

PANDEMIC INFLUENZA: ETHICS, LAW, AND THE PUBLIC'S HEALTH

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Editor's Note

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INTRODUCTION

Highly pathogenic Influenza A (subtype H5N1) (H5N1 or virus) has captured the close attention of policymakers who regard pandemic influenza as a national security threat.¹ The virus already is endemic in avian populations in Southeast Asia, with serious outbreaks now in Africa, Europe, and the Middle East.² H5N1 has moved steadily to many regions of the world, surfacing in Europe as far north as Germany, as far west as France,³ and as far south as the Mediterranean and Adriatic seas.⁴ The virus has spread to the Middle East in Iraq, Iran, Saudi Arabia, and Egypt.⁵ It has emerged in impoverished countries such as Nigeria and transitional economies such as India.⁶

Modeling suggests that the virus will eventually affect the entire globe through a number of transmission mechanisms such as commerce, migratory birds, and a highly mobile population.⁷ International trade and travel will play a major role in the spread of the virus. The majority of the outbreaks in Southeast Asia have already been attributed to the movement of poultry and poultry products.⁸ Frequent travel makes it difficult to contain a pandemic. However, even if trade and travel were severely

1. See U.S. DEP'T OF HEALTH AND HUMAN SERVS., HHS PANDEMIC INFLUENZA PLAN 60 (2005) [hereinafter HHS PANDEMIC INFLUENZA PLAN], available at <http://www.hhs.gov/pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf>; HOMELAND SECURITY COUNCIL, NATIONAL STRATEGY FOR PANDEMIC INFLUENZA 2 (2005) [hereinafter NATIONAL STRATEGY FOR PANDEMIC INFLUENZA], available at <http://www.whitehouse.gov/homeland/nspi.pdf>.

2. See World Health Organization (WHO), *Avian Influenza—Spread of the Virus to New Countries*, Feb. 21, 2006, http://www.who.int/csr/don/2006_02_21b/en/index.html.

3. See *id.*

4. See *id.*

5. See *id.*

6. See *id.*

7. See Ira M. Longini et al., *Containing Pandemic Influenza at the Source*, 309 SCI. 1083, 1083 (2005); H. Chen et al., *Establishment of Multiple Sublineages of H5N1 Influenza Virus in Asia: Implications for Pandemic Control*, 103 PROC. OF THE NAT'L ACAD. OF SCI., 2845, 2845 (2006) [hereinafter *Implications for Pandemic Control*].

8. See *Implications for Pandemic Control*, *supra* note 7, at 2845, 2849.

restricted, it is possible that migratory birds still would bring the virus to other continents.⁹

At present, the spread of the H5N1 strain is mainly confined to animal populations. While the virus is highly contagious among birds,¹⁰ it is still rare in humans because of a significant species barrier.¹¹ Confirmed cases of human infection have nonetheless been reported. As of May 29, 2006, 224 cases of H5N1 have been reported, with 127 deaths.¹² Most of these cases are attributable to close contact with infected poultry, particularly at poultry farms and markets, cock-fighting venues, or when poultry is used as backyard pets.¹³ While a few cases of human-to-human transmission have occurred, principally resulting from intimate household contact, transmission is not common beyond one person.¹⁴ The virus appears to be highly pathogenic when occurring among humans, with a reported death rate exceeding 50%.¹⁵ However, because of possible under-reporting, the prevalence, transmissibility, and fatality of H5N1 remain uncertain.

A series of compounding possibilities make it likely that a new influenza pandemic could emerge, although the timeframe and virulence are uncertain. The first five of the following six essential prerequisites for a pandemic have already occurred: (1) a novel viral subtype is identified in animal populations such as swine or poultry, (2) the virus spreads to animals in a wider geographic setting, (3) the virus jumps from animals to humans inefficiently, (4) the virus more efficiently spreads from animals to humans, (5) inefficient human-to-human transmission is documented, and (6) efficient human-to-human transmission emerges. Through adaptive mutation or viral reassortment, the H5N1 virus could become highly transmissible among humans, thus leading to a pandemic outbreak.¹⁶

Recent evidence that an avian influenza virus caused the 1918 pandemic lends credence to the theory that current outbreaks could have pandemic

9. See Dennis Normile, *Evidence Points to Migratory Birds in H5N1 Spread*, 311 SCI. 1225, 1225 (2006).

10. See Laurie Garrett, *Avian Flu Update*, FOREIGN AFF., Sept.-Oct. 2005, available at <http://www.foreignaffairs.org/20050701faessay84401/laurie-garrett/the-next-pandemic.html>.

11. See The Writing Committee of the World Health Organization Consultation on Human Influenza A/H5, *Avian Influenza A (H5N1) Infection in Humans*, 353 NEW ENG. J. MED. 1374, 1379 (2005) [hereinafter *Avian Influenza A (H5N1) Infection in Humans*].

12. See WHO, *Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO*, May 29, 2006, available at http://www.who.int/csr/disease/avian_influenza/country/cases_table_2006_05_29/en/.

13. See Tran Tinh Hien et al., *Avian Influenza A (H5N1) in 10 Patients in Vietnam*, 350 NEW ENG. J. MED. 1179, 1181, 1183 (2004).

14. See WHO, *Avian Influenza: Significance of Mutations in the H5N1 Virus*, Feb. 20, 2006, available at http://www.who.int/csr/2006_02_20/en/index.html.

15. Samson S.Y. Wong & Kwok-yung Yuen, *Avian Influenza Virus Infections in Humans*, 129 CHEST 156, 156 (2006).

16. See Robert G. Webster et al., *H5N1 Outbreaks and Enzootic Influenza*, 12 EMERGING INFECTIOUS DISEASES 3, 3-4 (2006).

potential.¹⁷ Historically, the number of deaths during a pandemic has varied greatly depending on the number of people who become infected, the virulence of the virus, and the effectiveness of preventive measures.¹⁸ Such variables lead to great difficulty in establishing accurate predictions of mortality, and as a result, estimates differ considerably. A mild pandemic, like the 1957 and 1968 pandemics, is likely to cause the death of 89,000 to 207,000 people in the United States¹⁹ and 2 million to 7.4 million people globally.²⁰ Conversely, other studies that extrapolate from the severe 1918 pandemic indicate that in the absence of intervention, an influenza pandemic would lead to 1.9 million deaths in the United States and 180 million to 369 million deaths globally.²¹

Characteristic	Moderate (1957/68-like)	Severe (1918-like)
Illness	90 million (30%)	90 million (30%)
Outpatient medical care	45 million (50%)	45 million (50%)
Hospitalization	865,000	9,900,000
ICU Care	128,750	1,485,000
Mechanical Ventilation	64,875	742,500
Deaths	209,000	1,903,000

Department of Health and Human Services (HHS) Health Outcomes: Number of Episodes of Illness, Healthcare Utilization, and Death Associated with Moderate and Severe Pandemic Influenza Scenarios²²

17. See, e.g., Jeffrey K. Taubenberger et al., *Characterization of the 1918 Influenza Virus Polymerase Genes*, 437 NATURE 889, 889 (2005) (asserting that the 1918 influenza virus polymerase genes more closely resembled avian-like flu strains than those of a reassortant virus); Terrence M. Tumpey et al., *Characterization of the Reconstructed 1918 Spanish Influenza Pandemic Virus*, 310 SCI. 77, 79 (2005).

18. See WHO, *Avian Flu vs. Pandemic Flu* (2005), available at http://www.wvdhhr.org/healthprep/common/avian_vs_pandemic_flu.pdf.

19. See Laurie Garrett, *The Next Pandemic?*, FOREIGN AFF., July-Aug. 2005, available at <http://www.foreignaffairs.org/20050701faessay84401/laurie-garrett/the-next-pandemic.html> (describing the Centers for Disease Control and Prevention's (CDC) prediction of the impact of a "medium-level epidemic"); U.S. DEP'T OF HOMELAND SEC., FLU PANDEMIC MORBIDITY/MORTALITY, available at http://www.globalsecurity.org/security/ops/hsc-scen-3_flu-pandemic-deaths.htm [hereinafter FLU PANDEMIC MORBIDITY/MORTALITY] (last visited Feb. 1, 2007).

20. See WHO, AVIAN INFLUENZA: ASSESSING THE PANDEMIC THREAT, (2005) [hereinafter AVIAN INFLUENZA: ASSESSING THE PANDEMIC THREAT]; World Health Organization, *supra* note 18.

21. See, e.g., FLU PANDEMIC MORBIDITY/MORTALITY, *supra* note 19 (discussing studies performed by the Departments of Homeland Security and Health and Human Services); Michael T. Osterholm, *Preparing for the Next Pandemic*, 84 FOREIGN AFF. 24, 26 (2005). Notably, seasonal (interpandemic) influenza causes worldwide yearly epidemics resulting in 1 to 1.5 million infections. *Id.*

22. Estimates are based on extrapolation from past epidemics in the United States and can be found in the HHS Pandemic Influenza Plan. For the original table, along with other information regarding HHS's planning assumptions, see HHS, *Pandemic Planning Assumptions*, <http://www.pandemicflu.gov/plan/pandplan.html> (last visited Feb. 9, 2007).

An influenza pandemic would also result in massive economic disruption. So far, the virus's global economic impact has been fairly limited. The rural areas of Southeast Asian countries currently are experiencing the principal economic effects, which relate mostly to the losses of poultry and to governmental control measures such as the culling of birds. In Asia, the total direct economic costs due to the H5N1 outbreak amount to \$10 billion.²³ Small and medium-sized farmers, who often have no alternative sources of income, have felt the impact the H5N1 outbreak most acutely. Further, the H5N1 outbreak has severely affected trade in poultry at the domestic, regional, and international level because many countries prohibit the importation of poultry meat from affected regions.

Since great uncertainties exist about the timing, virulence, and general scope of a future human influenza pandemic, any estimate of the economic impact is merely suggestive. On a global scale—extrapolating from the economic disruptions associated with Severe Acute Respiratory Syndrome (SARS)—a 2% loss of global gross domestic product (GDP) (\$800 billion) can be expected.²⁴ If the outbreak were more severe, it could result in a global GDP loss of 6% or \$3.2 trillion.²⁵ Within the United States, a severe pandemic would lower the U.S. GDP by as much as 5%, and a milder pandemic might reduce the U.S. GDP by about 1.5%.²⁶ In addition to these direct costs, a global flu pandemic would implicate a considerable loss of global work output.²⁷ Commerce would sharply decline as people avoid public spaces. The labor supply would shrink as workers become ill or stay home to care for others. The lack of an active workforce would place at risk essential goods and services such as food and water, electricity and gas, and transportation systems.

23. See WORLD BANK, *Report by Global Program for Avian Influenza and Human Pandemic*, in ECONOMIC IMPACT OF AVIAN FLU, available at <http://web.worldbank.org/WBSITE/EXTERNAL/COUNTRIES/EASTASIAPACIFICEXT/EXTEAPREGTOPHEANUT/0,,contentMDK:20713527~pagePK:34004173~piPK:34003707~theSitePK:503048,00.html> (last visited Feb. 1, 2007); UNITED NATIONS ECONOMIC & SOCIAL COMMISSION FOR ASIA AND THE PACIFIC, *An Effective Regional Response to the Threat of a Pandemic*, in 2 SOCIO-ECONOMIC POLICY BRIEF 1 (2005), available at <http://www.unescap.org/esid/hds/avianflu/policy-brief-n1-Oct2005.pdf>.

24. See THE WORLD BANK EAST ASIA AND PACIFIC REGION, SPREAD OF AVIAN FLU COULD AFFECT NEXT YEAR'S ECONOMIC OUTLOOK, available at <http://siteresources.worldbank.org/INTEAPHALFYEARLYUPDATE/Resources/EAP-Brief-avian-flu.pdf> (last visited Feb. 1, 2007).

25. See SHERRY COOPER, THE AVIAN FLU CRISIS: AN ECONOMIC UPDATE, available at <http://www.bmonesbittburns.com/economics/reports/20060313/report.pdf> (last visited Feb. 1, 2007).

26. See CONGRESSIONAL BUDGET OFFICE, A POTENTIAL INFLUENZA PANDEMIC: AN UPDATE ON POSSIBLE MACROECONOMIC EFFECTS AND POLICY ISSUES (2006), available at <http://www.cbo.gov/ftpdocs/72xx/doc7214/05-22-Avian%20Flu.pdf> [hereinafter A POTENTIAL INFLUENZA PANDEMIC] (summarizing the United States government's preparations for an avian flu pandemic).

27. See THE WORLD BANK EAST ASIA AND PACIFIC REGION, *supra* note 24.

Further, therapeutic countermeasures (e.g., vaccines and antiviral medications) and public health interventions (e.g., infection control, social separation, and quarantine) form the two principal strategies for prevention and response. Many of the barriers to effective interventions are technical and have been thoroughly discussed elsewhere.²⁸ This Article focuses on the formidable legal and ethical challenges that have yet to receive sufficient attention.²⁹ Part II examines the major medical countermeasures under consideration as an intervention for an influenza pandemic. This Part evaluates the known effectiveness of these interventions and analyzes the ethical claims relating to distributive justice in the allocation of scarce resources. Part III discusses public health interventions, exploring the hard tradeoffs between population health on the one hand, and personal (e.g., autonomy, privacy, and liberty) and economic (e.g., trade, tourism, and business) interests on the other. This Part focuses on the ethical and human rights issues inherent in population-based interventions. Pandemics can be deeply socially divisive, and the political response to these issues not only impacts public health preparedness, but also reflects profoundly on the kind of society we aspire to be.

I. MEDICAL COUNTERMEASURES: VACCINES AND NEURAMINIDASE INHIBITORS

A. General Considerations

Industrialized countries place great emphasis on scientific solutions. Vaccination and, to a lesser extent, antiviral medication (neuraminidase inhibitors: oseltamivir (Tamiflu®) or zanamivir (Relenza®)), are perhaps the most important medical interventions for reducing morbidity and mortality associated with influenza.³⁰ In the \$6.7 billion Department of Health and Human Services (HHS) influenza plan, \$4.7 billion is allocated

28. See World Health Organization Writing Group, *Nonpharmaceutical Interventions for Pandemic Influenza, International Measures*, EMERGING INFECTIOUS DISEASES 81, 81 (2006) [hereinafter *Nonpharmaceutical Interventions for Pandemic Influenza*] (noting that difficulties in influenza control include “peak infectivity” early in illness and short intervals between cases, among other factors).

29. See, e.g., Jaro Kotalik, *Preparing for an Influenza Pandemic: Ethical Issues*, 19 BIOETHICS 422, 424 (2005). For an example of this lack of attention to law and ethics, see HHS, MEDICAL OFFICES AND CLINICS PANDEMIC INFLUENZA PLANNING CHECKLIST (2006), available at <http://www.pandemicflu.gov/plan/medical.html#3>. This document purports to be a “checklist to help medical offices and ambulatory clinics assess and improve their preparedness for responding to pandemic influenza.” *Id.* However, it does not address the myriad legal and ethical issues that will arise.

30. See Timothy C. Germann et al., *Mitigation Strategies for Pandemic Influenza in the United States*, 103 PROC. OF THE NAT'L ACAD. OF SCI. 5935, 5935 (2006); Anthony B. Iton, *Rationing Influenza Vaccine: Legal Strategies and Considerations for Local Health Officials*, 12 J. PUB. HEALTH MGMT. PRAC. 349 (2006); Klaus Stöhr & Marja Esveld, *Will Vaccines be Available for the Next Influenza Pandemic?*, 306 SCI. 2195, 2195 (2004).

for cell-based vaccine technology and stockpiling experimental vaccine, and \$1.4 billion for antiviral medicines.³¹ Congress recently appropriated \$3.8 billion to address pandemic influenza.³² While Congress appropriated less money than HHS requested, Congress preserved the focus on medical countermeasures. The overwhelming majority of this money is to be spent on the development and purchase of vaccines and antivirals.³³

Internationally, countries have followed suit, devoting the majority of their resources towards medical countermeasures. For example, Russia is planning to have an antiviral stockpile sufficient to cover their entire population.³⁴ Other countries have set less ambitious coverage goals (such as Belgium—30%, Germany—20%, Italy—10%)³⁵ but still will be forced to allocate large amounts for antivirals. Most industrialized countries also are investing significant sums for vaccine development and stockpiles.³⁶

Despite the promise of medical countermeasures, there is a chronic mismatch of public health needs and private control of production. Vaccine production has been unreliable even for seasonal influenza, which is the leading cause of vaccine-preventable mortality; only a fraction of the recommended population is vaccinated each year.³⁷ For example, the United States lost half of its seasonal influenza vaccine supply in 2004-2005 when the United Kingdom withdrew Chiron Corporation's license because of bacterial contamination.³⁸

The best way to ensure pandemic preparedness is to increase the baseline for seasonal countermeasures. The World Health Organization (WHO) asserted that better use of vaccines for seasonal epidemics would help to ensure that manufacturing capacity meets demand in a future pandemic.³⁹ Even though this approach is a good long-term solution, more immediate

31. See A POTENTIAL INFLUENZA PANDEMIC, *supra* note 26; Stephen Spotswood, *HHS Flu Plan Aims to Lift Vaccine Supply*, U.S. MED. (2005), available at <http://www.usmedicine.com/article.cfm?articleID=1210&issueID=82>.

