For the Good of Us All:
Ethically Rationing Health Resources in Minnesota in a Severe Influenza Pandemic

Dorothy E. Vawter,* J. Eline Garrett,* Karen G. Gervais,* Angela Witt Prehn,* Debra A. DeBruin, Carol A. Tauer, Elizabeth Parilla, Joan Liaschenko and Mary Faith Marshall

* Guarantors responsible for the integrity of the work as a whole, from inception to this report.

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Minnesota Pandemic Ethics Project Team

Minnesota Center for Health Care Ethics (MCHCE): J. Eline Garrett, JD; Karen G. Gervais, PhD; Ruth Mickelsen, JD, MPH; Angela Witt Prehn, PhD;* Dorothy E. Vawter, PhD

University of Minnesota Center for Bioethics (UMCB): Debra A. DeBruin, PhD; Jeffrey Kahn, PhD, MPH; J. P. Leider; Joan Liaschenko, RN, PhD, FAAN; Mary Faith Marshall, PhD; Steven Miles, MD; Elizabeth Parilla, MPH;** Carol A. Tauer, PhD; Susan M. Wolf, JD

Corresponding author: J. Eline Garrett, JD
Minnesota Center for Health Care Ethics, Carondelet Center, 1890 Randolph Ave., St. Paul, MN 55105
612-964-9425, garrett@mnhealthethics.org, www.mnhealthethics.org

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* Midway through the project Dr. Prehn also became affiliated with Walden University.

** Ms. Parilla worked for the University of Minnesota Center for Bioethics during much of the project. When Ms. Parilla accepted a position with the Minnesota Department of Health, she moved to a solely advisory role on the project. Inclusion here reflects her early contributions to the project team.

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Executive Summary

The Minnesota Pandemic Ethics Project is part of the state of Minnesota's efforts to plan for the possibility of an influenza pandemic. Predicting the timing and severity of a future pandemic is impossible. Project organizers chose to focus this project on the possibility of a severe pandemic, because that is where the most difficult ethical choices lie and where a project such as this might provide the most assistance to pandemic planners and responders. In the spring of 2009 H1N1 novel influenza virus emerged, and soon thereafter the World Health Organization declared that its transmission around the globe had reached pandemic proportions. That pandemic was relatively mild. Nonetheless, this project remained focused on a hypothetical, severe pandemic.

Severe pandemic influenza occurs on a scale that distinguishes it from other public health disasters in terms of its global nature, size and impacts. It is experienced over years, not days, weeks or months, and threatens core public health, social and economic infrastructures. Unlike a mild pandemic, a severe pandemic has the potential to cripple normal health care and business operations and disrupt the distribution of essential goods and services globally. Unlike other disasters, states and communities cannot count on receiving assistance from others in a severe pandemic. Health-related resources will be particularly important public health tools, and must be managed and distributed to best serve Minnesotans' common good.

In 2007 the Minnesota Department of Health (MDH) contracted with ethicists from the Minnesota Center for Health Care Ethics and the University of Minnesota Center for Bioethics (project team) to develop and lead the Minnesota Pandemic Ethics Project. This project's purpose was to propose ethical frameworks and procedures for rationing scarce health resources in a severe pandemic.

While rationing protocols must be informed by science and the best available evidence, decisions about who should be prioritized for resources in a pandemic affect everyone, and science alone does not have the answers. Members of the project team informed, engaged and consulted with many Minnesotans in order to ground rationing strategies on commonly held values. The project encompassed an array of robust public engagement methods and benefitted from the wide range of perspectives shared. The project team convened a community-based resource allocation panel (panel), expert work groups and an implementation protocol committee, together comprising more than 100 people. In 2009 the team expanded its public engagement, soliciting input from hundreds more Minnesotans.

This report contains ethical frameworks for rationing antiviral medications, N95 respirators, surgical masks, vaccines and mechanical ventilators. Some of these resources can be stockpiled; others cannot. Some are for prevention; others are for treatment. Some are available only on medical orders; others are available for purchase without a prescription. The report makes clear that before any framework is implemented even in a severe pandemic, it needs to be adjusted to reflect the characteristics of the actual pandemic and to be used as part of a coordinated response. Thus, the frameworks themselves are decision-making tools, not algorithms that mandate a particular rationing scheme.

The frameworks were developed from a statewide perspective, that is, from a perspective of benefiting Minnesotans as a whole, and are offered as a guide to statewide rationing for both public and private decision-makers. The frameworks could assist not only the rationing of state-owned resources, but could inform hospitals, clinics and private sector entities about how resources could be distributed ethically within their own organizations.

Project participants made many assumptions—not predictions—about a severe pandemic and the resources being discussed. These assumptions focused the participants' discussions and signal the need for adjusting the frameworks to fit the circumstances of an actual pandemic.

Thus, project participants agreed to imagine the possibility of a pandemic that fit the following assumptions:

1. The influenza pandemic will be severe, based on projections from the “Spanish Flu” pandemic of 1918–19, with a case fatality rate more than 20 times higher than that of seasonal influenza. More than 100 million people worldwide could die, 38,000 in Minnesota alone.
2. The age-specific mortality curve will be W-shaped as opposed to the U-shaped curve associated with seasonal influenza. Healthy people aged 15–40 will join the very old and very young in being at elevated risk of dying from the flu.
3. 30% of Minnesotans will become ill with influenza sometime during the two year pandemic.
4. The pandemic has the potential to cripple essential health care, public health, public safety and other critical infrastructures. Supply chains and trade will be disrupted in the face of voluntary and mandated travel restrictions. Demand for medical services, drugs and other products will surge, leading to dramatic shortages. Absenteeism attributable to illness, death, the need to care for ill family members, and fear of contracting influenza may reach 40% during the peak weeks of an outbreak.
5. During the pandemic, public health officials will collect and analyze relevant data to determine, among other things, which groups are at highest risk of serious morbidity and mortality from the virus.
6. Antiviral medications can be used to treat patients who have influenza or other viral illnesses. They can also be prescribed for short-term post-exposure prophylaxis or for long-term prevention. Antivirals are stockpiled by the federal and state governments, as well as in the private sector.
7. N95 respirators and surgical masks are stockpiled by the federal government, the state of Minnesota, health care facilities and other private institutions and individuals. Because of the vast numbers of both N95s and surgical masks that would be needed in a pandemic, the panel assumed that they would be very scarce. N95s and masks would be distributed to the general public only in very limited circumstances.
8. Vaccines that are well-matched to the strain of pandemic virus cannot be manufactured or stockpiled in advance. Vaccines will not become available in any significant amount for five to six months after the World Health Organization has declared a pandemic. Minnesota will receive approximately 35,000 doses weekly for its population of 5.4 million.
9. The demand for mechanical ventilators is expected to increase sharply and drastically exceed supply at times during a pandemic. Between peaks of pandemic waves, ventilator supply will be more sufficient.

The panel concluded that no single ethical commitment or objective is sufficient to guide the rationing of different health care resources under different levels of scarcity during a severe pandemic. Instead, it is both feasible and necessary to balance several ethical objectives. The objective of reducing the number of deaths due to influenza needs to be balanced with objectives directed at protecting public safety and civil order, protecting against systematic unfairness and promoting fair access for all Minnesotans.

Though no single ethical framework is adequate to address resources that vary in their purpose, supply and efficacy, the frameworks share a similar structure. The following table comprises the ethical commitments, objectives and general strategies common to most of the frameworks.

Ethical Frameworks At-a-Glance

Ethical commitments for pandemic planning and response

Pursue Minnesotans' common good in ways that:

- Are accountable, transparent and worthy of trust;
- Promote solidarity and mutual responsibility;
- Respond to needs fairly, effectively and efficiently.

Ethical objectives for rationing resources in a severe pandemic

Steward scarce resources to promote Minnesotans' common good by balancing three equally important and overlapping ethical objectives.

- Protect the population's health by:
  - Reducing mortality and serious morbidity from influenza and its complications;
  - Reducing mortality and serious morbidity from disruption to basic health care, public health, public safety and other critical infrastructures.
- Protect public safety and civil order by:
  - Reducing disruption to basic health care, public health, public safety and other critical infrastructures;
  - Promoting public understanding about and confidence in resource distribution.
- Strive for fairness and protect against systematic unfairness by:
  - Reducing significant group differences in mortality and serious morbidity;
  - Making reasonable efforts to remove barriers to access;
  - Making reasonable efforts to reciprocate to groups accepting high risk in the service of others;
  - Rejecting strategies that are discriminatory or exacerbate health disparities;
  - Using fair random processes for those similarly prioritized.

General strategies

- Consider and adjust strategies as part of a comprehensive pandemic response plan.
- Revise strategies in light of new information about a specific pandemic.
- Extend supplies and conserve resources before rationing; ration only as a last resort.
- Scale rationing strategies to different levels of scarcity.
- Do not ration based on:
  - Race, gender, religion or citizenship;
  - First-come, first-served;
  - Predictions that some people's lives can be extended more than others (except for people who are imminently and irreversibly dying);
  - Judgments that some people have greater quality of life than others; or
  - Judgments that some people have greater "social value" than others.
- Generally, de-prioritize people who are unlikely to benefit from the resource.
- Generally, prioritize key workers on a separate track in parallel with a track for the general public, recognizing that in limited circumstances a two-track approach might not be justified.
- Ration different resources based on varying combinations of the following considerations (rather than resort to random processes from the start).
  - For the general public:
    - Risk of flu-related mortality and serious morbidity;
    - Good or acceptable response to resource;
    - Risk of exposure to flu;
    - Risk of transmitting flu.
  - When appropriate to prioritize key workers separately from the general public, consider:
    - Risk of occupational exposure to flu;
    - Risk of flu-related mortality and serious morbidity;
    - Irreplaceability in the critical infrastructure workforce;
    - Risk of transmitting flu;
    - Good or acceptable response to resource.
- When the supply is inadequate to serve all similarly prioritized people then use a fair random process. Note: Under limited circumstances and if feasible, before resorting to randomization among the general public in any given tier, consider prioritizing children. Then depending on the resource and its supply consider prioritizing younger adults before older (either after children or simultaneously with them, as the supply allows).

The panel decided that the same commitments and overall objectives apply to all of the resources it considered, but notes a few slight differences for one of the resources—namely, mechanical ventilators. For instance, since the rationing of ventilators is anticipated to have no bearing on the disruption to basic services and infrastructures, infrastructure disruption is irrelevant ethically to deciding who should be prioritized for access to ventilators.

When a resource is scarce, the question arises whether the fairest strategy is to straightaway resort to random processes equalizing everyone's chances of getting the resource. The project participants recommended applying several clinical, population health, and fairness considerations before resorting to randomization. Depending on the severity of the shortages at different times during the pandemic, various combinations of these characteristics warrant prioritizing some groups to receive resources before others:

- high risk of flu-related mortality and serious morbidity;
- good or acceptable response to the particular resource;
- high risk of exposure, particularly risk taken on behalf of others;
- key role in performing basic health care, public health, public safety or other critical functions;
- risk of transmitting flu to people at high risk of flu-related mortality; and
- lack of satisfactory alternative protections or treatment.

Because each of the resources that are the subject of this report works differently, each has a unique set of strategies for promoting the ethical objectives. Except for ventilators and the prophylactic use of antivirals, the panel recommends a two-track approach that simultaneously prioritizes two groups of Minnesotans. One track prioritizes groups of key workers within critical public health, health care and public safety infrastructures. The other track simultaneously prioritizes groups of the general public, regardless of where or whether they work. The ventilator prioritization strategy is a single-track strategy geared to the general public, including workers of all kinds. The antiviral prophylaxis strategy is a single-track strategy that only attends to those key workers who routinely experience disproportionately high occupational exposure to the flu.

In general, those prioritized first among key workers are those with high risk of mortality or high occupational exposure to the flu, so long as they are likely to respond well to the particular resource. Similarly and simultaneously, those groups of the general public who are at the greatest risk of mortality are also prioritized for resources, so long as they are likely to respond well to the particular resource.

Protecting the population from unfairness requires proactively identifying the health and social factors that heighten risks of flu-related complications. Statewide rationing guidance should not systematically de-prioritize or exclude any demographic group from protection and benefit. The panel expressly rejected prioritizations based on personal judgments by individuals in control of the resource and criteria such as gender, race, socioeconomic status or citizenship. Moreover, it calls for proactive efforts to remove barriers to fair access by everyone prioritized to receive resources.

Random selection techniques will be required to fairly distribute scarce resources among equally prioritized people. The panel rejected relying on first-come, first-served as a proxy for randomization, because it would likely exacerbate existing health care access inequities. A more random technique, such as a lottery or flipping a coin, should be used instead.

When supplies are insufficient to serve all in a given tier, a controversy arises about whether, why and how to consider differences in age.[*] Most participants supported using age as a rationing criterion under limited circumstances, but disagreement remains about which age groups to prioritize. Appreciating Minnesotans' diverse perspectives and uncertainty regarding age, a few of the frameworks signal where it may be appropriate to consider prioritizing younger people before older—especially children before adults—but only:

[*] In this instance "age-based rationing" does not refer to correlations of age and risk of mortality. There is no controversy about the importance of prioritizing different age groups because they are at different risk of mortality.

- When rationing among people prioritized in the same tier (that is, among people at the same risk and likelihood of benefit);
- When rationing among the general population (ignoring age among key workers); and
- When it can be justified based on either or both of two fairness considerations: (1) when it fulfills adults' obligations to protect children; and/or (2) it favors younger people who have not yet had as much chance at life as older people. Both these fairness considerations are secondary to those explicitly named in the ethical frameworks.

The panel was not charged with evaluating its recommendations in the context of the state's complete pandemic response. Before implementing a rationing plan, all resources and other pandemic responses (such as school and business closures) should be considered together as a comprehensive package. The final plan should be adjusted and integrated so that the resources and strategies collectively best serve Minnesotans' common good.

With the Minnesota Pandemic Ethics Project, the state joins a small cadre of states and nations in developing ethics guidance for a severe influenza pandemic. Its process has been intentionally inclusive and transparent. This report confirms that carefully designed public engagement on scientifically and ethically complex questions on rationing—one of the most daunting topics in health policy—is feasible and productive.

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1. Introduction

The Minnesota Pandemic Ethics Project began in 2007 as part of the Minnesota Department of Health's ongoing pandemic planning. Experts were warning that a worldwide outbreak of influenza was inevitable, though the timing and severity was impossible to predict.[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, resembling exaggerated versions of annual influenza epidemics.[2] In contrast, the pandemic of 1918-19 was severe because of its significant mortality rate and its demographic distribution, triggering massive social and economic changes and degradation.[3] In June 2009, the World Health Organization declared the first influenza pandemic of the 21st century. To date this pandemic is mild in the United States. Its challenges are important wake-up calls, highlighting the importance of preparedness for a severe pandemic of the sort the world experienced in the early 20th century.

Severe pandemic influenza occurs on a scale that distinguishes it from other public health disasters in terms of its global nature, size and impacts. It is experienced over years, not days, weeks or months, and threatens core public health, social and economic infrastructures. Unlike a mild pandemic, a severe pandemic has the potential to cripple normal health care and business operations and disrupt the distribution of essential goods and services globally.[4] Unlike other disasters, states and communities cannot count on receiving assistance from others in a severe pandemic. The federal government has made it clear that states should develop their own pandemic plans, including mechanisms for rationing scarce resources.[5] It is prudent to plan for a severe pandemic.

With the welfare of Minnesotans at stake, health and other leaders are directing a statewide, coordinated response.[6] Health-related resources will be particularly important public health tools, and are being stockpiled (when prudent and feasible), and plans are being made to manage and fairly distribute them to protect the population's health. Stockpiling alone will be insufficient, because not all resources can be stockpiled (like vaccines for a novel virus) and because investing in more equipment, like mechanical ventilators, may not be enough to ensure an adequate supply. Even if there could be enough mechanical ventilators for everyone who could benefit from one, there would likely be shortages of health care professionals with the expertise to run them. Rationing will be necessary. Pandemic plans that do not clearly articulate the ethical values that underlie their recommendations for distributing scarce resources risk generating noncompliance and mistrust.[7]

NOTE: All links to the worldwide web in this report were last accessed on August 23, 2010.

[1] Vawter DE, Gervais KG and Garrett JE (2007). Allocating pandemic influenza vaccine in Minnesota: Recommendations of the Pandemic Influenza Ethics Work Group. *Vaccine* 25(35):6522-6536.
[2] US Department of Health and Human Services (DHHS). *HHS Pandemic Influenza Plan*. 2005. Available at: http://www.hhs.gov/pandemicflu/plan/.
[3] Barry JM. *The Great Influenza: The Epic Story of the Deadliest Plague in History*. New York, NY: Viking Press. 2004; Crosby A. *America's Forgotten Pandemic: The Influenza of 1918*. Cambridge, UK: Cambridge University Press. 1989; Kolata G. *Flu: The Story of the Great Influenza Pandemic of 1918 and the Search for the Virus that Caused It*. New York, NY: Farrar, Straus and Giroux. 1999; Ott M, Shaw SF, Danila RN, Lynfield R (2007). Lessons learned from the 1918–1919 influenza pandemic in Minneapolis and St. Paul, Minnesota. *Public Health Rep.* 122:803-810. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1997248/.
[4] Trust for America's Health. *Pandemic Flu and the Potential for US Economic Recession: A State-by-State Analysis*. 2007. Available at: http://healthyamericans.org/reports/flurecession/FluRecession.pdf.
[5] DHHS. *HHS Pandemic Influenza Plan*. 2005. D-11; US Department of Health and Human Services. *Pandemic Planning Update VI*. 2009. Available at: http://www.flu.gov/professional/pdf/panflureport6.pdf.
[6] Minnesota's pandemic planning information is available at: http://www.health.state.mn.us/divs/idepc/diseases/flu/pandemic/index.html.
[7] Melnychuk RM, Kenny NP (2006). Pandemic triage: The ethical challenge. *CMAJ* 175(11):1393-1394.

2. The Minnesota Pandemic Ethics Project

In 2007 the Minnesota Department of Health (MDH) contracted with ethicists from the Minnesota Center for Health Care Ethics and the University of Minnesota Center for Bioethics (project team) to develop and lead the Minnesota Pandemic Ethics Project. The goal was to develop ethical frameworks and procedures for rationing scarce health-related resources in a severe influenza pandemic. To that end, the project team convened a community-based resource allocation panel (panel), expert work groups, an implementation protocol committee, and several public forums and discussion groups within a variety of communities. The panel and work groups met regularly over many months. The project team also reviewed the relevant ethics literature and the ethical guidance available in pandemic plans. All told, the recommendations contained in this report reflect the work and input of approximately 600 Minnesotans with diverse experience and expertise.

Pandemic influenza planning is underway locally, regionally, nationally and internationally, but few planning efforts encompass ethical guidance for severe pandemic. Because of its focus on severe pandemic, its concern for how best to ration a broad array of health-related resources and its commitment to public engagement in building ethical guidance, MDH broke new ground.

3. Scope of Recommendations

Global pandemics vary in type and severity and raise many types of ethical challenges.[8] This project focuses on developing ethical guidance for rationing a specific set of health-related resources in Minnesota during a *severe* influenza pandemic. The recommendations are developed for a single, hypothetical pandemic scenario. For instance, the pandemic is envisioned to consist of three waves, last two years, pose higher risk to certain demographic groups than others and wreak havoc on basic health care, public health, public safety and other critical infrastructures.

The recommendations rest on specific sets of assumptions about each type of health-related resource considered (e.g., assumptions about the available supply and the groups that can benefit from the resource). The set of health-related resources the panel was charged to consider comprises preventive resources as well as resources used for first-line and critical care therapy. It is more illustrative than exhaustive, as many other medications and supplies are anticipated to be scarce during a pandemic.

- Preventive resources:
  - Pandemic influenza vaccines;
  - N95 respirators;
  - Surgical masks;
  - Antiviral medications for prophylaxis.
- Treatment resources:
  - Antiviral medications for treatment;
  - Mechanical ventilators.

[8] American Health Lawyers Association. *Community Pan-Flu Preparedness: A Checklist of Key Legal Issues for Healthcare Providers*. Washington, DC. 2008. Available at: http://www.healthlawyers.org/Resources/PI/InfoSeries/Documents/Pan-Flu%20Checklist.pdf; Lemon SM, Hamburg MA, Sparling PF, Choffnes ER, Mack A. *Ethical and Legal Considerations in Mitigating Pandemic Disease: Workshop Summary*. Washington, DC: National Academies Press. 2007. Available at: http://www.nap.edu/catalog.php?record_id=11917; Thomas JC. *Ethical Concerns in Pandemic Influenza Preparation and Responses*. [white paper] Southeast Regional Center of Excellence for Emerging Infectious [sic] and Biodefense. 2007. Available at: http://cstsp.aaas.org/files/pandemic_flu_white_paper.May_25.pdf; Kass NE, Otto J, O'Brien, Minson M (2008). Ethics and severe pandemic influenza: Maintaining essential functions through a fair and considered response. *Biosecur Bioterror* 6(3):227-36.

3.1. Palliative care

Recommendations for rationing all types of health-related resources are beyond the scope of this project. The panel, however, believed it important to venture beyond its formal charge to offer a recommendation about palliative care resources. The panel recommends that Minnesota stockpile sufficient supplies of palliative care resources, including medications to ameliorate pain and other severe symptoms, to avoid the need to ration these resources.

> Providing hospice and palliative care is a way of achieving equity for those who cannot benefit (or who could benefit, but due to altered standards of care will not receive access to live [sic] saving resources) from more intensive therapies. It is also a way of respecting the dignity of those who will not survive by helping to mitigate their pain and suffering. Finally, the provision of hospice and palliative care is also a fulfillment of the obligation of non-abandonment—a basic tenet of professionalism in health care and the minimum requirement of an ethical duty to provide care.[9]

The companion report on implementation discusses issues of palliative care at greater length.[10]

3.2. Statewide population health perspective

Ethical frameworks crafted to guide rationing decisions are likely to differ depending on the perspective brought to the task. State, national, institutional and individual perspectives are not usually entirely co-extensive. The Minnesota Pandemic Ethics Project embraced a statewide population health perspective. A statewide perspective may differ, for instance, from a national perspective in that the state does not focus on national security. Similarly, a statewide perspective is likely to differ from an institutional perspective, which focuses on the needs of a particular set of employees and customers. Moreover, an individual perspective would be insufficient. Individuals will not be able to promote their personal interests successfully, nor will they be able, on their own, to address threats to their common good. Strategies for the good of Minnesota as a whole promise the best and fairest protections for all in a severe pandemic.

3.3. Containment

Containment of the disease is always the first strategy state leaders attempt in response to an initial outbreak of a new virus. N95s, surgical masks and antivirals are likely to be useful to slow the spread of influenza with the earliest cases. Efforts to slow the spread of the disease are especially important when it is still possible to trace the contacts of a flu patient. The panel acknowledges that a reasonable supply of preventive and treatment resources should be allocated to early containment, but it did not address what proportion of the state's resources should be used for this purpose. Early containment was not the focus of the rationing guidance developed in the Minnesota Pandemic Ethics Project. The recommended frameworks focus on how to ration resources once the virus is no longer contained, disease is widespread and supplies are insufficient.

3.4. Adapt and integrate into comprehensive plan

There are many things that cannot be known about the pandemic imagined for the purpose of this project and the resources that need to be rationed. For this reason, the panel fully anticipated that core assumptions and elements of its recommendations would need to be revisited and modified when the specifics of an actual pandemic become known. The panel's assumptions were just that—assumptions regarding a single, hypothetical pandemic scenario extrapolated in large measure from reports of the pandemic of 1918-19—not predictions about what would happen during the next severe pandemic (or the 2009 H1N1 pandemic). Similarly, the recommended ethical frameworks are not algorithms that mandate particular rationing schemes. Instead they offer guidance to state leaders, pandemic responders and

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[9] The Pandemic Influenza Ethics Initiative Workgroup of the Veterans Health Administration's National Center for Ethics in Health Care. *Meeting the Challenge of Pandemic Influenza: Ethical Guidance for Leaders and Health Care Professionals in the Veterans Health Administration* [draft]. 2009.

[10] DeBruin DA, Marshall MF, Parilla E, Liaschenko J, Leider JP, Brunnquell D, Garrett JE, Vawter DE. *Implementing Ethical Frameworks for Rationing Scarce Health Resources in Minnesota during Severe Influenza Pandemic,* University of Minnesota Center for Bioethics and Minnesota Center for Health Care Ethics. 2010. Available at: http://www.health.state.mn.us/divs/idepc/ethics/.

Minnesotans generally. The panel recognizes that its recommendations will need to be coordinated with a host of other mitigation strategies and considerations (e.g., fiscal, supply chain and regulatory) and integrated into the state's comprehensive pandemic response.

4. Process

4.1. Development of preliminary recommendations

4.1.1. Resource allocation panel

The project team convened a large, diverse resource allocation panel that was ultimately responsible for the recommendations reported here. Its charge was to recommend ethical framework(s) for statewide rationing of a set of scarce health-related resources in Minnesota during a severe influenza pandemic. It focused on scenarios involving different types and supplies of resources, some, but not all, of which can be stockpiled:

- Prevention (vaccines, antivirals and personal protective equipment, that is, N95s and surgical masks);
- First-line treatment (antivirals); and
- Critical care treatment (ventilators).

MDH and the team worked closely to compose a panel that collectively represented as broad a range of interests, expertise and experience as was possible. The panel comprised approximately 45 Minnesotans, including members of the team. It included public health professionals, ethicists, health care providers, representatives from faith communities, neighborhood organizations, health plans, emergency responders, law enforcement, the court system and advocates for seniors, children and people with disabilities.[11]

Project team members from the Minnesota Center for Health Care Ethics (MCHCE) led the panel. The panel met in half-day sessions, monthly from May 2007 through November 2007 and again in February 2008.

4.1.2. Work groups and other expert input

Resource-specific work groups were formed to advise the panel. Each work group included approximately 15 – 20 members with expertise either in the specific resource or in ethics, including at least three project team members and one other panel member.[12]

An ethics work group was formed to focus in greater depth on the philosophical and ethical issues associated with rationing health resources during a pandemic. It reacted to and informed the work of the panel and the other work groups.

Project team members from MCHCE led the work groups, which met monthly in mid to late 2007.

In addition, more than two dozen ad hoc non-voting advisors from state government, including the Minnesota Departments of Health, Human Services, Public Safety, Labor and Industry, Administration and Employee Relations were available to answer questions between and at project meetings.

A separate implementation protocol committee was formed to address rationing implementation issues. Project team members from the University of Minnesota Center for Bioethics (UMCB) led the protocol committee's work, and its recommendations are contained in a companion report.[13]

[11] See Appendix A: Resource Allocation Panel and Work Group Members.
[12] Ibid.
[13] DeBruin, 2010.

4.1.3. Literature and plan review

The project team presented the preliminary results of its literature and plan review on ethical guidance for rationing during an influenza pandemic to the panel and work groups.[14] The review revealed that as of April 2008, merely a handful of national, state and local pandemic response plans were for a severe pandemic; most addressed mild or moderate pandemic. Even fewer plans offered ethical guidance for rationing in a severe pandemic. The review suggested that it would be unlikely that a single ethical principle or goal would be sufficient. Effective ethical guidance for rationing resources in a severe pandemic was anticipated to include different ethical principles and goals than are relied on in non-disaster circumstances. Furthermore, the review suggested that it is vital to provide instruction about whether and how to prioritize or balance multiple ethical commitments and goals.

4.1.4. Facilitation techniques

The project team used small and large group structured discussion techniques to familiarize panel members with the issues and begin eliciting their perspectives and values about rationing. One of the panel's first tasks was to refine assumptions about a modern occurrence of a severe pandemic (e.g., viral transmission, population and infrastructure impacts, and operational assumptions) (see Section 5).

To provide common ground for the panel and work groups' discussions, the project team drafted several model frameworks for rationing each resource. Each model framework focused on a single ethical commitment, for instance, (1) equal access, (2) saving the most lives possible, (3) fairness to socially vulnerable groups, (4) long-term social and economic stability, and (5) health care professionals' duty of patient advocacy. The sample frameworks outlined the goals and strategies that would follow for each of the particular resources in question. This approach facilitated productive discussions, enabling the more concrete thinkers to work from the specific strategies to the ethical principles. The more conceptual thinkers could work from the ethical commitments and objectives to strategies.

The ethics work group guided the philosophical underpinnings of the project. Its first task was to refine the model frameworks and suggest useful ways in which the frameworks could and should be blended to serve multiple ethical commitments and objectives.

Meanwhile, the project team formed and convened the resource-specific work groups over the summer of 2007, starting with the ventilator work group and phasing others in gradually. The work groups met monthly, and their first tasks were to develop working assumptions about the supply, use, safety and effectiveness of each of the resources during a severe pandemic. As the resource-specific work groups completed their work on assumptions, they began considering the model ethical frameworks and shaping recommended frameworks for the panel's review. The panel then reacted to the work groups' recommendations and fed questions back to them.

4.1.5. Preparation of preliminary report

The panel, ethics work group and resource-specific work groups proposed frameworks iteratively, each building on the others' progress. The panel's and work groups' reflections were enhanced by extensive mutual education. Participants learned from one another about a wide range of topics, including influenza, pandemic, specific health resources, high-risk and vulnerable populations, infrastructure, operational issues, and individual and community values. Ultimately, each resource-specific work group forwarded a set of resource-specific assumptions and an ethical framework for rationing the resource under different degrees of scarcity to the panel, and the panel blended those recommendations into a set of preliminary ethical frameworks. The project team distilled the recommendations into a draft report, and the panel provided feedback. A preliminary report was issued for additional public input in January 2009.[15]

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[14] Prehn AW, Vawter DE. *Ethical Guidance for Rationing Scarce Health-Related Resources in a Severe Influenza Pandemic: Literature and Plan Review.* Minnesota Center for Health Care Ethics and University of Minnesota Center for Bioethics. 2008. Available at: http://www.health.state.mn.us/divs/idepc/ethics/.

[15] Vawter DE, Garrett JE, Gervais K, Prehn AW, DeBruin DA, Tauer CA, Parilla E, Liaschenko J, Marshall MF. *For the Good of Us All: Ethically Rationing Health Resources in Minnesota in a Severe Influenza Pandemic*. [Preliminary Report] Minneapolis: Minnesota Center for Health Care Ethics and University of Minnesota Center for Bioethics. 2009.

4.2. Further public engagement

To solicit broader public input than the panel and work group participants could offer, various subsets of the project team designed and conducted several additional public engagement activities in 2009 (Appendices B – O). The team sought diversity in these public engagement processes in many respects, considering the demographics of the state and budgetary constraints:

- Recent experience with disaster response (e.g., Red River flooding);
- People with and without disabilities;
- Geography;
- Race and ethnicity;
- Socio-economic status;
- Language;
- Work experience;
- Age; and
- Gender.

The public engagement activities encompassed:

1. Solicitation of written comments to the preliminary recommendations. Comments were accepted electronically and by mail. All comments were welcomed, but three specific questions about the panel's preliminary recommendations were asked on the website. Not all respondents chose to respond to these questions:
    - Do you agree with the three objectives and that they should be balanced?
    - Do you agree with the ways the panel addressed socially vulnerable groups?
    - Should age-based rationing or randomization be used when risk is equal?

    The project team received written comments from 116 individuals and 12 organizations.

    The solicitation of written input was carried out under the leadership of the Minnesota Center for Health Care Ethics and the University of Minnesota Center for Bioethics.

2. The Minnesota Center for Health Care Ethics led day-long Community Forums in Duluth and Owatonna in April and May 2009. Because all of the work leading up to the panel's issuance of preliminary recommendations had occurred in the Twin Cities, MCHCE and MDH decided that the two community forums should be held in northern and southern Minnesota. A total of 200 people participated. Each forum lasted six hours on a Saturday and was observed by members of the panel and either Minnesota Commissioner of Health, Dr. Sanne Magnan or State Epidemiologist, Dr. Ruth Lynfield, among others from the Minnesota Department of Health. They were conducted in English with American Sign Language interpretation available upon request. Participants received continental breakfast, lunch, refreshments and a stipend to offset their expenses (e.g., transportation and childcare). The format for each forum was as follows.
    - Presentations about flu and the panel's preliminary recommendations.
    - Small and large group discussions on 2 topics:
        - Ethical objectives for rationing;
        - Age-based rationing.
    - Electronic polling.
    - "Paper dolls" exercise, in which each participant was asked to arrange a stack of 10 cards (Appendix N). The cards depicted groups that varied according to:
        - Key worker status;
        - Age;
        - Risk of dying from flu.

    The task was to arrange the cards, with #1 assigned to the group(s) at highest priority. Ties among some or all of the cards were allowed. A tie signified that the groups represented by the cards should be prioritized at the same level.

3. Nine small group discussions were held in greater Minnesota and in the Twin Cities metro area during the summer of 2009. MCHCE led six of the groups, and UMCB led three. In each

community a local partner managed recruitment and registration of adults on a first-come, first-served basis. The small group discussions were held in English, and Spanish language translation was available in one group. Each group comprised 11 – 16 people, for a total of 125 people. The group discussions lasted six hours on a Saturday or three hours on two successive weekday evenings. There was no attrition in discussion groups held on two consecutive evenings. Participants received meals appropriate to the time of day and stipends to offset their expenses (e.g., transportation and childcare). The groups were held in the following communities (map below):

- Courage Center, Minneapolis;
- Eden Prairie;
- Leech Lake Band of Ojibwe;
- Moorhead;
- Powderhorn Phillips Neighborhood, Minneapolis;
- North Side Neighborhood, Minneapolis;
- Virginia;
- West Side, St Paul; and
- Worthington.

The format for each included:

- Presentations about flu and the panel's preliminary recommendations
- Discussions on three topics:
  - Ethical objectives for rationing;
  - Age-based rationing;
  - Barriers to accessing resources.
- "Paper dolls" exercise and discussion (Appendix N).

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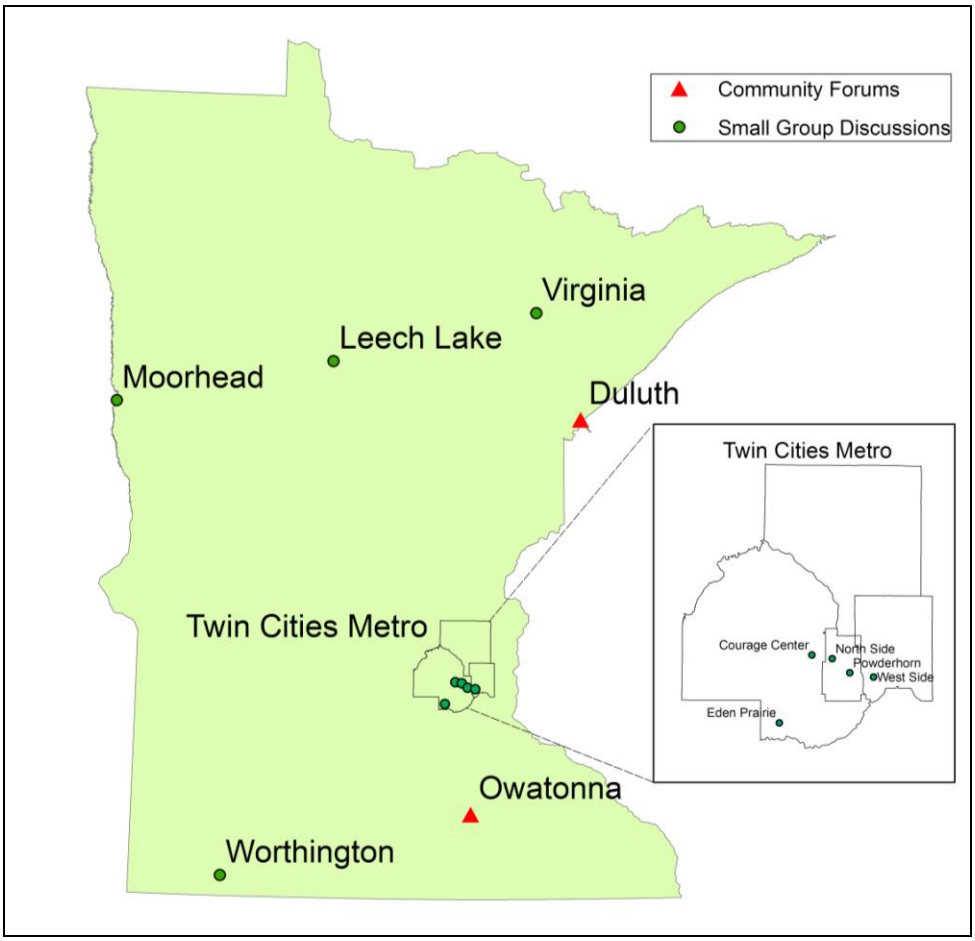
Map: Community Forums and Small Group Engagements



More detail about these public engagement activities, including demographic information about the participants and site selection, is contained in Appendix B.

4.3 Development of final recommendations

The panel reconvened in August 2009 to consider input from the large and small group engagement processes and from those who submitted written comments and discussed the range of issues prompted by these additional public engagement activities. Panel members asked to be surveyed after the meeting via email. They asked to review modifications to the "frameworks at-a-glance" table (see Table 6) to ensure that the table reflected their discussion about ethical objectives. They also asked to be polled about age-based rationing to give themselves more time to reflect on public input and a lively discussion that occurred during the meeting. The email survey also allowed those unable to attend the meeting an opportunity to be heard. The final recommendations in this report reflect the panel's deliberations during its final meeting and email input afterwards as well as a few suggestions offered by MDH staff.

5. Assumptions

The panel maintains that ethical frameworks for rationing are context-specific, and it is important to specify the underlying assumptions concerning the nature and impacts of the imagined severe pandemic to which the frameworks apply. The assumptions help to ground and focus the participants' discussions

and also signal the need to adjust the frameworks to fit the circumstances of an actual pandemic.[16] The assumptions also reflect the expert work groups' assessments of the best available knowledge about influenza and the various resources at the time of their meetings in mid-to-late 2007. ***These assumptions are not predictions about what kind of severe pandemic will next occur, nor do they describe the 2009 H1N1 pandemic.*** Many of the choices to be made in a severe pandemic were not faced in 2009. However, the project team and MDH agreed that the ethical frameworks developed under this project would be of greatest value if they tackled the toughest issues, that is, rationing during a severe pandemic.

In each of the sections below, the list of assumptions is numbered for the reader's convenience. The numbers do not imply priority. For example, assumption 1 is not more important than assumption 2 or 3 in any of these lists.

5.1. Pandemic assumptions

5.1.1. Severity level and population impacts

For the purposes of this project, the panel imagined a severe influenza pandemic, based on projections from the "Spanish Flu" pandemic of 1918–19.[17]

1. Global: A pandemic virus equivalent in pathogenicity to the virus of 1918 will kill more than 100 million people worldwide.[18]
2. US and MN: Over the two-year course of the pandemic, the number of people who will become ill, need various health care services, and die from influenza and its complications will be as follows:

Table 1: Potential Impact of Severe Pandemic[19]

	US	Minnesota
Total population (2007 estimates)	301,621,157	5,263,493
Illness	90 million (30% of population)	1,580,000 (30% of population)
Outpatient medical care	45 million (50% of those with flu)	790,000 (50% of those with flu)
Hospitalization	10 million	174,000
Intensive care	1.5 million	26,000
Mechanical ventilation	750,000	13,000
Deaths	1.9 million	38,000
Case-fatality rate[20]	2.1%	2.1%

[16] Adapted from Vawter et al, 2007.
[17] US Department of Health and Human Services. *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States: Early, Targeted, Layered Use of Nonpharmaceutical Interventions*. 2007. Available at: http://www.pandemicflu.gov/plan/community/community_mitigation.pdf; Taubenberger J, Morens D (2006). 1918 influenza: The mother of all pandemics. *Emerg Infect Dis* 12(1):15-22. Available at: http://www.cdc.gov/ncidod/EID/vol12no01/05-0979.htm; Crosby, 1989; Kolata, 1999.
[18] Osterholm MT (2005). Preparing for the next pandemic. *N Engl J Med* 352(18):1839-1842.
[19] Minnesota Department of Health (MDH). *Pandemic Influenza Plan: All-Hazards Response and Recovery Supplement*. 2006. Available at: http://www.health.state.mn.us/divs/idepc/diseases/flu/pandemic/plan/2006/mdhpanfluplan.pdf; MDH. *Minnesota Pandemic Influenza Planning Assumptions.* 2009. Available at: http://www.health.state.mn.us/oep/healthcare/flucenter/panflustats.pdf.
[20] Some plans assume an even higher case-fatality rate for a severe pandemic (see Ministry of Health. *New Zealand Influenza Pandemic Action Plan*. 2006. (No longer available on the worldwide web as of August 26, 2010.) The case-fatality rate for human H5N1 (bird flu) infection is currently about 60%, although this number is most likely an overestimate due to incomplete reporting (see World Health Organization. "Cumulative number of confirmed human cases of avian influenza A/(H5N1) reported to WHO." 2010. Available at: http://www.who.int/csr/disease/avian_influenza/country/cases_table_2010_08_12/en/index.html).

3. The disease is imagined to be exceptionally virulent in that 2.1% of those that develop the flu will die, a rate dramatically higher than for seasonal influenza.[21] In a typical year, approximately 600 Minnesotans die of influenza and pneumonia;[22] a severe pandemic may cause 38,000 deaths over a 2-year period.[23]
4. The pandemic is imagined to occur over 2 years with 3 waves of illness, each wave lasting 8–12 weeks.[24] One wave will be worse than the others.
5. Demographic groups at risk of mortality and serious morbidity:
   a. It is assumed that soon after the pandemic begins, public health officials will have sufficient data to determine which groups are at disproportionately high, high, moderate and low risk of serious morbidity and mortality from the virus, and those data will improve as the pandemic progresses.
   b. Mortality risk will vary according to age, health status and other demographic and social characteristics.
   c. The age-based mortality curve will be W-shaped as opposed to the U-shaped curve associated with seasonal influenza.[25] Healthy people aged 15–40 will join the very old and very young in being at elevated risk of dying from the flu.[26]
   d. Pregnant women will be one group at disproportionately high risk, because their immune systems are "dampened" so that their bodies will not reject a fetus.[27] It is assumed for purposes of this project that half of pregnant women who develop influenza may die.[28]
   e. The groups at greatest risk of long-term health consequences will be the same as the groups at greatest risk of mortality.

5.1.2. Illness characteristics

1. Some people will become infected but not develop clinically significant symptoms. Asymptomatic or minimally symptomatic individuals can transmit infection and develop immunity to subsequent infection.[29]
2. The vast majority (nearly 98%) of those who become ill will recover after approximately two weeks.[30]
3. Those with the flu will remain infectious for at least a week; treatment with antivirals may shorten the period of infectivity by one or two days.[31]

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[21] Taubenberger, 2006.
[22] Center for Health Statistics. *2006 Minnesota Health Statistics*. Minnesota Department of Health. 2007. Available at: http://www.health.state.mn.us/divs/chs/annsum/06annsum/Mortality06.pdf.
[23] MDH, 2009.
[24] DHHS. *HHS Pandemic Influenza Plan*, 2005.
[25] See Appendix P: 1918 Pandemic Influenza and Pneumonia Mortality Rates.
[26] Taubenberger, 2006; Among the small numbers of people who have died from bird flu (H5N1), 90% have been under the age of 40 and the case fatality rate is especially high in those ages 10-30. (See Abdel-Ghafar AN, Chotpitayasunondh T, Gao Z, Hayden FG, Nguyen DH, de Jong MD, et al. and the Writing Committee of the Second World Health Organization Consultation on Clinical Aspects of Human Infection with Avian Influenza A (H5N1) Virus (2008). Update on avian influenza A (H5N1) virus infection in humans. *N Engl J Med* 358(3):261-273. Available at: http://content.nejm.org/cgi/content/full/358/3/261#T4.) In the US early data from the CDC show that the highest the number of deaths from H1N1 is in persons between 25 to 49 years of age. See Pandemicflu.gov. "How have different age groups been affected by H1N1 flu in terms of death?" 2009. Available at: http://answers.flu.gov/questions/4247. One hypothesis is that a fatal inflammatory response may be due to a 'cytokine storm,' in which immune system cells accumulate in lung and other tissue and contribute to the development of acute respiratory distress syndrome. See Mok CK, Lee DC, Cheung CY, Peiris M, Lau AS (2007). Differential onset of apoptosis in influenza A virus H5N1- and H1N1-infected human blood macrophages. *J Gen Virol* 88(Pt 4):1275-1280; Sladkova T, Kostolansky F (2006). The role of cytokines in the immune response to influenza A virus infection. *Acta Virol* 50(3):151-162.
[27] Rasmussen SA, Jamieson DJ, Bresee JS (2008). Pandemic influenza and pregnant women. *Emerg Infect Dis* 14(1):95-100.
[28] Knobler SL, Mack A, Mahmoud A, Lemon SM (2005). *The Threat of Pandemic Influenza. Are We Ready?* Washington, DC: National Academies Press. Available at: http://www.nap.edu/catalog/11150.html.
[29] DHHS. *HHS Pandemic Influenza Plan,* 2005. Part I.
[30] Ibid.
[31] US Department of Health and Human Services. *Guidance on Antiviral Drug Use during an Influenza Pandemic.* December 16, 2008.; World Health Organization. *Clinical Management of Human Infection with Avian Influenza A (H5N1) Virus: Updated Advice.* 2007. Available at: http://www.who.int/csr/disease/avian_influenza/guidelines/clinicalmanage07/en/index.html.

5.1.3. Mechanism of transmission

1. Influenza viruses are spread from person to person primarily through infected persons' coughing and sneezing.[32] The virus is also spread by direct contact, e.g., shaking hands with an infected person and then touching one's mouth, nose or eyes.
2. It is generally agreed that the influenza virus is transmissible via droplets and can also be aerosolized in a small radius (up to six feet) around an infected person.[33] Thus, people lacking flu protection(s) who have sustained or routine direct contact with infectious people are at high risk of exposure and contracting influenza (e.g., parents who hold an ill child in their arms and health care professionals who perform aspirating procedures such as intubation).
3. It is not known whether the influenza virus aerosolizes over distances greater than six feet, which would warrant all caregivers and perhaps even the general public to wear protective gear.

5.1.4. Infrastructure disruption

A severe pandemic with a W-shaped age-specific mortality curve is anticipated to cause significant social and economic disruption and have the potential to cripple essential health care, public health and public safety infrastructures.

1. In a severe pandemic, absenteeism attributable to illness, death, the need to care for ill family members and fear of infection may reach 40% during the peak weeks of a community outbreak, with lower rates of absenteeism before and after the peak.[34]
2. The US gross domestic product is imagined to drop 4.5 – 5.5% in a year.[35]
3. Supply chains and trade will be disrupted in the face of absenteeism and voluntary and mandated travel restrictions.[36]
4. Demand for medical services, drugs and other products will surge, leading to dramatic shortages.[37]
5. Morgue and mortuary services will be overwhelmed.[38]
6. Some breakdowns in public order may occur.[39]

5.2. Demographic assumptions

1. Children (<18 years) account for about 25% of Minnesota's population, while those 65 and older make up about 13% of the population (Table 2). Approximately half of Minnesota's population will be at high risk of mortality and serious morbidity from a severe influenza pandemic, including very young children, young adults and the oldest among us.
2. Influenza pandemics can pose increased risks of mortality and serious morbidity to groups that may nor may not be at heightened risk from seasonal influenza.[40] Public health agencies at the

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[32] Tellier R (2006). Review of aerosol transmission of influenza A virus. *Emerg Infect Dis* 12(11):1657-1662. Available at: http://www.cdc.gov/ncidod/EID/vol12no11/06-0426.htm.

[33] Brankston G, Gitterman L, Hirji Z, Lemieux C , Gardam M (2007). Transmission of influenza A in human beings. *Lancet Infect Dis* 7(4):257-265.

[34] DHHS. *HHS Pandemic Influenza Plan*. 2005.

[35] Trust for America's Health, *Pandemic Flu and Recession*, 2007; Congressional Budget Office. *A Potential Influenza Pandemic: An Update on Possible Macroeconomic Effects and Policy Issues*. 2006. Available at: http://www.cbo.gov/ftpdocs/72xx/doc7214/05-22-Avian%20Flu.pdf; See also Meltzer MI, Cox NJ, Fukuda K (2005). The economic impact of pandemic influenza in the United States: Priorities for intervention. In Institute of Medicine *The Threat of Pandemic Influenza: Are We Ready?* Washington, DC: National Academies Press. Available at: http://www.nap.edu/catalog.php?record_id=11150.

[36] Brahmbhatt M. *Avian and Human Pandemic Influenza: Economic and Social Impacts*. November 2005. Available at: http://web.worldbank.org/WBSITE/EXTERNAL/NEWS/0,,contentMDK:20715087~pagePK:34370~piPK:42770~theSitePK:4607,00.html; Garrett L (2005). The Next Pandemic? *Foreign Affairs* 84(4):3-23. Available at: http://www.foreignaffairs.org/20050701faessay84401-p0/laurie-garrett/the-next-pandemic.html.

[37] Arnold R, De Sa J, Gronniger T, Percy A, Somers J. *Potential Influenza Pandemic: Possible Macroeconomic Effects and Policy Issues*. Congressional Budget Office. 2005. Available at: http://www.cbo.gov/ftpdocs/69xx/doc6946/12-08-BirdFlu.pdf.

[38] DHHS. *HHS Pandemic Influenza Plan*, 2005. D-16, F-40.

[39] US Homeland Security Council. *National Strategy for Pandemic Influenza: Implementation Plan*. 2006. Available at: http://georgewbush-whitehouse.archives.gov/homeland/pandemic-influenza-implementation.html.

[40] The Association of State and Territorial Health Officials. *At-Risk Populations and Pandemic Influenza: Planning Guidance for State, Territorial, Tribal and Local Health Departments*. 2008. Available at: http://www.astho.org/Programs/Infectious-Disease/At-

state, national and/or international levels will have information sufficient to identify subgroups that are at high risk.

3. Minnesota population estimates by race and income are summarized in Tables 3 and 4.

Table 2: Minnesota Population Estimates by Age Group, 2008[41]

Age Group (years)	Population	Percent
<5	355,334	6.8
5-17	894,493	17.1
18-20	220,756	4.2
21-44	1,704,277	32.6
45-54	815,087	15.6
55-64	579,292	11.1
65-84	548,655	10.6
85+	102,499	2.0
Total	**5,220,393**	
Select Groups		
Under 18	1,249,827	23.9
Under 21	1,470,583	28.1
55+	1,230,446	23.7
65+	651,154	12.6

Table 3: Minnesota Population Estimates by Race, 2008[42]

Race alone or in combination	Population	Percent
White	4,688,570	89.8
Black or African American	269,355	5.2
American Indian and Alaska Native	90,327	1.7
Asian	205,644	3.9
Native Hawaiian and other Pacific Islander	3,376	0.1
Some other race	64,274	1.2

Risk-Populations/At-Risk-Pop-and-Pandemic-Influenza-Planning-Guidance/; Blumenshine P, Reingold A, Egerter S, Mockenhaupt R, Braveman P, Marks J (2008). Pandemic influenza planning in the United States from a health disparities perspective. *Emerg Infect Dis.* 14(5):709-715. Available at: http://www.cdc.gov/EID/content/14/5/709.htm; Trust for America's Health (2009). *H1N1 Challenges Ahead*. Available at: http://healthyamericans.org/reports/h1n1/TFAH2009challengesahead.pdf; Garrett TA (2008). Pandemic economics: The 1918 influenza and its modern-day implications. *Federal Reserve Bank of St. Louis Review* 90(2):75-93. Available at: http://research.stlouisfed.org/publications/review/08/03/Garrett.pdf; Smith S. Cases of swine flu higher among city blacks, Hispanics. *The Boston Globe.* August 18, 2009. Available at: http://www.boston.com/news/local/massachusetts/articles/2009/08/18/cases_of_swine_flu_higher_among_bostons_blacks_hispanics/?rss_id=Boston.com+--+Local+news.

