

**NC IOM/DPH TASK FORCE ON ETHICS AND
PANDEMIC INFLUENZA PLANNING**
May 3, 2006
WakeMed, Raleigh, NC

MEETING SUMMARY

The NC Institute of Medicine and the NC Division of Public Health (DPH) are partnering to conduct a Task Force on Ethics and Pandemic Influenza Planning. The DPH has developed a pandemic influenza response plan focusing on the emergency response. However, it does not directly address the ethical issues that will arise in the event of a flu pandemic. Therefore, the Task Force is exploring some of the ethical issues that the state may face, including but not limited to: the responsibilities that healthcare professionals have to treat, how the state should balance individual freedoms with the public's need to restrict movement to protect the people's health, and allocation of limited health resources.

WELCOME AND INTRODUCTIONS

The co-chairs, Dr. Leah Devlin, State Health Director, Division of Public Health and Dr. Rosemary Tong, Center for Professional and Applied Ethics at the University of North Carolina at Charlotte, welcomed the task force members and thanked them for their willingness to serve on the task force. Dr. Devlin noted that in a pandemic flu outbreak, there will be heightened concern among the public. The Division of Public Health will be forced to make key decisions to protect the public's health. Therefore, they want to determine how to engage the public to have transparency and trust, so that every individual, family, and institution will understand their role and understand the Division's role and the decisions it will need to make.

PANDEMIC INFLUENZA PREPAREDNESS IN NORTH CAROLINA

Dr. Steve Cline, from the Epidemiology Section of the DPH provided background information regarding influenza. There are three different types of influenza. Types A, B, and C are of greatest concern for people, but only type A has pandemic potential and is the type most discussed in the media. Within type A there are sub-types characterized by, Hemagglutinin (H) and Neuraminidase (N), which are surface proteins on the edge of the influenza virus. There are many influenza type A viruses, and H5N1, which is the current concern in the media, is one subtype.

The most common influenza is the seasonal influenza, which is a highly contagious viral respiratory disease of humans (and can be either type A or B). In an average year, the national impact of seasonal influenza results in 36,000 deaths, mostly among the elderly, and 200,000 hospitalizations. North Carolina typically experiences about 1,000 deaths per year due to seasonal influenza activity.

Avian influenza (all type A) is a disease of birds and migratory waterfowl serve as the primary reservoir. Many birds carry the virus without getting sick. There are many more types of avian influenza circulating than there are types of influenza in humans, and avian influenza strains typically do not infect humans. The ones that have caused disease in humans

include H5N1, H7N7, H9N2, and H7N2. Avian influenza may not cause the same symptoms as the seasonal influenza. It can be quite mild, or it can cause death. Just because it infects humans does not mean there is a pandemic.

A pandemic occurs when there is a major shift in influenza type A virus' genetic material. It can happen as a genetic reassortment where an animal or an avian virus and a human influenza virus infect the same cell and recombine to form a new virus, or it can happen through direct animal to human contact via gradual adaptation. However, an avian virus in humans isn't a pandemic until it becomes a new human virus (from the genetic changes described) and becomes highly transmissible within humans. A pandemic can occur at any time of year and the existing seasonal influenza vaccine would not be effective against it. Most likely, a pandemic influenza would result in multiple simultaneous epidemics worldwide and would potentially occur in several waves, each lasting six to eight weeks.

The three influenza pandemics that occurred in the 20th century included the 1918-1919 Spanish influenza (H1N1) that led to 550,000 deaths, the 1957-1958 Asian influenza (H2N2) that led to 69,800 deaths, and the 1968-1969 Hong Kong (H3N2) influenza that led to 33,800 deaths. History indicates there are approximately three pandemics each century. Experts suggest that the effect of a new pandemic influenza on the United States would lead to approximately 18 to 45 million outpatient visits, 300,000 to 800,000 hospitalizations, and 88,000 to 300,000 deaths. One prediction of a moderate pandemic (1957-like) in North Carolina would be approximately 1.4 million outpatient visits, 29,000 hospitalizations, and 6,700 deaths. Compared to the seasonal influenza, a pandemic influenza could affect people regardless of age.