32. See Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006, Pub. L. No. 109-148, 119 Stat. 2680, 2782-87 (2005); see also A POTENTIAL INFLUENZA PANDEMIC, *supra* note 26.

33. HHS, *Pandemic Planning Update*, Mar. 13, 2006, at 2.

34. *Bird Flu: Country Preparations*, BBC NEWS, Feb. 21, 2006, <http://news.bbc.co.uk/2/hi/health/4380014.stm>.

35. *Id.*

36. *Id.*

37. Scott A. Harper et al., *Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices*, 54 MORBIDITY & MORTALITY WKLY. REP. 1, 2-3 (2005); Kathleen M. Neuzil & Marie R. Griffin, *Vaccine Safety—Achieving the Proper Balance*, 294 J. AM. MED. ASS'N 2763, 2763 (2005).

38. SUSAN THAUL, VACCINE POLICY ISSUES: CONGRESSIONAL RESEARCH SERVICE REPORT FOR CONGRESS 7 (2005) [hereinafter CRS REPORT].

39. See WHO, World Health Assembly, STRENGTHENING PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE 5 (2005), available at http://www.who.int/csr/disease/influenza/A58_13-en.pdf.

solutions are needed.⁴⁰ Moreover, supply is difficult to increase because of the lack of market incentives, intellectual property concerns, regulatory hurdles, and liability fears, as discussed below.

Despite these concerns, the global distribution of influenza vaccines is increasing rapidly, but questions remain about global distributive justice. In 2003, over 291 million doses were distributed globally.⁴¹ This is almost forty million doses more than in 2001.⁴² Unfortunately, only 35% of all doses reach the developing countries. Moreover, 85% of the world's supply of influenza vaccine is produced by companies located in eight industrialized countries: France, Germany, Italy, the Netherlands, the United Kingdom, the United States, Canada, and Australia.⁴³ Consequently, 40% of the doses used in central and eastern Europe, 60% of the doses used in the Western Pacific and Southeast Asia, and almost 100% of the doses used in Latin America, the eastern Mediterranean, and Africa are imported from one or more of the vaccine-producing developed countries.⁴⁴ It is quite likely that in the face of a new pandemic, governments will not export any of their nationally produced vaccines until domestic demand is satisfied.⁴⁵ For example, to ensure coverage for approximately half of its population, Canadian health officials have negotiated a contract with their domestic producer to provide five million doses of influenza vaccine.⁴⁶ Health officials in other countries have tried to reach similar agreements without success.⁴⁷ Further complicating matters is recent evidence that H5N1 floods the bloodstream with the virus, further calling into question the effectiveness of antivirals and vaccines.⁴⁸

Moreover, the U.S. government has become too focused on specific pathogens, disproportionately devoting resources towards developing medical countermeasures for the disease of the moment. Whether the threat is anthrax, smallpox, bioterrorism, or influenza, the government targets the immediately salient threat rather than strengthening the public health infrastructure so that it can recognize and respond to a range of risks.

40. *See id.*

41. *See* WHO, *Global Distribution of Influenza Vaccines, 2000-2003*, 40 WKLY. EPIDEMIOLOGICAL REC. 79, 357, 366 (2004), available at <http://www.who.int/wer/2004/en/wer7940.pdf>.

42. *See id.*

43. *See* David S. Fedson, *Pandemic Influenza and the Global Vaccine Supply*, 36 CLINICAL INFECTIOUS DISEASES 1552, 1553 (2003), available at <http://www.journals.uchicago.edu/CID/journal/issues/v36n12/20633/20633.web.pdf>.

44. *See id.* *See generally* JOHN M. BARRY, *THE GREAT INFLUENZA: THE EPIC STORY OF THE DEADLIEST PLAGUE IN HISTORY* (2004).

45. *See* BARRY, *supra* note 44; Stöhr & Esveld, *supra* note 30, at 2196.

46. *See* Fedson, *supra* note 43, at 1154-55.

47. *See id.* at 1555.

48. *See* G. F. Rimmelzwaan et al., *Pathogenesis of Influenza A (H5N1) Virus Infection in a Primate Model*, 75 J. VIROL. 6687, 6688-89 (2001).

States would bear a high proportion of these costs.⁴⁹ This “one bug, one drug” mentality is ineffective because it is impossible to predict and prepare for the wide variety of threats that society could face.⁵⁰ Developing medical countermeasure technologies and public health interventions that could respond to a wide range of emerging biological threats would be a better use of resources.

B. Planning and Market Incentives

The nation’s goal must be to build a system that will ensure a stable, economically viable supply of vaccines capable of meeting potentially massive public needs in a just manner. Public and private strategies rather than private markets are most likely to succeed because of the unique risks and constraints of vaccine production.⁵¹ Private market forces create suffer failures such as high investment costs, limited or variable markets, and regulatory non-compliance, each of which inhibits vaccine development. As vaccine manufacturers leave the industry, they create a risk of severe shortages. In 1967, twenty-six companies were licensed to distribute vaccines in the U.S. market, but less than half of this number are licensed today.⁵² Only four companies currently supply influenza vaccines, with only two manufacturing domestically—MedImmune (live attenuated influenza virus, intranasal (FluMist®)) and Sanofi Pasteur.⁵³

The Institute of Medicine recommends a National Vaccine Authority (NVA) to advance the development, production, and procurement of vaccines.⁵⁴ With or without an NVA, the government can create incentives by boosting demand through seasonal vaccine awareness programs, issuing purchasing contracts, and providing price guarantees or subsidies. Recognizing the need to increase output and availability, the G7 Finance Ministers recently announced a pilot Advance Market Commitment for vaccines of public health importance.⁵⁵

49. See, e.g., HHS PANDEMIC INFLUENZA PLAN, *supra* note 1, at 6 (illuminating some of the responsibilities that states and local planners might face, including: distributing information, planning for vaccine distribution, and implementing immunization registries).

50. Kendall Hoyt, *Bird Flu Won't Wait*, N.Y. TIMES, Mar. 3, 2006, at A23.

51. See WHO, VACCINES FOR PANDEMIC INFLUENZA 10 (2004) [hereinafter VACCINES FOR PANDEMIC INFLUENZA].

52. See Patricia M. Danzon et al., *Vaccine Supply: A Cross-National Perspective*, 24 HEALTH AFF. 706, 706 (2005).

53. See David Brown, *How U.S. Got Down to Two Makers of Flu Vaccine*, WASH. POST, Oct. 17, 2004, at A01.

54. See COUNCIL OF THE INSTITUTE OF MEDICINE, APPENDIX I: STATEMENT ON VACCINE DEVELOPMENT 262 (2001).

55. CTR. FOR GLOBAL DEV., GLOBAL HEALTH POLICY: G-7 TO PILOT ADVANCE MARKET COMMITMENTS 1 (2005), available at <http://blogs.cgdev.org/vaccine/archive/2005/12/>.

Even if vaccination supplies adequately meet mass needs, the distribution of the vaccines to the population remains problematic. Each year, drug companies produce millions of influenza vaccines but never distribute them.⁵⁶ Pandemic influenza would require mass vaccination in a short window of time, probably within months of the advent of an outbreak. Federal stockpiles must meet needs at the local level, requiring systems for transportation, storage, and safe administration of the vaccine. If two doses are required to achieve immunity, health service providers may need a call-back system or immunization registry. At present, the federal strategic plan fails to resolve these vital issues, instead delegating them to the states.⁵⁷

C. Sound Regulation

The vaccine industry must overcome rigorous regulatory hurdles to achieve safety and efficacy while avoiding increased costs and delays. To start, vaccines contain living organisms, making the threat of contamination greater than with drugs. Therefore, vaccines must adhere to higher purity standards than pills because they often are administered by injection.⁵⁸ Accordingly, the Food and Drug Administration (FDA) plays an active role during the development of the vaccine, as well as in its licensing.⁵⁹ Before licensure, the FDA reviews the data from clinical trials to assess the product's safety and effectiveness.⁶⁰ After licensure, the FDA conducts regular manufacturing practice inspections to ensure that the manufacturing facility produces a consistent product.⁶¹ Violations found during these inspections can result in the loss of a manufacturing license; companies must go through a lengthy reapplication process before the FDA allows them to continue producing vaccines for public consumption. Additionally, the FDA requires manufacturers to test each lot of vaccine for contaminants before public release.⁶²

56. See HHS PANDEMIC INFLUENZA PLAN, *supra* note 1, at 24 (citing the need for the availability of at least 81 million treatments, which is enough for about 25% of the U.S. population).

57. See *id.* at 7 (declaring that states and communities should have their own plans in case of an outbreak); see also NATIONAL STRATEGY FOR PANDEMIC INFLUENZA, *supra* note 1, at 24 (positing that one pandemic response action would be to administer the vaccine according to state and local distribution plans).

58. CRS REPORT, *supra* note 38, at 1.

59. See *id.* at 11-14 (presenting some of the Food and Drug Administration's (FDA) review methods, including fast-track drug development and accelerated approval).

60. *Id.* at 14.

61. See *id.* at 7 (describing the FDA's emphasis on the safety and effectiveness of the vaccines).

62. See *id.* at 2-3 (stating that each lot is evaluated based on its purity and potency).

Departing from these onerous regulations, the FDA amended its drug and biological product policies in 2002 in response to the possibility of a serious and immediate health threat.⁶³ Under the so-called “Animal Rule,” the FDA may approve drugs and biological products for marketing based on animal studies when human studies are unethical or infeasible.⁶⁴ The revamped procedure streamlines the process for quickly developing medical countermeasures in the face of a bioterrorism attack or pandemic outbreak.⁶⁵ While this may be an effective regulatory strategy, critics are concerned that the relaxed requirements could put large numbers of human lives at risk⁶⁶ because animal models often do not accurately predict human responses to drugs or biological products.⁶⁷ Using multiple species testing can mitigate, but not entirely remove, this concern.⁶⁸ Thus, the first human users essentially will be involved in a clinical trial. While an immediate threat may justify the need for a streamlined approval process, more public education is required, and care must be taken to avoid abusing the process.

In addition to the federal regulatory regime, states also regulate vaccines. For instance, three states, California,⁶⁹ Iowa,⁷⁰ and New York,⁷¹ regulate thimerosal-containing vaccines, while bills are pending in other states. Because influenza vaccines contain thimerosal, this legislation could undermine federal plans. In addition to federal and state regulation, agencies in other countries regulate vaccines. Therefore, industry faces multiple, overlapping regulatory requirements, which must be reconciled.

Recognizing that this problem of overlapping regulatory requirements is an issue nationally and internationally, the FDA and the European Medicines Evaluation Agency (EMA) recently published “regulatory pathways for licensing of pandemic vaccines.”⁷² Since manufacturers must

63. 21 C.F.R. §§ 314.600-314.650, 601.91 (2005).

64. *See id.* § 314.610 (showing that the animal tests must prove that the drug product is “reasonably likely” to benefit humans).

65. *See id.*

66. Andrew Pollack & William J. Broad, *Anti-Terror Drugs Get Test Shortcut*, N.Y. TIMES, May 31, 2002, at A1.

67. Kathi E. Hanna, *Extraordinary Measures for Countermeasures to Terrorism: FDA’s “Animal Rule,”* 32 HASTINGS CTR. REP. 9, 9 (2002).

68. *Id.*

69. CAL. HEALTH & SAFETY CODE § 124172 (West 2006).

70. IOWA CODE ANN. § 135.39B (2006).

71. *See* N.Y. PUB. HEALTH LAW § 2 (McKinney 2005) (prohibiting women who know they are pregnant from being vaccinated with an influenza vaccine that contains more than 1.25 micrograms of mercury per 0.50 milliliter dose, provided that the Commissioner of Public Health makes a yearly determination that an adequate supply of such low mercury vaccines exists). This provision goes into effect in 2008. *Id.* § 3.

72. *See* VACCINES FOR PANDEMIC INFLUENZA, *supra* note 51, at 13 (stating that this gives companies a more predictable environment for developing and producing the vaccine).

be licensed and begin commercial production in advance of, or soon after, the start of a pandemic, regulatory requirements should be timely, efficient, and well-coordinated.

D. Scientific Information and Intellectual Property

The rapid global dissemination of scientific information will be necessary to effectively respond to a pandemic outbreak. Such dissemination would require the speedy collection and sharing of data involving surveillance and scientific discovery. For example, comparing sequence data from each isolated case allows scientists to better understand and track the movement and evolution of the virus.⁷³ However, sharing information about H5N1 has been problematic. Scientists do not want to release their data until they have received published credit.⁷⁴ Similarly, many countries want to keep information confidential to protect national security and intellectual property (IP) interests. Therefore, international coordination is necessary to facilitate research. Such coordination should include exchanging study results to avoid duplication,⁷⁵ defining expectations and regulations to avoid conflicts in export and import, and supporting standardization to avoid quality divergence in industrialized and developing countries.⁷⁶ In an attempt to encourage collaboration, the WHO has maintained a restricted database, accessible by only a handful of laboratories.⁷⁷ Recently, this system has been criticized for being unnecessarily secretive.⁷⁸ Rather than allowing broad-based access to the data that would facilitate scientific research, the WHO has denied access to many groups.

It is equally important to share manufacturing and technical information. Potential patent disputes should be anticipated in advance because they have significant cost implications for commercial vaccines. The H5N1 virus is most effectively grown in fertilized chicken eggs with modification through reverse genetics.⁷⁹ However, this is a patented technology.⁸⁰

73. Martin Enserink, *As H5N1 Keeps Spreading, A Call to Release More Data*, 311 SCI. 1224, 1224 (2006).

74. *See id.* (quoting an Italian scientist who says, “[i]f publishing one more paper becomes more important, we have our priorities messed up”).

75. Stöhr & Esveld, *supra* note 30, at 2196.

76. JULIE MILSTIEN ET AL., DIVERGENCE OF VACCINE PRODUCT LINES IN INDUSTRIALIZED AND DEVELOPING COUNTRIES, http://www.who.int/immunization_supply/divergence_vaccines.pdf (last visited Feb. 1, 2007).

77. *See Secret Avian Flu Archive*, N.Y. TIMES, Mar. 15, 2006, at A26 (noting that restrictions might encourage otherwise reluctant scientists to share their findings on a limited basis prior to publication).

78. *See id.* (mentioning an Italian scientist who has refused to reveal her data to the WHO's secret database that holds the genetic information of the virus).

79. Emily Singer, *Pandemic Fears Hatch New Methods in Flu Vaccine Industry*, 11 NATURE MED. 4, 4 (2005), available at <http://www.nature.com/nm/journal/v11/n1/full/nm0105-4a.html>.

Newer cell-based technologies, which promise more efficient mass production, are also subject to IP protection.⁸¹ Although IP affords incentives for innovation, it can also impede rapid and large-scale vaccine production in a public health emergency.

The Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) allows countries to grant compulsory licenses to ensure access to essential medicines in a public health emergency.⁸² Compulsory licenses, which afford the right to produce a product without the patent holder's authorization, are usually discussed in the context of life-saving medications for resource-poor countries; however, some have considered compulsory licenses to ensure adequate Tamiflu production.⁸³ Hoffmann-La Roche Inc., the patent-holder until 2016, stated that the global demand is well in excess of production capacity.⁸⁴ It will take ten years of constant production for the company to produce enough of the drug to treat twenty percent of the world's population. However, the company opposes compulsory licensing, citing the scarcity of raw materials, the complex manufacturing process, and the necessity of patent protection to create incentives.⁸⁵

Whatever the merits of compulsory licensing, antivirals will have only limited utility in a pandemic. Gaining access to Tamiflu on time would entail visiting a physician or pharmacist. Because influenza is maximally infectious early in the course of the disease, doctor or pharmacy visits would seriously risk transmission to the public. Moreover, antiviral medications remain only partially effective against H5N1 and may not be effective against a human strain of the virus.⁸⁶ The potential for mass use and patient noncompliance within the five-day course of treatment pose a risk of drug resistance.⁸⁷ Consequently, reliance on stockpiling antivirals, although probably helpful in reducing hospitalizations, will not significantly impede a pandemic.

80. Erika Check, *WHO Calls for Vaccine Boost to Prepare for Flu Pandemic*, 432 NATURE 261, 261 (2004).

81. *Id.* (noting that one company holding a patent on technology might accelerate the process of vaccine selection).

82. *Other Use Without Authorization of the Right Holder*, Part II, § 5, art. 31, Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, available at http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm.

83. Keith Bradsher, *Pressure Rises on Producer of a Flu Drug*, N.Y. TIMES, Oct. 11, 2005, at C1.

84. *See id.* (clarifying that Tamiflu would have to produce at its full capacity).

85. *Id.*

86. Frederick G. Hayden, *Perspectives on Antiviral Use During Pandemic Influenza*, 356 BIOLOGICAL SCI. 1877, 1877-81 (2001).

87. *See id.* at 1880 (explaining the possibility of a loss of the drugs' efficacy, even for those treated over shorter periods of time).

E. Liability and Compensation

Tort liability for the pharmaceutical industry and fair compensation for patients offers a sound dual approach to vaccine policies. The Public Readiness and Emergency Preparedness (PREP) Act, enacted in December 2005, makes manufacturers immune from liability under federal and state law with respect to all claims resulting from the use of medical countermeasures during a pandemic influenza.⁸⁸ The liability protections only apply to products administered or used during the effective period of the declaration of a public health emergency issued by the Secretary of HHS.⁸⁹

The PREP Act also authorizes the Secretary to develop a compensation program for injured individuals. Such a system already exists in the national Vaccine Injury Compensation Program (VICP), but it needs reform. The VICP created a no-fault system that pays for injuries caused by specific immunizations⁹⁰ and Congress added influenza to VICP in 2005.⁹¹ The Federal Claims Court adjudicates compensation based on a Vaccine Injury Table. To recover, claimants must show that a listed vaccine caused their injury. Compensation comes from a Compensation Trust Fund financed by a tax levied on each administered dose.⁹²

Patients can opt-out of VICP, causing a sustained critique that legal liability represents a major disincentive for the industry. The President's influenza plan virtually bans all lawsuits except for willful misconduct and assigns liability determinations to a political figure—the HHS Secretary.⁹³ The political critique, however, overstates the negative influence of liability on vaccine production. Influenza vaccine litigation remains rare, with only ten reported cases during the past twenty years, most of which culminated in small-scale settlements.⁹⁴

88. See Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006, Pub. L. No. 109-148, 119 Stat. 2680, 2818 (2006); see also A POTENTIAL INFLUENZA PANDEMIC, *supra* note 26, at 12.

89. *Id.*

90. See HHS, HEALTH RES. AND SERVS. ADMINISTRATION, NATIONAL VACCINE INJURY COMPENSATION PROGRAM: FACT SHEET (2006), available at http://www.hrsa.gov/vaccinecompensation/fact_sheet.html.

91. *Id.*

92. 26 U.S.C. §§ 4131, 9510 (2000).

93. See *The HHS Pandemic Influenza Plan: Hearing Before the H. Comm. on Government Reform*, 109th Cong. 9 (2005) (statement of Michael Leavitt, Secretary, HHS) (setting out the guidelines for liability protections); see also HHS PANDEMIC INFLUENZA PLAN, *supra* note 1, at 33 (considering the effects of the protections on vaccine manufacturers, distributors, and healthcare providers).

94. See Michelle M. Mello & Troyan A. Brennan, *Legal Concerns and the Influenza Vaccine Shortage*, 294 J. AM. MED. ASS'N 1817, 1818-19 (2005) (charting the results of lawsuits against influenza vaccine manufacturers, most of which resulted in summary judgment in favor of the defendants).

Also, mass usage of an untried vaccine during a public health emergency could result in numerous adverse events. For instance, health care workers and patients might be less likely to volunteer without a fair compensation system, as the failed smallpox vaccination campaign demonstrated.⁹⁵ On the other hand, a no-fault system, like VICP, would provide relief for injured patients and greater certainty for industry. Experimental H5N1 vaccines currently are not covered under VICP, so the new vaccine would need to be added. Moreover, VICP has become adversarial, burdensome on claimants, and time consuming.⁹⁶ A reformed system must account for important issues, such as an overwhelmed program resulting in delays, insufficient money in the compensation trust fund, and injustices caused by excessive burdens placed on patients injured by a new vaccine. In return, the industry should be spared strict liability lawsuits, while remaining liable for recklessness or gross negligence.

F. Ethical Allocation of Scarce Resources

Considerable scientific uncertainty remains in predicting an influenza pandemic. Moreover, it is certain that there will be extreme scarcity of medical countermeasures in the short-term. Although H5N1 vaccines are in clinical trials,⁹⁷ companies cannot meet mass needs without dramatic improvements in production facilities and technologies (e.g., cell-based cultures and dose sparing).⁹⁸ Estimates suggest that the current combined global manufacturing capacity is only capable of making vaccines for 450 million people.⁹⁹ This is an optimistic estimate because it assumes low-dose vaccination, even though this dose might not be fully effective.¹⁰⁰ Given international trade law, which affords a single company exclusive manufacturing rights, along with complex production processes, the same scarcity might occur with antivirals. The United States, for example, has limited capacity, with only two domestic vaccine suppliers and no priority over purchasing orders for Tamiflu.¹⁰¹

95. See INST. OF MED., *THE SMALLPOX VACCINATION PROGRAM: PUBLIC HEALTH IN AN AGE OF TERRORISM* 68 (Alina Baciu et al. eds., 2005).

96. See Myron Levin, *Vaccine Injury Claims Face Grueling Fight*, L.A. TIMES, Nov. 29, 2004, at A1 (noting that a young girl became mentally retarded, physically handicapped, and legally blind after a routine vaccination).

97. See NAT'L INSTS. OF ALLERGY AND INFECTIOUS DISEASE, NAT'L INSTS. OF HEALTH, *QUESTIONS AND ANSWERS: H5N1 AVIAN FLU VACCINE TRIALS (2006)*, available at <http://www3.niaid.nih.gov/news/QA/H5N1QandA.htm> (stating that the National Institute of Allergy and Infectious Disease began their first clinical trial in April 2005).

98. Singer, *supra* note 79, at 4.

99. See David S. Fedson, *Preparing for Pandemic Vaccination: An International Policy Agenda for Vaccine Development*, 26 J. PUB. HEALTH POL'Y 4, 12 (2005) (discussing the possibility that people will require two doses of the vaccine because most people will never have been infected with an influenza virus).

100. Meredith Wadman, *Race is On for Flu Vaccine*, 438 NATURE 23, 23 (2005).

101. Gardiner Harris, *U.S. Stockpiles Antiviral Drugs, but Democrats Call Pace Too*

The most challenging question facing bioethics is how to ration scarce, life-saving resources: “Who shall live when not all can live?”¹⁰² “Blind justice” might dictate a random allocation of scarce interventions, such as a lottery or a first-come, first-served system. Yet, this procedure seems unsatisfying when life-saving countermeasures can be targeted more cost effectively. American society has accepted “need” as the singular principle for allocation of seasonal (interpandemic) influenza vaccine—e.g., the elderly and health care workers.¹⁰³ Given the devastating social, economic, and political ramifications of a serious pandemic, the following rationing criteria are worth consideration.

1. *Prevention/Public Health*

As the historic mission of public health is prevention, countermeasures to impede transmission should be a high priority. Thus, where feasible, rapid deployment of vaccines or prophylaxis to groups at risk of acquiring infection should be used to contain localized outbreaks. For example, ring vaccination of direct contacts in a family, congregate setting, or local community could be an effective intervention that would maximize lives saved.

2. *Scientific/Medical Functioning*

If the first political priority is public health, then it is essential to protect individuals who innovate and produce vaccines or antivirals, provide treatment, and protect the public's health. These are critical social missions necessary to save lives and provide care for the sick. Consequently, priority should be given to key personnel in developing countermeasures, delivering health care, and devising public health strategies.

3. *Social Functioning/Critical Infrastructure*

A large-scale pandemic could result in key sectors of society being unable to function. Many actors and elements are necessary for the public's health and safety: first-responders, security, essential product and

Slow, N.Y. TIMES, Mar. 2, 2006, at A21.

102. John D. Arras, *Ethical Issues in the Distribution of Influenza Vaccines*, YALE J. BIOLOGY & MED. (forthcoming 2006).

103. HHS, HHS PANDEMIC INFLUENZA PLAN, APPENDIX D: NVAC/ACIP RECOMMENDATIONS FOR PRIORITIZATION OF PANDEMIC INFLUENZA VACCINE AND NVAC RECOMMENDATIONS ON PANDEMIC ANTIVIRAL DRUG USE, available at <http://www.hhs.gov/pandemicflu/plan/appendixd.html> (last visited Feb. 1, 2007); Anthony B. Iton, *Rationing Influenza Vaccine: Legal Strategies and Considerations for Local Health Officials*, 12 J. PUB. HEALTH MGMT. PRACTICE 349, 349 (2006); James G. Hodge, Jr. & Jessica P. O'Connell, *The Legal Environment Underlying Influenza Vaccine Allocation and Distribution Strategies*, 12 J. PUB. HEALTH MGMT. PRACTICE 340, 340-41 (2006).

services, critical infrastructure, and sanitation. Similarly, the continued functioning of governance structures, such as the executive, legislative, and judicial systems, is important.

4. *Medical Need/Vulnerability*

As mentioned, medical need is a widely accepted rationing principle. This criterion focuses on reducing serious illness and death among the most vulnerable individuals. It requires a scientific or epidemiologic judgment about at-risk groups that may vary. Seasonal influenza disproportionately burdens infants and the elderly, but highly pathogenic strains may affect young adults, as occurred with the Spanish flu.

5. *Intergenerational Equity*

The “medical need” criterion often favors the elderly because they are the most vulnerable to influenza complications. However, interventions may be less beneficial to the elderly than to younger, healthier populations. Vaccines, for example, may be less effective in older people because of poor immune system function.¹⁰⁴ All human lives have equal worth, but interventions targeted toward the young may save more years of life. Would a “fair innings” principle militate in favor of children, young adults, and pregnant women?

6. *Social Justice/Equitable Access*

What does justice tell us about how to ration scarce, life-saving resources? The foregoing criteria have a clear utility but focus on key personnel and sectors such as government, biomedical researchers, the pharmaceutical industry, health care professionals, and essential workers or first-responders. These apparently neutral categories mask injustice. In each case, individuals gain access to life-saving technologies based on their often high-status employment. This kind of health planning leaves out individuals who are either unemployed or employed in “non-essential” jobs—a proxy for the displaced and devalued members of society. Consequently, public health planning based on pure utility, while understandable, fails to have sufficient regard for the disenfranchised in society.¹⁰⁵

Social justice demands more than “fair” distribution of resources in circumstances of extreme health emergency. The interests of vulnerable populations are undermined well beyond the detriments to their health. A

104. Elizabeth M. Gardner et al., *Age-Related Changes in the Immune Response to Influenza Vaccination in a Racially Diverse, Healthy Elderly Population*, 24 VACCINE 1609, 1610 (2006).

105. See generally Lawrence Gostin & Madison Powers, *What Does Justice Require for the Public's Health?*, 25 HEALTH AFF. 1053 (2006).

failure to act expeditiously and with equal concern for all citizens, including the poor and less powerful, harms the whole community by eroding public trust and undermining social cohesion. It signals to those affected and to everyone else that the basic human needs of some matter less than those of others, and it thereby fails to show the respect owed to all members of the community.¹⁰⁶

7. *Global Justice*

Justice is not bound by national borders but binds the human community around the globe. Scholars such as Martha Nussbaum¹⁰⁷ have drawn attention to the justice requirements of a shared humanity beyond citizenship. Realistically, however, resources will go to those countries where products are owned and manufactured. Major influenza vaccine producers operate and distribute almost exclusively in Europe, North America, Australia, and Japan.¹⁰⁸ This can have devastating consequences for resource-poor countries that cannot compete economically for expensive countermeasures. If all human life has equal value then there would be a strong moral justification for fair rationing from a global perspective. Even from a less altruistic perspective, there are reasons to invest in poor regions. Improved surveillance and response can help in early detection and containment of outbreaks, affording universal benefits.

8. *Civic Engagement/Fair Processes*

Public cooperation in a health emergency is more likely if citizens accept the fairness and legitimacy of allocation decisions. Advance discussion of ethical principles keeps the public informed and engages them in a participatory decisionmaking process. A pilot project on civic engagement found that stakeholders and citizens-at-large, at a high level of agreement, chose a functioning society and reducing deaths as priorities in vaccine allocation.¹⁰⁹ This altruistic consensus is comforting but may not reflect real behavior in a time of crisis, which could involve hoarding, stockpiling, and black marketeering. Citizens will agree to fair allocation if they believe the allocation process is fair. However, if they believe that others are jumping the queue through influence or money, they will be less likely to behave selflessly. This is all the more reason for transparent decisionmaking processes in advance of a pandemic.

106. *Id.*

107. See generally Martha C. Nussbaum, *Patriotism and Cosmopolitanism*, in *FOR LOVE OF COUNTRY?* ix, 4 (Martha C. Nussbaum ed., 2002) (advocating for an allegiance to the worldwide community of human beings).

108. *VACCINES FOR PANDEMIC INFLUENZA*, *supra* note 51, at 4.

109. *PUBLIC ENGAGEMENT PILOT PROJECT ON PANDEMIC INFLUENZA, CITIZEN VOICES ON PANDEMIC FLU CHOICES* 7 (2005).

Planning for an influenza pandemic is vital to success. It requires scientific innovation, modern laws, and ethical action. Private markets cannot create stable supplies of life-saving countermeasures or assure fair allocations. Rather, constructive partnerships among government, industry, and the community can vastly improve survival and functioning in an impending crisis.

II. PUBLIC HEALTH STRATEGIES: ETHICAL AND HUMAN RIGHTS CONCERNS

A. The Importance of Public Health Interventions

The United States has placed a high value on medical countermeasures to prevent or contain a future influenza pandemic.¹¹⁰ Given the limitations of medical countermeasures, however, public health interventions will be vital tools for slowing the spread of an emerging pandemic. Two recent IOM reports have also determined that the United States' emergency medical system is "at the breaking point."¹¹¹ In spite of these medical infrastructure concerns, Congress recently appropriated only \$350 million to upgrade state and local capacity—about 9% of the \$3.8 billion total allocation for pandemic influenza.¹¹² Furthermore, this limited funding will be significantly eroded by a recent \$105 million cut in federal support for state public health¹¹³ and an unfunded mandate for states to purchase antiviral drugs.¹¹⁴

This Part focuses on traditional public health interventions, drawing lessons from past influenza pandemics¹¹⁵ and the outbreaks of Severe Acute Respiratory Syndrome (SARS).¹¹⁶ Unfortunately, public health

110. See Lawrence Gostin, *Public Health Strategies for Pandemic Influenza: Ethics and the Law*, 295 J. AM. MED. ASS'N 1700, 1700 (2006) (noting that 90% of spending on pandemic preparation is devoted to countermeasures) [hereinafter *Public Health Strategies for Pandemic Influenza*].

111. INST. OF MED., HOSPITAL-BASED EMERGENCY CARE: AT THE BREAKING POINT, available at <http://www.iom.edu/CMS/3809/16107/35007.aspx> (last visited Feb. 1, 2007); INST. OF MED., EMERGENCY MEDICAL SERVICES AT THE CROSSROADS, available at <http://www.iom.edu/CMS/3809/16107/35010.aspx> (last visited Feb. 1, 2007).

112. Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006, 42 U.S.C. § 247, Pub. L. No. 109-148, 119 Stat. 2680, 2786 (2005).

