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THESIS

**ALTERED STANDARDS OF CARE: AN ANALYSIS OF
EXISTING FEDERAL, STATE, AND LOCAL GUIDELINES**

by

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December 2011

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STATE, AND LOCAL GUIDELINES**

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ABSTRACT

A disaster with mass casualties or event involving a weapon of mass destruction (WMD) is a profound, life-impacting event that can lead to further devastating consequences. Under austere conditions, however, the implementation of altered standards of care can greatly increase the quality of life of individuals injured by such an event. This thesis evaluates, compares, and contrasts, at the various federal, state, and local levels, guidance documents for altered standards of care and presents a policy recommendation for the inclusion of triggers, guaranteed minimums of care, and legal immunity into existing planning guidance documents for altered standards of care at the federal, state, and local levels. In formulating this policy recommendation, consideration was given to ethical values that should be used to develop policies for altered standards of care, which are recommended to guide and support decision making during both preparation and response at different levels of government.

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LIST OF ACRONYMS AND ABBREVIATIONS

AHRQ	Agency for Healthcare Research and Quality
AMA	American Medical Association
ANA	American Nurses Association
ASPR	Assistant Secretary for Preparedness and Response
CDC	Centers for Disease Control and Prevention
CMS	Center for Medicare and Medicaid Services
CUSEC	Central United States Earthquake Consortium
DHHS	Department of Health and Human Services
DHS	Department of Homeland Security
DNA	Deoxyribonucleic Acid
DNR	Do Not Resuscitate
DOPH	Department of Public Health
EMA	Emergency Management Agency
EMS	Emergency Medical Services
EMTALA	Emergency Medical Treatment and Labor Act
EPG	Emergency Planning Guidance
ER	Emergency Room
FEMA	Federal Emergency Management Agency
GAO	Government Accounting Office
H1N1	Swine Influenza Virus
HIPAA	Health Insurance Portability and Accountability Act
ICU	Intensive Care Unit
MDMP	Military Decision Making Process
MSEHPA	Model State Emergency Health Powers Act
NGO	Non-Governmental Organization
NHS	National Health Service
NIH	National Institutes of Health
NIMS	National Incident Management System

NMSZ	New Madrid Seismic Zone
NRF	National Response Framework
SARS	Severe Acute Respiratory Syndrome
SCEDC	Southern California Earthquake Data Center
SIR	Susceptible Infectious Recovery
TLP	Troop Leading Procedures
TPC	Tacoma Pierce County
UK	United Kingdom
USALFM	United States Army Leadership Field Manual
USGS	United States Geological Survey
VPA	Volunteer Protection Act
WHO	World Health Organization
WMD	Weapon of Mass Destruction

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I. INTRODUCTION

A. PROBLEM STATEMENT

The standard-of-care framework that currently guides healthcare in the United States assumes that each presenting patient, regardless of precipitating event, will receive care and attention that will not be diverted to the next patient until care for the first patient is underway or until that patient is transferred or referred. Additionally, the current framework relies on a high level of technology that may not be achievable after a disaster or WMD event if there are electrical outages, destroyed buildings, or extremely limited numbers of healthcare workers available and willing to work. For those who would work under such circumstances, the fear of potential legal action is not unfounded, given the charges filed against nurses and Dr. Anna Maria Pou for failure to care and inappropriate use of medication in New Orleans following the flooding associated with hurricanes Katrina and Rita (Okie, 2008, p. 4). Pou and two nurses were arrested in July 2006 and accused of administering lethal doses of medications to four older adult patients, thereby intentionally killing them. Dr. Pou has asserted that the medications were given only to relieve pain and distress. The attorney general in Louisiana did not pursue charges against the nurses in exchange for their cooperation, and the grand jury ultimately did not indict Dr. Pou. However, three civil suits, filed by the deceased patients' relatives, are pending against Pou (Okie, 2008, p. 5).

Given circumstances similar to those described above, altered standards of care in mass-casualty events have been shown to optimize patient outcomes (Koenig, 2006, p. 196). Altered standards of care would be enacted during a pandemic influenza, bioterrorist attack, or natural disaster in which healthcare providers would have to triage victims in order to apportion limited equipment, supplies, personnel, and medication in a manner that saves the greatest number of lives. There are, however, planning and legal issues that pervade emergency response and cause high levels of anxiety on the part of

hospital staff and others that they will be held responsible for actions taken that were, in fact, the best decision that could be made under such extreme conditions (U.S. Government Accountability Office [GAO], 2008; Hodge, 2006, p. 627).

1. Background

The threat of a catastrophic mass-casualty incident resulting in tens of thousands of victims related to a public health event—such as an influenza pandemic, or a terrorist event such as the detonation of an improvised nuclear device—is internationally accepted (Hawryluck, Lapinsky, and Stewart, 2005, p. 384). It is also internationally accepted that most countries do not necessarily have sufficient healthcare staff, equipment, and physical space to provide urgent care to those critically injured by such dire events (Institute of Medicine [IOM], 2006).

Disaster events with the potential for mass casualties occur on a frequent basis worldwide (International Disaster Database, 2010). Luckily, the overwhelming majority of these events do not produce extremely large numbers of victims that are critically injured. International planning efforts for mass critical care have been motivated by recent natural disasters, terrorist attacks, the severe acute respiratory syndrome (SARS) epidemic of 2002–2003 (Christain, Poutanen, and Loutfy, 2004, p. 1420), and the continued threat of the serious H1N1 influenza. While the current H1N1 influenza appears to be relatively less dangerous and fatal compared to other pandemics, it is important to understand that during the twentieth century alone there have been three recognized influenza pandemics—in 1918, 1957, and 1968—each causing an estimated 50 million deaths worldwide (Health Protection Agency [HPA], 2010).

2. Disasters and the Healthcare Sector

Disasters are becoming more frequent and more severe, and the capabilities of the medical sector are increasingly being pushed to the limit. Every disaster brings new challenges; a few disasters have created what seem to be problematic challenges, like the 2005 Gulf Coast hurricanes (Bower, 2005). There are cases of floods, hurricanes, earthquakes, and other physical hazards creating both an increased need for healthcare

services and a significant loss of capability to provide such services. On occasion, hospitals and emergency medical services (EMS) fall victim to these events at a time when they are expected to demonstrate leadership and provide help to the impacted population (American College of Emergency Physicians [ACEP], 2006).

Physical hazards alone are not enough to cause a disaster. Disasters result when vulnerable populations and infrastructure are exposed to these physical hazards. It is this exposure that results in destruction, injuries, and deaths. In turn, these outcomes reflect both the magnitude of the hazards and the level of vulnerability of the infrastructure and population (Shoaf et al., 2006). Although vulnerability is a difficult concept to directly measure, it is generally accepted that more vulnerable populations experience the worst impact from disaster events. There are a number of economic, social, and demographic variables that are linked to a population's vulnerability to disasters, including characteristics such as age and income level (Spedale, 2006).

The vulnerability of the medical community to disasters must be an important consideration for all involved in health care. First, the medical community centers around one of the most vulnerable segments of the population: patients. People seek medical care for different reasons, including chronic conditions, diseases, and injuries—nearly all of which can potentially impact the patient's physical ability to confront the challenges present during a disaster. Paradoxically, while the medical facility often provides safe refuge to shield patients' exposure to disasters, the unique vulnerability of these same facilities also threatens patients, healthcare providers, and their respective families following a disaster (Shoaf et al., 2006).

The second source of vulnerability for the healthcare community reflects the dependence of the medical system on outside resources. A fully functioning hospital consumes large amounts of energy; requires daily deliveries of medicine, food, and other supplies; and depends on a highly skilled and specialized workforce (Shoaf et al., 2006). In today's world, most hospitals also depend on high bandwidth telecommunications systems for a variety of lifesaving functions. During disasters some or all of these vital outside resources are disrupted, limiting the ability of the facility to function.

Finally, when discussing the vulnerability of the medical community, it is essential to consider the effects of a disaster on the people who work in health care, both at the provider and the responder levels. Often, when medical personnel must work through a disaster, they are very preoccupied with the safety of their homes, possessions, and loved ones. It is not unusual for doctors, nurses, administrators and first-responder personnel to face a basic conflict between their professional and their personal obligations during a disaster. Clearly, the personal stresses experienced by nurses, doctors, and other personnel during times of crisis create an additional vulnerability for the delivery of healthcare to the community (Van der Vink et al., 1998).

Disasters are complex processes with complex consequences. Because of this inherent complexity, analyzing disasters is difficult. Effective disaster planning, which requires a thorough analysis of hazards and vulnerability, is even more difficult. Thorough disaster planning requires the consideration of numerous hazards and the potential impact of the threat they pose to different populations and various types of infrastructures. Additional complications can result from the high degree of uncertainty, both in predicting the occurrence of an event and in estimating the consequences of that event.

3. Disaster Types and Their Impact

Disasters occur when vulnerable people and infrastructure are exposed to some type of physical hazard. Many types of hazards exist, and each type has certain associated impacts on citizens and on the healthcare system. These hazards include floods, earthquakes, hurricanes, and associated mass-casualty incidents. In general terms, floods are the most frequent disasters and are responsible for the greatest accumulated damage. Earthquakes tend to produce the most destructive and deadly events (Federal Emergency Management Agency [FEMA], 2009).

Floods are generally described as the presence of an accumulation of water in an otherwise dry location. They are the most common type of natural disaster. During 2008, the Federal Emergency Management Agency (FEMA) responded to 52 flood-related disaster declarations, approximately one every week (FEMA, 2009). Because floods are

so common, they are also responsible for the greatest loss in total when compared to other disaster types. A variety of processes causes the accumulation of water in an otherwise dry area, leading to varying types of flood events. The four main types of flooding are 1) coastal flooding, 2) river flooding, 3) dam breaks, and 4) floods resulting from poor urban area drainage (Center for Public Health and Disasters [CPHD], 2006). Additionally, flooding conditions can vary along a wide variety of physical characteristics. Naturally, water depth is an important physical characteristic of the flood, but the rate-of-rise, the flow velocity, the height of waves, the temperature of the water, and the duration of inundation all influence the severity of the flooding disaster.

The most obvious and direct impact of floods is the inundation of communities and structures. Such inundation causes damage to structures and creates a drowning risk for those exposed to flood waters (CPHD, 2006). Persons exposed to cold-temperature flood waters also face a significant risk of developing hypothermia. In addition to inundation, floods cause structural damage when the waters are either fast moving or have significant wave action. Damaged structures then become water-borne debris, which can cause a significant number of injuries and deaths.

Although not as common as floods, several of the most severe disasters are the result of earthquakes. This fact reflects the extensive structural damage that earthquakes typically cause. Within a matter of a few seconds, an earthquake can level thousands of buildings, including hospitals. In describing the 1971 San Fernando Valley Earthquake, two nurses said, “The earth shrugged, and 1,700 hospital beds were lost in 52 seconds” (Braverman and Jenks, 1971). Earthquakes occur when tectonic energy is suddenly released, resulting in seismic waves that cause shaking and displacement on the surface. The sudden release of stored energy results in ground shaking, surface faulting, and/or ground failures. Most earthquakes result in little or no damage, but they are potentially the most dangerous of all natural hazards. Over the past few years, several earthquakes have been large enough to be felt in the western portion of the state of Tennessee, which lies within the New Madrid Seismic Zone (NMSZ).

The NMSZ is a 150-mile-long fault that runs through southeast Missouri, northeast Arkansas, and most of western Tennessee (see figure 1). Historic earthquakes in the region, such as the 1811–1812 earthquakes, are believed to have had magnitudes of approximately 8.0 or greater. Since the central United States geology is susceptible to soil liquefaction, earthquake damage is magnified over a potentially wider area. Within Tennessee, there are 2,757,823 people residing in the 37 critical counties of the NMSZ. Of these, 911,438 reside in the Memphis/Shelby county area. There are 1,846,385 other Tennessee citizens who reside in one of the other 36 critical counties. In total, there are approximately 44 million people living within the NMSZ (U.S. Census Bureau, 2008).

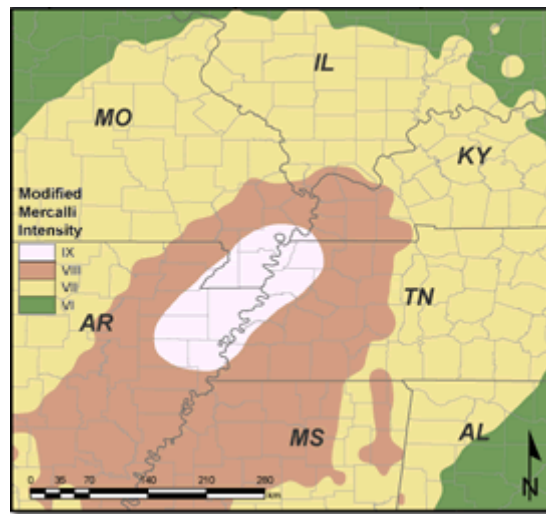


Figure 1. New Madrid Seismic Zone (from CUSEC, 2005)

In August 2005 the Central United States Earthquake Consortium (CUSEC), FEMA, and the United States Geological Survey (USGS) created an NMSZ scenario for planning purposes that encompassed the entire seismic zone. This scenario was based on the historic earthquake series of 1811–1812 that devastated the region and used a magnitude 7.7 as the base magnitude for planning. Based on the NMSZ modeling, Tennessee will sustain the following impact:

- 33,000 injured;
- 7,000 seriously injured and in need of advanced medical/surgical care;

- 3,000 deaths;
- 342,000 in shelters;
- 2.1 million without food, water, ice;
- 115, 589 structures totally destroyed;
- 88,219 structures with major damage;
- 900 damaged bridges with 330 bridge collapses;
- 404 schools collapsed and rendered unusable for shelters;
- 48 hospitals severely damaged and inoperable for at least 3 days.

By comparison, the 1994 Northridge earthquake in Southern California measured 6.7 on the seismograph (see figure 2). During the Northridge quake, there were a total of 57 earthquake-related fatalities, and 1,500 people were seriously injured. Although the time of the earthquake was significant in reducing the number of fatalities and injuries, it should be noted that the newer building stock played a significant role in this low injury and fatality rate, as many of these buildings were built with earthquake safety in mind (Southern California Earthquake Data Center [SCEDC], 2010). Unlike California, most of the building stock in the NMSZ of Tennessee was built without mitigating the impacts of a catastrophic earthquake (CUSEC, 2005).



Figure 2. Damage Area of the 1994 Northridge Earthquake in Comparison to the 1895 New Madrid Earthquake (from CUSEC, 2005)

4. Disasters' Effect on Health Care

Regardless of the type of disaster, the impact felt by the healthcare community can be summarized in four basic areas: 1) physical destruction of facilities, 2) loss of crucial facilities, 3) surge of injured needing medical care, and 4) loss of personnel. Floods and earthquakes are capable of causing considerable damage to healthcare facilities (Arendt and Hess, 2008). Floods can inundate lower levels, destroying any equipment, including data and supply centers that may be located on flooded lower-level floors. Earthquakes can cause sections of buildings or even the entire building to collapse.

When facilities and equipment sustain damage, the capacities and capabilities of the healthcare system become completely compromised. Certain procedures that require specialized equipment are not possible if that equipment is rendered inoperable. Making the situation even worse, damaged facilities sometimes must be totally evacuated. In rare occasions, the destruction of a facility has meant that medical care must be delivered in temporary (mobile) applications set up in parking lots or any available building of opportunity (ACEP, 2006). In addition to the destruction of buildings and equipment, the capabilities of the healthcare community are further limited when crucial utilities, such as electricity, water and sewage, supply deliveries, and telecommunications, are knocked offline due to the disaster. One very common issue with all disasters is the loss of electric power. Most hospitals have backup generators; however, generators only work if they survive the disaster without any major damage and if they have fuel. Once fuel stored at the facility is used, it must be obtained from outside sources, a very complicated task when roads are impassable by floodwaters or collapsed buildings. Delivery of other supplies, both basic and crucial lifesaving medicine and equipment, can also be difficult or impossible when the disaster has caused all roads to be impassable. Finally, no modern healthcare facility operates without broadband data systems for communications and the transference of data. Losing data systems during disasters cuts off access to electronic medical records, diagnostic systems, and staff. This situation ultimately leads to reduced patient care (Mann, 2005).

