

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

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Executive Summary

In response to experts' warnings that a worldwide outbreak of a respiratory virus is inevitable, pandemic influenza preparedness plans are being developed around the globe. Another pandemic will certainly occur, though no one knows when or whether it will be mild, moderate or severe. Severe pandemics raise unique and particularly difficult challenges, so it is prudent to prepare and plan for one.

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 federal assistance 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 is to propose ethical frameworks and procedures for rationing scarce health resources in a severe pandemic. 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. This preliminary report contains the proposed ethical frameworks for rationing antiviral medications, N95 respirators, surgical masks, vaccines and mechanical ventilators.

The proposed ethical frameworks developed during this early phase of the Minnesota Pandemic Ethics Project were designed for several specific scenarios involving a few particular (albeit very important) resources likely to be in short supply during a severe influenza pandemic. 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 to the public. 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 agreed that ethical frameworks are context-specific. They made many scenario-specific assumptions—not predictions—about the pandemic and resources being discussed. The purpose of these assumptions was to ground and focus the participants' discussions and also to signal the need for adjusting the frameworks to fit the circumstances of an actual pandemic.

Key project assumptions include the following:

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, over 32,000 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 persons 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 infection may reach 40% during the peak weeks of an outbreak.
5. During the pandemic, public health officials will collect data and begin to determine which groups are at highest risk of serious morbidity and mortality from the virus; those data will improve as the pandemic progresses.
6. Antiviral medications (antivirals) 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 currently being stockpiled by the federal and state governments, as well as in the private sector. If the supply is reserved for treatment and a standard regimen is effective, Minnesota would have enough antivirals to treat approximately 21% of Minnesotans during the first wave of the pandemic. If the dosage or duration is doubled and if Minnesota allocates portions of the supply for prevention, treatment courses will be available for fewer than 10% of Minnesotans.
7. Minnesota's estimated stockpile of personal protective equipment includes 2,445,000 N95 respirators (N95s). Unknown additional numbers of N95s have been stockpiled by health care facilities and other private institutions and individuals. MDH estimates that Minnesota will need one million N95s per week just for health care worker use. Assuming none of the stockpile of N95s is distributed to the public, the estimated supply can protect health care workers for less than three weeks.
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 5 – 6 months into World Health Organization (WHO) phase six (increased and sustained transmission in the general population). Minnesota then will receive approximately 35,000 doses weekly, for a total of 420,000 15-mcg doses rolling in over 12 weeks. Assuming two 15-mcg doses per person 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 24% of Minnesotans will have access over the period of a year. Young children will require smaller doses of vaccine than adults.
9. The demand for mechanical ventilators (vents) is expected to increase sharply and drastically exceed supply at times during a pandemic. Between peaks of pandemic waves, ventilator supply may be more sufficient. Approximately 12,900 flu patients in Minnesota are anticipated to suffer respiratory failure sometime during a severe pandemic and under current standards of care would be candidates for a vent. Approximately 1200 vents are currently available in acute care institutions in Minnesota; 85% of vents are currently in use.

Each of the ethical frameworks included in this report has four elements: ethical commitments, principles, goals and strategies for rationing a specific scarce resource during a severe pandemic. The following table comprises the ethical commitments, principles, goals and general strategies common to most of the proposed frameworks.

Proposed Ethical Frameworks At-a-Glance

Ethical commitments about how pandemic planning and response will be implemented 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
Principles for rationing resources in a severe pandemic Steward scarce resources to promote Minnesotans' common good by balancing three equally important ethical principles: • Protect the population's health • Protect public safety and civil order • Treat people fairly, recognizing the moral equality of all
Goals <i>Protect the population's health</i> • Reduce mortality and serious morbidity <i>Protect public safety and civil order</i> • Reduce disruption to the basic health care, public health, public safety and other critical infrastructures • Promote public understanding about and confidence in the distribution of health care resources <i>Treat people fairly, recognizing the moral equality of all</i> • Reduce significant group differences in mortality and serious morbidity • Make reasonable efforts to remove barriers to fair access • Reciprocate to groups accepting high risk in the service of others • Reduce significant differences in opportunities to live a normal lifespan • Promote equitable access through fair random processes for individuals equally prioritized
General strategies • Scale to scarcity • Do not resort to random processes prematurely • Do not ration based on: ○ Social value (gender, socioeconomic status, race, citizenship, etc.) ○ Quality of life ○ Duration of extended life ○ First-come, first-served • Generally, de-prioritize persons who have alternative protection or who are imminently and irreversibly dying • Ration different resources based on varying combinations of the following considerations (note several non-clinical considerations) ○ High risk of flu-related mortality and serious morbidity ○ Good or acceptable response to resource ○ High risk of exposure to flu ○ Key workers for essential functions ○ Risk of transmitting flu ○ Age? • Revise in light of new information • Consider and adjust as part of a comprehensive pandemic response plan, e.g., ensure that no group is systematically excluded or de-prioritized

The panel proposes that the same commitments and principles apply to all of the resources it considered, but notes that the goals differ slightly for two of the resources—namely, mechanical ventilators and surgical masks. For instance, since the rationing of ventilators will have no bearing on the disruption to basic services and infrastructures, that goal is irrelevant to deciding, ethically, who should be prioritized for access to ventilators.

In keeping with the commitment to the moral equality of all persons, the panel expressly rejected prioritizations based on social value criteria such as gender, race, socioeconomic status or citizenship.

Minimizing lives lost to influenza is an important goal, and rationing resources on the basis of risk of mortality/morbidity and effectiveness are familiar and widely accepted clinical considerations. Prioritizing on the basis of individual clinical need alone, however, guarantees neither population protection nor fairness. As a matter of fact, it could undermine a public health strategy in a severe pandemic, because it would not attend to the threat of infrastructure collapse. It could exacerbate health disparities and undermine fair and efficient stewardship of resources in support of Minnesotans' common good. To address these multiple considerations, the panel agreed that it is both feasible and necessary to balance several ethical commitments, principles and goals.

When a health-related resource is scarce, the question arises whether it would be most fair to straightaway resort to random processes equalizing everyone's chances of getting the resource. The project participants recommend that several clinical, population health, and fairness considerations be applied before employing random selection techniques. Depending on the severity of the shortages at different times during the pandemic and Minnesotans' perspectives on when and how to attend to the many goals when rationing preventive and treatment resources, 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 persons at high risk of flu-related mortality;
- lack of satisfactory alternative protections or treatment; and possibly
- age (i.e., opportunity for a normal lifespan—a notion of “fair innings” that could prioritize children before adults or younger groups before older more generally).

While all of the panel's recommendations require public input, the notion of age-based rationing was particularly controversial and merits broad public consideration.

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 principles and goals. Except for ventilators, 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.

In general, those prioritized first among key workers are those with high risks of mortality/morbidity 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/morbidity are also prioritized for resources, so long as they are likely to respond well to the particular resource.

At some point, random selection techniques will be required to decide how to allocate resources among equally prioritized persons. The panel rejected allocation based on first-come, first-served because it would likely exacerbate existing health care access inequities. A more random technique, such as flipping a coin or a lottery, should be used instead.

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.

For example, the panel assumes that vaccines will be less effective among the elderly than other age groups. Thus, the vaccine framework prioritizes various other groups before the elderly. But vaccines are just one form of protection. Others include prophylactic antivirals, pneumococcal vaccine (to prevent the most common fatal complication of influenza in the elderly), N95s, protection of those around the elderly and social isolation and other distancing measures. The coordinated rationing of these and other resources will assure effective attention to the needs of the elderly even though the elderly may not be early candidates for vaccines.

Infants are another age group that is very vulnerable to pandemic, but comparatively few resources are available to protect them. If, after considering all resources and strategies infants will be left with insufficient protections, then the plan could be adjusted to offer more indirect protections to infants (e.g., directing more preventive resources to those who work or live with infants, thus minimizing infants' exposure to influenza). Treating people fairly and recognizing the moral equality of all requires that Minnesota's pandemic response plan not systematically de-prioritize or exclude any demographic group from protection and benefit.

Ethically informed plans to ration resources in Minnesota require the considered judgment of Minnesotans with diverse experience and expertise. While rationing protocols must be informed by science and the best available evidence, the public may bring different value priorities to rationing than clinicians, epidemiologists, other scientists and even the panel. In a pandemic, Minnesotans' input, understanding and compliance will be essential to the effective pursuit of population health and fairness goals.

It is essential to inform, engage and consult with Minnesotans in order to ground rationing strategies on statewide values. The project team's next step is to solicit additional public response and reflective engagement on the ethical values that should guide rationing. It is important to know what different Minnesotans think about the recommended frameworks, their agreements and disagreements, and their suggestions for improvements. We anticipate that this public engagement process will begin promoting the community-building necessary for pandemic preparedness concerning scarce health-related resource rationing.

Introduction

In response to experts' warnings that a worldwide outbreak of a respiratory virus is inevitable, pandemic influenza preparedness plans are being developed around the globe. While the timing and severity of the next pandemic cannot be predicted, another pandemic will occur. Preparation is vital to mitigating its effects.¹

The last century saw three influenza pandemics—in 1918-19, 1957 and 1968. The pandemics of 1957 and 1968 were moderate in the United States, 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

Severe pandemics raise unique challenges of all kinds, including ethical challenges. 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 federal assistance 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 prepare and plan for greater rather than lesser severity.

Health-related resources will be particularly important public health tools, and must be stockpiled (when feasible), managed and fairly distributed to protect the population's health. A statewide plan that Minnesotans understand and are willing to comply with is needed for rationing scarce resources such as pandemic influenza vaccines (vaccines) and antiviral medications (antivirals). With the welfare of Minnesotans as a population and as individuals simultaneously at stake, health and other leaders must direct a statewide, coordinated response. A unified response will best promote Minnesotans' common good in a severe pandemic.

Health resources should be stockpiled to the extent possible, affordable and prudent given competing public health and other state needs. In addition to Minnesota's influenza defense system, communication protocols and distribution chains must be established, and simulations conducted to test the adequacy of these preparations. Such efforts are already underway throughout Minnesota.⁶

Stockpiling alone will be insufficient, because not all resources can be stockpiled (like vaccines for a novel virus) and money is tight in public health and health care sectors. Rationing will be necessary. The central aim of this project is to develop broad agreement among Minnesotans about how to ration resources ethically. Pandemic plans that do not clearly articulate the ethical values that underlie their recommendations for distributing scarce resources risk public noncompliance, mistrust in leaders and significant societal disruption.⁷ Minnesotans must agree on the resource prioritizations that are ethically justified for the sake of their common good.

¹ Vawter D, Gervais K and Garrett J (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. *HHS Pandemic Influenza Plan*. November 2005. Available at: <http://www.hhs.gov/pandemicflu/plan/>.

³ Kolata G (1999). *Flu: The Story of the Great Influenza Pandemic of 1918 and the Search for the Virus that Caused It*. New York, Farrar, Straus and Giroux. 133.

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*. November 2005. D-11.

⁶ Minnesota's current pandemic planning information is available at: <http://www.health.state.mn.us/divs/idepc/diseases/flu/pandemic/index.html>.

⁷ Melynchuk RM and Kenny NP (2006). Pandemic triage: the ethical challenge. *CMAJ* 175(11): 1393-1394.

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. This project has several components including developing ethical frameworks and procedures for rationing scarce health-related resources in a severe pandemic. To that end, MDH and 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. This draft report contains the recommended ethical frameworks for rationing a few different types of health-related resources. The project team will solicit broader public input on the values that should guide rationing decisions in MN by posting the recommendations on the web, and Minnesotans will be invited to participate in public engagement pilot exercises to consider and respond to these preliminary recommendations. After more Minnesotans have provided input, these frameworks will be revised as needed to reflect Minnesotans' perspectives and values.

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 and its commitment to public engagement in building ethical guidance, MDH is breaking new ground with the Minnesota Pandemic Ethics Project.

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 fairly rationing a specific set of health-related resources in Minnesota during a severe influenza pandemic. The panel's recommendations were developed for a single 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 and public safety infrastructures. The recommendations also 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 that the panel was charged to address include:

- Antiviral medications for treatment and prophylaxis
- N95 respirators
- Surgical masks
- Pandemic influenza vaccines and
- Mechanical ventilators.

This set 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. 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

⁸ American Health Lawyers Association. *Community Pan-Flu Preparedness: A Checklist of Key Legal Issues for Healthcare Providers*. Washington, DC, 2008. Available at: www.healthlawyers.org/panfluchecklist; Lemon SM, Hamburg MA, Sparling PF, et al., *Ethical and Legal Considerations in Mitigating Pandemic Disease: Workshop Summary*. National Academies Press; 2007. Available at: http://www.nap.edu/catalog.php?record_id=11917; Thomas JC. *Ethical Concerns in Pandemic Influenza Preparation and Responses*. [white paper] Southeast Regional Center of Excellence for Emerging Infectious [sic] and Biodefense 2007:1-19. Available at: http://www.serceb.org/wysiwyg/downloads/pandemic_flu_white_paper.May_25.FORMATTED.pdf.

other severe symptoms, to avoid the need to ration these resources. The companion report on implementation discusses issues of palliative care at greater length.⁹

Deciding how best to ration health-related resources from a statewide perspective during a global public health disaster raises novel ethical issues. Should some individuals and some groups have prioritized access to certain resources? If so, why? Should resources like vaccines go to those at greatest risk of dying from the flu even if they may not respond as well to vaccines as others? Should resources be used to protect persons who are taking risks to help others, because they are contributing to everyone's survival—whether they are irreplaceable workers at a power plant, health care workers caring for flu victims, or volunteers delivering Meals on Wheels? Should resources be given first to children, because they cannot fend for themselves, they are society's future, and society is responsible for their welfare? Should patients be removed from ventilators so that others more likely to benefit can be given a chance at survival? Ethical guidance is needed to help answer such wrenching questions. The ethical guidance offered in this report is developed from a statewide population health perspective.

Containment of the disease will of course be the first strategy state leaders will attempt in response to an initial outbreak of the pandemic in Minnesota. N95s, surgical masks and antivirals used for both prevention and treatment 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.

There are many uncertainties about the pandemic and the resources that need to be rationed. For this reason, the panel anticipates that core assumptions and elements of the proposed recommendations will need to be revisited and modified when the specifics of an actual pandemic become known. The panel's assumptions are just that—assumptions—not predictions about what will happen during the next pandemic. Similarly, the recommended ethical frameworks are not algorithms that mandate particular rationing schemes. Instead they offer guidance to state leaders, pandemic responders and Minnesotans generally. The panel recognizes that its recommendations will need to be coordinated with a host of other mitigation strategies and integrated into the state's comprehensive pandemic plan.

Process

The project team convened a large, diverse resource allocation panel that was ultimately responsible for making the recommendations reported here. Its charge was to recommend ethical framework(s) for statewide rationing of a set of scarce health-related resources in MN during a severe influenza pandemic. It focused on scenarios involving different types 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)
- Critical care treatment (ventilators)

The panel was diverse with respect to experience and expertise. It comprised approximately 45 Minnesotans, including members of the project team.¹⁰

⁹ DeBruin DA, Parilla E, Liaschenko J, Marshall MF, Leider JP, Brunquell D, Garrett JE, Vawter DE. *Implementing Ethical Frameworks for Rationing Scarce Health Resources in Minnesota during a Severe Influenza Pandemic*, University of Minnesota Center for Bioethics and Minnesota Center for Health Care Ethics, 2009.

¹⁰ See Appendix A: Resource Allocation Panel and Work Group Members.

Resource-specific work groups were formed to advise the panel. Each work group comprised 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. An ethics work group was formed to focus in greater depth on the philosophical and ethical issues associated with pandemic health resource rationing. It reacted to and informed the work of the panel and the other work groups.

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 led the protocol committee's work, and its recommendations are contained in a companion report.¹¹

Project team members from the Minnesota Center for Health Care Ethics led the panel and work groups. The panel began meeting monthly in May 2007 and continued through November 2007. 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).

To provide common ground for the participants' 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 frameworks outlined the principles, goals and strategies that would follow for each of the particular resources in question. This approach enabled the more concrete thinkers to work from the concrete strategies to the ethical principles. The more conceptual thinkers could work from the ethical commitments and principles to strategies.

Meanwhile, the project team formed and convened the resource-specific work groups over the summer 2007, starting with the ventilator work group and phasing the others in gradually. The work groups met monthly, and their first tasks were to develop working assumptions for 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.

