Ethical Guidance for Rationing Scarce Health-Related Resources in a Severe Influenza Pandemic: Literature and Plan Review

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Table of Contents

I. Background

A. Severe Pandemic Influenza

The development of pandemic influenza preparedness plans is occurring around the globe in response to experts' warnings that a worldwide outbreak of the respiratory virus is inevitable. While the timing and severity of the next pandemic are impossible to predict, there is certainty that it will occur, and preparation is vital to mitigating its effects.[1]

The last century saw three influenza pandemics—in 1918–19, 1957, and 1968. The pandemics of 1957 and 1968 were moderate in the United States and resembled exaggerated versions of typical, annual influenza epidemics.[2] The pandemic of 1918–19 was dramatically different from the other two because of its significant mortality rate, which triggered massive social and economic change and degradation.[3]

Severe pandemic influenza, like that of 1918-19, occurs on a scale that distinguishes it from other public health disasters, both in terms of nature and size. It is experienced over years, not days, weeks or months, and threatens core infrastructures. Preparing for such a pandemic raises many ethical issues for public health and health care, including the use of community mitigation tools, such as isolation and quarantine, and the scope of health care workers' duty to care. A key question with serious public health, social justice, and individual health implications is how best to ration health-related resources when demand will vastly outstrip supply.

If we envision the next pandemic as a modern version of a severe, 1918-type pandemic—which some predict—what ethical principles and goals should guide our preparations? How shall we distribute scarce health care and public health resources among us? Should some individuals and some groups have prioritized access to resources? If so, why?

B. Pandemic Rationing Guidance

There is no one-size-fits-all ethical framework for rationing plans for mild, moderate, and severe pandemics. Unlike a mild pandemic, a severe pandemic has the potential to cripple normal business operations and disrupt the distribution of essential goods and services globally, including in Minnesota.[4] Unlike other disasters, during a severe pandemic states and communities cannot count on receiving federal assistance. This impact on societal functioning makes planning for a severe pandemic unique. While planning is underway at the federal level, the federal government has made it clear that states should develop their own pandemic plans, including plans for rationing scarce resources.[5]

This literature and plan review is part of the Minnesota Pandemic Ethics Project, a collaborative effort that is developing recommendations for the ethical rationing of five health-related resources that will be scarce in a severe influenza pandemic: antiviral medications, N95

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[1] Vawter D, Gervais K, Garrett JE. Allocating pandemic influenza vaccines in Minnesota: recommendations of the pandemic influenza ethics work group. *Vaccine.* 2007;25:6522-6536.
[2] US Department of Health and Human Services (HHS). *HHS Pandemic Influenza Plan*. November 2005:S5-28. Available at: http://www.hhs.gov//pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf.
[3] Kolata G. *Flu: The Story of the Great Influenza Pandemic of 1918 and the Search for the Virus That Caused It*. New York: Farrar, Straus and Giroux;1999:133.
[4] Trust for America's Health. *Pandemic Flu and the Potential for US Economic Recession: A State-by-State Analysis*. March 2007. Available at: http://healthyamericans.org/reports/flurecession/FluRecession.pdf; Ott M, Shaw SF, Danila RN, Lynfield R. Lessons learned from the 1918-1919 influenza pandemic in Minneapolis and St. Paul, Minnesota. *Public Health Reports*. 2007;122:803-810.
[5] *HHS Pandemic Influenza Plan*: D-11.

respirators (N95s), surgical masks, vaccines and mechanical ventilators.[6] How best to ration during a global public health disaster of such duration, severity and scope raises novel ethical issues. For example, when should antiviral medications be rationed for prevention vs. treatment? When should patients be removed from ventilators so that patients more likely to benefit can be given a chance at survival? Should the supply of N95s be reserved for essential workers?

We reviewed pandemic influenza plans (including global, national, state and county plans) as well as scholarly publications in order to answer the following questions:

1) How do pandemic influenza plans address the need to ration scarce health-related resources? What ethical guidance do they provide?
2) What ethical guidance exists in scholarly publications for rationing scarce health-related resources in a severe pandemic?

II. Methods

A. National, State and County Pandemic Influenza Plans and Ethical Guidance

National pandemic influenza plans and ethical guidance were obtained through the World Health Organization's website, www.who.int, individual country's pandemic influenza websites, and through references in scholarly publications. National plans were limited to those published in English that contained ethical guidance. Pandemic influenza plans and ethical guidance in the United States were obtained through links on the federal government website, www.pandemicflu.gov. and the University of Minnesota's Center for Infectious Disease Research and Policy's website, www.pandemicpractices.org. Plans for all 50 states, the District of Columbia and 6 counties were obtained;[7] the available plans for West Virginia and Washington State were summary overviews only. County plans were included if they were readily available on the state websites and contained information about planning assumptions.

In addition, each state and county's website was searched for updated plans and additional documents using the following search terms in various combinations: antiviral, ethic, mask, pandemic, priority, rationing, vaccine and ventilator. Supplemental guidance documents referenced in individual plans were acquired. A few plans and guidance documents were obtained through personal communication with members of the project team and Minnesota Department of Health staff. Most plans and guidance documents were accessed between April 2007 and September 2007; guidance from the World Health Organization (WHO), the United Kingdom, Colorado, Iowa and Wisconsin was updated in March 2008.

For all plans, pandemic assumptions were reviewed to determine the severity of the pandemic being planned for. If the severity was not clearly indicated in the assumptions, the entire plan document (and attachments, when available) was searched for language about case-fatality, severity, clinical attack rates, the 1918 pandemic, and "%." Plans were considered to be preparing for a severe pandemic if they stated they were preparing for:

1) a case-fatality rate of 2.0% or higher;
2) a clinical attack rate of 40% or more;
3) a 1918-like pandemic; or
4) a severe pandemic.

[6] A general description of the Minnesota Pandemic Ethics Project can be found in the Jan/Feb 2008 Minnesota Department of Health Pandemic Influenza Newsletter, available at: http://www.health.state.mn.us/divs/idepc/newsletters/panflu/janfeb08.pdf.
[7] Links to state pandemic influenza plans available at: http://www.pandemicflu.gov/plan/states/index.html

Plans were considered to be preparing for a moderate pandemic if they stated they were preparing for: a case-fatality rate of 1.0-2.0%; a 1957/1968-like pandemic; or the same assumptions as the 2005 Department of Health and Human Services (HHS) plan.[8] Plans that did not clearly state their pandemic planning assumptions were labeled "ambiguous."

In addition to pandemic severity, all US plans were evaluated for the inclusion of ethical guidance and, if included: whether it was general guidance for ethical decision-making during a pandemic, or, more specifically, ethical guidance for the rationing of scarce health-related resources; the methods used to develop the ethical guidance; whether the ethical guidance was about fair procedures or whether it also included substantive guidance about which groups should have prioritized access to specific health-related resources; and the content of the guidance, i.e., ethical principles, values, goals, and strategies, including priority groups and exclusion criteria. We directed special attention to ethical guidance on the rationing of antivirals, personal protective equipment (PPE, which includes N95 respirators and surgical masks), vaccines and ventilators as well as the use of non-clinical, non-public health considerations, e.g., reciprocity, age-based and quality of life considerations.

B. Scholarly Publications

A bibliography of books and articles on pandemic influenza and rationing scarce resources that had been compiled for a previous pandemic ethics project conducted by the Minnesota Center for Health Care Ethics was used.[9] In addition, MEDLINE and EthxWeb online databases were searched for relevant articles using the following search terms in various combinations: 1918, age-specific, antiviral, children, efficacy, elderly, epidemiology, ethic, guidance, mortality, pandemic influenza, personal protective equipment, plan, pregnancy, rationing, respirator, SARS, surgical mask, triage, vaccine, and ventilator, with the emphasis on articles published during 2006-2007. Additional books and articles were found by reviewing the bibliographies of key publications and through personal communication with other members of the project team. Searches were conducted between March and September 2007.

In several cases, plans and articles contained similar, even identical, ethical guidance. As the purpose of this review is to provide an overview of the different guidance available, only representative literature of these different approaches is included in the results below in order to avoid redundancy. To this end, several recent critical reviews of pandemic influenza plans and ethical guidance were evaluated and included both to summarize the guidance they reviewed and to report on their conclusions and recommendations.[10]

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[8] *HHS Pandemic Influenza Plan*:18-19.
[9] Vawter et al. 2007.
[10] Holmberg SD, Layton CM, Ghneim GS, Wagener DK. State plans for containment of pandemic influenza. *Emerg Infect Dis*. 2006;12:1414-1417; Kotalik J. *Ethics of Planning for and Responding to Pandemic Influenza: Literature Review*. 2006. Available at: http://www.bag.admin.ch/nekcne/04229/04235/index.html?lang=en&download=M3wBUQCu/8ulmKDu36WenojQ1NTTjaXZnqWfVp3Uhmfhnapmmc7Zi6rZnqCkkIZ6fHyDbKbXrZ2lhtTN34al3p6YrY7P1oah162apo3X1cjYh2; Straetemans M, Buchholz U, Reiter S, Haas W, Krause G. Prioritization strategies for pandemic influenza vaccine in 27 countries of the European Union and the Global Health Security Action Group: a review. *BMC Public Health*. 2007;7:236. Available at: http://www.biomedcentral.com/1471-2458/7/236; Thomas JC. *Ethical Concerns in Pandemic Influenza Preparation and Responses*. [white paper] Southeast Regional Center of Excellence for Emerging Infectious [sic] and Biodefense 2007:1-19. Available at: http://www.serceb.org/wysiwyg/downloads/pandemic_flu_white_paper.May_25.FORMATTED.pdf; Thomas JC, Dasgupta N, Martinot A. Ethics in a pandemic: a survey of the state pandemic influenza plans. *Am J Public Health*. 2007;97(suppl 1):26-31. Available at: http://www.ajph.org/cgi/reprint/97/Supplement_1/S26.pdf; Uscher-Pines L, Omer SB, Barnett DJ, Burke TA, Balicer RD. Priority setting for pandemic influenza: an analysis of national preparedness plans. *PLoS Med*. 2006;3:e436. Available at: http://www.flu.org.cn/upfile/attachment/20061024152550696.pdf.

III. Results

A. Severity of Pandemic

1. Non-US Plans

While the severity of the next pandemic in unknown, WHO has warned of the possibility of a severe pandemic and instructed countries to develop pandemic plans accordingly.[11]

Most countries are planning for a moderate pandemic.[12] Canada,[13] New Zealand[14] and the United Kingdom[15] are important exceptions. These three countries have both planned for a severe or ultra pandemic and have developed ethical guidance. New Zealand is planning for an ultra pandemic, that is, a pandemic in which 40% of the population becomes ill over an eight-week period and the case fatality rate is 2%.[16]

2. US Plans

The United States has several pandemic influenza preparedness plans. Each agency and branch of the federal government is charged with developing its own. Most plans rely on the 2005 HHS planning assumptions, which are for a moderate pandemic (1957/1968-like). However, the HHS plan[17] contains a table that estimates the numbers of persons in the US that would fall clinically ill, be hospitalized and die under both moderate and severe (1918-like) scenarios. In late 2007 a federal interagency work group circulated proposed guidance for rationing vaccines and antivirals in a severe pandemic to various stakeholder groups; only the proposed vaccine guidance as yet has been made available publicly on government websites.[18]

The federal government has been building a Strategic National Stockpile that includes antiviral medications, N95 respirators and surgical masks, and ventilators, and has stated that in the case of a pandemic it will distribute the stockpiled items to states in proportion to their population.[19] It has also negotiated a discounted price for state and local health departments as well as a variety of other organizations and institutions interested in purchasing and stockpiling additional (private supplies of) antivirals for treatment purposes in a pandemic. Advice to the states is that they develop their own plans for the allocation of stockpiled and other scarce resources.[20]

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[11] World Health Organization. *Global Influenza Preparedness Plan*. 2005. Available at: http://www.who.int/csr/resources/publications/influenza/GIP_2005_5Eweb.pdf

[12] Uscher-Pines et al, 2006.

[13] Public Health Agency of Canada. *Canadian Pandemic Influenza Plan for the Health Sector*. December 2006. Available at: http://www.phac–aspc.gc.ca/cpip–pclcpi/.

[14] National Ethics Advisory Committee – Kāhui Matatika o te Motu. *Getting Through Together: Ethical Values for a Pandemic*. Wellington: Ministry of Health; 2007. Available at: http://www.neac.health.govt.nz/moh.nsf/indexcm/neac-resources-publications-gettingthroughtogether; National Ethics Advisory Committee – Kāhui Matatika o te Motu. *Ethical Values for Planning for and Responding to a Pandemic in New Zealand: A Statement for Discussion*. Ministry of Health, Wellington, New Zealand; 2006. Available at: http://www.neac.health.govt.nz/moh.nsf/indexcm/neac-resources-publications-pandemic; Ministry of Health. *New Zealand Influenza Pandemic Action Plan*. Version 16. Ministry of Health, Wellington, New Zealand; 2006. Available at: http://www.moh.govt.nz/moh.nsf/indexmh/nz-influenza-pandemic-action-plan-2006.

[15] Department of Health, United Kingdom. *Responding to Pandemic Influenza: The Ethical Framework for Policy and Planning.* 2007. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_080751; Department of Health, United Kingdom. *Pandemic flu: a national framework for responding to an influenza pandemic*. 2007. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_080751.

[16] *New Zealand Influenza Pandemic Action Plan*, 2006.

[17] *HHS Pandemic Influenza Plan:* 18.

[18] US Interagency Working Group. *Draft Guidance on Allocating and Targeting Pandemic Influenza Vaccine*. October 17, 2007. Available at: http://www.pandemicflu.gov/vaccine/prioritization.html.

[19] More information on the Strategic National Stockpile available at: http://www.bt.cdc.gov/stockpile/

[20] *HHS Pandemic Influenza Plan*: D-11

3. State Plans

States differ in the severity of pandemic for which they have planned (see Figure 1). Whereas some have planned for a severe and others for a moderate pandemic, most states have not specified or restricted the severity of pandemic their plan addresses.

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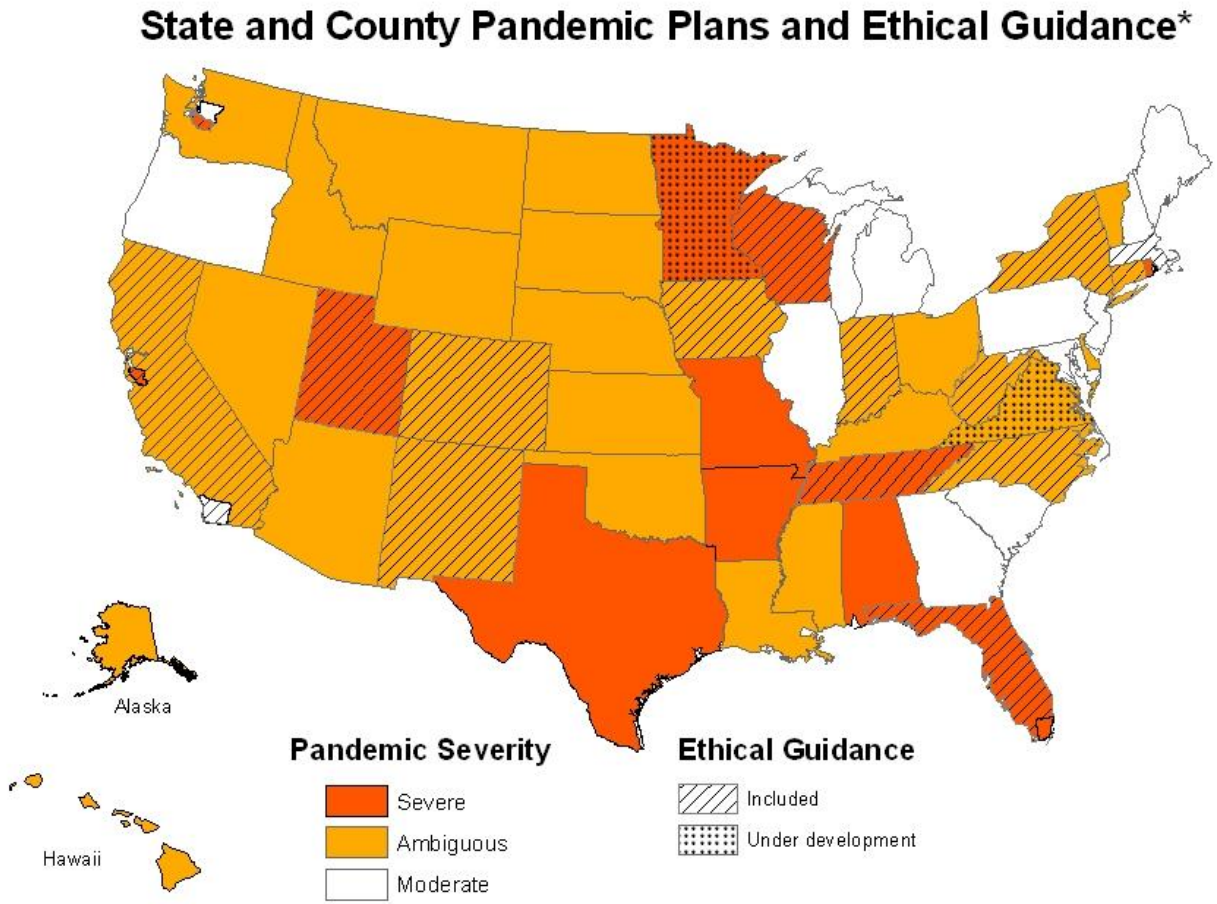
Figure 1.



