The National Center for the Study of Preparedness and Catastrophic Event Response

Crisis Standards of Care

4th Annual DHS University Network Summit

Agenda:

- Introduction
  Gabor D. Kelen, M.D., FACEP, FAAEM, FRCP(C)

- Crisis Standards of Care: Transition and Evolution of Planning
  Sally Phillips, RN, PhD

- Crisis Standards of Care: A Review of the IOM Report
  Dan Hanfling, MD

- Addressing the Operational Challenge: One Hospital's Experience
  Elizabeth Lee Daugherty, MD, MPH

- Crisis Standards of Care: Potential Legal Issues
  Darren P. Mareiniss, MD, JD

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Crisis Standards of Care:

Transition and Evolution of Planning

Sally Phillips, RN, PhD

Director, Public Health Emergency Preparedness Research
AHRQ

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Background

In the event of a catastrophic public health- or terrorism-related event, such as an influenza pandemic or the detonation of improvised nuclear devices, the resulting tens of thousands of victims will be likely to overwhelm the resources of a community's health care system. In this dire scenario, referred to as a mass casualty event (MCE), it will be necessary to ***allocate scarce resources in a manner that is different from usual circumstances but appropriate to the situation.*** Making optimal decisions concerning the allocation of scarce resources could make a big difference in the degree to which health care systems continue to function; ultimately it could mean saving many thousands of lives.

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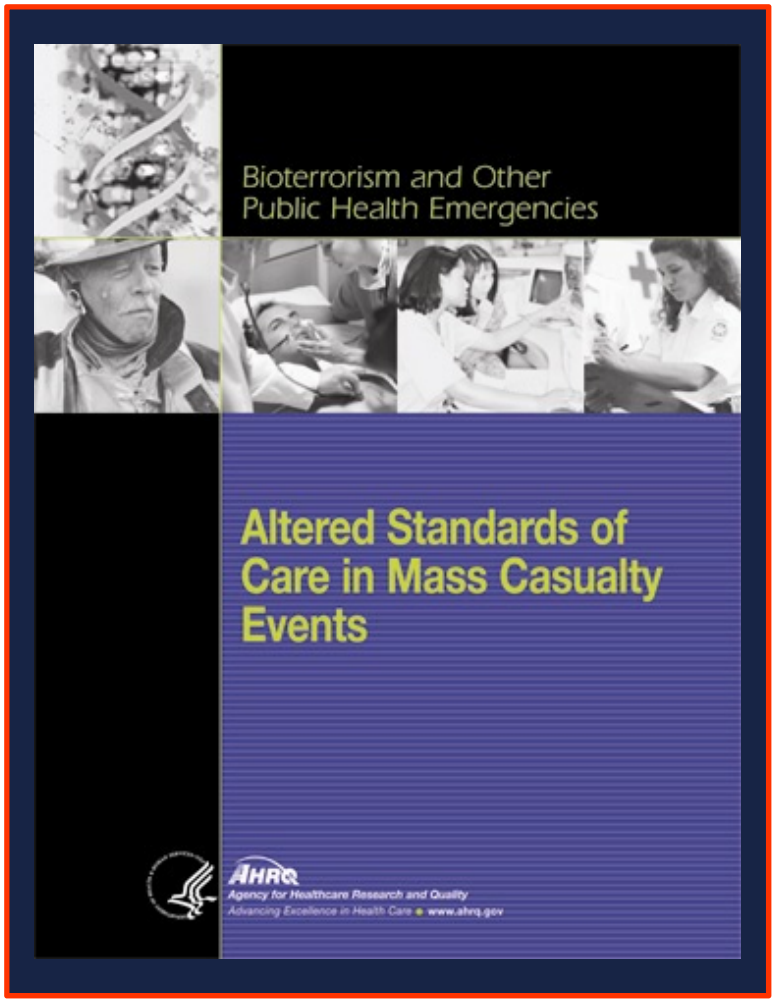
Altered Standards of Care in Mass Casualty Events

- Report offers guidelines for officials on how to plan for delivering health & medical care in mass casualty event
- Includes recommendations of an expert panel convened by HHS' AHRQ and the Office of Public Health Emergency Preparedness
- Available on the Web:2005



http://www.ahrq.gov/research/altstand/

Altered Standard of Care Recommendations

- Examine how current standards of care might need to be altered in a mass casualty situation
- Identify appropriate planning, guidance, and tools and related issues to ensure an effective health and medical care response
- Recommend specific action steps to address the needs of Federal, State, regional, community, and health systems planners
- Engaging the public to promote transparency of decisions and promote personal preparedness

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Duty to Plan

"Note that in an important ethical sense, entering a crisis standard of care mode is not optional – it is a forced choice, based on the emerging situation. Under such circumstances, failing to make substantive adjustments to care operations – i.e., not to adopt crisis standards of care – is very likely to result in greater death, injury or illness."

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Mass Medical Care with Scarce Resources

A Community Planning Guide (2007)

Collaboration between AHRQ and ASPR

- Ethical Considerations in Community Disaster Planning
- Assessing the Legal Environment
- Prehospital Care
- Hospital/Acute Care
- Alternative Care Sites
- Palliative Care
- Avian Influenza Pandemic Case Study

http://www.ahrq.gov/research/mce/

Ethical Principles

- Greatest good for greatest number
- Ethical process requires
  - Openness
  - Explicit decisions
  - Transparent reporting
  - Political accountability
- Difficult choices will have to be made; the better we plan the more ethically sound the choices will be

Legal Issues

- Advance planning and issue identification are essential, but not sufficient
- Legal Triage – planners should partner with legal community for planning and during disasters

PreHospital

- EMS considerations
  - Shift in scope of practice and protocols
  - Triage protocols and medical directives prescripted
  - EMAC and MOU agreements for resource sharing reexamined
  - Ambulance, Dispatch and transport regulations
  - Drug Caches- re: palliative care, pain management
  - Personal Protective Equipment

