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No work was performed on this project during the second grant year. Research was suspended until protocol approval by the chairman of Human Subjects Research Review Board (HSRRB) was secured. This occurred on September 17, 2003.

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1. Introduction

This research program focuses on the resuscitation of traumatic casualties in hypovolemic shock. The principal objectives are to determine:

- when it is necessary for a medic on the battlefield to resuscitate a trauma victim,
- how the effectiveness of the resuscitation effort can be measured objectively with outcome predictors, and
- what is the desired end point of resuscitation: can it be defined empirically by the survivors' values?

Human studies at a major Level I trauma center, Los Angeles County+USC Medical Center (LAC+USCMC), serve to precisely define the pathophysiology of traumatic/hemorrhagic shock and test the effectiveness of noninvasive (or minimally invasive) sensors of tissue perfusion failure. The investigation entails the consolidation of three large existing trauma data sets at LAC+USCMC into a new database containing existing medical record data without the possibility of patient identification. Our use of the term "existing medical record, EMR" data in this report automatically carries the qualifier "without the possibility of patient identification". The current database tracks the trauma victim beginning at the emergency department, then to the operating room, the radiology suite when indicated, and the surgical intensive care unit (SICU). It provides an excellent reference source and testing facility for the current state-of-the-art in U.S. resuscitative medicine. Our goal is to make the entire trauma database accessible to the combat-casualty-care community in an easy-to-use, straightforward fashion. Thus, each member of the community will be able to derive his or her own conclusions from a comprehensive, objective, unbiased database. Taken as a whole, the new database will allow optimum resuscitation strategies to be developed for the Army medic and will serve as a guide for implementing new sensor strategies. The LAC+USCMC data is being "packaged" with a database management program and augmented with a user-friendly, menu-driven program for standard analyses and data manipulation.

2 Body of Report

During the second grant year, no research was performed as part of this project. Because of the involvement of human subjects in the research program, approval by the chairman of the Human Subjects Research Review Board (HSRRB) had to be obtained prior to the re-initiation of any research activities. This entailed the submission of a protocol to HSRRB along with a detailed description/justification of the proposed research. As a stipulation for HSRRP approval of the submitted protocol, Health Insurance Portability and Accountability Act (HIPPA) authorization was required by the local Institution Review Board (IRB) at LAC+USCMC. Final approval of the submitted protocol with stipulations was granted by the HSRRB on September 17, 2003. Activation of funding for this project occurred after September 29, 2003.

3 Conclusions

The tasks expected to be accomplished during the third grant year are described below.

3.1 Background

As part of the work performed during the first year of this project, two LAC+USCMC relational databases were consolidated into a new integrated database. The main database includes medical information from the W. C. Shoemaker (WCS) data sets and from the LAC+USCMC Trauma Registry (TR). The need for the latter was not anticipated in the original statement of work. In addition, the Surgical Intensive Care Unit (SICU) database at LAC+USCMC was carefully analyzed and reduced in size without compromising any of the important medical information

required for this study. As indicated below, the SICU database is necessary if all patients are to be followed to the point of hemodynamic stability. In year 1, a reduced SICU data set was generated in a format consistent with the Sybase software used to assemble and access the main database. This database is very "clean" compared to the WCS data sets and the TR in that it has remarkably few keying errors, inconsistent data values, errors in demographic information, or artifacts. However, at the end of Year 1, it had not yet been formally included in the main database. The full SICU data set contains more than 2500 data items and often tracks a patient's medical history for many weeks after the point at which the WCS measurements end. Much of the SICU data is not directly material to our current study, but certain elements of the database are crucial for our investigation. At the request of the Government, approximately 50,000 lines of text related to patient therapy in the WCS data sets were parsed and included in the main database in Year 1. A total of eight refereed medical publications were written during the first year. Most of the publishable medical research was performed in parallel with the construction of the database. During the first year, the main database was extensively tested for accuracy and an initial study of outcome predictors was performed. During years 3, the main database is expected to serve as the focus of the research effort.