At the same time that disasters reduce the capacities and capabilities of the healthcare system, they also create a surge in demand for medical care. Every disaster causes a surge in patients with a variety of injuries. Many of the injured require treatment for injuries sustained by the disaster itself, while others seek treatment for chronic medical conditions that can be exacerbated due to the disaster. When a disaster forces a hospital to close and evacuate, those patients are typically taken to nearby facilities. Even though the nearby facilities may have escaped the worst of the disaster and may even have experienced no damage, they usually suffer from reduced capabilities alongside a surge of admissions. This surge, both in regular and emergency admissions, results in serious shortages in personnel and supplies. This situation leads to the implementation of altered standards of care (IOM, 2006).

The shortage of available personnel due to a disaster is another very important consideration for the healthcare community. For many healthcare professionals, these times of crisis create conflicting obligations. The need to take care of personal responsibilities oftentimes outweighs the obligation to perform professional duties after a disaster. Even when staff are willing to work, sometimes they are unable to work. Personal vehicles may have been destroyed and roads may be impassable. Other times, medical staff might find themselves in a situation where they deliver medical care to disaster victims at the scene. Although the community benefits when doctors and nurses are able assist in the treatment of the injured at the disaster site, this still leaves the hospital short of staff (ACEP, 2006).

5. Potential Disasters in the United States

Emergencies are an everyday occurrence within the United States. Few communities escape the impact of regularly occurring, low-level emergencies. Communities are likely to experience significant destruction from weather, earthquakes, or other possible disasters at some point. The impact of these disasters greatly varies as both a reflection of the hazard and the vulnerabilities of the population being affected. During times of disasters, hospitals and medical professionals must be prepared for a leadership role in preparedness and response efforts. Preparedness begins with the

recognition of what could happen in a major disaster. This section describes some of the major disasters that empirical evidence suggests will eventually happen in the United States (Hazard and Vulnerability Research Institute, [HVRI], 2008).

1. *New Madrid earthquake:* As previously discussed, a NMSZ event would cause damage to several states in four FEMA regions and would cause an estimated \$70 billion in damages (National Academy of Sciences, 1992, p. 159).
2. *Hurricane hits Miami/Herbert Hoover Dam breaks:* This situation presents two disaster scenarios for southern Florida. The first includes a break in the Herbert Hoover Dike around Lake Okeechobee, which would flood 45,000 people. The second scenario involves a hurricane directly hitting Miami. This event would impact 7 million people.
3. *California earthquake:* According to the USGS, within the next 30 years there is a 99% chance of a magnitude 6.7 earthquake around the San Andreas Fault and a 46% chance of a magnitude 7.5 or greater. Earthquakes of this magnitude would cause approximately 1,800 fatalities, 50,000 injured people seeking medical care, and 1,600 building fires. Total damage could exceed \$200 billion.
4. *Sacramento Flood:* Extreme rainfall in the Sacramento Valley would cause high water levels in the Sacramento River. If multiple levees are breached, most of the metropolitan Sacramento area would be under 5 to 15 feet of water.
5. *Mississippi River flood:* The Mississippi River floodplain stretches from southern Illinois through parts of Kentucky, Tennessee, Arkansas, Mississippi, and Louisiana and includes several major cities. A disastrous flood in this region would impact millions of people and displace thousands. Additionally the region would have to deal with injured people, as well as the disruption of medical services.

6. *Hurricane hits Houston/Galveston:* If the eye of a hurricane passes over Galveston Island and moves inland toward Houston, a 20-foot surge of water would be pushed over Galveston and toward downtown Houston. Flooding would be widespread and disastrous. Medical services in the sixth largest U.S. metropolitan area would be devastated.
7. *Hurricane hits New York City:* A major hurricane could push a storm surge up New York Bay into the Hudson River and even into the Long Island Sound. All five boroughs that make up New York City would be impacted by flooding, with Brooklyn and Queens being hit hardest. Much of south Manhattan would be under water.
8. *East Coast tsunami:* Experts fear a massive landslide on the Canary Islands could send a huge tsunami across the Atlantic Ocean, striking numerous U.S. cities along the east coast. Cities from Boston to Miami would suffer destructive and deadly flooding.
9. *National heat wave and blackout:* A widespread and sustained heat wave could cause enormous strains on vulnerable populations and the nation's vulnerable electric grid. Numerous patients would seek medical care for heat-related illness, but many hospitals that lack sufficient backup power would close and those that remained open would fill beyond capacity.
10. *Extreme winter and heating fuel shortage:* A particularly deadly disaster could result in a major supply disruption occurring during an extended period of widespread frigid weather.

B. RESEARCH QUESTIONS

Does existing altered-standards-of-care guidance at the federal, state and local government levels define the appropriate altered standards of care in order to optimize patient outcomes?

1. Supporting Questions

Triggers: What criteria, if any, do local, state, and federal guidelines have for shifting from normal standards of care, in which resources are used to optimize individual outcomes, to altered standards of care, in which resources are used to optimize population outcomes?

Minimum care: How are altered standards of care specified in the guidelines?

Immunity: How do existing guidelines suggest laws intended to provide legal immunity from negligence, constitutional claims, and criminal prosecution?

C. TENTATIVE SOLUTIONS

A large-scale disaster or terrorist attack on the United States utilizing a weapon of mass destruction (WMD) device could result in mass casualties and a surge in demand for nations with an already stressed healthcare system. During a disaster or WMD mass casualty event, medical priorities shift from focusing on individual patient-based outcomes to population-based outcomes (PricewaterhouseCoopers' Health Research Institute, 2007). Healthcare providers would have to triage victims in order to apportion limited equipment, supplies, personnel, and medication in a manner that saves the greatest number of lives (Burkle, 2006). Existing standards of care may need to be altered to respond to the imbalance between demands for healthcare and existing healthcare resources (Disaster Triage Systems for Large-Scale Catastrophic Events, 2008, p. 36). In addition, the scope of practice standards for physicians, nurses, and other healthcare professionals may need to be changed to allow them to provide care outside of their clinical specialty areas. Clinical decisions that involve altered standards of care will also present unique ethical challenges that may not be covered by state and federal liability laws.

It is evident that federal, state, and local guidance documents fail to address triggers, guaranteed minimums of care, and legal immunity issues due to the newness of this field of study. Because of this lack of guidance, the following recommendations are suggested:

Triggers: There should be clearly defined triggers that indicate the shift from normal standards of care, in which resources are used to optimize individual outcomes, to altered standards of care, in which resources are used to optimize population outcomes. Triggers may be defined by the size (surge volume) and scope (geographic) of the WMD/disaster event.

Guaranteed minimum care: There should be guaranteed medical interventions in the guidance regardless of surge volume and scope. This means that physicians, nurses, and other medial first-responders will not initiate such emergency procedures as mouth-to-mouth resuscitation, external chest compression, electric shock, insertion of a tube to open the patient's airway, injection of medication into the heart or open chest heart massage; however, it would guarantee the following minimum medical interventions:

- Oxygen administration by means other than intubation;
- Bleeding control;
- Establishment of peripheral intravenous therapy lines for fluid administration;
- Stabilization of fractures;
- Pain management.

Immunity: Patients may file lawsuits for monetary damages or other redress for injuries they believe they have suffered as a result of inadequate medical care received during disaster situations. The guidelines must suggest laws intended to provide legal immunity from liability for the payment of a judgment based on acts or omissions in providing services or immunity from being named as defendant in an action based on alleged acts or omissions, unless the conduct in question rises to the level of willful and wanton misconduct, or grossly negligent, reckless, or criminal conduct.

D. SIGNIFICANCE OF RESEARCH

The primary beneficiaries of this research are federal, state, and local disaster and WMD mass-casualty-response decision makers. As stated previously, there is little guidance available in the literature regarding the inclusion of triggers, guaranteed minimums of care, and legal immunity in the existing federal and state altered-standards-of-care planning guidance documents.

This research will also support existing literature dealing with altered standards of care by giving additional planning guidance to healthcare planners in order to provide them with a level of comfort and certainty that their planning decisions are underpinned by competent and comprehensive research on the topic of altered standards of care. Consequently, the resulting plans they develop will allay the anxiety of those healthcare providers who are ultimately responsible for providing care in extreme disaster conditions.

Further, this research will benefit homeland security practitioners and policy makers by exposing the vulnerabilities of existing altered-standards-of-care guidance documents and laws. Accordingly, the findings of this research will provide homeland security policy makers with the needed guidance to optimize patient outcomes in mass-casualty events. It is expected that the findings of this research may reveal additional research opportunities that should be pursued to further improve altered-standards-of-care planning guidance that responds to the imbalance between demands for healthcare and existing healthcare resources in a manner that saves the largest number of lives.

E. OVERVIEW OF THESIS CHAPTERS

This thesis consists of five chapters. Chapter I (Introduction) introduces the concept of altered standards of care and explains why guidance documents at the federal, state, and local levels are inadequate. Attention is focused on examples of the challenges that confront the healthcare community during disasters.

Chapter II (Literature Review) explores the literature surrounding altered standards of care from multiple federal, state, regulatory, and academic sources.

Chapter III (Methodology) provides background on the process, selection, and application of the analytical tool used and assesses federal, state, and local altered-standards-of-care plans against the analysis matrix.

Chapter IV (Analysis of Federal, State, Local, and International Altered-Standards-of-Care Planning Guidance Documents) encompasses an analysis of the information collected pursuant to answering the secondary and primary research questions. The goal of this chapter is to evaluate, compare, and contrast the various guidance documents that exist at the federal, state, and local levels.

Chapter V (Findings/Recommendations and Policy Implications) provides a summary of the findings of altered-standards-of-care information identified in previous chapters. Conclusions are presented and recommendations made to develop the inclusion of triggers, guaranteed minimums of care, and legal immunity into existing federal, state, and local altered-standards-of-care planning guidance documents.

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II. LITERATURE REVIEW

The literature is replete with recent sources regarding altered standards of care that would be most relevant during a pandemic influenza, bioterrorist attack, or natural disaster in which healthcare providers would have to triage victims in order to apportion limited equipment, supplies, personnel, and medication in a manner that saves the greatest number of lives. The categories of literature are 1) federal government documents including those at the policy level, as well as studies and reports; 2) foreign government policy-level documents; 3) state government documents at the policy level, including legal standards addressing liability and emergency declarations; 4) regulatory standards for both healthcare facilities and health professionals; and 5) scholarly reports and studies regarding the impact of implementing altered standards of care during disasters and their application to all people.

Overall, the literature indicates that in the healthcare industry, the term “standard of care,” as standards accepted by the healthcare profession, refers those standards that identify medical practice that is appropriate and acceptable. The literature reveals that these standards are typically developed by professional organizations, accrediting bodies, and government agencies at the federal and state level. Each source displays an intention that the development efforts associated with standards of care are intended to elucidate, create, and codify standards in an organized and accessible manner. Additionally, it is interesting to note the consistency in literature as to what serves as the core principle of altered standards of care—that being the principle that everyone is entitled to receive baseline medical care regardless of the disaster or emergency.

A. FEDERAL GOVERNMENT DOCUMENTS

The practice of receiving medical care from a healthcare professional is founded in a combination of generally accepted standards of professional practice (American Nurses Association [ANA], 2001b). These standards include standards of care, codes of ethics, legal regulation, institutional and personal values, and professional core competencies, as well as specific situational contexts (ANA, 2001a). Generally accepted

standards of care change when there is an extreme emergency, even before there is an official emergency declaration by a hospital or government authority. Such a change in context should not affect basic medical care standards, codes of ethics, professional core competences, or professional values. Although the National Incident Management System (NIMS) and the National Response Framework (NRF) are somewhat helpful, they are not designed specifically to guide physicians, nurses, paramedics, or other licensed healthcare professionals working in extremely challenging situations in which the expectation is to deliver safe, legal, ethical, efficient, and compassionate medical care.

The issue of addressing altered standards of care for use in emergency or disaster situations arose in 2004, when the Agency for Healthcare Research and Quality (AHRQ) and the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS) convened experts to discuss the issues directly. Their work led to a 2005 report, “Altered Standards of Care in Mass Casualty Events,” as a useful guide for developing protocols for an altered standard of care. A subsequent report, “Mass Medical Care with Scarce Resources: A Community Planning Guide,” (2007) outlines a proposed framework for planning efforts.

Since the release of the AHRQ reports, several federal documents have been published to assist states and the local healthcare community in developing altered-standard-of-care protocols for the allocation of scarce resources and for standards of care. Nevertheless, a recent report on state preparedness by the U.S. Government Accountability Office (GAO) and a review of HHS’s Hospital Preparedness Program by the Center for Biosecurity of UPMC concluded that, among the key comments of medical surge planning, standards of care during a mass casualty event remained in need of significant additional attention and planning. Areas of particular concern were the need for states to develop procedures and protocols for implementing altered standards of care in disaster and declared emergency situations. The literature affiliated with the federal government was found to be the most useful sources. The objective information provided by these sources is valuable in that it outlines many specific planning efforts that must take place in order to implement altered standards of care. These sources point to the

development of medical protocols and the allocation of scarce medical resources. Additionally, they emphasize a national interest in developing such processes by which altered standards of care can be implemented in order to ensure a positive outcome for those injured by and for those responding to a pandemic influenza, bioterrorist attack, or natural disaster.

B. FOREIGN GOVERNMENT DOCUMENTS

The threat of a catastrophic mass-casualty incident resulting in tens of thousands of victims related to a public health event, such as an influenza pandemic, or a terrorist event, such as the detonation of an improvised nuclear device, is internationally accepted (Hawryluck, Lapinsky, and Stewart, 2005, p. 384). It is also internationally accepted that most countries do not necessarily have sufficient healthcare staff, equipment, and physical space to provide urgent care to those critically injured by such dire events (IOM, 2006).

From the perspective of the United Kingdom's healthcare system, while much progress has been made in preparedness for medical disasters, the system is ill-prepared for catastrophic mass-casualty events. As a result of this significant shortfall, public health authorities in the United Kingdom have developed a planning guidance document to assist their country's healthcare infrastructure to plan for and respond to catastrophic mass-casualty events caused by a natural or manmade disaster.

The United Kingdom plan, "Mass Casualty Incidents: A Framework for Planning," provides a set of principles to guide National Health Service (NHS) organizations in England, Scotland, Wales, Northern Ireland, and the Republic of Ireland in planning for incidents that produce mass casualties. This document is supporting material to the NHS Emergency Planning Guidance (EPG) 2005, and NHS encourages planners to use this document in conjunction with that EPG guidance. This current document consolidates various aspects of planning guidance initially issued immediately after September 2001. As part of wider cross-government work on resilience planning, this document was written to strengthen planning and ensure greater resilience to a wider range and larger scale of disruptive mass-casualty incidents.

The international literature was extremely useful in demonstrating that events resulting in mass casualties occur on a frequent basis worldwide (International Disaster Database, 2010). Luckily, the overwhelming majority of these events do not produce extremely large numbers of victims who are critically injured. Sources indicate that, like the United States, international planning efforts for mass critical care have been motivated by recent natural disasters, terrorist attacks, the severe acute respiratory syndrome (SARS) epidemic of 2002–2003 (Christain et al., 2004, p. 1420), and the continued threat of a serious pandemic influenza. While the most recent H1N1 influenza pandemic was found to be relatively less dangerous and fatal compared to other pandemics, it is important to understand that during the twentieth century alone there have been three recognized influenza pandemics—in 1918, 1957, and 1968—each causing an estimated 50 million deaths worldwide (Health Protection Agency, 2010).

C. STATE GOVERNMENT DOCUMENTS

A majority of states have not adopted any form of altered-standard of care policy guidance for their healthcare communities. The few that have—California, Colorado, Massachusetts, Minnesota, New Jersey, and New York—only address altered standards of care for a pandemic event, not a large-scale natural disaster or emergency WMD situation. Those states that did address the altered-standard-of-care issues followed either the national standard of care or the locality rule, which tends to focus on local history to determine the appropriate level of medical care that will be provided. The locality rule, developed over one hundred years ago, was intended to protect small-town and rural physicians, who were assumed to be less educated and equipped than physicians in large cities. The standard of care under the locality rule measures the conduct of a physician against that of other physicians in the same field operating within the same community. Thus, it gauges medical care by the degree of care, skill, and proficiency commonly exercised by ordinarily careful, skillful, and prudent physicians at the same time the treatment was provided and in similar localities (Lewis, Gohagan, and Merenstein, 2007).

