



DO THE RIGHT THING.



Educational Resource on Pandemic Ethics

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Introduction

The field of Pandemic Ethics emerged as a legitimate subspecialty of bioethics in the wake of SARS in 2003, and amidst anticipation of a bird flu pandemic, which the SARS episode exposed as a potentially more problematic pandemic without more, focused planning. In 2005, a novel Canadian Report emerged from the SARS experience entitled *Stand On Guard For Thee: Ethical Considerations In Preparedness Planning For Pandemic Influenza*. This report outlined an ethical framework to guide planning efforts in the health sector, and led to a major research effort at the University of Toronto to establish an internationally focused Program of Research on Ethics in a Pandemic. This program published a White Paper Series in 2009, entitled *Ethics and Pandemic Influenza*. In 2008, the WHO published its own White Paper series entitled *Addressing Ethical Issues In Pandemic Influenza Planning*. These documents inform the substantive literature worldwide with respect to pandemic ethics. The core pandemic ethical issues include: duty to care of health professionals; priority setting (a.k.a. resource allocation) of limited health resources; restrictive measures (e.g., quarantine); and global governance. The need for an ethical framework to guide local pandemic planning has been reinforced in multiple disciplines engaged in pandemic planning. Ultimately, the public health goals identified by Pandemic Ethics researchers comprise:

- building and maintaining public trust
- protection of vulnerable populations
- establishing the obligations of health care workers in a pandemic
- establishing the reciprocal obligations of the health care system to health care workers
- establishing a framework to allocate strained resources such as ventilators, antiviral medication, or community health services
- establishing a framework for communicating information to the public

The purpose of this resource is to summarize the relevant issues and principles in Pandemic Ethics based on the works above, to assist with local pandemic planning. An excellent, practical and thoughtful “Ethical Framework for Pandemic Preparedness” (University of Toronto, 2009), appears as an Appendix to this Resource.

Ethical Duties of Healthcare Providers in a Pandemic

Health care workers (HCWs) -- both clinical and nonclinical -- face disproportionate health risks in a pandemic situation. They may face competing personal and professional obligations to their patients, colleagues, employers, family members, and to their own health. Research indicates that 25- 85% of HCWs report being unwilling to show up for work in a pandemic. Pandemic Ethics researchers have raised the following questions (University of Toronto, 2009): *Do HCWs have an obligation to treat patients despite risk of infection? What limits, if any, are there to health care workers' duty to care? What institutional supports are owed to health care workers in a pandemic?*

Health care workers' ethical duty to care (distinct from the legal duty to treat) is both a professional duty and societal duty, but professional codes are typically insufficient in addressing duty to care in a pandemic. Communicating duty to care to HCWs is best done within the context of societal obligations (a social contract framework) rather than professional obligations, but that reciprocity should be a consideration in priority setting. Research indicates that the public's perception of HCWs is that they have special obligations to care because of the profession they entered, but that their institutions or government must ensure they have *reciprocity*, meaning they are safe, and fairly compensated for their risk, and given priority for resources. Guidelines comprise the following, which appear verbatim (University of Toronto, 2009):

- 1. Pandemic planners should ensure the right of HCWs to safe working conditions is maximized to ensure the discharge of duties and that HCWs receive sufficient support throughout a period of extraordinary demands, which will include training on hygienic measures to reduce infection risk.*
- 2. Consideration should be given to needs of health care providers to ensure care to their families.*
- 3. Professional associations should provide, by way of their codes of ethics, clear guidance to members in advance of an influenza pandemic. This may include information regarding existing mechanisms to inform members as to expectations and obligations regarding the duty to provide care during a communicable disease outbreak.*
- 4. Pandemic planners should ensure that processes be in place to accommodate legitimate exceptions to the provision of clinical care (e.g. pregnancy, immunodeficiency).*
- 5. Pandemic planners should assess local circumstances and ensure the participation of the community sector in planning of formal and informal care networks and engage clinical and non-clinical, professional and non-professional HCWs.*

Ethical Frameworks for Allocation of Resources and Priority Setting

“Priority Setting” is the dominant term used by pandemic ethics researchers in the discussion of resource allocation in a pandemic setting, in which ordinary healthcare resources and services are expected to exceed demand.