3.2. Year 3 Research Activities

In Year 3, we plan to follow patient histories out to the point of hemodynamic stability + 6 hours. An operative definition of hemodynamic stability will be developed and an algorithm will be implemented and applied to the existing medical record data in the database to determine the point at which stability is achieved. Because many patients are not hemodynamically stable and some consequences and complications of resuscitation are not evident at the point where the W. C. Shoemaker data set ends and the Surgical Intensive Care Unit (SICU) data begins (with some overlap), it is necessary to add an appropriate interval of SICU data so that the patient data record extends to the point of hemodynamic stability + 6 hours. The reduced SICU data set shown in Table 1 (page 8) will be used for this purpose.

During Year 3, a user-friendly graphical viewer will be developed so that the data are accessible to users other than computer specialists. This will be done with the aid of MATLAB. The average non-specialist will require a simple menu-driven program to call up database results and perform relatively simple relational operations on the data. A form-based query system will be developed for the analysis of medical information in the database. This is expected to include a statistical analysis package for ANOVA, z- and t-tests, and simple and multiple regression analyses. Other items will be added to the user interface as it becomes clear what types of analyses the database will support. The intent is to make it easier for the people involved in the project (i.e., LAC+USCMC and Geospace Research, Inc.) to independently probe the database without requiring a computer professional to be present. This allows work to be performed in parallel by all of the investigators. In addition, such computer routines will be of great utility for the national trauma database that is expected to be assembled by the end of Year 3. As part of the Year 3 effort, a protocol will be written and submitted to HSRRB describing how data will be entered into a national trauma database for use by other investigators. This protocol will also address the protection of the data and the patient's privacy/confidentiality.

During Year 3, the existing database will be employed for ongoing studies aimed at evaluating and predicting the outcome of critically injured patients. Patient data routinely collected in the earliest stages of injury will be compared with the results of predictive models to refine and confirm the model's accuracy in identifying the outcomes of trauma cases. In addition, combinations of physiological parameters will be evaluated for their contribution to the sensitivity

and specificity of the prediction model. At the same time, we expect to add 300 "new" trauma cases to the database. By new we mean that we will access existing medical record data independently obtained under a separate ongoing program at LAC+USCMC during the period March 29, 2001 through March 28, 2004. These data are used for other internal studies at LAC+USCMC, and the proposed database application represents secondary analyses of existing medical record data. Data for the proposed study will be accessed six to nine months after patient discharge, and total patient de-identification will be achieved using previously submitted and approved protocols. The new patient histories will aid in the validation of outcome prediction models developed using the retrospective database assembled during Year 1. Within this context, it is anticipated that most data acquired after January 1, 2002 will enter a separate pool for validation studies.

In Year 3, our goal is to address the following questions with the aid of the medical database developed during Years 1 and 3. The extent to which the medical information contained within the current database can completely answer each of these questions is presently unknown, but we are certain that at least partial answers will emerge from this research.

1. What noninvasively monitored values characterize the earliest hemodynamic patterns of changes of survivors and nonsurvivors after gunshot wounds and other penetrating injuries of the abdomen and chest? We will focus on episodes of hypotension, low cardiac index, arterial hemoglobin desaturation, low transcutaneous oxygen, high transcutaneous carbon dioxide tensions, and low oxygen consumption (VO_2) during and shortly after the initial resuscitation. The noninvasive monitoring systems provides early warning with information similar to that of the invasive thermodilution method. Both approaches can identify low flow and poor tissue perfusion that tends to be more pronounced in the nonsurvivors.
2. How does hemodynamic/oxygen transport after head trauma affect outcome? The specific aims of this study are to describe the early time course of hemodynamic and tissue perfusion/oxygenation patterns after head injury, suggest physiologic mechanisms responsible for the observed patterns, and evaluate post injury parameters that may be useful for treatment.
3. What hemodynamic patterns characterize adequate resuscitation?
4. What is the hemodynamic pattern that precedes ARDS? There are three objectives. First, to describe the hemodynamic and tissue perfusion/oxygenation patterns of trauma patients immediately after admission to the emergency department (ED) to the time of adult respiratory distress syndrome (ARDS), or until hospital discharge in patients who did not develop ARDS. Second, to compare the temporal sequential hemodynamic patterns of the survivors' and nonsurvivors' of ARDS. Third, to identify early warning hemodynamic markers that precede the development of ARDS and may play a contributory role in its pathogenesis.
5. What noninvasively monitored values characterize the earliest hemodynamic patterns of changes of survivors and nonsurvivors after severe blunt trauma, and how do these patterns differ from those of penetrating injuries?
6. What are the early circulatory patterns of septic shock patients? The principal aim will be to identify, describe, and evaluate early circulatory events of patients with trauma and sepsis or septic shock using invasive and noninvasive monitoring of both central hemodynamics and peripheral tissue perfusion/oxygenation. A secondary aim is to test the hypothesis that increased cardiac output is an early compensation to increased body metabolism.
7. What are the earliest post-resuscitation hemodynamic patterns in patients who subsequently die during their present hospitalization? In this study, we will use both invasive pulmonary artery

