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

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Minnesota Pandemic Ethics Project

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

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

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1 Vawter et al. (2010).

2 Ibid.

The Minnesota Pandemic Ethics Project has worked throughout to provide practical guidance about how to implement the ethical commitments and objectives endorsed in the ethical frameworks. Thus, the ethical frameworks have been drafted to recommend not just ethical commitments and objectives, but strategies to be implemented to achieve those objectives. Because the ethical frameworks overlap to such a great degree at the level of fundamental ethical commitments and objectives, this report focuses on broad issues that arise in planning for the implementation of the ethical frameworks. It considers, for example, issues related to implementing the ethical frameworks' commitment to strive for fairness and protect against systematic unfairness, and 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 separately from the committee by the Implementation Team. The report states when a recommendation has been issued by the Protocol Committee and when it has been issued by the Implementation Team. A process of public engagement – including both a period of public comment and a number of small group public engagement meetings across the state – provided input for revisions of those preliminary recommendations. The Protocol Committee discussed that input to finalize recommendations. A summary of the report's recommendations follows.

Recommendations regarding health disparities and access to resources:
This report provides analysis of the ethical frameworks' specification of the fairness objective as it relates to health disparities and equitable access to resources, identifies challenges to the implementation of this objective, and recommends processes for implementing it.

1.1 The Protocol Committee recommends that public health officials carefully consider the best approach to gathering data to reflect risk across populations in the state, since the state can implement the Panel's recommendation regarding health disparities only to the extent that it works to understand risks confronting these populations. The Protocol Committee expressed some concern that certain sources of data may fail to adequately reflect the burden of disease in at-risk populations. For example, data gathered from hospitalizations may not capture rates of morbidity and mortality in populations that lack good access to care. The committee recognized that the state is best positioned to understand what types

of data it is possible to collect and what resources may be available for collection of data during a severe pandemic. Thus, it refrained from issuing recommendations about specific types of data that should be gathered.

1.2 The Implementation Team recommends that partnerships between MDH, the State Community Health Services Advisory Committee (SCHSAC), local health departments (LHDs) and tribal liaisons throughout the state attend specifically to efforts, both in the planning stages and during a pandemic, to alleviate health disparities and reduce access barriers. These partnerships will be critical to the promotion of equity given the special expertise of each of the partners. LHDs know the demographics, social and economic conditions, and general health needs of the people whom they serve. However, only the state has the entire picture and thus the capacity to compare mortality and morbidity across regions. Additional information will result from surveillance at the federal and even global level.

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 hospital pandemic plans attend specifically to efforts to alleviate health disparities and reduce access barriers. The demands of justice will mean that all hospitals, regardless of jurisdiction, should be open to accepting patients who typically confront access barriers that can block or delay care. Working toward strong, collaborative relationships between these entities will promote the development of mechanisms that allow for and facilitate the admission of patients and reimbursement for services. These complex negotiations are essential to the goals of removing barriers to access and reducing significant group differences in mortality and serious morbidity.

1.5 The Implementation Team recommends that distribution of resources such as vaccines and antivirals to sites across the state track target groups. In other words, more resources should be sent to communities with greater numbers of prioritized recipients, so that those at highest priority have best access to the resources. In contrast, if vaccine is shipped throughout the state in amounts proportional to area population, priority groups may not be reached as needed. Communities with lower rates of prioritizing factors may have more resources than needed for the targeted priority groups, and communities with higher rates of prioritizing factors may have supplies that fall far short of protecting their populations.

1.6 The Protocol Committee recommends that state, regional and local public health officials reach into communities to offer accessible, culturally sensitive

educational campaigns and work with community partners to distribute resources.

1.7 The Implementation Team recommends that efforts should be made to provide free or low cost services to disadvantaged communities.

1.8 The Protocol Committee recommends that immigration authorities not be present or involved in the distribution of resources during pandemic.

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.

Recommendations regarding emergency powers:

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

3.1 The Protocol Committee recommends that legal clarification be sought concerning the question of whether current legal protections provide sufficient coverage for volunteers in a pandemic, including volunteer responders who provide services other than health care, as described above, or who may volunteer with organizations other than a political subdivision, the state, or the Minnesota Responds Medical Reserve Corps.

3.2 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.

3.3 The Protocol Committee recommends that the state publicly clarify individuals' right to refuse interventions. Participants in the public engagement meetings expressed concern that the state would mandate vaccination or treatment during pandemic.

Recommendations regarding standards of care:

The Protocol Committee discussed the 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 should be carefully explained to patients and their families throughout the process in which decisions concerning care are made.

4.3 The Protocol Committee 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, among other things, on their status as key workers, their health needs and possibly their age. The Implementation Team and the Protocol Committee offer recommendations concerning the implementation of these criteria.

5.1 The Protocol Committee recommends that the decision about which workers to identify as key be understood as an event-dependent one. The Protocol Committee concurs with the Panel in this regard.

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

5.3 The Protocol Committee recommends that processes for identifying key workers 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 committee recognizes that no preordained limit can be applied to these processes. 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 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.

5.5 The Protocol Committee recommends that patients' self-reports be accepted as guiding rationing decisions where possible. The committee recognizes that judgments about the levels of risk faced by particular individuals will often depend on patients' underlying health status and that medical records may not be easily available when making rationing decisions. The committee strongly recommends that current privacy protections be enforced despite the need for health information when making rationing decisions.

5.6 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 to assess whether, and if so how, age-based rationing could be implemented.

5.7 The Implementation Team recommends that information about which priority groups may access resources at a given time be disseminated as widely as possible, in different languages, using a variety of strategies: written materials,

and venues for distribution of information (such as neighborhood “hubs” rather than simply posting information to the internet or making announcements on television). Health care clinics may be able to use information from medical records to notify their patients in priority groups that they are prioritized to receive vaccine, but such a strategy would be unavailable for populations that are not affiliated with a particular provider, or through providers other than private clinics such as walk-in clinics in retail stores or mass public health clinics.

5.8 The Implementation Team recommends that private clinics provide fair access to individuals who are not their regular patients if they serve as the primary distribution sites for resources.

5.9 The Protocol Committee recommends considering random selection of distribution sites serving prioritized populations to promote fairness if randomization among individuals poses insurmountable challenges. Randomization may be difficult when distributing some resources, but it should not be abandoned prematurely when supplies are inadequate to reach all who are equally prioritized.

Recommendations regarding protections for the public:

This report recommends the development of particular protections for the public, thus providing guidance on the ethical frameworks’ insistence that decision-making be “accountable, transparent, and worthy of trust”.[3]

3 Ibid.

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 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 support for providers and decision-makers when concerns are raised regarding the procedural and substantive propriety of such 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 support outlined in section 7 below. Since this proposed process for ethics support would work at two integrated levels – state and local – it can be adapted to retrospective and real time reviews of decision-making for each resource.

Recommendations regarding ethics support:

The Implementation Team proposes a process for ethics support that can be used at two levels of organization – the state (MDH and government officials) and the local or institutional level – 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, as well as to perform retrospective and real time reviews of rationing decisions.

7.1 The Implementation Team recommends that MDH implement and administer a system for ethics support at the state level, and require development of ethics support mechanisms at local levels. The primary function of the ethics support process is to facilitate consistent application of ethical frameworks for the allocation of scarce resources.

7.2 The Implementation Team recommends that the state pandemic ethics support group comprise representatives of local pandemic ethics support groups (reflecting the geographic and cultural diversity of the state), experts in public health, and ethics experts. In addition to serving as a resource for MDH, the state pandemic ethics support group would be responsible for 1) providing prospective education to local pandemic ethics support groups regarding state and federal guidance including ethical frameworks for rationing and principles of distributive justice, 2) review of requests for guidance from local pandemic ethics support groups relative to fair application of ethical frameworks, and 3) review of systemic

issues/challenges regarding the moral frameworks that arise at the local or state level.

7.3 The Implementation Team recommends that the composition of local ethics support teams be determined at the local level based on needs and resources. Given the probable scarcity of human resources during pandemic, members of ethics support teams could comprise rotating representatives of extant ethics committees or consultation services as well as volunteers such as community leaders, retired clinicians and retired public health and social service workers. Coordination of pandemic ethics support group services could occur among alternative care sites, long term care facilities, prisons and other healthcare entities to best meet needs with available resources.

7.4 The Implementation Team recommends that ethics support be sought when those attempting to resolve an ethical problem have reached an impasse, when the ethical problem involves a serious disagreement or dispute, when the problem is unusual, unprecedented, or very complex ethically, or when the need arises to review the policies and practices that have emerged in the pandemic and advise MDH on measures to alter or improve them.

7.5 The Implementation Team recommends that access to real time review by pandemic ethics support services be available to providers or decision-makers at the state or local level when questions are raised concerning the fair application of a relevant ethical framework. This process provides support for providers and decision-makers when concerns are raised regarding the procedural and substantive propriety of allocation decisions at the time that they are made. It

provides support for the state in assessing fair application of rationing decisions and addressing unforeseen issues in pandemic response as they arise. The Implementation Team further recommends that the findings of real time reviews be final and unilateral.

7.6 The Implementation Team recommends that, in order to avoid inappropriate and overwhelming claims on pandemic ethics support group members, each request for real time pandemic ethics review should be reviewed in a timely manner by a rotating member of the local pandemic ethics support group. This person would determine whether or not the request meets review criteria and thus merits attention.

7.7 The Implementation Team recommends that pandemic ethics support groups, especially at the local level, provide structured and systematic retrospective reviews to ensure compliance with and consistency in the application of the ethical frameworks.

Recommendations regarding palliative and hospice care:

This report emphasizes the vital need for palliative and hospice care for the terminally ill during pandemic[4] 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.