113. HHS, FY 2005 BUDGET IN BRIEF 105 (2005), available at <http://www.hhs.gov/budget/05budget/fy2005bibfinal.pdf>.

114. Jeffrey Levi et al., *Working Group on Pandemic Influenza Preparedness: Joint Statement in Response to Department of Health and Human Services Pandemic Influenza Plan*, 42 CLINICAL INFECTIOUS DISEASES 92, 93 (2006).

115. See generally BARRY, *supra* note 44, at 5 (expounding on the lessons learned in the great influenza pandemic of 1918, which the author describes as "the first great collision between nature and modern science").

116. Lawrence O. Gostin et al., *Ethical and Legal Challenges Posed by Severe Acute Respiratory Syndrome: Implications for the Control of Severe Infectious Disease Threats*,

strategies are difficult to evaluate. First, evidence of effectiveness is often historical or anecdotal, with few systematic studies.¹¹⁷ Adequate resources for population-based research are urgently needed.¹¹⁸ Second, an intervention's effectiveness depends on the transmission pattern, which cannot be fully understood in advance. Key issues in the transmission pattern include viral shedding (infectivity during pre- and post-symptomatic stages); mode and efficiency of transmission (large droplet, aerosol, contaminated hands and surfaces, etc.); incubation period (two days between infection to the start of symptoms); and serial interval between cases.¹¹⁹ Third, an intervention's usefulness depends on the pandemic phase. In the pandemic alert period, surveillance, medical prophylaxis, and isolation are important tools. Yet, "[d]uring the pandemic period, the focus shifts to delaying spread . . . through population-based measures."¹²⁰ Thus, the key question is which measure, or combination of measures, works best at each stage of the pandemic? Multiple, targeted approaches are likely to be most effective, but they can have deep adverse consequences for the economy and civil liberties. Even using the most optimistic scenario, containing an emerging H5N1 pandemic at its source will only delay, not stop, mass transmission because of likely simultaneous introductions of the pathogen.¹²¹

The remainder of this Article will examine the ethical and legal issues associated with public health interventions. However, first it is necessary to identify the human rights and ethical principles that will guide this analysis.

B. Ethics and Human Rights

Pandemics can be deeply socially divisive, and the political response to these issues not only impacts public health preparedness, but also is important to a good and decent society. It is for this reason that it is particularly important to show respect for public health ethics and

290 J. AM. MED. ASS'N 3229, 3229 (2003).

117. *But see* Neil M. Ferguson et al., *Strategies for Containing an Emerging Influenza Pandemic in Southeast Asia*, 437 NATURE 209, 209-10 (2005) (modeling systematically the pandemic spread of influenza in Southeast Asia and using studies done previously by the United States and Britain to show the downward trend of deaths that may be caused by an influenza pandemic).

118. INST. OF MED., THE FUTURE OF THE PUBLIC'S HEALTH IN THE 21ST CENTURY 17 (2003) [hereinafter THE FUTURE OF THE PUBLIC'S HEALTH IN THE 21ST CENTURY].

119. *See Nonpharmaceutical Interventions for Pandemic Influenza*, *supra* note 28, at 82-83.

120. *Id.* at 88 (noting that difficulties in influenza control include "peak infectivity" early in illness and short intervals between cases, among other factors).

121. Christina E. Mills et al., *Pandemic Influenza: Risk of Multiple Introductions and the Need to Prepare for Them*, 3 PUB. LIBR. SCI. MED. 1, 4 (2006), available at <http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0030135>.

international law—particularly human rights law—when developing national policy for pandemic influenza. This Section sets out the relevant ethical principles that should be considered when planning to combat a highly pathogenic pandemic influenza outbreak.

1. *International Human Rights*

Basic human rights are inherent to all people because they are human; they are universal, so that people everywhere are “rights-holders;” and they create robust duties for the state.¹²² State duties encompass the obligations to not interfere directly or indirectly with the enjoyment of human rights, to prevent private actors from interfering with human rights, and to take positive measures to enable and assist individuals and communities to enjoy their rights. Basic human rights are protected under international law so that a state can no longer assert that systematic maltreatment of its own nationals is exclusively a domestic concern.¹²³

The main sources of human rights law are the Universal Declaration of Human Rights and two international covenants on human rights: the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR), as well as an optional protocol to ICCPR.¹²⁴ The United Nations has promulgated numerous treaties dealing with specific human rights violations including racial and gender discrimination, the rights of children, genocide, and torture.¹²⁵ Human rights are also protected under regional systems, including those in the Americas, Europe, and Africa.¹²⁶

122. Sofia Gruskin & Daniel Tarantola, *Health and Human Rights* (Francois-Xavier Bagnoud Center for Health and Human Rights, Working Paper Series, Working Paper No. 10, 2000), available at http://www.hsph.harvard.edu/fxbcenter/FXBC_WP10-Gruskin_and_Tarantola.pdf.

123. See LOUIS B. SOHN & THOMAS BUERGENTHAL, *INTERNATIONAL PROTECTION OF HUMAN RIGHTS* 5 (1973).

124. See *Universal Declaration of Human Rights*, G. A. Res. 217(III), U.N. GAOR, 3d Sess., U.N. Doc. A/810 (1948); *International Covenant on Civil and Political Rights*, Dec. 19, 1966, 999 U.N.T.S. 171 [hereinafter ICCPR]; *International Covenant on Economic, Social and Cultural Rights*, Dec. 19, 1966, 993 U.N.T.S. 3 [hereinafter ICESCR].

125. See generally *International Convention of All Forms of Racial Discrimination*, Dec. 21, 1965, 660 U.N.T.S. 195; ICCPR, *supra* note 124; ICESCR, *supra* note 124; *Convention on the Elimination of All Forms of Discrimination Against Women*, Dec. 18, 1979, 1249 U.N.T.S. 13; *Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment*, Dec. 10, 1984, 1465 U.N.T.S. 85; *International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families*, G.A. Res. 45/158, U.N. GAOR, 45th Sess., Supp. No. 49, U.N. Doc. A/45/149 (Dec. 18, 1990).

126. See *Convention for the Protection of Human Rights and Fundamental Freedoms*, Nov. 4, 1950, 213 U.N.T.S. 222; *African [Banjul] Charter on Human and Peoples' Rights*, June 27, 1981, 21 I.L.M. 58; *American Convention on Human Rights*, Nov. 22, 1969, 1144 U.N.T.S. 123.

a. *The Universal Declaration of Human Rights (UDHR)*

The UDHR, adopted in 1948, identified specific rights and freedoms that deserve promotion and protection. The UDHR was the international community's first attempt to establish a common standard of achievement for all peoples and all nations to promote human rights. The UDHR represents a milestone in the struggle of humanity for freedom and human dignity, stating that human rights are self-evident and the highest aspiration of the common people. Article 1 proclaims that all human beings are born free and equal in dignity and rights.

The Universal Declaration is not a treaty, but a resolution with no explicit force of law. Nevertheless, its key provisions have so often been applied and accepted that they are now widely considered to have attained the status of customary international law.¹²⁷ The United Nations' General Assembly has declared that the principles embodied in the Universal Declaration "constitute basic principles of international law."¹²⁸ Moreover, it has "acquired a moral and political authority equal to that of the [United Nations] Charter."¹²⁹ In any event, the Declaration has inspired and influenced many international conventions and is reflected in national constitutions, legislation, and in the decisions of national and international tribunals.

Most relevant to the ethics of public health interventions, the UDHR provides that all people have the right to freedom from arbitrary arrest, detention, or exile; the right of movement and residence within and between the borders of each state, and the right to freedom from discrimination. While the UDHR served as the preliminary description of rights, two binding covenants, the ICCPR and ICESCR, followed.

b. *International Covenant on Civil and Political Rights & International Covenant on Economic, Social and Cultural Rights*

The ICCPR imposes an immediate obligation to respect and to ensure civil and political rights. A sister covenant, the ICESCR, requires state parties "to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its

127. See RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES § 702 (1987) (listing the following state practices as violating customary international law (CIL): genocide; slavery; murder or causing the disappearance of individuals; torture or other cruel, inhuman or degrading treatment or punishment; prolonged arbitrary detention; systematic racial discrimination; and consistent patterns of gross violations of internationally recognized human rights).

128. Creola Johnson, *Quarantining HIV-Infected Haitians: United States' Violations of International Law at Guantanamo Bay*, 37 HOW. L.J. 305, 314 (1994).

129. David W. Johnston, Comment, *Cuba's Quarantine of AIDS Victims: A Violation of Human Rights?*, 15 B.C. INT'L & COMP. L. REV. 189, 194 (1992).

available resources, with a view to achieving progressively the full realization of the rights recognized . . . by all appropriate means, including particularly the adoption of legislative measures.”¹³⁰ The language of progressive realization and maximum resources may have been inserted because economic and social rights typically require greater funding and more complex solutions than civil and political rights. Still, the Committee on Economic, Social and Cultural Rights, established by the ICESCR, made clear that state parties have immediate obligations. Steps towards the goal of full realization must be taken within a reasonably short time. States parties have a minimum core obligation to ensure the satisfaction of each of the rights and should immediately implement legislation and judicial remedies to ensure non-discrimination in the exercise of economic and social rights.¹³¹

These covenants provide a number of rights that are relevant to the implementation of public health interventions including the right to freedom from cruel, inhumane, or degrading treatment or punishment; the right to freedom of movement and residence; the right to freedom from arbitrary detention; and most notably the right to health. The right to health encompasses the international obligation for all nations to promote and protect the health of its civilians, especially by facilitating access to basic health care services. The right to health, however, is not equivalent to a right to health care, nor is it an absolute right. It must be evaluated against both the means available to the state and the biological and socio-economical characteristics of the individual concerned.¹³² Furthermore, the right to health cannot be seen in a vacuum; it depends on the realization of other human rights such as the right to life, the right to privacy and the right to non-discrimination. The right to health thus encompasses a broad spectrum of socio-economic factors and must be extrapolated to the underlying determinants of health such as hygiene, housing, environment, and clean drinking water.¹³³

130. ICESCR, *supra* note 124, at art. 2.

131. See Committee on Economic, Social and Cultural Rights, General Comment 3, The Nature of States Parties’ Obligations, 5th Sess., 1990, ¶ 5, *Compilation of General Comments and General Recommendations Adopted by Human Rights Treaty Bodies*, U.N. Doc. HRI/GEN/1/Rev.7 (May 12, 2004).

132. See Committee on Economic, Social and Cultural Rights, General Comment 14, The Right to the Highest Attainable Standard of Health, 22d Sess., 2000, ¶ 4, *Compilation of General Comments and General Recommendations Adopted by Human Rights Treaty Bodies*, U.N. Doc. HRI/GEN/1/Rev.7 (May 12, 2004).

133. See *id.* ¶¶ 8, 11.

c. Regional Conventions: The European Convention on Human Rights and Fundamental Freedoms and Its Protocols, and The American Convention on Human Rights

The European Convention on Human Rights and Fundamental Freedoms and its protocols (European Convention) and the American Convention on Human Rights (American Convention) identify many of the same rights and liberties as the Universal Declaration, including the right to privacy,¹³⁴ the right to be free from inhumane or degrading treatment,¹³⁵ the right to freedom of movement,¹³⁶ and the right to be free from discrimination—all of which public health measures could violate.¹³⁷

2. Valid Limitations on Human Rights

Human rights have transcending value, but international law allows restrictions when necessary for the public good. The ICCPR's most fundamental guarantees are so essential as to be absolute and no state may derogate from them, even in a time of an emergency. The ICCPR, however, allows state parties to suspend most other civil and political rights in times of national crisis. The state must officially proclaim the public emergency and cannot engage in discrimination. The principal conditions for restraints on civil and political rights are that they must be prescribed by law; enacted within a democratic society; and necessary to achieve public order, public health, public morals, national security, public safety, or the rights and freedoms of others.¹³⁸ However, state parties may not impose restrictions aimed at the destruction of rights or their limitation to a greater extent than provided in the Covenant.¹³⁹

134. See Eur. Council, Convention for the Protection of Human Rights and Fundamental Freedoms as amended by Protocol No. 11, Nov. 1, 1998, Art. 8, available at <http://www.echr.coe.int/NR/rdonlyres/D5CC24A7-DC13-4318-B457-5C9014916D7A/0/EnglishAnglais.pdf> [hereinafter Fundamental Freedoms]; American Convention on Human Rights, Nov. 22, 1969, 1144 U.N.T.S. 123, art. 11.

135. See Fundamental Freedoms, *supra* note 134, art. 3.

136. See Eur. Council, Protocol No. 4 to the Convention for the Protection of Human Rights and Fundamental Freedoms as amended by Protocol No. 11, Nov. 1, 1998, Europ. T.S. 46, Art. 2, available at <http://www.echr.coe.int/NR/rdonlyres/D5CC24A7-DC13-4318-B457-5C9014916D7A/0/EnglishAnglais.pdf>.

137. See Fundamental Freedoms, *supra* note 134, art. 14.

138. See ICCPR, *supra* note 124, art. 12 ¶ 3, art. 18 ¶ 3, art. 19 ¶ 3, art. 21, art. 22 ¶ 2 (permitting "limitations" or "restrictions" on the freedom of movement, religion, expression, assembly, and association).

139. See *The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights*, 7 HUM. RTS. Q. 3, 7 (1985) [hereinafter *Siracusa Principles*] (calling for all limitation clauses to be interpreted strictly and in favor of the human right at issue).

The Siracusa Principles, conceptualized at a meeting in Siracusa, Italy, are widely recognized as a legal standard for measuring the validity of limitations on human rights.¹⁴⁰ The Principles make clear that even when the state acts for a good reason, it must respect human dignity and freedom. Echoing the language of the ICCPR, the Siracusa Principles require that state limitations must be in accordance with the law; based on a legitimate objective; strictly necessary in a democratic society; the least restrictive and intrusive means available; and not arbitrary, unreasonable, or discriminatory.¹⁴¹ International tribunals have relied on the Siracusa Principles to require states to use the least restrictive measure necessary to achieve the public health purpose.¹⁴²

It is far more difficult to think about legitimate limitations on economic, social, and cultural rights. The ICESCR permits “such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society.”¹⁴³ Because the ICESCR includes a right to health, it is best to conceptualize as valid “limitations” those measures necessary to attain health protection for the population. For example, the Covenant requires states to take steps aiming at “prevention, treatment and control epidemic, endemic, occupational and other diseases.”¹⁴⁴ Thus, compulsory measures such as vaccination, treatment, or isolation would be permitted only if necessary to protect public health.

140. See U.N. Econ. & Soc. Council (ECOSOC), *Status of the International Covenants on Human Rights*, U.N. Doc. E/CN.4/1985/4 (Sept. 28, 1984).

141. *Id.* ¶¶ 15-21.

142. See *Enhorn v. Sweden*, 2005 Eur. Ct. H.R. 1; Robyn Martin, *The Exercise of Public Health Powers in Cases of Infectious Disease: Human Rights Implications*, 14 MED. L. REV. 132, 134 (2006) (expounding on the European Court of Human Rights’ use of the substantive requirements of Article 5 that the court consider all alternatives such that it is clear that less severe measures have been considered and that there is no arbitrariness in the deprivation of liberty in any and all circumstances (citing *Chahal v. U.K.*, 1996 Eur. Ct. H. R. 22414/93)).

143. The language of Article 4 suggests that cultural, economic, or social rights can be limited on grounds of the public’s health. The Committee on Economic, Social and Cultural Rights, however, stresses that states have the burden of justifying each element of Article 4: powers must be in accordance with the law, including international human rights, in the interest of legitimate aims, and strictly necessary for the general welfare in a democratic society. Public health powers also must be the least restrictive, of limited duration, and subject to review. ECOSOC, Sub-Comm. on Econ., Soc. & Cultural Rights, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: General Comment No. 14*, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000), available at [http://www.unhcr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En?OpenDocument](http://www.unhcr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En?OpenDocument) [hereinafter General Comment 14].

144. *Id.* art. 12(2)(c).