catheters with thermodilution cardiac output measurements and continuous noninvasive multicomponent hemodynamic monitoring to describe and compare patterns of hemodynamic changes during sudden circulatory deterioration in critically ill trauma patients. These data will be compared with the hemodynamic patterns in terminal patients monitored just prior to their death.

8. How do hemodynamic patterns in truncal injuries differ from those of the extremities? And those of the head and neck?
9. Can early attainment and maintenance of survival patterns improve outcome?
10. How can you tell when to stop fluids? What are the earliest hemodynamic characteristics of patients given too much fluid?
11. Can tissue perfusion and oxygenation be evaluated by DO2 and VO2? By transcutaneous O_2 and transcutaneous/sublingual CO_2?
12. What routinely monitored clinical laboratory findings are typical of survivors and nonsurvivors of severe injury in the immediate post-resuscitation period?
13. What are the noninvasively monitored patterns of circulatory deficiencies that ultimately lead to shock, organ failure, and death?
14. What are the earliest routine clinical laboratory findings that are associated with shock, organ failure, and death?
15. What are the precision and reliabilities of APACHE scores, TRISS scores, RTS, and PATI scores in predicting outcome?
16. How can a medic or clinician know when the endpoint of resuscitation is reached? For example, does SBP of 120 mm Hg ensure adequate tissue perfusion, or is a urine output of 60 ml per hour, or some other measure of tissue perfusion and oxygenation, more appropriate?

