Implementation of a Pediatric Mass Casualty Triage Plan during Crisis Standards of Care Deployment

April 11, 2014

BY
CHRISTINE M. GALL
B.S.N., University of Wisconsin Milwaukee, 1987
M.S., University of Wisconsin Milwaukee, 1993

DISSERTATION

Submitted as partial fulfillment of the requirements
for the degree of Doctor of Public Health
in the School of Public Health of the
University of Illinois at Chicago, 2014

Chicago, Illinois

Defense Committee:

Bernard Turnock, Committee Chair and Advisor, School of Public Health
Patrick Lenihan, School of Public Health
Suzet McKinney, Chicago Department of Public Health
Michael Petros, School of Public Health
Randall Wetzel, University of Southern California

DEDICATION

This Dissertation is dedicated to my parents, Jim and Carol Gall, who taught me to believe in myself, and to my husband, Morten, my best friend.

ACKNOWLEDGEMENTS

This work would not have been possible without my colleagues, Phillip Toltzis, Randall Wetzel, Alexander Kolker and Robert Kanter, who generously shared their expertise with me. I am ever in debt to my advisor and chair, Bernard Turnock, whose guidance and support helped me to successfully navigate this journey. To my committee, Patrick Lenihan, Suzet McKinney, Michael Petros and Randall Wetzel, I thank you for your direction, time and your belief in my scholarship. And a special thanks to Casey Lauer and Aaron Katch, who were always willing to help me work though challenging questions throughout this research effort.

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LIST OF ABBREVIATIONS

AHRQ	Agency for Healthcare Research & Quality
AMA	American Medical Association
BPHC	Bureau of Primary Health Care
CDC	Centers for Disease Control and Surveillance
DHHS	Department of Health and Human Services
DHS	Department of Homeland Security
DMAT	Disaster Medical Assistance Teams
DoD	Department of Defense
DV	Days on Ventilation
EMAC	Emergency Management Assistance Compact
FCFS	First Come First Served
FEMA	Federal Emergency Management Administration
FMS	Federal Medical Stations
HPP	Hospital Preparedness Program
HRSA	Health Resources and Services Administration
ICU	Intensive Care Unit
IOM	Institute of Medicine
MCE	Mass Casualty Event
NBHPP	National Bioterrorism Hospital Preparedness Program
NDMS	National Disaster Medical System
NIMS	National Incident Management System
OMPC	Ohio Medical Coordination Plan
PACU	Post Anesthesia Care Unit
PICU	Pediatric Intensive Care Unit
PIM 2	Paediatric Index of Mortality 2
PIM 3	Paediatric Index of Mortality 3
POD	Probability of Death
PRISM 3	Pediatric RISk of Mortality 3
UEVHPA	Uniform Emergency Volunteer Health Practitioner Act
US	United States
VA	Veterans Affairs
VPS	Virtual PICU Systems

Chapter I: SUMMARY

Evidence suggests that children are particularly at risk during a disaster that involves mass casualties. Further, the needs of children who become critically injured or ill are unique. Deliberate, distinct advanced preparation is required to protect the survival of the greatest number of child victims during a crisis.

When conventional care delivery becomes overwhelmed and surge capacity fails to mobilize the additional resources necessary to accommodate the demand for emergency critical care resources, crisis standards of care may be activated. In such events, the focus shifts away from the care of individual patients to the needs of the affected population.

This research project aims to provide leadership guidance and tools during a mass casualty event when crisis standards become necessary to achieve the greatest pediatric survival possible by assigning scarce pediatric critical care resources to the children most likely to benefit from limited access to critical care. Using secondary data sources as well as expert opinion from leaders in emergency preparedness, triage tools will be developed to guide effective victim triage and assignment of scarce pediatric critical care resources in a crisis.

Chapter 2: INTRODUCTION

Few events have served to mobilize action, instill cooperation and evaporate trivial differences amongst people as a catastrophe that overwhelms the social infrastructure. It is against the collective human spirit to accept adverse conditions without challenge. Deadly natural disasters and criminal acts of terror, and the emergence of novel diseases and infectious agents, particularly in recent years have fueled governments, organizations and individuals to prepare for the next mass casualty event as never before. Over the last decade, tremendous attention has been given to the enhancement of systems of emergency preparedness, to avoid disaster when possible, and to the swift and effective mobilization of personnel and resources when disaster hits, to minimize death and destruction. Despite the considerable effort and attention given to disaster preparedness and the voluminous information published, substantial gaps remain.

While great progress has been achieved in predicting and preventing potentially disastrous events from escalating to catastrophe, disasters continue to exert their influence at will throughout the globe. In the absence of opportunities to prevent disasters, the need for advanced preparedness strategies is paramount. Preparing for the next disaster requires effective anticipation of events that are likely to occur, an acute understanding of the groups of people likely to be impacted and the resources required to respond to their needs, and the development of a strategy that minimizes casualties in the event that demand for emergent and critical resources by survivors of the event overwhelms supply. Development of an effective and timely disaster response plan therefore requires the talent of skilled, resourceful and highly collaborative leaders in public health and health care.

The events of September 11, 2001 changed the psyche of this nation perhaps more than any other single event in the last 50 years. In the aftermath, new expectations have emerged regarding the responsibility of local, state, and national government, healthcare, and private sector organizations responsible for the protection of the population, to improve the systems of emergency management. At the same time, a distinct social expectation prevails that the loss of life, spread of destruction, and paralysis of society will be minimized whenever possible.

While the federal government in the United States has been involved in disaster management, response and recovery for over two centuries (United States Department of Homeland Security, 2010), public opinion regarding the effectiveness of the national response to contemporary catastrophic events indicates that the nation remains at risk and the public expects more. Emergency management is defined as "the managerial function charged with creating the framework within which communities reduce vulnerabilities to hazards and cope with disasters" (United States Department of Homeland Security, 2011). The primary components of emergency management include mitigation, preparedness, response and recovery (United States Department of Health and Human Services, 2012). While this research will describe the emergency management system overall and highlight key areas of importance for the creation of an effective state of readiness, the primary focus of this work will be on the execution of an effective response during an overwhelming disaster that substantially impacts children.

In 2002, a national study was conducted to understand the baseline level of preparedness of each state to respond to mass casualty events. The results revealed that while most states had developed disaster plans, most lacked critical components or standard operating procedures for effective disaster plan implementation. Further, the personnel charged with implementing disaster response systems lacked training, appropriate equipment and coordinated systems of communication. The study also described that certain segments of society were at particular risk, including the elderly and children (Mann, MacKenzie & Anderson, 2004). This study clearly highlighted areas of substantial deficits in the emergency preparedness infrastructure that needed further attention and development.

The scope of responsibility of the emergency management system is colossal. When disaster strikes, it is necessary to quickly determine whether emergency management systems can manage with conventional operations or whether extraordinary measures are necessary. The Institute of Medicine (IOM, 2009), in their landmark *Letter Report*, published national crisis standards of care (CSC) to guide state and local agencies, healthcare organizations, and the private sector to adapt the emergency management system for response to mass casualty events. These crisis standards aimed to create novel systems to preserve the greatest number of lives with limited resources when mitigation and preparedness strategies failed to deliver a successful response. The report underscored that in such times, drastic measures would be necessary and, like the findings from Mann et al (2004), substantial work was needed in the disaster response infrastructure to develop comprehensive crisis capabilities.

This research will be limited to the study of the disaster response in the event that pediatric casualties overwhelm the capability of the health care system to effectively respond and manage; when crisis standards of care become necessary. The IOM defines “crisis standards of care” as:

> “…a substantial change in unusual 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. 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. 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.”
> (IOM, 2009, p.3).

When emergency preparedness systems lack the capacity to effectively respond to the needs of disaster victims and casualties begin to mount, alternative strategies must be deployed to salvage the best possible survival outcomes. Crisis operations are designed to severely reduce individual and provider autonomy in order to support optimal allocation of scarce resources. Therefore, use of CSC must be judiciously applied and only when other viable options have become exhausted. For this reason, the trigger needed to transition from standard operations to crisis care begins with a formal declaration of disaster by the state government.

This research will specifically address the concerns of child victims of mass casualty scenarios when crisis standards of care become necessary. Triage tools and leadership guidelines will be developed to assist the disaster professionals to mitigate loss of young lives and preventable disability when possible. To accomplish this, this project will suggest strategies needed to effectively implement a triage plan using a data driven, validated approach for victim management and scarce resource allocation.

Problem Statement

Pediatric intensivists lack adequate preparation and tools to ethically and equitably triage pediatric victims and to best allocate scarce pediatric critical care resources in a CSC mass casualty event to improve the likelihood of survival for the greatest number of critically ill children.

Overarching Study Question

Can a triage algorithm be developed to effectively deploy scarce pediatric critical care resources during a disaster when crisis standards of care are implemented?

Study Sub-Questions

1.) How can a pediatric critical care triage algorithm be implemented in a disaster when Crisis Standards of Care are deployed?

2.) Can a triage algorithm achieve superior pediatric survival results to first come first served assignment of scarce resources in a simulated disaster?

Study Objectives

This study proposes to develop a pediatric triage algorithm to effectively allocate limited critical care resources to the child victims with the best chance of survival with limited treatment. The findings of this research will be summarized in two manuscripts that will contribute new knowledge in this important area of pediatric disaster response. The objectives of these articles will be to assist front-line intensivists and public health leaders to effectively identify the victims with the greatest opportunity to survive.

Further, triage tools developed in this study will use real time data to achieve the best possible survival rates by effectively translating data available at the triage station into meaningful, actionable information during activation of crisis standards of care.

While these aims may be ambitious, the information void in this specific focal area of disaster management is sufficient motivation to begin building the literature base. Throughout the emergency management literature is a prevailing theme underscoring the need to develop effective systems to address mass casualties involving children (Johnston & Redlener, 2006). This research will attempt to fill systemic gaps to aid in the optimal management of a pediatric mass casualty event.

The relevance of this project to the leadership role is clear. Effective performance of systems and staff under extreme situations requires sage leadership and confidence under pressure. Confidence may only be achieved if leaders have the tools and preparation required to make timely decisions and take deliberate action to effectively lead through the crisis.

This research will provide algorithms to guide leaders through difficult decisions regarding rationing of critical care resources in a data-driven, objective, and ethical manner. While stress cannot be avoided when a disaster reaches the level of crisis standard activation, knowledge and advanced preparation will support leaders to act swiftly, efficiently and effectively. As children present for treatment, the triage algorithm will enable front line providers to ethically triage pediatric victims and determine their course of treatment in an ethical and consistent manner. With a decision making algorithm and triage thresholds predetermined, the direct caregivers responsible for enacting the triage plan are released to focus on the plan implementation rather than on the formulation of the triage plan. If properly developed, the triage plan will remove direct providers of care from the accountability for setting triage thresholds independently and will support trust and confidence that the plan will yield the best possible victim survival.

To generate trust within the team that decisions regarding who will receive pediatric critical care services are being made ethically, using accurate data from the catchment area is important. The potential number of victims involved and the potential timing of arrival are key pieces of information that will be incorporated into the triage plan. As information is communicated about the scope and density of the disaster and a crisis is officially declared, the algorithm will empower the triage team to transition from contingency care to crisis care swiftly and effectively.

Conceptual and Analytic Framework

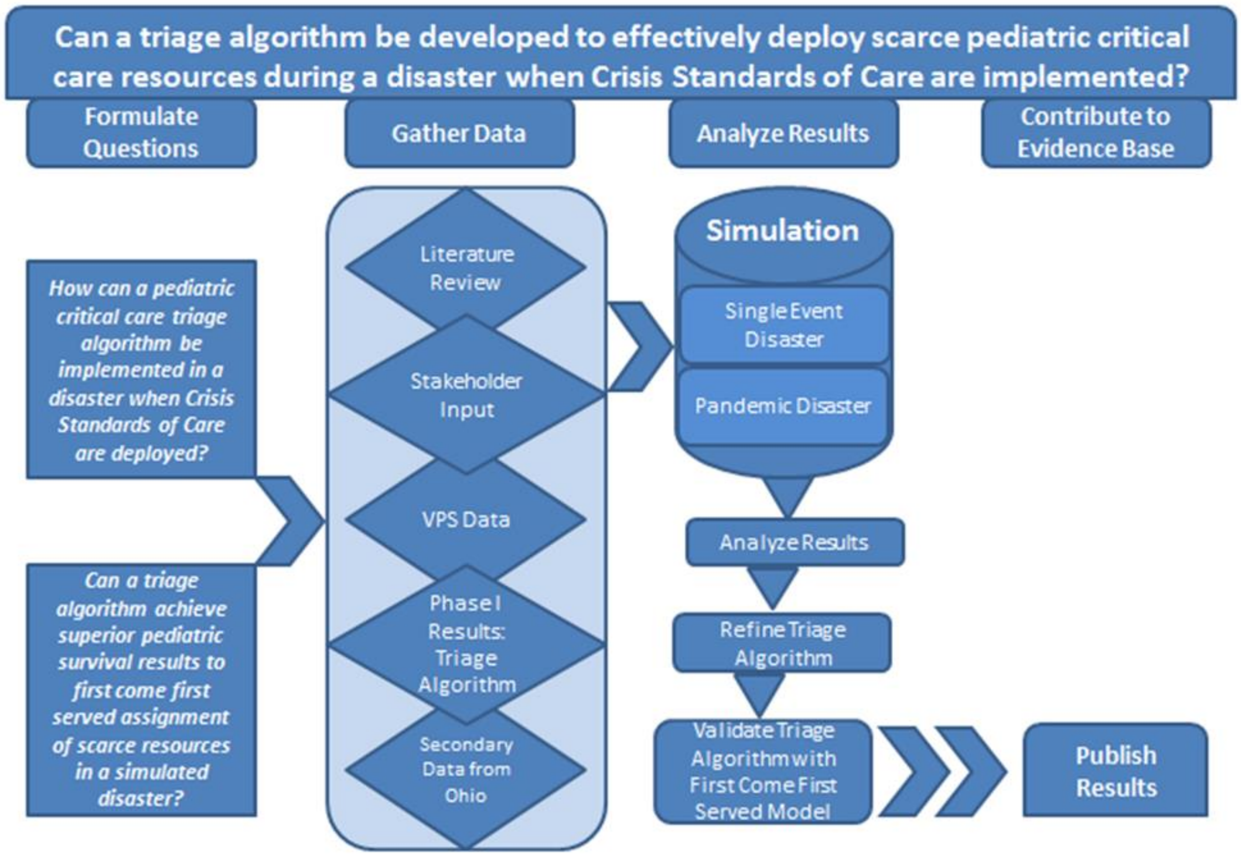

Figure 1: Project Conceptual Framework

Chapter 3: LEADERSHIP ISSUES AND PRACTICE SIGNIFICANCE

While this study aims to develop tools that will aid deployment of CSC strategies in a mass casualty disaster that overwhelms surge capacity, effective leadership is vital to achieving the best possible victim survival. Kapucu and Van Wart (2008) examined two contemporary disasters in the US to address the impact of poor leadership and the impact on avoidable loss of life. They concluded that of 37 competencies typically associated with effective senior leaders, 12 were essential strengths for leaders managing the disaster response during a catastrophe. Several of these competencies are interrelated and are represented below:

- The link between the need to be a good problem solver and the capacity to be decisive, making the best use of available information and considering the presenting context, are synergistic and necessary leadership strengths;
- Several competencies are essential for successful leadership during a mass casualty disaster related to management of staff, including the ability to effectively organize and deploy personnel, provide timely and effective communication of important information both vertically and horizontally, the purposeful creation of an environment where staff can be innovative and creative in a responsible and constructive manner, and the capacity to demonstrate flexibility in support of a novel idea or approach to an emerging problem;
- As a crisis extends from minutes to hours and hours to days, the ability to continue effectively building the team and motivate them to their best sustained effort;
- Leaders need to be able to scan the environment for data crucial to effective decision making, be ever-strategic and look for natural partnerships in atypical places to make the best use of insufficient resources.

Typically, development and implementation of a hospital disaster management plan requires the establishment of a chain of command (Shover, 2007), and it is imperative to identify leaders with the ability to effectively take charge. Iserson (1986) warns that while there is a natural hierarchy in hospitals, the person in the position of authority may not be equipped or inclined to lead. In other words, "authority is not equivalent to leadership." (p. 338).

This is an essential consideration in preparedness planning. While the intensivist may have the position of authority in the PICU and is responsible for execution of triage during CSC activation, he or she may not be prepared with key leadership strengths necessary for success in a disaster situation. For this reason, focused leadership competency development particularly in the area of crisis leadership, should be standard in medical curricula, particularly for physicians pursuing specialization in areas like intensive care medicine, where they will be likely called upon to take a lead role in a disaster. For the near term, it is advisable for organizations to evaluate and inventory the various leadership competencies among their administrative and physician teams and, where gaps exist, proactively identify leadership pairings that, together, possess the expertise needed to support ongoing implementation of the CSC plan.

A crisis, by definition, implies that a situation has escalated beyond the norm to a critical state. Staff attempting to deliver care in a crisis situation are bound to face unique and unanticipated circumstances, and are likely to require additional support and direction. This further reinforces the need for skillful leadership throughout a crisis, particularly when resources become overwhelmed.

Leaders must be comfortable with the identification of circumstances that indicate the need to activate the disaster plan or advance care standards to the next level of the continuum. When provision of care using conventional standards is no longer possible, contingency care takes its place. Contingency care is designed to expand the effectiveness of current resources by limiting the demands on those resources and create additional resources using staff, supplies, and space in atypical but pre-planned ways. When developing contingency plans, leaders must be sure to secure input from all key stakeholder groups to ensure that resources will be maximally utilized.

When contingency resources become overwhelmed and crisis standards are activated, effective leadership becomes even more critical. While activation of crisis standards of care requires a government declaration from the state or federal government, leadership at the local level, will ultimately determine the extent of loss of life. The need for effective integration between administrative and clinical leaders is absolute. A strong administrative and clinical leadership presence will ensure that space, staff and supplies are effectively adapted from conventional deployment to crisis standards. Figure 2 describes the various decision points that leaders must consider when transitioning to CSC (IOM, 2013).

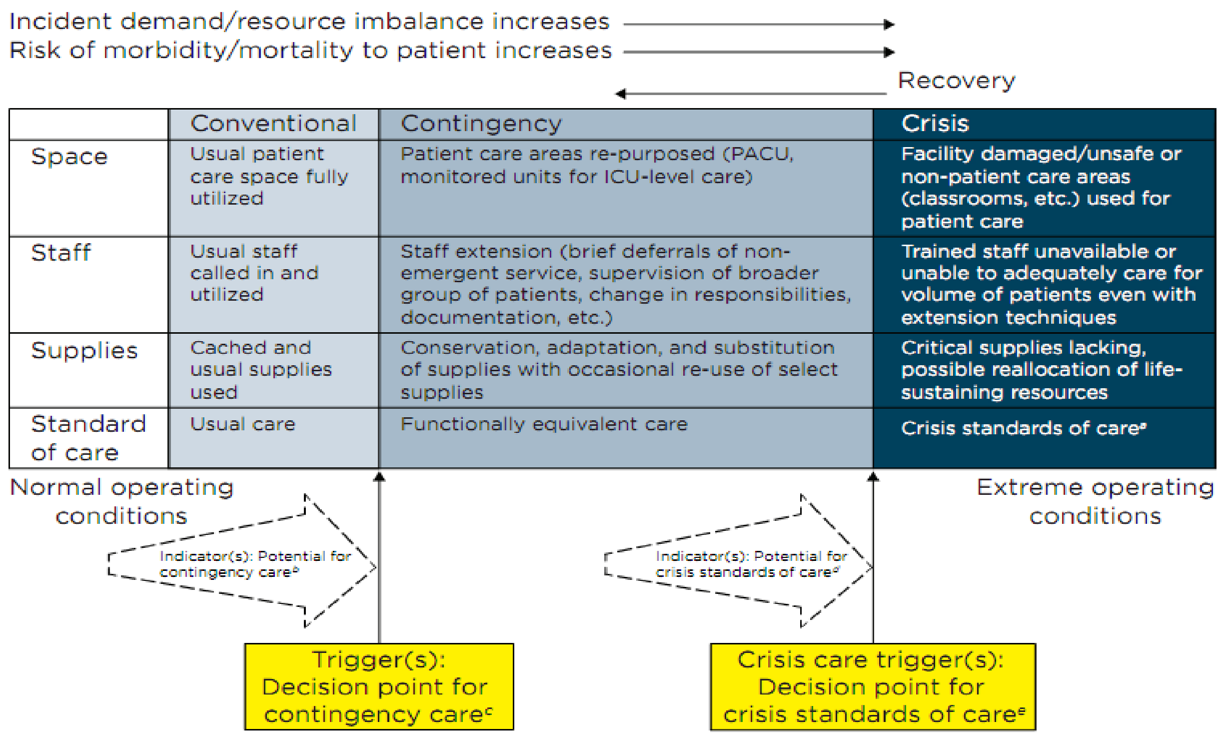

FIGURE 1-1
Allocation of specific resources along the care capacity continuum.
NOTE: ICU = intensive care unit; PACU = postanesthesia care unit. For clarity, the figure focuses on indicators and triggers for the transitions from conventional to contingency to crisis; it is also important to consider indicators and triggers that guide the return to conventional care.
[a] Unless temporary, requires state empowerment, clinical guidance, and protection for triage decisions and authorization for alternate care sites/techniques. Once situational awareness is achieved, triage decisions should be as systematic and well integrated into institutional process, review, and documentation as possible.
[b] Institutions may consider additional monitoring, analysis, and information sharing, and may prepare to implement select adaptive strategies (e.g., conserving resources where possible).
[c] Institutions implement select adaptive strategies and should consider impact on the community of resource use (i.e., consider "greatest good" vs. individual patient needs), but patient-centered decision making is still the focus.
[d] Institutions continue to implement select adaptive strategies, but also may need to prepare to make triage decisions and shift to community-centered decision making.
[e] Institutions (and providers) must make triage decisions—balancing the availability of resources to others and the individual patient needs—and shift to community-centered decision making.
SOURCE: Adapted from IOM, 2009, p. 53.

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Figure 2: Allocation of specific resources along the care capacity continuum

Smooth transitions along the continuum require early identification of indicators signaling the likely need to escalate a disaster response as well as clarification of the trigger(s) that will confirm the decision to move to the next level. It is critical that disaster plans include details that will enable the leaders responsible for execution to recognize these cues, proactively prepare the staff, and expertly navigate the transition when a trigger materializes. Recognition of indicators and triggers should therefore become second nature to leaders and as such, must be repeatedly reviewed until the information is committed to memory.

Chapter 4: LITERATURE REVIEW

Vulnerability of Children in Disasters

The needs of children in disaster events are unique as children are particularly vulnerable. In the aftermath of Hurricane Katrina, Johnston and Redlener (2006), pediatricians who had participated in the care of child victims this disaster, commented that the systems in place did not adequately address the unique needs of children and the pediatric resources in place were swiftly overwhelmed. They warned the nation that systems needed further development to care for the unique needs of one of our vulnerable populations; our children.