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 commitments and principles.

The project team presented the preliminary results of its literature and plan review on ethical guidance for rationing during an influenza pandemic¹² to the panel and each of the work groups. This guidance provided a useful context for the panel and work groups' thinking.

The panel, ethics work group and resource-specific work groups developed the 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,

¹¹ DeBruin DA, Parilla E, Liaschenko J, Marshall MF, Leider JP, Brunnquell D, Garrett JE, Vawter DE. *Implementing Ethical Frameworks for Rationing Scarce Health Resources in Minnesota during a Severe Influenza Pandemic*, University of Minnesota Center for Bioethics and Minnesota Center for Health Care Ethics, 2009.

¹² 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.

infrastructure, operational issues, and individual and community values. Ultimately, each resource-specific work group forwarded a set of recommendations to the panel, and the panel blended those recommendations into a coherent package. The project team distilled the recommendations into a draft report, and the panel met in February 2008 to provide feedback. This report is the result of those efforts.

Assumptions

The following are the assumptions concerning the nature and impacts of a severe pandemic for the purposes of this project.¹³ They are not a prediction about what kind of pandemic will next occur. Indeed, it is hoped that the next pandemic will be moderate. However, the project team and MDH agreed that the ethical frameworks developed under this project would be of greatest value if the panel tackled the toughest issues, i.e., 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.

Pandemic assumptions

Severity level and population impacts

It is assumed that the influenza pandemic will be severe, based on projections from the "Spanish Flu" pandemic of 1918–19.¹⁴

1. Global: A pandemic virus equivalent in pathogenicity to the virus of 1918 will kill more than 100 million people worldwide.¹⁵
2. US and MN: Over the two-year course of the pandemic, the number of persons who will become ill, need various health care services, and die from influenza and its complications will be as follows:

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¹³ Adapted from Vawter et al, 2007.

¹⁴ Centers for Disease Control and Prevention. *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States: Early, Targeted, Layered Use of Nonpharmaceutical Interventions*. Department of Health and Human Services. 2007. Available at: http://www.pandemicflu.gov/plan/community/community_mitigation.pdf; Taubenberger J and 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 A (1989). *America's Forgotten Pandemic: The Influenza of 1918*. Cambridge, UK, Cambridge University Press; Kolata, 1999.

¹⁵ Osterholm M (2005). Preparing for the next pandemic. *N Engl J Med* 352: 1839-1842.

Table 1: Potential Impact of Severe Pandemic¹⁶

	US	Minnesota
Total population (2004 estimates)	293,655,404	5,145,106
Illness	90 million (30% of population)	1,544,000 (30% of population)
Outpatient medical care	45 million (50% of those with flu)	772,000 (50% of those with flu)
Hospitalization	9.9 million	172,000
ICU care	1.48 million	25,700
Mechanical ventilation	742,500	12,900
Deaths	1.9 million	32,900
Case-fatality rate ¹⁷	2.1%	2.1%

3. The disease will be exceptionally virulent in that 2.1% of those that develop the flu will die, a rate more than 20 times higher than for seasonal influenza.¹⁸ In a typical year, approximately 600 Minnesotans die of influenza and pneumonia;¹⁹ a severe pandemic may cause 32,900 deaths over a 2-year period.²⁰
4. The pandemic will occur over 2 years with 3 waves of illness, each wave lasting 8–12 weeks.²¹ One wave will be worse than the others, but which one cannot be known in advance.
5. Demographic groups at risk of mortality and serious morbidity:
 - a. Soon after the pandemic begins, public health officials will have sufficient data to determine which groups are at highest 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 and health status. The age-based mortality curve will be W-shaped as opposed to the U-shaped curve associated with seasonal influenza.²² Healthy persons aged 15–40 will join the very old and very young in being at elevated risk of dying from the flu.²³
 - c. 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.²⁴ For instance, half of pregnant women who develop influenza may die.²⁵

¹⁶ Minnesota Department of Health. *Pandemic Influenza Plan: All-Hazards Response and Recovery Supplement*. April 2006. Available at: <http://www.health.state.mn.us/divs/idepc/diseases/flu/pandemic/plan/mdhpanfluplan.pdf>. MDH, *Pandemic Influenza Plan*, April 2006.

¹⁷ Some plans assume an even higher case-fatality rate for a severe pandemic (see Ministry of Health. *New Zealand Influenza Pandemic Action Plan*. 2006. Available at: <http://www.moh.govt.nz/moh.nsf/indexmh/nz-influenza-pandemic-action-plan-2006>). 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 Abdel-Ghaffar AN, Chotpitayasunondh T, Gao Z, Hayden FG, Nguyen DH, de Jong MD, Naghdaliyev A, Peiris JS, Shindo N, Soeroso S and Uyeki TM (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>.

¹⁸ Taubenberger and Morens, 2006.

¹⁹ Center for Health Statistics. *2006 Minnesota Health Statistics*. Minnesota Department of Health. December 2007. Available at: <http://www.health.state.mn.us/divs/chs/06annsum/Mortality06.pdf>.

²⁰ MDH, *Pandemic Influenza Plan*, April 2006.

²¹ DHHS. *HHS Pandemic Influenza Plan*. November 2005.

²² See Appendix B: 1918 Pandemic Influenza and Pneumonia Mortality Rates.

²³ Taubenberger and Morens, 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-Ghaffar et al., 2008). 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 and 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 and Kostolansky F (2006). The role of cytokines in the immune response to influenza A virus infection. *Acta Virol* 50(3): 151-162).

²⁴ Rasmussen SA, Jamieson DJ and Bresee JS (2008). Pandemic influenza and pregnant women. *Emerg Infect Dis* 14(1): 95-100.

²⁵ Knobler SL, Mack A, Mahmoud A and Lemon SM (2005). *The Threat of Pandemic Influenza. Are We Ready?* Washington, DC, The National Academies Press. Available at <http://www.nap.edu/catalog/11150.html>.

- d. The groups at greatest risk of long-term health consequences will be the same as the groups at greatest risk of mortality.

Illness characteristics

1. Some persons will become infected but not develop clinically significant symptoms. Asymptomatic or minimally symptomatic individuals can transmit infection and develop immunity to subsequent infection.²⁶
2. The vast majority (nearly 98%) of those who become ill will recover after approximately 2 weeks.²⁷
3. Those with the flu will remain infectious for at least a week; treatment with antivirals may shorten the period of infectivity by 1 or 2 days.²⁸

Mechanism of transmission

1. Influenza viruses are spread from person to person primarily through infected persons' coughing and sneezing.²⁹ 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,³⁰ Thus, caregivers who are in close contact with infectious patients are at high risk of contracting influenza (e.g., parents who hold an ill child in their arms and health care professionals performing aspirating procedures such as intubation).
3. It is not known whether the influenza virus aerosolizes over greater distances, which would warrant all caregivers and perhaps even the general public to wear protective gear. A recent study suggests that increased aerosolization of influenza virus may be associated with lower temperature and humidity levels.³¹

Infrastructure disruption

A severe pandemic with a W-shaped age-specific mortality curve will cause significant social and economic disruption and have the potential to cripple essential health care, public health and public safety infrastructures. The nature, duration and magnitude of the disruptions distinguish severe pandemic influenza from other public health emergencies.

1. The US gross domestic product will drop 4.5 – 5.5% in a year.³²
2. Supply chains and trade will be disrupted in the face of voluntary and mandated travel restrictions.³³
3. Demand for medical services, drugs and other products will surge, leading to dramatic shortages.³⁴
4. Morgue and mortuary services will be overwhelmed.³⁵
5. Breakdowns in public order can be expected.³⁶

²⁶ DHHS. *HHS Pandemic Influenza Plan*, November 2005. Part I, pp. 18-19.

²⁷ Ibid.

²⁸ World Health Organization. *Clinical Management of Human Infection with Avian Influenza A (H5N1) Virus: Updated Advice*. August 15, 2007. Available at: http://www.who.int/csr/disease/avian_influenza/guidelines/clinicalmanage07/en/index.html.

²⁹ Tellier R (2006). Review of aerosol transmission of influenza A virus. *Emerg Infect Dis* 11: 1657-1662. Available at: <http://www.cdc.gov/ncidod/EID/vol12no11/06-0426.htm>.

³⁰ Brankston G, Gitterman L, Hirji Z, Lemeux C and Gardam M (2007). Transmission of influenza A in human beings. *Lancet Infect Dis* 7(4): 257-265.

³¹ Lowen AC, Mubareka S, Steel J and Palese P (2007). Influenza virus transmission is dependent on relative humidity and temperature. *PLoS Pathog* 3(10): 1470-1476.

³² 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*. May 22, 2006 revised July 27, 2006. Available at: <http://www.cbo.gov/ftpdocs/72xx/doc7214/05-22-Avian%20Flu.pdf>.

³³ Brahmabhatt 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>.

³⁴ Arnold R, De Sa J, Gronniger T, Percy A and 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>.

³⁵ DHHS. *HHS Pandemic Influenza Plan*. D-16, F-40.

6. 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.³⁷

Demographic assumptions

Making decisions about rationing scarce health-related resources requires assumptions about Minnesota's population relative to age and key worker status.

- Children (<18 years) account for about ¼ of Minnesota's population, while those 65 and older make up about 12% of the population (see 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.

Table 2: Minnesota Population Estimates by Age Group, 2006³⁸

Age Group (years)	Population	Percent
<5	347,404	6.7
5-17	910,526	17.6
18-20	227,262	4.4
21-44	1,947,532	37.7
45-54	795,187	15.4
55-64	534,890	10.4
65-84	531,641	10.3
85+	96,464	1.9
Total	5,167,101	
<i>Select Groups</i>		
Under 18	1,257,930	24.3
Under 21	1,485,192	28.7
55+	1,162,995	22.5
65+	628,105	12.2

- The federal government estimates that approximately 4.5% of the population would qualify as key workers³⁹ during a pandemic,⁴⁰ amounting to approximately 210,000 workers in Minnesota. The majority of these (150,000) are healthcare and emergency services workers whose jobs will be vital to controlling the pandemic. The remaining 60,000 are workers whose job functions are critical to keep society functioning. The definition of "key workers for essential functions" will evolve as planning progresses and must be reassessed to fit the circumstances of an actual

³⁶ United States Homeland Security Council. *National Strategy for Pandemic Influenza: Implementation Plan*. 2006. Available at: http://www.whitehouse.gov/homeland/nspi_implementation.pdf.

³⁷ DHHS. *HHS Pandemic Influenza Plan*. November 2005. pp. 18-19.

³⁸ 2006 American Community Survey (2008). Minnesota ACS Demographic and Housing Estimates, 2006, United States Census Bureau. Available at: http://factfinder.census.gov/servlet/ADPTable?_bm=y&-geo_id=04000US27&-qr_name=ACS_2006_EST_G00_DP5&-context=adp&-ds_name=&-tree_id=306&-lang=en&-redoLog=false&-format=

³⁹ The term "key worker" is defined on page 11 of this report.

⁴⁰ National Infrastructure Advisory Council. *The Prioritization of Critical Infrastructure for a Pandemic Outbreak in the United States Working Group: Final Report and Recommendations by the Council*. 2007. Available at: http://www.dhs.gov/xlibrary/assets/niac/niac-pandemic-wg_v8-011707.pdf; "Key" = "Tier 1" in NIAC Report; Minnesota estimated at 1.7% of US population.

pandemic. Those charged with implementing pandemic response must balance the need for preserving infrastructures (which would tend to cause the key worker definition to expand) with directing sufficient resources to meet the needs of the general public (which would tend to cause the definition to contract).

Resource assumptions

Table 3 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 are currently being stockpiled,⁴¹ while pandemic vaccines cannot be stockpiled as they cannot be manufactured until after the pandemic virus is characterized. The effectiveness of one resource, such as mechanical ventilators, may depend in part of the availability and use of other resources, although the effectiveness of all of the resources is uncertain until the nature of the pandemic is known. Detailed assumptions and references about these resources are included below in conjunction with each resource-specific rationing framework.

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⁴¹ Information on state stockpiling for a pandemic is available at <http://pandemicflu.gov/plan/states/antivirals.html>.

Table 3: Overview of Assumptions for Specific Resources

	Antivirals (Relenza and Tamiflu)		N95 Respirators and Surgical Masks	Mechanical Ventilators	Pandemic Vaccines
	Treatment	Prevention			
Purpose	Treatment	Immediate temporary prevention either post-exposure or for longer-term	- N95s: reduce exposure of the wearer to the flu virus - N95s and surgical masks: 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 - Scarce for health care workers post first few weeks - Extremely scarce for community	- 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)	- Healthy persons in community or at work, especially persons with disproportionately high exposure to flu - Healthy persons and immunocompromised persons post-exposure to flu	- Masks: persons with flu-like symptoms - Masks: healthy persons in community or at work - Masks and/or N95s: healthy persons post-exposure to flu - N95s: persons caring for, or exposed to, persons who may be contagious and/or have flu-like symptoms	Hospitalized patients with respiratory failure (flu and non-flu patients)	Persons susceptible to the flu
Type of good	- Individual treatment of flu patients - Public health good: reduce duration & severity of illness; reduce transmission	- Individual time-limited prophylaxis - Public health good: reduce transmission	- Individual time-limited protection of healthy persons - Public health good: reduce transmission	Individual life-saving tertiary care for flu and non-flu patients	- Individual long-term prophylaxis - Public health good: reduce infection rates
Predictability 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 can reduce exposures to airborne viruses however, the airborne infectious dose of the flu virus is not known - Will depend upon use of hand hygiene and other measures (e.g., fit-testing for N95s)	- Initially low - Likelihood of survival depends on virulence of virus, severity of respiratory failure, availability of concomitant necessary resources	Uncertain, but possibly high
Limitations	- Viral resistance to antiviral may undermine efficacy - Improper use may be counterproductive	- Viral resistance to antiviral may undermine efficacy - Improper use may be counterproductive	- Improper use may be counterproductive - May create false sense of security	- 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 infants < 6 months

Definitions

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 immunocompromised are the groups at highest risk of influenza-related mortality and serious morbidity. For the purposes of this project, the assumption is that in a severe pandemic these groups are joined by healthy persons between the ages of 15 and 40.⁴² Other demographic groups may be at increased risk as well. 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.⁴³ Moreover, some socially vulnerable groups may be at heightened risk of flu-related mortality and serious morbidity. Surveillance measures need to be sufficiently sensitive to promptly recognize groups at higher than normal risk.

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.⁴⁴ Building on the set of critical sectors recommended by the National Infrastructure Advisory Council, a federal interagency working group has recommended a somewhat expanded list of key workers for a severe pandemic.⁴⁵ The panel embraced yet a few more categories of workers, e.g., child protection, day care, mortuary science and spiritual leaders (see also pages 8 – 9).

Irreplaceable key workers: 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.

High (including disproportionately high) occupational exposure: Key workers whose jobs require routine direct physical contact with influenza patients exemplify high occupational exposure. Health care workers who participate in procedures such as aspiration or intubation of influenza patients exemplify those at disproportionately high risk of exposure.

High risk of transmission: persons 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.

Socially vulnerable: groups that suffer health disparities due to factors such as race, ethnicity, poverty, education, geography, disability or sexual orientation.⁴⁶ Vulnerability may stem from many factors, including differences in exposure, susceptibility and treatment.⁴⁷

Rationing Options

A severe pandemic differs so dramatically from conditions Minnesotans are accustomed to, that it is doubtful that current ethical commitments and practices will be adequate to guide decisions

⁴² Taubenberger and Morens, 2006.

⁴³ Knobler et al., *The Threat of Pandemic Influenza*, 2005.

⁴⁴ See, e.g., the description of “tier one workers” in NIAC, *Critical Infrastructure*, 2007.

⁴⁵ US Vaccine Prioritization Interagency Working Group. *Draft Guidance on Allocating and Targeting Pandemic Influenza Vaccine*. October 17 2007. Available at: <http://www.pandemicflu.gov/vaccine/prioritization.html>.

⁴⁶ U.S. 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 vol 1. Available at http://www.healthypeople.gov/Document/html/uih/uih_2.htm#goals.