*Current as of September 2007; Colorado, Iowa and Wisconsin current as of March 2008

a. Severe Pandemic

Ten states including Minnesota[21] and three counties met our criteria as indicating that they were preparing for a severe pandemic; all of these plans defined a severe pandemic as having a high case-fatality rate, except for Wisconsin, which based its definition of severity on a high clinical attack rate.[22]

b. Ambiguous Severity

Twenty-nine states and one county were ambiguous as to the severity of the pandemic they for which they were planning. In most cases these ambiguous plans contained tables based on the calculations from the HHS plan for both moderate and severe scenarios, and they did not explain on which scenario the plan was based.

c. Moderate Pandemic

Eleven states, two counties and the District of Columbia met our criteria as indicating they were preparing for a moderate pandemic (1957/1968-like).

B. Ethical Guidance for Pandemic Influenza

1. Non-US

a. Types of Ethical Guidance

The WHO released *Ethical Considerations in Developing a Public Health Response to Pandemic Influenza* late in 2007.[23] This report stems from a series of WHO-sponsored work groups.[24] The WHO recommends several ethical principles (and accompanying definitions) to guide decisions about fair access to scarce resources from a public health perspective.

> Equity: The fair distribution of benefits and burdens. In some circumstances, an equal distribution of benefits and burdens will be considered fair. In others, the distribution of benefits and burdens according to individual or group need will be considered fair. For example, in some circumstances, it may be equitable to give preference to those who are worst off, such as the poorest, the sickest, or the most vulnerable. Inequities are differences in health that are unnecessary, avoidable, and are considered unfair and unjust.
>
> Utility/efficiency: The principle of utility requires that one act so as to maximize aggregate welfare. This implies an additional principle of efficiency, i.e. the idea that benefits should be obtained using the fewest resources necessary.
>
> Reciprocity: A relationship between parties characterized by corresponding mutual action. Reciprocity calls for providing something in return for contributions that people have made. For example, reciprocity implies that

[21] Minnesota Department of Health. *Minnesota Pandemic Influenza Control and Prevention Guidelines*. Draft Version 2.5. April 2006. Available at: http://www.health.state.mn.us/divs/idepc/diseases/flu/pandemic/plan/mdhpanfluplan.pdf

[22] Bureau of Communicable Diseases. Division of Public Health. Department of Health. *Wisconsin Pandemic Influenza Preparedness*. April 2004. Available at: http://dhfs.wisconsin.gov/preparedness/pdf_files/WIPandemicInfluenzaPlan.pdf

[23] World Health Organization. *Ethical Considerations in Developing a Public Health Response to Pandemic Influenza.* 2007. Available at: http://www.who.int/csr/resources/publications/WHO_CDS_EPR_GIP_2007_2/en/index.html.

[24] Gostin L, Berkman B for WHO Working Group Two. *Project on Addressing Ethical Issues in Pandemic Influenza Planning: Ethics of Public Health Measures in Response to Pandemic Influenza.* Draft report. October 6, 2006. Available at: http://www.who.int/eth/ethics/PI_Ethics_draft_paper_WG2_6_Oct_06.pdf; Verweij M for WHO Working Group One. *Project on Addressing Ethical Issues in Pandemic Influenza Planning: Equitable Access to Therapeutic and Prophylactic Measures*. Draft. October 20, 2006. Available at: http://www.who.int/eth/ethics/PIEthicsdraftpaperWG120oct06.pdf.; World Health Organization. *Global Consultation on Addressing Ethical Issues in Pandemic Influenza Planning: Summary of Discussions*. 2006. Available at: http://www.who.int/trade/Ethics_PI_consultation_report_WHO_2006.pdf.

> society should support those who face disproportionate burdens in protecting the public good, as well as taking steps to minimize those burdens as much as possible.
>
> Solidarity: Union or fellowship between members of a group or between peoples of the world. Individuals in solidarity with one another are firmly united by common responsibilities and interests, and undivided in opinion, purpose and action.

The WHO guidance rejects prioritizing groups based on social characteristics including race and ethnicity, religion, social or economic status among others. Age is not on the list of excluded characteristics.

Reasons are offered in support of age-based rationing, though the WHO guidance recommends that age be used only after broad public consideration. For example, age-based considerations can be based on the "fair innings" argument, namely, the

> … idea that everyone is entitled to some 'normal' span of life years. According to this argument, younger persons have stronger claims to life-saving interventions than older persons because they have had fewer opportunities to experience life. The implication is that saving one year of life for a young person is valued more than saving one year of life for an older person.

In addition to these substantive ethical principles, transparency is an important procedural principle, according to the WHO guidance.

One of the most cited documents on ethical guidance for pandemic influenza planning is *Stand on Guard for Thee*, a report by the Influenza Working Group at the University of Toronto's Joint Centre for Bioethics.[25] It lists ten substantive (individual liberty, protection from harm, proportionality, privacy, duty to provide care, reciprocity, equity, trust, solidarity and stewardship) and five procedural (reasonableness, transparency, inclusiveness, responsiveness, accountability) values to consider in pandemic planning. The report also identifies four key ethical issues to be addressed: duty to care, restricting liberty, priority setting, and global governance implications. Although the report recommends that pandemic influenza plans include an ethical component with both substantive and procedural values articulated, its own recommendations are focused on procedural justice in the decision-making process.

Canada (CN), New Zealand (NZ) and the United Kingdom (UK) offer general ethical guidance for pandemic planning and response, including, but not limited to the rationing of resources. Ontario (ON) and the Calgary Health Region (CHR) offer ethical guidance as well.[26] Both substantive and procedural principles are included. Major process principles include:

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[25] Joint Centre for Bioethics. Pandemic Influenza Working Group Members (Ross E.G. Upshur, Karen Faith, Jennifer L. Gibson, Alison K. Thompson, C. Shawn Tracy, Kumanan Wilson, Peter A. Singer). *Stand on Guard for Thee: Ethical Considerations in Preparedness Planning for Pandemic Influenza.* Toronto: University of Toronto Joint Centre for Bioethics. 2005. Available at: http://www.utoronto.ca/jcb/home/documents/pandemic.pdf.

[26] Calgary Health Region. Ethics of health care decision making during a pandemic crisis (Section 3). *Pandemic Influenza Response Plan*. 2007. Available at: http://www.calgaryhealthregion.ca/pandemic/pdf/chr_response_plan_0307.pdf; Ministry of Health and Long Term Care. Chapter #2. Roles, responsibilities and frameworks for decision making. *Ontario Health Plan for an Influenza Pandemic.* 2007. Available at: http://www.health.gov.on.ca/english/providers/program/emu/pan_flu/ohpip2/plan_full.pdf

transparency/openness (CHR, CN, NZ, ON); accountability/responsibility (CN, NZ, ON); inclusiveness (NZ, ON, UK); reasonableness (NZ, UK) and responsiveness/flexibility (NZ, UK).

Two major types of substantive principles are present in all of these guidance documents: principles to protect the population against harm and to treat persons fairly. Moreover, all the guidance documents tap multiple dimensions of fairness, rather than a single fairness principle. The ethical guidance invariably includes several other types of substantive principles. Table 1 summarizes the substantive ethical principles in non-US guidance for planning and responding to a severe influenza pandemic.

Table 1. Substantive Ethical Principles in non-US Guidance for Severe Pandemic

Protect from Harm Principles

Protect and promote the public's health (CN, ON)
Minimize harms (NZ, UK)
- Protect one another from harm (NZ)
- Accept restrictions on our freedom when needed to protect others (NZ)

Protect from physical, psychological, social and economic harm (UK)
Optimize the risk/benefit ratio, maximize efficacy (CN)
Minimize disruption to society (UK)
Attend to those in greatest need or at highest risk (WHO)

Fairness Principles

Respect for inherent dignity of all persons (CN, NZ)
Equal concern and respect, ensuring everyone gets a fair go (NZ)
Everyone matters and the interests of each person are the concern of all of us, and of society (UK)
People with equal chance of benefiting from resources should have an equal chance of receiving them (UK)
Treat equally the needs of those with influenza and those with other ailments (CHR, WHO)
Reciprocity
- Support those who bear extra burdens in caring for others, protecting the public good (CHR, NZ, ON, UK, WHO)
- Help one another (NZ)
- Act on any social standing, or any special responsibilities we may have, such as those associated with professionalism (NZ)

Minimize inequalities (NZ)
Protect against stigmatization (CHR)
Do not discriminate on the basis of gender, race, religion or social value (CHR, WHO)
Do not discriminate on the basis of age (CHR)
With broad public consultation consider prioritizing younger persons before older (WHO)

Other Substantive Principles

Stewardship (ON),
Solidarity (ON, WHO)
Unity – being committed to getting through the situation together, showing our commitment to strengthening individuals and communities (NZ)
Working together (UK)
Neighbourliness/whānaungatanga – helping and caring for our neighbours, friends and family, working together when there is a need (NZ)
Duty to provide care (CHR, ON)
Proportionality (CHR, UK)

Canada observes that in a pandemic there is a synergy between the interests of the collective and the interests of the individual.

> [A] population can be healthy only with the collective support of the many individuals within that population. This support arises from the recognition that it is in an individual's best interest to be part of a healthy population.[27]

The CHR notes that the principles and goals shift with different phases of the pandemic. As the pandemic intensifies there is an expected shift toward more utilitarian considerations, i.e., what is best for society as a whole. NZ's ethical guidance is especially detailed and culturally-specific and includes well-developed hypothetical cases that illustrate how to apply the principles to assist with decision-making.

b. Non-US Guidance for Rationing Scarce Resources

The WHO offers detailed guidelines for allocating antivirals for treatment and prophylaxis.[28] The guidelines distinguish between strong and weak recommendations and evaluate the strength of empirical support for underlying assumptions.

Two important and recent reviews of non-US plans summarize groups prioritized to receive access to vaccines and antivirals.[29] In general health care and essential service workers and high risk individuals are prioritized to receive treatment antivirals and vaccines.

CHR explicitly prohibits the use of social worth criteria in deciding priorities for treatment. "Matters such as social standing, contribution to society, or age should not be considered."[30] Essential workers, however, should be prioritized because "without their services, the health of the general population is at imminent risk."

The WHO guidance warns that policies that prioritize workers to receive scarce resources need to be developed with great care so they are not "perceived as unfair and undermine public trust."[31]

Ontario has developed guidance on allocating ventilators.[32] It excludes persons over age 85 based on clinical criteria. Further discussion is underway about whether to include non-clinical age-based considerations.

c. Methods Used to Develop Non-US Ethical Guidance

The WHO developed its guidance with the use of four working groups and a couple of joint meetings. NZ used a public consultation process that included an invitation to respond to a discussion document. The NZ National Ethics Advisory Committee developed the guidance; members were appointed by the Minister of Health and brought expertise in ethics, health and disability research, health service provision and leadership, public health, epidemiology, law, Māori health and consumer advocacy. The methods used to develop the other non-US guidelines are not detailed in the plans. According to a published review, ten (32% of the 31

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[27] Public Health Agency of Canada. Ethics and pandemic planning (Section 2, Subsection 6.0). *Canadian Pandemic Influenza Plan for the Health Sector*. December 2006:14. Available at: http://www.phac-aspc.gc.ca/cpip-pclcpi/s02_e.html#6.

[28] World Health Organization. Chemoprophylaxis of H5N1 infection: recommendations for use of antiviral drugs. In: *WHO Rapid Advice Guidelines on Pharmacological Management of Humans Infected with Avian Influenza A (H5N1) Virus*. 2006. Available at: http://www.who.int/csr/disease/avian_influenza/guidelines/pharmamanagement/en/index.html.

[29] Straetemans et al, 2007; Uscher-Pines et al, 2006.

[30] Calgary Health Region, 2007.

[31] WHO, *Ethical Considerations,* 2007.

[32] Christian MD, Hawryluck L, Wax RS, et al. Development of a triage protocol for critical care during an influenza pandemic. *CMAJ.* 2006;175:1377-1381. Available at: http://www.cmaj.ca/cgi/reprint/175/11/1377.

countries studied) countries have consulted and involved ethical experts to guide decisions related to vaccine prioritization.[33]

2. US

a. General Ethical Guidance

The 2005 HHS Plan does not contain general ethical guidance for decision-making in a pandemic. However, it does provide guidance for rationing vaccines and antiviral medications. Based on assumptions for a pandemic of moderate severity, the National Vaccine Advisory Council (NVAC) and Advisory Council for Immunization Practices (ACIP) developed vaccine and antiviral prioritization plans.[34] These prioritization plans resemble those used for seasonal influenza. The federal government is working on ethical guidance for rationing in a severe pandemic. Draft guidance documents for the use of vaccines and antivirals in a severe pandemic were circulated in late 2007 by federal interagency working groups.[35] Until these drafts are finalized, the 2005 HHS guidance remains in effect.

The National Infrastructure Advisory Council (NIAC), a consultant group to both HHS and the Department of Homeland Security, published a report on prioritizing critical infrastructure in the event of an influenza pandemic.[36] Basic municipal and other infrastructure support such as water, energy, communications and information technology are identified as crucial components of the infrastructure, as are public safety, health and medical care, transportation and financial services. The report notes that these definitions of critical infrastructure workers are broader than those included under the NVAC/ACIP prioritization plans. It is also acknowledged that all of these infrastructure sectors are interdependent, making prioritization of some to the exclusion of others problematic. The federal interagency working group used the NIAC report to propose the set of workers to be prioritized to receive vaccines in a severe pandemic.

b. Guidance for Rationing of Scarce Resources

The Ethics Subcommittee of the Advisory Committee to the Director for Centers for Disease Control and Prevention published a report addressing ethical issues in pandemic influenza, including the rationing of scarce resources.[37] It advocates for an ethical justification of rationing based on balancing the goal of providing the greatest good for the greatest number with considerations of justice (in particular, issues of equity and fairness), respect for persons and non-maleficence. The report specifically rejects distribution based on "first-come, first-served," arguing that it is not truly a fair procedure. In addition, although the report advocates for prioritizing workers key to maintaining the societal and healthcare infrastructure, it rejects prioritization of groups based on other social factors (e.g., race or ethnicity). The guidance does not include age in its list of examples of discriminatory social categories.