The states that follow the national standard of care base their policy standards on whether a physician has exercised the “care and skill expected of a reasonably competent physician in [that] specialty in the same or similar circumstances” (Rosenbaum, 2003, p. 1546). Interestingly, states that use the national standard still consider locality as a factor when considering whether a physician acted reasonably under the given circumstances. Twenty-nine states, including the District of Columbia, have adopted the national standard of care, and 21 states follow the locality rule (Kinney et al., 2008).

Sources affiliated with state government conflict with federal government sources in that the former tend to focus only on altered standards for a pandemic influenza event. Instead of focusing on expanding the use of altered standards of care for any disaster or emergency situation, these sources look critically and holistically at pandemic influenza policy and its effect on patients and healthcare providers.

D. REGULARITY STANDARDS

The healthcare industry is probably the most regulated industry in the United States. Countless numbers of federal, state, and industry-driven regulatory bureaucracies govern both healthcare professionals and facilities in an effort to achieve a variety of regulatory objectives. These regulatory objectives involve licensure, accreditation, and legal issues (Joint Commission, 2009).

A review of the federal Medicare program and joint federal-state Medicaid programs indicates a host of statutory and regulatory rules governing the delivery of health care and designed to ensure that citizens receive the highest quality health care available (Kinney, 2006, p. 559). These standards focus on the conduct of the providers, especially during very extraordinary situations where such standards can be waived by the Centers for Medicare and Medicaid Services (CMS). CMS is the agency within the Department of Health and Human Services (DHHS) that oversees Medicare and Medicaid. CMS has the sole authority to waive point liability for hospital emergency rooms under the Emergency Medical Treatment and Labor Act (EMTALA). This was found to be a significant issue since, even if a state issues a disaster declaration, without the CMS waiver, hospitals are not allowed to transfer patients to other facilities for

assessment if the original facility is located in an area where a public health emergency had been declared. CMS can also waive certain requirements of the Health Insurance Portability and Accountability Act (HIPAA) so that providers can talk to family members about a patient's condition when the patient is unable to grant that permission to the provider.

The literature supports the fact that during disasters and emergencies there is broad disparity among international, federal, state, and healthcare industry regulatory issues that are intended to enable both healthcare professionals and facilities to respond optimally to an event necessitating altered standards of care. As an example, all governors have special legal authority to declare a disaster and to suspend any laws, rules, and regulations they deem necessary to respond to the event; however, those special powers do not allow governors to suspend EMTALA or HIPAA regulations (Hoffman, Goodman, and Stier, 2008). That disparity is a significant flaw, and considering that both healthcare professionals and facilities have a vested interest in the outcome of altered standards of care, neither can be regarded as entirely objective.

E. SCHOLARLY REPORTS AND STUDIES

Although there is scholarly literature documenting the outcome of proposed altered standards of care and other scientific implications of such emergency situations, serious efforts to identify and characterize related altered standards of care were rare before the terrorist events of September 11, 2001. The gap in literature points to an uncertainty surrounding the potential risks for healthcare providers likely to become involved in a response to a pandemic influenza and other emergencies, including government employees, private-sector healthcare providers, and volunteers who may not choose to alter the standard of care they are providing their patients while others responding to the incident alter medical care for their patients (GAO, 2008). That risk can be summarized by the fear of legal action against those who would work under such disaster situations. Their fear is given credence in the face of the charges filed against nurses and Dr. Anna Maria Pou for failure to care and inappropriate use of medication in New Orleans following the flooding associated with hurricanes Katrina and Rita. Pou and

two nurses were arrested in July 2006 and accused of administering lethal doses of medications to four older adult patients, thereby intentionally killing them. Dr. Pou has asserted that the medications were given only to relieve pain and distress. The attorney general in Louisiana did not pursue charges against the nurses in exchange for their cooperation, and the grand jury ultimately did not indict Dr. Pou. However, three civil suits, filed by the deceased patients' relatives, are pending against Pou (Okie, 2008, p. 358). With such reports in the literature, the need to study the various sweeping generalizations about altered standards of care is great.

F. CONCLUSION

This section has reviewed the available literature as to the importance of being able to adapt and provide medical care under extreme disaster and emergency situations. A disaster event with mass casualties is a profound life-impacting event that can lead to devastating consequences. Under optimum conditions, however, the implementation of altered standards of care can greatly increase the quality of life of individuals injured by such an event. The consensus development process and quantitative methodology process described in the present literature is useful for planning. The concept of altered standards of care was not introduced until recently, and there is still much to be learned. The benefits are not yet completely known, but those benefits that have been documented cannot be ignored. Additionally, the paucity of literature supports the importance of continued research in this area, especially in the development of triggers, guaranteed minimums of care, and liability protection for healthcare providers.

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III. METHODOLOGY

A. METHODOLOGY

The methodology for this thesis will be a policy analysis examining altered-standard-of-care planning documents of the U. S. government, the United Kingdom, and nine U.S. states and local governments. The analysis will develop a policy recommendation for the inclusion of triggers, guaranteed minimums of care, and legal immunity into existing federal, state, and local altered-standard-of-care planning guidance documents.

The three components selected for analysis are strategically focused. Triggers are those specific conditions that when present give the responding agencies the best possible indication that an altered standard of care is warranted. A trigger can, for example, be likened to the presence, frequency, and intensity of particular signs and symptoms that indicate myocardial infarction and thus a specific protocol. In the conditions of a disaster mass-casualty event, certain triggers would indicate a change in approach or a different guaranteed level of care and thus a shift in legal ramifications for the medical care provided.

The guaranteed level of care is a critical component because of the phenomenal developments in medical science and care throughout the world. The citizens of the United States have come to expect and demand a certain level of care in all situations. We have seen these issues emerge in recent years. An example is the care and evacuation (or not) of patients and citizens in the wake of Hurricane Katrina in 2005.

In the event of the implementation of altered standards of care, the legal ramifications must be addressed, or the policies will break down at the caregiver level when malpractice risk is at its height. The analysis will consider what immunity is indicated and whether it is significant enough to provide protection from legal battles and extensive proofs in individual cases.

In formulating this policy recommendation, consideration will be given to ethical values that should be used to develop altered-standard-of-care policies that are recommended to guide and support decision making during both preparation and response at the federal and state levels.

B. SAMPLE

All research questions will be answered by conducting a policy analysis using the following steps:

1. Compile available policy planning documents;
2. Identify information gaps;
3. Perform an analysis of all information gathered;
4. Develop answers for secondary questions; and
5. Develop findings for the primary question.

Once answers to the secondary questions have been developed, an analysis of the answers will be performed to develop a solution to the primary research question. This solution will be evaluated for viability based on feasibility and impact on mass-casualty patient care.

C. DATA COLLECTION AND ANALYSIS

Steps 1 and 2 of this methodology have been addressed in the literature review. As discussed previously, the literature provides sufficient information on *existing* federal altered-standard-of-care documents, including those at the policy level, as well as studies and reports of state and local government documents at the policy level and legal standards addressing liability and emergency declarations. The review examined regulatory standards for healthcare facilities and health professionals, scholarly reports, and studies regarding the impact of implementing altered standards of care during disasters and their application to all people.

Step 3 will encompass an analysis of the plans collected from the U.S. government, the United Kingdom, and the following nine U.S. states and local governments in the attempt to answer the secondary and primary research questions. The

selection of these particular nine states within the United States is based on their use of the most developed policies for altered standards of care in disaster situations. The following nine states or locations were considered:

1. Tennessee;
2. Philadelphia, Pennsylvania;
3. Tacoma/Pierce County, Washington;
4. California;
5. Colorado;
6. New York;
7. Indiana;
8. Connecticut;
9. Virginia.

The goal of the analysis is to evaluate, compare, and contrast the various federal, international, and state guidance documents. The analysis will focus on the variables of triggers, guaranteed levels of care, and legal immunity. For example, in reviewing the plans, is there a clear articulation of what triggers the implementation of an alternate standard of care? How do these triggers compare to other equally developed state or federal guidelines? Is legal immunity specified to the degree that healthcare providers can act confidently, and if not, what are the gaps that must be addressed to improve the overall implementation of altered standards of care? Research obtained from this step will contribute to improved federal and state altered-standard-of-care policies that can serve as the bedrock for public policy.

Table 1. Components and Review Elements

COMPONENT	REVIEW ELEMENT
Triggers <i>A clear identifiable sign for care providers to see and know as “trigger”</i>	- Patient Volume Indicators - Land area involved (such as > 5 mile radius) - Availability of resources (time to scene; access to scene; technological resources) - Risk level for further damage (life, land, resource) - Evacuation access (location, distance, transportation, housing, etc.) - Length of “disaster mode” (hours, days, weeks +)
Guaranteed Level of Care <i>A standard of higher than palliative care</i>	- Comfort - Sustaining of life - Transportation out of danger for existing patients - Age limits/thresholds - Availability and distribution of scarce medical resources (oxygen, pain control medications, surgical accessories, etc.)
Legal Immunity <i>To offer protection, integrity, and excellence in the direst of conditions</i>	- Articulation of change in standards of care from normal medical practice - Articulation of the conditions in which lawsuits or actions against responders will be accepted in disaster conditions - Any established case law at the Supreme Court level

The goal of step 4 is to finalize the answers to the secondary questions. This information is vital to developing a solution(s) to the primary research question.

During step 4, the altered-standard-of-care information identified in step 3 will be further analyzed to develop a recommendation for the inclusion of triggers, guaranteed minimums of care, and legal immunity into existing federal, state, and local altered-standard-of-care planning guidance documents.

IV. ANALYSIS OF FEDERAL, STATE, LOCAL, AND INTERNATIONAL ALTERED-STANDARDS-OF-CARE PLANNING GUIDANCE DOCUMENTS

A. ANALYSIS

1. The United States: Mass Medical Care with Scarce Resources: A Community Planning Guide

a. Guiding Principle

The intent of the federal document is to provide healthcare planners at the hospital, community, state, and federal levels with credible information that will assist in planning for and responding to a potential mass-casualty incident. Developed by the Agency for Healthcare Research and Quality (AHRQ), the document is an updated version of an earlier plan that outlined the issues and principles associated with providing medical care in the face of an overwhelming number of casualties. The new document is the result of a collaborative effort between the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (DHHS) and AHRQ. The updated plan, which is 181 pages long, explores the relevant issues and challenges and makes recommendations associated with preparing for and responding to a mass-casualty incident affecting the entire healthcare spectrum.

The federal document leads off with a discussion of ethical and legal considerations and then outlines the issues linked to mass-casualty incident planning in three healthcare settings: prehospital, hospital, and alternative care sites. The document then discusses palliative care issues, which it stresses must be integrated throughout the entire planning and response process. The document concludes with a case study of an influenza pandemic. Key findings that emerge from examining the U.S. plan are summarized below.

The federal document outlines five principles that should be used to develop mass-casualty incident response plans. The first principle is to keep the healthcare system functioning and to deliver an acceptable quality of care in order to preserve as many lives as possible. The second principle emphasizes the need for plans to be comprehensive, community based, and coordinated. The third principle calls for an adequate legal framework for providing health and medical care during a mass-casualty incident. Principle four states that the rights of individuals must be protected to the extent possible and reasonable under the circumstances, and the last principle provides for clear communication with the public before, during, and after a mass-casualty incident.

Additionally, ethical considerations are included, emphasizing the importance that healthcare planners understand that, once a mass-causality incident occurs, immensely difficult healthcare decisions will have to be made. In order for those decisions to be ethically sound, the plan introduces major substantive and competing ethical theories relevant to planning efforts. The plan reviews these theories in the broadest terms and outlines more specific issues that each theory raises. By doing this, the document suggests that planning should follow a set of norms that are transparent, accountable, and capable of community outreach. This ensures that citizens are educated and prepared to accept the implementation of such plans when a mass-casualty incident occurs. Additionally, the document suggests that the planning process be grounded by the ethical principles of focusing on consequences, duties, obligations, rights, and the fairness aspect of community norms.

Legal Issues are a component of the document, which informs healthcare planners about the common legal issues that should be addressed in their plans; it is not intended to give specific legal advice for any jurisdiction. Planners should understand that laws at all government levels are an important element of emergency responses and healthcare decisions involving scarce resources during a mass-casualty incident. Legal issues that should be taken into consideration include understanding the changing legal landscape during emergencies, the balance of individual and community interests, the

suspension of existing legal requirements, interjurisdictional legal coordination issues, medical licensure reciprocity, liability and other protections for healthcare workers and volunteers, property management and control, and legal triage.

b. The Response Component

During a mass-casualty incident, prehospital care provided by emergency medical services (EMS) plays a vital role. EMS services rescue victims, assess injuries, provide medical care, and transport victims to appropriate medical facilities. This section of the document discusses how EMS systems operate and details recommendations to address the challenges associated with the planning and coordination of EMS due to the systems' fragmented nature of training, guidelines, and response capacity.

Some of the most difficult decisions associated with any mass-casualty incident are made at hospitals regarding acute care and altered standards of care. The overarching goal of any hospital during a mass-casualty incident response is to maximize care across the greatest number of people, while meeting at least minimal obligations for care to all who are in need. In the event of a mass-casualty incident, hospitals have to grapple with issues associated with surge capacity, supplies, limited staff, coordination, incompatibilities in communications systems, and the need for security. To address these issues, this section provides recommendations for hospitals to plan for allocating scarce resources during a mass-casualty incident. The section provides planners with ideas to develop integrated and coordinated response systems to provide the best medical care for all victims.

When hospitals are completely overwhelmed due to a mass-casualty event, planners should consider the establishment of alternate care sites. Alternate care sites are typically housed in tents or mobile units and are intended to provide the medical care that normally would be provided in an inpatient facility (hospital). Advance planning is critical to the establishment and operation of these sites; this planning must be coordinated with existing healthcare facilities as well as home-care entities. Planners must delineate the specific medical functions and treatment objectives of the site. The

principle of managing patients under relatively austere conditions—with only limited supplies, equipment, and access to pharmaceuticals, and with a minimal staffing arrangement—is the starting point for planning.

The federal document addresses the issue of how to provide optimal support with the least resources for dying victims of a mass-casualty incident. It is widely assumed that some victims may survive the initial part of the disaster but will have sustained such serious illness or injury that they will not survive for any length of time. Additionally, there will be vulnerable individuals (e.g., the elderly, those sick in hospitals and nursing homes, the disabled, children) who may be negatively impacted by the resulting scarcity of resources. In some instances, decisions will need to be made to withdraw resources from those not likely to survive and to divert those resources to others. When that happens, palliative care is utilized to aggressively manage symptoms, relieve suffering, and provide comfort to those whose lives will be lost as a result of the mass-casualty incident. These issues need to be carefully planned for, and this section offers guidance on how to address palliative care in the areas of decision making, supplies, resources, training, personnel, and patient education and communication.

c. Secondary Questions

Table 2. The Federal Document: Components and Review Elements

COMPONENT	REVIEW ELEMENT
Triggers	United States guidance does not include triggers.
Guaranteed Level of Care	No guaranteed level of care is suggested other than palliative care.
Legal Immunity	The federal document only points out what legal action could happen but fails to suggest federal or state legislative action to limit legal exposure to healthcare providers.
Does existing altered-standard-of-care guidance define the required appropriate altered standards of care in order to optimize patient outcomes?	The federal guidance document does not, as it leaves those decisions to individual physicians and administrators of healthcare facilities.

2. The United Kingdom: Mass-Casualty Incidents: A Framework for Planning

a. Guiding Principle

The U.K. document provides a set of principles to guide National Health Service (NHS) organizations in England, Scotland, Wales, Northern Ireland, and the Republic of Ireland in planning for incidents that produce mass casualties. This document is supporting material to the NHS Emergency Planning Guidance (EPG) 2005, and NHS encourages planners to use this document in conjunction with that EPG guidance. This current document consolidates various planning guidance initially issued immediately after September 2001. As part of wider cross-government work on resilience planning, this document was written to strengthen planning and to ensure greater resilience to a wider range and larger scale of disruptive mass-casualty incidents.

