MEETING THE CHALLENGE OF PANDEMIC INFLUENZA: ETHICAL GUIDANCE FOR LEADERS AND HEALTH CARE PROFESSIONALS IN THE VETERANS HEALTH ADMINISTRATION

Prepared by

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As part of the National Strategy for Pandemic Influenza, The White House tasked the Department of Health and Human Services (HHS) and other Federal agencies to develop guidance for allocating scarce health and medical resources during a flu pandemic. In concert with HHS, the National Center for Ethics in Health Care of the Department of Veterans Affairs (VA) has developed ethical guidance to assist VA facilities in pandemic workforce, communications, and patient care planning.

This guidance has been used in draft form for VHA pandemic planning and national VHA exercises. This approved version was signed by the VA Under Secretary for Health on July 7, 2010.

Although the need for this guidance is not high at this time, it addresses many issues, principles, and planning tools that are relevant to an all-hazards approach to emergency management.

We welcome your feedback on how you are using the guidance and any specific suggestions on how the guidance can be improved and updated. Please contact us at vhaethics@va.gov and use the subject line "Pan Flu Ethics Guidance Feedback" in your email message.

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EXECUTIVE SUMMARY

CHARGE

The *Implementation Plan for the National Strategy for Pandemic Influenza* (2006) charges Federal agencies to develop guidance for the allocation of scarce health and medical resources during a pandemic flu event. As the lead agency, the Department of Health and Human Services (HHS) produced initial guidance in 2007 (Agency for Health Care Quality and Research, 2007). This VA guidance document draws on the HHS planning guide and other key documents to provide specific guidance targeted to the Veterans Health Administration (VHA). This document also fulfils the charge in VA's Pandemic Influenza Plan (Department of Veterans Affairs, 2006) to develop "criteria and transparent processes for allocation decisions regarding resources that may not be available in sufficient quantities during a pandemic" (Department of Veterans Affairs, 2006, Section # 2.2.2.3).

This guidance addresses decision processes for allocation of scarce clinical resources that are potentially life saving, such as ventilators and other critical care resources, as well as related questions concerning the ethical duty to provide care and reciprocal institutional obligations, hospice and palliative care planning and response, and limits on individual liberties related to influenza containment. Guidance regarding allocation of countermeasures such as vaccines and antivirals is being developed by Federal interagency work groups (Department of Health and Human Services, 2007).

Scope of this Guidance
■ Applies to decision-making by VHA leaders and health care professionals regarding care for Veterans in VHA hospitals, clinics, Community Living Centers, and hospices.
■ Discusses health care professionals' ethical duty to provide care and reciprocal institutional responsibilities.
■ Discusses criteria and processes for allocation of scarce life-saving resources.
■ Discusses limits on individual liberties related to pandemic influenza containment.
■ Discusses hospice and palliative care planning and response.
■ Does ***not*** address allocation of countermeasures such as vaccine and antivirals.

BACKGROUND

In an influenza pandemic, the demand for health care services is anticipated to exceed the capacity of VHA facilities both to treat influenza patients and to sustain other health care services. Projections based on the peak period of a severe 1918-like influenza pandemic suggest that facilities may have only one ICU bed for every four to five influenza patients who require it, one ventilator for every two influenza patients who require it, and one non-ICU bed for every two influenza patients who require it. Facilities will be stressed by personnel shortages that result from workers becoming ill or remaining at home either to care for family or out of fear of infection. Due to the numbers of infected patients who will seek treatment, VHA facilities, in conjunction with their communities, will need to isolate patients and may need to advocate voluntary quarantine consistent with U.S. Community Mitigation Guidance (Department of Health and Human Services, February 2007) for potentially exposed patients and staff, resulting in further shortages in the availability of rooms, beds, and staff.

PURPOSE OF THE GUIDANCE

With resources scarce and the pressing need to contain the spread of the virus, VHA leaders and health care professionals will be faced with extraordinary ethical challenges centered on responsibilities (defining the scope and limits of VHA employees' ethical duty to provide care to patients and reciprocal institutional obligations), resource allocation (allocation of scarce resources), and restrictions (limiting individual liberty in the interests of public health).

Ethical Challenges in Pandemic Planning and Response

RESPONSIBILITIES: The ethical "duty to provide care." The obligation of health care workers to accept reasonable risk in the service of patients and the reciprocal obligation of health care institutions to minimize risk to health care workers.

RESOURCE ALLOCATION: The criteria and processes for decision-making regarding the fair and efficient use of scarce resources.

RESTRICTIONS: Limits on individual liberty in the interests of public health. Justifications and procedures for implementing limits on individual liberty to prevent the spread of infection.

The purpose of this guidance is to provide VHA leaders and health care professionals with an ethical framework to meet these challenges. This framework includes information, analysis, recommendations, and criteria for conducting ethical decision processes and for resolving substantive ethical dilemmas. In each of these areas, this document summarizes ethical principles about which there is consensus in clear, actionable language and communicates national guidance for VHA.

The expectation is that VHA leaders and health care professionals will use this information both *before* an outbreak of pandemic influenza as a basis for pandemic influenza planning, tabletop exercises, preparatory drills, and educational forums, and *during* an outbreak as a guide for decision-making.

CORE ETHICAL PRINCIPLES AND VALUES

The guidance provides information about the ethical bases for pandemic planning and response, addressing values and obligations of VHA leaders and VHA health care professionals.

As a starting point, the guidance is predicated on the fundamental assumption that decision-making in pandemic influenza planning and response must be based on achieving the greatest good for the greatest number (the principle of utility or efficiency) *within constraints of respect for human dignity and fairness* (the principle of justice applied across groups of people according to specified criteria). One of the most important roles that VHA leaders will play in pandemic planning and response will be determining, based on reasoned justification, how these principles will be balanced in particular decisions.

Ethical leadership in pandemic planning and response is grounded in the obligations and values that define all aspects of VHA health care based on leaders' roles as public servants, health care providers, and managers.

Ethical Leadership in Pandemic Planning and Response

As **public servants**, VHA leaders are responsible for maintaining the public trust, placing duty above self-interest, and managing resources responsibly.

As **health care providers**, VHA leaders have a fiduciary obligation to meet the health care needs of individual patients in the context of an equitable, safe, effective, accessible, and caring health care delivery system.

As **managers**, VHA leaders are responsible for creating a workplace culture based on integrity, accountability, fairness, and respect. They must ensure that staff members throughout the organization are supported in their adherence to high ethical standards.

The guidance discusses a leadership decision-making process that is:

- Informed and participatory
- Values-based
- Beneficial
- Systems-focused
- Reasonable
- Transparent

In addition to the values that guide pandemic planning and response at the VHA *leadership* level, the guidance discusses norms of health care professionalism that are relevant to *clinical* decision-making during a pandemic including:

- Ethical duty to provide care and non-abandonment
- Respect for persons
- Duty to benefit and to prevent harm
- Fairness

Assumptions of this Guidance
Assumption #1: Under circumstances of pandemic influenza, health care leaders and professionals will be faced with extraordinary ethical challenges centered on resource allocation, responsibilities, and restrictions. **Assumption #2:** Ethical leadership demands advance planning to meet the challenges of pandemic influenza. **Assumption #3:** Both the principle of utility (achieving the greatest good for the greatest number), and person-oriented principles of justice and human dignity should play a central role in guiding health care decision-making during a pandemic. **Assumption #4:** Specific local pandemic-related policies and procedures are especially important when practitioners are required to deviate from normal practice and follow crisis standards of care. Quality of care will be enhanced if practitioners are guided by institutionally promulgated policy, guidance and/or rules.

CHAPTER OVERVIEWS

Ethical Challenge #1: Responsibilities

Section 2: Work force Capacity and an Ethical "Duty to Provide Care" Under Conditions of Pandemic Influenza

VHA employees have an ethical "duty to provide care" (i.e., commitment to provide care to patients even when assuming personal risk) under conditions of pandemic flu. This ethical duty is grounded in fidelity to VHA's public service mission and an ethic of care and non-abandonment of the Veterans we are privileged to serve. The ability of caregivers to fulfill their "duty to provide care" under conditions of pandemic influenza is predicated on VHA meeting its reciprocal obligations. These reciprocal obligations center on addressing workplace conditions that enable employees to take care of patients, but also include reciprocity owed those employees who voluntarily assume a disproportionate risk of illness and even death to fulfill VHA's mission. Recommendations focus on (1) a fair and consistent decision-making process used to specify the limits or exceptions to an employee's duty to provide care, and (2) reciprocal obligations of VHA to safeguard employees and provide for their welfare, mitigate occupational risk, support stricken staff and their families, and assist employees in meeting competing obligations.

Ethical Challenge #2: Resource Allocation

Section 3 – Triage and the Allocation of Scarce Life-Saving Clinical Resources

Under conditions of dire scarcity, it is expected that need will outstrip resources and consequently it will not be possible to provide everyone the care that they require to survive. This guidance focuses specifically on "tertiary triage," that is, the allocation of scarce, potentially life-saving clinical resources such as ventilators, ICU beds, and certain medications used to treat those who are gravely ill from influenza and other illnesses. The protocol outlined here is intended to provide a fair, consistent and

rational allocation framework for making these difficult decisions. Specific recommendations focus on (1) establishment of a Scarce Resource Allocation (SRA) team and a Triage Team, and (2) a protocol for allocation of scarce life-saving resources.

Ethical Challenge #2: Resource Allocation

Section 4 – Hospice and Palliative Care Planning

VHA is committed to the provision of compassionate and humane care to the terminally ill Veteran and the Veteran's family. Although a strictly utilitarian approach to pandemic planning and response might justify concentrating health care resources (staff, beds, supplies, and drugs) only toward saving those lives that can be saved, an approach that balances utility, fairness, and human dignity requires that steps are also taken to provide for those who are not expected to survive. Providing hospice and palliative care is a way of respecting the dignity of those who will not survive by helping to mitigate their pain and suffering. It is a way of achieving equity for those who cannot benefit from more intensive therapies or who could benefit, but due to scarcity will not receive access to life-saving resources. The provision of hospice and palliative care is also a fulfillment of the obligation of non-abandonment – a basic tenet of professionalism and the minimum requirement of an ethical duty to provide care. Carrying forward these obligations into circumstances of pandemic influenza requires specific plans to (1) secure a dedicated stockpile of appropriate hospice and palliative care supplies (e.g., pain medication, anxiolytics), (2) identify non-clinical support staff who will assist in the provision of hospice and palliative care during a pandemic, (3) establish and augment linkages with community-based service organizations and personnel, and (4) develop educational materials for patients and family that help them understand how best to take care of themselves and dying family members when they do not have access to life-saving hospital care.

Ethical Challenge #3: Restrictions
Section 5 – Limiting Liberty in the Interests of Public Health

In public health crises such as pandemic influenza, a public health response is likely to include restrictions on the liberty of individuals in order to control the spread of infection within the population. Such a public health response poses predictable challenges to VHA health care professionals' obligation to give priority to the welfare of individual patients. Although many Veterans may voluntarily accede to some restrictions on their liberty, the usual emphasis on patient autonomy may cause professionals and their Veteran patients to chafe at such restrictions. However, ethical theories uniformly recognize that individual liberties may be limited to prevent harm to others; public health measures are established on this basis. To preserve liberty as much as possible, the Centers for Disease Control and Prevention's (CDC) Community Mitigation Guidance recommends that quarantine be voluntary and be applied to household members of the ill only (Department of Health and Human Services, February 2007). Similarly, this guidance emphasizes (1) strategies for achieving public

health goals through the least restrictive means possible and (2) effective communication with staff and Veterans during pandemic planning and a pandemic.

RECOMMENDATIONS

To ensure ethically informed pandemic influenza preparation and response, this guidance recommends a number of steps by VHA leadership.

In advance of a pandemic event, the Under Secretary for Health or designee should:

1) Issue disaster policies outlining special procedures for the provision or non-provision of scarce, potentially live-saving resources under crisis standards of care (Institute of Medicine, 2009).
2) Clarify with VACO, VISN, and facility leaders the White House Homeland Security Council's guidance that "VA's priority with respect to protecting human health is to deliver health care to enrolled Veterans and beneficiaries. VA also has a mission to provide medical surge capacity for treatment of casualties arising from DOD operations and can provide other support to the extent the VA's mission to serve Veterans is not compromised." (2006, p. 115). The purpose of this clarification should be to assist Facility Directors in decision-making regarding the provision of humanitarian care during pandemic.
3) Ensure that the communications response plan targeting employees and volunteers:
    a. Emphasizes the commendable nature of caring for Veterans during pandemic flu despite the great personal risk of exposure to contagion.
    b. Reinforces VHA reciprocal obligations to support staff members and volunteers who put themselves at risk. The plan should include communications concerning:

        i. Providing pay incentives, including overtime and hazardous duty pay in accordance with Federal statutory and regulatory authority. (VHA officials should consult with Human Resources Management officials for guidance on utilizing existing authorities.):
        ii. Providing immunity from personal liability for staff acting in good faith to fulfill VHA's mission;
        iii. Caring for the basic physical needs of staff members and volunteers;
        iv. Helping the staff to meet other competing social and personal obligations; and
        v. Providing safety and protection, including physical plant safety, vaccines, countermeasures, and personal protective gear.
4) Seek authority through VA's legislative program to provide reciprocal support to employees who place themselves at risk during a pandemic, including, as needed, but not limited to: Overtime pay (e.g., for Title 38 nurses).

5) Engage stakeholders, including Veterans, VSOs, labor unions, employees, the public, and Congress, in a discussion of the ethical issues contained in this guidance.
6) Ensure that national policies governing Time and Attendance and Leave are modified for use in emergency response to provide maximal flexibility to facilities to arrange work schedules and duty station assignments.
7) Ensure that the resources required to provide hospice and palliative care are included in national stockpiles and available for use when required.
8) Encourage facility leadership to incorporate a process for disaster credentialing and granting disaster privileges into their credentialing and privileging process and emergency management plan.

In advance of a pandemic event, VACO and VISN leaders should:

1) Determine and communicate the trigger and processes for instituting crisis standards of care at VHA facilities (Institute of Medicine, 2009).

During a pandemic event, VACO and VISN leaders should:

1) Ensure that VISN and facility leadership have timely, accurate, and complete information regarding the developing pandemic and the Federal government's response to it;
2) Implement protocols for clinical evaluation and allocation of scarce life-saving resources consistently across all VHA facilities that are operating under crisis standards of care; and
3) Clarify with Facility Directors that in the event of severe local resource scarcity, initiation of the tertiary triage protocol is at the discretion of the Facility Director, pending VISN approval.

In advance of a pandemic event, facility leaders should:
(See Appendix 2 for a detailed checklist for facility leaders.).

1) Update the facility work force plan to:
    a. Address the clinical staff duty to care;
    b. Specify the facility's reciprocal obligations to staff;
    c. Outline the role of non-clinical staff in clinical duties;
    d. Detail assignments for volunteers (including Disaster Emergency Medical Personnel System (DEMPS volunteers). (VHA Handbook 0320.03, Disaster Emergency Medical Personnel System (DEMPS) Program and Database);
    e. Detail plans for changes in scope of practice; and
    f. Inform contractors that legal authority does not currently exist to protect contract employees under the Federal Tort Claims Act, and that they should check with their malpractice insurer to make sure that their coverage would extend to actions taken under an altered scope of practice during a pandemic.

2) Update the facility patient care response plan to:
    a. Establish a scarce resource allocation (SRA) team and associated data management requirements and operating procedures (covering triage protocols and review and appeal mechanisms.).
    b. Describe the processes and resources required for implementing hospice and palliative care services during the pandemic (covering stockpiling supplies, coordinating with SRA, and staffing and training.).
3) Ensure the facility communications plan addresses the ethical issues covered in this guidance relevant to:
    a. Changes made to the work force plan;
    b. The allocation of scarce resources and crisis standards of care;
    c. The expectations about mandated public health measures;
    d. The expectations about quarantine, social distancing, and isolation; and
    e. Direct communication and education of Veterans and their families;
4) Ensure appropriate preparation, training, and testing of all of new elements of the facility pandemic flu response plan.
5) Actively engage stakeholders, including Veterans, VSOs, labor unions, employees, and the public throughout the pandemic flu planning and preparation process.

During a pandemic event, VHA facility leaders should:

1) Be physically present at their facilities and be actively involved in supporting both clinical and non-clinical staff in ensuring the delivery of care to Veterans and the provision of essential services to employees.
2) Activate the SRA team and support its implementation of crisis standards of care. Ensure that the team has the information and authority it needs to make decisions about triage and the allocation of scarce resources.
3) Ensure timely and accurate flow of information between the SRA team and top facility management; and the timely and accurate flow of information to employees, patients, family members, and the public, including the reasoning behind the decisions being made and the processes being used to make them.

In addition, VISN and facility leaders should review this entire guidance document and consider how best to address the principles discussed and to implement the specific protocols detailed. Facility managers, supervisors and IntegratedEthics program staff should also study this document and integrate these ethical principles and protocols into their pandemic influenza planning. Appendix 2 provides a checklist for facility leaders to ensure that these principles and protocols are implemented in pandemic preparation and response.

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This guidance was developed by the Pandemic Influenza Ethics Initiative Workgroup at the National Center for Ethics in Health Care. Development of the guidance was overseen and approved by Ellen Fox, MD, Chief Ethics in Health Care Officer.

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SECTION 1: ETHICAL CHALLENGES IN PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE

1.1 CHARGE

The U.S. Homeland Security Council's *Implementation Plan for the National Strategy for Pandemic Influenza* (2006) has charged the Department of Health and Human Services (HHS) in coordination with the Department of Defense (DoD) and the Department of Veterans Affairs (VA), to "develop guidance for allocating scarce health and medical resources during a pandemic" (U.S. Homeland Security Council, 2006, #6.1.2.4.).