Access to ventilators, vaccines, antivirals, and other necessary resources in hospitals and in the community will need to be prioritized. Clinical criteria is insufficient in priority setting. Value-based decisions in a pandemic setting will need to be made, but how? Should we give priority to sickest or should those most likely to survive should be the benchmark? The following questions have been raised by pandemic ethics researchers (University of Toronto, 2009): *Should resources be allocated to save the most lives or to give everyone a fair chance at survival? Should special consideration be given to vulnerable populations in determining access to resources? Who should make these allocation decisions?*

The ethical goals of resource allocation or priority setting are legitimacy, fairness, and equity. Research indicates the following parameters are acceptable to the public in resource allocation decisions: need, survivability, and social value. Need takes into consideration not just the sickest person; persons who are responsible for caring for others may take priority. Social utility of individuals (healthcare workers, critical infrastructure workers, etc.) who are sick is a key concept in prioritizing. Establishing transparent priority setting criteria in advance of a crisis is another key concept, to enforce fairness and public trust in priority setting. There is public consensus that priority should be given to healthcare workers, whose social utility value is high; and whose risk assumption is high. Research indicates there is public consensus that children should be given second priority after healthcare workers.

The WHO (2008) emphasizes that priority setting is typically based on the principle of efficiency (saving most lives), which prioritizes protecting individuals responsible for caring the sick, and is not necessarily based on prioritizing resources for the “sickest”. The principle of equity is typically a failed principle in priority setting because equitable distribution of resources may not achieve the goals of public safety in pandemic situations. The WHO White Paper on priority setting provides a detailed and thorough discussion of the strengths and weaknesses of various moral frameworks for establishing priority setting guidelines, however the 2009 University of Toronto report distills much of this information into a practical guidelines, stated here verbatim (University of Toronto, 2009):

- 1. Governments and health sector officials should engage the public actively in transparent, inclusive, and accountable deliberations about priority-setting issues related to the use of limited resources for treatment and prevention.*
- 2. Governments and health care sector officials should engage stakeholders (including health care workers and administrators, and the public) in determining what criteria should be used to make resource allocation decisions (e.g., access to ventilators, vaccines, antivirals).*
- 3. Governments and health care sector officials should provide an explicit rationale for resource allocation decisions, including priority groups for access to limited health care resources and services. The rationale should be publicly accessible, justified in relation to the defined criteria, and include a reasonable explanation for any deviation from the pre-determined criteria.*
- 4. Governments and health care sector officials 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.*

Ethical issues in Triage

The WHO (2008) emphasizes the following with respect to triage, stated verbatim:

Similar to judgments about medical futility, triage decisions should be based upon professional standards that are publicly justifiable. In this way, controversial and deeply troubling decisions are not left to the discretion or subjective assessment of individual caregivers. Priorities should be based upon general triage criteria that are reasonably acceptable to everyone. On the one hand this involves appeal to the basic normative principles discussed previously; maximization of health benefits (notably saving lives) and equity. On the other hand, criteria should be defined and specified on the basis of medical evidence about health needs and factors that determine the chance of recovery.

In critical care, the primary focus is on saving lives by responding to acute health crises. Triage decisions aimed at saving the most lives with limited resources will give less priority to patients who are expected to recover less easily. Although the implications of such decisions will be harsh and controversial, the basic principle to save the greatest number of lives possible can be reasonably justified to anyone.

Ethical Considerations regarding Vaccination Refusal and Mandated Vaccination

The main issues identified with pandemic flu vaccine is that it is typically not expected that an appropriate vaccine will be available to the public at least for the first six months after the start of any pandemic, and for large numbers of people this will be far too late. Yet even when a vaccine has finally been developed and approved, deployment will be incremental and there will be insufficient production capacity to accommodate the enormous demand worldwide. Priority Setting guidelines can help to get vaccine to the critical populations. However, there is a considerable ethical issue on the rise regarding vaccine refusal.

Vaccination refusal is linked to two issues in recent public health: (1) a flawed vaccine that was distributed in 1976, in anticipation of a flu pandemic, which produced a number of side-effects; (2) parental distrust of vaccines, and their unproven association with autism. There is an increasing distrust by the public regarding the safety of vaccines. Refusal of vaccines is also now seen among healthcare workers.

Vaccination refusal has been dealt with by Diekema (2005) in the context of the Harm Principle, originally outlined by J.S. Mill in his *On Liberty* treatise (1859). The Harm Principle states: “That the only purpose for which power can be rightfully exercised over any member of a civilised community, against his will, is to prevent harm to others... The only part of the conduct of any one, for which [an individual] is amenable to society, is that which concerns others. In the part which merely concerns himself, his independence is, of right, absolute. Over himself, over his own body and mind, the individual is sovereign.”