Incremental changes to standard of care

Usual patient care provided

Austere patient care provided

Low impact administration changes

High-impact clinical changes

Triage set up in lobby area	Significant reduction in documentation	Vital signs checked less regularly	Re-allocate ventilators due to shortage
Meals served by nonclinical staff	Significant changes in nurse/patient ratios	Deny care to those presenting to ED with minor symptoms	Significantly raise threshold for admission (chest pain with normal ECG goes home, etc.)
Nurse educators pulled to clinical duties	Use of non-healthcare workers to provide basic patient cares (bathing, assistance, feeding)	Stable ventilator patients managed on step-down beds	Use of non-healthcare workers to provide basic patient cares (bathing, assistance, feeding)
Disaster documentation forms used	Cancel most/all outpatient appointments and procedures	Minimal lab and x-ray testing	Allocate limited antivirals to select patients

Need increasingly exceeds resources

Alternative Care Sites

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Mass Casualty Response: Alternate Care Site Selector (2004)

- Tool helps regional planners locate and rank potential alternative sites during a bioterrorism or other public health emergency
- Recommendations for staff, supplies and equipment are included as appendices
  - Levels of Caches
  - Selecting an Alternative Site
  - The Supplemental Oxygen Problem
  - Staffing an Alternative Site
- **http://www.ahrq.gov/research/altsites.htm**

Disaster Alternate Care Facilities: Report and Interactive Tools

The report and tools provide help for community planners

- Developing a "concept of operations" manual for a specific iteration of an ACF.
- Determining staffing for an ACF.
- Selecting hospital inpatients that might be eligible for transfer to an ACF.
- Determining equipment / supplies necessary for an ACF.

The two new interactive tools are ***Disaster Alternate Care Facility Selection Tool*** and an ancillary tool, ***Alternate Care Facility Patient Selection Tool***; both are available at http://www.ahrq.gov/prep/acfselection/. 2010

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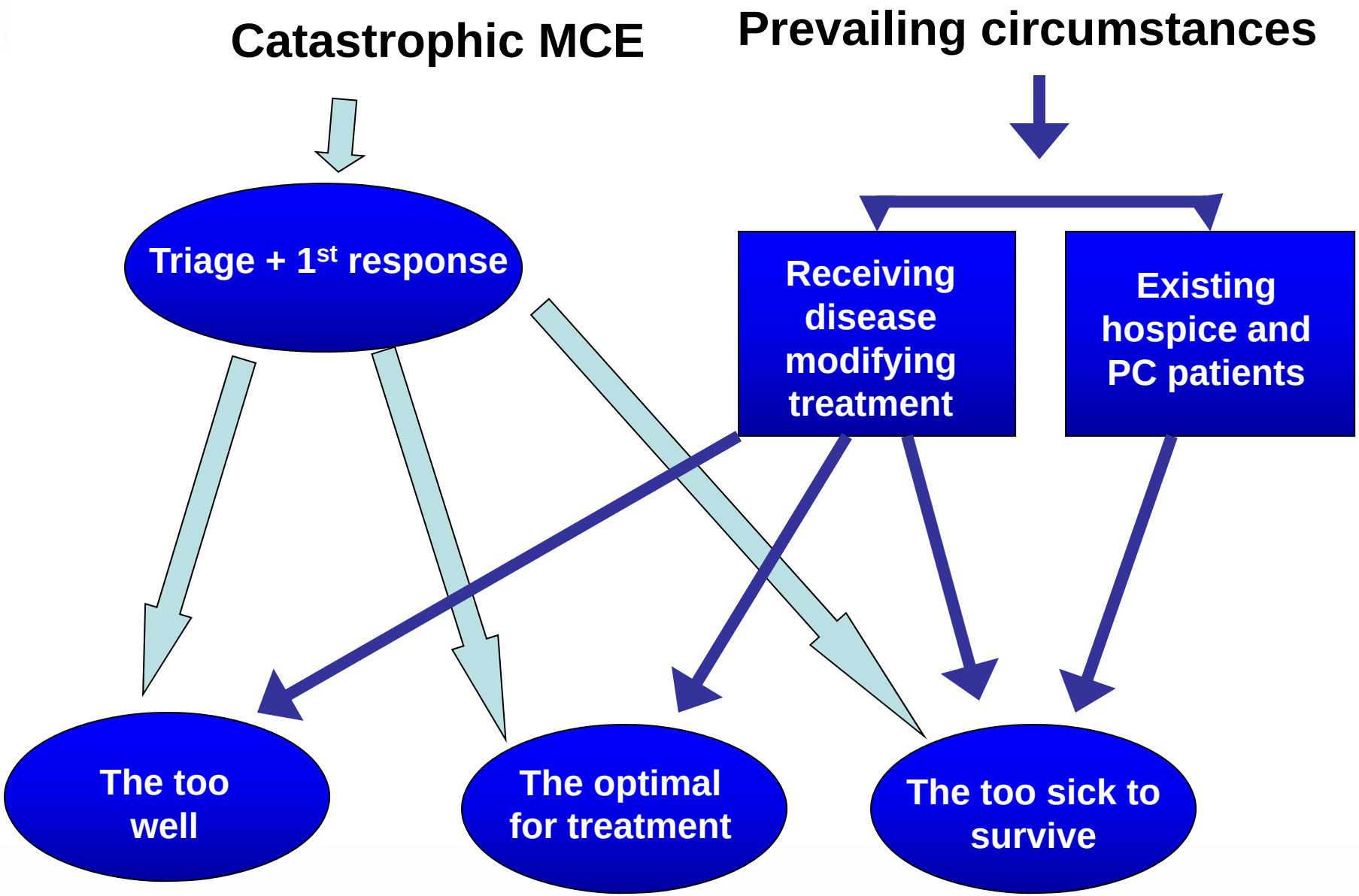
Catastrophic Mass Casualty Palliative Care

- Palliative Care is:
  - Evidence-based medical treatment
  - Vigorous care of pain and symptoms throughout illness
  - Care that patients want
- Palliative Care is not:
  - Abandonment
  - The same as hospice
  - Euthanasia
  - Hastening death


Catastrophic MCE
Prevailing circumstances
Triage + 1st response
Receiving disease modifying treatment
Existing hospice and PC patients
The too well
The optimal for treatment
The too sick to survive

