THE ORIGINS OF THE "GOLDEN HOUR" OF MEDICAL CARE AND ITS APPLICABILITY TO COMBAT MEDICINE

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The opinions and conclusions expressed herein are those of the student author and do not necessarily represent the views of the U.S. Army Command and General Staff College or any other governmental agency. (References to this study should include the foregoing statement.)

ABSTRACT

THE ORIGINS OF THE "GOLDEN HOUR" OF MEDICAL CARE AND ITS APPLICABILITY TO COMBAT MEDICINE, by LTC Joseph J. Hudak III, MD, 64 pages.

The Golden Hour standard is used in emergency medicine and trauma care and states a person must receive definitive care within one hour to ensure optimal outcomes. The medical community accepted this standard without supporting evidence. It is a cornerstone of modern trauma systems. Secretary of Defense Gates endorsed this standard for military medicine (Gates 2009). His stance, combined with strong opinions from the trauma community, resulted in a requirement for units to operate within one hour of ROLE III care during deployments. A review of the association between evacuation time and outcomes fails to support the Golden Hour. The evidence suggests if combat injury is properly treated in the first several minutes, focusing on hemorrhage, airway management, and treatment of tension pneumothorax, combined with high quality en route care during evacuation, there is significantly more time available to reach ROLE III care before outcomes suffer. Therefore, the Golden Hour is an improper standard for combat medicine resulting in increased resource requirements and unnecessary restrictions on units. A more appropriate approach is enhanced individual soldier training on the management of the major immediate causes of combat death as well as positioning advanced resuscitative care as far forward as possible.

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TABLE OF CONTENTS

	Page
MASTER OF MILITARY ART AND SCIENCE THESIS APPROVAL PAGE	iii
ABSTRACT	iv
ACKNOWLEDGEMENTS	V
TABLE OF CONTENTS	vi
ACRONYMS	viii
CHAPTER 1 INTRODUCTION AND OVERVIEW	1
Primary Research Question Secondary Research Questions Assumptions Definitions Limitations Delimitations Significance of Study	
CHAPTER 2 LITERATURE REVIEW	11
The Origin of the Golden Hour World War I Medical Care World War II Medical Care Korean War Medical Care Vietnam War Medical Care Scientific Evaluation of the Golden Hour since the Vietnam War Mechanism of Injury and Causes of Death in a Combat Setting Approaches other than Reducing Evacuation Time for Improving Outcome Current Doctrine Regarding the Golden Hour.	
CHAPTER 3 METHODOLOGY	33
CHAPTER 4 ANALYSIS	35
The Evidence behind the Initial Golden Hour Standard The Golden Hour in Practice Doctrine	

Doctrine	
Organizational	
Training	
Materiel	
Leadership and Education	
Personnel and Facilities	
Policy	

ACRONYMS

ADRP	Army Doctrine Reference Publication (Unites States Army)
ATP	Army Techniques Publication (United States Army)
CCATT	Critical Care Air Transport Team
COL	Colonel, (Unites States Army)
DOTMLP-F	Doctrine, Organizational, Training, Materiel, Leadership and Education, Policy, Facilities
DOW	Died of Wounds
EMEDS	Expeditionary Medial Support (United States Air Force)
EMS	Emergency Medical Services
FDA	Food and Drug Administration
FM	Field Manuel (United States Army)
JMATT	Joint Medical Attendant Transport Team
JP	Joint Publication (United States Department of Defense)
KIA	Killed In Action
MASH	Mobile Army Surgical Hospital
MAST	Military Assistance to Safety Transportation
mmHg	Millimeters of Mercury
OTSG	Office of The Surgeon General (United States Army)
TC3	Tactical Combat Casualty Care
TCMC	Tactical Combat Medical Care

CHAPTER 1

INTRODUCTION AND OVERVIEW

The purpose of this thesis is to evaluate whether the Golden Hour standard of medical care is appropriate for deployed military medicine and to make recommendations for further study of and-or changes to current doctrine and practices. It clarifies the evolution of combat medical care to illustrate how the United States military arrived at the Golden Hour standard. It discusses the evidence behind the Golden Hour standard with a focus on its applicability to medical care in an austere or hostile environment. Based on a systemic review of the evidence and a needs-based analysis, recommendations are made.

The Golden Hour is a standard used in emergency medicine and trauma care that states a person should receive definitive resuscitative and surgical care within one hour from injury. This is based on the belief that medical outcomes are improved if patients receive definitive care within the first sixty minutes after injury. This standard is one of the foundations of the national civilian trauma care system in the United States. It is based partially, however, on wartime data from Vietnam.

In a study published in 1981, McNabney described increased survival rates in medical facilities in Vietnam (McNabney 1981). In this study he described how survival rates among combat wounded who reached medical facilities alive increased 2 percent over previous wars to a 97.5 percent survival rate during the Vietnam War. He further went on to describe how the time to definitive care was decreased from an average of five hours during the Korean War to approximately one hour during the Vietnam War. This study exerted significant influence on the development of the civilian trauma system in

existence in the United States today. This contributed to various practices such as "scoop and run," aeromedical transport, and regional trauma centers with trauma teams in place and on continuous stand-by (Mullins 1999). This was despite a lack of rigorous scientific review to validate these practices or their impact on outcomes.

In response to this "normal" practice, on 16 September 2009 in a speech at the Air Force Association Convention, Secretary of Defense Robert Gates invoked the term "the Golden Hour" in a manner suggesting it was and would continue to be the standard for medical evacuation from injury on the battle field to ROLE III medical care (Gates 2009). This repeated his publicly stated position over the prior year that all combat injuries should reach resuscitative and surgical care in less than one hour from the moment of injury. As a result of this speech, as well as strong opinions from the trauma and surgical communities, operating within a one hour window to ROLE III medical care essentially became policy for deployed US forces. This is despite the fact that there is no current doctrine which governs how far US ground forces may operate from ROLE III care during combat operations.

Despite the absence of doctrine and a significant lack of high quality medical research, the "Golden Hour ring" is now a major limiting factor in planning combat operations. This time ring not only restricts operational reach with respect to distance from advanced trauma and initial surgical care, but it also creates a significant vulnerability by providing both a source of information to the enemy as well as a relatively soft target for irregular warfare. Enemy forces can now plan on no major US action outside this one hour ring which significantly shrinks in size when atmospheric conditions prevent rotary wing medical evacuation flight. Additionally, they can

anticipate major future action by the relocation of ROLE III medical as well as rotary wing medical evacuation assets. They can correctly assume there will be no major combat action initiated by the United States in an area until these assets are within adequate proximity. Finally, denying access to ROLE III care through irregular warfare measures can severely limit combat operations in an area. These issues raise the question of whether the Golden Hour is the appropriate standard form medical coverage planning. Additionally, it questions what doctrine should be regarding operational reach with respect to medical evacuation assets in an austere or hostile environment.

Primary Research Question

What should United States joint doctrine be regarding the operational reach of ground combat forces with respect to medical evacuation to ROLE III medical care?

Secondary Research Questions

- 1. What is the origin of the "Golden Hour?"
- 2. What scientific research is the Golden Hour standard based on?
- 3. What is current United States Army and Joint doctrine regarding time from injury to definitive care?
- 4. What injuries do United States forces routinely sustain on the battle field?
- 5. Of these injuries, which ones actually require surgical intervention within one hour or less in order to survive or prevent unnecessary morbidity?
- 6. What advances in point of injury care have been made since the Golden Hour was first suggested?

- 7. What impact does the "Golden Hour ring" have on current planning on ground combat operations?
- 8. What level of care is required within the initial critical period in order to prolong survival time until definitive care?
- 9. Are there any ground forces, United States or otherwise, who routinely operate outside of one hour from definitive care?
- 10. How do ground forces who operate outside of the Golden Hour ring mitigate risk?

Assumptions

The following assumptions are believed to remain true and are relevant to this research. First, there will be fatalities in conflict; not everyone can be saved. Second, all treatment subsequent to successful evacuation and live arrival at higher level medical care facilities will be correctly performed and appropriate to the injuries suffered. Third, the general classifications of injury sustained in combat will not significantly change in the next twenty to forty years. Fourth, there will not be a major advance or new evolution of evacuation capability in the next ten years such as when helicopters for medical evacuation were widely introduced in the Korean War. Fifth, while there will continue to be steady advances in advanced trauma care, there will not be a major breakthrough in management leading to currently uniformly fatal injuries being survivable at a significant rate. Sixth, appropriate force protection measures are in place and a physically healthy and robust force is deployed. Finally, there are limitations to the numbers of trained medical personnel, evacuation platforms, and medical supplies available in a theater of war, and these limitations are more restrictive than in a developed nation at peace.