4 See also Panel recommendation concerning palliative and hospice care in Vawter (2010) §3.1.

8.1 The Implementation Team recommends that MDH convene a workgroup administered by the Minnesota Network of Hospice & Palliative Care, in concert with statewide hospice and 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 and distributing palliative care resources, promulgating symptom management protocols and algorithms, developing caregiver educational programs for laypersons and clinicians, developing a process for ongoing community engagement and communication, planning for support of the dying and their caregivers.

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 the "Panel"), workgroups 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 process of public engagement supplied further input for the project. A presentation of the Panel's recommendations for ethical frameworks for rationing can be found in *For the Good of Us All: Ethically Rationing Health Resources in Minnesota in a Severe Influenza Pandemic*[5] (hereafter 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 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 only general analysis of abstract

5 Ibid.

values and principles that may offer guidance on these issues. While these discussions provide significant insight into important moral[6] 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. Because this report addresses broad practical issues with implementing rationing frameworks, the Implementation Team believes these analyses will be of interest beyond the borders of Minnesota, to anyone concerned with establishing ethical practice in situations of severe pandemic that necessitate rationing.

Indeed, the Minnesota Pandemic Ethics Project has worked throughout to provide practical guidance about how to implement the ethical commitments and objectives endorsed in the ethical frameworks. Thus, the ethical frameworks presented in the Panel Report have been drafted to recommend not just ethical commitments and objectives, but also strategies to be implemented for achieving those objectives. As such, the ethical frameworks marry endorsement of abstract moral commitments and objectives with detailed guidance about implementation concerning which groups it is reasonable to consider prioritizing for access to particular resources. This guidance is tailored to assumptions about the resources themselves, the disease threat being faced,

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

and the levels of scarcity creating the need for rationing. 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 Implementation Report, then, supplements the strategies and other operational recommendations included in the 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 and objectives, the Protocol Committee, the Panel 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 expert and painstaking work that MDH has undertaken 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' fairness objective concerning health disparities and barriers to access, identifies challenges to the implementation of this objective, and recommends processes for implementing it;
- addresses questions about who should be prioritized 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, health needs, and, possibly, 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"[7] ;
- proposes a process for ethics support that can be used at two levels of organization – the state and the local level – to provide advice on the implementation of the ethical frameworks during an influenza pandemic, on the possible need for updates to them as planning continues prior to a pandemic, and on performance of retrospective and real time reviews of rationing decisions; and
- 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.

It is critical to emphasize at the outset of this report that implementation of the guidance from the Minnesota Pandemic Ethics Project requires significant educational efforts. 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

7 Vawter et al. (2010).

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 significant theme in discussions of the Protocol Committee and the public engagement process related to the tremendous importance of community education. A process of community education will need to address both education about pandemic influenza itself and the proposed frameworks for rationing. In considering community education, the media merits special attention; it will play an important role in disclosure 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 an understanding of the most current scientific data, knowledge of local communities, and consideration of the framework(s) for rationing.

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 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. As with any group process, members of the group were not always in perfect agreement on all issues. 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 – to supplement the work of the Protocol Committee. The discussion of palliative and hospice care included herein presents such an example. In addition, the proposed process for ethics support 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. The working group, in concert with expert advisors and some feedback from the public engagement process, recast the state's request for a process of ethics consultation into a process of ethics support to avoid confusion and highlight differences between this process and the standard process of ethics consultation in health care institutions. Given the significant role that the ethics support 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.

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] To honor this principle the project included substantial processes for public engagement. The preliminary versions of both the Panel Report and this Implementation Report were posted to the web for a period of public comment. In addition, implementation issues were discussed at small group engagement meetings held in nine communities across the state in the summer of 2009. The communities included the Courage Center, the North Side and the Phillips/Powderhorn neighborhoods in Minneapolis, the West Side neighborhood in St. Paul, Eden Prairie, the Leech Lake Band of Ojibwe in Walker, Moorhead, Virginia,

8 Public Health Leadership Society (2002).

and Worthington. The project's preliminary recommendations were revised in light of input received from the public.

THE STANDING 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 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.

A number of factors may influence such choices. It is especially worth noting that availability of resources for pandemic preparedness may affect these institutions' ability to implement the recommendations of the Minnesota Pandemic Ethics Project. Public health initiatives perennially suffer from inadequate funding, making difficult choices about priorities unavoidable. Some of the recommendations in the project are revenue neutral. These include, among others, the recommendations that immigration authorities not be present or involved in distribution of resources during pandemic (1.8); that many pre-pandemic standards of good care continue to apply during pandemic (4.2); and providers not be fully immunized from liability in pandemic standards of care (4.3). Other recommendations require time and attention of institutions to be implemented, but are otherwise not resource intensive. For example, consider the recommendation 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 (5.6). To implement this recommendation, the state's legal advisors would need to devote time and attention to these issues, but additional resources would not be needed. Similarly, the recommendation that MDH convene a workgroup to plan a process for meeting palliative and hospice care needs during pandemic (8.1) would require collaboration with the Minnesota Network of Hospice and Palliative care, thus requiring time and attention to this issue in planning, but would not otherwise require additional resources.

However, some of the project's recommendations can be implemented only if appropriate resources are available. For example, stockpiling resources for palliative care will require more resources than the state's time and attention. Thus, the recommendation (8.2) that a workgroup develop proposals for stockpiling and distributing palliative care resources will require identification of funding and storage for such resources.

If resources fall short of need, difficult choices will be required about which recommendations to implement. The project did not include a process for prioritizing recommendations should such difficult choices become necessary. Should choosing among the recommendations contained in this report become unavoidable, the Implementation Team urges that, to the extent possible, priority be given to implementing guidance concerning (1) health disparities and equitable access to

resources (section 1 below), to avoid perpetuation of systemic unfairness with predictably tragic consequences; (2) palliative and hospice care (section 8 below), so that the dying and those who care for them will not be abandoned; and (3) ethics support at the state level (section 7 below), to address ethical challenges that will inevitably develop during a pandemic. It should be noted that not all of the recommendations in these sections require significant additional resources. Since a broader process to prioritize aspects of guidance was not included in the project, these suggestions should not be understood to reflect the views of other Minnesota Pandemic Ethics Project participants.

Not only is the project advisory in nature, but the recommendations expressed in the project's reports are also provisional. This is 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, and the relationship between federal and state authority for planning and response. 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.[9] The project also proposes a critically important process for ethics support 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.

9 DeBruin & Leider (2008).

Indeed, although this project began in a pre-pandemic period, its work continued during the H1N1 influenza pandemic. H1N1 effected a relatively mild pandemic, strikingly different in many ways from the assumptions underlying the recommendations in this project. Thus, the public health response to pandemics must adapt the recommendations offered by this project to fit the realities of that specific disease threat.

ANALYSIS OF IMPLEMENTATION ISSUES

1. Promoting Fairness Across Groups: Addressing Health Disparities and Access Barriers

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 health disparities or inequities of access to health care for the people in Minnesota. Rather, the pertinent objectives 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.”[10] These objectives are in keeping with Minnesota’s health mission at both the state and local levels. They are also in keeping with the Bellagio Statement of Principles which emphasizes the need for protecting the

10 Vawter et al. (2010).

disadvantaged.[11] These concerns about fairness across groups raise particularly sensitive, difficult, and unfortunately often overlooked issues in pandemic preparedness.

The objective relating to significant group differences in mortality and serious morbidity addresses health disparities, and other relevant factors. Ample evidence documents the role of social risk factors for disease; socially disadvantaged groups suffer greater burden of disease than do more privileged groups. It is important to note that poorer health outcomes correlate not only with poverty, but with lower social status as well. Such disparities cannot simply be attributed to barriers in access to care. Social conditions influence the risk of contracting disease and the ability to recover, regardless of whether one has access to health care. Examples of social factors include quality of nutrition, dependence on public transportation, social support networks, prevalence of dignity affirming or dignity denying experiences, and resources sufficient to mitigate stress in daily life. Although the mechanisms are not fully understood, research on the relationship between social status (one's position in social hierarchies of status) and health has repeatedly demonstrated a positive correlation between them.[12] Likewise, historical work has documented that poorer people were (and continue to be) disproportionately subjected to higher mortality and morbidity from infectious diseases.[13] The relationships between race, ethnicity, socio-economic status and these health disparities are complex and challenging but morally relevant to the just distribution of resources during a pandemic.

11 Bellagio Group (2006).

12 Lin et al. (2003); Piketty & Saez (2003); Woolf (2007); AHRQ (2007); Dowd & Aiello (2009); Victorino & Gauthier. (2009); Williams et al. (2009); Gerend & Pai. (2008); Rooks et al. (2008).

13 Craddock (2000); Farmer (1999); Rosenberg (1987).

Moreover, the Implementation Team advises that the concept of 'risk' is not a morally neutral term.[14] A person or group's social 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 pollution.[15] But risk is also "the calculating concept that modulates the relations between fear and harm."[16] Historically, groups different from the dominant group by poverty, race, language and other social markers have been feared as a source of harm and treated accordingly.[17] Infectious diseases in non-dominant groups were attributed by the dominant group to flawed morality.[18] The following observation by political scientist James Morone frames the question:

> 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"?[19]

The idea of 'risk' is and has been used to separate 'us,' meaning the dominant, privileged social group from 'them,' meaning those who are different and therefore perceived to be dangerous. This arbitrary separation subsequently justifies 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

14 Brandt & Rozin (1997); Ericson & Doyle (2003).

15 Douglas (1966); Douglas (1982).

16 Hacking (2003).

17 Craddock (2000).

18 Tomes (1997).

19 Morone (2003).

whether one is seen as deserving as indicated by a variety of measures.[20] The dominant cultural practice is to view the extent to which one does or does not have these goods as just desert 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 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.