Why are the needs of children in disasters distinct? There are many physiologic, social, and developmental reasons for this. Burke, Iverson, Goodhue, Neches and Upperman (2010) comprehensively summarized the unique susceptibilities of children in mass casualty events as follows:

- Children's organs are proportionally larger, closer together, and not as well protected as adults'

- In airborne chemical and biologic events, small children are more vulnerable as they breath faster and their hearts beat faster than their adolescent and adult counterparts, allowing these agents to spread more quickly throughout the body
- Children metabolize drugs differently so weight-specific dosing makes provision of medications more complicated than for adults, where standard dosing schemes are common
- Children require equipment and supplies that are of varying sizes and the training needs of providers to select/use the correct equipment is a concern
- Children's respiratory physiology varies by age and requires caregivers to have specialized expertise to appropriately protect and manage their airway
- Since children are typically shorter than adults, they have the potential of absorbing increased concentrations of hazardous substances, particularly if the substance is heavier than the surrounding air and lingers closer to the ground (i.e. chlorine, and sarin)
- Children have a greater surface area compared to body mass so they are more susceptible to agents absorbed through the skin
- Agents that cause vomiting and diarrhea will have a greater impact on children as they develop fluid and electrolyte imbalances more quickly, which lead to physiologic instability
- The developmental limitations of children may prevent them from recognizing and quickly reacting to a dangerous situation; limitations in motor function may prevent them from effectively evacuating
- While children are dependent on adults, the focus of an adult may be elsewhere in a disaster, thus increasing possible exposure to hazards
- Children's mental health suffers from both direct and indirect exposure to traumatic events and are more likely to develop anxiety disorders and post-traumatic stress disorder

While this summary clearly identifies the great number of physiologic, development and social factors that make children a vulnerable group, these disparities have not been adequately addressed through the disaster management system. The National Commission on Children and Disasters (2010) confirms that many disaster plans fail to adequately address considerations specific to children.

Further, unlike the 'natural selection' that typically takes place with critically ill or injured adults where the mortality rate in the ICU can approach approximately 30%, children have a resiliency that adults do not possess. The average mortality rate in pediatric intensive care units (PICUs) is just under 3% overall during the last 4 calendar years (Virtual PICU Systems, 2014, unpublished data). Due to superior rates of survival in critically injured children compared to similarly compromised adults, these data suggest that in times of pediatric mass casualty, a larger number of children may survive the initial disaster incident, and will then present for critical care services. Due to the relatively fewer number of facilities equipped to provide pediatric critical care services, the potential for proportionally higher numbers of children presenting for care needs to be addressed.

Predicting Victims in a Disaster

Given these special considerations for children, the importance of estimating the potential pediatric victim rate is essential, so that response strategies can be effectively organized. There are a couple of methods in the literature for estimating pediatric victim rates.

One approach uses Geographic Information System (GIS) analysis of the hospital catchment area and from there, extrapolates the number of potential child victims (Curtis, Curtis & Upperman, 2012).   The second approach runs pediatric surge simulations based on the most likely disaster scenarios confronting the region, to estimate potential victims and their associated supply needs (Neches, 2004). Both approaches have merit, and the proactive nature of these predictive tools may serve to improve the capacity of the critical care systems to respond to a disaster involving substantial numbers of children by reliably estimating the volume of casualties in order to determine the necessary thresholds to allocate scarce resources most effectively. Failure to have a prediction of the denominator, or the number of child victims, can lead to mismanagement of scarce pediatric resources.

When the scope of a disaster and expected victim counts can be effectively predicted, responders may have a greater opportunity to manage the response more effectively. Studies focusing on the estimation of casualty rates and severity of injury, not surprisingly, come from military sources and from regions under continual threat of war where this information becomes paramount for establishing an effective response.

In a study of 32 hospital multiple casualty incidents in Israel, it was determined that on average, 20% of casualties required immediate medical treatment (Koshashvili et al, 2009). Another study predicted that in terrorist bombings that use conventional weapons, one-third of bystanders will be critically injured while the remainder will require minimal health care services (CDC, 2013). In the absence of timely access to real data, these rough estimates can be used to reasonably predict the potential victim surge.

In addition to the challenge of estimating the number of children victims potentially impacted during a disaster event, it is similarly challenging to determine how to allocate scarce resources. In lieu of a plan, providers responsible for allocation of critical care resources are left with a first come first served (FCFS) approach which relies on the individual provider to select patients for treatment based on their impressions following the baseline victim assessment. The FCFS approach may lead to the allocation of scarce resources to victims that do not have the best chance of survival.

Effective prediction tools are invaluable for rapid execution of a disaster plan. However, the number of unknowns that can impact the demand for services or the availability of tools and providers to care for victims is a challenge. The need to be able to rapidly evaluate the effectiveness of the implemented plan and, as necessary, make changes to the plan to reduce unnecessary loss or misuse of limited resources is an important concept in effective disaster response. This is particularly needed in disasters that involve large numbers of children. Despite the fact that children have superior survival when requiring critical care when conventional standards are in place, the literature documents that kids experience higher mortality rates than adults in disasters (Allen, Parrillo, Will & Mohr, 2007).

Development of prediction models to estimate risk of mortality in pediatric critical care has been uses for more than 20 years. There are two validated prediction algorithms that are widely used in the United States (US) for evaluation of mortality in PICUs: Pediatric Index of Mortality (PIM 2) and Pediatric RISk of Mortality (PRISM 3) (Slater, Shann & Gearson, 2002) (Pollack, Patel & Ruttimann, 1996). In fact, the PIM 2 research team just released an updated version of their predication model: PIM 3 (Straney et al, 2013). Both tools use a combination of physiologic, laboratory and assessment data to generate a predicted risk of mortality for each patient. However, only PRISM 3 was developed using data from US PICUs. PIM 2, by contrast, was generated using PICU data from Australia, New Zealand and England, but was later validated using US data from the PICU (Scanlon et al, 2006). The successor model, PIM 3, was also validated using data from the countries mentioned above, and elsewhere in the United Kingdom and Ireland.

While these tools are helpful to the pediatric critical care community to compare outcomes, benchmark and determine best practices, they are intended to be used retrospectively. Stated differently, the existing risk adjustment tools were intended to be used to evaluate the outcomes of large groups of children who had previously accessed pediatric critical care services rather than to be prospectively applied to individual patients. Further, these tools were developed to predict mortality during times that conventional care practices were used rather than in a mass casualty crisis.

In a disaster that escalates to emergency declaration and the activation of crisis standards of care, retrospective risk adjustment is of little utility. Care providers need tools that will actively guide them in evaluating the level of illness of each presenting victim and in making resource allocation decisions that have the capability to produce the greatest rates of survival. A call for the development of a simple, validated tool for pediatric triage has been made (Antommaria, Powell, Miller & Christian, 2011).

A pediatric triage algorithm has been developed to address this gap, and offers the capacity to effectively triage pediatric victims and assign scarce pediatric critical care resources. The algorithm, if effectively operationalized and managed, has the capacity to improve the survival outcomes for child victims injured in a mass casualty event.

Toltzis-Wetzel Model for Pediatric Triage

A novel approach has been developed to aid front line pediatric intensivists to objectively triage pediatric victims when crisis standards are activated. This strategy uses basic physiologic and assessment data to develop a rapid determination of the severity of illness, the risk of death, and the need for extended use of limited pediatric critical care resources for presenting child victims. The model assists persons in the role of medical control to objectively and systematically determine which child victims should be admitted to the PICU during a disaster, and further, which children with actual or likely respiratory failure should be given access to a ventilator, which is a potentially life-saving therapy used in PICUs but also in limited supply.

Using traditional logistic regression techniques as well as advanced machine learning principles, data from 150,000 admissions to 116 PICUs submitted in the Virtual PICU Systems (VPS) database (2009-2011) were used to develop a new approach to pediatric disaster triage and PICU resource allocation. VPS is a database for pediatric critical care, based in the US, and with over 125 participating PICUs from the US, Canada and the Middle East. With consistent expansion over the last ten years, the VPS is arguably the largest single source of pediatric clinical critical care data in the world.

The algorithm uses seven statistically validated equations to predict mortality, the need for mechanical ventilation and the estimated PICU length of stay. The algorithm is designed to be used by clinicians responsible for managing and/or coordinating the triage process to determine which patients should be admitted to a PICU bed and provided with mechanical ventilation treatment, based on their status at initial arrival to the triage station. Figure 3 is the decision-tree framework that is used to apply the appropriate prediction equations that will enable to triage intensivist to determine how to classify each patient. (Toltzis, Sato-Campos, Kuhn & Wetzel, 2013). The prediction equations and composite variables for each equation are presented as Appendix I.

The first decision point determines whether the patient is intubated upon arrival, meaning an artificial tube has been placed to protect their airway and to allow either natural or mechanically supported respirations. Intubated victims are triaged first. Based on data collected at the point of triage, including vital signs, neurologic assessment data, blood gas data measured with point of care testing equipment, and available health history information, the intensivist can quickly apply the appropriate prediction equation s (1-3 for intubated, 4-7 for non-intubated. If a victim's scores are below the triage thresholds for each equation, they are considered optimal for treatment. Those excluded fall into one of two categories: too well to require use of PICU resources, and transferred for non-critical care elsewhere, or too sick to benefit from PICU resources within a short timeframe, and transferred for palliative care services in another location.

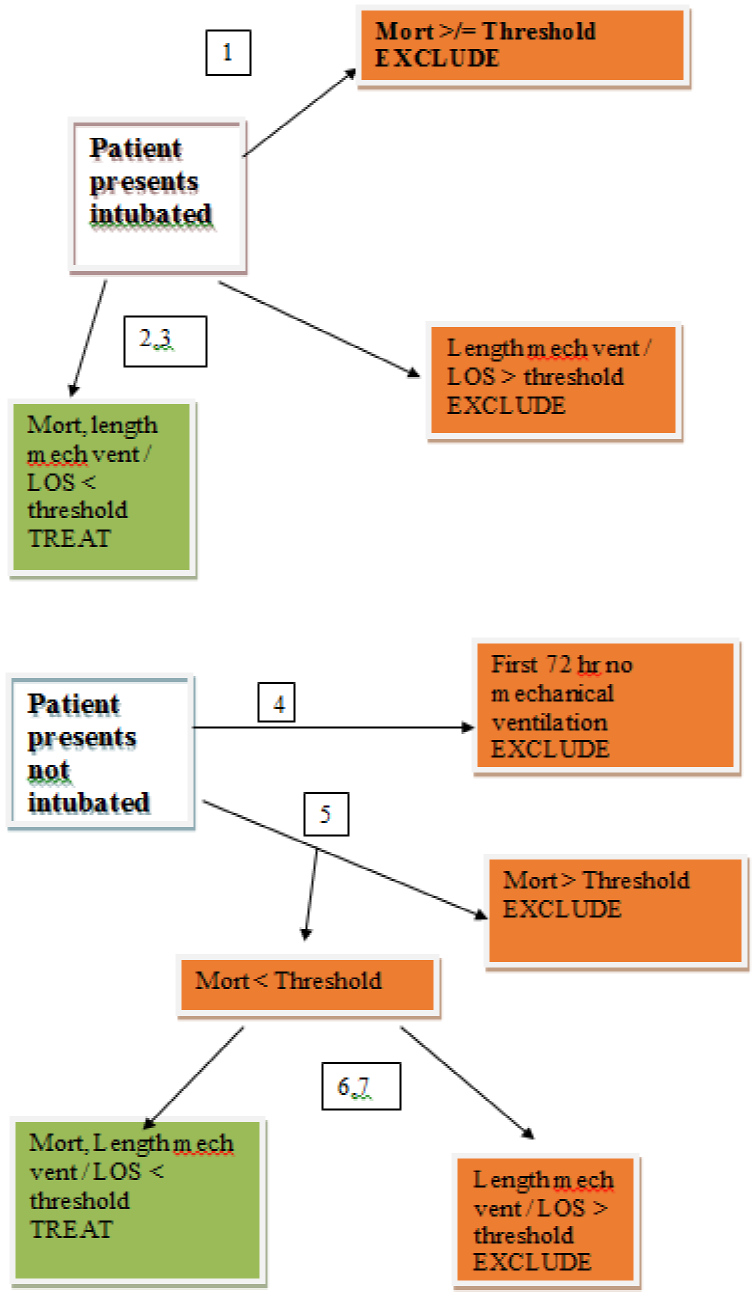

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Figure 3: Toltzis-Wetzel Pediatric Triage Algorithm

Figure 4 provides a visual depiction of how the pediatric triage algorithm may be used to determine how child victims of a disaster will be determined suitable for care. In a catastrophic mass casualty event (MCE) that overwhelms critical care resources, victims of the event will be triaged into three categories: those too well to continue using scarce medical resources, those deemed optimal for treatment, and those determined too sick to survive with limited access to scarce resources (Phillips & Knebel, 2007). PICU admission will be given to those determined optimal for treatment.

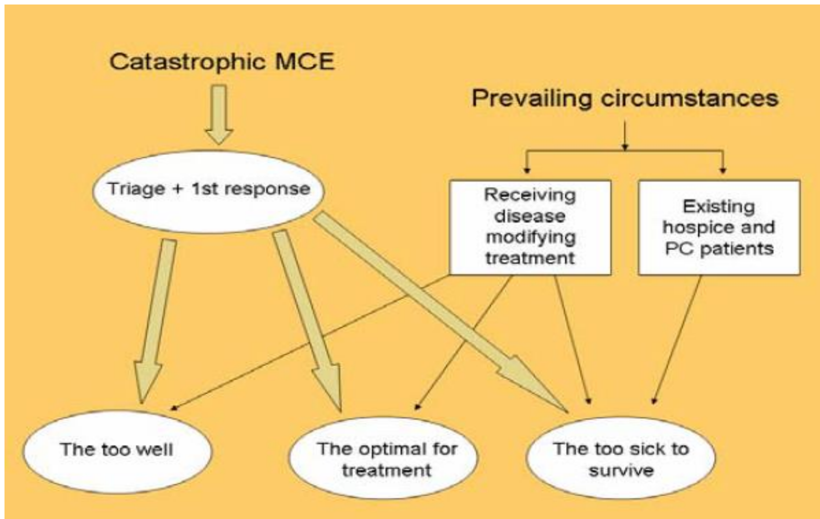

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Figure 4: Triage Tool Concepts in Crisis Standards of Care

This model describes that at the start of CSC activation, that both victims of the disaster that are arriving for care, as well as patients already using hospital or hospice services, might be subject to the triage process. This research project will focus only on the triage of disaster victims; decisions regarding those already in treatment will be made individually by the care team.

The Ohio Project

The Toltzis-Wetzel pediatric triage model was developed at the request of the Ohio Hospital Association and the Ohio Department of Health. The Planning Committee of the Ohio Medical Coordination Plan (OMCP) which provides guidance for the implementation of the disaster response, including crisis standards of care and allocation of scarce resources, recognized that their plan did not effectively address the needs of children. They further recognized that Ohio was not alone in this identified gap in their disaster management plan and therefore could not partner with neighboring resources to address the gap. Based on this assessment, the Ohio team contracted for the development of the pediatric triage algorithm previously described. The products of phase I of the Ohio project are foundational to this dissertation.

Ethical Use of Triage

This dissertation will take the next step; development of the optimal thresholds that enable the pediatric triage algorithm to be operationalized. For this research to be successful, it is necessary that the triage approach itself is accepted. To support the development of effective tools to support CSC activation, the Institute of Medicine *Letter Report* (2009) identified five critical elements to be incorporated in all plans for the implementation of crisis standards of care:

- Ethical considerations are maintained when developing crisis standards of care, guided by the key ethical values of transparency, consistency, proportionality, and accountability;
- Key community and provider stakeholders are engaged in the planning of crisis standards of care, the education of the community and emergency responders, and in ongoing communication;
- Proactive establishment of legal provisions to be activated when emergency declarations are made, including the establish of legal standards of care in crisis situations, mutual aid agreements, limitations of liability for responders and volunteers, as well as issues of licensing, credentialing, health care facility regulations, and provider scope of practice during emergencies;
- Establishment of indicators and triggers that assist emergency personnel to maintain situational awareness regarding the status of the Emergency Medical System (EMS) and the availability of resources, including incident specific information such as the incidence and severity of illness, the state of critical infrastructure stability, the success of contingency plans

such as surge response, and the availability of personnel, equipment, supplies, and space to address the needs of victims;

- Development of CSC plans that address the continuum of clinical capacity, from conventional, contingency, to crisis, and the implementation of incident command principles that address resource allocation and crisis communication to ensure the best possible coordination across all levels of the health care system.

These measures were intended to put both the public and providers of care at ease by ensuring that ethical standards will prevail even when scarce resources are severely taxed. The principle of equity is integral to the successful implementation of this pediatric triage tool, and supports the proactive establishment of thresholds to determine how to consistently classify each patient requiring medical care during the catastrophe into one of the three triage categories described above, based exclusively on their medical condition and known health history. This strategy is intended to eliminate other factors which may unfairly place disparate individuals in either a disadvantaged or beneficial position.

This pediatric triage tool is intended to enable a pediatric intensivist or other physician specialist to effectively triage presenting patients through the application of the triage algorithms and to efficiently assign scarce critical care resources. However, the medical education system in the United States is deficient in providing a curriculum that prepares physicians to respond effectively and ethically in a disaster (Holt, 2008). This adds to the mounting evidence highlighting the need for additional guidance in this area.

Further, how a triage process is implemented is of paramount importance. The establishment of triage thresholds must be made using objective and standard methods and equally important, management of triage thresholds must be done ethically, transparently and systematically to ensure ongoing trust in the triage process (O'Laughlin & Hick, 2008). This research will provide guidance not only on how to use the triage algorithm and associated thresholds, but how to ensure that the triage plan is operationalized in an efficient and ethical manner.

Ohio Project Phase II

This research is a continuation of Phase I of the Ohio project. The focus of this project is on developing the knowledge and tools needed to responsibly use the pediatric triage process to achieve optimal survival during a crisis. The research team postulates that the type of disaster, the duration of the disaster, and the number of disaster victims may influence the triage process. We therefore intend to consider two different disaster scenarios in the study design to explore this concept further.

Related Literature

Disaster Response in the United States: Capabilities and Limitations

In 2002, the U.S. Department of Health and Human Services (DHHS) established the National Bioterrorism Hospital Preparedness Program (NBHPP), which was later changed to Hospital Preparedness Program (HPP). The focus of this program is to provide guidance and federal funds to assist hospitals to build the necessary infrastructure to address the needs of civilians affected by public health emergencies, including terror attacks.

Each year, based on results of ongoing capacity assessments, national NBHPP priorities are established to iteratively build the nations preparedness infrastructure.

Preliminary results of the effectiveness of the program in achieving year one objectives identified that while movement towards compliance with some objectives was occurring across the nation, no state had achieved a critical benchmark of developing an effective response plan for the hospitals within their state to address an epidemic involving 500 victims (GAO, 2004). This report provided the needed reinforcement that there was more work to be done to prepare the nation to execute an effective disaster response in a mass casualty event.

Surge Capacity

Surge capacity is a strategy that allows hospitals and other organizations responsible for addressing the immediate medical needs of victims transition from conventional, to contingency and to crisis care when demand for scarce resources overwhelms supply (Hick, Barbera, Macintyre & Kelen, 2009). A seamless transition from normal operations to effective implementation of contingency measures requires proactive planning and development of strategies to create maximal capacity of the infrastructure. When the disaster event warrants a state of emergency declaration, transition to crisis standards of care becomes necessary, which establishes even greater reliance on the ability to sustain the expanded infrastructure of the surge effort.

To develop effective surge capacity, many key areas need to be addressed including:

- Infrastructure: advanced planning is needed to procure and at times stockpile additional beds, equipment and supplies, supervision and staffing, and support services for the expansion areas
- Coordination: establish inicident management systems, standard operating standards of care that are coordinated with local, state and national agencies

- Manpower: develop plans to increase the labor pool of trained resources for expanded ICU care, provide necessary education, training and opportunities to practice surge care, maintain an updated inventory of the capbilities of staff for role expansion in the event of disaster plan activation, and develop safeguards to ensure patient safety
- Protections: take measures to minimize the risk of staff and patients through the consistent availability and use of personal protective equipment, isolation techniques, access to handwashing facilities, and legal protections for staff and volunteers working outside of their normal domain
- Critical Care Triage: development of policies and practices that assure the fair and equitable distribution of scarce resources and consistency in triage decisions to withhold or withdraw care
- Medical Procedure Controls: proactive identification of high risk or high resource intensive procedures that will not be available in a disaster and development of universal guidelines regarding cancellation of elective procedures (Sprung, 2010).

A key consideration for critical care leaders in implementing a plan for surge capacity is the timeframe required for sustaining expanded capacity. In the Emergency Department, surge capacity timelines generally are developed in terms of minutes and hours. Intensive Care Units may need to sustain increased capacity for days or weeks. Effectively addressing surge in all of the key areas previously described, with the capability of sustaining the surge, is essential to the success of a surge plan (Christian, Bevereaux, Dechter, Geiling, & Rubinson, 2007).

Scarce Equipment

The ventilator is a common life-saving tool used in the critical care arsenal, responsible for delivering mechanical breaths and supplemental oxygen to victims in respiratory failure. Therefore, effective prediction of the needs for mechanical ventilation and availability of sufficient numbers of ventilators is a key consideration in a disaster.

Estimates of ventilator demand in a mass casualty vary from 17-23/100,000 population (Daugherty, Branson & Rubinson, 2007). The federal government stockpiles an estimated 4,600 ventilators with intentions to expand this resource. However, since a ventilator is one of the most essential tools to manage the emergent conditions of critically ill victims, the need to have ventilators immediately available is important. As such, while planning at the national level should focus on overall national ventilator capacity, there must be equal attentiveness to the need to rapidly deploy ventilator stockpiles when disaster hits. The logistical challenge of timely distribution, as well as provision of the training necessary to operate unfamiliar brands of ventilators safely and effectively, is a key consideration to effective deployment (Bernardo & Veenema, 2004).

Further, ventilators are not a one-size-fits-most piece of equipment. Ventilators are specifically designed to meet the unique needs of infants and children. The support supplies needed to operate these ventilators are also pediatric-specific which further complicates the logistics of the stockpile and rapid deployment strategy.

Another consideration related to provision of critical care equipment is the ability to use the equipment. As such, hospitals must plan not only for electrical circuits capable of handling the energy demand of medical equipment, but need to have redundent systems and generators to handle loss of power from traditional sources; a common occurrence during many disaster events.

Mobilization of Equipment and Supplies

In this era of cost reduction in health care, hospitals have responded by reducing inventory. Using “just in time” supply chain processes that focus on delivery of equipment and supplies close to the time of actual need, costly inventories have been reduced. While this is an effective and responsible strategy to support conventional care, it challenges the ability to surge to meet contingent or crisis care requirements. As a result, hospital supply systems may be quickly overwhelmed in a mass casualty event (Phillips, 2006).