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Catastrophic MCE and Large Volume

The too sick to survive *

Initially left in place

Then: **Transport** **Other than active treatment site**

*****

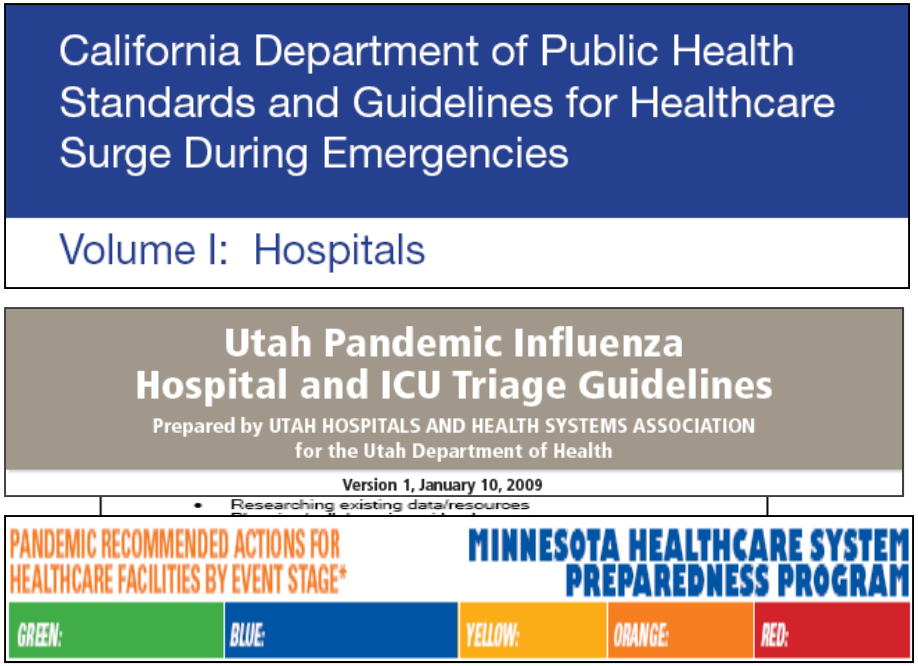
1. **Those exposed who will die over the course of weeks**
2. **Already existing palliative care population**
3. **Vulnerable population who become palliative care due to scarcity**

Introduction – Framing the Problem

- **Consider the scenarios**
  - Pandemic
  - Bioterrorism
  - Natural disaster/catastrophes
- **Regional IOM workshop descriptions**
  - Participants
  - Locations
  - Agenda
  - Goals
  - Outcomes

Crisis Standards of Care Protocol Development

- Who makes the plan?
  - Nurses
  - Physician assistants
  - Physicians
  - Pharmacists
  - Administrators
  - Morticians
  - Academia
  - Government
  - Many others



Surge Capacity Continuum of Care

NORTH DAKOTA'S EXAMPLE

- Stage 1: Small Outcome Impact
- Stage 2: Moderate Outcome Impact
- Stage 3: Severe Outcome Impact

BOX 4
Stages of Care in North Dakota's Plan

STAGE 1: SMALL OUTCOME IMPACT

- Tighter admission criteria
- Early discharge
- Eliminate comfort-care nursing
- Increase shift length
- Small increases in patient-to-provider ratio
- Eliminate dietary preference
- Limited post-mortem care
- Hospital access restriction
- Cohorting

STAGE II: MODERATE OUTCOME IMPACT

- Acute care remains at nursing homes
- Limitations in services, diagnostics
- Limited expansion of privileges
- Moderate increase in patient-to-provider ratio
- Provider recruitment (e.g., retired)
- Increased care by family members
- Decreased frequency of vital signs
- Changes in palliative care
- Changes in charting

STAGE III: SEVERE OUTCOME IMPACT

- Marked expansion in privileges
- Large increase in patient-to-provider ratio
- Use of volunteers for some patient care
- Family administration of meds
- Palliative threshold increase (low survival conditions)
- No cardiopulmonary resuscitation
- Clinical judgment replaces diagnostics
- Changes in informed consent requirements
- Minimal charting

Stakeholder - Provider Involvement and Engagement

- Those with a critical roles include
  - EMS
  - Physicians
  - Hospital officials
  - Nurses
- Engagement challenges cited
  - Time
  - Funding
  - Culture - resistant to crisis standards concepts

Public Engagement and Education

- Engagement challenges
  - Public is generally uneducated
  - History of distrust
- Changing the Culture of preparedness
  - Use awareness from recent disaster events
  - Include in educational curriculum
- Elected officials and media as allies

Developing Intra and Interstate Cooperation and Consistency

- Reasons for consistency
- Approaches by states
  - Massachusetts
  - Virginia
- Regional applications
  - FEMA Region 4
  - Capital region's "All-hazards" consortium
  - Interstate Disaster Medical Cooperative
  - Village-to-Village Communication

Clinical Operations - Components

- Indicators
- Triggers
- Triage
- Alternate care facilities
- EMS, community health & other components
- Resource availability and distribution
- Pediatrics and other “at risk” populations
- Palliative care
- Mental health
- Training

Conclusions

- Four Regional Workshops
- Highlighted work ongoing around the nation
- More work needed for
  - Palliative care planning
  - Mental/behavioral health
  - Vulnerable populations
  - Public and provider engagement
  - Consistency
- How far do we go?

http://www.ahrq.gov/prep/

Publications & Tools

- To order a copy of reports, tools, or resources:
  - contact the AHRQ Publications Clearinghouse at 800-358-9295
  - Send an E-mail to ahrqpubs@ahrq.hhs.gov.

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Crisis Standards of Care:
A Review of the IOM Report

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The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JUNE 18, 2009 VOL. 360 NO. 25

Emergence of a Novel Swine-Origin Influenza A (H1N1) Virus in Humans

Novel Swine-Origin Influenza A (H1N1) Virus Investigation Team*


Newsweek
THE CASE FOR
KILLING
GRANNY
CURBING EXCESSIVE END-OF-LIFE CARE
IS GOOD FOR AMERICA

Driving Considerations

- Which patients should receive limited resources, and who decides?
- Should professional standards of care change? And what are the indicators leading to such change? What are the triggers for implementation?
- Should the law grant civil or criminal immunity to professionals acting in good faith?