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[33] Straetemans et al, 2007.
[34] *HHS Pandemic Influenza Plan:* Appendix D.
[35] US Interagency Working Group, *Vaccine Guidance*, October 17, 2007.; US Interagency Working Group. *Proposed Guidance on Antiviral Drug Use Strategies during an Influenza Pandemic*. November 6, 2007. Available at: http://www.asisonline.org/newsroom/crisisResponse/Antiviral_strategies_Proposed%20Guidance_11-6-07.doc; US Interagency Working Group. *Summary of Proposed Guidance on Antiviral Drug Use Strategies for an Influenza Pandemic*. November 20, 2007.
[36] National Infrastructure Advisory Council. *The Prioritization of Critical Infrastructure for a Pandemic Outbreak in the United States Working Group: Final Report and Recommendations by the Council.* 2007. Available at: http://www.dhs.gov/xlibrary/assets/niac/niac-pandemic-wg_v8-011707.pdf
[37] Kinlaw K, Levine R. *Ethical Guidelines in Pandemic Influenza: Recommendations of the Ethics Subcommittee of the Advisory Committee to the Director.* Centers for Disease Control and Prevention. 2007. Available at: http://www.cdc.gov/od/science/phec/guidelinesPanFlu.htm.

The Agency for Healthcare Research and Quality (AHRQ) has published guidance on providing medical care with scarce resources in the context of a mass casualty event.[38] Among AHRQ's guiding principles are maximizing good outcomes for the greatest number of people, reasonably protecting the rights of individuals, and maintaining transparency. A template for ethical decision-making in rationing scarce resources is presented. In addition, the report includes a list of criteria developed by the American Medical Association for patient assessment in the face of scarce medical resources: the patient's need for the specific resource; potential to return to the baseline state; overall acute resource needs of the patient; age and functional assessment; underlying health and prognosis related to an underlying disease(s), and; event-specific or injury-specific prognostic factors.[39] AHRQ includes age on its list of prohibited social criteria for the allocation of scarce resources.

i. VACCINE

The primary goal for the 2005 HHS vaccine prioritization plan is to decrease health impacts including severe morbidity and death and secondarily to minimize societal and economic impacts.[40] In order to meet these goals, prioritization for vaccine is given to manufacturers of vaccine and antivirals, vaccinators and those involved in direct patient care. Persons at the highest risk of hospitalization and death are prioritized next, followed by pregnant women and household contacts of high-risk individuals who themselves cannot be vaccinated. Public health response workers and key government leaders would be the next to be vaccinated. Children are explicitly not made a priority in this plan, except as they are included in high-risk populations.

In November 2007 a federal interagency working group released draft guidance for prioritizing access to vaccines in a severe pandemic.[41] This guidance, when finalized, will replace or supplement the guidance currently in the 2005 HHS plan. It offers separate recommendations for four segments of the population (homeland and national security, health care and community support services, critical infrastructures, and the general population) for three types of influenza pandemic (severe, moderate, and less severe). In a severe pandemic, workers are prioritized based on their critical function, high exposure and risk of transmitting influenza to vulnerable clients. The guidance attends to many specific categories of essential workers and gives particular attention to risk of occupational exposure to influenza, primarily because everyone depends on these workers to reduce influenza-related harm. Reciprocity is noted to be a relevant ethical value, but is not generally referred to as a rationale for prioritizing workers.

The general population is prioritized to receive vaccines in a severe pandemic based on different ethical considerations, namely, risk of influenza complications and death, age, lack of alternative protections and in some cases vaccine response. With respect to age, the guidance asserts that the public particularly values children above other age groups. Healthy children are prioritized to receive vaccines before adults at high risk. At the other end of the age-spectrum persons $\geq$ 65 years old are prioritized before healthy adults because they are at higher risk of complications and death. Potential differences in vaccine response between younger and older adults are not factored into this recommended prioritization.

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[38] Phillips SJ, Knebel A, eds. *Mass Medical Care with Scarce Resources: A Community Planning Guide*. AHRQ Publication No. 07-0001. Rockville, MD: Agency for Healthcare Research and Quality. 2007. Available at: http://www.ahrq.gov/research/mce/.
[39] American Medical Association Council on Ethical and Judicial Affairs. Ethical considerations in the allocation of organs and other scarce medical resources among patients. *Arch Intern Med.* 1995;155:29-40.
[40] *HHS Pandemic Influenza Plan,* Appendix D.
[41] US Interagency Working Group, *Vaccine Guidance*, October 17, 2007.

ii. ANTIVIRAL MEDICATIONS

The primary goal for the 2005 HHS antiviral prioritization plan is the same as for the 2005 vaccine plan: to decrease health impacts including severe morbidity and death and secondarily to minimize societal and economic impacts.[42] The use of antivirals is prioritized for treatment, with limited recommendations for prophylactic use. First priority for treatment is given to patients admitted to the hospital, followed by healthcare and emergency medical services workers with direct patient contact. Individuals at highest risk of hospitalization and death (e.g., pregnant women) are given the next highest priority for treatment, followed by pandemic health responders, public safety workers and key government leaders. Other groups of high-risk individuals and critical infrastructure workers follow.

In November 2007 the federal government circulated to stakeholder groups proposed guidance on the use of antivirals in a pandemic.[43] As of this writing, it has yet to be posted on government websites for public comment or finalized. It assumes ample supplies of antivirals both at the start and during the pandemic. In the absence of a shortage, it proposes offering post-exposure prophylaxis (PEP) and long-term outbreak prophylactic antivirals to a wide array of groups. Should the supply be less, it recommends prioritizing treatment in accord with the 2005 HHS guidance and prioritizing inpatient and hospital-based critical care workers who have the greatest occupational exposure to influenza to receive PEP. Irreplaceable workers and immunocompromised persons are prioritized next for PEP. The primary rationale for prioritizing health care workers is that everyone depends on them for their health. In addition, it is consistent with considerations of reciprocity.

c. Methods of Developing Federal Ethical Guidance

The federal government used a combination of expert taskforces and public input to develop the vaccine prioritization recommendations in the 2005 pandemic influenza plan. Public input was obtained through the Public Engagement Pilot Project on Pandemic Influenza (PEPPPI), which included day-and-a-half stakeholder meetings, and one day-long and 3 half-day sessions with citizens-at-large.[44] The recent federal guidance on vaccine allocation in a severe pandemic has been developed using similar methodology. In addition to the interagency working group which developed the draft recommendations, stakeholder meetings, two public meetings on vaccine allocation and a three-day WebDialogue have been used to solicit feedback and foster informed discussions about the recommendations.[45]

3. US State and County

Thirteen states and one county provide ethical guidance for pandemic planning and response that goes beyond referring to the 2005 HHS plan (see Table 2). Four of these states and one county (Florida,[46] Tennessee,[47] Utah[48] and Wisconsin[49] and Tacoma-Pierce County[50]) offer

[42] *HHS Pandemic Influenza Plan,* Appendix D.
[43] US Interagency Working Group, *Antiviral Guidance,* November 6, 2007; US Interagency Working Group, *Summary of Antiviral Guidance*, November 20, 2007; Koonin LM, Schwartz B. *Antiviral Stockpiling: Stakeholder's Perspectives: Findings and Analysis*. 2008. Available at: http://www.iom.edu/Object.File/Master/50/642/Koonin.pdf.
[44] Public Engagement Pilot Project on Pandemic Influenza. *Citizen Voices on Pandemic Flu Choices: A Report of the Public Engagement Pilot Project on Pandemic Influenza*. 2005. Available at: http://www.keystone.org/spp/documents/FINALREPORT_PEPPPI_DEC_2005.pdf
[45] US Department of Health and Human Services. *Pandemic Planning Update V*. March 17, 2008. Available at: http://www.pandemicflu.gov/plan/panflureport5.html.
[46] Florida Department of Health. Appendix 2: Ethical framework for decision-making and legal strategy during an influenza pandemic. *Pandemic Influenza Annex, State of Florida Emergency Operations Plan.* Version 10.4. October 2006. Available at: http://www.doh.state.fl.us/rw_Bulletins/flpanfluv104final.pdf.
[47] State of Tennessee Department of Health. *Pandemic Influenza Response Plan [Section 4 Supplement 4: Ethical Allocation of Scarce Resources]* July 2006. Available at: http://health.state.tn.us/Ceds/PDFs/2006_PanFlu_Plan.pdf.
[48] Utah Department of Health. *Governor's Taskforce on Pandemic Influenza Preparedness: Final Report to Governor*. Salt Lake City, Utah, April 2007. Available at: http://www.pandemicflu.utah.gov/docs/PandInfluTaskforceFinalReport.pdf.

ethical guidance and a plan for a severe pandemic. New York's ethical guidance (limited to ventilators) is based on a severe pandemic, although the state plan is ambiguous as to its pandemic severity assumptions.[51] Massachusetts was the only state of eleven planning for a moderate pandemic that includes ethical guidance.[52] Three states indicate that ethical guidance is under development (California, Minnesota, Virginia). California's evolving guidance is unique in that details of the vaccine prioritization methods and analysis are available, but the final priority groups for implementation have not yet been publicly released.[53]

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[49] State Expert Panel on Disaster Ethics. *Ethical Decision-making in a Disaster.* October 2007. Wisconsin Division of Public Health Hospital Emergency Preparedness Program and the Wisconsin Hospital Association.
[50] Tacoma-Pierce County Health Department. *Pandemic Influenza Medical Response Model: Triage and Treatment Guidelines, Revision 1*. Draft. May 24, 2007. Available at: http://pandemicpractices.org/files/183/183_medical_response_model_v2.doc.
[51] New York State Workgroup on Ventilator Allocation in an Influenza Pandemic. *Allocation of Ventilators in an Influenza Pandemic: Planning Document.* 2007 draft. Available at: http://www.health.state.ny.us/diseases/communicable/influenza/pandemic/ventilators/docs/ventilator_guidance.pdf; New York State Department of Health. *Pandemic Influenza Plan.* February 2006. Available at: http://www.health.state.ny.us/diseases/communicable/influenza/pandemic/docs/pandemic_influenza_plan.pdf; Powell T, Christ KC, Birkhead GS. Allocation of ventilators in a public health disaster. *Disaster Medicine and Public Health Preparedness*. 2008;2:20-26.
[52] Massachusetts Department of Public Health. *Guidelines for the Development of Altered Standards of Care for Influenza Pandemic*. Draft. May 2007. Available at: http://pandemicpractices.org/files/63/63_guidelines.doc.
[53] California Department of Health Services. Attachment 6A - Pandemic influenza vaccine prioritization plan. *CDHS Pandemic Influenza Preparedness and Response Plan*. Available at: http://www.idready.org/pandemic_influenza/CDHS_plan_appendix6A.pdf.

Table 2: State and County Ethical Guidance for Pandemic Planning and Response*

Pandemic Severity Assumption	State or County	Type of Guidance: Procedural Guidance	Type of Guidance: Substantive Guidance	Guidance for Rationing Scarce Resources: General	Antivirals	PPE**	Vaccines	Ventilators	Guidance Under Development
Severe	Florida	+	+						
	Minnesota								+
	New York[1]	+	+					+	
	Tacoma-Pierce County, WA		+		+[2]		+[2]	+	
	Tennessee	+	+	+	+		+[2]	+	
	Utah	+	+						
	Wisconsin	+	+	+				+	
Ambiguous	California	+	+				+		+
	Colorado		+				+		
	Connecticut	+	+						
	Indiana	+	+		+			+[3]	
	Iowa	+	+	+				+	
	New Mexico	+	+						
	North Carolina	+	+	+	+	+	+	+	
	Virginia								+
	West Virginia	+			+		+		
Moderate	Massachusetts	+	+	+					

* Current as of September 2007; Colorado, Iowa and Wisconsin current as of March 2008
**PPE = personal protective equipment, including N95 respirators and surgical masks
[1] New York ethical guidance is based on a severe pandemic, although the state pandemic influenza plan is ambiguous as to its pandemic severity assumptions
[2] Prioritizes antivirals and/or vaccines insofar as their prioritization is important to maintaining the standards of care for ventilators
[3] Considered, but unable to reach consensus

a. General Ethical Guidance

Some plans provide ethical guidance for an influence pandemic generally, while others focus on guidance specific to the rationing of scarce resource(s). The majority of documents (12 of 15, including California's preliminary analysis) contain both procedural and substantive guidance.

Seven states provide general ethical guidance for planning for and responding to an influenza pandemic. Three states (Connecticut, [54] Tennessee, West Virginia[55]) adopt the largely procedural ethical framework in the *Stand on Guard for Thee* report.[56] New Mexico also refers to *Stand on Guard for Thee* and uses it as a framework to develop a questionnaire specific to their needs.[57]

Florida's ethical guidance outlines core public health values, including equity and fairness, compassion, respect for persons, and protection from harm. Two substantive recommendations are to: preserve as much equity as possible between the needs of influenza patients and those who need treatment for other diseases; and focus on medical criteria not social worth. The general ethical considerations offered in Iowa's guidance include do no harm, protect individual rights, make decisions for the common good of society and protect health professionals as a matter of reciprocity. Wisconsin's guidance emphasizes the principle of maximizing benefit to each patient as well as protecting vulnerable populations.

b. Guidance for Rationing of Scarce Resources

Several states offer general guidance for the rationing of scarce resources in an influenza pandemic (see Table 3). Tennessee's ethical guidance is noteworthy for several recommendations regarding stewardship: all other things being equal, preferentially use the scarce resource to treat the person with a greater than 5-year life expectancy, the person who is expected to achieve a greater absolute reduction in mortality by the use of that scarce resource, and/or the person who will use a specific scarce resource for a shorter amount of time.

Table 3: State and County Ethical Guidance: Summary of Goals and Strategies*

Influenza Pandemic Generally
Clinical and Public Health
Minimize spread of epidemic (**FL**)[1,2]
Minimize serious illness and death (**FL**)
Do no harm (IA)
Provide compassionate care throughout pandemic (**FL**)
Do as much good as possible for each patient (**WI**)
Societal and Economic Infrastructure
Minimize social and economic disruption (**FL**)
– Involve communities in planning, education and discussions (**FL**, NM)
– Assess public expectations and attitudes (**FL**)
Make decisions based on the common good of society (IA)
Fairness
Protect against stigmatization (NM)
Protect vulnerable populations (NM, **WI**)

[54] Connecticut Department of Public Health. Ethical framework for decision making (Section IC). *Pandemic Influenza Response Plan.* Draft. February 2006. Available at: http://www.ct.gov/dph/lib/dph/php/bt/pdf/ctdph_pan_flu_plan_2-feb-2006.pdf.
[55] State of West Virginia. *West Virginia Influenza Pandemic Preparedness Strategy.* December 2005.
[56] Joint Centre for Bioethics, 2005.
[57] New Mexico Department of Health. Attachment 12: Ethics guidance and matrix. *NMDOH Emergency Operations Plan – Appendix 2: Pandemic Influenza Emergency Response*. September 18, 2006. Available at: http://www.health.state.nm.us/ohem/documents/appendix%2012%20ethics%20Web%20Ready.pdf.