Critical Medications and Medical Gases

Inotropes and vasopressors are medications routinely used in critical care medicine. Stockpiling these expensive resources presents another challenge as medications have limited shelf life due to expiration dates. This introduces another layer of complexity; the need to monitor for and replace outdated medications.

Further, while many critically ill patients require supplemental oxygen, the availability of suppliers to rapidly increase the availability of medical grade oxygen is limited. Transport trucks that deliver medical grade oxygen require special functional and safety features and specially trained personnel. This specialty regulations limit the possible options for safe tranpsort of oxygen to the disaster area.

Surge Space

Even when necessary equipment, medications and supplies can be procured, the expansion of critical care resources also has space considerations as the accommodations necessary to support provision of critical care are highly specialized. In addition to availability of electricity, oxygen and other medical gases, suction, and extra monitoring equipment necessary to outfit additional ICU beds, finding space that can support these needs often limits expansion of ICU beds to the Emergency Department or the Post Anesthesia Care Unit (PACU). This practical consideration effectively how and where critical care services can be provided.

Staffing

Staffing is also a key consideration in mass casualty response. When a hospital is located within the disaster impact zone, it is likely that hospital staff may also be impacted personally by the effects of the disaster. Therefore, while hospital disaster plans call for increased staff availability, practically, the rate of absenteeism can increase in a disaster and must be considered in the disaster plan. (Wise, 2006).

Expertise is another limitation for personnel responsible for hospital disaster response. While critical care physicians and hospital administrators are charged with leading the multidisciplinary care team to implement the disaster response, experience in dealing with real disaster scenarios is limited among hospital leadership nationally. This supports the need for leaders and staff to participate in frequent simulated disaster activities, to develop experience with the disaster plan so that they are comfortable executing their duties in a true disaster.

When standards of care reach crisis mode in a disaster, it is probable that staff will be called upon to rapidly expand their scope of responsibility for care, taking on tasks for which they may have not been previously determined competent. Disaster plans should therefore include tools for just-in-time education of staff to serve in expanded capacities.

Evacuation

When it is determined that the best option for a victim is evacuation to another hospital or care area, the logistics of transport become another potential challenge. In addition to the aforementioned issue of lack of trained transport services nationally, transport requires two or three staff to manage each victim in transit. The allocation of a two:one or three:one staff to patient ratio can further compromise the ability of the critical care team to adequately manage all critical victims, and makes the consideration of supporting evacuation efforts a duanting challenge.

Despite the recognized challenges, there is mounting evidence to suggest that national, state and local efforts to improve emergency prepareness is working. In a report evaluating the first six years of the DHHS Hospital Prepareness Program (HPP), it was concluded that while work to integrate the various systems and agencies involved in preparedness required additional development, that hospitals and communities in the United States had demonstrably improved their resiliency to effectively respond to medical disasters (DHHS, 2009).

Emergency Standards and Accreditation

Principles of emergency management and preparedness have been incorporated into accreditation activities aimed at setting national standards in various areas of the private sector healthcare and public health infrastructure. Agencies including the Joint Commission, responsible for setting standards for the nation's health care delivery system, have joined the effort to define the hallmarks of quality in emergency management and prepareness. Other organizations have attempted to adopt national standards and integrate key concepts within their area of influence to further improve the cohesion and cooporation among preparedness partners. As an example, the Bureau of Primary Health Care (BPHC), a division of the Health Resources and Services Administration (HRSA) of the US Department of Health and Human Services has published expectations for community health centers. These include the statement of the important role that health centers play in the implementation of an effective disaster response, the requirement of all health centers to develop an emergency response plan and the communication of expectations of health centers in a mass casualty event (HRSA, 2007).

Further integrative efforts have been led by the Federal Emergency Management Administration (FEMA) through the establishment of the National Incident Management System (NIMS). NIMS seeks to develop a common vocabulary and systematic approach to aid agencies and juresdictions to work together to build a stable, sustainable preparedness insfrastructure (FEMA, 2013).

Table 1 provides a sample of how various emergency management plan components are addressed by the Joint Commission, the BPHC, and NIMS (National Association of Community Health Centers, 2010). The crosswalk illustrates the intentional efforts to build on and when possible, integrate various aspects of the emergency response effort and represents a small sample of the available data on the website.

Essential Components of Emergency Management Plans at Community Health Centers
Crosswalk of Plan Elements

Plan Components	BPHC PIN 2007-15	Joint Commission	NIMS
Health centers will have an emergency management plan	Plans and procedures for emergency management must be integrated into a health center's risk management approach to assure that suitable guidelines are established and followed so that it can respond effectively and appropriately to an emergency (page 4).	EM.02.01.01: The organization has a written Emergency Management Plan.	2008/2009 Objective 3: Revise and update emergency operations plans (EOPs), standard operating procedures (SOPs), and standard operating guidelines (SOGs) to incorporate NIMS and National Response Framework (NRF components, principles and policies, to include planning, training, response, exercises, equipment, evaluation, and corrective action.
Plan and organization are NIMS compliant	While it is not a requirement for health centers at this time, compliance with NIMS is strongly encouraged.		2008/2009 Objective 1: Adopt NIMS throughout the healthcare organization including all appropriate departments and business units. 2008/2009 Objective 2: Ensure Federal Preparedness awards support NIMS Implementation (in accordance with the eligibility and allowable uses of the awards).
Plan should be based on a Hazard Vulnerability Analysis (HVA)	Health centers should initiate emergency management planning by conducting a risk assessment such as a Hazard Vulnerability Analysis (page 5) Health centers are encouraged to participate in community level risk assessments and integrate their own risk assessment with the local community (page 5).	EM.01.01.01 / EP 2: The organization identifies potential emergencies and the direct and indirect effects that these emergencies may have on the need for its service or its ability to provide these services. Note: some organizations refer to this process as a hazard vulnerability analysis.	
Plan should address the four phases of emergency management	The EMP should address the four phases of emergency management – Mitigation activities lessen the severity and impact a potential disaster or emergency might have on a health center's operation (page 5) Preparedness activities build capacity and identify resources that may be used should a disaster or emergency occur (page 5). Response refers to the actual emergency and controls the negative effects of emergency situations (page 5). Recovery actions begin almost concurrently with response	EM.01.01.01 / EP 5: The organization uses its prioritized emergencies as a basis for defining mitigation activities (that is, activities designed to reduce the risk of and potential damage from an emergency). EM.01.01.01 / EP 6: The organization uses its prioritized emergencies as a basis for defining the preparedness activities that will organize and mobilize essential resources. EM.02.01.01 / EP 2: The organization has a written Emergency Management Plan that describes the response procedures to follow when emergencies occur. EM.02.01.01 / EP 4: The organization has a written Emergency Management Plan that describes the recovery strategies, actions, and individual responsibilities necessary to	2008/2009 Objective 3: Revise and update emergency operations plans (EOPs), standard operating procedures (SOPs), and standard operating guidelines (SOGs) to incorporate NIMS and National Response Framework (NRF components, principles and policies, to include planning, training, response, exercises, equipment, evaluation, and corrective action.

NOTE: This tool is provided for reference only. For full details about plan components and other requirements related to emergency management, please refer to the BPHC Policy Information Notice 2007-15, Joint Commission 2009 Emergency Management Standards, and FY 2008 & 2009 NIMS Implementation Objectives for Healthcare Organizations.

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Table 1: Emergency Management Plan Crosswalk

The National Disaster Medical Management Infrastructure

The National Disaster Medical System (NDMS) is the federal infrastructure developed to mobilize federal resources for disaster response to complement local, regional and state wide medical responses. NDMS supplements medical response capacity by supporting state and local governments in the management of manage peacetime disasters (DHHS, 2013). Directed by the Department of Health and Human Services (DHHS), the lead response agency at the federal level, the NDMS was originally purposed to support the needs of civilian and military victims of overseas conflicts (Lister, 2005). The original purpose of the formation of NDMS was never realized however, and it was subsequently recognized that the infrastructure of the NDMS was a natural fit to support the operations of the evolving emergency management system.

The Department of Homeland Security (DHS) leads coordination efforts for the NDMS. The Department of Defense (DoD) and the Veterans Administration (VA) manage logistics and transportation for the NDMS. These federal resources are also supplemented by agreements between the federal government and select private, non-federal hospitals for care delivery. (Franco, Toner, Waldhorn, Inglesby & O'Toole, 2007).

The key components to the NDMS include:

- Development of deployable medical response teams
- Development of a system of patient evacuation from the disaster area
- Provision of definitive hospital care

The NDMS supports 55 Disaster Medical Assistance Teams (DMATs). Depending on the severity of illness or injury, one DMAT can treat and release as many as 250 patients/day with minor conditions, though substantially less, if the medical needs are greater. There are only 2 pediatric DMATs in the NDMS, which creates cause for concern as children are likely not easily cohorted in a disaster and therefore, are reliant on disaster medical services from providers potentially lacking the appropriate specialized preparation needed to manage pediatric trauma and other pediatric specific conditions (Franco et al, 2007).

Since DMATs are not continually on active status and require deployment, their response time is not immediate. Further, the capacity of DMATs to care for conditions other than minor, limiting conditions is poor. Therefore, reliance on DMATs to support pediatric mass casualty events in a timely and comprehensive manner is unrealistic.

When the surge of casualties exceeds the capacity of the DMAT staff, the NDMS has the authority to initiate victim evacuation. Due to a shortage of trained transport personnel, the impact of evacuation efforts may be limited.

Federal Medical Stations (FMS) provide another potential layer of disaster response in the management of injured victims. However, FMS's are only activated during true disasters and, like DMATs, the requisite time for deployment is not immediate; this severely restricts rapid response. (Franco et al, 2007).

Another challenge that the NDMS faces in achieving optimal outcomes during disasters is the very structure of the United States health care system. Since the majority of hospitals are private and not integrated, they are not connected to effectively support a collaborative response. The federal government has little authority in the privatized U.S. health care system, which has necessitated the development of collaborative agreements with private hospitals for use in times of emergency. Despite the proactive execution of agreements aimed to make necessary hospital resources available during a disaster, disaster response is not the key responsibility of most hospital personnel in the private sector and therefore, this coverage model may not be as effective as other resources available through the NDMS.

The NDMS was activated during Hurricane Katrina in 2005 and, along with other aspects of the Emergency Management Plan, were universally criticized for their unsuccessful response. The awareness of the overall ineffectiveness of the disaster response prompted a Congressional request for the re-evaluation of the NDMS. Senate Report 109-322 (2006) reported that while the evacuation of thousands of patients out of the disaster zone was successful, the system failed overall. The findings concluded that:

- The medical teams that were deployed to the region were overwhelmed
- There was no effective command structure
- There was no patient tracking system to accompany deployment processes to track patient movement
- No system was in place to record the location that individual patients were evacuated to

Other recommendations made in the Senate report (2006) for the improved effectiveness of NDMS included:

- Increasing the engagement of private hospital/healthcare system engagement in preparedness and response activities, including the development of detailed expectations of hospitals when located in the impact zone
- Creating regional hospital networks as a supportive infrastructure for NDMS, which, if effectively developed, could improve response time by reducing reliance on mobilization of national resources
- Developing additional systems of patient transport linked to the NDMS tracking system to reduce reliance on the DoD long haul air system

To support these recommendations, DHHS has instituted Partnership Awards to encourage contiguous regions to work together. The intention of this initiative was to develop collaborative systems and cooperative agreements with the health care environment that is typically competitive. The proactive development of contingency plans and agreements enables resources from neighboring regions that are unaffected by the disaster to swiftly respond to victims' needs from the nearby disaster zone, reducing the reliance on resource mobilization beyond the contiguous region (Maldin, et al, 2007).

Amidst the backdrop of the federal NDMS system that has been challenged to provide timely and effective disaster response, the critical care systems responsible for responding to disastrous events that produce large-scale victim casualties are under-developed (Grissom & Farmer, 2005). Considering the limitations of the Federal NDMS system and the focus on building response systems within and near to the impact zone, this research project will concentrate on the activities of the local and state medical response systems to provide actionable strategies that may be used in a pediatric mass casualty event. For this work, when describing state response systems, tribal and territorial governments apply.

Legal and Ethical Issues

The importance of effectively addressing legal and ethical considerations in advance of activation of an emergency response cannot be underscored. If fact, the disaster response framework that emerged from the IOM L*etter Report* (2009) highlights the pivotal role that legal and ethical issues have in this discussion. Figure 5 provides a visual depiction of the disaster response framework, highlighting that legal and ethical considerations serve as the bedrock; foundational elements essential to the development of an effective catastrophic disaster response (IOM, 2009).

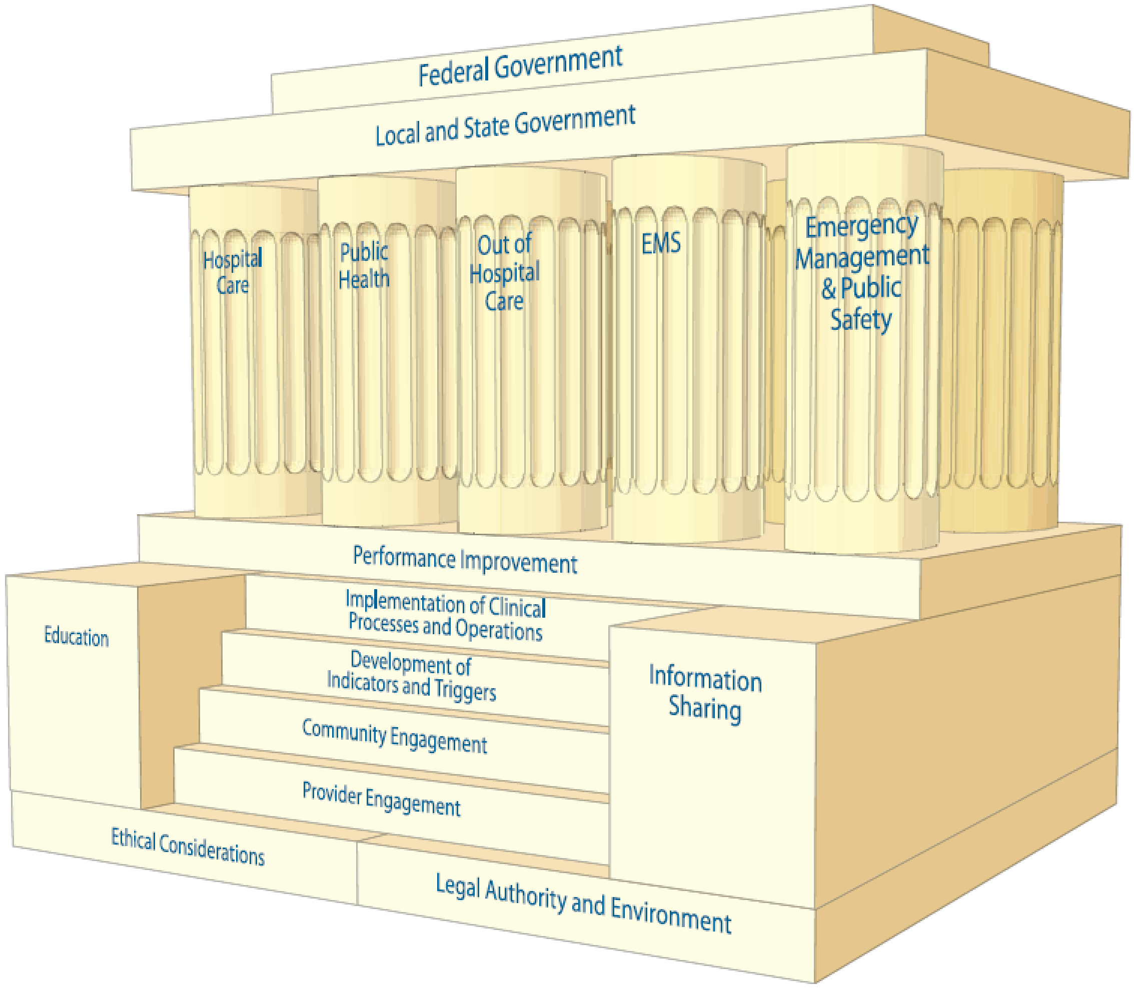

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Figure 5: IOM Disaster Response Framework

A mass casualty event represents a span of time where victims are at their most vulnerable, as are the providers of care. As standards of care are relaxed to address the immediate needs of an overwhelming disaster, legal and ethical considerations must keep pace to secure adequate protections for all under the law. The recommendation for establishment of laws for particular use during a declared disaster is not intended to give license to professionals to act in a careless manner or with willful misconduct. Instead, these legal provisions should clear barriers to the expanded liability protections needed by health care providers, volunteers and other members of the system charged with responding to the disaster, without requiring the safeguards typically governing the determination of liability. It is argued that when medical standards of care change, legal standards of care should follow to ensure that legal protections address the environment in which care is being delivered and decisions are being made (Annas, 2010).

Since professional licensure and legal liability concerns are largely addressed at the state level, state to state variation on disaster coverage exists. Therefore, as part of general preparedness activities, each state should assess their legal requirements regarding professional and volunteer liability coverage in a disaster. The American Medical Association (AMA) has taken a lead role on the legal front. They have formally advocated for the position that in times of declared emergencies, unexpected outcomes may occur through the particular fault of no one. The AMA adopted a resolution declaring the need for “national legislation that gives qualified physician volunteers… automatic medical liability immunity in the event of a declared national disaster or federal emergency” (AMA, 2005).

In 2008, the AMA encouraged state endorsement of the Uniform Volunteer Emergency Health Practitioners Act, developed to protect volunteer health care practitioners from liability on the grounds of negligence during a declared disaster (AMA, 2008).

There has been further attention to the development of protections of health care professionals and volunteers in crisis situations at the federal level. At minimum, the IOM (2009) recommends that the following elements are addressed to establish a legal authority and environment that protects care providers in extreme situations where crisis standards of care become necessary:

- Definition of both medical and legal standards of care
- Defined crisis scope of practice for providers of health care
- Mutual aid agreements to assist in the allocation of resources
- Definition around federal, state and local declarations of emergency
- Special emergency protections and waivers of sanctions
- Crisis licensing and credentialing guidelines
- Liability protections

Several other acts of legislation at the state and federal level have focused on the expansion of protections of volunteer health practitioners and indemnification from civil actions resulting from provision of treatment during a public health emergency, even outside of state licensure and organizational privileging processes. These include the Model State Emergency Health Powers Act which protects out of state emergency health care professionals, the Uniform Emergency Volunteer Health Practitioners Act (UEVHPA) which provides safeguards to volunteer health practitioner in the public or private sector, The Emergency Management Assistance Compact (EMAC) which renders immunity for government officers and employees who assist in disaster management outside of their jurisdiction, and the Federal Volunteer Protection Act (VPS) which protects uncompensated volunteers of nonprofit or governmental agencies from legal action (IOM, 2012).

From an ethical perspective, there are few topics more difficult to address than how to allocate scarce resources in a disaster when the consequence of the decisions can include compromised health or death. Concepts that must be actualized to secure a sound ethical position include utilitarianism and fairness. During times of crisis intervention the needs of the individual, typically the focus of care provision, shift to the needs of the entire group and to the assurance that decisions will result in the greater good for the largest number of people. Fairness dictates that decisions implemented to aid in the allocation of scarce resources must not favor a particular group and that decision to deny access to higher levels of care need to be applied consistently.

At-risk populations like the elderly, disabled and uninsured may be particularly vulnerable during a disaster. While rationing decisions may result in exclusion from treatment based on a particular physical characteristic, proactive measures should be taken to consider how to address the needs of vulnerable populations when services are severely taxed. Though important in all aspects of the development and planning process, engagement of the community as well as public and private partnerships aimed at addressing this disadvantaged group is particularly necessary. The greater the participation in this discussion, the better the opportunity may be to identify novel solutions and consensus.

Chapter 5: STUDY DESIGN AND METHODS

The investigators

This study is a continuation of the Ohio Project previously described. As the principal investigator, I led this project, developed the study design and proposed methods in collaboration with the team, expedited team communications and key decision points, and managed this project on a daily basis, ran simulations using the simulation models built for this project to explore optimal triage thresholds, facilitated team consensus on the interpretations and discussions of the study results. I am joined by several experts in the fields of pediatric disaster management, pediatric critical care, simulation, and management sciences.

My co-investigators include Dr Philip Toltzis, Dr Alexander Kolker, and Dr Randall Wetzel. Dr Toltzis and Dr Wetzel served as the key links between Phase I and this phase of the project, informing this team regarding the guiding concepts and rationale behind the development of the original triage scheme and related prediction equations, and to ensure that the prior work is appropriately applied to this research. As subject matter experts, they also contributed to the requirements and assumptions incorporated into the simulation activities and assisted in exploring results and identifying important discussion points. Dr Kolker served as the key statistical resource and discrete event simulation expert, building the simulation models based on the requirements generated by the entire team. Mid-way through this project, Dr Robert Kanter, a pediatric intensivist and extensive author on the topic of pediatric mass casualty, agreed to serve as a consultant on this project after I contacted him related to his work on pediatric mass casualty triage in a pandemic. Dr Kanter participated in weekly team update calls and offered invaluable input and advice.

Study Design

This study used a mixed methods approach to investigate the overarching and sub-questions. No primary data collection was performed. Secondary data were collected from a comprehensive literature review, key stakeholders, secondary data from Ohio contacts, results from phase I of the project, and deidentified data from the VPS database.

Two disaster scenarios were used in this study. The first disaster was a single event, region and time limited event such as a stadium collapse. The second disaster was a mass casualty pandemic. Discrete event simulation techniques were used to determine optimal triage thresholds during CSC activation for each disaster scenario. Several iterations of simulation were performed to derive updated triage algorithms specifically for the single event and pandemic disaster events. The performance of the triage algorithms and optimal thresholds were validated by comparing survival results of victims admitted to the PICU for treatment via the triage approach to a random first come first served assignment of treatment. Data from real PICU admissions was used for validation.

Methods

Database

The main source of data for this study was the VPS database. Data collected for VPS is held to rigorous quality control practices. In my role as Director of Quality for VPS, I am responsible for the development and administration of the quality control plan, which includes the use of data collection staff with certain clinical credentials, development of standardized definitions and standardized training programs for the data collection team, certification of the data collection team through initial and ongoing inter rater reliability and annual certification exams, validation of data through a combination of point of entry, case closure and customized automated and manual validations. The inter rater reliability concordance of the VPS data collectors exceeds 95% (VPS, 2014, unpublished data). These strategies have effectively positioned VPS as a trusted source of pediatric clinical critical care data for clinicians, leaders, and researchers and has supported hundreds of publications, abstracts and presentations.

Investigational Review Board

This study was determined not to meet the definitions for human subjects research due to the exclusive use of secondary, non-identifiable data. The Investigational Review Board from the University of Illinois at Chicago exempted this research from Investigational Review Board oversight.