Bad social circumstances, including ill health, low paying jobs, and poverty are seen to result from bad choices and are thus blameworthy.[21] Such ideas generally operate insidiously because the connection between social status and lack of access to social goods on one hand and personal responsibility for bad choices on the other often lie 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 desert by acting responsibly in making good choices. They view those who do not share in these goods as socially unworthy and as a risk to the deserving and their way of life. For these reasons, social 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 non-dominant groups during a pandemic may follow from ideas rarely conscious or spoken. In an attempt to recognize this phenomenon, the Panel has

20 Ibid.

21 Leichter (1997).

strongly voiced a commitment that social status is not an ethically justifiable reason for rationing.

The Panel Report recommends that people who are at higher risk of dying or becoming severely ill be prioritized for resources. It calls for public health and health care workers to gather as much data as possible during a pandemic so that groups who are at higher risk can be identified, and resources can be targeted to those at-risk populations. While this approach does not address underlying disparities, it may offer some protection to at-risk populations during an influenza pandemic.

The Protocol Committee expressed some concern that certain sources of data may fail to adequately reflect the burden of disease in at-risk populations. For example, data gathered from hospitalizations may not capture rates of morbidity and mortality in populations that lack good access to care. Thus, public health officials should carefully consider the best approach to gathering data to reflect risk across populations in the state. The committee recognized that the state is best positioned to understand what types of data it is possible to collect and what resources may be available for collection of data during a severe pandemic. Thus, it refrained from issuing recommendations about specific types of data that should be gathered. The committee also recognized that a severe pandemic will strain the state's ability to collect data, and acknowledged that, at times, public health officials will need to act on imperfect data. Ultimately, the state can meet its moral responsibilities regarding health disparities only to the extent that it works to understand the risks confronting these populations.

Once at-risk groups are identified, distribution of resources such as vaccines and antivirals to sites across the state should track target groups. In other words, more resources should be sent to communities with greater numbers of prioritized recipients, so that those at highest priority have best access to the resources. For example, if, according to the framework, members of the public at high risk of death are currently prioritized for vaccine, then proportionate vaccine should be sent to communities based on incidence of factors such as chronic illness that pose risk for influenza-related mortality. In contrast, if vaccine is shipped throughout the state in amounts proportional to area population, priority groups may not be reached as needed. Communities with low rates of chronic illness, for example, may have more vaccine than needed for the targeted priority group, and communities with high rates of chronic illness may have supplies that fall far short of protecting their populations.

The challenge with a prioritized distribution scheme stems from lack of data to guide distribution. To have a distribution scheme for resources that reflects the ethical framework for rationing, the state should gather data about prevalence across the state population of characteristics that would prioritize people for resources. When hard data cannot be acquired, the state can best approximate the information it needs through collaboration with local health departments and local social service agencies since these organizations have the best knowledge of the communities they serve, as will be explained below. Moreover, even with perfect information, efforts to target resources to at-risk populations can succeed only to the extent that the state makes reasonable

efforts to remove barriers to access. Thus the issues of health disparities and access to care, while distinct, are nevertheless inextricably linked.

The Protocol Committee discussed two major types of barriers to access: socio-economic barriers and geographical barriers. Both types of barriers present concerns regarding justice, and both can block or delay access to care and thus worsen outcomes. 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, personal protective equipment, and ventilators poses particular challenges, especially in relation to socio-economic inequalities.

Socio-economic and geographic barriers to access 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. Protocol Committee discussions of geographic barriers 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 such as health care providers and facilities, and one may have to travel great distances for care. This perspective reflects a macro level of geography, specifically, as regions of the state, whereas counties, voting districts, and neighborhoods are smaller scale units of analysis. Unfortunately, Native Americans living on reservations in rural areas and Native Americans living in cities experience socio-economic and health disparities and

inequities in access to care.[22] Within cities, wealthy neighborhoods frequently transition into poor neighborhoods separated by only a few blocks; vacation homes of city dwellers are often in rural areas. Thus, an urban/rural understanding of geographical disparities is an important paradigm. The Implementation Team contends that a micro level understanding and approach will also be essential in working towards the goals of addressing health disparities and access barriers.

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 via 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. However, 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.[23]

Because they are local to a given geographical area and conduct community health assessment and action planning (CHAAP) reviews, LHDs know the demographics,

22 Kunitz (1996).

23 Office Of Public Health Practice In The Minnesota Department Of Health (n.d.).

social and economic conditions, and general health needs of the people whom they serve. Obviously there will be differences both between LHDs in terms of incidence, rates of transmission, access to care of all sorts, and capacity to respond. Additionally, vaccines, antivirals, N95 respirators, surgical masks, and mechanical ventilators will be channeled through a variety of mechanisms involving government at both the federal and state levels as well as via the private system. LHDs have the best local knowledge of their communities including the ways in which social status intersects with other risk factors: the young, elderly, uninsured or underinsured, undocumented immigrants, and those with certain health conditions. 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, and faith-based communities that serve low income people. 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 thus the ability to compare mortality and morbidity across regions. Additional information will result from surveillance at the federal and even global level. The state will be the channel for

vaccines distributed by the federal government. The state will also be a central channel for stockpiled antiviral medications. Private groups such as corporations and private health care systems have also been stockpiling antivirals and personal protective equipment. Ventilators pose other challenges for several reasons. Though they may be critical to saving lives, 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 given system is sure to exceed availability. Regional hospital pandemic plans should attend specifically to efforts to alleviate health disparities and reduce access barriers. Federal guidance regarding hospital plans overlooks these concerns.[24] The demands of justice will mean that all hospitals, regardless of jurisdiction, should be open to accepting patients who typically confront access barriers that can block or delay care. Working toward strong, collaborative relationships between these entities will promote the

24 HHS Interagency Public Affairs Group on Influenza Preparedness and Response. Hospital Pandemic Influenza Planning Checklist.

development of mechanisms that allow for and facilitate the admission of patients and reimbursement for services.

In sum, promoting fair access will require vigilance at multiple levels and cooperation across all levels. The extent to which fairness 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.

Participants in the public engagement process echoed the Implementation Team's view that a micro level understanding and approach will be essential in working towards the goals of addressing health disparities and access barriers. For example, a local health department in Minnesota submitted feedback on this report as an organization during the public comment period, stating that "We appreciate the recognition that Local Health Departments have the best local knowledge of their communities. Our social service agencies also have critical knowledge in this regard." A recurring theme of the small group engagement discussions stressed the importance of working at the local level to address barriers to access.

Participants in the small group engagement meetings were asked to identify barriers to access in their communities. Barriers that were frequently mentioned included:

- Lack of accessible information about influenza or public health and health care services in their communities;

- Distrust of government and public health agencies and programming;
- Lack of insurance and inadequate insurance coverage;
- Poverty;
- Transportation/mobility issues;
- Distance to care.

Participants recommended a number of strategies to reduce barriers to access to care. They strongly emphasized the need to bring educational campaigns into communities to better inform the public about influenza, pandemic planning, and available health services in their communities. Participants advised that such educational campaigns be offered in different languages, using a variety of strategies rather than simple dissemination of written materials, and a variety of venues for distribution of information such as neighborhood "hubs" rather than simply posting information to the internet. To improve trust, participants felt strongly that educators should be culturally competent and represent diverse groups found in the communities where the educational campaigns will be offered. To address issues concerning trust, transportation, mobility and distance to care, participants stressed the need to bring resources into local communities, to use easily accessible sites or mobile units for distribution of resources, and to collaborate with trusted community organizations in offering care. Thus, participants felt that many access barriers could be alleviated through in-reach into communities and partnership with community organizations that understand the communities and are trusted within them.

Issues of lack of insurance and poverty are, of course, much more difficult to address. They raise the need for systemic change beyond pandemic preparedness efforts. Still, participants felt that efforts should be made to provide free or low cost services to disadvantaged communities, perhaps by targeting publicly subsidized resources from the Strategic National Stockpile to those communities and allowing more privileged communities to rely more heavily upon privately held resources. Participants in the small group engagements felt strongly that public health officials will need to offer credible assurance that immigration authorities will not be present or involved in the distribution of resources, both to allow undocumented immigrants to gain access to care, and to prevent intimidation of citizens or documented immigrants who may seek care when not carrying documentation.

Recommendations regarding health disparities and access to resources:

1.1 The Protocol Committee recommends that public health officials carefully consider the best approach to gathering data to reflect risk across populations in the state, since the state can implement the Panel's recommendation regarding health disparities only to the extent that it works to understand risks confronting these populations. The Protocol Committee expressed some concern that certain sources of data may fail to adequately reflect the burden of disease in at-risk populations. For example, data gathered from hospitalizations may not capture rates of morbidity and mortality in populations that lack good access to care. The committee recognized that the state is best positioned to understand what types of data it is possible to collect, and what resources may be available for collection

of data during a severe pandemic. Thus, it refrained from issuing recommendations about specific types of data that should be gathered.

1.2 The Implementation Team recommends that partnerships between MDH, the State Community Health Services Advisory Committee (SCHSAC), local health departments (LHDs) and tribal liaisons throughout the state attend specifically to efforts, both in the planning stages and during a pandemic, to alleviate health disparities and reduce access barriers. These partnerships will be critical to the promotion of equity given the special expertise of each of the partners. LHDs know the demographics, social and economic conditions, and general health needs of the people whom they serve. However, only the state has the capacity to compare mortality and morbidity across regions. Additional information will result from surveillance at the federal and even global level.

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 hospital pandemic plans attend specifically to efforts to alleviate health disparities and reduce access barriers. The demands of justice will mean that all hospitals, regardless of

jurisdiction, should be open to accepting patients who typically confront access barriers that can block or delay care. Working toward strong, collaborative relationships between these entities will promote the development of mechanisms that allow for and facilitate the admission of patients and reimbursement for services. These complex negotiations are essential to the goals of removing barriers to access and reducing significant group differences in mortality and serious morbidity.