⁴⁷ Blumenshine P, Reingold A, Egerter S, Mockenhaupt R, Braveman P, Marks J. Pandemic influenza planning in the United States from a health disparities perspective. *Emerg Infect Dis*. 2008;14(5):709-715. Available at <http://www.cdc.gov/EID/content/14/5/709.htm>.

about allocating health-related resources. Minnesotans have a range of options. For example, one option is to distribute resources first-come, first-served. 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. In a severe pandemic these simple, straightforward options raise fairness concerns and fail to protect and optimize Minnesotans' health.

The approach pursued in this report, is to develop ethical frameworks consisting of multiple ethical objectives—widely acceptable to Minnesotans—to more fairly, efficiently and effectively protect the common good. These ethical frameworks offer decision-makers an arrangement of ethical commitments, principles, goals and strategies to guide their decisions in fairly protecting the population's health. They are not hard-and-fast algorithms that define in advance exactly who should be prioritized for resources, because so much about a pandemic cannot be known in advance.

The frameworks in this report offer both clinical and non-clinical criteria to guide prioritization decisions. Examples of clinical criteria include factors such as high need based on high risk of mortality or high risk of exposure. These criteria are often used to guide decisions about who should get health-related resources in ordinary, non-pandemic circumstances. An example of a non-clinical criterion is a person's role in supporting critical infrastructures. Non-clinical criteria are not usually applied in ordinary, non-pandemic circumstances. (See Table 4.)

Table 4: Criteria for Prioritization: Today vs. Severe Pandemic

	Today	Severe Pandemic
Clinical considerations		
• High need, risk of dying	+	+
• High exposure	+	+
• High efficacy		+
Non-clinical considerations		
• Key worker		+
• Reciprocity obligations		+
• Younger before older		?
Procedural fairness		
• First-come, first-served	+	
• Randomization, e.g., lottery		+

Once all relevant criteria are applied if there are still not enough resources to go around, the frameworks call for randomly distributing the resources among people who are equally prioritized. The alternative to appealing to non-clinical criteria is to randomize sooner.

Proposed 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. In this section of its report, the panel offers ethical commitments, principles and goals to guide rationing. Because each resource works differently, the panel recommends a unique set of strategies for each.

The panel believes the same commitments and principles apply to the resources it considered, but notes that the goals differ slightly for two of the resources—namely, mechanical ventilators and surgical masks.

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
- Respond to needs fairly, effectively and efficiently.

These three ethical commitments are grounded in the assumptions that persons 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.

The panel concluded that rationing decisions must be made from a state population perspective, that of Minnesotans' common good. Distributing scarce health resources based on individual demands alone, with no correspondence to clinical need, efficacy or fairness, would be a recipe for disaster for Minnesotans as a population and, ironically, also as individuals. Individuals will not be able to promote their personal interests successfully in a pandemic. Nor will they be able, on their own, to address threats to their common good. The panel accepted that strategies for the good of the population as a whole promise the best protections for all in a severe pandemic.

Further, state leaders must support the public's trust through accessible, transparent, consistent communication before, during and in the recovery period after a pandemic. They are accountable for articulating and implementing plans consistent with Minnesota values gleaned from genuine, respectful public engagement on how resources should be rationed in support of the common good. MDH, in company with all levels of government, will be gathering and analyzing the facts emerging in the pandemic, determining strategies on the basis of ethical principles and goals that promote Minnesotans' interests as a population, and clearly communicating with the public. Minnesotans will need easy access to accurate, up-to-date information about the pandemic itself, about strategic rationing decisions and their rationales, and about their options and responsibilities. They will need this information in a wide range of media responsive to differences in language and culture.

Principles

A severe pandemic poses two distinct kinds of threats: (1) severe illness and death from the disease and its complications, and (2) death and social disorder due to the disruption of critical infrastructures. To address these threats, the panel recommends a set of three ethical principles expressive of the basic human values of utility, community and justice. These principles are:

- Protect the population's health
- Protect public safety and civil order
- Treat people fairly, recognizing the moral equality of all.

The panel recommends that any rationing decision promote each of these three ethical principles simultaneously, in a justifiable balance. An ethically justified decision is one that has given

balanced, maximal attention to each of these three principles in relation to the others. This means that each constrains the pursuit of the others. Decision-makers must determine the best possible adjustments among these principles and their associated goals, based on the nature and supply of the resource in question, the state of the pandemic and the good of the population.

Goals

To help with the finer-grained ethical analysis needed to honor the principles in the right balance, the panel recommends the following eight specific goals (corresponding principles are italicized):

To protect the population's health

- Reduce mortality and serious morbidity.

To protect public safety and civil order

- Reduce disruption to the basic health care, public health, public safety and other critical infrastructures; and
- Promote public understanding about and confidence in the distribution of health care resources.

To treat people fairly, recognizing the moral equality of all

- Reduce significant group differences in mortality and serious morbidity;
- Make reasonable efforts to remove barriers to fair access;
- Reciprocate to groups accepting high risk in the service of others;
- Reduce significant differences in opportunities to live a normal lifespan; and
- Promote equitable access through fair random processes for individuals equally prioritized.

Some have urged that the first goal—reducing mortality—is adequate on its own to guide rationing. Taken in isolation, however, this reflects too meager a concept of the common good. In a severe pandemic, threats come from influenza itself and from the failure of critical infrastructures. The goals that derive from the second ethical principle—protecting public safety and civil order—reflect that all Minnesotans depend on these infrastructures.

Fundamental to civil order and the welfare of Minnesotans will be their acceptance that rationing decisions are being made fairly. The third ethical principle requires treating people fairly because all are morally equal. Some fairness goals seek *substantive* fairness, namely that benefits (or burdens) are distributed among persons or groups based on ethically relevant differences among them. Other fairness goals stress the importance of *procedural* fairness; requiring that procedures equalize chances to receive benefits (or have burdens imposed) among those eligible for them. The panel recommends four substantive fairness goals to be used as guides to rationing, and calls for fair, random processes when resources are insufficient for all who are prioritized to receive them.

The first substantive fairness goal is to “reduce significant group differences in mortality and serious morbidity.” Such differences may be linked to a number of clinical and non-clinical factors. They might include heightened occupational exposure to flu patients, age, health, social or economic factors positively correlated with risk factors that make flu especially deadly. Early surveillance will be essential to determining the groups at greatest risk, the basis of their risk and their relative level of risk in the population.

Second, some population groups may have health care access barriers impeding them from getting resources for which they are eligible. The panel urgently recommends addressing such barriers before a pandemic; but in the context of rationing, the panel focuses on whether disparities in access to health care generally or health status are being exacerbated. For example, solely prioritizing groups that assume risk in the service of others could intensify access

barriers for some groups rather than relieve them, as it would give priority to those who already have access while creating another barrier for those who do not, thus increasing unfairness.

Nonetheless, the panel agreed that reciprocating and prioritizing the protection and treatment of workers at high occupational risk of exposure to pandemic influenza is a third type of substantive fairness goal. The type and scarcity of the resource, however, affects whether reciprocity justifies prioritizing one group over another. Reciprocity is usually insufficient on its own, but can add weight to prioritizations based on the other considerations.

Age was the final substantive fairness factor the panel identified as a consideration that might apply in situations of equal clinical need and equal potential to benefit from a resource. There was significant controversy in the discussion. All agreed that age should be considered only—if at all—after protecting critical infrastructures and those with heightened mortality and serious morbidity risks. Age-based rationing is discussed in more detail on pages 57 – 58.

Applying the goals to the specific resources: overview

The eight ethical goals just discussed clarify what the ethical principles require in a severe pandemic. Some groups will have a higher risk of mortality than others; a resource may be more beneficial for some groups than for others; some may be owed special protection (for example, because they are taking risks for others or have no ability to self-protect). In some cases, a goal may promote more than one principle. In the case of different resources, all of the goals may not apply, or they may apply in different ways or measure.

The panel concluded that the eight ethical goals apply to rationing vaccines, antivirals and N95s. For mechanical ventilators the panel decided that two goals should not apply. Since the rationing of ventilators will have no bearing on the disruption to basic services and infrastructures, that goal is irrelevant to deciding ethically who should be prioritized for access to ventilators. The panel also decided that the third fairness goal (reciprocity) should not apply, because the ventilator supply will be too scarce to serve that goal while also fulfilling the other fairness criteria.

With respect to rationing surgical masks, the goal of reducing significant differences in opportunities to live a normal lifespan is not part of the recommended framework. Masks are unusual and are not generally used to protect the wearers. Masks primarily offer indirect benefit to those exposed to persons wearing the masks, and offer less direct protection to persons who wear them. Among persons who can safely and effectively wear masks, the age of candidates for wearing a mask is ethically irrelevant to decisions about how to ration masks. The panel concluded that non-clinical age-based distinctions are neither necessary nor appropriate in decisions about how to ration masks.

Strategies: overview

In addition to the panel's ethical commitments, principles and goals just presented, the panel developed rationing strategies unique to each resource. Strategies for prioritization depend on both the severity of the shortage of particular resources relative to the demand, and Minnesotans' perspectives about when and how to attend to the frameworks' goals when rationing these resources.

The panel considered several different criteria in developing rationing strategies:⁴⁸

- Risk of flu-related mortality and serious morbidity;
- Good or acceptable response to the resource;
- Risk of occupational or non-occupational exposure to flu;
- Recent known unprotected exposure to flu by members of the general population or occupational exposure by key workers;

⁴⁸ Prehn and Vawter, 2008.

- Risk of transmitting flu to others at high risk of flu-related mortality and serious morbidity; and possibly
- Age (among the general population, e.g., children before adults or younger groups before older).

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 and most often combinations of characteristics drive the recommendations. 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 risks 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 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 exposed to the flu in the service of others. In addition, non-clinical age considerations may be considered in the general population in some circumstances as an alternative to resorting to a strictly random method of rationing resources to similarly prioritized persons.

The panel also proposed criteria for ineligibility or de-prioritization to receive a particular resource, depending on the scarcity of the resource. These characteristics include: assumed or confirmed immunity (e.g., have contracted and recovered from influenza or are successfully vaccinated); availability of satisfactory alternative protections, and; medical contraindications or imminent death (e.g., have a known co-morbidity incompatible with life beyond a short timeframe).

The panel rejected several criteria for rationing. These criteria are inconsistent with the fairness principle and its commitment to the moral equality of all Minnesotans. Specifically, resources should not be rationed based on:

- social value, e.g., race, gender, education, religion or citizenship;
- quality of life;
- duration of benefit (with the exception of persons who are imminently and irreversibly dying); or
- first-come, first-served.

Table 5 summarizes the ethical commitments, principles, goals and strategies that are generally recommended for the resources discussed in this report.

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Table 5: Ethical Frameworks At-a-Glance

Ethical commitments about how pandemic planning and response will be implemented 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
Principles for rationing resources in a severe pandemic Steward scarce resources to promote Minnesotans' common good by balancing three equally important ethical principles: • Protect the population's health • Protect public safety and civil order • Treat people fairly, recognizing the moral equality of all
Goals <i>Protect the population's health</i> • Reduce mortality and serious morbidity <i>Protect public safety and civil order</i> • Reduce disruption to the basic health care, public health, public safety and other critical infrastructures • Promote public understanding about and confidence in the distribution of health care resources <i>Treat people fairly, recognizing the moral equality of all</i> • Reduce significant group differences in mortality and serious morbidity • Make reasonable efforts to remove barriers to fair access • Reciprocate to groups accepting high risk in the service of others • Reduce significant differences in opportunities to live a normal lifespan • Promote equitable access through fair random processes for individuals equally prioritized
General strategies • Scale to scarcity • Do not resort to random processes prematurely • Do not ration based on: ○ Social value (gender, socioeconomic status, race, citizenship, etc.) ○ Quality of life ○ Duration of extended life ○ First-come, first-served • Generally, de-prioritize persons who have alternative protection or who are imminently and irreversibly dying • Ration different resources based on varying combinations of the following considerations (note several non-clinical considerations) ○ High risk of flu-related mortality and serious morbidity ○ Good or acceptable response to resource ○ High risk of exposure to flu ○ Key workers for essential functions ○ Risk of transmitting flu ○ Age? • Revise in light of new information • Consider and adjust as part of a comprehensive pandemic response plan, e.g., ensure that no group is systematically excluded or de-prioritized

General Recommendations

The panel recognized that for rationing frameworks to best promote the values and goals of Minnesotans and to be optimally implemented, a number of additional factors must be addressed. Although a detailed discussion is beyond the scope of this report, the panel offers the following general recommendations. Progress toward some of these recommendations, if not most, is already underway as part of the state's pandemic and all-hazards disaster planning.

1. Build Minnesota's capacity to communicate with the public, with special attention to diverse communities.
2. Build Minnesota's capacity to rapidly and safely dispense scarce health resources.
3. Build Minnesota's capacity to monitor statewide supply and demand for scarce health resources.
4. Establish mechanisms for identifying and tracking persons prioritized to receive scarce health-related resources.
5. 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 suffer health disparities currently are at increased risk of flu-related mortality and serious morbidity.⁴⁹ They may also be particularly dependent on certain critical infrastructures during a pandemic.
6. Adjust the ethical frameworks to respond to the best available evidence about the nature of the pandemic, risk, efficacy and effectiveness, and satisfactory alternative protections.
7. Make reasonable efforts to remove economic, social and geographic barriers to access to scarce health resources, e.g., remove cost as a barrier and distribute in ways convenient for socially vulnerable and underserved groups.
8. Coordinate rationing plans with other pandemic mitigation measures (e.g., social distancing).
9. Promote consistent use of public and private stockpiles of scarce health-related resources.
10. Take reasonable steps to reduce demand for and extend the supply of scarce health-related resources.
11. Secure informed public input and trust; commit to transparency in the development and implementation of the rationing framework; and inform the public about specific plans and their rationales.
12. Provide adequate training to promote the most efficient and effective use of resources.
13. Restructure working environments and deploy work forces in ways that will minimize person-to-person contact with large numbers of people so as to reduce demand for scarce preventive and treatment resources.
14. Provide clear legal protections for workers who comply with altered care standards.
15. Clarify work expectations for those who receive health resources as well as any penalties for those who refuse to work.
16. Clarify that rationing guidelines may preempt requests for interventions by patients and proxies and in advance directives.
17. Stockpile sufficient pain medications and other interventions 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. The companion report on implementation discusses issues of palliative care at greater length.⁵⁰

⁴⁹ Minnesota Department of Health. *Eliminating Health Disparities Initiative: Investing in Minnesota's Populations of Color and American Indians*. January 15 2008. Available at: <http://www.health.state.mn.us/ommh/legislative/pt2007.pdf>.

⁵⁰ DeBruin DA, Parilla E, Liaschenko J, Marshall MF, Leider JP, Brunquell D, Garrett JE, Vawter DE. *Implementing Ethical Frameworks for Rationing Scarce Health Resources in Minnesota during a Severe Influenza Pandemic*, University of Minnesota Center for Bioethics and Minnesota Center for Health Care Ethics, 2009.

In several instances, the feasibility of implementing the rationing strategies depends upon Minnesota's leaders attending to these general recommendations. For instance, the proposed rationing frameworks assume that public health officials will have sufficient data to say which groups are at highest risk of flu-related mortality, have a good response to the resource, are at high 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 implementation issues, the proposed 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 severe pandemic. The rich exchanges started in this project between persons interested in value issues and those concerned with the practicalities of rationing must continue in an open and transparent manner. A companion report developed as part of the Minnesota Pandemic Ethics Project explores in more depth challenges to implementing the proposed frameworks.⁵¹

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⁵¹ DeBruin et al., *Implementing Ethical Frameworks*, 2008; see also 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, April 25, 2008. Available at: http://books.nap.edu/catalog.php?record_id=12170.

Proposed Ethical Frameworks for Rationing Antivirals

Antiviral assumptions

The following table⁵² summarizes assumptions about the two antivirals most widely stockpiled: Zanamivir (Relenza) and Oseltamivir (Tamiflu). The frameworks focus on proposing rationing guidance for Tamiflu, the antiviral currently being stockpiled in the largest amounts.