[41] 2008 American Community Survey. Minnesota ACS Demographic and Housing Estimates, 2008, United States Census Bureau. 2009. Available at: http://factfinder.census.gov/servlet/ADPTable?_bm=y&-geo_id=04000US27&-gr_name=ACS_2006_EST_G00_DP5&-context=adp&-ds_name=&-tree_id=306&-_lang=en&-redoLog=false&-format=.

[42] 2008 American Community Survey. Minnesota ACS Demographic and Housing Estimates, 2008.

Table 4: Minnesota Income Estimates by Household, 2008[43]

Total Household Income + Benefits (2008 Dollars)	# Households	Percent
Less than $10,000	120,450	5.8%
$10,000 to $14,999	96,887	4.6%
$15,000 to $24,999	191,923	9.2%
$25,000 to $34,999	195,869	9.4%
$35,000 to $49,999	299,528	14.3%
$50,000 to $74,999	424,666	20.3%
$75,000 to $99,999	297,159	14.2%
$100,000 to $149,999	282,217	13.5%
$150,000 to $199,999	94,315	4.5%
$200,000 or more	86,435	4.1%
Median household income (dollars)	57,288	(X)
Mean household income (dollars)	74,789	(X)

4. In Minnesota, approximately 5% of the population will be considered key workers in a severe pandemic. The definition of "key workers for essential functions" will evolve as planning progresses and be reassessed to fit the circumstances of an actual pandemic (see Section 6). Similarly, the criteria for deciding which key workers are "irreplaceable" will be disaster specific. Pandemic responders need to balance the preservation of infrastructures (which would tend to cause the key worker-related definitions to expand) with protecting the general public (which would tend to cause the definitions to contract). The panel assumed that public health officials will have clear criteria for determining which jobs routinely place key workers at disproportionately high, high and moderate risk of occupational exposure to the flu. All criteria will be public and decision makers will be accountable for their determinations about who does and does not qualify as a key worker, which key workers are at various risks of occupational exposure, which are irreplaceable and which are at various risks of flu-related complications.

5.3. Resource assumptions

Table 5 presents an overview of assumptions made about the health resources addressed in this project. These resources differ in several ways, including use, supply and effectiveness. For example, some resources such as antivirals can be stockpiled, while pandemic vaccines cannot be stockpiled as they cannot be manufactured until after the pandemic virus is characterized. The effectiveness and availability of a resource depends on the availability and use of other resources (e.g., fit test kits and training for N95s, syringes to administer vaccine, and numerous resources to support the use of mechanical ventilators), although the effectiveness of all of the resources is uncertain until the nature of the pandemic is known. The panel assumed that public health officials will have sufficient data to determine which groups have a good, acceptable or unacceptable response to specific types of resources. Detailed assumptions and references about these resources are included below in conjunction with each resource-specific rationing framework (Sections 10.1, 11.1, 12.1, and 13.1). (Appendix Q includes selected bibliographic materials on each of these types of resources.)

[43] Ibid.

Table 5: Overview of Assumptions for Specific Resources

	Antivirals		N95 Respirators and Surgical Masks	Mechanical Ventilators	Pandemic Vaccines
	Treatment	**Prophylaxis**			
Purpose	▪ Treatment	▪ Immediate temporary prevention either post-exposure or for longer-term	▪ Reduce exposure of the wearer to the flu virus ▪ Reduce probability of spreading flu virus from the wearer to others	▪ Acute life-saving treatment	▪ Long-term prevention
Availability and Supply	▪ Treatment stockpiles available early and possibly throughout pandemic depending on re-supply capacity and dosage regimens ▪ Majority of supply	▪ Private stockpiles available early only ▪ Small regular supply may continue ▪ Limited supply	▪ Stockpiles available early ▪ Questionable availability later ▪ N95s scarce for health care workers after the first few weeks ▪ N95s extremely scarce for general population	▪ Available early ▪ Fixed but scarce supply including small stockpile	▪ Unavailable early ▪ No stockpile ▪ After 6 months small regular supply of about 35,000 doses/week
Control of supply	▪ Public and private sectors ▪ Individuals	▪ Public and private sectors ▪ Individuals	▪ Public and private sectors ▪ Individuals	▪ Public and private sectors	▪ Public sector only
Type of users	▪ Patients with recent flu-like symptoms (flu patients and some non-flu patients) able to take oral medication (intravenous formulation under study)	▪ Healthy people in community or at work, especially people with disproportionately high exposure to flu ▪ Healthy people and immune-compromised people post-exposure to flu	▪ Masks: people with flu-like symptoms, as well as healthy people in community or at work ▪ N95s: healthy people	▪ Hospitalized patients with respiratory failure (flu and non-flu patients)	▪ People susceptible to the flu
Type of good	▪ Individual good: treatment of flu patients ▪ Public health good: reduce duration and severity of illness; reduce transmission	▪ Individual good: time-limited prophylaxis ▪ Public health good: reduce transmission	▪ Individual good: time-limited protection of healthy people ▪ Public health good: reduce transmission	▪ Individual good: life-saving tertiary care for flu and non-flu patients	▪ Individual good: long-term prophylaxis ▪ Public health good: reduce infection rates
Predict-ability of benefit	▪ High if virus is not resistant; low if virus is resistant to antivirals	▪ High if virus is not resistant; low if virus is resistant to antivirals	▪ Uncertain: N95s and possibly masks can reduce exposures to airborne viruses, however, the airborne infectious dose of the flu virus is not known ▪ Depends upon use of hand hygiene and fit-testing for N95s ▪ N95s and masks can reduce transmission	▪ Initially low ▪ Likelihood of survival depends on virulence of virus, severity of respiratory failure, availability of concomitant necessary resources	▪ Uncertain, but possibly high
Limitations	▪ Resistance to antivirals may undermine efficacy ▪ Improper use may be counterproductive ▪ Pill and oral inhalation forms unsuitable for many (can be suspended or given by feeding tube)	▪ Resistance to antivirals may undermine efficacy ▪ Improper use may be counterproductive	▪ Improper use may be counterproductive ▪ May create false sense of security ▪ Inappropriate and unsafe for young children	▪ Vents may have variable effect on survival in different groups ▪ Very staff intensive	▪ Supply unavailable for 1st 6 months (after first wave of pandemic) ▪ Cannot use for very young infants ▪ Restricted use for inhaled formulation

6. Definitions

Groups at high risk (including disproportionately high risk) of influenza-related mortality and serious morbidity: In seasonal influenza outbreaks as well as moderate pandemics, the very young, the very old and those who are immune-compromised are the groups at high risk of influenza-related mortality and serious morbidity. For purposes of this project, the assumption is that in a severe pandemic these groups will be joined by other groups, including healthy people between the ages of 15 and 40, pregnant women, people with certain co-morbidities and other demographic and/or socially vulnerable groups (defined below).[44] Surveillance measures need to be sufficiently sensitive to promptly recognize groups at higher than normal risk.

"Disproportionately high risk of flu-related mortality/morbidity," refers to groups with a case fatality rate that dramatically exceeds the peaks of an age-specific mortality curve for the flu. In 1918–19 pregnant women suffered an exceptionally high risk with a case fatality rate as high as 70% in the late stages of pregnancy.[45]

"High" or "disproportionately high" risk should not be confused with being unlikely to benefit from flu-related resources and/or being so ill as to have little chance of survival. Some groups at high or disproportionately high risk of flu-related mortality and serious morbidity may respond well to certain preventive resources or treatments.

Key workers for essential functions: those whose functions are critical to limiting flu-related deaths and degradation of the health care, public health, public safety and other critical infrastructures, including volunteers. Various state and federal efforts are underway to define key workers across sectors for purposes of pandemic planning. Building on the set of critical sectors recommended by the National Infrastructure Advisory Council,[46] a federal interagency working group has recommended a somewhat expanded list of key workers for a severe pandemic.[47] Minnesota Pandemic Ethics Project participants embraced a few more categories of workers, including child protection, day care, service providers on whom people whose health is particularly precarious routinely rely, such as workers supporting people with profound physical disabilities, mortuary science and spiritual leaders (see also Section 5.2).[48]

Irreplaceable key workers: a subset of key workers whose expertise and/or experience is limited to a very small number of people and for whom replacements cannot be trained adequately during or shortly after a severe pandemic, e.g., air traffic controllers.

High (including disproportionately high) occupational exposure: key workers lacking influenza protection (e.g., immunity or infection control resources) whose jobs require sustained or routine direct physical contact with influenza patients have high occupational exposure. Health care workers who participate in procedures that are potentially aerosol-generating with influenza patients (e.g., bronchoscopy, intubation, cardio-pulmonary resuscitation, open airway suctioning, and sputum induction) exemplify those at disproportionately high risk of exposure.[49]

High risk of transmission: people who live or work in close contact with others, posing risk to large groups of people or to people who are at high risk of flu-related mortality and serious morbidity.

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[44] Taubenberger, 2006.
[45] Knobler, 2005.
[46] National Infrastructure Advisory Council (NIAC). *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.
[47] US Vaccine Prioritization Interagency Working Group. *Draft Guidance on Allocating and Targeting Pandemic Influenza Vaccine.* 2007. Available at: http://www.pandemicflu.gov/vaccine/prioritization.html.
[48] Though there was discussion of including food industry workers in the list of key workers, the panel decided against this. There are other ways to support and protect the food industry and the industry is so large that it might exhaust supplies of health resources.
[49] Centers for Disease Control and Prevention (CDC). *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/professional/hospital/maskguidancehc.html.

Socially vulnerable groups: groups that suffer health disparities due to factors such as race, ethnicity, low income, poor education, geography (e.g., live in high density urban centers or live in isolated areas far from access to critical care resources), disability or sexual orientation.[50] Vulnerability may stem from many factors, including poor access to health care resources, inability to stockpile resources recommended by public health authorities and differences in exposure, susceptibility, resiliency and treatment.[51] Groups with compounded social vulnerabilities may have particularly low resiliency during a severe pandemic and be at heightened risk of flu-related complications.[52]

7. Ethical Frameworks for Rationing

In the harsh circumstances of a severe pandemic, ethical guidance for rationing is imperative. Resources must be used to provide the most benefit, not be wasted and be distributed fairly. The value of an ethical framework to guide rationing decisions depends on how well it addresses varying levels of scarcity, clarifies connections between abstract principles and concrete rationing dilemmas and solutions, and reflects the community's values. This section introduces the recommended ethical frameworks to guide rationing. Because each resource works differently, the panel recommends a unique framework and set of assumptions for each (See Sections 10 (Antivirals), 11 (N95s and Surgical Masks), 12 (Vaccines) and 13 (Ventilators)).

Table 6 summarizes the ethical commitments, objectives and strategies that are generally recommended for the resources discussed in this report.

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[50] US Department of Health and Human Services. Healthy People 2010: Understanding and Improving Health. Goal 2: Eliminating Health Disparities. 2nd ed. Washington, DC: U.S. Government Printing Office, November 2000. Available at: http://www.healthypeople.gov/Document/html/uih/uih_2.htm#goals; Garrett TA, 2008.
[51] Blumenshine, 2008.
[52] The Association of State and Territorial Health Officials, 2008; Trust for America's Health, 2009.

Table 6: Ethical Frameworks At-a-Glance

Ethical commitments for pandemic planning and response

Pursue Minnesotans' common good in ways that:

- Are accountable, transparent and worthy of trust;
- Promote solidarity and mutual responsibility;
- Respond to needs fairly, effectively and efficiently.

Ethical objectives for rationing resources in a severe pandemic

Steward scarce resources to promote Minnesotans' common good by balancing three equally important and overlapping ethical objectives.

- Protect the population's health by:
  - Reducing mortality and serious morbidity from influenza and its complications;
  - Reducing mortality and serious morbidity from disruption to basic health care, public health, public safety and other critical infrastructures.
- Protect public safety and civil order by:
  - Reducing disruption to basic health care, public health, public safety and other critical infrastructures;
  - Promoting public understanding about and confidence in resource distribution.
- Strive for fairness and protect against systematic unfairness by:
  - Reducing significant group differences in mortality and serious morbidity;
  - Making reasonable efforts to remove barriers to access;
  - Making reasonable efforts to reciprocate to groups accepting high risk in the service of others;
  - Rejecting strategies that are discriminatory or exacerbate health disparities;
  - Using fair random processes for those similarly prioritized.

General strategies

- Consider and adjust strategies as part of a comprehensive pandemic response plan.
- Revise strategies in light of new information about a specific pandemic.
- Extend supplies and conserve resources before rationing; ration only as a last resort.
- Scale rationing strategies to different levels of scarcity.
- Do not ration based on:
  - Race, gender, religion or citizenship;
  - First-come, first-served;
  - Predictions that some people's lives can be extended more than others (except for people who are imminently and irreversibly dying);
  - Judgments that some people have greater quality of life than others; or
  - Judgments that some people have greater "social value" than others.
- Generally, de-prioritize people who are unlikely to benefit from the resource.
- Generally, prioritize key workers on a separate track in parallel with a track for the general public, recognizing that in limited circumstances a two-track approach might not be justified.
- Ration different resources based on varying combinations of the following considerations (rather than resort to random processes from the start).
  - For the general public:
    - Risk of flu-related mortality and serious morbidity;
    - Good or acceptable response to resource;
    - Risk of exposure to flu;
    - Risk of transmitting flu.
  - When appropriate to prioritize key workers separately from the general public, consider:
    - Risk of occupational exposure to flu;
    - Risk of flu-related mortality and serious morbidity;
    - Irreplaceability in the critical infrastructure workforce;
    - Risk of transmitting flu;
    - Good or acceptable response to resource.
- When the supply is inadequate to serve all similarly prioritized people then use a fair random process. Note: Under limited circumstances and if feasible, before resorting to randomization among the general public in any given tier, consider prioritizing children. Then depending on the resource and its supply consider prioritizing younger adults before older (either after children or simultaneously with them, as the supply allows).

7.1. Ethical commitments

What underlying commitments should be expected of those in Minnesota who manage health-related resources in a severe pandemic? Unlike other disasters, a highly virulent, lethal infectious disease imposes the ultimate catch-22: Minnesotans must achieve unprecedented solidarity and commonness of purpose while isolating, separating and protecting themselves from each other. Surely this is among the greatest challenges to thinking and acting as a true community—one that will require extraordinary leadership and collaboration.

The panel recommends that Minnesotans' common good be pursued in ways that:

- Are accountable, transparent and worthy of trust;
- Promote solidarity and mutual responsibility; and
- Respond to needs fairly, effectively and efficiently.

These three ethical commitments are grounded in the assumptions that people must be respected, and that those entrusted with the common good have responsibilities—not just to lead, but also to inspire Minnesotans to follow. These core notions of respect for individuals and responsibility to Minnesotans as a population are essential to a coordinated, effective statewide pandemic response.

7.2. Ethical objectives

A severe pandemic poses two distinct kinds of threats: (1) severe illness and death from the disease and its complications, and (2) death and possible social disorder due to the disruption of critical infrastructures. To address these threats, the panel recommends three sets of ethical objectives:

- Protect the population's health;
- Protect public safety and civil order; and
- Strive for fairness and protect against systematic unfairness.

The panel recommends that rationing plans promote these three ethical objectives simultaneously, in a justifiable balance to serve Minnesotans' common good. An ethically justified rationing strategy balances attention to each of these objectives in relation to the others. This means that each constrains the pursuit of the others. The three objectives are quite general, and each framework further specifies more concrete ways to promote and instantiate the objectives. The objectives overlap, so some of the more specific guidance supports more than one objective.

- Protect the population's health by:
  - Reducing mortality and serious morbidity from influenza and its complications; and
  - Reducing mortality and serious morbidity from disruption to basic health care, public health, public safety and other critical infrastructures.
- Protect public safety and civil order by:
  - Reducing disruption to basic health care, public health, public safety and other critical infrastructures; and
  - Promoting public understanding about and confidence in resource distribution.
- Strive for fairness and protect against systematic unfairness by:
  - Reducing significant group differences in mortality and serious morbidity;
  - Making reasonable efforts to remove barriers to access;
  - Making reasonable efforts to reciprocate to groups accepting high risk in the service of others;
  - Rejecting strategies that are discriminatory or exacerbate health disparities; and
  - Using fair random processes for those similarly prioritized.

There is little controversy about the importance of protecting the public's health during a public health emergency. Doing so requires attending both to the disease itself and to the other threats to health that can present if basic lifesaving and safety resources are impaired. Community resilience is increased when crisis plans have been carefully conceived in advance, the public has been included in the planning process and communications are clear during the crisis response.[53]

[53] Committee on Disaster Research in the Social Sciences. *Facing Hazards and Disasters: Understanding Human Dimensions*.

The ethical objective of fairness spurred significant discussion. Four of the specific fairness goals seek *substantive* fairness, namely that benefits (or burdens) are distributed among people or groups based on ethically relevant differences among them. The fifth fairness goal stresses the importance of *procedural* fairness; requiring that procedures equalize chances to receive benefits (or have burdens imposed) among those equally prioritized to receive them.

7.3. Strategies: Overview

The panel developed scalable rationing strategies specific to each resource for a hypothetical severe pandemic scenario. Strategies for prioritization depend on the severity of the shortage of particular resources relative to the demand.

For each resource, the panel determined whether key workers should be prioritized to the exclusion of the public, on a parallel track with the public or together with the general public.

The panel recommends that all but two of the resources considered in this report be rationed to key workers and to the general public on two separate but parallel tracks. Supplies of antivirals for long-term prophylaxis (one of three purposes for which antivirals can be used) are anticipated to be extremely scarce and should be rationed exclusively to a small group of key workers. Mechanical ventilators should be rationed to the general public without a separate carve-out or track for key workers. (Key workers should be considered as part of the general public and neither prioritized nor de-prioritized for ventilators by virtue of their work roles.)

The panel considered several different criteria in developing rationing strategies:[54]

- Risk of flu-related mortality and serious morbidity (disproportionately high, high, moderate and low);
- Good or acceptable response to the resource;
- Risk of occupational or non-occupational exposure to pandemic flu (disproportionately high, high or any risk of exposure);
- Recent known unprotected exposure to pandemic flu; and
- Risk of transmitting flu to key workers or people at high risk of flu-related mortality and serious morbidity.

Various combinations of these characteristics warrant prioritizing some groups of the general population and/or some key workers to receive a particular resource before others. These characteristics vary in their importance and relevance among resources.

The panel rejected several criteria for rationing. These criteria are inconsistent with the commitment to protect Minnesotans from systematic unfairness. Specifically, resources should not be rationed based on:

- Race, gender, religion or citizenship;
- First-come, first-served;
- Predictions that some people's lives can be extended more than others (except for people who are imminently and irreversibly dying);
- Judgments that some people have greater quality of life than others; or
- Judgments that some people have greater "social value" than others.

Most frameworks include one set of rationing criteria for the general population and another for key workers. In general, those prioritized first among key workers are those with the highest occupational exposure to the flu or high risk of mortality and serious morbidity, so long as they are likely to respond well to the particular resource. Similarly and simultaneously, those groups of the general public who are at the greatest risk of flu-related mortality or serious morbidity are also prioritized for resources, so long as

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Washington, DC: National Academies Press. 2006. Available at: http://www.nap.edu/catalog.php?record_id=11671; Schoch-Spana M, Franco C, Nuzzo JB, Usenza C (2007). Community engagement: Leadership tool for catastrophic health events. *Biosecur Bioterror.* 5(1):8-25. Available at: http://www.liebertonline.com/doi/pdfplus/10.1089/bsp.2006.0036.

[54] Prehn, 2008.

they are likely to respond well to the resources. The most significant differences between the general population and key workers are that key workers are also prioritized by virtue of their role in supporting core infrastructures on which all Minnesotans depend and by reciprocity obligations owed those key workers who accept high risk in the service of others.

The panel also proposed criteria for de-prioritization (not outright exclusion) to receive particular resources. These include: presumed or confirmed immunity (e.g., have recovered from pandemic influenza or are successfully vaccinated); availability of satisfactory alternative protections; and medical contraindications or imminent death (e.g., have an obvious co-morbidity incompatible with life beyond a short timeframe).

In addition, non-clinical age considerations may be considered in the general population in limited circumstances as an alternative to resorting to a strictly random method of rationing resources to similarly prioritized people. Project participants discussed whether, when and how it might be appropriate to consider differences in age when the demand for health-related resources vastly outstrips supplies. While most participants support attending to age under some circumstances, there was less agreement about the specifics. Some Minnesotans believe it can be fair to prioritize children before adults; some favor prioritizing younger people before older across the life-span; some favor prioritizing young adults before children and other age groups because this is the best way to protect children. A minority strongly opposed any age-based considerations. Many participants held their views very strongly; others struggled with clearly delineating age groups that should be prioritized.

In the end, the panel decided that there are limited circumstances in which age can be used as a rationing criterion among the general public before resorting to randomization. Specifically, it is only acceptable to prioritize younger before older people in the general population when the people are prioritized in the same tier (in other words, when all other relevant criteria such as risk of mortality or serious morbidity, response to the resource, or risk of transmission are equal) and demand significantly exceeds supply in that tier. Age-based rationing should not be considered when distributing health-related resources to key workers.

Which differences in age are significant enough to warrant considering age-based rationing differs depending on the resource. The panel offers several rules of thumb to guide those few instances in which it may be permissible to prioritize younger before older people. Age-based rationing is discussed in more detail in the frameworks for treatment antivirals, vaccines and mechanical ventilators and in Section 14.1.2.3.

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8. General Recommendations

For the rationing frameworks to best promote the values and goals of Minnesotans and to be optimally implemented, a number of additional factors must be addressed. Substantial progress toward some of these recommendations, if not most, is already underway as part of the state's all-hazards disaster planning and response to the H1N1 novel influenza pandemic.

8.1. Extend and manage supply

1. Take reasonable steps to reduce demand for and extend the supply of scarce health-related resources. For example, restructure working environments and deploy work forces in ways that minimize person-to-person contact with large numbers of people so as to reduce demand for scarce preventive and treatment resources.
2. Provide adequate training to promote the efficient and effective use of resources.
3. Improve capacity to monitor statewide supply and demand for health resources.
4. Improve capacity to rapidly and safely dispense scarce health resources.
5. Establish mechanisms for tracking the distribution of scarce resources.
6. Stockpile sufficient pain medications and other palliative care resources to manage serious symptoms so that these resources do not need to be rationed. Offer alternative care for people who do not receive or benefit from rationed health resources, including palliative and hospice care for dying patients. A companion report on implementation discusses issues of palliative care at greater length.[55]

8.2. Remove access barriers

1. Expand capacity to communicate with the public, with special attention to diverse communities.
2. Develop appropriate education strategies and infrastructures for prescribing and dispensing health resources in a timely fashion, including for people with cultural, communication, mobility, economic and geographic barriers.
3. Make reasonable efforts to remove economic, social and geographic barriers to access to scarce health resources, for example, remove cost as a barrier and distribute resources in ways convenient for socially vulnerable and underserved groups.
4. Collect, analyze and report relevant data to support effective, efficient use of scarce health resources. In particular collect age and demographic data to identify disparities in flu-related mortality and serious morbidity among Minnesotans. Monitor whether groups that currently suffer health disparities[56] are at increased risk of pandemic flu-related mortality and serious morbidity.
5. Determine which socially vulnerable groups are likely to have poor resiliency during a severe influenza pandemic and which infrastructures they depend on for their health and survival. Determine which of these infrastructures, if any, are not already included in the list of protected ones and consider whether to include them in the list of "other critical infrastructures" to be protected.

8.3. Adjust and refine ethical frameworks

1. Secure informed public input and trust, commit to transparency in the development and implementation of the rationing frameworks, and inform the public about specific plans and their rationales.
2. Adjust the ethical frameworks to respond to the best available evidence about the nature of the pandemic, relative risk, resources' efficacy and effectiveness, and alternative protections.
3. Coordinate rationing plans with other pandemic mitigation measures (such as social distancing).

[55] DeBruin, 2010.
[56] Minnesota Department of Health. *Eliminating Health Disparities Initiative: Investing in Minnesota's Populations of Color and American Indians*. 2009. Available at: http://www.health.state.mn.us/ommh/publications/legislativerpt2009.pdf.

8.4. Other recommendations

1. Clarify that rationing guidelines may preempt requests for interventions by patients and proxies and in advance directives.
2. Provide clear legal protections for workers who comply with altered care standards.
3. Clarify work expectations for those who receive health resources as well as any penalties for those who refuse to work.

In several instances, the feasibility of implementing the rationing strategies depends upon Minnesota's leaders attending to these general recommendations. For instance, the rationing frameworks assume that public health officials will have sufficient data to say which groups are at disproportionately high, high, moderate and low risk of flu-related mortality, have a good or acceptable response to the resource, are at disproportionately high, high or any risk of exposure to the flu, or at high risk of transmitting the flu to others. Without sufficient data to ground such determinations (recognizing that such determinations may be revised during the course of the pandemic as better information emerges) the rationing strategies cannot be implemented responsibly.

Though the Minnesota Pandemic Ethics Project attends to some implementation issues,[57] the frameworks were developed with a focus on identifying ethically acceptable options, taking care not to reject some options prematurely on the basis of preconceived ideas about what will or will not be feasible during a particular severe pandemic. The rich exchanges started in this project between people interested in value issues and those concerned with the practicalities of rationing must continue in an open and transparent manner.

9. How to Read and Apply the Frameworks

Each of the ethical frameworks presented in the following sections are depicted in tables. Here is guidance for reading them:

1. Each framework incorporates by reference the general recommendations contained in Section 8.
2. Each framework also incorporates by reference recommendations about the particular resource in question, such as supply, access barriers, and de-prioritization criteria. These resource-specific, general recommendations immediately precede each table.
3. The frameworks begin with the most general guidance (ethical commitments) and end with more specific guidance (strategies).
4. Most of the frameworks have separate, simultaneous tracks to depict distribution of resources among key workers in critical infrastructures (track A) and the general public (track B). The percentage of resources distributed to each track will depend on the circumstances of an actual pandemic. The panel assumed that key workers comprise approximately 5% of the total population.
5. Unless stated otherwise, scarce resources should not be held back from distribution to respond to a future wave of illness or other need. In general, scarce resources should be distributed straightaway as they are needed during the pandemic.
6. The frameworks rest on assumptions about pandemic influenza and about the particular resources in question (supply, demand, purpose, efficacy, safety, etc.). In particular, the panel assumes that sufficient information will be available to make morally relevant distinctions about relative risk of the disease and relative efficacy of the resources. If there isn't sufficient information available to support such distinctions or if other key assumptions prove wrong during the pandemic, the frameworks will need to be adjusted.

[57] Ibid.

7. Most of the frameworks contain several priority tiers. When people are included in more than one tier, they should be prioritized in the highest tier in which they are included.
8. Unless stated otherwise, if the resource supply is too scarce to serve everyone in a particular tier, then the resource should be distributed randomly among people within that tier.
9. It is important to reach as many people in each tier as possible before moving to the next tier. It is impractical to assume that everyone in a tier could be reached, though, especially under pandemic conditions. Indeed, to try to do so could slow down resource distribution unnecessarily. Accordingly, the tiers are offered to guide distribution efforts, but with the caution that forward momentum in distributing resources should be maintained.
10. If the tiers are too finely grained, that is, if it is infeasible to implement the rationing strategies with all the tiers offered, consider combining some adjacent tiers. Thus, tiers 2 and 3 could be combined; tiers 1 and 3 could not be combined without including tier 2 as well.

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10. Ethical Frameworks for Rationing Antivirals

10.1. Antiviral assumptions

The following table[58] summarizes assumptions about the two antivirals most widely stockpiled: zanamivir (Relenza) and oseltamivir (Tamiflu). The frameworks focus on proposing rationing guidance for oseltamivir, the antiviral currently being stockpiled in the largest amounts.

Table 7: Antiviral Assumptions

Types of antivirals	Zanamivir (Relenza)	Oseltamivir (Tamiflu)

Regulatory status	• FDA approved:
	  ○ Treatment > 7 years of age
	  ○ Prophylaxis > 5 years of age
		• FDA approved:[59]
		  ○ Treatment of uncomplicated viral influenza > 1 year of age
		  ○ Prophylaxis of uncomplicated viral influenza > 1 year of age

Indications	• Primary use is for treatment of people ill with influenza-like illnesses
	• Used for short-term post-exposure prophylaxis (PEP):
	  ○ Contacts of earliest cases to slow early outbreaks
	  ○ People with known unprotected exposure
	• Used for long-term or outbreak prophylaxis
	• Minnesota's stockpile is currently prioritized for treatment, per federal government requirements	

Dose, adminis-tration	• Oral inhalation • Treatment within 2 days of symptoms: 10 mg (2 inhalations) twice a day • Prophylaxis: 10 mg (2 inhalations) once a day for 10 – 28 days	• Oral tablet; oral suspension will be available for children (and others) who have difficulty swallowing • Treatment within 1 – 2 days of symptoms;[60] 75 mg twice daily for 5 days in adults • Smaller doses for children and those with renal insufficiency • PEP: 75 mg once a day for 10 days in adults; dosages vary for small children • Long-term prevention: Take daily for entire community outbreak (for example, 8 – 12 weeks)[61] • Non-standard courses may be required for critically ill;[62] maximum doses and duration are unknown; effectiveness may require a double dose or extended use

Anticipated supply	• Supply in Minnesota as of September 2009 was projected to be 1,112,175 standard treatment courses.
	  ○ Federal government will provide MDH 754,675 treatment courses
	  ○ MDH has purchased 312,000 government subsidized courses.[63]	

[58] Unless otherwise stated, the sources for the information in this table are the members of the antivirals work group, who agreed on reasonable assumptions for purposes of this project based on their expertise and experience. The work group met in 2007 and was not reconvened to consider its assumptions in light of the 2009 H1N1 pandemic.
[59] An emergency use authorization was approved allowing use of Oseltamivir in infants ≤ 1 year of age during the 2009 H1N1 pandemic.
[60] While early administration of treatment antivirals offers maximum benefit, this assumption may need to be adjusted in light of longer periods of viral replication (see WHO, *Clinical Management,* 2007).
[61] Assistant Secretary of Defense. *Health Affairs Policy for Release of Department of Defense Antiviral Stockpile during an Influenza Pandemic*. United States Department of Defense. 2007. Available at: http://fhp.osd.mil/aiWatchboard/pdf/131346-Policy_for_Release_and_Use_of_DoD_Antiviral_Stockpile_During_an_Influenza_Pandemic.pdf. HA Policy 07-015.
[62] WHO, *Clinical Management,* 2007; Beigel JH, Farrar J, Han AM, Hayden FG, Hyer R, de Jong MD, et al. (2005). Avian influenza A (H5N1) infection in humans. *N Engl J Med* 353(13):1374-1385.
[63] Larson M. Personal communication. September 2009; See also Flu.gov. "Antivirals – state allocations." 2009. Available at: http://pandemicflu.gov/professional/states/antivirals.html.

Table 7: Antiviral Assumptions *(cont.)*

<table>
<tr><td>Anticipated supply</td><td colspan="2">

At least 45,000 courses are in private stockpiles; exact size of private supply in MN is unknown.

Assuming supply is reserved for treatment, there are enough antivirals stockpiled to treat approximately 21% of Minnesotans. If the dosage or duration is doubled, approximately 10% of Minnesotans will have a course of treatment antivirals.[64]
If bulk of supply is reserved for treatment, expect to be able to treat all in Minnesota with flu-like symptoms in wave 1, most in wave 2 and few in wave 3 unless able to secure additional antiviral courses during the pandemic.
Approximately 50,000 standard doses (5% of stockpiled supply) will be needed to treat ill key workers. Approximately 95% of the supply is expected to be available to treat ill members of the general public.
As many as 80 million regimens of oseltamivir can be produced in the US per year.[65]

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<tr><td>Anticipated demand</td><td colspan="2">

1,117,000 (75%) of Minnesotans with flu-like symptoms (23% of the population) are anticipated to seek antivirals during a severe 2 year pandemic.
Requests for PEP antivirals are potentially numerous.
While community mitigation measures are likely to reduce the attack rate, any related reduction in demand for antivirals is anticipated to be offset by people with influenza-like illnesses due to simultaneous circulation of other infectious agents.
The availability of vaccines will reduce the demand for antivirals in the latter half of the pandemic.

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<tr><td>Composition of supply</td><td>Approximately 20% of MN stockpile</td><td>Approximately 80% of MN stockpile</td></tr>
<tr><td>Effectiveness</td><td colspan="2">

Effectiveness is assumed to be comparable to seasonal influenza.[66]
Can treat and prevent both influenza A and B viruses.
Treatment effectiveness may be reduced if virus is particularly virulent or patients have high viral loads.
Treatment is most effective when begun soon after symptoms appear. Similarly, preventive doses are most effective when begun soon after exposure.
Treatment effectiveness for pandemic influenza is unknown, but assume antivirals will:

Shorten illness by 1-2 days
Shorten period of infectiousness by 1-2 days[67]
Reduce symptoms and complications, for example: duration of fever, need for antibiotics, hospitalization, ventilators to treat lower respiratory complications and death.[68]

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</table>

[64] The federal government recommends that states have sufficient antivirals to treat 25% of their populations (see DHHS. HHS Pandemic Influenza Plan, 2005; Gani R, Hughes H, Fleming D, Griffin T, Medlock J, Leach S (2005). Potential impact of antiviral drug use during influenza pandemic. *Emerg Infect Dis* 11(9):1355-1362). More recent antiviral guidance suggests that governments, health care organizations and other employers consider whether to stockpile antivirals for prophylactic purposes (see DHHS. *Guidance on Antiviral Drug Use during an Influenza Pandemic*. 2008. Barriers exist to Minnesota significantly expanding its stockpile (see Koonin LM, Schwartz B. Antiviral stockpiling: Stakeholder's perspectives, findings and analysis. IOM Committee on Implementation of Antiviral Medication Strategies for an Influenza Pandemic: Washington DC. 2008. Available at: http://www.iom.edu/~/media/Files/Activity%20Files/Disease/FluAntiviralStrat/Koonin.ashx; Hearne SA, Segal LM, Earls MJ, Juliano C, Stephens T, Trust for America's Health. *Ready or Not? Protecting the Public's Health From Diseases, Disasters, and Bioterrorism*. 2005. Available at: http://healthyamericans.org/reports/bioterror05/bioterror05Report.pdf; US Government Accounting Office. *Influenza Pandemic: Efforts Underway to Address Constraints on using Antivirals and Vaccines to Forestall a Pandemic*. 2007. Available at: http://www.gao.gov/new.items/d0892.pdf).

[65] This estimate was reported by the US Interagency Working Group after the antiviral work group completed its meetings (see US Interagency Working Group. *Proposed Guidance on Antiviral Drug Use During an Influenza Pandemic*. 2008. Available at: http://aspe.hhs.gov/panflu/antiviraluse.pdf).

[66] Hota S, McGeer A (2007). Antivirals and the control of influenza outbreaks. *Clin Infect Dis* 45(10):1362-1368.

[67] American Academy of Pediatrics Committee on Infectious Diseases (2007). Antiviral therapy and prophylaxis for influenza in children. *Pediatrics* 119(4):852-860.

Table 7: Antiviral Assumptions *(cont.)*

	• Potential to control spread increases if used for directed short-term prevention.[69] • Unknown whether antivirals can prevent or control immune system over-response.	
Resistance	• No significant systematic absorption. • No evidence of resistance to H5N1.	• Long-term use of low doses increases likelihood of resistance. • Evidence of resistance in animal studies of several types of H5N1. • Resistance in human cases of H1N1 and H5N1 may be increasing.
Safety	Not recommended for those with underlying respiratory disease, such as asthma, chronic obstructive pulmonary disease, or those who cannot reliably use inhaler.	• Neuropsychological warning, particularly for children. • Gastrointestinal disturbance in < 10% of patients. • Difficult for people too sick to take pill or otherwise unable to accept medication by mouth. • Concurrent use of oseltamivir and intranasal live attenuated influenza vaccine (LAIV) has not been evaluated.[70]
Possession and control of supply	• Stockpiles of antivirals are purchased, held and distributed by the federal government, the state, hospitals, clinics and private businesses. • MDH has control over state stockpile (except as limited by contract), but not over private stockpiles. • MDH contractually binds others who purchase antivirals with a government subsidy to follow direction about use of stockpiled antivirals.	

10.2. General recommendations for rationing antivirals

1. Attend to the section above on General Recommendations (Section 8) and apply them as appropriate to the planning for rationing different uses of antivirals.
2. Allocate most of supply for treatment; allocate only small portions for post-exposure prophylaxis (PEP) and outbreak prophylaxis.
3. Do not hold portions of the supply of treatment antivirals in reserve to treat people in future waves.
4. If safety and effectiveness of PEP is established in immune-compromised people, reserve a small supply of antivirals for PEP in groups at high risk of death that lack alternative protections (such as elderly people during flu outbreak in a long-term care facility, young infants and immune-compromised people in hospitals, prisons and homeless shelters)..
5. Refrain from rationing antivirals based on such considerations as race, gender, citizenship, quality of life judgments or first-come, first-served.
6. De-prioritize people with immunity or medical contraindications (e.g., unable to take medication or have unacceptable side-effects) to receive antivirals.
    a. To the extent it is feasible, reliably and rapidly identify individuals who are immune so antivirals can be redirected to those who lack immunity.
    b. To the extent it is feasible, reliably and rapidly diagnose individuals with flu so antivirals are not unnecessarily used to treat other illnesses with similar symptoms or used prophylactically after exposure to a flu-like illness that is not actually flu.
7. Dispense and dose with attention to reducing the chances of inducing resistance.

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[68] Ibid.; Gani, 2005; McGeer A, Green KA, Plevneshi A, Shigayeva A, Siddiqi N, Raboud J, Low DE (2007). Antiviral therapy and outcomes of influenza requiring hospitalization in Ontario, Canada. *Clin Infect Dis* 45(12):1568-1575.
[69] Lee VJ, Phua KH, Chen MI, Chow A, Ma S, Goh KT, Leo YS. (2006). Economics of neuraminidase inhibitor stockpiling for pandemic influenza, Singapore. *Emerg Infect Dis* 12(1):95-102. Available at: http://www.cdc.gov/ncidod/EID/vol12no01/05-0556.htm; Hota, 2007.
[70] Roche Laboratories Inc. "Tamiflu: Dosing, administration and storage." Available at: http://www.tamiflu.com/hcp/dosing/default.aspx.

8. Develop broadly accessible information about the importance of prompt access to antiviral treatment and PEP antivirals and their effective use.
9. Develop appropriate infrastructures for prescribing and dispensing antivirals in a timely fashion to those with cultural, communication, mobility, economic and geographic barriers.
10. Ensure adequate availability of pediatric doses and formulations.
11. Work with the federal government to loosen restrictions on the use of stockpiled antivirals and extend their shelf-life.[71]
12. As important as it is to ration access to treatment antivirals wisely, fairly and consistently, it is important to treat the dying compassionately. The ethical importance of providing palliative and hospice care to dying patients who do not receive antivirals or other treatments cannot be overstated.[72]

Antivirals, unlike the other resources discussed in this report, have multiple uses. They can be used for long-term prophylaxis, post-exposure prophylaxis and treatment. Each of these uses requires separate strategies. Table 8 comprises the ethical commitments and objectives common to rationing antivirals for any purpose. Table 9 contains the strategies for rationing treatment antivirals. Table 10 presents the strategies for prophylaxis (both long-term and post-exposure).

Table 8: Ethical Framework for Rationing Antivirals: Parts I and II

I. Ethical commitments for pandemic planning and response Pursue Minnesotans' common good in ways that: • Are accountable, transparent and worthy of trust; • Promote solidarity and mutual responsibility; • Respond to needs fairly, effectively and efficiently.

II. Ethical objectives for rationing antivirals in a severe pandemic
Steward scarce resources to promote Minnesotans' common good by balancing three equally important and overlapping ethical objectives.
• Protect the population's health by:
  ○ Reducing mortality and serious morbidity from influenza and its complications;
  ○ Reducing mortality and serious morbidity from disruption to basic health care, public health, public safety and other critical infrastructures.
• Protect public safety and civil order by:
  ○ Reducing disruption to basic health care, public health, public safety and other critical infrastructures;
  ○ Promoting public understanding about and confidence in resource distribution.
• Strive for fairness and protect against systematic unfairness by:
  ○ Reducing significant group differences in mortality and serious morbidity;
  ○ Making reasonable efforts to remove barriers to access;
  ○ Making reasonable efforts to reciprocate to groups accepting high risk in the service of others;
  ○ Rejecting strategies that are discriminatory or exacerbate health disparities;
  ○ Using fair random processes for those similarly prioritized.

10.3. Antiviral treatment strategies

Table 9 presents the recommended strategies for rationing antivirals for treatment. These strategies follow the ethical commitments and objectives stated in Table 8.

[71] European Medicines Agency (2009). CHMP Assessment Report on Novel Influenza (H1N1) outbreak, Tamiflu (oseltamivir), Relenza (zanamivir). EMEA/H/A-5.3/1172.
[72] See Section 3.1 in this report.

Table 9: Ethical Framework for Rationing Antivirals: Part III[73]

III. Strategies for rationing treatment antivirals to the sick

- Attend to the general recommendations for rationing antivirals above (Section 10.2).
- De-prioritize people:
  - presenting with influenza-like illness too late for antivirals to be effective (such as >X hours after symptoms appeared);[74]
  - known to be imminently and irreversibly dying (for example, have an obvious co-morbidity incompatible with life beyond a short timeframe) unless the antivirals serve a unique palliative function; or
  - having satisfactory alternative treatment (should such a treatment become available).
- When there is a shortage of treatment antivirals, ration them for key workers (track A) and the general population (track B) as outlined below. When the shortage is severe, focus on the treatment priorities in tier 1; when the shortage is less, expand the treatment priorities as follows.

Supply	Treatment Priorities	Track A – Ill Key Workers[75]	Track B – Ill in General Population
Extreme shortage	**Tier 1**	Key workers at *high* risk of flu-related mortality/morbidity.	Groups, if any, at *disproportionately high* risk of flu-related mortality/morbidity[76] (for example, pregnant women[77]).
	Tier 2	• Key workers at *high* occupational exposure;[78] or • Irreplaceable key workers.[79]	Groups at *high* risk of flu-related mortality/morbidity;
Adequate supply	**Tier 3**	Key workers.	Groups at *moderate* risk of flu-related mortality/morbidity.
	Tier 4	All eligible patients.	

When the supply is inadequate to serve all similarly prioritized ill people use a fair random process to distribute treatment antivirals, with the following caveat. In track B if demand *within a single tier* vastly exceeds supply, before resorting to randomization and if it is feasible to do so:

1. Consider prioritizing children under 18. If the supply is inadequate to treat all children, randomize among children.
2. If the supply is sufficient to reach all children and a significant number of adults (though far less than everyone in the tier), rather than randomizing among adults consider prioritizing younger adults simultaneously with children. Raise the age limit to treat the largest group possible given the supply (such as age 50 and younger). As supply expands, prioritize all remaining age groups in the tier before moving to the next tier.

[73] Section 9 above in this report offers guidance about adjusting the frameworks to fit an actual pandemic, when to move from one tier to the next, whether to collapse tiers, etc.
[74] Should a rapid, accurate and inexpensive test become available for pandemic influenza, adjust the eligibility criteria to "present with pandemic flu symptoms $\leq$ X hours."
[75] "Key workers" are those (including volunteers) whose functions are critical to limiting flu-related deaths and deaths due to degradation of the health care, public health, and public safety and other critical infrastructures. (See NIAC, 2007 and Section 6 of this report).
[76] "Disproportionately high risk of flu-related mortality/morbidity" refers to groups with a case fatality rate that dramatically exceeds the peaks of an age-specific mortality curve for the flu.
[77] WHO, *Clinical Management*, 2007.
[78] "High occupational exposure" refers to workers whose jobs require sustained or routine direct physical contact with influenza patients.
[79] "Irreplaceable key workers" are a subset of key workers whose expertise and/or experience is limited to a very small number of persons and for whom replacements cannot be adequately trained during or shortly after a pandemic, e.g., air traffic controllers.

10.4. Antiviral prophylaxis strategies

The strategies in Table 10 for rationing antivirals for prophylaxis follow the ethical commitments and objectives stated in Table 8.

Table 10: Ethical Framework for Rationing Antivirals: Parts IV – VI[80]

IV. Strategies for rationing antivirals for *long-term prophylaxis* during an entire pandemic wave
• Attend to the general recommendations for rationing antivirals above (Section 10.2).
• The supply of antivirals for outbreak prophylaxis is extremely limited and is to be rationed only to a small group of eligible key workers[81] and not within the general population.
• Eligible key workers:
  ○ have *disproportionately high* occupational exposure to flu (for example, routinely participate in intubations of flu patients); and
  ○ lack satisfactory alternative protections.
• If the supply of these antivirals unexpectedly becomes more adequate, expand eligibility criteria to include other key workers with *high* occupational exposure to flu.

V. Strategies for rationing antivirals for *post-exposure prophylaxis* (PEP)
• Attend to the general recommendations for rationing antivirals (Section 10.2).
• De-prioritize people
  ○ exposed too long ago for PEP to be effective (such as >X hours after exposure);
  ○ known to be imminently and irreversibly dying (for example, have an obvious co-morbidity incompatible with life beyond a short timeframe); or
  ○ with satisfactory alternative protection.
• Consider capping the number of PEP courses per person (except for irreplaceable key workers), depending on anticipated demand and on PEP supplies and effectiveness.
• When there is a shortage of PEP antivirals, ration them for key workers and the general population as outlined below. When the shortage is severe, focus on tier 1; when the shortage is less, include additional tiers as follows.

[Table 10 continued on next page]

[80] Section 9 above in this report offers guidance about adjusting the frameworks to fit an actual pandemic, when to move from one tier to the next, whether to collapse tiers, etc.

[81] "Key workers" are those (including volunteers) whose functions are critical to limiting flu-related deaths and deaths due to degradation of the health care, public health, and public safety and other critical infrastructures. (See NIAC, 2007 and Section 6 of this report).

Table 10: Ethical Framework for Rationing Antivirals: Parts IV - VI *(cont.)*

VI. Strategies for rationing antivirals for *post-exposure prophylaxis* (PEP) *(cont.)*			
Supply	**PEP Priorities**	**Track A – Exposed Key Workers[82]**	**Track B – Exposed in General Population**
Extreme shortage	**Tier 1**	Exposed key workers • at disproportionately *high* occupational exposure;[83] or • at *high* risk of flu-related mortality/morbidity.	• People exposed to contained disease clusters; or • Exposed people at *disproportionately high* risk of flu-related mortality/morbidity.[84]
	Tier 2	Exposed key workers that • are irreplaceable;[85] or • have *high* occupational exposure.[86]	Exposed people who are both • at *high* risk of flu-related mortality/morbidity; and • at risk of transmitting to people at *high* risk of flu-related mortality/morbidity lacking alternative protections, such as young infants.
Adequate supply	If the supply of prophylactic antivirals unexpectedly becomes more adequate, consider raising the cap on the number of PEP courses per person in tiers 1 and 2 and/or expanding the PEP priorities as follows.		
	Tier 3	Exposed key workers at risk of transmitting to people at *high* risk of flu-related mortality/morbidity lacking alternative protections, such as young infants.	Exposed people at *high* risk of flu-related mortality/morbidity.
	Tier 4	Exposed key workers.	Exposed people who are both • at *moderate* risk of flu-related mortality/morbidity; and • at risk of transmitting to people at *high* risk of flu-related mortality/morbidity lacking alternative protections, such as young infants.
	Tier 5	All eligible people.	

[82] "Key workers" are those (including volunteers) whose functions are critical to limiting flu-related deaths and deaths due to degradation of the health care, public health, and public safety and other critical infrastructures. (See NIAC, 2007 and Section 6 of this report).
[83] "Disproportionately high occupational exposure" refers to workers who participate in aerosol-generating procedures with influenza patients such as intubations.
[84] "Disproportionately high risk of flu-related mortality/morbidity" refers to groups with a case fatality rate that dramatically exceeds the peaks of an age-specific mortality curve for the flu.
[85] "Irreplaceable key workers" are a subset of key workers whose expertise and/or experience is limited to a very small number of persons and for whom replacements cannot be adequately trained during or shortly after a pandemic, e.g., air traffic controllers.
[86] "High occupational exposure" refers to workers whose jobs required sustained or routine direct physical contact with influenza patients.

10.5. Discussion: Rationing antivirals

10.5.1. Antivirals as a public health good

Antiviral drugs are a public health good with significant potential to mitigate the effects of a pandemic. If effective against the circulating strain of influenza virus, they are anticipated to reduce deaths and the severity and duration of influenza-related illness and serious complications. They are therefore also expected to reduce the strain on health care services, particularly hospitals and critical care resources. Antivirals may reduce the viral loads in people ill with the flu, reduce the period of time people are infectious and hence also may limit the spread of the disease. Another important role for antivirals is to prevent people from becoming ill, for example, those who have had a recent exposure to influenza, or key workers who are at disproportionately high risk of flu-related mortality/morbidity or occupational exposure to flu. PEP is one preventive strategy (e.g., a course of 10 doses); long-term or outbreak prophylaxis (for example, for the duration of a community outbreak or for the entire pandemic) is a second preventive strategy.

The antivirals stockpile might be sufficient to treat all eligible patients during the first wave, assuming that standard dosages and duration of treatment are effective and that none of the supply is used for prophylactic purposes. The need to ration treatment antivirals is more likely during the second and third waves. The supply of antivirals for PEP and long-term prophylaxis will be very scarce, so rationing is likely to begin with the first outbreak in the state.

10.5.2. Special features

Antivirals are a flexible resource in that they can be used both to treat and prevent illness. Most pandemic guidance, however, recommends that antivirals be used primarily for treatment, with a small supply reserved for prophylactic purposes to limit isolated outbreaks.[87]

Antivirals are also unusual in that of all the resources the panel considered, antivirals promise benefit to the broadest range of demographic groups (though data on use in young infants are limited). The panel assumed that efficacy will be comparable across groups, with one important caveat, namely, that treatment and PEP antivirals should be dispensed and used soon after onset of symptoms or unprotected exposure to the flu. This narrow window of therapeutic opportunity signals the importance of removing access barriers to both treatment and PEP antivirals. Fair access requires appropriate educational measures and infrastructures for prescribing and dispensing this prescription drug in a timely fashion to those with cultural, communication, mobility, economic and geographic barriers.

Particular antivirals are available in different formulations and are safe and effective in different populations. Some can be taken orally in pill or liquid form or by feeding tube, others orally inhaled. In 2009 an emergency use authorization was approved for intravenous delivery of a new antiviral, Peramivir.

A final respect in which antivirals differ from other resources is the high likelihood that they will be used in an ineffectual or even harmful way. Improper use of antivirals (e.g., starting but not completing a treatment course or splitting a course with others) not only will not benefit those taking the medication but will increase the likelihood of a resistant virus taking hold in the population. Improper use may be more common among patients in the community than in hospital given differences in professional supervision. Patients will need clear instructions in a form that they can easily access and comprehend on the proper use of antivirals.