Simulation

Simulation was selected for this project as it is a technique specifically designed to explore complex hypotheses that have countless potential solutions. As previously described:

> "A discrete event simulation (DES) model of a system/process is a computer model that mimics the dynamic behavior of the system/process as it evolves with time in order to visualize and quantitatively analyze its performance. The validated and verified model is then used to study behavior of the original system/process and its response to input variables in order to identify the ways for its improvement (scenarios) based on some improvement criteria.
>
> DES models track entities moving through the system at distinct points of time (events). The detailed track is recorded for all processing times and waiting times. Then the system's statistics for entities and activities are gathered." (Kolker, 2012, p. 3). "Once the simulation is completed for any length of time, another set of random numbers from the same distributions is generated, and the procedure (called replication) is repeated. Usually multiple replications are needed to properly capture the system's variability. In the end, the system's output statistics is calculated, e.g. the average patient and server waiting time, its standard deviation, the average number of patients in the queue, the

> confidence intervals and so on." (Kolker, 2012, p. 4). "DES models are capable of tracking hundreds of individual entities arriving randomly or in a complex pattern, each with its own unique attributes, enabling one to simulate the most complex systems with interacting events and component interdependencies.
>
> Typical information required to populate the model includes the following: (1) Quantity of entities and their arrival time, e.g. periodic, random, scheduled, daily pattern, etc. There is no restriction on the arrival pattern distribution type; (2) The time that the entities spend in the activities, i.e. service time. This is usually not a fixed time but a statistical distribution. There is no restriction on the distribution type; (3) Capacity of each activity, i.e. the maximum number of entities that can be processed concurrently in the activity; (4) The maximum size of input and output queues for the activities." (Kolker, 2012, p. 5).

ProcessModel v5.5 simulation software was used to develop the simulation model and optimal triage thresholds for this study. (Baird, 2013).

The simulation model incorporated data provided by leaders from PICUs in Ohio regarding the number of available surge PICU beds and surge ventilators and deidentified clinical data from real consecutive PICU admissions from a US-based PICU database. The simulation model was developed to generate thresholds for factors important to the triage process that would guarantee peak efficiency of the triage process. Then, all possible combinations of values for the physiologic elements comprising the prediction equations were run through the model to simulate victim arrival for children impacted by the disaster. Virtual victims were created by combining unique combinations of values based on the true distribution of each variable from the VPS dataset to generate a pool of victims with varying levels of illness or injury.

The simulation explored various combinations of numbers of arriving victims, available beds, and acuity levels of victims to determine the triage thresholds that would allow for the maximal number of patients to be treated with optimal chance for survival. Separate simulation models were generated for each disaster type to generate thresholds for the prediction equations included in each model.

Following the development of optimal triage thresholds for each simulated disaster, the performance of the triage plan was tested. Ten, randomly selected groups of patients were generated from the VPS database. Each group contained 10,000 and 18,000 cases, for the single event and pandemic disaster, respectively. In ten separate experiments, cases were first run through all optimal solutions for each triage algorithm to select patients considered optimal for treatment. The number of treated patients and the survival rate for the treated group was recorded. The same number of patients was then selected from the same group, randomly ordered and with no triage parameters applied. This selection method mirrored the typical approach to assignment of scarce resources that typically occurs in an overwhelming disaster when time of arrival is the dominant consideration for selection of victims for treatment.

Chapter 6: MANUSCRIPT ONE

Development of Pediatric Triage Guidelines for use during an Overwhelming Single Event Disaster

Authors:
Christine Gall[1],DrPHc; Alexander Kolker[2,3],PhD; Randall Wetzel[1,4,5,],MBBS;
Robert Kanter[6,7],MD; Philip Toltzis[8,9],MD

Author Affiliations:
[1]Virtual PICU Systems, LLC, Los Angeles, California; [2]API Healthcare, A GE Healthcare Company, Hartford, Wisconsin; [3]University of Wisconsin Milwaukee, Milwaukee, Wisconsin; [4]Division of Critical Care Medicine, Department of Pediatrics and Anesthesiology, Children's Hospital Los Angeles; [5]USC Keck School of Medicine, Los Angeles, California; [6]Department of Pediatric Critical Care Medicine, SUNY Upstate Medical Center, Syracuse, New York; [7]National Center for Disaster Preparedness, Columbia University, New York, New York; [8]Case Western University School of Medicine, Cleveland, Ohio; [9]Rainbow Babies and Children's Hospital, Cleveland, Ohio.

Corresponding Author:
Christine Gall, DrPHc
Director, Quality and Client Relations
Virtual PICU Systems, LLC
4470 Sunset Blvd, Suite 440, Los Angeles, California
Telephone: (888) 999-4850 x102
Email: cgall@myvps.org

Abstract

Objective: To determine whether a triage algorithm can be developed to effectively deploy scarce pediatric critical care resources during a single event disaster when crisis standards of care are implemented.

Methods: 148,066 randomly selected cases (2009-2011) from the Virtual PICU Systems (VPS, LLC) database were used. Data were initially explored using discrete event simulation (DES) to determine optimal triage thresholds for triage in Crisis Standards of Care (CSC) deployment. Prediction equations generated in an earlier phase of this study were used to calculate each victim's Probability of Death (POD) using only assessment and lab data available at triage. Victim results were compared with optimal thresholds to select patients for treatment. Survival of treated group was compared for triage and a first com first served (FCFS) bed assignment.

Results: Survival (%) in the treatment group was significantly higher in the triaged group for all experiments. Victim/bed ratio 10:1 triage (98.32; 95% CI: 98.04-98.57) and FCFS (88.18; 95% CI: 87.50-88.84); 5:1 triage (98.41; 95% CI: 98.15-98.65) and FCFS (91.32; 95% CI: 90.75-91.86); 3:1 triage (98.46; 95% CI: 98.22-98.69) and FCFS (93.86; 95% CI: 93.39-94.30) with $P<0.001$ for all results.

Conclusions: Triage produced superior victim survival to FCFS in all experiments for a single event disaster.

Introduction

In both emergency medicine and disaster management, triage is a process used to sort patients into similar cohorts to effectively connect them to the appropriate services. When a mass casualty event overwhelms available definitive care staff, supplies and space, triage may take on an additional role. Triage becomes a tool for rationing scarce resources to achieve optimal outcomes in the impacted population. When this occurs, it is imperative to deploy processes to ensure decisions regarding who will be included and excluded from treatment are made in a consistent and ethical manner. State and national consortia have begun to work on defining guiding principles and establishing an effective framework for allocation of scarce resources in mass casualty events.[1]   Despite these efforts, a government survey highlighted that planning for crisis care has not been sufficiently addressed nationally.[2]

The Institute of Medicine (2009), in their landmark *Letter Report*, published national crisis standards of care to guide public health and healthcare organizations to develop and implement effective response strategies for mass casualty events.[3] These crisis standards aimed to create expanded capacity and novel systems to preserve the greatest number of lives with limited resources when mitigation and preparedness strategies failed to deliver a successful response.

Children have unique vulnerabilities in a disaster and are particularly at risk.[4,5] Despite this, a national survey revealed that many disaster plans do not recognize or address the great exposure risk to illness, injury and death that children may experience in a disaster.[6] This observation has led to a call for validated pediatric triage tools to assist clinicians and public health officials to achieve optimal survival for children in mass casualty events.[7]

This study aims to answer whether a pediatric triage algorithm can be efficiently used to achieve optimal pediatric victim survival during a region-specific, time-limited, single event mass casualty disaster when Crisis Standards of Care (CSC) are deployed. This effort is unique in that it employed empirically-derived pediatric intensive care (PICU) clinical data to develop prediction equations and triage thresholds, and to validate that the derived triage scheme produced superior victim survival rates to a random, first come first served (FCFS) process of selecting patients for treatment.

Methods

Database. The Virtual PICU Systems (VPS) is a United States (US) based database for pediatric critical care. There are over 700,000 patient records in the database to date, with about 100,000 new cases added annually. The VPS maintains stringent quality control processes to ensure data integrity, including use of clinical data collectors with specific credentials, standardized training, initial and ongoing evaluation of inter rater reliability, annual certification of competency, and a rigorous system of data validation. Current inter rater reliability concordance exceeds 95%.[8] VPS data was provided by the VPS, LLC. No endorsement or editorial restriction of the interpretation of these data or opinions of the authors has been implied or stated.

The records employed in this study were de-identified of patient name, medical record number and account number, as well as the PICU in which the child was treated. As such, this study was classified as non-human subject research by the Institutional

Review Board (IRB) at the University of Illinois at Chicago and was exempted from IRB review.

Derivation of Prediction Equations. This study represents an extension of previous work in which a triage algorithm and seven prediction equations were created to cohort patients into one of seven groups:

1) intubated, excluded from treatment because probability of death (POD) >= threshold;
2) intubated, excluded from treatment because length of stay (LOS) and/or Days on Mechanical Ventilation (DV) >= threshold;
3) intubated, determined optimal for treatment because POD, LOS and DV < threshold;
4) not intubated, excluded from treatment because determined too healthy;
5) not intubated, excluded from treatment because POS >= threshold;
6) not intubated, excluded from treatment because LOS and/or DV >= threshold; and
7) not intubated, determined optimal for treatment because POD, LOS and DV < threshold.

The triage algorithm (Figure 1) was developed for deployment during a pediatric mass casualty disaster when CSC becomes necessary.[9] In the triage algorithm that served as the basis for the current project, triage starts with identification of patients who arrive intubated (or require immediate intubation) and patients who do not require intubation at arrival. Victims arriving intubated or who require immediate intubation upon arrival to prepare for mechanical ventilation are triaged first. Prediction equations derived from clinical records included in the VPS database were used to estimate probability of death, length of stay and, and duration of mechanical ventilation. These equations then were used to assign child victims into one of three groups: 1) determined too healthy for PICU treatment and transferred to a lower level of care,

2) determined too sick for PICU treatment and transferred to palliative or an alternative level of care, and 3) determined optimal for treatment and admitted to a PICU bed.

Simulation. As previously described:

> "A discrete event simulation (DES) model of a system/process is a computer model that mimics the dynamic behavior of the system/process as it evolves with time in order to visualized and quantitatively analyze its performance. The validated and verified model is then used to study behavior of the original system/process and its response to input variables in order to identify the ways for its improvement (scenarios) based on some improvement criteria."[10,p.3]

For this study, a simulation model was constructed to guarantee maximal efficiency during the crisis. Specifically, the model was designed to assure that the greatest number of child victims would receive PICU treatment, assuming no wait time in the triage process. The triage thresholds were calculated for various combinations of available PICU beds and estimated number of victims using discrete event simulation methodology. *ProcessModel v5.5* simulation software was used to build a simulation model which reflects the process of a group of victims being triaged using the pediatric triage algorithm.[11]

Results

Selection of clinical records. For the current study, 148,066 records, randomly selected from the VPS database, were employed after 1,934 records were removed from the dataset following data cleaning measures.

Assumptions for simulation model development. Several assumptions were made in the development of the simulation model for the current study.

A. Numbers of victims can be accurately assessed. It was assumed that surge plans would be immediately activated and that all surge resources, including additional PICU beds, would be available for the victims of the disaster and that a mechanical ventilator would be available for all PICU surge beds. It was also assumed that a reasonable estimation of the number of potential pediatric victims would be made and that, once determined that the victim count would overwhelm available resources (PICU beds with mechanical ventilators), that CSC would be activated.

B. In CSC, only children requiring mechanical ventilation will be admitted to the PICU. If CSC was required due to resources becoming overwhelmed, many critical care services, such as cardio respiratory monitoring or vasopressor medication administration could be provided in alternative locations as non-critical care staff could provide these services with expert support. However mechanical ventilation was the exception. The investigators agreed that the expertise needed to manage mechanical ventilation could not reasonably be taught in crisis circumstances to providers not educated in critical care, and as such, was the single determinant of need for a PICU bed.

C. The duration of a single-event mass casualty CSC event will be short. The duration of the simulated disaster is 16 hours, as it was assumed that in a single event disaster, practically all victims would be identified and transported for treatment during this timeframe. It was further assumed that following this timeframe, additional resources from areas contiguous to the disaster zone could be mobilized to support ongoing critical needs and that services would swiftly return to conventional care.

D. In a single-event catastrophe, estimation of mortality will be the central criterion for PICU admission. The investigators concluded that in a single event disaster that was localized to a particular area, prediction of mortality is the key factor that would impact the selection of victims for PICU admission. The estimated length of stay and the predicted days on ventilation after admission would not impact the selection of victims for the further life-saving optimal treatment, since it was assumed that resources from areas contiguous to the disaster zone could be accessed to address resource demands of patients with ongoing critical care needs following the initial presentation and triage of the pediatric disaster victims.

Based on these considerations, the triage algorithm was simplified, leaving only the probability of death equation (POD) for the ventilated patient remaining. The simplified single event triage algorithm is displayed in Figure 2.

The simulation model. The probability of death prediction equation used in the simplified pediatric triage algorithm is given in Appendix 1, including the results of the validation of the performance of the equation. The statistical distribution of the probability of death POD used in the simulation model is presented in Figure 3. The simulation model layout is presented in Figure 4.

The model inputs were (i) the number of victims spread uniformly randomly within a 16 hours window, and (ii) the number of available beds at the moment of CSC activation. For each patient in the model input, a random value from the POD statistical distribution was generated (Figure 3). That random POD value was then compared to the tested value of the POD threshold. If the random patient POD value was less than the POD threshold, that patient passed the decision to admit to the PICU, and the model counted this patient as admitted. If the generated POD value was greater than or equal to the POD threshold, this patient was counted excluded from admission to the PICU. This admit/reject decision logic transpired for each input patient, and then the entire process was repeated (replicated) 120 times using a new set of random values from the statistical POD distribution to capture the inevitable variability of predictors in the POD logistic equation (Appendix 1).

The objective function (OF) for optimization was that the number of patients passed the admission criterion, *N pass*, over all 120 replications at the end of the simulation period fill all available beds, *N beds,* without wait. Expressed as:

$$OF = abs\left[\left(N\ pass/N\ beds - 1\right)\right] \rightarrow 0$$

Numerical experimentation with the model revealed a noteworthy pattern in the generated optimal thresholds. Probability of death thresholds were the same for any combination of number of victims and beds with the same ratio. For example, 1000 victims and 100 beds, or 500 victims and 50 beds, each with the victim to bed ratio of 10:1, produced the same optimal exclusion threshold for probability of death (POD). Based on this finding, the specific number of victims and available beds was no longer the essential input variables in threshold development. Instead, the *ratio* of the number of estimated victims to available beds became the critical input variable for the simulation model to establish the best threshold for POD that would include the maximum number of critically ill victims for treatment.

Victims with probability of death values lower than the established thresholds based on the associated victim to bed ratio will be admitted to the PICU as they are considered to have the best chance of survival. The plot (Figure 5) did not extend above a probability of death of 11.1% because the ratio of victims to beds approached 1:1 at that point. It was assumed by the investigators that when demand for PICU beds approached bed capacity that crisis standards of care would not be required and the triage plan would be terminated.

The hyperbolic-type shape of the plot in Figure 5 suggests that it can be accurately approximated by a simple function if it is first re-plotted in the double logarithmic coordinates ln (POD)-ln (volume/beds). It was found that a highly accurate fit is given then by the equation:

$$\ln Pdeath=-0.431 * \ln[\ \ln(victims/beds)] +1.117 \quad (R^2=0.9972),$$

(where Pdeath = POD) which is translated to:

$$Pdeath(\%)=\exp(-0.431*\ln[\ \ln(victims/beds)]+1.117).$$

Such an approximation greatly facilitates a practical use of the simulation results, since it can be easily loaded onto a computer or smart phone for use by clinicians and public health officials in the midst of a single event mass casualty disaster.

<u>Validation of the simulation</u>. VPS data were used to determine the effectiveness of the triage algorithm compared to a first come first served (FCFS) method of PICU bed assignment. First, groups of 10,000 unique PICU cases were created by randomly

selecting cases with no overlap for each group. Each group represented a potential pediatric victim pool. For each case the POD was calculated using the POD prediction equation (Appendix 1).

To test how the generated POD thresholds performed at various points along the victim to bed plot (Figure 5), the victim to bed ratios of 10:1, 5:1 and 3:1, with corresponding POD thresholds of <2.13%, <2.49%, and <2.93%, were chosen. Each group of 10,000, cases was divided into i) below the POD threshold or ii) equal to or above the POD threshold. "Below threshold" cases represent cases triaged as optimal for treatment and to receive a PICU bed. The number of treated cases ranged from 728-1229, 957-1043, and 750-1270 for the victim to bed ratios of 10:1, 5:1, and 3:1 respectively, in each of the ten groups of 10,000 patients using the triage algorithm.

For the treated group, the survival rate was calculated by using actual patient outcome data of survived or died, as recorded in the VPS database, and dividing the count of victims that survived by the total number of cases in the included group, expressed as a percent. To compare the results of the triage algorithm to a FCFS approach, the following processed was followed. For each of the ten 10,000 random samples, the same number of cases selected for treatment using the triage method were selected for treatment in the FCFS method. For example, if the triage method produced 750 treated cases, then the first 750 cases were selected from the same data set that was randomly ordered and unsorted. The survival rate was calculated for the FCFS treatment group using the actual mortality data from VPS as described above. This process was repeated for each group of 10,000 unique cases and for each victim to bed threshold for a total of 30 separate experiments.

Chi-squared tests were used to compare the survival results of the triage algorithm against FCFS for the three victim to bed thresholds with a p-value < 0.05 determining significance. All results were statistically significant, indicating that the performance of the triage algorithm significantly improved survival in the treated group, outperforming the FCFS approach, in all experiments and for 10:1 (Table 1), 5:1 (Table 2), and 3:1 (Table 3) victim to bed ratios.

Discussion

This work represents the first known attempt to develop a reliable algorithm using real PICU data for determination of scarce resource allocation during a mass casualty event involving children. The results are encouraging and suggest that the use of a physiologic based triage tool can assist professionals charged with triage to select an optimal group for treatment in an overwhelming catastrophe. Using data that are reasonably available at time of victim arrival at the triage station, decisions to treat or withhold treatment can be made using factors considered important to improved victim survival. This novel triage approach demonstrates substantial promise over a first come first served triage approach that relies primarily on the time of victim arrival as the primary driver of scarce PICU resource allocation.

The implications of these findings are substantial, but must be further evaluated and replicated to gain confidence for this approach in the public health arena, the critical care community, and from the general public. Given the immense regard held for individual freedoms in this country, the topic of rationing, even in a mass casualty disaster, can be difficult to imagine. When children are involved, the notion becomes even more challenging to contemplate. It is precisely for this reason that this topic requires additional exploration. A fact that needs to be understood is that in a crisis where mass casualties overwhelm medical resources, rationing will occur. The first come first served approach to resource allocation uses the timing of arrival as the key determinant of admission to a PICU bed. Victims arriving after all beds have been allocated, regardless of their likelihood of survival, are turned away from PICU care. A pediatric triage algorithm considers additional factors in determining admission to limited PICU beds, including the victim's severity of illness at time of arrival and their likelihood of survival. Understanding this important point is imperative for the conversation to move forward.

Like other public health threats, the debate on how to best implement scarce pediatric resource allocation during CSC activation is challenging as opinions vary. As such, this is an ideal topic for leaders in public health, pediatric critical care and disaster management to champion. It is important that the tools are trusted; that physicians charged with mass casualty triage and allocation of scarce resources have confidence that the triage plan will accurately identify the specific group of victims who are optimal for treatment and have the best likelihood of survival with access to limited critical care services. In addition, there should be no question that the triage method selects victims in an equitable, non-biased, statistically based manner.

To gain public trust that use of a triage algorithm is superior to traditional first come first served strategies, there must be assurance that triage parameters will be ethically and consistently applied to all victims considering only the physiologic and lab data needed to use the prediction equations. Further, there must be acknowledgement, at minimum, that in an event requiring CSC activation, the survival of individual victims becomes secondary to the interest in preserving the greatest survival among all affected victims. The best way for this concept to be generally accepted is for all stakeholders to believe that the triage process will objectify the process of disaster resource allocation.

To assist in the development of trust for the triage approach for CSC resource allocation, the results of this study and future work on the topic need to be disseminated through both professional and mass media outlets. Educational strategies for key stakeholder groups need to be developed and implemented to bring an understanding of the benefits of CSC disaster triage to the forefront of public awareness. Consensus building strategies need to be led by skilled facilitators in advance of the next mass casualty event. If these efforts are successful, public opinion on this important topic may iteratively evolve and the difficult decisions that lie ahead may be made in an informed manner with broad-based support.

This work focused exclusively on deployment of resources during activation of crisis standards of care. The study did not consider how to determine the need for CSC activation, or how to identify circumstances that signal the appropriate return to conventional care at the earliest possible juncture. This should be considered in future studies to ensure that crisis standards of care are not carelessly or excessively deployed. The Institute of Medicine (2013) has developed an exceptional resource to assist groups developing disaster response plans to recognize indications for and triggers to CSC activation.[12]

Last, the investigators believe that success in implementation of a pediatric mass casualty triage plan depend upon the establishment of a process that is easy to use and assures consistent application of the triage tool. The simplification of the triage algorithm is believed to be an important enhancement that will support its consistent and ethical triage application.

Limitations

This study involved the use of several key assumptions, each discussed and sometimes debated by the investigators. Assumptions related to the estimation of pediatric victims, arrival patterns and duration of the arrival surge, and eligibility to enter the triage queue for treatment consideration are key areas were assumptions where developed. While replication of these assumptions may validate their appropriateness to the single event CSC disaster scenario, exploration of alternative assumptions is also important to expand the knowledge base. Each new study will add to the collective understanding of how triage may be used to ration scarce resources most effectively, and which approaches yield the most favorable survival outcomes.

The use of VPS data was an attempt to utilize real data from PICU patients to address the topic of pediatric single event triage. A potential limitation of this approach is that the VPS dataset contains patients that received PICU care when conventional care standards were in place, which assumes that patients received optimal care. Results could vary if data from victims of a pediatric mass casualty event, when care standards were relaxed, were exclusively used.

Leaders responsible for emergency preparedness and provision of critical care during a true disaster must develop strategies to continue the conversations, share future research findings and facilitate consensus on strategies for scarce resource deployment during CSC. The best way to educate key stakeholders and the general public is to expand awareness and the base of evidence on this important topic.