In fulfillment of this task, the Agency for Health Care Research and Quality (AHRQ) has developed a planning guide, *Mass Medical Care with Scarce Resources* (AHRQ, 2007) to assist communities in their efforts to plan for and respond to a mass casualty event (AHRQ, 2007, p. iii). AHRQ has also funded the American College of Chest Physicians (ACCP) to develop two products: (1) operational guidance for providing mechanical ventilation outside of traditional ICUs (Rubinson, 2008), and (2) triage algorithms for initiating, withholding and withdrawal of critical care resources for emergency mass critical care. (Devereaux, 2008).

This Veterans Health Administration (VHA) guidance document draws on the Agency for Health Care Research and Quality (AHRQ) planning guide and other Federal and non-Federal resources to provide guidance informed by and specifically targeted to VHA. This document fulfils the charge in VA's Pandemic Influenza Plan to develop "criteria and transparent processes for allocation decisions regarding resources that may not be available in sufficient quantities during a pandemic." (Department of Veterans Affairs, 2006, Section 2.2.2.3).

1.2 PURPOSE OF THE GUIDANCE

The purpose of this guidance is to provide VHA leaders and clinicians with an ethical framework to meet the challenge of pandemic influenza. This framework includes information, analysis, recommendations, and criteria for conducting ethical decision processes as well as for resolving substantive ethical dilemmas concerning:

- The scope and limits of VHA employees' duty to provide care to patients;
- Allocation of scarce life-saving resources;
- Hospice and palliative care planning and response; and
- Limitations on individual liberty in the interests of public health.

In each of these areas, this document summarizes consensus ethical principles in clear, actionable language; communicates national guidance for VHA (where appropriate), and, on issues where no consensus is apparent, provides a framework for decision-making by VHA leaders and clinicians.

This guidance focuses specifically on decision processes for allocation of scarce life-saving resources such as ventilators and other critical care resources as well as related issues. Guidance regarding allocation of countermeasures such as vaccines and antivirals is being developed by Federal interagency work groups informed by expert and lay opinion (Department of Health and Human Services, October 17, 2007).

The expectation is that VHA leaders and health care professionals will use this information both *before* an outbreak of pandemic influenza as a basis for tabletop exercises, preparatory drills, and educational forums, and *during* an outbreak as a guide for decision-making.

1.3 How The Guidance Was Developed

This guidance was prepared by a work group of the National Center for Ethics in Health Care and was reviewed by individuals in VHA facilities and in VA Central Office. A list of work group members and reviewers is provided in the front matter. The work group developed the guidance on the basis of literature review and on consultation with experts in the areas touched on by the guidance. Adaptation of analysis or recommendations from specific resources is indicated in the text.

1.4 Background

In an influenza pandemic, the demand for health care services is anticipated to exceed the capacity of VHA facilities both to treat influenza patients and to sustain other health care services. Facilities will be stressed by personnel shortages that result from workers becoming ill or remaining at home either to care for family or out of fear of infection. Due to the numbers of infected patients who will seek treatment, VHA facilities, in conjunction with their communities, will need to isolate patients and may need to advocate voluntary quarantine as part of U.S. Community Mitigation Guidance (Department of Health and Human Services, February 2007) for potentially exposed patients and staff, resulting in further shortages in the availability of rooms, beds, and staff. Scarcity projections and the need for public health containment measures highlight the need for ethically informed planning and decision processes (Schoch-Spana et al., 2007; Hick and O'Laughlin, 2006; Christian et al., 2006; OHPIP, 2006; Kraus et al., 2007).

1.4.1 Pandemic scenarios and projected scarcity

In its community planning guide, *Mass Medical Care with Scarce Resources*, the Agency for Health Care Research and Quality (AHRQ, 2007) describes prolonged-impact, mass casualty events, including severe influenza pandemic. Such events entail a gradual increase in the number of people affected, rising to a catastrophic number of patients. Unlike localized disasters such as an earthquake or bombing, pandemic flu, as a contagious illness, is expected to spread gradually in multiple waves of community outbreaks across the country.

Table 1 is the HHS projection of the possible impact of moderate and severe pandemic influenza scenarios for the entire United States population (300 million).

Table 1
Number of Episodes of Illness, Health Care Utilization, and Death Associated with Moderate and Severe Pandemic Influenza Scenarios -- U.S. population, 300 million

Characteristic	Moderate (1957/68-like)	Severe (1918-like)
Illness	90 million (30%)	90 million (30%)
Outpatient medical care	45 million (50%)	45 million (50%)
Hospitalization	865,000	9,900,000
ICU care	128,750	1,485,000
Mechanical ventilation	64,875	745,500
Deaths	209,000	1,903,000

Note: Estimates are based on extrapolation from past pandemics in the United States. Note that these estimates do not include the potential impact of interventions not available during the 20th century pandemics (HHS 2007).

Based on HHS planning assumptions for both scenarios, the Center for Biosecurity at the University of Pittsburgh Medical Center has projected the following average impacts on hospitals for influenza patients alone (Table 2). In a moderate scenario, influenza patients would require 19 percent of non-ICU beds, 46 percent of ICU beds, and 20 percent of ventilators. In a severe scenario, influenza patients would require 191 percent of non-ICU beds, 461 percent of ICU beds, and 198 percent of ventilators (Toner and Waldhorn, 2006). In other words, in a severe 1918-like pandemic, “local hospitals can expect to have only one mechanical respirator for every two influenza patients, and only one bed for every four to five influenza patients who need them at the peak of the crisis” (Schoch-Spana et al, 2007).

Table 2
FluSurge Projection of Average Impact on Hospitals

Moderate scenario (1968-like)	Severe scenario (1918-like)
19% of non-ICU beds	191% of non-ICU beds
46% of ICU beds	461% of ICU beds
20% of ventilators	198% of ventilators

Note: These projections were derived using FluSurge 2.0 with national population statistics, 750,000 non-ICU beds, 90,000 ICU beds, 105,000 ventilators, an 8-week duration, a 25 percent attack rate, and accepting the other default assumptions (1968 based). For a severe pandemic, the assumed number of hospitalizations was changed from 992,000 to 9.9 million to correspond with the HHS planning assumptions (Toner and Waldhorn, 2006).

Using the same HHS planning assumptions, Table 3 estimates impacts on a population of 540,065 eligible VA enrollees in Veterans Integrated Service Network (VISN) 8, the largest of VHA's health care networks.

Table 3
Number of Episodes of Illness, Health Care Utilization, and Death Associated with Moderate and Severe Pandemic Influenza Scenarios – VISN 8 (540,065 enrollees)

Characteristic	Moderate (1957/68-like)	Severe (1918-like)
Illness	162,020 (30%)	162,020 (30%)
Outpatient medical care	81,010 (50%)	81,010 (50%)
Hospitalization	1558	17,823
ICU care	233	2674
Mechanical ventilation	167	1337
Deaths	390	3426

Note: Estimates are based on extrapolation from past pandemics in the United States. Note that these estimates do not include the potential impact of interventions not available during the 20th century pandemics (HHS 2007).

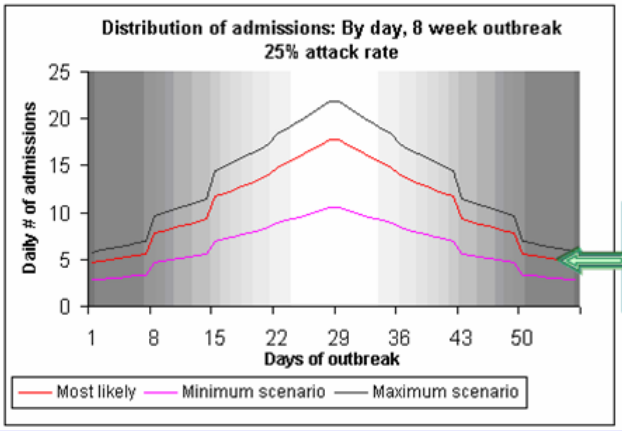
VISN 8 has also developed more specific projections for a 239-bed (Table 4) and a 62-bed (Table 5) hospital, based on a moderate 1968-scale pandemic. As indicated, the demand for resources is anticipated to significantly tax or exceed supply in VHA facilities. For a 12-week outbreak at a 25 percent attack rate, projections for the 239-bed hospital are that influenza patients alone would require 47 percent of non-ICU beds, 84 percent of ICU beds, and 37 percent of ventilators. For the 63-bed hospital, influenza patients alone would require 90 percent of non-ICU beds, 227 percent of ICU beds, and 107 percent of ventilators.

Although projections are by their nature uncertain, these figures indicate that even under a moderate scenario such as that used in the specific VISN 8 projections, the impact on VHA facilities would be significant as they, like most health care institutions, already run at or near capacity.

Table 4

239-Bed VA Hospital 1968-Scale Influenza Pandemic (Moderate Scenario)

239 Bed VA Hospital 1968-Scale Influenza Pandemic (Moderate Scenario)



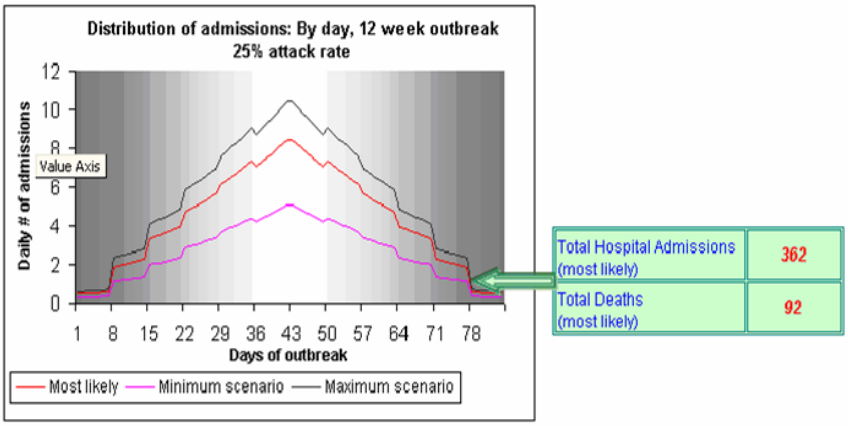
Total Hospital Admissions (most likely)	598
Total Deaths (most likely)	152

Pandemic Influenza Impact / Weeks		1	2	3	4	5	6	7	8	9	10
Hospital Admission	Weekly admissions	36	60	90	114	114	90	60	36		
	Peak admissions/day				18	18					
Hospital Capacity	# of influenza patients in hospital	26	44	66	84	86	76	58	38		
	% of hospital capacity needed	14%	24%	36%	46%	47%	42%	32%	21%		
ICU Capacity	# of influenza patients in ICU	5	11	18	23	25	24	19	13		
	% of ICU capacity needed	18%	38%	58%	77%	84%	81%	65%	45%		
Ventilator Capacity	# of influenza patients on ventilators	3	6	9	12	13	12	10	7		
	% usage of ventilator	8%	17%	26%	34%	37%	36%	28%	20%		
Deaths	# of deaths from influenza			9	15	23	29	29	23	15	9
	# of influenza deaths in hospital			6	11	16	20	20	16	11	6

Radonovich, 2006; derived from FluSurge 2.0.

Table 5
62-Bed VA Hospital 1968-Scale Influenza Pandemic (Moderate Scenario)

62 Bed VA Hospital 1968-Scale Influenza Pandemic (Moderate Scenario)



Pandemic Influenza Impact	/ Weeks	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Hospital Admission	Weekly admissions	4	14	25	36	47	54	54	47	36	25	14	4		
	Peak admissions/day						8	8							
Hospital Capacity	# of influenza patients in hospital	3	11	19	27	35	40	41	37	31	24	16	8		
	% of hospital capacity needed	6%	23%	40%	58%	75%	87%	90%	80%	68%	52%	35%	18%		
ICU Capacity	# of influenza patients in ICU	1	2	5	7	10	11	12	12	10	8	6	3		
	% of ICU capacity needed	10%	46%	91%	135%	180%	215%	227%	222%	190%	149%	106%	62%		
Ventilator Capacity	# of influenza patients on ventilators	0	1	2	4	5	6	6	6	5	4	3	2		
	% usage of ventilator	5%	22%	43%	64%	85%	101%	107%	105%	90%	70%	50%	29%		
Deaths	# of deaths from influenza			1	4	6	9	12	14	14	12	9	6	4	1
	# of influenza deaths in hospital			1	3	5	6	8	10	10	8	6	5	3	1

Radonovich, 2006; derived from FluSurge 2.0.

Focusing on ventilators as a representative resource, Tables 4 and 5 list projected ventilator use in individual hospitals (239-bed and 62-bed, respectively) within VISN 8. The overall availability of ventilators within a VISN 8 Medical Center as of May 2007 can be found in Table 6 (Note: There are no ventilators typically used in VISN 8 Community Living Centers). On average, approximately 36.8 percent of all available ventilators are in use by current inpatients at any one time. VISN 8 as a whole would likely be able to absorb the increased demand for mechanical ventilators related to a moderate outbreak of pandemic influenza (167 = 32 percent of the current total ventilators, and 50 percent of those not already in use). However, a severe outbreak would result in a critical shortage of ventilators (1137 = 251 percent of the current total ventilators, and 397 percent of available ventilators).

Due to unequal distribution of ventilators within networks, there may be local shortages under either scenario. One VISN 8 facility, for example, reports that it has no ventilators on site, while another has only a small percentage of its ventilators in use at any point. Also, it should be noted that these projections are for a single 12-week outbreak, and do not factor in shortages created by subsequent outbreaks, or the effect of any carryover patients from a previous outbreak. Finally, disposable ventilators are designed for use by a single patient and the supply must be replenished. The number of available disposable ventilators will be dependent on national supply and demand.

Table 6
Number of Ventilators Available and in Use in VHA Facilities – VISN 8

	VISN 8 Medical Centers Combined
Total number of ventilators	**523**
Number of ventilators typically in use by chronic care patients	**65**
Number of ventilators typically in use by acute care patients	**131**

1.4.2 The Infectious Nature of Pandemic Influenza: Implications for Health Care Institutions

For health care institutions, the infectious nature of a severe pandemic influenza virus will mean that traditional strategies to divert staff and resources to an affected area may not be feasible, both because local areas must preserve resources that will be needed if the pandemic arrives and because mobilization of staff and supplies can contribute to the spread of the virus.

According to HHS, as the pandemic progresses, social distancing measures including travel restrictions, closure of schools and day care centers, cancellation of public events, voluntary quarantine of household members of ill persons, and workplace measures to limit workers being in contact with one another, would likely be imposed. In addition, because pandemic influenza will, by definition, be a new human viral strain, definite information about its virulence and modes of transmission may not be immediately understood, giving rise to fear and uncertainty. In light of these factors, a large percentage of people would likely choose to stay home to care for children and to minimize exposure. HHS estimates that in a severe pandemic, absenteeism attributable to illness, the need to stay home under voluntary quarantine during the illness of a household member, and fear of infection may reach 40 percent during the peak weeks of a community outbreak (Department of Health and Human Services, February 2007).

Fear and uncertainty about the infectious nature of the viral strain as well as estimates regarding absenteeism highlight the need for explicit discussion and institutional planning around health care providers' duty to provide care and the reciprocal obligations of the institution to safeguard and support these providers.

1.5 ETHICAL CHALLENGES IN PANDEMIC INFLUENZA PREPARATION AND RESPONSE

As indicated in the scenarios described in Section 1.4.1, pandemic influenza is expected to generate demand for clinical services and health care that significantly exceeds the availability of beds, critical equipment (e.g., ventilators), medications, and health care staff. With resources scarce and the pressing need to contain the spread of the virus, health care leaders and professionals will be faced with extraordinary ethical challenges centered on responsibilities (defining the scope and limits of VHA employees' duty to provide care to patients and reciprocal institutional obligations), resource allocation, and restrictions (limiting individual liberty in the interests of public health) (Wynia, 2007). Table 7 summarizes these challenges.

Table 7
Ethical Challenges in Pandemic Influenza Preparation and Response

1. RESPONSIBILITIES: The ethical "duty to provide care." The obligation of health care workers to accept some level of risk in the service of patients and the reciprocal obligation of health care institutions to minimize risk to health care workers.
2. RESOURCE ALLOCATION: Allocation of scarce resources. The criteria and processes for decision-making regarding the fair and efficient use of scarce resources.
3. RESTRICTIONS: Limits on individual liberty in the interests of public health. Justifications and procedures for implementing restrictions on individual liberty to prevent the spread of infection.

1.6 CORE ETHICAL PRINCIPLES

Decision-making in pandemic influenza planning and response must be based on achieving the greatest good for the greatest number (the principle of utility or efficiency) *within constraints of respect for human dignity and fairness* (the principle of justice applied across groups of people according to specified criteria). This view is echoed in the CDC's "Ethical Guidelines in Pandemic Influenza," which states that "a classic utilitarian approach to defining priorities…is not a morally adequate platform for pandemic influenza planning. We recommend…an approach to ethical justification, that, like utilitarianism, evaluates the rightness or wrongness of actions or policies primarily by their consequences, but…that planning should take into account other checks…grounded in the ethical principles of respect for persons, nonmaleficence, and justice" (Kinlaw and Levine et al., 2007).

One of the most important roles that VHA leaders will play in pandemic planning and response will be determining, based on reasoned justification, how these principles will be balanced in particular decisions. Ethical leadership in this area is grounded in the obligations and values that define all aspects of VHA health care.