Table 1. Physiologic Parameters in the Reduced SICU Data Set

Physiologic Parameter	SICU Data Management Variable	Organ System	Maximum Frequency	Usual Frequency
heart rate maximum	heart rate max	cardiac	1 min	1 hour
heart rate minimum	hrmin	cardiac	1 min	1 hour
heart rate average	hravg	cardiac	1 min	1 hour
temperature maximum	temperature max	infectious	1 hour	4 hour
temperature minimum	tempmin	infectious	1 hour	4 hour
temperature average	tempvag	infectious	1 hour	4 hour
diastolic blood pressure maximum	diastolic BP max	cardiac	1 min	1 hour
diastolic blood pressure minimum	diamin	cardiac	1 min	1 hour
diastolic blood pressure average	diaavg	cardiac	1 min	1 hour
systolic blood pressure maximum	systolic BP max	cardiac	1 min	1 hour
systolic blood pressure minimum	sysmin	cardiac	1 min	1 hour
systolic blood pressure average	sysavg	cardiac	1 min	1 hour
mean blood pressure maximum	mean BP max	cardiac	1 min	1 hour
mean blood pressure minumum	meanmin	cardiac	1 min	1 hour
mean blood pressure average	meanavg	cardiac	1 min	1 hour
invasive diastolic blood pressure maximum	adia arterial diastolic BP max	cardiac	1 min	1 hour
invasive diastolic blood pressure minimum	adiamin	cardiac	1 min	1 hour
invasive diastolic blood pressure average	adiaavg,	cardiac	1 min	1 hour
invasive systolic blood pressure maximum	asys arterial systolic BP max	cardiac	1 min	1 hour
invasive systolic blood pressure minimum	asysmin	cardiac	1 min	1 hour
invasive systolic blood pressure average	asysavg	cardiac	1 min	1 hour
invasive mean arterial blood pressure maximum	amean arterial mean BP max	cardiac	1 min	1 hour
invasive mean arterial blood pressure minimum	ameanmin	cardiac	1 min	1 hour
invasive mean arterial blood pressure average	ameanavg	cardiac	1 min	1 hour
thermodilution cardiac output maximum	co cardiac output max	cardiac	1 hour	8 hour
thermodilution cardiac output minimum	comin	cardiac	1 hour	8 hour
thermodilution cardiac output average	coavg	cardiac	1 hour	8 hour
thermodilution cardiac index	ind cardiac index max	cardiac	1 hour	8 hour
thermodilution cardiac index minimum	indmin	cardiac	1 hour	8 hour
thermodilution cardiac index average	indavg	cardiac	1 hour	8 hour
right ventricular pressure systolic	srv systolic right ventricle max	cardiac	1 hour	8 hour
right ventricular pressure mean	srvmin	cardiac	1 hour	8 hour
right ventricular pressure average	srvavg	cardiac	1 hour	8 hour
Hemodinamic SRVI	srvi systolic right ventricle index max	cardiac	1 hour	8 hour
Hemodinamic SRVI	srvimin	cardiac	1 hour	8 hour
Hemodinamic SRVI	srviavg	cardiac	1 hour	8 hour
fluid set	volume_anet	renal	1 hour	8 hour
fluid delivered	volume_in	renal	1 hour	8 hour
net fluid balance	volume_net	renal	1 hour	8 hour
fluid output	volume_out	renal	1 hour	8 hour
urine volume	urin_net	renal	1 hour	8 hour
volume of blood administered	blood_net	hematologic	1 hour	8 hour
potassium maximum	kmax potassium	electrolytes	1 hour	1 day
potassium minimum	kmin	electrolytes	1 hour	1 day
potassium average	kavg	electrolytes	1 hour	1 day
phosphorus maximum	pmax, phosphorus	electrolytes	1 hour	1 day
phosphorus minimum	pmin	electrolytes	1 hour	1 day
phosphorus average	pavg	electrolytes	1 hour	1 day
calcium maximum	camax, calcium	electrolytes	1 hour	1 day
calcium minimum	camin	electrolytes	1 hour	1 day
calcium average	caavg	electrolytes	1 hour	1 day
creatine phosphokinase maximum	ckmax, creatine phosphokinase	cardiac/muscle	8 hours	1 day
creatine phosphokinase minimum	ckmin	cardiac/muscle	8 hours	1 day
creatine phosphokinase average	ckavg	cardiac/muscle	8 hours	1 day
chloride maximum	clmax, chloride	electrolytes	1 hour	1 day
chloride minimum	clmin	electrolytes	1 hour	1 day
chloride average	clavg	electrolytes	1 hour	1 day
low density lipoproteins maximum	ldmax, low density lipoproteins	electrolytes/nutrition	1 hour	1 day
low density lipoproteins minimum	ldmin	electrolytes/nutrition	1 hour	1 day

