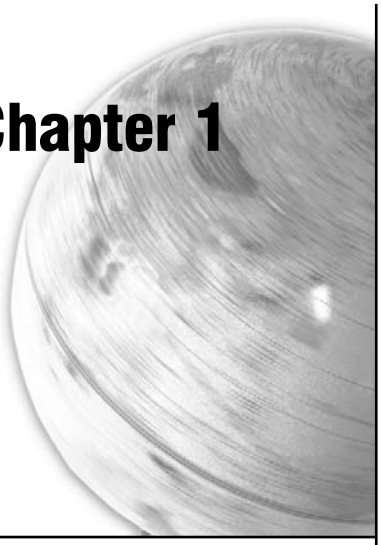
Introduction

Chapter 1



Recent cases of avian influenza have heightened the public's awareness of the possibility of a flu pandemic in the near future. Many experts warn it is not a question of *if* but *when* the next flu pandemic will arrive. A severe pandemic influenza would most likely be widespread and last for six to eight weeks. During the height of an influenza pandemic, approximately 40% of workers will be out of the workforce due to their own illnesses or the need to care for a sick family member.[1] This prediction is alarming, particularly as it affects the healthcare industry, which may be overwhelmed by demands for services to treat the ill. Additionally, other critical industries, such as utilities, food, and transportation, will need to continue functioning in order to prevent damage to society's infrastructure or mass social unrest.

North Carolina will confront many ethical challenges if faced with a severe pandemic.

A severe pandemic is likely to overwhelm our healthcare system, with shortages in medications, hospital beds, and equipment, in addition to workforce shortages. In North Carolina alone, a severe pandemic may result in 1.6 million outpatient visits to healthcare providers, 290,000 hospitalizations, and 65,000 deaths over an eight-week period.[2] We, as a state, will confront many ethical challenges if faced with a severe pandemic. Questions will arise such as who should get first priority for limited healthcare resources, how should we balance the rights of individuals versus the need to protect the public, and what responsibility do people have to work when working could place the individual at heightened risk.

When an influenza pandemic arrives, it will be up to the North Carolina Department of Health and Human Services, Division of Public Health (DPH) and local public health agencies to coordinate a public health response to help reduce morbidity, mortality, and social disruption. DPH determined the need to involve a larger group of stakeholders and the public to develop an ethical framework from which to base implementation of its Pandemic Influenza Response Plan. DPH asked the North Carolina Institute of Medicine (NC IOM) to convene a task force to explore some of the ethical issues the state may face during an influenza pandemic.

The Task Force's work was informed by the experience in Toronto, Ontario, of an outbreak of Severe Acute Respiratory Syndrome (SARS) in early 2003 and by the ethical dilemmas that our country faced in responding to the Katrina disaster. Upon reflecting on their experiences during the SARS epidemic, public health and government leaders in Toronto realized that the healthcare system had been unprepared to deal with the difficult ethical choices that arose during the crisis, and they spoke of the need to develop an ethical framework in advance of a future pandemic:

> ...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.

The lesson learned from the SARS crisis is to establish the ethical framework in advance, and to do it in a transparent manner.

Leaders in governments and health care systems had not previously developed an ethical framework or held prior consultations on how 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."[3]

Background on Pandemic Influenzas

There are three different types of influenza viruses: A, B, and C. The most common influenza for humans is seasonal influenza, which is a highly contagious viral respiratory disease caused by influenza types A and B. In an average year, seasonal influenza results in 36,000 deaths, mostly among the elderly and very young, and in 200,000 hospitalizations.[4] Type A, B, and C influenza viruses can all infect humans, but only type A has the potential to become a pandemic, a world-wide outbreak of a disease.

All known flu viruses in birds (ie, avian flu viruses) are of type A influenza.[a] Migratory waterfowl serve as the primary carriers of avian influenza. While most avian influenza strains do not infect humans, there are at least four strains that have caused diseases in humans.[b] Avian influenza in humans may not cause the same symptoms as the seasonal influenza. It can be quite mild or can cause death.

