuss any further insights or ideas resulting from the period of silent reflection.

Continued on other side

STEP 3: MAKE A DECISION

Choose among the possible alternatives and make the decision or recommendation.

- Which option best advances the organization's mission, values, strategies, and core commitments?
- Which option produces the greatest benefit and the least harm?
- Make the "right" or best decision by evaluating the effects of each alternative on the relevant stakeholders.

Evaluate the decision

- Does the solution best address the defined problem?
- Would a discussion of the previous steps help confirm the favored decision?

Determine a communication plan.

STEP 4: IMPLEMENT AND EVALUATE THE DECISION

Implement the decision and the communication plan, which includes the rationale for the decision.

- Identify a process for carrying out the decision.
  - Who will implement the decision?
  - How and when will the decision be communicated to all stakeholders?

Immediately address unavoidable negative effects on stakeholders.

Evaluate the process.

- Determine a future time to review the process, decision, and outcomes.

This model process for decision making is based on similar models used by Ascension Health, CHRISTUS Health, Providence Health System, the Sisters of Mercy Health System, and Trinity Health. CHA thanks these and other organizations that contributed to this model process for decision making.

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Appendix D-1

Allocation of Ventilators in a Influenza Pandemic: Planning Document

Allocation of Ventilators in an Influenza Pandemic: Planning Document

NYS Workgroup on Ventilator Allocation in an Influenza Pandemic
NYS DOH/ NYS Task Force on Life & the Law

Executive Summary:

A powerful strain of avian influenza has generated concern about a possible pandemic, though scientists do not know with certainty whether or when a pandemic will occur. However, the better-prepared New York State is, the greater its chances of reducing morbidity, mortality and economic consequences. In a pandemic, many more patients could require the use of mechanical ventilators than can be accommodated with current supplies. A federal ventilator stockpile exists, and New York State plans to buy additional ventilators that would meet the needs of patients in a moderately severe pandemic. In a disaster on the scale of the 1918 influenza pandemic, however, stockpiles 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 would not be available to operate them. If the most severe forecast becomes a reality, New York State and the rest of the country will need to confront the rationing of ventilators.

An ethical framework must guide recommendations for allocating ventilators in a pandemic. Key ethical concepts are the duty to care for patients and the duty to use 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.

The workgroup recommends an ethically and clinically sound system for allocating ventilators in a pandemic, containing the following elements:

1) Pre-triage requirements: Facilities must reduce the need for ventilators and expand resources before instituting ventilator triage procedures.
2) Patient categories for triage: All patients in acute care facilities will be equally subject to triage guidelines, regardless of their disease category or role in the community.
3) Implications of triage for facilities: State-wide consistency will prevent inequities; chronic care facilities will maintain different standards from acute care facilities.
4) Clinical evaluation: Clinicians will evaluate patients based on universally applied objective criteria, and offer time-based trials of ventilator support.
5) Triage decision-makers: Supervising physicians will take responsibility for triage decisions. Primary care clinicians will care for patients and will not determine ventilator allocation.
6) Palliative care: Palliative care will play a crucial role in providing comfort to patients, including those who do not receive ventilator treatment.
7) Appeals process: Physicians and patients require a means of requesting review for triage decisions; ethics committee members and others should be prepared to assist in the appeals process.
8) Communication about triage: Government and clinicians need to provide clear, accurate and consistent communication about triage guidelines. Data gathering and public comment can help improve the triage system.

The workgroup recommends that these guidelines be reviewed in public settings, including medical centers and community forums, with the explicit goals of encouraging education, comment and revision. After such public review, NYSDOH should incorporate improvements to these recommendations, and issue the revised document as a set of voluntary guidelines for acute care facilities.

NYSDOH is empowered to issue voluntary, non-binding guidelines for health care workers and facilities; such guidelines are readily implemented and would provide hospitals with an ethical and clinical framework for decision-making. The workgroup expects that compliance with voluntary guidelines would be extremely high. The complex legal issues raised by altered standards of care in a public health emergency create vulnerabilities for individual facilities as they draft policies. Facilities have requested

detailed procedural advice from the state, and do not seek wide latitude in devising their own policies.

NYSDOH is also empowered to issue binding regulations for hospitals that would apply to standards of care during a pandemic. However, these rationing recommendations remain untested in actual circumstances; issuing them as binding regulations may produce unforeseen consequences. A ventilator allocation system must be designed with sufficient flexibility to adjust to changing clinical information. The static nature of regulation could make it an awkward mode for clinically detailed recommendations.

Among the most challenging legal questions related to the pandemic is the issue of liability protection for clinicians and facilities that adhere to rationing criteria in a public health crisis. Voluntary guidelines issued by NYSDOH for ventilator allocation provide strong evidence for an acceptable standard of care during the dire circumstances of a pandemic. However, there is no guarantee that a court would accept adherence to the guidelines as a defense against liability should lawsuits arise.

Legislation is the only avenue certain to provide robust protection for providers who adhere to the guidelines. Such legislation could offer immunity to health care providers who follow guidelines for ventilator allocation, or alternatively, could guarantee defense and/or indemnification to providers. The combination of voluntary guidelines based on sound ethical and clinical principles, paired with legislation that protects providers who comply with the guidelines, offers the best possible balance of clarity, flexibility, and confidence in designing public health policy for allocating ventilators in a pandemic.

I. INTRODUCTION

The U.S. Department of Homeland Security "views pandemic influenza as both the most likely and most lethal of all threats facing the United States."[1] Scientists and policymakers cannot know with certainty whether an influenza pandemic will occur. However, the better-prepared New York State is, the greater its chances of reducing morbidity, mortality and economic consequences.

Both federal and state governments have drafted plans for a possible pandemic. The federal Department of Health and Human Services (DHHS) released a pandemic influenza plan that offers an assessment of public health and medical preparedness, and guidance to state and local health departments. The New York State Department of Health (NYSDOH) released its draft preparedness plan for pandemic influenza in February, 2006. The state plan includes a review of actions to be taken by health officials, emergency responders and care providers at different phases of the pandemic. The healthcare planning section deals with hospital surge capacity issues and addresses the roles of triage centers and home care. Finally, the communications section discusses effective strategies for conveying to the public risks and steps to cope with them.

In March 2006, the New York State Task Force on Life and the Law, at the request of NYSDOH, convened a workgroup to consider clinical and ethical issues in the allocation of mechanical ventilators in an influenza pandemic. The group brought together experts in law, medicine, policymaking and ethics with representatives from medical facilities and city, county, and state government to address necessary alterations in the standard of care in an emergency. The efforts of the workgroup will inform

NYSDOH plans for coping with the large number of critically ill patients thrust upon the medical care system during a pandemic. Pandemic planning must address potential shortfalls in many resources, including staff, protective equipment, and medications, including oxygen. The goal of the workgroup was to develop recommendations for healthcare institutions specifically for the allocation of ventilators in a public health emergency. The recommendations presented here are intended to guide health professionals and others to act in a manner consistent with ethical principles while preserving as many lives as possible. These guidelines should be publicly reviewed with the explicit goals of achieving publicity and transparency, inviting comment and ensuring that they reflect the values of New Yorkers. After such public review, NYSDOH should incorporate improvements to these recommendations, and issue the revised document as a set of voluntary guidelines for acute care facilities.

This document draws upon the expertise of the workgroup, literature review, and the incorporation of extensive commentary on earlier drafts. NYSDOH and the Task Force wish to thank the workgroup members for their exceptional efforts in helping develop the recommendations through their presentations, their comments, and the generous donation of their time and wisdom. A full list of workgroup members is in Appendix III.

II. BACKGROUND

Influenza viruses can be designated as A, B, or C, with influenza A viruses being the most dangerous. Because influenza A viruses mutate and spread rapidly, and can affect various species, they are often responsible for seasonal influenza epidemics and rarer pandemics.

Influenza

Seasonal Influenza: Despite the availability of vaccines and immunity present in the population, each year seasonal influenza kills 250,000-500,000 people worldwide. In the United States, seasonal influenza causes an annual average of 36,000 deaths, 200,000 hospitalizations and 37 billion dollars in economic costs. Peak influenza season runs from November through March. 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.

