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A MODEL OF CREATING INPATIENT HOSPITAL SURGE CAPACITY THROUGH EARLY DISCHARGE

by

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September 2018

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A MODEL OF CREATING INPATIENT HOSPITAL SURGE CAPACITY THROUGH EARLY DISCHARGE

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ABSTRACT

When catastrophic disasters strike, health care systems are often faced with overwhelming volumes of patients to treat (patient surge). While many governmental and policy organizations have outlined recommendations to build "surge capacity," there has been little research on specific strategies to accommodate these significant patient loads. Specifically, a concept known as "reverse triage," which allows clinicians to assess current patients for possible discharge or reduction in the level of their clinical care, is still poorly understood.

This research study investigated the utility of a structured assessment tool to predict the ability of a current patient to be discharged or downgraded in the event of a catastrophic disaster. Clinicians were provided a mock scenario and asked to use their clinical judgment or a structured assessment tool. The charts of patients were then reviewed 96 hours after the assessments were completed to determine whether predictions were accurate. This pilot study showed that the assessment tool was slightly better at predicting which patients could be safely discharged and which needed to remain admitted.

This project serves as a first foray of research into this area and will initiate broader discourse and additional studies. The goal is to provide clinicians with stronger guidance vetted in scientific evidence and supported in ethical, legal, and moral context to make difficult decisions in the face of catastrophic disaster situations.

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LIST OF ACRONYMS AND ABBREVIATIONS

ADLs	Activities of Daily Living
CPR	Cardiopulmonary Resuscitation
ECG	Electrocardiogram
ECMO	Extracorporeal Membrane Oxygenation
G/J Tube	Gastric/ Jejunostomy Tube
HVAC	Heating/Ventilation/Air Conditioning Systems
ICS	Incident Command System
IOM	Institute of Medicine
IRB	Institutional Review Board
IV	Intravenous
LP	Lumbar Puncture
MCI	Mass Casualty Incident
MEWS	Modified Early Warning System for Clinical Deterioration
NPS	Naval Postgraduate School
OR	Operating Room
PPV	Positive Pressure Ventilation
SOFA	Sequential Organ Failure Assessment
SOP	Standard Operating Procedure
START	Simple Triage and Rapid Treatment
STM	Sacco Triage Method
TPN	Total Parenteral Nutrition
UCLA	University of California Los Angeles
USGS	United States Geological Survey

EXECUTIVE SUMMARY

Disasters and catastrophic mass casualty incidents continue to occur in the United States and around the globe. These events challenge their communities to preserve life and often require responders to go to extraordinary measure and utilize austere conditions to fight injury, illness, and disease. These communities are often stressed to prioritize planning activities with limited funds to improve resilience. Therefore, a focus on efficiency and utility for day to day activities that support broader flexibility is key.

One such area of preparedness is in health care systems. Hospitals, specifically, are often operating at high capacity to ensure efficiency and effectiveness. When catastrophic events in the community create large influx of emergency patients or a disaster strikes and impacts the physical infrastructure including health systems, these organizations must have capacity to support "patient surge." In events such as the terror attacks of September 11th, 2001, Hurricane Katrina, Super storm Sandy, and the mass shooting in Las Vegas in October of 2017, hospitals had to make rapid decisions on how to manage the large influx or movement of patients while providing high quality medical care for existing as well as these new patients.

The construct of "surge capacity," strategies to manage these large influxes of patients, have been discussed for many years in emergency management and health care spheres. Experts have offered many opportunities to address the challenges of surge which include the development of cached space or alternate care sites, patient evacuation/transfer, modification of standards of care, and triage/reverse triage including early discharge. They also described the key contributors of success which are defined as "System, Stuff,

Staffing, and Space"¹ However, few of these strategies have been developed in detail or studied with academic/scientific rigor.

This research project dives into the concept of reverse triage and early discharge/transfer as a strategy to create surge capacity. Building on the work of a multidisciplinary team at UCLA Health who developed a structure assessment tool to safety predict patients who could be discharged from their acute care hospital bed or transferred to a lower level of care, this study compared the clinical judgment and the utility of this structured assessment tool in the event of a catastrophic disaster. Clinicians (nurses) were provided a mock scenario and asked to use their clinical judgment in phase one and use the structured assessment tool in phase two. The charts of patients were then reviewed ninety-six hours (four days) after the assessments were completed to determine if they had needed any predefined critical interventions or if they had been discharged. This process leveraged work² at Johns Hopkins University by Kelen and his colleagues who created benchmarks of critical interventions that should be performed on patients in this acute care setting.

Eight-seven (87) clinicians were consented to participate in the study and forty-two (42) assessments were completed in each phase (control and test). The data was analyzed

² Gabor D. Kelen et al., "Inpatient Disposition Classification for the Creation of Hospital Surge Capacity: A Multiphase Study," *The Lancet* 368, no. 9551 (2006): 1984–90, <u>http://www.sciencedirect.com/science/article/pii/S0140673606698085</u>. ; Gabor D. Kelen et al., "Creation of Surge Capacity by Early Discharge of Hospitalized Patients at Low Risk for Untoward Events," *Disaster Medicine and Public Health Preparedness* 3, no. S1 (2009): S10–S16, <u>http://journals.cambridge.org/abstract_S1935789300001981</u>. ; Kelen, Gabor D., Lauren Sauer, Eben

¹ Amy Kaji, Kristi L. Koenig, and Tareg Bey, "Surge Capacity for Healthcare Systems: A Conceptual Framework," *Academic Emergency Medicine* 13, no. 11 (November 2006): 1157–59, doi:10.1197/j.aem.2006.06.032.; Bruce M Altevogt, Institute of Medicine (U.S.), and Forum on Medical and Public Health Preparedness for Catastrophic Events, *Medical Surge Capacity Workshop Summary* (Washington, D.C.: National Academies Press, 2010), http://site.ebrary.com/id/10379896. ; Jamil D. Bayram et al., "Critical Resources for Hospital Surge Capacity: An Expert Consensus Panel," *PLoS Currents* 5 (October 7, 2013), doi:10.1371/currents.dis.67c1afe8d78ac2ab0ea52319eb119688. ; Dan Hanfling, Institute of Medicine (U.S.), and Committee on Guidance for Establishing Standards of Care for Use in Disaster Situations, *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response* (Washington, D.C.: The National Academies Press, 2012).

Clattenburg, Mithya Lewis-Newby, and James Fackler. 2015. "Pediatric Disposition Classification (Reverse Triage) System to Create Surge Capacity." Disaster Medicine and Public Health Preparedness, March, 1–8. <u>https://doi.org/10.1017/dmp.2015.27</u>

to assess the prediction, validation, assessment appropriateness utilizing a Chi-Square and Fischer's Exact Test with the statistical significance assessed for a p-value of < 0.05.

In the limited number of assessments, there was only significantly statistical difference in outcome data between the clinicians' clinical judgment and their utilization of a structured tool. This existed in the predictive ability difference in the accuracy of predicting safety of discharge (p<0.05). The control group (clinician judgment) performed nearly as well in all areas as the treatment group (structured assessment). Both groups erred on the side of patient safety and only a small percentage of patients would have been discharged inappropriately.

The tool proved to have stronger sensitivity but weaker specificity than the clinician judgment alone. The positive predictive values of the tool were also fairly strong: PV+ of 97.77% and PV- of 66.63%. This means that it accurately predicted those that were safe to discharge but it was less accurate in predicting those who were unsafe to discharge.

The additional key finding in the test group was that when the tool/prediction was inaccurate, the clinicians erred on the side of caution and recommended the patient remain admitted (over-triage) in 4 of 5 (80%) cases. This is compared to 4 of 6 (66.67%) cases in the control group. In summary, this pilot study showed that the assessment tool was a slightly better, but not statistically significant, at predicting patients who could be safely discharged (without the need for critical intervention) or those who needed to remain admitted (in need of additional care/critical interventions).

While this data is promising, the study had a number of limitations. The study was originally designed to capture a larger number and wider diversity of clinicians. The study was also limited with a relatively small number of assessments which constricts statistical analysis and broader generalizability of the results. The patient populations were less diverse than desired which also limits the analysis and strength of the study.

This project serves as a first foray into research into this area and will initiate broader discourse and additional studies. Opportunities include replicating the study with greater numbers and diversity of clinicians, assessments, patients, and perhaps sites. Another significant consideration is engaging the electronic health record (EHR) in real time to evaluate current patient status and interventions in place to allow for more rapid evaluation and objective decision-making.

Ultimately, the goal in this field is to provide clinicians with stronger guidance vetted in scientific evidence and supported in ethical, legal, and moral context to make difficult decisions in the face of catastrophic medical disaster situations. This will lead to the stronger ability of healthcare organizations to handle large "patient surges" related to these disasters. In turn, our communities will become more resilient to both man-made and natural catastrophic events.

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I. INTRODUCTION

Health care institutions in the United States are over utilized and bed capacity is often full.¹ This day-to-day overcrowding especially in emergency departments makes hospitals vulnerable in their ability to care for patients involved in mass casualty incidents or slower moving patient producing disasters such as pandemic infectious diseases. In Hurricane Katrina medical professionals were also faced with decisions to make about the allocation of scare resources. In several cases, they needed to choose between life and death for their patients.² To address this challenge, many experts have discussed the factors involved in creating surge capacity to include staffing, stuff (equipment and supplies), and space (patient rooms).³ Other experts discuss allocation of scare resources and the need for medical and ethical frameworks which would help direct care to allow the most patients to be helped based on the resources available.⁴ However, there have not been any documented cases of health care organizations who have been able to develop and validate a model to accurately and safely discharge patients who are currently receiving in hospital care so that these organizations could care for those new patients who had been affected by whatever disaster or event occurred.

¹ For a full discussion of the issue, seeInstitute of Medicine (IOM), *Hospital Based Emergency Care: At the Breaking Point* (Washington, DC: The National Academies Press, 2006).