1.5 The Implementation Team recommends that distribution of resources such as vaccines and antivirals to sites across the state track target groups. In other words, more resources should be sent to communities with greater numbers of prioritized recipients, so that those at highest priority have best access to the resources. In contrast, if vaccine is shipped throughout the state in amounts proportional to area population, priority groups may not be reached as needed. Communities with lower rates of prioritizing factors may have more resources than needed for the targeted priority groups, and communities with higher rates of prioritizing factors may have supplies that fall far short of protecting their populations.

1.6 The Protocol Committee recommends that state, regional and local public health officials reach into communities to offer accessible, culturally sensitive educational campaigns and work with community partners to distribute resources.

1.7 The Implementation Team recommends that efforts should be made to provide free or low cost services to disadvantaged communities.

1.8 The Protocol Committee recommends that immigration authorities not be present or involved in the distribution of resources during pandemic.

2. Eligibility to Receive Resources: Border Issues and Residency

Since the pool of resources will be extremely limited in a severe pandemic, the Protocol Committee discussed 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. The public comment period made clear that some Minnesotans feel they are more deserving of government-held resources because they paid for them in taxes. However, 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. Moreover, it should be noted that when reference is made to individuals who are not legal residents of the state, this group includes not only undocumented immigrants (the focus of most of the

public comment submissions on this issue) but also legal residents of border states and Canada who may routinely travel to Minnesota.

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 and 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 containment of infection. 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 the lack of acceptable strategies for identifying 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 that 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. Participants in the small group public engagement meetings urged that public health officials offer credible assurance that immigration authorities will not be present or involved in the distribution of resources, both to allow undocumented immigrants to gain access to care, and to prevent intimidation of citizens or documented immigrants who may seek care when not carrying documentation. Thus, the committee recommends against establishment of a plan that allows only legal residents of the state of Minnesota access to scarce resources in the state.

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 and may routinely access medical care across state lines. 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.[25] By clearly addressing possible questions and concerns in these border regions the state will better serve its residents. The Protocol Committee recommends

25 Association of State and Territorial Health Officials (2005).

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**.**

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 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. The Emergency Management Act is codified in Minnesota Statutes Chapter 12.[26] MDH provided the Protocol Committee with background on the Act to inform its work; the Implementation Team provides a

26 Minn. Stat. § 12.31.

summary below. This discussion is not intended to offer legal analysis. Indeed, the need for legal analysis will be highlighted with respect to particular issues.

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.[27]

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 terminate the state of emergency if they so desire.[28] 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.[29] 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

27 Minn. Stat. § 12.31 Subd. 2.
28 Minn. Stat. § 12.31 Subd 2.
29 Livingston (2007).

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 cannot be continued for more than three days unless consent is given by the governing body of the political subdivision.[30] The governor's powers during a state of emergency supersede those of local government.[31] 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.[32] The regulations 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 health care 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

30 Minn. Stat. § 12.29 Subds 1-3.

31 Minn. Stat. § 12.32.

32 Minn. Stat. § 12.

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.[33]

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 training, liability, licensure, and mandatory provision of services or use of a resource.

3.3.1 Training

The Division of Emergency Management is required to "maintain and administer an emergency management training curriculum" and offer such training for "state employees whose essential job duties involve emergency management."[34] State agencies participating in emergency response must ensure that their workforce is trained in this role, as set forth is Minnesota Statute 12.09 subdivision 10.

3.3.2 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 the emergency executive order is in effect, a responder in an impacted region who

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33 Minn. Stat. § 12.61.

34 Minn. Stat. § 12.09 Subd 10.

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.[35] 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.[36]

Moreover, if the state director of the Division of Homeland Security and Emergency Management activates a specialized emergency response team – a team whose purpose is "supplementing state or local resources for responding to an emergency or

35 Minn. Stat. § 12.61 Subd 2.

36 Minn. Stat. § 12.61 Subd 1c.

disaster"[37] – team members will be provided workers' compensation and liability protection.[38]

There was some concern voiced in the Protocol Committee that medical professionals would be apprehensive about implementing rationing frameworks 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 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. However, concerns about liability go well beyond these particular procedures, and relate to difficulties with providing care at alternative care sites, the challenges of asking personnel to perform duties outside their normal practice when the system is overwhelmed, the need to implement interventions based on limited information as the pandemic evolves, and the burden of withholding resources – not just ventilators – from patients so that others in higher priority groups may have access. 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.

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37 Minn. Stat. § 12.03 Subd 9b.

38 Minn. Stat. § 12.351.

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.[39] 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 and b which define volunteers as "individuals who volunteer to assist" either a local political subdivision (2a) or the state (2b) "during an emergency or disaster, who register with that subdivision [or the state], and who are under the direction and control of that subdivision [or the state]." Persons who fall under that definition would be considered employees of the state in regards to tort claim defense and indemnification. Further protections for Minnesota Responds Medical Reserve Corps volunteers were added in the 2008 Legislative Session after the Protocol Committee's meetings on this topic.[40] Legal clarification should be sought concerning the question of whether this language provides sufficient coverage for volunteers in a pandemic, including volunteer responders who provide services other than health care, as described above, or who may volunteer with organizations other

39 Minn. Stat. § 144.4197.

40 MN Session Law 2008 c 202.

than a political subdivision, the state, or the Minnesota Responds Medical Reserve Corps.

3.3.3 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 allowed 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

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."[41] 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.[42] It should be noted; however, that the governor cannot suspend statutes.

3.3.4 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. Minnesota Statute §12.34 subdivision 1 states that the governor, state director of emergency management, or persons designated by the governor may "require any person, except

41 Minn. Stat. §144.4197.
42 Minn. Stat. § 12.32.

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.[43] 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).[44]

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.

3.3.5 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."[45] Participants in

43 Minn. Stat. § 12.34 subd. 3.

44 Coleman & Reis (2008).

45 Minn. Stat. §12.39.

the public engagement meetings expressed concern that the state would mandate vaccination or treatment during pandemic. The Protocol Committee recommends that the state respond to this concern by publicly clarifying the public's right to refuse interventions. 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.[46] 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.[47] 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.

3.3.6 Unions

A final observation made by the Protocol Committee regarding workers' role in a pandemic is that the state government and health care systems should work with unions

46 Ibid.

47 Minnesota Department of Health (April 2007).

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.[48] 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.[49] 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 commandeer medical supplies that are an individual's personal property being used by that individual. Thus only private, non-healthcare businesses are possible candidates for commandeering resources.[50]

48 Minn. Stat. § 12.34 subd. 1.
49 Minn. Stat. § 12.34 subd. 2.
50 Livingston (2007).

The Protocol Committee was informed that 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 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."[51] 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.[52] The aftermath of Hurricane Katrina provides ample evidence of the strong moral and cultural importance of the respectful treatment of the dead.[53] The statute also outlines the process required for identification of bodies.[54] Although the ethical frameworks for rationing do not contain recommendations concerning respectful treatment of the dead, the Protocol Committee feels that the issue should be highlighted given its ethical importance and its relation to the public's trust in pandemic response efforts.

51 Minn. Stat. § 12.381 subd. 1.

52 Ibid.

53 Clark (2005-2006).

54 Minn. Stat. § 12.381 subd. 2.

Recommendations regarding emergency powers:

3.1 The Protocol Committee recommends that legal clarification be sought concerning the question of whether current legal protections provide sufficient coverage for volunteers in a pandemic, including volunteer responders who provide services other than health care, as described above, or who may volunteer with organizations other than a political subdivision, the state, or the Minnesota Responds Medical Reserve Corps.

3.2 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.

3.3 The Protocol Committee recommends that the state publicly clarify individuals' right to refuse interventions. Participants in the public engagement meetings expressed concern that the state would mandate vaccination or treatment during pandemic.

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.[55]

Although there appears to be some controversy over whether “adjusted” standards of care would be needed in a pandemic,[56] 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 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 Panel Report for the Minnesota Pandemic Ethics Project provides guidance on how to answer these questions.[57]

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.

55 AHRQ (2005).

56 Koenig et al. (2006).; Hick & O’Laughlin (2006).

57 Vawter et al. (2010).

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 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 should 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. Shortly before this report was finalized, the Institute of Medicine Committee on Guidance for Establishing Standards of Care for Use in Disaster Situations (hereafter IOM Committee) issued a report arguing that current federal and state law provides a

patchwork of liability protections that may be insufficient for public health emergencies. The IOM Committee recommends that

> Absent national comprehensive liability protections, state and local governments should explicitly tie existing liability protections (e.g. through immunity or indemnification) for healthcare practitioners and entities to crisis standards of care. [58]

The Protocol Committee counsels 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 IOM Committee notes that "Significant legal challenges may arise in establishing and implementing crisis standards of care." [59] Thus, it recommends that

> In disaster situations, tribal or state governments should authorize appropriate agencies to institute crisis standards of care in affected areas, adjust scopes of practice for licensed or certified healthcare practitioners, and alter licensure and credentialing practices as needed in declared emergencies to create incentives to provide care needed for the health of individuals and the public.[60]

The Protocol Committee urges that further discussion of these complicated issues is needed, incorporating public health, medical, ethical and legal analysis. Thus, the

58 IOM (2009).

59 Ibid.

60 Ibid.

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 should be carefully explained to patients and their families throughout the process in which decisions concerning care are made.

4.3 The Protocol Committee 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 neither duplicates nor supplants 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 Protocol Committee recommends, in agreement with the Panel, 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 that 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 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 be prioritized for access to resources based on their health needs, among other things. 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 recommends the public health partnerships

that will be required in the state to promote this greater understanding. Section 7 proposes a process for ethics support 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 depend on patients' underlying health status. 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. 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 these decisions do not rely substantially on patients' self-reports.