Table 6: 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: - 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 persons ill with influenza-like illnesses - Used for short-term post exposure prophylaxis (PEP): - Contacts of earliest cases to slow early outbreaks - Persons with known unprotected exposure - Used for long-term or outbreak prophylaxis - Minnesota's stockpile is currently prioritized for treatment, per federal government requirements	
Dose, administration	- 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;⁵³ 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 (e.g., 8 – 12 weeks)⁵⁴ - Non-standard courses may be required for critically ill;⁵⁵ maximum doses and duration are unknown; effectiveness may require a double dose or extended use
Anticipated supply	- Supply in Minnesota as of December 2007 is assumed to be 1,078,314 standard treatment courses. - Federal government will provide MDH 754,675 treatment courses - MDH is purchasing 295,092 government subsidized courses.⁵⁶	

⁵² 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.

⁵³ 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).

⁵⁴ Assistant Secretary of Defense. *Health Affairs Policy for Release of Department of Defense Antiviral Stockpile during an Influenza Pandemic*. United States Department of Defense. August 10, 2007. Available at:

[http://fhq.osd.mil/ai/Watchboard/pdf/131346-Policy for Release and Use of DoD Antiviral Stockpile During an Influenza Pandemic.pdf](http://fhq.osd.mil/ai/Watchboard/pdf/131346-Policy%20for%20Release%20and%20Use%20of%20DoD%20Antiviral%20Stockpile%20During%20an%20Influenza%20Pandemic.pdf). HA Policy 07-015.

⁵⁵ WHO, *Clinical Management*, 2007; Beigel JH, Farrar J, Han AM, Hayden FG, Hyer R, de Jong MD, Lochindarat S, Nguyen TK, Nguyen TH, Tran TH, Nicoll A, Touch S and Yuen KY (2005). Avian influenza A (H5N1) infection in humans. *N Engl J Med* 353(13): 1374-1385.

⁵⁶ Leitheiser A., Personal communication. December 2007.

Table 6: Antiviral Assumptions (cont.)

Anticipated supply	○ At least 28,547 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.⁵⁷ ● 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.⁵⁸	
Anticipated demand	● 1,117,000 (75%) of Minnesotans with flu-like symptoms (23% of the population) are anticipated to seek antivirals within 48 hours of symptoms sometime during a severe 2 year pandemic. ● While community mitigation measures are likely to reduce the attack rate, any related reduction in demand for antivirals is anticipated to be offset by persons 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.	
Composition of supply	Approximately 20% of MN stockpile.	Approximately 80% of MN stockpile.
Effectiveness	● Effectiveness is assumed to be comparable to seasonal influenza.⁵⁹ ● 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 effectiveness for pandemic influenza is unknown, but assume antivirals will: ○ Shorten illness by 1-2 days ○ Shorten period of infectiousness by 1-2 days⁶⁰ ○ Reduce symptoms and complications, e.g., duration of fever, need for antibiotics, hospitalization, ventilators to treat lower respiratory complications and death.⁶¹	

⁵⁷ The federal government recommends that states have sufficient antivirals to treat 25% of their populations (see DHHS. HHS Pandemic Influenza Plan, November 2005; Gani R, Hughes H, Fleming D, Griffin T, Medlock J and 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. 2008. *Guidance on Antiviral Drug Use during an Influenza Pandemic*. December 16, 2008. Available at: http://www.pandemicflu.gov/vaccine/antiviral_use.html). Barriers exist to Minnesota significantly expanding its stockpile (see Koonin LM and 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/Object.File/Master/50/642/Koonin.pdf>; Hearne SA, Segal LM, Earls MJ, Juliano C and Stephens T. Ready or Not? Protecting the Public's Health From Diseases, Disasters, and Bioterrorism. December 2005. Available at: <http://www.rwjf.org/files/newsroom/TFAHBioTerrorReport.pdf>; US Government Accounting Office. Influenza Pandemic: Efforts Underway to Address Constraints on using Antivirals and Vaccines to Forestall a Pandemic. 2007).

⁵⁸ 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*, June 3, 2008).

⁵⁹ Hota S and McGeer A (2007). Antivirals and the control of influenza outbreaks. *Clin Infect Dis* 45(10): 1362-1368.

⁶⁰ American Academy of Pediatrics Committee on Infectious Diseases (2007). Antiviral therapy and prophylaxis for influenza in children. *Pediatrics* 119(4): 852-860.

Table 6: Antiviral Assumptions (cont.)

	- Potential to control spread increases if used for directed short-term prevention.⁶² - 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 H5N1 may be increasing.
Safety	Not recommended for those with underlying respiratory disease, e.g., 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 persons too sick to take pill. - Concurrent use of Tamiflu and intranasal live attenuated influenza vaccine (LAIV) has not been evaluated.⁶³
Possession and control of supply	- Stockpiles of antivirals are purchased, held and distributed by the federal government, the state 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 government subsidy to follow MDH direction about use of stockpiled antivirals.	

General recommendations for rationing antivirals

1. Attend to the section above on General Recommendations (pages 18 – 19) and apply them as appropriate to the planning for rationing different uses of antivirals. Refrain from rationing antivirals based on social value, quality of life, duration of benefit or first-come, first-served.
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 in reserve to treat persons in future waves.
4. If safety and effectiveness of PEP is established in immune-compromised persons, reserve a small supply of antivirals for PEP in groups at high risk of death that lack alternative protections, e.g., elderly persons during flu outbreak in a long-term care facility, young infants and immune-compromised persons in hospitals, prisons and homeless shelters, etc. who have low response to vaccine.
5. Exclude persons with immunity or medical contraindications (e.g., unacceptable side-effects). In the absence of satisfactory methods of confirming immunity, de-prioritize (rather than exclude) persons with *assumed* immunity.
6. Dispense and dose with attention to reducing the chances of inducing resistance.
7. Develop broadly accessible information about the importance of prompt access to treatment and PEP antivirals and their effective use.
8. Ensure adequate availability of pediatric doses and formulations.
9. Develop protocols to conserve and extend antiviral supplies, e.g., recoup from hospitalized patients remaining doses from partially used courses.

⁶¹ Ibid.; Gani et al., 2005; McGeer A, Green KA, Plevneshi A, Shigayeva A, Siddiqi N, Raboud J and Low DE (2007). Antiviral therapy and outcomes of influenza requiring hospitalization in Ontario, Canada. *Clin Infect Dis* 45(12): 1568-1575.

⁶² Lee VJ, Phua KH, Chen MI, Chow A, Ma S, Goh KT and Leo YS. (2006). Economics of neuraminidase inhibitor stockpiling for pandemic influenza, Singapore. *Emerg Infect Dis* 12 Jan [April 4, 2008]. Available at: <http://www.cdc.gov/ncidod/EID/vol12no01/05-0556.htm>; Hota and McGeer, 2007.

⁶³ Roche Laboratories Inc. (2007). "Tamiflu: Dosing, Administration and Storage." Retrieved April 4, 2008, from <http://www.tamiflu.com/hcp/dosing/default.aspx>.

10. To the extent it is feasible, reliably and rapidly identify individuals who are immune so antivirals can be redirected to those who lack immunity.
11. To the extent it is feasible, reliably and rapidly identify individuals with influenza-like illnesses so antivirals are not unnecessarily used for misidentified post-exposure events.
12. Work with the federal government to loosen restrictions on the use of stockpiled antivirals and extend their shelf-life.
13. Clarify work expectations for workers who receive outbreak, PEP and treatment antivirals.

Table 7: Ethical Commitments, Principles and Goals for Rationing Antivirals

I. Ethical commitments about how pandemic planning and response will be implemented 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. Principles for rationing resources in a severe pandemic Steward scarce resources to promote Minnesotans' common good by balancing three equally important ethical principles: • Protect the population's health • Protect public safety and civil order • Treat people fairly, recognizing the moral equality of all
III. Goals <i>Protect the population's health</i> • Reduce mortality and serious morbidity <i>Protect public safety and civil order</i> • Reduce disruption to the basic health care, public health, public safety and other critical infrastructures • Promote public understanding about and confidence in the distribution of health care resources <i>Treat people fairly, recognizing the moral equality of all</i> • Reduce significant group differences in mortality and serious morbidity • Make reasonable efforts to remove barriers to fair access • Reciprocate to groups accepting high risk in the service of others • Reduce significant differences in opportunities to live a normal lifespan • Promote equitable access through fair random processes for individuals equally prioritized

Antivirals can be used both for treatment and prophylaxis. The strategies for each follow.

Antiviral treatment strategies

Table 8 presents the recommended strategies for rationing antivirals for treatment. These strategies follow the ethical commitments, principles and goals stated in Table 7.

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Table 8: Antiviral Treatment Strategies

IV. Strategies for rationing treatment antivirals to the sick (e.g., Tamiflu)			
- Attend to the general recommendations for rationing antivirals above (pages 22 – 23). - Various combinations of characteristics warrant prioritizing some groups to receive treatment antivirals before others: - risk of flu-related mortality and serious morbidity; - risk of occupational exposure to flu (for key workers); and possibly - age (among ill groups within general population at similar risk of flu-related mortality, children before adults or younger before older more generally). - De-prioritize persons: - presenting with influenza-like illness > 48 hours;⁶⁴ - known to be imminently and irreversibly dying (unless the antivirals serve a unique palliative function). - having satisfactory alternative treatment (should such a treatment become available). - When there is a shortage of treatment antivirals (which might not occur until the second wave), ration treatment antivirals for key workers and the general population as outlined below. When the shortage is severe, focus on the highest treatment priorities; when the shortage is less, expand the treatment priorities as follows.			
Supply	Treatment Priorities	Track A – Ill Key Workers⁶⁵	Track B – Ill in General Population
Extreme shortage	Tier 1	Key workers with high risk of flu-related mortality/morbidity.	Groups, if any, at <i>disproportionately high</i> ⁶⁶ risk of flu-related mortality/morbidity (e.g., pregnant women ⁶⁷).
	Tier 2	- Key workers with high occupational exposure;⁶⁸ or - Irreplaceable key workers.⁶⁹	Groups at <i>high risk</i> of flu-related mortality/morbidity; If supply is insufficient to meet the needs of these groups either: - straightaway apply a fair random process to select individuals to receive treatment; or - first prioritize ill high risk younger groups before older groups, as many groups as the supply can accommodate, for example: - groups of children (< age of majority); - groups < X years of age (e.g., 55); or - groups < Y years of age (e.g., 85).
	Tier 3	Key workers.	Groups with $\geq$ moderate risk of flu-related mortality/morbidity.
	Tier 4	All eligible patients.	
Adequate supply			

⁶⁴ Should a rapid, accurate and inexpensive test become available for pandemic influenza, adjust the eligibility criteria to “present with pandemic flu symptoms $\leq$ 48 hours.”

⁶⁵ “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, *Critical Infrastructures*, 2007 and page 11 of this report).

⁶⁶ “Disproportionately high risk of flu-related mortality/morbidity,” refers to groups that have a spike in their case fatality rate that dramatically exceeds the peaks of an age-specific mortality curve for the flu.

⁶⁷ WHO, *Clinical Management*, 2007.

⁶⁸ “High occupational exposure” refers, for example, to workers whose jobs require routine direct physical contact with influenza patients.

⁶⁹ “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.

The strategies in Table 9 for rationing antivirals for prophylaxis follow the ethical commitments, principles and goals stated in Table 7.

Table 9: Antiviral Prophylaxis Strategies—Long and Short-Term

V. Strategies for rationing antivirals (e.g., Tamiflu) for outbreak prophylaxis (long-term prophylaxis during an entire pandemic wave) • Attend to the general recommendations for rationing antivirals above (pages 22 – 23). • The supply of outbreak prophylactic antivirals is extremely limited and is to be rationed only to a small group of eligible key workers⁷⁰ and not within the general population. • Eligible key workers: ○ have disproportionately high occupational exposure to flu (e.g., routinely participate in intubations of flu patients); ○ lack medical contraindications to antivirals (or to Tamiflu specifically, e.g., unacceptable side effects); ○ lack assumed/confirmed natural immunity; and ○ lack satisfactory alternative protections. • If the supply of these antivirals unexpectedly becomes more adequate, expand eligibility criteria to include other key workers with <i>high</i> occupational exposure to flu.
VI. Strategies for rationing antivirals (e.g., Tamiflu) for post-exposure prophylaxis (PEP) (short term prophylaxis following an exposure to flu) • Attend to the general recommendations for rationing antivirals above (pages 22 – 23). • The supply of PEP antivirals is extremely limited (e.g., assumed to be approximately 34,000 courses out of approximately 1,117,000 courses). Ration them to key workers and the general population as outlined below in tracks A and B. • Exclude persons receiving outbreak prophylactic antivirals. • Various combinations of characteristics warrant prioritizing some persons to receive PEP antivirals before others: ○ risk of flu-related mortality and serious morbidity; ○ risk of occupational exposure to flu (for key workers); ○ risk of transmitting flu to persons at high risk of flu-related mortality and serious morbidity; and possibly ○ age (among the general population exposed and at high risk of flu-related mortality, children before adults or younger before older more generally). • De-prioritize persons ○ exposed to flu > 48 hours ago; ○ known to be imminently and irreversibly dying (e.g., have a known co-morbidity incompatible with life beyond a couple of weeks or months); or ○ with satisfactory alternative protection (other than outbreak prophylactic antivirals as persons with this form of protection are ineligible for PEP). • Consider capping the number of PEP courses per person (except for irreplaceable key workers), depending on anticipated demand and on PEP supplies and effectiveness.

[Table 9 continued on next page]

⁷⁰ “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, *Critical Infrastructures*, 2007 and page 11 of this report).

Table 9: Antiviral Prophylaxis Strategies—Long and Short-Term (*cont.*)

VI. Strategies for rationing post exposure prophylaxis (PEP) antivirals (e.g., Tamiflu) (<i>cont.</i>)			
Supply	PEP Priorities	Track A – Exposed Key Workers ⁷¹	Track B – Exposed in General Population
Extreme shortage	Tier 1	Exposed key workers with - disproportionately <i>high</i> occupational exposure;⁷² or <i>high</i> risk of flu-related mortality/morbidity.	- Persons exposed to contained disease clusters; or - Exposed persons with disproportionately high risk of flu-related mortality/morbidity.
	Tier 2	Exposed key workers that also - are irreplaceable;⁷³ or - have <i>high</i> occupational exposure.⁷⁴	Exposed persons - with <i>high risk</i> of flu-related mortality/morbidity; and - at risk of transmitting to persons at <i>high risk</i> of flu-related mortality/ morbidity lacking alternative protections, e.g., young infants.
	If the supply of prophylactic antivirals unexpectedly becomes more adequate, consider increasing the cap on the number of PEP courses per person in tiers 1 and 2 and/or cumulatively expanding the PEP priorities as follows.		
	Tier 3	Exposed key workers with risk of transmitting to persons at <i>high risk</i> of flu-related mortality/morbidity lacking alternative protections, e.g., young infants.	Exposed persons with <i>high risk</i> of flu-related mortality/morbidity. If supply is insufficient to meet the needs of these groups either: - straightaway apply a fair random process to select individuals to receive PEP; or - first prioritize exposed high risk younger persons before older persons consistent with the supply, for example: - children (< age of majority); < X years of age (e.g., 55); or < Y years of age (e.g., 85).
Adequate supply	Tier 4	Exposed key workers.	Exposed persons - with moderate risk of flu-related mortality/morbidity; and - risk of transmitting to persons at <i>high risk</i> of flu-related mortality/morbidity lacking alternative protections, e.g., young infants.
	Tier 5	All eligible persons.	

⁷¹ “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, *Critical Infrastructures*, 2007 and page 11 of this report).

⁷² “Disproportionately high occupational exposure” refers, for example, to workers who routinely participate in intubations of influenza patients.

⁷³ “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.

⁷⁴ “High occupational exposure” refers, for example, to workers whose jobs require routine direct physical contact with influenza patients.

Discussion: rationing antivirals

Antivirals as a public health good

Antiviral drugs are a public health good with significant potential to mitigate the effects of a pandemic. If well matched to the circulating strain of influenza virus, they are anticipated to reduce deaths and the severity and duration of influenza-related illness and serious morbidities. They are therefore also expected to reduce the strain on health care services including clinics, pharmacies, hospitals and critical care resources. Antivirals may reduce the viral loads in persons ill with the flu, reduce the period of time persons are infectious and hence also may limit the spread of the disease. Another important role for antivirals is to prevent persons from becoming ill, for example, those who have had a recent exposure to influenza, or workers that are at disproportionately high risk of flu-related mortality/morbidity or occupational exposure to flu. Short-term post-exposure prophylaxis (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.