- Provide services free or at low cost (NM)

Protect health professionals (IA)
Preserve equity between flu and non-flu patients (**FL**)
Make decisions based on medical criteria; do not make decisions based on social criteria (**FL**)

Other

Balance public health needs and individual rights (**FL,** IA)
Use least restrictive measures possible (FL)
Ongoing review and revision of decisions (FL)
Protect privacy (NM)

Rationing of Scarce Resources Generally

Clinical and Public Health

Minimize mortality and morbidity (**TN**, MA, NC)
- Assess capacity to benefit from hospitalization (**TN**)
- Prioritize persons with greater 5-year life expectancy (**TN**)
- Prioritize persons with greater capacity to benefit (**TN**)
- Prioritize persons who will use resource more efficiently (**TN**)

Save as many lives as possible (IA, **WI**)
- Prioritize those most likely to spread disease (IA)

Maximize positive patient outcomes (MA)
Prioritize care and protection of health care workers (MA)

Societal and Economic Infrastructure

Minimize social disruption (IA, NC, **TN**)
- Support those who care for the sick (**TN**)

Preserve society's critical infrastructure (IA)
Distribute resources to support the greater good (**WI**)

Fairness

Ensure equitable treatment of groups (IA, MA, NC)
- Do not prioritize based on connectedness to those with resources (MA) or ability to pay (IA)
- Make reasonable efforts to ensure that economically underprivileged groups receive resources (MA)
- Prioritize and distribute resources based on medical, not social criteria (MA, NC, **WI**)

Reciprocity: Prioritize and support those whose work puts them at risk of morbidity or mortality (IA, MA)
Reciprocity: Support those who take on a disproportionate burden of personal risk to care for the sick (TN)
Prioritize most vulnerable (IA)
Provide alternative care for those not receiving resources (**WI**)

Antivirals

Clinical and Public Health

Decrease death and illness (IN, NC, **TN**, WV)
- Prioritize for treatment those at high risk of complications and death (NC)
- Prioritize in first tier hospitalized patients with best chance of survival, pregnant women and high-risk children for treatment (IN)
- Prioritize in second tier immunocompromised patients for post-exposure prophylaxis (IN)

Enhance survival by assessing medical effectiveness (capacity to benefit) (IN)
Maintain effective and quality health care (IN, NC, **TC-WA**[3])
- Prioritize in first tier health care and EMS providers with direct patient contact for treatment (IN)
- Prioritize in second tier health care workers with daily patient exposure for outbreak prophylaxis (IN, **TC-WA**)
- Prioritize caregivers with direct patient contact and essential healthcare support workers for prophylaxis (**TC-WA**)

Societal and Economic Infrastructure

Maintain effective public health and safety infrastructure (IN)
- Prioritize in first tier pandemic health responders and critical infrastructure workers for treatment (IN, NC)
- Prioritize in second tier families of critical infrastructure workers on first-come, first-served basis for post-exposure prophylaxis (IN)
- Prioritize for prophylaxis caregivers with direct patient contact and essential support workers (**TC-WA**)
- Minimize societal and economic impact (IN, NC, WV)

Fairness

Promote the life of future generations (IN)

– Prioritize in second tier all non-high risk children for treatment (IN)

Personal Protective Equipment (including N95 respirators and surgical masks)

Clinical and Public Health

Minimize the spread of disease (NC)

– Prioritize healthcare and other critical workers at high risk of contracting and spreading the disease (NC)

Societal and Economic Infrastructure

Assure functioning of society (NC)

Vaccines

Clinical and Public Health

Decrease health impacts (CA, NC, WV)

– Prioritize based on probability of successful vaccination (CA)
– Prioritize based on risk of transmission, infection or complication (CA)
– Prioritize based on minimizing spread of disease in high-risk populations (CO, NC)
– Prioritize persons at highest risk of mortality (CO)

Minimize mortality in hospital (**TN**)

– Prioritize ICU staff (**TN**)

Societal and Economic Infrastructure

Minimize societal and economic impact (CA, CO, NC, WV)

– Prioritize those who perform essential emergency response or community role (CA)

Protect medical infrastructure to maintain capacity (CO, **TC-WA**)

– Prioritize caregivers with direct patient contact and essential healthcare support workers (NC, **TC-WA**)

Fairness

Reciprocity: Prioritize health care and first responders because they are risking their own health to care for others (CO)

Ventilators

Clinical and Public Health

Minimize mortality (**NY**)

– Limit non-critical use of ventilators (**NY**)

Reduce illness, hospitalizations and deaths (NC)

Minimize mortality by assessing capacity to benefit (IA, IN, NC, **NY**,[4] **TC-WA**)

– Identify "too sick" patients who would be de-prioritized for scarce resources (**NY, TC-WA**)
– Prioritize based on severity of illness and likelihood of recovery (NC)
– Remove those with less capacity to benefit in favor of those with higher likelihood of benefit, using time trials to assess benefit (**NY**)

Protect medical infrastructure to maintain capacity (**TC-WA, TN**)

Provide best medical care to all who are ill (NC, **NY, TC-WA**)

Fairness

Provide care regardless of social worth (NC, **NY, TC-WA**)

Treat flu and non-flu patients equally (**NY**)

Do not prioritize access for healthcare workers (**NY**)

Minimize exacerbation of disparities in access (**NY**)

– Designate resources for most vulnerable (**NY**)
– Maintain consistency of triage criteria throughout state (**NY**)
– Spread financial resources for surge capacity across state (**NY**)

Favor younger over older persons, all else being equal (IN, **TC-WA**)

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* The goals and strategies included here are those that go beyond the guidelines for vaccine and antiviral prioritization in the 2005 HHS pandemic influenza plan.

[1] **Bold** text indicates states preparing for a severe pandemic.

[2] Although strategies may address more than one goal, they are listed only once for ease of presentation.

[3] "TC-WA" refers to Tacoma-Pierce County in the state of Washington.

[4] New York's ethical guidance for allocation of ventilators is based on a severe pandemic, although the state's plan is ambiguous as to the severity of pandemic for which it is preparing.

Massachusetts focuses on the goal of maximizing the number of lives saved and in particular emphasizes doing so in a fair and equitable manner. Their guidance specifically states that social factors, including age, disability and insurance status, should not be used as a basis for prioritizing scarce resources. They also prioritize the protection and treatment of health care providers based on the principle of reciprocity (i.e., the Commonwealth owes these workers protections as they incur increased risks in their work of helping others).

Iowa[58] and Wisconsin both recommend that a primary goal of rationing scarce resources be to save as many lives as possible. In order to accomplish this goal, Iowa recommends prioritizing those who are most likely to spread the disease. Iowa's guidance also recommends rationing scarce resources in such a way to preserve critical infrastructure and minimize social disruption, while Wisconsin's guidance addresses the more general principle of distributing resources to support the greater good. Both Iowa and Wisconsin include several fairness goals in their rationing recommendations. Iowa states a societal obligation to prioritize the most vulnerable and to maintain a goal of valuing all human life equally. Iowa also recommends prioritizing health care workers for resources based on the principle of reciprocity. Wisconsin's guidance recommends using only clinical, not social, criteria to prioritize persons for resources, and suggests that alternative care for those not receiving resources should be provided.

The only state to offer ethical guidance on rationing all four health-related resources (antivirals, PPE (e.g., N95 respirators and surgical masks), vaccines and ventilators) is North Carolina. [59] In their report they conclude that the goals and priority systems are not uniform for these resources or throughout the pandemic. That is, although there may be some general goals for rationing resources, the rationing of specific resources may accomplish different subsets of those goals and do so in different ways.

i. Antiviral Medications

Three states and Tacoma-Pierce County discuss the prioritization of antiviral medications beyond referencing the priority groups listed in the 2005 HHS plan. All four plans embrace minimizing mortality and morbidity as a main goal in rationing antiviral medications, and all would prioritize use of antivirals for treatment over prophylaxis. The plans differ in who they would prioritize to accomplish this goal. North Carolina's guidance would prioritize those at high risk of complications and death. Indiana recommends prioritizing not all hospitalized patients, but those with the best chance of survival, along with pregnant women and high-risk children.[60] If there is enough antiviral medication, Indiana's guidance also recommends prioritizing immunocompromised patients for post-exposure prophylaxis. West Virginia's plan discusses the goal only and does not recommend priority groups.

Another goal for rationing antiviral medications is to maintain effective and quality clinical care by protecting the health care infrastructure. Indiana's plan would do so by prioritizing for treatment health care and emergency medical service providers with direct patient contact; if enough medication were available, they would also prioritize health care workers with daily patient exposure for outbreak prophylaxis. Similarly, Tacoma-Pierce County's guidance recommends ensuring the health care infrastructure by prioritizing caregivers with direct patient

[58] Massaquoi D. *An Ethical Framework for Use in a Pandemic: Report of the Iowa Pandemic Influenza Ethics Committee*. Iowa Department of Public Health: September 10, 2007.
[59] North Carolina Institute of Medicine. *Stockpiling Solutions: North Carolina's Ethical Guidelines for an Influenza Pandemic*. 2007. Available at: http://www.nciom.org/projects/flu_pandemic/panflu.html.
[60] Indiana State Department of Health. *Report to the State Health Commissioner on the Findings and Recommendations of the Pandemic Influenza Community Advisory Groups*. November 15, 2006. Available at: http://www.in.gov/isdh/bioterrorism/PandemicFlu/pdfs/FindingsRecommendationPanInfluenza2006.pdf.

contact and essential support workers for prophylaxis. Their guidance is primarily aimed at supporting critical care and the use of ventilators.

West Virginia, Indiana and North Carolina's guidance all include goals for the rationing of antiviral medications that are aimed at minimizing societal and economic impact, in part by maintaining an effective public health and safety infrastructure. North Carolina and Indiana both recommend prioritizing health care and critical infrastructure workers for treatment; if enough medication is available, Indiana also prioritizes the families of critical infrastructure workers on a first-come, first-served basis for post-exposure prophylaxis. Again, West Virginia offered no guidance beyond the statement of the goal.

Indiana's guidance for antiviral medications is unique in that it explicitly prioritizes children for antiviral treatment, based on the goal of promoting the life of future generations.

ii. Personal Protective Equipment

The only plan to address the prioritization of personal protective equipment (PPE, e.g., N95 respirators and surgical masks) is North Carolina's. This guidance expresses two goals for the rationing of PPE: to assure the functioning of society and to minimize the spread of disease. To this end, they recommend prioritization of PPE to healthcare workers and other critical workers at high risk of contracting and spreading the disease, including healthcare workers with direct patient contact and emergency response and public safety workers.

iii. Vaccine

Five states and Tacoma-Pierce County discuss the rationing of pandemic vaccine, although California's prioritization plan is still under development. Two plans, Tennessee and Tacoma-Pierce County, discuss vaccine prioritization solely in the context of how it can help support critical care and the use of ventilators. To this end, they recommend maintaining the clinical infrastructure by prioritizing critical care staff, other healthcare workers with direct patient contact, and essential healthcare support workers for vaccination. North Carolina also recommends prioritizing these same groups of workers, albeit to support the broader goal of ensuring the basic functioning of society. West Virginia and California also name this as a goal of rationing vaccines; California recommends supporting this goal by prioritizing vaccine for those who perform essential emergency response or community roles.

Another common goal for rationing vaccines is to decrease public health impacts. California's preliminary guidance recommends prioritizing individuals to receive vaccine based on the probability of successful vaccination, and based on the risk of transmission, infection or complication. Similarly, North Carolina's guidance advocates for prioritizing vaccine based on minimizing the spread of disease, particularly in high-risk populations.

Colorado's guidance is similar in that it recommends prioritizing persons at highest risk of transmission or mortality. In addition, the guidance recommends a fairness goal that prioritizes health care workers and first responders based on reciprocity, because they are risking their own health to take care of others. Colorado's guidance also emphasizes the need to preserve societal and critical infrastructures.

iv. Ventilators

The ethical rationing of ventilators is considered by several states. Uniquely, New York's ethical guidance focuses solely on the rationing of ventilators. Though Indiana convened a work group

to develop recommendations for rationing ventilators, the group was unable to reach consensus.

Plans rationing ventilators place high value on the goal of minimizing mortality**.** To this end, New York's guidance recommends limiting the non-critical use of ventilators. All plans emphasize that a key way to minimize mortality would be to do so via assessing capacity to benefit (Indiana, Iowa, North Carolina, New York, Tacoma-Pierce County). Several ideas are proposed on how to assess this capacity. North Carolina's guidance prioritizes ventilator use based on severity of illness and likelihood of recovery. New York's guidance suggests using time trials to assess likelihood of benefit and removing those individuals with less capacity to benefit in favor of those with greater likelihood of benefit. Tacoma-Pierce County developed a category of the "too-sick" patient (that can include the oldest among us) who would be de-prioritized for scarce resources. This category is based on a combination of clinical factors in conjunction with age.

North Carolina, New York and Tacoma-Pierce County all express a desired goal of rationing ventilators to provide the best medical care to all who are ill, defined as providing care regardless of social worth. However, Tacoma-Pierce leaves open the option of considering younger aged persons over older. New York's guidance further expresses a recommendation to treat flu and non-flu patients equally, and deny priority access for healthcare workers. New York's guidance is the only plan to include the goal of minimizing exacerbation of disparities in access when rationing ventilators. They explicitly recommend the strategies of designating resources for the most vulnerable, maintaining consistency of triage criteria throughout the state, and spreading financial resources for surge capacity across the state.

c. Methods of Developing State Ethical Guidance

States employed a variety of methodologies for the development of ethical guidance. Some states either reproduced or customized previously published work in pandemic ethics (West Virginia, Connecticut, Tennessee, New Mexico, Wisconsin). Indiana and Tacoma-Pierce County convened community advisory groups, while Iowa, Massachusetts, New York and Utah relied on expert taskforces to develop guidance. Whether labeled community advisory groups or expert taskforces, these groups typically included experts in medicine, public health, public policy, bioethics and emergency preparedness, as well as government officials and representatives of various community groups. North Carolina combined the efforts of an expert taskforce with information gathered from public forums to discuss rationing of scarce resources. Wisconsin has published initial guidance with plans to provide forums for public and professional discussion, incorporating feedback from these forums into the final version. California chose a quantitative methodological approach. The California Department of Health Services developed the Decision Analysis Scoring Tool to assist in creating prioritization groups and rankings for vaccination. Florida and West Virginia do not indicate how their guidance was developed or by whom.

4. Scholarly Publications

(see Selected Resources below for additional citations)

a. General Ethical Guidance

Two recent reviews examine general ethical guidance for planning and responding to pandemic influenza.[61] Kotalik asserts that in a pandemic it will not be business as usual and we need to rethink how ethical principles and values are prioritized in planning for such an event. His recommendations include consideration of the precautionary principle (that we have a duty to

[61] Kotalik, 2006; Thomas, *Ethical Concerns,* 2007.

prevent harm when possible, and should attempt to do so even in the face of uncertainty) and of subsidiarity (local decision-making); he advocates for a decision-making framework that blends ethical principles.

Thomas focuses on procedural fairness and emphasizes related principles for consideration, including collaboration, communication with the public and the inclusiveness of the public in policymaking. He also recommends that in preparing for pandemic influenza we should not ignore other ongoing public health concerns (e.g., clean water), and that ethicists and local public health personnel need to work together.