5.3 Age

The Panel Report tentatively recommends that age-based rationing be considered in certain circumstances. Specifically, it tentatively recommends that when supplies of some resources are insufficient to serve all people similarly prioritized by the frameworks, then consideration may be given to prioritizing children over adults and,

depending on the resource and its supply, young adults over older adults.[61] The Panel Report suggests that such age-based rationing could be used instead of resorting immediately to random processes to allocate among persons who are equally prioritized.

To clarity this recommendation, it should be noted that 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. 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 regarding verification of 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.

61 Vawter et al. (2010).

On the other hand, age has 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 over older adults, on the grounds that the latter have already had more of an opportunity to live a fuller life? If ten year old children face the same risk of illness and death from influenza as 30 year old adults, is there a reason to prioritize the children for resources over the adults? To answer these questions in the affirmative is to endorse truly age-based (as opposed to clinically-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 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] Moreover, it does not appear that the governor can set aside the protections of the Age Discrimination Act under state emergency powers. 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. Should this strategy be attempted, transparency would require that the legislature be fully informed of the public engagement data regarding age-based rationing.

The IOM Committee on Guidance for Establishing Standards of Care for Use in Disaster Situations also points to anti-discrimination laws in its analysis of crisis standards of care. It states that:

> Some liability protections will not apply – even during emergencies – to acts of discrimination. Specific limitations on liability or indemnity protections focused on willful or wanton misconduct should be interpreted to include unlawful acts of discrimination. [64]

62 45CFR91.11.

63 US Dept. of Health and Human Services, Office of Civil Rights (2007).

64 IOM 2009 at 51.

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."[65] 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.

5.4 Allocating Resources Among Equally Prioritized Persons

In circumstances in which a scarce resource such as a vaccine or antiviral must be allocated among or between equally prioritized persons, the Panel Report recommends that an egalitarian approach govern the rationing scheme. In this unfortunate situation, individual factors that distinguish or discriminate between persons such as social status should have no role in decision making. Traditionally, an allocation scheme that employs choice-by-chance is applied when all prospective beneficiaries are to be treated as equals.

65 45CFR 91.14.

The Panel rejected one such mechanism— first-come, first-served – because existing inequities such as restricted physical mobility, financial constraints, or geographic location may limit access and thus corrupt the process. A fully egalitarian method must be truly random.

In the absence of data illuminating patient preferences on choice of randomization strategies, the Protocol Committee does not recommend a particular strategy above others. However, when selecting a method for randomization, it should be noted that:

> A haphazard assignment procedure does not substitute for a random one, because the probability of assignment is unknown and cannot be controlled or determined (e.g., when treatment assignment depends on the participant's birth date or social security number, or when treatment assignment alternates depending on the day of the week). This is precisely when selection and confounding biases seep in….[66]

Some options for randomizing strategies and concerns that may be associated with them follow.

In acute care settings, computer randomization may be used, where possible, as the method of randomization. It is a commonly employed and truly egalitarian technology used in the health care setting. A variety of systems exist for automated patient registration and treatment, and for human subjects and laboratory animal research in randomized controlled trials. Such systems are also used in other contexts, e.g.,

66 Blume & Peipert (2004).

randomized drug testing by schools or employers, the military draft, allocation of immigration visas when supply falls short of demand, and order of priority in course registration or dormitory room selection in colleges and universities.[67] Many such systems can be accessed remotely via touch tone phone and allow for immediate randomization with complex allocation schemes. They feature 24 hour accessibility, are relatively easy to use, and accommodate secure and accurate data collection. They could be easily adapted for centralized or decentralized randomization of treatment or other resources during a pandemic. Of course, the use of such a randomization system assumes a sufficiently intact infrastructure to support the technology. If computer systems are down, or power fails, cruder methods such as drawing lots might become necessary.

Some concern was expressed in the Protocol Committee that computer based randomization may not seem transparent enough to patients to foster trust. This concern was attributed in part to the practice of not only randomizing assignment of persons into arms of clinical trials, but also of blinding that assignment. Blinding surely conflicts with transparency, but it is a separable process from randomization. In other words, the allocation can be randomized without the results of the random selection being blinded, as can be seen from the examples of uses of random lotteries above. If the concern about transparency with computer based randomization relates more to the concern that the randomization happens "behind the scenes" in a computer-based process that cannot, in a full sense, be witnessed, then providers wishing to

67 Silverman & Chalmers (2001).

accommodate this concern may adopt methods such as drawing lots or flipping coins. If transparency is the concern motivating the use of these methods, then they ought to be employed openly. It should be noted that these methods are not immune from bias as they can rather easily be manipulated.[68]

The methods of randomization addressed above can work in an acute care setting because ill patients have already presented for care (needing ventilators or treatment antivirals, for example), medical records supply information needed to determine which patients are similarly enough situated with respect to the rationing criteria to be equally prioritized for resources, and information systems allow for computer randomization. Randomization becomes much more difficult in settings involving mass dispensation of resources such as vaccines. Vaccines will be used as a case study to illustrate this analysis; however, many of the concerns extend to other resources like antiviral medications as well. Unlike the acute care setting in which ill patients present for care, prioritized individuals must be notified that they may present themselves at the dispensation site to be vaccinated. If the number of prioritized individuals exceeds the number of doses of vaccine available, the Panel Report recommends that a method of randomization be used. Public health officials may wish to avoid randomizing on site; inviting individuals to a vaccine clinic only to send them away unvaccinated risks not only public frustration but also potential exposure to large groups during a time when

68 Diaconis et al. (2007).

infection risk justifies the use of social distancing strategies. Tremendous challenges present themselves in such an effort.

Assuming that demand for vaccine exceeds supply, the first challenge concerns distribution of vaccine to sites across the state. Ideally, as explained in section 1 above, distribution of vaccine would track target groups. In other words, more resources would be sent to communities with greater numbers of prioritized recipients, and then distributed to clinics serving priority populations (e.g. obstetric clinics if pregnant women are at disproportionately high risk).If demand still exceeds supply once efforts to target vaccine to priority populations have been exhausted, then consideration could be given to random allocation of vaccine to sites serving prioritized populations to preserve fairness.

Once vaccines have been distributed appropriately throughout the state, a second challenge arises in bringing individuals in prioritized groups, and only those individuals, in to clinics to receive vaccine. Individuals in priority groups will need to be notified that they are prioritized to receive vaccine. Certainly, individual invitations would not be uniformly possible. Health care clinics may be able to use information from medical records to notify their patients in priority groups that they are prioritized to receive vaccine, but such a strategy would be unavailable for populations that are not affiliated with a particular provider, or through providers other than private clinics such as walk-in clinics in retail stores or mass vaccination clinics. Thus, information about priority groups should be disseminated as widely as possible, in different languages, using a

variety of strategies and venues for distribution of information (such as neighborhood "hubs" rather than simply posting information to the internet or making announcements on television). There are no guarantees that only individuals who fit the priority group will answer such a call and appear at vaccination distribution sites (hereafter "clinics"). However, the possibility that some individuals may try to "game" the system by falsely claiming to fit priority groups will be simply unavoidable. Again, the limiting factor is data: access to individual health records may simply be impossible or too severely impractical under the circumstances. For further discussion of this issue, see section 5.2 above, and recommendation 5.5.

Different types of sites – private providers or mass vaccination clinics – confront different challenges regarding randomization. Understandably, as noted above, public health officials may wish to avoid randomizing on site; inviting individuals to a mass vaccination clinic only to send them away unvaccinated risks not only public frustration but also potentially unnecessary exposure to large groups during a time when infection risk justifies the use of social distancing strategies. However, given lack of information about how many people are likely to present at any given venue, randomizing on site may simply be unavoidable. To be truly random, a process must employ choice by chance strategies, like a lottery. As noted above, haphazard assignment procedures – such as inviting only those persons with asthma whose last names begin with the letters A, S, or W, or only those persons with COPD whose birthdays fall in January, March or October – are not genuinely random. On the other hand, if, given a general call for prioritized individuals to present at a mass vaccination clinic, 1000 people are waiting at

the door when the clinic opens but the supply of vaccine available amounts to only 500 doses, half of the individuals can be sent home (randomly). But what if 250 are waiting at the door when the clinic open and people arrive gradually throughout the day? In this circumstance, the only way to avoid allocating vaccine on a first come, first served basis would be to turn away some individuals without vaccine to reserve supply for individuals who may seek vaccine at the clinic later in the day. Given uncertainties about how many individuals may appear, insistence upon randomization in such a circumstance would fit the letter, but not the spirit, of the Panel's recommendations.

Health care clinics may be able to use information from medical records to determine which patients are prioritized to receive vaccine and to conduct a lottery among them for invitations to present for vaccination. However, such an involved strategy may be unrealistic for a clinic strained by heavy caseloads in a severe pandemic. Even if possible, such a strategy would be complicated by lack of information about numbers of people in these groups who wish to be vaccinated. Clinics may wish to avoid the burden of randomizing in advance as well as the possibility of turning away people seeking vaccine from a mass vaccination clinic. In such a case, clinics could invite all of their patients in priority groups to make appointments for vaccine. However, the practice of giving vaccine to those who manage to make appointments before the supply of vaccine is exhausted is not a random process. If, given the realities of a particular pandemic, the harms of inviting groups of people to vaccine clinics only to turn some away unvaccinated are great enough, then the use of first come first served strategies may be warranted to avoid those harms. This is a decision that health officials and providers

would have to make, perhaps in consultation with an ethics support team, in the context of that particular pandemic.

In any case, the Implementation Team believes it is important to acknowledge that any strategy that involves issuing invitations (randomized or not) to patients of a clinic who fall in priority groups would be unavailable for populations that are not affiliated with a particular provider, or to providers other than private clinics such as walk-in clinics in retail stores or mass vaccination clinics. If private clinics will serve as the primary distribution sites for vaccine, fairness requires that they provide access to individuals who are not their regular patients.