1.7 THE UNIQUE OBLIGATIONS OF VHA LEADERS – MORE PRONOUNCED IN PANDEMIC INFLUENZA

Leaders in VHA have a unique set of obligations that flows from their overlapping roles as public servants, providers of health care, and managers of both health care professionals and other staff. These obligations are sharpened by VA's commitment to providing health care to Veterans as a public good, a mission born of the Nation's gratitude to those who have served in its armed forces.

- As public servants, VHA leaders are specifically responsible for maintaining the public trust, placing duty above self-interest, and managing resources responsibly.
- As health care providers, VHA leaders have a fiduciary obligation to meet the health care needs of individual patients in the context of an equitable, safe, effective, accessible, and caring health care delivery system.
- As managers, VHA leaders are responsible for creating a workplace culture based on integrity, accountability, fairness, and respect.

To fulfill these roles, VHA leaders not only have an obligation to meet *their* fundamental ethical obligations, they also must ensure that staff members throughout the organization are supported in their adherence to high ethical standards.

All of these responsibilities become more pronounced in the context of a public health crisis such as pandemic influenza. In anticipating and responding to the uncertainty and upheaval of a pandemic flu, it is crucial that VHA leaders maintain trust with employees, patients, and with the public. Most challenging will be the need to provide health care to individual patients in the context of severe resource shortages, contagion risk, and the overarching goals of VA pandemic response: "to stop, slow, or limit the spread of disease, reduce suffering and death, and sustain the operations of the Department of Veterans Affairs" (Department of Veterans Affairs, 2006, Section 3. p. 27).

Experts in ethics and public health have pointed out that ethical considerations must be a central part of pandemic influenza planning and response (Hodge et al., 2007). This insight is prompted in part by the Severe Acute Respiratory Syndrome (SARS) experience in Toronto. In that case, researchers state, "the costs of not addressing the ethical concerns are severe: loss of public trust, low hospital staff morale, confusion about roles and responsibilities, stigmatization of vulnerable communities, and misinformation" (Thompson et al, 2006). In addition, the SARS experience highlighted that "where guidance is incomplete, consequences uncertain, and information constantly changing, where hour-by-hour decisions involve life and death, fairness is more important, rather than less." (Bell et al., 2004).

Because a pandemic influenza crisis will affect entire facilities and the VHA system as a whole, policies concerning crisis standards of care (e.g., allocation of scarce life-saving resources and other triage decisions) must be the product of

participatory, reasonable, and transparent decision-making at the national and local leadership level. Decision-making at this level not only promotes consistency and fairness, but also preserves as much as possible the clinician-patient relationship by shielding clinicians from *ad hoc* allocation decisions.

1.8 LEADERSHIP DECISION PROCESS FOR PANDEMIC INFLUENZA PLANNING AND RESPONSE

As with any ethical decision, the process used by VHA leaders to make decisions for pandemic planning and response should be informed, participatory, values-based, beneficial, systems-focused, reasonable, and transparent (Department of Veterans Affairs, 2007).

Leadership Decision Process

- **Informed and Participatory:** Collect the full range of facts that bear on a given decision and understand the perspectives of those involved in the decision and those who will be affected by it.
- **Values-based:** Weigh options carefully in relation to important organizational and social values such as fidelity to mission, fairness, stewardship, proportionality, and reciprocity.
- **Beneficial:** Weigh the short- and long-term consequences, both positive and negative, and make sure that the benefits of the decision outweigh potential harms.
- **Systems-focused:** Examine and address underlying systems issues that may cause or contribute to ethical concerns.
- **Reasonable:** Ensure that decisions rest on a defensible decision-making process and sound reasoning.
- **Transparent:** When communicating final decisions, explain how the decision was made, who was involved in making it and the reasoning behind it.

1.8.1 Informed and Participatory

The more value-laden a decision is or the more it involves uncertainty about the right course of action, the more important it is that the decision be well informed. Leaders must ensure not only that they have collected the full range of facts that bear on a given decision but also that they understand the perspectives of those who are (or should be) involved in making the decision and those who will be affected by it.

Stakeholders (those who stand to benefit or be harmed by institutional decisions) should participate actively in pandemic influenza planning (and *post hoc* response evaluation). This includes volunteers, employees whose duties place them at a disproportionate risk of infection and their labor union representatives, and Veterans whose care may be affected by public health measures and/or triage protocols, and

VSOs. Stakeholders are more likely to accept leadership decisions if the decision-making process is perceived to be informed and participatory.

To assist VHA leaders in their planning and to ensure that decision-making is both informed and participatory, VHA's National Center for Ethics has developed an educational packet for health care staff discussion forums on ethics issues including scarce resource allocation and the ethical "duty to provide care" in pandemic preparedness. The packet contains information for forum planners and participants and includes: explanation as to why staff discussions are important, a sample discussion agenda, an overview, planning points for setting up a discussion, PowerPoint slides, scenarios and questions. This material is available at http://www.ethics.va.gov/ETHICS/activities/pandemic_influenza_preparedness.asp

1.8.2 Values-based

Values-based decision-making pays explicit attention to strongly held beliefs, ideals, principles, or standards that inform ethical decisions or actions. Well-made decisions weigh options carefully in relation to important organizational and social values. This requires that the values at stake in a decision, such as fairness, stewardship, or fidelity to mission, be clarified and explicitly considered

A number of key ethical values have been identified as central to pandemic influenza planning and response (University of Toronto 2005, Kinlaw and Levine et al., 2007). They include:

Advance Planning and Goal Setting – Commitment to developing and clearly communicating preparedness goals and procedures in advance of a pandemic. One of the basic roles and responsibilities of VHA, and all health care institutions, is to promote health and prevent disease. Anticipating, planning for, and communicating strategies for effectively meeting the demands of pandemic influenza are essential for health care institutions to continue to serve this mission. In addition, health care institutions and their missions are sustained by professionalism and the commitment of staff to patient care. Creating and effectively communicating coherent protocols for operations during a crisis are essential to preserving staff commitment and professionalism. For example, clear work force policies indicating expectations and institutional responsibilities during a crisis will make it easier for staff to report to work. Uniform triage protocols will prevent ad hoc decision-making, promote fairness, and enhance trust. Isolation protocols that use the least restrictive means will limit the spread of the virus while maintaining the value of individual liberty. Advance planning, when there is adequate time available, also makes it easier to ensure transparency in decision-making.

Stewardship – Commitment to the responsible management of resources. Responsible management of resources in VHA health care facilities requires

decision-making that not only optimizes resource use but does so in a way that preserves fairness and human dignity. When resources are especially scarce, as is anticipated in a pandemic, responsible stewardship depends upon fair decision processes that avoid placing clinicians in the untenable position of making *ad hoc* and independent allocation decisions for individual patients.

Fair Process – Commitment to:

Ensuring that decisions are based on reasons (i.e., evidence and principles) that stakeholders can agree are relevant to meeting health needs in a pandemic influenza crisis.

- Ensuring that decision makers are impartial, neutral, and accountable.
- Ensuring consistent application of allocation principles across people and time (treating like cases alike).
- Ensuring that those affected by decisions have a voice in decision-making.
- Ensuring a practicable process for disputes and appeals.
- Ensuring opportunities to revisit and revise decisions as new information emerges throughout the crisis.

Proportionality – Commitment to balancing individual liberty and community interests by:

- Using the least restrictive public health measures necessary to protect the public from harm.
- Not exceeding what is necessary to address the actual level of risk to or critical needs of the community.
- Minimizing the negative impacts of public health measures on individuals and communities.
- Protecting, as much as possible, those who are affected by quarantine or isolation restrictions from stigmatization and unwarranted disclosure of private information.
- Supporting, as much as possible, those who are affected by quarantine or isolation restrictions with social supports.

Reciprocity – Institutional commitment to supporting those who face a disproportionate burden in serving VHA's health care mission to Veterans and taking steps to minimize burdens as much as possible. Institutional commitment to employees who face a disproportionate burden in caring for patients. Just as the VHA mission of service to Veterans is based on reciprocity to those who bore a disproportionate burden in protecting the public good, so too should reciprocity extend to support for those who face a disproportionate burden in serving the VHA mission in times of pandemic influenza.

Solidarity – The commitment to a common purpose and collaborative approaches that set aside self-interest among individuals, health care services, and facilities.

This guidance uses these values as reference points for leadership decision-making in circumstances of pandemic influenza. See Sections 2-5.

1.8.3 Beneficial

Ethical decision-making requires that leaders weigh the short- and long-term consequences, both positive and negative, and make sure that the benefits of the decision outweigh potential harms. Making those determinations involves fairly balancing the different interests of stakeholders, including Veterans, staff, the organization, and often, the community. Leaders may find it helpful to consider best-case and worst-case scenarios as a way of thinking about the impact a decision will have on different parties or different activities across the organization. Leaders should also recognize that decisions can result in unintended and unforeseeable consequences as well as unintended but foreseeable consequences. To the greatest extent possible, leaders should assess the impact of their decisions prospectively and after implementation of these decisions in order to mitigate the effect of any negative consequences. One of the predictable ethical challenges of any public health crisis involves balancing the welfare of individuals and the public welfare in order to stop the spread of disease and optimize resource use.

This document provides leaders with specific guidance on balancing these interests in circumstances of pandemic influenza. See Sections 2-5.

1.8.4 Systems-focused

Ethical decision-making should include an examination of underlying systems issues that may cause or contribute to ethical concerns. Addressing underlying systems issues can help to ensure that these concerns do not recur since the underlying cause of the ethical concern has been removed. Focusing on systems issues can help to ensure that the decision establishes a precedent that can be applied to other similar cases.

This document provides leaders with specific guidance on coordination to achieve integrated and consistent practices in the event of pandemic influenza. See Sections 2-5.

1.8.5 Reasonable

Leaders should consider how their decisions will be perceived by persons other than those directly involved in the decision-making process or immediately affected by a given decision itself. Imagining whether a decision would seem reasonable to a friend or family member or to a mentor or respected colleague outside the organization can be a useful exercise. Asking, “Would I be able to defend this decision to patients, external stakeholders, the media, or the general public?” can be another test to ensure that decisions have been considered from all angles and are ethically justifiable. Even people who disagree with a decision will be more likely to accept it if they perceive the decision-making process as fair and understand the rationale behind the decision.

1.8.6 Transparent

Practicing ethical decision-making requires that decisions be transparent to those affected by them. Leaders should explain to the individuals who have a stake in an ethical decision both the process used to make the decision and the reasons why certain options were chosen over others. Even people who disagree with a decision will be more likely to accept it if they perceive the decision-making process as fair and understand the rationale behind the decision.

This document provides leaders with well reasoned and explicit justifications for difficult choices that will need to be made in the event of pandemic influenza. See Sections 2-5.

1.9 THE OBLIGATIONS OF VHA CLINICIANS AS HEALTH CARE PROFESSIONALS

In addition to the values that guide pandemic planning and response at the VHA leadership level, there are norms of health care professionalism that are relevant to *clinical* decision-making during a pandemic. These norms stem from the unique nature of the clinician-patient relationship. Anticipating the significant strain that a pandemic influenza will place on health care professionals, this document provides guidance on interpretation and implementation of professional obligations in a crisis situation and on institutional steps to preserve, as much as possible, the clinician-patient relationship and its traditional governing norms.

1.9.1 The Ethical Duty to Provide Care and Non-Abandonment

Beyond the general obligation to benefit patients, the ethical duty to provide care embodies a commitment by health care professionals to deliver this care even at some personal risk to themselves. Non-abandonment is the minimum requirement of a duty to provide care. Ordinarily, the obligation of non-abandonment requires clinicians to ensure that patients in their care are appropriately transferred to a comparable provider should the circumstances require it. In a pandemic situation when staff resources are limited, there may be no realistic option for transfer. Under such circumstances, where health care professionals are subject to significantly higher personal risk while caring for patients, fulfilling this obligation will depend on facilities taking concrete steps to remove barriers to work attendance including assisting staff with meeting competing role-based obligations (e.g., family), meeting basic needs while on the job (e.g., food, rest), mitigating occupational risk (e.g., through provision of personal protective equipment, antivirals, and vaccines), and clarifying what stricken staff and their families can expect in terms of institutional care and support. Although Title 5, United States Code (U.S.C.) § 5536 prohibits a Federal employee from receiving compensation in addition to the pay and allowances fixed by law, an exception, for example, the provision of food and sustenance, can be made in circumstances where employees are working in unanticipated emergency situations involving danger to human life or destruction of federal property – circumstances that would likely occur during a pandemic influenza outbreak. In addition, VA's ability to provide care to family members will depend on the

availability of equipment, supplies and medications, and the facility's responsibilities and assignments, if any, under the National Response Framework.

Because the level of risk accompanying a pandemic is significantly greater than what health care professionals assume under ordinary circumstances, this document provides specific guidance on the scope and limits of the ethical duty to provide care as well as reciprocal institutional obligations to support personnel who place themselves at risk. See Section 2.

1.9.2 Respect for Persons

The principle of respect for persons is a key element of professional codes of ethics, patients' rights documents, and philosophical and theological frameworks for health care ethics. The principle assumes the inherent worth and dignity of human beings and, on this basis, establishes both the equality of persons and the notion that persons should be treated as ends in themselves (Purtilo, 2004 p. 2152). This principle has been expressed most prominently in terms of respect for patient autonomy.

Patient autonomy will be limited in a number of ways during pandemic influenza. (Kuschner et al, 2007) In some cases, autonomy will be limited by absolute scarcity of resources. In others, it will be in tension with compelling public health goals to limit the spread of disease and to optimize the use of resources that are scarce:

- Under circumstances of dire scarcity, fairness and efficiency will require the implementation of triage criteria. Only those patients who meet stringent inclusion criteria will be eligible for life-saving equipment such as ventilators and other critical care resources. Patients who do not meet inclusion criteria will be triaged to receive palliative care only.

- Because of resource scarcity, clinicians will not have the ordinary array of treatment options to offer, and patients will not have the ordinary range of options from which to choose. Despite the constrained choices patients may have under conditions of pandemic influenza, informed consent discussions should occur according to clinical standards.

- In order to prevent the spread of the virus, a patient's freedom of movement may be restricted. For example, patients who are exposed to the influenza virus may be subject to liberty-limiting restrictions such as isolation. (Note: Regional Counsel should be consulted whenever a VA facility seeks to hold a patient against his or her will).

Given these limits on patient choice, a narrow focus on autonomy must, of necessity, give way to a broader focus on respect for the dignity and humanity of patients and their families in the crisis situation. This will entail making it as clear as possible to patients and their families which goals of care are attainable under these circumstances; how decisions regarding their care will be made; respecting, as much as

possible, patient preferences; and, in cases in which patient treatment preferences cannot be met, acknowledging the toll that the curtailment of options may take on a patient and family.

Where limitations on patient autonomy are required to achieve public health goals, clinicians must be supported by institutional protocols that use standard decision procedures and the least restrictive means possible to achieve those goals. Just as in ordinary circumstances, institutional policies and procedures regarding resource use or constraints on patient autonomy are necessary to, as much as possible, preserve the clinician-patient relationship.

This document anticipates the ways in which patient autonomy will be limited during pandemic influenza and provides guidance for VHA leaders and clinicians regarding justifications for such limits and measures to minimize burdens on patients. Guidance is also provided regarding respect for the humanity and dignity of patients through palliative and supportive care. See Sections 3-5.

1.9.3 Duty to Benefit and Prevent Harm

Expressed in the Hippocratic writings as “to help or at least to do no harm”, the obligation to benefit patients and prevent harm to them is the oldest and most basic tenet of medical ethics. This elemental presumption is embodied in professional standards of care. In a pandemic, ordinary standards of care will need to be adjusted as a result of resource scarcity and the need to sustain overall health care operations. For example, lack of resources will limit the range of beneficial treatments that are available to patients. Similarly, protocols to optimize resource use will exclude some patients from receiving life-saving treatments if they do not meet objective triage criteria. In addition, preventing harm, in particular by preventing the spread of infection to patients or third parties, may involve limiting patients’ access to their families and loved ones.

Although obligations to benefit and prevent harm may be justifiably overridden in these circumstances, they can never be erased. Even in extreme circumstances, clinicians must find ways of minimizing harm to individual patients and providing whatever benefit is obtainable under the circumstances.

This document provides guidance to clinicians who are faced with providing benefit and minimizing harm under crisis standards of care. See Sections 3 and 4.

1.9.4 Fairness

As an obligation of health care professionals, fairness or justice requires that clinicians treat patients in a manner that is unbiased, consistent, and based on the best available clinical evidence and protocols. *See Section 3.*

SECTION 2: RESPONSIBILITIES – WORK FORCE CAPACITY AND A "DUTY TO PROVIDE CARE" UNDER CONDITIONS OF PANDEMIC INFLUENZA

Under conditions of pandemic influenza, VHA employees have an obligation to provide care to patients (i.e., an ethical "duty to provide care") even at some personal risk to themselves. This duty is grounded in fidelity to VHA's public service mission as well as an obligation of care and non-abandonment owed to the Veterans VHA is privileged to serve. The ability of caregivers to fulfill their ethical duty to provide care to patients under conditions of pandemic influenza is predicated on facility leaders meeting their reciprocal obligations. These reciprocal obligations center on addressing workplace conditions that enable caregivers to take care of patients, but also include reciprocity owed those employees who voluntarily assume a disproportionate risk of illness and even death to fulfill VHA's mission. VHA facility leaders must incorporate into pandemic influenza planning considerations regarding the scope and limits of a duty to provide care both on the part of VA employees and the institution itself.