Physiologic Parameter	SICU Data Management Variable	Organ System	Maximum Frequency	Usual Frequency
low density lipoproteins average	ldavg	electrolytes/nutrition	1 hour	1 day
magnesium maximum	mgmax, magnesium	electrolytes	1 hour	1 day
magnesium minimum	mgmin	electrolytes	1 hour	1 day
magnesium average	mgavg	electrolytes	1 hour	1 day
sodium maximum	namax, sodium	electrolytes	1 hour	1 day
sodium minimum	namin	electrolytes	1 hour	1 day
sodium average	naavg	electrolytes	1 hour	1 day
troponin maximum	tpmax, troponin	cardiac	4 hours	1 day
troponin minimum	tpmin	hepatic	4 hours	1 day
troponin average	tpavg	hepatic	4 hours	1 day
albumin maximum	albmax albumin	hepatic	1 day	1 day
albumin minimum	albmin	hepatic	1 day	1 day
albumin average	albavg	hepatic	1 day	1 day
alkaline phosphatase maximum	alkmax, alkaline phosphatase	hepatic	1 day	1 day
alkaline phosphatase minimum	alkmin	hepatic	1 day	1 day
alkaline phosphatase average	alkavg	hepatic	1 day	1 day
alanine aminotransferase (SGPT) maximum	altmax, alanine aminotransferase (SGPT)	hepatic	1 day	1 day
alanine aminotransferase (SGPT) minimum	altmin	hepatic	1 day	1 day
alanine aminotransferase (SGPT) average	altavg	hepatic	1 day	1 day
aspartate aminotransferase (SGOT) maximum	astmax, aspartate aminotransferase (SGOT)	hepatic	1 day	1 day
aspartate aminotransferase (SGOT) minimum	astmin	hepatic	1 day	1 day
aspartate aminotransferase (SGOT) average	astavg	hepatic	1 day	1 day
bilirubin maximum	bilmax, bilirubin	hepatic	1 day	1 day
bilirubin minimum	bilmin	hepatic	1 day	1 day
bilirubin average	bilavg	hepatic	1 day	1 day
blood urea nitrogen maximum	bunmax, blood urea nitrogen	renal	1 day	1 day
blood urea nitrogen minimum	bunmin	renal	1 day	1 day
blood urea nitrogen average	bunavg	renal	1 day	1 day
bicarbonate maximum	co2max, total CO2 (bicarbonate)	acid base	1 hour	1 day
bicarbonate minimum	co2min	acid base	1 hour	1 day
bicarbonate average	co2avg	acid base	1 hour	1 day
creatinine maximum	cremax, creatinene	renal	1 day	1 day
creatinine minimum	cremin	renal	1 day	1 day
creatinine average	creavg	renal	1 day	1 day
glucose maximum	glumax, glucose	endocrine	1 hour	1 day
glucose minimum	glumin	endocrine	1 hour	1 day
glucose average	gluavg	endocrine	1 hour	1 day
uric acid maximum	uricmax, uric acid	endocrine	1 hour	1 day
uric acid minimum	uricmin	endocrine	1 hour	1 day
uric acid average	uricavg	endocrine	1 hour	1 day
base excess arterial maximum	beamax	acid base	1 hour	1 day
base excess arterial minimum	beamin	acid base	1 hour	1 day
base excess arterial average	beaavg	acid base	1 hour	1 day
pH arterial maximum	phamax	acid base	1 hour	1 day
pH arterial minimum	phamin	acid base	1 hour	1 day
pH arterial average	phaavg	acid base	1 hour	1 day
arterial blood oxygen tension maximum	pao2max, arterial blood oxygen tension	pulmonary	1 hour	1 day
arterial blood oxygen tension minimum	pao2min	pulmonary	1 hour	1 day
arterial blood oxygen tension average	pao2avg	pulmonary	1 hour	1 day
arterial blood hemoglobin	thbamax	pulmonary	1 hour	12 hour
arterial blood hemoglobin	thbamin	pulmonary	1 hour	12 hour
arterial blood hemoglobin	thbaavg	pulmonary	1 hour	12 hour
arterial blood CO Stat	cohbmax	pulmonary	1 hour	12 hour
arterial blood CO Stat	cohbmin	pulmonary	1 hour	12 hour
arterila blood CO Stat	cohbavg	pulmonary	1 hour	12 hour
inspired oxygen concentration	fio2max, fractional inspired O2	pulmonary	1 hour	12 hour
inspired oxygen concentration minimum	fio2min	pulmonary	1 hour	12 hour
inspired oxygen concentration average	fio2avg	pulmonary	1 hour	12 hour
Blood Gas Bicarb	hco3max	pulmonary	1 hour	12 hour

