PRELIMINARY REPORT
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IMPLEMENTING ETHICAL FRAMEWORKS FOR RATIONING SCARCE HEALTH RESOURCES IN MINNESOTA DURING SEVERE INFLUENZA PANDEMIC

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For the Minnesota Pandemic Ethics Project

A Collaboration of the
University of Minnesota Center for Bioethics and
Minnesota Center for Health Care Ethics

Funded by the Minnesota Department of Health

A companion report to
For the Good of Us All:
Ethically Rationing Health Resources in Minnesota in a Severe Influenza Pandemic.
Preliminary Report January 30, 2009

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IMPLEMENTING ETHICAL FRAMEWORKS FOR RATIONING SCARCE HEALTH RESOURCES IN MINNESOTA DURING SEVERE INFLUENZA PANDEMIC

A Companion Report to *For the Good of Us All: Ethically Rationing Health Resources in Minnesota in Severe Influenza Pandemic*[1]

EXECUTIVE SUMMARY

In 2007, the Minnesota Department of Health (MDH) contracted with ethicists from the University of Minnesota's Center for Bioethics and the Minnesota Center for Health Care Ethics to develop and lead the Minnesota Pandemic Ethics Project. This project's primary goal is to develop guidance regarding how scarce health resources should be rationed in Minnesota during severe influenza pandemic. A presentation of the project's preliminary recommendations for ethical frameworks for rationing can be found in the report entitled *For the Good of Us All: Ethically Rationing Health Resources in Minnesota in a Severe Influenza Pandemic*.[2] The project committed not only to the development of ethical frameworks for rationing, but also to the identification and analysis of issues relating to the implementation of those ethical frameworks. This report, *Implementing Ethical Frameworks for Rationing Scarce Health Resources in*

1 Vawter DE, Garrett JE, Gervais KG Prehn AW, DeBruin DA, Tauer CA, Parilla E, Liaschenko J, Marshall MF. For the Good of Us All: Ethically Rationing Health Resources in Minnesota in a Severe Influenza Pandemic. Minneapolis, MN: Minnesota Center for Health Care Ethics and University of Minnesota Center for Bioethics. Preliminary Report January 30, 2009.

2 Vawter DE, Garrett JE, Gervais KG, Prehn AW, DeBruin DA, Tauer CA, Parilla E, Liaschenko J, Marshall MF. For the Good of Us All: Ethically Rationing Health Resources in Minnesota in a Severe Influenza Pandemic. Minneapolis, MN: Minnesota Center for Health Care Ethics and University of Minnesota Center for Bioethics. Preliminary Report January 30, 2009.

Minnesota During Severe Influenza Pandemic, presents preliminary analysis of those implementation issues.

The Minnesota Pandemic Ethics Project has worked, throughout, to provide practical guidance about how to implement the ethical commitments and principles endorsed in the ethical frameworks. Thus, the ethical frameworks have been drafted to recommend not just ethical commitments and principles, but also goals for action based on those commitments and principles, and strategies to be implemented to achieve those goals. Because the ethical frameworks overlap to such a great degree at the level of fundamental ethical commitments, principles, and even goals, this report focuses on broad issues that arise in planning for the implementation of the ethical frameworks, for example, issues about how to implement the ethical frameworks' fundamental requirement that access to resources be equitable, or the frameworks' recommended criteria for prioritizing persons' access to resources.

This report has been produced through the combined efforts of many people. Members of the Minnesota Pandemic Ethics Project team from the University of Minnesota's Center for Bioethics (hereafter referred to as the Implementation Team) led the process to analyze implementation of the ethical frameworks developed in the project, working in collaboration with project team colleagues from the Minnesota Center for Health Care Ethics. A Protocol Committee was assembled and charged with the task of analyzing issues related to the implementation of the ethical frameworks being developed in the project. This report is largely based on the work of the Protocol Committee. This report

also contains some discussions of implementation issues produced by the Implementation Team (again, those project team members from the University of Minnesota who led the process of analyzing implementation issues) and by a working group convened by the Implementation Team, separately from the committee. The report will state when a recommendation has been issued by the Protocol Committee and when it has been issued by the Implementation Team. Rarely, a recommendation will be attributed to the Minnesota Pandemic Ethics Project team (including members of the team from both the University of Minnesota and the Minnesota Center for Health Care Ethics). A summary of the report's recommendations follows.

Recommendations regarding equitable access to resources:

This report provides analysis of the ethical frameworks' fundamental requirement that access to resources be equitable, identifies challenges to the implementation of this requirement, and recommends processes for implementing it.

1.1 The Implementation Team urges vigilance at multiple levels to protect against exacerbations of inequities during a pandemic. The extent to which equity is achieved will depend on the nature and quality of collective action, knowledge, interaction, and moral commitment between public health, social service, and public and private health care organizations at the local, regional, and state levels.

1.2 The Implementation Team recommends the further development, as needed, of partnerships between MDH, the State Community Health Services Advisory

Committee (SCHSAC), local health departments (LHDs) and Native American liaisons throughout the state. These partnerships will be critical to the promotion of equity, given the special expertise of each of the partners.

1.3 The Implementation Team recommends collaboration between LHDs and social service agencies, home care providers, free clinics, community organizations such as the Salvation Army, faith-based communities that serve low income people, etc. These groups work directly with populations that are most likely to face barriers to access during a pandemic. Given their commitment to and direct contact with their at-risk populations, these groups are well-positioned to know what pandemic response strategies will be useful to their constituents and to bear witness to their needs.

1.4 The Implementation Team recommends that regional planning efforts attend to the goals of removing barriers to access and reducing significant group differences in mortality and serious morbidity.

Recommendations regarding eligibility to receive resources:

Since the pool of resources will be extremely limited in a severe pandemic, the Protocol Committee addressed the issue of whether Minnesota should allow persons from other states or countries to access resources in the state (because, for example, they live at the borders of the state and become ill while in the state).

2.1 The Protocol Committee recommends against establishment of a plan that allows only legal residents of the state of Minnesota access to scarce resources in the state.

2.2 The Protocol Committee recommends continued communication and planning for rationing during an influenza pandemic with border states and Canada.

Recommendation regarding emergency powers:

The Minnesota Emergency Management Act (Minnesota Statutes Chapter 12) gives the Governor, Commissioner of Health, and other officials the legal tools to respond to a public health emergency like an influenza pandemic. This report provides an overview of the Act and highlights particular issues in that legal context needing further action if the frameworks are to be implemented appropriately.

3.1 The Protocol Committee recommends that rather than relying upon state power to mandate provision of services, employers create emergency plans with their employees before the pandemic in order to best address issues like absenteeism.

Recommendations regarding standards of care:

The Protocol Committee discussed the potential need for the creation of standards of care that should prevail in a severe pandemic, at least during certain phases, given the realistic possibility that a severe pandemic could impair the ability of health systems to provide services in accordance with established standards of care.

4.1 The Protocol Committee recommends that any guidance issued for pandemic response provide local service providers with the flexibility that they will need to respond to the particularities of the contexts in which they work, while also protecting against acts of discrimination based on personal bias, etc.

4.2 The Implementation Team recommends that, even with the adoption of pandemic standards of care, many norms of good care carry over from non-pandemic standards. For example, if patients face the realistic prospect that they may be removed from a ventilator if it is needed by another, then these possibilities must be carefully explained to patients and their families throughout the process in which decisions concerning care are made.

4.3 The Protocol Committee strongly recommends that even in the highly challenging context of a pandemic, providers not be fully immunized from liability; there must be safeguards and protections for patients as well.

4.4 The Protocol Committee recommends that MDH assemble a working group of relevant experts to provide direction on the complex issues concerning the establishment of pandemic standards of care and appropriate provisions for liability. It is of great importance that emergency plans are meticulously written and that further policy maker guidance be sought on life-and-death issues such as the removal of a patient from a ventilator against the patient's wishes or those of the patient's family. The Emergency Management Act and other laws on professional health care services may need to be reviewed in this novel context to determine the need to offer greater legal protection to responders, and the appropriate balance between liability protections and safeguards for patients.

Recommendations regarding the implementation of rationing criteria:

The project's ethical frameworks recommend that persons be prioritized for access to resources based on their status as key workers or their health needs. The project also considered possibly recommending that age also function as a prioritization criterion. The Implementation Team and the Protocol Committee offer recommendations concerning the implementation of these criteria.

5.1 The Minnesota Pandemic Ethics Project team recommends that the decision about which workers to identify as key be understood as an event dependent one.

5.2 The Protocol Committee notes that the definition of "key workers for essential roles" developed in this project recognizes that some volunteers may play such essential roles during a pandemic, and recommends that processes for identifying key workers consider the role of volunteers. The Protocol Committee concurs with the Panel in this regard.

5.3 The Protocol Committee recognizes that no preordained limit can be applied to processes for identifying key workers, but recommends that these processes reflect a commitment to strive for balance between the Panel's two recommended rationing strategies of prioritizing key workers and prioritizing those groups in the general public who are at greatest risk for morbidity and mortality. The Protocol Committee's deliberations were consistent with those of the Panel on this issue.

5.4 The Protocol Committee recommends that, once decisions are made about which types of workers are deemed key during a pandemic, individual workers who may receive priority on these grounds are identified, in cooperation with workplaces, in advance of a pandemic. This pre-identification of individual workers will facilitate their access to resources when it is needed.

5.5 The Protocol Committee recognizes that medical records may not be easily available when making rationing decisions, and strongly feels that current privacy protections be enforced despite the need for health information when making rationing decisions. Thus, access to health records cannot be presumed, and the Protocol Committee recommends that patients' self-reports be accepted as guiding rationing decisions where possible.

5.6 The Protocol Committee recommends that the community engagement process seek public input on the issue of genuinely age-based rationing. The Protocol Committee's deliberations were consistent with those of the Panel on this issue.

5.7 The Protocol Committee recommends that age-based rationing be undertaken only after a legal determination is made on behalf of the State that such actions are compatible with federal and state laws on age discrimination. If the community engagement process reveals broad, strong support for age-based rationing, the state should undertake such a legal analysis to assess whether, and if so how, age-based rationing could be implemented.

Recommendations regarding protections for the public:

This report recommends the development of particular protections for the public, thus providing guidance on the implementation of the ethical frameworks' insistence that decision-making be "accountable, transparent, and worthy of trust";[3]

6.1 The Protocol Committee recommends that, during a pandemic, decisions about allocation of resources be monitored to ensure that they are made in as principled and effective a way as possible. Thus, the committee recommends that any institution that delivers care during a pandemic create a local process for routine retrospective performance reviews. These processes will vary from one type of institution to another, given differences between institutions and among resources being allocated.

6.2 The Protocol Committee recommends the development and implementation of a time limited, simple process to allow for real time reviews of rationing decisions. This process provides a safeguard for individuals or their families to question the procedural and substantive propriety of decisions at the time they are made.

6.3 The Protocol Committee recommends that real time reviews be considered only on grounds that are consistent with the ethical frameworks that are adopted to guide decision-making.

6.4 The Implementation Team recommends that the implementation of retrospective and real time reviews of decision-making involve the process for ethics consultation outlined in section 7 below. Since this proposed process for ethics

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consultation would work at multiple levels – state, regional and local – it can be adapted to retrospective and real time reviews of decision-making for each resource.

Recommendations regarding ethics consultation:

The Implementation Team proposes a process for ethics consultation that can be used at multiple levels of organization – the state (MDH and government officials), the region (networks of healthcare or other organizations), and the institution (individual facilities and at the bedside) – to provide advice on the implementation of the ethical frameworks during an influenza pandemic, and on the possible need for updates to them as planning continues prior to a pandemic.

7.1 The Implementation Team recommends that MDH sponsor an organization to develop, implement and administer a system for ethics consultation at state, regional and local levels. The system would include the development of a website and other resources for ongoing education and community engagement.

7.2 The Implementation Team recommends that this system comprise a centralized resource, the Pandemic Ethics Advisory Group (PEAG), to address issues at the state level for MDH and to develop coordinated mechanisms for review processes at regional and local levels; a regional ethics advisory group (REAG) operating in concert with the eight regional offices of MDH, and a network of local ethics committees, and local institutional ethics advisory groups (LEAG).

7.3 The Implementation Team recommends that ethics consultation mechanisms at each level of organization be multidisciplinary, include ethics expertise and

community representation, and reflect the demographics and cultures of their respective communities.

7.4 The Implementation Team recommends that ethics consultation be sought when those attempting to resolve an ethical problem have reached an impasse when the ethical problem involves a serious disagreement or dispute, or when the problem is unusual, unprecedented, or very complex ethically.

7.4.1 The Implementation Team recommends that the LEAG's findings regarding individual allocation decisions be determinative and unilateral at the institutional level.

7.5 The Implementation Team recommends that the PEAG provide a mechanism to review the policies and practices that have emerged in the pandemic and to advise on measures to alter or improve emerging practices.

7.6 The Implementation Team recommends that ethics advisory bodies, especially at the local level, provide structured and systematic retrospective performance reviews to ensure compliance with and consistency in the application of MDH framework or the frameworks adopted by individual institutions.

Recommendations regarding palliative and hospice care:

This report emphasizes the vital need for palliative and hospice care for the terminally ill during pandemic and supplements the discussion of allocation of specific resources in the ethical frameworks with a suggested process for planning for the implementation of palliative and hospice care during a pandemic.