References

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Figure 1: Pediatric CSC Triage Algorithm

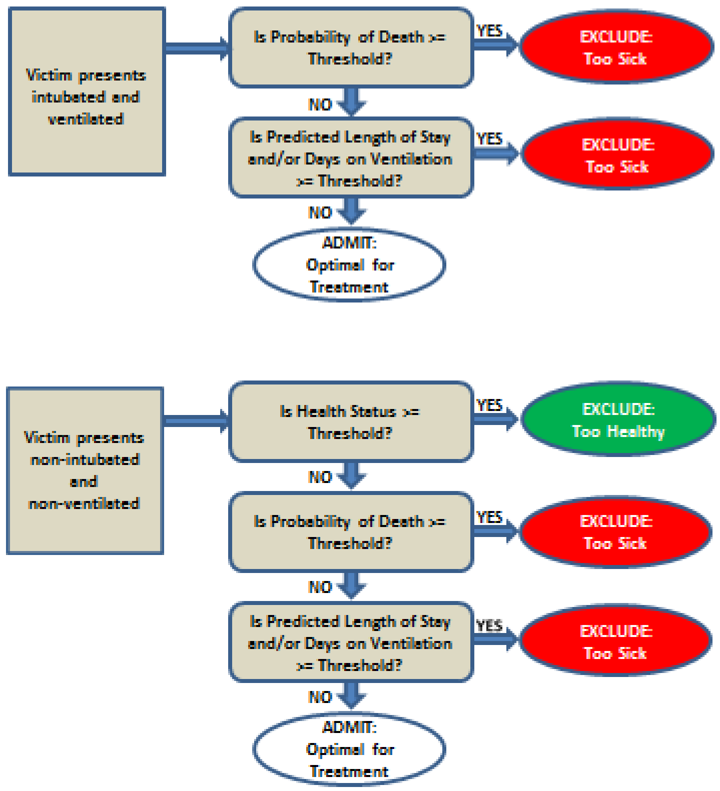

Figure 2: Revised Triage Algorithm

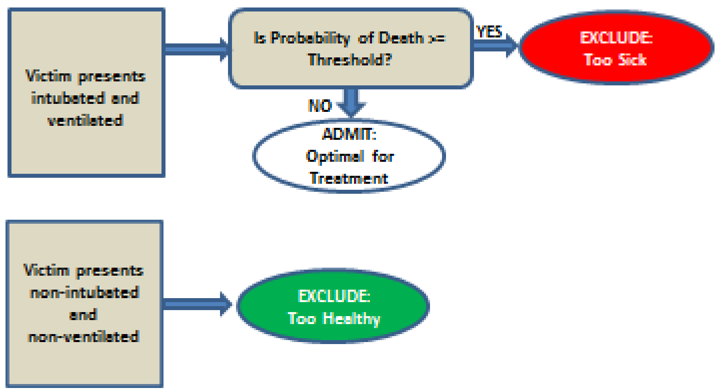

Figure 3: Distribution frequency of Probability of death (POD)

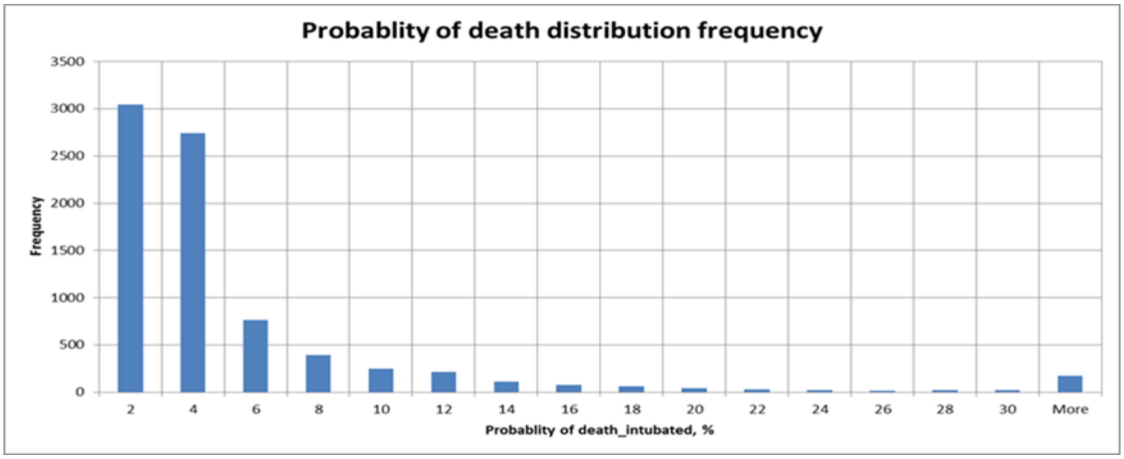

Figure 4: Layout of the simulation model

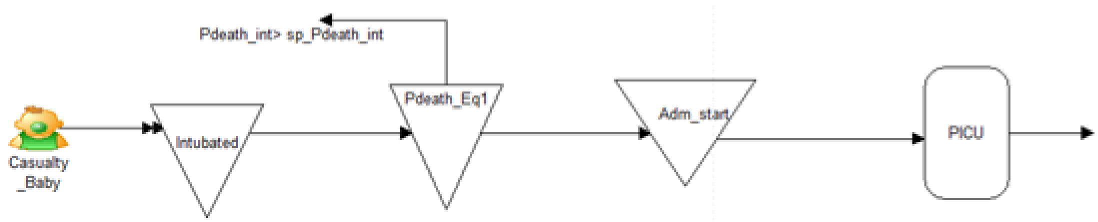

Figure 5: Probability of death threshold curve for selected victim to bed ratios

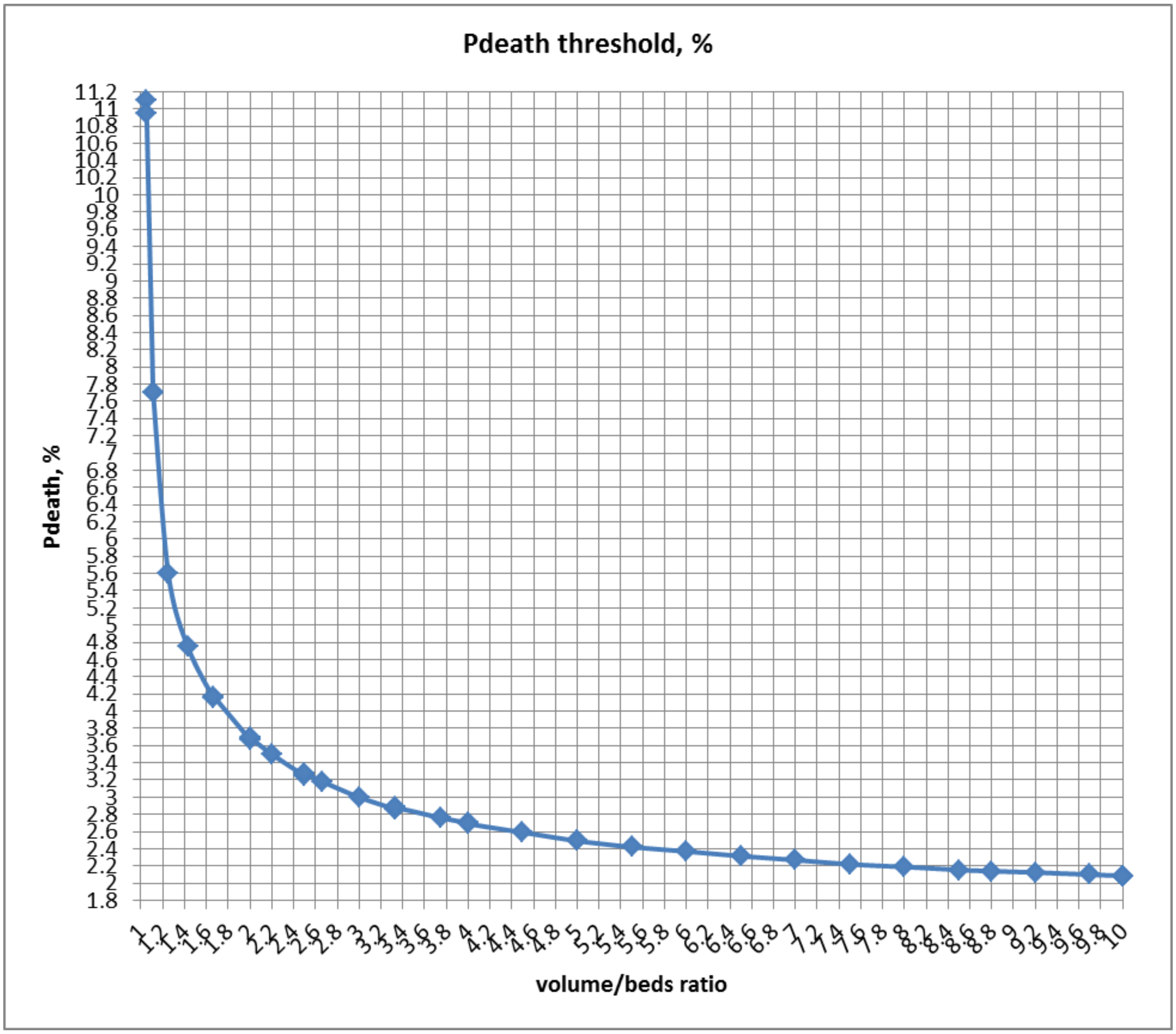

Table 1: 10:1 Victim/Bed Survival Comparison-Triage and First Come First Served

Average Survival (%) for all experiments:

	Average	95% CI
10:1 victim/bed triage	98.32%	(98.04%-98.57%)
FCFS	88.18%	(87.50%-88.84%)
P-value	<0.001	

Experiment	Survival	Threshold: POD < 2.13%	No Threshold: First Come First Served	*P*-value
1	Cases Treated (n)	770	770	--
	Survivors in Treated Group (n)	757	655	--
	% Survivors in Treated Group	**98.31**	**85.06**	**<0.001**
2	Cases Treated (n)	1229	1229	--
	Survivors in Treated Group (n)	1200	1120	--
	% Survivors in Treated Group	**97.64**	**91.13**	**<0.001**
3	Cases Treated (n)	728	728	--
	Survivors in Treated Group (n)	717	617	--
	% Survivors in Treated Group	**98.49**	**84.75**	**<0.001**
4	Cases Treated (n)	792	792	--
	Survivors in Treated Group (n)	782	700	--
	% Survivors in Treated Group	**98.74**	**88.38**	**<0.001**
5	Cases Treated (n)	812	812	--
	Survivors in Treated Group (n)	801	707	--
	% Survivors in Treated Group	**98.65**	**87.07**	**<0.001**
6	Cases Treated (n)	815	815	--
	Survivors in Treated Group (n)	807	708	--
	% Survivors in Treated Group	**99.02**	**86.87**	**<0.001**
7	Cases Treated (n)	767	767	--
	Survivors in Treated Group (n)	762	648	--
	% Survivors in Treated Group	**99.35**	**84.49**	**<0.001**
8	Cases Treated (n)	1219	1219	--
	Survivors in Treated Group (n)	1187	1104	--
	% Survivors in Treated Group	**97.37**	**90.57**	**<0.001**
9	Cases Treated (n)	793	793	--
	Survivors in Treated Group (n)	785	686	--
	% Survivors in Treated Group	**98.99**	**86.51**	**<0.001**
10	Cases Treated (n)	1189	1189	--
	Survivors in Treated Group (n)	1163	1092	--
	% Survivors in Treated Group	**97.81**	**91.84**	**<0.001**

Table 2: 5:1 Victim/Bed Survival Comparison-Triage and First Come First Served

Average Survival (%) for all experiments:

	Average	95% CI
5:1 victim/bed triage	98.41%	(98.15%-98.65%)
FCFS	91.32%	(90.75%-91.86%)
P-value	<0.001	

Experiment	Survival	Threshold: POD < 2.49%	No Threshold: First Come First Served	*P*-value
1	Cases Treated (n)	1002	1002	--
	Survivors in Treated Group (n)	983	910	--
	% Survivors in Treated Group	**98.10**	**90.82**	**<0.001**
2	Cases Treated (n)	1008	1008	--
	Survivors in Treated Group (n)	985	918	--
	% Survivors in Treated Group	**97.72**	**91.07**	**<0.001**
3	Cases Treated (n)	965	965	--
	Survivors in Treated Group (n)	944	876	--
	% Survivors in Treated Group	**97.82**	**90.78**	**<0.001**
4	Cases Treated (n)	1020	1020	--
	Survivors in Treated Group (n)	1004	941	--
	% Survivors in Treated Group	**98.43**	**92.25**	**<0.001**
5	Cases Treated (n)	1043	1043	--
	Survivors in Treated Group (n)	1030	962	--
	% Survivors in Treated Group	**98.75**	**92.23**	**<0.001**
6	Cases Treated (n)	1033	1033	--
	Survivors in Treated Group (n)	1023	951	--
	% Survivors in Treated Group	**99.03**	**92.06**	**<0.001**
7	Cases Treated (n)	987	987	--
	Survivors in Treated Group (n)	979	893	--
	% Survivors in Treated Group	**99.19**	**90.48**	**<0.001**
8	Cases Treated (n)	986	986	--
	Survivors in Treated Group (n)	963	892	--
	% Survivors in Treated Group	**97.67**	**90.47**	**<0.001**
9	Cases Treated (n)	1029	1029	--
	Survivors in Treated Group (n)	1018	943	--
	% Survivors in Treated Group	**98.93**	**91.64**	**<0.001**
10	Cases Treated (n)	957	957	--
	Survivors in Treated Group (n)	942	873	--
	% Survivors in Treated Group	**98.43**	**91.22**	**<0.001**

Table 3: 3:1 Victim/Bed Survival Comparison-Triage and First Come First Served

Average Survival (%) for all experiments:

	Average	95% CI
3:1 victim/bed triage	98.46%	(98.22%-98.69%)
FCFS	93.86%	(93.39%-94.30%)
P-value	<0.001	

Experiment	Survival	Threshold: POD < 2.93%	No Threshold: First Come First Served	*P*-value
1	Cases Treated (n)	1219	1219	--
	Survivors in Treated Group (n)	1195	1148	--
	% Survivors in Treated Group	**98.03**	**94.18**	**<0.001**
2	Cases Treated (n)	814	814	--
	Survivors in Treated Group (n)	798	744	--
	% Survivors in Treated Group	**98.03**	**91.04**	**<0.001**
3	Cases Treated (n)	1197	1197	--
	Survivors in Treated Group (n)	1172	1124	--
	% Survivors in Treated Group	**97.91**	**93.90**	**<0.001**
4	Cases Treated (n)	1246	1246	--
	Survivors in Treated Group (n)	1225	1182	--
	% Survivors in Treated Group	**98.31**	**94.86**	**<0.001**
5	Cases Treated (n)	1270	1270	--
	Survivors in Treated Group (n)	1253	1206	--
	% Survivors in Treated Group	**98.66**	**94.96**	**<0.001**
6	Cases Treated (n)	1249	1249	--
	Survivors in Treated Group (n)	1236	1185	--
	% Survivors in Treated Group	**98.96**	**94.88**	**<0.001**
7	Cases Treated (n)	1197	1197	--
	Survivors in Treated Group (n)	1188	1130	--
	% Survivors in Treated Group	**99.25**	**94.40**	**<0.001**
8	Cases Treated (n)	751	751	--
	Survivors in Treated Group (n)	737	684	--
	% Survivors in Treated Group	**98.14**	**91.08**	**<0.001**
9	Cases Treated (n)	1245	1245	--
	Survivors in Treated Group (n)	1231	1174	--
	% Survivors in Treated Group	**98.88**	**94.30**	**<0.001**
10	Cases Treated (n)	750	750	--
	Survivors in Treated Group (n)	735	689	--
	% Survivors in Treated Group	**98.00**	**91.87**	**<0.001**

Appendix 1: Probability of Death Predication (POD) Equation (generated during an earlier phase of this project)-Provided with permission from the authors

The POD equation has the following logistic regression form:

POD=1/(1+exp(-r)),

where exponent r is:
r=-a0-a1*rec_from_surg-a2*NoHighRiskDX+a3*NoLowRiskDX+a4*PupilsNonReact+a5*(SysBP_forpim-120)+a6*BaseExcess+a7*gcs_lt8+a8*ageMonths+a9*under1_year+a10*categ_infec-a11*categ_resp

Variable	Coefficient	Notes
Y intercept (constant)	(-)a0	
Recovery from surgery*	(-)a1	Recovery from surgery is the main reason for PICU admission
No high risk diagnosis*	(-)a2	see table 1; select yes if patient has one or more
No low risk diagnosis*	(+)a3	see table 2; select yes if dx is main reason for PICU admission
Both pupils non-reactive*	(+)a4	pupils fixed and dilated (>3mm)
First SBP**	(+)a5	First measured systolic blood pressure; subtract from 120 and record. Missing value-record 0
First base excess(deficit)**	(+)a6	First measured base excess(deficit);missing value-record 0
GCS < 8*	(+)a7	Glasgow Coma Scale score less than 8
Age in months**	(+)a8	Age recorded in months
age under 1 year*	(+)a9	Infant; age under 1 year
Infectious diagnosis*	(+)a10	One or more active infectious diagnoses
Respiratory diagnosis*	(-)a11	One or more active respiratory diagnoses

Categorical Variable: Yes=1; No=0 **Continuous variable: Enter recorded value

Table 1: PIM 2 High Risk Diagnosis
Cardiac arrest immediately preceding ICU admission
Severe combined immune deficiency
Leukemia or lymphoma (after first induction)
Spontaneous cerebral hemorrhage
Cardiomyopathy or myocarditis
Hypoplastic left heart syndrome
HIV infection
Liver failure is the main reason for PICU admission
Neurodegenerative disorder

Table 2: PIM 2 Low Risk Diagnoses
Asthma
Bronchiolitis
Croup
Obstructive Sleep Apnea
Diabetic Ketoacidosis

A training set with 28273 ventilated patients was used. Validation for the POD logistic regression equation was tested by calculating the area under Receiver Operation Curve (AROC) for discrimination. This tests both the sensitivity and specificity of the prediction equation. Traditionally, predictions are judged to discriminate well when AROC > 0.85. The ROC curve for the POD equation is presented on Figure 1 with an AROC=0.87.

Validity of the logistic regression equation was tested using the Hosmer-Lemeshow (H-L) test for goodness of fit. Prediction models are assumed to be adequately calibrated when the H-L test, comparing the predicted to actual outcomes after stratifying the population by deciles, registers at P-value > 0.05. H-L test with a test set of ventilated patients (N=14,144) produced the chi-square=11.37 and P-value=0.181.

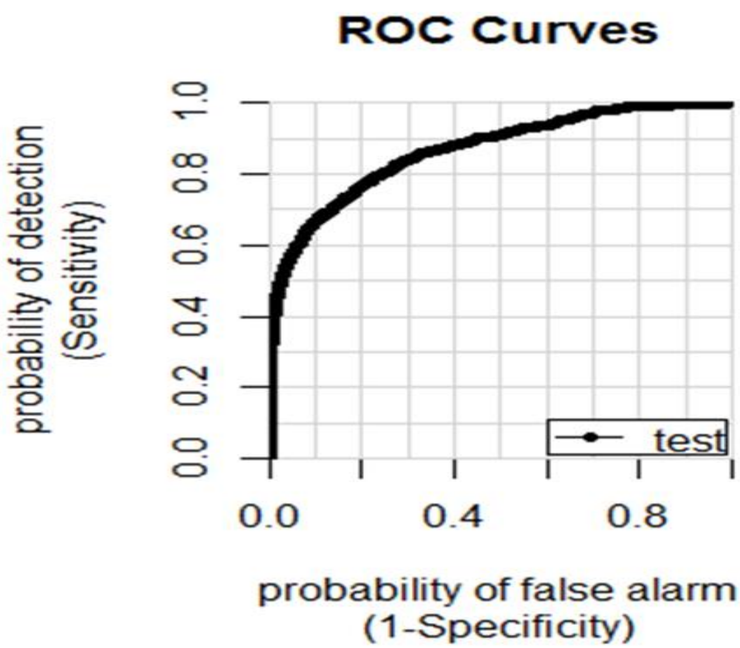

Figure 1: ROC plot for POD intubated test set logistic regression

Acknowledgements:

The authors would like to thank Casey Lauer, BS, Manager, Data Management for VPS, for his assistance in developing the requested datasets, including randomization of case selection, and for his contributions to the analysis of the results. We would also like to thank Aaron Katch, MS, Biostatistician for VPS, for his assistance in the calculation of P-values, confidence intervals and for his contributions to the analysis of data.

Conflicts of Interests: None
Funding Source: This project is funded through a contract with the Ohio Hospital Association.
Financial Disclosure: The authors have no financial relationships relevant to this article to disclose.

Chapter 7: MANUSCRIPT TWO

Development of Pediatric Triage Guidelines for use during a Severe Pandemic

Authors:

Christine Gall[1],DrPHc; Alexander Kolker[2,3],PhD; Randall Wetzel[1,4,5,],MBBS; Robert Kanter[6,7],MD; Philip Toltzis[8,9],MD

Author Affiliations:

[1]Virtual PICU Systems, LLC, Los Angeles, California; [2]API Healthcare, A GE Healthcare Company, Hartford, Wisconsin; [3]University of Wisconsin Milwaukee, Milwaukee, Wisconsin; [4]Division of Critical Care Medicine, Department of Pediatrics and Anesthesiology, Children's Hospital Los Angeles; [5]USC Keck School of Medicine, Los Angeles, California; [6]Department of Pediatric Critical Care Medicine, SUNY Upstate Medical Center, Syracuse, New York; [7]National Center for Disaster Preparedness, Columbia University, New York, New York; [8]Case Western University School of Medicine, Cleveland, Ohio; [9]Rainbow Babies and Children's Hospital, Cleveland, Ohio.

Corresponding Author:

Christine Gall, DrPHc

Director, Quality and Client Relations

Virtual PICU Systems, LLC

4470 Sunset Blvd, Suite 440, Los Angeles, California

Telephone: (888) 999-4850 x102

Email: cgall@myvps.org

Abstract

Objective: To determine whether a triage algorithm can be developed to effectively deploy scarce pediatric critical care resources during a pandemic disaster when Crisis Standards of Care (CSC) are implemented.

Methods: 111,174 non-elective, randomly selected cases (2009-2011) from the Virtual PICU Systems (VPS, LLC) database were used for the single event and pandemic disaster analysis, respectively. Discrete event simulation (DES) was used to determine optimal triage thresholds in CSC deployment. Prediction equations generated in an earlier phase of this study were used to calculate each victim's Probability of Death (POD) and Days on Ventilation (DV) using only assessment and lab data available at triage. Victim results were compared with optimal thresholds to select patients for treatment. Survival of treated group was compared for triage and a first com first served (FCFS) bed assignment.

Results: Two optimal triage thresholds were established. Survival (%) in the treatment group was significantly higher in the triaged group for all experiments. Triage solution 1: (95.51; 95% CI: 95.26-95.75) and FCFS 1 (91.29;95% CI: 90.95-91.62), ($p<0.001$); triage solution 2: (97.90; 95% CI: 97.72-98.08) and FCFS 1 (91.18;95% CI: 90.82-91.54)), ($p<0.001$).

Conclusions: Triage produced superior victim survival to FCFS for both optimal pandemic disaster solutions.