Definitions

Advanced medical care: This denotes the appropriate level and aspects of care necessary to survive an injury. It differs from ROLE I care which is emergency buddy aid and unit-level care. It includes advanced trauma life support care as well as possible emergency surgical care and is aimed at significantly prolonging survival time until reaching definitive care. It also includes continued advanced care provided during medical evacuation as is standard practice in today's military medical system (US Department of the Army 2009a).

<u>Conflict</u>: This includes all military operations deployed to a hostile environment. It covers the entire spectrum from stability operations through high-intensity combat against an enemy with near-peer capabilities. Additionally, it includes peacekeeping and peace enforcement activities where armed conflict is a possibility. It does not include activities such as foreign humanitarian assistance or domestic activities such as defense support to civil authorities where armed conflict is not anticipated or direct access to the United States civilian trauma system is possible.

Definitive medical care: This denotes care directed at completely addressing an injury. It defines a transition from initial injury management, including initial advanced medical care and *en route* care during evacuation, to the period where recovery and healing begins. It does not preclude the need for further procedures and-or treatments to manage an injury during the healing process or to address complications such as infection. Additionally, reaching this point in care does not guarantee survival.

<u>Evacuation time</u>: This is the time from the moment of injury until arrival at ROLE III medical care. It includes the time from injury until initial care is received, time at point of injury while awaiting evacuation, and time until evacuation is complete with arrival at ROLE III care. In the context of this thesis, evacuation time as defined above is synonymous with "the Golden Hour" time frame.

<u>Killed in Action, (KIA), and Died of Wounds, (DOW)</u>: Killed in action specifically refers to service members who died of combat injuries prior to reaching ROLE III care. Died of wounds refers to service members whose death was due to combat injures but occurred after reaching a ROLE III facility. This distinction is important in understanding the research on combat injury as many studies limit their review of potentially survivable injuries based on DOW statistics.

Potentially survivable and Non-survivable: Potentially survivable is a common classification used in review of trauma, both combat related and otherwise, where based on mechanism of injury the patient may have survived. In general, and in the context of this thesis, this refers only to patients who died but based on classification of injury mechanism may have survived if ROLE III or above, or in a civilian system Level 1 trauma, care was immediately available at the moment of injury. This is a very inclusive definition which ignores the realities of combat casualty as well as civilian trauma care, but it is a standard classification in trauma outcomes literature. Non-survivable injuries include those injuries that would result in death even if ROLE III care or Level 1 trauma care was immediately available at the time and location of injury. This category of injuries usually includes severe injuries such as decapitation.

<u>ROLEs of medical care</u>: Using Joint Doctrine definitions, this denotes the echeloned levels of medical care at each successive stage of the United States military medical system.

ROLE I refers to the first level of care injured personnel receive. It occurs at the individual soldier and unit level and is focused on immediate, life-saving interventions.

ROLE II refers to advanced trauma and emergency medical care. It includes continuation of resuscitation started at ROLE I. This level of care usually takes place at the battalion aid station or the brigade support medical company level.

ROLE III refers to care at a medical treatment facility, (or veterinary treatment facility for working animals), capable of providing advanced care to all categories of patients to include continued advanced resuscitation, damage control and/or definitive surgery, and post-operative intensive surgical care.

ROLE IV refers to care provided in either United States based hospitals or robust overseas medical facilities where definitive and potentially rehabilitative care is performed (US Department of Defense 2012).

Statistically significant: For the purposes of this thesis this term refers to the

standard definition from general statistics. It includes all data that falls within two standard deviations of the mean with a 95 percent confidence interval. This means that there is a less than 5 percent chance that any conclusion drawn from data occurred purely

by chance, often represented in data sets by the statistical shorthand p<0.05.

<u>Suitable, feasible, and acceptable</u>: The United States Army's change management model searches for solutions that are suitable, feasible, and acceptable. Suitability is the effectiveness of a solution across a range of foreseeable environments. Acceptability is the willingness of stakeholders to support the proposed solution with respect to their culture, traditions, and professional judgment. Feasibility is the economic affordability of the proposal in terms of life-cycle costs, implementation, and project management (Long 2011; US Department of the Army 2012b).

Limitations

While my definition of conflict above does include stability operations in a mature theater, this thesis is limited to addressing the range of conflict from highintensity combat through lesser levels of conflict, but where the theater is not mature. This is to account for the ability in a very mature theater where stability operations predominate for a deployed medical care system to closely resemble a civilian trauma care system in a developed nation at peace.

Additionally, while the raw data from the Joint Trauma System—Joint Theater Trauma System is available, I will not independently classify and analyze this raw data. There are multiple publications where this has already been done. I consider the analysis and classification of that data which is published in peer-reviewed journals to be accurate and representative of the ongoing data set.

This thesis is also limited by the fact that medical technology is a rapidly evolving area. There will certainly be new developments in immediate, advanced, and definitive medical care that impact outcomes. This thesis is limited to the currently existing injury and survival data. Advances in medical technology over time will require a future review of any conclusions reached in this thesis.

Finally, this thesis does not address public perception of what the standard of care and evacuation time should be. Public opinion is a vital input to any policy decision, but it is at times formed primarily on emotion instead of rational evaluation of fact. Any conclusions drawn from this thesis will certainly require reconciliation with public opinion, particularly in an environment where the public is growing conflict weary and relatively casualty averse.

Delimitations

I will not address force protection measures that can reduce the severity of injuries or increase physiologic ability to survive a given injury. While a vitally important area that has tremendous impact on casualty rates as well as injury severity, it is beyond the scope of this thesis. Furthermore, I will not address current force structure in my analysis including the possibility of increasing personnel or equipment dedicated to either further forward deployed surgical capability or the evacuation mission.

I will not discuss treatment at higher levels of medical care, specifically ROLE III and above. This thesis will discuss the window of time between the moment of injury and arrival at ROLE III care, (evacuation time). I will only evaluate medical evacuation systems used by joint United States military forces. While the systems of multi-national partners are often similar in many ways, there are different medications, devices, and procedures in medicine approved by various nations. By restricting my evaluation to care provided within the United States military system this ensures the use of only Food and Drug Administration, (FDA), approved medications and devices are included in my analysis. Additionally, it ensures t

hat any conclusions reached and recommendations made are supportable by the United States regardless of which multinational partners are also involved.

I will review the evolution of military medicine through the 20th century as part of this thesis. This review is not intended to be a comprehensive review of the evolution of military medicine, but to highlight some of the important advances that contributed to the system in place during the Vietnam War. It will not include analysis from periods prior to World War I as military medical care prior to that conflict bears little

resemblance to current practices and does not enhance understanding of this topic in a meaningful way.

I will not cover psychological injury in this thesis. While it is important and possibly impacted by evacuation times, this area of medicine is beyond the scope of this thesis. Finally, I will not consider injuries resulting from non-conventional weapons such as chemical, biological, or nuclear materials. While they are important potential weapons, injuries from these systems present a completely different medical problem from conventional warfare and must be considered separately.

Significance of Study

Severe trauma will always occur during conflict. There will be loss of life, loss of limbs, loss of eyesight, and many other lingering effects from combat injury. In fact, the rate of killed in action has remained steady at around 20 percent over the past 150 years of conflict, and the rate of service members who died of wounds has remained steady at around 4 percent since at least the Korean War (Champion et al. 2003). This is despite the tremendous advances in medical care and evolution of trauma systems over those time periods. Initial care of these injuries, including the evacuation time to appropriate care, intuitively appears to impact survivability and long-term complications. It is appropriate for military medical systems to make every effort to minimize poor outcomes, including making reasonably appropriate efforts to reduce evacuation time. There are limits to what is possible however. This thesis seeks to define these reasonable limits and describe their impact on combat medical care.

CHAPTER 2

LITERATURE REVIEW

The Origin of the Golden Hour

The first step necessary to understand this topic is to determine where, how, and why the "Golden Hour" concept originated. The origin of the Golden Hour is actually unclear. This is despite the extensive use of this standard in the civilian, and now military, medical systems. Most attribute the origin of the Golden Hour concept to Dr. R. Adams Cowley. Dr. Cowley was a prominent surgeon and a founder of Baltimore's Shock Trauma Institute. In a 1975 article he stated the "first hour after injury will largely determine a critically-injured person's chances for survival" (Rogers and Rittenhouse 2014, 1). This statement was similar to ones made throughout 1974 and 1975 by Dr. Cowley. Even though he regularly made this claim, he provided no data during that time or later to support it.