² Bradford H. Gray and Kathy. Hebert, "Hospitals in Hurricane Katrina: Challenges Facing Custodial Institutions in a Disaster," *Journal of Health Care for the Poor and Underserved* 18, no. 2 (2007): 283–98, doi:10.1353/hpu.2007.0031. and Charles I. Lugosi, "Natural Disaster, Unnatural Deaths: The Killings on the Life Care Floors at Tenet's Memorial Medical Center after Hurricane Katrina," *J. Health & Biomedical L.* 2 (2006): 195.

³ Bruce M Altevogt, Institute of Medicine (U.S.), and Forum on Medical and Public Health Preparedness for Catastrophic Events, *Medical Surge Capacity Workshop Summary* (Washington, D.C.: National Academies Press, 2010), <u>http://site.ebrary.com/id/10379896</u>. ; Jamil D. Bayram et al., "Critical Resources for Hospital Surge Capacity: An Expert Consensus Panel," *PLoS Currents* 5 (October 7, 2013), doi:10.1371/currents.dis.67c1afe8d78ac2ab0ea52319eb119688. ; Dan Hanfling, Institute of Medicine (U.S.), and Committee on Guidance for Establishing Standards of Care for Use in Disaster Situations, *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response* (Washington, D.C.: The National Academies Press, 2012).

⁴ Chadd K. Kraus, Frederick Levy, and Gabor D. Kelen, "Lifeboat Ethics: Considerations in the Discharge of Inpatients for the Creation of Hospital Surge Capacity," *Disaster Medicine and Public Health Preparedness* 1, no. 01 (2007): 51–56. ; James G. Hodge, Dan Hanfling, and Tia P. Powell, "Practical, Ethical, and Legal Challenges Underlying Crisis Standards of Care," *The Journal of Law, Medicine & Ethics* 41, no. s1 (2013): 50–55.

This research study tests the hypothesis of "can a qualitative standardized tool be used by physicians and nurses to safely discharge patients in order to create surge capacity for disaster situations?" A standardized too developed at UCLA Health was trialed to compare the validity and safety of a reverse triage patient discharge model versus clinician judgment to accommodate for surges of mass casualty/disaster related patients. Currently, there are no models for healthcare organizations to utilize in order to create surge capacity.

II. PROBLEM STATEMENT

A. MODEL FOR REVERSE MEDICAL TRIAGE IN AUSTERE HEALTHCARE DISASTER SITUATIONS

From a man-made, natural, or terrorism based domestic disaster, healthcare plays a key role in responding to the needs of the community. The challenge is that many health care organizations operate on such a thin economic margin that there is little capacity to handle catastrophic patient surges from any of these disasters. The capacity limitations can be a function of "space, staff, or stuff" of which these components can be affected by both internal and external events.

To highlight this challenge, I offer three examples. The first is the New Orleans healthcare response to Hurricane Katrina. In this situation, the disaster did not generate significant increase in patient populations, however the physical infrastructure impact caused problems with "space." These medical centers no longer had enough safe space to care for patients that was supplied with appropriate utilities.

The second example is based on the medical response to the H1N1 Influenza Pandemic of 2009/2010. While there were not significant surges of patients, relative minor shifts in patient volumes caused stresses on the collective healthcare systems and may have caused an increase in mortality for patients that were being cared for in the medical centers even though they were not victims of the influenza.⁵ In this situation, a relative and slow moving surge may provide us a predictive sense on what may occur in more rapidly developing or more lethal events.

The third example is one, which has yet to occur. As an employee of a large health system in Los Angeles, a constant concern is that of a massive earthquake. In 2008, the United States Geological Survey (USGS), in concert with additional Southern California stakeholders, presented a research model of a large earthquake, which it referred to as the "Great Shakeout." In summary, the ShakeOut Scenario estimates this earthquake will

⁵ Theodore J. Iwashyna, Brendan Carr, and Raina Merchant, "Impact of the Fall 2009 Influenza A (H1N1) pdm09 Pandemic on US Hospitals," *Change* 2004 (2003).

cause over 1,800 deaths, 50,000 injuries, \$200 billion in damage and other losses, and severe, long-lasting disruption.⁶ If a similar earthquake hits the Southern California area, it may cause healthcare organizations internal challenges to accommodate patient care as well as a large surge of traumatized patients that will arrive from external sources.

In recognizing this challenge, the Institute of Medicine (IOM) recently developed guidance to all local, state, and federal resources for the need to more fully develop medical surge planning.⁷ This guidance however was not specific and has no specific models that have been researched and validated to achieve potential surge capacity. There has been some research modeling pandemics, rapid controlled discharge,⁸ or around hospital moves⁹ but these have not lead to more specific strategies to help organizations create policies or procedures.

In further researching this topic, a multidisciplinary team at UCLA Health developed a specific model to deal with challenges of space (bed capacity) in disaster situations. This study is the first step in validating the model for the health care community and will allow individual health care organizations to utilize it as a preliminary discussion in developing standard operating procedures (SOPs) for their jurisdictions. This will give health care organizations the opportunity to more successfully support their communities in the face of a catastrophic disaster while maintaining a high level of care for their current patients.

⁶ Keith Porter et al., "The ShakeOut Scenario: A Hypothetical Mw7.8 Earthquake on the Southern San Andreas Fault," *Earthquake Spectra* 27, no. 2 (2011): 239–61.

⁷ Medical Surge Capacity: Workshop Summary Bruce M. Altevogt, Clare Stroud, Lori Nadig, Matthew Hougan, Rapporteurs; Forum on Medical and Public Health Preparedness for Catastrophic Events; Institute of Medicine

⁸ Gabor D. Kelen et al., "Creation of Surge Capacity by Early Discharge of Hospitalized Patients at Low Risk for Untoward Events," *Disaster Medicine and Public Health Preparedness* 3, no. 2 Suppl (June 2009): S10–16, doi:10.1097/DMP.0b013e3181a5e7cd.

⁹ Howard C. Jen et al., "Creation of Inpatient Capacity during a Major Hospital Relocation: Lessons for Disaster Planning," *Archives of Surgery* 144, no. 9 (2009): 859–64.

B. STRUCTURE/SUMMARY OF METHOD(S) USED

Research Approach

Utilizing an evaluative approach I hope to answer the following questions:

How effective is a standardized tool to predict safe patient discharges to create inpatient surge capacity? Are nurses and doctors able to use this tool? Is the predictive value of the tool independent of the type of clinician?

This question would allow me to measure the effectiveness of a developed tool. Secondarily I could test inter-rater reliability between types of clinicians to determine generalizability of the tool's utility.

Is there a relationship between predictive clinical indicators and a patient's ability to be safely discharged in a mass casualty incident to create surge capacity?

This question would allow me to focus on looking at multiple variables and determining if the outcome was linked to parts or the whole assessment tool. This type of question may lead to the best causal study design to determine straight quantitative support for the specific tool or its sub-components.

III. OVERVIEW OF UPCOMING CHAPTERS

Chapter II – Literature Review

In this chapter, a thorough review of relevant research is engaged. This includes case examples of the necessity and value of research and summaries of past studies and academic exploration in five key areas:

- 1. The definition of Surge Capacity
- 2. Tenets to create surge capacity
- 3. Alternate Care Sites
- 4. Ethical considerations
- 5. Triage and Reverse Triage

Chapter III - Method - Detailed Description, Steps, Data, Evidence

In this chapter, the methodology of the research will be explained. This will include the review of the development of the assessment tool, a detailed description of methods utilized to obtain consent from providers to participate in the study, and the steps to collect and evaluate data. This will review the control portion of the study where data was collected utilizing the clinicians judgment and the test portion where they utilized the proposed assessment tool. The methodology to review patient charts for outcomes and interventions will also be explained.

Chapter IV – Analysis

In this chapter, the data from the study will be presented along with the statistical analysis. This will include demographics of providers, demographics of patients, and outcomes of the clinical judgments and assessments for both research groups. The patient outcome and intervention data as related to control and test groups will also be presented with a focus statistical significance, sensitivity/specificity, and predictive value for these groups.

 $Chapter \ V - Findings/Conclusion \ (recommendations, limits, opportunities \ for future research, implementation issues, etc.)$

In the final chapter, the focus will discuss the findings and conclusions of the research study. This includes recommendations based on the outcomes of the data analysis, limitations of the methodology and constraints of the study design, and opportunities for future research. Finally, there is a discussion on opportunities for implementation of the research findings.

IV. LITERATURE REVIEW

This review identifies relevant sources concerning the development of surge capacity for acute care hospitals to identify strategies to provide emergency care for victims of natural or manmade disasters. The review's scope has been confined largely to post-2001 literature utilizing September 11, 2001, and Hurricane Katrina as sentinel recent events, which have stimulated much of this discussion. There are numerous sources, which identify expert opinion, consensus based findings, case studies, and qualitative and quantitative studies.

The sources have been organized into the following five categories:

- 1. The definition of Surge Capacity
- 2. Keys to create surge capacity
- 3. Alternate Care Sites
- 4. Ethical considerations
- 5. Triage and Reverse Triage

These sources address both national and international expertise calling for the ability of health care organizations to be able to expand their patient care capacity above their day-to-day operations in order to take care of emergent sick and injured patients. This review intends to highlight this important body of work and show the need for continued research in this area.

A. THE DEFINITION OF SURGE CAPACITY

Surge Capacity can be defined as the development of additional abilities of healthcare organizations to care for patients above and beyond their normal activities. This is a huge concern in United States (US) medical centers as emergency rooms are often running at or above licensed capacity, so even small mass casualty incidents (MCI) can overwhelm the organizations ability to provide their normal standard of care. As Cherry and Trainer state "hospital emergency departments show a characteristic crisis of overcrowding, boarding, diversions, ambulance bypasses up to 50% of the time, medical care delivered in hallways, makeshift examination rooms, and increased risk of medical error."¹⁰

MCIs and disasters can create significant capacity surges based on community based patient generators (mass casualty events, pandemics, etc.) or the need for other health care organizations to decrease operations and transfer patients to alternate hospitals due to infrastructure collapse of concern (flood, fire, power outage).