Introduction

Substantial attention and resources have been allocated to prepare the health care and public health infrastructure to effectively respond to mass casualty events such as an influenza pandemic. Despite these efforts much work is still needed. A report by the United States (US) Government Accountability Office stated that a mass casualty event such as a pandemic has the potential to overwhelm medical resources.[1] Advanced preparation is warranted to develop proactive strategies to alter established standards of care so that the greatest number of victims may survive. The report called for the development of systems to triage patients to allocate scarce resources in a consistent and ethical manner.

Further guidance has been offered to aid local, state and national governments as they develop and integrate strategies to allocate scarce resources in extreme disasters.[2,3] The term 'crisis standards of care' (CSC) was established to describe the most severe conditions of mass casualty events when surge efforts cannot fail to address the needs of victims. CSC activation allows the alteration of conventional standards of care to ensure optimal use of overwhelmed acute and critical care resources with the ultimate aim of improving overall victim survival. CSC is therefore not focused on the treatment of individual patients but rather, the outcomes of the entire impacted population.

Triage is an established medical process used to sort patients into similar cohorts to effectively provide them with available resources. When a mass casualty event overwhelms available care staff, supplies and space, triage is an appropriate response.

In this context, triage becomes a tool for rationing scarce resources to achieve optimal outcomes in the impacted population. Consortia at the national and state levels have developed guiding principles for allocation of scarce resources in mass casualty events.[4]

It is well-documented that children have unique susceptibilities in mass casualty events.[5,6] Despite this, many disaster plans fail to adequately address the specific needs of children who are among the most vulnerable populations.[7] Thus, there is a pressing need for a validated pediatric triage tool to aid clinicians and leaders in healthcare and public health to respond effectively to a pediatric mass casualty event.[8]

Researchers are beginning to explore how triage may be used to improve pediatric survival rates during pandemics.[9] This study aims to answer whether a pediatric triage algorithm can be efficiently used to achieve optimal pediatric victim survival during an overwhelming pandemic mass casualty disaster when Crisis Standards of Care (CSC) are deployed. Empirical data were used to develop the prediction equations and triage thresholds, and for validation, making this the first known study of this type to use this approach. This study will test whether a triage plan based exclusively on patient assessment and laboratory data immediately available at triage can provide superior victim survival to a random, first come first served (FCFS) process of resource deployment.

Methods

Basic triage algorithm and prediction equations. This research is a continuation of a project that created a series of seven prediction equations and a validated pediatric triage algorithm for use during crisis standard of care activation.[10] In this scheme, victims first are divided into mechanically ventilated and non-ventilated groups and then assigned to one of three groups (Figure 1): too sick for PICU admission, too healthy for PICU admission, and optimal for PICU admission. Assignment is based on seven prediction equations derived from analysis of 150,000 patient records randomly selected from in the Virtual PICU System (VPS) database.

Database. The VPS database is a multicenter PICU database containing over 700,000 clinical records of children hospitalized in over 100 North American PICUs. The VPS maintains stringent quality control processes to ensure the highest levels of data integrity, including use of data collectors with specific credentials, standardized training, initial and ongoing evaluation of inter rater reliability, annual certification of competency, and a rigorous system of data validation. Current inter rater reliability concordance for certified data collectors exceeds 95%.[11] VPS data was provided by the VPS, LLC. No endorsement or editorial restriction of the interpretation of these data or opinions of the authors has been implied or stated.

The VPS provided a limited data set with patient name, medical record number and account number removed. With the identification of the PICU providing services to each case also blinded, identification of individual patients is virtually impossible. As a result, the Institutional Review Board at the University of Illinois at Chicago exempted this study from IRB review.

Simulation. As previously described:

> "A discrete event simulation (DES) model of a system/process is a computer model that mimics the dynamic behavior of the system/process as it evolves with time in order to visualized and quantitatively analyze its performance. The validated and verified model is then used to study behavior of the original system/process and its response to input variables in order to identify the ways for its improvement (scenarios) based on some improvement criteria."[12,p.3]

To study whether a pediatric pandemic triage algorithm can achieve maximal number of patients being admitted for treatment with greater survival than the first come first served approach, discrete event simulation methodology was utilized to generate the optimal triage thresholds for the simplified triage algorithm. *ProcessModel v5.5* simulation software was used to build a model that incorporated the prediction equations and other input variables determined important by the researchers.[13] The simulation model explores various combinations of input variable values to derive optimal triage thresholds through thousands of repetitions of the triage sequence.

Results

<u>Assumptions</u>

We made several assumptions when considering how the triage algorithm would be utilized in a mass casualty pandemic disaster:

A. Revision of the Original Triage Scheme. Patients arriving with a spontaneous respiratory effort not requiring mechanical ventilator support could be cared for outside of the PICU and were not considered for PICU admission. This position was taken because care of a mechanically ventilated patient was considered the only critical care procedure offered during CSC activation that could not be effectively provided by non-critical care resources. It further was assumed that every PICU bed would have an available ventilator. Since length of stay (LOS) and days on ventilation (DV) are highly correlated (Pearson correlation coefficient 0.94) only one of these measures was included in the model. Finally, following extubation, it was assumed that a patient would be transferred out of the PICU bed to another level of care within the next eight hours following separation from mechanical ventilation.

As a result of these assumptions, the original algorithm was modified. The four prediction equations representing triage points for non-ventilated patients were removed because respiratory failure and the need for mechanical ventilation was determined to be the starting point for the triage process. Victims not arriving to the triage station on mechanical ventilation would be determined too healthy and would be transferred to an alternative level of care.

The simplified layout of the simulation model which represents how the triage algorithm is used to allocate available PICU beds is displayed in Figure 2. The Probability of death (POD) and predicted Days on Ventilation (DV) equations for the ventilated patient remain in the triage algorithm. The variables used to generate these prediction equations, related definitions, and the work to validate the performance of these equations are presented as Appendix I (POD) and Appendix 2 (DV).

B. *Patient flow during an extreme pandemic.* To apply the triage algorithm to a pandemic disaster we used data from an actual pandemic disaster and extrapolated those data to estimate the patient flow in a single state (Ohio). The last extreme mass casualty pandemic in the United States was the Spanish Influenza outbreak of 1918-1919. While the discipline of critical care did not exist at that time, and records of the incidence of infected patients seeking medical treatment were not comprehensively recorded during this disaster, the mortality rates attributed directly to influenza and related respiratory complications were reported.[14] The excess weekly death rate per 100,000 in 35 US cities attributable to the influenza outbreak began in week 38 of 1918 and lasted 32 weeks through week 16 of 1919. Deaths peaked during a 6 week period (weeks 40-45 in 1918). These mortality data were used as a surrogate for patient arrival activity for this project with crisis standards of care deployment occurring during a six week period of peak activity for this simulated pandemic. The use of the 1918-1919 death data to model victim pandemic arrival patterns was previously described.[5]

Initial determination of the estimate of pediatric victims during a pandemic in Ohio was developed using the following approach. According to national guidelines, during a severe pandemic an estimated 5,277 per million population will be affected.[15] Given data provided by the Ohio Hospital Association that the number of children in Ohio aged zero-19 is 2,354,054, pediatric victim estimates for a severe pandemic total 12,422. Considering that 64% of excess mortality during the 1918 pandemic occurred during the six weeks pandemic peak,[14] and with mortality rates from the historic pandemic serving as a surrogate for patient arrival for purposes of our simulation, an estimated 7,970 children would arrive seeking treatment during the six weeks when crisis standards of care were activated during the peak of the disaster (64% of 12,400).

Finally, using the estimate that 38% of presenting victims in the VPS dataset used to develop the original algorithm required mechanical ventilation at time of arrival), we estimated that approximately 3,000 victims would arrive in respiratory failure and therefore be eligible for triage during the six week pandemic peak when requiring CSC activation in the simulated pandemic.

With the estimated number of pediatric victims determined for the peak of the pandemic, weekly death rates (surrogate for victim arrivals) were translated into estimated daily arrivals, applying Poisson distribution techniques to the weekly death data previously described.[14] The Poisson distribution creates whole daily volumes to address the arrival pattern of victims which cannot be expressed as a fractional average. The Poisson parameter (the average daily arrival) was constant during each day of the week but changed from one week to another according to the corresponding average daily patient volumes within each week. This technique allowed the introduction of data from the 1918 pandemic into the simulation. Arrival time throughout each day was uniformly randomly distributed to mimic uncertain patient arrival time to the triage station. The arrival pattern will be further described in the results section as a modification to this approach was introduced following analysis of the initial simulation results.

C. Conditions During CSC. During the height of the pandemic, it would be likely that elective admissions and admissions that required extraordinary resources like cardiac bypass or major elective surgeries would be cancelled. Therefore, elective PICU admissions and admissions following procedures that used cardiac bypass were removed from the original VPS dataset for use with this simulation.

To simulate how available PICU beds would be occupied during the course of a severe pandemic, we used data regarding PICU capacity from the State of Ohio. It was assumed that surge capacity activities would have been fully operationalized. To estimate surge capacity, we used data provided by the PICU leaders from the eight PICUs in Ohio, which reported that the number of PICU beds could be increased from 232 to 280, and that a mechanical ventilator would be available to every bed.

It further was assumed that at the beginning of the activation of CSC, nearly all PICU beds (including surge beds) would be occupied. This was derived from expert opinion based on the premise that CSC would not be activated until the limiting resources were overwhelmed. It was also assumed that patients occupying a PICU bed at the start of CSC activation would not be subject to the triage process as this would likely be a too extreme a request for the critical care team to execute. Instead, the triage process assumed that clinicians would use their judgment regarding the progression of the medical plans of care for patients in the PICU at the start of the CSC activation.

<u>Simulation</u>

The goal of the simulation was to create the admit/reject thresholds for POD and DV that enabled the maximal number of victims to be admitted to the PICU with the assumption that this would result in maximal victim survival. The objective function (criterion) for establishing the optimal thresholds was maximizing the total number of treated patients without wait for admission at the end of the six weeks period, meaning that the PICU had free bed capacity sufficient to admit victims. This is equivalent to maximizing the total number of treated patients subject to the additional constraint that the number of patients that pass the triage thresholds is equal to the number of patients that can actually be admitted to PICU because beds are available. If a bed is not available at the time of victim arrival to the triage station, the victim would be excluded from treatment, even if their assessment determined that they were optimal for treatment.

Victims arriving non-ventilated and not requiring immediate ventilation were immediately designated as too healthy and transferred to a lower level of care without further triage. If respiratory failure developed later, these victims were re-triaged. For each remaining victim, a probability of death and days on ventilation were calculated according to the POD and DV triage prediction equations. The scores for each victim were compared to the thresholds generated through simulation. Victims in respiratory failure requiring mechanical ventilation were cohorted into two groups based on their individual scores relative to the triage thresholds: too sick, therefore unlikely to benefit from allocation of limited PICU resources and optimal for treatment with a high probability of survival despite limited access to scarce pediatric critical care resources.

The simulation model incorporated the two prediction equations remaining in the revised pandemic triage algorithm. For each potential combination of thresholds for DV and POD, each simulation experiment used 100 random values (replications) generated from the distributions for DV (Figure 3) and POD (Figure 4) generated from the VPS dataset.

The optimization process for maximizing the objective function using the simulation model outlined in Figure 2 is based on a genetic and evolution strategies algorithm. An evolutionary algorithm is a numerical optimization technique that generates various possible solutions in the defined range that must adapt to their environment to be retained for further steps. The algorithm efficiently explores the response surface that is defined by the output of the model, i.e. by its objective function. The algorithm then focuses only on those narrow areas that could contain better solutions in the sense that they produce a higher value of the objective function than some other solutions, which are rejected. The process goes on until no further improvement in maximizing the objective function is possible within a reasonable computational time.

The estimates of 3000 pediatric victims and six week duration of peak pandemic activity when CSC would be activated were incorporated into the simulation model. Surprisingly, the results demonstrated that the Ohio surge plan, designed to provide 280 surge PICU beds in a disaster, will accommodate 3,000 pediatric pandemic victims with the arrival pattern imitating the pandemic activity reported previously[14] during a six week period of peek activity, without need activation of this triage plan to allocate scarce resources.

While this finding is instructive and suggests the need to revisit the method for estimation of victims in a pandemic disaster, the investigators remained committed to studying the question regarding the best method for achieving optimal pediatric victim survival. The investigators decided to double the victim count to 6,000 pediatric victims to test the performance of the optimal triage solutions generated through simulation. The arrangement of victim arrivals remained consistent with the original pattern but updated to reflect the two fold increase in victims. The six week arrival pattern of 6,000 children used as the simulation input is presented in Figure 5. The percentage of victims requiring mechanical ventilator support at time of arrival was adjusted to 33% to reflect data from the subset of VPS data (N=111,274) used to test the performance of the optimal triage solutions. It was also clarified that patients requiring triage at a later point could re-enter the triage process if mechanical ventilation became necessary. Doubling the number of pediatric pandemic victims in respiratory failure created the scenario needed to justify activation of CSC in this study, as this volume of victims would overwhelm Ohio surge resources.

The simulation was repeated incorporating the increase in victims from 3,000 to 6,000 children. Two optimal solutions for the threshold values were generated using the simulation method representing extreme ranges for POD and DV:

- Solution 1: Probability of Death < 59.5% and Days on Ventilation <2.25 Days which produced a theoretical limit (maximum) of 4254 treated victims (CI: 4242-4266 victims)(71% of admitted patients out of 6000)
- Solution 2: Probability of Death < 3.3% and Days on Ventilation < 7 Days which produced a theoretical limit (maximum) of 4045 treated victims (CI: 4032-4059 victims) (67% of admitted patients out of 6000)

These solutions will allow treatment of the most number of pediatric victims in a pandemic disaster involving 18,000 victims, 6,000 of whom require mechanical ventilation, during a six week pandemic peak where CSC activation is required to optimally utilize the 280 PICU beds.

Validation

With the optimal triage thresholds established, we then evaluated the performance of these solutions to determine whether they yielded survival results superior to a first come first served (FCFS) assignment of PICU resources. A subset of the original training and testing dataset was used to generate ten groups containing 18,000 randomly selected records each, equaling the size of the estimated pediatric pandemic victim pool. The two optimal triage solutions were applied to each of the cases in the ten randomly generated groups and the number of patients triaged for treatment was established for each group.

To compare the results of application of the triage algorithm with a FCFS approach, the assumption was made that the same number of victims would be treated in the FCFS group as in the triaged group for each optimal solution result. This approach assured an equivalent demand for PICU admission so that survival could be compared.

Survival rates are provided in Table 1 (solution 1) and Table 2 (solution 2). Chi-squared tests were used to compare the results of each triage algorithm against FCFS with a P-value < 0.05 determining significance. In all experiments, the triaged group had superior survival rates compared to FCFS. All results were statistically significant, indicating that both triage algorithms significantly improved survival, outperforming the first come first served approach. It follows from Tables 1 and 2 that while both solutions significantly outperform FCFS, solution 1 is preferred because it consistently results in a higher number of treated victims and a higher overall number of survivors in the treated group than solution 2.

Discussion

This study produced several noteworthy findings: 1) it is possible to model victim arrival in a pandemic using influenza mortality data from a real pandemic, replicating earlier results;[5] 2) with the assumptions made in this study, Ohio has sufficient beds to manage a severe pandemic without escalation to CSC; 3) when doubling the estimate of pandemic victims to model a disaster where CSC activation was required, validated that triage methods improve survival over FCFS; and 4) demonstrated the power of using simulation modeling with real VPS data.

When crisis standards of care become necessary in a pandemic, this study demonstrated that the use of a validated triage algorithm promises better survival of child victims than the random assignment of PICU beds achieved in a first come first served process. The optimal solutions generated from this research become the thresholds used in the triage process. The physicians responsible for critical care triage during CSC activation may use these thresholds to identify patients with the best chance of survival with reduced access to critical care services.

These results revealed that both optimal triage solutions outperformed FCFS. As expected, the first solution, which used a lower threshold for days on ventilation in exchange for a higher threshold for probability of death compared to the second solution, consistently supported the inclusion of more victims for PICU treatment and a larger number of total survivors. It could be interpreted that the first solution is superior to the second solution. However, determination of which solution to utilize in a specific pandemic disaster should involve consideration of the actual treatment course for ventilation required for effective treatment of the condition causing the illness. Applying a specific solution inappropriately (i.e. using solution 1 for a pandemic where the victims typically required six to eight days of mechanical ventilation to survive) could impact the victim survival rates in the treated population.

Determination of the size of the treatment group for FCFS was challenging as the true proportion of victims served using this method is unknown. The investigators decided to apply the same number of victims served in the triage process to the FCFS scenario to enable equivalent comparison of the results of each method. While this method supported the ability to compare the two approaches to resource allocation in an equitable manner, the investigators agree that FCFS will serve fewer patients in a true pandemic. Practically, FCFS would incorrectly assign some patients requiring extended DV for treatment which would reduce the rate of bed turnover and subsequently decrease the number of future admissions. FCFS would also incorrectly select some patients for treatment too sick to benefit from care with limited access to PICU resources. This would likely result in higher mortality rates in the treated group. Both of these interpretations are likely to have influenced the results of this study.

The decision to simplify the pandemic triage algorithm was considered a favorable product of this study. Reduction in the number of prediction equations considered in the algorithm translates to less assessment and lab data needed to make the triage decision. The investigators believe that the ease of use of the simplified triage algorithm may also reduce the risk for user error when utilizing this tool in the field.

To further support the practical use of this triage algorithm, calculation of the POD and DV scores for each patient should be automated to avoid computational errors that would be likely if triage providers who are already under heightened stress, would be tasked with manual calculation. Software can easily be developed to allow providers to input the requisite input data and to receive the auto generated POD and DV scores for each patient. Further, comparison of individual scores to the established thresholds could also be automated with the outcome of treat or not treat determined by the software.

For triage providers to develop acceptance that this triage method is superior to FCFS during a CSC pandemic activation, several things must happen. First, stakeholders need to be educated to the premise that both triage and FCFS use rationing to determine resource allocation. The difference is in the metric used to ration. The triage algorithm developed in this study uses a prediction of need for ventilation and the victim's probability of death to determine PICU bed allocation. FCFS uses only the time of arrival to allocate PICU beds with victims fortunate to arrive at the exact time that a bed is available selected for treatment, and without regard to the required resource consumption or likelihood of dying.

Next, these results must be replicated in future research. Repetition is the most practical way to strengthen the association between improved survival in the treatment group and the use of a triage algorithm to assign victims to treatment. Future studies should also test the assumptions used in this research, as well as explore alternative assumptions. These efforts will expand the knowledge base on this important topic.

It should be cursory for professionals charged with triage activities in the PICU to review the methods and results of this study and contribute to future efforts to study the use of CSC triage in a mass casualty pandemic. This is a crucial step to developing professional confidence that the performance of a CSC triage algorithm is superior to FCFS and encourages a unified position from the professional body that this triage process is ethical. Without buy in from professionals in the field as well as the general public, and achieved through targeted education, future research efforts, and ongoing public discussions on this sensitive and emotional topic, it may be difficult to generate the broad base of support required for the triage tool to be effectively incorporated into the CSC process.

Limitations

The investigators made a series of assumptions in this study in the absence of real data to inform this project. Assumptions involved the estimated number of pediatric victims, their pattern of arrival, required need for ventilation, and decisions about who will be eligible for consideration of admission to a PICU bed. While each assumption was discussed at length by the investigators to ensure a reasonable study approach, further exploration of these and other parameters are necessary to either validate the assumptions used or to identify better assumptions. Since each pandemic is certain to produce a unique combination of these factors, it is important for the public health and disaster preparedness infrastructure to be prepared with information such as the findings of this study. Future work should explore reasonable alternative assumptions and, whenever possible, utilize real data from actual pandemic disasters to develop updated strategies to identify the optimal treatment group.

The use of VPS data was an attempt to use data from real PICU patients to address the topic of pediatric pandemic triage. A potential limitation of this approach is that the VPS dataset contains only patients that received PICU care and only with conventional care standards in place. While the case counts used for this work lend credibility to the findings of this study, results could vary if data from victims of a pediatric mass casualty pandemic were exclusively used. This point requires further exploration.

The best method for determining the number of victims served using a FCFS model was a substantial challenge to the team. The investigators intrinsically believe that the FCFS method for resource allocation would result in substantial misclassifications of patients into treatment which would impact both the survival of the treated group and the overall number of victims served. Intuitively, the investigators believe that FCFS would result in longer PICU stays, lower survivorship and less victims admitted for treatment but without a method to determine the size of the FCFS treatment group to study the true results, this approach was not feasible. The decision to make the size of the FCFS treatment group equivalent to the triaged treatment group is an assumption that must be validated in future work.

Next Steps

This preliminary work demonstrates promise but should be replicated. If the possibility presents, real data from a true pandemic should be applied to this pandemic triage algorithm to evaluate the performance of the tool. In the absence of real-world pandemic data, the use of simulation is an excellent alternative to the ongoing development of strategies to support optimal survival of pandemic victims. Simulation also allows exploration of various assumptions without impacting actual treatment or victim outcomes.

In the first come first served approach to resource allocation, patients are excluded only when a PICU bed is unavailable, which may reduce the sense of responsibility of the triage providers for turning away victims. It is essential that the providers charged with triage and the families of the victims being triaged have trust that the best selection decisions are being made and consistently applied when a triage algorithm that will select victims for exclusion from care is utilized. Education of these key stakeholder results on the benefits of triage need to be undertaken on a national level.

Future work should further explore that patients included and excluded from PICU care are appropriately triaged. A recommended next step is to measure the sensitivity (the proportion of victims optimal for treatment that are treated) and specificity (the proportion of victims that are too ill to benefit from treatment that are excluded from PICU care) of the triage algorithm.

The validation that CSC triage demonstrates superior survival, not only in the treated group, but in the total victim group overall, to FCFS is essential for future adoption of this methodology universally into CSC plans. Comparison of the performance of these two methods to validate this point is essential. The study limitation involving the determination of the size of the FCFS treatment group must be explored further to develop an approach that accurately identifies the true capacity of the treatment group when FCFS resource allocation strategies are applied. In the absence of true pandemic data to inform this issue, discrete event simulation is a promising alternative and should be considered in future research studies on pediatric pandemic triage.