2.1 RISK, RESPONSIBILITY, AND WORK FORCE CAPACITY: LESSONS FROM PUBLIC HEALTH EMERGENCIES

In a sobering assessment of work force availability during pandemic flu, HHS projects that during the peak period of a severe pandemic, "absenteeism attributable to illness, the need to care for ill family members, and fear of infection may reach 40 percent" (U.S. Department of Health and Human Service, 2007). In fact, the risk of morbidity and mortality to frontline health care workers in a pandemic is estimated to be much higher than the level of risk implicitly accepted by virtue of being a care provider. The SARS epidemic is instructive. Health care professionals were disproportionately infected relative to the population as a whole. For example, in Canada, of 141 probable cases of SARS, 65 percent of these diagnoses involved health care professionals. In Vietnam, nearly all reported deaths from SARS were of doctors and nurses. In Hong Kong, a quarter of all patients treated for SARS were health care workers (Emanuel, 2003).

Absenteeism among healthy employees may occur if employees are uncertain whether they have an obligation to continue to provide care to patients when that care entails more than minimal risk to the employee. This uncertainty will be especially pronounced for non-clinicians who are asked to assume clinical support roles outside of their usual duties. Professional associations have offered only limited guidance on this issue. For example, the American Nurses Association asserts that nurses must take limited personal risks if the benefit to patients outweighs that risk (ANA, 1994). The American College of Physicians Ethics Manual (American College of Physicians, 1998) states that "[t]raditionally, the ethical imperative for physicians to provide care has overridden the risk to the treating physician, even during epidemics." Although an ethical duty to provide care was conceded by professional associations in relationship to human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS)

(Morin et al., 2006), this duty was based on an assessment that the risk of infection to care providers was minimal and, therefore, that the obligation was proportionate to that risk (Reid, 2005).

2.2 THE ETHICAL DUTY TO PROVIDE CARE: CONSIDERATIONS FOR PANDEMIC PLANNING IN VHA

Continuing to provide care to patients during a public health emergency depends on the availability of a work force that can respond to the crisis. Given the known challenges of sustaining an adequate work force during public health emergencies, it is incumbent on VHA leaders to incorporate into pandemic influenza planning the following considerations regarding the scope and limits of an ethical duty to provide care both on the part of VA employees and the institution itself through its policies and procedures.

2.2.1 Scope and Limits of an Ethical Duty to Provide Care

Do health care professionals have an ethical duty to provide care under conditions of pandemic influenza in spite of the elevated risk of morbidity and mortality associated with the discharge of these duties? If such an ethical duty exists, is it a limited or unlimited duty?

A strong but limited ethical duty to provide care (i.e., ethical obligation to provide care to patients even at some personal risk) exists for all VHA employees but especially for professional caregivers such as doctors, nurses, and other allied health care professionals. This duty to provide care is grounded in a number of ethical tenets. Central among these are VHA's public service mission to Veterans, an ethic of care that includes non-abandonment of patients, solidarity with one's colleagues in terms of burden sharing (e.g., work load, risk of infection), and a "contract" with society that subsidizes clinician education and allows professionals to regulate themselves on the condition that professionals will serve the general good.

Although a clear ethical duty to provide care exists, especially for health care professionals, this duty is not without limit. However, there is no bright line demarcating when, or even if, the level of personal risk relieves clinicians from the duty to their patients. In its 2004 opinion, "Physician Obligation in Disaster Preparedness and Response" (AMA, 2004), the American Medical Association (AMA) stated that "National, regional, and local responses to epidemics, terrorist attacks, and other disasters require extensive involvement of physicians. Because of their commitment to provide care to the sick and injured, individual physicians have an obligation to provide urgent medical care during disasters. This ethical obligation holds even in the face of greater than usual risks to their own safety, health or life" (AMA, 2004). The AMA also notes that the clinician work force is a limited resource, and as such, the level of risk that clinicians assume in disaster response may have an effect on the ability of clinicians to provide care to patients in the future. Institutions play an important role in mitigating that risk by providing clinicians and other front-line caregivers with adequate protections.

Strikingly, during the SARS epidemic, most health care professionals continued to care for patients, in spite of convincing evidence that the risk to these caregivers

exceeded minimal risk (Farrow, 2003). In circumstances of pandemic influenza, individual employees will likely establish their own limits by weighing and balancing their obligation to patients and colleagues (i.e., if not me, then who?) with other obligations (e.g., self, family) against the backdrop of heightened personal risk. Health care workers' willingness to expose themselves to risk will be significantly affected by their level of confidence in the protections and support provided to them by the institution that employs them. (Mackler et al., 2007; Anantham et al, 2008)

If an ethical duty to provide care exists, does it apply equally to all facility employees (e.g., leaders, clinical support staff, other support staff such as accountants, housekeepers) or only to professional caregivers (e.g., doctors, nurses and allied health providers)?

For non-professional health care workers (e.g., nursing assistants, food service workers, housekeepers, lab technician, therapy aides, volunteers) or others who indirectly support care delivery (e.g., clerks, accountants, health care record management personnel), the duty to provide care has not been thoroughly debated in the ethics literature. Unlike doctors or nurses, non-professional health care workers are not generally obligated by history, tradition or a particular code of ethics to assume significant personal risk when caring for patients. These workers, however, may be obligated by virtue of their employment (Reid, 2005, North Carolina Institute of Medicine, 2007). Further, as public servants, all VHA employees have an ethical duty not only to assist the VHA in maintaining essential functions under conditions of pandemic influenza but also to serve the VHA mission of service to Veterans. Importantly, many of these employees (including non-clinical staff) may be called upon to assume an expanded role in support of patient care, and they should be prepared (to the extent possible) in advance of pandemic influenza for the assumption of these duties. Importantly, because the wages of many non-professional health care workers are low, these workers and their families may be disproportionately burdened if the worker is stricken by influenza. In weighing the institution's reciprocal duties towards employees, VHA leaders must factor this disproportionate burden into their decision-making.

2.2.2 Reciprocal Institutional Obligations

Are there reciprocal institutional duties to be borne by VHA in solidarity with "at risk" facility employees?

As a health care institution, VHA has an obligation not to leave patients without care during a public health emergency. Likewise, VHA's public service mission to Veterans entails that VHA will accord priority during a pandemic to the delivery of health care to enrolled Veterans and beneficiaries (U.S. Homeland Security Council, 2006, p. 115). Whereas clinicians meet their obligations directly through ongoing care of patients, VHA leaders and managers meet this obligation indirectly through shaping the overall care delivery system.

Specifically, VHA facility leaders have an obligation (in planning for and in responding to pandemic influenza) to optimize workplace conditions in order to *enable*

doctors, nurses and other caregivers to discharge their duty to patients. A minimum floor of *enabling* obligations to be borne by VHA facilities includes:

- Taking the steps necessary to ensure an adequate work force;
- Providing for employees' and volunteers basic human needs while on the job;
- Ensuring a safe and secure work environment; and
- Mitigating occupational health risks and attending to those employees (and their families) who succumb to pandemic influenza (Department of Veterans Affairs, 2006, Sections 2.2.3.2 and 2.2.3.8) (See Table 8 for specific VA authorities).

The principle of reciprocity obligates facilities to support those employees and volunteers who assume a disproportionate burden (heightened risk of morbidity and mortality) in service of the public good (care of Veterans), and to minimize those burdens to the greatest extent possible (Emanuel, 2003; Joint Center for Bioethics, 2005; North Carolina Institute of Medicine, 2007).

Fairness demands that these reciprocal obligations be applied across categories of employees and not be differentially allocated without justification. For example, during Hurricane Floyd, solidarity among employees and between employees and managers was compromised when a facility provided only physicians, and not nurses and other direct care providers, with places to sleep and shower (French, 2002). All of these employees were working multiple back-to-back shifts in order to continue to provide care to patients. VHA facility leaders should ensure that all direct care providers are treated similarly (e.g., provision of facilities to rest). In order to maintain trust in our health care system, fairness becomes more, not less important during a public health crisis (Thompson et al., 2006).

The role of facility leadership will be crucial during a pandemic – to show solidarity with care providers, to optimize work place conditions and to skillfully manage surge capacity in order to ensure a consistent level of personnel and other resources. The code of ethics for health care executives requires that leaders act as "moral role models," thereby meriting the trust, confidence, and respect of health care professionals and the general public (ACHE, 2003). To merit the trust and confidence of employees and patients during a pandemic, leaders should be physically present at their respective facilities and be actively involved in supporting both clinical and non-clinical staff in ensuring the delivery of care to Veterans and the provision of essential services to employees. Among the many lessons from Hurricane Katrina is the importance of developing an effective administrative operation in a chaotic setting (Curiel, 2006; Sine, 2007; Chaffee, 2006), including effective policies and procedures for the care of staff family members, clear staff recall procedures, and provisions for communication, compensation, and rest. (Sine, 2007).

Table 8 summarizes the range of reciprocal obligations cited in the ethics literature and specifies current VHA authority to fulfill them.

Table 8
Reciprocal Obligations Cited in the Ethics Literature and Current VHA Legal Authority*

Reciprocal Ethical Obligations		Current VHA Legal Authority	
(A) Provide practical assistance to remove barriers to work attendance.	Help employees meet multiple role obligations including child or dependent care	Yes	See 38 USC 7809 and VA Pandemic Influenza Plan Appendix B-2, TABLE OF LEGAL AUTHORITIES AND POLICIES RELEVANT TO EMERGENCIES, Section I, subsection D.
	Medical care for staff member families	Yes	VA's ability to provide care to family members will depend on the availability of equipment, supplies and medications, and the facility's responsibilities and assignments, if any, under the National Response Framework. See VA Pandemic Influenza Plan Appendix B-2, TABLE OF LEGAL AUTHORITIES AND POLICIES RELEVANT TO EMERGENCIES, Section I C & D: VA Authority to Provide Hospital Care and Medical Services to non-VA Beneficiaries.
	Pet care	No	Appropriated funds may not be used.
	Provide employees transportation assistance to get to and from work if needed	Limited Authority	See VA Pandemic Influenza Plan Appendix B-2, TABLE OF LEGAL AUTHORITIES AND POLICIES RELEVANT TO EMERGENCIES, Section V: Home-to-Work Transportation of Employees.
(B) Utilize all available pay flexibilities for employees†	Authorize hazardous duty pay for Title 5 (General Schedule (GS)) employees	Yes	5 USC 5545(d). See 5 CFR 550.904 and Office of Personnel Management, Frequently Asked Questions About Hazardous Duty Pay For Federal Employees. Available at http://www.opm.gov/oca/pay/html/hazduty.asp
	Authorize environmental differential for Federal Wage System (FWS) employees	Yes	5 USC 5343(c)(4). See 5 CFR 532.511 and Office of Personnel Management Federal Wage System Operating Manual, subchapter S8 and Appendix J.
	Authorize overtime pay for FWS employees	Yes	5 USC 5544. See 5 CFR 532.503 and VA Handbook 5007 Part V Chapter 2

Table 8 (continued)
Reciprocal Obligations Cited in the Ethics Literature and Current VHA Authority

	Authorize overtime pay for GS employees	Yes	5 USC 5542. See 5 CFR 550.111 and VA handbook 5007 Part V Chapter 2
	Authorize overtime for certain Title 38 employees	Yes limited	Currently authorized for nurses, physician assistants, expanded function dental auxiliaries and designated hybrid employees. Physicians, dentists, podiatrists, chiropractors, and optometrists are not entitled to overtime. 38 USC 7453 and 7454. See VA Handbook 5007 Part V Chapter 2
	Authorize exception to biweekly premium pay limitation	Yes	5 USC 5547(b); See 5 CFR 550.105 and VA Handbook 5007 Part V Chapter 2
(C) Minimize legal exposure of employees.	Provide immunity from personal liability for non-clinical staff providing clinical support for hospice and palliative care	Yes	Current authority exists under the Federal Tort Claims Act. Recommend to Department of Justice that employees' actions in providing pandemic treatment support be found within the scope of their employment. NOTE: Legal authority does not currently exist to protect contractors or their employees under the Federal Tort Claims Act. Contract employees should check with their malpractice insurer to make sure that their coverage would extend to non-clinical staff providing clinical support.
	Provide immunity from personal liability for employees practicing outside scope of practice under crisis standards of care	Yes	Current authority exists under the Federal Tort Claims Act. Recommend to Department of Justice that employees' actions in providing pandemic treatment support be found to be within the scope of their employment. Legal authority does not currently exist to protect contractors or their employees under the Federal Tort Claims Act. Contract employees should check with their malpractice insurer to make sure that their coverage would extend to actions taken under an altered scope of practice during a pandemic.
(D) Safeguard employees health and well-being while at work.	Ensure that basic human needs (e.g., food, water, rest) are met while on the job Ensure priority access to vaccines, antivirals, personal protective equipment and other non-medical counter measures to limit occupational hazards Provide sufficient security to ensure personal safety	Limited Authority	See: VA Pandemic Influenza Plan, §2.2.3.2; §2.2.3.8 Although 5 U.S.C. § 5536 prohibits a Federal employee from receiving compensation in addition to the pay and allowances fixed by law, an exception – for example, the provision of food and sustenance – can be made in circumstances where employees are working in unanticipated emergency situations involving danger to human life or destruction of federal property – circumstances that would likely occur during a pandemic influenza outbreak. Consult with Human Resources Management and Occupational Safety and Health Officials for detailed information on policies (such as VA Handbook 5019, *Occupational Health Services;* VA Directive 7700 and VHA Handbook 7701.1, Occupational Safety

			and Health Procedures; Directive 5810, and VA Directive 5819, *Managing Workers' Compensation Cases and Costs*) addressing VA's authority to provide care and protective equipment to employees. See 38 U.S.C. 1785 and 7421; VA Pandemic Influenza Plan §§ 3.2.3.4 and .5.
	Ensure (to extent possible) access to medical resources, if stricken	Yes	See VA Pandemic Influenza Plan Appendix B-2, TABLE OF LEGAL AUTHORITIES AND POLICIES RELEVANT TO EMERGENCIES, Section I C & D: VA Authority to Provide Hospital Care and Medical Services to non-VA Beneficiaries.
	Provide critical incident de-briefing and access to mental health and chaplaincy services	Yes	See: VA Pandemic Influenza Plan, §2.2.3.9
(E) Authorize income replacement to stricken employees and their families.	Authorize death benefits to ensure income replacement	Limited Authority	Federal Employees Compensation Act. See: VA Pandemic Influenza Plan, Section 4: RECOVERING FROM PANDEMIC INFLUENZA. VA states that it will assist in providing death benefits to surviving family members of staff who die from exposure to pandemic influenza in the course of their duties. Consult with Human Resources Management personnel for detailed information on filing a claim under the Federal Employees Compensation Act (VA Directive 5009/1).
	Provide enriched disability benefits	No	
	Provide enriched life insurance	No	

* VHA officials should consult with Human Resources Management officials for guidance on utilizing existing authorities.
†For additional information, see the Human Resources Flexibilities Templates & Resources at the VA Office of Human Resource Management Pandemic Resource Center. Available at http://www1.va.gov/ohrm//Worklife/Pandemic/HRTemplates_Resources.htm

2.3 RECOMMENDED ACTIONS

2.3.1 Stakeholder Participation

- Facility leaders should actively engage stakeholders in pandemic influenza planning and preparation. Primary stakeholders are those employees (e.g., direct care providers, employees who will be asked to assume clinical support roles, volunteers) whose duties place them at disproportionate risk of occupational exposure during pandemic flu. Not only does this type of engagement increase employee trust in leaders and in the fairness of decision-making processes, but training and discussion about a duty to provide care may be one method facility leaders can utilize to promote greater commitment and responsibility at the individual level (Wynia, 2007) and thereby optimize the available work force. To assist leaders, the National Center for Ethics in Health Care has developed an educational packet for staff discussion forums on ethics issues in pandemic preparedness. The packet contains information for forum planners and participants and includes: an explanation as to why staff discussions are important, a sample discussion agenda, an overview, planning points for setting up a discussion, PowerPoint slides, scenarios, and questions. This material is available at http://www.ethics.va.gov/ETHICS/activities/pandemic_influenza_preparedness.asp

2.3.2 The Ethical Duty to Provide Care

- VHA leaders should communicate to employees and volunteers that coming to the aid of those who fall ill during an influenza pandemic or other large disease outbreak may be one of the most important and commendable activities of a lifetime. Veterans have entrusted their lives to the VHA employees who serve and support them. The need for the collective skills of all staff will never be more crucial than during a pandemic.

- Facility leaders should explicitly articulate employer expectations and employee responsibilities in advance of pandemic flu. Leaders should unambiguously communicate that <u>all</u> employees in a health care system are “essential” during a health care crisis, not only clinicians and clinical support staff. Reinforcing the employees’ duty to provide care in the context of a public health emergency is a crucial component of surge planning.

- Facility leaders should adopt and implement a fair and consistent decision-making process to specify the limits or exceptions to employees’ duty to provide care. Criteria that have been cited in the literature to exempt employees from disaster duty include:

- An employee who is a parent and whose spouse/partner is also required to work during a disaster/pandemic (e.g., fire/rescue, nurse, law enforcement).

- An employee who is the sole provider for care of elderly, disabled or chronically ill persons.

- An employee who is a single parent of young children.

- Facility leaders should exercise maximal flexibility in scheduling and worksite assignments to enable employees to come to work yet maintain home responsibilities as well.

- Facility leaders should avoid coercive strategies (e.g., threats of terminating employment) in work force planning on both ethical and prudential grounds. Coercive strategies are ethically problematic given the exigent circumstances that many employees will be grappling with (e.g., more patients than resources, personal risk of morbidity or mortality, sick family members), and as a result are unlikely to succeed. Incentives, such as hazardous duty pay, are an ethically permissible means of motivating employees to continue to discharge their workplace responsibilities during conditions of pandemic flu. For certain Title 5 and wage grade employees, premium pay is required for exposure to hazards. (See Table 8 for specific authorities. VHA officials should consult with Human Resources Management officials for guidance on utilizing existing authorities). However, lack of incentives such as overtime or hazardous duty pay does not eliminate the employees' obligations.