There was no trauma system or formalized emergency medical services, (EMS), system in the United States in the early 1960s. The only place the United States had anything resembling a formal trauma system during that time was in Vietnam. This was noted and commented on by Dr. Frank H. VonWagoner, formally the Chief Surgical Consultant to the Surgeon General Department of the Army. In 1961 Dr. Von Wagoner published a study of soldier deaths after unintended injury in the continental United States. In this study he concluded that service members were experiencing needless deaths from delayed diagnosis or inappropriate treatment after trauma within the United States. This study, among other things, highlighted the need for rapid intervention in traumatic injury (Mullins 1999).

This occurred during a time when the general public within the United States was becoming aware of the medical care available within the military. The Vietnam War was broadcast in people's living rooms on a daily basis. A ground swell grew regarding civilian trauma care which began to counter what had been a general public apathy toward a formalized trauma care system. This eventually led a landmark report in 1966.

In 1966 a report titled "Accidental Death and Disability: The Neglected Disease of Modern Society" was released. This report addressed public indifference to civilian trauma care. It framed this apathy in terms of dollars lost both in cost of care and loss of productive work. This report made civilian trauma care a prominent political issue, especially since it now had a dollar value attached to it. It also made recommendations that ultimately lead to the current concept of the emergency room as well as to the rise of Emergency Medicine as a distinct medical specialty (Division of Medical Sciences, National Academy of Sciences, National Research Council 1997; Celso et al. 2006).

The Unites States Congress responded to this report with the National Highways Safety Act of 1966. This law included several key aspects. First, it stressed the need for coordination of transportation and communication during movement of injured civilians. This was deemed necessary to bring the injured individual to definitive medical care in the shortest possible time. This law formally elevated time as a critical factor in trauma patient survival but did not define what the time limit should be. It did so without any scientific study to back up this stance. This law also laid the foundations for formalized EMS systems and regional trauma systems (U.S. Congress 1966). Later laws such as the Emergency Medical Services Systems Act of 1973, and revised in 1976 actually provided funding for these systems (U.S. Congress 1973). As a consequence of these laws and the

resulting medical systems, there were significant improvements in civilian trauma outcomes (Mullins 1999).

Three states led the way in development of formalized civilian trauma systems, Florida, Illinois, and Maryland. In Maryland, Dr. Cowley was developing the Shock Trauma Institute in Baltimore at that time. He pointed to the past use of helicopters in Korea, and current use in Vietnam, in evacuation of severely injured service members, and he began to argue for the development of a rotary wing patient transport system in Maryland (Mullins 1999). The concept for civilian use of helicopters to transport patients was novel at the time, but not without precedent. In Georgia and Alabama by 1967, Military Assistance to Safety Transportation (MAST), helicopter units were coordinating with state authorities to transport patients. By 1968, the first formal proposal for a civilian helicopter evacuation system was made in Colorado by a Vietnam War veteran who was by that time the president of St. Anthony's Hospital in Denver (Sheehy 1995).

By this time, civilian trauma was a nationally recognized problem. Subsequent data showed that in 1969 there were at least 11,000 more civilians killed in motor vehicle accidents alone within the continental United States than the entire number of United States KIA in eleven years of conflict in the Vietnam War (McNabney 1981). In 1969 the Maryland Institute for Emergency Medicine, the University of Maryland hospitals, and the Maryland State Police created the first formalized, pure civilian system for using helicopters to evacuate trauma patients. By the mid 1970s, however, this system was not yet universally accepted as either necessary or cost effective. It was during this time that Dr. Cowley made his now-famous remarks regarding the Golden Hour (Mullins 1999). With Maryland, Florida, and Illinois all showing significant improvement in outcomes for civilian trauma patients, other states and hospital systems imitated their models. They recognized the systems problems as universal, and copied the solutions developed to those problems. The Golden Hour was an intuitive concept, championed by a national leader in trauma care. It was a central concept of a system showing major improvements in patient outcomes. It was therefore accepted nationwide, essentially without question.

The development of civilian trauma systems was clearly influenced in major ways by the United States military system in place during the Vietnam War. Rapid evacuation of combat injured was a cornerstone of that system. Therefore, even if Dr. Cowley and essentially all other medical professionals failed to provide evidence for the Golden Hour, if this critical time period was scientifically established by the system they borrowed heavily from it would remain valid. It is therefore necessary to investigate how the US military arrived at the trauma system of the Vietnam War.

World War I Medical Care

For the purposes of this thesis it is most appropriate to begin with a review of military medicine's evolution during World War I. This is the time period around which many concepts of "modern" medicine gained widespread acceptance. There was recognition of aseptic technique (the need to sterilize instruments for all surgical procedures). Antibacterials were used for wound care (sulfa-based medications as well as silver preparations). Finally, there was the development of anesthesia (pain and consciousness suppression), as opposed to pure analgesia (pain suppression only), for major surgery.

It was during this period that timely evacuation of combat wounded through echeloned levels of care became standard protocol (Mullins 1999). In this time period the early evolution of the current system of ROLE I-IV medical care is evident. This was the first conflict where all soldiers carried a universal field dressing to be used either by the wounded individual or for buddy aid (Baker 1995). This closely resembles the concept of ROLE I care today.

Wounded were then brought to "dressing stations" where pain medication was provided, hemorrhage control was attempted, and fractures were splinted. This roughly equates to between current ROLE I and II care today. Seriously injured were then evacuated to "clearing stations" where emergency surgery could be attempted. This surgery was mostly wound debridement and equates to between ROLE II and III care today.

Finally, survivors of the clearing station were evacuated to hospitals remote from the battlefield for definitive care and hopefully return to duty. This is the equivalent of between ROLE III and IV today. The total time required to evacuate a patient from the point of injury to a location of first major surgical capability, (the clearing station), averaged somewhere between twelve and eighteen hours (Baker 1995; Mullins 1999). This is the World War I equivalent of the Golden Hour period of care.

Interestingly, the first reported evacuation of patients by air also occurred during World War I. In 1915 a French pilot evacuated a wounded Serbian Air Force officer. There are several instances of air evacuation of injured from World War I, but there was no ability to provide any care during the flight. This would not be available until around 1923 (Sheehy 1995).

World War II Medical Care

By World War II, there were major improvements to the military medical system. The role of the combat medic was established. The practice of systematically evaluating and treating multiple injuries on a single patient was widely implemented. This is in essence the equivalent of the primary and secondary survey steps in current Advanced Trauma Life Support. Blood transfusion for trauma resuscitation was widespread. Surgical intervention became much more effective due to improvements in surgical technique and more rigorous medical training. Finally, many civilian surgeons, anesthesiologists, and other physicians were called to service. These factors all tremendously improved patient survival (Mullins 1999).

Evacuation time to field hospitals also decreased. Field hospitals of World War II can best be equated to ROLE III care today. The average time to evacuate a service member from point of injury to a field hospital was reduced almost 50 percent compared to World War I, to around ten hours (McNabney 1981). As a result of these improvements, while the percentage of KIA remained at approximately 20 percent, the percentage of patients who DOW dropped from nearly 8 percent at Flanders in World War I to around 4 percent for American forces in Italy 1944-1945 (Eastridge et al. 2012; Champion et al. 2003).

A second historical event regarding patient evacuation also took place during World War II. The first use of a rotary wing aircraft to transport a patient occurred in 1945. In Burma, a plane crashed approximately five miles from the nearest airstrip. The pilot survived, but he was severely injured. It was impossible to move him by ground through the jungle due to his injuries and the dense terrain. Eventually a Sikorsky R-4 helicopter landed in an area cleared nearby. The injured pilot was loaded and transported to further medical care (Sheehy 1995).

Korean War Medical Care

The Korean War saw continued evolution of the United States military medical system. It saw the creation of Mobile Army Surgical Hospitals, (MASH), which had coordinated surgical teams. Helicopter evacuation of wounded service members from near the point of injury also became widespread (Mullins 1999). Care during helicopter evacuation was severely limited however. Initially, patents were transported in baskets attached to the outside of the helicopter. The only care provided during evacuation was intravenous fluids. The flow rate of these fluids was controlled by the pilot who had to focus most of his attention on flying. Eventually with improvements to helicopters the patients were moved inside during flight and *en route* care became possible. This was a critical development in medical evacuation as it eliminated a period of lost time where no effective or ongoing care was provided (Sheehy 1995).

As a result of the widespread use of helicopters for patient evacuation and the location of surgical hospitals closer to the point of injury, the average evacuation time was again decreased by about 50 percent to approximately 5 hours. In discussing the effect of decreased evacuation time on trauma patient outcomes, the survival rate of 95.5 percent for all patients who reached a MASH unit alive is regularly cited as a baseline for future reference (McNabney 1981). It was against this survival rate that success in Vietnam would be measured and used to support the argument for decreasing evacuation times.