Supply

Antivirals are a prescription medication that can be stockpiled, and the federal government, the state of Minnesota and some private entities are doing so. At the start of a pandemic the supply is expected to be sufficient for standard courses of treatment antiviral for approximately 21% of Minnesotans, assuming that standard dosages and duration of treatment are effective and that none of the supply is used for prophylactic purposes. The federal government recommends that states have available enough to treat 25% of their population.⁷⁵

The antivirals stockpile might be sufficient to treat all eligible patients during the first wave, depending on specific circumstances. The need to ration treatment antivirals is likely during the second and third waves. The supply of antivirals for PEP will be very scarce, so rationing would begin with the first outbreak in the state.

Special features

Antivirals are a flexible resource in that they can be used both to treat and prevent illness.

Antivirals are also unusual in that of all the resources the panel considered, antivirals promise benefit to the broadest range of demographic groups. Young infants are the notable exception. The panel assumed that efficacy will be comparable across groups, with one important caveat, namely, that the treatment and PEP antivirals should be dispensed and used within 48 hours of onset of symptoms or unprotected exposure to the flu. This narrow window of therapeutic opportunity signals the importance of removing access barriers to treatment antivirals. Appropriate educational measures and infrastructures for prescribing and dispensing this prescription drug in a timely fashion to those with cultural, communication, mobility and geographic barriers are required as a matter of fairness.

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.

Most pandemic guidance recommends that antivirals be used primarily for treatment, with a small supply reserved for prophylactic purposes to limit isolated outbreaks.⁷⁶ The panel's

⁷⁵ DHHS. *HHS Pandemic Influenza Plan*, November 2005.

⁷⁶ Prehn and Vawter, 2008.

recommendations for allocating Minnesota's supply of antivirals are consistent with this guidance. Based on the panel's current assumptions of approximately 1,117,000 courses, most would be earmarked for treatment and only small portions would be allocated for prophylaxis.

How these recommendations fit with federal guidance

The 2005 HHS Pandemic Influenza Plan included guidance (developed by the National Vaccine Advisory Committee and the Advisory Committee on Immunization Practices) for allocating antivirals in a *moderate*, not severe, influenza pandemic. The guidance recommended the use of antivirals primarily for treatment (with priority given to hospitalized patients), for PEP under a single condition (i.e., outbreaks in nursing homes and other residential settings) and for long-term prophylaxis (i.e., 4 or more courses) in some key workers and the highest risk outpatients.

In June 2008 (after the panel ceased to meet), the federal government released for public comment proposed guidance for the use of antivirals during the first wave of a severe pandemic.⁷⁷ The final federal guidance, issued in December 2008, likewise focuses on wave one, when prioritization is unnecessary as states are anticipated to have sufficient supplies of antivirals to treat everyone with influenza-like symptoms.⁷⁸ 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.

When the Minnesota Department of Health 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.⁷⁹ The Minnesota Department of Health, as the funder of this work, directed that project participants be informed by federal guidance but not be limited by it, because federal guidance is 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.⁸⁰

Remaining questions

There are important questions left open which were beyond the scope of this project and the panel's expertise. One is what proportion of the supply can and should be allocated for outbreak prophylaxis and PEP. Should antivirals be reserved for treating persons suspected of having contracted pandemic influenza or should a portion remain available to treat other conditions?

Another question is whether Minnesota's stockpile is sufficient. The optimal size of Minnesota's stockpile is a complex question that the panel was not charged with addressing. 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? How effective will the state pressure be on the federal government to 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?

⁷⁷ US Interagency Working Group. *Proposed Guidance*, June 3, 2008. Available at: <http://aspe.hhs.gov/panflu/antiviraluse.pdf>; Gervais KG, Vawter DE, Garrett JE, Prehn AW. Letter to U.S. Department of Health and Human Services Re: Pandemic Influenza Antiviral Comments. July 3, 2008.

⁷⁸ DHHS. *Guidance on Antiviral Drug Use*. December 16, 2008. Available at: http://www.pandemicflu.gov/vaccine/antiviral_use.html.

⁷⁹ DHHS. *HHS Pandemic Influenza Plan*, November 2005.

⁸⁰ DHHS. *Pandemic Planning Update VI*. January 8, 2009. Available at: <http://www.pandemicflu.gov/plan/panflureport6.html>.

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 key workers, 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 persons 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 recent report by the Institute of Medicine.⁸¹

Proposed ethical frameworks for antivirals

The recommended strategies combine clinical, population health and non-clinical fairness considerations consistent with balancing the frameworks' principles and corresponding goals. In addition to identifying morally relevant considerations for prioritizing some groups before others under different conditions of scarcity, the strategies include a couple of exclusion criteria and 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 recommendation is not to rely on first-come, first-served, but to remove barriers to fair access and then either use a fair random procedure or else first apply non-clinical age-based fairness considerations.

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.

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 tier 3 or higher. 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

⁸¹ 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) April 25, 2008. Available at: http://books.nap.edu/catalog.php?record_id=12170.

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.⁸²

When the supply is extremely scarce but can accommodate more persons 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 with 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. When the demand exceeds supply among influenza patients in the general population, either randomly select persons to receive treatment or (if Minnesotans generally agree that it is fair to treat younger groups first) treat those below a selected age cut-off. among similarly prioritized groups. See the discussion on pages 57 – 58 for more on age-based rationing.

Rationing antivirals for outbreak prophylaxis and PEP

CRITERIA FOR PRIORITIZATION

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, i.e., critical care workers who routinely intubate or aspirate influenza patients and are thus at disproportionately high risk of occupational exposure.

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. Again these considerations work together to honor the multiple recommended ethical commitments, principles and goals:

- exposure to one of the earliest cases of influenza or to a contained outbreak;
- 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;
- risk of transmitting influenza to persons at high risk of flu-related mortality; and possibly
- age.

Tier 1, track A includes key workers with disproportionately high occupational exposure (unless they have access to outbreak prophylactic antivirals) and exposed key workers who are at high risk of flu-related mortality/morbidity. The only persons 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 persons at high risk of flu-related mortality/morbidity who lack alternative protections (e.g., persons caring for infants).

⁸² Knobler et al., *The Threat of Pandemic Influenza*, 2005.

It is highly unlikely that the supplies of antivirals will be sufficient to provide PEP to persons in tiers 3, 4 or 5. Thus, the anticipated supplies of PEP and outbreak prophylactic antivirals are so limited that the panel does not anticipate that age-based rationing would be implemented in practice.

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Proposed Ethical Frameworks for Rationing N95s and Masks

Assumptions about N95s and masks⁸³

Use

1. N95s and surgical masks approved by the National Institute for Occupational Safety and Health (NIOSH) can reduce and slow transmission of influenza.⁸⁴
2. NIOSH-approved N95s are worn by healthy persons to *limit the wearers' exposure* to droplet and airborne virus (among other types of biohazards).⁸⁵ 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.⁸⁶ Currently they are generally used by healthy (or pre-symptomatic) persons to *protect others* from unexpected coughs and sneezes, but in a severe pandemic will also be worn by persons presumed to be infectious in order to protect those around them.
4. N95s are filtering face pieces. These models are often disposable, single-use and easily contaminated. Most guidelines recommend that filtering face piece respirators (e.g., "N95s") and surgical masks be changed when they become contaminated, difficult to breathe through, or damaged, whichever comes first.⁸⁷
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 issued a report on reusability of N95s.⁸⁸
6. N95s and masks can be stored indefinitely under dry conditions within reasonable temperature range.⁸⁹ The manufacturer will be consulted to determine how long they can be stored.

Safety

1. N95s and masks are safe for the vast majority of population.⁹⁰
2. N95s and masks may be unsafe or difficult to use for those with cardiac or respiratory problems (either chronic or acute).

⁸³ Unless otherwise stated, the sources for the information in this table 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.

⁸⁴ Centers for Disease Control and Prevention. *Interim Guidance on Planning for the Use of Surgical Masks and Respirators in Health Care Settings during an Influenza Pandemic*. 2006. Available at: <http://pandemicflu.gov/plan/healthcare/maskguidancehc.html>; Centers for Disease Control and Prevention. *Interim Public Health Guidance for the Use of Facemasks and Respirators in Non-occupational Community Settings during an Influenza Pandemic*. May 2007. Available at: <http://www.pandemicflu.gov/plan/community/commaskguidance.pdf>; Jefferson T, Foxlee R, Del Mar C, Dooley L, Ferroni E, Hewak B, Prabhala A, Nair S and Rivetti A (2007). Interventions for the interruption or reduction of the spread of respiratory viruses. *Cochrane Database Syst Rev*(4): CD006207.

⁸⁵ CDC, *Use of Surgical Masks and Respirators in Health Care Settings*, 2006; CDC, *Use of Facemasks and Respirators in Non-occupational Community Settings*, May 2007; Balazy A, Toivola M, Adhikari A, Sivasubramani SK, Reponen T and 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.

⁸⁶ Ibid.

⁸⁷ 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>.

⁸⁸ Ibid.

⁸⁹ Weiss MM, Weiss PD, Weiss DE and 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.

⁹⁰ CDC, *Use of Facemasks and Respirators in Non-occupational Community Settings*, May 2007.

3. N95s have not been designed or proven safe for children under age three. Masks may also be unsafe for children under age three, for instance when children are unable to remove the masks if they are having respiratory difficulty.

Efficacy

1. Limited knowledge about how influenza virus is transmitted makes the efficacy of both N95s and masks unclear. N95 respirators will help reduce exposures if the virus is transmitted via the aerosol route. Most experts recommend use of N95s or even masks as a last line of defense, based on their unknown efficacy against viral agents. However, most also agree that use in a pandemic is probably better than no protection at all.⁹¹
2. A properly used N95 can reduce exposure by a factor of 10.⁹² 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 significant protection (along with hand hygiene) during the SARS outbreak.⁹³ We assume that N95s will provide wearers at least some protection against airborne particulates and droplets.
3. N95s perform best when properly fitted, which requires education/training and a clean-shaven face.⁹⁴ There is some research on efficacy (leaking, etc.) of non-fit tested N95s; they afford some protection.⁹⁵ Non-fit tested N95s reduced exposure to 2/3 of particles in one study.⁹⁶
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).⁹⁷
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.⁹⁸
6. Masks do not form a seal with the face and therefore are assumed to be less effective at protecting wearers against airborne particulates. Masks, however, provide at least some protection from liquid splashes and very large droplets.
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 should be roughly as effective as a mask in protecting others, because exhaled air will be directed out through the valve or around the edges of the N95.
 - A well-fitted, non-valved N95 should provide greater protection than either a poorly fit N95 or a surgical mask in protecting others, because exhaled air goes back through the filter.

Supply and demand

1. It is likely that protective gear such as N95s will be in great demand because of the possibility of aerosolized transmission. Estimating the demand for N95s and masks for

⁹¹ Institute of Medicine, *Reusability of Facemasks*, 2006.

⁹² 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.

⁹³ Teaman MD, Boudville IC, Heng BH, Zhu D and 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 and Lim WW (2005). Respiratory infections during SARS outbreak, Hong Kong, 2003. *Emerg Infect Dis* 11(11): 1738-1741.

⁹⁴ CDC, *Use of Surgical Masks and Respirators in Health Care Settings*, 2006; Derrick JL and Gomersall CD (2005). Protecting healthcare staff from severe acute respiratory syndrome: filtration capacity of multiple surgical masks. *J Hosp Infect* 59(4): 365-368.

⁹⁵ Lawrence RB, Duling MG, Calvert CA and Coffey CC (2006). Comparison of performance of three different types of respiratory protection devices. *J Occup Environ Hyg* 3(9): 465-474.

⁹⁶ 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.

⁹⁷ CDC, *Use of Surgical Masks and Respirators in Health Care Settings*, 2006.

⁹⁸ Ibid.

- influenza-related uses is difficult, as some people will need them for a few days and others for many months. Recent guidance from the Occupational Safety and Health Administration (OSHA) suggests that an average of four “single use” respiratory protection devices (N95s or masks) per shift will be required for those workers at high or very high risk of exposure (e.g., healthcare and emergency response workers).⁹⁹
2. Supplies of N95s are currently available and being stockpiled in both public and private sectors, from state to business to household. The capacity to replenish supplies will be reduced during a severe pandemic.
 3. MDH currently estimates there are about 1,000,000 N95s in state and regional stockpiles.¹⁰⁰ MDH also reports state stockpiles of about 2,000 surgical masks, 19 fit test kits and 15 powered air purifying respirators (PAPRs) (these last three were inventoried March 2006). Minnesota's allocation from the Strategic National Stockpile is 725,000 NIOSH/FDA respirators, 720,000 NIOSH respirators, and 854,000 surgical masks.¹⁰¹ Therefore, Minnesota's total estimated stockpile consists of 2,445,000 N95s and 856,000 surgical masks. An unknown additional number of N95s and masks have been stockpiled by health care facilities and other private institutions and individuals; barriers to stockpiling include cost and storage space.
 4. MDH estimates that MN will need 1,000,000 N95s per week just for health care worker use. Assuming that none of the stockpile of N95s is distributed to the public, the current estimated supply can protect health care workers for less than three weeks.
 5. A portion of FDA-cleared N95s will be reserved for use in operating rooms, as they have additional fluid resistance.
 6. European approved and other non FDA-approved respirators and masks may be available for purchase and use.
 7. Supplies will be expanded by using reusable half-face piece respirators (with disposable filters) to the extent possible.
 8. Private individuals are encouraged to stockpile some N95s and surgical masks for their personal use in a disaster.¹⁰² Surgical masks currently are less available for purchase by private individuals than N95s.

General recommendations for rationing N95s and masks

1. Attend to the section above on General Recommendations (pages 18 – 19) and apply them as appropriate to the planning for rationing different uses of N95s and masks. Refrain from rationing N95s and masks based on social value, quality of life, duration of benefit or first-come, first-served.
2. Expand distribution mechanisms for surgical masks as their availability is currently often limited to purchase by contract to health care purchasers.
3. Remove barriers to the manufacture of N95s and masks for children, e.g., develop pressure drop specifications for pediatric N95s and surgical masks.
4. Masks rather than N95s should be used by ill patients whenever reasonable to prevent transmission, e.g., when masks protect others from infectious agents as well as N95s.

⁹⁹ Occupational Safety and Health Administration. *Proposed Guidance on Workplace Stockpiling of Respirators and Facemasks for Pandemic Influenza*. November 7, 2007.

¹⁰⁰ Leitheiser A., personal communication. January 17, 2008.

¹⁰¹ Information on the Strategic National Stockpile can be found at www.bt.cdc.gov/stockpile/.

¹⁰² University of Minnesota. (May 2, 2007). "Minnesota Emergency Readiness Education and Training." Retrieved February 8, 2008, from <http://cpheo.sph.umn.edu/meret/>; 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*. November 2007. Available at: <http://www.bag.admin.ch/influenza/01120/01134/03058/index.html?lang=en>; US Interagency Working Group. *Interim Guidance on the Use and Purchase of Facemasks and Respirators by Individuals and Families for Pandemic Influenza Preparedness*. June 3, 2008. Available at: <http://aspe.hhs.gov/panflu/facemasks.pdf>.

5. If reuse 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.

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Table 10: Ethical Framework for Rationing N95s¹⁰³

I. Ethical commitments about how pandemic planning and response will be implemented 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. Principles for rationing resources in a severe pandemic Steward scarce resources to promote Minnesotans' common good by balancing three equally important ethical principles: • Protect the population's health • Protect public safety and civil order • Treat people fairly, recognizing the moral equality of all
III. Goals <i>Protect the population's health</i> • Reduce mortality and serious morbidity <i>Protect public safety and civil order</i> • Reduce disruption to the basic health care, public health, public safety and other critical infrastructures • Promote public understanding about and confidence in the distribution of health care resources <i>Treat people fairly, recognizing the moral equality of all</i> • Reduce significant group differences in mortality and serious morbidity • Make reasonable efforts to remove barriers to fair access • Reciprocate to groups accepting high risk in the service of others • Reduce significant differences in opportunities to live a normal lifespan • Promote equitable access through fair random processes for individuals equally prioritized
IV. Strategies for rationing N95s to protect persons at risk for contracting flu • Attend to general recommendations for rationing N95s and masks (pages 34 – 35). • The supply is anticipated to be extremely scarce and most stockpiles should be allocated for use by key workers. • Exclude persons: ○ with immunity* (e.g., have contracted and recovered from influenza or are successfully vaccinated); ○ with medical contraindications (e.g., co-morbidities that hamper breathing or too young to safely wear N95s); ○ who refuse or are unable to comply with wearing instructions. • Various combinations of characteristics warrant prioritizing some groups of key workers and groups within the general population to receive N95s before others: ○ risk of flu-related mortality and serious morbidity; ○ risk of exposure to flu; and possibly ○ age (among groups at high risk of flu-related mortality within the general population, children before adults or younger before older more generally). • De-prioritize persons: ○ known to be imminently and irreversibly dying (e.g., have obvious known co-morbidity incompatible with life beyond a couple weeks or months); or ○ with alternative satisfactory protection. * In the absence of satisfactory methods of confirming immunity, de-prioritize (rather than exclude) persons with assumed immunity.