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

September 24, 2009

Nicole Lurie, M.D., M.S.P.H.
Assistant Secretary for Preparedness
and Response
Office of the Assistant Secretary for
Preparedness and Response
Department of Health and Human Services
200 Independence Ave., S.W.
Washington, DC 20201

Dear Dr. Lurie:

On behalf of the Institute of Medicine (IOM) Committee on Guidance for Establishing Standards of Care for Use in Disaster Situations, we are pleased to report our conclusions and recommendations. At the request of the Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services, the IOM convened this committee to develop guidance that state and local public health officials and health-sector agencies and institutions can use to establish and implement standards of care that should apply in disaster situations—

Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations

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When To Adopt Crisis Standards of Care?

- severe shortages of equipment, supplies, and pharmaceuticals
- an insufficient number of qualified healthcare providers
- overwhelming demand for services
- lack of suitable resources

Under these circumstances, it may be impossible to provide care according to the conventional standards of care used in non-disaster situations, and, under the most extreme circumstances, it may not even be possible to provide the most basic life-sustaining interventions to all patients who need them.

Crisis Standards of Care

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., earthquake, hurricane) disaster.

Crisis Standards of Care

This change in the level of care 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.

Crisis Standards of Care

The formal declaration that crisis 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.

Key Elements of Crisis Standards of Care Protocols	**Components**
Ethical considerations	o Fairness o Duty to care o Duty to steward resources o Transparency o Consistency o Proportionality o Accountability
Community and provider engagement, education, and communication	o Community stakeholder identification with delineation of roles and involvement with attention to vulnerable populations o Community trust and assurance of fairness and transparency in processes developed o Community cultural values and boundaries o Continuum of community education and trust building o Crisis risk communication strategies and situational awareness o Continuum of resilience building and mental health triage o Palliative care education for stakeholders

Key Elements of Crisis Standards of Care Protocols	**Components**

Legal authority and environment	○ Medical and legal standards of care
	○ Scope of practice for healthcare professionals
	○ Mutual aid agreements to facilitate resource allocation
	○ Federal, state, and local declarations of:
	  ○ Emergency
	  ○ Disaster
	  ○ Public health emergency
	○ Special emergency protections (e.g., PREP Act, Section 1135 waivers of sanctions under EMTALA and HIPAA Privacy Rule)
	○ Licensing and credentialing
	○ Medical malpractice
	○ Liability risks (civil, criminal, Constitutional)
	○ Statutory, regulatory, and common-law liability protections

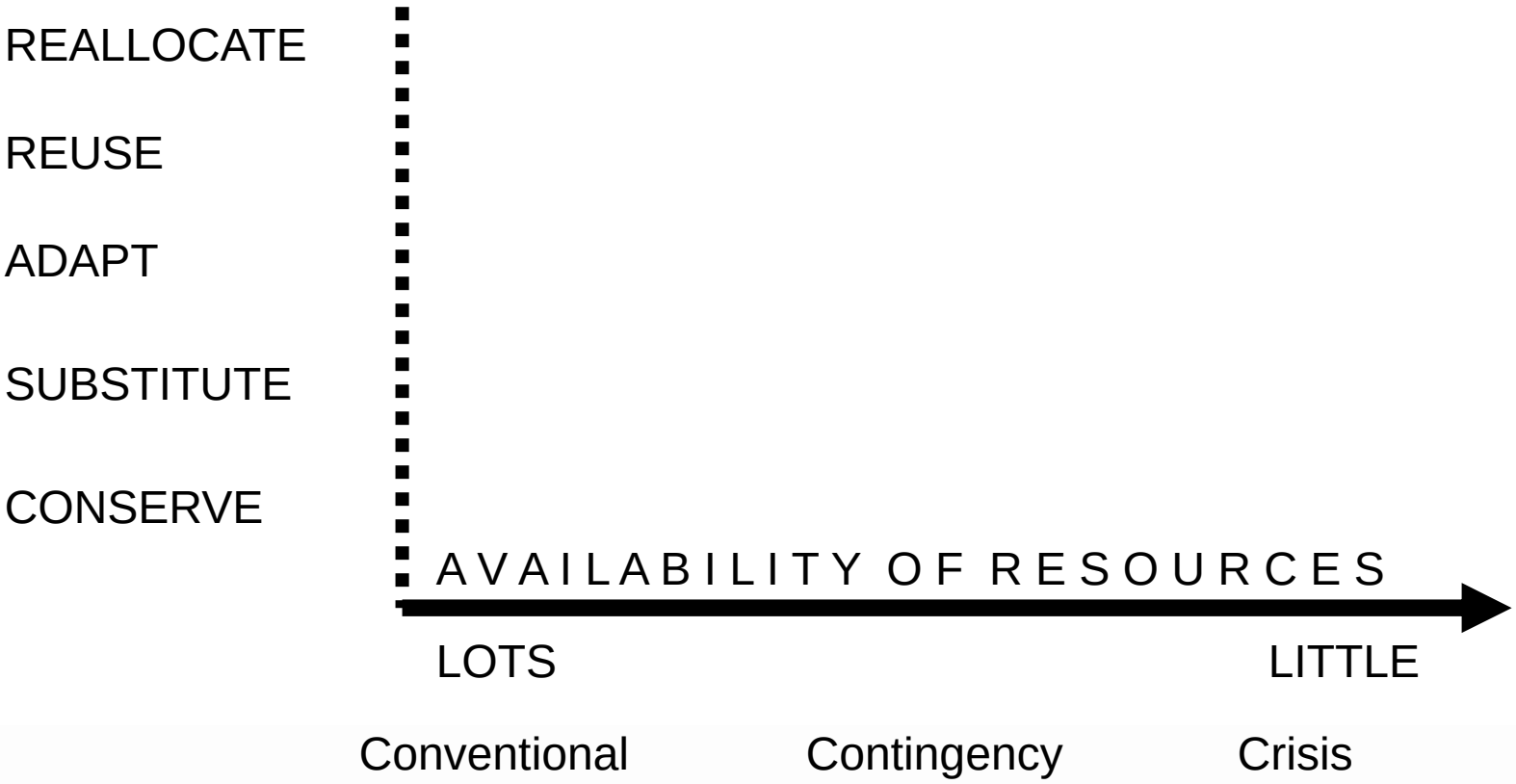
Key Elements of Crisis Standards of Care Protocols	**Components**
Indicators and triggers	Indicators for assessment and potential management ○ Situational awareness (local/regional, state, national) ○ Event specific ○ Illness and injury—incidence and severity ○ Disruption of social and community functioning ○ Resource availability Triggers for action ○ Critical infrastructure disruption ○ Failure of "contingency" surge capacity (resource-sparing strategies overwhelmed) ○ Human resource/staffing availability ○ Material resource availability ○ Patient care space availability