The U.K. planning document, which is 35 pages long, begins with an explanation of the framework used to develop the document. The crux of the guidance is that it is built on best practices and shared knowledge from all NHS programs. Throughout the plan, NHS stresses that communication among all components of the U.K.'s healthcare delivery systems should remain appropriate in order to ensure that response efforts across the healthcare spectrum are structured and cohesive. Key findings that emerge from examining the U.K. plan are summarized below.

b. Response Component

Considering the varying and complex nature of any mass-casualty incident, the U.K. document provides NHS organizations with a framework to reference while writing their mass-casualty incident response plans. The framework assists planners in defining the size of a mass-casualty incident as a means to begin their planning process (see below). By encouraging planners to base planning assumptions on the scale provided in the framework, the NHS attempts to ensure that planners fully understand the potential scale and nature of disruption that their organization will need to address once a mass-casualty incident begins.

Table 3. NHS Mass Casualties Levels

NHS Level	Description	No of Casualties	Local NHS Response	Regional Response	National Response
Major	Individual trusts handle incident within current and long established major incident plans	10's	Local NHS organisations activate local command & control arrangements. Participate in local multi-agency command arrangements	SHA advised for information only	DH Emergency Preparedness Division (DH EPD) informed
Mass	Larger scale incident with possibility of involving the closure or evacuation of major health facility or persistent disruption over many days. Collective mutual aid response required from neighbouring trusts.	100's	Local NHS organisations activate local command & control arrangements. Participate in local multi-agency command arrangements, SHA advised. All trusts link in to SHA Strategic Command arrangements. SHA co-ordinates mutual aid across the region.	SHA command & control activated to co-ordinate the health care system across the region. DH Emergency Preparedness Division notified. Consider the implementation of revised clinical treatment protocols	DH EPD available to support SHA as required. Facilitate requests for national mutual aid support. Participate in the cross-government response. Brief ministers
Catastrophic	An incident that is of such proportions that it severely disrupts health & social care and other support functions (for example, water supply, electricity supply, transport etc). The required response exceeds collective local capacity	1000's	Local trust plans activated. SHA advised. All trusts link in to SHA strategic Command arrangements. SHA co-ordinates mutual aid across the region	Potential for more than one SHA region to be directly affected by the incident. Each SHA activates their Strategic Command Arrangements. SHA contributes to Regional Civil Contingencies Committee DH EPD notified	DH EPD national Major Incident Coordination Centre activated. National coordination of NHS strategic response and mobilisation of national mutual aid efforts Participate in cross-government response including Devolved Administrations.

Every day, the NHS manages the care and wellbeing of many people. Decisions about the clinical care of patients in the U.K. is made by multidisciplinary teams of specialists, providing in-depth and complex care within established clinical protocols and guidance. However, during an event that causes mass casualties, the U.K. document demonstrates steps to planners to expand the capacity of certain types of specialties based upon the type of incident, e.g., burn trauma victims, pediatrics, etc. Under these horrible circumstances, the need to temporarily realign treatment protocols for patient care must be made. While the U.K. plan states that this decision must ultimately be made by physicians at the time of the incident. taking into account the circumstances, the ultimate aim at that point is to plan for providing the best care possible under the circumstances within the healthcare capacity available.

Figure 3 illustrates planning assumptions that NHS expects planners to use when calculating the potential number of patients in each category listed.

Category	<i>Patient condition</i>	<i>% of total</i>
<i>P1</i>	Casualties needing immediate life-saving resuscitation and/or surgery	25%
<i>P2</i>	Stabilised casualties needing early surgery but delay is acceptable	25%
<i>P3</i>	Casualties requiring treatment but a longer delay is acceptable	50%

Figure 3. NHS Planning Assumptions

The component of the plan related to managing clinical care gives consideration to the fact that incidents can occur beyond those for which hospital buildings are designed to cope and that this, combined with potential staff constraints, would have an impact on the way in which patient care could, and would, be delivered. This section further illustrates how planners can develop integrated plans to set up and provide facilities—away from acute hospital sites—to assist in the triage, diagnosis, treatment, and support of mass-casualty victims who are not seriously ill or injured. This section outlines three components that should be included in any mass-casualty incident plan. The first component calls for the development of contingencies to avoid the need to move patients from one community to another and to avoid referrals to acute hospitals as far as possible. The second includes the suggestions to develop plans to deploy healthcare providers to supplement acute services and lastly to provide clinical indemnity and support for colleagues who may be working in a different environment from their normal place of work. The overall aim of this entire section is a systems approach to admit to hospitals those most seriously ill or injured by the mass-casualty incident.

The United Kingdom recognizes that effective mutual aid across the healthcare sector requires leadership and coordination in advance of any incident. This section of the document guides planners in developing mutual aid agreements beyond hospitals alone, but to include the military and ambulance service providers. With the exception of immediate lifesaving action, any requests for U.K. military assistance must

be carefully considered in advance and should be directed at the time of the incident via regional strategic command teams. Ambulance services in the United Kingdom require that plans be in place to deploy large numbers of vehicles, staff, and equipment to the scene. The establishment of mutual aid agreements that detail early command, control, and triage arrangements at the scene is critical to a successful response.

Since all disasters are local, the U.K. plan recognizes that, for the majority of major incidents, local interagency command and control mechanisms will be sufficient, but for bigger, truly catastrophic events further strategic coordination of the NHS may be needed. Since strategic health authorities and their regional directors of public health have pivotal roles in coordination, the U.K. document recognizes the need to link the local response to national coordination. The strategic command arrangements section points out that during the planning phase it is important that an agreement is reached among all healthcare providers so that disruption of essential services is limited.

The impact of an actual mass-casualty incident will severely challenge the coordination and communications capacity of all NHS organizations. Local NHS organizations must plan for a management structure in a mass-casualty incident with a clear understanding of how things will be organized and particularly of who is directing resources. The NHS guidance makes clear that the Department of Health will establish national coordinating arrangements if an incident escalates outside the capacity of an SHA region or where the incident has a national impact. Since this involves multiple levels of coordination and communication, the document outlines planning considerations that must be made.

c. Secondary Questions

Table 4. United Kingdom: Components and Review Elements

COMPONENT	REVIEW ELEMENT
Triggers	The plan does provide triggers.
Guaranteed Level of Care	The UK plan ultimately leaves the decision to alter standards of care to local physicians.
Legal Immunity	The plan does not address legal issues.
Does existing altered-standard-of-care guidance define the required appropriate altered standards of care in order to optimize patient outcomes?	It does not define.

3. Tennessee

a. Guiding Principle

The altered-standard-of-care plan of the Tennessee Department of Health for allocation of resources to physicians and healthcare workers in a health crisis does not delineate between different types of disasters that might trigger a need to allocate resources differently. A terrorist attack is deemed to create the same type of allocation concerns as a pandemic outbreak of a type A influenza virus. Patient care and reciprocal health organization collaboration are presented as being identical regardless of the health emergency facing providers. This is a logical weakness that fails to note that a terrorist-inspired biological weapons attack is limited to specific regions and that infrastructures and resources beyond the immediate need zone may affect how critical shortages are and the circumstances under which replacement of critical resources can occur.

The plan is designed to “provide governmental leaders and healthcare professionals with an ethical framework to guide and support decision-making at the state, local and facility level” (Tennessee Department of Health, 2009, p. 2) in the preparation and response to disasters. The ethical issue is utilitarian in its approach to

resolving problems. The ethical concern is presented as the welfare of the community over the welfare of individuals, and the unspoken guideposts are a need to foster the greatest good for the greatest number of people.

The plan offers six guidelines for the allocation of scarce medical resources and the triage of patients. The six guidelines are: Duty to Plan; Duty to Care; Reciprocity; Stewardship of Resources; Respect for Human Dignity; and Communication. Each of these guidelines supports the foundational ethical imperative to serve the interests of the community. The role of the individual is defined by the individual's value to the community, and throughout the plan this perspective is repeatedly stressed. The guidelines presented are fluid according to the level of healthcare crisis facing the community. The plan classifies healthcare emergencies into three categories: Early Public Health Emergency; Worsening Public Health Emergency; and Worst-Case Public Health Emergency.

There is no discussion of the underlying ethical framework that allows physicians, nurses, and other hospital staff (presumably administrators, if they are present in the physical plant) to evaluate the various likelihoods of survival and then make triage decisions accordingly. The plan provides concrete examples of needs that are already recognized but fails to discuss any ethical issues that may allow physicians, nurses, and other staff and government officials to create a carefully articulated manifesto of what, exactly, constitutes the greatest good for the greatest number of people.

b. Response Component

The overriding concern for the greatest good for the community is present even in the least dire category, Early Public Health Emergency. The scenario suggests that the public and healthcare professionals will view early warnings of potential healthcare disasters with skepticism. A special condition is evaluated in each scenario that sets possible healthcare professional absenteeism as a contributing factor to determining allocation of care. The skepticism present with Early Public Health Emergencies is demonstrated by a projected zero absenteeism rate for hospital workers.

The Worsening phase is projected to have a 20–30 percent absenteeism rate among hospital staff, and the Worst-Case scenario projects a 40 percent absenteeism rate for hospital staff.

One failing of the plan is its unknown definition of hospital staff workers. While the plan does on occasion refer to hospital and healthcare professionals, there is no formal definition of what constitutes a healthcare professional versus a healthcare worker. The authoring committee for the plan included three hospital administrators, three attorneys, four physicians, a Ph.D. in public health, and a single registered nurse. Given traditional schisms that continue to exist between physicians and nurses regarding whether nursing is a profession or a job, the absence of any fixed definition regarding the meaning of worker versus professional makes the understanding of the absenteeism projections difficult. Are nurses included in the term *staff*? Are physicians and administrators included in the term? The definition of staff segments should be expanded to allow for a comprehensive understanding of how absenteeism among specific classes of healthcare personnel might affect the quality of care that can be provided.

Additional issues with the broad use of the term *staff* include the absence of any discussion of nurse practitioners. If anesthesiologists have a high rate of absenteeism at a hospital during a Worst-Case Condition crisis, but the number of nurse anesthesiologists is more than sufficient to meet patient needs, the absence of anesthesiologists is rendered moot. The failure to segment and carefully define hospital staff remains a problem with the state's 2010 addendum to the drafted protocols.

Concerns with appropriate triage models are more specific and relevant to the need to create fluid guidelines that allow a certain degree of autonomy among healthcare workers to deal with the real-world and real-time needs of a major medical crisis when few resources are available.

Reverse triage guidelines follow frameworks that also follow a “greatest good for the greatest number of people” construct. Telephone triage constructs are prominent and used primarily to screen for those who actually need the attention of a “hospital staffer,” although, again, the precise nature of who or what constitutes a hospital staffer is left to the reader to decide.

The most concrete protocols involve segmenting resources by type of resource: oxygen, medications (although no subsets of medication are listed), hemodynamic support and IV fluids, mechanical ventilation, nutrition, and staffing. The protocols for all resources except staffing are clear and follow what appear to be realistic adaptations to the three levels of crisis (Early, Worsening, and Worst-Case). The protocols for staffing are less clear and suggest possible remedies that do not, at first evaluation, appear to have a realistic foundation.

There is a consensus that reciprocity of staffing can occur between medical and healthcare institutions, but no consideration is given as to how “extra” staff can be found at one institution if a pandemic is affecting populations on a local, regional, or even national level. It is also suggested that academics can assume clinical roles in providing assistance to patients, but there is no requirement that academic physicians have clinical hours each year to prepare for full-time clinical care in an emergency.

There are lengthy sections devoted to alternatives for diminishing resources such as oxygen and vital fluids. However, the protocols show little in the way of strategic planning, other than suggestions that inventories be maintained and that backup generators and alternative forms of electrical power be available for periods of as long as thirty days.

c. Secondary Questions

Table 5. Tennessee: Components and Review Elements

COMPONENT	REVIEW ELEMENT
Triggers	Tennessee developed three categories to serve as triggers.
Guaranteed Level of Care	Defined by protocols geared around the availability of healthcare workers.
Legal Immunity	The plan does not address legal issues.
Does existing altered-standard-of-care guidance define the required appropriate altered standards of care in order to optimize patient outcomes?	Tennessee defines palliative care as optimal.

4. Philadelphia, Pennsylvania

a. Guiding Principle

The plan of the Philadelphia Department of Public Health (DOPH) is limited to scenarios involving pandemic disease, specifically a pandemic outbreak of a type-A virus related to the Spanish influenza outbreak of 1918–1919. The concentration on a single type of crisis allows the Philadelphia plan to be far more specific and detailed in its protocols than the Tennessee plan. The Philadelphia plan, for example, assumes that the long duration of an influenza pandemic will preclude the possibility of federal assistance to augment state and local operations. The pandemic outbreak pattern can be extrapolated with reasonable accuracy to either the traditional U pattern (with most deaths occurring in the elderly and the young) or the classic W pattern of the Spanish influenza outbreak (where most deaths occur in age groups 18–40 and the elderly and very young are far less affected). It is also possible to project public health needs more accurately since pandemic influenza can infect and cause non-life-threatening illness in as many as one-third to half of all living people. Infection rates will create great demand for medical examinations and secondary medications for those persons who are infected but do not fall prey to the actual influenza.

Frameworks are more detailed because the period of need where no outside assistance occurs is far greater than that of a natural disaster such with hurricanes Camille or Katrina or even a biological attack by terrorists. The existence of well-established and credible paradigms for pandemic influenza response, such as the Pandemic Severity Index constructed by the United States Centers for Disease Control (CDC), allows the plan to provide very carefully delineated response models for very specific phases of a pandemic influenza outbreak.

b. Response Component

There are numerous diagrams and sociograms for communication and collaboration among agencies and organizations and additional graphic illustrations of how communication and collaboration can occur within each agency and organization. The Tennessee plan never moves beyond very broad generalizations of response, in part because it is not a plan for a variety of public health crises. The Philadelphia plan has the luxury of a known topic with a well-understood life cycle. Extrapolation of response is also aided by the presence of significant technology that can rapidly develop vaccines for new strains of pandemic influenza. The assumptions of time frames to develop vaccines and the difficulties with shifting construction of an influenza virus are demonstrated by the 2009 swine flu pandemic.

In April 2009, a new form of A/H1N1, later labeled 2009 A/H1N1, was identified in Mexico (Cohen, 2009). Initial identification of the new strain mistakenly determined that it was a far less virulent B-type virus (Cohen, 2009). The outbreak was correctly identified seven weeks later as a new strain of A/H1N1. The first cases in Mexico were followed by the appearance of the virus in the United States in April 2009 (Cohen, 2009). Physicians in Mexico sent samples of the new virus to labs at the World Health Organization (WHO) and the Centers for Disease Control (CDC).

Scientists also posted samples of the virus to GenBank, a public web site operated by a division of the United States National Institutes of Health (NIH). The site provides free online access to all known virus DNA sequences. More than two hundred samples of the new virus were posted within the first four weeks of the appearance of the

virus (Cohen, 2009). The ability to view hundreds of samples of the virus facilitated the design of a vaccine in approximately four weeks (Cohen, 2009). The existence of this type of technology resolves many problems that might ordinarily arise with non-influenza pandemics.

An ethical care committee working with established life cycles of pandemic influenza outbreaks developed ethical triage and care frameworks. The specificity of the health crisis permits greater articulation of ethical protocols that reflect the utilitarian ideal of the greatest good for the greatest number of people. The response model consists of care and treatment facilities designed to work with four levels of patients. All patient levels are assigned a high likelihood for survival. The design of the program incorporates a reverse triage process that ensures that only those likely to survive or with a high potential for survival receive vital and scarce resources.

For all of its specificity, the plan does not conclusively identify a criterion to determine whether a patient is too ill to receive treatment. The plan states that an “ethics committee” continues to work on this pressing issue. The plan required approximately eighteen months to complete, and its total length is 320 pages. The ethics question is the only unfinished portion of the plan.