Pandemic Influenza: A pandemic is defined as an illness "occurring over a wide geographic area and affecting an exceptionally high proportion of the population."[2] According to the World Health Organization (WHO), there are three prerequisites for a pandemic: (1) emergence of a new virus to which there is little or no immunity, (2) virus replication that can cause serious illness in humans, and (3) efficient human-to-human transmission.[3] Because such a virus would be new and there would be no available vaccine, efficient transmission could have a devastating global impact.

There were three influenza pandemics during the 20th century. The 1918 influenza was the deadliest, killing an estimated 40–50 million people worldwide, when the world population was less than a third of today's population.[4] The influenza

pandemics of 1957 and 1968 were less severe, causing an estimated 2 million and 1 million deaths respectively. All three pandemics likely resulted from a mixture of genetic material from human and avian influenza viruses.[5]

Avian Influenza: Generally, influenza viruses are "highly species-specific, meaning that viruses that infect an individual species (humans, certain species of birds, pigs, horses, and seals) stay 'true' to that species, and only rarely spill over to cause infection in other species."[6] The highly pathogenic avian influenza (HPAI) subtype H5N1, which emerged in 1997 and has spread throughout the Eastern Hemisphere, is one of few HPAI viruses that has crossed the species barrier to infect humans.

H5N1 virus is highly contagious in wild waterfowl and can easily infect domestic poultry. The virus is also known to have infected other animals including mice, cats, and tigers. Bird-to-human transmission has occurred, mostly via direct human contact with the secretions and/or excretions of infected poultry. The effect on migratory birds is not fully established. Human-to-human transmission is inefficient and rare. Evidence suggests that spread beyond first generation close contacts occurred in Indonesia, though without significant viral mutations.[7]

Presently, there is no H5N1-specific vaccine licensed and available to the public. The vaccines produced to thwart yearly seasonal influenza outbreaks will be ineffective in the event of a human avian influenza pandemic.

Rapid onset, severe illness, and a high mortality rate characterize H5N1. Of the first 18 human cases that were reported in Hong Kong in 1997, six patients died. Since the second outbreak began in 2003, the WHO has confirmed 278 human cases resulting in 168 deaths (See Table 1).

Table 1: Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO as of March 12, 2007.

Country	2003		2004		2005		2006		2007		Total	
	cases	deaths	cases	deaths	cases	deaths	cases	deaths	cases	deaths	**cases**	**deaths**
Azerbaijan	0	0	0	0	0	0	8	5	0	0	**8**	**5**
Cambodia	0	0	0	0	4	4	2	2	0	0	**6**	**6**
China	1	1	0	0	8	5	13	8	1	0	**23**	**14**
Djibouti	0	0	0	0	0	0	1	0	0	0	**1**	**0**
Egypt	0	0	0	0	0	0	18	10	6	3	**24**	**13**
Indonesia	0	0	0	0	19	12	56	46	6	5	**81**	**63**
Iraq	0	0	0	0	0	0	3	2	0	0	**3**	**2**
Lao People's Democratic Republic	0	0	0	0	0	0	0	0	1	1	**1**	**1**
Nigeria	0	0	0	0	0	0	0	0	1	1	**1**	**1**
Thailand	0	0	17	12	5	2	3	3	0	0	**25**	**17**
Turkey	0	0	0	0	0	0	12	4	0	0	**12**	**4**
Viet Nam	3	3	29	20	61	19	0	0	0	0	**93**	**42**
Total	**4**	**4**	**46**	**32**	**97**	**42**	**116**	**80**	**15**	**10**	**278**	**168**

Total number of cases includes number of deaths. WHO reports only laboratory-confirmed cases. All dates refer to onset of illness.
(Source: The World Health Organization,
http://www.who.int/csr/disease/avian_influenza/country/cases_table_2007_03_12/en/index.html)

A true infection rate and death rate are impossible to determine because of the unknown number of people with less severe or subclinical illness who do not seek medical care. For this reason, although the measured death rate has been high (>60%), this is likely an overestimation.

The clinical course of H5N1 infection in humans is not fully understood, but is thought to be highly aggressive. In recent experience, onset of disease occurred within a median of 3-4 days post exposure; the time from disease onset to hospitalization was a median of 3-8 days, and the time from disease onset to death ranged from 4-30 days.[8]

Unlike seasonal influenza, H5N1 influenza disproportionately affects young, previously healthy children and adolescents. Most patients are critically ill, commonly presenting symptoms such as high fever, lower respiratory tract infection, abdominal pain, diarrhea, and vomiting. Pneumonia caused by secondary bacterial infection is a common complication of seasonal influenza. In H5N1 influenza patients, primary viral

pneumonia can occur without secondary bacterial infection; in seasonal influenza patients, primary viral pneumonia is relatively rare in adults.

Acute renal failure is estimated to occur in approximately 10-29% of avian influenza cases, with multi-organ failure occurring in almost all fatalities. To date, the majority of avian influenza patients have required a ventilator within 48 hours of hospitalization.[9] Acute respiratory distress syndrome (ARDS) occurs frequently, with respiratory failure expected in more than half of hospitalized patients.

Estimates of the Possible Impact of Pandemic Influenza in New York State

NYSDOH officials have used several outbreak scenarios to estimate the potential impact of pandemic influenza on New York. Officials relied upon the following baseline assumptions in crafting two possible scenarios:

- a specific H5N1 vaccine will not be available for at least 6 months, and will be in short supply thereafter; antiviral medications may be ineffective and in short supply
- the attack rate (percentage of people with pandemic flu out of the total population at risk) will vary, but may be as high as 35%
- the population of New York State is approximately 19 million,
- there are currently 3,981 adult and pediatric ICU beds staffed,
- 15% of the admitted patients with pandemic influenza will require intensive care,
- 7.5% of the admitted patients with pandemic influenza will require ventilators,
- there are currently 6,100 ventilators in acute care settings in New York State,
- at any given time, 85% of the ventilators in acute care settings are in use, and
- 70% of deaths related to pandemic influenza are projected to occur in a hospital.

The two outbreak scenarios are the DHHS moderate scenario, based on the 1957 and 1968 influenza pandemics, and the DHHS severe scenario, based on the 1918 influenza pandemic. The following estimates were calculated using the Centers for Disease Control and Prevention software programs FluAid2.0 and FluSurge2.0.

1. *The DHHS moderate scenario* with a 35% attack rate (percentage of population infected) and 6-week outbreak duration. Using New York State figures, there could be more than 93,753 total influenza-related hospital admissions with nearly 14,062 total influenza patients requiring intensive care unit (ICU) beds (*See Table 2*). More than 7,000 cumulative influenza patients would require ventilator support during at least part of the outbreak's duration, with over 2,171 patients needing them simultaneously during peak weeks. Those 2,171 ventilators represent 36% of the New York State capacity, which is critical considering the baseline assumption that 85% of the ventilators in acute care settings are in use during any given week. When this 85% normal utilization rate is considered, there is a projected shortfall of 1,256 ventilators. 18,650 total influenza-related deaths could be anticipated.

2. The *DHHS severe scenario* with a 35% attack rate during a 6-week outbreak. Though the attack rate is the same as the HHS moderate scenario, the impact will be far greater in this severe scenario; it assumes a more aggressive illness with a higher demand for intensive care and a much greater fatality rate. New York could expect over 770,000 hospital admissions with 115,500 influenza patients requiring ICU beds. During peak weeks, 35,000 patients—nearly 9 times current capacity—would require ICU care. Approximately 58,000 influenza patients would require ventilators during the 6-week outbreak, with 17,844 needing them in peak weeks. This is almost 3 times New York State's current ventilator capacity. The State could anticipate almost 153,000 total deaths over the duration of the outbreak; more than 107,000 deaths will occur in the hospital.

Table 2

	DHHS Moderate Scenario	DHHS Severe Scenario
Attack Rate	35%	35%
Total Admissions	93,753	770,640
Total Deaths	18,650	153,301

Deaths in Hospital	13,055	107,311
Total ICU Beds Needed	14,062	115,596
Peek Week Ventilator Need	2,171	17,844
Total Ventilators Needed	7,031	57,798
Ventilators Available (15%)	915	915
Projected Ventilator Shortfall	1,256	16,929
2006 NYS Ventilator Purchase	850	850
Amended Ventilator Availability	-406	-16,079

(Adapted from Bruce Fage, "Health Care Planning for New York State Pandemic Influenza," presentation at March 2, 2006 meeting)

NYSDOH pandemic planning includes careful consideration of the potential shortage of ventilators, based on the estimates discussed above and on federal plans. There is a federal government stockpile of ventilators, but its use is limited for any one locality; there are not enough ventilators to be distributed if many regions need them at once.