In sum, the Protocol Committee recognizes that, in certain scenarios, it may be preferable to forgo randomization and instead allocate vaccine on a first come, first served basis. Of course, randomization ought not to be abandoned prematurely. However, the most critical measure to ensure fairness when allocating public health resources among equally prioritized persons is to distribute such resources in a way that tracks priority groups across the state, rather than distributing them to reflect proportion of population in general. A general population-based distribution scheme fails to reflect the ethical frameworks for rationing – priority groups may not be reached as needed, and those without priority may receive undue access to scarce resources. If demand still exceeds supply once efforts to target vaccine to priority populations have been exhausted, then consideration could be given to random allocation of vaccine to sites serving prioritized populations to preserve fairness. Randomization at the macro

level – among sites serving prioritized populations – could promote fairness even if randomization at the micro level – among individuals – poses insurmountable challenges.

Recommendations regarding the implementation of rationing criteria:

5.1 The Protocol Committee recommends that the decision about which workers to identify as key be understood as an event-dependent one. The Protocol Committee concurs with the Panel in this regard.

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

5.3 The Protocol Committee recommends that processes for identifying key workers 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 committee recognizes that no preordained limit can be applied to these processes. 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 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.

5.5 The Protocol Committee recommends that patients' self-reports be accepted as guiding rationing decisions where possible. The committee recognizes that judgments about the levels of risk faced by particular individuals will often depend on patients' underlying health status but medical records may not be easily available when making rationing decisions. The committee strongly recommends that current privacy protections be enforced despite the need for health information when making rationing decisions.

5.6 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 to assess whether, and if so how, age-based rationing could be implemented.

5.7 The Implementation Team recommends that information about which priority groups may access resources at a given time be disseminated as widely as possible, in different languages, using a variety of strategies: written materials, and venues for distribution of information (such as neighborhood "hubs" rather than simply posting information to the internet or making announcements on television). Health care clinics may be able to use information from medical records to notify their patients in priority groups that they are prioritized to receive vaccine, but such a strategy would be unavailable for populations that are not affiliated with a particular provider, or through providers other than private clinics such as walk-in clinics in retail stores or mass public health clinics.

5.8 The Implementation Team recommends that private clinics provide fair access to individuals who are not their regular patients if they serve as the primary distribution sites for resources.

5.9 The Protocol Committee recommends considering random selection of distribution sites serving prioritized populations to promote fairness if randomization among individuals poses insurmountable challenges. Randomization may be difficult when distributing some resources, but it should not be abandoned prematurely when supplies are inadequate to reach all who are equally prioritized.

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, public health and health care providers among them. As the Panel Report states, decision-making must be "accountable, transparent and worthy of trust."[69]

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

69 Vawter et al. (2010).

Pandemic Ethics Project, including the process of community engagement 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, and the capacity of various institutions to respond to the threat given absenteeism. The Implementation Team recommends the use of a process for ethics support, to help address these issues as they arise. This process and recommendations for its implementation will be described in section 7 below.

The Protocol Committee feels strongly that, during a pandemic, decisions about allocation of resources should 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 duty to care for individual patients and concomitant responsibility for decisions about what resources that patient may receive.[70] The Protocol Committee recommends that this triage team, perhaps with the input of others such as a pandemic ethics support team, also conduct routine retrospective reviews or audits of decisions made, so that the decision-making process can be improved or adjusted as needed.

Of course, ventilators are not the only type of resource that raises 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 or allocates scarce resources create a local process for routine retrospective reviews. These processes will vary from one type of institution to another, given differences between institutions and among resources being allocated. The discussion of ethics support (section 7 below) will provide guidance on the development and implementation of these processes.

While routine retrospective 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 to question whether ethical frameworks are being fairly and consistently applied at the time decisions are made. Only a process for real time review of decisions can supply such a safeguard. Questions may arise, for example, concerning a decision that a patient be withdrawn from a ventilator or the verification of an individual's status as a key worker to determine that she fits rationing criteria. There are justice considerations and time

70 Hick & O'Laughlin (2006) at 223-229.

constraints involved in real time review. Lengthy deliberation of a decision to remove an individual from a ventilator could cost others their lives. Since antiviral medications need to be administered promptly to be effective, inefficient and time-consuming processes for performing real time reviews of decisions could delay access for the patient in question 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 real time review processes is controversial.[71] However, the Protocol Committee feels that the safeguard of such a process should be available, and 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 support outlined in section 7 below serve this purpose. Since this discussion proposes ethics support at two integrated levels – state 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 local or state levels, depending on the type of issue that arises. The need for ventilator-related reviews would likely arise at the local level. They would need attention at the state level if systemic problems arise in implementation of the framework.

71 Meslin et al. (2007); NYS Task Force On Life & The Law. (2007) at 32 ;Powell et al. (2008) at 20-26; Ontario Health Plan (2007) at 13;Hick et al. (2007) at 217.

The availability of accurate data is central to any real time or retrospective review mechanism. Review without data is neither possible nor morally tenable. For example, if judgments are to be made about the overall fairness of mechanisms for vaccine distribution, a retrospective review (or audit) would need to consider multiple factors. These would include data about patterns of allocation (including geographic location); the rationale for prioritizing recipients for vaccine (key worker, health risk, etc); race, ethnicity and socio-economic status of recipients (to address concerns about disparities and access); and types of reasons given for turning individuals away from vaccine clinics unvaccinated.

Real time reviews that provide triage personnel with additional information could be relatively straightforward in that they focus on the application of established framework(s) with clearly articulated rationing strategies. A legitimate request for real-time review might entail a situation in which providers request review of a case involving a challenge to an individual's status as a key worker. Review requests based on grounds that are inconsistent with the ethical frameworks for rationing would be inherently inappropriate. Inappropriate requests might encompass purely personal concerns ("You can't let my father die!") or reasons relating to perceived social worth ("You can't deny this patient a vaccine if you are going to vaccinate _______," where the blank is filled in with reference to some individual or social group deemed less socially worthy by the individual raising the objection). These entreaties may be heartrending or prejudicial; they would also be potentially catastrophic if allowed to

move forward in review processes. Such cases would add unnecessary and inappropriate strain on the system for conducting reviews and, if successful, 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 ultimate finding by the real time ethics review process is unilateral and final.

The CDC's ethical guidelines for pandemic influenza maintain that procedural justice requires the "Inclusion of processes to revise or correct approaches to address new information, including a process for appeals and procedures that are sustainable and enforceable."[72] While a number of pandemic plans across the United States and in Canada mention the need for review or appeals processes, few plans describe how such processes might be implemented, and none offers a clearly delineated process. Indiana recommends the use of retrospective reviews (audits), but not real time reviews.[73] The Veterans Health Administration in the U.S,[74] the states of Texas[75] and New Mexico,[76] and Ontario, Canada[77] all appear to endorse both retrospective and real time reviews.

72 Kinlaw & Levine at 5.

73 Meslin et al. at 38.

74 The Pandemic Influenza Ethics Initiative Workgroup at 40.

75 Texas Dept of State Health Services at 128.

76 New Mexico Deparment of Health (2006) at 10.

77 Ontario Ministry of Health and Long-Term Care (2008).

Recommendations regarding protections for the public:

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 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 support for providers and decision-makers when concerns are raised regarding the procedural and substantive propriety of such 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 implementation of retrospective and real time reviews of decision-making involve the process for ethics support outlined in section 7 below. Since this proposed process for ethics support would work at two integrated levels – state and local – it can be adapted to retrospective and real time reviews of decision-making for each resource.

7. Ethics Support

This section outlines a systematic model (and supporting structure) for an ethics support process that is dynamically responsive to a broad range of evolving issues. Development of a model for ethics support was stipulated by MDH in the Minnesota Pandemic Ethics Project contract. To address this task, the Implementation Team convened a work group comprising two clinical ethicists (Mary Faith Marshall and Donald J Brunnquell) in consultation with a representative of MDH (Patricia Bloomgren). The clinical ethicists are professionals who direct ethics committees and consultation services at public, private, and academic health care organizations in Minnesota. The plan was crafted in consultation with the following experts:

- Arthur Derse, MD, JD, Director for Medical and Legal Affairs, and Acting Director, Center for the Study of Bioethics, Professor of Bioethics and Emergency Medicine, Medical College of Wisconsin; Consultant to the state of Wisconsin for pandemic planning;
- Charles Gessert, MD, MPH, Division of Education and Research and Chair, St. Mary's Duluth Clinic Health System Institutional Review Board;
- John Hick, MD, Medical Director for Bioterrorism and Disaster Preparedness and Assistant Director for Emergency Medical Services, Hennepin County Medical Center; Medical Director, Office of Emergency Preparedness, MDH;
- Daniel T. O'Laughlin, MD, FACEP, Medical Director for Emergency Preparedness and Trauma, Abbot Northwestern Hospital and Assistant Professor of Emergency Medicine, University of Minnesota Medical School;

- Jonathan Sande, MD, Director, St. Mary's Medical Center Ethics Program, Duluth, MN.

During a pandemic a structured approach for identifying, analyzing and resolving ethical issues will be needed at two organizational levels: the institution (e.g. individual primary care facilities, alternative care sites, and acute care triage teams); and the Minnesota Department of Health.

Ethics consultation is a familiar process in the majority of healthcare institutions, certainly among those accredited by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). The JCAHO accreditation standards for patient rights and organizational ethics require a mechanism for the resolution of ethical problems.[78] 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.[79] The two traditional domains of ethics consultation are clinical and organizational ethics. Research ethics consultation is a less frequent, but growing service. Within these domains, consultation may address a spectrum of issues ranging from individual cases at the bedside to broad issues of organizational policy.