10.5.3. How these recommendations fit with federal guidance

The federal government released for public comment guidance for the use of antivirals during the first wave of a severe pandemic.[88] The final guidance, issued in December 2008, likewise focused on wave one, when prioritization is unnecessary as states are anticipated to have sufficient supplies of antivirals to

[87] Prehn, 2008.
[88] US Interagency Working Group. *Proposed Guidance,* 2008; Gervais KG, Vawter DE, Garrett JE, Prehn AW. Pandemic Influenza Antiviral Comments. [letter to U.S. Department of Health and Human Services] July 3, 2008.

treat everyone with influenza-like illness.[89] With increased opportunities to stockpile antivirals, the federal government recommends that whenever the supplies exceed the amount needed for treatment, a portion be allocated to protect health care workers at high and moderate risk of exposure to the flu. The guidance notes that should treatment antivirals become scarce later in the pandemic, prioritizing access is ill-advised on grounds of feasibility and fairness. Treatment antivirals then would be rationed first-come, first-served to those who can benefit from them. As an aside, it is interesting to note that this federal antiviral guidance differs from the federal guidance on vaccines in a pandemic, which, like the panel's recommendations, are scalable to different levels of scarcity, attend to multiple ethical objectives and prioritize some groups before others.[90]

When MDH originated this project with a request for proposals in late 2006, federal pandemic planning expressly called for states to develop rationing plans for resources like antivirals.[91] MDH, as the sponsor of this work, directed that project participants be informed by federal guidance but not be limited by it, because federal guidance was still evolving. In its 2009 annual update, the US Department of Health and Human Services reiterated that though it has offered guidance, some allocation decisions are best made locally and it supports communities developing local plans.[92]

10.5.4. Remaining questions

There are important questions beyond the scope of this project. What proportion of the supply can and should be allocated for outbreak prophylaxis and PEP? Should antivirals be reserved for treating people suspected of having contracted pandemic influenza or should a portion remain available to treat other conditions? How much should Minnesota invest in stockpiling antivirals for a pandemic (the timing and severity of which are impossible to predict) at the expense of spending for other worthy health or societal needs?

The unknowns are daunting. For example, how likely is it that the stockpiled antivirals will be effective? What is the likelihood that the virus will become resistant? How often will Minnesota need to discard and replace its stockpile given the drug's limited shelf-life and federal prohibitions against rotating stockpiled drugs? Will the federal government relax restrictions on antiviral use and shelf-life? How will demand for treatment antivirals be affected by other preventive measures? How frequently will non-pandemic influenza-like illnesses circulate in the population and increase demand for antivirals? What are the opportunities to restock antivirals during a pandemic? And what other policy objectives are competing for financial support?

The relationship between receiving treatment antivirals and access to other scarce preventive health-related resources remains unsettled. For instance, if someone receives antivirals shortly after the appearance of symptoms of influenza-like illness and that illness was not pandemic influenza, what priority should this person have to receive N95s, vaccine or PEP later? The answer depends on many factors, including the supply and demand for these additional resources. The answer also depends on whether the person is a key worker and, if so, on judgments about the importance of the worker's function to the common good, the extent of society's obligations of reciprocity toward this key worker, the likelihood that the worker has become naturally immune, the worker's risk of flu-related mortality, and how likely it is that the use of antivirals increases indirect protection for people who cannot be directly protected. The infrastructure to track who has received which resources might be adequate in the workplace, but is less likely to be feasible among members of the general population.

Numerous implementation strategies and challenges are explored in a report by the Institute of Medicine.[93]

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[89] DHHS. *Guidance on Antiviral Drug Use*. 2008.
[90] DHHS and Department of Homeland Security. *Guidance on Allocating and Targeting Pandemic Influenza Vaccine*. 2008. Available at: http://www.flu.gov/individualfamily/vaccination/allocationguidance.pdf.
[91] DHHS. *HHS Pandemic Influenza Plan*, 2005.
[92] DHHS. *Pandemic Planning Update VI,* 2009.
[93] Institute of Medicine Committee on Implementation of Antiviral Medication Strategies for an Influenza Pandemic *Antivirals for Pandemic Influenza: Guidance on Developing a Distribution and Dispensing Program*. Washington, DC: National Academies Press. 2008. Available at: http://www.nap.edu/catalog.php?record_id=12170.

10.5.5. Ethical frameworks for antivirals

The recommended strategies combine clinical, population health and non-clinical fairness considerations consistent with balancing the frameworks' objectives and corresponding goals. In addition to identifying morally relevant considerations for prioritizing some groups before others under different conditions of scarcity, the strategies include considerations for de-prioritizing groups under conditions of elevated scarcity.

With respect to the goal of assuring equitable access to those who are similarly prioritized, the panel recommends against distributing first-come, first-served. Instead, remove barriers to fair access. Use a fair random procedure or consider first applying non-clinical age-based fairness criteria.

10.5.5.1. Rationing antivirals for treatment

Based on assumptions about the supply of and demand for treatment antivirals, the panel anticipates that during the first several months of the pandemic there could be ample supply. However, large fluctuations in the supply are possible, and it is necessary to plan accordingly.

10.5.5.1.1. Criteria for prioritization

A small portion of the supply of antivirals will be needed to treat ill key workers. Key workers are estimated to be approximately 5% of Minnesotans and even fewer are anticipated to develop flu-like symptoms.

When the treatment supply is adequate, patients should have access to treatment antivirals per tier 4. When the anticipated demand begins to exceed the supply, state and local leaders may recommend that treatment antivirals be rationed in accord with tiers 3, 2 or 1, depending on supply. As the supply of antivirals allows, include as many tiers of prioritized groups as possible on a cumulative basis, such that rationing at tier 3, for instance, includes everyone in tiers 1 and 2 as well. When rationing in accord with tier 3, the supply of antivirals is sufficient to treat all key workers ill with influenza and all in the general population who are at least at moderate risk of flu-related mortality.

For periods of extreme shortages in the overall supply, tier 1 prioritizes the subset of ill key workers that are at high risk of influenza-related mortality and groups in the general population that are at disproportionately high risk of influenza-related mortality. Based on experience with previous pandemics it is reasonable to assume that pandemic influenza can cause case-fatality rates for some groups that are significantly higher than the rates of other high risk groups. For example, it may become evident during a pandemic that a particular demographic group or group with compounded social vulnerabilities may prove to be at exceptionally high risk of death. Pregnant women who contracted influenza, especially those late in their pregnancies, were at disproportionately high risk of dying compared with other high risk groups during the 1918-19 pandemic.[94]

When the supply is extremely scarce but can accommodate more people than prioritized in tier 1, the framework recommends that the groups at second highest priority be added to those in tier 1. Tier 2 prioritizes in track A two groups of key workers (1) those who had high occupational exposure to influenza and (2) those few who are irreplaceable during or shortly after a pandemic because their expertise and/or experience is highly specialized and it is unrealistic under the circumstances that replacements can be trained. At the same time in track B, tier 2 prioritizes those in the general population who are at high risk of influenza-related mortality/morbidity.

10.5.5.1.2. Prioritization within tiers

When the supply is inadequate to serve all ill people within the same track and tier, use a fair random process to distribute treatment antivirals, with the following caveat. In track B if demand *within a single tier* vastly exceeds supply, before resorting to randomization and if it is feasible to do so:

[94] Knobler, 2005.

1. Consider prioritizing children under 18. If supply is inadequate to treat all children, randomize among children.
2. If the supply is sufficient to reach all children and a significant number of adults (though far less than everyone in the tier), rather than randomizing among adults consider prioritizing younger adults simultaneously with children. Raise the age limit to treat the largest group possible given the supply (such as age 50 and younger). As supply expands, prioritize all remaining ages in the tier before moving to the next tier.

This prioritization of children and younger adults before older can be justified as a matter of fairness, because it prioritizes younger people who have not had as much chance at life as older people. It also acknowledges adults' obligations to protect children. See the discussion in Section 14.1.2.3 for more on age-based rationing.

10.5.5.2. Rationing antivirals for long-term prophylaxis

Outbreak antivirals are unusual in that they are one of the few health-related resources that are not available to the general population. A small (but as yet undefined) portion of the antivirals supply should be allocated for outbreak prophylaxis to protect a single group of key workers, that is, critical care workers who routinely intubate or aspirate influenza patients and are thus at disproportionately high risk of occupational exposure.

10.5.5.3. Rationing antivirals for post-exposure prophylaxis (PEP)

Another small portion of the antiviral supply should be allocated for PEP. The PEP antiviral supply is anticipated to be so small that it may be reasonable to impose caps on the number of courses of PEP antivirals any person can expect. Irreplaceable key workers are one exception; they should receive PEP as many times as necessary.

The list of population health and fairness considerations relevant for prioritizing groups to receive PEP expands the set of considerations for prioritizing groups for treatment antivirals:

- risk of exposure;
- risk of influenza-related mortality and serious morbidity;
- key role in supporting basic health care, public health, public safety or other critical functions; and
- risk of transmitting influenza to people at high risk of flu-related mortality.

Tier 1, track A includes key workers with disproportionately high occupational exposure (unless they have access to long-term prophylactic antivirals) and exposed key workers who are at high risk of flu-related mortality/morbidity. The only people in track B (general population) who are prioritized in this first tier are those who are exposed to contained disease clusters or who have been exposed to flu and also are at a disproportionately high risk of flu-related mortality/morbidity.

Tier 2 extends PEP to irreplaceable key workers and to key workers with high occupational exposure. Simultaneously, tier 2 extends PEP to those in the general population who are both at high risk of flu-related mortality/morbidity and at risk of transmitting flu to people at high risk of flu-related mortality/morbidity who lack alternative protections (e.g., people caring for infants).

It is highly unlikely that the supplies of antivirals will be sufficient to provide PEP to people in tiers 3, 4 or 5. Should the supply be sufficient to include some but not all in the general population, then some age-based rationing could be considered prior to randomly selecting who in tier 3 track B receives PEP antivirals. See the discussion above on age-based rationing of treatment antivirals and in Section 14.1.2.3.

11. Ethical Frameworks for Rationing N95s and Masks

11.1. Assumptions about N95s and masks[95]

11.1.1. Use

1. N95s and surgical masks approved by the National Institute for Occupational Safety and Health (NIOSH) can reduce and slow transmission of influenza.[96]
2. NIOSH-approved N95s are worn by healthy people to *limit the wearers' exposure* to droplet and airborne virus (among other types of biohazards).[97] In a severe pandemic N95s may also be valued for the protection they can offer others from exposure to the wearers` droplets and airborne particulates.
3. Surgical masks limit droplet transmission from coughs and sneezes.[98] Customarily they are used by healthy (or pre-symptomatic) people to *protect others* from unexpected coughs and sneezes, and by people presumed to be infectious in order to protect those around them. They may also be worn by key workers when serving people with suspected or confirmed cases of influenza in order to protect the wearers.
4. N95s are filtering face pieces. These models are often disposable, designed for single-use and easily contaminated. Most guidelines recommend that filtering face piece respirators (such as "N95s") and surgical masks be changed when they become contaminated, difficult to breathe through, or damaged, whichever comes first.[99]
5. Although very little is known about the potential to disinfect and reuse either surgical masks or disposable N95s, it is reasonable to assume that in times of severe shortage reuse will occur whenever it is possible and safe to do so. The Institute of Medicine and Occupational Safety and Health Administration (OSHA) have issued reports on reusability of masks and N95s.[100] Reuse may increase the potential for contamination, and this risk needs to be weighed against the risk of exposure without a facemask.
6. N95s and masks can be stored long-term under dry conditions within reasonable temperature range.[101] Consultation with the manufacturer is recommended for specifics on long-term storage.

[95] Unless otherwise stated, the sources for the assumptions are the members of the N95 respirators/surgical masks work group, who agreed on reasonable assumptions for purposes of this project based on their expertise and experience. The work group met in 2007 and was not re-convened to consider debates about relative efficacy between N95s and surgical masks that occurred in late 2009.

[96] CDC. *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/professional/hospital/maskguidancehc.html; CDC. *Interim Public Health Guidance for the Use of Facemasks and Respirators in Non-occupational Community Settings during an Influenza Pandemic*. 2007. Available at: http://pandemicflu.gov/professional/community/maskguidancecommunity.html ; Jefferson T, Foxlee R, Del Mar C, Dooley L, Ferroni E, Hewak B, et al. (2007). Interventions for the interruption or reduction of the spread of respiratory viruses. *Cochrane Database Syst Rev* (4):CD006207; MacIntyre CR, Cauchemez S, Dwyer DE, Seale H, Cheung P, Brown G, et al. (2009). Face mask use and control of respiratory virus transmission in households. *Emerg Infect Dis* 15(2):233-241. Available at: http://www.cdc.gov/EID/content/15/2/233.htm.

[97] CDC. *Infection Control in a Healthcare Setting.* 2009; CDC, *Recommendations for Facemask and Respirator Use to Reduce Transmission*. 2009; CDC, *Use of Surgical Masks and Respirators in Health Care Settings,* 2006; CDC, *Use of Facemasks and Respirators in Non-occupational Community Settings,* 2007; Balazy A, Toivola M, Adhikari A, Sivasubramani SK, Reponen T, Grinshpun SA (2006). Do N95 respirators provide 95% protection level against airborne viruses, and how adequate are surgical masks? *Am J Infect Control* 34(2):51-57.

[98] Ibid.

[99] Institute of Medicine. *Reusability of Facemasks during an Influenza Pandemic: Facing the Flu*. 2006. Available at: http://www.iom.edu/CMS/3740/32033/34200.aspx.

[100] Ibid.; Occupational Safety and Health Administration. *Pandemic Influenza Preparedness and Response Guidance for Healthcare Workers and Healthcare Employers*. (2007) Available at: http://www.osha.gov/Publications/3328-05-2007-English.html

[101] Weiss MM, Weiss PD, Weiss DE, Weiss JB (2007). Disrupting the transmission of influenza A: Face masks and ultraviolet light as control measures. *Am J Public Health* 97(Suppl 1):S32-37.

11.1.2. Safety

1. N95s and masks are safe for the vast majority of the population.[102]
2. N95s and masks may be unsafe for those with cardiac or respiratory problems (either chronic or acute).
3. N95s have not been designed or proven safe for young children. Masks may also be unsafe for young children, for instance when children are unable to remove the masks if they are having respiratory difficulty.

11.1.3. Efficacy

1. Limited knowledge about how influenza virus is transmitted makes the efficacy of both N95s and masks unclear. However, most experts agree that use in a pandemic is probably better than no protection at all.[103]
2. A properly used N95 can reduce exposure.[104] Since the infectious dose of a pandemic influenza virus is unknown, it is uncertain whether this reduction in exposure is sufficient to prevent infection. N95s conferred protection (along with hand hygiene) during the SARS outbreak.[105] N95s are assumed to provide wearers some protection against airborne particulates and droplets.
3. N95s perform best when properly fitted, which requires fit-test kits, training and a clean-shaven face.[106] There is some research suggesting that non-fit tested N95s afford some protection.[107]
4. Neither N95s nor masks protect against contact transmission. They must be used with other infection control measures in order to be maximally effective (e.g., hand hygiene).[108]
5. N95s are uncomfortable, they must be removed for eating and drinking, and no models are made for young children. Compliance and proper use will be a challenge.[109]
6. Masks provide some protection from liquid splashes and droplets. Masks do not form a seal with the face and therefore are assumed to be less effective at protecting wearers against airborne particulates.
7. Although N95s have not been evaluated for this purpose, it is plausible that they may also protect others from unexpected coughs and sneezes by the wearer.
    - A valved or poorly fit N95 may be roughly as effective as a mask in protecting others, because exhaled air is directed out through the valve or around the edges of the N95.
    - A well-fitted, non-valved N95 may provide greater protection than either a poorly fit N95 or a surgical mask in protecting others, because exhaled air goes back through the filter.

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[102] CDC. *Use of Facemasks and Respirators in Non-occupational Community Settings,* 2007.
[103] Institute of Medicine, *Reusability of Facemasks*, 2006; Radonovich Jr LJ, Perl TM, Davey V, Cohen H (2009). *Disaster Med Public Health Prep.* 3(Suppl. 2):S203-10.
[104] Occupational Safety and Health Administration. *Regulations (Standards - 29 CFR) Respiratory Protection. - 1910.134.* Available at: http://osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=12716.
[105] Teleman MD, Boudville IC, Heng BH, Zhu D, Leo YS (2004). Factors associated with transmission of severe acute respiratory syndrome among health-care workers in Singapore. *Epidemiol Infect* 132(5):797-803; Lo JY, Tsang TH, Leung YH, Yeung EY, Wu T, Lim WW (2005). Respiratory infections during SARS outbreak, Hong Kong, 2003. *Emerg Infect Dis* 11(11):1738-1741.
[106] CDC. *Infection Control in a Healthcare Setting.* 2009; CDC, *Recommendations for Facemask and Respirator Use to Reduce Transmission*. 2009; CDC, *Use of Surgical Masks and Respirators in Health Care Settings*, 2006; Derrick JL, Gomersall CD (2005). Protecting healthcare staff from severe acute respiratory syndrome: Filtration capacity of multiple surgical masks. *J Hosp Infect* 59(4):365-368.
[107] Lawrence RB, Duling MG, Calvert CA, Coffey CC (2006). Comparison of performance of three different types of respiratory protection devices. *J Occup Environ Hyg* 3(9):465-474; Lee MC, Takaya S, Long R, Joffe AM (2008). Respirator-fit testing: Does it ensure the protection of healthcare workers against respirable particles carrying pathogens? *Infect Control Hosp Epidemiol* 29(12):1149-1156; Centers for Disease Control and Prevention (1998). Laboratory performance evaluation of N95 filtering facepiece respirators, 1996. *MMWR Morb Mortal Wkly Rep* 47(48):1045-1049.
[108] CDC. *Infection Control in a Healthcare Setting.* 2009; CDC, *Recommendations for Facemask and Respirator Use to Reduce Transmission*. 2009; CDC, *Use of Surgical Masks and Respirators in Health Care Settings*, 2006.
[109] Ibid.; Radonovich, 2009.

11.1.4. Supply and demand

1. If the virus is thought to transmit through aerosolized particles, protective gear such as N95s will likely be in great demand. If the virus is shown to be transmitted primarily through droplets, demand for masks will be high. Estimating the demand for N95s and masks for influenza-related uses is difficult, as some people will need them for a few days and others for many months. Proposed OSHA guidance suggests that an average of four "single use" respiratory protection devices (N95s or masks) per shift will be required for those workers at high risk of exposure (e.g., health care and emergency response workers).[110]
2. Supplies of N95s and masks are stockpiled in the Strategic National Stockpile and by health care providers, public health agencies and other public and private entities. The capacity to replenish supplies will be reduced during a severe pandemic.[111]
3. A portion of FDA-cleared N95s will be reserved for use in operating rooms, as they have additional fluid resistance.
4. European approved and other non FDA-approved respirators and masks may be available for purchase and use.
5. Supplies will be expanded by using reusable half-face piece respirators (with disposable filters) to the extent possible.
6. Private individuals may be encouraged to stockpile some N95s and surgical masks for their personal use in a disaster.[112]

11.2. General recommendations for rationing N95s and masks

1. Attend to the section above on General Recommendations (Section 8) and apply them as appropriate to planning for the rationing of different uses of N95s and masks.
2. Expand distribution mechanisms for surgical masks, as their availability is currently often limited to purchase by contracts between health care organizations and manufacturers.
3. Remove barriers to the manufacture of N95s and masks for children, for example, develop pressure drop specifications for pediatric N95s and surgical masks.
4. If re-use of disposable N95s and masks becomes necessary, collect data on re-used N95s' and masks' safety and efficacy and how best to disinfect them; provide adequate training about appropriate re-use.
5. Distribute masks for protection instead of or interchangeably with N95s whenever reasonable; for example, when droplets are the primary mode of transmission.
6. Refrain from rationing N95s and masks based on such considerations as race and gender, quality of life judgments or first-come, first-served.

[110] US Department of Labor. *Proposed Guidance on Workplace Stockpiling of Respirators and Facemasks for Pandemic Influenza*. 2008. Available at: http://www.osha.gov/dsg/guidance/proposedGuidanceStockpilingRespirator.pdf.
[111] Trust for America's Health, 2009.
[112] US Interagency Working Group. *Interim Guidance on the Use and Purchase of Facemasks and Respirators by Individuals and Families for Pandemic Influenza Preparedness.* 2008. Available at: http://aspe.hhs.gov/panflu/facemasks.pdf. Switzerland asks everyone to purchase 50 masks to have on hand for a 12 week wave. Swiss Federal Office of Public Health. *Swiss Influenza Pandemic Plan*. 2007. Available at: http://www.bag.admin.ch/influenza/01120/01134/03058/index.html?lang=en.

Table 11: Ethical Framework for Rationing N95s[113]

I. Ethical commitments for pandemic planning and response

Pursue Minnesotans' common good in ways that:

- Are accountable, transparent and worthy of trust;
- Promote solidarity and mutual responsibility;
- Respond to needs fairly, effectively and efficiently.

II. Ethical objectives for rationing N95s in a severe pandemic

Steward scarce resources to promote Minnesotans' common good by balancing three equally important and overlapping ethical objectives.

- Protect the population's health by:
  - Reducing mortality and serious morbidity from influenza and its complications;
  - Reducing mortality and serious morbidity from disruption to basic health care, public health, public safety and other critical infrastructures.
- Protect public safety and civil order by:
  - Reducing disruption to basic health care, public health, public safety and other critical infrastructures;
  - Promoting public understanding about and confidence in resource distribution.
- Strive for fairness and protect against systematic unfairness by:
  - Reducing significant group differences in mortality and serious morbidity;
  - Making reasonable efforts to remove barriers to access;
  - Making reasonable efforts to reciprocate to groups accepting high risk in the service of others;
  - Rejecting strategies that are discriminatory or exacerbate health disparities;
  - Using fair random processes for those similarly prioritized.

III. Strategies for rationing N95s to protect people at risk for contracting flu

- Attend to general recommendations for rationing N95s and masks (Section 11.2).
- The supply is anticipated to be extremely scarce, and most supplies should be allocated for use by key workers in track A.
- De-prioritize people:
  - with immunity (for example, have contracted and recovered from pandemic influenza or are successfully vaccinated against the pandemic virus);
  - with medical contraindications (for example, co-morbidities that hamper breathing or too young to safely wear N95s);
  - known to be imminently and irreversibly dying (for example, have an obvious co-morbidity incompatible with life beyond a short timeframe);
  - who refuse or are unable to comply with wearing instructions; or
  - who have alternative satisfactory protection.

When there is a shortage of N95s, give them to key workers and the general population in tier 1 as outlined below. When the supply is more adequate, retain a small supply (for example, a 2-week supply) for tiers 1 and 2 before moving to tier 3.

[Table 11 continued on next page]

[113] Section 9 above in this report offers guidance about adjusting the frameworks to fit an actual pandemic, when to move from one tier to the next, whether to collapse tiers, etc. This framework does not limit the use of N95s for non-influenza-related purposes, such as using them in a tuberculosis clinic.

Table 11: Ethical Framework for Rationing N95s *(cont.)*

<table>
<tr><th>Supply</th><th>N95 Priorities</th><th>Track A – Key Workers[114]</th><th>Track B – General Population</th></tr>
<tr><td rowspan="5">Extreme shortage

No shortage</td><td>Tier 1</td><td>Key workers at disproportionately high risk of occupational exposure[115] to flu.</td><td rowspan="2">• People exposed to contained disease clusters; or
• People at disproportionately high risk of flu-related mortality/morbidity[116] and at high risk of exposure (for example, pregnant women or immune-compromised people using public transportation or requiring treatment at a health care facility that treats flu patients).</td></tr>
<tr><td>Tier 2</td><td>Key workers
• at high risk of occupational exposure;[117] or
• who are irreplaceable.[118]</td></tr>
<tr><td colspan="3">Should the supply of N95s unexpectedly become more adequate, expand the priorities as follows, but retain a small supply (for example, a 2-week supply) for tiers 1 and 2 before distributing to tier 3.</td></tr>
<tr><td>Tier 3</td><td>Key workers who are both
• at risk of occupational exposure; and
• at high risk of flu-related mortality/morbidity.</td><td>People who are both
• at high risk of exposure; and
• at high risk of flu-related mortality/morbidity.</td></tr>
<tr><td>Tier 4</td><td colspan="2">All eligible people.</td></tr>
</table>

11.3. Discussion: Rationing N95s

N95s provide a seal around the face and a high level of filtration, so that the wearer is protected from droplets and most aerosolized particles. Their primary purpose during pandemic is to help protect the wearer from contracting disease. In addition to identifying morally relevant considerations for prioritizing some groups before others under different conditions of scarcity, the strategies include considerations for de-prioritizing groups under conditions of elevated scarcity.

11.3.1. De-prioritization criteria

Wise stewardship and fairness support de-prioritizing people with any of these characteristics:

- immunity (e.g., presumably have contracted and recovered from pandemic influenza or are successfully vaccinated against the pandemic virus);
- medical contraindications (e.g., people with co-morbidities that hamper breathing or who are too young to safely wear N95s);
- are known to be imminently and irreversibly dying (e.g., have an obvious co-morbidity incompatible with life beyond a short timeframe);
- refusal or inability to comply with wearing instructions; or
- alternative satisfactory protection.

[114] "Key workers" are those (including volunteers and irreplaceable workers) whose functions are critical to limiting flu-related deaths and deaths due to degradation of the health care, public health, and public safety and other critical infrastructures. (See NIAC, 2007 and Section 6 of this report.)

[115] "Disproportionately high occupational exposure" refers, for example, to health care workers who participate in aerosol-generating procedures such as intubation of influenza patients.

[116] "Disproportionately high risk of flu-related mortality/morbidity" refers to groups with a case fatality rate that dramatically exceeds the peaks of an age-specific mortality curve for the flu.

[117] "High occupational exposure" refers to workers whose jobs require sustained or routine direct physical contact with influenza patients.

[118] "Irreplaceable workers" are a subset of key workers whose expertise and/or experience is limited to a very small number of persons and for whom replacements cannot be adequately trained during or shortly after a pandemic, e.g., air traffic controllers.

11.3.2. Criteria for prioritization

Various combinations of the characteristics below warrant prioritizing groups of key workers and the general population for N95s. These criteria work together to protect public health, wisely steward resources, preserve civil order and strive for fairness:

- risk of influenza-related mortality and serious morbidity;
- risk of exposure (occupational and non-occupational) to pandemic influenza; and
- irreplaceability in the critical infrastructure workforce.

As with other resources, the panel recommends a two-pronged approach to limiting influenza-related mortality and serious morbidity. The proportion of N95s that should be allocated between these two tracks should be informed by the epidemiological data emerging during the pandemic itself, the size of the supply, and information about which infrastructures are threatened. The size of the groups in track A will also be influenced by how broadly or narrowly "key workers" are defined. If N95s are very scarce, most of the supply would likely be allocated to track A.

11.3.2.1. Tier 1

Track A prioritizes key workers who are at disproportionately high risk of exposure to flu in the workplace. Track B prioritizes disease containment by protecting those in the general public who have been exposed to contained disease clusters. If there is also a group that is at disproportionately high risk of death or severe complications and that is also at high risk of exposure, then track B prioritizes them for N95s simultaneously.

11.3.2.2. Tier 2

Track A prioritizes key workers with high risk of occupational exposure to flu. It also prioritizes that small subset of key workers who are "irreplaceable," regardless of their occupational exposure. This would allow irreplaceable workers to obtain N95s to protect them from generalized exposure to the flu even outside the workplace. There are no new groups in track B at this level; groups in tier 1 would continue to be prioritized.

Given the importance of protecting groups in the first two tiers, the panel calls for holding a small supply of N95s (for example, a 2-week supply) in reserve at all times before any other groups are given access to N95s. *It is likely, then, that groups in tiers 3 and 4 will not receive N95s.* The panel offers the third and fourth tiers in the event N95 supplies are greater at times than expected.

11.3.2.3. Tier 3

Track A prioritizes all key workers with risk of occupational exposure to flu who are also at high risk of flu-related mortality and serious morbidity. Track B prioritizes people in the general population who are both at high risk of exposure to flu and at high risk of flu-related mortality and serious morbidity.

11.3.2.4. Tier 4

Tier 4 attends to everyone in the general population including workers of all kinds who is at risk of exposure and at risk of flu-related complications. Tier 4 is applicable when the supply is ample and rationing is unnecessary.

Table 12: Ethical Framework for Rationing Surgical Masks[119]

I. Ethical commitments for pandemic planning and response

Pursue our common good in ways that:

- Are accountable, transparent and worthy of trust;
- Promote solidarity and mutual responsibility;
- Respond to needs fairly, effectively and efficiently.

II. Ethical objectives for rationing masks in a severe pandemic

Steward scarce resources to promote Minnesotans' common good by balancing three equally important and overlapping ethical objectives.

- Protect the population's health by:
  - Reducing mortality and serious morbidity from influenza and its complications;
  - Reducing mortality and serious morbidity from disruption to basic health care, public health, public safety and other critical infrastructures.
- Protect public safety and civil order by:
  - Reducing disruption to basic health care, public health, public safety and other critical infrastructures;
  - Promoting public understanding about and confidence in resource distribution.
- Strive for fairness and protect against systematic unfairness by:
  - Reducing significant group differences in mortality and serious morbidity;
  - Making reasonable efforts to remove barriers to access;
  - Making reasonable efforts to reciprocate to groups accepting high risk in the service of others;
  - Rejecting strategies that are discriminatory or exacerbate health disparities;
  - Using fair random processes for those similarly prioritized.

III. Strategies for rationing masks

- Attend to general recommendations for rationing N95s and masks (Section 11.2).
- People (both key workers and those in the general population) are eligible for surgical masks if they are potentially infectious, that is, because they are ill with the flu or at the very least, presumably have been exposed to the flu.
- If best available evidence suggests that the virus is transmitted primarily through droplets, prioritize masks for healthy key workers in addition to the general population.
- Prioritize key workers based on high risk of occupational exposure and high risk of flu-related morbidity and mortality.
- Prioritize groups within the general population to have access to surgical masks based on high or moderate risk of transmitting to people at high risk of flu-related mortality.
- De-prioritize people:
  - with immunity (for example, have contracted and recovered from pandemic influenza or are successfully vaccinated);
  - with medical contraindications (for example, co-morbidities that hamper breathing or too young to safely wear masks);
  - who refuse or are unable to comply with wearing instructions; or
  - with alternative satisfactory protections.

When there is a shortage of masks, give them to key workers and the general population in tier 1 as outlined below. When the supply is more adequate, retain a small supply (for example, a 2-week supply) for tier 1 before distributing to other tiers.

[Table 12 continued on next page]

[119] Section 9 above in this report offers guidance about adjusting the frameworks to fit an actual pandemic, when to move from one tier to the next, whether to collapse tiers, etc. This framework does not limit the use of surgical masks for non-influenza-related purposes, such as using them in an operating room.

Table 12: Ethical Framework for Rationing Surgical Masks *(cont.)*

Supply	Surgical Mask Priorities	Track A – Key Workers	Track B – General Population
Extreme shortage	**Tier 1**	Healthy key workers who are both • at *high* risk of occupational exposure[120] and • at *high* risk of flu-related mortality/morbidity.	Infectious people posing risk of transmission • to key workers or • to those at *high* risk of flu-related mortality/morbidity.
	Should the supply of surgical masks unexpectedly become more adequate, expand the mask priorities as follows, but retain a small supply (for example, a 2-week supply) for tier 1 before distributing to tier 2.		
Adequate supply	**Tier 2**	Healthy key workers who are both • at *high* risk of occupational exposure and • at *moderate* risk of flu-related mortality/morbidity.	Infectious people posing risk of transmission to others because they cannot reasonably avoid contact with many other people.
	Tier 3	Healthy key workers • at risk of occupational exposure.	Healthy people who are both • at *high* risk of exposure and • at *high* risk of flu-related mortality/morbidity.
	Tier 4	All eligible people.	

11.4. Discussion: Rationing masks

The ethical commitments and objectives for rationing N95s and masks are the same, but the strategies differ.

11.4.1. De-prioritization criteria

Fairness and wise stewardship would de-prioritize groups based on these factors:

- Confirmation of immunity;
- Medical contraindications (for example, people with co-morbidities that hamper breathing or who are too young to wear masks safely);
- Refusal or inability to comply with wearing instructions;
- Have alternative satisfactory protection.

11.4.2. Criteria for prioritization

Various combinations of these characteristics warrant prioritizing groups of key workers and the general population for masks:

- Risk of exposure;
- Risk of transmission to key workers;
- Risk of transmission to those at high risk of morbidity/mortality;
- Risk of transmission to many other people.

[120] "High risk of occupational exposure" refers to workers whose jobs require sustained or routine direct physical contact with influenza patients.

11.4.2.1. Tier 1

Two groups are prioritized for masks at this level. Track A prioritizes healthy key workers who are at high risk of workplace exposure to flu and high personal risk of flu-related mortality/morbidity. This prioritization reflects that masks should be available to these workers when the best available evidence indicates that masks protect the wearer. At the same time, track B prioritizes masks to infectious people who pose a risk of transmission to key workers or people at high risk of flu-related mortality/morbidity. Track B reflects the importance of indirectly protecting key workers and those at heightened risk from flu from exposure to infectious people.

Given the importance of protecting these first-priority groups, the panel calls for holding a small supply of masks in reserve (for example, a two-week supply) before any other tiers are given access to masks. *It is likely, then, that those in tiers 2, 3 and 4 will not receive masks.* The panel offers the second through fourth tiers in the event mask supplies are greater at times than expected.

11.4.2.2. Tier 2

Track A prioritizes healthy key workers who have *high* risk of workplace exposure to flu and are at *moderate* risk of flu-related mortality/morbidity. Track B prioritizes infectious people who cannot reasonably avoid contact with many other people.

11.4.2.3. Tier 3

Track A prioritizes healthy key workers who have workplace exposure to flu. Track B prioritizes people with a *high* risk of exposure to the flu who are at *high* risk of flu-related mortality/morbidity.

11.4.2.4. Tier 4

At this tier the supply of masks is ample, and they are available to the general population.

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12. Ethical Framework for Rationing Vaccines

12.1. Vaccine assumptions[121]

1. This framework addresses two types of influenza vaccine: inactivated virus vaccines delivered by injection and live attenuated vaccines delivered by nasal spray, both of which can only be developed after the strain of virus has been identified. The largest supply will be of inactivated virus vaccines. These vaccines will match the influenza virus (unless the virus undergoes significant change from the beginning of the pandemic). If there are differences among groups that make one type of vaccine safer or more effective than the other, then vaccines should be allocated accordingly as the supply of both types allows.
2. Vaccines that are well-matched to the strain of pandemic virus cannot be stockpiled in advance. When the influenza pandemic first reaches the stage of increased and sustained transmission in the general population (WHO pandemic phase six), there will be no vaccines against the specific strain of influenza. Vaccines will not become available in any significant amount for 5 – 6 months into WHO phase six.[122]
3. Two million 15-mcg doses of vaccine will become available weekly in the US.[123] Minnesota's population is roughly 2% of the total US population, so Minnesota will receive approximately 35,000 doses weekly, for a total of 420,000 doses rolling in over 12 weeks. Assuming that two 15-mcg doses will be necessary, about 6% of Minnesotans will have access to two vaccine doses during the first 12 weeks that vaccines are available and about 26% of Minnesotans will have access over the period of a year. Young children will require smaller doses of vaccine than adults.
4. Pandemic influenza vaccines can reduce transmission, disease severity, rates of serious morbidity and mortality and absenteeism. Influenza vaccines benefit direct recipients, assuming that they have sufficient vaccine response, but can also have a multiplier effect. That is, they can benefit those who would otherwise be exposed to influenza by the recipient and those who would otherwise fail to receive needed goods or services because the recipient was absent from work due to influenza or influenza-related death.
5. Herd immunity within the general population will likely not be achievable six months into WHO pandemic phase six, because of the scarcity of vaccines and the highly contagious nature of severe influenza.
6. Vaccine efficacy and response will vary depending on dose, adjuvants, delivery routes, availability and efficacy of pre-pandemic vaccination, quality of the match between the vaccine and the influenza strain, and demographic factors (e.g., age-specific attack rates, age-specific mortality rates and immunologic senescence). In general, most people will have good vaccine response. The elderly[124] will have poorer vaccine response than the rest of the population.

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[121] Unless otherwise stated, vaccine work group members offered these assumptions based on their expertise and experience. The work group met in 2007 and was not reconvened to consider these assumptions in light of the 2009 H1N1 pandemic.

[122] Scientists are working to develop influenza vaccines that need not be matched to a particular strain in order to be effective (see e.g., Lu X, Edwards LE, Desheva JA, Nguyen DC, Rekstin A, Stephenson I, et al. (2006). Cross-protective immunity in mice induced by live-attenuated or inactivated vaccines against highly pathogenic influenza A (H5N1) viruses. *Vaccine* 24(44-46):6588-6593.) New vaccine manufacturing technology may someday reduce the time it takes to produce well-matched vaccines. While these developments are promising, it is premature to assume an earlier and larger supply of vaccines.

[123] The 2005 HHS plan assumes three to five million doses will be available weekly in the US and that two doses will be needed per person. US manufacturing capacity currently is 150 million 15-mcg doses and is expected to be 250 million. "Sanofi Pasteur receives order from United States' government to produce new influenza A(H1N1) vaccine." [press release] (2009). Available at: http://www.sanofipasteur.com/sanofi-pasteur2/sp-media/SP_CORP/EN/54/759/FLU%20A%20H1N1%20US%20ORDER%20ENG%20250509.pdf?siteCode=SP_CORP; "Sanofi Pasteur announces completion of construction of new U.S. influenza manufacturing facility." [press release] (2007). Available at: http://www.vaccineplace.com/docs/us_new_flu_facility_eng_200707.pdf; McKenna M (2007). "The pandemic vaccine puzzle: A 7-part series on the chances for immunizing the world against pandemic flu." Available at: http://www.cidrap.umn.edu/cidrap/content/influenza/panflu/news/nov1507panvax.html.

[124] Nichol KL, Nordin JD, Nelson DB, Mullooly JP, Hak E (2007). Effectiveness of influenza vaccine in the community-dwelling elderly. *N Engl J Med* 357(14):1373-1381; Simonsen L, Taylor RJ, Viboud C, Miller MA, Jackson LA (2007). Mortality benefits of influenza vaccination in elderly people: An ongoing controversy. *Lancet Infect Dis* 7(10):658-666.

7. Influenza vaccines are not currently approved by FDA for use in children less than 6 months of age. During a severe pandemic, the risk of influenza compared to the risk of vaccination might warrant vaccinating children as young as 2 months of age.
8. Infants less than 2 months of age and severely immune-compromised people will have unacceptable vaccine responses.
9. Indirect immunization (immunizing people in order to protect those with whom they come into contact) may sometimes provide better protection for some groups than direct immunization, depending on the group's likely vaccine response.
10. The safety of pandemic influenza vaccines will be comparable to current influenza vaccines. Vaccines will be relatively safe for all populations, except for those in whom the vaccines are contraindicated, e.g., those seriously allergic to eggs if the vaccines are egg-based. (Adverse events may increase with higher doses of vaccine.[125] Moreover, if vaccine development during a pandemic is fast-tracked, FDA approval of new vaccines may be based on less evidence than would be required in a non-pandemic situation.)
11. Five months into WHO pandemic phase six, useful information will exist about the disease profile, including relative mortality and morbidity rates among some populations. The first wave of illness will have passed, if not in Minnesota then elsewhere, and that wave of illness will have provided information about the disease. There will also be preliminary information about vaccine efficacy and safety. Groups will be separable, for instance, into those with good, acceptable and unacceptable vaccine response as well as into those with disproportionately high, high and moderate mortality/morbidity.
12. A portion of key workers and the general public will develop natural immunity in the months prior to vaccine being available. To the extent that it is feasible reliably and rapidly to identify individuals who are naturally immune, vaccines will be redirected to those who lack immunity.

12.2. General recommendations for rationing vaccines

1. Attend to the section above on General Recommendations (Section 8) and apply them as appropriate to the planning for rationing vaccines.
2. Refrain from rationing vaccines based on differences in quality of life, life-expectancy, ability to pay, judgments about differences in "social value," or first-come, first-served.
3. Clarify work expectations for people who receive vaccine on account of their key worker status during the two-week period immediately following vaccination (while they are developing immunity) and thereafter (when immunity is presumed).

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[125] McKenna, 2007.

Table 13: Ethical Framework for Rationing Vaccines[126]

I. Ethical commitments for pandemic planning and response

Pursue Minnesotans' common good in ways that:

- Are accountable, transparent and worthy of trust;
- Promote solidarity and mutual responsibility;
- Respond to needs fairly, effectively and efficiently.

II. Ethical objectives for rationing vaccines in a severe pandemic

Steward scarce resources to promote Minnesotans' common good by balancing three equally important and overlapping ethical objectives.

- Protect the population's health by:
  - Reducing mortality and serious morbidity from influenza and its complications;
  - Reducing mortality and serious morbidity from disruption to basic health care, public health, public safety and other critical infrastructures.
- Protect public safety and civil order by:
  - Reducing disruption to basic health care, public health, public safety and other critical infrastructures;
  - Promoting public understanding about and confidence in resource distribution.
- Strive for fairness and protect against systematic unfairness by:
  - Reducing significant group differences in mortality and serious morbidity;
  - Making reasonable efforts to remove barriers to access;
  - Making reasonable efforts to reciprocate to groups accepting high risk in the service of others;
  - Rejecting strategies that are discriminatory or exacerbate health disparities;
  - Using fair random processes for those similarly prioritized.

III. Strategies

- Attend to general recommendations for rationing vaccines (Section 12.2).
- De-prioritize people:
  - with unacceptable vaccine response (for example, severely immune-compromised);
  - with medical contraindications (such as a serious egg allergy if vaccine is egg-based);
  - with immunity (such as those who have contracted and recovered from pandemic influenza);
  - known to be imminently and irreversibly dying (for example, have an obvious co-morbidity incompatible with life beyond a short timeframe); or
  - with satisfactory alternative protections.
- Various combinations of characteristics warrant prioritizing some groups to receive scarce vaccines before others:
  - high risk of influenza-related mortality and serious morbidity;
  - occupational exposure to flu;
  - good or acceptable vaccine response;
  - risk of transmitting influenza to groups that are at high risk of influenza-related mortality and serious morbidity.

[Table 13 continued on next page]

[126] Section 9 above in this report offers guidance about adjusting the frameworks to fit an actual pandemic, when to move from one tier to the next, whether to collapse tiers, etc.

Table 13: Ethical Framework for Rationing Vaccines *(cont.)*

Sequence	Track A – Key workers	Track B – General population
First	Key workers at *disproportionately high* occupational exposure to flu.[127]	None.

Second	Groups of key workers (including irreplaceable workers):
	• who are either
	  ○ at *high* risk of occupational exposure;[128] or
	  ○ at *high* risk of flu-related mortality/morbidity
	• and who have *good* vaccine response.
		Groups, if any:
		• at *disproportionately high* risk of flu-related mortality/morbidity;[129] and
		• with *good* vaccine response.

Third	Irreplaceable key workers with *good* vaccine response. Groups of key workers: • at *high* risk of transmitting flu to people best protected indirectly (that is, people with poor or unacceptable vaccine response who are also at high risk of flu-related mortality/morbidity); and • with *good* vaccine response.	Groups: • at *high* risk of flu-related mortality/morbidity; and • with *good* vaccine response.
Fourth	None.	Groups: • at *high* risk of flu-related mortality/morbidity; and • with *acceptable* vaccine response.
Fifth	None.	Groups: • at *moderate* risk of flu-related mortality/morbidity; and • with *acceptable* vaccine response.
Sixth	All remaining eligible people.	
When the supply is inadequate to serve all similarly prioritized people, use a fair random process to distribute vaccines, with the following caveat. In track B if demand *within a single step* vastly exceeds supply, before resorting to randomization and if it is feasible to do so: 1. Consider prioritizing children under 18. If the supply is inadequate to vaccinate all children, randomize among children. 2. Next, if the supply is sufficient to reach a significant number of adults as well (though far less than everyone remaining in the step), rather than randomizing among all adults consider prioritizing younger adults after children. Raise the age limit to vaccinate the largest group of younger adults possible given the supply (such as adults between ages 18 and 50). As supply expands, prioritize all remaining age groups in the step before moving to the next step.		

[127] "Disproportionately high occupational exposure" refers, for example, to health care workers who participate in aerosol-generating procedures such as intubation of influenza patients.
[128] "High risk of occupational exposure" refers to workers whose jobs require sustained or routine direct physical contact with influenza patients.
[129] "Disproportionately high risk of flu-related mortality/morbidity" refers to groups with a case fatality rate that dramatically exceeds the peaks of an age-specific mortality curve for the flu.

12.3. Discussion: Rationing vaccines

The panel referred to the efforts of another group, the Pandemic Influenza Ethics Work Group, as a starting point for its work. That work group, formed by the Minnesota Center for Health Care Ethics, issued recommendations for rationing pandemic vaccines in 2006, which were published in *Vaccine* the following year.[130] The panel's recommendations in this report reflect its decision largely to accept but in important ways update and adapt that earlier work group's assumptions and recommendations.

The panel agreed on criteria that are relevant to deciding which groups to prioritize to receive vaccines and some considerations for de-prioritizing groups from being vaccinated.

12.3.1. Criteria for de-prioritization

When vaccine is scarce, wise stewardship and fairness would de-prioritize groups based on these criteria:

- confirmation of immunity, (e.g., have survived pandemic influenza or been successfully immunized with pre-pandemic vaccine);
- medical contraindications (e.g., serious egg allergy if vaccine is egg-based);
- unacceptable vaccine response (e.g., severely immune-compromised);
- known to be imminently and irreversibly dying (e.g., have an obvious co-morbidity incompatible with life beyond a short timeframe); or
- have satisfactory alternative protections.

12.3.2. Criteria for prioritization

Various combinations of these characteristics warrant prioritizing groups for vaccines:

- risk of influenza-related mortality and serious morbidity;
- good or acceptable vaccine response;
- key role in supporting basic health care, public health, public safety or other critical functions;
- risk of occupational exposure to influenza;
- risk of transmitting influenza to groups at high risk of influenza-related mortality and serious morbidity.

The panel recommends a two-pronged approach to rationing vaccines. Track A recommends the sequence according to which key workers should access pandemic influenza vaccine. Track B suggests the sequence that should be followed for the general population, regardless of employment status.

The proportion of vaccines that should be allocated between these two tracks should be informed by the epidemiological data emerging during the pandemic, as well as by information about the viability of critical infrastructures. The size of the groups in track A will also be influenced by how broadly or narrowly Minnesota specifies the basic health care, public health, public safety and other critical infrastructures with guidance from the federal government.

Vaccines will become available in relatively small amounts, rolling in fairly steadily once manufacture begins. They could become available between waves of the pandemic or at the peak of a wave. They should be distributed as soon as they are available, regardless of where we are in the pandemic. In this way, vaccines will be distributed quite differently than other resources. The strategies describe the order in which people would be vaccinated.

12.3.2.1. First

The first step in the sequence pertains only to key workers (track A). There is no one from the general public in track B in the first step. This step prioritizes key workers at disproportionately high risk of occupational exposure to flu (that is, health care workers assigned to intensive care units serving flu patients or those who perform aerosol-generating procedures on flu patients).

[130] Vawter, 2007.

12.3.2.2. Second

The second step in the sequence addresses the first large group to be vaccinated. Track A rations vaccines to key workers who are at high risk of occupational exposure (e.g., health care workers with direct contact with flu patients) who are also at high risk of flu-related mortality/morbidity and likely to respond well to vaccines. If there is also a group in the general population that is at disproportionately high risk of flu-related death or serious complications and that will also respond well to vaccines, then track B allows for this group's vaccination simultaneously.

12.3.2.3. Third

In track A irreplaceable workers, regardless of their risk of death or complications, would be vaccinated so long as they are likely to respond well to vaccines. Track A also vaccinates key workers, regardless of their personal risk, if they care for people who are at high risk of death or serious complications but are not good candidates for vaccination. Track B protects those in the general population at high risk of death or serious complications who have good vaccine responses by directly vaccinating them.

12.3.2.4. Fourth

Starting with the fourth step, all vaccines are directed to track B; key workers who were not prioritized in Track A will be prioritized along with everyone else in the general population, depending upon their relative risk and vaccine response.

The fourth step prioritizes groups that are at high risk but have only an acceptable (as opposed to good) vaccine response.

12.3.2.5. Fifth

The fifth step prioritizes groups at moderate risk with an acceptable vaccine response.

12.3.2.6. Sixth

The sixth step is the final step in the sequence, allowing for vaccination of all remaining eligible groups.

12.3.2.7. Prioritizing within sequential steps

When the supply is inadequate to serve all similarly prioritized people, use a fair random process to distribute vaccines, with the following caveat. In track B if demand *within a single step* vastly exceeds supply, before resorting to randomization and if it is feasible to do so:

1. Consider prioritizing children under 18. If supply is inadequate to vaccinate all children, randomize among children until all children in the step are vaccinated.
2. Next, when the supply is sufficient to reach a significant number of adults as well (though far less than everyone remaining in the step), rather than randomizing among all adults consider prioritizing younger adults after children. Raise the age limit to vaccinate the largest group of younger adults possible given the supply (e.g., adults between ages 18 and 50). As supply expands, prioritize all remaining age groups in the step before moving to the next step in the sequence.

This prioritization of children and younger adults before older can be justified as a matter of fairness, because it prioritizes younger people who have not had as much chance at life as older people. It also acknowledges adults' obligations to protect children. See Section 14.1.2.3 for further discussion of age-based rationing.

12.3.3. How these recommendations fit with federal guidance

When the Minnesota Department of Health originated this project in late 2006, federal pandemic planning expressly called for states to develop rationing plans for resources like vaccines.[131] The 2005 HHS

[131] DHHS. *HHS Pandemic Influenza Plan*, 2005.

Pandemic Influenza Plan included guidance (developed by the National Vaccine Advisory Committee and the Advisory Committee on Immunization Practices) for allocating vaccine in a *moderate* influenza pandemic, not a severe pandemic.

In December 2007 the federal government issued draft guidance for rationing pandemic vaccines, providing a range of priorities depending on a pandemic's severity.[132] The federal guidance was finalized 2008.[133] MDH, as the sponsor of the Minnesota Pandemic Ethics Project, directed that the work move forward. The department asked that the project be informed by federal guidance but not be limited by it, because federal guidance was still evolving. In its 2009 annual update, the US Department of Health and Human Services reiterated that though it has offered guidance, some allocation decisions are best made locally and it supports communities developing local plans.[134]

In several important ways, the panel's recommendations are consistent with the federal guidelines.[135] Both these recommendations and the federal guidelines recognize that:

- Pandemic influenza may be very different from seasonal influenza, posing threats of serious complications and mortality to more groups in the general population.
- A severe pandemic poses not only the risk of disease but also risks associated with crippled infrastructures.
- Vaccines should be used in conjunction with other strategies to control the disease and mitigate the pandemic's effects.
- Prioritizing children before adults in some instances for non-clinical reasons of fairness may be justified.

Both also attend to multiple objectives and use multiple tracks and sequential steps to respond to infrastructure and disease threats simultaneously.

The federal guidelines differ from the panel's recommendations in that they:

- Do not take into account the relative efficacy of influenza vaccines among different groups of people;
- Do not explicitly and consistently take into account any differences in the severity of risk of mortality and serious complications;
- Do not explicitly take into account the availability of other protective resources; and
- Allocate large portions of the resources for homeland security and national defense.