New York State plans to buy ventilators to help avoid rationing in the face of the DHHS moderate scenario; there are no current plans to buy enough ventilators for the most severe DHHS model. This plan balances the need to prepare for a potential pandemic against the need to maintain adequate funding for current and ongoing health care expenses. Moreover, severe staffing shortages are anticipated; purchasing additional ventilators beyond a certain level will not save additional lives, since there would not be sufficient personnel to operate them. In the event of an overwhelming burden on the healthcare system, New York will not have sufficient ventilators to meet critical care needs despite its emergency stockpile. If the most severe forecast becomes a reality, New York State, and the rest of the country, will need to confront the rationing of ventilators and other scarce resources.

A number of technical considerations will guide the purchase and use of these supplemental ventilators. Since a pandemic supposes excess numbers of patients requiring critical care, the extra ventilators should be portable so that they can be used

outside of typical ICU settings. Ventilators should have settings that adjust for volume and pressure, important in caring for patients with the severe respiratory symptoms of patients with H5N1-related pneumonia. Supplemental oxygen may be in short supply, so ventilators that are relatively oxygen-sparing are preferable. Staffing will be severely limited; ventilators should therefore be easy to use, since less experienced staff may need to manage patients on ventilators. This type of ventilator should be introduced as soon as possible into regular use in hospitals, for instance when transporting patients, so that many workers will be competent in their use.

III. ETHICAL FRAMEWORK FOR ALLOCATING VENTILATORS

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, then have ethics applied as an afterthought, and hope to withstand ethical scrutiny. Discourse in medical ethics has generated various sets of principles and values. Different ethical considerations have greater or lesser weight in the process of resolving any particular dilemma; a number of authors have addressed ethical principles for decision-making in public health crises.[10]

The workgroup has articulated the following ethical framework in support of this specific effort to allocate ventilators in a pandemic:

Ethical Framework for Allocating Ventilators

- Duty to care
- Duty to steward resources
- Duty to plan
- Distributive Justice
- Transparency

Duty to Care: First and most importantly, an ethical rationing scheme must respect the fundamental obligation of health care professionals to care for patients. Indeed, in a pandemic, clinicians will try to care for as many patients and save the lives

of as many patients as is possible. However, doctors, nurses, and other health professionals offer care at the bedside to individual patients, not to populations. An ethically sound rationing system must sustain rather than erode this relationship between patient and provider. Physicians must not abandon, and patients should not fear abandonment, in a just system of allocation. Patients who are not eligible to receive mechanical ventilation will receive other forms of curative and/or palliative treatment.

In day-to-day health care in the U.S., the preferences of capable patients are generally the deciding factor in whether recommended treatments will or will not be initiated. However, patient preference is not and cannot be the primary factor in devising a rationing system for ventilators in a pandemic; more patients will want ventilators than can be accommodated. A public health disaster such as a pandemic, by virtue of severe resource scarcity, will impose harsh limits on decision-making autonomy for patients and providers. Allocation guidelines must reflect those limits. Nonetheless, a just rationing scheme must endeavor to support autonomy, when possible, in ways that also honor the duties of care and stewardship. Guidelines must stress the provision of care that is possible when ventilation is not. An ethically sound triage system will include other treatment or palliative measures for patients denied access to ventilators.

Duty to Steward Resources: The second element in the ethical framework is the obligation for government and health care providers to steward resources during a period of true scarcity. The effort to balance this obligation to the community of patients against the primary duty to care for each patient generates the ethical tension in devising a rationing system. Even under ordinary circumstances, critical care providers question whether the estimated benefit of an intervention merits the use of scarce resources.

Providers struggle to decide whether a unit of platelets (or antibiotics, or surgical intervention) is appropriate or justified for a particular patient, given that the quantity of a particular resource is limited. Yet a disaster on the scale of a severe pandemic will force providers to confront limits far more starkly than they now do. Patients who might survive under ordinary circumstances cannot be given the ordinary level of resources, or numerous other patients will die without any resources at all. Clinicians will need to balance the obligation to save the greatest possible number of lives against that of the obligation to care for each single patient. As the number of affected patients increases, accommodating these two goals will require more and more difficult decisions.

Duty to Plan: A motivating force in designing a triage system is the knowledge that planning is an obligation. An absence of guidelines leaves allocation decisions to exhausted, over-taxed, front-line providers, who already bear a disproportionate burden in a disaster. A failure to produce acceptable guidelines for a foreseeable crisis amounts to a failure of responsibility toward both patients and providers. Health care providers are aware that some who served in the aftermath of Hurricane Katrina have been accused of serious crimes. Appropriate guidelines may help prevent both the actuality and the fear of similar consequences for those who provide care in a future emergency.

Though plans are obligatory, any guidelines the group devises will be imperfect, both ethically and medically. Ethically, current access to health care is unequal; no rationing system for a crisis can resolve inequities in pre-existing health status resulting from unequal access. Medically, the clinical parameters of a pandemic are as yet uncertain, increasing the difficulty of predicting survival or duration of critical symptoms. Nonetheless, the workgroup accepts the importance of creating guidelines

under conditions of uncertainty, including plans for allocating ventilators for this foreseeable public health emergency.

Distributive Justice: A just system of allocation must be applied broadly in order to be fair. The same allocation system should be in use across the state, and the decision to implement rationing must be authorized by the state. The timing and content of just rationing systems cannot be hospital-based, but must be coordinated within the community, among communities, and between the local communities and the State. A just or equitable healthcare system cannot allow for more expansive access at a prestigious private facility and more restrictive access at a community or public hospital. Cooperative agreements to pool scarce resources among local hospitals may help alleviate shortages. The allocation of ventilators from state and federal stockpiles must take into account the ratio of local populations to available resources, and supplement those resources accordingly. Ethically sound responses to disaster must not exacerbate disparities in access to care. Rather, planners must designate appropriate resources for the most vulnerable, who are most likely to suffer the greatest impact in any disaster.

Transparency: Transparency is the next element in the ethical framework. Any just system of allocating ventilators will require robust efforts to promote transparency, by seeking broad input in the design of the system, and educating the public about the evolving plan. The state should publicize proposed guidelines, translate them into different languages as necessary, and share them with health care leaders and the community, including historically underserved communities. After assessing comments, revisions that will assure a just allocation process should be incorporated.

Pitfalls: In building an ethical framework, there are pitfalls that an allocation system must avoid. Disaster planning must not serve as a covert means to resolve long-standing problems in health care. For instance, a rationing system does not alleviate the need to provide adequate resources. In a resource-constrained environment, rationing may lead to the acceptance of a lack of resources without challenging the problem of scarcity. A just system will seek to avoid rationing by first implementing less drastic means of limiting and deferring the use of scarce resources. Prior appropriate steps will include the purchase and use of supplemental ventilators, cancellation of elective surgeries, and altered standards of care for staffing ratios. Triage should not be lightly invoked, but must be reserved for situations of true scarcity.

Additionally, guidelines for ventilator allocation in a pandemic must not be used to summarily resolve the controversial question of ventilator use for severely and permanently impaired patients. Covert quality of life judgments must not substitute for ethically sound principles that are available for public scrutiny. Guidelines must reflect our common duty to protect the rights of the disabled, even while potentially encompassing them in a rationing system

Taking into account this ethical framework, parameters for an allocation system for ventilators emerge. The workgroup accepted the idea of removing patients with the highest probability of mortality from ventilators in order to benefit patients with a high likelihood of survival. However, they struggled with the notion of removing less ill patients from ventilators, particularly those who might recover with continued mechanical ventilation. Guidelines should reflect this tension by minimizing circumstances that

require patient extubation, the most ethically and emotionally challenging aspect of any ventilator rationing system.