8.1 The Implementation Team recommends that MDH convene a workgroup administered by Hospice Minnesota, in concert with statewide palliative care programs, to plan and implement a process for meeting the palliative and hospice care needs of the desperately ill during a severe pandemic.

8.2 The Implementation Team recommends that the workgroup be tasked with developing recommendations for stockpiling palliative care resources, developing and promulgating symptom management protocols and algorithms, developing caregiver educational programs for members of the community, and developing a process for ongoing community engagement/communication.

INTRODUCTION

In 2007, the Minnesota Department of Health (MDH) contracted with ethicists from the University of Minnesota's Center for Bioethics and the Minnesota Center for Health Care Ethics to develop and lead the Minnesota Pandemic Ethics Project. This project's primary goal is to develop guidance regarding how scarce health resources should be rationed in Minnesota during severe influenza pandemic. To that end, the project created a Resource Allocation Panel (hereafter referred to simply as "Panel"), working groups with expertise in specific resources under discussion in the project as well as in ethics, and a Protocol Committee to analyze issues regarding the implementation of the Panel's recommendations. A presentation of the Panel's preliminary recommendations for ethical frameworks for rationing can be found in *For the Good of Us All: Ethically Rationing Health Resources in Minnesota in Severe Influenza Pandemic*[4] (hereafter

4 Ibid.

referred to simply as the Panel report). This report, *Implementing Ethical Frameworks for Rationing Scarce Health Resources in Minnesota During Severe Influenza Pandemic* (hereafter referred to simply as the implementation report), presents preliminary analysis of implementation issues performed by the Protocol Committee and members of the implementation team.

Discussion of implementation issues plays a crucial role in the creation of guidance for pandemic planning and response. All too often, discussions of the ethical issues involved in pandemic planning and response offer general analysis of abstract values and principles that may offer guidance on these issues. While these discussions provide significant insight into important moral[5] issues, they often leave unanswered critical questions about how their moral guidance can be practically implemented in the enormously complex context of actual pandemic planning and response. To be truly practical, ethical frameworks for guiding pandemic planning and response should be supplemented with expert analysis of such implementation issues. It is the aim of this report to provide such analyses concerning the Panel's recommended frameworks for rationing of scarce resources in Minnesota during a severe pandemic.

Indeed, the Minnesota Pandemic Ethics Project has worked throughout to provide practical guidance about how to implement the ethical commitments and principles endorsed in the ethical frameworks. Thus, the ethical frameworks presented in the Panel report have been drafted to recommend not just ethical commitments and

5 This report uses the terms "ethical" and "moral" interchangeably, as synonyms.

principles, but also goals for action based on those commitments and principles, and strategies to be implemented for achieving those goals. As such, the ethical frameworks marry endorsement of abstract moral commitments and principles with detailed guidance about implementation concerning which groups it is reasonable to consider prioritizing for access to particular resources, tailored to assumptions about the resources themselves, the disease threat being faced, the levels of scarcity creating the need for rationing, and so on. Such a marriage has been enabled by the involvement of the expert resource specific workgroups as well as many members of the Protocol Committee in the deliberations of the Panel. Thus, the ethical frameworks themselves reflect the Minnesota Pandemic Ethics Project's thoroughgoing commitment to the complementary goals of providing ethical guidance and strategies for its implementation.

This preliminary implementation report, then, supplements the strategies and other operational recommendations included in the preliminary Panel report. This report focuses on broader issues that arise in planning for the implementation of the ethical frameworks. Because the ethical frameworks recommended by the Panel overlap to such a great degree at the level of fundamental ethical commitments, principles, and even goals, the Protocol Committee and the Minnesota Pandemic Ethics Project team consistently identified broad practical issues that span the ethical frameworks as fundamental priorities for implementation analysis. Moreover, as the Protocol Committee and Implementation Team developed greater awareness of the very expert and painstaking work that MDH has been doing to develop operational and logistical

plans for a pandemic, it became clear to the Implementation Team, the Protocol Committee, and MDH that the analyses of implementation issues provided in this report should supplement but not supplant MDH's operational and logistical planning activities. Thus, it was decided that the project would best guide the work of MDH if it analyzed the broader implementation issues that are largely raised in common by all of the ethical frameworks, for example, issues about how to implement the ethical frameworks' fundamental requirement that access to resources be equitable, or the frameworks' recommended criteria for prioritizing persons' access to resources.

Thus, this report takes up those broad issues. It:

- provides analysis of the ethical frameworks' fundamental requirement that access to resources be equitable, identifies challenges to the implementation of this requirement, and recommends processes for implementing it;
- addresses questions about who ought to be eligible to receive the resources at issue in the frameworks, and offers recommendations concerning the allocation of resources to those who are not legal residents of Minnesota (because, for example, they live at the borders of the state and become ill while in the state);
- outlines the legal context within which the ethical frameworks will be implemented – the Minnesota Emergency Management Act (Minnesota Statutes Chapter 12) – and highlights particular issues in that legal context needing further action if the frameworks are to be implemented appropriately;
- identifies challenges associated with the creation of standards of care for a pandemic and suggests a process for meeting them;

- discusses the criteria for prioritizing persons for access to resources that are recommended by the ethical frameworks – status as a key worker for essential functions and health needs – as well as the criterion discussed extensively in the project but not yet recommended for use – age – identifying challenges in and making recommendations for the implementation of each of these criteria, highlighting further action that needs to be taken to implement them, and recommending a process for making rationing decisions when these criteria do not, on their own, determine who should be prioritized for access to resources;
- recommends the development of particular protections for the public, thus providing guidance on the implementation of the ethical frameworks' insistence that decision-making be "accountable, transparent, and worthy of trust"[6] ;
- proposes a process for ethics consultation that can be used at multiple levels of organization – the state (MDH and government officials), the region (networks of healthcare or other organizations), and the institution (individual facilities and at the bedside) – to provide advice on the implementation of the ethical frameworks during an influenza pandemic, and on the possible need for updates to them as planning continues prior to a pandemic;
- emphasizes the vital need for palliative and hospice care for the terminally ill during a pandemic, and supplements the discussion of allocation of specific resources in the ethical frameworks with a suggested process for planning for the implementation of palliative and hospice care during a pandemic.

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PROCESS

This report has been produced through the combined efforts of many people. Members of the Minnesota Pandemic Ethics Project team from the University of Minnesota's Center for Bioethics (hereafter referred to as the Implementation Team) led the process to analyze implementation of the ethical frameworks developed in the project, in close collaboration with project team colleagues from the Minnesota Center for Health Care Ethics. A Protocol Committee was assembled, including experts in public health, public safety, infectious disease control, hospital administration, law, ethics, and other relevant areas specifically targeted to the task of analyzing issues related to the implementation of the ethical frameworks being developed in the project. While not officially members of the Protocol Committee, representatives from MDH briefed the committee on issues related to pandemic planning and response, and participated in meetings to lend their expertise on public health issues and advise the committee on state planning efforts.

The Protocol Committee met regularly during the project, discussed the draft ethical frameworks as they were being formulated, provided feedback to the panel on opportunities for and impediments to the implementation of the developing frameworks, and offered invaluable analysis of these implementation issues. This report is largely based on the work of the committee. Like any group process, it cannot be said that members of the group were always in perfect agreement on all issues. This report attempts to indicate areas of uncertainty or controversy. While the report reflects a serious effort to reflect the discussions of the committee, in the end, responsibility for the content of the report lies with the Implementation Team.

This report also contains some discussions of implementation issues produced by the Implementation Team – those project team members from the University of Minnesota who led the analyses of implementation issues -- separately from the Protocol Committee. The discussion of palliative and hospice care included herein presents such an example. In addition, the proposed process for ethics consultation included in this report was produced outside the context of Protocol Committee meetings. As reflected in the contract for the Minnesota Pandemic Ethics Project, MDH requested that the implementation team provide a process for ethics consultations with the state during pandemic. The Implementation Team convened a working group to take the lead on this issue. Given the significant role that the ethics consultation process plays in implementation of the ethical frameworks, the proposal for it has been included in this report. The report will state when a recommendation has been issued by the Protocol Committee and when it has been issued by the Implementation Team. Rarely, a recommendation will be attributed to the Minnesota Pandemic Ethics Project team as whole (including individuals from the University of Minnesota Center for Bioethics and the Minnesota Center for Health Care Ethics.)

THE STATUS OF THE MINNESOTA PANDEMIC ETHICS PROJECT

The primary goal of the Minnesota Pandemic Ethics Project is to develop guidance regarding how scarce health resources should be rationed in Minnesota during a severe influenza pandemic. As such, the reports outlining preliminary recommendations of the project concerning ethical frameworks and their implementation are meant to be

advisory only. This advice may guide the work of a number of types of institutions – from state departments and agencies such as MDH, to local public health departments, to hospitals and clinics – should they choose to adopt it.

Not only is the project advisory in nature, but the draft recommendations expressed in the project's reports are also provisional and preliminary. The recommendations are provisional because they are premised on numerous assumptions about the pandemic threat for which the state prepares, the effectiveness and availability of the resources to be used in response to the pandemic, the relationship between federal and state authority for planning and response, etc. It is likely that the recommendations of the Minnesota Pandemic Ethics Project will need to be revised given changing realities concerning any of these assumptions. Toward that end, the project proposes a process for updating MDH on changes that may require a reconsideration of the recommendations in the pre-pandemic period.[7] The project also proposes a critically important process for ethics consultation during the context of pandemic itself to address unforeseen issues in pandemic response as they arise (section 7 below). No guideline, ethical or otherwise, can specify every contingency that may arise.

The project's recommendations are preliminary because some members of the project team will go on to seek broad public input on the issues under consideration and genuinely embrace the possibility that recommendations may need to be revised in light

7 DeBruin DA, Leider JP. A Process for Updating Guidance in the Minnesota Pandemic Ethics Project. Minneapolis, MN: University of Minnesota Center for Bioethics. April 1, 2008.

of this public input. The code of ethics for the practice of public health emphasizes that "Public health policies, programs, and priorities should be developed and evaluated through processes that ensure an opportunity for input from community members."[8] Some members of the Minnesota Pandemic Ethics Project team have recommended a process for community engagement to MDH. MDH has contracted with these team members to undertake this proposed process. Community engagement activities will take place next, and the public input received will be used to amend and finalize the project's reports.

Many public health and health care professionals are already aware of the potential impact of a pandemic. Public health and health care delivery systems are planning for a pandemic, and issues related to pandemic planning and response are discussed in the professional literature. However, state plans, including guidance on ethical issues, will need to be disseminated broadly to help promote preparedness throughout response systems. Moreover, professionals directly involved in pandemic response will have concerns about their own protection and that of their families, which can be addressed through provider education.

A process of community education will need to address both education about pandemic influenza itself and the proposed framework for rationing. In considering community education, the media merits special attention; it will play an important role in disclosure

8 Principles of the Ethical Practice of Public Health, Version 2.2. 2002 Public Health Leadership Society. Accessed 3/12 08 at http://www.apha.org/NR/rdonlyres/1CED3CEA-287E-4185-9CBD-BD405FC60856/0/ethicsbrochure.pdf.

of information to the public. The Protocol Committee acknowledges that a potential tension exists between adequately informing the public and creating fear. Public education will require collaboration between public health professionals, ethicists and the media. This collaboration will need to be based upon attention to the best state of scientific knowledge, knowledge of local communities, and consideration of the framework for rationing.

ANALYSIS OF IMPLEMENTATION ISSUES

1. **Promoting Equitable Access to Resources**

The goals recommended by the Panel to guide rationing include the following: "reduce significant group differences in mortality and serious morbidity" and to "make reasonable efforts to remove barriers to fair access."[9] Reflective analysis is an essential and ongoing aspect of morality; perhaps it is most important and most necessary with sensitive topics. One of the particularly sensitive issues in pandemic preparedness relates to inequities in access to resources. The Protocol Committee discussed two major issues in relation to equity of access: socio-economic disparities and geographical disparities. Of these two, the more sensitive issue was socio-economic status – poor people, to put a human face on an abstract categorization. This is not surprising given the long-standing challenges with inequities in the United States.[10]

9 Vawter et al. January 30, 2009

10 Morone, J. (2003). American Ways of Welfare. Perspectives on Politics, 1, 137-146.

Poverty is central in two ways: one is access to health care; the other relates to social conditions that influence either the risk of contracting disease or the ability to recover, regardless of whether one has access to health care. Examples of the latter include such things as the quality of nutrition, dependence on public transportation, social support networks, prevalence of dignity affirming or dignity denying experiences, and resources sufficient to mitigating stress in day-to-day life. The relationships between socio-economic status and health disparities are complex and challenging but morally relevant if institutions and persons are committed to the just distribution of resources during a pandemic. Both of the ways in which poverty are central to pandemic preparedness were discussed throughout this project, although access to health care received more attention. This emphasis on access to health care stems from the project's primary aim of providing guidance regarding the rationing of specific health care resources: vaccines, antivirals, and ventilators. Personal protective equipment is not a health care resource, per se, but discussion of their allocation in this project (as in many similar projects) focuses on its use in health care settings. In spite of the project's focus on medical interventions, it is important not to ignore the relevance of non-medical resources (e.g. adequate nutrition) and other social determinants of health (e.g. social hierarchies) to the outcome of surviving a pandemic.