[132] US Vaccine Prioritization Interagency Working Group, *Draft Guidance on Allocating and Targeting Pandemic Influenza Vaccine*, 2007.
[133] DHHS and Department of Homeland Security. *Guidance on Allocating and Targeting Pandemic Influenza Vaccine*. 2008. The CDC also issued guidance for allocating H1N1 novel influenza vaccine in 2009. This guidance applies only to the mild pandemic that began in 2009 and is limited to prioritizing certain health care and emergency medical services personnel and groups in the general population that are at increased risk of death or serious complications from the H1N1 novel influenza virus. National Center for Immunization and Respiratory Diseases, CDC. Use of Influenza A (H1N1) 2009 Monovalent Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep* 2009;58(RR-10):1-8. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0821a1.htm.
[134] DHHS. *Pandemic Planning Update VI: A Report from Secretary Michael O. Leavitt*. 2009. Available at: http://www.flu.gov/professional/pdf/panflureport6.pdf.
[135] Garrett JE, Gervais KG, Vawter DE, DeBruin DA, Prehn AW, Liaschenko J. Comments to Draft Guidance on Allocating and Targeting Pandemic Influenza Vaccine. [letter to US Department of Health and Human Services] Dec. 31, 2007.

13. Ethical Framework for Rationing Ventilators

13.1. Ventilator assumptions[136]

1. There are different types of mechanical ventilators and not all will be appropriate for medically unstable flu patients in respiratory failure.[137] Some require highly trained clinicians to run and monitor them.
2. The demand for ventilators is expected to increase sharply and drastically exceed supply at times during a pandemic.[138] Between peaks of pandemic waves, ventilator shortages may be much less severe.
3. Approximately 13,000 flu patients in MN are anticipated to suffer respiratory failure sometime during a severe pandemic and under current standards of care would be candidates for a vent.[139]
4. The need for vents could be reduced by approximately two days in some influenza patients by treating them promptly with antivirals.
5. Previously healthy people are most likely to benefit from vents.
6. Approximately 1,200 vents are currently available in acute care institutions in MN;[140] including 171 transport and 58 MRI-compatible vents. A few of these vents can only be used for small infants. In addition, Minnesota will be allocated 37 vents from the strategic national stockpile.
7. On average, 85% of vents are currently in use at any given time.
8. Approximately 10% of vents currently used for patients undergoing elective procedures could be redirected to care for influx of acutely ill flu patients.
9. A portion of vents will be unavailable during severe pandemic due to absenteeism or lack of other required concomitant resources.[141] Additional health care workers will be trained to manage less complex (medically stable) patients on vents to free up highly trained clinicians to attend to more complex ventilator-related activities.[142]

13.2. General recommendations for rationing ventilators

1. Attend to the section above on General Recommendations (Section 8) and apply them as appropriate to the planning for rationing of non-infant, acute-care ventilators.
2. Ration vents only as a last resort. Efficiently manage the use of vents and related resources to stave off as long as possible the need to ration with techniques such as:[143]
   - Postponing elective procedures that may require mechanical ventilation.
   - Using the various types of ventilators and other respiratory supports efficiently so that in times of shortage, patients have access to the simplest type of support they need consistent with reasonable effectiveness.
   - Taking reasonable steps to minimize downtime for cleaning vents; for example, stockpiling supplies of ventilator circuits to reduce the time needed to prepare ventilators for waiting patients.

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[136] Unless otherwise stated, the sources for these assumptions are the members of the ventilator work group, who agreed on reasonable assumptions for purposes of this project based on their expertise and experience. The work group met in 2007 and was not reconvened to consider these assumptions in light of the 2009 H1N1 pandemic.
[137] Hick JL, Rubinson L, O'Laughlin DT, Farmer JC (2007). Allocating ventilators during large-scale disasters: Problems, planning, and process. *Critical Care* 11(3):217.
[138] Hick JL, O'Laughlin DT (2006). Concept of operations for triage of mechanical ventilation in an epidemic. *Acad Emerg Med* 13(2):223-229.
[139] MDH, 2009.
[140] Ibid.
[141] Minnesota Department of Health (MDH). *Mechanical Ventilation Strategies for Scarce Resource Situations.* 2008. Available at: http://www.health.state.mn.us/oep/healthcare/scarcevent.pdf; Christian M, 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*. April 2006.
[142] See generally, Minnesota Department of Health. *Staffing Strategies for Scarce Resource Situations.* 2008. Available at: http://www.health.state.mn.us/oep/healthcare/scarcestaff.pdf.
[143] Ibid.

- Implementing oxygen conservation initiatives and initiatives to expand the oxygen supply; considering strategies to conserve and redirect oxygen supplies from non-critical manufacturing activities to health care institutions for ventilator use during periods of oxygen shortages.[144]

3. Ration ventilators to the general population without consideration for key worker status.
4. Refrain from rationing ventilators based on differences in socioeconomic status, quality of life, life-expectancy or first-come, first-served.
5. Clarify whether and how end-of-life policies will be modified, e.g., advance directives, DNR, withdrawing life-sustaining interventions, palliative care and brain death policies. For example, advance directives and patient or proxy requests for care will be very helpful in making care decisions for the critically ill and should be honored to the greatest extent possible. Nevertheless, these rationing guidelines will pre-empt patient, proxy and advance directives' requests for ventilators.
6. When feasible, decisions about ventilator access should be made by a specially trained team of triage clinicians who are not directly involved in patient care.
7. As important as it is to ration access to scarce vents wisely, fairly and consistently, it is important to treat the dying compassionately. The ethical importance of providing palliative and hospice care to patients who are not put on ventilators in the first place or who are removed from them cannot be overstated.[145]

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[144] Minnesota Department of Health. *Oxygen Use Strategies for Scarce Resource Situations.* 2008. Available at: http://www.health.state.mn.us/oep/healthcare/scarceoxygen.html.
[145] See Section 3.1 in this report.

Table 14: Ethical Framework for Rationing Ventilators

I. Ethical commitments for pandemic planning and response

Pursue Minnesotans' common good in ways that:

- Are accountable, transparent and worthy of trust;
- Promote solidarity and mutual responsibility;
- Respond to needs fairly, effectively and efficiently.

II. Ethical objectives for rationing ventilators in a severe pandemic

Steward scarce resources to promote Minnesotans' common good by balancing three equally important ethical objectives.

- Protect the population's health by:
  - Reducing mortality and serious morbidity from influenza and its complications.
- Protect public safety and civil order by:
  - Promoting public understanding about and confidence in resource distribution.
- Strive for fairness and protect against systematic unfairness by:
  - Reducing significant group differences in mortality and serious morbidity;
  - Making reasonable efforts to remove barriers to access;
  - Rejecting strategies that are discriminatory or exacerbate health disparities;
  - Using fair random processes for those similarly prioritized.

III. Strategies for rationing non-infant,[146] acute-care[147] ventilators

- Attend to general recommendations for rationing ventilators (Section 13.2).
- Provide access to vents only to those who need mechanical ventilation in order to save their lives.
- De-prioritize patients if they have an underlying condition that makes it relatively certain that they will die within a very short time (such as a couple of weeks or months), even if acute short-term ventilation is successful.
- Patients from the general population (including workers of all types) should be prioritized for access to vents in this order:
  1. Prioritize patients who have a significantly greater likelihood of survival according to a standardized, evidence-based, clinical tool recommended by MDH.[148]
  2. Prioritize patients not likely to require more than short-term reasonable levels of critical care resources.

[Table 14 continued on next page]

[146] Neonatal ventilators can be used only for very young infants and cannot be adapted for older, heavier patients. Ventilators currently in use for pediatric and adult patients can be adapted for use by either. These recommendations concern only pediatric and adult ventilators.

[147] These recommendations do not consider rationing or reallocating ventilators currently in use by patients with chronic needs for ventilation.

[148] See MDH, 2008.

Table 14: Ethical Framework for Rationing Ventilators *(cont.)*

- Once a patient has been placed on vent, s/he is reassessed to determine if s/he is substantially more likely to benefit from the vent than new vent candidate(s).
  - So long as a patient who has received a vent is significantly improving, this patient has priority over other eligible patients presenting later.
  - The shorter the length of time a patient has been on the vent, the more significant the difference must be for a new patient to take over the vent (in other words, a new vent candidate must be much more likely to benefit from the vent than a vent patient who has only been on the vent a few hours to warrant extubating that patient and giving the vent to the new candidate).
- During most of the pandemic, decisions about vent rationing can be made at individual health care institutions.
- During times of particularly severe ventilator scarcity, regionalized rationing strategies may also be needed. Regionalized strategies may:
  - Exclude patients from being considered for vents if they do not have a specified likelihood of survival according to a standardized, evidence-based, clinical tool recommended by MDH.[149]
  - Allow access to vents only through access to time-limited (for example, 48-hour) therapeutic trials.[150] If the constant reassessment of vent patients becomes unworkable or saves fewer lives than would allowing patients to have a reprieve from reassessments for an initial trial period, reassess whether patients' health status is improving using MDH's recommended clinical tool at the end of standardized trial periods (for example, 48 hours or earlier if there is a major decline in clinical status). Extend the vent trial for patients who are significantly improving. After the initial vent trial (for example, 48 hours) if the patient is not significantly improving, s/he may be removed from the vent in favor of another vent candidate significantly more likely to benefit.
- When there are more equally prioritized patients than ventilators, use a fair random process to determine who has access to a ventilator trial, with the following caveat: Before resorting to randomization, consider prioritizing children < 18 years of age, but do not prioritize younger children before older children (rather, randomize among competing children). Among adults, consider prioritizing younger before older when the age difference is very large (such as 20 years or more). Do not consider age among adults when the age difference is smaller.

13.3. Discussion: Rationing ventilators

Mechanical ventilation is a life-saving intervention that breathes for a patient who cannot otherwise do so. If health care is described on a continuum with preventive and primary care on one end, mechanical ventilators would be at the far opposite end. Resources like vaccines, masks and antivirals can reach masses of people, but ventilators are part of an intensive strategy to save individual lives. Minnesota has a ventilator for every critical care bed in the state. This number of ventilators is so small that even when all are efficiently and effectively used, few lives could be saved in comparison to the numbers saved with antivirals and the like.

For critically ill patients (flu and non-flu patients alike) in need of a ventilator, their families and loved ones and their health care professionals, hard choices must be made about how best to use these life-saving devices. Though a state's overall mortality might not be greatly affected by how critical care resources like ventilators are used, these choices could influence how well its residents and workers hold together as a society during and after a pandemic. Minnesotans will surely be judged and will judge themselves by how compassionately and fairly they care for the critically ill and ration scarce health resources among them.

Rationing is a last-ditch strategy. Before rationing access to vents, health care providers should increase their capacity to provide acute care ventilation with methods such as cancelling elective surgeries, using

[149] Ibid.
[150] A "trial" as used in this framework means a time-limited, therapeutic trial, not a research study.

oxygen-conservation techniques, and using other devices instead of ventilators where possible.[151] If ventilators are still scarce, as expected during the peaks of a pandemic wave, then rationing guidelines are needed.

This recommended ethical framework emphasizes clinical[152] criteria. The clinical considerations help identify those most likely to benefit from access to a ventilator and reflect the panel's commitment to reduce mortality and serous morbidity effectively and efficiently.

Ventilators are particularly time-critical resources. When someone develops breathing problems a decision needs to be made in short order whether a ventilator is available and who should receive it. There will be times that ventilators are extremely scarce and several people with similar likelihood of benefit will compete for access. Ventilators are given to people who are seriously ill from any number of causes. Therefore rationing decisions are less about which *groups* should receive ventilators before others and more narrowly focused on comparing the clinical likelihood of benefit of specific *individual* patients in a particular critical care unit.

If age (the only non-clinical criterion discussed) is used to ration access to mechanical ventilators, it must be applied differently than for other resources considered by the panel. The panel recommends that if clinical considerations are equal and some patients are children and others adults, consider prioritizing the children to receive ventilation. When there are more children who are clinically equal than there are ventilators, then use a random process to select which child receives a ventilator and which does not. In other words, do not use age as a criterion when deciding among children. The panel recommends that if younger adults are prioritized to receive ventilators before older adults, the difference in age must be 20 years or more.[153] Prioritization of children and younger adults before older can be justified as a matter of fairness, because it prioritizes younger people who have not had as much chance at life as older people. It also acknowledges adults' obligations to protect children. See the discussion in Section 14.1.2.3 for more on age-based rationing.

The panel considered whether key workers should be prioritized for access to ventilators either to preserve critical infrastructures or on reciprocity grounds. For the reasons expressed in Section 14.1.2.1 of this report, the panel recommends against prioritizing key workers. Key workers should be considered along with all other ventilator candidates, according to the criteria in the framework.

Access to a ventilator is provisional. That is, once a patient has been placed on a vent, that vent remains a community asset and is subject to being reallocated to another patient. The patient is subject to re-assessment if there are other candidates for the vent.

If feasible, decisions about ventilator access should be made in each health care facility by a team of clinicians who are not directly involved with bedside care. In hospitals that are large enough, a vent triage committee should be established to apply the recommended criteria and decide which patients best qualify for the vents. Smaller facilities should consider collaborating with other hospitals in or near their communities to decide together which patients best qualify for vents.

Except in extreme circumstances, geographic uniformity and equity can and should be obtained by managing patient flow among hospitals on a regional basis. Health care facilities in a given community or

[151] MDH, 2008; Agency for Healthcare Research and Quality. *Mass Medical Care with Scarce Resources: A Community Planning Guide*. 2007. Available at: http://www.ahrq.gov/research/mce/mceguide.pdf.

[152] The clinical guidance in this ethical framework reflects recommendations from the Minnesota Department of Health Science Advisory Team; MDH, 2008.

[153] The panel and ventilator work group members discussed at length what difference in age between adults is ethically relevant, if younger adults are to be prioritized before older, all clinical considerations being equal. Most agreed that a difference of 7 years was too short, but there was much uncertainty about whether a 10 or 20 year difference was sufficient. The panel's preliminary recommendations suggested that the difference should be greater than 10 years. No additional input was received on this specific recommendation. In keeping with the spirit of the panel's other recommendations regarding age-based rationing, the recommended age difference to consider has been expanded to two decades. Based on the project's additional public engagement activities, Minnesotans are more likely to find a large age difference reasonable than a small one.

region should share information daily to ensure that they are operating at approximately the same level of relative scarcity.

During extreme shortages of ventilators, some regional decision-making may be appropriate. For example:

- A clinical threshold such as a maximum SOFA score[154] could be established, beyond which access to vent trials would not be provided by the health care institutions in that region.
- Time periods for patient reassessment could be adjusted to allow for a therapeutic trial on a vent for a specified period, e.g., 48 hours, during which the patient would not be removed from a vent unless his or her clinical status significantly declines (or improves to the point where ventilation is not needed). This mechanism is recommended as a means of preventing "churning" of patients on and off vents too quickly to allow for any benefit from being on a vent in the first place and to support wise stewardship of scarce resources.

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[154] SOFA is the Sequential Organ Failure Assessment tool, which is currently part of the standardized, evidence-based, clinical tool recommended by MDH for use in assessing patients for access to scarce ventilators. SOFA score is offered only as an example of an assessment tool, other tools may become available in the future. See MDH, 2008.

14. Discussion of Panel Recommendations

A severe pandemic differs so dramatically from conditions Minnesotans are accustomed to, that usual ethical commitments and practices will likely be inadequate to guide decisions about allocating health-related resources. Minnesotans have a range of options. For example, one option is to distribute resources first-come, first-served or by ability to pay. Another option is to leave decisions to the ad hoc subjective judgments of individuals in control of the resources. A third option is to allocate resources with the single goal of reducing deaths due to the flu. Yet another option is to distribute all resources randomly, for instance, by use of a lottery. Participants in this project rejected each of these simple, straightforward options because each on its own would be systematically unfair and would fail to protect Minnesotans' health adequately. Instead, project participants strongly support ethical frameworks that balance multiple ethical objectives.

Some of the panel's rationing recommendations may be controversial, at least at first blush. Today Minnesotans access resources based on various combinations of need, first-come first-served, and ability to pay. The panel maintains that in this project's pandemic scenario a statewide plan that focuses on protecting the common good is far preferable to leaving decisions to individuals in a consumer-based, free market-style system. Similarly, relying on ad hoc subjective judgments about who should and should not receive scarce resources would not only be inconsistent but would likely reflect personal bias and prejudice, posing serious affronts to fairness.

Participants in the Minnesota Pandemic Ethics Project generally agree that when rationing in a severe pandemic:

- A population health perspective constrained by several specific fairness considerations should guide rationing decisions.
- The objective of reducing the number of deaths due to flu needs to be balanced with objectives directed at protecting public safety and civil order, protecting against systematic unfairness and promoting fair access for all Minnesotans.
- Protections against unfairness must befit the scale and scope of this type of public health disaster, and among other things should therefore:
    - Prohibit rationing based on ability to pay, quality of life, social or economic status, political power, race, gender or citizenship.
    - Make reasonable efforts to remove barriers to fair access.
    - Use fair and transparent, random processes when rationing is in effect rather than the customary use of first-come, first-served.
- When some resources are too scarce to serve everyone equally prioritized, it is acceptable in limited circumstances to consider prioritizing younger people before older, especially children before adults.

The recommended strategies offer both familiar clinical and less customary non-clinical criteria to guide access to health resources. Examples of clinical criteria include high need based on high risk of mortality or high risk of exposure. An example of a criterion that is not strictly clinical is a person's role in supporting critical infrastructures. Non-clinical criteria are less customarily applied in ordinary, non-pandemic circumstances. Table 15 contrasts key differences between commonly recommended clinical, non-clinical and procedural fairness criteria for access to resources during a severe pandemic with prevailing criteria guiding access to health resources in ordinary times.

Table 15: Access Criteria: Ordinary Times vs. Severe Pandemic

	Ordinary Times	Severe Pandemic
Clinical considerations		
• High need, risk of dying	+	+
• High exposure	+	+
• High efficacy		+
Non-clinical considerations		
• Ability to pay	+	
• Key worker status		+
• Reciprocity obligations		+
• Younger before older		+
Procedural fairness		
• First-come, first-served	+	
• Randomization, such as a lottery		+

The recommended frameworks do not define in advance exactly who should be prioritized for resources. Rather, they are guidelines for decisions to be made once more facts are known in an actual pandemic.

14.1. Rationing strategies

The frameworks recommend several strategies and also explicitly reject some strategies used during ordinary times.

14.1.1. Clinical considerations

Clearly, the risk of serious health complications and death and the likelihood of benefit from a particular health resource are ethically relevant clinical considerations in a severe pandemic. Reducing the number of lives lost to influenza is an important objective, and allocating and even rationing resources on the basis of risk of mortality/morbidity and effectiveness are familiar and widely accepted. When supplies are ample, the goal is to provide the intervention to everyone who might possibly benefit. When supplies are scarce, it is common to prioritize groups at highest clinical risk so long as they are likely to respond well to the resource.

The frameworks consistently emphasize—for both population health and fairness reasons—the importance of prioritizing groups that are at the highest risk of flu-related mortality or serious morbidity and for whom the resource has high effectiveness.

14.1.2. Non-clinical considerations

Clinical need and chance of efficacy are often the only relevant bases for allocating scarce resources outside of disaster, but when pursuing Minnesotans' common good in a severe pandemic, nonclinical factors at times also can be appropriate. Influenza is not the only mortality threat in a severe pandemic. Potential breakdown of critical infrastructures also threatens life and health. Clinical considerations alone are insufficient guides to rationing because they only address mortality threats from the flu. Some non-clinical considerations are also relevant for protecting population health, protecting critical infrastructures, protecting against systematic unfairness or acknowledging people for undertaking high risk in the service of others. Key worker status and reciprocity are two non-clinical considerations the panel embraced as relevant; younger before older people is another non-clinical consideration that may be considered under limited conditions when rationing to the general public.

14.1.2.1. Key worker status

Given the project's assumptions about a severe pandemic with a W-shaped age-based mortality curve (Section 5.1.1), maintaining society's core infrastructures will be challenging. Most of the frameworks prioritize groups of workers that have key functions in health care and other critical infrastructures for reasons beyond any high personal risk of dying that they might have. These workers are prioritized because everyone's life depends on these key functions.

Some project participants noted that many key workers are systematically prioritized and advantaged in everyday society compared with other people. For instance, highly trained health care professionals are well educated and enjoy financial security, health insurance and social status. It is important, therefore, not to exacerbate these types of disparities by systematically prioritizing health care professionals to receive key resources before others in the general population.

Sensitive to this point, the panel concluded that prioritizing groups based on key worker status is only justified when it clearly supports critical infrastructures and the health of the population. Therefore, key workers are not always prioritized ahead of the general population and not all key workers are at highest priority to receive all of the resources. Groups of key workers that are recommended to be at highest priority must have additional characteristics as well. For instance, depending on the particular resource, prioritized key workers must also have disproportionately high risk of occupational exposure or be at high risk of flu-related mortality or serious morbidity.

The panel recommends against prioritizing key workers for ventilators for two reasons. First, patients ill enough to require mechanical ventilation are not expected to recover and return to work for many weeks, and some substantial number might never be well enough to return to their jobs.[155] It is unlikely that prioritizing key workers to receive ventilators could accomplish the goal of getting ill workers quickly back on the job to help other Minnesotans weather the pandemic. Second, if key workers were prioritized to receive ventilators for reciprocity reasons alone, it is possible that they would use most, if not all, of the short supply of ventilators; other groups systematically would be deprived access. The panel concluded this would be unfair to many, such as those who do not work outside the home, who are students, young children or retired or who have jobs not considered key to preserving critical infrastructures. Some health care workers on the panel argued in addition that prioritizing key workers (specifically, health care professionals) to receive ventilators would conflict with the very nature of the helping professions. They stated that it is inconsistent with their professional norms to suggest that they should go to the head of the line and their patients go to the end.

In sum, the panel recommends prioritizing some groups of workers for preventive resources and for treatment antivirals. A few panel members suggested that if these resources are unavailable or ineffective, the question of prioritizing key workers for ventilators on the basis of reciprocity should be re-evaluated.

14.1.2.2. Reciprocity

Reciprocity refers to the fairness-based obligations of gratitude owed to groups that accept unusually high risks and burdens in the service of others. The project participants widely agreed that reciprocity merits consideration relative to specific groups of key workers (including volunteers), but were in less agreement about when this obligation should be limited by other factors. Many participants agreed that key workers usually deserve to have prioritized access to protection and treatment when their work is essential, they are at increased risk of exposure and/or they are at high risk of flu-related mortality or serious morbidity. There was general agreement that reciprocity obligations are not unlimited, but constitute one fairness criterion among others.

Some argued that there is an obligation to guarantee resources to key workers not so much out of societal gratitude, but so that they will go to work. On this latter point, there was wide disagreement. Some panel members asserted that there is scant empirical support for the claim that large numbers of key workers will work only if they are prioritized. Not all key workers are at high risk, and it would be difficult for many to leave work for the whole course of a two-year pandemic.

[155] New York State Workgroup on Ventilator Allocation in an Influenza Pandemic and NYS DOH/NYS Task Force on Life & the Law. *Allocation of Ventilators in an Influenza Pandemic: Planning Document* [draft]. 2007. Available at: http://www.health.state.ny.us/diseases/communicable/influenza/pandemic/ventilators/docs/ventilator_guidance.pdf; White DB, Katz MH, Luce JM, Lo B (2009). Who should receive life support during a public health emergency? Using ethical principles to improve allocation decisions. *Ann Intern Med* 150(2):132-138.

Generally, the panel concluded that reciprocity is a fairness obligation, but one that needs to be balanced with other objectives and fairness considerations. In this way, reciprocity is a justification for prioritizing some groups of key workers in addition to the justification that they are needed to reduce flu-related mortality and serious morbidity and disruption of critical infrastructures. The type and scarcity of the resource, however, affects whether reciprocity justifies prioritizing one group over another. For instance, though key workers are prioritized to receive vaccines, they are not prioritized to receive ventilators (Section 14.1.2.1). Reciprocity is usually insufficient on its own, but can add weight to prioritizations based on the other considerations.

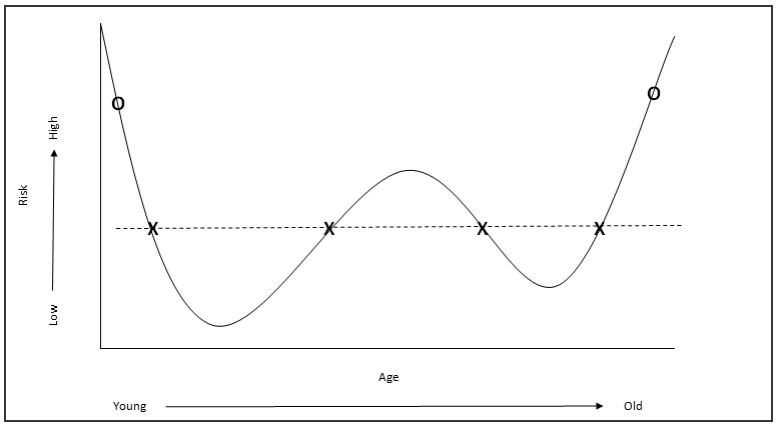
Community member participants stressed the importance of transparency and accountability when identifying who is and is not a key worker. Public support for reciprocity obligations to key workers depends on trust that the criteria for key worker status are narrow, well-defined and not allowed to expand unnoticed and without consequence.

The practical challenges of fairly extending reciprocity obligations to groups in the general population, for example, people who agree to stay home while a household member is infectious, led the panel to set this question aside.

14.1.2.3. Younger people before older (considering age as a non-clinical criterion)

The issue. The participants in this project discussed when age-based rationing might be permissible and ultimately focused on the following question: *After* applying clinical considerations of need and efficacy, when the supply is inadequate to serve all equally prioritized people, is it better to ration randomly or is it ever appropriate to ration based on differences in age? The question is of particular import in a pandemic with a W-shaped age-based mortality curve, because of the unusual way that people of several different ages are at the same risk of dying (Figure 1). If age is not considered, everyone at X risk along the dotted line in Figure 1 would be randomized for the resource. If age is considered, when, how and why should it be considered?

Figure 1: Illustrating Age and Risk on a Hypothetical Age-Based Mortality Curve



Age-based rationing in a pandemic is a controversial but not unprecedented proposal.[156] The ethical appropriateness of rationing on the basis of non-clinical age considerations (quite apart from any age-

[156] DHHS and Department of Homeland Security, 2008; White, 2009; Powell T, Birkhead G, Christ K. Allocation of scarce resources during disasters. [electronic letter] *Ann Intern Med.* (February 13, 2009). Available at: http://www.annals.org/content/150/12/890.1.full.pdf+html; Persad G, Wertheimer A, Emanuel EJ (2009). Principles for allocation of scarce medical interventions. *Lancet* 373(9661):423-431; University of Toronto Joint Centre for Bioethics. *Ethics and Pandemic Influenza: White Paper Series*. 2009. Available at: http://www.canprep.ca/CanPREP_WP_Series.pdf; 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; Jakubowski E. *Eleventh Futures Forum*

associated clinical considerations such as risk of mortality or likelihood of benefit) remains unsettled in the literature on pandemic ethics. Among authors who support prioritizing some age groups before others (e.g., children, anyone under the age of 40, older children and young adults, etc.), many recommend that age be considered *before* or *in combination with* clinical considerations including need and efficacy.

Project participants' perspectives. Non-clinical, age-based rationing was the most challenging ethical issue for project participants.

Each work group recommended to the panel that age could be considered among equally prioritized people under some circumstances. The panel and work groups considered and easily rejected considering differences in age *before* or *simultaneously with* differences in need and efficacy; they were open to considering differences in age only *after* prioritizing access based on need and efficacy. The panel then asked for more input from a broader cross-section of Minnesotans.

A large majority of participants in the community forums and small group discussions and approximately half of those who submitted written comments about age favored considering non-clinical differences in age under limited circumstances and for varied reasons. Some, though, were strongly opposed to ever considering age. Those opposed to any age-based rationing most often favored randomizing among people with similar risk and likelihood of benefiting from the resource.[157] They judged age-based rationing to be unjustifiably discriminatory or too arbitrary to be fair, or said it felt too closely akin to eugenics to be ethically acceptable. A few participants remained undecided about whether and when age-based rationing might be acceptable.

Though there was widespread agreement that age-based rationing is acceptable at times, there was less agreement about how and why to prioritize different age groups within a tier. Many specified ages for prioritization only reluctantly, but did so because they thought it important. The proposed types of age-based rationing within a single tier included:

1. Prioritize children before adults, then randomize among adults;
2. Prioritize across the lifespan starting with children, then young adults, then older adults and the very old;
3. Prioritize children and young adults together (such as everyone <50 years of age) before older adults;
4. Prioritize young adults first, then children and finally older adults; and
5. Prioritize seniors, then other adults, then children.

While no single age-ranking scheme was supported by a majority of participants, most (including panel and work group members), embraced some version of prioritizing younger people before older " (options 1, 2 or 3 above).

A plurality of participants in the two community forums and several in the small groups supported option 4 on various grounds: protecting young adults is the best way to protect children; if society does not protect young parents there will not be enough adults to care for young children and the elderly; and/or young adults are productive, tax-paying workers.

Extremely few participants (and no panel members) advocated option 5. For greater detail about Minnesotans' perspectives on whether, when, how and why to employ age-based rationing see Appendix B.

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on the Ethical Governance of Pandemic Influenza Preparedness. 2008. Available at: http://www.euro.who.int/__data/assets/pdf_file/0008/90557/E91310.pdf.

[157] Another alternative to age-based rationing suggested by some was to preserve the status quo of age distribution. The idea was that scarce resources should be allocated in proportion to the size of different age groups in the population and then distributed randomly within each age group.

Panel recommendations. The panel carefully considered the range of input from Minnesotans about age-based rationing and the overwhelming support for attending to differences in age in some way under limited circumstances in a severe pandemic. Appreciating Minnesotans' diverse perspectives and uncertainty regarding the controversial value question of age-based rationing, the recommendations carefully circumscribe when, how and why age-based rationing may be considered. Consider prioritizing younger people before older—especially children before adults—only:

- When rationing among the general population and without considering age among key workers;[158]
- When rationing among people prioritized in the same tier (that is, among people at the same risk and likelihood of benefit); and
- When it can be justified based on either or both of two fairness considerations: (1) when it fulfills adults' obligations to protect children; and/or (2) it favors younger people who have not yet had as much chance at life as older people. Both are secondary to the five fairness considerations explicitly named in the recommended ethical frameworks.

The panel rejected prioritizing young adults before children, because it felt that doing so would be inconsistent with its commitment to fairness and its rejection of using social value as a rationing criterion.

The ethical frameworks for rationing are context-specific. Treatment antivirals, pandemic vaccines and mechanical ventilators are such different types of health resources that the panel recommended different ways of considering age for each:

Treatment antivirals: Within the same tier consider prioritizing children before adults or prioritizing children and younger adults simultaneously before older adults when and as the supply allows. More specifically:

- Consider prioritizing children under 18. If the supply is inadequate to treat all children, randomize among children.
- If the supply is sufficient to reach all children and a significant number of adults (though far less than everyone in the tier), rather than randomizing among adults consider prioritizing younger adults simultaneously with children. Based on the best available information about the demand and supply, consider specifying the oldest age possible that allows treatment (on a first-come, first-served basis) of the most people in the tier given the supply (such as age 50 and younger). As supply expands, prioritize all remaining ages in the tier before moving to the next tier.

Vaccines: Within the same tier consider prioritizing children before adults, then consider sequentially prioritizing younger adults (such as 18-50, 50-80, >80) before older:

- Consider prioritizing children under 18. If supply is inadequate to vaccinate all children, randomize among children.
- Next, if the supply is sufficient to reach a significant number of adults as well (though far less than everyone remaining in the tier), rather than randomizing among all adults consider sequentially prioritizing younger adults before older. Raise the age limit to vaccinate the largest group of younger adults possible given the supply (such as adults between ages 18 and 50). As supply expands, prioritize all remaining ages in the tier before moving to the next tier.

Mechanical ventilators: Among those similarly prioritized, consider prioritizing children before adults. Among adults, consider prioritizing younger before older if the age difference is very large (such as 20 years or more).

The recommendations to consider prioritizing children before adults are stronger than the recommendations about when Minnesota's health leaders could consider prioritizing younger before older adults. There is less agreement about the ethical acceptability of age-based rationing among adults than about prioritizing children before adults.

[158] No one on the panel, in the work groups or the public engagement activities suggested attending to differences in age among key workers, as differences in age are irrelevant to assessing which functions and roles are needed to protect critical infrastructures.

Most panel members disagreed that children are better protected if young adults receive health-related resources before children in the same tier, because fears about losing an entire generation of young parents are unfounded given the panel's assumptions about a severe pandemic.

The panel also rejected prioritizing some age groups before others based on differences in the purported value of different age groups to society. Judgments that certain groups have greater "social worth" than others were inconsistent with the panel's commitments to fairness.[159]

The panel discussed at length whether prioritizing younger people before older in the same tier would be systematically unfair or even discriminatory. The panel concluded that at times it could be fairer than the alternative, namely, randomizing people without considering significant differences in age, such as 9 versus 90 years of age. The panel agreed that limited, particular attention to age within a single tier in the extreme circumstances of a severe pandemic need not be perceived as wrongful age discrimination.

Attending to age only within a single tier of people equally prioritized based on need and efficacy avoids systematically de-prioritizing older people from protection or access to scarce supplies in a severe pandemic. Age is extremely unlikely to be considered among the general population in tier 1 who are at disproportionately high risk of dying, as the supplies are likely sufficient to meet the demand in the highest tier. Between tiers, when older people are at higher risk than younger people, older people will consistently be prioritized for resources so long as the resources are effective for them. When the resources are less effective, then older people at high risk will be prioritized for indirect protection (e.g., vaccinating the workers who care for them). Another example: If PEP antivirals are safe and effective for immune-compromised groups, then a small supply of PEP antivirals would be reserved for groups at high risk of death who lack alternative protections, such as elderly people during a flu outbreak in a long-term care facility.

Given Minnesotans' differences about how to consider age, these are the panel's most tentative recommendations.

14.1.3. Non-clinical considerations: Rejected by panel

The panel and others who have developed pandemic guidance generally agree that some considerations are unfair bases for rationing, such as ability to pay, social or economic status, political power, race, citizenship and gender. The panel also specifically recommended against considering assessments of quality of life or predictions about how much the length life would be extended. These considerations do not promote the ethical objectives of protecting the population's health, protecting public safety and social order, or protecting Minnesotans from systematic unfairness. Instead, they would harm the common good in a severe pandemic.

14.1.3.1. Quality of life

The panel discussed the appropriateness of de-prioritizing people who would be unaware of any benefit they might receive from a scarce resource, such as people suffering from advanced dementia.[160] Ultimately, though, the panel rejected this criterion because of reluctance to consider the very subjective notion of quality of life and in order to protect against bias and systematic unfairness.

[159] This rejection of "social worth" is not inconsistent with the panel's decision to prioritize the approximately 5% of Minnesotans that comprise the workers whose function is key to supporting core infrastructures. Moreover, the panel agreed that while the need to protect critical infrastructures was important enough to warrant prioritizing key workers, the need to balance fairness with the other objectives requires rejecting prioritization of additional, overwhelmingly large numbers of people in the general population according to their social role.

[160] Few pandemic guidance documents address this issue directly. The New York State Workgroup on Ventilator Allocation in an Influenza Pandemic is an important exception. New York State Workgroup, 2007. Some guidance suggests that severe cognitive impairment may be an exclusion factor in some circumstances. Tacoma-Pierce County Health Department. *Pandemic Influenza Medical Response Model, Revision 1* [draft]. 2007. Available at: http://www.pandemicpractices.org/files/183/183_updated_model.pdf; Hick, 2007.

14.1.3.2. Predictions about life-extension

Some plans consider projected years of life saved when allocating resources.[161] The panel concluded that it is unfair to prioritize access to resources based on differences in anticipated life span (such as likelihood of extending life by five years vs. 15 years) except for the very narrow circumstance of de-prioritizing individuals with an underlying condition that makes it relatively certain that they will die within a couple of weeks or months.

The panel rejected considering differences in years of lives saved because: (1) it would exacerbate health disparities and (2) in a severe pandemic it would be infeasible to access the individual health records necessary to apply the principle fairly. The health disparities concern arises because the life expectancy of some groups, like affluent white women, is significantly higher than the life expectancy for others, like Native American men. The panel rejected considering life expectancy, because it would result in prioritizing privileged groups simply because they are more likely to live longer.[162]

14.1.4. Remove barriers to fair access

The panel struggled with how to protect socially vulnerable groups during a global public health disaster. During a pandemic it will be impossible for a rationing plan to redress all existing disparities in health status and inequities in access to health care. That said, existing disparities must not be exacerbated in a pandemic. If a socially vulnerable group is at heightened risk of mortality and serious morbidity, then the members of that group are prioritized for access accordingly. In addition, the panel strongly recommended steps to remove social, economic, language and geographic barriers to accessing resources. Many access barriers cannot adequately be addressed if responders wait to consider them only after a pandemic has begun. Access barriers must be addressed during the planning process as well as during the pandemic itself. The panel therefore recommends that Minnesotans take reasonable proactive steps in advance of and during the pandemic to reduce access barriers for socially vulnerable groups, while also avoiding inadvertently stigmatizing any groups.

Groups with heightened vulnerability to disease affect the health of the population as a whole. Reducing access barriers and disparities is required first on grounds of fairness, but also on grounds of protecting the population's health.

14.1.5. Fair random processes

The panel (and almost all participants in the public engagements) rejected relying solely on random selection procedures (e.g., flipping a coin, rolling a die or reaching in a jar for a colored ping pong ball) for the population as a whole, without consideration of any other prioritization criteria. Employing random procedures too soon is itself a source of unfairness and can undermine population health and safety objectives. The arbitrariness of distributing antivirals, masks, N95s, vaccines and ventilators purely on the basis of chance is unfair to everyone. The panel maintains that enough will be known about the pandemic (e.g., which groups are at high risk of influenza-related harm, most likely to benefit from the resource, and most necessary to maintain core infrastructure functions) to allow for drawing fair distinctions among different groups. A purely random approach to distributing scarce resources among Minnesotans, including to those who may not need or may not benefit from them, will undermine both population and individual goals and fail to protect all from the worst consequences of a pandemic.

After all ethically relevant considerations (such as risk of dying or serious complications, key worker status, risk of exposure, efficacy of the resource, etc.) are applied and there are still not enough resources for those at a given priority tier, then random processes should be applied. The panel rejected first-come, first-served as a proxy for randomization, because first-come, first-served would exacerbate existing inequities in access to health care resources.

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[161] State of Tennessee Department of Health. *Pandemic Influenza Response Plan [Section 4 Supplement 4: Ethical Allocation of Scarce Resources]* 2006. Available at: http://health.state.tn.us/Ceds/PDFs/2006_PanFlu_Plan.pdf; Persad, 2009; White, 2009.
[162] Vawter DE, Garrett JE, Gervais KG. Considering life-years and age: Another perspective. [electronic letter] *Ann Intern Med* February 23, 2009. Available at: http://www.annals.org/content/150/2/132.abstract/reply; Vawter DE, Garrett JE, Gervais KG, Prehn AW, DeBruin DA (2010). Dueling ethical frameworks for allocating health resources. *AJOB* 10(4):54-56.

Not everyone is sanguine about randomization procedures. Some participants observed that random procedures are more prone to unfairness than prioritizing younger people before older when supplies are insufficient for all equally prioritized people. They warned that many people distrust randomization procedures, because it is notoriously difficult to prevent people with access and power from unfairly circumventing and gaming such procedures to their advantage. To protect against widespread suspicion and cynicism it is essential that the randomization methods be trustworthy, transparent and designed to avoid perceived or real efforts to game the system.

14.2. Considering input from a broader range of Minnesotans

After the panel issued preliminary rationing recommendations in January 2009, the project team and MDH launched an expanded effort to engage more Minnesotans in the conversation. The team:

- Solicited written comments via the web and by mail (Appendix O);
- Conducted two large community forums, one in Owatonna and the other in Duluth (Appendices C – D);
- Conducted nine small group engagements around the state designed to expand on the dialog of the large community forums (Appendices E – M).

The team's methods and results are summarized in Appendix B. The following summarizes the input on the issues most relevant to the final panel report, and explains how the panel incorporated public input into these final recommendations.

14.2.1. Perspectives about ethical objectives for rationing

Results were mixed on whether to rank one or more objectives higher than the others or to balance them equally. Many participants urged that all three be balanced; others suggested that protecting critical infrastructures and/or protecting public health should be first. Most participants recommended re-writing the fairness objective and the panel agreed. The panel considered and rejected ranking the objectives, and chose in the end to recommend that all three objectives be balanced.

14.2.1.1. Protecting the population's health

Participants reinforced the importance of protecting the population's health. The panel retained its commitment to this objective.

14.2.1.2. Protecting public safety and civil order

In general, most participants agreed on the importance of protecting health care, public health, public safety and other critical infrastructures. Two additional infrastructures were often named as potentially meriting priority: (1) infrastructures on which particular vulnerable populations, such as people with disabilities, rely (e.g., personal care attendants, specialized transportation services) and (2) the food industry, ranging from farming and production to wholesale and retail distribution to restaurants.

The panel agreed that the definition of critical public health and health care infrastructures should include infrastructures on which particularly vulnerable populations, such as people with physical disabilities, rely. The definition should be carefully crafted so that only infrastructures truly relied upon for health and personal safety are prioritized.

The panel decided against prioritizing the food industry, in part because the industry is so large that it might exhaust supplies of health resources. It was also suggested that there may be ways other than prioritizing workers for health resources to support and protect the food industry during a severe pandemic.

14.2.1.3. Striving for fairness

The panel's preliminary report separated an ethical principle of "treating people fairly" from a set of more specific goals describing the fairness principle. In the abstract, fairness was often viewed as too lofty. Frequently, the argument was that life isn't fair, getting sick isn't fair, and trying to be fair during a disaster would be impossible. Others opined that fairness is in the eye of the beholder: What one person sees as fair could feel terribly unfair to another. Some participants warned against including an overly broad

ethical objective to “treat people fairly,” as this overpromises and could be counterproductive if it leads to doubt and mistrust. These concerns with fairness were voiced at both large community engagements in Owatonna and Duluth, and to a much smaller extent in the written comments.

The small group engagements offered an important opportunity to delve into perspectives about fairness more deeply. In the small groups, too, many people expressed concerns with the ambitiousness or appropriateness of the original call to “treat people fairly”. Yet, when shown particular ways in which fairness was described (such as not rationing based on gender, race, ability to pay, or first-come, first served), the people who objected to the term “fairness” generally embraced the specific strategies and goals that followed from the fairness principle.

Participants showed their embrace of the fairness principle in other important ways. For most, recognizing morally relevant differences, such as differences in risk of exposure or risk of dying, was accepted as fair. It would be unfair to resort to randomization before attending to such differences. They agreed that rationing decisions should be made and implemented in ways that are transparent and accountable.

Thus, it became clear that the principle of fairness needed to be restated, without losing the substantive and procedural commitments that were behind it. The panel made important changes to every ethical framework in response to public input. Rather than a bald call to “treat people fairly,” this final report says to “strive for fairness and protect against systematic unfairness.” In addition, the list of ways in which fairness is described was moved to a more prominent place with the fairness objective itself. By so doing, the panel retained the fundamental commitment to fairness while addressing the communication challenges that had been a barrier for many during the general public engagement process.

Finally, a commitment to “reduce significant differences in opportunities to live a normal lifespan” that appeared in the preliminary recommendations is not included in the final recommendations. The panel clarified that this fairness concern is secondary. Rather than balance this type of fairness with other core objectives, it only may be considered after the general population has been prioritized based on clinical considerations of high risk of mortality or serious morbidity and the effectiveness of the resource (Section 14.1.2.3).

These important clarifications regarding fairness underscore the multiple meanings of the term and the importance of specifying its precise usage and application.

14.2.2. Perspectives about social vulnerability and access barriers

The panel’s commitment to fairness is in part expressed by its attention to socially vulnerable groups and its call for removing access barriers, both during the process of planning for a severe pandemic and to the extent possible during the pandemic itself. Participants strongly agreed with the panel’s call for identifying and responding to barriers. They urged MDH and other state leaders to work closely with local partners, community representatives and advocates for communities such as the disability community to identify and remove barriers (Appendix B). The conversations in the small groups were particularly rich, and the summaries of those events are replete with concerns and suggestions (Appendices E – M).

Accessible, transparent and consistent communication before, during and in the recovery period after a pandemic is key to supporting the public’s trust in the fairness and reasonableness of rationing activities. Minnesotans will need easy access to accurate, up-to-date information about the pandemic, how resources will be rationed and the rationales for doing so, as well as their options and responsibilities. They will need this information in a wide range of media responsive to differences in language and culture.

14.2.3. Perspectives about age

The panel recommended considering age as a matter of fairness but only after first attending to other fairness concerns. Most participants agreed that age should be attended to in some circumstance, but there was less agreement about how to do so (Section 14.1.2.3 and Appendix B).

15. How Some Groups are Prioritized: A Snapshot

15.1. Socially vulnerable groups

The ethical frameworks attend to the needs of socially vulnerable groups in several ways. Foremost, they balance commitments to public health and fairness, requiring that both be honored simultaneously and equally. Two of the themes that emerged repeatedly during discussion were the need to take proactive steps to reduce access barriers for socially vulnerable groups in advance of a pandemic and the notion that while existing disparities might not be removed during a time of crisis, it is essential that such disparities not be exacerbated and that stigma not be compounded. The panel also prohibited rationing based on differences in socio-economic class, race, gender, citizenship, etc. Judgments about differences in quality of life, life-expectancy and using first-come, first-served as a proxy for randomization were expressly rejected, because they would further disadvantage some socially vulnerable populations. The panel emphasized the need for conducting surveillance during a pandemic to identify groups at high risk of death and serious complications. If particular socially vulnerable groups emerge at high risk of death and serious complications, then they would be prioritized for resources accordingly.

15.2. Particular age groups: Seniors, children and young adults

Project participants were asked to envision a W-shaped, age-based mortality curve, in which infants and young children, older adolescents and young adults, and the elderly are all at high risk of serious complications and death. Thus, these age groups are generally prioritized highly for all resources, so long as the resources are effective. Some of the resources are safer or more effective for some age groups than for others. For example, masks and N95s are unsafe for children aged three and under, so three-year-olds and under are excluded from receiving them. Vaccines were assumed to be relatively less effective among seniors than other age groups, so the elderly would be de-prioritized for vaccines. When a high-risk group is de-prioritized or excluded from a resource, then it is necessary to seek to protect the group in other ways, such as prioritizing them for a safer or more effective alternative (such as antivirals for seniors) or protecting them by protecting those around them so they are not exposed to influenza (such as providing N95s, prophylactic antivirals and vaccines to those who work in nursing homes or hospital neo-natal units).

The frameworks also indicate the limited circumstances when it may be reasonable to ration according to age. Among groups prioritized equally because they are at similar risk of flu-related complications and have a similar response to the resource, when the demand vastly outstrips supply, then it is acceptable to consider prioritizing children before adults. The rationale is that it is fair to prioritize those among us who have not yet had a chance to live into adulthood and because children are vulnerable and need protection. There is some support among Minnesotans to go further and under these very limited circumstances to also consider prioritizing younger adults before older adults, based on similar fairness considerations. But everyone at high risk, regardless of age, would still be prioritized over those at more moderate risk, so long as the resource in question is effective in the high-risk group. The only time those at moderate risk are prioritized over those at high risk is when the resource in question is unsafe or relatively ineffective in the high risk group.

15.3. Key workers

The frameworks prioritize key workers for all resources except for ventilators. Various additional criteria are used in combination with key worker status. These criteria include: risk of death and serious complications; effectiveness of the resource; risk of occupational exposure; irreplaceability in the critical infrastructure workforce; and role in protecting others who are at high-risk of death and serious complications. Thus, for example, a key worker who is at high risk of death and serious complications is prioritized for preventive resources and treatment antivirals over other key workers who are not at high risk. Key workers who are at disproportionately high risk of exposure, such as health care workers caring for influenza patients in intensive care units and performing aspirating procedures, are also highly prioritized.

16. Rationing as Part of a Comprehensive Plan

This project focused on a few scenarios involving the rationing of different types of health-related resources during different degrees of scarcity. The panel was not charged with evaluating its recommendations in the context of the state's complete pandemic response. Before implementing a rationing plan, all resources and other pandemic responses (such as school and business closures) should be considered together as a comprehensive package. The final plan should be adjusted so that the resources and strategies collectively best serve our common good and so that no demographic group is systematically de-prioritized from protection.

17. Conclusion

With the Minnesota Pandemic Ethics Project, the state joins a small cadre of states and nations in developing ethics guidance for a severe influenza pandemic. The project's resource allocation panel offers a set of ethical frameworks for rationing several types of health-related resources—scaled to different levels of scarcity—to be used as decision-making tools. The panel members concluded that no single ethical commitment or objective is sufficient to guide the rationing of different health care resources. They further agreed that no single framework is adequate to address resources that vary in their purpose, supply and efficacy.

The Minnesota Pandemic Ethics Project demonstrates that extended public engagement on scientifically and ethically complex questions on rationing—one of the most divisive topics arising in health policy—is both feasible and productive. As the Minnesota Commissioner of Health assured more than once, the ethical guidance offered here needed to reflect the "fingerprints and footprints" of as many Minnesotans as possible.[163] Because the consequences of rationing during a severe pandemic would be felt by everyone, rationing decisions should reflect the values of as many Minnesotans as possible. These recommendations reflect the thoughtful, extensive input of hundreds of people across the state and evince the value of genuine collaboration around health policy and public health ethics.

[163] Minnesota Commissioner of Health Sanne Magnan, MD, PhD. Oral statements made during a media event at the Minnesota Department of Health, St. Paul, MN (January 30, 2009) and at the Community Forum in Duluth, MN (May 2, 2009).

Appendix A: Panel and Work Group Members

Affiliations are listed in order to show the breadth of participation, but participants were not asked to represent or bind their respective organizations.

Resource Allocation Panel Members

J. Eline Garrett, JD, Minnesota Center for Health Care Ethics (co-chair)
Karen G. Gervais, PhD, Minnesota Center for Health Care Ethics (co-chair)
Dorothy E. Vawter, PhD, Minnesota Center for Health Care Ethics (co-chair)
Owais Bayunus, Islamic Center of Minnesota
Barbara Bor, RN, ICP, CIC, University of Minnesota Medical Center, Fairview
Julie Brunner, JD, Minnesota Council of Health Plans
Donald Brunnquell, PhD, Children's Hospitals & Clinics of Minnesota
Rynn Burke, RN, MD
Mary Quinn Crow, Northfield Hospital
Debra A. DeBruin, PhD, University of Minnesota Center for Bioethics
Matthew P. Eggebrecht, Phillips Neighborhood Clinic
Kris Eide, Minnesota Homeland Security & Emergency Management
James Franklin, Minnesota Sheriffs' Association
Jim Gangl, St. Louis County Public Health & Human Services
Ora Hokes, Sabathani Community Center, Inc.
Pamela Hoopes, JD, Minnesota Disability Law Center
Jeffrey Kahn, PhD, MPH, University of Minnesota Center for Bioethics
Allan Kind, MD, Park Nicollet Health Services
Barbara A. Koenig, PhD, RN, Mayo Clinic
J. P. Leider, University of Minnesota Center for Bioethics
Joan Liaschenko, RN, PhD, FAAN, University of Minnesota Center for Bioethics
Jan Malcolm, Courage Center
Mary Faith Marshall, PhD, University of Minnesota Center for Bioethics
Elizabeth McClure,MD, University of Minnesota Center for Infectious Disease Research and Policy
Ruth Mickelsen, JD, MPH, MA, Minnesota Center for Health Care Ethics
Steven Miles, MD, University of Minnesota Center for Bioethics
James Nordin, MD, MPH, HealthPartners Research Foundation
Elizabeth Parilla, MPH, University of Minnesota Center for Bioethics[164]
Bruce Pederson, Fairview Health Services
Angela Witt Prehn, PhD, Minnesota Center for Health Care Ethics
Holly Rodin, PhD, Service Employees International Union St. Paul
Laura Rydholm, MSN, BAN, Presentation College
Art Serotoff, Sabathani Community Center, Inc.
Patrick Shea, City of St. Cloud
Mary Sheehan, RN, MPH, Chisago County Department of Health and Human Services
Sharon Smith, White Earth Tribe
Patsy Stinchfield, RN, MS, CPNP, Children's Hospitals & Clinics of Minnesota
Carol A. Tauer, PhD, University of Minnesota Center for Bioethics
Mao Heu Thao, St. Paul/Ramsey County Department of Public Health; Hmong Healthcare Professionals
Mary Jane Thompson, RN, Minnesota Board on Aging
Sandy Tubbs, Douglas County Public Health
Don Uden, PharmD, FCCP, University of Minnesota College of Pharmacy
Susan M. Wolf, JD, University of Minnesota Center for Bioethics
Daniel Yeazel, Community Presbyterian Church

[164] When Ms. Parilla accepted a position with the Minnesota Department of Health, she moved to a solely advisory role on the project. Inclusion in this list reflects her early contributions to the panel.