Clinicians and family members will be reluctant to withdraw ventilators from patients. Guidelines that rely heavily on withdrawal of ventilators will generate great concern and controversy and may be set aside in an emergency. Further, the experience of withdrawing ventilation and observing the subsequent demise of patients will be traumatic for all concerned, including clinicians. Doctors and nurses forced to extubate patients, even to save other patients, may not recover full professional confidence until long after the pandemic is resolved. Finally, the withdrawal of ventilation without patient consent raises significant liability issues; again, appropriate guidelines will limit instances of tragic choices.

IV. Medical Factors in Triage System Design

In order to design a perfect critical care triage system, clinicians would need a method that accurately differentiates in advance those patients who will survive without critical care, those who will survive only with critical care, and those who will die despite treatment. There are a number of proposed systems for estimating critical care mortality, 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 an epidemic; others focus on trauma patients and so are less applicable for an influenza pandemic.[11] Further, no scoring system is accurate enough to provide finely calibrated, reliable distinctions among similar patients; existing data may support estimates of survival among broad categories of patients. In sum, no known clinical scoring system offers a quick, resource-sparing, and accurate prediction of mortality in an influenza pandemic. Our limited ability to assess survival capacity except in broad categories has critical implications for the design of a ventilator rationing system. These guidelines incorporate features of existing triage systems, yet the workgroup finds that the result remains imperfect. The workgroup urges critical care and emergency physicians to pursue the goal of perfecting a clinical scoring system appropriate to an influenza pandemic.

Scoring systems may help determine which patients will benefit from interventions; a well-designed triage plan will also focus on the limited number of critical care interventions likely to have the greatest impact. For a febrile illness likely to cause respiratory failure, mechanical ventilation will be one of the most important interventions.

One way in which an epidemic in the 21st century differs from that of 1918 is the increased ability to collect and analyze data quickly. Guidelines must incorporate new data as they become available, based either on resource availability or clinical circumstances. Systems set up in advance, as part of the planning process, could support the collection of information on symptoms, disease course, treatments, and survival.

Existing Triage Protocols

Hick and O'Laughlin: Very few authors have explicitly addressed the problem of allocating ventilators in a pandemic. Drs. John Hick and Daniel O'Laughlin propose guidelines that would 1) be implemented on a regional, not an institutional basis; 2) provide liability protections for providers and institutions; and 3) provide tiers so that as patients increase and resources are depleted, the criteria become more stringent. [12]

Hick and O'Laughlin devised three tiers of criteria; the first tier would eliminate access to ventilators for patients with the highest probability of mortality, including ventilator-dependent patients with persistent hypotension, and/or failure of greater than four organ systems. If resources continue to fall short, Hick and O'Laughlin propose a second tier that would be denied access to ventilators, containing patients with respiratory failure as well as high use of additional resources. This tier includes patients who have a pre-existing illness with a poor prognosis, including: severe congestive heart failure; acute renal failure requiring hemodialysis; severe chronic lung disease; AIDS with a low CD4 count; active malignancy with a poor potential for survival; cirrhosis with ascites; hepatic failure; and irreversible neurologic impairment, including persistent vegetative

state. In sum, this tier includes patients with respiratory failure and other chronic or potentially fatal conditions.

The third tier in this system is left intentionally vague. The authors suggest that a guideline development committee examine survival data in real time, and add categories of patients who would not have access to ventilators in an overwhelming disaster.

Hick and O'Laughlin propose the extubation of any patient "who might be stable, or even improving, but whose objective assessment indicates a worse prognosis than other patients who require the same resource."[13] Thus, patient A's continued use of the ventilator appears to depend not only on the estimated survival probability of patient A, but also upon that of newly arriving patient B, whose better health status leads to the extubation and probable death of A, and the intubation of B (at least until C arrives).

The workgroup members applauded Hick and O'Laughlin's effort to address the problem of ventilator allocation, and in particular to develop an analysis of regional, as opposed to local rationing. However, the workgroup expressed significant reservations about the plan to extubate a patient because a newly arriving patient had a better health assessment. First, patients require a sufficient trial on the ventilator in order to determine its benefit. More importantly, though, patients expect that doctors will provide treatment, to the extent possible, based on assessments of their health as individuals. If ventilator use is primarily determined by the health of *other* potential users of the ventilator, clinicians must abandon their obligation to advocate for individual patients. This proposal evokes an ICU war of all against all that ignores deeply felt professional obligations to advocate and care for individual patients. Though Hick and O'Laughlin offer many useful insights on the design of a triage system, workgroup members rejected

this aspect of the proposal upon ethical grounds. Participants also believed that clinicians would resist implementing guidelines based upon these premises.

Ontario Health Plan for an Influenza Pandemic (OHPIP): An additional pandemic triage protocol that merits consideration was proposed in April 2006 by the OHPIP Working Group on Adult Critical Care Admission, Discharge and Triage Criteria. Finding that no triage system has been developed for use in critical care or medical illnesses, the OHPIP authors present a new critical care triage tool based in part on the Sepsis-related Organ Failure Assessment (SOFA) score.[14] The SOFA score adds points based on objective measures of function in six key organs and systems: lungs, liver, brain, kidneys, blood clotting, and blood pressure. A perfect SOFA score, indicating normal function in all six categories, is 0; the worst possible score is 24 and indicates life-threatening abnormalities in all six systems. The components of SOFA scoring are listed in Appendix I.

The OHPIP triage protocol is based on three evaluative components: inclusion criteria, exclusion criteria, and minimum qualifications for survival (MQS). Inclusion criteria focus on respiratory failure and refractory hypotension, and identify patients who will benefit from admission to critical care. Exclusion criteria include a list of severe ailments. These exclusion criteria focus on illnesses that draw extensively upon resources. MQS, a term taken from military triage, refers to limits placed on resources used for any individual patient. The authors recognize this concept is "very foreign to western medical systems," but suggest such ceilings would be essential to optimizing resource allocation in a pandemic.

Patients are initially assessed for inclusion and exclusion criteria; if inclusion criteria are present and exclusion criteria are absent, patients are then evaluated with a SOFA score. Patients are reevaluated at 48 and 120 hours and either continue with similar levels of care or are re-assigned to a different category, based on SOFA scores and other objective criteria. In the OHPIP protocol, patients may lose access to ventilators and other critical care resources if their SOFA score increases. They may also lose access if SOFA scores fail to improve within the allocated period; OHPIP experts argue that failure to improve during the designated interval is associated with a high probability of mortality and thus these patients should be assigned to a different treatment category. Tables describing the protocol are presented in Appendix II. The overview of the protocol is as follows, with colors corresponding to triage categories:

- *Blue:* High probability of mortality; should be discharged from critical care and should receive medical management and palliative care as appropriate;.
  - Initial: Exclusion criteria *or* SOFA > 11
  - 48 hours: Exclusion criteria *or* SOFA > 11 *or* SOFA 8-11 unchanged
  - 120 hours: Exclusion criteria *or* SOFA > 11 *or* SOFA < 8 unchanged
- *Red:* Highest priority for critical care
  - Initial: SOFA ≤ 7 *or* single organ failure
  - 48 hours: SOFA < 11 and decreasing
  - 120 hours: SOFA < 11 and decreasing progressively
- *Yellow:* Intermediate priority for critical care
  - Initial: SOFA 8-11
  - 48 hours: SOFA < 8 unchanged
  - 120 hours: SOFA < 8 with minimal decrease (< 3 point decrease in 72 hours)
- *Green:* Low probability of mortality; defer admission/ discharge from critical care
  - Initial: no significant organ failure
  - 48 hours: no longer ventilator dependent
  - 120 hours: no longer ventilator dependent

Appeals: OHPIP also proposes a Central Triage Committee to perform ongoing modifications of the triage protocol as the pandemic progresses, and to consider appeals

and/or exemptions requested by clinicians. For example, the committee could be consulted if a triage officer or clinician thinks a patient is inappropriately designated "blue" under the protocol. OHPIP contemplates a 48-hour trial for such a patient, followed by re-triage at 120 hours.

The OHPIP proposal presents an ethically promising approach to triage. Appropriately, the patient's access to the ventilator depends on the patient's own clinical status, as objectively measured, rather than on a direct competition with other patients presenting for care. Nonetheless, patients will be re-assessed and those who do not benefit over time will lose access to ventilators; this system thus honors the ethical principles of caring for patients while stewarding resources wisely. This proposal suggests a form of appeals process. Workgroup participants were divided about the practicality of permitting appeals to the allocation protocol.