Vietnam War Medical Care

Building on success during the Korean War, the forward deployed acute care hospital became the norm for the Vietnam War. Patients were no longer expected to survive through the entire echeloned system of care to reach definitive treatment, but could expect it at these forward deployed facilities. This is the first real ROLE III equivalent seen in the United States military medical system. Due to terrain restrictions, helicopter evacuation also became the norm for patients in the Vietnam War. In fact, the Huey evacuating combat wounded became one of the most enduring images from that war. Due to the continued forward placement of surgical hospitals and the widespread use of helicopters, evacuation time decreased 50-80 percent to an average between one to one and a half hours. Despite the fact that evacuation times were often well over two hours, a one hour upper time limit for evacuation is usually stated as fact (Mullins 1999).

Survival statistics from the Vietnam War which were in part used to justify the Golden Hour standard are reported as 97.5 percent. It is important to note that this is the survival rate after reaching a field hospital, and not the overall survival rate. This is a 2 percent increase over survival statistics from the Korean War despite the argument that the average evacuation time was reduced from five hours to less than one (McNabney 1981). This argument is a bit misleading as complete data reveals only 84 percent of combat injured in the Vietnam War survived when KIA numbers are added to the analysis (Eastridge et al. 2012).

This 84 percent survival statistic, while low, was probably unnecessarily so with the technology available at the time. The use of tourniquets was actually discouraged during the Vietnam War. This was due to fears that their use would lead to "unnecessary" loss of limbs (Cordts, Brosch and Holcomb 2008). It is not unreasonable to claim there were significant numbers of potentially survivable injuries that resulted in death as a result of hemorrhage. Still, by this time survivability was increasing, even in those with severe trauma. Due to the near-real time television coverage of the war, the general public in the United States became aware of the high quality inherent in the nation's military medical system. It is not surprising that Dr. Cowley's claim of a one hour upper time limit on evacuation of trauma patients gained widespread acceptance despite the fact that it was not subject to rigorous investigation.

Early inclusion in the foundations of regional trauma systems in the United States which showed remarkable success allowed the concept of the Golden Hour to remain an unchallenged "fact" for many years. In effect, this "concept became so widely adopted that consumers, and their elected legislators, expect it" (Berger 2010, 19A). Over the past fifteen to twenty years, however, this concept has been subject to more formal, rigorous investigation. This revisitation of the Golden Hour concept was motivated at least in part by the economics of regional trauma systems.

Scientific Evaluation of the Golden Hour since the Vietnam War

Timely, appropriate care is a reasonable goal for any medical condition. Without directly addressing what "timely" care is, Esposito et al. evaluated several factors that led to patient demise in "preventable" circumstances. This study, which was based on a rural Montana patient population, was intended to evaluate the appropriateness of initial care. This initial care was sometimes provided at non-trauma facilities. It also evaluated the time from injury to initial formal care. The authors concluded that around 13 percent of

hospital deaths were preventable. They also determined that 32 percent of all trauma cases had at least some initial inappropriate care. That percentage was increased, however, to 68 percent when specifically reviewing patients with preventable death. Mistakes leading to inappropriate care were most likely to involve airway management, chest injuries, and head injuries.

In their analysis, the authors determined that 40 percent of preventable deaths had some system access delay as an associated factor but stopped short of concluding it was a contributing factor (Esposito et al. 1995). Combined with the overall 13 percent of all death being classified as preventable, this leads to an overall rate of around 5 percent of all trauma patients in the study having preventable death with access delay at least an associated finding.

The concept of time delay was more specifically investigated in a study by Newgard et al. They reviewed civilian trauma in a large cohort of fifty-one North American hospitals between 2005 and 2007. All patients included in the study had significant physiologic abnormalities, (systolic blood pressure below 90mmHg, respiration rate less than ten breaths per minute, depressed neurologic exam), upon EMS arrival. Many patients had multiple physiologic abnormalities at multiple time periods during care, equating to critical and-or unstable patients. In this large study the authors concluded that there was no association between time and death for any time interval for patients with trauma. They investigated time from injury to EMS activation, time from activation to response, (EMS arrival at the patient's location), on-scene time, transport time, and total time from injury to arrival at a trauma center. This last time interval equates to the Golden Hour period. They did, however, conclude that there was at least one condition which definitively established a correlation between decreased total time and improved outcomes, non-traumatic cardiac arrest (Newgard et al. 2010).

Contrary to the Newgard study, Clark et al. published a study suggesting the opposite may be true. Their study demonstrated a possible increase in mortality at four hours after injury with increasing time to definitive care (Clark, Winchell and Betensky 2013). As a result, they concluded that decreased time to definitive care may have a small effect on four-hour survival rates.

In an attempt to clarify if arrival at definitive care within one hour was necessary to ensure optimal outcomes, Rogers et al. investigated the outcomes of patients initially brought to non-Level 1 trauma centers. They sought to determine whether patients initially brought to non-Level 1 trauma centers had different outcomes compared to patients brought directly to the highest level of care. To clarify, Level 1 is the highest level designation of trauma care a hospital can be certified in within the current trauma system format in the United States. Levels of care decrease with capability, subspecialty access, the immediate availability of trauma surgeons, and other factors. The closest association to a Level 1 trauma center in a deployed military setting is a combat support hospital, or ROLE III medical care.

This study, like Esposito's, was based on a patient population in a rural setting. Its purpose was to investigate whether or not it is better to bypass a closer, but lower level trauma center, and go directly to a Level 1 center at the expense of significantly increased evacuation time. While this study does not directly address the Golden Hour time limit, it does address a related point which is involved in the evacuation process. It investigates if initial stabilization at a facility capable of Advanced Trauma Life Support can

significantly improve outcomes if an injury occurs remote from definitive care. It questions if initial proper stabilization, but delayed access to definitive care, adversely impacts outcomes. It therefore indirectly challenges the Golden Hour concept which requires arrival at definitive care less than one hour from injury.

Interestingly, patients in this study initially stabilized at a lower level facility then transferred to a Level 1 trauma center were more severely injured than those taken directly to Level 1 centers. Despite an average time of 182 +/- 139 minutes at the lower level facility and 72 +/- 32 minutes in actual transport time from the initial hospital to a Level 1 facility, the study concluded there was no adverse impact on mortality (Rogers et al. 1999).

It is possible that some subsets of traumatic injury do have a critical period that is less than one hour. This possibility is suggested by Newgard's study which did demonstrate a clear, time-dependant association with survival in non-traumatic cardiac arrest (Newgard et al. 2010). Closed head injury is one area of trauma that was specifically investigated for a time-outcomes association.

Dinh et al. investigated if there was a difference in survival for patients with closed head injury due to blunt trauma, mostly from motor vehicle accidents, who arrived at care before or after one hour from injury. This type of injury is similar to traumatic brain injury from blast damage in combat, though the mechanism is different. They determined that there was no statistically significant difference in survival for those patients who arrived at care before or after one hour from injury. They did, however, determine that there was a statistically significant difference at some undefined point

between ninety and one hundred twenty minutes, though their data set was not large enough to further define that time point (Dinh et al. 2013).

The authors also concluded that there was a statistically significant difference in discharge condition between their two groups. They concluded that those patients who arrived before one hour were more likely to be discharged directly home as opposed to a rehabilitation facility. They did not define the discharge criteria used in making the determination of discharge location however (Dinh et al. 2013).

Another category of injury that received individual evaluation for a time-outcome association is intra-abdominal bleeding. Clarke et al. investigated if time in the emergency department prior to surgical intervention impacted survival for patients with intra-abdominal bleeding secondary to trauma. The authors only evaluated patients with low blood pressure, (defined as systolic blood pressure <90mmHg), recorded at least once in the emergency department. While not specifically intended to evaluate the time period prior to emergency department arrival, they did not show any statistically significant changes in outcome associated for any time interval up to 185 minutes from injury to arrival at the hospital. They did, however, demonstrate worse outcomes for the time interval between sixty and ninety minutes spent in the emergency department prior to undergoing surgery. They did not demonstrate any decrease in outcomes for any other time interval spent in the emergency department (Clarke et al. 2002).