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Figure 1: Pediatric CSC Triage Algorithm

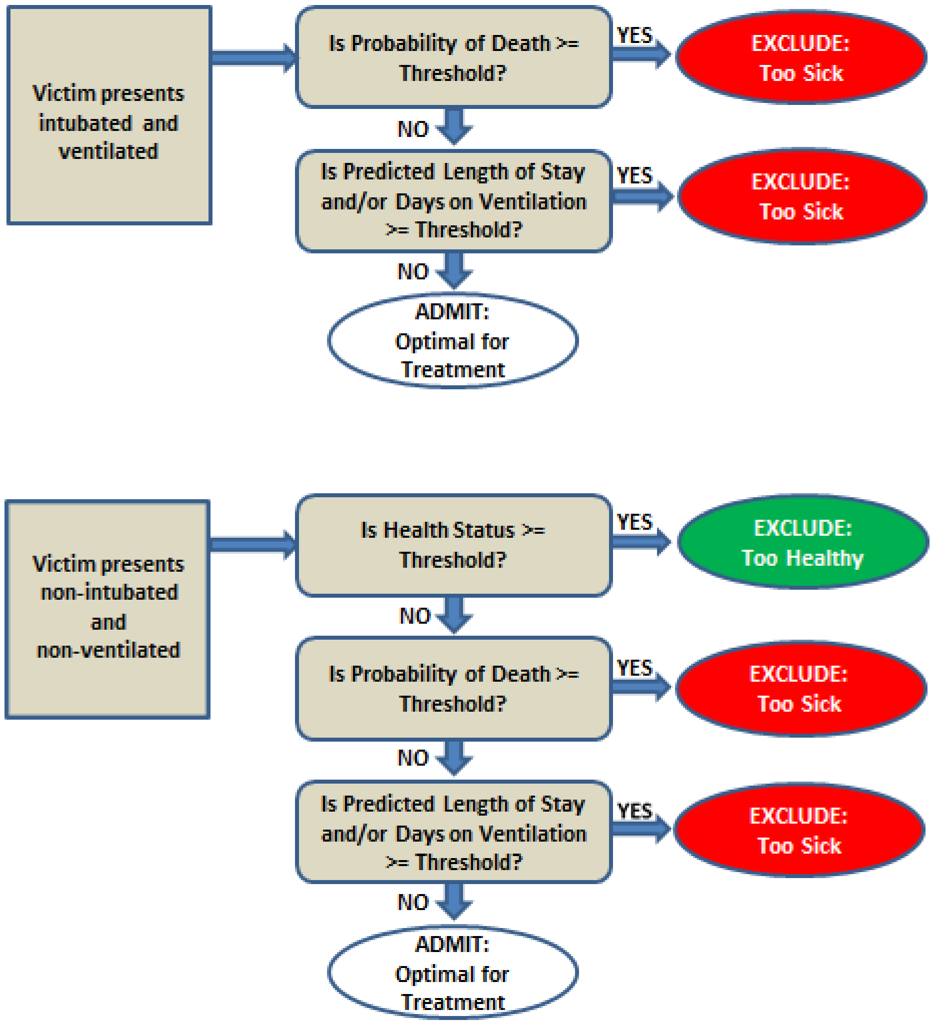

Figure 2: The simplified layout of the simulation model

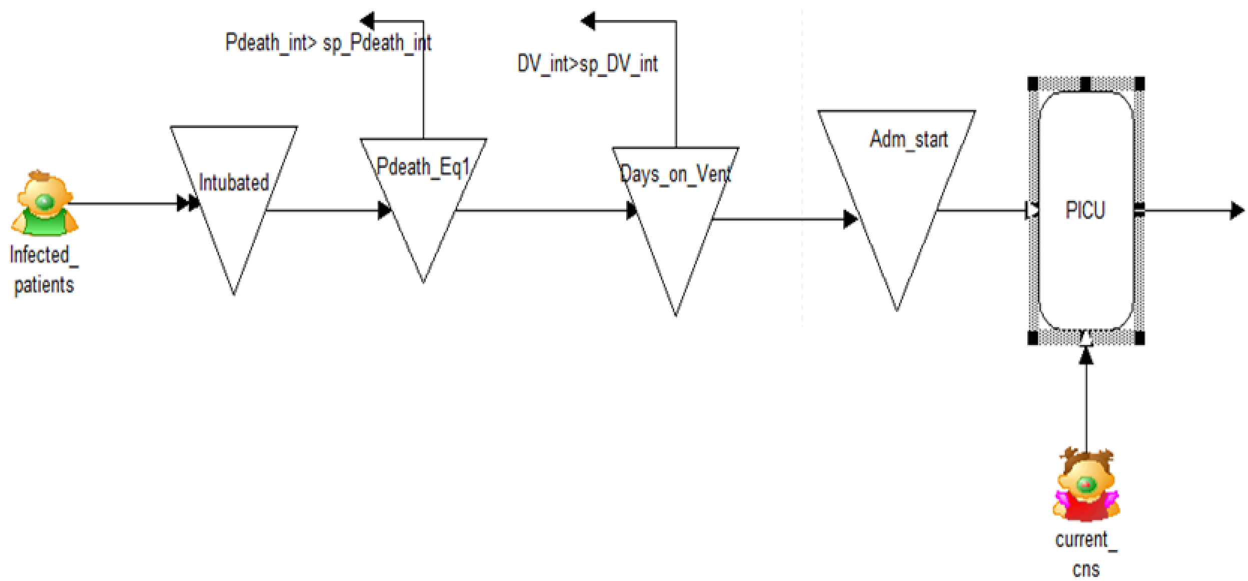

Figure 3: Distribution Frequency for Days on Ventilator

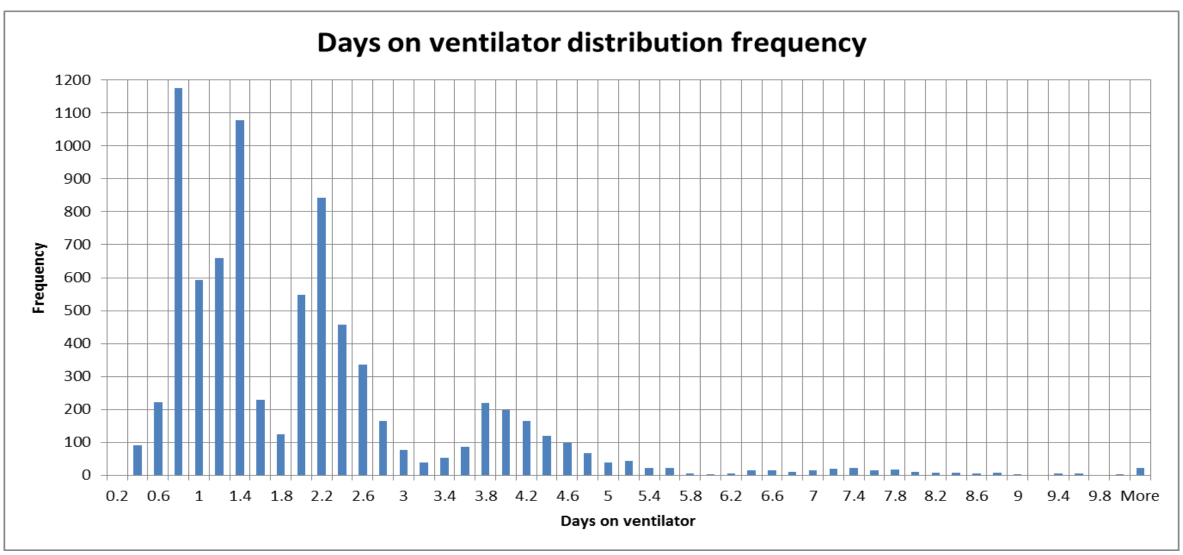

Figure 4: Distribution Frequency for Probability of Death

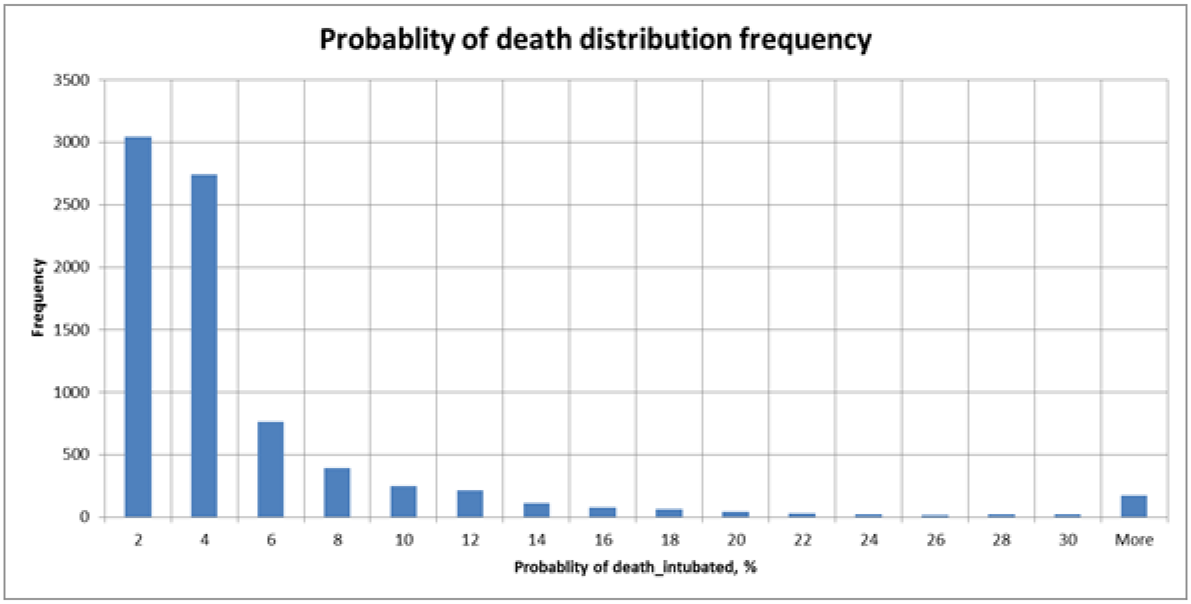

Figure 5: Patient arrival pattern

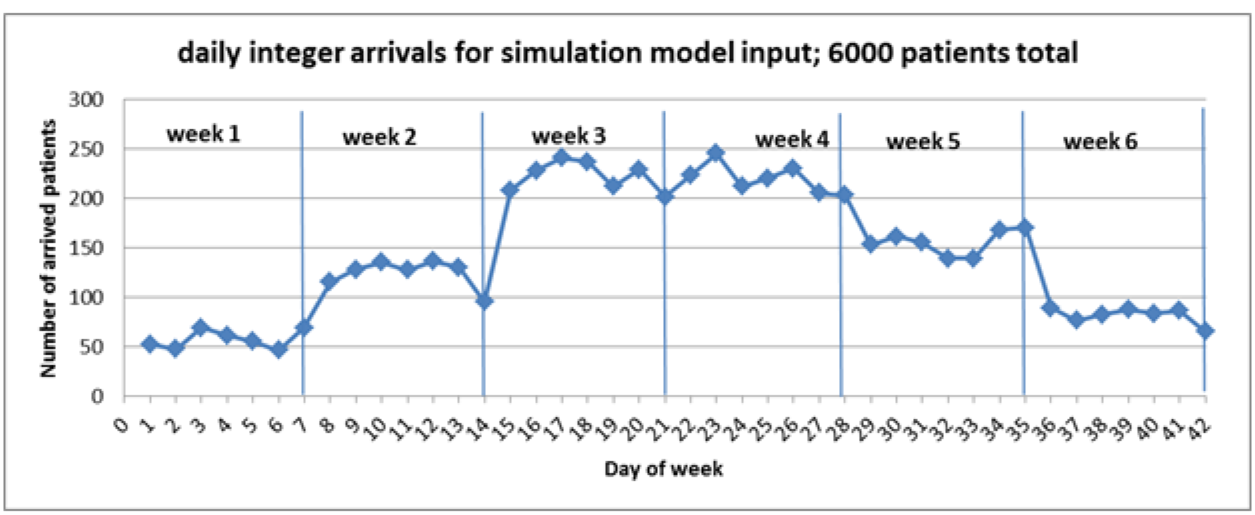

Table 1: Pandemic Disaster Results of Optimal Triage Solution 1 vs First Come First Served

Average Survival (%) for all experiments:

	Average	95% CI
Solution 1	95.51%	(95.26%-95.75%)
FCFS	91.29%	(90.96%-91.62%)
P-value	<0.001	

Experiment	Survival	Threshold: POD < 59.5% DV < 2 .25 Days	No Threshold: First Come First Served	*P*-value
1	Cases Treated (n)	2801	2801	--
	Survivors in Treated Group (n)	2672	2532	--
	% Survivors in Treated Group	**95.39**	**90.40**	**<0.001**
2	Cases Treated (n)	2722	2722	--
	Survivors in Treated Group (n)	2577	2483	--
	% Survivors in Treated Group	**94.67**	**91.22**	**<0.001**
3	Cases Treated (n)	2868	2868	--
	Survivors in Treated Group (n)	2750	2633	--
	% Survivors in Treated Group	**95.89**	**91.81**	**<0.001**
4	Cases Treated (n)	2797	2797	--
	Survivors in Treated Group (n)	2748	2577	--
	% Survivors in Treated Group	**98.25**	**92.13**	**<0.001**
5	Cases Treated (n)	2868	2868	--
	Survivors in Treated Group (n)	2748	2603	--
	% Survivors in Treated Group	**95.82**	**90.76**	**<0.001**
6	Cases Treated (n)	2767	2767	--
	Survivors in Treated Group (n)	2583	2505	--
	% Survivors in Treated Group	**93.35**	**90.53**	**<0.001**
7	Cases Treated (n)	2710	2710	--
	Survivors in Treated Group (n)	2583	2481	--
	% Survivors in Treated Group	**95.31**	**91.55**	**<0.001**
8	Cases Treated (n)	2853	2853	--
	Survivors in Treated Group (n)	2719	2607	--
	% Survivors in Treated Group	**95.30**	**91.38**	**<0.001**
9	Cases Treated (n)	2880	2880	--
	Survivors in Treated Group (n)	2760	2640	--
	% Survivors in Treated Group	**95.83**	**91.67**	**<0.001**
10	Cases Treated (n)	2854	2854	--
	Survivors in Treated Group (n)	2718	2611	--
	% Survivors in Treated Group	**95.23**	**91.49**	**<0.001**

Table 2: Pandemic Disaster Results of Optimal Triage Solution 2 vs First Come First Served

Average Survival (%) for all experiments:

	Average	95% CI
Solution 2	97.90%	(97.72%-98.08%)
FCFS	91.18%	(90.82%-91.54%)
P-value	<0.001	

Experiment	Survival	Threshold: POD < 3.3% DV < 7 Days	No Threshold: First Come First Served	*P*-value
1	Cases Treated (n)	2431	2431	--
	Survivors in Treated Group (n)	2385	2189	--
	% Survivors in Treated Group	**98.11**	**90.05**	**<0.001**
2	Cases Treated (n)	2376	2376	--
	Survivors in Treated Group (n)	2328	2165	--
	% Survivors in Treated Group	**97.78**	**91.12**	**<0.001**
3	Cases Treated (n)	2482	2482	--
	Survivors in Treated Group (n)	2449	2290	--
	% Survivors in Treated Group	**98.67**	**92.26**	**<0.001**
4	Cases Treated (n)	2313	2313	--
	Survivors in Treated Group (n)	2287	2125	--
	% Survivors in Treated Group	**98.88**	**91.87**	**<0.001**
5	Cases Treated (n)	2455	2455	--
	Survivors in Treated Group (n)	2406	2225	--
	% Survivors in Treated Group	**98.00**	**90.63**	**<0.001**
6	Cases Treated (n)	2427	2427	--
	Survivors in Treated Group (n)	2298	2194	--
	% Survivors in Treated Group	**94.68**	**90.40**	**<0.001**
7	Cases Treated (n)	2338	2338	--
	Survivors in Treated Group (n)	2298	2134	--
	% Survivors in Treated Group	**98.29**	**91.27**	**<0.001**
8	Cases Treated (n)	2464	2464	--
	Survivors in Treated Group (n)	2415	2247	--
	% Survivors in Treated Group	**98.01**	**91.19**	**<0.001**
9	Cases Treated (n)	2464	2464	--
	Survivors in Treated Group (n)	2422	2252	--
	% Survivors in Treated Group	**98.30**	**91.40**	**<0.001**
10	Cases Treated (n)	2402	2402	--
	Survivors in Treated Group (n)	2358	2202	--
	% Survivors in Treated Group	**98.17**	**91.67**	**<0.001**

Appendix 1: Probability of Death Predication (POD) Equation (generated during an earlier phase of this project)-Provided with permission from the authors

The POD equation has the following logistic regression form:

$$POD=1/(1+\exp(-r)),$$

where exponent r is:

r=-a0-a1*rec_from_surg-a2*NoHighRiskDX+a3*NoLowRiskDX+a4*PupilsNonReact +a5*(SysBP_forpim-120)+a6*BaseExcess+a7*gcs_lt8+a8*ageMonths+a9*under1_year +a10*categ_infec-a11*categ_resp

Variable	Coefficient	Notes
Y intercept (constant)	(-)a0	
Recovery from surgery*	(-)a1	Recovery from surgery is the main reason for PICU admission
No high risk diagnosis*	(-)a2	see table 1; select yes if pt has one or more
No low risk diagnosis*	(+)a3	see table 2; select yes if dx is main reason for PICU admission
Both pupils non-reactive*	(+)a4	pupils fixed and dilated (>3mm)
First SBP**	(+)a5	First measured systolic blood pressure; subtract from 120 and record. Missing value-record 0
First base excess(deficit)**	(+)a6	First measured base excess(deficit);missing value-record 0
GCS < 8*	(+)a7	Glasgow Coma Scale score less than 8
Age in months**	(+)a8	Age recorded in months
age under 1 year*	(+)a9	Infant; age under 1 year
Infectious diagnosis*	(+)a10	One or more active infectious diagnoses
Respiratory diagnosis*	(-)a11	One or more active respiratory diagnoses

Categorical Variable: Yes=1; No=0 **Continuous variable: Enter recorded value

Table 1: PIM 2 High Risk Diagnosis
Cardiac arrest immediately preceding ICU admission
Severe combined immune deficiency
Leukemia or lymphoma (after first induction)
Spontaneous cerebral hemorrhage
Cardiomyopathy or myocarditis
Hypoplastic left heart syndrome
HIV infection
Liver failure is the main reason for PICU admission
Neurodegenerative disorder

Table 2: PIM 2 Low Risk Diagnoses
Asthma
Bronchiolitis
Croup
Obstructive Sleep Apnea
Diabetic Ketoacidosis

A training set with 28273 ventilated patients was used. Validation for the POD logistic regression equation was tested by calculating the area under Receiver Operation Curve (AROC) for discrimination. This tests both the sensitivity and specificity of the prediction equation. Traditionally, predictions are judged to discriminate well when AROC > 0.85. The ROC curve for the POD equation is presented on Figure 1 with an AROC=0.87.

Validity of the logistic regression equation was tested using the Hosmer-Lemeshow (H-L) test for goodness of fit. Prediction models are assumed to be adequately calibrated when the H-L test, comparing the predicted to actual outcomes after stratifying the population by deciles, registers at P-value > 0.05. H-L test with a test set of ventilated patients (N=14,144) produced the chi-square=11.37 and P-value=0.181.

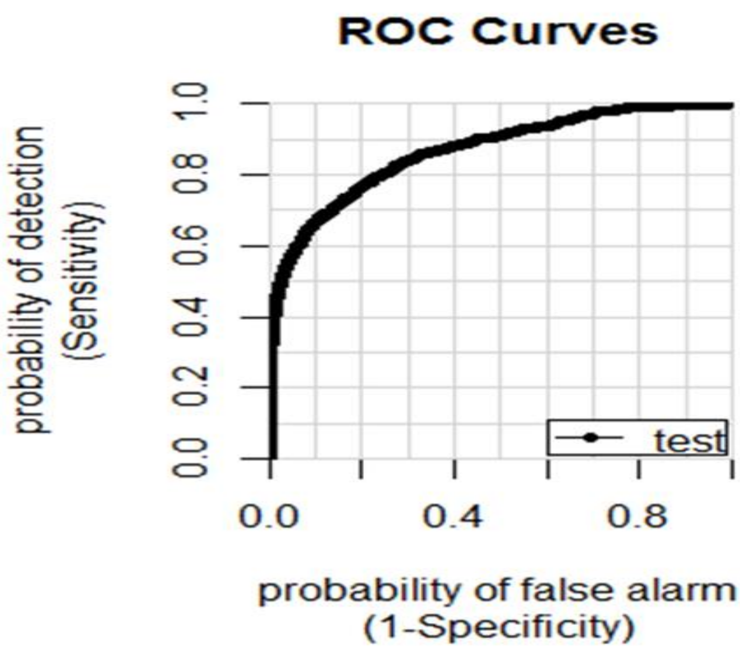

Figure 1: ROC plot for POD intubated test set logistic regression

Appendix 2: Days on Ventilation Prediction Equation (generated during an earlier phase of this project)-Reprinted with permission from the authors

The days on ventilation equation (DV) has the form of the logarithm of the event that was fitted using multi-linear regression methodology and using a training set of ventilated patients (N=24,871).

ln (VentDays)=a0- a1*rec_from_surg -a2*adm_card_bypass-a3*NoHighRiskDx +a4*(SysBP_forpim-120) + a5*fiO2_paO2+a6*gcs_lt8+a7*neonate+a8*under1_year – a9*age18plus+a10*categ_infec-a11*categ_card-a12*categ_inj-a13*categ_neur+a14*categ_resp

and DV is calculated as: DV=exp(ln VentDays)

Variable	Coefficient	Notes
Y intercept (constant)	(+)a0	
Recovery from surgery*	(-)a1	Recovery from surgery main reason for PICU admission
Admitted following bypass*	(-)a2	Admitted to the PICU following cardiac bypass
No high risk diagnosis*	(-)a3	see table 1; select yes if patient has one or more diagnoses in the table
First SBP**	(+)a4	First measured systolic blood pressure; subtract from 120 and record. Missing value-record 0
FiO2/PaO2 ratio**	(+)a5	Fraction of inspired oxygen / Partial pressure of oxygen X 100
GCS < 8*	(+)a6	Glasgow Coma Scale score less than 8
Neonate*	(+)a7	Neonate; age under one month
Age under 1 year*	(+)a8	Infant; age under one year
Age over 18 years*	(-)a9	Adult; age >= 18 years
Infectious diagnosis*	(+)a10	One or more active infectious diagnoses
Cardiac diagnosis*	(-)a11	One or more active cardiac diagnoses
Injury diagnosis*	(-)a12	One or more active injury diagnoses
Neurologic diagnosis*	(-)a13	One or more active neurologic diagnoses
Respiratory diagnosis*	(+)a14	One or more active respiratory diagnoses

*Categorical Variable: Yes=1; No=0 **Continuous Variable: Enter recorded value

Table 1: PIM 2 High Risk Diagnosis
Cardiac arrest immediately preceding ICU admission
Severe combined immune deficiency
Leukemia or lymphoma (after first induction)
Spontaneous cerebral hemorrhage
Cardiomyopathy or myocarditis
Hypoplastic left heart syndrome
HIV infection
Liver failure is the main reason for PICU admission
Neurodegenerative disorder

Validation for the DV multi-linear regression was performed by calculating the adjusted value of R^2 which measures the goodness of fit of the data to the regression line. The adjusted R^2 =0.1816.

Acknowledgements:

The authors would like to thank Casey Lauer, BS, Manager, Data Management for VPS, for his assistance in developing the requested datasets, including randomization of case selection, and for his contributions to the analysis of the results. We would also like to thank Aaron Katch, MS, Biostatistician for VPS, for his assistance in the calculation of P-values, confidence intervals and for his contributions to the analysis of data.