2.3.3 Reciprocal Institutional Obligations

VHA leaders and facility leaders should:

- Clearly delineate and communicate in advance what employees can and cannot expect in terms of reciprocity from VHA. Importantly, VHA does not presently have the authority to realize all of the reciprocal obligations cited in the literature. (See Table 8 for specific authorities);

- Openly acknowledge that the risks anticipated to be associated with pandemic influenza exceed risks to which employees are normally exposed in the course of enacting their duties. VHA leaders should clearly delineate how the facility will safeguard employee well being (e.g., security, building and infrastructure safety), mitigate occupational risk (e.g., availability of protective equipment such as masks, gloves, vaccine), and clarify what stricken staff and their families can expect in terms of institutional care and support;

- Ensure that at a minimum, their facility has a plan to affirmatively help employees fulfill their duty to provide care by taking concrete steps to remove barriers to work attendance, including assisting staff in meeting competing role-based obligations (e.g., family), meeting basic needs (e.g., food, rest), and taking actions to safeguard health and well-being;

- Ensure that a work force plan is developed (and communicated) that anticipates the degree to which non-clinical support staff, designated volunteers and management will be called upon to assume roles in support of direct delivery of care to Veterans and fallen colleagues. Staff should be aware of the range of duties they may be called upon to fulfill and the potential liability issues should be discussed. An important aspect of facility planning will include "cross training" and the development of "just in time" training capabilities (North Carolina Institute of Medicine, 2007) for these employees, as well as for clinical employees. (See VHA Handbook 1100.19, Credentialing and Privileging); and

- Ensure that advance planning is rigorous, is tested in field conditions, and includes extensive preparation and training of staff. Disaster response depends on a level of operational interdependency and horizontal functioning that is uncommon in day-to-day care delivery. More typically, institutions function vertically, like silos, both before and after disasters. As experts have observed, there is a false belief that the onset of a public health emergency will suddenly and magically lead to "robust horizontal communication and cooperation" (Deputy Editor et al., 2007).

SECTION 3: RESOURCE ALLOCATION – TRIAGE AND THE ALLOCATION OF SCARCE LIFE-SAVING CLINICAL RESOURCES

Resource allocation is an aspect of normal operations in the VHA medical care system. At the policy and administrative level, macro allocation decisions are made with regard to eligibility for VHA health benefits and to the distribution of funds and resources among hospitals and programs. At the clinical level, clinical criteria are applied to determine appropriate allocation of drugs, devices, and ICU beds to individual patients. The goal of these allocation practices is to efficiently and fairly steward limited resources.

Under ordinary circumstances, triage is a particular clinical strategy for optimizing the use of resources that are insufficient to meet the needs of all patients. Triage (also called "secondary triage" in this context) is routinely used to prioritize patients who present for emergency treatment. Typically, a triage nurse will assess all incoming patients on arrival to determine acuity level and appropriate disposition (e.g., to registration, waiting room, exam room, urgent care, or clinics).

In mass casualty events, such as natural or man-made disasters, the National Disaster Medical System has designated Simple Triage and Rapid Treatment (START) as the method for initial or "primary field triage" to sort patients into four care categories: non-salvageable, major injury, minor injury, and walking wounded. A second-phase field triage process called Secondary Assessment of Victim Endpoint (SAVE) is used to sort those in the major and minor injury categories who can derive the most benefit from scarce treatment resources. Depending on the nature of the event (e.g., infectious versus non-infectious), the number of persons seeking medical assistance, and the availability of medical resources, field triage may entail sending patients to hospitals, clinics, alternate care sites, or to their homes.

A different level of triage, "tertiary triage" for patients who are in or who have presented to an acute care facility, is the focus of the guidance provided in this document. At this level, triage decisions focus specifically on the allocation of scarce life-saving clinical resources such as ventilators, ICU beds, and medications used to treat those who are gravely ill from influenza and other illnesses. Under conditions of dire scarcity, it is expected that need will outstrip resources and consequently that it will not be possible to provide everyone the care that they require to survive. The allocation protocol is intended to provide a fair, consistent, and rational basis for making these difficult decisions.

In what follows, this guidance provides specific proposals for (1) establishment of a Scarce Resource Allocation (SRA) team and a Triage Team and (2) a protocol for allocation of scarce life-saving resources in VHA during an influenza pandemic. (Tabery et al, 2008).

3.1 ESTABLISHMENT OF SCARCE RESOURCE ALLOCATION (SRA) AND TRIAGE TEAMS

The VHA Facility Director or chief of staff should identify, before the need arises, specific members of a Scarce Resource Allocation (SRA) team (Kuschner et al., 2007) or comparable structure (See Figure 1) as part the facility Incident Command structure (ICS) and Emergency Operations (VHA Directive 0320 Comprehensive Emergency Management Program). The team's principal responsibility is to provide a command structure that formally oversees operations during a crisis period characterized by a need for rapid and ethically challenging decision-making. In a context of increasing scarcity of resources, the team provides a structure for addressing the inevitable tensions that arise between clinicians' professional commitment to individual patients and the simultaneous goal of maximizing the survivability of the greatest numbers of persons. In the event of a pandemic (marked by declaration of a public health emergency), the Director or chief of staff should activate the SRA team to assist in the shift to crisis standards of care and to guide implementation of triage protocols (Institute of Medicine, 2009).

Figure 1

Scarce Resource Allocation (SRA) Team and Triage Team Membership and Roles (adapted from Kuschner et al., 2007).

Scarce Resource Allocation (SRA) Team Membership and Roles

Scarce Resource Allocation Team Leader. The SRA team leader should have broad-based knowledge of the resources and capabilities of the health care organization. The team leader must possess situational awareness - the ability to acquire and act on knowledge as the pandemic unfolds in a manner that is consistent with the health care organization's mission and ethical tenets. The team leader should be an experienced and respected member of the health care organization staff with proven leadership skills and a top-to-bottom understanding of the health care organization's strengths, reserves, and limitations. The team leader should have final responsibility for and authority over clinical decisions that involve triage and scarce resource allocation including, in consultation with the Triage Team, monitoring the event-specific, real-time epidemiologic data to determine whether and how the assessment tools in the tertiary triage protocol should be adjusted. Throughout the public health emergency, the team leader should report to the Facility Director and chief of staff or designee, as appropriate within the Incident Command structure.

Logistics/Management Representative. A representative of the health care organization's management team should provide guidance on the capabilities of the organization with respect to resources, personnel, and external support. This person should have knowledge of logistics related to the acquisition and distribution of critical supplies, security, fiscal matters, internal and external communication, control of patient information, and cooperative capabilities with other health care organizations. The management representative may also report to a larger Emergency Operations Committee responsible for directing the organization's overall response to pandemic influenza.

Ethics Representative. A member of the organization's IntegratedEthics program, generally from the Ethics Consultation Service, should provide guidance to resolving ethical conflicts, disputes, and dilemmas. This person should have knowledge of widely accepted ethical principles and the special ethical challenges that community medical disasters and public health emergencies present. This person should ensure that ethical values are an integral part of any decision process.

Critical Care Medicine Representative. A physician with expertise in critical care medicine should provide guidance about the management of intensive medical care and proposed implementation of crisis standards of care.

Nursing Representative. The Nurse Executive or other designated nurse leader should provide information about nurse staffing capacity to meet additional health care service needs of patients. Nursing judgments must be reflected in the SRA team's decisions to alter standards of care that result in the nursing staff performing duties that are normally performed by physicians, in the modification of nurse–patient ratios, and in decisions to include non-clinical staff in clinical support roles.

Emergency Department Representative. This role should be filled by a nurse or physician who is capable of providing real-time information about surge capacity and clinical decision-making in the emergency department.

Infectious Diseases Representative. An infectious diseases physician or infection control specialist should provide regular updates regarding the status and impact of the pandemic and the management of patients with influenza.

Palliative Medicine Representative. A physician with experience in palliative medicine should provide updates on the demands for palliative care and strategies to meet these demands. A qualified physician assistant or nurse practitioner may fill this role when a qualified physician is not available.

Social Work Representative. A licensed clinical social worker should provide updates on the social service demands imposed on the health care organization as a consequence of pandemic influenza.

Chaplain Representative. A chaplain should provide regular updates on the capacity of the health care organization to address the special spiritual needs of patients and family members, especially of those patients a physician deemed ineligible to receive care that would normally be delivered.

Patient/Veteran or VSO Representative. A representative of the Veteran community can provide specific insight on Veterans' issues and help to ensure transparency in the functioning of the team.

Ad Hoc Representatives from Other Departments. Representatives from other departments significantly affected by the pandemic may be necessary to provide updates on their capacity to meet surge demands for care – for example, an engineering representative who can advise on available supplies of oxygen and utilities.

Triage Team Membership and Roles

A group functioning under the direction of the SRA team, the Triage Team, should be designated and is responsible for tertiary triage scoring and decisions based on the tertiary triage protocol and available resources. Membership of the Triage Team includes, at minimum, a critical care medicine, nursing, and logistics/management representative. The Triage Team will consider regional and local circumstances and the resources available, and use the triage protocol to determine which patients are eligible for life-saving resources. Although the Triage Team functions under the direction of the SRA, the Triage Team's role within the SRA should, ideally, be limited to triage implementation, that is, collecting data, ensuring its accuracy, and directing bedside clinicians on triage decisions.

3.1.1 SRA Team Procedures

The SRA team should work to acquire the information necessary to facilitate and oversee informed and ethical triage and scarce resource allocation decisions. Information should include, but not be limited to, resources (bed census, staffing, projected needs for care, existing medical resources, resource gaps, and projected availability of life-saving and hospice and palliative care resources) and influenza management (up-to-date treatment options and prognostic factors).

The team should collaborate and make judgments in association with health care organization leaders and staff to implement appropriate crisis standards of care that are necessary to address the special demands that the pandemic imposes or could reasonably be expected to impose on the health care organization.

During the emergency, the SRA team should meet at least daily. Alternative meeting options may be appropriate, including telephone conference calls and videoconferencing. The team should advise and assist, as required, and make definitive decisions, if necessary, to resolve uncertainties and disputes that affect the health care organization's capacity to carry out its dual missions during a public health emergency. The team should prepare information briefs at least daily for the chief executive officer, chief of staff, or designee(s) about the emergency's status and the health care organization's response so that the information may be communicated to appropriate staff and stakeholders.

Multiple individuals may fill the position of SRA team leader on a rotating basis. A team leader should be available 24 hours per day, seven days per week as should the Triage Team members. All other members of the team should be available throughout business hours and for extended periods, as necessary and feasible, seven days per week. In order to allow for illness or absence of SRA team members, there should be a continuity plan in the staffing of this team.

3.1.2 Triage Team Procedures

The Triage Team should meet at least daily to review initial tertiary triage assessments made by emergency department practitioners, bed status, the case definition of pandemic, or other activities deemed appropriate by the SRA team. It will be the responsibility of the Triage Team to insure compliance by the treating team in ordering lab tests required for Sequential Organ Failure Assessment (SOFA) scoring, and to collect data, insure its accuracy, and direct bedside clinicians on triage decisions. On a defined 48-hour schedule, the Triage Team will consider clinical assessments of all patients who are receiving or who are candidates to receive scarce life-saving resources, and make triage decisions based on the allocation protocol and on resource availability as determined by the SRA team.

The Triage Team will communicate its triage decisions to the clinician(s) caring for the patients for implementation of its decision, and to the SRA team leader for oversight and reporting to the organizational leadership.

The Triage Team should develop and maintain a record of triage decisions and the data upon which the decisions were based. A daily retrospective of all triage decisions should be conducted as a routine quality review process.

3.2 PROTOCOL FOR ALLOCATION OF SCARCE LIFE-SAVING RESOURCES IN VHA DURING AN INFLUENZA PANDEMIC

VHA has developed this protocol for clinical evaluation and allocation of scarce life-saving resources (i.e., critical care resources including ventilators and hemodynamic support). This protocol is based on the ethical framework outlined in Appendix 1 and on previously developed pandemic influenza and mass casualty event protocols, including the Ontario Health Plan for Influenza Pandemic (OHPIP) (Ontario Health Plan for Influenza Pandemic, 2006), draft New York State Task Force on Life and the Law Report (New York State Task Force on Life and the Law, 2007), Task Force for Mass Critical Care guidance (Devereaux, 2008), and on the SOFA score (Ferreira, et al, 2001).

In the event of an influenza pandemic, the protocol should be used in affected VISNs throughout VHA to ensure patients fair access to life-saving resources in circumstances when the demand is greater than the supply and use of those resources must be optimized. Generally, the protocol will be applied throughout an affected VISN at the discretion of the VISN Director, but if significant clinical urgency exists at a particular facility, initiation of the protocol can be at the discretion of the Facility Director, pending VISN approval. The VISN Director is encouraged to take into account that his or her decisions regarding initiation of the tertiary triage protocol should take into consideration local or regional declarations (e.g., state-wide declaration of emergency by a governor). The VISN Director must ensure that the protocol is applied consistently and fairly whenever and wherever it is initiated within the VISN.

The protocol is based on a nested approach to allocation criteria as described in Appendix 1. The overarching criterion is that of medical success or survivability as determined by the application of established clinical criteria, including SOFA scores. Once a determination has been made that a patient qualifies for the resource under the SOFA score, and a patient's priority category has been determined (e.g., red or yellow, See Table 11), within-category priority is established on a first-come, first-served basis or a random selection/lottery basis, depending on the feasibility of implementation. *Because the shift to crisis standards is predicated upon conditions of scarcity, it is only at the point where demand for the life-saving resource overwhelms supply that the application of pandemic triage algorithms will apply.*

The protocol is based on the assumption that resource allocation will take local and regional circumstances into consideration. This "situational awareness" is described in the White House Homeland Security Council's *Implementation Plan for the National Strategy for Pandemic Influenza* (2006, p. 115) as follows: "VA's priority with respect to protecting human health is to deliver health care to enrolled veterans and beneficiaries. VA also has a mission to provide medical surge capacity for treatment of casualties arising from DOD operations and can provide other support to the extent the VA's mission to serve veterans is not compromised." The organization's leadership will maintain situational awareness, communicate information regarding resource availability, and communicate guidance regarding implementation of VA priorities to the SRA team, staff, and other stakeholders.

Although this protocol has been designed based on consensus and available literature, it has not been tested or implemented during an actual pandemic. As part of pandemic influenza planning, this protocol should be tested in drills and exercises, with lessons learned being then communicated to the Office of Public Health and Environmental Hazards and the National Center for Ethics in Health Care so that necessary modifications can be made in advance of a pandemic.

During a pandemic, the SRA team leader in consultation with the Triage Team should monitor the event-specific, real-time epidemiologic data to determine whether and how the assessment tools in the tertiary triage protocol should be adjusted. If national, regional, or local pandemic influenza leaders believe that it is necessary to adjust or modify the protocol based on actual circumstances during an influenza pandemic (e.g., new knowledge of specific predictors of outcome for pandemic influenza patients), the goal should be to maintain a consistent protocol in affected VISNs throughout VHA so that all patients are assessed according to the same criteria.

3.2.1 Clinical Assessment

During an influenza pandemic, clinicians will thoroughly assess all patients who present for care. Those patients who have clinical indications for scarce life-saving resources (e.g., critical care patients who require ventilators or hemodynamic support) will be subject to the tertiary triage protocol unless they elect not to be candidates for critical care.

3.2.1.1 Exclusion Criteria

Those who have clinical indications for scarce life-saving resources will be assessed for exclusion criteria to determine the appropriateness of the initiation or continuation of scarce life-saving treatment. If an exclusion criterion is present (Table 9), the patient is no longer a candidate for scarce life-saving resources, including scarce resources that may be needed for cardiopulmonary resuscitation. Clinicians should offer palliative and other supportive care to the patient and follow clinical standards for withdrawal of scarce life-saving resources and writing of DNR orders.

Exclusion criteria are intended to identify and exclude patients with a short life expectancy irrespective of the current acute illness. Exclusion criteria, drawing upon the work of the New York State Task Force on Life and the Law, the OHPIP, and the Task Force for Mass Critical Care, and incorporating suggestions from additional VHA reviewers and critical care experts, are presented in Table 9, below.

Table 9
Exclusion Criteria for Access to Scarce Life-Saving Resources

1. Confirmed presence of any advanced disease with average life expectancy of 6 months or less (e.g., advanced cancer or end-stage organ failure with less than 6 months average survival).
2. Recent cardiac arrest: unwitnessed arrest, recurrent arrest, arrest unresponsive to standard measures, trauma-related arrest.
3. Confirmed severe irreversible cognitive impairment (e.g., Persistent Vegetative State (PVS) or advanced dementia).

3.2.1.2 Triage Priority Categorization

The threshold for receipt of scarce life-saving resources will vary depending on availability of resources.

Because many patients will present to the emergency department for care, emergency physicians should be prepared to apply the initial assessment tool for patients who have clinical indications for critical care. For patients already receiving acute care, the Triage Team will conduct the initial assessment as well as 48-hour reassessment for all patients eligible for critical care resources.