Mechanism of Injury and Causes of Death in a Combat Setting

There are significant challenges drawing any direct comparisons between the civilian trauma system and the requirements of a military medical system in a combat

setting. There is a different injury profile between the two groups. Civilian trauma is mostly due to motor vehicle accidents and resulting blunt trauma with gunshot wounds and other penetrating trauma making up a smaller percentage. Military injuries, however, involve a high percentage of injuries due to other mechanisms. For example, burns account for between 5 percent and 10 percent of combat injuries (White and Renz 2008). Additionally, explosive blast currently causes 43 percent of injuries to Special Forces members and 55 percent of conventional ground forces. Gunshot wounds account for 28 percent of injuries to Special Forces and 19 percent of injuries to conventional forces. Aircraft crashes resulting in multi-system trauma account for 23 percent of Special Forces injuries and 1 percent of conventional forces injuries. Finally, blunt trauma due to motor vehicle crashes or falls accounts for only 6 percent of combat injuries to Special Forces and 24 percent for conventional forces (Holcomb et al. 2007). Therefore it is necessary to evaluate the injuries common to combat units, with particular focus on those injuries leading to fatalities, when evaluating the requirements of a military medical system to include evacuation time limits.

In a paper by Unlu et al. the authors argued that "the urban legend of the 'Golden Hour of shock' does not quite apply to combat trauma" (Unlu et al. 2013, 84). They suggested that casualties may only have a critical five to fifteen minutes instead. This is, in fact, consistent with what Dr. Cowley actually argued when he made his Golden Hour statement. Immediately after making his Golden Hour claim, Dr. Cowley went on to state that the trauma patient may in fact have only a critical fifteen minutes (Lerner and Moscati 2001).

A review of the literature already demonstrated that the Golden Hour concept for trauma is has questionable evidence. It is possible that claims of a critical first fifteen minutes are also unsubstantiated. MacLeod et al. investigated civilian trauma deaths that occurred within the first sixty minutes after injury to determine if they were all non-survivable. The authors concluded that the overwhelming majority of patients with all causes of death were most likely to die in the first fifteen minutes of injury (MacLeod et al. 2007).

Several others directly investigated if this held true for combat injuries and similar injuries in civilian settings. These studies concluded that there are at least two peaks of death. They are the time interval from five to fifteen minutes and the interval between sixty and one hundred eighty minutes (Champion et al. 2003; Clarke et al. 2002; Osterwalder 2002; Demetriades et al. 2005). In light of these studies Remik et al., during their review of trauma literature, made recommendations regarding medical evacuation for military medical systems. They acknowledged the lack of data for a Golden Hour time limit and suggested that increased quality of *en route* care can significantly extend the survival window for combat injured (Remick et al. 2010).

Proper investigation of evacuation time and any other aspect of combat medical care systems requires investigation of what specifically causes combat deaths. A review of United States Special Forces deaths from 2001 to 2004 reveals a 15 percent potentially survival rate with twelve of eighty-two combat deaths deemed potentially survivable (Holcomb et al. 2007). Interestingly, this is very close to the 13 percent preventable rate from the Esposito study of trauma deaths in rural Montana discussed earlier (Esposito et al. 1995). The determination of potentially survivable was based on an artificial standard

that the service member could immediately receive optimal care at a ROLE III facility. The study acknowledged that only one in three of these potentially survivable deaths actually could be cared for with current technology. For these potentially survivable deaths, evacuation times ranged from four and a half to ten hours (Holcomb et al. 2007). This low rate of potentially survivable deaths despite operating remotely from ROLE III care was likely due to factors such as enhanced training of special operations forces medics as well as others.

Analysis of pre-ROLE III deaths of US forces in Operation Iraqi Freedom and Operation Enduring Freedom reveals that 24.3 percent of those deaths were potentially survivable (Eastridge et al. 2012). It is important to note that for the purposes of that study the determination of potentially survivable was based on autopsy and recorded mechanism of injury. The authors acknowledge this determination was intentionally slanted to include injuries in the potentially survivable category in order to "be introspective and critical to further develop the paradigm of combat casualty care performance improvement and identify potential gaps requiring further research and development" (Eastridge et al. 2012, S432).

Of the potentially survivable deaths, 91 percent were due to hemorrhage and 8 percent were due to problems with airway management. The number and percentage of potentially survivable deaths due to hemorrhage was likely inflated because the universal use of approved combat tourniquets was not standard until 2007 (Cordts, Brosch, and Holcomb 2008). Both of these causes of death must be addressed within the first few minutes. Brain death can result after as little as five minutes without adequate oxygen.

Therefore, delays of more than five minutes in re-establishing adequate volumes of circulating, oxygenated blood can lead to death.

Consistent with the above analysis are the causes of death in potentially survivable injuries that occurred after arrival at ROLE III care, (DOW, potentially survivable). 80 percent or more of these deaths are also due to hemorrhage. This is different than the 83 percent of non-survivable deaths occurring after arrival at ROLE III, (DOW, non-survivable), which were determined to be due to traumatic brain injury. Of the potentially survivable deaths that occurred due to hemorrhage, 31 percent were from extremity wounds readily controllable with proper application of tourniquets. 21 percent were due from junctional injuries, (neck, axilla, groin), which while not amenable to tourniquet use are potentially controllable by hemostatic field dressings currently available. 48 percent were due to truncal bleeds which currently require surgery for control (Eastridge et al. 2011). This last category may soon change with the proven effectiveness of tranexamic acid and its recent recommendation for use in the prehospital setting in a combat environment (Blackbourne et al. 2012). This therapy helps control bleeding due to coagulopathy, the loss of ability for the blood to clot, and may slow noncompressible bleeding. This would increase the time available to reach surgical intervention.

Other studies support these findings that hemorrhage is the overwhelming cause of potentially survivable deaths. Kelly et al. determined that 83 percent to 87 percent of these deaths had hemorrhage and 10 percent to 15 percent of these deaths had inadequate airway management as contributing factors (Kelly et al. 2008).

Approaches other than Reducing Evacuation Time for Improving Outcome

There are courses taught within the current United States military medical system specifically tailored to teach the skills necessary for proper treatment in the immediate post injury period. They include the Tactical Combat Casualty Care, TC3, course and the Tactical Combat Medical Care, TCMC, course. These are taught at the Army Medical Department Center and School at Fort Sam Houston and other locations. Their goal is to improve the soldier's medic's, and-or provider's skills in hemorrhage control, airway control, and to improve the quality of care under fire (Sohn et al. 2007). In 2006, the office of the Surgeon General of the Army (OTSG), released a policy which standardized the recommended pre-deployment trauma training for all Army components (Cordts, Brosch, and Holcomb 2008). This included Advanced Trauma Life Support, Advanced Cardiac Life Support, TC3, and TCMC as strongly recommended training prior to deployment. This policy did not, however, require this training. The final decision was left to the unit level commanders. They currently hold responsibility for determining the medical treatment capabilities of their units and deciding what additional specialized predeployment medical training is required. They also are responsible for funding any training deemed necessary. In essence, this requires the unit commander to determine what level of risk is acceptable in pre-deployment medical training.

The provision of additional training does not necessarily translate into improved outcomes, however. It is necessary to investigate if receiving this, or similar training, can result in improved survival and therefore make evacuation time more or less relevant. Review of another specialized Army unit, the 75th Ranger Regiment, provides some clear answers to this question.
In 1998, then COL Stanley McChrystal initiated among other things a requirement that all Rangers focus on medical training. This led to TC3 training becoming mandatory for all personnel in the Ranger Regiment. There was additional, higher level training, for small unit leaders as well. Analysis of October 2001 to March 2010 Operation Enduring Freedom and March 2003 to March 2010 Operation Iraqi Freedom Ranger Regiment casualties revealed only an 8 percent overall death rate. Importantly, none of these combat deaths were due to hemorrhage, airway management problems, or tension pneumothorax. These are the solidly established causes of potentially survival combat deaths from these conflicts demonstrated in every study investing recent combat injury. Of the thirty-two total deaths identified, only one was deemed potentially survivable. It was due to a gunshot wound and death was due to post-operative complications (Kotwal et al. 2011).

As stated early on, the purpose of this thesis is to review if a one hour upper time limit for evacuation is necessary. This concept has garnered a lot of attention in the civilian literature over the past fifteen to twenty years. Unfortunately, there are very few studies that specifically address the impact of evacuation times on survival for combat injuries. For those studies that do exist, they make at least one key assumption. They assume that proper care is given within the first few minutes of injury. This is a large assumption considering this care is often given while still receiving enemy fire.

Parker et al. did investigate the specific impact on evacuation time for combat injured. They determined that if the airway is properly managed and hemorrhage is controlled, there may be window of up to two hours to reach definitive and-or surgical care before outcomes suffer. Their conclusions came with the caveat that there was ongoing intensive care management during the evacuation (Parker 2007). This is a capability that currently exists within the United States military medical system.

This concept of up to two hours for evacuation is further supported by another study by Tai et al. The authors determined that there is likely some upper limit to evacuation time before death rates begin to rise. It appeared that this is longer than one hour as long as proper care is delivered within the first fifteen minutes. The authors concluded that two hours, possibly longer, is a reasonable limit with current medical capabilities (Tai et al. 2009).