The OHPIP proposal has many excellent features yet does reveal some technical limitations. The list of exclusion criteria requires additional refinement as well as simplification for use in an emergency. The workgroup wished to exclude factors that reflect quality of life judgments rather than estimates of mortality. In addition, the SOFA score upon which the OHPIP proposal partly relies is a technically complex measure. Although some components of the score require only simple laboratory tests such as bilirubin and creatinine, the blood pressure measure depends upon invasive monitoring and pharmacologic therapy available in the intensive care unit. Thus, SOFA scores may prove more useful in determining continued use of ICU resources, rather than initial entrance to this level of care. The workgroup revised these exclusion criteria, based on the work of OHPIP and the SOFA criteria; see chart on page 33.

V. Recommended Process for Allocating Ventilators in an Influenza Pandemic

The workgroup proposes the following ethically acceptable process for allocating ventilators in a public health emergency. These recommendations should be publicly presented, with the explicit goal of inviting comment and revision. The system includes the following components:

1) Pre-triage requirements
2) Patient categories for triage
3) Implications of triage for facilities
4) Clinical evaluation
5) Triage decision-makers
6) Palliative care
7) Appeals process
8) Communication about triage

1) Pre-triage Requirements

Limiting Need: As the pandemic spreads, hospitals should limit the non-critical use of ventilators. Elective procedures should be canceled and/or postponed during the period of emergency. As a pandemic stretches from days to weeks, facilities will require a review system for procedures that decrease morbidity or mortality, but are not of an emergency nature. In addition, the state may wish to limit outpatient procedures that require a back-up option of hospital admission and ventilator support if complications arise.

Securing Resources: Before rationing procedures are implemented, facilities should institute all available means of creating "surge capacity." Staffing issues are critical, for personnel are the most valuable resource in any healthcare facility. Staff members will fall ill, will leave work to care for family, or may decline to serve from fear of contagion, while the number of infected patients reaches unprecedented levels. The

stockpiling of protective equipment, including masks and gloves, is a critical planning responsibility for facilities. Without adequate protective measures, facilities may undermine their capacity to provide adequate staffing during a public health disaster. Alternate levels of staffing should be permitted during the pandemic emergency, and systems for extending the skills of available staff must be utilized.

Facility, state, and federal ventilator stockpiles should be assessed, and additional ventilators should be brought into the system as rapidly as possible. Systems for sharing information about the number and severity of cases, equipment availability, and staffing shortages could be activated throughout hospital systems and regional networks. For instance, not all facilities may be equipped to care for infants who need ventilatory support; clinicians and families need rapid access to information about where such support is available. Federal and NYSDOH pandemic plans address these and related issues.

2. Patient categories for triage

A just rationing system must be applied to all hospitalized patients, and not only to patients with influenza. As a practical matter, clinicians could not limit the use of triage criteria to patients solely with influenza; critically ill patients may have multiple diagnoses or no clear diagnosis. Furthermore, a system that suggests a preference of one disease over others might result in inaccurate reporting of diagnoses, and heighten the danger of contagion.

Workgroup members debated whether various characteristics should factor into assessments of access to ventilators, including age. Age factors indirectly into any

criteria that assess overall health, since chronic disease generally increases with age. Existing triage proposals vary on this issue; some decline to refer to age overtly, while others list age as an exclusionary factor, but do so at a range that varies from 65 to 85. These recommendations do not include age as an exclusion criterion. Social worth, such as being the parent of many children or an important community member, was also rejected as a factor in determining access.

Health Care Workers and First Responders: Participants debated with great concern the question of offering enhanced access to ventilators to health care providers, first responders, or other special groups. Many participants argued that patients should be assessed on medical factors only, regardless of their work role, for various reasons. First, health care workers sick enough to require ventilators are unlikely to regain health and return to service during the pandemic. The predicted period of recovery will be at a minimum several weeks; the worst phase of the pandemic will likely end before a stricken individual can return to work. Second, workers in many occupations risk exposure and provide crucial services in a pandemic. Doctors and nurses face risks, but so do respiratory therapists, orderlies who keep rooms clean, morgue workers, laundry workers, ambulance staff, security personnel, fire fighters, police and others. Nor is it always easy to determine who is and is not a health care worker. Part-time volunteers staff ambulances in some communities; an unpaid family member may serve as the full-time caregiver for a disabled relative. These unpaid providers take risks comparable to or greater than some paid health care providers. Expanding the category of privilege to include all the workers listed above may mean that *only* health care providers win access to ventilators in certain communities. All other community members, including all

children, would be denied access; this plan was unacceptable to the workgroup. Participants also objected strongly to the appearance of favoritism, in which those who devised the rationing system appeared to reserve special access for themselves. Participants ultimately found that access to ventilators should depend on clinical factors only. Of note, the allocation of other scarce resources, such as vaccine or anti-viral medications, as well as personal protective equipment, may well favor health care providers based on differing ethical and clinical considerations.[15]

3. Implications of triage for facilities

Statewide Application: It is in the nature of an epidemic that some facilities will be hit harder, or sooner, than others; one facility may run out of critical supplies, including ventilators, while other facilities still have capacity. Participants considered a number of options for balancing need and resources. One suggestion was for the transfer of patients to facilities with available resources, although the transfer of large numbers of critically ill and highly infectious patients is not easily, or perhaps wisely, undertaken. During the pandemic, leadership of facilities within a region should be encouraged to work out voluntary plans for loans of equipment and staff in a crisis. Hospital associations might play a role in convening such planning meetings. State and federal assets, including ventilator stockpiles, should be allocated to areas with the greatest discrepancy between population and resources.

Statewide policies are crucial; large variations among facilities will lead to inequities. Equitable rationing systems, particularly ones that contemplate limiting access to life-saving treatment, must assure that the same resources are available and in use at similarly situated facilities, i.e., all facilities in one city gripped by the pandemic.

Participants found morally unacceptable a rationing system that allowed terminal extubation at one hospital, while patients with similar symptoms survived by virtue of being in a neighboring hospital. Hospitals in less affluent neighborhoods typically serve a far larger population base. Thus, a system of rationing that permits wide variation between hospitals in different areas will likely result in excess mortality for the poor.

Acute and Chronic Care Facilities: Distinctions should be maintained between acute and chronic care facilities once triage begins, permitting chronic care facilities to maintain their specific mission. Patients using ventilators in chronic care facilities would not be subjected to acute care triage guidelines. If, however, such patients required transfer to an acute care facility, they would be assessed by the same criteria as all other patients, and might fail to meet criteria for continued ventilator use. Chronically ill patients will be vulnerable to the pandemic; chronic care facilities will have to provide more intensive care on site as part of the general process of expanding care beyond standard locations. Barriers to transfer are appropriate and likely during a phase in which acute care hospitals are overwhelmed.

An alternative approach would require assessing all intubated patients, whether in acute or chronic care facilities, by the same set of clinical criteria. Depending on the design of these criteria, the result might be the sudden and fatal extubation of stable, long-term ventilator dependent patients in chronic care facilities. The proposed justification for such a strategy would be that more patients could ultimately survive if these ventilators were used by the previously healthy victims of the flu epidemic. This strategy would, however, make victims of the disabled. More patients might survive, but they would also be different survivors. It is hard to avoid the conclusion that such a

strategy relies heavily upon ethically unsound judgments based on third-party assessments of quality of life.

Applying acute care triage guidelines to chronic care facilities fails to adhere to the ethical principle of providing care for each patient, including the most vulnerable. The second principle of using resources wisely must also be considered. Setting aside the small number of ventilators in chronic care facilities for use by the chronically ill, who likely will have severely limited access to ventilators in acute care facilities, offers an appropriate balance between the duties to care and to allocate wisely.

Small but increasing numbers of persons who depend on mechanical ventilators reside in the community, rather than in institutions. Workgroup participants concurred that community-dwelling persons should not be denied access to their ventilators. The rationing scheme must take into account the needs of this group of patients.

