

**Report to the
Committee on guidance for establishing standards of care for use in
disaster situations**

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Introduction

Guidance for Establishing Standards of Care for use in a Disaster or Pandemic

This paper was written at the request of the Institute of Medicine (IOM), as a result of a request from the Assistant Secretary of Preparedness and Response (ASPR) for recommendations regarding the standard of care during a disaster or pandemic. This paper is written to provide background information for the IOM committee charged with providing this guidance to ASPR.

The intent of this paper is to summarize the most important information available regarding altered standards of care in a disaster, particularly as it would apply to a potential influenza pandemic this coming year. The information sources used to write this paper include published and web based manuscripts, draft recommendations from States that have currently completed work to this level, other known resources, and the expert input from the authors. The objectives of this paper are two-fold:

1. Examine the key elements in existing standard of care protocols including the triggers employed to implement them, the indications for increasing surge capacity to the necessary degree, and the circumstances necessary for implementing allocation of scarce resource protocols. Though not directly requested for this project, we have also included standards for communication and coordination of care between hospitals and healthcare organizations, as they have an immediate and necessary relationship on the information required for implementing altered standards of care. We have also briefly addressed disaster financing, for in our experience this factor, too, has a direct and immediate potential impact on the care that may be delivered in a disaster.
2. The altered standards of care presented in this paper are in the context of the potential for a pandemic flu epidemic of H1N1 for this coming flu season, 2009-2010. Specifically, we have focused our recommendations on the most important issues that can be reasonably accomplished in the next 3-6 months, the time frame in which a pandemic flu caused by H1N1 could occur.

This paper was commissioned in early August to be completed and presented by September 1, 2009. There was an extensive review of all available resources in putting this paper together. Due to the focused nature of this project and relatively short time frame, many of these resources were not formally incorporated. The authors hope that we have not offended anyone if all relevant work was not included.

We hope that this background information on disaster altered standards of care will be valuable to the IOM committee members in their deliberation and recommendations to the Assistant Secretary of Preparedness and Response.

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**Executive Summary of Recommendations for
Guidance for Establishing Standards of Care for use in a Disaster or Pandemic**

Section One Recommendations: Communication and Coordination during a Pandemic, and Development of Healthcare Coalitions

1. Support, promote, and facilitate Healthcare Coalition development in all communities, especially those where one does not already exist.
2. Promote formation and definition of Healthcare Coalition official organizational agreements, governance, and leadership, if they do not already exist. These may need to be informal, as formal written agreements may not be practically completed in the compressed time frame of an upcoming flu season.
3. Promote and facilitate Healthcare Coalition (continued) development of defined communication standards and protocols, utilizing tools that include internet based programs, conference calls, phone contact, and any other available means.
4. Develop a database of common elements, including accurate and up to date information on the number and severity of cases, utilization and capacity (“staff, space, and stuff”), and other information crucial for situational awareness. The variables collected should be consistent from the regional level up to the national level and will contribute to the development of a common information picture.
5. Continue to promote and facilitate Healthcare Coalition familiarity and trust. Activities that may further this mission include:
 - a. Coalition partners meeting in person and sharing direct and reliable contact information. Experience has demonstrated that informal contacts are remarkably effective for developing communication links in the midst of a looming crisis, such as a pandemic.[5]
 - b. Organize committees and/or working groups composed of representatives from member organizations, with particular focus on hazard vulnerability analysis (HAV) for a pandemic.
 - c. Having local experts available for consultation, by defined communication vehicle(s) to other healthcare professionals in the coalition, and having regularly scheduled conference calls to update all involved. These were both recommended strategies learned from experience during the SARS epidemic.[6-8]
 - d. Consider developing support groups, or other support mechanisms, for healthcare professionals within the coalition. Again, previous experience with the SARS epidemic demonstrated that an epidemic creates circumstances that lead to damaged healthcare provider morale.[6-8]
6. At the individual hospital level, continue to promote hospital based preparedness
 - a. But also encourage the integration of effective communication and planning with their coalition partners

Section Two Recommendations: Triggers and Supports for Altered Standards of Care in a Pandemic

1. The earliest potential trigger for activating ASC's is a large or rapidly rising number of hospitalized H1N1 flu cases. It is acknowledged that the timing of this decision is difficult to precisely define, and a specific recommendation regarding the number of cases cannot be offered. However, in order to facilitate the greatest beneficial impact of altered standards of care, particularly surge strategies (see next section), ASC's should be initiated at the *earliest* point where there is evidence of the healthcare system potentially becoming overwhelmed, and likely (hopefully) before any hospital is yet overwhelmed. Each local community may be affected differently, and initiation of altered standards of care may be implemented by region, as/when/if needed.
2. We strongly recommend that a "hard" ASC regional activation trigger during a pandemic be when one hospital either declares an "internal disaster" (as described above) *or* goes on "ER divert status," or otherwise determines that it has insufficient resources to provide routine care without moving to an altered standards of care status. When even one hospital is overwhelmed with flu cases to this point, all regional coalition hospitals are presumed to be at imminent risk.
 - a. Under these conditions, a further recommendation is that individual hospitals be authorized to implement altered standards of care internally for a limited time of no more than 24 hours, unless further authorization is received from a jurisdictional government.
3. When either of the above conditions is met, we recommend that government leadership at the federal, state, and local levels declare a healthcare emergency at the earliest appropriate time, in order to facilitate and support the healthcare systems' efforts to provide the most amount of care to the greatest number of patients.
4. Develop a database of common elements, including accurate and up to date information on the number and severity of cases, utilization and capacity ("staff, space, and stuff"), and other information crucial for situational awareness. The variables collected should be consistent from the regional level up to the national level and will contribute to the development of a common information picture.
5. Healthcare Providers should be protected from professional or legal consequences when providing care in good faith during a declared state of public health emergency.
 - a. Additionally, there should be attempts at providing emergency credentialing and providing legal protections for health care professionals from other states, the District of Columbia, or Canada to provide care in affected states.
6. The trigger for terminating altered standards of care would be when all hospitals in a regional coalition or region are able to provide normal care to all patients with usual resources, and no longer require altered standards of care. Government issued emergency declarations should also be discontinued at this time. This de-escalation can also be accomplished step-wise regionally, as

appropriate. Similar to initiation of altered standards of care, a specific termination trigger is difficult to define, and no corresponding specific recommendation is offered.