This principle makes it clear that when parents exercise their right to refuse to vaccinate a child, that right infringes on another’s right, and may harm another child. Vaccines in a pandemic situation not only provided for the benefit of the individual receiving the vaccine but also for the benefit of the public. The process of creating “herd immunity” allows for individuals who do not get vaccinated, cannot get vaccinated, or do not develop sufficient immunity from vaccination to derive some measure of protection from others in the population being successfully immunized. Determining the purpose of the vaccination program is a key concept: is it to protect the public or individual? If it’s to protect the individual, then the individual’s autonomy to refuse vaccination should be honored. However, if the program is designed to protect the public, then the principle of “solidarity” and protecting the public from harm justifies coercive policies in mandating vaccination, and infringing upon individual liberty. Pandemic ethics researchers assert that in order for public health officials to justify the use of more coercive measures, they need to have scientific evidence that supports the population health benefits of the vaccination program. Coercive policies can include consequences for HCWs who refuse to get the vaccine. Some work places have introduced laws that require health care workers to go home without pay when an influenza outbreak occurs if they refuse vaccination. Mandated school vaccination programs are also common. Coercive policies could be justified, such as not permitting school attendance during an outbreak if the child is not vaccinated. While there may be a reluctance to use and justify coercion, public health officials also have a responsibility to justify the lack of use of coercive policies for vaccination, particularly if there is evidence for the population health benefits of such policies. The failure to do so would violate the principle of solidarity and protecting the public from harm, resulting in avoidable illness and death. In making this decision, officials will have to balance the potential risks and benefits of the vaccination program taking into account the strength of evidence for both of these. Officials will also have to be guided by the “precautionary principle”, which advocates a lower

evidentiary standard for taking action to protect against a large scale risk than what is traditionally used in evaluating the benefit of health technologies at the individual level.

In any mandated vaccine program, there are reciprocal responsibilities of the state to vaccine recipients: ensuring the safety and effectiveness of the vaccine, and providing just compensation to those who suffer an adverse event following vaccination.

Individual Liberty Restrictions

Research indicates that roughly 85% of the population supports states and governments to suspend some individual rights (e.g. traveling, right to assemble) during an influenza pandemic. However, such rights can only be suspended in the public's view, with reciprocity: reciprocal obligation of governments to provide for the basic needs of restricted individuals, as well as support services after the restrictive measures end. For example, restricted individuals should not be penalized by an employer for following a quarantine order (e.g., losing a job).

Pandemic Ethics researchers have summarized guidelines regarding individual liberty restrictions as follows, which appear verbatim (University of Toronto, 2009):

- 1. Public health officials 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 to appeal.*
- 2. Governments and the health care sector should ensure that the public is aware of the rationale for restrictive measures, the benefits of compliance, and the consequences of non-compliance.*
- 3. All pandemic influenza plans should include measures to protect against stigmatization and to safeguard the privacy of individuals and/or communities affected by quarantine or other restrictive measures.*
- 4. Measures and processes ought to be implemented in order to guarantee provisions and support services to individuals and/or communities affected by restrictive measures during a pandemic influenza emergency. Plans should state in advance what backup support will be available to help those affected by restrictive measures (e.g., food, bills, loss of income). Government should have public discussions of appropriate levels of compensation, including who is responsible for compensation.*
- 5. In order to get the public "on board" with decisions regarding restrictive measures, policymakers need to include the public in deliberations about public policy with respect to pandemic influenza.*

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Appendix 1

“Ethical Framework for Pandemic Preparedness”. Appears verbatim (University of Toronto, 2009).

SUBSTANTIVE VALUES	DESCRIPTION
Individual Liberty	<p>In a public health crisis, restrictions to individual liberty may be necessary to protect the public from serious harm. Restrictions to individual liberty should:</p> <ul style="list-style-type: none"> • be proportional, necessary, and relevant; • employ the least restrictive means; and • be applied equitably.
Protection of the public from harm	<p>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:</p> <ul style="list-style-type: none"> • weigh the imperative for compliance; • provide reasons for public health measures to encourage compliance; and • establish mechanisms to review decisions.
Proportionality	<p>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.</p>
Privacy	<p>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.</p>
Duty to care	<p>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 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.</p>
Reciprocity	<p>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</p>

	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.
PROCEDURAL VALUES	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 addressing disputes/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.