Hick et al¹¹ go further and identifies three types of surge capacity issues:

1. Conventional capacity: Traditional and normal patient-care facilities and staff meet their normal goals in providing care. Status quo.

2. Contingency capacity: Minor adaptations are made that may have minor consequences for standards of care, but adaptations are not enough to result in significant changes to standards of care.

3. Crisis capacity: A fundamental, systematic change into a system in which standards of care are significantly altered.

This construct creates a normative flow or transition from day to day census challenges and throughput challenges to minor emergencies to catastrophic events.

Independent of the cause of the patient surge, health systems are met with challenges to maintain a standard of care and ensure equity of care for all those in need. The opportunity to fully understand different types of surges and practice processes to manage these impacts on a day to day basis will allow organizations to ensure that they are creating sound standards for the low frequency, high acuity catastrophic events. This would also allow for organizations to address patient throughput challenges in the current environment of tight fiscal margins and limited resources.

¹⁰ Cherry and Trainer, "The Current Crisis in Emergency Care and the Impact on Disaster Preparedness."

¹¹ John L. Hick, Joseph A. Barbera, and Gabor D. Kelen, "Refining Surge Capacity: Conventional, Contingency, and Crisis Capacity," *Disaster Medicine and Public Health Preparedness* 3, no. S1 (2009): S59–S67, http://journals.cambridge.org/abstract_S1935789300002056.

B. KEYS TO CREATE SURGE CAPACITY

- Multiple sources describe the need for disaster related surge capacity. In turn, these sources identify several major components of surge capacity development or the 4S model. These are typically identified as "system, staffing, stuff and space"12 Each of these keys have their own unique challenges and dependencies.
- 2. "System" refers to the response and management infrastructure. This includes the organizations pre-planning, exercising, and training. It also includes the development of the response infrastructure such as organizing command, control, and communications in emergencies around the concept of the Incident Command System (ICS).
- 3. "Staffing" refers to the ability to provide healthcare professionals and support personnel in order to care for not only current patients, but also those generated by the crisis. This key component is often addressed through the utilization of recalled staff and the use of credentialed volunteers in the case of an emergency. Challenges exist when the disaster impacts the ability of the workforce to access the healthcare organization and in credentialing volunteer providers who are unfamiliar with the physical, logistical, and operational procedures of the organization.
- 4. "Stuff" refers to the medical and diagnostic equipment, supplies, and pharmaceuticals needed by these diverse medical professionals and support personnel in order to care for their patients. This component is

¹² Amy Kaji, Kristi L. Koenig, and Tareg Bey, "Surge Capacity for Healthcare Systems: A Conceptual Framework," *Academic Emergency Medicine* 13, no. 11 (November 2006): 1157–59, doi:10.1197/j.aem.2006.06.032.; Bruce M Altevogt, Institute of Medicine (U.S.), and Forum on Medical and Public Health Preparedness for Catastrophic Events, *Medical Surge Capacity Workshop Summary* (Washington, D.C.: National Academies Press, 2010), <u>http://site.ebrary.com/id/10379896</u>.; Jamil D. Bayram et al., "Critical Resources for Hospital Surge Capacity: An Expert Consensus Panel," *PLoS Currents* 5 (October 7, 2013), doi:10.1371/currents.dis.67c1afe8d78ac2ab0ea52319eb119688.; Dan Hanfling, Institute of Medicine (U.S.), and Committee on Guidance for Establishing Standards of Care for Use in Disaster Situations, *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response* (Washington, D.C.: The National Academies Press, 2012).

often addressed with stockpiling or cache development of these items or requests from other institutions. Challenges exist when the supply chain is impacted by the disaster or organizations are unable to sustain the cost or space requirements in building and maintaining these caches.

5. "Space" refers to the physical environment and infrastructure necessary to support patient care. More specifically, this is the patient care rooms and interventional areas that are supported by utilities such as power, heating/ventilation/air conditioning (HVAC), medical gases/vacuum, steam, and water. Because of the utility requirements, these spaces are very difficult to maintain or develop in the face of many types of disasters. These requirements are often addressed with the pre-identification and development of alternate care sites/spaces and triage strategies to only allow critical victims of the disaster entre into the hospital. As previously stated, the challenge arises when current hospital census is at or near capacity (or often exceeds capacity) and the number of victims created in the disaster exceeds the ability to create space with alternate care sites or initial triage.

Hick et al¹³ propose a slightly different model, the <u>CO-S-TR model</u>. "CO" engages the concepts of command, control, communications, and coordination. "S" engages the logistical requirements for staff, stuff, space, and special (event-specific) considerations. "TR" reminds leadership to consider tracking, triage, treatment, and transportation: basic patient care and patient movement functions. This model is a slightly different take on the 4S model, but on the whole is fairly similar to it.

The identification of these key areas of planning allows healthcare organizations to plan and prepare for catastrophic surge events. In tightening fiscal environments, redundant resources become increasingly difficult to maintain. Other planning options become more

¹³ John L. Hick et al., "Surge Capacity Concepts for Health Care Facilities: The CO-S-TR Model for Initial Incident Assessment," *Disaster Medicine and Public Health Preparedness* 2, no. S1 (2008): S51–S57, http://journals.cambridge.org/abstract_S193578930000135X.

viable and interesting since simply having extra capacity is not feasible when considering fiscal responsibility and daily efficiency.

C. ALTERNATE CARE SITES

In one mechanism to address the challenges of space, many experts have suggested the concept of alternate care sites.¹⁴ This concept is based on the premise of utilizing non-traditional spaces to care for the sick or injured. This may include parking lots, auditoriums, conference rooms, or hallways. The challenge that this creates is the outfitting of these spaces to care for whatever patient population is placed in the space. As non-traditional spaces, they do not have the utility infrastructure, supplies, equipment or personnel to handle these patients. Therefore, everything must be brought into these spaces and outfitted appropriately.

The practice of using alternate care sites brings up the concern of standard of care.^{15/1617} Will these patients receive the same quality of care that they would in a traditional space? With the tightening fiscal and regulatory environment, there is often not the ability to pre-develop these spaces with the entire infrastructure to adequately support patient care. Therefore, this opportunity is often seen to be less desirable.

¹⁴ Hick, J. L., Christian, M. D., & Sprung, C. L. (2010). Chapter 2. Surge capacity and infrastructure considerations for mass critical care. Intensive Care Medicine, 36(S1), 11–20. https://doi.org/10.1007/s00134-010-1761-4

¹⁵ Hougan, Matthew, Lori Nadig, Bruce M. Altevogt, Clare Stroud, and others. 2010. Crisis Standards of Care:: Summary of a Workshop Series. National Academies Press.

http://books.google.com/books?hl=en&lr=&id=iThkAgAAQBAJ&oi=fnd&pg=PR1&dq=%22(Contract+N o.+HSHQDC-07-C-

 $^{00097),} the + Department + of + Veteran\%22 + \%22 copies + of + this + report + are + available + from + The + National + Academies + Press, \%22 + \%22\%C2\%A9 + National + Academy + of + Sciences. + All + rights\%22 + & ots = Zrh8Uc vItz&sig = 5p2F5U2_DVIJhZITf4psCez5WbA$

¹⁶ Phillips, SJ, Ann R. Knebel, and K Johnson, eds. 2009. "Mass Medical Care with Scarce Resources: The Essentials." Agency for Healthcare Research and Quality.

¹⁷ Hanfling, Dan, Institute of Medicine (U.S.), and Committee on Guidance for Establishing Standards of Care for Use in Disaster Situations. 2012. Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response. Washington, D.C.: The National Academies Press.

D. ETHICAL CONSIDERATIONS

Related to the previous description on standard of care, ethical considerations play a chief role in determining the need and acceptance of alterations in care. The ethical considerations are also precursors to legal standards and local, regional, and national policy decisions. The literature supports a necessary dialogue concerning this important process.

Wizeman et al¹⁸ developed consensus with a group of healthcare experts and published that the following are key ethical factors in catastrophic care decisions:

- Fairness
- Duty to care
- Duty to steward resources
- Transparency
- Consistency
- Proportionality
- Accountability

¹⁸ Theresa Wizemann, Bruce M. Altevogt, and Anne B. Claiborne, "Barriers to Integrating Crisis Standards of Care Principles into International Disaster Response Plans: Workshop Summary," 2012.

Further discussion specific to disaster ethics both in mass casualty events and slow moving events such as pandemics have been thoroughly discussed¹⁹

The ethical concerns were extremely evident in the healthcare response to Hurricane Katrina²⁰ and Super Storm Sandy.²¹ Physicians and nurses needed to decide which patients would receive care or evacuation and which would not. During these events there was considerable anxiety and distress on the part of these providers to make these difficult decisions. After the event, there was even more legal, ethical and moral reaction to these decisions.

These considerations and examples make the scientific support of an evidencebased study even more important. Once there is scientific support, there can be legal, ethical and community vetting of any tools to support clinical decision making in these situations. The availability of this type of decision-making tool would allow for the best

¹⁹ Matthew D. Sztajnkrycer, Bo E. Madsen, and Amado Alejandro Báez, "Unstable Ethical Plateaus and Disaster Triage," *Emergency Medicine Clinics of North America* 24, no. 3 (2006): 749–68.; Daniel J. Barnett et al., "Resource Allocation on the Frontlines of Public Health Preparedness and Response: Report of a Summit on Legal and Ethical Issues," *Public Health Reports* 124, no. 2 (2009): 295, <u>http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2646457/</u>.; James G. Hodge, Dan Hanfling, and Tia P. Powell, "Practical, Ethical, and Legal Challenges Underlying Crisis Standards of Care," *The Journal of Law, Medicine & Ethics* 41, no. s1 (2013): 50–55,

Charles I. Lugosi, "Natural Disaster, Unnatural Deaths: The Killings on the Life Care Floors at Tenet's Memorial Medical Center after Hurricane Katrina," *J. Health & Biomedical L.* 2 (2006): 195, http://heinonlinebackup.com/hol-cgi-bin/get_pdf.cgi?handle=hein.journals/jhbio2§ion=17.

http://onlinelibrary.wiley.com/doi/10.1111/jlme.12039/abstract.; Douglas B. White et al., "Who Should Receive Life Support during a Public Health Emergency? Using Ethical Principles to Improve Allocation Decisions," *Annals of Internal Medicine* 150, no. 2 (2009): 132–38,

http://annals.org/article.aspx?articleid=744219.; Chadd K. Kraus, Frederick Levy, and Gabor D. Kelen, "Lifeboat Ethics: Considerations in the Discharge of Inpatients for the Creation of Hospital Surge Capacity," *Disaster Medicine and Public Health Preparedness* 1, no. 01 (2007): 51–56,

http://journals.cambridge.org/abstract_S1935789300000239 .; C Ozge Karadag and A Kerim Hakan, "Ethical Dilemmas in Disaster Medicine," *Iranian Red Crescent Medical Journal* 14, no. 10 (October 2012): 602–12, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3518976/.