Ad Hoc Advisors to the Resource Allocation Panel

Minnesota Department of Health
Denise Dunn, RN, MPH (facilitator)
Craig Acomb
Judy Bifulk, RN, BSN
Patricia Bloomgren, MS
Jane Braun, MS, CTR
Jo-Ann Champagne
Norman Crouch, MS, PhD
Kristen Ehresmann, RN, MPH
Buddy Ferguson
Jane Harper, RN, MS, CIC
Wendy Kvale
Michelle Larson
Aggie Leitheiser, RN, MPH
Emily A. Litt, RN, MSN, DNP, PHN
Franci Livingston, JD, MPH
Ruth Lynfield, MD
LuAnne McNichols, RN, MN
Jean Rainbow, RN, MPH
Sarah Roach
Don Sheldrew, MSW, LICSW, NREMT-P
Christopher Tate, MPH
Pat Tommet, RN, PhD, CNP

Minnesota Department of Human Services
Virginia Casey
Nancy J. Doucette, MPH, CHES
Neil Doughty, MS, LP
Alan Q. Radke, MD, MPH
Munna Yasiri

Minnesota Department of Administration
Todd Christenson (formerly from Minnesota Department of Employee Relations)

Minnesota Department of Public Safety
Victoria Fodor
Barb Fonkert
Onalee Grady-Erickson
Robert Hines

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Antivirals Work Group

J. Eline Garrett, JD, Minnesota Center for Health Care Ethics (co-chair)
Dorothy E. Vawter, PhD, Minnesota Center for Health Care Ethics (co-chair)
Jean Rainbow, RN, MPH, Minnesota Department of Health (facilitator)
Sheri Altepeter, Polk County Public Health
Judy Bifulk, RN, BSN, Minnesota Department of Health
Aaron DeVries, MD, MPH, Minnesota Department of Health
Denise Dunn, RN, MPH, Minnesota Department of Health
Mariclaire England, RN, BSN, Minnesota Board of Nursing
Karen G. Gervais, PhD, Minnesota Center for Health Care Ethics
Robert Hines, Minnesota Department of Public Safety
Ruth Lynfield, MD, Minnesota Department of Health
Elizabeth Parilla, MPH, University of Minnesota Center for Bioethics
Alan Q. Radke, MD, MPH, Minnesota Department of Human Services
Kevin Sell, Minnesota Department of Health
James Swenson, JD, Hennepin County District Court
Dean Tsukayama, MD, Hennepin County Medical Center

Ethics Work Group

J. Eline Garrett, JD, Minnesota Center for Health Care Ethics (co-chair)
Karen G. Gervais, PhD, Minnesota Center for Health Care Ethics (co-chair)
Dorothy E. Vawter, PhD, Minnesota Center for Health Care Ethics (co-chair)
Denise Dunn, RN, MPH, Minnesota Department of Health (co-facilitator)
Emily A. Litt, RN, MSN, DNP, PHN, Minnesota Department of Health (co-facilitator)
Donald Brunnquell, PhD, Children's Hospitals & Clinics of Minnesota
Neil Doughty, MS, LP, Minnesota Department of Human Services
Debra A. DeBruin, PhD, University of Minnesota Center for Bioethics
Buddy Ferguson, Minnesota Department of Health
Pamela Hoopes, JD, Minnesota Disability Law Center
J. P. Leider, University of Minnesota Center for Bioethics
Joan Liaschenko, RN, PhD, FAAN, University of Minnesota Center for Bioethics
Mary Faith Marshall, PhD, University of Minnesota Center for Bioethics
Ruth Mickelsen, JD, MPH, MA, Minnesota Center for Health Care Ethics
Elizabeth Parilla, MPH, University of Minnesota Center for Bioethics
Bruce Pederson, Fairview Health Services
Angela Witt Prehn, PhD, Minnesota Center for Health Care Ethics
Don Sheldrew, MSW, LICSW, NREMT-P, Minnesota Department of Health
Christopher Tate, MPH, Minnesota Department of Health
Carol A. Tauer, PhD, University of Minnesota Center for Bioethics

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N95 Respirators/Surgical Masks Work Group

J. Eline Garrett, JD, Minnesota Center for Health Care Ethics (co-chair)
Dorothy E. Vawter, PhD, Minnesota Center for Health Care Ethics (co-chair)
Jane Harper, RN, MS, CIC, Department of Health (facilitator)
Patricia Bloomgren, MS, Minnesota Department of Health
Barbara Bor, RN, ICP, CIC, University of Minnesota Medical Center, Fairview
Todd Christenson, Minnesota Department of Administration (formerly from Minnesota Department of Employee Relations)
Cheryl Colton, CIH, MPH, Allina Health Systems
Denise Dunn, RN, MPH, Minnesota Department of Health
Karen G. Gervais, PhD, Minnesota Center for Health Care Ethics
Rob Hines, Department of Public Safety
Birch Holt, Target
Jim Kubisiak, Minnesota Department of Employee Relations
J. P. Leider, University of Minnesota Center for Bioethics
Elizabeth Parilla, MPH, University of Minnesota Center for Bioethics
Mitch Peterson, Torgerson Properties
Angela Witt Prehn, PhD, Minnesota Center for Health Care Ethics
Jason Reames, RPh, Cub Foods
Christopher Tate, MPH, Minnesota Department of Health
Mary Jane Thompson, RN, Minnesota Board on Aging
Nicole Vars McCullough, PhD, CIH, 3M

Vaccine Work Group

J. Eline Garrett, JD, Minnesota Center for Health Care Ethics (co-chair)
Dorothy E. Vawter, PhD, Minnesota Center for Health Care Ethics (co-chair)
Denise Dunn, RN, MPH, Minnesota Department of Health (facilitator)
Judy Bifulk, RN, BSN, Minnesota Department of Health
David Brandwein, 3M
Mary Carrol, Minnesota Visiting Nurse Association
Kristen Ehresmann, RN, MPH, Minnesota Department of Health
Karen G. Gervais, PhD, Minnesota Center for Health Care Ethics
Cynthia Hiltz, RN, MS, School Nurse Organization of Minnesota
Robert Hines, Minnesota Department of Public Safety
Barb Hoegland, Bethel Nurse Educator
J. P. Leider, University of Minnesota Center for Bioethics
James Nordin, MD, MPH, HealthPartners Research Foundation
Elizabeth Parilla, MPH, University of Minnesota Center for Bioethics
Angela Witt Prehn, PhD, Minnesota Center for Health Care Ethics
Mary Sheehan, RN, MPH, Chisago County Department of Health & Human Services

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Ventilator Work Group

J. Eline Garrett, JD, Minnesota Center for Health Care Ethics (co-chair)
Dorothy E. Vawter, PhD, Minnesota Center for Health Care Ethics (co-chair)
Pat Tommet, RN, PhD, CNP, Minnesota Department of Health (facilitator)
Rynn Burke, RN, MD
Debra A. DeBruin, PhD, University of Minnesota Center for Bioethics
Denise Dunn, RN, MPH, Minnesota Department of Health
Karen G. Gervais, PhD, Minnesota Center for Health Care Ethics
Jayne Griffith, MA, MPH, Minnesota Department of Health
John Hick, MD, Hennepin County Medical Center
Mary Helen Hoffman, Fairview Home Care and Hospice
Allan Kind, MD, Park Nicollet Health Services
Nick Kuhnley, RCP, RRT, North Memorial Health Care
Wendy Kvale, Minnesota Department of Health
J. P. Leider, University of Minnesota Center for Bioethics
Joan Liaschenko, RN, PhD, FAAN, University of Minnesota Center for Bioethics
Mary Faith Marshall, PhD, University of Minnesota Center for Bioethics
Ruth Mickelsen, JD, MPH, MA, Minnesota Center for Health Care Ethics
Sheila Mirembe-Larsen, Minnesota Department of Health
Elizabeth Parilla, MPH, University of Minnesota Center for Bioethics
Don Postema, PhD, Gillette Children's Specialty Health Care
Angela Witt Prehn, PhD, Minnesota Center for Health Care Ethics
Thomas Schrup, MD, CentraCare Health System
Laura Vose, MD, CentraCare Health System

Protocol Committee

Members of the protocol committee are listed in the companion report: DeBruin DA, Marshall MF, Parilla E, Liaschenko J, Leider JP, Brunnquell D, Garrett JE, Vawter DE. *Implementing Ethical Frameworks for Rationing Scarce Health Resources in Minnesota during Severe Influenza Pandemic,* University of Minnesota Center for Bioethics and Minnesota Center for Health Care Ethics. 2010. Available at: http://www.health.state.mn.us/divs/idepc/ethics/.

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Appendix B: Synthesis of Community Forums, Small Group Engagements and Written Comments

The Minnesota Pandemic Ethics Project embraced public engagement as its method from the outset, involving close to 600 Minnesotans by the project's end. The work of over 100 Minnesotans with a wide range of expertise and experience was represented in the preliminary ethical recommendations issued in January 2009. In the following months the project's reach was expanded, with a series of strategies to obtain the input of a broader and larger range of Minnesotans. These new public engagement activities were launched on January 30, 2009, with a media event featuring Minnesota Commissioner of Health Sanne Magnan, MD, PhD, State Epidemiologist Ruth Lynfield, MD, and project team members J. Eline Garrett, JD, and Debra A. DeBruin, PhD.

The project team employed three public engagement strategies in 2009:

1. Issuance of the preliminary recommendations for written comments.
2. Two six-hour community forums, together reaching approximately 200 members of the general public. The forums were conducted in Owatonna and Duluth, Minnesota.
3. Nine six-hour small group engagements, each reaching 11 – 16 people (125 total). These were conducted in various locations in the Twin Cities and around the state.

Public engagement project team

Various subsets of the main Minnesota Pandemic Ethics Project Team led this work:

- Team members for soliciting written comments (written comments team):
  - Minnesota Center for Health Care Ethics(MCHCE): J. Eline Garrett (MCHCE team leader), Karen G. Gervais, Angela Morley,[165] Angela Witt Prehn and Dorothy E. Vawter
  - University of Minnesota Center for Bioethics (UMCB): Debra A. DeBruin (UMCB team leader), Joan Liaschenko, and Angela Morley
- Team members for conducting the two community forums (community forums team):
  - Minnesota Department of Health (MDH): Ruth Lynfield (principal investigator) and Franci Livingston
  - Minnesota Center for Health Care Ethics: J. Eline Garrett (MCHCE team leader), Julia Anderson, Karen G. Gervais, Kerry Hjelmgren, Angela Morley, Angela Witt Prehn and Dorothy E. Vawter
- Team members for conducting the nine small group engagements (small group team):
  - Minnesota Center for Health Care Ethics: J. Eline Garrett (MCHCE team leader), Julia Anderson, Karen G. Gervais, Kerry Hjelmgren, Angela Morley, Angela Witt Prehn and Dorothy E. Vawter
  - University of Minnesota Center for Bioethics: Debra A. DeBruin (UMCB team leader), Joan Liaschenko, and Angela Morley

Process

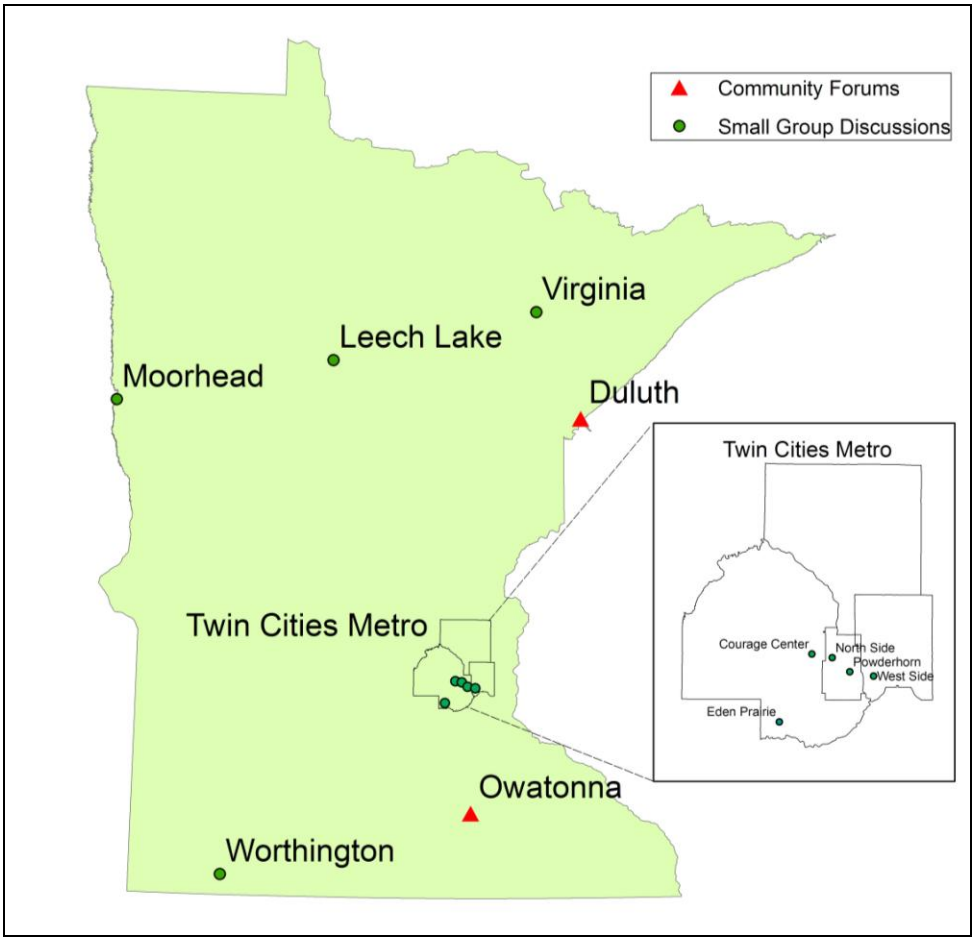
Solicitation of written comments

The written comments team posted the preliminary recommendations for public comment the web. Lists of "questions to think about" accompanied electronic copies of *For the Good of Us All: Ethically Rationing Health Resources in Minnesota in a Severe Influenza Pandemic: Preliminary Report,* and *Implementing Ethical Frameworks For Rationing Scarce Health Resources in Minnesota During Severe Influenza Pandemic: Preliminary Report,* with space for public comment. The team asked for input on the overarching values that should guide rationing, age-based rationing, palliative care and how to attend to socially vulnerable groups including concerns about barriers to access. The team also asked for any comments the public might have on any aspect of the recommendations, without regard to specific questions asked on the website. The team mailed a printed copy of the reports to people who mailed or phoned to request it. The team accepted comments via the web and mail.

[165] Ms. Morley was employed part-time by both MCHCE and UMCB during this project.

Comments were sought from both individuals and organizations, and from those who consider themselves pandemic or disaster planners along with the general public. Extensive print, radio and television coverage was received following the January 30, 2009, media event, and that coverage generated many comments on the website. The written comments team and MDH also widely circulated invitations to comment via email and existing list serves.

Map: Community Forums and Small Group Engagements



Community forums

Site selection

Site selection began before the project was funded and continued thereafter. Sites were chosen based on the availability of interested partners and volunteers, diversity needs of the project as a whole, availability of suitable conference facilities and likelihood of attracting the targeted 100 people per event. When MDH learned of the opportunity to seek CDC funding for public engagement projects, it invited all local public health and tribal health departments in Minnesota to express interest. The Public Health Department for Steele County, located in the farmland of south-central Minnesota and whose county seat is the small city of Owatonna, indicated its enthusiastic interest.

The community forums team agreed that the second community forum should also be conducted outside of the Twin Cities. All of the meetings leading up to the development of preliminary recommendations were held in St. Paul and most of the more than 100 people who participated in developing those recommendations were from the Twin Cities. It was important to extend the work into Greater Minnesota. Duluth was chosen as the site for the second event, because it is the largest city in the northern half of

Minnesota and because it offered an opportunity further to diversify public input into the project. Northern Minnesota's economic base and geography differs greatly from southern Minnesota's. Duluth is a major port on Lake Superior, is a hub of the region's timber and mining industries, is located near the reservation of the Fond du Lac Band of Lake Superior Chippewa and is the southern gateway to the resort communities along Lake Superior's north shore. Local partners were quickly identified, and they readily agreed to volunteer time and energy to the project.

National partners and funding

The CDC funded the community forums through a cooperative agreement with MDH. Following a competitive application process, CDC chose Minnesota as one of six states to pilot public engagement activities in pandemic influenza planning. Ruth Lynfield, MD, state epidemiologist, was the principal investigator. MDH contracted with MCHCE to design and conduct the community forums. The CDC's six-state project had five purposes: 1) to inform and assist local decision-makers involved in pending, values-oriented policy decisions related to pandemic influenza planning; 2) to evaluate the effectiveness of engaging both citizens-at-large and other stakeholders in public health policy decisions; 3) to increase state and local capacity to engage the public effectively on policy choices; 4) to empower citizens to participate effectively in public decision-making work; and 5) to achieve results that enhance public trust in public health decisions regarding policy choices. The other states funded through the CDC's program were Hawaii, Massachusetts, Nebraska, Ohio and Washington. The CDC had an active role in the planning and execution of each of these state projects. The CDC also funded the University of Nebraska Public Policy Center to evaluate the projects.

As part of the cooperative agreement, additional facilitation assistance was provided by The Keystone Center. The Keystone Center's staff contributed to planning the events, handled registration and other logistics, assisted with training the small group facilitators and notetakers, provided and ran the audience response system (electronic keypads for polling), and served as small group facilitators and notetakers. The Keystone Center also paid for advertisements to publicize the events and support recruitment.

Local partners

The community forums team recruited local partners for each event, whose names are included in Appendices C – D. The local partners provided invaluable guidance in date and venue selection. They worked diligently to publicize the event and recruit participants. Many volunteered as small group facilitators or notetakers and helped to recruit others to serve in such capacities.

Recruitment

The team's goal was to reach as diverse a population as possible, recognizing that the small group engagements would offer additional opportunities to diversify public input. The team actively encouraged people with expertise in disaster or pandemic planning to volunteer to be trained as small group facilitators or notetakers, and to discourage them from registering as participants. The voices of professionals were well-heard as the preliminary recommendations were developed and in the written comments, so the forums and small group engagements were viewed as important opportunities to hear from the general public.

The events were conducted in English, and American Sign Language Translation was made available upon request. No one requested ASL translation.

Given a limited advertising budget, the community forums team and its local partners employed a variety of relatively inexpensive but time-intensive recruitment activities. Local partners encouraged participation by word-of-mouth, announcements at public meetings, and distributing hundreds of flyers at area businesses, hospitals, clinics, public gathering places, and faith communities. The team aggressively sought free media coverage and was particularly successful in securing print and radio coverage. The radio coverage reached diverse markets, with news spots and interviews on talk and music programs geared to different age groups and listening preferences. Local partners were invaluable in advising where to place advertisements. Advertisements were placed in local newspapers and the "shopper" circulars that were distributed freely to all residents across multiple towns and counties.

Participants who attended the full six-hour event received a small stipend to help cover any expenses, such as childcare or transportation, and acknowledge the value of their time. Continental breakfast, lunch and refreshments were provided.

Format

The format is described in greater detail in the summaries of the Duluth and Owatonna events (Appendices C – D).

The team employed a combination of techniques during these six-hour engagements, each conducted on a Saturday. The days opened with presentations on pandemic influenza and the preliminary ethical recommendations for rationing in order to ground participants in the subject matter. Participants engaged in small and large group facilitated discussions concerning (1) ethical objectives for rationing and (2) age-based rationing. The small group discussions were conducted around tables of 8 – 10 people, plus a trained facilitator and notetaker for each. Nearly 60 people, mostly volunteers, were trained as facilitators and notetakers. They were recruited mostly from state and local health departments, local partner organizations, hospitals, colleges and emergency and disaster response organizations.

Participants were polled twice during the day using audience response technology. The last exercise of the day tasked participants individually to arrange a set of cards, prioritizing the groups depicted in the cards for access to a scarce influenza treatment (Appendix N).

Small group engagements

Site selection

The small group team used county and state census data to guide selection of particular communities, seeking diversity in many respects:

- Geography
- Recent experience with disaster response (e.g., Red River flooding)
- Socio-economic status
- Race and ethnicity
- People with and without disabilities
- Age
- Gender

To this end, the team chose the following communities and agreed to divide leadership and facilitation between the two ethics centers as follows:

- MCHCE-led events
  - Courage Center, Minneapolis
  - Eden Prairie
  - Moorhead
  - Virginia
  - West Side, St. Paul
  - Worthington
- UMCB-led events
  - Leech Lake Band of Ojibwe, Walker
  - North Side Neighborhood, Minneapolis
  - Powderhorn/Phillips Neighborhood, Minneapolis

Local partners

A local organization or individual was retained in each community to provide logistical advice and support and to manage recruitment. Different kinds of organizations (or individuals with varying connections) were tapped in each community, so that their varied ways of connecting with their communities could lend to the project's diversity overall.

- Clay County Public Health, Moorhead, whose proximity to Clay County Services made it possible to recruit people receiving public assistance, including homeless people, as well other residents in the area, most of whom had experienced a recent flood disaster;
- Courage Center, Minneapolis, a nonprofit organization serving people with disabilities;
- Community Education Division of Independent School District 518, Worthington, which offers a wide range of enrichment programs for all ages;
- Peggy Kvam, Eden Prairie, an active member of the League of Women Voters;
- Leech Lake Band Health Division, which serves the health needs of tribal members;
- Minneapolis Urban League, which assisted in recruitment for both the North Side and Powderhorn/Phillips Neighborhood events;
- Phillips Neighborhood Clinic, a free clinic in an ethnically diverse and low-income urban neighborhood;
- Virginia Rotary Club, whose members are active in service to others;
- West Side Citizens Organization, a organization in an ethnically diverse neighborhood empowering residents to participate in and advocate for solutions to West Side community issues.

Recruitment

The small group team's goal was to reach as diverse a population as possible. The team discouraged health care professionals and people with expertise in disaster or pandemic planning from registering for the events. Such professionals had already had extensive opportunities for input.

Local partners were in charge of recruiting the targeted 11 – 15 people for each group. The team created flyers for distribution. Local partners used a variety of techniques to recruit participants, including word-of-mouth, seeking free coverage in local print news media, and liberal distribution of flyers. No paid advertisements were used. Recruitment targets were met for all events, and in a few cases interested people were turned away for lack of space.

For the most part, the project budget limited the ability to include non-English speakers. Bilingual volunteers provided free Spanish translation at the Powderhorn/Phillips Neighborhood engagement.

Courage Center advised that its event be split into three-hour sessions, because an all-day session would be physically burdensome for many participants. Accordingly, recruitment was targeted to people with disabilities who had sufficient oral communication capacity and physical endurance to participate in two three-hour sessions. The team compensated Courage Center for providing personal care attendants for participants who required them.

Participants who attended the full six-hour event (or both three-hour events) received a stipend to help cover any expenses, such as childcare or transportation, and acknowledge the value of their time. Meals and refreshments appropriate to the time of day were provided. As anticipated, a few registrants did not attend. There was no attrition in any of the events that were held on successive evenings.

Format

The format of small group activities is described in the summaries of each event in Appendices E – M. The team patterned the nine small group engagements on the preceding community forums. The methods employed were similar and the length (six hours) was the same. The small group format allowed more in-depth discussion and exploration of an additional topic, because there was no need to switch back and forth between large and small group discussion. Three of the events were single, six-hour sessions; the remaining were divided into two three-hour discussions on successive evenings. Background in the form of oral presentations about pandemic influenza and preliminary ethical recommendations was provided. Ample time was allotted for questions and discussion after the presentations. The topics explored at each were (1) ethical objectives for rationing, (2) age-based rationing, and (3) barriers to access to resources. The last exercise of the day tasked participants individually to arrange a set of cards, prioritizing the groups depicted in the cards for access to a scarce influenza treatment (Appendix N).

Demographic data about participants

Participants in the large and small group engagements, as well as those who submitted written comments were asked voluntarily to provide demographic information about themselves. Comparable data were not collected in all steps of the process. Aggregated data for the largest number of each set of respondents are provided below. More detail is contained in Appendices C – M and O.

Total number of participants (not all of whom volunteered demographic information):

- Written: 116 individuals; 12 organizations
- Community forums: 200
- Small groups: 125
- Total: 453

Gender: small groups, community forums and written comments

- Female: 66%
- Male: 34%

Minnesota residence: small groups, community forums and written comments

- Metro: 35%
- Non-metro: 65%

Age: small groups and written comments

- 18 – 29: 15%
- 30 – 39: 10%
- 40 – 54: 33%
- 55 – 64: 21%
- 65 – 84: 21%

Ethnicity: small groups and community forums

- Hispanic/Latino: 9%
- Non-Hispanic/Latino: 87%
- Unknown: 2%

Race: small groups and community forums

- American Indian/Alaska Native: 10%
- Asian: 1%
- Black: 8%
- Native Hawaiian/Pacific Islander: 1%
- White: 82%
- Other: 4%

Synthesis of results

The results of each of the public engagement activities are described in more detail in Appendices C – M and O. This is a brief synthesis of results on the areas of most importance to the panel's work.

Ethical objectives for rationing

Many participants supported balancing the objectives as proposed, but many others expressed discomfort with regard to the way the objective of fairness was presented. Fairness was viewed as too lofty a goal. Their argument was that life isn't fair, getting sick isn't fair, and trying to be fair during a disaster would be impossible. This theme emerged at the Owatonna forum and many in Duluth echoed it. The small group engagements offered an important opportunity to delve into this concern more deeply. In the small groups, too, many people expressed concerns with the ambitiousness or appropriateness of the fairness principle. Some voiced distrust that they or their communities would be treated fairly, even if fairness was included as a principle. Yet, when shown the particular ways in which fairness was

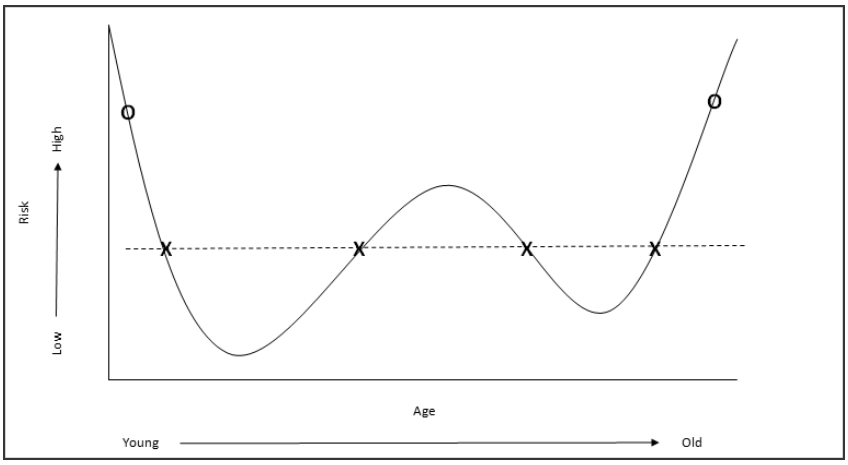
described (such as not rationing based on gender, race, ability to pay, or first-come, first served), the people who objected to the term “fairness” generally embraced the specific strategies and goals that followed from the fairness principle. Thus, it became clear that the principle of fairness needed to be restated, without losing the substantive commitments that were behind it. Accordingly, the panel clarified the fairness objective so that it would be more clearly understood and embraced.

Age-based rationing

There may be times when the supply of a given resource is too small to serve all similarly prioritized people. The panel asked for public perspectives on the question of whether age should ever be used to prioritize among groups of people who are at the same level of risk of flu-related mortality and serious morbidity. The alternative would be to straightaway resort to randomization.

The following figure was used to illustrate how different ages can be at the same level of risk.

Figure 1: Illustrating Age and Risk on a Hypothetical Age-Based Mortality Curve



In the above graph, the question was about whether to use age to ration among those at X level of risk. Participants were asked to assume that people above X level of risk (e.g., people at “O” risk level) would already have received treatment. Participants were also asked to assume that ill key workers had already been treated.

A large majority of participants, including those who addressed age in written comments, supported age-based rationing at times. The results were mixed when participants addressed the question of which age groups should come first. In the Duluth forum and seven of nine small discussion sites, two-thirds or more of the participants prioritized:

- Children before adults;
- Children and young adults; or
- Young adults, then children, followed by older adults and seniors in ascending order of age.

While no single age-ranking scheme was supported by a majority of participants, more than a third of participants supported prioritizing children and roughly a third of participants supported age-based rationing across the lifespan. In four out of nine small discussion groups, two-thirds or more of the participants prioritized children before adults. Very few participants prioritized seniors; indeed, almost half of participants went so far as to de-prioritize seniors over the age of 85.

The justifications for and against age-based rationing were varied, but for the most part fell into a few large categories:

Those who supported prioritizing children offered the following kinds of arguments:

- It's fair to prioritize children:
  - Children haven't had a chance to live a full life;
  - They don't have the capacity to protect themselves; adults owe them protection;
  - They don't have a seat at the table in policy decisions and voting.
- Children are special; it is instinctive to protect children.
- We need children, because they will be the ones each of us relies on in the future.

Some participants agreed with the importance of protecting children, but said that the best way to do so would be either to prioritize their parents first (analogizing to airline attendants' admonishments to put on one's own oxygen mask before helping others) or to prioritize parents at the same time as children. Others disagreed, claiming that expanding the first priority group to include parents would mean that there might not be enough to go around for children. It's worse to contemplate children dying than orphaning them.

Participants who supported rationing across the lifespan (starting with children and then prioritizing younger adults before older) offered the following kinds of arguments:

- It's fair to consider age. Younger people haven't had as much chance to live a full life as older people.
- Many older people prioritize younger people generally, not just minor children.
- Each generation is valued for different reasons, and should be prioritized in the following order:
  1. Children are special; they deserve protection; they don't have a seat at the table in policy decisions and voting; they are our future.
  2. Young adults are the parents of young children and should be next in line for protection. Along with older adults, they are the most productive members of society. We will need them in order to recover from the pandemic.
  3. Older adults are the bridge between generations, caring for both children and elders. Along with younger adults, they are the most productive members of society. We will need them in order to recover from the pandemic.
  4. Elders are valued for their wisdom and experience and for the roles many of them still play as caretakers.

A small minority objected to all age-based rationing:

- All age groups are equally valued and valuable. Age discrimination is wrong.
- Using age is too arbitrary to be fair.
- There is a risk of adverse social consequences if Minnesota picks the "wrong" age group to prioritize. For example, prioritizing children but not their parents could create orphans.

Attending to social vulnerabilities and removing barriers to fair access to resources

The panel's commitment to fairness is in part expressed by its attention to socially vulnerable groups, including groups suffering health disparities and the disabled community. Participants generally stressed the importance of paying attention to the needs of vulnerable populations and not overlooking them in the urgency of pandemic response. They also strongly called for including diverse representation in the planning process.

It also calls for removing access barriers, both during the process of planning for a severe pandemic and to the extent possible during the pandemic itself. Written comments were solicited about the panel's attention to social vulnerabilities and about access barriers. Small group participants were asked specifically about barriers that are concerning to them and for ideas about how best to address them.

The conversations about vulnerability and access barriers in the small groups were particularly rich, and the summaries of those events are replete with concerns and suggestions (Appendices E – M). Few of those who submitted written comments expressly addressed the general topic of social vulnerabilities. Those who did called for even greater attention to the needs of groups already suffering health disparities. Several more written comments included suggestions about removing barriers.

The kinds of barriers mentioned include:

- Communication
- Language
- Inaccurate or unnecessarily alarming media coverage
- Trust
- Lack of documentation demonstrating legal status
- Lack of insurance, inadequate coverage
- Poverty
- Transportation/mobility issues
- Distance to care
- Particular barriers experienced by people with disabilities

Many solutions were offered, such as:

- Educate the general public about influenza and strategies for personal and community response. Culturally responsive education should be provided in many languages and in combinations of oral and written materials. Locally trusted leaders and organizations should be empowered as educators.
- Draw on the strength of communities and partner with local businesses and service organizations to assist, such as forming networks of people to provide transportation to mass-dispensation sites for health-resources and home delivery to the homebound.
- Use easily accessible sites, including sites that are on bus or other mass transportation lines, or mobile units for distribution of resources.
- Modify plans for mass distribution of resources to meet the needs of people with disabilities, and in particular allow people in wheelchairs to receive resources at their homes or in sites other than those set up for mass distribution.
- Credibly assure that immigration authorities will not be present or involved with the delivery of public health or health care services.
- Provide resources freely or at low cost, considering the needs of poor people and under- and un-insured people.

Participants stressed the importance of identifying and responding to barriers. Ethical rationing plans are not useful if they cannot be implemented fairly. They urged MDH and other state leaders to work closely with local partners, community representatives and advocates for communities such as the disability community to identify and remove barriers.

Conclusion

Most participants in the events expressed sincere appreciation for the opportunity to provide input. They were similarly impressed with the educational opportunity the events afforded and voiced a new understanding of the complexity of pandemic-related policy-making. The events were not disconnected from political, economic and cultural experiences, so events in a few communities were at times marked by degrees of mistrust. Even in these events, participants valued the opportunity to provide input and learn about pandemic. They expressed empowerment to extend pandemic education and planning into their communities. Many participants were effusive, explicitly stating the value of the democratic process to allow citizens a voice in policy-making.

Appendix C: Community Forum, Duluth

College of St. Scholastica
May 2, 2009
9:00 a.m. – 3:00 p.m.

Forum contributors

Minnesota Pandemic Ethics Project Resource Allocation Panel Representatives

Jim Gangl
Allan Kind

Minnesota Department of Health (MDH)

Marilyn Cluka
Richard Danila
Franci Livingston
Ruth Lynfield
Marie Margitan
Jean Rainbow
Amy Westbrook

Minnesota Center for Health Care Ethics (MCHCE)

Julia Anderson
Ellie Garrett
Karen G. Gervais
Kerry Hjelmgren
Angela Morley
Angela Witt Prehn
Dorothy Vawter

Community Health Information Collaborative

Therese Campbell
Cheryl Stephens

Min No Aya Win Human Services Center, Fond du Lac Reservation

Debra Smith

St. Louis County Public Health & Human Services
Jim Gangl

Additional Duluth Area Partners

Tony Guerra, American Red Cross, Northland Chapter, Duluth
John Jordan, SMDC Health System
Mike Marturano, St. Luke's

The Keystone Center

Jody Erikson
Niki Koszalka
Johanna Raquet

US Centers for Disease Control & Prevention (CDC)

Roger Bernier
Caitlin Wills-Toker

University of Nebraska Public Policy Center

Tarik Abdel-Monem
Denise Bulling
Mark DeKraai
Stacey Hoffman

Additional Volunteer Facilitators and Notetakers

Sarah Carlson, St. Olaf College
Cara Cowdrey, St. Olaf College
Amy Deeg, St. Olaf College
Deb Fletcher
Teri Heathcote, American Red Cross, Northland Chapter, Duluth
Lauren Henke, St. Olaf College
Seth Huiras, St. Olaf College
Amy Lucas, St. Olaf College
Bill Maloney, Head of the Lakes Counseling Resources & Consulting
Timothy McIndoo, Walden University
Lan Nguyen, St. Olaf College
Jody Ondich, Lake Superior College
Ryan Pickard, St. Olaf College
Sommer Wild, St. Olaf College

Attendance

One hundred fourteen people registered for the meeting, and 92 attended. Eighty-one attendees were willing to answer some or all demographic questions.[166]

Age	
18 – 24	12%
25 – 34	14%
35 – 44	5%
45 – 54	25%
55 – 64	27%
65+	17%

Sex	
Male	38%
Female	62%

Race and Ethnic Origin	
Hispanic or Latino (of any race)	5%
White	83%
Asian	1%
Black or African American	4%
American Indian or Alaska Native	5%
Native Hawaiian or Other Pacific Islander	--
Other	1%

All participants were Minnesota residents. They were recruited from among the general public in Duluth and surrounding communities. Local partners widely distributed flyers about the event, and the event was publicized highly through local print, radio and television media. Participants received a modest stipend in exchange for participating in the day-long event.

Local steering committee

The Forum benefited greatly from the planning and recruitment assistance provided by members of the Duluth-area steering committee:

- Therese Campbell, Community Health Information Collaborative
- Jim Gangl, St. Louis County Public Health & Human Services
- Tony Guerra, American Red Cross, Northland Chapter, Duluth
- John Jordan, SMDC Health System
- Mike Marturano, St. Luke's
- Debra Smith, Min No Aya Win Human Services Center, Fond du Lac Reservation
- Cheryl Stephens, Community Health Information Collaborative
- Amy Westbrook, Minnesota Department of Health

Local partners

Saint Louis County, Fond du Lac Reservation's Min No Aya Win Human Services Center, and the Community Health Information Collaborative each partnered on the project and gave permission to use their logos on flyers and advertisements to recruit participants.

[166] The Public Policy Center University of Nebraska. *Evaluation of Public Engagement Demonstration Projects for Pandemic Influenza* [draft]. 2009.

Small group facilitators and notetakers

Several members of the community forums team from MCHCE served as facilitators and notetakers. The team recruited additional facilitators and notetakers for the small-group discussions from among the local steering committee, colleges, the panel that developed the preliminary rationing recommendations, and other personal contacts. They each participated in a 1-hour training session. Personnel from The Keystone Center also served as facilitators and notetakers.

National partners and funder

The CDC funded the event through a grant to MDH. Ruth Lynfield, MD, state epidemiologist, was the principal investigator. MDH contracted with MCHCE to design and conduct the community forums.

As part of the grant, additional facilitation assistance was provided by The Keystone Center. The Keystone Center's staff contributed to planning the event, handled registration and other logistics, assisted with training the small group facilitators and notetakers, provided and ran the audience response system (electronic keypads for polling), and served as small group facilitators and notetakers. The Keystone Center also funded the paid advertisements that were used to support recruitment.

Presenters

Commissioner Sanne Magnan, MD, PhD, Minnesota Department of Health presented background on pandemic influenza and the emerging H1N1 novel influenza virus.

Karen G. Gervais, PhD, Minnesota Center for Health Care Ethics, summarized the Minnesota Pandemic Ethics Project.

Allan Kind, MD, Park Nicollet Health Services and a member of the Resource Allocation Panel that issued preliminary ethical recommendations for rationing, welcomed participants on the panel's behalf.

J Eline Garrett, JD, Minnesota Center for Health Care Ethics, moderated the day's discussions and facilitated the large-group exercises.

Jim Gangl, St. Louis County Public Health & Human Services and a member of the Resource Allocation Panel thanked participants for their attendance at the day's conclusion. Mr. Gangl also served as a member of the forum's local steering committee.

Format

The event began at 9:00 a.m. and ended at 3:00 p.m. on Saturday, May 2, 2009. It began with a presentation by Commissioner Magnan about seasonal and pandemic influenza. She included content about the H1N1 novel influenza that was identified in the week prior to the event. Commissioner Magnan took questions after her presentation and again during lunch. Karen G. Gervais presented an overview of the Minnesota Pandemic Ethics Project and set the stage for the rest of the day's discussions. She, too, took questions briefly following her presentation.

Following the presentations, participants were engaged in both small and large group facilitated discussions on two separate topics. The small group discussions were conducted around tables of approximately eight to ten participants each, with one notetaker and one facilitator per table. Small groups reported out to the large group. Large group discussions also incorporated audience response polling (instant polling on electronic keypads), The first discussion topic concerned broad objectives to guide ethical rationing of scarce preventive resources. The second concerned the use of age as a potential rationing criterion for scarce medications for people ill with influenza.

The final exercise of the day was an individual exercise in which each participant was asked to arrange a series of 10 cards depicting groups of people suffering from influenza, all of whom needed a medication for which there was not enough to go around. Participants prioritized the groups for access to the

medication. The variables represented on the cards were age, risk of death from influenza, and key worker status (Appendix N).

Exercise one: Ethical objectives for rationing

Participants were asked to consider a hypothetical scenario about rationing preventive resources for people who have not contracted influenza. They were asked to assume:

- Severe influenza pandemic (like 1918-19);
- 30% of population get the flu at some time during a 2 year period;
- On average 2.1% of flu patients die, but in some groups 50% die;
- 40% absenteeism during peak outbreaks;
- Major disruption of key health and public safety infrastructures;
- Major shortages of supplies, including resources to prevent the flu.

They were further told that the panel had developed a preliminary set of recommendations to guide rationing decisions. The preliminary recommendations call for balancing three objectives when rationing health care resources during a severe pandemic:

- Reduce the number of flu-related deaths and other serious complications;
- Reduce disruption in basic public health, public safety and health care infrastructures;
- Treat people fairly, recognizing that we are all morally equal. By fairness, we mean:
    - protect groups at especially high risk of death from flu;
    - protect groups that take risks on behalf of others (reciprocity);
    - remove barriers to access (like cost, transportation, language);
    - protect against inconsistency and bias:
        - do not ration based on first-come first-serve, ability to pay, or judgments about differences in “social value”;
        - use random procedures (like lottery or toss of a coin) to select among people with equal need.

They were told that the Minnesota Department of Health and others sought their best advice about how Minnesota should ration scarce preventive resources. The overarching questions posed in this exercise were which rationing objectives would best serve Minnesota’s common good, and how should they relate to each other (in other words, are some more important than others, or should they be balanced?) Why?

More specifically, they were asked to discuss the following questions in small groups:

1. How appropriate is this proposed set of objectives for rationing preventive resources to promote Minnesotans’ common good? Why? (Preventive resources are things like drugs, vaccines, and masks to prevent people from catching the flu in the first place.)
    a. Do you agree the 3 objectives should be equally balanced? Why or why not?
    b. OR If you would advise Minnesota’s leaders to rank some rationing objectives as more important than others, which objectives would you prioritize and why?
2. What objectives should be added? Why?
3. What other changes would you make? Why?
4. How strongly do you hold these opinions? Are you very certain, on the fence or somewhere in between?

For the most part, the discussions weren’t strictly linear. That is, many and perhaps most of the facilitators did not attempt to get one question completely answered before moving onto the next. The questions closely related to each other, and small groups tended to move among the questions rather organically.

Several themes emerged in the small group discussions:

- Many participants agreed with balancing the three objectives as proposed. For many, it was important to attend to all three because they are interconnected: protect public health and infrastructure to reduce deaths, and use fairness as a means to reduce deaths. Each is nested within the others.
- Most participants argued that protecting infrastructure was an important objective.

  - Health care infrastructure is particularly critical during a health-related disaster like pandemic.
  - It is important that key employees, including volunteers, are identified carefully. Not all employees in a prioritized infrastructure are key. Not all are at risk, and not all are performing a critical function.
- A few argued strongly against prioritizing key workers within critical infrastructures. Employment shouldn't be prioritized. Protecting against death and treating each other fairly are more important.
- There was little, if any, controversy expressed about the importance of prioritizing according to risk of death and serious complications from the flu. One small group went so far as to discuss the possibility of physicians assigning health "ranks" to their patients, so that those who needed a vaccine most would be assured of getting it. Some participants in this small group questioned the feasibility of such a physician-driven ranking system.
- The topic of fairness was explored from more than one angle.
  - Some participants emphasized the need to attend to fairness not just in planning, but in action. These participants stressed the importance of fairness, ranking it more important than protecting key workers and critical infrastructures. Fairness requires that groups that are at highest risk be prioritized. Clear commitments to fairness will help reduce civil unrest. Fairness requires strict procedures and policies.
  - Many said that fairness required increased, explicit commitments to prioritize and protect vulnerable populations. Examples of vulnerability included disability, mental illness and homelessness.
  - Transparency and public education are critically important to treating people fairly. Many creative means of communication should be used, because no single avenue of communication will reach everyone. Even television doesn't reach all Minnesotans, because not everyone in the state owns or watches TV. Communication must be culturally and linguistically appropriate for diverse audiences.
  - Some argued that "being fair" was somewhat nebulous, especially in crisis response, and that it would be more important to reduce deaths from influenza and preserve infrastructure.
  - At least one person said that fairness required that no one be vaccinated if there weren't enough to go around for all.
- Some argued in favor of using social value – above and beyond the priority for key workers – as a rationing criterion. They argued that preventive resources should go to those who were productive members of society; others disagreed strongly, arguing that such determinations of social value would inherently be unfair. As noted below, a large majority of participants rejected social value criteria during the electronic polling.

Electronic polling

Approximately two-thirds of participants agreed strongly (33%) or somewhat (37%) that Minnesota should balance all three ethical objectives, as preliminarily recommended by the panel. Eighteen percent disagreed somewhat, and the remaining 12% disagreed strongly.

During large group discussion, it became apparent that many of those who agreed somewhat did so because they felt that two of the recommended objectives (reducing deaths from the flu and protecting critical infrastructures) should be balanced, with the third objective (fairness) ranked below those two.

More than half of the participants agreed that at least two of the objectives should be balanced, with no single objective emerging as more important than the others. When forced to rank—rather than balance—the objectives, most prioritized them in this order:

1. Protect infrastructures
2. Reduce flu-related deaths
3. Treat people fairly

During the small group discussions, facilitators were asked to identify any new objectives that emerged. Facilitators reported such new objectives during the break so that they could be added to the electronic poll. Two objectives were offered:

- Protect productive members of society (which in discussion was also described as prioritizing according to social value).
- Prioritize according to vulnerability.

Two-thirds of the participants rejected prioritization in order to protect productive members of society or according to social value. During brief discussion immediately following the polling, those who rejected this prioritization did so on grounds of fairness.

Just over half (54%) of participants rejected prioritization according to vulnerability. During discussion, though, many participants stressed that they had voted against it only because they thought that the existing fairness objective already included the notion of protecting the vulnerable. Thus, the importance of protecting vulnerable populations was endorsed even though the group recommended against making it a separate ethical objective.

Polling results about ethical objectives for rationing

1. Do you agree/disagree MN should balance all 3 objectives?	Responses
Agree strongly	33%
Agree somewhat	37%
Disagree somewhat	18%
Disagree strongly	12%

2. Should we add an additional critical infrastructure objective (4): Protect productive members of society?	Responses
Yes	32%
No	68%

3. Should we add an additional critical infrastructure objective (5): Add vulnerable populations?	Responses
Yes	46%
No	54%

4. Which objective should be prioritized first?	Responses
Reduce flu related deaths	29%
Protect infrastructure	46%
Treat people fairly	18%
Add vulnerable populations	7%

5. Which objective should be prioritized second?	Responses
Reduce flu related deaths	48%
Protect infrastructure	23%
Treat people fairly	24%
Add vulnerable populations	5%

6. Which objective should be prioritized third?	Responses
Reduce flu related deaths	23%
Protect infrastructure	12%
Treat people fairly	58%
Add vulnerable populations	7%

7. Should any 2 or more of these objectives tie for first priority and be balanced?	Responses
Yes	55%
No	33%
Undecided	12%

Other comments

During both small and large group discussions, several participants raised pandemic planning issues that were not limited to identifying rationing priorities.

- Rationing should be a last resort. Public health officials should capitalize on opportunities to control the disease's spread so that demand for resources—whether preventive or treatment—can be reduced.
- Transparency and public education are critically important. Many creative means of communication should be used, because no single avenue of communication will reach everyone. Even television doesn't reach all Minnesotans, because not everyone in the state owns or watches TV. Communication must be culturally and linguistically appropriate for diverse audiences.

Exercise two: Age-based rationing

While the first exercise of the day concerned rationing resources that help to prevent people from contracting influenza, this second exercise considered rationing a treatment for people ill with the flu. Participants were asked to consider the following hypothetical scenario for rationing medicine:

- Severe influenza pandemic (like 1918-19)
- Major shortages of supplies (at times) including medicines to treat the flu
- Assume that the health department has decided to prioritize people for medicine according to their risk of dying from the flu. Those who are at the higher risk will be prioritized over those who are at lower risk.
- Many people will be at the same risk of dying, and there won't be enough medicine to treat everyone at that same risk.
- This exercise is about sick people who are at the SAME RISK of dying from the flu.

The discussion questions for the small groups were as follows:

1. How should Minnesota ration flu medicines among those in general public at the same risk of dying from the flu?

- Should Minnesota always randomly select who—among those at the same risk of dying—gets the medication? Why or why not?
- Should Minnesota ever first prioritize some age groups to get flu medicines before others? Why or why not? When?

2. If Minnesotans generally agree that it is acceptable at times to ration based on age, which age group(s) should receive flu medicine first, second, and so on? Why?
   - Children under 18
   - Adults 18 – 40
   - Adults 41 – 65
   - Seniors 66 – 85
   - Seniors 86 and over
   - Some other age range (like a bigger or smaller age group)

3. After the first group is prioritized, should age-ranking continue (and if so, which age groups), or should the remaining resources be distributed randomly regardless of age?

4. How strongly do you hold these opinions? Are you very certain, on the fence or somewhere in between?

Two competing positions emerged. Interestingly, more people polled in favor of using age-based rationing than appeared in favor of it during either the preceding large or small group discussions.

- Rejection of age-based rationing in favor of distributing randomly:
  - Every age group has value. Each is so important, that the medicine should be distributed across age groups according to the percentage of that age in the total population, and then randomly distributed among people in each age group.
  - Age groups should not be selected in advance, but identified during a pandemic. In other words, it is acceptable to consider age only if it is associated with increased risk of dying.
  - Age is too arbitrary. Who decides which age groups? What is the cut-off?
  - Everyone is going to die someday, and we shouldn't choose who dies when.
  - Individuals should be offered the opportunity to refuse a medication or vaccine. Many, maybe most, adults and especially the elderly will voluntarily forego a resource in favor of a child receiving it. But the choice should be left to the individual, and not enforced as a matter of rationing.

- Support for age-based rationing before resorting to randomization:
  - Prioritize people from age 20 to 50. They will "clean up the mess" and are the hard workers in society taking care of others. Then prioritize the children.
  - Assuming that 98% of people who catch the flu will survive, there is no risk of losing an entire generation. Children should be prioritized in such an instance.
  - Prioritize children and parents of young children over the elderly.
  - The elderly have had a chance to live a long life. Children haven't, and they are our future.

Electronic polling

Close to 80% responded that rationing by age is sometimes (59%) or always (19%) preferable to randomization. Twenty-two percent rejected rationing by age completely. Interestingly, participants said that they were very firm in their opinions on this subject, with 87% being very or moderately certain about their responses.

When forced to prioritize an age group, half (51%) ranked adults between 18 and 40 first. Thirty-nine percent ranked children first. Nearly half (46%) said that age-based ranking should end after one age group was prioritized, and opted for randomization rather than choosing a second age group to prioritize.