Because health care in the United States is a complicated mix of public and private relationships negotiated largely through employment, ensuring equity in access to vaccines, antivirals, masks, and ventilators poses particular challenges, especially in relation to socio-economic disparities. Although Minnesota is among the states with

lowest percentage of people living below the poverty level and ranks among the healthiest of states, a pandemic will nonetheless challenge its moral commitment to equity. The Panel acknowledged that any ethical framework for rationing in a pandemic could not, on its own, redress existing inequities of access to health care for the people in Minnesota. Rather, the pertinent goals of the proposed framework are to "reduce significant group differences in mortality and serious morbidity" and to "make reasonable efforts to remove barriers to fair access."[11] These goals are in keeping with Minnesota's health mission at both the state and local levels. It is also in keeping with the Bellagio Statement of Principle which emphasizes the need for protecting the disadvantaged.[12] Discussions in the Protocol Committee indicated that there was some uncertainty about why people are at undue risk in an influenza pandemic for socioeconomic reasons. The Implementation Team was asked to clarify reasons for including some socioeconomic groups as being at undue risk in this context as well as the definition of 'at risk.'

Socio-economic status is not limited to income alone but includes one's position in social hierarchies of status. That is to say, poorer health outcomes correlate with lower social status, not only poverty. Socio-economic disparities reflect significant differences in economic status and social opportunities relative to some group. These opportunities include such social goods as quality education, high-paying and meaningful work, and the ability to live in the area of one's choosing. Although the mechanisms are not fully

11 Vawter et al. January 30, 2009.

12 Bellagio Group. Bellagio Statement of Principles. 2006. Accessed on 4/1/08 at http://www.hopkinsmedicine.org/bioethics/bellagio/Bellagio_Statement.pdf.

understood, research on the relationship between socio-economic status and health has repeatedly demonstrated the positive correlation between them.[13] Likewise, historical work has documented that poorer people were (and continue to be) disproportionately subjected to higher mortality and morbidity from infectious diseases.[14]

There are many ways in which to understand risk. One of the most obvious is that risk is the probability that something bad will happen[15] – in this case, that people will become ill through exposure to the influenza virus. There are numerous reasons why the poor are at high risk for infection, many of them that follow from poverty. They are more likely to rely on public transportation, to work several low-paying jobs to make ends meet, to have less time and money for good nutrition, etc. New immigrants, both documented and undocumented, are likely to have difficulties because of language. Beliefs, traditions, and practices may conflict with the dominant culture thus further disadvantaging them regarding access to resources. The concept of 'risk,' however is not a morally neutral term.[16] A person or group's socio-economic status reflects not only material realities but also cultural meanings. Some of the earliest work on 'risk' by philosophers and social scientists illustrates the association between risk and dirt or

13 Lin, C.C., Rogot, E., Johnson, N.J., Sorlie, P.D., Arias, E.A. (2003). A further study of the life expectancy by socioeconomic factors in the National Longitudinal Mortality Study. Ethnicity and Disease, 13(2), 240-47; Piketty, T., Saez, E. (2003). Income inequality in the United States, 1913-1998. The Quarterly Journal of Economics, 118(1), 1-39.; Woolf , S.H. (2007). Future health consequences of the current decline in US household income. JAMA, 298(16), 1931-1933. The Agency For Healthcare Research And Quality . (n.d.). Highlights: Key Themes and Highlights from the National Healthcare Disparities Report. Retrieved Mar. 20, 2008, from http://www.ahrq.gov/qual/nhdr06/highlights/nhdr06high.htm.

14 Craddock, S. (2000). City of Plagues: Disease, Poverty, and Deviance in San Francisco. Minneapolis: University of Minnesota Press; Farmer, P. (1999). Infections and Inequalities: The Modern Plagues. Berkeley: University of California Press; Rosenberg, C.E. (1987). The Cholera Years: The United States in 1832, 1849, and 1866. Chicago: The University of Chicago Press.

15 Ericson, R.V. and Doyle, A. (2003) (Eds). Risk and Morality. Toronto: University of Toronto Press; Hacking, I. (2003). Risk and Dirt. In R.V. Ericson, A. Doyle (Eds.), Risk and Morality (pp. 22 – 47). Toronto: University of Toronto Press.

16 Brandt, A., Rozin, P. (Eds). (1997). Morality and Health. New York: Routledge.

Ericson, R.Vand Doyle, A. (2003). (Eds.), Risk and Morality. Toronto: University of Toronto Press.

pollution.[17] But risk is also "the calculating concept that modulates the relations between fear and harm."[18] Historically, groups different from the dominant group, (by poverty, race, language and other social markers) most saliently when they have been poor, have been feared as the source of harm and treated accordingly.[19] Infectious diseases in the poor, or otherwise different, were attributed by the dominant group to flawed morality.[20] Here the words of political scientist James Morone come to mind:

> At the heart of every welfare debate [is] – the definition of American community. Who are we? And more to the point, how do we distinguish "us" from "them"?[21]

The idea of 'risk' is and has been used to separate 'us,' meaning the dominant social group of socioeconomic privilege from 'them,' meaning the different and therefore, dangerous, thereby justifying all kinds of punitive responses meted out by the former to the latter. For these reasons, 'risk' has great ethical significance. In the United States, the distribution of social goods is tied to whether one is seen as deserving as indicated by a variety of measures.[22] To the extent that one does or does not have these goods, it is the dominant cultural practice to view this as just dessert for having made good or bad choices. In a highly individualistic society such as the United States, certain behaviors and circumstances are viewed as a matter of individual choice, the common

17 Douglas, M. (1966). Purity and Danger: An Analysis of the Concepts of Pollution and Taboo. London: Routledge; Douglas, M. and Wildavsky, A. (1982). Risk and Culture: An Essay on the Selection of Technological and Environmental Dangers. Berkeley: University of California Press.

18 Hacking, I. (2003). Risk and Dirt. In R.V. Ericson, A. Doyle (Eds.), Risk and Morality (p. 27). Toronto: University of Toronto Press.

19 Craddock, et al., Ibid.

20 Tomes, N. (1997). Moralizing the microbe: the germ theory and the moral construction of behavior in the late-nineteenth-century antituberculosis movement. In A. Brandt, P. Rozin (Eds.), Morality and Health (pp. 271-294). New York: Routledge

21 Morone, J. (2003). American Ways of Welfare. Perspectives on Politics, 1, 137-146., p. 145.

22 Morone, J. (2003). American Ways of Welfare. Perspectives on Politics, 1, 137-146.

understanding being that a person 'chooses' not to work or not work hard enough, not to study, to use illegal substances, to smoke, to be obese, not to adhere to medical treatment regimes, and so forth. If people experience bad social circumstances, including ill health, low paying jobs, and poverty, it is viewed as being because they made bad choices and therefore it is their fault[23]. These ideas generally operate insidiously because the connection between poverty and lack of access to social goods on one hand and personal responsibility for bad choices on the other hand often lies below the level of conscious awareness. The result is that those who share in the goods of society see themselves as socially worthy of them, as having earned their just dessert by acting responsibly in making good choices. They view those who do not share in these goods as having earned their just dessert; not only are the latter viewed as socially unworthy, they are also viewed as a risk to the deserving and their way of life. For these reasons, socioeconomic status constitutes an ethical red flag for those recommending policy and those enacting it – it is a reminder to be vigilant precisely because the outcome for the poor during a pandemic may follow from ideas rarely conscious or spoken.

In an attempt to recognize this, the Panel has strongly voiced a commitment that social worth (for example, addiction or severe disabilities) is not an ethically justifiable reason for rationing. Understanding the ways in which judgments of social worth are tied to the poor is a goal worth striving for; it is a goal equally relevant to individuals, the state, and

23 Leichter, H.M. (1997). Lifestyle correctness and the new secular morality. In A. Brandt, P. Rozin (Eds.), Morality and Health (pp. 359-378). New York: Routledge.; Ericson, R.V., Doyle, A., Barry, D. (2003). Insurance as Governance. Toronto: University of Toronto Press.

private groups understood as actors. Most importantly, it is goal for moral communities of work, at whatever level – social life is not simply a collection of separate entities but a network of human relationships.

Socio-economic status and geographical disparities are highly interdependent in the sense that people of a given economic and social class are more likely to live in the same geographical areas. Discussions of geographical disparities in Protocol Committee meetings focused largely on the urban/rural mix of the state, with the belief that rural areas are vulnerable because, for example, they have fewer resources in terms of health care providers and facilities. This way of thinking reflects a more macro level of geography, specifically, as regions of the state, whereas counties, voting districts, and neighborhoods are smaller scale units of analysis. Clearly, the urban/rural, macro level analysis reveals socio-economic and health disparities and inequities. For example, both Native Americans living on reservations in rural areas and Native Americans living in cities experience socio-economic and health disparities and inequities when compared with other urban groups.[24] Within cities, very wealthy neighborhoods frequently transition into very poor neighborhoods with only a few blocks between them, and vacation homes of city dwellers are often in rural areas. Thus, an urban/rural understanding of geographical disparities is only part of the story. A more micro level understanding and approach will be essential in working towards the goal of protecting against exacerbations of inequities in access.

24 Kunitz, S.J. (1996). The history and politics of US health care policy for American Indians and Alaskan Natives. American Journal of Public Health 86(10), 1464 – 1473

The State of Minnesota seems well positioned to monitor and respond to the pandemic at multiple geographical levels because an infrastructure is already in place. For more than 30 years, responsibility for the health of the people of Minnesota has been shared by the State Department of Health, through the Office of Public Health Practice (OPHP), and local governments through the creation of community health boards, local health departments (LHDs), and the State Community Health Services Advisory Committee (SCHSAC). These partnerships are organized so that services are provided at the local level with LHDs setting their own priorities but both MDH and SCHSAC are concerned with reducing disparities and emergency planning. The state supports public health research, provides technical assistance, and develops tools, templates, and guidelines.[25]

Because they are local to a given geographical area and conduct community health assessment and action planning (CHAAP) reviews, LHDs know the demographics, social and economic conditions, and general health needs of the people they serve. Obviously there will be differences both between LHDs in terms of incidence, rates of transmission, access to care of all sorts, capacity to respond, and so forth. Additionally, vaccines, antivirals, N95 respirators, surgical masks, and mechanical ventilators will be channeled through a variety of mechanisms, depending on the item, involving government at both the federal and state level as well as through the private system.

25 Office Of Public Health In The Minnesota Department Of Health. (n.d.). History of MN Public Health System and Community Health Services Act. Retrieved Mar. 22, 2008, from http://www.health.state.mn.us/divs/cfh/ophp/system/administration/history.html;
OPHP. (n.d.). Office of Public Health Practice - Strengthening Minnesota's Public Health System. Retrieved March 12, 2008, from http://www.health.state.mn.us/divs/cfh/ophp/system/index.html.

LHDs have the best local knowledge of their communities including the ways in which socio-economic status intersects with other risk factors: the young, elderly, uninsured or underinsured, undocumented immigrants, and those with certain diseases. And, importantly, they are where the rubber meets the road – it is here that actual people will be engaged in real time and space.

Indeed, this local knowledge of the needs of vulnerable communities can be deepened through collaboration between LHDs and social service agencies, home care providers, free clinics, community organizations such as the Salvation Army, faith-based communities that serve low income people, etc. These groups work directly with populations that are most likely to face barriers to access during a pandemic. Given their commitment to and direct contact with their at-risk populations, these groups are well-positioned to know what pandemic response strategies will be useful to their constituents and to bear witness to their needs.

On the other hand, only the state has the entire picture and will be able to compare mortality and morbidity across regions. Additionally, the state will be the channel for vaccines which will be issued by the federal government and given to the state. The state will also be a central channel for antivirals which they have stockpiled. However, private groups such as corporations and private health care systems have also been stockpiling antivirals. The same is the case for personal protective equipment. Ventilators, pose other challenges for several reasons. While they will be critical to saving lives, they are a last ditch effort that may or may not be effective. There are a

limited number of ventilators in the state, most of which are the property of private health care systems.

Collaborative efforts between hospitals will require complex negotiations that nonetheless are essential to the goals of removing barriers to access and reducing significant group differences in mortality and serious morbidity. Hospitals in the state fall under various jurisdictions that have different reimbursement sources and serve different clients: federal, including the Department of Veteran Affairs (VA) and the Indian Health Service (IHS), state and local departments of health, and private corporations. Each of these groups has its own interests and challenges and each is developing plans accordingly. Nonetheless, demand for hospital beds at any one time within any one system is surely to be greater than availability. The demands of justice will mean that all hospitals, regardless of jurisdiction, must be open to accepting patients not among their usual clientele. Working toward strong, collaborative relationships between these entities will facilitate the development of mechanisms that allow for and facilitate the admission of patients and reimbursement for services.

In sum, ensuring equity of access will require vigilance at multiple levels. The extent to which it is achieved will depend on the nature and quality of collective action, knowledge, interaction, and moral commitment between public health and public and private health care organizations at the local, regional, and state levels.

Recommendations regarding equitable access to resources:

1.1 The Implementation Team urges vigilance at multiple levels to protect against exacerbations of inequities during a pandemic. The extent to which equity is achieved will depend on the nature and quality of collective action, knowledge, interaction, and moral commitment between public health, social service and public and private health care organizations at the local, regional, and state levels.