Current Doctrine Regarding the Golden Hour

As noted earlier, then Secretary of Defense Robert Gates repeatedly endorsed a one hour standard for evacuation time, the Golden Hour (Gates 2009). His statements effectively made this time limit policy throughout the Department of Defense. Before evaluating the appropriateness of this any further it is necessary to determine if there is any current Department of Defense doctrine which places a one hour time limit on medical evacuation, or requires combat units to operate within a one hour ring of ROLE III care.

There is some confusion on this point when reading doctrine due to the medical evacuation categories described. There are two evacuation categories that do have a one hour limit associated with them, though this does not equate to the Golden Hour period. Priority 1, Urgent, and Priority 1A, Urgent Surgical, are two of the possible evacuation categories that can be assigned by a provider. Both define the need for the patient to begin evacuation in no more than one hour from the time the request is made (US Department of Defense 2012, B12). This does not, however, equate to a Golden Hour requirement. There is a sixty minute time limit from the request for evacuation until the patient begins movement to the next higher echelon of medical care.

Several other doctrinal publications cover issues related to casualty care and evacuation. ADRP 4-0 defines medical evacuation but makes no mention of timelines involved (US Department of the Army 2012a). JP 4-02 refers to the need to move patients in a timely manner from the site of injury or onset of disease, through successive ROLEs of care, to a military treatment facility that can meet the patient's needs. Again, while stating this movement must be timely, there is no further definition of what timely means (US Department of Defense 2012).

ATP 4-25.13 describes the specifics of casualty evacuation but makes no reference to timelines other than describing the medical evacuation categories described earlier (US Department of the Army 2013b). ATP 4-02.5 discusses the tactical evacuation phase and states "time is of the essence to remove the casualty as quickly as possible to where further treatment can be provided" (US Department of the Army 2013a, 1-9 to 1-10). It does not quantify an appropriate upper limit on time. FM 4-02 states "timely stabilizing care is required to increase survivability, decrease morbidity and mortality, enhance the prognosis of recovery, and minimize long-term disability" (US Department of the Army 2013a, 1-2). There is no further definition of "timely". This manual further discusses overall timeliness of evacuation. It does not, however, discuss any specifics of time or distance. Finally, FM 4-02.2 discusses in great detail the planning factors for medical evacuation to ensure timeliness. Again, this publication fails to define timeliness any further (US Department of the Army 2009b).

There is an Army Regulation which does put a one hour upper limit on a segment of evacuation time, further restrictive than the above mentioned doctrinal publications. Army Regulation 40-3, Chapter 16-2 states the Army "has implemented the aeromedical evacuation standard of a one-hour mission completion time for urgent and urgent surgical missions" (US Department of the Army 2013c). This regulation defines this time interval as the time from mission request until the patient is delivered to the appropriate level of medical care. Again, while this regulation does place a time limit on a specific phase of the chain of combat medical care, this phase does not equate to the Golden Hour time period as it does not include the time from injury until the request for evacuation is made.

CHAPTER 3

METHODOLOGY

This research uses the Case Study research method. This is the most appropriate methodology because I describe a set of decisions, why they were made, how they were implemented, and what the results of that implementation were. For this particular thesis, I discuss the evolution of the Golden Hour concept and its ultimate utilization as a standard for military medicine. The case study methodology is well-suited for detailing a rich description of a complex problem, tightly bounded in time and space, which requires a mix of data and analysis from many different types of resources. The ultimate intent of this method is to produce a comprehensive framework for making policy decisions under conditions of constraint (Yin 2009).

I start by describing where the Golden Hour originated and for what purpose. I then analyze the quality and completeness of scientific evidence used to develop the concept. I discuss where, why, and how that concept was initially applied. I then discuss what decisions were made by the military community during the evolution of the United States military medical system in the 20th century. Finally, I discuss how the Golden Hour standard is currently implemented and the implications of that decision.

Once I determined how the United States military community arrived at its current state and the implications of its current standard I conduct a needs-based and a capabilities-based assessment to determine if that standard is appropriate. This involves analyzing what the current goals for battle field injury care are, and what they really should be. I address any identified gaps in current perception of goals and capability versus reasonable reality and why those gaps may exist. At the conclusion of this analysis

33

I suggest what realistic expectations regarding evacuation times may be based on current needs, capabilities, and prudent risk. I determine suitable solutions, feasible solutions, and acceptable solutions. Recommendations are made based on possible changes that meet these criteria.

CHAPTER 4

ANALYSIS

The Evidence behind the Initial Golden Hour Standard

The statements by Dr. Cowley were made during a time when he was trying to increase support for a regional trauma system in Maryland. It was common practice in medicine during that period for the opinions of prominent physicians to be accepted without providing evidence. This is very different from today's standard of evidencebased research and medical care. It was also made on the background of the early evolution of the civilian trauma system in the United States (Rogers and Rittenhouse 2014). Therefore, without supporting evidence it is inappropriate to require adherence to the Golden Hour standard for trauma in any medical system.

The one hour standard for evacuation in combat medicine as described by McNabney in 1981, despite having some roots in wartime trauma care, is not appropriate for current military medicine. First, McNabney's research only evaluated survival of those individuals who reached medical facilities alive. This does not account for individuals who died prior to arrival at a medical facility. Second, there is a growing body of research that demonstrates different "critical windows" for care based on the type of trauma. This includes not only the mechanism of injury but the organ systems involved as well. Third, this type of system is designed and only appropriate for a civilian system in a developed nation at peace. In such a system there are generally fewer limits on evacuation resources. Ground evacuation routes are secure. Emergency Medical Services assets can be created or increased as populations grow. Local populations usually clear roads to allow emergency medical response vehicles to pass. Trauma services of varying care levels can be created in multiple hospitals spread throughout regions to create a permanent network of tiered trauma coverage. In general, there are few obstacles outside of funding or the time necessary to train emergency response personnel to increasing the ability to rapidly identify, locate, and move trauma patients to definitive care in the civilian world. These same conditions are almost never possible in a wartime environment.

Ensuring a one hour upper limit on evacuation time in a deployed setting is expensive and resource intensive. The cited improvements in survival during the Vietnam War attributed to this concept ignored several important developments that culminated at that time. Transfusion of whole blood, (which contains red blood cells and clotting factors), as opposed to plasma only was widely available during the Vietnam War. Skilled, organized, and efficient medical teams provided care in well equipped, semipermanent forward deployed hospitals. Specific surgical and medical subspecialists were much more likely immediately available in Vietnam than to a civilian injured in the continental United States. There was effective management of available medical resources due to improvement in medical logistics. Finally, the cited survival rate of 97.5 percent focused only on those who reached ROLE III care alive and ignored all KIA deaths (McNabney 1981).

The Golden Hour concept therefore has its origin on a shaky foundation. This foundation was the expressed opinion of a recognized expert in the field at a time when civilian trauma systems were in early development. This opinion was based, at least partially, on the success of the military medical system in place during the most recent, (and actually ongoing), conflict of the time. Certainly Dr. Cowley's statements were also at least partially motivated by his desire to promote and expand the regional trauma system he was the director of. It is impossible to know the extent this impacted his thought process. This opinion was at least partially rooted, however, in the observation that a significant number of patients die from exsanguinations (Schinco and Tepas 2002).

The Golden Hour in Practice

The study by Esposito et al. suggests that proper initial management, regardless of where that management takes place, is key to outcomes and is independent of time to care (Esposito et al. 1995). One weakness making it difficult to draw conclusions from this study is the authors did not cross-analyze inappropriate care with delayed access. Also, the 13 percent preventable death rate is low compared to other studies. The authors argued that this was due to the rural nature of the environment. They argued that time and distance may serve as a "natural triage" where people with non-survivable injuries died prior to receiving any care. In their final analysis, they concluded that time to definitive care may not be as important as the type of care rendered during that time such as fluid resuscitation, airway control, and hemorrhage control. Another weakness is they never stratified time intervals in their analysis or stated overall evacuation times. Therefore, it is unknown what standard the authors used to determine which patients had delayed access (Esposito et al. 1995). Objectively, this study supports the concept that delay in appropriate care may contribute to death, but it neither validates nor refutes the Golden Hour time limit.

The study by Clark et al. argued that there may be a positive benefit, at least at four hours, if evacuation times are decreased. There are several major issues with this

study, however. First, all patients included in the study were forty to eighty years old or more. They were all male, and were all involved in motor vehicle accidents which has blunt force trauma as the mechanism of injury. This contrasts with Newgard's study where the authors included all patients fifteen years old or above and all sources of trauma (Newgard et al. 2010).