A strain of avian influenza infecting humans does not necessarily create a pandemic. For a flu pandemic to occur there must be a major change in the genetic material of a type A virus. The change could be the result of an avian virus and a human virus infecting the same cell, forming a new strain of the virus, or the gradual adaptation of an avian virus, allowing it to directly infect humans. Regardless, an avian virus in humans is not a pandemic until it becomes a new human virus and becomes highly transmissible between humans. The World Health Organization (WHO) has identified six stages in the development of an influenza pandemic. (See Table 1.1.) According

Table 1.1
Current Phase of Alert in the WHO Global Influenza Preparedness Plan, March 2007[5]

Inter-pandemic phase	Low risk of human cases	1
New virus in animals, no human cases	Higher risk of human cases	2
Pandemic alert	No or very limited human-to-human transmission	(3)
New virus causes human cases	Evidence of increased human-to-human transmission	4
	Evidence of significant human-to-human transmission	5
Pandemic	Efficient and sustained human-to-human transmission	6

a Type A influenza viruses are distinguished from each other based on the different protein combinations that are on the surfaces of the viruses. All Type A viruses are made up of some combination of hemagglutinin (H) and neuraminidase (N) proteins.

b There are many more types of avian influenza circulating than there are types of influenza in humans. Avian influenzas that have caused disease in humans include H5N1, H7N7, H9N2, and H7N2.

to the WHO, we are currently in Phase 3, with animal-to-human transmission of the avian influenza, but limited human-to-human transmission.[5]

Because an influenza pandemic will arise from a completely new strain of influenza virus, people will not have any immunity to this new flu virus even if they have had seasonal flu in the past. The seasonal flu vaccine will not protect people from this new pandemic flu strain. A different flu vaccine must be made for this new flu virus. Because people have little or no immunity to a new virus and because there will be no vaccine immediately available, the disease can sweep across the country and around the world in a very short time.

Unlike seasonal influenza, a pandemic can occur at any time of year. Most likely, an influenza pandemic would result in multiple simultaneous epidemics worldwide and would potentially occur in several waves, each lasting six to eight weeks.[6] A second wave can occur as much as six to twelve months after the first wave. An influenza vaccine will probably not be available for six to twelve months after a new strain is recognized due to limitations of current vaccine manufacturing technology.[7]

The disease can sweep across the country and around the world in a very short time because people have little or no immunity to a new virus and because there will be no vaccine immediately available.

History indicates that there are typically three influenza pandemics each century. Three influenza pandemics occurred in the 20th century: Spanish influenza (1918-1919), Asian influenza (1957-1958), and Hong Kong influenza (1968-1969).[8]

- *The Spanish Flu (H1N1 virus) in 1918-1919* led to at least 675,000 deaths in the United States and up to 50 million deaths worldwide. The Spanish Flu pandemic remains the deadliest epidemic since the Black Death (bubonic plague) of 1346. During the Spanish Flu, 20% to 40% of the worldwide population became ill. The attack rate and mortality was highest among adults between the ages of 20 and 50.
- *The Asian influenza (H2N2 virus) in 1957-1958* led to at least 70,000 deaths in the United States and up to 2 million deaths worldwide. The virus arrived in the United States in the summer, and children spread it when they went back to school in the fall. Infection rates were highest among school children, young adults, pregnant women, and the elderly.[9] The elderly had the highest mortality rates.
- *The Hong Kong influenza (H3N2 virus) in 1968-1969* led to about 34,000 deaths in the United States and 700,000 deaths worldwide. There are several reasons why this virus resulted in fewer deaths:[9] people may have had some immunity due to the Asian flu virus, the virus peaked when school was out of session, and medical treatment for influenza had improved.

According to the WHO and other public health experts, we are closer now to an influenza pandemic than at anytime since the last outbreak in 1968-1969.[5] Experts suggest that a new influenza pandemic in the United States would lead to approximately 45 million outpatient visits, 865,000 to 9,900,000 hospitalizations, and 209,000 to 1,903,000 deaths, depending on the virulence of the disease.[1] Unlike the seasonal influenza, an influenza pandemic could affect people regardless of age. During a regular flu season, the people who are most likely to die are the very old, very young, and people who have heightened health risks. However, pandemics can affect younger, healthier individuals.