Several authors focus on the issue of social justice in pandemic planning.[62] They generally stress the need for procedural fairness, particularly inclusiveness and transparency, in pandemic planning in order to reduce injustice. They urge planners to consider where social injustice might occur (including from a global perspective) and implement ways to reduce the injustices to the extent possible. Prioritizing essential workers, for example, can raise serious fairness concerns for many disadvantaged groups unless steps are also taken to consider the interests of disadvantaged groups.

b. Rationing Scarce Resources in a Pandemic

Arras and Kotalik note the lack of discussion around rationing in a pandemic and highlight the need to involve the public in setting societal priorities.[63] Kotalik names four principles of justice to consider when rationing scarce resources: distribution according to need, to everyone an equal share, distribution to maximize health or distribution to maximize a person's contribution. He suggests that as a matter of justice we must strive to not exacerbate existing inequalities among groups.

i. ANTIVIRALS

Much of the literature on the role of antiviral medications in pandemic influenza is based on epidemiological modeling and is beyond the scope of this review. However, it is important to note that the assumptions underlying these models (e.g., efficacy, resistance) vary because there are many unknowns about antivirals in the context of pandemic influenza. This dearth of information makes prioritization issues complicated.[64] One of the key issues is whether to use a limited supply of antiviral medications for treatment or preventative purposes. In one of the only articles to discuss prioritizing antivirals, Letts states that one option is to prioritize health care workers for prophylaxis based on the principle of reciprocity, while allocating treatment doses based on medical need and to maintain societal functioning.[65]

ii. N95 RESPIRATORS AND SURGICAL MASKS

There is little ethical guidance for rationing N95 respirators and surgical masks specifically or personal protective equipment more generally. In a recent article, Aledort and colleagues report that an expert panel prioritized personal protective equipment (including N95 respirators and

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[62] Arras J. Rationing vaccine during an avian influenza pandemic: why it won't be easy. *Yale J Biol Med.* 2005;78:287-300; Faden R. Social justice and pandemic planning and response. In Lemon SM, Hamburg MA, Sparling PF, et al., *Ethical and Legal Considerations in Mitigating Pandemic Disease: Workshop Summary*. National Academies Press; 2007. Available at: http://www.nap.edu/catalog.php?record_id=11917; Kayman H, Ablorh-Odjidja A. Revisiting public health preparedness: Incorporating social justice principles into pandemic preparedness planning for influenza. *J Public Health Manag Pract.* 2006;12:373-380; Uscher-Pines L, Duggan PS, Garoon JP, Karron RA, Faden RR. Social justice and disadvantaged groups. *Hastings Cent Rep*. 2007;37:32-39; See also: Bellagio Group. *Bellagio Statement of Principles*. 2006. Available at http://www.hopkinsmedicine.org/bioethics/bellagio/statement.html.

[63] Arras, 2005; Kotalik, 2006.

[64] Ibid.

[65] Letts J. Ethical challenges in planning for an influenza pandemic. *N S W Public Health Bull*. 2006; 17:131-134.

surgical masks) for health care providers and hospital and ambulatory patients.[66] However, they do not state underlying ethical principles for choosing these populations; they are concerned about protecting against viral resistance.

iii. VACCINE

Arras concludes that Americans are unlikely to reach agreement about how to ration pandemic vaccines given our lack of agreement about how to decide whether and when to ration—not on the basis of need alone—but on the basis of such different considerations as social function or age.[67] Zimmerman invokes principles of medical neediness and random chance and warns that prioritization based on social worth or likelihood of survival raise substantial justice issues.[68]

The Minnesota Pandemic Influenza Ethics Work Group developed one of the most detailed ethical frameworks for rationing vaccines.[69] It makes explicit its assumptions about a severe pandemic, the vaccine supply and efficacy, and related operational assumptions. The framework balances several ethical commitments including several fairness principles, i.e., reduce differences in influenza-related mortality, respect moral equality and use fair procedures, in addition to principles of limiting harm and wisely stewarding scarce resources. The primary goal is to limit deaths due to influenza and due to the disruption of infrastructure both during the pandemic and shortly thereafter. The secondary goals are to promote social cohesiveness and collaboration and protect against the loss of any generation. Groups are prioritized to be vaccinated based on different combinations of five characteristics: high risk of death, high vaccine response, classification as an essential worker, high risk of transmission, and lack of satisfactory alternative protections.

Emanuel and Wertheimer advocate an unusual age-based fairness principle.[70] They call for prioritizing persons to receive vaccine based on the life-cycle allocation principle, which promotes maximizing an individuals' life span and the opportunity to reach life goals. They propose that individuals ages 15-40 should be prioritized to receive vaccine because they are old enough to have developed life goals but young enough not to have had the opportunity to meet them.

iv. VENTILATORS

Most of the literature addressing the rationing of ventilators in an influenza pandemic focuses on using clinical criteria for prioritization of these extremely ill patients. Christian and colleagues suggest excluding from receiving a ventilator those who have an extremely poor prognosis, those with serious underlying illness, and those who require resources that will be unavailable in a pandemic.[71] They also raise the issue of excluding those over the age of 85, although indicate more discussion needs to take place around including age as an exclusion criteria. The authors state their work was based on the University of Toronto's list of ethical values, yet they do not articulate how they prioritized these values in the development of their protocol.[72] Guerrier

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[66] Aledort JE, Lurie N, Wasserman J, Bozzette SA. Non-pharmaceutical public health interventions for pandemic influenza: an evaluation of the evidence base. BMC *Public Health.* 2007;7:208. Available at: http://www.biomedcentral.com/1471-2458/7/208.

[67] Arras, 2005.

[68] Zimmerman RK. Rationing of influenza vaccine during a pandemic: ethical analyses. *Vaccine*. 2007;25:2019-2026.

[69] Vawter et al, 2007.

[70] Emanuel EJ, Wertheimer A. Who should get influenza vaccine when not all can? *Science*. 2006; 312: 854–855; See also: The ethics of influenza vaccination. Letters. *Science* 2006;313:758-760.

[71] Christian MD for the OHPIP Adult Critical Care Admission, Discharge, Triage Working Group. *Critical Care during a Pandemic: Final report of the Ontario Health Plan for an Influenza Pandemic (OHPIP) Working Group on Adult Critical Care Admission, Discharge and Triage Criteria*. Hamilton, ON: McMaster University Medical Centre, April 2006; Christian MD et al, *CMAJ,* 2006.

[72] Joint Centre for Bioethics, 2005; Melnychuk RM, Kenny NP. Pandemic triage: the ethical challenge. *CMAJ*. 2006;175:1393-1394. Available at:

emphasizes that, in a situation with altered standards of care, ventilator prioritization should be based on individual benefit, rejects the use of social criteria, and explicitly calls for effort to minimize discrimination and injustice in the plan and its implementation.[73]

Two articles assert that in a pandemic, ventilators shift from an individual good to a public health good and thus the prioritization of ventilator use needs to reflect this.[74] Hick and colleagues have developed a multi-tiered approach based on the severity of the shortage, prioritizing patients most likely to benefit. They explicitly reject using age as a social criterion for prioritization, and question the value of using quality of life. Lo suggests giving high priority to those with a high likelihood of survival, and emphasizes the need for fairness, perceptions of fairness and transparency.

IV. Discussion

Pandemic influenza preparedness plans vary in their underlying assumptions about: (1) whether the pandemic will be mild, moderate, or severe; (2) what the supply and availability of scarce health-related resources will be during different times throughout the pandemic; and (3) what information will be available about who is at risk, who can benefit, and other operational matters.

There is also considerable variety among pandemic plans in their attention to guidance for ethical decision-making; many pandemic plans contain no ethical guidance at all. This is due, at least in part, to the fact that the assumptions about the pandemic are left vague given all the uncertainties about what it will actually look like. While this ambiguity is fine for allowing flexibility in a planning document, it makes the development of ethical guidance more difficult as goals and strategies may change significantly depending upon the severity of the pandemic.

Although the uncertainties about the nature of a future pandemic can be paralyzing, this review of the literature suggests that ethical guidance can be developed, even in the face of uncertainty. Four US states and one county, as well as several national plans, both explicitly plan for severe pandemic and offer ethical guidance; Minnesota will be the fifth state to do so. Ethical guidance for pandemic planning is also starting to be developed at the federal level. The CDC released ethical principles for pandemic planning in February 2007, and an interagency working group released guidance documents for rationing vaccines and antivirals in a severe pandemic later in the year. Developing ethical guidance for planning for and responding to a severe pandemic is important because the ethical issues are in the sharpest relief during a severe pandemic, when critical societal and economic infrastructures are threatened and demand for health care resources is expected to vastly outstrip supply.

A. General Ethical Principles

Although the ethical guidance specific to a severe pandemic may be sparse, it is instructive to look at all guidance developed for pandemic influenza planning, regardless of the pandemic severity assumptions. The principle expressed most consistently is that of minimizing harm, both to individuals and to populations. Non-US guidance is more likely to value promoting social

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http://www.cmaj.ca/cgi/reprint/175/11/1393?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&searchid=1&FIRSTINDEX=0&minscore=5000&resourcetype=HWCIT.

[73] Guerrier M. Considering restricting access to intensive care. *Pandemics*. 2006;1:39-42. Available at: http://www.espace-ethique.org/fr/documents/pandemics/pandemics01.pdf.

[74] Hick JL, Rubinson L, O'Laughlin DT, Farmer JC. Clinical review: allocating ventilators during large-scale disasters: problem, planning, and process. *Critical Care.* 2007;11:217; Lo B. Intensive care unit triaging during an influenza pandemic: the need for specific clinical guidelines. In Lemon SM, Hamburg MA, Sparling PF, et al., *Ethical and Legal Considerations in Mitigating Pandemic Disease: Workshop Summary*. National Academies Press; 2007. Available at: http://books.nap.edu/catalog.php?record_id=11150.

solidarity and neighborliness than the guidance developed in the US. Rationing guidance for severe pandemics is more likely to emphasize population health than individual clinical interests. Rationing plans, however, are usually only a small piece of much larger pandemic plans. It is important to review plans and guidance documents in their entirety to fully understand the ethical attention they direct to the care of individuals.

Most state plans address some aspect of the rationing of scarce resources. The most common approach is to adopt the 2005 HHS recommendations for vaccine and antiviral prioritization designed for use in a moderate pandemic. Of those states that provide alternative guidance, many emphasize procedural vs. substantive fairness. Those that include substantive principles usually state one or more of the following three broad principles: minimize mortality, maintain societal and economic infrastructure, and act fairly. Whereas some also explicitly include concern for the wise stewardship of resources, most do not. The guidance documents differ both in the specifics of these principles and in the goals and strategies they use to implement these principles. For example, minimizing mortality may be interpreted as minimizing mortality from flu only, or minimizing mortality due to flu and degradation of critical infrastructures. In order to minimize mortality, some states prioritize persons at high risk of death, others prioritize persons at high likelihood of benefiting from access to the resource or those at high risk of transmitting the virus to others. Fairness, too, has multiple dimensions and most states embrace a combination of fairness principles.[75]

The extent to which guidance is offered for specific resources also varies. Guidance for the prioritization of N95 respirators and surgical masks is virtually nonexistent. Yet a considerable amount of attention has been given to rationing ventilators, which is interesting given the small role they are expected to play in protecting and promoting a population's health and because states have little direct control over the supply. North Carolina's report is the only guidance that attends to rationing several specific resources, namely antivirals, vaccines, ventilators and PPEs; it emphasizes that the goals of rationing different types of resources differ.

B. Non-Clinical Considerations

Whereas rationing on the basis of need and efficacy is widely accepted, there is less consensus on the appropriateness of rationing on the basis of a broad range of fairness considerations. This review reveals appeals to the following list of fairness considerations:

- Equal concern and respect
- Treat flu and non-flu patients equally
- Reciprocity
- Do not exacerbate disparities
- Do not rely on first-come, first-served
- Take reasonable steps to remove barriers to access
- Protect against stigmatization
- Fair access for those similarly prioritized
- Save groups at disproportionate risk
- Protect against the loss of groups, e.g., a generation
- Younger before older, all other matters being equal

[75] Rhodes R. Justice in allocations for terrorism, biological warfare, and public health. In: M. Boylan ed. *Public Health Policy and Ethics*. Boston, MA: Kluwer Academic Publishers; 2004.

Discussed most were social function (i.e., essential worker status), reciprocity, age and quality of life. Some plans explicitly reject using social factors such as age or quality of life in prioritization for scarce resources. Other plans, however, have proposed criteria for access to resources based on age, generally prioritizing younger over older persons on the basis of fairness, i.e., giving younger persons the opportunity to live a normal life-span. More attention to these questions is critical, including under what circumstances these considerations are ever justified.

1. Essential Worker Status

Several reasons and combinations of reasons are offered for prioritizing essential workers ahead of the general population. Reasons include: to maintain the health care or other critical infrastructures; to protect workers with critical roles or high exposure; to reduce transmission to patients/clients; to reduce transmission to disadvantaged persons; and to honor reciprocity in light of high exposure or any increased risk of exposure. High occupational exposure to influenza often is the basis of the prioritization of essential workers, and this is the case in the federal draft vaccine guidance. Workers at especially high risk of exposure are prioritized first.

Pandemic rationing guidance for severe pandemics recognizes the importance of preserving core infrastructures. For this reason people who have essential roles in health care and other critical infrastructures are usually prioritized to receive scare health resources regardless of their individual risk of dying. They are not prioritized because they are morally superior. Rather they are prioritized because everyone's life depends on these essential functions. In essence, it is the workers' function in society that is prioritized and not the workers themselves. Prioritizing groups based on social function is a novel utility-based consideration, rarely applied in non-disaster circumstances. The CDC's ethical guidance is unique in that it treats prioritizing essential workers as a rare, but acceptable form of attending to differences in social value.[76] Others suggest that prioritizing some essential workers under some circumstances is consistent with respecting the moral equality of all and does not constitute prioritization based on attention to social value.[77]

2. Reciprocity

Given the attention in pandemic plans to prioritizing essential workers, it is noteworthy that only four states appeal to the principle of reciprocity to justify prioritizing essential workers to receive scarce resources, specifically prophylactic antivirals and vaccines. This principle is not included in CDC's ethical guidance, but is included in the draft guidance documents proposed by the federal interagency working group on vaccines and antivirals. It is mentioned once in the vaccine guidance, but it is unclear how it was considered or applied in the end to the prioritization recommendations. The antiviral guidance notes while that prioritizing outbreak prophylaxis of health care workers with direct patient contact and front-line emergency service workers is consistent with reciprocity, it is not the main or most important reason for prioritizing essential workers. This guidance is unique in that it would extend reciprocity obligations to household members who stay home while members are sick and give them post-exposure prophylactic antivirals. CHR, NZ, ON, UK, and WHO all include reciprocity among the key ethical principles for pandemic response, but the question remains about when it should be applied and how important it is in determining order of priority to access scarce resources.

Another important outstanding issue regarding reciprocity is what limits there are on this obligation to essential workers. Should they always be at the head of the line to receive any kind

[76] Kinlaw and Levine, 2007.
[77] Vawter et al., 2007.

of scarce resource? Does reciprocity require that their household members also be prioritized? Does it require hazard pay or special disability and life insurance policies? The New York State Task Force asserts that reciprocity does not extend to prioritizing ill essential workers to receive mechanical ventilators. Otherwise, most guidance says little about how far reciprocity obligations extend and what other ethical considerations can counter them.

3. Age

Some people judge age-based rationing to be unfair[78], some consider it fair or accept it provisionally assuming additional conditions can be satisfied (e.g., that it is preceded by wide public consultation and agreement),[79] and others are still considering its acceptability.[80] Whereas some guidance includes age in the list of prohibited social worth factors, other guidance does not. Among those who consider it unfair, many are planning for a moderate pandemic and it is unclear whether they would reconsider the fairness of age-based rationing in a severe pandemic during times of severe shortages.

4. Quality of Life

Few pandemic guidance documents address quality of life directly. The New York State Workgroup on Ventilator Allocation in an Influenza Pandemic is an important exception.[81] In addition, a couple of guidance documents suggest that severe cognitive impairment may be an exclusion factor in some circumstances.[82]

C. Methods

A variety of methods were used to develop the guidance reviewed here (a quantitative survey; consultation with various experts; community advisory and engagement activities). While it is not yet clear what the best methodology for guidance development may be, it is evident that decisions to allow rationing on the basis of non-clinical and non-public health related considerations require community engagement.

The importance of articulating the ethical rationales for planning and prioritization should not be underestimated. Being clear about the ethical values that underlie rationing decisions promotes decisions that reflect widely held societal values, and promotes trust and acceptance. Plans that do not clearly articulate the ethical values that underlie them risk noncompliance, mistrust and at worst possible civil unrest and societal disruption.[83]

The current ethical guidance for planning for and responding to a severe influenza pandemic leaves plenty of room for continued development and improvement. Some of the guidance reviewed here is of questionable applicability, as it was designed for moderate pandemic or fails to specify the severity of the pandemic. Many issues are under-analyzed, including ethical justifications, rationing in the context of a global public health disaster, age-based rationing, quality of life considerations, the concept of reciprocity for health care workers and first responders, the definition of essential functions, and how best to balance or prioritize multiple ethical commitments, to name a few.