1.2 The Implementation Team recommends the further development, as needed, of partnerships between MDH, the State Community Health Services Advisory Committee (SCHSAC), local health departments (LHDs) and Native American liaisons throughout the state. These partnerships will be critical to the promotion of equity, given the special expertise of each of the partners.

1.3 The Implementation Team recommends collaboration between LHDs and social service agencies, home care providers, free clinics, community organizations such as the Salvation Army, faith-based communities that serve low income people, etc. These groups work directly with populations that are most likely to face barriers to access during a pandemic. Given their commitment to and direct contact with their at-risk populations, these groups are well-positioned to know what pandemic response strategies will be useful to their constituents and to bear witness to their needs.

1.4 The Implementation Team recommends that regional planning efforts attend to the goals of removing barriers to access and reducing significant group differences in mortality and serious morbidity.

2. Eligibility to Receive Resources: Border Issues and Residency

Since the pool of resources will be extremely limited in a severe pandemic, there has been some discussion by the Protocol Committee about whether Minnesota should allow persons from other states or countries to access resources in the state. In previous public health emergencies, prophylaxis or treatment has been provided to all persons without considering residency or citizenship. By preventing or treating disease in as many people as possible the number of contagious individuals is decreased and fewer people are newly infected, thus promoting public health and safety in the state.

A key difference from other public health emergencies will be the scarcity of resources in a severe pandemic. Some Minnesotans may feel that they are more deserving of government-held resources because they paid for them in taxes. However, here it should be recognized that not all resources to be marshaled against a pandemic threat would be state-held resources purchased with state or federal tax dollars. Many resources in the state will be held in both public and private hands. Vaccines will be a resource that is fully under the public sector; whereas, a large number of ventilators in Minnesota are in the private sector. Antivirals, respirators, and masks will all be held in both the public and private sectors.

The Protocol Committee recommends against establishment of a plan that allows only legal residents of the state of Minnesota access to scarce resources in the state. Several aspects of the issue were discussed including infection control in the

importance of saving human lives. In the early stages of an outbreak of pandemic influenza, resources should be used in any way that will best slow the outbreak including giving resources to individuals who are not legal residents of the state. Once the pandemic is widespread, the resources addressed in the ethical frameworks may be relatively ineffective for infection control. The committee also recognizes the value of all human life regardless of residency or citizenship. Since its charge involves the implementation of the project's ethical frameworks, the committee emphasized that there is no good way to identify who should have access to resources and who should not if resources were to be rationed only to legal residents of the state. There is not a state or federal photo identification card that is required for all people. Those who do not have photo identification like a driver's license may be disproportionately members of vulnerable populations such as the mentally impaired. It is not uncommon for people to have misplaced their birth certificate or social security card or to have them stored in a location that may be difficult to access during a pandemic. Given these considerations, the committee felt strongly that any plan that requires identification proving a person is a legal resident of the state in order to receive access to resources will have the consequence of denying treatment to many legal residents who do not have the requisite forms of identification, or do not have them at hand when they fall ill and need them. Thus, the committee recommends that Minnesota should attempt to treat all people meeting the rationing criteria outlined in the Panel report who become ill while in Minnesota.

At the same time, it is prudent that the state and federal government are engaging in planning efforts to collaborate with surrounding states and Canada to plan the response for border areas. There are many Wisconsin residents who commute to the Saint Paul/Minneapolis metro for work and may require medical assistance while in Minnesota rather than Wisconsin. Likewise some rural areas in western Minnesota may be closer to large cities in North and South Dakota than Saint Paul/Minneapolis or Saint Cloud. For people who commute between two states for work or live in border regions there may be some confusion if they are receiving different information from each state about the pandemic, where to receive treatment or vaccination, or the rules surrounding allocation of a resource[26]. By clearly addressing possible questions and concerns in these border regions the state will better serve its residents. The Protocol Committee recommends continued communication and planning for pandemic influenza with border states and Canada.

Recommendations regarding eligibility to receive resources:

2.1 The Protocol Committee recommends against establishment of a plan that allows only legal residents of the state of Minnesota access to scarce resources in the state.

2.2 The Protocol Committee recommends continued communication and planning for rationing during an influenza pandemic with border states and Canada**.**

26 Association of State and Territorial Health Officials. (2005). Preparedness Training for State Health Officials: Interstate Planning for the Strategic National Stockpile: Experiences in Five Regions. Washington, DC. Available at http://www.astho.org/pubs/SNSfinalreport.pdf

3. The Legal Context: Emergency Powers For Extraordinary Times

3.1 Overview

The Minnesota Emergency Management Act (Minnesota Statutes Chapter 12) gives the governor, commissioner of health, and other officials the legal tools to respond to a public health emergency such as an influenza pandemic. The Act was modified on May 23, 2002 and again revised in 2005. The Emergency Management Act includes information on the requirements for declaring a health emergency, changes in officials' management powers, individual rights during the crisis and legal responses to situations that may arise in a state of emergency[27]. The Emergency Management Act is codified in Minnesota Statutes, Chapter 12[28].

The Emergency Management Act stipulates when the governor can declare a national security or peacetime emergency. A severe influenza pandemic would be classified as a peacetime emergency because it is considered an act of nature. A peacetime emergency may be declared once a public health emergency risks life and property and local government resources are insufficient to respond properly[29].

The governor can declare a state of emergency for up to five days. A state executive committee can extend the state of emergency for 30 more days. After 35 days the governor must call both houses of the legislature to a special session where they can

27 Minnesota. (2004). The Minnesota Emergency Health Powers Act Saint Paul: Available at http://www.house.leg.state.mn.us/hrd/pubs/mnehpa.pdf

28 Minnesota Emergency Management Act of 1996, Minn. Stat. § 12, https://www.revisor.leg.state.mn.us/statutes/?id=12

29 Minn. Stat. § 12.31 Subd. 2.

terminate the state of emergency if they so desire[30]. The extension will automatically terminate 35 days after its declaration. The governor may renew the state of emergency with approval by the executive committee for additional 35 day periods. The legislature can actively end a state of emergency but inaction by the legislature will not terminate the state of emergency. The termination of the state of emergency by the legislature overrides a renewal by the governor.[31] Due to the long-term nature of pandemic influenza it may be difficult to determine when to end the state of emergency. The governor or legislature may also need to discuss whether to remain in a state of emergency throughout the pandemic or to declare a state of emergency only in periods of high morbidity and mortality.

A local emergency can be declared by a mayor of a municipality or the chair of a county board of commissioners. A local emergency can not be continued for more than three days unless consent is given by the governing body of the political subdivision.[32] The governor's powers during a state of emergency supersede those of local government.[33] It is thought that pandemic influenza will be widespread after the initial outbreak thus there will likely be a statewide state of emergency rather than local emergencies.

Most of the emergency management powers of the governor, the executive council, and other officials can be found in Chapter 12 of the Minnesota Statutes[34]. The regulations

30 Minn. Stat. § 12.31 Subd 2.

31 F Livingston, presentation, July 17, 2007

32 Minn. Stat. § 12.29 Subds 1-3.

33 Minn. Stat. § 12.32

34 Minn. Stat. § 12

of importance to resource allocation planning will be discussed in detail in the following sections.

3.2 Temporary Medical Care Facilities

When the number of seriously ill or injured persons overwhelms the emergency hospital or medical transport capacity of one or more regional hospital systems the governor may issue an emergency executive order to offer healthcare in temporary care facilities (aka alternative care sites). During the effective period of the emergency executive order a responder in an impacted region who acts consistently with emergency plans is not liable for any civil damages or administrative sanctions from good faith acts or omissions. This legislation does not protect the worker in cases of malfeasance in office or willful or wanton actions.[35]

3.3 Workers

In a pandemic several issues arise for workers who are critical for a robust response to the pandemic or to support critical infrastructure. The Emergency Management Act addresses questions of liability, licensure, and mandatory provision of services or use of a resource.

3.3.1 Liability

As previously mentioned, the governor can issue an emergency executive order to offer health care in temporary care facilities when medical capacity is overwhelmed. While

35 Minn. Stat. § 12.61

the emergency executive order is in effect, a responder in an impacted region who follows emergency plans is not liable for any civil damages or administrative sanctions from good faith acts or omissions. There is no legal protection for the worker in cases of malfeasance in office or willful or wanton actions.[36] An emergency plan is defined in the Emergency Management Act Statute 12.61 subdivision 1a as follows:

> (i) any plan for managing an emergency threatening public health developed by the commissioner of health or a local public health agency;
>
> (ii) any plan for managing an emergency threatening public health developed by one or more hospitals, clinics, nursing homes, or other health care facilities or providers and approved by the commissioner of health or local public health agency in consultation with emergency management officials; or
>
> (iii) any provision for assistance by out-of-state responders under interstate or international compacts, including but not limited to the Emergency Management Assistance Compact.

A responder is defined as a person or organization that provides healthcare or other health-related services. A responder can be a paid worker or a volunteer.[37]

There was some concern voiced in the Protocol Committee that medical professionals would be apprehensive about performing certain actions due to concerns regarding liability. The majority of this discussion revolved around palliative care and removal of ventilators from patients for the purpose of allocating the ventilator to a person who is

36 Minn. Stat. § 12.61 Subd 2.

37 Minn. Stat. § 12.61 Subd 1c.

more likely to survive. Both of these procedures have the potential to arouse strong feelings from individuals and families which may subsequently lead to legal action. It is of great importance that emergency plans are meticulously written and that further policy guidance be sought on life-and-death issues of this nature. Further discussion of liability is offered in section 4 below on pandemic standards of care, along with Protocol Committee recommendations on this subject.

During its deliberations, the Protocol Committee expressed concern that liability protection may need to be strengthened for volunteers. The liability protection discussed above includes volunteers who fall into the category of responders as defined in Minnesota Statute 12.61 Subdivision 1c. This definition is focused on health care providers or health-related services. Likewise persons assigned by the commissioner of health for providing vaccination and dispensing legend drugs have legal protection.[38] However the legal protections are less clear for volunteers who participate in other aspects of the pandemic response, for example, those who deliver food to homes, provide transportation for the elderly, or provide social services to newly orphaned children. Some protection for volunteers in areas other than health care may be found in Minnesota Statute 12.22 Subdivision 2a which defines volunteers as "individuals who volunteer to assist a local political subdivision during an emergency or disaster, who register with that subdivision, and who are under the direction and control of that subdivision." Persons who fall under that definition would be considered employees of the state in regards to tort claim defense and indemnification. Further protections for

38 Minn. Stat. § 144.4197

Minnesota Responds Medical Reserve Corps volunteers were added in the 2008 Legislative Session after the Protocol Committee's final meeting.[39]

3.3.2 Licensure

Due to high levels of absenteeism from illness and fear of infection, there may be a lack of workers with the specific skills to aid in the response to pandemic influenza. This will be especially evident in the health care sector. For this reason certain individuals who would not normally be legally able to perform a procedure or occupation in Minnesota may be enabled to during the state of emergency. The Emergency Management Act Statute 12.42 addresses the issue of licensure as follows:

> During a declared emergency, a person who holds a license, certificate, or other permit issued by a state of the United States, the District of Columbia, or a province of Canada evidencing the meeting of qualifications for professional, mechanical, or other skills, may render aid involving those skills in this state when such aid is requested by the governor to meet the needs of the emergency. The license, certificate, or other permit of the person, while rendering aid, has the same force and effect as if issued in this state, subject to such limitations and conditions as they may prescribe.

Concern was also raised within the Protocol Committee about regulations surrounding procedures performed by medical professionals. A shortage of medical professionals able to work in a pandemic may result in workers prescribing medication or performing procedures that they are not regulated to perform. The commissioner of health may

39 MN Session Law 2008 c 202 at https://www.revisor.leg.state.mn.us/laws/?id=202&doctype=Chapter&year=2008&type=0 accessed January 28, 2009

approve any person to administer vaccinations or distribute legend drugs if the commissioner deems this necessary to protect the safety and health of the public. Any person authorized by the commissioner to perform such actions "shall not be subject to criminal liability, administrative penalty, professional discipline, or any other administrative sanction for good faith performance of the vaccination or drug dispensing duties assigned according to this section."[40] Certain medical practices beyond vaccination and legend drug distribution may be required of medical professionals who would not normally be regulated to perform such actions. If this situation arises during the state of emergency the governor can create orders or rules which have the full force of law. This may lead to the suspension of rules and ordinances of any agency or political subdivision of the state that are inconsistent with the new orders or rules. In this way certain regulations surrounding medication and treatment could be suspended during a pandemic.[41] It should be noted; however, that the governor cannot suspend statutes.

40 Minn. Stat. §144.4197

41 Minn. Stat. § 12.32

3.3.3 Mandatory Provision of Services

In a severe pandemic, high levels of absenteeism may occur due to personal and family illness, fear of infection, and death. The concern surrounding high rates of absenteeism has led to the question whether individuals can be legally required to work. It has been determined that the governor has the power to require an individual to provide services. Minnesota Statute 12.34 subdivision 1 states that the governor, state director, or persons designated by the governor may "require any person, except members of the federal or state military forces and officers of the state or a political subdivision, to perform services for emergency management purposes". If an able-bodied person whose service has been ordered refuses, neglects, or fails to perform the service, he or she is guilty of a misdemeanor and may be punished by imprisonment for 10 to 90 days.[42] Health care professionals who refuse to work during a pandemic may be subject to repercussions in the workplace such as losing their clinical privileges for failing to meet contractual work obligations. Likewise health care professionals who do not work could be penalized under certain statutes or regulations such as state licensing laws or the Emergency Medical Treatment and Active Labor Act (EMTALA).[43] The Protocol Committee expressed the concern that it would be counterproductive in a pandemic to penalize health care workers by withdrawing their clinical privileges given the need for workers in this type of emergency. Thus, the committee recommends that employers create emergency plans with their employees prior to the pandemic in order to best address issues such as absenteeism.