Recently, the World Health Organization and other public health and government officials have been following a subtype (H5N1) of type A influenza. Between 2003 and March 1, 2007, there have been 277 human cases of the H5N1 bird flu. More than half (167) of these cases have been fatal.[10] The H5N1 bird flu has infected humans in twelve countries.[c] This outbreak could result in a pandemic if the virus mutates so that it can spread easily between people through coughs or sneezes. It is important to note that if this virus does become a pandemic strain, experts do not think that half of the cases will be fatal.

Impact of an Influenza Pandemic on North Carolina

A major challenge facing public health officials is that they do not know when the next influenza pandemic will occur or how severe it will be.

Pandemic influenza will probably begin in a developing country where there is close contact between humans and animals and a limited public health infrastructure. The virus is likely to be introduced into the United States by an international traveler. A major challenge facing public health officials is that they do not know when the next influenza pandemic will occur and how severe it will be.

In all likelihood, a flu pandemic will result in large numbers of people getting sick with the flu. In a regular flu season lasting about six months, North Carolina typically experiences about 750,000 doctor visits, 6,000 hospitalizations, and 1,100 deaths.[11] The vast majority of deaths occur in people over the age of 65 years. Compared to the regular flu season, more people will need to be hospitalized and more will die in an influenza pandemic. Table 1.2 shows the projected differences between doctor visits, hospitalizations, and deaths for a moderate pandemic and a severe pandemic. In North Carolina, a *moderate* pandemic wave lasting approximately eight weeks could result in about 3 million infected individuals, 1.6 million doctor visits, 35,000 hospitalizations, and 8,000 deaths. An influenza pandemic could also result in a larger number of younger people dying compared to the seasonal flu. A severe pandemic like the Spanish Flu of 1918 could cause as much as eight times more hospitalizations and deaths.

Table 1.2
Impact of Regular Flu versus Projected Impact of Pandemic Flu in North Carolina[2,d]

Characteristic	Moderate Pandemic (1957-like)	Severe Pandemic (1918-like)
Illness	2,989,442	2,989,442
Outpatient medical care	1,594,655	1,594,655
Hospitalization	35,252	289,762
Deaths	7,949	65,334

Government's Role during a Pandemic

State and local public health and other government leaders are charged with protecting the public during emergencies—whether natural or man-made. An influenza pandemic that affects thousands of people would fall into the category of

c The following countries have confirmed human cases of H5N1 influenza: Azerbaijan, Cambodia, China, Djibouti, Egypt, Indonesia, Iraq, Nigeria, Thailand, Turkey, and Vietnam.

d These estimates were obtained using FluAid 2.0 software available online at the National Vaccine Program website: http://www2.cdc.gov/od/fluaid/default.htm. The figures were calculated using North Carolina's total population of 8,541,263, obtained from 2004 population estimates available at http://demog.state.nc.us/frame_start.html, and a clinical attack rate of 35%.

a natural disaster, and the response would follow the guidelines set forth in the North Carolina State Emergency Operations Plan. Under these conditions, state and local government officials must take actions needed to maintain order and protect lives. For example, government might restrict movement or the operation of businesses where people congregate. (See Appendix B for a description of state and local government responsibility and authority during emergencies in North Carolina.)

When an influenza pandemic arrives, state and local public health agencies have primary responsibility for protecting the public's health. The public health response will be an integral part of a larger state and national emergency response effort. The State Health Director is charged with examining and testing persons that may have been exposed to the virus, procuring and allocating vaccines and prophylactic treatment, and taking steps necessary to prevent the spread of disease. DPH prepared the *North Carolina Pandemic Influenza Response Plan* and, in conjunction with other state and local agencies and partner organizations, will work to reduce morbidity, mortality, and social disruption.[2] The core components of this plan include command and control, surveillance, vaccine preparedness and response, antiviral preparedness and response, medical surge, preparedness in healthcare facilities, and risk communication. An influenza pandemic will affect the entire nation, so North Carolina cannot count on significant assistance from other states or federal agencies.

Overview of Ethical Considerations

DPH identified a need to develop an ethical framework to use in implementing the Pandemic Influenza Response Plan. Such an ethical framework also can help guide other governmental and private actions and will help inform the public of its rights and responsibilities during an influenza pandemic. DPH asked the NC IOM to convene a task force with broad stakeholder participation to explore some of the ethical issues the state may face during an influenza pandemic.