¹⁰³ These recommendations for rationing N95s in a severe influenza pandemic do not limit the use of N95s for other purposes and circumstances.

Table 10: Ethical Framework for Rationing N95s (cont.)

Supply	N95 Priorities	Track A – Key Workers ¹⁰⁴	Track B – General Population
Extreme shortage	Tier 1	Key workers with <i>disproportionately high</i> occupational exposure ¹⁰⁵ to flu.	Groups exposed to contained disease clusters; or Groups at <i>disproportionately high</i> risk of flu-related mortality/morbidity and at <i>risk of exposure</i> (e.g., pregnant women ¹⁰⁶ or immune-compromised persons using public transportation or requiring treatment at a health care facility that treats flu patients).
	Tier 2	Key workers - with <i>high</i> occupational exposure;¹⁰⁷ or <i>irreplaceable</i>.¹⁰⁸	
	Should the supply of N95s unexpectedly become more adequate, expand the priorities as follows, but retain a 2-week supply for tiers 1 and 2 before distributing N95s for lower tiers.		
No shortage	Tier 3	Key workers - with occupational exposure; and - high risk of flu-related mortality/morbidity.	Persons with <i>high risk</i> of flu-related mortality/morbidity and at <i>risk of exposure</i> . If supply is insufficient to meet the needs of these persons, either: - straightaway apply a fair random process to select individuals to receive N95s; or - first prioritize exposed high risk younger persons before older persons consistent with the supply, for example: - children (< age of majority); < X years of age (e.g., 55); - or < Y years of age (e.g., 85).
	Tier 4	All eligible persons.	

Discussion: rationing N95s

N95s provide a seal around the face and a high level of filtration, so that the wearer is protected from 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 a couple of exclusion criteria and considerations for de-prioritizing groups under conditions of elevated scarcity.

¹⁰⁴ “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, *Critical Infrastructures*, 2007 and page 11 of this report).

¹⁰⁵ “Disproportionately high occupational exposure” refers, for example, to health care workers who participate in procedures such as aspiration or intubation of influenza patients.

¹⁰⁶ WHO, *Clinical Management*, 2007.

¹⁰⁷ “High occupational exposure” refers, for example, to workers whose jobs require routine direct physical contact with influenza patients.

¹⁰⁸ “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.

Exclusion and de-prioritization criteria

Fairness and wise stewardship would exclude or at least de-prioritize groups based on these factors:

- Confirmation of immunity;
- Medical contraindications (e.g., co-morbidities that hamper breathing or too young to safely wear N95s);
- Refusal or inability to comply with wearing instructions; or
- Have alternative satisfactory protections.

Criteria for prioritization

Various combinations of these characteristics warrant prioritizing groups of key workers and the general population for N95s. These criteria work together to reflect the panel's commitment to fairness, wise stewardship, preserving civil order and protecting public health:

- risk of influenza-related mortality and serious morbidity;
- risk of occupational and non-occupational exposure to influenza; and possibly
- age.

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, as well as by information about the viability of infrastructures. The size of the groups in track A will also be influenced by how broadly or narrowly the infrastructures (and in turn how key workers supporting those infrastructures) are defined. Key workers, for the purposes of this project, are estimated to make up 5% of Minnesota's population.

Tier 1

Track A prioritizes key workers who are at disproportionately high risk of exposure to flu in the workplace. Track B prioritizes protecting those in the general public who have been exposed to contained disease clusters, so that the cluster remains contained. If there is also a group that is a 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.

Tier 2

Track A prioritizes key workers with high 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 two-week supply of N95s in reserve at all times before any other groups are given access to N95s. *It is likely, then, that groups in tiers three and four will not receive N95s.* The panel offers the third and fourth tiers in the event N95 supplies are greater at times than expected.

Tier 3

Track A prioritizes all key workers with occupational exposure to flu who are also at high risk of flu-related mortality and serious morbidity. Track B prioritizes persons in the general population who are both exposed to flu and at high risk of flu-related mortality and serious morbidity. If the supply is insufficient to meet the needs of those in track B, then N95s should either be distributed randomly or prioritized according to age. See the discussion on pages 57 – 58 for more on age-based rationing.

Tier 4

Tier 4 attends to everyone in the general population who satisfies the eligibility criteria, including workers of all kinds. The supply is sufficient and rationing is unnecessary.

Table 11: Ethical Framework for Rationing Surgical Masks¹⁰⁹

I. Ethical commitments about how pandemic planning and response will be implemented: 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. Principles for Rationing Resources in a Severe Pandemic Steward scarce resources to promote our common good by balancing three equally important ethical principles: • Protect the population's health • Protect public safety and civil order • Treat people fairly, recognizing the moral equality of all
III. Goals <i>Protect the population's health</i> • Reduce mortality and serious morbidity <i>Protect public safety and civil order</i> • Reduce disruption to the basic health care, public health, public safety and other critical infrastructures • Promote public understanding about and confidence in the distribution of health care resources <i>Treat people fairly, recognizing the moral equality of all</i> • Reduce significant group differences in mortality and serious morbidity • Make reasonable efforts to remove barriers to fair access • Reciprocate to groups accepting high risk in the service of others • Reduce significant differences in opportunities to live a normal lifespan • Promote equitable access through fair random processes for individuals equally prioritized
IV. Strategies for rationing masks • Attend to general recommendations for rationing N95s and masks (pages 34 – 35). • Persons 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. • Prioritize groups within the general population to have access to surgical masks based on high or moderate risk of transmitting to persons at high risk of flu-related mortality. • As a last resort consider rationing surgical masks to healthy key workers who lack better protection. • Exclude persons: ◦ with immunity* (have contracted and recovered from influenza or are successfully vaccinated); or ◦ with medical contraindications (e.g., co-morbidities that hamper breathing or too young to safely wear masks). • De-prioritize persons: ◦ who refuse or are unable to comply with wearing instructions; or ◦ with alternative satisfactory protections. * In the absence of satisfactory methods of confirming immunity, de-prioritize (rather than exclude) persons with assumed immunity.

¹⁰⁹ These recommendations for rationing surgical masks in a severe influenza pandemic do not limit the use of masks for other purposes and circumstances.

Table 11: 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 - lack any other protection (e.g., N95s, PEP antivirals or vaccines) - are at <i>high occupational exposure</i>¹¹⁰ and - are at <i>high risk</i> of flu-related mortality/morbidity.	Infectious people posing risk of transmission to those at <i>high risk</i> of flu-related mortality/morbidity. Healthy key workers who lack alternative protection e.g., N95s, PEP antivirals or vaccines.
	Should the supply of surgical masks unexpectedly become more adequate, expand the mask priorities as follows, but retain a 2-week supply for tier 1 before distributing to lower priorities.		
Adequate supply	Tier 2	Healthy key workers who - lack any other protection (e.g., N95s, PEP antivirals or vaccines) - are at <i>high occupational exposure</i> and - are at <i>moderate risk</i> of flu-related mortality/morbidity.	Infectious people who cannot reasonably avoid contact with many other people.
	Tier 3	Healthy key workers who - lack any other protection (e.g., N95s, PEP antivirals or vaccines) - have occupational exposure.	Infectious people who have household members at <i>high risk</i> of flu-related mortality/morbidity.
	Tier 4	All eligible persons.	

Discussion: rationing masks

The ethical commitments, principles and goals for rationing masks are the same as for rationing N95s. The panel offers different strategies for masks, because they work differently from N95s. Masks do not provide a seal around the face or the same level of filtration as N95s. Thus, masks do not protect the wearer like N95s do. Rather, surgical masks protect those around the wearer from the wearer's coughs and sneezes. Masks are often described as a "catcher's mitt" to catch droplets. The panel and work group agreed that masks should be worn to protect the wearer only as a last resort.

Exclusion and de-prioritization criteria

Fairness and wise stewardship would exclude or at least de-prioritize groups based on these factors:

- Confirmation of immunity
- Medical contraindications (e.g., co-morbidities that hamper breathing or too young to safely wear masks)

¹¹⁰ "High occupational exposure" refers, for example, to workers whose jobs require routine direct physical contact with influenza patients.

- Refusal or inability to comply with wearing instructions
- Have alternative satisfactory protection.

Criteria for prioritization

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

- Risk of transmission to key workers
- Risk of transmission to those at high risk of morbidity/mortality
- Risk of transmission to many other people
- Unavailability of better preventive resources to protect healthy key workers.

Tier 1

Two groups are prioritized for masks at this level. Track A prioritizes healthy key workers who lack alternative protection e.g., N95s, prophylactic antivirals or vaccines and who are also at high workplace exposure to flu and high personal risk of flu-related mortality/morbidity. This prioritization reflects the panel's acknowledgment that masks should be available to protect these workers as a last resort. At the same time, track B prioritizes masks to infectious people who pose a risk of transmission to those at high risk of flu-related mortality/morbidity or to key workers who lack alternative protection e.g., N95s, prophylactic antivirals or vaccines. Both tracks protect key workers consistently with all of the goals. Track B reflects the importance of indirectly protecting key workers and those at heightened risk from flu from exposure to infectious persons.

Given the importance of protecting these first-priority groups, the panel calls for holding a two-week supply of masks in reserve at all times before any other groups are allowed 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 priorities in the event mask supplies are greater at times than expected.

Tier 2

Track A prioritizes healthy key workers who lack alternative protection, have *high 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.

Tier 3

Track A prioritizes healthy key workers who lack alternative protection and have workplace exposure to flu. Track B prioritizes infectious people with household members at *high risk* of flu-related mortality/morbidity.

Tier 4

At this tier masks are available to the general population.

Proposed Ethical Framework for Rationing Vaccines

Vaccine assumptions¹¹¹

1. This framework addresses two types of influenza vaccine:¹¹² inactivated virus vaccines and live attenuated vaccines that are 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 allow.
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.¹¹³
3. Two million 15-mcg doses of vaccine will become available weekly in the US.¹¹⁴ Minnesota's population is 1.75% 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 6 months into WHO pandemic phase six, because of the scarcity of vaccines and the highly contagious nature of severe influenza.

¹¹¹ Unless otherwise stated, the sources for the information in this table are the members of the vaccine work group, who agreed on reasonable assumptions for purposes of this project based on their expertise and experience.

¹¹² Though FDA has approved an H5N1 influenza vaccine and a small supply is available in the federal stockpile, rationing this supply is beyond the scope of this framework.

¹¹³ Scientists are working to develop influenza vaccines that, by offering broader cross-reactive immunity and protection, need not be matched to a particular strain in order to be effective (see Lu X, Edwards LE, Desheva JA, Nguyen DC, Rekstin A, Stephenson I, Szretter K, Cox NJ, Rudenko LG, Klimov A and Katz JM (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.

¹¹⁴ 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 when a new Sanofi Pasteur plant comes online in 2008 (see Sanofi Pasteur. (2007). "Sanofi Pasteur announces completion of construction of new U.S. influenza manufacturing facility [press release]." Retrieved April 4, 2008 from http://198.73.159.217/sanofi-pasteur/ImageServlet?imageCode=19330&siteCode=AVPI_US); McKenna M. (2007). "The pandemic vaccine puzzle: a 7-part series." Retrieved April 4, 2008, from <http://www.cidrap.umn.edu/cidrap/content/influenza/panflu/news/nov0207panvax1.html>; There is evidence that doses several times higher than the standard 15-mcg dose will be necessary to induce immunity to H5N1. The FDA approved H5N1 vaccine will be administered to adults in two 90-mcg doses (see Center for Biologics Evaluation and Research. (2007). "H5N1 Influenza Virus Vaccine: Questions and Answers." Retrieved April 4, 2008, from <http://www.fda.gov/cber/products/h5n1san041707qa.htm>).

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 elderly¹¹⁵ will have poorer vaccine response than the rest of the population.
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 immunocompromised persons will have unacceptable vaccine responses.
9. Indirect immunization (i.e., immunizing persons who come into contact with a target subpopulation that is at high risk of flu-related complications, but for which vaccines are not effective) may sometimes provide better protection for some groups than direct immunization, depending on the subpopulation'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 allergic to eggs if the vaccines are egg-based. (We note, though, that this assumption may be optimistic. Adverse events may increase with higher doses of vaccine.¹¹⁶ 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 nonpandemic 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 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.

General recommendations for rationing vaccines

1. Attend to the section above on General Recommendations (pages 18 – 19) and apply them as appropriate to the planning for rationing vaccines. Refrain from rationing vaccines based on social value, quality of life, duration of benefit or first-come, first-served.
2. Clarify work expectations for workers who receive vaccine during the two-week period immediately following vaccination (while the recipient is developing immunity) and thereafter (when immunity is presumed).

¹¹⁵ Nichol KL, Nordin JD, Nelson DB, Mullooly JP and 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 and Jackson LA (2007). Mortality benefits of influenza vaccination in elderly people: an ongoing controversy. *Lancet Infect Dis* 7(10): 658-666.

¹¹⁶ McKenna M, 2007.

Table 12: Ethical Framework for Rationing Vaccines

I. Ethical commitments about how pandemic planning and response will be implemented 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. Principles for rationing resources in a severe pandemic Steward scarce resources to promote Minnesotans' common good by balancing three equally important ethical principles: • Protect the population's health • Protect public safety and civil order • Treat people fairly, recognizing the moral equality of all
III. Goals <i>Protect the population's health</i> • Reduce mortality and serious morbidity <i>Protect public safety and civil order</i> • Reduce disruption to the basic health care, public health, public safety and other critical infrastructures • Promote public understanding about and confidence in the distribution of health care resources <i>Treat people fairly, recognizing the moral equality of all</i> • Reduce significant group differences in mortality and serious morbidity • Make reasonable efforts to remove barriers to fair access • Reciprocate to groups accepting high risk in the service of others • Reduce significant differences in opportunities to live a normal lifespan • Promote equitable access through fair random processes for individuals equally prioritized
IV. Strategies • Exclude persons: ○ with medical contraindications (e.g., egg allergy if vaccine is egg-based); ○ known to be imminently and irreversibly dying (e.g., have a known co-morbidity incompatible with life beyond a couple weeks or months); or ○ with immunity* (e.g., have contracted and recovered from influenza) • De-prioritize persons with: ○ unacceptable vaccine response (e.g., severely immune-compromised); or ○ satisfactory alternative protections. • Various combinations of characteristics warrant prioritizing some groups to receive scarce vaccines before others: ○ 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; and possibly ○ age. *In the absence of satisfactory methods of confirming immunity, de-prioritize (rather than exclude) persons with assumed immunity.

Table 12: Ethical Framework for Rationing Vaccines (cont.)

Sequence	Track A – Key workers	Track B – General population
First	Key workers at <i>disproportionately high</i> occupational exposure to flu.	None.
Second	Groups of key workers (including irreplaceable workers): - at <i>high</i> occupational exposure;¹¹⁷ or - at <i>high</i> risk of flu-related mortality and serious morbidity; and - with <i>good</i> vaccine response.	Groups, if any: - at <i>disproportionately high</i> risk of flu-related mortality and serious morbidity and - with <i>good</i> vaccine response.
Third	Irreplaceable key workers with <i>good</i> vaccine response. Groups of key workers: - at <i>high</i> risk of transmitting flu to people best protected indirectly (i.e., people at high risk of flu-related mortality and serious morbidity and poor or unacceptable vaccine response), and - with <i>good</i> vaccine response.	Groups: - at <i>high</i> risk of flu-related mortality and serious morbidity and - with <i>good</i> vaccine response.
Fourth	None.	Groups: - at <i>high</i> risk of flu-related mortality and serious morbidity and - with <i>acceptable</i> vaccine response. Possibly groups of children: - at <i>moderate</i> risk of flu-related mortality and serious morbidity and - with <i>acceptable</i> vaccine response.
Fifth	None.	Groups of adults: - at <i>moderate</i> risk of flu-related mortality and serious morbidity and - with <i>acceptable</i> vaccine response.
Sixth	All remaining eligible persons.	