Section Three Recommendations: Surge Capacity & Response Strategies

The recommendations in this section are being will be presented first with a general recommendation and subsequently, where appropriate, specific targeted aspects will be outlined.

1) Any initiatives put forth by the committee must recognize the nature of surge as a continuum from common minor daily events through to rare overwhelming events. Thus, communities coalitions should develop systems for moderate and major surges (such as H1N1) which build upon the process and systems used to address minor surge. Stand alone systems should be avoided.

2) Health care coalitions should have a central committee, imbued with adequate situational awareness, that will make decisions regarding the de-escalation of services. Specifically, decision about which services can/will be provided and which cannot/will not be provided should be based upon a consideration of the a) the consequence to patients of suspending or delaying the service, b) the resource requirements of that service and c) the ability to provide the resources in the context of altered standards of care. These activities should be supported at a national level by professional societies developing classifications for prioritizing patients. When possible these should be based upon existing scheme.

- i. Similar to the examples provided for surgical services in Utah or cancer and renal services in Ontario, all hospital departments should complete a matrix similar to that in figure 1 for all services they provide.

3) Targets for service de-escalation should first address those services which if de-escalated are most likely to make available staff, staff or space that are in scarce supply.

- i. Services that are high yield for freeing up critical care resources include elective cardiovascular surgeries, transplants other than renal, and elective oral-maxillofacial surgeries requiring post-op ICU admission and any elective surgery with medical conditions that are likely to require post-operative ICU care or monitoring.
- ii. Surgical procedures, such as total-hip arthroplasty, which require in-patient post-op admission for greater than 24 hours.
- iii. Screening radiological and endoscopic procedures.

4) Health care coalitions should work co-operatively to ensure that within a geographic region or between regions access some capacity to provide non-deferrable essential services are maintained.

5) Health care institutions should prepare plans which detail options for substituting, adapting, conserving and where appropriate re-using critical supplies which may face shortfalls during a H1N1 surge. This activity should be supported by scientific guidance from organizations such as the CDC and FDA. Hospitals should specifically consider planning for substituting, adapting, conserving and re-using the following:

- i. ventilators and components (i.e. circuits, endotracheal tubes)
- ii. antibiotics
- iii. sedatives and analgesics
- iv. vasopressors/inotropes
- v. oxygen
- vi. vascular access devices (i.e. central lines, PICC lines and peripheral i.v.s)

6) Health care institutions should prepare plans to altering the standard of care to extend staff and space resources. Drawing upon the advice from the Task Force on Mass Critical Care we specifically recommend:

- i. Critical care should occur in hospitals or similarly designed and equipped structures (eg, mobile medical facility designed for critical care delivery, veterinary hospital, or outpatient surgical procedure center). After ICUs, post-anesthesia care units, and emergency departments reach capacity, hospital locations for EMCC should be prioritized in the following order: (1) intermediate care units step-down units, and large procedure suites; (2) telemetry units; and (3) hospital wards.
- ii. Nonmedical facilities should be repurposed for critical care only if disasters damage regional hospital infrastructure by making hospitals unusable, and if immediate evacuation to alternate hospitals is not available.
- iii. Principles for staffing models should include the following: (1) patient care assignments for caregivers should be managed by the most experienced clinician available; (2) assignments should be based on staff abilities and experience; (3) delegation of duties that usually lie within the scope of some workers' practice to different health-care workers may be necessary and appropriate under surge conditions; and (4) systematic efforts to reduce care variability, procedure complications, and errors of must be used when possible. Plans to implement these recommendations should be established for all categories of health care workers including physicians, nurses and other allied health care workers.

Section Four Recommendations: Allocation of Scarce Resources

1. Given that it is unlikely the necessary infrastructure or liability issues can be addressed in the next 3-6 months, government officials should recognize that entering into a triage situation would carry with it significant risks of inequities and system failure. Therefore all efforts should be made to avoid resource shortfalls.
2. If triage was necessary, coordination of the triage process should occur at a state level. Health care coalitions cannot possess a sufficiently broad level of situational awareness to make independent decisions regarding the initiation or coordination of triage.
3. States governments should use the Utah & Colorado approaches as models to develop plans for triage utilizing the protocol developed through the Task Force on Mass Critical's collaborative process and their existing state legislation to implement the protocol. These plans should include mechanisms to address triage infrastructure and triage officer liability issues. The infrastructure should include a process to systematically review of the decisions of the triage officers by a review committee to ensure that inequities are not occurring and assess patient outcomes to modify the triage protocol if required.
4. The allocation committee established by health care coalitions to oversee resource allocation should liaise with the state level central triage committee to provide information on resource supply and demand status to the state triage committee and communicate triage directives from the state to coalition members.
5. Critical care should be rationed only after all efforts at augmentation have been exceeded a Tier level 6 has been attained or exceeded.
6. Each health care institution should develop a pandemic staffing plan that includes a senior intensivist acting as a triage officer and a team to support the triage officer. Prior to resource shortfalls occurring, the role of this senior intensivist should be to coordinate resource utilization (ICU admissions & discharges) across the expanded critical care units within an institution established as part of the EMCC response. This individual should remain free of direct clinical responsibilities so that he/she can maintain a level of objectivity and be available to liaise when required with the hospital's emergency management group in the emergency operations center.

Section Five Recommendations: Financing Healthcare Costs during a Pandemic

1. The federal government should consider compensating hospitals, healthcare organizations, and healthcare providers during the time that a formally declared healthcare emergency for a pandemic is in effect, based on the following (or similar) proposed formula:
 - a. A daily rate that is equal to the average daily income for the previous 365 days immediately before the emergency declaration.
 - b. This daily rate will begin the day of the emergency declaration, and will continue through the day the declaration is discontinued.