The protocols and chain of command to establish collaboration methods and sharing of scarce resources is very similar to the Tennessee plan, except that protocols are offered in greater detail due to the limitation of the crisis being discussed. A pandemic influenza outbreak is a known situation. The plan does definitively create a classification for “too sick” patients in situations where life-saving resources are subject to shortages. But the plan only defines a “too sick” patient as “chances for survival of this type of patient are assessed to be minimal” (Philadelphia Department of Public Health, 2007, p. 18). The ethical imperatives of deciding what to do with “too sick” patients and whether proactive lethal medication, such as that practiced by Dr. Pou in New Orleans during Katrina and its aftermath, is an option in certain crisis situations.

The plan is detailed but unremarkable in its recommendations for altered standards of care and for resource allocation during a pandemic influenza outbreak. It skirts the ethical question of how to best allocate resources through an ethics mechanism that remains a work in progress. It is likely that the conclusions of the ethics committee will remain a work in progress for some time. The outbreak of 2009 A/H1N1 was insufficient to push Philadelphia’s DOPH to resolve the ethical concerns of “too sick” patients. This may be due to the DOPH’s limited mandate over the metropolis of Philadelphia, or it may involve political fears that defining “too sick” could result in political and social repercussions that include, but are not limited to, loss of federal and state funding and adverse social reactions that could harm tourism.

c. Secondary Questions

Table 6. Philadelphia, Pennsylvania, Components and Review Elements

COMPONENT	REVIEW ELEMENT
Triggers	Triggers are based solely on a pandemic event and follow phases established by the CDC.
Guaranteed Level of Care	Relies on protocols based on reverse triage.
Legal Immunity	The plan does not address legal issues.
Does existing altered-standard-of-care guidance define the required appropriate altered standards of care in order to optimize patient outcomes?	The definition is hinged on the use of reverse triage to allocate scarce resources only to those patients who have a high likelihood of survival.

5. Tacoma/Pierce County, Washington

a. Guiding Principle

The Tacoma Pierce County (TPC) Pandemic Influenza Medical Response Model is figuratively and literally a twin of the Philadelphia plan. The sections defining “too sick” patients are identical, and the composition of the ethics committees that are continuing to investigate the best approach to allocating resources in a crisis situation is

different only in the makeup of committee members. The PRC committee includes a wider sampling of healthcare personnel and institutions and includes representatives of the emergency medical response teams and paramedic teams, United States military personnel from the Rapid Response Division of the United States Department of Medical Military Preparedness, members of the CDC, members of nonprofit nongovernmental organizations such as the Red Cross, and several representatives of private community for-profit medical practices. The wider representation appears to reflect a genuine effort to mold an all-inclusive response model for pandemic influenza outbreaks.

The TPC plan differs somewhat from the Philadelphia plan in that nongovernmental organizations (NGOs) have a more prominent role in assessing patients and providing early triage of populations during the first stage of an influenza outbreak. The graphic representations of chain of command, public communication practices, and collaborative protocols between hospitals and healthcare agencies are verbatim that of Philadelphia's plan. Both plans were drafted in 2007, and both rely heavily on the CDC pandemic influenza community and medical response model.

Both plans apply the Susceptible Infectious Recovered model, or SIR model, to projected actions and protocols. The SIR model has been transformed in the past fifty years to allow public health agencies to extrapolate various outcomes of epidemics based on how populations respond to suggested vaccination and treatment regimens (Corburn, Wagner, & Blower, 2009). Critics of most variations of the SIR model point out that those projections are usually based upon theoretical behaviors by the public.

Most SIR models for 2009 A/H1N1 were based on assumptions of mass vaccination, but in "the 'real world' where vaccination is voluntary, high vaccination coverage is rarely achieved" (Corburn, Wagner, & Blower, 2009, p. 34). SIR models do provide public health agencies with real-world alternatives to unlikely vaccination models. Models developed by the WHO and the CDC for 2009 A/H1N1 showed that successful vaccination of 80 percent of all persons under the age of 19 years would be as successful as vaccinating 80 percent of all people aged one year and over (Corburn, Wagner, & Blower, 2009).

However, the cross-species transmission of a pandemic virus such as 2009 A/N1H1 makes modeling efforts relatively futile since cross-species infections and transmissions can cause the virus to evolve in ways that allow it to defeat vaccination defenses (Corburn, Wagner, & Blower, 2009). The ability of 2009 A/H1N1 to recombine across species effectively eliminates modeling as a realistic means of projecting the path of the illness (Corburn, Wagner, & Blower, 2009), but this is never discussed in either the Philadelphia or the PTC plans. This is a critical weakness of both plans and a weakness of the Tennessee plan as well.

b. Response Component

All discussed plans examine allocation and scarcity issues in a vacuum. The designation of scarcity may shift as the nature of the virus shifts due to cross-species contamination. A vaccine designed for the pandemic influenza may become useless if a cross-species contamination and recontamination occurs. The previously vaccinated population may require new vaccinations: if this is the case, how will providers know whether previously vaccinated individuals now require a second vaccine in a way that is more urgent than populations that received no vaccine at all? Public health agencies are reluctant to admit that scientific modeling supporting the use of vaccination is relatively useless in actually projecting the benefits of vaccination against a virus such as 2009 A/N1H1 (Corburn, Wagner, & Blower, 2009). This is a mistake.

c. Secondary Questions

Table 7. Tacoma/Pierce County Components and Review Elements

COMPONENT	REVIEW ELEMENT
Triggers	Triggers are based on the CDC pandemic model and do not address other mass-casualty incidents.
Guaranteed Level of Care	Plan does not address.
Legal Immunity	Legal issues are not addressed.
Does existing altered-standard-of-care guidance define the required appropriate altered standards of care in order to optimize patient outcomes?	Based on recommendations of ethics committees.

6. California

a. Guiding Principle

California's Department of Public Health issued its "Standards and Guidelines for Healthcare Surge During Emergencies" in late 2007. The plan is a series of written protocols to be used as tools for preparing for staffing shortages in medical-surge emergencies. There is no discussion of allocation of scarce resources other than two brief mentions regarding triage strategies and the allocation of "supplies, pharmaceuticals, and equipment" during surges (California Department of Public Health, 2008, pp. 113, 136). No ethical framework is offered, and no justification is offered other than two sentences justifying careful allocation of equipment and pharmaceuticals as a "stabilizing" method and the careful allocation of triage resources as a means of ensuring that such action "saves the largest number of lives in contrast to saving the individual" (p. 113).

The issue of how to obtain the greatest collective saving of lives is left to the reader's imagination. The presumption is that the tool guides found in the plan will allow physicians, nurses, hospital administrators, emergency medical technicians,

operators of home healthcare services and operators of live-in elderly and special-needs patients to come to the right decision. Even as the plan avoids the boilerplate of the Philadelphia and TPC plans, there are no templates for actually determining how to alter standards of care and allocate scarce resources and no suggestion on how the level of medical surge might require adjustments to the way in which scarce resources are allocated.

The Philadelphia, TPC, and Tennessee plans all include brief discussions of how and when to identify “too sick patients” and how to generate a hierarchy of need through a utilitarian perspective. California’s plan omits all discussion of these issues and fails to even suggest that the target audience will be responsible for exercising judgment in these matters. The plan does describe the concept of reverse triage in greater detail than the first three plans and provides a very brief legal and ethical defense of the practice that illustrates the utilitarian premise of most response plans. The plan warns that traditional triage perspectives must be avoided. The most severely injured are no longer considered priorities unless they have a high likelihood of survival. Those with less severe injuries are treated first if treatment is the tipping point for survival.

The California plan falls into the same ethical trap that Tennessee, TPC, and Philadelphia create in failing to list actual categories and classes of those too injured to be considered candidates for treatment: it places the full responsibility for these decisions on the individual physicians, nurses, and emergency care providers who are treating patients. This creates an ad hoc screening method that is neither uniform nor objective; rather, it is based on the perspectives of each individual working the triage station.

b. Response Component

The variation of personal views regarding the viability point of life, the sacredness of life, and the moral and ethical obligations of physicians, nurses, and healthcare providers to preserve life is dismissed with the use of the simple phrase “the greatest good for the greatest number of people.” The plan, like those from Philadelphia,

TPC, and Tennessee, does not mention the variation of views regarding the sacredness of life or the possibility that a utilitarian approach might well conflict with the moral, religious, and ethical beliefs and practices of healthcare personnel.

There is an unspoken assumption that all healthcare personnel in an emergency or crisis situation will essentially share the utilitarian perspective of each plan. Philadelphia and TPC plans casually declare that any newborn or infant with a genetic disorder that is likely to be fatal before the age of two should be treated in the same way as an adult who requests a “do not resuscitate” (DNR) order. There is no discussion regarding how different individuals will be able to comply with this directive. There are no plans or templates for holding discussions with all healthcare personnel as part of the preparedness stage of crisis management or medical surge management. There is only an assumption that during a moment of crisis all personnel will know what to do and will do it in the most ethical and moral way possible.

The California plan includes worksheets for more than twenty-nine functions and processes to prepare and engage a medical event triggering a surge in care needs. The plan expends fewer than 53 words on how to prepare staff for the utilitarian decision-making process that could haunt them for the rest of their personal and professional lives. This approach might well work in a military situation where chain-of-command is sufficient to ensure that all personnel follow the orders of those above them. But even this assumption is questionable, given the broad religious beliefs held by members of the military regarding the sanctity and value of individual life.

The California plan fails to guide healthcare workers in how to craft a hierarchy of care for various health-surge situations. It also fails to define moments when existing plans and guides must be changed to fit realistic real-world needs. The legal implications of the surge policy are not discussed at all. This may be due to the plan’s absence of any real discussion regarding how to accomplish the utilitarian goals in a variety of situations.

c. Secondary Questions

Table 8. California Components and Review Elements

COMPONENT	REVIEW ELEMENT
Triggers	Triggers are based on 29 function/processes but do not define how to implement altered standards of care.
Guaranteed Level of Care	Based on staffing and supply level protocols.
Legal Immunity	The plan has a very limited legal immunity discussion.
Does existing altered-standard-of-care guidance define the required appropriate altered standards of care in order to optimize patient outcomes?	It does not define; leaves the ultimate decision to the attending physician.

7. Colorado

a. Guiding Principle

Colorado's August 2009 "Influenza Planning Guidelines for Hospitals" was published as the 2009 A/H1N1 pandemic was already showing itself to be much less of a national health threat than first predicted. The guidelines do not address a WMD event or other mass-casualty event and are limited to hospital operations. There is no discussion of private medical practices and the public health infrastructure that may well be affected by the increase in infected persons with non-life-threatening symptoms who use the healthcare system, including emergency rooms at hospitals, rather than the less immediate alternatives of family physicians and nurse practitioners.

The Colorado plan also relies on a utilitarian approach to allocation of scarce human, equipment, and medicine resources during the highest level of crisis. Unlike all previous plans discussed, the Colorado plan strongly urges hospitals to prepare staff for harsh utilitarian decision making and to identify and resolve personal ethical and religious beliefs among the staff that might interfere with the mission of serving the greatest good through helping the greatest number of people.

Education protocols mandate that hospital staff participate in programs that discuss “the challenges a pandemic may present and the ethical difficulties that may arise during a pandemic. Staff should be aware of the hospitals [sic] altered standards of care and alternate care facility protocols and procedures ... if care is different from normal care procedures” (Colorado Department of Public Health and Environment, 2009, p. 14).

b. Response Component

In addition to programs that educate staff personnel about the altered standards of care and allotment protocols, the need for counseling and psychological support for staff is recognized. Counseling should be provided in the training phase as well as the implementation phase during a pandemic outbreak “to assist staff” who are having a difficult time adjusting to standards that move away from the needs of the individual and toward the needs of the collective community (Colorado Department of Public Health and Environment, 2009, p. 19). This may be particularly useful for staff concerned with pediatric care. The notion that children and infants with a low likelihood of survival must be denied treatment or access to critical resources is expected to be difficult for staff.

Elder-care decisions regarding the allotment of resources is presented as “possibly” being similar to pediatric issues. Hospitals should have both a pediatric plan and an elderly plan prepared for allocation concerns, although the section on elder-care issues suggests that shifts in triage and allocation frameworks for the elderly will be less difficult to manage than those impacting infants. The plan also suggests that hospitals plan for and add additional security staff and security measures for physical plants since the allocation of resources may be misunderstood (or possibly fully understood) by the public, who will then express their anger through violent action directed against hospital property and staff.

The Colorado plan also addresses legal issues pertaining to worker’s benefits, cancellation of vacation time and sick time, suspension of labor contracts and collective bargaining agreements, and the process for reciprocal staffing by hospitals on

an as-needed basis during a crisis. Cross-training is also encouraged as a proactive and presumptive means of dealing with staff shortages. It is also suggested that hospitals consider crating a civilian or lay auxiliary corps for ancillary tasks during the crisis that can facilitate cross-training for medical staff.

The Colorado plan takes a different position from the TPC and Philadelphia plans regarding the potential for federal assistance. The Colorado plan allows for federal assistance even in a worst-case scenario setting and recommends that key medical supplies and resources be inventoried to ensure an uninterrupted supply (albeit an insufficient supply) of critical products, equipment, and pharmaceuticals.

The plan does not deal with any other type of mass-causality event or public-health crisis. The plan is clear that, while certain aspects of the plan can be applied to non-pandemic influenza situations, there is no attempt to specify which parts apply or to suggest the adaptation of influenza strategies to other situations.

c. Secondary Questions

Table 9. Colorado Components and Review Elements

COMPONENT	REVIEW ELEMENT
Triggers	Follows CDC pandemic level triggers.
Guaranteed Level of Care	Suggests hospitals develop protocols to implement altered standards of care and allocation of resources based on patient's age.
Legal Immunity	Only addresses employee human recourses issues and not liability/immunity.
Does existing altered-standard-of-care guidance define the required appropriate altered standards of care in order to optimize patient outcomes?	Not defined.

8. New York

a. Guiding Principle

The draft plan for ventilator distribution and use allotment was written in 2007. The plan is specific in its intent and does not attempt to extend conclusions and protocols to any other area of healthcare resource allocation or to a mass-casualty event. The setting for the protocol is an influenza pandemic. There is no literature available regarding whether the plan served as a basis for policies of New York hospitals during the 2009 A/H1N1 outbreak in the United States. The plan may have not been required since the outbreak was far less wide ranging than expected. The CDC estimated that approximately 60 million Americans were infected with the virus, approximately 270,000 were hospitalized, and 12, 270 Americans died from the virus (U.S. Centers for Disease Control [CDC], 2010). The number of hospitalizations represents the low range of CDC projections (192,000–400,000), and it is doubtful that critical equipment such as ventilators were rationed along the lines in the plan.

b. Response Component

The plan assigns responsibility for allocation and triage decisions to the supervising physician of a hospital. A clear chain of command is established, although the supervising physician of each hospital is granted broad authority for developing a method for their hospital to follow. Primary-care physicians are expressly excluded from participating in triage and allocation frameworks. No reason is provided for this decision. Palliative care provisions are emphasized, and palliative care is a key provision for patients who are denied ventilators due to reverse triage guidelines. The plan also allows for the creation and use of an ad hoc appeals process. The hospital's ethics committee will serve as the ad hoc appeals committee, and hospital ethics committees are encouraged to prepare for that role in an influenza crisis.

A need for constant, clear, and legally sanctioned guidelines is expressed in the plan at various points. This emphasis may reflect the composition of the authoring committee, which has more attorneys than physicians, nurses, or public health officials.

The plan stresses that all hospitals in the state must follow the same protocol, and this suggests a concern with litigation claims once the pandemic has subsided. That concern is paired with a concern that transparency be evident in each step of the plan and that the public be apprised of the plan as it is developed, as it is completed, and at regular intervals when public health and hospital officials suggest a pandemic outbreak may occur.