State Epidemiologist, Dr. Jeffrey Engel provided information regarding pandemic influenza planning. The major challenge facing public health officials is that there are no predictors for seasonal influenza or pandemic influenza. Additionally, a severe pandemic influenza (1918-like) would most likely be widespread, long in duration, overwhelm healthcare services, and may result in shortages of medications, equipment, hospital beds, and personnel. The North Carolina pandemic influenza response plan is developed in an effort to reduce morbidity, mortality, and social disruption. Its core components include command and control, surveillance, vaccine preparedness and response, antiviral preparedness and response, medical surge, preparedness in healthcare facilities, and communication. An influenza pandemic will affect the entire nation, so North Carolina should not expect to receive any interstate or Federal Emergency Management Agency (FEMA) assistance.

Pandemic influenza will most likely begin in a developing country where there is close contact between humans and animals and limited public health infrastructure. An international traveler will then bring it to North Carolina. A typical pandemic influenza wave lasts for six to eight weeks, but a second wave can occur as much as six to twelve months afterwards. An influenza shot or vaccine will probably not be available for 12 months after a strain is recognized due to limitations of the current vaccine technology. To improve this response rate, it is very important that the majority of the federal dollars allocated to influenza response are allocated to improving vaccine technology, moving from an egg-based production system to a cell-based system.

ETHICAL CONSIDERATIONS IN PREPAREDNESS PLANNING FOR PANDEMIC INFLUENZA

Alison Thompson, post doctoral fellow at the Centre for Research on Inner City Health and research associate at the University of Toronto Joint Centre for Bioethics, gave a presentation on the ethical considerations included in the Canadian pandemic influenza preparedness plan. Many of their decisions were based on lessons learned from the 2003 Severe Acute Respiratory Syndrome (SARS) outbreak experienced in their country. Ethics are important in the case of a pandemic influenza because moral analysis is part of a good, accountable formation for decision making. Leadership will have to make decisions about managing risks, which will involve applying value judgments to science.

If ethics are not addressed prior to the outbreak, it can lead to a loss of public trust, confusion about rules and guidelines, stigmatization of vulnerable communities, and low morale among healthcare providers. Procedurally, ethical decision making for a pandemic influenza outbreak should be reasonable, open and transparent, inclusive, responsive, and accountable. In addition, ethical decisions should consider issues related to individual liberty, protection of the public from harm, proportionality, privacy, equity, duty to provide care, reciprocity, trust, solidarity, and stewardship. The key ethical issues that the Joint Centre considered were: a) duty to care, b) restrictive measures, c) priority setting, and d) global governance.

In terms of duty to care, it is important that professional associations, particularly healthcare professions, guide their members regarding their duty to work in the case of a major communicable disease outbreak. In addition, the government and healthcare sector should ensure that providers' safety is protected at all times and that disability and death benefits are available to staff and families adversely affected while performing their duties. Lastly, governments and the healthcare sector should develop human resource strategies for diverse occupational roles to ensure equitable management of risk among individuals and occupational categories.

From the SARS experience in Toronto, it is expected that if nonessential employees are asked to stay home from work, most will do so. However, it is important there is a transparent protocol for implementing restrictive measures that are based on proportionality and the least restrictive means necessary. People who are not considered essential workers may become a critical part of managing the outbreak at hospitals or other institutions. Additionally, the public should be made aware of the rationale for restrictive measures, the benefits of compliance, and the consequences of noncompliance. It is also important to ensure the privacy of individuals and/or communities affected by restrictive measures to protect against stigmatization. During the SARS experience, communities affected by restrictive measures were stigmatized, which hurt the economy in those areas. Processes need to be in place to provide provisions and support services to affected individuals and/or communities. People have generally said that they strongly agree with restrictive measures if these recommendations are followed. A lot of compliance depends on the level of trust the public has for government.

Healthcare priority setting is a difficult issue. Many people scheduled for important treatments may have their care postponed so that hospital space, staff, and equipment can be

redirected to serve in the emergency response. In addition, there will likely be limited vaccines, anti-viral medications, ventilators, and hospital beds for the emergency victims. Therefore, governments and the healthcare sector should publicize a clear rationale for giving particular groups priority access to healthcare services. Stakeholders should be engaged in determining what criteria should be used to make resource allocation decisions. Also, there should be a formal mechanism through the government or healthcare sector for people to appeal or raise concerns regarding particular allocation decisions.