Polling results about randomization vs. age

1. Should MN ration scarce flu medicine by age or distribute it randomly?	Responses
Never ration by age	22%
Rationing by age is sometimes preferable to randomizing	59%
Rationing by age is always preferable to randomizing	19%

2. How certain are you about your previous response?	Responses
Very certain	53%
Moderately certain	34%
Moderately uncertain	9%
Very uncertain	4%

3. Which age group should MN prioritize first?	Responses
Children under 18	39%
Adults 18-40	51%
Adults 41-65	7%
Seniors 66-85	3%
Seniors 86 and older	0%

4. Which age group should MN prioritize second?	Responses
Children under 18	19%
Adults 18-40	15%
Adults 41-65	17%
Seniors 66-85	3%
Seniors 86 and older	0%
None. Start to randomize	46%

5. Which age group should MN prioritize third?	Responses
Children under 18	12%
Adults 18-40	5%
Adults 41-65	22%
Seniors 66-85	4%
Seniors 86 and older	1%
None. Start to randomize	56%

6. Which age group should MN prioritize fourth?	Responses
Children under 18	0%
Adults 18-40	1%
Adults 41-65	1%
Seniors 66-85	14%
Seniors 86 and older	8%
None. Start to randomize	76%

Exercise three: "Paper dolls"

Each participant received a set of 10 cards or "paper dolls," each of which depicted a different group of Minnesotans (Appendix N). All people depicted on the cards were ill, and there was not enough medicine available to treat them. Participants were tasked with arranging the cards in the order in which they should be prioritized for access to the scarce medicine. The variables represented on the cards were:

- key worker status;
- risk of dying from the flu;
- age.

Participants were directed to arrange the cards in as many or few different levels of priority as they wished. Ties among cards were allowed, but the more cards tied at the same level, the more likely it would be that there wouldn't be enough medicine for everyone at that level. Then MDH would have to randomize within that priority level.

Though a few participants declined to complete the exercise, most completed it. In declining, one wrote that she or he felt overwhelmed at the prospect of making such choices.

Most prioritized risk, usually placing those at high risk of dying before those at more moderate risk. Most also prioritized key workers, particularly those at high risk of death, though a few commented that it would be appropriate to prioritize key workers only for preventive resources and not for treatments. Young adults and children generally were prioritized over older age groups. That said, nearly 30% prioritized seniors ahead of other age groups, and some even ranked them among the first. Roughly 20% prioritized children before young adults, 20% prioritized young adults before children and another 20% prioritized equally children and young adults. All told, approximately 40% prioritized children or children and young adults first. Only three participants chose to randomize all groups regardless of differences in risk of dying, key worker status or age. Nevertheless, close to 60% of participants assigned the same level of priority to three or more groups, signaling their openness to randomization in some instances.

The paper doll exercise suggests that the participants generally supported rationing flu treatment by seeking to protect key workers (especially those at high risk) and to protect people at high risk of flu-

related mortality. When needing to ration among groups in the general population who are at the same level of risk, participants split between randomizing among everyone without regard for age, prioritizing children, prioritizing young adults, and prioritizing both children and young adults.

Participants were not expressly asked to share the results of their paper doll exercises with other people at their tables. They were asked to discuss how the information shared during the community forum influenced how they arranged the cards. A range of comments were offered, including:

- I changed my mind about age-based rationing.
- Family and societal functions are important.
- Age is important. I gained clarity. Strengthened beliefs I already had. My opinion about age is shared by others.
- Gained understanding of demographic age issues. Previously I knew only about key workers.
- An impressive amount of work has gone into the project. It is an opportunity to educate the public.
- New information was very helpful in making educated decisions.
- All things being fair, no one would get treated when medicine is scarce.
- After all the discussion, it was harder to do the exercise than it would have been if done at the beginning of the day.
- Voting and polling focused my thinking.
- The discussion of infrastructure helped to shape ideas.
- The issue of fairness is very difficult to define.
- I had preconceived notions and core beliefs that the presentation did not persuade.
- Watching the process helped to give better understanding.
- I gained respect for everyone's opinion.
- I saw the importance of people coming together to discuss these topics.
- I am upset that there is not enough money in this country for medicine, but military funding is high.
- We haven't put enough emphasis on people's health, but Minnesota has been good at being proactive.
- The current epidemic (H1N1) plays a factor in influencing decisions/opinions.
- I learned a lot about pandemic.
- Yes, I arranged ages differently because of what was learned.
- Key workers are the priority.
- Key worker status is no longer applicable because they're sick. They can't treat patients or work if they're already sick (and they are for the purpose of the activity) so they no longer have special value.

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Appendix D: Community Forum, Owatonna

Holiday Inn Hotel & Suites
March 28, 2009
9:00 a.m. – 3:00 p.m.

Forum contributors

Minnesota Pandemic Ethics Project Resource Allocation Panel Representatives

Pamela Hoopes
Bruce Pederson

Minnesota Department of Health (MDH)

Richard Danila
Mary Jeanne Levitt
Franci Livingston
Ruth Lynfield
Geri Maki
Elizabeth Parilla
Jean Rainbow

Minnesota Center for Health Care Ethics (MCHCE)

Julia Anderson
Ellie Garrett
Karen G. Gervais
Kerry Hjelmgren
Angela Morley
Angela Witt Prehn
Dorothy Vawter

Steele County Public Health

Karen Fountaine
Dee Ann Pettyjohn

Dodge County Department of Health

Kelly Corbin
Peggy Espey

Steele County Community Awareness & Response

Elizabeth Auppl

Additional Members of the Steele – Dodge Counties Team

Ken Schuck, Kasson Police Department
Jerry Nyquist, Federated Insurance
Dave Severson, Steele County

The Keystone Center

Jody Erikson
Niki Koszalka
Johanna Raquet

US Centers for Disease Control & Prevention (CDC)

Roger Bernier
Caitlin Wills-Toker

University of Nebraska Public Policy Center

Tarik Abdel-Monem
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Additional Volunteer Facilitators and Notetakers

Sarah Adamson
Eric Anderson
Char Carlson
Amy Deeg
Matt Groen
Mary Ho
Nathan Johndro
Brad Krier
Mary Beth Kuehn
Ed Langerak
Marija Lum
Matt Maas
Erin McHugh
Timothy McIndoo
Jose Ramirez
Katie Rogotzke
Tom Shea

Attendance

One hundred twenty-one people registered for the meeting, and 108 attended. Most voluntarily answered demographic questions.[167]

Age	
18 – 24	6%
25 – 34	10%
35 – 44	8%
45 – 54	26%
55 – 64	25%
65+	25%
Sex	
Male	34%
Female	66%
Race and Ethnic Origin	
Hispanic or Latino (of any race)	5%
White	93%
Asian	0%
Black	1%
American Indian or Alaska Native	1%
Native Hawaiian or Other Pacific Islander	0%
Other	

All participants were Minnesota residents. They were recruited from among the general public in Steele and Dodge counties and other southeastern Minnesota communities. Local partners widely distributed flyers about the event, and the event was publicized highly through local print and radio and television media. Participants received a modest stipend in exchange for participating in the day-long event.

Local steering committee

The Forum benefited greatly from the planning and recruitment assistance provided by members of the Dodge-Steele Counties steering committee:

- Elizabeth Auppl, Steele County Community Awareness & Response
- Kelly Corbin, Dodge County Department of Health
- Peggy Espey, Dodge County Department of Health
- Karen Fountaine, Steele County Public Health
- Jerry Nyquist, Federated Insurance
- Dee Ann Pettyjohn, Steele County Public Health
- Ken Schuck, Kasson Police Department
- Dave Severson, Steele County

Local partners

Steele County Public Health, Dodge County Department of Health and Steele County Community Awareness & Response each partnered on the project and gave permission to use their logos on flyers and advertisements to recruit participants.

[167] The Public Policy Center University of Nebraska. *Evaluation of Public Engagement Demonstration Projects for Pandemic Influenza* [draft]. 2009.

Small group facilitators and notetakers

Several members of the Minnesota Pandemic Ethics Project team from MCHCE served as facilitators and notetakers. The team recruited additional facilitators and notetakers for the small-group discussions from among the local steering committee, colleges, and other personal contacts. They each participated in a 1-hour training session. Personnel from the CDC and The Keystone Center also served as facilitators and notetakers.

National partners and funder

The CDC funded the event through a grant to MDH. Ruth Lynfield, MD, state epidemiologist was the principal investigator. MDH contracted with the Minnesota Center for Health Care Ethics to design and conduct the community forums. Through the cooperative agreement, the CDC had an active role in the planning and execution of each of the project. The CDC also funded the University of Nebraska to evaluate it.

As part of the grant, additional facilitation assistance was provided by The Keystone Center. The Keystone Center's staff contributed to planning the event, handled registration and other logistics, assisted with training the small group facilitators and notetakers, provided and ran the audience response system (electronic keypads for polling), and served as small group facilitators and notetakers.

Presenters

State Epidemiologist Ruth Lynfield, MD, MDH, welcomed and thanked participants on the department's behalf and took questions throughout the day.

Richard Danila, PhD, MPH, Deputy State Epidemiologist, MDH, presented background on pandemic influenza.

Dorothy Vawter, PhD, MCHCE, summarized the Minnesota Pandemic Ethics Project.

Bruce Pederson, Fairview Health Services and a member of the Resource Allocation Panel that issued preliminary ethical recommendations for rationing welcomed participants on the panel's behalf.

J Eline Garrett, JD, MCHCE, moderated the day's discussions and facilitated the large-group exercises.

Pamela Hoopes, JD, Minnesota Disability Law Center and a member of the Resource Allocation Panel thanked participants for their attendance at the day's conclusion.

Format

The event began at 9:00 a.m. and ended at 3:00 p.m. on Saturday, March 28, 2009. It began with a presentation by Richard Danila about seasonal and pandemic influenza. Dorothy Vawter presented an overview of the Minnesota Pandemic Ethics Project and set the stage for the rest of the day's discussions. Both took questions briefly following their presentations.

Following the presentations, participants were engaged in both small and large group facilitated discussions on two separate topics. The small group discussions were conducted around tables of approximately eight participants each, with one notetaker and one facilitator per table. Small groups reported out to the large group. Large group discussions incorporated audience response polling (instant polling on electronic keypads). The first discussion topic concerned broad objectives to guide ethical rationing of scarce preventive resources. The second concerned the use of age as a potential rationing criterion for scarce medications for people ill with influenza.

The final exercise of the day was an individual exercise in which each participant was asked to arrange a series of 10 cards depicting groups of people suffering from influenza, all of whom needed a medication for which there was not enough to go around. Participants prioritized the groups for access to the

medication. The variables represented on the cards were age, risk of death from influenza, and key worker status.

Exercise one: Ethical objectives for rationing

Participants were asked to consider a hypothetical scenario about rationing preventive resources for people who have not contracted influenza. They were asked to assume:

- Severe influenza pandemic (like 1918-19);
- 30% of population get the flu at some time during a 2 year period;
- On average 2.1% of flu patients die; in some groups 50% die;
- 40% absenteeism during peak outbreaks;
- Major disruption of key health and public safety infrastructures;
- Major shortages of supplies, including resources to prevent the flu.

They were further told that the panel had developed a preliminary set of recommendations to guide rationing decisions. The preliminary recommendations called for balancing three objectives when rationing health care resources during a severe pandemic:

- Reduce the number of flu-related deaths and other serious complications;
- Reduce disruption in basic public health, public safety and health care infrastructures;
- Treat people fairly, recognizing that we are all morally equal. By fairness, we mean:
    - protect groups at especially high risk of death from flu;
    - protect groups that take risks on behalf of others (reciprocity);
    - remove barriers to access (like cost, transportation, language);
    - protect against inconsistency and bias:
        - do not ration based on first-come first-serve, ability to pay, or judgments about differences in "social value";
        - use random procedures (like lottery or toss of a coin) to select among people with equal need.

They were told that the Minnesota Department of Health and others sought their best advice about how Minnesota should ration scarce preventive resources. The overarching questions posed in this exercise were which rationing objectives would best serve Minnesota's common good, and how should they relate to each other (in other words, are some more important than others, or should they be balanced?) Why?

More specifically, they were asked to discuss the following questions in small groups:

1. How appropriate is this proposed set of objectives for rationing preventive resources to promote Minnesotans' common good? Why? (Preventive resources are things like drugs, vaccines, and masks to prevent people from catching the flu in the first place.)
    a. Do you agree the three objectives should be equally balanced? Why or why not?
    b. OR If you would advise Minnesota's leaders to rank some rationing objectives as more important than others, which objectives would you prioritize and why?
2. What objectives should be added? Why?
3. What other changes would you make? Why?
4. How strongly do you hold these opinions? Are you very certain, on the fence or somewhere in between?

For the most part, the discussions weren't strictly linear. That is, many and perhaps most of the facilitators did not attempt to get one question completely answered before moving onto the next. The questions closely related to each other, and small groups tended to move among the questions rather organically.

Several themes emerged in the small group discussions:

- Some argued that the three objectives are appropriate and should be balanced.
- The objectives about reducing the number of flu-related deaths and protecting critical infrastructures are closely related. The state can't minimize deaths without protecting infrastructures.

- For some, protecting key workers was the most important objective, both because their functions are life-saving and because many of them (especially health care workers) take risks on behalf of the rest of us. The public safety infrastructure is also critical, because many feared the prospect of civil unrest.
- Key workers' families should be prioritized, because otherwise key workers are not likely to report to work. They will care for their families before the rest of society.
- For others preventing deaths from flu was the most important objective.
- Several suggested that preventing deaths from the flu and protecting key workers are equally important.
- One group suggested that after prioritizing key workers, a lottery should be used to distribute resources among the general population. They argued that doing so would limit favoritism.

The objective of fairness was somewhat controversial.

- Fairness is difficult to achieve. Some felt that it should be removed as an unrealistic goal. No matter what the strategy, some will find it fair and others unfair. Fairness isn't the appropriate criterion, because it's not objective.
- Similarly, some believed that money and power would control; attempts to distribute without regard to money and power weren't realistic.
- Some observed that fairness and equality are not necessarily the same. Fairness can justify treating people unequally, e.g., prioritizing children and de-prioritizing or excluding criminals.
- Others thought fairness would be more easily achieved in rationing strategies than in other aspects of pandemic response, such as business closures.
- Fairness is an important goal and should help guide rationing decisions.
- Fairness should not be considered as a separate objective, but as a way the other two objectives (about reducing deaths and preserving infrastructures) are addressed.
- Some objected to the possibility that undocumented people could have access to scarce resources. Others thought that lack of documentation should be ignored, because controlling the spread of disease was more important than worrying about documentation.
- People who have a terminal disease shouldn't be prioritized for vaccines. Vaccines should go to those whose lives are likely to be longer.
- A few participants wanted complete randomness, arguing that plans created by committee or government are not good. No one should have the right to determine who gets what.

Additional or expanded ethical objectives were offered:

- Civil liberties should be protected both during and after the pandemic. Heightened concern for protecting civil liberties should be added as an ethical objective.
- Some suggested that additional infrastructures should be protected.
    - Life-sustaining infrastructures, such as food (from farming to distribution) should be prioritized.
    - Truck drivers who deliver food, internet providers who deliver information, teachers who deliver education are all important.
    - Sewer and utility workers should be prioritized.
    - Financial infrastructures should possibly be added as critical infrastructures to be prioritized.

Tensions between promoting uniformity and maintaining local flexibility emerged.

- Some argued that the state should not be making rationing decisions, particularly with regard to the goal of preserving infrastructures. Individual communities and businesses should be the ones to decide who are key workers and which infrastructures are most important.
- On the other hand, others argued in favor of greater uniformity. They said that the state or federal government should be making rationing decisions. Allowing local controls could introduce nepotism and favoritism.

Several offered suggestions about pandemic response more generally.

- All possible measures should be employed to reduce the disease's spread.
- Key workers in particular should be educated about how to prevent spread of flu by simple measures such as hand washing and covering coughs. Communities should implement control measures like isolation.
- Families should be educated on how to prepare and how to control the spread of disease in households.
- Communication is essential. Information must be translated into many languages, and key messages disseminated widely.
- Employers' policies that penalize workers for staying home when ill are a major barrier to controlling the spread of disease.
- One person suggested that placebos be distributed to those who for whom there were not enough resources, with the goal being to diminish the likelihood of civil unrest. Others argued that such deception would increase, rather than diminish, the likelihood of mistrust and unrest.
- People should be able to refuse resources in favor of giving them to others.
- The focus should be on the long-range results of pandemic response, of projecting what will happen three or four decades hence rather than on a near term of a couple of years.
- Border issues were mentioned by some, and there was disagreement about how to respond to borders. Some said that Minnesota's resources should be reserved for Minnesotans. People who live in bordering states shouldn't be allowed to have access to the resources. Others disagreed, feeling that such restrictions would be impractical.

Electronic polling

The vast majority of participants agreed strongly (48%) or somewhat (40%) that Minnesota should balance all three objectives as proposed by the panel.

During large group discussion, it became apparent that many of those who agreed somewhat did so because they felt that two of the recommended objectives (reducing deaths from the flu and protecting critical infrastructures) should be balanced, with the third objective (fairness) ranked lower.

More than half (54%) of the participants agreed that at least two of the objectives should be balanced, with no single objective emerging as more important than the others. When forced to rank—rather than balance—the objectives, most prioritized them in this order:

1. Protect infrastructures
2. Reduce flu-related deaths

During the small group discussions, facilitators were asked to identify any new objectives that emerged. Facilitators reported such new objectives during the break so that they could be added to the electronic poll. Two objectives were offered:

- Prioritizing an additional critical infrastructure, such as transportation, communication, teachers, food supply and distribution
- Adding an additional objective focused on long-term social stability

Participants initially agreed that adding such additional objectives was important, but neither emerged as a top priority when compared with the objectives of reducing flu-related deaths or protecting public health, public safety and health care infrastructures. Interestingly, adding additional infrastructures emerged as slightly more important to the group than the panel's proposed objective of treating people fairly.

Polling results: Ethical objectives for rationing

1. Do you agree/disagree MN should balance all 3 objectives?	Responses
Agree strongly	48%
Agree somewhat	40%
Disagree somewhat	8%
Disagree strongly	4%

2. Should we add an additional critical infrastructure objective (4): transportation, communication, teachers, food/supply?	Responses
Yes	71%
No	29%

3. Should we add an additional long-term social stability objective (5)?	Responses
Yes	64%
No	36%

4. Which objective should be prioritized first?	Responses
Reduce flu related deaths	32%
Protect infrastructure	50%
Treat people fairly	6%
Protect additional infrastructures	7%
Protect long-term social stability	5%

5. Which objective should be prioritized second?	Responses
Reduce flu related deaths	30%
Protect infrastructure	32%
Treat people fairly	15%
Protect additional infrastructures	21%
Protect long-term social stability	2%

6. Which objective should be prioritized third?	Responses
Reduce flu related deaths	16%
Protect infrastructure	7%
Treat people fairly	27%
Protect additional infrastructures	42%
Protect long-term social stability	8%

7. Which objective should be prioritized fourth?	Responses
Reduce flu related deaths	9%
Protect infrastructure	0%
Treat people fairly	30%
Protect additional infrastructures	32%
Protect long-term social stability	29%

8. Should any 2 or more of these objectives tie for first priority and be balanced?	Responses
Yes	54%
No	33%
Undecided	13%

Exercise two: Age-based rationing

While the first exercise of the day concerned rationing resources that help to prevent people from contracting influenza, this second exercise considered rationing a treatment for people ill with the flu. Participants were asked to consider the following hypothetical scenario for rationing medicine:

- Severe influenza pandemic (like 1918-19)
- Major shortages of supplies (at times) including medicines to treat the flu
- Assume that the health department has decided to prioritize people for medicine according to their risk of dying from the flu. Those who are at higher risk will be prioritized over those who are at lower risk.
- Many people will be at the same risk of dying, and there won't be enough medicine to treat everyone at that same risk.
- This exercise is about sick people who are at the SAME RISK of dying from the flu.

The discussion questions for the small groups were as follows:

1. How should Minnesota ration flu medicines among those in the general public at the same risk of dying from the flu?
    - Should Minnesota always randomly select who—among those at the same risk of dying—gets the medication? Why or why not?
    - Should Minnesota ever first prioritize some age groups to get flu medicines before others? Why or why not? When?

2. If Minnesotans generally agree that it is acceptable at times to ration based on age, which age group(s) should receive flu medicine first, second, and so on? Why?
    - Children under 18
    - Adults 18 – 40
    - Adults 41 – 65
    - Seniors 66 – 85
    - Seniors 86 and over
    - Some other age range (like a bigger or smaller age group)

3. After the first group is prioritized, should age-ranking continue (and if so, which age groups), or should the remaining resources be distributed randomly regardless of age?

4. How strongly do you hold these opinions? Are you very certain, on the fence or somewhere in between?

Discussion

Competing perspectives were offered on the subject of age-based rationing. Many argued in support of using age as a criterion, but there were differences of opinion about which age ranges should be used and which age groups should come first. Others rejected using age as a criterion, preferring random distribution.

Examples of comments in support of employing age-based rationing

- Some argued that children under 18 should be prioritized, followed by those between 18 and 50. Many parents are over the age of 40, so it's important to reach a decade or so over 40. Then prioritization should continue across the life span with 50-70 year olds, followed by 71 and older. It's important to prioritize adults, because children need their parents.
- Similarly, some argued that children under 18 should be prioritized and everyone between 18 and 65 should be next, because of their caretaking roles. Others suggested flipping those age groups around, prioritizing caretaking ages first, and then children.
- Another group suggested that children should be prioritized, then everyone between 18 and 70. Those over 70 should be excluded or de-prioritized.
- Prioritizing key workers will result in many people of working age being prioritized. Age-based rationing should be used to adjust for an underrepresented group – to correct for inequities based on the prioritization of workers.
- One group suggested lowering the age of those considered "young adults" to 16 to 35. They would prioritize these young adults first, because they are needed to care for children and are the biggest group moving the economy forward toward long-term sustainability. After prioritizing that age group, resources should be randomized.
- People who have actual roles in care-giving to children, whether parents or grandparents, should be prioritized. Then a lottery should distribute remaining resources within each age group.
- Dignified comfort care should be a priority for people over age 85 if there are not enough antivirals and vaccines for them.
- Key workers should come first, then children and parents. Age and role as a parent should be considered. There's nothing equal about flu, and randomness isn't right. We should take into consideration other aspects of people's lives.
- Pregnant women should be prioritized, because then we are saving two lives.
- Children are our future. Kids should be prioritized first.
- Some people thought children should be prioritized, because otherwise there could be civil unrest. People expect their kids to come first.

Examples of comments opposed to age-based rationing or about how to administer a lottery

- Age-based rationing shouldn't be used if risk is equal. Age is arbitrary. People altruistically can choose not to enter a lottery for resources. Those who opt out should not be allowed to designate a specific person to receive their share of resources; rather the resources should be distributed randomly to those in the pool.
- Some criticized age being used as a proxy for caretaking.
- Medicines should be allotted to families for the families to choose how to distribute, rather than having a government policy about age.
- If the pandemic is very bad, more stringent policy should be set for distribution and age could possibly be used as a criteria. But in the end, it will probably come down to first-come, first-served and the decisions of individual health care providers about whom to treat with what resources.
- Some were concerned that prisoners or people with advanced Alzheimer's disease should not be considered eligible for a lottery; others though that making such decisions would be opening a can of worms.
- All ages are important and have value to society. Age shouldn't be used as a rationing criterion. Randomness is better.

- There are productive and unproductive people in all age groups. Old people are needed because of their knowledge; children are needed because they are the next generation. People in between are workers, parents and caretakers. Life is a gift, and we should not play God. Distributing randomly is best.
- Age-based rationing amounts to social engineering. Randomness is better.
- Some thought that children should be required to take medicine if it is offered, but adults should be allowed to opt out of a lottery.
- Some felt that complete randomness might end up disadvantaging some age groups more than others because of the luck of the draw. Each age group is important. Thus, the lottery should be managed in order to distribute resources to every age group.
    - Each age group should receive a percentage of resources according to the size of age group in relation to the total population. Within each age group, resources should be distributed randomly. Individuals who "win" the lottery should have the opportunity to give or trade away their tickets.
    - Similarly, both sexes should receive an equal percentage of resources, and then resources should be randomly distributed among men and women, boys and girls.

Comments about which age groupings should be used if age-based rationing is employed

- Most participants didn't have suggestions for altering the age groups that were offered for discussion.
- Some suggested that people as young as 16 should be considered as young adults, because they can drive and work.
- Some suggested that all adults between ages 18 and 65 should be clumped together, because all are of working age and take care of those who are younger and older.
- Some suggested that adults up to age 70 or 75 should be considered as working age, because more seniors are postponing retirement and people live longer and have more productive years.
- Some suggested that people up to age 50 should be considered with young adults in "caretaking" roles, because many people postpone parenting until they are older.
- Others suggested that the definition of young adults should be cut off at age 35 rather than 40.
- None who supported age-based rationing supported prioritizing elders first.

Electronic polling

Nearly half (48%) of participants said that rationing by age is sometimes preferable to distributing resources randomly, and another quarter (24%) said that age is always preferable to being random. The remaining quarter (27%) supported random distribution instead of using age as a criterion. Most participants were very certain (55%) or moderately certain (39%) about their opinions on this question.

When forced to choose an age group to prioritize, most opted for adults between 18 and 40 (48%). Thirty-three percent prioritized children under 18 first. Eighteen percent of participants prioritized adults between 41 and 65.

After prioritizing one age group, approximately a quarter of participants (27%) said that age-based rationing should stop, and the remainder of resources should be distributed randomly. The rest of the participants said that age should continue to be used as a criterion, with a tie between prioritizing adults between 18 and 40 second (29%) and prioritizing children (29%) second. Thirteen percent of participants prioritized adults between 41 and 65 second.

After choosing a second priority, the percentage of participants who said that remaining resources should be distributed randomly increased to nearly half (47%). Other participants continued to opt for distributing according to age across the lifespan, with seniors prioritized last.

Polling results: Randomization vs. age-based rationing

1. Should MN ration scarce flu medicine by age or distribute it randomly?	Responses
Never ration by age	27%
Rationing by age is sometimes preferable to randomizing	49%
Rationing by age is always preferable to randomizing	24%

2 How certain are you about your previous response?	Responses
Very certain	55%
Moderately certain	39%
Moderately uncertain	5%
Very uncertain	1%

3. Which age group should MN prioritize first?	Responses
Children under 18	33%
Adults 18-40	47%
Adults 41-65	18%
Seniors 66-85	1%
Seniors 86 and older	1%

4. Which age group should MN prioritize second?	Responses
Children under 18	29%
Adults 18-40	29%
Adults 41-65	13%
Seniors 66-85	1%
Seniors 86 and older	1%
None. Start to randomize	27%

5. Which age group should MN prioritize third or random?	Responses
Children under 18	11%
Adults 18-40	7%
Adults 41-65	30%
Seniors 66-85	3%
Seniors 86 and older	2%
None. Start to randomize	47%

6. Which age group should MN prioritize fourth or random?	Responses
Children under 18	3%
Adults 18-40	2%
Adults 41-65	2%
Seniors 66-85	21%
Seniors 86 and older	3%
None. Start to randomize	69%

Exercise three: "Paper dolls"

Each participant received a set of 10 cards or "paper dolls," each of which depicted a different group of Minnesotans (Appendix N). All people depicted on the cards were ill, and there was not enough medicine available to treat them. Participants were tasked with arranging the cards in the order in which they should be prioritized for access to the scarce medicine. The variables represented on the cards were:

- key worker status;
- risk of dying from the flu;
- age.

Participants were directed to arrange the cards in as many or few different levels of priority as they wished. Ties among cards were allowed, but the more cards tied at the same level, the more likely it would be that there wouldn't be enough medicine for everyone at that level. Then MDH would have to randomize within that priority level.

Summary of paper doll exercise

The vast majority (99%) of participants chose to ration flu treatment by prioritizing some groups over others rather than randomizing across the board. One participant randomized across all groups and another participant randomized all groups in the general population after prioritizing key workers. Of those who prioritized, most (87%) prioritized key workers (66% prioritized key workers at high risk of dying, and 21% prioritized those at moderate risk). Some respondents (27%) ignored risk with regard to key workers and prioritized high and moderate risk workers together.

Close to 40% prioritized groups in the general population based solely on differences in risk (13% prioritized high risk over moderate; 27% prioritized moderate risk over high). More than 60% of participants attended to age either some or all of the time; close to 40% did not seem to favor considering age.

Nearly half (47%) prioritized children and/or young adults (23% prioritized children and 24% prioritized both children and young adults). Twenty percent prioritized young adults and/or adults ahead of children. Most considered various combinations of differences in risk and age, but 23% prioritized based solely on differences in age. Half the participants appeared to accept randomization under some circumstances, as they ranked three or more groups at the same level of priority.

Appendix E: Small Group Engagement, Courage Center, Minneapolis

July 28 and 29, 2009
5:00 – 8:00 p.m.

Demographics

14 people with a range of disabilities participated: Some people had disabilities from birth, others acquired them as adults. Some participants considered themselves to be in excellent health, while others' disabilities left them with weaker immune systems or skeletal/muscular disorders that made them more vulnerable to respiratory infections, such as influenza.

Twelve (86%) of the 14 participants voluntarily answered a set of demographic questions. Responses were anonymous. Seven (58%) of the respondents were women and 5 (42%) were men. One (8%) respondent belonged in the group of 18-29 year olds; 5 (42%) belonged in the group of 30-39 year olds; 4 (33%) were 40-54 year olds; and 2 (17%) were 55-64 year olds. One respondent was Hispanic or Latino; 9 were not. One was Black. One was American Indian or Alaskan Native. Eleven (92%) of the respondents were White.

Presenter, facilitator and notetakers

- Dorothy E. Vawter, PhD, presented overviews of seasonal and pandemic influenza and the Minnesota Pandemic Ethics Project.
- J. Eline Garrett, JD, facilitated the group's discussions.
- Julia J. Anderson, RN, BSN, and Dorothy E. Vawter, PhD, took notes of the event.

Dr. Vawter, Ms. Garrett and Ms. Anderson are all from the Minnesota Center for Health Care Ethics (MCHCE).

Questions about pandemic influenza

Participants raised many questions, including:

- How effective is hand sanitizer? Does it wear out? How many times can you use it before you need to wash your hands?
- Has there been research about past pandemics or are they too different to learn from? If people get the flu in the first wave, do they get it again in a later wave?
- Are personal care attendants (PCAs) considered key workers? Are they included in the 5% of MN population estimated to be key workers?

Panel's preliminary rationing objectives

The definitions of fairness and what count as core infrastructures are important. Illustrative comments included:

- PCAs should be considered key workers, if they are not already. A recent Minnesota Department of Human Services report found an unexpectedly large number of home care workers in the population. Key workers should include people who come in contact with large numbers of people, such as bus drivers, taxi drivers, grocery store cashiers, doctors, and police officers. A home supervising nurse may go into 10-15 homes a day, and so we don't want the nurse spreading illness to clients at risk. We need to protect food workers, especially those who produce and handle food and who work in grocery stores. People who work with stressed clients should be protected. Staff in women's shelters often contract illnesses from the women and children they serve, as these clients are often stressed and tend therefore also to be ill. Nursing home workers should be key workers, because in a nursing home when one person gets sick, everybody gets sick. Consider the vulnerability of the clients being served by the worker. For instance, some people with disabilities have high levels of dependence on a support team (they need someone to help them get out of bed and to get nutrition and fluids) and are at high risk of complications from the flu. Consider a person's immediate risk of jeopardy if their support team is

too ill to work and protect that person's support team. "I prefer that my support team be vaccinated rather than me." Support team workers tend not to have many back-up workers who can fill in for them when they are ill and it is especially important that they be considered part of the core infrastructure and be protected.
- Everybody depends on police, firefighters, doctors, nurses, food workers, water and power plant operators, and transportation workers, so they, too, should be considered key workers within critical infrastructures.
- "Fairness makes me nervous. Who decides what is fair? Would they think that I don't have a good quality of life?"
- All three objectives are good ones. They cover all the things you think about. A large portion of the disability community does not pay taxes and we worry we may be the last group on the totem pole. Some worry that the rich guys, such as the CEO's son, will get the vaccine before others who are at higher risk. Others countered that the wealthy don't always get what they want. All three things are important, and they go hand in hand.
- Some said infrastructure is vital. After protecting key workers, attend to those at highest risk. One person recommended prioritizing those at highest risk, specifically those who live in close quarters like nursing or group homes, and then vaccinate parents and others people depend on.
- Others said that prevention of death is #1. Populations at the highest risk of dying should get resources first.
- Someone suggested that fairness is a way to attend to objectives 1 and 2.

Age-based rationing

The group included several vocal advocates for prioritizing children and pregnant women:
- This is because children are the next generation. They are our future.
- You've got to give kids a shot.
- With technology, kids are 100 times smarter than we are. They may find a cure for cancer and diabetes.

Several agreed that many older people would be glad to forgo vaccine and pass it on to younger people. Several said that they personally would want kids to get it instead of themselves.

Some worried about who will take care of the children, if children get the vaccine before adults. "Even if we have half the adults, there is no way that half the adults can take care of all the kids. . . I don't think we can put all our eggs in a single age basket, because it may turn out it is the wrong basket. We need young adults to keep society running."

One participant said, "I hate age. My little social worker self hates telling someone they are of more value at any time. Part of me gets the creeps because I have a disability and I do not feel valued in this society. We may not be on the high end of the totem pole. As a child I would not have been able to survive. Don't give it to me as a child, give it to my parents." Another countered that there are lots of latch-key kids that fend for themselves just fine.

Someone suggested that a random lottery, like drawing social security numbers, would be the most fair.

Another participant suggested that vaccine be allocated in proportion to the size of different age groups in the population, perhaps weighted by differences in risk in different age groups. Several others liked the idea of striving to retain the same relative proportions of each age group. They argued that we need to give a proportion of the vaccine supply to each age group, not just children. Everybody has a right to life, and lots of people are living long and healthy lives.

In a straw poll, three people favored prioritizing groups based on age. Three other people favored maintaining the status quo of age distribution across the population by giving a portion of the supply to each group in accord with its distribution in the population (then randomly distributing among members of each age group). One person was opposed to any consideration of age. Other participants were not sure.

Barriers to access

People with disabilities will need access to emergency assistance, food, medicine and protective gear, but they face many barriers.

Poverty

- During flu outbreaks I want my PCAs to wear a mask. Medical Assistance does not pay for masks, though it should. A box of good masks costs $45, which is very expensive and few of us can afford. And by the time I arrived at the store, they were all gone.
- There are strict rules about income. In the nursing home, we receive $89 a month. This doesn't allow us to do any stockpiling, even though we know what the government advises us to do. Relax rules about access to money and relax the purse strings. If a pandemic occurs at the end of a month it will be worse than at the beginning of the month. "We're screwed." "It will be another Katrina."

Rules and regulations

- I am not allowed to fill prescriptions ahead of time. I cannot have more than 30 days of medicine.
- In nursing homes, residents cannot have any over-the-counter remedies without a doctor's order. We have limited access to doctors for the purpose of getting such orders.
- PCA rules need to be relaxed. When you get the flu you will probably need an increase in your cap on attendant hours. People with anxiety issues, OCD and other mental illnesses many need more support and more frequent support during a severe pandemic. There are rules about changing your need for PCAs. Consider suspending caps on hourly PCA requirements and the frequency with which PCA needs are reassessed. Relax rules about sharing PCAs so that one PCA can assist another person while visiting their client. Excuse your PCA when you don't need them so they are free to help others. The rules need to be made more flexible. Just when more physical and emotional care is needed, less could be available.

Transportation

- Metro Mobility is only available in metro area, and not even in all counties of the metro area. Greater Minnesota does not have it. Public buses only have 2 slots for wheelchairs. In a severe pandemic, how will people with disabilities get to the doctor? We don't even know if the buses will be running.
- Season and weather can have big impacts on mobility. Wheelchairs don't work well in snow. Though people with wheelchairs can ride the bus in good weather, they cannot in bad weather.
- Crowds and wheelchairs don't mix, which will make it difficult to attend mass vaccination centers, and the like.

Limited capacity to stockpile

- Financial barriers to stockpiling are compounded by limited space to store supplies. Many people with disabilities live in small apartments, group homes and nursing homes. Participants stated that items left in common areas of group homes are frequently stolen. They wondered if some apartment complexes might be able to make some storage space available for stockpiling.

Communication

- There needs to be a central government service that knows where all the people with disabilities are located. We need to have a database and a way of checking on everyone. Currently, only our individual agencies know where we are. Everyone has a different agency, and my agency only checks with me once a year. That is not a good safety net.
- The ham radio club at Courage Center is a good resource for communicating with and among people with disabilities.

"Paper doll" exercise

We offered participants the option of breaking into three small groups or engaging in the exercise together as a single group, as some of the participants' disabilities made completing the exercise individually too onerous. Someone said, "20 heads are better than four," and the group agreed to engage in the exercise together. Rather than give each person a stack of paper dolls, we projected the 12 paper dolls as 12 PowerPoint slides in the slide-sorter view. Then the slides were moved around as suggestions were made. The group offered 2 slightly different orders of priority and one participant offered an alternative prioritization.

Key workers were uniformly prioritized, though one of the group prioritizations would prioritize key workers at moderate risk to receive flu treatment before those at high risk. The rationale was that workers at moderate risk may recover and return to work sooner than workers who are at high risk.[168] The two recommended arrangements by the group next prioritized high risk children and high risk young adults, though one proposal prioritized moderate risk children simultaneously with high risk children and high risk young adults. Both arrangements by the group prioritized children and young adults before older adults and seniors.

The participant who earlier said she hated the idea of age-based rationing, said that she was not so sure about the group's proposed prioritizations, but she didn't know how she would change it. A few participants indicated that they would feel better about age-based rationing if an earlier recommendation were adopted: to apportion resources among different age groups according to the size of the group in relation to the general population, and then distribute randomly among members of each age group. It was observed that the paper doll exercise was not designed to take such a strategy into account.

The participant who submitted an individual set of recommendations prioritized high risk and moderate risk seniors and moderate risk adults ahead of children.

No one advocated randomizing everyone.

Protecting core infrastructures and attending to risk and age were emphasized in all the prioritizations. Prioritizing younger people before older was favored by most in the group (some would prioritize children ahead of adults, others would prioritize children and young adults ahead of older adults), though not unanimously embraced.

Concluding Comments

People with disabilities have serious barriers to access to:

- health resources they will continue to need on a daily basis during a severe pandemic, as well as resources they to need to prevent and treat the flu;
- the ability to stockpile resources of any kind to protect themselves in the event of a severe pandemic; and
- ability to remain mobile.

Fairness requires that state and federal leaders find ways to remove unnecessary administrative, regulatory and logistic barriers in advance of a severe pandemic for people with disabilities living both in urban and rural areas.

Participants expressed their hope that their input will make a difference. They would like the panel and MDH to use their recommendations

[168] Note: Initially, during the group paper doll exercise, participants prioritized moderate risk ahead of high risk. They assumed that "high risk" meant that people at high risk would take longer to recuperate than persons at moderate risk of dying. When the facilitator explained that high and moderate risk referred to the group's relative probability of dying and did not mean that the groups at high risk cannot respond as well to treatment as groups at moderate risk of dying from the flu, some participants shifted and prioritized groups at high risk ahead of moderate risk. The exercise points to the importance of clarifying what it means for a group to be at high risk and to add information about the assumed equal efficacy of flu treatments across groups.

Appendix F: Small Group Engagement, Eden Prairie

August 1, 2009
9:00 a.m. – 3:00 p.m.

Demographic information on age, gender, ethnicity and race

15 participants: 12 female; 3 male

Age distribution:
18-29 years: 2
30-39: 1
40-54: 5
55-64: 3
65-84: 4

Hispanic or Latino: 2
Not Hispanic or Latino: 13
White: 15

Presenter, facilitator and notetakers

J. Eline Garrett, JD, Minnesota Center for Health Care Ethics, presented overviews of seasonal and pandemic influenza and the Minnesota Pandemic Ethics Project. She also facilitated the group's discussions.

Karen G. Gervais, PhD, Minnesota Center for Health Care Ethics, and Peggy Kvam took notes of the event.

Local partner

Peggy Kvam, who resides in Eden Prairie, served as the local partner for the event. She managed recruitment and registration, arranged for a room and catering and provided other planning expertise. Peggy is active in the League of Woman Voters, and it was through the League that the project team identified her as a potential partner.

Activity one: Ethical objectives for rationing

Do you agree that the following three objectives should be equally balanced? Why or why not? If you would advise Minnesota's leaders to rank some rationing objectives as more important than others, which would you prioritize and why? What objectives should be added? How strongly do you hold these opinions?

1. Reduce the number of flu-related deaths and other serious complications;
2. Reduce disruption in basic public health, public safety and health care infrastructures;
3. Treat people fairly (protect groups at especially high risk of death from flu, reciprocity, remove barriers to access, protect against inconsistency and bias).

Discussion:

- Concern was expressed that key people are educated and have good jobs, that different values will be put on people due to work status, and that if prioritization criteria are established, people will define themselves as having those criteria ("men will say they are pregnant"). Exposure to the sick, not employment alone, should be considered. Drill down to who is doing the work.
- Without key workers, no one has a chance. We must keep them healthy and create a contract with them that receiving scarce resources obligates them to work unless they are sick.
- "I'd give up my shot if I knew the infrastructure will be there to help me."

- We all need basic public health, public safety and health care infrastructures, and we should protect additional infrastructures (such as utilities, food, water, sewer, and communications), so we can practice social distancing to the extent possible. Plow the roads.
- Perhaps public health and health care workers are not the most important infrastructures in a pandemic: Are medical workers as crucial to our functioning as food workers?
- But there will be many sick people, and they will need health care professionals.
- It is important to fine tune who in which key categories of workers should get scarce resources in order to be fair to others. With respect to infrastructures, we need balance among infrastructures and should not expand too far, and we must give resources only to essential workers in each infrastructure.
- We need different strategies triggered at different times in the pandemic depending on changes in its severity.
- Many thought objective 2 was crucial, but they disagreed on why: "Because we all need it" seemed to appeal to most. Some thought it important, because protecting infrastructures accomplishes the other objectives (e.g., because protecting infrastructures is fair, which also serves to save lives and protect the public's health, one person suggested).
- After infrastructures, we should worry most about those at highest risk.
- We shouldn't go too far to expand infrastructure, because then the only ones who will have access to resources will be key workers. They will exhaust the supply. The needs of the general public at high risk should be balanced with key workers.
- Concern was expressed that not all areas of Minnesota are as well-off as the Eden Prairie/Hopkins suburbs.

Results of activity # 4 (paper dolls) insofar as it relates to prioritizing key workers and the general public at high or moderate risk

All participants chose to prioritize some groups rather than randomizing among everyone. Participants tended to create small prioritized groups. Key workers were generally put in the first tier. Relative risk was also used as a prioritization factor. With regard to risk, most prioritized high risk before moderate risk, but a few did the reverse. Those who prioritized moderate risk first did so under the assumption those with moderate risk were more likely to recover quickly if given medication and those with higher risk might be too ill to recover at all.

Activity two: Age-based rationing

How should Minnesota ration flu medicines among those in the general public who are sick with the flu and at the same risk of dying from the flu? Always randomly select who gets the medication? Why or why not? Should Minnesota ever first prioritize some age groups before others? Why or why not? If Minnesotans generally agree, which age group(s) should receive flu medicine first, second, and so on? Why? How strongly do you hold these opinions?

Discussion

- Concerns were expressed about creating lopsided generations if resources are rationed by age, and the needs of orphans. Many single parents are responsible for children who perhaps should be prioritized.
- Some thought that the level of risk or vulnerability was more important than age. One thought using age to ration was a slippery slope.
- Certain age groups have other things in common that make them a priority. It's what goes with an age group that really matters, such as dependency of others on that person, and being parents of minors (because young people are a priority).
- One person suggested that adults should all be asked whether they are willing to forego treatment and conjecture that seniors would do so in favor of children (all seniors in the room seemed to agree).
- Other social roles matter to making finer discriminations. But do prioritize children.
- As a society, we prioritize kids, so do so here too, up to age 18. If I opt out, then I should be able to give it to someone I choose.

- It depends on how the pandemic affects the population. If there is very high mortality, people of reproductive age should be prioritized. Working adults assure that our economic backbone is secure. So attend to reproductive and economic functions.
- Should age be used as a factor? Approximately 2/3 of the group said yes, 1/3 said no.
  - Yes: ½ to kids; ¼ to people of reproductive age
    - A random system can't really be random (e.g., the Vietnam draft).
  - No: Randomize; the human race is resilient; variety is the recipe for survival.
- One person suggested distributing placebos to those who were not prioritized. People will panic if they know they will not be given treatment but another age group of sick people will. Give all the sick at the same risk random access to Medication or placebo, but don't tell them that is the arrangement. What are the societal repercussions if all under 30 are treated and you just turned thirty? Panic will be the social impact of age-based rationing, which will feel arbitrary to many. Give everyone something to avoid panic.
  - The group rejected this idea. "We need to make a conscious decision so everyone knows what they are getting or there will be no trust in government."

Results of Activity 4 (paper dolls) insofar as it relates to age-based rationing

- Age-based rationing appeared to be more embraced in the cards than in the age conversation. One person who opposed age-based rationing said that because 10 of 12 of the cards had age as a characteristic, there was implicit pressure to use age to sort the cards. Others disagreed.
- There was a range of perspectives offered, but it was fairly common that key workers and kids were prioritized. For some participants, age trumped risk. For example, some prioritized high risk children before moderate risk children, but placed all kids (including moderate risk) ahead of some other age groups at high risk. For others, risk was considered before age. For example, high risk children were followed by other age groups at high risk, then followed by children at moderate risk and so on. Some participants prioritized adults of parenting and working age before children.
- Perhaps the groups should include people with dependents, it was suggested.
- Avoid making judgments about the people's worthiness to be prioritized for medication.

Activity three: Barriers to accessing resources

Cost and uninsurance

One participant offered her personal case: She turned 25 and lost health coverage through her parents, she was refused insurance due to preexisting condition, and she doesn't qualify for government assistance. She can't afford medications for her condition ($1000-$2000 per month) and does not get them. She does not know if she could afford flu-related resources.

Many people are not working or are chronically underemployed. This economy is hard on everyone. There is fear that those who are well-off will be able to game the system.

Mobility

There are layers of mobility issues: elderly in apartments, the homebound, and those unable to drive for reasons of illness or disability. The participant who cannot afford drugs to treat her narcolepsy can no longer drive because of that untreated medical condition. Metro Mobility does not serve all of the metropolitan area, even though it's needed in all corners of the Twin Cities. Those who live in greater Minnesota have even more mobility problems.

Population diversity

Language and cultural diversity.
Eden Prairie is home to a large immigrant community with uneven access to health care and communication systems.

Geographic

Minnesotans in rural settings don't enjoy the same access to health care as those in the metro area. Rural and outstate: fewer resources and health care providers.

Stigma

Some participants feared being stigmatized or discriminated against if they suffered a chronic cough or allergies (thus appearing to be ill), even though they were not contagious.

Religious and ideological barriers

Personal and faith beliefs might prevent or inhibit some people from seeking necessary care or taking other appropriate measures, such as social isolation.

Isolated people

We need connections to social support. Isolation can be chronic or short-term. Examples:

- People with disabilities
- Single people living alone and without substantial community or family connections;
- People with communication impairments
- Bad weather can leave people homebound.

Other ideas for addressing barriers

- Metro Mobility: expand beyond Hennepin and Ramsey Counties and make available 24/7
- Home care/home visits
- Use lay people to identify situations requiring a community health worker
- When designating vaccination sites, make sure the transit system goes there
- Rural residents should have temporary housing options in more populated areas so they can access care more easily
- Connect with churches
- Grocery delivery
- Give state assistance to those who have to keep working to keep their home, pay bills and yet are told to stay home because they are symptomatic or are taking care of someone who is ill
- Prepare for school closing impacts
- Dispensing clinics: many cannot drive and won't be able to drive
- Schools are a primary source of health information for many families. Liaisons to poor and immigrant groups are needed—groups that might spin out of the orbit of public communications
- A lot of communities learn a lot from their kids; teach the children in school, and send messages home to parents
- Use gymnasiums as mass sites for care, dispensing medications, etc.
- Use buses to deliver resources
- Privacy may be vulnerable in improvised health care settings or overworked clinics, leading to vulnerability to identity theft; worry about maintaining consistency, quality, honesty of care, identifying scams
- Pandemic has a relationship to health care reform: we need affordable health care and not coverage limited to the healthy and wealthy
- Get medicine out to the people, and figure out payment issues later
- Create an "FDIC" for pandemic: Set aside a large amount of money for a quasi-public corporation to manage, disperse to individuals and public health agencies as needed for aid
- What can help volunteerism continue to flourish? Remove barriers to volunteerism, provide no-fault guarantees for communication, checking on people, comfort care by non-licensed people
- Train citizens in emergency management
- Give vouchers to doctors to respond to needs
- Create triage centers where people can request assistance
- Use phone banks for many purposes

- Community action and education must start now
- Know your neighborhood
- Barriers to personal preparation are many, including health insurance restriction on prescriptions allowed to be filled only for one month
- Take examples from other countries in how they are dealing with hardships.

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Appendix G: Small Group Engagement, Leech Lake Band of Ojibwe

Walker, MN
July 29, 2009

Demographic information about participants

1) How old are you?

a. 18-29 years	3
b. 30-39 years	2
c. 40-54 years	1
d. 55-64 years	2
e. 65-84 years	3
f. 85 or older	0

2) What gender are you?

a. Female	7
b. Male	4

3) What is your ethnic origin?

a. Hispanic or Latino	0
b. Not Hispanic or Latino	7
c. Unknown	1
no answer	3

4) What is your race? (circle all that apply)

a. White	1
b. Asian	0
c. Black	0
d. American Indian or Alaska Native	10
e. Native Hawaiian or other Pacific Islander	1
f. Other	0
g. Unknown	0

Total number of participants: 14

Administration of event

Pamela LeMaster, Minnesota Department of Health (MDH) Central Region Field Services Epidemiologist, gave a presentation and answered questions about influenza and pandemic influenza. Debra DeBruin, PhD, Associate Director, Center for Bioethics, University of Minnesota (UMCB), gave a presentation and answered questions about the Minnesota Pandemic Ethics Project and facilitated discussion. Candace Holmbo, Administrative Director, UMCB, also a member of the Leech Lake Band, took notes and assisted with administration at the event.

Local partner

Leech Lake Band Health Division: Tonya Losh, Emergency Preparedness Coordinator, Leech Lake Band of Ojibwe provided planning advice and expertise, assisted in date selection, arranged for a venue, and managed recruitment.

Activity one: Ethical objectives for rationing

Participants overall agreed that these three principles are important. A strong theme in the discussion was that one should have a choice to be vaccinated or use other interventions, and that there should be

no coercion. There was a lot of discussion about fairness as an ideal that tends not to be realized in treatment of this community, and widespread expression of lack of trust in the system.

Participants also emphasized the need for the state to provide more information to this community about influenza and plans for response to pandemic. Strong concerns were expressed about lack of information, and about media sources of information promoting panic and misinformation rather than providing helpful information.

Activity two: Age-based rationing

About 2/3 of participants were willing to place some priority on protecting children, the other 1/3 were not. There was a good deal of support for prioritizing elders, given their importance in this community. Participants discussed the value that the community places upon elders. One member expressed gratitude that this discussion could be held with a group that included young adults, middle aged adults, and elders, so that all could be heard, and younger members of the community could learn from elders. Others were quite moved by these comments, and participants in general seemed to agree with this sentiment.