The Triage Team will monitor patients using established criteria for initial assessment. Patients will be placed in categories based on a SOFA score (Table 10) and assigned a priority category according to an algorithm that is a variation of the OHPIP and draft New York State Protocol (Table 11). Acute care patients already receiving scarce life-saving resources when triage begins will be categorized by the Triage Team according to the initial assessment to see whether they will remain eligible for continued use of these resources. Depending on resource availability, the assigned priority category of the patient will determine whether or not that individual may receive scarce life-saving resources. In other words, the threshold for receipt of scarce life-saving resources will vary, depending on availability of resources. Patients assigned to the same category will be allocated resources on a first-come, first-served basis or a random selection/lottery basis, depending on the feasibility of implementation. The Triage Team will provide information to treating clinicians regarding patients' triage status. In the unlikely event that a patient triaged to palliative care shows significant improvement, the patient may be referred to the Triage Team for a second initial assessment.

Table 10
Sequential Organ Failure Assessment (SOFA) Score*

Variable	SOFA Score				
	0	1	2	3	4
PaO2/FiO2 mmHg	> 400	301 – 400	201 – 300	101 – 200	≤ 100
Platelets, x 10^3/µL or x 10^6/L	> 150	101 – 150	51 – 100	21 – 50	≤ 20
Bilirubin, mg/dL (µmol/L)	<1.2 (<20)	1.2-1.9 (20 – 32)	2.0-5.9 (33 – 100)	6.0-11.9 (101 – 203)	>12 (> 203)
Hypotension	None	MABP < 70 mmHg	Dop ≤ 5	Dop 6 – 15 or Epi ≤ 0.1 or Norepi ≤ 0.1	Dop >15 or Epi > 0.1 or Norepi > 0.1
Glasgow Coma Score	15	13 - 14	10 - 12	6 - 9	< 6
Creatinine, mg/dL (µmol/L)	< 1.2 (<106)	1.2-1.9 (106 – 168)	2.0-3.4 (169 - 300)	3.5-4.9 (301 – 433)	> 5 (> 434) or anuric

Note: Clinicians will determine the total SOFA score for each patient by summing the scores for each variable. Dopamine [Dop], epinephrine [Epi], norepinephrine [Norepi] doses in ug/kg/min. SI units are noted in parentheses ( ).

*Adapted from: Ferreira et al., 2001. Explanation of variables: PaO2/FiO2 indicates the level of oxygen in the patient's blood. Platelets are a critical component of blood clotting. Bilirubin is measured by a blood test and indicates liver function. Hypotension indicates low blood pressure; scores of 2, 3, and 4 indicate that blood pressure must be maintained by the use of powerful medications that require ICU monitoring, including dopamine, epinephrine, and norepinephrine. The Glasgow coma score is a standardized measure that indicates neurologic function; low score indicates poorer function. Creatinine is measured by a blood test and indicates kidney function.

Table 11
Adapted OHPIP Triage Tools

The triage tools (tables) below will be used to assign patients to priority categories (i.e., color codes) at initial assessment either by the emergency department physician or the Triage Team, and on an established 48-hour schedule by the Triage Team thereafter. NOTE: There is a specific triage tool for the initial and the 48-hour assessment intervals.

Initial and 48-Hour Triage Assessments – Clinical assessment and calculation of a SOFA score at the designated time intervals will result in patients being assigned to a color coded priority category.

In conformity with other tertiary triage protocols, the following color coding categories will be used:

Blue – Patients with very poor expected outcomes even if life-saving resources are used.

Red – Patients who require life-saving resources and are most likely to recover by receiving those resources.

Yellow – Patients who require life-saving resources and are less likely than patients in the Red category to recover by receiving those resources.

Green – Patients who do not require life-saving resources to recover.

Triage Review – The threshold for receipt of scarce life-saving resources will vary depending on the supply of resources and patient demand. The SRA team will consider regional and local circumstances, as well as the resources available, and subsequently determine which priority category or categories are eligible for life-saving resources. The Triage Team will apply this determination to its triage decisions for individual patients. NOTE: Patients within the same priority category will be supported on a first-come, first-served basis or a random selection/lottery basis, depending on the feasibility of implementation.

Life-Saving Resources Triage Tool for INITIAL ASSESSMENT			
Category	Initial Criteria	Priority	Action
Blue	Exclusion Criteria or SOFA > 11	None	Do not use life-saving resources Use other resources including palliative measures
Red	SOFA ≤ 7 or Single Organ Failure	Highest	Use lifesaving resources, as available
Yellow	SOFA 8 - 11	Intermediate	Use life-saving resources, as available
Green	No requirement for life-saving resources	None	Use other medical management Reassess as needed

This initial assessment tool is to be used to assess patients with clinical indications for critical care. For patients already admitted to acute care, this initial assessment tool is to be used only by the Triage Team. For patients presenting to the emergency department, this initial assessment tool is to be used by the emergency physician.

Life-Saving Resources Triage Tool for 48-HOUR REASSESSMENT			
Category	48-Hour Criteria	Priority	Action
Blue	Exclusion Criteria or SOFA > 11 or SOFA 8 – 11 and increasing since last assessment	None	Discontinue life-saving resources Use other resources including palliative measures
Red	SOFA 8 – 11 and decreasing since last assessment or SOFA < 8	Highest	Continue life-saving resources, as available
Yellow	SOFA 8 – 11 and no change since last assessment	Intermediate	Continue life-saving resources, as available
Green	No longer requiring life-saving resources	None	Discontinue life-saving resources. Reassess as needed

This 48-hour reassessment tool is to be used to reassess patients with clinical indications for critical care. This reassessment tool is to be used only by the Triage Team.

3.2.2 Reassessment

Continued use of the scarce life-saving resources will be reviewed on an established 48-hour schedule of the Triage Team. Patients who continue to meet criteria for inclusion will receive the resources until they either meet an exclusion criterion or are reassessed according to the 48-hour Triage Team schedule. Patients assigned to the same category will be allocated resources on a first-come, first-served or a random selection/lottery basis, depending on the feasibility of implementation. Those who no longer meet the criteria after reassessment will no longer be eligible for access to the scarce life-saving resources and should be informed of the need for withdrawal of these treatments and offered palliative and other supportive care. In the unlikely event that a patient triaged to palliative care shows significant improvement, the patient may be referred to the Triage Team for a second initial assessment.

The 48-hour schedule for reassessment is based on the SOFA tool (Ferreira et al., 2001) and reflects the expected time course of beneficial treatment for respiratory failure, sepsis, or other likely complications of severe influenza. A shorter trial interval does not reflect the period in which benefit would be expected. A longer trial interval, by contrast, might entail continued use of scarce resources by patients who are unlikely to benefit from them, resulting in inefficient use of the resource in times of scarcity. That being said, some patients will be admitted for critical care between the Triage Team's scheduled 48-hour reassessment interval. Newly admitted patients will need to be fit into the 48-hour triage assessment schedule, which will require some rounding of the time interval for the first 48-hour assessment. As a rule of thumb, no patient should receive his or her first reassessment sooner than 36 hours from the initial assessment.

3.2.3 Triage Decision Makers

The clinicians treating a patient should not, ideally, have the responsibility of deciding whether to institute or remove a patient from life-saving resources. This is the responsibility of the Triage Team, which will assess the patient's condition, note the existence or absence of exclusion criteria, and, if no exclusion criteria are present, assign the patient to an appropriate priority category (per Table 10). The Triage Team will make triage decisions based on the allocation protocol and resource availability as determined by the Scarce Resource Allocation (SRA) team or comparable structure. The Triage Team will communicate its decision to the treating clinician, who will implement a treatment plan consistent with the Triage Team's decision. Because of staff shortages during pandemic influenza, a clinician may be called to serve both as a Triage Team member and a treating clinician. In such circumstances, involved professionals should make every effort to act according to expectations for the role they occupy at any given point in time.

This approach is consistent with the recommendations of the ACCP Working Group on Emergency Mass Critical Care, a group of experts that produced a 2005 guidance document for improving surge capacity in public health disasters (Rubinson et al., 2005). The use of a Triage Team has a number of advantages; the Triage Team will have better access to information about both regional and local circumstances and the number and nature of patients awaiting scarce life-saving resources, and it can set triage goals accordingly. Such role sequestration will enhance the capacity for maintaining professionalism by allowing treating clinicians to fulfill their obligations to care for their individual patients without facing a conflict of interest about triage. The use of a Triage Team may help decrease burnout and stress for clinicians providing critical care during the finite duration of the pandemic. Placing responsibility for triage with a team that is not involved in a particular patient's care will help to sustain, post-pandemic, the ordinary obligations that define the physician-patient relationship. Finally, placing responsibility with a team that has the best information on the current balance of need versus supply will help to ensure consistency of triage decision-making across a group of patients.

3.2.4 Review and Appeals

In order to ensure fairness and accountability for the quality of triage decisions, the triage process must include mechanisms for review and appeal.

During a pandemic, a daily retrospective of all triage decisions by the Triage Team will provide a regular mechanism to ensure consistency and fairness in the application of triage criteria and will present an opportunity for correcting the guidelines or their implementation as needed.

In addition to a routine retrospective quality review process, a real-time clinical appeals process is also needed to ensure process accountability for triage decisions. The assumption behind such a process is that the established triage protocol meets conditions of fairness and efficiency, such that any appeal is based on claims of failure to adhere to established triage processes (e.g., an appeal based on an error in calculating SOFA score, or based on a challenge to the timing of reassessment), rather than an appeal for an exception to the process itself. Ideally, even under conditions of limited staffing, personnel involved in the appeals process will be different from personnel on the Triage Team. These persons should also be experienced in conflict mediation and have clinical expertise; drawing upon members of the Ethics Consultation Service, the patient representative service, clinicians, and the chaplaincy may be ways to provide a rapid appeals process even during the period of limited staffing. If feasible, members of an SRA team or comparable command structure excluding those members of the Triage Team could be involved in the clinical appeals process. Appeals review should consider whether applicable standards are being followed consistently and correctly in an attempt to ensure fairness and resolve conflict.

3.2.5 Communication About Triage

Initiation of protocols for allocation of scarce life-saving resources will require clear communication about goals, implementation, and options. Even before a patient comes to the hospital, political leaders, VHA leaders, and health officials will have to emphasize publicly that pandemic influenza is potentially fatal, that clinicians and health care organizations are doing all they can with the available resources, and that everyone will need to adjust to a different way of providing and receiving health care than is customary. Patients and families must be notified immediately that use of life-saving resources represents *a trial of therapy*, which, if it does not improve the patient's condition sufficiently, will be removed according to the triage protocol (New York State Task Force on Life and the Law, 2007, p. 37). Notification establishes the expectation that care standards have been altered according to triage algorithms. Even when the protocol is in effect, patients can refuse any treatments with the exception of those mandated to maintain the health of the public. (See Section 5.)

Training of staff for pandemic readiness should include guidance on how to implement this protocol and how to discuss it with patients and families. Communication should be clear upon hospital admission and ICU admission, as well as during decision-making about withholding or withdrawal of treatment. Since a pandemic may develop rapidly at any time, facility leaders should ensure that a communication strategy and tools explaining the nature of a pandemic, the impact on health care delivery, the allocation protocol and its implementation, are developed in advance and tested in tabletop exercises.

3.2.6 Resuscitation Status for Patients Excluded from Scarce Life-Saving Resources

During implementation of the triage protocol, patients who are excluded from scarce life-saving resources based on established criteria will, of necessity, be excluded from access to scarce resources that may be needed for cardiopulmonary resuscitation. DNR/DNAR orders which are entered into a patient's record under these circumstances should be reviewed after the period of scarcity has ended and crisis standards of care are no longer appropriate.

3.2.7 Application of Triage Algorithms to Patients Already Receiving Life-Saving Treatments

There is general agreement that in circumstances of extreme resource scarcity, critical care triage algorithms should apply to all patients receiving care in acute care facilities, regardless of their illness or their current treatment modalities (OHPIP, 2006, Hick et al, 2006, Christian et al, 2006). In practice, this means that patients who have a legitimate expectation of continued use of a life-saving treatment may have the treatment withdrawn under circumstances of severe resource scarcity. Although under ordinary circumstances the withdrawal of life-saving therapies in order to benefit another would be unjustified, in extreme circumstances, application of established algorithms to

patients similarly situated according to their clinical criteria is understood to be the fairest way of optimizing scarce resources. In times of extreme resource scarcity, patients and their families must be notified that life-saving treatment is initiated as a trial therapy that may be withdrawn if the patient's response does not meet established algorithms for continued use.

Among organizations considering resource allocation in a pandemic, there is, however, debate about whether patients in long-term care settings or at home and who are chronically receiving life-saving treatments (such as patients with quadriplegia or patients who receive long-term mechanical ventilation) should be subject to the same triage algorithms that apply to acute care settings during a pandemic. A recent draft report by the New York State Task Force on Life and the Law (2007), for example, supports exempting from triage protocols those patients who are maintained on ventilators (or comparable life-saving treatments) in Community Living Centers, long-term care facilities, and their own homes. Whereas the report accepts the need for triage protocols for withdrawal of life-saving treatments from patients in acute care settings, it argues that a single triage protocol for patients in both acute care and chronic care settings is pragmatically and ethically unsound. Sudden extubation of long-term ventilator patients residing in long-term care facilities or in their own homes, the report argues, is not justifiable even if the use of those ventilators allows greater numbers of healthier patients to survive. A policy of withdrawal of life-saving treatments from patients who require such treatments on a chronic basis, the report argues, is vulnerable to the critique of disadvantaging the disabled and/or making inappropriate quality-of-life assessments.

If, however, patients in chronic care settings require transfer to an acute care setting, the report's recommendation is that they should then be considered as part of that cohort and be subject to established critical care triage protocols. In a pandemic, this shift would almost certainly result in many such patients failing to meet triage criteria for continued life-support. In such circumstances, patients or families contemplating such transfers must be informed of the likely consequences of a decision to transfer.

By contrast, in its working paper, "Equitable Access to Therapeutic and Prophylactic Measures," the World Health Organization (WHO) Working Group on Addressing Ethical Issues in Pandemic Influenza Planning (Verweij, 2007) opposes the exemption of patients living in long-term care settings from pandemic triage protocols. This conclusion is based on an argument that an equitable sharing of sacrifice requires that triage criteria must be applied across the board.

The report acknowledges that many physicians and other health care workers may feel that their duty of non-abandonment means that they should give priority to patients for whom they have already accepted responsibility. Though there are good pragmatic reasons for such special obligations in normal circumstances (for example, they support relationships of trust), in the context of a pandemic such considerations are, the report maintains, less appropriate. For example, if very large numbers of

people get infected and require care, health care workers can no longer prioritize patients who are already under their care. They should, the report contends, give equal attention to all who need it and aim to save as many patients as possible including patients already being treated as well as those waiting for treatment.

Although there are viable ethical arguments on both sides of this issue, there is a general consensus that the emotional impact of withdrawing a life-saving treatment is different from reactions to a treatment modality being withheld. Even the WHO report acknowledges that the strategies it recommends may prove very difficult for the public at large. It recognizes that health care professions and the public may simply not accept a triage policy, even if rationally justified. Withdrawing treatments from chronically vulnerable patients may present even greater emotional hurdles.

Given these considerations, VHA patients who reside in long-term care facilities or at home and who require life-saving resources for their daily maintenance will not be subject to the pandemic triage protocols. Setting aside the small number of ventilators in long-term care facilities for use by the chronically ill, who likely will have severely limited access to ventilators in acute care facilities, offers an appropriate balance between the duties to care and to allocate wisely. Should such patients require transfer to acute care, however, they would, in that context, be subject to established critical care triage protocols.

SECTION 4: RESOURCE ALLOCATION – HOSPICE AND PALLIATIVE CARE PLANNING AND RESPONSE

VHA is committed to the provision of compassionate and humane care to the terminally ill Veteran and to support for the dying Veteran's family. One aspect of this commitment is VHA's hospice program, a coordinated program of palliative and supportive services provided in both home and inpatient settings for persons in the last phases of incurable disease so that they may live as fully and as comfortably as possible. The program emphasizes the management of pain and other physical symptoms as well as the management of the psychosocial problems and the spiritual comfort of the patient and the patient's family or significant other. Services are provided by a medically-directed interdisciplinary team of health care providers and volunteers. (Veterans Health Administration, Directive 2008-066)

The need for hospice and palliative care services to comfort the dying and lessen their suffering is expected to increase, possibly dramatically, during circumstances of pandemic influenza. In what follows, we offer an ethical justification for the use of resources to support hospice care during a pandemic, and provide recommendations for VHA leaders in developing pandemic preparedness plans for hospice and palliative care resources, training, and education.

4.1 WHY USE RESOURCES TO SUPPORT HOSPICE CARE DURING PANDEMIC INFLUENZA?

This guidance is based on the fundamental assumption that decision-making in pandemic influenza planning and response must be based on achieving the greatest good for the greatest number (the principle of utility) *within constraints of fairness and human dignity* (Kinlaw and Levine, 2007; Wynia, 2005; Gostin and Powers, 2006). Although a strictly utilitarian approach to pandemic planning and response might justify concentrating health care resources (staff, beds, supplies, and drugs) on saving those lives that have a high likelihood of being saved, an approach that balances utility, fairness and human dignity, as advocated in this guidance, requires that steps are also taken to provide for those who are not expected to survive (Rosoff, 2006).

In general, the utilitarian goal of maximizing survivability would direct health care resources (staff, beds, supplies, and drugs) toward saving those lives that can be saved. This is especially true in the acute care setting where life-saving resources are concentrated. One important planning implication of an ethical approach that seeks to balance overall good with respect for fairness and human dignity is the need to secure dedicated hospice and palliative care resources in the acute care setting for those patients who cannot be discharged to home or who are excluded from receiving life-saving resources based on triage protocols. Providing hospice and palliative care is a way of achieving equity for those who cannot benefit (or who could benefit, but due to scarcity will not receive access to live saving resources) from more intensive therapies. It is also a way of respecting the dignity of those who will not survive by helping to mitigate their pain and suffering. Finally, the provision of hospice and palliative care is also a fulfillment of the obligation of non-abandonment – a basic tenet of professionalism in health care and the minimum requirement of an ethical duty to provide care. Carrying forward these obligations into the circumstances of pandemic influenza has implications for VHA's planning for patients in the acute care setting, Community Living Centers, and for ill Veterans in the community.