Key Elements of Crisis Standards of Care Protocols	**Components**
Clinical process and operations	Local/regional and state government processes to include: o State-level “disaster medical advisory committee” and local “Clinical care committees” and “triage teams.” o Resource-sparing strategies o Incident management (NIMS/HICS) principles o Intrastate and interstate regional consistencies in the application of crisis standards of care o Coordination of resource management o Specific attention to vulnerable populations and those with medical special needs o Communications strategies o Coordination extends through all elements of the health system, including public health, emergency medical services, long-term care, primary care, and home care Clinical operations based on crisis surge response plan: o Decision support tool to triage life-sustaining interventions o Palliative care principles o Mental health needs and promotion of resilience

THE CONTINUUM OF CARE: CONVENTIONAL, CONTINGENCY AND CRISIS

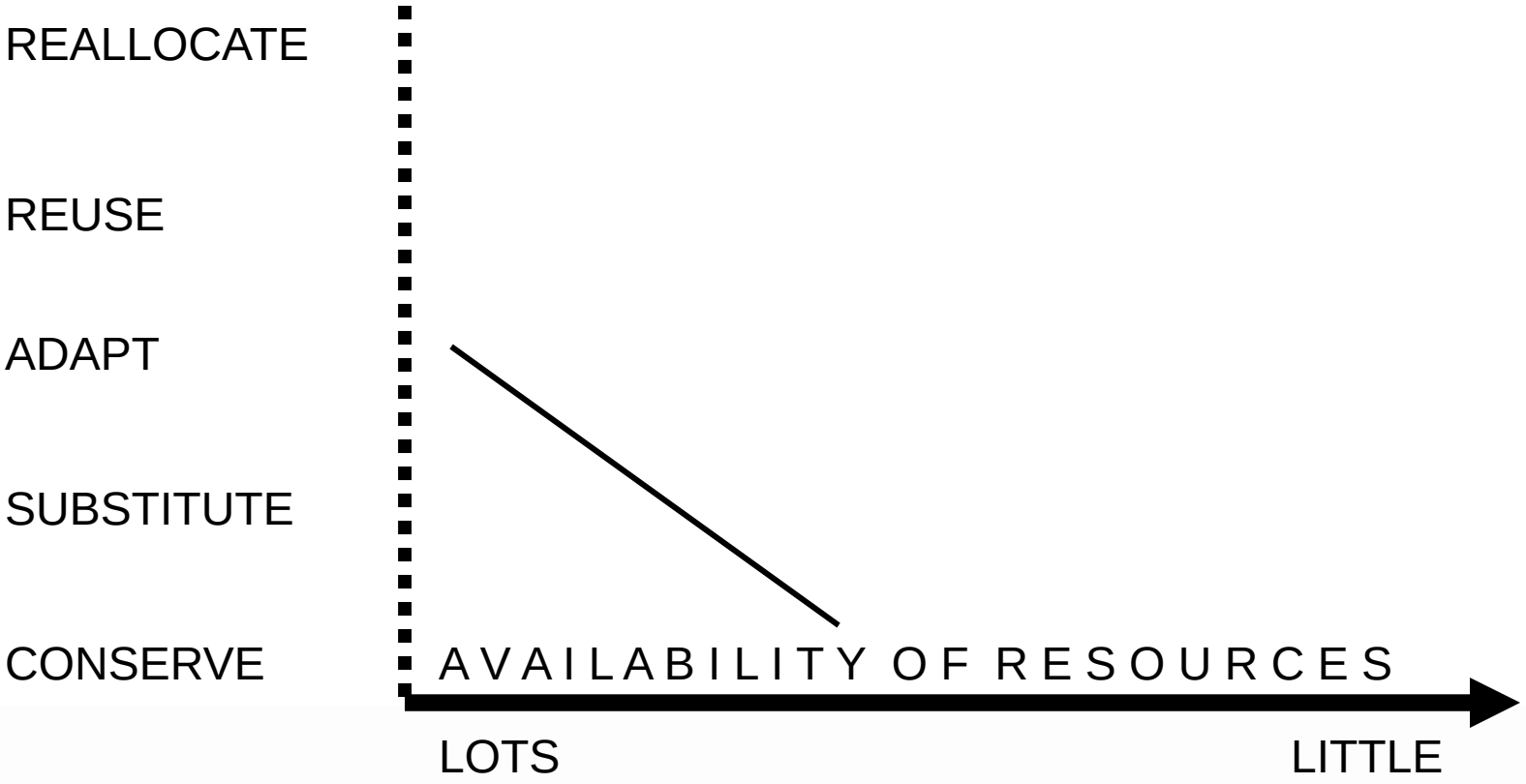
	Altered Standard of Care	Resource Constrained	Practicing Outside Experience	Focus of Care
Conventional	No	No	No	*Patient*
Contingency	Slightly	Slightly	No	*Patient*
Crisis	Yes	Yes	Yes	*Population*

WHAT TO 'EFFECT' WHEN YOU ARE EXPECTING (the worst)



SIR…..WE HAVE A PROBLEM

Conventional Capacity/ Standard of Care



VANISHING RESOURCES

Contingency Capacity/Standard of Care

THERE ARE NO MORE…….