- i. Additionally, hospitals, Healthcare organizations, and healthcare providers may continue to bill and collect for services rendered, but these services would be subject to all usual and standard documentation and regulatory requirements.
- c. Alternatively, hospitals, Healthcare organizations, and healthcare providers may bill and collect for services rendered. Modifications to usual and standard documentation and regulatory requirements should be markedly decreased or waived given the difficulty with documentation in a pandemic.

Section one: Communication and Coordination During a Pandemic, and Development of Healthcare Coalitions[1, 2]

Situational awareness based on accurate, timely and complete information is mandatory in planning for potential implementation of any altered standards of care during a pandemic.[1] Hospitals and their other local healthcare partners must share information with each other effectively, and then use it to coordinate resources in providing the best possible patient care across their region. Communication and coordination are therefore the foundations for situational awareness, and effective implementation of altered standards of care during a pandemic.

In a large scale disaster, such as a potential pandemic due to H1N1, our healthcare and hospital system remains underprepared to contend with a large scale disaster.[2] However, as a result of the Hospital Preparedness Plan (HPP) in 2002, there has been increasing emphasis, and success, on strengthening communication and coordination between hospitals and healthcare organizations in the same local communities or regions. These aptly termed *Healthcare coalitions* may be defined as a formal collaboration among hospitals and health systems, public health departments, emergency management and response organizations, and other organizations that provide support during a disaster.[2, 3] Coalitions serve to facilitate interaction between the first 3 tiers of the MSCC handbook, from individual hospitals to local coalitions to jurisdictional response agencies.[2] Mature Healthcare coalitions have developed to a level of sophistication that is capable of providing effective and coordinated disaster care to their communities, and have been recommended as being the foundation of a national disaster health system.[4] If a pandemic due to H1N1 were to occur this year, healthcare coalitions will be the mechanism for communication and coordination in delivering optimal care, and in determining when altered standards of care are needed.

The key deliverables required of healthcare coalitions during a pandemic virtually all revolve around situational awareness, and are characteristics that mature coalitions have already accomplished (see Box 1). Perhaps the most important functions in the event of a pandemic this year include developing effective 2-way communication protocols and processes between coalition hospitals and partners; providing accurate and up to date information on the number and severity of cases, utilization and capacity (“staff, space, and stuff”), and other information crucial for situational awareness; and collaborating together and with local health departments in determining when altered standards of care need to be implemented, to what degree, and when scarce resource allocation protocols are to be used.

In approaching a potential pandemic for the coming flu season, the objective is to facilitate local Healthcare Coalition development in all communities, and the implementation of their coordination and communication capabilities to the extent possible in this time frame. This may already be accomplished in some communities with well developed healthcare coalitions; for others, this may mean helping them establish a new coalition from the beginning. It is not clear from the literature at present what is known overall about America’s healthcare community’s current and potential coalitions.[2, 3]

Once a healthcare coalition is defined, Boxes 2 and 3 describe the organizational and functional characteristics for success.[2] Organizational success is determined by the commitment of member organizations to the coalition, defined through written agreements and strong leadership and governance. Incorporation of local health departments is also important, and the significance of this will

be discussed further under section 2, Triggers. Functional success is ultimately determined by the level of trust and teamwork that is built within the coalition. Further, coalitions are far stronger if they have a well respected local leader or organization to coordinate and direct the coalition. Successful coalitions likely demonstrate iterations of these characteristics of success over months to years, a time frame longer than that for an approaching flu season. However, there is still much that can be accomplished to facilitate healthcare coalition development within this time frame.

The formal recommendations for coordination and communication in preparation for a potential H1N1 pandemic this flu season focus on further development of America's Healthcare coalitions, and are presented below. (These are intended to be used in parallel, and do not necessarily require a sequenced approach)

Recommendations

1. Support, promote, and facilitate Healthcare Coalition development in all communities, especially those where one does not already exist.
2. Promote formation and definition of Healthcare Coalition official organizational agreements, governance, and leadership, if they do not already exist. These may need to be informal, as formal written agreements may not be practically completed in the compressed time frame of an upcoming flu season.
3. Promote and facilitate Healthcare Coalition (continued) development of defined communication standards and protocols, utilizing tools that include internet based programs, conference calls, phone contact, and any other available means.
4. Develop a database of common elements, including accurate and up to date information on the number and severity of cases, utilization and capacity ("staff, space, and stuff"), and other information crucial for situational awareness. The variables collected should be consistent from the regional level up to the national level and will contribute to the development of a common information picture.
5. Continue to promote and facilitate Healthcare Coalition familiarity and trust. Activities that may further this mission include:
 - a. Coalition partners meeting in person and sharing direct and reliable contact information. Experience has demonstrated that informal contacts are remarkably effective for developing communication links in the midst of a looming crisis, such as a pandemic.[5]
 - b. Organize committees and/or working groups composed of representatives from member organizations, with particular focus on hazard vulnerability analysis (HAV) for a pandemic.
 - c. Having local experts available for consultation, by defined communication vehicle(s) to other healthcare professionals in the coalition, and having regularly scheduled conference calls to update all involved. These were both recommended strategies learned from experience during the SARS epidemic.[6-8]
 - d. Consider developing support groups, or other support mechanisms, for healthcare professionals within the coalition. Again, previous experience with the SARS epidemic demonstrated that an epidemic creates circumstances that lead to damaged healthcare provider morale.[6-8]
6. At the individual hospital level, continue to promote hospital based preparedness

- a. But also encourage the integration of effective communication and planning with their coalition partners

The challenges and potential problems in developing successful coalitions are noted in Box 4. Of these, financing the cost of coalition involvement may be the most significant, and is discussed separately in section 5.