The need for transparency is presented as a critical key to public acceptance of the plan. Recommendations include gathering public commentary as a genuine way of adapting the plan to conform to public concerns about the reverse triage and allocation protocols for pandemic outbreaks. Communication is seen as a critical legal step to securing acceptance of the reverse triage for ventilator patients as a standard of care in emergency situations. The creation of a standard of care for reverse triage is presented as a way to protect physicians and healthcare staff from potential liability from the families of those denied ventilators during a crisis (New York Department of Health, 2007, p. 3). The creation of a professional standard of care, shared with the public in a transparent way, will allow hospitals to lobby the state legislature for amendments to Good Samaritan laws protecting physicians from decisions made in emergency life-threatening situations.

The unspoken message is that reverse triage and denial of treatment following a scarcity in ventilators has a greater chance of succeeding if physicians making the decision do not have to worry that they may follow in Dr. Anna Pou's footsteps. While standards of practice can, and often do, effectively indemnify decisions made by physicians and healthcare providers in immediate life-threatening decisions, the only avenue to absolute indemnification is through legislative action. A large portion of the plan serves as a validation for the implementation of guidelines as a fixed standard of practice.

The plan relies on protocols and evidence cited by the United States Department of Homeland Security (DHS) regarding the occurrence of pandemic influenza. This information is accompanied by statistics showing the available number of ventilators in ICU units in New York hospitals. Projections for ventilators needed to

assist influenza patients are created using SIR model calculations. There is some discussion regarding the weakness of SIR projections, but the plan makes a strong case that any pandemic influenza outbreak approaching the high-middle to high range of projected hospitalizations will create a crisis in ventilator access.

The plan is not a description of necessary allocation strategies as much as it is a political document for obtaining legislative consent to new standards of practice for public-health crisis situations. The transparency arguments are presented as both the ethical responsibility of hospitals to inform the public of serious changes to expected medical practices and as a way of having the public support these changes and communicate this support to legislators. The language of the document often ventures beyond medical and legal frameworks. Projected pandemic influenza viruses “attack” the public and the viruses also “attack” children, the elderly, and the helpless.

The ethical concerns for formulating an alternative care model are discussed in detail, and the point is made several times that ethical decision making cannot rest solely on technical considerations. A set of guidelines similar to those found in the Tennessee plan are set forth: Duty to Care; Duty to Steward Resources; Duty to Plan; Distributive Justice; and Transparency. “Distributive Justice” is essentially identical to “Respect for Human Dignity,” and “Transparency” is essentially the same as “Communication.” “Reciprocity” as expressed in the Tennessee plan has no direct counterpart in the New York plan, although the “Duty to Plan” function includes arranging for reciprocity contingency plans among local and regional hospitals.

A somewhat lengthy consideration of what is termed “distributive justice” involves the allocation of federal government reserve stockpiles of ventilators. The plan argues that distribution of stockpiled ventilators must follow a pattern that mirrors the ethnic composition of local and regional districts. The “allocation of ventilators from state and federal stockpiles must take into account the ratio of local populations to available resources, and supplement those resources accordingly” (New York State Department of Health, 2007, p. 16). This creates a dichotomy for reverse triage guidelines that must on one hand address the greatest good for the greatest number of

people, while on the other hand implementing concerns for ratio of care that mimics the ratio of ethnicity in a region. This can be particularly difficult given the predisposition of certain types of illness in ethnic populations.

It is possible, if one assumes a cynical perspective, that this concern represents a political effort to please various segments of the state legislature necessary to establish reverse triage guidelines as legal standards of care and practice. It is also possible that a desire for genuine social justice on the part of the authoring committee resulted in an exception to the concept that the needs of the individual must not serve as an obstacle to the needs of the community if saving an individual preserves the ethnic ratios of a community. It is an issue that is not addressed beyond the cited references, and the lack of clarification creates a lacuna that threatens the ethical authenticity of the ventilator policy.

The authenticity of the ventilator policy is its most valuable asset. The presumed natural inclination of a medical professional is to save life at all costs except in the instance of patient- or legal guardian-directed DNR orders. Extubation of a ventilator is a physical process composed of several steps, and each step is the result of deliberation preceding the act. The consequences of extubation are perfectly understood by physicians, nurses, and other care providers. Extubation undertaken to transfer the lifesaving qualities of the equipment to another human being is not an easy task even when the moral right is on the side of the person engaging in the extubation. The possibility of healthcare personnel refusing to follow established protocols for extubation following reverse triage are discussed in the plan. The point is acknowledged that the existence of a rule does not in itself guarantee that the rule will be followed. A rule requires credibility from those issuing the rule, and credibility is founded in a perception of authenticity.

The final section of the plan creates a method for evaluating which patients are treated and which are, in effect, left to their own devices to survive but who receive palliative care for pain. The plan of physical classifications subject to some physician interpretation and subjective judgment by the presiding physician emerges, one that is similar to the Tennessee plan. The precise criteria are not as important as the

process for developing the criteria and the criteria’s universal applicability to resolving the problem. There is also a presumption that the public’s ultimate acceptance of the criteria will be shaped by an emergency situation perceived by the public to be as life threatening, as much if not more than a campaign of transparency and healthcare training.

The plan represents a careful, thorough, and extensive presentation of all options related to reverse triage and allocation of scarce resources in a public-health crisis. The underlying issues that shape protocols are for the most part dealt with directly, and the potential adverse consequences of such policies are planned for in discussions regarding how to protect physicians and healthcare workers through the passage of standard-of-care legislation.

c. Secondary Questions

Table 10. New York Components and Review Elements

COMPONENT	REVIEW ELEMENT
Triggers	Follows CDC pandemic level triggers and not other mass-casualty events.
Guaranteed Level of Care	Suggests this be dictated by the attending physician.
Legal Immunity	Limited discussion as it only suggests concern for litigation claims. Advocated for the expansion of existing Good Samaritan laws.
Does existing altered-standard-of-care guidance define the required appropriate altered standards of care in order to optimize patient outcomes?	Not defined.

9. Indiana

a. Guiding Principle

The justification of Indiana’s plan for dealing solely with pandemic influenza borrows liberally from New York’s plan and from general CDC publications concerning reverse triage allocation of treatment and resources. The general application portion of the plan for ventilator allocation is a verbatim presentation of the New York

plan. The Indiana plan requires that all other possibilities for dealing with a patient surge be considered before deciding upon reverse triage as the means for determining who should be granted access to ventilators and who must be denied, but it provides no articulated guidelines for what all possible alternatives. The consideration of various legal and ethical issues is discussed using language very similar to that found in the New York plan. The triage guidelines specify that “age, social worth, and job function will not affect triage allocation decisions” (Indiana Department of Health, 2008, p. 6), although there is no discussion regarding how this policy might be carried out, given that age can be a significant factor for the elderly and the young in all other plans considered.

The Indiana plan also discusses the role of ventilators for at-home patients and patients residing in private chronic-care facilities. These patients are exempt from any triage allocation decisions and are not subject to extubation decisions that are followed when evaluating an identical hospital patient receiving ventilation. There is no discussion about why two classes of patients are treated differently, and this raises questions regarding whether qualities other than age, social worth, and job functions determine reverse triage determinations. The category of personal wealth or insured status that allows private care either at home or in chronic-care facilities suggests that “personal worth” does serve as an exception to a process designed to provide the greatest good for the greatest number of people. The exemption of at-home and chronic care facility patients ends once a patient is moved to a hospital setting. But the reasons for which a patient might be transferred and who might order such a transfer are not discussed.

A critical care triage tool is introduced, and the criterion for exclusion of ventilator care is identical to the New York plan. Like the New York plan, clinical-care physicians have no authority to exclude treatment. That decision is left to a triage review officer, who is described as the supervising physician for a unit. The standards for extubation are more articulated than in the New York plan, and specific tools are presented for daily evaluation of a patient’s benefits from intubation. When a patient’s score fall bellows a certain point, the triage review officer must be consulted for extubation consideration.

b. Response Component

The focus of the plan is procedural, and this differs significantly from the all-encompassing medical, legal, social, ethical, and political concerns of the New York plan. The authoring committee of the Indiana plan has only two attorneys among eight physicians, six nurses, and four public-health officials. This may explain the difference in the framework's perspective. The Indiana plans does not extent its findings to any other type of mass-casualty event, and no discussion is offered regarding how a pandemic shapes response options differently from other public-health challenges caused by natural disasters, terrorist incidents, or other medical crises.

c. Secondary Questions

Table 11. Indiana Components and Review Elements

COMPONENT	REVIEW ELEMENT
Triggers	Follows CDC pandemic-level triggers.
Guaranteed Level of Care	None; however, the decision to alter care is based solely upon the triage decision made by the facility triage officer.
Legal Immunity	Does not consider legal liability/immunity.
Does existing altered-standard-of-care guidance define the required appropriate altered standards of care in order to optimize patient outcomes?	Not defined.

10. Connecticut

a. Guiding Principle

The 2009 draft document of the Connecticut Department of Public Health was presented to the public in October, and the effects of the 2009 A/H1N1 were well known by that time. The general plan is not designed to be implemented for any single

specific type of health crisis. It is an all-hazards plan that extends an ethical framework of allocation to a variety of circumstances that can affect the nature of resource availability and operations requiring allotment based on scarcity.

b. Response Component

Like the New York plan, the Connecticut plan seeks to create an altered standard of care for disaster medicine that serves to indemnify physicians, nurses, and other healthcare personnel from criminal or civilian liability for actions taken during a public-health crisis. The diminishing presence of “staff, stuff and space” (Connecticut Department of Health, 2010, p. 8) is presented as significantly changing the nature of how healthcare can be provided, to whom care should be provided, and the format to communicate the changing standards to patients, healthcare personnel, and the public. Any altered-standard-of-care plan must provide the framework for doing these things without restricting the autonomy of workers to decide how to best adjust to constantly and rapidly changing circumstances.

Connecticut, unlike New York, delineates specific ethical value categories that must be addressed to devise reverse triage protocols and to set standards for withholding of care. Ten substantive values are listed: Individual Liberty; Protect the Public from Harm; Proportionality; Privacy; Duty to Provide Care; Reciprocity; Equity; Trust; Solidarity; and Stewardship (Connecticut Department of Health, 2010, pp. 10–14). Five procedural values are also listed for how the plan is administered: Reasonable; Open and Transparent Communications; Inclusive; Responsive; and Accountable Standards (Connecticut Department of Health, 2010, p. 14). The articulation of these values conforms to the general concepts found in all other plans, although the detail provided to each value results in more confidence that values can actually be effected.

All altered-standard-of-care protocols must be openly and transparently communicated to the public, and public responses must be actively received and considered as the plan continues to evolve. Social justice and personal ethics must be directed toward the greatest good for the greatest number of people, but as in all other plans the means of achieving this lofty goal are never discussed. Reciprocity and

stewardship expand from other plans to consider the problems posed to healthcare workers who may need to choose between helping family members and helping the public (and no resolution of such a dilemma is offered). Reciprocity is also extended to the need for a uniform level of care that all hospitals provide all patients. This will avoid a loss of public trust in the public-health system, and also buttress altered-standard-of-care defenses that can be used by healthcare personnel to justify decisions made during a crisis.

c. Secondary Questions

Table 12. Connecticut Components and Review Elements

COMPONENT	REVIEW ELEMENT
Triggers	Triggers are based on ten ethical value categories and are all-hazards focused.
Guaranteed Level of Care	Allows for a uniform level of care for all patients.
Legal Immunity	Seeks to indemnify healthcare workers/responders via altered-standard-of-care protocols.
Does existing altered-standard-of-care guidance define the required appropriate altered standards of care in order to optimize patient outcomes?	Not defined but allows for a uniform level of care.

11. Virginia

a. Guiding Principle

The state of Virginia Department of Health, in a collaborative effort to determining allocation of scarce resources in a variety of medical-disaster situations, creates a perspective that is similar to but still different from the perspective found in the New York plan. The plan represents a legal perspective that is guided by its authors, public-health consultants, physicians, and nurse consultants. The “client” for the plan is the state, and all commentaries and advanced plans represent that relationship.

The key to a successful strategy of withholding treatment through the use of reverse triage methods is the removal of liability claims that can be made against healthcare personnel for following such plans. The first page of the plan states:

Healthcare providers are not accustomed to having to allocate inadequate equipment and supplies on the scale they will confront in a pandemic. The prospects of allocation on this scale, understandably, cause profound concern within the Healthcare community because such decisions are inextricably tied to liability. These providers understand that they have a duty to render care in accordance with the applicable standard of care or face liability. ... Providers in Virginia, both hospitals and physicians, expressed concern about this very issue. ... [T]hese concerns were so strong that, at the extreme, some providers were contemplating closing their doors during a pandemic instead of providing care under “altered” standards unless they had some degree of liability protection. (Virginia Department of Health, 2008, p.3)

b. Response Component

The thesis of the plan is that execution frameworks are secondary to creating a secure environment for healthcare personnel to follow alternative crisis treatment regimens. If alternative practices are viewed as imposing significant criminal or civil liability risks for engaging in state policy, healthcare personnel will either not show up for work, engage in violations of allocation protocols, or perform their work in ways that significantly limit their ability to successfully treat the public. The plan suggests that the fear of liability originates with a misunderstanding of the legal precedents that protect physicians and healthcare workers from engaging in alternative standards of care during a public-health disaster or crisis.

Confusion regarding liability results from the absence of “consistency about the exact nature of those standards” to be used to limit allocation of critical resources (Virginia Department of Health, 2008, p. 4). The alternative to this situation is to employ a process of alternative care that is sufficiently fluid as to allow healthcare personnel to adjust the process to real-world challenges during the course of a healthcare crisis event. The preplanning process is critical to education and communication of the

process to the healthcare community and the public. Preplanning amounts to managing the expectations of healthcare personnel and the public regarding what must be done and how it will be accomplished. When expectations and concerns are effectively managed, the fear and uncertainty are resolved.

Like the New York and Connecticut plans, the Virginia plan suggests legislative action to legally protect healthcare providers. The remainder of the plan outlines various ethical values to guide in the creation of equitable and ethical alternative models for care. This section draws from sections found in the plans drafted by Connecticut and New York. These sections include provisions for identifying the person responsible for making reverse triage decisions and the construction of an ad hoc appeals process operating through an ad hoc appeals committee. The planning and research methods and processes recommended also follow the general guidelines and recommendations of the Connecticut and New York plans.

c. Secondary Questions

Table 13. Virginia Components and Review Elements

COMPONENT	REVIEW ELEMENT
Triggers	No triggers but is an all-hazards plan.
Guaranteed Level of Care	Based on the decisions of ad hoc committees.
Legal Immunity	Accounts for the removal of liability claims during disaster events. Suggests legislative action to address legal issues.
Does existing altered-standard-of-care guidance define the required appropriate altered standards of care in order to optimize patient outcomes?	Not defined.

B. KEY FINDINGS

The earliest published plans stress the development of guidelines using instruments and tools that are believed to bestow legitimacy and equity upon the guidelines. The later plans, beginning in late 2007 and in 2008 after a significant federal

requirement linked to pandemic planning funds, struggle with additional ethical issues pertaining to how allocation plans are presented to two audiences: healthcare personnel and the public. Although most plans attempt to achieve social justice and equity for patient selection methods, the plans contain often self-contradictory rules regarding how protocols are applied to all populations.

Criminal and civil liability remains a major concern among healthcare providers. Although Anna Pou and her legal and civil problems in Louisiana are never mentioned in any plan, the underlying causes of Pou's difficulties are expressed in all documents. It may be that liability is a particular worry for American physicians and that this fuels concerns with altered standards of care. The absence of altered-standard-of-care protocols may also be due to an American political divide on what constitutes the sacredness of life. During the debate on President Obama's healthcare reform plan, many opponents of the plan pointed to provisions they claimed created "death squads," concerned with saving costs over saving lives. Given the intense and often highly contentious debates over healthcare, the question of liability is a genuine one for physicians and other healthcare personnel.

As the legal aspects of the application of altered standards of care continue to be examined, there remains a danger that altered-standard-of-care protocols will emerge that are too restrictive. As Justice Stuart Potter of the United States Supreme Court, in ruling that obscenity is something that cannot be precisely described, put it, "I know it when I see it." This approach may need to be applied to altered-standard-of-care protocols.