Crisis Capacity/Standard of Care

Incident demand / resource imbalance increases →
Risk of morbidity / mortality to patient increases →
← Recovery

	Conventional	Contingency	Crisis
Space	Usual patient care space fully utilized	Patient care areas re-purposed (PACU, monitored units for ICU-level care)	Facility damaged / unsafe or non-patient care areas (classrooms, etc) used for patient care
Staff	Usual staff called in and utilized	Staff extension (brief deferrals of non-emergent service, supervision of broader group of patients, change in responsibilities, documentation, etc)	Trained staff unavailable or unable to adequately cae for volume of patients even with extension techniques
Supplies	Cached and usual supplies used	Conservation, adaptation, and substitution of supplies with occasional re-use of select supplies	Critical supplies lacking, possible re-allocation of life-sustaining resources
Standard of care	Usual care	Functionally equivalent care	Crisis standards of care[1]

Usual operating conditions

Indicator: potential for crisis standards[2]

Trigger: crisis standards of care[3]

Austere operating conditions

1) Unless temporary, requires state empowerment, clinical guidance, and protection for triage decisions and authorization for alternate care sites / techniques. Once situational awareness achieved, triage decisions should be as systematic and integrated into institutional process, review, and documentation as possible.
2) Institutions consider impact on the community of resource utilization (consider 'greatest good' vs. individual patient needs – for example, conserve resources when possible) but patient-centered decision-making is still the focus
3) Institutions (and providers) must make triage decisions balancing the availability of resources to others and the individual patient's needs – shift to community-centered decision-making

IOM Letter Report, September 2009

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Crisis Standards of Care
Addressing the Operational Challenge: One Hospital's Experience

Elizabeth Lee Daugherty, MD, MPH
Medical Control Chief
Office of Emergency Management
Johns Hopkins Hospital and School of Medicine

Usual capacity

- U.S.
  - 87-88,000 non-federal critical care beds
  - 65-80% occupancy
- The Johns Hopkins Hospital
  - 100 critical care beds
  - Variable occupancy – higher than national average

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The challenge

Table 1. Number of Episodes of Illness, Healthcare Utilization, and Death Associated with Moderate and Severe Pandemic Influenza Scenarios*

Characteristic	Moderate (1958/68-like)	Severe (1918-like)
Illness	90 million (30%)	90 million (30%)
Outpatient medical care	45 million (50%)	45 million (50%)
Hospitalization	865,000	9,900,000
ICU care	128,750	1,485,000
Mechanical ventilation	64,875	742,500
Deaths	209,000	1,903,000

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

HHS Pandemic Influenza Plan. U.S. Department of Health & Human Services . 2005.

Chlorine Tanker Explosion

Casualties	17,500 fatalities; 10,000 severe injuries; 100,000 hospitalizations
Infrastructure Damage	In immediate explosions areas, and metal corrosion in areas of heavy exposure
Evacuations/Displaced Persons	100,000 instructed to temporarily shelter-in-place as plume moves across region 50,000 evacuated to shelters in safe areas 500,000 self-evacuate out of region
Contamination	Primarily at explosion site, and if waterways are impacted
Economic Impact	Millions of dollars
Potential for Multiple Events	Yes
Recovery Timeline	Weeks

CHEST Supplement

DEFINITIVE CARE FOR THE CRITICALLY ILL DURING A DISASTER

Summary of Suggestions From the Task Force for Mass Critical Care Summit, January 26–27, 2007*

Asha Devereaux, MD; Michael D. Christian, MD, FRCPC; Jeffrey R. Dichter, MD; James A. Geiling, MD, FCCP; Lewis Rubinson, MD, PhD†

Chest Recommendations

- Capability
  - Provide EMCC at 300% baseline capacity
  - Deliver EMCC independently for 10 days
- Therapeutics and interventions
  - Mechanical ventilation
  - Pressors and fluids
  - Sedation and analgesia
  - 30% additional disposable equipment

SURGE CAPABILITY

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Core Issues

- Bed Capacity
  - Space
  - Infrastructure
- Staffing
- Equipment

Maximizing Baseline Capacity

- Beds
  - Utilization of fully capable alternate space
  - Cancelling procedures
  - Repurposing alternate space
- Staffing
  - Overtime
  - Recalling staff from vacation and leave
  - Agency staffing
- Equipment

Emergency Mass Critical Care

- Modifications
  - Spectrum of critical care interventions
  - Staffing
  - Medical equipment
  - Triage
- Goal: provide core set of interventions to as many critically ill patients as possible

Crisis Standards of Care

- Space
  - Repurposing non-critical care space
- Staffing
  - Tiered models
  - Pre-event and just-in-time training
- Equipment
  - Repurposing equipment
  - Accessing stockpiles

ALLOCATION OF SCARCE RESOURCES

Taking it to the next level

Allocation of Scarce Resources

- Framework
- Implementation Plan

Building a Framework

- Assessment of Ethical Principles
- Exclusion Criteria
- Multi-Principle Strategy

Ethical Principles

- Maximizing Life-Years
- Life-Cycle Principle
- Broad Social Value
- Instrumental Value

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Exclusion Criteria

Table 6—*Exclusion Criteria*

1. SOFA score criteria: patients excluded from critical care if risk of hospital mortality ≥ 80%
   - A. SOFA > 15
   - B. SOFA > 5 for ≥ 5 d, and with flat or rising trend
   - C. ≥ 6 organ failures
2. Severe, chronic disease with a short life expectancy
   - A. Severe trauma
   - B. Severe burns on patient with any two of the following:
     - i. Age > 60 yr
     - ii. > 40% of total body surface area affected
     - iii. Inhalational injury
   - C. Cardiac arrest
     - i. Unwitnessed cardiac arrest
     - ii. Witnessed cardiac arrest, not responsive to electrical therapy (defibrillation or pacing)
     - iii. Recurrent cardiac arrest
   - D. Severe baseline cognitive impairment
   - E. Advanced untreatable neuromuscular disease
   - F. Metastatic malignant disease
   - G. Advanced and irreversible neurologic event or condition
   - H. End-stage organ failure meeting the following criteria:
     - i. Heart
       - a. New York Heart Association class III or IV heart failure
     - ii. Lungs
       - a. COPD with FEV_1 < 25% predicted, baseline PaO_2 <55 mm Hg, or secondary pulmonary hypertension
       - b. Cystic fibrosis with postbronchodilator FEV_1 < 30% or baseline PaO_2 < 55 mm Hg
       - c. Pulmonary fibrosis with vital capacity or total lung capacity < 60% of predicted, baseline PaO_2 < 55 mm Hg, or secondary pulmonary hypertension
       - d. Primary pulmonary hypertension with New York Heart Association class III or IV heart failure, right atrial pressure > 10 mm Hg, or mean pulmonary arterial pressure > 50 mm Hg
     - iii. Liver
       - a. Child-Pugh score ≥ 7
   - I. Age > 85 yr
   - J. Elective palliative surgery