Conflicts of Interests: None
Funding Source: This project is funded through a contract with the Ohio Hospital Association.
Financial Disclosure: The authors have no financial relationships relevant to this article to disclose.

Chapter 8: CONCLUSIONS AND IMPACT OF RESEARCH ON PRACTICE

A number of findings were identified in this study with great promise to inform future implementation of crisis standards.

A. Optimal triage method is disaster specific. The results demonstrate that the optimal triage algorithm to use in a CSC disaster depends, in part, on the characteristics of the disaster. In this study, two contrasting disaster scenarios were selected to explore that point. The analysis of iterative simulation results informed that not only do the optimal triage thresholds vary by disaster type, but so do the predictors required to select the victims determined optimal for treatment.

These findings are important as this clarifies that a one-size-fits-all triage approach is impractical. This also suggests that future studies need to further explore and articulate the specific factors that impact the selection of the best triage approach. For example, while our research concluded that duration of ventilation therapy was not an important triage consideration for a time-limited, region-specific, single event disaster, it was imperative to the selection of the ideal treatment group in the pandemic disaster scenario.

B.Revising the pediatric triage algorithm improved ease of use and assured optimal survival in the treated group. The use of discrete event simulation allowed the research team the opportunity to study the impact that hundreds of combinations of inputs to the simulation model had on the selection of the optimal triage thresholds. Each simulation experiment considered 100 (pandemic) or 120 (single event) various combinations of possible values for the physiologic, lab and health history data used to generate predicted probability of death and days on ventilation scores for each simulated victim. With the simulation software using thousands of experiments, all likely combinations of these triage data were explored to derive the triage thresholds that would select the optimal victims for treatment. In this study, the optimal treatment group was defined as the largest number of victims served with the best possible survival.

This level of analysis is impossible using manual statistical and mathematical methods. Since the simulation approach examines virtually all possible combinations of patient data, the optimal thresholds produced through simulation can be trusted, provided the inputs used to develop the simulation model are accurate and complete.

During the analysis of the preliminary results of the single event simulation data, an opportunity to simplify the triage algorithm became evident. As the output of the simulation were reviewed using all seven prediction equations from the original algorithm, the optimal thresholds generated did not follow an obvious pattern. In other words, as beds or victims were incrementally changed from one experiment to the next, the seven prediction equation thresholds did not follow a consistently increasing or decreasing trend. The team explored the meaning of these results, and made several conclusions that had implications for single event and/or pandemic disasters when CSC activation is initiated:

- Respiratory failure and the immediate need for mechanical ventilation was the single definitive condition that determined that a victim needed a PICU bed as other critical care services could feasibly by provided in an alternative location by non-critical care staff quickly educated in critical care tasks, critical assessment focal areas and triggers highlighting clinical deterioration

- In Ohio, following evaluation of their surge plans, it was determined that a ventilator would be available for every PICU bed
- Predicted PICU length of stay and predicted days on ventilation are highly correlated and therefore, only one of the equations needs to remain in the algorithm
- During CSC, the duration of time spent in the PICU following extubation (cessation of mechanical ventilation) would be severely restricted to allow for maximal bed turnover (in the pandemic disaster); the team determined that length of stay could be estimated by adding eight hours (0.33 days) to the duration of ventilation to reflect the average time in the PICU post ventilation

As a result of these decisions, informed by the analysis of the preliminary simulation results and interpreted by the research team, the triage algorithms for the single event and pandemic disasters were significantly simplified as previously described. From an operational perspective, the simplification of the triage algorithms substantially reduced the complexity of the triage assessment as the number of variables that needed to be assessed for the equations that remained decreased. It is possible that this could also reduce the potential for error in the triage process that could occur by inaccurate measurement of physiologic or lab values, key stroke errors in documentation of assessment findings, or other human factors.

Removal of the four prediction equations the original algorithm developed for victims that were not in respiratory failure had an additional effect. It removed the triage providers from the role of determining the true acuity of their condition. Making the decision to refer this group to a lower level of care based exclusively on a victim's ability to breath may also reduce variation in triage decisions between clinicians as fewer assessment variables would be required.

C. Establishment of optimal triage thresholds. This study demonstrated that optimal triage thresholds may be established and used to operationalize a pediatric triage algorithm. The study further demonstrated that the approach to pediatric triage as well as the thresholds determined best for selection of the optimal treatment group varies with the type of disaster (single-event or pandemic), the duration of the disaster, the number of disaster victims, and the availability of scarce resources.

The optimal results generated for the single event disaster, such as a stadium collapse, revealed that the ratio of victims to beds, rather than the actual number of victims and beds, was the key determinant in establishing the effective threshold. The benefit to this finding for the State of Ohio and potentially for other states that do not have a process for centralized management of an isolated, time-limited single event disaster, is that individual PICUs may use the established triage thresholds based on information from the field regarding estimated pediatric victims and their knowledge of available surge bed capacity in each PICU. This will also satisfy the ethical requirement for consistent application of the triage algorithm if all PICU teams select the threshold appropriate for the victim/bed ratio they anticipate.

For the pandemic disaster, while the number of anticipated victims and available beds is essential, the additional dynamic of victim arrival patterns during the peak of the pandemic and the duration of ventilation is crucial. The work to establish optimal thresholds for the pandemic was necessarily more complex, due to the introduction of these additional factors. This is reflected in the result that two optimal solutions were identified. The investigators appreciate that the development of two optimal triage solutions may allow this work to be more effectively utilized in a true disaster as they represent the extremes for the POD and DV prediction equations. One solution had a low DV and high POD threshold; the second solution had a low POD and high DV threshold. The practical utility of these options is that based on the typical disease course caused by the pandemic organism and the usual need for mechanical ventilation, the solution that best addresses the characteristics of the emerging pandemic may be selected. Ideally, lower days on ventilation would enable more victims to be treated but this solution would not be optimal if extended ventilator support was necessary to save lives.

The goal of the triage algorithm is consistent regardless of the disaster type. That is, to achieve the best survival by selecting victims determined optimal for treatment to available PICU beds. The single event disaster focuses exclusively on making this decision based exclusively on the patients' severity of illness (and associated predicted survival) at time of presentation to the triage station, to fill all available beds with the specific victims who will benefit from treatment, excluding victims that are either too healthy or too sick from PICU admission. The pandemic disaster considers both severity of victims' illness or injury and the length of time they will be occupying a bed as optimal bed turnover in a pandemic disaster must be achieved to achieve the goal of treating the greatest number of victims.

Future studies should evaluate the internal validity of these results so that public health and health care leaders, clinicians and the general public have confidence that the superior victim survival rates in the treatment group are related to the use of the triage algorithm. Consideration needs to be given to the possibility of confounders, factors outside of this study that may have influenced the results.

Further, evidence of bias introduced in the design or execution of this study should also be explored. As an example, the use of VPS data to develop the simulation model and to test the capacity of the simulation results to achieve optimal survival via triage raises a reasonable question. While the investigators posited that VPS data represent an extremely robust sample of real critically ill patients and as such could be reasonably considered an acceptable representation of the distribution of a subset of critically ill patients—namely victims of a disaster—is this assumption introducing bias? Without the ability to test this question, due to lack of a comparable dataset containing physiologic, lab and health history data from actual child disaster victims of similar counts (> 100,000 cases), the question lingers.

Another potential threat to internal validity of these results is the lack of ability to explore victim survival in the children triaged to non-treatment. Such an experiment would violate laws governing the rights of human subjects in research, and as such, is fittingly impossible to conduct prospectively. Exploration of this question could only be reasonably done by using similar methods used in this study; through future simulated experimentation using discrete event simulation and software that allows virtually infinite combinations of potential study variables to be considered to identify an optimal solution.

If this or a similar validated triage tool were to be deployed during a real CSC disaster and the survival experience of all triage groups (excluded because too healthy, excluded because too sick, excluded because although optimal for treatment, PICU resources were not available, or selected for treatment) were recorded, the true efficiency and effectiveness of the triage tool could be measured. Until that occurs, this represents a study limitation.

Future studies on this topic should also explore the consideration of external validity; that the results of the study can be applied to other groups with similar survival results. Since VPS is a voluntary database and a substantial number of PICUs in the United States participate, the investigators believe cases in VPS to be representative of the true population of pediatric critical care patients. However, if a disaster produced child victims with a specific collection of conditions or injuries, would this sample also represent the population?

A possible benefit of this study is that the use of a triage algorithm may reduce treatment bias in the triage group if correctly utilized. As the triage personnel collect the data for each patient needed to assign the appropriate predictive values to each victim (probability of death and days on ventilation) the assignment of these values may reduce potential subjectivity of the assessment. With the triage “scores” for POD and

DV (in the pandemic disaster only) determined at the triage station, and comparison to the pre-determined thresholds for POD and DV, the identification of the victim's scores in relation to the thresholds is easy to ascertain. In contrast, the "selection" of the treatment group in a first come first served strategy of PICU admission may be influenced by other factors, such as access to transportation to the hospital or a victim's early recognition of their level of illness or injury.

As internal and external validity is explored, the interpretation of the appropriateness of the study methods and design and the application of the assumptions generated will evolve. This is an essential step in gaining public confidence in the advantages of the use of triage in CSC disaster scenarios.

E. CSC Triage Integration. Even with the development of validated pediatric crisis standard of care triage tools, execution of a triage plan to allocate scarce PICU resources requires the support and integration of effective systems and effective leadership. Specifically from the PICU perspective, it is important to be sufficiently integrated with both down-stream and up-stream triage services to achieve the best possible survival given overwhelmed resources. Bostick et al (2008) suggests that there are four discrete triage points that need to be connected and integrated:

- First order triage occurs in the field (community) and advises victims requiring medical attention effective interim protective strategies and information on available venues and indications for accessing medical resources. First order resources offer the earliest information about the scale of a disaster and the effectiveness of the emergency preparedness infrastructure, essential information to inform the need and timing of CSC activation and for PICU leaders, staff and resources to prepare.
- Second order triage occurs in the pre-hospital setting according to emergency preparedness plans. Incorporating information from first order triage providers as well as assessment of the numbers, condition, and needs of arriving victims, triage

protocols are implemented to sort victims into groups with similar needs for care. As critically ill victims arrive, the need for second order triage personnel to maintain continual communication and integration with PICU leaders.

- Third order triage occurs in the hospital or alternatively designated setting for triage of patients requiring stabilization or hospital-based services. This is the venue in which the pediatric triage algorithms generated in this study would be used during CSC activation. Effective use of the pediatric triage tools require an understanding of the anticipated number of child victims, their need for scarce critical care resources, in addition to assessment of victim severity of illness/injury at time of arrival. Securing this information in a pediatric mass casualty disaster certainly requires exceptional integration with first and second order triage resources as well as horizontally with other third order triage sites. Communication with fourth order triage is also essential to communicate shortages of staff, space, services, and supplies to gain prompt access to emergency stockpiles.
- Fourth order triage occurs at the regional level and serves to oversee the effectiveness of the emergency response, integration of emergency response resources and the allocation and distribution of resources in a CSC disaster. Fourth order triage resources may support PICU triage and resource allocation activities by mounting a timely and effective response to requests from critical care teams.

Effective vertical and horizontal integration of these four key points of the disaster triage response system is essential to achieving optimal survival during crisis standard of care activation. Like a chain, weaknesses at any of these junctures will deteriorate the effectiveness of the response.

F. Stewardship of the triage algorithm concept. With the development of valid and reliable, popularly accepted pediatric CSC triage tools, the creation of an integrated network within which the tools will be deployed, and with prepared, capable leaders in place to implement the CSC triage plan, the last important consideration to a successful deployment plan relates to the effective stewardship of the concept of pediatric triage in a CSC disaster. As previously mentioned, regardless of the resource allocation method selected, in a CSC mass casualty disaster, rationing will occur. Children that would survive with conventional standards of care in place will undeniably die in a crisis.

Effective stewardship of CSC preparedness strategies requires that this point is globally communicated to and accepted by stakeholders. Failure of achieving this imperative will most certainly impact confidence in the use of the triage approach in CSC. It is plausible that the first come first served resource allocation method may offer a sense of relief to triage providers if they feel that the best deployment is to keep all available PICU beds occupied with no further considerations. Buy in for a triage approach that considers other patient-centric factors may occur when stakeholders are convinced in the validity of the science used to generate the triage algorithm and prediction equations, and moreover that their use will save more lives than a random method of resources assignment.

While public health officials are generally ahead of the curve in the recognition that relaxation of conventional standards of care and rationing of scarce resources is inevitable of CSC needs to be deployed, another challenge remains for the public health community to address. While triggers for crisis standards of care have been developed and improved over the last decade, the factors that signal a timely return to conventional care aren't as well-developed. Stakeholders must develop trust that just as the decision to implement CSC is done systematically and in accordance with accepted methods, the decision to decommission CSC procedures at the earliest possible juncture must also be obvious and inevitable to those charged with decisions of such public importance.

G. Integration with the IOM CSC Toolkit. Development of an infrastructure capable of managing a successful CSC response is compulsory for the achievement of optimal victim survival. The IOM CSC Toolkit (2013) offers superb guidance to ensure that disaster plans are proactive and reliably support effective and timely escalation and de-escalation of crisis standards. For hospitals, the focus is on effective management of information (surveillance data), interaction with community based resources, and deployment of staff, space and supplies and on the identification of circumstances that signal the need for a possible transition along the continuum from conventional to crisis care.

While there are global recommendations that may be applicable to most organizations, it is essential that every organization customizes their disaster plan to most effectively and efficiently launch a sustained response. Indicators and triggers that assist leaders to recognize the likelihood of resources to be overwhelmed and to launch an effective response. Tactics are predefined actions that can be used to achieve optimal use of limited resources and optimal disaster response.

Expanding upon an example from the toolkit (IOM, 2013) related to crisis management of staff:

a) Indicators for activation may include:
- Determination that surge plan capacity has been exhausted
- Staff are working expanded hours without reprieve or replacements available
- Staff absenteeism increasing due to disaster-related factors
- Victims requiring greater care from specialized staff and demand exceeds supply

b) Triggers for CSC activation include:
- Staff unable to provide safe or timely care using conventional care practices
- Staff unable to physically sustain work effort
- Staff lack competencies necessary to provide effective care

c) When triggers are realized and the appropriate declaration of disaster has been made, CSC tactics may be deployed, such as:
- CSC leaders designated, including leadership pairings when necessary disaster competencies are weak

- Launch just in time training strategy to expand specialty skillset to lower level providers
- Transition to team nursing to expand number of patients maximally served
- Defer all non-essential care
- Incorporate parents and family members into care team; delegate specific activities
- Effectively use volunteer pool by requesting desired skill sets and numbers of volunteers needed
- Keep staff in direct care areas by making provisions for food, drink, rest/sleep areas, and child care services

The key to the development of an effective infrastructure to support CSC is to prepare with strategies that are easy to understand and use. The indicators and triggers in the above example are easy to recognize, allowing leaders the proactivity necessary in a disaster. The tactics are actionable and can be easily communicated.

A natural and necessary progression of this study is to develop indicators, triggers and tactics for deployment of the pediatric triage algorithm and for return to conventional care.

Study Limitations

Traditional risk adjustment tools, while designed to assign various “scores” to individuals, were intended to be retrospectively interpreted and only for groups of patients. This study switches focus to the prospective use of predictive tools for use on individual patients. Their use in determining inclusion or exclusion from treatment for a single victim includes a margin for error. This means that for a single victim, there is a reasonable chance of misclassification, which can lead to children that should have been determined optimal for treatment being falsely excluded, and children that should have been determined too sick or too healthy to benefit from treatment with limited access to PICU resources being given a PICU bed in the place of a better candidate.

While the investigators went to substantial lengths to use real data or previous research findings in place of assumptions whenever possible, the lack of accurate, complete, and sufficiently detailed data on real disaster victims posed a limitation to this study. With this identified deficit, disaster plans should include a strategy for collection of data that would be critical to informing future studies, though data collection should not replace the appropriate focus on optimal treatment of disaster victims.

While data from true PICU admissions was used to develop the initial and updated triage algorithms, prediction equations, the simulation model, and to test the optimal thresholds created through simulation, it remains that the data used represents the results of PICU patients that were believed to receive top quality care with conventional standards of care in place. Further study of the application of these data to a disaster where crisis standards are deployed is warranted.

The researchers were challenged by the ability to estimate the size of the FCFS treatment group. The simulation models were not designed to estimate the characteristics of victims that arrive early for treatment versus late, which is the greatest factor impacting the FCFS approach. This study was limited to evaluation of survival in the treatment group. Since the true size of the FCFS group could not be accurately determined, we decided to make the FCFS treatment group equivalent in size to the triaged group. This allowed for the comparison of survival using each method in an equivalent manner. Since overall survivorship in a disaster will be determined by the number of critically ill victims admitted for PICU care, it is important to verify that the triage approach will accomplish this in a superior manner to FCFS. These represent crucial next steps in the development of an effective CSC response.

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APPENDIX I: Toltzis-Wetzel Pediatric Triage Algorithm- Seven Prediction Equations [CONFIDENTIAL Unpublished Data]

Prediction Equations (arriving intubated/vented and arriving intubated/non vented):

PRESENTS INTUBATED	PRESENTS NON-INTUBATED
Equation 1: Mortality r = -3.86-0.78*ElectiveAdmit-0.79*RecFromSurg -1.48*NoHiRskDx +1.05*NoLoRskDx +2.48*PupilsNonReact+0.02*SystBP_forpim +0.06*BaseExcess+1.07*gcs+.003*ageMonths+0.53*underly+0.82*categ_infect-0.22*categ_resp. **P_{death}=1/1+ep(-r)** **AROC = .868; H-L P < .181**	**Equation 4: Low-Risk (0 DMV + Mort < .05 + LOS ≤ 3 days)** r = 1.46+0.33*ElectiveAdmit+.64*RecFromSurg-.391*AdmitAftCardBypass+.77*NoHiRskDx-.96*NoLoRskDx-.007*SystBP_forpim-.96*gcs-.23*neonate-.46*underly-0.45*categ_infect-0.45*categ_card +1.26*categ_inj +.25*categ_neur-.483*categ_resp. **$P_{low\text{-}risk}$ = 1/1+exp(-r)** **AROC = .703; H-L < .01**
Equation 2: LOS logLOSInt = 1.33-0.17*RecFromSurg-0.36*NoHiRskDx +0.09*NoLoRskDx-0.65*PupilsNonReact +.003*SystBP_forpim +.023*FiO2_piO2_pim+0.15*gcs+0.37*neonate+0.34*underly+0.37*categ_infect+0.07*categ_card-0.18*categ_inj-0.34*categ_neur +0.26*categ_resp. **LOSIntr=exp(logLOSInt)** **R^2 = .18**	**Equation 5: Mortality** r = -5.32-.88*ElectiveAdmit-1.86*RecFromSurg-1.60*NoHiRskDx+2.1*NoLoRskDx+0.86*PupilsNonReact+.02*SystBP_forpim+.08*BaseExcess+1.63*gcs-2.34*categ_inj-1.003*categ_neur. **P_{death} = 1/1+exp(-r)** **AROC = .871; H-L < .265**
Equation 3: DMV logVentDays = 0.84-0.07*ElectiveAdmit-.055*RecFromSurg-0.25*AdmitAftCardBypass-0.53*NoHiRskDx +.005*SystBP_forpim+.03*FiO2_piO2_pim+0.27*gcs+0.59*neonate+0.46*underly-0.15*age18plus+0.71*categ_infect-0.20*categ_card-0.42*categ_inj-0.70*categ_neur+0.49*categ_resp. **DMV = exp(logVentDays)** **R^2 = .11**	**Equation 6: LOS** logLOSNonInt = 0.45-.16*ElectiveAdmit-.18*RecFromSurg+.23*AdmitAftCardBypass-.40*NoHiRskDx +.36*NoLoRskDx-.004*SystBPforpim+.406*gcs+.0003*ageMonths+.21*neonate+.24*underly+.25*categ_infect+.19*categ_card-.47*categ_inj-.07*categ_neur+.21*categ_resp. **LOSNonInt = exp(logLOSNonInt)** **R^2 = .10**
	Equation 7: DMV logVentDays = 1.13-.57*RecFromSurg-.79*AdmAftCardBypass-.43*NoHiRskDx +.45*underly +.62*categ_infect-.56*categ_inj-.18*categ_neu r+.55*categ_resp. **DMV = exp(logVentDays)** **R^2 = .11**

Variables used in each equation:

AV=arrive vented ANV=arrive non vented	Eq 1: Probability of Death (AV)	Eq 2: Length of Stay (AV)	Eq 3: Days on Vent (AV)	Eq 4: Probability Low Risk (ANV)	Eq 5: Probability of Death (ANV)	Eq 6: Length of Stay (ANV)	Eq 7: Days on Vent (ANV)
Elective Admit	X	X		X	X		X
Recovery from Surgery	X	X	X	X	X	X	X
Admit After Cardiac Bypass		X		X			X
No High Risk Diagnoses	X	X	X	X	X	X	X
No Low Risk Diagnoses	X	X		X	X		
Pupils Non Reactive	X				X	X	
Systolic BP (PIM2)	X	X		X	X	X	X
Base Excess (PIM2)	X				X		
FiO2/PaO2 ratio (PIM2)						X	X
Glasgow Coma Scale Score<8	X	X		X	X	X	X
Age (in months)		X		X	X		X
Neonate		X		X		X	X
Under One Year		X	X	X	X	X	X
Age 18 Years Plus	X						X
Infectious Diagnosis		X	X	X		X	X
Cardiology Diagnosis		X		X		X	X
Injury Diagnosis		X	X	X		X	X
Neurology Diagnosis		X	X	X		X	X
Respiratory Diagnosis		X	X	X		X	X

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I will properly acknowledge and credit the National Association of Community Health Centers for this work. Could you respond to this email with your verification of authorization. I will retain it for my files.

Thank you in advance for your assistance and support.

Respectfully,

Christine

Christine Gall, DrPHc, MS, RN
Director, Quality and Client Relations
Virtual PICU Systems (VPS, LLC)
333 Bishops Way Suite 110 | Brookfield, WI 53045
Ph1: 888-999-4850 x102 | Ph2: 262-439-9640
E-Mail: cgall@myvps.org

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From: Lewin, David (AHRQ) [mailto:David.Lewin@ahrq.hhs.gov]
Sent: Tuesday, April 01, 2014 2:58 PM
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Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850
+1 301-427-1895 phone
+1 301-427-1873 fax
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4. Dr Toltzis

From: Toltzis, Philip [mailto:Philip.Toltzis@UHhospitals.org]
Sent: Wednesday, April 09, 2014 9:27 AM
To: Christine Gall
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Best,

Philip Toltzis, MD
Professor of Pediatrics
Case Western University School of Medicine
Cleveland, Ohio
44106
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