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42 Minn. Stat. § 12.34 subd. 3.

43 Coleman, Carl H., Reis, Andreas. Potential Penalties for Health Care Professionals Who Refuse to Work During a Pandemic. JAMA. March 2008; 299(12):1471.

3.3.4 Mandatory Use of a Resource

Consistent with established principles of bioethics, the Emergency Management Act states that individuals have the right to refuse "medical treatment, testing, physical or mental examination, vaccination, participation in experimental procedures and protocols, collection of specimens, and preventive treatment programs."[44] The commissioner of health may request examination, testing, treatment, or vaccination of an individual. If the individual is believed by the commissioner of health to be infected with pandemic influenza and refuses to submit to the above actions, he or she may be placed in quarantine or isolation.[45] It is unlikely the state would use this power after the initial outbreak. Once transmission of the illness has become widespread, non-voluntary quarantine can do little to protect the public's health[46], thus there would be scant justification for such an infringement of liberty.

During a pandemic an employer may request that its employees make use of a resource for a variety of purposes. A medical professional or an employee working with a group that has high-risk of severe morbidity from influenza may be asked to become vaccinated once vaccine is available. This is the right of the employer, but the employer's requirement of a resource does not change the employee's prioritization level to receive the resource from a governmental source.

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44 Minn. Stat. § 12.39

45 Minn. Stat. § 12.39

46 Minnesota Department of Health. Mitigation Strategies: Use of Non-pharmaceutical Interventions. April 2007 [cited 29 March 2008]; Available from: http://www.health.state.mn.us/divs/idepc/diseases/flu/pandemic/plan/npioverview.pdf

3.3.5 Unions

A final observation regarding workers' role in a pandemic is that the state government and health care systems should work with unions prior to a pandemic. A well-laid plan that both sides can agree upon before a pandemic could reduce the likelihood of problems regarding workers' rights arising during a pandemic.

3.4 Commandeering

The governor, state director of emergency management, or a member of a local or state emergency management organization selected by the governor may commandeer medical supplies and facilities for purposes of emergency management. Likewise, requiring service by an individual for emergency management falls under commandeering.[47] Mandatory service is discussed in the section on workers (3.3.3 above). The owner of commandeered goods must be paid just compensation for the use of the resource or property and for any damages that may occur during such use. Likewise, the owner of commandeered goods may appeal within 30 days to the district court in the county in which the goods or property were commandeered.[48] Medical supplies can only be taken from a healthcare facility if the health care provider considers the resources non-essential to the continued operation of the provider's practice or facility. Medical facilities will require all of their resources during a pandemic, thus it is not logical to consider them a source of resources for commandeering. The state cannot commander medical supplies that are an individual's personal property

47 Minn. Stat. § 12.34 subd. 1.

48 Minn. Stat. § 12.34 subd. 2.

being used by that individual. Thus only private, non-healthcare businesses are possible candidates for commandeering resources.[49]

The state would like businesses to stockpile resources for the sake of continuity during a pandemic. The risk of commandeering resources would decrease the likelihood of pre-pandemic stockpiling in the private sector. For this reason the state government has made it very clear that it would strongly prefer not to commandeer resources during a pandemic.

3.5 Quarantine and Isolation

Quarantine and isolation are tools that the commissioner of health may employ to prevent spread of disease in specific circumstances. Quarantine is the limitation of activities and movement of persons without symptoms who are believed to have been exposed to a specific contagious disease for the purpose of preventing the spread of said disease. Isolation is the restriction of activities and movement of persons who are known to be infected.[50] A person can be placed in quarantine or isolation if he or she has or may have certain communicable diseases believed to be caused by bioterrorism or a new, novel, or previously controlled or eradicated airborne, infectious agent or toxin.[51] This does not apply to diseases that require direct contact such as those that are sexually transmitted, bloodborne, or transmitted through direct skin contact.[52]

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49 F Livingston, presentation, July 17, 2007

50 Minnesota Department of Health. Minnesota Department of Health Pandemic Influenza Plan: Attachment B: Glossary. March 2006 [cited 2 April 2008]; Available from: http://www.health.state.mn.us/divs/idepc/diseases/flu/pandemic/plan/b-glossary.pdf

51 Minn Stat. § 144.419 Subd. 1.

52 Minn. Stat. § 144.4172 Subd. 5.

Persons infected with pandemic influenza would be eligible for quarantine and isolation due to its airborne spread. Procedures and standards of care for quarantine or isolation are spelled out in Minnesota Statutes 144.419 and 144.4195. Any person may refuse medical testing, treatment, and examination, but a person who refuses to act as ordered by the commissioner may be subjected to quarantine or isolation[53]. An appeals process for persons isolated or quarantined is outlined in Statute 144.4195. It appears likely that quarantine and isolation will only be used to try to contain the outbreak at the very beginning of the pandemic. Once pandemic influenza has spread through the population it is illogical to use legal enforcement of quarantine or isolation[54].

3.6 Safe Disposition of Dead Human Bodies

The governor is permitted to take direct measures to ensure safe disposition of dead human bodies including "transportation, preparation, temporary mass burial, and other interment, disinterment, and cremation of dead human bodies."[55] The statute states that the governor is encouraged to respect cultural customs, family wishes, religious rites, and pre-death directives to the extent possible in a pandemic.[56] The aftermath of Hurricane Katrina provides ample evidence of the strong moral and cultural importance

53 Minn. Stat. § 144.419 Subd. 4.

54 Minnesota Department of Health. Mitigation Strategies: Use of Non-pharmaceutical Interventions. April 2007 [cited 29 March 2008]; Available from: http://www.health.state.mn.us/divs/idepc/diseases/flu/pandemic/plan/npioverview.pdf

55 Minn. Stat. § 12.381 subd. 1

56 Ibid.

of the respectful treatment of the dead.[57] The statute also outlines the process required for identification of bodies.[58]

Recommendation regarding emergency powers:

3.1 The Protocol Committee recommends that rather than relying upon state power to mandate provision of services, employers create emergency plans with their employees prior to a pandemic in order to best address issues such as absenteeism.

4. Standards of Care

Both the Panel and the Protocol Committee discussed the potential need for the creation of standards of care that should prevail in a severe pandemic, at least during certain phases. According to the federal Agency for Healthcare Research and Quality:

> [I]t is possible that a mass casualty event … could compromise, at least in the short term, the ability of local or regional health systems to deliver services consistent with established standards of care.[59]

Although there appears to be some controversy over whether "adjusted" standards of care would be needed in a pandemic,[60] the disagreement actually surrounds the question of what the pandemic standards of care ought to be, not whether they will likely be needed. Thus, for example, there are questions about whether pandemic standards

57 Clark, Mary L. Keep Your Hands Off My (Dead) Body: A Critique of the Ways in Which the State Disrupts the Personhood Interests of the Deceased and His or Her Kin in Disposing of the Dead and Assigning Identity in Death; Rutgers L. Rev. 2005-2006; 92: 58.

58 Minn. Stat. § 12.381 subd. 2

59 Altered Standards of Care in Mass Casualty Events. Prepared by Health Systems Research Inc. under Contract No. 290-04-0010. AHRQ Publication No. 05-0043. Rockville, MD: Agency for Healthcare Research and Quality. April 2005, accessed 3/12/08 at http://www.ahrq.gov/research/altstand/altstand.pdf.

60 See, e.g., Koenig KL, Cone DC, Burstein JL, Camargo Jr. CA. 2006. Surging to the Right Standard of Care. Academic Emergency Medicine 13(2): 195-198. Hick JL, O'Laughlin DT. 2006. Concept of Operations for Triage of Mechanical Ventilation in an Epidemic. Academic Emergency Medicine 13 (2): 223–229.

of care ought to be based solely on meeting health needs or whether other factors – e.g. key worker status, or age – should be taken in account in making decisions about allocating resources. The preliminary Panel report for the Minnesota Pandemic Ethics Project provides guidance on how to answer these questions.[61]

Pandemic standards of care would presumably play two roles. First, they would give providers guidance about how to handle the challenges they will face during a pandemic. With respect to this role, the Protocol Committee recommends that any guidance issued for pandemic response provide local service providers with the flexibility that they will need to respond to the particularities of the contexts in which they work, while also protecting against acts of discrimination based on personal bias, etc. Differences in availability of trained providers or resources, levels of risk predominant in different populations, and other factors may create local variations in need and response capacity. One size will not necessarily fit all.

Second, pandemic standards of care may serve to protect providers from liability if they practice in accordance with them, especially if a pandemic forces choices that deviate from currently established standards of care, for example, withdrawing patients from ventilators without patient or family consent in order to allocate the ventilator to another patient when demand exceeds supply or in other ways acting contrary to a patient's advance directive (see section 3.3.1 above). In such a circumstance, it should be noted

61 Vawter et al. January 30, 2009

that many norms of good care should carry over from non-pandemic standards. For example, if patients face the realistic prospect that they may be removed from a ventilator if another individual in need is judged to be a better candidate, then these possibilities must be carefully explained to patients and their families throughout the process in which decisions concerning care are made.

Moreover, the Protocol Committee strongly recommends that even in the highly challenging context of a pandemic, providers not be fully immunized from liability; there must be safeguards and protections for patients as well. The Emergency Management Act and other laws on professional health care services may need to be reviewed in the novel context of a pandemic to determine the need to offer greater legal protection to responders, and the appropriate balance between liability protections and safeguards for patients. The Protocol Committee counseled that issues concerning liability may become even more complicated if state action is involved in the establishment of standards of care, as state action may trigger constitutional protections of due process and equal protection. If Medicare and Medicaid rules apply to a facility, the liability issues may become even more complex. The Protocol Committee urges that further discussion of these complicated issues is needed, incorporating public health, medical, moral and legal analysis. Thus, the committee recommends that MDH assemble a working group of relevant experts to provide direction on these issues.

Recommendations regarding standards of care:

4.1 The Protocol Committee recommends that any guidance issued for pandemic response provide local service providers with the flexibility that they will need to respond to the particularities of the contexts in which they work, while also protecting against acts of discrimination based on personal bias, etc.

4.2 The Implementation Team recommends that, even with the adoption of pandemic standards of care, many norms of good care carry over from non-pandemic standards. For example, if patients face the realistic prospect that they may be removed from a ventilator if it is needed by another, then these possibilities must be carefully explained to patients and their families throughout the process in which decisions concerning care are made.

4.3 The Protocol Committee strongly recommends that even in the highly challenging context of a pandemic, providers not be fully immunized from liability; there must be safeguards and protections for patients as well.

4.4 The Protocol Committee recommends that MDH assemble a working group of relevant experts to provide direction on the complex issues concerning the establishment of pandemic standards of care and appropriate provisions for liability. It is of great importance that emergency plans are meticulously written and that further policy maker guidance be sought on life-and-death issues such as the removal of a patient from a ventilator against the patient's wishes or those of the patient's family. The Emergency Management Act and other laws on professional health care services may need to be reviewed in this novel context to determine the need to offer greater legal protection to responders, and the appropriate balance between liability protections and safeguards for patients.

5. Implementing Rationing Criteria

5.1 Status as a Key Worker for Essential Functions

The ethical frameworks recommend prioritizing certain workers for access to certain resources, on the grounds that their functions are critical to limiting deaths due to degradation of the health care, public health, and public safety infrastructure in the state. Preserving vital infrastructures will serve to benefit and protect the public's health and safety. Federal and state agencies are already working across sectors to operationalize such a priority for these key workers for essential functions. The Minnesota Pandemic Ethics Project will neither duplicate nor supplant those efforts.

However, the Panel and Protocol Committee recommend that the implementation of this criterion for rationing adheres to certain principles. The fundamental justification for prioritizing these workers for access to resources stems from the need to preserve vital infrastructures so that the public may be best protected. The process for identifying workers as key should reflect this justification. It must be recognized that different sorts of emergencies will impact social infrastructures in different ways. For example, the detonation of a dirty bomb at the Mall of America poses a very different threat than pandemic influenza. The widespread absenteeism anticipated with a severe pandemic could weaken critical infrastructure systems that provide clean water or power, for example, while the bomb may not do so. Thus, the Minnesota Pandemic Ethics Project team recommends that the decision about which workers to identify as key should be understood to be an event-dependent one. It also notes that the definition of "key

workers for essential roles" developed in this project recognizes that some volunteers may play such essential roles during a pandemic, and processes for identifying key workers should consider the role of volunteers.

When deciding which workers ought to be identified as key in a pandemic, other rationing priorities must also be kept in mind. It is vital to protect key workers, since doing so helps to protect the public. However, the ethical frameworks also recommend that some individuals be prioritized for access to resources based upon their health needs, completely independent of their work roles. As the preliminary Panel report emphasizes, a balance must be struck between these two strategies for protecting the public's health. As the numbers of workers identified as key increases in size, the supply of resources available to care for the pressing health needs of others diminishes. No preordained limit can be applied to processes for identifying key workers. However, these processes should reflect a commitment to strive for balance between these two recommended strategies.