3. *Public Health Ethics*

These international human rights principles stress the importance of individual rights and freedoms, but make clear that freedoms can be restricted when the public health is threatened. Striking a balance between the individual and the collective can be a difficult task, especially under conditions of scientific uncertainty and crisis. Therefore, it is important to articulate the values of public health ethics that should influence pre-pandemic planning.

a. Public Health Necessity

Public health powers are exercised under the theory that they are necessary to prevent an avoidable harm. Early meanings of the term “necessity” are consistent with the exercise of police powers: to necessitate was to “force” or “compel” a person to do that which he would prefer not to do, and the “necessaries” were those things without which life could not be maintained.¹⁴⁵ Government, to justify the use of compulsion, therefore, must act only in the face of a demonstrable health threat. Public health officials must be able to prove that they had “a good faith belief, for which they can give supportable reasons, that a coercive approach is necessary.”¹⁴⁶

The standard of public health necessity requires, at a minimum, that the subject of the compulsory intervention must actually pose a threat to the community. In the context of infectious diseases, for example, public health authorities could not impose personal control measures (e.g., mandatory physical examination, treatment, or isolation) unless the person was actually contagious or, at least, there was reasonable suspicion of contagion. While this standard is obviously resistant to precise definition, it is important that countries clearly delineate what criteria for suspicion will be used and provide procedural safeguards.

b. Reasonable and Effective Means

Under the public health necessity standard, government may act only in response to a demonstrable threat to the community. The methods used, moreover, must be designed to prevent or ameliorate that threat. In other words, there must be a reasonable relationship between the public health intervention and the achievement of a legitimate public health objective. Even though the objective of the legislature may be valid and beneficial, a public health intervention must be an effective means of combating the

145. THE CONCISE OXFORD DICTIONARY OF CURRENT ENGLISH 728 (6th ed. 1976).

146. James F. Childress et al., *Public Health Ethics: Mapping the Terrain*, 30 J.L. MED. & ETHICS 170, 173 (2002).

public health threat. A policy that entails personal burdens and economic costs is only justified if the government can demonstrate that there is a reasonable chance of protecting the public health.¹⁴⁷ Because it is extremely difficult to exactly define “reasonable chance” for all potential situations, the government has the burden of proof and has to engage in ongoing evaluation of the public health intervention and its effectiveness.

c. Proportionality

The public health objective may be valid in the sense that a risk to the public exists, and the means may be reasonably likely to achieve that goal—yet a public health regulation is unethical if the human burden imposed is wholly disproportionate to the expected benefit. Public health authorities have a responsibility not to overreach in ways that unnecessarily invade personal spheres of autonomy. This suggests a requirement for a reasonable balance between the public good to be achieved and the degree of personal invasion. If the intervention is gratuitously onerous or unfair, it may overstep ethical boundaries.

d. Distributive Justice

This ethical principle requires that the risks, benefits, and burdens of public health action be fairly distributed, thus precluding the unjustified targeting of already socially vulnerable populations. Tom Beauchamp and James Childress view distributive justice as the “fair, equitable, and appropriate distribution in society determined by justified norms that structure the terms of social cooperation.”¹⁴⁸

In the context of public health, this principle requires that officials act to limit the extent to which the burden of disease falls unfairly upon the least advantaged and to ensure that the burden of interventions themselves are distributed equitably.¹⁴⁹ Thus, in the exercise of compulsory powers, distributive justice requires a fair allocation so as not to burden unduly particularly vulnerable populations. Distributive justice has been viewed as so central to the mission of public health that it has been described as its core value. As Dan Beauchamp has said, “[t]he historic dream of public health . . . is a dream of social justice.”¹⁵⁰

147. *Id.*

148. TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 327 (4th ed. 1994).

149. See Council for International Organizations of Medical Sciences, *International Guidelines for Ethical Review of Epidemiological Studies*, 19 *LAW, MED. & HEALTH CARE* 247 (1991); Council for International Organizations of Medical Sciences, *Report of the Fifth CIOMS Core Group Meeting on the Revision of 1991 International Guidelines for Ethical Review of Epidemiological Studies* (2005).

150. Dan E. Beauchamp, *Public Health as Social Justice*, in *NEW ETHICS FOR THE PUBLIC'S HEALTH* 105 (Dan E. Beauchamp & Bonnie Steinbock eds., 1999).

Distributive justice does not merely require a fair allocation of risks and burdens. It also recognizes that public health often distributes benefits such as vaccines, treatment, or other services. Problems of fair benefits allocation arise under conditions of scarcity, where there is a competition for resources. This might occur, for example, with a scarcity of medical treatment in the midst of an influenza pandemic.

e. Trust and Transparency

Public health officials have the responsibility to involve the public in the process of formulating public health policies as well as to explain and justify any infringement on general moral considerations. Public health officials should honestly disclose relevant information to the public. Accordingly, citizens should have the right to request and receive information. Moreover, citizens' input should be solicited.¹⁵¹

The need for transparency stems in part from the government's ethical imperative to treat citizens with respect by offering reasons for policies that infringe on moral considerations.¹⁵² Transparency also is essential to create and maintain public trust and accountability.¹⁵³ Openness and accountability are important to public health governance because of their intrinsic value and capacity to improve decisionmaking. Citizens gain a sense of satisfaction by participating in policymaking and having their voices heard. Even if the government decides that personal interests must yield to common needs, the individual feels acknowledged if she is listened to and her values are taken into account.

Transparency also has instrumental value because it provides a feedback mechanism—a way of informing public policy and arriving at more considered judgments. Open forms of governance engender and sustain public trust, which benefits the public health enterprise more generally. Without public support, and the voluntary cooperation of those at risk, coercive public health interventions would be difficult to achieve. The populace must be able to trust that its government is acting in its best interest.

151. See Childress et al., *supra* note 146, at 174; PUBLIC HEALTH LEADERSHIP SOCIETY, PRINCIPLES OF THE ETHICAL PRACTICE OF PUBLIC HEALTH 3 (2002), available at <http://www.apha.org/codeofethics/ethicsbrochure.pdf> [hereinafter PRINCIPLES OF THE ETHICAL PRACTICE OF PUBLIC HEALTH].

152. PRINCIPLES OF THE ETHICAL PRACTICE OF PUBLIC HEALTH, *supra* note 151, at 4; Jayne Parry & John Wright, *Community Participation in Health Impact Assessments: Intuitively Appealing but Practically Difficult*, 6 BULLETIN OF THE WORLD HEALTH ORGANIZATION 388, 388 (2003), available at <http://www.who.int/bulletin/volumes/81/6/parry.pdf>.

153. See Parry & Wright, *supra* note 152, at 388 (citing the Gothenburg consensus paper, which “makes clear the need for participation to underpin the assessment process in order to maintain values of democracy, transparency and equity”).

In the following Sections, we examine ethical issues raised by major public health interventions available for combating influenza. These interventions often present hard tradeoffs between population health on the one hand, and personal and economic interests on the other. Each Section describes a proposed public health intervention and explains the ethical problems connected with its implementation. An ethical solution to these problems will follow. Because of the incredible strains that pandemic-created crises put on even the best laid plans, in addition to the difficulty in asserting one set of ethical ideals, each Section will also discuss the mitigating factors that might make an ethical “ideal” impracticable. The accompanying recommendations are designed to promote the ultimate ethical ideal, but in a manner sensitive to the practical realities of a pandemic. However, before beginning the ethical analysis of specific public health interventions, it is useful to define these tools, as well as to articulate some of the general themes that run throughout this Article.

D. Public Health Interventions

Given the limitations of medical countermeasures, public health interventions will be vital for slowing the spread of an emerging pandemic.¹⁵⁴ The following Section will briefly identify and describe the various interventions. The Sections after that will explore general ethical concerns that permeate all influenza pandemic public health interventions. Subsequent sections will discuss each intervention in detail, focusing on ethical issues and drawing lessons from past influenza pandemics¹⁵⁵ and the outbreaks of SARS.¹⁵⁶

E. General Ethical Themes in Public Health Responses to a Pandemic

1. Community Participation

The WHO’s 1948 constitution states that “[i]nformed opinion and active co-operation on the part of the public are of the utmost importance in improving health.”¹⁵⁷ Community participation in pandemic preparedness

154. See Gostin et al., *supra* note 116, at 555 (emphasizing that “where feasible, rapid deployment of vaccines or prophylaxis to groups at risk of acquiring infection should be used to contain localized outbreaks”); Gostin, *supra* note 110, at 1700 (elaborating that during the pandemic alert phase of an outbreak important intervention measures include “surveillance, medical prophylaxis, and isolation”).

155. See generally BARRY, *supra* note 44 (chronicling the developments in the 1918 influenza epidemic).

156. See Gostin et al., *supra* note 116, at 3229-36.

157. WHO CONST. pmbl., available at http://www.searo.who.int/LinkFiles/About_SEARO_const.pdf (last visited Feb. 1, 2007) (stating that “[i]nformed opinion and active co-operation on the part of the public are of the utmost importance in the improvement of the health of the people”).

and response is critically important and ethically required. The ethical principles of trust and transparency require that the public be involved in decisions affecting their lives. During a pandemic, many actions taken will impose losses on members of society, both in terms of money and autonomy. Similarly, actions not taken will leave society at risk of disease. Public health policymakers must use education and input from the public to balance the risks of action versus inaction. This will help ensure that the policies ultimately adopted are well-suited to local circumstances and values.

At the national level, community participation will include advocacy, delivery of services, cost-sharing, and support to patients. Each person should have the opportunity to contribute to public discourse and thus must be adequately informed instead of being “managed” by the authorities. The government needs to identify its priorities, expectations, and financial capacity. Thus, an ethically appropriate policy in one country, or even one city, may be ethically inappropriate in another because of varying norms and differing benefits or losses caused by intervention.

Community participation has a positive impact on the success of project development and implementation and can reduce alienation of socially excluded groups.¹⁵⁸ Time and resource constraints may considerably complicate community outreach programs during a pandemic. Consequently, governments must gain the public's trust by providing it with adequate and accurate information well in advance. Of course, some issues will develop very quickly or unexpectedly during a pandemic, precluding advance information. In this case, governments should provide necessary information as quickly as possible, and community involvement in decisionmaking should be as great as allowed by the circumstances of a situation. When expediency does not allow full community involvement before policies are enacted, a post-enactment review process is particularly important to ensure transparency and accountability and should incorporate community involvement.

2. Expanded Research Agenda

The government must consider all possible strategies because it is difficult to predict and evaluate the effectiveness of any specific intervention. The key question is which measure, or combination of measures, works best at each stage of the pandemic. A number of considerations make this difficult to answer. First, evidence of effectiveness is often historical or anecdotal, with few systematic studies

158. See Parry & Wright, *supra* note 152 (noting that community participation also may “reorient power relationships with the professional decision-makers”).

available.¹⁵⁹ Second, an intervention's effectiveness depends on the pandemic's transmission pattern, which is unpredictable.¹⁶⁰ Third, an intervention's usefulness depends on the stage of the pandemic. In the pandemic alert period, surveillance, medical prophylaxis, and isolation are important tools. Yet, during a pandemic, the focus shifts to delaying spread through non-pharmaceutical measures.¹⁶¹ Evaluation of effectiveness is important not only from a public health perspective, but also from an ethical perspective. To the extent that interventions impose costs and burdens on individuals or the population, they are ethically warranted only to the extent that they are effective and proportionate in terms of benefits and burdens.

Multiple targeted approaches are likely to be most effective, but they can have significant adverse consequences for the economy and civil liberties. As such, governments should employ the least restrictive options possible. Given this principle and the uncertain utility associated with public health interventions, evidence of effectiveness is important and relevant to the ethical implications of public health interventions. Therefore, adequate resources for population-based research are urgently needed.¹⁶²

3. Resource Allocation

Perhaps the greatest ethical issues of pandemic preparedness and response deal with the allocation of scarce resources. A pandemic will overtax the immediately available resources of even the richest countries on the planet while overwhelming less wealthy countries. For example, in 1918, influenza-related mortality was highest in the least developed parts of the world and lowest among the wealthiest countries.¹⁶³ Given the greater baseline levels of mortality, the higher prevalence of HIV/AIDS (and many other diseases such as malaria and tuberculosis), and reduced access to health care that is found in many developing countries, one can reasonably expect these countries to experience greater morbidity and mortality from influenza in a modern pandemic as well. At the same time, these countries will have the least resources available to protect their citizens and to slow the transmission of the disease.

159. *But see* Neil M. Ferguson et al., *supra* note 117, at 213-14 (delineating various models and data sources used to predict the success of possible interventions).

160. *See Nonpharmaceutical Interventions for Pandemic Influenza, supra* note 28, at 92 (adding that because of this and other uncertainties, "WHO guidance is subject to revision based on additional information").

161. *See id.* at 88-93 (describing measures such as social distancing, procedures for those leaving or entering infected zones, and hygiene measures and personal protection).

162. THE FUTURE OF THE PUBLIC'S HEALTH IN THE 21ST CENTURY, *supra* note 118, at 6.

163. Niall P.A.S. Johnson & Juergen Mueller, *Updating the Accounts: Global Mortality of the 1918-1920 "Spanish" Influenza Pandemic*, 76 BULL. HIST. MED. 105, 105-15 (2002).

The demands of distributive justice require that resources be expended equitably, with attention paid to meeting the needs of those who are most vulnerable. In the context of pandemic influenza, this means that resources must be used in a fashion that can alleviate the greatest amount of human suffering and death. If the developing world is at the greatest peril from the disease, then wealthy countries have a duty to assist them to provide the greatest degree of protection that is feasible given the worldwide scarcity of resources. Furthermore, at least early in a pandemic, resource sharing will benefit both wealthy and developing countries. Models of influenza transmission indicate that a pandemic can be stopped early on if adequate resources are used,¹⁶⁴ but all available measures are expected only to slow transmission once a full-fledged pandemic is underway.¹⁶⁵ To the extent that a pandemic is likely to begin in a less developed country, effectiveness of the intervention demands that wealthy countries assist poorer countries to combat a nascent pandemic.

Additionally, in all countries, a fair system for allocating health-promoting resources must be developed, as the demand for medical care, hygienic measures, and other resources is likely to exceed the supply. This should be done with attention paid to obtaining the greatest degree of health promotion possible. To the extent possible, there should be transparency and broad participation in the rationing scheme.

4. *International Cooperation and Coordination*

The protection of the public health and national risk management is primarily the responsibility of national authorities. All countries therefore should develop a national influenza preparedness plan. In designing a justifiable containment strategy, each state needs to consider state-specific factors such as national political structures and principles, educational and cultural environment, the prevalence of the virus, and the strengths and weaknesses of the state's health care system. While different national approaches ordinarily are not a problem, considerable variation in response plans could prevent or delay an efficient response in a multi-country public health emergency.¹⁶⁶ Cooperation among national authorities and coordination by international bodies is therefore necessary.¹⁶⁷

164. Neil M. Ferguson et al., *Strategies for Mitigating an Influenza Pandemic*, 442 NATURE 448 (2006).

165. *Id.* at 210-12.

166. Lawrence O. Gostin et al., *The Model State Emergency Health Powers Act: Planning for and Response to Bioterrorism and Naturally Occurring Infectious Diseases*, 288 J. AM. MED. ASS'N 622, 624 (2002).

167. *Id.*

The WHO put particular emphasis on cooperation and coordination in its 2005 International Health Regulations (the Regulations), a revision of the 1969 text. The Regulations require countries to develop, strengthen, and maintain core public health capacities to detect, assess, and notify the WHO of events that may constitute a public health emergency of international concern via National IHR Focal Points in each State Party.¹⁶⁸ In June 2007, the Regulations will become legally binding on all WHO Member States, except those that have rejected them or submitted reservations. In light of the concern surrounding avian influenza, in May 2006, the 59th World Health Assembly adopted Resolution 59.2, which called upon WHO Member States to comply immediately and voluntarily with the provisions of the Regulations relevant to the pandemic influenza risk.

In addition to cooperation at the state level, there is a need for cooperation between international agencies. The response to a pandemic, especially in its early stages, will be borne by many international agencies, including the WHO, the Food and Agriculture Organization (FAO), and the World Organization for Animal Health (OIE). Additionally, national entities, such as the Centers for Disease Control and Prevention (CDC) in the United States, will be responsible for picking up international burdens during a pandemic. It will be important for knowledge gained by one entity to be disseminated quickly to other entities. Further, given the scarcity of resources that will be available to stem a pandemic, it will be important that work done by one agency not be unnecessarily duplicated by others—efforts spent unnecessarily will trade off with other, potentially life-saving efforts.