Box 1: Key Deliverables Needed From Healthcare Coalitions During A Pandemic

- Effective 2-way communication protocols and processes between coalition partners and member organizations, and with other coalitions through regional authority.
 - Communication processes may be as simple conference call capability, web based tools, telephones, or even ham radios as a back-up system.
- Effective information exchange between coalition partners
 - Accurate and updated Information on the number and severity of cases that are being seen
 - Accurate and updated information on internal resources already utilized and remaining capacity still available
 - Tracking patients and beds, assets and resources, staff and volunteers, and other resources
- Develop the means to establish a database of key information, and analysis capability.
- Utilizing available information to develop situational awareness in knowing when to implement altered standards of care, and awareness for how far to go, including implementation of scarce resource and allocation protocols.
- Support for each other
 - “Share” local academic experts or specialists available to all partners
 - Peer support during very stressful periods in a Pandemic
 - Working together in coordinating public relations

Box 2: Organizational Characteristics That Contribute To Coalition Success

- Cooperation between coalition partners, which is strengthened through formal compacts or mutual aid agreements, and the establishment of defined governance.
 - This provides the basis for information exchange, cooperation with resource sharing, and coordination/redistribution of patient movement
- A high level of coalition leadership and involvement, and members' commitment to the organization
 - Often built on pre-existing relationships and structures, or by having a "dominant" health system organize the group.
- Having the public health department involved in the coalition, with other members contributing as a resource for policy and decision making, and to provide support.
 - Facilitates the state/local government's ability to exercise legal authority to support local healthcare organizations if a pandemic occurs.
- Geographically flexible, and inclusive of most, if not all, local organizations

Box 3: Functional Characteristics That Contribute to Coalition Success

- Plan together, and then train together
- Develop communication plans together
 - Develop common communication protocols and tools
 - Jointly determine back-up communication strategies: ham radios' etc.
 - Work on public relations together
 - Others
- Develop hazard vulnerability analyses together
- Provide each other with real time data and information, to optimize situational awareness

Box 4: Challenges To Coalition Success

- Organizational sensitivities
 - Insufficient trust between member organizations, which must be developed through relationship building over time
 - Sharing proprietary information
 - Insufficient funding and/or staff shortages
- May need public health department/legal authority to support and expect equal and fair participation.
- Financing of the pandemic or other disaster- The financial cost of a disaster may be great to both healthcare organizations and providers.
 - Without a means to help underwrite disaster services, the potential cost serves as a disincentive for involvement.

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Section Two: Triggers and Supports for Altered Standards of Care during a Pandemic

The recommendations for triggers to initiate Altered Standards of Care (ASC's) are based on the volume of patients that are actually being hospitalized, or at risk for being admitted, compared to available resources. Though this data is focused at the individual hospital level, having a broader perspective of this information, particularly at the regional coalition level, is crucial in determining when to implement ASC's. As discussed in Section One, Regional Healthcare Coalitions are the vehicle for obtaining this data, and transmitting decisions back to individual hospitals.

The formal decision to implement altered standards of care is likely, and ideally, based in regional, state, and federal government agencies. The reasons for this are their likelihood at having the sufficient information available through coalition involvement to make best decisions, and because they possess the legal authority to implement them. This authority is crucial for mobilizing resources, and in providing support for healthcare professionals who will be providing care in a suddenly different, altered environment. This section will focus on the high level triggers for globally implementing ASC's, with the specific triggers for escalating surge levels addressed in section 3, and triggers for implementing allocation of scarce resource protocols in section 4.

The data assessed regarding triggers for implementing altered standards of care comes from four states that have formally developed ASC protocols or studied them (Colorado, Minnesota, Utah, and New York), the Veteran Administration, from the work done in Ontario, Canada, and documents published in CHEST.[1-11] These references were chosen among other known outstanding resources as they were refined to the highest level of operational definition.

The common theme from these documents emphasize the urgency in implementing altered standards of care when either 1) the demand for hospital services exceeds any given hospital's capacity, and/or 2) the rate of increasing cases is so rapid that there is risk that a regional coalition's capacity may be overwhelmed. The most specific identified triggers were either an increasing number of hospitals declaring "internal disasters" (elective procedures delayed, staff recalled, etc.) or an increasing number of hospitals "going on ER divert." [1, 8, 11] The triggers for terminating ASC's were equally non-specific, and highlighted that the need for altered standards of care would end when capacity came back into balance with the needs. The Colorado document also highlighted that this may occur in different regions at different times.[1]

All four state protocols would be activated in a pandemic with an emergency declaration by the governor, often in conjunction with the state department of Health. Such an emergency could be declared based on the volume of cases being seen within regions of the state, or based on an imminent crisis, such as a rapidly rising case count.

Three state documents (Colorado, Minnesota, and Utah) suggest that current state laws provide legal protections for healthcare professionals working in good faith during the time of a declared emergency for a pandemic. In addition, the states' recognized that support from the federal government was also important, as any potential violation of federal laws would not be covered under state jurisdiction and actions. The Veterans' administration's altered standard of care could be activated from either the head

of the system or at the institutional level by the chief administrative officer, and did not address legal protections. Minnesota also has specific measures addressed that would enable licensed professionals from other states, the District of Columbia, and from Canada being urgently credentialed to work in a declared emergency, and be covered under state liability and workers compensation laws.[12]

The trigger for implementing ASC's in a potential pandemic this year is proposed to be either the absolute number of hospitalized cases of H1N1, or the rate at which cases are rising. This again is based largely on all 3 state protocols already using this indicator in determining the need to surge capacity and implement altered standards of care processes. None of the documents reviewed were able to provide guidance for what these specific number of cases should be, nor do we have a specific recommendation. On an individual hospital level, this number is likely surpassed in a pandemic when an internal disaster is called, or the emergency room goes on divert status, and we also recommend this as a regional trigger for implementing ASC's.