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 2006.¹¹⁸ The panel's recommendations in this report reflect its decision largely to accept but in important ways update, adapt and modify 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 a smaller number of criteria that should exclude groups from being vaccinated.

Criteria for exclusion and de-prioritization

Fairness and wise stewardship would exclude or at least de-prioritize groups based on these criteria:

¹¹⁷ High occupational exposure" refers, for example, to workers whose jobs require routine direct physical contact with influenza patients.

¹¹⁸ Vawter et al, 2007.

- confirmation of natural immunity, (e.g., have contracted and survived influenza or been successfully immunized with pre-pandemic vaccine);
- medical contraindications (e.g., 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 a co-morbidity incompatible with life beyond a few weeks or months); or
- have satisfactory alternative protections.

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;
- risk of transmitting influenza to groups that are at high risk of influenza-related mortality and serious morbidity; and possibly
- age.

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 itself, as well as by information about the viability of infrastructures. The size of the groups in track A will also be influenced by how broadly or narrowly Minnesota specifies the infrastructures with guidance from the federal government. Key workers, for the purpose of this project, are estimated to make up 5% of Minnesotans.

The panel recommends sequencing the allocation of vaccines. Vaccines will become available in relatively small amounts, rolling in fairly steadily once manufacture begins. They could become available between waves 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. Thus, the strategies described below operate somewhat differently from the strategies for other resources. These strategies describe the order in which people will be vaccinated.

Early in vaccine distribution it is especially important to reach as many members of the prioritized groups as possible. It is impractical to assume that 100% of all eligible members of a group could be reached, though, especially under pandemic conditions. Indeed, to try to do so could slow down vaccine distribution unnecessarily. Accordingly, the sequence is offered to guide distribution efforts, but with the caution that forward momentum in distributing vaccine must be maintained.

First

The first step in the sequence pertains only to key workers (track A). There is no one in track B at this tier. This tier prioritizes key workers at disproportionately high occupational exposure to flu (i.e. health care workers assigned to intensive care units serving flu patients or those who perform aspirating or intubation procedures on flu patients).

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 occupational risk of exposure (e.g., health care workers with direct patient contact) 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 death or severe complications and that will also respond well to vaccines, then track B allows for their vaccination simultaneously.

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 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.

Fourth

Starting with the fourth step, all vaccines are directed to track B. The fourth step prioritizes two groups simultaneously:

- groups of all ages that are at high risk but have only an acceptable (as opposed to good) vaccine response, and
- possibly groups of children that are at moderate risk but have an acceptable vaccine response.

See the discussion on pages 57 – 58 for more on age-based rationing.

Fifth

The fifth step prioritizes adults at moderate risk with an acceptable vaccine response. If the public rejects the notion of age-based rationing, the effect would be to move all those with moderate risk and acceptable vaccine response into tier 5, allowing for randomization within this large group to determine who is prioritized first among them.

Sixth

The sixth step is the final step in the sequence, allowing for vaccination of all remaining eligible members of the general population, including all workers.

How these recommendations fit with federal guidance

When the Minnesota Department of Health 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 vaccines.¹¹⁹ The 2005 HHS Pandemic Influenza Plan includes guidance (developed by the National Vaccine Advisory Committee and the Advisory Committee on Immunization Practices) for allocating vaccine only in a *moderate* influenza pandemic, not a severe pandemic.

In December 2007 (near the end of the resource allocation panel's meetings), the federal government issued draft guidance for rationing pandemic vaccines, providing a range of priorities depending on a pandemic's severity.¹²⁰ As of this writing, these federal recommendations are not yet final. The Minnesota Department of Health, as the funder of this work, directed that the Minnesota Pandemic Ethics Project move forward. The department asked that the project be informed by federal guidance but not be limited by it, because federal guidance is still evolving.

In several important ways, the draft federal guidelines are consistent with the panel's recommendations.¹²¹ Both these recommendations and the federal guidelines recognize that:

¹¹⁹ DHHS. *HHS Pandemic Influenza Plan*, November 2005.

¹²⁰ US Vaccine Prioritization Interagency Working Group, *Allocating Vaccine*, 2007.

¹²¹ Garrett JE, Gervais KG, Vawter DE, DeBruin DA, Prehn AW, Liaschenko J. Letter to U.S. Department of Health and Human Services Re: Comments to Draft Guidance on Allocating and Targeting Pandemic Influenza Vaccine. Dec. 31, 2007.

- Pandemic influenza may be very different from seasonal influenza, posing threats of serious complications and mortality to more groups in the general population than does seasonal influenza.
- 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 goals and use multiple tracks and sequential steps to respond to infrastructure and disease threats simultaneously.

The draft federal guidelines differ from the panel's recommendations in that for the most part they:

- do not take into account relative efficacy of influenza vaccines among different groups of people;
- do not explicitly and consistently take into account relative risk of mortality and serious complications;
- do not explicitly take into account the availability of other protective resources;
- allocate large portions of the resources to protect homeland security and national defense goals.

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Proposed Ethical Framework for Rationing Ventilators

Ventilator assumptions¹²²

1. There are different types of ventilators and not all will be appropriate for medically unstable flu patients in respiratory failure.¹²³ 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.¹²⁴ Between peaks of pandemic waves, ventilator shortages may be much less severe.
3. Approximately 12,900 flu patients in MN are anticipated to suffer respiratory failure sometime during the pandemic and under current standards of care would be candidates for a vent.¹²⁵
4. The need for vents could be reduced by approximately 2 days in some influenza patients by treating them with antivirals within 48 hours of symptoms.
5. Previously healthy persons are most likely to benefit from vents.
6. Approximately 1200 vents are currently available in acute care institutions in MN,¹²⁶ 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. 85% of vents are currently in use.
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.¹²⁷ We can expect to train persons to manage less complex patients (i.e., medically stable patients) on vents to free up highly trained clinicians to attend to more complex ventilator-related activities.

General recommendations for rationing ventilators

1. Attend to the section above on General Recommendations (pages 18 – 19) 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:
 - Postponing elective procedures that may require mechanical ventilation.¹²⁸
 - Rationing types of ventilators and other respiratory supports efficiently so that in times of shortage, patients have access to the simplest type of support consistent with reasonable efficacy.

¹²² Unless otherwise stated, the sources for the information in this table are the members of the ventilator work group, who agreed on reasonable assumptions for purposes of this project based on their expertise and experience.

¹²³ Hick J, Robinson L, O'Laughlin D and Farmer J (2007). Clinical review: allocating ventilators during large-scale disasters: problem, planning, and process. *Critical Care* 11: 217.

¹²⁴ Hick J and O'Laughlin D (2006). Concept of operations for triage of mechanical ventilation in an epidemic. *Acad Emerg Med* 13: 223-229.

¹²⁵ Minnesota Department of Health. *Pandemic Influenza Plan: All-Hazards Response and Recovery Supplement*. March 2006. Available at: <http://www.health.state.mn.us/divs/idepc/diseases/flu/pandemic/plan/mdhpanfluplan.pdf>.

¹²⁶ Ibid.

¹²⁷ Christian M and 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.

¹²⁸ Ibid.

- Taking reasonable steps to minimize downtime for cleaning vents; for example, stockpiling supplies of ventilator circuits to reduce the time needed to prepare a ventilator for a waiting patient.
 - 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.¹²⁹
3. Ration ventilators to the general population without consideration for key worker status.
 4. Refrain from rationing ventilators based on social value, quality of life, duration of benefit or first-come, first-served.
 5. Clarify whether and how end-of-life policies will be modified, e.g., advance directive, 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.¹³⁰

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¹²⁹ Minnesota Department of Health. *Oxygen Use Strategies for Scarce Resource Situations*. 2008. Available at: <http://www.health.state.mn.us/oepr/healthcare/scarceoxygen.html>.

¹³⁰ DeBruin DA, Parilla E, Liaschenko J, Marshall MF, Leider JP, Brunquell D, Garrett JE, Vawter DE. *Implementing Ethical Frameworks for Rationing Scarce Health Resources in Minnesota during a Severe Influenza Pandemic*, University of Minnesota Center for Bioethics and Minnesota Center for Health Care Ethics, 2009.

Table 13: Ethical Framework for Rationing Ventilators

I. Ethical commitments about how pandemic planning and response will be implemented 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. Principles for rationing resources in a severe pandemic Steward scarce resources to promote Minnesotans' common good by balancing three equally important ethical principles: • Protect the population's health • Protect public safety and civil order • Treat people fairly, recognizing the moral equality of all
III. Goals <i>Protect the population's health</i> • Reduce mortality and serious morbidity <i>Protect public safety and civil order</i> • Promote public understanding about and confidence in the distribution of health care resources <i>Treat people fairly, recognizing the moral equality of all</i> • Reduce significant group differences in mortality and serious morbidity • Make reasonable efforts to remove barriers to fair access • Reduce significant differences in opportunities to live a normal lifespan • Promote equitable access through fair random processes for individuals equally prioritized
IV. Strategies for rationing non-infant,¹³¹ acute-care¹³² ventilators • Attend to general recommendations for ventilator rationing (pages 49-50). • 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 (e.g., 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 the Minnesota Department of Health.¹³³ 2. Prioritize patients not likely to require more than short-term reasonable levels of critical care resources. 3. Clinical considerations being equal, possibly prioritize children before adults. 4. Among adults, clinical considerations being equal, possibly prioritize the younger when the difference in age is > X (e.g., 10) years. 5. If all relevant criteria are equal, use a random process for rationing vents. Access should not be based on first-come, first-served as this will exacerbate existing inequalities in access to critical care. (However, as described below, so long as a patient who has received a vent is significantly improving, this patient has priority over other eligible patients presenting later.)

¹³¹ 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.

¹³² These recommendations do not consider rationing or reallocating ventilators currently in use by patients with chronic needs for ventilation.

¹³³ See for example, Minnesota Department of Health. Patient Care Strategies for Scarce Resource Situations: Mechanical Ventilation: Re-Allocation Strategy. Draft 2007. Available at: <http://www.health.state.mn.us/ocp/healthcare/scarcestrategies.html#reallocation>.

Table 13: 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). 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 the Minnesota Department of Health.¹³⁴
 - Allow access to vents only through access to time-limited (e.g., 48-hour) therapeutic trials.¹³⁵ 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 the Minnesota Department of Health's recommended clinical tool at the end of standardized trial periods (e.g., 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 (e.g., 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.

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 so few ventilators 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. Nonetheless, 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. The public should weigh in on those choices. Though a state's overall mortality rates might not be greatly affected by how 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 oxygen-conservation techniques, and using other devices instead of ventilators where possible.¹³⁶ If ventilators are still scarce, as expected during the peaks of a pandemic wave, then rationing guidelines are needed.

¹³⁴ See for example, Minnesota Department of Health. Patient Care Strategies for Scarce Resource Situations: Mechanical Ventilation: Re-Allocation Strategy. Draft 2007. Available at: <http://www.health.state.mn.us/oep/healthcare/scarcestrategies.html#reallocation>.

¹³⁵ A "trial" as used in this framework means a time-limited, therapeutic trial, not a research study.

¹³⁶ 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>. Chapter 5; MDH, *Patient Care Strategies*, 2007.

This recommended ethical framework combines clinical¹³⁷ and non-clinical fairness criteria. The clinical criteria should be applied first, and non-clinical criteria (such as age) used only when clinical considerations are insufficient given the extremely high demand for ventilators. For example, the panel considered recommending that a child be prioritized for a ventilator before an adult in situations where their clinical need and efficacy are equal. The clinical considerations help identify those most likely to benefit from access to a ventilator and reflect the panel's desire to steward scarce resources wisely. The non-clinical considerations spring from commitments to fairness.

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 on pages 56 – 57 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 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 score¹³⁸ 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 isn't 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.

¹³⁷ The clinical guidance in this provisional ethical framework reflect recommendations from the Minnesota Department of Health Science Advisory Team available at <http://www.health.state.mn.us/oep/healthcare/scarcevent.html>.

¹³⁸ SOFA is the Sequential Organ Failure Assessment tool, which is currently part of the standardized, evidence-based, clinical tool recommended by the Minnesota Department of Health 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.

Discussion

The panel asks Minnesotans to consider how best to ration scarce health-related resources during a severe pandemic. How compelling are the recommended ethical commitments, principles, goals and strategies for rationing different types of resources under varying conditions of supply and scarcity?

The panel's rationing recommendations are likely to be controversial, at least at first blush. Underlying the recommendations is the conviction that the way health resources are distributed in a global public health disaster needs to differ radically from the status quo. 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 all decisions to individuals in a consumer-based, free market-style system. Ad hoc subjective judgments about who should and should not receive scarce resources will not only be made inconsistently but are likely to reflect personal bias and prejudice, posing serious affronts to fairness. The recommendations therefore include uncustomary concepts of the common good, public and population health, and fairness to guide the development of rationing strategies protective of the interests of all Minnesotans.

Do Minnesotans agree that when rationing in a severe pandemic:

- A population health perspective constrained by several fairness goals should guide rationing decisions.
- The goal of reducing the number of deaths due to flu needs to be supplemented and balanced with goals directed at protecting public safety and civil order, and assuring fairness and fair access for all Minnesotans.
- Fairness goals and strategies need to befit the scale and scope of this type of public health disaster, and should therefore:
 - Honor Minnesotans' moral equality and prohibit rationing based on ability to pay, quality of life, social or economic status, political power, social worth, gender or duration of extended life.
 - In addition to clinical factors, consider several non-clinical factors (i.e., key worker status, reciprocity and age under some circumstances).
 - Make reasonable efforts to remove barriers to fair access.
 - Use fair, random processes to replace the customary use of first-come, first-served.

Fairness goals

Fair random processes

When many more people need a resource than there is supply, is it always fairest to resort to a thoroughly random process, like flipping a coin, rolling a die or reaching in a jar for a colored ping pong ball?

The panel rejected relying solely on random selection procedures for the population as a whole, without consideration of any other prioritization criteria. There will often come a time when fairness requires resorting to random procedures, but the panel recommends applying random procedures only after weighing a set of rationing criteria (including clinical and non-clinical considerations) relative to available resources. In a pandemic, employing random procedures too soon would itself be a source of unfairness and would undermine population health and safety goals. 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 highest 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 between different groups. A purely random approach to distributing scarce resources among Minnesotans, including to those who may not need and may not benefit

from them, will undermine both population and individual goals and fail to protect all from the worst consequences of a pandemic.

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. If a socially vulnerable group is at heightened risk of mortality and serious morbidity, then the members of that group should be prioritized for access accordingly. In addition, the panel strongly recommended steps to remove social, economic, language and geographic barriers. The time to most adequately increase fair access and reduce health disparities is before a pandemic strikes. 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.

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

Rationing strategies

Clinical considerations

Clearly, the clinical and public health considerations of risk of serious complications and death and the likelihood of benefit from a particular health resource are ethically relevant in a severe pandemic. Minimizing lives lost to influenza is an important goal, 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 needs it. 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 proposed 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 which the resource has high effectiveness.

Non-clinical considerations: reciprocity, key worker status and age

Clinical need and chance of efficacy are often the only relevant bases for allocating scarce resources, but when pursuing Minnesotans' common good in a severe pandemic, clinical factors are not the only ethically acceptable considerations. Influenza is not the only mortality threat in a severe pandemic. Potential breakdown of critical infrastructures also threaten life and health. Clinical considerations alone are insufficient guides to rationing because they only address individual mortality threats from the flu.

Some fairness goals and other non-clinical considerations are relevant to the protection of population health or are necessary for honoring the moral equality of all and the risks some undertake for others in a severe pandemic. For example, some groups have greater risk of exposure to flu and have assumed that risk on behalf of others (e.g., some groups of key workers); and some are more likely to lose a chance for a normal life span due to premature death (e.g., children).

Reciprocity

Reciprocity refers to the fairness-based obligations of gratitude owed to groups that accept unusual 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. All agreed that health care 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.