[78] Phillips and Knebel, 2007; Swiss Federal Office of Public Health. *Swiss Influenza Pandemic Plan*. November 2007; Calgary Health Region, 2007; Massachusetts Department of Public Health, 2007; North Carolina Institute of Medicine, 2007.
[79] Arras, 2005; WHO, *Ethical Considerations*, 2007; Indiana State Department of Health, 2006; Tacoma-Pierce County, 2007.
[80] Straetemans, 2006; Christian, 2006; Tacoma-Pierce County, 2007.
[81] New York State Workgroup, 2007.
[82] Christian MD et al, *CMAJ,* 2006; Tacoma-Pierce County, 2007.
[83] Vawter et al, 2007; Melnychuk and Kenny, 2006.

V. Conclusion

This literature review has highlighted the need for detailed ethical guidance for the rationing of scarce health-related resources in the context of a severe influenza pandemic. It is important that future guidance clearly specifies the assumptions it is working under and the perspective that it is taking, as a statewide or national perspective may differ from an institutional or individual perspective. The guidance development process should build on the work of others and engage persons with a wide range of experience and expertise. It is unlikely that a single ethical principle or goal will be sufficient to guide rationing of health-related resources in a severe pandemic. Effective ethical guidance for rationing resources in a severe pandemic is expected to include different ethical principles and goals than we are accustomed to now. It is vital to provide rationales as well as instruction about how to prioritize or balance multiple principles and goals.

VI. Selected Resources

(Partially Annotated*)

Introduction

This bibliography of resources contains citations to resources relevant to ethical issues in planning for and responding to an influenza pandemic, with a particular emphasis on the rationing of scarce health-related resources. This partially annotated bibliography is a selective list of scholarly publications and ethical guidance by governments and organizations; it is not intended to be comprehensive. Annotations generally were excerpted from abstracts, overviews or summaries. To assist the reader, the list is organized topically and entries may appear in more than one section.

I. Ethical Guidance for Pandemic Planning and Response

Ardagh M. Criteria for prioritising access to healthcare resources in New Zealand during an influenza pandemic or at other times of overwhelming demand. *N Z Med J.* 2006;119(1243):U2256.

Calgary Health Region. Ethics of health care decision making during a pandemic crisis (Section 3). *Pandemic Influenza Response Plan*. 2007. Available at: http://www.calgaryhealthregion.ca/pandemic/pdf/chr_response_plan_0307.pdf.

California Department of Health Services. Attachment 6A - Pandemic influenza vaccine prioritization plan. *CDHS Pandemic Influenza Preparedness and Response Plan.* Available at: http://www.idready.org/pandemic_influenza/CDHS_plan_appendix6A.pdf.

Capron AM. Ethical considerations in international preparedness planning efforts. In Lemon SM, Hamburg MA, Sparling PF, et al., *Ethical and Legal Considerations in Mitigating Pandemic Disease: Workshop Summary.* National Academies Press; 2007. Available at: http://books.nap.edu/catalog.php?record_id=11917.

> This chapter examines a variety of ethical approaches to pandemic planning, noting that ethics may be applied to both the content of policies and the processes by which they are established and implemented. It specifically addresses the implications of pandemic influenza for human rights, access to health care, obligations of and to health-care workers, and obligations of countries and intergovernmental organizations.

Connecticut Department of Public Health. Ethical framework for decision making (Section IC). *Pandemic Influenza Response Plan.* Draft. February 2006. Available at: http://www.ct.gov/dph/lib/dph/php/bt/pdf/ctdph_pan_flu_plan_2-feb-2006.pdf.

Department of Health, United Kingdom. *Responding to Pandemic Influenza: The Ethical Framework for Policy and Planning.* 2007. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_080751.

Department of Health, United Kingdom. *Pandemic Flu: A National Framework for Responding to an Influenza Pandemic*. 2007. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_080751.

European Centre for Disease Prevention and Control. *Technical Report: Expert Advisory Groups on Human H5N1 Vaccines: Public Health and Operational Questions.* Stockholm: August 2007. Available at: http://ecdc.europa.eu/pdf/PH%20Questions%20final.pdf.

Faden R. Social justice and pandemic planning and response. In Lemon SM, Hamburg MA, Sparling PF, et al., *Ethical and Legal Considerations in Mitigating Pandemic Disease: Workshop Summary*. National Academies Press; 2007. Available at: http://www.nap.edu/catalog.php?record_id=11917.

Florida Department of Health. Appendix 2: Ethical framework for decision-making and legal strategy during an influenza pandemic. *Pandemic Influenza Annex, State of Florida Emergency Operations Plan.* Version 10.4. October 2006. Available at: http://www.doh.state.fl.us/rw_Bulletins/flpanfluv104final.pdf.

Gostin LO. Medical countermeasures for pandemic influenza: ethics and the law. *JAMA*. 2006;295:554–556.

Gostin LO. Public health strategies for pandemic influenza: ethics and the law. *JAMA*. 2006;295:1700–1704.

* All internet links accurate as of March 25, 2008.

The White House strategic plan and congressional appropriation both devote more than 90% of pandemic influenza spending to vaccines and antiviral medications. Yet, medical countermeasures…will not impede pandemic spread: experimental H5N1 vaccines may not be effective against a novel human subtype, neuraminidase inhibitors may become resistant, and medical countermeasures will be extremely scarce. This Commentary focuses on traditional public health interventions, drawing lessons from past influenza pandemics and the outbreaks of severe acute respiratory syndrome (SARS).

Gostin L, Berkman B. Pandemic influenza: ethics, law, and the public's health. *Admin L Rev*. 2007;59:121-175.

Gostin L, Berkman B for WHO Working Group Two. *Project on Addressing Ethical Issues in Pandemic Influenza Planning: Ethics of Public Health Measures in Response to Pandemic Influenza.* Draft report. October 6, 2006. Available at: http://www.who.int/eth/ethics/PI_Ethics_draft_paper_WG2_6_Oct_06.pdf.

Holmberg SD, Layton CM, Ghneim GS, Wagener DK. State plans for containment of pandemic influenza. *Emerg Infect Dis*. 2006;12:1414-1417.

Indiana State Department of Health. *Report to the State Health Commissioner on the Findings and Recommendations of the Pandemic Influenza Community Advisory Groups.* November 15, 2006. Available at: http://www.in.gov/isdh/bioterrorism/PandemicFlu/pdfs/FindingsRecommendationPanInfluenza2006.pdf.

The report outlines recommendations on: 1) the role of antiviral medication, 2) community containment measures, 3) altered standards of care, and 4) mental health issues.

Joint Centre for Bioethics. Pandemic Influenza Working Group Members (Ross E.G. Upshur, Karen Faith, Jennifer L. Gibson, Alison K. Thompson, C. Shawn Tracy, Kumanan Wilson, Peter A. Singer). *Stand on Guard for Thee: Ethical Considerations in Preparedness Planning for Pandemic Influenza.* Toronto: University of Toronto Joint Centre for Bioethics. 2005. Available at: http://www.utoronto.ca/jcb/home/documents/pandemic.pdf.

The Working Group developed a 15-point ethical guide for planning and decision-making for a pandemic. It identified four key ethical issues that need to be addressed, and made specific recommendations for each: health workers' duty to provide care during a communicable disease outbreak; restricting liberty in the interest of public health by measures such as quarantine; priority setting, including the allocation of scarce resources such as vaccines and antiviral medicines; and global governance implications, such as travel advisories.

Kayman H, Ablorh-Odjidja A. Revisiting public health preparedness: Incorporating social justice principles into pandemic preparedness planning for influenza. *J Public Health Manag Pract.* 2006;12:373-380.

Kinlaw K, Levine R. *Ethical Guidelines in Pandemic Influenza: Recommendations of the Ethics Subcommittee of the Advisory Committee to the Director.* Centers for Disease Control and Prevention. 2007. Available at: http://www.cdc.gov/od/science/phec/guidelinesPanFlu.htm.

Kotalik J. *Ethics of Planning for and Responding to Pandemic Influenza: Literature Review*. 2006. Available at: http://www.bag.admin.ch/nekcne/04229/04235/index.html?lang=en&download=M3wBUQCu/8ulmKDu36WenojQ1NTTjaXZnqWfVp3Uhmfhnapmmc7Zi6rZnqCkkIZ6fHyDbKbXrZ2lhtTN34al3p6YrY7P1oah162apo3X1cjYh2

Kotalik J. Preparing for an influenza pandemic: ethical issues. *Bioethics*. 2005;19:422–431.

Examination of the pandemic plans of Canada, the United Kingdom and the United States, from an ethical perspective, raises several concerns. One: scarcity of human and material resources is assumed to be severe. Plans focus on prioritization but do not identify resources that would be optimally required to reduce deaths and other serious consequences. Hence, these plans do not facilitate a truly informed choice at the political level where decisions have to be made on how much to invest now in order to reduce scarcity when a pandemic occurs. Two: mass vaccination is considered to be the most important instrument for reducing the impact of infection, yet pandemic plans do not provide concrete estimates of the benefits and burdens of vaccination to assure everyone that the balance is highly favorable. Three: pandemic plans make extraordinary demands on health care workers, yet professional organizations and unions may not have been involved in the plans' formulation and they have not been assured that authorities will aim to protect and support health care workers in a way that corresponds to the demands made on them. Four: all sectors of society and all individuals will be affected by a pandemic and everyone's collaboration will be required. Yet, it appears that the various populations have been inadequately informed by occasional media reports. It is essential that plans not only inform but also create an atmosphere of mutual trust and solidarity.

Lemon SM, Hamburg MA, Sparling PF, et al., *Ethical and Legal Considerations in Mitigating Pandemic Disease: Workshop Summary*. National Academies Press; 2007. Available at: http://www.nap.edu/catalog.php?record_id=11917.

This workshop identified barriers to equitable and effective responses to future pandemics, and examined opportunities to overcome these obstacles through research, policy, legislation, communication, and community engagement.

Letts J. Ethical challenges in planning for an influenza pandemic. *N S W Public Health Bul*l. 2006;17:131-134.

Massachusetts Department of Public Health. *Guidelines for the Development of Altered Standards of Care for Influenza Pandemic*. Draft. May 2007. Available at: http://pandemicpractices.org/files/63/63_guidelines.doc.

Includes a draft process for decision making on priorities for the allocation of limited health care resources. Age, disability and insurance status are specifically named as characteristics that will not affect prioritization decisions.

Massaquoi D. *An Ethical Framework for Use in a Pandemic: Report of the Iowa Pandemic Influenza Ethics Committee*. Iowa Department of Public Health: September 10, 2007.

McKenna M. Anatomy of a pandemic: emergency departments woefully unprepared for bird flu outbreak. *Annals of Emergency Medicine*. 2006;48:312-314. Available at: http://www.kff.org/mediafellows/upload/Fellow040507McKennaBirdFlu-2.pdf.

Meltzer MI, Cox NJ, Fukida K. The economic impact of pandemic influenza in the United States: priorities for intervention. *Emerg Infect Dis.* 1999;5:659–671. Available at: http://www.cdc.gov/Ncidod/eid/vol5no5/meltzer.htm.

Ministry of Health and Long Term Care. Chapter #2. Roles, responsibilities and frameworks for decision making. *Ontario Health Plan for an Influenza Pandemic.* 2007. Available at: http://www.health.gov.on.ca/english/providers/program/emu/pan_flu/ohpip2/plan_full.pdf

National Ethics Advisory Committee – Kāhui Matatika o te Motu. *Ethical Values for Planning for and Responding to a Pandemic in New Zealand: A Statement for Discussion*. Ministry of Health, Wellington, New Zealand; 2006. Available at: http://www.neac.health.govt.nz/moh.nsf/indexcm/neac-resources-publications-pandemic.

National Ethics Advisory Committee – Kāhui Matatika o te Motu. *Getting Through Together: Ethical Values for a Pandemic*. Wellington: Ministry of Health; 2007. Available at: http://www.neac.health.govt.nz/moh.nsf/indexcm/neac-resources-publications-gettingthroughtogether.

National Infrastructure Advisory Council. *The Prioritization of Critical Infrastructure for a Pandemic Outbreak in the United States Working Group: Final Report and Recommendations by the Council.* 2007. Available at: http://www.dhs.gov/xlibrary/assets/niac/niac-pandemic-wg_v8-011707.pdf.

New Mexico Department of Health. Attachment 12: Ethics guidance and matrix. *NMDOH Emergency Operations Plan – Appendix 2: Pandemic Influenza Emergency Response*. September 18, 2006. Available at: http://www.health.state.nm.us/ohem/documents/appendix%2012%20ethics%20Web%20Ready.pdf.

North Carolina Institute of Medicine. *Stockpiling Solutions: North Carolina's Ethical Guidelines for an Influenza Pandemic*. 2007. Available at: http://www.nciom.org/projects/flu_pandemic/panflu.html.

Phillips SJ, Knebel A, eds. *Mass Medical Care with Scarce Resources: A Community Planning Guide*. AHRQ Publication No. 07-0001. Rockville, MD: Agency for Healthcare Research and Quality. 2007. Available at: http://www.ahrq.gov/research/mce/.

Public Engagement Pilot Project on Pandemic Influenza. *Citizen Voices on Pandemic Flu Choices: A Report of the Public Engagement Pilot Project on Pandemic Influenza*. 2005. Available at: http://www.keystone.org/spp/documents/FINALREPORT_PEPPPI_DEC_2005.pdf.

Public Health Agency of Canada. Ethics and pandemic planning (Section 2, Subsection 6.0). *Canadian Pandemic Influenza Plan for the Health Sector*. December 2006. Available at: http://www.phac-aspc.gc.ca/cpip-pclcpi/s02_e.html#6.

Schuklenk U, Gartland KM. Confronting an influenza pandemic: ethical and scientific issues. *Biochem Soc Trans*. 2006;34:1151-1154.

State Expert Panel on Disaster Ethics. *Ethical Decision-making in a Disaster.* October 2007. Wisconsin Division of Public Health Hospital Emergency Preparedness Program and the Wisconsin Hospital Association.

State of Tennessee Department of Health. *Pandemic Influenza Response Plan [Section 4 Supplement 4: Ethical Allocation of Scarce Resources]* July 2006. Available at: http://health.state.tn.us/Ceds/PDFs/2006_PanFlu_Plan.pdf.

State of West Virginia. *West Virginia Influenza Pandemic Preparedness Strategy.* December 2005.

Swiss Federal Office of Public Health. *Swiss Influenza Pandemic Plan*. November 2007.

Tacoma-Pierce County Health Department. *Pandemic Influenza Medical Response Model: Triage and Treatment Guidelines, Revision 1*. Draft. May 24, 2007. Available at: http://pandemicpractices.org/files/183/183_medical_response_model_v2.doc.

> This model proposes a four-tiered medical response built primarily on the principle of medical utility, i.e. maximizing the amount of medical benefit to the most number of people. This includes protecting the medical infrastructure so as to maintain a robust medical capacity, and treating all patients based solely on the amount of benefit they are likely to receive from treatment.

Thomas JC. *Ethical Concerns in Pandemic Influenza Preparation and Responses*. [white paper] Southeast Regional Center of Excellence for Emerging Infectious [sic] and Biodefense 2007:1-19. Available at: http://www.serceb.org/wysiwyg/downloads/pandemic_flu_white_paper.May_25.FORMATTED.pdf.

Thomas JC, Dasgupta N, Martinot A. Ethics in a pandemic: a survey of the state pandemic influenza plans. *Am J Public Health*. 2007;97(suppl 1):26-31. Available at: http://www.ajph.org/cgi/reprint/97/Supplement_1/S26.pdf.

Thompson AK, Faith K, Gibson JL, Upshur RE. Pandemic influenza preparedness: an ethical framework to guide decision-making. *BMC Med Ethics*. 2006;7:E12.