The timing of when to implement ASC's is a balance between the risk of early activation prior to a clear need, versus late activation and potentially not being fully prepared if the pandemic escalates. Given the potential lag time required for surge capacity response, the earliest appropriate trigger is recommended, and this is consistent with others' recommendations.[13]

Protecting Healthcare professionals from liability during ASC's is also strongly recommended at both the state and federal level, based largely on the practices found in the three states (Colorado, Minnesota, and Utah). Without such provisions, Healthcare provider liability concerns regarding legal or professional reprisals for practicing altered standards of care and/or triage would serve as a further disincentive for coming to work in a potential pandemic. Additionally, having provisions to protect licensed professionals who cross state, district, and international boundaries to provide emergency care should have responsible legislative support, similar to that currently present in Minnesota.

The summary of recommendations for triggers for activation for altered standards of care during a Pandemic and protections for Healthcare workers are presented below.

Recommendations

1. The earliest potential trigger for activating ASC's is a large or rapidly rising number of hospitalized H1N1 flu cases. It is acknowledged that the timing of this decision is difficult to precisely define, and a specific recommendation regarding the number of cases cannot be offered. However, in order to facilitate the greatest beneficial impact of altered standards of care, particularly surge strategies (see next section), ASC's should be initiated at the *earliest* point where there is evidence of the healthcare system potentially becoming overwhelmed, and likely (hopefully) before any hospital is yet overwhelmed. Each local community may be affected differently, and initiation of altered standards of care may be implemented by region, as/when/if needed.
2. We strongly recommend that a "hard" ASC regional activation trigger during a pandemic be when one hospital either declares an "internal disaster" (as described above) *or* goes on "ER divert status,"

or otherwise determines that it has insufficient resources to provide routine care without moving to an altered standards of care status. When even one hospital is overwhelmed with flu cases to this point, all regional coalition hospitals are presumed to be at imminent risk.

- a. Under these conditions, a further recommendation is that individual hospitals be authorized to implement altered standards of care internally for a limited time of no more than 24 hours, unless further authorization is received from a jurisdictional government.
3. When either of the above conditions is met, we recommend that government leadership at the federal, state, and local levels declare a healthcare emergency at the earliest appropriate time, in order to facilitate and support the healthcare systems' efforts to provide the most amount of care to the greatest number of patients.
4. Healthcare Providers should be protected from professional or legal consequences when providing care in good faith during a declared state of public health emergency.
 - a. Additionally, there should be attempts at providing emergency credentialing and providing legal protections for health care professionals from other states, the District of Columbia, or Canada to provide care in affected states.
5. The trigger for terminating altered standards of care would be when all hospitals in a regional coalition or region are able to provide normal care to all patients with usual resources, and no longer require altered standards of care. Government issued emergency declarations should also be discontinued at this time. This de-escalation can also be accomplished step-wise regionally, as appropriate. Similar to initiation of altered standards of care, a specific termination trigger is difficult to define, and no corresponding specific recommendation is offered.

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Section Three: Surge Capacity & Response Strategies

1. Definitions and Conceptual Frameworks

Surge capacity is a broad term which is applicable to a continuum of daily fluctuations in demand for services through to extraordinary circumstances and from technical through to clinical settings in health care.[1-5] Given this great span for the concept of operations for surge capacity, it is not surprising that we found great variability in the definitions offered for surge capacity as well as a fairly heterogeneous collection of research and academic publications on this topic[6]. The focus of this paper and its recommendations will be on moderate to major surge given the H1N1 context. However, it is essential that the concept of a continuum of surge is not lost as systems and processes used to address moderate and major surge should build upon daily systems used to address minor surge.

The defining works most relevant to conceptualizing moderate and major surge has been done by Joseph Barbera and his colleagues[7,8]. They highlight the critical distinction between two important concepts 'surge capacity' and 'surge capability'.

Surge capacity: is the ability to respond to a markedly increased number of patients;

Surge capability: is the ability to address unusual or very specialized medical needs.

These definitions focus on the objectives or aims of the actions, however they do not identify the specific process through which these are achieved. In its most simplified construct, mechanisms to mitigate surges address either the demand for health care services or the supply of health care services. Health care services are dependent upon the availability of necessary inputs of staff, stuff and space. In almost all cases, the rate limiting factor is either staff or stuff.[9]

Approaches to decrease demand entail two components, (i) decreasing existing demands upon the system there by freeing capacity for surge response and; (ii) diverting new demands for services away from the system thus preventing the consumption of that resource. When resources become scarce decisions about allocation including prioritization and rationing are required and constitute the process of triage. Triage and resource allocation will be addressed separately in the following section of this paper. The discussion here will focus on diversion of non-essential demands for services.

Barbera states "the controlled (planned and monitored) degradation of services when maximum capacity is exceeded is engineered failure".[7] This orderly de-escalation of services serves two purposes, the first is to protect the ability to provide essential services by preventing catastrophic failure of the system and secondly to free up resources for the response. The most commonly cited example of this is to 'cancel elective surgery'. This is often a knee-jerk response that is easier to operationalize in a sudden isolated surge event but much more complex in a prolonged surge situation such as H1N1.[2] When considering what services to de-escalate,

considerations should include the potential impact on patients, the potential of critical resources being made available by cancelling the service, and finally the ability to provide the service at all when significantly altered standards of care are in practice. For example cancelling all elective surgeries that are day-surgeries, performed primarily with local or regional anesthetics will do little to make available ventilators. However, stopping all but emergent cardiac surgeries will make available a large number of ventilators and critical care resources. Certain procedures such as heart-lung transplants may be emergent and life-saving, but if the situation is such that the alterations in the standards of care only allow for 1:4 post-op ICU nursing and limited availability of a single vasopressor this level of care could not support such a resource intense procedure.

The key to diverting non-essential demands for service and relieve pressure on the health care institution is to identify earlier points of contact in the overall system and institute appropriate diversionary tactics at these points of contact. This requires health care institutions to think and engage partners beyond their own walls.

On the supply side, response efforts focus on increasing the amount of resources that are available or maximizing the output that can be obtained from existing resources. Increasing the amount of resources available primarily involves increasing acquisitions or stockpiling. Given the context of this document preparing for the very near future as well as the financial and logistical constraints of stockpiling, the focus of the discussion will be on maximizing the output from existing resources. Further, many resources, in particular staff, simply cannot be stockpiled or acquired rapidly.[9] However, we will assume that working within the financial and logistical constraints they face, in their requirement to exercise due diligence, institutions and authorities will take actions to stockpile critical resources.