Deveraux et al, Chest , 133: 5, May 2008, Supplement

Table 3. **Illustration of a Multiprinciple Strategy to Allocate Ventilators During a Public Health Emergency**

Principle	Specification	Point System*			
		1	2	3	4
Save the most lives	Prognosis for short-term survival (SOFA score)	SOFA score <6	SOFA score, 6–9	SOFA score, 10–12	SOFA score >12
Save the most life-years	Prognosis for long-term survival (medical assessment of comorbid conditions)	No comorbid conditions that limit long-term survival	Minor comorbid conditions with small impact on long-term survival	Major comorbid conditions with substantial impact on long-term survival	Severe comorbid conditions; death likely within 1 year
Life-cycle principle†	Prioritize those who have had the least chance to live through life's stages (age in years)	Age 12–40 y	Age 41–60 y	Age 61–74 y	Age ≥75 y

SOFA = Sequential Organ Failure Assessment.
* Persons with the lowest cumulative score would be given the highest priority to receive mechanical ventilation and critical care services.
† Pediatric patients may need to be considered separately, because their small size may require the use of different mechanical ventilators and personnel.

White et al, Annals of Internal Medicine, 150: 2, 20 January 2009

Implementation Plan

- Triggers
- Decision Makers
- Team Structure and Function
- Review Committee
- Community Engagement
- Liability Protection

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Crisis Standards of Care and Potential Legal Issues

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Crisis Standards of Care and Potential Legal Issues

- Public health powers
- Liability concerns
- Criminal and civil liability
- Protections
- Gaps and suggested solutions

Federal – Public Health Powers

- ESF # 8 resources can be activated (1) by declaration of a public health emergency by Secretary of DHHS; (2) under the Biological Incident Annex; or (3) under the Stafford Act
- NIH, CDC, SNS, US Public Health Service, NDMS
- The support of state, local and tribal jurisdictions focuses on:
  - Assessment of public health/medical needs
  - Public health surveillance
  - Medical care personnel
  - Medical equipment and supplies

Federal – Public Health Service Act

- After consulting with such public health authorities "as may be necessary," the DHHS Secretary finds:
  - "(1) a disease or disorder presents a public health emergency; or
  - (2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists"

Public Health Service Act

- PHS Act during an emergency:
  - Isolation and quarantine – entry into the US or movement between states
  - Utilize the Strategic National Stockpile
  - Waive federal regulations – allow use of unapproved drug, biologic or device for a military emergency, domestic emergency or during a declared emergency
  - Waiver of individual participation requirements of Medicare/Medicaid, actions under EMTALA, and sanctions for HIPAA privacy violations

Section 1135 Social Security Act

State Public Health Powers

- Safeguarding public health falls largely to the states under their police powers

  U.S. Const. Amend. X.

- *Jacobson v. Massachusetts*, 197 U.S. 11, 29 (1905)
  - "[I]n every well-ordered society charged with the duty of conserving the safety of its members the rights of the individual in respect of his liberty may at times, under the pressure of great danger, be subjected to such restraints, to be enforced by reasonable regulations, as the safety of the general public may demand"
  - Finding that a Massachusetts statute requiring vaccination was constitutional

State Public Health Emergency

- A public health emergency is an occurrence or imminent threat of an illness or health condition that:
- (1) is believed to be caused by the following:
  - (i) bioterrorism;
  - (ii) the appearance of a novel or previously controlled eradicated infectious agent or biological toxin;
  - (iii) [natural disaster];
  - (iv) [chemical attack or accidental release]; or
  - (v) [nuclear attack or accident]; and
- (2) poses a high probability of any of the following harms
  - (i) a large number of deaths in the affected population;
  - (ii) a large number of serious or long-term disabilities in the affected population; or
  - (iii) widespread exposure to an infectious or toxic agent that poses a significant risk of substantial future harm to a large number of people in the affected population.

The Model State Emergency Health Powers Act

- Creates broad public health powers for a Public Health Authority including:
  - Creation of a public health emergency plan – § 201
  - Reporting and tracking of persons – § 301-303
  - Closure, evacuation, decontamination of any facility and decontamination or destruction of any material – § 302
  - Declaration of emergency and mobilization of the state militia/National Guard – § 401-405
  - Close, decontaminate and/or control/manage any facility; possess immediately any medical supplies reasonably necessary – § 501-506
  - Isolation or quarantine, vaccination and examination of any individual; require the participation of any health care providers in the state – § 601-608
  - Public information – § 701
  - Compensation for takings/immunity from liability – § 801-808

Liability Concerns – AHRQ Report

- Determine the authority and trigger to activate altered care
- Address liability for providers utilizing different care strategies and operating outside the scope of typical practice
- Licensing issues

Liability Concerns

- 2008 GAO – States had not begun guidelines b/c of difficulty addressing the medical, ethical and legal issues
- 2010 IOM report – publicly-available protocols – CA, CO, MA, MN, NY, UT, VA and WA
- 2008 Devereaux et al – ICU triage – model for CO, MN, UT and VHA

Liability Concerns

- 2006 American Public Health Association Survey
- 1,077 of 10,000 responded
- Individuals in clinical practice – 27.3% (294) of responding individuals
- How important is immunity from civil lawsuits in deciding whether to volunteer during an emergency?
  - **69.4%** essential or important
  - 25% somewhat important
  - 5.5% not important