The World Health Organization (WHO) travel recommendation against Canada due to the SARS outbreak had a serious, negative economic impact on the country. Therefore, Canada believes global governance is another important issue. Dr. Thompson's recommendations suggest that the WHO should make every effort to be as transparent and equitable as possible when issuing travel recommendations. Also, federal governments should comply with the new International Health Regulations, and developed countries should continue to invest in the communicable disease surveillance capacity of developing countries.

Dr. Thompson also mentioned that feedback from her presentation has brought up the issues of the ethics of research during a public health emergency, particularly the difficulty getting protocol through a research ethics board in a timely manner. Another issue that has arisen is the ethical treatment of animals, especially around the mass killing of poultry flocks.

TASK FORCE DISCUSSION

Task Force discussion following the presentations focused around duty to care, the media, openness/transparency, and review processes and litigation. Dr. Thompson noted that SARS revealed Canada's biggest mistake was its lack of preparedness to respond to an outbreak through a public health process. Many years of government cutbacks in public health and a lack of understanding of the need for public health infrastructure weakened its emergency response capabilities.

Task force members discussed the other professions that would be critical during a crisis and for whom there need to be duty to care guidelines. These include, but are not limited to, the National Guard, local police, critical infrastructure professions, such as water and electricity, spiritual leaders, and mental health workers. Almost across the board, there is a lack of professional guidance regarding duty to care. In the SARS experience, duty to care was decided by each organization's supervisor. Also, many people lost their jobs or quit because they did not show up for work. It is important that equitable policies are in place. Particularly in the healthcare profession, reciprocity is critical to implementation of duty to care policies. It was also noted that ethical documents should be living documents so that they can be revised to add critical groups and react to the emergency.

Media played an important role in getting information to the public during the emergency. They were a part of the infection tracing, which was very helpful. However, the media contributed to emergency-related problems as well as solutions, particularly through compounding the stigmatization of affected communities.

Task Force members had some concerns about the feasibility of implementing a timely review process, as recommended by Dr. Thompson. However, she suggested that there are probably occupational safety mechanisms already in place that could be used for a review process and it is important to identify those ahead of time. Dr. Thompson also suggested developing an ethical review process. In the case of SARS, there was no such process. However, there was a 1-800 hotline to hear the public's concerns and a standing conference call to feed that information back to decision makers.

The task force also noted that the United States is a very litigious society. Dr. Thompson said that there are still outstanding lawsuits in Canada from the SARS experience for failure to protect the workplace and nonessential services. There was concern expressed that providers could be subject to lawsuit for providing care during a pandemic influenza outbreak that was different than or less comprehensive than the care that would normally be provided absent a pandemic.

These issues call for public involvement and openness and transparency in the development of an ethical code. It is expected that the number of lawsuits could be mitigated if the public is trusting of the process that is developed to respond to the emergency. Public input will legitimize the process and increase trust. However, determining the best way to get the public's feedback and input is a challenge. Additionally, there will be very difficult decisions to make in the case of a pandemic influenza. A study by the Centers for Disease Control and Prevention found that citizens and experts chose different priorities when given the choice about the priority for vaccines. The CDC study asked citizens, stakeholders and healthcare experts to prioritize the distribution of vaccines to: a) those at greatest risk, b) those critical for ensuring the functioning of society, c) children first, d) first-come, first-serve, and e) lottery system. The citizens and stakeholders participating in the study agreed that vaccinating to ensure the functioning of society was most important, compared to the healthcare experts who said that protecting the most high risk and vulnerable individuals was of primary importance. The group noted that there may be some information that you do not want to share with the public. However, Dr. Thompson encouraged making the parts of the plan that are about value judgments transparent.

TASK FORCE ATTENDANCE

Task Force members: Leah Devlin (co-chair), Rosemarie Tong (co-chair), James Ball, Granger Barrett, Jennifer Brandenburg, Allison Breedlove, Linda Burhans, Sally Cameron, Steve Cline, Lynne Doss, Jeffrey Engel, Leigh Foushee, Merrill Holden, Joycelyn Johnson, Jill Moore, John Morrow, John Moskop, Diane Packard, George Reed, Janelle Rhyne, Don Ritter, Philip Rosoff, Rudy Rudisill, Zulayka Santiago, Jane Stein, Jim Thomas, Norris Tolson, Tom Williams
Steering committee, staff, and other interested guests: Kristen Dubay, Joanna Forrester, Thalia Fuller, Mark Holmes, Pam Silberman, Kristina Simeonsson, Kristie Thompson, Lou Turner, Maribeth Wooten