The use of such an "on the spot" approach is that physicians will not have the guaranteed protection they seek. The benefit is that altered-standard-of-care practice will actually conform to constantly shifting needs to provide the best care possible to patients during a mass casualty, WMD event, or other public-health disaster. Troutman Sanders is correct to stress a process over unbreakable protocols. But communicating how this can still serve to protect healthcare personnel is a significant challenge for public health administrators.

C. DISCUSSION

The elephant in the room concerning the management of mass-casualty incidents originating from natural disasters, disease outbreak, or terrorist attack is the issue of how much authority and latitude needs to be granted to field physicians and healthcare personnel facing literal life and death decisions. In traditional military command processes the first step begins with the receipt of mission and the mission analysis. Any command, whether a traditional “take that hill” or a command to complete a simple mundane act, begins with a strong sense of the mission and its limits. Mass-casualty incidents run counter to the notion of defining the mission because mass-casualty incidents are predominately complicated by nature. Military decision making rests on a model designed to accomplish complex tasks. Processes targeting the successful completion of complex tasks do not always lend themselves to success in accomplishing complicated tasks.

“Complex” and “complicated” are terms that are often used interchangeably, but the processes are entirely different from one another. *Complex* problems are often composed of multiple components requiring careful and attenuated steps to reduce components to easily identifiable steps that can then be resolved by direct solutions. Complex problems are difficult but ultimately resolvable and are characterized as having a finite absolute number of resolutions (Hurlimann, 2009). *Complicated* problems are “characterized by having a multitude of different influencing factors ... heavily interconnected with one another” (Hurlimann, 2009, p. 14). *Complicated* problems are not static due to the interconnectedness of influencing factors, and as one or more factors changes the nature of the interconnected nature of the problem, the potential resolutions to the problem also shift and change (Hurlimann, 2009).

Military decision making rests on the military decision-making process (MDMP) formulated in the U.S. Army Leadership Field Manual (USALFM). While the MDMP is a fine system for formulating decisions and actions, it “is designed for organizations with staff” (U.S. Army, 2004, p. 91). Decisions made in the field rest on the process of troop leading procedures (TLP) (U.S. Army, 2004). But neither the TLP nor the MDMP are

designed to meet the complicated nature of mass-casualty incidents. The complicated nature of mass-casualty incidents makes the design of a plan difficult because there is no guaranteed order of needs or absolute circumstances surrounding the problem.

The USALFM does not contain the word “autonomy.” The USALFM does contain the word “independent,” but only once: an “individual leader with initiative is willing to decide and initiate independent actions when the concept of operations no longer applies or when an unanticipated opportunity leading to accomplishment of the commander’s intent presents itself” (U.S. Army, 2004, p. 33). The USALFM states that initiative “drives the Army leader to seek a better method ... and perform without waiting for instructions. ... [B]alanced with good judgment, it becomes *disciplined* initiative, an essential leader attribute” (U.S. Army, 2004, p. 33, emphasis in original).

The military’s solution to solving significantly complicated problems is to approach the problem with traditional problem-solving methods and, in the face of field events that simply prove too difficult or too unique to be resolved using traditional solutions, allow the commander to exercise disciplined initiative. “Disciplined initiative” is not defined in precise terms in the USALFM. It is noteworthy that, in the page following the use of disciplined initiative, a quote is offered from General Omar Bradley regarding judgment: “I learned that good judgment comes from experience and that experience grows out of mistakes” (U.S. Army, 2009, p. 34). The commander’s experience is presented as a source of impromptu field decisions. But even impromptu decisions must be grounded in a framework of battlefield tactics and command hierarchies. Disciplined initiative is not an abandonment of military protocol but a key part of the military protocol concerned with command decision making. Impromptu decision making requires the leader to “juggle hard facts, questionable data, and gut level intuition” to arrive at a decision (U.S. Army, 2004, p. 34). The leader must be prepared to engage in effective gut level intuition. Preparation will assist the leader in determining the best course of action in any given unique situation.

Gut level intuition requires support in the form of knowledge and thought—frameworks that will allow the medical leader to make difficult decisions in mass-casualty incidents. This knowledge set involves intimate familiarity with leadership

concepts and practices, legal issues, and operational and supply chain concepts and a willingness to exercise disciplined initiative when necessary.

On July 12–13, 2011, a conference was held in New Orleans to discuss the lessons and implications of the events at the Memorial Medical Center during Hurricane Katrina. Among the speakers was Dr. Anna Pou, who spoke to a closed session about the decision-making process and the need to protect physicians and healthcare workers in mass-casualty incidents such as Katrina. Pou distinguished between a Katrina-like natural disaster and an outbreak of a disease such as an influenza pandemic. Her principal message was the need to grant blanket immunity to any healthcare professional who must make hard and often impromptu choices during a mass-casualty incident based on limited information and rapidly shifting access to critical supplies (Pou, 2011). Dr. Pou remains in civil litigation with families of Memorial Medical Center patients who died, and this prevents her from supplying concrete examples drawn from the events at Memorial Medical Center.

In other public venues Dr. Pou has advocated for a special immunity for physicians and healthcare personnel working in a mass-casualty incident such as Katrina. Her position is that physicians and nurses are the best persons to determine appropriate life-saving protocols in a mass-casualty incident such as Katrina. Her views are the underlying rationale of legislation passed in Louisiana that expands the concept of the Good Samaritan shield offered to physicians to include the withholding of medical care and the use of only palliative care when medical resources are severely limited (Fink, 2009b).

Pou's perspective on the withholding of medical care for patients with poor prognoses for survival is summed up by her question "How long should healthcare workers have to be with patients who may not survive" (Fink, 2009a)? This perspective likens healthcare workers to a valuable medicine in short supply and appears to employ a utilitarian principle of the greatest good for the greatest number of people. Her answer is that physicians and healthcare workers alone should make the determination of what constitutes appropriate care without any risk of prosecution other than for willful misconduct. She does not provide a definition of what constitutes willful misconduct.

This position suggests that physicians and healthcare workers, by virtue of their medical education, medical training, and medical experience are best suited to make difficult field decisions during a mass-casualty incident. Dr. Pou does not discuss any type of special preparation that might be used to better equip professionals with knowledge sets to guide emergency field decisions during a mass-casualty incident. The presumption is that physicians and healthcare personnel are fit to act without any special preparation (Fink, 2009).

Pou is correct in asserting that physicians and healthcare personnel have no available legal or professional standards to fall back on as guides for allocating precious medical resources in a time of crisis. Federal regulations do exist that define liability issues for physicians in emergency healthcare situations. But none of these regulations apply in massive casualty incidents such as those caused by Hurricane Katrina. The federal Emergency Medical Treatment and Active Labor Act (EMTALA) requires all hospitals that accept Medicare and Medicaid patients to screen all emergency room (ER) patients to determine whether they require immediate treatment or simply urgent care. If a patient requires immediate treatment, the hospital must either treat the patient or quickly arrange for transfer of the patient to a facility that can provide immediate care (Bailey, 2010). But Dr. Pou was not treating ER patients; she was treating in-patients not admitted through the ER (Bailey, 2010). EMTALA creates a two-tier care system that can avoid imposing requirements on physicians in a mass-casualty incident. In a mass-casualty event patients already admitted to hospitals are not protected by EMTALA requirements.

The federal Volunteer Protection Act of 1997 (VPA) extends significant immunity to volunteer healthcare personnel and physicians providing treatment for the public during an emergency or a health epidemic. The immunity essentially allows physicians complete protection from civil liability and criminal liability unless a provider can be shown to have acted with malice or engaged in willful misconduct involving violations of accepted canons of practice (Bailey, 2010). The VPA, however, does not

apply to healthcare personnel who are not volunteers, and any physician or healthcare worker receiving remuneration for their services during a mass-casualty event is not protected under the VPA.

Traditional Good Samaritan laws in nearly all fifty states do extend limited immunity to physicians and healthcare workers who “in good faith gratuitously rendered emergency care or services at the scene of an emergency” or who in good faith responded to an imminent life-threatening situation within a hospital or clinic where the worker is performing professional duties but would not ordinarily have had to treat the recipient of services as part of those duties (Bailey, 2010). But on-duty staff treating patients as part of their professional responsibilities are not protected under any Good Samaritan laws. The United States Centers for Disease Control (CDC) recognized the lacunae of protection for physicians and healthcare workers when it introduced its Model State Emergency Health Powers Act (MSEHPA) in December 2001 (Bailey, 2010).

The Louisiana legislature used the MSEHPA guidelines to enact its own emergency healthcare act in 2003. Louisiana’s law, passed in part as a response to what occurred at Memorial Medical Center, states that “during a state of public health emergency, any health care provider shall not be civilly liable for causing the death or injury, to any person, except in the event of gross negligence or willful misconduct” (Louisiana, 2003). Gross negligence is defined as “the want of even slight care and diligence” and as “the want of that diligence which even careless men are accustomed to exercise” (Bailey, 2010, p. 728).

The precise protections offered by laws based on the MSEHPA guidelines remain unknown since no physician or healthcare worker has yet claimed any immunity offered by the various state laws modeled on MSEHPA. There is a growing consensus, that is also challenged by a sizeable number of healthcare ethicists and physician groups (Richards, 2011), that the protections offered by emergency healthcare power acts will prove to be insufficient to properly define the limits of a physician or healthcare worker’s disciplined initiative (Richards, 2011). A Katrina-like disaster may create situations involving more sympathetic patients who are permitted to die based on a physician’s gut instinct. The deaths at Memorial Medical Center involved the elderly and the infirm who

had led relatively long lives. Suppose in the next Katrina-like situation a ward of premature infants is allowed to die because a physician determines that most of the premature infants have a lower quality of life expectation if they survive than several white upper-middle-class businessmen who are vying for the use of respirators? Legal protections do not always suffice when public sentiment is aroused (Richards, 2011).

Legal liability for physicians is segmented into type 1 and type 2 errors. Type 1 errors include liability due to faulty judgment even when there is no negligence by the physician. A physician believes that his or her patient may require hospitalization when in fact hospitalization was not required. While hospitalized the patient acquires a serious infection and dies. The physician has done nothing to actually cause the infection, but the poor judgment that led to hospitalization is a proximate cause of death. Type 2 errors involve direct negligence of some sort that causes harm, injury, or death to a patient: a drunken surgeon kills a patient, or a physician administers the wrong drug to a patient (Richards, 2011).

Two additional types of physician errors are being recognized, and these two types of errors are linked to emergency and mass-casualty incidents. A type 3 error is “the unintentional solving of the wrong problem precisely” (lay persons might simply label this as a mistake) and a type 4 error is “the intentional error of solving the wrong problem” (Richards, 2011). Both types can be applied to a physician choosing to withhold medical treatment for a patient. Physicians do not, and should not, operate in a vacuum. The current laws governing emergency mass-casualty events are broad and very nonspecific regarding how decisions are made, documented, and carried out. This can create multiple opportunities for decisions to be challenged in civil and criminal venues. Existing laws, even those passed in Louisiana post-Memorial Medical Center, remain insufficient to define how physicians can determine who should be treated and who should be placed at the end of the line.

Ethical guidelines for treating patients in emergency situations can provide some guidance for physicians and healthcare workers, but ethics do not have the same power and force as laws. The ethical debate regarding proper care frameworks in mass-casualty events is active and highly productive. Ethical codes do offer some degree of protection

to physicians since ethical codes represent a standard of practice that courts will consider when determining whether an action is reasonable under the law (Richards, 2011; Taylor, 2011).

Ethical issues for mass-casualty events must start with the question of whether ethics are situational (Taylor, 2011). The existence of laws establishing different standards of conduct for physicians and healthcare workers in different situations suggests that ethics are situational, at least where medical care is concerned. Ethicists suggest that situational ethics incorporate certain absolute ethics as foundations for formulating actions (Taylor, 2011). This allows for certain types of situational variations that permit, for example, the acceptance of reverse triage practice in mass-casualty events.

But ethical exceptions create a slippery slope for professionals charged with protecting the public. If it is appropriate for a physician to withhold care to certain patients, is it also ethical for firefighters or police officers to withhold their services or protective actions to certain persons and locations during mass-casualty crises (Taylor, 2011)? Can a police officer choose to summarily execute looters who are believed to be infected with pandemic influenza, rather than take them to a holding area where other persons can be infected?

The withholding of care is not the same thing as the balancing of care. The American Medical Association (AMA) policy statement E-9.067 recognizes that physicians are a limited commodity in an emergency situation. While the number of people requiring treatment can rise dramatically in an emergency event, the number of physicians available to treat these people remains fixed. Statement E-9.067 calls for “balance” in treating victims of an emergency or infectious disease outbreak (Taylor, 2011; Bailey, 2010). But “balance” remains undefined, and again the initiative of the physician is presented as the arbiter of what is best for the general good.

The American Nursing Association (ANA) requires nurses to care for all patients in a “non-discriminatory manner” and labels the nursing profession a “sacred duty” that cannot be broken (Taylor, 2011). The ANA code of ethics demands that nurses treat all

patients requiring assistance, even if the potential for harm to the nurse is significant. Yet the ANA also recognizes that in emergency situations with mass casualties resulting from natural disasters, infectious outbreak, or terrorist attacks, “standards must change” to accommodate the reality of a fixed number of nurses available to care for an expanding population of patients (Veenema and Toke, 2007, p. 72B).

The ethical debate regarding mass-casualty incidents becomes one of utilitarianism versus egalitarianism (Taylor, 2011). Do treatment ethics assume a position of offering the greatest good for the greatest number of people (utilitarianism) or do ethics require that all patients receive the same quality of treatment (egalitarianism)? The most recent reports issued by state health divisions for best efforts during natural disasters, pandemics, and terrorist incidents resulting in mass casualties all follow utilitarian guidelines. The direction of statutory protections for physicians and healthcare workers also appears to follow utilitarian mandates. The general ethical debate now appears to be increasingly focused on the individual’s responsibility for following utilitarian mandates (Taylor, 2011).

Stassi (2011) argues for the creation of three distinct ethical frameworks for healthcare providers: conventional, contingency, and crisis levels of care. Each level allows providers to establish certain parameters of care, based on what is known and what resources are presumed to be available to healthcare providers during each type of event. It is possible to construct scenarios based on numerous potential events since many factors of possible events are known, including infrastructures, vital materials and equipment, maximum number of healthcare providers, maximum number of potential patients, transport options, and the contingencies created by various types of trigger events.

Stassi (2011) argues that contingency and crisis standards of care must include input from the public at large and that this input must be present from the beginning of the process. Since altered ethics and practice of care will be used in crisis situations, the altered standards must reflect the consent of those who will ultimately be cared for using the altered standards. This will go a long way toward legitimizing the altered standards. Stassi also suggests that the situational nature of emergency ethics be incorporated on a

daily or hourly basis. If altered standards for care result from the contingent circumstances of the moment, some mechanism must be placed in effect that can assess standards in light of contingent factors as they change.

This may mean reassessing crisis standards every hour or half hour, particularly if the standards of care become more draconian. Individuals must be assigned responsibility for reassessing contingent circumstances, and these individuals cannot be the persons charged with administering altered standards. This will result in the creation of a new triage model that is tied to the existing contemporaneous situation and subject to immediate change as the contingent situation improves or becomes worse.

Wallace (2011) supports the fluid ethical model suggested by Stassi (2011). The design of mass incident treatment models depends on the surge capacity and surge capabilities of the local or regional healthcare network. Surge capacity is the ability to “care for a markedly increased volume of patients—one that challenges or exceeds normal operating capacity.” Surge capability is the “ability to manage patients requiring unusual or very specialized medical evaluation and care.”

Surge planning requires the acceptance that the duration of a surge is unknown and can last for weeks or months rather than simply days. It also requires accepting that surge patients will be in addition to non-surge-related patients. Babies are born during surge events, people get cancer and pneumonia, and this population is as deserving of treatment as surge patients. It requires planning to manage as much as is possible to manage during a surge incident.

Ali (2011) notes that different types of mass-casualty events may require different standards of care since the characteristics of a surge will vary by the type of initial incident. The 2009 H1N1 pandemic created a different surge pattern than the 2001 anthrax mailing, and both were different from Hurricane Katrina. The infrastructure damage during the H1N1 and anthrax incidents was nonexistent, while Hurricane Katrina destroyed most infrastructures that could have negated the crises at Memorial Medical Center.