Civil Liability

- Negligence: (1) duty; (2) breach because of a failure to meet the applicable standard of care; (3) harm; and (4) causal link between the breach and the harm
- "Standard of care is defined by reference to a physician using the knowledge, skill and care ordinarily possessed and employed by members of the profession in good standing, good medical practice within the area of specialty practice and reasonable, customary and accepted care under the circumstances"
- Vicarious liability
- EMTALA, HIPAA, privacy & confidentiality

Civil Liability

- Titles II and III (public accommodation) of ADA prohibit disability-based discrimination
  - Title III – private right of action
  - Do not need to accommodate if doing so would be an “undue hardship”
- Constitutional claims:
  - Depriving life, liberty or property without due process
  - Violation of body integrity
  - Illegal search and seizure
  - Equal protection violations

Criminal Liability

- Criminally negligent manslaughter – omission to act when there is a duty to do so, or a failure to perform a duty owed, which leads to a death
- Murder – unlawful killing of another person with intent or malice aforethought
- Memorial Medical Center, New Orleans – 7th Floor, LifeCare, Acute Long Term Care Unit
  - Dr. Anna Pou was arrested in July 2006 and charged with the murder of 4 patients
  - Administered morphine and versed to patients on September 1, 2005

Protections – State Laws

- 50 state jurisdictions have a variety of laws regarding immunity
- Good Samaritan laws – uncompensated & at the scene
- Protections usually do not apply to:
  - Willful or reckless conduct
  - Gross negligence
  - Criminal action

Protections – Emergency Management Assistance Compact

- Enacted in all states
- Triggered by gubernatorial declaration of disaster and a request for aid
- Provides licensing reciprocity
- Civil immunity to any "party state or its officers or employees" offering aid to another state – shall not be liable for an act or omission in good faith
- Does not cover willful misconduct, gross negligence or recklessness

Protections – Volunteer Protection Act

- Uncompensated volunteers of NGO or government
- Must act within the scope of responsibilities
- Properly licensed and authorized by the state
- Emergency does not need to be declared
- Does not cover willful or criminal misconduct, gross negligence or reckless misconduct

Protections – Uniform Emergency Volunteer Health Practitioner Act

- Adopted – UT, CO, NM, ND, OK, AR, LA, IN, KY and TN
- Licensed health practitioners in a state where an emergency declaration is in effect
- Compensation may be allowed, but no pre-existing employment relationship
- Covers vicarious liability
- Does not cover willful, reckless, wanton, grossly negligent or criminal conduct

Protections – Model State Emergency Health Powers Act

- Adopted by 38 states and D.C. – created in 2001
- 804(b)(2) – 23 states
  - Any person who "renders assistance or advice at the request of the state or its subdivisions"
  - Does not include gross negligence or willful misconduct
- 608(b) – 13 states
  - Any out-of-state emergency health care provider appointed by the Public Health Authority is not liable
  - Except reckless disregard for the consequences so as to affect the life or health of the pt.

Protections – Public Readiness and Emergency Preparedness Act

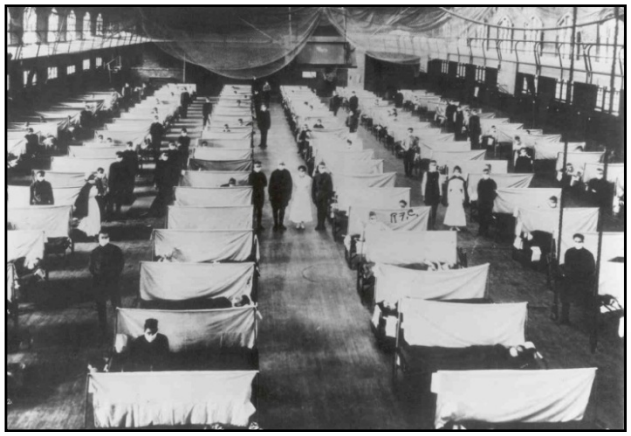
- DHHS Secretary declares a Public Health Emergency or one is likely to exist
- Shields manufacturers, distributors and dispensers of covered countermeasures from civil liability
- E.g., H1N1 vaccine – June 15, 2009
- Willful conduct is not covered

Sovereign Immunity

- Federal, state and local governmental entities and their employees are immune from tort suits
- Limited waivers of this immunity – e.g., FTCA, state TCAs
- However, discretionary functions within the scope of duties typically create immunity

Gaps – Individuals Not Covered

- Depends on state law
  - Providers continuing to work in an affected area
  - Providers acting outside the scope of their expertise may not be covered – some states allow, i.e., MI, MD and MA
  - Entities
  - Compensated providers



Gaps – Conduct Not Covered

- Criminal conduct – manslaughter & murder
- Gross negligence – an intentional failure to perform a manifest duty in reckless disregard of the consequences as affecting the life or property of another
- Willful misconduct – conscious intent to undertake the injurious activity with a realization of the likelihood of harm

Gaps – 2010 IOM Report

- Crisis standards may involve re-allocating or not offering life-saving interventions

- "*When we willfully and knowingly withdraw or withhold life support, knowing there maybe a bad outcome, we tread that line of willful misconduct*."

  Cheryl Starling – California Dept. of Public Health

Two Potential Solutions

- Broader legislation providing immunity for:
  - Triage decisions involving life-saving interventions
  - Crisis standards of care and withholding/withdrawing treatment
  - Compensated providers in disaster zone
  - Care outside the scope of expertise – e.g., MI, MA, MD
  - Immunity for institutions providing care
- State or federally deputized triage officers – sovereign immunity for discretionary actions, regardless of willfulness

Virginia and Maryland-Broad

- Virginia - Va. Code Ann 8.01-225.02
  - No liability for any injury or wrongful death from delivery or withholding of health care when (1) a state or local emergency has been declared and (2) the emergency caused a lack of resources preventing healthcare providers from rendering standard care
- Maryland – MD Code Ann. Pub. Safety 14-3A-06
  - “[a] healthcare provider is immune from civil or criminal liability if the healthcare provider acts in good faith and under a catastrophic health emergency.”

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Crisis Standards of Care

Discussion…