²⁰ Bradford H. Gray and Kathy. Hebert, "Hospitals in Hurricane Katrina: Challenges Facing Custodial Institutions in a Disaster," *Journal of Health Care for the Poor and Underserved* 18, no. 2 (2007): 283–98, doi:10.1353/hpu.2007.0031.

²¹ Amesh A. Adalja et al., "Absorbing Citywide Patient Surge During Hurricane Sandy: A Case Study in Accommodating Multiple Hospital Evacuations," *Annals of Emergency Medicine*, January 2014, doi:10.1016/j.annemergmed.2013.12.010.

Tia Powell, Dan Hanfling, and Lawrence O. Gostin, "Emergency Preparedness and Public Health: The Lessons of Hurricane Sandy," *JAMA* 308, no. 24 (2012): 2569–70, http://archpedi.jamanetwork.com/article.aspx?articleid=1392488.

care for the most and reduce the anxiety of these decisions for the healthcare providers in an already stressful time.

E. TRIAGE AND REVERSE TRIAGE

The concept of triage is derived from the French word meaning "to sort." Triage has been used for many centuries especially in caring for battlefield wounded and mass casualty incidents in order to provide the best care for the most people with the available resources. This sorting is typically utilized in the initial provision of care, which is often referred to as traditional triage. In less traditional fashions, it is also used to identify those who are currently receiving care but are stable enough to no longer receive care, which is referred to as reverse triage.

Traditional triage is meant to identify those patients who need immediate care versus those who can receive care at some time in the future, those who do not need any care or minimal care, or those who based on the current resources will not receive any care as they are dead or close to death.²² There are a number of well-established methods to facilitate this type of triage including START, JumpSTART, CareFlight, and Sacco Triage Method (STM).²³ Significant research has been completed to assess these methodologies in various settings and populations.²⁴

²² Michael D. Christian, J. Christopher Farmer, and Brian P. Young, "Disaster Triage and Allocation of Scarce Resources," *Fundamentals of Disaster Management, Eds. Geiling, J., Burns, S., and Rubinson, L. (Society of Critical Care Medicine, Mount Prospect, IL, 2009)*, 2002, http://www.ceep.ca/resources/Disaster-Triage-Allocation-Resources.pdf.

²³ Keith P. Cross and Mark X. Cicero, "Head-to-Head Comparison of Disaster Triage Methods in Pediatric, Adult, and Geriatric Patients," *Annals of Emergency Medicine* 61, no. 6 (June 2013): 668–676.e7, doi:10.1016/j.annemergmed.2012.12.023.

²⁴ E R Frykberg and J J Tepas, "Terrorist Bombings. Lessons Learned from Belfast to Beirut.," *Annals of Surgery* 208, no. 5 (November 1988): 569–76, <u>http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1493790/</u>.

Christopher A. Kahn et al., "Does START Triage Work? An Outcomes Assessment After a Disaster," *Annals of Emergency Medicine* 54, no. 3 (September 2009): 424–430.e1, doi:10.1016/j.annemergmed.2008.12.035.

D. Michael Navin, William J. Sacco, and Thomas B. McCord, "Does START Triage Work? The Answer Is Clear!," *Annals of Emergency Medicine* 55, no. 6 (June 2010): 579–80, doi:10.1016/j.annemergmed.2009.11.031.

Carl H. Schultz, "Comparing Disaster Triage Algorithms: Selecting the Right Metric," *Annals of Emergency Medicine* 62, no. 6 (December 2013): 642–43, doi:10.1016/j.annemergmed.2013.05.034.
Reverse triage is less well established. There has been some work done in the area of pandemic situations with the development of systems such as the Ontario Protocol²⁵ and the use of Sequential Organ Failure Assessment (SOFA)²⁶ scores however the evidence and utility are very limited. These specific tools are very data and labor intense and intended for only the sickest patients.

Several publications have described the ability of reverse triage practices to create surge capacity. Satterthwaite and Atkinson²⁷ studied the utilization of clinicians' best judgment to create capacity during the Ashmore Reef Disaster. Warriner et al²⁸ describes the concept of using some reverse triage process to aid in day-to-day throughput challenges in admitting emergency department patients but is unable to describe a tool to implement change. Jen et al²⁹ also describe the reverse triage process in reducing inpatient census in preparation for a hospital move. However, the process of reverse triage is often confined to professional judgment by clinical teams who frequently review patient status in emergency rounding processes.

In a series of landmark studies, Kelen et al. developed the beginnings of a scientifically sound reverse triage tool. The researchers started with establishing professional consensus on twenty-one critical interventions³⁰ that patients may receive in the inpatient setting. These researchers then utilized these interventions and created

²⁵ M. D. Christian et al., "Development of a Triage Protocol for Critical Care during an Influenza Pandemic," *Canadian Medical Association Journal* 175, no. 11 (November 21, 2006): 1377–81, doi:10.1503/cmaj.060911.

²⁶ Michael D. Christian et al., "Introduction and Executive Summary: Care of the Critically III and Injured during Pandemics and Disasters: CHEST Consensus Statement," *CHEST Journal*, 2014, http://journal.publications.chestnet.org/article.aspx?articleid=1899971.

²⁷ P. S. Satterthwaite and C. J. Atkinson, "Using 'Reverse Triage' to Create Hospital Surge Capacity: Royal Darwin Hospital's Response to the Ashmore Reef Disaster," *Emergency Medicine Journal* 29, no. 2 (February 1, 2012): 160–62, doi:10.1136/emj.2010.098087.

²⁸ Ik Warriner et al., "Reverse Triage: Useful for Day-to-Day Access Block?," *The Lancet* 368, no. 9551 (December 2006): 1965–72, doi:10.1016/S0140-6736(06)69742-0.

²⁹ Howard C. Jen et al., "Creation of Inpatient Capacity during a Major Hospital Relocation: Lessons for Disaster Planning," *Archives of Surgery* 144, no. 9 (2009): 859–64, http://archpedi.jamanetwork.com/article.aspx?articleid=405265.

³⁰ Gabor D. Kelen et al., "Inpatient Disposition Classification for the Creation of Hospital Surge Capacity: A Multiphase Study," *The Lancet* 368, no. 9551 (2006): 1984–90, http://www.sciencedirect.com/science/article/pii/S0140673606698085.

retrospective case reviews³¹ for medical/surgical patients over a ninety-six hour (four day) benchmark and found that 50% to 60% of these patients could have been safely discharged with no critical interventions. Discharging the patients would have created a significant surge capacity. The limit of this study was that there was no predictive tool utilized to determine which of these patients would be safe to discharge.

While there has been significant work done in developing initial triage practices and policies, the area of reverse triage still remains largely unresearched. The availability of "space" which exists with normal infrastructure support, staffing, and equipment/supplies is the ideal area to maintain the standard of care. This has provided significant impetus to the author to further investigate this area.

F. CONCLUSION

As identified in this literature review, there is a significant amount of research identifying the challenges of disaster healthcare response. Surge capacity remains a difficult concept to prepare for and overcome. Physical space within the organization's normal environment is often the most ideal solution to maintain the highest standard of care. However, with chronic overcrowding in emergency departments and inpatient environments, this solution is not possible without some means to discharge existing patients. This thesis examines the opportunity to create capacity with the validation of reverse triage methodologies.

³¹ Gabor D. Kelen et al., "Creation of Surge Capacity by Early Discharge of Hospitalized Patients at Low Risk for Untoward Events," *Disaster Medicine and Public Health Preparedness* 3, no. S1 (2009): S10–S16, http://journals.cambridge.org/abstract_S1935789300001981.

V. METHOD – DETAILED DESCRIPTION, STEPS, DATA, EVIDENCE, STATISTICAL ANALYSIS

The objective of the research project is to validate a patient assessment tool to assist clinicians with reverse triage. This tool would only be applied in the event of a disaster to create surge capacity through the early discharge of existing patients. Surge capacity creation is a key component of medical care in the case of a disaster or terrorist attack. Currently there are no predictive patient assessment models which exist to aid clinicians in making these decisions for early discharge.

In 2012–13, a small subcommittee of the UCLA Health Emergency Management, Management of Patients Committee, attempted to look at the problem of reverse triage. This multidisciplinary group including physicians: Arthur Ohannessian (Family Medicine), Benjamin Bengs (Orthopedic Surgery), Daniel Uslan (Infectious Disease), David Boldt (Anesthesology/Critical Care), Doron Blumfeld (Obstetrics/Gynecology), Hong-Phuc Tran (Geriatrics), Ian Smith (Critical Care/Medicine), Philip Levin (Anesthesiology / Hospital Administration), Sharon Kaminker (Pediatrics), Spencer Adams (Hospitalist/Medicine), Steve Rottman (Emergency Medicine/Public Health), and Wally Ghurabi (Emergency Medicine) and non-physicians: James Hynds (Ethics), Kathleen Hunt (Nursing Leadership). Marcia Colone (Care Coordination/Social Work/Case Management), Timothy Thorstenson (Spiritual Care), and Sabrina Adelaine, Soraya Sutherlin, Kurt Kainsinger, and William Dunne (Emergency Preparedness) met to draft a tool for use at UCLA. This tool was built based on the expert opinion of this group via consensus and the use of a nominal group technique. This tool can be found in Appendix A and is the basis of this study. This study is an attempt to scientifically validate the tool to determine whether or not it accurately predicts safe discharge or downgrade (movement of the patient to a lower level of care) of current patients. The reverse triage process is only designed to be used in the face of a catastrophic disaster in the effort to create surge capacity for additional patients.