Once decisions are made about which types of workers should be deemed key during a pandemic, individual workers who may receive priority on these grounds should be identified, in cooperation with workplaces, in advance of a pandemic. This pre-identification of individual workers will facilitate their access to resources when it is needed.

5.2 Health Need

As noted above, the ethical frameworks recommend that individuals sometimes be prioritized for access to resources based on their health needs. On this recommendation, greater levels of risk of illness and death from influenza warrant higher prioritization for access to resources, so long as the resource can be used safely and to good effect by the persons in question. This recommendation straightforwardly reflects commitments to protect the public's health and to treat people fairly.

Some difficulties arise with its implementation. First, it may be difficult to determine which groups suffer which levels of risk, especially early in the pandemic when little information exists about the disease threat being faced. This uncertainty may pose little actual difficulty in certain situations. For example, early in the pandemic, when uncertainties about the epidemiology of influenza are most likely to be a problem, the Panel report assumes that there may be little shortage of antiviral medications and thus little need to distinguish between levels of risk suffered by different individuals or groups. All eligible patients could receive antivirals in this scenario, where eligibility is defined in terms of the safety and potential effectiveness of these medications for the patients in question. In any case, as the pandemic proceeds, greater understanding of its epidemiology will be gained, and judgments about levels of risk may be supported by greater evidence. Section 1 of this report on inequalities of access to resources outlines the public health partnerships that will be required in the state to promote this greater understanding. Section 7 proposes a process for ethics consultation that could address unforeseen issues that may arise as information is gathered about the epidemiology of the pandemic.

Second, judgments about the levels of risk faced by particular individuals will often require access to individually identifiable health information. For example, a patient's pre-existing lung disease may place him or her at higher risk of mortality from influenza. However, medical records may not be easily available, especially when care is provided at sites other than the patient's usual clinic or hospital. Moreover, the Protocol Committee strongly feels that current privacy protections should be enforced despite the need for health information when making rationing decisions. Thus, access to health records cannot be presumed, and patients' self-reports should be accepted as guiding rationing decisions where possible. The framework for rationing ventilators recommends that decisions concerning this resource take into account objective clinical assessment measures such as Sequential Organ Failure Assessment (SOFA) scores, and so cannot rely substantially on patients' self-reports.

5.3 Age

Age has not been recommended by the Panel as a criterion for rationing decisions as key worker status and health need have been. However, since the question of whether, and if so when, to ration based on age was deliberated so carefully and seriously by the Resource Allocation Panel and various resource specific work groups, the Protocol Committee's consideration of the issues related to implementing such a possible criterion is included here.

As the Panel report explains, age can be used in two ways in rationing decisions. It can be a factor to consider in assessment of risk or prognosis for particular individuals or groups of individuals. Perhaps, for example, evidence indicates that antivirals are not safe and effective in infants, or that morbidity and mortality risks for seasonal influenza are especially high for the elderly. Resource allocation decisions need to take such information into account. For example, it may be recommended that infants not be prescribed antivirals. When there are shortages of seasonal influenza vaccine, it might be recommended that the elderly be given priority in vaccination. However, these allocation decisions are not based on age per se, but on information about health risks and prognoses faced by members of certain age groups. That is, they are clinically-based decisions, not truly age-based decisions. Were the risks to shift – e.g., if an antiviral that is safe and effective for infants were to become available – the allocation decisions would presumably also be modified. Assuming that evidence supports the correlation between age and health risk or prognosis, this use of age raises no special moral issues. Questions may arise as to verify an individual's age so that it can be properly factored into decision-making. Here, as with health status, there may be no option but to rely upon self reporting.

On the other hand, age has also been considered as a criterion for rationing quite distinct from its correlation to health considerations such as risk and prognosis. Is there a special obligation to provide first for children when not all can be given resources? Should younger adults be prioritized for care over older adults, on the grounds that the latter have already had more of an opportunity to live a fuller life? To

answer these questions in the affirmative is to endorse truly age-based (as opposed to clinically-based rationing). The Panel report grapples with the moral issues involved in age-based rationing. While it does not recommend that age per se function as a criterion for rationing resources, it does recognize the significance of the debate and outlines the moral controversies. The Protocol Committee recommends that the community engagement process seek public input on the issue of genuinely age-based rationing.

The prospect of age-based rationing raises implementation issues concerning the possible violation of age discrimination law. The Protocol Committee identified several state and federal laws that could be relevant to this issue but did not perform a thorough legal analysis of those acts or case law. Under the Minnesota Human Rights Act (MHRA), age discrimination is illegal in education and employment. However, age is not a protected characteristic in access to public services or public accommodations — the areas included under the act most directly relevant to the rationing of health resources in pandemic. Thus, it appears that rationing based on age would not violate the MHRA. Similarly, the federal Age Discrimination in Employment Act is limited in scope, applying only to the context of employment.

However, the federal Age Discrimination Act of 1975 prohibits age discrimination in programs or activities that receive financial assistance from the federal government. It states, “no person in the United States shall, on the basis of age, be denied the benefits of, be excluded from participation in, or be subject to discrimination under, any program

or activity receiving Federal financial assistance."[62] Given the federal support involved in the Strategic National Stockpile program, the Age Discrimination Act may apply to state guidelines for rationing resources during pandemic. Medicare and Medicaid providers must also comply with the Age Discrimination Act.[63] It should be noted that the Age Discrimination Act allows for exceptions when programs involving age-based decisions are adopted by an elected legislature. Should the state legislature adopt a statute permitting age-based rationing in a pandemic, this use of age would appear to be permitted by the Age Discrimination Act. However, it does not appear that the governor can set aside the protections of the Age Discrimination Act under state emergency powers. The Age Discrimination Act also may not prohibit actions that have a disproportionate impact on persons of different ages, if the actions are based on "reasonable factors other than age."[64] Thus, it appears that the clinically-based decisions described above would not violate the Act even if they have a disproportionate effect on persons of different ages.

Protocol Committee members raised the possibility that other legal requirements concerning age discrimination may also apply to the implementation of a plan for rationing health supplies and services. Given the complexity of these legal issues, the Protocol Committee recommends that age-based rationing be undertaken only after a legal determination is made on behalf of the State that such actions are compatible with federal and state laws on age discrimination. If the community engagement process

62 45CFR91.11

63 US Dept. of Health and Human Services, Office of Civil Rights. 2007. Accessed on 3/13/08 at http://www.hhs.gov/ocr/discrimother.html

64 45CFR91.14

reveals broad, strong support for age-based rationing, the state should undertake such a legal analysis to assess whether, and if so how, age-based rationing could be implemented.

Recommendations regarding the implementation of rationing criteria:

5.1 The Minnesota Pandemic Ethics Project team recommends that the decision about which workers to identify as key be understood to be an event dependent one.

5..2 The Protocol Committee notes that the definition of "key workers for essential roles" developed in this project recognizes that some volunteers may play such essential roles during a pandemic, and recommends that processes for identifying key workers consider the role of volunteers. The Protocol Committee concurs with the Panel in this regard.

5.3 The Protocol Committee recognizes that no preordained limit can be applied to processes for identifying key workers, but recommends that these processes reflect a commitment to strive for balance between the Panel's two recommended rationing strategies of prioritizing key workers and prioritizing those groups in the general public who are at greatest risk for morbidity and mortality. The Protocol Committee's deliberations were consistent with those of the Panel on this issue.

5.4 The Protocol Committee recommends that, once decisions are made about which types of workers are deemed key during a pandemic, individual workers who may receive priority on these grounds are identified, in cooperation with

workplaces, in advance of a pandemic. This pre-identification of individual workers will facilitate their access to resources when it is needed.

5.5 The Protocol Committee recognizes that medical records may not be easily available when making rationing decisions, and strongly feels that current privacy protections be enforced despite the need for health information when making rationing decisions. Thus, access to health records cannot be presumed, and the Protocol Committee recommends that patients' self-reports be accepted as guiding rationing decisions where possible.

5.6 The Protocol Committee recommends that the community engagement process seek public input on the issue of genuinely age-based rationing. The Protocol Committee's deliberations were consistent with those of the Panel on this issue.

5.7 The Protocol Committee recommends that age-based rationing be undertaken only after a legal determination is made on behalf of the State that such actions are compatible with federal and state laws on age discrimination. If the community engagement process reveals broad, strong support for age-based rationing, the state should undertake such a legal analysis to assess whether, and if so how, age-based rationing could be implemented.

6. Protections For The Public

The people of Minnesota will be affected in many ways by pandemic response plans. The challenges inherent in pandemics impose extraordinary responsibilities on those who affect the lives and well-being of others – the state government, and public health and health care providers among them. As the preliminary Panel report states, decision-making must be "accountable, transparent and worthy of trust."[65]

There are a number of ways that these responsibilities can be met. First, planning must seriously and thoughtfully engage the moral issues raised by pandemics. MDH has exhibited a commitment to these responsibilities through its investment in the Minnesota Pandemic Ethics Project, including the process of community engagement now built into the project.

In the midst of pandemic, challenges will likely arise that were not foreseen in the planning process. No planning process can possibly anticipate all of the contingencies that may need to be faced during an emergency, especially when planning must be done before much is known about the disease threat being faced, the effectiveness of various public health and clinical resources in relation to that threat, the levels of resource abundance or scarcity, the capacity of various institutions to respond to the threat given absenteeism, and so on. The Implementation Team recommends the use of a process for ethics consultation, to help address these issues as they arise. This

65 Vawter et al. January 30, 2009.

process will be described in section 7 below, with recommendations for its implementation.

The Protocol Committee feels strongly that, during a pandemic, decisions about allocation of resources must be monitored to ensure that they are made in as principled and effective a way as possible. Discussion in the committee about this need for monitoring focused on the case of decision-making concerning the allocation of ventilators in hospitals. In this case, the Panel recommends that wherever possible, a multidisciplinary triage team, distinct from the providers working at the bedside, make decisions about how to allocate ventilators among individual patients. Multi-hospital triage teams could be formed for smaller facilities with insufficient providers to allow the triage team to be distinct from the team providing care at the bedside. Using triage teams, when possible, frees providers at the bedside to serve as advocates for their patients, and avoids the conflicts of interest inherent in working to care for a patient while at the same time being responsible for decisions about what resources that patient may receive.[66] . The Protocol Committee recommends that this triage team, perhaps with the input of others such as an ethics consultation team, also conduct routine retrospective review of decisions made, so that the decision-making process can be improved or adjusted as needed. Of course, ventilators are not the only resources that raise moral issues; it is equally important that all resources be allocated fairly and effectively. Thus, the Protocol Committee recommends that any institution that delivers care create a local process for routine retrospective performance reviews. These

66 J. L. Hick, D. T. O'Laughlin, Concept of Operations for Triage of Mechanical Ventilation in an Epidemic, Academic Emergency Medicine, 2006;3(2):223-229.

processes will vary from one type of institution to another, given differences between institutions and among resources being allocated. The discussion of ethics consultation (section 7 below) will provide guidance on the development and implementation of these processes.

While such routine monitoring of rationing will help to ensure that it is done appropriately, it does not serve the same purpose as processes that provide a way for individuals or their families to question the procedural and substantive propriety of decisions. Only a process for real time review of decisions can supply such a safeguard. A patient's family may wish to request review of a decision that the patient be withdrawn from a ventilator, for example. Or an individual who is denied access to antiviral medication may wish to have his or her status as a key worker verified to demonstrate that she fits rationing criteria. There are time pressures involved in these decisions. Lengthy deliberation of a family's request for review of a decision to remove their loved one from a ventilator could cost others their lives. Since antiviral medications need to be administered in the first two days of illness to be effective, time-consuming processes for performing real time reviews of decisions could delay access for the patient who requests such a review as well as for others. Complicated review processes would further strain care systems that may already be stretched beyond capacity due to the burden of illness. Thus, complicated, protracted review processes would undermine the fair and effective allocation of resources. For this reason, the

implementation of such real time review processes is controversial.[67] However, the Protocol Committee feels that the safeguard of such a process should be available, and thus recommends the development and implementation of a time limited, simple process to allow for real time reviews while avoiding the unacceptable consequences described above. The Implementation Team recommends that the process for ethics consultation outlined in section 7 below serve this purpose. Since this discussion proposes ethics consultation at multiple levels – state, regional and local – it can be adapted to retrospective and real time reviews of decision-making for each resource. For example, mass distribution of vaccines and antivirals may warrant retrospective and real time review at regional or multi-region levels whereas ventilator-related reviews may need to operate at regional levels only at the height of a pandemic wave and can otherwise operate at the institutional level.