It is difficult if not impossible to make any long-term outcome conclusions based on Clark's research, and any conclusions made may not apply to combat injury. The difficulties in drawing any conclusions from this study for military populations are multiple. First, there is an age mismatch with the overwhelming majority of military combat injuries occurring in service members twenty-two to twenty-nine years old (Eastridge et al. 2011). Second, there is a mechanism of injury mismatch. As opposed to motor vehicle accident as the leading mechanism of injury resulting in blunt force trauma in Clark's research, 55 percent of combat injuries to conventional forces are currently due to explosive blast, 28 percent are due to gunshot wounds, and only 24 percent are due to blunt force trauma, (due to motor vehicle accidents or falls) (Holcomb et al. 2007). Finally, the authors only studied survival up to four hours after injury. Therefore, the results of Newgard's study are much more relevant to evaluating military medical systems as the patient population and mechanism of injury better match the realities of combat trauma.

The study by Rogers et al. was intended to evaluate if initial care at a Level 1 trauma center was superior to faster access but initial care at a lower level facility. Their results suggest that time to initial advanced resuscitative care and not time to definitive care may be the more important variable if evacuation time is in fact a critical factor. The study does not, however, address the interval from injury to initial resuscitation so the concept of the Golden Hour cannot be evaluated from this study, even if it is redefined in those terms. Another issue with this study is the authors did not evaluate the quality of initial care. Unlike the Esposito study, the authors did not determine if any patients received inappropriate care at the varying hospitals (Rogers et al. 1999). Therefore, the concerns of the Esposito study about initial inappropriate care impacting outcomes remain valid (Esposito et al. 1995).

The study by Dinh et al. attempted to determine if closed head injury, as a subset as trauma, did have a Golden Hour for initial care. Taken in aggregate, the author's conclusions can be interpreted as some evidence, though certainly not conclusive, for a Golden Hour in closed head injury. This study did not, however, clearly state why some patients required discharge to a rehabilitation facility. Additionally, it did not follow the patients through final recovery so it is impossible to determine if the initial treatment delay resulted in higher rates of permanent disability. Finally, the authors did not describe the locations of the hospitals. It is possible that those patients arriving in less time live in an area with more readily accessible outpatient rehabilitation. This could allow discharge directly home as opposed to patients in more remote locations. This second group may have benefited from discharge directly to a rehabilitation facility in order to ensure access to rehabilitation services.

The study by Clarke et al. attempted to determine if there was any association between delays in surgical intervention for traumatic injury resulting in intra-abdominal bleeding. From this study in is only possible to conclude that significant delays for patients with low blood pressure between sixty and one hundred twenty minutes after initiation of resuscitation may impact outcomes. These conclusions are more applicable to improving the quality and speed of treatment after arrival at advanced care. It is problematic to extend this conclusion to evacuation time.

Based on the review of literature, it is not possible to draw any solid conclusions that support the Golden Hour concept. Clearly there is a critical time period for some common medical emergencies such as non-traumatic cardiac arrest (Newgard et al. 2010). There may be a critical period of less than one hour for some injuries such as closed head injury due to blunt force trauma, though this is certainly not conclusively proven (Dinh et al. 2013). The remainder of the evidence is conflicting. Because non-traumatic medical emergencies are common in civilian emergency medical systems, the balance of evidence argues in favor a limited window to reach care in that setting. It is therefore best practice to create and maintain medical systems capable of providing definitive care at less than one hour from onset of a condition in a civilian setting.

Combat deaths, however, often result from injuries either impossible to manage, or improperly managed immediately after they occurred. Considering these deaths likely occur in less than fifteen minutes from injury, adhering to a one hour time limit, or even further decreasing evacuation times will not likely have any impact on outcomes. This argues for placing advanced resuscitative care, including Advanced Trauma Life Support, closer to anticipated points of injury in military medical systems. This is necessary because evacuation to ROLE III care in less than fifteen minutes from injury in a combat setting is not usually possible. It is therefore necessary to determine if there is anything else that can reasonably be done to prevent these deaths.

40

The 3 percent rate of potentially survivable deaths within the 75th Ranger Regiment in Iraq and Afghanistan through March 2010 stands in stark contrast to the 24 percent rate established in other studies using similar criteria. While the combat injury statistics of the 75th Ranger Regiment may not ultimately endure at such a low rate, it is clear that enhanced, focused medical training targeted at causes of death in the immediate post-injury period has tremendous potential to increase survival rates.

Doctrine

While current United States doctrine repeatedly refers to the need for timely evacuation of combat casualties, it does not define any actual limit on evacuation time. This concept of timeliness is consistent with Secretary of Defense Gate's statements. There is no doctrinal requirement, however, for medical evacuation to be completed within the Golden Hour. There is also no doctrine which governs operational reach of combat forces with respect to ROLE III care facilities, though this concept is reinforced at the Combined Arms Center, Mission Command Training Program in Fort Leavenworth, Kansas as well as throughout the United States military professional education system. There is, however, an Army Regulation which does set a one hour upper time limit from mission request to mission completion for urgent and urgent surgical patients.

Current doctrine discusses the appropriate considerations of time and distance and does require continued delivery of care during movement through all echelons of care. It also appropriately focuses on the need to provide immediate, lifesaving care. Due to the clearly defined evacuation priority categories, there is a doctrinal requirement to be able to initiate medical evacuation to a higher echelon of care within one hour, and Army Regulations mandate that for at least some patient categories that mission must be complete within one hour. Therefore, there remains some ambiguity regarding the actual requirements for medical evacuation.

CHAPTER 5

CONCLUSIONS AND RECOMMENDATIONS

Using the Doctrine, Organizational, Training, Materiel, Leadership and Education, Policy, and Facilities, (DOTMLP-F), construct, the Golden Hour medical evacuation standard is analyzed and recommendations are made. These recommendations are based on a capability-needs assessment and identification of capability gaps. Recommendations are made which are assessed as suitable, feasible, and acceptable.

The Golden Hour evacuation standard was an initial reasonable approximation by a prominent member of the surgical community during early development of the initial civilian trauma system. This standard was not based on empirical evidence at the time it was introduced. Subsequent empirical studies question its validity. Despite this research, civilian emergency medical services systems should still be designed to bring patients to definitive care within one hour of onset of symptoms or injury. The Golden Hour civilian evacuation standard does not logically translate to combat injuries. Combat injured that survive the first fifteen minutes and receive high quality *en route* care appear no less likely to survive for at least two hours of evacuation time compared to one hour.

The capability required for deployed military medical systems is rapid, highquality, and appropriate care to the combat wounded service member in potentially austere and hostile environments that minimizes the possibility of preventable death or unnecessary morbidity, (long-term complications from injury or disease). This is an essential mission of combat casualty care and the deployed health care system. The current echeloned system of medical care with forward placed advanced resuscitative capability meets this requirement, but improvements can be made. Reducing the number of combat deaths is a major goal of any system changes.

The goals for a military medical evacuation system are rapid initial management of injury, safe and efficient transport to advanced care, and an unbroken continuum of high-quality *en route* care throughout the process. There is still a significant rate of death from "potentially survivable injuries." Additionally, while many service members survive their injuries, there remains significant long-term morbidity associated with those injuries. A goal of system changes needs to be reduction in morbidity. An additional goal is to reduce any negative effect the current medical system has on operational reach for combat forces.

<u>Doctrine</u>

Current doctrine is unclear regarding the time limits on medical evacuation. The purpose of United States doctrine in this area is to ensure medical evacuation is accomplished within appropriate time limits based on the severity of injury, and to ensure that there is common language, methods, and systems to accomplish those goals. There is currently no doctrinal mandate to adhere to the Golden Hour standard. United States doctrine should, therefore, be clarified to eliminate any confusion between different publications. Any time limits imposed should be based upon rigorous scientific review. Most preventable combat deaths occur due to problems associated with care delivered within the first fifteen minutes. It is not possible to ensure all combat wounded are evacuated to definitive care within this time interval. With improvements in forward advanced and *en route* medical care, an upper limit of at least two hours is a reasonable initial change. This change is suitable based on current evidence described above. Additionally, it is absolutely feasible given the current capabilities of medical transport.

A two hour upper limit on evacuation time is also acceptable from a scientific standpoint, but a change such as this is subject to the psychological trap of anchoring. Public opinion, as well as beliefs held within military circles have established a one hour limit on evacuation as the standard. This is the baseline against which all evacuation times are currently measured, and any change has both large scientific psychological obstacles to overcome. Therefore, any doctrinal change must be accompanied with a targeted informational program explaining the evidence behind it. Additionally, a rigorous, post-implementation review of patient outcomes must accompany any change to determine if the new limit is appropriate. If there is no significant negative impact on patient outcomes, this time limit should be increased to between three and four hours and re-assessed.