In phase one of the study, physicians and nurses at UCLA Health System (a large academic health system consisting of four hospitals) were asked to assess their current patients and using their clinical expertise (with little direction and without the use of the tool), complete a basic assessment to provide their opinion about whether or not the patient would be safe to move to a lower level of care in a disaster situation. After the assessment and with no change to patient's standard of care, the patient's chart was then reviewed after 96 hours. The chart was assessed to determine if the patient had been discharged or if they required any critical interventions (as defined by criteria in Appendix B and B1) during that time. This phase would serve as a control.

In phase two, clinicians were asked to conduct a similar assessment utilizing the same scenario and request, however, they would utilize and complete the patient assessment tool (Appendix A) as well as their clinical expertise to derive their decision. After the assessment and with no change to patient's standard of care, the patient's chart was then reviewed after 96 hours utilizing the same aforementioned criteria. This occurred two weeks later and included a mostly new cohort of patients.

The hypothesis was that the clinicians utilizing the assessment tool would be more accurate in predicting patients who would not need any critical interventions after the assessment and therefore would be safe candidates for early discharge. Patient care or course was not impacted by this hypothetical scenario or the clinical assessment for the study.

The methodology of this research existed in several phases: Institutional Review Board Review (IRB), provider recruitment and consent, phase one assessments, phase two assessments, and patient chart review. IRB review was submitted to the Naval Postgraduate School (NPS) in collaboration with the University of California at Los Angeles (UCLA). Review was compete and authorized on April 13, 2016 with approval # NPS.2016.0024-EP5&7-A (with an expiration date of September 30, 2016 with an extension provided until September 30, 2017).

Provider consent and recruitment occurred via direct meetings with nurses and physicians at various group and individual venues. Mass emails were also sent to introduce potential clinicians to the study and gather interest. All participants completed an approved consent form and ultimately 87 participants enrolled in the study. Ultimately, 100% of the

participants were registered nurses. As part of the initial clinician consent, basic demographic information was collected as identified in Appendix D.

Clinicians were asked to complete the patient assessment and document their assessment to determine if the patient is safe for discharge. The patient's chart was then accessed after 96 hours to determine what care was needed during that time. The assessment was compared with the need for interventions for each patient. The clinicians were assessed for success. All data was maintained at the academic health system. All patient and employee data was de-identified at the point of database input. All employees accessing the patient information did this as part of the course of their normal patient care activities. All employees are trained annually in HIPPA and patient privacy and sign a non-disclosure agreement at the time of hire. All patients are informed of the potential that their medical record may be accessed for academic purposes as part of their conditions of admission.

The standard scenario was as follows:

"Today, X medical center census is at 103%, Y medical center at 95%, and Z medical center at 99%. An earthquake of 6.0 magnitude hits your large urban area. Patients will be presenting at your large academic health system's medical centers for medical treatment and the health system must create surge capacity to accommodate the influx of patients. The goal is to create 25% of our normal inpatient capacity to accommodate this surge."

Phase one assessments occurred over a two-week period. Study participants utilized the standard scenario and then were asked to provide an assessment of whether or not individual patients could be discharged or downgraded to a lower standard of care. This assessment was to be strictly based on their professional judgment. In phase one, clinicians were asked "In a disaster, could this patient be discharged from their current acute care bed? Yes No ."

Phase two assessments occurred over the next two-week period. Study participants utilized the standard scenario and then were asked to provide an assessment of whether or not individual patients could be discharged or downgraded to a lower standard of care. This assessment utilized the ten-step assessment tool developed at UCLA Health. If the provider identified that the patient was stable in all ten clinical areas, they would then determine that the patient could be discharged or downgraded. Then, clinicians were asked "In a disaster, could this patient be discharged from their current acute care bed? Yes _____ No _____." In phase two, clinicians utilized the assessment tool located in Appendix A.

After assessments in each phase, patient care was maintained and there was no deviation in patient care by the clinical team. The patient chart was then reviewed twenty-four (24) and ninety-six (96) hours post assessment. The chart was assessed to determine if the patient needed any significant interventions as defined utilizing vetted criteria from Gabor and team's work in 2006 and 2015 studies (*Kelen, Gabor D., Chadd K. Kraus, Melissa L. McCarthy, Eric Bass, Edbert B. Hsu, Guohua Li, James J. Scheulen, Judy B. Shahan, Justin D. Brill, and Gary B. Green. "Inpatient Disposition Classification for the Creation of Hospital Surge Capacity: A Multiphase Study." The Lancet 368, no. 9551 (2006): 1984–90. And Kelen, Gabor D., Lauren Sauer, Eben Clattenburg, Mithya Lewis-Newby, and James Fackler. 2015. "Pediatric Disposition Classification (Reverse Triage) System to Create Surge Capacity." Disaster Medicine and Public Health Preparedness, March, 1–8. <u>https://doi.org/10.1017/dmp.2015.27</u>.). These critical interventions are identified in Appendix B (adults) and B1 (pediatrics).*

Using SPSS software package, the two tests for identifying patients safe for discharge were analyzed to determine if significant differences in performance could be detected. As a first pass, NCSS software was used to determine if the two tests could be determined to be statistically equivalent. If this was found not to be the case (the hoped for outcome), then additional analyses were conducted to assess the prediction, validation, assessment appropriateness utilizing a Chi-Square and Fischer's Exact Test with the statistical significance assessed for a p-value of < 0.05.

A. ANALYSIS

Eighty-seven nurse providers ultimately enrolled in the study. The breakdown is as follows in Table 1.

Total Provider Study Enrollment

Total Participants		
87		
		-
	C	

Table 1.

	Sex	
Male	12	13.79%
Female	75	86.21%
	87	

	Years	of	
	Experienc	e	
<1 year	4		4.60%
1-3 years	24		27.59%
4-5 years	8		9.20%
6-10 years	26		29.89%
11-25 years	19		21.84%
>25 years	6		6.90%
	87		

	Primary	
	Service	
Medicine	46	52.87%
Oncology	1	1.15%
Surgical	18	20.69%
Obstetrics/Gynecology	1	1.15%
Pediatrics	21	24.14%
	87	

1. Phase One – Professional Judgment

Forty-two assessments were conducted on 34 unique patients as part of phase one; see Table 2 for demographics.

Sex		
Male	17	50.00%
Female	17	50.00%
Total	34	

Table 2.Patient Demographics – Phase One

Ethnicity		
Asian	3	8.82%
Black	3	8.82%
Hispanic	5	14.71%
Other	3	8.82%
White	20	58.82%
Total	34	

Age Range		
<18	7	20.59%
18-34	2	5.88%
35-44	2	5.88%
45-54	3	8.82%
55-64	11	32.35%
65-74	3	8.82%
>75	6	17.65%
Total	34	

Admission Source		
Elective or Direct		
Admission	10	29.41%
Emergency Department	24	70.59%
Total	34	

Service		
Medical	19	55.88%
Pediatrics	8	23.53%
Surgical	6	17.65%
Oncology	1	2.94%
Obstetric/Gynecology	0	0.00%
Psychiatry	0	0.00%
Total	34	

a. Phase One Findings

	Number of patients	Percentage of patients
Identified by clinicians to be able to be discharged in the theoretical disaster scenario	23	54.76%
Identified by clinicians to be unable to be discharged in the theoretical disaster scenario	19	45.23%
Total Patients	42	

	True Status as determined 96 hours post assessment		
Clinical Judgement	No critical events 1 or more critical even		
Safe to discharge	21	2	
Unsafe to discharge	4	15	

Given these results, the following were calculated using <u>https://www.medcalc.org</u>

<u>/calc/diagnostic_test.php</u>. For the accuracy of prediction, see Table 4.

Sensitivity:

Sensitivity= true positives/(true positive + false negative) Clinical Judgment (Control) - 21/(21+4) = 84.00%Specificity: Specificity=true negatives/(true negative + false positives) Clinical Judgment (Control) - 15/(15+4) = 88.24%Predictive value for a positive result (PV+): PV+= true positive/(true positive + false positive) Clinical Judgment (Control) - 21/(21+2) = 91.30%Predictive value for a negative result (PV-): PV-= true negatives/(true negatives + false negatives) Clinical Judgment (Control) - 15/(15+4) = 78.95%

	Number	
	of	
	Patients	
Assessments were appropriate predictors of safe	36	85.71%
discharges or the need for continued admission		
Assessments were inaccurate	6*	14.28%
Total Assessments	42	

Table 4.Phase One – Accuracy of Prediction

*With 4 of 6 erring on the side of caution and recommending the patient remain admitted (over triage).

2. Phase Two – Clinical Assessment Tool

Forty-two assessments were conducted on 35 unique patients as part of phase two. See Table 5 for demographics.

Sex		
Male	20	57.14%
Female	15	42.86%
Total	35	

Table 5.Phase Two – Patient Demographics

Ethnicity		
Asian	2	5.71%
Black	1	2.86%
Hispanic	7	20.00%
Other	2	5.71%
White	23	65.71%
Total	35	

Age Range		
<18	8	22.86%
18-34	3	8.57%
35-44	5	14.29%
45-54	2	5.71%
55-64	8	22.86%
65-74	4	11.43%
>75	5	14.29%
Total	35	

(continued on next page)

Admission Source		
Elective or Direct		
Admission	7	20.00%
Emergency Department	28	80.00%
Total	35	

Table 5 (continued from previous page)

Service		
Medical	21	60.00%
Pediatrics	8	22.86%
Surgical	6	17.14%
Oncology	0	0.00%
Obstetric/Gynecology	0	0.00%
Psychiatry	0	0.00%
Total	35	

a. Phase Two Findings

Table 6.	Phase Two – Findings	
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	of	Percentage of patients
	patients	
Identified by clinicians to be able to be discharged	31	73.81%
in the theoretical disaster scenario		
Identified by clinicians to be unable to be	11	26.19%
discharged in the theoretical disaster scenario		
Total Patients	42	

	True Status as determined 96 hours post assessment		
Clinician Judgment Using	No critical events 1 or more critical events		
the Assessment Tool			
Safe to discharge	30	1	
Unsafe to discharge	4	7	

Given these results, the following were calculated using https://www.medcalc.org

/calc/diagnostic_test.php.