Activity three: "Paper dolls"

Eleven out of 15 prioritized key workers, meaning they were given a priority of 1, not that they were listed alone at that priority. Only one person in this group ranked each card individually 1 through 12 without any ties among the cards.

Even with all the support for children in this group, only five people prioritized children over other age groups. Six people prioritized adults equally with children or with higher priority than children. This analysis relates specifically to age groups, not to key workers. Also, this counts only those individuals who prioritized by age at all, rather than, e.g., those who refused to prioritize or who ranked only by risk.

Two out of 11 refused to prioritize at all, assigning all cards a priority of 1. One additional person commented on the cards that he/she preferred equal opportunity over prioritizing, but if forced to prioritize, offered a ranking.

Activity four: Access barriers

Transportation was named as the biggest access barrier in this community. It was suggested that resources like the casino shuttle be used to transport people to vaccine sites or flu centers. It was also suggested that resources be brought into the community, using community centers and satellite clinics as flu centers and vaccine distribution sites.

Lack of information is also a significant barrier. People need information to understand the need to seek services and to know how to seek services. Suggestions for ways to disseminate information included: local newspapers, churches, community centers, grocery stores, billboards, mass mailings and schools. A desire was expressed for assistance with conducting community forums on influenza to educate the community.

Concern was expressed about financial barriers to care. The Emergency Preparedness Coordinator stated that she did not believe that there would be a charge for vaccine at tribal clinics.

Comments and key messages

There was **tremendous** interest in more education about influenza/pandemic influenza expressed by these participants. **Every** participant said that the reason they came to the group was to learn more about the influenza. There was a clear need and desire expressed for more education on influenza/pandemic influenza in this community.

There was a fair amount of distrust of government expressed at this meeting, a sense that this community tends to be left behind, that treatment of this community has been very unfair, and there is little confidence that treatment will be fair in this pandemic.

There was a request for information about how to help special populations, given the high incidence of underlying health issues in this community.

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Appendix H: Small Group Engagement, Moorhead

July 28 and 29, 2009
5:30 – 8:30 p.m.

Demographic information on age, gender, ethnicity and race

16 participants: 10 female; 6 male
Age distribution and race/ethnicity of participants:

18-29 years:	8
30-39:	3
40-54:	3
55-64:	1
65-84:	1
Hispanic or Latino:	1
Not Hispanic or Latino:	11
White:	14
American Indian or Alaskan Native:	1
Unknown:	1

Presenter, facilitator and notetaker

Karen G. Gervais, PhD, Minnesota Center for Health Care Ethics (MCHCE), presented overviews of seasonal and pandemic influenza and the Minnesota Pandemic Ethics Project. She also facilitated the group's discussions.

Isaac Triebold, MS, West Central District Epidemiologist, Minnesota Department of Health (MDH), attended to answer questions about influenza and pandemic planning, as well as to represent MDH at the session.

Kerry Hjelmgren, MCHCE, took notes of the discussion.

Local partner

Clay County Public Health served as the local partner for the event.

Activity one: Ethical objectives for rationing

Do you agree that the following three objectives should be equally balanced? Why or why not? If you would advise Minnesota's leaders to rank some rationing objectives as more important than others, which would you prioritize and why? What objectives should be added?

1. Reduce the number of flu-related deaths and other serious complications
2. Reduce disruption in basic public health, public safety and health care infrastructures
3. Treat people fairly (protect groups at especially high risk of death from flu, reciprocity, remove barriers to access, protect against inconsistency and bias)

How strongly do you hold these opinions?

Discussion

- Concern was expressed about who would make the decisions: ethicists, upper-class white people?
- Other infrastructures such as fuel production and transportation (trucking) seem relevant.
- Concern was expressed for people who service high risk populations (transient, homeless and those without access to health care) and are exposed to great risk themselves.
- Objective 1 seems limited. We should be worried not only about deaths from the flu but also about deaths due to other consequences of the pandemic.

- Objective 1 is the primary goal. Objective 2 is a means to it. There are many functions rolled into the infrastructure objective. Public safety and health care are different, and public health sounds like a vague bureaucratic entity. Maybe these are different, perhaps they should be thought about on different levels.
- We are talking about how to make decisions when the system is overwhelmed and lacking resources. Are these infrastructures the right ones? What about teachers and daycare providers? People servicing the higher risk populations? What does "fairly" mean under these circumstances?
- All of the objectives relate to each other. We are not going to be able to achieve 1 (protecting public health) unless 2 (protecting infrastructures) is in place. The infrastructure objective implies the other two, since we cannot preserve public health or be fair without protecting infrastructures. Similarly, protecting infrastructures and being fair will also serve the public health.
- Fairness matters to prevent riots. Cost barriers are unfair.
- It's not fair to include only public health, public safety and health care infrastructures. Teachers and all those working directly with the sick should be included.
- If we prioritize infrastructures, then we will not necessarily protect public health. We would have to protect those at the highest risk to achieve the first objective. Will we have succeeded in being fair if we only protect infrastructures? Not necessarily. It depends on how we prioritize key workers and what remains for the general population.
- Balancing (and re-balancing) the three objectives seems problematic for decision-making. We need to rank the objectives.

Activity two: Age-based rationing

How should Minnesota ration flu medicines among those in the general public who are sick with the flu and at the same risk of dying from the flu? Always randomly select who gets the medication? Why or why not? Should Minnesota ever first prioritize some age groups before others? Why or why not? If Minnesotans generally agree, which age group(s) should receive flu medicine first, second, and so on? Why? How strongly do you hold these opinions?

Discussion

- Random is fairest after we have taken care of our most vulnerable.
- Random allows for entire spectrum of ages to continue.
- While random might seem to hurt children, if we save them and their parents die, they are harmed.
- Each generation has its unique value.
- Ration to age groups proportionately.
- Be fair within each age category by randomizing within it.
- Prioritize younger adults to keep the economy and society going. Leave out the oldest and youngest.
- Consider the social roles of various age groups.
- People over 65 years of age do a lot of volunteering, and are very important to the community when volunteers are needed.
- It's unfair to a specific age group if randomization is not used.
- Many advocated randomization under the assumption that if we prioritize certain age groups for resources we would be in danger of losing an entire generation.
- If we randomize by age, which groups should come first?
    - 18-40: people on whom others are dependent, then children
    - under 18
    - 0-40
    - older generations would not accept resources in favor of kids

Activity three: Access barriers

What kinds of problems can people in your community have getting access to care?

- Health insurance.
- Acceptance of immunization.
- Finding quality care in our region.
- Need for more clinics, urgent care centers, and health care workers.
- Time off of work to get immunizations and access to immunization site in a timely way.
- Homeless people have no access to health care or find it difficult to get health care. We need an alternative care arrangement for the homeless in a pandemic.
- Shelters with people living so close together increase risk and needs.
- Transportation: The area is pretty rural with a few regional hospitals. People living in town need the bus service (bus service was stopped during the flood, so no one could get anywhere). A lot of families don't have transportation.
- Weather: concern about infrastructures for water and heat.
- Oxygen supply: 3-4 days maximum at a local hospital. Concern about trucking, loss of needed supply.
- "Not everyone has the financial resources to stockpile. People are on food-stamps and very low income. We're all dirt poor."
- The most vulnerable in our community are the homeless, low income, minorities, elderly and disabled. Strategies need to be in place for each group.

What types of things can the state do to improve access to care prior to a crisis, and during a crisis?

- We have space to expand. Use schools and the dome for shelters.
- Need for police escorts (as in the flood) to obtain needed resources.
- Mobile vans for medical assessment and distribution of medicine to promote social distancing goals and reach rural population.
- We have a lot of volunteerism here: How can volunteers be kept functioning? Concern that volunteers would be putting themselves in harm's way.
- Communication strategies: TV, radio
- Some participants expressed distrust in the government.
- Give out free stuff (like sanitizer and masks) to help the population prevent and slow the spread of disease and educate the public
- "If our state wants to help us they need to distribute what we should have."
- Concern about fairness: In the flood, some families took a number of clean-up kits, while some families got none. We need some way of knowing who is getting antivirals. Black market concerns.
- Create a registration system for fair distribution. Use the National Guard or another service to do it.
- The many relief services we had during the flood will likely not be good in a pandemic when everyone is dealing with their own issues. As a community, we need to plan how we are going to manage when we will not have the help of outside volunteer groups.
- Recent immigrants or illegal immigrants are not on the census. They will be exposed and could spread disease, so we'll have to serve that population. Randomizing will miss that population.

Activity four: "Paper dolls"

<u>Discussion</u>

- Group 1 should include people at moderate and high risk up to age 40, and key workers. That is our future; 41-65 year olds have already had a chance at life.
- Group 1 should include young adults to age 40, children under age 18 and all key workers.
- Younger people will be needed to clean up after the pandemic.

- It is not fair to let the people at highest risk die. If those at the highest risk are not prioritized, there is greater risk to everyone. Prioritize those at high risk from young to old and then prioritize those at moderate risk from young to old.
- 41-65 year olds are economic leaders. It might be wise to prioritize them.
- Implement a weighted distribution to assure appropriate population balance, so we don't lose an entire generation.
- Group 1 should include everyone at high risk. Grandparents can take over from parents and those ages 41-65 have economic know-how.
- Randomize everyone: That's the fair way of doing it, giving everyone an equal chance.
- Another suggestion: Group 1 should include high risk kids, young adults, key workers, seniors over 85 and all children under 18. Those at highest risk of mortality and children should come first.
- The vulnerable (young and old) should be taken care of first before key workers and policy people.

Participants highlighted the risk of mortality, concern for children and concern for social stability when determining priorities. Among those who preferred to prioritize children, the primary justifications were that children are our future and they have not had a chance to live a full life. Participants demonstrated a strong concern for infrastructure as a means to getting through and recovering from the pandemic.

Paper Doll Results

The vast majority (94%) of participants chose to ration flu treatment by prioritizing some groups over others rather than randomize across the board (6%). Of those who prioritized, most (86%) prioritized key workers at high risk of dying (29% prioritized both key workers at moderate and high risk). Most participants (79%) prioritized among groups in the general public based on a mix of differences in the level of risk of dying and differences in age. High risk children and high risk young adults were generally (57%) prioritized ahead of other groups. (21% prioritized young adults or young adults and adults ahead of children. 14% prioritized children ahead of adults and key workers.) Most participants appeared to accept randomization under some circumstances as they ranked 3 or more groups at the same level of priority.

Final question

How did the information shared in this discussion influence your thoughts about prioritization?

- You should do the card exercise first and then again at the end.
- The news has desensitized me to what is really happening with pandemic.
- It's reality that pandemic could be here.

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Appendix I: Small Group Engagement, North Side Neighborhood, Minneapolis

August 1, 2009

Demographic information about participants

1)	How old are you?	
	a. 18-29 years	2
	b. 30-39 years	2
	c. 40-54 years	6
	d. 55-64 years	2
	e. 65-84 years	0
	f. 85 or older	0
2)	What gender are you?	
	a. Female	8
	b. Male	4
3)	What is your ethnic origin?	
	a. Hispanic or Latino	0
	b. Not Hispanic or Latino	10
	c. Unknown	1
	no answer	1
4)	What is your race? (circle all that apply)	
	a. White	0
	b. Asian	0
	c. Black	11
	d. American Indian or Alaska Native	0
	e. Native Hawaiian or other Pacific Islander	0
	f. Other	1
	g. Unknown	0

Total number of participants: 12

Administration of event

Debra DeBruin, PhD, Associate Director, Center for Bioethics, University of Minnesota (UMCB), gave a presentation and answered questions about influenza and the Minnesota Pandemic Ethics Project and facilitated discussion. Makeda Norris, Minneapolis Urban League, assisted with administration of the event. Jacob Owens, Public Health Preparedness Consultant, Minnesota Department of Health (MDH) Office of Emergency Preparedness, also offered his expertise and assisted with facilitation of discussion.

Community partner

Minneapolis Urban League: Makeda Norris provided planning advice and expertise, assisted in date selection, arranged for a venue, managed recruitment, and assisted with administration of the event.

Activity one: Ethical objectives for rationing

There was broad agreement on the principles. It was suggested that the second principle—protect public safety and civil order—includes the other two principles. In other words, that the other two principles regarding protecting the public's health and promoting fairness follow from or fall under the concern with public safety and the civil order.

While there was substantial support for the principle about fairness, there was also substantial discussion about how our society does not tend to live up to this principle, in the experience of the members of this community. There was discussion about how fairness relates to trust and a widespread expression of lack of trust in the system.

As for protecting critical services, participants named hospital and other health care workers, police and firefighters, the National Guard, water and sanitation workers, as well as people who provide direct human services. Among these, only those who are at higher risk (including with greater exposure) and who provide really critical services should be prioritized (so not, e.g., the fire department mascot).

Activity two: Age-based rationing

Participants broadly rejected the use of age as a criterion for rationing. There was some sentiment in favor of lower priority for those over the age of 85, since they have already lived a fairly full life, but this was a minority view. There was no support for prioritizing children, *unless* we also protect their parents, since the best way to protect children is to have families remain intact as much as possible. There was *substantial* talk about the need to protect families, both because this is the best way to protect children, and because parents support the broader society through their work.

Activity three: "Paper dolls"

Seven participants out of 12 prioritized key workers at #1, with some of them including other groups (like people at high risk) in the top priority.

Three participants (¼ of those present) refused to prioritize at all, and assigned all cards a priority of 1.

Only three people prioritized children before adults. One person prioritized adults before children. Most participants prioritized explicitly by risk (e.g., 1 = key workers at high and moderate risk + all other high risk groups, and 2 = all other moderate risk groups, or 1 = key workers at high and moderate risk, and 2 = all others at high risk, 3 = all others at moderate risk).

Activity four: Access

Participants named significant barriers to access: transportation; lack of information; and lack of affordable insurance coverage. Participants felt strongly that there should be more outreach into the community, with education and services brought right into the community. They recommended that MDH and local public health agencies partner with community groups and advocacy groups to implement this sort of outreach.

Comments and key messages

The participants expressed a strong desire for more information about the influenza in this community. Concern was expressed about how people would know about influenza or about responses to it. It was suggested that one of the project's recommendations should relate to more education for the public.

There was significant support for use of first-come, first-served as a strategy for distributing resources within risk groups. It was felt that any other approach involves too much micromanaging to be realistic. It was also felt very strongly that if resources were brought into at-risk communities, then first-come, first-served would not disadvantage these communities. So if the participants' recommendations about improving access by reaching into these communities were implemented, they felt that this would address the panel's reasons for rejecting first-come, first-served.

Appendix J: Small Group Engagement, Powderhorn/Phillips Neighborhood, Minneapolis

August 4 and 5, 2009

Demographic information about participants

1. How old are you?
   - a. 18-29 years 3
   - b. 30-39 years 0
   - c. 40-54 years 5
   - d. 55-64 years 5
   - e. 65-84 years 3
   - f. 85 or older

2. What gender are you?
   - a. Female 9
   - b. Male 7

3. What is your ethnic origin?
   - a. Hispanic or Latino 4
   - b. Not Hispanic or Latino 6
   - c. Unknown 1
   - no answer 5

4. What is your race? (circle all that apply):
   - a. White 3
   - b. Asian 0
   - c. Black 6
   - d. American Indian or Alaska Native 3
   - e. Native Hawaiian or other Pacific Islander 0
   - f. Other 2
   - g. Unknown 0
   - no answer 3

Total number of participants: 17

Administration of event

Debra DeBruin, PhD, Associate Director, Center for Bioethics, University of Minnesota (UMCB), gave a presentation and answered questions about influenza and the Minnesota Pandemic Ethics Project and facilitated discussion. Sarah Ekerholm and Kristen Godfrey from the Phillips Neighborhood Clinic assisted with administration. Grace Fleming, intern at UMCB, assisted with notetaking. Minnesota Commissioner of Health Dr. Sanne Magnan attended the event and answered questions about influenza, influenza-related health resources, and Minnesota Department of Health (MDH) preparedness work.

While all participants spoke some English, one participant spoke predominantly Spanish during the event. Another participant spoke some Spanish. Translators were present at the event to assist as needed.

Community partners

The community partners were Phillips Neighborhood Clinic and Minneapolis Urban League. Makeda Norris from the Minneapolis Urban League provided planning advice and expertise. Sarah Ekerholm from the Phillips Neighborhood Clinic provided planning advice and expertise, assisted in date selection, arranged for a venue, managed recruitment and arranged for translators to assist Spanish speaking participants. Kristen Godfrey from the Phillips Neighborhood Clinic provided planning advice and expertise and assisted with administration of the event.

Activity one: Ethical objectives for rationing

There was fairly widespread rejection of rationing in this group. Main concerns:

1. There was strong support expressed for the principle about fairness and recognizing the equality of all, but it was felt that this principle conflicts with the prospect of rationing.
2. Participants were outraged that we can pay for war and bail out banks but not acquire enough resources to protect people from influenza.
3. Groups in this community tend to suffer health disparities and tend to be left behind. They do not trust that they will not be left behind again. They intend to organize to protect themselves and hold planners and responders accountable. They feel that any response to risks of influenza must take disparities seriously and respond to this community as a high risk community.
4. The view was expressed that if participants indicate agreement with the principles, then their agreement can be used against them to commit them to a rationing plan that supposedly follows from the principles, when they do not support such a plan.

Activity two: Age-based rationing

1. There was a lot of sympathy for planning to protect children. However, there were strong views expressed that in order to protect children, we must also protect parents.
    a. Participants were very worried that if we did not protect parents, children would be orphaned. Even if someone else could care for the children, they felt that this would be very harmful and damaging to the children. This was by far the main reason participants felt that we must also protect parents.
    b. Some participants were also concerned that if we vaccinate children, we will then feel free to send them to school. But then they could easily bring home virus on their hands, clothes, belongings, and thus put the rest of their families at risk. So protecting children may increase risk for those in their families. This was a minority view, however.
2. Other than the concern about children/parents, participants expressed the view that other prioritizations based on age—as distinct from risk—amounted to ageism, akin to racism and other problematic bases for rationing. We shouldn't use race or wealth as a criterion for rationing if risks were equal, and likewise we ought not to use age in this sense.
3. Participants strongly supported the use of age in making decisions about care for individuals to the extent that age relates to risk.

Activity three: "Paper dolls"

Five out of 17 participants refused to prioritize at all, assigning all cards a priority of 1. An additional participant assigned all groups a priority of 1 except seniors aged 85 or older.

Five participants prioritized key workers, meaning they were included among those in first priority, not that they were listed alone at that priority.

Only two people prioritized children before adults. Three gave adults equal priority to children, while four prioritized adults over children.

Activity four: Access barriers

Barriers to access included language, trust, lack of documents (for immigrants), lack of insurance, poverty, unemployment, transportation, child care, lack of education about influenza.

Participants also commented that members of these communities receive differential treatment if they do get access to care.

Participants stressed that there is a need for education to be brought into communities, in different languages, and not all of it written, since some cultures in these communities are cultures with oral traditions. Education should be about influenza, and about what people can do to protect themselves and their families. Educators should look like community members (be from same racial and ethnic groups) so there is greater trust.

Participants commented that there will be a need for translators and recommended that the community should start preparing a volunteer force of translators now.

Participants emphasized that effective planning in the community will need to encompass smaller community plans involving women's groups, early childhood centers, local pharmacies that serve niche cultural markets, barbershops, churches, and schools. Planners should also use community organizations like Phillips Neighborhood Clinic, Sabathani Community Center and health networks within the Baptist Church and African American community. In general, participants pointed to a need for greater outreach into the community, to bring not only education but also services into the community and to the people, since otherwise there is too much trouble with access.

Comments and key messages

Participants raised an objection to the use of "social value" to refer to categories like race, socio-economic status, etc.

Participants highlighted a need to find a way to help these communities protect themselves. For example, many people in these communities cannot stay home from work if they are sick or to protect themselves, since they do not have paid sick days and they can't afford to lose their jobs.

This group's strongest message, by far, was the importance of culturally sensitive education of and outreach into their communities on influenza, and about organizing to protect their communities and to hold the state accountable in a process of shared power rather than one-way input. "We are here today to start a movement. The power to hold people accountable is right here in this room."

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Appendix K: Small Group Engagement, Virginia

August 3 and 4, 2009
5:30 – 8:30 p.m.

Demographic information about participants

11 participants: 9 female; 2 male
Age distribution:
18-29 years: 1
30-39: 2
40-54: 6
55-64: 2

Hispanic or Latino: 2
Not Hispanic or Latino: 9

White: 10
Other than white, Asian, black, American Indian/Alaskan Native or Native Hawaiian/ Pacific Islander: 1

Presenters, facilitator and notetaker

Karen G. Gervais, PhD, presented an overview of seasonal and pandemic influenza. She also took notes during the event.

J. Eline Garrett, JD, presented a summary of the Minnesota Pandemic Ethics Project and facilitated the group's discussions.

Both Dr. Gervais and Ms. Garrett are from the Minnesota Center for Health Care Ethics (MCHCE).

Local partner

The Virginia Rotary Club partnered to make this event a success. The Club provided planning advice and expertise, assisted in date selection, arranged for a venue and catering, and managed recruitment and logistics.

Activity one: Ethical objectives for rationing

Do you agree the following three objectives should be equally balanced? Why or why not? If you would advise Minnesota's leaders to rank some rationing objectives as more important than others, which would you prioritize and Why? What objectives should be added? How strongly do you hold these opinions?

1. Reduce the number of flu-related deaths and other serious complications
2. Reduce disruption in basic public health, public safety and health care infrastructures
3. Treat people fairly (protect groups at especially high risk of death from flu, reciprocity, remove barriers to access, protect against inconsistency and bias)

Fairness

The topic of fairness was the first thing mentioned, and many perspectives were offered.

- "We can't treat people fairly the way our world is today." Life is unfair.
- Fair means giving to those in greatest need and key workers.
- "It has nothing to do with fairness—it's the practical thing to do. Infrastructure matters, because we all depend on it. None of it is fair, but we need to take a long-term view of what saves the most lives."
- There are reasons to de-prioritize to use resources well: e.g., age at the extremes, terminally ill, chronically ill with a life-threatening disease. The act of prioritizing and de-prioritizing is unfair, but it must be done.

- So why is fairness a problem in the list of objectives? “Because fairness is not possible.” Should we pursue objectives 1 and 2 as fairly as possible? *No*, most said. Treat people in ways that minimize the death toll. Take the statement about “treating people fairly” out. Instead, say “Avoid unfairness as much as possible” or “treat people as fairly as possible.”
- Risk of mortality is an important consideration in avoiding unfairness.
- What about fairness to people of different ethnic backgrounds, asked one person. Undocumented workers? One person said public health must be inclusive. Lack of legal status should not be considered when rationing. Many in the group nodded and seemed to agree.

Participants agree that ideal fairness is impossible to attain, but were highly in favor of the more specific ways fairness was talked about, e.g., not rationing by social position, race, ability to pay, etc. They agreed with ways the panel suggested for trying to be fair but did not like the term “fairness.”

Infrastructure

There was wide agreement about the importance of protecting critical infrastructures, including both paid and volunteer key workers.

- Who is crucial to infrastructure? That must be defined.
- Infrastructures needing protection are so broad—trucking, postal, utilities. Among health care workers, prioritize those with direct patient contact. Basic population needs (like heat and water) need protection.
- Concern was expressed for police, fearing that they would be needed in order to maintain calm. Military needs protection because they are in such close quarters.
- Infrastructure objective is the highest priority to keep things going on.
- Should faith leaders be prioritized because we will need them? A lot of recovery is based on faith. There is comfort to the ill and to those who lose loved ones. It helps us be a compassionate community in a very difficult situation.
- Volunteers should be considered key workers in their community because they give direct help to people.

Risk of dying

There was general agreement, and little controversy, that considering risk was important. The participants did not discuss this criterion at length.

How the objectives fit together

This group as a whole recognized their common need for infrastructure stability. They saw objective 2 (critical infrastructures) as a means to achieving objective 1 (public health), and could not make sense of objective 3 (fairness) as stated. Most endorsed the following list of ways in which the panel described fairness, but strongly objected to using the term “fairness” to encompass them:

- Do not ration based on ability to pay, first-come first-serve, or judgments about differences in “social value”;
- Remove barriers to fair access;
- Protect groups who assume risk serving others (reciprocity);
- When all other criteria are equal, use random procedures (lottery, coin toss).

Participants saw fairness as impossible to achieve, but they did appreciate the importance of avoiding unfairness. They worried that commitments to fair processes could be corrupted.

Activity two: Age-based rationing

How should Minnesota ration flu medicines among those in general public who are sick with the flu and at the same risk of dying from the flu? Always randomly select who gets the medication? Why or why not? Should Minnesota ever first prioritize some age groups before others? Why or why not? If Minnesotans generally agree, which age group(s) should receive flu medicine first, second, and so on? Why? How strongly do you hold these opinions?

- "The only way to be fair when all are at equal risk in different age groups is that all get it or none get it, and whatever happens, happens." Any random process will be corrupted. Since we have protected infrastructure and those at high risk, it should be all or none. No one should play God.
- Kids should come first.
- Should offer people the right to waive their treatment in a document like a living will.
- An accountable, random process is impossible to set up. It will be undermined by panic.
- In a family, they would consider age. Others will accept this.
- If you used the family principle, you would not solve the problem. How would you decide which kid in your family to give it to?
- Government is the decision-maker, not a family. Population outcomes should be the focus, or do it randomly.
- Don't use any one variable like age, because it is not fair. Do it randomly.
- Use life expectancy.
- Use proportional distribution among age groups so we don't wipe out a certain age group.
- We should do age-based like this: over 60, no; under 21, yes. Why? Because the over 60s have lived most of their life.

These opinions predominated:

- Don't use age at all. Randomizing is not unfair.
- Use age. Prioritize:
  - Kids, because they have not lived life yet
  - Ages 20-45 because they are caretakers and out of concern for social stability and recovery after pandemic
- Proportional representation to age groups so no age group is wiped out

Several thought many would be glad to give their medications up for younger people but not for an older age group, and not if distribution were random.

Activity three: Access barriers

What kinds of problems can people in your community have getting access to care? What types of things can the state do to improve access to care prior to a crisis, and during a crisis?

- Medical transportation/mobility.
- People without access to a car.
- Home care is essential.
- Mass dispensation at mall, grocery stores, casinos especially on the 1st and 16th of month when seniors have money.
- Invisible people in society: Some allow you into their homes, some don't. Need trusted people to deliver resources to homes.
- Volunteerism:
  - Volunteer infrastructures in Virginia are already incredible. How to prepare them for pandemic?
  - "People need a better grasp of how big a role volunteers play. They save you for free."
  - Volunteers and volunteer organizations, churches: transportation, places to go, they know where the isolated people are.
  - Use professional or other community organizations. They are listed and easy to find, e.g., the Rotary Club.
- Communication:
  - Concern that media is making us hysterical about flu. Media is also a barrier, e.g., we've learned that you can't do education about sexually transmitted disease through media. It doesn't work. Flu education won't be any better.
  - Educate the community about how they can get information: radio, TV, internet, phone.
  - Tell people how to stay healthy and what to do if they are sick.
  - A local phone-in health-line is available, but linked to insurance. It should be made available to any citizen, regardless of insurance status.

  - Need better attention to communication.
  - Media and communications: local, state, national. Misinformation and speculation are great concerns. “No speculation like on the national media. We need facts!”
  - Local media need accurate information delivered by trusted people.
  - People who construct this kind of message will be trusted: Here is what you need to do, how to use resources, and how to avoid utter panic.
- Education:
  - “We need preemptive education so we can ignore misinformation. Ignorance will instill fear in people. From government, we need the same, seamless message.”
  - Educate volunteers, community leaders, local media connections beforehand.
- Financial barriers:
  - Seasonal flu shots cost $20 cash.
  - Cost means parents will give it to their kids, not themselves.
  - The unemployment rate in Virginia is 17%.
  - Allow people to pay for shots with an at-will donation like an item for the food shelf. That will allow them to help and serve others’ needs, while still accessing an affordable vaccination.
- Weather:
  - Be prepared for change.
  - Beef up local networks for the homebound.
  - Be prepared for rescheduling mass clinics and contacting those who are rescheduled.
- Legal status:
  - Undocumented people need to access treatment and vaccinations, otherwise the disease will spread.
  - Amnesty: We don’t care who you are, you will be treated.
  - Randomizing could miss them, depending on how randomization is administered (e.g., using last 4 digits of social security number). Need to use non-government IDs only.
  - “It’s about the virus, not the law.”
  - All or most nodded in agreement with these comments. No one expressed disagreement.

Activity four: “Paper dolls”

There was no one who called for randomizing among all of the cards. Few people had any ties at all among their cards.

All put key workers first, echoing their preference for preserving infrastructure. There was some variation in how they considered risk in relation to key workers. All but one ranked key workers at high risk first, and some ranked key workers at moderate risk second. One person reversed that order, under the assumption that medication provided to moderate risk workers would return them to the workforce earlier. Others ranked key workers at moderate risk lower than people at high risk in the general public.

Children at high risk were ranked next by most people. All ranked according to age across the full lifespan, but some prioritized non-senior adults over children, for the reason that they are caretakers and workers. Most, but not all, de-prioritized seniors. One person ranked all groups of seniors as high or higher than other age groups.

At the end of the discussion, one person offered the following arrangement, and many in the group agreed:

1. Key workers at high risk of dying
2. Children at high risk of dying
3. Young adults at high risk of dying
4. Adults at high risk of dying
5. Children at moderate risk of dying
6. Key workers at moderate risk of dying
7. Young adults at moderate risk of dying
8. Adults at moderate risk of dying
9. Seniors 66-85 at high risk of dying

10. Seniors 66-85 at moderate risk of dying
11. Seniors over 85 at high risk of dying
12. Seniors over 85 at moderate risk of dying

Final comments

- "It's hard to plan. I see why you want our guidance. I give MDH a lot of respect for having to make these decisions, because it's hard and I'm stumped."
- "Thank you for coming here and participating with a community north of Forest Lake. We don't often get that kind of representation. I'll do what I can to impact this community."
- "I volunteer to pass good information on to my community."

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Appendix L: Small Group Engagement, West Side, St. Paul

August 5 and 6, 2009
5:30 – 8:30 p.m.

Demographics

16 people participated (15 registered participants and our local partner).
15 participants responded to an anonymous demographic survey: 11 were women and 4 were men. Four participants were between 18 and 29 years of age; 5 were between 30 and 39; and 5 were between 40 and 64. Eighty-five percent were Hispanic or Latino. Racial groups represented included American Indian or Alaska Native, White, Black, Native Hawaiian or other Pacific Islander and other.

Questions about pandemic influenza

The group had many questions about H1N1 and pandemic influenza. The questions were compiled in a list, and the project team will follow up to provide answers. Questions included: What is known about the effects of vaccines and antivirals on pregnant women and the unborn? Will the state recommend or require that people receive vaccines and antivirals? Will the state be honest about what is known and not known about flu interventions? Will the state provide information about alternative, non-traditional methods of preventing and treating the flu? What is the state doing to make information available in Spanish and to reach people who do not have internet access, watch TV or read newspapers?

Presenter, facilitator and notetakers

Angela W. Prehn, PhD, Minnesota Center for Health Care Ethics (MCHCE) and Walden University, presented overviews of seasonal and pandemic influenza and the Minnesota Pandemic Ethics Project.
Dorothy E. Vawter, PhD, MCHCE, facilitated the group's discussions.
On the second evening, Buddy Ferguson was present to observe and represent the Minnesota Department of Health (MDH). He also answered questions.

Activity one: Preliminary rationing objectives

The preliminary objectives were presented, but it was made clear to participants that we were looking for their fresh ideas and opinions.

Several people stressed the importance of fairness in the process, but were concerned about implementation. There was a suggestion that transparency and accountability were paramount in order to minimize suspicion of rationing plans. It was stated by more than one participant that fairness should be an assumed goal and was implicit in all the other goals. It didn't necessarily need to be named separately.

Others felt that fairness should be the overall objective, ranked above the other two objectives.

Several people raised issues around distribution of vaccine. Some mentioned that there will be a subset of the population that will refuse vaccine, which would make vaccine more available to those who want it.

Others were concerned about fair access to the vaccine supplies and barriers for people without health insurance, who are poor, who do not speak English and who have questionable immigration status.

The issue of prioritizing children for the vaccine was raised from several perspectives: as a matter of fairness; to reduce deaths; and to reduce risk of transmission. Someone also discussed prioritizing those who work with children as a means to reduce deaths and illness. It was pointed out that unless we explicitly state other goals, the default goal will be to reduce deaths and serious illness by attending to those at highest risk.

The group did not generally feel that the second objective (protecting infrastructure) should be the only objective. Several participants voiced that none of the objectives should be only objective on the list, and some stated that all three objectives were important. There was some disagreement as to whether fairness should be stated separately or assumed as part of the other objectives.

Concern was raised again about the implementation of fairness, about processes for fair distribution. However, the idea that the historically disadvantaged should be prioritized was soundly rejected as being unfair and likely to cause stigmatization.

There was a discussion about how key workers would be defined. Some mentioned including garbage collectors. They asked whether the families of key workers would be included and also inquired about prioritization for the military. There was an acknowledgement that federal planning included military, but that it wasn't appropriate to do so for the state.

Some in the group were concerned about education and information, and stressed that communication was critical, particularly about alternatives for those who do not embrace Western biomedical beliefs.

One person favored attending to high-risk/reducing risk as a first objective, with key workers/infrastructure second, but stressed that fairness is important overall and suggested using a lottery to attend to that.

There was much discussion about putting kids first for multiple reasons: high-risk, fairness (longer lifespan) and to reduce spread of disease.

In the end, the group agreed that none of the objectives should be taken off the list.

The discussion ended with the consideration of education, its importance and where it would fit in the objectives. Someone suggested it fit under removing barriers to fair access.

Activity two: Age-based rationing

Note: For the following discussions, Buddy Ferguson was present as a representative and observer from MDH.

One participant raised the issue of uncertainty around the virus and societal health and whether vaccines/treatments will be safe and effective.

Another participant mentioned that people he had talked to would prioritize kids, with elderly self-selecting not to receive resources (or choosing alternatives). His reasoning was that he had lived already, and kids hadn't had that chance. He would like to be able to opt-out. However, he also mentioned that kids would be prioritized in his mind because they are at high risk. There was general agreement that kids should be prioritized, the reasons given included risk of mortality, and risk of transmission, as well as fairness.

One participant raised the issue of the arbitrariness of age cutoffs and definitions and expressed concern about loss of elders (collective wisdom and memory would be lost). However, she also stated that kids would be more important in the end.

The issue of quality-of-life of elders was raised, with a participant wondering if that would be part of the criteria for prioritization. The panel's recommendation to make no distinctions according to "social value" was reiterated.

Two possibilities were put forward based on conversation: 1) Give elders the option to forgo treatment so more would be available for younger people; 2) all age groups are important, so maybe randomize? There was a discussion about the importance of allowing elders, and maybe all adults, to choose to opt-out in favor of kids.

The arguments for and against age-based rationing and preliminary recommendations were then shared with the group.

Randomization was discussed as an option that would be fair and good for society in that it wouldn't group people. It would preserve all age groups; none would be risked in favor of others. Another mention was made about how it would not be good to lose elders disproportionately.

Some participants mentioned that prioritizing elders could also be beneficial as they have ability to help care for children and have knowledge and wisdom. Others mentioned opting-out to give resources to younger people. In general, the idea of being able to opt-out was strongly supported.

There was a discussion about how antivirals would be distributed, the need for a prescription, and the possibility of flu centers. This spurred a conversation about access and barriers (lack of insurance, lack of prescription).

The group was polled about randomization vs. age-based rationing among people at equal risk. Several (at least four) felt that randomization was the best strategy. Another equally sized group liked the idea of prioritizing kids, then randomizing everyone else. Others were uncertain or did not express an opinion.

Activity three: Access barriers

Several participants discussed the idea of having community health workers and advocated that the state develop and fund (or expand) such a program. It was stressed that community health workers know the community, know the language and culture and are more trusted.

It was mentioned that the local Spanish-speaking clinic is always packed and there are currently long waiting times for appointments. There is a need for more sites in the community where people can get flu-related resources.

The participants agreed that citizenship status should not be a part of decision-making around rationing pandemic flu resources. The only thing that should matter is need for services.

Participants asked for more description of current plans and requested clarity in messages that public receives. Lack of clarity creates chaos. It was mentioned that MDH is working on better communication with community-based organizations. Participants also questioned the process by which different voices are at the decision-making table and suggested that diversity is essential for good communication, community education and trust.

A barrier that was named in addition to not being insured was the fact that even in insured families, co-payments could be prohibitive particularly for large families. This is a problem, because people will opt not to be treated and then spread disease.

The issue of immigration officials was brought up in terms of the community's deep fear that they would be present at flu clinics/centers. This is a significant barrier in some communities, and there will need to be clear agreements that immigration officials will not be present and clear communication to alleviate fear. It was pointed out that history shows that immigration officials can't be trusted, and that it really can't be guaranteed they won't show up because they are an independent federal agency and have their own rules. They also dress and act in an intimidating manner. One participant said that the enemy was the virus, the medical system was the soldier, and that immigration should not be in the picture at all. It was stressed that information about access and issues around immigration needed to come from a trustworthy messenger. The involvement of faith-based communities in flu response was considered as a way of keeping immigration officials at bay.

One participant said that if he were to be the community health person, he'd need to feel that he had the backing of the government before he could or would try to assure community members that immigration officials would not be at the clinic and wasn't sure he could feel that. This was a barrier to his participation. However, another participant said that information on how community members could volunteer and/or be trained to help out in a pandemic should be available. There was substantial support for this recommendation.

Another participant mentioned that individuals are their own barriers, in terms of lack of education and knowledge. The public needs to know what all the alternatives are, not just the medical ones. Someone else mentioned that the education should not just be about their options, but also about how decisions will affect others.

In a discussion about building trust, one participant said it's important that officials are honest about uncertainty. Several participants thought the idea of MDH having information available about alternative/non-traditional approaches to preventing and treating the flu would enhance respect for and trust in MDH. Another participant said that the presentation of options and individual choice was important to enhance trust.

Another suggested that information be disseminated orally as well as in writing. Many people don't read the newspaper, have TV (because of digital transition), or have a computer. The suggestion was made that foot soldiers and door-to-door information would be important.

It was mentioned that community-based organizations already have many of the networks and connections in place to make this type of information dissemination happen and are a great resource/solution to being prepared. They just need the tools. It was also mentioned that when officials sit down to educate and inform groups, they generate buy-in. Someone else recommended that MDH hire one or more community organizers like other Minnesota government agencies have done.

Activity four: "Paper doll" exercise

None chose across-the-board randomization. Everyone prioritized some groups ahead of others.

Those who were willing to discuss their prioritizations generally put high-risk groups, key workers and/or children as the first priorities, and the oldest seniors were generally at the bottom of the list. Reasons given were varied, from fairness issues for children, to the need to prioritize key workers to help and protect others. One participant justified de-prioritizing the oldest old because if the flu was not to be their fate, something else would be. Children were also prioritized because they are our future, we are attached to them, and they have the longest lifespan. One participant mentioned that in her culture children already did the work of taking care of younger children and so they could help each other if need be.

Key workers were unanimously prioritized. Fifteen participants prioritized high-risk key workers, and one prioritized moderate-risk key workers. Four participants prioritized key workers without regard for differences between high and moderate risk.

Nearly everyone attended to age in some way. Ninety-four percent of participants prioritized high-risk children. Half prioritized children without regard for differences between high and moderate-risk. Half recommended prioritizing young adults, especially high-risk young adults. Approximately 25% of participants also prioritized high-risk seniors aged 66-85 and 13% prioritized seniors over age 85.

Overall, 75% of participants sometimes, if not always, prioritized groups at high risk of mortality over similar groups at moderate risk.

Belonging to a group at high risk of dying of the flu, being a key worker and being young at age, especially being a child, were the three most important considerations guiding rationing decisions. When pressed about the reasons some would prioritize children, a few expressed surprise that this was necessary. They considered it obvious or self-evident why children should be prioritized.

A couple of participants noted that if this discussion were happening with the kids, they would probably prioritize their parents. Another brought up the idea of putting a limit on the amount of resources key workers should get, so that there are resources for more people in the general population. Yet another participant prioritized key workers along with children because she felt they were important for helping the children. She also prioritized some high-risk elders to have continuity in knowledge and wisdom.

Another reason that was mentioned for prioritization was risk of transmission. Children play together and spread virus, while many elderly are more isolated socially.

Additional recommendations

One participant mentioned that she thought the definition of key workers was important and that both the definition and how it was decided needed to be transparent to the public. Also, individuals making decisions about who is or is not a key worker needed to be held accountable.

Another participant stressed that honesty and communication were important in moving forward, as was the presence of consistent, clear messages. A couple of other suggestions for communication were through the schools and through posters in meeting and gathering places, in languages appropriate to the community. Different schools with children with H1N1 responded very differently and communicated with parents very differently. Develop best practices so schools are consistently effective educators of the community on pandemic flu.

A passionate plea was made to include people of color on decision-making bodies, like the panel and within MDH. This type of inclusion is one of the most important ways to remove barriers and build mutual respect, trust and understanding. A participant asked whether the panel meeting was open to small group participants. She was assured that panel meetings were open to the public.

Comments

The group highly values transparency and honesty, as many have significant distrust of government officials. They requested transparency at every step and reiterated the role it plays in building trust and removing barriers. Minnesota's leaders need to work to build trust, rather than assume trust exists in sufficient measure for pandemic response plans to be effective in this community. Participants identified a full range of barriers to fair access to health services and agreed that if these barriers are to be removed, they must be removed before a serious pandemic is upon us. They recommend recruiting members of the community to serve as volunteers (to get the public health messages to people in the community, especially those with language barriers and without internet access, telephones and newspapers) and to be trained as community health workers and community organizers. Participants were eager for resources, especially those in Spanish, which they could share with others in their community. A few said they were ready to learn more and to help spread the word in their community.
Regarding the panel's preliminary recommendations, they generally supported the objectives, but wondered if there could be a better way to refer to the group of fairness objectives. They recommended clarity and transparency regarding who are key workers and those instrumental to protecting core infrastructures, and who is accountable for determining that someone is a high-risk key worker. High-risk key workers, people at high risk in the general population and children were given highest priority for access to scarce health resources.

Appendix M: Small Group Engagement, Worthington

August 5 and 6, 2009
5:30 – 8:30 p.m.

Local partner

The Community Education Division of Independent School District 518 served as the local partner for this engagement. The division was in charge of distributing flyers and recruiting participants, as well as providing a room for the event and arranging logistics such as catering.

Participants

Fourteen people attended, and all attended both sessions. Eight women and six men participated. All 14 volunteered anonymous demographic information. The ages of participants were:

- 18 – 29 (2 people)
- 30 – 39 (2 people)
- 40 – 54 (1 person)
- 55 – 64 (4 people)
- 65 – 84 (5 people)

Seventy-nine percent of participants identified as being white; 7% as Hispanic/Latino; 7% as black; 7% as other than white, Asian, black, American Indian/Alaskan Native or Native Hawaiian/Pacific Islander.

Presenters, facilitators, notetakers

Kim Wm. Jeppesen, Minnesota Department of Health (MDH) regional epidemiologist, presented an overview of seasonal and pandemic influenza. He attended both evenings to answer questions and to listen on MDH's behalf.

J. Eline Garrett, Minnesota Center for Health Care Ethics (MCHCE), presented an overview of the Minnesota Pandemic Ethics Project and facilitated the small group engagement.

Angela Morley, MCHCE, took notes of the discussion.

Questions about influenza

Participants had many questions about influenza and how to prevent spread of the disease. Questions included:

- Why does the age group 0-29 represent such a large percent of those ill with H1N1?
- How long do you usually close a school?
- In my church we give the sign of peace and shake hands. Have there been studies about the health effects of this? What do we do?
- Should we get our regular flu shot this fall, and when will it be available?
- How long does the flu shot protect us? Does it wear off?
- Will there be a cost for the shot or will it be free?
- Why is the current pandemic called H1N1?
- Why can't we have a boatload of vaccine if we have already identified the virus?
- How safe is the new vaccine for novel H1N1?
- Why do eggs have to be used? Why can we send a man to the moon and still have to make vaccine in eggs?
- My granddaughter is allergic to eggs, and has never been able to get the flu vaccine. She also has asthma. Should she start getting vaccinated even though she's allergic to eggs?
- Where are vaccines manufactured?
- Why isn't more of our vaccine supply manufactured in the US? Isn't the lack of domestic capacity a security issue? Can the domestic manufacturing capacity be increased rapidly?

- How will results from the public engagement process be reported and released?
- Is there guidance from the government about who should stockpile what? About what individuals and families should do?
- How does pandemic end? What makes it stop after a year or two?
- Will we know who is at risk during a severe pandemic? How quickly will the information be known? Will it be something we only know in hindsight?
- Will a seasonal flu shot protect me from pandemic flu?
- What can be done to slow the spread of flu so that that not as many people need vaccines and medicine? When will businesses and schools be closed?
- Are flu vaccines safe for children? Many mothers are concerned about giving kids vaccinations because of autism.
- Is flu vaccine safe for pregnant women? Does it harm the fetus?
- What are the stages of a pandemic? What is a pandemic and where does it go from here?
- What makes a pandemic severe and who declares it to be severe? Can it be worse in some places than others?
- Where did the H1N1 pandemic originate?
- Is the US helping other countries respond to the pandemic? Can other countries help us?
- What are other states and the federal government thinking about rationing?
- Have we learned much from SARS?
- If a vaccine is harmful and you got it for free what are the legal implications? Are public recipients protected? Do you have more legal protection if you paid for the vaccine?
- Are masks even worth buying? What kind should I buy?
- How is flu transmitted?
- How successful was the model of isolating people with TB? Could you use this here?

Mr. Jeppesen and Ms. Garrett responded to the questions.

Activity one: Ethical objectives for rationing

The discussion was wide-ranging. One participant compared pandemic to battle and asked what an acceptable percentage of losses or death would be. Another changed the subject and asked about key leaders, such as elected officials and teachers. Others chimed in with questions and observations about key workers and infrastructure:

- Health care workers are important. If they are sick who will care for people? They are the primary people who should have the first shot.
- The food system is so complicated. Grocery stores need supplies. Truck drivers bring the food. Everyone, including prioritized health care workers, needs food.
- Everyone connected with the food system should be prioritized.
- Pharmacists and drugstores are important.
- Does it come down to education/training level? Can you train someone to replace a clerk versus a nurse? Does that become a factor in who is in a higher category?
- For nurses, education/training takes long time so they should have priority, but people who work on a farm are also important.
- Did we not learn from Katrina? Can we apply some of those lessons we learned?
- What about other infrastructures? Public safety? Does that include electricity and water?
- There is potential for conflict among workers if some are vaccinated and others are not, so many people may complain. All or most workers will believe that their jobs are important and should be prioritized.
- The broader the definitions of critical infrastructures, the more arguments there will be about who should be considered key. The definitions should be kept narrow. Most people will understand why health care workers are prioritized.
- Think back to World War II when talking about rationing. I was born at home at the end of the month. The doctor had run out of gasoline rationing stamps, so he couldn't drive to the house. My dad had to go get him. There was no "social value" used in rationing then.

The discussion also encompassed concerns about the general population, risk of dying from the flu, and how objectives about minimizing risk and protecting infrastructures fit together.

- Contact physicians in nursing homes, because they know which people are vulnerable to infections. Nursing home residents live in confined spaces, and all are vulnerable. On the other hand, children are our future. Why vaccinate a 90-year-old in a nursing home when there isn't enough vaccine to go around?
- It's important to balance between protecting the general public and key workers. I like the way the panel recommended two tracks at the same time.
- Give the highest prioritized people the vaccine. Give the next in line a mask or some other preventive resource until more vaccine becomes available. Keep educating people about the importance of hand-washing and how to do it. Not everyone knows the importance of flu shots, either.
- Two years ago I was in Phoenix for the summer and there was a big flu outbreak. They told certain people to go to the hospital, and others to avoid the hospital. We took an elderly friend to the hospital and there was no one there. An admissions nurse said perhaps the ads worked too well.

The topic of fairness was somewhat controversial.

- The objective about fairness should be removed. Life is not fair. The flu isn't fair. We need to have someone qualified, not a politician, to be able to make a hard decision. The whims of government and politics shouldn't control these decisions.
- The fairness objective should remain. If you take fairness out then you will have more riots, looting and anger as you have taken away a basic hope: I hope I will be treated as fairly as a 16-year-old. I hope I will be treated as well as a healthy person if I have asthma.
- Who is the person who makes the decision? One of the problems with health care is that they are talking about having a board and people are fearful of giving too much power to too few, but there is tension because in the long run we have to trust someone in politics at some point. That is why we have input and democracy.
- I'm on the fence on the fairness issue and rejecting first-come, first-served. What if a mother with a small child is working very hard to keep on top with researching how to get help. If someone else who doesn't care as much wins the lottery and she can't get the resource for herself and her child, that seems unfair.

In response to a direct question about how many people thought the food infrastructure should be added to the list of critical infrastructures:

- A few said yes.
- A few more said no.
- A few were on undecided.

In response to how many thought the fairness objective should be removed:

- One person said yes, emphatically.
- Almost all said no, the objective should be kept. The term "fairness" was confusing to some, though.
- Three people were undecided.

How should the three objectives be related to each other? Should they be balanced, with each tugging against the others, or are one or two objectives more important?

- A few said that they should be balanced equally.
- Many said that the objectives about reducing risk and protecting infrastructures are more important than fairness. One person observed that the clearer the infrastructure objective is defined, the less of a "fairness problem" we would have. Another argued that prioritizing those at highest risk is one way to be fair. So what's important is that the first two objectives be implemented fairly. They affect fairness.

Paraphrasing, the panel essentially defined fairness as including the following concepts (postponing the age-related fairness criterion for a later discussion):

- Do not ration based on ability to pay, first-come first-serve, or judgments about differences in "social value";
- Remove barriers to fair access;
- Protect groups who assume risk serving others (reciprocity);
- Use random procedures (lottery, coin toss).

In response to a question about each of these fairness concepts, a few participants said that they agreed with the list. One person thought that random procedures should not be used. Most participants were silent.

Activity two: Age-based rationing

The discussion concerned whether age should be used as a rationing criterion among groups who are at the same level of risk. The alternative to age would be randomization. The question was asked in the context of rationing a scarce medication among people who are ill with the flu.

Discussion

- For hundreds of years when the ship was sinking, it was women and children first and it was never argued. Would that work here, too?
- As a 25-year-old with kids, my gut reaction is to give it to children first, and not necessarily my kids either, but to any and all children.
- Kids tend to spread germs like crazy and they are dependent unlike grownups.
- Are you asking me to say who lives and dies? From my Judeo-Christian background, there has to be some reasoning considered in why the older on the age graph are not as important as the others. All life is equal.
- The entire family could all be sick: Dad, Mom and kids and then the doctor has a tough decision because the kids need parents. As a grandma, I would want to give it to the kids.
- I would still have my kids prioritized even if I as a parent was ill. I strongly feel that age should be considered, not sure how far, but definitely children before adults. It is clear that children should be above adults.
- It's difficult if you have a young family where all are sick and kids get medicine but parents don't-that is a tough question.
- My grandma said one of her sisters died of flu, and she had six kids. The kids were shuffled around because their widowed dad was not a good caretaker.
- A designated caregiver should decide who gets what in families.
- The 1918 flu happened at a time where families had ten kids, and leaving ten kids orphaned was horrible. Few could take in ten kids, so the kids were split up and families were lost. But now we have two or three kids, so looking at society as a whole we have fewer cases of families spread out and split up if kids are orphaned. It is easier for an orphan population in our society now. Worrying about orphaning children shouldn't keep us from prioritizing them.
- If each one of those categories was divided up equally and I was lucky enough to get the medicine and my grandson was not selected, I would like to have the option to give up my winning lottery to my grandson. I am not sure I would give it up for someone else's kids.
- In response, one person said that she would give her medicine up for a stranger's child.
- We're not going to lose an entire generation of people. Given that, maybe it's more important to prioritize those in the workforce. It's easier for a kid to stay home with the flu than the breadwinner.
- If you give medicine to middle-aged people, you might lose the kids who are our future. If you prioritize kids, you'll lose some workers and parents. This is difficult.
- It seems that most all of us agree that age is a factor. Age should be considered.