78 Joint Commission Resources (2008) at 18.

79 American Society for Bioethics and Humanities (1998).

During a pandemic, the traditional goals of ethics consultation in the clinical, organizational and research settings may continue to serve many needs of health care institutions, patients, families and clinicians. In a severe pandemic, however, 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.[80] Issues of justice and fairness as understood and articulated in the ethical frameworks will be paramount in moral decision making. Thus, in addition to the traditional ethics committee/consultation mechanism for resolving issues of clinical and organizational ethics, a *supplemental* mechanism of applied ethics will be required to assure fair and consistent application of the ethical frameworks adopted or adapted by institutions and organizations.

The goals of ethics support during a pandemic will be:

- To facilitate consistent and fair application of the ethical frameworks for the allocation of scarce resources;
- To assist state officials and healthcare professionals to recognize and resolve ethical problems as the pandemic unfolds;[81]
- To facilitate communication and effective decision making in resource allocation and patient care;

80 Trotter (2007).
81Fletcher et al. (1997).

- To foster greater awareness among state officials and health care professionals of the role of professional values and norms in public health, clinical and organizational decision making during a pandemic; and
- To prevent and minimize harm to members of the public, patients, healthcare professionals and institutions.

To meet these goals, the Implementation Team recommends a model for ethics support based on existing mechanisms for resolving ethical issues at the local level, and the development of a state-level ethics support mechanism appointed by the Minnesota Department of Health. Proposed complementary structures such as Hospital Incident Command systems linked by Regional Medical Coordinating Centers and a State Disaster Medical Advisory Committee could operate synergistically with this model.[82] Such a structure would allow for the development of hospital coalitions, coordination of rural sites, and liaison among hospitals, public health, EMS, and emergency management services. Conference calls and web-based information sharing systems established for clinical and emergency management could integrate parallel ethics support services.

The primary function of the ethics support process is to facilitate consistent application of ethical frameworks for the allocation of scarce resources. To avoid role or mission confusion, it is important to distinguish clearly between typical/traditional clinical, organizational and research ethics services and the novel pandemic ethics support

82 IOM (2009).

process proposed in this report. Ethics support during a pandemic will occur relative to a variety of needs. The process will encompass approaches to health care ethics that inform public health, mass casualty medicine, "ordinary" clinical medicine, and healthcare organizational governance.

During a pandemic, ethics support 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;
- The ethical problem involves a serious disagreement or dispute among those involved. This would include the real time review mechanism that providers or decision-makers could avail themselves of to resolve disagreements about initial or continued access to clinical resources. It could 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;
- The need arises to review the policies and practices that have emerged in the pandemic and to recommend measures to alter or improve them.

The primary role of the local pandemic ethics support group will be to serve as a mechanism for real time and retrospective reviews. The function of local pandemic ethics support groups in the real time review process is not to second guess clinical decision making by triage teams, but to ensure fair and consistent application of the

ethical framework(s) adopted by their institutions. It is likely that small review teams with staggered membership, who can review records electronically and communicate via teleconference and web-based mechanisms will be the most effective means for dealing with requests for review even if the volume of requests is high.

In order to avoid inappropriate and overwhelming claims on pandemic ethics support group members, each request for real time pandemic ethics review should be reviewed in a timely manner by a rotating member of the pandemic ethics support group. This person would determine whether or not the request meets review criteria and thus merits the attention of the entire ethics support team, or whether the request should be forwarded to the state pandemic ethics support group since it involves systemic allocation issues.

It is crucial that findings from real time review be final and unilateral at the level of review. It is anticipated that findings contravening acute clinical triage or public health allocation decisions would be rare given the use of concrete protocols and algorithms by triage and public health officials. Any instance of a contravention would require mandatory reporting to institutional administrators and the state pandemic ethics support group. The state pandemic ethics support group would have the responsibility and prerogative to provide oversight and assistance to local pandemic ethics support groups.

Communication up the chain to the state ethics support group would facilitate and trigger a larger *retrospective* review of the allocation process as a means of "checks and balances" to identify systemic issues and determine whether substantive changes would need to be made to any approach to allocation being used during a pandemic. Since a challenge to the result of a *real time* review made at the local level and moved up the chain of command to the state would take a significant amount of time, divert personnel and could increase morbidity and mortality, the state ethics support group should not override local decisions. Should the state pandemic ethics support group determine that there are legitimate concerns regarding how the frameworks are being applied locally, MDH would need to make a decision about intervening to protect public health. This would generally occur only under extreme circumstances. The state pandemic ethics support group could, at its own initiative, retrospectively review real-time reviews on a for-cause or random basis, not to overturn them but to determine whether improvements in review processes are warranted.

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

It is critically important to note that the reality and efficacy of real time or retrospective ethics review at the local and state levels depend on timely and accurate data. Review

mechanisms are data driven and data dependent. With the exception of allocation of mechanical ventilators in acute care settings (based on clearly defined prognostic indicators), review of other resources may not be feasible unless data are available.

The pandemic ethics support process is not analogous to traditional ethics consultation services provided by hospital or institutional ethics committees or consultants. There are three important differences between the pandemic ethics support process and traditional ethics consultation services.

First, findings based on real time pandemic ethics support process reviews are (depending on the context or resource) final and unilateral, not advisory. This differs from the findings and recommendations of traditional ethics consultants or committees which are generally understood to be advisory only. However, in contexts other than real time reviews, ethics support serves an advisory function.

Second, the primary aim of the pandemic ethics support process is to ensure fair and consistent application of frameworks for the allocation of resources during pandemic. The scope of the ethics support process is clearly and narrowly delineated, and will not comprise the wide array of cases and issues generally encountered by ethics committees/consultation services.

Third, access to pandemic ethics support services will be limited. While traditional ethics consultation is an open mechanism (i.e. anyone with legitimate standing in a case — patient, family member, surrogate decision maker, clinician — can request ethics consultation), access to real time review by pandemic ethics support services will be limited to providers or decision-makers at the state or local level when questions are raised concerning the fair application of a relevant ethical framework. This process provides support for providers and decision-makers when concerns are raised regarding the procedural and substantive propriety of allocation decisions at the time that they are made. It provides support for the state in assessing fair application of rationing decisions and addressing unforeseen issues in pandemic response as they arise.

A central criterion for the organization of ethics support mechanisms at each level is that they are multidisciplinary, that they include ethics expertise, and that they, ideally, include community representatives and reflect the demographics and cultures of their communities. A fundamental tenet of the ethics support process is that its task consists of applied ethics. Its work is morally, not clinically evaluative — its primary goal is to assure fair application of ethical frameworks, not to second guess clinical decisions made by triage teams or public health officers. Just as traditional clinical, research or organizational ethics consultation does not require the degree of in-depth knowledge possessed by direct providers (be they acute care or public health workers), the members of pandemic ethics support mechanisms need not be experts in critical care

medicine/nursing or health disaster response in order to assess the application of ethical frameworks. While some understanding of the challenges of pandemic response is desirable, the appropriate primary domain of specialized knowledge and expertise for those engaged in the ethics support process includes robust understanding of the ethical frameworks, and emerging state and federal guidance.

Consistent with JCAHO standards, the composition of local ethics support groups will be determined at the local level based on needs and resources. These groups could utilize existing resources such as ethics committees/consultants. Given the probable scarcity of human resources during pandemic, members of ethics support teams could comprise rotating representatives of extant ethics committees or consultation services as well as volunteers such as community leaders, retired clinicians and retired public health and social service workers. For efficiency's sake, the local pandemic ethics support group could comprise the chairperson of the institutional ethics committee (or designee with ethics expertise/experience), a community representative (ideally with ethics committee experience), and (depending on the nature of the institution) a clinician or public health professional. The triage officer for this group could serve as the liaison with incident command systems and clinical triage teams. Coordination of pandemic ethics support group services could occur among alternative care sites, long term care facilities, prisons and other healthcare entities to best meet needs with available resources.

The state pandemic ethics support group should comprise representatives of local pandemic ethics support groups (reflecting the geographic and cultural diversity of the state), experts in public health, and ethics experts. In addition to serving as a resource for MDH, the state pandemic ethics support group would be responsible for 1) providing prospective education to local pandemic ethics support groups regarding state and federal guidance including ethical frameworks for rationing and principles of distributive justice, 2) review of requests for guidance from local pandemic ethics support groups relative to fair application of ethical frameworks, and 3) review of systemic issues/challenges regarding the frameworks that arise at the local or state level. The state pandemic ethics support group would respond to evolving issues surrounding both macro and micro allocation of resources such as antivirals, vaccines, personal protective equipment, ventilators, evolving triage guidance from the Regional Medical Coordinating Center, and emerging new technologies.