Uscher-Pines L, Duggan PS, Garoon JP, Karron RA, Faden RR. Social justice and disadvantaged groups. *Hastings Cent Rep*. 2007;37:32-39.

> Because an influenza pandemic would create the most serious hardships for those who already face most serious hardships, countries should take special measures to mitigate the effect of a pandemic on existing social inequalities.

Uscher-Pines L, Omer SB, Barnett DJ, Burke TA, Balicer RD. Priority setting for pandemic influenza: an analysis of national preparedness plans. *PLoS Med*. 2006;3:e436. Available at: http://www.flu.org.cn/upfile/attachment/20061024152550696.pdf.

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A. Rationing Antivirals

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Letts J. Ethical challenges in planning for an influenza pandemic. *N S W Public Health Bull*. 2006; 17:131-134.

Uscher-Pines L, Omer SB, Barnett DJ, Burke. TA, Balicer RD. Priority setting for pandemic influenza: an analysis of national preparedness plans. *PLoS Med*. 2006;3:e436. Available at: http://www.flu.org.cn/upfile/attachment/20061024152550696.pdf.

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US Interagency Working Group. *Proposed Guidance on Antiviral Drug Use Strategies during an Influenza Pandemic*. November 6, 2007. Available at: http://www.asisonline.org/newsroom/crisisResponse/Antiviral_strategies_Proposed%20Guidance_11-6-07.doc

US Interagency Working Group. *Summary of Proposed Guidance on Antiviral Drug Use Strategies for an Influenza Pandemic*. November 20, 2007

Utah Department of Health. *Governor's Taskforce on Pandemic InfluenzaPreparedness: Final Report to Governor*. Salt Lake City, Utah, April 2007. Available at: http://www.pandemicflu.utah.gov/docs/PandInfluTaskforceFinalReport.pdf.

World Health Organization. Chemoprophylaxis of H5N1 infection: recommendations for use of antiviral drugs. In: *WHO Rapid Advice Guidelines on Pharmacological Management of Humans Infected with Avian Influenza A (H5N1) Virus*. 2006. Available at: http://www.who.int/csr/disease/avian_influenza/guidelines/pharmamanagement/en/index.html.

B. Rationing N95 Respirators and Surgical Masks

Aledort JE, Lurie N, Wasserman J, Bozzette SA. Non-pharmaceutical public health interventions for pandemic influenza: an evaluation of the evidence base. BMC *Public Health.* 2007;7:208. Available at: http://www.biomedcentral.com/1471-2458/7/208.

> We evaluated the evidence base for non-pharmaceutical public health interventions and, based on the collective evidence, identified a set of recommendations for and against interventions that are specific to both the setting in which an intervention may be used and the pandemic phase.

Brankston G, Gitterman L, Hirji Z, Lemieux C, Gardam M. Transmission of influenza A in human beings. *Lancet Infect Dis*. 2007;*7*:257-265.

Centers for Disease Control and Prevention. *Interim Guidance on Planning for the Use of Surgical Masks and Respirators in Health Care Settings during an Influenza Pandemic*. 2006. Available at: http://pandemicflu.gov/plan/healthcare/maskguidancehc.html.

> Provides background information on influenza transmission, pathogenesis, and control. Gives recommendations on kinds of masks and respirators, as well as their proper use.

Centers for Disease Control and Prevention. *Interim Public Health Guidance for the Use of Facemasks and Respirators in Non-Occupational Community Settings during an Influenza Pandemic***.** May 2007. Available at: http://www.pandemicflu.gov/plan/community/commaskguidance.pdf.

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C. Rationing Vaccines

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Emanuel EJ, Wertheimer A. Who should get influenza vaccine when not all can? *Science*. 2006; 312: 854–855. See also: The ethics of influenza vaccination. Letters. *Science* 2006;313:758-760.

European Centre for Disease Prevention and Control. *Technical Report: Expert Advisory Groups on Human H5N1 Vaccines: Public Health and Operational Questions.* Stockholm: August 2007. Available at: http://ecdc.europa.eu/pdf/PH%20Questions%20final.pdf.

Germann TC, Kadau K, Longini IM, Macken CA. Mitigation strategies for pandemic influenza in the United States. *PNAS*;103:5935-5940.

Haque A, Hober D, Kasper LH. Confronting potential influenza A (H5N1) pandemic with better vaccines. *Emerg Infect Dis.* October 2007; Available at: http://www.cdc.gov/eid/content/13/10/1512.htm.

Holmberg SD, Layton CM, Ghneim GS, Wagener DK. State plans for containment of pandemic influenza. *Emerg Infect Dis*. 2006;12:1414-1417.

Infectious Diseases Society of America. *Request for information (RFI): Guidance for Prioritization of Prepandemic and Pandemic Influenza Vaccine*. [letter to US Department of Health and Human Services] January 18, 2007.

North Carolina Institute of Medicine. *Stockpiling Solutions: North Carolina's Ethical Guidelines for an Influenza Pandemic*. 2007. Available at: http://www.nciom.org/projects/flu_pandemic/panflu.html.

Olick RS. Ethics in public health: rationing the flu vaccine. *J Public Health Manag Pract*. 2005;11:373–374.

Straetemans M, Buchholz U, Reiter S, Haas W, Krause G. Prioritization strategies for pandemic influenza vaccine in 27 countries of the European Union and the Global Health Security Action Group: a review. *BMC Public Health*. 2007;7:236. Available at: http://www.biomedcentral.com/1471-2458/7/236.

US Department of Health and Human Services. *HHS Pandemic Influenza Plan*, *Appendix D*. 2005. Available at: http://www.hhs.gov/pandemicflu/plan/appendixd.html.

US Interagency Working Group. *Draft Guidance on Allocating and Targeting Pandemic Influenza Vaccine*. October 17, 2007. Available at: http://www.pandemicflu.gov/vaccine/prioritization.pdf

Uscher-Pines L, Omer SB, Barnett DJ, Burke. TA, Balicer RD. Priority setting for pandemic influenza: an analysis of national preparedness plans. *PLoS Med*. 2006;3(10):e436. Available at: http://www.flu.org.cn/upfile/attachment/20061024152550696.pdf.

Vawter D, Gervais K, Garrett JE. Allocating pandemic influenza vaccines in Minnesota: recommendations of the pandemic influenza ethics work group. *Vaccine.* 2007;25:6522-6536.

> A public-private, multidisciplinary work group developed recommendations for rationing vaccines in Minnesota during a worst-case influenza pandemic. The recommendations encompass an ethical framework of principles, goals, and strategies. The primary goal is to maximize Minnesotans' chances of surviving both the pandemic and the years immediately thereafter and to limit two major causes of death: (a) influenza and complications of influenza, and (b) disruption of basic health care, public health, and public safety infrastructures. The work group also developed a sample rationing plan, but stressed that any final plan must reflect the best available evidence during an actual pandemic.

Wynia MK. Ethics and public health emergencies: rationing vaccines, *AJOB.* 2006;6:4-7.

Zimmerman RK. Rationing of influenza vaccine during a pandemic: ethical analyses. *Vaccine*. 2007;25:2019-2026.

D. Rationing Ventilators

Challen K, Bentley A, Bright J, Walter D. Clinical review: mass casualty triage – pandemic influenza and critical care. *Critical Care.* 2007;11:212.

Christian MD for the OHPIP Adult Critical Care Admission, Discharge, Triage Working Group. *Critical Care during a Pandemic: Final report of the Ontario Health Plan for an Influenza Pandemic (OHPIP) Working Group on Adult Critical Care Admission, Discharge and Triage Criteria*. Hamilton, ON: McMaster University Medical Centre, April 2006.

Christian MD, Hawryluck L, Wax RS, et al. Development of a triage protocol for critical care during an influenza pandemic. *CMAJ.* 2006;175:1377-1381. Available at: http://www.cmaj.ca/cgi/reprint/175/11/1377.

> We applied a collaborative process using best evidence, expert panels, stakeholder consultations and ethical principles to develop a triage protocol for prioritizing access to critical care resources, including mechanical ventilation, during a pandemic. The triage protocol uses the Sequential Organ Failure Assessment score and has 4 main components: inclusion criteria, exclusion criteria, minimum qualifications for survival and a prioritization tool. It would apply to patients both with and without influenza, since all patients must share a single pool of critical care resources.

Guerrier M. Considering restricting access to intensive care. *Pandemics*. 2006;1:39-42. Available at: http://www.espace-ethique.org/fr/documents/pandemics/pandemics01.pdf.

Hick JL, O'Laughlin DT. Concept of operations for triage of mechanical ventilation in an epidemic. *Acad Emerg Med* 2006;13:223-229. Available at: http://www.aemj.org/cgi/reprint/13/2/223.

> We must develop triage criteria that depend on clinical indicators of survivability and resource utilization to allocate scarce health care resources to those who are most likely to benefit. These criteria must be tiered, flexible, and implemented regionally, rather than institutionally, with the backing of public health agencies and relief of liability.

Hick JL, Rubinson L, O'Laughlin DT, Farmer JC. Clinical review: allocating ventilators during large-scale disasters: problem, planning, and process. *Critical Care.* 2007;11:217.

> A proposed decision tool uses predictive scoring systems, disease-specific prognostic factors, response to current mechanical ventilation, duration of current and expected therapies, and underlying disease states to guide decisions about which patients will receive mechanical ventilation.

Lo B. Intensive care unit triaging during an influenza pandemic: the need for specific clinical guidelines. In Lemon SM, Hamburg MA, Sparling PF, et al., *Ethical and Legal Considerations in Mitigating Pandemic Disease: Workshop Summary*. National Academies Press; 2007. Available at: http://books.nap.edu/catalog.php?record_id=11150.

Melnychuk RM, Kenny NP. Pandemic triage: the ethical challenge. *CMAJ*. 2006;175:1393-1394. Available at: http://www.cmaj.ca/cgi/reprint/175/11/1393?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&searchid=1&FIRSTINDEX=0&minscore=5000&resourcetype=HWCIT.

New York State Workgroup on Ventilator Allocation in an Influenza Pandemic. *Allocation of Ventilators in an Influenza Pandemic: Planning Document.* 2007 draft. Available at: http://www.health.state.ny.us/diseases/communicable/influenza/pandemic/ventilators/docs/ventilator_guidance.pdf.

North Carolina Institute of Medicine. *Stockpiling Solutions: North Carolina's Ethical Guidelines for an Influenza Pandemic*. 2007. Available at: http://www.nciom.org/projects/flu_pandemic/panflu.html.

Powell T, Christ KC, Birkhead GS. Allocation of ventilators in a public health disaster. *Disaster Medicine and Public Health Preparedness*. 2008;2:20-26.

State of Tennessee Department of Health. *Pandemic Influenza Response Plan [Section 4 Supplement 4: Ethical Allocation of Scarce Resources]* July 2006. Available at: http://health.state.tn.us/CEDS/pandemic.htm.

Tacoma-Pierce County Health Department. *Pandemic Influenza Medical Response Model: Triage and Treatment Guidelines, Revision 1*. Draft. May 24, 2007. Available at: http://pandemicpractices.org/files/183/183_medical_response_model_v2.doc.

Talmor D, Jones AE, Rubinson L, Howell MD, Shapiro NI. Simple triage scoring system predicting death and the need for critical care resources for use during epidemics. *Crit Care Med*. 2007;35:1251-1256. Available at http://www.aemj.org/cgi/content/full/14/5_Supplement_1/S157-a.

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II. Rationing, Triage, and Disaster Ethics

A. General

American Medical Association Council on Ethical and Judicial Affairs. Ethical considerations in the allocation of organs and other scarce medical resources among patients. *Arch Intern Med.* 1995;155:29-40.

Baker R, Strosberg M. Triage and equality: an historical reassessment of utilitarian analyses of triage. *Kennedy Inst Ethics J.* 1992;2:103–123.

> We distinguish and review aspects of the history of two models of triage: egalitarian and utilitarian. Egalitarian triage is widely and successfully practiced in battlefield medicine, as well as in the emergency room and the ICU. Utilitarian triage has been sporadically practiced and typically collapses under the pressure of public scrutiny. Unfortunately, the two models tend to be conflated, confusing our understanding of the past and confounding our ability to plan for the future.

Berg, J, King, N. Strange bedfellows? Reflections on bioethics' role in disaster response planning. *Am J Bioeth*. 2006;6:3-5.

Brock DW. Priority of the worse off in health-care resource prioritization. In: Rhodes R, Battin MP, Silvers A, eds. *Medicine and Social Justice: Essays on the Distribution of Health Care*. New York: Oxford University Press; 2002.

Burkle FM. Mass casualty management of a large-scale bioterrorist event: an epidemiological approach that shapes triage decisions. *Emerg Med Clin North Am*. 2002;20:409–436.

> Triage planning permits society to see cases in the context of diverse moral perspectives, limited resources, and compelling health care demands. This includes a competent and compassionate management and triage system and an in-depth and accurate health information system that appropriately addresses every level of threat or consequence.

Burkle FM. Population-based triage management in response to surge-capacity requirements during a large-scale bioevent disaster. *Academic Emergency Medicine*. 2006;13:1118-1129. Available at: http://www.blackwell-synergy.com/doi/pdf/10.1111/j.1553-2712.2006.tb01634.x.

> Both the naturally occurring and deliberate release of a biological agent in a population can bring catastrophic consequences. Although these bioevents have similarities with other disasters, there also are major differences, especially in the approach to triage management of surge capacity resources. Conventional mass-casualty events use uniform methods for triage on the basis of severity of presentation and do not consider exposure, duration, or infectiousness, thereby impeding control of transmission and delaying recognition of victims requiring immediate care. Bioevent triage management must be population based, with the goal of preventing secondary transmission, beginning at the point of contact, to control the epidemic outbreak. Whatever triage system is used, it must first recognize the requirements of those Susceptible but not exposed, those Exposed but not yet infectious, those Infectious, those Removed by death or recovery, and those protected by Vaccination or prophylactic medication (SEIRV methodology). This article addresses a population approach to SEIRV-based triage in which decision making falls under a two-phase system with specific measures of effectiveness to increase likelihood of medical success, epidemic control, and conservation of scarce resources.

Calabresi G, Bobbitt P. *Tragic Choices: The Conflicts Society confronts in the Allocation of Tragically Scarce Resources*. New York: Norton;1978.

Childress JF. Just care: Rationing in a public health crisis. *Loma Linda University Center for Christian Bioethics Update*. 2005;20:1–7. Available at: http://www.llu.edu/llu/bioethics/documents/update203.pdf?PHPSESSID=%23HPRO+531#search=%22childress%20update%20Just%20care%3A%20rationing%20in%20a%20public%20health%20crisis%22.

Churchill L. *Rationing Health Care in America: Perceptions and Principles of Justice*. Notre Dame, Indiana;1987.

Daniels N. Justice, health, and healthcare. *Am J Bioeth.* 2001;1:2–16.

> Since the distribution of goods other than healthcare affect population health and its distribution, I claim that Rawls's principles of justice describe a fair distribution of the social determinants of health, giving a partial account of when health inequalities are unjust. I supplement a principled account of justice for health and healthcare with an account of fair process for setting limits of rationing care. This account is provided by three conditions that comprise "accountability for reasonableness."

Daniels N, Sabin JE. *Setting Limits Fairly: Can we Learn to Share Medical Resources?* New York: Oxford University Press; 2002.

> In Western democracies, there is no agreement on substantive principles for the distribution of health care services. Consequently, the challenge is to define the conditions under which it is ethically acceptable for institutions to set limits on health care. They propose four conditions, collectively termed "accountability for reasonableness": first, publicity (decisions to limit health care and their rationales must be publicly accessible); second, relevance (the rationales invoked must be based on evidence, reasons, and principles that fair-minded persons would affirm); third, appeals (mechanisms for challenging allocation decisions must exist); and fourth, regulation (public procedures must ensure the fulfillment of these three conditions). They believe that requiring the use of public, explicit decisions "will improve the quality of decisions making" and will improve public confidence that decisions are made for ethical and not self-interested reasons. People are entitled not to the same set of services but, rather, to determinations made through fair procedures. What is at issue is whether accountability for reasonableness is the right approach.