Different standards of care must be uniform at the local, regional, state, and federal levels. Response planning can only be coordinated if all players are following the same paradigms. Ali (2011) notes that there is no genuine coordination of ethics and triage on any level and that even states supporting situational practice, such as Louisiana, simply provide written guidelines and leave individual hospitals, clinics, and healthcare personnel to fend for themselves in creating hard guidelines for action.

The current state of mass-casualty event planning can best be described as a series of noncoordinated guidelines that may or may not extend into detailed scenario planning. Mass-casualty incident planning is often theoretical rather than practical, and most players remain unsure of their legal and ethical options to engage in contingency treatment standards during an emergency. The solution advocated by Dr. Pou—that the physician in the field should be the *arbiter mundi* of treatment standards and that whatever decisions are made should be absolutely protected by legal immunity—remains a solution that is unacceptable to most healthcare personnel. It amounts to extending to all physicians in a mass-casualty incident a blank check for behavior that may or may not be appropriate.

The problem is that contingent situations often require contingent decisions made in the midst of crisis. It is possible to create numerous contingency plans and to prepare medical personnel to utilize the menu of contingency plans as appropriate to each circumstance. However, there is also a reason the dictionary contains the words “unknown,” “unexpected,” and “surprise.” It is difficult to create oversight that can serve as a control mechanism for dangerous or inappropriate decisions and actions in certain types of emergency situations. In a pandemic there will remain open lines of communication for field personnel to remain in close and immediate contact with supervisors. In a Katrina-like situation communication may be highly difficult or nonexistent. Each situation can require different frameworks of decision making.

D. CONCLUSION

Providing blanket immunity to physicians and healthcare personnel in the field making life and death decisions during a mass-casualty incident is not a prudent solution to the problems posed by mass-casualty incidents. Blanket immunity eliminates accountability, and accountability must be present in some form, even if it exists as an after-the-fact examination of contingent decisions. The MSEHPA guidelines include the requirement that healthcare workers and physicians exercise appropriate diligence in executing emergency actions. The absence of a universal standard for emergency care in mass-casualty incidents significantly reduces the ability to gauge whether a physician in the field is exercising appropriate diligence.

The issue of appropriate standards for behavior in a mass-casualty incident is a vastly complicated one. There is no single solution in the traditional sense of the word. The intertwined nature of the multiple factors contributing to mass-casualty situations precludes the creation of a single specific application of guidelines. What was appropriate for Memorial Medical Center during hurricane Katrina might be criminally negligent in a pandemic situation or in the aftermath of a terrorist attack.

Preparedness can only take players so far in preparing them for the many contingencies of a real mass-casualty incident. It is possible to create models of available critical materials and likely casualty numbers and patterns of growth. It is possible to model various contingencies based on infrastructure integrity and communications accessibility, but actual disasters have a way of not always adhering to the plans created for dealing with them. The ultimate responsibility for actions in the field is with the personnel in the field.

The use of *disciplined* initiative is the only recourse available to health authorities. This places a tremendous responsibility on field personnel, but they are the ones dealing with the results of the crisis situation. It is the responsibility of commanders to prepare field personnel as much as possible to exercise their duties to care for all parties in a crisis. It must also be accepted that certain situations will occur that are not

covered by existing plans and that do not allow for field personnel to communicate with higher authorities to determine a course of action. This is the type of situation described in the USALFM, and the final resolution of the problem remains the choices made by personnel in the event.

The solution to creating standards of care for mass-casualty incidents is to nurture field personnel in ways that will allow them to make appropriate decisions as necessary. This does not mean providing personnel with blanket immunity and simply advising them to do their best in an emergency not applicable to existing plans. It means providing personnel with the knowledge sets to allow them to exercise initiative in appropriate ways. Planning is the key to supporting independent decision making. The presence of extensive contingency plans can act to define the type of situation where disciplined initiative must be applied. The threshold for disciplined initiative can be, ironically, a situation not covered by a contingency plan.

Careful planning can mitigate many of the issues that result in the creation of crisis situations requiring disciplined initiative. Communication alternatives can result in the field staff remaining in constant contact with higher authorities who can advise on sanctioned actions in mass-casualty incidents. The creation of transport contingency plans and material to prevent a recurrence of the Memorial Medical Center gridlock can prevent the type of circumstance that required physicians to engage in extreme reverse triage.

Since each type of crisis situation is unique, a wide array of contingency plans must be created to guide field personnel. However, exercises for situations not covered by plans must also be a part of the preparedness protocols. Every nuclear reactor in the United States is required by federal law to stage simulations of various crisis situations annually. There should be a similar mandate for medical personnel. Simulations will provide personnel with the opportunity to experience various scenarios that will test and shape their real-world decision-making processes. It is true that one can never prepare completely for the unknown, but it is possible to prepare somewhat for the unknown. Simulations will provide a key set of experiences for personnel to fall back on in a real mass-casualty event.

By preparing field personnel for the possible moment when disciplined initiative is required, the commander will have done all that he or she can do to prepare personnel to act independently in a crisis situation. The solution, then, is to properly train the right people to perform at their best in unexpected situations. Training is primarily composed of extensive contingency planning and simulated exercises designed to prepare field personnel for unexpected contingencies in a mass-casualty situation. This will establish a set of behaviors and actions that form a nexus for a standard of practice for crisis situations. It is not perfect, but it is the best approach possible at this time.

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V. FINDINGS, RECOMMENDATIONS, AND POLICY IMPLICATIONS

A. DISCUSSION

The purpose of this chapter is to outline and endorse explicit altered-standard-of-care policies that research demonstrates should be used by interdisciplinary agencies to develop all-hazards (pandemic, WMD, disaster) mass-casualty response policies that are recommended to guide and support decision making during both preparation and response at the state, local (EMS, EMA), and facility (hospital) levels. Research indicates that by making altered-standard-of-care policies explicit and using them, the result is to increase trust and solidarity among all interdisciplinary stakeholders (IOM, 2006).

To this end, as discussed in the previous chapter, there must be a clear distinction between the mechanics of a process and the underlying ethical mandates for designing the process in the way it functions. The concerns with equity, social justice, and the prevention of criminal and civil liability to healthcare practitioners during a mass-casualty public-health disaster that experiences a surge of care demands must be applied to policies with caution. Too much rigidity will render policies useless when employed against a rapidly changing virus or bacteria. Policies that allow too great a degree of autonomy for healthcare providers risks eliminate the liability protections extended to providers. If providers believe that they are at risk of being retrospectively blamed for their individual decisions, they will not follow altered-standard-of-care protocols. Subsequently they will not follow the plan and make ineffective decisions, becoming subject to liability claims. In designing altered-standard-of-care policies, the unintended consequences paradigm must be avoided at all costs.

In the aftermath of the grand jury investigation of Anna Pou, the issue of altered standards of care and the allocation of resources to critical patients during a disaster situation where life-saving supplies are insufficient to meet all needs remains underresearched. Federal, state, and local specialists in disaster medicine planning appear to be either ignoring the issue or acknowledging the issue without providing any

trenchant commentary or devising altered-standard-of-care protocols to guide physicians, nurses, and other healthcare workers on how to alter standards of care. Policies issued by states, counties, and cities largely address the issue with silence, and there is an implicit “between the lines” assumption that careful planning and proactive strategies can avoid the possibility of any future crises like the one faced by Dr. Pou and nurses Cheri Landry and Lori Budo. More recently issued altered-standard-of-care protocols and drafts for protocols address the issue of liability more openly; this is a positive shift in guideline development.

The absence of any discussion regarding paradigms for altered standards of care and the allocation of scarce life-saving medicines and devices during a Katrina-like emergency resulting from natural disasters, pandemic outbreaks, or terrorist attacks involving biological or radioactive weapons suggests that the U.S. medical establishment is either very certain that actions similar to Pou’s will be either accepted by medical and legal communities or that careful planning will eliminate the possibility that altered standards of care and supply allocation crises will recur at all. In this sense the medical establishment throughout the United States personifies the proverb that “pride goeth before destruction and an haughty spirit before a fall” (*Proverbs* 16:18). Physicians regularly warn patients not to ignore symptoms and hope that a problem will simply disappear. Yet this is exactly what is being done with regard to altered standards of care in a disaster situation.

Research indicates policies for altered standards of care due to WMD disaster or mass-casualty events should be practical and feasible given available resources, evidence-based (supported by the best available medical and epidemiological evidence at the time), and concordant with federal guidance, insofar as federal guidance is concurrent with the best available medical and epidemiological knowledge. The underlying assumption of the federal guidance is that the key objectives of a WMD mass-casualty response are to minimize mortality, morbidity, and social disruption (Barbera and Macintyre, 2002).

Changes in the usual standards of the healthcare response will be required to achieve the goal of saving the most lives. It will be necessary to alter standards of care in order to allocate scarce medical resources in ways that can save as many lives as possible (Hawryluck, Lapinsky, and Stewart, 2005).

B. RECOMMENDATIONS

As demonstrated in the previous chapter, research indicates that there is a need to further develop interdisciplinary federal, state, territorial, local, and health-sector agency and institution protocols around the same key elements and components to ensure coordination, consistency, and implementation of altered standards of care during a WMD disaster or mass-casualty event. Based on the analysis of currently available federal, state, and local government altered-standard-of-care protocols, there is an urgent and clear need for a new single national guidance for altered standards of care that can be generalized to include ethically driven triggers, guaranteed minimums of care, and legal protection for all crisis events, including mass-casualty WMD events. In the absence of a specific national guidance, it is the intent to recommend that interdisciplinary healthcare stakeholders follow the general guidance provided in this document until such time as specific national guidance is published.

The term “altered standards of care” is defined as a substantial change in usual healthcare operations and the level of care it is possible to deliver, which is made necessary by a pervasive (e.g., pandemic influenza) or catastrophic (e.g., WMD, earthquake, hurricane) disaster. This change in the level of healthcare delivered is justified by specific circumstances and is formally declared by a state government, in recognition that crisis operations will be in effect for a sustained period (AHRQ, 2007). The formal declaration that altered standards of care are in operation enables specific legal/regulatory powers and protections for healthcare providers in the necessary tasks of allocating and using scarce medical resources and implementing alternate care facility operations.

Research indicated that an overarching ethical framework serves as the bedrock for public policy. There are many principles that can contribute to an ethical framework (Childress et al., 2002). The focus here is on a limited set of essential elements that reflect both core substantive ethical values and processes and that can serve as a model or a starting point for interdisciplinary deliberations for triggers, guaranteed care minimums, and legal protection.

The overarching ethical goal in developing crisis standard-of-care protocols for scarce medical resources is that the protocols be recognized as fair by all affected parties. All subsequent ethical considerations reflect an effort to achieve such fairness (University of Toronto, 2005). Interdisciplinary policy makers must seek to eliminate ways in which irrelevant factors such as class, race, ethnicity, neighborhood, or personal connections shift the burden of the WMD or disaster mass-casualty event toward vulnerable groups. By the same token, if particular groups receive favorable treatment, for instance in access to vaccines, this priority should stem from relevant factors (e.g., greater exposure or vulnerability) and should promote important community goals. Interdisciplinary policies should reflect awareness of existing disparities in access, take account of the needs of the most vulnerable, and support the equitable and just implementation of altered standards of care and the distribution of scarce goods and resources.

The implementation of altered standards of care based on evidence is one way to reflect the principle of fairness. Interdisciplinary planning for triggers, guaranteed care minimums, and legal protection must include advance ethical guidance (CDC, 2006).

The primary duty of an interdisciplinary professional is to the victim. This duty holds true during a WMD or disaster mass-casualty event, even when providing care entails some risk to the professionals (AMA, 2004). In crisis situations professionals cannot relinquish their obligations to individuals without sacrificing core professional values. Recognizing that altered standards of care and scarce medical resources may restrict treatment choices, professionals must not abandon victims, and victims should not fear abandonment when an ethical framework informs an altered-standard-of-care policy.

While professionals have a duty to care for victims, healthcare institutions have a reciprocal duty to support workers. Personal protective equipment, engineering controls, and a variety of mechanisms to reduce the risk of infection recognize the institutional obligation to protect workers who face risks in providing care (AMA, 2004). Various types of mass-casualty event disasters might call for other or additional protections to safeguard workers who face risks, including mental health risks, as they provide care to the community.

Healthcare institutions, public-safety responders, and public-health officials also have a duty to steward alternate care protocols, reflecting the utilitarian goal of saving the greatest possible number of lives. Professionals must balance this duty to the community against that to the individual victim. As the number of victims increases, accommodating the two competing duties of care and stewardship will require more difficult choices. There is no uniform answer about how to weigh such competing values. Addressing this balancing act under very difficult conditions, with the goal of making decisions that will be recognized as fair under the circumstances, makes it critical to establish ethical alternate-standard-of-care processes for decision making.

Interdisciplinary public entities charged with protecting communities during times when altered-standard-of-care protocols are in effect have profound responsibilities. They must draw on the best available research, collect and develop expert opinion, and draw attention to gaps in knowledge and resources needed to implement those protocols and protect the community. In addition to sound ethics, altered-standard-of-care policies must reflect specific values in choices about contested issues, such as priority setting for access to scarce resources and restrictions on individual choice. A public engagement process is crucial for drafting altered-standard-of-care policies that reflect the community's values and deserve its trust. The goal of effective community participation in disaster policy development and evaluation is insufficiently realized at this time (CDC, 2009). Given that any disaster can emerge before the completion of a robust process of public engagement, officials must strive to communicate clearly those plans currently in place and must also rely on real-time communication with communities and after-the-fact review.

As evidenced by research, a truly inclusive process will not rely only on input from professional groups and other organized stakeholders, but it will also incorporate the views of those who are less well represented in the political process but who may be greatly affected by altered-standard-of-care policy choices. Enlisting the public to discuss a future disaster when current stressors overwhelm many will prove challenging. Values that drive altered-standard-of-care policy should be explicitly stated so that communities can articulate, examine, affirm or reject, and modify proposed choices.

Transparency also implies candor in communication about disasters and the implementation of alerted standards of care, from clinicians to patients and throughout all levels of the healthcare system. Limitation of choice for both patients and providers is a reality of a WMD or disaster mass-casualty event and will affect many aspects of healthcare delivery. Professionals and victims will have fewer treatment options. Evidence-based criteria, rather than victim preference or clinical judgment, will determine access to the most limited medical resources. Though victim autonomy is reduced by the circumstances of an event, victims still deserve clear information about available choices, respect for preferences within resource constraints, and empathic acknowledgment of the sometimes dire consequences of resource limitation.

Consistency in treating like groups alike is one way of promoting fairness. The public may find that, due to altered standards of care being implemented, scarce medical resources have not been allocated fairly if victims at different hospitals in the same affected area receive vastly different levels of care. However, efforts to keep altered-standard-of-care policies consistent across institutions or geographic regions may limit local flexibility in implementing guidance.

Altered-standard-of-care policies for WMD and disaster mass-casualty events will include aspects that are burdensome to individuals and interdisciplinary professionals. Burdens such as the allocation of scarce resources, social distancing, school closures, or even quarantine should be necessary and commensurate with the scale of the WMD or disaster event. Those restrictions imposed must serve important public needs—such as the need to limit spread of an infectious agent—and must be appropriately limited in time and scale according to the scope and severity of the event.

C. CONCLUSION

Effective interdisciplinary altered-standard-of-care policy planning that includes ethically based triggers, guaranteed minimums of care, and legal protection for all mass casualty events including WMD and disasters is imperative and will require individuals at all levels to accept and act on their appropriate responsibilities. As part of their duties to respond and to ethically alter standards of care and steward scarce resources, individual professionals are responsible for a good-faith effort toward education of all parties concerned with the implementation of altered standards of care during a WMD or disaster mass-casualty event. Government entities are accountable to their communities to plan and implement altered-standard-of-care policies related to WMD or disaster events, and members of the community must know which interdisciplinary entities take responsibility for various elements of altered-standard-of-care policies. All decision makers should be accountable for a reasonable level of situational awareness and for incorporating evidence into decision making, including revising implementation decisions as new data emerge.

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