Finances and Special Centers: Financial factors will significantly affect the ability of hospitals to provide adequate care. Hospitals with more limited resources might not be able to buy or rent supplemental ventilators either before or during the crisis. State pandemic plans should assess how to balance the differences among facilities in their ability to pay for and provide surge capacity.

The creation of "special centers of excellence" to care exclusively for influenza patients is controversial, since such a plan could prove financially burdensome to selected hospitals. Elective surgeries would be canceled, and patients with other illnesses would stay away. In contrast, non-designated hospitals would perform a greater share of well-compensated procedural work not related to influenza. This dilemma affected the delivery of care for SARS patients in Toronto during the outbreak in 2003. Ultimately, four

hospitals in Toronto were designated centers for SARS patients; such an arrangement may be easier under Canada's single payer system than it would be in the U.S.

Centers of excellence for pediatric, as opposed to adult, influenza patients may be more appropriate, since the requisite expertise will not be widely distributed. Planning assumptions must adequately reflect the needs of infants and children. Special expertise, likely to be in short supply, is needed to care for this population, who may also be especially vulnerable to morbidity and mortality in a pandemic. Stockpiled ventilators accommodate patients weighing as little as 10 kilograms; these ventilators will not support infants. NYSDOH pandemic planning for pediatric patients is assessing these issues.

4. Clinical evaluation

A clinical evaluation system based on the OHPIP protocol and on the SOFA score is adapted for use in these guidelines.[16] Incoming patients who meet the inclusion criterion of pulmonary failure will be assessed for exclusion criteria and will then be placed in categories based on a variation of the OHPIP system (see Appendix II). Patients on ventilators when triage begins will also be assessed to see whether they meet criteria for continued use. Candidates for extubation during a pandemic would include patients with the highest probability of mortality. These include patients like those in Hick and O'Laughlin's first tier, or those described in the OHPIP blue category. When a ventilator becomes available and many potential patients are waiting, clinicians may choose the patient with pulmonary failure who has the best chance of survival with ventilatory support, based on objective clinical criteria.

Emergency Services: Some patients arrive in the emergency department with endotracheal tubes already inserted. Participants disagreed about whether EMS personnel should continue to intubate patients before arrival at the hospital. Workgroup members express concern that EMS personnel might not have sufficient data to apply allocation criteria in the field. However, participants concurred that emergency department staff may reassess patients upon arrival and extubate as necessary those patients who do not meet criteria for ICU admission and ventilator use.

Time Trials: Continued use of the ventilator will be reviewed and reassessed at intervals of 48 and 120 hours. Patients who continue to meet criteria for benefit or improvement would continue until the next assessment, while those who no longer met these criteria would lose access to mechanical ventilation. Access for a specific single period of time was considered but rejected as excessively arbitrary.

Time trials for ventilator use should reflect the expected duration of beneficial treatment for acute respiratory distress syndrome (ARDS) or other likely complications of severe influenza. Too brief a trial, for instance of only a few hours, might not provide any significant benefit to patients, including those who might survive with a limited but longer trial. Excessively brief trials might permit use of ventilators by more patients, but without decreasing overall mortality. Moreover, very short trials would raise the option of terminal extubation for large numbers of patients, a circumstance that the guidelines should attempt to minimize if possible.

Exclusion Criteria: Clinicians will assess patients for exclusion criteria both to determine the appropriateness of the initiation and continuation of ventilator use. Selecting and defining exclusion criteria is a challenging aspect of designing a triage

system. A model set of exclusion criteria would objectively define those patients with a high risk of mortality even with ventilator support, but would not rely on subjective judgments of quality of life. Exclusion criteria should focus primarily on current organ function, rather than on specific disease entities. A revised set of exclusion criteria, drawing upon the work of OHPIP and incorporating suggestions from workgroup members and additional critical care experts, is presented below.

Exclusion Criteria for Ventilator Access*

- Cardiac arrest: unwitnessed arrest, recurrent arrest, arrest unresponsive to standard measures; Trauma-related arrest
- Metastatic malignancy with poor prognosis
- Severe burn: body surface area >40%, severe inhalation injury
- End-stage organ failure:
  - Cardiac: NY Heart Association class III or IV
  - Pulmonary: severe chronic lung disease with FEV_{1}** < 25%
  - Hepatic: MELD*** score > 20
  - Renal: dialysis dependent
  - Neurologic: severe, irreversible neurologic event/condition with high expected mortality

*Adapted from OHPIP guidelines
** Forced Expiratory Volume in 1 second, a measure of lung function
*** Model of End-stage Liver Disease

The primary clinicians treating a patient would have neither the main nor the sole responsibility for deciding to remove a ventilator from the patient. The clinicians directly caring for the patient would assess the patient's condition and note the emergence of any exclusion criteria; a triage review officer, the supervising clinician in charge of intensive care patients (either in the unit or in its overflow areas), would make triage decisions based on the allocation protocol.

This approach is consistent with the recommendations of the Working Group on Emergency Mass Critical Care, a distinguished group of experts that produced a 2005 guidance document for improving surge capacity in public health disasters.[17] That document directs senior clinicians to take on a role of supervising those with less critical care experience. An epidemic will create shortages of personnel for intensive care, both because the need will increase and because fewer personnel may be available. Clinicians providing direct care for patients in the intensive care unit during a pandemic may be far less experienced with critical care than would ordinarily be the case. Second, primary clinicians could fulfill their obligation to care for their individual patients without facing a conflict of interest; they could advocate for their patients and would not also be responsible for deciding to end treatment. Third, staff with the best information on the current balance of need versus resources would make triage decisions, and would be most likely to make the decisions consistently within a group of patients. The triage officer will be a supervising clinician with better access to information about the number and nature of patients awaiting admission to the unit, and can set triage goals accordingly. Fourth, this form of role sequestration would enhance the capacity for maintaining professionalism. The pandemic will have a finite duration. Guidelines for triage should minimize the erosion of the clinicians' duty to care for individual patients. Role sequestration may help decrease burnout and stress for clinicians providing critical care during the epidemic, and help sustain their integrity as healers.

6. Palliative care

Patients who fail to meet rationing criteria have poor prognoses and will be taken off ventilators. Clinicians should then endeavor to follow existing facility protocols for withdrawing and withholding life-sustaining care. Palliative care should be offered to patients who fail to meet rationing standards for continued ventilator support. Typically, terminal weaning in response to patient preferences can include sedation, so that the patient need not suffer from air hunger. Patients who are extubated *against* their wishes may be offered sedation, but may choose to decline. Clinicians should clearly document the rationale and decision regarding sedation with extubation; transparency is a crucial element in adhering to ethical standards. Facility protocols for terminal extubation may offer guidance for appropriate dosing and procedures. In addition, facilities should prepare for a significant increase in demand for palliative care expertise. Extubated patients could receive nasal cannula oxygen if available, or other supplements to breathing. Facilities will need to address whether family or community members will be allowed to supplement ventilation, perhaps after transfer out of the ICU, with hand-held devices such as ambu-bags.

7. Appeals process

Triage decisions will engender controversy and objections. Workgroup participants disagreed about whether a real-time or retrospective form of review would better serve the goal of providing a just and workable triage system. Some review process is needed to assure consistency and justice in the application of the criteria.

OHPIP and others call for a system in which on-going triage decisions may be appealed.[18] Ideally, even under conditions of limited staffing, personnel involved in the

appeals process would differ from those who made the initial triage determination, and if possible, the review should be made by several persons rather than an individual. These persons should also be experienced in conflict mediation and have clinical expertise; drawing upon members of the ethics committee, the patient representative service, retired clinicians, and the chaplaincy may be ways to provide an appeals process even during the period of limited staffing. This system offers the benefit of review for individual cases, but also creates potentially unworkable delays in implementing triage decision during the public health emergency.

Some argue that a real-time appeals process could invite explosive debate during a time of scarce manpower and other resources. An alternate to a real-time appeals process could involve daily retrospective review of all triage decisions. The review would assure that standards are followed consistently and correctly, and would present an opportunity for correcting the guidelines or their implementation as needed. Such retrospective review would provide oversight and accountability for triage decisions, but would not permit intervention for individual decisions regarding access to ventilators.