Physiologic Parameter	SICU Data Management Variable	Organ System	Maximum Frequency	Usual Frequency
Blood Gas Bicarb	hco3min	pulmonary	1 hour	12 hour
Blood Gas Bicarb	hco3avg	pulmonary	1 hour	12 hour
Blood Gas O2 Sat	o2hbmax	pulmonary	1 hour	12 hour
Blood Gas O2 Sat	o2hbmin	pulmonary	1 hour	12 hour
Blood Gas O2 Sat	o2hbavg	pulmonary	1 hour	12 hour
Blood Gas PCO2	paco2max	pulmonary	1 hour	12 hour
Blood Gas PCO3	paco2min	pulmonary	1 hour	12 hour
Blood Gas PCO4	paco2avg	pulmonary	1 hour	12 hour
Blood Gas Sample Site	siteamax	pulmonary	1 hour	12 hour
Blood Gas Sample Site	siteamin	pulmonary	1 hour	12 hour
Blood Gas Sample Site	siteaavg	pulmonary	1 hour	12 hour
Blood Gas Body Temerature	tempamax	pulmonary	1 hour	12 hour
Blood Gas Body Temerature	tempamin	pulmonary	1 hour	12 hour
Blood Gas Body Temerature	tempaavg	pulmonary	1 hour	12 hour
Blood Gas Approximate CO Content	coconamax	pulmonary	1 hour	1 day
Blood Gas Approximate CO Content	coconamin	pulmonary	1 hour	1 day
Blood Gas Approximate CO Content	coconaavg	pulmonary	1 hour	1 day
Blood Gas Met Hgb	methbmax	pulmonary	1 hour	1 day
Blood Gas Met Hgb	methbmin	pulmonary	1 hour	1 day
Blood Gas Met Hgb	methbavg	pulmonary	1 hour	1 day
Blood Gas Approximate O2 Content	o2conmax	pulmonary	1 hour	1 day
Blood Gas Approximate O2 Content	o2conmin	pulmonary	1 hour	1 day
Blood Gas Approximate O2 Content	o2conavg	pulmonary	1 hour	1 day
Blood Gas Calc O2 Stat	calcmax	endocrine	1 hour	1 day
Blood Gas Calc O2 Stat	calcmin	endocrine	1 hour	1 day
Blood Gas Calc O2 Stat	calcavg	endocrine	1 hour	1 day
Respiratory Mean Airway pressure	MAPmax	pulmonary	1 min	4 hour
Respiratory Mean Airway pressure	MAPmin	pulmonary	1 min	4 hour
Respiratory Mean Airway pressure	MAPavg	pulmonary	1 min	4 hour
Respiratory Peak inspiratory Pressure	Pipmax	pulmonary	1 min	4 hour
Respiratory Peak inspiratory Pressure	Pipmin	pulmonary	1 min	4 hour
Respiratory Peak inspiratory Pressure	Pipavg	pulmonary	1 min	4 hour
Respiratory End inspiratory Pressure	EIPmax	pulmonary	1 min	4 hour
Respiratory End inspiratory Pressure	EIPmin	pulmonary	1 min	4 hour
Respiratory End inspiratory Pressure	EIPavg	pulmonary	1 min	4 hour
Respiratory Rate Observed	RateOmax	pulmonary	1 min	4 hour
Respiratory Rate Observed	RateOmin	pulmonary	1 min	4 hour
Respiratory Rate Observed	RateOavg	pulmonary	1 min	4 hour
Respiratory Rate Set	RateSmax	pulmonary	1 min	4 hour
Respiratory Rate Set	RateSmin	pulmonary	1 min	4 hour
Respiratory Rate Set	RateSavg	pulmonary	1 min	4 hour
Respiratory Dynamic Compliance	DYACmax	pulmonary	1 min	4 hour
Respiratory Dynamic Compliance	DYACmin	pulmonary	1 min	4 hour
Respiratory Dynamic Compliance	DYACavg	pulmonary	1 min	4 hour
Respiratory Expired Minute Volume	ExMVmax	pulmonary	1 min	4 hour
Respiratory Expired Minute Volume	ExMVmin	pulmonary	1 min	4 hour
Respiratory Expired Minute Volume	ExMVavg	pulmonary	1 min	4 hour
Respiratory Static Compliance	StaCmax	pulmonary	1 min	4 hour
Respiratory Static Compliance	StaCmin	pulmonary	1 min	4 hour
Respiratory Static Compliance	StaCavg	pulmonary	1 min	4 hour
Respiratory Tidal Volume Expired	TVXmax	pulmonary	1 min	4 hour
Respiratory Tidal Volume Expired	TVXmin	pulmonary	1 min	4 hour
Respiratory Tidal Volume Expired	TVXavg	pulmonary	1 min	4 hour
Respiratory Tidal Volume Inspired	TVImax	pulmonary	1 min	4 hour
Respiratory Tidal Volume Inspired	TVImin	pulmonary	1 min	4 hour
Respiratory Tidal Volume Inspired	TVIavg	pulmonary	1 min	4 hour