Influenza Pandemic Preparedness: Legal and Ethical Dimensions

by Lawrence O. Gostin

Severe acute respiratory syndrome garnered public attention because it was novel and its potential for transmission was unknown. However, the SARS corona virus is significantly less virulent than pandemic influenza infections. The Spanish influenza pandemic of 1918 caused over twenty million deaths in a world with less than one-third of its current population. Modern epidemiologists now estimate that over fifty million people died, about half of whom were in the prime of their lives. As John Barry explains in his recent book, "One cannot know with certainty, but if the upper estimate of the death toll is true, as many as 8 to 10 percent of all young adults then living may have been killed by the virus. And they died with extraordinary ferocity and speed.""

Influenza pandemics have occurred roughly two to three times per century. Research has identified three essential prerequisites: the emergence of a novel viral subtype in animals (typically swine or poultry), viral replication that causes disease in humans, and efficient human-to-human transmission. Since 1997, the first two prerequisites—a novel viral strain in animals and a "species jump" from animals to humans—have been met on four occasions. The most recent episode occurred in 2004, when H5N1 influenza was found in Viet Nam and Thailand. The outbreak resulted in the culling of large chicken populations, including on farms in the United States. There is now intense interest in influenza preparedness, with major planning initiatives being undertaken by the World Health Organization and Institute of Medicine. (A disclaimer is warranted here: I am working with WHO on revising the International Health Regulations and on influenza preparedness, and with IOM on influenza preparedness, but the views I express here do not necessarily reflect those of WHO or IOM.)

The potential for pandemic spread of a "fit" influenza strain (as well as other novel infections, both naturally occurring and intentional) leads to intriguing ethical and legal questions about public health interventions that could severely disrupt trade, economics, travel, and personal liberty. National and global public health agencies have mooted a wide range of interventions.

Animal-human interchange. A critical early prevention strategy is to control animal populations and avert the species jump. Close proximity of animal and human populations poses a high risk. Strategies to diminish the risk include separating animal and human populations; bolstering occupational health and safety in animal work (including infection control and disinfection); and controlling diseased or exposed animal populations. But the international community faces daunting problems in implementing these strategies. The Codex Alimentarius Commission administered by WHO and the Food and Agricultural Organization (FAO) regulates food hygiene and labeling rather than animal-human interchange. Sovereign nations, moreover, have economic incentives to continue intensive farming and food distribution. Premature intervention can have profound economic implications, yet weak or tardy intervention might devastate both animals and humans.

Surveillance. Surveillance of novel infections in humans offers the possibility of an early warning and a quick response. Experts recommend various surveillance activities, many of which were used in the 2003 SARS outbreaks: testing and screening; health questionnaires; notices and declarations; fever monitoring; and reporting and monitoring trends. The WHO’s draft revised International Health Regulations (IHR) would facilitate surveillance through country notifications, reports from unofficial sources, and real-time event management. Global surveillance could further benefit from ‘small-world networks’ consisting of health professionals, scientists, and non-governmental organizations continuously monitoring disease threats. But while surveillance is an essential public health strategy, even modest measures entail government collection of sensitive health information and can therefore impinge on personal privacy. Acute outbreaks could trigger more extreme measures, such as continuous monitoring of health care workers, immigrants, and travelers, for example. An outbreak of a novel influenza strain will inevitably raise questions about the appropriate scope of surveillance.

Case contact investigations. Identifying infected and exposed persons and following their contacts, making it possible to treat or isolate exposed persons, is a classic form of surveillance. Contraception is ostensibly voluntary because the “index case”—the person initially infected—is under no formal obligation to reveal his or her contacts. Nevertheless, its use in sexually transmitted infections, especially HIV/AIDS, has proved highly controversial. The index case may feel coerced into giving information, investigations pose privacy risks, and individuals may experience stigma and discrimination.

Medical interventions. The dominant strategy for seasonal influenza is to use vaccinations...
and antiviral therapy. In developed countries, governments now standardly recommend that high-risk populations receive vaccinations, and mass vaccination could be recommended in the event of a more severe outbreak. Antiviral therapy, although not as effective as vaccination, can be used for prophylaxis, alleviation of symptoms, and reduction of infectiousness.