Domres B, Koch M, Manger A, Becker HD. Ethics and triage. *Prehosp Disast Med*. 2001;16:53–58.

Currently, no Europe-wide agreement on triage and ethics exists. One system based on a categorization into four groups is proposed. Triage should be avoided whenever possible, but, when it is required, there is an obligation to respect human rights and the humanitarian laws, especially with reference to the Geneva Convention of 1864 and the Universal Declaration of Human Rights of 1948. The condition of informed consent must be followed, even in mass casualty situations. Triage always must follow established medical criteria and cannot be based on any other principles. Triage implies constant re-evaluation of victims as conditions of the victims and of available resources change continuously. In order to facilitate international coordination and cooperation, a universal classification system must be adopted.

Eisenberg D, Freed GL. Reassessing how society prioritizes the health of young people. *Health Affairs*. 2007;26:345-354.

Ham C, Robert G. *Reasonable Rationing: International Experience of Priority Setting in Health Care*. Open University Press, Maidenhead; 2003.

Hurst SA, Danis M. A framework for rationing by clinical judgment. *Kennedy Institute of Ethics Journal*. 2007;17:247-266.

Iserson KV, Pesik N. Ethical resource distribution after biological, chemical, or radiological terrorism. *Camb Q Health Ethics*. 2003;12:455-465.

Lo B, Katz MH. Clinical decision making during public health emergencies: ethical considerations. *Ann Intern Med*. 2005;143:493-8. Available at: http://www.annals.org/cgi/reprint/143/7/493.pdf.

Recent public health emergencies involving anthrax, the severe acute respiratory syndrome (SARS), and shortages of influenza vaccine have dramatized the need for restrictive public health measures such as quarantine, isolation, and rationing. Front-line physicians will face ethical dilemmas during public health emergencies when patients disagree with these measures. Patients might request interventions that are not recommended or for which they are not eligible, or they might object to intrusive or restrictive measures. The physician's primary responsibility in such emergencies is to the public rather than to the individual patient. In public health emergencies, physicians need to address the patient's needs and concerns, recognize their changed roles, and work closely with public health officials. Physicians can still work on behalf of patients by advocating for changes in policies and exceptions when warranted and by mitigating the adverse consequences of public health measures. Before an emergency occurs, physicians should think through how they will respond to foreseeable dilemmas arising when patients disagree with public health recommendations.

Moreno JD, ed. *In the Wake of Terror: Medicine and Morality in a Time of Crisis*. Cambridge, MA: MIT Press; 2003.

This collection of essays looks at the implications for ethics and public health of the prospect of terrorism against the United States. The subjects covered range from the proposed law that would considerably expand the power of the government to investigate, detain, and curb those who supposedly pose a threat to public health, to the problem of triage after a terrorist attack, to the ethical obligations of clinicians -- including whether they have a duty to expose themselves to danger -- and to the nature of corporate responsibility in a world of terrorist threats. The country that did the worst in dealing with the outbreak of SARS, China, used its limitless authority to suppress information, eliminate transparency, and undermine trust.

Naughton D. Drug lotteries raise questions: some experts say system of distribution may be unfair. *The Washington Post*. September 26, 1995. p. Z14.

Phillips SJ, Knebel A, eds. *Mass Medical Care with Scarce Resources: A Community Planning Guide*. Prepared by Health Systems Research, Inc., an Altarum company, under contract NO. 290-04-0010. AHRQ Publication No. 07-0001. Rockville, MD: Agency for Healthcare Research and Quality 2007.

Rhodes R. Justice in allocations for terrorism, biological warfare, and public health. In: M. Boylan ed. *Public Health Policy and Ethics*. Boston, MA: Kluwer Academic Publishers; 2004.

A variety of appropriate and compelling principles can express the complex and varied considerations that make different policies just. We should avoid the allure of a single simple ideal conception of justice. The just allocation of medical resources is and should be governed by a variety of considerations that reasonable people endorse for their saliency. Several principles have a legitimate place in public health allocation. They include: the anti free-rider principle, avoid undue burdens, avoid the worst outcome, the difference principle, efficiency, equality, maximin, provide public goods, the vital and constant importance to well-being.

Rubinson L, Nuzzo JB, Talmor DS, O'Toole T, Kramer BR, Inglesby TV for the Working Group on Emergency Mass Critical Care. Augmentation of hospital critical care capacity after bioterrorist attacks or epidemics: recommendations of the Working Group on Emergency Mass Critical Care. *Crit Care Med*. 2005;33:2393-2403. Available at: http://www.sccm.org/professional_resources/disaster_resources/Documents/Rubinson_Online.pdf.

Truog RD, Brock DW, Cook DJ, Danis M, Luce JM, Rubenfeld GD, Levy MM, for the Task Force on Values, Ethics, and Rationing in Critical Care. Rationing in the intensive care unit. *Crit Care Med*. 2006;34:958-963.

Veatch RM. Disaster preparedness and triage: justice and the common good. *Mt Sinai J Med*. 2005;72:236–241.

> Understanding how contemporary organ transplant policy utilizes triage can help us clarify our mass disaster triage policy. Two organ transplant examples--tissue typing for kidneys and geographical priority for allocating livers--show that American social policy, when forced to choose between allocating on the basis of efficiency or allocating on the basis of justice, will consider both principles, but give equal or dominant priority to justice--even though this priority is understood to be relatively inefficient. Since health care professionals have a recognized preference for efficiency over justice and lay people are inclined towards justice, leaving mass disaster triage policy in the hands of health professionals will predictably structure the policy in a way that conflicts with the moral priorities of the lay population. Formal public debate that recognizes the conflict between efficiency and equity--professional and lay priorities--is therefore essential.

Winslow GR. *Triage and Justice: The Ethics of Rationing Life-saving Medical Resources*. Berkeley, CA: University of California Press; 1982.

Wynia MK, Gostin LO. Ethical challenges in preparing for bioterrorism: barriers within the health care system. *Am J Public Health.* 2004;94:1096–1102.

> Although public health ethics and preparedness have received attention recently, health care ethics must also be considered. In epidemics, the health care system assists public health in 3 tasks: detection, containment, and treatment. Detection might fail if all patients do not have access to care, or if physicians do not understand their obligation to report infectious diseases to public health authorities. Containment might fail if physicians view themselves only as advocates for individual patients, ignoring their social obligations as health professionals. Treatment might fail if physicians do not accept their professional duty to treat patients during epidemics.

B. SARS

Bell JA, Hyland S, DePellegrin T, Upshur RE, Bernstein M, Martin DK. SARS and hospital priority setting: a qualitative case study and evaluation. *BMC Health Serv Res*. 2004;4:36. Available at: http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=15606924.

Bernstein M, Hawryluck L. Challenging beliefs and ethical concepts: the collateral damage of SARS. *Crit Care*. 2003;7:269-271. Available at: http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=12930546.

Emanuel EJ. The lessons of SARS. *Ann Intern Med*. 2003;139:589–591. Available at: http://www.annals.org/cgi/reprint/139/7/589.pdf.

> The SARS experience has provided at least 4 lessons. First, by providing a test of the capacity of each part of the public health system, it has better prepared the world for the next pandemic. Second, SARS has reemphasized that from housing, sexual practices, and slaughtering techniques to health care capacity, the situation in other, especially developing, countries affects us. Global cooperation is necessary not only for justice but to ensure our own health. Third, the response of health care professionals reaffirmed dedication to caring for the sick even at great personal risks as the core ethical principle of medicine. Finally, SARS also emphasized the importance of the duty of health care administrators and senior physicians to rapidly institute procedures to maximize the safety of frontline physicians and nurses.

Gomersall CD, Tai DY, Loo S, Derrick JL, Goh MS, Buckley TA, Chua C, Ho KM, Raghavan GP, Ho OM, Lee LB, Joynt GM. Expanding ICU facilities in an epidemic: Recommendations based on experience from the SARS epidemic in Hong Kong and Singapore. *Intensive Care Med.* 2006;32:1004-1013.

Gostin LO, Bayer R, Ethical and legal challenges posed by severe acute respiratory syndrome: implications for the control of severe infectious disease threats. *JAMA*. 2003;290:3229–3237.

> National and international responses to SARS have profound implications for 3 important ethical values: privacy, liberty, and the duty to protect the public's health. This article examines, through legal and ethical lenses, various methods that countries used in reaction to the SARS outbreak:

surveillance and contact tracing, isolation and quarantine, and travel restrictions. These responses, at least in some combination, succeeded in bringing the outbreak to an end. The article articulates a set of legal and ethical recommendations for responding to infectious disease threats, seeking to reconcile the tension between the public's health and individual rights to privacy, liberty, and freedom of movement. The ethical values that inform the recommendations include the precautionary principle, the least restrictive/intrusive alternative, justice, and transparency.

Kahn J. It's a small world after all: ethics and the response to SARS. *Hastings Cent Rep*.. 2003;33:6.

Singer PA, Benatar SR, Bernstein M, et al. Ethics and SARS: lessons from Toronto. *BMJ*. 2003;327:1342–1344. Available at: http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=14656848.

Upshur RE. Enhancing the legitimacy of public health response in pandemic influenza planning: lessons from SARS. *Yale J Biol Med*. 2005;78:335-342.

III. Public Health Ethics

American Public Health Association. *Principles of the Ethical Practice of Public Health.* Available at: http://www.apha.org/NR/rdonlyres/1CED3CEA-287E-4185-9CBD-BD405FC60856/0/ethicsbrochure.pdf.

This code of ethics states key principles of the ethical practice of public health. An accompanying statement lists the key values and beliefs inherent to a public health perspective upon which the ethical principles are based. Public health is understood within these principles as what we, as a society, do collectively to assure the conditions for people to be healthy.

Bayer R, Fairchild AL. The genesis of public health ethics. *Bioethics*. 2004;18:473–492.

As bioethics emerged in the 1960-1970s little attention was given to the ethics of public health. This was all the more striking since the core values and practices of public health, often entailing the subordination of the individual for the common good, seemed opposed to the ideological impulses of bioethics. Of what relevance is autonomy-focused bioethics for public health, with its mix of justifications including those that are either implicitly or explicitly paternalistic or that seek to impose strictures on individuals and communities in the name of collective welfare? We focus on a series of controversies implicating the concepts of privacy, liberty, and paternalism. As we commence the process of shaping an ethics of public health, it is clear that bioethics is the wrong place to start when thinking about the balances required in defense of the public's health.

Bensimon CM, Upshur RE. Evidence and effectiveness in decisionmaking for quarantine. *Am J Public Health*. 2007;97 (suppl 1):44-48.

Childress JF, Bernheim RG. Beyond the liberal and communitarian impasse: a framework and vision for public health. *Florida Law Review*. 2003;55:1191.

Childress JF, Faden RR, Gaare RD, et al. Public health ethics: mapping the terrain. *J Law Med Ethics.* 2002;30:170–178.

Davis MM, Lantos JD. Ethical considerations in the public policy laboratory. *JAMA*. 2000;284:85–87.

Dawson A, Verweij M. (eds.) *Ethics, Prevention and Public Health*. Clarendon Press, Oxford; 2007.

Francis LP, Battin MP, Jacobson JA, Smith CB, Botkin J. How infectious disease got left out—and what this omission might have meant for bioethics. *Bioethics*. 2005;19:307–322.

The authors document the absence of infectious disease examples and concerns at the time bioethics emerged as a field. They argue that this oversight was not benign and show how informed consent and distributive justice might have been framed differently. Taking infectious disease into account requires understanding the patient as victim and as vector, as both embodied and vulnerable in relationships with others.

Gostin LO, ed. *Public Health Law and Ethics: A Reader*. Berkeley: University of California Press and Milbank Memorial Fund; 2002.

This selection of government reports, scholarly articles, and court cases is designed to illuminate the ethical, legal, and political issues in the theory and practice of public health. The excerpts and commentaries analyze the legal and constitutional foundations of public health, juxtaposing them with the emerging importance of public health ethics and human rights. The book offers a systematic account of public health law, ethics, and human rights in promoting the common good.

Gostin LO. Public health law in an age of terrorism: rethinking individual rights and common goods. *Health Aff (Millwood)*. 2002;21:79–93.

The balance between individual interests and common goods needs to be recalibrated in an age of terrorism. This paper explains modern efforts at public health law reform: a Model Public Health Statute and the Model State Emergency Health Powers Act (MSEHPA), which has been enacted wholly or in part by nineteen states and the District of Columbia. The paper shows why existing public health laws provide a weak foundation for public health practice and offers a systematic defense of MSEHPA, which has galvanized the public debate around the appropriate balance between public goods and individual rights.

Jennings B. Public health and civic republicanism: toward an alternative framework for public health ethics. In Dawson A, Verweij M. (eds.) *Ethics, Prevention and Public Health*. Clarendon Press, Oxford; 2007.

Kass NE. An ethics framework for public health. *Am J Public Health*. 2001;91:1776–1782.

Given its population-based focus, public health perennially faces dilemmas concerning the appropriate extent of its reach and whether its activities infringe on individual liberties in ethically troublesome ways. In this article a framework for ethics analysis of public health programs is proposed. To advance traditional public health goals while maximizing individual liberties and furthering social justice, public health interventions should reduce morbidity or mortality; data must substantiate that a program (or the series of programs of which a program is a part) will reduce morbidity or mortality; burdens of the program must be identified and minimized; the program must be implemented fairly and must, at times, minimize preexisting social injustices; and fair procedures must be used to determine which burdens are acceptable to a community.

Kass NE. Public health ethics: from foundations and frameworks to justice and global public health. J Law Med Ethics. 2004;32:232–242.

Ethics dilemmas have been present throughout the history of public health, and bioethics has devoted considerable attention to issues relevant to public health. Only recently, however, has public health ethics emerged as a recognized subfield of bioethics. Public health ethics requires that public health improvement come through just and respectful means.

Loff B, Black J. Principles for public health action on infectious diseases. *Issues Med Ethics.* 2003;11:113-115.

Markovits D. Quarantines and distributive justice. *J Law Med Ethics*. 2005;33:323–344.

May T. Public communication, risk perception, and the viability of preventive vaccination against communicable diseases. *Bioethics*. 2005;19:407–421.

Because of the nature of preventive vaccination programs, the viability of these public health interventions is particularly susceptible to public perceptions. This is because vaccination relies on a concept of 'herd immunity', achievement of which requires rational public behavior that can only be obtained through full and accurate communication about risks and benefits. This paper describes how irrational behavior that threatens the effectiveness of vaccination programs--both in crisis and non-crisis situations--can be tied to public perceptions created by media portrayals of health risks.

Melnick A, Kaplowitz W, Lopez W, Murphy, AM. Public health ethics in action: flu vaccine and drug allocation strategies. *J Law Med Ethics*. 2005;33:102–105.

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Smith CB, Battin MP, Jacobson JA, et al. Are there characteristics of infectious diseases that raise special ethical issues? *Dev World Bioeth*. 2004;4(1):1–16.

This paper examines the characteristics of infectious diseases that raise special medical and social ethical issues, and explores ways of integrating both current bioethical and classical public health ethics concerns. The individual fear and community panic associated with infectious diseases often leads to rapid, emotionally driven decision making about public health policies needed to protect the community that may be in conflict with current bioethical principles regarding the care of individual patients.

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IV. Severe Pandemic Influenza

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V. Pandemic Influenza Plans

Pandemic influenza plans are constantly being created, revised and updated. These websites provide the most up-to-date pandemic influenza plans for US and non-US (including state and local plans):

The official United States Pandemic Influenza website: http://www.pandemicflu.gov.

The World Health Organization's Pandemic Influenza website: http://www.who.int/csr/disease/influenza/nationalpandemic/en/index.html.