Sensitivity:

Sensitivity= true positives/(true positive + false negative) Using Tool - 30/(30+4) = 88.24%Specificity: Specificity=true negatives/(true negative + false positives) Using Tool - 7/(7+1) = 87.50%Predictive value for a positive result (PV+): PV+= true positive/(true positive + false positive) Using Tool - 30/(30+1) = 96.77%Predictive value for a negative result (PV-): PV-= true negatives/(true negatives + false negatives) Using Tool - 7/(7+4) = 63.64%

See Table 7 for the accuracy of prediction. For a side-by-side comparison of the two phases, see Tables 8 and 9.

	Number of Patients	
Assessments were appropriate predictors of safe	37	88.10%
discharges or the need for continued admission		
Assessments were inaccurate	5*	11.90%
Total Assessments	42	

Table 7.Phase Two – Accuracy of Prediction

*With 4 of 5 erring on the side of caution and recommending the patient remain admitted (over triage).

3. Side-by-Side Comparison

	Phase		Phase	
Sex	1		2	
Male	17	50.00%	20	57.14%
Female	17	50.00%	15	42.86%
Total	34		35	

Table 8.Side by Side – Patient Demographics

	Phase		Phase	
Ethnicity	1		2	
Asian	3	8.82%	2	5.71%
Black	3	8.82%	1	2.86%
Hispanic	5	14.71%	7	20.00%
Other	3	8.82%	2	5.71%
White	20	58.82%	23	65.71%
Total	34		35	

	Phase		Phase	
Age Range	1		2	
<18	7	20.59%	8	22.86%
18-34	2	5.88%	3	8.57%
35-44	2	5.88%	5	14.29%
45-54	3	8.82%	2	5.71%
55-64	11	32.35%	8	22.86%
65-74	3	8.82%	4	11.43%
>75	6	17.65%	5	14.29%
Total	34		35	

	Phase		Phase	
Admission Source	1		2	
Elective or Direct				
Admission	10	29.41%	7	20.00%
Emergency Department	24	70.59%	28	80.00%
Total	34		35	

(continued on next page)

	Phase		Phase	
Service	1		2	
Medical	19	55.88%	21	60.00%
Pediatrics	8	23.53%	8	22.86%
Surgical	6	17.65%	6	17.14%
Oncology	1	2.94%	0	0.00%
Obstetric/Gynecology	0	0.00%	0	0.00%
Psychiatry	0	0.00%	0	0.00%
Total	34		35	

Table 8 (continued from previous page)

Table 9.	Side by Side – Sensitivity/Specificity/Predictive
	Values

Assessment Methodologies

	Phase 1	Phase 2
Sensitivity	84.00%	88.24%
Specificity	88.24%	87.50%
PV+	91.30%	96.77%
PV-	78.95%	63.64%

B. DATA ANALYSIS

Using the NCSS "Comparison of two diagnostic tests – Independent Samples" routine, the results of which are presented in Appendix E, statistical equivalence between the test could not be established. Looking at the comparison data, it seems like the Test using the Tool could be providing an improvement. In order to explore this, a Chi-Square and Fischer's Exact Test with the statistical significance assessed for a p-value of < 0.05 were run on the prediction, validation, and assessment appropriateness. Prediction is defined as comparing the number of patients that were recommended to be discharged or remained admitted in both control and test groups. Validation is defined as comparing the control and test groups (recommendation to discharge with no critical interventions over the following 96 hours). Assessment appropriateness is defined as comparing the control and test groups based on the number of accurate assessments leading to discharges or retained admissions with zero critical interventions or more than one critical intervention.

1. Chi-Square Test

	Control (Phase 1)	Test (Phase 2)
Able to discharge	23 (27) [0.59]	31 (27) [0.59]
Unable to discharge	19 (15) [1.07]	11 (15) [1.07]

a. **Prediction**

The chi-square statistic is 3.3185. The *p*-value is .068504. Comparing the number of patients that were recommend to be discharged or remained admitted in both control and test groups is <u>not significant</u> at p < .05.

b. Validation

	Control (Phase 1)	Test (Phase 2)
Safe to Discharge with 0 interventions	21 (25.15) [0.68]	30 (25.85) [0.67]
Unsafe to Discharge with 1 or more interventions	15 (10.85) [1.59]	7 (11.15) [1.55]

The chi-square statistic is 4.4845. The *p*-value is .034204. Comparing the ability of the control and test groups in predicting safe discharge (recommendation to discharge with no critical interventions over the following 96 hours) is <u>significant</u> at p < .05.

c. Assessment appropriateness

	Control (Phase 1)	Test (Phase 2)
Assessment - Appropriate	36 (36.50) [0.01]	37 (36.50) [0.01]
Assessment inappropriate	6 (5.50) [0.05]	5 (5.50) [0.05]

The chi-square statistic is 0.1046. The *p*-value is .746369. Comparing the control and test groups related to assessment appropriateness (number of accurate assessments leading to discharges or retained admissions with zero critical interventions or more than one critical intervention) is <u>not significant</u> at p < .05.

2. Fischer's Exact test

a. **Prediction**

	Control (Phase 1)	Test (Phase 2)
Able to discharge	23	31
Unable to discharge	19	11

The p-value is .11. Comparing the number of patients that were recommend to be discharged or remained admitted in both control and test groups is <u>not significant</u> at p < .05.

b. Validation

	Control (Phase 1)	Test (Phase 2)
Safe to discharge with 0 interventions	21	30
Unsafe to discharge with more than 1 intervention	15	7

The *p*-value is .043. Comparing the ability of the control and test groups in predicting safe discharge (recommendation to discharge with no critical interventions over the following 96 hours) is <u>significant</u> at p < .05.

	Control (Phase 1)	Test (Phase 2)
Assessments were appropriate	36	37
Assessments were inappropriate	6	5

c. Assessment Appropriateness

The p-value is 1.0. Comparing the control and test groups related to assessment appropriateness (number of accurate assessments leading to discharges or retained admissions with zero critical interventions or more than one critical intervention is <u>not</u> significant at p < .05.

VI. FINDINGS

In the limited number of assessments, there was only significantly statistical difference in outcome data between the clinicians' clinical judgment and their utilization of a structured tool. This existed in the predictive ability difference in the accuracy of predicting safety of discharge (p<0.05). The control group (clinician judgment) performed nearly as well in all areas as the treatment group (structured assessment). Both groups erred on the side of patient safety and only a small percentage of patients would have been discharged inappropriately.

The tool proved to have stronger sensitivity but weaker specificity than the clinician judgment alone. The positive predictive values of the tool were also fairly strong: PV+ of 97.77% and PV- of 66.63%. This means that it accurately predicted those that were safe to discharge but it was less accurate in predicting those who were unsafe to discharge.

The additional key finding in the test group was that when the tool/prediction was inaccurate, the clinicians erred on the side of caution and recommended the patient remain admitted (over-triage) in 4 of 5 (80%) cases. This is compared to 4 of 6 (66.67%) cases in the control group.

A. SUMMARY OF THE ANALYSIS

In Table 10, we find a side by side comparison of the outcomes of the study. In a similar sample size, there was a larger volume of patients in the treatment group that were recommended for discharge and smaller number that were recommended for further admission. This comparison was not statistically significant and may be related to patient acuity differences or at what phase of clinical care progression in the patients who were assessed. The second comparison (Safe/Unsafe) showed that the treatment group (using the structured tool) was stronger in predicting patients who were safe to discharge with no identified critical interventions over the next 96 hours. This finding was statistically significant. The third area compared the overall accuracy and appropriateness of the assessments in the control and treatment groups and found that the treatment group was only slightly stronger. This finding was not statistically significant.

	Phase 1 - control		Phase 2 - treatment	
Able to Discharge	23/42	54.76%	31/42	73.81%
Unable to Discharge	19/42	45.23%	11/42	26.19%
Safe to Discharge with 0 intervention	21/23	91.30%	30/31	97.77%
Unsafe to discharge with 1 or more	15/19	78.95%	7/11	66.63%
Assessments were appropriate predictor	36/42	85.71%	37/42	88.10%
Assessments were inappropriate	6/42	14.28%	5/42	11.90%

Table 10.Outcomes of the Study

B. RECOMMENDATIONS

This study served as a strong pilot and first step at evaluation and identification of specific clinical factors and a tool which could help clinicians make difficult reserve triage decisions in the face of complex patient surge incidents. While the structured assessment tool provided a strong prediction of clinical appropriateness for early discharge or continued admission (~88% reliability), this was only slightly better than the clinical judgment alone (~86% reliability). However, given the delicate nature of the decision, even a small improvement may be useful in practice. Ideally, the value of the structured tool is greater in validation of a reproducible action that could be more readily used by clinicians in a disaster and in turn would allow for greater confidence from a clinical, moral, legal, and ethical standing. In addition, the tool could also be useful if it makes the clinicians more comfortable with making these incredibly difficult and important decisions. Further study is definitely warranted in this situation.

C. LIMITATIONS

The limitations of this study were numerous. The study was designed to include nurses and physicians and there was ultimately no physician participation. Recruiting efforts in this area were challenging and would need to have better participation in future research.

The number and diversity of patient assessments was also limited. The overall number of assessments limits the statistical evaluation and validity of the results. A larger study would permit a regression analysis to be done both on the impact of patient demographics and on physician demographics. This is not possible given the current sample size. Ideally, 6000 to 10000 assessments would provide stronger analytical data. The limited diversity of patient types including surgical, oncological, critical care, psychiatry, and obstetrics/gynecology may impact the results as there was more participation in some clinical specialty areas of the organizations than others. Again, more patient types would strengthen analytical evaluation.