If Minnesotans generally agree that it is acceptable at times to ration based on age, which age group(s) should receive flu medicine first, second and so on? Why?

- Most of us would say children first, but then what to do about caretakers? There was strong agreement in the room that children should come first.
- Assuming this is our actual graph, we have a big chunk of middle-aged people who have already received medicine. They'll be prioritized because they're at higher risk than the people at the X's. Among the X-risk people I would rank children first, because we have some workers and caretakers who have already been treated.
- Isn't it the pig through the python? You have a big number of middle-aged people prioritized because of their risk. They will move through and get older over ten years, so if you don't treat the second, younger group you won't have anyone following them up for a significant time.

Does anyone prefer a lottery over using age?

- No, and no one is on the fence about it.

How many think we should prioritize children first?

- More than half raised their hands. Even more affirmed when someone suggested dropping the age to 14 and younger.

To clarify, do you think younger children should be prioritized over older children?

- Only one said yes. Others said that a child is a child, and all are equal.

Should the working population be prioritized first?

- Two people said yes.

Should any older group be prioritized first?

- All said no.

After the first age group is prioritized, should age-ranking continue or should the remaining resources be distributed randomly regardless of age?

- Most supported a lottery. Remaining resources should be distributed randomly. Life isn't fair—it's luck of the draw.
- My reason for prioritizing children is that it's objective. They are minors and can't take care of themselves. When looking at adults, questions about their caretaking and productive roles become more subjective. I don't think we should be making those subjective decisions. After children, all other ages should receive resources randomly.
- Some think that adult caretakers should be next.

Note: Activity Four, below, showed more agreement about using age as a criterion across the lifespan than was evident in the above discussion.

Activity three: Access barriers

What kinds of problems can people in your community have getting access to care?

- Language is a barrier in our community; many languages are spoken here.
- Cost and insurance: What will insurance cover? What if my covered provider isn't the one with the resources?
- Transportation—no cars
- Isolated individuals
- Advertising and communication: Different age and cultural groups respond to different avenues of communication. Newspapers alone aren't enough to reach people.
- The US is a country of immigrants. How will the state reach people who are undocumented? They will be afraid to seek care or vaccinations, but they need it.
- Religion and gender value can be a barrier. Some people are opposed to vaccinations and medical treatment.

- Many parents are worried about vaccinating their children.
- How far is it reasonable to expect folks to drive? Are services in place for those who can't drive?
  - Many in Worthington drive to Sioux Falls for health care. It's about an hour away. Some would say that one hour is ok, given that is where they have a doctor.
  - Sixty miles is the limit. College kids can't afford more gas than that.
  - People prefer not to drive as far in winter.
  - It's tough to drive with a sick kid.
  - It depends on my health insurance coverage area. I'm willing to drive as far as necessary, so long as my insurance will cover the cost of my care there.
- Borders- where do I go if I live on the border? Worthington is a border town. Many of us go to Iowa or South Dakota for care, and many Iowans come to Minnesota. We live and work in different states. College students often go to school out of state.

What solutions should be considered?

- Communication
  - Emergency broadcast systems and local channels that post school closings. School closure notices work for lots of families.
    - But, not everyone listens to the radio, and parents who go to work early miss the announcements.
  - Post information in grocery stores and Wal-Mart.
  - Getting as local as possible. Filter to the public health nurse that knows the best way to advertise in Worthington, not at the MDH level.
  - Partner with employers who can get information to employees.
  - Talk to trusted community leaders.
  - Use the Internet—Facebook, MySpace, email, homepages.
  - Distribute information in schools (give to kids to give to parents).
  - Internet service providers: Partner with them to send out information to anyone who logs on.
  - Use church bulletins.
- Transportation
  - If we don't have transportation, partner with local school system and get buses going. The local community knows most of its own citizens. This would work for people who can sit in a car or bus but don't have their own transportation.
  - That is where home health comes in, right?
  - Bring the resources to the community. Distribute at the schools.
- Personal preparedness and response
  - If you're sick, have a family member call you from time to time to check in. If you don't answer the phone a couple of times, make sure your family knows to call a neighbor to check on you.
  - Stockpiling at home in preparation for the pandemic. Educate people about the importance of stockpiling.
    - It's not possible for all people to stockpile at home. Many can't afford it.
    - Still, it's important to convince as many people as can stockpile to do so.
  - Teach people about how to avoid catching the flu.
- Physical and mental disabilities? How to accommodate them?
  - Home health would help, to a point.
  - To a certain point, if someone wants to seclude themselves they will not have access to health care.

What types of things can be done prior to a crisis to improve access?

- Build as many relationships as possible so that during a pandemic you can get out and help (for example, with home health and other community groups). You are then better able to disseminate what you need to, whether it's information or supplies, by having relationships at the local level.
- Worthington did not initially have an urgent care. Now it does, but we need to expand hours of availability. We also need to expand hours of access and languages so those who work can get in after hours.

- The problem with the clinic is that everyone there would be ill. It would be better to go to a pharmacy for medication. It's important to figure out how to keep the sick flu patients away from others, including people who are sick with something other than the flu.
- Employers need to improve sick time and vacation. In other countries people don't have to go to work sick in order to keep their jobs.
- Worthington needs a sick-child day care. It could be staffed by people who are vaccinated.

Activity four: "Paper doll" exercise

All participants prioritized either key workers or children first. Many of them suggested that they should be tied for first priority. The remainder was roughly split between those who prioritized children over key workers and those who prioritized key workers over children.

Most participants prioritized those at high risk over those at moderate risk, in order to reduce deaths among those at high risk. Two participants argued in favor of prioritizing moderate risk people first, because of their assumption that ill people at high risk might be too ill to recover even if they received medication.

Most used age throughout the lifespan as a prioritization criterion, with younger people prioritized before older. A few of them used age to "trump" risk, ranking moderate risk younger people before high risk older people. A few others grouped ages into larger groups, so that young adults and older adults were considered together, and all seniors were considered together; non-senior adults were prioritized over seniors in these cases.

One person rejected age as a criterion after prioritizing children. Another prioritized children, and then ranked other age groups in reverse age order with the oldest prioritized before the next oldest and so on.

Final reactions, concerns and comments

We heard some big differences of opinion and some smaller differences, and we also heard some agreement. It's impossible for MDH to incorporate everyone's comments, because there are some conflicts. Is it good enough to know that you have had a chance to offer opinions, even if the final recommendations reflect opinions other than yours?

- My arch political enemy is on the left, and I'm way over on the right. We have agreed that if we want the boat to go straight down the river, we need a little of the right and a little of the left. We each have to give a little. This was a good use of our time. This is democracy at work. Thank goodness we live here.
- It's important that we listen to each other and that government listens to us. We're all in this together.
- This will give me more confidence in whatever they decide, even if I disagree because at least they heard different opinions.
- We need to educate the public on pandemic influenza.
- We appreciate that you came out to talk with us in Worthington. So often if it isn't said in St. Paul, St. Cloud or Rochester, it doesn't matter!

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Appendix N: Paper Dolls Exercise Used in Community Forums and Small Group Engagements

The concluding exercise in both the community forums and small group events was an individual exercise. Each participant received a set of cards or "paper dolls," and each card depicted a different group of Minnesotans.

Here are the instructions provided to participants:

> This exercise brings today's discussions all together. It asks you to think about:
> - key workers
> - risk of dying
> - age
>
> You have a clipped stack of 12 cards. Each card represents a different group of Minnesotans. All of these people are sick with the pandemic flu and want some medicine. Unfortunately, there isn't enough medicine for everyone.
>
> **Arrange the cards and number them according to the order in which they should get medicine (with 1 being the first or highest priority). Which groups should the Minnesota Department of Health prioritize in order to best serve the common good?**
>
> *Arrange them in as many or few different levels of priority as you wish. It's OK if some cards tie, but the more cards tied at the same level, the more likely it is that there won't be enough medicine for everyone at that level. Then the Department of Health would have to randomize within that priority level.*
>
> **Write a number on each card (remember, they can each have a different number, or you may assign some or all cards the same number).**
>
> To get started, think about whether you want to sort the cards into 2 or 3 different priority groups. Then think about whether or not you should sort them further.
>
> Once you have numbered the cards, clip them and give them to your facilitator.
>
> There are some examples on the next page.

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Example A: Children at high risk and key workers at high risk tie for priority #1 (highest priority). Seniors 66 – 85 years old at high risk and children at moderate risk tie for the next priority level #2. Key workers at moderate risk are alone at priority level #3. All other groups tie for priority level #4.

Example B: There are no ties. Each card is assigned a separate priority level, like:

1. seniors older than 85 years old at high risk of dying from flu
2. young adults 18 – 40 years old at high risk of dying from flu
3. seniors older than 85 years old at moderate risk of dying from flu
4. adults 41 – 65 years old at high risk of dying from flu
5. key workers at high risk of dying from the flu
6. seniors 66 – 85 years old at high risk of dying from flu
7. key workers at moderate risk of dying from the flu
8. children (under 18) at high risk of dying from the flu
9. adults 41 – 65 years old at moderate risk of dying from flu
10. young adults 18 – 40 years old at average or unknown risk of dying from the flu
11. children (under 18) at moderate risk of dying from the flu
12. seniors 66 – 85 years old at moderate risk of dying from flu

Small group discussion:

- How did you arrange your cards and why?
- How did the information shared today influence how you arranged the cards and prioritized those groups for resources?

Facilitators collected each set of completed, numbered cards. The project team tabulated and analyzed the results. Results are reported in the summaries for each of the forums and small group events.

Methodological variation between the forums and small groups

Ten cards were used at the forums, and two more were added at the small group engagements. The two added cards depicted seniors (aged 66 to 85) and seniors (85 and older) at moderate risk of dying from the flu. Prior to the emergence of H1N1 novel influenza virus, the project team thought that the prospect of seniors being at only moderate risk of death was so unusual that it would be a distraction during the exercise. Thus, during the community forums (both of which were organized before H1N1's emergence) those two cards were not used. Since H1N1's emergence, the prospect of seniors being at moderate risk during a hypothetical, severe pandemic might not be so surprising. The project team agreed to add cards depicting seniors at moderate risk to reflect that possibility.

The other methodological variation concerned the concluding discussion. Time did not permit a robust concluding discussion at the forums. More discussion time was allotted during the small groups. The discussions about the paper doll exercise at the small group engagements were therefore much richer.

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Number: _____ !! high risk

Young adults (18 - 40) at high risk of dying from the flu

Number: _____ ! moderate risk

Young adults (18 - 40) at moderate risk of dying from the flu

Number: _____ !! high risk

Children (under 18) at high risk of dying from the flu

Number: _____ ! moderate risk

Children (under 18) at moderate risk of dying from the flu

Number: _____ !! high risk

Adults (41 - 65) at high risk of dying from the flu

Number: _____ ! moderate risk

Adults (41 - 65) at moderate risk of dying from the flu

Number: _____ !! high risk

Key workers at high risk of dying from the flu

Number: _____ ! moderate risk

Key workers at moderate risk of dying from the flu

Number: _____ !! high risk

Seniors (66 - 85) at high risk of dying from the flu

Number: _____ ! moderate risk

NOT USED AT OWATONNA AND DULUTH FORUMS

Seniors (66 - 85) at moderate risk of dying from the flu

Number: _____ !! high risk

Seniors (over 85) at high risk of dying from the flu

Number: _____ ! moderate risk

NOT USED AT OWATONNA AND DULUTH FORUMS

Seniors (over 85) at moderate risk of dying from the flu

Note: At full size, each card is 4¼" x 5½".

Appendix O: Summary of Written Comments

Written comments project team

The Minnesota Center for Health Care Ethics (MCHCE) and the University of Minnesota Center for Bioethics (UMCB) collaborated to solicit written comments. Team members were:

- MCHCE: J. Eline Garrett (MCHCE team leader), Karen G. Gervais, Angela Morley,[169] Angela Witt Prehn and Dorothy E. Vawter;
- UMCB: Debra A. DeBruin (UMCB team leader), Joan Liaschenko, Angela Morley.

This analysis was prepared by Angela Morley, J. Eline Garrett, Debra A. DeBruin and Dorothy E. Vawter.

Process

In an effort to elicit widespread public engagement on the panel's preliminary recommendations for ethically rationing health resources during a severe pandemic, the Minnesota Pandemic Ethics Project team posted the recommendations online for public comment. Comments were sought from both individuals and organizations, and from those who consider themselves pandemic or disaster planners along with the general public. The Minnesota Department of Health (MDH) and project team launched the solicitation of written comments with a large media event on January 30, 2009. Extensive print, radio and television coverage was received. Project team members and MDH representatives widely circulated invitations to comment via email and existing list serves. The team mailed printed copies of the reports to people upon request. The team accepted comments via the web and mail.

The project team posted "questions to think about" with space for public comment, along with electronic copies of two project reports:

- "For the Good of Us All: Ethically Rationing Health Resources in Minnesota in a Severe Influenza Pandemic" (preliminary panel report)
- "Implementing Ethical Frameworks for Rationing Scarce Health Resources in Minnesota During Severe Influenza Pandemic" (preliminary implementation report).

The panel was particularly interested in soliciting public input on the overarching values that should guide rationing, how to attend to socially vulnerable groups and age-based rationing, but welcomed all comments the public might have on any aspect of the recommendations. The team included questions about barriers to access and palliative care.

Overview

Although the project team asked questions about issues of particular concern, very few people answered the questions directly. The vast majority chose instead to provide their own prioritization hierarchies or priority guidelines, with or without explanation, for rationing resources.

Of the nearly 70 respondents who offered some rationing guidance, over half prioritized, in some fashion, on the basis of age. Many, however, failed to offer explanation or insight into their priority lists. Younger generations were most often prioritized, although a significant number recommended priority for the middle-aged, primarily for their caretaking function. Some respondents declared elder generations ineligible. Despite a substantial number of respondents who incorporated age as a rationing criterion, many expressed a reluctance or hesitance to do so, and were only willing to entertain age in the event of a disaster. Chances at life, maximizing significant years of life, and "children are our future" were frequent rationales for prioritizing younger generations, particularly children.

Risk of exposure and the importance of limiting disease transmission commanded priority among several respondents. Respondents often preferred to offer resources first to those with the greatest likelihood of recovery, and conversely, de-prioritize those with an already diminished chance of survival.

[169] Ms. Morley was employed part-time by both MCHCE and UMCB during the solicitation of written comments. She was employed by MCHCE when analyzing the comments.

An overwhelming majority of respondents felt that key workers (particularly health care workers) deserved first, or nearly first, priority. Explicit justification for this sentiment was less common; however, a sizeable number preferred to minimize risk of exposure to ensure that health care workers perform their occupational functions. Caregivers, often defined according to their function and occasionally defined in terms of their age, were frequently offered priority to ensure they can perform their caretaking function. Both caregivers and their charges, typically children and the ill, were often identified for priority. A few suggested expanding the definition of key workers beyond that in the preliminary recommendations.

Some advocated for prioritizing according to societal contribution and demonstrated commitment to improve social welfare, de-prioritizing those who were a "drain" on society. A few argued against the eligibility of undocumented workers. On the other hand, a few respondents rejected rationing based on economic status, race, disability or lack of documentation.

Demographic data on respondents

Prior to submitting comments, respondents were asked to designate themselves as individuals or organizations and to complete some optional questions designed to elicit demographic information. Of the 116 respondents commenting as individuals, Minnesota residents comprised nearly 90%. While more than half lived in the metro area, approximately a quarter lived in rural areas or small towns. Residents of smaller cities such as Duluth, Rochester, Mankato and St. Cloud provided around 10% of the total comments. Among Minnesota residents, most worked or went to school in Minnesota. A sizeable number of stay-at-home parents and retired persons submitted comments. Border state residents (Wisconsin, Iowa, North Dakota and South Dakota) submitted several comments, and residents of non–border states submitted several more. Two respondents hailed from outside the United States.

Although around half of all respondents were involved in pandemic planning, half were not at all involved. Key workers, under the definition in the preliminary recommendations (those whose functions are critical to limiting flu-related deaths and degradation of the health care, public health, public safety and other critical infrastructure, including volunteers), comprised around half of respondents, and the other half were either not key workers or unsure of their status. An experienced facilitator and a worker with children were among the few who did not satisfy the key worker definition but nonetheless felt they ought to be designated key workers.

A strong majority of respondents identified as caretakers, primarily for children or elderly parents, and occasionally both. Many others defined themselves as caretakers in their professional roles, ranging from nurses, physicians, teachers, volunteers, and church workers to a bus driver. Nearly half of the respondents were 40 – 54 years old, approximately a quarter were 55 – 64, and another quarter were 65 – 85. Eight people were between the ages of 18 and 29. None were between 30 and 39 or over 85. Approximately 67% were female and 33% male. A few individuals did not answer any of the demographic questions.

All except one of the organizations that responded were located in Minnesota. One organization was located in a state not bordering Minnesota. Of the organizations that responded, half of them employed key workers.

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Overarching values and priorities for rationing

The team posed these questions on the website:

Given the challenges posed by a severe pandemic, what are the overarching values that should guide rationing? The recommendations call for balancing three equally important priorities when rationing health-related resources:

- limit the number of deaths;
- protect public safety and civil order; and
- treat people fairly.

Are these the right priorities? If so, do you agree that they should be equally balanced or do you believe that some of these priorities are more important than others? Please explain.

Are these the right priorities?

Among the few respondents who examined the panel's priority list, more than half agreed they were correct. Inclusion of the fairness priority ("treat people fairly") and its appropriate weight, was debated.

Respondents who agreed with the priorities observed that they are directly linked or related. Protecting health care workers and infrastructure necessarily limits lives lost to the pandemic, and limiting lives lost to the pandemic reduces deaths from civil disorder, according to one respondent.

> *I believe you have the values correct. I think that limiting the number of deaths and protecting the public safety and civil order are linked. Each separate value contributes to the other. For example, limiting deaths contributes to public safety and civil order. The same can be said of public safety and civil order limiting deaths…*

Additional or complementary values were offered, including avoiding discrimination in rationing resources, recognizing that every life is precious and considering the value some cultures place on the elderly.

If the recommendations contain the right priorities, should they be equally balanced?

Even fewer respondents examined the issue of balance, and only one advocated for equal balance. Protecting public safety and civil order, for the remaining respondents, should be the first, and for one respondent, the only priority. Characterized as "minimize social unrest" and "preserve our ability to 'weather the storm' of societal disruption," this value took precedence as an umbrella for the other values.

> *I believe there should be 1 priority: to protect public safety and civil order. Limiting the number of deaths and treating people fairly should come under that one priority. If our one goal is to protect public safety and civil order many of the other considerations such as age, vulnerability etc. become irrelevant. The relevant question and consideration is how we can best protect public safety and civil order. To protect civil order we need to limit the number of deaths and thus we protect those that are exposed to large numbers of others.*

The appropriateness, and weight, of the fairness priority was debated by two respondents, (including one organization), each offering strikingly different positions.

> *At the top of the 3 values you listed should be fairness. As an educator of 30 years and an expert on human behavior, I can guarantee you that if people perceive that they are being treated fairly, they will accept the decisions made far more readily. This then prevents problems in public safety and civil disorder and thereby will also limit additional*

deaths. Most people know when something is fair or not. By making decisions fairly it will also help solve ethical questions.

The two values that should guide rationing are: 1. Limiting the number of deaths. 2. Protect the public safety and civil order. Fairness is a laudable goal. The New Webster's Thesaurus includes equitable and impartial as synonyms for the word "fair." Certain populations have been identified and have been given preferential status for receiving medications and other resources. These include "key" workers, and vulnerable populations. This is in fact not either impartial or equitable. This tiered guide to rationing is in place to increase the number of survivors, and to prevent anarchy. This approach is for the common good. To use the term "fair" is misleading and inappropriate. Priorities for distribution of vaccines and resources should go to the "key" workers who will increase the number of survivors by their work.

Removing access barriers and attending to socially vulnerable groups

The team posed related questions about removing barriers to care and attending to socially vulnerable groups:

- The recommendations address socially vulnerable groups (such as poor people and uninsured people) in several ways, including removing barriers to fair access and stressing the importance of not making existing health disparities worse in a crisis like pandemic influenza. The recommendations stop short of prioritizing socially vulnerable groups in a pandemic simply because they are currently disadvantaged. Rather, if existing health disparities place some groups at higher risk of flu-related complications, then they are prioritized in accord with that risk. What are your thoughts regarding how the recommendations attend to socially vulnerable groups?
- People who are poor, chronically ill or disabled, or who have problems obtaining access to care often suffer disproportionately during public health emergencies. How can barriers to access be removed or reduced both prior to and during a crisis like pandemic influenza? What steps can be taken to promote fairness among all groups of people, including those likely to suffer disproportionately during an influenza pandemic?

Very few respondents directly addressed these questions, and those who did either (1) responded with dissatisfaction on how the panel's recommendations attend to socially vulnerable groups, (2) provided recommendations for identifying and removing barriers for groups prior to a pandemic or (3) felt additional consideration should be paid to socially vulnerable groups and suggested means for prioritizing these groups.

While these respondents expressed some level of dissatisfaction, most of them were pleased that the reports made efforts to address vulnerable populations. Their most common complaint was lack of specificity in the preliminary panel report on which particular barriers to address or remove. One respondent criticized the lack of reference to health disparities among people of color.

A few suggested establishing a universal health care system and strengthening transportation systems for the poor and feeble as means to remove barriers prior to a pandemic. Some expressed skepticism about whether access barriers would be removed or reduced, or requested more information about how the recommendation that barriers be removed or reduced would be implemented.

Advocating a more affirmative approach to vulnerable populations, some respondents felt specialized planning for the disadvantaged is "prudent and the right thing to do" and that we should "prioritize ethnic groups that appear most vulnerable to the virus." Another respondent offered suggestions to help ensure that those who cannot leave their residences would receive resources.

> *I know the ethics group stopped short of prioritizing socially disadvantaged groups, yet isn't specialized planning needed for those that don't have a social safety net (like a family or other friends that care)? What do we do for the people that just can't care for themselves and have no one to care for them? I'm thinking about influenza cases that normally would be taken care of at home by a relative or friend and would not require hospitalization. What about the homeless? How will they be helped? How will they know where to get help?... I think making special plans for these groups is prudent and the right thing to do.*

One respondent further recommended that consideration of vulnerable groups extend beyond the resources discussed in the reports.

> *It is important for people to have a stockpile of food, water and supplies in case of a pandemic. However, due to the state of the economy most folks would have a hard time stockpiling anything. It would be nice to have supplies at an affordable cost for the people who cannot easily afford them.*

Age-based rationing or randomization?

The team posed these questions:

Once those with the greatest health needs and/or key workers have been prioritized to receive a particular resource, what is a fair way to ration remaining resources? The [panel] discussed both randomization (such as a lottery) and age-based rationing (children before adults and/or younger adults before older adults). Which of these methods do you think is fairer? Why? Do you have alternative ideas for ways to ration remaining resources?

Nearly 70 respondents offered some guidance on how to ration scarce health resources. Some of these respondents provided priority schemes to address the entire population, including those at greatest health risk and key workers; some offered priority schemes to allocate resources remaining after those with the greatest health needs and/or key workers were prioritized. Priorities for rationing were often presented without explanation.

Prioritizing on the basis of age

Most of the nearly 70 respondents who provided some rationing guidance prioritized particular age groups and/or explained that age-based rationing is appropriate in some circumstances. Often age was one of several characteristics offered priority among respondents. Despite a substantial number of respondents who suggested age as a rationing criterion, many expressed a reluctance or hesitance to do so, and were only willing to entertain age in the event of a disaster.

Younger generations and/or children were most often prioritized, although a significant number of respondents prioritized the middle-aged because of their caretaking functions. Some respondents declared elder generations ineligible. Chances at life, maximizing significant years of life, vulnerability, and "children are our future," were frequent justifications for prioritizing younger generations, particularly children.

Older respondents, generally over 50 years of age and from both rural and metro areas, often stated that younger generations should be prioritized in order to have a chance at life. Fairness emerged as the prominent justification, requiring that we try to allow "as many people as possible to grow old and experience a full life." While these respondents highlighted their love for their own children and grandchildren, and their desire to protect their own families, they tended to take a population view in allocating resources, to protect all children, not designating their own as recipients. (Note: While a few respondents believed that entire families and generations could be annihilated in a severe pandemic, a majority seemed to recognize that most would survive in all groups.)

> *I just want to say that as an adult in the 55 – 64 age range, I have lived a good part of my life! Yes! I hope to see great grandchildren, etc. But—if there isn't enough vaccine for everyone—then you give the newborn[s] to 40 the 1st dosages! Along with those key workers who are critical to limiting flu-related deaths and will keep the public healthy & safe (police officers, fire fighters, pharmacists, doctors, nurses, etc.), then the 40 – 45 year olds, etc. until it is gone! Though the elderly (meaning 55+) are more [likely] to succumb to the pandemic, as one of those people myself, it still should go to the younger people. We that are 55+ have lived a good part of our lives! And again—I have no death wish—but I would want my children/grandchildren/nieces/nephews/the young person next door to have a chance to live as long as I have at least over prolonging my life! Just because I don't get the vaccine, doesn't mean I will die from it either! I feel those of us 55+ should take our chances, while assuring the younger generation survives.*

> *Prioritize those who defend democracy first, then those who must risk themselves by serving the public every day should receive the vaccine. Resources should not be allocated on the basis of age for adults. Rather, those adults who are able to seclude themselves from society for reasons such as independent wealth or retirement should not be in line for the vaccine. Rather, the ones that should receive the vaccine are children and those adults who are on the front lines of society, the ones that work to make society function better and risk themselves by so doing by increasing their likelihood of getting the flu, regardless of what their age might be.*

Under the assumption that younger generations would have a greater probability of survival and more significant years of life, some advocated prioritizing younger generations to maximize years of life gained. Prioritizing according to the future longevity of survivors was one means to maximize the benefit of the resources. Finally, others justified prioritizing children because they have great potential and are our future.

> *If I had to prioritize, I would choose children and young adults, as they are our future. I enjoy the wisdom of the elderly and it breaks my heart to even think it, but I'd place less priority on those over 70 who are in poor health.*

A smaller number of respondents, including an organization, felt middle-aged generations deserved priority over or in addition to others, primarily due to their caretaking roles (such as parents with small children) and working productivity. While some respondents suggested prioritizing the middle-aged as a means of prioritizing caretakers and producers, others simply suggested prioritizing these groups on their function, without reference to their age.

> *Adults should have priority over children, (unless a family decides otherwise). A good example for this reasoning is as follows: On an airplane, the adult puts on the oxygen mask before the children. Adults should have priority to better take care of the children.*

> *On age-based rationing: (1) If children are to be prioritized, so must their parents. Saving children while allowing their parents to be debilitated or die simply does not secure the benefit of the children. This is a very narrowly focused, unrealistic picture of child well-being. Children may survive the flu, but not survive other threats if there is no one available to care for them in a timely manner. Even if a social support network is in place so children are not left alone (as they were in 1918), the aftermath of the trauma of loss of parents could be devastating, especially on a broad scale as may occur. Such a consequence violates all three fundamental principles of the report.*

A few respondents de-prioritized the elderly, because the elderly have lived long lives, have prepared for their deaths and have minimal potential for future contributions.

> *The old—perhaps everyone over the age of 80—[should be ineligible]. They have lived a long life, and it can be assumed many in this group have prepared for their demise, in*

> *terms of their family, finances and spirituality. With some exceptions, most people by this age are not making significant contributions to the greater community that would be difficult to replace if they passed on.*

Observing that many of the elderly would prefer to opt-out or refuse to accept resources in favor of younger generations, or stating their own personal desire to refuse, several older respondents (generally over 55 years of age) expressed concern that an option to opt-out must be available.

> *If a pandemic occurs, the majority of us feel that medical help that might be in short supply should be given to people who are young or those who are in critical helping situations. I personally would refuse any medical intervention other than palliative care, should supplies be as critical as you posited on tonight's newscasts. I believe there are quite a few elderly persons who would refuse to accept medical intervention, preferring it be used for younger persons. The problem might arise that medical personnel would insist on giving such intervention and maybe not be willing to accept the decision of the ill person. That is my only recommendation, that we who voluntarily refuse treatment should be free to do so.*

> *In a pandemic, take those who want to be treated vs. those who are at peace and want minimal care (volunteers, akin to a large company buyout). Everyone at some point will face death, but we all will think about our contribution to society and whether we have a future contribution.*

A few of the respondents felt that age-based rationing is inappropriate, arguing that age-based rationing is discriminatory and that there are better criteria on which to allocate resources.

> *I think it is likely beyond our power to compensate for the inherent and generalized unfairness of a severe illness like a pandemic. Illness is never fair. I think that the only unfairness we can fix is to equalize healthcare access for all citizens and that we should do so NOW, before a pandemic arrives. I think we'd be well served if we simply did not add to the unfairness. I think that age is a characteristic like race and gender and should be treated the same way they are in all cases. To do otherwise violates your ethic that everyone is "morally equal."*

> *It is important NOT to discriminate in rationing resources. It is good that the reports say that we should provide care to everyone even if they are not citizens. To deny care to noncitizens would be discrimination. It is also discrimination to ration based on age. It might benefit me but it would not be fair.*

> *We agree that age-based rationing is questionable from a legal standpoint, given existing laws that prohibit discrimination.*

Randomization

A few respondents felt that randomization such as a lottery is the fairest approach for allocating scarce health resources, either after key workers have been prioritized or at the outset. After key workers are prioritized, one respondent felt that we should not "discriminate anymore against young or old—we will need both their youth and vitality and their wisdom and expertise following a pandemic. That is why a lottery is the fairest."

> *Randomization is the most fair. I say this because everyone would have an equal chance of getting care. However, the fair way isn't always the best. I can certainly see treating younger adults and children before older people.*

Several respondents argued that randomization is either unfair or undesirable.

> *I don't think a lottery is perceived as fair. It leaves out all educated information and reasoning, which people expect from the experts.*
>
> *I believe that having a "lottery draw" would create pandemonium.*
>
> *A lottery and any process of choosing will promote chaos.*

Other rationing criteria

Risk

Groups at the greatest risk of exposure, and those who would bear the greatest burden of illness should be prioritized, according to several respondents (with the presumption that the state would assess burdens of various demographic groups).

> *Clinicians/scientists should be able to identify from the first wave [those] most vulnerable to mortality and severe reactions to the epidemic. Overall, if a clinical approach is not taken or integrated there will be much waste of resources and no assurance the right people are actually getting the resources. [long-term care nurse]*
>
> *[After health care and key workers are prioritized,] I do not think that we are going to know until it is manifested, which age population that we need to target first. If it tends to be more specific to young adults I feel we need to look at that population first, etc.. [public health director]*

Adults working outside their homes, health care workers caring for the ill, teachers, first responders and those living in close proximity (such as nursing home residents) all were identified as being at risk. Hospitality workers in high-traffic areas with dependents and the immune-suppressed (individuals with transplants, HIV-positive individuals and those who take medications for MS) were also suggested as populations at risk.

Limiting transmission of virus

For those living in close proximity and unable to seclude themselves, some respondents suggested prioritization on the basis of minimizing transmission as well as reducing risk of exposure. Recipients in this category included school children, the homeless and the elderly living in senior housing facilities. Younger female respondents, generally between ages 20 and 40, several with health care experience (including doctors and nurses), tended to prefer prioritization based on risk of exposure and limiting transmission of the virus.

> *When vaccine becomes available, I would prioritize military, emergency, medical and staff at medical sites first. Then I would recommend vaccinating those in close living groups (elderly in senior housing and nursing homes, college students, daycare, preschool and school age students). We should focus on all elderly (keep them healthy and out of the crowded medical system) and all children under 8 (because of their high transmission rate and high risk). Our goal needs to focus on young and old but especially on diminishing transmission. [pediatrician]*

Social value

Societal contributors, particularly those productive in business and those demonstrating a desire to protect the welfare of society deserve protection, unlike those with limited potential to contribute, according to several respondents (generally females between 40 and 54, living in the metro area). Respondents defined contribution as wage-earning ability, productivity, and tax contribution, rather than by specific function (such as health care workers, key workers and caregivers).

> *Treatment should be for productive, taxpaying members of society. The dregs of society and users rather than producers should be last to avail the limited services.*

A demonstrated commitment to improve the welfare of society—such as proof of receiving flu shots in the past to protect themselves and others, or doing volunteer work—was a characteristic deserving of priority according to a few respondents. Others suggested the ability of individuals to contribute in the future as a rationing criterion.

> *For example, the working population (ages 22 – 55) will be a priority group. They and families (children) should be a first priority, since history shows that they are a vulnerable group and would be instrumental in keeping business going. [nurse]*

> *I think it should be based on how much you are contributing to your community. Are you serving your neighbors and helping in any way to better the world around you? Or are you receiving help from all the free programs our state offers with the taxes from us working Minnesotans and not giving anything back in return? I know this sounds harsh but I've lived in Minnesota my whole life, and I know there are thousands of ways you can volunteer and serve without spending any money. I think the flu shot vaccine should not be wasted on the "deadheads" in our state.*

> *Since [terminally ill people] know they only have a set amount of time to live and have, or will be actively preparing for their deaths, this goes back to the argument of how much opportunity this group has to contribute to the greater community over the remainder of their life. Although there are always exceptions, as a category, this group has limited opportunities to help our society.*

Some respondents disagreed, arguing that such distinctions are unacceptable. (See page O-11.)

Likelihood of recovery

Several respondents, particularly those with health care backgrounds, preferred to prioritize those most likely to recover from illness and, conversely, de-prioritize those who have a diminished chance of survival. Co-morbidities, chronic diseases and other health problems should be assessed, they argued, in determining the chance for survival and the effectiveness of the resource. Assuming that younger generations would respond better to treatment, some chose to prioritize based on age. (Note: Alzheimer's and dementia patients were de-prioritized by some for low quality of life. Otherwise, quality of life was not addressed as a basis for rationing.)

> *It's my opinion that people who are most likely to recover, that is, to their quality of life prior to a flu pandemic, should be the first priority. All co-morbidities should be considered when establishing this priority. [nurse]*

> *I do not necessarily agree that those with the greatest health needs should receive treatment before healthy people. This is not the triage approach. Those with an already diminished chance of survival should not use up limited resources.*

Key worker status (particularly health care)

An overwhelming majority of respondents who reflected upon the priority lists in the preliminary recommendations or suggested a novel priority list felt that key workers—and most particularly health care workers—were deserving of first, or nearly first, priority. Explicit justification or explanation for this priority was less common; many simply placed health care workers at the top of the list without a rationale. Unlike the preliminary recommendations, respondents did not often consider varying levels of occupational exposure; rather, they grouped all health care workers together. Underlying the general consensus that health care workers deserve priority was the desire to minimize their risk of exposure to ensure they perform their occupational function. Reciprocity, or some sort of social duty, was not offered as a justification.

> *I am especially concerned that all health care providers including all areas of health care like nursing homes, assisted living and clinics receive meds or vaccines so that they can take care of the people who do become ill without fear of losing their lives. [infection control, long-term care nurse]*
>
> *All health workers will be drawn in and must be inoculated for two obvious reasons, they are needed and will be working long hours in a tired run down state, and they will actively be confronted by incoming exposure to sick patients.*

A substantial number of organizations and individuals, particularly those in the field of public health, insisted that the families of key workers must also be protected in order to ensure these individuals come to work.

> *Key workers need to be the priority as far as receiving medication once it is available. To me that means health care workers, police, fire and facility management of cities. Also to insure that these people come to work at their respective jobs, medication should be provided to their families as well. It has been shown that people will not necessarily go to work if their family members are at risk. [volunteer nurse for an emergency response organization]*
>
> *If I am to be on the front lines, so to speak, I imagine I will receive vaccine. For any of us to do our best handling such a stressful incident, we must be assured our families are as protected as possible. If not, I am afraid we will be preoccupied with worry and not able to perform our functions as well as needed. I believe the families of the workers dealing with the situation must also be high on the priorities list for receiving vaccine and or antivirals. [county environmental services department worker]*

Caregiving

Caregivers appeared in many respondents' priority lists. While parents of small children were the most commonly defined group of caregivers, respondents accorded protection to health care workers, daycare workers, teachers and nursing home staff for their caregiving functions. Both the caregivers and their charges, typically children and the ill, were identified for priority. Occasionally, respondents prioritized the middle-aged for their caretaking function. Ensuring they perform their caretaking function was the most common justification for this priority group.

> *I would prefer to see age based rationing. I think children and older adults are more vulnerable populations and should receive the first allocation of supplies. Younger adults who are caregivers for either of the previous groups should receive care as soon as possible so they can continue to care for the above groups.*
>
> *The items mentioned (vaccines, antivirals, masks and respirators) will not be all that needs to be rationed. The respirators do not run without respiratory therapists and nursing staff. It's good that health care workers will be some of the first treated with antivirals (so that they can care for the ill). But there will be a real caregiver shortage! So a plan must be in place to acknowledge that. [nurse practitioner]*

First-Come, First-Served

A few participants considered, and came to mixed conclusions, on the appropriateness of a first-come, first-served approach to rationing scarce health resources. Some people thought that first-come, first-served would never be appropriate; others could imagine times in which it would be.

Unacceptable rationing criteria

A very small number of respondents volunteered criteria they deemed unacceptable for rationing, including wealth or economic disadvantage, race and disability.

People are people, regardless of social or economic situations.

This is a very difficult and complex issue. People with disabilities represent a large portion of the population and as our society ages, this population will dramatically increase. It is reassuring that disability status will not be used as a stand-alone indicator as to whether or not one will receive the influenza vaccine.

Absolutely do not talk about which life has the greatest value as in the lifeboat mentality. Look for ways to preserve as many lives as possible knowing that you won't be able to save everyone. Understand that there will be a hierarchy of vaccination to maximize quality care and life preservation for everyone.

Recommendations for de-prioritization or exclusion

Respondents identified groups that should be ineligible for resources more often than they suggested groups to be prioritized. They suggested excluding terminally ill patients, prisoners, undocumented immigrants and in a very few cases people with Alzheimer's disease or dementia.

According to some respondents, prisoners, particularly those with life sentences and without the possibility of parole, have limited potential for societal contribution and have a propensity to commit crimes in the future, justifying their exclusion from priority.

In addition, a substantial number of respondents felt that terminally ill patients should be ineligible for priority, and according to some respondents, ineligible for all scarce resources. While the majority of respondents with this position did not explain their rationale, those who did justified exclusion for the terminally ill on the basis of limited contribution, reduced likelihood of a successful recovery and lack of successful outcome, and having already had the opportunity to anticipate and prepare for their deaths.

People with the ability to seclude themselves (that is, limit their contact with infected people and the public) were de-prioritized or completely excluded by a substantial number of respondents. Examples offered included retirees, the wealthy, people living in small towns, those dwelling in single family homes, the elderly and the young. Some respondents distinguished the elderly who rarely leave their homes as ineligible for priority, but advocated priority for those living in assisted living and nursing homes.

Also, as a retiree in my own home, my shot should come after those in assisted living or nursing home facilities. I can stay home and avoid contact with others, they cannot.

If supplies are low I don't see much sense in immunizing people who rarely leave their house. That is, the elderly, disabled, and institutionalized should be advised to avoid going in public until the supplies are increased to include them, and to only come in contact with people who are already immunized (their health care workers have already been immunized).

Recommendations about palliative care

The team posed the following questions on the website:

An estimated 33,000 Minnesotans could die during a severe influenza pandemic, compared to 1,350 that die on average from seasonal influenza during a similar period. Many dying people will be cared for outside of hospitals in alternative care sites and by family and friends in private homes. These unfortunate circumstances mandate planning for end-of-life care in diverse settings, in order to compassionately care for those who are dying. What steps should the state of Minnesota, health care facilities and others take to stockpile medications (such as pain medications) for care at the end of life? What steps should be taken to ensure that dying people and their loved ones have timely access to appropriate supportive care especially in alternative care settings and at home?

Three respondents addressed this question. They praised the attention to palliation and hospice care in the preliminary implementation report.

> *We particularly appreciate the thoughtful work that has been done to increase awareness of the need for palliative and hospice services during a pandemic. These services have not been addressed adequately in many other pandemic preparedness documents. The report's focus on palliative and hospice services may have several laudable effects, including strengthening the development of the palliative and hospice infrastructure prior to a pandemic, and signaling that during a pandemic all patients will be regarded as deserving of comfort and care, regardless of their occupational priority.*

> *Hospice or palliative care may be better off utilizing family members in this process especially if there's many other affected patients that aren't at the end stage that require medical attention.*

Other notes, concerns and questions

Approximately 40% of the comments were received on the first weekend the website was available to the public (Friday, January 30 through Sunday, February 1, 2009). By the end of the first week, this figure had raised to nearly 60%. Many comments appeared to be in response to media coverage rather than the reports themselves.

More than a few respondents confirmed the need for pandemic planning.

> *The need to be prepared for a pandemic flu outbreak can never be understated. This is serious business.*

A number of respondents also stressed the need for providing accurate and timely information to the public about flu and steps individuals and families can take to protect themselves. Concern was also expressed about the media's tendency to sensationalize.

> *People often like to say, "Knowledge is power." Well, in the political circle that is rarely considered of value. I understand in such an event you will want to avoid public panic, but information also gives the power of action. Inactive citizens will have lots of time on their hands to panic. Please plan a communication method that values the intellect of the listeners.*

Respondents posed a range of questions in their comments, ranging from requests for clarification on the preliminary recommendations to questions about implementation and preparedness. Clarification was requested on a few more technical aspects of the preliminary recommendations, including:

> *Maybe I did not read the text thoroughly enough, but what are the thresholds to go from "tier" to "tier" (for instance for vaccine distribution)? I am concerned about vaccine prioritization based on perceived vaccine response. What is the definition of acceptable vaccine response, good vaccine response etc.? Will this be based on a blood test to determine immune system function?*

Additional information on the rationale for certain recommendations was requested:

> *Thanks very much, folks, for taking this on and for sharing it…. I'm working with my county to develop a plan and found your draft quite helpful. A couple of questions: Why did you decide to exclude quality of life as a valid ethical consideration? While I can appreciate you don't want to start sliding down some dangerous slopes, surely we can rightly make judgments between—to use an extreme case—someone in a persistent vegetative state and an otherwise healthy 25- year-old. Also, we've been playing around*

> *with who counts as a "first-responder," with corresponding priority for medications and treatment. How did you handle police and (non-paramedic) fire personnel? For a natural disaster, both groups seem obvious; for a pandemic? How about National Guard troops?*

Occasionally, respondents asked about how the state would educate people prior to a pandemic, enforce the guidelines and implement lotteries.

> *Can you give some examples of how antivirals could be given randomly? Would they have to be distributed in advance? What about immune globulin? I assume it will be produced. Rationed?*

> *How will it be assured that the ethical framework regarding the distribution of limited supplies of the vaccine at the height of a pandemic will be followed? Assuming that the demand for the vaccine (to the extent that it is perceived as a "life saver") will be much greater than the supply of the vaccine, how will it be assured that the limited supply is distributed fairly, equitably and consistent with the framework?*

Additional questions were raised as respondents examined and offered different approaches to rationing:

> *Should caretakers be given shots, on the theory they can try to keep those in our care from a pandemic flu? I guess my question is whether or not you consider teachers on the elementary level "key." I can certainly see treating younger adults and children before older people. The question becomes: What is older? It is tragic when anyone dies before their time. However, how does one determine what that time is?*

Criticism

Approximately a dozen respondents (predominantly female health professionals aged 40 – 55) criticized the project and perceptions of state action. Many were skeptical of the need to ration or assume conditions of scarcity.

Lack of disclosure on the imminence and magnitude of a pandemic, as well as failure to inform the public on how to protect itself was a particularly common criticism, in addition to accusations that the threat was a farce by the government, designed to cover-up a failure to stockpile sufficient resources. Some charged fiscal irresponsibility with tax revenue, both in failure to stockpile and in funding the project, coupled with general attacks on the political system itself.

Irresponsibility on the part of the panel for "sensationalizing" the threat of a non-existent pandemic (at the time the comment was submitted), especially in light of current economic stress, was another form of criticism. Critics feared mass hysteria would result from such unnecessary fear generation.

> *This discussion is scarier than the pandemic itself. Have we really been reduced to this?*

> *The last flu pandemic was almost 100 years ago. Medicine has come a long way since then, as has our knowledge of disease and contagiousness. The general public knows all about hand-washing, wearing masks, quarantines, etc. With today's economy and its problems, promoting fear over a nonexistent influenza pandemic seems sensationalistic and irresponsible. Can you put your money into reassuring the public about childhood vaccines instead? Thanks. [physician]*

Frustrated at what they perceived as lack of stockpiling and preparedness on the part of the state, others criticized the report as "planning to fail" or an act of government resigning itself to a crisis. Rationing should not be necessary, according to these individuals; preparedness should be the focus. A few insisted natural remedies such as garlic and raw food diets would cure the problem or alleviate the risk.

A few respondents criticized clinical and other assumptions (defining public safety workers and their proper role) in the report.

> *It is unethical to be asking for input (which usually gets ignored) on these "siloed" issues when the public was never told everything, and never told how to properly prepare for the issues listed on the under-publicized Individual's page at www.pandemicflu.gov the past 39 months. Resources would not be so "critically scarce" if government had bothered to buy them, and told the private sector and public they had to buy them, as of 2005 (or sooner).*

> *Fire and police only need the select and educated first responders inoculated; they are not at all equally trained and skilled. Those individuals who are capable should be extensively trained in concert with potential possible demands and needs. The police may possibly have a much reduced workload due to the massive number of sick and scared people remaining at home. Some of the police and fire workers may also be unable to help in a pandemic. This seems to be an assumption on your behalf. They did not go into the careers of police and fire work because they were interested in health issues. You might be requiring them to utilize skill sets they do not have or lack through lack of training. You may have jumped to a conclusion, by the attachment of the terms public safety and civil order. Be cautious of the expectations you assume and what they are trained and capable of offering, you may need a bridge for a potential gulf between.*

Similarly, a couple of respondents offered constructive criticism of the implementation report's recommended process for ethics consultation, for example:

> *We have specific comments regarding the System for Ethics Consultation During a Pandemic. The proposed system has admirable goals, and we agree that it needs to occur at multiple levels. Who the members of these Ethics Advisory Groups are and how they are selected is not defined in this report. In the graphic… the Local Ethics Advisory Group and Local Health Departments are presented as side by side. We wonder if it may be more appropriate and efficient to merge the two into one for this purpose.*

Compliments

Praise, both in terms of the thoughtfulness and thoroughness of the preliminary recommendations, was expressed by many respondents. Appreciation for the efforts on both a difficult and timely topic was extended frequently. Pandemic planners in other states, health care professionals and other members of the public often found the report informative and useful.

> *I found the preliminary report to be informative, well laid out, clear and detailed. It certainly raises many questions that I had not considered.*

> *Thanks very much, folks, for taking this on and for sharing it with the [American Society for Bioethics and Humanities] list. I'm working with my county to develop a plan and found your draft quite helpful.*

> *I commend the ethics committee and the people involved with this study for their persistent diligence and thoroughness in their accomplishment of addressing the ethical and health policy issues. It is always good to have a well thought-out plan for dealing with an imminent crisis. Any recommendations would have to include the awareness and implications of further discoveries.… I thank you all for your hard work. Thank you very much.*

> *In conclusion, thank you for your efforts on behalf of the citizens of Minnesota.*

Conclusion

Written comments varied dramatically in their length and content. Collectively, they depicted a range of comments, concerns and affirmations that were echoed in other public engagement activities undertaken by the project team. The project team was very pleased to receive such a large quantity of comments, and appreciated respondents' time and thoughtfulness.

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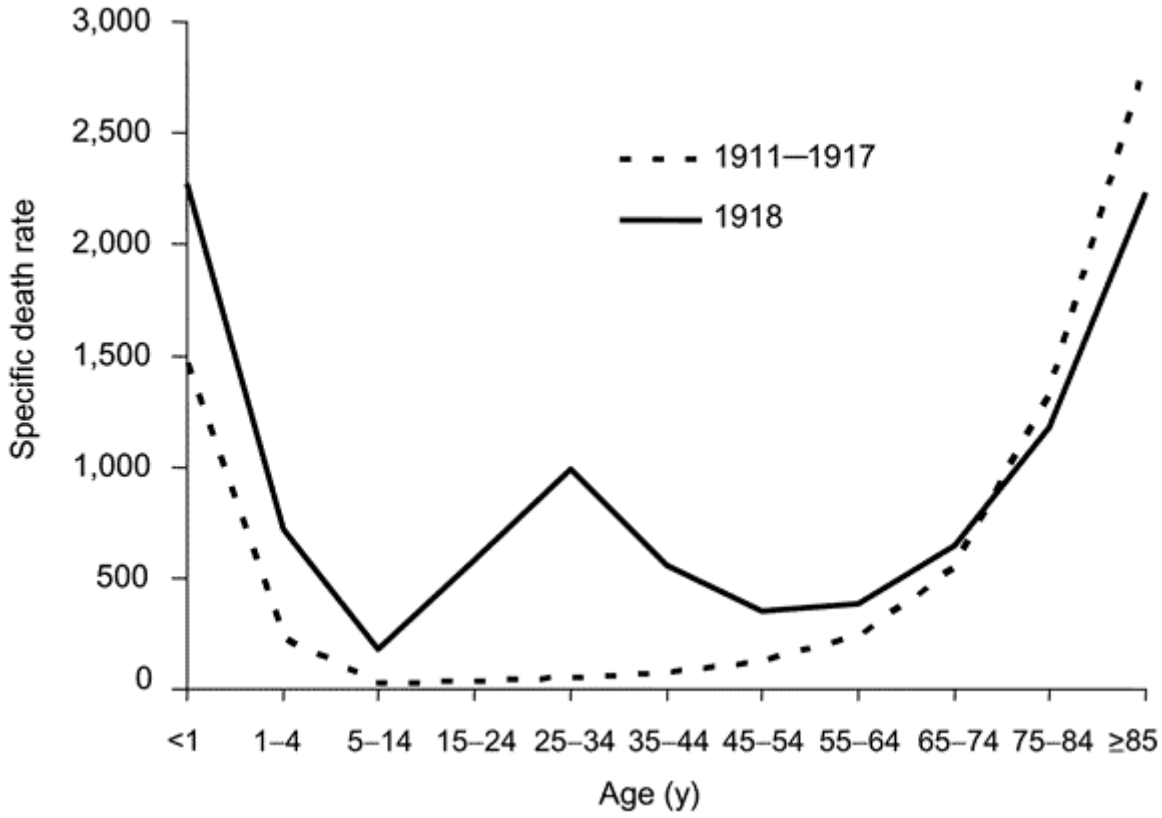
Appendix P: 1918 Pandemic Flu and Pneumonia Mortality Rates

"U–" and "W–" Shaped Combined Influenza and Pneumonia Mortality, by Age at Death, per 100,000 Persons in Each Age Group, United States, 1911–1918.



Influenza– and pneumonia–specific death rates are plotted for the inter-pandemic years 1911–1917 (dashed line) and for the pandemic year 1918 (solid line).[170]

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