Currently, VHA provides hospice care to Veterans in a variety of settings, including VA Community Living Centers, or through partnerships with community care providers in community nursing homes, or in the home setting (Veterans Health Administration, Handbook 1140.3). In circumstances of pandemic influenza, many Veterans who are seriously ill with influenza or other conditions will not make it to a hospital, and as a result, the number of patients needing hospice and palliative care outside of the hospital setting may increase. To insure that this group of patients is supported, VHA leaders need to take steps in advance of a pandemic to establish and augment collaboration with community-based service organizations.

4.2 RECOMMENDATIONS FOR HOSPICE AND PALLIATIVE CARE PLANNING

The following recommendations are drawn from national standards proposed by the Agency for Healthcare Research and Quality (2007). Taken in advance of a pandemic, these recommended steps will play an essential role in VHA's ability to meet its obligation to provide care to all patients across the treatment continuum. Currently,

every VHA facility has a Palliative Care Consultation team (Veterans Health Administration, Directive 2008-066). Facility Directors should include this team in the development and implementation of the following recommendations.

4.2.1 Education of Veterans and Family

VACO leaders should:

- Disseminate educational materials for patients and their family as part of existing and ongoing home care education about pandemic influenza, that can help them understand how best to take care of family members who do not have access to hospital care.

4.2.2 Resource Enhancement

Facility Directors should:

- Establish protocols for a dedicated stockpile of appropriate hospice and palliative care supplies (e.g., pain medication, anxiolytics);
- Develop a plan identifying dedicated space for the provision of hospice care. This space may be located in the hospital facility itself or at an alternate care site;
- Incorporate a process for granting disaster privileges into their facility's credentialing and privileging process and emergency management plan (VHA Handbook 1100.19, Credentialing and Privileging). Such plans should include the identification and training of additional providers to support hospice and palliative care of patients;
- Develop staffing plans identifying personnel resources, including retired health care professionals, volunteers, and support staff, which can be called on to provide for differing aspects of hospice and palliative care during a pandemic, (e.g., clinical support such as turning and suctioning patients), spiritual support, psychological support);
- Establish a communication network and chain of command that regularly updates information about VHA and community-based palliative service capacity; and
- Establish and augment linkages with community-based service organizations and personnel (e.g., home health, long-term care settings, hospice and palliative care providers) (Department of Veterans Affairs, Office of Public Affairs, 2008).

4.2.3 Training

Facility Directors should establish a training program for those identified to provide hospice care during pandemic influenza that includes:

- Skills required for the provision of clinical, spiritual, and psychological support to the dying under circumstances of a pandemic;
- Appropriate use of personal protective equipment to prevent disease transmission to the caregivers providing palliative care to patients with influenza;
- Pain management training for front line clinicians;
- A discussion of the implications of resource scarcity (e.g., implementation of triage protocols for life-saving resources and exclusion of ineligible patients from those resources); and
- How to talk with patients and families about the implications of triage protocols.

4.3 EUTHANASIA AND PRACTITIONER-ASSISTED SUICIDE ARE NEVER ALLOWED IN VHA

The practice of euthanasia – the direct administration of a lethal dosage of an agent to a patient with the intent to end the patient's life – is prohibited within VHA (42 USC 14402). Physician/practitioner-assisted suicide (PAS) – intentionally providing the necessary means to facilitate death (e.g., a prescription for barbiturates for the purpose of enabling the patient to perform a life-ending act) – is similarly prohibited. This prohibition applies equally to VA practitioners in states that have laws permitting PAS.

SECTION 5: RESTRICTIONS – LIMITING LIBERTY IN THE INTERESTS OF PUBLIC HEALTH

In responding to pandemic influenza, VHA will implement public health strategies for detection and containment of the virus and for treatment of those who fall ill. These strategies, which may entail limitations on individual liberty, pose predictable challenges to VHA health care professionals' obligation to give priority to the welfare of individual patients. Although many Veterans will voluntarily accede to some restrictions on their liberty, the emphasis on patient autonomy in the last 50 years of American medical ethics may cause professionals and their Veteran patients to chafe at such restrictions. However, ethical theories uniformly recognize that individual liberties may be limited to prevent harm to others, and public health measures are established on this basis. To preserve liberty as much as possible, the CDC's Community Mitigation Guidance recommends that quarantine would be voluntary and would be applied to household members of the ill only (Department of Health and Human Services, February 2007). Similarly, this VA guidance emphasizes that, inevitably, balancing these values depends on strategies and safeguards that preserve each without undermining either. This section provides an overview of these challenges, guidance for achieving public health goals through the least restrictive means possible, and recommendations for VHA leaders in communicating with staff and Veterans.

In public health crises such as pandemic influenza, there are four primary ways in which restrictions on the liberty of individuals may be necessary to control the spread of infection within the population. They are: infectious disease reporting, mandated preventive health measures, quarantine and social distancing, and isolation.

Quarantine is the separation of potentially exposed persons from those who have not been exposed.
Social distancing is the cancellation of public gatherings in order to lessen contacts that could result in disease transmission.
Isolation is the separation of ill persons from others.

As with any public health practice that may impose restrictions on individuals, transparent decision-making and the provision of clear information in advance of a pandemic (CDC, 2007) is the best way to ensure that Veterans will be aware of and understand the need for these restrictions and the role that their clinicians must play. Likewise, transparent decision-making and clear information and guidance to health care professionals will help them to understand and appropriately implement their responsibilities regarding public health measures. Patients and health care professionals alike must understand that physicians have no discretion over public health orders (Lo and Katz, 2005).

5.1 INFECTIOUS DISEASE REPORTING

Infectious disease reporting is a long-standing public health strategy to enable effective disease surveillance. Because they are privy to patients' communicable disease status, health care professionals are understood to have legal and ethical obligations to report certain information to public health authorities. Nonetheless, many clinicians may be unaware of this obligation or uncomfortable playing a role that could undermine their advocacy for individual patients. Patients too may be unaware that their information must, under certain circumstances, be provided to public health authorities.

In anticipation of a pandemic, VHA leaders should, in accordance with VHA Handbook 1605.1 Privacy and Release of Information, Section 27:

- Communicate expectations regarding health care professionals' role in communicable disease reporting during a flu pandemic.
- Explain the value of reporting in safeguarding the public health.
- Ensure that protected health information is appropriately communicated so that patient information goes only to those who need it to reduce risk associated with spread of infection.

5.2 MANDATED PREVENTIVE HEALTH MEASURES

Because medical countermeasures such as vaccines and antivirals are expected to be in short supply before and during a pandemic, it is unlikely that patient populations will be mandated to receive them. Rather, the reverse ethical problem is anticipated:

how should these scarce resources be fairly and efficiently allocated when not all patients can receive them?

Since health care workers have a much greater risk of exposure to a pandemic influenza virus due to their role in patient care and in sustaining health care operations, they are the likely candidates for mandated preventive health measures. Indeed, providing such protection is necessary from both an ethical and a practical perspective. Ethically, health care institutions have an obligation to minimize the risk to staff who bear a disproportionate burden in caring for patients (See Section 2). In addition, because health care workers can themselves be vectors for transmission, countermeasures are an important means for fulfilling the obligation to prevent harm to patients. From a practical point of view, staff will be more likely to come to work and be better able to help others if they feel that they are protected.

In general, health care workers understand and welcome access to protective measures when those measures are regarded as necessary and effective. These professionals also recognize that they have an ethical obligation to prevent harm to patients by protecting against the spread of infection.

In addition to operational steps outlined in the VA Pandemic Influenza Plan, in anticipation of a pandemic, VHA Facility Directors should educate staff about:

- The possible need for mandatory preventive health measures.
- The rationale for giving priority to health care workers in access to preventive measures.

5.3 QUARANTINE AND SOCIAL DISTANCING

The CDC defines quarantine as "separation and restriction of movement of persons who, while not yet ill, have been exposed to an infectious agent and therefore may become infectious" (CDC, 2005). Under the 10th Amendment to the U.S. Constitution, states have authority to enact laws and regulations to promote health, safety, and welfare of citizens. Quarantine is one such state action that has been used as a tool to manage some infectious disease outbreaks. State quarantine orders would be implemented under the authority of state and local public health agencies.

Federal quarantine authority is available to the Secretary of Health and Human Services (Department of Health and Human Services), the Surgeon General, and the President. In April 2005, President Bush issued an executive order to include influenza with pandemic potential as a quarantinable disease (EO 13375, April 1, 2005).

In circumstances of pandemic influenza, VHA facilities may be called upon to implement involuntary quarantine orders issued under the authority of state and local public health authorities, or the Federal government. VHA implementation of involuntary quarantine may be an ethically appropriate response to the public health crisis in support of community/regional pandemic mitigation efforts but, as discussed below, only when it is implemented in a transparent and least restrictive way. Regional

Counsel should be consulted whenever a VA facility seeks to hold a patient against his or her will.

Experts on public health law and ethics observe that there has been "no large-scale human quarantine implemented within U.S. borders during the past 8 decades" (Barbera et al., 2001, p. 2712). As a result, it has been necessary to reexamine quarantine as a modern means of infection control in light of past actions and current scientific, legal and ethical considerations.

In light of these conditions, mandatory quarantine should be understood as a last resort. Unlike in the past, there is now greater recognition that deprivation of individual liberties to serve a public good must be legal, necessary, proportionate, by the least restrictive means available, and guided by due process considerations (Gostin and Berkman, 2006). Experts agree that mandatory quarantine would be justifiable only under circumstances where the following conditions are met (Barbera et al., 2001, p. 2714-15; Kinlaw and Levine et al., 2007):

- The imposition of quarantine must "have a reasonable scientific chance of substantially diminishing the spread of disease,"
- The disease must be one which has been determined to pose a "serious risk of widespread human-to-human transmission," and must confer a high risk of "serious illness or death."
- The quarantine must have a reasonable chance of containing diseases.
- The quarantine must be equitably applied with clear explanations why particular communities are being restricted.
- There must be sufficient material and human resources to "enforce the confinement of large groups of persons, perhaps against their will,"
- Those who are quarantined must be detained "in safe and hygienic locations" with "adequate food and other necessities" provided.
- Those who are quarantined must have access to "competent medical care."
- Public education and support are essential to high rates of compliance with voluntary quarantine (Rothstein et al., 2003).

In lieu of mandatory quarantine, public health authorities now recommend voluntary quarantine in circumstances of a pandemic (Department of Health and Human Services, February 2007).

In addition to operational steps outlined in the VA Pandemic Influenza Plan, in anticipation of a pandemic, VHA leaders should develop communications materials that:

- Clearly communicate to Veterans and staff why quarantine measures and social distancing are vital to control transmission of influenza for public safety and solidarity; and
- Clearly communicate barriers and challenges presented by quarantine and social distancing, including the closure of day care centers used by VHA

staff, the impact on staff ability to report to work, and the cancellation of group activities and therapies.

When a quarantine order is issued by public health authorities, research has found that frequent communication by a single, or a very limited number of credible spokesperson(s) throughout an epidemic is essential to improving public understanding of and maintaining public support for quarantine, isolation, and other public health measures (Rothstein et al., 2003). This approach is reflected in the VA Pandemic Influenza Plan and has been presented in three workshops on VA Pandemic Influenza Emergency Communication.

5.4 ISOLATION

Quarantine applies to healthy people who have been potentially exposed to a contagious disease. Isolation, by contrast, refers to the "separation of persons who have a specific infectious illness from those who are healthy and the restriction of their movement to stop the spread of that illness" (CDC, 2005). Although isolation restrictions may be one aspect of a formal quarantine, in some cases, isolation as a containment strategy will be necessary before quarantine. Given their knowledge of a patient's infection status, health care professionals in particular may be called upon to implement these restrictions.

As Wynia and Gostin (2004, p.1098) observe, "using professional powers to hold patients involuntarily poses a fundamental ethical challenge for physicians, because it entails overriding an individual patient's wishes in deference to the community's needs." Whether supported by the utilitarian rationale of overall public benefit, the public health principle of preventing harm to third parties, or the paternalistic rationale of clinical benefit to the individual who suffers involuntary isolation and treatment, such restrictions must not be imposed without adequate justification and safeguards.

As in the imposition of formal quarantine, the legal authority to compel isolation is historically derived from a state's inherent "police power." State and local jurisdictions have primary responsibility for isolation and quarantine within their borders. Because these laws vary greatly from state to state and, in some cases, within local jurisdictions, Regional Counsel should be consulted whenever a VA facility seeks to isolate and hold a patient against his or her will.

In general, Federal authorities defer to state and local health authorities in the primary use of their separate quarantine and isolation powers. However, the Federal government has residual authority under the Commerce Clause of the U.S. Constitution to prevent the interstate spread of disease. The federal government also has primary responsibility for preventing the introduction of communicable diseases from foreign countries into the United States. The Secretary of the Department of Health and Human Services is responsible for preventing the introduction, transmission, and spread of communicable diseases from foreign countries into the United States and within the United States and its territories and possessions (42 U.S.C. § 264). This statute is

implemented through regulations found at 42 C.F.R. Parts 70 and 71. Under its delegated authority, CDC is empowered to detain, medically examine, or conditionally release persons suspected of carrying certain communicable diseases (as specified in an Executive Order of the President). In addition to these authorities, special quarantine powers are available to the Surgeon General in a time of war. The Surgeon General may apprehend, examine, and detain individuals reasonably believed infected with communicable disease if they present a probable risk of infection to the armed forces or its suppliers (42 U.S.C. § 266). Finally, the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. §§ 5121, *et seq.*) could be invoked to implement health and safety measures, including isolation and quarantine.

Isolation decisions by VA leaders and recommendations by facility Infection Control Committees should be informed by the following ethical considerations (Barbera et al., 2001, p. 2714-15):

- The imposition of isolation must "have a reasonable scientific chance of substantially diminishing the spread of disease."
- The disease must be one which has been determined to pose a "serious risk of widespread human-to-human transmission", and must confer a high risk of "serious illness or death."
- There must be sufficient material and human resources to enforce the isolation of persons, perhaps against their will.
- Those who are subject to isolation must be confined "in safe and hygienic locations" with "adequate food and other necessities" provided.
- Those who are subject to isolation must have access to competent medical care.

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APPENDIX 1: AN ETHICAL FRAMEWORK FOR DECISION-MAKING REGARDING ALLOCATION OF SCARCE LIFE-SAVING RESOURCES

Background Ethical Assumptions about the Goal(s) to be Achieved Through Triage

The California Department of Health Services (California Department of Health Services, 2006) has developed an ethical framework for decision-making regarding scarce resource allocation specifically for pandemic influenza vaccine. The framework, based on foundational work by Gerald Winslow in his book, *Triage and Justice*, is used to assess the feasibility (ethical, legal, political, and practical) of patient selection criteria. This framework as well as analysis by others (Kilner, 1990; Verweij, 2006, Kinlaw and Levine et al., 2007) was used as a guide for identifying the ethical bases for allocation of scarce life-saving medical resources under circumstances of pandemic influenza in VHA. We include this framework as a way of demonstrating transparency regarding the basis for the protocol for allocation of scarce life-saving resources presented in Section 3.

NOTE: This ethical framework might be used as a tool to make decisions not addressed in this guidance, for example, non life-saving resource allocation decisions or life-saving resource allocation decisions in non-pandemic mass casualty events.

Consequentialist and Person-Centered Approaches to the Allocation of Scarce Life-Saving Resources

There are two widely accepted theoretical approaches to allocation of scarce resources: consequentialist and person centered (Kilner, 1990; Winslow, 1982; Gostin and Powers, 2006; Roberts 2006; Vawter et al., 2007;Verweij, 2006; Kinlaw and Levine et al., 2007; Vawter et al., 2008). A consequentialist approach aims to create the greatest good for the greatest number and regards individuals as instrumental to that overall goal. Such an approach can be the basis for public health decision-making that focuses on the best interest of the population as a whole. A person-centered approach, by contrast, is based on the equal worth of all humans and focuses on allocation strategies that emphasize equitable treatment of people as a way of respecting their inherent worth.

Consequentialist and person-centered approaches are often in tension, yet both are understood to be necessary in public health decision-making. For example, triaging to save the greatest number of lives (a consequentialist objective) will inevitably depend on a principle of fairness (a person-centered approach) for deciding between individuals when there are still insufficient resources to treat all who meet the inclusion criteria. Likewise, a person-centered approach would endorse the efficient use of the limited resources (a consequentialist objective) in order to increase the probability of saving more lives. Similarly, a public health policy of mandatory quarantine to contain disease outbreak (a consequentialist goal) is understood to be tolerable to the extent that it uses the least restrictive means (a person-centered approach) to achieve that end.

In addition, from a practical point of view, public health measures will be more readily accepted if they are developed through processes that are fair, reasonable, and open.

Tables A-1 and A-2 provide a variety of commonly used allocation criteria and strategies that stem from each approach. Tables A-1 and A-2 make no judgment about whether a particular strategy is appropriate, legal, ethical, or feasible. This section only describes how particular strategies for allocation of scarce life-saving resources could be applicable to an outbreak of pandemic influenza. One important caveat to keep in mind when assessing these strategies is that *they are being applied only to the allocation of scarce life-saving resources*. In other words, these allocation criteria apply specifically to very ill patients in the tertiary care setting, not to selection for countermeasures such as vaccines or antivirals. Although there will be overlap in these criteria, an allocation framework for countermeasures is outside the scope of this guidance.