D. OPPORTUNITIES FOR FUTURE RESEARCH

This research has shown the need for broader research in the future. The research problem that was proposed has still not been solved. There are several key opportunities that were raised as a result of this project.

- The first is to replicate the study with larger numbers of patient assessments and providers especially physicians. This study was truly a pilot and great numbers of assessments and diversity of patient type would strengthen results.
- The second opportunity is to consider conducting a multi-site study. This would help to control for regional variations in patient population as well as provider education and diversity. This would also likely increase total number of assessments and participants to strengthen analytical data.
- The third opportunity is to consider engaging the electronic health record (EHR) in real time to evaluate current patient status and interventions in place to allow for more rapid evaluation and objective decision-making. Since the inception of the research study, improvements in analytical technology which is directly capturing real time data from clinical patient

care entries into the medical record and biotelemetry data including vital signs have been significant. Machine learning and the use of big data in vast patient data storehouses are creating the opportunity for stronger predictive analytics. UCLA Health recently adopted a Clinical Surveillance Team (CST) approach to monitor analytics and respond to patients who are deteriorating. This team is attempting to leverage scoring systems such as LACE Index³² and Modified Early Warning Score (MEWS)³³ with Electronic Health Record Systems (EHS- *EPIC*) and analytic software such as *PeriHealth*.

E. ADDITIONAL OPPORTUNITIES FOR FUTURE RESEARCH

As mentioned, the study is a good pilot to show the potential validity and utility of a structured assessment tool. Health care systems must have legal, risk management, and ethics teams vet this or similar tools through their processes to ensure policy based validity. Clinicians must be exposed to the tool and a process developed for its utilization to include tipping points (such as size and complexity of a community based disaster) by which the tool would be implemented. The goal of the tool is to safely modify the standard of care but to do this with real patients in a real emergency must be fully vetted and a process captured to ensure reliability and consistency of approach and application.

This allows for the following additional research questions to be discussed:

³² Robinson, Robert, and Tamer Hudali. "The HOSPITAL Score and LACE Index as Predictors of 30 Day Readmission in a Retrospective Study at a University-Affiliated Community Hospital." *PeerJ* 5 (March 29, 2017). <u>https://doi.org/10.7717/peerj.3137</u>.

³³ Gardner-Thorpe, J, N Love, J Wrightson, S Walsh, and N Keeling. "The Value of Modified Early Warning Score (MEWS) in Surgical In-Patients: A Prospective Observational Study." *Annals of The Royal College of Surgeons of England* 88, no. 6 (October 2006): 571–75. https://doi.org/10.1308/003588406X130615.

(1) Can a standardized predictive patient assessment by the UCLA Health System utilizing nationally recommended frameworks be used to effectively and safely discharge patients to create surge capacity?

This style of question may elicit more of the ethical and moral considerations which are addressed in many of the high level recommendations from the Institute of Medicine and other expert panels. It would engage more of the process description and perhaps have less focus on the qualitative effectiveness of a tool.

(2) Are there predictive factors that could be used to create an ethically acceptable model for patient discharge to create disaster surge capacity?

This question may lead to the development of potential versus specific recommendations. It is really asking if it is even possible to gain agreement between perhaps clinicians and the general public. The design of the study could be changed to determine if a wide number of clinicians could develop consensus on an unproven model for testing and if lay persons could ethically and morally accept these recommendations.

(3) Would a theoretical discharge assessment tool to create disaster surge capacity be acceptable to healthcare organizations, regulatory agencies, and legal tests?

This question engages the possibility of acceptance in multiple frames of reference. The study design may survey multiple stakeholders to determine the importance and substantive opportunity for a tool to exist. THIS PAGE INTENTIONALLY LEFT BLANK

VII. CONCLUSION

The goal of this research study was to test an assessment tool to determine its validity and safety for use in reverse triage situations in response to the need for surge capacity in a disaster situation. The research study showed that an assessment tool is a feasible and reliable strategy to "reverse" triage admitted patients for early discharge in an effort to create surge capacity. Opportunities exist to strengthen and advance the research in this field based on this initial pilot study.

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APPENDICES

APPENDIX A. PATIENT ASSESSMENT TOOL А.

Level I Patient Assessment

Patient MRN: _____

Clinician UID:_____

Criteria	Positive Example	Negative Example	Circle (+ o	or -
Adequate Nutritional Support	 Ability to swallow, self feed & appropriate resources G/J Tube with self administration/Planned provider administration and appropriate resources TPN with planned provider administration and appropriate resources 	 Unable to maintain adequate nutritional support for self and no support to maintain outside hospital 	+ -	-
Pain Management Plan	 No Pain management issues; or managed through IV fluids Prescribed and filled oral medication to manage pain Adequate pain management through non- pharmaceutical interventions 	 Pain uncontrolled or no plan for pain management out of hospital 	+ -	-
Established Plan for Treatment upon discharge	Adequate level of care to be provided	 Care level outside hospital will not meet patients needs Unable to coordinate care level need for patient outside of the hospital 	+ -	-
Pulmonary Stable	 Adequate airway management Adequate ventilatory status Normal Baseline for patient (including home ventilator) 	 Active respiratory/pulmonary complication which is unresolved Unable to maintain airway 	+ -	-
Hemodynamic Stable	 Adequate perfusion Normal Baseline for patient 	 Unstable perfusion status Signs of shock 	+ -	-
Neurologically Stable	Alert and Oriented Normal Baseline for patient (pre-admission or "new" accepted)	 Altered compared to baseline (preadmission or "new" accepted) 	+ -	-
Metabolic Stable/Lab Stable	 Laboratory results (chemistry, CBC, Markers, etc) within normal limits or Normal Baseline for patient or steady improvement with follow-up in an outpatient setting 	 Clinical laboratory testing indicative of additional hospital based therapies 	+ -	-
Dangerous to Self or Others	 No suicidal or homicidal ideation If gravely disabled – appropriate care resources 	Meet 51/50 criteria or gravely disabled	+ -	-
Pulse Ox monitoring	No monitoring required No monitoring required Within normal limits or baseline for patient for last 24 hours	 Current monitoring required due to pulmonary instability Monitoring required and cannot be maintain outside of hospital 	+ -	-
Cardiac EKG monitoring	 No monitoring required Within normal limits or baseline for patient for last 24 hours 	 Current monitoring required due to cardiovascular instability or unstable cardiac rhythms/frequent ectopy Monitoring required and cannot be maintain outside of hospital 	+ -	-
Oxygen requirement	No Oxygen requirement stable	 Supplement Oxygen need that cannot be maintained outside of hospital No discharge support for current requirement 	+ -	
IV Requirement	 No IV Requirement Pre admission baseline and support with discharge Discharge Support available 	 IV therapies required that cannot be support outside of hospital No discharge support available 	+ -	

Major Interventions	CPR or defibrillation
<u>Major Interventions</u>	Intubation/airway management
	Major surgery
	Cesarean section
	IV medication/pressors/fluids
	Oxygen requirement
	Burn care
	Cerebral bolt placement/monitoring
	Dialysis
	Thoracostomy tube placement/requirement
	Noninvasive PPV
	Thrombolytic administration
Moderate Interventions	Blood or blood product administration
	Other invasive procedure
	Psychiatric monitoring
	Cardiac catheterization
	Thoracentesis
	Wound care
	Central line placement/requirement
	Minor surgery: incision and drainage
	Parenteral nutrition requirement
	Paracentesis
	Vaginal delivery
Less Critical Interventions	Arterial line requirement
	Lumbar puncture
	Cardiac EKG monitoring
	Parenteral pain medication requirement
	Support for ADLs

B. APPENDIX **B.** ADULT CRITICAL INTERVENTIONS*

*As defined by Kelen, Gabor D., Chadd K. Kraus, Melissa L. McCarthy, Eric Bass, Edbert B. Hsu, Guohua Li, James J. Scheulen, Judy B. Shahan, Justin D. Brill, and Gary B. Green. "Inpatient Disposition Classification for the Creation of Hospital Surge Capacity: A Multiphase Study." *The Lancet* 368, no. 9551 (2006): 1984–90.

Major Interventions	CPR or defibrillation
	Interventional Cardiac Catheterization
	Acute Renal Replacement Therapy (e.g. Dialysis)
	ECMO
	Continuous Cardiorespiratory Monitoring
	Invasive Positive Pressure Ventilation
	Continuous IV or Aerosolized Medication
	Emergency and Essential Surgeries in the OR
	Setting
	Interventional Endoscopy
	Emergent/Essential Bedside Procedures (e.g. LP,
	thoracentesis, paracentesis)
Moderate Interventions	Blood or blood product administration
	Noninvasive Positive Pressure Ventilation
	Non-obstructing Airway Foreign Body Removal
	Plasmapheresis
Less Critical Interventions	IV Fluids
	Intermittent IV Medication
	Supplemental Oxygen
	Central Venous Access Requirement
	Intracranial Monitoring and Drainage
	Psychiatric Monitoring
	Arterial Line Requirement
	Parenteral Pain Medication
	Wound Care (Major)
	Assistance with Activities of Daily Living (ADLs)
	Parenteral Nutrition

C. APPENDIX B1. PEDIATRIC CRITICAL INTERVENTIONS*

*As defined by Kelen, Gabor D., Lauren Sauer, Eben Clattenburg, Mithya Lewis-Newby, and James Fackler. 2015. "Pediatric Disposition Classification (Reverse Triage) System to Create Surge Capacity." *Disaster Medicine and Public Health Preparedness*, March, 1–8. <u>https://doi.org/10.1017/dmp.2015.27</u>.