Response efforts to maximize the potential output from existing resources forms the core of what has come to be referred to as 'altered standards of care'. The works of Rubinson[10-14] and Hicks[15,16] have significantly advanced the understanding of mechanisms through which the standard of care may be altered to maximize health care services during a surge. They advocate the considerations of various strategies to substitute, adapt, conserve, and re-use staff, space and staff to extend their capacity.

A particular challenge faced when implementing response strategies that address either demand or supply issues is how to scale the responses and implement triggers for their deployment. Scaling on the supply and demand side occur in opposite directions but should be based upon common information sources and integrated triggers. The requirement for scaling the response is derived from the ethical principal of proportionality, which dictates that actions to mitigate resource shortfalls should be proportionate to the degree of the shortfall expected or experienced[17,18]. Implicit in any discussion of scaling and triggers is the need for situational awareness and an effective communication network as detailed earlier. Two common approaches to scaling were found within the published literature. The first is that of Hicks who divides responses into 'conventional', 'contingent', and 'crisis'. [16] This scaling approach is largely descriptive and does not provide specific data inputs or thresholds upon which the scales are based. A more widely used approach is to construct triggers based upon

the 6 tier system propagated by Barbera and colleagues.[8] Triggers based upon the tier system typically set thresholds based upon resources in geopolitical regions becoming overwhelmed. There are two primary limitations of this approach. The first is that in order to recognize that a threshold has been reached and trigger a response, data collection, data analysis and communications capabilities must already be in place. This can be particularly challenging during the initial phases of an event. The second limitation is that this tends to set up a reactive rather than proactive response. Once established in a reactive mode it can be challenging to 'get ahead of the curve' in responding to the crisis.

2. Operationalized Examples

A number of specific examples of plans to de-escalate care were identified. The Utah pandemic plan provides a very good example of plans to de-escalate surgical services in a pandemic. The plan first defines what it labels triage levels 1, 2 and 3 representing levels of severity and phases a pandemic. Subsequently elective surgical procedures are categorized into 3 groups based upon the time sensitivity of the procedure. Finally the plan specifies which categories of surgeries will be suspended based upon the level of triage reached. A similar approach has been taken for both cancer care and renal care in the Ontario pandemic plan. The plans prioritize services based upon the impact on patients of delaying therapy. Subsequently the plans then detail which services will be suspended depending upon the phase of the pandemic in addition to outlining how standards of care may be altered. Although these represent very good examples of planned de-escalation and all take into account the impact the patients, none of the examples consider the potential yield in terms of making available resources (e.g. preferentially targeting the most resource intense services), nor do they take into account the ability to provide such services or the necessary support services (i.e. critical care) required in the face of significantly altered standards of care.

Several examples can be found where plans exist to divert non-essential patients away from hospitals. The Ontario pandemic plan builds upon the experience during SARS in utilizing telephone triage to provide advice and minimize the impact on hospitals. The UK has also employed this strategy during the first wave of H1N1 in order to provide both screening, advice and treatment with antivirals. A US example of plans to do this can be found in the Colorado pandemic plan. Additional methods of minimizing the demand are to prevent transmissions through the use of various public health countermeasures.

The most well developed frameworks for altering standards of care to extend capacity exist within the critical care field[10-14]. The Minnesota recommendations for health care facilities to manage surge provides the most concrete application of this framework. California has also made significant strides with their ESCAPE project in developing guidance for altering standards of care during a disaster. This work provides an example of the explicit use of triggers.

3. Recommendations

The recommendations in this section will be presented first with a general recommendation and subsequently, where appropriate, specific targeted aspects will be outlined.

1) Any initiatives put forth by the committee must recognize the nature of surge as a continuum from common minor daily events through to rare overwhelming events. Thus, healthcare coalitions should develop systems for moderate and major surges (such as H1N1) which build upon the process and systems used to address minor surge. Stand alone systems should be avoided.

2) Health care coalitions should have a central committee, imbued with adequate situational awareness, who will make decisions regarding the de-escalation of services. Specifically, decision about which services can/will be provided and which cannot/will not be provided should be based upon a consideration of the a) the consequence to patients of suspending or delaying the service, b) the resource requirements of that service and c) the ability to provide the resources in the context of altered standards of care. These activities should be supported at a national level by professional societies developing classifications for prioritizing patients. When possible these should be based upon existing scheme.

- i. Similar to the examples provided for surgical services in Utah or cancer and renal services in Ontario, all hospital departments should complete a matrix similar to that in figure 1 for all services they provide.

3) Targets for service de-escalation should first address those services which if de-escalated are most likely to make available staff, stuff, or space that are in scarce supply.

- i. Services that are high yield for freeing up critical care resources include elective cardiovascular surgeries, transplants other than renal, and elective oral-maxillofacial surgeries requiring post-op ICU admission and any elective surgery with medical conditions that are likely to require post-operative ICU care or monitoring.
- ii. Surgical procedures, such as total-hip arthroplasty, which require in-patient post-op admission for greater than 24 hours.
- iii. Screening radiological and endoscopic procedures.

4) Health care coalitions should work co-operatively to ensure that within a geographic region or between regions access some capacity to provide non-deferrable essential services are maintained.