8. Communication about triage

Initiation of each phase of treatment, but especially of ventilator support, will require clear communication about goals and options. Even before a patient comes to the hospital, political leaders and health officials will have to emphasize publicly that pandemic flu is potentially fatal, that clinicians are doing all they can with the available resources, and that everyone will need to adjust to a different way of providing and receiving health care than is customary. Patients and families must be informed

immediately that ventilator support represents a trial of therapy that may not improve the patient's condition sufficiently, and that the ventilator will be removed if this approach does not enable the patient to meet specific criteria. Training of staff for pandemic readiness should include guidance on how to discuss such time trials. Communication should be clear upon hospital admission and ICU admission, as well as upon initiation of ventilator treatment.

VI. LEGAL ISSUES

The law must inform any ethical and clinical recommendations of the workgroup. In devising a rationing scheme for ventilators, the state should examine various current health laws, regulations, and policies. The best resolution for the challenging issue of liability and/or indemnification for providers and facilities during a public health emergency is as yet unclear; various options, including new legislation, merit consideration.

Emergency Powers

A pandemic could meet the criteria of a "disaster" needed to trigger the emergency powers of the Governor and local officials enumerated in New York's Executive Law. In a disaster, the Governor may temporarily suspend "any statute, local law, ordinance, or orders, rules or regulations." Suspensions are subject to "the state constitution, the federal constitution and federal statutes and regulations," and "no suspension shall be made which does not safeguard the health and welfare of the public and which is not reasonably necessary to the disaster effort." Suspensions are limited to 30 days, but can be renewed.[19] Prudence compels consideration of which laws should be suspended by the Governor in a pandemic.

DNR Orders: Ventilator triage in a public health emergency will change the context in which decisions are made to attempt resuscitation. If pandemic triage guidelines endorse the removal of ventilators from patients in certain circumstances, physicians cannot then resuscitate such patients by reintubation. Article 29-B of the Public Health Law presumes that a patient consents to cardiopulmonary resuscitation

unless there is consent for a Do Not Resuscitate (DNR) Orders.[20] Thus, the protocol described in these ventilator allocation guidelines appears to conflict with the DNR statute.

In a disaster emergency the Governor might suspend provisions of the DNR law that conflict with these ventilator guidelines. Specifically, patients who lose access to ventilator support under rationing criteria will also require DNR orders, and these cannot depend upon the consent of patients and surrogates. The specific provisions requiring suspension would be those sections of Article 29-B that establish presumed consent for cardiopulmonary resuscitation and require consent to issuance of a DNR order.

As noted above, any suspension of law by the Governor in an emergency is subject to the requirements of the federal and state constitutions, as well as federal law. Whether the emergency suspension of the DNR law (or portions thereof) to support emergency ventilator allocation would be viewed as running afoul of these requirements cannot be predicted with certainty.

DNR orders in other contexts, for instance for hospice patients and others for whom ventilator use is not an issue, should continue to rely upon consent from patients or surrogates, even during the public health emergency.

Brain death: Evaluations of brain death in New York follow voluntary guidelines issued by NYSDOH. As such, they can be revised or amended by NYSDOH before or during an emergency without invocation of the Governor's emergency powers. These guidelines call for two separate assessments of brain stem reflexes separated by a six-hour interval. Revised guidelines for brain death evaluations for use during a public health emergency should be reviewed as part of pandemic planning, so that they may be

promulgated quickly if an emergency is declared. Criteria for removal of ventilator support during a pandemic might include an abbreviated assessment for brain death, relying upon only one assessment of brain stem reflexes and the elimination of various confounding factors such as substance overdose.

Liability: Among the most challenging legal questions related to the pandemic is the issue of liability protection for clinicians and facilities that adhere to rationing criteria in a public health crisis. Patient consent, the mainstay of ordinary medical care, will not be the determining factor in allocating ventilators. These emergency allocation guidelines represent a significant departure from standard non-emergency practice and will generate distress for clinicians and patients. Threatened and actual legal actions are reasonable concerns in response to any emergency rationing scheme.

NYSDOH takes the view that voluntary guidelines issued by DOH for ventilator allocation would provide strong evidence for an acceptable standard of care during the dire circumstances of a pandemic. But while the guidelines offer the prospect of liability protection for providers and facilities, NYSDOH cannot promise in advance that a court would accept its view. Further, New York State law does not clearly empower the Governor to offer legal immunity to providers, even in a state of emergency.

In regard to potential lawsuits related to ventilator allocation, legislation is the only avenue certain to provide robust protection for providers who adhere to the guidelines. Protections should extend to facilities and a wide range of clinicians, including doctors, nurses, respiratory technicians, emergency medical personnel and others. Such legislation could offer immunity to health care providers engaged in ventilator allocation, or alternatively, could guarantee defense and/or indemnification to providers. One statute

that may prove useful in this regard is section 17 of the Public Officers Law, which provides for indemnification and defense of state employees. "Employee" is given broad meaning in the statute by numerous subsections of section 17(1).[21] It may be appropriate to recommend legislation adding to this list of indemnified "employees" those persons who engage in conduct pursuant to NYSDOH-issued ventilator allocation guidelines.

Another indemnification option worth exploring is the "volunteer" provision of section 17, which includes among indemnified persons "volunteer[s] expressly authorized to participate in a state-sponsored volunteer program."[22] It may be possible to design a state-sponsored volunteer program including those providers who participate in a ventilator allocation triage process, thereby offering them defense and indemnification under the Public Officers Law. Providers who act in good faith by adhering to the voluntary guidelines could be offered defense and indemnification by statute, even if the ventilator guidelines themselves remained voluntary and non-statutory. Such a statute would need to clarify that "volunteers" defined for this purpose include paid health care providers who comply with ventilator allocation guidelines.

Form of Recommendations

NYSDOH will present this planning document for ventilator allocation for public review and then incorporate any appropriate revisions. NYSDOH will then issue recommendations for allocating ventilators in an avian influenza pandemic as voluntary guidelines. NYSDOH is empowered to issue voluntary, non-binding guidelines for health care workers and facilities; such guidelines could be readily published and would provide hospitals with an ethical and clinical framework for decision-making. Some question

whether voluntary guidelines offer a sufficient guarantee of state-wide consistency. However, facility representatives stress that they are eager to follow state-level guidance, and do not seek wide latitude in devising their own policies. The complex legal issues raised by altered standards of care in a public health emergency create vulnerabilities for facilities. Hospitals perceive greater safety in accepting state guidance than in drafting their own policies. Moreover, designing a link between liability protection and compliance would increase adherence to the voluntary guidelines.

NYSDOH is also empowered to issue binding regulations for hospitals that would apply to standards of care during a pandemic. However, statutory law precludes NYSDOH from regulating physician practice.[23] Moreover, these rationing recommendations remain untested in actual circumstances; issuing them as binding regulations may produce unforeseen consequences. Creating regulations for the provision of medical care, especially in the absence of direct experience, poses significant problems and may produce negative unforeseen consequences. A ventilator allocation system must be designed with flexibility to adjust to changing clinical information; even if a pandemic arrives it may only occur some years from now, when technological advances may demand revisions in the guidelines. The static nature of regulation could make it an awkward mode for clinically detailed recommendations.

Finally, NYSDOH could request that recommendations for rationing be drafted as new legislation. Setting recommendations into law would reflect support from elected leaders, yet would face significant difficulties. Rationing recommendations must include flexibility for revision; as with regulation, legislation that permits such flexibility is challenging to draft. In addition, the timing and pace of a pandemic is inherently

unpredictable. Should the pandemic occur, the legislature will face numerous challenging issues, and health care providers may require guidance long before appropriate measures can become legislative realities.

VII. Review and Implementation

This document presents recommendations for an ethically and medically sound system for allocating ventilators in a pandemic. These recommendations should now be publicly presented in a variety of settings, with the explicit goal of requesting review and improvement. This public review is an important component in fulfilling the ethical obligation to promote transparency and develop just guidelines. Appropriate forums for presentation include medical facilities, professional associations, and citizen groups. Table-top exercises designed to test the guidelines are a useful way to reveal strengths and liabilities of the current proposal. In addition, after an initial opportunity for public review and revision, the guidelines could be published to increase their accessibility.