Real time reviews that provide triage personnel with additional information could be relatively simple to resolve using this mechanism. For example, there may be cases in which an initial denial of access to a vaccine or antiviral medication is reviewed on grounds of missing information about the individual's status as a key worker. On the other hand, individuals may also wish to mount reviews based on grounds that are inconsistent with the ethical frameworks for rationing – e.g., purely personal reasons ("You can't let my father die!") or reasons relating to perceived social worth ("You can't

67 Indiana University Center For Bioethics. (2007). Pandemic Flu Preparedness: Ethical Issues and Recommendations to the Indiana State Department of Health. NYS Workgroup On Ventilator Allocation In An Influenza Pandemic Nys Doh/ Nys Task Force On Life & The Law. (2007, Mar. 15), p. 32. Allocation of Ventilators in an Influenza Pandemic. Tia Powell, Md, Kelly C. Christ, Mhs, And Guthrie S. Birkhead, Md, Mph. (2008). Allocation of Ventilators in a Public Health Disaster. Disaster Medicine and Public Health Preparedness, 2, 20-26; Ontario Health Plan for an Influenza Pandemic Working Group on Adult Critical Care Admission Discharge and Triage Criteria. (2007). Critical Care During a Pandemic. pp. 13, 25. Hick, J, et al., (2007). Clinical review: Allocating ventilators during large-scale disasters - problems, planning, and process. Critical Care, 11, 217. ,

deny me a vaccine if you are going to vaccinate _____", where the blank is filled in with reference to some individual or social group deemed to be less socially worthy by the individual raising the objection). While these types of objections may be unfortunate and heart-wrenching, they are also potentially catastrophic if they are allowed to move forward in review processes. Such cases would not only add unnecessary and inappropriate strain on the system for conducting reviews, but if they are successful, they could undermine public trust in the rationing system. Thus, the Protocol Committee recommends that real time reviews be considered only on grounds that are consistent with the ethical frameworks that are adopted to guide decision-making.As explained in section 7, the determination of the relevant ethics consultation process is unilateral.

Recommendations regarding protections for the public:

6.1 The Protocol Committee recommends that, during a pandemic, decisions about allocation of resources must be monitored to ensure that they are made in as principled and effective a way as possible. Thus, the committee recommends that any institution that delivers care during a pandemic create a local process for routine retrospective performance reviews. These processes will vary from one type of institution to another, given differences between institutions and among resources being allocated.

6.2 The Protocol Committee recommends the development and implementation of a time limited, simple process to allow for real time reviews of rationing decisions.

This process provides a safeguard for individuals or their families to question the procedural and substantive propriety of decisions at the time they are made.

6.3 The Protocol Committee recommends that real time reviews be considered only on grounds that are consistent with the ethical frameworks that are adopted to guide decision-making.

6.4 The Implementation Team recommends implementation of retrospective and real time reviews of decision-making involve the process for ethics consultation outlined in section 7 below. Since this proposed process for ethics consultation would work at multiple levels – state, regional and local – it can be adapted to retrospective and real time reviews of decision-making for each resource.

7. Ethics Consultation

To address the task of developing a plan for ethics consultation during a pandemic stipulated in the Minnesota Pandemic Ethics Project contract, a working group was convened by the implementation team comprising adult and pediatric clinical ethicists (Mary Faith Marshall and Donald J Brunnquell) in consultation with a representative of MDH (Patricia Bloomgren). The clinical ethicists involved are professionals who direct ethics committees and consultation services at public, private and academic health care organizations in Minnesota . The plan was reviewed by outside expert Art Derse, M,D., JD, Director for Medical and Legal Affairs, and Associate Director, Center for the Study of Bioethics, Professor of Bioethics and Emergency Medicine, Medical College of Wisconsin, and consultant to the state of Wisconsin for pandemic planning. This section will (1) outline a systematic model for ethics consultation that responds in a dynamic fashion to a broad range of evolving issues, and (2) recommend an implementation structure.

Ethics consultation during a pandemic will occur on multiple levels relative to a variety of needs. The process will, of necessity, encompass disparate approaches to health care ethics, including those that respectively inform public health, mass casualty medicine, “ordinary” clinical medicine, and healthcare organizational governance. The primary function of ethics consultation, as it endeavors to assist others in resolving pandemic-related ethical issues, will be to facilitate consistent application of the ethical framework(s) for the allocation of scarce resources.

During a pandemic a structured approach for identifying, analyzing and resolving ethical issues will be needed at three organizational levels:

- MDH
- The region (networks of healthcare or other organizations), and
- The institution (individual facilities and at the bedside).

Ethics consultation is a familiar process in the majority of healthcare institutions, as most healthcare organizations are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). JCAHO accreditation standards for patient rights and organizational ethics require a mechanism for the resolution of ethical problems.[68] While JCAHO does not mandate a particular method, most healthcare organizations use consultation by an ethics committee, an ethics consultation service, or a professional ethics consultant. Core competencies for ethics consultation have been promulgated by the American Society for Bioethics and Humanities.[69]

The two traditional domains of ethics consultation are clinical and organization ethics. Research ethics consultation is a less frequent, but growing service. Within the two domains, consultation may address a spectrum of issues ranging from individual cases at the bedside to broad issues of organizational policy.

68 Joint Commission Resources: 2008 Comprehensive Accreditation Manual for Hospitals, RI Chapter, Patient Rights and Organizational Ethics Standards, Oakbrook Terrace, Ill: Joint Commission on Accreditation of Healthcare Organizations, 2008, RI-1 – RI – 18.

69 Core Competencies for Health Care Ethics Consultation, American Society for Bioethics and Humanities.

The traditional goals of ethics consultation in the clinical, organizational and research settings will continue to serve the needs of MDH, institutions and individuals, albeit in fundamentally altered circumstances. In a severe pandemic, the "rescue paradigm" of mass casualty medicine, with the goals of preserving and protecting life and minimizing pain, will supersede the more familiar paradigm of "ordinary clinical medicine" with its focus on respect for autonomy and shared decision making."[70] Issues of justice and fairness as understood and articulated in the ethical framework will be paramount in moral decision making.

Thus, the goals of ethics consultation during a pandemic will be:

- To assist state officials and healthcare professionals to recognize and resolve ethical problems as the pandemic unfolds;[71]
- To facilitate consistent and fair application of the ethical frameworks for the allocation of scarce resources;
- To facilitate communication and effective decision making in resource allocation and patient care;
- To foster greater awareness among state officials and health care professionals on the role of professional values and norms in public health, clinical and organizational decision making during a pandemic;
- To prevent and minimize harm to members of the public, patients, healthcare professionals and institutions.

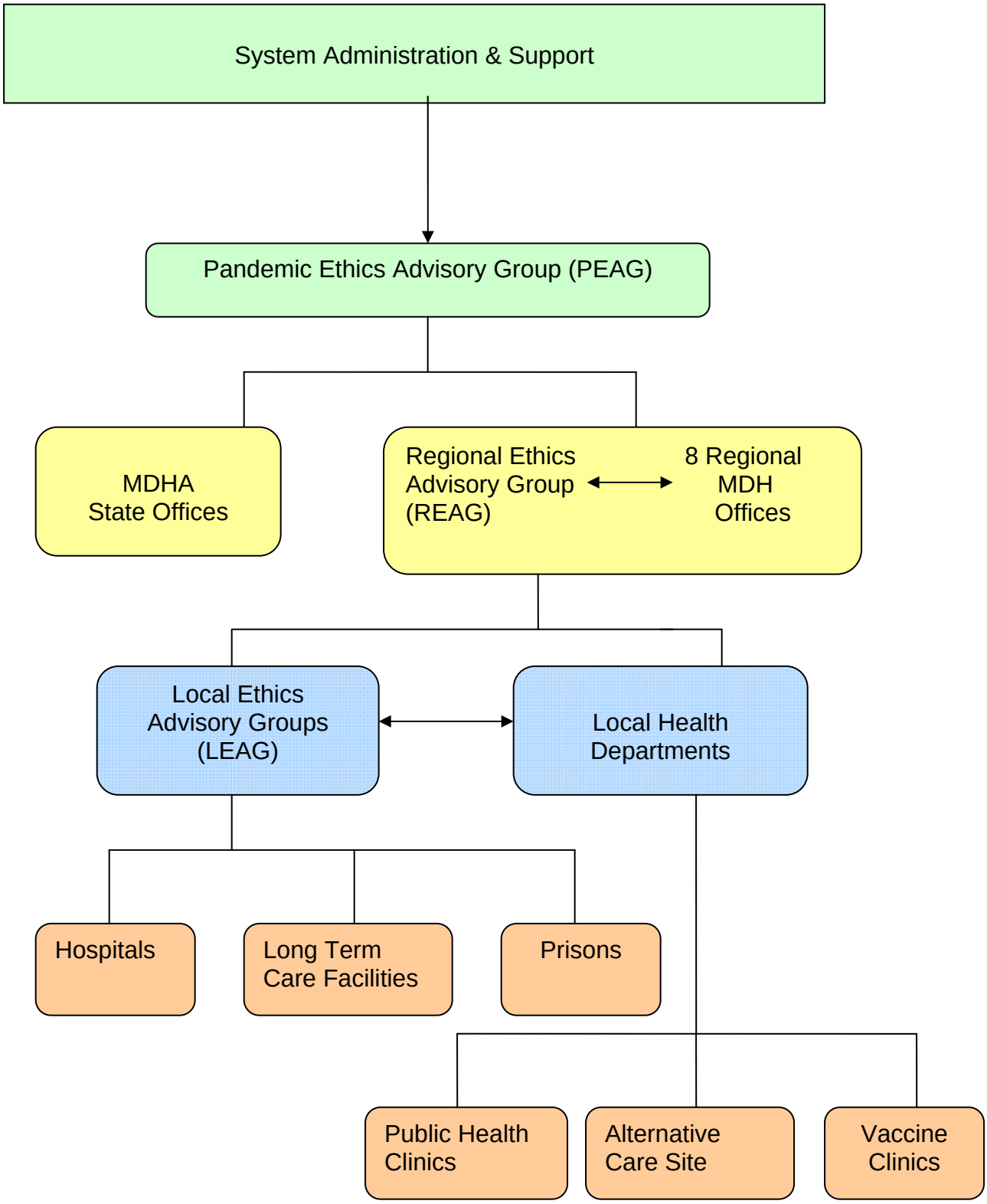
70 Trotter G. The Ethics of Coercion in Mass Casualty Medicine, 2007 Johns Hopkins University Press

71Fletcher JC, Lombardo P, Marshall MF, Miller F, eds. Introduction to Clinical Ethics, 2 ed., University Publishing Group, 1997

These goals must be augmented by consultation services tailored to the specific needs of consultees at various levels. To accomplish this, the Implementation Team recommends a model for ethics consultation based on the organizational scheme articulated above. This would be a hierarchical system that corresponds to the organization of the Minnesota Department of Health in its state, regional and local capacities and to regional and local networks of healthcare organizations. This organizational scheme would optimize effective communication between ethics consulting services (which are traditionally organized in a similar hierarchy of local, regional and statewide networks) and MDH, as well as with constituent healthcare organizations, and the public at large.

The ethics consultation model would comprise a centralized resource, known as the Pandemic Ethics Advisory Group (PEAG) to advise both MDH at the state level, and a regional network of ethics committees (Regional Ethics Advisory Group or REAG). REAG would operate in concert with the eight regional offices of MDH. In addition to providing consultation to regional MDH officials, this network would coordinate resources for local, or institutional, ethics committees (Local Ethics Advisory Groups or LEAG) and local health departments. At the local level, ethics services would need to be coordinated among institutions such as long term care facilities, prisons, or other healthcare entities that may lack mechanisms for ethics consultation. The figure below illustrates this system:

System for Ethics Consultation During a Pandemic



PEAG would comprise ethics consultants from facilities and institutions around the state, experts in public health, and members of the Minnesota Pandemic Ethics Project's Ethics workgroup. In addition to serving as a resource for MDH, it would be responsible for coordinating REAG and LEAG activities. PEAG would promulgate policies and protocols for access to and the process of ethics consultation. It would respond to evolving issues surrounding both macro and micro allocation of resources such as antivirals, vaccines, personal protective equipment, ventilators, and emerging new technologies. It would develop educational tools and programs for ethics consultants at all levels. The Program in Clinical Ethics at the University of Minnesota's Center for Bioethics could serve as an administrative home for the enterprise. The Program in Clinical Ethics, in concert with the University of Minnesota Medical Center, Fairview, coordinates the largest and most frequently used ethics consultation service in the state, a service that other institutions have replicated. Administrative details about funding, selecting a program to provide the overall system, evaluation of performance, and contract management would be the responsibility of MDH.

A central criterion for the organization of ethics consultation mechanisms at each level is that they are multidisciplinary, and include ethics expertise, experts in public health, and community representation. They should, ideally, reflect the demographics and cultures of their communities. This obtains throughout the organizational hierarchy, from

PEAG to REAG to LEAG. Ethics consultation availability should be 24/7 via teleconferencing mechanisms (most frequent) or an on-site presence (less likely given contagion concerns, but certainly possible in some contexts).

Initial and continuing education of ethics consultants regarding the ethical framework, policies and procedures adopted by MDH, and general principles and practices of ethics consultation are central to an effective system. This would be accomplished via initial statewide and regional workshops hosted by MDH and conducted by members of the PEAG. In addition, annual training and continuing education would address new developments and knowledge, and changes in the moral framework adopted by MDH.

A PEAG website and online educational programs, in concert with continued workshops would serve to disseminate information to regional and local ethics consultants (PEAG and LEAG). The website would be a central resource for bi-directional information dissemination throughout the network as the pandemic unfolds. It would be a means for coordinating documentation of consultation reports statewide. The website would also provide a mechanism for community access and engagement.

During a pandemic, ethics consultation should be sought when:

- The efforts of MDH staff, government officials, or health providers have reached an impasse in attempts to resolve an ethical problem. This circumstance indicates a “tipping point” for generating consultation.