D. APPENDIX C. PATIENT DEMOGRAPHIC DATA

Age		Ethnicity	White Black Hispanic Asian Other
Sex	Female Male	Admission source	Emergency department Elective or direct admission
Service	Medical Surgical Oncology Obstetrics/Gynecology Psychiatry	Disposition	Discharged Discharged with service needs Transferred Died in hospital Remained hospitalized

E. APPENDIX D. PROVIDER DEMOGRAPHIC DATA

Age	$ \begin{array}{r} < 18 \\ 18-34 \\ 35-44 \\ 45-54 \\ 55-64 \\ 65-74 \\ \geq 75 \\ \end{array} $	Type of Provider	Physician – Attending Physician – Fellow Physician – Resident/Intern Nurse Nurse Practitioner
Sex	Female Male		
Service	Medical Surgical Oncology Obstetrics/Gynecology Psychiatry Emergency Medicine	Years of Clinical Experience	$ \begin{array}{c} <1 \\ 1-3 \\ 4-5 \\ 6-10 \\ 11-25 \\ \geq 26 \end{array} $

F. APPENDIX E. NCSS "COMPARISON OF TWO DIAGNOSTIC TESTS – INDEPENDENT SAMPLES" ROUTINE

Counts for	Tests 1 and 2	2					
Counts for	Test 1			Counts fo	or Test 2		
True	Diagnosti	: Test Resu	lt	Diagnosti	c Test Result		
Condition	Positive		Total	Positive	Negative	Total	
Present	21	4	25	30	4	34	
Absent	2	15	17	1	7	8	
Total	23	19	42	31	11	42	
Table Propo	ortions for Te	ests 1 and 2					
Table Prope	ortions for T	est 1		Table Pro	portions for T	est 2	
True	Diagnosti	c Test Resu	lt	Diagnost	ic Test Result		
Condition	Positive		Total	Positive	Negative	Total	
Present	0.5000	0.0952	0.5952	0.7143	0.0952	0.8095	
Absent	0.0476	0.3571	0.4048	0.0238	0.1667	0.1905	
Total	0.5476	0.4524	1.0000	0.7381	0.2619	1.0000	
Row Propo	rtions for Te	sts 1 and 2 ·					
Row Propo	rtions for Te	st 1		Row Prop	portions for Te	est 2	
True		c Test Resu			ic Test Result		
Condition	Positive		Total	Positive	Negative	Total	
Present	0.8400	0.1600	1.0000	0.8824	0.1176	1.0000	
Absent	0.1176	0.8824	1.0000	0.1250	0.8750	1.0000	
Total	0.5476	0.4524	1.0000	0.7381	0.2619	1.0000	
Column Pro	oportions for	r Tests 1 and	d 2				
Column Pre	oportions fo	r Test 1		Column I	Proportions fo	or Test 2	
True		c Test Resu			ic Test Result		
Condition	Positive		Total	Positive	Negative	Total	
Present	0.9130	0.2105	0.5952	0.9677	0.3636	0.8095	
Absent Total	0.0870	0.7895	0.4048	0.0323	0.6364	0.1905	
	1.0000	1.0000	1.0000	1.0000	1.0000	1.0000	

Two Sample Binary Diagnostic Tests

Sensitivity Confidence Intervals Section -

•			Lower 95.0%	Upper 95.0%
Statistic	Test	Value	Conf. Limit	Conf. Limit
Sensitivity (Se1)	1	0.8400	0.6535	0.9360
Sensitivity (Se2)	2	0.8824	0.7338	0.9533
Difference (Se1-Se2))	-0.0424	-0.2434	0.1394
Ratio (Se1/Se2)		0.9520	0.7345	1.1819

Sensitivity: proportion of those that actually have the condition for which the diagnostic test is positive. Difference confidence limits based on Gart and Nam's score method with skewness correction. Ratio confidence limits based on Gart and Nam's score method with skewness correction.

Specificity Confidence Intervals Section -

			Lower 95.0%	Upper 95.0%
Statistic	Test	Value	Conf. Limit	Conf. Limit
Specificity (Sp1)	1	0.8824	0.6566	0.9671
Specificity (Sp2)	2	0.8750	0.5291	0.9776
Difference (Sp1-Sp2)	0.0074	-0.2629	0.3710
Ratio (Sp1/Sp2)		1.0084	0.7253	1.6815

Notes:

Specificity: proportion of those that do not have the condition for which the diagnostic test is negative. Difference confidence limits based on Gart and Nam's score method with skewness correction. Ratio confidence limits based on Gart and Nam's score method with skewness correction.

Hypothesis			Prob	Decision at	
Test of	Value	Chi-Square	Level	5.0% Level	
Se1 = Se2	-0.0424	0.2205	0.6387	Cannot Reject H0	
Sp1 = Sp2	0.0074	0.0028	0.9579	Cannot Reject H0	
Likelihood Ratio S	ection —		Lower 95.0%	Upper 95.0%	
Statistic	Test	Value	Conf. Limit	Conf. Limit	
LR(Test=Posivitive)	1	7.1400	2.4760	38.9755	
. ,	2	7.0588	1.8727	119.9241	
		0.1813	0.0609	0.3977	
LR(Test=Negative)	1	0.1010			

Notes:

LR(Test = +) = P(Test = + | True Condition = +) / P(Test = + | True Condition = -).LR(Test = +) > 1 indicates a positive test is more likely among those in which True Condition = +.

LR(Test = -): P(Test = - | True Condition = +) / P(Test = - | True Condition = -).LR(Test = -) < 1 indicates a negative test is more likely among those in which True = -.

Two Sample Binary Diagnostic Tests

Odds Ratio Section — — — — — — — — — — — — — — — — — — —								
			Lower 95.0%	Upper 95.0%				
Statistic	Test	Value	Conf. Limit	Conf. Limit				
Odds Ratio (+ 1/2)	1	29.6222	5.5301	158.6725				
	2	33.8889	4.5264	253.7216				
Odds Ratio (Fleiss)	1	29.6222	5.1657	406.0300				
	2	33.8889	4.2093	1511.4109				

Notes:

.

Odds Ratio = Odds(True Condition = +) / Odds(True Condition = -)

where

Odds(Condition) = P(Positive Test | Condition) / P(Negative Test | Condition)

Hypothesis Tests of the Equivalence of Sensitivity -

Hypothesis lests		Lower	Upper			Reject H0 and Conclude
		90.0%	90.0%	Lower	Upper	Equivalence
	Prob	Conf.	Conf.	Equiv.	Equiv.	at the 5.0%
Statistic	Level	Limit	Limit	Bound	Bound	Significance Level
Diff. (Se1-Se2)	0.2764	-0.2084	0.1083	-0.1000	0.1000	No
Ratio (Se1/Se2)	0.3467	0.7716	1.1372	0.9091	1.1000	No

Notes:

Equivalence is concluded when the confidence limits fall completely inside the equivalence bounds. Difference confidence limits based on Gart and Nam's score method with skewness correction. Ratio confidence limits based on Gart and Nam's score method with skewness correction.

Hypothesis Tests of the Equivalence of Specificity -

	Duch	Lower 90.0%	Upper 90.0%	Lower	Upper	Reject H0 and Conclude Equivalence
	Prob	Conf.	Conf.	Equiv.	Equiv.	at the 5.0%
Statistic	Level	Limit	Limit	Bound	Bound	Significance Level
Diff. (Sp1-Sp2)	0.2918	-0.2148	0.3049	-0.1000	0.1000	No
Ratio (Sp1/Sp2)	0.3342	0.7729	1.5020	0.9091	1.1000	No

Notes:

Equivalence is concluded when the confidence limits fall completely inside the equivalence bounds. Difference confidence limits based on Gart and Nam's score method with skewness correction. Ratio confidence limits based on Gart and Nam's score method with skewness correction.

Two Sample Binary Diagnostic Tests

Tests Showing the	Soneitivity	Non-inferi	ority of Tee	et 1 Compa	red to Test	2
rests Showing the	e Genanitaity	Homenicin	only of rea	it i compa	icu to reat	
						Reject H0
						•
		Lower	Upper			and Conclude
		90.0%	90.0%	Lower	Upper	Non-inferiority
		30.0%	30.0%	Lower	opper	Non-Interiority
	Prob	Conf.	Conf.	Equiv.	Equiv.	at the 5.0%
Statistic	Level	Limit	Limit	Bound	Bound	Significance Level
						-
Diff. (Se1-Se2)	0.2764	-0.2084	0.1083	-0.1000	0.1000	No
Ratio (Se1/Se2)	0.3467	0.7716	1.1372	0.9091	1.1000	No
Nalio (SelfSez)	0.0401	0.1710	1,1072	0.3031	1.1000	NU

Notes:

H0: The sensitivity of Test 1 is inferior to Test 2.

Ha: The sensitivity of Test 1 is non-inferior to Test 2.

The non-inferiority of Test 1 compared to Test 2 is concluded when the lower c.l. > lower bound. Difference confidence limits based on Gart and Nam's score method with skewness correction. Ratio confidence limits based on Gart and Nam's score method with skewness correction.

Tests Showing the Specificity Non-inferiority of Test 1 Compared to Test 2

	Prob	Lower 90.0% Conf.	Upper 90.0% Conf.	Lower Equiv.	Upper Equiv.	Reject H0 and Conclude Non-inferiority at the 5.0%	
Statistic	Level	Limit	Limit	Bound	Bound	Significance Level	
Diff. (Sp1-Sp2)	0.1992	-0.2148	0.3049	-0.1000	0.1000	No	
Ratio (Sp1/Sp2)	0.2374	0.7729	1.5020	0.9091	1.1000	No	

Notes:

H0: The specificity of Test 1 is inferior to Test 2. Ha: The specificity of Test 1 is non-inferior to Test 2.

The non-inferiority of Test 1 compared to Test 2 is concluded when the lower c.l. > lower bound.

Difference confidence limits based on Gart and Nam's score method with skewness correction.

Ratio confidence limits based on Gart and Nam's score method with skewness correction.

Data Tab Data Values	
T11:	21
T10:	4
F11:	2
F10:	15
T21:	30
T20:	4
F21:	1
F20:	7
Confidence Interval Method Difference C.I. Method:	Score w/ Skewness (Gart-Nam)
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