Table A-1
Consequentialist Criteria for Allocating Scarce Life-Saving Medical Resources

CONSEQUENTIALIST CRITERIA FOR ALLOCATING SCARCE LIFE-SAVING MEDICAL RESOURCES		
Consequentialist Criteria	**Definition**	**Description**
Medical success/ Survivability.	Priority is given to those for whom treatment has the highest probability of medical success/survival.	Allocate resource by probability of successful treatment. Those who will probably live even without treatment and those who will probably die even if treated are left aside in order to treat those for whom the specific resource has the highest probability of preventing severe illness and/or death. Further selection within this category can be made on the basis of length of benefit and/or quality of benefit.
Immediate usefulness.	Priority is given to the individuals who are most useful under the immediate circumstance.	Allocate the resource to those who perform a role essential to the immediate emergency. Individuals will be identified according to essential role, indispensability, and ability to perform role, if treated.
Conservation of resources.	Priority is given to those who can benefit by proportionately smaller amounts of the resource or shorter length-of-use time.	Allocate the resource in the smallest effective increments to benefit the most. Conservation benefits those individuals who require a smaller portion of the available resource or shorter length-of-use time.
Parental/Caretaker role.	Priority is given to those who have a caretaking role for dependents.	Allocate the resource to those who provide primary home care for children, elderly, and the unwell. This principle is based on the idea that providing the resource to caregivers will benefit both the caregiver and the dependents.

Social worth/Moral worth.	Priority is given to those who are believed to have the greatest social or moral “worth.”	Allocate the resource to those who are most socially or morally “worthy.”

Table A-2
Person-Centered Criteria for Allocating Scarce Life-Saving Medical Resources

PERSON-CENTERED CRITERIA FOR ALLOCATING SCARCE LIFE-SAVING MEDICAL RESOURCES		
Person-Centered Criteria	**Definition**	**Description**
Medical need/rule of rescue.	Priority is given to those with the greatest medical need.	Allocate resources according to greatest medical need. This strategy assumes that the medically worse-off should be given priority and favors those individuals who are most at risk for severe illness and/or death. This strategy does not necessarily consider need relative to probability of survival.
General need.	Priority is given to those with the greatest general need or helplessness. "General need" may include a range of characteristics including: lack of political power, social status, intelligence, physical strength, or financial power. This is relevant because having these characteristics/ conditions often limits one's access to medical resources.	Priority allocation of resources to those with minimal access to medical care.
Fair innings.	Priority is given to those who have had less opportunity for a full lifespan.	Where probability of benefit from treatment is on par and age difference is great, priority allocation to the 20-year old over the 60-year old.
First -come, first – served.	Priority is given to those who arrive first, that is, who have been waiting longest.	This strategy, which depends on the establishment of a waiting list or queue, gives priority to those individuals who arrived first in the queue to receive a needed resource.
Lottery	Priority is given to those selected by chance through a lottery.	This strategy gives all who require a particular resource an equal chance of being selected.

Evaluating the Allocation Criteria

In order to determine whether these ten allocation criteria are reasonable, they were evaluated on the basis of five types of test: meets intervention goals, ethics, legality, political feasibility, and practicality of implementation:

1. Does the criterion meet the VHA intervention goals? (Each criterion must achieve at least one of these goals to be included for further analysis.)

- To stop, slow, or limit the spread of disease,
- To reduce suffering and death,
- To sustain operations.

2. Does the criterion meet moral intuitions regarding important values such as fair process, proportionality (balance between individual liberty and community interests), and stewardship? (Each criterion must be consistent with at least two of these values to be included for further analysis.)

3. Is the criterion legal?
Does the criterion conform to statute and regulation governing VA, and is it a legitimate exercise of public health authority?

4. Is the criterion politically feasible?
Is the criterion likely to be accepted by VHA stakeholders, including Veterans, VHA employees, Congress, and the public?

5. Can the criterion be practically implemented given the emergency circumstances?
Will it be practical to implement the criterion? For example, can the relevant group be easily identified?

All of the criteria were evaluated on a point scale. Each was allocated between zero and two points for each test, with zero points indicating that the criterion did not pass a given test and two points indicating that the criterion is completely acceptable on a given test. One point in a test indicates that either there are some reservations about the criterion or that the acceptability of the criterion is uncertain.

In order to be considered reasonable for scarce life-saving resource allocation, each criterion was required to pass all of the tests; in other words, each criterion must have received one or two points on each test. Because VA's intervention goals for pandemic influenza are central to any allocation criterion, any criterion that received zero points on the first test was not considered for subsequent tests.

On this basis, seven of the ten criteria were determined to be reasonable bases for scarce life-saving resource allocation. These criteria passed all five of the tests, though with varying final scores. Among the passing scores, we selected the highest

scoring criterion as the most reasonable basis for initial allocation. Table B-1 and B-2 below summarize the results of these tests.

The results of this evaluation support a "nested approach" to allocation criteria. That is, the reasonableness of most of the above criteria depends on meeting an initial screen for probability of success (the medical success/survivability criterion) – which received the highest overall score. So, for example, the use of smallest effective increments or first-come, first-served in the allocation of scarce life-saving resources only makes sense from an efficiency standpoint if it is determined that those selected for the resource can use it successfully. Likewise first-come, first served is inadequate from the perspective of fairness – as it favors those who have means of access and disfavors those who do not. As such, first-come, first-served is insufficient as an initial criterion but may be justifiable as a second-order criterion, once an initial criterion (the medical success/survivability criterion) has been met. One of the problems with the "medical need/rule of rescue" criterion is that it does not necessarily consider need relative to probability of survival. Likewise, one would only consider giving priority for ventilators to those who provide an "essential service" immediately relevant to a pandemic if that treatment would be successful in allowing them to immediately function in that role.

Although older age is an exclusion criterion in other allocation protocols (ACCP, 2008), the fair innings criterion (priority allocation to those who have had less opportunity for a full lifespan) did not receive a high enough score to be the basis for our VHA protocol. There are a number of reasons for this. First, a younger patient may be much sicker physiologically than a patient who is older, and thus, the older patient may be more likely to achieve benefit from the scarce resource. For this reason, survivability based on physiologic assessment as reflected in the SOFA score was determined to be the appropriate and highest scoring allocation criterion. In addition, the VHA protocol is designed to take into account the fact that the VHA population is older than patient cohorts generally. In the event that VHA facilities provide humanitarian care to non-VHA patients during a pandemic, the VHA protocol ensures that the older VHA population is not disproportionately excluded from access to the critical care resources.

Table B-1
Evaluating Consequentialist Resource Allocation Criteria

TABLE B-1: EVALUATING RESOURCE ALLOCATION CRITERIA							
Consequentialist Strategies							
CRITERION	**Test 1: Limits spread, reduces death, suffering, sustains operations.**	**Test 2: Ethical values**	**Test 3: Legal**	**Test 4: Politically feasible**	**Test 5: Feasible to implement**	**Final Score**	**Pass or Fail**
Survivability Allocate resource by probability of successful treatment.	2	2	1 - legal concerns re withdrawal of life-saving treatment	2	2	9	**Pass**
Immediate usefulness Allocate the resource to those who perform a role essential to the immediate emergency.	1	1 - may challenge trust and equity if perceived to be applied too broadly	2	1 - who defines "essential" to immediate emergency ?	1 - re. life-saving resources, "essential" persons may already be too ill to serve role	6	**Pass** re. life-saving resources, Fail if "essential" persons already too ill to serve role
Conservation of resources Allocate the resource in the smallest effective increments.	2	2/1 Arbitrary relative to survivability. Not a sufficient initial criterion.	2	2	1 may not always be easy to predict	8/9	**Pass**
Parental/Care taker role Allocate the resource to those with dependent caretaker role.	1	1 - may challenge trust and equity if perceived to be applied too broadly	2	1	0	5	**Fail**
Social worth/Moral worth. Allocate resource to those who are perceived worthy.	0	0 – reinforces bias and discrimination - not consistent with equal moral worth	0	0	0	0	**Fail**

Table B-2
Evaluating Person-Centered Resource Allocation Criteria

TABLE B-2: EVALUATING RESOURCE ALLOCATION CRITERIA							
Person-Centered Strategies							
Strategy	**Test 1: Limits spread, reduces death, suffering, sustains operations.**	**Test 2: Ethical values**	**Test 3: Legal**	**Test 4: Politically feasible**	**Test 5: Feasible to implement**	**Final Score**	**Pass or Fail**
Rule of rescue Allocate according to criterion of medical need.	1	1 problematic re: stewardship if not tied to likelihood of success. Unfair priority to identified individuals	2	2	1	7	**Pass**
General need Priority allocation to those with limited access to medical care.	1	1	? - may not be consistent with VHA eligibility priorities	1	0 - difficult to identify this class of people	3+	**Fail**
Fair innings Priority allocation to those who have had less opportunity for a full lifespan.	2	2	1	1 -may be seen as discriminating against elderly and thus large % of VHA population	1	6	**Pass**
Allocate on a **first-come, first-served** basis.	1	0/1 - problematic re. fairness - favors those who have access. Arbitrary relative to survivability. Not a sufficient initial criterion. Legitimate 2nd- order criterion.	2	2	2	7/8	**Fail as a first-order criterion. Pass as second order criterion**
Allocate via **lottery**.	1	1 - supports fairness, arbitrary relative to survivability. Legitimate 2nd-order criterion.	1	1	0/1 depending on circumstances	4	**Fail as a first-order criterion. Pass as second order criterion**

APPENDIX 2: CHECKLIST FOR IMPLEMENTING THIS GUIDANCE

In advance of a pandemic event, VHA facility leaders should:

- ☐ Actively engage stakeholders in pandemic influenza planning and preparation by encouraging them to read and understand this guidance, including them in planning and decision-making groups as appropriate, and/or soliciting input through forums, discussions, or call for comments and opinions (in facility publications, by email, public notices, web postings, etc.). Stakeholders include all those who will be affected, including employees, Veterans, VSOs, labor unions, volunteers, and others.

- ☐ Update the facility work force plan (Department of Veterans Affairs, 2006, Sections 3.4.3.1, 3.2.3.4, 3.2.3.6) to delineate the following specific points:
  - ☐ The values and ethical principles governing VHA personnel, including the duty to provide care to Veterans and the institution's reciprocal obligation to support and care for the employee during a pandemic flu event. (Section 2)
  - ☐ The employer's expectations of employees' responsibilities during a pandemic influenza event. (Section 2)
  - ☐ That legal authority does not currently exist to protect contract employees under the Federal Tort Claims Act and that contract employees should check with their malpractice insurer to make sure that their coverage would extend to actions taken under an altered scope of practice during a pandemic.
  - ☐ A fair and consistent decision-making process that will be used to specify the limits or exceptions to an employee's duty to provide care. (Who may be excused from service, why, and how?) (Section 2)
  - ☐ The ways in which the facility will:
    - ☐ Safeguard employees (e.g., security, building and infrastructure safety).
    - ☐ Mitigate occupational risk (e.g., protective equipment and vaccines).
    - ☐ Clarify for stricken staff and their families available institutional care and support for those who become ill from influenza.
    - ☐ Assist employees in meeting competing obligations (e.g., family care). (See Table 8 for specific authorities)
    - ☐ Provide for employee's welfare (e.g., basic needs such as food, sleep, clean clothes, and the availability of showers). (See Table 8 for specific authorities)
  - ☐ The strategies that may be used to encourage and support staff to come to work (e.g., overtime pay, hazardous duty pay, etc.) while also articulating that coercive strategies (e.g., threats of termination) should be avoided. (Table 8 for specific authorities)

- ☐ The ways in which non-clinical staff will be expected to participate in the facility's clinical response – in particular the use of non-clinical staff in the provision of palliative care – and how training will be provided to them.
- ☐ How emergency scopes of practice will be established and the legal framework under the FTCA for immunity from personal liability.
- ☐ Incorporation of a process for disaster credentialing and granting disaster privileges into the credentialing and privileging process and emergency management plan. (VHA Handbook 1100.19, Credentialing and Privileging and VHA Directive 2006-067, Credentialing of Health Care Professionals)

☐ Update the facility patient care response plan to establish in advance of a pandemic:

- ☐ A scarce resource allocation (SRA) team.
- ☐ A continuity plan for the SRA team to allow for illness and absence of members.
- ☐ A process whereby data required for the SRA team to oversee triage and resource allocation decision-making will be gathered and shared.
- ☐ Operating procedures governing the SRA team. Those procedures will:
  - ☐ Describe the processes and criteria used to initiate the use of and withdrawal of scarce life-saving resources consistent with the protocols described in this guidance.
  - ☐ Mandate appropriate Do Not Resuscitate (DNR/DNAR) protocols during the pandemic.
  - ☐ Specify a mechanism for review and appeal to ensure fairness and accountability for the quality of triage decisions.
  - ☐ Require that the triage algorithms for life-saving resources are applied to all critical care patients, regardless of their illness or their current treatment modalities. However, the plan should also specify that the triage algorithms will NOT be applied to patients housed in VHA long-term care beds and/or facilities (e.g., patients chronically dependent on life-sustaining resources like ventilators in long-term care facilities will not fall under the triage protocols until and unless such patients require transfer to an acute care setting).

☐ Guidance regarding the implementation of involuntary isolation for contagious medical conditions. Such guidance should be informed both by state and federal law with the assistance of Regional Counsel, and by the ethical principles outlined in Section 5.4.

☐ The need for hospice and palliative care and describe the processes and resources required to implement such care, including:

- ☐ Establishment of protocols for stockpiling appropriate hospice and palliative care supplies (e.g., pain medication, anxiolytics).
- ☐ Description of the ways in which non-clinical staff will help support the provision of hospice and palliative care and the training to be completed by non-clinical staff who will act in this role.
- ☐ Clarification of responsibility for identifying community resources for hospice and palliative care and assignment of responsibility for

building relationships with such programs in advance of a pandemic.
    - ☐ Inclusion of information about hospice and palliative care in the data collection and communication activities of the SRA team, facility leadership, and staff.

- ☐ Ensure that the communications plan (Department of Veterans Affairs, 2006, Appendix D-3):
    - ☐ Addresses the work force plan prepared for pandemic flu. Leaders should particularly focus on the values message that coming to the aid of those who fall ill during an influenza pandemic may be one of the most important and commendable actions that staff undertake in their VHA careers.
    - ☐ Openly acknowledges the risks associated with providing care during a pandemic.
    - ☐ Describes the crisis standards of care expected during a pandemic.
    - ☐ Addresses how decisions about triage and crisis standards of care will be communicated to employees and Veterans during a pandemic. At a minimum, this will include the preparation of patient and staff education materials in advance of a pandemic flu event to be used during the event to describe to Veterans and their family members what triage means, how it will work, what care may or may not be available to them, and the ethical principles behind these protocols.
    - ☐ Provides a means to effectively and efficiently share information about the availability of palliative care options in the community.
    - ☐ Includes educational materials for patients and their families on how best to take care of themselves and dying family members when they do not have access to life-saving hospital care. (Department of Veterans Affairs, 2006, Appendix E-6)
    - ☐ Communicates expectations regarding the duty to provide hospice and palliative support to dying patients who do not have access to life-saving hospital care.
    - ☐ Communicates expectations regarding health care professionals' role in communicable disease reporting in accordance with VHA Handbook 1605.1, Privacy and Release of Information, Section 27.
    - ☐ Explains the value of reporting to safeguarding the public health.
    - ☐ Explains that protected health information is appropriately communicated so that patient information goes only to those who need it to reduce risk.
    - ☐ Communicates expectations about mandatory preventive health measures.
        - ☐ Explains the rationale for requiring health care workers to be vaccinated against pandemic influenza or to take antivirals.
        - ☐ Explains the rationale for giving priority access to health care workers for preventive measures.
    - ☐ Communicates expectations about quarantine, social distancing, and isolation.

- ☐ Clearly communicates to Veterans and staff why quarantine measures and social distancing are vital to control transmission of influenza, to guarantee public safety and to promote solidarity.
- ☐ Clearly communicates barriers and challenges presented by quarantine and social distancing including the closure of day care centers used by VHA staff, the impact on staff's ability to report to work, the cancellation of group activities and therapies as well as medical care/treatments not essential during a pandemic (e.g., routine eye exams, dental visits, audiology, etc.).
- ☐ Clearly communicates to Veterans and staff why isolation measures are important, including the need to prevent the transmission of the virus, and the values of public safety and solidarity.
- ☐ Clearly communicates barriers and challenges presented by isolation, including stigma and the psychological toll on patients who are separated from loved ones.

☐ Ensure extensive preparation and training of staff in the application of this guidance, the facility work force plan, the facility patient care plan, and the communications response plan including the use of the triage protocol and how to discuss its use with patients and their families.

☐ Conduct rigorous, repeated tests of the pandemic influenza response plan that include the ethical principles and protocols described in this guidance. Report "after action" findings to the Office of Public Health and Environmental Hazards and the National Center for Ethics in Health Care.

During a pandemic event, VHA facility leaders should:

☐ Be physically present at their facilities and be actively involved in supporting both clinical and non-clinical staff in ensuring the delivery of care to Veterans and the provision of essential services to employees.

☐ Activate the SRA team and support its implementation of crisis standards of care. Ensure that the team has the information and authority it needs to make decisions about triage and the allocation of scarce resources.

☐ Ensure timely and accurate flow of information between the SRA team and top facility management; and the timely and accurate flow of information to employees, patients, family members, and the public, including the reasoning behind the decisions being made and the processes being used to make them.