After appropriate review and revision, NYSDOH will present the results as voluntary guidelines for acute care facilities for ventilator allocation in a pandemic. Legislation that provides legal protection for facilities and providers who conform to the voluntary guidelines should also be pursued.[24]

Clear state-level guidance and the consistent policies that result will provide the best possible care for New York's patients if a pandemic occurs. Policies for rationing ventilators in an emergency will not have credibility if issued by individual facilities; rather, guidelines issued by the State are more likely to be viewed as appropriately grounded in concern for public health.

With luck, an influenza pandemic will never emerge in New York. With planning, even if a pandemic does occur, community members, health care providers and public officials may be able to diminish the impact. These recommendations for allocating ventilators in a pandemic rely upon both ethical and clinical standards in an effort to offer the best possible care under gravely compromised conditions.

Appendix I. Sequential Organ Failure Assessment (SOFA) score

SOFA Scale

Variable	0	1	2	3	4
PaO2/FiO2 mmHg	>400	≤ 400	≤ 300	≤ 200	≤ 100
Platelets, x $10^3/\mu L$ (x $10^6/L$)	> 150 (>150)	≤ 150 (≤ 150)	≤ 100 (≤ 100)	≤50 (≤50)	≤ 20 (≤ 20)
Bilirubin, mg/dL (µmol/L)	<1.2 (<20)	1.2-1.9 (20 – 32)	2.0-5.9 (33 – 100)	6.0-11.9 (101 – 203)	>12 (> 203)
Hypotension	None	MABP < 70 mmHg	Dop ≤ 5	Dop > 5, Epi ≤ 0.1, Norepi ≤ 0.1	Dop > 15, Epi > 0.1, Norepi >0.1
Glasgow Coma Score	15	13 - 14	10 - 12	6 - 9	<6
Creatinine, mg/dL (µmol/L)	< 1.2 (<106)	1.2-1.9 (106 – 168)	2.0-3.4 (169 - 300)	3.5–4.9 (301 – 433)	>5 (> 434)

Dopamine [Dop], epinephrine [Epi], norepinephrine [Norepi] doses in ug/kg/min
SI units in brackets

Adapted from:
Ferreira Fl, Bota DP, Bross A, Melot C, Vincent JL. Serial evaluation of the SOFA score to predict outcome in critically ill patients. JAMA 2001; 286(14): 1754-1758.

Explanation of variables:
PaO2/FiO2 indicates the level of oxygen in the patient's blood.
Platelets are a critical component of blood clotting.
Bilirubin is measured by a blood test and indicates liver function.
Hypotension indicates low blood pressure; scores of 2, 3, and 4 indicate that blood pressure must be maintained by the use of powerful medications that require ICU monitoring, including dopamine, epinephrine, and norepinephrine.
The Glasgow coma score is a standardized measure that indicates neurologic function; low score indicates poorer function.
Creatinine is measured by a blood test and indicates kidney function.

Appendix II. Adapted OHPIP Triage Tool

Critical Care Triage Tool (Initial Assessment)		
Color Code	Criteria	Priority/Action
Blue	• Exclusion Criteria* or • SOFA > 11*	Medical Mgmt +/- Palliate & d/c
Red	• SOFA ≤ 7 or • Single Organ Failure	Highest
Yellow	• SOFA 8 - 11	Intermediate
Green	• No significant organ failure	Defer or d/c, reassess as needed

*If exclusion criteria or SOFA > 11 occurs at any time from the initial assessment to 48 hours change triage code to Blue and palliate.
d/c = discharge

Critical Care Triage Tool (48 Hour Assessment)		
Color Code	Criteria	Priority/Action
Blue	• Exclusion Criteria or • SOFA > 11 or • SOFA 8 – 11 no Δ	Palliate & d/c from CC
Red	• SOFA < 11 and decreasing	Highest
Yellow	• SOFA < 8 no Δ	Intermediate
Green	• No longer ventilator dependant	d/c from CC

Δ = change
CC = critical care
d/c = discharge

Critical Care Triage Tool (120 Hour Assessment)		
Color Code	Criteria	Priority/Action
Blue	• Exclusion Criteria* or • SOFA > 11* • SOFA < 8 no Δ	Palliate & d/c from CC
Red	• SOFA score < 11 and decreasing progressively	Highest
Yellow	• SOFA < 8 minimal decrease (< 3 point decrease in past 72h)	Intermediate
Green	• No longer ventilator dependant	d/c from CC

* If exclusion criteria or SOFA > 11 occurs at anytime from 48 – 120 hours change triage code to Blue and palliate.
CC = critical care
d/c = discharge

Appendix III. Workgroup Members
Ethical Issues in Ventilator Allocation in an Influenza Pandemic

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[17] L. Rubinson, et al.

[18] OHPIP.

[19] Executive Law 2-B § 29-a.

[20] A physician may issue a DNR for a patient without that patient's consent in specific circumstances described in Article 29-B.

[21] Public Officers Law § 17(1)(a)-(s).

[22] Public Officers Law § 17(1)(a).

[23] Education Law § 6532.

H

Glossary of Terms

Accountability – Obligation or willingness to accept responsibility.

Adaptive – The modification of behavior to fit changing situation.

Autonomy (self determination) - To respect an autonomous agent is to acknowledge that person's right to make choices and take action based on that person's own values and belief system.

Principle of Beneficence - Traditionally understood as the "first principle" of morality, the dictum "do good and avoid evil" lends some moral content to this principle.

Best Interests - A standard of surrogate decision-making often employed by courts for making end-of-life decisions regarding incompetent patients.

Common Good - In general, the common good consists of all the conditions of society and the goods secured by those conditions, which allow individuals to achieve human and spiritual flourishing.

Consistent – The reliability or uniformity of successive results or events.

Dignity of Work – To perform the duties of ones profession in such a way as to inspire respect.

Duty to Provide Care – Inherent to all codes of ethics for health care professionals is the duty to provide care and to respond to suffering. Health care providers will have to weigh demands of the professional roles against other competing obligations to their own health, and to family and friends. Moreover, health care workers will face significant challenges related to resource allocation, scope of practice, professional liability and workplace conditions.

Equality – The rights of different groups of people to receive the same treatment.

Equity – The state, quality or ideal of being just, impartial and fair.

Fairness---this is an important organizing word in the concept of justice. Fairness has come to mean that each individual in a community will be treated in the way most appropriate for that individual. This does not mean that every one is treated the same, but that everyone is treated appropriately for that individual. Fairness means that everyone is treated as they ought to be treated. This idea is incomplete because what is appropriate for each person remains to be decided.

Holism – To deal with health problems in their physical, psychological, social, cultural and existential dimensions.

Inclusive – Decisions should be made explicitly with stakeholder views in mind and there should be opportunities to engage stakeholders in the decision-making process.

Informed Consent - It is the right and responsibility of every competent individual to advance his or her own welfare. This right and responsibility is exercised by freely and voluntarily consenting or refusing consent to recommended medical procedures, based on a sufficient knowledge of the benefits, burdens, and risks involved.

Integrity - A virtue that coordinates all other virtues. To have integrity is to have organized and controlled all the important traits of your character in such a way that you are expected to act well.

Justice - This bioethics principle is concerned with treating patients fairly in healthcare systems through access to care, quality of care received, and sharing the burden of cost throughout society.

Non-malfeasance - The literal translation is "do not harm". The principle is meant to prevent harming a person through acts of another person.

Privacy - The right of patients to not have information about them shared freely with others. In a public health crisis it may be necessary to override this right to protect the public from serious harm.

Professionalism - The adherence to the values professed by individuals engaged in the practice of a specific discipline such as religion, law, or medicine.

Reasonableness – To behave in such a way as to maintain the ability to defend one's position.

Reciprocity - the give and take of a relationship is reciprocity. Reciprocity in ethics is the mutual regard that persons hold for one another.

Responsive – There should be opportunities to revisit and revise decisions as new information emerges throughout the crisis. The should be mechanisms to address disputes and complaints.

Service – The performance of labor for the benefit of another.

Solidarity - An entire union or consolidation of interests and responsibilities; fellowship; community.

Stewardship – The careful conduction, supervising or managing of something.

Transparency - Sharing information and acting in an open manner.

Trust – A sense of assurance.

Unity – The state of being one; oneness.

Value - The core beliefs we hold regarding what is right and fair in terms of our actions and our interactions with others.

Veracity – The habitual observance of truth.