F. Public Health Surveillance

Surveillance is the backbone of public health, providing essential data to understand the epidemic threat and inform the public. Surveillance strategies include rapid diagnosis, screening, reporting, case management reporting, contact investigations, and monitoring trends. It is clear that surveillance will be necessary to quickly identify and respond to a pandemic influenza outbreak. The revised regulations require that, once a country identifies a signal suggesting human-to-human transmission, the country must immediately investigate and notify WHO of the event because any human influenza caused by a new subtype must be reported to

168. David P. Fidler & Lawrence O. Gostin, *The New International Health Regulations: An Historic Development for International Law and Public Health*, 33 J. LAW, MED. & ETHICS 85 (2006); WHO, *Revision of the International Health Regulations* (2005), available at http://www.who.int/csr/ihr/WHA58_3-en.pdf (last visited Feb. 1, 2007) [hereinafter *Revision of the International Health Regulations*].

WHO. The “triggering criteria” of early pandemic activity cannot be fully set out ahead of time. Public health officials should thus be vigilant and report all plausible signals that a pandemic virus may be emerging.

1. Global Responsibility to Develop Core Surveillance Capacities

Ideally, all countries would have the capacity to perform core surveillance functions. However, such a recommendation is impractical for many developing countries, which often lack the resources for animal or human surveillance and containment of outbreaks.¹⁶⁹ Specifically, in sub-Saharan Africa, the capacity for veterinary and human surveillance is limited or nonexistent.¹⁷⁰ In this and in other impoverished regions, allocating resources for the development or improvement of surveillance infrastructure may divert resources from a country's other, more immediate needs.¹⁷¹ It can be difficult, for example, to convince the government of a developing country that has a high incidence of HIV or malaria to invest scarce resources towards the monitoring of a potential influenza threat.

Developed countries should be aware of this tradeoff and take measures to ensure that enhanced surveillance does not occur at the expense of managing the multitude of ongoing public health threats many developing countries face. Recognizing this imperative, many countries have pledged significant funds to meet the costs estimated by the World Bank to contain avian influenza.¹⁷² These funds will only temporarily address the need for surveillance, however. The avian flu threat might not manifest itself for years, and future pandemics are almost certain to occur. Thus, it would be desirable to pursue the larger goal of creating sustainable public health systems across the globe. To this end, WHO's Commission on Macroeconomics and Health estimates that industrialized countries would have to spend \$27 billion in 2007 to meet global needs for essential public health services.¹⁷³

169. *Public Health Strategies for Pandemic Influenza*, *supra* note 110.

170. Cathy A. Petti et al., *Laboratory Medicine in Africa: A Barrier to Effective Health Care*, 42 *CLINICAL INFECTIOUS DISEASES* 377 (2006).

171. *See id.* (contending, however, that failure to improve surveillance infrastructure ultimately costs more as “unreliable and inaccurate laboratory diagnostic testing leads to unnecessary expenditures”).

172. *See* Beijing Declaration, International Pledging Conference on Avian and Human Pandemic Influenza, Jan. 18, 2006, *available at* <http://siteresources.worldbank.org/PROJECTS/Resources/40940-1136754783560/beijingdeclaration.pdf>; WORLD BANK, AVIAN AND HUMAN INFLUENZA: FINANCING NEEDS AND GAPS 8 (2005), *available at* <http://siteresources.worldbank.org/PROJECTS/2015336-1135192689095/20766293/AHIFinancingGAPSFINAL12-21.pdf>.

173. *See* COMM'N ON MACROECONOMICS AND HEALTH, WHO, MACROECONOMICS AND HEALTH: INVESTING IN HEALTH FOR ECONOMIC DEVELOPMENT 11 (2001), *available at* <http://www.emro.who.int/cbi/pdf/CMHReportHQ.pdf> (adding that the funding required would increase over time, rising to \$38 billion by 2015).

2. *Mitigating Privacy and Autonomy Risks*

Surveillance poses privacy risks as governments must collect sensitive medical information from patients, travelers, migrants, and other vulnerable populations.¹⁷⁴ Many countries have data protection statutes; however, these laws often make exceptions for surveillance in the context of a public health threat.¹⁷⁵ In a crisis situation, however, disclosure may be warranted when the immediate use of the information is necessary for an important public health purpose and disclosure is restricted to the confines of the public health system. Under these circumstances, the identity of the affected person should be protected as much as possible. The inclusion of any uniquely identifiable characteristics, such as a name, government identification number, fingerprint, or phone number should be avoided, particularly when the information is released outside of the public health system. Cases should stay anonymous or encrypted when reasonably feasible. Only the minimum amount of information necessary to achieve the goal should be released, and to as few people as possible.

Screening and testing also can pose serious threats to a person's privacy and bodily integrity. Ideally, public health officials should receive the individual's informed consent prior to performing any medical tests; however, in rare cases, mandatory testing might be necessary to advance the public good. A mandatory testing policy may be permissible when it is clearly necessary and effective in protecting the public health, it is performed by competent public health officials, and the least intrusive means are being used. At a minimum, compulsory testing should be limited to individuals known or at least suspected to be infected and should be done in a fair and non-discriminatory way. In addition, the individuals whose rights are being infringed should be informed of the reasons for the infringement.

Countries should enact public health information privacy laws to require justifiable criteria for data disclosure and to prohibit wrongful disclosures, for example, to employers, insurers, and immigration or criminal justice authorities.¹⁷⁶ Whenever a government authorizes or mandates the

174. See generally Ronald Bayer & Amy Fairchild, *The Limits of Privacy: Surveillance and the Control of Disease*, 10 HEALTH CARE ANALYSIS 19 (2002) (discussing the "ethics of surveillance" through analysis of the history of surveillance and reporting in the context of HIV and other infectious diseases).

175. See, e.g., Eur. Parl. and Council Directive 95/46, arts. 3, 13, 1995 O. J. (L 281) 35 (EC); Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. § 1320 (1996).

176. See Lawrence O. Gostin et al., *Informational Privacy and the Public's Health: The Model State Public Health Privacy Act*, 91 AM. J. PUB. HEALTH 1388 (2001).

disclosure of identifiable health data, it should make public the proposed use of the data, the reason for disclosure, and the extent to which third parties can have access to the data.

G. Limiting Animal/Human Pathogen Interchange

Close proximity between animals and humans poses serious risks as novel pathogens mutate and jump species.¹⁷⁷ Live bird markets, traveling poultry workers, fighting cocks, and migratory birds are vectors for spreading avian influenza.¹⁷⁸ Recently, Influenza (A) H5N1 also has spread to tigers,¹⁷⁹ leopards,¹⁸⁰ pigs,¹⁸¹ domestic cats,¹⁸² and stone martens.¹⁸³ Consequently, an early preventive strategy is critical to limiting animal/human interchange. Strategies to diminish the risk include separation of animal and human populations, health and safety in animal farming, and proper management of diseased or exposed animals.

1. Avoiding Proximity

Safe farming practices and the separation of animals and humans are critically important from a public health and economic perspective. Avoiding proximity between animals and humans can reduce the risk that the avian H5N1 virus will mutate and jump species.¹⁸⁴ The separation is hard to accomplish, however, given a culture of close contact between animals and humans in most countries. For example, the domestication of poultry is often necessary for family survival¹⁸⁵ and in many African and Asian countries, backyard chickens are kept not only for food but also as pets.¹⁸⁶ As one researcher reports, in Hong Kong, “thousands of residents are avid birdwatchers and Kowloon’s famed Bird Garden is one of the world’s largest marketplaces for exotic birds of all kinds.”¹⁸⁷ Given these

177. See William B. Karesh & Robert A. Cook, *The Human-Animal Link*, 84 FOREIGN AFF. 38, 38, 42 (2005).

178. See *Avian Influenza A (H5N1) Infection in Humans*, *supra* note 11, at 1374.

179. See Roongroje Thanawongnuwech et al., *Probable Tiger-to-Tiger Transmission of Avian Influenza H5N1*, 11 EMERGING INFECTIOUS DISEASES 975 (2005).

180. See Food and Agricultural Organization (FAO), *Avian Influenza—Related Issues*, http://www.fao.org/ag/AGAinfo/subjects/en/health/diseases-cards/avian_issues.html [hereinafter *FAO Report*] (last visited Feb. 1, 2007) (reporting that the avian flu has been detected in a leopard in Thailand).

181. See *id.* (noting that in Vietnam the avian flu virus has been discovered in a limited number of pigs).

182. See WHO, *H5N1 Avian Influenza in Domestic Cats* (Feb. 28, 2006), http://www.who.int/csr/don/2006_02_28a/en.

183. See WHO, *Avian Influenza—H5N1 Infection Found in a Stone Marten in Germany* (Mar. 9, 2006), http://www.who.int/csr/don/2006_03_09a/en.

184. See *Public Health Strategies for Pandemic Influenza*, *supra* note 110, at 1701.

185. See *Playing Chicken with Bird Flu*, N.Y. TIMES, Feb. 21, 2006, at A18.

186. See *id.*

187. MIKE DAVIS, *THE MONSTER AT OUR DOOR: THE GLOBAL THREAT OF AVIAN FLU* 45 (2005).

cultural norms, policies separating animal and human populations can cause not only economic hardship but also social unrest. Thus, governments and health care sectors should publicize clear rationales for such separation orders and should initiate and facilitate constructive public discussion about measures that can be taken to suppress the transmission of the virus.

2. *Due Process and Compensation for Culling Decisions*

Given that disease containment strategies can have a profound impact on the lives of individuals, it is ethically imperative that governments carefully construct their animal control policies. While mass slaughter of diseased and exposed animals seems to be the most logical way to achieve eradication of H5N1, it raises significant ethical concerns. A massive culling of birds can have a devastating economic toll on the poultry industries of the affected nations and the livelihoods of all classes of poultry owners, producers and their employees. Economic studies further indicate that those hardest hit by culling of flocks are individual farmers whose sole source of income generation is their poultry.¹⁸⁸ While culling has already played an important role in combating the current avian influenza strain, more convincing scientific evidence of its effectiveness in combating a pandemic influenza is needed for it to be ethically acceptable. Moreover, the appearance of H5N1 in wild birds and mammals has significantly diminished the possible advantages culling could bring.

For culling decisions to be justified, the public benefit should outweigh the personal and economic burdens placed on individuals. Judicial procedures are necessary to fairly balance societal interests and the interests of affected individuals. Governments should incorporate due process into their culling procedures by creating an a priori procedure for fair reviews of a decision to cull. Affected individuals should receive some notice of the proposed containment measure and be permitted to consult with counsel; if they cannot afford counsel, the government should provide one; a subsequent hearing should be held as soon as possible after the decision to cull; and the hearing should be held before an independent and accountable tribunal so as to allow farmers and families to protest erroneous or arbitrary decisions. Ideally, individuals should be allowed to appeal the tribunal's final order.

The extent to which procedures can be implemented depends, however, on the urgency of the emergency and the availability of resources. Public health officials might have to mitigate the ideal procedural standards in certain circumstances. Therefore, at the very least, to ensure non-

188. FAO Report, *supra* note 180.

discrimination and proportionality, public health officials need to publicly justify their decisions and the criteria applicable to the proposed measures. Moreover, the process by which decisions are made should be open to scrutiny, and the basis upon which decisions are made should be publicly accessible. Transparency and community participation in the decisionmaking process will enhance trust and acceptance. Post hoc review measures should be put in place to ensure that decisionmakers are accountable for their actions.

The economic impact of culling decisions, especially on small farmers, is significant. Consequently, the principles of distributive justice and reciprocity require adequate compensation as an ethical imperative.¹⁸⁹ This compensation could include providing alternate sources of food if culling involves depleting a family's source of nourishment. A recommendation of this nature will be useless, however, without financial aid from developed countries. In light of the economic consequences, when poultry export industries and the livelihood of farmers are at stake, it is uncertain that affected countries and individuals will be sincere about reporting the extent to which their flocks are infected.¹⁹⁰ Adequate compensation and open communication will, however, increase the incentive to report outbreaks. In addition, education programs should be directed to decreasing the stigma and social hostility toward infected people and countries. International cooperation and coordination will be essential.

3. *Mitigating the Economic Impact of Trade Restrictions*

Avian influenza causes severe financial and trade impacts. Recent H5N1 outbreaks have adversely affected industry profitability, employment, household livelihoods, and, potentially, food security, in many countries around the globe. Hundreds of millions of domesticated fowl have been culled or have died of infection, devastating domestic poultry production.¹⁹¹ The overall impact of the current strain of avian influenza hurts all livestock sectors by increasing price volatility and generating uncertainties in markets. Research shows that "[t]he short-term costs to economies are considerable, and even short-term market impacts have long-term implications for trading patterns, policy formulation, longer-term investment in the sector, and overall industry and sector development."¹⁹²

189. Karesh & Cook, *supra* note 177.

190. See Lydia Polgreen, *Nigeria Tries TV Jingles, Anything to Chip Away at Ignorance of Spreading Bird Flu*, N.Y. TIMES, Feb. 26, 2006, at 17 ("The rapid spread of the disease to neighboring states, along with the near-impossibility of enforcing bans on moving birds around the country, has led veterinary experts to conclude that the virus will be nearly impossible to stamp out in Africa.")

191. Dennis Normile, *Are Wild Birds to Blame?*, 310 SCI. 426, 426 (2005).

192. TOBY MOORE & NANCY MORGAN, AVIAN INFLUENZA: TRADE ISSUES 6 (2006), available at <http://www.cast-science.org/cast/news/aviantrade.pdf>.

The detection of the avian influenza virus threatens not only to transform the eating habits of the population, but also to sharply curtail the export market. Many countries have introduced large-scale import controls and bans in response to outbreaks. For example, the United States and India ban the import of all birds from affected areas;¹⁹³ European authorities ban poultry and feathers from the Black Sea region;¹⁹⁴ Japan bans the import of all poultry products from France;¹⁹⁵ China, Japan, Malaysia, Singapore, and the Republic of Korea banned imports from the United States following a reported outbreak of a less virulent strain of avian influenza.¹⁹⁶ Some countries even prohibit the importation of birds from nations that vaccinate their flocks, arguing that the vaccines (although usually protective) mask symptoms in infected birds.¹⁹⁷ When considering a trade restriction, ethical considerations should balance the risk to the public's health against the harm that will be done by the restriction.

Nuisance bans on poultry imports because of small, localized outbreaks of the H5N1 virus in exporting countries should be avoided. In May 2005, the OIE advised governments to "allow trade to occur from certain zones or from compartments within a country even though avian influenza may be present in a completely separate zone or compartment in that country."¹⁹⁸ To that end, the regionalization of bans should be promoted. Timely dissemination of all relevant information about influenza outbreaks, interactions among animal and human health authorities, and rapid containment and eradication of the virus where it has emerged are necessary conditions for regional bans to be effective.

H. Community Hygiene and Hospital Infection Control

Hygienic measures to prevent the spread of respiratory infections are broadly accepted and have been widely used in previous influenza pandemics¹⁹⁹ and the SARS outbreaks, although with uncertain benefits.²⁰⁰

193. CNTRS. FOR DISEASE CONTROL AND PREVENTION, EMBARGO OF BIRDS FROM SPECIFIED COUNTRIES (2005), available at <http://www.cdc.gov/flu/avian/outbreaks/embargo.htm>.

194. Commission Decision 2006/7/EC, art. 1, 2006 O. J. (L. 205) 1 (EC).

195. Andrew Jack et al., *Farmers Angry as 20 Countries Ban French Poultry Imports*, FIN. TIMES, Feb. 28, 2006, at 3.

196. FAO Report, *supra* note 180.

197. Elaine Sciolino, *The Discovery of Avian Flu on a Turkey Farm Sends French Poultry Industry Into a Tailspin*, N.Y. TIMES, Feb. 26, 2006, at 17.

198. MOORE & MORGAN, *supra* note 192, at 4.

199. *Influenza: A Report of the American Public Health Association*, 71 J. AM. MED. ASS'N 2068 (1918).