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. Others maintained that reciprocity obligations are not unlimited, but constitute one fairness criterion among others.

Generally, the panel concluded that reciprocity is an important obligation, but one that should be balanced with other fairness obligations. In this way, reciprocity is a justification for prioritizing some groups of key workers to receive N95s, masks, antivirals and vaccines in addition to the justification that they are needed to reduce flu-related mortality and serious morbidity and disruption of critical infrastructures. Key workers are not, however, prioritized to receive ventilators (see below). It remains a question whether and when reciprocity obligations might be extended to groups in the general population, e.g., persons who agree to stay home while a household member is infectious.

Key worker status

Given the project's assumptions about a severe pandemic with a W-shaped age-based mortality curve (see appendix B), 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. This prioritization does not violate the commitment to the moral equality of all, because these selected groups of workers are not considered morally superior in any way. It is the workers' function in society that is prioritized and not the workers themselves.

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 unfairly 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 a population health consideration, rarely applied in non-disaster circumstances, and not uniformly justified even in a severe pandemic. Therefore, 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 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.¹³⁹ 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

¹³⁹ New York State Workgroup on Ventilator Allocation in an Influenza Pandemic. *Allocation of Ventilators in an Influenza Pandemic: Planning Document*. 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. Who should receive life support during a public health emergency? Using ethical principles to improve allocation decisions. *Ann Intern Med*. 2009;150:132-138.

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 those who do not work outside the home, who are students, young children, retired, or have jobs not considered key to preserving Minnesota's critical infrastructures. Some health care workers involved in the project 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 other resources are unavailable or ineffective, the question of prioritizing key workers for ventilators on the basis of reciprocity should be re-evaluated.

Age

Age-based rationing is one way to achieve the fairness goal of reducing significant differences in opportunities to live a normal life-span. The ethical appropriateness of rationing on the basis of non-clinical age considerations (quite apart from any age-associated clinical considerations like risk of mortality or likelihood of benefit) remains unsettled, both in the literature on pandemic ethics and in the panel's preliminary recommendations. Non-clinical, age-based rationing proved to be the most difficult question for the project participants—a question the panel and each of the work groups discussed frequently during the project's course. Some participants judged age-based rationing to be unfair, some considered it fair under specific circumstances or accepted it provisionally assuming that it is preceded by wide public consultation and agreement, and others continue to consider its acceptability.

When the number of persons similarly prioritized (e.g., with similar risk and likelihood of benefiting from a particular type of resource) exceeds the supply of the resource, on what basis should the resource be rationed? One option is to prioritize younger groups before older or to at least prioritize children before adults with the goal of reducing significant differences in opportunities to live a normal lifespan. The panel, with some reservation, agreed to propose age-based rationing for some resources, as a way of prioritizing groups after clinical criteria had been considered but before resorting to random selection. Age-based rationing is a controversial and unprecedented proposal, and project participants agreed to reconsider the question after public input.

Though the panel could not reach agreement on all matters regarding age-based rationing, it did agree that:

- There are numerous reasons in support of and against age-based rationing in a severe pandemic.
- Age-based rationing should be undertaken only if a broad range of Minnesotans have considered the issues and support doing so.
- Under some circumstances it is ethically acceptable to prioritize children before adults.
- Further consideration should be given to the separate question as to whether and when it might be ethically acceptable to prioritize younger before older adults.
- The unsettled questions include:
 - On what basis are non-clinical age-based considerations ethically justified?
 - Which differences in age are morally relevant?
 - When, if ever, should age-based rationing be applied to groups and when to specific people vying for the same particular resource?

Each resource-specific work group recommended to the panel that age could, with sufficient public support, be considered under some circumstances during periods when the supply is very scarce within a particular tier. The participants were reluctant to specify ages, but concluded that if age is to be considered, Minnesotans must be willing to engage in the quasi arbitrary act of

choosing age cut-offs. The treatment antiviral, PEP antiviral, N95¹⁴⁰ and vaccine frameworks signal when and how an age cut-off could be entertained.

Though the frameworks make room at times for age-based rationing, they do not (individually or considered as a package) systematically de-prioritize older persons. For instance, if an older age group was at disproportionately high risk of flu-related mortality/morbidity and treatment antivirals were effective, then this group would be prioritized in tier 1 without regard to age. With respect to PEP antivirals, the strategies recommend that if PEP is safe and effective for immune-compromised groups, then a small supply of PEP antivirals be reserved for groups at high risk of death that lack alternative protections, e.g., elderly persons during a flu outbreak in a long-term care facility.

The vaccine framework makes two recommendations with respect to age-based rationing. The panel recommends against using age-based considerations among groups at high risk of influenza-related mortality and serious morbidity that have good vaccine response. When the only groups that remain to be vaccinated are at moderate risk or less, then the panel recommends that children at moderate risk be vaccinated before adults at the same risk.

A different type of age-based rationing is proposed in the ventilator framework. Mechanical ventilators are unusual in that they 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 persons 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.

The panel recommends that if clinical considerations are equal and some patients are children and others adults, then prioritize 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 trial and which does not. In other words, do not use age as a criterion when deciding among children. When the pool of equally situated adult patients exceeds the supply, the panel recommends that Minnesotans consider prioritizing younger adults over older adults when the difference in age is greater than some minimum number of years. The panel remained uncertain about what interval of years to recommend, but many participants felt a difference in age of 7 years was too short to be ethically relevant and some thought that a 10 or 20 year age difference might be appropriate. Picking an age cut-off, such as over or under age 55 is not a fair method for rationing among *individuals* as it may result in selecting persons on the basis of ethically irrelevant differences in length of life. Rationing ventilators on the basis of substantially younger persons before older persons with similar need and likelihood of benefit is consistent with the goal of reducing significant opportunities to live a normal lifespan.

The surgical mask framework does not include age-based rationing. Masks are unusual and are not generally used to protect the wearers. Masks primarily offer indirect benefit to those exposed to persons wearing the masks, and offer less direct protection to persons who wear them. Among persons who can safely and effectively wear masks, age is ethically irrelevant to decisions about how to ration them. The panel concludes that non-clinical age-based distinctions are neither necessary nor appropriate in decisions about how to ration masks.

Non-clinical considerations: rejected by panel

The panel and others who have developed pandemic guidance generally agree that some considerations are ethically unacceptable bases for rationing, namely ability to pay, social or

¹⁴⁰ In the scenarios considered in this project, the anticipated supplies of PEP antivirals and N95s are so limited that it is unlikely that age-based rationing would ever be implemented.

economic status, political power, social worth and gender. The panel also specifically recommended against considering quality of life or duration of extended life. These considerations do not promote the ethical principles of protecting the population's health, protecting public safety and social order, or respecting the moral equality of all Minnesotans. Instead, they would harm the common good in a severe pandemic.

Quality of life

The panel discussed the appropriateness of de-prioritizing persons who would be unaware of any benefit they might receive from a scarce resource, such as persons suffering from advanced dementia.¹⁴¹ Ultimately, though, the panel rejected this criterion because of reluctance with opening the door to considering the very subjective notion of quality of life.

Duration of extended life

The panel concluded that it is unfair to prioritize access to resources based on differences in anticipated extension in duration of life (e.g., likelihood of extending life by 5 years vs. by 15 years) with the exception of the very narrow circumstance of de-prioritizing persons with an underlying condition that makes it relatively certain that they will die within a very short time (e.g., a couple of weeks or months). For example, the panel concluded that it would be unfair to give priority to those for whom the resource is likely to extend their life the most.¹⁴² Project participants noted that consulting actuarial tables to assess and compare how likely different groups are to survive X number of years if they receive a particular resource compounds rather than reduces inequities and health disparities.

How Some Groups are Prioritized: A Snapshot

Socially vulnerable populations

The panel attended to the needs of socially vulnerable populations in several ways. Foremost, it balanced its commitments to public health and fairness, requiring that both be honored simultaneously and equally. The panel comprised representatives of some socially vulnerable groups, and emphasized the need to consult with diverse communities before its recommendations are finalized. 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. The panel also prohibited rationing based on social value criteria such as socio-economic class, race, gender, citizenship, etc. Criteria such as quality of life, life expectancy, and using first-come, first-served as a proxy for randomization were expressly rejected, because they would disadvantage 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.

Particular age groups: seniors, children and young adults

The panel assumes 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

¹⁴¹ 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, *Ventilator Allocation*, 2007). A couple of guidance documents suggest that severe cognitive impairment may be an exclusion factor in some circumstances (Tacoma Pierce County, *Triage and Treatment Guidelines*, 2007; Hick et al, *Allocating ventilators*, 2007).

¹⁴² State of Tennessee Department of Health. *Pandemic Influenza Response Plan [Section 4 Supplement 4: Ethical Allocation of Scarce Resources]* July 2006. Available at: http://health.state.tn.us/Ceds/PDFs/2006_PanFlu_Plan.pdf.

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 are relatively less effective among seniors than other age groups, so the elderly are de-prioritized for vaccines. When a high-risk group is de-prioritized or excluded from a resource, then the frameworks call for protecting 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 when they become available to those who work in nursing homes or hospital neo-natal units).

The frameworks also consider rationing according to age, as a consideration of fairness. If this criterion is accepted, then among groups at similar risk children would be prioritized over adults, and younger adults could be prioritized over older adults. 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.

Key workers

The frameworks prioritize key workers for all resources except for ventilators. Various additional criteria are used in combination with key work status. These criteria include risk of death and serious complications; effectiveness of the resource; risk of occupational exposure; “irreplaceable” work status; 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.

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. For example, the panel assumes that vaccines will be less effective among the elderly than other age groups. Thus, the vaccine framework prioritizes various other groups before the elderly. But vaccines are just one form of protection. Others include prophylactic antivirals, pneumococcal vaccine (to prevent the most common fatal complication of influenza in the elderly), N95s, protection of those around the elderly and social isolation and other distancing measures. The rationing for these and other resources should be adjusted to make sure that the elderly are not systematically de-prioritized for all resources even though they may not be early candidates for vaccines. Infants are another age group that is very vulnerable to pandemic, but comparatively few resources are available to protect them. If, after considering all resources and strategies infants will be left with insufficient protections, then the plan could be adjusted to offer more indirect protections to infants (e.g., directing more preventive resources to those who work or live with infants, thus preventing infants from influenza exposure). Treating people fairly and recognizing the moral equality of all requires that Minnesota’s pandemic response plan not systematically de-prioritize any demographic group from protection and benefit.

Next Steps

Ethically informed plans to ration resources in Minnesota require the considered judgment of Minnesotans with diverse experience and expertise, including the public. While rationing protocols must be informed by science and the best evidence, the public may bring very different value priorities to rationing than epidemiologists, clinicians, other scientists and experts, and even the panel. In a pandemic, Minnesotans' input, understanding and compliance will be essential to the effective pursuit of social and public health goals.

Upon completion and approval of these draft proposed frameworks, the project team will solicit public response in order to elicit reflective engagement on the ethical values that should guide Minnesota-wide rationing of scarce health-related resources. We need to know what Minnesotans' think about the recommended frameworks, their agreements and disagreements, and their suggestions for improvements that will best represent the values of our statewide community. We anticipate that this public engagement process will begin promoting the community-building necessary for pandemic preparedness concerning scarce health-related resource rationing.

Conclusion

The prospect of a severe influenza pandemic is daunting, yet it is even worse to contemplate being unprepared. Though some challenges cannot be predicted, certainly many resources will be scarce. Failing to think through in advance the challenges of how best to ration would itself be an ethical failure.

With the Minnesota Pandemic Ethics Project, the state joins a small cadre of states and nations in developing ethical guidance for a severe pandemic. Unlike some, its process has been intentionally inclusive and transparent and promises to involve a growing cross-section of Minnesotans. The panel and work groups showed the richness and utility of genuine collaboration around health policy.

One of the most divisive aspects in Minnesotan and American health care reform discussions stems from an unwillingness to confront the reality that health care resources are neither infinite nor fairly distributed. The concept of rationing is anathema, with the term often referred to as the "r" word among health policy analysts. Admittedly, the prospect of severe pandemic that gave rise to project participants' willingness to confront rationing is very different from the invisible rationing mechanisms common in American health care. Nonetheless, the conduct of a successful, explicit health care rationing conversation in relation to pandemic is giving a growing range of stakeholders, including the public, experience in participating in these crucial discussions.

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

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Ventilator Work Group

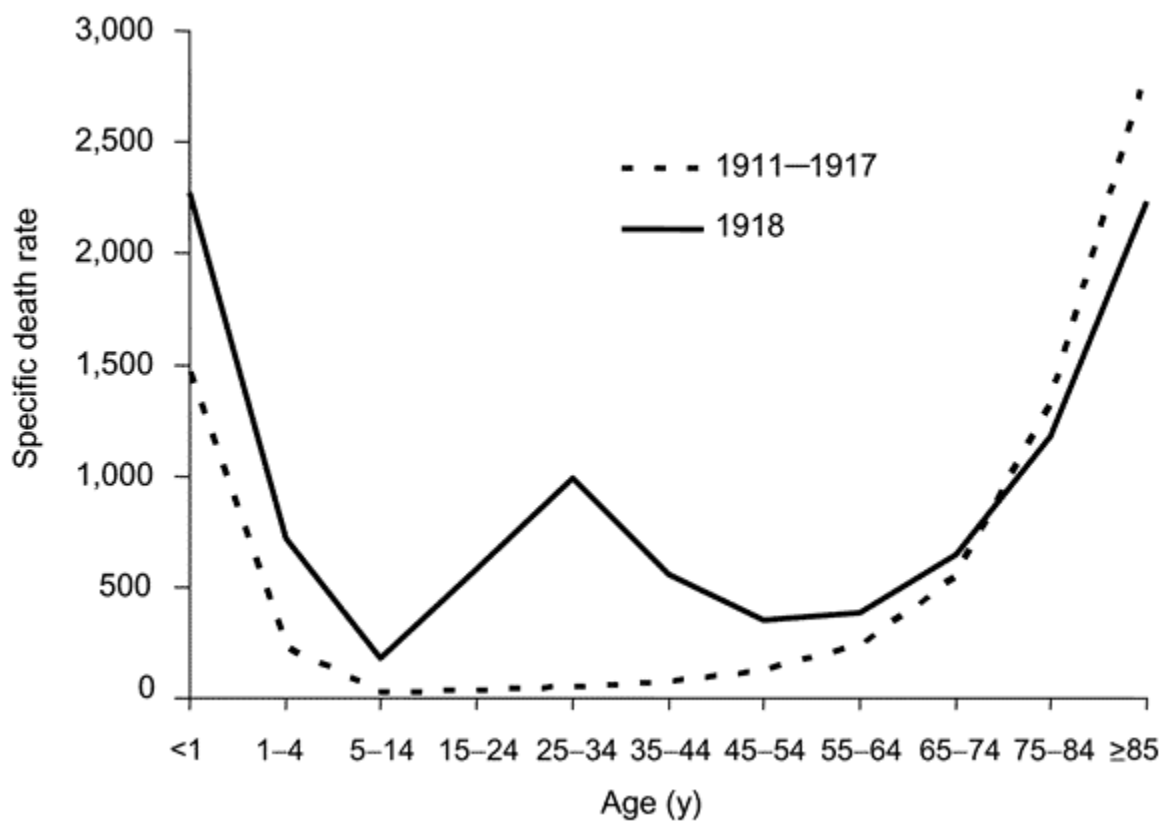
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Protocol Committee

Members of the protocol committee are listed in the companion report: DeBruin DA, Parilla E, Liaschenko J, Marshall MF, Leider JP, Brunquell D, Garrett JE and Vawter D. *Implementing Ethical Frameworks for Rationing Scarce Health Resources in Minnesota During a Severe Influenza Pandemic*, University of Minnesota Center for Bioethics and Minnesota Center for Health Care Ethics, 2008.

Appendix B: 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).¹⁴³

¹⁴³ Taubenberger JK, Morens DM. 1918 influenza: the mother of all pandemics. *Emerg Infect Dis* [serial online]. 2006;12(1):19 (figure 2). Available at: <http://www.cdc.gov/ncidod/eid/vol12no01/05-0979.htm>.

Appendix C: Selected References

For a list of references and analysis pertaining to pandemic influenza planning, rationing scarce resources and available ethical guidance, please see: 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.

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