5) Health care institutions should prepare plans which detail options for substituting, adapting, conserving and where appropriate re-using critical supplies which may face shortfalls during a H1N1 surge. This activity should be supported by scientific guidance from organizations such as the CDC and FDA. Hospitals should specifically consider planning for substituting, adapting, conserving and re-using the following:

- i. ventilators and components (i.e. circuits, endotracheal tubes)
- ii. antibiotics
- iii. sedatives and analgesics
- iv. vasopressors/inotropes

- v. oxygen
- vi. vascular access devices (i.e. central lines, PICC lines and peripheral i.v.s)

6) Health care institutions should prepare plans to altering the standard of care to extend staff and space resources. Drawing upon the advice from the Task Force on Mass Critical Care we specifically recommend:

- i. Critical care should occur in hospitals or similarly designed and equipped structures (eg, mobile medical facility designed for critical care delivery, veterinary hospital, or outpatient surgical procedure center). After ICUs, post-anesthesia care units, and emergency departments reach capacity, hospital locations for EMCC should be prioritized in the following order: (1) intermediate care units step-down units, and large procedure suites; (2) telemetry units; and (3) hospital wards.
- ii. Nonmedical facilities should be repurposed for critical care only if disasters damage regional hospital infrastructure by making hospitals unusable, and if immediate evacuation to alternate hospitals is not available.
- iii. Principles for staffing models should include the following: (1) patient care assignments for caregivers should be managed by the most experienced clinician available; (2) assignments should be based on staff abilities and experience; (3) delegation of duties that usually lie within the scope of some workers' practice to different health-care workers may be necessary and appropriate under surge conditions; and (4) systematic efforts to reduce care variability, procedure complications, and errors of must be used when possible. Plans to implement these recommendations should be established for all categories of health care workers including physicians, nurses and other allied health care workers.

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Section Four: Allocation of Scarce Resources

1. Overview

If shortages of vital resources occur during a disaster despite efforts to substitute, adapt, conserve and re-use, then re-allocation strategies must be employed. Triage should be used to direct the allocation of those resources in order to optimize efficiency, maintain ethical tenets, and help the greatest number of people possible.[1-11] Triage of scarce resources entails two elements: i) prioritizing patients for treatment, and ii) rationing of resources. Such decisions must be made within a sound ethical framework. A variety of ethical perspectives may inform the triage process, but a utilitarian perspective is most commonly applied. In order to maintain ethical distribution it is important both horizontal and vertical equity are achieved. This means, similar patients are treated equally and unlike patients are treated differently. Achieving such ethical standards requires appropriate structures and systems are in place.

Types of triage protocols can be categorized based upon the where they are intended to be applied. Primary triage protocols are used in the pre-hospital phase, secondary triage protocols in the ER and tertiary triage protocols are used within hospitals to allocate patients to definitive care areas. The primary and secondary triage protocols which have been used over the past centuries were developed in response to mass casualty incidents caused by events caused by warfare, natural disasters and man-made disasters for example bombings or plane crashes.[12,13] These types of events rarely produce large volumes of patients requiring critical care[14]. Further, since World War II on only a few occasions in western societies has triage been conducted in civilian health care systems where there been the need to make decisions which required that life supportive therapies would be denied to some patients. In most cases, given the isolated nature of the event, additional resources can be deployed to the affected area or patients transferred to unaffected areas.

Specific types of events, such as pandemics (i.e. H1N1) and CBRN incidents, do however have the potential to create surges in demand for critical care resources impacting broad geographic regions. The remainder of the discussion will focus on triage considerations is these types of events, specifically during a potential H1N1 pandemic.

2. Comparisons & Contrasts of Proposed Triage Protocols

Although much of the attention with regard to allocation of scarce resources during a pandemic has focused on decisions around critical care (tertiary triage), primary and secondary triage will also play a vital role in the response to a pandemic. Unfortunately however, the existing primary and secondary triage protocols developed for traditional mass casualty events have little applicability in the setting of a pandemic. Despite this, as discussed in the earlier section on surge, there is a need to divert non-essential demands for service prior to presentation to the hospital and if resources in the pre-hospital and emergency department become scarce decisions as to how to allocate these resources will also be required. Primary, secondary and

tertiary triage are intrinsically connected and must build upon each other for effective resource management to occur.

Primary triage may be required if either pre-hospital resources are exhausted, or if services that would be required for the continuation of care initiated in the pre-hospital setting are not available. For example, if a patient who requires intubation would clearly meet exclusion criteria for admission to critical care under tertiary triage protocols then a paramedic in the field should not intubate that patient. Thus, appropriate primary triage protocols would include easily identifiable exclusion criteria that are present in the tertiary triage protocol. The Colorado protocol provides an excellent example of how primary triage should be applied by EMS during a pandemic incorporating both alterations to dispatching based upon EMS resources and consideration of exclusion factors if tertiary triage is occurring. The Utah protocol provides an example of how primary care physicians and clinics can apply primary triage.

Secondary triage in the ER should build upon the criteria applied in primary triage by including broader exclusion criteria which require more complex data than is available in the pre-hospital setting. Again both the Utah and Colorado protocols incorporate secondary triage into their plans.

The first draft of a comprehensive tertiary triage protocol was published in 2006 by a working group of the Ontario pandemic planning committee.[15] The Ontario protocol is composed of detailed inclusion criteria, exclusion criteria, minimum qualifications for survival (MQS) and a prioritization tool using the SOFA score. The exclusion criteria and MQS are aimed at identifying patients with a low (< 50%) 1-2 year survival rate even if they were to receive critical care, particularly in the face of altered standards of care. This protocol has formed the basis for the majority of pandemic protocols that have been developed internationally and nationally including in New York, Colorado, Utah, and Alaska to name only a few. The Ontario protocol also provided the foundation for the triage protocol developed by the Task Force on Mass Critical Care which elaborated upon the Ontario protocol by providing details regarding the infrastructure required to support a triage system and suggested triggers for initiating triage.[16]

A group in Minnesota led by Hicks has also provided guidance regarding the allocation of ventilators during a pandemic.[17] This group also suggested using the SOFA score however, they recommend that every time a new patient is being considered for critical care that patient should be triaged against all patients currently in the ICU. This presents both logistical challenges in addition to applying information from the SOFA in a fashion that is significantly different than the manner in which the SOFA score was validated. The Ontario protocol attempts to match the application of the SOFA score with the manner in which it was derived. The most significant contribution of the Minnesota approach is the use of a tiered application of exclusion criteria as resources become increasingly scarce. This tiered approach provides a concrete method through which the restrictions can be balanced to match the degree of the resource shortfall. This is consistent with the philosophy recommended in the Ontario protocol and several of the more recent triage protocols developed by states have incorporated this approach into their adaptations of the Ontario protocol. The Utah protocol provides an example

of this adapted approach, although they have dropped 'single organ failure' as a criteria that would place patients in the 'high priority' group. This change may result in many young and otherwise healthy H1N1 patients being denied access to critical care based upon their SOFA scores alone.