But these interventions raise their own concerns. Few would require competent adults to be vaccinated or treated for their own protection, yet the law permits a reasonable interference with bodily integrity to prevent harm to the community.\(^3\) Vaccination and treatment pose risks as well as confer benefits. Mass vaccination or treatment to avert an influenza epidemic can go badly wrong, as occurred with swine flu in 1976. The CDC campaign to immunize the American population cost $134 million and caused Guillain-Barre Syndrome in some who received the vaccine. An influenza pandemic would also raise the hard problem of fair allocation of scarce resources. More likely than not, there will not be enough vaccines and antiviral medications. What should guide rationing decisions? Should we, for example, give priority to the sick, the vulnerable, or those who maintain essential services—health care workers and “first responders”? The global reality is that rich countries will have much less scarcity than poor countries. Should the United States forgo some of its precious stockpile of vaccines and antivirals for the sake of poorer countries experiencing a higher burden of morbidity and mortality from the illness?

**Community hygiene.** One of the most valuable means of infection control is also the least intrusive. Health education to promote safer behaviors—hand washing, disinfection, masks, ventilation, and avoidance of risky contacts—can be highly effective. Yet while they are largely uncontroversial, these steps can impose costs and cause social unrest. Hygiene measures are also culturally sensitive—notice the difference in mask-wearing habits in Asia compared with North America and Europe. Under what circumstances should public health authorities issue recommendations for aggressive hygiene, given the costs and cultural expectations?

**Travel and border controls.** One of the first instincts in the face of infectious disease threats is to protect national borders. International or national health agencies may issue travel advisories, establish border restrictions, or regulate transportation. They might also use “stop-lists” to prevent specified individuals or groups from traveling. The IHR afford WHO considerable authority to regulate international travel and control borders. Of course, these measures can be politically charged. A delicate balance exists between trade and health. Indeed, the draft revised IHR direct WHO to “provide security against the international spread of disease while avoiding unnecessary interference with international traffic.” When faced with a trade-off between maximization of health or of trade, which should prevail and why?

**Decreased social mixing.** Most Americans take for granted their freedom to associate with others in a variety of social settings. Yet public health authorities could restrict social mixing and increase social distance to avert a serious infectious disease threat. This might involve closing down civic activities, meeting places, large gatherings, and transportation systems. Although the U.S. Constitution affords individuals the freedom to associate, courts would likely permit reasonable regulation of congregate settings to prevent transmission of infection. As with other interventions, closures could entail heavy costs in lost revenue as well as in diminished freedoms.

**Civil confinement.** The potential for a mass outbreak raises the specter of civil confinement to separate the infected or exposed from healthy individuals. This might entail isolation of infected persons, quarantine of exposed persons, or quarantine of a geographic area (a cordon sanitaire). New conceptions include “sheltering in place,” which public health authorities compare to a “snow day.” Isolation and quarantine are judicially sanctioned, provided the state acts with reasonable evidence and fair procedures.\(^4\) These interventions, however, raise powerful civil liberties concerns. Among the dilemmas: the logistics of providing individual hearings; the intrusiveness of enforcement (some countries used electronic bracelets, web cameras, and police during the SARS outbreaks); the necessity of offering a humane and habitable environment; and whether to offer compensation for lost work. Beyond all, public health authorities need to maintain the public’s trust. To what extent would orders for civil confinement dissipate it?

**Planning under conditions of uncertainty.** Influenza pandemic preparedness requires consideration of both public health strategy and its legal and ethical implications. Several scientific questions loom: (1) Are the interventions proven cost effective? (2) What combination of measures is most cost effective? (3) During what phase of the pandemic should interventions be implemented? and (4) When should public health measures be discontinued?

The decision to intervene is hard because public health authorities may be acting under conditions of scientific and political uncertainty. It may not be clear whether serologic tests are reliable, vaccines or treatment are safe and effective, and coercive interventions are acceptable to the population. To be effective, agencies may have to intervene at the earliest stages, before the threat level is clear. If interventions are well targeted and timed, then public health officials may prevent untold economic and human harm. However, if they overreach, officials will be accused of disregarding essential economic interests and fundamental human rights.