- The ethical problem involves a serious disagreement or dispute among those involved. At the local level, this would include the aforementioned review mechanism (LEAG) that patients or families could avail themselves of to resolve disagreements about initial or continued access to clinical resources. It would also address disagreements among clinicians and between bedside caregivers and members of triage teams.
- The issue is unusual, unprecedented, or very complex ethically. As the pandemic evolves, uncertainties, newly available knowledge, and unforeseen contingencies will provide challenges to state and local officials. This represents a second tipping point for ethics consultation.
- The need arises to review the policies and practices that have emerged in the pandemic and to advise MDH on measures to alter or improve them.

The primary role of the Local Ethics Advisory Groups will be to serve as a review mechanism for patients, family members, or others serving as patient advocates. They will, most likely, receive consultation requests from institutional staff on a less frequent basis. The function of LEAGs in the review process is not to second guess clinical decision making by triage teams, but to ensure fair and consistent application of the ethical framework adopted by their institutions. Because such a review mechanism could be easily overwhelmed by family members desperate for access to potentially lifesaving resources, it is crucial that prospective review criteria and procedures be clearly articulated during the PEAG planning process. It is likely that small review teams with staggered membership, who can review records electronically and communicate

via teleconference will be the most effective mechanism for dealing with initial high volumes of requests for review.

LEAGs will also serve as ethics resources for local health departments. Controversies that arise in the allocation of resources such as vaccines or antivirals in public health clinics or alternative care sites will also be resolved through the use of this mechanism.

It is crucial that the LEAG's findings regarding individual cases be determinative and unilateral at the institutional level. It is anticipated that findings contravening triage team decisions would be rare. Any instance of a contravention would require mandatory reporting to institutional administrators, the REAG and the PEAG. The REAG and/or the PEAG have the responsibility and prerogative to provide oversight and assistance to LEAGs. The REAG or the PEAG will, at their own initiatives, monitor individual case reviews on a for-cause or random basis.

As it does in normal circumstances, the ethics consultation process will reveal institutional or system inequities in addition to concerns with individual cases. The case review process will thus provide a method for real time institutional oversight. Ethics advisory bodies will serve as a safeguard by providing structured and systematic retrospective process/performance reviews to ensure compliance with and consistency in the application of the ethical frameworks. These reviews should be conducted in concert with representatives of the institutional triage teams.

Monitoring collective reviews on a routine basis would be the responsibility of the PEAG. This would facilitate consistent application of the framework regionally and statewide. The PEAG would thus be positioned to discover system, multi-institutional or regional inequities, e.g. that patients in hospitals are favored over patients in prisons.

Recommendations regarding ethics consultation:

7.1 The implementation team recommends that MDH sponsor an organization to develop, implement and administer a system for ethics consultation at state, regional and local levels. The system would include the development of a website and other resources for ongoing education and community engagement.

7.2 The Implementation Team recommends that this system comprise a centralized resource, the Pandemic Ethics Advisory Group (PEAG), to address issues at the state level for MDH and to develop coordinated mechanisms for review processes at regional and local levels; a regional ethics advisory group (REAG) operating in concert with the eight regional offices of MDH, and a network of local ethics committees, and local institutional ethics advisory groups (LEAG).

7.3 The Implementation Team recommends that ethics consultation mechanisms at each level of organization be multidisciplinary, include ethics expertise, public health experts, and community representation, and should reflect the demographics and cultures of their respective communities.

7.4 The Implementation Team recommends that ethics consultation be sought when those attempting to resolve an ethical problem have reached an impasse, when

the ethical problem involves a serious disagreement or dispute, or when the problem is unusual, unprecedented, or very complex ethically.

7.5 The Implementation Team recommends that the LEAG's findings regarding individual allocation decisions be determinative and unilateral at the institutional level.

7.6 The Implementation Team recommends that the PEAG provide a mechanism to review the policies and practices that have emerged in the pandemic and to advise on measures to alter or improve emerging practices.

7.7 The Implementation Team recommends that ethics advisory bodies, especially at the local level, provide structured and systematic retrospective process/performance reviews to ensure compliance with and consistency in the application of the MDH framework or the frameworks adopted by individual institutions.

8. Palliative And Hospice Care

While not representing an official charge by MDH, issues related to a widespread need for palliative and hospice care during severe pandemic were recognized early on by members of the Implementation Team. The Implementation Team considers palliative and hospice care to be of paramount importance in pandemic planning, and has thus recommended an implantation strategy that will be outlined below. The resultant recommendations are solely the result of the Implementation Team's deliberations

An estimated 33,000 Minnesotans could die during a severe pandemic. Prospective planning and the allocation of sufficient resources for compassionate care for the terminally ill are of moral significance that is equal to the just allocation of health preserving and life-saving resources. This dynamic is reflected in the primary objectives of mass casualty medicine, which are: maximizing survival, minimizing morbidity, and, when possible, minimizing pain.[72] Officials charged with pandemic planning and preparedness should strive to meet each of these ends, not just those concerned with preserving and protecting life.

During a severe pandemic, dying persons will be cared for in a variety of settings ranging from sophisticated intensive care units to alternative care sites to private homes. Those who are desperately ill and dying will be cared for not only by health care and other professionals, but by family members and friends. Clinicians who routinely

72 Trotter G. The Ethics of Coercion in Mass Casualty Medicine, 2007 Johns Hopkins University Press: 6.

encounter critical illness and death may face morbidity and mortality on an unprecedented scale, one that overwhelms both physical and psychological resources leading to compassion fatigue or post-traumatic-stress disorder. Likewise, family members and other caregivers will experience the novel and tragic challenge of shepherding loved ones through the dying process in the home care setting. In the interests of patients and their caregivers, these unfortunate circumstances mandate prospective planning for the support of end-of-life care in diverse settings, a plan that will provide the best deaths possible for the terminally ill.

Given the anticipated level of suffering of individuals, families and communities during a pandemic, the role of palliative care and hospice professionals in symptom management, communication, and grief and bereavement will be vital. Palliative care aims not to cure disease or illness, but to prevent and relieve suffering and improve quality of life. Hospice professionals provide palliative care for the terminally ill. Both palliative care and hospice professionals attend to the psychological and spiritual needs of patients and their caregivers, and provide a compassionate approach to pain and symptom management.

MDH (to promote and protect the interests of citizens who will provide and receive home care), as well as health care facilities (to promote and protect the interests of patients and clinicians) should consider the following in developing plans and protocols for the administration of palliative and hospice care:

- An adequate/stockpile of medications: primarily opioids for pain and respiratory distress, benzodiazepines for anxiety, and acetaminophen and other analgesics in multiple forms of administration for patients in facilities and home settings (emergency kits). If not prevented by pharmacologic intervention, breathlessness and anxiety will be the primary symptoms experienced by individuals with a respiratory influenza and patients undergoing ventilator withdrawal.
- A mechanism for distributing emergency kits for home and alternative site use must be developed.
- Development and distribution of symptom management protocols and algorithms for clinicians, including guidelines for ventilator withdrawal (both terminal weaning and immediate withdrawal).
- Support for families who are caring for dying loved ones with the anticipated likelihood that current hospice agencies may not be able to meet demand.
- Development of caregiver education for people in the community assisting or engaged in care of the dying. Development and distribution of symptom management protocols and algorithms for use by laypersons. This is especially important given beliefs and misconceptions about hastening or causing death with palliative medications.
- Recognition of the burden of grief on individuals, families and communities

To assist MDH in achieving these ends, the palliative and hospice care consultants to the project recommend the development of a workgroup, administered by the statewide professional organization, Hospice Minnesota, in concert with statewide palliative care programs for both implementation planning and ongoing consultation. A similar model has recently been undertaken by the state of Washington.

Recommendations regarding palliative and hospice care:

8.1 The Implementation Team recommends that MDH convene a workgroup administered by Hospice Minnesota, in concert with statewide palliative care programs, to plan and implement a process for meeting the palliative and hospice care needs of the desperately ill during a severe pandemic.

8.2 The Implementation Team recommends that the workgroup be tasked with developing recommendations for stockpiling palliative care resources, developing and promulgating symptom management protocols and algorithms, developing caregiver educational programs for members of the community, and developing a process for ongoing community engagement/communication.

CONCLUSION

There is little doubt that another influenza pandemic will occur at some point in the future. Depending on its severity, a pandemic has the potential to be a traumatic and life-changing time that will deeply test society. The pandemic of 1918 caused tremendous morbidity and mortality, and created an immense strain on the

infrastructure of our nation. In our increasingly complex world the ramifications of a pandemic are difficult to predict. The State of Minnesota has a responsibility to pursue Minnesotans' common good in pandemic planning in ways that: are accountable, transparent and worthy of trust; promote solidarity and mutual responsibility; and respond to needs fairly, effectively and efficiently.[73] Plans for rationing scarce resources in a pandemic should protect the population's health, protect public safety and civil order, and treat people fairly, recognizing the moral equality of all.[74] MDH has demonstrated a strong commitment to the ethics of pandemic planning through its support for the Minnesota Pandemic Ethics Project.

The recommendations contained in this report cohere in three overarching themes:

Equity and Fairness: MDH's commitment to individual and social justice in allocating resources during a pandemic originally motivated this project. Thus, this commitment has driven and informed the development of the ethical frameworks contained in the Panel report, and the implementation analyses contained in this report. As guiding constructs, the principles of equity and fairness justify the normative aspiration to promote the well being of all who live in Minnesota, even when their interests conflict. These principles operate not only at the level of moral theory, providing the justification for the rationing schemes, but also at the level of applied ethics. They are, therefore, apparent and inherent in the policies and procedures that provide for such procedural

73 Vawter et al. January 30, 2009.

74 Ibid.

safeguards as ongoing monitoring, decision-making review mechanisms, and public and professional protections.

The Evolving Nature of the Pandemic: It is abundantly clear that the pandemic will be dynamic in nature; it will evolve over time in response to biologic, environmental, and structural contingencies. Needs and resources will wax and wane, knowledge and understanding will grow. The systematic response of the MDH and its affiliates must mirror the dynamics of the pandemic. Strategies for accruing and assessing data, and subsequently revising and adapting response mechanisms such as allocation schemes, treatment approaches, and public engagement must be planned for prospectively, and must be inherently and responsively dynamic. This need for dynamic response highlights the critical need for a process for ethics consultation during the pandemic to address unforeseen issues in pandemic response as they arise (see section 7 above). No guideline, ethical or otherwise, can specify every contingency that may arise.

Building on Existing Strengths: MDH and the state of Minnesota are relatively well positioned to mount an effective response to pandemic. This derives from the logistics already in place on the part of a duly diligent MDH, on the above average health and educational status of many persons living in Minnesota, and on the robust social support structures effected by caring communities. Additional protections abound in the mundane entities that order our daily lives, things such as laws, standards, policies and procedures. These extant and effective public safeguards will need to be prospectively adapted for pandemic. These include, for example, legislation, professional roles and

responsibilities, standards of care, personnel plans during emergencies, and consultation mechanisms.

Many of this report's recommendations can be incorporated into current planning processes. However, some recommendations propose that additional processes be created so that the ethical frameworks may be implemented appropriately. In particular, the report urges MDH to convene a working group to provide direction on the complex issues concerning the establishment of pandemic standards of care and appropriate provisions for liability. This report identifies a number of challenges relating to these issues; further expert guidance must be sought so that emergency plans can be crafted in a way that does not run afoul of legal, ethical, or health professional standards.

Similarly, the report recommends that MDH convene a workgroup administered by Hospice Minnesota, in concert with statewide palliative care programs, to plan and implement a process for meeting the palliative and hospice care needs of the desperately ill during a severe pandemic. This workgroup should be tasked with developing recommendations for stockpiling palliative care resources, developing and promulgating symptom management protocols and algorithms, developing caregiver educational programs for members of the community, and developing a process for ongoing community engagement and communication. Given the vital role that palliative and hospice care will surely play in a severe pandemic, the importance of this task cannot be overstated.

The report provisionally recommends that legal counsel be sought on the question of whether, and to what extent, age-based rationing is consistent with federal and state laws regarding age discrimination. Although age has not yet been recommended in the ethical frameworks as a criterion for prioritizing access to resources, the community engagement process will seek the public's input on this issue. If this process reveals broad, strong support for age-based rationing, the state should undertake such a legal analysis to assess whether, and if so how, age-based rationing could be implemented.

Finally, the report recommends that MDH should sponsor an organization to develop, implement and administer a system for ethics consultation at state, regional and local levels. The Implementation Team provides a detailed outline for such a system. This report highlights a number of services that could, and indeed should, be provided by a system organized in this way: to provide advice on the implementation of the ethical frameworks during an influenza pandemic; to offer expert judgment on the possible need for updates to the frameworks or implementation analyses as planning continues prior to a pandemic; to assist as needed with routine retrospective reviews of rationing decisions during a pandemic, to help ensure that they remain faithful to the ethical frameworks, and to aid in resolving real time reviews of rationing decisions during pandemic. Thus, ethics consultation plays a critical and very central role in the implementation of the ethical frameworks for rationing.

Given that this is a preliminary report, some members of the Minnesota Pandemic Ethics Project team also has further work to do. Many of the discussions during the

course of the project to date have emphasized the importance of community engagement on the ethical issues at stake in the project. These members of the project team will now take up that work, with the assurance that the input received from the public will drive revisions of the ethical frameworks and implementation analyses as needed.

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