Despite these recent advances in developing draft protocols, the ability to conduct triage, especially tertiary triage, in a pandemic faces a number of significant and potentially insurmountable obstacles. First, while many of the tertiary triage protocols were developed by extrapolating from research evidence where it existed, overall like most primary triage[12] protocols, tertiary triage protocols are not strictly evidence based and are only in the earliest stages of testing. Early results of a small pilot study [currently under review for publication in Critical Care] shows promising results of the Ontario triage protocol's ability to identify patients that are most likely to benefit from ICU and to mobilize resources. However, the study also reveals that further modifications of the protocol are required to improve its sensitivity and specificity. The second major obstacle is the lack of infrastructure necessary to support an ethical and effective triage process in civilian health care systems.[18] This includes the need to have systems or processes to train triage officers, achieve situational awareness, modify protocols as needed, communicate changes and monitor triage outcomes.[16] Thirdly, a legal process to create this infrastructure and provide appropriate legal (civil and criminal) protections for triage officers is required. No jurisdictions have fully addressed these legal issues yet. Colorado has established through legislation the committee that would oversee triage in a pandemic but this legislation does not provide protections for triage officers. Louisiana has produced legislation that discusses triage and provides protections to health care workers who practice the standards of disaster medicine, but the legislation does not specify what that standard is.

Regardless of whether a formal triage process is in place, if resource shortfalls occur, allocation decisions will be made. However, without a standardized process these decisions are unlikely to result in an ethical or efficient use of resources. The inequities that result from these decisions have the risk of undermining public confidence in the health care system and could lead to collapse of the health care system during the time it is most required.[18] It may be feasible in many settings to develop a process to implement triage, similar to what Utah and Colorado propose, using the protocol proposed by the Task Force on Mass Critical Care,[16] and executed through existing emergency legislative powers. However, this fails to address the essential infrastructure and liability issues.

3. Recommendations

1. Given that it is unlikely the necessary infrastructure or liability issues can be addressed in the next 3-6 months, government officials should recognize that entering into a triage situation would carry with it significant risks of inequities and system failure. Therefore all efforts should be made to avoid resource shortfalls.

2. If triage was necessary, coordination of the triage process should occur at a state level. Health care coalitions cannot possess a sufficiently broad level of situational awareness to make independent decisions regarding the initiation or coordination of triage.

3. States governments should use the Utah & Colorado approaches as models to develop plans for triage utilizing the protocol developed through the Task Force on Mass Critical's collaborative process, and their existing state legislation, to implement the protocol. These plans should include mechanisms to address triage infrastructure and triage officer liability issues. The infrastructure should include a process to systematically review of the decisions of the triage officers by a review committee to ensure that inequities are not occurring and assess patient outcomes to modify the triage protocol if required.

4. The allocation committee established by health care coalitions to oversee resource allocation should liaise with the state level central triage committee to provide information on resource supply and demand status to the state triage committee and communicate triage directives from the state to coalition members.

5. Critical care should be rationed only after all efforts at augmentation have been exceeded a Tier level 6 has been attained or exceeded.

6. Each health care institution should develop a pandemic staffing plan that includes a senior intensivist acting as a triage officer and a team to support the triage officer. Prior to resource shortfalls occurring, the role of this senior intensivist should be to coordinate resource utilization (ICU admissions & discharges) across the expanded critical care units within an institution established as part of the EMCC response. This individual should remain free of direct clinical responsibilities so that he/she can maintain a level of objectivity and be available to liaise when required with the hospital's emergency management group in the emergency operations center.

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Section 5: Financing Healthcare costs during a Pandemic

Though Healthcare financing of a disaster, such as a Pandemic, is beyond the mandate for this document, it is addressed briefly as it has such profound implications for all of the recommendations herein contained.

The cost of disaster care during a Pandemic would likely be huge for hospitals, healthcare organizations, and Healthcare professionals, and is often the “elephant in the room” when discussing disasters. The costs include providing care for a much larger population, many likely to be uninsured, and expending far greater resources in the process. It also includes the cost of likely foregoing many of the services that are revenue generating, such as elective surgeries. In addition, usual documentation of services during an emergency might necessarily be drastically decreased, in order to focus on the delivery of care. Though healthcare organizations and providers are driven by their passion and love of caring for their patients, it is unfair to ask them to shoulder the entire financial responsibility, too. Furthermore, failing to address this most important issue essentially penalizes those who are ethically most compelled to act and participate, and an incentive for others who might look for opportunities to participate less, or not at all. This issue is well addressed by the Agency for Healthcare Research and Quality.[1] However, potential solutions, even if pursued, will not be available this year.

Given the urgency of a potential pandemic this year, the following recommendation is made regarding financing for a pandemic.

Recommendation

1. The federal government should consider compensating hospitals, healthcare organizations, and healthcare providers during the time that a formally declared healthcare emergency for a pandemic is in effect, based on the following (or similar) proposed formula:
 - a. A daily rate that is equal to the average daily income for the previous 365 days immediately before the emergency declaration.
 - b. This daily rate will begin the day of the emergency declaration, and will continue through the day the declaration is discontinued.
 - i. Additionally, hospitals, Healthcare organizations, and healthcare providers may continue to bill and collect for services rendered, but these services would be subject to all usual and standard documentation and regulatory requirements.
 - c. Alternatively, hospitals, Healthcare organizations, and healthcare providers may bill and collect for services rendered. Modifications to usual and standard documentation and regulatory requirements should be markedly decreased or waived given the difficulty with documentation in a pandemic.

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