200. See WHO, HOSPITAL INFECTION CONTROL GUIDANCE FOR SEVERE ACUTE RESPIRATORY SYNDROME (SARS) (2003), available at <http://www.who.int/csr/sars/infectioncontrol/en/> [hereinafter HOSPITAL INFECTION CONTROL GUIDANCE]; CENTERS FOR DISEASE CONTROL AND PREVENTION, PUBLIC HEALTH GUIDANCE FOR COMMUNITY-LEVEL PREPAREDNESS AND RESPONSE TO SEVERE ACUTE RESPIRATORY SYNDROME (SARS) (2005),

Infection control includes hand-washing, disinfection, respiratory hygiene, and personal protective equipment (PPE).²⁰¹ Evidence supports the use of hand hygiene and hospital infection control measures, but the effectiveness of disinfection, respiratory hygiene, and PPE in the community is unclear.²⁰² Research is needed to understand the appropriate role of community hygiene in a future pandemic. For example, mask use was common during the 1918 influenza pandemic and SARS outbreaks, but no controlled studies have evaluated its effectiveness.²⁰³

1. Encouraging Community Hygiene

Even if hygienic measures are effective, professionals and the public must use them properly and sustainably. Infection control is challenging (e.g., appropriately-fitted N95 respirators) and must be used reliably until the risk subsides. Studies demonstrate inconsistent infection control in hospitals, and the general public has not uniformly adopted even basic hygiene practices such as hand-washing.²⁰⁴ During the SARS epidemic, people in affected areas used protective measures inconsistently.²⁰⁵

It is important to accurately inform the public of the need for hygienic measures, including the uncertainty of the measures' effectiveness. In past epidemics, misinformation has been rampant, leading to substantial public anxiety, reliance on word of mouth for knowledge, and purchase of ineffective and expensive products.²⁰⁶ Issues of distributive justice arise because ineffective or inaccurate communications will impact the most marginalized members of society most heavily. Marginalized members of society are those without access to alternative, credible sources of information and those for whom wasting resources would have the greatest adverse effects. Finally, information should be provided to the public so individuals are able to make informed decisions about their health. The information disseminated through public education campaigns should be clear, uncomplicated, and not sensational or alarmist. Research indicates that panic is rare during civil emergencies, but that providing clear,

available at <http://www.cdc.gov/ncidod/sars/guidance/I/index.htm>.

201. See HOSPITAL INFECTION CONTROL GUIDANCE, *supra* note 200.

202. See generally *Influenza: A Report of the American Public Health Association*, *supra* note 199; Bernard Lo & Mitchell H. Katz, *Clinical Decision Making During Public Health Emergencies: Ethical Considerations*, 143 ANN. INTERNAL MED. 493 (2005); CENTERS FOR DISEASE CONTROL AND PREVENTION, COMMUNITY CONTAINMENT MEASURES, INCLUDING NON-HOSPITAL ISOLATION AND QUARANTINE (2004), available at <http://www.cdc.gov/ncidod/sars/guidance/D/index.htm>.

203. *Nonpharmaceutical Interventions for Pandemic Influenza*, *supra* note 28.

204. See, e.g., AMER. SOC. FOR MICROBIOLOGY, HAND WASHING SURVEY FACT SHEET, available at http://www.washup.org/assets/fact_sheet.pdf (last visited Feb. 1, 2007).

205. Janice Y.C. Lo et al., *Respiratory Infections During SARS Outbreak*, Hong Kong, 2003, 11 EMERGING INFECTIOUS DISEASES 1738 (2005).

206. Lesley Rosling & Mark Rosling, *Pneumonia Causes Panic in Guangdong Province*, 326 BRIT. MED. J. 416 (2003).

consistent, credible, and instructive information will assist the public in coping with fear.²⁰⁷ It is important to avoid information that fails to treat members of the public as rational agents. The public should be treated as a partner, enhancing the principle of transparency.

Planning for community-level preparedness should account for variations in settlement patterns. Different types of settlements will present unique risks and challenges during a pandemic. Similarly, communities' unique cultural characteristics can interact with emergency preparedness endeavours. Public education campaigns are difficult when multiple languages are spoken in a community and when individuals have varying levels of literacy and access to media. Preparation plans must account for these geographic and cultural differences. They also must include diverse media sources, which can be achieved by encouraging community involvement in the planning and implementation process and by utilizing leaders from community subpopulations.

A lack of mass media infrastructure will impede broad dissemination of information in some areas. Resource constraints also prevent some populations from receiving messages that are distributed via costly media and a lack of governmental infrastructure may make dissemination of messages much more difficult. Furthermore, media may not be universally available to cater to particular subpopulations and insufficiently educated portions of the population.

However, countries should strive to reduce these problems by using existing communication networks. Health care workers and trusted community sources should be consulted and informed about hygiene measures in order to assist communication efforts by tailoring messages and making them accessible to target audiences. Messages should be posted in places such as markets, where the whole community is likely to see them.

2. *Ensuring the Appropriate Use of Hospital Infection Control*

Guidance exists to prevent the SARS-associated corona virus from spreading quickly in hospitals.²⁰⁸ Disinfection, hand hygiene, PPE, and aerosol-generating procedures should be standard hospital practices.²⁰⁹ Because of the historically high attack rate of influenza among health care workers,²¹⁰ the high degree of transmission from people not demonstrating

207. Thomas A. Glass & Monica Schoch-Spana, *Bioterrorism and the People: How to Vaccinate a City Against Panic*, 34 CLINICAL INFECTIOUS DISEASES 217, 218-20 (2002).

208. See, e.g., HOSPITAL INFECTION CONTROL GUIDANCE, *supra* note 200.

209. *Id.*

210. C. Beguin, B. Boland & J. Ninane, *Health Care Workers: Vectors of Influenza Virus? Low Vaccination Rates Among Hospital Health Care Workers*, 13 AM. J. MED. QUAL. 223, 223, 227 (1998).

clinical illness,²¹¹ and the ease of transmission in crowded areas,²¹² health practitioners who do not practice strict infection control may amplify disease transmission. It is vital to train health care workers and monitor the use of such measures. This could be done through legal oversight or licensing requirements.

There also are ethical concerns relating to hospital infection control and distributive justice. The level of resources that can be dedicated to infection control will vary substantially between and within countries. Recognizing this, a fair system of allocating scarce infection control resources should be developed. It is important to involve hospital staff in planning for the implementation of heightened infection controls and the creation of a fair system for determining who carries out high-risk tasks. Cultural sensitivity should be employed and control methods that require restricting valued personal and cultural behaviors (such as the shaving of beards to properly fit masks) should be carried out through consultation with affected people. Additionally, one should ensure that the implemented policies reflect the best available scientific research.

Nations should create training and monitoring programs to ensure that hospitals effectively use standard infection control procedures. Training programs are most effective when based on available science and provide practitioners with the information needed to minimize risks to them and their patients. Programs should be created with the involvement of practitioners, while implementation of these programs should be adapted to the specific features of health care institutions.

Limitations may impede countries' abilities to implement an ideal training and monitoring program. Some countries will lack the resources to purchase adequate PPE for a disease of long duration, while other countries may lack sufficient health care infrastructure to implement new programs on a speedy basis. Civil unrest may impede monitoring of programs. In such cases, legal infrastructure may have to be developed to enforce compliance with training and monitoring efforts.

Alternatives exist for countries facing substantial limitations. The strictness of infection control may have to be relaxed; for example, surgical masks may have to be substituted for N95 respirators. If areas do not have access to isolation rooms, segregating infectious patients into separate wards or hospitals or recommending home stay for mildly ill patients may be appropriate. Additionally, training without full oversight may be necessary should monitoring become infeasible.

211. C. Fraser et al., *Factors that Make an Infectious Disease Outbreak Controllable*, 101 PROCS. OF THE NAT. ACAD. OF SCI. 6146, 6151 (2004).

212. *Nonpharmaceutical Interventions for Pandemic Influenza*, *supra* note 28.

Countries will also have to develop a method to ration scarce protective equipment. Governments will have to determine how to distribute masks and other PPE in a fair manner. Such plans should give serious consideration to questions of justice and seek to find a rationing scheme that maximizes health protection. Plans should be devised openly, with an opportunity for both experts and the public to be heard. It is important to enact a fair distribution process.

Additionally, policymakers will have to address the problem of critical shortages in infection control and patient care equipment (e.g., particulate respirators, surgical facemasks, hand sanitizers, disinfectants, ventilators, intensive care beds, and the like).²¹³ Given the potential duration and scope of a pandemic, even increased production of PPE will be overwhelmed by the demand, especially if use in hospitals and the community is widespread. International collaboration will be needed to address this problem. Further research is needed to develop reusable respirators²¹⁴ and to determine the effectiveness of alternatives to N95 respirators.²¹⁵ It is critical that research is conducted collaboratively and that results are shared in a fashion that fosters trust and transparency. Cooperation between companies, governments, and researchers will facilitate improved production and greater efficiency at meeting shortages of equipment.

I. Decreased Social Mixing/Increased Social Distance

Past experience shows that social separation and community restrictions form a significant response to pandemics.²¹⁶ There is limited evidence that school closure reduces seasonal influenza transmission,²¹⁷ and it is assumed that decreased social mixing slows the spread of respiratory disease.²¹⁸ Thus, societies have closed public places and cancelled public events in the face of pandemics. As fear rises, individuals may shun social gatherings. Predicting the effect of policies to increase social distance is difficult because infected persons and their contacts may be displaced into other settings, and individuals may voluntarily separate in response to perceived

213. Donald G. McNeil, Jr., *States and Cities Lag in Readiness to Fight Bird Flu*, N.Y. Times, Feb. 6, 2006, at A1 (predicting that 67% of all intensive care beds would be filled with patients suffering from influenza).

214. INST. OF MED., REUSABILITY OF FACEMASKS DURING AN INFLUENZA PANDEMIC: FACING THE FLU 63 (2006), available at <http://www.nap.edu/catalog/11637.html>.

215. *Id.* at 68.

216. See AVIAN INFLUENZA: ASSESSING THE PANDEMIC THREAT, *supra* note 20, at 6. See generally Alexandra Minna Stern & Howard Markel, *International Efforts to Control Infectious Diseases, 1851 to the Present*, 292 J. AM. MED. ASS'N 1474 (2004).

217. Anthony Heymann et al., *Influence of School Closure on the Incidence of Viral Respiratory Diseases Among Children and on Health Care Utilization*, 23 PEDIATRIC INFECTIOUS DISEASE J. 675, 677 (2004).

218. *Nonpharmaceutical Interventions for Pandemic Influenza*, *supra* note 28, at 81.

risk.²¹⁹ For these reasons, additional research needs to be conducted on behavior during epidemics and the effects of social distancing on transmission.

Social separation, particularly for long durations, can cause loneliness and emotional detachment, disrupt social and economic life, and jeopardize individual rights. Community restrictions raise profound questions of faith (religious worship), family (funeral attendance), and protection of the vulnerable (food, water, clothing, medical care).

1. Government Authority and Accountability

Undoubtedly, most judicial systems would uphold reasonable community restrictions, but legal and logistical questions loom: Who has the power to order closure, under what criteria do they have such power, and for how long? What threshold of disease should trigger closure, and should thresholds be different for different entities? Under what circumstances should compensation for closures be paid? What should be the penalties for non-compliance? Enforcement and assurance of population safety remain critically important, but unanswered, questions in most countries.

One might fear that governments would restrict personal liberties unnecessarily. This could occur through implementing restrictions before they are needed, extending restrictions beyond a disease crisis, or enacting restrictions that do not decrease influenza transmission. In these situations, closures could encroach on the important values of necessity and proportionality. Furthermore, it is important to remember that restrictive policies will be borne most heavily by those with the fewest resources, so errant social distancing actions have distributive justice implications. Lastly, one might worry that governments would use social distancing in a discriminatory fashion, scapegoating ethnic or religious minorities, or using social distancing to pretextually crack down on dissidents who assemble to protest.

Ideally, questions of government authority and accountability would be answered by policy decisions made before a pandemic hit and created as part of an open and transparent process that encourages input from all portions of society. Governments should explicitly define who has the power to order social distancing strategies, and for what period of time. Governments should also clearly state the criteria under which such power is exercisable and clearly delineate the legitimate bases for any differential treatment. Penalties should be proportional to offenses and not based on irrational fears or discriminatory beliefs.

219. Ferguson et al., *supra* note 117, at 211-12.

However, one must recognize that detailed pandemic influenza preparations are not the highest priorities for many countries dealing with important and immediate concerns. Furthermore, some countries lack the legal and governmental infrastructures to implement the ideal plan outlined above. At the very least, governments should dedicate themselves to non-discrimination and transparency before an influenza pandemic occurs. It is important that social distancing policies are implemented fairly and with broad planning involvement. This will not only help safeguard important ethical considerations, but also will improve the likelihood that the public will accept social distancing. Given that compliance with social distancing instructions will be difficult to enforce, public acceptance is critical to the measures' success.

2. *Workplace Closings*

Workplace and school closings present difficult ethical issues. Apart from the uncertainty of their effectiveness, the most important questions are those of distributive justice. Workplaces represent the livelihoods of both employees and entrepreneurs, so closing them can cause severe financial hardships. Lost profits caused by closures may force companies to go out of business, leading to job losses and other economic hardships. These problems may have a significant effect on anyone, but especially for those living at a subsistence level. Prior to an emergency, public health authorities should cooperate with industry and trades unions to establish mutually agreeable work closure procedures. However, for situations where workplaces should close but do not, employment protections are needed for workers who wish to comply with a social distancing order against the wishes of their employer. Similarly, one can imagine businesses closing in compliance with instructions, but workers seeking other work for need of income. Government needs mechanisms to encourage compliance with a social distancing order. Though governments should retain the legal power to enforce closures if absolutely necessary, it would be preferable to subsidize lost profits and incomes as necessary. The latter approach was used extensively in countries affected by SARS for people placed in quarantine.²²⁰

Practical constraints prevent some countries from being able to enact this solution. Many countries have more pressing needs than addressing a potential pandemic. Furthermore, some countries may be unable to provide compensation for closure. In 1918, each wave of the pandemic lasted for

220. MARK A. ROTHSTEIN ET AL., QUARANTINE AND ISOLATION: LESSONS LEARNED FROM SARS 139 (2003), available at <http://www.louisville.edu/medschool/ibhpl/images/pdf/SARS%20REPORT.pdf>.

several months, and most locations were hit by multiple waves.²²¹ The amount of resources needed to compensate for lost income or profits for this amount of time may be well out of the reach of many of the world's governments.

In light of these constraints, governments should, at the very least, weigh seriously the risks to health and welfare from workplace closures and other social distancing measures against the preventive effects on disease transmission. For each country, the balance of risks may be resolved differently, depending on the country's resources and financial situation of the population. Countries should consider tactical closures if necessary. Perhaps only those entities that most facilitate transmission should be closed. Schools have been identified as a primary driver of seasonal influenza²²² and are also believed to be a substantial factor during pandemics. Countries might also consider using closures as a means to buy time for other preparations. Finally, closures could be implemented until the level of disease in a community exceeds a predetermined level and then relaxed, with the hope of slowing the initial spread of disease through the community.

3. Provision of Necessities

If people are instructed to avoid public places or if those places are required to close, there will be a need for people to procure food, medicine, and other necessities. Similarly, stoppage of mass transit may prevent people from being able to access facilities that remain open, and it may prevent some people from being able to seek medical care. There is a distributive justice concern relevant to all of these issues—namely, those with the least resources are least likely to be able to procure additional resources before closures occur. They are also the least likely to have private transportation available to seek medical care. Thus, they are both less likely to be able to receive care and more likely to have to remain in homes with infectious people.

Ideally, governments would set up networks for the distribution of necessary provisions to citizens' homes. Distribution would be conducted in a manner that takes into account ease of access in particular communities. It would be consistent and reliable and provide necessities such as food and medicine for the duration of social distancing measures. It should also be conducted in such a manner that minimizes interaction with potentially infectious people and infection control precautions should be employed to decrease the likelihood that supply distributors will vector disease. Transportation for medical care should be provided as needed by

221. Johnson & Mueller, *supra* note 163, at 107.

222. See Ferguson et al., *supra* note 117; Germann et al., *supra* note 30.

personnel who are apprised of the risks involved and provided with appropriate personal protective equipment. Similarly, a program should be put in place for the removal of bodies from homes in a safe and efficient manner.

Resource constraints and logistical difficulties are likely to impede such a program in many areas. Many governments may lack the resources to provide food, medicine, and other necessities to its citizens during a pandemic. Even if the resources are available, the workforce needed to conduct distribution may be absent, especially at the height of a pandemic. Furthermore, there may be a lack of people who want to interact closely with potentially infectious people to allow such a system to function. This may be especially true for medical transport and mortuary services.