During a major influenza pandemic, it is likely there will not be enough time to discuss the ethical trade-offs inherent in critical decisions. Likewise, it is impossible to anticipate all of the key decisions that could be required during an emergency. Therefore, it is important to identify ethical principles that should be considered while deliberating key decisions. Developing an ethical blueprint that incorporates public input in advance of a pandemic and later applying these recommendations during a pandemic will help assure the public that decision makers are making reasoned responses to the crisis, and that the actions taken to protect the public are equitably applied.

The Task Force identified key ethical principles that should guide the state's response to any future influenza pandemic. These principles include the need to ensure accountability, equitable treatment among similarly situated individuals, proportionality of actions, and inclusiveness and timeliness in decision making. Government must act as the public steward, operate in a transparent fashion, and

The Task Force considered the following ethical principles in developing its ethical blueprint:

- Accountability
- Cooperation and collaboration
- Duty to work
- Equity
- Honesty and truth-telling
- Inclusiveness
- Proportionality
- Protecting individual liberties and privacy rights
- Protecting the public
- Reasonableness
- Reciprocity
- Responsiveness
- Stewardship
- Timeliness
- Transparency
- Trust

make decisions that are reasonable and responsive in order to garner the public's trust. Public trust and cooperation is essential to controlling the spread of disease and maintaining social order. The Task Force also recognized the importance of fostering cooperation and collaboration among different governmental agencies, the public and private sectors, and private citizens. The summary of the ethical principles is listed below, with a more complete description provided in Appendix A.[e]

During an influenza pandemic, some of these ethical considerations may take precedence over others. For example, in order to protect the public and prevent the spread of disease, we may need to restrict freedom of movement, normally a valued personal liberty. Although certain ethical principles or values may assume greater weight during an influenza pandemic, the Task Force considered all of these principles in developing this plan. After the Task Force completed its work, the Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention, published its own ethical guidelines for an influenza pandemic.[12] The topics addressed and the conclusions reached in that document are similar to the ones presented in this report.

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Task Force Work

The NC IOM/DPH Task Force on Ethics and Pandemic Influenza Planning met over a period of nine months to examine the issues and develop an ethical framework for an influenza pandemic. The Task Force was cochaired by Leah Devlin, DDS, MPH, State Health Director, and Rosemarie Tong, PhD, Professor, Department of Philosophy, and Director, Center for Professional and Applied Ethics, at the University of North Carolina at Charlotte. The Honorable Carmen Hooker Odom, Secretary of the NC Department of Health and Human Services, served as the honorary co-chair. The Task Force was comprised of 34 other members, including representatives of public health and other governmental agencies, healthcare providers, business and industry, the faith community, advocacy groups, community leaders, healthcare ethicists, and representatives of underserved communities.

The work of the NC IOM/DPH Task Force on Ethics and Pandemic Influenza Planning was an initial attempt to get stakeholders to think about the ethical dilemmas that are likely to arise in the event of an influenza pandemic. In addition, NC IOM partnered with DPH, the Old North State Medical Society, and El Pueblo to host four regional forums, in order to obtain public input into these difficult ethical decisions. (See Appendix C.) These forums were targeted to the public and included outreach to racial and ethnic minorities and other underserved populations to ensure that their input was considered in the priority-setting process.

The Task Force was charged with developing an "ethical template" to guide public health officials, other government officials, business and community leaders, and individuals. It was impossible for the Task Force to consider all of the ethical issues that decision makers may encounter during a pandemic (eg, how are we going to deal with the deceased, are we going to recognize patient's personal treatment wishes, are we going to reallocate resources from less infected locations to more

e In developing its ethical principles, the Task Force reviewed the pandemic preparedness planning of the University of Toronto, Joint Center for Bioethics.[3,13]

infected locations, what are the opportunity costs of investing so much time and money into pandemic influenza preparation when there are many other public health concerns already occurring). Ultimately, the Task Force decided to focus on four areas:

(1) Responsibilities of healthcare workers to work and reciprocal obligations to protect and support these workers;

(2) Responsibilities of critical workers to work and reciprocal obligations to protect and support these workers;

(3) Rights of individuals versus protection of the public; and

(4) Prioritization and utilization of limited resources.

The following chapters discuss these areas in more detail.

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