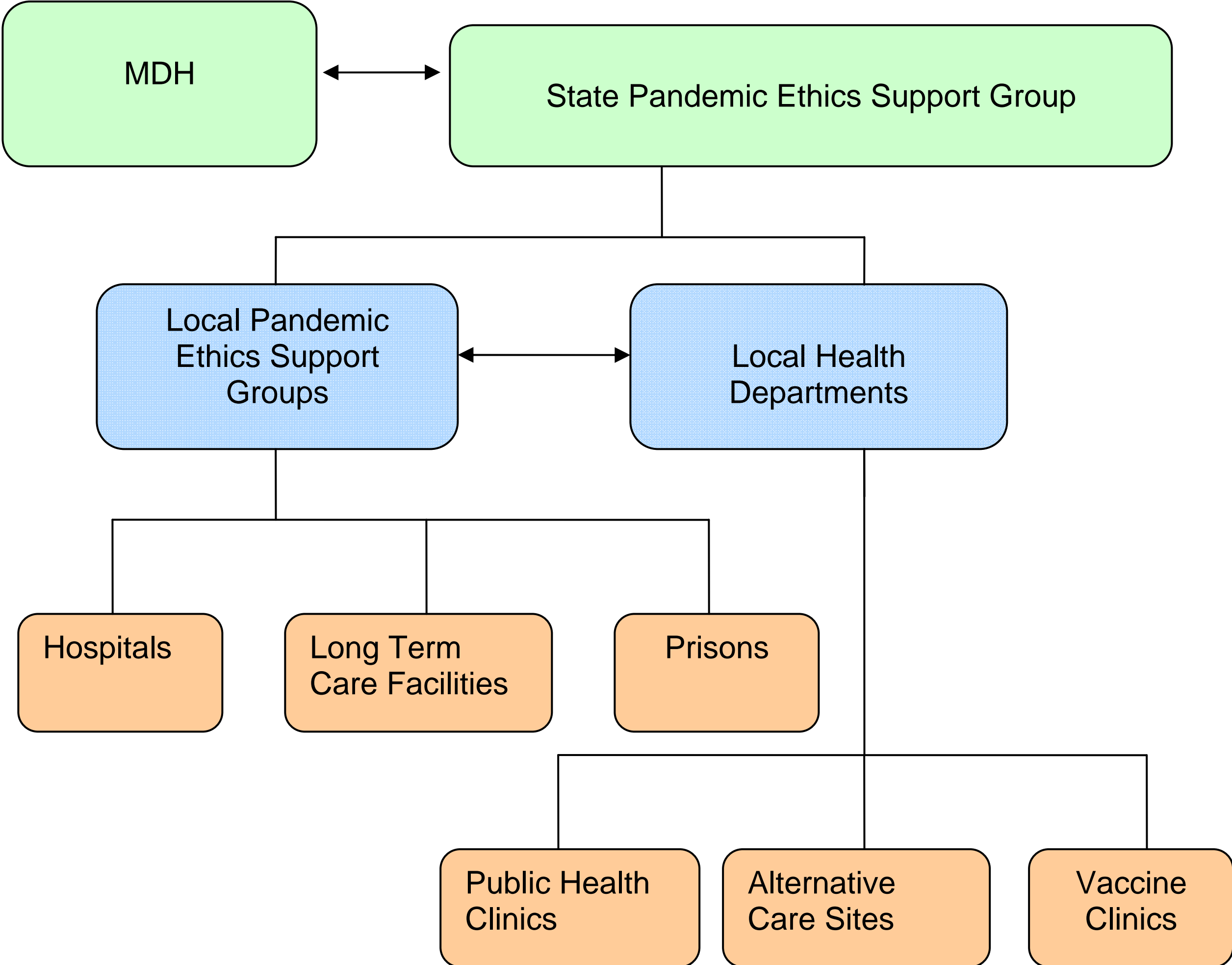
Ideally, ethics support availability should be 24/7 via online and teleconferencing mechanisms (most frequent) or an on-site presence (less likely given contagion concerns, but certainly possible in some contexts). Demands on the system may require that members of pandemic ethics support groups give priority to direct patient care/public health needs of their respective institutions. There may be times in which ongoing functioning of the ethics support mechanism is not feasible.

Initial and continuing education of pandemic ethics support group members regarding the ethical frameworks and policies and procedures adopted by MDH could be

accomplished via initial workshops hosted by MDH and conducted by members of the state pandemic ethics support group. In addition, annual training and continuing education could address new developments and knowledge, and changes in the ethical framework adopted by MDH. Existing educational materials could be used towards this end.

A state pandemic ethics support group website (possibly linked to the Regional Medical Coordinating Center data bases) could serve to disseminate information to local pandemic ethics support group members. The website could be a central resource for bi-directional information dissemination throughout the network as the pandemic unfolds.

System for Ethics Support During a Pandemic



Recommendations regarding ethics support:

7.1 The Implementation Team recommends that MDH implement and administer a system for ethics support at the state level, and require development of ethics support mechanisms at local levels. The primary function of the ethics support process is to facilitate consistent application of ethical frameworks for the allocation of scarce resources.

7.2 The Implementation Team recommends that the state pandemic ethics support group comprise representatives of local pandemic ethics support groups (reflecting the geographic and cultural diversity of the state), experts in public health, and ethics experts. In addition to serving as a resource for MDH, the state pandemic ethics support group would be responsible for 1) providing prospective education to local pandemic ethics support groups regarding state and federal guidance including ethical frameworks for rationing and principles of distributive justice, 2) review of requests for guidance from local pandemic ethics support groups relative to fair application of ethical frameworks, and 3) review of systemic issues/challenges regarding the moral frameworks that arise at the local or state level.

7.3 The Implementation Team recommends that the composition of local ethics support teams be determined at the local level based on needs and resources. Given the probable scarcity of human resources during pandemic, members of ethics support teams could comprise rotating representatives of extant ethics committees or consultation services as well as volunteers such as community

leaders, retired clinicians and retired public health and social service workers. Coordination of pandemic ethics support group services could occur among alternative care sites, long term care facilities, prisons and other healthcare entities to best meet needs with available resources.

7.4 The Implementation Team recommends that ethics support be sought when those attempting to resolve an ethical problem have reached an impasse, when the ethical problem involves a serious disagreement or dispute, when the problem is unusual, unprecedented, or very complex ethically, or when the need arises to review the policies and practices that have emerged in the pandemic and advise MDH on measures to alter or improve them.

7.5 The Implementation Team recommends that access to real time review by pandemic ethics support services be available to providers or decision-makers at the state or local level when questions are raised concerning the fair application of a relevant ethical framework. This process provides support for providers and decision-makers when concerns are raised regarding the procedural and substantive propriety of allocation decisions at the time that they are made. It provides support for the state in assessing fair application of rationing decisions and addressing unforeseen issues in pandemic response as they arise. The Implementation Team further recommends that the findings of real time reviews be final and unilateral.

7.6 The Implementation Team recommends that, in order to avoid inappropriate and overwhelming claims on pandemic ethics support group members, each request

for real time pandemic ethics review should be reviewed in a timely manner by a rotating member of the local pandemic ethics support group. This person would determine whether or not the request meets review criteria and thus merits attention.

7.7 The Implementation Team recommends that pandemic ethics support groups, especially at the local level, provide structured and systematic retrospective reviews to ensure compliance with and consistency in the application of the ethical frameworks.

8. Palliative and Hospice Care

While not representing an official charge by MDH, issues related to the 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 thus raised the issue with the Protocol Committee despite the deviation from the project's formal charge inherent in the discussion. The Panel also issued a recommendation in favor of stockpiling palliative care resources.[83] The Protocol Committee discussed challenges with providing hospice and palliative care during pandemic, and agreed that the Implementation Team should formulate a strategy to address these challenges. The resultant recommendations are solely the result of the Implementation Team's deliberations.

83 Vawter (2010) §3.1.

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 equals 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.[84] 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 volunteers, family members and friends. Clinicians who routinely 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, volunteers, family members and other caregivers will experience the novel and tragic challenge of shepherding loved ones or strangers through the dying process in the home care setting or in alternative hospice care sites. 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.

84 Trotter (2007) at 6.

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.

To promote and protect the interests of individuals who will provide and receive care across settings – traditional institutional settings, alternative care sites, and home care –, MDH and health care facilities should consider the following in developing plans and protocols for the administration of palliative and hospice care:

- An adequate/stockpile of medications: relatively low cost comfort care kits have already been developed for home hospice and palliative care. These kits typically include generic morphine, lorazepam, atropine and haldol to address respiratory distress, pain, anxiety, pulmonary secretions, agitation and terminal delirium, the primary symptoms experienced by individuals dying from respiratory influenza.
- A mechanism for distributing comfort care kits for home and alternative site use should be developed.

- Distribution of symptom management protocols and algorithms for clinicians, including guidelines for ventilator withdrawal (both terminal weaning and immediate withdrawal). These have already been developed in the context of pandemic preparedness initiatives.
- Support for families who are caring for dying loved ones with the anticipated likelihood that current or newly established alternative 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. Distribution of symptom management protocols and algorithms for use by laypersons; these have already been developed within the context of home hospice. 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 Implementation Team recommends the development of a workgroup, administered by the statewide professional organization, Minnesota Network of Hospice & Palliative Care, in concert with statewide hospice and palliative care programs, for implementation planning, ongoing consultation, and care delivery. 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 the Minnesota Network of Hospice & Palliative Care, in concert with statewide hospice and 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 and distributing palliative care resources, promulgating symptom management protocols and algorithms, developing caregiver educational programs for laypersons and clinicians, developing a process for ongoing community engagement and communication, planning for support of the dying and their caregivers.

CONCLUSION

The H1N1 influenza pandemic was relatively mild. 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 experience 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. The ramifications of a pandemic are difficult to predict in our increasingly complex world. 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."[85] Plans for rationing scarce resources in a pandemic should "protect the population's health, protect public safety and civil order, strive for fairness and protect against systematic unfairness."[86] 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. 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 safeguards as ongoing monitoring, decision-making review mechanisms, and public and professional protections. They also drive substantive protections for at-risk populations.

85 Vawter et al. (2010).

86 Ibid.

The Evolving Nature of the Pandemic: It is abundantly clear that any 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 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 support 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 should 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 the Minnesota Network of Hospice & Palliative Care, in concert with statewide hospice and 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 also recommends that legal counsel be sought on the question of protections for volunteers during pandemic, and to assess whether, and if so how, age-based

rationing could be implemented consistent with federal and state laws regarding age discrimination.

Finally, the report recommends that MDH should sponsor an organization to develop, implement and administer a system for ethics support at the state 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 institutions remain faithful to the ethical frameworks; and to aid in resolving real time reviews of rationing decisions during pandemic. Thus, ethics support plays a critical and central role in the implementation of the ethical frameworks for rationing.

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