At the least, governments should try to facilitate the provision of resources before areas are affected by disease. To the extent possible, governments should give advance warning of disease and make recommendations about how much food, medicine, and other supplies should be stockpiled. If possible, governments should provide these for people unable to afford their necessities. Governments should provide access to medical care to the greatest extent possible and assign public safety officers for this purpose. Governments also should provide a means by which people who have recovered from influenza (and are therefore immune), could assist others in the provision of necessities.

J. International Travel and Border Controls

Transnational public health law is increasingly important in global health, as evidenced by the WHO's International Health Regulations and national agencies' proposed communicable disease regulations.²²³ These legal initiatives reflect recommendations for border controls by the WHO.²²⁴ Transnational containment measures can include entry or exit screening, reporting, health alert notices, collection and dissemination of passenger information, travel advisories or restrictions, and physical examination or management of sick or exposed individuals. These kinds of powers were exercised in Asia and North America during the SARS outbreaks, although their effectiveness is not established.²²⁵ The IHR also

223. HHS., Quarantine, Inspection, Licensing Rule, 42 C.F.R. §§ 70-71 (2005).

224. WHO, WHO SARS RISK ASSESSMENT AND PREPAREDNESS FRAMEWORK (Oct. 2004), available at http://www.who.int/csr/resources/publications/CDS_CSR_ARO_2004_2.pdf; INST. OF MED., QUARANTINE STATIONS AT PORTS OF ENTRY: PROTECTING THE PUBLIC'S HEALTH (2005).

225. See David M. Bell & World Health Organization Working Group on Prevention of International and Community Transmission of SARS, *Public Health Interventions and SARS Spread, 2003*, 10 EMERGING INFECTIOUS DISEASES 1900 (2004); Ronald K. St. John et al., *Border Screening for SARS*, 11 EMERGING INFECTIOUS DISEASES 6 (2005).

authorizes sanitary measures at frontiers or on conveyances, such as inspection, fumigation, disinfection, pest extermination, and destruction of infected or contaminated animals or goods.²²⁶

1. *Economic Impact of International Travel and Border Controls*

Sovereign nations seek to safeguard their citizens' health from external threats, even in a global world where people, animals, and goods rapidly travel across state boundaries. Although border protection is legitimate, it can severely disrupt travel, trade, and tourism. The World Trade Organization (WTO) defends free commerce but permits science-based trade restrictions to protect the public's health.²²⁷ As with trade restrictions, protection of the public's health needs to be balanced against the global economic impact of any travel restrictions or border control policies. Closure of borders will have an enormous global economic impact. World travel and tourism account for about 10% of global GDP and 8% of global jobs, generating more than \$4 trillion in economic activity and over 200 million jobs in 2005.²²⁸ During the SARS outbreaks, tourism in Asia dropped 30% to 80% for various countries in the region. After travel bans were put in place, almost half the planned international flights to Southeast Asia were cancelled. Even Australia saw a 20% decline in international arrivals. Even if countries will not officially close their borders during an influenza pandemic, voluntary social distancing would disrupt trade, transport, and travel.²²⁹ In fact, studies suggest that European travel bookings have already diminished due to H5N1 fears.²³⁰

Given the sensitivity of economic disruptions of trade and travel during a pandemic, international coordination of border control policies is essential to avoid misunderstanding and promote cooperation. While the economic impact of a pandemic will be considerable for both developed and developing countries, the long-term consequences will be harder to overcome for the latter. Industrialized countries should be aware of this when making decisions with transnational impact. Governments should only take those measures that are necessary to address the actual risk to the community. Travel and border control measures should be implemented in a non-discriminatory fashion, and only when the harms caused by the intervention are proportionate to the benefits.

226. See *Revision of the International Health Regulations*, *supra* note 168; see also 42 C.F.R. §§ 70-71.

227. See, e.g., Appellate Body Report, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*, ¶ 172, WT/DS135/AB/R (Mar. 12, 2001).

228. See COOPER, *supra* note 25.

229. See *id.*

230. See *id.*

2. *Governmental Transparency and Coordination*

Given the transboundary nature of travel advisories as well as the economic impact they can have on affected countries, it should be left to the WHO to issue transparent and clearly justified travel recommendations in accordance with the revised IHR. Individual countries should communicate all relevant information on the emergence of a public health threat to the international community. Ultimately, it is the responsibility of the national government to use any policy instruments available to ensure compliance with the requirements of the new IHR. Reporting and surveillance responsibilities may be beyond the capacity of developing countries. The industrialized countries should show solidarity and be open in the way they carry out health protection responsibilities.

Fear of infection and uncertainty about the risk and virulence of the virus can have a negative impact on the global economy. Reactive and uncoordinated national actions to close borders or embargo trade could fuel unfounded fears in the early days of a pandemic, similar to the early stages of the SARS epidemic when public fears were amplified by concerns that some governments were withholding information about the disease. To avoid unwarranted travel disruptions and economic burdens governments have the responsibility to honestly disclose credible scientific information as early as possible.

3. *Civil Liberties*

International travel and border control also can infringe upon civil liberties. The freedom of movement is a basic right protected by national laws and international treaties, but it is subject to limits when necessary for the public's health.²³¹ In particular, these strategies can present serious privacy risks. For example, containment measures may require the travel industry to collect and disclose passenger data.²³² Privacy burdens are justified only if necessary to obtain high-quality surveillance data and in accordance with fair information practices. To avoid discrimination and to ensure proportionality, public health officials should inform the affected individuals about the reasons for the infringement, the intended use of the information and the extent of third parties access to the data.

231. *Shapiro v. Thompson*, 394 U.S. 618 (1969); General Comment, Human Rights Comm., Continuity of Obligations Under the International Covenant on Civil and Political Rights, U.N. Doc. CCPR/C/21 (1999).

232. Ctrs. for Disease Control and Prevention, "Regulatory Impact Analysis of Proposed 42 C.F.R. Part 70 and 42 C.F.R. Part 71," *available at* http://www.cdc.gov/ncidod/dq/nprm/docs/draft_ria_final.pdf (last visited Feb. 1, 2007).

K. Isolation and Quarantine

The terms “quarantine” and “isolation” often are used interchangeably, but they are, in fact, distinct. The modern definition of quarantine is the restriction of the activities of asymptomatic persons who have been exposed to a communicable disease, during or immediately prior to the period of communicability, to prevent disease transmission.²³³ In contrast, isolation is the separation, for the period of communicability, of known infected persons in such places and under such conditions as to prevent or limit the transmission of the infectious agent.²³⁴ Quarantine and isolation can be accomplished by various means, including having the person stay in his or her home, restricting travel out of an affected area, or having the individual stay at a designated facility.²³⁵ Whatever techniques are used, it is important to treat symptomatic, potentially exposed, and non-exposed populations differently. It would be inappropriate to place infected individuals in the same room as those who are only potentially exposed.

Isolation and quarantine were used widely in Asia and Canada during the SARS outbreaks in 2003.²³⁶ In Toronto, between 13,000 people²³⁷ and 30,000 people²³⁸ were quarantined. In Beijing and Taiwan those numbers were even higher—specifically, 30,000 people in Beijing and 131,000 people in Taiwan were quarantined.²³⁹ While quarantine and isolation played a major role in the containment of SARS, they will be less appropriate as containment measures during a pandemic influenza. Unlike SARS, influenza’s transmission characteristics allow little time for isolation and quarantine.

233. See *id.* at 541-43 (describing two forms of quarantine: absolute and modified); see also Daniel S. Reich, *Modernizing Local Responses to Public Health Emergencies: Bioterrorism, Epidemics, and the Model State Emergency Health Powers Act*, 19 J. CONTEMP. HEALTH L. & POL’Y 379, 406-07 (2002) [hereinafter *Modernizing Local Responses*]; *Revision of the International Health Regulations*, *supra* note 168 (defining quarantine as “the restriction of activities and/or separation from others of suspect persons who are not ill . . . in such a manner as to prevent the possible spread of infection or contamination”).

234. See CONTROL OF COMMUNICABLE DISEASES MANUAL 539-40 (Abram S. Benenson ed., 16th ed. 1995) (describing six forms of isolation: strict, contact, respiratory, tuberculosis, enteric precautions, drainage/secretion precautions); see also Marguerite M. Jackson & Patricia Lynch, *Isolation Practices: A Historical Perspective*, 13 AM. J. INFECTION CONTROL 21 (1985).

235. U.S. Dep’t of Homeland Sec., *Flu Pandemic Mitigation: Quarantine and Isolation*, available at http://www.globalsecurity.org/security/ops/hsc-scen-3_flu-pandemic-quarantine.htm. (last visited Feb. 1, 2007).

236. See Gostin et al., *supra* note 116.

237. Jane Speakman, *Quarantine in Severe Acute Respiratory Syndrome and Other Emerging Infectious Diseases*, 31 J.L. MED. & ETHICS 63 (2003).

238. *Id.* at 5.

239. *Id.*

Whatever their effectiveness, quarantine and isolation are the most complex, not to mention legally and ethically controversial, of the public health powers. Quarantine and isolation represent the tension between the interests of society in protecting and promoting the health of its citizens and the individual's rights of privacy, non-discrimination, freedom of movement, and freedom from arbitrary detention.²⁴⁰ The legitimacy of such coercive public health powers rests on a careful balancing of these competing interests,²⁴¹ with the public benefit outweighing the burden quarantine may place on individual rights. Additionally, each country should comply with the internationally agreed upon Siracusa principles, which hold that restrictions of liberty should be legal, proportionate, necessary, and according to the least restrictive means that are reasonably available.²⁴²

1. *Legal Authority*

Clearly defined jurisdictional boundaries and limits on governmental power are necessary to create public accountability. Statutory criteria should incorporate rigorous scientific measures of risk and allow quarantine only when necessary for the public's health. Governments should use coercive health measures only when a disease is known through extensive scientific study to be contagious. Moreover, governments should limit application of the measures to those actually exposed to the disease.²⁴³

Occasionally, resource and time constraints will justify immediate government action without prior medical testing of each individual. In addition, the availability of accurate tests and competent medical staff can be limited. However, to ensure the legitimacy of such measures, public health authorities should fully and honestly disclose their reasons for action and allow community participation in such decisions. Transparency will enhance public trust and acceptance of the proposed containment measures.²⁴⁴

2. *Due Process (Natural Justice)*

In addition to substantive protections, judicial procedures—specified in terms of the process, rather than the outcome—are necessary to ensure the legitimate use of isolation and quarantine. Ideally, quarantine and isolation

240. *Id.* at 3.

241. *Id.* at 4.

242. See *Siracusa Principles*, *supra* note 139.

243. See *Modernizing Local Responses*, *supra* note 233.

244. Daniel Markovitz, *Quarantines and Distributive Justice*, 33 J.L. MED. & ETHICS 323, 323 (2005); DAVID HEYMAN, CTR. FOR STRATEGIC AND INT'L STUD., MODEL OPERATIONAL GUIDELINES FOR DISEASE EXPOSURE CONTROL 16-17 (2005), available at http://www.csis.org/media/csis/pubs/051102_dec_guidelines.pdf.

would affect only those that are actually infected with H5N1. However, such infallibility is unlikely. Therefore, governments should design judicial procedures that reach toward the more feasible goal of protecting the public health while minimizing human rights violations and ethical concerns.

Of particular concern is the protection of groups of people—especially minority populations—from the inappropriate use of state power. Regardless of a country's judicial system and infrastructure, governments should avoid restrictions on individual movement that are arbitrary, unreasonable, or discriminatory. Isolation or quarantine orders should last no longer than scientific review justifies. Public health officials should publicly explain their decisions and re-evaluate any orders on a regular basis. Moreover, countries should have procedural mechanisms for groups to challenge the unjustified use of quarantine or isolation power.

As important as individual due process rights are, the urgency of a pandemic outbreak might preclude individual hearings. Many countries do not possess the judicial infrastructure to cope with the volume of hearings that would result from a mass quarantine, particularly since the high morbidity and mortality associated with a highly pathogenic influenza pandemic would strain the already existing infrastructure. However, developing countries with strong judicial infrastructures should maintain individualized due process to the extent feasible.

3. *Monitoring and Enforcement: Voluntary or Least Intrusive Means*

Quarantine and isolation should be voluntary whenever possible. When mandatory containment is necessary, governments should first apply the least restrictive measures followed, when necessary, by a graded application of more restrictive measures.²⁴⁵ For example, while Canadians generally complied voluntarily with quarantine requests during the SARS outbreak,²⁴⁶ public health officials elsewhere—including China, Hong Kong, and Singapore—had to use more coercive measures. In Hong Kong, barricades and tape were used to confine infected residents in a large housing complex.²⁴⁷ In Singapore, three telephone calls were made per day

245. WHO Pandemic Influenza Draft Protocol for Rapid Response and Containment, at 11-12 (Jan. 27, 2006), available at http://www.who.int/csr/disease/avian_influenza/guidelines/RapidResponse_27%2001.pdf.

246. UNIV. OF TORONTO JOINT CTR. FOR BIOETHICS, PANDEMIC INFLUENZA WORKING GROUP, STAND ON GUARD FOR THEE: ETHICAL CONSIDERATIONS IN PREPAREDNESS PLANNING FOR PANDEMIC INFLUENZA 13 (2005), available at <http://www.utoronto.ca/jcb/home/documents/pandemic.pdf>.

247. Nola M. Ries, *Public Health Law and Ethics: Lessons from SARS and Quarantine*, 13 HEALTH L. REV. 1, 3 (2001), available at http://www.law.ualberta.ca/centres/hli/pdfs/13-01/13-1-01_Ries.pdf.

to the home of each quarantined individual to confirm compliance.²⁴⁸ Surveillance cameras were placed in homes where people were quarantined, and inhabitants were required to take their own temperatures on camera to avoid fraud.²⁴⁹ Electronic wrist or ankle-bands also were used as enforcement measures.²⁵⁰

Different countries have different norms and needs, and one must view different enforcement measures in the context of what a given society considers to be reasonable. At a minimum, the monitoring and enforcement measures adopted should have a logical and proportionate relationship to the achievement of the public health objective and should be implemented in a fair and non-discriminatory manner. Finally, all measures taken should be culturally accepted and collectively approved by the populace.²⁵¹

4. *Ensuring Safe, Humane Implementation of Isolation or Quarantine*

When quarantine and isolation are necessary, the principle of reciprocity obliges society to provide those affected with the necessities of life during the period of quarantine, including safe and humane housing, as well as high quality medical care and psychological support. Recent studies have confirmed that quarantine imposes serious financial and psychological hardships on affected individuals: about 30% of quarantined individuals suffer from post-traumatic stress disorder and depression.²⁵² All countries should be required to provide and pay for these basic needs. Furthermore, quarantine needs to be implemented in a humane manner that is sensitive to gender, religious, and ethnic issues.

Distributive justice requires that officials limit the extent to which the personal and economic burdens of a public health threat fall unfairly upon individual citizens. To this end, governments and national and international organizations should stockpile medical supplies and food in an effort to fairly and equitably address any lack of resources and amenities. A pandemic influenza will require solidarity among nations and collaborative approaches that set aside traditional values of self-interest and territoriality.

248. ROTHESTEIN ET AL., *supra* note 220, at 25.

249. *See id.*; *see also* Ries, *supra* note 247, at 3.

250. *See* ROTHESTEIN ET AL., *supra* note 220, at 25.

251. *Id.*

252. *See, e.g.*, Laura Hawryluck et al., *SARS Control and Psychological Effects of Quarantine, Toronto, Canada*, 10 EMERGING INFECTIOUS DISEASES 7 (2004) (recording incidences of Post-Traumatic Stress Disorder (PTSD) among individuals quarantined during the Canadian SARS outbreak).

CONCLUSION

Preparing for an influenza pandemic presents difficult challenges, many of which transcend mere scientific effectiveness. Even when successful, coercive public health interventions can have deep, adverse consequences for economic and civil liberties. Therefore, it is vital that individual rights are sacrificed only when necessary to protect the public health. As such, laws must clearly establish the criteria for the exercise of such emergency powers and provide adequate due process to minimize infringements on individual rights.

The threat of an influenza pandemic is real and could affect millions of lives. If such a disaster occurs, we must not allow the widespread erosion of individual rights to compound the tragedy. We must form an immediate political and social response to the effect coercive public health measures will have on civil liberties. Only then are we equipped—ethically as well as scientifically—to deal with the impact of a global pandemic.