There is a clear need to critically evaluate the current standard of medical evacuation in a combat environment and revise doctrine as required. Currently medical evacuation is only covered briefly and superficially within United States Army doctrine (US Department of the Army 2013a; US Department of the Army 2013b; US Department of the Army 2009a; US Department of the Army 2012a). These publications limit their discussion regarding evacuation time to stating it should be accomplished as rapidly as possible and-or feasible. This conflicts with an Army Regulation 40-3 which requires completion of all medical evacuation missions for both urgent and urgent surgical patients within one hour (US Department of the Army 2013c). This conflict between doctrine and regulations must be resolved. Based on the evidence currently available, this

45

limit should be no shorter than two hours from the time of injury to reaching advanced resuscitative care.

Additionally, there is a conspicuous lack of United States joint doctrine regarding medical evacuation in a combat setting. This is a significant gap in doctrine which must be addressed. A joint publication regarding medical evacuation is necessary to standardize this process across the United States Department of Defense. This doctrine must not only address the total time from point of injury to arrival at the appropriate level of enhanced medical care, but must also directly address the misconception surrounding the one hour standard. Additionally, doctrine must emphasize the need for immediate, lifesaving care provided at the point of injury. It must emphasize the need for high-quality *en route* care during evacuation. Finally, it must emphasize the importance of positioning advanced, though not necessarily definitive, trauma care as far forward on the battle field as possible.

With the changing nature of deployed medical care, the ROLE classification and function currently in use also needs reevaluation. This is a legacy system which evolved, as described above, while the United States military medical system matured over the past one hundred years. It is no longer necessary for all significant combat injuries to be evacuated to ROLE III care. There is advanced trauma life support and emergency surgical care available far forward of the United States military's combat support hospitals. With the robust inter-theater medical evacuation system currently available, particularly the capabilities of the Joint Medical Attendant Transport Team (JMATT), and the Critical Care Air Transport Team (CCATT), it is now possible for a stabilized patient to depart directly from a forward location provided there is a capable air field. The

46

patient can leave theater directly to ROLE IV care without passing through ROLE III. A far better doctrinal approach would center around ensuring the patient passes through only those locations capable of providing the care necessary at that point. This would result in potentially more rapid definitive care or evacuation out of theater.

Organizational

There are limits to the number of military medical personnel trained in advanced trauma life support and higher levels of care. While additional personnel would certainly improve access to care and potentially improve outcomes, it is not feasible to redesign organizations to significantly increase the number of advanced care providers, (physicians, physician assistants, and advanced practice nurses). It is feasible, however, to place some of our current medical capability closer to where combat injuries are expected. In particular, attachment of forward surgical teams to combat units of brigade size or larger is feasible. These small surgical units can be added to current Brigade Medical Support Companies to enhance forward resuscitative care and provide emergency surgical capability. They can leverage the patient hold and pharmacy capabilities already in place within these units. Additionally, the Brigade Nurse can be leveraged to assist in post-operative patient care. Finally, the Brigade Surgeon structure can administratively handle the addition of this unit. These changes would shorten the evacuation distance to initial surgical care and likely improve outcomes without the need to immediately evacuate to a ROLE III facility. Personal experience with a collocated United States Air Force EMEDS 10+ during deployment demonstrated the profound impact on survival that this capability can have at the brigade level. This organizational change is suitable, feasible, and would likely be welcomed by combat units.

Current United States Army force projections are for a standing force between 24 and 33 active brigade combat teams as well as at least 22 brigade combat teams in the National Guard (Roulo 2013). Therefore, the United States Army would require a similar number plus several additional forward surgical teams to meet this realignment goal if augmentation is to occur at division level as well. Currently there are 38 forward surgical teams in the Army; therefore, it's necessary to increase the number of forward surgical teams to meet this change (U.S. Department of the Army 2015). Further, it is recommended that these forward surgical teams align routinely with the unit they support in order to ensure seamless coordination of care once deployed.

<u>Training</u>

The 75th Ranger Regiment clearly demonstrated the impact universal enhanced medical care training. Care directed at treating the three most significant causes of potentially survivable death in the first fifteen minutes after injury has profound positive impact on outcomes. These causes are hemorrhage, airway problems, and pneumothorax. This type of training must become the standard for all United States service members prior to deployment. It is suitable because it addresses the largest causes of preventable death and has proven effective. It is feasible as demonstrated by the 75th Ranger Regiment. This additional training will require increased resources; both funding and time spent on pre-deployment medical training, but is a small price to reduce combat deaths. The Tactical Combat Medical Care course is centrally funded for all United States active duty service members and those National Guard or Army Reserve soldiers activated under Title 10 (AMEDD Center and School 2015). Therefore, only those service members not on active duty would require funding from their individual unit. The course is 7 days long and would require incorporation into unit training plans.

The 2006 OTSG pre-deployment training recommendations must become requirements. Individual unit commanders, who are usually not medical personnel, should not be given the authority to waive these training requirements as they lack the expertise to properly assess risk. Additionally, while common practice in many units, all units should be required to train all personnel as combat life savers prior to deployment. This training takes 4-5 days to complete and costs approximately \$72 per student (Dewitt Health Care Network 2013). This course is taught at every large military base so travel is unnecessary. This low-cost, easily accessible training must be required of all soldiers with annual refresher. The total cost to a 4,500 soldier brigade is approximately \$324,000 annually in FY-2015 dollars.

This recommendation to require all soldiers be trained as combat lifesavers differs from current recommendations. Currently it is recommended that at least one member of each squad, team, crew, or equivalent-sized unit is trained as a combat lifesaver (The Army Institute for Professional Development n.d.). The current recommendation allows for the possibility that an injured soldier may be the only trained combat lifesaver in a small unit. This can lead to improper or incomplete treatment by untrained personnel during the crucial first few minutes prior to arrival of a combat medic. A better approach is to ensure all soldiers are trained in these lifesaving tasks.

Materiel

There are no materiel changes recommended from this thesis. This does not imply that there are no materiel solutions which can significantly impact outcomes. A stated limitation of this thesis is that it does not evaluate emerging medical technologies. This is an area; however, that merits formal investigation in the immediate future.

Leadership and Education

Major changes to leadership and education are required. First, as addressed above, there are education requirements for each soldier, (universal combat lifesaver training). Additionally, United States Army leaders at all levels must be reeducated regarding the combat medical evacuation requirements. As discussed earlier, most Army leaders believe the Golden Hour is an absolute requirement to ensure optimal outcomes. This perception, while false, is deeply rooted. It is necessary to change the paradigm which dictates adherence to this standard. This will require a major overhaul to how planning for combat operations is taught. The Officer Basic Course, Captain's Career Course, and Intermediate Level Education must incorporate within their planning curriculum the revised doctrinal recommendations described above. These changes must also be taught at the enlisted level, starting no later than the Warrior Leader Course. Finally, training rotations at the National Training Center and other locations must emphasize the new standards during rotation evaluations, eliminating the requirement to adhere to the Golden Hour. These changes must be reinforced at the Mission Command Training Program at Fort Leavenworth, Kansas. Only through consistent effort and education throughout the Army training system can the misconception about the Golden Hour paradigm be changed.

Finally, the multiple trauma care training programs, both within the military and in the civilian sector, undergo constant evaluation and modification. This needs to continue. The United States military medical system must ensure that it remains agile enough to change along with these programs. As the field of medicine continues to advance, the United States military medical system must stay abreast of these changes. It must continually review current practices, and constantly revisit doctrine and policy to ensure it remains at the forefront of trauma care.

Personnel and Facilities

Evaluation of personnel and-or facilities solutions to improving combat injury outcomes is beyond the scope of this thesis.

Policy

Current United States military medical policy, as established by Secretary of Defense Gates, is that all combat injuries are expected to be evacuated to ROLE III care within the Golden Hour. This de facto standard must change. The one hour upper limit is not a suitable standard based on the scientific evidence. Additionally, it is neither a feasible standard as it places significant and unnecessary limits on the operational reach of ground combat forces. In sum, the existing de facto medical evacuation policy is not acceptable for medicine in an austere or hostile environment. United States policy must be evidence-driven. It must focus on positioning advanced resuscitative and stabilizing care as far forward as possible given available resources. It must continue to require highquality care *en route* during evacuation by providers specifically trained in this task. Finally, it should focus on providing care essential for survival as rapidly as possible instead of attempting to provide definitive care either within a specified time limit, or within a theater of operations.

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